

# Transanal Minimally Invasive Surgery (TAMIS) and Transanal Total Mesorectal Excision (taTME)

Sam Atallah  
*Editor*

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 Springer

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*To all the minds filled with youthful curiosity for surgery and the life sciences, who endeavor to learn and to achieve and who have witnessed an entire body of knowledge materialize in the span of a decade – this is for you. It is for those who believe that the ingenuity of the human mind can capture imagination itself. It is for those who believe that the future of surgery is ours to shape.*

*Upon writing this, I finally understood the true meaning of the expression “labor of love.” And it’s with deep love that I dedicate this book to the people who made me who I am today. To the surgeons who have mentored me throughout my arduous years of training and, most of all, to my mother Areej, my father Bisher, my brother Asa, and my wife Michelle. To my four children, whom I love more than they can possibly imagine – Olivia, Andrew, Sidney, and Addyson.*

Sam Atallah

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## Foreword

It is now been over 5 years since Sam Atallah first published on the subject of TAMIS TME surgery. I was invited to respond by the editor of *Techniques in Coloproctology* and wrote at the time: “I believe that 2013 will be the year of endoscopic transanal approaches to radical low rectal cancer dissection and anastomosis.” I should have said 5 years, or perhaps 10! I had been following the NOTES initiatives in Strasbourg by Jacques Marescaux, Joel Leroy, and their colleagues and so was conscious of the unexploited potentials of the fundamental orifice!

About the same time, I was invited by Antonio Lacy to share in his endeavors to develop and spread the transanal TME operation in Europe. He used the medium of a dedicated TV channel, perhaps more effectively than anyone has done before – “Advances in Surgery” (AIS) – and thus reached surgeons in far-off places who could never have afforded direct access to the pioneers and teachers. Regular visits to South America and elsewhere have repeatedly confirmed the impact of this channel on surgical practice worldwide.

All clinicians involved will find that the documentation and technical detail in this book provide a valuable practical reference, volumes to digest all that threatens to change our surgical lives as we work in the depths of the pelvis.

Twenty years ago, the late Professor Takahashi and I co-convoked the “First International Conference on the Lateral Ligament of the Rectum” in Tokyo. The very term “lateral ligament” summarizes the widespread ignorance of that time about the true anatomy of the lowest one third of the true pelvis. The ignorance of that century persists as the key surgical challenge of this one: how best to dissect the mesorectal envelope from the inferior hypogastric plexus and the neurovascular bundles – from above or from below? Add to that the challenge of the perineal body in abdominoperineal resection and you have two of the battlegrounds that will decide the defining importance of TAMIS.

I have followed throughout the intervening years the details of the posterior compartment of deep pelvic surgery both from above and from below: open, laparoscopically, and with the robots. Starting with the simplest comparison between “from above” and “TAMIS” – the stapling is intrinsically better with the latter – despite all improvements with angled instruments, etc., the placement of the transverse staplers from above by any form of minimally invasive surgery is often less than optimal both in angle and placement and sometimes removes more rectum than is necessary to clear the cancer.

Provided enough care is taken to avoid cell implantation, the actual anastomosis can be more precisely placed to optimize the retained anorectal segment in a TAMIS operation. It is on this segment and its nerve supply, and incidentally its freedom from radiation damage, that surgeons desperately seek functional improvement for their patients. This is particularly true for the lowest possible anastomoses where function may be threatened.

At the time of going to the press, it remains unproven as to which route best facilitates access to the nerves and muscles of “pelvic happiness” and how the oncological results from rectal cancer surgery can best be optimized. The “happiness” aspect is perhaps at the top of the priority list at this time, comorbidity and metastatic disease fast becoming the final frontiers. Having performed and then watched many thousands of TME operations by various approaches, I have become acutely conscious that each important step requires just the right amount of traction and countertraction, the correct wattage, and the gentlest of touches with the diathermy, what my friend Amjad Parvaiz calls “painting.”

Above all, perfect vision from 4 K and more is the greatest single gift of technology to surgery this century and a key component of the potential of much in this book. But in order to exploit what she/he can now see, the surgeon must acquire a total understanding of the anatomy of the fascial layers of the human pelvis and retroperitoneum.

When it comes to the visualization and preservation of the autonomic nervous system within the pelvis, a skirmish continues between minimally invasive abdominal surgery, particularly when performed robotically, and TAMIS. The battle is not as fundamental as it might sound, since the great majority on the TAMIS side favor laparoscopic support from above. It is really an argument of whether the key dissection deep in the pelvis is best done from above or from below, which operating team is dominant, and whether or not it can all be done perfectly from above. Comparisons between approaches need to analyze the angles that best facilitate the pursuit of the correct planes.

Embryologically defined envelopes of tissue, with surgical and MRI definable margins and recognizably shiny surfaces, present the careful surgeon with particular opportunities for cure – reflecting the fundamental truth that the primary spread of carcinoma is often contained within these envelopes. These same margins provide the basis for modern image guidance from MRI scanning, not only in planning for surgery but in modern radiotherapy (RT) as well. Furthermore, respect for the surrounding layers and the understanding of their anatomy, in both surgery and radiotherapy, have a major potential – not only for more actual “cures” but also for the preservation of the important autonomic functions of the surrounding nerve plexuses. The areas that demand the greatest attention are those that we used, in our ignorance, to call the “lateral ligament” and in the lowest anterior plane in the male.

The importance of understanding those crucial two extra layers between the mesorectal and parietal fasciae – Denonvilliers’ and Waldeyer’s – is seminal to pelvic anatomy. When the transanal route is chosen, the great dangers of extending laterally outside Waldeyer’s fascia cannot be overemphasized

and have indeed threatened the good name of the whole transanal enterprise. All is revealed herein!

The talent and creative imagination in these pages gathers together the experience and skill of most of those great pioneers who have established what is essentially a major new subspecialty – transanal minimally invasive surgery.

The Pelican Cancer Foundation has been administering and recording an international database which is carefully monitoring progress. How much of our work will in 10 years time be performed transanally? What follows will help you make some current decisions for yourselves. It is certain, however, that technology, instrumentation, and surgical virtuosity will continue to be as fascinating in the coming years as this book is right now.

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## Preface

A decade of new knowledge has been neatly compressed into this first of its kind surgical textbook. Although a decade has eclipsed us seemingly with the blink of an eye, it is hard to recall a time before TAMIS and before taTME. Neither of these acronyms, which are this book's rubric, were spoken prior to 2009 – and yet today, they are household names to anyone in the field. It was exactly 2 years to the day, after completing my colorectal fellowship in Houston, that on June 30, 2009, I performed the first TAMIS in OR Rm. #2 at a small, unassuming community hospital. As a young impressionable surgeon fresh out of training, it left me totally entranced, and I realized at that very moment that life had been given to an altogether new kind of operation.

Of course, at that time, the operation lacked a name. I can still recall the afternoon that Sergio, Matt, and I sat down for Turkish cuisine in Winter Park, Florida, to establish one. In hand were a few sheets of blank paper and a pen as we brainstormed what to call this “thing” we had just invented. After scratching out what seemed like 100 potential names, we rationalized that, at its core, it was a minimally invasive surgical (MIS) technique, and this had to be its key identifier. We narrowed our selection down to “minimally invasive transanal surgery” (MITA) and “transanal minimally invasive surgery” (TA-MIS). Eventually, we decided on the latter, the hyphen was dropped, and the term TAMIS was officially coined.

Innovation is often a function of circumstance. The impetus for TAMIS was borne out of necessity. You see, my local hospital system could not afford the upfront capital requirement of a TEM platform. This forced consideration for alternative options and, with a little ingenuity, paved the way for the quite serendipitous creation of TAMIS. In this context, many commonly referred to TAMIS as a “poor man's TEM” during the early days after inception. For the first time, it allowed advanced transanal surgery to be performed by ordinary colorectal surgeons like myself, whose only prerequisite was an MIS skillset and access to an operating theater. With just six TAMIS cases under our belts, we were certain this was going to be the next big thing.

Sure, there was instant value in the technique for high-quality local excision of rectal neoplasia. But one could begin to envision TAMIS as a technique that could be applied more broadly – only to be honest, at the time, I really didn't have *any* clue how. It was not long afterward that the puzzle pieces would find their fit the day taTME materialized, and these two separate techniques would soon be melded into a singular one. As though on a

preordained collision course, the original article describing TAMIS was published in the same scientific journal and on the same week as the first human case of, what would later be termed, taTME – originally performed by Sylla, Lacy, and colleagues in Barcelona (both articles published online in *Surgical Endoscopy*, February, 2010). This would bring together not only two techniques but, far more importantly, a group of pioneers and innovators (the vast majority of which are authors herein) who would collectively shape TAMIS and taTME into what they are today. Indeed, the union of TAMIS and taTME marked the dawn of a new era in advanced transanal surgery and a quantum leap forward for our field.

The modern taTME is a harmonious amalgam of the most important developments in rectal cancer surgery to transpire over the past 40 years. Specifically, taTME is a unification of Heald's TME, Marks' TATA, Buess' 1984 TEM invention, and the concept of natural orifice specimen extraction (NOSE) as developed by Franklin. In addition, it built upon the evolution of natural orifice transluminal endoscopic surgery (NOTES) to include the creation of the single-port access channel, keyhole surgery, and, finally, the advent of TAMIS. As these techniques merged into one, we began to understand the newfound value of the taTME approach. Routed in methods for improved access to the most difficult portion of the rectum and deep pelvis, better-quality surgery was possible, not only for invasive rectal neoplasia but also for benign and premalignant disease spectra.

But, there was something intangible about TAMIS and taTME that extended beyond technical sophistication. The two approaches, in fact, had sparked our imagination and interest in exploring what could be accomplished through innovation. Rather than merely thinking outside of the box, we were, instead, kicking the box to the curb, thereby bringing a renaissance of new ideas and unorthodox surgical strategies for consideration. Hence, TAMIS and taTME had a truly transforming effect, and these approaches successfully granted mainstream appeal to advanced transanal surgery – which once had been an obscure niche mastered by only a relative handful.

It was this zest for exploring new pathways that had placed these techniques at center stage and had led to adjunctive advancements in rectal cancer surgery, including robotics for taTME, of which a multitude of next-generation platforms are actively being tooled for transanal applications. We have also witnessed the utility of biofluorescence for perfusion analysis and structure localization, as well as image-guided navigation for taTME, which collectively represents key steps toward the digitization of complex pelvic surgery and the integration of artificial intelligence into operative algorithms. Indeed, we now stand on the precipice of exponential growth in technology that will lead us to realize possibilities never before imagined.

The uptake of TAMIS and taTME has been so rapid that unique academic models had to be developed to meet the educational demand. It inspired the development of resource apps, modules, and synchronized deferred live surgery – all recently introduced to aid with the educational process for delegate trainees. These have been painstakingly designed as adjuncts to de novo training pedagogies and mentorship programs for taTME worldwide.



Moreover, transcontinental registries have been established to assure responsible and safe implementation.

This book captures the cornerstone developments in a new body of knowledge. Like fabric, it encompasses content woven together by leading TAMIS and taTME authorities from across the globe, thereby assuring a collective representation. It is through this circle of pioneers, who reside in the four corners – Asia, Europe, Australia, and the Americas – that this book is able to deliver enriching perspectives.

Soon, we will embark upon a new journey, with 2030 visible on the horizon. What new challenges and discoveries lie ahead? With finite and precious time on Earth, fulfillment comes from knowing our collective contributions will remain indefinitely – and may provide the foundation for what transpires next. I consider myself truly fortunate to be part of a group shaping the future of surgery. To be able to ride atop this epic wave of innovation has been the stuff of dreams.

Orlando, FL, USA

Sam Atallah

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**Part I**

**Transanal Minimally Invasive Surgery  
(TAMIS)**



# Historical Perspectives and Rationale for Development

# 1

Sergio W. Larach and Beatriz Martín-Pérez

## Introduction

Rectal lesions, whether of benign or malignant histology, present a special challenge for surgeons because of the difficulty of access and exposure to the rectal lumen. Traditional transanal methods, such as Parks transanal excision (TAE), have been associated with a high incidence of local recurrence, thus unleashing the development of newer approaches. Heralding the era of the expansion of endoscopic surgery, transanal endoscopic microsurgery (TEM) represented a milestone in the approach to rectal lesion excision, as it achieved minimally invasive access to the upper rectum, a better quality of excision with improved likelihood of achieving negative resection margins. As a result, decreased recurrence rates and improved disease-free survival were observed, all due to improved access and the concomitant improvement of visual field and dissection quality. Despite these advantages, TEM use was limited, mainly due to a steep learning curve, complex surgical setup, and cost of instrumentation. It was with this pretext that transanal minimally invasive surgery (TAMIS) was born, combining TEM

principles with conventional laparoscopic instrumentation, creating an important new option for appropriately trained minimally invasive colorectal surgeons.

## From Miles Resection to Parks Excision

Surgical management of rectal lesions represents a challenge for the colorectal surgeon. Through the twentieth century, the approach to rectal cancer has largely evolved from invasive radical resections to organ-sparing techniques. Jacques Lisfranc de St. Martin (1790–1847) pioneered transanal rectal cancer excision, when in 1826 he described the removal of the anus and rectum through the perineum, resulting on a perineal colostomy [1]. In 1875, Kocher and Verneuil tried to improve rectal access and described the posterior approach including coccygectomy; this was subsequently refined by Paul Kraske (1851–1930) [2]. Abdominoperineal resection (APR) for rectal cancer was later described in 1908 by Dr. Ernest Miles, reducing local recurrence rates from 100% to 30% [3]. However, the morbidity associated with APR was high, ranging from 15% to 61% [4–7].

Surgeons continued to search for less-invasive options to manage rectal cancer, particularly within the distal one-third of the rectum. The objective would be to develop sphincter-preservation techniques that could spare patients

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from the high morbidity of APR while maintaining acceptable oncologic outcomes. In the case of premalignant lesions including carcinoma in situ, the benefits of local operations for tumor removal present a significant advantage, as such less-invasive surgery by this modality avoids the morbidity of radical surgery with virtually no oncologic compromise.

In the early twentieth century, screening and endoscopic techniques were less developed than at present, for which these group of patients with benign neoplasia or T1 cancers were subjected to a radical surgery, permanent colostomy, and a high rate of morbidity. Despite radical surgery, patients had a high rate of local recurrence even for early-stage rectal cancer [4, 6]. In this quest for better approaches, local excision for rectal lesions was born as an organ preservation surgery for suitable lesions.

The pathway for management of early-stage rectal cancer followed the treatment model of early-stage breast cancer – which was treated with either (a) breast-conservation surgery and radiotherapy or (b) radical mastectomy alone [8]. Local excision for premalignant and early-stage rectal cancer (predominately via Parks transanal excision, TAE) aimed to offer patient an improved quality of life, through stoma-free surgery and maintenance of normal bowel and urogenital function, while obtaining similar disease-free survival and cure rates to those observed with radical resection. This technique was performed with transanal retractors, which provide suboptimal exposure of the rectal lumen (Fig. 1.1). Electrocautery and conventional surgical instruments were used for the local excision of rectal neoplasms, and the full-thickness defects were closed with suture. Illumination of the rectal lumen and overall operative field exposure was limited by external field lights (headlights only modestly improve visualization, and are difficult to direct and maintain onto targets). Due to these constraints, only low-lying rectal lesions (i.e., palpable lesions, whose upper edge does not extend beyond <7 cm from the verge) were accessible by this approach, and complete, margin-negative excision of specimens could be quite challenging due to this limited exposure.



**Fig. 1.1** Parks anal retractor

Despite these limitations, early series from the 1970s were able to demonstrate that local excision for early-stage rectal cancer with favorable histopathological features had equivalent oncologic outcomes when compared with radical resection. In a landmark study by Morson et al., the data for local excision revealed a failure rate (as defined by locoregional recurrence) that measured 8.4%, which was felt to be quite acceptable [9].

In the 1990s, the results of a prospective, multi-institutional study from the Cancer and Leukemia Group B (CalGB) reinforced the idea of local excision and organ preservation for select, early-stage rectal cancer [10]. Fifty-nine cases of T1 were treated with local excision alone and 51 cases of T2 undergoing adjuvant external beam radiotherapy after local excision (local excision was performed utilizing the conventional Parks TAE technique). The 6-year overall survival of 85% and disease-free survival rates of 78% for this treatment seemed promising, particularly when compared to the 20–30% failure rates after standard oncologic resection prior to the era of TME surgery [5, 6]. These encouraging early results were very well received by the surgical community, which resulted in an overall increased rate of local excision as a modality of treatment [11]. Unfortunately, subsequent series published inferior results even in the same selection of T1 patients, whereby the observed local recurrence rate increased from 8% to 18% for T1



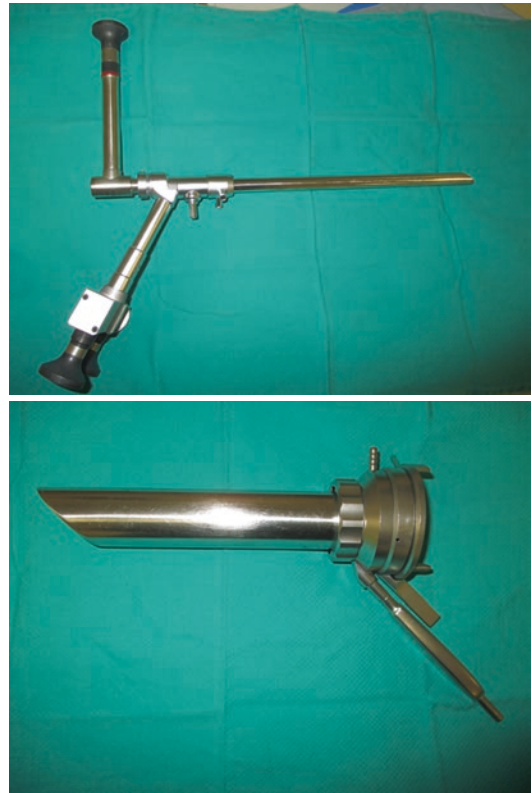
lesions and, even a more alarmingly, from 18% to 37% for the T2 cancers treated in this fashion [12–14]. Parallel to these results, the technique for radical surgery was evolving. Lead by RJ Heald, total mesorectal excision (TME) was being implemented around the globe. It was learnt that through proper sharp dissection along the embryonic plane of the TME envelope, local recurrence for stage I rectal cancer could be reduced to 7.1% [15]. Parks TAE had inferior oncologic results compared to new-era TME surgery [12, 16]. The awareness that the improvement on patient's quality of life with local excision and organ-sparing surgery was at the expense of worse oncologic outcomes resulted in an overall decrease on the use of local excision for invasive lesions [17].

### Transanal Endoscopic Microsurgery (TEM)

Surgical evolution has been largely influenced by instrumentation development, and the advances in the technique of local excision would undoubtedly come from creative applications of these advancements. The discovery of the first rigid endoscopes presented by Desormeaux in 1865 later would evolve into the first fiberoptic endoscopic procedure in 1957 [18], heralding the new era of laparoscopy and minimally invasive surgery, which would find fitting applications in the late 1980s toward a multitude of common abdominal operations [18–20].

In such a way, the design of an advanced endoscopic transanal platform with an endoscopic camera and laparoscopic-style surgical instruments would yield access to the rectal cavity with superior visibility when compared to the traditional Parks approach and even provided access to more proximal lesions that were not accessible before with conventional techniques for local excision.

In 1983, predating the first laparoscopic cholecystectomy by a few years, Dr. Gerhard Buess designed transanal endoscopic microsurgery (TEM) (Fig. 1.2). It was a platform that, for the first time, allowed for excision of benign neoplasia



**Fig. 1.2** Transanal endoscopic microsurgery (TEM) equipment. Developed in 1983 by Gerhard Buess, It allowed for high definition access to the rectal vault for the purpose of performing local excision

of the mid and upper rectum [21]. TEM consists of a rigid transanal platform, which allows insufflating of the rectal cavity, creating a pneumorectum. TEM has three working channels, one for a fixed camera and other two for working instruments (cautery, suction, suture, etc.). The improved visualization from a stereoscopic magnified view in the pneumatically distended rectum allows for precise excision in an operative space that would be otherwise difficult to reach. Initially, Buess designed TEM for local excision of nonmalignant lesions not within reach of conventional transanal methods, addressing the limitations of the Parks excision. It was not designed with the purpose of performing higher-quality excision. However, the platform was soon utilized also for resection at any level of the rectum and for early malignant lesions, since TEM became increasingly recognized as the better platform for this [22].



Since its first description, the use of TEM has proven to result in high-quality excisions with outcomes that were more favorable than standard transanal techniques for local excision, with a low recurrence rate [23–29]. Winde et al. [22] described no difference in disease-free and overall survival for patients with T1 rectal cancer operated with local excision via TEM versus radical resection. A 10-year single center experience demonstrated that for 70 patients who underwent TEM for T1 rectal cancer, a local recurrence rate of 8.5% was observed [30]. Furthermore, data surmised from other studies, indicated that local excision via the traditional (Parks) approach has inferior 5-year survival rates compared to anterior resection for patients with T1N0M0 disease; while, when local excision of T1 lesions was performed with TEM, the oncologic results were comparable to those achieved with radical surgery for early rectal cancer [16, 31, 32].

For 25 years, TEM was the only available advanced transanal platform. However, this advanced transanal platform required specific instrumentation (with associated higher cost), posed ergonomic difficulties, and resulted in a steep learning curve for even experienced trainees [33, 34]. The economic pressure for cost containment in the healthcare system limited the investment in TEM, and few institutions could afford the TEM apparatus, as a high volume of cases was necessary to amortize the price of the platform [20]. For these reasons, widespread adoption was limited, and TEM for local excision remains, to this day, an operative technique primarily performed by a small number of high-volume specialists in referral centers [35, 36]. Over the decades, the system's design has not been significantly modified, and it is essentially unchanged since its development by G. Buess. Transanal endoscopic operation (TEO) (Fig. 1.3) emerged as a similar platform to TEM, with analogous principles, indications, and results [37]. Together, TEO and TEM are considered advanced transanal platforms capable of performing high-quality excision of rectal neoplasia. They are often referred to as “rigid platforms.” In general, most experts believe the quality of excision achievable with TEM and TEO is the same.



**Fig. 1.3** Transanal endoscopic operation (TEO) platform. (Reproduced with permission of Karl Storz SE & Co.)

### Transanal Minimally Invasive Surgery (TAMIS)

The beginning of the twenty-first century was marked by further evolution in abdominal laparoscopy and abdominal access strategies. Meanwhile, the concept of natural orifice transluminal endoscopic surgery (NOTES) emerged in 2004. This led to the idea of consolidating laparoscopic trocars into a combined port that could be delivered through the umbilicus (an embryonic natural orifice). Thus, the birth of the “single port” was based on (a) decreased abdominal wall access trauma and (b) the ability to provide a minimally invasive route via an embryonic natural orifice. Although the concept of single-wound minimally invasive access was reported by Pelosi et al. in 1992 as a transumbilical approach for appendectomy [38], it was not until the mid-2000s, in the wake of NOTES, that single ports were manufactured, and this approach was subsequently applied to a broad range of abdominal procedures including colonic resection [39, 40].

Although not intended by design to be used for transanal access, the single port seemed ideal for this purpose. In 2009, this was performed for the first time, giving birth to a new operation for rectal surgery. The new approach would have a profound effect on how colorectal surgeons would operate within the rectum. The technique was termed transanal minimally invasive surgery (TAMIS) by its founders S. Atallah, M. Albert, and SW. Larach [41].

It is often said that *necessity is the mother of invention*. TAMIS represented an alternate option for advanced transanal access for surgeons and hospital systems that did not have the highly specialized and costly TEM system. After all, TAMIS was simple to set up, relied on conventional laparoscopic equipment, and was predicated on laparoscopic skills and familiar techniques. Additionally, TAMIS did not appear to have a long learning curve and did not require specialized training (as is the case with TEM) [41]. TAMIS provided the surgeon with improved visualization and reach. In short, it allowed colorectal surgeons to translate their familiar laparoscopic skill set to transanal surgery, which resulted in rapid dissemination of the TAMIS technique [42].

The first platform placed transanally and the first series reported on TAMIS utilized the SILS Port (Covidien, Mansfield, MA) (Fig. 1.4). While suitable for access, this and other single ports were not designed for transanal access and required modification. An important limit of the SILS port was that it did not allow for access into the lumen, without completely removing the port; there were other limitations as well, including cannula diameter which was restricted to 5 mm at the time.

With input from the surgeons who developed TAMIS, dedicated platforms were designed specifically for transanal access – the first of which

remains the one most widely used today: Namely, the GelPOINT path transanal access platform (Applied Medical, Inc., Rancho Santa Margarita, CA) (Fig. 1.5). The GelPOINT Path, often simply referred to as the “TAMIS Port”, is constructed from single-use flexible material composed of two main parts, an access channel and a removable lid. Three 10 mm cannulas are usually used, one for the camera lens and two working ports, through which standard laparoscopic instruments can be introduced. The TAMIS platform is quite versatile and even allows for robotic access – a technique termed robotic TAMIS or robotic transanal surgery (RTS) [43–45].

TAMIS utilization has rapidly spread worldwide because of its accessibility and the increasing number of training courses available for surgeons. Its global adoption has been reflected by the increasing number of publications and citations since 2009 [36, 42, 46–60].

## Future of TAMIS

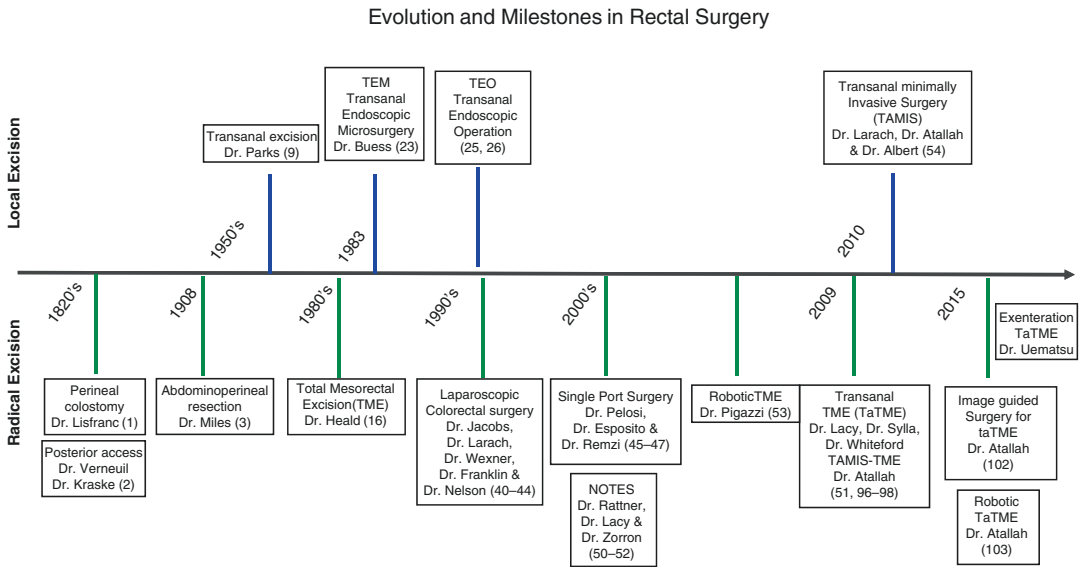
TAMIS was created to evolve, and not remain static. The future will likely represent new avenues for TAMIS as surgeons explore new applications. To date, many applications beyond local excision have been realized. Most notably, TAMIS became the standard route of access for the



**Fig. 1.4** Shown is a Single-Incision Laparoscopic (SILS) Port. Although it was not intended to be used transanally, it was used to develop the TAMIS technique. The SILS port was used for all cases published in the first series on TAMIS and predated the creation of TAMIS-specific ports



**Fig. 1.5** Transanal minimally invasive surgery (TAMIS) platform, or TAMIS Port. This device was developed specifically for transanal access and was created and designed with the aid of the surgeons who developed the technique



**Fig. 1.6** Evolution and milestones in rectal surgery

modern day transanal total mesorectal excision. From a technical standpoint, further instrumentation and platform refinements will likely contribute to the advancement of TAMIS. Next-generation flexible robotic transanal systems are poised to be part of the future evolution of TAMIS.

Figure 1.6 shows the evolution and milestones in rectal surgery.

## Conclusion

TAMIS arose serendipitously and represents an amalgam of innovations in laparoscopy, single-port surgery, NOTES, and TEM. The impetus behind its development was the need for improved access to the rectal lumen, thereby providing a practical and effective alternative to TEM.

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# TAMIS: Indications and Contraindications

# 2

Uma R. Phatak and Justin A. Maykel

## Introduction

Transanal minimally invasive surgery (TAMIS) was first reported in 2010 as a technique for performing natural orifice surgery [1]. This was quickly identified as a cost-effective alternative to transanal endoscopic microsurgery (TEM) which was pioneered in the 1980s [2]. The principle advantage of TAMIS is similar to TEM in that it provides the ability to perform high-quality local excision of rectal lesions, thereby avoiding the morbidity of abdominopelvic surgery. TAMIS has a higher rate of margin-negative excision compared to traditional transanal excision; it also has decreased rate of specimen fragmentation. It is believed that, for these reasons, TAMIS-based local excision results in a lower rate of local recurrence compared to patients who undergo conventional traditional transanal excision for early-stage rectal cancer [3, 4]. Other advantages that separate TAMIS from TEM are more univer-

sal equipment availability, the relatively faster set up time, and potential decreased risk of incontinence as it utilizes a 34 mm malleable access channel compared to the rigid 40 mm access channel (shaft) of the TEM scope [5]. Similar to TEM or perhaps more so, TAMIS requires advanced laparoscopic skills with in-line instrument manipulation in a tight operative field. Since TAMIS represents an alternate method for transanal excision, the indications are similar to TEM. In certain cases, the TAMIS platform can be more versatile and able to reach and visualize lesions which may be impossible to access due to inability to maneuver a long, relatively wide and rigid TEM scope beyond rectal valves or angulations at the sacrum or rectosigmoid junction.

## Indications

The indications for TAMIS range from benign to malignant disease and mirror historical indications for transanal excision and for TEM [2, 6]. The traditional indications for transanal excision were for lesions within 8 cm of the anal verge, less than 3 cm in size, and occupying less than 40% of the circumference of the rectum [2, 6]. These were practical parameters given the limitation of the instrumentation at the time. However, surgeons have pushed the limits of TEM and TAMIS to far beyond what is feasible by traditional transanal access. TAMIS is best suited for

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removal of benign, mobile lesions of the rectum that cannot be removed endoscopically and especially for those lesions that are too proximal to be approached via Parks transanal excision. Traditionally, target lesions for local excision with TAMIS are relatively small in diameter and do not occupy more than 40% of the circumference of the rectal lumen. However, in experienced hands, excision of circumferential lesions has been reported [7]. Rarely does abdominal entry necessitate an conversion to a transabdominal approach to adequately close the defect and to rule out injury to other viscera. Alternatively, benign polyps of the proximal rectum that do not require full-thickness excisions may be approached using TAMIS via a submucosal dissection plane – a quite prudent approach to (especially anterior) benign neoplasia  $\geq 10$  cm from the anal verge.

Other tumors of the rectum such as neuroendocrine and gastrointestinal stromal tumor may also be excised using TAMIS. Local excision is especially suited for these tumor types as they do not spread via lymphatic channels. Thus, the concern about leaving behind disease in lymph nodes is irrelevant. The traditional parameters for excision of such pathology include mobile tumors that are  $< 2$  cm in diameter and that do not demonstrate evidence of distal disease. With greater experience and expertise, larger lesions can be approached via TAMIS approach; however, for neuroendocrine lesions that measure  $> 2$  cm in diameter, a radical resection is recommended [4, 8, 9].

While TAMIS is well suited for local excision (full or partial thickness) of benign neoplasia throughout all three segments of the rectum, it can be very carefully applied as a method of local excision for select, early-stage rectal cancer, in the proper setting, with curative intent. Deciding which patients with rectal cancer are good candidates for local excision is multifactorial and should require a thorough workup and multispecialty tumor board evaluation. Central to the discussion is assessing the risk of nodal disease. Focusing on the technical ability of the TAMIS approach, one of the key factors to consider is the ability to achieve negative margins. For rectal cancer, a neg-

ative margin, classically defined as 1 cm, should be the objective of local excision of invasive neoplasia, and a negative deep margin is mandatory. Preoperative staging with rectal protocol 3-Tesla-weighted magnetic resonance imaging (3 T MRI) or endorectal ultrasound (ERUS) is important to assess depth of invasion and, as best as possible, the presence or absence of lymph node metastases. The ideal candidate for local excision of rectal cancer has cT1 N0 disease, without high-risk histologic features. Although imaging with ERUS or rectal protocol 3 T MRI may not reveal gross lymphadenopathy, depth of invasion has been shown to be a surrogate for predicting the presence of lymph node metastases – one of the most important reasons that curative intent local excision with TAMIS (or TEM) has never been recommended for tumors that violate the rectal wall (i.e., cT3, T4 lesions). Tumors with the least likelihoods for lymph node metastases and local recurrence are T1 cancers. These are further stratified using the Kikuchi classification system [10]. This subdivides T1 tumors into three categories: slight submucosal invasion from the muscularis mucosa to the depth of 200–300  $\mu\text{m}$  (sm1), intermediate submucosal invasion (sm2), and submucosal adenocarcinoma invading near the inner border of the muscularis propria (sm3). Tumors that are T1 sm3 have been shown to behave more like T2 tumors in that they have similar risk of lymph node metastases – 12% to 25% vs 23.1%, respectively [11, 12]. For this reason, both T2 cancers and those which are histologically staged pT1sm3 are not considered to be adequately treated by local excision alone. Another predictor of lymph node metastases is tumor histology. Tumors that are well differentiated without lymphovascular invasion, mucinous features, tumor budding, or perineural invasion are less likely to have tumor deposits in lymph nodes and are more suitable candidates for local excision [11, 13, 14].

Perhaps one of the most important factors in determining a patient's candidacy for local excision is deciding the probability and risk of local recurrence. In addition to depth of invasion, lymphovascular invasion, and poor differentiation, another predictor of local recurrence is tumor size. Tumors less than 3 cm in maximum diameter

without lymphovascular invasion are associated with <5% risk of local recurrence at 3 years [14]. Another surrogate for potential lymph node tumor deposits is anatomic location of the tumor within the rectum. Of tumors that are located in the distal third of the rectum, 34% have lymph node metastases compared to 8% found in the upper rectum [15].

Certain patients may choose transanal excision as a strategy to avoid a permanent stoma and also to avoid the morbidity associated with pelvic surgery when reconstruction is possible. In this setting, patients with histologically unfavorable cT1 cancers or T2 lesions may undergo local excision against the preferred recommendation of radical surgery and en bloc resection. On protocol, this may be an option for local excision in combination with external beam radiotherapy. Additionally, more advanced malignant lesions can be excised via the TAMIS approach when patients are not considered fit for a major surgery or for palliation of symptoms such as bleeding. This may be performed in conjunction with chemotherapy and radiation as well.

Beyond the excision of rectal neoplasia, the TAMIS technique can be used to treat and surgically manage other conditions affecting the rectum. There are case reports of the TAMIS platform being used to repair rectourethral fistula after cryoablative treatment of prostate cancer, ligation of a rectal Dieulafoy's lesion, extraction of a sigmoid foreign body [16], and repair of a vesicorectal fistula after prostatectomy [17]. TAMIS has also been described for the treatment of rectovaginal fistula, repair of anastomotic leak, and control of rectal bleeding and to address benign stenosis [18, 19]. Complex fistulae (fistula-*in-ano*, rectovaginal, rectourethral) are approached via this innovative technique as a tool to create a rectal advancement flap with or without biologic or native tissue interposition.

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## Contraindications

Definitive contraindications to TAMIS are the same as for any transanal excision. Fixed masses, when malignant, should not be locally excised –

except in rare cases, for palliation. Patients with any node-positive cancers should not undergo transanal excision as this will rarely provide definitive therapy. The inability to define and obtain a clear margin would risk leaving behind diseased tissue and would be considered futile, although salvage re-excision after positive margin resection has been described. As referenced above, T1 tumors with a depth of invasion of sm3 should be treated like T2 tumors, and transanal excision alone as definitive treatment should not be offered. Instead, salvage radical resection is recommended for good-risk operative candidates.

Technical aspects of the procedure relate to the available access platforms and procedure conduct. Lesions that are low in the rectum or border the anal canal can be obscured by the currently available disposable TAMIS access platform; although there are techniques available which allow for access to the distal most one-third of the rectum. One such technique is to suspend the access channel to a LoneStar retractor so that only part of the channel is introduced into the anal canal. Alternatively, the distal most dissection (inferior to the lesion's caudal extent) can be addressed by direct visualization. Once this is completed, conversion to a TAMIS approach can be performed to achieve more precise visualization and dissection of the proximal aspect of the lesion.

Inability to adequately insufflate the rectal lumen in patients with massive obesity or non-compliant tissues may prevent adequate visualization of the lesion and maintenance of exposure. Finally, transanal access and placement of the platform, both flexible and rigid, may be impossible due to the presence of an anorectal stricture or loss of rectal compliance.

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## Controversial Areas

While the idea of transanal excision for rectal cancer is not new, much controversy remains regarding proximal tumors, T2 tumors, and those with a complete pathologic response following neoadjuvant treatment (ypTON0). Full-thickness



excision of proximal T1 N0 rectal adenocarcinomas risks violation of the peritoneum and entry into the abdomen. However, there are multiple case series that document safe transanal excision of tumors greater than 8 cm from the anal verge [7, 20]. Thus, proximal rectal tumors may be considered a relative contraindication to local excision depending upon surgeon experience and ability to securely close the rectal wall following resection.

Another area under investigation is local excision after chemoradiation for T1 N0 rectal cancers with adverse features and T2 N0 rectal cancers. A retrospective study from Japan evaluated 53 patients with T1 N0 lesions with adverse features and 4 patients with T2 N0 lesions [21]. For those with T1 N0 disease, the 5-year disease-free survival rate was 94%, and the overall survival rate was 98%. There was one patient who developed local recurrence in the T1 group and one in the T2 group. This disease-free survival rate compares to the rate for patients with T1 N0 disease with adverse features who underwent total mesorectal excision (TME) [22]. However, the local recurrence rate is higher in the local excision group. A study of the National Cancer Database evaluated outcomes in patients with T2 N0 who underwent transabdominal resection, chemoradiation followed by local excision, and local excision followed by chemoradiation [23]. The results of the study suggest that the differences in 5-year overall survival rates are not statistically significant. The GRECCAR 2 trial evaluated outcomes in patients with T2 or T3 rectal cancer  $\leq 8$  cm from the anal verge and tumors  $< 4$  cm who underwent preoperative chemoradiation followed by either local excision or TME [24]. Patients were only randomized if they had good response to therapy defined as residual lesion/scar less than or equal to 2 cm. After local excision, patients with ypT2 or ypT3 disease or those who have a margin-positive excision underwent salvage radical surgery. Results showed that 3-year local and distant recurrence rates were not statistically different.

Disease-free survival and overall survival were also not statistically different. In the TME group the rates of node-positive disease for ypT0,

ypT1, and ypT2 diseases were 0%, 0%, and 8%, respectively. The ACOSOG Z6041 non-randomized trial included patients with cT2 N0 rectal cancer less than 40% of the bowel wall circumference and less than 4 cm in greatest dimension. Patients were assigned to receive preoperative chemoradiation followed by local excision. After a median follow-up of 56 months (IQR 46–63), using intention to treat analysis, the 3-year disease-free survival was 88.2% (95% CI 81.3–95.8). By the end of the follow-up period, 10% developed recurrences (all received local excision as their initial treatment) – 6% distant and 4% local – and 91% of the cohort had rectal organ preservation. This study revealed that neoadjuvant chemoradiation followed by local excision may be an organ-preserving option for those with cT2 N0 rectal cancer who cannot or will not undergo transabdominal resection [25].

Aside from disease characteristics, patient characteristics also play a large role in determining suitability for local excision. The patient's ability to tolerate an abdominal operation or to live with a permanent stoma is considered. Local excision is associated with lower perioperative mortality (RR 0.31, 95% CI 0.14–0.71), lower post-op complications (RR 0.16, 95% CI 0.08–0.30), and decreased need for permanent ostomy (RR 0.17, 95% CI 0.09–0.30) [26]. Thus, for patients with more advanced stage rectal cancer who are poor operative candidates for LAR or APR, local excision may be discussed in spite of increased risk of local and distant failure. For good operative candidates, patients should be counseled that subsequent radical resection may be necessary depending upon final pathology and that the TAMIS procedure for local excision ultimately should be considered an “excisional biopsy” in this instance.

Another subset of patients who may be considered for local resection are those with good response to preoperative chemoradiation. The rate of lymph node metastasis in those found to have ypT0–1 rectal cancer after transabdominal resection was 3–8% [27–30]. Thus a good response to preoperative therapy may be used as an indicator of low risk of spread to lymph nodes. Though the risk of nodal metastases is low, it is

not zero, so a thorough discussion with the patient is warranted. Caution should be noted as wound dehiscence, and delayed excision site healing can have a major impact on postoperative rectal pain, hospital readmission, and quality of life [31].

## Conclusion

In conclusion, TAMIS is ideal for benign lesions of the rectum, small carcinoid, and GIST tumors and is also an option for select, early-stage rectal adenocarcinomas. Compared to traditional transanal excision, TAMIS provides better exposure and results in more complete excision of the specimen. Compared to TEM, TAMIS is less costly, more widely available, and accordingly has led to broader access and surgeon adoption. Proper patient selection remains paramount. In addition, TAMIS can be used as a palliative option for patients whose comorbidities prohibit transabdominal resection.

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# An Algorithm for Local Excision for Early-Stage Rectal Cancer

# 3

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## Background

In 2018, an estimated 49,000 new cases of rectal cancer were diagnosed in the United States, and colorectal cancer remains the third most common newly diagnosed cancer in both men and women [1]. The standard surgical approach to most patients with rectal cancer includes radical resection with total mesorectal excision. Total mesorectal excision (TME), originally described by Heald and colleagues in 1982, has been widely established as the gold standard surgical treatment of rectal cancer [2]. In combination with stage-appropriate neoadjuvant chemoradiation therapy (CRT), the TME technique has dramatically lowered the traditionally high rates of local recurrence in rectal cancer [3]. However, complete dissection and removal of the lymph node-bearing mesorectum, combined with low pelvic anastomoses often in the setting of an irradiated field, have been associated with up to 40% rate of perioperative morbidity [4]. Despite the advantages of minimally invasive surgery, patients undergoing radical resection even at high-volume centers are still at significant risk for complications [5]. Radical resection for rectal cancer is also associated with a significant risk for bowel dys-

function and low anterior resection syndrome [6]. Finally, patient factors such as the growing obesity epidemic in the United States [7] increase the risk for overall mortality, need for colostomy, and morbidity following proctectomy [8]. Thus, for patients with early-stage rectal cancer without sphincter involvement, concern for the morbidity risk and quality of life impact of radical surgery has led to increased consideration of local excision strategies that are associated with substantially lower operative risk and provide potential for organ preservation [9].

## Techniques for Local Excision

Local excision (LE) via the conventional transanal excision (TAE) approach has historically been utilized to excise distal rectal tumors directly through the anus. Traditional local excision via TAE is limited to tumors smaller than 4 cm located within ~7 cm from the anal verge so that they can be visualized and accessed using traditional anal retractors [10]. The poor visibility of the anal canal and limited standard transanal instrumentation contribute to high rates of specimen fragmentation and specimen margin positivity [11]. Despite these limitations, TAE procedures potentially offer lower complication rates when compared to radical surgery. Additionally, transanal excision is almost universally associated with sphincter preservation and

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improved quality of life. To overcome these challenges of TAE, in the early 1980s, Gerald Buess developed transanal endoscopic microsurgery (TEM), the first of a series of platforms to accomplish transanal endoscopic surgery (TES). The TEM system consists of a rigid proctoscope anchored to the operating room table to provide a stable platform to accommodate pneumorectum, specialized dissecting instruments, and a magnifying stereoscope (Richard Wolf Company, Tubingen, Germany). In a recent meta-analysis by Clancy et al. comparing outcomes from TAE and TEM, there were no differences in complication rates between approaches (OR, 1.018; 95% CI, 0.658–1.575;  $p = 0.937$ ). There was a significantly higher rate of negative resection margins (OR, 5.281; 95% CI, 3.201–8.712;  $p < 0.001$ ), decreased specimen fragmentation (OR, 0.096; 95% CI, 0.044–0.209;  $p < 0.001$ ), and reduced incidence of lesion recurrence (OR, 0.248; 95% CI, 0.154–0.401;  $p < 0.001$ ) with TEM in comparison to standard TAE [12]. Despite the improvement in exposure of mid- to proximal rectal lesions, wider adoption of TEM has been limited to select high-volume centers due to the expense of the system, prolonged learning curve, and relative scarcity of training programs.

Transanal minimally invasive surgery (TAMIS) has improved the popularity of TES by providing a more affordable and accessible option. Atallah first described the transanal placement of a commercially available single port platform to perform transanal surgery with standard laparoscopic instruments and insufflators in 2010 [13]. The TAMIS platform is disposable, more readily available, and compatible with existing laparoscopic equipment (SILS Port, Covidien, Mansfield, MA; GelPOINT Path, Applied Medical, Rancho Santa Margarita, CA). The familiar instruments and lack of a rigid proctoscope appear to translate into a shorter learning curve for TAMIS procedures [14–16]. In 2010, the da Vinci Robotic Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) was used to perform TAMIS surgery in cadavers [17]. This off-label use of the robotic system, in combination with the FDA-approved GelPOINT Path TAMIS port, has subsequently expanded with prelimi-

nary results demonstrating feasibility [18]. Recently, Lee et al. published their 3-year follow-up results of 200 consecutive TAMIS operations, with 11% rate of postoperative complications, 93% of specimens with negative margins, and 95% of specimens submitted without fragmentation. Fifteen of these procedures were performed with the da Vinci robotic platform [19]. These results compare favorably to the results of a recent meta-analysis of over 1400 TEM procedures, reporting 82% of specimens with negative margins and 95% submitted without fragmentation [20]. Although no long-term oncologic results of TAMIS procedures have been described, it is the authors' opinion that the TEM data can be safely extrapolated to all TES procedures, including laparoscopic and robotic TAMIS, as long as the operating surgeon has sufficient proficiency in the platform of choice and quality improvement measures are in place to continuously evaluate surgical outcomes.

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### Traditional Indications for Local Excision

Traditional indications for the local excision of rectal tumors include excision of benign rectal pathologies and early-stage neoplasia, such as large rectal adenomas, incompletely excised rectal adenomas, adenomas with dysplasia, and intramucosal adenocarcinoma with or without foci of submucosal invasion [21]. The strategy of local excision of these pathologies has demonstrated safety, efficacy, and local recurrence rates of less than 10%, and progression to malignancy is rare [22]. Often a rectal polyp is biopsied or resected in a piecemeal fashion during colonoscopy, and additional en bloc tissue is necessary to ensure complete resection or assess depth of invasion. In such cases, full-thickness resection of the polypectomy scar can be both diagnostic and therapeutic. This approach should be used with caution in cases where more advanced neoplasia or invasion is suspected. Especially in low-lying rectal lesions where the perirectal fat is thinnest, full-thickness excisions can result in violation of the mesorectal fascial plane impairing



subsequent radical resection or even sphincter preservation if deemed necessary based on pathological review of the surgical specimen. Furthermore, it is important to note that if local excision is possible, then radical resection with anastomosis, including intersphincteric resection and coloanal anastomosis, will also be possible but will be associated with a much greater impact on bowel function. In cases where malignancy is not suspected, often submucosal excision alone is sufficient and avoids full-thickness rectal defects.

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### **Risk Factors for Failure of Local Excision of Early Rectal Cancer**

Complete surgical management of rectal cancer consists of obtaining tumor-free margins of the resected specimen and treating the lymph node basin that drains the tumor site. Local excision techniques, by necessity, are only able to accomplish the first goal [23]. Local excision of invasive rectal cancer has largely been reserved for patients with severe comorbidities such that radical resection poses undue risk, or for patients refusing radical surgery due to concerns for potential complications, side effects, and stoma formation. Performing local excision as a curative procedure for early-stage rectal cancer has long been a controversial topic due to early reports of unacceptably high rates of local recurrence. In 1992, Nivatvongs and Wolff outlined acceptable indications for local excision of rectal cancer via the transanal approach. The authors reported that tumors located within 7 cm of the anal verge, less than 3 cm in diameter, confined to the submucosa or superficial muscularis and with a favorable pathologic grade, either well differentiated (G1) or moderately differentiated (G2), were acceptable candidates for local excision – provided adequate resection margins of at least 15 mm could be obtained [24]. The authors also note that less than 5% of patients presenting with rectal cancer would meet these criteria. Indeed, many studies have evaluated the intramural spread of rectal cancer. In 2007, Guillem et al. published their comprehensive whole mount pathological analysis of 109 locally advanced

rectal cancers treated with neoadjuvant multimodal therapy. Of these tumors, only two specimens demonstrated intramural extension beyond the mucosal edge of the tumor, and both were less than 0.95 cm [25]. Shimada et al. retrospectively reviewed 381 consecutive rectal cancer specimens to evaluate distal spread, both intramural and mesorectal, in patients without neoadjuvant therapy. They found intramural spread was rare in early-stage rectal cancers (T1 = 3%) and did not exceed 4 mm. By comparison, T2 tumors demonstrated intramural spread up to 19 mm, beyond the standard accepted margin for transanal excision [26]. *Thus, it would appear that a 1 cm resection margin in T1 tumors should be sufficient, even in the absence of neoadjuvant therapy, and a more generous margin should be considered in more advanced tumors.*

Besides tumor size, depth of invasion, positive resection margins (R1 resection), and degree of differentiation, additional risk factors for local recurrence and distant metastases that have been born out in the literature include lymphovascular invasion and tumor budding.

In a retrospective study of 125 patients who underwent either local excision ( $n = 56$ ) or radical resection (APR,  $n = 69$ ) of T1–T2 rectal adenocarcinomas, the authors found that for tumors removed via local excision with favorable histopathology (G1, G2, and no lymphovascular invasion), the 5-year local recurrence rate was 4%. Conversely, when the histopathology was unfavorable (poorly differentiated or with lymphovascular invasion), the 5-year local recurrence rate was 32%. Similarly, in the favorable pathology cohort, the disease-free survival (DFS) was 87% compared to 57% in those tumors with unfavorable pathology [27]. This difference in DFS could likely be attributed to inadequately treated lymphatic metastases.

Depth of invasion appears to be a primary risk factor for lymph node metastasis and subsequent failure of local excisional techniques. The general incidence of nodal metastases in T1 tumors is about 10%, whereas nodal metastases can be present in as many as 22% of T2 tumors. Work by Kikuchi et al. has further subdivided T1 tumors arising in the setting of adenomatous polyps

based on the depth of submucosal invasion into sm1, those that invade only the upper third of the submucosa; sm2, those that invade the middle third; and sm3, those that invade the deepest third of the submucosa [28]. T1 tumors confined to the most superficial third of the submucosa (sm1) have been associated with as low as 6% rates of lymph node positivity, whereas T1 tumors invading into the deepest third of the submucosa (sm3) have approached the same rates of occult lymph node metastases as T2 tumors (23%) [29]. As local excision techniques cannot address the draining lymph node basin, the long-term oncologic success of local excision is closely tied to the risk of occult lymph node metastases.

Tumor budding is defined as small (less than five cells) clusters of tumor cells at the invasive edge of the tumor [30]. In a case-control study comparing 48 rectal cancer patients with local recurrence to 82 rectal cancer patients without local recurrence, tumor budding was an independent prognostic factor for local recurrence, irrespective of TNM staging [31]. A 2013 meta-analysis by Beaton et al. reviewed 23 cohort studies to analyze 4510 early-stage colon and rectal tumors managed with RR, either as the primary procedure or salvage of malignancy following endoscopic resection. The authors identified four factors associated with significantly increased risks of lymph node metastases: depth of submucosal penetration >1 mm [OR 3.87, 95% CI 1.5–10.0,  $p = 0.005$ ], lymphovascular invasion [OR 4.81, 95% CI 3.14–7.37,  $p < 0.0001$ ], poorly differentiated histopathology [OR 5.60, 95% CI 2.90–10.82,  $p < 0.0001$ ], and tumor budding [OR 7.74, 95% CI 4.47–13.39,  $p < 0.001$ ] [32].

Additionally, the classical indications may be inadequate predictors of lymphatic involvement. In a retrospective review of 76 early-stage rectal cancers managed by RR, 29% of lesions smaller than 2 cm ( $n = 7$ ) had evidence of lymph node metastases at time of radical resection [33]. A more recent report of 62 patients with T1 tumors excised via TEM described a significantly higher local recurrence rate for tumors greater than 3 cm in diameter when compared to tumors less than 3 cm in diameter (39% vs 11%,  $p = 0.03$ ), with an

overall rate of local recurrence of 31%. When the extent of submucosal spread was confined to the superficial 2/3 (Sm1/Sm2) in tumors smaller than 3 cm, the local failure rate was 7% at 3 years [34]. Based on the available literature, it seems that tumor size larger than 3 cm, depth of invasion beyond the superficial submucosa, poorly differentiated histopathology, lymphovascular invasion, and tumor budding are all primary tumor features associated with high rates of occult lymph node metastases. As local excision is unable to manage these lymph node basins, only tumors without these factors should be considered for local excision, provided complete R0 resection can be achieved.

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## Results of Local Excision of T1 Rectal Cancer

The earliest reports of long-term follow-up in the local excision of rectal cancer were published in the 1980s and 1990s. In 1990, a review of 16 series ( $n = 404$ ) with mid- to long-term follow-up data of rectal cancers managed with local excision demonstrated that the risk of local recurrence was increased with poorly differentiated histologic grade (relative risk =6) or positive resection margins increased risk of local recurrence (relative risk =27). The overall rate of local recurrence for the series was 19% (range 0–27%): 5% in T1 rectal cancers and 18% in T2 cancers [35]. These studies were retrospective case series and therefore subject to selection biases, heterogeneous cohorts of tumor stage, and lack of modern staging techniques including pelvic MRI and were often not analyzed according to known pathologic risk features. Over the subsequent two decades, multiple single-institution retrospective series were published to further evaluate the oncologic feasibility of local excision of T1 rectal cancers. Table 3.1 summarizes the results of retrospective single institution studies comparing local excision alone (either TAE or TEM) to radical resection of T1 rectal tumors (Table 3.1) [36–42]. Note the rate of local recurrence following local excision alone varies from 4% to 24%. Possibly the largest series of prospectively

**Table 3.1** Oncologic outcomes comparing local excision (LE) and radical resection (RR) of early-stage rectal cancer

Author, year	Local excision			Radical resection			Follow-up (y)
	<i>N</i>	5-year OS (%)	5-year local recurrence (%)	<i>N</i>	5-year OS (%)	5-year local recurrence (%)	
Single institutional cohort studies							
Winde, 1996 [36]	24 (TEMS)	96	4.1	26	96	0	3.8
Mellgren, 2000 [37]	69	72	18	30	80 <sup>a</sup>	0 <sup>a</sup>	4.8
Lee, 2003 [38]	52 (TEMS)	96 <sup>b</sup>	4.1	100	94 <sup>b</sup>	0	2.6
Nascimbeni, 2004 [39]	70	72	6.6	74	90 <sup>a</sup>	2.8 <sup>a</sup>	8.1
Bentrem, 2005 [40]	152	89	15	168	93	3 <sup>a</sup>	4.3
de Graaf, 2009 [41]	80 (TEMS)	75	24	75	77	0 <sup>a</sup>	3.5
Nash, 2009 [42]	137	87 <sup>b</sup>	13.2	145	96 <sup>a</sup>	2.7 <sup>a</sup>	5.6
Multi-institutional cancer registries							
Endsreth, Norwegian Rectal Cancer Group, 2005 [43]	35	70	12	256	80 <sup>a</sup>	6 <sup>a</sup>	Not reported
You, National Cancer Database, 2007 [44]	601	77	12.5	493	82	6.9 <sup>a</sup>	6.3
Ptok, German Colon/Rectal Cancer study group, 2007 [45]	85	84	5.1	359	92	1.4 <sup>a</sup>	3.5
Folkesson, 2007 [46]	256	87	7	1141	93	2 <sup>a</sup>	Not reported

<sup>a</sup>Denotes statistically significant difference

<sup>b</sup>Denotes disease-free survival

collected data includes 282 T1 rectal cancer patients undergoing either local excision via the standard transanal approach (TAE) or radical resection (RR) from 1985 to 2004 at Memorial Sloan Kettering Cancer Center. Tumors were located within 12 cm of the anal verge and patients who underwent adjuvant therapies were excluded from analysis. The mean distance from the anal verge was shorter [TAE 5.9 cm (SD 1.9) vs RR 7.8 cm (SD 2.6),  $p < 0.001$ ] and the mean tumor diameter was smaller [TAE 2.3 cm (SD 1.4) vs RR 3.1 cm (SD 2.2),  $p = 0.001$ ] in those tumors removed via TAE. The rates of lymphovascular invasion [TAE 12% vs RR 17%,  $p = 0.18$ ], perineural invasion [TAE 4% vs RR 2%,  $p = 0.50$ ], and poorly differentiated histopathology [TAE 4% vs RR 6%,  $p = 0.46$ ] were comparable between groups. Local recurrence was higher [TAE 13.2% vs RR 2.7%,  $p = 0.001$ ], and 5-year disease-specific survival was inferior

[TAE 87% vs RR 96%,  $p = 0.03$ , HR 2.8 (range, 1.04–7.3)] for tumors removed via local excision. Interestingly, of the 145 patients whose tumors were removed via RR, 20% of resected specimens harbored lymph node metastases [42]. Many of these patients were staged with CT scan and endorectal ultrasound, and none of the patients underwent high-resolution MRI imaging. In recent years, several national cancer registries have reported oncologic outcomes of early-stage rectal cancers managed with either local excision or RR (Table 3.1) [43–46]. Although these registries report substantially larger sample sizes than the previously mentioned single institution series, they are limited in lack of the pathological details, inherent selection biases, and represent outcomes of a wide range of preoperative assessment and surgical techniques. Notwithstanding, these studies confirm the higher rates of local recurrence after local excision



(5–13%) when compared to RR (1.4–7%). It is worth mentioning that again the overall survival at 5 years is comparable between groups and not statistically different in many studies. In the 2007 study of the US National Cancer Database (NCDB), You et al. report that after excluding patients with a positive resection margin, local excision remained an independent predictor of local failure. Yet the overall survival was not significantly different even after 8 years of surveillance. Instead, patient-related factors, including age and number of comorbidities, were more influential on overall survival than type of procedure (LE vs RR) [44]. From these studies, it seems clear that the main oncologic risk of local excision is local recurrence, and patient-related factors must be taken into consideration when planning either approach.

Perhaps the most meaningful information on local recurrence following local excision of early-stage rectal cancer come from two prospective multi-institutional trials: the Radiation Oncology Therapy Group (RTOG) 89-02 and the Cancer and Leukemia Group B (CALGB) 8984. Long-term results from the RTOG 89-02 study were published in 2000. Of 27 patients with T1 disease who were followed, only 1 patient (4%) suffered from local failure after a mean follow-up of 6.1 years. Although the details of this particular case were not specifically reported by the authors, only 40% of all patients enrolled were found to be in complete compliance with the surgical protocol [47]. Long-term results of the CALGB study were published in 2008. This study had clear inclusion criteria: T1 or T2 tumors; mobile tumors within 10 cm of the anal verge, <4 cm in size, and 40% of the circumference of the rectum; and full-thickness resection with negative margins. Of the initial 180 patients accrued to the study, 51 were deemed ineligible due to failure to meet these criteria and excluded from subsequent analysis. Instead of attempting to randomize patients to local excision versus radical resection, the authors sought to (1) compare the survival of patients with early rectal adenocarcinoma (T1/T2) undergoing local excision to historical controls treated with abdominoperineal resection (APR), (2) assess the local

failure rates of limited resection across tumor stage, and (3) evaluate the possibility of managing low-lying T2 rectal adenocarcinomas with local excision and adjuvant combined modality therapy. Of the 59 patients with T1 adenocarcinoma managed with local excision alone, the 6- and 10-year local failure rates were 6.8% and 8%, the 10-year disease-free survival was 75%, and the overall survival at 5 and 10 years was 91% and 84% [48]. The authors report that results compare favorably to historical data queried from the NCDB, whose 5-year overall survival for T1 patients managed with APR was 94%. Interestingly, recurrences after local excision of T1 adenocarcinoma occurred as late as 8 years after local excision, corroborating findings by other authors [49] that local and distant recurrences can occur at long intervals and that prolonged surveillance is advisable.

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### Local Excision of T2 Rectal Cancer

With rates of lymphatic spread in tumors invading beyond the submucosa as high as 30%, local excision has traditionally been reserved for patients either unfit or unwilling to undergo radical resection. Five-year rates of local failure as high as 47% after local excision of T2 tumors, compared to only 6% after radical resection of staged matched cancer, have been demonstrated in prior studies [50]. Additionally, a comparison of local excision versus radical resection of T2 tumors has been performed by NCDB studies, confirming the alarmingly high rate of local recurrence (LE 22% vs RR 14%,  $p = 0.01$ ) and associated reduction in 5-year overall survival (LE 68% vs RR 77%,  $p = 0.02$ ) [44]. *These results suggest that local excision should not be considered adequate oncologic management as the primary treatment modality of rectal tumors that extend beyond the submucosa.* As the use of multimodality adjunctive therapy has been shown to improve oncological outcomes in locally advanced rectal cancer, this approach has been considered to enable local excision of T2 rectal tumors. Several single institution studies with relatively small patient numbers have been reported (Table 3.2) [51–54].

**Table 3.2** Local excision followed by adjuvant therapy for T2 rectal tumors

Author, year	Number of patients	Local recurrence, <i>n</i> (%)	Overall survival
Minsky et al., 1991 [51]	7	1 (14%)	88% at 3 years
Benson et al., 2001 [52]	36	5 (15%)	58% at 5 years
Wagman et al. 1999 [53]	25	6 (24%)	70% at 5 years
Bouvet et al., 1999 [54]	27	5 (20%)	89% at 4 years

These studies report a local failure rate of 14–24% for T2 rectal tumors treated by local excision followed by adjuvant multimodal therapy with chemotherapy and radiation. While potentially improved compared to surgery alone, the rate of failure was still much higher than rates that have been reported following TME. The earliest prospective data on this topic comes from the CALGB 8984 study, wherein 51 patients with low-lying rectal tumors were treated with local excision followed by postoperative adjuvant radiotherapy (5400 cGy in 30 fractions) with concurrent 5-fluorouracil (5-FU). Long-term outcomes of this study demonstrate a 10-year local recurrence rate of 18% and overall survival 66% [48]. However, improved outcomes may be achieved by moving the multimodality therapy to the neoadjuvant setting. This strategy was explored in the ACOSOG z6041 trial. Strict entry criteria were observed; patients were staged by endorectal ultrasound or endorectal coil MRI and had tumors less than 4 cm in diameter and involving less than 40% of the rectal circumference located within 8 cm of the anal verge. In this multi-institutional, non-randomized, phase II trial, 79 patients with clinically staged T2 N0 distal rectal cancer completed the protocol between May 2006 and October 2009. These patients underwent neoadjuvant chemoradiotherapy [capecitabine (825 mg/m<sup>2</sup> twice daily on days 1–14 and 22–35), oxaliplatin (50 mg/m<sup>2</sup> on weeks 1, 2, 4, and 5), and radiation (1.8 Gy per day, 5 days a week for 5 weeks totaling 45 Gy, followed by a boost of 9 Gy for a total dose of 54Gy)] followed by local excision. Patients with ypT3

tumors or positive margins after excision underwent salvage total mesorectal excision. All patients were followed for a median of 56 months (IQR 46–63), with local recurrence rates reported as 4%, distant metastases developed in 6%, the disease-free survival was 88% (95% CI 81.3–95.8), and the overall survival was 95% (95% CI 91.1–100). At the end of the study, 91% of patients who received neoadjuvant chemoradiotherapy had rectal preservation, with no substantial deterioration in rectal function as measured by the Fecal Incontinence Severity Index (FISI) [55, 56]. The main problem with this approach lies in the treatment toxicity; after 53 patients were recruited, the regimen was altered to 50.4 Gy radiation by reducing the 9 Gy boost to 5.4 Gy, and capecitabine was reduced to 725 mg/m<sup>2</sup>, twice daily, 5 days a week for 5 weeks. Of the 79 patients who completed protocol, 29% had severe gastrointestinal adverse events, 15% had severe pain, and 15% had severe adverse hematological adverse events [55]. It seems that appropriately selected, highly motivated T2 N0 patients with excellent response to neoadjuvant therapy managed by local excision approach the oncologic outcomes of T1 N0 patients managed by local excision alone. However, these patients could also be managed with radical surgical extirpation of their rectal tumor and avoid the toxicity of radiation therapy [57]. More recently the results of the GRECCAR 2 study have been published [58]. This was a prospective, randomized, multi-institutional phase III study performed in France and enrolled patients from March 2007 through September 2012 with clinically staged T2–3 N0–1 that demonstrated a good clinical response (residual tumor ≤2 cm) to neoadjuvant chemoradiotherapy [capecitabine (1600 mg/m<sup>2</sup> per day, 5 days per week), oxaliplatin (50 mg/m<sup>2</sup> per week), and concurrent radiation therapy (2Gy per day, 5 days per week for 5 weeks, total 50Gy)]. Tumors were less than 4 cm in maximum diameter and less than 8 cm from the anal verge. Patients were randomly assigned to either local excision or radical resection prior to surgery, and those randomized to local excision that were found to have a poor pathological response (ypT2–3) or incomplete resection (R1) underwent completion total mesenteric

excision. A total of 145 patients met criteria for randomization, and of the 71 patients randomized to local excision, 26 underwent subsequent TME due to findings at interpretation of pathology. Median follow-up was 36 months (IQR 36–36). Primary endpoint was a composite outcome of death, recurrence, morbidity, and treatment side effects. Between study groups there were no differences in local recurrence (LE 3% vs RR 3%,  $p = 0.63$ ), metastatic recurrence (LE 15% vs RR 13%,  $p = 0.47$ ), 3-year DFS (LE 75% vs RR 82%,  $p = 0.84$ ), and 3-year OS (LE 89% vs RR 95%,  $p = 0.40$ ). No patients who were randomized to local excision and converted to radical resection based on pathologic criteria developed local recurrence. Although there were no differences in oncologic outcomes, the authors failed to demonstrate superiority of local excision over radical resection, which they attributed to the high rates of conversion to TME [58]. Interestingly, the combination of local excision and adjunctive therapies seems to prolong the time interval to local recurrence when compared to local excision alone [49, 59]. In the long-term results of the aforementioned Memorial Sloan Kettering series, patients undergoing adjunctive therapies had a median time to recurrence of 2.1 years compared to 1.1 years for those undergoing local excision alone [59]. Chakravarti et al. report local failures beyond 5 years in patients managed by adjuvant chemoradiotherapy, again supporting the need for long-term follow-up in these patients [49]. The long-term results of the GRECCAR 2 trial may provide additional insights into rates of late recurrences and are eagerly anticipated.

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## NCCN and National Guidelines

A number of organizations have published guidelines regarding the management of early rectal cancers. The 2018 guidelines for the management of rectal cancer set forth by the National Comprehensive Cancer Network state that transanal excision (TAE) is only appropriate for T1 N0 early-stage rectal cancers without evidence of high-risk features: small tumors (<3 cm) located within 8 cm of the anal verge, occupying <30%

of the rectal circumference, and without evidence of nodal metastasis. Transanal endoscopic surgery (TEM, TAMIS) may facilitate local excision of more proximal tumors. Tumors should be carefully resected en bloc and without fragmentation, and the specimens should be oriented with the surgical pathologist. Pathologic evidence of positive margins, lymphovascular invasion, poor differentiation, or invasion into the deeper layers of the submucosa (Sm3) or muscularis propria (T2) should prompt consideration of radical resection [57]. These recommendations are mirrored by the European Association of Endoscopic Surgery (EAES), the European Society of Coloproctology (ESCP) [60], the practice parameters of the American College of Colon and Rectal Surgeons (ASCRS) [61], and the Japanese Society for Cancer of the Colon and Rectum (JSCCR) [62]. It should be noted that the JSCCR only recommends local excision for rectal cancers with limited submucosal invasion (malignant polyp, Sm1), as the national cancer registry in Japan reports approximately 10% incidence of nodal metastases in T1 rectal cancer. Thus, Japanese surgeons routinely perform a minimum D2 lymphadenectomy in the setting of cT1 disease. Finally, adherence to the NCCN guidelines has been previously demonstrated to impart a survival benefit in locally advanced colon cancer patients [63]. One could extrapolate this finding to rectal cancer, and the authors prefer to err on the side of caution when managing these patients.

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## Patient-Related Factors

Besides tumor location and primary characteristics that can be used to determine oncologic feasibility of local excision of early rectal tumors, patient-related factors should be taken into consideration. For patients with significant comorbidity or limited life expectancy, optimizing oncologic control should be balanced with risk for surgical or functional morbidity. Often these early rectal tumors being considered for local excision are low lying, and radical resection would result in loss of sphincter function or resection of the sphincter complex entirely (abdominoperineal resection, APR). When

considering local excision for an early-appearing rectal cancer, the patient's willingness to undergo subsequent salvage resection or adjunctive therapies, as well as to be compliant with surveillance strategies, should also be considered.

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### Technical and Surgeon-Related Factors

The feasibility of performing local excision or radical resection should take into consideration the local expertise of the surgeon and available technologies. Radical resection of rectal cancer has increasingly been performed with sphincter preservation. Despite relatively high rates of low-grade (Clavien-Dindo I and II) complications, major morbidity and mortality (Clavien-Dindo III–V) after radical resection remain relatively low in high-volume centers of expertise. Sphincter-preserving radical resection of mid to distal rectal cancers has been described with good oncologic outcomes in the setting of adjunctive multimodality therapy [5]. Additionally, local recurrence of 5% or less should be considered the standard for well-selected early-stage rectal cancer patients undergoing local excision alone. If these nationally accepted standards cannot be met, then consideration for referral to a high-volume center should be considered.

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### Salvage of Recurrence After Local Excision

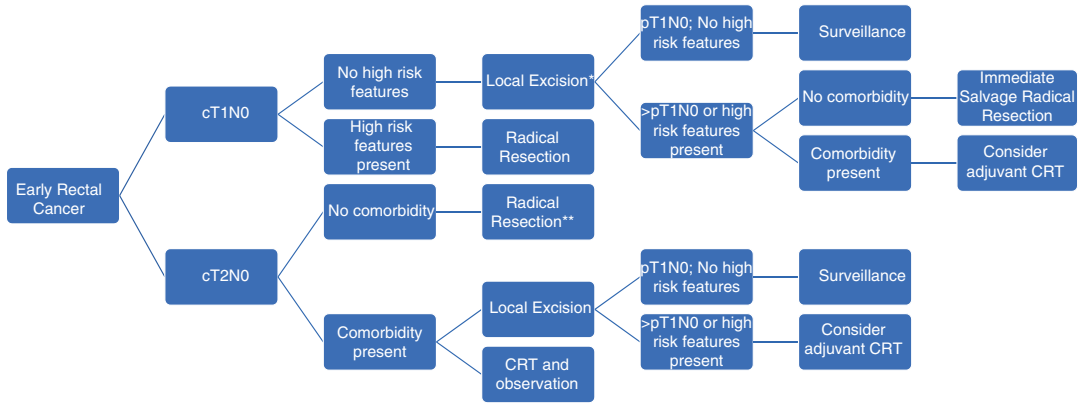
Given the wide spectrum of local failure rates, prior to embarking on local excision as definitive treatment, with or without adjuvant therapies, the surgeon must consider the feasibility of salvage after local recurrence occurs. In a review of 8 studies with a total of 493 patients undergoing local excision, 73 patients experienced locoregional recurrence with or without distant disease. Sixty percent were successfully treated with a curative radical resection, but approximately 50% eventually died from disease [23]. In those instances where high-risk features were found on pathologic review after local excision, immediate

radical resection appears to offer a survival benefit over salvage surgery at the time of recurrence [5-year DFS 94.1% for immediate radical resection vs 55.5% for salvage at time of recurrence,  $p < 0.05$ ] [64]. Salvage surgery at the time of recurrence often involves multivisceral resection and is associated with high rates of perioperative complications, and a significant portion of patients will present with unsalvageable recurrence. At the University of Texas MD Anderson Cancer Center, among 46 patients with recurrence after initial treatment with TAE, 91% were candidates for surgical salvage and 87% elected to proceed. The R0 resection rate was 80%, and the required resections were complex, requiring multivisceral resection (33%), total pelvic exenteration (5%), or metasectomy (25%). The rate of sphincter preservation was 33%, perioperative morbidity was 50%, and 5-year OS was 63% [65]. In a similar fashion, Doornebosch et al. reviewed 18 patients who developed local recurrence after TEM excision of pT1 rectal cancer. Two of these recurrences were unsalvageable, and the remainder underwent TME without multivisceral resection for salvage. The 3-year OS reported in this series was 31% [66]. Current NCCN guidelines recommend immediate salvage surgery if high-risk histopathological features are noted after local excision [57]. Clearly, waiting until the patient develops a recurrence is associated with a poorer prognosis. Newer data considering adjunctive chemoradiotherapy as salvage after local excision of high-risk pT1 tumors has some promise, with some studies reporting 5-year OS and DFS as 94% and 89%, respectively; however these patients still require very close follow-up and may remain at increased risk for disease recurrence. Locoregional recurrence at 5 years remains as high as 9% [67]. More studies are needed to determine if this is an acceptable approach in LE with high-risk features.

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### An Algorithm

The authors' algorithm for consideration of local excision of rectal neoplasia is shown in Fig. 3.1. All patients presenting with rectal tumors



\* Radical resection may be considered based on surgeon/patient discussion  
 \*\* May consider neoadjuvant CRT with intersphincteric resection for low rectal cancer desiring sphincter preservation

**Fig. 3.1** An algorithm for management of early-stage rectal cancer. \*Radical resection may be considered based on surgeon/patient discussion. \*\*May consider neoadju-

vant CRT with intersphincteric resection for low rectal cancer desiring sphincter preservation

undergo a full history and physical examination, including digital rectal exam and either rigid proctoscopy or flexible sigmoidoscopy to confirm the anatomical position of the tumor within the rectum and obtain additional tissue via biopsy if clinically indicated. If diminished sphincter function is detected, we proceed with FISI questionnaire [68] and anorectal manometry to further evaluate. When considering local excision and organ preservation, understanding and documenting the baseline sphincter function is crucial. For patients with poor sphincter function, often appropriate counselling is more useful than organ preservation, as these patients can demonstrate improved quality of life with a colostomy.

Staging images are obtained with high-quality computed tomography (CT) of the chest, abdomen, and pelvis, to rule out metastatic disease, and pelvic magnetic resonance imaging (MRI) with rectal cancer protocol for further characterization of the tumor and locoregional disease including risk for lymph node metastasis. Patients with early T category tumors may require evaluation by endorectal ultrasound, to improve the accuracy of determination of T1 vs T2 tumors. All pertinent information is reviewed by a multidisciplinary treatment team prior to recommendation for local excision. Patients with

rectal cancer exhibiting nodal metastasis are not considered for local excision; instead these patients proceed to neoadjuvant therapy as indicated and followed by TME except in rare cases of patients unwilling to undergo a radical surgery.

After nearly 30 years of ongoing investigation, the previously established initial recommendations of Wolff and Nivatvongs have changed little [24]. Based on the aforementioned studies, it follows that T1 N0 tumors 3–4 cm or less in maximal diameter, within reach of modern transanal instrumentation, and involving less than 30–40% of the rectal circumference, would be candidates for local excision – provided the tumor can be completely excised and specimen fragmentation can be avoided. Sometimes this is performed as a radical biopsy, to evaluate for the presence of the previously mentioned high-risk features on histopathology: (1) depth of invasion beyond 1 mm into the submucosa or into the deepest one-third of the submucosa (Sm3); (2) poorly differentiated features on histopathology; (3) presence of lymphovascular invasion; and (4) tumor budding. If these features are found on final analysis by an experienced pathologist, the patient should undergo immediate salvage resection, as delaying salvage until the recurrence occurs is associated with unfavorable outcomes. Patients who lack



these high-risk features can be safely observed, with an expected local recurrence rate of approximately 4%. Often these patients are candidates for minimally invasive surgical resection with sphincter preservation and are willing to undergo radical surgery up front. Those patients who elect local excision should be carefully counselled about the risks of subsequent salvage surgery or unresectable recurrence. Patients who are unwilling to accept this slight risk of local recurrence and the morbidity of subsequent salvage surgery or unknown lymph node status, or patients in whom the primary tumor can be safely removed via radical resection with sphincter preservation, are offered radical resection.

The indications for local excision may be extended to patients with cancers that exhibit high-risk features and who have a limited life expectancy or those with concurrent severe medical comorbidities and/or competing health risk. In these cases, we advocate for patient counselling and multidisciplinary review to determine the most appropriate course of action.

Rectal tumors that have penetrated into the muscularis propria (T2) are often discernable on pelvic MRI. In the absence of radiographic evidence of nodal metastases, these patients can be considered for up-front radical resection or neoadjuvant chemoradiotherapy and re-evaluation. As the GRECCAR 2 trial demonstrated, local excision is acceptable for patients with a good clinical response to neoadjuvant therapy [58]. Complete clinical responders could be considered for close observation, although current guidelines advocate the “watch and wait” approach only in the setting of a clinical trial. Although TES has extended the reach of transanal excision to proximal rectal and distal sigmoid tumors, often these patients are amenable to radical resection with sphincter preservation. The authors’ strategy is to tailor the approach to these tumors based on the patient’s concerns and preferences, taking into consideration the risk of postoperative complications of radical resection compared to the risk of tumor recurrence and subsequent salvage operation.

## Conclusions

Although safety and efficacy of local excision of rectal neoplasia via TES has been demonstrated in multiple studies, the surgeon must take into account tumor characteristics, patient concerns, and feasibility of safely performing a radical resection with sphincter preservation. We reserve local excision as the primary oncological management strategy for low-lying rectal tumors with favorable features.

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# Complete Clinical Response in Rectal Cancer After Neoadjuvant Therapy: Organ Preservation Strategies and the Role of Surgery

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## Introduction

Surgical management of low rectal cancer is associated with a significant rate of postoperative complications. Even mortality may be quite significant, depending on patients' age and comorbidities [1]. In addition, even after an uneventful recovery, patients may still have to deal with significantly negative functional consequences. A major proportion of patients will develop fecal incontinence and considerable rates of low anterior resection syndrome [2, 3]. These symptoms may be so significant that a proportion of these patients will require antegrade enemas performed

through an endoscopically placed cecostomy as the last resource to avoid a definitive stoma [3]. Even though definitive colostomy rates have been reported to be  $\leq 10\%$  in dedicated centers for the management of rectal cancer, long-term colostomy rates may increase to  $\geq 22\%$  due to anastomotic failures related to poor function, leaks, or even local recurrence [4]. Finally, patients who underwent a radical surgery for rectal cancer have more than twofold increased risk for being out of work, despite being recurrence-free. The risk increased according to the type of operation performed (higher for APR compared to AR) and to the presence of surgical/postoperative complications [5].

Neoadjuvant CRT may lead to significant tumor regression of rectal cancers that can be observed not only in the primary tumor but also in perirectal nodes, setting the "perfect" scenario for organ preservation strategies such as transanal excision (TAMIS) of small and superficial residual tumors [6, 7]. In addition, the observation that this effect may be so intense leading to complete tumor regression in up to 30% of patients [pathological complete response (pCR)] prompted surgeons to an attempt in the identification of these patients before surgical resection, known as complete clinical response (cCR) [7]. These patients with complete tumor regression to

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nCRT would also constitute the ideal candidates to consider organ preservation strategies such as no immediate surgery and strict surveillance (also known as the “watch and wait” strategy (WW)) [8]. In order to even consider these approaches, colorectal surgeons have to address several aspects of the assessment of the disease, patients, and treatment modalities that may be quite relevant during their clinical decision-making process.

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### **Neoadjuvant Chemoradiation (nCRT): Indications and Options**

Following the results of the German trial, nCRT was considered the preferred initial strategy for most cT3–4 or cN+ rectal cancer patients due to the potential benefits in terms of local disease control after radical surgery [9, 10]. However, the MERCURY study suggested that nCRT could preferably be restricted only to patients at highest risk for local recurrence after TME. This would include patients with radiological evidence of a threatened or positive circumferential margin (cCRM+), presence of extramural venous invasion (cEMVI+), and  $\geq 3$  positive lymph nodes (cN2) [11]. In addition, preoperative radiation following radical surgery was shown to result in inferior functional outcomes and higher surgical morbidity when compared to surgery alone [12, 13]. Altogether, these findings suggested that the sole benefit of nCRT would be to improve local disease control only in high-risk rectal cancer patients (defined by high-resolution MR). Considering that baseline staging may affect rates of response to nCRT, one could expect that very few patients with considerably advanced disease would ever develop a complete clinical response and benefit from avoiding radical surgical resection.

Instead, the idea of offering nCRT to intentionally achieve a cCR and avoid radical surgery with its related comorbidities led colorectal surgeons to consider nCRT to more early-stage disease, particularly in most distal tumors otherwise candidates for abdominal perineal resections or ultralow intersphincteric anastomosis (and worse

expected anorectal function). Patients with cT2 N0 or early cT3N0 are potentially more likely to develop a complete clinical response following nCRT and could benefit the most from nCRT if organ preservation is considered [14–16].

Therefore, nCRT should be considered for local disease control purposes in patients with high-risk features (threatened cCRM, cN2, or cEMVI+) if total mesorectal excision (TME) is to be performed regardless of response. However, it could be offered to most rectal cancer patients if organ preservation is an option (including stage I disease—mrT2N0M0) [17].

Different regimens of neoadjuvant chemoradiation may influence response rates and should be considered if an organ preservation approach is an option. Long-course CRT was the first regimen associated with significant rates of complete response. However, with the idea of prolonged interval period for the assessment of response, short-course RT may result in similar rates of response to long-course regimens [18]. In addition to the effect of time interval, the final dose of radiation therapy and the method of delivered may also influence the odds of developing a cCR. Dose escalation studies have demonstrated a direct relationship between CR rates with doses of RT delivered to the primary tumor [19]. In this mathematical model, depending on tumor size (as an estimate of tumor volume), progressive increases in RT dose (dose escalation) would lead to predictive rates of major and complete response [19]. Dose escalation may be facilitated with the combination of external beam or intensity-modulated RT (EBRT or IMRT) with endorectal brachytherapy (HBRT) or even with contact RT. The idea of adding significant doses of RT with these approaches may ultimately maximize the chances of developing complete clinical response and still avoid major treatment-related toxicity [20–22]. Recently, one study has investigated the role of CXB in patients with an initial incomplete clinical response (residual tumor  $\leq 3$  cm) in successfully achieving a complete clinical response and improving the chances of organ preservation [23].

Finally, another way of increasing the rates of cCR and organ preservation is optimization of concomitant or even exclusive chemotherapy regimens.

The incorporation of additional chemotherapy cycles in standard nCRT has been suggested. The incorporation of additional chemotherapy during the interval between RT completion and assessment of response using 5FU-based chemotherapy (consolidation CRT regimens) demonstrated an increase of CR rates to more than half of consecutive patients with T2/T3 rectal cancer [24, 25]. Although the observation that chemotherapy may have an important role in tumor regression, the incorporation of additional drugs to 5FU has been disappointing. The addition of oxaliplatin did not improve pCR rates in most studies. Instead, it resulted in significantly higher toxicity rates [26].

Alternative neoadjuvant strategies that could spare patients from the potential detrimental effects of radiation (with the same benefits) are an attractive alternative. Patients may develop worse functional outcomes after TME in the setting of previous exposure to RT [13]. Even patients that develop a cCR and avoid radical surgery may not have perfect function [27, 28]. In this setting, the use of chemotherapy alone is an attractive option and has been used to restrict standard CRT to patients showing poor response to chemotherapy alone and therefore decreasing the number of patients receiving RT [29]. Also, the incorporation of biological agents including anti-EGFR or anti-VEGF has been tested in the neoadjuvant setting of patients with rectal cancer. Even though these agents have demonstrated good safety profiles, their real benefits in terms of tumor regression have been even more disappointing with pCR rates even lower than usually observed with standard CRT regimens [30–32].

A recent study reported the results with the use of total neoadjuvant treatment (TNT, induction of fluorouracil- and oxaliplatin-based chemotherapy followed by CRT) for patients with rectal cancer. The authors compared patients treated with standard long-course neoadjuvant regimen followed by postoperative adjuvant chemotherapy with patients receiving TNT. TNT

consisted of systemic chemotherapy first (FOLFOX) followed by nCRT and finally radical surgery. The comparison of TNT to standard nCRT-surgery-adjuvant suggested higher rates of complete planned treatment among patients with TNT regimen. Although very promising and attractive, the implementation of TNT in clinical practice should be done with caution. The inclusion of systemic chemotherapy, including oxaliplatin in this regimen, may lead to overtreatment of a significant proportion of patients that may have ultimately never have required oxaliplatin in the adjuvant setting. Also, TNT will need to be compared to standard nCRT with consolidation chemotherapy (without oxaliplatin) already with considerably high cCR and organ preservation rates.

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### Assessing Tumor Response to nCRT

Assessment of tumor response to nCRT becomes crucial when considering patients for organ preservation management. During this process two important issues remain as challenges: the optimal timing for assessment and clinical/radiological tools for this purpose.

Assessment of tumor response should be routinely performed independently of the decision for an organ-preserving strategy. Even if the plan is radical surgery, it is important to consider that CRT may lead to significant modifications in the primary tumor dimension and architecture and its relationship with surrounding tissues. Knowing these potential anatomical changes between pre- and posttreatment status ahead of time may help in optimization of intraoperative surgical strategies and anticipate surgical challenges during the procedure [33].

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### Intervals After nCRT

Tumor regression after nCRT appears to be time-dependent. The first association between different time intervals (from CRT completion and surgery) and tumor response was reported by the French randomized trial comparing 2 versus

6 weeks from nCRT. The study showed that those patients with longer interval to surgery (6 weeks) were more likely to present tumor regression after nCRT [34]. Six-week intervals from nCRT completion to assessment of tumor response shortly became the standard of care for many years. However, retrospective data suggested that patients operated on after longer intervals from CRT completion, as long as 12 weeks, were more likely to develop pCR [35]. After the observation that these considerably longer intervals could increase response to CRT, a hypothesis was made suggesting that waiting more time to surgery could lead to tissue fibrosis and increased technical difficulties and postoperative morbidity after radical surgery. In order to address this concern, a prospective, non-randomized study evaluated patients in nCRT regimens with progressively longer interval periods prior to surgical resection [36]. Patients after a 6-week interval showed similar postoperative complications than patients after a 12-week interval. In addition, after progressively longer intervals (6, 12, 18, and 24 weeks), the study showed that longer intervals were associated with significantly higher rates of pCR with no negative impact on postoperative morbidity, even with additional chemotherapy cycles during the longer intervals (consolidation mFOLFOX) [37]. However, another recently published prospective randomized study failed to demonstrate increased rates of pCR when comparing 7- and 11-week intervals from standard nCRT. Moreover, the trial observed that more postoperative complications and worse quality of the mesorectum were associated with the 11-week interval group, suggesting the potentially negative effects of prolonged time intervals after nCRT associated with fibrotic changes in the surgical and previously irradiated fields [38].

The optimal interval after nCRT remains undetermined, and additional ongoing trials will provide more data to allow us to understand the benefits and risks of waiting extended intervals after treatment. One recently published study suggested that patients with an excellent radiological response and minor irregularities during the clinical exam, referred as “near”-complete responses, may benefit from additional waiting

period. In this study, patients with a “near” clinical complete response and mrTRG1 or 2 were deferred from immediate radical surgery and underwent further reassessment in a 6–8-week interval. Outcomes revealed that 90% of these patients went on to achieve a cCR and were successfully managed by organ preservation [39]. Altogether, it is possible that individual tumors respond differently to nCRT as a function of time. In this setting, responsive tumors may require and benefit from extended intervals, whereas unresponsive tumors may not [40].

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## Studies for the Assessment of Response

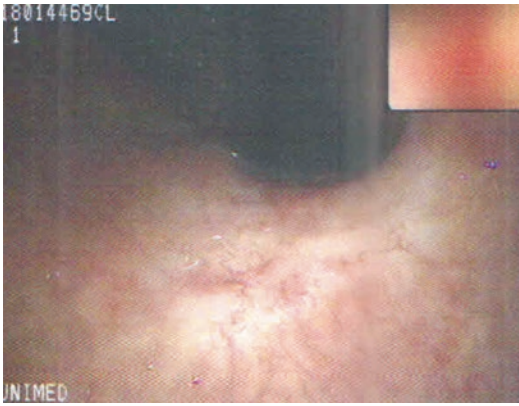
### Clinical and Endoscopic Findings

Clinical assessment remains as one of the most important tools in the evaluation of tumor response to treatment. Digital rectal examination (DRE) may be able to detect subtle residual irregularities within the rectal wall, residual masses, ulceration, or stenosis, even in the absence of clinical symptoms after nCRT. During DRE, the surgeon has to be able to feel a regular and smooth surface with only mild induration and subtle loss in the pliability of the rectal wall. These are acceptable findings consistent with a cCR [7].

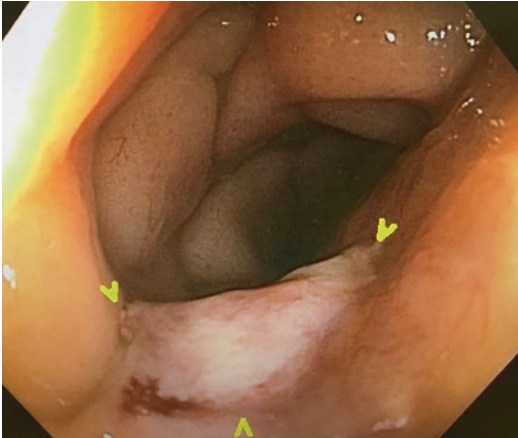
Suspicious findings of incomplete clinical response (irregularity or superficial ulcer missed during DRE) are easily detected during endoscopic evaluation. Instead, a flat white scar and telangiectasia are normal findings encountered during endoscopic assessment of patients with a cCR (Fig. 4.1).

In the context of a cCR (during clinical and endoscopic assessment), routine endoscopic biopsies are not recommended. In other words, in the presence of a regular and smooth mucosa, there is no need for a negative biopsy to confirm a complete clinical response. Even in the presence of an incomplete clinical response, endoscopic biopsies should be interpreted with caution. A *negative* biopsy in the context of residual ulcers, mass, or stenosis (incomplete clinical





**Fig. 4.1** Typical endoscopic findings of a cCR with whitening of the mucosa and the presence of telangiectasias. No ulceration or evident mass is present. cCR complete clinical response



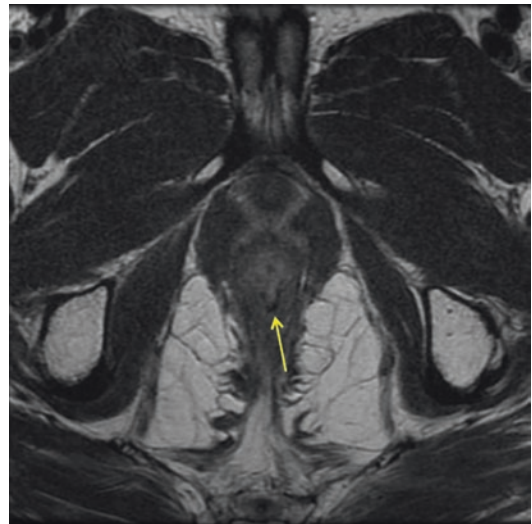
**Fig. 4.2** Endoscopic findings consistent with incomplete clinical response including the presence of an obvious ulcer and significant amount of fibrin covering it (*yellow arrows*)

response) is rarely associated with no residual cancer. Most of these patients will have residual viable cancer in nearly 80% of the cases despite a negative endoscopic biopsies [41] (Fig. 4.2). An interesting study has revealed that after nCRT, the mucosa is the layer of the rectal wall less likely to harbor residual cancer cells [42]. Therefore, the presence of a negative biopsy should not be interpreted as a complete clinical response or as an accurate marker of a complete pathological response.

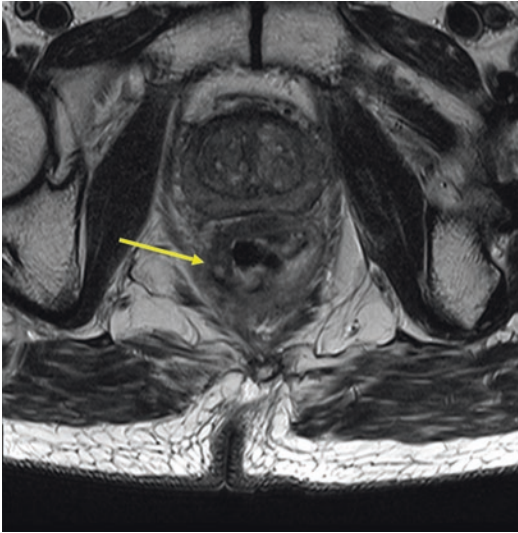
## Radiological Assessment

Radiological studies are also essential for the assessment of response not only to confirm clinical and endoscopic findings of a cCR but also provide additional information of the mesorectum compartment unavailable to the finger or the endoscope. High-resolution magnetic resonance (MR) is routinely used for the assessment of tumor response. The ability to discriminate between fibrotic changes and residual disease has improved with advances in technology, placing MR as an integral part in the assessment of response to nCRT [43]. Typical findings of complete tumor regression include the presence of low-signal intensity areas in the area previously harboring the rectal cancer with multiple patterns [43] (Figs. 4.3 and 4.4). MR may estimate the pathological tumor regression grade (TRG) by providing a similar radiological scoring system (mrTRG) and therefore able to identify patients with poor or good response prior to surgical treatment and with a significant correlation between response and survival [33, 44].

Diffusion-weighted magnetic resonance imaging (DWI-MR) may provide additional information to standard MR imaging. The properties of



**Fig. 4.3** Radiological assessment of tumor response with high-resolution magnetic resonance showing findings of complete response with the presence of low-signal intensity signal in the area harboring the original tumor (*yellow arrow*)



**Fig. 4.4** Radiological findings consistent with incomplete response in magnetic resonance indicated by the presence of a mixed signal intensity area (*yellow arrow*)

water molecule diffusion may vary within areas of tissue necrosis, high cellularity (commonly observed within residual tumor) or fibrotic scarring. This could be used to improve the identification of responders and represent an additional tool during assessment of tumor response [45, 46].

Finally, the addition of PET/CT by providing an estimate of tumor metabolism could be used to help assess tumor response to nCRT. The variation in mean standard uptake values (SUV) and metabolic tumor volume reduction between pre- and posttreatment scans was found to be one of the best predictors of response to nCRT among patients with rectal cancer [47].

In fact, it has been suggested that the combination of all these studies (including clinical, endoscopic, and radiological) may increase the accuracy in the detection of complete tumor response to nCRT [48].

### Transanal Full-Thickness Local Excisions (FTLEs)

Definitive information on pathological response including final ypT status, TRG, lymphovascular/perineural invasion placed excisional biopsies as an attractive tool for the assessment of primary

tumor response to nCRT [49]. Performance of transanal local excision with the use of transanal endoscopic platforms (TEMs or TAMIS) will provide an ideal specimen with lower risk of positive margins (in the case of residual cancer) and specimen fragmentation when compared to standard transanal surgical techniques, often associated with poor illumination and exposure of the surgical field [50]. In addition, appropriate pathological information and resection margins of the tumor may aid in the decision regarding the need for additional TME. Otherwise, in the case of a complete pathological response, it could be used as an objective confirmation of pCR (ypT0) and obviate the need for additional TME.

However, these attractive advantages should be balanced against by several potential disadvantages. First, healing of the rectal defects created by local resection after nCRT may be quite challenging. In the setting of a dehiscence, pain is frequently quite significant, and it could take as long as 8 weeks to completely heal. Although, Grade III or IV postoperative complications are not usually observed, pain is a common cause for readmission to the hospital [51]. As a result of difficult healing, scarring with significant distortion and irregularities may occur within areas of the rectal wall previously resected. This may ultimately also contribute to difficulties in differentiating postoperative fibrosis or local recurrences during follow-up of these patients by clinical, endoscopic, and radiological surveillance studies [52]. Secondly, sphincter preservation may be significantly compromised after a FTLE. When patients with cCR and non-operative management were compared to patients with “near-complete” response and FTLE following nCRT, functional outcomes were significantly better among patients under WW [53]. In this setting, even though organ preservation has been achieved with FTLE, anorectal function may be far from normal in these patients.

Even if patients are found to have incomplete pathological response, FTLE may significant disadvantages. Patients that required additional TME after FTLE (due to the presence of unfavorable pathological features) frequently ended up with an APR, despite the fact that they originally were candidates for a sphincter-preserving strategy [54, 55].

In addition, completion of TME in this setting has been associated with a risk factor for poor quality of the mesorectal specimen. A recent review of patients undergoing completion TME indicated that previous TEM was a risk factor for poor quality of the TME specimen [56]. Finally, in the prospective GRECCAR 2 study, patients with baseline small cT2/T3 tumors ( $\leq 4$  cm) underwent nCRT. Those with “good” clinical response ( $\leq 2$  cm) were randomized to TME or local excision (LE). In an “intention to treat” analysis (using a composite primary endpoint including mortality, morbidity, function, and recurrence), patients who underwent LE had similar oncological and functional outcomes to those after TME. On a first glance, this could suggest that local excision after nCRT is a valid alternative in this highly selected patient population (small baseline tumors and excellent clinical response). However, in a subgroup analysis of patients that needed completion TME due to the presence of high-risk/unfavorable pathological features in the LE specimen, outcomes were not as good. These patients had significantly more postoperative complications, need for APR, and worse functional outcomes. In conclusion, patients that underwent LE alone (with favorable pathological features) did the best when compared to TME or LE + TME. Patients who underwent LE and required TME (unfavorable pathological features) did the worse when compared to LE alone or TME alone [38].

### **Special Situation: Salvage for Local Recurrence After a Transanal Local Excision**

Several series reported on the outcomes of local excision with or without the use of preoperative CRT. A few significant issues may represent challenges in the setting of a local recurrence following local excision with significant consequences in terms of optimal salvage. First, local recurrences after a previous local excision usually present as more advanced disease when compared to initially resected. One interesting series looking at pT1 managed by transanal endoscopic microsurgery revealed that local recurrences were frequently salvaged in the setting of pT3 or

even pT4 disease [57]. Also, the risk of a pCRM+ specimen may be quite significant here [58]. Second, after undergoing previous transanal endoscopic microsurgery, patients requiring salvage resection often require abdominal perineal resections (APRs) [55]. Finally, these patients requiring salvage or completion total mesorectal excision frequently present suboptimal TME specimens at the time of resection [56]. In this setting, salvage resection after a local recurrence following transanal local excision should be considered at high risk for unfavorable outcomes, and surgical management should be optimized to provide a R0 resection. One recent case-matched study has compared the short-term outcomes of patients undergoing completion TME after previous local excision with transanal TME or standard TME. The study suggests superior quality of the specimen and decreased risk of rectal perforation with the transanal approach [59]. Still, further studies comparing taTME to standard TME in the setting of local recurrences after previous local excision are warranted. The reason is that completion TME and salvage TME may have distinct surgical outcomes. Still, transanal TME seems to be an attractive approach for the management of these patients requiring salvage TME in an attempt to provide optimal oncological and functional outcomes.

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### **Complete Clinical Response: Watch and Wait Strategy**

Non-operative management of patients with a complete clinical response has to be coupled to a relative intensive follow-up strategy. The importance to adhere to this strict follow-up program is to allow early recognition of any local or systemic recurrence and, therefore, increase the chances of successful salvage. Visits have been recommended with 1–2-month intervals in the first year, 3-month intervals for the second year, and 6-month for the remaining years of follow-up. Complete clinical and endoscopic assessments are recommended in all visits. Even though not yet standardized, radiological assessment of response has been performed at least every 6 months for the first 2 years and yearly thereafter



in our practice [60]. PET/CT imaging has been reserved for equivocal cases.

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## Outcomes

Even though there are very few series looking at oncological outcomes after local excision after ypT0, the available data is excellent [61]. Long-term oncological outcomes appear to be similar between patients undergoing watch and wait strategy after a cCR following nCRT and patients managed by TME in the presence of a pCR [8]. Additional retrospective studies further supported this similar oncological outcomes between these subgroups of patients [62, 63].

Local recurrences after WW are still a concern and have been considered a significant limitation in widespread implementation of such strategy. However, considering that the majority of local recurrences appears to develop within the first 24 months of follow-up and nearly all of them (90%) have an endoluminal component, a strict follow-up and simple clinical assessment may allow early detection of regrowths without compromising oncological outcomes [64, 65]. Patients with more advanced cT stage at baseline staging appear to be at greater risk for local recurrence after initial cCR and should be carefully monitored [16]. Ultimately, the pooled local recurrence rate including all published series analyzed in a systematic review suggested to be around 16–22% [62, 63].

Systemic recurrences may also develop after non-operative management of patients that achieve a cCR. A recent meta-analysis reported similar incidences of systemic recurrence among patients managed non-operatively with a cCR and patients with pCR after radical surgery [63]. Curiously, overall survival among these patients with cCR was 93% without the use of adjuvant chemotherapy. These rates compare favorably with the 90% overall survival after radical surgery in patients with pCR with nearly 40% of patients undergoing adjuvant systemic chemotherapy [66]. Finally, the largest series of patients with cCR managed non-operatively has been recently reported from a multinational registry including nearly 1000 patients. Similar outcomes of successful salvage after local

recurrence and excellent survival long-term results further support this organ preservation strategy as an attractive alternative for the management of selected patients with rectal cancer and complete clinical response to nCRT [67].

## Future Perspectives in Organ Preservation

With the increasing interest of organ preservation strategies and the use of nCRT regimens to intentionally develop complete clinical response, accurate prediction of tumor response with molecular biology studies will become increasingly relevant. Identification of ideal candidates for non-operative management would allow better selection of patients who would benefit the most from nCRT and avoidance of potentially unnecessary treatment to poor responders [17, 68]. However, the presence of significant inter- and intratumoral heterogeneity observed in rectal cancer may have contributed for the lack of clinically useful gene expression signatures in predicting tumor response [68–70]. Considering this intratumoral heterogeneity within a single rectal cancer, the coexistence of subpopulations of cancer cells resistant and sensitive to treatment may render that gene signatures derived from single biopsy specimens may not work simply because these fragments are not representative of the entirety of the tumors. Instead of prediction of tumor response, introduction of liquid biopsies for the assessment and monitoring of tumor response may also represent a clinically useful tool for the management and surveillance of patients during this approach [71].

**Conflicts of Interest** The authors have no conflicts of interest to declare.

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# Salvage Surgery After TAMIS Excision of Early-Stage Rectal Cancer

# 5

Sook C. Hoang and Charles M. Friel

## Introduction

Radical resection with a total mesorectal excision (TME) is the gold standard for mid and low rectal cancers. Utilizing these techniques there has been substantial improvement in rates of local control and in some studies overall survival over the last several decades. However, these procedures are associated with considerable morbidity and, in some series, a 1–2% rate of mortality. Furthermore, many patients will require either a permanent or a temporary stoma. Understandably, while recognizing the importance of a TME for patients with locally advanced rectal cancers, many investigators have questioned the need for such an aggressive approach for patients with an early (T1) rectal cancer. Under these circumstances the rate of lymph node metastases can be less than 10% which begs the question of whether a TME is oncologically necessary. Because of this, local excision is very appealing for the treatment of early-stage rectal cancer. In principle, if the tumor can be completely excised and the surgeon is confident there is no lymph node metastases, patients can be saved from the considerable morbidity of

TME. Initially, local excision was performed via a transanal approach using anal retractors. However, there are now more elegant options to a transanal excision (TAE) which include transanal endoscopic microsurgery (TEM) and transanal minimally invasive surgery (TAMIS) using either a laparoscopic or robotic platform. These newer techniques allow for improved visibility resulting in surgical specimens that are more likely to remain intact with negative margins. However, despite improvements in imaging and surgical techniques and our understanding of rectal cancers, local excision for a T1 rectal cancer, independent of approach, still has a local recurrence rate of approximately 10%. Furthermore, once a tumor is completely excised and analyzed pathologically, there will be some patients with tumors who have aggressive pathological features that mandate an immediate TME. In both circumstances surgeons must now perform a radical proctectomy with a TME in an attempt to salvage the initial failed local excision. It is critical, therefore, for surgeons to understand the outcomes of these salvage procedures so that patients are fully informed of potential outcomes. For the purpose of this discussion, salvage proctectomy will be classified as delayed, when it is done for a locally recurrent cancer, or immediate, when performed for unexpected aggressive pathological features. The outcomes will focus on both local control and surgical morbidity.

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## Immediate Salvage Surgery for Disease Upstage

Patients with T1 rectal cancers who are candidates for local excision must be thoroughly assessed prior to surgery. This includes imaging studies to accurately determine the depth of invasion. Prior studies have shown that T1 rectal cancers can have lymph node metastases in approximately 10% of patients, while those with T2 cancer, the rate of lymph node metastases approaches 20% [1, 2]. Both endorectal ultrasound (ERUS) and high-definition MRI have been used to determine the depth of invasion and to detect pathological lymph nodes in the mesorectum. Unfortunately, neither is 100% reliable resulting in rectal lesions that can be either understaged or overstaged. One study found 44.3% of pT1 and 31.2% of pT2 tumors were thought to be benign lesions prior to surgery [3], highlighting the imperfections of current selection processes. Underestimation of T category preoperatively can lead to partial-thickness rectal wall excision and a subsequent sixfold increase in odds of an R1 margin [3]. Furthermore, tumors may have aggressive pathological features (poor differentiation, lymphovascular invasion, tumor budding) that increase the chances of having lymph node metastases substantially but are only fully identified once a complete excision is performed. While surgeons strive for perfect patient selection, the reality is that a local excision serves as an excisional biopsy of the lesion. Most of the time, the final pathology is consistent with preoperative evaluation, and compulsive surveillance is all that is necessary. However, in approximately 4–23% of patients, the final tumor will either have unrecognized aggressive features, be deeper than expected, or have a close surgical margin [3, 4]. Because of a high rate of local failure under any of these circumstances immediate salvage surgery, with TME, is indicated.

It is currently unclear if the outcomes of immediate salvage TME for disease upstaging vary from upfront radical surgery with TME. Some studies suggest immediate salvage TME after a failed local excision does not compromise oncologic outcomes compared to pri-

mary upfront radical surgery [5, 6]. For example, Baron et al. noted no difference in long-term oncologic outcomes in patients that had immediate salvage surgery following a failed local excision [6]. They compared patients who underwent immediate resection for adverse features encountered in the local excision specimen with patients who underwent delayed resection only after the emergence of local recurrence. The disease-free survival in the immediate resection group was 94.1% compared to 55.5% in the delayed resection group. Similarly, a study performed by Levic et al. found that the recurrence rates for radical surgery after TEM for rectal cancer were similar to historical controls [7]. They identified 25 patients within their institution who underwent TME after local excision with TEM. Outcomes were matched with historical controls who had primary upfront radical excision with TME. There were no significant differences between the two groups in the number of harvested lymph nodes, median circumferential resection margin, and completeness of mesorectal fascial plane. Additionally, there were no recurrences in the salvage TME group within 25 months. Despite these promising oncologic results, this study reports a compromise in oncologic principles during definitive resection including:

1. Intraoperative perforation was reported at 20%, likely secondary to weakening of the specimen from the previous TEM.
2. Thirty-seven percent of patients had an incomplete mesorectal excision.

The significance of these findings remains unclear but does suggest there may be some oncologic compromise as a result of the previous attempt at local therapy.

While at first glance there seems to be no significant compromise to first attempting a local excision, this algorithm certainly raises some concern. Patients are subjected to two surgical procedures often within a short period of time. Additionally, there is currently no consensus in the timing of salvage surgery following TEM for lesions that are upstaged on pathology. Some centers report salvage surgery as early as 4 weeks

from the initial TEM, and some centers report delay of up to 3 months [5]. What is clear is that surgical morbidity after salvage TME is reported to be as high as 56% [7]. More importantly, in the same study from Levic et al., 40% of the patients having a salvage procedure required an APR and permanent colostomy which raises the possibility that these patients could have had a LAR if upfront radical surgery was performed and the surgical planes not disrupted by the previous full-thickness excision. These findings suggest that salvage TME after local excision may be more technically challenging. The local excision scar has to be completely excised, resulting in a more distal resection margin, which could increase the rate of a permanent colostomy. Van Gijn et al. evaluated the risk of local recurrence, effects on survival, and rate of ostomy after immediate salvage TME [8]. Patients who had a local excision for presumed benign or superficial malignant rectal lesions and had subsequent pathologic upstaging underwent salvage TME within 15 weeks. They found a greater risk for colostomy (OR 2.51,  $p < 0.0006$ ) and a greater local recurrence rate (HR 6.8,  $p < 0.0001$ ) in patients who had salvage surgery. There was no difference in development of distant metastasis at 2.5 years. These data suggest that salvage TME is technically more challenging in a re-operative field. Because of these challenges, both rates of local recurrence and colostomy creation are likely increased.

In summary, following a local excision, some patients will have unfavorable pathological features that mandate a radical resection. Under these circumstances immediate (within 3 months) salvage surgery is recommended since waiting for a local recurrence tends to have worse oncological outcomes. When performed early survival may be equivalent to upfront radical resection. However, radical surgery may be more technically challenging as a result of scarring and fibrosis from a previous local excision. Unfortunately, this may increase the likelihood of requiring a permanent colostomy. Furthermore, the impact on local recurrence remains ill-defined with some studies suggesting similar outcomes and others hinting at a higher rate of local failure. What does seem clear, however, is that a failed local excision

has important repercussions which highlight the importance of proper preoperative selection.

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### Delayed Salvage Surgery for Recurrent Disease

While local excision for an early rectal cancer may be an excellent option for carefully selected patients, there is little doubt it is an oncologically inferior option when compared to a radical resection. Local excision removes the tumor with a limited mucosal margin and spares the mesorectal lymph nodes. Unresected disease in regional lymphatics has been identified as a cause of failure after local excision [9]. As a result, there is an increased risk for recurrence after local excision compared to proctectomy with a TME [3]. Local recurrence rates after local excision can range from 0 to 33% compared to local recurrence rates after upfront proctectomy with total mesorectal excision at 0–2.4% [10].

Surveillance and follow-up of patients who have undergone local excision for T1 rectal cancer are therefore critical for detection of local recurrence. Since local recurrence may present as an intraluminal or extraluminal mass, a multimodal surveillance scheme should be followed. Current guidelines recommend proctoscopy every 3 months for the first 2 years and then every 6 months for a total of 5 years [11]. However, surveillance with proctoscopy alone may still lead to missed recurrences. Additionally, despite imaging modalities such as MRI or endorectal ultrasound (ERUS), lymph node metastasis may also be missed [12]. For these reasons, some centers argue for aggressive surveillance with surveillance proctoscopy and ERUS in addition to yearly pelvic MRI for patients who have had local excision for early rectal cancer [12, 13]. Close surveillance may lead to an earlier detection of recurrence and subsequent need for a less involved salvage surgery. However, even with active surveillance, outcomes following salvage surgery is poor with 3-year overall survival at 31% and disease-free survival of 58% [12].

Bach et al. sought to identify predictors to recurrence after local excision for rectal cancer.

Recurrence after local excision occurs at a median of 13 months (range of 3–55 months) [3]. They found that recurrence is independently predicted by depth of tumor invasion, maximum tumor diameter, and presence of intramural lymphovascular invasion. Additionally, as the maximum tumor diameter increased by 1 cm, the risk of recurrence also increased by 18% (95% CI, 3–35%). Lymphovascular invasion was noted to increase the risk of recurrence by a factor of 1.86. This is consistent with previous studies that have found lymphovascular invasion to be an independent predictor of local recurrence [9].

In general, local recurrence portends a poor prognosis. In most patients, when recurrence occurs after local excision, the stage of the recurrent tumor is more advanced than the initial primary tumor [14]. Another study noted 41% finding of positive node involvement in the surgical specimen, despite the use of preoperative radiation therapy in patients with recurrence [14]. Bikhchandani et al. identified 27 patients who underwent multimodal salvage therapy for locally recurrent rectal cancer after previous local excision for early rectal cancer [15]. Compared to 5-year disease-free sur-

vival rates of 92–97% after upfront proctectomy for a T1 lesion, they found a 5-year overall survival rate of 50% (95% CI, 30–74%) and a 5-year recurrence-free survival rate of 47% (95% CI, 25–68%) after salvage surgery for recurrence. There are now several studies (Table 5.1) showing similar disappointing outcomes with overall survival hovering around 50%. Recalling that upfront TME for a T1 rectal cancer has nearly a 100% overall survival, these data remind us that salvage surgery for a local recurrence does not achieve similar oncologic success and therefore cannot be relied upon for patients that have a recurrence following a local excision.

Additionally, salvage TME for recurrence after local excision for early-stage rectal cancer often involves an extensive operation with increased morbidity. Pelvic recurrence is often advanced requiring an extended pelvic resection of adjacent pelvic organs to achieve salvage [16]. For example, in the study from Weiser et al., 50 patients underwent attempted surgical salvage for local recurrence following initial transanal excision [16]. Thirty-one of the 50 patients underwent an APR and only 11 patients had an

**Table 5.1** Summary of studies regarding salvage surgery after local excision for rectal cancer

Author, year	N (study years)	Initial tumor stage	Median time to recurrence	Location of recurrence	Sphincter preservation	OS, DFS
Friel et al., 2002 [14]	1988–1999	T1, T2	–	–	34%	DFS 55%
Weiser et al., 2005 [16]	50 (1970–2003)	T1, T2	20 months	17 patients within rectal mucosa, metastatic disease 8 patients	–	5-year OS 53%
Doornbosch et al., 2010 [12]	88 (1996–2010)	pT1	10 months	Intraluminal 10 (11%), Extraluminal 6 (6.8%), Distant mets 39%	56%	3-year OS 31%, cancer-related survival 58%
You et al., 2012 [17]	43 (1993–2011)	cT1 43% cT2 7% cT3 22% unknown 28%	1.9 years	Local/regional 67%, Distant 18%, Both 15%	33%	5-year OS 63%, 3-year recurrence-free survival 43%
Bikhchandani et al., 2015 [15]	27 (1997–2013)	T1, T2	52 weeks	Luminal 23 patients, Locoregional 3 patients, Locally advanced disease(T3/T4) 73%	33%	5-year OS 50%, recurrence-free survival 47%

OS overall survival, DFS disease-free survival, – not reported



LAR. Additionally, 55% of patients required an extended resection involving the pelvic sidewall, prostate, seminal vesicle, bladder, vagina, ureter, and ovary, with a resulting 5-year disease-free survival rate of 53%. Similarly, in a series by You et al., 33% of patients with recurrence after local excision required a multivisceral resection and 5% required a pelvic exenteration to achieve R0 disease [17]. Additionally, they noted that only 33% of patients who underwent salvage surgery achieved sphincter preservation which was consistent with sphincter preservation rates of 30–50% across studies [12, 15, 17]. The goal of salvage surgery is to achieve R0 resection which often requires extensive resection and sphincter compromise. When R0 resection is achieved, survival rates of up to 59% can be achieved. However, in situations where an R1 or R2 resection is achieved, survival rates drop to 0% [16].

In efforts to improve outcomes and survival after salvage surgery, multimodality therapy is frequently adopted. This includes the use of both neoadjuvant and adjuvant chemotherapy and radiation, in addition to intraoperative radiotherapy in some centers [15]. However, morbidity rates after salvage surgery is consistently reported at 40–50%. Bikhchandani et al. were able to achieve R0 resection in 93% of patients with the use of multimodality therapy and salvage surgery [15]. Despite this, they reported 5-year recurrence-free survival rate and 5-year overall survival rate of <50%. Similarly, despite aggressive multimodal therapy including neoadjuvant chemoradiation and intraoperative radiation to achieve R0 resection in 80% of patients, You et al. also reported modest outcomes (5-year OS 63%, 3-year re-recurrence-free survival 43%) [17]. Therefore, even with the use of multimodality therapy, recurrences after a failed local excision are significant challenges with overall outcomes which remain disappointing given the initial stage of these tumors.

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## Summary

There have been significant advances in the treatment of rectal cancer. Local excision for benign rectal lesions and T1 rectal cancers has become

more technically possible with the introduction of TEM and TAMIS, with lower associated morbidity compared to radical surgery. For many reasons, local excision for properly selected patients with a T1 rectal cancer remains an appealing option. Since T1 rectal cancers have up to a 10% risk for lymph node metastasis, preoperative staging is extremely important. Unfortunately, available modalities such as MRI and endorectal ultrasound are not able to detect micrometastases that may be associated with T1 lesions [18]. Therefore, despite careful patient selection, some patients will require a salvage TME for either poor pathological features or a local recurrence. Initially surgeons believed that outcomes of these salvage procedures would likely be similar to primary surgery for these early rectal cancers. When performed in a timely fashion, salvage surgery for pathologic upstaging results in acceptable survivability. However, salvage surgery can be technically more challenging compared to upfront radical surgery which increases the likelihood of a permanent colostomy. Furthermore, local recurrence rates for a salvage TME is likely higher. For patients that recur following a local excision, the recurrence is often at a higher stage compared to the initial stage of presentation. As a result, more extensive surgical resection is needed to achieve tumor-free resection, resulting in greater morbidity and compromised functional outcomes. This includes diminished sphincter preservation rates of only 30–50% across studies and often requires an extended resection to achieve an R0 resection. Survival outcomes following salvage surgery, even with multimodality therapy, are also disappointing and hover at about 50%. These data suggest that salvage surgery is not a panacea for the patients who develop a local recurrence. What it does suggest is that compulsive and aggressive surveillance is critical in the management of these patients. Presumably if local recurrences are found early, then salvage surgery may have better overall outcomes. It is our recommendation that all patients be followed by endoscopic evaluation and careful exam every 3 months for 2 years and biannually until 5 years. Since there are examples of late recurrence, an annual exam after 5 years may be reasonable. Ideally this is done by the operating surgeon who

is more attuned to subtle recurrence patterns. While most recurrences are intraluminal, there will be some local recurrence outside of the lumen. Therefore, a pelvic MRI should be done at least once per year. Similarly, some patients will develop distant metastases so a CT scan of the chest, abdomen, and pelvis annually is also reasonable. By staggering the CT scans and the pelvic MRI every 6 months, the patient can get pelvic imaging every 6 months with this approach.

## Conclusion

Since salvage surgery cannot be relied upon for a failed local excision, the best opportunity to improve outcomes for local excision is by improving the patient selection process. Until we can reliably rule out disease within the mesorectum, there will be patients that will recur. We now know that salvage surgery clearly results in inferior outcomes. Therefore, since our “first shot is our best shot,” when considering local excision as a treatment option, we must choose and inform our patients carefully.

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# Organ Preservation and Palliative Options for Rectal Cancer

# 6

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## Introduction

Local excision is a well-accepted organ preserving method for early rectal cancer with substantial lower morbidity and impact on quality of life compared to radical surgery. However, only rectal cancers staged as a T1 tumor limited to the superficial third of the submucosa (sm1) and less than 3 cm in diameter without signs of poor differentiation, lymphatic or vascular invasion, budding, or clustering in the final pathology are oncologically safely treated with radical local excision [1]. These tumors have local recurrence rates of less than 5%. Small locally excised lesions with more risk factors as budding, poor differentiation, and lymphovascular invasion or even T2 lesions have been associated with relatively high recurrence rates [2–4]. Due to the increased recurrence rate, most guidelines recommend completion radical surgery after local excision of high-risk lesions [5].

Local excision for palliation could be considered in patients who are either too fragile for or who refuse radical surgery. This seems to be a valuable option for those that have symptomatic bleeding, changed defecation, or even incontinence. However, local excision alone for higher-

risk tumors in the rectum is not without risks. The relatively high recurrence rate within 2–3 years is a substantial problem, since recurrences are often symptomatic. Combining local excision with radiation for palliative reasons could be an option, but unfortunately data to support this theory are scarce.

Other organ-preserving strategies after local excision of high-risk lesions are being investigated in prospective cohorts and randomized trials. A potential curative option is adjuvant chemoradiation (CRT) following local excision, which has proven to decrease local recurrence rates and offers acceptable morbidity with organ preservation. The other option is no further therapy but instead offer close surveillance with salvage radical surgery if a local recurrence presents itself (about 20%).

Several combinations of local excision, radiotherapy, chemotherapy, and/or close observation are being investigated for treatment of higher-staged tumors. The aim of this chapter is to summarize data of organ preservation options with a focus to palliative options.

## Treatment Options

### Local Excision

Treatment with solely local excision offers the lowest burden for patients, since it is a minimally invasive technique and results in low morbidity

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and colostomy rates. You et al. reported an overall 30-day morbidity rate of 5.6% compared to 14.6% for radical resections, because of less gastrointestinal and infectious complications, with a consequent shorter hospital stay after local excision [6]. However, the question remains whether it is a sufficient treatment since local excision only treats the primary tumor and not the potential remaining tumor cells in the mesorectum. The clinically pathological features such as depth of submucosal invasion, differentiation, lymphovascular invasion, budding, and clustering are related to recurrence, whether endoluminal or within the mesorectum. When local excision is carried out, the surrounding muscular wall and mesorectum are left untreated. Therefore, tumor cells are potentially left behind where they may propagate and eventually develop into a clinically detectable local recurrence.

Many cohorts and population-based studies have provided data concerning oncological outcome after local excisions for T1 and T2 tumors. A meta-analysis of local excision as sole treatment, covering all published data from 1990 to 2018, revealed local recurrence rates of 10% in 2120 patients with a T1 tumor and 32% in 357 patients with a T2 tumor as shown in Table 6.1 (Tuynman et al. in preparation [7]). Distant failures occurred in 6% of 1805 patients and 12% of 230 patients with, respectively, T1 and T2 tumors. The substantial increase in recurrences of T2 tumors indicates the reduced effectiveness of local excision for more advanced early rectal cancer.

**Table 6.1** Recurrence rates

	T1	T2	T3
Local recurrence			
LE	10% (n = 2120)	32% (n = 357)	58% (n = 19)
LE + adjuvant	7% (n = 278)	16% (n = 382)	33% (n = 27)
Distant recurrence			
LE	6% (n = 1805)	12% (n = 230)	31% (n = 13)
LE + adjuvant	5% (n = 214)	7% (n = 254)	4% (n = 23)

*n* number of patients included in this analysis, *LE* local excision, adjuvant (chemo)radiation

The recurrence rates after local excision of T3 cancer are expected to be even higher and are the reason that local excision for T3 is not supported by clinical guidelines as treatment strategy with curative intent. As expected, data is scarce concerning this group of advanced disease. Some publications report a few cases of patients who refused radical surgery or were deemed unfit for major surgery. In seven publications which address this subject, an overall recurrence rate of 68% (15 of 22 patients) was reported [8–14].

This increase in recurrences might be an acceptable clinical outcome if a radical resection is not desirable nor possible in frail patients who present unacceptably high risk of perioperative morbidity and mortality. Therefore, expected longevity and predicted survival rates are important factors when a deliberate choice for a substandard operation is carried out by performing local excision. Allaix et al. [15] reported 5-year survival rates of 76% in 32 patients after TEM and 96% of 33 patients after anterior resection or APR. However, radical resection was indicated in all patients. Those who underwent a TEM procedure were either not fit for surgery or refused radical surgery. A meta-analysis showed overall 5-year survival rates of 65–100% for T1 tumors and 30–95% for T2 tumors [7]. The majority of all recurrences appears within 3 years after initial treatment. Salvage treatment usually consists of major surgery or less effective radiotherapy, and it is often associated with complications.

In conclusion, local excision for rectal cancer is accompanied by low morbidity rates and good functional outcome. However, it is also associated with poor oncological outcome in high-risk tumors which increases with tumor (T) stage. In case of low-risk T1 tumors, local excision alone is a viable and accepted treatment strategy.

### Local Excision with Adjuvant Therapy

Especially for infirm patients, local excision is an attractive strategy compared to radical surgery concerning morbidity. Therefore, other additional options to improve the associated oncological compromise have been studied. One of these

explored options is addition of adjuvant (chemo) radiation following local excision. This might increase oncological outcomes including survival, while still offering organ preservation.

A meta-analysis reported average local recurrence rates of 7% in 278 patients with T1 and 16% in 382 patients with T2 tumors (Table 6.1). Distant recurrence rates were 5% in 214 patients and 7% in 254 patients with, respectively, T1 and T2 tumors [7]. In particular, it was noted that recurrence rates of T2 tumors decreased remarkably with the addition of adjuvant therapy compared to local excision alone. Overall recurrence rate of local excision with adjuvant (chemo)radiation of T3 tumors was 38% (12 of 32 patients) [8, 9, 12, 14, 16–19].

A US National Cancer Database analysis showed a 5-year survival rate of 79.7% for T2N0M0 tumors, similar to radical surgery [20]. After exclusion of 90-day mortality, survival was significantly worse than after radical surgery. Others report 5-year overall survival rates are 63–98% for T1 tumors and with 61–93% slightly lower for T2 tumors [7]. Compared to local excision alone, the survival benefit of adjuvant therapy seems to be substantial for T2 tumors. However, due to serious heterogeneity of the studies, direct conclusions cannot be established. Nevertheless, the addition of adjuvant CRT after local excision seems to be a promising strategy as tailored approach for tumors at high risk of recurrence, such as T1 tumors with risk features or T2 tumors.

The TESAR trial was initiated in 2015 to gain insight into the oncological and functional outcome of local excision with adjuvant chemoradiotherapy [21]. In this study, local excision of intermediate and high-risk T1 tumors and T2 tumors without adverse features is followed by randomization of patients between either adjuvant chemoradiotherapy or completion TME. The hypothesis is that both treatments offer similar recurrence and survival rates, while adjuvant chemoradiation offers better quality of life and functional outcome. The trial remains ongoing at the time of this writing.

Summarized, addition of adjuvant therapy to local excision potentially improves recurrence rates and survival in locally excised rectal cancer staged as T1 with risk features or T2 tumors. T3

tumors seem to benefit from adjuvant therapy as well, but oncological outcome remains poor with high recurrence rates.

### **Neoadjuvant Therapy Followed by Local Excision**

The incorporation of neoadjuvant chemoradiotherapy and subsequent local excision is a possible treatment strategy. Neoadjuvant therapy might lead to downstaging and shrinkage of the primary lesion, which could enable local excision of what were initially larger tumors. More importantly, such a protocol targets the mesorectum via irradiation, which could sterilize occult nodal disease.

Local recurrence rates of 7–17% have been reported for T2 and T3 tumors treated with neoadjuvant chemotherapy prior to local excision [22–24]. This is substantially lower than the previously mentioned rates of local excision alone and slightly better than adjuvant therapy. Focusing on survival, an American National Cancer Database analysis revealed 5-year overall survival of 76.1% for T2N0M0 tumors [20]. This was similar to radical surgery and local excision with adjuvant chemoradiation. Allaix et al. reported a comparable 5-year survival rate of 77.8% in 11 patients, which was equal to local excision alone [15]. Based on these numbers, neoadjuvant and adjuvant therapy seem to be equally effective strategies.

However, morbidity of neoadjuvant treatment is highly underestimated. Local excision after neoadjuvant chemoradiation is associated with higher risk of wound dehiscence (61% vs. 23%), post-procedural pain (52% vs. 15%), and an increase of hospital readmissions (44% vs. 7%) compared to local excision alone [25]. Another series reported the increase in wound-related morbidity following TEM [26]. This series by Marks et al. included 43 patients with neoadjuvant therapy, of whom 36 received chemoradiation. The remaining seven patients were deemed not fit for chemotherapy and therefore underwent radiotherapy only. In total, 11 (25.6%) patients suffered wound complications. None of the 19 patients treated with TEM *alone* had wound complications.



Despite the increased short-term morbidity associated with neoadjuvant therapy, the promising oncological outcomes account for ongoing studies on this subject. An example is the multicenter international randomized STAR-TREC trial [27]. In this study, small cT1–3 N0 lesions are randomized between primary TME and rectal preserving therapy. In the rectal preservation arm, neoadjuvant chemoradiotherapy is followed by local excision in case of good clinical response. In case of complete clinical response, crossover to a watch and wait regime is offered. The hypothesis behind this protocol is that chemoradiation could be sufficient as sole treatment for early stage rectal cancer.

This hypothesis is supported by the group of Professor Angelita Habr-Gama (São Paulo, Brazil) among others. They described complete responses up to 22.4% of the irradiated tumors, omitting the need for surgery and enabling a watch and wait follow-up regimen [28, 29]. In another publication, they reported improvement of absolute survival after chemoradiotherapy alone in the setting of complete clinical response, compared to incomplete responses to neoadjuvant therapy followed by radical surgery in octogenarians (age 80), regardless of whether they were fit or if they had significant comorbid conditions [30]. Absolute survival advantage, after chemoradiotherapy without versus with radical surgery, was 10.1% for fit octogenarians and 13.5% for comorbid octogenarians after 1 year.

In summary, the addition of neoadjuvant chemoradiation appears to improve oncological outcome of local excisions. However, the increased morbidity after neoadjuvant radiotherapy requires caution. Complete responses after chemoradiation are found in less than one of four patients. Nevertheless, this might offer opportunities to improve survival and organ preservation, if the good responders can be identified.

## Palliative Radiotherapy

The administration of short course radiotherapy can be regarded in an attempt to avoid surgical intervention. Radiotherapy is often used for palliative relief of symptoms associated with tumor

growth, such as pain, obstruction, bleeding, or tenesmus. A systematic review was performed in 2014 to assess the efficacy of radiotherapy on palliation [31]. Improvement of symptoms occurred in 75% of patients. However, all included studies used different dosages.

More recently, a study was published administering 5 fractions of 5 Gy in 5 days for palliation of locally advanced rectal cancer [32]. They reported reduction or resolution of pain in 87.5% and of bleeding in 100% of cases. Colostomy-free rates were 100% after 1 year, 71.4% after 2 years, and 47.6% after 3 years. Toxicity of this dose was low.

Endorectal brachytherapy has been shown to be effective in patients with inoperable tumors and in the palliative setting. When used as a boost, it seems to improve the pCR (complete response) but does not impact recurrence rates or overall survival. Local administration of radiotherapy by brachytherapy for palliation is an option whose use is derived from experience with prostate and cervical cancer. Brachytherapy as local treatment of rectal cancer has been reviewed, but data are sparse.

In a study by Hoskin et al., 50 patients with either inoperable or incurable tumors were treated with brachytherapy as sole treatment or as a boost to external beam radiotherapy (EBRT) [33]. A clinical response was achieved in 75% of all patients, including 14 complete responses. Median survival for patients treated with definitive EBRT and brachytherapy boost was 25 months and 7 months for patients treated with a palliative intent. Of the 28 patients with rectal bleeding at presentation, 57% achieved a complete clinical resolution with a median response duration of 10 months. The HERBERT trial also examines the efficacy of the combination of EBRT followed by high-dose-rate endorectal brachytherapy boost in elderly and medically inoperable patients with rectal cancer. The first results have shown that response occurred in 29 of 33 patients (87.9%), with 60.6% complete response (CR). The local progression-free survival and overall survival rates were 42% and 63%, respectively, at 2 years [34].

In conclusion, radiotherapy as sole treatment for infirm and otherwise inoperable patients seems to be a valid option as palliative treatment with significant improvement of tumor related symptomology. The combination of external beam radiotherapy with endoluminal brachytherapy shows especially high response rates. More data on long-term outcome after radiotherapy is needed to evaluate toxicity.

## Radical Surgery

Currently, radical surgery following the principal of total mesorectal excision (TME) remains the best available treatment of rectal cancer, in terms of oncological outcome. However, the risk of anastomotic leakage is substantial with 3–10%, which might be catastrophic, particularly in frail, elderly patients [35]. Therefore, resection with creation of an end colostomy (Hartmann's procedure) might be a valid option in this setting.

From an epidemiological standpoint, the majority of patients diagnosed with rectal cancer are older than 75 years of age. Therefore, a significant subset may be considered for palliative treatment rather than curative-intent therapy due to frailty, severe comorbidities, and/or reduced life expectancy. A systematic review by Manceau et al. concluded that severity of comorbidities had more influence on postoperative complications than advanced age [35]. This suggests that age on its own should not be a discriminator.

Unfortunately, few studies report exclusively on this older, comorbid population. Postoperative 30-day mortality in patients with colorectal cancer aged between 75 and 84 years is approximately 9%. For patients older than 85 years of age, 30-day mortality is 20%, which increases when surgical intervention is performed in the emergent setting [36, 37]. Mamidanna et al. described a higher 30-day mortality of 31% which increased to 51% at 12 months follow-up in patients older than 80 years [38]. However, this data includes procedures with restoration of bowel continuity. Survival rates in younger patients are more promising. For T1 rectal cancer, 5-year overall survival is approximately 80% and for T2 tumors 77% [6, 20, 39].

In conclusion, radical surgery offers the best oncological outcome. By opting for a Hartmann procedure, anastomosis-related morbidity and mortality could be avoided in high-risk patients, while still maintaining superior oncological outcomes.

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## Conclusion: Tailoring Palliative Treatment

Local excision is associated with low morbidity rates, but when compared to radical resection, local excision has inferior oncological outcome for rectal tumors other than low-risk T1. Although theoretically attractive, addition of neoadjuvant (chemo)radiation results in relatively high morbidity. Local excision with tailored adjuvant treatment seems to be a promising option for T1 and T2 tumors. Local excision alone for tumors staged T2 or higher stage seems to be associated with unacceptably high recurrence rates that could be very symptomatic. Therefore, local excision is not advised as part of palliative treatment.

The best treatment should be highly tailored to each individual patient and discussed with the patient, the family, and a multidisciplinary tumor board. If it is only for short-term symptom relief, short course radiotherapy might be the best option. If next to low morbidity, a recurrence-free period is also of relevance; a more invasive treatment strategy might be the best option. This could include local excision with adjuvant therapy for T1–2 tumors. As an alternative, endoluminal brachytherapy with or without external beam radiotherapy could be administered for palliative treatment of rectal cancer. For patients who are deemed medically fit to tolerate radical surgery and want optimal oncological control, then radical surgery seems to be the best option. For patients where the risk of anastomotic leak is unacceptably high, rectal extirpation without configuration of an anastomosis (with permanent end colostomy) seems to be a valid option with the best oncological control and a relatively good quality of life.



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# Operative Equipment and Insufflator Options

# 7

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## Introduction

Access to the proximal rectum via the anus has been the limiting factor for transanal surgery since the earliest records of colorectal surgery [1, 2]. Access has always been dependent on instrumentation. Transanal surgery is limited by these four factors:

- (a) Access
- (b) Illumination
- (c) Insufflation
- (d) Instruments

The earliest proctoscopes and sigmoidoscopes were limited in all of these areas [3]; however, it is the development of these simple devices into the currently available rectal devices [4] that has led to the very significant change in the scope of transanal surgery. In this chapter, we will explore how the development of the anal and rectal access devices and the associated equipment has led to the current revolution in transanal surgery.

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## History

Transanal intraluminal and extra-luminal rectal surgery has four limiting factors, which are as follows: (1) the maximum dilation of the anus that can be achieved without damage to the anal sphincter muscle, (2) illumination and visualization of the rectal lumen, (3) distension of the rectal lumen or pelvic space by insufflation, and (4) the operative instruments which can function within the restriction of the rectum or pelvis. Historically rectal access has been achieved by dilating the anus with a retractor such as a Parks retractor or dilating the anus and inserting some form of tube described by Phillip Bozzini in 1804 [5]. Alternatively, access can be obtained by the buttock or anus [6] or by dividing the sphincter complex and entering the rectum directly [7]. Access by dividing the anus or an incision through the buttock while allowing good access to some portions of the rectum has proved to have the insurmountable problem of reconstruction of the rectum and anus. Historic and more recent series have unacceptable rates of severe infection and incontinence which render this approach unacceptable in current medical practice [8].

## History of Transanal Access Excluding Endoscopy

The development of transanal access can be divided into two streams; open access using a mechanical retractor to hold the anus open, and operative sigmoidoscopies which use a tubular device to form a gastight seal while the operation is performed via the lumen of the tube [9]. Open access has the advantage of direct vision and external illumination to allow resection of lesions. However, this approach is only suitable for lesions in the lower rectum, and even then the restrictions of illumination, view, and access of the operating instruments mean that local recurrence rates for both polyps and cancers are prohibitively high [10, 11].

Historically, operations performed via an operating rigid sigmoidoscope had the advantage of superior access in the upper rectum. The design of the instrument allowed the rectum to be insufflated with air while the sigmoidoscope was being advanced giving excellent access to the upper rectum and the distal sigmoid colon. Because of the design of the instrument, it was not possible to operate via the lumen of the tube while maintaining insufflation. This limited the possibility of dissection under vision, and while a simple snare biopsy of lesions could be completed, more complex procedures and excisions could not be performed in this fashion. In Europe and the United States, this type of operating sigmoidoscope has largely been consigned to the museum although it may still be in use in other more rural health care systems.

## Flexible Sigmoidoscopy

The introduction of flexible sigmoidoscopes in the late 1950s [12] represented the first real change in the way that the rectum could be accessed. The vision obtained and the operations that could be performed were changed forever. Vision and illumination were provided via fiberoptic bundles, and the tip of the instrument could be maneuvered in every plane. The lumen of the rectum and colon could be insufflated with air or

CO<sub>2</sub>. Operative instruments introduced via one or two operating channels allowed both biopsy and snare excision. The operating instruments are “steered” by manipulation of the tip of the instrument and advancing or retracting the instruments. The development of flexible endoscopy has continued in parallel to operative transanal access with some degree of crossover [13]. There have been a number of advances in the use of flexible endoscopes including endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) [14] which have broadened the scope of flexible endoscopy. More recently it has become possible to perform full-thickness dissection of the rectum using a flexible endoscope [15]. Figure 7.1 shows an Olympus-OSF-2 flexible sigmoidoscope, Olympus UK and Ireland, KeyMed House, Stock Road, and SS2 5QH



**Fig. 7.1** Olympus-OSF-2 flexible sigmoidoscope, Olympus UK and Ireland, KeyMed House, Stock Road, SS2 5QH Southend-on-Sea

Southend-on-Sea. Further development of the flexible sigmoidoscope and colonoscope is beyond the scope of this chapter – however it is possible and even likely the currently divergent technologies will converge in the arena of transanal robotic surgery [16].

## Transanal Endoscopic Microsurgery

The introduction of the transanal endoscopic microsurgery (TEM) device by Wolf, designed by Professor G. Buess [17] (Fig. 7.2), represented a step change in transanal surgery. The device allowed microscopic, stereoscopic, illuminated vision within the lumen of a stable insufflated rectum with the ability to extract both smoke and fluid. With this equipment it was possible to perform operative surgery using specialized instruments with excellent vision. The inflation of the rectum was maintained by the special TEM insufflator and by the presence of seals on all of the instrument and optical channels. While the entire TEM setup represents an unprecedented development in the instrumentation of transanal surgery, the TEM insufflator, in particular, has



**Fig. 7.2** The TEM telescope introduced in 1983 by Richard Wolf. <https://www.richard-wolf.com/company/history.html>

not been refined in more than 20 years of further development.

Early TEM series have confirmed that it is possible not only to resect luminal lesions in the upper rectum but also to perform full-thickness resection of the rectal wall and then close the defect by suturing [11, 18, 19]. Outcomes in terms of morbidity, mortality, completeness of resection, and completeness of specimens are improved compared to conventional transanal excision [11].

The contribution of Karl Storz GmbH and the development of the Hopkins rod lens system must be recognized and their development of a similar device, the transanal operating endoscope (TEO). This provided similar access but without stereoscopic vision, stable insufflation, or smoke extraction. Comparative series have, however, shown no difference in the outcome between TEM and the TEO system when using a high-definition 2D camera [20].

These so-called rigid platforms (TEM/TEO) have enjoyed more than 20 years of predominance as the equipment of choice for advanced transanal surgery. There have been a number of series published which have confirmed that such systems can be used to achieve complete excision of both benign polyps and early rectal cancer and achieve very low local recurrence with minimal mortality and morbidity [21–26]. Furthermore, there is evidence that the quality of specimen achieved is independent of the platform used with Lee et al. demonstrating equivalence between all advanced transanal platforms for transanal local excision of rectal neoplasia [27].

While the majority of transanal surgery using TEM/TEO devices has been limited to the excision of benign tumors and early rectal cancer leaving the rectum and mesorectum intact, there have been a number of small series whereby these systems have been used to remove the entire rectum and in some cases the sigmoid colon. Using a TEM scope for access, M. Whiteford et al. described the first transanal proctectomy without abdominal access and with anastomotic reconstruction in a cadaveric model in 2007 [28], which would ultimately serve as the prequel to the modern taTME operation.



This extended use of TEM-type equipment to remove the rectum has not entered into mainstream practice but, as a point of distinction, the first cadaveric series [28] and the first report of taTME in a human was reported in May 2010 using the TEM system [29]. As will be discussed in the following section, the parallel development of single-incision laparoscopic surgery (SILS) and the subsequent use of such ports for rectal access represented a paradigm shift and was an important step forward in the evolution of advanced transanal surgery [30].

TEM and TEO platforms continue to be used and may have some advantage in the resection of intraluminal lesions in the upper rectum and are still preferred by some surgeons as a platform for taTME. Small comparative trials have shown no difference in specimens retrieved with either the rigid or flexible platforms when used for taTME in cadavers [31].

### **SILS, TAMIS, and the Glove Port**

SILS ports have been developed to meet the demand to improve the cosmetic outcome of laparoscopic surgery by performing operations through a single abdominal incision, particularly, via the embryonic natural orifice, the umbilicus. Whereas previously a laparoscopic cholecystectomy might have required the insertion of three or typically four ports, the SILS technique required a single point of access [32]. A number of multichannel laparoscopic ports have been developed for abdominal access and some specifically designed for transanal access. The GelPOINT path transanal access platform (Applied Medical, Rancho Santa Margarita, California, USA) was developed specifically for transanal access, and the SILS port (Covidien, Norwalk, Connecticut, USA) was the first port to be used for transanal access. Atallah et al. in a series of 6 patients [30] showed that the SILS port could be used to provide rectal access to operate within the rectum with the minimum of additional equipment over and above that which would normally be found on a laparoscopic colorectal tray. The authors termed this technique

transanal minimally invasive surgery (TAMIS). Subsequently, Hompes et al. similarly showed that by using a combination of an CAD (circular anal dilator) and a GelPOINT mini access sheath, it was possible to preform intraluminal surgery using standard laparoscopic equipment including the ports, laparoscope, and instruments [33]. The same group also described the use of the glove port for transanal access [34]. The further development of TAMIS to taTME is discussed below.

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## **Transanal Access Platforms**

### **Transanal Retractors**

Open access to the low rectum and anus can be achieved by metal retractors which typically have two or three opposing metal blades. Once inserted into the anus, these blades are separated providing access. This is the simplest form of low rectal access device and includes the Parks anal retractor and the Pratt or Eisenhammer type of instrument.

### **Operating Sigmoidoscopes**

The use of rigid sigmoidoscopies is now predominantly limited to diagnosis and biopsy [35, 36]. However the operating sigmoidoscope may continue to be used for the removal of foreign bodies from the rectum [37].

### **Lone Star Retractor**

The Lone Star retractor is a patient-mounted retractor employing multiple hooks on elastic mounts. This can be used to evert the anus and to stabilize the pelvic floor. It is particularly useful when placing the flexible access channel in the anus to ensure that the top edge of the channel engages above the levator plate.

The Lone Star retractor can also be used to operate at the in the inter-sphincteric space and is very useful in the initial phase of surgery of the anorectal junction [38, 39].

## Rigid Access Channels with Insufflation

The two current rigid access devices have a rigid, operating table mount to support a rigid tube (access channel) introduced into the rectum via the anus. The distal end of the tube is closed with a gastight end plate through which the endoscope and instruments are introduced via gastight ports. The whole device forms a gastight seal between the tube and the anus, and so the rectum can be insufflated.

## TEM

The endoscope in the case of the TEM equipment is a precision binocular operating microscope with a 70-degree field of view which is directed inferiorly by 50° in relation to the long axis of the scope. The scope is mounted in a fixed channel within the access tube. This allows the scope to be advanced and retracted and rotated about its length. The scope however remains coaxial to the access tube at all times. The TEM telescope has a third optical channel to allow a laparoscopic camera head to be attached. This is below the binocular eyepieces and gives a very slightly different field of view. This is suitable for teaching and allows the surgeon to operate either via a television monitor or by using the binocular stereoscopic eyepieces, depending on surgeon preference. The TEM device is mounted on the operating table via a lockable arm. Richard Wolf manufactures and supplies complete sets of instruments designed to be used with the TEM equipment. This includes angled graspers, needle holder, and diathermy needle knives. The equipment is reusable apart from parts of the end plate and the connecting tubing. The connecting tubing provides insufflation, continuous suction, continuous pressure monitoring, and a lens washing channel which allows the telescope to be cleaned without removing it from the access channel. In use the patient must be placed on the operating table so that the lesion to be removed is in a dependent position [4].

## TEO

In the case of the TEO device, the telescope is monocular, and the single eyepiece is mounted above the axis of the access tube. This is of some advantage as it reduces clashing between the instruments and the eyepiece of the monocular scope. The eyepiece is designed to allow a standard laparoscopic camera to be mounted. The TEO equipment is used, in most cases with standard laparoscopic equipment including the insufflator. One of the most significant problems with the TEO equipment when used for taTME is the possibility of billowing of the rectum [40]. The phenomenon of billowing will be discussed later in the chapter.

Some surgeons prefer the TEM apparatus, while others prefer TEO. In terms of its technical complexity, the TEM equipment is certainly the more challenging to use and maintain. However, the trade-off for this effort is an extremely stable platform, with stable insufflation, lumen visibility, suction, and irrigation. Comparative trials have shown no measureable difference in patient outcomes between TEM and TEO. Despite the TEM equipment having been used for the first taTME, it is not well suited for this operation in our opinion. This is principally because of the limited utility of the video optics, since only the operating surgeon maintains the benefit of the binocular vision and it can be difficult to operate in a 360-degree field when using the binocular microscope.

TEO equipment is less challenging. It is set up utilizing a standard laparoscope, laparoscopic instruments, and insufflator. Its simplicity is also its limitation as unstable insufflation can make anything more than very simple surgery challenging. The TEO equipment can however be used in the full 360° of the rectum, and as the monocular operating images are displayed on a video screen, it is possible for an assistant to take part in the surgery. TEO equipment has been used by a number of centers to perform taTME [41]. Following a consensus meeting in St. Gallen in 2016, where a group of invited experts drew consensus via a Delphi process [42], 59.5% supported the use of the TEO equipment and 40.5% the use of the TEM equipment.



## TAMIS

There are a number of flexible ports that utilize the TAMIS technique currently available. They are discussed below.

### GelPOINT Path Transanal Access Platform

The GelPOINT path transanal access platform (Fig. 7.3) (Applied Medical, Rancho Santa Margarita, California) is perhaps the most commonly used access channel for transanal surgery and, with the aid of the surgeons who developed TAMIS, was designed specifically for this purpose. The single-use, disposable device comprises of a deformable semirigid access channel with a proximal flange and a distal flange supported by a metal ring. The access channel can be introduced into the anus with gentle pressure. The second part of the device, a gel cap, is attached to the distal end of the channel. Three, or if required four, ports are inserted through the gel. This provides a semirigid gastight support for the camera and instruments. The gel cap has two luer lock connections for insufflation and evacuation of gas. A recent development of the GelPOINT path system has been the incorporation of a special high flow port to be used with the insufflation stabilization bag (ISB; see below). The access channel is available in three lengths and with or without the proximal flange. Of the experts performing taTME, 91% utilize the GelPOINT path as the access channel of choice [43].



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**Fig. 7.3** GelPOINT path

## SILS

The Covidien (Medtronic, 710 Medtronic Parkway, Minneapolis, Minnesota, USA) SILS port (Fig. 7.4) is a foam port which is seated in the anal canal and is sutured in place. This has three preformed holes which allow the insertion of three ports (usually one 10 mm and two 5 mm ports) to allow rectal access and insufflation. The SILS port was the platform used to perform the initial report of TAMIS surgery as reported in the literature [30].

### OCTO Port

The OCTO port (DalimSurgNET, B1401 Woolin Blue Nine, 583, Yangcheon-ro, Gangseo-gu, Seoul, Korea) is a flanged sleeve which can be inserted into the anal canal and a plate carrying multiple access ports attached. In Europe and North America, it is not commonly used, and its use was supported by only 21.6% of the St. Gallen expert group – although availability of this platform may limit its use by this group and the port itself has not been compared to other TAMIS ports in a meaningful way. There are a number of other ports suitable for TAMIS including the Dapri-Port (manufactured by Karl Storz) (Fig. 7.5) and the KeyPort flex (Richard Wolf) (Fig. 7.6).



**Fig. 7.4** SILS port (Covidien)



**Fig. 7.5** D-port manufactured by Karl Storz (KARL STORZ Endoscopy (UK) Ltd. 415 Perth Avenue, Slough, Berkshire, United Kingdom)

rent limitation to the utility of transanal surgery. While clashing can be avoided with experience, this forms a significant part of the learning curve and adds to the fatigue of the operators. The development of a robotic device with stereoscopic, 3D optics and articulating effector arms specifically for transanal surgery is likely to be the next significant step change in the advancement of transanal surgery [51]. For the time being, however, it is possible but not common to use a robot to perform transanal surgery.

## Transanal Instrumentation

### Ordinary Laparoscopic Instruments

With utilization of the TAMIS technique, the majority of transanal surgery can be completed with normal laparoscopic instruments on standard laparoscopic colorectal tray. Additional instruments might include two needle holders, curved graspers, and various curved instruments, but these are considered optional.



**Fig. 7.6** KeyPort flex Richard Wolf (Richard Wolf GmbH, Pforzheimer Strasse 32, 75,438, Knittlingen, Germany)

### Modified Instruments

There are a number of modified instruments which have been developed by Richard Wolf specifically for use with the TEM equipment. These include right- and left-handed angled graspers and needle holders which make suturing more straightforward. Instruments with angled shafts designed for single-incision laparoscopic surgery (SILS) have not generally found favor among the majority of transanal surgeons who use the TAMIS approach. However, the use of angled instruments may in some circumstances make performing certain tasks less arduous. Likewise, articulated instruments are not in general use with TAMIS as, for the most part, straight instruments are sufficient for local excision.

### Robotic-Assisted TAMIS

There is very limited data regarding the use of any form of robotic assistance to perform TAMIS or taTME surgery although it has been shown to be possible to perform transanal surgery with the assistance of a robot [44, 45]. The current generation of surgical robots are bulky, and their multi-arm instruments and mounting systems are not well suited to transanal surgery. There are, however, indications that a wristed or flexible robotic instrument may improve the utility of transanal surgery. Furthermore, the current design of the available robots makes docking in the transanal position difficult. Notwithstanding, there are pioneering centers which have shown that robotic TAMIS can be achieved [46–50]. In the future, robotic access may offer a number of significant advantages specifically the elimination of clashing of the camera and instruments which is a cur-

### Suturing Devices

There have been a number of automated suturing devices which have been developed which accelerate the suturing process when closure is performed

after local excision. While preferred by some TAMIS experts, automated suturing devices are generally not in widespread use due to cost limitations. Furthermore, for most closures of rectal wall defects after full-thickness excision of rectal neoplasia, a laparoscopic needle holder and absorbable suture are sufficient to reapproximate most defects in the rectal wall. Endoluminal suturing is however made more straightforward by the use of a self-locking, barbed suture such as the V-Loc suture (Medtronic, 710 Medtronic Parkway, Minneapolis, Minnesota, USA,) or the STRATAFIX suture (Ethicon, Bridgewater, New Jersey).

## Diathermy

Monopolar diathermy is the most commonly used option for transanal surgery. The choice of instrument tip, hook, spatula, or needle knife is very much dependent on the operator. The advantage of monopolar diathermy, as a method of tissue division, is that the energy released leads to tissue vaporization with separation of the tissue [52]. This causes a release of the anatomical planes allowing them to separate. In comparison, energy devices such as ultrasonic shears or other tissue-sealing devices tend to seal the anatomical planes together. The diathermy effect may be adjusted to provide more or less hemostasis by blending the “pure cut” current with the “coagulation” current. As the dissection is predominantly in an avascular plane, there is usually no need for advanced energy devices. Most experts prefer low-energy settings for electrosurgery to minimize the accumulation of smoke and to lessen the effect of tissue charring. The use of foot switch or finger switch to operate the diathermy machine based upon surgeon’s preference although foot switching may allow more accurate dissection with less fatigue [53].

Bipolar energy is not generally used for transanal surgery although it may be used to control troublesome bleeding from venous channels on the pelvic side wall, presacral veins, or the prostate gland’s neurovascular bundles. It is not used

in general dissection. The St. Gallen consensus meeting reached 94.6% consensus on the statement that monopolar and bipolar diathermy were the energy source of choice [43] and vessel-sealing devices for transanal access, although used, are less preferred for both local excision and more advanced procedures.

## Energy Devices

Ultrasonic dissection is most suited for full-thickness dissection of the rectal wall and close dissection of the rectal wall from the mesorectum when performing proctectomy for inflammatory bowel disease. The ultrasonic dissector has the advantage of providing division of tissue with simultaneous hemostasis. This is an advantage when dividing the full thickness of the rectal wall including the rectal mucosa. These layers of tissue have a robust blood supply and may bleed especially during full-thickness excision of a large polyp or an early rectal cancer.

In some circumstances however, the sealing process can also seal the tissue planes together causing the dissection to pass unnoticed by the surgeon from one tissue plane to another. This is particularly so during taTME. This sealing effect can impede the surgeon’s attempts to stay within the correct anatomical planes.

Advanced energy devices use a low voltage and a high electrical current between bipolar electrodes along with pressure to plasticize and fuse tissue. The overall effect is similar to the effect created by an ultrasonic dissector. Advanced energy devices can be used in a similar way to ultrasonic dissectors to complete dissection. There are no published data to suggest which may be more effective. As mentioned above, the close dissection of the rectum during proctectomy for inflammatory bowel disease is facilitated by using either an ultrasonic dissector or any commercially available advanced energy device. Advanced energy devices are not commonly used for local excision or rectal neoplasia or advanced procedures such as taTME dissection [54].

## Insufflation and Billowing

### The Gas Laws

In order to understand insufflation, it is important to understand the basic physical laws that apply to the gas which is used and the materials which form the walls of space into which the gas is insufflated. CO<sub>2</sub> is by far the most commonly used insufflation gas, and the remainder of this chapter assumes that this is the gas being used. For the purpose of this discussion, we will consider CO<sub>2</sub> as an ideal gas [55].

There are a number of physical laws which apply to gasses, and perhaps one of the most important of these is Boyle's law [56] which is stated as follows:

$$K = P \times V$$

Whereby, **P** represents the pressure of the gas, and **V** is the volume within which it is contained and **K** the amount of gas (the number of molecules of the gas). We must also be careful to understand the difference between what we mean when referring to the insufflation rates and the volume of gas within the abdomen. One liter of CO<sub>2</sub> delivered by the insufflator at atmospheric pressure (1020 cm of water) has a slightly lower volume when compressed within the abdomen at a pressure of 20 cm of water (atmospheric pressure + 20 cm water).

One liter of CO<sub>2</sub> at atmospheric pressure becomes 1020/1040 x 1 liters = 0.98 liters of CO<sub>2</sub> when compressed within the abdomen with a pressure of 20 cm of water. For the purposes of this chapter, we will ignore temperature as the changes to volume or pressure which occur over a physiological temperature range are small enough to be considered negligible.

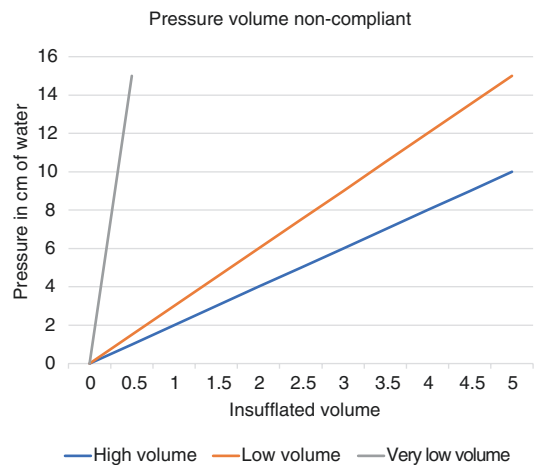
Because the changes in pressure  $\delta P$  are very small and so the changes in volume with pressure  $\delta V$  are also very small, it is reasonable to assume that 1 liter of gas delivered to by the insufflator is equal to 1 liter of gas within the abdomen or rectum. During insufflation when gas is added to the abdomen, both the pressure and the volume change. The abdomen does not behave like a box of a fixed volume – if it were as such, then the

pressure within the abdomen would be directly related to the volume of gas insufflated. This is not the case within the human body as many of the tissues have a degree of elasticity and the structures are compliant. It is important to understand compliance in relation to insufflation.

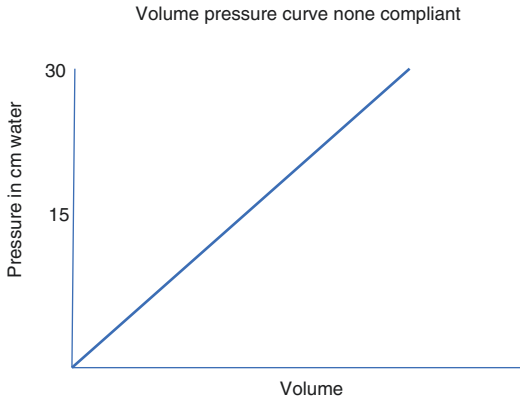
### Compliance

In the previous section, we have discussed the relationship between **K** the amount of gas, its pressure **P**, and the volume within which it is contained **V** as being a constant linear relationship. This is true when there is no compliance. It is possible to draw the relationship between different pressure and volume when gas is introduced into spaces of different volumes (Fig. 7.7) [57]. The tissues of the body are, however, compliant (i.e., they exhibit elasticity). This means that the relationship between the pressure of the gas in the abdomen and volume of the abdomen at the beginning of insufflation is different to the relationship between the pressure of the gas and the volume of the abdomen at the end of insufflation.

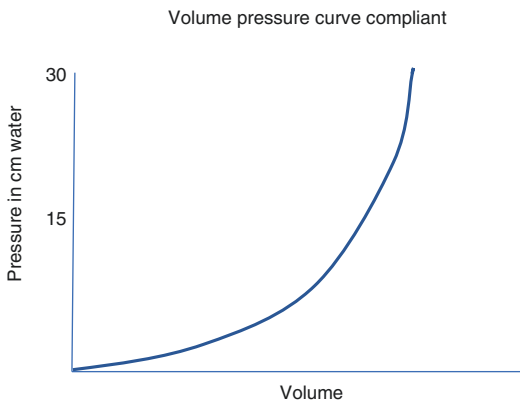
At the beginning of insufflation, the abdomen is very compliant in that with the addition of an amount of gas (**K**) there will be a very small change in the pressure within the abdomen and a very large change in the volume of the abdomen.



**Fig. 7.7** Linear pressure-volume graphs for high- and low-volume non-compliant spaces



**Fig. 7.8** Pressure-volume graph for a non-compliant space during insufflation



**Fig. 7.9** Pressure-volume curve during insufflation of a compliant space (the abdomen) to the point of non-compliance

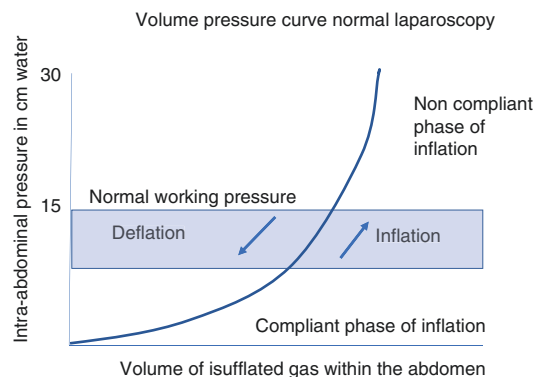
However at the end of insufflation *the addition of the same amount of gas ( $K$ ) will produce a very large change in the pressure within the abdomen for only a very small change in the volume* [57]. If the abdomen was non-compliant, then the pressure-volume curve might look like that shown in Fig. 7.8. However, since the abdominal wall is compliant, then the pressure-volume curve will look like that shown in Fig. 7.9.

## Insufflation

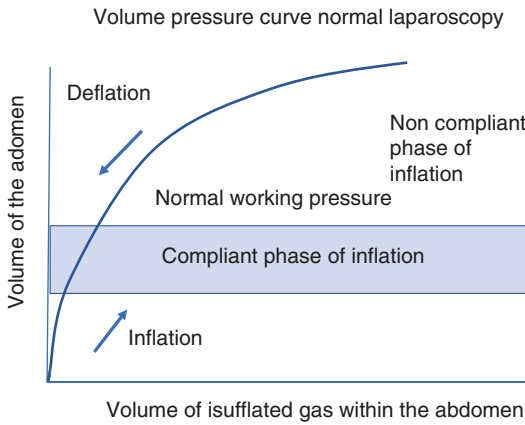
The insufflator increases the amount of gas in the abdomen until the required pressure is reached

[58]. Almost all insufflators in current use are pressure and flow rate controlled [59, 60]. The insufflator is set to a pressure which creates sufficient distension of the abdomen to create a working space [61] and a flow rate which replaces any lost gas at a rate which is greater than the rate of loss. The increasing volume of the abdomen is resisted by the weight of the abdominal wall (or its nonelastic compliance) and the elastic tension of the abdominal wall structures.

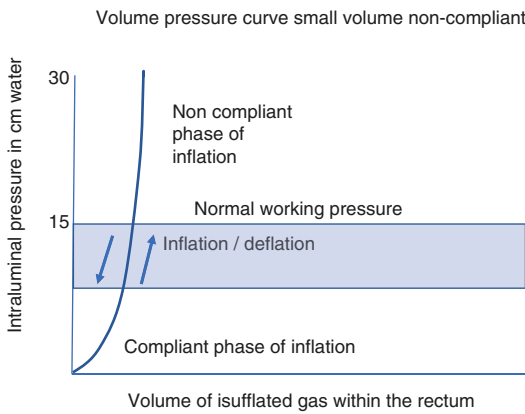
There is a very complex relationship between the amount of gas introduced into the abdomen, the working volume, the tension in the abdominal wall, and the compliance of the abdominal wall. The walls of the abdominal cavity are not uniform; parts of the abdominal wall are more elastic than others. The abdominal wall is also dynamic and may contract if the patient is not completely paralyzed [62, 63]. Because of this, the physical equations which govern the relationship between the volume, pressure, and tension are complex. This complex relationship has been explored by Becker et al. [57], who have shown that the pressure-volume relationships vary from patient to patient. The compliance curve for normal laparoscopy should appear as shown in Fig. 7.10. In Fig. 7.10, the insufflation pressure is within the compliant phase of the distension of the abdomen, and so an increase in the volume of gas produces a modest increase in pressure. This diagram could be redrawn to show the volume of the abdomen in relation to the volume of gas added (Fig. 7.11).



**Fig. 7.10** Compliance curve for normal laparoscopy



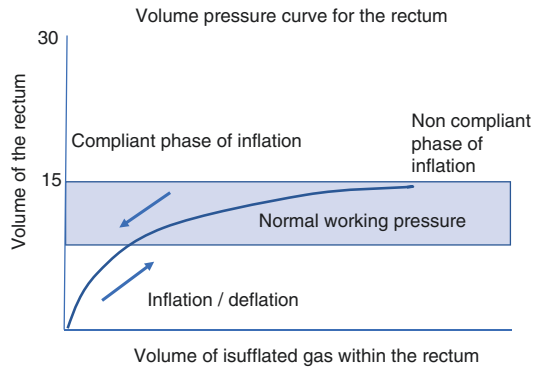
**Fig. 7.11** Volume of gas insufflated and the change in the measured volume of the abdomen



**Fig. 7.12** Volume-pressure curve of the insufflated rectum, a small volume of insufflated gas leads to a high pressure in the rectum

The situation in the pelvis is more complex. The bony anatomy of the pelvis forms a solid truncated cone with either end of the cone covered by an elastic membrane. It is bound by the pelvic floor inferiorly and the abdominal peritoneum and pelvic contents superiorly. The dynamics of insufflation are quite different in this situation. As a smaller proportion of the inflated volume of the pelvis is compliant and the volume of the pelvis is very small, the rate of change of pressure for a given amount of insufflated gas will be greater (Fig. 7.12).

As the insufflated volume decreases and the overall compliance of the insufflated volume decreases, the change in pressure for any volume



**Fig. 7.13** Volume of insufflated gas against the volume of the insufflated rectum

of gas added increases. This is the situation at the beginning of a TAMIS for local excision or TAMIS for tTME immediately following placement of the purse string [40]. Figure 7.12 can also be redrawn to show the change in volume of the rectal working space for a given change in volume of gas added (Fig. 7.13).

At this point, the insufflated volume is less than 200 ml and may be as small as 62 ml (e.g., this is the baseline internal volume of the GelPOINT path platform prior to initiating insufflation). The compliance of the system is very low as the access channel is rigid and only the gel cap and the closed rectum are elastic. If it were assumed that both the sutured rectum and the gel cap of the GelPOINT path TAMIS port were rigid, then the pressure in the rectum would rise in direct proportion to the amount of gas added (a non-compliant system). In this situation the rise in pressure can be calculated. If it is assumed that the whole system does not exhibit elasticity and the total volume of the system is 100 ml, then, for each 100 ml of gas at atmospheric pressure added, the pressure will increase. As an example, when  $P = 1$  and  $V = 100$  ml and  $K =$  amount of gas in the rectum equates to 100 ml of  $CO_2$  at atmospheric pressure.

Expressed mathematically:  $1(\text{atmospheric pressure}) \times 100\text{ml (rectal volume)} = 100$  ml  $CO_2$  at atmospheric pressure. This can be rewritten as  $P =$  amount of  $CO_2$  added in ml at atmospheric pressure divided by rectal volume in ml or  $P = 100/100 = 1$ . If a further 100 ml of  $CO_2$  at



atmospheric pressure is added, then  $P = 200/100$   $P = 2$ . That is, the pressure in the rectum would rise to 2x atmospheric pressure or 1020 cm of water above atmospheric pressure.

Clearly, this does not happen in vivo, and, in fact, two things do happen. First, in the example using the GelPOINT path TAMIS port, the volume of the system is not fixed, and so the gel cap and the rectum both stretch. Second, only a small amount of gas is added before the insufflator senses an increase in pressure and stops delivering additional gas. It can be seen that in these circumstances the pressure in the rectum increases almost in direct relation to the amount of gas added. The smaller and less compliant the insufflated volume, the larger the pressure rise for a given amount of gas insufflated. With very small non-compliant volumes such as a rectal access device in a closed rectum, there can be very rapid and large change in pressure for only a small amount of gas added. *The rate of change of pressure is directly related to the rate of insufflation of the gas. It is this relationship between pressure, volume, insufflation rate, and the method of control of the insufflator that leads to billowing and overpressure in the rectum [64].*

### Insufflators and Insufflation Control

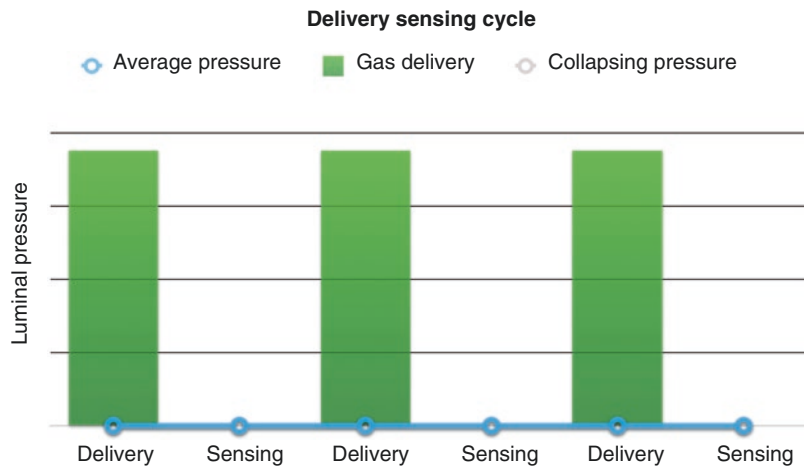
The earliest versions of what we would now recognize as a laparoscopic insufflator began to appear in the 1960s and have largely been attrib-

uted to the work of Dr. Kurt Semm (1927–2003). Semm, an experienced toolmaker and gynecologist, had developed a device for controlled CO<sub>2</sub> insufflation of the fallopian tubes. This was the basis of his electronically controlled CO<sub>2</sub> insufflation device for laparoscopy produced by the Wisap Company in the 1960s (Wisap® Medical Technology GmbH, Fichtenstrasse 27, 85,649 Brunnthal/Hofolding, Germany).

The most simple insufflation control circuit allows insufflation and pressure sensing to occur through a single tube connected to the laparoscopic port which has been inserted into the abdomen. This is the delivery and sensing cycle (Fig. 7.14) [65]. The controls of the insufflator allow the rate of insufflation (as measured in liters per minute) and maximum pressure (as measured by cm of water) to be set before insufflation begins. Typically, the insufflator will display the preset pressure and the actual intra-abdominal pressure measured by the insufflator, the preset flow rate and the actual flow rate, and the volume of gas which has been delivered. The sensing and insufflation cycle is governed by a control algorithm within the device (Fig. 7.15).

In order to achieve insufflation in a reasonable time and with the restriction imposed by insufflation being achieved via a standard luer lock connections to the insufflation tube and laparoscopic port, during insufflation, the pressure in the delivery tubing will be much higher than the set pressure of the insufflator. With a single tube

**Fig. 7.14** The delivery and sensing cycle of the most simple insufflator control system



insufflation system, it is not possible to measure the pressure in the abdomen during insufflation, and so insufflation is briefly suspended and the pressure in the delivery tube allowed to equilibrate with the abdominal pressure. Then the true abdominal pressure can be measured. The insufflator employs a control algorithm to allow it to reach the preset intra-abdominal pressure by cycling between gas delivery and pressure sensing until the required set pressure is reached. Once this has occurred, sensing continues and insufflation is suspended when the set pressure is reached. Should the abdominal pressure fall for any reason, then the insufflation process will resume. Should the abdominal pressure increase above the preset value, the insufflator will automatically vent gas from the system, retrograde via the insufflation tube, until the pressure again reaches the preset value [66].

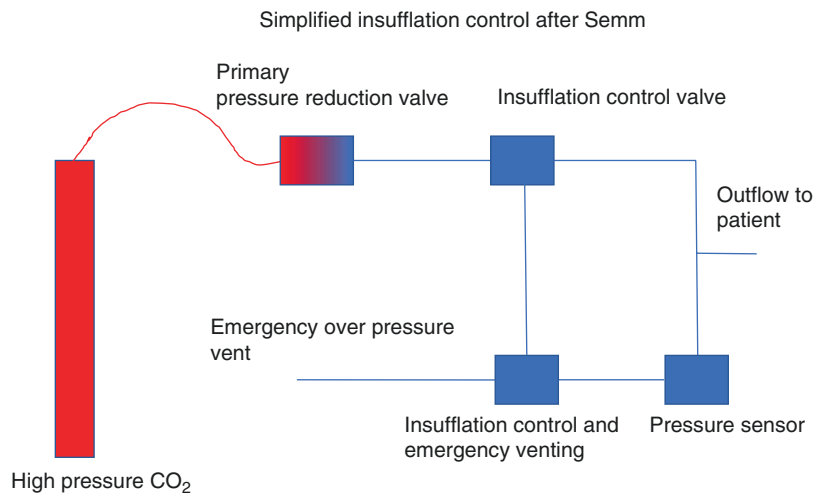
In this system, it is not possible to simultaneously deliver gas and sense the pressure in the abdomen. This is the basis of the control circuit employed by the majority of simple insufflators used for laparoscopy. While the simple insufflation control circuit is suitable for basic laparoscopy, by the nature of its design, it is not possible to maintain the abdominal pressure at exactly the set pressure all of the time. It is always an approximation. Furthermore, as the flow rate increases and the volume and compliance of the space decrease, there is a greater deviation from the set

pressure. In these circumstances, very high pressures compared to the set pressure can be achieved (Fig. 7.16).

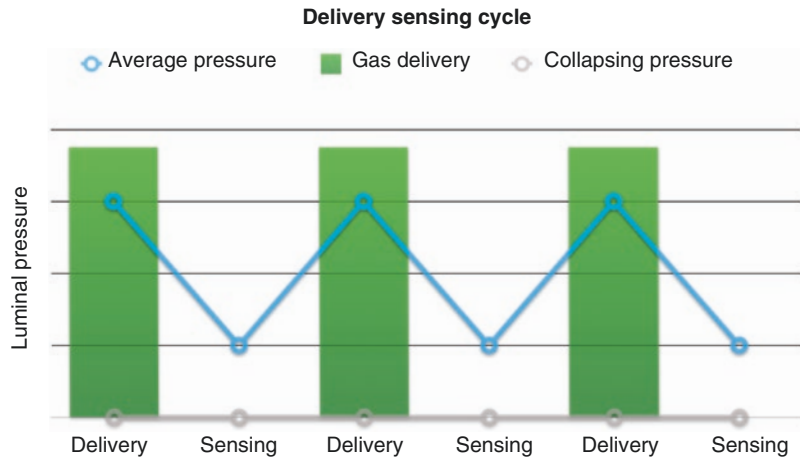
As discussed previously, the commonly used insufflation devices have a single channel to both insufflate the abdomen and measure the pressure in the abdomen. There is a brief pause in insufflation during the sensing phase, and then insufflation is resumed. This continues until the set pressure is reached. The intermittent nature of the insufflation is not generally noticeable during abdominal laparoscopy because the volume of the abdomen is high and the changes in the volume of gas are small as a percentage of the total volume. The insufflator is working in the compliant phase of the pressure-volume curve of the abdomen (see above). The damping effect caused by the compliance of the abdomen creates the impression that the insufflation pressure is stable. This compliance also moderates any changes in volume related to a small change in pressure. This is not the case when the insufflated volume is small, such as in the closed rectum, and when the compliance is low, with a rigid or flexible access channel. When this is the case, insufflation of a small volume of gas can lead to very large changes in the pressure and almost no change in volume of the rectum.

In the majority of current systems, insufflation is achieved via a standard luer lock connector and small bore tubing. The dimension of the

**Fig. 7.15** Diagrammatic representation of the control systems of a simple laparoscopic insufflator



**Fig. 7.16** Delivery and sensing cycle during abdominal laparoscopy



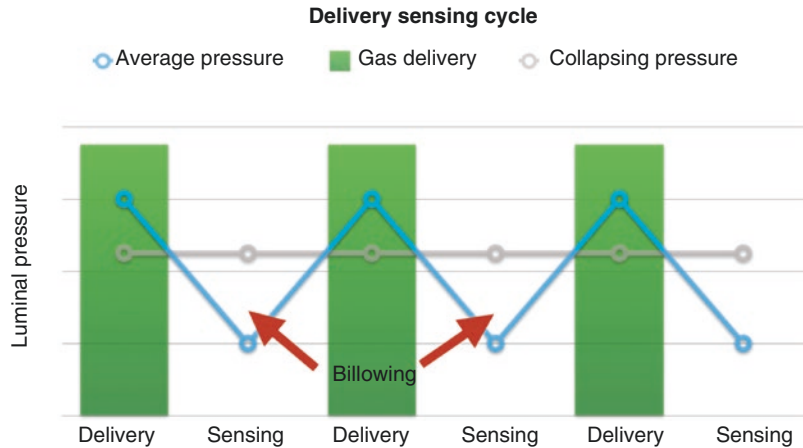
luer lock connector is governed by an international standard (ISO 80369) which requires that the internal diameter of the male connector be 2.7 mm in diameter. This is generally the smallest diameter pipe in the system although the valves have a similar internal diameter. This narrow point in the gas pathway provides a significant restriction to flow. To overcome this and to deliver a sufficient volume of gas in a short time, the pressure difference across these restrictions must be high. To produce a flow rate of 20 L/pm would require a pressure difference across the connector of 60 mmHg. This, in turn, can lead to high pressures within the inflated volume once it has reached its maximum capacity. In the abdomen, the maximum volume is governed by the compliance of the abdominal wall and diaphragm and the compressibility of any intra-abdominal organs. As discussed above, this creates a compliant system, and so there may be a relatively small change in pressure with quite large changes in the volume of gas within the abdomen. This is not however the situation when inflating the rectum within the confines of the bony pelvis where the volume is constrained [67]. The rectal volume within the pelvis is relatively small and the compliance is low. Insufflating a small volume of gas can lead to very large changes in pressure. This is most apparent with a standard insufflator during the initial step of taTME. In this situation, after placement of the purse string suture, the insufflated volume of the access channel and rectum

may be as small as 62 ml as discussed previously. During insufflation especially at high flow rates, the pressure in the delivery tubing is much higher than the pressure in the rectum. As the rectum begins to fill, the pressure in the rectum rises. During the sensing phase of the insufflation sensing cycle, the rectal pressure equilibrates to the pressure in the delivery tubing. As the pressure in the rectum nears the set pressure on the insufflator, one of three things can happen:

1. The insufflator senses that the rectal pressure is lower than the set pressure and resumes insufflation.
2. The insufflator senses the rectal pressure has reached the set pressure and pauses insufflation.
3. As the pressure in the insufflation tubing equilibrates with the rectum, the pressure is higher than the set pressure and the system vents.

In the third scenario, as the system vents CO<sub>2</sub>, the pressure in the rectum can fall below the set pressure, and so the sensing insufflation cycle resumes. *Persistent overshooting of the set pressure and subsequent venting is observed as billowing.* The overshoot of the set pressure can be substantial [68] and may be exaggerated if there is a constant loss from the system due to smoke extraction or suction. Billowing may also occur without overshooting of the set pressure if losses from the system are high (Fig. 7.17).

**Fig. 7.17** Intraluminal pressure in the rectum during billowing



During billowing, rectal pressure falls below the collapsing pressure of the rectum (the pressure at which the rectal distension is no longer maintained). It is at this point that movement of the rectum is observed. It is also possible that unintentionally high pressures may occur, dependent on the insufflator settings and design, as the insufflator attempts to achieve the set pressure. The resultant movement can be a very significant impediment to safely continuing the operation. Billowing is most prominent when the inflated volume is very small. Billowing can occur with any of the currently available TAMIS ports when used with a standard insufflator. Billowing occurs infrequently with the TEM-specific insufflator and rarely when the AirSeal® insufflator (ConMed, Inc. Utica, New York) is employed together with a TAMIS port, as discussed in the following sections.

Smoke extraction can require rapid exchange of the gas in the rectum. These high flow rates demand high pressures to overcome the resistance of small bore insufflation tubing *but more so the luer lock connections which are found universally on both ports and anal access channels*. The need for high pressure to create enough flow to overcome leakage and the suction used to evacuate smoke can lead to overpressure of the system. Overpressure occurs when the insufflator continues to insufflate despite the luminal pressure reaching the set pressure on the insufflator. Depending on the type of device being used, the set pressure, its flow settings, and the sensitivity

of its pressure control systems, these periods of overpressure can be small and short-lived or more prolonged and more severe. It is possible that overpressure in the rectum could drive CO<sub>2</sub> into the blood stream and thus a potential cause a CO<sub>2</sub> embolus, a rare but serious complication of taTME surgery [64, 69].

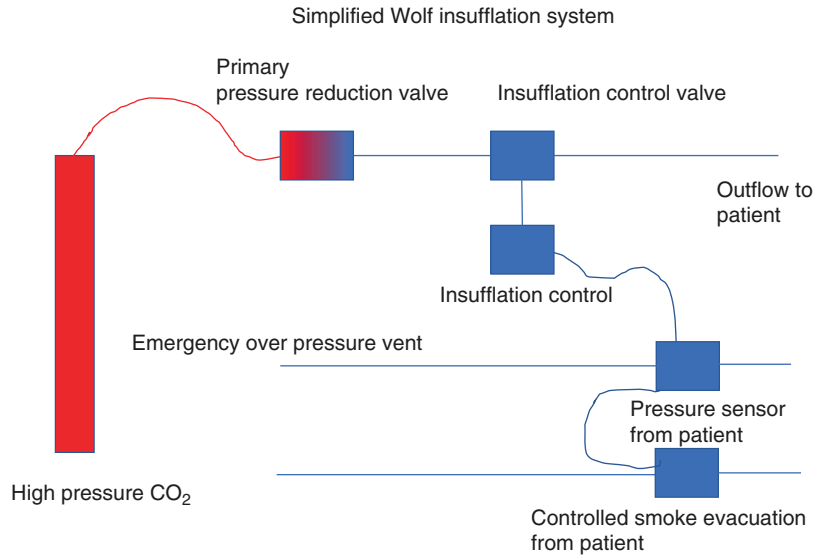
### The TEM Insufflator

It was the problems with the simple insufflation system that spurred Professor Buess to pursue the development of the TEM insufflator (Wolf GmbH). In this system there are four separate connections to the TEM apparatus. They are as follows:

1. Gas delivery
2. Pressure sensing
3. Smoke evacuation
4. Camera washing

In this system, gas delivery is continuous apart from very brief periodic interruptions when the machine has to recalibrate. Pressure sensing is also continuous as is smoke evacuation. Camera washing is via a separate channel and is controlled by the operator and does not take part in the insufflation circuit. The rate of smoke evacuation never exceeds the rate of gas delivery, and the evacuated smoke is lost from the system (Fig. 7.18). Because both the delivery and loss of

**Fig. 7.18** Simplified diagram representing the type of control system employed by the TEM insufflator



gas from the system is controlled, it is possible, once the rectum is inflated, to maintain almost absolute stability of the inflation pressure. One of the great advantages of the TEM system is this method of insufflation which allows very accurate dissection under very controlled conditions.

### AirSeal® Insufflator System

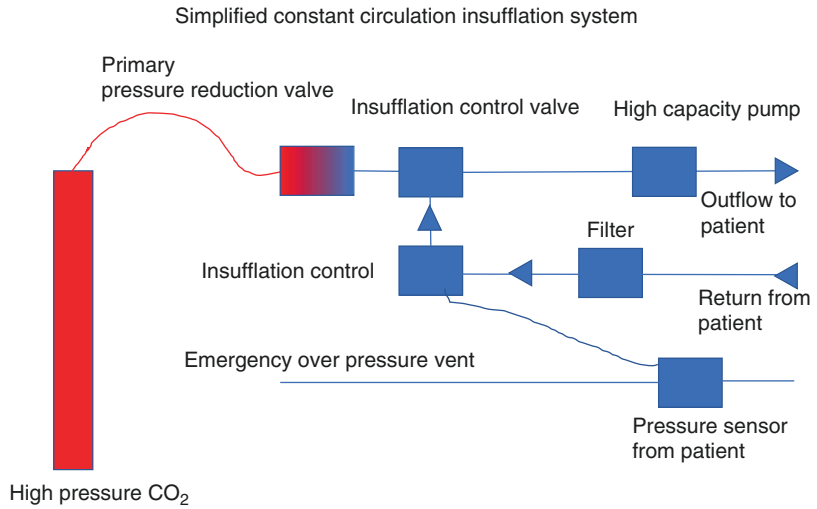
The AirSeal® system (ConMed, 525 French road, Utica, New York, USA) was not developed specifically for TAMIS or taTME, but because of its design and the way in which it controls and maintains the pressure within the system, it has been found to have significant advantages. In “AirSeal® mode” the AirSeal® insufflator (Fig. 7.19) uses a pump to circulate CO<sub>2</sub> through the AirSeal® trocar – commonly placed through the gel cap of the GelPIONT Path TAMIS Port. The design of the hub of the trocar creates a vortex which effectively creates a local high-pressure barrier which prevents CO<sub>2</sub> from escaping the abdomen (i.e., there is no trapdoor barrier, only an invisible pressure barrier). A separate channel continuously measures the pressure of the tip of the AirSeal® trocar. CO<sub>2</sub> is circulated through a high-capacity filter which removes the smoke and the gas and then recirculates the gas. If gas is lost from the system, it is



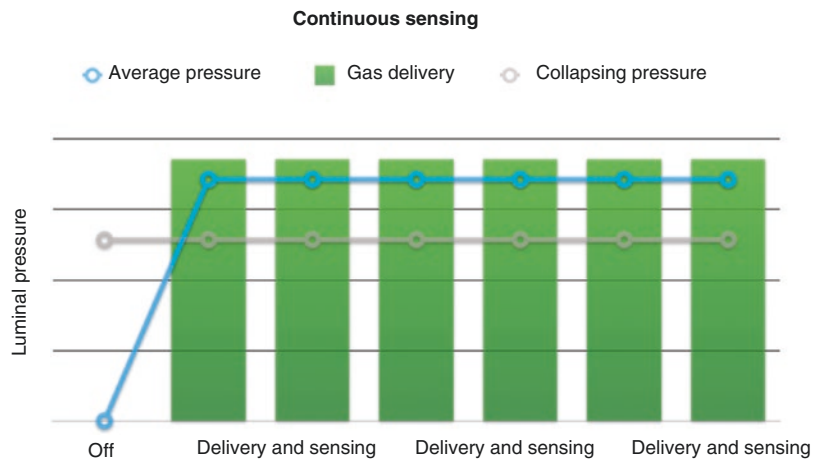
**Fig. 7.19** The AirSeal insufflator (ConMed, 525 French road, Utica, New York, USA)

replaced into the circulating volume by the insufflator without pausing circulation of the gas. The gas flow created at the tip of the AirSeal® trocar is turbulent, and so the smoke is mixed with the inflow gas and is removed as the gas is recirculated. As it is a constantly sensing system, the AirSeal® insufflator is able to create a very stable operating environment with reduced levels of smoke in the operating field (Fig. 7.20). It is not, however, possible to remove fluid via the AirSeal® insufflation system, and if fluid or blood enters either the recovery side of the circulating loop or the pressure sensing channel, the system may shut down. Furthermore, if fluid passes through the filter in the system, the insufflator may be damaged (Fig. 7.21).

**Fig. 7.20** Constant circulation and pressure measuring system similar to the AirSeal system



**Fig. 7.21** The constant sensing system of the Wolf insufflator or the AirSeal device gives a very stable insufflation



The published data for the AirSeal<sup>®</sup> insufflation system show that it provides a significantly more stable luminal pressure than a standard insufflator. Bucur et al. showed in a randomized trial of patients undergoing renal surgery with an insufflation pressure of 12 mm hg that the actual pressure was between 12 and 18 mm for 79% of the time with a standard insufflator, while the AirSeal<sup>®</sup> device maintained the actual pressure within this range for 87.4% of the time.

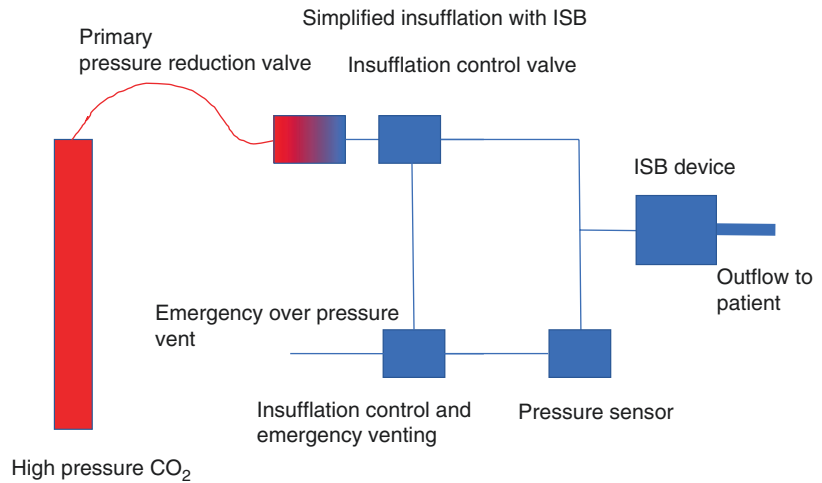
**ISB and EPIX**

The insufflation stabilization bag (ISB) and EPIX (Applied Medical, Rancho Santa Margarita,

California) system is a novel approach to the problem of billowing [64]. The ISB creates a large, compliant dead space between the insufflator and the GelPOINT path (Fig. 7.22). This increases the insufflated volume and also the compliance of the system. The effect of this is to simulate insufflation of a much larger, abdominal volume where billowing is not observed (Fig. 7.23). In this circumstance, the control systems of the insufflator work in a predictable manner, and fluctuations in pressure are minimized. The compliant nature of the ISB ensures that insufflation occurs in the compliant phase of distension of the ISB. The device is connected to the rectum via a custom port placed through the GelPOINT path (Fig. 7.24). This large diameter



**Fig. 7.22** A standard insufflator control system with the ISB in place



**Fig. 7.23** ISB device connected to the GelPOINT path and the insufflation stabilization bag (ISB) (Applied Medical)



**Fig. 7.24** Custom large bore connector to link the ISB device to the GelPOINT path

insufflation port allows instantaneous equilibration between the rectum and the ISB device. The ISB device is more compliant than the rectum, and so movement is seen in the ISB but not in the rectum. This creates a more stable pressure with variation in the amount of CO<sub>2</sub> in the ISB caused by gas loss or suction. The EPIX probe (Fig. 7.25) is designed to work in conjunction with the ISB to provide smoke evacuation without loss of pressure. This is achieved by ensuring that the flow rate in the EPIX probe is less than the deliverable flow rate from the insufflator.

Experimental, dry lab, cadaveric, and early clinical experience with the ISB-EPIX combination indicates that it provides a stable insufflation of the rectum during TAMIS for local



**Fig. 7.25** The EPIX probe, (Applied Medical)

excision of neoplasia and for taTME. Figure 7.26 depicts lab experience testing the EPIX probe and the ISB device in a bovine colon model. The stabilizing effect of the ISB on a sensing/delivery system is demonstrated in Fig. 7.27. Waheed et al. also showed a considerable variation in

luminal pressure in an experimental taTME model. With a constant loss from the system to imitate smoke evacuation and the insufflation pressure set at 12mmhg, the pressure reading from within the rectum ranged from 0.72 mmHg to 28.24 mmHg (mean 14.6 mmHg SD  $\pm$  4.27) using a standard insufflator without stabilization. With the ISB in place, the pressure readings within rectal lumen were significantly lower ranging from 8.73 mmHg to 14.52 mmHg (mean 11.84 SD  $\pm$ 1.66)  $P < 0.001$  [64].

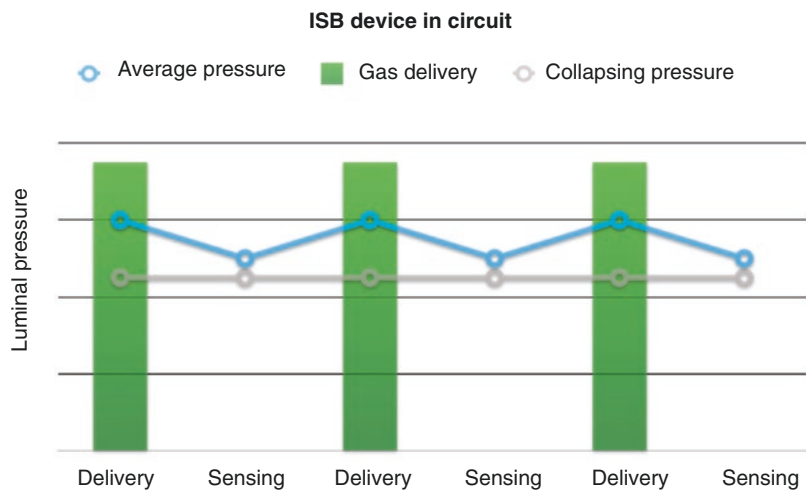


**Fig. 7.26** Lab experience testing the EPIX probe and the ISB device in a bovine colon model

### Hazards of Insufflation

CO<sub>2</sub> embolization is probably a common occurrence in laparoscopic surgery however microscopic bubbles of CO<sub>2</sub> traveling through the heart are occult, without clinical sequelae [70]. Problems do occur however if a macroscopic bubble of CO<sub>2</sub> enters the heart and 600 ml bolus of gas will cause fatal cardiac arrest in an adult pig. It has been found that an intravenous insufflation pressure of 20 cm H<sub>2</sub>O was sufficient to cause an “airlock” in the heart and lead to fatal circulatory collapse. Insufflation at 15 cm H<sub>2</sub>O was better tolerated [71–73]; CO<sub>2</sub> embolus is a recognized complication of laparoscopic surgery and has an incidence ranging from 0.0016% to 100% depending on the method of detection [74, 75] of CO<sub>2</sub>.

**Fig. 7.27** The stabilizing effect of the ISB on a sensing/delivery system



The risk of CO<sub>2</sub> embolus may be reduced by maintaining as low an insufflation pressure [69, 71] as will allow the operation to proceed, employing steep Trendelenberg position to allow lower working pressure in the rectum and employing a stabilized insufflation device which reduces peak pressures during insufflation. It is likely that, as in other laparoscopic surgery, CO<sub>2</sub> embolus occurs when the insufflation pressure is high enough to allow CO<sub>2</sub> to enter an open venous channel. *The open channel may not bleed, while the insufflation pressure is higher than the venous pressure.* Bleeding may become apparent however if the insufflation pressure is reduced or released altogether [76–78]. It has been noted that CO<sub>2</sub> embolus may be related to re-insufflation following pressure reduction to check for bleeding [79].

It is clear from experimental data that the actual pressure experienced by the patient is not equal to the set pressure of the insufflator [80, 81]. In the case of under-pressure, troublesome “billowing” may occur. In the case of overpressure, which may be as high as 121.4% of the set pressure in a bench top model of the abdomen. From laboratory experiments in piglets [69], it is clear that should open venotomy occur then the survivability of CO<sub>2</sub> embolization is inversely related to the insufflation pressure.

Stabilized insufflation will reduce the risk of overpressure and, thus in theory, the risk of CO<sub>2</sub> embolization.

## Summary

The ongoing development of TAMIS and taTME is entirely dependent on the equipment which is available to the surgeons operating in this field. While the challenge of access and illumination has very much been overcome, the problems of insufflation and instrumentation to perform the operation remain very much in the improvement phase. It is clear that the further development of procedure specific insufflation and smoke evacuation will overcome current insufflation problems. Furthermore it is very likely that the ongoing development of single-access docking robotic systems will provide a solution which

will allow improved maneuverability within the confines of the pelvis [51]. The field of advanced transanal surgery is expanding exponentially. This expansion is dependent on surgeons continuing to explore novel ways of using the equipment that is available to them and assisting the equipment manufacturers to develop new and more useful devices.

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# Operating Theater Setup and Perioperative Considerations

# 8

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## Introduction

With any new technique, careful consideration should be given to the equipment required, the setup of the operating theater, as well as ensuring that the patient is properly prepared for the case and the relevant personnel informed (surgical assistants, anesthesiologists, and nursing staff). This chapter will look to cover these areas for TAMIS, much of which can also be applied toward the setup for taTME which is discussed separately in a dedicated chapter. Since there is considerable overlap between these two techniques, this chapter will cover what is required for both procedures, with notes on where TAMIS or taTME setup differs.

## Equipment

An important distinction between TAMIS and TEM is that TAMIS can be performed with equipment that most standard laparoscopic operating theaters possess [1, 2]. However, there has been the development of specialized equipment that will make the procedure technically less demanding. First, the essential equipment for these procedures will be described, followed by

descriptions of the recommended equipment that the authors regularly use.

## Essential Equipment

The key piece of equipment for transanal surgery is an access device. In the authors' institution, the preferred port is the GelPOINT path (Applied Medical, CA, USA, Fig. 8.1) [3]. This is composed of three components: an access channel made of molded plastic which comes in three lengths (4 cm, 5.5 cm, and 9 cm), a gel cap which seals the system to allow pneumorectum and which serves as a faceplate for admission of cannulas – up to four 10 mm cannulas (one of which can be substituted for a trocar) can accommodate a variety of laparoscopic instruments. The gel cap has two stopcocks which allow smoke evacuation and connection of insufflation tubing. Depending



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**Fig. 8.1** GelPOINT path device. (Taken with permission from Applied Medical, CA, USA)

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on the length of the patient's anal canal, the correct access channel should be selected to ensure that the proximal end of the port is seated above the anorectal ring when inserted. In the United States, this port is an FDA-approved device for TAMIS and has been specifically designed for transanal access. Alternatively, the SILS™ port (Medtronic, MN, USA), although not designed for TAMIS, has been used for this procedure and is quite suitable as well; it is also FDA approved [2]. Other commercially available ports designed for single incision laparoscopy have been described [4].

Standard laparoscopic equipment is essential. This includes a camera and light system, a 30-degree 5 mm or 10 mm rigid laparoscope, laparoscopic graspers such as a Maryland grasper, laparoscopic needle holders, monopolar cautery, a laparoscopic suction/irrigation set, and laparoscopic insufflator. Other required equipment includes betadine to irrigate the surgical field, a 0-silk suture to secure the port in place from rotating during surgery, and open suction tubing.

One of the challenges with using standard laparoscopic insufflation is the “billowing” due to gas continuously escaping through the proximal colon at an uneven rate. This, combined with the fact that CO<sub>2</sub> insufflation disrupts the pressure sensing unit, results in uneven CO<sub>2</sub> cycling within the rectum [5]. The consequence of this is that the rectum can move in a cyclic fashion during the operation making precise dis-

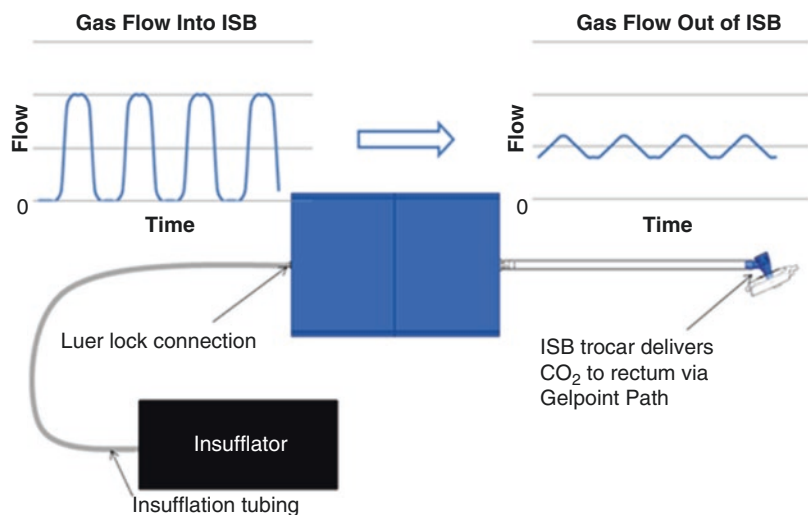
section difficult. One solution is the use of an advanced insufflator such as the AirSeal (ConMed, NY, USA, see below) [6]; however, there is a considerable upfront capital cost. Another solution, which now is included in the GelPOINT path kit, is an insufflation stabilization bag (ISB) (Applied Medical, CA, USA, Fig. 8.2) [7]. This device, placed between the insufflator and access valve, helps stabilize the rate of insufflation and reduces the amount of billowing in the rectum (Fig. 8.3).

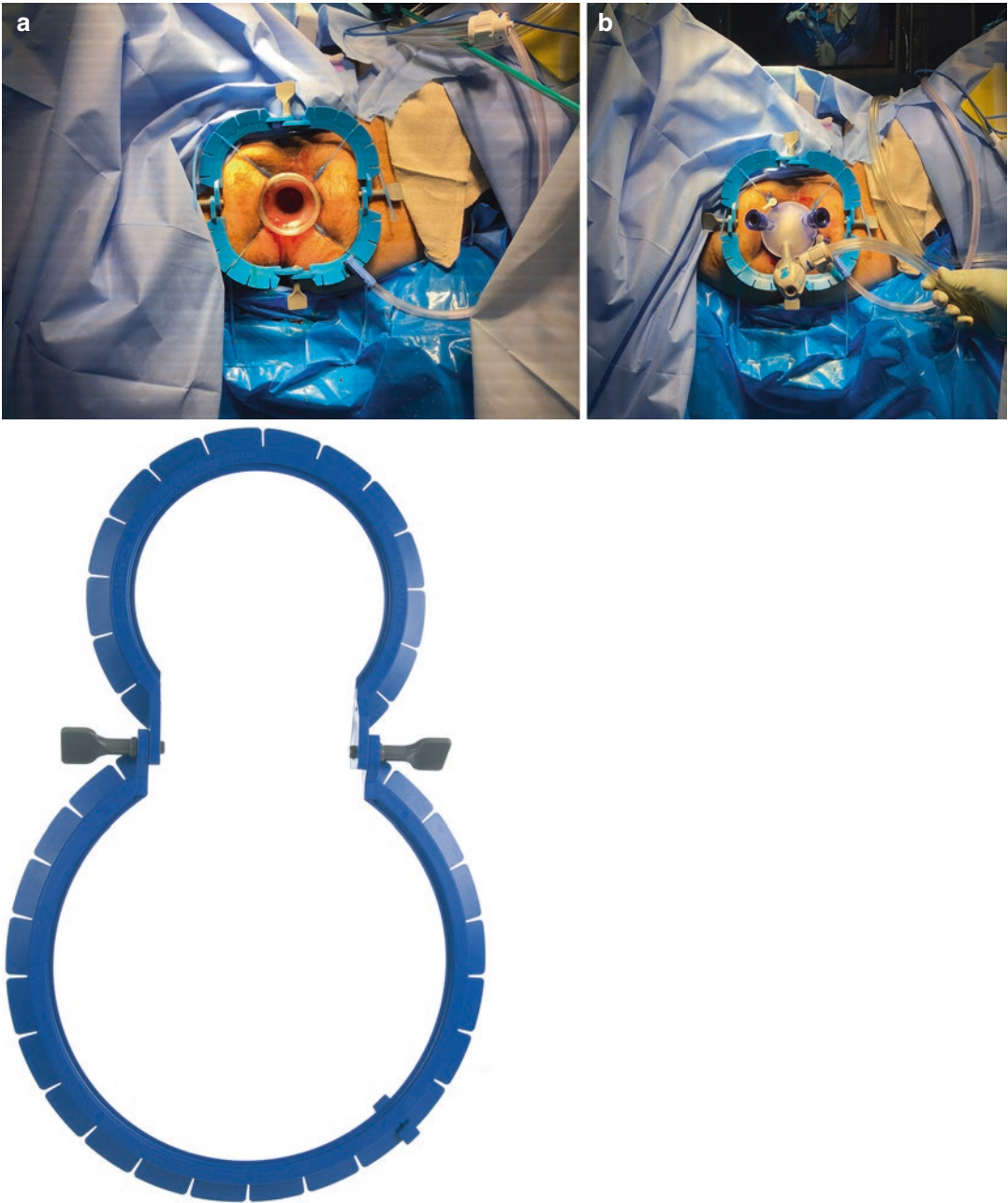
For taTME cases, a Lone Star retractor (CooperSurgical, CT, USA) is preferred (Fig. 8.4). By retracting the anal skin in this area, the dentate line is everted and exposed in a more



**Fig. 8.2** Insufflation stabilization bag (ISB), used during a TAMIS case

**Fig. 8.3** Demonstration of the ISB setup. It is usually placed between the insufflator and GelPOINT path port. Note that the average flow rate with and without the ISB is the same, but the fluctuations in flow are much reduced with an ISB





**Fig. 8.4** Insetion of GelPOINT into anus. Note the placement of the Lone Star retractor: (a) without cap, (b) with cap and ports in place

satisfactory manner. This assists in the placement of the transanal access port and also improves access to the lower rectum when the purse-string suture is secured under direct vision. This retractor comes either as disposable or reusable sets, and alternative brands are available.

### Recommended

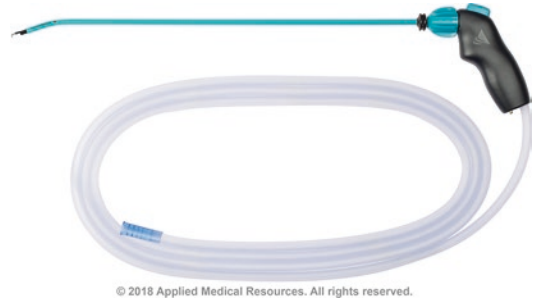
The majority of high-volume TAMIS (or taTME) surgeons advocate the use of the AirSeal insufflator (Fig. 8.5) for TAMIS and TaTME



**Fig. 8.5** AirSeal device

cases [6]. This system allows for continuous pressure sensing as well as continuous insufflation resulting in a stable platform during the operation. The ISB can alternatively be used to maintain a more stable pneumorectum compared to standard insufflation alone, though it does not provide any additional smoke evacuation. Standard laparoscopic smoke evacuators often are insufficient for TAMIS, and it is noted that the AirSeal usually provides a clear field due to its optimized smoke evacuation capabilities [8]. An important limitation of AirSeal for insufflation is that it requires a conventional “long” 5 mm versus 8 mm trocar designed for laparoscopy and adapted to TAMIS. This valveless trocar makes fixed-angled instruments difficult to use in this port and reduces the surgeon’s flexibility in port placement. The manufacturer is redesigning the port to be more suitable for transanal access and to be better adapted to the TAMIS port.

Although advanced hemostatic devices such as ultrasonic dissectors and vessel-sealing coagulators can be used, the authors prefer low-wattage monopolar cautery for its increased



**Fig. 8.6** Epix electrocautery probe. (Taken with permission from Applied Medical, CA, USA)

precision, and, if dissection along embryonic fusion planes is maintained, the need for more advanced vessel sealers for hemostasis is obviated. For dissection, the authors recommend the use of a monopolar electrocautery device and prefer a hook tip over pinpoint or spatula tips, although these are all valid options. A laparoscopic hook cautery with a fine smoke evacuator which is operator-controlled at the trigger handle is preferred. When activated, the smoke evacuation can be done in a gradual fashion to minimize insufflation loss. This can be accomplished with standard suction irrigators with cautery attachments. Alternatively the Epix electrocautery probe (Applied Medical, CA, USA, Fig. 8.6) has an angled L-shaped tip that allows for instruments to be directed toward the operative field at a different angle to the laparoscope, reducing clashing and optimizing view. Others have found the SILS™ hook (Medtronic, MN, USA) useful due to its flexible angled tip though it does not have a built-in smoke evacuator [9].

The confined space of the rectum with the close placement of ports makes tying knots extremely difficult, and therefore traditional suture closure is technically demanding. The authors prefer to close TAMIS defects with an automatic suturing device to reduce operative times and assist in an aligned closure. Alternatively, standard absorbable suture may be used for a running closure. This is further facilitated by use of barbed sutures that obviates the need for knot tying and prevents sliding of the wound edges during closure.

A flexible-tip laparoscope can also be employed for use at the surgeon’s preference. Although the authors have found this cumbersome to use within the strict confines of the rectum, some experts have found this option beneficial. Proponents would argue that the flexible-tip scope would be useful to reduce instrument clashing and to allow for greater visualization of the operative field. However, the small operating space actually causes the instruments to collide with the tip of the camera, causing it to deflect away from the field of view.

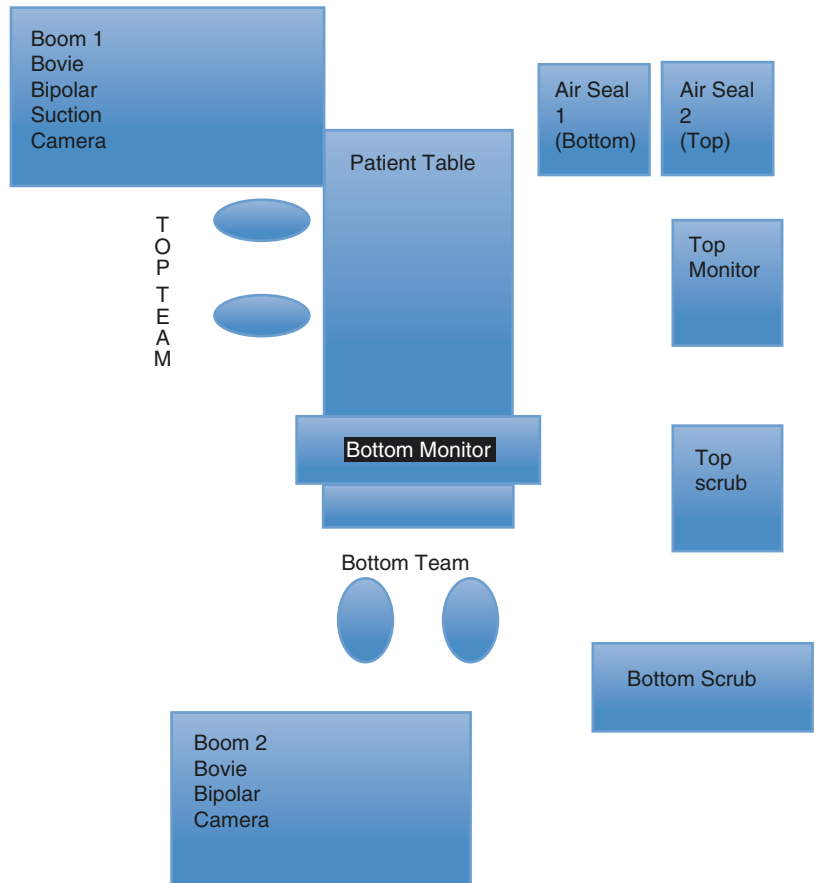
Finally, anti-stick solutions such as Electro Lube® (Eagle Surgical Products, TX, USA) placed onto the hook diathermy tip can reduce the char deposited on the instrument, reducing the need to clean the tip. In addition, a needle board is also recommended to pin the specimen immediately after extraction to facilitate pathological examination. Local excision specimens should be placed appropriately oriented and sent to pathology as

fresh specimens to minimize shrinkage and for a more accurate interpretation of margins.

### Operating Theater Setup

The setup for TAMIS is similar to the setup for TAMIS-based taTME. Figure 8.7 is a diagrammatic representation of the typical theater setup during a taTME procedure. For the purposes of TAMIS setup, only the bottom-labeled elements in the picture and Boom 2 are required. In addition, due to the absence of an abdominal component, Boom 2 is often placed on the right side of the patient where the top team would be standing so that laparoscopic cables are all running cephalad over the patient’s leg. The surgeon and assistant are positioned as for any perineal case, and the scrub nurse usually stands to the right of them.

**Fig. 8.7** Diagrammatic representation of TAMIS/taTME setup. Please note that only the elements marked with “bottom” are required for a TAMIS setup





## Perioperative Considerations

### Patient Selection

#### TAMIS

Patient selection for TAMIS is detailed elsewhere in this textbook. Briefly, all prospective patients must be able to tolerate muscle-relaxing general anesthesia. The Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) recently published a guideline that recommended the following for TAMIS cases [10]:

- Anatomically accessible lesions localized to the bowel wall, either benign polyps or Tis/T1 lesions
- Well- or moderately differentiated lesions
- Lesions without lymphovascular and/or perineural invasion
- Lesion <4 cm

Some caveats need to be included with these recommendations. T1 lesions with deeper submucosal invasion (sm2 or sm3) should be treated as T2 lesions, as the surgeon must consider the risk of lymph node metastasis in these patients. T2 and T3 lesions may be excised when patients are considered to be medically unfit for radical resection. These should be discussed at a multidisciplinary tumor board to confirm mutual agreement of all treating physicians prior to proceeding. In addition, in experienced hands, excision of lesions >4 cm or > 50% of the circumference of the bowel lumen is also possible with TAMIS.

### Other Considerations

Before TAMIS, the patient should undergo a cathartic bowel preparation. The authors place the patient on a clear fluid diet the day before, with the patient taking one bottle (296 ml) of magnesium citrate the afternoon prior to their scheduled surgery. On the day of their procedure, the patient is given two, 250 ml saline laxative enemas prior to arrival at the hospital. This is to ensure that the left side of the colon is sufficiently cleared of solid

fecal matter. Giving full bowel preparation has also been described in the literature [11], however, is unnecessary in the authors' opinion and may create a more difficult operative field to control with the presence of liquid stool. However, for taTME, consideration should be given to full mechanical bowel preparation if diversion is planned, and ostomy evaluation and marking should be undertaken preoperatively if required. Appropriate prophylaxis includes single-dose systemic antibiotics administered 30 minutes prior to incision (our preference is ertapenem 1gm IV).

A general anesthetic with muscle paralytics is required to ensure that the pneumorectum is not overcome with any increase in intra-abdominal pressure due to contraction of the abdominal wall, as well as diaphragmatic excursion which occurs with negative pressure respiration. The patient is placed in lithotomy position with slight Trendelenburg to facilitate access to the perianal region. Ensuring the patient is on a nonslip mat is essential to prevent any movement of the patient intraoperatively. An anorectal field block with bupivacaine can be performed prior to introducing the TAMIS port to relax the sphincter complex and to reduce pain postoperatively.

### Postoperative Care

Patients are often discharged on the same day of surgery without dietary restrictions. Antibiotics after TAMIS local excision is no longer recommended, and analgesics are not warranted. Restrictions on physical activity are not imposed. Patients typically follow up for clinical re-evaluation within 14 days. Clinical examination typically includes bedside proctoscopy to assess healing. For patients in whom the excision was time-intensive, complicated by bleeding or peritoneal entry, inpatient observation is indicated.

### Conclusion

Careful preparation before any case will alleviate many of the potential technical problems that may arise during TAMIS. Although much of the



recommended equipment is not essential, it is highly recommended to have this available as it will provide important adjuncts to the safe and expeditious completion of TAMIS. Most patients who undergo TAMIS for local excision can be managed in an ambulatory fashion.

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# Surgical Technique for Local Excision of Rectal Neoplasia

# 9

Matthew R. Albert and Paul Kaminsky

## Introduction

The treatment of rectal neoplasms has evolved greatly over the last four decades.

In addition to an aging population, the increasing implementation of screening programs worldwide, as well as improvements in the radiologic evaluation, has led to an increasing incidence of early rectal neoplasms amenable to local excision.

More importantly, surgical techniques and transanal access platforms, initially TEM (transanal endoscopic microsurgery) and subsequently TAMIS (transanal minimally invasive surgery), have evolved to permit high-quality resection of rectal tumors. Compared to tradition local excision utilizing rectal retractors, both TEM and TAMIS have consistently and unequivocally demonstrated improved outcomes with decreased margin positivity, less tumor fragmentation, lower local recurrence rates, and higher long-term survival [1, 2]. Conversely, radical resection (low anterior resection and abdominoperineal resection) provides excellent oncologic outcomes, but these approaches are associated with significant morbidity and mortality, including anastomotic leak (5–15%), septic complications,

sexual and bladder dysfunction, and permanent stoma [3]. *The treatment of malignant neoplasia of the rectum is a balance between the morbidity of classical radical surgery with the increased risk of recurrence with local excision.*

Since the introduction of TAMIS in 2010, which utilized a single-incision laparoscopic surgery port, flexible access devices specifically FDA approved for transanal surgery have been designed and are commercially available. The commonest of these “TAMIS ports” used today is probably the GelPOINT path transanal access platform (Applied Medical, Rancho Santa Margarita, CA, USA). Widespread availability, shorter learning curve, and easy training and implementation have led to extensive adoption of TAMIS compared to other modalities in the last decade. TAMIS is a valuable technique for local excision of lesions in the rectum that can be performed using readily available equipment and a minimally invasive skillset.

## Patient Selection

As cure rates for early rectal cancer are excellent with radical surgery, local excision must offer cure rates comparable to radical surgery while allowing for improved functional outcomes and reduced morbidity. The main disadvantage of local excision compared to radical surgery is the inability to properly assess for lymph node basin

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within the mesorectum, and every effort must be made to select patients with minimal risk of nodal metastasis for curative-intent local excision [4]. Published rates of lymph node metastasis (LNM) for all T1 and T2 rectal tumors range from 10% to 14% for T1 and ~20% to 25% for T2 cancers [5–9]. However, when lesions with unfavorable histology are excluded (poor differentiation, lymphovascular, and perineural invasion), these rates drop significantly (T1, 2.2–6%; T2, 11%) [5, 7]. The National Comprehensive Cancer Network rectal cancer guidelines state that patients with mobile, well to moderately differentiated, cT1N0 lesions that are less than 3 cm in diameter with no lymphovascular or perineural invasion are appropriate candidates for local excision. Lesions larger than 3 cm may also be eligible for local excision depending on risk of postoperative rectal lumen stenosis. Although current recommendations suggest that lesions that demonstrate invasion deeper than the first third of the submucosa (i.e., sm2/3) are at higher risk of lymph node metastases, recent literature suggests that sm2 tumors with favorable histology have rates of lymph node metastasis similar to sm1 [5–7, 9].

Strict adherence to these criteria may result in equivalent oncologic outcomes for local excision of malignant neoplasia, when compared to radical surgery. An analysis of the Surveillance, Epidemiology, and End Results database reported that comparable cancer-specific survival between local excision and transabdominal resection [10] and a meta-analysis comparing TEM local excision and radical surgery for T1 rectal cancer also demonstrated equivalent 5-year overall survival [2, 11]. Additionally, patients must be informed that a final pathological analysis may yield high-risk factors and warrant additional radical surgery.

Patients with T1 sm3 or T2 tumors who are considered high risk for radical surgery or patients with tumors that would result in a permanent stoma may consider local excision, albeit with informed discussion over the increased risk of local and mesorectal recurrence, in the context of current guidelines and patient desired outcomes [5, 6]. Treatment of these tumors should be discussed in a multidisciplinary setting, par-

ticularly regarding any benefit to adjuvant chemoradiation therapy.

Patients with T3 tumors with a response to neoadjuvant therapy can, in select instances, be considered for local excision – however, the authors caution that complete pathologic response in the primary tumor does not imply complete nodal response. T3 tumors frequently have nodal metastasis (40–50%) and may have positive nodes despite a complete pathologic response in the primary tumor [5, 12]. Therefore, we do not recommend local excision in these cases unless the patient cannot tolerate radical surgery. There are no specific contraindications for TAMIS local excision other than those outlined above.

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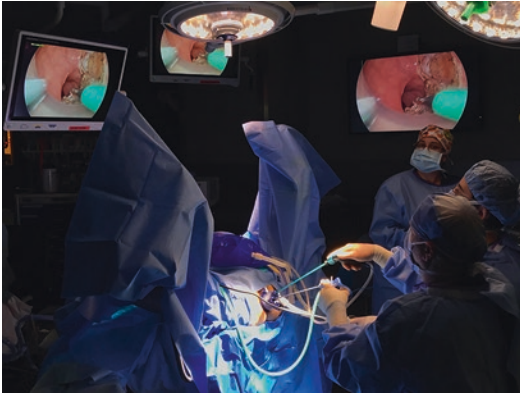
## Operative Technique

### Preparation and Positioning

Mechanical bowel preparation is essential in TAMIS as a clear field of view is required to operate endoluminally. A simple enema preparation is often sufficient. In the setting of a poor preparation, high-volume irrigation utilizing a rigid proctoscope can easily be performed. Patients with mid-rectal or higher, especially anterior lesions, should undergo complete mechanical bowel preparation to minimize contamination in case of peritoneal entry. Current evidence supports the use of oral antibiotics in addition to a mechanical bowel preparation in patients undergoing a large bowel anastomosis for reduction in wound-related complications; however its effect in transanal surgery is unclear.

Surgical site infection and thromboprophylaxis are given within 30 minutes of surgery in accordance with guidelines for colonic surgery. Foley catheterization is optional as urinary retention is rare.

Patients can be placed in lithotomy position regardless of lesion position within the rectal lumen. The main operative monitor is placed at the head of the operative bed, and both surgeon and assistant are seated between the legs of the patient (Fig. 9.1).



**Fig. 9.1** Intraoperative setup for TAMIS showing patient in lithotomy, surgeon and assistant operating position, and the placement of the monitor

### TAMIS Equipment and Setup

Basic laparoscopic instruments (including graspers, monopolar cautery, and needle drivers) can be used and are all that is required to perform TAMIS local excision of neoplasia. A 5 mm angled (30–45 degree) scope is preferable as it offsets the operating surgeon's hands and minimizes instrument collision as well as displays a more circumferential view of the rectum compared to a non-angled camera lens. An angled camera lens also facilitates assessment of the lateral and proximal margins and can improve visualization around the angulations of the rectal valves. Simple monopolar cautery, as well as energy devices, can all be utilized for dissection and hemostasis. Monopolar cautery is preferable, providing greater precision, and is more cost-effective than alternatives such as vessel sealers and harmonic scalpels. A suction device is most commonly used to facilitate smoke evacuation, in addition to controlling minor bleeding or removal of fecal contents. Combined suction and monopolar devices designed for TAMIS are highly beneficial in providing both functions.

Following a perianal block and dilatation of the anal canal, the access port is inserted and secured, and the gel cap (which contains three cannulas) is placed (Fig. 9.2). Pneumorectum is created with carbon dioxide insufflation kept at 15–18 mmHg and can be increased up to 20 mm Hg if required. Next-generation insufflators,



**Fig. 9.2** GelPOINT path with cap and trocars - FDA-approved platform designed specifically for TAMIS and other transanal applications

including AirSeal® insufflation system (ConMed, Inc., Utica, NY, USA) and Stryker PneumoClear with TAMIS mode (Stryker Endoscopy, San Jose, CA, USA), have dramatically improved the stability of pneumorectum. The development of an insufflation stabilization bag (ISB) used in conjunction with the GelPOINT path provides a cost-effective alternative to newer insufflators [13]. Traditional laparoscopic instruments are then introduced through the TAMIS port for dissection.

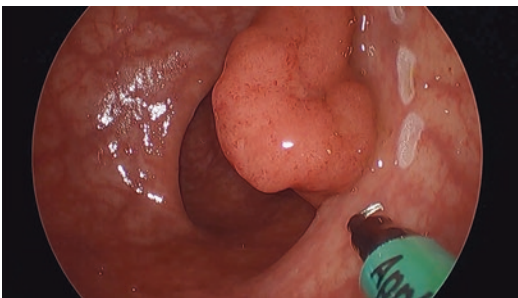
### Lesion Assessment and Excision Level

Complete assessment of the tumor is performed with any bleeding from port insertion trauma gently irrigated. Precise extension of the lesion, especially in large carpeting adenomas, is easily assessed with a high-definition laparoscope. A quality excision, defined as a non-fragmented, full-thickness, margin negative tumor resection, is mandatory for the treatment of early rectal cancer by local excision regardless of the technique used. However, for benign neoplasia, a submuco-

sal (partial-thickness) excision is an alternative as full-thickness excision is not necessary in this setting. This is particularly important for proximal, proven benign anterior lesions, as the risk of peritoneal entry is minimized by this approach. Furthermore, for large, flat carpeted benign lesions (classically, tubulovillous adenomas) whereby the defect after excision is too large to reapproximate, a planned partial-thickness excision is a good option. It should be stressed that partial-thickness excision is never considered an option for polyps suspected to harbor a cancer based on staging or endoscopic assessment and lesion morphology.

### Technique for Local Excision

The procedure begins by defining the excision perimeter of the lesion with at least a 1 cm margin circumferentially using electrocautery (Fig. 9.3). For malignant lesions, a full-thickness division of the rectal wall distal to the lesion is then performed, which allows manipulation of the specimen without directly contacting the tumor. Perpendicular division through the entire rectal wall until the mesorectal fat is encountered is critical to achieving a complete specimen when the lesion is known or suspected to be invasive (Fig. 9.4). During excision and manipulation, the specimen must be grasped on the edge of normal mucosa or underneath the lesion on the mesorectal fat to minimize fragmentation of the tissue and tumor. It should be noted that many rectal lesions are extremely friable and



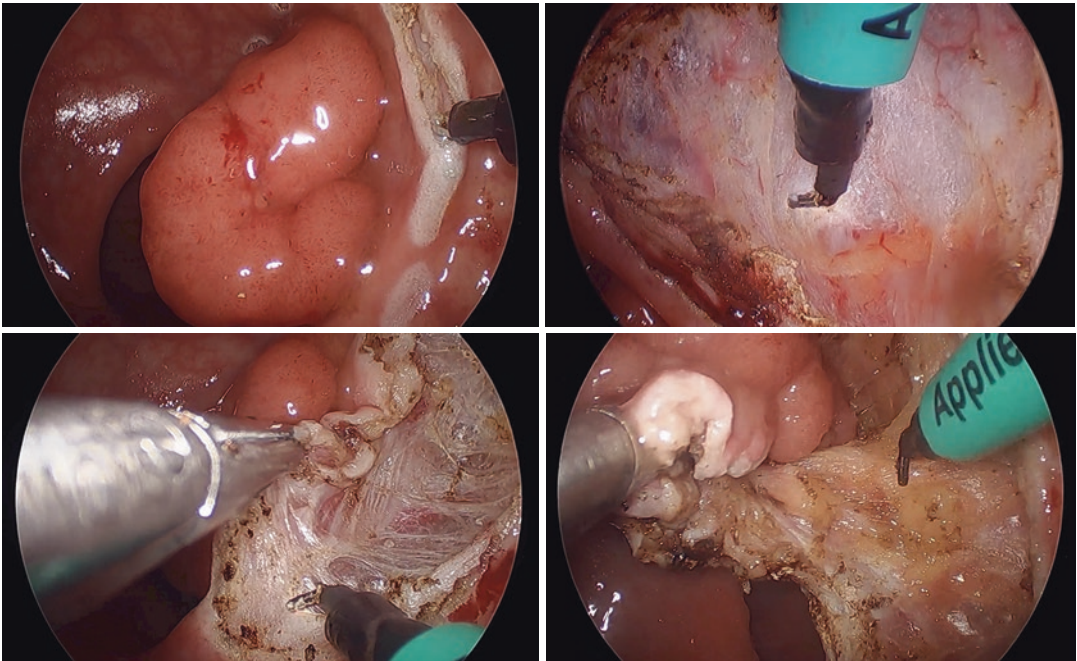
**Fig. 9.3** Lesion excision margin being delineated during TAMIS local excision. Monopolar cautery device is used to score the rectal mucosa with a 1 cm circumferential margin

exhibit tumor shedding with even minor instrument manipulation; this can theoretically result in the implantation of live tumor cells within resection bed. Although controversial, some surgeons advocate en bloc removal of mesorectal fat beneath the lesion to retrieve lymph nodes, especially when the lesion is located posteriorly in the rectum. No literature supporting the superiority of this technique exists, although theoretically the sampling of positive or negative juxtaposed mesorectal lymph nodes potentially may significantly alter treatment recommendations when the node is found to be positive. This notion is supported by several small studies of sentinel lymph node biopsy in rectal cancer. The dye-containing nodes are typically near the primary tumor. Care must be taken to avoid breaching the mesorectal fascial envelope to minimize disruption of the anatomic planes should proctectomy become necessary [14].

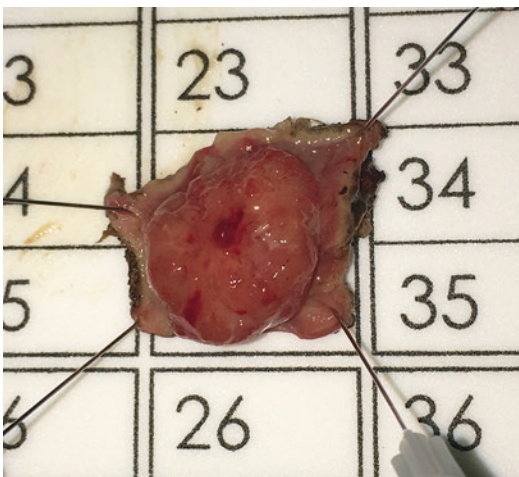
### Anterior Lesions and Peritoneal Entry

Anterior lesions are still best accessed in the lithotomy position, in contrast to conventional transanal excision or TEM where the prone jack-knife position is necessary. Careful attention must be given for anterior lesions, as there is a risk of prostate or vagina injury, and this dissection can be quite challenging since the anterior mesorectum is much thinner than it is posteriorly. Anterior organ injury was described in the early literature of TEM in the 1980s; however, it has not been reported in any series on TAMIS. Familiarity with the anatomical planes and surrounding critical structures is important. Peritoneal entry is an uncommon event, occurring in up to 4% of patients with anterior tumors located in the mid- and upper rectum. If this occurs, mandatory closure of the rectal wall is performed by first closing the peritoneum and then the rectal wall. Transient loss of pneumorectum may occur but is re-established following peritoneal closure. Rarely, laparoscopic access is required to cleanse the pelvis, facilitate wall closure, or perform a leak test. Informed consent in patients at risk of peritoneal entry should be obtained prior to surgery and the operating room prepared accordingly.





**Fig. 9.4** Full-thickness excision. Note the mesorectal fat underneath the lesion, signifying that the entire rectal wall has been transected



**Fig. 9.5** Specimen removed by TAMIS is pinned and oriented

Following resection, the specimen should be immediately retrieved and oriented (Fig. 9.5). It should be pinned out and sent to the pathologist as a fresh, non-preserved specimen to facilitate improved margin evaluation. A positive margin for rectal cancer should be re-excised or con-

verted to formal radical surgery. For benign disease, margin positivity does not guarantee recurrence, and these patients can be followed with routine proctoscopy. Small, benign recurrent polyps can be removed with snare polypectomy or other endoscopic means as long as these patients are enrolled in a surveillance program post TAMIS excision.

### Managing the Ultralow Rectal Lesion

Lesions that are located within 3 cm of the anal verge may be difficult to fully access by TAMIS due to the length of operating port (37 to 44 mm in length), which may obscure the distal extent of the lesion. For these cases, a hybrid approach in which dissection of the distal-most aspect is begun transanally is used. Once the distal dissection is completed, then the TAMIS port can be introduced to complete the majority of the dissection. This approach allows for the advantages of the advanced endoscopic platforms to be applied for lesions that would otherwise be at high risk of R1 resection and fragmentation by conventional transanal excision.

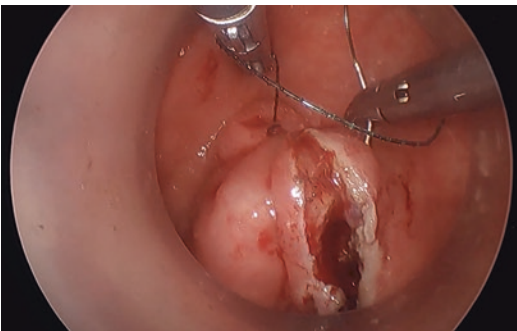


## Management of Defects After

### Local Excision

Following TAMIS local excision, it is our practice to irrigate the defect with betadine to minimize bacteria and tumor contamination. Rectal wall closure is then performed; full-thickness defects are reapproximated transversely with interrupted or continuous suturing to avoid narrowing the lumen. The pneumorectum is decreased to 7–8 mmHg to reduce tension on the suture lines. A running closure beginning in the lateral portion of the incision can be achieved but is technically more challenging. The use of a V-Loc™ suture (Covidien, Mansfield, MA) or other commercially available types of self-locking, barbed absorbable suture can expedite continuous closure by maintaining tension and negating the need for endoluminal knot tying (Fig. 9.6). Conversely, closure can be performed in an interrupted fashion with knot tying facilitated by laparoscopic knot pushers. In some cases, automated suturing devices – such as the combination RD180/TK device (LSI Solutions, Victor, NY) or the Endo Stitch™ suturing device (Medtronic, Minneapolis, MN) – can be utilized to expedite the closure process but may not be available, and such devices increase per-case costs as well.

Alternatively, defects which do not violate the peritoneum can be left to heal with expectation of a minimal scar within 4–6 weeks and few complications. Hahnloser et al. reported outcomes from 75 TAMIS excisions performed at three centers and found no difference in complications



**Fig. 9.6** Rectal wall defect being closed using continuous V-Loc suture

between closed defects and those that were left open [15]. A rigid or flexible sigmoidoscope can be used to assess luminal diameter and patency, if a concern about narrowing has been raised.

## Conclusions

TAMIS relies on fundamental minimally invasive surgical skill and equipment. With proper TAMIS technique and for carefully selected patients, high-quality local excision of rectal neoplasia is a valid option with low morbidity that maintains the advantages of organ preservation.

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# Pyramidal Excision for Early Rectal Cancer and Special Closure Techniques

# 10

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and Emanuele Lezoche

No other topic in general and colorectal surgery has had similar dramatic changes such as the therapy of low rectal cancer in the last two decades. The changes are not only related to the new minimally invasive technologies but also to the doctrinal acceptance that more aggressive surgery does not necessarily translate into improved oncologic results applicable to all stages rectal cancer. In other words, the same revolution that occurred in the 1980s for breast cancer is now in progress within the community of colorectal surgeons. *pyramidal excision* (PE) of rectal tumors is the counterpart of the “lumpectomy” for breast cancer. The partial removal of the rectum obtained by PE has relevant advantages when compared to TME in terms of postoperative morbidity, mortality, and functional sequelae.

Comparing PE with conventional *local excision* (LE), the main benefit is represented by the possibility of examining the locoregional nodes in order to arrive at a more accurate tumor stage. In this regard, it is useful to emphasize that for rectal cancer (in the literature), there is no evidence of metastatic skip lesions in lymphatic nodes. This observation has been noted in the

case of histologically high-risk tumors, which are not eligible for PE or other local procedures.

Furthermore, the full-thickness LE, which is the most frequent operation reported in TEM & TAMIS literature, does not permit examination of the locoregional lymphatic stations. On the contrary, PE performed by TEM/TAMIS allows one to remove the locoregional nodes, and for these reasons we have termed this *endoluminal locoregional resection* (ELRR). In fact, the rationale of this operation is to remove (en bloc) the lesion and all the surrounding tissue, performing a wide round incision including a minimum of 1 cm of normal mucosa. Radially, the rectal wall and the mesorectum are excised to the level of the “holy plane,” in order to obtain a surgical specimen in the shape of a pyramid, whose base is very large and composed by the mesorectal fascia (i.e., the circumferential deep diameter is greater than the mucosal resection diameter).

Analyzing the papers that report the clinical results of LE, it has been observed that in absence of an internationally accepted definition, in the majority of cases, the employed surgical technique is not sufficiently described. Therefore, the different results reported in terms of local recurrences can also be related to the different techniques applied towards LE. It is hoped that Scientific Societies organize a Consensus Conference to define the terminology of the different local operations that can be performed to treat rectal lesions through traditional surgery

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and TEM/TAMIS. Proper nomenclature is often not properly used, and this is clarified in the following section.

### Nomenclature: Excision versus Resection

The majority of medical terminology originates from ancient Greek and Latin. A paradigmatic example of misunderstanding semantics is the operation described by Prof. RJ “Bill” Heald in 1982, termed total mesorectal ‘excision’ (TME). Nowadays, the term TME is universally accepted despite the fact that it is a *contradiction in terms*: in fact “excidere” comes from the Latin language and is the union of two terms “ex” and “cidere.” The term “ex” has implicit the concept of *a part of the whole* and “cidere” to cut. Consequently, the correct meaning of “excidere” is *to remove a part of the whole*. Therefore, in coining the name “total mesorectal excision,” Bill Heald utilized conflicting terms that conveyed a meaning that is quite opposite to the message intended.

On the other hand, the term “resection” draws its origin from another Latin word that likewise represents the synthesis of two different words: “re” and “secare.” “Re” plays the role of strengthening the term “secare,” which means to cut, with the final meaning of *to take*

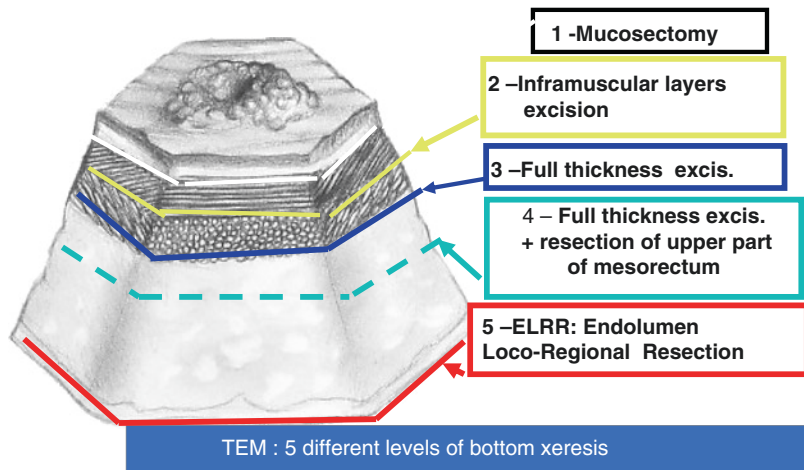
*out the whole*. Consequently the term “total mesorectal *resection*” (and its acronym “TMR”) seems to be more appropriate instead of “total mesorectal *excision*” or TME.

Another matter of lexical confusion is the term “local excision,” as in the majority of published research does not specify which extension (depth) of tissue has been removed. To define the spatial model of the “LE” dissection, several items should be characterized, as follows: (a) the modality to assess tumor-free margins, (b) width of free mucosa included in the circumferential excisional margin, (c) depth of incision, (d) angle (or degree) of the lateral margin with respect to the mucosal surface, (e) depth of basal dissection, as well as other factors. These data are important elements to evaluate the amplitude and quality of dissection.

Utilizing either TEM or TAMIS, it is possible to follow five different levels of dissection as shown in Fig. 10.1 and as delineated below:

- A. *Submucosal dissection*. This has the advantage of removing “en bloc” the specimen without violating the entire bowel wall and is considered acceptable for benign neoplasia, especially large sessile polyps which are more difficult to excise endoscopically.
- B. *Infra-muscle layer dissection*. This procedure requires high surgeon dexterity. Usually it is performed only to remove large benign

**Fig. 10.1** Five different levels of excision possible with TEM or TAMIS



polyps of the upper part of the rectum to avoid intraperitoneal entry. Furthermore, in case of flat degenerative polyps, it allows the morphologist to analyze cancer cell penetration into the submucosa space without thermal artefacts.

- C. *Full-thickness rectal wall excision.* In this technique, generally employed from the majority of the authors and too often is defined erroneously as a TEM procedure, the entire rectal wall is excised circumferentially including the neoplasm, with a typically recommended 1 cm minimal radial margin (mucosal margin).
- D. *Full-thickness rectal wall removal combined with the resection of the upper part of the mesorectum.* This follows the principles of full-thickness local excision but also includes a small portion of mesorectum underlying the rectal wall.
- E. *Full-thickness rectal wall resection combined with resection of all the mesorectum adjacent to the tumor.* In this case the resection reaches the lower level of the mesorectum, and the base dissection is performed following the so-called holy plane, that is, a pyramidal local excision.

The possibility for the surgeon to choose so many different levels of deep dissection during the TEM (or TAMIS) procedure makes clear that expressions, such as “the patient underwent TEM,” are simply an insufficient descriptor. Depth of excision, as well as the status of the radial margins (including minimum distance of normal mucosa to involved edge of tumor), should be, but is not always, routinely described. This is a likely factor contributing to the wide variability among series when describing local recurrence rates [1].

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## Rationale of Pyramidal Excision

Pyramidal excision (PE) is a *full-thickness rectal wall resection combined with resection of all the mesorectum adjacent to the tumor* and is synonymous with *endoluminal locoregional resection*

(ELRR). With this approach, the excised specimen resembles the shape of a pyramid. When Gerard Buess, in the 1980s, introduced TEM into clinical practice, the operation that he proposed was a mucosectomy, or a partial-thickness excision of a portion of the rectal wall. During the early 1990s, Buess subsequently adopted the technique of ELRR.

It is intuitive that by removing a larger amount of lymphatic tissue juxtaposed to the tumor, the risk of local recurrence could be reduced. While this is fundamental to the principles of en bloc radical resection, whereby tumor resection is predicated upon the vascular supply and draining lymph node basin. The same concept of “removing more” is probably also applicable for early-stage (T1) rectal cancers.

The assessment of tumor diffusion depth into submucosa (Kikuchi Classification, sm1–sm3) on the biopsies performed with flexible endoscopy is not usually reliable. At the same time, literature clearly demonstrated that sm1 lesions have a risk of nodal metastasis up to 3%; sm2 have a risk of 5–8%; and sm3 have a risk of  $\geq 25\%$ . Thus T1sm3 nodal metastatic risk is similar to that of T2 tumors [2]. Interestingly, T1sm3 tumors represent more than 40% of all cases [3].

The data and concepts presented thus far can be surmised in the following key points:

- Full-thickness excision alone (without pyramidal excision) is likely an *inadequate therapy* in the majority of T1 rectal cancer, except for very well-selected, histologically favorable lesions.
- It is very important to perform multiple macrobiopsies to assess preoperatively tumor depth particularly to characterize T1 submucosal penetration.
- As a significant fraction of T1 rectal cancers have a similar risk of lymphatic involvement as T2 cancers, it is not appropriate to treat T1 lesions (e.g., T1sm3) differently than T2 staged cancers. For these lesions, standard full-thickness local excision alone, in the authors’ opinion, is insufficient and is more likely to result in treatment failure than pyramidal excision.

The inadequacy of conventional full-thickness local excision for T1 cancers is clearly demonstrated by available data. In fact, the percentages of recurrence in pT1 patients reported by three institutions are significantly different. However, despite the utilization of advanced instrumentation (TEM), the operations performed in each institution are heterogeneous, as illustrated in Fig. 10.2. The Dutch group [4] examined 88 pT1 treated with full-thickness local excision and reported an unacceptably high recurrence rate of 20.5%. Comparatively, other investigators [5] who performed full-thickness excision combined with the resection of the upper part of the mesorectum reported percentages of local recurrences that were significantly lower – approximately 12% – for 86 patients who underwent transanal local excision for pT1 rectal cancer.

In our experience, ELRR utilizing the TEM apparatus was successfully performed on 270 patients with pT1 rectal cancer. On follow-up, the local recurrence rate measured less than 3%.

The literature reports that administration of neoadjuvant treatment (NT) reduces the risk of local recurrence and probably increases survival rate. According to the Dutch Trial (CKVO

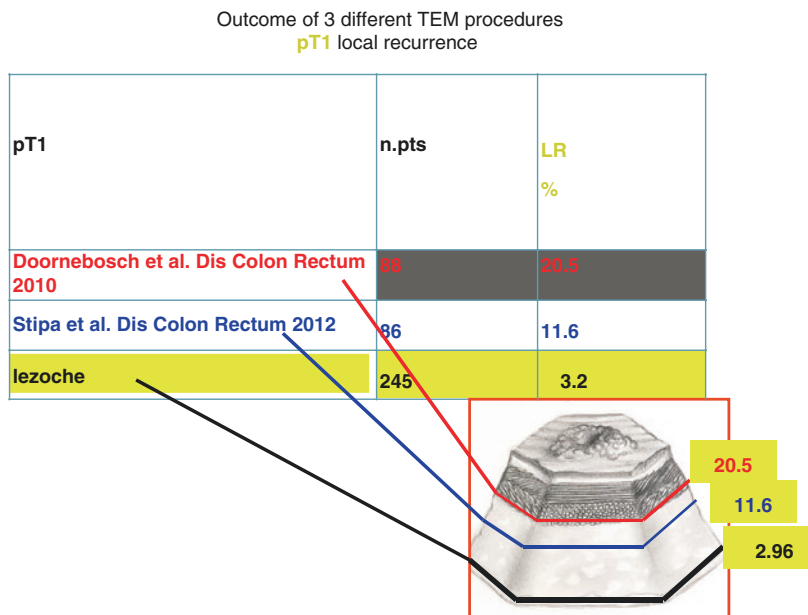
95–04), radiotherapy reduces the percentage of local recurrences by one-half (from 11.4 to 5.8%). These positive results combined with the observation that after NT, the number of lymph nodes detectable in the mesorectum is significantly lower when compared with untreated patients – suggesting that NT can also sterilize metastatic lymphatic nodes.

Furthermore, NT has the advantage that it can significantly shrink the tumor mass, making local excision more feasible; for this reason, standard long-course radiotherapy is preferable to short-course XRT that is less effective in tumor mass reduction.

On the bases of these clinical observations, a protocol to treat small (diameter <3) iT2N0M0 rectal cancer performing ELRR after completion of long-course therapy with 50.4 GY (1cNT) was developed.

With encouraging clinical results as well as confirmatory 5-year follow-up data, our center developed a protocol for a prospective randomized trial on T2 rectal cancer, entitled the “Urbino Trial” – named after the renaissance city where the meeting to design this protocol was held. The results of the Urbino Trial are detailed in the last section of this chapter.

**Fig. 10.2** Markedly different rates of local recurrence, based on three different levels of local excision performed using an advanced transanal platform





## Patient Selection

Patient selection is fundamental. Although discussed elsewhere in this textbook, the protocol followed at our center is briefly delineated.

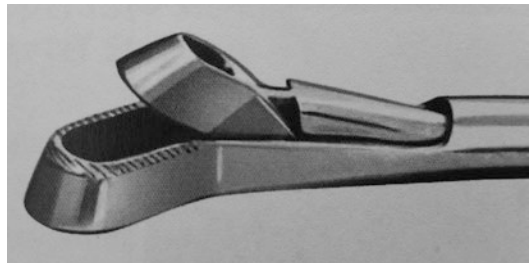
## Index Staging (Pre-NT)

- *Digital rectal examination (DRE).* The fixity and the distance of the tumor margin from the anal ring must be registered and documented by DRE. Sphincter tone must be carefully assessed, and if indicated, formal pelvic floor testing, including manometry, should be performed to determine baseline function.
- *Flexible endoscopy and biopsy.* It is advisable to use dye to identify tumor limits especially for flat lesions or adenomas with ambiguous margins. In our protocol it is always mandatory to take 5–6 biopsies, circumferential to the tumor at 1 cm distance from the lesion's perimeter, on what appears to be normal, native rectal mucosa. Every biopsy must be identified by a number corresponding the anatomic position and sent to pathology for careful histologic examination. The rationale for this is to exclude or confirm the presence of malignant histology.
- *Tattooing.* We consider it *mandatory* to perform tattooing at each biopsy site in order to reduce the risk of an incomplete excision of the lesion during ELRR. The excision line must include all the tattoo spots to avoid this and to assure tumor-free margins. Surprisingly, incomplete local excisions are not infrequently reported and measure as high as 22% in some series [1]. In this regard, it is crucial to understand that after NT, the tumor borders are generally not clearly identifiable. Furthermore, when the tumor is downsized from the effect of NT, clusters of neoplastic cells can still be identified in the area where the cancer was present prior to treatment-induced regression. The meaning and the evolution of these persistent neoplastic cell clusters remain elusive; therefore prudentially,

in our protocol, *we consider it mandatory to remove all the area where the neoplasia was located prior to NT.*

- *Rigid rectoscopy* is extremely useful in identifying circumferential tumor location (i.e., anterior vs. posterior, right or left lateral) and consequently the appropriate patient position on the operative table, which is relevant for the rigid TEM scope (with the TAMIS technique, patients can be positioned dorsal lithotomy for the vast majority of lesions, but information from rigid proctoscopy is still invaluable).
- *Macro-biopsies.* Utilizing the rigid rectosigmoidoscope, it is possible to perform macro-biopsies using the conventional forceps (Fig.10.3) that can remove a substantial amount of tissue, allowing pathologists to better assess the histological tumor grade and, in case of T1 cancers, a correct sm depth assessment which is critical to determining the optimal therapeutic strategy.
- *Imaging. Advancements in magnetic resonance imaging (MRI) including* stronger magnets (3-Tesla), diffusion-weighted imaging, and new MRI-compatible contrast agents have significantly improved the diagnosis of metastatic nodes (N) and the more precise tumor (T) stage. It is our preference to perform rectal protocol MRI for all stages of rectal cancer.

*Endorectal ultrasound (EUS)* is useful to differentiate T1 vs. T2 but is unable to evaluate the submucosal infiltration despite the remarkable technological improvement of 3D ultrasound instrumentation. Therefore, macro-biopsies



**Fig. 10.3** Conventional forceps for “macro-biopsies”

remain the preferred method to evaluate submucosal infiltration. Furthermore, surgeons who perform EUS have the advantage of acquiring in their mind the virtual spatial reconstruction of the lesion with its anatomic location, extension, and limits. All this allows one to perform a surgical dissection following optimal plans to obtain a pyramidal shaped specimen containing the tumor, with equidistant free margins.

**PET-CT.** This imaging modality has no proven diagnostic value for the staging of rectal cancer. When performed after ELRR, it may result in false positive results, which can be caused by the long process of healing required for some large defects created during the process of pyramidal excision. Therefore, when PET-CT is used, it is recommended to not be performed prior to 9 months post-ELRR.

- **Anal Sphincter Manometry.** Preoperative assessment of sphincter function is advisable in patients with low-lying rectal cancer, in all elderly subjects, and/or in patients with reduced sphincter tone.
- **Quality of Life Forms.** All patients should complete a specific quality of life (QoF) forms (C39 and C38): upon diagnosis and prior to surgical intervention; the assessment is ideally completed at 6, 12, and 24 months after ELRR.

### Neoadjuvant Therapy (NT)

NT is generally considered mandatory for advanced tumors. However, in recent years the realization that early T-stage rectal cancer (e.g., T1sm3 and T2) can harbor occult metastatic nodes has improved our understanding of the possible effect of full-dose NT (fdNT) in treating the draining lymph node basins. Coupled with the favorable clinical results observed with ELRR for such lesions, the addition of fdNT for non-advanced, select rectal cancer has provided improved cure rates.

At our center, the preferential surgical option for treating early-stage rectal cancer is

by utilizing a local procedure (namely PE) rather than radical resection for several reasons. First, TME, even with the advent of less invasive (laparoscopic/robotic) techniques, maintains the same risk of morbidity and mortality unmodified from open techniques. Second, postoperative urinary, sexual, and bowel dysfunctions are very high (Fig. 10.4). Last but not least, quality of life is strongly compromised by stoma creation (even when constructed for temporary fecal stream diversion). In Mediterranean countries, patients (and their treating surgeons) generally try to avoid stomas, even if it is temporary. This is particularly important for specific cultures and locales [6] Fig. 10.5.

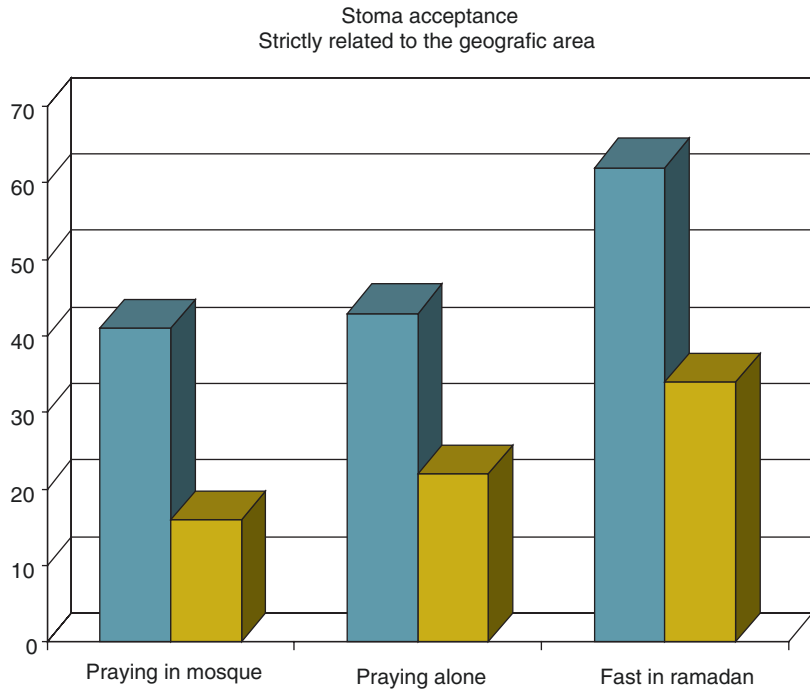
For these reasons, in the past decades, many surgeons, to avoid the postoperative risk of TME, have preferred to perform unstandardized local excision despite the disappointing high percentage of local recurrence. According to the data from the US National Cancer Database (NCDB), the local excision rate from the 1990s to the beginning of this century doubled for T1 and tripled for T2, as shown in Fig. 10.6.

Combining conventional LE with NT does not significantly increase the clinical results in terms of local recurrences (Fig. 10.7) and prob-

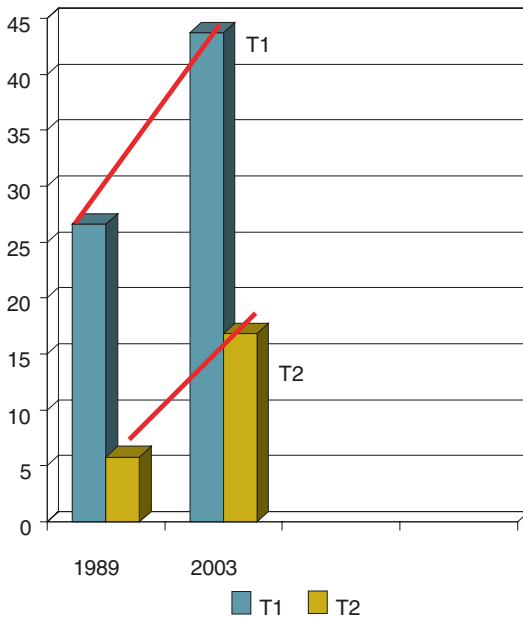
<b>TME : Morbidity &amp; Mortality</b>	
• <b>Morbidity</b>	<b>20–30%</b>
• <b>Mortality</b>	<b>2–5%</b>
<b>in high risk pts ~ 10%</b>	
• <b>Local recurrence</b>	<b>5–15%</b>
• <b>Metastatic disease</b>	<b>&gt; 30%</b>
<b>Functional sequelae</b>	
• <b>Urinary dysfunctions</b>	<b>10%</b>
• <b>Sexual dysfunctions</b>	<b>13–70%</b>
• <b>Anastomotic leaks</b>	<b>5–17%</b>
• <b>Definitive colostomy</b>	<b>10–15%</b>
• <b>Temporary oostomy</b>	<b>20–100%</b>
<i>(Data from literature)</i>	

**Fig. 10.4** Morbidity, mortality, and functional sequelae of TME according to the data from literature

**Fig. 10.5** The stoma acceptance is strictly related to the geographic area. In Mediterranean countries, it is not infrequent that patient refuses operation for the risk of stoma. (Kuzu et al. [6]. <https://link.springer.com/article/10.1007/s10350-004-6425-4>. Data only)



USA NATIONAL CANCER DATA BASE  
1989-2003 Local Excision rate for Rectal Cancer  
(sample 2124 pts: L.E. 765)



**Fig. 10.6** Number of local excision performed in the USA in 1989 and 2003 for T1 and T2 rectal cancer

Local recurrence rate after transanal excision  
(Surgery + Pre/PostOp. Adjuvant Therapy)

	N.	Loc. Rec.
Benoist et al. 1998	30	13
Baron et al. 1995	91	21
Read et al.1995	22	9.1
Willet et al. 1994	46	18
Rounet et al. 1993	18	11
Bailey et al. 1992	53	8
DeCosse et al. 1989	57	NS

**Fig. 10.7** Combining conventional, full-thickness LE with NT does not significantly increase local recurrences

ably survival rate. These data are another indication that the clinical results of local treatment depend on complete tumor excision with negative margins (R0) and, in addition, the complete removal of the lymphatic tissue surrounding the segment of bowel containing the neoplasm.

## Patients' Eligibility for ELRR (Pyramidal Local Excision)

### Basic Exclusion Criteria

1. Histologically high-risk tumors (undifferentiated and mucous histology).
2. Tumors with highly suspicious metastatic lymph nodes (identified on imaging before initiation of NT).
3. Tumors with lymphatic, neuronal, and vessel infiltration (not responsive to NT).
4. T4 cancers.
5. T2 and T3 cancers which are not responsive to NT.

### cT1

#### *cT1 Inclusion Criteria:*

- *sm1 and sm2*: without histological high-risk features,
- Rectal Protocol MRI negative nodes, diameter <5 mm, iso-echogenic, with smooth, regular shape.
- Located in the extraperitoneal rectum.
- *cT1sm3*, treated with NT.

#### *cT1 Exclusion Criteria:*

- *sm3*, in patients refusing NT,
- Tumor located mainly in the intraperitoneal rectum.
- Mucinous or undifferentiated cancer.
- Patient refusing close follow-up and informed consent.
- Imaging suspicious for nodal disease.

### cT2

#### *cT2 Inclusion Criteria:*

- Patients who completed NT with a good response (downstaged >50%).
- Tumor diameter <4 cm.
- Tumor located in the extraperitoneal rectum.
- MR- and CT-negative nodes (<5 mm, iso-echogenic, non-spiculated appearance).
- Tumor is non-fixed (mobile on palpation).
- Patient accepting close follow-up and informed consent.

#### *cT2 Exclusion Criteria:*

- Non-responders to NT: Tumor mass reduction <50%.
- High undifferentiated or mucous rectal cancer.
- Tumor diameter >4 cm after NT.
- Tumor located in the intraperitoneal rectum.
- MR and CT imaging suspicious nodes (>5 mm, not iso-echogenic, irregular shape) after NT.
- Tumor is fixed (nonmobile by palpation).
- Patient refuses to accept a program of close follow-up and informed consent.

### cT3

#### *cT3 Inclusion Criteria:*

- High-risk patients: age over 80 yo, comorbid conditions (ASA 3 or 4), and/or patients who refuse permanent or temporary stoma.
- Patients who underwent NT with good response (downstaged >50%).
- Tumor diameter <4 cm.
- Tumor located in the extraperitoneal rectum.
- MR- and CT-negative nodes (<5 mm, iso-echogenic, regular shape).
- Tumor is non-fixed (mobile on palpation).
- Patient accepting close follow-up and informed consent.

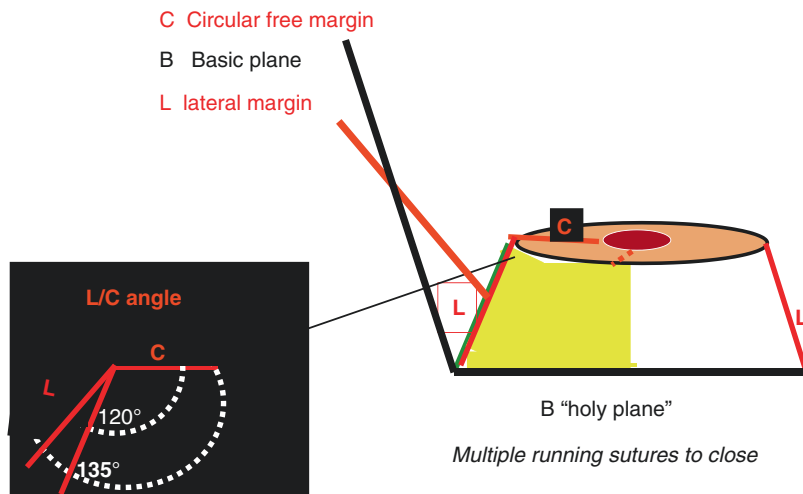
#### *cT3 Exclusion Criteria:*

- Non-responders to NT: Tumor mass reduction <50%.
- High undifferentiated or mucinous rectal cancer.
- Tumor diameter >4 cm.
- Tumor located in the intraperitoneal rectum.
- MR and CT imaging reveal suspicious nodes (>5 mm, not iso-echogenic, irregular shape) after NT.
- Tumor is fixed.
- Patient refuses to accept a program of close follow-up and informed consent.

### Informed Consent

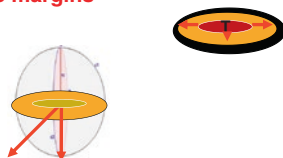
The informed consent form will include all the possible options possible in relation to the

**Fig. 10.8** Geometric model to standardize endoluminal locoregional resection (ELRR)



...Extent of circular free margins

- Radial margins geometric model



- Amount of removed tissue (cc)
- Identification of residual lymphatic tissue (NUCLEOTIDE-GUIDED MESORECTAL EXCISION)

**Fig. 10.9** Criteria to standardize endoluminal locoregional resection (ELRR)

patient general conditions. Patients who undergo ELRR must agree to be enrolled into a strict follow-up program.

**Anesthesia**

General anesthesia is not mandatory for TEM/TAMIS procedures, when the lesion is located in the posterior circumference of the rectum and the procedure is presumably short.

**Pyramidal Excision or ELRR**

To perform this type of operation, it is necessary that the surgeon be skilled in TEM or TAMIS. Before

attempting ELRR, it is advisable to have performed at least 50 standard full-thickness excisions and have gained experience in TEM or TAMIS suturing. Furthermore, an appropriate background in open and laparoscopic rectal surgery is required.

**Surgical Dissection**

As in every surgical procedure, it is strongly recommended to standardize the ELRR technique. To this purpose, as in TME, we have considered the following parameters:

1. Extent of circular free margins (indicated as C in Fig. 10.8).
2. Extent of radial free margins.
3. To be sure that all the lymphatic structure, which drains the tumor, has been removed, the bottom dissection must follow as in traditional surgery the “holy plane” (indicated as B in Fig. 10.9).
4. The lymphatic drainage of the tumor has a pyramid shape, and the tip is represented by the first locoregional lymphatic station, and for a correct tumor staging, it is mandatory to remove this station. As already mentioned, lymphatic metastasis of rectal cancer do not present skip phenomena. To be sure that the specimen includes this station,

it is mandatory to enlarge laterally the margin of the resection following an obtuse angle of at least 135°. We call this angle L/C – where C is the plane of the mucosal circular free margin and L is the lateral margin of the dissection (see Fig. 10.9).

5. It is very important to remove as much mesorectal tissue as possible to include a high number of excised/sampled lymph nodes.
6. We register the volume of the removed specimen in cubic centimeters (cc).
7. To prove that all the nodal tributaries of the tumor have been removed, we have developed a modified sentinel node technique that is routinely used for assessment, which is termed “nucleotide-guided mesorectal excision” (which will be discussed in a later section).

*Note: The description of the following steps are indicated for a right-handed surgeon.*

### **Posterior Lesions (Patient Supine)**

- In case of posterior lesions, if the tumor is very close to the anal ring, it is preferable to start the full-thickness dissection of the rectal wall from the 6–7 o’clock to 3 o’clock position, making a transverse circular incision 1 cm from the margin of the neoplasia. The mucosa and the muscle layer are cut with the TEM Wolf scalpel.
- Once the mucosal and muscular layers have been transected, the avascular plane between the mesorectal fascia and the endopelvic fascia can quite easily be established.
- If the neoplasia is very close to the sphincter, a limited resection of the internal sphincter muscle can also be done, leaving those fibers attached to the specimen that will be removed en bloc.
- The further preparation of the mesorectal fascia is performed by smooth dissection following the avascular holy plane.
- A large dissection of the holy plane is performed widely exceeding the limit of the neoplasia.
- Next, the circular incision of mucosa and muscles around the tumor is completed at 360°, including 1 cm of free margin.
- At this point the mesorectum is widely mobilized and pulled caudally; the division of the mesorectum is performed following an obtuse angle (Fig. 10.8), circumferentially.
- Upon completion, the specimen takes on the characteristic shape of a pyramid.
- The specimen volume is estimated by placing it into a graduated cylinder.
- Then, the specimen is fixed onto a cork pad with pins – taking care to orient the lesion.
- The surgeon should then wash carefully the operative field and the defect with a continuous lavage of saline containing diluted Betadine for 5 minutes before starting the suture closure of the defect. This step is important to remove any exfoliated tumor cells.
- The distal rim of the defect should be assessed to assure it is well mobilized; if not, the surgeon should extend cranially and laterally the dissection.
- The proximal and distal aspects of the defect should be reapproximated without tension.
- At this point it is possible to start the suture closure.

### **Lateral Lesions (Patient Positioned Lateral, Lying Ipsilateral to the Lesion in Jackknife Position)**

- In case of lateral lesions, the rectoscope degree of freedom can be limited by obesity and impaired mobility of hip articulations.
- For lesions of the left side, it is advisable to start the full-thickness dissection of the rectal wall from the 8 o’clock position to the 4 o’clock position (with an anticlockwise progression); in case of right-side lesions, it is advisable to start from the 4 o’clock to 8 o’clock position. The rationale is to start the dissection from where the mesorectum has more thickness, which facilitates the identification of the “holy plane.”
- The following surgical steps are similar to those reported for posterior lesions.



## Anteriol Lesions (Patient Prone)

### Female

- It is advisable to start the full-thickness dissection of the rectal wall as laterally as possible, starting the incision from the 3 to the 5 o'clock position.
- At this level, as soon as the rectal wall has been transected, it is easier to find adipose tissue; this facilitates the smooth dissection of the rectal wall along the rectovaginal septum.
- With a delicate grasper, the rectum wall can be pulled and the dissection continued with a clockwise progression utilizing a cautery with low wattage settings.
- Once the correct plane has been identified, it is easy to perform a smooth dissection of all the rectovaginal septum.
- During this maneuver, it is recommendable that the surgeon introduces one finger of the left hand in the vagina to better control the pressure applied during dissection.
- In relationship to the tumor position, it is mandatory to remove as much as possible the mesorectum adjacent to the tumor. If the tumor is localized in a position corresponding exactly to the midline of the vagina, both the hemispheres of the mesorectum must be completely removed en bloc with the specimen.
- The remaining procedures are similar to those reported for posterior lesions.

### Male

- It is advisable to start the full-thickness dissection of the rectal wall as lateral as possible starting the incision from the 3 o'clock and extending it to the 6 o'clock position.
- At this level, the prostatic capsule is usually recognizable, as a smooth, pale-colored organ.
- Once the right plane is identified, a smooth dissection is recommended to avoid significant bleeding from the prostate gland. Severe bleeding can occur if the capsule is damaged,

and hemorrhage control can require argon beam laser coagulation.

- As for females, it is mandatory to remove a high volume of mesorectum juxtaposed to the tumor. If the tumor is localized in a position corresponding exactly to the midline of the prostate gland, both the mesorectum structures located in the left and right sides of the gland must be removed en bloc with the specimen.
- The remaining procedures are similar to those reported for posterior lesions.

## Peritoneal Entry

During the dissection of large proximal specimens during ELRR, peritoneal entry can occur in around 6–7% of cases.

Management Recommendations:

- The first sign is generally a reduction of rectum distention; in other cases it is possible to note a bubbling at level of the opening.
- As a first maneuver, it is advisable to immediately close the opening in order to avoid the CO<sub>2</sub> from distending the abdominal cavity which can reduce the working space within the rectal lumen.
- If the gas leakage into the peritoneal cavity is problematic, a Veress needle should be placed to desufflate the abdominal cavity.
- In order to avoid peritoneal contamination, a suction tube is used to aspirate all the fecal contaminants present in the operative field and in the rectal lumen.
- Irrigate the operative field and the opening area with saline containing diluted Betadine solution.
- While suturing the peritoneum, the transanal surgeon must be certain that stitches do not inadvertently incorporate loops of small bowel that easily herniate into the opening, due to the increased pressure within the abdominal cavity.
- Generally, a double-layered suture repair is recommended.

## Intraoperative Histological Assessment of the Cranial and Caudal Margins

Before suturing the defect, two half rings of rectal wall (obtained from the cranial and caudal margins after the excision of the specimen) are removed and sent intraoperatively to the pathologist. Both of the half rings are marked with blue dye at the side of the defect. In this way, the surgeon is able to assure an R0 resection. The principle objective of this protocol is to avoid an incomplete excision of the tumor.

## Nucleotide-Guided Mesorectal Excision (NGME)

### Basic considerations:

- The histologically high-risk tumors (mucinous or undifferentiated) are an absolute contraindication to any type of local treatment. In the literature, except for histologically high-risk rectal cancer, cases that present skip metastasis overpassing the first lymphatic node station are not reported.
- The ELRR generally removes a large amount of mesorectum adjacent to the tumor, and consequently the first lymphatic station is removed with reasonable certainty.
- However with the delivery of NT, which utilizes a higher dose of radiation to the primary tumor, first nodal station sterility can be observed, a phenomenon less likely in more peripheral locales.

On the bases of these considerations, we were interested in developing a methodology able to detect the nodal disease within the non-excised portion of the mesorectum after ELRR. NGME is an in-house technique developed by E. Lezoche, designed with the purpose of increasing the number of removed nodes during ELRR, in order to have a correct staging of the cancer.

NGME is a technique which is fairly rapid and simple to perform. After induced general anesthesia, and immediately prior to ELRR, the radio-

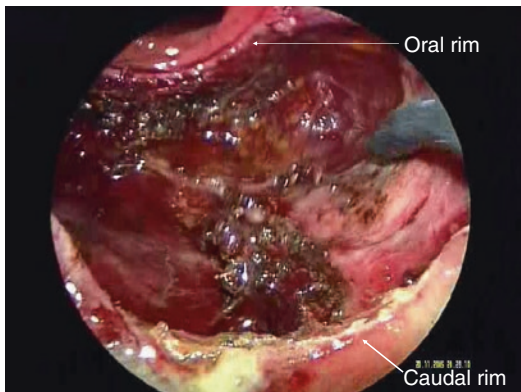
nucleotide is injected behind and around the lesion through an anoscope or a rectoscope utilizing a spinal needle. Once pyramidal excision has been completed, the specimen has been removed, and the lavage of the rectum has been performed (before suture reapproximation), the TEM rectoscope is left in situ, and through this point of access, a gamma camera (encased in a sterile package) is inserted to explore accurately the defect created by ELRR, in order to detect any area of residual radioactivity. In case of local activity at least ten times the baseline radioactivity, the high-activity tissue is marked with a metallic clip. Once the wall of the defect has been checked, the optics and TEM faceplate are replaced, and the tissues where the metallic clips have been placed are resected and sent to pathology for frozen section evaluation of the removed lymphatic nodes [8]. The same technique could also be adapted to the TAMIS platform.

## Suture Closure of the Defect

Suturing is one of the most difficult parts of ELRR for several reasons:

- The space in which the needle is moved is very narrow.
- The needle must go through not only the rectal wall but also the mesorectum.
- Depending on the level (distance from the anorectal ring) where the ELRR has been performed, a discrepancy generally occurs in the length of the caudal and cranial edges of the defect. If the tumor is located very close to the anal canal, the proximal edge will exceed significantly the length of the caudal edge; the opposite happens in case of tumors located in the upper rectum.

Typically, the defect created by the ELRR is quite large and deep, as shown in Fig.10.10. Therefore, to close the defect, several stitches are required. Suturing the defect, a double-zero polydioxanone suture (PDS) with a half-ring (SH) needle is usually utilized. The narrow space

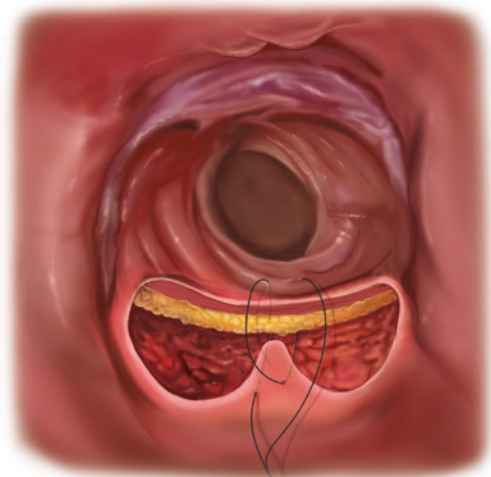


**Fig. 10.10** The defect created by the ELRR is very large and deep. In the pelvic floor are easy recognizable muscles, levator ani of both sides

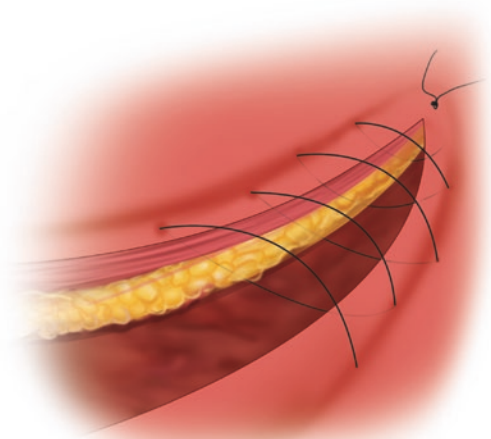
makes it difficult to tie the suture line. To obviate the need for suture knot tying, a silver clip is placed at both ends of the suture. Previously, silver clips were utilized, but this metal creates interference with MR, making subsequent images interpretation difficult. This problem has been solved by the introduction in the clinical use of titanium clips, which are nonferrous and do not interfere with the magnet.

Due to the narrow space, it is advisable that the length of each suture does not exceed 6–7 cm; a suture longer than this makes suturing motion more difficult inside the narrow operative field.

1. If the defect of the ELRR is very wide, it is advisable to place a first stitch in the middle of the cranial edge and then pass the needle to the corresponding level of the middle of the caudal edge. This stitch must not be tightened but rather should be left loose to allow reapproximation by another, separate running suture. When the running suture reaches the midline, the stitch is removed (Fig. 10.11).
2. For right-handed surgeons, the suture starts from the right side of the defect (right to left closure).
3. The needle of the first stitch must be placed 1 cm lateral to the defect, so that at the first passage, the needle tip must appear inside the defect (Fig. 10.12).

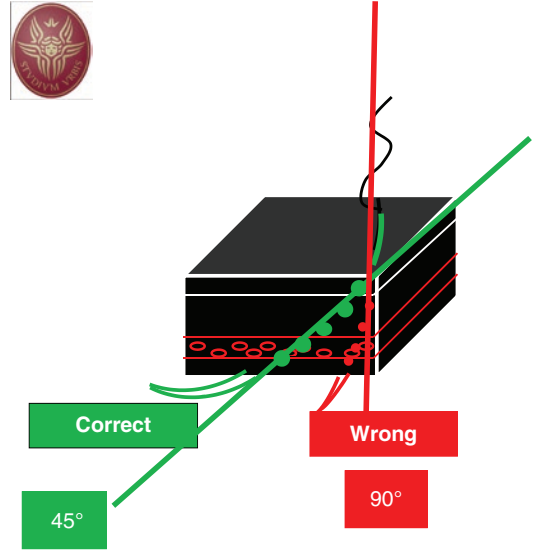


**Fig. 10.11** When the defect is very wide and with a discrepancy in length between the two rims, it is advisable to place a first stitch in the middle



**Fig. 10.12** The suture starts from the right side of the defect (for right-handed surgeon)  
 First passage: the needle at the first stitch must be placed 1 cm laterally to the defect, and then the needle tip must appear inside the defect  
 Second passage: the needle crosses the cranial rim entering at the level of the holy plane and coming out on the mucosal surface  
 Third passage: the opposite cross must be made in the caudal rim, so the needle crosses the mucosa and exits at the bottom of the perirectal fat

4. Then, the needle crosses the cranial edge entering at the level of the holy plane and exiting along the mucosal surface.
5. An opposite cross must be made in the caudal edge, so the needle crosses the mucosa and exits at the bottom of the perirectal fat.
6. The needle enters at the level of the mesorectal fascia crossing the residual mesorectum and the rectal muscle tube and finally exits at the level of the cranial edge of mucosa.
7. This step is repeated several times to utilize entirely the suture.
8. For large defect closure, the rectoscope position inside the rectum must be continuously moved, in order to find the most convenient position for the suturing motion.
9. The most difficult part of the suture is at the level of the terminal part of the defect (left side in this case), when the suture must be performed at 10–12 o'clock position, relative to the operative field. This is related to the fact that, at level of the left upper part of the operative field, the instruments, due to the tight space, conflict with one another and with the optical lens, as well.



**Fig. 10.13** If one of the two rims is wider, the needle must move with an angle at least of 45° instead of 90°

We observed two different possibilities of dehiscence of the suture line after pyramidal excision, which can be classified as early and late and which are characterized as follows:

*Early Dehiscence:* The first type occurs in the first 7–10 days postoperatively. This adverse event is generally related to the existence of tension on the suture line, often caused by reapproximation of large defects, whereby the gap between the cranial and caudal edge is considerable, even after appropriate mobilization. Dehiscence is often heralded by tenesmus, sentinel bleeding, and pelvis pain. DRE, when within reach, will often confirm the partial dehiscence of the suture line.

*Late Dehiscence:* The second type of dehiscence occurs much later, 30–60 days postoperatively, and the etiology is related to the fluid collection within the dead space that after suturing is created by the lack of tissue apposition (i.e., the local mesorectal defect left after pyramidal excision). As clearly shown in Fig. 10.10, the defect created by ELRR is quite wide, and the specimen has an average volume of ~40–50 ml. The creation

## Important Tips

- Due to the *length discrepancy of the two edges*, the plane on which the needle moves drawing the curvilinear line cannot be the same. For example, in the case that the cranial edge is wider (as in the case with low rectal cancers), at this upper side, the needle must advance along with an angle of at least 45° with respect to the mucosal surface. Conversely, at the level of the typically shorter caudal edge, the needle must advance orthogonally (90°) relative to the mucosal surface (Fig. 10.13). In this manner, it is possible to compensate for the discrepancy in length of the two rims and to obtain a good reapproximation of the proximal and distal margins, avoiding the formation of weak points along the closure line.
- *Filling of the residual defect with glue.*

of a dead space induces the formation of fluid collection that, with microbial seeding, evolves into a pelvic abscess that initially can be asymptomatic. The abscess naturally and spontaneously drains through the path of least resistance, as at the level of the suture line. To avoid fluid accumulation, before placing the last stitch, it is recommended that the defect be filled with 10 ml of FloSeal® (Ethicon, Inc.).

- *Filling the rectal ampulla with iodine-impregnated sponges.* With the same purpose (to avoid the fluid collection behind the suture line), at the end of the operation, once the TEM (or TAMIS) apparatus has been removed, the rectal ampulla is filled with three iodine sponges that reduce the presence of bacteria and dead space in the residual cavity, by serving as a wick. The sponges are removed 48 hours postoperatively.

## Conclusions

The quest to preserve function for stage I rectal cancer has encouraged colorectal surgeons to explore alternatives other than radical resection for curative intent. The crux of controversy remains in the inability to accurately stage rectal cancer in terms of nodal positivity. Even with NT, there remains uncertainty about nodal treatment. Such limitations have led to the development of pyramidal excision (ELRR after NT), combined with NGME as the best approach to treat highly selected non-advanced rectal cancers. The tech-

nique is closure of the surgical wound after PE must be meticulous.

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# Closure Versus Non-closure After Local Excision

11

Dieter Hahnloser

## Introduction

Closure of the rectal wall defect after transanal excision is controversial. Closing defects can be technically difficult and may significantly increase operative time without a clear benefit. The current literature suggests that there is no difference in morbidity and functional outcome between closure and non-closure of the rectal defect. However, more bleeding complications may occur in open defects. Defect closure is clearly necessary if the abdominal cavity has been opened. In the absence of clear data favoring closure or non-closure, the management of the rectal wall defect after TAMIS is left to the surgeon's discretion and skill set.

## To Close or Not to Close

Once the specimen is excised, the question arises whether to close or not to close the defect in the rectal wall. There is currently no consensus among surgeons, and nearly all studies state that the decision to close or not to close the defect was made individually at the surgeon's discretion. This is not very helpful in the daily clinical setting.

Lesions in the distal rectum removed by transanal excision are easily amenable to closure using open instruments and anal retractors. This is in contrast to higher lesions in the rectum after TEM or TAMIS where closure is technically more challenging. Endoscopic suturing is difficult and can be time-consuming.

Many authors have recommended suturing of the defect on the basis of improved wound healing, better bleeding control, and a reduction in the risk of stenosis of the lumen. Closing the defect may provide a hemostatic advantage as the mesorectum is highly vascularized. Another, theoretical advantage of adapting the mucosa is preserving rectal compliance as only little scarring occurs and regrowth of the mucosa is not necessary. However, compliance after defect closure versus non-closure has not yet been studied.

Because endoscopic suturing is technically difficult, some surgeons leave full-thickness defect open, when the defect lies in the subperitoneal rectum and in the absence of peritoneal entry. The rectum and its surrounding mesorectum are well vascularized, which provides an excellent medium for granulation tissue and recannulization of the rectal wall. Signs and symptoms of infection including pain, fever, and elevated white blood cell count can be observed after TAMIS as inflammatory reaction of the surrounding mesorectum. Not closing the defect may increase the risk of infection. However, the mesorectum is also a barrier to infection, as

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witnessed in the literature by the low incidence of pelvic sepsis even with open defects. Prolonged antibiotics are not necessary and do not change the infection rate (6% non-closure vs. 10% in the closure group;  $p = 0.2$ ) [1].

Finally, defect closure may also not always be feasible because of the potential for rectal lumen narrowing or the difficulty of endoluminal suturing. For all these reasons, closure of the defect after excision remains a controversial point.

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### Closure Is Mandatory if the Abdominal Cavity Is Entered

Peritoneal entry occurs in up to 28% and mandates defect closure after full-thickness defect excision of proximal rectal neoplasia [2]. Suturing these defects can be very difficult, as the pneumorectum is often lost once the abdominal cavity is entered. When the rectal wall collapses, the operative view is diminished. Insertion of a rigid TEM (or TEO) proctoscope may help stabilizing the defect and may allow endoluminal suturing. However, 30% of defects are deemed not amenable to endoluminal closure [3], and laparoscopic or even open suturing might become necessary which increases morbidity modestly. The technical ability to close the peritoneal defect endoluminally has therefore definitive advantages. Care must be taken as closure of large defects may result in subsequent stricture formation or stenosis, although the incidence of stenosis in the literature in large series is low [4, 5].

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### Technical Issues of Closure

Suturing remains very challenging as instruments clash, adequate tension is difficult, and, hence, the procedure is time-consuming. Studies have reported that defect closure using the TAMIS platform increased operative time by 30 minutes [1]. In the literature different methods of suturing have been described using Endo-GIA staplers [6], intracorporeal running sutures [7, 8], or extracorporeal single suturing with a knot pusher [9]. In addition, the use of self-locking barbed

suture obviates the need for knot-tying, and the use of mechanical suturing devices can expedite the process of defect closure but can add substantial per-case costs as well. It is recommended to close the defect completely “watertight” to avoid abscess formation. However, after radiotherapy and transanal excision, it is not recommended to close subperitoneal defects, as wound dehiscence can be as high as 47% [10].

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### Review of the Literature

Table 11.1 lists studies comparing patients whose defects were either closed or left open [1, 11–14]. A recent meta-analysis including 4 of these trials with 489 patients (317 in the closed and 182 in the open group) did not find a significant difference in overall morbidity (OR 1.26) [15]. Postoperative bleeding (5.6% vs. 7.7%), local infection (3.1% vs. 4.9%), as well as the need for reintervention (1.9% vs. 1.1%) were comparable between the left open and the closed group. A recently published three-institution study using propensity score matching compared open and closed defects each after full-thickness ( $n = 220$ ) and partial-thickness ( $n = 210$ ) excisions [12]. The incidence of 30-day complications was similar for open and closed defects after full- (15% vs. 12%,  $p = 0.43$ ) and partial-thickness excision (7% vs. 5%,  $p = 0.55$ ). However, there were more bleeding complications in open defects after full-thickness excision. For these reasons, it is recommended to carefully check the mucosal resection margins and the mesorectal defect for bleeding before concluding the operation and removing the TAMIS platform. We recommend a stepwise reduction in the insufflation pressure keeping the defect under direct vision. Even minor bleeding should be treated by cauterization. Another possibility is to leave a swap in the defect for a couple of minutes to check for venous bleeding once the pneumorectum has been discontinued, since the pneumatic pressure may lessen the effect of venous bleeding, giving a false reassurance that the operative site is hemostatic.

The use of TEM versus TAMIS did not affect the decision to close the defect in the

**Table 11.1** Literature comparing closure versus non-closure of the rectal wall defect

	N=	Study type	Surgical technique	% left open	Closure technique	Results open vs. closed
Ramirez et al. (2002) [11]	40	RCT	LE, TEM	50%	Running suture, 3–0 absorbable microfilament	Overall complication NS
Hahnloser et al. [1]	75	Prospective	TEM, TAMIS	47%	Single stitches (75%) or running suture (25%) of Vicryl 3–0 or V-Loc 3–0	Bleeding (11% vs. 3%, $p = 0.2$ ) Infection (6% vs. 10%, $p = 0.3$ )
Brown et al. [14]	341	Prospective	TEM	30%	Running suture PDS 2–0 and secured with clip	Overall complication (19% vs. 8.4%, $p = 0.03$ ) Bleeding (7.6% vs. 4.7%, $p = 0.27$ ) Infection (6.7% vs. 2.1%, $P = 0.06$ )
Noura et al. [13]	43	Retrospective	LE, TAMIS	51%	–	Bleeding (0% vs. 24%, $p = 0.02$ ) Fever (0% vs. 5%, $p = 0.49$ ) > = Clavien grade IIIa (0% vs. 19.0%, $p = 0.04$ )
Lee et al. [12]	220 FT 210 PT	Retrospective, paired matched	TEM, TAMIS	50% 50%	3–0 absorbable suture, endostitch	Overall complications (15% vs. 12%, $p = 0.43$ ) Overall complications (7% vs. 5%, $p = 0.55$ )

LE local excision, TEM transanal endoscopic microsurgery, NS not significant, FT full thickness, PT partial thickness

abovementioned studies. Surgeons seem to more often close smaller defects and leave large defects open. Also, partial-thickness excisions seem to be more frequently closed than full-thickness defects. In a small prospective randomized study of 44 TEM operations for local excision, no difference in outcome was noted if the defect was sutured closed or left open [11]. At 4 weeks, the rectal wound had completely healed in 85% in the non-closure group and in 95% in the closure group. At follow-up endoscopy at 3 months, all defects in the “left open” group healed. In another study 47% of rectal defects were not sutured closed and rather left open. Although this was mainly depending on the participating centers, there was no difference in size and location of the defect, and, most interestingly, there was no increased complication rate in the group of patients whose excision defect was left open [1]. This suggests that defects can be left open without increased morbidity. However, all studies were not designed to answer this particular question, and therefore

caution must be exercised in the interpretation of this finding.

Functional impairments do not seem to be affected by defect closure. There was no difference in Vaizey incontinence scores at 12 months with regard to defect closure in two studies [1, 13]. Disturbances in anal manometry and fecal incontinence after TAMIS appear to be related to the depth of excision [16, 17]. Moreover, continence and outlet function tend to improve after local excision due to the otherwise obstructive effect that (especially bulky) neoplasms tend to create and which resolves upon successful TAMIS excision.

There are several limitations in each of these studies with differences in perioperative management, surgeons’ experience, and operative technique used (for instance, energy source used). Also, the location (anterior-posterior) and the distance from the anal verge and therefore the risk of peritoneal entry varied among these studies. This could have affected the decision to close or not to close the defect.

## Recommendations and Conclusions

The current literature suggests that there is no difference in morbidity and functional outcome between closure and non-closure of the rectal defect after transanal excision. Furthermore, benefits of closure remain unclear. However, no study was specifically designed to answer this particular question. Therefore, the decision to close rectal wall defects may be left to the surgeon's preference and skills.

We recommend to close all large full-thickness defects if possible. It might be sometimes necessary to further mobilize the rectal wall to allow a tension-free closure. In large defects we start suturing laterally on both sides joining in the middle. If the defect cannot be closed "watertight," we recommend to leave it open. Marsupialization stitches of the rectal wall to the mesorectum are of little use. Early endoscopy after 6–10 weeks might be indicated to exclude or treat narrowing of the lumen by balloon dilatation. Medium-sized and small full-thickness defects as well as all partial-thickness excisions are left open as they will granulate rapidly and be relined with neomucosa; stricturing and stenosis are extremely rare. Results from the ESD (endoscopic submucosal dissection) literature with comparable wounds to partial-thickness excisions demonstrate that stenosis never occurred in cases with <90% circumferential extent of mucosal defect [18]. Because post-TAMIS excision bleeding can occur when the excision defect is left open, keeping the patient in-house for observation is encouraged.

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# Operative and Perioperative Outcomes

# 12

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and George Melich

## Introduction

Traditionally, rectal neoplasms that were not resectable by colonoscopy required segmental oncologic resection, either via abdominoperineal or low anterior resection. These procedures come with a high risk of operative and postoperative complications that can result in significant patient morbidity as well as significant perioperative costs. Transanal minimally invasive surgery (TAMIS) emerged in 2009 [1], as there was a need for a more widely accessible (easier setup, easier to learn, less expensive) approach to transanal endoscopic excision that was safe and equivalent to transanal endoscopic microsurgery (TEM) for removal of rectal lesions [2]. TAMIS is now a well-established technique for removal of benign lesions and select early rectal cancers (T1) not resectable by endoscopy. This chapter describes the operative and perioperative outcomes associated with TAMIS, emphasizing the technique and complications of this procedure.

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## Intraoperative Complications

### Peritoneal Entry

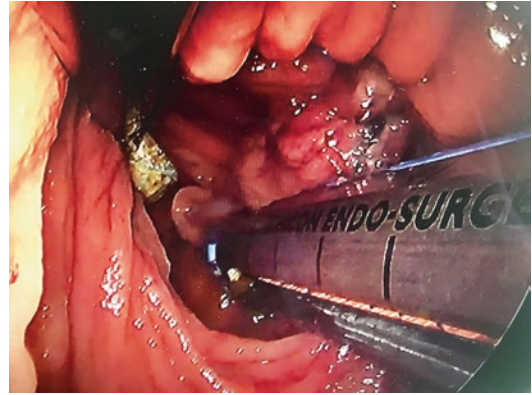
One of the complications of TAMIS is potential abdominal entry, particularly for rectal lesions located above the peritoneal reflection [3–5]. In the literature, peritoneal entry ranges from 10% to 28% [4, 6, 7] and has been described in transanal endoscopic microsurgery (TEM) as an expected event for high-risk lesions [8]. In the authors' (unpublished) experience, there were nine cases of unplanned intraperitoneal entry out of 230 (3.9%). Abdominal entry has been described as primarily in woman of small body habitus with low peritoneal reflections and generally in anterior lesions above 10 cm from the anal verge. Our data suggests a relatively equal distribution of males and females (five males and four females) and generally anterior or lateral lesions ranging from 8 to 12 cm from the anal verge [5].

Options for repair include transanal repair via the TAMIS platform, laparoscopy, or laparotomy. Occasionally, large defects can even require segmental resection if the defect is not amenable to simple local closure. Generally, the defect can be closed via the TAMIS platform using laparoscopic needle drivers and a 3-0 barbed self-locking absorbable suture. This requires a stable pneumoperitoneum and the conversion to general anesthesia if the procedure is initiated under spinal anesthesia. Though local repair is the ideal approach, if unable

to maintain stable pneumorectum, consideration can be given to laparoscopic transabdominal repair either via direct closure of the defect or segmental resection of the rectum. Generally, given the relative ease of adoption of TAMIS suturing techniques for those who have mastered laparoscopy, closure of the defect should be done routinely, so that in more challenging closures such as peritoneal breach, conversion to laparoscopy can be avoided.

Caycedo et al. [7] describe five peritoneal violations in 50 cases (10%). All peritoneal violations were repaired using the TAMIS platform and AirSeal® Insufflation System (ConMed, Inc., Utica, NY, USA). The authors of this article recommended not operating on anterior lesions suspected to be above the peritoneal reflection if the surgeon is not facile at laparoscopic suturing, as they carry a high risk of peritoneal entry. Our current data suggests an unplanned intraperitoneal entry rate of 3.9%, where repair was primary performed by intracorporeal suturing via the TAMIS platform (6 of 9 patients), while 2 patients required conversion to laparoscopy to close the defect and 1 necessitated a laparoscopic low anterior resection, as the defect was too large to close primarily. Subcostal needle catheterization using a 14-gauge needle in the left upper abdomen at Palmer's point was used to evacuate the intra-abdominal CO<sub>2</sub> and facilitate transanal repair, with successful completion of the surgery in 3 of the 6 patients who had repair transanally. Interestingly, one patient who sustained a peritoneal violation went on to have two further TAMIS procedures for recurring adenomas in the same position (despite clear circumferential margins on previous TAMIS excisions), and these two further TAMIS local excisions were not complicated by peritoneal entry, likely secondary to scarring from the initial procedure [5].

In a series (pending publication), the application of a transanal laparoscopic stapling device is described that could circumvent this complication by simultaneously removing lesions while closing the defect that are suspected to be above the peritoneal reflection [9]. This article examines TAMIS operations for local excision whereby a laparoscopic stapler is used to define, remove, and seal the defect, all with full-thickness



**Fig. 12.1** Intraoperative view of the rectal polyp being stapled with a laparoscopic Echelon stapler

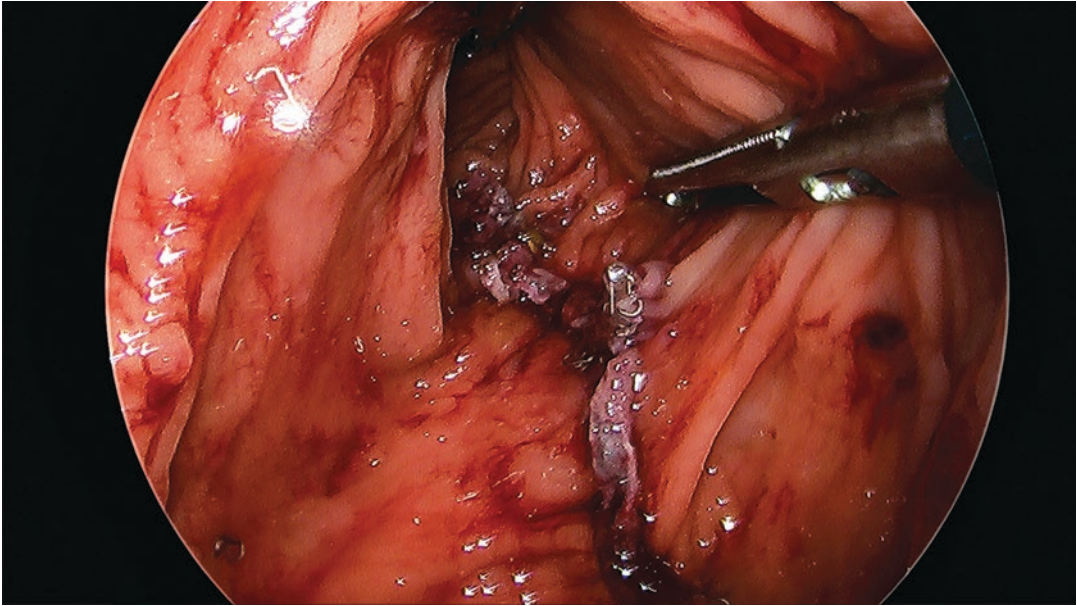
complete excisions of the rectal lesions (see Figs. 12.1, 12.2, and 12.3).

Diverting ileostomy has also been described [10] but is generally not advised if no major fecal contamination has occurred and primary repair is successful.

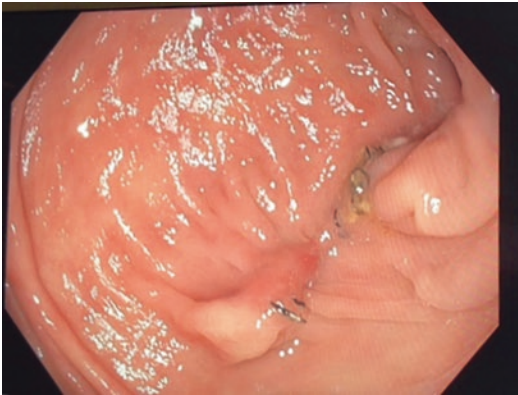
### Vaginal Entry and Rectovaginal Fistulae

Vaginal entry can occur for anterior lesions in women. Infiltrating the rectovaginal septum with local anesthetic and digitizing the vagina during dissection can help to define the planes and prevent vaginal trauma. Keller et al. [10] describe an electrocautery injury to the vaginal wall that healed with conservative measures. Very early in our own TAMIS experience, we described one case of vaginal entry that occurred for removal of an anteriorly located neuroendocrine tumor. This was recognized intraoperatively and primarily repaired but recurred within 30 days with a clinically apparent rectovaginal fistula. The approach to wound care was irrigation with daily enemas and broad-spectrum oral antibiotics to encourage healing as per treatment of other traumatic rectovaginal injuries. The fistula was deemed closed at 60 days and has remained closed. Of course, if rectovaginal fistula occurs, other operative techniques can be employed as described in the section below on long-term complications.





**Fig. 12.2** End result of the closure of the rectal defect with a laparoscopic stapler



**Fig. 12.3** Flexible sigmoidoscopy 3 months after a stapled TAMIS

### Inadvertent Closure of Rectal Lumen

Closure of the rectal lumen is a potential risk in any anorectal procedure, and, therefore, extreme vigilance is required when doing any significant intervention after removal of the specimen in TAMIS, particularly after removal of large or circumferential lesions. This has been described in stapled hemorrhoidopexy [11] and could potentially be an issue in TAMIS as well. A simple approach to identify the rectal lumen and keep it patent throughout the procedure is to insert a small sponge into the rectal lumen proximal to the lesion at the start of

dissection (nb: care must be taken to assure the gauze sponge does not “drift up” due to the active pneumorectum, as this has been described by TAMIS surgeons). Retrieval of this sponge after suturing of the defect confirms an open lumen. In addition, if there is any doubt, or the sponge was not utilized, a patent lumen can be confirmed with a rigid proctosigmoidoscope in the operating room or by simply advancing the camera lens (used for TAMIS) beyond the area of local excision.

### Intraoperative Hemorrhage

Intraoperative bleeding is rare, as electrocautery is usually sufficient for hemostasis. However, a laparoscopic tissue sealer device or laparoscopic clip applier via the TAMIS platform can always be used, if necessary.

### Short-Term Complications

#### Postoperative Hemorrhage

Generally, postoperative bleeding is uncommon if hemostasis has been maintained throughout the procedure. Nevertheless, it has been described in up to 10% of patients, occasionally even requiring



blood transfusion [5, 7, 12]. As our most common short-term complication, postoperative rectal bleeding occurred in 25 of 230 cases, with only 5 requiring intervention (2.2%). Of the five patients who required blood transfusion, one was taken back to the operating room the same operative day, while two others were treated endoscopically on postoperative days 16 and 17, respectively. Successful cessation of bleeding was achieved by hemostatic agent placement or endoscopic clipping [5].

Closure of the defect has been thought to influence hemostasis. While numerous studies demonstrate a trend toward a higher bleeding incidence [12–16] leaving the defect open, none show statistical significance. Regardless, an attempt to close all defects could potentially influence clinically significant bleeding and is a mandatory technique to master in cases of potential peritoneal breach. Since TAMIS is a novel procedure, utilizing existing techniques for hemostasis postoperatively in other anorectal procedures, such as hemorrhoidectomy, can be useful. Rosen et al. [17] treated post-hemorrhoidectomy bleeding using hemostatic agent (Gelfoam) packing at the site of the defect. In TAMIS, in addition to suturing, placement of a hemostatic agent, such as Surgicel or Gelfoam, can be considered.

### Urinary Retention and Infection

Urinary retention is a frequent postoperative complication of anorectal procedures and certainly can occur after TAMIS. Generally, urinary catheter insertion is not required for a short operation with no hospital stay. When utilized, catheters increase the risk of urinary retention and infection. In TAMIS, it has been suggested that circumferential lesions predispose patients to urinary retention [7] and replacement of the Foley catheter for urinary retention has been shown to increase the incidence of urinary tract infection [18]. Urinary retention is reported to occur from 2% to 19% of patients after TAMIS [7, 12, 18]. Our data suggest a rate of 7% with 13 men and 2 women, having clinically significant urinary retention. Of these 15 patients, 8 had anterior

lesions, and 13 had not been taking prophylactic perioperative tamsulosin, which has now been introduced at our center as part of a routine protocol. A clinical trial in progress TEMPOUR [19] addresses the use of perioperative tamsulosin in TEM, which is hypothesized to decrease the incidence of urinary retention, and this data may be translatable to TAMIS practices for local excision of rectal neoplasia. This could be a simple and cost-effective approach to minimizing this complication.

### Subcutaneous Emphysema

Subcutaneous emphysema has been described previously in TAMIS [4] and is generally an uneventful complication in similar transanal procedures [20]. However, it can lead to intraoperative hypercapnia [21] and is occasionally an indication of peritoneal breach. If ventilatory difficulty is encountered secondary to hypercarbia, decreasing the rectal insufflation pressure, completing the procedure quickly, and potentially delaying extubation can all be utilized [22]. At our center, the overall rate of subcutaneous emphysema for  $n = 230$  was 0.4%. Generally, this is a self-limited complication and is managed conservatively. Rarely, patients can become symptomatic and may even develop free air on plain radiographs [5].

### Postoperative Pain

For most patients, pain is minimal after TAMIS. It is a concern mostly for lesions below or near the dentate line. A common practice with other anorectal procedures is to prescribe metronidazole to patients to reduce postoperative pain. A meta-analysis in 2018 [23] demonstrated that both topical and oral metronidazole were effective in managing postoperative pain after hemorrhoidectomy. Given its anti-inflammatory effects and proven safety in other anorectal procedures, metronidazole can be prescribed for a total of 5–7 days as an efficient and cost-effective treatment for post-TAMIS pain, particularly for patients who have undergone ultra-low-lying excisions [24].

## Fecal Incontinence

The equipment for TAMIS includes an access channel that is placed into the anal canal for the duration of the procedure. This sustained anal dilatation could potentially be a concern for continence after the surgery. A descriptive, prospective study was published in 2015 studying the impact of an anal port on anorectal function during TEM/TEO procedures [25]. The baseline and the voluntary contraction pressures were decreased at 1 and 4 months after the surgery. However, there was no correlation with clinical incontinence. The TEM/TEO instrumentation is rigid at 40 mm in diameter, compared to 30 mm for the flexible TAMIS port [26], suggesting that there would be less influence on continence with the TAMIS procedure.

Schiphorst and Clermonts [27, 28] examined long-term functional outcomes post TAMIS, and, ultimately, there was no clinically significant impact on continence. Schiphorst's study measured functional results after TAMIS. While 51% of the patients had normal continence prior to the surgery, 17% (3/18) of those had worse continence after TAMIS. Interestingly, in the remaining 49% of patients with previously impaired continence, continence was seen to improve in 88% of patients, likely secondary to removal of the inciting lesion causing poor preoperative anorectal function and symptomatology consistent with outlet obstructive defecation due to the mass effect of the lesion prior to excision. In conclusion, short-term functional results are good, with the majority of patients preserving their continence.

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## Long-Term Complications

### Rectal Stricture

Rectal strictures have been described in 1–3% of patients after TAMIS [5, 7, 10, 18]. Generally they are managed with serial dilations either via rigid proctoscopy or endoscopy. These were seen after large, circumferential adenomas and recurrent rectal lesions. Failed endoscopic dilation has been reported, however, and salvage with TAMIS re-excision of the rectal stenosis has been successfully utilized [18]. Nevertheless, most rectal

strictures can be treated with endoscopic dilatation or Hegar dilators as outpatients, particularly for low-lying strictures [29].

### Rectovaginal Fistula

The distal two thirds of the rectum anteriorly lie in close proximity to the posterior vaginal wall. The identification of the vagina, as well as the rectovaginal septum, is essential when operating on an anterior rectal lesion transanally. Any trauma to these structures can potentially result in a rectovaginal fistula. Keller [10] described one case of rectovaginal fistula (1.3%) in TAMIS secondary to electrocautery injury. It was managed conservatively, as previously described in the section on vaginal entry.

A surgical approach may be required if conservative management fails. Transanal or transvaginal operations are options for local repair. Depending on the location of the defect, consideration could be given to transanal repair with endorectal advancement flap, which can be created using the TAMIS platform [5]. Generally, endorectal advancement flaps are effective in about 50% of patients with previously normal sphincter function [29]. At our center, six patients have undergone successful endorectal advancement flap repair of rectovaginal fistulae via TAMIS. Other local repairs would include endovaginal advancement flap, fibrin glue, mesh interposition, or sphincteroplasty. Complex cases that fail local repair may require more aggressive options, such as a pedicled muscular flap interposition, low anterior resection, or, very rarely, abdominoperineal resection.

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# Functional Outcomes After Local Excision for Rectal Neoplasia

# 13

Elizabeth R. Raskin

## Introduction

The transanal approach can be a viable surgical option for most benign and select malignant rectal neoplasms. The decision to proceed with transanal surgery is typically based upon the size of a lesion, its location within the anorectal canal, and its particular pathologic characteristics. Advances in technology, such as the advent of transanal endoscopic microsurgery (TEM) and transanal minimally invasive surgery (TAMIS), have allowed for improved optics and access within the anorectum, translating into superior surgical margins and enhanced oncologic outcomes [1, 2]. While a large focus has been placed on the safety, feasibility, and oncologic soundness of transanal techniques compared to traditional proctectomy, functional outcomes following transanal surgery have received much less attention.

Postoperative anorectal functional outcomes can be summarized as gas and stool continence, fecal frequency/urgency, and quality of life following surgery. Multiple factors play a role in postoperative function, such as preoperative baseline function, tumor characteristics, surgical technique, and the extent of resection.

Preoperative measurement, both with qualitative and quantitative tools, is critical to establishing a baseline from which to assess the effect of transanal surgery on function. This chapter aims to define anorectal function, elucidate preoperative and intraoperative factors that contribute to functional outcomes, and compare postoperative outcomes after traditional transanal (TA) surgery, transanal endoscopic microsurgery (TEM), and transanal minimally invasive surgery (TAMIS).

## Anorectal Function

Normal anorectal continence involves complex contributions from the pelvic and perineal musculature, rectal compliance and capacity, as well as neuronal pathways which potentiate various reflexes.

## Anatomy of Anorectal Continence

The pelvic floor – or levator ani, perineal body, and the internal and external anal sphincter muscles – comprises the muscular framework for the continence mechanism. Parasympathetic innervation of the pelvic floor arises from S4, while S1–S3 and S2–S4 innervate the internal and external sphincter, respectively. These branches of the pelvic plexus help coordinate activity of both the striated and smooth muscle of the pelvis

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and perineum, although it is unclear in the exact manner they behave. Unquestionably, excitatory activity is elicited from sympathetic innervation from the hypogastric and pelvic plexus.

Anal canal sensation originates from the inferior rectal branch of the pudendal nerve, which arises from S2 to S4, and helps to discriminate between gas and liquid/solid stool. In contrast, the rectum senses only distention; it also receives innervation from S2 to S4. The perception of flatus is attributed to receptors in the walls of the rectum and the fascia of the pelvis. Surgical trauma to either the mucosa of the anal canal or the wall of the rectum can distort the ability to differentiate stool consistency and lead to incontinence and/or urgency. In addition, postoperative inflammation can lead to hyper-acute sensation, precipitating poor accommodation and subsequent fecal frequency.

### Compliance and Capacity

Rectal compliance and capacity refer to the distensibility of the walls and the volume of the rectal reservoir, which directly impact continence. Compliance can be altered in the early postoperative period by inflammation and edema and, in the later postoperative phase, by fibrosis. Similarly, prior radiotherapy can negatively impact the reservoir function, resulting in fecal urgency, frequency, and stool fragmentation.

### Anorectal Reflexes

The rectoanal inhibitory reflex (RAIR) describes the relaxation of the IAS upon distention of the rectum, and it allows for the sampling process within the anal canal. This enables stool and/or gas to make contact with receptors within the walls of the anal canal to signal the nature of the substance above in the rectal vault. While this reflex can be lost following low anterior resection, it typically remains intact following transanal surgery, as it is contingent upon intrinsic innervation.

The rectoanal excitatory reflex (RAER) denotes the contraction of the EAS upon rectal distention, which manifests as an anorectal squeeze. Unlike the RAIR, this reflex is determined by S2–S4 innervation and can be disrupted by injury to the pudendal nerve endings. Continence can be disrupted if the RAER is either blunted or abolished secondary to pudendal nerve block or surgical trauma. Specifically, the external anal sphincter is largely responsible for maintaining continence with increases in intraabdominal pressure, such as during coughing, sneezing, or heavy lifting [3].

### Measuring Anorectal Function

Functional assessment tools such as the Fecal Incontinence Severity Index (FISI) and the Fecal Incontinence Quality of Life (FIQL) scale have been utilized to quantify the magnitude of incontinence and the impact it has on patients' lives [4, 5].

The FISI, a severity rating score for fecal incontinence (FI), assesses the types of leakage experienced by those with FI (gas, mucus, liquid, or solid) and the frequency of the occurrences of incontinence [4]. This validated score has been shown to be a useful measure of anorectal function, with good concordance between patient and surgeon assessment of the condition.

On the other hand, the FIQL scale is a tool for specifically measuring the impact of FI on the quality of life (QOL) [5]. There are 29 items addressed in 4 general categories: (1) lifestyle, (2) coping/behavior, (3) depression/self-perception, and (4) embarrassment. Given the reliability of this score, it has become a standard instrument in subsequent studies for qualifying QOL after interventions [6, 7].

Multiple other incontinence scores exist, such as the Pescatori score, the Wexner Continence Scale, and the American Medical Systems score. These grading systems evaluate the type of incontinence experienced, the frequency, severity, and impact of incontinence on lifestyle [8].



## Preoperative Evaluation

A thorough preoperative evaluation should be performed to understand a patient's baseline function and to anticipate the potential risks for postoperative anorectal disturbance. Direct questions regarding continence are warranted to understand preoperative status. If FI is described, validated questionnaires, as described above, can be helpful for accurate assessment and documentation. In addition to prior anorectal and/or pelvic surgery, a history of pelvic malignancy, obstetrical injury, or pelvic radiation therapy should be elicited.

## Physical Exam

Visual inspection of the anal and perineal areas can reveal scarring from prior treatment, trauma, or surgery. In women, the width of the perineum should be noted, as a thin perineal body may be associated with prior injury and a weakened sphincter mechanism. Anal canal resting tone and squeeze, as well as moderate to large sphincter defects, can be subjectively assessed on digital exam. Intact sensation

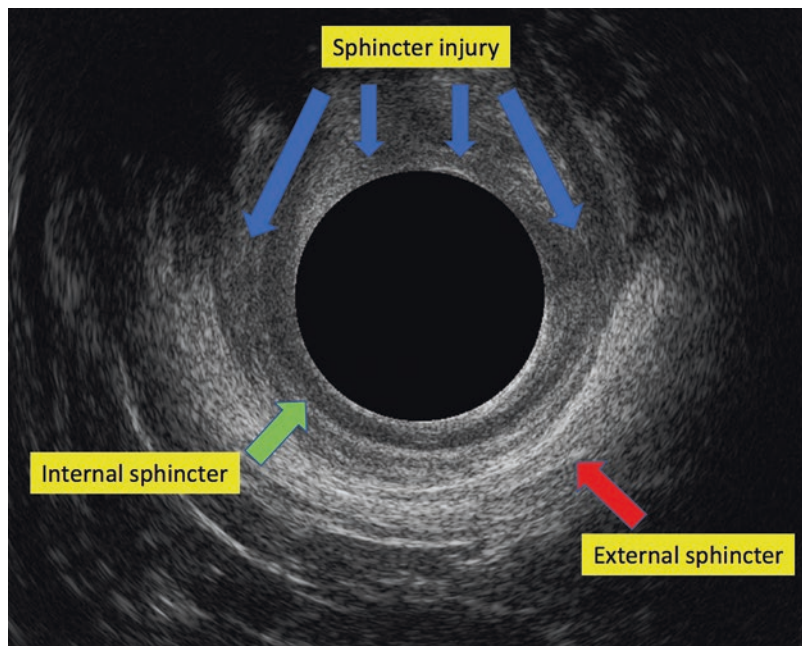
of the perianal skin and anus can be tested with a cotton swab or electrical stimulation.

## Imaging and Functional Assessment Technology

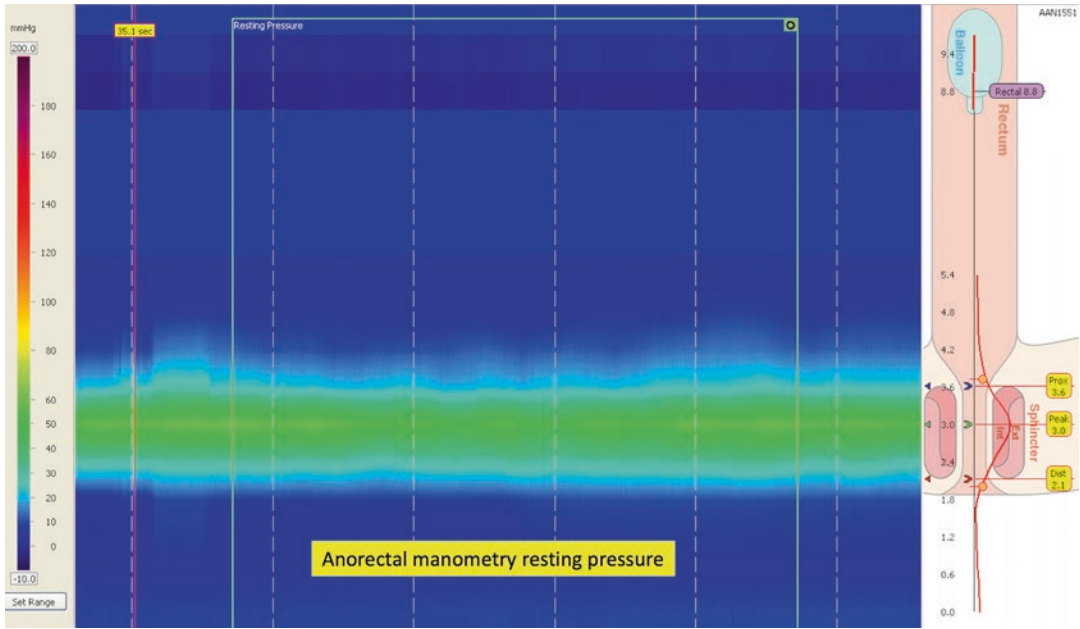
Endoanal ultrasonography and magnetic resonance imaging (MRI) can provide anatomic detail such as sphincter width and integrity. These modalities are useful for classification of sphincter defects, noting level, depth, and size within the anal canal [9]. Interestingly, there is no direct correlation between the presence of a sphincter injury and incontinence. In a study of 1495 women with prior third- or fourth-degree obstetrical tears who underwent endoanal ultrasonography, no significant difference was noted in continence scores between those with residual sphincter defects and those with normal sphincters [10] (Fig. 13.1).

Anorectal manometry and rectal barostat measurements can give more objective functional data in the form of anal resting pressure, anal squeeze pressure, rectal wall compliance, and rectal perception [11] (Figs. 13.2 and 13.3).

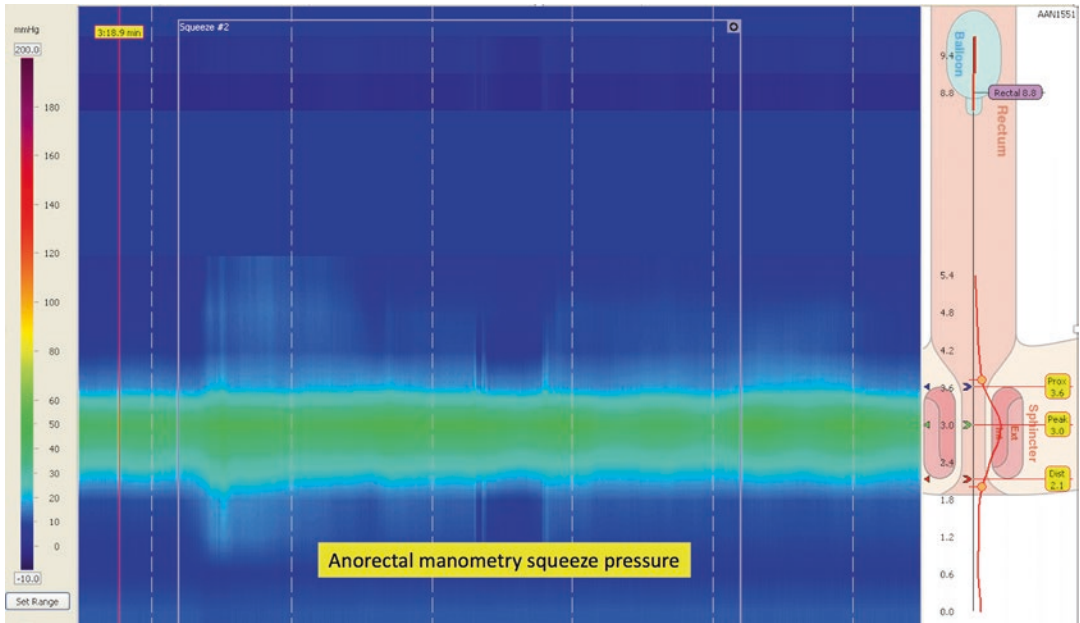
**Fig. 13.1** Endoanal ultrasound demonstrating anterior internal and external sphincter injury. (Photo credit: Dr. Yan Zhao)







**Fig. 13.2** Anorectal manometry resting pressure. (Photo credit: Dr. Yan Zhao)



**Fig. 13.3** Anorectal manometry squeeze pressure. (Photo credit: Dr. Yan Zhao)

## Intraoperative Factors

### Transanal Excision (TAE)

Anal dilatation and the utilization of an anoscope present the first potential impacts on the sphincter mechanism during transanal surgery. The duration of anoscopic use and the degree of stretch depend upon the size, location, and complexity of the rectal tumor, to allow for adequate exposure. Uncontrolled manual anal dilatation has been associated with loss of continence in close to 27% of patients undergoing anorectal excisional surgery [12]. Stretch of the internal anal sphincter or excision of a portion of IAS may contribute to postoperative loss of function [13].

van Tets et al. looked at the effect of utilizing the Parks' anal retractor for non-sphincter dividing procedures, studying both preoperative and postoperative manometric readings [14]. Postoperative mean resting pressures at 6 weeks decreased by 23% after the use of the anal retractor compared with 8% when the retractor was not used ( $p > 0.05$ ). After 12 weeks, the mean resting pressure remained significantly lower in the group where the retractor was utilized ( $p = 0.01$ ). This suggests a negative effect by the anoscope on the IAS, as the IAS is largely responsible for resting pressure.

Fenech and colleagues studied 84 patients with benign and malignant tumors, evaluating continence status and health-related quality of life after TAE [15]. Utilizing preoperative endoanal ultrasonography, Wexner Continence Scale, and FIQL, the authors found that continence status significantly worsened after TAE. Unfortunately, postoperative ERUS was not performed to indicate whether injury to the sphincter mechanism occurred. Patients who had undergone preoperative radiation therapy experienced the worst changes in continence, resulting in similar postoperative symptoms to those undergoing low anterior resection.

However, some patients experienced an improvement in continence after excisions of large villous tumors, as these lesions created partial obstruction (i.e., outlet dysfunction) and often exhibit increased mucus production.

Interestingly, the loss of function was not associated with a decrease in QOL. They postulated that the maintenance of QOL may be attributed to the fact that small changes in continence did not significantly change FIQL scores. Symptoms, such as obstruction, bleeding, mucus production, tenesmus, and urgency, may have been alleviated, leading to an improvement in QOL. Alternatively, some patients may have experienced psychological relief following tumor excision, despite the decline in sphincter function.

### Transanal Endoscopic Microsurgery (TEM)

The development of transanal endoscopic microsurgery (TEM) by Buess in 1983 expanded the capacity for transanal excisional surgery, especially for tumors in the mid and upper rectum [16]. While TEM has allowed for more precise excisions of rectal lesions, the effect of the technology on anorectal function warrants close attention.

### Effect on Sphincter Complex

Utilizing a 4-cm wide specialized rectoscope, the TEM procedure produces a sustained and controlled anal dilatation to allow for insufflation and visualization of the rectal vault. Although the insertion of the device entails a gradual dilatation of the sphincter complex, several studies have demonstrated that significant changes to the width and length of the sphincter muscle occur following the use of the TEM rectoscope [9]. In a study of 106 consecutive patients undergoing TEM for both benign and malignant rectal lesions, endoanal ultrasound (EUS) was used to preoperatively and postoperatively evaluate the sphincter complex. Injuries were noted in 29.2% of patients at 1 month following surgery. It is unclear whether the injuries were due to rectoscope use or the extent of resection. A significant change in IAS width was noted 1 month from surgery ( $p = 0.0008$ ), although it appeared to

have resolved at the 4-month postoperative mark ( $p = 0.05$ ). In fact, only 6.6% of patients were noted to have EUS abnormalities at the later evaluation. Interestingly, no reports of incontinence occurred, despite the noted disruptions in the sphincter muscle.

These findings were corroborated by a study from Allaix et al. in which 100 patients were followed after TEM, utilizing manometry, incontinence scores, and quality of life scores [17]. Thirty percent of patients had decreased postoperative anorectal resting pressures at 3 months following surgery, but all had completely returned to preoperative baseline pressures by 12 months. Initial decreases in manometric measurements were not correlated to the length of the operation or the distance of the tumor from the anal verge. No significant decline in QOL was found at 12 and 60 months, despite transient reports of fecal urgency that gradually improved by the 60-month mark.

These findings suggest that the TEM procedure likely stretches or fractures the sphincter complex, but that continence is contingent upon other factors besides IAS integrity [3, 7, 11, 18]. Other studies have suggested that female sex, age, length of surgery, location of rectal tumor, low preoperative anal resting pressure, and extended full-thickness excisions are associated with postoperative incontinence [6, 19, 20]. However, the majority of these studies demonstrate a resolution of symptoms over a discrete amount of time. Fairly consistently, these univariate and multivariate analyses have not indicated patient or operative factors that directly lead to loss of anorectal function following TEM.

### Fecal Incontinence Scores

Incontinence scores and quality of life following TEM have been investigated in multiple studies [6, 7, 17, 19, 21, 22]. Cataldo and colleagues performed one of the first studies evaluating continence and QOL after TEM [21]. In their prospective study involving 41 patients, no significant increase in number of daily bowel movements and no loss of ability to defer defecation were noted after surgery. In addition, FIS1 and

FIQL questionnaires revealed no significant changes in continence and little impact on QOL. Similar to previously mentioned studies, continence changes did not correlate with length of surgery, location within the rectum, nor the size of the rectal lesion.

### Effects of Chemoradiation on TEM Outcomes

An increase in FI has been observed following TEM after preoperative radiation therapy [20, 23]. Poor wound healing, suture dehiscence, and older age have been suggested as contributors to poor anorectal function following excision in this setting. A study by Habr-Gama et al. evaluated patients who were enrolled in a “watch and wait” protocol following neoadjuvant chemoradiation for rectal cancer. The patients that underwent subsequent TEM for local excision experienced significantly lower resting pressures ( $p < 0.001$ ), squeeze pressures ( $p = 0.004$ ), and rectal capacity ( $p = 0.002$ ). This particular cohort of patients also reported significantly worse incontinence and quality of life as measured by questionnaires.

A corroborating study by Gornicki et al. demonstrated worse functional outcomes after chemoradiation therapy followed by full-thickness local excision compared to those who underwent chemoradiation alone [24]. These findings were comparable to the functional outcomes following radical resection via proctectomy. The majority of the manometric measurements, incontinence scores, and QOL scores were within normal ranges when chemoradiation therapy alone was given, suggesting that there is probably a compounding effect of neoadjuvant treatment when combined with TEM/full-thickness local excision resulting in poorer anorectal function.

### Transanal Minimally Invasive Surgery (TAMIS)

First described in 2009, transanal minimally invasive surgery (TAMIS) emerged as a more accessible and affordable option to supplant TEM

[25]. Given the well-demonstrated advantages of TEM over traditional transanal excision, proponents of TAMIS have quickly gained a substantial experience with the technology and have shown comparable results to TEM [26, 27]. Functional outcomes and quality of life data following TAMIS have not been well-studied given the relatively short amount of time the technology has been utilized, but several small studies exist which address these topics.

Reporting on their initial experience in 37 patients with benign and early malignant rectal lesions, Schiphorst and colleagues were the first to investigate short-term functional results following TAMIS [28]. Fecal Incontinence Severity Index (FISI) scores were obtained preoperatively and postoperatively at 3, 6, 9, and 12 months. A significant decline in mean FISI scores was observed (10 pre-TAMIS vs. 5 post-TAMIS;  $p = 0.02$ ), suggesting an improvement in continence following surgery. Specifically in patients with decreased preoperative continence, postoperative FISI scores were significantly lower (21 pre-TAMIS vs. 9 post-TAMIS;  $p = 0.001$ ). Although postulated that FISI scores improved in those with low-lying rectal lesions that produced excessive mucus, univariate analysis revealed no independent factors associated with change in FISI score.

A study by Verseveld et al. investigated similar parameters in a prospective study involving 24 patients but also included quality of life measurements [22]. Mean FISI scores decreased overall, although a number of patients (21%) experienced a minor deterioration in FISI score. Contrary to the findings of Schiphorst, patients who had an increased FISI score post-TAMIS local excision had a significantly shorter distance of the tumor to the dentate line (4.4 vs. 7.4 cm;  $p = 0.04$ ) and had larger tumors (21 vs. 9cm<sup>2</sup>;  $p = 0.05$ ).

Improvements in quality of life were seen after TAMIS excision in this study. Utilizing FIQL scores to assess change following surgery, the authors found an improvement in the subscale "coping behavior." Similar to the previously mentioned study, no correlation could be made between distance of the tumor to the dentate line

and the size of tumor. Better general quality of life scores were also noted and proposed to be associated with an alleviation of tumor symptoms, although this was not demonstrated specifically on the questionnaires.

Longer-term functional results were evaluated by Clermonts and colleagues, assessing FISI scores at 1-year and 3-year post-TAMIS [29]. Forty-two patients were followed after TAMIS local excision of benign and early-stage malignant rectal neoplasms. FISI scores were noted to diminish at 1-year post-TAMIS (8.3 pre-TAMIS vs. 5.4 post-TAMIS) but rebound significantly higher at 3 years following surgery (5.4 pre-TAMIS vs. 10.1 post-TAMIS;  $p = 0.01$ ). Of those with normal continence prior to TAMIS, 63% experienced a decline in anorectal function at 3 years. Univariate and multivariate analyses did not reveal any significant variables that resulted in either an improvement or decline of FISI scores at these follow-up intervals. The authors emphasize that short-term results of both their study and the prior studies suggest that TAMIS has no detrimental effect on continence; however, longer-term results indicate poorer outcomes. Multiple hypotheses exist regarding the etiology of the deterioration of function – i.e., tumor size, location, extent of resection, age of patient, stretch of sphincters with platform placement, and total amount of operating time (>2 hours) – but no statistically significant contributors to functional decline have been identified [7, 17, 20].

Although a small study of ten patients, Karakayali and colleagues used preoperative and postoperative anal manometry and Cleveland Clinic Incontinence Score (CCIS) to evaluate anorectal function after TAMIS [30]. Resting pressure, maximum squeeze pressure, squeeze endurance, minimum rectal sensory volume, and rectoanal inhibitory reflex during cough were recorded. Manometry readings and CCIS were normal preoperatively for all patients. At the 3-week follow-up, CCIS declined in one patient (0 pre-TAMIS vs. 3 post-TAMIS), although it was resolved by 6 weeks following surgery. Despite maintaining continence, mean minimum rectal sensory volume was significantly decreased

at 3 weeks after surgery ( $p \leq 0.004$ ). A possible explanation for the change in rectal sensory volume is the resulting inflammation and fibrosis following full-thickness excision. This notion may support the etiology of longer-term dysfunction that was noted by Clermonts et al. [29]. A larger and more comprehensive study is warranted to corroborate this hypothesis.

## Conclusions

Functional outcomes following local excision for rectal neoplasms are important measurements for assessing risk of the procedure and for obtaining appropriate informed consent. While safety, feasibility, and oncologic soundness of transanal surgical approaches have largely been the focus of early studies involving TEM and TAMIS, a shift toward investigating the effects of newer technology on anorectal function and quality of life has occurred. The insertion and utilization of either an anoscope or a minimally invasive platform can affect the sphincter complex and potentially cause postoperative dysfunction. Careful consideration to preoperative functional status is warranted to avoid exacerbation of existing continence issues and for setting appropriate expectations for potential disturbances in continence and quality of life in the postoperative setting. Size of tumor, location within the rectum, extent of resection, duration of surgery, age, and female gender have been postulated to affect functional outcomes; however, no robust data exist to uniformly vilify any preoperative or intraoperative factor. There is a singular exception: Patients who have received chemoradiation therapy prior to transanal excision have been shown to have an elevated risk for postoperative anorectal dysfunction [23, 31, 32]. While injury to the sphincter complex and rectal wall is possible during transanal excisional surgery, the majority of continence and quality of life data demonstrate acceptable results and support the use of transanal surgical approaches over traditional proctectomy when oncologically appropriate.

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# Oncologic Outcomes for Local Excision of Rectal Neoplasia

# 14

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## Introduction

The treatment of rectal cancer with total mesorectal excision (TME) represents the best chance of cure; however, it is associated with significant morbidity and poor functional outcome [1]. Local excision is ideal for benign pathology, such as adenomas that are otherwise endoscopically unresectable, thus avoiding the need for radical resection. Curative-intent local excision can also be performed for patients with early rectal cancer without adverse pathologic features. Local excision has emerged as an appealing alternative to

TME because of the benefits of decreased post-operative morbidity and faster recovery, superior functional outcomes, and avoidance of a stoma. However, the indications for local excision are expanding, especially with the addition of neoadjuvant or adjuvant chemoradiotherapy. This chapter will review the oncologic outcomes of local excision for benign and malignant rectal neoplasms.

## Local Excision for Benign Pathology

Outcomes after local excision for large rectal polyps are highly dependent on margin status (Table 14.1). Recurrence rates are minimal in the presence of an R0 resection and may be as high as 40% if there is residual disease. There is still debate in the literature regarding the need for partial- versus full-thickness local excision for benign pathology [10]. It is the authors' practice to routinely perform full-thickness excision regardless of indication due to the important percentage of patients that will have unexpected pathology that upstages lesions from premalignant to malignant. Bach et al. reported that an initial partial-thickness excision was independently associated with positive margins [11]. Furthermore, full-thickness excision can be curative if malignancy is found in the specimen, as long as there are no adverse pathologic features. There are few large studies that have reported

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**Table 14.1** Outcomes after local excision for rectal adenomas

Study	N	Mean FU	R1/2 rate	Recurrence	Mean time to recurrence
Allaix et al. (2012) [2]	233	Median 110 mos	11.1%	Overall: 5.6% + margin: 23.1% – margin: 3.4%	Median 10 mos (range 4–33)
Barendse et al. (2018) [3]	89	24 mos	34% (R1 16%, Rx 18%)	Overall: 11%	Median 12 mos (IQR 7–21)
Guerrieri et al. (2006) [4]	530	Median 44 mos	NR	Overall: 4.3%	13% after 3 mos 34.8% after 6 mos 43.5% after 21 mos 8.7% after 18 mos
Amann et al. (2012) [5]	103	21.8 mos	NR	Overall: 6.8%	NR
Tsai et al. (2010) [6]	120	24.5 mos	NR	Overall: 5.0%	NR
McCloud et al. (2006) [7]	75	Median 31 mos	37.3%	Overall: 16.0% + margin: 35.7% – margin: 4.3%	NR
Ramirez et al. (2009) [8]	149	43 mos	5.8%	Overall: 6.0% + margin: 28.2% – margin: 4.3%	20.8 mos (range 12–112)
Whitehouse et al. (2006) [9]	146	39 mos	4.5%	Overall: 4.7% + margin: 40.0% – margin: 4.4%	23.3 mos (range 5–48)

outcomes for local excision using the TAMIS platform for benign rectal adenomas [12]. However, Lee et al. demonstrated that resection quality is similar between TAMIS and TEM, as there was no difference in the incidence of specimen fragmentation and margin involvement between these two platforms as long as a full-thickness excision is performed [13].

## Local Excision for Malignant Pathology

Early rectal cancer can be managed by local excision instead of TME surgery in carefully selected patients (Table 14.2). These patients, who have well-to-moderately differentiated clinical T1 tumors with the absence of lymphovascular and perineural invasion, are at the lowest risk of lymph node metastasis and local recurrence and therefore are amenable for local excision with curative intent. While oncologic outcomes after radical surgery (i.e., TME) for T1 tumors are excellent, with 5-year survival approaching 90% [16–18], TME is also associated with significant perioperative complications and long-term functional impairments [19, 20]. The lower perioperative

**Table 14.2** Indications for curative-intent local excision for early rectal cancer [14, 15]

Less than 30% of the bowel
Less than 3 cm in size
Mobile
T1 only (without high-risk features)
Absence of lymphovascular (LVI) and perineural (PNI) invasion
Well or moderately differentiated
No evidence of lymphadenopathy on preoperative staging investigations

morbidity and mortality, as well as the improved functional outcomes associated with local excision, should be balanced against the potentially higher risk of recurrence. Several studies have reported lower postoperative morbidity and similar long-term outcomes between local excision and radical resection for T1 rectal adenocarcinoma. In the only published randomized clinical trial, Winde et al. randomly assigned 52 patients with well-to-moderately differentiated T1 tumors to TEM versus anterior resection [21]. The TEM group had fewer complications and equal survival outcomes, but this study was limited by the small sample size and was underpowered to detect any real differences in these outcomes.

Other published meta-analyses have reported significantly lower postoperative morbidity (8.2% vs. 47.2%,  $p = 0.01$ ) and mortality (0% vs. 3.7%,  $p = 0.01$ ) for local excision by TEM compared to TME [22]. These pooled analyses also demonstrated higher risk of local recurrence for TEM compared to radical resection, but without any differences in disease-free or overall survival [22–24]. In the subgroup of “low-risk” T1 cancers (well-to-moderate differentiation, absence of lymphovascular invasion), the incidence of recurrence was similar between TEM and radical surgery (4% vs. 3%), but for “high-risk” T1 tumors (poor differentiation or presence of lymphovascular invasion), TEM had significantly higher rates of local recurrence (33% vs. 18%) [24]. Quality of life is also superior in patients undergoing TEM compared to radical surgery for early rectal cancer. In a study by Lezoche et al., the quality of life impairments (using the EORTC QLQ-C30 and -CR38) after TEM local excision persisted only for 1 month postoperatively, whereas these impairments remained up to 6 months after laparoscopic TME [25]. However, quality of life measures returned to baseline at 1 year in both groups. Other studies have demonstrated similar results, but with a higher incidence of defecation problems in patients undergoing radical surgery [26].

The main limitation of local excision is the inability to pathologically assess the draining nodal basins; therefore careful selection of patients is necessary. T1 lesions have a 5–10% risk of harboring nodal metastases depending on other histological features [27]. Kikuchi et al. showed that further division of T1 cancers into three levels of submucosal invasion also correlates with the risk of nodal involvement (Sm1 0–3%, Sm2 8–11%, Sm3 11–25%) [28]. An analysis of T1 tumors undergoing radical excision from the Surveillance, Epidemiology, and End Results database reported that tumors over 1.5 cm in size which exhibited poorly differentiated histology were at significantly higher risk of nodal involvement [29]. Moreover, a meta-analysis of 23 studies including 4510 patients found that T1 tumors with >1 mm invasion into the submucosa (OR 3.87, 95% CI 1.50–10.00), lymphovascular

invasion (OR 4.81, 95% CI 3.14–7.37), and poor differentiation (OR 5.60, 95% CI 2.90–10.82) were independent risk factors for lymph node metastasis [30]. Finally, Bach et al. reviewed prospectively collected data from 21 regional centers in Great Britain and Ireland and found that larger tumors, depth of invasion beyond sm1, and lymphovascular invasion were independent predictors of local recurrence after local excision of rectal cancer [11]. Patients with any of these risk factors should not undergo curative local excision, or if these features are found on final pathology after local excision, radical surgery should be recommended. The risk of nodal metastases progressively increases with T stage [31]. T2 lesions have a 25% risk of lymph node involvement [31]. Current society guidelines also deem local excision an acceptable definitive treatment option for patients with more advanced disease who are medically unfit for radical surgery [14].

### Quality of Local Excision

Local excision can be performed using several different methods. Upon introduction, local excision was performed using Parks transanal excision (TAE) technique, which utilized traditional surgical retractors and instruments to expose and resect tumors in the distal rectum. TAE can be technically challenging and lacks precision due to poor visualization and exposure of more proximal rectal lesions or larger tumors but remains a commonly performed procedure. Moreover, specimen fragmentation occurs in up to 24–35% of cases, and negative margins can be a challenge [32–34]. Clear margins have been reported to be as low as 50–70% with TAE [32–34]. Multiple case series demonstrated local recurrence rates of 8–26% for T1 lesions, 18–47% for T2 lesions with 5-year disease-free survival (DFS) ranging from 72% to 87% for T1 lesions, and 54–65% for T2 lesions [35–39]. In the context of these data, it is not surprising that local excision was initially reserved for palliation or patients who were medically unfit to undergo radical surgery.

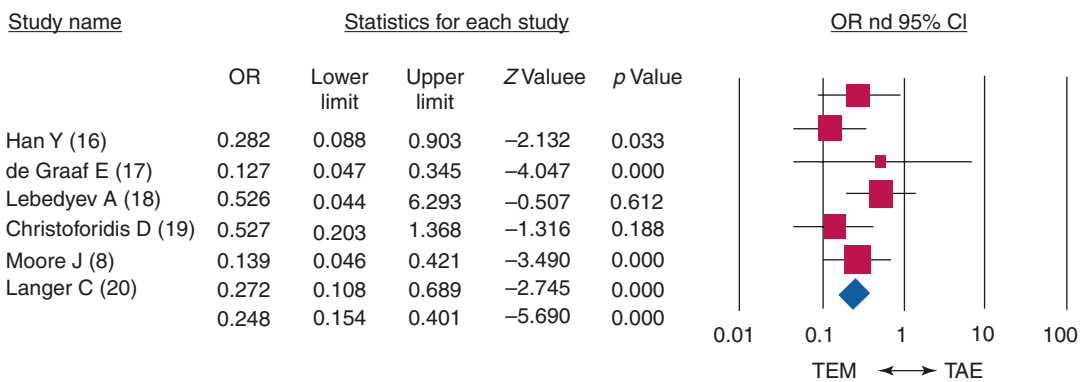
The advent of transanal endoscopic surgery with transanal endoscopic microsurgery (TEM)

and transanal minimally invasive surgery (TAMIS) platforms has greatly improved the quality of local excision. Buess et al. published their single-center data reporting improved local recurrence rates of 4–10% and 5-year DFS of 96–100% for T1 lesions [40]. The improvement in oncologic outcomes was credited to better visualization due to the magnified view provided by the laparoscopic camera and a more precise technique established with pneumorectum and laparoscopic instruments [21, 41–45].

A recent systematic review and meta-analysis, which included 6 studies and 927 local excisions, found no difference in the rate of postoperative complications but reported a higher rate of negative margins (OR 5.28, 95% CI 3.20–8.71), lower rate of specimen fragmentation (OR 0.10, 95% CI 0.04–0.21), and fewer local recurrences (OR 0.25, 95% CI, 0.15–0.40) following TEM compared with TAE (Fig. 14.1) [46]. As a result of improvements in the quality of local excision, excellent oncologic outcomes can be obtained with TEM in carefully selected patients and meticulous surgical technique. In a meta-analysis comparing local excision (subgrouped by TAE and TEM) and radical resection for early rectal cancer, disease-free and overall survival was worse for local excision in the TAE vs. radical surgery comparison, but no differences were found between local excision and radical surgery in the TEM subgroup [24]. These data suggest

that local excision using TAE should be largely abandoned [47]. However, local recurrence remained higher after local excision compared to radical surgery for both TAE and TEM, thus stressing the importance of careful patient selection. Data from the multi-institutional Association of Coloproctology of Great Britain and Ireland TEM Collaboration identified submucosal depth of invasion, T-stage size, lymphovascular invasion, poorly differentiated histology, and elderly patients (>80 years) to be predictive of local recurrence following TEM [11]. Advanced T stage was also associated with increased local recurrence and worse disease-free survival (Table 14.3 and Fig. 14.2).

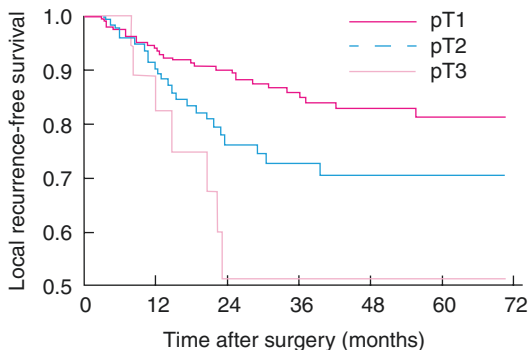
TAMIS is similar to TEM but uses a soft operating platform and standard laparoscopic instrumentation. First described in 2010, large series with long-term follow-up are lacking. Lee et al. reported outcomes after the first 200 cases with a mean follow-up of 14.4 months [48]. The quality of excision was similar to large TEM series, including 7% margin positivity and 5% specimen fragmentation rate. In patients with rectal adenocarcinoma, the incidence of local recurrence was 6% with a mean time to recurrence of 16.9 months. Cumulative 1-, 2- and 3-year disease-free survivals were 96%, 93%, and 86%, respectively. There have been few direct comparisons between the different transanal endoscopic surgery platforms. A multi-institutional matched cohort study



**Fig. 14.1** Meta-analysis of TEM vs. TAE for lesion recurrence.  $N = 918, p < 0.001$ . TAE traditional transanal excision, TEM transanal endoscopic microsurgery. (Adapted from Clancy et al. 2015 [46])

**Table 14.3** Local recurrence and disease-free survival after local excision by T stage

	Year	N	Local recurrence (%)			5-year disease-free survival (%)		
			T1	T2	T3	T1	T2	T3
<i>Multicenter</i>								
Bach [11] UK	2009	424	18	29	>50	~85	~70	~50
Baatrup [71] Denmark	2009	143	13	26	100	94 v 84	70	
<i>Single center</i>								
Zacharakis [72] UK	2007	28	7	43	67			
Bretagnol [73] UK	2007	52	9	11	75	81	79	
Maslekar [74] UK	2007	52	0	14				
Stipa [75] Rome	2006	44	8	9		100	70	
Lee [43] Korea	2003	52	4	19		96	80	

**Fig. 14.2** Kaplan–Meier estimates of local recurrence-free survival in 361 patients after transanal endoscopic microsurgery for rectal cancer.  $P < 0.001$ , logrank test. pT pathological tumor stage. (Adapted from Bach et al. 2009 [11])

included three high-volume centers, one that used TAMIS and two that used TEM [13]. Of 428 match patients, TAMIS was associated with shorter operative time and length of stay. However, margin positivity (7% vs. 6%,  $p = 0.65$ ), lesion fragmentation (4% vs. 3%,  $p = 0.25$ ), 5-year disease-free survival (78% vs. 80%,  $p = 0.82$ ), and local recurrence (7% vs. 7%,  $p = 0.86$ ) were similar regardless of approach, TAMIS vs. TEM, respectively [13]. This study demonstrated that high-quality local excision with excellent oncologic outcomes for early rectal cancer can be equally achieved using either TAMIS or TEM.

### Local Excision for More Advanced Tumors

With the limitations in T staging with the current locoregional imaging modalities, there may be an important percentage of patients that will be understaged or will have adverse prognostic features on final pathology. Completion radical excision should be performed for these cases within a short interval of the initial local excision. The ideal time interval for completion surgery is not clear [49]. It is generally recommended to perform the completion surgery within 30 days. It may be important to wait for endoscopic healing prior to excision, but an interval more than 7 weeks may also be associated with worse TME resection quality [50]. Perioperative outcomes appear to be similar between completion TME after local excision and up-front TME [51, 52], and oncologic outcomes have not been shown to be compromised [42, 53]. In a systematic review of 10 studies with 262 completion TMEs, local recurrences occurred in 6%, which compares favorably with up-front TME [49]. Redo local excision is not recommended in this setting and is associated with local recurrence rates up to 18% [49]. However, certain select patients that refuse more invasive surgery or who are medically unfit can be considered for adjuvant chemoradiotherapy, although there are no level I data to support

this management strategy. Adjuvant radiotherapy with or without chemotherapy may result in adequate local control [54, 55], but oncologic outcomes are still inferior to radical resection. Long-term follow-up of the Cancer and Leukemia Group B (CALGB) 8984 trial reported 10-year local recurrence rates for T2 lesions treated with local excision and postoperative chemoradiation were high at 18% compared to 8% for T1 lesions treated with curative intent local excision [38]. Disease-free and overall survival was also lower for the T2 lesions despite chemoradiotherapy. A pooled analysis of 14 studies including 405 patients treated by local excision with salvage adjuvant chemoradiotherapy and 7 studies with 130 patients treated with local excision followed by radical surgery reported that the weighted local recurrence rate for local excision with adjuvant chemoradiation was 10% (95% CI 4–21) for high-risk T1 compared to 6% (95% CI 3–15) for local excision with radical surgery [56]. In patients with T2 lesions, the weighted local recurrence was 15% (95% CI 11–21) for adjuvant chemoradiation compared to 10% (95% CI 4–22) for radical surgery.

With the increasing awareness of the functional impairments and high morbidity after TME surgery, there is significant interest for organ preservation for patients with cT2 lesions. However, locoregional recurrence for T2 tumors is high, ranging from 13% to 30% [36, 57, 58] which is likely secondary to the 30–40% incidence of occult nodal involvement [59]. Therefore, local excision alone for T2 lesions is insufficient. Administration of neoadjuvant chemoradiation prior to local excision may be a potentially viable management strategy for patients with T2 lesions who wish to avoid radical TME surgery.

Lezoche et al. randomly assigned 100 patients with T2N0M0 tumors less than 3 cm within 6 cm of the anal verge that underwent neoadjuvant long-course chemoradiation to local excision by TEM versus laparoscopic TME. There was favorable tumor downstaging in both groups, with 28% in the TEM and 26% in the surgery arm achieving ypT0. After a long-term follow-up, local recurrence was similar for both arms (TEM

12% vs. surgery 10%,  $p = 0.686$ ), as was cancer-related (89% vs. 94%,  $p = 0.687$ ) and overall (72% and 80%,  $p = 0.609$ ) survival. The ACOSOG Z6041 phase II trial also investigated preoperative chemoradiation followed by local excision for patients with clinical T2 N0 tumors [60]. Of the 77 patients that completed the preoperative regimen and underwent local excision, 64% experienced tumor downstaging with 44% overall achieving a pathologic complete response [61]. At 3-year follow-up, only 4% of patients experienced local recurrence, and 6% experienced distant metastasis, resulting in a cumulative 3-year disease-free and overall survival of 88.2% and 94.8%, respectively. The GRECCAR 2 trial also demonstrated similar oncologic outcomes between 148 patients with pretreatment cT2/3 tumors and good response to neoadjuvant chemoradiotherapy that were randomly assigned to local excision or TME surgery [62]. The trial protocol required patients in the local excision group to subsequently undergo TME surgery if final pathology demonstrated ypT2-3 or R1 disease. Three-year local recurrence (5% vs. 6%,  $p = 0.68$ ), disease-free (78% vs. 76%,  $p = 0.45$ ), and overall survival (92% vs. 92%,  $p = 0.92$ ) were similar between the local excision and TME surgery arms, but 36% of patients in the local excision arm underwent subsequent TME surgery for adverse pathology.

While these data appear promising, the success of this neoadjuvant chemoradiation followed by local excision for more advanced tumors is dependent on the tumor response. Local recurrence is high in these patients if a pathologic complete response is not obtained after preoperative chemoradiotherapy [63]. Although local recurrence is 4.0% (95% CI 1.9–6.9) in patients with ypT0, the incidence of local recurrence increases with more advanced T stages. In patients with ypT1, local recurrence is 12.1% (95% CI 6.3–19.4), but in tumors  $\geq$  ypT1, the incidence was 21.9% (95% CI 15.9–28.5). Similarly, distant metastasis occurred in 2.8% (95% CI 0.8–6.1) for ypT0 and 20.9% (95% CI 14.7–27.9) for  $\geq$  ypT1 tumors. These findings are likely explained by the high incidence of residual nodal involvement (>20% of ypT1/2 tumors)



[64]. Furthermore, Perez et al. demonstrated that patients with cT2–4N0M0 that do not result in complete clinical response after chemoradiation are likely to exhibit unfavorable histology (ypT2 or 3 in at least 66%) [65]. These data suggest that local excision alone after neoadjuvant chemotherapy in patients without complete clinical or pathologic response would result in understaging and undertreatment in a significant proportion of patients, thus tempering enthusiasm for this approach.

### Recurrence After Local Excision

Local recurrence after local excision usually occurs within the first 1–2 years after resection [49]. Initial data has suggested that local recurrences after local excision were often advanced and required multivisceral resection to obtain clear margins [66–68]. Oncologic outcomes were poor in these patients and not equivalent to those undergoing up-front radical resection. Conversely, recent studies have reported more favorable data. Patients with locally recurrent disease after TEM were eligible for curative salvage surgery in 61–88% of cases and oncologic outcomes similar to those patients that underwent up-front surgery [69, 70]. However, these data are heterogeneous and therefore difficult to interpret. Improvement in imaging modalities for staging and surveillance may allow for better patient selection for local excision. Oncologic outcomes were superior for patients with recurrences after initial T1 tumors compared to those with initial T2 tumors [49]. Furthermore, Weiser et al. reported that higher 5-year survival was associated with luminal recurrences, low CEA, absence of lymphovascular and perineural invasion, and R0 margins at salvage [66].

### Summary

Oncologic outcomes of local excision for rectal neoplasia are similar to radical TME surgery in carefully selected patients. Patients with early rectal cancer, i.e., those with well-differentiated

T1sm1N0 tumors without lymphovascular invasion or perineural invasion, have the best results with curative-intent local excision. The quality of local excision will also translate to superior oncologic outcomes. Transanal endoscopic surgery platforms, including TEM and TAMIS, likely result in better resection quality compared to traditional transanal excision. Organ preservation techniques involve perioperative chemoradiation, and local excision may be a viable treatment strategy for patients with more advanced tumors that refuse or are medically unfit to undergo TME surgery. Careful patient selection and high resection quality are essential to optimize the outcomes of local excision for rectal neoplasia.

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# Applications Beyond Local Excision

# 15

Deborah S. Keller

## Introduction

Transanal minimally invasive surgery (TAMIS) is an advanced videoscopic endoluminal platform that blends single-incision laparoscopy with local excision techniques. TAMIS was first introduced by Sam Atallah et al. in 2009 as an alternate transanal endoscopic platform to transanal endoscopic microsurgery (TEM) [1, 2]. Since its inception, TAMIS has been used increasingly worldwide as an alternative to traditional transanal excision and transanal endoscopic microsurgery for local excision of benign and early-stage rectal cancers in the distal and mid rectum [3]. The TAMIS platform offers specific value of a superior magnified high-definition 360° view of the rectum with stable insufflation for more precise dissection and resection. For rectal cancers, these benefits translated to greater resection precision, a higher rate of negative margins, lower rates of specimen fragmentation, and lower lesion recurrence compared to traditional transanal excision [4, 5]. TAMIS also has benefits over other advanced videoscopic platforms, such as transanal endoscopic microsurgery (TEM), in that there is no capital investment for equipment, specialized instruments, set-up time, learning curve, and device-related risk of anal sphincter trauma that could negatively impact

postoperative anorectal function [1, 2, 4, 6–8]. With experience, the platform evolved beyond rectal mass excisions, and the utility continues to grow. In this chapter, we review several applications of TAMIS beyond local excision, for performing established procedures in a minimally invasive transanal approach, facilitating new technology and the development of new approaches, and managing complications.

## TAMIS for Colorectal and Pelvic Procedures

The improved visualization, access to the pelvic, and minimally invasive approach are a catalyst to expand the TAMIS approach to perform procedures other than simply excising rectal lesions. Safety is always paramount, and the risks and benefits of a new approach are carefully weighed before entering into safety and feasibility trials. In innovative hands, the applications of TAMIS are nearly limitless. Here, we describe the use of TAMIS to perform specific colorectal and pelvic procedures.

## The TAMIS-Ileal Pouch-Anal Anastomosis (TaIPAA)

The TAMIS-ileal pouch-anal anastomosis (TaIPAA) is an ideal procedure for extending the bounds of the TAMIS platform past rectal tumor

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excisions, and the feasibility and outcomes have been described [9, 10]. The specific benefits for a TaIPAA include avoiding the most difficult part of the operation—the difficult dissection of the distal rectum by approaching the pathology from *below* and potentially reducing the risk of anastomotic leakage with the precise, hand-sewn anastomosis instead of multiple firings of the stapler [10]. For the procedure, a total abdominal colectomy with an end ileostomy is performed using a single-incision or multiport laparoscopic technique. The ileostomy site is used as the extraction site for the specimen. The patient is positioned in modified lithotomy for the transanal completion proctectomy and restorative stage. The ileostomy is detached through a circumstomal incision, and a stapled pouch is created through the ileostomy site after full mobilization of the small bowel and mesenteric root using a single port with three cannulas and returned to the abdominal cavity after the anvil is inserted and secured. An 18-French catheter is secured on the tip of the anvil to facilitate positioning from the transanal side. The focus is then shifted to the transanal portion. The anus is everted with a LoneStar retractor for greater exposure (CooperSurgical, Trumbull, CT, USA), and a purse string is placed and tied at ~3 cm above the dentate line, cautery is used to circumferentially mark 2 cm distal to the purse string, and a transmural, circumferential incision is then made just distal to the purse string. After the initial distal rectal wall is incised, the TAMIS port—GelPOINTPath transanal platform (Applied Medical, Santa Margarita, CA, USA)—is placed in the anus, and stable insufflation is obtained with the AirSEAL® System (Conmed, Inc., Utica, NY, USA). A circumferential rectal dissection is performed with a vessel sealer, and the rectum is extracted through the stoma site. The 18-French catheter on the pouch anvil is grasped and retracted through the anus. A purse string is placed at the free edge of the distal rectal cuff, the pouch is then pulled into the rectal cuff, and the purse string is secured. The orientation is reconfirmed to assure the mesentery is properly oriented and that the pouch is not twisted, and the posterior vaginal wall is free anteriorly in females. Then the anvil is mated

with the shaft of the stapler, and a single-stapled anastomosis is performed. Studies have shown outcomes of a transanal ileal pouch-anal anastomosis (ta-IPAA) with TAMIS have lower odds for postoperative morbidity than laparoscopic IPAA [11].

## Pelvic Exenteration

Total pelvic exenteration utilizing TAMIS-based taTME techniques was introduced by Uematsu et al. as a potentially curative strategy in T4 locally advanced primary rectal cancer [12]. Transanal total pelvic exenteration involves en bloc resection of multivisceral pelvic organs enveloped within the visceral pelvic fascia with the objective of completing this radical resection with tumor-free distal and circumferential margins. The authors of this study advocated that the transanal approach had significant advantages including improved visibility, a broader working field than the conventional transabdominal approach, reduced blood loss, and ease in the pelvic dissection to prevent injury of the visceral pelvic fascia [13]. With the success of the transanal total pelvic exenteration, the same authors then performed a sphincter-preserving transperineal total pelvic exenteration, avoiding the double stoma. The procedure was successful, and they noted it suitable for large rectal cancers with widespread invasion to the adjacent organs within the visceral pelvic fascia and vascular ligation that would be otherwise difficult to mobilize laparoscopically [14].

## Hysterectomy with Vaginal Access Minimally Invasive Surgery (VAMIS)

Vaginal hysterectomy is among the most common gynecologic operations performed, and an incisionless procedure, making it ideal to advance the concept of natural orifice surgery. The TAMIS access channel can also be applied vaginally, extending the incisionless, minimally invasive approach into vaginal access minimally invasive surgery (VAMIS) for a hysterectomy. Atallah



et al. showed the feasibility and standardized the steps for the procedure in a cadaveric model [15]. The authors used both laparoscopic access for monitoring and transvaginal access to perform the operation. The patient was positioned in Trendelenburg, and small bowel loops were removed from the pelvis through the laparoscopic port to prevent iatrogenic injury bowel during VAMIS). Otherwise, there was no laparoscopic assistance during VAMIS hysterectomy. Next, the GelPOINT Path platform (Applied Medical, Santa Margarita, CA, USA) was inserted transvaginally, and pneumatic inflow was attained. Three 5 mm trocars were used for the procedure—an atraumatic grasper was used to provide counter tension and a hook electrocautery was used for the dissection. The authors (1) circumscribed the cervix with electrocautery, (2) entered the peritoneal cavity at the pouch of Douglas, (3) entered the vesicouterine pouch, (4) divided the cardinal ligaments with the uterine vessels, (5) divided the fallopian tube and ovarian ligaments, (6) extracted the specimen vaginally, and (7) primarily closed the vaginal cuff under direct vision [15]. The intra-abdominal monitoring showed no inadvertent injury. With the feasibility demonstrated and improvements in the ability to securely close the vaginotomy, VAMIS) for hysterectomy and movement toward complete natural orifice surgery without abdominal access has great potential and has since been utilized clinically by gynecologists [16, 17].

## Proctectomy

A completion proctectomy can be performed in patients without restoring continuity, as well. Atallah et al. described the TAMIS proctectomy in a patient with symptomatic ulcerative colitis in her rectal stump after prior subtotal colectomy 14 years previously with functional end ileostomy [18]. For the procedure, authors introduced and seated a single-port device (TAMIS port) transanally, established pneumorectum, and performed a full-thickness incision proximal to the dentate line. To work at this level, the TAMIS port was manually pulled back and manipulated

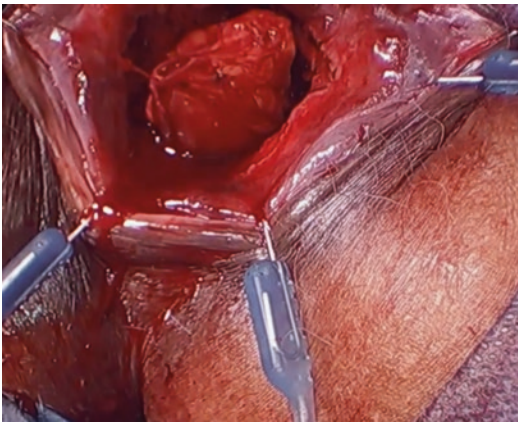
to allow access. A circumferential purse-string suture was placed around the rectum under direct vision, and an extrarectal dissection was performed until the rectal stump was circumferentially mobilized, and then the specimen was then removed transanally.

A TAMIS proctectomy can also be performed in reoperative cases. Reoperative pelvic surgery is inherently complex and fraught with complications. Using TAMIS provides great benefit to enter a hostile pelvis from “bottom-up,” thereby approaching the pathology from a clean plane. Borstlap et al. demonstrated the feasibility of TAMIS for redo pelvic surgery with a low colonic anastomosis or an ileoanal pouch in a series—14 anastomotic reconstruction and 3 completion proctectomy. The authors were able to successfully perform these complex cases with simultaneous transabdominal access in 15 patients and TAMIS alone in 2 cases. There were five patients who were readmitted, two developed an anastomotic leakage, and four developed a pelvic abscess requiring reintervention within 30 days. After a median follow-up of 9 months, intestinal continuity was restored in 71% of the patients. The authors found TAMIS was a valuable approach in redo pelvic surgery. While there was a high complication rate, this is related to the complexity of the underlying pathology and not the platform [19].

## Rectal Prolapse

Rectal prolapse is a relatively common condition with no accepted standard surgical approach described to repair, as all have considerable recurrence rates [20]. Current management follows the basic approach that frail, elderly patients are dispositioned to undergo a perineal repair, while more fit, younger patient undergo an abdominal approach. Perineal rectosigmoidectomy (or the Altemeier procedure) is a historic repair previously relegated to those unfit for an abdominal repair for high recurrence rates [21]. More recent work has shown the Altemeier procedure for rectal prolapse provides excellent results across all age

groups with minimal morbidity and recurrence rates comparable to other procedures [21]. Althoff et al. advanced the Altemeier procedure using the TAMIS platform to perform a rectopexy with rectosigmoidectomy in a patient with procidentia [22]. The authors initially follow the classic Altemeier procedure steps, with eversion of the prolapse segment, full-thickness circumferential division proximal to the dentate, dissection into the peritoneal cavity, and division of the mesentery. Instead of performing a sutured anastomosis at this point, they divided the sigmoid colon with a linear stapler. Next, a TAMIS port (GelPOINT Path Transanal Access Platform, Applied Medical, Inc., Rancho Santa Margarita, CA, USA) was introduced and pneumorectum established. They then examined the abdominopelvic cavity, identified the sigmoid colon segment serving as the neorectum and the sacral promontory, and then used absorbable tacks to fixate the bowel to the sacral promontory. The TAMIS access facilitated the fixation by providing an ideal angle. After the rectopexy, the stapled end of the sigmoid is delivered transanally, removed, and the sutured anastomosis is performed (Fig. 15.1). This approach may offer a more durable repair with the lower morbidity of a minimally invasive, transanal approach in all ages.



**Fig. 15.1** Remove of the rectum with TAMIS prolapse repair

## Parastomal Hernia

Parastomal hernias are a common problem with a significant impact on patient quality of life after stoma construction. Multiple approaches, using open, laparoscopic, and robotic platforms, have been described, with recurrence rates still leaving room for a more ideal approach to management. Furajii et al. described a combined, two-team approach for a TAMIS completion proctectomy and concomitant parastomal hernia repair with transperineal mesh fixation in a pilot series of three patients [23, 24]. The intra-abdominal adhesions and upper rectal mobilization were performed from the abdominal approach and mobilization and removal of the low and mid-rectum via the perineal TAMIS port (GelPOINT Path) after an intersphincteric dissection. The airtight transperineal access provided excellent visualization of a parastomal hernia and facilitated treatment of the synchronous pathology. A glove port was placed into the peristomal incision after mobilization of the end ileostomy, and mesh was introduced, orientated, and fixed via the transperineal access. The authors reported no perioperative complications nor were there (short-term) recurrences with this innovative technique.

## Retrorectal Masses

Primary tumors of the retrorectal (or presacral) space are often rare presacral embryologic remnants. While usually found incidentally and while the majority is asymptomatic, they may present with lower back or pelvic pain, defecatory dysfunction, and concern for malignancy, prompting resection. There is a wide range of retrorectal masses, with origins including congenital, inflammatory, neurogenic, osseous, and miscellaneous. Most are benign, but management should be undertaken by an experienced specialist. Depending on the height and location of the lesion, traditional options for resection have been a posterior parasacrococcygeal approach, an abdominal approach, or a combined abdominal and posterior approach.

TAMIS provides an alternative option for transanal resection of clinically benign retrorectal cysts with excellent exposure and visualization of the cephalad extent of the cyst, decreased risk for sacral neurologic injury, and decreased overall morbidity [25]. McCarroll et al. described the steps for TAMIS resection of a retrorectal cyst with the patient in the lithotomy position, where the contour of the lesion could be seen distorting the posterior wall of the rectum after establishing pneumorectum. The authors used a vessel-sealing device to incise through the rectal wall overlying the cyst, expose the surrounding avascular plane, and dissect the cyst free from all attachments using a hybrid TAMIS and transanal approach for the most caudal aspect. As no rectal wall was excised, the proctectomy was easily closed in one layer without tension or ischemia. While not a common procedure, TAMIS can, in select cases, provide a minimally invasive option for complete excision with rapid recovery in those patients requiring surgery.

### Robotic TAMIS

Robotic TAMIS was introduced as an alternative to help overcome the limitations of conventional TAMIS for the local excision of rectal lesions [26], but the application can be applied broadly beyond rectal lesions. Robotic TAMIS allows for greater versatility in motion while operating in the limited space of the rectum. Procedures generally use the GelPOINT Path (Applied Medical, Rancho Santa Margarita, CA, USA) TAMIS port with the patient positioned either dorsal lithotomy or in the prone jack-knife position, with three robotic arms docked from the patient's left or right side (da Vinci Xi System, Intuitive Surgical Inc., Sunnyvale, California, USA). The margins of the lesions can be marked with the robotic spatula tip cautery, and then the mucosa over the lesion is held with forceps in one hand, while the lesion is dissected and excised in the other hand. Depending on the pathology and surgeon preference, either the cautery or a vessel-sealing device can be used for the dissection. The subsequent defect can be easily sutured closed,

such as with a continuous V-Loc suture, or left open, depending on the location of the lesion and the surgeon's preference. To date, the safety and feasibility have been described for excising a variety of rectal lesions and neoplasia over a wide range of anatomical levels [26–28]. The Xi platform may allow greater intraluminal excision and suturing following excision [28]; however, the Si platform permits 5 mm instruments, which could permit more room to “move” intraluminally. Expanded options with new platforms, such as the da Vinci single-port system robotic platform (SPS) [29] and flexible robotic platforms, have the potential to access anatomy along circuitous paths [30].

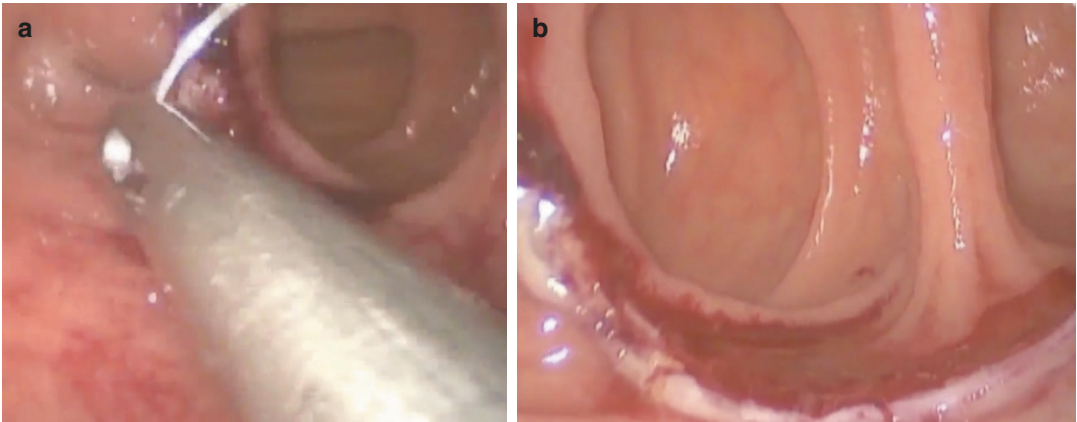
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### Managing Complications

In addition to performing stand-alone procedures, TAMIS has great utility in managing complications. The TAMIS approach allows the surgeon to perform both diagnostic and therapeutic maneuvers, with the enhanced visualization and working ports on the transanal platform. TAMIS also offers benefits, such as improved visibility and a minimally invasive, incisionless tool to approach the complication without added morbidity.

### Anastomotic Bleeding After a Colorectal Anastomosis

In reality, all stapled anastomoses bleed. Luckily, few are clinically significant enough to require intervention. In these cases, TAMIS is a valuable tool as it enables the precise localization of the bleeding site and intervention under direct visualization. Evaluating the staple line endoscopically is safe and feasible and routinely done with a colonoscope after creation to assess the integrity of the anastomosis. In our practice, we have found that addressing a bleeding staple line with the TAMIS platform is safe and feasible. With the endoscopic assessment, if there is significant bleeding, a TAMIS platform can be placed transanally and pneumorectum established to



**Fig. 15.2** TAMIS repair of staple line bleeding. (a) Visualization of the bleeding area. (b) Direct suture repair

12 mmHg. The insufflation adds benefit, as it helps reduce intraluminal venous bleeding. A 30° laparoscopic camera is then used to identify the exact location of the bleed. The 360° magnified endoscopic view can aid in visualization for the ideal repair. If needed to control the bleeding, the gal cap can be removed, and a Raytec sponge is introduced and held in place over the area of the bleeding, applying direct pressure. Using regular laparoscopic instruments, the staple line can be directly repaired, such as with a V-Loc stitch for a continuous running repair. After the repair, a suction irrigator can be used to clear any clots and assure hemostasis (Fig. 15.2).

### Anastomotic Stenosis and Strictures

Anastomotic stricture is a well-described complication after low anterior resection and more likely to occur after radiation therapy, anastomotic leakage, ischemia, and inflammation around a double-stapled anastomosis. Such factors can narrow the lumen post-anastomosis and sometimes result in the development of luminal stenosis and obstruction. Endoscopic dilation is the usual management, but in situations where the proximal lumen is not patent, TAMIS can be an alternative. Bong et al. describe the use of the TAMIS technique to manage a patient with a completely occluded lumen at a double-stapled colorectal anastomosis [31]. The authors used a

TAMIS port transanally and established pneumorectum and then punctured the blind stricture with a 21 gauge needle and injected contrast medium through the needle to fluoroscopically confirm the position of the proximal lumen. The lumen was incised by electrocautery, and fibrotic tissue was removed around the stenosis to maintain the bowel continuity. The authors reassessed the area weeks after the procedure, both digitally and using a contrast enema, confirming the patency. While unconventional, the TAMIS port allowed a minimally invasive solution to a complex problem that could otherwise have required major revisionary surgery which could have resulted in a permanent stoma.

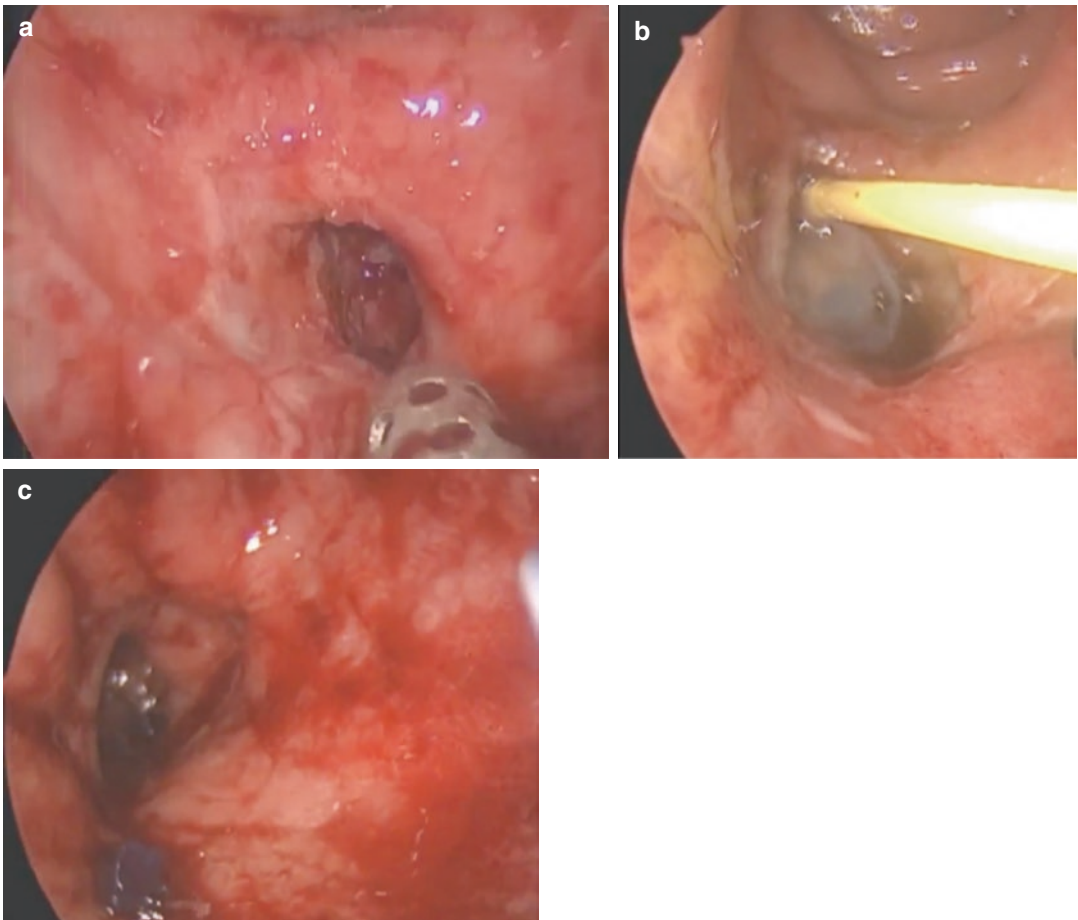
### Anastomotic Defects and Sinuses

Low anastomotic defects or sinuses are a feared complication after a colorectal or ileal pouch-anal anastomosis. Anastomotic sinuses can have a major impact on patient outcomes, and improper management can result in pelvic sepsis, often leading to loss of the pouch, and life with a permanent ileostomy. Other noninvasive means to manage an anastomotic breach, such as the use of an endo-sponge, is not feasible at the low level of an IPAA [32]. While a defunctioning loop ileostomy diminishes septic sequelae, it does not prevent leakage and anastomotic failure. When a contained leak or sinus forms, a chronically

infected presacral cavity can form along with fibrosis which negatively impact defecatory function and stoma closure rates.

A TAMIS approach can be used for low anastomotic sinuses, with excellent short-term outcomes. We advocate that the pouch-anal or colorectal anastomoses should be protected with a diverting loop ileostomy and treated if it fails to resolve with observation before intestinal continuity is restored. For the procedure, the patient is placed in lithotomy position in moderate Trendelenburg, the transanal access platform is inserted and secured, insufflation pressure is set to 12 mmHg, and pneumorectum is established. A 30° 5 mm laparoscopic camera lens is used to identify the sinus opening. The common wall

between the sinus and the bowel lumen can be divided under direct vision with a laparoscopic vessel-sealing device, and the sinus cavity can be debrided with the suction cautery wand. Depending on the quality of the tissue, it can be primarily repaired or left open (Fig. 15.3). In clinical practice, we wait 4–6 weeks after the procedure to perform a contrast enema to identify any residual anastomotic problems before ileostomy closure. In our experience, when used in conjunction with fecal diversion, TAMIS division of the common wall between the sinus and bowel lumen can effectively treat low pelvic sinuses, improving patient outcomes and function and allowing closure of the diverting ileostomy.



**Fig. 15.3** TAMIS management of an anastomotic sinus. (a) The sinus is localized. (b) The common channel is opened to the rectal lumen. (c) The defect is closed



## Urethral, Vaginal, and Bladder Fistula Repairs

Rectourethral, rectovaginal, and rectovesical fistulae represent significant postoperative or postradiation complications that are difficult to definitively treat, due to the poor quality of the tissue attempting to be repaired as well as the anatomic locale. Multiple approaches have been applied for repair, but none are considered the gold standard due to morbidity and high failure rates. A TAMIS approach allows for an incisionless, minimally invasive repair with excellent visualization in these conditions. Atallah et al. described the use of TAMIS for repair of a rectourethral fistula in patient after cryoablative treatment for prostate cancer [18, 33]. Gastrografin enema and colonoscopy were used to confirm the communication between the rectum and the urinary system. In this case, the TAMIS platform was used to repair the fistula in two layers, with separate closure of the urethral defect using an automated suturing device (Endo Stitch™, Covidien, Mansfield, MA, USA) in combination with LAPRA-TY® (Ethicon, Inc., Summerville, NJ, USA). A full-thickness rectal wall flap was then created as a second layer and primarily closed [33]. In their experience, the authors advocate considering TAMIS as modality of repair for rectourethral fistulae that are not radiation induced [33]. Tobias-Machado et al. used TAMIS for successful management of a rectovesical fistula after radical prostatectomy, performing cystoscopy with implant of guidewire through fistula, then positioning the patient in prone jack-knife position and inserting the transanal access device to identify the fistula. The authors dissected the tissue around the bladder side, closed the bladder wall and injected fibrin glue in defect, and then closed the rectal wall. They reported challenged in instrumentation and suturing, but showed the procedure was feasible with no recurrence [34].

## Foreign Body Retrieval

Rectal foreign bodies may be inserted transanally in association with sexual acts, assault, or self-treatment of constipation. When rectal foreign

body become entrapped and patients present for management, the surgeon must be cognizant that extended time may have passed before the patient reported for medical aid due to embarrassment. Attempts at extraction may have already occurred by the patient, causing spasm and possibly further trauma as sharp or breakable objects may have been used, which can be hard to retrieve and which risk perforation. In such a setting, an abdominal operation for foreign body retrieval may be required. In cases where there is no peritonitis or free air on imaging, and the foreign body is below the rectosigmoid junction, but cannot be removed with forceps, TAMIS can be considered an option for extraction before resorting to an abdominal operation [35]. With TAMIS, after the transanal platform is inserted and insufflation is achieved, laparoscopic instruments can be used to grasp and remove the foreign body. After removal, the cap can be replaced and pneumorectum reestablished to allow a high-definition magnified view of the mucosa for inspection and identification of any defects or perforations [36]; if identified, any injuries could also be directly repaired with suturing or clips through the TAMIS platform.

## TAMIS as a Bridge to taTME with Image-Guided Surgery

Stereotactic navigation allows for real-time, image-guided surgery, thus providing an augmented and potentially safer intraoperative working space [37]. With TAMIS, the technique can be applied to fixed anatomic targets. TAMIS with stereotactic navigation can be used to facilitate bringing new procedures safely into practice, such as the transanal total mesorectal excision (taTME), by helping operators map the anatomy as they ascend the learning curve. The taTME was born from the need for a technique that combined the benefits of minimally invasive abdominal surgery with the visualization and functional benefits of TAMIS and the precise distal dissection of the transanal transabdominal (TATA) bottom-up approach to the total mesorectal excision. This “reverse” proctectomy is particularly helpful in the obese male patient with a narrow pelvis, providing excellent exposure, despite the difficulty



imposed by body habitus [18]. In the learning curve for the procedure, TAMIS with stereotactic navigation can serve as a gateway for safer surgery, although this remains highly experimental and is reserved to few centers that have the expertise to perform such operations [38]. A tool such as stereotactic navigation could help surgeons implement the taTME safety into practice and potentially improve the resection quality by improving the surgeon's spatial awareness [37].

### Neuromapping with TAMIS for taTME

Sparing the extrinsic autonomic innervation of the internal anal sphincter during total mesorectal excision is important for maintaining anal sphincter function postoperatively. Kniest et al. described electrophysiologically confirming the topography of the internal anal sphincter nerve supply with TAMIS prior to a transanal total mesorectal excision in six patients with low rectal cancers. The authors described key zones of risk for pelvic autonomic nerve damage with the advantageous visualization and the ability to detect extrinsic innervation to the internal anal sphincter near the levator ani muscle with this tool [38].

### Conclusions

TAMIS is a versatile platform with proven purpose beyond local excision of rectal neoplasia. The introduction of the TAMIS has revolutionized minimally invasive surgery, and the success in rectal excisions has opened the gateway to performing more kinds of procedures through this transanal platform. With the clinical and functional benefits of the TAMIS approach, the applications of TAMIS will likely continue to evolve.

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## Introduction

The initial impetus behind robotics in surgery was telepresence and telesurgery [1, 2]. The idea was to enable surgeons to operate on patients in remote locales. In some fields of science remote, “teleoperation” is not only possible but also a proven standard, such as for manned and unmanned space craft which are managed at centralized sites including the Jet Propulsion Laboratory (Pasadena, CA) and the National Aeronautics and Space Administration (Houston, TX). In 2001, robotic telesurgery became a reality after J. Marescaux (L’Institut de Recherche contre les Cancers de l’Appareil Digestif, IRCAD – France) performed the first transcontinental robotic cholecystectomy, heralding the dawn of a new era in medical robotics [2]. However, with the transition of the robot from military and telesurgical centers to civilian hospitals, practical applications for this technology were needed.

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Soon after its introduction at the turn of the century, medical robotics became accessible to surgeons who became attracted not to the telepresence aspect, but rather to other key features of the platform – including 3D, stereoscopic vision, tremor cancelation, video image magnification, and surgeon control of a camera lens that locks onto a specific field of view. Interestingly, the initial target for the da Vinci Surgical System (Intuitive, Inc. Sunnyvale, CA) was not the abdominopelvic cavity, but rather it was to improve cardiac surgery [3–7]. However, in the early 2000s, it was realized that fixed abdominopelvic targets represented an excellent application for the robot, initiating a fierce arch rivalry between laparoscopy and robotic that remains strong to this day in the field of minimal access surgery.

In 2001, J. Binder and W. Kramer reported the first robotically assisted radical prostatectomy [8], quickly followed by the reports from others centers in the same year [9, 10]. In 2002, the first robotic colon resection was reported by P. Weber et al. using the da Vinci Surgical System for right and sigmoid colectomies for nonmalignant disease [11], giving rise to the era of robotics in colorectal surgery [12]. Over the next 16 years, the focus of robotics in this field would center on one aspect more than any other: the pelvic dissection, specifically for total mesorectal excision [13–15]. Soon, robotic surgeon proponents, convinced this would allow for improved operative

precision and therefore quality, attempted to demonstrate an advantage of robotic surgery over laparoscopic surgery [16–18]. The two minimally invasive techniques share much in common, and a definite advantage has not been demonstrated for robotics over laparoscopy for colon and rectal surgery [19–22].

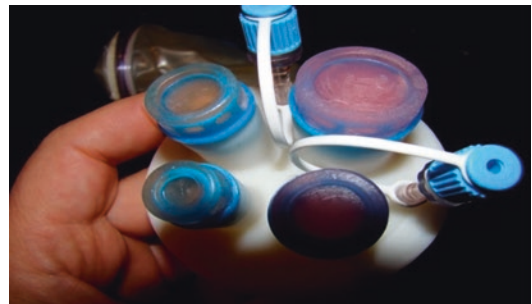
At first, it seemed as though the objective in surgery was to somehow prove that the existing robotic, multi-arm systems were somehow superior to laparoscopy, thereby justifying the known cost differential. However, with the advent of transanal minimally invasive surgery (TAMIS) [23], a new quest to access anatomic targets and apply robotics to (specifically) endoluminal surgery has refocused current interest in developing systems that do not mimic laparoscopy but instead are completely different systems that fuse next-generation computer processors with platforms configured in such a way as to address problems and challenges in surgery whose solutions had heretofore been unattainable. Thus, the general impetus and drive behind robotics in surgery has completely shifted over time. The original objective of telesurgery replaced by a quest for precision; the rivalry between laparoscopy and robotics placed on pause as the potential for robotics to access anatomic targets in ways not otherwise possible is currently being explored. It is with this pretext that the evolution of robotic TAMIS can be best understood.

## Initial Dry Laboratory Experiments

Advancements in TAMIS would give rise to a new paradigm in transanal surgery which melded concepts of single-port surgery, with laparoscopy and transanal endoscopic microsurgery (TEM). The natural step forward was to create an amalgam by combining TAMIS with the surgical robot – with the objective of refining precision and thus the quality of surgery. Initially, the concept of docking a multi-arm robotic cart through a narrow radius single port was still novel and first described in the literature by J Kaouk et al. in 2009 [24] (the same year TAMIS was created) with other reports emerging 2 years later [25, 26]. Therefore, robotic TAMIS

required careful dry laboratory testing to determine how to dock a robotic cart through a single-port apparatus (aka, TAMIS port) so that it could be used for transanal surgery. This testing took place in 2010 and predated the era of transanal-specific platforms, when most TAMIS – including the original description of the technique [23] – utilized the SILS™ Port (Covidien-Medtronic) and other such “single ports” designed for transabdominal access. However, the SILS™ Port was not able to admit robotic 8 mm effectors, and the port radius was too small to allow multi-arm robotic access. In 2010, a new kind of single port had emerged, which had a faceplate that would accommodate robotic 8 mm instruments. This first-generation QuadPort+ (Olympus, Shinjuku, Tokyo, Japan) was FDA approved for abdominal single-port access, and the initial robotic transanal experiments were performed utilizing this port (Fig. 16.1). Initially, the objective was to simply answer this question: could a da Vinci robotic cart be docked through this narrow channel while preserving the robot’s functionality?

Initial experiments were conducted in a dry laboratory setting to determine the feasibility and ergonomics of robotic cart docking through a single port. This was performed in September, 2010 (S. Atallah et al. in Orlando, FL, USA), utilizing the da Vinci Si platform with 8 mm effec-



**Fig. 16.1** First-generation QuadPort+ (Olympus, Shinjuku, Tokyo, Japan) became available circa 2010 in the USA. Although intended for abdominal (not transanal) access minimally invasive surgery, this port would accommodate larger diameter instruments, making it a suitable interface for robotic TAMIS. The first dry laboratory experiments with robotic TAMIS were conducted using this port





**Fig. 16.2** With vertical docking of the Si platform and the QuadPort+, the first dry laboratory experiments were conducted for robotic TAMIS in September, 2010. Arrangement and working arm encroachment were among the parameters assessed in the first preclinical assessment of robotic TAMIS

tor arms and a 30° lens. With vertical docking, the system's working arms and camera lens were delivered through the faceplate of the first-generation Olympus QuadPort+, whereby manipulation in a cylinder (so as to replicate the confined space of the rectum) was successfully performed (Fig. 16.2). It was learned that it was possible to operate the system quite precisely in this fashion. Vertical docking was performed because of the simplicity of doing so in the dry lab model, and work was then performed to determine the best orientation of docking of the Si system. In a series of dry lab experiments, it was determined that robotic cart side docking relative to the operating table would allow for the best access to the anorectum as the working arms and camera lens could be delivered over either the right or left thigh; alternatively, the robotic cart could be docked over the patient's shoulder.

## Robotic TAMIS in the Cadaveric Model

In 2011, after a preliminary work in a dry laboratory setting, the next step was validation in a cadaveric model. This was conducted using the da Vinci S model, which, at the time, was the only system for cadaveric evaluation (Fig. 16.3). With the introduction of the GelPOINT Path Transanal Access Platform (Applied Medical, Inc. Rancho Santa Margarita, CA), the first single port specifically designed for transanal access, the experiments were conducted utilizing this platform at the Global Robotics Institute (Celebration, FL, USA), and it was demonstrated that intricate, precise operative maneuverability was quite feasible [27]. Specifically, local excision (full thickness) and suturing with intraluminal knot tying was possible, and the level of difficulty was subjectively determined to be low by the operators [27]. Potential advantages of robotic TAMIS over standard TAMIS include image stabilization under single-surgeon control, 3D stereoscopic video processing, tremor cancelation, and image magnification. In theory, this could lead to improved excision quality, which is believed to be a factor as to why advanced transanal platforms carry an advantage over conventional parks local excision [28–31]. While TEM had been the gold standard for advanced endoluminal rectal surgery for over a quarter century, the birth of TAMIS seemed to give rise to other options—since it was not only disposable, but also economical (as the material from which the platform is constructed are much less important in retaining the quality of excision, and for single-use devices the durability is not relevant). Perhaps the most economical of all modern platforms is the simplest – the glove port. Introduced first in 2012 by A. Carrara as a technique for TEM [32], the glove port was subsequently applied by R. Hompes as an interface for robotic TAMIS with excellent results later that year [33] and represented an effective, low-cost interface quite suitable for transanal access [34].

Robotic TAMIS in a cadaveric model remains an important, ongoing modality for research. In

**Fig. 16.3** In 2011, at the Global Robotics Institute (Celebration, FL, USA), the first robotic TAMIS was conducted in a cadaveric model. In a series of experiments, maneuverability and functionality of the da Vinci S system utilizing the GelPOINT Path Transanal Access Platform were assessed. Local excision, suturing, and intraluminal knot tying were assessed



2017, the application of the next-generation da Vinci SP platform (not currently FDA approved for colorectal surgery at the time of this writing) was demonstrated to be feasible in preclinical evaluation [35]. In a study by J Marks et al., 12 lesions were successfully removed from all three segments of the rectum without fragmentation and with negative >1 cm margins from where the mock lesion perimeter had been marked [35]. The operative technique utilized a TAMIS port (GelPOINT Path Transanal Access Platform) for an interface. Advantages of the SP platform are that it allows for “wrist and elbow” motion of 6 mm effector arms, a “cobra” angulation of the camera lens, and the ability to admit three (as opposed to two) working arms—with a navigational aid provided at the console the surgeon’s knowledge about the instruments’ positions. Perhaps most importantly, the robot cart is essentially reduced to a singular device arm, which greatly simplifies transanal access and docking – a part of the operation that is otherwise difficult in some patients, especially those with a challenging body habitus. The flexible working instruments of the SP, together with the compact robotic cart’s single-arm configuration, make such a system ideal for endoluminal access and surgery.

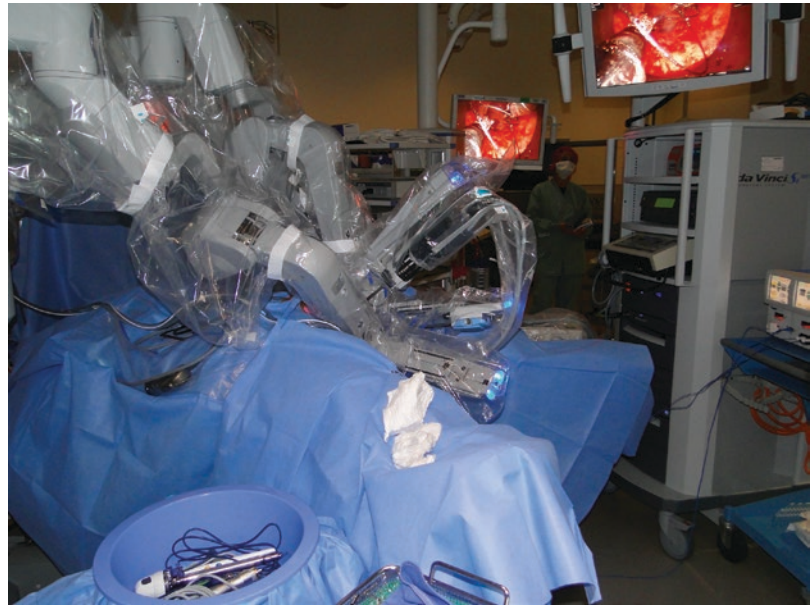
### Clinical Experience with Robotic TAMIS

In 2012, the first robotic TAMIS for local excision of a rectal neoplasm in a human was reported [36]. Here, a 3.0 cm tubulovillous adenoma with focal intramucosal adenocarcinoma was removed transanally (intact and with negative margins) utilizing a da Vinci Si robotic system with 8 mm Maryland grasper and hook cautery, using a standard laparoscopic insufflator and GelPOINT Path Transanal Access Platform (TAMIS platform) (Fig. 16.4). Barbed absorbable suture (3–0 V-Loc) was used to reapproximate the bowel wall after excision, operative time was 102 min, and the authors sited increased cost as an important limitation, with an approximated additional per-case cost of \$1500 USD.

Afterward, validation via other, mainly single-surgeon series and case reports on robotic transanal surgery (under the moniker RTS or robotic TAMIS) emerged in the literature [37–46], and are summarized in Table 16.1. Essentially, this demonstrated that the technique was feasible for local excision (Fig. 16.5). The platform has also been used to repair rectovaginal fistulae, rectourethral fistulae, and more advanced procedures including taTME [41, 52, 53]. Current data on robotic

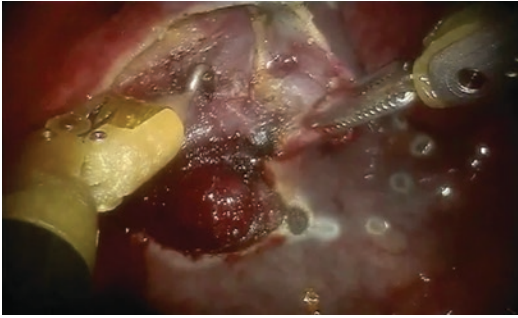


**Fig. 16.4** 2012: The first robotic transanal excision of a neoplasm in a human. The da Vinci Si platform was used in conjunction with the GelPOINT Path Transanal Access Platform, the lesions were completely excised, and the defect reapproximated robotically using barbed absorbable suture. Note the patient's modified Lloyd-Davies position and the docking of the cart over the right shoulder



**Table 16.1** Chronological publications on robotic TAMIS

Author	Date	Country	Interface	Model	<i>n</i>	Remarks
Atallah [27]	September 2011	USA	GelPOINT	Cadaver	2	1st experiment with robotic TAMIS
Atallah [36]	May 2012	USA	GelPOINT	Human	1	1st robotic TAMIS in a human
Hompes [33]	May 2012	UK	Glove	Cadaver	2	1st report of glove as interface for transanal robotic access
Bardakcioglu [37]	December 2012	USA	GelPOINT	Human	1	2nd robotic TAMIS in a human to be reported
Atallah [47]	June 2013	USA	GelPOINT	Human	1	1st robotic taTME in a human
Valls [42]	August 2013	Spain	Glove	Human	1	
Buchs [38]	August 2013	Switzerland	Glove	Human	3	1st description of the lateral approach
Hompes [40]	April 2014	UK	Glove	Human	16	
Atallah [48]	June 2014	USA	GelPOINT	Human	3	1st pilot series on robotic taTME
Gómez-Ruiz [49]	January 2015	Spain	Custom	Human	5	Totally robotic (above and below) taTME
Atallah [41]	February 2015	USA	GelPOINT	Human	18	Includes local excision, fistula repair, taTME
Atallah [50]	May 2015	USA	GelPOINT LoneStar	Human	1	1st report of robotic taTME with robotic ISR
Kuo [51]	October 2016	Taiwan	GelPOINT	Human	15	Single port + 1 combined with robotic taTME
Gómez-Ruiz [46]	December 2017	Spain	Custom	Human	9	da Vinci Si utilizing specialized hybrid port
Erenler [45]	April 2017	Turkey	GelPOINT	Human	1	1st published case using Xi platform
Marks [35]	July 2017	USA	GelPOINT	Cadaver	12	1st preclinical series with da Vinci SP
Atallah [50]	October 2017	USA	Flex robot port	Cadaver	2	1st preclinical report utilizing flexible robotic system for TAMIS and taTME

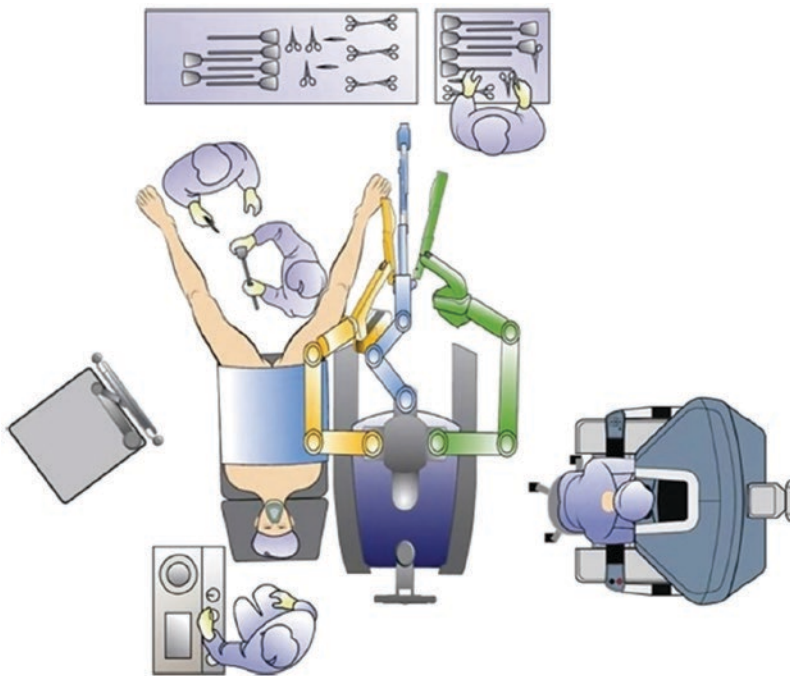


**Fig. 16.5** Local excision via robotic TAMIS. 8 mm wristed, instrumented, and stereoscopic magnified optics are among the perceived advantages of the robotic platform. Here, rectal neoplasm borders have been delineated with cautery marks, and a full-thickness excision is in progress. A Maryland grasper and hook cautery are the only instruments required to complete the excision

TAMIS remains limited, with mostly single-surgeon retrospective series reported in the literature [39].

## Docking and Configuration

Today, docking of the multi-arm da Vinci robotic cart can be performed in various methods and is often predicated by surgeon preference, as well as the specific platform's design and interface. For S and Si platforms, with the patient in dorsal lithotomy, cart docking can be parallel and flush against the operating table (Fig. 16.6) or tangentially with the robotic arms delivered over the shoulder. In general, the Xi<sup>®</sup> system with its long



**Fig. 16.6** Docking and patient configuration is often dependent on the specific robotic platform, the type of TAMIS port or glove port, and sometimes the position of the lesion. Surgeons who perform robotic TAMIS may also have a specific preference; although for robotic TAMIS (as compared to conventional TAMIS), there is more likely to be position and docking variability.

Notwithstanding, one of the most common configurations of the da Vinci Si systems with GelPOINT Path Transanal Access Platform is shown. Note that the robotic cart is docked flush with the operating table and working arms one and two are delivered over the thigh to prevent encroachment and collision during robotic TAMIS. The patient is typically positioned in steep Trendelenburg

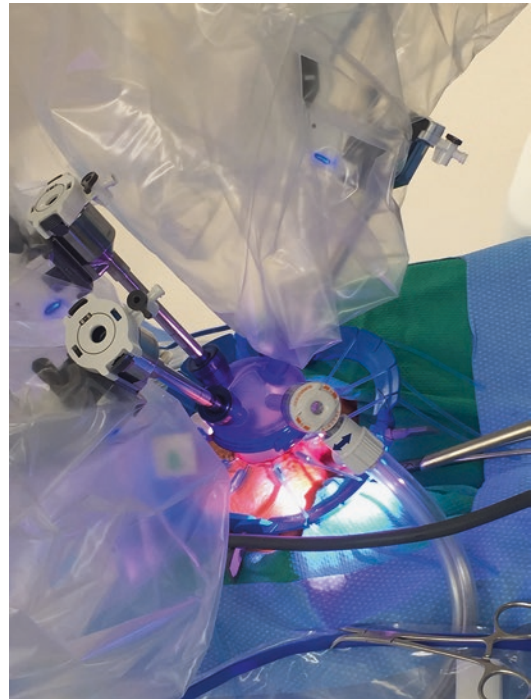
**Fig. 16.7** The Xi<sup>®</sup> system has been docked orthogonally to the operating table, and the patient's steep Trendelenburg, Lloyd-Davies position is evident. The low-profile arms and large wingspan of the Xi<sup>®</sup> system allow for improved transanal access with less collision. Compared to the Si, however, 5 mm effector arm instrumentation is not (currently) available representing a potential limitation since, in general, it is advantageous to have small diameter instruments so as not to restrict workspace



arm span and low-profile configuration, provides more leeway in cart-to-patient arrangement. Common approaches using the Xi<sup>®</sup> system include perpendicular docking relative to the side of the operating table (Fig. 16.7), but other options are valid.

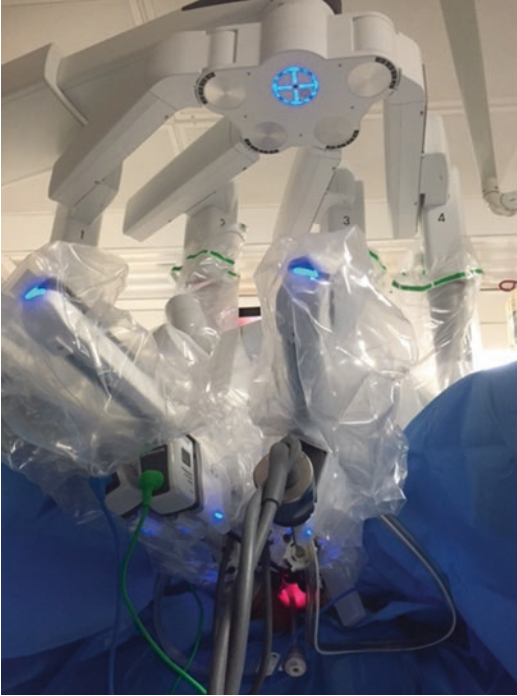
While TAMIS is almost always performed with the patient in dorsal lithotomy, robotic TAMIS may or may not require the patient to be positioned in this fashion. Indeed, other patient positioning may be desirable. For example, anterior lesions are best approached with the patient positioned prone jack-knife. The advantage here is that the lower extremities do not collide with the working arms during the process of dissection, leaving the effector arms with less likelihood for collision (Fig. 16.8).

In the spring of 2014, the da Vinci Xi<sup>®</sup> was introduced, providing significant advantages for the operator, especially regarding versatility with docking. The first robotic TAMIS utilizing the Xi<sup>®</sup> platform was believed to have been performed on July 28, 2015 by S. Atallah (Fig. 16.9). The first published report using the Xi<sup>®</sup> was reported in a video vignette by Erenler et al. in 2017 [45]. The Xi<sup>®</sup> platform allows for various options in docking, and some experts prefer the prone jack-knife position with orthogonal cart



**Fig. 16.8** Common configuration for robotic TAMIS using the Xi<sup>®</sup> system is adapted with 5 mm AirSeal for pneumatics. Here, an anterior distal rectal lesion is targeted for local excision. Two working arms and a 30° 8 mm lens are mated to the TAMIS port. Note that the GelPOINT Path Transanal Access Platform (TAMIS port) is suspended by the hooks of the Lone Star Retractor, which allows the access channel sleeve to be only partly admitted into the anal canal. This allows for improved distal access for low-lying lesions





**Fig. 16.9** July 28, 2015: The first robotic TAMIS using the Xi® system was performed by S. Atallah in Orlando, FL, USA. The lesion was a 2.8 cm adenoma and was excised with negative margins. Note the configuration of the working arms with a 30° downward lens placed superiorly and equidistant to two 8 mm working arms. An additional 5 mm AirSeal port (ConMed, Inc., Utica, NY, USA) was used to provide stable pneumorectum. This fourth port allows for access of 5 mm instruments (such as a suction irrigator) which can be operated by a bedside assistant

positioning for anterior rectal wall pathology. Another option is the lateral approach, which when combined with a glove port results in improved robotic arm excursion, as demonstrated by N. Buchs in 2013 with the Si system [38]. Furthermore, Gómez-Ruiz et al. have described the use of a specialized interface in which the platform is part rigid and bedrail mounted and part reusable. The rigid portion is similar to a 40 mm dia. TEM scope, but the faceplate utilizes an 80 mm GelPOINT membrane that is twice the diameter of the standard TAMIS port (Fig. 16.10). This likely allows for improved instrument maneuverability, decreased arm collisions, and a simplification of the port-to-robot rendezvous.



**Fig. 16.10** A custom-made port, developed by Marcos Gómez-Ruiz, MD, is a hybrid cross between a TEM scope and a TAMIS port. The rigid reusable portion of the device is secured to the bedrail with a mount to hold it in position. The faceplate (disposable) is an 80 mm GelPOINT (Applied Medical, Inc.). The configuration improves ergonomics and decreases collisions between working arms

## Applications of Robotics Beyond Local Excision

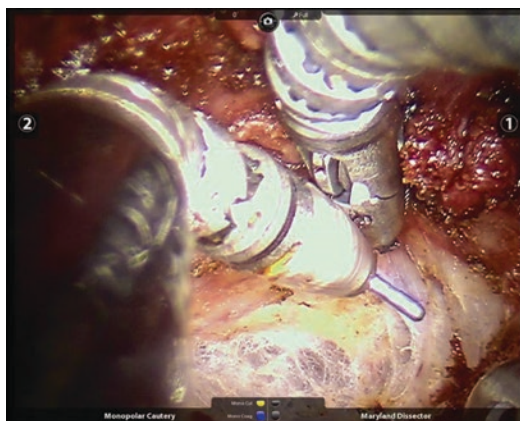
In 2013, just 3 years after the first reported human case of taTME by P. Sylla and A. Lacy, robotic taTME was successfully performed on a human for the first time [54]. The patient was an obese female with familial adenomatous polyposis (FAP) syndrome and synchronous hepatic flexure and rectal cancers. The abdominal resection was performed laparoscopically, and the taTME was performed by docking the da Vinci Si transanally with GelPOINT Path Access Platform as an interface. While there were limitations of reach, the robotic taTME was successfully completed in 87 min; the mesorectal envelop contained one

defect measuring 1.5 cm and therefore was graded as a Quirke II (near complete); all margins were negative [54].

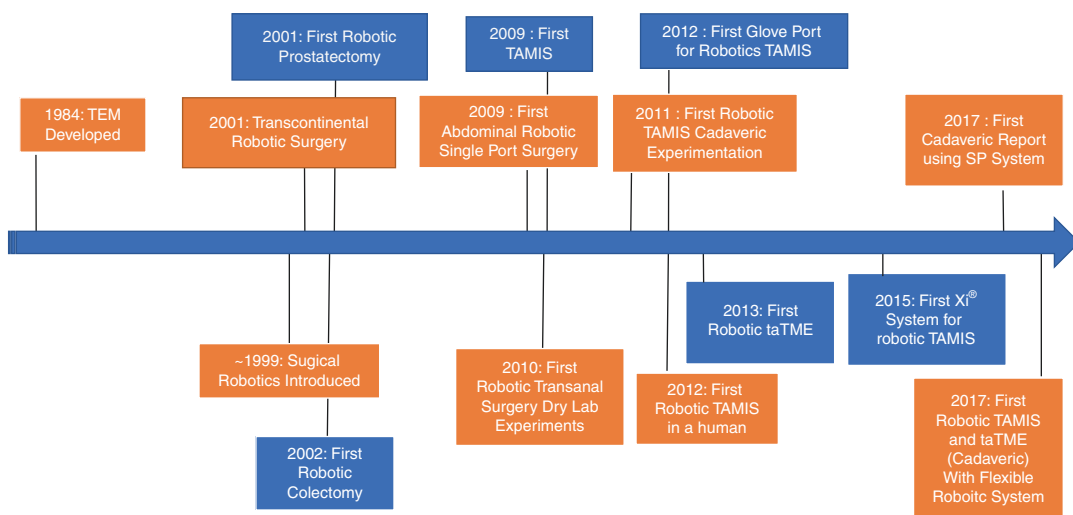
While limited to expert centers, small series and pilot studies on robotic taTME have been published in both the preclinical and clinical settings [47–49, 51, 55, 56], each series concluding that high-quality excision is feasible with the robotic platform (Fig. 16.11). Although most robotic approaches to taTME have applied the platform transanally in conjunction with laparoscopy for the abdominal portion of the operation, Marcos Gómez-Ruiz has used a totally robotic approach by double docking abdominally and then subsequently transanally [49]. This technique utilizes a specialized platform that is a hybrid between TEM and TAMIS with some components reusable and others disposable, as described previously.

There has been an accelerated advancement in minimally invasive approaches to transanal surgery over recent years (Fig. 16.12). Robotic approaches are continuing to evolve with several new vendors rapidly filling the space with creative systems that, instead of mimicking laparoscopy, are being designed with computerized, remodeled mechanics that provide improved flexibility and thus an ability to access anatomic targets not previously believed possible [50, 57]. Today, much of the focus on robotic transanal

surgery is toward the development of taTME, with the objective of improving the operative approach and reducing the challenges of conventional instrumentation [58–60]. Image-guided surgery in conjunction with robotics for complex surgical procedures, such as taTME, is also an area actively being investigated. Robotic taTME is discussed further in Chap. 44.



**Fig. 16.11** Robotic taTME represents the next step in the evolution of advanced, robotic transanal access. Here the da Vinci Si platform with a 5 mm hook monopolar cautery and 5 mm grasper is used to initiate the posterior TME dissection. The theoretical advantage of the robotics in a confined space is the potential to improve resection quality by providing a platform with superior optics, magnification, and surgeon control



**Fig. 16.12** Timeline delineating the milestones in robotics in colorectal surgery including transanal approaches

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# Transanal Robotic Surgery and Future Directions

# 17

Kevin M. Izquierdo, Thushy Siva, Jean Salem, Brigitte Anderson, and John Marks

## Abbreviations

MIS	Minimally invasive surgery
NOTES	Natural orifice transluminal endoscopic surgery
RATS-TME	Robotic transanal total mesorectal excision; robotic taTME
RTAS	Robotic transanal surgery
SILS	Single incision laparoscopic surgery
TAMIS	Transanal minimally invasive surgery
TATA	Transanal transabdominal proctosigmoidectomy
taTME	Transanal total mesorectal excision
TEM	Transanal endoscopic microsurgery

## Introduction

The challenges inherent to rectal cancer surgery have inspired ideological innovations in the field. Driven by high recurrence rates and high morbidity seen with the earliest rectal cancer operations, and by the technical difficulty of operating in the deep and narrow confines of the pelvis, the surgical treatment of rectal cancer has continued to evolve. The total mesorectal excision (TME) as described by Dr. Bill Heald [1] and the transanal transabdominal proctosigmoidectomy (TATA) as described by Dr. Gerald Marks [2], which ensures a clear distal margin in the rectum pre-treated with radiation, have both become core oncologic tenets of rectal cancer surgery. Furthermore, the TATA allows sphincter preservation, even for patients with low rectal cancers, without sacrificing the quality of oncologic outcomes [3]. Combined with TEM, these concepts have given rise to the transanal total mesorectal excision (taTME).

Benefits and advances in minimally invasive surgery (MIS) have been applied successfully to rectal cancer surgery. Prior to the 1980s, transanal excision of rectal neoplasms was restricted by limited reach and exposure. In 1983, Dr. Gerhard Buess invented transanal endoscopic microsurgery (TEM) [4], setting the stage for a long technological evolution in rectal surgery. Building off of Dr. Buess' TEM technique, the

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applications of transanal surgery have been extended by Atallah, Albert, and Larach using single-port transanal laparoscopy, today known as transanal minimally invasive surgery (TAMIS); and most recently, robotic surgical technology is applied transanally (Robotic TAMIS). By addressing many of the technical challenges that have hindered wider adoption of TEM, TAMIS, and taTME, robotic transanal surgery promises to increase surgeon access to these techniques so that more patients can benefit. Future directions of transanal robotic surgery will undoubtedly lead to a new era of pure natural orifice transluminal endoscopic surgery (NOTES), the ultimate in minimally invasive surgery.

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## Evolution of Transanal Surgery

Dr. Gerhard Buess' transanal endoscopic microsurgery (TEM) platform in 1983 represented a disruptive change in surgical approach and technology. TEM predates laparoscopy – the first demonstration of the laparoscopic cholecystectomy was presented in 1989 at the Surgical Association of Gastrointestinal and Endoscopic Surgeons (SAGES) conference by Drs. Perissat and Mouiel [5, 6]. In 1983, open surgery was the only approach in the surgical treatment of rectal cancer. The original application of TEM was in the removal of rectal polyps and was later expanded to treating malignant lesions with local excision. Although unpublished, it is believed that in 2008 Dr. John Marks performed the first transanal total mesorectal excision (taTME) using the TEM platform.

Key technological features of TEM are binocular stereotactic optics, improved access to more proximal lesions, and incisionless natural orifice surgery via the anus. As applications of TEM expanded to T1 cancers, the technical advantages became evident with significantly lower recurrence rates as compared to open transanal approaches. Experiences at the University of Minnesota and the Cleveland Clinic reported local recurrence rates of 4.2–9% with TEM compared to 25–33% with conventional transanal excision for T1 rectal cancers [7, 8]. This disruptive transanal minimally invasive approach set

the stage for the rapid evolution of technology in colorectal surgery over the next three decades. However, the steep learning curve and significant cost were major barriers to its universal adoption.

Transanal minimally invasive surgery (TAMIS), first described in 2009 by Drs. Atallah, Albert, and Larach, is a cost-effective alternative to TEM [9]. Building upon TEM concepts, TAMIS uses a flexible single incision laparoscopic surgery (SILS) port transanally rather than the rigid proctoscope used in TEM. Cost is decreased by avoiding the large start-up cost of TEM equipment and through the use of laparoscopic instrumentation readily available in modern-day operating rooms. Atallah et al. published their experience with TAMIS in the excision of both malignant and benign lesions of the rectum, and early data suggests that oncologic outcomes are comparable to TEM [10].

From a technical standpoint, TAMIS, allows access to the full 360 degrees of the lumen, whereas with TEM, the workspace is limited to the lower 180 degrees of the visualized operative field. Furthermore, the flexible platform allows better access to more proximal structures, allowing its application to expand to complete transanal total mesorectal excision. However, TAMIS initially suffered from the lack of a stable pneumatic platform that TEM provides. Drs. Lacy, Rattner, and Sylla published a systematic study of the transanal total mesorectal excision using the TAMIS platform [11]. In doing so, they successfully melded the core principles of TATA, hybrid NOTES, and TAMIS.

Pushing the limits of transanal surgery using the TAMIS technique, Dr. Leroy pioneered “pure” NOTES proctosigmoidectomy with transanal completion of the TME dissection, release of the splenic flexure, transection of the inferior mesenteric vessels, and coloanal anastomosis. He coined the procedure perirectal oncologic gateway for retroperitoneal endoscopic single site surgery (PROGRESSS) [12]. Select centers have further pioneered pure NOTES taTME [13, 14].

As it was with TEM for local excision of rectal lesions, a steep learning curve is the primary obstacle to wider adoption of pure NOTES for rectal cancer as it requires the highest level of

mastery of single-port laparoscopy. Robotic TAMIS, or robotic transanal surgery (RTAS) is a natural evolution of the approach and promises to address the technical challenges of reach, visualization, retraction, and ergonomics that has limited endoluminal surgery.

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## Current Applications and Outcomes

Atallah et al. demonstrated the feasibility of robotic TAMIS using the da Vinci Si robotic platform in a cadaveric model in 2011 and reported the first human case with resection of an early stage rectal cancer in 2012 [15, 16]. Subsequently several authors have reported on the feasibility and safety of robotic TAMIS. The advantage of robotic surgery comes with its magnified 3D view, wristed movements, tremor elimination, and excellent ergonomics, which allow for greater precision. Initially used for local excision of rectal neoplasms, robotic TAMIS was soon adopted for more complex procedures, with the first report of RTAS-TME (i.e., robotic taTME) in 2013 by Atallah et al. [17]

Robotic TAMIS using the da Vinci multi-arm robotic platforms works through a transanal disposable access channel, for example, the GelPOINT path transanal access platform [18]. Such access channels are required to create a seal that maintains the insufflation within rectum needed for adequate visualization. The da Vinci Si robotic system, while demonstrated to be feasible for local excision of distal rectal tumors, is limited by its multiple bulky arms and restricted field of view which prevent effective treatment of more proximal lesions. Hompes et al. in a series of 16 patients, where both malignant and benign rectal lesions were locally excised, used a transanal glove port which permitted wider movement of instruments within the rectum and reduced arm collision externally [19]. The next-generation Xi system addressed this partially with decreased arm bulk, in turn, allowing easier transanal docking and more proximal operative reach. The major disadvantage with this platform is the lack of 5-mm instrumentation, a significant issue in the small working space of the anus and rectum (currently, only 8 mm instrumentation is available with the Xi platform).

Despite the limitations of these multi-arm robotic platforms, Atallah et al. have successfully performed taTME and repair of complex fistulae via robotic TAMIS [20]. They reported on four patients who underwent RTAS-TME for invasive adenocarcinoma of the distal rectum. All specimens were found to be complete or near complete mesorectal excisions with negative distal and circumferential margins. Similarly, in a prospective pilot study by Gomez et al. using the da Vinci Si, RTAS-TME was performed in five patients, and all TME specimens showed complete mesorectal excision with negative distal and circumferential margins [21]. Robotic TAMIS for these applications has only been reported in small series, and long-term oncologic outcomes have yet to be studied.

Transanal surgery is highly demanding due to the confined anatomic space in the pelvis, restricted exposure, and limited proximal reach. The conventional multi-trocar robotic platforms were originally designed for transabdominal access [22]. The effector arms of these systems are not flexible, limiting dexterity in the narrow pelvis, and the 8 mm instruments add bulk and subtract from field view in this confined space [22]. Furthermore, the sacral angulation in the pelvis and instrument torque prevents dissection beyond 7–8 cm from the anal verge. The current platforms have limitations with control of operative field, endoluminal suturing, and surgeon ergonomics – making it challenging even for those with extensive experience [23]. Most importantly, while workable, the Si and Xi da Vinci platforms used transanally represent a potential risk to the external sphincter complex and present ergonomic obstacles which cannot be overcome. Due to these factors, it is not likely that robotic transanal approach will be widely adopted without platform innovation.

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## New Platforms in Robotic TAMIS

Despite the demonstrated benefits of minimally invasive surgery (MIS), the field of colorectal surgery has been slow to adopt MIS techniques, especially for transanal procedures. The high



technical difficulty of TEM and TAMIS is the primary barrier to wide adoption. The effectiveness of an operative technique is determined by the level of difficulty relative to other approaches. Thus, broadly speaking, a specific operative approach is highly effective if the majority of surgeons can perform the operation with high completion rates and good/excellent clinical outcome. If an operation is so difficult that few surgeons can perform it with good outcome, it is effective in the hands of a select few but has limited effectiveness in the wide world of surgical practice. Thus any technology which reduces the technical difficulty in the execution of an operation will automatically increase its effectiveness and ultimately benefit patient care. This aim motivates ongoing innovation in robotic transanal surgery.

An ideal platform for robotic TAMIS addresses four challenges of robotic TAMIS: (1) optimal visualization, (2) ergonomic instrument control, (3) improved proximal access, and (4) ease of tissue extraction and manipulation. To address these goals, a multitude of systems have been and are under development. The Flex® Robotic System, STRAS (Single-Access Transluminal Robotic Assistant for Surgeons) robot, and the da Vinci Single-Port (SP) Surgical System are all emerging robotic platforms designed to meet the challenges of transanal surgery.

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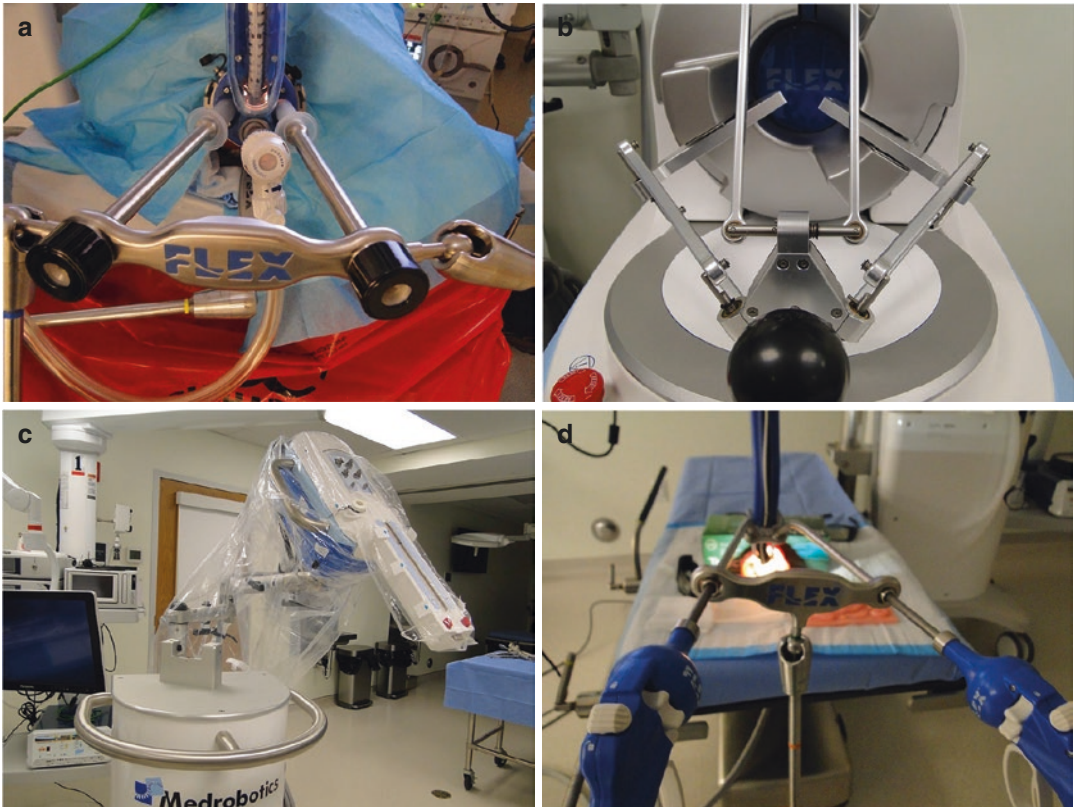
## Flex® Robotic System

The Flex® Robotic System together with the Flex® Colorectal (CR) Drive (MedRobotics, Corp. Raynham, MA, USA) is a semi-robotic apparatus specifically indicated for transanal surgery. This single-port access platform with flexible effector arms allows for instrument triangulation and purposeful steering of the instrument head along nonlinear circuitous pathways making it more suitable for NOTES, even for transluminal lesions proximal to the rectosigmoid junction (Fig. 17.1a). The robotic console or Flex® cart, driven by the operating surgeon at the bedside, has a control knob that can be

manipulated to control the Flex® scope (Fig. 17.1b). The Flex® Base accommodates a disposable Flex® Scope CR drive, which is then docked transanally (Fig. 17.1c). The two main units of this system are operated by a single surgeon, eliminating the need for a bedside assistant. Flexible, pistol-grip instruments are used to perform the surgery, through a bedrail-mounted apparatus, permitting triangulation (Fig. 17.1d). This flexible robotic system allows access to remote anatomic fields with an operative reach of 17 cm. In addition, smaller 3.5 mm instruments allow for minimal restriction of the field of view [24].

Obias, Sylla, and Pigazzi presented their initial experience of this system for transanal access in a preclinical setting during the proceedings of the American Society of Colon and Rectal Surgeons and Tripartite Meeting in Seattle, Washington, in 2017 [25]. Feasibility of this platform in performing targeted NOTES operations in a cadaveric model was reported by Atallah in 2018 [22].

Visualization with the Flex® Robotic System is improved compared to laparoscopic TAMIS in that it does not require an assistant and the operative field of view can be set by the operating surgeon. The primary advantage of the Flex® Robotic platform is that it allows transmission of the platform along circuitous pathways for better access to more proximal lesions than would otherwise not be possible by conventional methods. Drawbacks of this platform are that the robotic camera and platform movements use separate modules and redefining the operative field of view is time consuming [22]. In addition, the flexible arms are not robotically assisted, and thus this system is considered semi-robotic. This introduces the problem of tremor, and this can detract from the precision of an operation. The flexible pistol-grip instruments also require a high level of laparoscopic technical skill, even more so than the straight instruments used in laparoscopic TAMIS. While this platform addresses some of the fundamental challenges of transanal surgery, it has significant ergonomic shortcomings that are likely to limit its adoption.

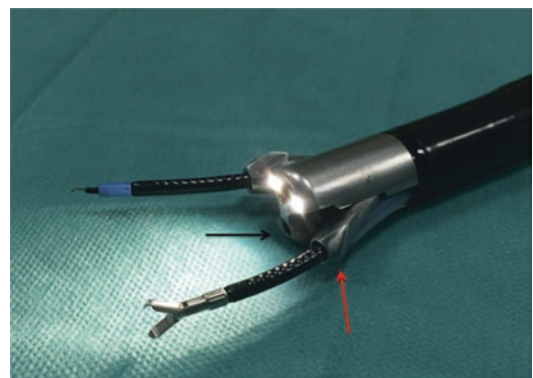


**Fig. 17.1** Flex® Robotic System. (a) Two 3.5-mm diameter flexible effector arm interface. (b) Round control knob that serves as the master control for the Flex® Robotic Scope. (c). Flex® Robotic base accommodates

the Flex® Robotic Colorectal Drive. (d). Simulation of a transanally docked Flex® Robot System with Colorectal Drive. (From Atallah [24])

### STRAS Robot (Single-Access Transluminal Robotic Assistant for Surgeons)

The STRAS is an ergonomic master–slave system, with an intuitive control interface allowing the surgeon to comfortably operate the system. Andras et al. reported the feasibility of this system in colonic endoscopic submucosal dissection in animal models in 2017 [26]. The slave unit consists of a carrier cart and a detachable flexible endoscope, which is a 50 cm flexible device with two 4.2 mm working channels for instruments and one 2.8 mm working channel for conventional flexible endoscopic instruments (Fig. 17.2) [27]. The 50 cm endoscope should allow access to lesions within the sigmoid colon. The motorized endoscope is initially inserted under endo-



**Fig. 17.2** STRAS operating tip. Comprised of a 50 cm flexible device with two 4.2 mm channels through which instruments are passed. The black arrow indicates the 2.8 mm working channel for conventional endoscopic tools, and the red arrow identifies the two arms on the open side, which allow for the triangulation of robotic instruments. (From Légner et al. [27])

scopic visual control, and once it reaches the target, the endoluminal view is established as it is re-attached to the slave cart. Like the Flex® Robotic System, the STRAS robot requires significant time to redefine the operative visual field. The endoscope needs to be positioned into place manually, and the STRAS master console provides limited control of the endoscope.

The robotic instruments consist of a proximal motor and a flexible shaft with a bendable distal tip. The two opening arms at the tip of the endoscope allow for endoluminal triangulation for the instruments. The master console provides continuous feedback regarding the actual position of the tools. With only two robotically controlled instruments, a notable limitation of this system is the lack of effective retraction. Additionally, this platform lacks suturing capabilities, thus limiting its use beyond partial thickness excisions.

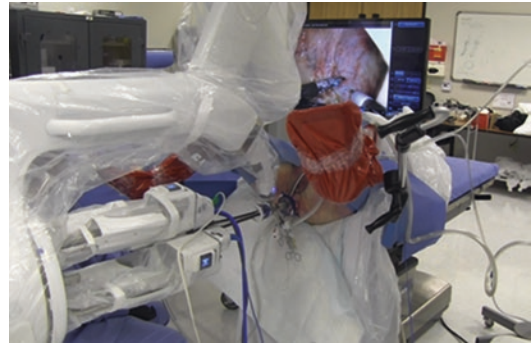
As currently configured, both the Flex® Robotic System and the STRAS robot are optimized for partial thickness local excisions of the rectum. However, the current generation's limitations hinder these platforms' adoption to more complex operations such as taTME, fistula repair, and pure NOTES proctocolectomy. Notwithstanding, these platforms improve ergonomics to a significant degree compared to standard, laparoscopic-based TAMIS.

### Future Directions: da Vinci SP Surgical System

The next-generation da Vinci robotic platform, which is pending FDA clearance for use in TAMIS procedures, is a single-arm, single-port system. The da Vinci *SP* system includes three 6 mm, multi-jointed, wristed instruments and the first da Vinci jointed 3D 0° HD camera. Collectively, the three instruments and the camera head are transmitted through a single 25-mm cannula (Fig. 17.3). This advanced platform with its unique “cobra camera” and flexible end effector arms allow for more proximal reach transanally (Fig. 17.4). Significant benefits of this new technology are many. A rotating 360° platform



**Fig. 17.3** The da Vinci SP system's single 25-mm cannula through which three 6 mm, multi-jointed, wristed instruments and a 3D 0° HD camera extend

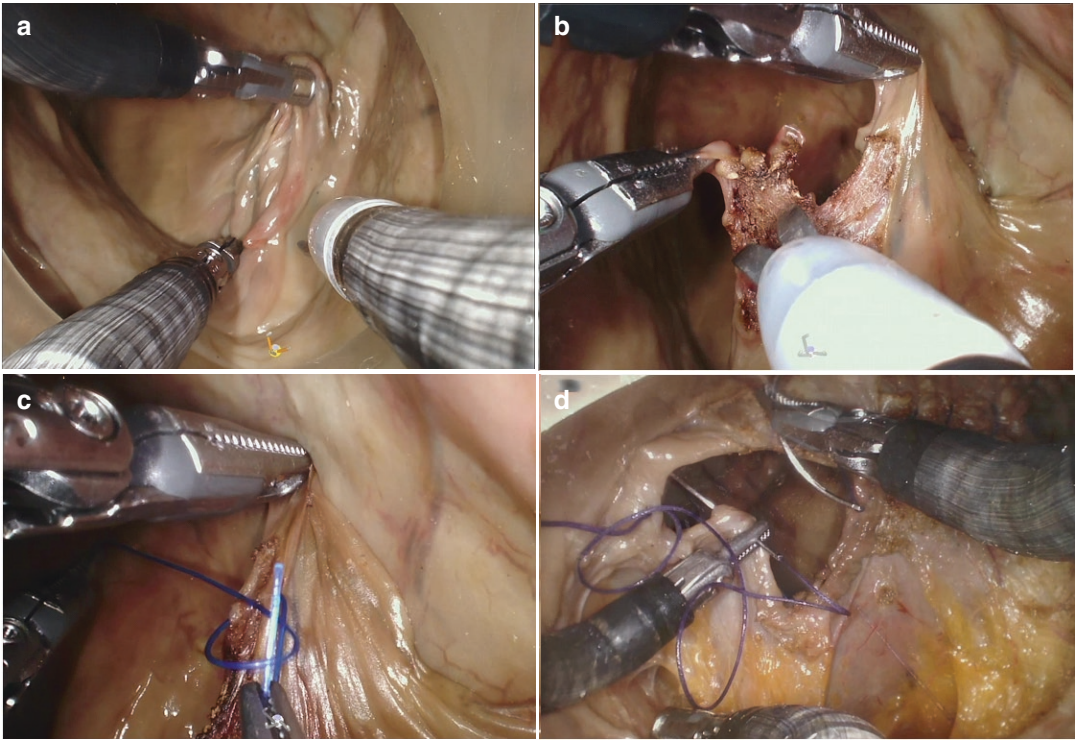


**Fig. 17.4** At-large view of the da Vinci SP platform's set up intraoperatively

(Fig. 17.5) allows for manipulation of the operative field so that all quadrants of the rectum can be accessed without repositioning the patient. A holographic monitor of instrument position assists the surgeon to better understand intraluminal instrument collisions; effectively, it serves as a navigational aid to keep track of instrument position. This feature combines well with three-arm control that assists in creating optimal instrumental retraction easily. The fully robotic wrist with 6° of movement articulation allows for the control that previous surgeons have become accustomed to with the robot.

RTAS approaches will expand the armamentarium of the transanal surgeon. Current limitations include the absence of an RTAS suction device, vessel sealer, and stapler. However, these same challenges have been overcome with every new generation of robot, so it can be reasonably predicted the same will take place here. This





**Fig. 17.5** da Vinci SP Surgical System. (a) Three-arm control shown working in the rectum. (b) Local excision using three-dimensional retraction. (c) Transanal knot tying. (d) Full thickness transanal rectal closure

**Fig. 17.6** The da Vinci SP Surgical System with Applied GelPOINT Path Transanal Access Platform



system has been studied in the preclinical setting by Marks et al. [23] The da Vinci *SP* Surgical System with Applied GelPOINT Path Transanal Access Platform (Fig. 17.6) was used to perform transanal local excision in cadavers. Twelve simulated lesions were excised with negative margins and without fragmentation. In addition,

suture closure of the defect and endoluminal knot tying were carried out with relative ease [23].

To date, the feasibility and safety of this flexible single-arm robot has been studied primarily for transanal applications. This system is yet to be validated in a clinical setting for transanal surgery in the United States; in Hong Kong, it is

being used in early clinical trials for colorectal applications, including taTME. This exciting new technology in endoluminal access will likely expand its applications, stepping into the current era of NOTES.

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### **Future Directions: Pure NOTES Colorectal Surgery**

The concept of NOTES has gained popularity since the first transgastric appendectomy performed by Rao and Reddy in 2004. In concept, however, Dr. Buess' TEM in 1983 was the first NOTES procedure. Now, nearly 40 years later, technology has advanced to a point where this concept can be revisited by surgeons.

Avoiding altogether an abdominal incision and its associated risks, such as surgical site infections and incisional hernias, as well as providing perfect cosmesis, RTAS represents a paradigm shift in MIS. The final step on the path of transanal NOTES colorectal surgery would be to perform a rectal resection via a transanal endoscopic approach without requiring access through the abdominal wall.

Cumulatively, the published data from case series on taTME demonstrate technical feasibility and preliminary oncologic safety in carefully selected patients. The quoted benefits of a transanal endoscopic approach for very low rectal cancers in particular include the ability to expand the upper limit of intersphincteric resection under much improved visualization and exposure and the facilitation of a complete rectal and mesorectal dissection. This is especially helpful in male patients with narrow pelvises in whom a laparoscopic approach poses substantial technical difficulty, with a high risk of conversion, as well as a high rate of poor quality, incomplete mesorectal excision.

The natural extension of the taTME movement has been to perform the entirety of the operation transanally; however, the general applicability outside of a few centers remains limited.

With the existing robotic platforms, which were originally designed for transabdominal surgeries, proper working angles (and the inability to obtain them) represent an important limitation. Interesting developments in robotic surgery, as described above, promise to increase the ability to perform larger portions or even entire colorectal operations transanally. This has been demonstrated in cadavers by Marks, Ng, and Mak with transanal dissection and transection of the inferior mesenteric artery using the da Vinci SP Surgical System (Fig. 17.7).

However, taTME in its current form using the available transanal platforms has several limitations. Lesions located in the upper rectum are more difficult to reach. The anastomosis in taTME for lesions at this level is more difficult due to inadequate visual exposure and requires endoscopic placement of the purse-string suture rather than by hand. Another major limiting factor of pure NOTES is its extreme technical demand, including the preference for having two complete surgical teams to perform the operation (at most centers).

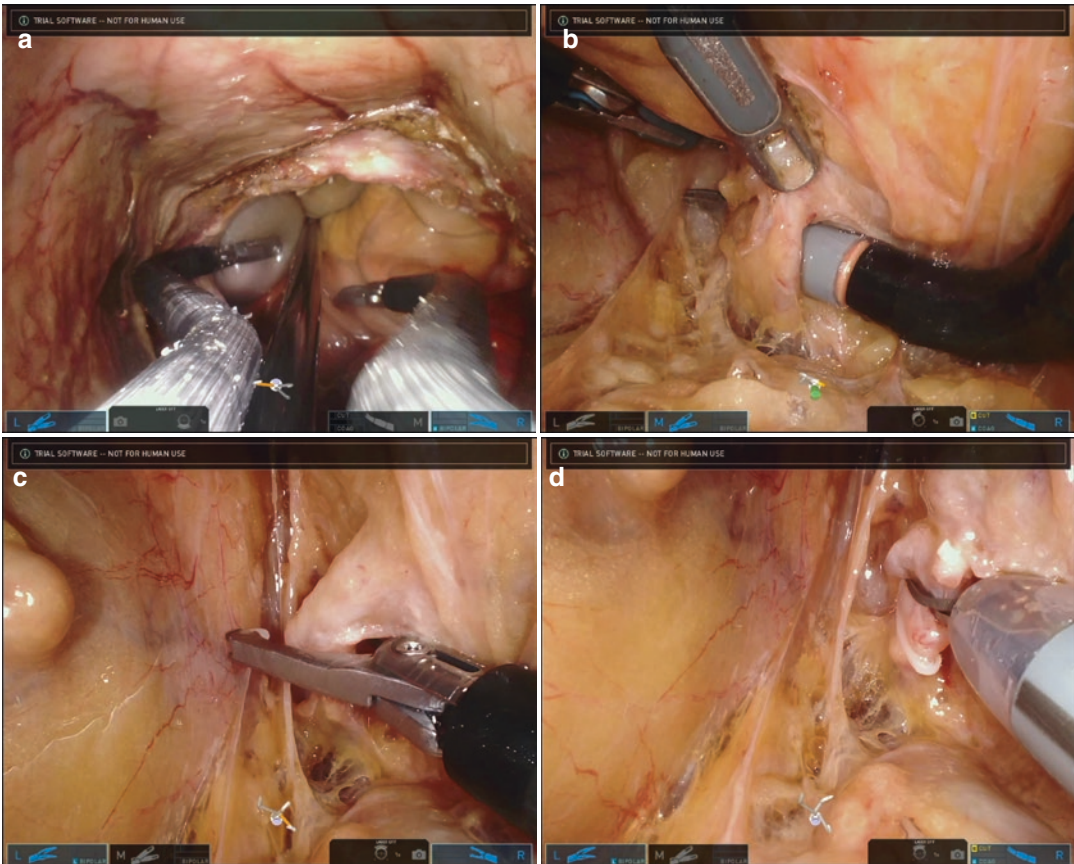
With the newly FDA-approved Single-Port da Vinci robot, the performance of transanal NOTES and its democratization in the surgical community will undoubtedly be facilitated.

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### **Conclusions**

An ideal platform for robotic TAMIS would have single-port access and flexible camera and effector arms capable of triangulation for optimal visualization and ergonomics. Additionally, the system would be able to adapt and navigate itself along the circuitous pathways of the distal gastrointestinal tract, reaching beyond the anal verge with the curve of the sacrum. The da Vinci *SP*, Flex® Robotic System, and STRAS robot realize some of these specifications and will serve as high-utility platforms in the continued evolution of robotic TAMIS.





**Fig. 17.7** RTAS Transection of IMA. (a) After entry into the peritoneum, the arms of the da Vinci SP Surgical System retract the small bowel out of the pelvis. (b)

Transanal inferior mesenteric artery dissection. (c) Transanal inferior mesenteric artery is clipped. (d) Transanal inferior mesenteric artery is transected

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# TAMIS: Current Controversies and Challenges

# 18

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## Introduction

Transanal minimally invasive surgery (TAMIS) is increasingly being used as an alternative to transanal endoscopic microsurgery (TEM) for transanal excision of both rectal adenomas and early rectal cancer. There are multiple ongoing controversies about the benefits of and limitations of TEM and TAMIS. Given the relatively recent and limited experience with TAMIS as compared to TEM, published data on this platform is more limited, with no prospective series that compare the two platforms (and their respective techniques) directly. What is known about the current controversies regarding TAMIS will be summarized in this chapter.

## Local Recurrence and the Use of TAMIS for Early Rectal Cancer

Arguably the most significant ongoing controversy about both TEM and TAMIS is the appropriateness of their use in local excision of early

rectal cancer. This debate is not specific to TAMIS, and much of the available evidence has been extrapolated from experience with TEM. Relative to the large body of literature on TEM, or even to published data on the transanal endoscopic operation (TEO), few studies have reported specifically on TAMIS. Furthermore, there have been no prospective clinical trials comparing TEM and TAMIS and few studies reporting long-term follow-up for oncologic outcomes after TAMIS.

One review published by Martin-Perez et al. reviewed 390 TAMIS procedures encompassing 33 published retrospective case series as well as 3 abstracts [1]. Of these, over half of TAMIS procedures were performed for rectal adenocarcinoma, with adenoma representing the second most common indication. Margins were positive in 4.4% of cases overall, specimen fragmentation occurred in 4.1%, and overall morbidity was 7.4%. Larger TAMIS series have generally found similar short-term oncologic results, supporting the conclusion that TAMIS is likely a safe alternative to TEM for carefully selected, T1 rectal cancer [1–9]. A matched analysis comparing 419 patients who underwent TEM and 228 patients who underwent TAMIS for both benign and malignant disease found no differences in the rates of positive margins or lesion fragmentation, again suggesting similar results for the two operative platforms [10].

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In terms of local recurrence, in a retrospective series of 50 patients undergoing TAMIS excision for rectal cancer, Albert et al. reported one case of local recurrence in a patient with a pT1 tumor (6.3% of all pT1 lesions reported) with a mean follow-up of 20 months [8]. Lee et al. and McLemore et al. reported a series of 25 and 34 patients undergoing TAMIS with no cases of local recurrence but with only short-term follow-up (9.8 months or 3–23 weeks, respectively) [3, 11]. Schiphorst et al. in a series of 37 patients found one case of local recurrence for a pT1 lesion (25% of pT1 lesions) with 11 months mean follow-up [12]. In a recent series of 50 patients by Caycedo-Marulanda et al., there were two cases of local recurrence (6%) after TAMIS for early rectal cancer, with a median follow-up of 21 months [13]. More recently, Lee et al. reported outcomes of 200 TAMIS cases for local excision of rectal neoplasia from the center that established TAMIS as a technique (Orlando, FL, USA). The authors reported a 7% overall margin positivity and 5% rate of specimen fragmentation. Of 110 malignant lesions excised using the TAMIS technique, 6% recurred locally, and 2% presented with distant organ failure (follow-up was 14.4 months) [14]. Overall, these results suggest that local recurrence after TAMIS for early rectal cancer is similar to TEM; however, large series with long-term oncologic outcomes are lacking.

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### **Technical Limitations with the TAMIS Platform: Low and High Rectal Lesions**

TAMIS, given the shorter length of the disposable platform, is generally limited to the first 8–10 cm from the anal verge. Beyond this point it becomes difficult to provide adequate retraction to visualize upper rectal lesions, particularly those located behind and beyond the rectal valves [15].

TEM and TEO, on the other hand, have rigid rectoscopes as long as 15–20 cm in length [16, 17]. While these platforms may be limited by a narrow rectosigmoid junction or other anatomical

constraints, TEM and TEO generally allow the surgeon to stent past the rectal valves to access high rectal tumors [18]. This underscores a fundamental difference between the two platforms; as with TEM and TEO, the access channel (shaft) itself is advanced to the target lesion, whereas, with the TAMIS technique, the access channel remains in the same position, and, instead, only the laparoscopic instruments are navigated to the target lesion.

TAMIS, on the other hand, is limited in access to very low rectal tumors because the TAMIS transanal port occupies the first several centimeters of the anal canal [19]. The TEM platform, by virtue of being secured to the operative room table, can be withdrawn to the level of the anal verge itself, allowing access to very low rectal tumors [18]. A hybrid approach can be used with TAMIS for these low lesions, dissecting the distal margin using a conventional transanal approach with retractors, followed by insertion of the TAMIS port for the proximal dissection [20].

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### **Peritoneal Entry in TAMIS Versus TEM**

Peritoneal entry during transanal endoscopic surgery is not uncommon and is not usually considered a complication, so long as the surgeon can adequately repair the defect without conversion to a transabdominal procedure. For TEM, the rate of peritoneal entry in the reported literature varies widely from 0% to 32.3% [21–23]. More recent series with over 300 patients have demonstrated lower rates of 5–10.7% [24, 25]. However, expanding indications for TEM and TAMIS including the increasing use for resection of more proximal, anterior, and circumferential tumors have the potential to make peritoneal perforation a more common occurrence over time [23, 26].

The loss of pneumorectum that occurs following peritoneal entry can impede visualization and retraction, presenting a significant technical challenge for the surgeon. Prone positioning of the patient with a high anterior lesion can help to minimize the impact of CO<sub>2</sub> leakage into the abdominal cavity should peritoneal entry occur [26].

Complete muscle paralysis, decompression of the pneumoperitoneum with a Veress needle, and higher insufflation pressures can also help maintain a stable pneumorectum in the face of peritoneal entry [8]. With increasing experience, the rate of conversion following peritoneal entry during TEM has steadily decreased to below 10% [16, 26, 27].

It is unclear whether TAMIS has an increased risk of peritoneal entry as compared to TEM. Two recent case-matched studies comparing TEM/TEO and TAMIS did not find any difference in the rate of peritoneal entry between the two methods [10, 28]. The larger of these studies compared 181 TAMIS resections to 247 matched TEM resections and found similar rates of peritoneal entry (3% versus 3%,  $p = 0.97$ ) for lesions with a median tumor distance of 7.0 cm from the anal verge in both groups [10]. However, other studies have indicated that TAMIS is associated with a higher risk of peritoneal entry. Molina et al. examined this issue in 78 transanal resec-

tions using both TEO/TEM and TAMIS platforms [29]. They found that peritoneal entry occurred in 22 cases (28%) and the use of a TAMIS platform was associated with a higher risk of peritoneal entry. Furthermore, of four cases where peritoneal entry occurred during TAMIS, all four required conversion to a rigid platform to adequately expose and suture the defect. Overall, the risk of peritoneal entry during TAMIS appears to increase with distance from the anal verge, as does the risk of conversion to an alternative transanal or transabdominal approach (Table 18.1).

When it does occur, peritoneal entry during TAMIS has been identified as a particular challenge [29]. In a training model comparing TEM and TAMIS, surgeons consistently found TEM to be superior for dissection, quality of vision, and suturing difficulty and found that TAMIS was not effective for suture of the simulated rectal lesion [30]. However, others have argued that this ex vivo study did not account for either the variety

**Table 18.1** Summarization of recent, larger TAMIS series and rates of peritoneal entry, as well as the need for conversion to an alternative surgical approach

Series	N	Platform	Median distance from anal verge (cm)	Rate of peritoneal entry	Rate of conversion following peritoneal entry
Albert et al. [8]	50	Gelpoint path	8.1	1 (2%)	Not converted
Lee et al. [3]	25	SILS	9	0	N/A
McLemore et al. [11]	34	Gelpoint path	4	3 (9%)	3/3 (100%) converted to laparoscopic
Hahnloser et al. [2]	75	SILS	6.4	3 (4%)	3/3 (100%) converted to laparoscopic or open
Schiphorst et al. [12]	37	SILS, SSL	7 <sup>a</sup>	1 (3%)	1/1 (100%) converted to laparoscopic
Gill et al. [59]	65	Gelpoint path	7.5	0	N/A
Sumrien et al. [60]	28	Gelpoint path, SILS	NR	1 (4%)	Not converted
Haugvik et al. [61]	51	Gelpoint path, SILS	8	0	N/A
Verseveld et al. [35]	24	SSL	8 <sup>a</sup>	0	N/A
Quaresima et al. [62]	31	Gelpoint path, SILS	9.5	5 (16%)	1/5 (20%) converted to transanal excision (TAE)
Keller et al. [32]	75	Gelpoint path, SILS	10	3 (4%)	3/3 (100%) converted to laparoscopy
Caycedo-Marulanda et al. [13]	50	Gelpoint path	7	5 (10%)	No conversions
<i>Total</i>	545			22 (4%)	11/22 (50%)

<sup>a</sup>Distance from the dentate line



of TAMIS platforms available or the use of automated suturing and knot-forming devices [31]. Worryingly, multiple TAMIS series have reported conversion to laparoscopy or laparotomy for an inability to close a rectal defect, detailed in Table 18.1 [2, 11, 12, 32]. In contrast to TEM, the overall rate of conversion following peritoneal entry in TAMIS appears to be as high as 50% across larger series. It is unclear if this difficulty is primarily reflective of the long learning curve required for managing complex rectal lesions via TAMIS. In a large series of 50 TAMIS cases by Caycedo-Marundo et al., there were five cases of peritoneal entry, and all defects were closed transanally via TAMIS [13]. The authors noted that for this to be feasible, the surgeon must have considerable experience suturing using TAMIS.

Thus, a reasonable approach may be to recognize that there may be increased risk of peritoneal entry with TAMIS as compared to TEO and TEM and that when TAMIS is used for lesions in the upper rectum, particularly larger and more anterior lesions, the surgeon should have experience and comfort with closing the defect using the TAMIS platform [23, 26]. If the surgeon does not have extensive experience with TAMIS, it may be worthwhile to consider prone positioning, availability and experience with TEM equipment if difficulty is encountered in closing via TAMIS, or discussing the risk of conversion to an abdominal approach with the patient prior to surgery.

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### **Oncologic Outcomes After Peritoneal Entry During TAMIS**

Risk of peritoneal entry is similar or even increased with TAMIS as compared to TEM, as previously mentioned [28, 33]. Thus, peritoneal seeding is also a concern in TAMIS. However, the literature on long-term oncologic impacts of peritoneal entry during TEM for rectal cancer is sparse, and there is no published literature related specifically to the concern of tumor seeding in the abdominal cavity with TAMIS. With regard to TEM, Morino et al. followed 13 patients where peritoneal perforation occurred during TEM performed for rectal adenocarcinoma [26]. Although

there were cases of local recurrence and lung metastases, no cases of liver or peritoneal metastases occurred with a median follow-up of 48 months. Similarly, Mege et al. followed 13 patients where peritoneal perforation occurred after TEM for adenocarcinoma, with no cases of local recurrence or distant metastasis after a median follow-up of 11.5 months [23]. Again, even with regard to TEM, long-term oncologic outcomes after peritoneal perforation are sparse.

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### **Fecal Incontinence**

There is an ongoing debate with regard to whether functional outcomes differ between TAMIS and TEM, particularly with regard to fecal incontinence. TAMIS has been hypothesized to be less likely to result in damage to the anal sphincter given the relative flexibility of the disposable transanal ports as compared to the rigid TEM design [34]. Alternatively, outcomes could theoretically be worse given the more extreme movements and stretch exerted on the sphincter in TAMIS. Although the literature on functional outcomes after TEM, both short and long term, is robust, there are few studies that have explored functional outcomes after TAMIS.

Short-term functional outcomes after TAMIS have been explored in two small prospective studies [12, 35]. Schiphorst et al. examined outcomes in 37 patients using the fecal incontinence severity index (FISI) and found that 88% of patients with abnormal baseline function experienced improvement in FISI scores, while 5% of patients overall experienced postoperative impaired continence [12]. Similarly, Verseveld et al. examined functional outcomes in 24 patients after TAMIS and found that 79% of patients with abnormal baseline FISI experienced improvement in continence after TAMIS, while 21% of patients overall experienced postoperative impaired continence [35]. These studies had a median follow-up of 11 and 6 months, respectively. These short-term results appear to be comparable to TEM, which has been shown to have rates of postoperative impaired continence ranging from 0% to 21% [36–39].

However, a recent study by Clermonts et al. was the first to examine long-term functional outcomes of TAMIS, with 42 patients and median follow-up of 36 months [40]. The authors found that FISI score 1 year after TAMIS was similar to preoperative FISI (5.4 vs. 8.3,  $p = 0.501$ ), although worse at 3 years (10.1,  $p = 0.01$ ). In this study, 80% of patients with an abnormal FISI prior to TAMIS exhibited improved FISI at 3 years; however, 63% of patients with normal continence at baseline experienced worsened incontinence at 3 years. This far exceeds the number of patients found to have impaired continence in studies with long-term follow-up after TEM [41–43]. However, the authors noted that most of the functional impairment that developed after TAMIS was minor and perhaps with minimal impact on quality-of-life (QOL) measures. Indeed, a recent follow-up demonstrated that the worsened FISI scores did not affect broader QOL measures for these patients [44]. Given the current lack of head-to-head comparisons of TEM and TAMIS, it is unclear if one approach is superior in regard to functional outcomes.

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### **Sleeve Resections for Circumferential Lesions**

There are currently no published reports of the use of TAMIS for circumferential or “sleeve” resections. Arezzo et al. reported the use of TEO for resection of 17 circumferential rectal adenomas encompassing greater than three-quarters of the rectal wall circumference [45]. Lesions were at a median of 4 cm from the anal verge, with lesions’ longitudinal extent of 7 cm. Sleeve resection was performed, with circumferential full-thickness dissection of the distal margin, followed by tunneling through perirectal fat to the proximal margin, and then circumferential incision of the rectal wall at the proximal margin. The anastomosis was performed transanally using a full-thickness running suture with 3–0 Maxon secured with silver clips (Richard Wolf, Knittlingen, Germany). All patients had negative margins. Two patients were upstaged to T2 rectal cancer

and underwent radical resection, with no recurrence at 42 and 24 months follow-up, respectively. One patient who was upstaged to a T3 lesion and did not undergo resection due to comorbidities developed a local recurrence at 18 months. One patient with high-grade dysplasia on final pathology had a local recurrence that was salvaged with transanal excision, with no recurrence at 30 months. No other patients had local recurrence on follow-up.

The authors reported no incidence of fecal incontinence or sexual dysfunction. However, stenosis at the level of the anastomosis occurred in four patients. These patients were all treated with endoscopic balloon dilation. One patient developed a urinary fistula after dilation that was managed conservatively. Similarly, Mege et al. documented 6 cases of rectal stenosis managed with endoscopic or surgical dilatation in a series of 194 patients undergoing resection with TEM, all of which occurred in large, circumferential adenomas (>50% of the rectal lumen) [23].

Although there are no published reports of the use of TAMIS for resection of circumferential adenomas, it is reasonable to believe that this could be a feasible and effective option given the prior experience with the use of TEM for this purpose, provided the surgeon has experience with suturing via a TAMIS platform. Furthermore, TAMIS platforms have been used for transanal total mesorectal excision (taTME), which required full-thickness and circumferential rectal dissection, indicating the technical feasibility of performing the anastomosis transanally [46, 47]. The concerns about the high rate of stenosis observed in the previously described study of TEM for circumferential adenomas, however, would also be germane to the application of TAMIS for these lesions. The use of TEM or TAMIS to accomplish full-thickness excision of these lesions, as compared to partial-thickness excisions using endoscopic submucosal dissection (ESD) or endoscopic mucosal resection (EMR), has the advantage of avoiding the need for further surgery if lesions are upstaged to early and low-risk rectal cancer, as is frequently the case for these bulkier lesions [48, 49].

## Partial- Versus Full-Thickness Resections and Risk of Stenosis

Overall, the risk of rectal stenosis with either TEM or TAMIS appears low, but it is much more common in patients undergoing TEM for circumferential lesions, with rates as high as 78% reported in the literature [50]. Some have argued that TAMIS should not be used for circumferential adenomas because of this high risk of rectal stenosis [18]. Management of rectal stenosis after TAMIS or TEM is similar to stenosis seen after low anterior resection. Most cases described in the literature have been treated endoscopically with balloon dilatation or stenting, or as a procedure under general anesthesia using Hegar dilators. The stenosis usually improves with one to two treatment sessions [50].

It is unclear if partial-thickness resection in cases of larger, circumferential lesions is associated with lower rates of stenosis when compared to full-thickness resection. Given concerns for higher rates of upstaging in such large adenomas, full-thickness resection may be preferable. For esophageal and gastric lesions involving more than three-quarters of the luminal circumference, endoscopic submucosal dissection (ESD) is associated with higher rates of stenosis as compared to endoscopic mucosal resection (EMR). However, these findings may not be true for colorectal lesions, perhaps because the presence of stool in the rectum provides a dilating pressure as the scar heals. Ohara et al. found that only about 20% of ESD resections for these circumferential colorectal lesions developed stenosis at 1 month [51]. However, others have found that while asymptomatic stenosis may occur, symptomatic stenosis requiring intervention was rare, and the role of prophylactic endoscopic dilatation is unclear [52]. It is also unclear what role endoluminal injection of steroids might play in preventing stenosis for colorectal lesions, although this has been used after ESD for esophageal and gastric lesions to prevent stenosis [53, 54].

Currently, there is no published evidence comparing stenosis rates after full-thickness resection using TAMIS to those seen after partial-thickness resection using ESD or EMR. Although there is a

theoretical benefit to full-thickness resection of large adenomas over partial-thickness resection given higher rates of occult malignancy in these lesions, it is unclear if this benefit is outweighed by the risk of stenosis.

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## Economics

There are no formal cost analyses comparing TAMIS to TEM, although it is broadly accepted that TAMIS is less expensive. The upfront cost of the TEM platform is approximately \$80,000, while the cost per disposable transanal port is approximately \$500 to \$800 [11]. Other authors have noted that the cost of the insufflation tubing to TEM is equivalent to the cost per disposable port [20]. A matched analysis comparing TEM and TAMIS found that TAMIS had significantly lower median operative time (70 min versus 108 min,  $p < 0.001$ ) as well as lower median hospital length of stay (0 days versus 1 day,  $p < 0.001$ ) [10]. So while it appears that TAMIS is likely cost-effective relative to TEM, there are no published studies showing this.

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## Unusual Applications

Typical indications for transanal endoscopic surgery have been for removal of rectal adenomas not amenable to standard endoscopic resection, treatment of early rectal cancer, and scar excision following neoadjuvant therapy [55]. However, TEM has been used for a variety of rectal lesions including neuroendocrine tumors, gastrointestinal stromal tumors (GIST), presacral tumors, benign stricture, rectourethral fistula, endorectal condylomas, rectal prolapse, pelvic abscess, and management of traumatic or iatrogenic rectal perforation [55]. TEM has also been used in the management of even more rare rectal lesions such as isolated rectal ulceration, rectal endometriosis, ganglioneuroma, and melanoma [56].

Considering TAMIS specifically, published applications have been more limited, but the use of TAMIS has been reported in the management of neuroendocrine tumors [8, 11, 57] as well as

GIST excision and pelvic abscess drainage [57]. TAMIS has also been used to correct stenosis occurring after low anterior resection as well as pouch-related issues after proctocolectomy for inflammatory bowel disease [58]. Finally, technology developed for use in TAMIS has now been used for transanal total mesorectal excision (taTME), which will be the topic of the remainder of this book.

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## Part II

# Transanal Total Mesorectal Excision (taTME)



# Indications for Malignant Neoplasia of the Rectum

# 19

Reagan L. Robertson and Carl J. Brown

The surgical management of rectal cancer continues to present surgeons with many challenges. Total mesorectal excision (TME) is the standard of care in rectal cancer surgery, with the goal of negative circumferential and distal resection margins (CRM and DRM) and clearance of the associated lymph nodes. High-quality TME is associated with lower locoregional recurrence rates and improved patient outcomes [1]. Innovations in rectal cancer surgery have led to the introduction of laparoscopic and robotic techniques of TME dissection. Regardless of operative approach, the traditional “top-down” TME retains several significant challenges. Operating in the confined space of the pelvis is technically challenging due to several tumor- and patient-related factors, particularly for low lesions. High rates of conversion, positive margins, and suboptimal TME quality remain ongoing issues. Additionally, as transanal minimally invasive approaches to rectal neoplasms are increasingly used, radical resection following local excision is more common, which poses new technical challenges related to perirectal inflammation and fibrosis.

The “bottom-up” approach of taTME has several advantages in overcoming the chal-

lenges of abdominal TME. The novel transanal vantage point, in theory, could facilitate better margins and higher rates of success with minimally invasive procedures in patients with rectal cancer. Currently, long-term outcomes of the procedure are not known, and there are no standardized methods for patient selection. The procedure should not be applied to all patients, and careful consideration of the potential risks and benefits to the individual patient is required. This chapter reviews the various indications for taTME in malignant disease of the rectum and its proposed advantages for certain patient populations.

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## Operative Approach for TME

### Abdominal TME

The gold standard for rectal cancer resection is high-quality TME, as described by Heald [1]. Conventionally, TME has been performed via an open abdominal approach in the “top-down” fashion. Laparoscopic and robotic TME have recently become more widely adopted in recent years. Whatever the approach, low pelvic dissection presents many well-described technical challenges. The bony pelvis creates a rigid and narrow operative field, and visualization is often suboptimal. The use of long instruments leads to problems with conflict and angulation. Delineation of the

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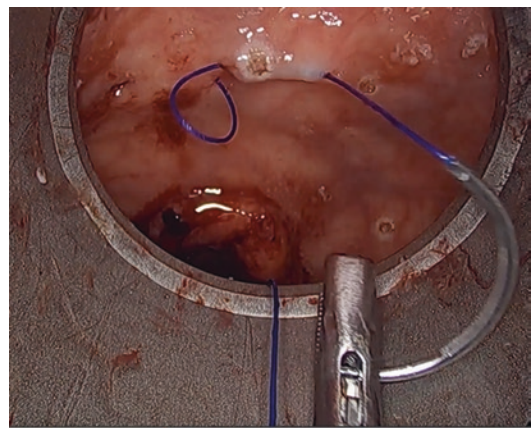
distal margin and rectal transection with stapling devices can be difficult and imprecise. These difficulties become further exaggerated in the narrow male pelvis or in obese patients with a bulky mesorectum [2, 3]. In laparoscopic surgery, the traction required to obtain adequate visualization may lead to mesorectal tearing and defects. Multiple laparoscopic stapler firings may also be required for distal transection, which may lead to more anastomotic complications [3–6]. These challenges may have negative effects on patients' pathologic and oncologic outcomes. Correct plane of dissection is critical when performing TME. Wrong plane dissection can lead to poor quality TME (incomplete mesorectal envelope), which is associated with worse long-term oncologic outcomes [1, 7]. Alternatively, dissecting outside the mesorectal plane can lead to injury to other critical structures such as the pelvic nerves, presacral and side-wall vasculature, or urogynecologic structures. Such injuries can have important deleterious effects on patient function and quality of life.

Laparoscopic TME (lapTME) has some short-term advantages over open TME, including shorter length of stay and return of bowel function, less postoperative pain, and lower rates of wound infection [8]. Multiple studies have also shown that lapTME appears to be a safe alternative to open TME for rectal cancer in terms of morbidity and oncologic outcomes [9, 10]. Regardless, lapTME continues to pose some significant challenges. A need for conversion to an open procedure has been reported in 10–34% of patients, particularly for males, the morbidly obese, and those with a narrow pelvis [9, 11, 12]. In the COLOR II trial, 16% of patients were converted to open; a narrow pelvis (22%), obesity (10%), and issues with visualization and tumor bulk were also cited as common reasons [9]. Robotic TME hoped to address some of the issues seen with lapTME, but conversion rates remain high in certain patients with predictors of difficult TME, such as obesity [13]. Converted procedures are known to have worse oncologic outcomes than both their open and laparoscopic counterparts [2]. These results raise concern regarding the use of lapTME, especially in these

patient populations. In addition, two recent studies, the ALaCaRT and ACOSOG Z6051, failed to show non-inferiority of lapTME over open TME for rectal cancer when assessing margin status and TME quality [14, 15]. Traction injuries to the mesorectum sustained while attempting to gain exposure in the deep pelvis and difficulty with accurate definition of the distal resection margin from above are thought to have contributed to the results. Abdominal TME has reported rates of positive CRM of 1.2–18.1% and incomplete or near-complete TME in 11–13% and 25–28% of patients, respectively [16]. These findings highlight the ongoing challenges with performing TME dissection and the need for alternate operative strategies that may improve outcomes.

### Transanal TME

taTME combines a variety of surgical approaches, including lapTME, open and endoscopic transanal dissection, and natural orifice surgery. It has become apparent that the “bottom-up” dissection addresses some of the problems inherent to abdominal TME. Precise delineation of the distal margin is easily accomplished with the transanal operating scope and placement of a distal purse string (Fig. 19.1). Accurate definition of a clear



**Fig. 19.1** Demonstration of delineation of the distal margin with the purse-string suture during taTME. The rectal tumor is visible in the proximal rectal lumen with a clear distal margin between the lesion and the proximal purse-string suture

distal margin may allow reanastomosis for some low tumors that would have otherwise required APR. Purse-string closure of the distal rectal stump obviates the need for surgical staplers and their associated problems. Enhanced visualization of the tissue planes also allows for more accurate circumferential TME dissection, without the need for traction on the rectum from above [2, 4, 16, 17]. Unobstructed views of the circumferential plane may improve preservation of surrounding critical structures such as the pelvic nerves [2]. Lower rates of pelvic and urinary dysfunction have been reported for taTME [16]. Finally, the effect of pneumodissection from below is not entirely clear, but may help better delineate planes for the abdominal portion of the procedure [16, 18].

Initial results suggest the transanal approach improves the ability to perform minimally invasive TME dissection. Low rates of conversion to open have been reported in most series [16, 19, 20]. The first 720 patients collected in the international taTME database had a conversion rate of 6.4%, as reported by Penna et al. [19]. taTME also had a significantly lower rate of conversion to open when compared to lapTME on meta-analysis of 573 patients (OR 0.29, 0.11–0.81,  $p$  0.02) [20]. Histopathologic results have also been promising. taTME has been associated with fewer involved circumferential and distal resection margins, and more complete TME than lapTME on several comparative studies [12, 21]. Of the 634 patients with pathology data in the series reported by Penna, 97.3% had negative margins, and only 4.1% had an incomplete TME. Ninety-two percent of patients had “good-quality” surgery, comprised of a composite measure of negative distal and circumferential margins with complete or near-complete TME (Table 19.1). None of the patient factors that have previously been shown to be high risk for incomplete TME were significantly related to poor TME on meta-analysis, possibly suggesting the taTME approach may mitigate the influence of these factors [19]. In a meta-analysis by Ma et al., compared to lapTME, taTME was associated with significantly better rates of complete TME (OR 1.75, CI 1.02–3.01), greater distance to CRM (WMD 0.96, 0.6–1.31,

**Table 19.1** Quirke grading system for completeness of total mesorectal excision (TME) [44]

TME grade	Definition	Description
Grade 1	Incomplete	Poor, incomplete excision of mesorectum with defects down to rectal muscularis propria
Grade 2	Nearly complete	Fair, superficial defects in mesorectum that do not expose muscularis propria
Grade 3	Complete	Good, intact mesorectum with only minor irregularities and no defects >5 mm

$p < 0.01$ ), and fewer positive CRMs (OR 0.39, 0.17–0.86,  $p = 0.02$ ) [20].

Despite these encouraging results, other small series have failed to show any advantage of taTME, possibly in the setting of increased complication rates with taTME [22, 23]. However, it is likely that learning curve-related factors can mask technical advantages in early reports. It is not known if improved histopathologic and short-term outcomes will translate into better long-term outcomes. Until long-term data are known, a cautious approach to the adoption of taTME with careful patient selection remains critical.

## Patient Selection

No standard criteria exist for selecting taTME for patients with malignant disease. There is heterogeneity in the literature for most patient- and tumor-related factors considered when choosing the technique. Many studies exclude T4 and high (>10 cm) rectal tumors, yet others do not. The first taTME consensus statement including indications for patient selection was published in 2014, following the second international taTME consensus conference (Table 19.2). The group concluded that taTME can be used for any malignant condition where accurate dissection of the distal to mid-rectum is required [4]. Due to the technical challenges of lapTME, the group stated that taTME may be the preferred approach for cancer in the following patients: males, patients with narrow and/or deep pelvis, obese patients (visceral obesity or BMI > 30), low to mid-rectal



cancers (<12 cm from anal verge), tumor diameter >4 cm, prostatic hypertrophy, distortion of tissue planes from neoadjuvant therapy, and impalpable low tumors. Additionally, taTME is indicated in any case where failure to progress during a transabdominal approach would necessitate conversion to an abdominoperineal resection (APR). Contraindications listed by the

consensus group included T4 tumors, obstructing tumors, and emergency resections.

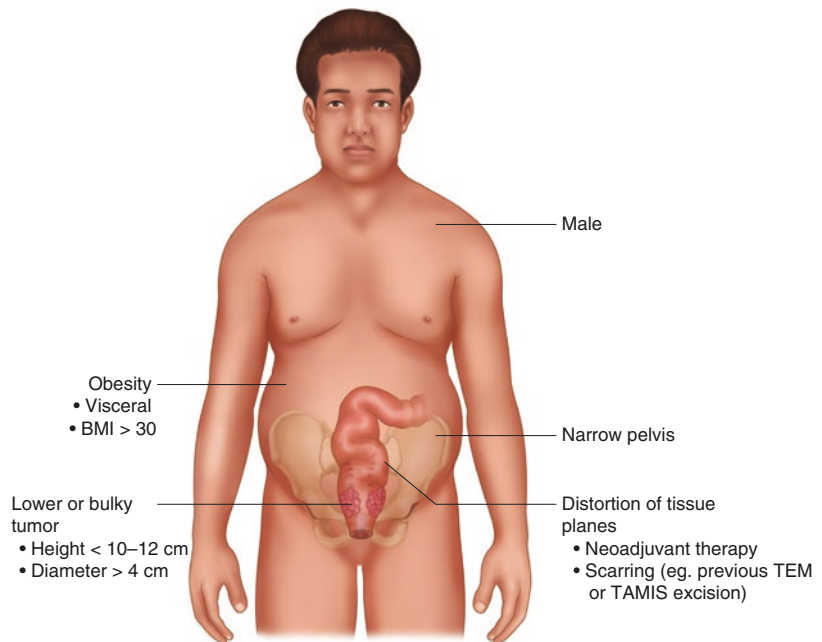
The recently published protocol for an upcoming randomized control trial assessing oncologic outcomes of taTME compared to lapTME (COLOR III) has set out clear guideline for patient selection [24]. Patients with biopsy-proven stage I–III rectal cancer with tumors of the low (0–5 cm) and mid (5–10 cm) rectum will be eligible for inclusion. Tumors must be within 10 cm of the anal verge on staging MRI. Patients will not be excluded on the basis of BMI, previous abdominal or pelvic surgery, or receipt of neoadjuvant therapy. Locally advanced tumors will be eligible for inclusion, so long as significant downstaging occurs with neoadjuvant therapy. A downstaged tumor may be included provided after treatment there is no evidence of residual T4 disease, no anal sphincter or levator ani involvement, and evidence of a CRM >2 mm.

Using the published literature as a guide, factors that may influence selection of patients for taTME technique can be divided into patient-, tumor-, and procedure-related factors (Fig. 19.2).

**Table 19.2** Consensus statement indications and contraindications for taTME [4]

Preferred indications	Relative contraindications
Failure to progress from the abdominal approach where APR would be required	Obstructing tumor
Obesity (visceral or BMI > 30)	T4 tumor
Male	Emergency surgery
Narrow or deep pelvis	
Low tumor (<12 cm)	
Tumor diameter >4 cm	
Distortion or scarring of tissue planes	
Prostatic hypertrophy	
Low, impalpable primary tumor	

**Fig. 19.2** Summary of preferred patient indications for taTME in malignant disease. (Data source from Motson et al. [4])



## Tumor-Related Factors

### Local Stage

In theory, taTME can be utilized as a surgical technique for any T or N stage in patients with adenocarcinoma of the mid and lower rectum. However, caution should be exercised when selecting this technique for locally advanced lesions. Many series have excluded T4 tumors, and the results of taTME for these lesions are not well known. Given the novel view of the “bottom-up” approach, with many practitioners still in the early phases of their learning curve, risks of injury to surrounding structures and a positive resection margin must be carefully considered. The current taTME consensus statement lists T4 tumors as a relative contraindication to the technique [4]. Other sources suggest tumors initially staged as T4 may be treated with taTME if there is downstaging to a lower T stage after neoadjuvant therapy [3, 24]. The taTME database registry showed inclusion of all tumor stages including T1–T2 (33.1%), T3 (61.4%), and T4 (5.5%) [19]. At our institution, taTME is considered for T1–T3 tumors and downstaged tumors on a case-by-case basis. The authors advise extreme caution and careful patient selection when considering taTME for T4 tumors, tumors with threatened CRM, or multi-visceral resection.

Of note, there are uncommon rectal cancers (e.g., neuroendocrine tumors, gastrointestinal stromal tumors, etc.) where total mesorectal excision is indicated for curative intent. While there is limited experience with these cancers, similar principles regarding taTME and potential for R0 resection apply.

### Tumor Height

taTME is best suited for low and mid-rectal tumors where “complete” TME, to the pelvic floor with low pelvic dissection, is required. Multiple studies have shown that during lapTME, low tumors are at higher risk for conversion and poor histopathologic outcomes [9, 11]. Conversely, lapTME is very successful for patients with upper rectal cancers, so the cost and additional time required for taTME are unwar-

ranted. Many taTME studies have only included patients with low and mid-rectal tumors (generally defined as <5 cm and <10 cm from the anal verge, respectively) [12]. Other series, including the initial consecutive patient cohort reported by Lacy et al., include all rectal tumors up to a height of 15 cm [3]. The second taTME consensus statement suggests the technique may be of maximal benefit to patients with tumor height <12 cm [4]. The COLOR III trial plans to recruit only those with mid to low tumors (<10 cm), and the GRECCAR II trial will exclusively look at taTME for low tumors requiring hand-sewn anastomosis [24, 25]. The current evidence supports the use of taTME for low to mid tumors. For higher tumors, the benefit of taTME is less certain, but can be considered in selected cases depending on other patient factors that may limit abdominal visualization and dissection in the pelvis.

## Patient-Related Factors

### Obesity

High BMI and visceral obesity are factors repeatedly associated with difficult TME dissection. Obesity was a reason for conversion in 10% of converted patients in the COLOR II study and 26% of patients in the CLASICC trial [9, 11]. A large volume of visceral fat makes retraction from above difficult and contributes to a bulky mesorectum that fills the pelvis and impairs visualization. A thick abdominal wall can further hinder the surgeon during laparoscopy due to increased torque and decreased range of motion. Higher BMI has been shown to negatively affect local recurrence rates for low rectal tumors. Recurrence rates of 2.5–6.1% were reported for underweight and normal weight patients as opposed to 9.2–13.8% in overweight and obese patients [26]. During transanal dissection, the low pelvic tissue planes are accessed without encountering the abdominal wall and intra-abdominal adipose tissue. Both BMI >30 and visceral obesity are listed by the consensus group as patient factors that may benefit when the taTME approach is employed [4].

## Narrow Pelvis

The narrow pelvis, particularly in male patients, leads to worse visualization and access for dissection when performing TME. A narrow pelvis increases the difficulty of surgery and has been associated with poorer-quality TME [27–29]. Indeed, narrow pelvis was the most common reason for conversion in the COLOR II trial (22%) [9]. Although the narrow pelvis is often associated with male gender, gender itself has not been a significant multivariate factor in all studies. Several authors have sought to better define pelvic anatomy and determine specific pelvic volume measurements that predict difficult TME. Certain pelvic measurements indicative of a narrow pelvis are associated with longer operative times and higher rates of conversion in lapTME [27, 30]. Ferko et al. assessed 14 pelvimetry measurements using CT and MRI and found the angle between the upper and lower pubic symphysis borders and the sacral promontory to be a significant predictor of Grade 3 mesorectal dissection (Fig. 19.3). No other pelvic measurements were found to be significant predictors of poor-quality TME [28]. Presently, there are no formalized measurements to guide surgeons on patient selection for taTME. Regardless, careful review of patient

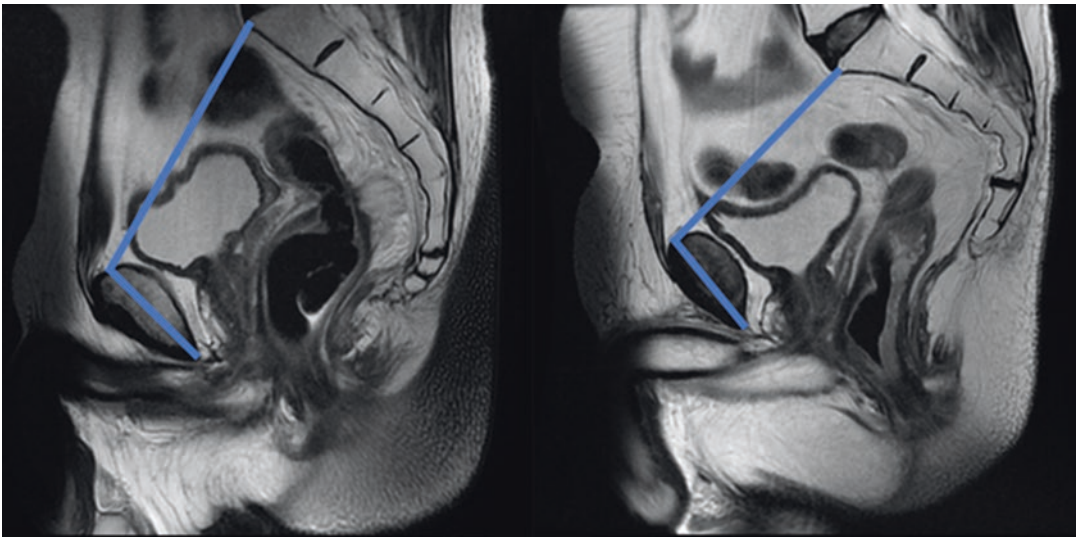
imaging, including an assessment of the pelvic anatomy, is beneficial when deciding on the use of taTME.

## Procedure-Related Factors

### Following Local Excision with Transanal Endoscopic Surgery (TES)

Transanal endoscopic surgery (TES) is indicated in patients with T1 cancers with favorable histopathologic features [31]. However, poor specificity of preoperative imaging modalities leads to unexpectedly advanced lesions (e.g., high-risk histopathologic features,  $\geq$ T2 cancer) identified after TES. Timely TME is recommended to mitigate a high risk of local recurrence and is performed in up to 23% of these patients.

Unfortunately, completion TME following TES of a rectal malignancy is associated with high rates of APR and significant patient morbidity [32–35]. Scarring from the previous excision can distort tissue planes and makes completion or salvage TME technically challenging. In two small studies, completion taTME after TES appears to be oncologically safe [35, 36]. Koedam et al. showed advantages in the taTME approach in the pathologic specimen, with significantly



**Fig. 19.3** The angle between the superior and inferior pubic symphysis and the sacral promontory was shown to be significantly associated with quality of TME. A smaller angle was associated with poorer-quality TME [28]

fewer rectal perforations [36]. Letarte et al. demonstrated fewer conversions to open surgery and a lower APR rate in these patients. While more investigation is necessary, this is an important indication where patients may benefit from the taTME approach [35].

### Low/Ultra-Low Anterior Resection

By and large, taTME is performed for rectal malignancies requiring a low pelvic dissection with planned restoration of intestinal continuity. The technique has a theoretical benefit in these situations, where accurate definition of the distal margin for transection and anastomosis may not be possible from the abdominal approach.

### Intersphincteric Dissection

Increasingly, there is a shift toward the use of sphincter-preserving operations in patients with low rectal cancer, many of whom would have conventionally been managed with APR. Rullier et al. first classified low rectal cancer into four types (Table 19.3). Type I–III lesions are candidates for sphincter preservation via partial or total intersphincteric techniques. Intersphincteric dissection has comparable 5-year local recurrence rates (5–9% vs. 6%) and disease-free survival (70–73% vs. 68%) to patients undergoing APR and should be considered in appropriate

patients with low tumors who desire sphincter preservation [37].

With the use of high-definition cameras and magnification with the minimally invasive “bottom-up” approach, taTME provides often superior visualization of intersphincteric tissue planes, which is another unique situation where taTME may be advantageous to patients. Further study is needed to ascertain the impact of taTME on the quality of intersphincteric dissection and the number of patients who are selected for the intersphincteric approach. The application of taTME for intersphincteric resection is addressed more completely in a dedicated chapter on this topic.

### Abdominoperineal Resection

To a lesser extent, taTME has been described and utilized for patients undergoing APR for low rectal cancer. Only 9% (65/720) of patients from the international registry have undergone taTME for APR. No individual outcomes for patients undergoing APR vs. LAR with the use of taTME have been reported. taTME may provide advantages for some patients undergoing APR where margin status or quality of TME may be threatened, but this area requires further study to provide further recommendations.

**Table 19.3** Classification of low rectal tumors with standardization of surgical approach [37]

Classification	Definition	Surgical procedure
Type I	Supra-anal tumor >1 cm from the anal ring	Conventional coloanal anastomosis
Type II	Juxta-anal tumor <1 cm from the anal ring	Partial intersphincteric resection
Type III	Intra-anal tumor Internal sphincter invasion	Total intersphincteric resection
Type IV	Transanal tumor External sphincter invasion	Abdominoperineal resection

### Patient Counselling

Although several potential benefits of taTME exist, long-term outcomes have not been established. Early recurrence data have been encouraging, with similar local and distant recurrence rates compared to lapTME [3, 19]. Lacy et al. reported an overall recurrence of 8.4% in their group’s first 140 patients undergoing taTME at median follow-up of 15 months (6.1% distant, 0.8% local, and 1.5% both local and distant) [3]. Well-designed randomized control trials are in development, and long-term survival results are pending. As such, taTME has not been shown to be equivalent to more conventional approaches at this time.

taTME is an innovative surgical procedure, and patients undergoing innovative procedures

are not subject to the same ethical scrutiny as patients receiving experimental treatment [38]. The IDEAL framework has been developed as a method to standardize the adoption of innovative techniques and treatments [39–41]. Checkpoints for the research and evaluation of a novel treatment are integrated along the natural innovation adoption curve. These measures aim to ensure acceptable patient safety and outcomes. With this in mind, in-depth counselling regarding the risks and benefits of an innovative technique by the surgeon is a critical aspect of patient selection and consent. The authors also encourage discussion of patient selection at multidisciplinary rounds or patient case conferences when possible. Surgeons must be transparent about unknown long-term cancer-specific survival and functional results during the informed consent process. In this regard, selection of patients who have a clear understanding of the innovative nature of taTME, and who are keen to accept currently unknown risks for the possibility of better short-term outcomes, is critical. Ideally, these patients would be agreeable to anonymized sharing of their data with one of the taTME registries (such as the OSTRiCh registry), or participation in a randomized control trial where available, to expedite the global acquisition of this important information [24, 42].

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### Surgeon Training and Experience

taTME remains a novel surgical approach with multiple technical challenges. Much has been published on the specialized nature of the procedure and the need for adequate training and case volumes. At present, taTME cannot be recommended for all patients from all surgeons. As such, appropriate surgeon selection is as important as patient selection.

Those wishing to perform the procedure should have adequate case volume in laparoscopic pelvic dissection and minimally invasive transanal techniques. Participation in proctored courses or mentorships is strongly encouraged [43]. Other methods to optimize patient safety include involvement of two surgeons per case

when feasible, participation in clinical registries, and reporting and publication of outcomes. The first 720 cases reported from the taTME registry had 50% of patients provided by institutions that had only performed 1–5 cases [19]. The total cohort had acceptable clinical outcomes, so it appears good outcomes are possible even early in the learning curve, especially when methods to ensure safe adoption are considered. Therefore, surgeons must consider their own expertise and experience and how to sensibly integrate taTME into their practice prior to offering the technique to patients with malignant disease.

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### Summary

High-quality TME remains the gold standard for rectal cancer resection, regardless of the approach. Complete TME is essential to ensure optimal oncologic outcomes. There are currently no long-term outcomes available to support the use of taTME over conventional laparoscopic or open TME approaches. Regardless, short-term histopathologic and survival outcomes for taTME are acceptable and comparable to standard approaches. taTME may provide some benefit in challenging patients at high risk for incomplete TME, such as the narrow male pelvis, obesity, and low tumors. Additional high-quality, randomized studies are needed to further support these findings and provide clear evidence for the preferential use of taTME over other approaches. Careful patient selection and counselling are critical when choosing taTME for the management of malignant disease. Discussion of patient selection at multidisciplinary rounds or case conference should be strongly considered. Finally, adequate training and case volumes of surgeons and institutions offering taTME for rectal cancer are essential to ensure safe practices and good patient outcomes.

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# Indications for Benign Disease of the Rectum

# 20

Willem A. Bemelman

## Introduction

The transanal approach pioneered for rectal cancer brought to light all of the learning curve issues that could be imagined. As the era of taTME launched, a déjà vu reminiscent of the implementation of laparoscopic cholecystectomy and laparoscopic colorectal surgery and their known early challenges existed. However, the learning curve issues have been clearly appreciated thanks to the taTME registry [1]. Apart from a new set of short-term complications (such as injury to the male urethra) that have been realized, the long-term oncologic safety of the transanal approach still has to be established. The quality of resection with taTME, such as the risk of margin positivity with this technique, is still being established. Furthermore, taTME is unique in that the rectum is intentionally divided or “perforated,” and we are still uncertain about the risk of such specimen perforations as the potential exposure of the dissection area with tumor cells might negatively influence long-term outcomes [2].

As a point of reference, however, laparoscopic colorectal surgery was also met with challenges when first implemented for colorectal cancer – with valid concerns about the oncologic adequacy of the approach raised in the beginning (e.g.,

regarding the risk of port site metastasis). Likewise, the common bile duct injuries that occurred during the introduction of laparoscopic cholecystectomy in the early 1990s must be remembered, as this represents a similar paradigm to urethral injury observed with institution of the taTME approach. Appreciating and dealing with these learning-related challenges ensured that these once novel techniques finally had become safely standardized and broadly implemented; today, they are the standard of care. TaTME will likely follow the same pathway of implementation and will be the standard approach for distal rectal cancer in the future.

In transanal surgery for benign indications, there are no oncologic factors to be examined and compared to other operative methods. Since there is no need to perform a radical excision in transanal surgery for benign disease, one can choose for a safer mode of dissection staying close to the bowel avoiding vital structures – such as ureters, the urethra, hypogastric nerves, and nervi erigentes. For this reason, the application of the transanal approach (which applies the techniques of TAMIS and taTME) to pelvic pathology is an excellent alternative for top-down surgery, especially for the complicated and challenging pelvis.

The objective of the transanal approach is not at all to complete the entire operation in the bottom-up direction. However, the most difficult part – i.e., along the deep pelvis – is best

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approached transanally. Typically, the transanal dissection is completed to the level of the peritoneal reflection anteriorly. The transanal approach is particularly well-suited for the horizontal anterior plane along the rectovaginal septum or, in males, along the rectoprostatic (Denonvilliers') fascia to the level of the seminal vesicles. This access is quite difficult to achieve in a top-down manner. When this point is reached in the bottom-up dissection, the rendezvous can be made with the top-down dissection, which can be accessed either via lower midline laparotomy incision, optional Pfannenstiel incision, or, laparoscopically depending on patient characteristics, the indication for surgery and the presence of intra-abdominal adhesions and other factors which define case complexity. Ultimately, surgery is not about one technique per se, but rather about *combining the best of all approaches tailored to the characteristics of the patient, to their condition, and to the characteristics of the pathology to create a safe and effective operation.*

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## Inflammatory Bowel Disease

Inflammatory bowel disease basically consists of two major types – ulcerative colitis and Crohn's disease. In ulcerative colitis, the disease is restricted to the rectum and colon. If the disease is refractory to medical therapy, proctocolectomy is indicated. In Crohn's disease both small as well as large bowel can be affected. Mostly, Crohn's disease is located in the terminal ileum. Up to 25% of the patients develop perianal fistulas sometimes in combination with proctitis or proctocolitis. Most surgeons would defunction the rectum as a first step if proctitis with or without complex perianal fistula has caused such a disability that creation of an ostomy restores quality of life. If defunctioning does not relieve the symptoms adequately or there is a risk of cancer, surgical resection is indicated.

## Ta Proctectomy and Ileoanal Pouch Surgery

Restorative proctocolectomy and reconstruction with an ileoanal pouch is the procedure of choice

in patients with ulcerative colitis and polyposis syndromes. Reconstructive surgery creating an ileal pouch started in the late 1970s. Several surgical groups experimented with different types of reservoirs. This resulted in a variety of small bowel reservoirs. The three most well-known today are the J-, the S-, and the W-pouch. Over time, accumulative evidence demonstrated that the J-pouch is the superior pouch, because of its relatively ease of construction and its superiority in emptying compared to the S- and W-pouches [3, 4].

The reservoirs can be stapled to the anus using the double-stapling technique leaving a small rim of rectal mucosa, or "cuff." When applying a hand-sewn technique, this is done mostly in combination with a mucosectomy. The current standard for most surgeons is to perform a stapled ileoanal J-pouch reservoir with a remaining rectal cuff of less than 2 cm. If the cuff is longer than 2 cm, the remaining rectum is called a "retained rectum," which should be considered a technical error and which may ultimately lead to revisionary pouch surgery.

Most patients require proctocolectomy because the disease process is, or has become, refractory to medical therapy. A minority of patients require proctocolectomy because of dysplasia or cancer that has developed, likely in the background of chronic proctocolitis. Proctocolectomy done for refractory inflammation is mostly done as a three- or modified two-stage procedure [5]. As a first step, a colectomy is performed, followed by completion proctectomy and pouch creation with defunctioning ileostomy (three-stage) or without it (modified two-stage). When it comes to colectomy, patients are generally immunocompromised due to therapy with biologics (e.g., immunomodulatory agents, TNF-alpha antagonists), chronic malnutrition, a persistent negative nitrogen balance, and anemia of chronic disease. Combined data of three referral institutes demonstrated that defunctioning the pouch in these deconditioned patients – in the setting of a two-stage procedure – is ineffective in preventing anastomotic leakage and is associated with long-term complications. In contrast, the three-staged procedures enable such patients to be wean from the immunomodulators and often corticosteroids and recover physiologically before embarking on pouch constructing.

Ultimately, this resulted in lower leak rates and thus improved clinical outcomes [6]. For this reason, a modified two-stage or three-stage procedure is preferred for UC. Nowadays, the colectomy is often completed laparoscopically with reduced postoperative complications, reduced incidence of clinically significant adhesions, and preserved fecundity [7]. Due to the relative absence of adhesions with this approach, the completion proctectomy can be done via the Pfannenstiel incision or, alternatively, with a combination of a single-port introduced via the ileostomy site and a TAMIS platform, which provides a minimally invasive option. There are a number of reasons why the transanal approach for completions proctectomy for UC might be advised:

1. The Ta platform enables a tailored transection of the distal rectum, thus assuring a precise length of the rectal cuff and thus avoiding the risk of a retained rectum.
2. Laparoscopic cross-stapling of the distal rectum has been shown difficult resulting in too long cuffs and the necessity to use multiple staple cartridges, thereby increasing the risk for anastomotic leakage [8].
3. Using the TAMIS technique, the difficulty of the double stapling is obviated and is replaced by a single-stapled (double purse-string) anastomosis [9].
4. The best plane of dissection is still being debated. The TME plane is an avascular plane and surgeons are used to do this for rectal cancer. In order to avoid nerve injuries, most IBD surgeons would do a “bad” TME anteriorly staying close to the rectum anteromedially. A possible drawback of the techniques is the relatively large pelvic cavity that remains, which cannot be adequately filled with the pouch, resulting (hypothetically) in a larger presacral cavity. This may prevent a potential anastomotic leak from sealing, and it could create an opportunity for proximal small bowel to become entrapped posterior to the pouch. Alternatively, a close rectal dissection can be applied, which hold the dissection perimeter away from autonomic nerves, and, keeping the surrounding “cushion of mesentery” in situ, avoids a wide pelvic cavitation and limits extra-pelvic space that can be problematic. Furthermore, it is suggested that by preserving the mesorectum and its nerves, a greater awareness of pouch filling is achieved compared to removing the mesorectum, probably due to different proprioception provided by proprioceptors that are intrinsic to the mesorectum itself [10]. It should be noted that *top-down* dissection close to the rectal muscle tube and especially deep within the pelvis is difficult because of lack of exposure due to the mesorectal fat. In contrast, *bottom-up* dissection along the muscle tube of the rectum using either the electric hook or vessel sealing devices is relatively easy.
5. The Ta approach allows the pouch anastomosis to be completed with a single-stapled construction, and this obviates the need for a double-stapled technique, which is associated with problematic intersecting staple lines and the “dog ears” on both sites of the circular anastomosis [8, 9].
6. Combining the Ta *bottom-up* approach with single-port *top-down* proctectomy via the stoma site, abdominal access trauma is minimized, and the requirement for an incision for the purpose of extraction or pouch creation is avoided (Fig. 20.1).

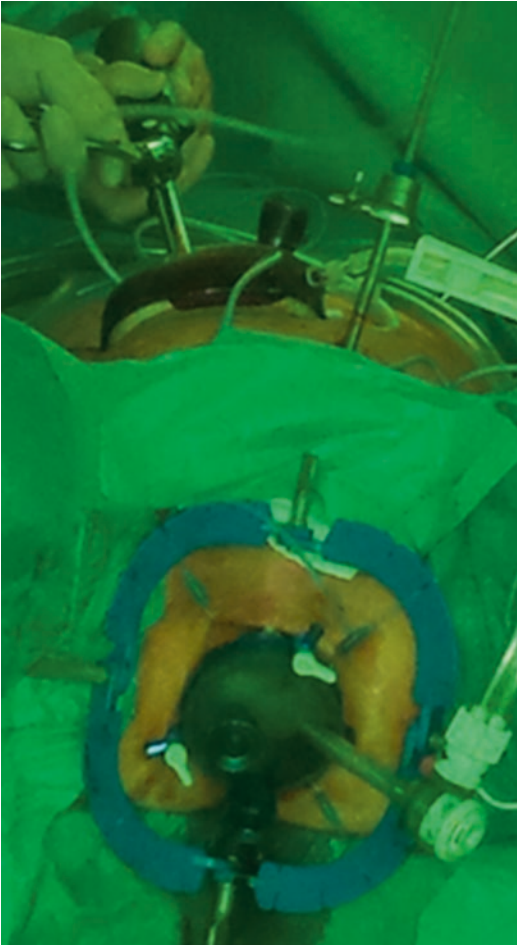
## Technique

*Preparation:* Patients are managed perioperatively in an enhanced recovery program. Patients are positioned in the Lloyd Davis position on a short beanbag. The right arm is tucked and positioned alongside the body. The rectum is washed out with an iodine solution. Prophylactic antibiotics are administered.

## Procedure Described for a Single-Team Procedure

*Step 1.* The ileostomy is dissected and provisionally closed with a running suture to prevent stool spillage. A single-port laparoscopic platform (GELPOINT Advanced Access Platform, Applied Medical, Rancho Santa Margarita, CA, USA) is placed in the stoma site. At the





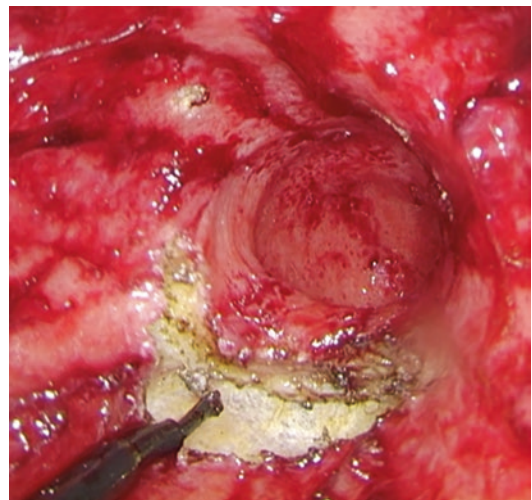
**Fig. 20.1** Transabdominal and transanal single-port platforms in place

fascial level, releasing incisions are often made to increase exposure to the abdominal cavity. After establishing pneumoperitoneum, adhesions and the length of the rectal stump is assessed. The proctectomy is started bottom-up, in order to prevent an early rendezvous with the top-down dissection, because rendezvous between TAMIS and laparoscopy means less exposure working via the TAMIS, bottom-up approach.

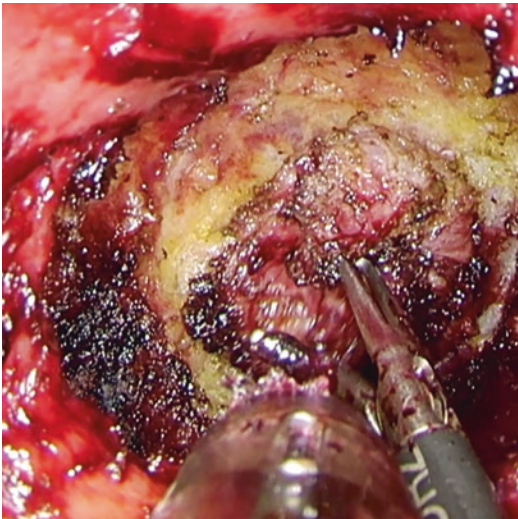
*Step II.* A perianal block is injected at 3 and 9 o'clock positions using 10 ml of an amide local anesthetic (such as bupivacaine), with 5 ml on either site to make the external sphincter muscle relax. The Lone Star Retractor (Cooper Surgical, Inc., Trumbull, CT, USA) is

then positioned. Using blunt retractors the dentate line is exposed. The level of transection is marked  $\pm 3$  cm proximal to the dentate line to guarantee a remaining rectal cuff of  $\pm 1$  cm after the double purse-string stapled ileoanal anastomosis. The TAMIS platform GelPOINT® Path Transanal Access Platform, Applied Medical, Rancho Santa Margarita, CA, USA, is inserted with two 10 mm cannulas in the gel cap, as well as a valveless 8 mm trocar to allow for operation of the AirSeal® Insufflation System (ConMed, Inc., Utica, NY, USA). Insufflation pressures are set on 15 mm Hg. In case of combined laparoscopy and TAMIS, the pressure settings must be increased to 20 mmHg because of the competitive abdominal pressure. Using the electrocautery hook, the bowel wall is circumferentially transected, with care to assure that the transection of the bowel wall is full-thickness and circular (Fig. 20.2).

Unlike the approach to taTME for cancer, the rectal lumen is not closed, because in this setting the rectum is blind-ending and because it is thoroughly cleansed with iodine solution. Next, dissection is carried out in close proximity to the rectum using electrocautery or ultrasonic dissection. Care should be taken to maintain a plane near to the rectal muscular tube and to avoid an outward extension of this



**Fig. 20.2** Transection rectal wall full thickness

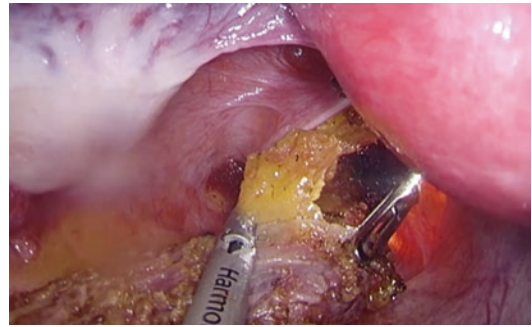


**Fig. 20.3** Close rectal dissection

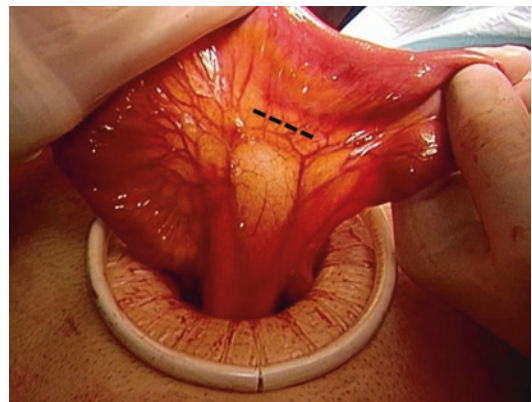
plane, with entry into the mesorectal fat plane (Fig. 20.3). The dissection next proceeds as far as possible avoiding prematurely opening the pouch of Douglas, because the moment the connection is established with the abdominal cavity, the exposure of the bottom-up dissection diminishes. If connection is made, the top-down dissection is started.

*Step III.* With the single-port platform inserted at the stoma site, pneumoperitoneum and visualization of the abdominal cavity is established laparoscopically. The procedure is simplified when an additional 5 mm trocar is inserted in the left lower quadrant, which can be used at the end of the operation to insert a pelvic drain. The rectal stump is identified, and using the ultrasonic vessel sealing device, the “top-down” close rectal proctectomy is initiated. Often, the rendezvous can be made with the bottom-up dissection quite rapidly (Fig. 20.4). The specimen can be extracted either transanally or via the stoma site.

*Step IV.* The mesentery of the small bowel is fully mobilized over the pancreatic head and duodenum to obtain maximal length. Transverse incisions are made over the anterior and posterior mesentery in order to increase pouch reach. This can be done best with the electrocautery hook.



**Fig. 20.4** Transabdominal view on the rendezvous with the bottom-up dissection



**Fig. 20.5** Exteriorized terminal ileum taking the connecting vessels to the inner arcade to increase length

*Step V.* Pouch creation. The terminal ileum is exteriorized via the Alexis ring of the single-port platform. If there is still not enough reach, the connecting vessels to the arcade of the terminal ileum can be ligated (Fig. 20.5). Using linear staplers a pouch of 10–15 cm can be constructed. The redundant efferent loop is removed with a linear stapler and oversewn with a running suture to completely incorporate the blind loop into the pouch to avoid future blind loop syndrome. An anvil is placed in the base of the pouch and fixed with a purse string. The size of the circular stapler depends on the diameter of the anus and the relative length of the remaining rectal cuff. If the cuff is relatively long, a larger diameter stapling device can be chosen.

*Step VI.* Purse-string creation of the rectal cuff. Using a monofilament 0-Prolene or equiva-

lent, the purse string is made taking care to create symmetric bites and to not have either too much or too little bowel wall in the purse string. The muscular layer must be incorporated.

*Step VII.* Under laparoscopic control the pouch is positioned in the pelvis without rotation and without herniation of small bowel beneath the mesentery. Transanally, a long clamp is advanced to grab the tip of the anvil and pull the tip of the anvil through the anal purse string. With graspers the peritoneum and the mesorectal fat is positioned alongside the pouch to facilitate a smooth advancement of the pouch in the pelvis. The anvil is mated to the arm portion of the circular stapler. The stapler is closed and fired. Typically, the rectal donut is quite thick as a result of the double purse-string single-stapling technique. Having pneumoperitoneum the anastomosis is checked for leaks (reverse air leak test). It might be useful to reinforce the anastomosis with interrupted or running suture. A pouch drain (Chap. 32) is inserted in the pouch for decompression. In our unit, it is a common practice not to defunction the ileoanal anastomosis, accepting a leak rate of ~10–15%.

*Step VIII.* Via the single-port access platform, a pelvic drain is positioned after removal of the additional 5 mm trocar. The position of the mesentery and small bowel is checked. The single-port platform is removed and the stoma site is closed in layers. The skin is closed with a monofilament purse string (Fig. 20.6).

The nasogastric tube is removed upon case completion. The pelvic drain is removed after 48 h. The suprapubic catheter is clamped in the following days after surgery, and if there is no retention after voiding, the catheter is removed. Patients are allowed to have a liquid diet until the pouch drain is removed at day 6. C-reactive protein is measured at day 4 and day 7. If there is any indication of anastomotic leakage being clinical symptoms or elevation of CRP at day 7, a CT scan with oral and transanal contrast is performed. If a leak is identified radiographically, the patient must be taken back to theater and an



**Fig. 20.6** Final result of double single-port TAMIS proctectomy and pouch

ileostomy fashioned; an Endo-SPONGE is inserted transanally via the anastomotic dehiscence in the septic cavity [11]. Typically, one or two Endo-SPONGE exchanges are necessary to have a clean cavity over a time period of a week in order to resuture the anastomotic defect in the following week. Using this protocol, we have been able to close all ileoanal pouch leaks within 3 weeks after diagnosis [12].

If the pouch has been defunctioned primarily for any reason, one should monitor the plasma CRP level, which can help elucidate a silent leak. In addition, the anastomosis is routinely checked endoscopically within 2–4 weeks after surgery. If there is a silent leak, Endo-SPONGE-assisted early closure of the anastomosis is still feasible.

## Preliminary Results

De Buck et al. [13] compared a cohort of nearly 100 Ta pouches to conventional laparoscopic pouches in a three tertiary referral center study.



It was demonstrated that the odds for postoperative complications were 0.52 times lower for the Ta pouch patients compared to the patients who had undergone a conventional laparoscopic pouch. This finding was primarily attributed to reduction in surgical site infections. Ta pouches therefore seem to be a safe and promising alternative for conventional laparoscopic pouches, but long-term data are still awaited with respect to functional outcomes.

### Ta Redo Surgery for Pouch Dysfunction

Pouch dysfunction is a serious long-term complication of this restorative procedure. Causes are often multifactorial and can be medical or surgical in origin. Careful multidisciplinary assessment of the pouch is therefore mandatory to find the correct cause of the problem and decide on the appropriate therapy. Cross-sectional imaging and joint endoscopic assessment of the pouch are essential in decision-making.

#### Surgical Causes of Pouch Dysfunction

- (a) Dysfunction related to the rectal cuff length: A rectal cuff that is of an improper length may be resultant from the double-stapling technique for performing the ileoanal anastomosis. The cuff should not be larger than 2 centimeters; otherwise this will result in a retained rectum. It is believed that having such a cuff has a role in the fine continence discriminating passage of air versus fluid. The problem with having a long cuff (retained rectum), however, is the occurrence of cuffitis in ulcerative colitis and recurrent polyps in familial polyposis. If these conditions cannot be treated medically or by endoscopic removal, respectively, the cuff requires surgical excision.
- (b) Retained rectum: A retained rectum is defined if the remaining rectum is >2 cm. Proctitis of the retained rectum can cause urge and increased bowel movements, thus negatively impacting anorectal function. If symptomatic, this should be corrected by

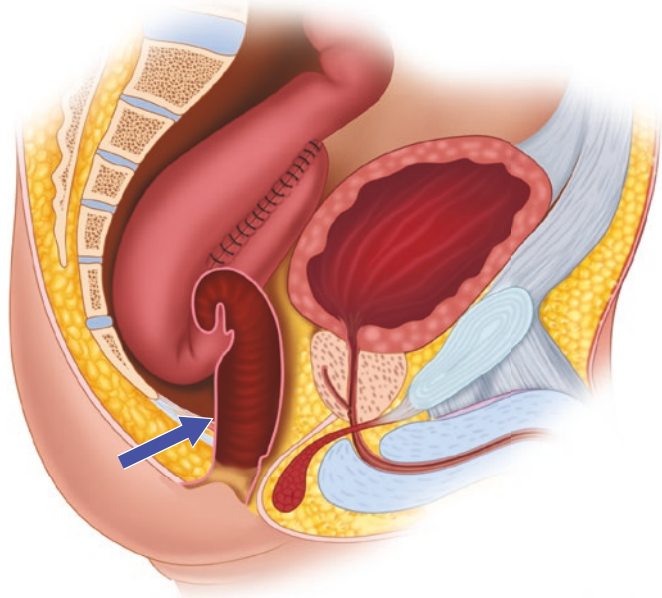
pouch advancement – that is, excising the retained rectum and bringing down the pouch to an appropriate cuff size (Fig. 20.7).

- (c) Redundant efferent loop of S-pouch. S-pouches have an efferent loop (Fig. 20.8). This loop should not be longer than 2 cm, because otherwise there is a risk of kinking of the efferent loop causing evacuatory dysfunction. When the dysfunction from evacuation becomes chronic, the pouch enlarges and decompensates, as it is unable to build sufficient pressure to overcome the outlet resistance. If the pouch is not too large, the efferent loop can be shortened and a new hand-sewn anastomosis made. In case the pouch is already too large, probably the overall size of the pouch needs to be corrected as well (Fig. 20.9).
- (d) Mega-pouch: Mega-pouches (Fig. 20.9) can develop as result of chronic outlet obstruction and particularly the larger reservoirs are sensitive for this (e.g., S-pouches, W-pouches,



**Fig. 20.7** Specimen of pouch on retained rectum

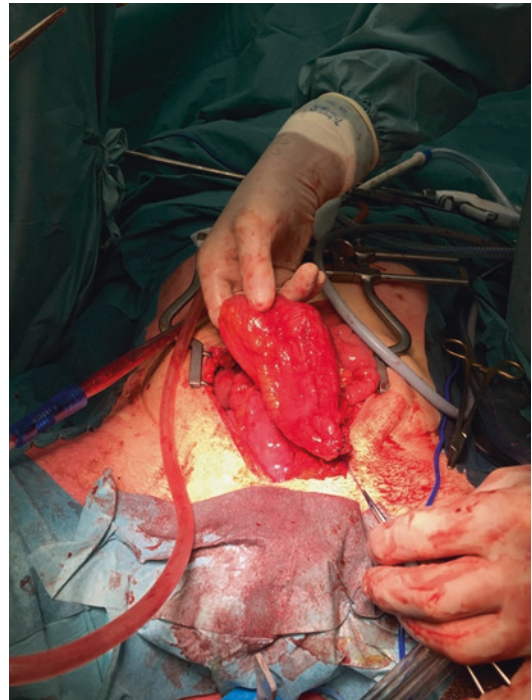
**Fig. 20.8** Efferent loop of S-pouch (arrow)



**Fig. 20.9** Overdistended S-pouch before remodeling

and long J-pouches). If symptoms of problematic evacuation warrant a redo pouch, and if the patients prefer not to have an ileostomy, the pouch needs to be dissected and remodeled, or an altogether new pouch should be fashioned (Fig. 20.10).

(e) Chronic sinus: A chronic sinus is defined as an anastomotic leak that persists for longer



**Fig. 20.10** Remodeled pouch



than 1 year. These sinuses can be quite clinically evident and may be the reason that prevents closure of a defunctioning ileostomy; or the sinus(es) can be clinically silent causing pouch dysfunction often misdiagnosed as refractory pouchitis [14]. Cross-sectional imaging is therefore imperative in case of chronic pouch dysfunction (Fig. 20.11).

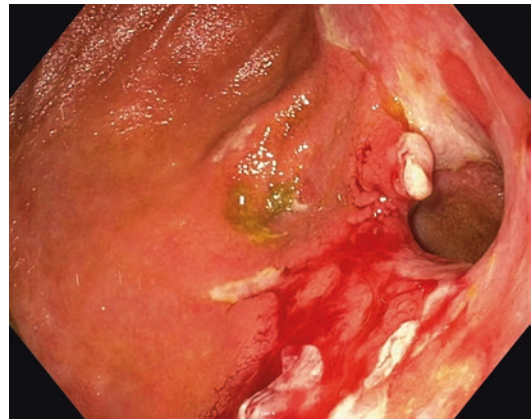
- (f) The failed pouch. The top three causes for pouch failure are Crohn's disease (Fig. 20.12), prior anastomotic leakage/pelvic sepsis, and refractory pouchitis [15]. The chronic dysfunctioning pouch can be diverted with an ileostomy. If symptoms persist (e.g., severe perianal fistula in Crohn's disease or uncontrollable anal discharge), it is best if the pouch is excised. The remaining space within the pelvic cavity must be filled, and typically omentum or small bowel mesentery is placed in the cavity in order to prevent abscess formation in the pelvis.

## Surgical Approach

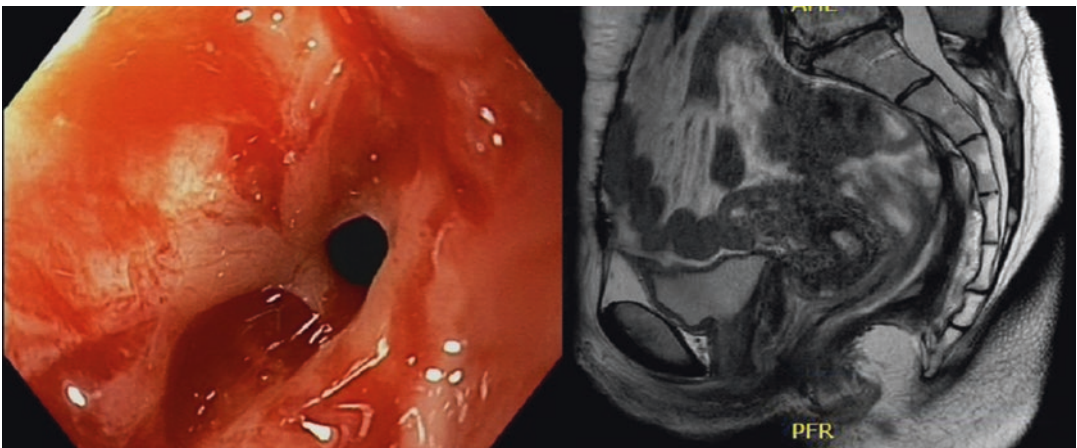
- (a) *Transanal excision of cuff, retained rectum or efferent loop, and sleeve advancement of the pouch with or without transabdominal mobilization of the pouch*

The patient is placed in the Lloyd Davis position. A perianal nerve block is done to relax the external sphincter muscle. A Lone Star Retractor is secured to expose the anorectum.

*Cuff/efferent loop excision* Depending on the level of the pouch-anal anastomosis, the rectal mucosa is incised just below the ileoanal anastomosis using either retractors or the TAMIS platform. If the ileoanal anastomosis was already at the level of the dentate line (e.g., as is the case for an S-pouch), care must be taken not to damage the internal sphincter muscle. Transection of the muscular layer should be done at the level of the ileoanal anastomosis in



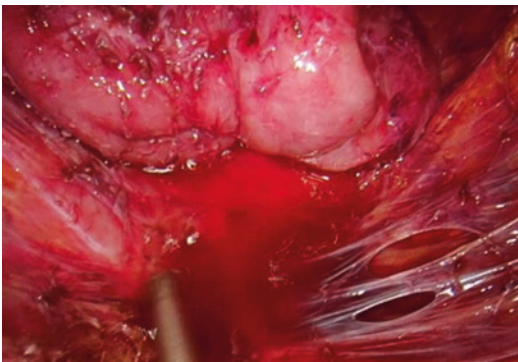
**Fig. 20.12** Crohn's disease in pouch



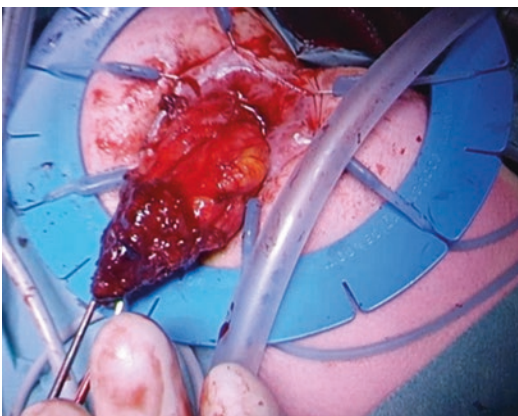
**Fig. 20.11** Endoscopic image of sinus (left), MRI with sinus (arrow, right)

order to preserve the internal sphincter muscle. In case of cuffitis, a mucosectomy can be done to preserve the internal sphincter muscle. Careful dissection of the distal pouch or the efferent loop is performed. If mobilization of the distal pouch and cuff or efferent loop proceeds successfully (Fig. 20.13), the mobilized portion can be exteriorized via the anus, the cuff or efferent loop can be excised, and a hand-sewn anastomosis can be constructed. If bottom-up mobilization is insufficient, either open or laparoscopic mobilization of the proximal part of the pouch and its mesentery must be performed. In the latter case, it is advisable to defunction the hand-sewn anastomosis (Fig. 20.14).

**Retained rectum** The rectal wall is transected 2–3 cm cranial from the dentate line. Applying a close rectal dissection technique,



**Fig. 20.13** Transanal view on TAMIS mobilized pouch



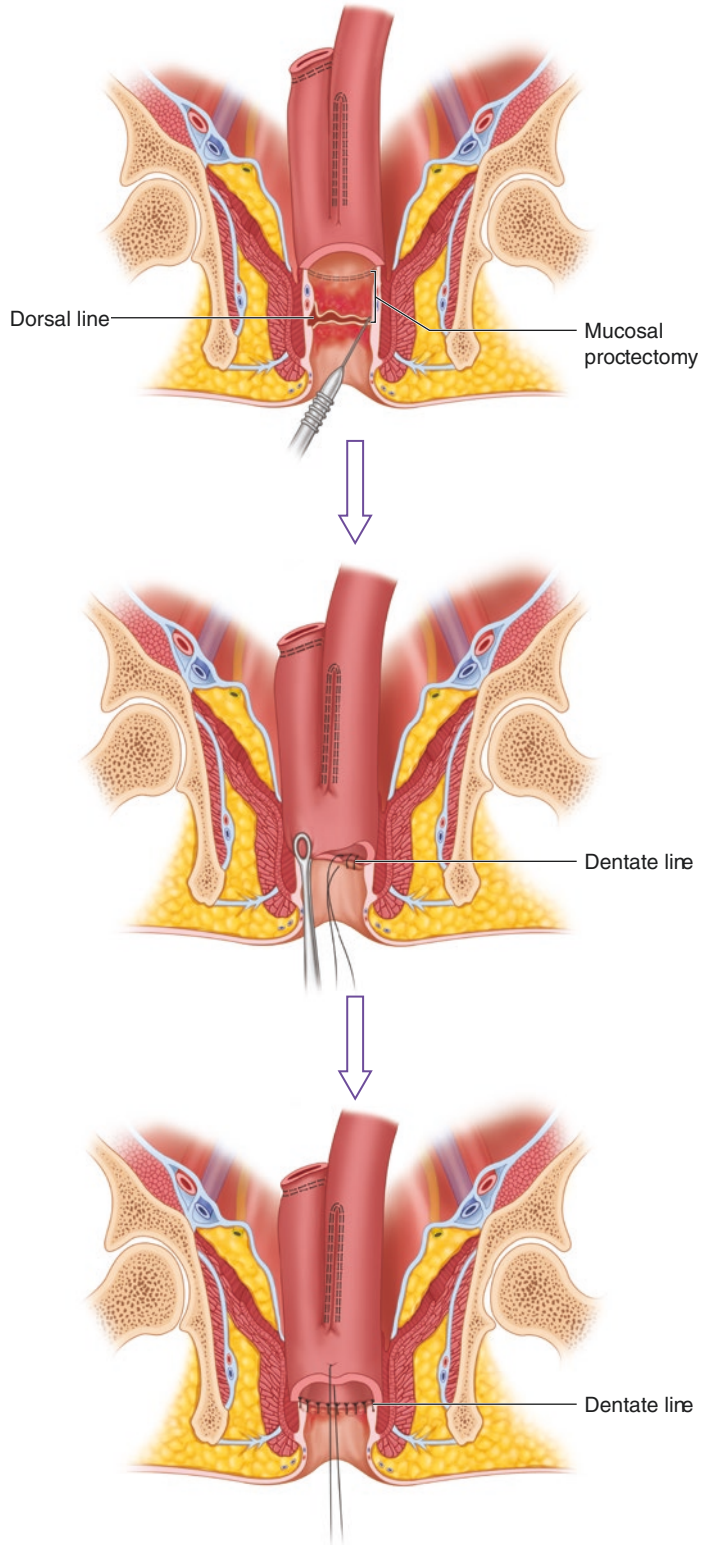
**Fig. 20.14** Distal part of pouch can be exteriorized for excision

the retained rectum is dissected until the ileo-rectal anastomosis is encountered. Thereafter, the pouch is carefully mobilized in order to preserve the pouch. Since the pouch must be brought down over a considerable distance, either laparoscopically or via an open (i.e., Pfannenstiel or low midline) incision, mobilization of the pouch and its mesentery is necessary to gain the additional reach required. After freeing the pouch, including the pouch rectal anastomosis and the retained rectum, the latter two are excised. Preferably a single-stapled, double purse-string ileoanal anastomosis is constructed, thereby creating a union between the pouch and anus. This removes another 1.5 cm of rectal cuff. In the end, a small rim of cuff 1–1.5 cm is preserved for better fine continence (Fig. 20.15).

- (b) *Transanal and transabdominal mobilization of the pouch with revision of the pouch or new pouch in case of mega-pouch or chronic pelvic sepsis.*

Again, the patient is placed in the Lloyd Davis position; a Lone Star Retractor is placed transanally and a perianal nerve block performed. The TAMIS platform is also utilized for Ta surgery. Depending on the type of prior ileoanal anastomosis, hand-sewn after mucosectomy or double stapled, the rectal cuff is transected just below the anastomosis avoiding any damage to the internal sphincter muscle. A mucosectomy and transection of the muscular wall at a higher level might be appropriate. The first part of the bottom-up dissection can be done using retractors or via the TAMIS platform. The bottom-up TAMIS dissection proceeds as far proximal as possible after which the rendezvous is made with the top-down dissection of pouch and its mesentery. The completely detached and mobilized pouch can be remodeled. In case of revisionary surgery for a mega-pouch, the pouch must be reduced in size. Care must be taken in case of reducing the pouch in size longitudinally, so that the vascularization to the remaining pouch is not compromised (Figs. 20.9 and 20.10).

**Fig. 20.15** Schematic excision of cuff (Litzendorf et al.) [16]

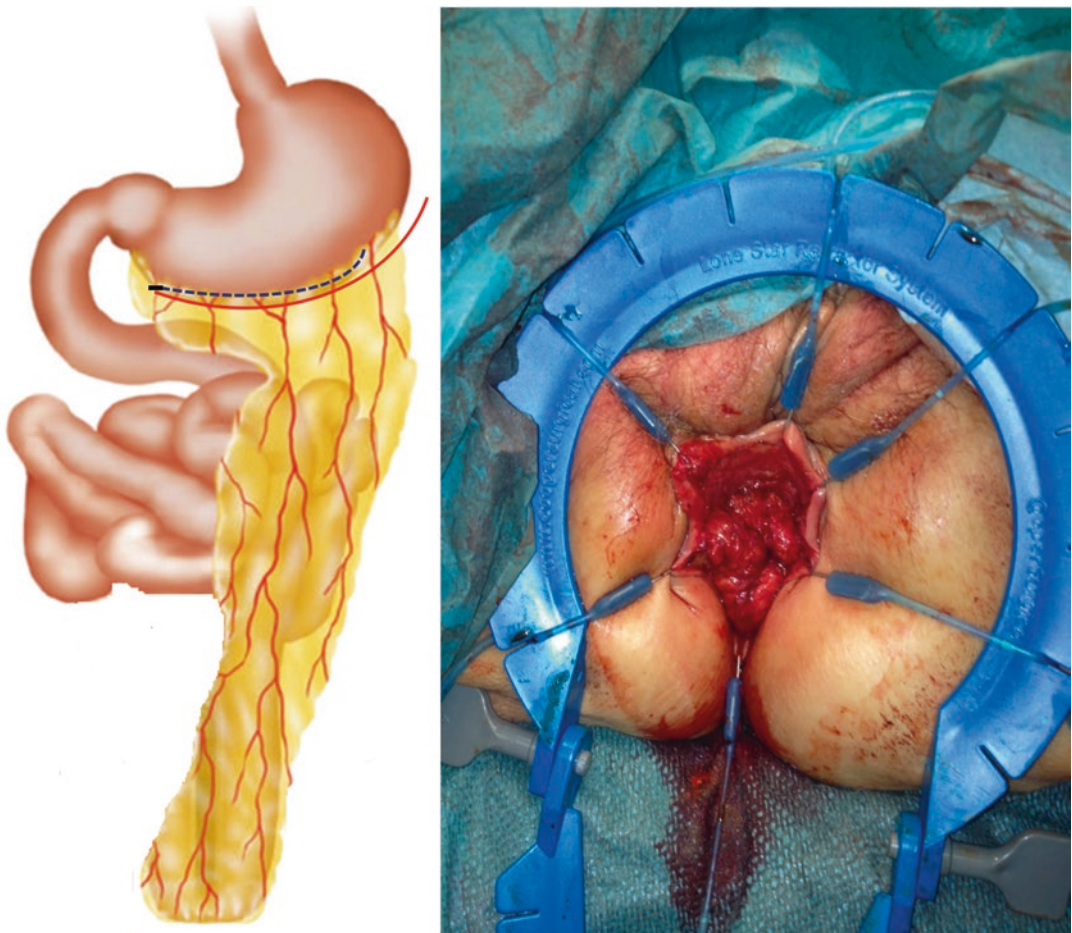




In case of pelvic sepsis, the pouch is often reduced in size due to fibrosis, and the required excision is of this fibrotic distal part of the pouch. Quite often, a blind loop is present, giving the opportunity to enlarge the pouch by incorporating the blind loop into the lumen of the pouch using linear staplers. Presacral sinuses must be carefully debrided to prevent recurrent abscesses. The ileoanal anastomosis is made using a hand-sewn technique, with interrupted 3-0 Vicryl sutures; defunctioning is routinely performed. A pelvic drain is left in place for 48 h and 5 days of antibiotics are prescribed in the patients that were operated on for an index diagnosis of pelvic sepsis.

- (c) *Transanal and transabdominal intersphincteric excision of the pouch with omentoplasty in case of pelvic sepsis or Crohn's disease of the pouch.*

Similar to previous approaches, the patient is placed in the Lloyd Davis position; a Lone Star Retractor placed transanally and a perianal nerve block performed. The TAMIS platform is also utilized for Ta surgery. The incision is done at the level of the intersphincteric groove. The intersphincteric plane of dissection is followed up to the ileoanal anastomosis. Next, the TAMIS port is inserted and the bottom-up dissection is proceeded via TAMIS. Either via low midline laparotomy or laparoscopy when feasible, the top-down dissection is proceeded until the rendezvous is made. The pouch is excised and an end-loop ileostomy is made. If there is sufficient omentum, a pedicled omentoplasty is created after careful debridement of any septic pockets in the pelvis (Fig. 20.16). If there is no omentum,



**Fig. 20.16** Pediculated omentoplasty schematic (left) and in the intersphincteric wound (right)

a close bowel excision of the pouch can be done in order to use the pouch's mesentery to occupy the pelvic cavity.

## Results

The largest series of pouch redo operations originates from the Cleveland Clinic, Ohio. Remzi et al. [17] described over 500 patients who had redo pouch surgery over a 20-year time period. The main indications for pouch redo surgery were septic problems of the anastomosis (61%), emptying problems (23%), and pouch vaginal fistulae (17%). Success rates were 90% at 5-year and 82% at 10-year follow-up. Independent factors of failure of redo surgery were (a) sepsis as indication for pouch revision and (b) postoperative complications after redo pouch surgery. Smaller series confirmed Remzi's observation that results of redo surgery were best in patients having mechanical causes of pouch dysfunction as opposed to those who have inflammatory/septic causes [18, 19]. *Patients with true Crohn's disease had less favorable results. It has to be stressed that many patients with septic pouch problems are labelled as having Crohn's disease, while they only have a discrete pouch complication.*

In a systematic review by Theodoropoulos et al. [20], favorable results were observed, in terms of (a) redo, (b) revisional, and (c) local/perineal pouch procedures, with healing rates reported as 82.2%, 79.6%, and 68.4%, respectively. However, due to the considerably lower morbidity rate associated with the performance of local/perineal pouch procedures, as demonstrated in this review (specifically, 13.6% for local procedures vs 44.2% for the revisional surgery), some authors have suggested that all revisional surgery should be first attempted transanally, with the aim of avoiding higher morbidity, when this option is feasible. Theodoropoulos et al. reported functionally worse outcomes for urgency and nighttime soiling (26% and 38.4%, respectively), compared to the reported rates for urgency (7.3%), mild nighttime incontinence (17.3%), and severe nighttime

incontinence (7.6%), after initial restorative proctocolectomy. This functional deterioration might be attributable to repeated sphincter trauma, mucosectomy, hand-sewn anastomosis, and/or decreased small bowel length; a subset of these patients whose symptoms become clinically significant will ultimately require revisionary procedures.

TAMIS revisional pouch surgery has only been reported by Borstlap et al., demonstrating its feasibility and promising feature of more precise dissection of the distal pouch [21]. Although published reports are sparse, the TAMIS technique to revision is becoming accepted and is commonly utilized by field experts when Ta approach seems logical, as delineated in the previous sections.

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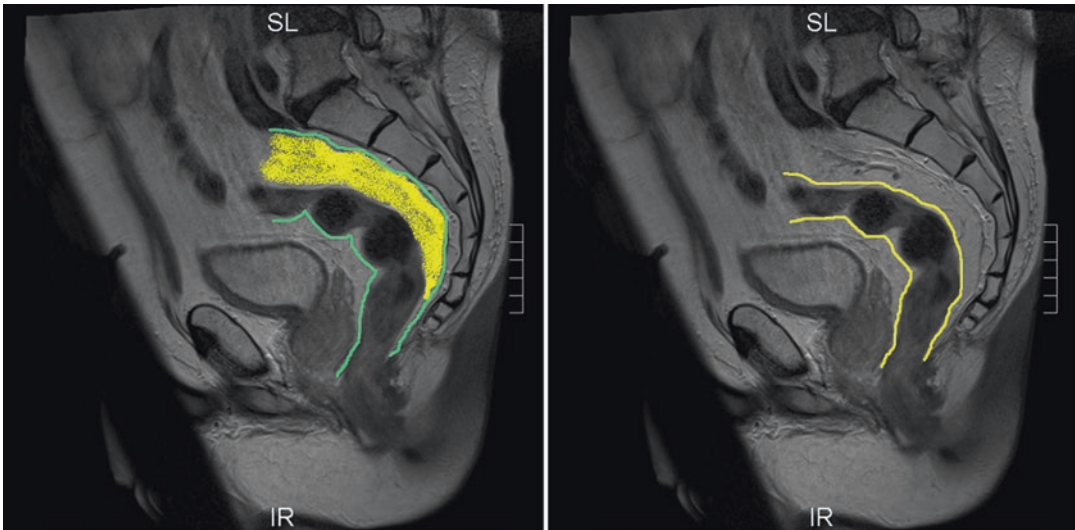
## Ta Completion Proctectomy in Crohn's

### Heading

Severe refractory proctitis, anal stenosis, and perianal fistulae with chronic sepsis are all indications to remove the rectum in patients with Crohn's disease. The type of procedure is still a controversial topic. The rectum can be excised en bloc with the mesentery or a close rectal dissection can be done (Fig. 20.17).

The resection at the level of the sphincter can be handled in three ways: (a) full excision of the anal sphincter including (parts of) the levator muscle, (b) creation of an ultralow Hartmann's pouch, or (c) intersphincteric resection. The Achilles heel of the procedures is perineal wound healing and local septic complications within the pelvis. Intuitively, leaving the smallest dead space in the pelvis might reduce the risk of pelvic abscesses and improve wound healing. However, it seems to indicate that this may not be true, specifically for Crohn's disease. De Groof et al. [22] compared two groups of patients, those who underwent close rectal proctectomy versus those who underwent a more standard TME-type resection, and concluded that the risk of pelvic abscesses was reduced in





**Fig. 20.17** TME type of proctectomy (left) and close rectal dissection (right)

the TME-type proctectomy and perineal wound healing facilitated. These clinical findings could be correlated with the pro-inflammatory characteristics of the Crohn's mesentery, a relatively new finding related to the pathogenesis of this disease process. For this reason, in our practice we perform a TME type of proctectomy for Crohn's disease in combination with omentoplasty to limit pelvic dead space. *Since in ulcerative colitis the mesentery is not pro-inflammatory, a close rectal dissection can be applied.* An intersphincteric resection of the anus removes all the at-risk mucosa and at the same time preserves the integrity of the pelvic floor.

### Surgical Technique

As previously outlined, the patient is placed in the Lloyd Davis position; a Lone Star Retractor is placed transanally and a perianal nerve block performed. When required, the TAMIS platform is utilized for Ta surgery. The incision is carried out at the level of the intersphincteric groove. The intersphincteric plane of dissection then proceeds along the mesorectum posteriorly. The TAMIS port is next inserted, and the bottom-up dissection advances cephalad following standard TME

planes. Anteriorly, however, a close bowel dissection is performed to preserve the autonomic nerves. After extraction of the colorectum, the pelvic cavity is filled with a vascular pedicled omental flap (Fig. 20.16).

### Pelvic Sepsis After Low Anterior Resection for Rectal Cancer

Anastomotic leakage of the ultralow colorectal/coloanal anastomosis is a known complication, which occurs not infrequently. Published rates in literature differ considerably, mainly because of differences between studies with regard to length of follow-up. Most surgeons would dysfunction the low anastomosis and would only investigate its integrity at the time the closure of the stoma approaches. Importantly, 30- or 90-day morbidity rates do not capture the clinically occult, defunctioned leaks. Several authors from experienced centers report that one out of five of the intentionally temporary ileostomies becomes permanent – and this is mostly attributed to anastomotic failure. Borstlap et al. [23] clearly showed that overall 1-year leak rates amount to 20% for both partial and total mesorectal excisions. Particularly in patients that have had neoadjuvant radiotherapy

in combination with full TME surgery, the leak will not heal and will result in a chronic presacral sinus. This accounted for almost 10% of all anterior resections with anastomoses [23]. These chronic sinuses, even if they are still defunctioned, can cause severe septic complications, for example, septic coxarthrosis, necrotizing fasciitis, fistulae to the buttocks, ureter strictures, etc. [24].

For this reason, source control with resection of the leaking anastomosis and debridement of the septic cavity is warranted.

In a shared decision-making process, it must be decided either to fashion a permanent colostomy (with omental flap of the pelvic cavity) or to perform a pull-through of the colon and redo coloanal anastomosis. Redo coloanal anastomosis is often a reasonable option for the fit and motivated patients who want to invest time and effort to restore continuity.

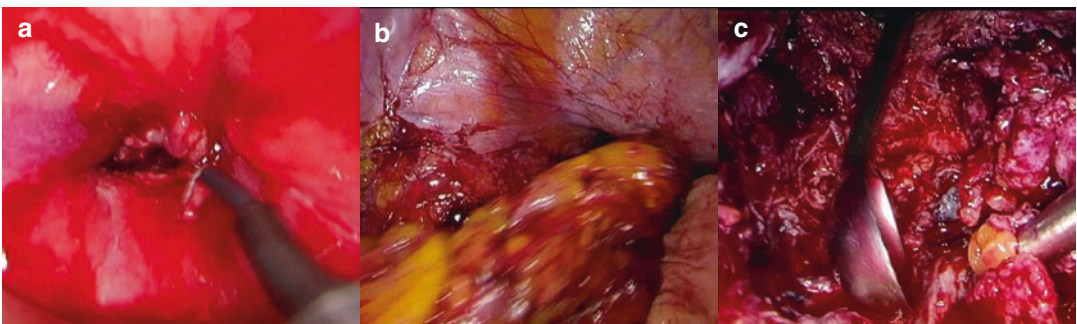
Notwithstanding, even for fit and motivated patients, such intervention can be quite arduous, for a few reasons. First, the pull-through of the afferent colon must be possible. The pelvic organs (e.g., vagina and prostate) can be displaced posteriorly in such a way that the pull-through is not technically possible. Second, there is no guarantee that the newly created anastomosis will heal, as obviously a recurrent leak can recur. Finally, if the stoma can be closed, provided the anastomosis is healed, the function of the neorectum is unpredictable, and there is a high chance of having a low anterior resection syndrome [25].

## Surgical Technique

### (a) *Redo Anastomosis*

The procedure can be done utilizing either a one- or two-team approach. The patient is positioned in the Lloyd Davis position (stirrups) on a short beanbag. Perianal block is performed, and a Lone Star Retractor is positioned transanally. In this setting, most patients still had their defunctioning ileostomy. Intraoperatively, the ileostomy is managed with a Foley catheter and draped with a sterile gauze and adhesive bandage. Depending on the level of the leaking anastomosis, the remaining rectum is transected immediately below the leaking anastomosis. Often, this can be done using the TAMIS port, particularly in male patients, whereby the anal canal is long and the anastomosis is difficult to expose using conventional specula.

With the TAMIS technique, diathermy monopolar hook electrocautery is used to transect the rectum directly below the coloanal/colorectal anastomosis. It is important to find the plane of dissection along the neorectum (Fig. 20.18). When in doubt, one can stay close to the neorectum avoiding damage to the autonomic nerves, venous plexus, urethra, and ureters. Obviously, this can be done without any oncologic compromise. The dissection proceeds cephalad as far as possible. *If the bottom-up dissection has reached the peritoneal cavity anteriorly, then the most difficult part, coming from the top, has already been completed.*



**Fig. 20.18** (a) Transection just distal from anastomosis. (b) The leaking anastomosis is pulled out of the Dutch after TAMIS dissection. (c) TAMIS debridement cavity

In order to redo the coloanal/colorectal anastomosis, the afferent colon loop needs to be mobilized further to have enough reach. In most of the cases, the left flexure has not been mobilized fully. Preferably, the left colonic artery is preserved, and the inferior mesenteric vein is ligated at the level of the inferior border of the pancreas. The left flexure is fully mobilized to allow the colon to rotate along the middle colic pedicle. Depending of the degree of adhesions, the top-down dissection and mobilization of the splenic flexure can be done with straight laparoscopy, with hand-assist laparoscopy (using Pfannenstiel extraction incision), or using a midline lower straight incision and an open technique. If the bottom-up dissection via TAMIS is successful in reaching the anterior peritoneal reflection, the top-down dissection can be done laparoscopically or via the Pfannenstiel incision in most cases. The mobilized section of bowel, including the segment containing the anastomotic leak, is exteriorized via the Pfannenstiel incision and excised. Extensive debridement of the presacral cavity is done by removing all infectious and devitalized tissue. If a sufficient rectal cuff remains, a single-stapled, double purse-string side-to-end anastomosis can be fashioned. If the rectum is transected within the anal canal, then a hand-sewn anastomosis is performed.

The diverting stoma is left in place. It is advisable to prescribe antibiotics for at least 3 days, because the most important complication is recurrent abscesses at the level of the former presacral sinus. On day 4, the CRP is measured. In case of an elevated CRP or any suspicion of anastomotic dehiscence, computed tomography imaging of the pelvis is performed. If work-up reveals no evidence of a leak, the anastomosis is checked for its integrity within 2–3 weeks. Within 3 weeks, Endo-SPONGE-assisted early closure is still an effective option for controlled anastomotic leaks.

(b) *Intersphincteric Resection, End Colostomy, and Omentoplasty*

The procedure is quite similar to the TAMIS redo anastomosis. However, the procedure is started with an open intersphincteric dissection. When there is sufficient space for the TAMIS

port, the access channel is seated into position and the procedure is continued via TAMIS techniques. Mobilization of the left colon and splenic flexure is not necessary, since the objective of the procedure is to create an end colostomy. Furthermore, after resection of the leaking anastomosis, sufficient length remains to make a tension-free anastomosis. An omental pedicled flap based on the left gastroepiploic artery is made and positioned in the pelvis by either via retrocolic approach (beneath the transverse colon) or via the left paracolic gutter. The omental flap is then used to fill the pelvic cavity after extensive debridement of all infectious tissue.

### Preliminary Results

In our unit, a total of 104 patients underwent redo pouch surgery, of which 47 underwent a redo anastomosis (18 conventional; 29 TAMIS) and 57 underwent ICP (35 conventional and 22 TAMIS). In all TAMIS procedures, the bottom-up dissection could be completed and connected with the top-down dissection, with 72% of the transabdominal approach after redo anastomosis being completed laparoscopically, versus 59% of the ICP being performed laparoscopically. However, laparoscopic success was significantly less for the group who underwent conventional transabdominal approaches: specifically, 6% for the redo anastomosis group and 34% for the ICP group ( $P < 0.001$  and  $P = 0.100$ ). In the redo anastomosis group, a stapled anastomosis could be done in 62% in the TAMIS cohort; however, all conventional redo anastomosis were hand-sewn ( $P < 0.001$ ). There were no significant differences in 90-day postoperative outcome between conventional and TAMIS techniques. After redo anastomosis, 11 patients (61%) in the conventional group and 21 patients (72%) after TAMIS had their bowel continuity restored at the end of follow-up ( $P = 0.524$ ). These data suggest that TAMIS is a valid alternative to conventional top-down redo surgery for pouch anastomotic leak, with more procedures likely to be completed laparoscopically when this approach is utilized [26].

## Miscellaneous Procedures

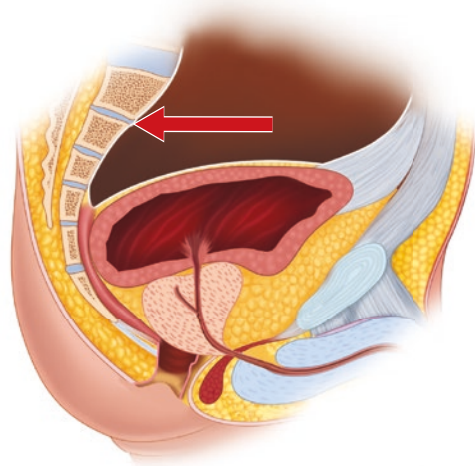
In all procedures where there is difficulty to enter the pelvic cavity due to (inflammatory) adhesions, collapsed pelvis after prior rectal resection, radiation therapy, endometriosis, and other confounding factors, the TAMIS platform is very suitable to start the dissection along virgin operative planes, bottom-up, as this can help to facilitate the top-down dissection.

- (a) Hartmann's closure. Mostly, the rectal stump is of sufficient length to localize its apex. This is often the case if the Hartmann's pouch had been constructed secondary to complicated diverticulitis. Hartmann's closure of dismantled low anterior anastomosis because of leakage is much more difficult, however. The rectal stump is often short (usually <10 cm), and sometimes the apex of the rectal cuff is not healed and is in continuity with a chronic septic cavity. Under both circumstances, the rectal stump can be plastered with densely adherent small bowel, the bladder, or even the posterior vaginal wall. If the stump is really short (<7 cm), then the prostate or vagina can be displaced posteriorly. Finding the correct plane toward the rectal stump from above can, in this setting, be extremely difficult, and TAMIS-based techniques can be very helpful in finding the proper planes (Fig. 20.19).

Even if a safe rendezvous is reached by simultaneously operating bottom-up and top-down, the passage toward the anus behind the prostate or vagina can be very narrow making even passage of the colon loop to the anus very difficult. Lateral lysis of the posteriorly displaced prostate or vagina can be done more safely via TAMIS; and this is detailed on the chapter entitled *taTME as a Technique for Hartmann's Reversal*.

### Colovaginal Fistula

TAMIS can be very helpful in the takedown of a colovaginal fistula, whereby a bottom-up dissection is performed in an untouched, uninfamed area where it is much safer and easier to define the proper dissection planes,



**Fig. 20.19** Posteriorly displaced prostate and bladder after breakdown leaking low anastomosis. Top-down dissection toward the anus is very difficult

as opposed to the top-down dissection where antecedent surgery and/or radiation therapy might have occluded the pelvis, causing the anatomic approach to be hazardous (Figs. 20.20 and 20.21). Another possibility is to insert the TAMIS port in the vagina, to perform a very precise excision of the fistula – a technique termed VAMIS [27].

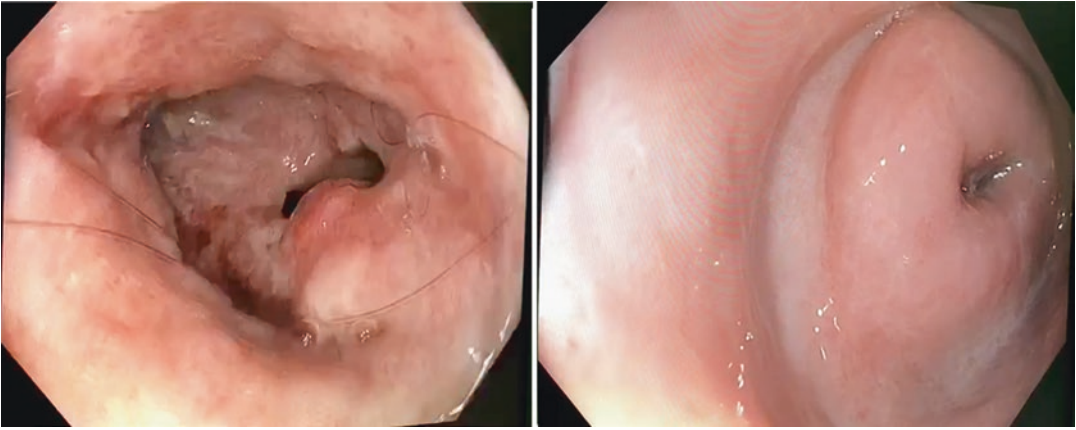
- (b) Perforation of the Rectum

TAMIS is very useful modality to close fresh perforations of the rectum up to 15 cm from the anal verge, regardless of the etiology. In case of old perforations (>2 weeks), the cavity might need to be cleaned first (typically with the aid of an Endo-SPONGE) after diversion with a loop ileostomy before embarking on TAMIS-assisted closure.

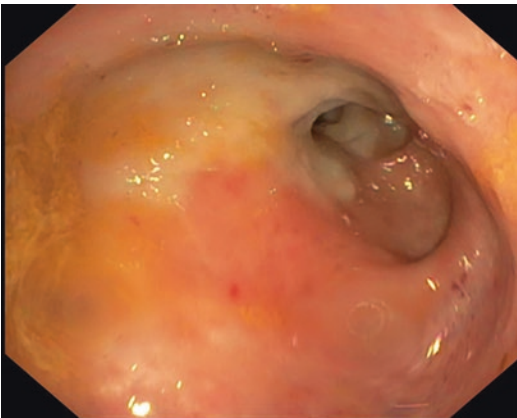
## Final Remarks

The TAMIS approach for benign pelvic pathology might become even more important than the application of TAMIS for rectal cancer (taTME). There are no competing techniques for this (such as robotics). Except in rare circumstances, there are no oncologic concerns with the TAMIS





**Fig. 20.20** (Left) Anastomotic defect with connection to the vagina. (Right) Endoscopically, the portion is visualized via the anastomotic defect



**Fig. 20.21** Stenosis and rectovaginal fistula after radiotherapy for cervix cancer

approach for IBD. More precise dissection deep in the pelvis without the standard requirements of a perfect TME which are otherwise imposed by the principles for rectal cancer surgery makes the TAMIS platform the procedure of choice for complex and challenging problems of the low pelvis. This is particularly true, under conditions in which top-down access to the pelvis is hindered by sepsis, adhesions, radiation effects, and distorted anatomy due to prior surgery.

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# Operating Theater Setup and Two-Team Coordination

# 21

Aimee E. Gough, Phillip R. Fleshner,  
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## Introduction

Transanal total mesorectal excision (taTME) has emerged as a safe and feasible minimally invasive approach to overcome some of the pitfalls of traditional transabdominal TME [1–3]. Potential advantages of taTME include improved access to the mid and distal rectum, improved precision of the distal rectal transection, omission of multiple staple firings of the distal rectum, and opportunity for transanal specimen extraction [4]. While taTME was initially described for cancer, the procedure has also been extended to benign disease. The most common indication for proctectomy in benign disease is ulcerative colitis requiring total proctocolectomy and ileal pouch-anal anastomosis (IPAA). The taTME technique has been carried over to IPAA surgery [5, 6] with early reports of transanal IPAA (taIPAA) suggesting feasibility and safety [7] with potentially lower morbidity compared with transabdominal minimally invasive IPAA [8].

Both single-team [9] and two-team taTME [10, 11] have been described with similar safety profiles [3]. However, advantages of a two-team approach include reduced operative times and reduced conversion to open surgery [11]. While difficulties with dual surgeon availability may

hinder uptake of a two-team approach, this remains our preference for a successful taTME. In this chapter, we will outline our operative room setup and two-team coordination for taTME as it is applied to malignant and benign disease.

## Operating Theater Setup

Since the operating theater setup for taTME requires two instrument sets as well as two sets of laparoscopic cameras with monitors and insufflation setup, we recommend performing taTME in a large operating room to facilitate the circulation of personnel and accommodate the setup of necessary equipment (Table 21.1).

The operating table is positioned for modified lithotomy with anesthesia setup at the patient's head. Convuluted foam is used to provide padding and prevent patient movement during positioning in extreme Trendelenburg and table tilt position (Fig. 21.1). The back table for the abdominal dissection is positioned just lateral and beyond the patient's right leg (Fig. 21.2). The abdominal team generally stands on the patient's right side during laparoscopic portions of the case with their video and insufflation tower directly across from them near the patient's left hip (Figs. 21.2 and 21.3).

The transanal back table is placed beyond the patient's left leg (Fig. 21.2). The transanal team is seated between the patient's legs (Fig. 21.3) and

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**Table 21.1** Equipment suggested for two-team taTME approach

Equipment	Abdominal dissection	Transanal dissection
Instrument tray	Standard laparoscopic	1. Minor instrument tray 2. Single laparoscopic grasper 3. Lone Star® disposable retractor ring (14.1 cm × 14.1 cm) and eight 5 mm sharp stay hooks <sup>a</sup>
Laparoscope	Standard 30 degree 10 mm scope <sup>b</sup>	3D 10 mm scope with articulating tip <sup>c</sup>
Monitor	Standard	3D compatible
Insufflation	Standard insufflation	Continuous insufflation platform <sup>d</sup>
Trocars	Option 1: two 10 mm and two 5 mm trocars <sup>e</sup> Option 2: single-incision platform <sup>f</sup>	Soft disposable transanal access platform <sup>g</sup> and 12 mm AirSeal® trocar
Energy device	Advanced energy device <sup>h</sup>	Energy device with combination suction and hook cautery <sup>i</sup>
Rectal anastomosis	None	Option 1 (stapled anastomosis) 29 mm EEA stapler <sup>j</sup> 0-Prolene suture x 2 Option 2 (hand-sewn) seven 2-0 chromic sutures on SH needle
Endoscope		Adult flexible sigmoidoscope

<sup>a</sup>Lone Star® Retractor System, CooperSurgical, Inc. Trumbull, CT, USA

<sup>b</sup>ENDO EYE II 10 mm, 30°, rigid video laparoscope, Olympus, Center Valley, PA, USA

<sup>c</sup>ENDO EYE FLEX 10 mm articulating tip video laparoscope, Olympus, Center Valley, PA, USA

<sup>d</sup>AirSeal®, Conmed Inc., Utica, NY, USA

<sup>e</sup>Laparoscopic trocars rounded tip with balloon, Applied Medical Inc., Rancho Santa Margarita, CA, USA

<sup>f</sup>GelPOINT® Mini Advanced Access Platform, Applied Medical Inc., Rancho Santa Margarita, CA, USA

<sup>g</sup>GelPOINT® Path Transanal Access Platform (4 × 5.5 cm), Applied Medical Inc., Rancho Santa Margarita, CA, USA

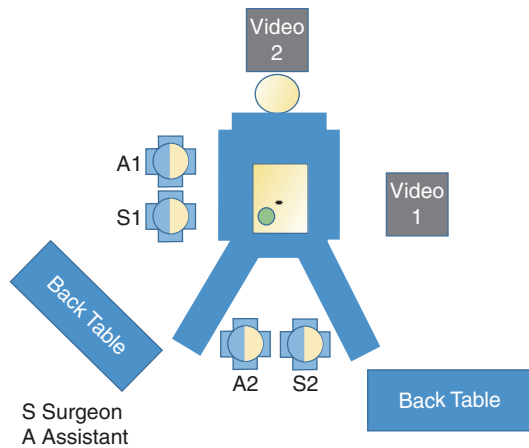
<sup>h</sup>LigaSure™, Medtronic Inc., Minneapolis, MN, USA

<sup>i</sup>Endopath® Probe Plus II, Ethicon Inc. Somerville, NJ, USA

<sup>j</sup>CDH29A 29 mm circular stapler; Ethicon Inc., Somerville, NJ, USA



**Fig. 21.1** Operating table setup with foam padding to prevent patient falls in taTME surgery



**Fig. 21.2** Operating theater schematic demonstrating surgeon positioning, video tower, and back table setup for abdominal and transanal teams



**Fig. 21.3** Operating theater setup for simultaneous abdominal and transanal team operation

their video tower is placed near the patient's left shoulder to allow the anesthesiologist access to the patient (Fig. 21.4). At our center, the AirSeal® iFS insufflation management system (Conmed Inc., Utica, NY, USA) is utilized, and it is positioned lateral to the patient's left leg between the transanal back table and the abdominal team's laparoscopic tower (Fig. 21.5). Our transanal back table has a bottom shelf which houses the electrocautery unit to help reduce the footprint of the transanal equipment as the operating room quickly becomes very congested.

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### Patient Preparation and Positioning

The patient is given a mechanical and oral antibiotic bowel preparation the day before surgery. Preoperative heparin subcutaneous is administered and sequential compression device is placed in the preoperative care unit. After induction of general endotracheal anesthesia and placement of an orogastric tube to decompress the stomach, the patient is repositioned from supine to low lithotomy position with supplemental padding lateral to the knees to protect from peroneal nerve injury. The arms are tucked. Intravenous antibiotic is administered. A urinary catheter is placed and draped over the left leg so that is not in the way of the transanal team. The abdomen and perineum are prepped and draped and an under the buttock drape with a pocket is placed. The energy device and suction for the abdominal dissection is passed

off the patient's right and the laparoscopic equipment toward the patient's left. The transanal setup consists of passing all tubing and power cords over the patient's left leg secured with a towel clamp (Fig. 21.5). The cord of the 3D laparoscopic camera used for transanal dissection is run parallel to the left and through the pocket of the abdominal drape to reach the video tower near the patient's left shoulder. It can be helpful to have a Mayo stand near the left foot to rest the 3D camera and other transanal equipment (Fig. 21.5).

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### Two-Team Coordination: Low Anterior Resection

#### Abdominal Team: Abdominal Access and Sigmoid Colon Mobilization

The abdominal and transanal teams each consist of one attending surgeon and either a resident, fellow, physician's assistant (PA), or surgical scrub (Fig. 21.2). The abdominal team begins the operation by achieving pneumoperitoneum and placing trocars as one would do for laparoscopic low anterior resection. Alternatively, as in our preferred approach, single-site access is obtained at the future ileostomy site in the right lower quadrant (Fig. 21.6). At the marked ileostomy site, the stoma aperture is created per standard technique with splitting of the rectus muscle, the GelPOINT® Mini Advanced Access Platform (Rancho Santa Margarita, CA, USA) is prepared



**Fig. 21.4** Operating theater setup for taTME with 3D transanal tower placed near patient's left shoulder to allow anesthesia access to the patient and video screen arm extended to allow the screen to be in the transanal team's line of sight



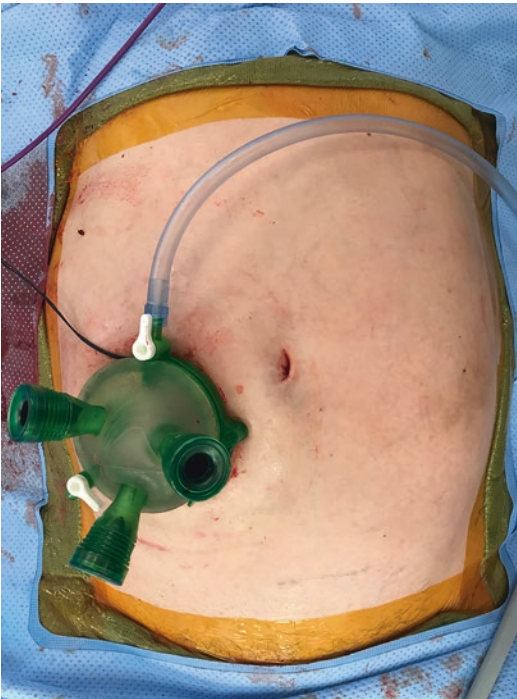
with three 10 mm ports triangulated placed through the cap and placed through the future ileostomy site, and pneumoperitoneum is achieved. Often an additional 5 mm trocar is placed in the suprapubic location to aid in triangulation during splenic flexure mobilization and used for a fan retractor which retracts the uterus or bladder during the TME dissection. After confirming absence of peritoneal or liver metastases, the two teams can begin working simultaneously. The patient is positioned with the table tilted to the right and in Trendelenburg position.

The small bowel is swept out of the pelvis. The dissection of the sigmoid colon is begun in a medial to lateral fashion. After identification of the left ureter, the inferior mesenteric artery is divided high on its pedicle near the aorta using a vessel sealing device (e.g., LigaSure™, Medtronic, Inc., Minneapolis, MN) and the retroperitoneal dissection carried to the white line of Toldt and inferior border of the pancreas where the inferior mesenteric vein can be divided. Next, the white line of Toldt is divided and the colon medialized. As this is being performed abdomi-





**Fig. 21.5** AirSeal® iFS insufflation management system placed lateral to the patient's left leg between the transanal back table and the abdominal team's laparoscopic tower. The cords for the transanal setup passed over the patient's left leg



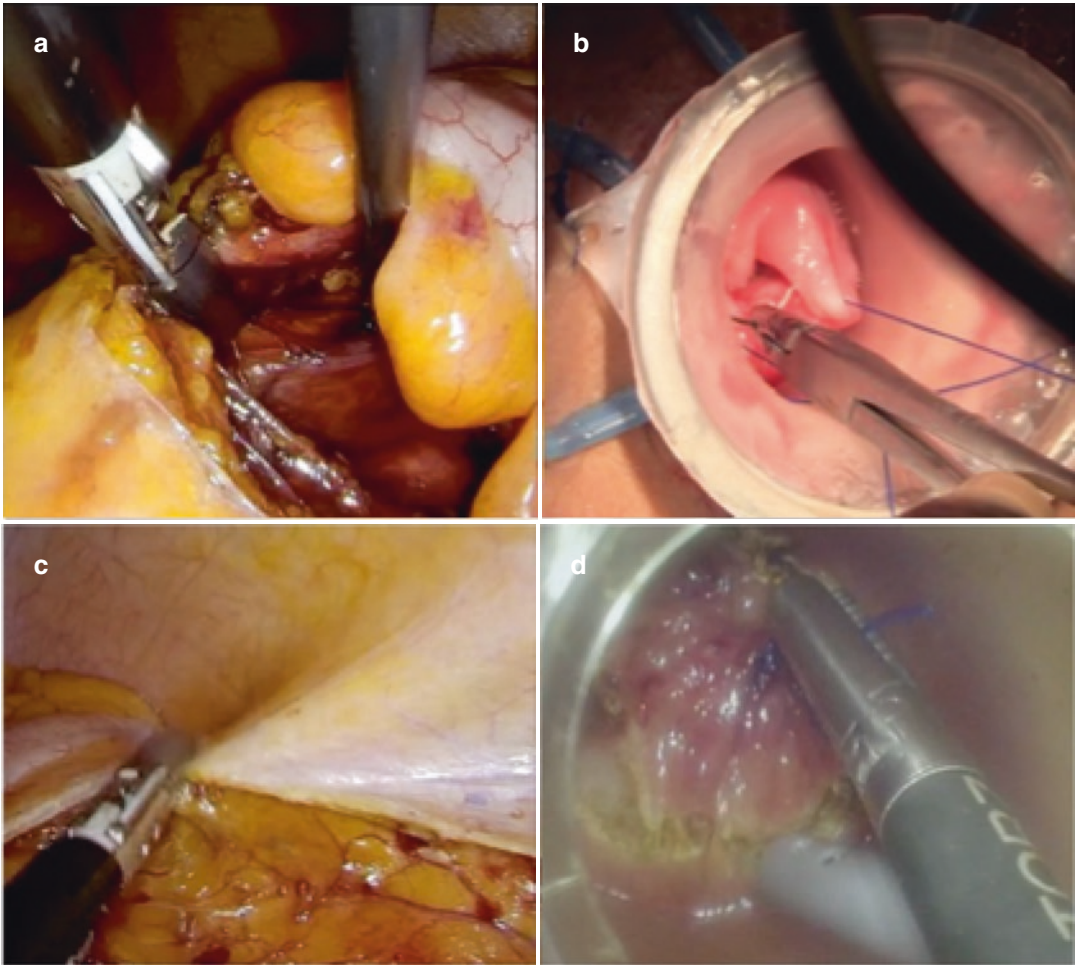
**Fig. 21.6** GelPOINT® Mini placed at future ileostomy site as single-site access for abdominal dissection

nally, the transanal team is also beginning their work (Fig. 21.7). However, when the splenic flexure mobilization is begun, the transanal dissection must halt temporarily, due to limitations imposed by table positioning during this portion of the operation.

## Transanal Team: Rectal Transection and Mobilization

The beginning portions of the transanal dissection are performed simultaneously with the abdominal team mobilization of the sigmoid and descending colon (Fig. 21.7). Digital rectal examination and, if needed, flexible sigmoidoscopy are performed to confirm the location of the tumor and distance from the anal verge. Prior to colonic insufflation, the abdominal team is asked to occlude the sigmoid colon with an atraumatic bowel grasper to prevent insufflation of the entire colon and the position of the tumor is verified endoscopically. If the distal purse string is to be placed endoscopically (for tumors in the upper rectum), the colon must remain occluded from above until the purse string is secured. First, a Lone Star® Retractor (CooperSurgical, Inc., Trumbull, CT, USA) is placed, and the GelPOINT® Path Transanal Access Platform (4 × 5.5 cm) (Applied Medical Inc., Rancho Santa Margarita, CA, USA) is inserted and insufflated using AirSeal® (Conmed Inc., Utica, NY, USA). Alternatively, for low-mid-rectal tumors, the purse string may be placed directly through the GelPOINT® (aka TAMIS port) with the gel cap removed or an intersphincteric dissection can be performed, as predicated by tumor level. In this case, the abdominal team can un-occlude the colon and continue their dissection. Once the purse string is performed, the GelPOINT® path transanal access platform is capped and pneumorectum achieved at 12 mmHg using AirSeal® (Conmed Inc., Utica, NY, USA). At this point, it is important to ask the abdominal surgeons to also turn insufflation to  $\leq 12$  mmHg to prevent competing pressures.

The rectum is transected full thickness at a 90° angle with the bowel wall circumferentially using electrocautery; at our center, the Endopath® Probe Plus hook (Ethicon Inc., Somerville, NJ, USA) is utilized. Next, the dissection is advanced cephalad toward the peritoneal cavity. When the abdominal dissection has reached the point of splenic flexure mobilization, the transanal dissection must be temporarily interrupted due to positioning of the patient in reverse Trendelenburg position.



**Fig. 21.7** Transanal and abdominal teams work simultaneously during the beginning portions of the operation. While the abdominal team performs the inferior mesen-

teric artery ligation (a) and sigmoid colon mobilization (c), the transanal team places the transanal purse string (b) and begins the taTME dissection (d)

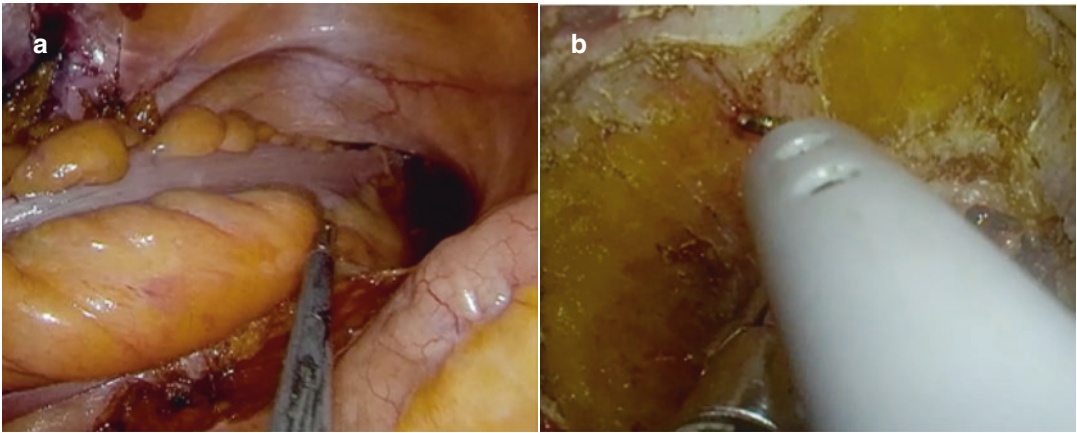
### Abdominal Team: Splenic Flexure and Upper Rectal Mobilization

After splenic flexure mobilization, during which time only the abdominal team can work, the table position is again changed to Trendelenburg and the abdominal team begins the upper TME dissection. The amount of dissection performed from above is dependent on many factors including surgeon preference and difficulty of the abdominal and transanal dissections. The lateral stalks can be divided and anterior peritoneal reflection opened to assist in meeting of the two planes. At this time, the abdominal team can also

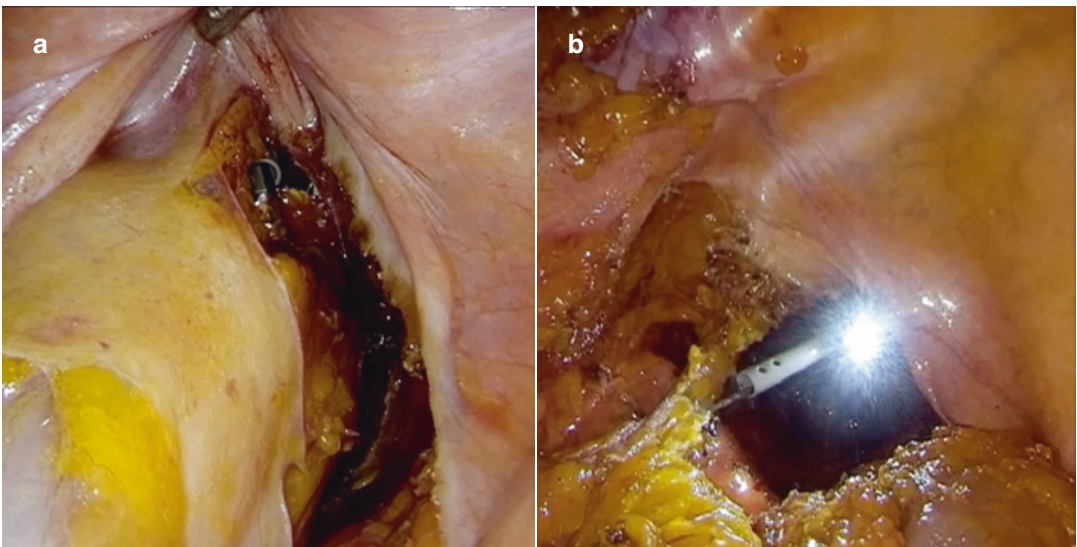
retract the rectum upward as the transanal team continues to progress in their dissection toward the rendezvous (Fig. 21.8).

### Both Teams: The Rendezvous

The anterior plane is typically an easier point to enter into the peritoneal cavity from below; however sometimes if the posterior dissection is further ahead or if the anterior dissection is challenging, then posterior rendezvous is possible and can be helpful as well. Once the rendezvous has occurred, the abdominal team can help



**Fig. 21.8** The abdominal team pulls the rectum upward (a) as the transanal team gets further along in the transanal dissection (b) to prevent collapse of the mobilized rectum in the limited transanal field



**Fig. 21.9** When the rendezvous is achieved, the abdominal team can retract the peritoneal reflection anteriorly (a), place a grasper into the opening to provide retraction, or

pull the rectum upward into the abdomen and either assist in the dissection or allow the transanal team to completely dismount the rectum from below (b)

by retracting the anterior peritoneal reflection upward, placing a retractor through the opening to facilitate the dissection, or continuing to retract the rectum upward and into the abdominal cavity where the dissection can be completed by the transanal or abdominal team (Fig. 21.9). When the entire rectum is dismantled, the transanal cap is removed, the table position is leveled,

and the pelvis is copiously irrigated from above with warm saline or sterile water and allowed to drain transanally. Next, the distal purse-string suture is grasped and the specimen can often be retrieved transanally. In the case of a bulky tumor or mesentery precluding transanal extraction, a Pfannenstiel incision can be used for specimen extraction.



## **Transanal Team: Specimen Extraction and Anastomosis**

In the case of transanal extraction, the access channel is removed and the entire rectum and sigmoid colon is eviscerated through the anus. If available, fluorescence imaging can help guide the proximal transection point. Otherwise, the proximal transection is made using electrocautery proximal to the IMA pedicle.

The anastomosis is then performed entirely transanally. Either a stapled, double purse-string anastomosis can be chosen, or the colon can be hand-sewn to the rectal cuff. In a double purse-string anastomosis, when the transanal team is placing the distal purse string, the abdominal operator can place the camera into the pelvis to visualize the suturing of the distal rectum to assure full-thickness bites are taken and extra-rectal tissue is not incorporated into the purse-string suture. Prior to closure of the distal purse string, the abdominal operator confirms that the colon and mesentery lay straight across the retroperitoneum and that no small bowel loops are caught under the colonic mesentery. The two ends of the EEA are mated and the distal purse string is secured before closing and firing the EEA stapler. The abdominal operator can maintain pneumoperitoneum at this point to assess for a “reverse” air leak by having the taTME surgeon (bottom team) check for air escaping into the lumen through defects in the staple line. If present, this can be oversewn transanally. If a hand-sewn anastomosis is preferred, it can be performed directly to the cut edge of the rectal cuff using interrupted 2–0 chromic sutures. A 0.25 inch Penrose drain is placed transanally.

## **Abdominal Team: TAP Block and Ileostomy Creation**

While the transanal team is performing the anastomosis, the abdominal team performs a laparoscopic transversus abdominis plane (TAP) block [12], places a pelvic drain through a 5 mm port site, and creates the diverting loop ileostomy.

## **Two-Team Coordination: Total Proctocolectomy with Ileal Pouch-Anal Anastomosis**

### **Abdominal Team: Laparoscopic Colectomy and Assessment of Pouch Reach**

Transanal Ileal pouch-anal anastomosis also uses an abdominal team and a transanal team, each with a surgeon and an assistant. The operating room setup is unchanged from the description above. The abdominal colectomy is first performed by the abdominal team through a single-port access system (GelPOINT® Mini Advanced Access Platform, Applied Medical Inc., Rancho Santa Margarita, CA, USA) prepared with three 10 mm cannulas widely spaced in a triangle through the gel cap. An additional 5 mm port is placed at the suprapubic position to assist in the dissection and tissue triangulation. After complete colonic mobilization and mesenteric division with preservation of the ileocolic pedicle, the small bowel and its mesentery are assessed for length to ascertain pouch reach. If there appears to be adequate length, the terminal ileum is transected laparoscopically with a stapling device (Echelon Flex™ Powered Plus 60, Ethicon Inc., Somerville, NJ, USA), and the terminal ileal attachments to the level of the duodenal sweep are mobilized. During this dissection, the patient position is continuously changing as is the position of the surgeons across the operating table precluding any transanal work. Once the terminal ileum is mobilized, it is exteriorized through the GelPOINT® Mini and ileal pouch created. At this point the transanal team may also commence proctectomy.

While the transanal team begins the proctectomy, the abdominal team may create the ileal pouch per standard fashion through the ileostomy site. The pouch apex is secured by placing a betadine-soaked gauze into the pouch and securing it with 2–0 Prolene purse-string suture to prevent spillage of bowel contents. This suture also acts as a handle for pouch manipulation. The pouch is then reinserted into the abdomen and laparoscopy commenced.

## **Transanal Team: Transanal Proctectomy**

Once adequate pouch reach is assured, the transanal team begins as in the previous section. The patient is positioned in Trendelenburg position. The Lone Star® Retractor and GelPOINT® path access channel are placed. Working directly through the access channel, the purse string is placed above the edge of the access channel. The GelPOINT® is capped and AirSeal® insufflation begun at 12 mmHg. At this time, if the abdominal team is also working laparoscopically, they are asked to also turn their abdominal insufflation pressure  $\leq 12$  mmHg to avoid pressure mismatch. However, if the abdominal team is still working open through the GelPOINT® Mini to create the pouch, transanal insufflation can create a vacuum effect in the de-insufflated abdomen. Thus, lower transanal AirSeal® pressures (8 mmHg or lower) may be necessary to maintain visibility and avoid suctioning of the rectum upward into the abdomen. The rectal wall is scored and transected 1 cm distal to the purse-string closure, and the taTME dissection proceeds. Dissection is carried cephalad toward the abdominal operator.

## **Abdominal Team: Upper Rectal Mobilization**

After creation of the pouch and re-insufflation of the peritoneal cavity, the upper rectum is mobilized by dividing the superior hemorrhoidal artery near the rectal wall to avoid hypogastric nerve injury. The presacral space is entered and dissection carried out along the TME plane. A 5 mm suprapubic port is helpful during this portion of the procedure for anterior retraction of the pelvic organs.

## **Transanal Team/Abdominal Team: Bringing Down the Pouch, Anastomosis, and Final Steps**

At the point of top and bottom rendezvous, the paired teams can work together to dismount the rectum. The pelvis is irrigated and fluid drained

transanally followed by transanal specimen removal. A laparotomy pad is placed in the anus to allow abdominal insufflation with the transanal access channel removed. The abdominal team then orients the pouch, places it at the pelvic brim, and retracts the pelvic organs to allow the pouch to be grasped and delivered down to the anus by the transanal team.

The transanal surgeon delivers a ring forcep alongside the laparotomy pad and, using the laparoscopic monitor as a guide, grasps the pouch and gently delivers it toward the anus. The level of the anastomosis and residual mucosa retained can now be tailored to pouch reach. A hand-sewn or double purse-string anastomosis can be chosen. While the transanal team is working on the anastomosis, the abdominal team places a drain (optional), performs a laparoscopic TAP block, and creates a diverting loop ileostomy.

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## **Perfecting the Two-Team Approach**

One of the largest challenges but also most advantageous aspects of two-team taTME is the transanal-abdominal rendezvous. As the dissections continue toward each other, coordination between teams so that the same quadrant is being worked on can be helpful. Furthermore, as more of the rectum is mobilized, it can occlude the transanal view. During this critical time, it is often advantageous to have the abdominal team pull up on the rectum to allow it to straighten out, providing more working room for the transanal team. Attempting to maintain a circumferential transanal dissection so as to allow only a thin ring of tissue to remain prior to rendezvous is most ideal. When the transanal team proceeds too far posteriorly, peritoneal entry can occur before the anterior and other key portions of the taTME dissection have been completed. This can result in spillage of air and fluid from the abdominal dissection obscuring the transanal view.

However, when the rendezvous is reached, the two teams must work together to completely dismount the rectum. The abdominal team can initially pull up on the rectum and provide anterior retraction using a fan retractor through the 5 mm



suprapubic port. As the dissection continues circumferentially, the abdominal team can fully deliver and evert the mobilized rectum into the peritoneal cavity, thereby completing the dissection beyond the reach or vision of the transanal team.

Insufflation pressures during two-team taTME also play a large role in a successful operation. In the initial portions of the transanal dissection prior to rectal transection, if using continuous insufflation platform (AirSeal®), the abdominal pressure has little effect on the transanal dissection. Once the rectum is transected and the TME dissection has begun, it is our experience that maintaining equal abdominal and transanal pressure throughout the latter half of the transanal dissection provides optimal transanal view. While some authors have recommended maintaining transanal pressure higher than abdominal pressure [13], in our experience, this can sometimes displace the rectum proximally and flatten the TME plane along the sidewall making the dissection more challenging. It can also be challenging for the abdominal team to operate at a lower insufflation pressure. Thus, being mindful of the balance between abdominal and transanal pressure throughout the case is important, and generally a matched pressure of 12 mmHg works well.

Lastly, the two teams must be able to work together and maximize available resources to assure successful and timely surgery. First, training and familiarity of the OR team with the procedure and necessary equipment as well as having a dedicated team of nurses and surgical technicians routinely assigned to taTME cases is crucial to a successful program. Similarly, dual training of surgeons planning to work together in taTME surgery is important. During surgery, compromise between transanal and abdominal teams helps carry the case along. For example, the use of a headlight during rectal suturing allows the room lights to be kept dim so the abdominal operator can continue laparoscopy. The abdominal operators may need step stools to compensate for the higher table position when the transanal team is placing the purse string. When the operating table is tilted to the right to allow mobilization of the sigmoid colon, the

transanal team must adjust accordingly. Early communication with the team when asking for instruments is essential as these cases can become overwhelming for the staff. Finally scheduling the surgery so that both surgeons are available for the entire duration of the surgery without other commitments is essential, especially during the implementation phase of a taTME program.

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## Introduction

The management of rectal cancer has evolved rapidly over the last four decades. Clearly, the contribution with the highest impact in the evolution of the surgical therapy of rectal cancer was the description of the mesorectal plane by Professor RJ Heald in the early 1980s [1]. Multiple advances have been made focusing on enhancing outcomes while trying to minimize the invasiveness of surgical therapy. There is a broad range of approaches in rectal cancer – from the traditional open surgical excision of the rectum and mesorectum extending to the novel “watch and wait” non-operative management pioneered by Angelita Habr-Gama [2].

In recent decades, there have been significant improvements to surgical techniques with the introduction of a minimally invasive or laparoscopic approach. Minimal invasion has been further modified with the introduction of robotic-assisted surgery [3]. The past decade has

seen the introduction of local excision endoscopically and transanally [4]. Selection of the optimal surgical approach for rectal cancer depends on intricate considerations including tumor and patient characteristics, skills and expertise of the surgical team, and resources available to the institution.

In many instances the introduction of new technology/procedures lacks robust evidence to support their implementation; therefore it should follow a careful and monitored process in order to prevent unnecessary harm to patients; this is relevant for any innovative surgery, but it is certainly of paramount importance in the single-surgeon TaTME setting [5].

Transanal total mesorectal excision (taTME) has recently been introduced to the surgical community as a surgical approach which enables the surgeon to excise the mesorectum in a minimally invasive approach while providing excellent visualization of pelvic structures and the mesorectal fascia [6]. Some of the benefits touted by taTME advocates are enhanced visualization, perpendicular division of the rectum, and potential for increased preservation of distal rectum.

The literature on this approach is rapidly emerging with most experience focused on the two-team, or Cecil, approach [7, 8]. There have been several select centers which have published their experience with a single-team (or single surgeon) approach [9, 10]. The description and early results of the single team demonstrate that such

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approach can be feasible in the correct environment and with careful considerations prior to implementation of such a program. A dual-team approach is most likely safer; however this might not be feasible at every center. Perhaps, there will be institutions that otherwise meet the criteria to perform taTME surgery but lack the resources of having a two rectal cancer surgeons available simultaneously [11].

The single-team taTME approach provides a formidable technical and logistical challenge to surgeons and operating room personnel. Those situations and all the relevant factors regarding feasibility and sustainability of a taTME program should be considered prior to any attempt to introduce the technique. Adoption and successful implementation of taTME may prove to be quite difficult, in some situations even prohibitive.

In our experience, appropriate implementation of a single-team taTME program requires an insightful assessment of the local patient population, surgical expertise, availability of institutional resources, and receptive culture of the team for innovation and learning. Some of the key individuals include the following: (a) a colorectal surgeon or gastrointestinal surgical oncologist, (b) a minimally invasive trained surgical assistant, (c) a specialized nursing team, (d) supportive administration, and (e) dedicated surgical equipment and product specialist support. While these considerations and key elements may coincide with those described in other chapters regarding the two-team approach, the technical and perioperative considerations that are described herein are unique to the single-team taTME technique.

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## Considerations

When a surgeon is motivated to introduce taTME surgery at their respective institution, they should start by asking themselves several questions. Am I the right person to do this? Do I have the volume to perform this procedure regularly and safely? Is my institution the right place to do taTME? If the answer to all of those is yes, then it is appropriate to consider taking steps toward implementing a taTME program.

Whether it is a single-team or a two-team program does not change the need to follow an organized pathway [12, 13].

Seeking institutional support becomes important to acquire the necessary resources to perform the procedure. Having a dedicated team will enhance the chances of success, which is particularly relevant for single-team taTME implementation. Adequate training and proctorship are also vital to ensuring its safe introduction [11].

## Institution

There is significant evidence available to support the concept of high-volume rectal cancer institutions obtaining better outcomes when compared with those considered to have low volumes and suboptimal expertise [14, 15]. It is challenging to determine a specific number which defines high vs low volume. Concern has risen around the increasing complexity of the decision-making and surgical technique of rectal cancer which ultimately led to different organizations and health-care systems to advocate for centralization of the management of rectal cancer [16, 17]. The advent of taTME has added a new level of complexity; therefore, most experts believe, this technique should only be considered in high-volume specialized centers.

The institution should be equipped and situated to enable implementation of advanced surgical techniques. In general, minimally invasive surgery requires a longer time than open procedures, particularly during the learning curve period, and it is crucial to have administrators who understand that single-team taTME surgery will initially take much longer than the traditional open or laparoscopic procedure. A progressive and informed administration understands that such a venture is worthwhile, since ultimately patients benefit through improved oncologic outcomes.

Some institutions may evaluate current taTME data and opt against a single-team program, due to unfavorable operating room efficiency. If the institution is not supportive or the infrastructure for surgical innovation or advancement is not

present, the taTME effort will inevitably fail. This is why it is crucial to ensure the environment at the local institution is amenable to a single-team program prior to advocating for it. Both surgeon and institution should act with extreme caution when considering taTME implementation; this is a particularly sensitive issue in the single-surgeon setting, because operative times may be longer and the approach is more challenging [11].

## **Specific Challenges to a Single Surgeon**

### **Advocating for a Single-Team taTME Program**

It can be quite difficult for a single colorectal surgeon to advocate an ambitious program that requires an important amount of resources, such as a significant financial investment by the institution as well as a large quantity of human resources dedicated to this operation.

Firstly, a proposal delineating the advantages of the single-team taTME operation using current data from the institution could be created to demonstrate the potential benefits for patients as well as institutional progress and the intangible value added by innovation. The proposal should consider the training of the surgeon, the volume of minimally invasive rectal cases at the institution, the potential for growth, and the need for continuous support for a sustainable program (equipment maintenance, slow and yet progressive learning curve, specialized assistants, alignment with goals of administration, and hospital leadership). The audience of the proposal should be considered and may include surgical colleagues and nursing staff, hospital administration, hospital leadership, and community agencies. Once a proposal has been created, sources of funding will vary depending on the characteristics of the health-care system.

### **Securing Sustainable Funding**

The initial implementation of a single-team taTME program requires an investment in education and training, purchase of specialized equip-

ment, and utilization of facility resources – such as longer initial operative time, additional nursing and surgical scrubs for the taTME setup, and hospital resources in the case of complications associated with implementation of a novel procedure. While the training of a single surgeon may be easier than coordinating the schedule of two high-volume surgeons to train for a procedure, advocating for funding of a single-team TaTME program is certainly more difficult for the single surgeon.

The balance between cost, safety, and effectiveness is a fundamental consideration for successful adoption of any new procedure [18]. The frequent lack of supportive evidence for new techniques leads to making decisions mainly based on qualitative information [19]. The introduction of new technology is frequently oriented toward enhancing existing approaches, either by minimizing the invasiveness of procedures, improving clinical outcomes, optimizing cost, or expanding the number of treated patients [20].

The initial cost of a taTME program should consider carefully the decision regarding the selection of the transanal platform. This has a different impact in the short term than it does on the long term and is largely dependent on economies of scale, as the different existing options carry different economic burdens. There are two different types of platforms, either disposable, single-use ones (based on the TAMIS technique) or reusable, multi-use ones (based on the technique of TEM). The latter, so-called “rigid” platforms are manufactured by either Richard Wolf™ or Karl Storz™. Their technology incorporates an insufflating system that is built-in to the apparatus. The initial capital cost can be offset in time depending on the volume of procedures performed.

There are now a variety of TAMIS-based platforms available through various vendors; of these, the GelPOINT Path Transanal Access Platform (Applied Medical™, Rancho Santa Margarita, California) is perhaps most frequently used for taTME (where available) since it was specifically designed for transanal access and is thus quite versatile and, in the short-term, relatively affordable. However, this latter is best used in combination with a separate and quite



costly insufflation system (AirSeal® Conmed, Utica, NY, USA). Thus with TAMIS-based taTME, whether a single- or two-team approach is used, such a system is considered integral to the modern taTME since it stabilizes insufflation in a reduced space. Recently, however, an alternative to that has emerged which is a new stabilizing insufflation bag, which is discussed elsewhere.

Our experience has been entirely with the TAMIS-based, GelPOINT Path Platform (aka TAMIS platform); initially we introduced it to perform TAMIS for local excision as a segue to taTME [21]. This greatly facilitated the transition to taTME, especially when approaching hospital administrators to fund the new program, as the value of advanced transanal surgery was already appreciated.

The importance of teamwork cannot be overemphasized. Single-team taTME mandates cooperation through all OR channels. This includes physician leadership, anesthesiologists, nursing and surgical scrubs, intensive care providers, as well as hospital administration. A cost-impact analysis for the institution should be conducted and should include a realistic understanding of case complexity and operative time and, as best as possible, quantify these values into an appropriate health-care economic model. All of the above contributed toward helping hospital administration identify the financial benefits of minimally invasive rectal surgery (reduced length of stay, early mobilization, decreased wound complication, and decreased hernia rates) improving financial sustainability of our taTME program [22]. If long-term oncologic outcomes are someday proven with the taTME technique (versus other minimally invasive approaches), then it will ultimately drive both surgeons and institutions toward a permanent adoption.

## Patient Consent

Patient consent should be transparent and intentional [23]. The explanation of the taTME should be clear and concise, and it is of great importance to clarify that it is a novel approach to an existing

procedure. The discussion must include not only the perceived benefits of the procedure but also the potential risk specific to taTME, such as urethral injury [24]. In addition, the possible alternatives to the procedure are worth including. Ample time should be allotted to the consent process as the patient's understanding is crucial. Consent must include discussing the proficiency of the operator and the specific innovative technique of the taTME which has the objective of improving resection quality and thereby patient outcomes. It is relevant to discuss the single-surgeon presence and its implications, including how the procedure is performed in a sequential fashion rather than synchronously. All this will definitively help to make the consent as informative as possible [23].

## Potential Complications

Complications specific to taTME include injury to the urethra, the pelvic nerves, and the iliac vessels [24–26]. These potential complications are not exclusive of a single-surgeon setting; however it is possible that they may occur more easily in this type of scenario [11].

The planes of taTME are different than those from a transabdominal approach, and it is much easier to dissect in the wrong plane from a transanal approach [27]. This is due to the improved visualization and superior retraction of the mesorectum allowing multiple planes to appear avascular and amenable to safe dissection. This is particularly risky in a single-team approach; therefore the single surgeon needs to constantly reassess his or her own work and identify when he or she is in the wrong plane.

## Training

Excellent training courses exist to introduce a surgeon to the taTME technique. The major benefit of these programs is the opportunity to learn the fundamentals of this complex operation and gain cadaveric-based, hands-on experience. Recent publications have focused on the inadequacy of a single, 1- or 2-day training course in providing

surgeons with the skill set necessary to safely implement taTME [28]. Despite completion of a didactic component, live case demonstration, and cadaver-based training, mentoring and proctoring are crucial to successful implementation of a taTME program [13, 29]. All of the abovementioned elements are mainly focused on patient safety [30]. The learning curve of different procedures is variable [31], and for taTME it has been estimated to be around 40 procedures [32].

In a single-surgeon model, identifying a mentor/proctor in the early phases of the process is particularly relevant; this relationship should be maintained as long as necessary in order to achieve proficiency. This will allow the novice taTME surgeon to gain confidence and expertise with more complex cases as the experience grows. Identification of an appropriate mentor is discussed in existing training pathways [12, 33]. In addition a number of other aids, including electronic tools, such as the D-Live® platform and the iLapp educational app, are easily available to anyone interested in adopting taTME [34].

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## Required Personnel

A standard single-surgeon taTME team is comprised of six members: a colorectal surgeon, a surgical assistant, an anesthesiologist, two scrub nurses, and a circulating nurse. Germane details regarding personnel for single-surgeon taTME are discussed in the following sections.

### Surgeon

It is strongly recommended that the surgeon be a high-volume, experienced rectal cancer surgeon who has completed colorectal fellowship training [15]. She or he must also be comfortable with platform-based transanal endoscopic surgery using either TAMIS (transanal minimally invasive surgery) or TEMS (transanal endoscopic microsurgery) prior to embarking on a taTME program.

Training to achieve proficiency is a long process. It requires the completion of structured

training courses as well as integration into a taTME proctorship model. Training and acquisition of skill has been discussed. The surgeon must be determined, patient, and willing to accept that initial implementation may be frustrating and difficult. In a single-team approach, the surgeon must be able to deal with challenging situations independently but also have the insight and wisdom to convert to a conventional approach or ask for help from a colleague when necessary. It should be understood that the level of difficulty of an already quite complex operation is substantially increased when it is performed via the single-surgeon approach.

### Specialized Assistant

A proficient surgical assistant is a key element of the team, since her/his ability to provide traction and countertraction facilitates exposure, therefore enhancing plane recognition by the surgeon. This is imperative in the single-surgeon setting, for instance, at the rendezvous and then during the whole process of circumferential detachment [35] (Fig. 22.1). In this sense, the specialized assistant functions as a skilled first assistant in a manner similar to a resident in surgical training.

Not having an experienced assistant in a single-surgeon taTME operation will undoubtedly have an impact on the performance of the procedure, and the authors do not recommend single-team taTME without a skilled assistant. The role of the assistant is thus not limited to driving the camera; therefore in order to assist in a meaningful manner, it is very important that he or she has a clear understanding of all the anatomy relevant to the operation and has considerable assist experience in advanced laparoscopy [9, 10].

### Dedicated Nursing Team

A knowledgeable resource nurse is important to the success of the single-team. He or she must be cognizant of the case sequence at all times and be able to troubleshoot equipment as needed with or

**Fig. 22.1** Assistant on top



**Fig. 22.2** Nurse setting up



without the aid of a product specialist. Due to the many intricate steps and details of the procedure, it is necessary to have at least one dedicated nurse who can choreograph all the necessary moves within the theater and anticipate every potential pitfall to facilitate seamless procedural operation.

We consider it is fundamental to have three nurses available at each taTME case. A minimum of two circulating nurses should be present

for the entire duration of the procedure. One of these nurses serves as a dedicated taTME nurse, who invariably scrubs in during the transanal portion of the operation, she/he should be responsible for orchestrating the surgical equipment and instrumentation, and this individual serves an assist to the primary surgeon by driving the camera during the dissection during taTME (Figs. 22.2 and 22.3).





**Fig. 22.3** Nurse holding camera



**Fig. 22.4** Extreme position

## Equipment

The type of equipment used in a single-surgeon setting is not different than what is used during dual-team approach. There is a need to have two laparoscopic towers, one for the top and one for the bottom. The generalities regarding the equipment for taTME have been previously discussed in this textbook; therefore we will limit our discussion to a few specifics that are essential for the single-surgeon approach.

It is important to have a system device that keeps the patient secured to the operating table preventing him/her from sliding down or falling off the table during the procedure while on extreme positions, such as steep Trendelenburg and/or lateral tilt (Fig. 22.4). There is no fixed recommendation regarding what specific system should be used. At our institution, we use the Pink Pad (Pigazzi Patient Positioning System™) for its safety, versatility, and ease of use. For a single surgeon, this device allows steep Trendelenburg position facilitating pelvic dissection, even with a

novice assistant. This is because gravity alone keeps the otherwise view-obstructing loops of small bowel free from the pelvis during abdominal and transanal dissection.

In our experience a regular insufflator at the top is sufficient. We have implemented the Synergy® LEXION insufflation ports, which eliminate the issues that were initially encountered with smoke during deep dissection in the pelvis. For the transanal dissection, it is crucial to prevent billowing which is common with the use of regular insufflators; we have found it useful to incorporate the AirSeal® IFS which can dramatically improve the operative clarity of the transanal approach by delivering a stable surgical space and allowing continuous visualization of the field.

## Equipment Setup for a Single Team

As discussed previously, the setup of equipment for a taTME is a complex process that requires

very specific planning and experience. Due to the complexity of devices and the large footprint of instruments and equipment, setup is critical to the success of the procedure. Setup for a single-surgeon taTME is no different in that it requires knowledge of the steps of the procedure and an understanding of the special limitations that the surgeon may experience throughout the operation. It is critical for a single surgeon to ensure that the team members know the operative plan and are able to set up according to a preoperative floor plan.

The setup for a single-team taTME can be divided into the transabdominal equipment and transanal equipment:

#### Transabdominal:

- Laparoscopic tower with air supply for insufflation
- Additional laparoscopic monitor
- Cautery and energy device sources
- Suction
- Equipment tray table with scrub nurse

#### Transanal:

- Laparoscopic tower with air supply for insufflation (may require separate freestanding machine)
- Cautery and energy device sources
- Suction
- Equipment tray with scrub nurse

As a single surgeon, the length of time of the surgery must also be factored into the operative plan and minimized when possible, and therefore we set up in stages in order to allow for initiation of the procedure. The specimen is then extracted either through a Pfannenstiel incision or transanally. Pfannenstiel incision extraction of the TME specimen holds the advantage of limiting shearing and mesenteric disruption and the potential for seeding of tumor cells.

The patient's abdomen and perineum are then prepped extensively. It is important to prep the perineum first so that any splashing of contaminant up toward the abdomen will be cleaned with the abdominal prep. We use an alcohol-free solution for the perineum and chlorhexidine for the abdomen.

Familiarity with equipment setup is essential to the taTME procedure and can vary largely depending on the layout of the operating theater. We suggest two equipment setup formats, among many conformations that exist, as these setups have worked well at our respective institutions. The specific position of laparoscopic equipment and monitors can be modified to fit the available infrastructure of the institution (Fig. 22.5. HSN taTME room setup).

Setup 1: The transabdominal laparoscopic tower is set up by the patient's right shoulder with cords draped over the right shoulder. The surgical team (both assistant and primary surgeon) stand on the patient's right side, and the abdominal dissection is performed from here. The monitor for the abdominal surgeon is placed across the operating table just beyond the patient's left hip. The abdominal surgical instruments and scrub nurse are also across the operating table on the patient's left side.

The transanal component is set up with the second laparoscopic tower beside the patient's right leg with cords and insufflation tubing draped along the right leg. The insufflation tubing is draped across the pubic symphysis, while the transanal suction, cautery, and instruments are laid on a Mayo stand that rests across the surgical field similar to a typical perineal setup. This tower typically consists of two monitors, one with the abdominal laparoscopic view and one for the transanal view. The monitors rest on top of the transanal laparoscopic tower beside the patient's right leg to enable the transanal surgeon to visualize both perspectives while performing the taTME dissection. This also allows the transanal surgeon to monitor the assistant's movements and ensure appropriate traction.

Setup 2: The transabdominal laparoscopic tower is set up by the patient's right leg with the monitor positioned directly between the patient's legs. The light and camera cords to this tower should be positioned over the patient's right leg. The additional laparoscopic monitor is positioned above the patient's left shoulder. The cautery, energy device source, and suction canister are placed over the patient's right shoulder.





**Fig. 22.5** Room setup

The instrument table and scrub nurse should be positioned on the patient's left side. With this initial setup, the transabdominal component of the operation can begin.

The transanal component setup consists the second laparoscopic tower setup above the patient's right shoulder and in front of the energy source of the abdominal component. The monitor for this tower is positioned directly in the midline over the patient's head. The light and camera cords to this tower should be placed along the patient's right side going down to the transanal field. The cautery and energy source for the transanal component should be positioned by the patient's left leg. If there is an additional free-standing insufflator, it too should be positioned by the patient's left leg. The instrument tray and scrub nurse for the transanal component should be positioned on the patient's left side adjacent to the left leg.

As a single surgeon, it is imperative that the nursing team understands the setup such that the setup for the second component of the operation can occur while the first component is underway.

## The Procedure

### Where to Start

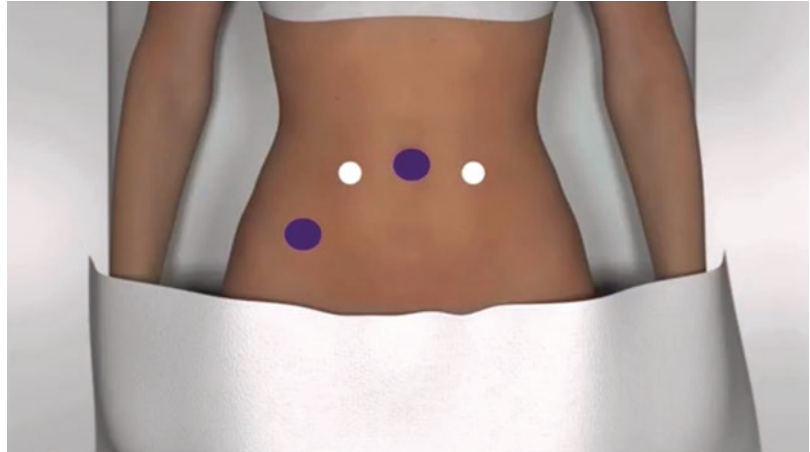
It is recommended to start the operation from the abdomen. Valid rationale for this includes the ability to survey the abdominopelvic cavity so as to exclude carcinomatosis or other unforeseen findings which would otherwise preclude radical resection. Another reason this "top-first" approach is preferred by experts especially for single-team taTME is to familiarize the first assistant with the anatomy and countertraction to enable transanal dissection when the single surgeon goes to the bottom to complete the taTME dissection.

### Transabdominal Approach

The operation is initiated laparoscopically with the surgeon on the patient's right side and the assistant on the patient's left side. Once access is obtained via a Hasson entry at the umbilicus, 3 additional 5 mm ports are inserted (Fig. 22.6).

**Fig. 22.6** Port placement

Port placement



The patient is then positioned in Trendelenburg. The order of steps for the single-surgeon approach has been previously described [36]. The transabdominal portion is not different than any laparoscopic dissection conducted for a low anterior resection; our preferred technique includes the following recommendations:

- Medial to lateral mobilization of the sigmoid and descending colon with careful identification and protection of left ureter
- Medial to lateral mobilization of the splenic flexure, careful identification, and protection of the pancreas
- Ligation of the inferior mesenteric vein, close to the inferior edge of the pancreas
- Lateral mobilization of the left colon, including the lateral attachments of the splenic flexure
- Identifying and maturation of posterior rectal plan
- Ligation of the inferior mesenteric artery, proximal to the takeoff of the left colic artery, either using clips or an energy device, approximately 1 centimeter distal to the origin at the aorta
- Transection of the mesentery of the proximal margin from the ligated pedicle to the level of the colon
- Systemic delivery of indocyanine green (ICG) 5 ml to verify point of transection via fluorescence angiography

- Circumferential TME dissection until the level of the anterior peritoneal reflection
- Opening of anterior peritoneal reflection

During the transabdominal approach, while the team is working toward the pelvis, the assistant is at the patient's left side facing the monitor stationed on the patient's left side. At the next point in the procedure, the patient is positioned in reverse Trendelenburg with the left side up. The assistant moves to between the patient's legs, and the surgeon remains on the patient's right side but is now working via the left shoulder monitor for improved ergonomics. At this stage, the surgeon will employ steps to take down the splenic flexure to obtain adequate colonic length for the conduit. This completes the transabdominal component and the team then moves to the transanal component of the surgery.

### Transanal Approach

Once the transanal component is initiated, the patient is again positioned in Trendelenburg and the abdominal pressured is decreased. The assistant is then positioned between the patient's leg on the right side and the surgeon is seated centrally between the patient's legs. In this position, the surgeon then employs the following steps:

- Placement of the transanal platform including air insufflation setup
- Placement of purse string to close the rectum below the lesion
- Washout of the distal rectal stump
- Rectotomy circumferentially into the TME plane
- Transanal TME until circumferential communication with abdominal component
- Continued dissection of TME until it is either complete or it becomes excessively challenging in which case convert back to transabdominal component to complete final TME attachments

A bilateral pudendal nerve block using local anesthetic is performed. This helps relax the anal sphincter for effacement of the anus, facilitating introduction of the TAMIS access channel. The Lone Star® Retractor (Cooper Surgical) can be used in combination with the TAMIS platform. Alternatively, particularly with obese patients, the anal canal can be effaced by placing temporary interrupted 2-0 sutures in the four quadrants which encompass the top of the anal sphincter, the anal verge, and the perineal skin. These steps facilitate the introduction of the transanal platform.

Once the platform is introduced, it can be secured with silk stitches or in some cases with the stays of the Lone Star Retractor. Once it is secured, the subsequent step is to place the purse string, and this is then followed by cleansing with povidone and washing abundantly with sterile water.

Circumferential incision of the rectum is performed, until full division is achieved.

In the single-surgeon setting, it is important to be prepared to revert to the transabdominal approach in order to complete the circumferential detachment. Eventually, the surgeon will then return to the transanal component in order to complete the anastomosis and may need to subsequently go back to the transabdominal component to confirm colonic orientation and create a diverting loop ileostomy if indicated.

## Systematic Approach to Single-Surgeon taTME

The operation is conducted sequentially using a regular laparoscopic technique; the steps have been previously reported [35] and are summarized below:

1. Positioning (proper padding and security strap for steep Trendelenburg to facilitate pelvic dissection without the help of a second surgeon)
2. Adjunctive monitoring (Foley catheter, arterial line, bilateral IV access) and ERAS protocol
3. Single-surgeon abdominal component (transabdominal laparoscopic dissection to level of peritoneal reflection)
4. Recognition of transition point (below peritoneal reflection, prior to acute angulation of rectum)
5. Single-surgeon perineal component (perineal retractor to efface anus, insertion of platform, identification, and purse string of distal margin)
6. Sterilization of perineal field (generous washout with antibacterial agent)
7. Recognition of full-thickness proctotomy
8. Constant reassessment for the identification of “safe” anterior and posterior planes
9. Recognition and preservation of critical neurovascular structures
10. Rendezvous transition point (abdominal retraction by surgical assistant) to facilitate circumferential dissection
11. Meticulous hemostasis and extraction plan (transanal vs transabdominal)
12. Reconstruction

## When to Transition to the Bottom

As opposed to the two-team approach, in which the team can be conducting the transabdominal TME dissection simultaneous with the team conducting the taTME, the single-team approach can

only conduct one dissection at a time. This makes the decision to switch between the two approaches more crucial and strategic as it can affect the efficiency of the operation.

As previously described, the transabdominal approach is conducted first, and the upper TME is dissected prior to moving to the transanal approach. It is important to employ a “take what is easy” philosophy as a single surgeon. Therefore, from the top-down approach, the dissection is continued until it becomes challenging as the pelvis narrows; at a minimum the single surgeon should reach the anterior peritoneal reflection. Once the decision is made to go to the bottom, it is important to remember to decrease the peritoneal insufflation pressure in order to facilitate dissection and avoid billowing.

### **Roles and Assignments of the Dedicated Nurse and Surgical Assistant**

*During the transanal approach, the assistant is standing on the patient’s right side, to the left of the seated surgeon, remaining at the top and preparing to exert traction and countertraction as required by the surgeon, with a scrub nurse at the top, holding the camera temporarily.* Our preference is to have our dedicated taTME nurse to scrub for the transanal part and hold the camera. The assistant will stand on the left side of the surgeon; the use of a flexible-tip camera lens prevents any interference with the surgeon’s hands. The camera holder should be familiar with the taTME procedure, the capabilities of the camera, and the specific views that facilitate dissection within a narrow field (Figs. 22.3, 22.4, 22.5, and 22.6).

### **Rendezvous: Meeting of the Planes**

The rendezvous time and the circumferential dissection are slightly different for the single-surgeon approach. In a two-team setting, both surgeons are dissecting in synchrony, providing retraction and exposure to one another. In the single-surgeon scenario, it is possible to replicate these retraction and exposure components; how-

ever, it strictly depends on the assistant’s ability to generate adequate traction and countertraction, hence the importance of having an experienced and knowledgeable surgical assistant who can interpret the anatomy as well as the surgeon’s need for exposure.

Just prior to peritoneal entry, the assistant may pull the specimen upward – this facilitates visualization of the planes while the surgeon synchronously pushes the specimen from below. It is important to realize, as the surgeon conducts the “bottom-up” portion of the taTME operation, it may become more difficult than the two-team taTME approach; this is the time when the assistant’s role is crucial by pulling the rectum up and out of the pelvis as the dissection is done transanally.

Once communication between the two spaces has been established, the assistant will help by providing countertraction as needed. Retraction can be limited if the surgical assistant is not familiar with laparoscopic tissue handling as excessive or deficient force can compromise the integrity of the TME dissection. The point of rendezvous is variable and depends on the location of the lesion as well as how much dissection from above has been performed. If the operation starts transanally, then the role of the assistant is much more limited.

The assistant remains at the top providing retraction. By looking at both screens (transanal and transabdominal), the primary surgeon utilizes the additional vantage point provided by the dual vantage point provided by the laparoscopic video display. This can significantly help with the intraoperative decision-making. In addition, the assistant should ensure the bowel stays properly oriented and not twisted for the transanal extraction or the reconstruction.

### **Top-to-Bottom Transfers**

A caveat for the single-team approach is the need to alternate between top and bottom at least once and more typically twice during the operation; this means having to change gowns and gloves at those times, but this can still be done efficiently by a team that has planned accordingly.

As the transanal approach is begun, it is important to ensure the space for the surgeon and assistant at the patient's left and right side for the transabdominal approach is maintained and not filled in with equipment. The surgeon should have no reservation about transferring back and forth to complete the taTME dissection.

After the purse string and rectotomy are complete and the TME is begun from the bottom upward, dissection is carried cephalad. In most cases this will be continued until the communication is made between the two fields and the rectum is liberated. If extreme difficulty arises during taTME, reverting to the top should be an easy decision. The team likely will find the remainder of the TME quite straightforward as the distal margin and the very distal TME has been completed.

### Managing Difficult Dissection

In the single-team taTME setting, the surgeon must utilize both surgical fields as needed. The two-team approach naturally lends itself to the easier dissection with synchronous and thus faster TME dissection times until the fields meet. However, when only one surgeon is switching between the fields, she/he must use their discretion to ensure they are always pursuing the most straightforward dissection (up to down versus down to up).

### Extracting the Specimen and Creating the Anastomosis

Once the rectal dissection is completed, a Pfannenstiel incision can be used for extraction in individuals with narrow pelvises or bulky specimens. Using a wound protector in this setting is invaluable. If the anal canal is patulous and the mesenteric envelope is relatively narrow, transanal extraction can be considered.

With single-team taTME, the surgeon rescrubs and returns to the top for the creation of the Pfannenstiel incision, extraction, deployment of the anvil, and closure of the incision. It is beneficial to decrease the number of surgeon top-to-

bottom position changes to maximize operative efficiency. In order to do this, all of the steps that can be performed at that given time should be performed. It is also valuable to select the segment of bowel that would be used for the creation of the loop ileostomy, when planned diversion is part of the operative plan. The selected loop is marked with electrocautery in order to identify afferent and efferent limbs and should be held with a locking grasper for future exteriorization.

When ready for the anastomosis, the surgeon must go back to the bottom and recover the bowel through the anal canal in a pull-through fashion for reconstruction. During this section, the input of the assistant from the top is very important, emphasizing that the assistant must be able to function at the same level of a surgical resident for key portions of single-team taTME (such as anastomotic construction). In the single-surgeon setting, recommendations for reconstruction (hand sewn or stapled) are not different than the usual considerations for rectal cancer surgery, and the decision algorithm includes tumor location in relation to the sphincter, patient's age, preference, and predicted functional outcome.

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### Auditing Your Results

Regardless of which approach one is using, either single or double team, it is imperative to keep a record of all the procedures and the short- and long-term outcomes. To ensure quality, auditing results is a must for innovative and disruptive technologies such as taTME; currently there exist two main international registries in which surgeons can enroll their patients. They are the Pelican Cancer Foundation (Europe) and Ostrich Consortium (United States and Canada); the direct website links to patient enrollment are as follows:

<https://tatme.medicaldata.eu/>

<https://tatme.ostrichconsortium.org>

As with many surgical interventions, keeping a logbook of surgical and oncological outcomes is recommended. The aforementioned is crucial to ensure any taTME program runs safely and successfully and also permits both surgeon and



institution to compare their results against the standards and outcomes from other jurisdictions.

It has been said that for difficult procedures, the learning curve rises quickly after a critical number of cases; however this is not accurate for single-team taTME. The learning curve for single-team taTME is slow with high risk of complications during the initial stages of implementing a program. For this reason, we strongly encourage participation in an audit and feedback forum such as a national registry.

## Conclusion

In summary, the implementation of a single-surgeon institution must be carefully considered. The institution, local support, financial sustainability, patient population, and surgeon skills and intent should be aligned to ensure success for a single-team taTME program. We have outlined elements that we consider essential for success at our institutions; however factors in the local setting (access to equipment, available personnel) may require modification to what has been described above. We believe that single-surgeon taTME is feasible and should be carefully considered at selected institutions.

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# Transanal Access Platform Options and Instrument Innovations

# 23

Giovanni Dapri

## Introduction

In the last 20 years, drawing inspiration from transanal endoscopic microsurgery (TEM) [1], natural orifice transluminal endoscopic surgery (NOTES) [2, 3], and natural orifice site extraction (NOSE) [4], attention from surgeon innovators as well as research and development has been refocused on the refinement of transanal endoscopic techniques [5–7]. This led to the development of transanal minimally invasive surgery (TAMIS) by Atallah et al. in 2009 [8]. TAMIS represents an innovative modification of conventional laparoscopy, one which adapts the instrumentation and optical scopes of abdominal laparoscopy for procedures performed via natural orifice access [7].

TAMIS was initially developed for the local excision of benign and well-selected neoplasia of the rectum, but as progress in advanced transanal surgery continued, it became apparent that the versatility of the TAMIS platform was well suited for transanal total mesorectal excision (taTME) [9–13]. taTME has multiple theoretical advantages, including the ability to precisely define the distal margin, thereby initiating the dissection inferior to this point, to reveal the so-called holy

plane [14]. A magnified view and pneumatic dissection exposes the embryonic fusion planes of dissection with preservation of the lateral and posterior sacral autonomic nerve plexi. The specimen can then be removed transanally, avoiding enlarging the abdominal trocar scar or performing a supplementary abdominal incision, with consequent reduces abdominal wall access trauma and thus the risk of postoperative incisional hernia formation. However, the technique is challenging, and a relatively steep learning curve is required to gain proficiency [15–17].

Additional applications of TAMIS include the resection of endoluminal benign rectal lesions or early-stage rectal adenocarcinoma [18, 19] and treatment of colorectal anastomotic complications such as leak and fistula [20, 21], bleeding [22], and stenosis [23]. TAMIS and taTME can be performed adopting various transanal platforms and instruments. In this chapter, the different characteristics of these platforms are discussed.

## Platform Options

Different transanal platforms are nowadays available for advanced transanal surgery, most of which have only emerged over the past decade. There are multiple nuances of these platforms and important differences and similarities as well. For simplicity, they can be classified into

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three main categories, based on their material characteristics. These are as follows: (a) flexible, (b) rigid, and (c) semirigid transanal access platforms.

### Transanal Flexible Platforms (TAMIS Based)

Flexible, single-use platforms are those utilized by what has been defined as the TAMIS technique. Most of these platforms were originally developed for single-incision laparoscopy (SIL) through the abdomen and were simply adapted for transanal access. However, some were designed specifically for transanal surgery, including for TAMIS and taTME. There are three main TAMIS platforms and one robotic platform in use currently.

(A) The disposable SILS Port (Covidien, New Haven, Connecticut, USA) (Fig. 23.1). It is a malleable port, made of a specialized thermoplastic elastomer which allows for an atraumatic conforming fit. In most patients the inner lip of the port seats above the ano-

rectal ring. The SILS Port has an option to accommodate three cannulas from 5 mm to 12 mm. The SILS Port's dimensions are 1.5 (L) × 3.6 (W) × 3.7 (H) cm. This was used to perform the original series which described the technique of TAMIS [1]. It is currently FDA approved for use for transanal access surgery.

(B) The reusable KeyPort (Richard Wolf GmbH, Knittlingen, Germany) (Fig. 23.2). It is formed by a flexible silicone tube of 55 × 33 cm, a flex mount with an inner lumen of 24 mm, and a silicone sealing insert with three valve ports allowing to accommodate three instruments from 5 mm to 15 mm. Two additional Luer Lock connectors permit CO<sub>2</sub> insufflation and active or passive smoke evacuation.

(C) The disposable GelPOINT Path Transanal Access Platform (Applied Medical, Rancho Santa Margarita, California, USA) (Fig. 23.3). This FDA-approved platform remains the most common for TAMIS and taTME worldwide; it was specifically designed for transanal use. The apparatus includes a proprietary GelSeal cap, an access



**Fig. 23.1** SILS Port (Covidien, New Haven, Connecticut, USA)



**Fig. 23.2** KeyPort (Richard Wolf GmbH, Knittlingen, Germany)

channel with introducer, three 10 mm sleeves, and one insufflation stabilization bag. The GelSeal cap provides a flexible fulcrum for triangulation of standard laparoscopic instruments. Two stopcock valves are provided for smoke evacuation and insufflation; alternatively, a valveless 5 or 8 mm trocar together with an AIRSEAL® system can be easily adapted to the TAMIS platform for pneumatic stabilization. A simple clasp device secures the access channel sleeve to the GelSeal cap that it can be removed quite easily, facilitating the specimen extraction and access to the operative field, if needed.

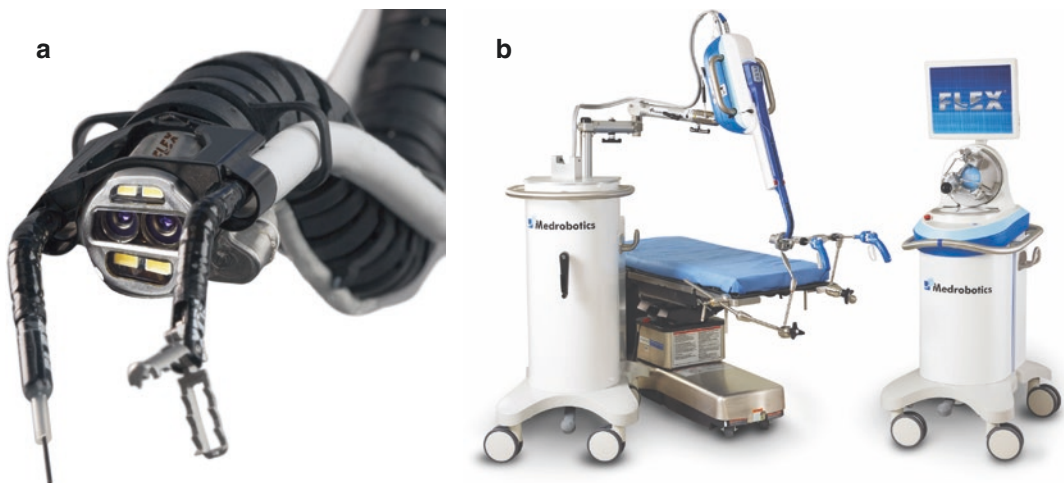


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**Fig. 23.3** GelPOINT Path (Applied Medical, Rancho Santa Margarita, California, USA)

The access channel itself includes keyholes to allow for suture tie placement. This permits to the device to be sutured to the skin, whereby it remains securely in position throughout the duration of the procedure. The GelPOINT Path is currently available in three access channel lengths: 4 cm, 5.5 cm, and 9 cm. The faceplate (GelSeal) measures 40 mm in diameter, and the inner diameter of the access channel measures 34 mm. The sleeves accommodate 5 mm and 10 mm instruments. The insufflation stabilization bag stabilizes the surgical space with an expandable reservoir that dampens the effect of cyclic billowing [24, 25].

- (D) The reusable, rigid platform adapted to the Flex® Robotic System (Medrobotics, Raynham, Massachusetts, USA) (Fig. 23.4a–b). It is the world's first commercially available robotic-assisted surgical platform FDA approved for transanal access that offers surgeons the ability to define a nonlinear path to a surgical site and achieve satisfied exposure [26, 27]. The surgeon is able to sit or stand comfortably as they choose, while also remaining at the patient bedside throughout the procedure. The flexible robotic scope is comprised of inner and outer mechanisms, with magnified 3D-HD view, and navigation nearly 180°. The total



**Fig. 23.4** (a–b) Flex Robotic System (Medrobotics, Raynham, Massachusetts, USA): flexible system (a) and console (b)



diameter of the flexible system (its working head) is 28 mm. This hybrid system is part flexible and part rigid. The access channel is similar in design to a rigid TEM scope, with inner diameter measuring 40 mm. This reusable, rigid access channel is also bedrail mounted. The flexible working head that is navigated through a robotic-assisted console by the surgeon is disposable and designed for single use.

### Transanal Rigid and Semirigid Platforms (TEM Based)

Transanal endoscopic microsurgery (TEM) was developed by Gerhard Buess in 1983 [1]. Until the advent of TAMIS [7], TEM was the gold-standard in advanced transanal surgery. Currently, there are a variety of rigid, reusable platforms available, all of which are predicated upon the original design by Buess. Some surgeons prefer to perform local excision and taTME utilizing these platforms, rather than using the TAMIS platforms. Based on available data, the quality of excision achieved with advanced transanal platforms appears to be equivalent [28]. Of note, for local excision of lesions, it is typically recommended that the patient be positioned such that the lesion is dependent. For example, for a mid-anterior lesion of the rectum, the patient should be positioned prone jackknife. In contrast to this, for local excision with the TAMIS technique, the patient is most often positioned dorsal lithotomy and not based on lesion locale. Notwithstanding, for taTME, both rigid and flexible systems are used with the patient in modified lithotomy. In addition, the two-team approach is a valid option regardless of platform type.

#### Rigid Platforms

(A) The transanal endoscopic operation (TEO) system (Karl Storz Endoskope, Tuttlingen, Germany) (Fig. 23.5) was developed in the mid-2000s and is quite similar in principle



**Fig. 23.5** Transanal endoscopic operation (TEO) system (Karl Storz Endoskope, Tuttlingen, Germany)

and design to the TEM scope. It is formed by three parts: the access channel with its holding arm, the obturator, and the metal cap or faceplate used as a point of access for surgical instrumentation and for general access to the operative field. The holding (Martin) arm contains a connector for vapor evacuation. The access channel is available in three lengths: 7.5 cm, 15 cm, and 20 cm. The cap is formed by four port orifices, where one is filled up by the scope, with its lavage. Different operative instruments from 3 mm to 14 mm can be introduced.

(B) The reusable Wolf TEM system (Richard Wolf GmbH, Knittlingen, Germany) (Fig. 23.6) was the original system designed and developed by Gerhard Buess in the early 1980s. It is a fixed arm platform with the option to work by the telescope plus camera as well as by a binocular, stereoscopic view alone. The optics can be cleaned by an accessory tube for the lavage. Out of the optical view orifices, three other port orifices are in the cap to allow the introduction of the 5 mm working instruments. The access channel is available in three lengths: 12 cm, 13.7 cm, and 20 cm.

## Semirigid Platforms (TEM/TAMIS Hybrid)

(A) The DAPRI Port or D-Port (Karl Storz Endoskope, Tuttlingen, Germany) (Fig. 23.7a–b) is a semirigid platform that was designed for advanced transanal surgery, including for the application of taTME. This platform has been developed based primarily on TAMIS. Unique to the D-Port design is that it merges the main principle of optics and tri-

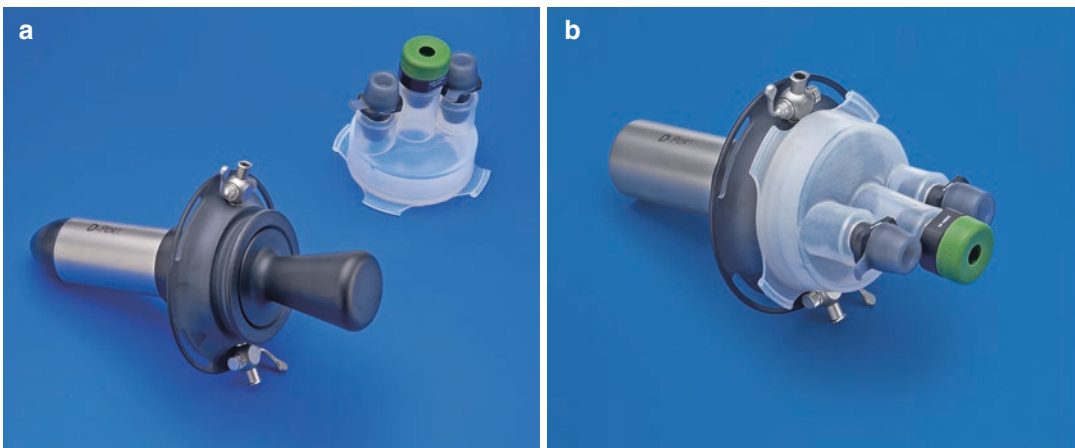


**Fig. 23.6** Wolf TEM system (Richard Wolf GmbH, Knittlingen, Germany)

angulation of general laparoscopy – which is to maintain the optical system in the center as the bisector of the working triangulation formed by two ancillary tools [13] – with an advanced transanal access platform. It is formed by three parts: a rigid tube, an obturator, and a flexible cap. The tube is 30 mm diameter and 7.5 cm length, facilitating its introduction through the anal verge, and anal dilation prior to insertion is typically not required. It allows the use of a center axis positioned 10 mm scope and two 5 mm instruments. An advantage of this port's design is that instrument tip clashing during the dissection is limited, and, when required, the process of intraluminal suturing is facilitated.

Supported by two lock connectors, it permits conventional insufflation of CO<sub>2</sub> through one connection and evacuation of the smoke created by electrosurgery during dissection through the second lock-connector outlet. The D-Port is supported by four oval holes, which allow the port to rotate, when necessary, and to optimize transanal access. Finally, four cardinal points are marked inside the tube to orientate the surgeon during the different steps of the procedure and to help the surgeon maintain a frame of reference.

The obturator is used for the introduction of the shaft of the access channel through the anal verge, and it is removed before the silicon



**Fig. 23.7** (a–b) D-Port or DAPRI Port (Karl Storz Endoskope, Tuttlingen, Germany): the components (a) and the port once inserted in the anus (b)

cap is secured onto the access channel. The reusable silicon cap is formed by three port orifices (left 6 mm, center 11 mm, right 6 mm) aligned in the horizontal axis. It permits the instruments to move freely outside of the port, and the device is designed to function without securing the shaft to the bedrail (as is the case with rigid platforms). The orifices allow the introduction of the 10 mm scope in the center, and of the two ancillaries, 5 mm instruments are placed into the right and left ports for operation by the transanal surgeon.

- (B) The reusable silicon cap modified TEO system (Karl Storz Endoskope, Tuttlingen, Germany) (Fig. 23.8). This platform is the same TEO platform described above, but it differs in its cap because it is supported by a silicon flexible cap with four port orifices. Like standard TEO and TEM, the device is bedrail mounted for stability. The TEO scope's shortened, 7.5 cm shaft allows better maneuverability of instruments, which is particularly important for taTME. This system allows for the admission of both specialized TEO-specific instruments and more traditional laparoscopic instruments.

### Instruments for taTME

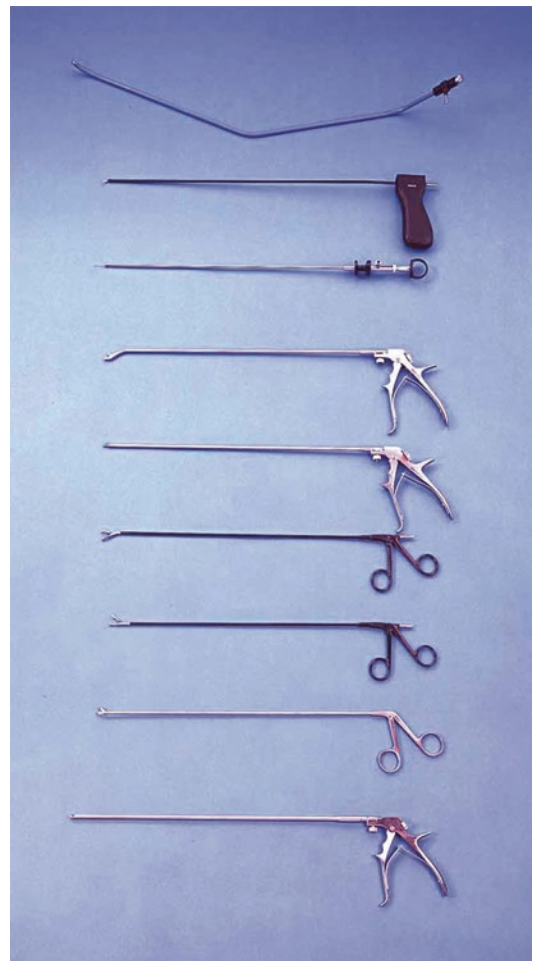
The instruments implemented through the transanal platforms can be conventional straight-shaft instruments used for general laparoscopy,



**Fig. 23.8** Silicon cap-modified TEO system (Karl Storz Endoskope, Tuttlingen, Germany)

specialized flexible tip or articulating laparoscopic instruments, or custom-made instruments such as those designed specifically for TEM and TEO surgery. The dedicated instruments for the transanal platforms are:

- (A) The reusable BUESS instruments (Richard Wolf GmbH, Knittlingen, Germany) (Fig. 23.9a–g). These instruments are supported by a straight shaft; however, the distal working end of the effector arm is curved slightly. A consequent limited space between the surgeon's hands can be present.
- (B) The reusable instruments for TEO (Karl Storz Endoskope, Tuttlingen, Germany) (Fig. 23.10a–b). The shaft is curved proxi-



**Fig. 23.9** BUESS instruments (Richard Wolf GmbH, Knittlingen, Germany)

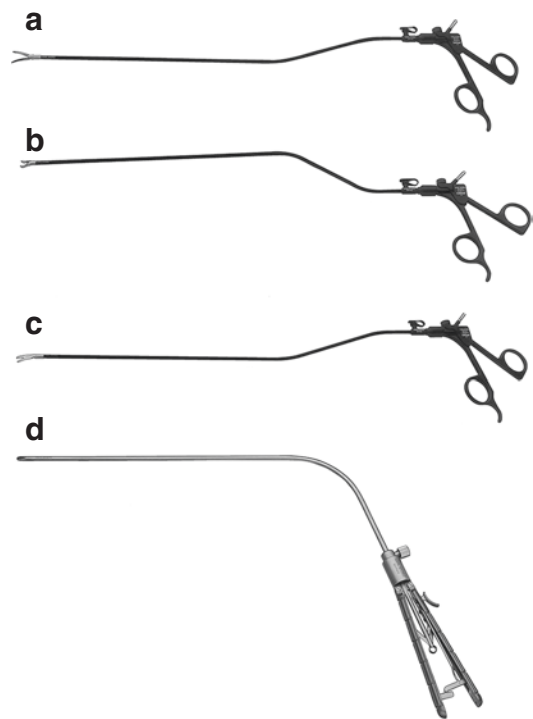
mally to the tip and to the handle as well, maintaining a straight shape in the center. This configuration allows a limited freedom and the absence of conflict between the surgeon's hands and the instrument's tips.

- (C) The reusable WEXNER instruments (Karl Storz Endoskope, Tuttlingen, Germany) (Fig. 23.11a–d). Two curves are present on the instrument's shaft, one at the orifice insertion, allowing a distance with the telescope placed medially, and another one close to the handle, allowing the surgeons to work without enlarged arms. The main shaft, inside the tube and at the extremity tip, is kept straight.
- (D) The reusable DAPRI instruments (Karl Storz Endoskope, Tuttlingen, Germany) (Fig. 23.12a–g). These monocurved instruments are similar and shaped in a semioval form, allowing a certain degree of freedom in intraluminal work, thereby providing an ergonomic benefit to the surgeon. Because of the main curve, the surgeon is able to dissect and to suture intraluminally without any conflict between hands or between the camera-assistant holder's hand. The surgeon's arms movements are similar to those observed during conventional laparoscopy.

These instruments are inserted through the D-Port laterally to the main central port orifice used for the optical system. In the port orifice at 9 o'clock position, one of two monocurved instruments are typically utilized for right-handed surgeons: the grasping forceps (Fig. 23.12a) and the anvil grasping forceps (Fig. 23.12b). This latter is inserted at the step of circular mechanical colorectal anastomosis, allowing the stapler's anvil to remain under control in the pelvis as the arm portion of the circular stapler is introduced transanally

in preparation for mating with anvil. In the port orifice at 3 o'clock position (surgeon's right hand), five other monocurved, custom-designed instruments are typically used. They are as follows: the needle holder (Fig. 23.12c), the scissors (Fig. 23.12d), the coagulating hook (Fig. 23.12e), the bipolar forceps (Fig. 23.12f), and the bipolar scissors (Fig. 23.12g).

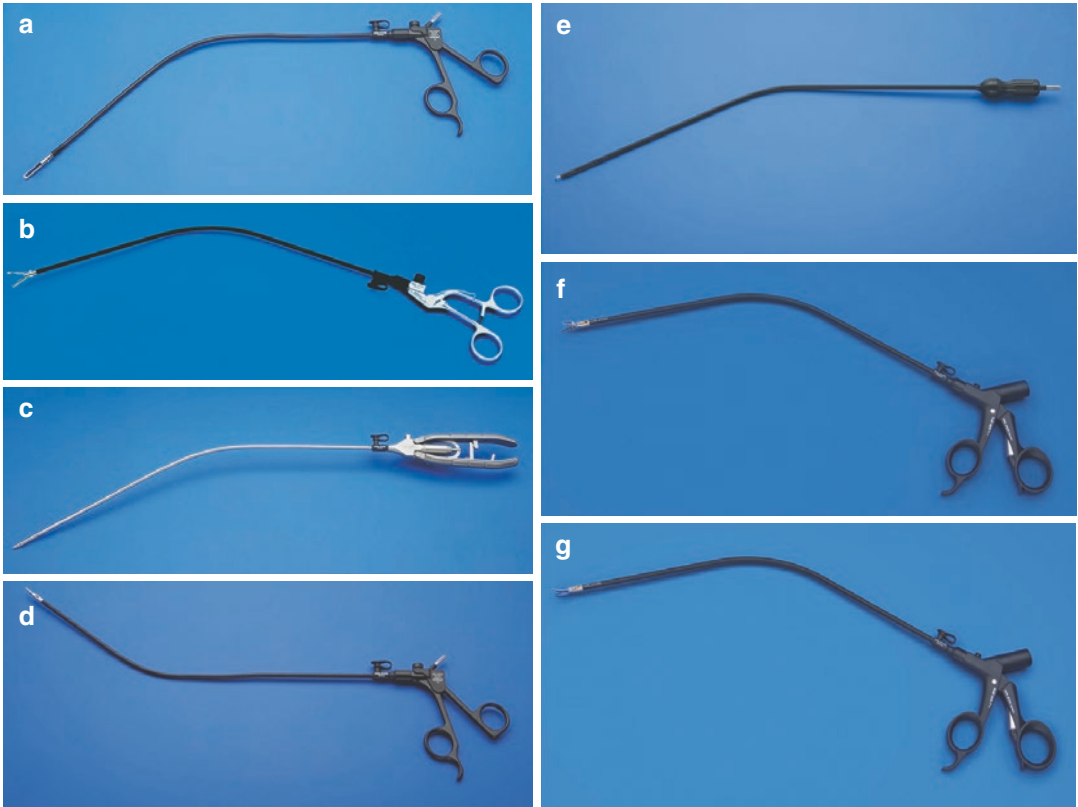
- (E) The reusable Flex Robotic instruments (Medrobotics, Raynham, Massachusetts, USA) (Fig. 23.13a–h). The diameter of these articulating instruments is 3.5 mm and the



**Fig. 23.11** (a–d) WEXNER instruments (Karl Storz Endoskope, Tuttlingen, Germany): dissector (a), grasping forceps (b), scissors (c), needle holder (d)

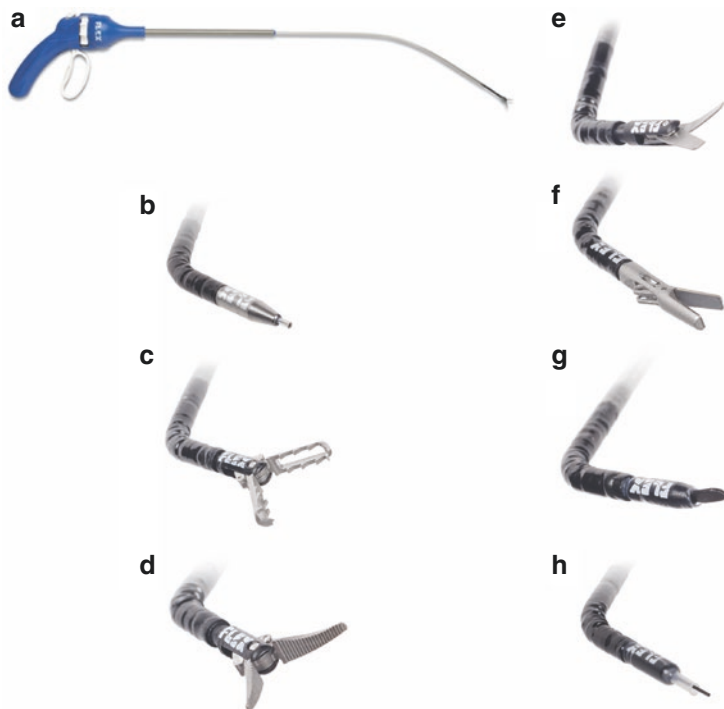
**Fig. 23.10** (a–b) TEO instruments (Karl Storz Endoskope, Tuttlingen, Germany): coagulating hook (a) and needle holder (b)





**Fig. 23.12** (a–g) DAPRI instruments (Karl Storz Endoskope, Tuttlingen, Germany): grasping forceps (a), anvil grasping forceps (b), needle holder (c), scissors (d), coagulating hook (e), bipolar forceps (f), bipolar scissors (g)

**Fig. 23.13** (a–h) Flex Robotic instruments (Medrobotics, Raynham, Massachusetts, USA): handle and shaft (a), laser holder tip (b), fenestrated grasper tip (c), Maryland dissector tip (d), scissors (e), needle driver (f), spatula (g), needle knife (h)





operative length is 24 cm. They're inserted through an instrument support and follow guide tubes positioned along the robotic scope. They allow triangulation from the anus, through the rectum and into the distal colon [27, 29]. The handles are similar to the laparoscopic handles, including the ring for the rotational tip.

## Conclusion

Recent advancements in transanal surgery, specifically the development of TAMIS and taTME, have led to a surgery interest in developing new forms of access and new instrumentation that can aid the operator to perform complex procedures. What was once only possible through TEM is today feasible with multiple, equally effective platforms. This provides surgeons and hospitals with more options.

**Editor's Comment** *While transanal access platforms are most often divided by whether or not they are rigid or flexible, this is really an oversimplified division, and it does not highlight the most important difference between the TEM and TAMIS techniques. It is important to realize that TEM and TAMIS are techniques associated with platforms – not platforms alone. Perhaps one of the most important differences in technique is that with TEM, the shaft of the access channel is meant to be navigated to a localized target. In contrast, with TAMIS, the access channel remains seated above the anorectal ring, while the TAMIS instrumentation alone is delivered to the target of interest. TAMIS' short access channel and free moving camera have made this design quite suitable for working in multiple sectors at various distances from the anal verge without having to reposition the platform, as is the case for most rigid platforms, which require constant readjustment of the Martin Arm. This is one key reason why the TAMIS technique and platform are so commonly used for taTME as opposed to others. Notwithstanding, surgeon preference and resource availability govern which approach is selected for this operation.*

**Authors' Disclosures** The author keeps the patent license for the D-Port platform and monocrurved instruments manufactured by Karl Storz Endoskope, Tuttlingen, Germany.

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# Intraoperative Decision-Making: Converting to taTME, When and for Whom?

# 24

Isacco Montroni and Antonino Spinelli

## Introduction

Converting from one approach to another always comes as a tough pill to swallow. It is so for the surgeon, whose plans have to change while accepting that the initially preferred strategy has failed. It also poses challenges for the operating room (OR) staff who must rapidly modify the work setting in order to create the best possible environment to complete the case. There are challenges for the hospital administration as well, since there is evidence that conversion increases the intraoperative and postoperative costs of the surgical process [1]. Most importantly, for the patient, as in the vast majority of cases, converting from a minimally invasive approach to open surgery leads to worst short- and long-term outcomes [2].

With the introduction and adoption of transanal total mesorectal excision (taTME), we may assist, for the first time, at a situation when the majority of those downsides can be potentially

nullified, or reduced to a minimum, allowing surgeons to complete their task in a minimally invasive fashion promoting better outcomes for complex patients. In sum, it is one of the few exceptions in which conversion is not to a more invasive approach, but rather to an approach which conserves minimally invasive principles.

Because of the extreme paucity of published material on this matter, the following chapter, probably a first in itself, will be based on authors' personal experiences and from the limited available current scientific literature.

## Anatomy of a Conversion

By the Cambridge English Dictionary, "conversion" means "the process of converting something from one thing to another." [3]. The word comes from Latin, *conversio*/*convertō*, and it was originally used to describe a change of direction while turning toward something or someone else. The concept was then adopted in the religious field to signify a change in someone's beliefs, while most American football lovers became familiar with it as it's used when an extra point (or two) is scored by kicking a field goal or carrying the ball into the end zone after scoring a touchdown! Instead of a "touchdown," in the medical field, conversion is equitable to "failure" of one's original approach and pursuing something different, which is usually less

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“appealing” (otherwise it would have been the initial option). Surgeons convert to strategies that may be suboptimal in regard to modern surgical principles (e.g., conversions which increase the degree of abdominal wall access trauma) but which carry the advantage of control and familiarity.

Since minimally invasive approaches have been developed and broadly adopted the word *conversion* has been used to describe the shift from a laparoscopic/robotic approach to open surgery. With increased experience in minimally invasive surgery (MIS), the conversion rate has been widely reduced, and it is now globally accepted at around 5–6%, in expert hands, for colonic surgery [4]. Bahma et al. described data from the American College of Surgeons National Surgical Quality Improvement Project (NSQIP) database, and they pointed out that on multivariate analysis, conversion was higher in patients with advanced age (>80 years old), BMIs classified as overweight or obese, ASA 3 or 4, history of smoking, history of weight loss, and, most significantly, the presence of ascites. While conversion rates have been consistently reduced with increased expertise in minimally invasive colonic surgery, a high number of minimally invasive rectal resections still require conversion to laparotomy. This appears to be one of the major unmet needs of laparoscopic or robotic rectal cancer surgery. The COLOR II randomized controlled trial (RCT) showed a conversion rate near 17% [5], while the ROLARR trial reported a non-significant difference in conversion between robotic and laparoscopic TME of one in ten patients (8.1% for robotic and 12.2% for laparoscopic surgery) [6]. Interestingly, the ROLARR study did not report data about conversion from robotic surgery to laparoscopic surgery. Both laparoscopic and robotic cases were more likely to fail completion in cases of obese, male patients undergoing low anterior resection (vs abdominoperineal resection). The problems associated with those characteristics are obviously increased by the presence of a large tumor, above all if the tumor is located on the anterior side of the rectum where the very thin mesorectum makes the procedure far more challenging.

Once these clear unmet needs of MIS are accepted, three more elements should be considered. First, there are significant concerns about the possible worse outcome for patients requiring conversion to open surgery. Second, even after converting to laparotomy, performing a good quality TME – in a case of an obese male with a narrow pelvis and a bulky tumor – may not come as a simpler task. Third, converting to a different technique still requires proficiency at the new strategy of choice, which may require a different skill set by the surgeon.

In order to answer the first question, Yang et al. [7] demonstrated that of the many factors that may lead to conversion including bowel injury, bleeding, unclear anatomy, and lack of progression. All of these factors can be classified into two categories: (a) reactive or (b) preemptive conversion [8]. Reactive conversion (RC) has been defined as one that follows an intraoperative complication such as bleeding or organ injury, whereas preemptive conversion (PC) is defined as one undertaken to avoid complications. The reasons for PC included poor progression caused by unclear anatomy, obesity, or adhesions, inability to identify the ureter, and other similar situations. After analyzing a total of 222 laparoscopic procedures that had been converted to laparotomy, authors were able to show that patients whose conversion was reactive to intraoperative adverse events were more likely to have a postoperative complication (50% vs 27%;  $p = 0.02$ ), to require a longer time to tolerate a regular diet (6 vs 5 days;  $p = 0.03$ ), and to have a longer hospital stay (8.1 vs 7.1 days;  $p = 0.08$ ) than patients who underwent a PC. Based on these findings, the authors advocated for not considering conversion a “surgical complication” and that an early (preemptive) conversion should be preferred over a delayed laparotomy when major intraoperative complications have occurred.

In order to address the second and third issues, there are unfortunately very little published evidence, but it’s a common experience that even with the best self-retaining (e.g., Bookwalter, St. Mark’s) retractors in place, it’s sometimes extremely complex to access the pelvis when conversion to an open approach occurs.

The limited visibility of the lower third of the rectum together with suboptimal access may lead to several surgical mistakes, from injuring surrounding structures (presacral vessels, prostate, vagina, etc.) to performing a suboptimal cancer operation while tearing the mesorectum or proceeding with an intra-mesorectal dissection. In addition, when hostile pelvic anatomy is present, poor access to the most distal margin of the rectum, below the mesorectal fat, may occur. In addition, passing a linear stapler distal to the bulky mesorectum down to the pelvic floor and then safely firing it, at the determined level, could be extremely challenging and lead to suboptimal results with the need for multiple firings or inadvertently firing through the distal tumor. Nevertheless, this is what most colorectal surgeons have proficiently learned to do over the course of their operative experience, as attested by progressively improved oncologic outcome of rectal cancer over time.

Regarding the third issue previously raised, this is of crucial importance. Converting to a different approach does require increased confidence in the newly adopted strategy, and this can only be achieved with experience. Deciding to move from a transabdominal MIS approach to a taTME approach requires more than a theoretical knowledge of the potential benefit of this technique. Being proficient at dissecting the rectum from the bottom up in complex cases is absolutely feasible, as showed by several studies [9], but specific, advanced skills have to be previously established.

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### **Proficiently Converting from Minimally Invasive Surgery to Minimally Invasive Surgery for the First Time... And What About from Open to a Minimally Invasive Approach?**

Converting from a robotic procedure to standard laparoscopy has been previously described. Nevertheless, this is rarely performed because abdominal laparoscopy can very infrequently overcome issues not solvable with the same trans-

abdominal approach already facilitated by robotic instrumentation. The only occasion this may proficiently happen is when a technical problem is encountered in the robotic system or in case of difficulty mobilizing the splenic flexure and the case is switched to standard laparoscopy, often in a planned, hybrid, robotic-assisted MIS approach. Given the paucity of reports in the literature, this might be considered quasi-anecdotal [10].

On the other end, converting from laparoscopy/robotic transabdominal approach to taTME seems to have the potential to fill the gap of about 10% of these rectal cancer cases that are reported to be converted to open [6]. This will allow, for the first time, to provide a large number of patients with an oncologically appropriate procedure, despite the presence of those challenging features that prompted a conversion, without trading the benefits of MIS. Moreover, a transanal approach to the pelvis could also be a viable option in those open cases where laparoscopy could not be successfully completed because of a number of reasons (e.g., a history of numerous previous surgery, inability to maintain pneumoperitoneum, limited access to the pelvic inlet, and so on). All these patients may still benefit from better visualization and a better dissection of the lower third of the mesorectum, while directly visualizing the pelvic autonomic nerves, without “fighting with” and torquing with significant force on St. Mark’s retractors.

The benefits of the taTME technique are related to both the dissection and the ability to execute a double purse-string, single-stapled anastomosis. Even in the case that the dissection is performed with an open approach, but issues are encountered at the moment of the rectal wall transection or during the double-stapled anastomosis (i.e., breakdown of the cross section on the distal rectum/anal canal), a transanal approach could still be utilized. In these cases, performing a purse string via the transanal platform (TAMIS or TEM) as well as the proctotomy could be of absolute value. At the same time, in case of disruption of the staple line along the anorectal cuff, being able to perform an anastomosis “taTME”-style may help the surgeon overcome this hurdle. This is probably the first time we can discuss a



very likely proficient, nontheoretical, non-fictitious conversion from open surgery to MIS for rectal surgery.

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### **Converting Laparoscopy/Robotic to taTME Approach**

While discussing conversion from a laparoscopic/robotic to a transanal approach, it should be kept in mind that performing a taTME should be planned in advance (as a potential alternative) since in rectal cancer surgery, there is very little room for improvisation. Prerequisite read of the pelvic MRI together with an accurate physical examination of the patient are the key elements to reduce to a minimum the risk of inappropriate surgical planning. Colorectal surgeons should always remember that taTME is a complex operation, not just from a technical point of view, and that it may also require extra equipment (and surgical staff preparedness) not routinely available or immediately available in the OR. For this reason, a preemptive conversion should be promoted over a reactive change of mind in order to reduce the risks for the patients while giving the OR staff the time to arrange the proper setup.

The reason for converting from abdominal MIS TME to taTME is usually when identifying, for the first time during the surgery, those conditions that are considered the “classic” indications for a transanal approach, namely, difficult access to the distal third of the rectum for the dissection, rectal wall cross-stapling, and/or the safe creation of a colo-anal anastomosis. Patients who are routinely considered at higher risk for conversion (obese males with a narrow pelvis and bulky rectal tumor) should rarely surprise the surgeon, and evidence is present that a well-planned transanal approach can reduce the risk of conversion to a laparotomy while promoting a good oncological operation with extremely low circumferential and distal margin cancer involvement [11]. On the other hand, unplanned anatomical situations can occur, perhaps in the case of the presence of an unusually narrow female pelvis or a

particularly bulky uterus that cannot be proficiently retracted. Extreme cases of disproportionately large tumors of the middle/upper rectum in which the mass is so wide that it impedes access to the lower third of the mesorectum. In such circumstances, the approach could be amenable for conversion to taTME. Exploiting the utility of a transanal approach, in those cases, can provide clear benefits worth the added effort of conversion.

Because an intraoperative conversion is performed in particularly difficult cases, a two-team approach might be advisable; and surgeons should plan to have this resource available when conversion to taTME becomes necessary. The help of a synchronous transanal and transabdominal approach, not just in the dissection, but also in the specimen retraction and countertraction in the phase of the rendezvous, can allow the most difficult part of the case to become greatly simplified and to be carried out more precisely. This could potentially improve patient short- and long-term outcomes. No literature is available in this regard, but it seems logical, in those challenging cases, to benefit not only from a dynamic abdominopelvic approach but also to gather together the experience of two trained colorectal surgeons, one for each team.

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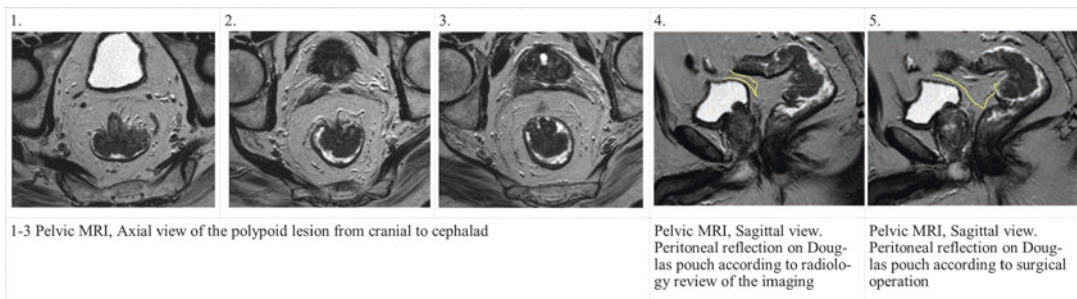
### **Converting from TAMIS to taTME**

Over the last 5 years, local techniques to reduce the impact of surgery while effectively treating rectal cancer have been exponentially growing. Among those, transanal local excision techniques are currently playing a rising role in the armamentarium of every colorectal surgeon. First developed by the precocious Gerhard Buess in 1983, transanal endoscopic microsurgery (TEM), created for higher reach of principally benign neoplasia, almost immediately showed superiority over the standard local excision for early-stage rectal cancer [12]. Despite clear advantages [13], the technique disseminated slowly in the surgical community, because of the steep learn-

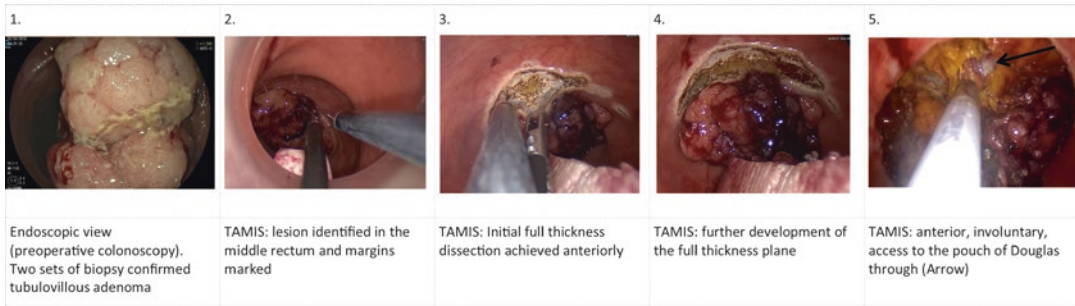
ing curve, high upfront cost of the apparatus, and the small number of eligible cases. In recent years, a renewed interest for transanal endoscopic surgery, due to increased knowledge on the natural history of rectal cancer, increasing number of patient candidates for an organ-sparing approach, and development of easy-to-use platforms which utilize transanal minimally invasive surgery (TAMIS) techniques. Among the possible indications for TAMIS, large tubulovillous adenomas of the rectum are probably the ones with the greatest benefit from this approach. Those lesions would most likely necessitate prolonged and often piecemeal endoscopic mucosectomies, while a TAMIS full-thickness excision can be achieved in a reasonable amount of time and in a single outpatient operation. TAMIS allows both the possibility of precisely resecting the neoplasia in one piece and, by establishing full-thickness dissection, a potential cure (depending on a number of parameters) in cases where T1 invasive adenocarcinoma is diagnosed at final pathology. Because of the growing skill set of colorectal surgeons, tumor location and extension have been increasingly challenged. While excision of circumferential neoplasia is no longer considered a contraindication for TAMIS, the distance from the anal verge still is, to some degree. In particular, the more proximal the lesion is (especially when positioned anteriorly), the greater the challenge for full-thickness local excision. This is due to the higher risk of entering the abdominal cavity, above the pouch of

Douglas, during the dissection, which often results in loss of pneumatic distention of the rectum and which typically requires laparoscopic-assisted sutured closure of the point of peritoneal violation.

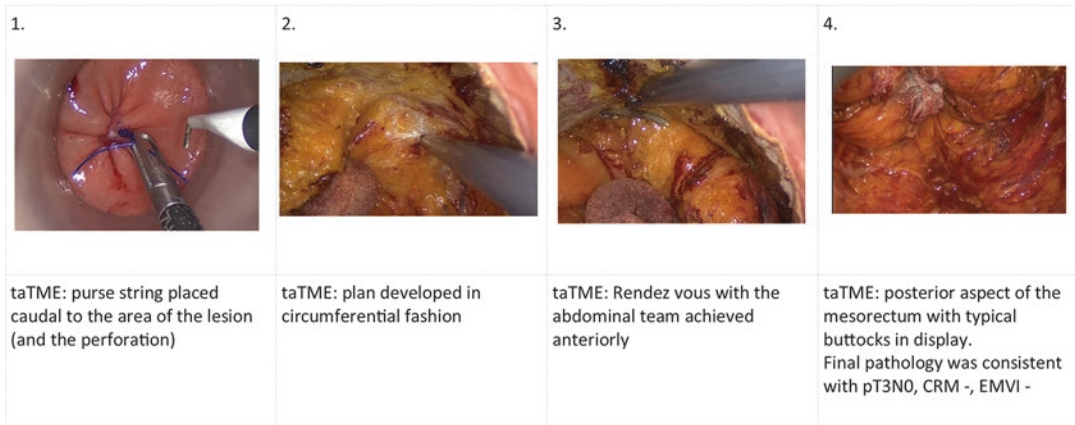
Other options include completing the resection and closing the defect endoluminally, but in some instances it may be advisable to convert the TAMIS local excision to a standard TME. In order to complete the resection and stitch the gap closed, the pneumorectum might be safely maintained for a prolonged amount of time. This may not be achievable if the dissection is just at the initial step or if the gap is too large, even after counterbalancing the abdominal pressure with a Veress needle or laparoscopic insufflation. If this occurs, the surgeon becomes committed to a TME, and conversion to a transanal approach appears to be the most logical solution. Figures 24.1, 24.2, and 24.3 report a case of an anteriorly located large rectal polyp (tubulovillous adenoma at two consecutive biopsy sets). The tumor was considered to be located inside the pelvis by two expert radiologists that described it as below the peritoneal reflection for its entire extension. The lesion was instead located a significant distance above the peritoneal reflection, and the abdominal cavity was entered very soon after beginning the transanal dissection with immediate loss of the pneumorectum despite the use of an advanced insufflation device. Among the advantages of converting to a taTME are:



**Fig. 24.1** Preoperative MRI of a large neoplasia in the mid-rectum, radiological report displayed a T1 N0 rectal mass



**Fig. 24.2** Intraoperative pictures of the TAMIS procedures; abdominal cavity is entered anteriorly, and the local excision cannot proceed safely even after insertion of an abdominal trocar and induction of the pneumoperitoneum



**Fig. 24.3** Intraoperative pictures of the conversion to taTME from the previously unsuccessful TAMIS attempt. Final pathology showed a T3 N0 mid-rectum adenocarcinoma with no pathological high-risk features and negative CRM

- The ability to create a purse string while directly identifying the level of the lesion/gap.
- The possibility to perform a high-quality cancer operation since a “virgin” mesorectal plane is entered from below without interference by the gap at the level of the lesion.
- The opportunity to perform a minimally invasive restorative procedure while also exploiting the transanal equipment already in place.
- The lesion in the case turned out to be a T3 N0 (0/23 lymph nodes, negative circumferential resection margins, extramural vascular invasion negative), and despite the obvious higher risk of perforation, resection was carried out in the same operation without delay, in an oncologically radical fashion via taTME.

### Conclusion

Modern rectal cancer care cannot be an extemporary attempt but needs to be planned and prepared in advance. Nevertheless, finding unpredicted situations when a conversion is needed might occur to any colorectal surgeon. Above all, if considering conversion to taTME, this should be performed preemptively rather than reactively, especially because specialized equipment is necessary.

The sense of conversion is to switch from one approach to another in which the surgeon considers her/himself more proficient or familiar. Thus, converting to taTME requires proficient taTME surgeons.

Converting from a laparoscopy/robotic approach to a transanal one could potentially not

be a rare event given the recently published 10% conversion rate from reasonably high-quality studies. *This is the first time we have a reliable option to convert from MIS to MIS and also from open to a MIS approach.*

Conversion from TAMIS to taTME might also become more frequent as the indications to perform TAMIS increase and surgeons are tempted to push the boundaries to treat anteriorly located tumors in the mid-rectum. In these cases, conversion to taTME offers an immediate and oncologically appropriate restorative approach.

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# Key Aspects of the Abdominal Dissection

# 25

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## Introduction

Modern gastrointestinal surgery has changed notably with respect to surgical modality since the advent of endoscopic surgery. The introduction of endoscopic surgery in rectal cancer treatment has enabled “better visualization of structures that could not be seen with conventional techniques,” especially in the deep areas of the narrow pelvic cavity. Good surgical operation under magnified vision that was not possible with laparotomy became possible. As a result, laparoscopic total mesorectal excision (TME) has now been standardized as a procedure for the treatment of rectal cancer. Several randomized comparative studies from around the world have recently been published that have shown that compared to laparotomy, laparoscopic surgery for rectal cancer is associated with certain concerns regarding the technique’s application toward curative-intent rectal resection [1–4]. This shows that laparoscopic surgery is a complex surgical procedure requiring good surgical skills. Even when a magnified view is obtained under laparoscopic assistance, one cannot deny that restrictions remain in the manipulation of forceps and dissectors in the deep pelvic areas.

Under such pretext, transanal total mesorectal excision (taTME) has emerged as a treatment modality for rectal cancer [5, 6]. While TME surgery is conventionally performed from the abdomen, taTME is performed in the reverse direction from the anus – i.e., the bottom-up approach. Although the pelvic floor is the region most distal from the abdomen and for which visibility and dissection manipulations are difficult, the taTME approach has enabled a direct and close-up view of this area – which is the technique’s *major* advantage.

In clinical practice, this surgery has several advantages that account for its potential usefulness. In particular, the deep dissection layers close to the tumor can be selected, and autonomic nerves that should be left intact can be visualized. Thus, an increased efficacy in curability and function preservation could be realized. Rectal cancer surgery, originally established amidst various constraints, is considered “a surgical procedure that is performed in the most distal area.” However, when approached from the opposite direction (as is the case with taTME), *what was the distal most region becomes the most proximal*. Thus, taTME is a surgical procedure with vast possibilities. This chapter reviews the important points on abdominal dissection while performing taTME.

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## Positioning of taTME in Abdominal Maneuvers

taTME is a surgical procedure whereby the critical portions of dissection, particularly the distal and mid-mesorectal excision, are performed from the anal side. Abdominal detachment maneuvers are usually performed from the abdominal side. taTME can be performed by two methods, either a two-team surgery whereby the abdominal maneuvers and perineal maneuvers are performed simultaneously, or as a single-team operation, in which the abdominal maneuvers and perineal maneuvers are performed sequentially. In the two-team arrangement, abdominal maneuvers are performed simultaneously with the perineal maneuvers; therefore, the perineal team performs the majority of the TME dissection. For that reason, the tasks that the abdominal maneuvers team must handle are primarily vascular management and mobilization maneuvers from the sigmoid colon through to the splenic flexure.

On the other hand, in the single-team surgery, the detachment maneuvers that must be performed from the abdominal side are often slightly different depending on whether the intraperitoneal maneuvers or perineal maneuvers take precedence. The advantages and disadvantages of the intraperitoneal maneuvers taking precedence and those when the perineal maneuvers take precedence in the single-team surgery are summarized in Table 25.1.

Laparoscopic TME is a commonly performed surgical procedure, and there are no notable problems associated with the anatomical understanding regarding the dissection procedures from the abdominal side. However, the anatomical understanding for dissection procedures from the perineal side is difficult, and such procedures are not easy; therefore a certain amount of experience and familiarity are essential for adeptly performing taTME. When taTME is to be performed, each institution must decide whether to use the two-team or single-team approach and if it is the single-team surgery, whether the abdominal procedures or perineal procedures would take precedence. Such choices must be decided based on the experience of the surgical team and the

**Table 25.1** Above first or below first?

	Above first	Below first
Surgical field of view	Familiar	Takes time to get used to
Difficulty of dissection in the pelvis	Difficult	Comparatively easy
Forceps operation in the pelvis	Some restrictions	Less restrictions
Understanding of surgical anatomy	Comparatively easy	Occasionally difficult
Evaluation of intraperitoneal tumor progression	Possible	Impossible
No touch isolation	Possible	Difficult
Risk of the urethral injury	Rare	Certain risk in the lower rectum
Autonomic nerve preservation	Possible	Better visibility of NVB and PSN
Selection of dissection plane	As usual	Possible selection depend on tumor depth

level of technical familiarity with dissection procedures from below. When there is no familiarity with taTME procedures from the anal side, we would recommend collaborative surgical procedures by a single-team or dual-team approach whereby the abdominal portion of the operation takes precedence.

## Key Aspects for Performing TME from the Abdominal Side

### Understanding the Perirectal Fascia Structure

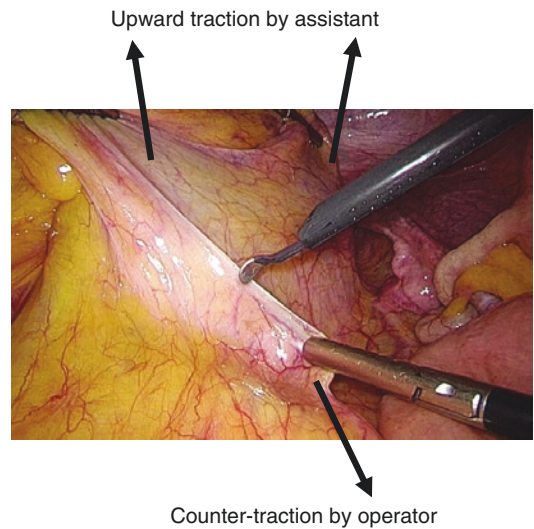
A clear understanding of the perirectal fascia structure is necessary for performing procedures from the perineal side and even while performing TME procedures from the abdominal side to avoid pitfalls. The mesorectal envelope, the thin fascial layer that covers the rectum and surrounding fat, is the most important landmark while performing TME. The mesorectum is surrounded by a layer of pre-hypogastric nerve fascia. Preserving

this layer results in the preservation of the hypogastric nerves, the pelvic autonomic nerve plexus, and the paired neurovascular bundles. The prehypogastric nerve fascia reaches the anterior wall of the rectum, where it transitions into the Denonvilliers' fascia. The endopelvic fascia, which lies further exterior to the prehypogastric nerve, is present in the posterior wall of the rectum and covers the blood vessels running in the anterior plane of the sacrum. The anatomical understanding of these fascial layers becomes critical during dissection around the rectum (Fig. 25.1).

While performing the TME procedure from the abdominal side, the post-rectal space is entered from the promontory angle to accurately identify the mesorectum. In this area, there is a potential space between the mesorectum and prehypogastric nerve fascia, which makes it easy to identify the mesorectum. As a technique for expanding the visual field, the vicinity of the sigmoid colon is grasped with two forceps and retracted upward, away from the pelvis. By doing so, the mesentery of the sigmoid colon is pulled to the peritoneal surface of the anterior abdominal wall (Fig. 25.2). The mesentery is incised upwardly, at approximately 1 cm from the root of the sigmoid mesentery; it is then opened to the left and right to enter the plane of the post-rectal space (Fig. 25.2b). By pulling the prehypogastric nerve fascia dorsally (at the S2/3 level of the

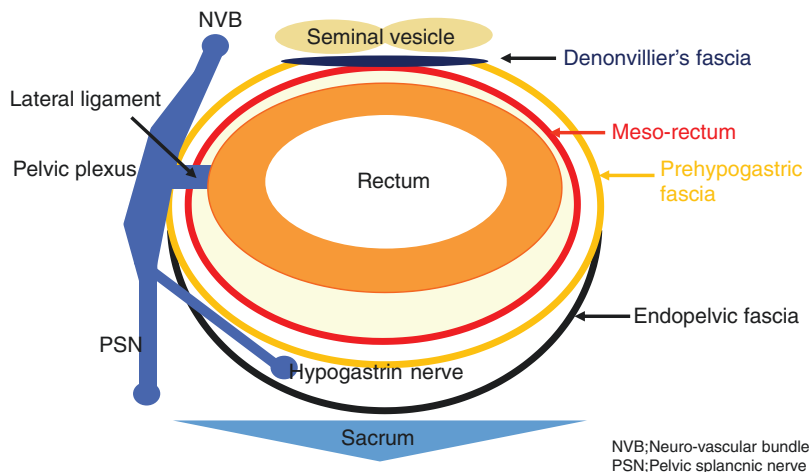
sacrum) from the promontory angle, it becomes easier to recognize the plane between the fascia and the mesorectum, which is identified as a thick, yellow membrane (Fig. 25.3). If the mesorectum is not identified with absolute accuracy, one cannot guarantee a proper TME dissection layer.

The basic concept of TME is to identify the mesorectum during surgery and then to perform dissection along this fascia. For early-stage lesions, such as T1 and T2 rectal cancers, radical



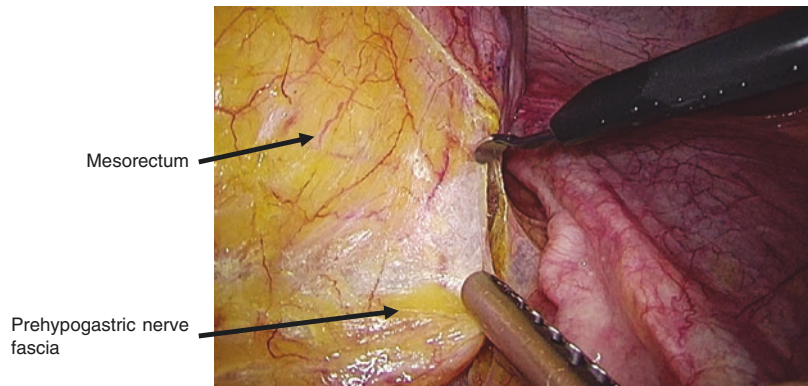
**Fig. 25.2** Effective exposure entering the post-rectal space

**Fig. 25.1** Fascias around the rectum

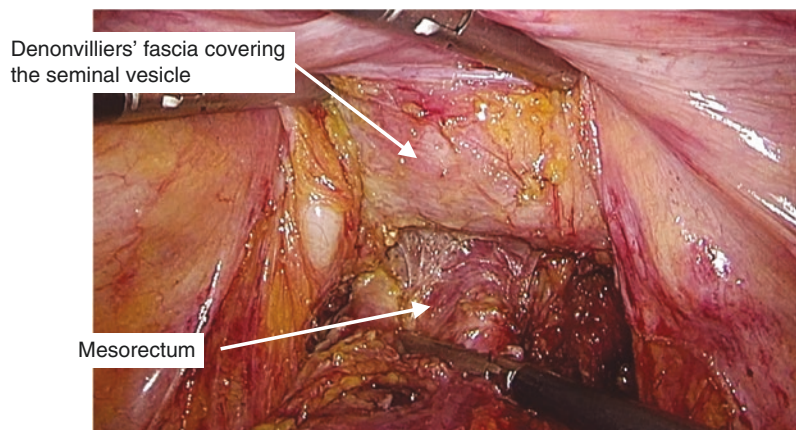


NVB; Neuro-vascular bundle  
PSN; Pelvic splanchnic nerve

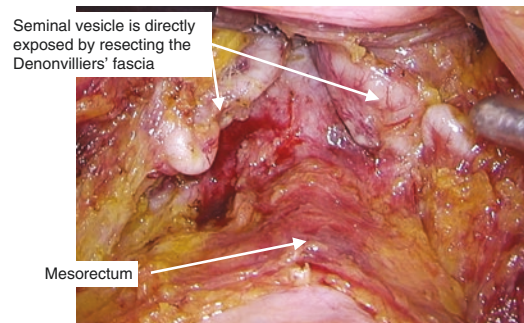
**Fig. 25.3** Identification of mesorectum



**Fig. 25.4** Identification of Denonvilliers' fascia covering the rectum in anterior side of the rectum



resection is possible in the conventional TME dissection plane. For T3 and T4 rectal cancer lesions, selection of a more inclusive dissection layer is sometimes necessary to ensure adequate circumferential resection margin (CRM). In these cases, the dissection layer intentionally includes the pre-hypogastric nerve fascia which is located more externally than the mesorectum. The pre-hypogastric nerve fascia is a series of membrane structures that include the hypogastric nerve and pelvic plexus on the lateral side and Denonvilliers' fascia on the anterior side. With the regular TME dissection layer, Denonvilliers' fascia is recognized as the fascia that covers the seminal vesicle (Fig. 25.4). Meanwhile, if the selected dissection plane is one layer deeper than the regular TME dissection layer, then Denonvilliers' fascia becomes the dissection layer in the anterior wall, while on the lateral side of the rectum, it is the pre-hypo-



**Fig. 25.5** External dissection plane in anterior side of the rectum

gastric nerve fascia that becomes the dissection layer to be selected for the resection. If the Denonvilliers' fascia is resected together with the rectum, for males, the layer that exposes the seminal vesicles is where the dissection will take place (Fig. 25.5). However, for females, the same fascia is usually thin and may not be accu-

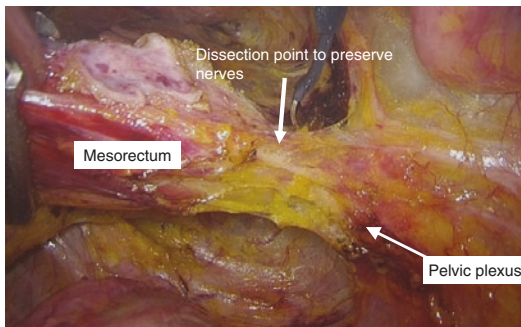
rately recognizable. When dissection occurs in the layer that includes the hypogastric nerve, neurovascular bundle (NVB), and pelvic plexus in the vicinity of the resection site, caution must be taken to avoid injury to these structures as urinary and sexual dysfunction may likely be induced postsurgically.

However, on the lateral side of the rectum, an adequate plane between the hypogastric nerve and pelvic plexus is acquired by pulling the mesorectum inward, and cutting that peak yields nerve preservation (Fig. 25.6). If the TME procedure is continued unmodified in the vicinity of the anal canal, which is the endpoint of the TME, the intersphincteric space (ISR) is identified behind the NVB, and dissection of the ISR is initiated (Fig. 25.7).

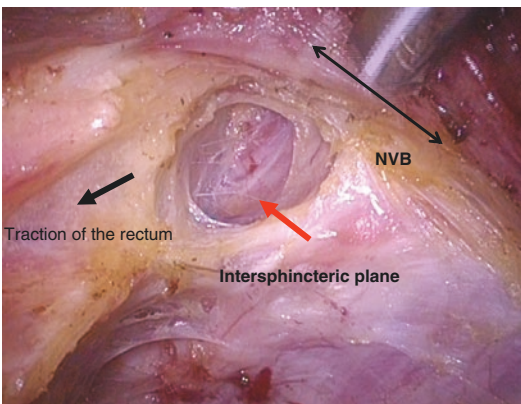
If taTME is performed from the anal side, there are mainly two choices for the dissection

layer in the posterior wall of the rectum: these are the dissection layer of the abdominal side or that of the posterior side of the endopelvic fascia (Fig. 25.7). In taTME, due to the presence of recto-sacral ligament with fusion of several fascial layers in the vicinity of the S2–3 sacral vertebrae, then isolation of this ligament is necessary. In this region, if the dissection proceeds in a direct line with no change toward the peak of the curve of the L-shaped sacrum, caution is required to avoid injury to the blood vessels located in the anterior surface of the sacrum. The direction of the dissection shifts upward after the recto-sacral ligament is resected; this results in dissection that conforms to the shape of the sacrum. In contrast, typical perirectal dissection from the abdomen involves the dissection layer between the mesorectum and pre-hypogastric nerve fascia. However, as with taTME, resection of the recto-sacral ligament in the region of the S2–3 vertebrae is necessary.

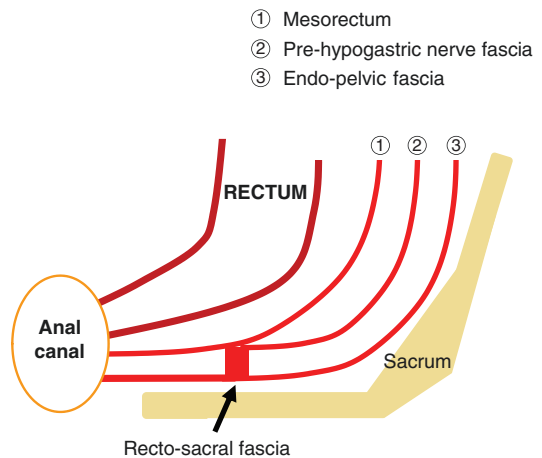
Figure 25.8 presents a case where the surgery was performed from the perineal side, with the dissection layer lies behind the endopelvic fascia for T3 lesions of the posterior wall of the rectum. Such difference of the dissection planes from the abdomen to those from the perineum is occasionally found in two-team taTME procedures.



**Fig. 25.6** Dissection between mesorectum and the pelvic plexus in lateral side of the rectum



**Fig. 25.7** Identification of the intersphincteric space behind the neurovascular bundle



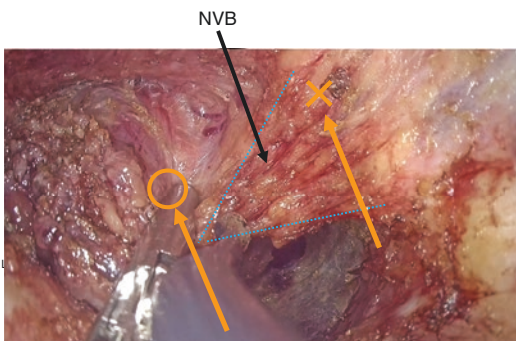
**Fig. 25.8** Fascias in posterior side of the rectum



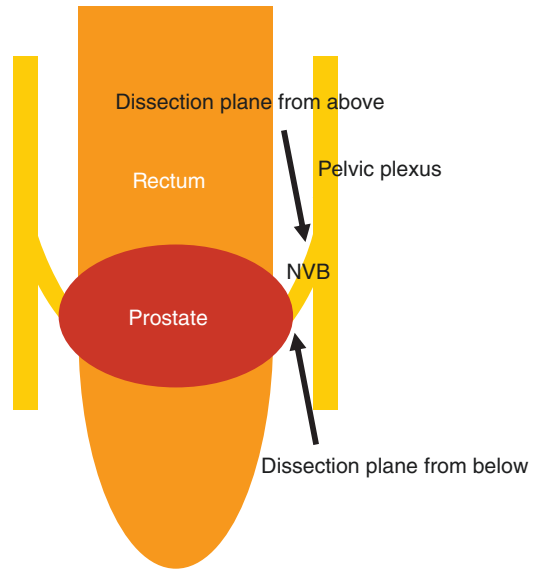
## Caution During the Dissection in the Neurovascular Bundle (NVB)

In TME procedures approached from the peritoneal side, the dissection procedures of the anterolateral region of the rectum are particularly challenging. The anterolateral region of the rectum is in close proximity to the NVB, where bleeding can be readily triggered. Moreover, if the surgeon-selected dissection plane is slightly exterior, autonomic nerve injury may occur. We have often experienced cases of voiding dysfunction and sexual dysfunction occurring because of this injury.

In males with a narrow, android pelvis, dissection procedures in the vicinity of NVB may be difficult as forceps maneuvers are restricted. In cases where the tumor mass is located anterolaterally and where the depth of tumor invasion is  $\geq T3$ , a dissection plane where a part of the NVB is also resected has to be chosen. However, even when the rectal cancer is T1 or T2, dissection manipulations in this region are not always easy due to restriction of the bony pelvis. One of the important and recently recognized advantages of the taTME procedure is good visibility of NVB from the perineal side. In taTME, NVB is known as a bundle structure of a certain length. Therefore, a dissection at the superior aspect of the NVB will not result in nerve injury (Fig. 25.9). Even in our experience, the incidence of voiding dysfunction has been less in patients in whom nerve preservation was done during taTME. Therefore, when taTME is performed from the perineal rather the abdominal side, selective dissection procedures can be performed



**Fig. 25.9** Neurovascular bundle from below



**Fig. 25.10** Difference of dissection point between from above and from below

under good NVB visibility. As shown in Fig. 25.10, when the TME is performed from the abdominal side, there exists a potential to injure the nerves located toward the central side of the NVB. In taTME, dissection in the periphery (i.e., in a plane too lateral) is quite possible. Therefore, even from the viewpoint of nerve preservation, it is preferable to obtain a certain level of familiarity before performing dissection procedures in TME. Thus, when one senses that dissection in the region of the NVB by the abdominal approach to TME would be difficult, it is better to select a dissection layer in this area that would work cooperatively with the perineal (taTME) technique, so as to optimize correct-plane surgery and subsequent patient outcomes.

## Key Aspects for Adequate Blood Flow Preservation in the Colon

While performing taTME, regardless of it being executed in single-team or dual-team fashion – the team performing the abdominal dissection is responsible for blood vessel management in the vicinity of inferior mesenteric artery (IMA) and the mobilization of the colon. The important



issues in abdominal procedures are (1) preservation of adequate colonic blood flow and (2) mobilization of the colon that is long enough to avoid tension in the anastomotic site.

In case of high anastomotic sites following low anterior resection (LAR), the branching site of the left colic artery (LCA) can be easily preserved with a comparatively low level of ligation. However, if an anastomotic site is predicted to become a low-level anastomosis in the vicinity of the anal canal, it is essential for the abdominal dissection team to perform the mobilization of the splenic flexure, so as to assure ample length, with care to preserve the intrinsic vascular arcades to the colon and conduit. To accomplish this, three things must be performed: (1) high division at the root area of IMA, (2) complete mobilization of the splenic flexure, and (3) division of the inferior mesenteric vein (IMV) at the inferior margin of the pancreas. By completing these three procedures, an adequate mobility of the colon can be obtained, and an anastomosis using the colon with good blood flow becomes possible. Other steps include mobilization of the descending and sigmoid mesentery, division of the White Line of Toldt, and intracorporeal division of the marginal artery at the site selected for proximal bowel division. The latter is particularly important to perform, especially prior to transanal extraction of the specimen, since the blood supply (especially the marginal artery) is prone to shear during this process.

In particular, the evaluation of blood flow during surgery by indocyanine green (ICG) fluorescence imaging has recently become available. Consequently, through real-time perfusion angiography utilizing ICG intraoperatively, it is possible to mitigate the risk of using a colon with inadequate blood flow – such as when due to the presence of *Sudeck's point* which is an anastomotic site in the sigmoid colon susceptible to ischemic colitis.

in the pelvic cavity needs to be maintained. Therefore, it is desirable that the dissection layers of the abdominal procedures and perineal procedures are not connected in the early phase of the surgery. In particular, the rendezvous point is commonly the peritoneal reflection. Therefore, during the abdominal dissection with two teams (top and bottom), *it is preferable not to dissect the peritoneal reflection located in the anterior wall of the rectum until both teams are ready to carry out the rendezvous*. Similarly, during the dissection of the posterior wall of the rectum, it is better not to connect the dissection plane between the abdominal space and the perineal space just close to the recto-sacral ligament. Once the abdominal and perineal sides are connected, the abdominal air pressure on the perineal side and that on the peritoneal side must be the same; otherwise the subsequent abdominal procedures will be affected.

After all the dissections are completed, the rectal cancer mass (en bloc with the rectum and mesorectal packet) is excised and extracted. Extraction can be done by two different routes – transabdominal or transanal. Each route has its own advantages and disadvantages. In patients whose tumor volume is relatively small, and the mesentery is not overly bulky, extraction of the specimen via the anus is a reasonable option. However, when the tumor size is large or the mesentery bulky due to visceral obesity, there is a risk of injury to the mesenteric blood vessels and shearing of the mesentery itself. Hence, a transabdominal route is preferred in this setting. Another advantage of the transabdominal route is that the surgeon can check whether the marginal vessels are correctly preserved. In particular, for cases of ISR and in cases of low-level anastomosis, the colon must be fully mobilized so that adequate colon length and good blood flow are preserved.

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### **Caution for the Abdominal Dissection Team in the Dual-Team taTME**

There are several points that the abdominal dissection team of the two-team approach must be cautious about. In taTME, abdominal air pressure

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### **Summary**

taTME is a surgery procedure that is performed from the perineal side, which is the reverse of the conventional TME. This technique has demonstrated many advantages compared to conventional TME, especially in the treatment of male

patients with a narrow pelvis and in patients with visceral obesity. In properly selected patients, it may be superior to TME in terms of resection quality and patient outcomes.

In this chapter, the salient points pertaining to the abdominal dissection have been highlighted. The abdominal portion of taTME is critical for assuring safe and proper conduct of the taTME operation. Coordination and dual-team orchestration is important, as is the anatomical understanding of the structure of the membranes surrounding the rectum is necessary.

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# Zen and the Art of the Purse-String

# 26

Andrew R. L. Stevenson

## Introduction

Just like a storybook, every surgical procedure has a beginning, middle and an end. Each part of the operation requires careful attention, but perhaps the most important part of transanal total mesorectal excision (taTME) surgery is the beginning – the purse-string. The creation of a sound and perfect purse-string sets the foundation for successful surgery to follow. This chapter is largely based on personal experience with observations made by myself and colleagues conducting workshops from around the globe. This is often found to be a time-intensive exercise for novice surgeons, who typically require multiple attempts to achieve the goal of a water- and airtight purse-string.

It has been through these various workshops that I was reminded of the cult book from the 1970s, *Zen and the Art of Motorcycle Maintenance* by Robert M. Pirsig. This has become a classic book on modern philosophy in which the author explores both the meaning and concept of “qual-

ity” through his own dynamic personal quest for quality and value. It is this same pursuit of excellence that is required of surgeons to create the perfect purse-string in an efficient and reproducible manner. Taking the time to slow down, reflect and allow yourself to become totally absorbed in the task – a state of *flow* – a highly focused mental state as described by eminent psychologist Mihaly Csikszentmihalyi.

The perfect purse-string is the beginning and also the end of many taTME operations. This chapter will provide the surgeon with the knowledge and helpful tips in their own personal quest for quality and the perfect taTME.

## The Setup

There is basically two ways that a purse-string can be created. This will largely depend on the height of the tumour from the anal verge or anorectal junction. The purse-string can be placed either by using retractors and placed transanally under direct vision or placed endoscopically via the chosen transanal endoscopic platform.

Most surgeons will be more familiar with transanal placement of purse-string with skills that may have been developed when performing stapled hemorrhoidectomy or similar procedures. As with all steps of any operation, the key is adequate retraction, exposure and illumination.

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Retraction can begin with eversion of the distal anal canal either with sutures or using proprietary retractors such as Lone Star retractor (Cooper Surgical, Inc). Various proctoscopes can then be employed to demonstrate the lower edge of the tumour. If the lesion is higher than the anorectal junction, the operating platform anoscope can be inserted to provide exposure. However, for tumours that are close to the anorectal junction or into the upper anal canal, the purse-string would need to be inserted using a proctoscope only, before insertion of the operating platform and endoscopic equipment. Illumination is best provided by means of a surgeon's headlight or self-illuminating proctoscope. As the operating theatre becomes crowded with all the equipment required for these complex operations, the use of a battery-powered headlight can be quite helpful, if available. Long needle holder and forceps can facilitate access to the distal rectum via the proctoscope.

For tumours that are situated higher in the rectum, it is more desirable to place the purse-string endoscopically using the chosen platform for taTME. Good-quality laparoscopic needle holders will be required for placement of the purse-string. The preferred suture is an 0-Prolene on a 26 mm, semi-half circle (SH) needle. This is less likely to break when tying the suture or during the TME dissection, and the smaller-diameter needle is both easier to use in a small space and also less likely to take too much tissue at once.

If the operation is being performed as a synchronous procedure with two teams, it is important for the perineal surgeon to have good access and appropriate ergonomics to be able to perform the perfect purse-string. It is important for the abdominal surgeon to also appreciate the importance of this step of the operation and allow the position or height of the patient to be adjusted to suit the perineal surgeon. Although I prefer to perform the taTME dissection in a standing position (with elbows slightly extended and assistant camera holder standing or sitting comfortably next to me), I will usually perform the purse-

string whilst seated but raising the operating table for head-down tilt as required, to gain perfect access.

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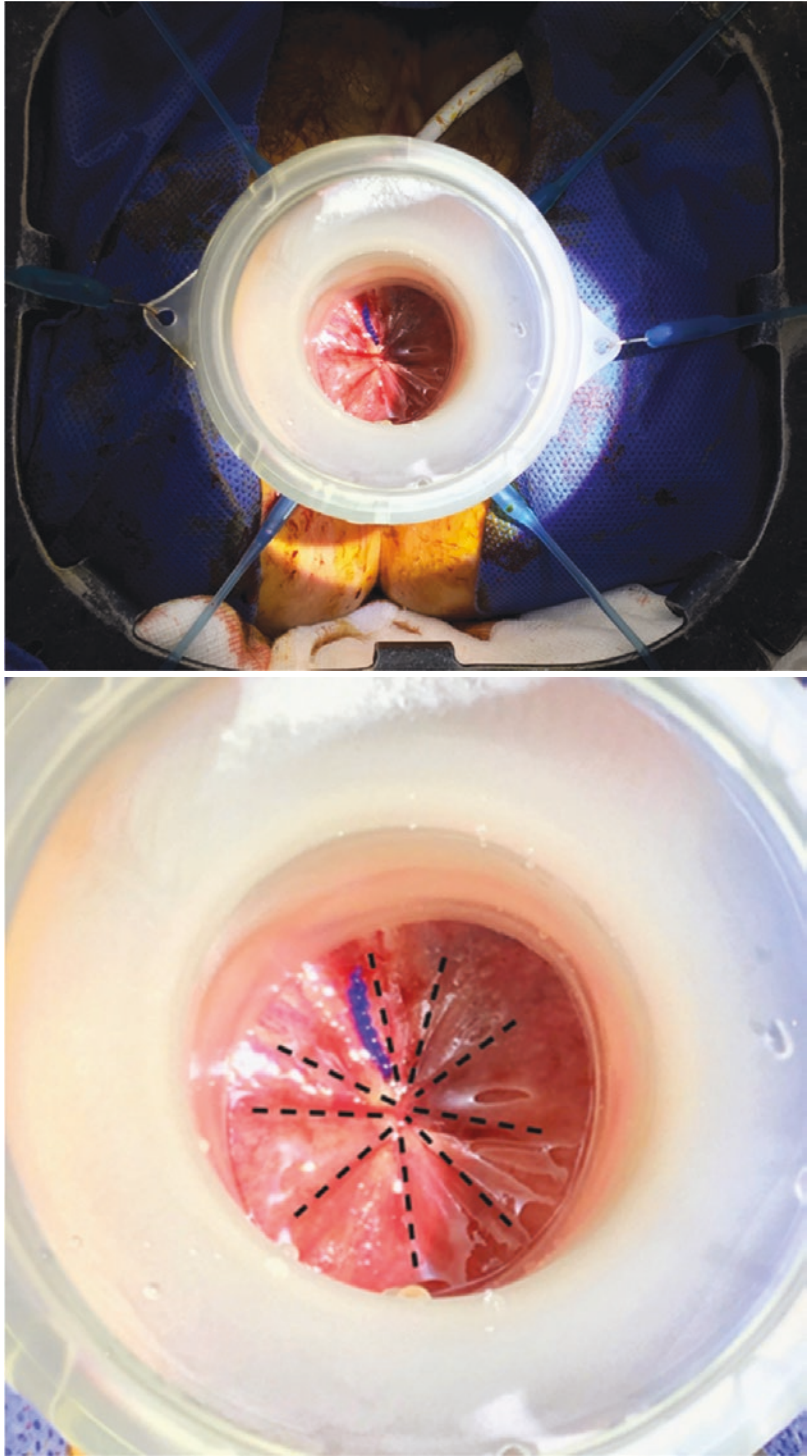
## Purse-String Principles

Generally, the purse-string is placed 1 cm distal to the lower edge of the tumour, and the rectotomy performed 1 cm distal to the purse-string; thus the rectotomy is created 2 cm distal to the inferior extent of the tumour. Depending on the height of the tumour and its position in relation to the anorectal junction, the distance below the tumour at which the purse-string is placed may be slightly greater to or less than 2 cm. When the purse-string has been tightened and tied, the ideal appearance is a centrally placed knot with a number of shallow radial folds extending out towards the periphery from the central knot (Fig. 26.1).

The perfect purse-string is achieved by assuring equal needle placement and taking equal size radial bites, typically 8–12 bites depending on the width of the rectum. It is important that the sutures are placed evenly and not too far apart, not too close together, but “just right”. The needle should enter the tissue just a few millimetres along from where the needle exits the tissue of the previous bite. When the purse-string is tightened and secured, this will invert the rectal wall evenly, providing a good platform around which the rectotomy can be made. It is vital that the purse-string is centrally secure to prevent the egress of bowel content or, or potentially, exfoliated malignant cells to enter the operative field. Whether the purse-string is performed “open” via proctoscope or endoscopically via the chosen platform, it is advisable to have minimal amount of the suture within the rectum. This will help to prevent looping and excess suture affecting visibility or forming inadvertent knots.

There are no hard and fast rules about the best position to start the purse-string (I typically start at the three o'clock position), but it is often useful

**Fig. 26.1** The perfect purse-string (low)

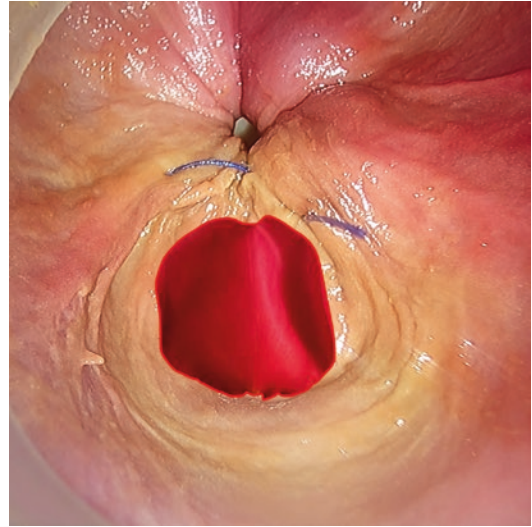




to start the purse-string distal to the visible tumour to ensure correct height of the suture.

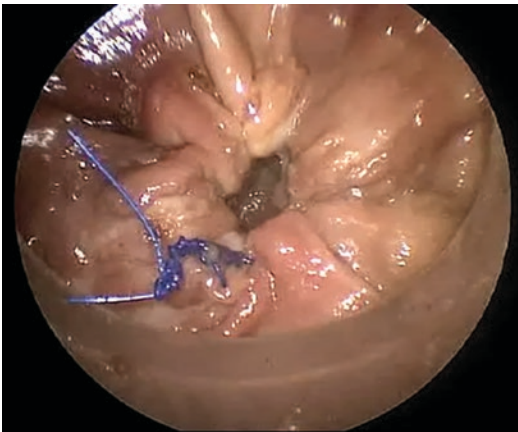
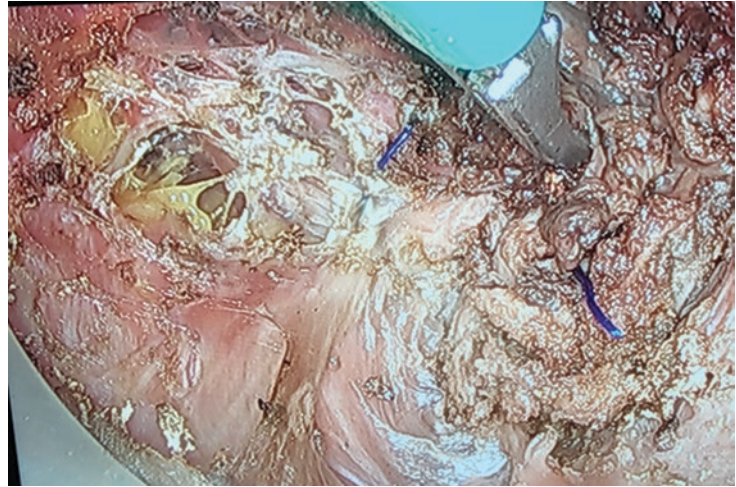
## Common Pitfalls

1. The “spiral” – It is not uncommon for novice surgeons to place the suture at different levels from the anal verge. This is typically too far proximal in the anterior aspect and often going too distal in the posterior aspect. This then creates a *spiral* or eccentrically placed purse-string which will make for a difficult rectotomy and the potential for uneven length of remaining rectal tube. The surgeon needs to be mindful of placing each suture at an equal distance from the anal verge or anorectal junction to avoid this common mistake.
2. The “rose petal” (Fig. 26.2) – This is one of the most feared pitfalls when performing the purse-string. This is created by having the suture needle taking too much of the rectal wall circumference, i.e. taking too much tissue in one pass of the needle or simply stated, “taking too big of a bite”. The resultant appearance when a suture is tightened and secured is to have an obvious segment which lacks symmetrical radial folds. This will become more evident once pneumorectum has been initiated. Indeed, if the pneumorectum is allowed to continue, there is a high probability that a gap in the mucosa and rectal wall will become apparent which may then lead to failure of the purse-string and the potentially catastrophic egress of bowel content or mucous in the operative field. Furthermore, gas can distend the entire colon making the laparoscopic portion of the operation arduous.
3. The “overzealous” – The converse of the rose petal is the surgeon who passes the suture needle in and out so many times in going around the circumference of the rectum that it makes it very difficult to bring the tissue edges together. This may create difficulties when tying the suture and again result in a central gap in the purse-string.
4. The “stuck on you” (Fig. 26.3) – The ideal depth of each suture for the purse-string should be through mucosa and at least the circular muscle layer of the rectal wall. However, some surgeons may become frustrated with their initial attempts to achieve a secure purse-string that they then take very deep bites through the rectal wall. These deep sutures risk including adjacent tissue such as the pelvic floor muscles, vagina or prostate. Whilst the purse-string may have appeared to be secure, this will cause problems once the dissection has commenced and often leading the surgeon to proceed in the incorrect plane or causing injury to the adjacent structures.
5. The “locked” (Fig. 26.4) – You’ve placed the sutures perfectly! The sutures are at the appropriate and equal height from the anal verge or anorectal junction, equal bites, perfectly spaced. But, the job of achieving the purse-string is not yet over. All too commonly observed through the workshops, the enthusiastic surgeon, eager to commence taTME dissection, will quickly throw a few knots and often locking the second knot without properly bringing together the edges of the rectum. It is important for the surgeon to pay careful attention to this part of the procedure, not to



**Fig. 26.2** The “rose petal” seen here in the upper left corner of the photograph

**Fig. 26.3** The “stuck on you” suture inadvertently including deeper tissues, becomes evident after dissection has begun, leading into deeper incorrect planes



**Fig. 26.4** The “locked” suture, leading to inadequate seal

have their hands unnecessarily holding needle holders or forceps. If a single throw is used to tie the suture, the second throw should also be in the same direction so as to allow the surgeon to “snug down” the knot and pulling together the purse-string. It is often the second throw that causes the problem if this is done in the opposite direction to the first throw. When it comes time to tying a perfectly placed purse-string, it is time for returning to your highly focused mental state (flow), finding your Zen.

6. The “limbo” – How low can you go? Sometimes this is unnecessarily low, particularly in larger patients or those with a long anal canal. This is more commonly a problem when using a proctoscope for the

placement of the suture as the height from the anal verge will be limited by retraction and exposure. This may lead to an unnecessarily low anastomosis, possibly requiring a handsewn coloanal anastomosis, leading to potentially worse bowel function. If access to place the purse-string is limited using direct vision and a proctoscope, it is recommended to place the purse-string under endoscopic guidance with pneumorectum (such as with the TAMIS platform) to hopefully reduce the risk of an unnecessarily low rectotomy and anastomosis.

## Special Considerations

Whilst most purse-strings will be placed in the “sweet spot” at about 5–6 cms proximal to the anal verge, there may be other times when it will need to be very low or much higher. With very low tumours requiring an intersphincteric dissection, it may not be possible to perform a purse-string until the dissection has been initiated. In this situation, the Lone Star retractor can be utilized to gain exposure and the dissection commence in the mid-anal canal extending into the intersphincteric space. Once this has released the tension on rectal tube, it may then be possible to perform a purse-string. If a purse-string has been placed prior to beginning the dissection, for these very low tumours, it may be helpful to place a further purse-string or at least figure of eight on

the distal rectum once the dissection has *released the tension* on the tissue with dissection in the intersphincteric plane.

When the purse-string is higher than the sweet spot, it may become difficult to reach by surgeon's hand to secure the knot. In this case, it will become necessary to tighten and secure the purse-string and tie it endoscopically. This can be quite challenging, especially for surgeons not familiar with intracorporeal knot tying. An endoscopic knot pusher can be employed. Alternatively, the formation of preformed loop can facilitate the tightening of the purse-string. This can be readily made with the loop 12–15 cms from the needle. The “tail” should only be 3 cm long to make it easier for the surgeon to finish off the tie.

Once tied, the ends of the purse-string suture are often used for retraction during the initial rectotomy and dissection. The utility of holding the tied purse-string ends can be improved by placing multiple knots (15–20). This then creates a “handle” for the surgeon to manipulate and improve tissue tension and retraction when performing the next step of the operation, the rectotomy.

The rectotomy should proceed once the surgeon is confident that the lumen of the rectum has been completely occluded by the creation and tying of the perfect purse-string. This can be tested by using a grasper or suction device, probing centrally once the pneumorectum has been initiated. If the purse-string is tight and complete without the formation of a “rose petal”, the surgeon may then lavage the rectum with a cytotoxic solution and proceed with the rectotomy and dissection with confidence. If at any stage the purse-string should fail during the dissection, either through technical failure, inadvertent cutting of suture or excessive pressure on the specimen, the surgeon needs to have appropriate skills to rescue the situation. This again may involve placement of further purse-string or figure eight suture endoscopically. Other possible solutions include using an ENDOLOOP® Ligature (Ethicon, Somerville, NJ, USA) around the distal divided rectum followed by copious lavage or bringing the specimen down to the anal canal and suturing under direct vision.

## The Distal Purse-String

For the majority of patients undergoing a restorative procedure, a circular-stapled anastomosis will be utilized. Unlike the double-stapled technique, which closes the distal rectum, by definition the taTME technique will have an open distal rectal stump. This will then require placement of a further purse-string which is secured to the central spike of the circular stapler. Although this will be also addressed in the chapter on anastomotic technique, it is again another time where the perineal surgeon needs to pay close attention to the formation of the purse-string. This is more commonly achieved using a handheld proctoscope under direct vision, but occasionally this needs to be performed endoscopically if the rectotomy has been at a higher level. An 0-Prolene or equivalent heavy-gauge monofilament suture is also used for the distal purse-string, again starting at the 3 o'clock position. The suture is placed from the lumen through the rectal wall and continued in an over and over fashion. It may be useful to use a “boomerang” suture technique going from outside the rectal wall into the lumen. A “boomerang” suture is where the needle is held by the needle holder oriented back towards the surgeon's hand. This will ensure a full-thickness bite of tissue and subsequent complete doughnut upon completion of the stapled anastomosis. Focus, or *flow*, is again needed when tying this distal purse-string around the central spike of the circular stapler. Of course, the third time a purse-string is required in this operation is for the proximal colonic conduit for placement of the stapler anvil.

Every step of the operation is equally important. Each subsequent step can only proceed depending on the success of the preceding step. The formation of a perfect purse-string in the operation of taTME lays the foundation for a good-quality TME and helps assure a negative distal resection margin. It is important for the surgeon to appreciate the importance of the purse-string and to give all attention – breathe, relax, have that special Zen moment and *slow down* – to be sure to achieve your goal of achieving the perfect purse-string.



# An Overview of Operative Steps and Surgical Technique

# 27

F. Borja de Lacy, María Clara Arroyave,  
and Antonio M. Lacy

## Preoperative Preparation

Preoperative evaluation by an enterostomal therapist, a trained nurse or a surgeon is highly recommended for demarcation of a potential stoma site to avoid postoperative ostomy-related complications. Mechanical bowel preparation plus oral antibiotics should be administered the day before surgery; intravenous antibiotic prophylaxis against aerobic and anaerobic bacteria should be administered 1 h prior to skin incision, as clinical evidence supports its use to reduce surgical site infections [1].

To avoid deep venous thrombosis and pulmonary thromboembolism, sequential compression socks are recommended from the induction of general anaesthesia and in the postoperative period until patient mobilization is fully achieved. During the anaesthetic period, a deep pharmacologic muscle paralysis is induced to facilitate rec-

tal distension and pneumoperitoneum. A urinary catheter must be placed. The rectum is irrigated thoroughly with both saline and cytotoxic solutions such as povidone-iodine to remove any faecal residue that may disturb the transanal vision or which may lead to postoperative infection.

For the transanal team, a regular laparoscopic instrumental set and a laparoscopic unit are required. If available, the authors recommend the use of a 3D scope with a flexible tip and a continuous insufflator with smoke evacuation as better depth perception, proper hand-eye coordination and a steady pneumorectum field are achieved. For the abdominal team, another regular laparoscopic instrumental set and a complete laparoscopy unit are needed.

## One Versus Two Teams

TaTME can be performed consecutively (one-team approach) or simultaneously (two-team approach). The latter is recommended for the following reasons: possibility to perform traction and countertraction, visualization of the surgical plane from two points of view and shorter operative time. The collaboration between the two teams is a valuable feature of this technique. If only one team is available, it is advisable to start in the abdominal field and stop the dissection just before opening the peritoneal reflection and then proceed with the

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transanal dissection. This sequence avoids the appearance of retroperitoneum, which makes the abdominal dissection harder due to distortion of the retroperitoneal space. Single-team taTME is described in further detail in a chapter dedicated to this topic.

Only case reports and small series have been published about pure natural orifice transluminal endoscopic surgery (NOTES) taTME, and in the meanwhile, it should only be performed as part of an investigation protocol in highly specialized centres [2–4].

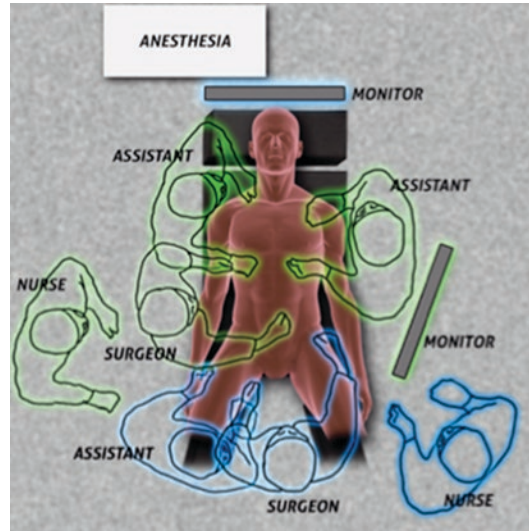
## Positioning the Patient

The patient is placed in the modified lithotomy (Lloyd-Davies) position with adjustable boot stirrups that allow easy mobilization of the legs without compromising the sterile field. The surgical table must allow steep Trendelenburg inclination when required during the procedure (Fig. 27.1).

Placement of the team for the transanal phase is with the principal surgeon and assistant between the patient's legs and scrub nurse in the left lower side of the patient. For the abdominal phase, the team is placed with the principal surgeon, second assistant and scrub nurse in the right upper side and first assistant in the left upper side of the patient (Fig. 27.2).



**Fig. 27.1** Patient positioned in Lloyd-Davies and steep Trendelenburg



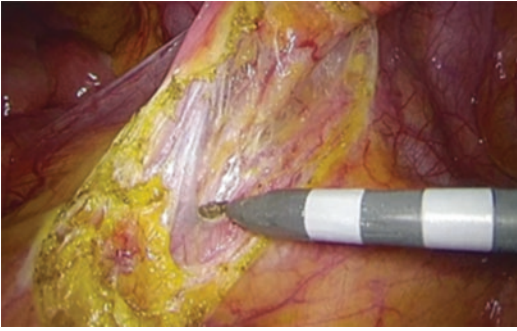
**Fig. 27.2** Abdominal and transanal teams working together

## Abdominal Approach

The abdominal approach will be described separately in a chapter dedicated to this topic. Briefly, the transabdominal phase is initiated with 12–15 mmHg pneumoperitoneum and insertion of a 10 mm trocar above the umbilicus for the optical instrument. Under direct vision, a 12 mm trocar is inserted in the right iliac fossa, and two 5 mm ports are placed in the right and left flanks. The distal sigmoid is cross-clamped to allow construction of transanal purse-string suture without colon distension. Once the purse string is made and confirmed to be airtight, both teams work synchronically.

A medial to lateral approach is advised for cancer resections. The inferior mesenteric artery is divided 1 cm away from its origin at the aorta, following the oncological principles of mesenteric resection with lymph nodes alongside the vascular arcade (Fig. 27.3). After exposure of the retroperitoneal plane and identification of the left ureter, artery ligation is performed with a vessel-sealing device, a vascular stapler or using regular clips. The inferior mesenteric vein is visualized more caudally and laterally at the level of the inferior border of the pancreas and is ligated in the same fashion. Descending colon dissection is





**Fig. 27.3** Division of the inferior mesenteric artery at its origin

continued by releasing the fusion plane along Toldt's fascia and mobilizing the splenic flexure when needed.

Following the posterior avascular plane, rectal and mesorectal dissection is started. Circumferential dissection preserving Denonvilliers' fascia in males is continued until rendezvous with the transanal team.

## Transanal Approach

### Restorative Total Mesorectal Excision

#### Mid and Low Tumours to 2 cm Above the Dentate Line

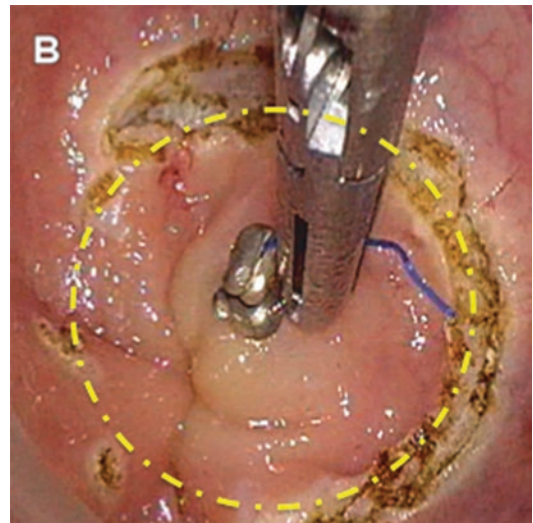
After digital rectal examination and proper irrigation, an anal retractor (Lonestar, Cooper Surgical, Trumbull, CT, USA) is placed to efface the anus and thereby visualize the dentate line, followed by the introduction of the endoscopic platform, which is fixed to the perineal skin. At our centre, a TAMIS Port (GelPOINT Path Transanal Access Platform, Applied Medical, Rancho Santa Margarita, CA, USA) is used. Three cannulas are inserted into the TAMIS Port's gel cap, forming an inverted triangle, with the camera lens positioned at 6 o'clock. In case of a challenging posterior mesorectal dissection, the camera can be switched to one of the TAMIS Port's lateral cannulas. The abdominal team then clamps the distal sigmoid, the pneumorectum is initiated, and the transanal phase is started with

standard laparoscopic instruments. As stated previously, occlusion of the distal sigmoid by the abdominal team is essential to minimize colonic distention.

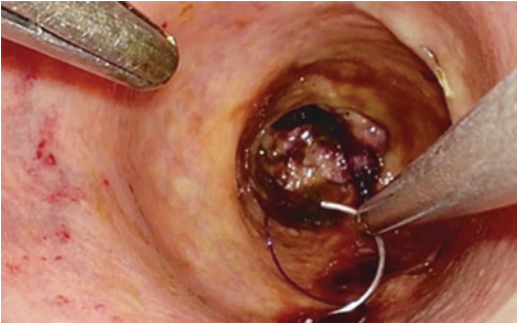
With taTME, locating the distal edge of the tumour is relatively easy as it is done under direct vision. Distally, a purse-string suture with a 26 mm needle and a size 0 polydioxanone suture (with small equal bites at the same rectal level) is made, to close the rectal lumen (Fig. 27.4). Performing a tight purse-string suture prevents translocation of liquid stool and tumour cells, reducing the risk of pelvic abscesses and locoregional recurrences.

After washing out the closed rectal stump with povidone-iodine solution, the rectotomy is started just distal to the purse string. It is performed with monopolar cautery in a circumferential fashion (Fig. 27.5). The insufflation pressure should be set to  $\leq 15$  mmHg.

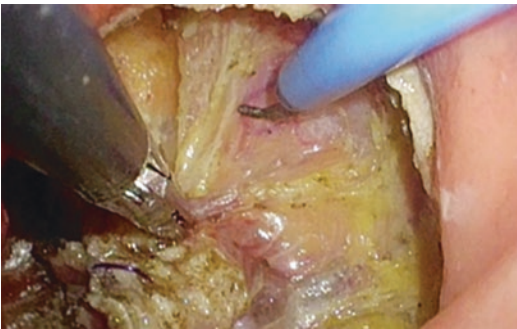
By preference, the rectotomy commences along the anterior surface of the rectum, at the 12 o'clock position, and is then extended in counter-clockwise fashion. A full-thickness dissection is carried out until reaching the avascular "angel's hair" plane, sharply following the TME plane described by Heald [5]. TaTME is not an easy operation, and finding the correct plane may be challenging. However, once correctly identified,



**Fig. 27.4** Purse-string suture to close the rectal lumen



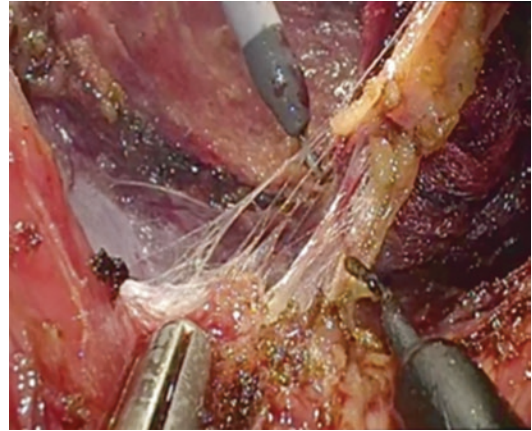
**Fig. 27.5** Circumferential rectotomy



**Fig. 27.6** Down-to-up transanal dissection following the “holy plane”

this technique is characterized by a more natural dissection inside Denonvilliers’ and Waldeyer’s fascias due to pneumatic dissection and direct line of site visualization of, in particular, the anterior plane in males. This leads to a potential decrease of intraoperative complications, such as haemorrhage, and autonomic nerve injury – while maintaining the integrity of the mesorectal envelope.

The cephalad dissection is performed with electrocautery and bipolar forceps (Fig. 27.6). A circumferential dissection is preferred by the authors, with a focus on maintaining the envelope’s symmetry – since this medium (i.e. insufflation using the TAMIS apparatus) enables pneumatic-assisted dissection to help localize the mesorectum’s innermost correct plane. The TME plane is always easier to find at the anterior and posterior aspects; that is why connecting them might help if any doubt arises while dissecting the lateral boundaries. Compared to abdominal TME, the risk of damaging the pelvic sidewall



**Fig. 27.7** “Rendezvous”, meaning that both planes are connected and both teams work together

may be increased. The improved visualization by laparoscopic instruments may help the surgeon in identifying the correct lateral planes and avoiding dissecting laterally to the endopelvic fascia, in false planes that become exposed due to pneumatic dissection during taTME.

Once at the level of the peritoneal reflection, the anterior surface is divided, and the peritoneal cavity is entered. This is made lastly to maintain a stable pneumoperitoneum. This rendezvous point in dissection allows both teams to work synchronously until the rectosigmoid is released from its attachment in toto (Fig. 27.7).

### **Low Tumours, Distally to 2–3 cm Above the Dentate Line**

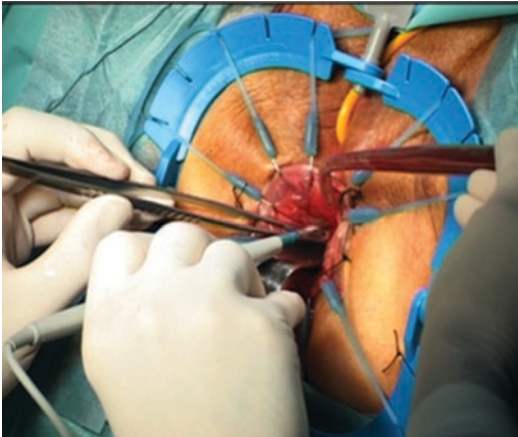
The length of the TAMIS Port’s access channel measures approximately 4.5 cm. When the tumour is so low that its insertion is limited, an intersphincteric dissection with conventional open instruments may be necessary (Fig. 27.8). Rullier et al. [6] suggested that a partial intersphincteric resection might be necessary for juxta-anal tumours (<1 cm from the anal ring) and a total intersphincteric resection in intra-anal tumours which do not encroach on the external anal sphincter. One must remember that a partial or a total intersphincteric resection is technically feasible, but with an increased risk of postoperative poor bowel function.

Once there is enough tissue to close the lumen, the purse-string suture is placed to prevent spillage of liquid stool and cancer cells. It is possible to insert the endoscopic platform afterwards, and the transanal dissection with laparoscopic instruments can be continued as explained above.

### Abdominoperineal Excision

This topic is discussed more completely in a dedicated chapter. Here, a brief description is provided. In cases of tumours invading the external sphincter or when there is a poor bowel function expectation after surgery, an abdominoperineal excision is required. The abdominal approach

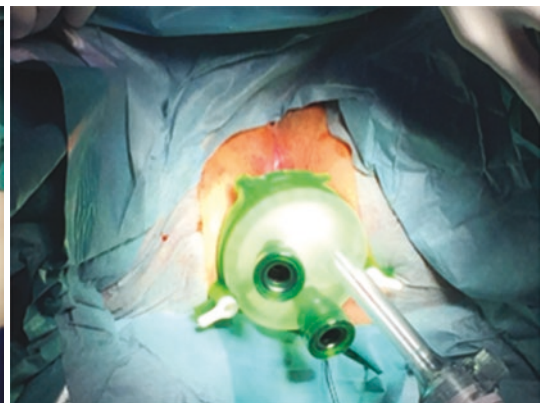
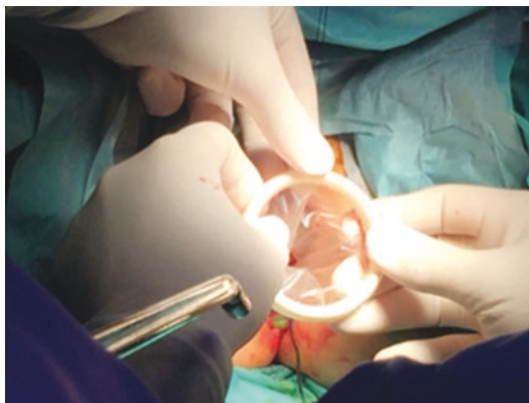
should be performed in a standardized laparoscopic fashion. Once in the perineal phase, the anus is closed with a purse-string monofilament suture, and the threads might serve as traction. A circular perianal skin incision is made, approximately 2 cm from the closed anus. The incision is performed along the loose areolar tissue and the anobulbar or anovulvar raphe. Posteriorly, the incision extends to distal extent of the coccyx. Laterally, it is dividing the fat from both ischio-rectal fossae. With taTME for APR, the dissection should start posteriorly to find the presacral plane. Once located, our preference is to utilize the TAMIS technique with the GelPOINT Mini Advanced Access Platform (Applied Medical, Rancho Santa Margarita, CA, USA). Three canulas should be placed in an inverted triangle position, and transanal dissection should be continued as described above (Fig. 27.9).



**Fig. 27.8** Intersphincteric dissection with conventional open instruments

### Partial Mesorectal Excision

The surgical community has embraced taTME mostly based on its benefits when dissecting mid and low rectal tumours. However, at our centre, taTME is also performed for higher lesions because with appropriate experience, these patients may benefit from shorter operative times and lower conversion rates. In those higher tumours in the upper rectum, it has been proven that, although total mesorectal excision is not necessary, mesorectal residual cancer cells can



**Fig. 27.9** Transanal field during abdominoperineal excision



be found 5 cm below the level of the tumour [7]. This is the reason why, when a partial mesorectal excision (PME) is intended, the transection of the mesorectum should be at least 5 cm below the distal edge of the tumour. After occluding the rectal lumen with the purse string, both the rectum and mesorectum are transected perpendicularly until reaching the proper TME plane. There is an increased risk of bleeding while dissecting inside the mesorectum, which can be limited using sealing devices, although this could lead to increased procedure costs. Partial mesorectal excision with the taTME technique is very challenging and is only recommended for experienced surgeons.

### Critical Anatomic Landmarks

Through the transanal approach, the pelvic anatomy is novel even for very experienced colorectal surgeons. TaTME carries potential pitfalls, which could lead to a more difficult dissection or to intra- or postoperative complications. Therefore, early recognition of errors is crucial, to be able to return to the correct plane [8–10].

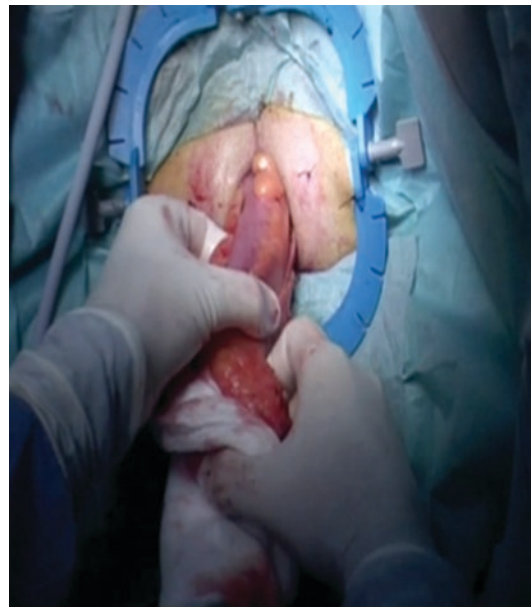
Anteriorly, the prostate and seminal vesicles in males can be injured [10]. In females, the vagina can be opened, although this complication can be safely repaired intraoperatively. The most feared complication is urethral injury, typically when an excessive lateral dissection is made, followed by prostate mobilization and putting the urethra at risk during the initial anterior dissection [10, 11]. *If in doubt, the endoscopic platform should be removed, and the surgeon should palpate the prostate and urinary catheter.*

Posteriorly, dissection must respect Waldeyer's fascia, avoiding the presacral venous plexus (Fig. 27.12) and minimizing the confusion about correct versus incorrect plane of dissection when coming along lateral and anterior sides. Moreover, when dissecting laterally, neurovascular bundles must be respected, to decrease the risk of impaired bowel, urinary and sexual function.

### Specimen Extraction

There exist two ways to extract the specimen: transanally or transabdominally. The latter has the advantage of maintaining the integrity of the abdominal wall and reducing the risk of surgical site infections and incisional hernias while improving postoperative pain and cosmesis. The size of the tumour, the mesorectum, the length of the colon and the width of the pelvis are conditions that must be considered before a transanal extraction is performed (Fig. 27.10). To avoid excessive vascular tension during the specimen retrieval, splenic flexure mobilization is recommended. In case of a circular, endoluminal stapled (double purse string) anastomosis, the purse string on the opened distal rectal cuff should be performed before transanal extraction to prevent any mucosal retraction that may make this step more difficult post-extraction. For a hand-sewn coloanal anastomosis, the transanal extraction must be performed after placing the four cardinal stitches.

Transabdominal specimen extraction is a better option than transanal extraction when facing large tumours and bulky mesenteric envelopes –



**Fig. 27.10** Transanal specimen extraction

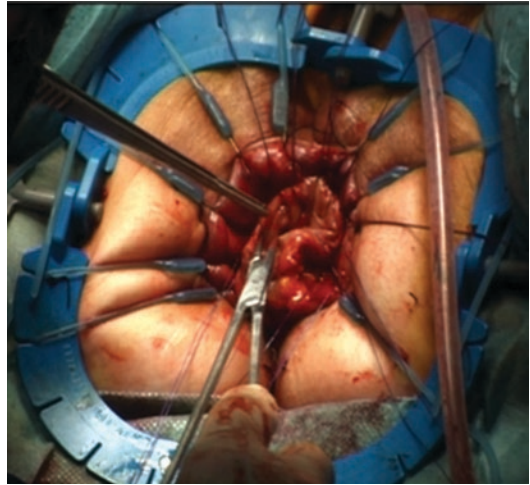
especially in the setting of android narrow pelvises, where both the specimen and the sphincter complex are at risk of damage. A Pfannenstiel incision can be carried out in most cases, with the incision length tailored to the specimen size. The wound should be protected to prevent wound infections and cancer cell implantation. Regardless of which modality is selected for specimen extraction, an intracorporeal division of the proximal mesocolon and colon is compulsory so as not to shear the marginal artery during extraction.

## Anastomosis

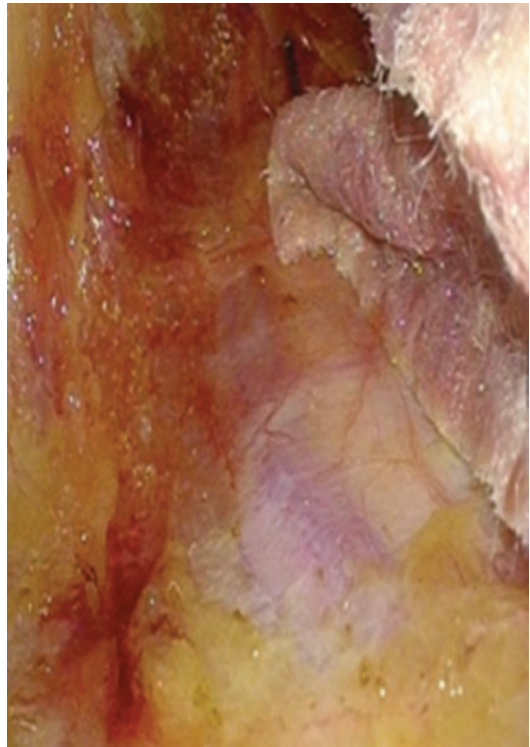
Although there is a need for standardization of the procedure, the anatomy of every patient is heterogeneous. For this reason, the surgeon should be familiar with the different anastomotic techniques, including end-to-end, side-to-end or colonic J pouch and stapled versus handsewn.

When a stapled anastomosis is attempted, we favour the single-stapled double-purse-string one. The anvil is inserted into the proximal colon, either to perform a side-to-end or an end-to-end anastomosis. A second purse string, usually with a monofilament size 0 polypropylene suture, is placed in the opened distal cuff, through the access channel of the endoscopic platform. This purse string may be performed by hand after the removal of the endoscopic platform in mid and low rectal tumours. Suturing by hand can be extremely challenging in cases of higher tumours (i.e. longer rectal cuffs), so performance with the transanal platform and laparoscopic instruments is highly recommended. This rectal cuff purse string is then tied to the anvil, and the stapler is connected. This can be performed with a variety of staplers, including an endoluminal circular stapler or, alternatively, a hemorrhoidal stapler. The latter has a longer spike (measuring 13.5 cm) making it easier to mate with the arm of the stapler for ultralow taTME anastomoses. Such staplers tend to provide wider doughnuts and robust staple lines. However, its larger diameter (33 mm) may sometimes represent a handicap, depending on patient anatomy. In either case, with low anas-

tomoses, the open rectal cuff can be handsewn (Figs. 27.11 and 27.12). Anastomotic techniques are discussed in more detail in a separate chapter.



**Fig. 27.11** Handsewn colorectal anastomosis



**Fig. 27.12** Presacral dissection, venous plexus vessel can be seen



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# Strategies for Ultralow-Lying Rectal Cancer

# 28

Sam Atallah and Eric Rullier

## Introduction

While taTME has in general been a useful modality for managing rectal cancer, its greatest appeal remains toward the management of ultra-distal rectal tumors that are extremely difficult to clear from the abdominal approach without adjunctive, perineal techniques. Such techniques include those that preserve at least a portion of the sphincter complex, as well as those that sacrifice the anorectal complex altogether. Due to the technical complexity of sphincter preservation for ultralow-lying tumors, the vast majority of such clinical cases were historically managed with abdominoperineal resection, subjecting patients to significant morbidity and to life with a permanent stoma.

As technical expertise advanced, paradigms shift, and surgeons explored options to permit sphincter preservation for low-lying rectal cancer with the intent for cure. It was the refinement of the technique for intersphincteric resection coupled with neoadjuvant therapy that made sphincter preservation for low rectal cancers an eligible

surgical option, with the singular exception being those lesions which invade the external sphincter mechanism. It is possible to combine perineal techniques with taTME, but this requires subtle yet important modifications. In this chapter, the strategies for radical resection for ultralow-lying rectal tumors using the taTME technique are outlined.

## The Development of ISR for Rectal Cancer and a Farewell to the 2 cm Rule

Prior to the introduction of sphincter preservation techniques, the only oncologic surgical option for ultralow-lying, advanced-stage rectal cancer was the Miles' Operation (aka, abdominoperineal resection, APR); developed in 1908 and named after William Ernest Miles (1869–1947) [1]. The operation could be complete with one or even two teams [2] as is the case for the current approach to taTME. For most of the twentieth century, it was not that the technical ability to perform ultralow, sphincter-preserving surgery did not exist but rather that such techniques were not applied to surgical management of cancer. Interestingly, the techniques were developed as early as 1888 by Hochenegg [3, 4], and the so-called pull-through was quite commonly employed during the 1950s and 1960s, but this was performed principally in the pediatric population [5].

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With the advent of modern instrumentation, such as endoluminal surgical staplers developed by Mark Mitchell Ravitch in 1972 [6–8], and with important, new approaches to restorative proctocolectomy introduced by Sir Alan Parks at St. Mark's Hospital (London, UK) in the late 1970s [9], the concept of total removal of the ultralow rectum with maintenance of a functional sphincter mechanism became quite achievable. While at the time such radical techniques were only applied toward removing the at-risk rectum and colon for benign pathology (especially ulcerative colitis) and, subsequently, for premalignant conditions such as familial adenomatous polyposis syndrome [10, 11], the challenge of removal of the rectum for low rectal cancer remained – since cure was difficult and local failure rates were quite high. Thus, for this subset of tumors, surgical treatment was historically radical, with complete removal of the anorectum by APR.

During the 1980s, RJ Heald introduced surgeons to the importance of proper embryonic-based resection [12, 13]. Meanwhile, neoadjuvant therapy for local control together with the unique perineal techniques proposed by G. Marks was combined to, for the first time, provide patients with a curative-intent resection for ultralow-lying, advanced-stage rectal cancer [14–16]. This technique is commonly referred to as the “TATA” (transanal abdominal transanal) operation and is a well-known, important prequel to the modern-day taTME operation – as it is essentially the first description of a “down-to-up,” sphincter-preserving technique for curative, rectal cancer surgery. Interestingly, TATA predated TAMIS [17] and the first report of taTME in a human [18] and the melding of TAMIS and taTME [19–23] by almost a quarter century.

It was during the 1990s and early to mid-2000s that the true maximal distal limits of radical rectal resection and reconstruction were finally achieved with acceptable oncologic outcomes [24–29]. By recognizing that a part or all of the internal sphincter muscle could be sacrificed (especially with tumor downstaging), intersphincteric resection (ISR) for extremely low-lying lesions became a feasible option, obvi-

ating the need for a permanent stoma for many patients. Increasingly, a rethink of the 5 cm minimum distal margin requirement shifted the new “safe margin” to just 2 cm [30]. This was partly based on the earlier work of Golligher and subsequently others investigators who demonstrated tumor spread to be rarely distal to the tumor's caudal extent [31–33]. Meanwhile, increasing data suggested that *any* grossly negative margin was acceptable [34] and a renewed focus on assuring circumferential margin clearance in conjunction with resection quality (i.e., TME grade) was paramount to all else [35, 36].

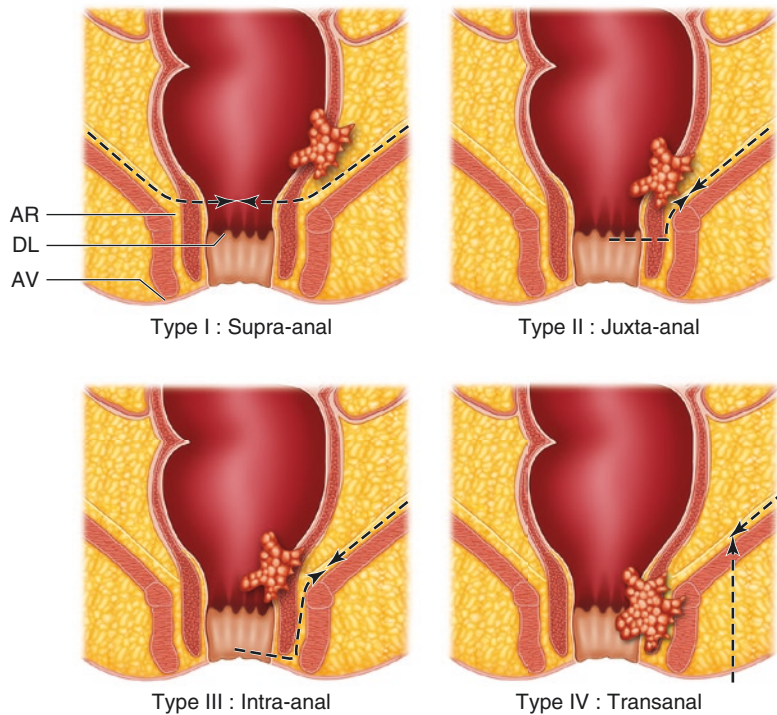
In 2005, Rullier et al. (Bordeaux, France) reported the results of 92 patients with invasive carcinoma localized to the distal rectum ( $\leq 4.5$  cm from the anal verge) who underwent curative radical resection with ISR [37]. With an 89% R0 resection rate, 2% local recurrence rate, and a 5-year overall survival rate of 81%, it was concluded that the technique of ISR permits curative intent radical resection and sphincter preservation without oncologic compromise, and therefore rectal tumor distance from the anal verge should “no longer [be] a limit for sphincter-saving resection.” This put an official end to the 2 cm rule, *without* oncologic compromise, thus creating a new and important axiom in rectal cancer surgery. Namely, candidacy for sphincter preservation for patients with ultralow-lying rectal cancer *depends not on the tumor's distal extent but rather the lateral extent* (specifically, the presence or absence of external sphincter invasion).

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## A Standardized Classification System for Low Rectal Cancers

The relationship of low-lying rectal tumors with respect to the anal sphincter complex can be defined in a standardized fashion and is based upon the *Rullier Classification System* for distal rectal cancer [38] (Fig. 28.1). There are essentially four types of ultra-distal rectal cancer which can be defined in relation to the anorectal ring and levator plate muscles. The four types are as follows:

**Fig. 28.1** A standardized classification system for low rectal cancers. AR, Anorectal Ring; DL, Dentate Line; AV, Anal Verge



- Type I: Supra-anal, >1 cm from the anorectal ring  
 Type II: Juxta-anal, <1 cm from the anorectal ring  
 Type III: Intra-anal, with internal anal sphincter (IAS) invasion or encroachment  
 Type IV: Trans-anal, with invasion of tumor into the levator ani muscle or the external anal sphincter (EAS)

The suggested surgical options for these tumors are as follows:

- Type I: (Ultralow) anterior resection  
 Type II: Partial ISR  
 Type III: Total ISR  
 Type IV: Abdominoperineal resection (APR)

While taTME has been applied to Types I–IV, in this chapter, we examine the technical nuances of taTME for Type I, II, and III rectal cancers providing a practical approach to the management of these special problems in rectal cancer surgery. The technique described herein is with the utilization of the TAMIS platform; similar

modifications are possible with TEM but are not addressed. The special application of taTME for APR (such as for extirpation of Rullier Type IV tumors) is addressed in detail elsewhere.

### Standard Educational Programs for taTME

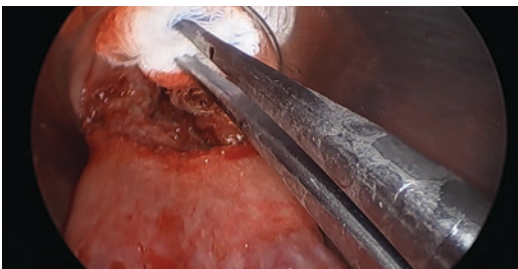
The introduction of taTME into surgical practice has required specific training programs to be implemented so as to assure the safe delivery of this new kind of surgery [39–46]. Even online learning modules and web-based, deferred live (d-LIVE) surgery are available for taTME education [47–49]. While most courses provide comprehensive education and practical instruction on this novel approach through cadaveric training session(s), such training primarily focuses on taTME as applied to distal rectal cancer, but not necessarily for extreme distal lesions (Rullier Types I–III). Ironically, *it is this group of ultralow rectal cancers which are best suited for the taTME approach*, and descriptions

of this technique are rarely reported in the literature [50, 51]. Here, the technical steps necessary to approach Type I–III rectal cancers are delineated.

## General Technical Principles

The general approach to taTME for Type I–III rectal cancer (Fig. 28.2) should follow a standardized protocol. While some authors have advocated a perineal-first approach [52, 53], it is prudent to perform an abdominopelvic oncologic survey, such as through diagnostic laparoscopy, as a first step prior to any radical oncologic surgery [54].

For mid-rectal cancers and the majority of low rectal cancers (excluding ultralow-lying Type I–III tumors), the taTME approach utilizing TAMIS and specifically the GelPOINT path transanal access platform (Applied Medical, Inc., Rancho Santa Margarita, CA, USA) requires the placement of the TAMIS access channel with one of two options utilized. *Option 1:* The access channel is seated in position with its inner lip secured just above the anorectal ring. Next, the rectum is sutured closed using a handheld, conventional needle driver, and *then* the gel cap is secured to the access channel. After establishing pneumatic insufflation, the dissection is carried out using standard taTME techniques. *Option 2:* The access channel is seated in position, and the gel cap is placed, pneumatic inflow is established, and lap-



**Fig. 28.2** A posterior ulcerated 3 cm rectal cancer is visible with direct exposure using a handheld anal retractor. The tumor's relationship to the dentate line is clearly visible. As the lesion is positioned within 1 cm of the anorectal junction, this is classified as a Type II rectal cancer and requires at least partial ISR for tumor clearance

aroscopic needle drivers and instruments are then used to conduct every step, including securing the purse string. Knot-tying can be accomplished via a knot pusher with handmade extracorporeal knot creation; however, the entire process of knot-tying is commonly done by hand using conventional hand-tying techniques. For these two common options, the use of a self-retaining anorectal retractor (most typically, the Lone Star Retractor System, Cooper Surgical, Inc.) is optional.

As a footnote, it should be realized that the general technique of TAMIS and the design of the GelPOINT access channel and apparatus were created with the objective of local excision of higher neoplasia, not low-lying lesions which are approachable with the Parks technique [55]. This “higher reach” was precisely the impetus behind the 1984 development of the TEM scope by G. Buess as well [56, 57]. Furthermore, the development of TEM, TEO, and TAMIS all predated the evolution of taTME, and, thus, *no transanal access platform has yet been designed specifically for the purpose of taTME.*

In the following sections, the detailed approach to taTME for resection of more complex, ultralow-lying rectal cancer is discussed. taTME for Type I tumors will be discussed separately from the approach to Type II/III rectal cancer, as there are important differences.

## taTME for Rullier Type I Tumors

The operative approach to taTME commences with the standardized approach with either single-team or two-team (Cecil) approach. When the transanal portion of the operation begins, the operator must be prepared to modify the initial steps, albeit only slightly for Type I tumors.

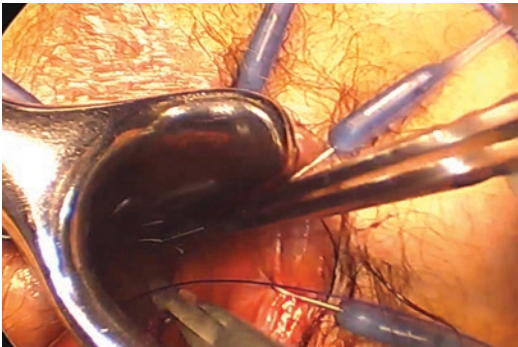
The first step is to perform a digital examination to localize the position of the primary tumor, and, in males, it is strongly recommended to digitally inspect the prostate gland [58]. An intraoperative review of MRI to assess pelvic geometry, the rectum, and the tumor in relation to the anorectal junction is particularly important as it provides a road map for the taTME surgeon [59].



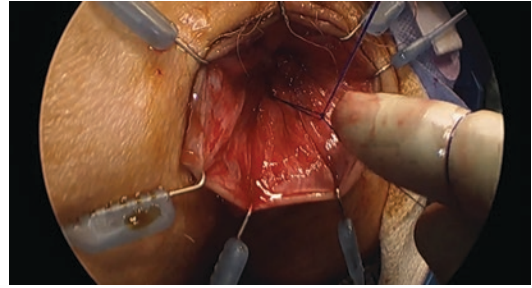
Next, the rectal irrigation is conducted, and a self-retaining retractor (such as the Lone Star Retractor or equivalent) is positioned which acts to efface the anal canal, and this ultimately facilitates access to the ultralow rectum. Such retractors are typically left in place throughout the taTME operation; it serves as a useful adjunct to facilitate construction of the anastomosis upon completion of the resection. This applies to anastomoses that are either handsewn or stapled; however, Rullier Type I–III anastomoses, when performed post-resection, are typically handsewn.

With a self-retaining retractor in place, and the patient positioned in modified lithotomy, for Type I rectal cancers, it is best to close the rectal lumen with the aid of a handheld anorectal retractor prior to the introduction of the access channel (Fig. 28.3). The reason for this is because, if the access channel is placed first, the inner portion of the sleeve will prevent visualization of the lesion, preventing lumen closure distal to the tumor. Thus, the placement of the purse string below the level of the tumor – *prior to access channel placement* – is an important first step for management of Type I lesions (Fig. 28.4).

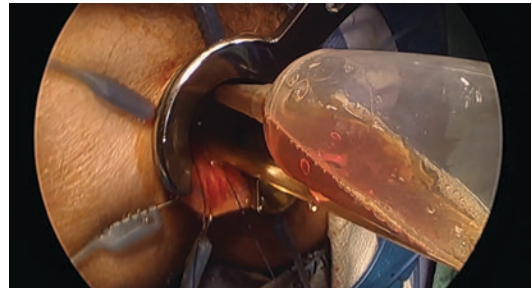
After application of the purse string, the anorectum is irrigated once more in preparation for



**Fig. 28.3** For Type I rectal cancers, a self-retaining (Lone Star) retractor can be positioned to efface the anal verge and improve exposure. Next, under direct vision, a handheld anorectal retractor (in this case, a small-size Hill-Ferguson) is used to access the anal canal so that a purse-string suture can be applied just distal to the lesion, which should be in direct view of the surgeon. This step is an important departure from standard taTME and is necessary to address low-lying, Type I tumors

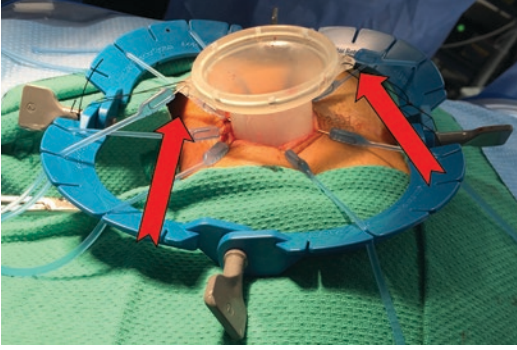


**Fig. 28.4** Upon completion of the purse string, usually utilizing 2–0 monofilament suture on an SH needle, the purse string is tightened and the lumen closed by knotting manually. Note the distal extent of the purse string. This is far too distal to apply and seat the TAMIS port's access channel, and so the dissection must proceed initially under direct vision until adequate operating space has been created



**Fig. 28.5** Bactericidal and tumoricidal agents can be used to irrigate the rectal lumen before, after, and even during purse-string placement. Here, the lumen is being irrigated just prior to securing (cinching down) the purse string. The retractor is in place to help expose the lumen and to perform an effective rinse. The next step will be to remove the handheld anal retractor and hand tie the purse string with multiple knots, assuring it is airtight and watertight prior to commencing dissection

transanal dissection (Fig. 28.5). This commences with dissection under direct vision, with full-thickness rectotomy. Here, care is given to create a circumferential incision that opens all quadrants, in a plane and level that is equidistant from the dentate line, so as to facilitate further steps of the anatomical taTME dissection. The transanal dissection then proceeds in a sequential manner cephalad, allowing enough distance to admit and position the TAMIS port's access channel. At this point, the access channel can be suspended with the aid of a self-retaining retractor (Fig. 28.6). Next, the gel cap is secured to the “suspended”



**Fig. 28.6** An important adaptation to access is illustrated. Ordinarily, the TAMIS access channel is delivered transanally where the inner lip is designed to seat above the anorectal ring. Since this would not allow for exposure of the ultra-distal rectum, a modification is performed whereby the hooks of the Lone Star retractor are used to anchor the channel (arrows). In such a setting, the channel is only partly inserted and is instead “suspended” by the Lone Star Retractor pegs. This significantly improves distal rectal access and allows taTME to be performed at a lower than normal distal starting point

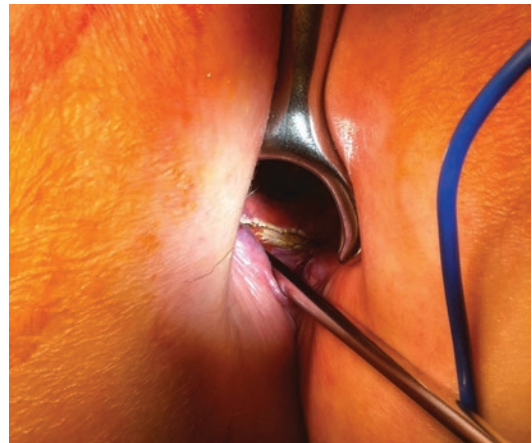
access channel, and the dissection proceeds along a plane (that does not require ISR) using the established techniques for taTME. The analog for this level of resection is the ultralow anterior resection. As the dissection advances, the access channel is further introduced until it is seated just above the anorectal ring, and the outer rim is then sutured to the dermis to prevent torque rotation during dissection. When the operation is completed, a handsewn anastomosis is commonly performed, although stapled anastomosis is possible, depending on the length of the rectal cuff.

### taTME for Rullier Type II and III Tumors

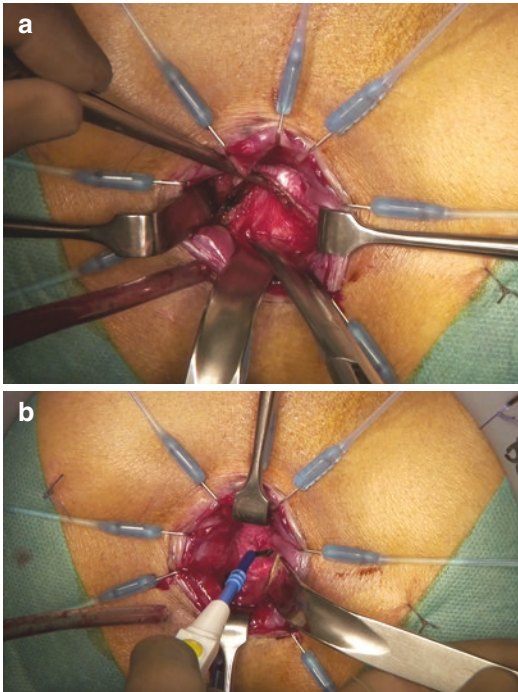
As for Type I tumors, the operative approach to taTME for Type II/III tumors commences with the standardized approach with either single-team or two-team approach. However, modifications for taTME for Type II lesions (which require a partial ISR) and Type III tumors (requiring a total ISR) are necessary. To perform this, a self-retracting retractor is positioned, thereby effacing the anorectum and providing exposure to the

anal canal. The dissection then proceeds so as to include the entire IAS within the scope of dissection or just a portion of the IAS depending on tumor level and the ability to obtain a negative distal margin. Sometimes the initiation of the ISR dissection can take place under direct vision, using a handheld anorectal retractor (Fig. 28.7). Classically, however, the dissection proceeds after placement of a self-retracting retractor, and the ISR technique for this utilizes sharp dissection (Fig. 28.8a, b). Recently, this component of the operation has been described with the robotic taTME approach [51], whereby the da Vinci Surgical System is “dry-docked” (without a TAMIS platform) to perform this dissection meticulously (Fig. 28.9a, b).

Upon completion of the ISR (partial or complete) (Fig. 28.10), the dissection proceeds cephalad under direct vision, until there is enough mobility of the distal anorectum to form an airtight purse string. This can then be completed manually or with the aid of a robotic surgical system (Fig. 28.11). Next, the access channel can be secured by suspending it onto the self-retracting



**Fig. 28.7** The distal-most extent of dissection has been initiated under direct vision. The white muscle fibers of the internal sphincter muscle can be seen, and the internal anal sphincter itself has been defined at its distal-most extent. In this case, a total ISR is being performed for a Type III rectal cancer. Whether for partial or total ISR, this portion of the operation is completed prior to purse-string application, thus underscoring an important technical difference in operative management between Type I and Type II/III rectal cancers

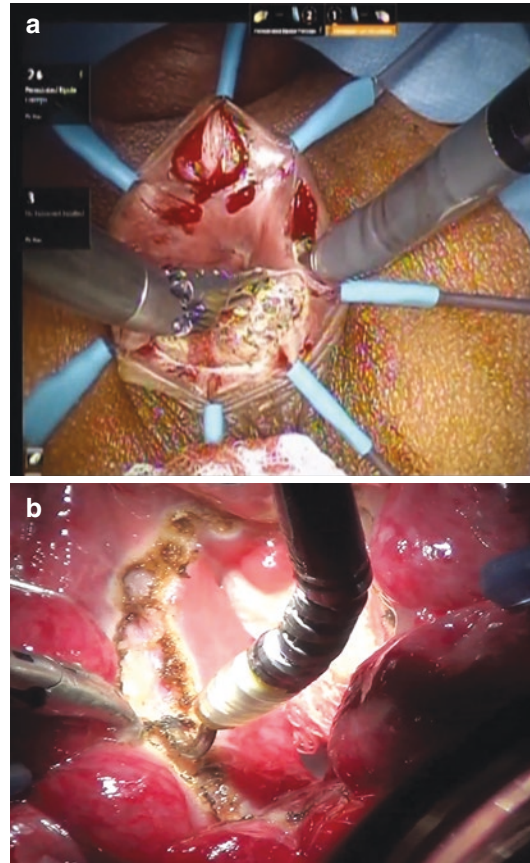


**Fig. 28.8** (a) With the aid of a Lone Star Retractor and manual retractors, sharp dissection along the ISR plane is performed with Metzenbaum scissors or (b) electrocautery; meticulous dissection is crucial

retractor as described previously. Finally, the TAMIS port's gel cap can be secured, pneumatic inflow is established, and taTME then proceeds along embryonic fusion planes until the point of rendezvous at the anterior peritoneal reflection (Fig. 28.12).

## Functional Outcomes

In the 1950s, J. Goligher and E. Hughes rightly concluded that anorectal function after reconstructive, sphincter-preserving surgery is directly related to rectal cuff length [60]. That is, the longer the rectal cuff (e.g., distance from the anorectum to the anastomotic line), the more likely defecatory function will be preserved. Therefore, even when perfectly executed, taTME for ultralow tumors (Types I–III) with reconstruction will invariably result in functional compromise. These effects can be further compounded by

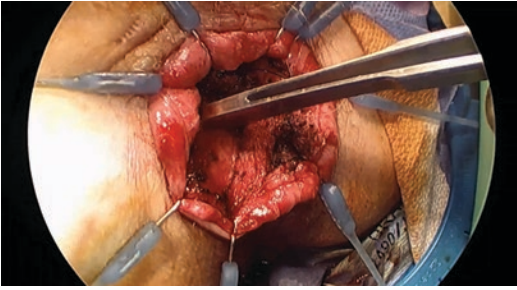


**Fig. 28.9** (a) ISR can be completed by “dry-docking” a da Vinci Surgical System with only a Lone Star or similar retractor to maintain exposure (Photograph (a) courtesy of J. Kuo). Both Xi and Si da Vinci systems have been used and (b) demonstrate the use of 5 mm instruments and the Si platform to perform a total ISR. Note that a gauze has been placed within the rectal lumen and the distal tumor is visible posteriorly

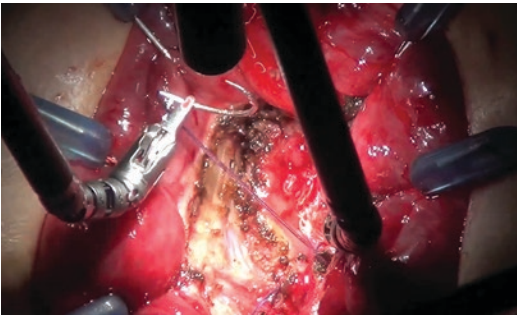
radiation-induced fibrosis, age, gender, local sepsis, and other factors.

Despite these challenges, the outcomes after ISR for rectal cancer have been quite acceptable. In a series of  $n = 101$  patients who had undergone ISR, although two-thirds reported having <3 bowel movements per day, about half reported having defecatory urgency, while one-quarter reported difficulty evacuating [61]. Although general data on taTME is now available through single-center series and registry data [62, 63], the functional outcomes specifically for the subset of patients who have undergone ISR in conjunction

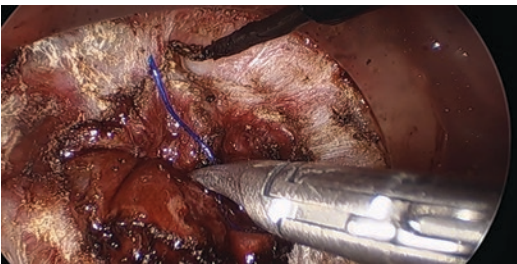




**Fig. 28.10** ISR dissection has been completed. It is after ISR dissection that the purse string is applied to the distal rectum. The next step will be suspension of the TAMIS access channel using the Lone Star Retractor and then initiation of the formal taTME dissection



**Fig. 28.11** For Type II and Type III tumors which require ISR, purse-string application is not the first step but is rather placed after initiation of the dissection. Most typically this is performed under direct vision, but recently some centers have demonstrated feasibility utilizing the da Vinci Surgical System. Here shown is the robotic Si da Vinci Surgical System which is being used to create the purse string after ISR



**Fig. 28.12** A partial ISR has been completed, the purse string applied under direct vision, and then the access channel suspended onto the Lone Star Retractor. The TAMIS apparatus is then connected to pneumatic inflow (in this case, using AirSeal®) after placement of the gel cap, and the dissection then proceeds cephalad to the level of the peritoneal reflection using standard taTME techniques, as shown

with taTME has not been well studied to date, and this remains an area of ongoing investigation. Urogenital function can also be altered but is attributable to the autonomic nerve-sparing dissection, TME quality, and local factors (especially radiation) [64–67] – and not directly related to the ISR dissection. However, it should be noted that the TME is more technically challenging in this setting.

## Oncologic Outcomes

Although the outcomes *specifically for* taTME using TAMIS and ISR for Type II and III rectal cancers have not been examined, inferences can be determined from series and systematic reviews which examine ISR for such lesions, with or without the use of advanced transanal platforms. These data appear quite encouraging and support the technique of ISR for ultralow rectal cancer [68–79]. In a 2017 study by Denost et al.,  $n = 100$  patients were randomized to either a transanal approach with ISR or standard laparoscopic anterior resection. With mean 60.2-month follow-up, the local recurrence rate was 3% for those undergoing ISR, while 5-year, disease-free survival was 72%. The study reported no statistically significant difference in either the rate of local recurrence or 5-year disease-free survival for the two groups. In a study by J Marks et al.,  $n = 106$  patients underwent TATA utilizing TEM. Outcomes were retrospectively compared to those undergoing anterior resection versus local excision via TEM for case-matched cohorts. For patients undergoing TATA for ultralow rectal cancer, the rate of local recurrence was 3%, and the overall survival measured 95% with mean follow-up of 37.9 months [16].

## Future Directions

The ability to address ultralow-lying tumors defines the most useful advantage of taTME. Thus, advanced training and curricula should focus on this important application. Next steps toward the mastery of this complex technique

include the creation of advanced courses for those who already have clinical taTME experience who wish to augment their skill set – with the objective of expanding fundamental knowledge to address ultralow-lying cancers. Specific training modules should focus on an understanding of the ultralow pelvic anatomy, particularly in males, and the ability to define the prostatic anatomy is paramount when performing ultralow taTME [39, 58, 80].

New protocols including the selective use of radiotherapy [81] which may include systemic chemotherapy as an alternative for (some) locally advanced tumors [82, 83] and total neoadjuvant therapy (TNT) [84–87] may improve oncologic clearance. Moreover, this may obviate the need for surgical resection altogether by achieving mural sterilization—which, at some expert centers, is managed with watch and wait protocols and observation alone [88–91].

As further experience and data are collected, understanding the oncologic outcomes for Type I, II, and III tumors with taTME (via the approaches described herein) should be carefully assessed. As a cautionary note, taTME does not result in a 100% rate of distal margin clearance. To date, in the largest single-center series on taTME ( $n = 186$ ) for mid and distal rectal cancer, the rate of distal margin positivity was 8.1% [92]. Given that this data is from the leading center of expertise on taTME, great care and careful understanding of the technical steps are necessary. This underscores the importance of careful assessment and surgeon education as these new techniques, including taTME with ISR, become globally implemented.

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# Critical Anatomical Landmarks in Transanal Total Mesorectal Excision (taTME)

# 29

Stephen W. Bell

## Introduction

The advancement of transanal endoscopic techniques to the surgical management of rectal neoplasia (particularly for taTME) has led to an improvement in surgical technique but also the development of different potential complications. The cornerstone to all surgical dissection is a clear understanding of and identification of anatomical landmarks and the correct and incorrect anatomical planes. The anatomy of the extraperitoneal rectum is familiar to most practicing colorectal surgeons; however this familiarity is predominantly from an abdominal approach, entering the pelvis from above. The anatomy when viewed from below (transanally) is the same; however the view is quite different, and this necessitates a relearning of the anatomy as it is seen from this direction. This chapter will focus on the applied surgical anatomy required for a transanal total mesorectal excision (taTME). It will not detail all anatomic structures of the anorectum, pelvis, and pelvic floor as this is assumed knowledge.

The description of the anatomy will follow the steps of the operation:

1. The anorectal junction and the pelvic floor.
2. Luminal anatomy of the rectum in relation to the purse string.
3. Rectal wall layers in relation to the rectotomy.
4. The extrafascial, subserosal, and sub-endopelvic fascia planes.
5. Variations in pelvic floor anatomy.
6. Maintaining the correct plane and signs of changing planes.
7. (a) Too deep posteriorly: presacral veins and the sacrum, (b) Too deep laterally: major vessels, the ureter, and the “pelvic tonsils”. (c) Too deep anteriorly: vagina, prostate, and urethra
8. Entering the peritoneal cavity.

## The Anorectal Junction and the Pelvic Floor

The three-dimensional anatomy at and around the anorectal junction can be complex and variable. There are multiple tissue planes, which vary depending on the height within the bowel and also radial position. The tissue planes are different anteriorly from posteriorly, and there are variations between women and men. The position of the tumor will determine the position of the purse string and subsequently the position of the rectotomy. It is important to have a clear idea of where the rectotomy will be and how this relates to the anal sphincters and pelvic floor. The circular

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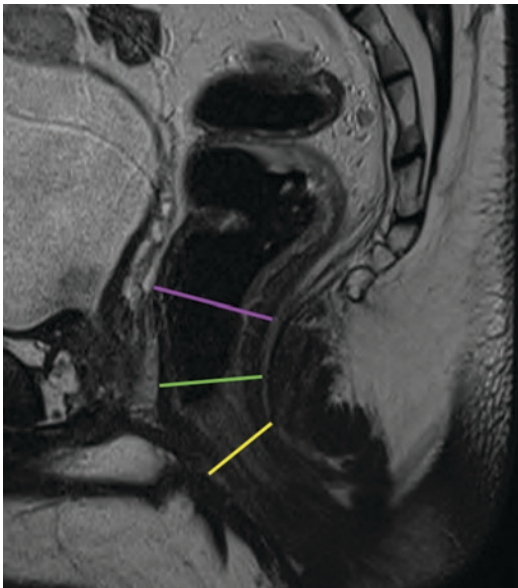


muscle coat of the rectum is in continuity with the internal anal sphincter. The external anal sphincter is in continuity with puborectalis and the pelvic floor muscles. The longitudinal muscle of the rectum continues rostrally in the intersphincteric plane, thinning significantly and fanning out in the lower anal canal to be relatively unrecognizable. When the rectotomy is positioned above the anorectal junction, the dissection usually falls straight on to the cranial side of the endopelvic fascia (posteriorly) in the correct plane for further dissection. When the dissection starts as a partial intersphincteric dissection in the mid-to-upper anal canal, this can often lead to dissection over puborectalis but rostral to the endopelvic fascia. In the common situation of the rectotomy being at the anorectal junction, it remains important to identify the endopelvic fascia and stay on the cranial side of it but not to dissect in the subserosal plane (see Fig. 29.1). There is often very little tissue between these two planes as there is usually

little or no mesorectum at this level. The serosa of the bowel is white and is seen “centrally” in the dissection. The endopelvic fascia is a fibrous structure overlying the skeletal muscle of the pelvic floor. If the dissection is under the endopelvic fascia, pink skeletal muscle is visible, and it contracts when in contact with diathermy.

### Luminal Anatomy of the Rectum in Relation to the Purse String

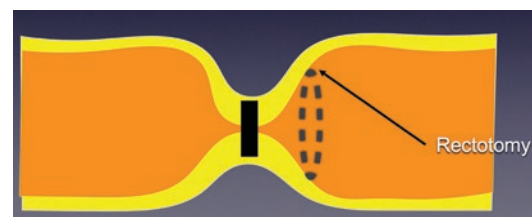
The art of the purse string has been addressed in detail in Chap. 26. As such this will not be dealt with in great detail here. It is important, however, to note that correct positioning of the purse string will lead to a symmetrical indrawing of the rectal wall, with the center of the purse string being centrally placed in the lumen of the bowel. This also distorts the anatomy of the rectal wall and the angle at which one must dissect to pass through the wall perpendicularly. It is necessary to angle outward from the lumen but not at 90 degrees to the lumen. The angle is a little more subtle than this, and depending on the exact position of the rectotomy and the laxity of the bowel wall, this could be as much as 45 degrees (see Fig. 29.2).



**Fig. 29.1** MRI scan of the anorectal junction demonstrating the change in angle between the anal canal and the lower rectum. The colored lines indicate potential sites of a rectotomy. The yellow line sits within the anal canal, when a partial intersphincteric dissection is undertaken. The green line sits at the anorectal junction, with the posterior aspect being at the level of the puborectalis muscle. The purple line is in the lower rectum above the pelvic floor

### Rectal Wall Layers in Relation to the Rectotomy

The rectal wall is composed of the mucosa, submucosa, and circular and longitudinal muscle layers, before encountering the mesorectum and



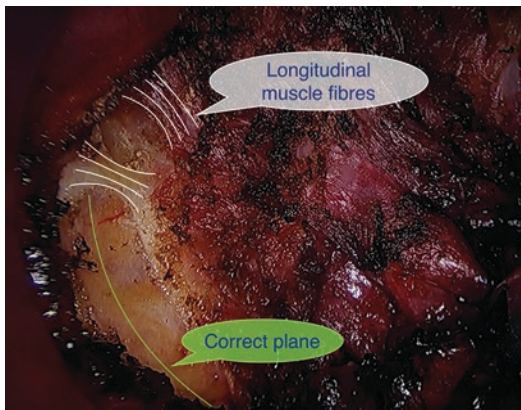
**Fig. 29.2** Diagram representing the effect of a purse-string suture on the rectal wall. The indrawing of the muscle layers changes the angle of dissection through the rectal wall when performing a rectotomy

the extrafascial plane of the mesorectum. It is common to divide each of these layers circumferentially before proceeding on to the next layer. As such, one would initially mark out with diathermy the planned incision on the mucosa and then divide the mucosa/submucosa and finally divide the muscle layers. The longitudinal fibers of the muscle layer are relatively easily visible as white fibers and can commonly be easily distinguished from the underlying fibro-fatty tissue (see Fig. 29.3). Once the muscle layer is com-

pletely divided circumferentially, the rectal wall is more mobile and often moves cranially under the force of the pneumopelvis. If this “release” has not been observed, then it may well be that the muscle layer has not been completely divided circumferentially.

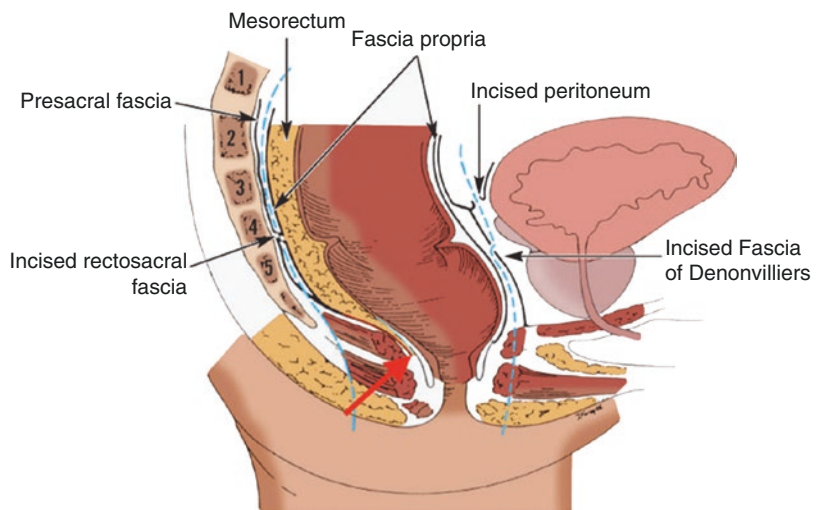
### The Extrafascial, Subserosal, and Sub-Endopelvic Fascia Planes

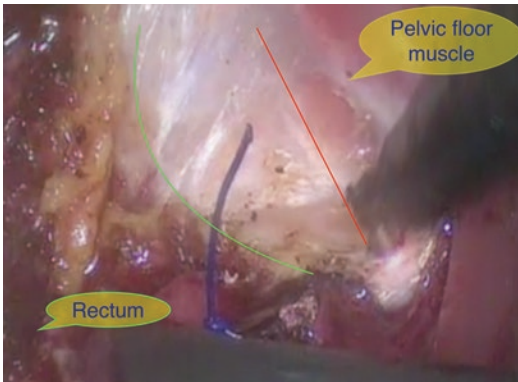
Identification of the extrafascial plane of the mesorectum (the “Holy Plane” as described by Bill Heald when dissecting from the abdomen into the pelvis) is one of the main key anatomical landmarks of the taTME operation. When dissecting from the abdomen into the pelvis, there is a broad mesorectum separating the extrafascial plane from the subserosal plane. As described above, the point at which one performs the rectotomy will determine where the extrafascial plane will be encountered when operating transanally. The mesorectum at this point is usually either very thin or nonexistent (see Fig. 29.4). As such there is very little tissue between the subserosal plane, the true extrafascial plane, and the plane under the endopelvic fascia. The rectotomy is most commonly 1–2 cm distal to the lower margin of the tumor. As such any dissection in the subserosal plane brings one closer to the tumor and therefore a threatened positive mar-



**Fig. 29.3** Operative photograph during rectotomy (with and without annotation). The cut edge of mucosa is seen on the left of the image. The extrafascial plane is seen in the left lower quadrant of the image, and the undivided longitudinal muscle fibers are seen in the left upper quadrant of the image. These muscle fibers are seen in live tissue as whiter than surrounding tissue

**Fig. 29.4** Lateral view drawing of extraperitoneal pelvis. The red arrow indicates the common point of the rectotomy. At this point there is little or no mesorectum, meaning there is little tissue differentiation between the subserosal and extrafascial planes





**Fig. 29.5** Dissection deep to the endopelvic fascia with exposed puborectalis muscle. The red line indicates an inviting loose areolar plane, being too deep. The green line indicates the correct line of dissection, allowing the endopelvic fascia to fall back onto the pelvic floor

gin. As has also been noted, once the rectotomy has been completed circumferentially, the rectal wall tends to be pushed cranially by the pneumoperitoneum. At this point it is important to assess the planes and not be drawn to the loose areolar tissue underlying the muscle layer. It is usually best to try to define the endopelvic fascia as the deep landmark and then proceed to dissect cranial to this. If the endopelvic fascia is lifted and dissection continues in a plane too deep, this will lead the dissection into vital anatomic structures (to be described below) (see Fig. 29.5). Exposing the pink skeletal muscle which will contract when contacted by diathermy is an important visual clue – along with recognition of the white fibrous tissue being retracted centrally, with a visible cut edge distally.

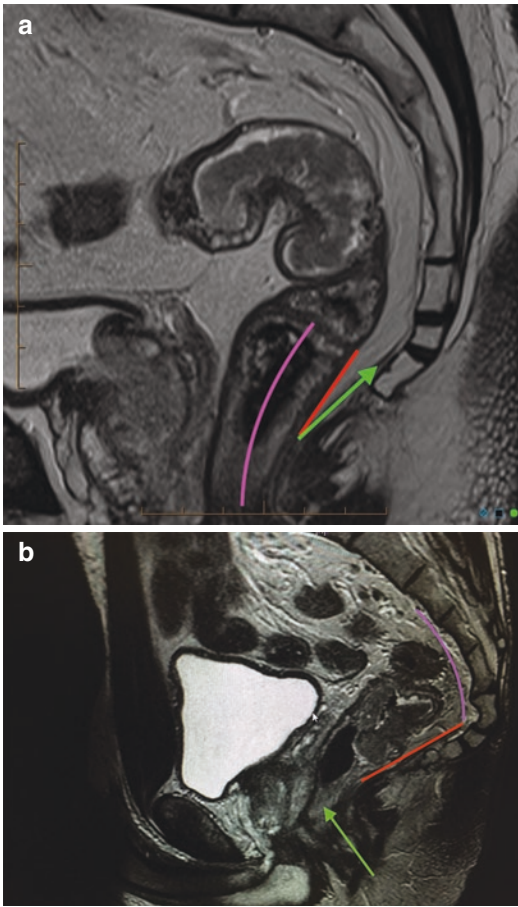
The anterior plane is usually *almost horizontal in a direct line with the view from the access channel, and it is most common that the dissecting instrument is horizontal when dissecting this plane*. If this instrument is angling upward, this may indicate dissection is too anterior. *In comparison, the posterior plane is varying degrees toward the vertical*, at times being up to 90 degrees from the angle of the access channel. When beginning the dissection along the pelvic floor posteriorly, the surgeon must be aware of this angle so as to avoid dissecting into the meso-

rectum or along the subserosal plane. Familiarity with the specific patient's MRI scan is important to plan this dissection and have an understanding of the expected changes in angles of dissection to stay in the correct plane.

## Variations in Pelvic Floor Anatomy

The direction of dissection is primarily determined by the visual cues encountered during the dissection; however there is a lot of additional information that is available on the patient's preoperative imaging (particularly MRI scan) that can offer a "road map" of what will be expected during the dissection. There is significant variability between patients as to the verticality of the pelvic floor and the angles between the anus, lower third of the rectum, and the mid-sacrum. When the surgeon is forewarned of such angles and can be prepared for changes in the direction of dissection, this will assist in avoiding drifting into a deeper plane and causing injury to structures such as the presacral veins and the pelvic autonomic nerves. Figs. 6a and 6b highlight this point, with the patient in Fig. 29.6a having a very vertical pelvic floor and very little angle between the direction of the anal canal and the lower and the mid-rectum, with the pelvic floor running in a similar direction to the rectal wall. The patient in Fig. 29.6b, however, demonstrates a significant change in direction of ~90 degrees between the anal canal and the lower rectum/pelvic floor. There is another significant change in direction of almost 90 degrees anterior to the lower sacrum. If the first angle is not appreciated, it could be possible to dissect into the subserosal plane, thus putting the tumor margin at risk. If the second angle is not appreciated, it would be possible to dissect into the presacral plane and cause significant bleeding. Albeit that one must pay particular attention to the visual cues during the surgery to keep the dissection in the correct plane, having an awareness of the patient's particular anatomy is also important to assist guidance of the dissection.





**Fig. 29.6** (a, b) Vertical pelvic floor (a) and horizontal pelvic floor (b) demonstrating significant variation between individual patients' lower pelvic anatomy

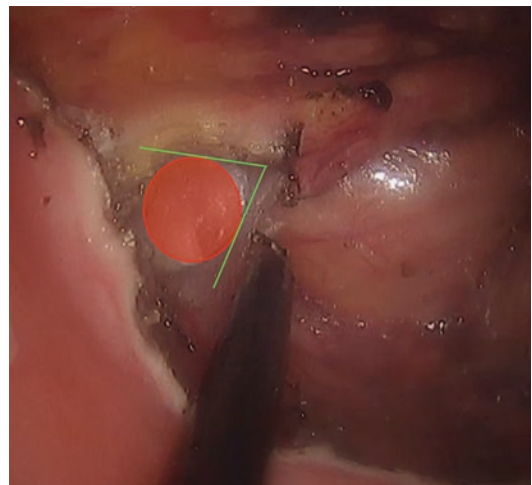
### Maintaining the Correct Plane and Signs of Changing Planes

The point during an operation when the extrafascial plane has been clearly defined circumferentially is often accompanied by some acceleration in dissection, particularly anteriorly. It remains important to stay in the correct plane, and some of the visual cues can confuse the surgeon leading to inappropriate dissection in a plane that is too deep. The correct plane is an areolar plane, but it must be recognized that this requires active dissection, as opposed to gentle pushing and “pneumodissection.” *The plane too deep is a very inviting loose areolar tissue that needs little dis-*

*section, and it is possible to dissect quickly over a moderate distance in this plane before realizing the error.*

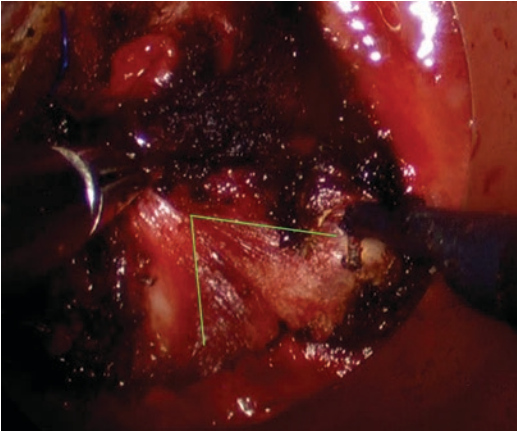
The pneumopelvis provides a very important clue when the dissection changes planes. When a fascial plane is incised, even only minimally, the gas dissects into the new plane and creates an “O” or “halo” (see Fig. 29.7). This is a very important sign to recognize and should cause the surgeon to assess the local anatomy and decide on the correct plane of dissection, either continuing in the original plane or dissecting into the deeper plane if this is believed to be appropriate. Most commonly when the dissection is proceeding in the correct plane, the appearance of an “O” or “halo” signals the surgeon to avoid the deeper plane and recorrect to the original plane.

Along with the “O” sign, triangles of tissue are often seen as a response to tissue retraction. When the rectum and mesorectum are retracted away from an area being dissected, the underlying tissues of the deeper plane are tented up. The apex of this tented tissue is the point of maximal

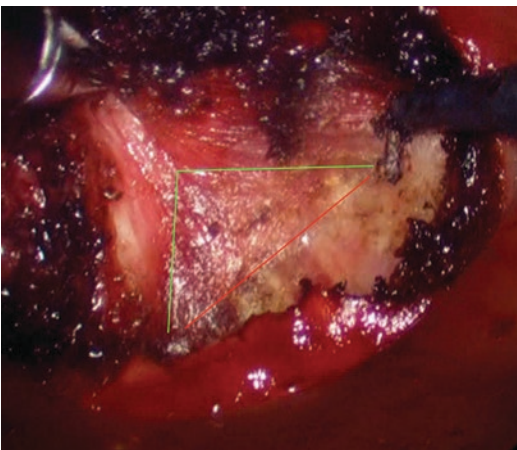


**Fig. 29.7** Incising a fascial layer under the pressure of the pneumopelvis creates an often sudden circular opening (an “O sign” or “halo sign”). This indicates the dissection has changed planes into a deeper plane. If the dissection was already in the correct plane, then the deeper, often more inviting plane should be avoided (red circle). Dissection should be returned to the top of the green triangle to maintain the original plane of dissection

tension from the retraction, and the tissue being lifted broadens out from this point. Figure 29.8 demonstrates this triangle appearance, and in this example the underlying fascial plane has been lifted because the dissection has been at the base of the triangle. The dissection should be at the apex of the triangle, allowing the tented tissues to fall away, as opposed to dissection in the deeper plane as seen in Fig. 29.9.



**Fig. 29.8** Retracting the rectum/mesorectum tents up the attached underlying tissues producing a triangle appearance. Dissection should be guided to the apex of the triangle not the base



**Fig. 29.9** Dissection has been in a plane too deep, at the base of the triangle (red line), thus lifting the endopelvic fascia and exposing the puborectalis muscle. The correct position for dissection is at the apex of the green triangle

### Too Deep Posteriorly: Presacral Veins and the Sacrum

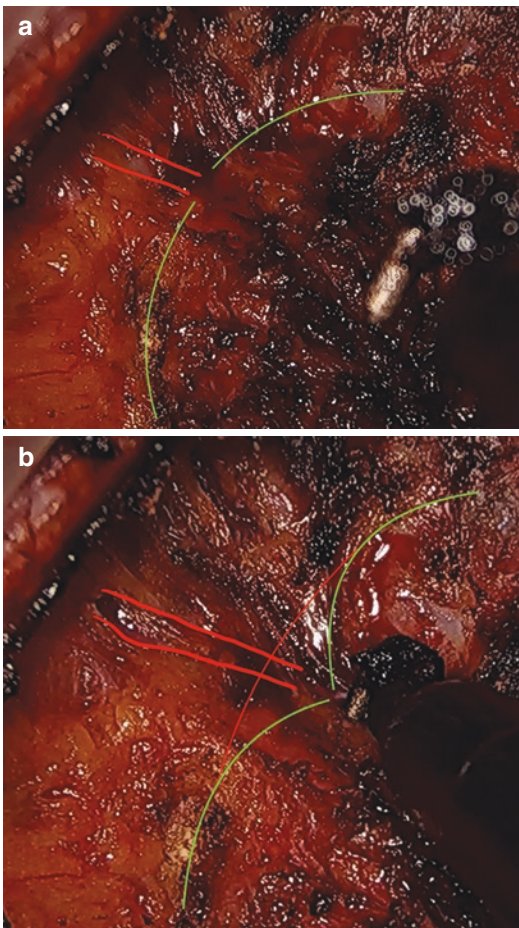
Immediately posterior to the deep layer of the fascia propria is a loose areolar plane with little adipose tissue that opens very easily. Posteriorly the contents of this space are the presacral veins. This is a venous plexus that results from anastomoses between the lateral and median sacral veins. These drain into the internal and common iliac veins and also communicate to the deeper veins within the sacrum via the sacral foramina. Injury to these veins can lead to profuse and potentially catastrophic bleeding as they are large veins. If the injury involves the region of the sacral foramina, the vein can retract into the foramen making hemostasis more difficult. As the posterior taTME dissection extends proximally, it is imperative that the surgeon anticipates the sacral curvature, executing an upward turn before colliding with the sacrum as it becomes in-line with the plane of dissection. Alternatively, this portion of the dissection (the proximal TME dissection) can be performed by the abdominal surgeon who likely has a better vantage point, in most instances.

### Too Deep Laterally: Major Vessels, the Ureter, and the “Pelvic Tonsils”

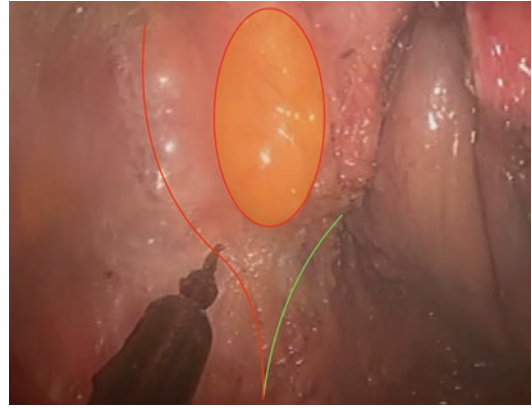
When dissecting laterally it is important to maintain the correct plane, and the tendency can be to dissect too deeply, particularly in the mid and upper pelvis. There is a fear of dissecting too medially, into the mesorectum and to breach the oncologic principles of a TME. This, along with the often inviting loose areolar plane deep to the extrafascial plane, can lead the surgeon to dissect more widely. There are numerous important anatomical structures in this space, with some loose supporting fatty tissue. The internal iliac artery and its branches, along with the accompanying veins, lie in this space, including the middle rectal artery. When the mesorectum and specimen are retracted medially, this draws up the underlying tissues, again creating a triangle. In this lateral position, this is not just fibro-fatty tissue



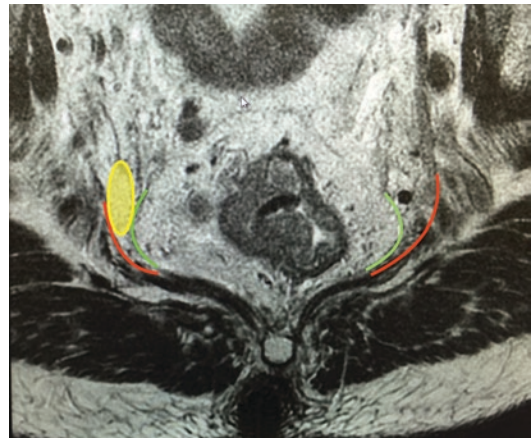
underlying but may also include the terminal branches of the internal iliac artery including the superior vesical artery and the obturator artery. These vessels normally run parallel to the plane of dissection but appear to be crossing the plane if they are retracted medially (see Fig. 29.10a, b). If dissection continues lateral to this fatty tissue, it will “hang down” and become shifted slightly medially to give the appearance of a tonsil (see Fig. 29.11). This has been coined the “pelvic tonsil” by Dr. Matthew Albert. The appearance of a tonsil should alert the surgeon to the fact that the dissection is too deep and the appropriate correction be made to the more medial plane. If this is not recognized, and the dissection is continued in



**Fig. 29.10** (a) Lateral pelvic side wall without traction, with a vessel lying flat. (b) Lateral pelvic side wall with traction on the rectum, tenting the side wall vessel into the apparent plane of dissection (red line). The green line indicates the correction that needs to be made to avoid injury to the vessel

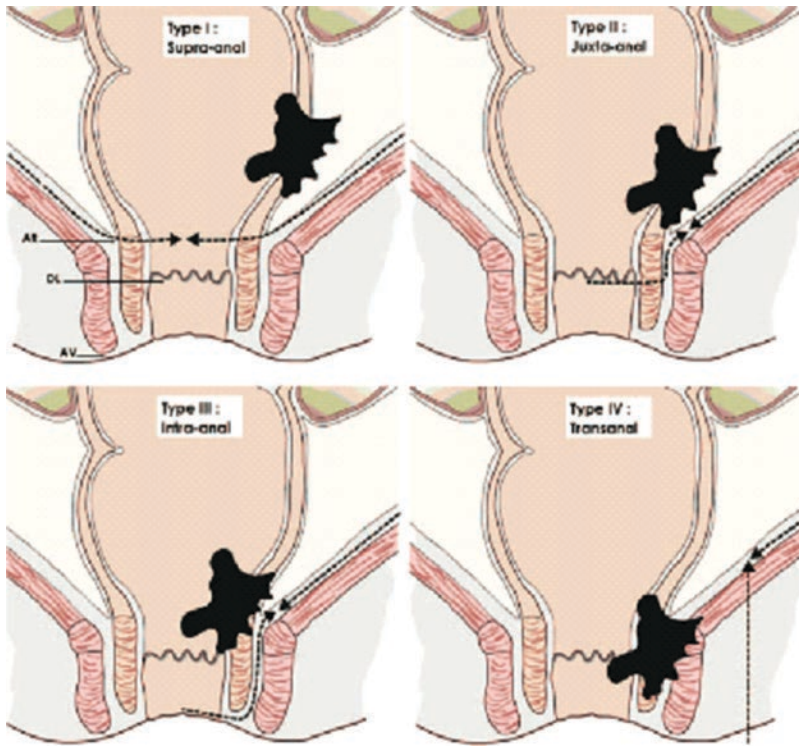


**Fig. 29.11** Operative photo of dissection on the right pelvic side wall with the specimen on the right of the photo. Dissection too far laterally exposes the fatty tissue, coined the “pelvic tonsil” (shown in yellow). Dissection deep to the tonsil (red line) will result in significant bleeding, whereas the green line indicates the appropriate correction into a more medial plane

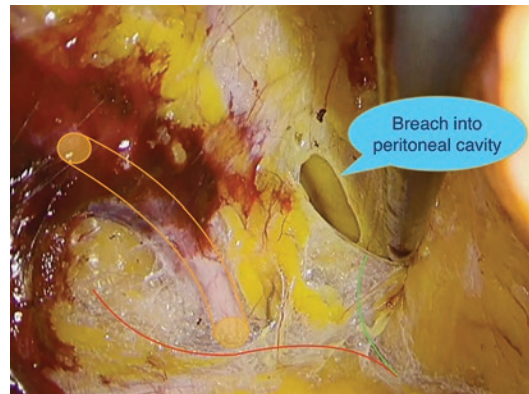


**Fig. 29.12** Pelvic MRI scans demonstrating the incorrect (red) and correct (green) planes of dissection on the lateral pelvic side wall. If dissection is too lateral, the pelvic tonsil (yellow) may appear, and dissection further in this plane could result in major vascular injury and significant bleeding

this deep plane, significant vessels will be encountered and possibly injured, leading to major bleeding and a loss if the surgical view and clear appreciation of the tissue planes. It is important to note that this tonsil does not appear when performing an abdominal dissection of the pelvis as the dissection passes directly over these tissues and they are not lifted. As such, this appreciation of the pelvic side wall anatomy is unique to the taTME operation (see Fig. 29.12).



Proximal to the pelvic tonsils in the antero-lateral quadrant are the ureters. These are usually defined more proximally when performing an abdominal dissection and are then followed caudally into the pelvis. This maneuver is not possible when dissecting from below; however if there are concerns during taTME dissection, then identifying the ureters abdominally should be completed. The ureters are often not seen during a taTME dissection but are only one plane deeper than the dissection. It should be recognized that the direction of dissection in the upper half of the pelvis is from a lateral position heading centrally and medially, as the specimen narrows toward the upper rectum. It is most common to breach the peritoneum and join the peritoneal cavity close to or in the midline anteriorly. Having defined the correct position, the division of the peritoneum can be taken further laterally. This will keep the dissection medial to the ureter



**Fig. 29.13** The position of the right ureter (yellow) at the point of breaching into the peritoneal cavity as seen from below. The red line indicates dissection too laterally putting the ureter at risk, whereas the more medial dissection along the green line is the correct plane

and should avoid the dissection drifting too far laterally (Fig. 29.13).

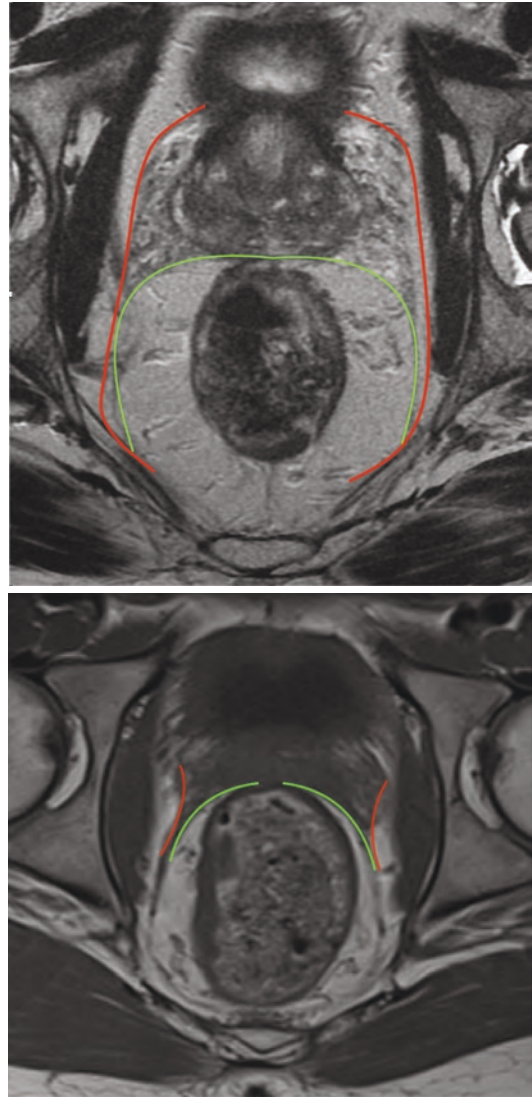


## Too Deep Anteriorly: Vagina, Prostate, and Urethra

The anterior dissection is distinctly different in a male and female patient. In the female the rectovaginal septum is often very clear, and the more anterior structures including the urethra are not in danger. This plane can be affected by tumor, radiotherapy, and previous surgery such as gynecological prolapse procedures. In the normal state, however, this plane is clear and often the easiest to define. The direction of dissection is quite “horizontal,” with the operating instruments passing horizontally and the surgeon’s hands at the same level as the access channel.

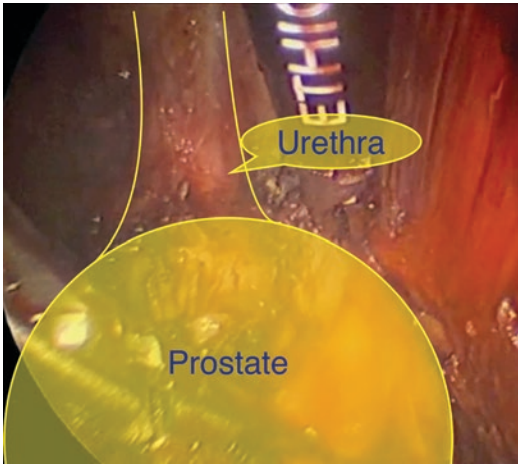
Anterior dissection in a male must be undertaken with some caution. One of the more publicized and feared complications of taTME is male urethral injury, and this can be prevented with a clear understanding of the anatomy and careful dissection and recognition of the anatomical landmarks. When the urethra has been exposed and at risk, the problem has usually occurred earlier in the dissection. Having placed a purse-string suture and performed a rectotomy, the rectum becomes mobile. Retraction posteriorly on this mobile rectum transmits posterior traction on the prostate while it is still attached. It is usually necessary to mobilize the prostate laterally to expose the urethra, and this occurs when dissection has been in a plane too deep around the distal rectum posteriorly and laterally and continued anteriorly and cranially. Figure 29.14 demonstrates the correct and incorrect planes that lead to lateral mobilization of the prostate. With posterior retraction and the weight of the rectum and prostate assisting, the urethra comes into view (Fig. 29.15). The dumbbell appearance of the rectum and attached prostate may be able to be seen. The urethra may also be visible as a longitudinal cord centrally. There is no plane to dissect here, and efforts to try to dissect this tissue will lead to urethral injury.

The clues that the prostate has been mobilized include:



**Fig. 29.14** MRI scans of the pelvis demonstrating the correct (green) plane of dissection around the mesorectum and the incorrect (red) deeper plane of dissection that leads to mobilization of the prostate along with the rectum. This deeper dissection drops the prostate posteriorly, exposing the urethra and placing it at risk of injury

1. The dumbbell appearance of the rectum and prostate fused together, both being posterior to the plane of dissection.
2. Visible muscle fibers on the anterolateral pelvic wall (there should be no muscle fibers anteriorly in a man).



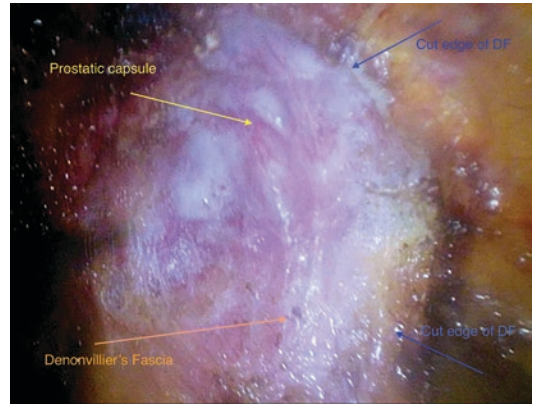
**Fig. 29.15** Operative images during taTME demonstrating inadvertent mobilization of the prostate, exposing the urethra as a midline cord

3. The longitudinal midline cord without a tissue plane.
4. The operating surgeon's hand being placed low with the instruments angling upward, indicating the dissection is too anterior.
5. Bleeding at the 10 and 2 o'clock position from the neurovascular bundle of Walsh, when this is distracted downward into the plane of dissection.

Denonvilliers' fascia can be clearly identified from below, and the dissection can pass anterior or posterior to this at the surgeon's discretion. The caudal end of Denonvilliers' fascia is not a distinct structure and so can be difficult to define at its distal most extent where it inserts onto the urogenital diaphragm. Once dissection has passed a short distance, the fascial tissue becomes clearer. At this point a decision can be made to dissect anteriorly with the capsule of the prostate gland on view, or posteriorly, lifting Denonvilliers' fascia and leaving it attached to the prostate (see Fig. 29.16).

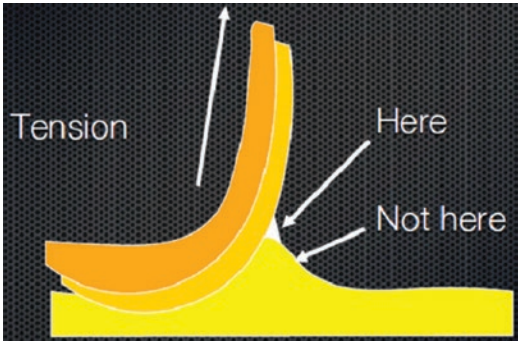
### Entering the Peritoneal Cavity

Identifying the peritoneal reflection is most clear when operating synchronously with both a transanal and an abdominal surgeon. With both views



**Fig. 29.16** taTME view of Denonvilliers' fascia being reflected posteriorly, with dissection passing between this and the prostatic capsule. The lower most extent of Denonvilliers' fascia is not a clear structure. As such, when it is identified, it may be necessary to actively incise to pass into the plane anteriorly

the dissection can be guided safely, and vital structures, including intraperitoneal organs such as the small bowel, can be easily avoided. When operating with a single team, there are a number of cues that the peritoneal reflection is being approached. When dissecting anteriorly, in both females and males, there is slightly more extra-peritoneal fat in the region of the peritoneal reflection compared to more distally. The tissues here are also more loosely attached. The pressure differential between the pneumopelvis and the pneumoperitoneum can lead to a "fluttering" of the tissues, both just before and just after incising the peritoneum. As the defect in the peritoneum enlarges, this fluttering diminishes and disappears as the two cavities merge and the pressures equalize. There may also be the impression of small bowel or other intraperitoneal organs moving subtly, seen through the thin peritoneum before division. This is an important sign to recognize so as to avoid inadvertent injury when incising the peritoneum. Laterally it is important to be aware of the position of the ureters and avoid dissecting too laterally, as described previously and shown in Fig. 29.13. It is often safer to breach the peritoneal reflection anteriorly and then continue division of the peritoneum toward the lateral structures to be certain that these are protected.



## Conclusion

The critical anatomical landmarks encountered when performing taTME have been described. It is important to recognize the variability between patients and also pathologies. The effect of radiotherapy and previous pelvic surgery can either alter the anatomy or make the appearance of the anatomy slightly different. Finding the correct plane and maintaining dissection in the correct plane are the cornerstones to performing taTME. Adherence to the principles described in this chapter and this textbook will help the surgeon maintain a safe dis-

section, achieving a high-quality total mesorectal excision and avoiding complications.

## Suggested Reading

- Atallah S, Albert M, Monson JR. Critical concepts and important anatomic landmarks encountered during transanal total mesorectal excision (taTME): toward the mastery of a new operation for rectal cancer surgery. *Tech Coloproctol*. 2016;20(7):483–94. <https://doi.org/10.1007/s10151-016-1475-x>. Epub 2016 May 17.
- Atallah S, Mabardy A, Volpato AP, Chin T, Sneider J, Monson JRT. Surgery beyond the visible light spectrum: theoretical and applied methods for localization of the male urethra during transanal total mesorectal excision. *Tech Coloproctol*. 2017;21(6):413–24. <https://doi.org/10.1007/s10151-017-1641-9>. Epub 2017 Jun 6.
- Bernardi MP, Bloemendaal AL, Albert M, Whiteford M, Stevenson AR, Hompes R. Transanal total mesorectal excision: dissection tips using ‘O’s and ‘triangles’. *Tech Coloproctol*. 2016;20(11):775–8. Epub 2016 Oct 1.
- Knol J, Chadi SA. Transanal total mesorectal excision: technical aspects of approaching the mesorectal plane from below. *Minim Invasive Ther Allied Technol*. 2016;25(5):257–70. <https://doi.org/10.1080/13645706.2016.1206572>.





# Urethral Injury: The New Challenge for taTME

# 30

Heather Carmichael and Patricia Sylla

## Introduction

Transanal total mesorectal excision (taTME) allows for improved exposure and visualization of the distal rectum, improving the quality of resection. However, there is a unique risk for iatrogenic injury to the male urethra due to the fact that the prostate can be inadvertently mobilized from below, but not from above, thus exposing the prostatic urethra [1]. This risk is particularly important given that, thus far, taTME has been a preferred approach in men, given its benefits in approaching a narrow or deep pelvis [2], as demonstrated by data from the international taTME registry (LOREC) showing that 1080 of 1594 cases (67.8%) were performed in male patients [3]. Moreover, urethral injury has not been documented in other sphincter-preserving methods of rectal resection (i.e., low anterior resection) and is only a rare complication in abdominoperineal resection, with reported incidence ranging between 1.5% and 3.0% [4]. Specific training to understand anatomic landmarks and risk factors and prevent wrong-plane surgery will be neces-

sary to avoid urethral injury as use of taTME becomes more widespread.

## Incidence of Urethral Injury

There is significant variability in the rates of urethral injury reported in current case series, and not all series reporting on the initial results of taTME have documented complications including the incidence of urethral injury. To date, rates of urethral injury have varied from 0% in several large case series to 6.7% in a study of  $n = 30$  male patients by Rouanet et al. [5]. A number of large case series have reported no incidences of urethral injury including a study of  $n = 140$  patients by de Lacy et al. [6], a study of  $n = 80$  patients by Velcamp Helbach et al. [7], and a study of  $n = 50$  patients by Chen et al. [8]. Three other series have reported single cases of urethral injury, with a rate of 2% in a study of  $n = 50$  patients by Burke et al. [9], a rate of 5% in a study of  $n = 20$  patients by Kang et al. [10], and a rate of 1% in a study of  $n = 100$  patients by Perdawood et al. [11]. Results from the voluntary international taTME registry noted that of  $n = 1594$  patients undergoing taTME, 12 patients were documented to have a urethral injury (0.8%), similar results to those found in the initial publication including  $n = 720$  patients [3, 12]. Of note, most series report rates that are not broken down by patient sex and therefore do not report the incidence in males

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alone [1]. This may partially explain the high rate of injury noted by Rouanet et al. in their series of male patients only. The rate of urethral injury in all patients and in male patients only for large case series ( $\geq 20$  patients) are reported in Table 30.1.

The true incidence of urethral injury may be underreported in these large case series. Indeed, as many as 18 urethral injuries have been reported to international registries, according to experts in the field, but only a handful have been documented in the surgical literature (Table 30.2) [13]. Anonymous feedback from  $n = 38$  surgeons who had undergone a formal cadaver-based taTME training in North America demonstrated that 20% of survey participants had experienced at least one urethral injury in their experience since course completion [14]. A recent international survey of urethral injury during taTME

reports a total of 34 urethral injuries that have occurred during taTME; only 18 of these had been reported to an international registry and only 5 were included in published series, indicating that underreporting of this complication is a serious concern (Sylla et al., manuscript submitted for publication) [15].

Furthermore, rates of injury may increase with uptake of taTME unless surgeons are specifically trained about the risk of male urethral injury and how to avoid it. Rates of inadvertent mobilization of the prostate (wrong-plane surgery) are high in reports on cadaveric trainees, despite the fact that most trainees have extensive rectal cancer experience. In one study, nearly 20% of cadaveric trainees unintentionally mobilized the prostate, and 2 out of 103 trainees accidentally completed a pelvic exenteration during taTME training [14]. However, there is evidence

**Table 30.1** Large series of taTME with rates of urethral injury when complications were noted

Author	Year	Country	N	% male	N urethral injury	% total injured	% male injured
de Lacy [33]	2013	Spain <sup>a</sup>	20	55.0	0	0.0	0.0
Rouanet [5]	2013	France	30	100.0	2	6.7	6.7
Velthuis [34]	2014	Netherlands <sup>b</sup>	25	72.0	N/A		
Atallah [35]	2014	USA <sup>c</sup>	20	70.0	0	0.0	0.0
Fernandez-Hevia [36]	2015	Spain <sup>a</sup>	37	64.9	0	0.0	0.0
Veltcamp Helbach [7]	2015	Netherlands <sup>b</sup>	80	60.0	0	0.0	0.0
Tuech [37]	2015	France <sup>d</sup>	56	73.2	0	0.0	0.0
Muratore [38]	2015	Italy	26	61.5	0	0.0	0.0
de Lacy [6]	2015	Spain <sup>a</sup>	140	63.6	0	0.0	0.0
Perdawood [39]	2015	Denmark <sup>c</sup>	25	76.0	0	0.0	0.0
Buchs [40]	2015	UK <sup>f</sup>	20	70.0	0	0.0	0.0
Chen [8]	2015	Taiwan	50	76.0	0	0.0	0.0
de'Angelis [41]	2015	France	32	65.6	0	0.0	0.0
Rink [42]	2015	Germany	24	75.0	0	0.0	0.0
Serra-Aracil [43]	2016	Spain	32	75.0	N/A		
Burke [9]	2016	USA <sup>c</sup>	50	60.0	1	2.0	3.3
Rasulov [44]	2016	Russia	22	50.0	0	0.0	0.0
Buchs [45]	2016	UK <sup>f</sup>	40	80.0	0	0.0	0.0
Kang [10]	2016	China	20	60.0	1	5.0	8.3
Lelong [46]	2016	France <sup>d</sup>	34	67.6	N/A		
Perdawood [11]	2016	Denmark <sup>c</sup>	100	72.0	1	1.0	1.4
Maykel [17]	2017	USA	40	60.0	0	0.0	0.0
Marks [47]	2017	USA	373	68.9	0	0.0	0.0
Caycedo-Marulanda [48]	2017	Canada	27	51.9	0	0.0	0.0
de Lacy [49]	2017	Spain <sup>a</sup>	186	63.4	N/A		
Penna [12] (registry)	2016	N/A	720	67.9	5	0.7	1.0

<sup>a-f</sup>Indicate prospective cohorts with likely patient overlap

**Table 30.2** Descriptions of urethral injury during taTME reported in the surgical literature

	Series	Tumor and patient characteristics	Type and timing of injury	Management and morbidity	Timing relative to surgeon experience
1	Rouanet [5]	Bulky anterior rectal tumor	Unspecified	Noted intraoperatively, suture repair with TEO, no long-term morbidity	Beginning of experience
2	Rouanet [5]	Concurrent T4 prostatic carcinoma	Unspecified	Noted intraoperatively, suture repair with TEO, no long-term morbidity	Unspecified
3	Burke [9]	Low, anterior rectal tumor (<3 cm from anal verge)	Injury to posterior wall of preprostatic urethra that occurred during mobilization of rectum from prostate	Noted intraoperatively, managed nonoperatively, no long-term morbidity	Middle of experience
4	Kang [10]	Large, circumferential tumor 5 cm from anal verge in a patient with benign prostatic hypertrophy	Prostatic and urethral injury accompanied by massive hemorrhage after dissection too far anteriorly	Conversion to laparoscopic assistance	Beginning of experience
5	Perdawood [11]	Advanced low rectal cancer, treated with neoadjuvant chemoradiation	Unspecified	Managed nonoperatively, no long-term morbidity	Unspecified

that this risk can be mitigated by training specific to urethral injury – the same group found that the rate of prostate mobilization could be decreased with additional training about landmarks and how urethral injuries occur, decreasing substantially from 20% to 3.3% after specific training on urethral injury and anatomic landmarks was provided [14].

Urethral injuries, when they do occur, can have exceedingly debilitating effects on urinary and even sexual function. Of the 34 injuries documented by Sylla et al., 32 (94.1%) were identified intraoperatively [15]. Of these, 12 were converted to a transabdominal approach or unplanned APR or Hartmann’s procedure (37.5%). Of 34 injuries, 9 patients (26.4%) went on to develop complications from the repair including stricture ( $n = 4$ ), rectourethral fistula ( $n = 3$ ), urethral dehiscence ( $n = 1$ ), or urethra-perineal fistula ( $n = 1$ ). These patients with complications experienced a 30% rate of failed urethral repair requiring permanent cystostomy. Sexual function was assessed in 22 patients, with 13 (59%) noting erectile dysfunction.

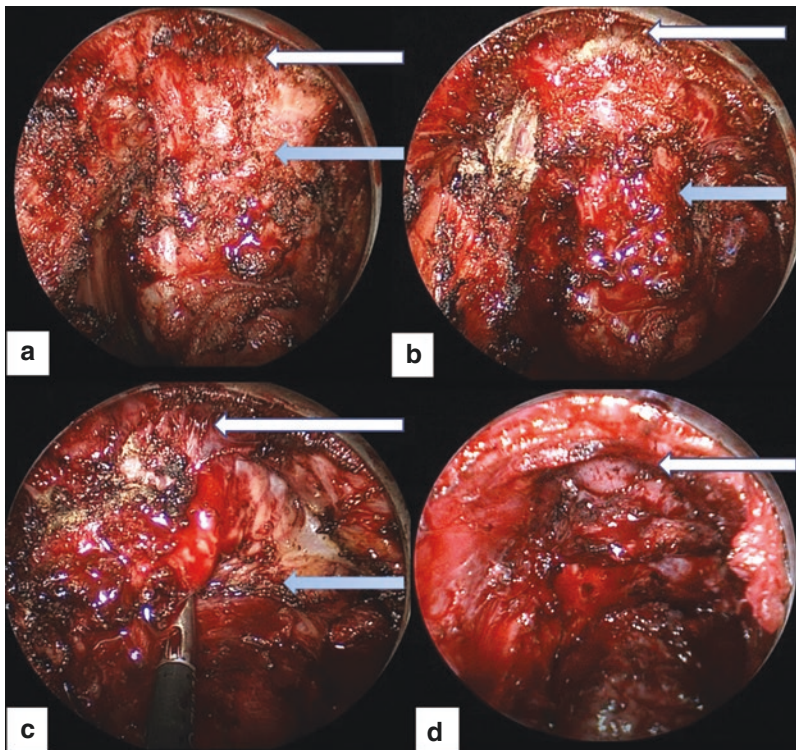
## Understanding the Anatomic Landmarks

Understanding the critical anatomic landmarks is crucial to avoid wrong-plane surgery in taTME and therefore prevent urethral injury [1, 9, 16, 17]. Atallah et al. have highlighted the importance of three key anatomic aspects that should be recognized by the taTME surgeon [16]. The first is the paired neurovascular bundles of Walsh which are located laterally between the rectum and the prostate (at the 10 and 2 o’clock positions during taTME dissection) and each include two 3–4 mm paired arterial vessels [18]. The dissection in taTME should always be posterior (superficial) to these structures as well as the rectoprostatic (Denonvilliers’) fascia [16, 19]. Secondly, the surgeon should recognize the smooth, spherical, and symmetric shape of the inferior lobe of the prostate, which is normally a pale yellow in color [1, 16]. Unfortunately, rectoprostatic plane identification can be severely complicated by dense postradiation fibrosis, prostate enlargement, or plane distortion from

bulky T4 anterior rectal tumors. Finally, the surgeon should be able to recognize the cylindrical shape of the prostatic urethra in case the wrong plane of dissection is entered [13, 16].

Another important anatomic landmark is the rectourethral muscle (RUM), and understanding the relationship between this muscle, the anterior rectal wall, the posterior prostate, and other muscles of the pelvic floor is vital, although underappreciated until recently (Sylla et al., manuscript submitted for publication) [15]. The RUM is a dense band of smooth muscle fibers that extends from the muscular propria of the rectum anteriorly to the external urethral sphincter. The anatomic significance of the RUM has been described

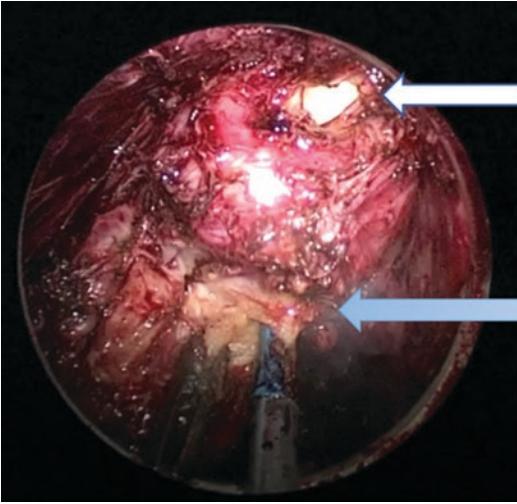
extensively in the urologic literature on radical perineal prostatectomy [20, 21]. During taTME for low rectal tumors (within 5–6 cm of the anal verge), the RUM must be divided in order to access the plane between the anterior rectum and posterior surface of the prostate. The RUM must be divided close to the rectum, as division of this muscle too far anteriorly leads to dissection along the inferior lobe of the prostate in an anterior direction, toward the membranous urethra [22]. If unaware of these anatomic relationships, the surgeon may mistake the RUM for residual muscularis propria of the rectum and direct dissection too far anteriorly in an attempt to avoid rectal perforation (Figs. 30.1 and 30.2).



**Fig. 30.1** Near-miss injury to the prostatic urethra during taTME. Transanal TME dissection initiated shortly after complete intersphincteric resection was completed for a very low rectal tumor. The anatomically correct plane between the anterior mesorectum and posterior prostate was difficult to identify. Fibers of the rectourethral muscle are seen coursing anteriorly between the anterior rectal wall and the apex of the prostate and should have been divided close to the anterior rectal wall (a, blue arrow). Instead, and out of concern of erring too close to the anterior rectal wall and risking anterior rectal wall perforation, the dissection is inadvertently carried out too anteriorly (a, white arrow). Dissection was erroneous and briefly

extended close the apex of the prostate (b, white arrow), but the surgeon quickly realized the error and corrected the dissection back to the correct plane, more inferiorly and closer to the anterior rectal wall (b, blue arrow). The prostate is finally visualized along its left lateral aspect (area between the white and blue arrows, c), and dissection proceeds along the correct anatomic plane, close to the anterior rectal wall (c, blue arrow). After taTME is completed, the prostatic urethra is visualized along with a small defect in the surrounding urethral sphincter muscle (d, white arrow). Fortunately in this near-miss case, the urethra remains intact, as confirmed with intraoperative cystoscopy under transanal endoscopic perineal visualization





**Fig. 30.2** Partial urethral transection during taTME. Anterior taTME dissection proceeds along the incorrect plane, too far superiorly and erroneously heading toward the apex of the prostate. The posterior aspect of the prostatic urethra is transected; the injury is recognized by visualization of the Foley catheter (white arrow). The dissection is redirected inferiorly and closer to the anterior rectal wall (blue arrow). The correct plane of dissection between the rectum and prostate is finally identified and dissected, after which the urethral injury is primarily repaired with sutures

In the series of 34 urethral injuries collected by Sylla et al., the most common technical error leading to urethral injury was a failure to identify the correct anterior TME plane or landmarks as noted above, usually because of distortion of tissue planes (Sylla et al., manuscript submitted for publication) [15]. Many surgeons noted continuing the dissection in the posterior and lateral planes in the face of a difficult anterior dissection can lead to a “drooping” of the prostate into the rectum and actually increases the risk of carrying the dissection along the inferior lobe of the prostate, placing the posterior membranous urethra at risk (Figs. 30.1 and 30.2).

In addition to recognizing anatomic landmarks, understanding the particular anatomy of a patient undergoing taTME with review of the rectal protocol magnetic resonance imaging (MRI) prior to the case is critical [13, 16]. This allows the surgeon to review the location of the tumor, height from the anal verge, and circumferential resection margin (CRM). However, as pointed out by Atallah et al., preoperative review of the MRI in midline sagittal section allows for a better

understanding of the slope of the sacral curvature and length of the horizontal rectum [13]. Such review also allows the surgeon to evaluate the dissection plane between the prostate and the anterior rectum, including factors that might affect the positioning of this plane including a tight or narrow pelvis, which may push the prostate more cephalad and bring the prostatic urethra in closer proximity to the anterior rectum, or a hypertrophied prostate, which may alter the normally inline or horizontal orientation of the rectoprostatic fascia and anterior dissection plane in taTME [23].

### Recognizing Patients at Risk

In addition to understanding critical anatomic landmarks, it is also important to understand patient-specific risk factors that may put certain individuals at higher risk for urethral injury with taTME. As mentioned previously, normal anatomic relationships may be distorted in the setting of benign prostatic hypertrophy, a large anterior tumor with threatened circumferential radial margin (CRM), a narrow pelvis, or bulky pelvic musculature [13, 23]. Of the 34 cases of urethral injury analyzed by Sylla et al., 33% of patients had a baseline prostatic abnormality, most commonly benign prostatic hypertrophy [15]. Other risk factors include history of prior pelvic radiation, transrectal prostate biopsy, radical prostatectomy, brachytherapy, or other pelvic surgery. Patients with these risk factors are likely to have fibrosis, scarring, and fusion of the rectoprostatic fascia, leading to unclear dissection planes and increased chance of wrong-plane surgery [1]. Finally, tumor characteristics can also increase the risk of urethral injury, with low and anterior tumors posing the highest risk for injury, especially when taTME is completed with partial or complete intersphincteric resection (ISR) [1].

### Intraoperative Prevention Strategies

Several intraoperative techniques have been described to help better locate or visualize the correct planes of dissection during taTME. The



first is the use of simple tactile feedback in the form of preoperative digital rectal examination (DRE) [1]. This exam allows for localization of the prostate prior to the start of the operation and identification of geometry of the anterior dissection plane. If the anterior dissection is unclear during the course of taTME, the surgeon can also use this technique to confirm dissection in the correct plane by removing the transanal access port and performing DRE.

There is some data to suggest that use of a two-team strategy as opposed to a one-team strategy may reduce the risk of urethral injury. In the review of 34 urethral injuries by Sylla et al., the majority of injuries by both inexperienced and more experienced taTME surgeons occurred during operations performed using a one-team approach [15]. The two-team approach may lead to better visualization and identification of the correct anatomical planes during taTME.

Finally, in cases of urethral injury, surgeons in the prior study noted that persisting with a taTME approach despite difficulties in identifying anatomical landmarks and tissue planes was a common reason for injury [15]. It is essential that the surgeon be prepared to change strategy in the face of a difficult dissection and complete the anterior dissection via either a transabdominal or open transperineal approach (similar to the perineal portion of an APR). The surgeon should have a low threshold to convert in the face of inability to recognize the correct plane of dissection.

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## Emerging Technologies

New technologies may help prevent urethral injury, particularly in difficult cases of anatomical distortion as mentioned above. The use of infrared-lighted urethral stents (Infravision Imaging System, Stryker, Inc. Kalamazoo, MI) placed through a clear Foley catheter has been described as a technique to identify the male urethra and avoid injury [24, 25]. The stents can be identified with the use of a special infrared laparoscopic camera filter and allow for transillumination through up to 12 mm of tissue. Multiple

infrared stents can be used at once to improve visualization [1]. Because infrared light is utilized, there is minimal heat emission and low risk for tissue damage.

Fluorescence imaging with indocyanine green (ICG) has also been used in taTME to identify structures using visualization in the near-infrared wavelength [25]. The dye can be injected systemically to highlight blood vessels in the operative field, and due to the fact that near-infrared wavelengths are more translucent through the same tissue visualized in visible wavelengths, vessels beneath the operative surface can be effectively identified [26]. Peri-tumoral injection of ICG has been used in taTME to better identify planes of dissection, and ICG has also been used to evaluate adequacy of blood supply to the rectal anastomosis [27]. Recently, transurethral injection of ICG has been used to visualize the urethra in a cadaver model of taTME, demonstrating how this technique could be used to provide better identification of the urethra during taTME to prevent injury [28].

Laparoscopic ultrasound can also be used to identify the urethra during taTME. This technique is widely used in other surgical disciplines for tumor localization and identification of anatomic landmarks [29, 30]. A similar technique can be used in taTME to visualize the prostate and detect the urethra by means of color Doppler ultrasound imaging and irrigation through a Foley catheter. This technique has been described by Atallah et al. although it is not commonly used in practice [1].

Finally, the use of real-time stereotactic navigation for taTME has been described and used in a small pilot study of three patients with anterior rectal cancer [31, 32]. This technique uses specialized software to integrate preoperative imaging and camera image to locate the position of surgical instruments relative to multi-planar MRI or CT images or a three-dimensional rendering of the operative field. This technique can successfully identify the prostate and urethra and prevent wrong-plane surgery; however, it is limited by its inability to differentiate between the contiguous planes of the mesorectal envelope and surrounding endopelvic fascia, which puts the nearby

autonomic nerves at risk [31]. Furthermore, this technique is limited to specialized centers with the required equipment and requires imaging immediately preoperatively, which can lead to substantial increases in operative time [1].

## Conclusions

Transanal total mesorectal excision (taTME) is a promising new approach to distal and mid-rectal cancer but is associated with a risk for iatrogenic injury to the male urethra. Although rates of injury reported in the literature are low, this likely underestimates the true incidence of this complication. Urethral injury may become more common as use of taTME becomes more widespread. Structured taTME training that incorporates extensive didactics on perineal anatomy and strategies to avoid organ injuries (as well as the ability to promptly recognize and repair them), cadaver training, and proctored surgery with a mentor surgeon can help minimize urethral injury in the future. Additionally, new techniques using infrared and near-visual light spectrum imaging may be helpful in identifying the urethra and preventing injury.

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# How to Avoid Urethral Injury in Males

# 31

Sam Atallah and Itzel Vela

## Introduction

With early experience in taTME, it became evident that a new type of procedure-specific, gender-specific morbidity had emerged, as described by one of the original clinical series on this new operation by P. Rouanet [1]. Namely, this was iatrogenic injury to the male urethra during the transanal dissection. In this 2013 series by Rouanet, taTME (then using the moniker transanal endoscopic proctectomy (TAEP)) was performed utilizing the transanal endoscopic operating (TEO) platform. Of the 30 male patients who underwent taTME, two (6.7%) had iatrogenic injury to the urethra. Subsequently, Burke et al. reported initial outcomes of taTME with 50 consecutive patients (male and female) using the transanal minimally invasive surgery (TAMIS) platform whereby a single urethral injury occurred [2]. Importantly, urethral injury during taTME is specific to males. There were 30 male patients in this series by Burke et al., and thus the gender-adjusted incidence of urethral injury was 1/30 (3.3%).

The true incidence of urethral injury is difficult to ascertain, and reports vary in the frequency of this complication, including a recent series on taTME for mid and low rectal cancer in which no injuries were observed in the study group of 186 patients [3]. Funded by the Pelican Foundation, the Low Rectal Cancer Development (LOREC) database has been used to collect and register clinical and pathologic details on taTME operations, as self-reported by surgeons. While subject to reporting bias, this data was analyzed by M. Penna et al. on behalf of the taTME registry collaborative [4]. It revealed that, of the 720 taTME operations performed for benign and malignant disease, 489 (67.9%) were male. There were five urethral injuries (presumably all male patients), and thus the observed incidence of this morbidity in the registry data was 5/489 (1%).

While generally it appears that the risk of urethral injury is  $\leq 5\%$ , this may not accurately reflect the true incidence of this morbidity as there are several anecdotal cases of urethral injury that are currently unpublished. Furthermore, other data are available to suggest that the risk of urethral injury may indeed be significantly higher. Much of this is based on data gathered from training courses and analysis of the uptake of taTME in clinical practice. To date, in the largest training center in North America, over 220 surgeons have received specialized cadaveric-based training, and during wet lab sessions, it was observed that 1 in 5 delegate trainee

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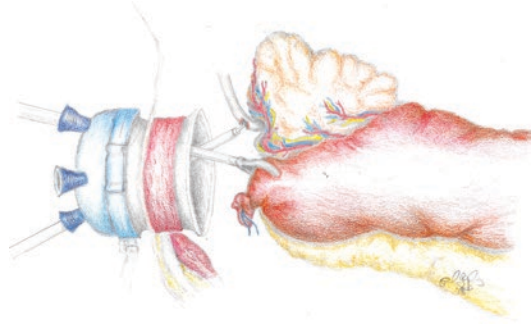


teams would inadvertently mobilized the prostate during taTME [5]. In the same study, it was also found that, upon course completion, 25% of survey respondents reported having had a urethral injury after implementing a taTME program at their respective institutions [5]. Even inadvertent extenteration by delegate surgeons was observed at these cadaveric training sessions, highlighting the gravity and scope of potential iatrogenic injury to the urinary system [6]. Based on this, the importance of this potentially catastrophic complication must be very carefully understood.

Although urethral injury has been described with the abdominoperineal resection (APR), it is uncommon, and urethral injury with sphincter-preserving rectal extirpation appears to *only* be a risk with taTME [6]. Even when compared to the transanal abdominal transanal (TATA) operation (often considered the prequel to the modern-day taTME), the incidence of urethral injury distinctly differs [6–9], and this can be attributed to the constant tactile feedback surgeons utilize during TATA to confirm the position of the prostate gland, a subtle yet crucial distinction between taTME and TATA. Notwithstanding, male urethral injury appears to be contingent upon a perineal approach to organ extirpation. Here, the factors related to urethral injury during taTME are analyzed and discussed. Avoiding male urethral injury during taTME represents one of the most paramount modules in training and is absolutely essential to the maturation of the taTME surgeon.

### Specific Point of Urethral Injury

Male urethral injury occurs during distal anterior dissection, when the anterior taTME rectotomy lies within  $\leq 3$  cm from the anorectal ring [10]. With distal dissection, the prostate can be distracted dorsally, and, in the process, the pre-membranous urethra can become exposed leading to iatrogenic injury to its posterior aspect (Fig. 31.1). Immediate recognition of the urinary catheter has prevented complete urethra disruption, and to date, in vivo urethral injury has not involved complete transection through the ventral wall of the urethra.



**Fig. 31.1** The anatomic relationship of the prostate gland and urethra in relation to the rectum during distal taTME dissection can place the pre-membranous portion of the urethra at risk for iatrogenic injury. Note the “vertical” presentation of the urethra which is typical when the prostate gland is dorsally distracted

### Assessment of Patient Risk for Injury

The first step is to assess the patient’s independent risk of urethral injury during taTME [6]. This is important for surgeons to understand beforehand and is considered a vital step in case preparedness. The objective is to risk-stratify patients for the potential for this injury, since not all patients pose the same risk for urethral injury [6, 10]. As detailed in Table 31.1, urethral injury risk stratification is dependent upon these six factors: (a) prior local therapy, (b) previous local operations, (c) congenital malformations of the genitourinary system, or a history of male pelvic penetrating or blunt trauma, (d) pre-existing history of benign prostatic hypertrophy or pathology intrinsic to the male urethra, (e) history of prior, especially chronic or recurrent inflammatory disease of the anus, rectum, or prostate, and (f) tumor-specific factors – such as is the case for radiated, low-lying anterior and fixed lesions which exhibit desmoplastic changes. Such locally advanced cancers pose a challenge for surgical clearance and, with taTME, may dorsally distract the prostate-urethral complex in the process, which could place the organ structures at risk for injury.

Patients who possess significant risk of urethral injury based on preoperative assessment, including the six categories mentioned, should be

**Table 31.1** Patient-related factors which could potentially increase the risk of iatrogenic urethral injury in males undergoing taTME

<i>Previous nonoperative local therapy</i>
Prior external beam radiotherapy neoadjuvant treatment
Prior external beam radiotherapy for prostate cancer treatment
Prior implantation of radiation seeds
Prior injection of SpaceOAR® hydrogel (possible)
<i>Previous local operations of the anus, rectum, or prostate</i>
Prior radical prostatectomy
Prior prostate biopsies (multiple)
Prior anterior local excision in the distal rectum (via TEM, TEO, TAMIS)
Prior surgical treatment of complex anorectal fistulae and abscess
Prior rectourethral fistula repaired via any approach
Prior implantation of artificial urinary or anal sphincter
<i>History of congenital malformations or trauma</i>
History of pelvic trauma with urethral transection or urethroplasty
History of imperforate anus congenital malformations of the rectum, urethra, and urogenital diaphragm
History of prior rectourethral fistula repaired via any approach
<i>Factors related to intrinsic disease of the prostatic and membranous urethra</i>
Benign prostatic hypertrophy
Synchronous prostate cancer
Urethral stricture(s)
Difficult urinary (Foley) catheter insertion at the time of surgery
<i>Factors related to local sepsis</i>
Prior pelvic sepsis, for instance, related to ileal pouch failure
Complex, chronic anterior fistulae (e.g., suprasphincteric, extrasphincteric)
Recent or active prostatitis
Recent or active urethritis
<i>Factors related to the rectal tumor</i>
Low lying, fixed tumor $\leq 3$ cm from anal verge
Anterior, distal rectal cancer $\leq 3$ cm from the anal verge
Tumor abutting the prostate with limited CRM based on imaging

considered for alternative approaches, including laparoscopic and robotic abdominal techniques to accessing the deep pelvis. Even the sphincter-preserving TATA operation may hold an advan-

**Table 31.2** Steps to prevent urethral injury during taTME

1. Assess preoperative imaging (midsagittal rectal MRI); assess the shape and size of the prostate gland; recognize which patients may be at increased risk for urethral injury.
2. Prior to initiating taTME, the surgeon should perform a digital rectal exam; in addition to feeling for the tumor in low rectal cancers, the prostate should be examined by palpation, and its size, shape, and relative position should be noted.
3. When there is uncertainty about the anterior plane during dissection, the taTME platform should be removed, and the prostate gland should be reassessed by palpation.
4. Utilize the urinary catheter in a way analogous to a ureteral stent. When the prostate gland is inadvertently mobilized, the catheter can be palpated once the taTME platform has been removed.
5. Detection of applied vibratory or pulling (tugging) motion to urinary catheter, with simultaneous palpation.
6. Use of a lighted, infrared urethral stent placed through a clear-coated urinary catheter.
7. Use of injected indocyanine green for localization of the male urethra (currently experimental).
8. Critical understanding of the neurovascular bundle of Walsh and its relationship to the prostatic capsule.
9. Critical understanding of the morphology of the mobilized posterior lobe of the prostate gland.
10. Critical understanding of the extra-rectal muscle structure, including the rectourethralis muscle, the fibers of Luschka, and the anterior sling of the puborectalis.
11. Understand the effect of perceptual completion, loss of frame of reference, and human factors that can predispose to improper plane dissection and injury to the urethra.
12. Comprehension that uncertainty about the position of the prostate gland and urethra mandates discontinuation of taTME and completion of the operation abdominally.

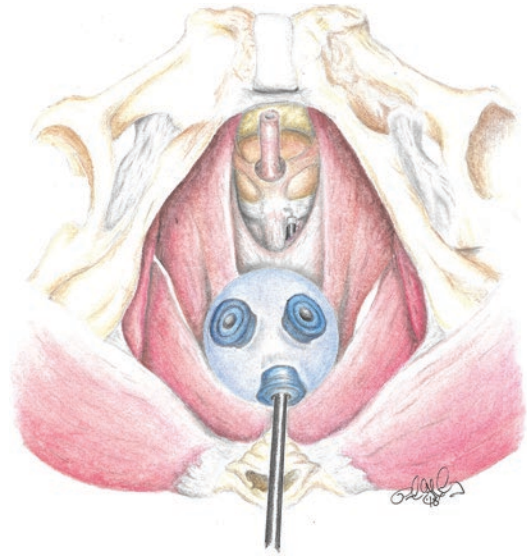
tage over taTME in this setting as it is conducted with constant tactile feedback to confirm the position of the prostate gland and urethra.

Nevertheless, with requisite training and experience, a taTME technique can still be successfully executed, and adjunctive techniques to localize the urethra in an effort to minimize iatrogenic injury can be employed [6, 10, 11]. These are delineated in Table 31.2, and crucial anatomic pearls and

important nuances of taTME related to urethral injury prevention are detailed in the following sections.

### The Rectourethralis Muscle and the Pre-rectal Muscle Fibers of Luschka

The first step in the transanal portion of taTME is the application of the purse string [12, 13]. Care must be taken to have symmetric suture bites which do not extend beyond the outer, longitudinal muscle of the rectum as this can inadvertently incorporate tissue that is beyond the scope of dissection, such as the periprostatic fascia and extra-rectal muscle fibers intrinsic to the pelvic floor. However, even with correct purse-string placement, entry into the proper TME plane – especially anteriorly – can sometimes be challenging because an often dense structure is encountered, and this can create a barrier to holy plane entry. This specifically applies to taTME dissections carried out  $\leq 3$  cm of the anorectal ring. Extra-rectal bands of muscle extend from the rectum and are properly inserted onto the endopelvic fascia and the preprostatic fascia [14–18]. This is the most pronounced anterior to the rectum and likely represents a composite of the pre-rectal muscle fibers of Luschka and the rectourethralis muscle, both of which lie medial to the puborectalis and the levator ani muscle complex (Fig. 31.2). They also contain muscle fibers from the conjoined longitudinal muscle of the anal canal. Anteriorly, the rectourethralis and pre-rectal muscle appear fused, becoming quite defined. During the taTME dissection, they appear as broad “vertical” bands of muscle extending from the pre-membranous urethra and posterior lobe of the prostate gland to the anterior rectal wall which makes distinction between the two organs difficult to discern (Fig. 31.3). A common error is to assume that these bands of muscle “belong to the rectum” and novice taTME surgeons will tend to include the rectourethralis muscle and fibers of Luschka in the specimen by purposely dissecting too far anteriorly. This is one of the most important factors predisposing to

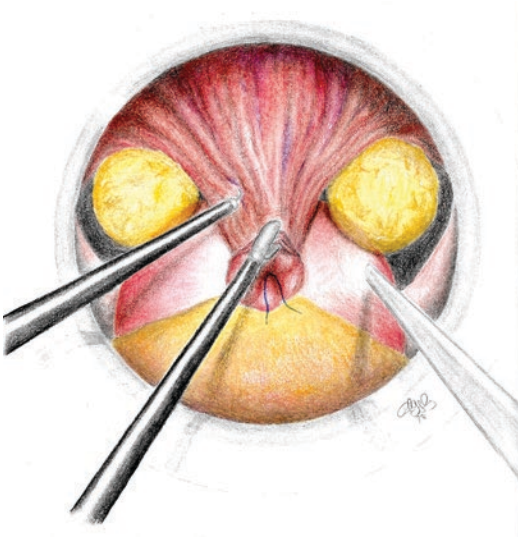


**Fig. 31.2** An anatomic plate delineates the muscles of the pelvic floor in relation to the prostate gland, urethra, and taTME apparatus. The first step after purse-string application is to divide the rectal wall, which is often thickened anteriorly as it is fused with the fibers of Luschka and the rectourethralis muscle. The surgeon must transect these attachments when operating distally to enter the holy plane. The contiguous muscle fibers appear homogenous from the taTME perspective, and this makes proper division challenging. Note the puborectalis muscle flanking the prostate gland. This is the skeletal muscle that becomes visible anteriorly when the prostate gland is inadvertently mobilized

male urethral injury. Thus, taTME surgeons, specifically when performing the distal anterior rectal dissection, must remain vigilant of these factors and must have a remastered comprehension of the relevant extra-rectal muscle anatomy.

### Morphology of the Prostate Gland and Urethra

Should the prostate gland become mobilized during taTME, the posterior lobe will be distinctly recognizable as a pale-yellow spherical and symmetric gland that is characteristically smooth [19]. Surgeons may sometimes confuse this “mass” anteriorly for that of an anterior positioned rectal tumor. However, the smooth contour of the mobilized gland is not a characteristic of invasive rectal cancer. Furthermore, the cylindrical urethra can

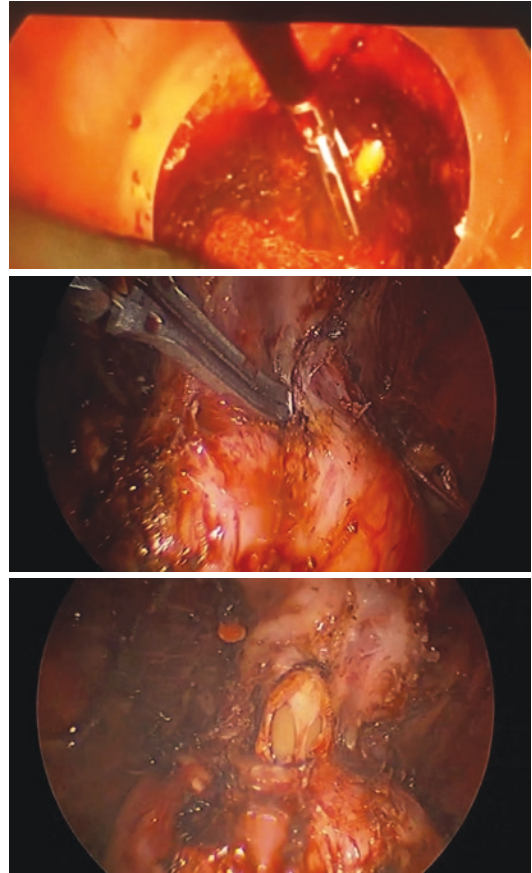


**Fig. 31.3** The anterior, distal taTME dissection presents the surgeon with an obscure sheet of muscle that directly communicates with the rectal wall and is contiguous with the rectourethralis and muscle of fibers of Luschka. The challenge for the operator is to transect this muscle bundle at a point that precisely separates the prostate gland from the anterior rectal wall without injury to either structure

also be seen at the 12 o'clock position (Fig. 31.4). Finally, the mobilized prostate appears as a separate structure ventral to the anterior, mobilized rectum, and the two structures together form the shape of a figure “8” [20], and surgeons should be trained to quickly discern this. To do so, taTME surgeons are encouraged to maintain a global view during dissection – such that the purse string and rectum remain in view as this provides an important frame of reference for the operator.

### Anterior Exposure of the Puborectalis Muscle

The striated skeletal muscle of the pelvic floor is a conical extension of the anal canal. Through the taTME vantage point, depending on prostate size, this skeletal muscle should not be visible to within approximately  $\pm 20^\circ$  from the  $0^\circ$  anterior midline. Exposure of this muscle at this level typically implies mobilization of the prostate gland and should warrant immediate reassessment of the plane of dissection (Fig. 31.2).

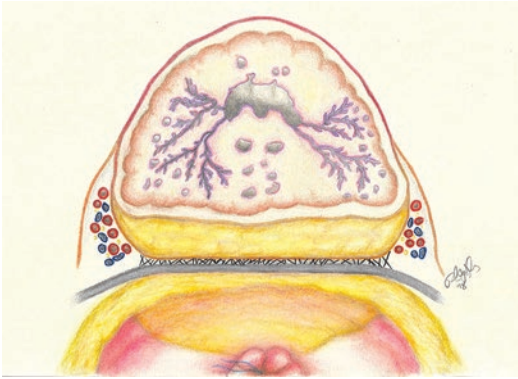


**Fig. 31.4** Video still frames of iatrogenic urethral injury during taTME in males

### Denonvilliers' Fascia

Denonvilliers' fascia is unique to males. This dual-layered envelope establishes the plane between the anterior rectal wall and the posterior aspect of the prostate gland (Fig. 31.5). Extending from its point of insertion at the urogenital diaphragm to the peritoneal reflection, this fascia helps separate the two structures. With the taTME approach and with perineal insufflation, the anterior plane often is established easily, resolving what is otherwise one of the greatest challenges of conventional radical rectal resection, namely, the anterior dissection along the horizontal portion of the rectum. However, this fascial plane and the associated neurovascular bundles of Walsh which flank Denonvilliers' fascia can be



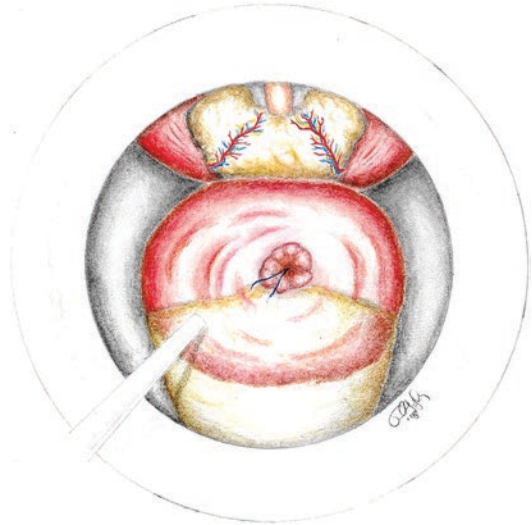


**Fig. 31.5** The anatomic arrangement of Denonvilliers' fascia relative to the neurovascular bundle of Walsh (NVBW) and the anterior rectal wall is crucial to the mastery of the taTME approach. The NVBW flanks the bilayered fascia and can be distracted dorsally during taTME dissection. Surgeons must be cognizant of these structures as early recognition helps surgeons maintain the correct anterior TME plane

dorsally distracted, moving the pre-membranous urethra into the operative field where it becomes prone to insult.

### The Neurovascular Bundle of Walsh

In general, colorectal surgery training has heretofore not included formal study of the prostate gland and its neurovascular complex. Essentially exclusive to the taTME vantage point, the neurovascular bundle of Walsh (NVBW) [21] can not only be visualized, but it can often serve as an important landmark, which, when recognized, can help the operator remain on the correct plane thereby avoiding injury [10, 19, 22]. The NVBW contains paired nerves, veins, and arteries. Of these, it is the arteries that are most recognizable during taTME (Fig. 31.6). Along the anterior hemisphere, at the two and ten O'clock positions and flanking Denonvieller's fascia, course the arteries of the neurovascular bundle. These ~ 4 mm arteries are known as prostatic capsular arteries and derive from the inferior vesicle arteries. When the prostate gland is inadvertently deflected downward, and when the taTME surgeon enters a plane of dissection which is too anterior, the visible vessels of the NVBW become

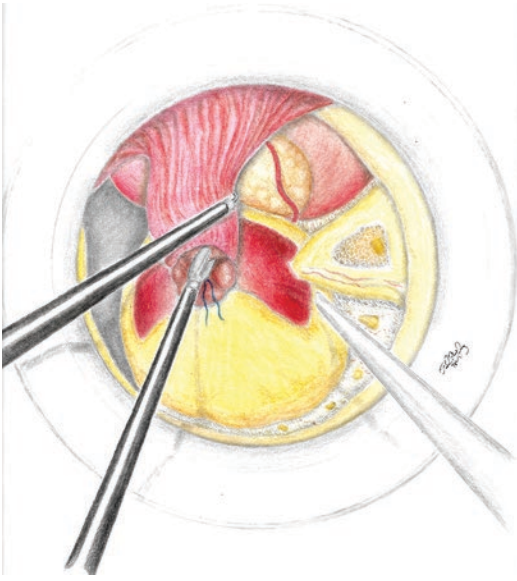


**Fig. 31.6** The paired arteries are visible components of the NVBW and can be identified along the lateral borders of Denonvilliers' fascia at the 10 and 2 o'clock position. These landmark vessels should always be identified during the taTME dissection and reflected ventrally. This is a critical step in the distal anterior dissection that prevents posterior distraction of the prostate and preprostatic urethra

apparent, and this serves as an opportunity to readjust the plane of dissection before injury to the midline urethra occurs. Occasionally, the NVBW is not recognized and is instead transected. However, this often results in arterial bleeding that is readily recognized and often not controlled with monopolar cautery alone due to vessel diameter. After gaining control of hemorrhage, it is important to reassess the plane of dissection, reflecting the NVBW ventrally so as to maintain the correct anterior taTME plane.

A reproducible and safe approach to the anterior dissection is to begin along the dorsal rectum and then gradually extend the dissection laterally. This leads to identification of the nerve branches derived from the S4 and S5 arcade as they innervate the rectum to become part of the distal rectal plexus. These are often visible laterally creating "triangles" that extend to the mesenteric envelope [23] and can be reflected laterally at what is often a triangular entry point to the mesorectal envelope. As the dissection then proceeds ventrally in a stepwise manner from the 3 (or) 9



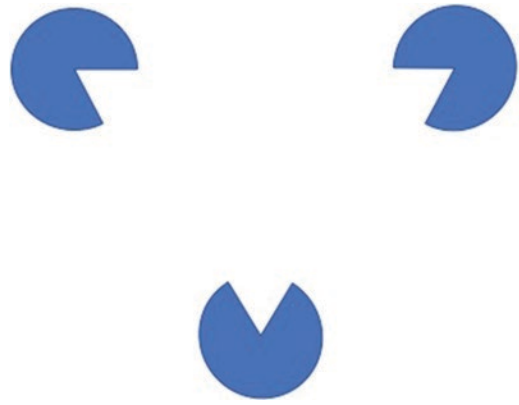


**Fig. 31.7** This critical view allows surgeons to maintain a safe frame of reference and identify the correct division point anteriorly. In a stepwise approach, the lateral nerve branches, including those that derive from the S4 and S5 nerve roots, are reflected away from the mesorectal envelope. Anterolaterally, the NVBW is then identified, which defines the ventral most extent of the taTME plane. Once this structure is identified, the fusion of anterior rectal wall together with fibers of Luschka and fibers of the rectourethralis muscle can be safely transected

o'clock position toward to the midline 12 o'clock position, the visible artery of the NVBW can be identified as it is seen coursing along the lateral aspect of the prostate gland. Once identified, the surgeon is provided with the perspective needed to then safely divide the rectourethralis muscle and fibers of Luschka in the proper plane (Fig. 31.7).

### Surgeon Misperception and Visual Completion

Surgeons operate through comprehension of anatomic planes in a specific context and with cognition derived from having a frame of reference [24]. With camera-based minimally invasive surgery, the visual scope and the frame of reference it provides are derived by the anatomic landmarks contained within the visual field. Typically, the



**Fig. 31.8** The Kanizsa triangle is the archetypal example of perceptual (visual) completion, whereby the mind “fills in” a picture that is not true reality. Here, our mind envisions an equilateral triangle, although there is no such triangle in actuality. Filling in what is not real can result in misperception that results in iatrogenic injury. This is more likely to occur when the frame of reference is lost and when anatomic structures are misidentified

field of view with laparoscopy is broad, thereby constantly enabling the surgeon to define and redefine the visual frame of reference during the process of dissection. While the optics achieved through laparoscopic high-definition systems delivers superb video quality, with taTME, there is a potential hazard of tunnel vision as close proximity positioning of the camera’s lens in relationship to the point of dissection may lead to disorientation. While telescoping the lens toward the vicinity of dissection provides the operator with enhanced anatomic detail, the frame of reference within the visual field can be lost. This can result in misperception that leads to the phenomenon of visual completion.

Visual or perceptual completion occurs when the human mind “fills in” a visual defect to complete a picture that is only an illusion [25]. The archetypal example of this is the Kanizsa triangle [26, 27], whereby one’s mind “completes” the image of a triangle that in reality does not exist (Fig. 31.8). Thus, visual completion can result in a specific kind of disorientation in which the surgeon is not aware that the visual cues being processed are incorrect.

One can consider common bile duct (CBD) injury during cholecystectomy as a paradigm to

urethral injury during taTME. As such, it has been learned that CBD injury is not most likely to occur due to challenging body habitus or aberrant biliary anatomy, but rather due to surgeon misperception [28–30]. Thus, through incorrect identification of anatomic structures, which results from a lost frame of reference, and through errors in cognition secondary to visual completion, a surgeon can be led to make incorrect assumptions about anatomy within the operative field. Furthermore, surgeons are less likely to change their operative course once this has been established – a consequence of confirmatory bias [31–34]. According to Way et al. [28], “once we commit to a specific judgment, we tend to discount the significance of new dis-confirmatory evidence and remain in favor of the confirmatory evidence.” Thus, confirmatory bias can unfortunately contribute to (rather than minimize) operative morbidity.

In summary, urethral injury can result from the surgeon’s mind incorrectly processing information. Leading factors include (a) loss of frame of reference (by failing to maintain critical anatomic landmarks in the field of view), (b) perceptual completion (an assumption of anatomic relationships “filled in” and assumed to be real in the mind of the operator), and (c) confirmatory bias, whereby a surgeon is more likely to continue along a perilous plane of dissection than to process new information that suggests this approach is not correct.

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## Other Human Factors

Establishment of the correct anterior taTME dissection in males can be one of the most challenging aspects of this operation. The increased workload coupled with the high stakes of operative morbidity can dramatically increase the surgeon’s mental stress. In the balance is the risk of dissecting too anteriorly with subsequent urethral injury, while dissection in a plane too dorsally can result in violation of the rectal wall and potentially insult to the tumor itself—resulting in an irrecoverable compromise to the oncologic integrity of the operation. With only millimetric

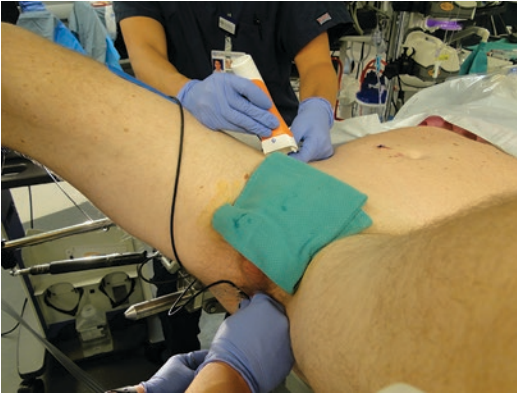
differences between correct and incorrect plane, this point of the male taTME dissection is considered to be the most stressful point of the entire operation. Particularly for less experienced taTME surgeons, this psychologic state increases anxiety which can diminish judgment and which can lead to operative error. This is one reason that taTME surgeon proctorship is vital toward the safe implementation of this complex procedure [5, 35–38]. It specifically allows the operating surgeon to gain confidence until proficiency with taTME is established.

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## Methods to Localize the Urethra

Today, there are essentially three perineal approaches to extirpation of the rectum. They are APR, TATA, and now taTME [39]. With APR and with the original description of TATA, confirmatory tactile feedback allows the operator to constantly assess the anterior plane, and when the prostate gland is inadvertently mobilized during perineal dissection, it is typically recognized and the appropriate adjustments made. However, taTME – whether with TEO, TEM, or TAMIS – relies on instruments and haptic (not tactile) feedback that does not reliably assess when the prostate gland has been mobilized. Thus, most experts now advocate removal of the platform and direct palpation of the prostate when there is uncertainty about the anterior dissection. It is so important that training courses for taTME now advise a digital rectal exam with a baseline assessment of the prostate gland prior to purse-string application and introduction of the access channel.

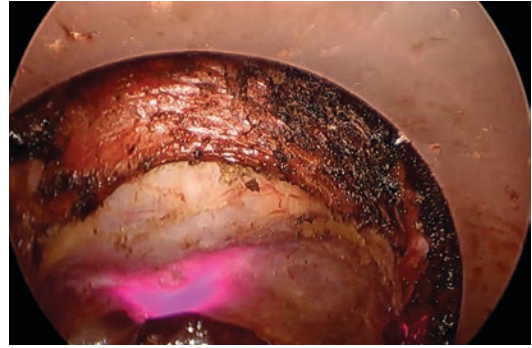
Additionally, it should be recognized that the urethra is effectively stented with a urinary catheter, which allows this structure to be palpated when the posterior lobe of the prostate gland and pre-membranous urethra are inadvertently mobilized en bloc with the anterior rectum and mesorectum [6]. New approaches for urinary system and urethral localization capitalize on the fact that the urethra is stented by a catheter. Effective examples of how the urinary catheter can be utilized for localization (other than direct tactile



**Fig. 31.9** A urinary catheter is also a urethral stent. This concept is important and can be used by the taTME surgeon to localize the male urethra when there is uncertainty about its position. Here, a vibratory stimulus is transmitted using an ordinary electric skin clipper which when applied to the catheter can be registered as a vibratory signal along its entirety, including the preprostatic portion of the urethra. The surgeon can then register this vibration either electronically via Doppler wave form or audible signal (shown) or more simply by tactile feedback

feedback) include applied vibratory stimuli that can be transmitted and palpated by the operating surgeon (Fig. 31.9), laparoscopic ultrasonography with or without retrograde catheter irrigation, and the use of lighted near-infrared urethral stents [6, 40].

Newer techniques focus on the use of bio-fluorescence and organic dyes [6, 41, 42]. This includes indocyanine green (ICG) – the best studied of the organic dyes for surgical applications (Fig. 31.10). Since it is cleared hepatically, ICG is not excreted in the urinary system, and thus systemic administration will not produce fluorescence of the urethra. However, it can be directly instilled into the urinary system, whereby it avidly binds to urothelium and fluorescence can be observed [41]. ICG, like most organic dyes, has an important translucency property that allows deep soft tissues to become visible. This enhanced visibility “beyond the visible light spectrum” [6] allows surgeons to see what they otherwise cannot. Newer organic dyes may significantly improve detection of deeper structures allowing surgeons to appreciate vital structures, including the urethra, before injury occurs [42].



**Fig. 31.10** A near-infrared luminescent stent has been placed in the male urethra during taTME. It is visible during the dissection, providing augmented information about the position of the urethra during dissection

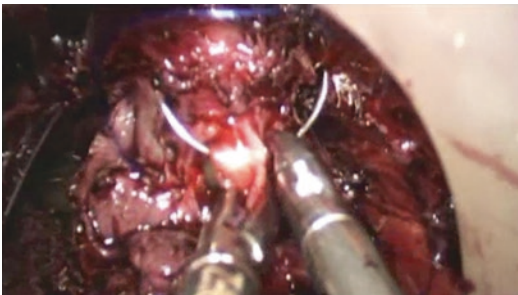
**Table 31.3** Emerging and theoretical techniques to localize the urethra during taTME

<i>Currently applied techniques</i>
Direct tactile feedback
Application of traction release on urinary catheter to detect movement
Transmission of vibratory stimuli along urinary catheter
Ultrasound detection of urethra ± retrograde irrigation
Doppler detection of urinary catheter with vibratory stimuli transmission
Use of infrared luminescent urethral stent
Augmented reality with stereotactic navigation/cybernetic surgery (select centers only)
<i>Future directions</i>
Use of organic dyes and near-infrared imaging
Accelerometers and laser Doppler vibrometry
Passive millimeter-wave imaging
Magnetic or radioisotope impregnated urinary catheter
Piezoelectric sensors coating of urinary catheter
Intraoperative X-ray fluoroscopy

Future developments may include urinary catheters which are impregnated with materials that exhibit luminescence in the near-infrared spectra [6]. This may include photostable quantum dots and single-walled carbon nanotubes that represent hexagonal lattices of graphene [6, 43–46]. Finally, although currently experimental for pelvic visceral surgery, stereotactic intraoperative imaging and navigation holds promise to localize pelvic viscera which include the prostate gland and urethra [47–54]. Table 31.3 summarizes current and evolving methods to localize the male urethra during taTME.

## Urethral Injury Management

While iatrogenic urethral disruption represents a major complication not encountered during abdominal approaches to mesorectal excision, there is ample experience with urethral injury management which is derived primarily from the trauma literature. In particular, males subjected to blunt force trauma and subsequent pelvic rami fractures are prone to urethral transection. A urethral disruption proximal to the urogenital diaphragm is considered a Type 2 injury based on the Goldman classification [55]; this is the type of injury that occurs with taTME, albeit from sharp rather than blunt insult. In the setting of trauma, a Type 2 injury is managed by suprapubic catheter drainage and delayed urethral repair. In this setting, urinary catheter placement is contraindicated, even when urethral disruption is only suspected as placement can lead to creation of a false passage. However, intraoperatively, with iatrogenic injury to the urethra during taTME, the urinary catheter should be left in place and not removed as it serves as a stent so that the defect can be allowed to heal after primary repair. Most taTME experts recommend primary sutured repair of the urethral disruption with absorbable suture and delayed catheter removal (Fig. 31.11).



**Fig. 31.11** The transected urethra during taTME is here being repaired using a laparoscopic needle driver and absorbable suture via the transanal access platform. Most experts recommend repair of a urethral disruption and continued catheter drainage. Note the vertical bands of muscle which likely represent a composite of the rectourethralis muscle and fibers of Luschka

## Related Injuries to the Urinary System

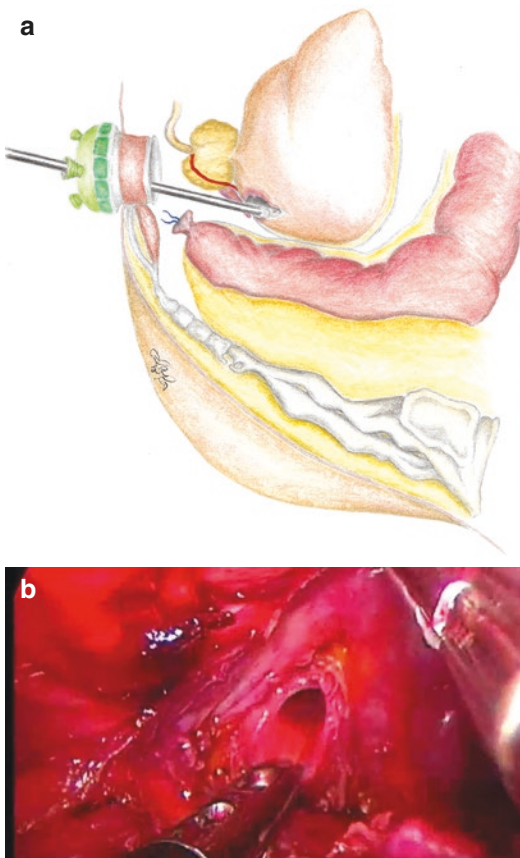
The tri-compartment structure of the male pelvis is composed of the rectum posteriorly and the bladder anteriorly. The structures are normally separated by the mid-compartment – occupied by the prostate gland. However, this “textbook” arrangement is not always exact as a patulous, atonic bladder can be displaced into the middle pelvic compartment in males – and in post-hysterectomy females as well.

Bladder atony results in bladder volumes in excess of normal (~400 ml) with volumes of 6000 ml being reported [56]. Implicit is an increased surface area that, even with adequate urinary catheter drainage, can result in risk of injury if this structure. Thus, it is possible during the anterior, sub-peritoneal taTME dissection to injure the bladder without displacing the prostate gland or urethra as this injury tends to occur more proximally (Fig. 31.12a, b).

Fortunately, bladder injury with taTME is uncommon. When the bladder is forcibly distracted ventrally – as is often the case with the two team taTME approach – injury to the bladder becomes less likely. Thus, synchronicity of the abdominal and perineal surgeons during taTME is important in reducing the risk of iatrogenic bladder injury as the dissection approaches the peritoneal reflection from below.

If injury to the bladder is recognized at the time of taTME, then it is recommended the patient undergo urologic evaluation to exclude injury to the trigone and to assess the extent of the bladder injury. This can be performed via cystoscopy. Furthermore, the camera lens used for taTME can be advanced into the bladder to evaluate the organ and to insure the ureterovesical junctions are uninjured. A layered repair with absorbable suture utilizing the transanal platform is recommended, with prolonged catheter drainage postoperatively. Interval cystoscopy or contrast imaging is also advised to assess healing.





**Fig. 31.12** (a) Bladder injury during taTME occurs in the proximal anterior dissection as demonstrated in this illustration. Note that the bladder itself does not always lie in the anterior pelvic compartment. (b) Bladder injury during taTME which was repaired with absorbable sutures via the transanal apparatus

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# A Roadmap to the Pelvic Autonomic Nerves During Transanal Dissection

# 32

Werner Kneist

## Introduction

In addition to the principle of oncologic radicality, a total mesorectal excision (TME) should take into account the principle of functional preservation, by maintaining pelvic autonomic nerves [1]. From the start, the taTME approach has brought hope of better preservation of autonomic nerve fibers [2–4]. However, it can be difficult to identify subperitoneal nerve structures in the minor pelvis intraoperatively, due to the complex neuroanatomical topography and various patient-, tumor-, and surgery-related factors. The difficulty in achieving intraoperative pelvic autonomic nerve preservation (PANP) appears to parallel the difficulty in achieving a qualitatively adequate TME specimen. Therefore, it is not surprising that more challenging cases, with an implicit high degree of operative difficulty, portend an increased risk of nerve injury. The difficulty in PANP increases with severe obesity, a narrow male pelvis with a voluminous mesorectum, neoadjuvant chemoradiation therapy, a local advanced tumor in the mid-rectal third, or a very low cancer [5, 6]. Since all of these factors are improved by the taTME technique, it stands to reason that taTME can result in PANP.

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As this book makes very clear, the video endoscopic-assisted, bottom-up (taTME) approach is promising, but it requires special knowledge of surgical anatomy, excellent technical skills, training, and experience driven by high volumes. These requirements are particularly important for achieving nerve preservation.

## Transanal Nerve-Sparing Mesorectal Dissection

In its reflection of the different steps involved in the taTME procedure, a macroscopic description of the topographical location of nerves should give the surgeon at least an idea of where caution is warranted for preserving the urogenital and internal anal sphincter nerve supply. Table 32.1 documents the findings and experiences reported previously by individual authors that performed taTME. Didactically, this chapter is arranged according to the topography of extrinsic autonomic pelvic innervation.

## Terminal Branches of the Internal Anal Sphincter Nerves

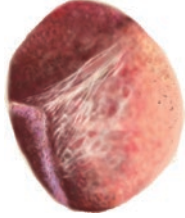




A complete intersphincteric resection removes the entire internal anal sphincter (IAS), and thus, it renders the innervation inconsequential. Nevertheless, it is desirable to preserve some relevant nerves

**Table 32.1** Roadmap to the pelvic autonomic nerves – focus on transanal total mesorectal excision

Author	Nerves	Based on	Topography	Other aspects
Lacy et al. [2]	Autonomic nerves	Video endoscopy	Excellent visualization, especially in the narrow male pelvis	Believe that it allows more precise PANP
Atallah et al. [3]	IHP and nerves	Transanal robotics (3D)	Clear visibility with the robotic approach facilitates PANP	Further refinements necessary
Sylla et al. [7]	HN, IHP, PSN, NVB	Video endoscopy	Dissections too close to IHP and NVB may cause functional disturbances	Excessive retraction and dual use of monopolar diathermy and bipolar energy can lead to nerve damage
Bertrand et al. [8]	IHP, NVB	Fetal and adult anatomy; CAAD for pelvic anatomy; taTME experience	Nerves are at risk during anterior, lateral, and posterior mesorectal dissection in the lower and middle thirds	3D reconstruction of fetal anatomy gives an idea of the plane for PANP
Aigner et al. [9]	HN, IHP, NVB, LAN, IASN	Adult anatomy; macroscopic dissections, caudal to cephalic direction; taTME experience	Nerves are at risk at the superior aspect of the anal canal; along the “holy plane,” at the level of the sacral promontory	The NVB above the levator ani muscle serves as a landmark
Kneist et al. [10]	IHP, PSN, NVB, IASN	Video endoscopy; neuromapping	Five key zones of risk for pelvic autonomic nerve damage (Table 32.2)	Intraoperative verification of functional integrity seems possible
Atallah et al. [11]	IHP	Video endoscopy; real-time image-guided neuronavigation	Insufficient differentiation for separating fascia layers from the pelvic nerve plexus	Helpful for assuring the correct plane of dissection
Chouillard et al. [12]	NVB	Video endoscopy; pure NOTES cases	Significantly more frequent nerve identification, compared to the laparoscopic approach (78% vs. 33%)	Specimen quality comparable, including pathohistological detection of neurovascular elements
Kneist et al. [13]	PSN, IRP	Video endoscopy; neuromapping	Identification rates significantly higher with neuromapping compared to visual assessment alone	Intact neural pathways covered or embedded in the endopelvic fascia could be confirmed
Atallah et al. [14]	NVB, IHP, PSN	taTME experience, teaching experience	S2/S3 IHP routes appear “bow” shaped, approx. 6–8 cm from the anal verge; no risk of nerve injury in the posterior hemisphere 4–5 cm from the anal verge	4 mm vessels of the NVB at a 10 o’clock position, superficial to the prostate and the urethras, serve as a landmark; pneumodissection can occur deep to the IHP
Kneist et al. [15]	IRP	Cadaver teaching course with video endoscopy	Identification and preservation of the IRP is an element of training	Identifying IRP leads to a significantly higher number of NVB visualizations
Watanabe et al. [16]	PSN (S4), NVB	Video endoscopic case	Identifying the prostate gland, with autonomic nerves as a landmark	Avoiding urethral injury
Schiemer et al. [17]	PSN, IHP, IRP, NVB, IASN	Robotics; video endoscopy; neuromapping	Surgeon easily neuromapped both pelvic sidewalls	Monitoring is integrated at the surgical console; video documentation of the map

HN hypogastric nerve, NVB neurovascular bundles, PSN pelvic splanchnic nerves, IHP inferior hypogastric plexus, IRP inferior rectal plexus, LAN levator ani nerve, IASN internal anal sphincter nerve, IAS internal anal sphincter, APR abdominoperineal excision, CAAD computer-assisted anatomic dissection, PANP pelvic autonomic nerve preservation

**Table 32.2** Five key zones where autonomic nerves are at risk during transanal approach

Key zone	Level	Nerve segments	Dissection	Depiction
1	Upper anal canal, at dentate line	Terminal branches of the IASN	Intersphincteric	
2	Levator ani muscle	IASN	(Postero-) lateral at the 4 and 8 o'clock lithotomy positions	
3	Pelvic sidewall above the level of the levator ani muscle	Posterior-inferior edge of the IRP	Lateral at the 3 and 9 o'clock lithotomy positions	
4	Sacral nerve routes S4 and S3	PSN	Posterolateral	
5	Prostate/vagina	IHP with its anterior parts and NVB	Anterolateral at the 2–3 and 10–11 o'clock lithotomy positions	

*IASN* internal anal sphincter nerves, *IRP* inferior rectal plexus, *PNS* pelvic splanchnic nerves, *IHP* inferior hypogastric plexus, *NVB* neurovascular bundles

during a partial intersphincteric resection. With diameters of 0.1 mm, intersphincteric nerves are barely visible, even when an incision is performed at or below the dentate line, during an initially open approach (Table 32.2). The nerves are embedded in

fatty tissue and tend to course along the internal, rather than the external, anal sphincter. Injections to enhance tissue volume and careful preparation seem to comprise the method of choice to optimize nerve-preserving dissection [10, 18–20].



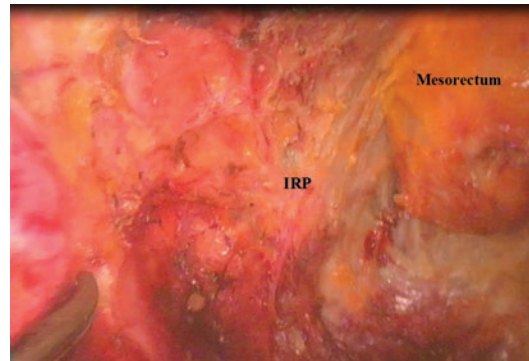
## Internal Anal Sphincter Nerves

In the 1950s, Otto Goetze described tuft-shaped, branched, fine fibers that projected from the lowest section of the pelvic ganglion in a specimen after abdominoperineal excision. He reasoned that extrinsic IAS innervation could be spared with a transanal, bottom-up approach, and he stated that the lower the resection and the less IAS nerve preservation, the worse the continence outcome [18].

When an incision is performed above the dentate line or the IAS level, the transanal video endoscope-assisted approach is suitable for verifying the internal anal sphincter nerves (IASNs) [10]. The extrinsic IAS innervation approaches the anorectal junction with a varying number (two to six) of nerve fascicles bilaterally, from the 5 and 8 o'clock location (with patients positioned dorsal lithotomy), at the level of the levator ani muscle. This nerve location might vary somewhat, due to changes in the perspective, according to different lengths of anal canal, the angle of the anorectum (90–100°), and the position of the platform shaft (and the nerve displacement this may cause). Nevertheless, the initial posterior dissection appears to be safe with respect to this innervation. During the subsequent bottom-up mesorectal dissection, the IASN can be traced in the caudal to cephalic direction, and it curves from a lateral to an anterolateral position [8–10, 15, 20].

## Inferior Rectal Plexus

During the lateral dissection, tracing the IASN within the triangle that lies between the anterolateral aspect of the rectum and the posterolateral border of either the prostate or the vagina leads to the inferior rectal plexus (IRP). The sub-plexus of the inferior hypogastric plexus (IHP) is located anterolaterally, along the pelvic sidewall, starting at the 3 and 9 o'clock locations (lithotomy position), above the inferior medial level of the levator ani muscle (Fig. 32.1). The areas revealed at



**Fig. 32.1** Inferior rectal plexus (IRP) on the right pelvic side in a male patient with taTME for rectal cancer

the 2–3 and 10–11 o'clock positions, at the level of the distal rectum, have been reported to be nerve-rich zones [10, 13, 15, 20, 21].

## Neurovascular Bundles

During the anterolateral dissection, one must recognize the combined structure of cavernous nerves and blood vessels – the neurovascular bundles (NVB) of Walsh. A very low, strictly anterior dissection of the perineal body does not cause injury to these cavernous nerves. At the beginning, the NVB should first be identified by locating paired pulsatile arteries anterolaterally. To avoid injuries to the nerves, blood vessels, vagina, prostate, or urethra, it is necessary to find an adequate plane of dissection. This plane is behind the NVB of Walsh and anterior to the urogenital septum (Denonvilliers' fascia in males).

With a caudal to cephalic approach, the nerves diverge from the lateral aspects of the perineal body and follow the anterolateral surface of the mesorectum. They pass along the inferior border of the prostate – or along the lateral surface of the vagina, at the level of the junction of the lower and middle thirds of the vagina. Then, the nerves can be traced to the lower anterior part of the IHP, at the 2–3 and 10–11 o'clock locations (patient positioned dorsal lithotomy) [8–10, 12–17] (Fig. 32.1).

## Pelvic Splanchnic Nerves

A cephalad posterolateral dissection enables the identification of the pelvic splanchnic nerves (PSNs). However, parts of these nerve fiber diameters are less than 150  $\mu\text{m}$ ; thus, identification and preservation might be relatively difficult. The sacral spinal nerves (mainly from S3 and S4) course across the piriformis muscle. A thin parietal fascial sheath covers these routes. Approximately at the height of the transition from the lower third to the middle third of the rectum, the PSN connects with the IHP in a “bow”-shaped manner, particularly evident from the taTME vantage point. With careful preparation and pneumodissection, the PSNs can be reflected dorsolaterally, and then, they can be traced to the anterior aspect. By following the autonomic nerves to the anterior aspect and recognizing the S4 and the NVB, the prostate gland can be identified, and a central dissection of the perineal body can be performed [10, 14–16].

## Inferior Hypogastric Plexus

Described as a triangle, the IHP is located between the leaves of the parietal fascia, and it spreads over the lateral walls of the pelvis minor. It contains nerves from different sources, including hypogastric nerves, pelvic splanchnic nerves, sacral splanchnic nerves, the sympathetic chain, and the mesenteric plexus.

A vertical organization of the IHP has been described according to the pelvic organs and anatomical structures. The bladder lies at the superior extent, the genital organs are in the medial region, and the rectum is positioned at the inferiormost extent. The length, width, and depth of the IHP are approximately 40 mm  $\times$  10 mm  $\times$  3 mm [22, 23]. The ganglion cell clusters are located lateral to the urinary bladder, seminal vesicles, paracervix, and middle rectum. Starting from the vesical plexus, there are up to eight efferent branches, and from the prostatic and rectal plexuses, there are up to six

efferent branches [24, 25]. In addition to efferent nerves, the IHP also contains afferent fibers.

Topographically, the dorso-cranial angle of the IHP forms at the confluence of the internal iliac vein. The ventro-caudal angle forms at the lateral aspect of the prostate gland, or at the entry point of the ureter into the uterine ligament, at the base of the parametrium. During a down-to-up TME dissection, the dorso-caudal angle of the IHP could project to the fourth sacral region. As described above, the PSN must be identified, and during a lateral dissection, care must be taken to avoid opening the parietal fascia (violations to the fascia result in the so-called halo sign), due to the risk of entering a false plane with subsequent inadvertent total denervation of the hemipelvis autonomic. According to an international consensus statement, the lateral dissection should be performed last, after dissecting the dorsal and ventral parts, to minimize the risk of damaging neurovascular structures (alternative approaches may also be valid). The extra-mesorectal, avascular fat (“adipose pillars”), at 3 and 9 o’clock positions, at the level of the mid-rectum, represents an important landmark, and these pillars, often visible during taTME, must remain in the lateral region as they are prone to medial displacement [10, 14, 26, 27].

## Hypogastric Nerve

After dividing the lateral rectal ligaments, a dissection along the “holy plane” (the plane between the presacral fascia and the mesorectal fascia) proceeds in a caudal to cephalic course, up to the peritoneal reflection, until reaching the level of the sacral promontory. Originating in the IHP within the parietal pelvic fascia, the hypogastric nerves (HN) run medially from the ureter, internal iliac artery, and veins and could be identified shining through in caudal-lateral to a cranio-medial direction. The left HN is described as significantly shorter ( $53.0 \pm 1.0$  mm) and narrower ( $1.7 \pm 0.2$  mm) than the right HN ( $73.8 \pm 19.4$  mm and  $1.9 \pm 0.0$  mm, respectively).

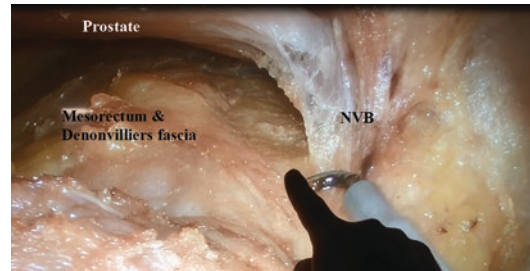
The risk of injury to the HN and the nerve segments above (i.e., the superior hypogastric plexus and inferior mesenteric plexus) is lower than the risk of injury to nerves in the pelvis minor. Results from the international taTME registry showed only two (0.1%) HN divisions in 1594 cases, although this may be a gross under estimation and the true incidence remains unknown. On the other hand, the risk of injury with the abdominal approach is also low. However, an uncoordinated, simultaneous operation from abdominal and transanal can pose a risk in the pelvic autonomics. Finally, a well-rehearsed, two-team approach can provide an additional dimension, by perfecting the traction - countertraction strategy. Hence, autonomic nerve visualization and preservation at the level of the sacral promontory might be easier to achieve than it was before [4, 7, 9, 12, 24, 28].

### Future Aspects of Nerve-Sparing taTME

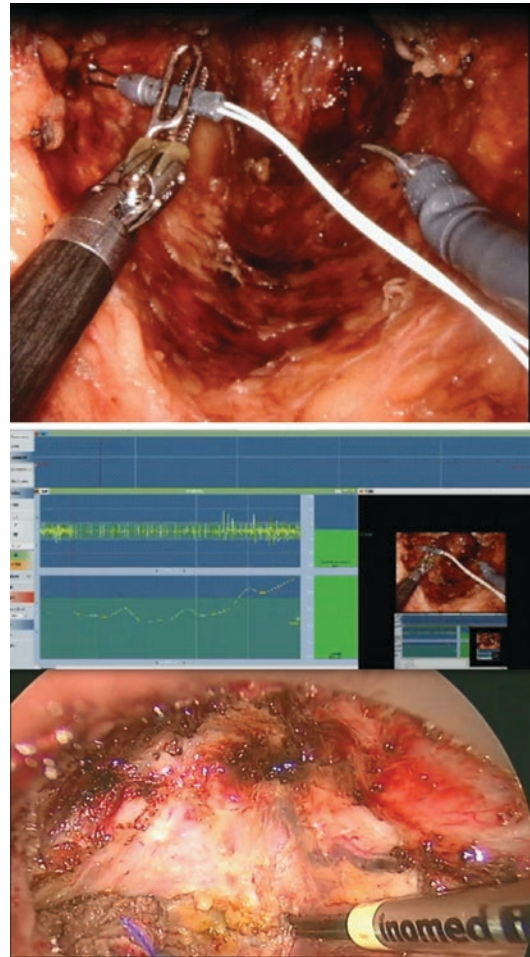
Currently, cadaveric dissection is a recommended key module in taTME training. Subperitoneal autonomic nerve preservation can be studied in detail in prepared didactics and other resources, including this one, which help surgeons to understand the intricate nerve anatomy, as well as the relevant evidence and pitfalls. Furthermore, anatomic specimens prepared for training and coursework should be used to demonstrate autonomic nerve tissues, followed by a hands-on module with formalin-fixed pelvises. TaTME performed in a cadaveric model should be used for teaching visual identification and preservation of the different nerve segments [15] (Fig. 32.2).

Intraoperative electrophysiological assessments (i.e., neuro-mapping) might provide new insights into the complex issue of how to incorporate PANP into minimally invasive TME approaches (laparoscopic, transanal, robotic, hybrid, etc.). Indeed, during taTME, identifying the IRP and its posterior branches (IASN) with an electrophysiological assessment (80% accuracy) was more meaningful than with visual assessment (45% accuracy), for both sides of the pelvis. Fully robot-guided pelvic neuro-mapping

is even more precise and rapid; this approach could be used transanally in the future (Fig. 32.3).

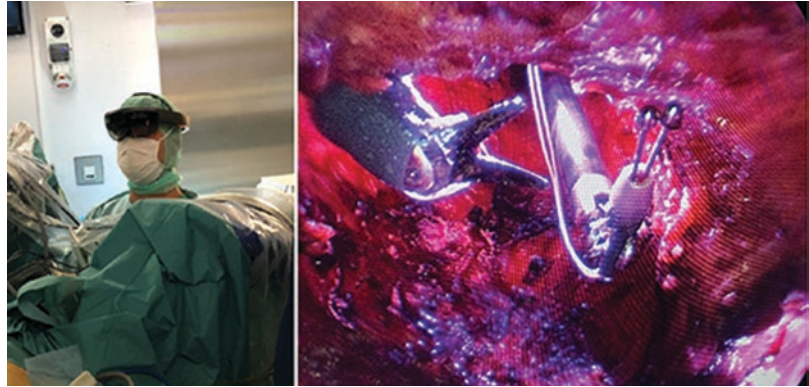


**Fig. 32.2** Left-sided neurovascular bundle (NVB) demonstrated by the proctor and preserved by the participating surgeons (taTME in cadaver courses [15])



**Fig. 32.3** Robotic-guided and transanal neuromapping. Documentation of the innervation with EMG of the internal anal sphincter and manometry of the urinary bladder [17]

**Fig. 32.4** Mixed reality in taTME opens up further possibilities [31]



Mixed reality technology and future developments in the field will facilitate precision in nerve-sparing surgery. Technological advances will improve individualized planning, spatial awareness, navigation, and the simultaneous display of rendezvous maneuvers, neuro-monitoring, and staining results (Fig. 32.4). In addition, better visualization, electrophysiological measurements, postoperative specimen immunostaining, MRI nerve status assessment, and retrospective video analysis can improve quality control procedures to confirm the efficacy of PANP [11, 13, 17, 29–31].

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# Operative Vectors, Anatomic Distortion, and the Inherent Effects of Insufflation

Sam Atallah, Albert M. Wolthuis,  
and André D'Hoore

## Introduction

Prerequisite to taTME is a fundamental surgeon skillset. This typically includes advanced colorectal MIS experience as well as experience with an advanced transanal platform – such as for TAMIS or TEM – especially as applied toward local excision of rectal neoplasia. However, there are important aspects of taTME that must be understood as this operation is not simply a hybrid combination of minimally invasive laparoscopy and TAMIS. One reason for this relates to how the workspace during taTME is created and how this potential space is actualized by the pneumatic forces of insufflation. To some extent, the creation of this space and operation in this modality are more similar to the techniques and viewpoint achieved during totally extraperitoneal endoscopic surgery, such as is the case for inguinal hernia repairs. Thus, taTME radically differs from how workspace and operative field exposure occurs during laparoscopy, whereby transabdominal insufflation almost instantly creates a sustained workspace. Carbon

dioxide insufflation separates fusion planes during taTME pneumatically, thus insufflation itself is a crucial aspect of this complex operation. In this chapter, focus is given to understanding aspects germane to operation within the subperitoneal pelvis, to examining the important aspects related to insufflation, and to the peculiar effects of gas flow observed during the transanal portion of the taTME operation.

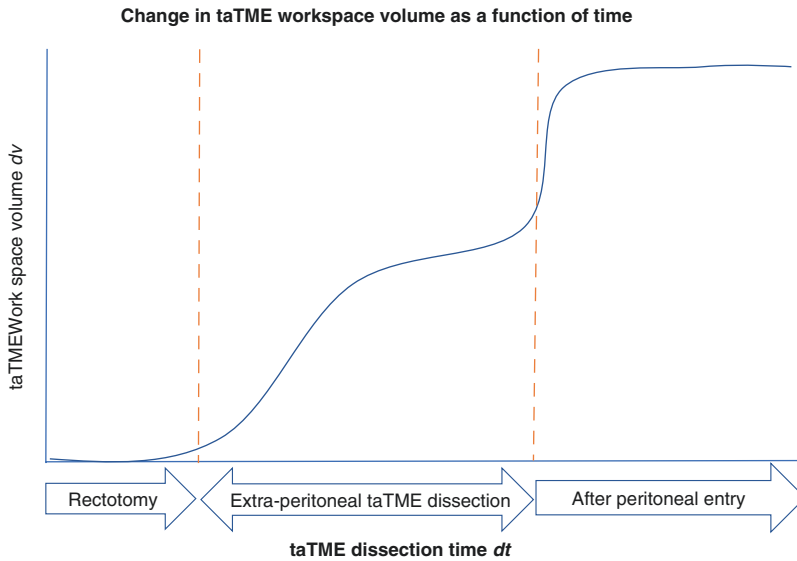
## Operation in the Subperitoneal Space

Commencing with the rectotomy (created after purse-string application) until the point of peritoneal entry during the taTME operation, the dissection is created in an actualized, potential space along the fascial fusion planes which surround the mesorectal envelope circumferentially. This is perhaps one of the most fundamental differences between the so-called *up-to-down* and *down-to-up* approaches to TME. Hence, unlike with laparoscopy where the operative field and workspace are defined immediately upon insufflation of the peritoneal cavity, with taTME (during the down-to-up portion of dissection), the space created is a potential space. This space is gradually developed along embryonic fusion planes by the combination of sharp and gas dissection as the field is actualized. The dissection may or may not proceed along the correct plane,

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**Fig. 33.1** The actualized workspace volume increases as a function of time during the transanal portion of taTME and then can be mathematically expressed as  $\Delta v_{\text{taTME}}/\Delta t_{\text{taTME}}$  or simply  $dv/dt$ , whereby  $\Delta v_{\text{taTME}}$  represents the change in volume and  $\Delta t_{\text{taTME}}$  equates to dissection time. The rate of change in workspace volume (e.g., the viewable surgical field) is not constant and is depen-

dent on the phase of dissection. The subperitoneal workspace is negligible during rectotomy but increases exponentially during taTME dissection. Finally, upon rendezvous with the abdominal cavity, which usually occurs anteriorly along the peritoneal reflection, the abdominopelvic cavity becomes one common space

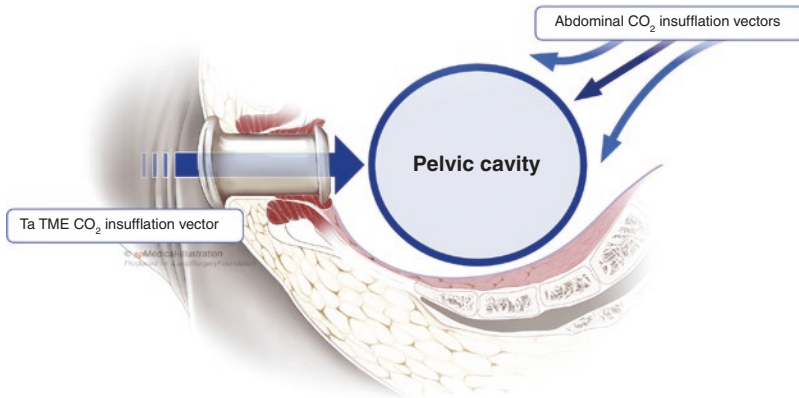
however, and it is well known that with taTME, especially laterally and posteriorly, as the plane is developed by pneumatic dissection, it is possible to actualize deep planes that lie beyond the scope of dissection. When the correct plane is achieved, however, pneumatic dissection augments sharp dissection in the TME plane in accordance to the standards set forth by Professor RJ Heald.

In some regards, actualizing the subperitoneal space during taTME is similar to extraperitoneal surgery – such as for endoscopic totally extraperitoneal hernia repair [1, 2]. However, in those approaches, typically a balloon is used to actualize the potential space prior to proceeding with dissection, creating a constant workspace for the entire procedure. In contradistinction, with taTME, *the workspace volume changes in relation to dissection time* – since this space is not established with balloon dissection but rather with sharp, meticulous dissection in accordance with the principles of TME surgery [3–5]. Thus, the more the dissection progresses, the more the workspace volume (and thus the field of view) increases. Therefore, the change in volume of the

operative field's workspace is a function of time and can be mathematically expressed as  $\Delta v_{\text{taTME}}/\Delta t_{\text{taTME}}$  or simply  $dv/dt$  (Fig. 33.1) [6].

## Operative Vectors

With standard multiport laparoscopy or robotic abdominal surgery, gas flow delivery can be arranged by connecting inflow tubing to any trocar in any quadrant. Most often the choice of which trocar to use is arbitrary, although many surgeons prefer to insufflate through a trocar not occupied by the camera lens as this can increase lens fogging leading to diminished optic clarity. Because of the large volume of the abdominal cavity, however, the *direction* of gas flow into the cavity is generally not clinically relevant. That is, there is no distortion of target anatomy and only symmetric doming of the anterior abdominal wall can be appreciated. However, during taTME, the direction and magnitude of gas flow and the resultant effect on the surgical field during operation, including the effect this imparts on the process of dissection itself, are quite relevant.



**Fig. 33.2** The insufflation “vector” can be thought of as the force of insufflation *together with* its direction. With abdominal minimally invasive surgery, insufflation vectors have no appreciable effect on the operative field and

anatomy, but with taTME, the direction of insufflation has very specific effects on the target anatomy and the fascial envelopes that surround the rectum and mesorectum

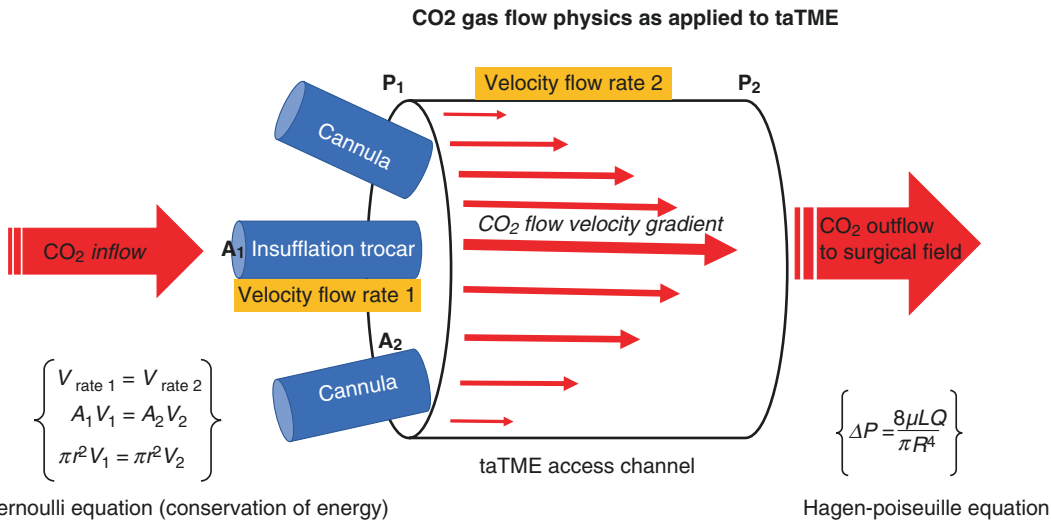
With transanal access, insufflation has a specific direction and specific force or magnitude. In physics, the magnitude of a force *together with* its direction defines a *vector*. Thus the force of CO<sub>2</sub> gas insufflation plus the direction of gas delivery can be defined as an *insufflation vector* [6]. The insufflation vector achieved with taTME (Fig. 33.2) results in a compounded effect that, on the one hand, greatly facilitates sharp dissection by pneumatically delineating surgical planes and maintaining what can be a remarkably pristine operative view; on the other hand, the taTME insufflation vector poses new challenges. Most notable of these challenges are the following: (a) exposure of false planes beyond the TME envelope, (b) lifting and “standing up” of pelvic autonomic nerves, creating a potential for their injury if not recognized, and (c) in the event of pelvic venous bleeding during dissection, introducing a vehicle for CO<sub>2</sub> venous embolization.

## Gas Flow Mechanics

Gas kinetics and the physics of Newtonian fluid dynamics within a closed system have been well studied, but not as it pertains to insufflation systems and the effect such systems impart on human anatomy during operation. Thus, little is known about how precisely Newtonian fluids

(such as exogenous CO<sub>2</sub>) effect anatomy, and much of what can be learned is based on observational data and known physical principles of continuum mechanics [7–11].

It is known that, because the insufflated gas is delivered via a closed cylinder (the transanal platform’s access channel), that gas flow is governed by laws which define fluid movement in such a cylinder. In particular, there are two important laws pertaining to gas flow. First, the Hagen-Poiseuille Law [12] defines the rate of flow of CO<sub>2</sub> as it is transmitted through the taTME access channel. Essentially, this states that there is a variable rate of flow through the channel, whereby the highest flow velocity is observed at the center of the access channel, while the lowest flow velocity is at the periphery. Thus, there exists a velocity gradient which effects the target anatomy in a specific way. Based on observational data, this tends to create a concavity of the mesorectal envelope during the posterior taTME dissection, thus contributing the classic anatomic distortion observed. It also produces a central “forward compression” of the mobilized anatomy. Second, although of lesser importance, Bernoulli’s Law [13] states that energy is conserved, and as CO<sub>2</sub> gas is transmitted from the narrow radius of the insufflation tubing and trocar to the much larger diameter access channel, the overall gas rate of flow is constant, although



**Fig. 33.3** The principles of fluid mechanics that govern CO<sub>2</sub> flow through the taTME apparatus are illustrated. Conceptually, two laws of physics should be understood. First, the Hagen-Poiseuille Law states that pressure diminishes along the forward direction of gas flow, thereby creating a pressure gradient,  $\Delta P$  ( $P_1 - P_2$ ). Furthermore, this law states that gas flow velocity is highest at the center of the cylinder and lowest at its periphery, thereby creating a velocity gradient. Bernoulli's Law is synonymous with the Law of Conservation of Energy, and thus velocity flow rate is constant, as gas flows faster in a smaller diameter cylinder (such as a trocar or insufflation

tubing) and slower in a large cylinder such as the taTME's access channel, but the overall flow rate remains the same due to the larger cross-sectional area of the apparatus.  $\Delta P$  pressure differential;  $P_1$ , pressure at the outer rim of the access channel;  $P_2$ , pressure at the end of the access channel near the surgical field;  $\mu$ , dynamic (shear) viscosity coefficient;  $L$ , cylinder length;  $Q$ , volumetric flow rate;  $R$ , radius of cylinder;  $A_1$ , trocar cross-sectional surface area;  $A_2$ , taTME access channel's cross-sectional surface area;  $V_1$ , velocity of CO<sub>2</sub> within trocar;  $V_2$ , velocity of CO<sub>2</sub> within taTME access channel

the velocity is decreased (Fig. 33.3). Understanding gas kinetics helps one to understand the observed pneumatic effects and the classic anatomic distortion (see later) that is often evident during taTME dissection.

## Cyclic Billowing

Since the introduction of TAMIS for local excision via endoluminal surgery [14] and subsequent use of this technique for taTME [15–19], an important operative limitation has been overcome. Initially, both TAMIS and TAMIS-based taTME relied on laparoscopic insufflation systems designed for abdominal access surgery, and not transanal surgery or limited space, subperitoneal pelvic surgery. This was at the time believed to be an advantage of the technique of TAMIS and taTME via TAMIS, because no specialized

equipment was required [14–16] (as is the case with rigid platforms, which have unique and specifically designed insufflation systems as component of the apparatus). While currently TAMIS and even taTME can be performed with standard laparoscopic insufflators, when available alternate modes of insufflation are often advocated to resolve the nuisance problem of cyclic billowing and smoke accumulation with loss of visual field stability.

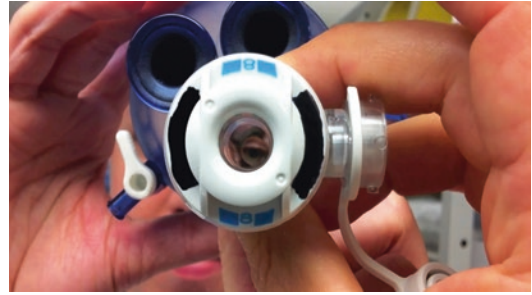
Cyclic billowing is defined as the sudden, periodic collapse of the workspace – including the lumen of the rectum in the case of TAMIS and the actualized subperitoneal workspace of the pelvis during taTME. Cyclic billowing is sometimes referred to as “pelvic breathing” due to the rhythmic collapse of operative workspace during transanal surgery. Advanced transanal surgery such as TAMIS and taTME mandates a sustained pneumatic dissection that is not volatile and is

not subject to collapse as this can dramatically limit the ability to continue with safe dissection.

Traditional insufflators were designed to dissend the relatively large volume of the peritoneal cavity. Such insufflation technology was actually based on a quite rudimentary mechanical model. In simple terms, the system delivers CO<sub>2</sub> gas in a pulsed fashion via a singular disposable insufflation tubing. The laparoscopic insufflator then senses the pressure via sampling and delivers or ceases to deliver gas in response to an arbitrary set pressure. Thus, when the pressure in the insufflated cavity falls to below the set level, gas is actively pumped into the cavity until the designated pressure set point is reestablished. Minor fluctuations in pressure do not exhibit an appreciable effect on larger spaces such as the abdominal cavity and insufflation through this modality is quite reliable. However, minor fluctuations in pressure in a small operative field can result in collapse of the workspace – before the insufflation system can respond to the change, thereby resulting in noticeable loss of the operative field of view (since this field is essentially created by pneumatic distension which must remain stable). Furthermore, the restricted view is also limited as plumes of smoke often accumulate as there is poor smoke dissipation, since the smoke is not able to be distributed over the larger volume of the peritoneal cavity.

Most insufflators for laparoscopy have not evolved since their inception, and have essentially remained unchanged in their technology over the decades. Existing systems had worked quite well for laparoscopy and given there had not been any incentive to alter this technology it remained perfectly well suited for most rudimentary laparoscopic procedures. However, the increasing use of complex laparoscopy and especially robotics in MIS leads to refinements that would serendipitously benefit transanal platforms and especially TAMIS-based procedures.

Insufflation system that had been developed to improve clarity with abdominal (and especially robotic) minimally invasive surgery emerged. In particular, one system (AirSEAL® iFS) was developed (originally by SurgiQuest and currently, ConMed, Inc.) with the objective of utiliz-



**Fig. 33.4** The faceplate of the TAMIS port commonly used for taTME is shown. One of the cannulas has been replaced by an 8 mm valveless trocar (AirSEAL®), which maintains a pressure barrier seal pneumatically rather than with the trapdoor design that typically smudges the lens during camera lens entry. As can be seen, the trocar is completely transparent along its long access

ing a valveless trocar system that would create an invisible pressure barrier [20] so as to prevent smudging of the camera's lens with repeated trocar withdraws and reinsertions – a known problem with trapdoor style trocars (Fig. 33.4). The system also was designed to maintain stable pneumatics and to address the problem of smoke accumulation. Specifically, by adapting a specialized, no-valve trocar to triple lumen insufflation tubing, (a) smoke evacuation, (b) pressure monitoring, and (c) CO<sub>2</sub> delivery could be separately managed. While these were considered important advantages for advanced robotic and laparoscopic abdominal surgery [21, 22], it should be underscored that the AirSEAL® system was not designed for transanal surgery per se, nor was the system designed to rectify the problem of cyclic billowing with TAMIS. Instead, like TAMIS itself, the advantage of AirSEAL® iFS for transanal access in resolving the issue of pelvic breathing and smoke accumulation was realized completely by accident [23, 24].

Today, AirSEAL® iFS is the commonest insufflation system preferred by experts for use in conjunction with the TAMIS platform for both local excision and taTME to resolve the issue of cyclic billowing, which is otherwise considered to be one of the most significant intraoperative limitations based on European Registry data [25]. However, AirSEAL® iFS may or not be available, and thus other substitutes can be considered, including a



hand-fashioned apparatus, whereby a surgical sterile glove is used as an interposition in the CO<sub>2</sub> tubing [26], providing a reservoir that serves as a proxy for operative space, thereby minimizing the effect of billowing, but not necessarily smoke accumulation. This makeshift solution is a useful construct and represents an important low-cost alternative to the valveless trocar system. Furthermore, in 2018, the manufacturer of the GelPOINT Path Transanal Access Platform (Applied Medical, Inc.) began including a reservoir bag (at no additional cost) which reduces billowing in the same manner [27]. There are other options that have recently become available, including PneumoClear® Insufflation (Stryker, Inc. Kalamazoo, MI, USA) with TAMIS mode that is designed to achieve a more stable pneumoretum and pneumopelvis than standard laparoscopic insufflators.

The AirSEAL® iFS system is often incorrectly classified as a “high-flow” insufflator. In actuality, however, in AirSEAL Mode, the typical rate of flow during taTME is quite low at 8 L/min, and pressure limits are set to ~8–12 mmHg. The system is designed to respond instantly to pressure changes by increasing the rate of flow. For example, if plumes of smoke or blood require ancillary suctioning to clear the field, the process of suctioning will result in a quite sudden decrease in the pressure which can threaten the stability of the pneumatic distention essential in maintaining the operative field of view. To compensate for this, the AirSEAL® iFS system is designed to increase flow to up to 40 L/min transiently. This rapid, real-time response is one of the important factors that allows for TAMIS and taTME to be performed with a stable operative view that has minimal billowing. Cyclic billowing is also greatly dampened (if not completely eliminated) by the constant sampling of gas pressure by this system.

Even with AirSEAL® iFS and other advanced platforms, during taTME at the point of peritoneal entry, there is potential for loss of the operative field of view as pneumatic distention diminishes when the taTME insufflation pressure “competes” with the abdominal insufflation pressure. With the two-team approach, laparoscopic

access and insufflation are present, and pressure settings should always be slightly less for abdominal insufflation relative to taTME insufflation. This is to maintain a *positive down-to-up pressure gradient*, otherwise the actualized workspace will collapse. This is true even if there is only one AirSEAL® iFS system in use, and a traditional laparoscopic insufflator is being used to insufflate the abdominal cavity. In such a setting, cyclic billowing can occur at the point of peritoneal entry. In general, the peritoneal entry, which is most commonly achieved along the anterior reflection (as this is the shortest distance to the abdominal cavity) should be the last major step in the taTME dissection. After this step, even with correct pressure settings, a diminished operative view can often be observed.

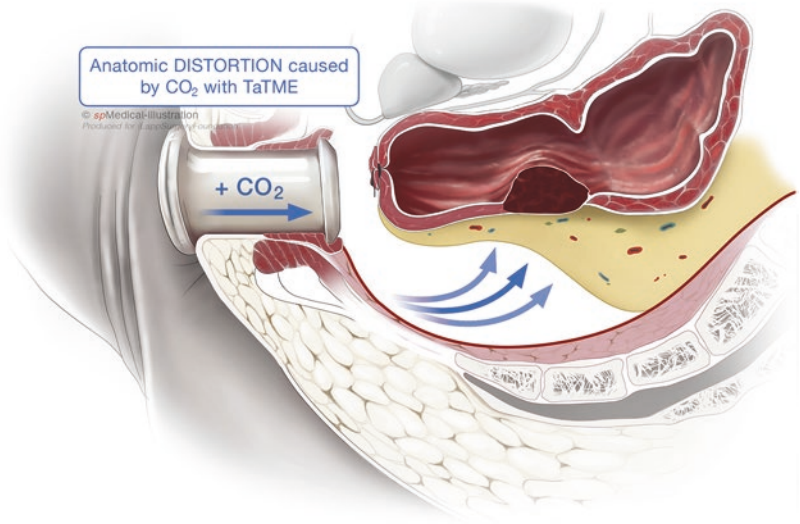
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## Anatomic Distortion

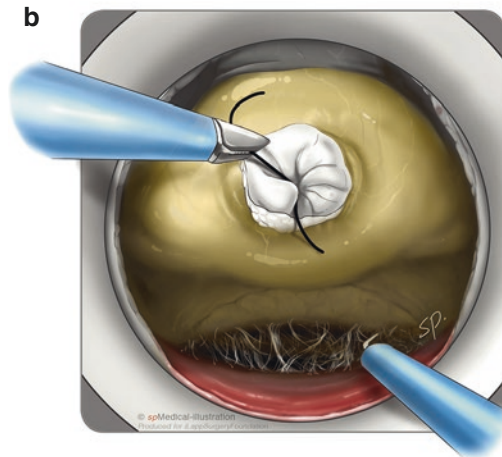
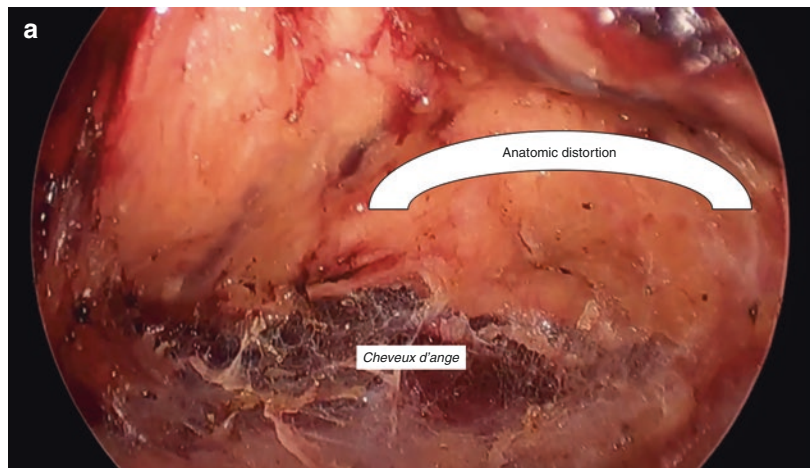
With abdominal minimally invasive surgery (MIS), whether laparoscopic or robotic, the insufflation applied does not substantially distort the native viscera as the insufflation is evenly distributed over a large area, and the only noticeable distortion is the symmetrical doming of the anterior abdominal wall. However, during the transanal portion of taTME, anatomical distortion can be quite pronounced. This occurs as the operative insufflation vector exerts an effect which aids in establishing the taTME dissection plane but, at the same time, creates gross anatomic distortion as the mesorectal envelope and rectum proper become mobilized (Fig. 33.5) [6]. Classically, this produces a concavity of the mesorectal envelope and also a forward compression of the entire rectum and mesentery that can sometimes render the anatomy unrecognizable. During the posterior dissection, the mesenteric distortion creates a central concavity with a ventral bend to the mesenteric envelope (Fig. 33.6a, b). As the lateral and anterior dissections are completed, the distortion compresses the entire rectum and its mesentery cephalad.

Because of the distortive effects imparted by operative vectors, the mesentery does not typically appear elliptical, and its completeness

**Fig. 33.5** Gas flow for taTME is delivered via transanal access. This insufflation vector matures planes naturally and is considered a fundamental component of the operation, greatly assisting with sharp dissection and with actualizing the subperitoneal workspace. However, as the planes develop, especially posteriorly, the rectum and mesentery exhibit a characteristic gross anatomic distortion, as illustrated



**Fig. 33.6 (a)** The posterior plane of dissection during taTME is shown with separation between the angel hair (cheveux d'ange) and the mesenteric envelope correctly established. Clearly shown is a concavity of the dorsal mesentery which represents gross anatomic distortion that occurs due to the insufflation vector required during taTME. On occasion, such anatomic distortion can challenge the surgeon's understanding of the operative anatomy, and this may lead to wrong-plane surgery. **(b)** An artist's rendition of anatomic distortion illustrating the classic concavity of the mesorectal envelope

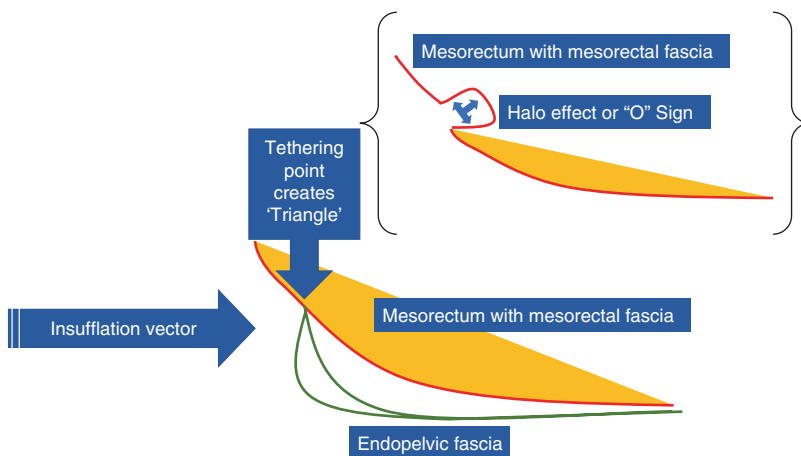


cannot be assessed until the specimen is extracted. This implies that the operator must instead rely on the interpretation of the fusion planes and must understand and appreciate the typical appearance of anatomic distortion during the transanal portion of the operation. This is one reason that taTME dissection presents unfamiliar anatomy to the novice surgeon and why significant experience is required to gain proficiency with this challenging technique.

## Triangles and Halos

As a result of pneumatic dissection, release along natural anatomical planes of fusion is observed, but occasionally there are tethering points which are adherent and must be released through deliberate sharp dissection. As the tethered point tents the fascia in the shape of a triangle, this is often recognizable as such, and thus fascial plane “triangles” can be an important clue as to the location of the correct plane. Such triangles occur in all aspects of surgical dissection, particularly when

tissue is placed on stretch, and when a lead point has not been released. Such phenomena are not infrequently encountered during dissection with laparoscopic and robotic colorectal surgery. Thus, triangles from tethering of unreleased points are not unique to taTME, but tend to be quite pronounced with this operation in particular. When the point of tethering (usually the ventral tip of the triangle) is not recognized and the dissection proceeds dorsal to this point, the fascia is violated, and it results in disruption of the fascial plane. Because the pneumatic force is uniformly distributed at this point of violation, the appearance of a linear fascial disruption will take on the shape of a circle and has thus been termed the “halo sign” [28]. Triangles and halos are important signs in maintaining plane recognition during taTME. Due to the unique fascial layering patterns, entry into false planes is quite typical during the natural course of taTME dissection. Especially along the posterior dissection, it is critical that the triangle and halo phenomena are recognized and appropriately managed (Fig. 33.7).



**Fig. 33.7** Triangles and halos are pneumatic phenomena observed during all minimally invasive surgery, but are particularly important with taTME. As originally described by Bernardi and colleagues, triangles are created when a tethering point of a fascial plane has not been released by sharp dissection. Such a point must be recognized and dissected free, thereby releasing the adherent fascia. This is of particular importance along the posterior dissection where the endopelvic fascia tends to be adher-

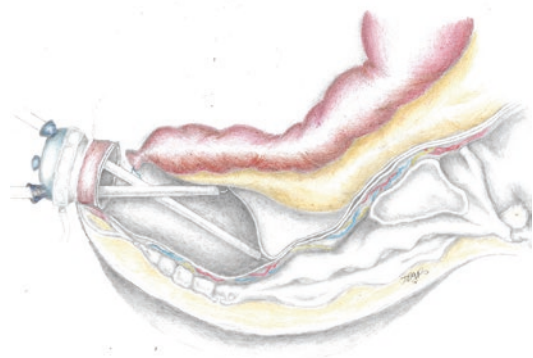
ent, and when the mesentery is projected anteriorly by the insufflation vector, the tethered plane “stands up” in the shape of a triangle. If this or any fascial plane is violated at a point other than its fusion point, a linear cut along the fascia takes on the appearance of a halo or circle since the pneumatic force evenly distributes tension. Triangles and halos are important clues, and taTME surgeons must remain vigilant, making plane adjustments accordingly

## False Planes

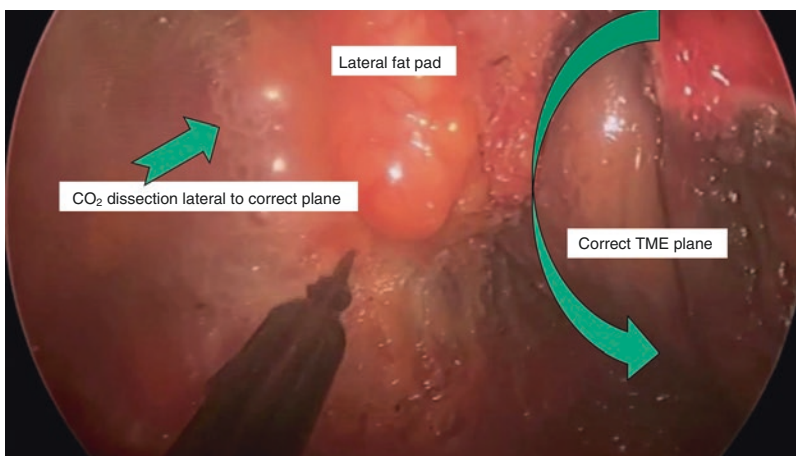
The insufflation vector of taTME affects the anterior dissection differently than it does to the posterior dissection, and this is one of the most fundamental principles to understand that is quite unique to this operative approach. For the anterior dissection, there is no appreciable difference in the opening of fascial planes, and operative progress is similar to the standard, up-to-down approach. This is because there is no directional layering of fascia anteriorly. In contradistinction, during the posterior and lateral dissections, there is a specific orientation to the extra-mesorectal fascia, which layers in such a way that when the dissection is carried out from below, fascial planes are pneumatically opened, as they tend to “stand up” during the taTME dissection (Fig. 33.8). Thus, during the posterior and to some degree the lateral dissection, the planes beyond the mesenteric envelope are exposed as dissection proceeds “against the grain” of fascial layering. The most pronounced effect of this is observed along (a) Waldeyer’s fascia, (b) the lateral fat pillars (Fig. 33.9), and (c) the inferior hypogastric roots of S2 and S3 autonomic nerve plexi (Fig. 33.10).

Importantly, the tapered distal mesenteric envelope can be dissected by airflow jets causing

the mesentery itself, in some instances, to take on an areolar appearance that can be confused for a plane of dissection. However, this often leads to one of the most common errors in taTME surgery, namely, intramesorectal dissection and violation of the mesenteric envelope with consequent oncologic compromise (when the operation is per-



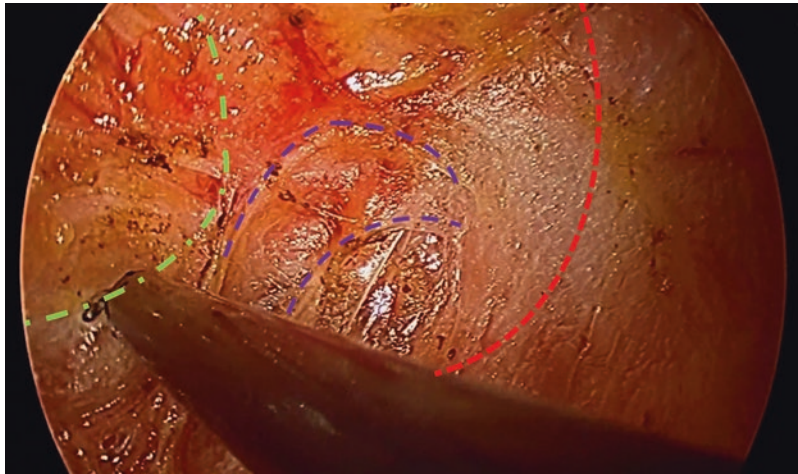
**Fig. 33.8** The transanal approach to taTME with the applied insufflation vector from the perineum tends to “stand up” fascial planes that may lead a surgeon to enter a plane that is too deep. Here shown is the standing up of Waldeyer’s fascia. The correct plane is to proceed ventrally along the mesorectal envelop, but a more dorsal plane deep to the endopelvic fascia is often incorrectly selected. The standing up of planes is not typical of the abdominal approach to TME and is a characteristic specific to taTME



**Fig. 33.9** Between 6 and 8 cm from the anal verge at the 3 and 9 o’clock position lie avascular fat pads that are separate from the TME plane and do not follow its elliptical shape (curved arrow). Pneumatic dissection due to the

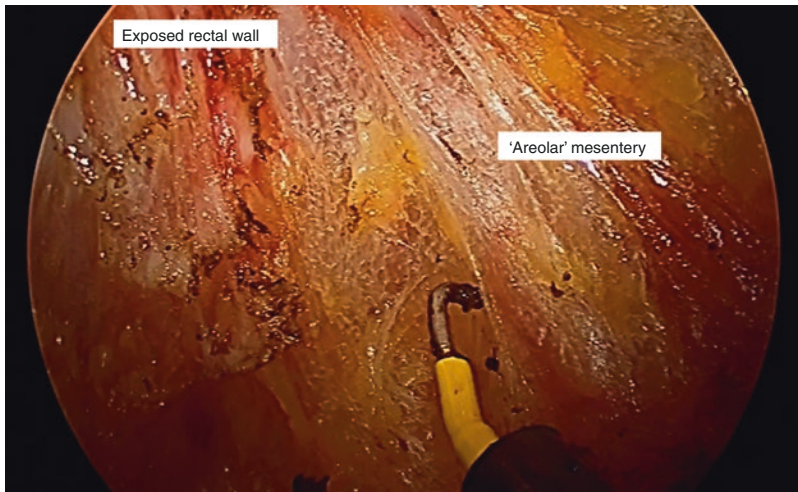
insufflation vectors creates a misleading, areolar plane of dissection that can incorrectly direct the surgeon to this lateral plane, which often results in sacral bleeding





**Fig. 33.10** Posterior taTME dissection is shown, whereby dashed lines in green delineate the correct plane of dissection, while a dashed red line overlies a lateral, areolar area that is an incorrect plane. Between the correct and incorrect plane lie the inferior hypogastric nerve roots from the S2 and S3 tributaries. These nerve roots, denoted

by dashed purple lines, “stand up” in a vertical orientation, and they often take on the shape of a bow or shoe strings. It is imperative that taTME surgeons recognize these roots and are not drawn to more lateral areolar planes which would result in significant autonomic nerve injury



**Fig. 33.11** It is classically stated by RJ Heald that the correct TME plane is the “innermost dissectable plane.” However, insufflation vectors can dissect the mesentery itself, giving it the appearance of being correct. Here, the posterior TME plane is being dissected. Note that the

mesentery appears quite areolar and thus dissectable. However, in fact, it is not and instead dissection of this areolar mesentery has exposed the rectal muscle tube, which is clearly visible in this video still frame

formed for cancer). The innermost dissectable plane – as described by RJ Heald – can thus give a *false* appearance of having yet a more inner dissectable plane as the mesenteric envelope presents an areolar appearance due to constant-pressure pneumatics, delivered from the taTME vantage

point. In surgical practice, this error tends to occur in the initial posterior dissection. It happens not only because of the mesentery itself becomes areolar (Fig. 33.11), but because the mesenteric envelope itself may have a steep posterior slope along the sacrum requiring compulsory steep



angulation of the instruments during this portion of the operation to accommodate the patient's pelvic geometry [29].

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## CO<sub>2</sub> Entrainment and Embolization

CO<sub>2</sub> embolization during laparoscopy can be lethal [30, 31]. While most abdominal laparoscopic operations present at least some risk of CO<sub>2</sub> venous entrainment and subsequent air embolization, this risk is generally nominal, and the incidence of clinically relevant air embolization during such procedures is exceedingly rare [32]. However, one of the first small series to report outcomes with taTME by Rouanet et al. included CO<sub>2</sub> embolism as a morbidity [33], and although unreported in the initial registry data series [34], it has now become apparent that this risk may be moderately higher than with conventional laparoscopy and at the time of this writing is actively being studied [35]. The most likely mechanism for this is exogenous gas entrainment into low-pressure venous vessels which may become injured during the process of taTME dissection [6]. This may be further exacerbated by the type of insufflator being used and the insufflator's operational mode; however, this remains an area of ongoing investigation.

When the pressure of the venous system is less than the pneumatic pressure of insufflation, insufflated CO<sub>2</sub> gas enters into the venous system where it can result in cardiovascular collapse as it creates a right ventricular airlock. In the observed events, the venous bleeding is not excessive and tends to tamponade by the force of pneumatic insufflation. Because CO<sub>2</sub> entrainment results when the pressure exceeds venous pressure, it is strongly recommended that insufflation pressure be set to less than normal venous pressure and to the lowest possible setting which allows for maintenance of the visual field – particularly when constant flow systems such as AirSEAL® iFS are employed. Furthermore, it should be noted that venous pressure may be decreased by steep Trendelenburg positioning while flow increases by gravity and via respiration. These are factors which can exacerbate the rate of CO<sub>2</sub> gas entrainment into lacerated vessels.

Paroxysmal and otherwise unexplained alteration in end-tidal CO<sub>2</sub> (ET-CO<sub>2</sub>) should immediately alert the taTME surgeon and anesthesiologist to the possibility of air embolization. This sudden change in ET-CO<sub>2</sub> is usually the sentinel event detected, heralding the onset of cardiovascular compromise. In most instances, ET-CO<sub>2</sub> *decreases*, but an increase in this parameter has also been observed during air embolization. Treatment of CO<sub>2</sub> embolization requires rapid intervention and mandates that surgeon and anesthesiologist work in concert to rectify the problem. These steps include the immediate cessation of CO<sub>2</sub> gas delivery, flooding of the operative field with saline, or gauze soaked in saline to prevent further gas entrainment, while controlling ongoing venous hemorrhage. Simultaneously, the anesthesiologist should perform Durant's maneuver – that is, maintain moderate Trendelenburg (head lower than level of feet) while placing the patient in left lateral decubitus position (left-side rotation of the operating table); this is believed to decrease or at least limit gas from traveling through the right side of the heart into the pulmonary arterial tree where right ventricular outflow can become obstructed due to an air lock. Furthermore, increasing positive end-expiratory pressure (PEEP) can decrease the pressure gradient between the lacerated venous vessels and the central cardiovascular system, thereby limiting the potential of further gas entrainment [36, 37].

Investigation into understanding the process of gas embolization during taTME remains an area of active research. Alternative exogenous gases, unfortunately, are not currently feasible for use with taTME. For example, helium, although essentially inert with no pharmacologic effects and although noncombustible, is relatively insoluble in blood and more likely to result in embolization [38], leaving exogenous CO<sub>2</sub> gas as the only practical option at present.

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## CO<sub>2</sub> Aerosolization of Bacteria and Tumor Cells

Among the pragmatic differences between taTME and other sphincter-preserving, anterior operations for extirpation of the rectum is that an

intentional rectal wall violation (rectotomy distal to the purse string) is performed [6, 29, 39]. Theoretically, bacteria and even live exfoliated tumor cells can shed [40–45], thereby seeding the pelvis during taTME. This could be related to the following factors: (a) poor mechanical bowel preparation, or, in the case of invasive cancer, observation of a friable tumor; (b) improper purse string, or purse string/rectal wall violation during taTME dissection; and (c) the aerosolization of cells by the force of CO<sub>2</sub> insufflation during the process of dissection. The theoretical implications are, in the immediate postoperative time-frame, pelvic sepsis and abscess formation can ensue, and perhaps more importantly, in the long term, an increased risk of local recurrence due to tumor cell implantation may be observed. It should be noted that the latter has not been realized by clinically available data, which, it should be cautioned, only includes short- and midterm follow-up.

Due to the complexity of metastasis, tumor cell deposit volume, and the requirements to successfully implant a viable metastatic focus, it is probable that even live exfoliated tumor cells that seed the resection bed do not result in cancer recurrence in most instances. In contradistinction, bacterial cells are easily able to thrive in the abdominopelvic cavity and probably require a lower inoculum to result in clinically relevant infection. This is particularly true when the inoculum is a mixed flora of anaerobes and facultative bacteria which exhibit a synergistic effect in sepsis [46, 47].

To minimize the risk of cell spillage, the purse string should be tightly and securely fastened and tested prior to rectotomy by insufflation. Small gaps and imperfections should be oversewn. Prior to and after purse-string application, most experts recommend antiseptic-tumoricidal irrigation [28]. Even meticulous care may not fully prevent bacterial and (potentially) tumor cell spillage into the operative space as it is developed, in part, by pneumatic dissection. In 2015 Velthuis et al. examined intra-abdominal contamination of bacteria during TAMIS-based taTME [48]. In this study, 23 patients underwent the operation with povidone iodine rinsing of the

rectal lumen before and after purse-string application and prior to commencing the transanal dissection. Next, during the course of taTME dissection, cultures were obtained from the sterile, laparoscopic ports from the four quadrants of the pelvis, and later the patients were followed clinically. The data revealed that 39% had positive cultures for enteric microbes (e.g., *Escherichia Coli*). Furthermore, 17% of patients had localized infections within the pelvis managed nonoperatively with systemic antibiotics with or without percutaneous drainage. These data suggest that despite irrigation, contamination of the sterile abdominopelvic cavity occurs not infrequently during taTME and pneumatic insufflation with aerosolization of microbes may be a contributing factor in some circumstances, although the exact mechanism is not known. A powerful tool in the assessment and safe implementation of taTME has been the registry data, which at the time of this writing includes over 3000 cases which have been entered into the European taTME Registry [49]. These data extracted from this invaluable resource are expected to greatly enrich our understanding of this emerging operation in the coming years.

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# Total Hindgut Mesenteric Mobilization for taTME

# 34

J. Calvin Coffey and Rishabh Sehgal

## Introduction

The hindgut refers to the intestine distal to the junction between the second and third part of the transverse colon. Hindgut mobilization refers to detachment of the hindgut from its surrounding attachments. This alone is not enough to enable its resection. To enable resection, the mesentery that is contiguous with the hindgut must be also detached, and any analysis of good-quality colorectal resections will show that most operative time is spent in mobilizing the mesentery [1–5]. In contrast, division and reconstitution of the intestine can be rapidly achieved, once the mesentery has been adequately released.

The importance of the mesentery in hindgut mobilization stems from the embryological development of both mesentery and intestine. During development, the mesentery arises first, and the intestinal tube gradually takes shape at the mesenteric periphery, receiving cellular and connective tissue inputs from the mesentery. Once the mesentery and intestine have assumed their final position within the abdominal cavity,

the mesentery becomes attached to the posterior abdominal wall. This is mediated by the peritoneal reflection at the periphery of the digestive system, by Toldt's fascia between mesentery and posterior abdominal wall and by vascular points of connectivity such as the inferior mesenteric artery [6, 7].

Hindgut mobilization requires that the mechanisms by which the mesentery and intestine are held in position are disrupted. The peritoneum must be incised and the plane between the mesentery and fascia disrupted by separating both [8–11].

This chapter contains an explanation of the anatomical and surgical foundation underpinning total hindgut mobilization during taTME. Fortunately, the anatomical basis is the same for this as it is for visceral surgery everywhere from the esophagogastric to the anorectal junction, and so the same anatomical principles apply throughout. This means the technical requirements are the same at all levels from transverse mesocolon, through splenic flexure, left mesocolon, mesosigmoid and mesorectum.

The following will commence with a brief overview of the development of the technique by which the hindgut is mobilized for taTME. It is followed by a detailed description of the anatomical basis of the technique. Some references will be made to the embryological development of the hindgut, but a detailed description of that aspect is beyond the scope of this chapter. The chapter

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will then include a description of the surgical technique involved followed by a summary of the current status of different technical platforms.

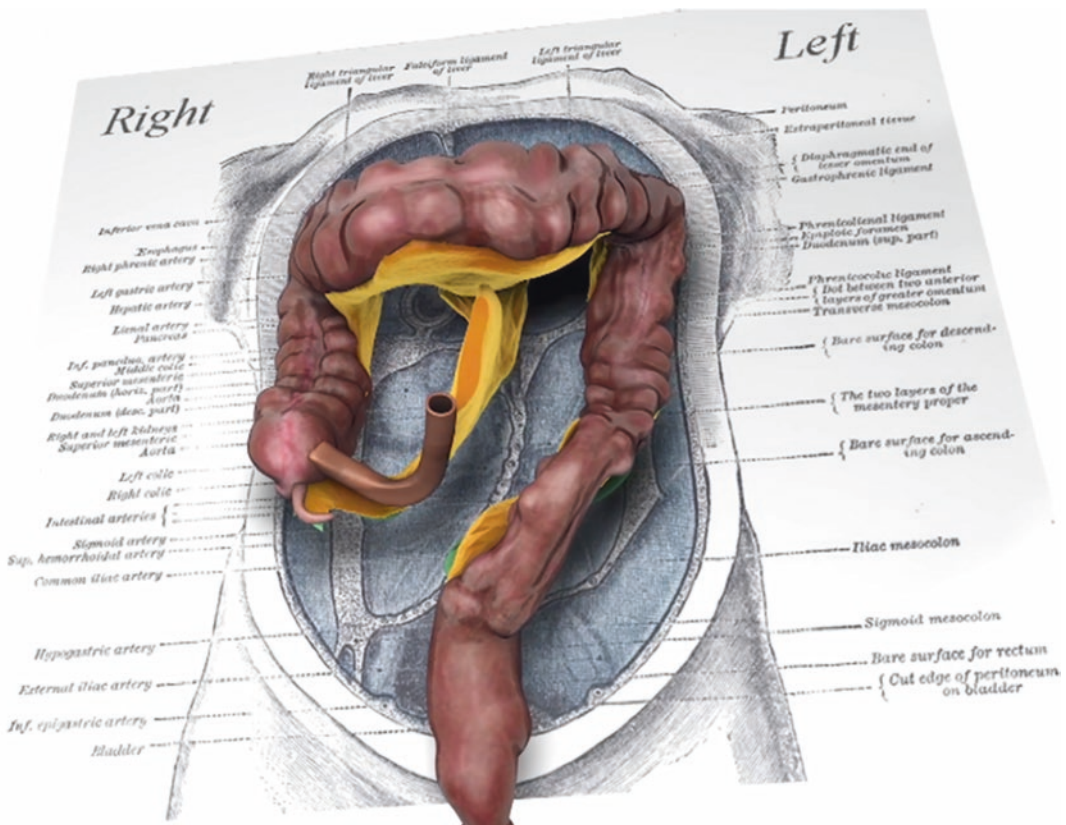
## History

Until recently, mesenteric anatomy was considered complex. As the anatomy of the peritoneum is determined by the mesentery, it follows that peritoneal anatomy was also considered complex [12–14]. The main reason for this is that the mesentery was described as being made up of multiple separate regions (or “mesenteries”) (Fig. 34.1). This dogma dominated almost all anatomical, surgical, radiological and other appraisals of mesenteric anatomy [13, 15]. As the mesentery is a pivotal structure for the intestinal

surgeon, it follows that technical descriptions related to the mesentery, the peritoneum and underlying fascia, lacked a formal anatomical foundation.

Mesenteric mobilization was dogmatically summarized along the following lines. The White Line of Toldt (if present) was identified and used as a landmark at which to commence division of the peritoneum. The mesentery was then “stripped” back to the midline, in order to facilitate division of the vessels within it. The mesentery was then divided up to the intestine, which in turn was divided [16–20].

Most intestinal surgeons on both sides of the Atlantic were long aware of the importance of mesenteric mobilization. Jamieson and Dobson, in the United Kingdom, emphasised this as far back as 1909 [14, 21]. In 1942 Congdon et al.



**Fig. 34.1** Depiction of classic model of mesenteric and intestinal anatomy. According to this model, multiple mesenteries attached directly to the posterior abdominal

wall. A mesentery was not normally found associated with the ascending and descending colon

emphasised the importance of the mesentery in saying that American surgeons generally got into a particular plane and mobilized along this, with minimal blood loss [22]. Still the anatomical foundation remained unchanged in reference literature (Fig. 34.1).

The importance of the mesenteric basis of oncological surgery was identified by RJ Heald in 1982 [23–25]. Heald spent a considerable amount of time convincing the surgical community about the importance of mesenteric, fascial and peritoneal anatomy, in describing the technique which he called total mesorectal excision [26–33]. This coincided with the emergence of laparoscopic means of conducting intestinal surgery. With this, surgeons were afforded a 20-fold magnification of anatomical landmarks and high resolution imaging of these. The new degree of separation between surgeon and tissues (i.e. surgeons no longer directly held tissue) meant their anatomical approach had to be based on an accurate model. While this was the case, the details of one such model remained elusive and, in fact, were largely ignored. Surgeons learned how particular patterns of activities permitted good-quality mesenteric-based surgery, without having an anatomical correlate for these.

In 2012 our group clarified the anatomy of the mesentery [34]. We showed that it is a continuous structure from the duodenojejunal flexure to

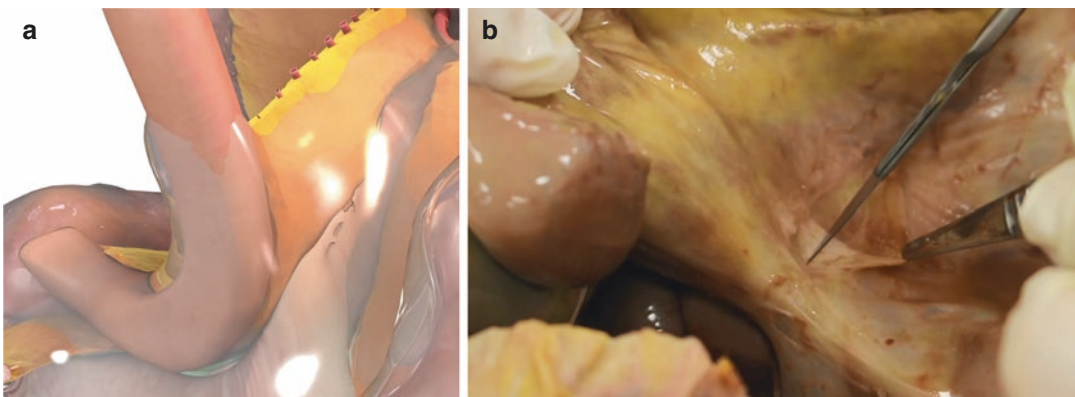
anorectal junction [1, 5, 12, 15, 34–40]. This was followed by an update in *Gray's Anatomy*, thereby reversing over 150 years of dogma relating to the attachment of the small intestinal mesentery [41].

The original quote from the textbook that would become *Gray's Anatomy* (circa 1858) stated:

“It's root, the part connected with the vertebral column, is narrow, about six inches in length, and directed obliquely from the left side of the second lumbar vertebra to the right sacroiliac symphysis.” [42] The updated description in the 41st edition of *Gray's Anatomy* now states:

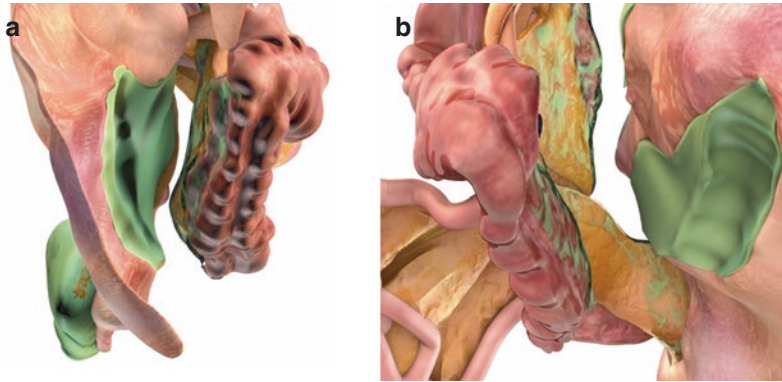
The mesocolon extends along the entire length of the colon and is continuous with the small bowel mesentery proximally and the mesorectum distally... [43].

Mesenteric continuity is a simple property with major implications. These are increasingly emerging as the systematic characterization of the mesentery gathers momentum. For example, it is now recognized that the mesentery is not simply a double fold of peritoneum that holds the intestine in place but rather a collection of tissues that maintains all abdominal digestive organs in position and in continuity with other systems. Once the mesenteric frame and associated organs adopt their final position, the peritoneal reflection develops around the digestive system to hold all in position (Fig. 34.2). In addition, certain regions of the mesentery are anchored to the posterior



**Fig. 34.2** The peritoneal reflection: (a) digital depiction of the reflection where the small intestinal mesentery reaches the posterior abdominal wall and continues as the right mesocolon. The reflection is the translucent membrane of peritoneum that bridges the gap between the

posterior abdominal wall and the mesentery. (b) Similar view to that presented in (a) of the reflection where the small intestinal mesentery continues laterally as the right mesocolon. The reflection has been partially divided



**Fig. 34.3** Toldt's fascia. The fascia has been coloured green. (a) Image demonstrating Toldt's fascia after the right colon and mesocolon have been detached from the posterior abdominal wall via mesofascial separation. (b)

Image demonstrating Toldt's fascia after the left colon and mesocolon have been detached from the posterior abdominal wall via mesofascial separation

abdominal wall, with Toldt's fascia interposed between both (Fig. 34.3) [44, 45].

Perhaps the most important implication of mesenteric continuity is that surgeons can formally depart from the peritoneal-based model of surgical anatomy and adopt a mesenteric-based and more accurate model. It is not surprising, that an appraisal of the technical approach to hindgut mobilization will reveal that the surgical community had long ago adopted the mesenteric model over the peritoneal one.

## Nomenclature

Any textual description of a surgical activity (i.e. taTME with its multiple operative steps) requires a set of specialized terms. For example, division of the peritoneal reflection is called *peritonotomy*. Separation of the mesentery from the underlying fascia is called *mesofascial separation* [37, 38, 46–53].

As the terms describe the surgical disruption of anatomy, they must be anatomical in their derivation and meaning. This in turn requires that the anatomical foundation on which they are based must be accurate.

Such a set of terms was lacking until recently, due largely to the erroneous classical model of mesenteric and peritoneal anatomy [5, 13, 15, 38]. Clarification of mesenteric and peritoneal anatomy has meant that a set of anatomically accurate and sensible terms can be generated. Examples are those described above (i.e. *peritonotomy* and *mesofascial separation*).

The terms routinely used throughout the rest of this chapter are defined in the next section. While these may not be widely used throughout the rest of this book, they are increasing in general and international adoption [5, 13, 15, 47, 54]. The set of terms is a utility of considerable importance as it enables authors and surgeons to accurately describe a technical activity. In addition, the components of the set are intuitive, which further improves the ability of the reader to understand the concepts described, by providing detail in an entirely anatomic-based manner. Since any operation is made up of multiple individual activities happening either in sequence or in tandem, appropriate terminology enables a comprehensive description of hindgut mobilization in general [8–11, 55]. Adoption of this anatomical-based approach permits a rigorous standardization of the operation, irrespective of the platform used to achieve it.

## Definitions and Terminology

- *Hindgut*: intestine and mesentery from distal transverse colon (mesocolon) to anorectal level.
- *Mesentery*: the organ that maintains all abdominal digestive organs in position and in continuity with systems of the body.
- *Peritoneal reflection*: The bridge of peritoneum that occurs between abdominal wall peritoneum and organ, wherever an organ comes into close proximity with the abdominal wall.
- *Plane*: A plane is the conceptual zone between two contiguous (i.e. touching) and continuous surfaces.
- *Mesofascial plane*: conceptual zone between mesentery and underlying fascia.

*Comment* This is arguably the most important plane in colorectal surgery. It occurs throughout and is of considerable technical importance.

- *Toldt's fascia*: The areolar connective tissue that occurs between an organ and the posterior abdominal wall, whenever an organ comes into close contact with the abdominal wall.
- *Mesofascial separation*: Separation of components that make up the mesofascial plane.

*Comment* The components that generate the mesofascial plane are the mesentery and underlying fascia. Mesofascial separation refers to separation of the mesentery from the underlying fascia. It is a critical activity required to achieve mesenteric (and hence intestinal) detachment. Detachment is required before mesenteric disconnection can be achieved.

- *Peritonotomy*: Division of the peritoneal reflection.

*Comment* This is a crucial activity in so far as when one first inspects the abdominal cavity one cannot visualize the mesofascial plane. In order

to expose this plane, the peritoneal reflection must first be divided.

- *Attachment*: Mechanism of anchorage of regions of the mesentery to the posterior abdominal wall.
- *Detachment*: Separation of the mesentery from the posterior abdominal wall.
- *Disconnection*: Complete separation of the mesentery from the body.

## Anatomy

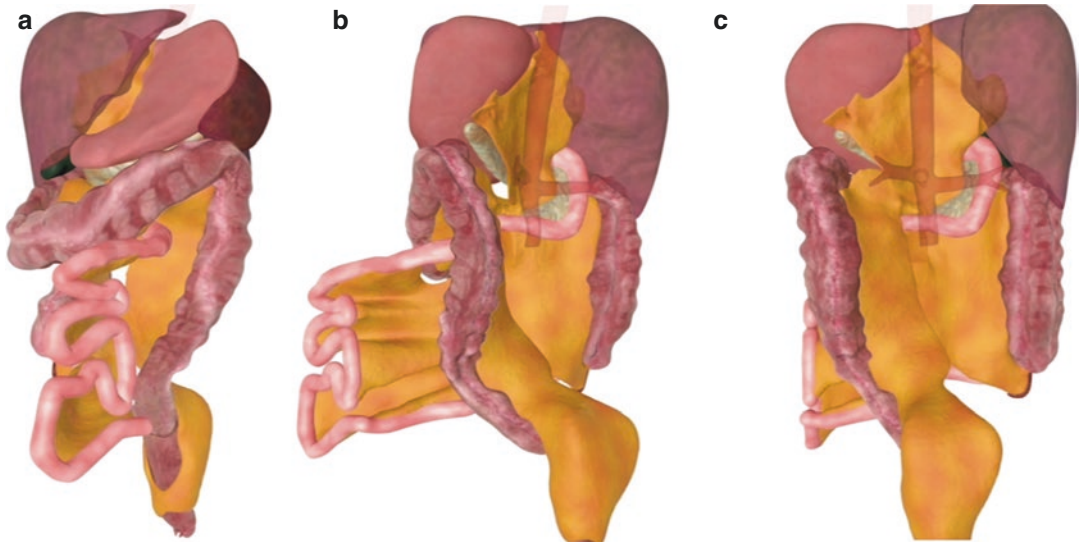
The mesentery is continuous; this means the mesentery of transverse colon continues as that of the left colon (i.e. the left mesocolon) (Fig. 34.4). The left mesocolon then continues distally as the mesosigmoid and the continuation of the mesosigmoid is the mesorectum [1, 5, 12, 15, 34, 35].

The term hindgut traditionally referred to the intestine only, as the mesentery was previously regarded as absent in certain regions (including at the left mesocolon). In the following the “hindgut” is taken to refer to both intestine *and mesentery* from the splenic flexure distally (Fig. 34.5). The mesorectum terminates at an apex just above the pelvic floor. This is the distal anatomical termination of the mesentery. The proximal termination of the abdominal mesentery is at the esophagogastric junction [1, 5, 12, 15, 34, 35].

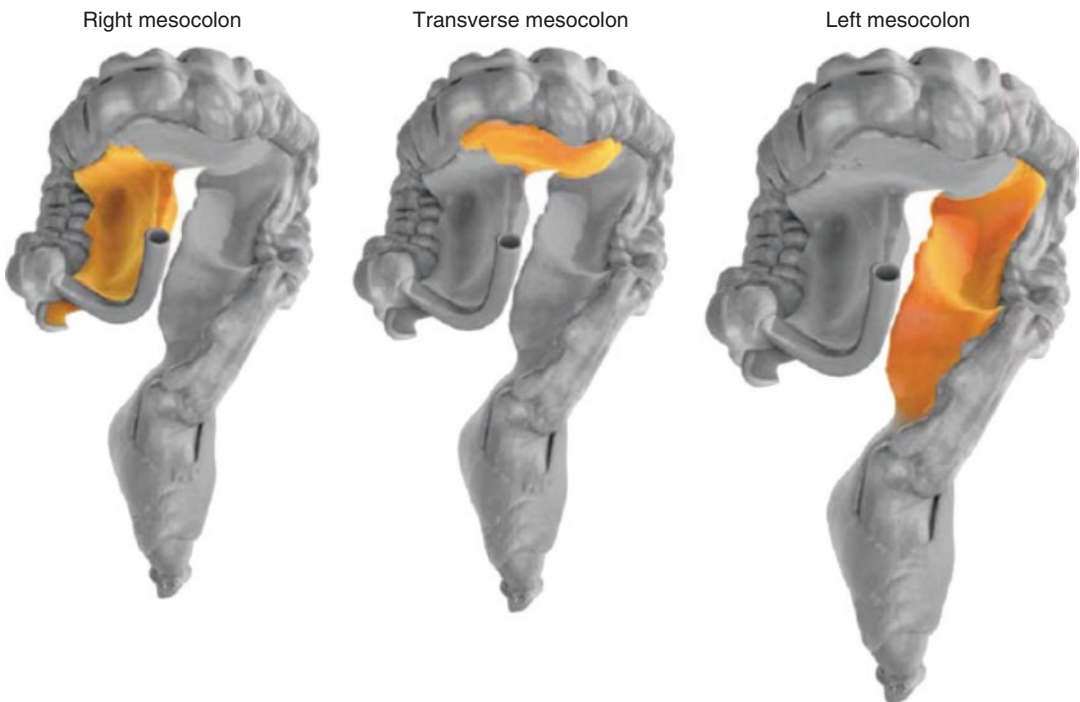
The left mesocolon is attached to the posterior abdominal wall and Toldt's fascia occurs between it and the abdominal wall [1, 5, 12, 15, 34, 35, 56]. The same applies for the medial aspect of the mesosigmoid. The lateral aspect of the mesosigmoid is not attached and is mobile. As a result, if one were to follow the mesosigmoid from medial to lateral, one would observe that the medial region is attached while the lateral region is detached (Fig. 34.6) [1, 5, 12, 15, 34, 35, 56].

The medial and lateral regions of the mesosigmoid then converge at the rectosigmoid junction to continue as the mesorectum. This is





**Fig. 34.4** The mesentery (current model). (a) Anterior, (b) anterolateral and (c) posterior view



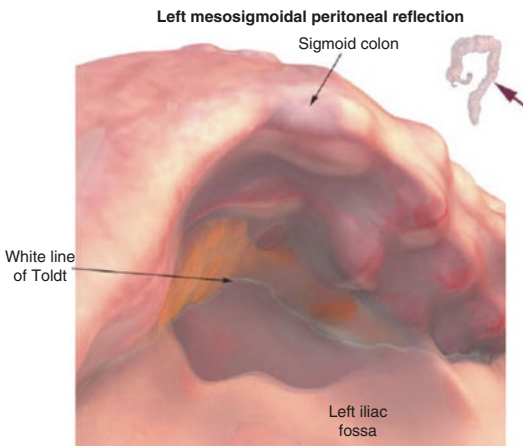
**Fig. 34.5** The left mesocolon. (Taken from Chap. 2, “Mesenteric and peritoneal anatomy”. In Mesenteric Principles of Gastrointestinal Surgery: Basic and Applied Principles)



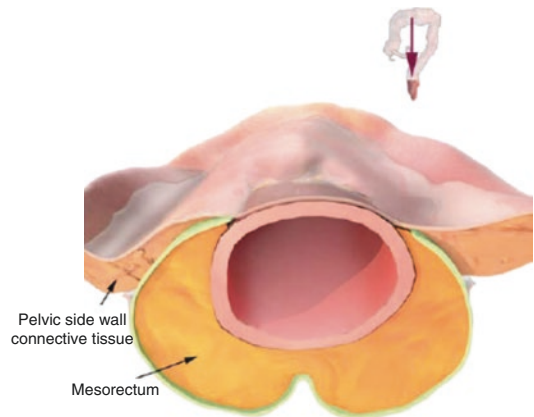
confined to the posterior and lateral aspects of the upper and mid-rectum (Fig. 34.7). At the level of the distal rectum, the mesorectum continues around anteriorly and forms a collar or cuff of mesorectum (Fig. 34.8) [1, 5, 9, 12, 15, 34, 35, 56–59].

There are three major mechanisms by which the mesentery (and hence the abdominal digestive system itself) is maintained in position. These are central, intermediate and peripheral.

Centrally, the mesentery is suspended at the inferior mesentery artery origin. Peripherally, the mesentery is suspended by formation of the reflection. In between both, Toldt's fascia is an intermediate mechanism of attachment. These mechanisms of attachment develop during embryological growth and must be disrupted during colorectal surgery on the hindgut. They are separately described in the following [1, 5, 9, 12, 15, 34, 35, 56–59].

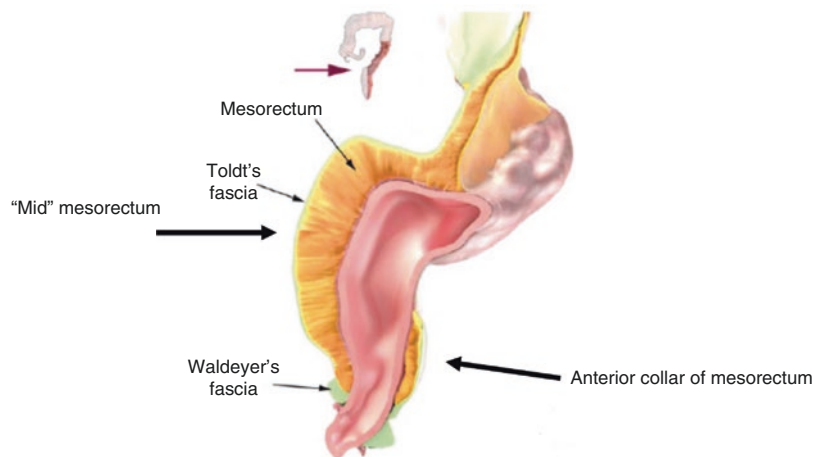


**Fig. 34.6** The lateral aspect of the mesosigmoid. (Taken from Chap. 2, “Mesenteric and peritoneal anatomy”. In Mesenteric Principles of Gastrointestinal Surgery: Basic and Applied Principles)



**Fig. 34.7** Axial view of the mesorectum viewed from above down. (Taken from Chap. 2, “Mesenteric and peritoneal anatomy”. In Mesenteric Principles of Gastrointestinal Surgery: Basic and Applied Principles)

**Fig. 34.8** Sagittal view of the mesorectum. (Taken from Chap. 2, “Mesenteric and peritoneal anatomy”. In Mesenteric Principles of Gastrointestinal Surgery: Basic and Applied Principles)



The mesorectum is attached/anchored to the pelvic side wall via a continuation of Toldt's fascia between it and the pelvis. The fascia continues between the mesorectum and adjacent structures, towards the pelvic floor where it condenses to form the so-called Waldeyer's fascia. *Waldeyer's fascia is not a separate fascia, but rather it is a continuation of Toldt's fascia* [1, 5, 9, 12, 15, 34, 35, 56–59].

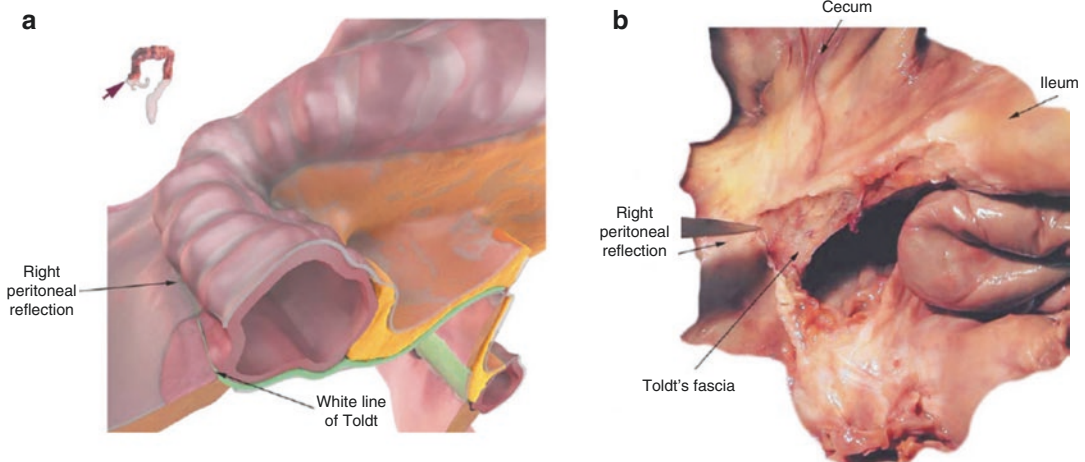
Anterior to the mesorectum, the fascia is also interposed between the mesorectum and anterior structures. In males, these anterior structures are the seminal vesicles and prostate, while in females they are the cervix and vagina. Toldt's fascia continues around the posterolateral aspect of the mesorectum to occupy the position between the mesorectum and anteriorly located structures. This region of the fascia has been called Denonvilliers' fascia. *As with Waldeyer's fascia, Denonvilliers' is not a separate fascia, but rather a continuation of Toldt's fascia* [1, 5, 9, 12, 15, 34, 35, 56–59].

The peripheral mechanism by which the mesentery is held in position is the peritoneum. Wherever an organ comes into close contact with the posterior abdominal wall, the peritoneum

“leaves it” to reach across to the organ and bridge the space between the organ and the posterior abdominal wall. This is the peritoneal reflection and it is of considerable surgical importance (Fig. 34.9) [1, 5, 6, 9, 12, 15, 34, 35, 56–59].

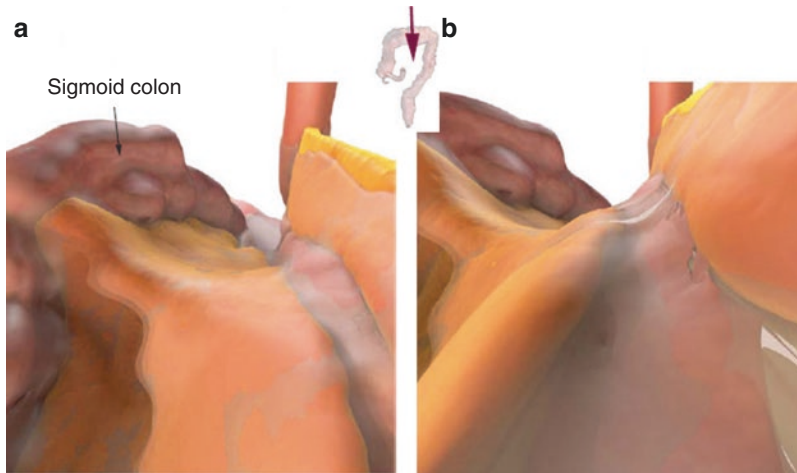
The reflection is continuous around the entirety of the mesentery and intestine. It is present at the lateral aspect of the descending colon. It continues from here along the lateral aspect of the mesosigmoid, in the region where the mesosigmoid separates away from the posterior abdominal wall to become mobile [1, 5, 6, 9, 12, 15, 34, 35, 56–59]. A reflection of the peritoneum also occurs at the medial aspect of the mesosigmoid and left mesocolon, in the region of the abdominal midline (Fig. 34.10). From the duodenojejunal flexure, this reflection continues caudally along the medial aspect of the left mesocolon and then along the medial aspect of the mesosigmoid, to reach the upper mesorectum and rectum [1, 5, 6, 9, 12, 15, 34, 35, 56–59].

The reflection at the medial aspect of the mesosigmoid continues caudally along the right side of the mesorectum where it is termed the *right pararectal reflection*. The reflection at the lateral aspect of the mesosigmoid continues dis-



**Fig. 34.9** The peritoneal reflection: (a) digital depiction of the reflection where it bridges the space between the posterior abdominal wall and the right side of the colon. (Taken from Chap. 2, “Mesenteric and peritoneal anatomy”. In *Mesenteric Principles of Gastrointestinal Surgery: Basic and Applied Principles*). (b) Similar view

to that presented in (a) in a cadaveric setting. The reflection has been divided sharply using a scalpel. Submesothelial connective tissue is apparent beneath the surface of the reflection. (Taken from Chap. 2, “Mesenteric and peritoneal anatomy”. In *Mesenteric Principles of Gastrointestinal Surgery: Basic and Applied Principles*)



**Fig. 34.10** The peritoneal reflection at the medial border of the mesosigmoid: (a) Digital depiction of the reflection where it bridges the space between the posterior abdominal wall and the mesosigmoid viewed from above and from left to right. (Taken from Chap. 14, “The appearance of the mesentery during open surgery”. In *Mesenteric Principles of Gastrointestinal Surgery: Basic and Applied*

*Principles*). (b) Digital depiction of the reflection where it bridges the space between the posterior abdominal wall and the mesosigmoid viewed from above down in the midline. (Taken from Chap. 14, “The appearance of the mesentery during open surgery”. In *Mesenteric Principles of Gastrointestinal Surgery: Basic and Applied Principles*)

tally along the left lateral aspect of the mesorectum where it is termed the *left pararectal reflection*. In the mid-pelvic region, the right and left pararectal regions of the reflection come around anteriorly to form the anterior reflection of the peritoneum. This is true end of the peritoneal cavity [1, 5, 6, 9, 12, 15, 34, 35, 56–59].

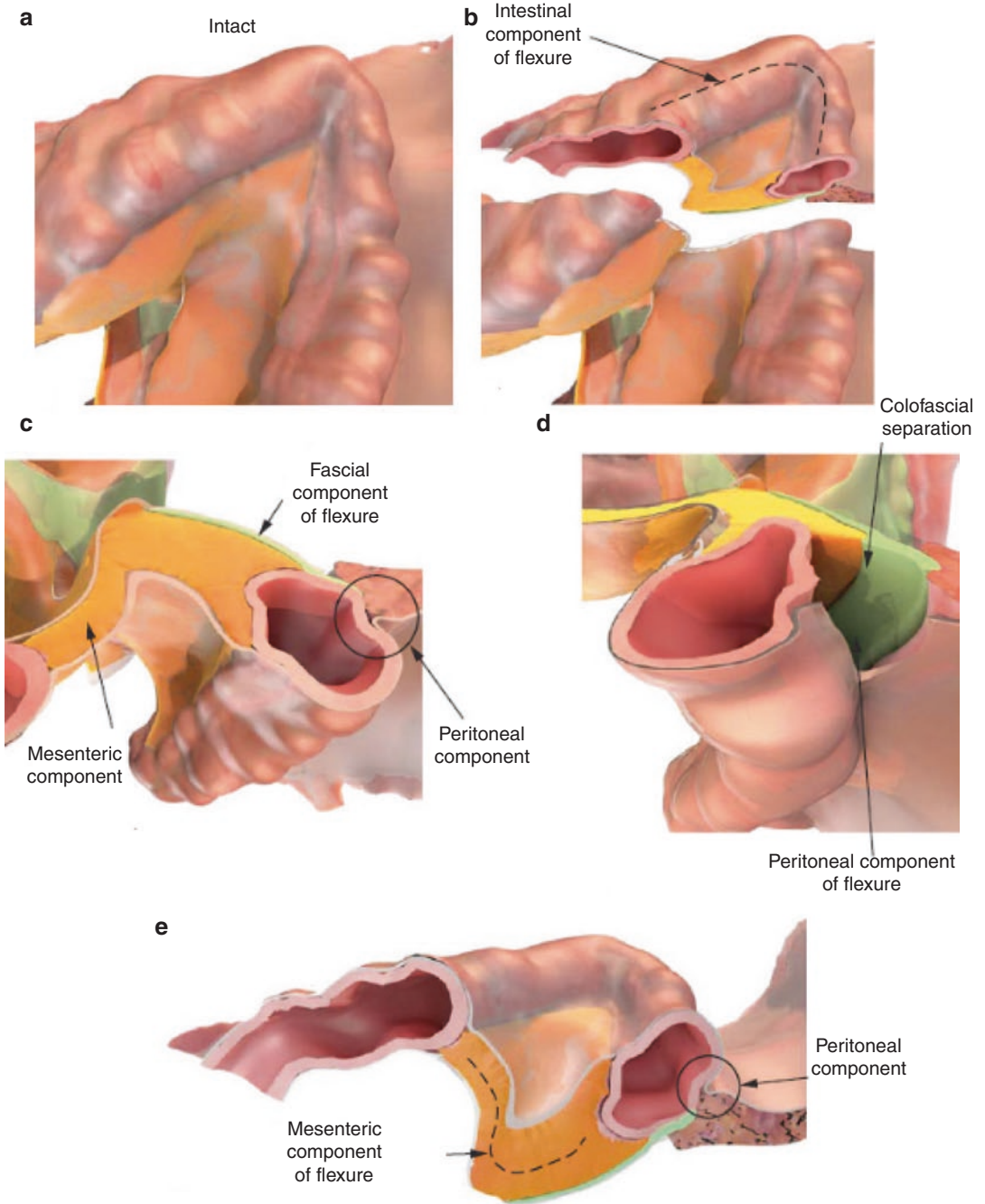
The inferior mesenteric artery (IMA) branches ventrally from the abdominal aorta, proximal to its bifurcation and enters the sigmoid mesentery. As the IMA enters the mesentery, it is surrounded by a sheath of connective tissue that is continuous with Toldt’s fascia and that also receives contributions from the connective tissue of the mesentery into which the vessel is incorporated [1, 5, 6, 9, 12, 15, 34, 35, 56–59].

As the fascia is located between the mesentery and the posterior abdominal wall, it provides a useful landmark for the abdominal surgeon. The mesenteric domain of the abdomen is located anterior to the fascia, while the non-mesenteric domain is located posterior to the fascia. Posterior to the fascia are retroperitoneal structures such as the kidneys, the ureters, and gonadal vessels. Toldt’s fascia thus separates the mesenteric and non-mesenteric domains of the abdomen.

Importantly, it is not necessary to excavate through the fascia to identify underlying structures [1, 5, 6, 9, 12, 15, 34, 35, 56–59].

The final point to be mentioned relates to the colonic flexures [5, 10, 12]. There are numerous flexures, but the ones that exert the greatest challenge are the hepatic and splenic. The flexures are best understood as comprising four components centred on a central mesenteric component (Fig. 34.11). At each flexure, the mesentery changes from attached to non-attached and thus undergoes considerable conformational changes. The mesenteric component of the flexures can be considered in terms of a longitudinal component and a radial component. The radial component of the splenic flexure extends from the middle colic origin. At the middle colic, it is fixed in position to the mesenteric root region, and as one extends along the radial axis, the mesentery detaches to become mobile. The longitudinal axis of the transverse mesocolon extends from the transverse mesocolon (where it is mobile) to the left mesocolon (where it is attached) [1, 5, 10, 12].

The other components of the flexures are the peritoneum, colon proper and fascia. The fascia is interposed between attached regions of



**Fig. 34.11** The splenic flexure. (Taken from Chap. 20, “Mesenteric Principles of Gastrointestinal mobilisation”. In *Mesenteric Principles of Gastrointestinal Surgery: Basic and Applied Principles*). (a) The intact splenic flexure. (b) Flexure conceptually disconnected from non-flexural regions. (c) View of the remaining non-flexural mesentery after removal of the flexure. Colic, mesenteric, fascial and peritoneal components are apparent. (d) View from the

left side, after conceptually removing the flexure. The reflection has been divided through to demonstrate the relationship between the peritoneum, colon, mesentery and fascia. (e) View of the in situ flexure if the non-flexural regions of the intestine and mesentery were removed. The view demonstrates the relationship between the colon, mesentery, reflection and fascia



mesentery and posterior abdominal wall. The reflection is somewhat more complex to visualize. It is best if one starts by considering the left peritoneal reflection and tracking this proximally towards the splenic flexure. At the splenic flexure, it is obscured from direct visualization because the omentum adheres to the reflection to varying degrees. This anatomical relationship obscures the anatomical relationship of other components of the splenic flexure from view, unlike at the hepatic flexure, where their position in relation to each other is directly visualized [1, 5, 10, 12].

## Mobilization Techniques, Including for taTME

### Obtain Unimpeded Mesenteric Access

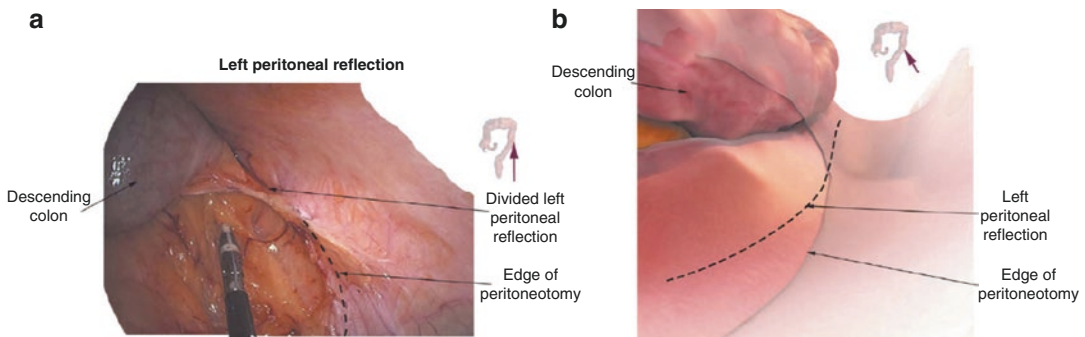
In the case of laparoscopic or robotic hindgut mobilization during taTME, the tendency is to adopt a medial to lateral approach. In open procedures, a lateral to medial approach is favoured. In either case, it is crucial to first obtain unimpeded mesenteric access. This means that the surgeon can directly access the mesentery and conduct the procedure. Impediments include the greater omentum and adhesions between the small intestinal mesentery and the left mesocolon and meso-

sigmoid. It is advisable to spend time ensuring these anatomical impediments have been adequately mobilized away from the left mesocolon and mesosigmoid before ever commencing mobilization [54].

### Lateral to Medial Detachment and Disconnection of the Mesosigmoid: Peritonotomy

Assuming one has obtained unimpeded mesenteric access, the next step is to identify the reflection at the *left* side of the mesosigmoid (Fig. 34.12). This is achieved by lifting the mesosigmoid away from the posterior abdominal wall which places the mesosigmoid and underlying fascia on stretch. The reflection comes under stretch (i.e. is placed on tension), and one frequently observes the indentation formed where the peritoneum separates from the posterior abdominal wall to join the mesothelium of the mesosigmoid [9, 54, 58, 59].

This indentation marks the starting region of the peritonotomy. The division is of the peritoneum alone, and not the underlying adipose tissue. If one is in the correct position, then during laparoscopy CO<sub>2</sub> gas will diffusely inflate through the areolar tissue of the fascia thereby making it more clearly visible to the surgeon. Classical surgical texts describe the importance of identifying



**Fig. 34.12** The lateral mesosigmoidal reflection at the lateral aspect of the mesosigmoid. (a) Intraoperative view of the lateral reflection at the left lateral aspect of the mesosigmoid as it is undergoing division. (b) Digital view of the divided reflection at the lateral aspect of the meso-

sigmoid. (Both images taken from Chap. 13, Appearance of mesentery during laparoscopic surgery, in *Mesenteric Principles of Gastrointestinal Surgery: Basic and Applied Principles*)



a *White Line of Toldt* and dividing the peritoneum just medial to this. We do not advocate relying on this landmark, as its presence and extent are variable. In addition, it also occurs in areas other than in association with the peritoneal reflection, a point that can cause confusion if overly relied upon. Where it does occur, *the White Line of Toldt marks the line of intersection of Toldt's fascia, with the peritoneum* [1, 9, 15, 54, 58, 59].

### **Detachment and Disconnection: Mesosigmoid – Mesofascial Separation**

The aim of peritonotomy is to identify the mesofascial plane. Without peritonotomy (whether of the visceral or parietal peritoneum), one cannot identify the mesofascial plane. If the mesofascial plane is not evident after peritonotomy (which is common), the surgeon is either supra-fascial (dissecting directly towards or within the mesentery) or retrofascial (with the dissection proceeding along a plane too deep, that enters into the retroperitoneum) [1, 9, 15, 54, 58, 59].

To identify the correct plane, the mesosigmoid is lifted off the retroperitoneum, thereby placing the fascia under greater tension via retraction. As the fascia comes under stretch, the interface between it and the mesentery is also placed under tension, and the interface between both is apparent [1, 9, 15, 54, 58, 59]. The instruments used to achieve this are beyond the scope of this chapter, and one is referred elsewhere for a detailed description of how to achieve this safely in open, laparoscopic and robotic contexts [60].

Once the mesofascial interface has been established, the mesentery is separated from the fascia and in this manner *detached* (but *not disconnected*). Separation of *both* is called *mesofascial separation* and is one of the most important surgical steps in abdominal and intestinal surgery. Eventually, a limit of mesenteric detachment will arise. In this case, the peritonotomy must be extended and another zone of contiguous mesentery identified for detachment. If this process is continued cephalad and caudad, and, as far medially as the *left* peritoneal reflec-

tion, then the mesosigmoid has been fully detached [5, 8, 9, 12].

The left mesosigmoidal reflection is then divided and the IMA circumferentially isolated by [1] detaching the mesentery around it and [2] dividing the fascia that coalesces around the IMA. The latter is then divided to commence the process of *disconnection* (i.e. where the mesentery is entirely freed from the underlying non-mesenteric domain of the abdomen) [5, 8, 9, 12].

### **Medial to Lateral Detachment of the Mesosigmoid**

The technical activities are the same as those detailed above. The reflection at the left side of the mesosigmoid is divided. The mesofascial plane is identified and the mesentery detached from the underlying fascia via mesofascial separation. This is repeated circumferentially around the IMA pedicle until the latter has been circumferentially isolated. Toldt's fascia coalesces around the IMA, and this must be divided to complete its isolation for division of the vessel near its point of origin. Once divided, the surgeon can then dissect beneath the mesosigmoid, gradually detaching the latter from underlying fascia until eventually the left lateral reflection is reached. This can be divided directly, or alternatively one can change the direction of dissection and approach this from inferior to superior, dividing the reflection from the left iliac fossa towards the splenic flexure. In this manner, the mesosigmoid becomes fully detached [5, 8, 9, 12, 58, 59].

### **Lateral to Medial Detachment and Disconnection of the Left Mesocolon**

The lateral peritonotomy is extended proximally in the direction of the spleen. The descending colon is generally fused to the posterior abdominal wall with Toldt's fascia, which is interposed between both of these structures. Lifting the colon away from the posterior abdominal wall places the interface between both on stretch, and,

with appropriate tension and counter tension, these can be sharply separated. As this is continued medially, the mesentery is encountered and the same principles of reflecting the mesentery away from the posterior abdominal wall, then separation from underlying fascia, apply. This is continued medially as far as the medial reflection which is then divided. It is also continued as far proximally as possible where the attachment of the mesenteric component of the splenic flexure usually impedes further dissection. The surgeon may elect to disconnect the left mesocolic mesentery at this point or formally mobilize the mesenteric component of the flexure. The latter is generally recommended as it is usually required to provide sufficient reach for an anastomosis in the setting of taTME. Either way, mesenteric disconnection requires that the mesentery (containing the inferior mesenteric vein (IMV)) is divided through to the level of the surface of the intestinal wall [5, 8, 9, 12, 58, 59].

*It is important to note that the IMV is contained in the mesentery and that it does not connect the mesentery to the non-mesenteric domain of the abdomen.* As a result, it is not included in mechanisms by which the mesentery is generally maintained in position, but it is important when it comes to *disconnecting* contiguous regions of mesentery in order to permit a resection [5, 8, 9, 12, 58, 59].

### **Medial to Lateral Detachment and Disconnection of the Left Mesocolon**

Given the continuity of the mesentery, peritoneum and fascia, the technique of medial to lateral detachment involves the same activities with these being conducted utilizing a medial to lateral approach. In keeping with this method, the medial reflection is firstly divided. The left mesocolon is lifted away from the fascia placing the interface on tension. This helps in identification of the interface and separation of its components. Of note, a white line will often be visualized at the interface between the mesentery and the underlying fascia. This is also a region of the

White Line of Toldt, and it is mentioned here in order to emphasise that one should not rely on the identification of this landmark to guide dissection. Instead one should rationalize the anatomical appearance and landmarks in mesenteric, fascial and peritoneal terms. As with lateral to medial mobilization, further detachment is ultimately impeded by attachment of the mesenteric component for the flexure. This must be formally detached before mobilization can be considered complete [5, 8, 9, 12, 58, 59].

### **The Splenic Flexure**

The anatomy of the flexures has always been poorly described. It is likely this was mainly due to the fact that according to the classic model, regions of mesentery commenced or ended at the flexures. In other words, anatomical correlates of start or end structures should be apparent (Fig. 34.1) [1, 5, 10, 12]. Mesenteric anatomy is readily explained by the current mesenteric-based model of abdominal anatomy. Each flexure is comprised of four structures centred on a mesenteric confluence. At the splenic flexure, the confluence is between the distal transverse mesocolon and the left mesocolon (Fig. 34.11). The intestine rounds the periphery of the mesenteric confluence. The upper and lateral aspects of the confluence are obscured from direct visualization by the peritoneal reflection. The greater omentum fuses with the splenocolic region of the reflection to varying degrees. When the flexure is considered in terms of these components, then flexural mobilization becomes a matter of disrupting each of these components [1, 5, 10–12].

### **Splenic Flexure Mobilization: Medial to Lateral Approach**

If the dissection had commenced from medial to lateral, then the left mesocolon would be detached as far cephalad as possible, where further detachment would be limited by attachment of the mesenteric component of the flexure. It is possible to disrupt the relationship between this, and

the underlying fascia, until the mesentery is fully detached and lesser sac entry is achieved. At this point, the last structures to assist in maintaining the position of the flexure are the greater omentum and the reflection [1, 5, 10–12].

The greater omentum can be divided just outside the epiploic arcade of the greater curvature of the stomach and the division continued from medial to lateral until the spleen is encountered. At this point, the omentum is fused to the splenocolic reflection, obscuring the latter from view. If the omentum is divided, then the region where it is attached can be retracted infero-medially, thereby exposing the underlying splenocolic region of the reflection. This can then be divided and the division extended towards the left lateral reflection at the lateral aspect of the descending colon. If this is divided, then the mesentery of the flexure is fully detached and can be liberated as far medially as the region where the middle colic pedicle arises [1, 5, 10–12].

### **Splenic Flexure Mobilization: Lateral to Medial Approach**

If a medial to lateral mobilization was conducted, then the order in which the components of the flexure are disrupted differs from that described above. Firstly, the left lateral reflection is divided as far cephalad as possible. It is usually impeded by the region where the greater omentum fuses with the splenocolic region of the reflection. At this point, the surgeon may begin dividing through the omentum to enter the lesser sac, and then continue division of the omentum as far laterally as possible. Then the surgeon can retract the flexure infero-medially, thereby placing the omentum under gentle tension, and allowing its division in this region. As the omentum and reflection have fused, division of the former is usually associated with division of the latter. With division of the reflection, the mesenteric component of the flexure comes into view. It is attached to the posterior abdominal wall with Toldt's fascia interposed between both. Detachment follows the rules (detailed above) involving identification of the interface then separating the mesentery from the

fascia. This is then completed to the point where further detachment is impeded by the middle colic vascular pedicle [1, 5, 10–12, 57–59].

### **Future Directions**

Hindgut mobilization for taTME can be achieved reliably and safely using the mesenteric-based approach described above. In addition, the terminology that has been derived from the mesenteric based model, enables one to rigorously standardise mobilization. It also allows the surgeon repeatedly and reproducibly explain the precise anatomical basis to taTME. Furthermore, the new terminology greatly aids in standardization of operative documentation and descriptions. This is particularly important for the process of taTME, because transanal extraction for specimen retrieval and generally ultra-low anastomoses mandate careful and complete mobilization of the hindgut, often in its entirety.

Most debate in rectal surgery at the moment centres on which is the best modality to use: open, laparoscopic, robotic or (most recently) taTME. As the anatomical basis of colorectal surgery has only recently been clarified, it has not been possible to rigorously standardize resectional surgery with a view to formally testing how each of these surgical techniques performs against each other. The result is that it is unlikely we will know which platform is the best for a long time to come. In that context, it is probably best that surgeons employ the modality they feel is best allows them to access the embryological roadmap that is routed in the mesenteric model of abdominal anatomy. That will vary depending on the surgeon, the patient and the pathology.

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# The Role for Perfusion Angiography

# 35

António S. Soares and Manish Chand

## Fluorescence-Guided Surgery

The vast majority of surgery takes place in the visible ‘white light’ spectrum. Utilizing other areas of the electromagnetic spectrum, in particular near-infrared (NIR) light, could aid surgical decision-making and ultimately improve patient outcomes in selected patients. Fluorescence-guided surgery incorporates the use of a fluorophore or fluorescent dye to identify anatomical, physiological and pathological processes when injected intravenously or interstitially. This approach can provide important additional information to help guide the surgical procedure and potentially reduce specific complications such as anastomotic leak. In this chapter, we will detail the theoretical basis of fluorescence-guided surgery as well as the clinical applications in colorectal surgery, in particular transanal surgery, and future areas of research.

## Fluorophore Characteristics

Fluorophores are compounds that emit energy as fluorescence when excited by light of a specific wavelength [1]. As the spectrum of absorption and emission of these substances is commonly known, these photophysical characteristics have enabled the use of fluorescence in many industrial applications including selective use during surgery. The near-infrared (NIR) spectrum (700–900 nm) is most commonly used for intraoperative applications [2]. This spectrum optimizes the wavelengths in which the common fluorophores present in the human body do not exhibit fluorescence [3]. At lower wavelengths the fluorescence of haemoglobin predominates, and at higher wavelengths the fluorescence of water predominates. These endogenous fluorophores will pollute the signal if wavelengths outside the near-infrared spectrum are used intraoperatively. The ideal fluorophore will have the ability to clearly fluoresce with minimal distortion from background signal and have the ability to sufficiently penetrate tissues with increasing depth. At present, most fluorophores are only able to fluoresce through a few millimetres of tissue limiting their clinical application.

Besides the photophysical properties, the pharmacodynamic and pharmacokinetic profiles are also important as a clinically useful fluorophore can be given before or during surgery [4]. If a fluorophore is administered before surgery,

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the ideal situation would be to have a predictable half-life. For fluorophores used intraoperatively, rapid distribution and excretion are more important considerations.

A camera using a special filter needs to be used to be able to identify light at this spectrum and several options are available in the market [5]. There are differences in the specific range of wavelengths covered by the different equipment [6]. This technology naturally lends itself to the minimally invasive surgery setting, be it laparoscopic or robotic.

### Indocyanine Green (ICG)

ICG is the most widely used fluorophore in clinical practice. The compound is a heptamethine cyanine fluorophore. It circulates bound to albumin when injected intravenously, due to its hydrophobicity. The half-life in serum is 3–5 minutes [7], after which ICG undergoes biliary excretion. This fluorophore has a peak excitation wavelength of 807 nm and a peak emission wavelength of 822 nm [5]. Allergic reactions have been described, but the overall frequency is low (0.103%), and they are generally mild [8]. Hypotension may occur in 0.034% of patients. Due to ICG's structure containing iodine, patients with previously documented iodine allergy (e.g. allergy to CT contrast) should avoid contact with ICG as there is considerable cross-reactivity.

### Definition of Perfusion Angiography

Angiography is a technique used to visualize vascular structures. This was done initially through the injection of radiopaque contrast agents into the vessels followed by X-ray imaging through the efforts of pioneers like Osborn, Egas Moniz and Forssmann in the first half of the twentieth century [9]. In recent years, there has been increasing interest in this technique with several new fluorophores being developed along with more complex imaging systems. This has allowed surgeons to use the principles of perfusion angiography in real time during surgery rather than

limiting it to preoperative uses, such as with conventional angiograms.

Intraoperative angiography provides the potential to assess perfusion of organs including the colon. Colonic perfusion is most important during bowel resection and anastomosis, as this remains one of the key determinants of an anastomotic leak [10]. Currently, there is no standardized method to assess colonic perfusion during construction of an anastomosis. The common practice is to check for the pulsation of the marginal artery, to document bleeding from the cut edges of the bowel, and to assess the colour of the bowel segments to be anastomosed [7]. But these are all subjective methods and lend themselves to a non-quantified degree of variability. Furthermore, they rarely provide a clear demarcation between well-perfused and non-perfused tissue. ICG can be used during bowel surgery to provide a more objective assessment of perfusion at the time of anastomosis and can lead to a change in resection margin when compared to standard clinical assessment [11, 12]. The role of perfusion angiography (PA) is a dynamic one with a growing field of applications and rapidly accruing data on its usefulness.

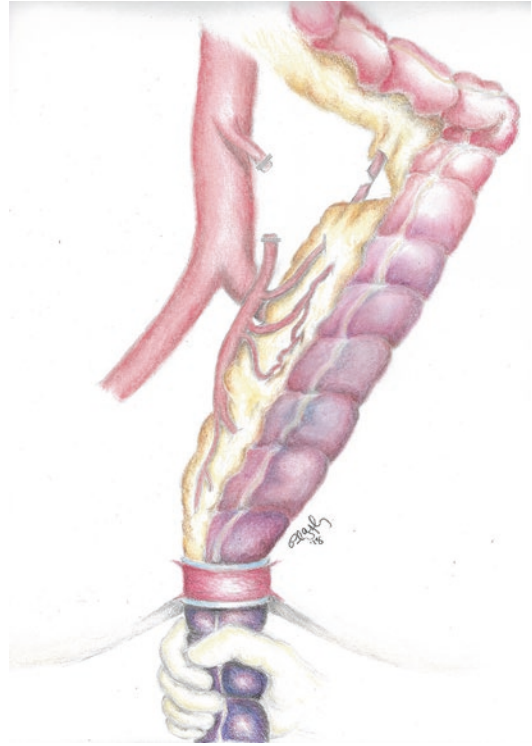
### Current Status of Perfusion Angiography in Colorectal Surgery

Anastomotic leak (AL) remains one of the most challenging complications in colorectal surgery. AL leads to increased morbidity, longer hospital admissions and increased use of intensive care units, incurring additional annual costs of £1.1–35 million in the United Kingdom's National Health Service alone [13]. The additional cost per patient with AL is between £3372 and £10,901. In addition to the financial burden, there is also a risk of worse survival outcomes for those patients undergoing surgery for colorectal cancer [14].

Despite advances in perioperative care and surgical technique, the risk of anastomotic leak is still up to 19% in colorectal anastomoses [15]. The leak rate is higher in patients who require a low rectal anastomosis which is often seen in patients undergoing taTME. Indeed, these are up

to 91.6% of rectal cancers operated through this approach as demonstrated by the data submitted to the taTME registry [16]. The registry has captured data on 1594 patients submitted to surgery through the transanal platform with a documented leak rate of 15.7% [16]. Previous work has shown that a blood flow reduction in the rectal and colonic stumps was associated with an increase in AL [17]. Perfusion angiography using ICG offers a method of reducing this complication and is currently the most studied application of fluorescence in colorectal surgery. By assessing the proximal colonic transection point and the anastomosis itself in a more objective manner, perfusion can be optimized. Most data published to date has been on the effect of using PA for left-sided bowel resections, although data on right-sided resections has been accruing recently.

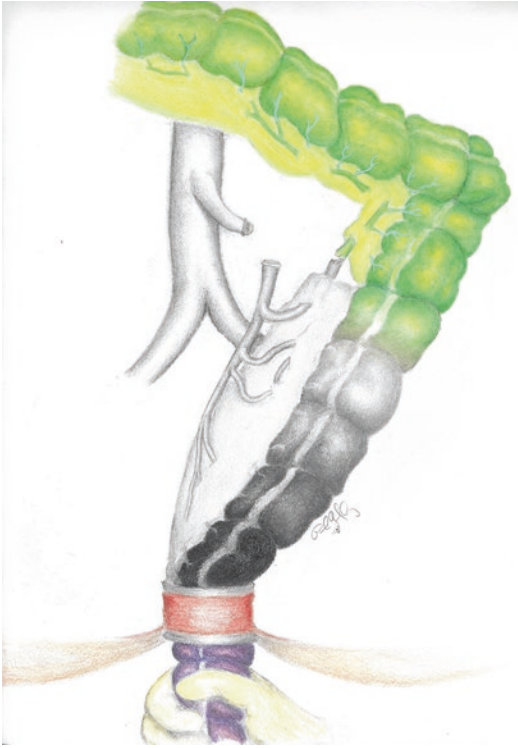
Perfusion angiography can be used at the point of bowel transection to identify where the bowel remains ischaemic. ICG is given intravenously and acts rapidly (often within a minute) allowing the surgeon to make an assessment of the bowel using the NIR equipment. A clear demarcation between perfused and non-perfused tissue is generally evident and used as a guide for the proximal transection [11, 18, 19]. For left-sided resections, the proximal colon needs to be mobilized to achieve the adequate position for a tension-free anastomosis, and the conduit relies purely on perfusion from the marginal artery [20]. It is plausible that the need for more proximal bowel mobilization entails an increased risk of vascular insufficiency that could lead to AL based on a vascular cause. This is a fundamental consideration when using a NOSE (natural orifice specimen extraction) technique for colonic surgery – the favoured method of specimen extraction in taTME. A review has shown that transrectal specimen extraction when compared with open extraction results in less pain, comparable operative time and length of hospital stay [21]. The degree of mobility required from the proximal colon is higher in this setting because it is necessary to consider enough extension to be able to transect the specimen extracorporeally through the anus. As demonstrated in Figs. 35.1 and 35.2, the marginal artery may be torn due to shear stress



**Fig. 35.1** Demonstration of injury to the marginal artery during natural orifice specimen extraction in transanal surgery. (Illustration courtesy of Sam Atallah and Paulo Gonzalez)

imposed by transanal extraction during taTME. This is especially true with the high degree of proximal mobilization required. When the marginal artery is disrupted proximally, the end result is loss of terminal bowel perfusion, conduit ischemia and anastomotic failure. PA assessment of the proximal colon provides an objective assessment of perfusion also in this context and therefore is a very helpful adjunct.

Mechanical patency tests are used after anastomosing the colon in left-sided resections and have shown to be associated with a smaller rate of complications [22]. However, this does not provide information on the vascular status of the anastomosis. Standard tests performed in this setting to assess vascular integrity are limited to visual assessment for discoloration either extraluminally or endoluminally through endoscopy in the cases of left-sided resection. The use of PA can assess the vascular status of the tissue



**Fig. 35.2** Perfusion of affected areas after marginal artery injury during transanal specimen extraction (green, well perfused; black, non-perfused). (Illustration courtesy of Sam Atallah and Paulo Gonzalez)

included in the anastomosis. This technique has been described both to assess the serosa (extraluminally) and the mucosa (endoluminally) [23].

### Clinical Outcomes in Colorectal Surgery

The clinical outcomes of using ICG in the assessment of colorectal anastomoses have been well documented with no significant concerns over technique or safety. Assessment was performed successfully in a significant majority of cases (97–100%) [24]. The additional time required for using ICG during surgery has been shown to be between 30 seconds and 6.8 minutes per patient [24].

A systematic review from 2016 [19] included 1388 patients with colorectal anastomosis in 13 studies. The anastomotic leak rate among patients who underwent FA intraoperatively (irrespective

of change in surgical decision) was 3.3%, while patients included in the control arms had an anastomotic leak rate of 7.58% with a statistically significant difference ( $p < 0.01$ ). Importantly, the definition of anastomotic leak differed among studies including clinical diagnosis, radiological diagnosis or no mention as to diagnosis method – entailing a high risk of bias.

A more recent systematic review and meta-analysis from Blanco-Colino et al. [18] were performed in 2017. It included 1302 patients from 5 non-randomized studies that took place between 2003 and 2015. The risk of bias in assessing the outcomes was considered low to moderate in the studies included. The definition of AL was also variable in the papers included. When the results were pooled for all patients included in this review, ICG has not shown a significantly lower odds ratio for AL (OR 0.51, confidence interval 0.23–1.13). When the results for patients undergoing surgery for colorectal cancer were pooled (956 patients), a significantly lower AL rate was observed (OR 0.34, CI 0.16–0.74). The same result was found for rectal cancer patients, when these data were pooled (OR 0.19, 95% CI 0.05–0.75). Changes in surgical decision on the point of transection occurred in 7.4% of cases overall (range 2.5–10.6%).

A series of 504 patients was recently published after the systematic reviews mentioned above [11] that included patients submitted to colorectal surgery for both benign and malignant indications. In this group, 143 (28.4%) patients underwent right-sided resections. The AL rates for right-sided resections were similar between patients in this study and historical controls (2.8% vs 2.6%, respectively,  $p$ -value 0.928). For left-sided surgery, rates were 2.6% for the study group versus 6.9% in the historic controls ( $P = 0.005$ ). This represents an unselected larger number of patients than previously described in single studies.

### Changes in Management Decisions

Utilization of PA with a minimally invasive (laparoscopic or robotic) approach can result in a

change in intraoperative management, mostly leading to a more proximal transection of the colon (i.e. conduit) [11, 12, 25–29]. When considering only studies with more than 100 patients, there was a change in intraoperative management in 3.7–19% of cases [24]. The perfusion of the proximal colon is a key determinant in the success of the anastomosis and commonly reliant on the integrity of the marginal artery. A clearly ischaemic section of colon is apparent to all surgeons, but often it can be difficult to assess the last few millimetres of bowel. The use of a fluorophore to highlight perfusion to the edge of the transection margin is helpful to make a more confident assessment of the bowel viability. A clear cut-off is demonstrated which allows the anastomoses to be constructed with a healthy, perfused section of bowel.

### **Decision on the Use of Diverting Ileostomy**

PA can also be used as an adjuvant to inform the decision of not creating a diverting ileostomy in the context of low anterior resections [30]. A decision not to proceed with diversion was made in 6% of 90 low anterior resections in the VOIR network study [11], none of which had an anastomotic leak. It is stated that the results of the perfusion angiography provided enough assurance not to proceed with the ileostomy. Further study is warranted to explore this finding, but this has financial and quality of life (QoL) implications. Diverting stoma is often kept for a period of months and associated with morbidity. In addition, there is a financial burden which must be borne out by healthcare systems.

### **Ileo-Anal Pouch Assessment**

The TAMIS platform and general taTME techniques have been used for restorative proctocolectomy with ileo-anal pouch. The current data seems promising [31–33], and this surgical approach has been used more frequently. For the pouch to reach the distal site prior to anastomo-

sis, sometimes lengthening techniques must be employed [34]. These involve specific mobilization of the mesentery but may also involve vascular ligation of the ileocolic, right colic and superior mesenteric artery at its distal third, taking advantage of the perfusion through the right branch of the middle colic and the marginal artery. Due to the need to ligate several important vessels, perfusion angiography could be a useful adjunct during surgery. The use of fluorescence in this context has been described previously [11, 35, 36], and this is an area of active research.

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### **Limitations**

While the data on the use of PA is rapidly accumulating, there is still a need to identify its exact indications and in which patients there is most benefit. This would require higher level evidence on the clinical outcomes after PA, a better understanding of the aetiology of AL, the quantification of the fluorescent signal and the development of targeted fluorophores.

### **Current State of Data on PA to Reduce Anastomotic Leaks**

So far, no randomized evidence exists on the use of PA and its effect on AL rates. The current stage of this application of fluorescence is an IDEAL phase 2b [37]. Despite having opened for recruitment, the PILLAR III randomized trial was closed in June 2017 [38]. The IntAct (intraoperative fluorescence angiography to prevent anastomotic leak in rectal cancer surgery) trial is currently open for recruitment [39]. The trial will include both patients undergoing laparoscopic TME and taTME. This is an international multi-centre randomized trial that will allocate patients to surgery with or without FA. The primary outcome is clinical anastomotic leak within 90 days of surgery. The recruitment target is 880 patients over 36 months. The impact of PA in the decision to proceed with diverting ileostomy after colorectal anastomosis and after pouch surgery also merits further study given the potential benefits.



## Multifactorial Aetiology of AL

PA assesses the blood flow to the tissue but does not consider other factors that might play a causal role in the occurrence of AL. Surgeon prediction of AL is not reliable [40]. It seems plausible that patient factors (nutritional status, previous chemoradiotherapy, frailty) and technical aspects play an important role in AL [41]. Recently, dysbiosis and the impact of the microbiome in anastomotic integrity have been pursued in mechanistic studies. Surgery represents a major physiological stress, and postsurgical recovery is not fully understood. Recent evidence has shown that the preoperative bowel preparation, prophylactic antibiotics and surgical trauma have a significant impact in the microbiological environment at the anastomosis. The extent to which these factors shape the microbiome has not been completely elucidated [42]. This may lead to a disproportionate increase in bacteria with a more virulent phenotype [41]. The absence of the normal bacteria may favour the occurrence of disseminated infection and sepsis, AL or superinfection (e.g. *C. Difficile*). Preclinical models have suggested that inflamed and injured intestinal tissues undergoing repair select strains of bacteria that express a high collagenase-producing phenotype which contributes to anastomotic leak [43]. The culture-based methods have been replaced by RNA sequencing and transcriptomic analysis that expands the ability to study the microbiological environment [42]. Therefore, there is great potential to explore the microbiome to improve health and prevent AL, as this becomes a more developed area of research.

## Fluorescence Quantification

At present there is no method of quantifying fluorescence in real time in the operating theatre. Benefits of achieving this include standardization of the technique by different operators and a possibility of relating fluorescence intensity to outcomes. This is not achieved in practice where a qualitative assessment is performed.

## Targeted Fluorophores

ICG is a nonspecific fluorophore. The knowledge of cell markers [44] and the improvement of technical capabilities have enabled the synthesis of targeted fluorophores [45]. The development of this new area of fluorescence-guided surgery opens the gateway to tailored fluorescence and improved benefit for patients. The regulatory pathways for these molecules are not yet standardized [46] which is an area of active intervention by the scientific societies.

## Conclusions and Future Directions

The use of fluorescence angiography has been shown to be promising in observational studies in colorectal surgery and especially in the context of colorectal cancer. Lowering the Anastomotic leak rate and its attendant consequences is of extreme importance. Randomized trials are underway to better define the contribution of this technique to patient management. As data accrues, a rise in dissemination of the technique is expected. Further work will also be necessary to elucidate the role of non-vascular factors in anastomotic leak. The influence of the microbiome might be a relevant factor as preliminary reports have shown.

Fluorescence-guided surgery will continue to evolve. Future developments include the definition of quantitative measures and synthesis of targeted fluorophores. Aiming to improve patient care and outcomes, this field will certainly increase the precision of the surgical armamentarium. It is then the job of surgeons, scientists and healthcare industry to collaborate to introduce these developments into clinical practice in an efficient and safe manner.

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# Perioperative Preparation and Postoperative Care Considerations

# 36

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## Preoperative Assessment

### History and Physical Examination

The preoperative assessment for transanal total mesorectal excision (TaTME) should begin with a thorough history and physical examination, which is the most important part of the patient's evaluation. Typically, patients will present for their first visit to a surgeon already carrying a diagnosis, and it is the surgeon's task to assess if surgery is indicated and formulate the optimal surgical plan. It is important to elicit a thorough description of the patient's current symptoms, which may indicate either benign or malignant pathology, and to get a sense of the patient's understanding of his or her condition. In the setting of malignancy, the patient could be asymptomatic as the lesion may have been identified on

a routine screening examination. Other patients may present with rectal bleeding, incontinence, rectal pain, weight loss, anemia "change in bowel habits," diarrhea, constipation, or abdominal pain [1]. Patients should be asked about their bowel habits including the quality of their stool – "pencil thin" stools may be a sign of impending obstruction. Patients may also complain of bloating, abdominal cramping, nausea, or vomiting. It is important to assess for these types of symptoms as they may be indicative of partial obstruction and may alter the initial operative strategy with diversion prior to the initiation of neoadjuvant therapy, if indicated.

Baseline urinary and sexual function should be documented for all male patients. The rates of urinary dysfunction following surgery for rectal cancer have been reported to be between 30% and 70% [2–5]. Similarly, the rates of sexual dysfunction in men following rectal cancer surgery is reportedly 30–64% [6–8]. Therefore, it is important to document function preoperatively to assess for any postoperative changes from baseline. Importantly, it is critical that the prostate gland is adequately assessed by history and physical examination. By DRE, the gland's shape and size should be established at baseline. Furthermore, a history of prior prostatic surgery, such as prior radical prostatectomy, or a history of prior urethral reconstructive surgery is germane to the planning of the TaTME operation. This can help alert the transanal surgeon of the potential difficulty with the anterior plane.

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A detailed obstetric history should also be obtained for women including assessment of number of pregnancies, vaginal deliveries, and any instrument-assisted deliveries; this history is important for assessing potential sphincter function. Along these lines, an assessment of preoperative continence is necessary to determine if a coloanal anastomosis will be tolerated. In cases concerning for possible difficulty with postoperative continence, anal manometry may be utilized to objectively assess sphincter function.

Additional history should include past medical, surgical, and family history. Past medical history will often guide further preoperative testing. Assessment of baseline functional and cardiopulmonary status may warrant preoperative evaluation by specialists in cardiology, vascular medicine, pulmonary medicine, or anesthesia. These specialists may also assist in temporarily stopping or bridging anticoagulation therapy or determine if an inferior vena cava filter is required preoperatively. Frequently, patients with history of renal impairments undergo optimization and coordination with their nephrologists for medication and fluid management, as well as for planning perioperative dialysis. Diabetes, immunosuppression, obesity, and smoking must all be addressed and managed preoperatively [9]. Consideration should be given to these various comorbidities that may contribute to an increased risk of anastomotic leak.

A thorough physical examination should focus on the abdominal and digital rectal examinations. The abdominal examination should assess for prior scars or hernias that should be taken into consideration for operative planning. The abdomen should be examined for distension, suggestive of partial obstruction, and organomegaly or masses, suggestive of potential metastatic disease. Body habitus should be noted as it plays a role in patient positioning and port placement in the operating room. Obesity also influences potential sites for stoma marking.

Given that the goal of TaTME is sphincter preservation, a careful anorectal examination is crucial. This examination can be done in left lateral position or prone jackknife position, depending on the patient's tolerance and the surgeon's

preference. First, an external inspection of the perianal skin should be performed to assess for fissures, fistulas, abscesses, and skin tags. Patients undergoing TaTME for ileal pouch creation in ulcerative colitis should have a thorough anorectal examination to ensure there are no signs of unexpected perianal Crohn's disease. The patient should be asked to squeeze with their sphincter muscles to assess function of the external anal sphincter. Next, a digital rectal examination is essential, as this will provide information regarding function as well as the extent and location of any malignant disease. The state of the pelvic floor muscles can be evaluated on digital exam as well. In cases of malignancy, the surgeon should note relation of the tumor to the anal verge and sphincter complex, possible adherence to or invasion of local structures, size of the mass, and qualities of the mass such as texture and mobility. TaTME is an especially helpful technique for obese males with bulky low rectal cancers, as the transanal approach allows for more direct visualization and definition of the distal margins, which is typically more challenging in these patients when utilizing the traditional transabdominal approach [10]. In women, if there is suspicion that the tumor invades the vaginal walls, then a vaginal exam should be performed. A bimanual exam, with a finger in the rectum and a finger in the vagina, may be helpful in delineating the true extent of invasion. This can be further characterized on preoperative staging MRI.

## Preoperative Testing

During the general preoperative evaluation, the surgeon should always be cognizant of and searching for factors that may influence the risk of anastomotic leak. Several studies have identified the following as possible risk factors for leak: male gender, obesity, smoking, chronic immunosuppression, hypoalbuminemia, tumors >25 mm, and preoperative steroid and nonsteroidal anti-inflammatory drug use [11, 12]. As part of the preoperative screening evaluation, all patients undergoing abdominal surgery should generally have routine laboratory tests drawn,



including a complete blood count, serum chemistry, as well as coagulation studies. Blood should be typed and screened. Testing should also include an assessment of the patient's nutrition levels and protein stores. In patients with rectal cancer, a baseline preoperative CEA level should also be established. Women of childbearing age must have a urine pregnancy test. Patients may be evaluated at a pre-anesthesia clinic, which can determine the need for any further testing such as hemoglobin A1C levels, thyroid function studies, iron studies, electrocardiogram, stress testing, or other testing. Attention should be paid to nutritional status, substance abuse screening, preoperative opioid utilization assessments, and any special medications. This may include anticoagulation, immunosuppression, and chemotherapy.

Endoscopic visualization of the lesion is necessary following the digital rectal exam. This can be accomplished with flexible or rigid proctoscopy, with or without sedation. In cases of benign indications, proctoscopy should be performed to rule out any underlying malignancy. Visualizing the lesion endoscopically will allow for characterization of the lesion in regard to circumference, friability, and both distal and proximal extent. The level of obstruction of the lumen can also be judged during the endoscopic examination. This will help determine if the patient requires diversion prior to the initiation of neoadjuvant therapy. Biopsies can be taken to confirm pathology. If not already done, all patients should undergo a complete colonoscopy to exclude synchronous lesions.

Staging is key to the preoperative assessment of any cancer patient. In regard to the history and physical, inquiring about systemic symptoms such as weight loss and fatigue is important. On exam, special attention should be given to signs such as muscle wasting, abdominal distension, hepatomegaly, and lymphadenopathy [13]. As mentioned previously, asking questions regarding change in bowel habits and signs of obstruction is important. Utilization of ASCRS and NCCN staging guidelines is necessary for all patients with rectal cancer to direct both local and distant staging. A CT of the chest, abdomen, and pelvis should be obtained for distant staging, and

a pelvic MRI with contrast should be obtained for local staging [14]. In patients with a contraindication to MRI, an endorectal ultrasound can be utilized for local staging. All patients are presented at a multidisciplinary tumor board, where the clinical presentation, radiologic findings, and pathology slides can be reviewed by a multidisciplinary group of experts to create an individualized plan of care for each patient [15, 16]. The principles of neoadjuvant therapy for patients undergoing TaTME are consistent with those applied to any other preoperative rectal cancer patient. Depending on multidisciplinary tumor board recommendations, patients will typically undergo short- or long-course chemoradiation therapy followed by resection at the appropriate time interval. PET scans are not routinely indicated and should be reserved for select situations, typically following the guidance of a multidisciplinary tumor board recommendation.

### **Preoperative Stoma Marking**

Prior to surgery patients should be marked for ostomy sites. This includes both diverting loop ileostomy and end colostomy. Patients who undergo preoperative marking have better results postoperatively [17]. Patients should always be counseled as to the need for an ostomy. In the case of diverting loop ileostomy, the ostomy does not help prevent anastomotic leak but does minimize the clinical severity if one were to occur [18]. In some cases, even with the intention of performing a TaTME with primary anastomosis, there are situations in which an anastomosis cannot be performed and an end colostomy must be created. Patients should be marked and counseled for this possibility, regardless of the low probability of this occurring.

### **Sphincter Evaluation**

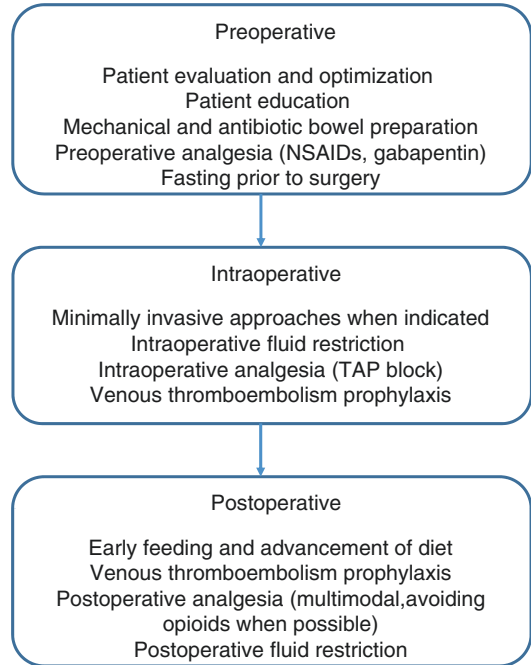
In addition to a thorough physical examination, several studies are available to evaluate the function and anatomy of the internal and external sphincter muscle. Since a transanal approach is

used, it is important to document baseline function for planning and comparative purposes. Anorectal manometry, which can be performed without sedation, can provide information regarding the anatomy and function of the sphincter muscle. First, the length of anal canal can be measured; men typically have a longer sphincter complex than women. Functional metrics that may be assessed include rectoanal reflexes, rectal sensation, rectal compliance, and intraluminal pressure changes when bearing down. Resting and squeeze pressures are provided. The volume to first sensation, volume to first urge to defecate, and maximum tolerate volume are also measured. Balloon expulsion testing is typically performed. Patients who are unable to expel the balloon within 1 min are suspected to have defecatory disorders [19, 20]. Patients with abnormal manometry may require defecography or endoanal ultrasound as well. Endoanal ultrasound, especially in women, will provide information regarding the anatomy of the sphincter muscles and whether or not there are any defects in the muscles from prior obstetric injuries. Patients with abnormal studies should be thoughtfully evaluated if proctectomy with sphincter preservation is appropriate, and patients should be selected on an individualized basis.

## Enhanced Recovery After Surgery (ERAS)

Though titled enhanced recovery *after* surgery, the ERAS pathways include preoperative, intraoperative, and postoperative components for patients undergoing colorectal surgery that allows for optimization of their entire perioperative care (Fig. 36.1).

The preoperative phase includes the initial evaluation of the patient, patient education, mechanical and antibiotic bowel preparation, preoperative analgesia, and fasting prior to the operation. The intraoperative phase of ERAS includes the utilization of minimally invasive approaches, such as TaTME, intraoperative fluid restriction, analgesia, and venous thromboembolism prophylaxis. The postoperative phase includes early



**Fig. 36.1** Enhanced recovery after surgery

feeding and advancement of diet, venous thromboembolism prophylaxis, specific analgesia regimens, fluid restriction, and discharge planning. While each institution typically has its own specific regimen for ERAS, generalized guidelines exist.

### Preoperative

Preoperative evaluation should focus on optimization of the patient's general condition as well as specific presurgical elements. Smoking cessation and limiting alcohol consumption have been shown to have improved postoperative outcomes when carried out for greater than 4 weeks prior to operation [21]. Optimization of nutritional support, through patient education and/or the addition of protein supplements, may improve the overall status of the patient as well. Evaluation and optimization of medical comorbidities are also necessary and may include several evaluations by subspecialty physicians. Preoperative evaluation may include utilization of a modified frailty index (MFI) that has been shown to

correlate with increased length of stay and can assist in identification of patients who may require additional resources. These patients may be identified to participate in prehabilitation programs to further optimize outcomes.

Along with optimization of the patient, education is paramount in preparation for surgery. Clear goals should be set with the patient in regard to pain control, diet advancement, patient participation in recovery, and discharge criteria. In preparation for the operation, all patients should undergo mechanical bowel preparation. Though the utility in bowel preparation in preventing infection or leak remains in question, it is still commonly utilized as it provides several benefits in the laparoscopic setting. The decompressed bowel after mechanical bowel preparation allows for easier manipulation and specimen extraction [22]. The addition of oral neomycin and metronidazole with the mechanical bowel prep remains controversial, but some studies have shown a significant decrease in rate of postoperative surgical site infection when utilized [23]. Given the transanal nature of the operation, the rectum should be completely cleared of stool for visualization of the rectal mucosa during placement of the purse-string suture in the TaTME approach. Furthermore, colon preparation can help limit the soiling of bacteria into the surgical field in the event a purse-string failure is encountered intraoperatively.

Traditionally, patients have remained fasting from midnight the night prior to surgery. Some centers have chosen to allow patients to continue to consume clear liquids up until 2 h prior to surgery and/or provide patients with various carbohydrate loading fluids to consume the morning of surgery. The theory behind this strategy is that reduction of insulin resistance may lead to a faster recovery [24]. There is no definitive data that this improves surgical outcomes and may in fact increase the anesthetic risks [25]. More research on this topic is necessary prior to drawing a firm conclusion.

Prior to the operation, patients should be given venous thromboembolism prophylaxis. 5000 units of heparin administered subcutaneously prior to the induction of anesthesia has been shown to

decrease the rate of venous thromboembolism [26]. The use of preoperative intravenous antibiotics administered within 60 minutes of the incision, and in adherence with SCIP (Surgical Care Improvement Program) guidelines, has been shown to minimize the risk of surgical site infection [27]. Several antibiotic regimens are utilized (isolated or in combination), including cefoxitin, ertapenem, ampicillin/sulbactam, ceftriaxone, cefazolin, Flagyl, Cipro, gentamycin, and clindamycin [28]. Administration of IV antibiotics within 60 min prior to incision has been found to result in a significant reduction in surgical site infection following colorectal surgery [29, 30]. Anti-nausea prophylaxis should also be administered. The utilization of alvimopan in minimally invasive surgery remains controversial, and current indications in colorectal surgery include open operations without creation of a diverting ostomy [31, 32].

## Intraoperative

There are several intraoperative elements that are involved in the ERAS guidelines that require participation by both the surgical and anesthesia teams. First, surgeons should attempt to utilize minimally invasive techniques whenever possible, either laparoscopic or robotic. Laparoscopy has been shown to have improved outcomes including decreased surgical site infection, infectious complications, pain scores, anastomotic leak, and decreased length of stay [33–38].

Long-acting opioids should be avoided as they contribute to postoperative ileus. In the preoperative area, patients may be given various nonsteroidal (acetaminophen, celecoxib) or neuropathic (gabapentin) pain medications to minimize the need for opioids [39]. Another adjunct that may reduce the need for opioids is the transverse abdominus plane (TAP) block [40, 41]. This can be performed by either the anesthesia or surgical teams. This block is designed to anesthetize the nerves that supply the abdominal wall (T6 to L1). Studies have shown that TAP blocks improve immediate postoperative pain outcomes and decrease opiate requirements [42].

The routine utilization of nasogastric decompression postoperatively is no longer recommended. Patients may forgo the use of gastric decompression altogether, or an orogastric tube may be utilized during the operation when indicated with removal at the end of the operation [43]. The patient's body temperature should be maintained at normothermic temperatures (36–38 °C). Methods to achieve normothermia include use of warm airflow blankets, warming the ambient temperature of the operating room, and warm intravenous fluids. Maintenance of normothermia has been shown to decrease surgical site infection [44, 45]. Surgical drains should also be used judiciously, as the data regarding drain placement are conflicting [46, 47].

One of the more controversial intraoperative ERAS items is the management of fluid administration. There are two approaches to intraoperative fluid resuscitation – traditional and restrictive [48]. Traditionally, fluids are given liberally at a maintenance rate with additional fluids given to replenish insensible losses and estimated blood loss. Newer data has emerged that demonstrates that this liberal approach to fluid resuscitation has been associated with adverse postoperative outcomes [49, 50]. Several randomized control trials have demonstrated mixed results. Some have shown that a restrictive, goal-directed approach is associated with decreased postoperative complications, earlier return of bowel function, and reduced length of hospital stay [51]. Other studies, still, have demonstrated that a liberalized fluid management approach confers improved outcomes [52]. Further randomized studies are needed to determine the ideal approach to fluid management in colorectal patients.

## Postoperative

Postoperative ERAS is essential for patient recovery. Over the last decade, there has been a substantial paradigm shift in postoperative care in the colorectal surgery patient in regard to nearly every aspect of their care. Typically, no

nasogastric tubes are left in place and patients are advanced on a diet rather quickly. Patients initially start on clear liquids and advance to full liquids and then a low-residue diet within the first day postoperatively. Studies have shown that patients who are provided with a solid diet immediately postoperatively have shorter overall lengths of stay than those who are started on liquids [53, 54]. Patients are allowed to self-regulate their diets based upon their own tolerance levels. If a nasogastric tube is left for gastric decompression, it is closely monitored for output and quality of drainage. The tubes are removed as soon as possible, and the patient is advanced on a diet as tolerated. Multimodal analgesia utilizing nonsteroidal anti-inflammatory drugs and neuropathic pain medications helps avoid the need for narcotics, which decreases ileus and in turn decreases length of stay. Early mobilization is also a major factor in reducing ileus, and patients are encouraged to ambulate in the hallway of the surgical unit five times per day with assistance. Again, fluid management is judicious, and as patients tolerate oral intake, intravenous fluid rates are minimized.

Post discharge planning starts immediately upon admission to the surgical unit. If necessary, physical therapy evaluations and recommendations are obtained, and discharge needs are identified early. Patients start working with wound ostomy care nursing on the first postoperative day to become accustomed to managing their ostomy.

Enhanced recovery after surgery requires collaboration and participation from all members of the patient care team. This includes not only the surgery team but the preoperative nursing staff, the postoperative nursing staff, and the anesthesia teams for management of intraoperative elements. With careful attention to patients' specific needs, ERAS can allow patients to successfully be discharged home safely without a risk for readmission or increased complications. The ERAS protocols used for traditional laparoscopic and open rectal cancer surgery should also be applied to those patients undergoing the TaTME approach.

## Conclusion

Proper patient selection and perioperative management are the first steps to good postoperative outcomes in TaTME surgery. This procedure, which combines pneumoperitoneum and patient position changes, results in unique physiologic alterations as compared to open surgery. While there are many similarities between the perioperative evaluation and care of patients undergoing TaTME surgery, nuances do exist. Decisions for preoperative testing and evaluation should be made in conjunction with the anesthesiology staff, medical physicians, and surgeon. Even a brief evaluation can often identify risk factors for perioperative comorbidity that can be closely monitored and intervened upon if and when necessary.

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## Introduction

Intraoperative complications during laparoscopic rectal surgery are fortunately an infrequent event for experienced surgeons. Most articles evaluating morbidity include all adverse events within 30 days after the procedure [1]. Some authors that specify intraoperative complication rates report percentages of approximately 12–13% [2, 3].

Transanal total mesorectal excision (taTME) gives new options for the treatment of distal and mid rectal cancer patients. Specifically, the obese male patient with a narrow pelvis might benefit the most from the access and vantage point provided by taTME. By approaching the rectum both from above and below might improve resection margins both distally and circumferentially. However, there are also possible risks related to

the new technique. Even though the embryologically derived planes are the same as during standard laparoscopic rectal cancer surgery, changing the approach to a transanal one makes the recognition of these planes more difficult [4].

With this down-to-up technique, the anatomy may appear distorted and unfamiliar, and this may result in serious procedure-related complications. The international taTME registry reported in 1594 patients an overall morbidity of 30.4% and re-intervention needed in 8.0% of the patients. Intraoperative complications were reported in 30.6% of the patients who underwent taTME, which was mainly caused by technical problems during the transanal phase (18.0%). Visceral injuries during the transanal phase were reported in 1.8%, including urethral, rectal, vaginal, bladder, and hypogastric nerve injuries [5]. Perdawood et al. reported a 13% rate of intraoperative complications after taTME, which was comparable to laparoscopic and open approach [6].

Koedam et al. reported on the learning curve of taTME. Even though no learning curve effect is described for intraoperative complications, major morbidity was increased during the first 40 patients. The same learning curve was observed for anastomotic complications and abscess formation [7].

Most intraoperative complications can be prevented by standardizing the sequence of the procedure, this will be discussed in detail in other chapters of this book. Most serious complications occur due to misjudgment of the accurate dissection plane,

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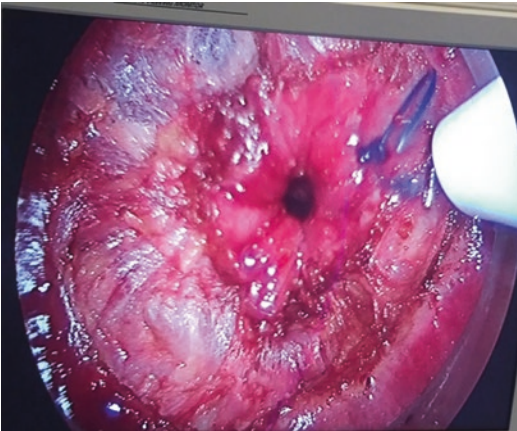
specifically on the lateral side wall and ventral to the rectum. Incorrect plane surgery has been described in the registry in 5.7% of all patients, although this is likely underreported [5]. Dissection too close to the rectum will result in violating the mesorectum or damaging the specimen via injury to the rectal wall proper with perforation, which is known to increase the likelihood of local recurrence [8]. Dissection outside the TME plane can, of course, result in damage to the neurovascular structures or an increased bleeding risk.

taTME can be broken down in clear steps which should be followed. For each step of the procedure, there exists a potential for complications. These are delineated in the following sections.

### Purse-String Application and Preparation of the Lumen

During taTME the rectal lumen is closed using a purse-string suture.

Both the correct position and quality of this suture are essential for a successful dissection and an adequate distal margin. The purse string should



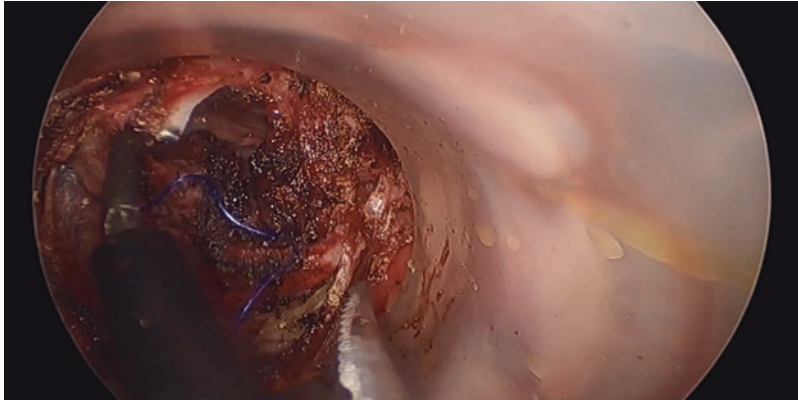
**Fig. 37.1** A purse string has been applied to the distal rectum, and the rectotomy has been completed circumferentially. While the purse string is intact, note that there is clearly a defect in the center as the purse string did not cinch down completely. The operator should at this point stop the taTME operation and secure this using a second stitch, typically in a figure-of-eight fashion. Failure to close even this small defect can lead to inadvertent spillage of stool and overdistension of the lumen rendering further dissection difficult

close the rectum completely (Figs. 37.1 and 37.2). Insufficient closure or disruption of the purse string during dissection might cause contamination of the surgical field (Fig. 37.3) with bacteria and tumor cells, increasing the risk of infection and potentially negatively influencing the oncological outcome as is observed in patients with a rectal perforation [9]. In addition, if the closure of the purse string is not airtight, the lumen of the bowel can become distended during the process of taTME, which thereby renders the abdominal portion of the operation more difficult.

Infection may be a special problem during taTME since the rectal wall is intentionally divided during the course of the operation, which could negatively impact the sterility of the procedure (i.e., compared to abdominal approaches which typically utilize staplers to simultaneously divide and seal the lumen). In a study by Velthuis et al. [17], 23 consecutive patients underwent taTME utilizing the TAMIS approach. Prior to and after purse-string application, the lumen was irrigated with a bactericidal agent. During the dissection, three samples were obtained sterilely via a swab delivered into the pelvis from the abdominal laparoscopic ports. This revealed that 39% of the cultures were positive for colonic flora and, of these, 44% developed pelvic infection requiring therapy. The authors concluded that taTME is associated with positive cultures in more than one-third of patients, and the data suggests that locoregional infectious complications are more common. Thus, while infection is a postoperative complication, its incidence may be increased if during taTME, adequate irrigation and a properly constructed purse string are not assured.

### Full-Thickness Rectotomy

After complete closure of the rectum, the next step of taTME is a full-thickness, circumferential dissection of the rectal wall. For this step, a sufficient purse string is essential. Without adequate pressure it is difficult to find the proper layer of dissection. It is easy to get off-plane in the muscular layer of the bowel wall. The consequence of insuf-



**Fig. 37.2** In this example of a purse-string failure, the purse string itself was intact with a complete seal. However, during the anterior dissection, the purse string itself was violated causing it to unravel. Anteriorly, the

exposed lumen is visible. Such a violation to the purse-string proper occurs when the dissection proceeds in a plane too close to the rectum or when the purse string is applied in tissue planes beyond the rectal wall



**Fig. 37.3** In an unprepped colon, in the event that the purse-string failure occurs during taTME dissection, extensive spillage of stool can sometimes occur, as shown, underscoring the importance of an adequate seal

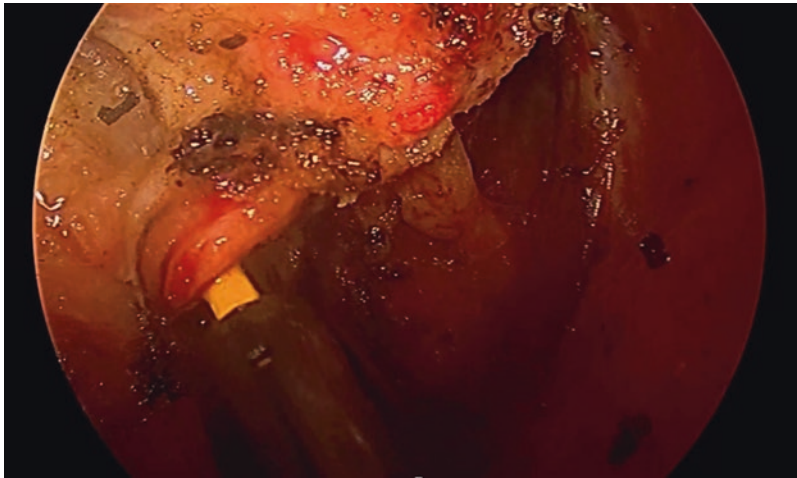
ficient tissue tension could therefore result in an inadvertent violation of the rectal wall proper. Such iatrogenic perforation not only make the next step of the taTME more difficult; it also may contaminate the surgical field and may compromise the oncologic integrity of the operation as well. The anterior dissection through the rectal wall in males is particularly challenging, because crossing fibers that extend to the prostate and urethra (the rectourethralis muscle and fibers of Luschka) create a smooth sheet of muscle that appears to be part of the rectal wall, but is not, and which must be properly divided to assure entry into the correct anterior plane and to assure that the prostate is not distracted posteriorly where injury to the posterior aspect of the pre-prostatic urethral is possible.

## Posterior and Anterior Plane

After the circumferential full-thickness rectotomy, most taTME surgeons start dissecting the TME plane at the safe dorsal side. The posterior midline is avoided because the rectal sacral ligament can make the localization of the proper plane difficult. It is easy to be pushed behind the rectal sacral fascia with possible bleeding from presacral venous plexus.

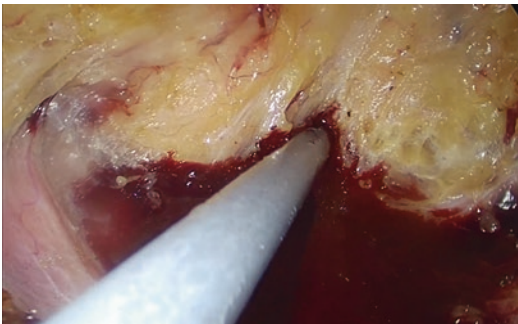
After localization of the TME plane on the dorsal side, the posterior dissection plane should be extended laterally, but not beyond 4 and 8 o'clock positions. The dissection next proceeds from the posterior to the anterior plane, and this can be done continuously through the lateral aspects. Here, there is the potential for morbidity which results from extending the dissection lateral to the envelope proper. In effect, due to pneumatic dissection of false, lateral planes, the surgeon may extend the dissection into an extra-mesorectal plane with possible injury to pelvic autonomic nerve plexi with a resultant compromise and impairment of postoperative functional results (Fig. 37.4). This lateral dissection may result in sacral venous injury that may be challenging to control, with hemorrhage from pelvic side wall veins or even iliac vessels (Fig. 37.5). Pelvic bleeding of more than 100 mL has been





**Fig. 37.4** The left nervi erigentes, a splanchnic nerve which provides parasympathetic innervation to the genitalia and which is responsible for erectile function in males, is shown in the grasp of a hook cautery just moments

before it was transected. Postoperatively, this patient suffered from erectile dysfunction. Note the exposed muscle laterally signifying that the dissection is too lateral to the mesenteric envelope



**Fig. 37.5** Posterior sacral venous bleeding occurs when the plane becomes too deep, especially posteriorly but also laterally. It is important that surgeons follow the natural curvature of the sacrum and not continue straight without anticipating this curvature. Failure “turn upward” will result in violation of the often elaborate venous plexus that is not only difficult to control but also renders the fusion planes much more difficult to visualize

anterolateral side (Fig. 37.6), it should warn the surgeons that wrong plane is followed; specifically, in male patients, it indicates that the prostatic complex including the urethra is being mobilized inadvertently.

This can result in one of the most important, procedure-specific complications of taTME, transection of the urethra, which is detailed further in a separate chapter. Briefly, however, in male patients, the angle of the anal canal and the TAMIS platform are directed toward the prostate gland, which could easily result in the taTME surgeon entering a plane that is too anterior, thereby leading to mobilization of the prostate, which is in very close juxtaposition to the anterior rectal wall (Fig. 37.7). The posterior lobe of the prostate gland will rotate downward leaving the urethra as a structure vulnerable to injury. With prerequisite training and experience, mobilization of the prostate is recognizable by the experienced taTME surgeons prompting immediate plane correction. The taTME registry noted that a urethra injury occurred in 0.8% of the patients; however, true male urethral injury rates may be significantly higher as such cases may simply not self-reported in the registry data available. In female patients, vaginal injury of the posterior

described in 4.2% of the patients undergoing taTME [5].

The conical skeletal muscles of the pelvic floor surround the rectum and mesorectum. Normally, the muscle is surrounded by investing fascia. However, this fascial layer can be violated during the process of taTME dissection. When this muscle is exposed and clearly visible on the

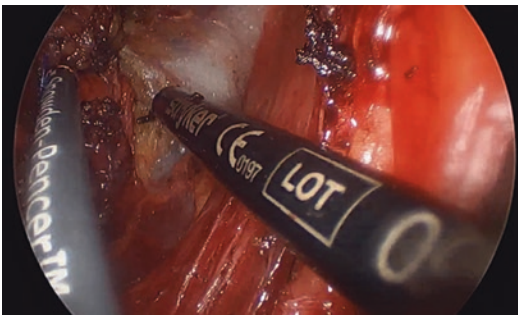
wall can occur. This injury might be less critical than urethral injury but can and should be avoided by digital manipulation of the posterior vaginal wall during taTME dissection along the anterior plane. Bladder injury is rare (0.1%) and can often be managed by placement of a urine catheter and sutured closure of the defect via transanal access (Fig. 37.8). Furthermore, cystoscopy may be indicated to assess the urinary trigone depending on the point of injury [5].

This mobilization of the prostate and dissection of the urethra can be prevented by a stepwise dissection. Before dissecting the lateral plane, the anterior plane is localized. The lateral plane can

be dissection by connecting both the dorsal and anterior plane. In the future, fluorescence with indocyanine green could help identify the urethra and prevent dissection in patients who received neoadjuvant radiotherapy or by surgeon in their learning curve. Currently, this remains investigational with the only data showing feasibility derived from cadaveric work [10]. Lighted near-infrared urethral stents appear to represent another valid option for urethral localization [11–13].

## The Anastomosis

Given the fact that taTME always starts with a dissection of the rectal wall, the technique always leaves an open rectal stump to be purse-string closed in preparation for anastomosis. Depending on the length of the rectal cuff, either a stapled or hand sewn anastomosis is performed. In case of a stapled anastomosis, a purse string should be placed at the rectal cuff, and this should be done with meticulous care, of comparable quality as the first one, so as to assure proper tissue union upon endoluminal stapling. An insufficient purse string might result in an anastomotic failure (leak) due to technical error. Fortunately, this can often be localized and

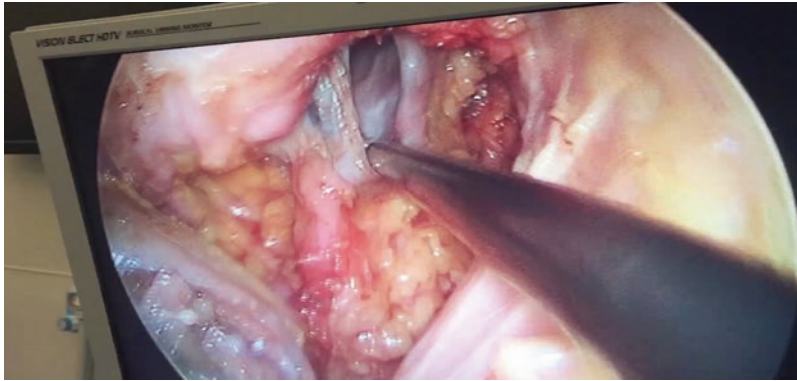


**Fig. 37.6** The exposed skeletal muscle of the pelvic floor is clearly visible during the posterolateral dissection. This muscle is typically covered by investing fascia, and exposure of bare muscle signifies dissection in a plane that is too deep



**Fig. 37.7** The close juxtaposition of the prostate gland to the distal anterior rectal wall makes injury to the urinary system one of the most dreaded complications of taTME. During the process of dissection, the prostate

gland can become dorsally distracted leading to the pre-prostatic urethra becoming inadvertently drawn into the plane of dissection. (Photo courtesy of Ichiro Takemasa, MD (Japan))



**Fig. 37.8** The bladder can be subject to posterior distraction and injury. Here, the anterior dissection proceeded anteriorly beyond the prostate gland and seminal vesicles in the proper plane, but then the bladder was encountered

and injured. Such injuries may be preventable with a synchronous approach as the abdominal team can distract the bladder ventrally to expose the anterior reflection at the point of rendezvous

corrected through the transanal port or under direct vision since the anastomosis is typically quite low (Fig. 37.9).

### Other Complications

Although rare, carbon dioxide (CO<sub>2</sub>) embolism can be a severe, life-threatening complication that occurs during taTME of which both the surgeon and the anesthesiologist should be keenly aware of this risk and prepared to initiate treatment if necessary. Due to the pneumoperitoneum with CO<sub>2</sub>, insufflation gas can be introduced into the relatively low-pressure venous system during dissection when inadvertent bleeding is encountered. In the current literature, only one case report has been described, although this is an area of ongoing investigation. It reports a classic CO<sub>2</sub> embolism with a decrease of saturation and blood pressure, which were restored after the cessation of insufflation [14]. The absolute risk during taTME is still under investigation, but anecdotes in the taTME community suggest that it might occur more often than currently reported.

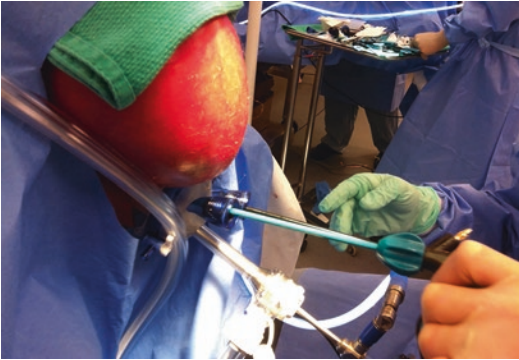
A complication not seen during standard laparoscopy is pneumatosis of the retroperitoneum. The pneumatosis of the retroperitoneum can develop when the transanal approach is performed



**Fig. 37.9** A stapled anastomosis after taTME is shown. The ultralow position allows for direct, inline operative access. Thus, if a small defect in the anastomotic line is identified, it can easily be oversewn

with one team and the procedure is started transanally. The insufflated CO<sub>2</sub> accumulates in the retroperitoneum making subsequent transabdominal surgery more difficult. Furthermore, an incomplete purse-string closure may result in significant dilation of the bowel itself, making exposure of the operative field from above more challenging. Pneumatic dissection along tissue planes can also lead to crepitus to the level of the neck. In males, the scrotum is particularly at risk for pneumatic dissection during taTME (Fig. 37.10). However, these effects are transient and resolve without further sequelae.





**Fig. 37.10** Pneumo-dissection is possible in several kinds of minimally invasive procedures and especially with taTME. Here, severe pneumo-scrotum is evident. Pneumatic dissection of this kind is self-limited and requires no specific therapy. The condition resolves without sequelae

Other concerns have also been raised that are specific to the taTME operation, including the potential to seed the operative resection bed with tumor cells, and at least one known case of tumor implantation after taTME has been reported [15]. Therefore, care should be given to assure that proper irrigation with tumoricidal agents (such as sterile H<sub>2</sub>O) is employed prior to and after purse-string application [16]. Finally, transanal extraction can lead to conduit ischemia due to shear stress on the marginal artery. This will be detailed in a separately in another chapter.

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# Functional Outcomes to Transanal Minimally Invasive Surgery (TAMIS) and Transanal Total Mesorectal Excision (taTME)

Elisabeth C. McLemore and Patricia Sylla

## Anorectal Function and Assessment

Transanal minimally invasive surgery (TAMIS) and transanal total mesorectal excision (taTME) may impact defecatory, sexual, and urinary function. There are a number of ongoing clinical trials assessing the impact of these procedures on functional outcomes; however, the current data available for review is limited. This chapter will address what is currently known regarding changes in bowel function following TAMIS and taTME.

Anorectal physiology and bowel continence are the result of a complex and dynamic interplay between pelvic floor musculature and timely contraction and relaxation of the sphincter muscle complex [1]. Formal and functional assessment of anorectal function includes anal manometry, dynamic defecography, cross-sectional imaging, and continence scoring systems such as the Cleveland Clinic Incontinence Index (CCII, Table 38.1) [1, 2]. Anal manometry measures rectal compliance and capacitance as well as anal resting and squeeze pressures. Defecography

evaluates the coordination of the pelvic floor muscles, rectum, and sphincter muscle relaxation during evacuation [3].

Assessing the severity of fecal incontinence (FI) can be measured using a variety of instruments ranging from healthcare-directed question to response grading scoring system such as the CCII [1]. The CCII assesses the frequency and severity of accidental loss of gas, liquid stool, and solid stool [1]. There are a variety of validated questionnaires assessing patient's perception of the severity of their bowel, bladder, and sexual function and impact on their quality of life. These are particularly helpful to assess preoperative and monitor postoperative functional outcomes [1, 4–7].

The Colorectal Functional Outcome Questionnaire (COREFO) is a validated instrument that focuses on assessing bowel function after colorectal surgery [4]. Low anterior resection syndrome (LARS) is a well-established syndrome characterized by alteration in bowel habits following low anterior resection. Patients with LARS typically have increased fecal urgency, frequency, and clustering of bowel movements. A validated scoring system known as the LARS Score [8] is another instrument available to assess the impact on function after rectal surgery. TAMIS and taTME are relatively modern evolutions of transanal microscopic surgery (TEM) and low anterior resection (LAR), respectively. As such, the functional outcome data available for review is limited at this time. The bowel

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**Table 38.1** Cleveland clinic incontinence index

Incontinence	<1x per month (1)	1–2x per month (2)	Weekly (3)	Daily (4)
Gas				
Liquid				
Stool				
Pad usage				
Lifestyle alteration				

Scale of 5–20

Minimal–No fecal incontinence: score of 5

Full fecal incontinence: score of 20

functional outcomes after TAMIS and taTME will be reviewed separately in the remainder of this chapter.

## Functional Outcomes: TAMIS

TAMIS [9] is a modern evolution of the transanal endoscopic microsurgery (TEM) technique pioneered by Gerhard Buess in 1983 [10]. TEM has been a disruptive technique in colorectal surgery. The initial results comparing TEM to the standard of care, transanal excision (TAE) revealed that TEM was associated with superior quality of resection demonstrated by the higher rate of achieving negative margins [10, 11]. Long-term results revealed that TEM resection of rectal lesions also resulted in a lower local recurrence rate compared to TAE [12–16]. More recently, multiple transanal platforms have been developed, and new techniques and terminology (such as TAMIS) have broadened the utility and applications of the TEM technique.

Prior to consideration of any transanal endoscopic surgical resection technique for removal of rectal lesions, patients must first undergo a systematic evaluation to properly characterize and stage the rectal lesion. The history and physical examination is the cornerstone of preoperative evaluation prior to considering a surgical technique, such as TAMIS. An overall assessment of the patient's general health is important to determine the ability to tolerate general anesthesia and determine the surgical approach. Previous anorectal surgery is an important consideration when planning TAMIS. The presence

of an anal or anastomotic stricture will hinder the surgeon's ability to position the operating transanal access platform.

The coexistence of fecal incontinence or borderline continence may alter the operative plan, as temporary and permanent fecal incontinence have been reported with transanal endoscopic microsurgery (TEM) [17, 18]. Multiple small TEM studies have documented a transient decrease in sphincter resting pressures on anal manometry that was proportional to the duration of the procedure, with resting pressures returning to baseline 12 months postoperatively [19–22]. Alterations in resting anal sphincter pressures did not translate into any detrimental effects on continence. In a study of 41 TEM cases, Cataldo et al. found no significant changes in the Fecal Incontinence Severity Index (FISI) or Fecal Incontinence Quality of Life (FIQL) scores 6 weeks postoperatively relative to preoperative scores [17].

A recent study that longitudinally assessed anorectal function and quality of life in 102 TEM patients preoperatively and at 6, 12, 26, and 52 weeks postoperatively found that the general quality of life scores (EQ-5D) were significantly lower at 6 and 12 weeks but returned to baseline at 26 weeks. Similar to prior studies, anorectal function as assessed by colorectal functional outcome (COREFO) was worse at 6 weeks postoperatively but returned to baseline at 12 weeks postoperatively [23]. However, two TEM series reported persistent sphincter dysfunction following TEM on long-term assessment using either St. Mark's fecal incontinence score or Wexner and Kamm incontinence scores [24, 25]. Dafnis et al. reported a 37% rate of various degrees of fecal incontinence in 48 patients at a median follow-up of 22 months following TEM and found a correlation with OR time [25]. Restivo et al. also reported a 28% incidence of variable degrees of fecal incontinence at a median follow-up of 40 months among a cohort of 89 patients who underwent TEM. Preoperative radiotherapy and perioperative complications were found to be independent risk factor for functional disturbances [24].

TAMIS is a more recent surgical technique compared to TEM, and naturally, the reported

functional outcome data after TAMIS is less robust in comparison. Albert and Atallah have reported their outcomes after TAMIS in their first 50 cases in 2013 reporting on margin status, specimen integrity, and postoperative complications [26]. The adoption of TAMIS has since then grown, as reflected by several additional midsize case series that have been published [27]. However, most early TAMIS case series have not reported on functional outcomes. In a small prospective study conducted by Schiphorst et al., functional outcomes following TAMIS were assessed in 37 patients using FISI score preoperatively and at 3, 6, 9, and 12 months postoperatively [28]. Among 17 patients with decreased preoperative fecal continence at baseline, improved FISI scores were noted in 88%, while among 18 patients with normal continence at baseline, no change in FISI scores was found in 83%, suggesting preserved long-term anorectal function following TAMIS procedures.

In 2017, Clermonts et al. published the incidence of impaired fecal incontinence in 42 patients who underwent TAMIS [29]. The fecal incontinence severity index (FISI) [30] was utilized to assess fecal continence over a median follow-up time period of 36 months (range 24–48). The preoperative FISI score was 8.3 points. One year following TAMIS, the mean FISI score was 5.4 points ( $p = 0.5$ ). Three years after TAMIS, the mean FISI score was 10.1 points ( $p = 0.01$ ). Overall, fecal continence improved in 11 patients (26%) and decreased in 20 patients (48%) [29].

More recently, 37 patients who underwent TAMIS were compared to healthy controls in an attempt to further evaluate the quality of life in patients following TAMIS [31]. The quality of life outcomes were measured using the Short Form 36 health survey (SF-36) questionnaire. The postoperative quality of life scores in the TAMIS group were similar to those reported by Dutch healthy controls. The quality of life scores for the “social functioning” domain were lower in patients who had undergone TAMIS compared to healthy controls (84 vs. 100 points,  $p = 0.03$ ). The authors concluded that TAMIS is a safe technique with postoperative quality of life scores

similar to that of healthy case matched controls at 3-year follow-up. There seems to be no association between fecal incontinence scores and reported quality of life. However, the potential negative impact of TAMIS on fecal continence and/or quality of life should not be underestimated and should be discussed during preoperative counseling.” [31]

There is growing interest in formal evaluation of functional outcomes after TAMIS and other transanal endoscopic surgical resection techniques. We eagerly await long-term functional outcomes following TAMIS in the setting of larger multicenter studies. In the meantime, it is advisable to follow the cautionary report by Clermonts and colleagues and continue to counsel patients preoperatively regarding the potential impact on social and functional outcomes after transanal endoscopic surgery using any type of transanal access device.

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## Functional Outcomes: taTME

With increasing interest in natural orifice surgery, the dynamic evolution of transanal and endoluminal surgical techniques continues. These techniques began with transanal endoluminal surgical removal of rectal masses and have progressed to transanal radical proctectomy for rectal cancer. The first case of taTME was performed in 2009 by Sylla, Rattner, Delgado, and Lacy [32]. The improved visibility and working space associated with the taTME technique are appealing and have resulted in many surgeons to return to the cadaver lab for additional rectal cancer surgical training in the taTME technique [33, 34].

There are several ongoing clinical trials further evaluating the safety and efficacy of the taTME technique. Many of these trials are also assessing functional outcomes in addition to oncologic outcomes after taTME. A multicenter phase II study of transanal TME (taTME) led by Patricia Sylla (Mt. Sinai Hospital, New York City) is currently enrolling patients with Stage I–III rectal cancer (NCT03144765, [ClinicalTrials.gov](https://clinicaltrials.gov) Identifier). A single-center clinical trial titled “Transanal total mesorectal excision for rectal

cancer on anal physiology plus fecal incontinence” led by Dr. Tracy Hull (Cleveland Clinic, Ohio) is also actively enrolling patients for further evaluation of this technique (NCT03283540, [ClinicalTrials.gov](https://clinicaltrials.gov) Identifier). The COLOR III, an international multicenter randomized clinical trial comparing taTME versus laparoscopic TME for mid and low rectal cancer, has also added functional outcome assessment to the secondary endpoints and is also actively enrolling patients.

Without any results from multicenter phase II and randomized phase III clinical trials, there is little known at this time regarding functional outcomes after taTME. Preliminary comparative reviews published in July 2018 by Velcamp Helbach et al. demonstrated comparable functional and quality of life outcomes in patients undergoing taTME and laparoscopic TME [35]. A total of 27 patients who underwent taTME and 27 patients who underwent laparoscopic TME were asked to complete 5 questionnaires related to functional outcomes and quality of life. All of the taTME procedures were performed by a single surgeon at the Gelderse Vallei Hospital with a minimum of 7 months follow-up [27]. One item concerning fecal incontinence was scored worse for taTME. The LARS symptoms and urinary functional outcomes were similar between the two groups [35].

Understanding the impact of TME on anorectal physiology and fecal continence is complex and likely depends on several anatomic, medical, and surgical factors including patient age and preoperative function, whether preoperative radiotherapy was administered, whether intersphincteric resection was performed, the extent of rectal resection, and the level and type of colorectal or coloanal anastomotic reconstruction. The dynamic loss of the reservoir functional capacity of the rectum, potential dyscoordination of the pelvic floor musculature, and impact of the timely contraction and relaxation of the sphincter muscle complex after TME is an area of increasing interest in academic, social, and public health research communities. In the meantime, it would be wise to follow the cautionary reports currently available in the literature and continue to counsel patients preoperatively regarding the potential

impact on social and functional outcomes after TME for rectal cancer using any surgical technical approach.

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## Grading of TME Specimen

Total mesorectal excision (TME) is considered the gold standard surgical procedure for mid and low rectal cancer since Bill Heald described it and showed dramatic improvements in the long-term oncologic outcomes [1–3]. Thus, the goal of the surgery is to achieve a perfect quality TME, where the mesorectum is excised “totally” as the name implies. This goal is unfortunately not always achievable in every case, especially in challenging cases where there are anatomical factors that render the dissection difficult; prototypically this occurs when the dissection is performed on an obese male patient with a narrow pelvic inlet. With the introduction of TME in the era of open surgery, perfect specimens could be retrieved by well-trained colorectal surgeons in most cases, and data were reproducible in numerous studies. Even recently, data from open surgery show very high rates of satisfactory results [4, 5]. With the available evidence from open surgery, new minimal invasive techniques must be rigorously compared to these standards, as the oncological quality should never be jeopardized. Ever since the introduction of laparoscopic surgery, the question of whether it can reproduce the results from open surgery remains essentially unanswered for

rectal cancer. With no doubt about the short-term benefits of laparoscopy, the oncologic results continue to be questioned [6–12]. In search for the optimal method to achieve a perfect TME, technological advances like robotic and transanal surgeries are to be regarded as ongoing efforts to achieve Heald’s TME in a minimal invasive manner, especially where access to the low rectum is challenging by other modalities.

Regardless of the approach used, surgeons must assure that the quality of the TME is as close to perfect as possible. Fortunately, TME grading is well-standardized for the excised specimen. Efforts by pathologists alongside advances in the surgical technique and the surgeons who help modernize the approach to rectal cancer surgery have led to a standard and reproducible description of the excised specimens [13–15]. The plane of surgery during TME constituted an independent factor for local recurrence in a recent analysis of a randomized clinical trial ( $P = 0.002$ ) [16]. While rates of “complete” specimens after open TME are acceptable in most publications from high-volume centers, laparoscopic surgery seems to lag behind. For this reason, taTME (a minimally invasive technique with improved access) could show immediate signs of improvement in the quality of the performed surgery through an improvement in the rates of “complete” mesorectal specimen as defined by Phil Quirke [15].

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The initial reported cases of taTME demonstrated a remarkably high rate of “complete” mesorectal envelopes, and some even reported 100% intact TME specimens [17–24]. However, terms like “satisfactory” or “good” results should be interpreted with caution of whether the specimens were “complete” or “nearly complete.”

With the increasing adoption of the procedure and liberal inclusion of difficult cases, a tendency is seen toward a fall in the rates of specimen “completeness” [25–28]. These studies have showed rates of “complete” specimens ranging from 47% to 84%. The largest published series with number of patients included ranging from 50 to 186 plus taTME registry data have shown promising results, with rates of specimen “completeness” that are comparable with those achieved through standard laparoscopic approach [28–37].

In the taTME registry study by Penna et al. [29], the TME specimen was “complete or near complete” in 96% of cases (85% complete, 11% near complete, 4% incomplete). However, patients were registered from several centers, and there is probably a case selection bias, especially of the initial cases. The two reports from Barcelona with 140 and 186 patients are probably overlapping; nonetheless the series of 186 patients is the largest published to date [30, 31]. The authors reported rates of specimen “completeness” of 97.1% and 97.5%. These are without a doubt excellent results from experienced team that standardized the technique of taTME, which is still considered by most colorectal surgeons to be a challenging and complex approach. The second largest published series from one center to date is from Denmark [34] and shows a rate of 86% specimen “completeness.” Other series have similarly acceptable rates of at least 84% [28, 32, 37]. A comparative study by Velthuis et al. (2014) demonstrated that the TME quality was improved with the taTME approach versus the laparoscopic approach (96% vs. 72%,  $p < 0.05$ ) [37].

An apparent conclusion of the investigators has been that to improved surgical access with taTME, translated into improved TME quality. This has been shown to be the case with transanal dissection in similar fashion without using the transanal platforms, prior to the advent of the

modern approach to taTME. Marks et al. [37] reported results of 370 rectal cancer surgeries where TME was initiated from below. In 96% of cases, the TME specimen was either “complete” or “nearly complete.” In conclusion, taTME seems to overcome difficulties in the dissection of the lowest part of the rectum and may result in superior TME quality in select cases, although comparative, randomized trials are still lacking.

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## Circumferential Resection Margin

One of the most important goals of surgery for rectal cancer is to achieve a free resection margin, mainly through retrieval of a perfect specimen. The circumferential resection margin of the mesorectal specimen has a great prognostic impact on the local recurrence and distant metastasis [38, 39]. It is the circumferential resection that is more frequently involved and is one of the more challenging aspects of TME surgery. Numerous studies have shown alarmingly high rates of circumferential resection margin involvement, worse in tumors located in the lowest part of the rectum [40–42]. To date, published series of taTME have shown quite acceptable rates of involved circumferential resection margins. Even in advanced cases of rectal cancer selected for taTME, Rouanet et al. [19] reported a free margin in 87% of 30 patients with advanced rectal cancer. Overall, most studies report no involved circumferential resection margins; this can be partly attributed to selection of less challenging cases. The rates of circumferential margin involvement in the reported series range from zero to 11.8% [22, 25, 34, 36, 43–47]. Data from the international registry showed an involved circumferential margin rate of 2.4%; however as a cautionary note, 7.1% of this registry was “not reported” [29]. With the largest published number of consecutive cases from a single center, De Lacy et al. have reported a rate of involved margin of 8.1% (defined as CRM  $\leq 1$  mm, excluding T4 tumors) [31]. Perdawood et al. [48] have shown comparable rates of margin involvement among patients treated by open, standard laparoscopic and transanal procedures. In analyzing these rates with those of standard laparoscopic approach, clear

benefits of taTME could be demonstrated, showing at least comparative rates of involvement of circumferential resection margin [49–52]. Finally, in a randomized trial comparing the transanal approach to radical rectal resection versus laparoscopic surgery by Denost et al., the rate of circumferential resection margin was significantly lower with the transanal approach (4% vs. 18%,  $p = 0.02$ ).

These data suggest that taTME has the potential to improve rectal cancer care, through lower rates of positive circumferential resection margins when compared to standard laparoscopic approaches, as realized by most published series to date. However, this must be interpreted with caution since they are mostly from centers with special interest and experience in taTME surgery. With appropriate training and experience, the rate of circumferential resection margin positivity may be lowered by utilizing this novel approach to radical rectal cancer resection.

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### Distal Resection Margin

In laparoscopic or open TME, transection of the rectum is done without direct view of the tumor itself and these techniques depending on tactile assessment of the tumor. Potentially, this can lead to lower anastomosis than necessary. Even worse, with such top-down approaches, there exists a real risk of transecting across the tumor and jeopardizing the oncologic outcome of the operation. This risk can be theoretically eliminated in taTME, due to direct visualization of the tumor allowing for a precise transection of the rectal lumen with a suitable safe margin.

While theoretically the risk of a positive distal resection margin should be zero, this is not what has been observed. While registry data suggests that the distal resection margin positive rate is quite low (0.3%) [29], other data contradict this finding. In fact, the rate of positive distal resection margin has been reported to be as high as 8.7% in the center with the most experience with this approach [53]. While positive distal resection margins are still inexplicably observed with taTME for rectal cancer, overall, a longer distal resection margin is appreciated [54]. In a 2015

study by Fernandez-Hevia et al., the distal resection margin was longer with the taTME approach when compared to the laparoscopic approach (2.8 vs. 1.7 cm,  $p < 0.01$ ). This is not necessarily an advantage, and a very low anastomosis can be the end result, which compromises the functional outcomes.

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### Local Recurrence

The most crucial goal of surgery for rectal cancer is disease-free survival by providing local tumor clearance. Local cancer recurrence is therefore an important parameter of the quality of surgery. In standard laparoscopy, a local recurrence rate of 5% was observed in both laparoscopic and open TME groups in a randomized clinical trial comparing the two approaches for rectal cancer [55]. The study had locoregional recurrence at 3 years as the primary end-point.

While taTME is still a relatively new procedure and long-term results from the largest series are not yet available, several cases of local recurrences have already been reported. Rouanet et al. [19] reported local recurrence in 1 patient out of 30 with an observation period of 21 months. The circumferential resection margin was involved in this case. Veltcamp et al. reported two cases of local recurrence among 80 (2.5%) patients who underwent taTME [32]. The follow-up time was 30 months. A similar rate of local recurrence rate of 2.3% was reported among 140 patients by Lacy et al. where the mean follow-up time was 15 months [30]. One case of local recurrence among 32 (3.1%) operated patients was reported by de Angelis et al. [56], and here the follow-up time was 24 months. Burke et al. [35] reported local recurrence in 2 out of 50 patients (4%) after a median follow-up period of 15.1 months.

After nearly a decade since the introduction of taTME, more studies to be awaited with special focus on the long-term results, including local recurrence. The pattern of recurrence is also an interesting subject due to the inherent nature of the procedure that involves transluminal transection, insufflation of CO<sub>2</sub>, fixation of the anal sphincter retractor with traumatic instruments, and transanal

specimen retrieval. All of these can potentially lead to tumor cell implantation and increase the risk of local recurrence. One published case of local recurrence raises the suspicion of implantation similar to port-site metastasis [57], which is seen in laparoscopic colorectal surgery.

## Distant Metastasis

There is slowly emerging data on distant metastases after taTME for rectal cancer. However, the follow-up periods remain relatively short. Atallah et al. [25] reported 1 distant metastasis in 20 patients (5%) after a mean 6 months of follow-up. Lacy et al. [30] found 7.6% metastasis in 140 patients with a follow-up period of 15 months. Buchs et al. [36] found metastases in 6 out of 40 patients (15%). In this study, a case mix is seen, with a relatively high number of low tumors, and the complications rate is relatively high despite acceptable specimen grading quality. Burke et al. [35] reported 8 distant metastases in 50 patients (16%) after a follow-up of 15.1 months. Mege et al. [58] reported metastases of 15% in 34 patients with mean follow-up of 13 months.

It is not evident from the literature, whether these reported metastatic cases occurred in patients with more advanced cancers or in patients with a poor quality of the retrieved specimen. Further studies with longer follow-up and larger patient population can probably give a clearer picture of the rates and the metastatic pattern after taTME.

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## Introduction

The transanal total mesorectal excision (taTME) was pioneered with the objective of optimizing the oncologic outcomes of the distal rectal dissection. Surgeons have noted an improved visualization and dissection of the TME plane with hopes of improving the oncologic outcomes given the ease of access via a perineal approach. The “head-on” view of the bottom-up approach, pioneered by Sylla and Lacy [1], has been reported to be associated with excellent R0 resection rates and low incidences of CRM positivity. However, in some situations, despite the best efforts of the multidisciplinary team to downsize the tumor with neoadjuvant adjuncts to improve both the amenability to resection and the likelihood of a negative CRM, the malignancy involves adjacent structures that, if resected, can still afford the patient a disease-free state post-resection. Excellent results – with a high rate of R0 resections – have been observed in high-volume specialty centers, when coordinated between the appropriate specialties [2]. These exenterative

techniques rely on the individual surgical teams having a strong familiarity of embryologic planes, the vascular anatomy of the pelvis and supply of other pelvic organs, the distribution of the nerves in the sidewall and sacral foramina, and, finally, the need at the time for reconstructive techniques based on the structures resected and local factors, such as prior radiation exposure.

Few cases of exenterative techniques in taTME have been reported in the literature, often referred to as transanal total pelvic exenteration (taTPE). Moreover, they tend to mostly be performed at a few specialty and high-volume institutions only [3, 4]. The rationale for taTPE may be, in part, related to the remarkable ease of mobilizing the prostate gland and the urethra noted during taTME. Ironically, the *Achilles’ heel* of taTME (i.e., inadvertent urethral injury) has likely been a contributing factor in why the taTPE approach has been pioneered, as the urethra is now *intentionally* divided as part of the planned operation. Thus, the vantage point of taTPE together with the known, high-quality excisions achieved with taTME in expert hands has intrigued surgeons to explore this technique as a valid approach to curative-intent resection.

It should be highlighted that a “total” exenteration is not necessarily always the objective; selective anterior or posterior exenterations are also possible, based on the oncologic requirements of the resection. The main individual cases that have been presented have included those in

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patients without systemic disease or those with a burden of metastatic disease that would otherwise preclude an attempt at curative resection. Furthermore, patients who have undergone taTPE have had underlying tumor extension into the prostate gland, the posterior vaginal wall, and/or the presacral and lateral sidewall fascia. Involvement of the levator ani muscles or the external sphincters is also amenable to a dissection under pneumoperitoneum (taAPR) via an extralevator approach; this will be discussed in a separate chapter.

Given the early experiences with taTPE, we will discuss the various principles of treatment as well as the operative approaches that have proven to be crucial in planning a radical exenteration under pneumoperitoneum, focusing on the technical aspects of the procedure. The oncologic principles of exenterative procedures will be discussed briefly, as they pertain to the technicalities of a taTPE.

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## Patient Indications

Indications of treatment can be categorized in baseline performance characteristics as well as the oncologic resectability of the primary tumor. It is crucial to ensure the patient is well informed of both the physical demands imposed by exenteration and the extended recovery and changes in quality of life – even in instances whereby reconstruction via low colorectal/coloanal anastomosis is possible [5]. Patients have been shown to perform best when they demonstrate high levels of baseline quality of life metrics and should be advised that improvements in quality of life can take between 2 and 12 months to manifest [5, 6]. Minimally invasive approaches to an exenteration may facilitate both the recovery process and the resumption of an active lifestyle but can only be performed in select cases [7]; however, the extent of the resection remains a significant source of morbidity, and the procedure is only possible in highly selective patients. The majority, if not all patients, will have been treated with neoadjuvant therapy to both decrease the burden and improve the likelihood of an R0 resection [2,

8]; however, receiving neoadjuvant therapy has been consistently associated with a more comorbid postoperative course.

Oncologically, surgeons must be confident in the likelihood of being able to achieve a margin-negative (R0) resection, prior to embarking on such an endeavor. As such, it is crucial to involve colleagues from all appropriate subspecialties – which may include urology, gynecology, orthopedics, as well as plastic surgery for reconstruction when necessary in the planning phases. *Having the patient assessed by each subspecialty surgeon is imperative to ensure specialty-specific assessments of resectability and discussions of the consent and perioperative/postoperative expectations.* Furthermore, a multidisciplinary cancer conference (MCC) discussion can allow for further optimization of the approach and assessment of resectability, as well as determining appropriate adjuvant and/or neoadjuvant protocols.

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## Anatomical Planning

Prior to embarking on the procedure, it is important for surgeons to plan all aspects with subspecialty collaborators. This is even more important with a taTPE where many other subspecialists may not be aware of the details and requirements of the technique. Sequencing the procedure through a rehearsal process is crucial to address all potential impediments of surgery from patient positioning, repositioning when necessary, intraoperative difficulties in dissection, and staging specialty-specific involvement in the procedure as well as staging reconstruction (gastrointestinal, urologic, or plastic myogenous/myocutaneous).

Imaging is crucial in these procedures. CT imaging can be helpful in demonstrating systemic disease as well as local tumor extent. The details of the locoregional extent of disease can be optimized with MRI. This can help clarify details including fascial involvement, extent of other pelvic organ involvement, and adherence to or invasion of pelvic vasculature. Furthermore, MRI has been shown to improve assessments of both tumor viability and regression following the

administration of neoadjuvant therapy [9]. The extent of involvement of the external sphincter or levator musculature can be further optimized with transanal ultrasound which has a higher sensitivity (compared to MRI) for delineating early T-staging [10]; this may further inform the surgical team regarding the potential for sphincter preservation.

The details of the extent of the oncologic resection will depend on the preoperative imaging which is best repeated following the completion of neoadjuvant therapy and at the appropriate time interval. This will vary by institution and by the modality of neoadjuvant therapy that was administered. The extent of the resection should be dictated by the consensus decision of the MCC discussion. The ability to salvage other pelvic organ structures will depend on the inter-specialty assessments. Sphincter preservation is not usually possible when there is a resection of the pelvic floor musculature such as in cases of invasion or sacrectomy. Considerations of sphincter preservation can be stratified into functional and oncologic factions. Functional factors are considered on an individualized basis and are based on the patient's preference, depending on preoperative continence as well as postoperative expectations of gastrointestinal function. Pertinent oncologic factors include distance of the tumor from the anorectal junction (ARJ) and, in cases of partial or total intersphincteric resections, the clearance of the intersphincteric plane or lack of involvement of the external sphincter.

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## Operative Approach

The feasibility of a transanal approach to the resection has been reported in male patients with en bloc prostate and seminal vesicle resections [3, 4, 11] as well as anecdotal experiences with resections of the posterior wall of the vagina. Hayashi and colleagues discuss performing a lateral pelvic node dissection as part of a laparoscopic total pelvic exenteration with taTPE technique for perineal completion and extraction; during this technique, the authors performed the pelvic sidewall dissection during the abdominal

phase; and it should be noted that the prostatectomy was completed from the abdominal phase of the operation as well [11].

## Platforms

The main platforms to consider for taTPE are the disposable transanal platforms (Gelpoint Mini<sup>®</sup> and Gelpoint Path<sup>®</sup>, Applied Medical, Rancho Santa Margarita, CA, USA; SILS Transanal port, Medtronic<sup>®</sup>, Minneapolis, MN, USA; Keyport Flex<sup>®</sup>, Richard-Wolf, Knittlingen, Germany) and the fixed or rigid platforms (Transanal Endoscopic Microsurgery, Richard-Wolf, Knittlingen, Germany; TEO<sup>®</sup>, Karl Storz Endoskope, Tuttlingen, Germany). Each port has advantages afforded to the surgeon and procedure. Most surgeons will use the port they are comfortable with during standard taTME and transanal endoscopic procedures.

## Sphincter Preservation or En Bloc Perineal Resection

One of the first decisions that needs to be made is to determine whether or not sphincter preservation is feasible. If the patient's sphincter can be preserved, then the dissection can be initiated through a standard approach used in taTME. The details of initiating this dissection will be discussed elsewhere and will depend on the distal extent of the tumor. The modified Rullier criteria, proposed by Knol and Chadi, can provide a pictorial frame of reference to this assessment [12]. Briefly, if the tumor is present more than 2 cm from the ARJ, the transanal dissection can be initiated under pneumoperitoneum with the TAMIS port's access channel seated in place. If it is less than 2 cm from the ARJ, the dissection is often initiated with a non-endoscopically placed purse string, usually after anal effacement with the Lonestar<sup>®</sup> device, or similar. If a total or partial intersphincteric proctectomy is planned, the dissection is often initiated in the appropriate plane prior to, or after, which the purse string is formed. The dissection is then transitioned from a traditional transanal approach (often described as the

transanal transabdominal or TATA) to one under pneumopelvis when the TAMIS port apparatus has been docked. This approach is generally more straightforward to perform (especially for surgeons have not performed a taAPR) given the relatively more traditional perirectal anatomy of a taTME.

If sphincter preservation is not possible, surgeons should have had some experience with taAPR as the planes of dissection can be quite different and require a detailed knowledge of the pelvic floor musculature to navigate proximally. This will be covered here briefly and in more detail in a separate, dedicated chapter.

The decision of an intralevator or extralevator dissection needs to be made. The extralevator dissection tends to be more amenable to a taAPR approach as the fascial planes of the pelvic floor musculature tend to be more straightforward to follow. The landmark of the coccyx and the gluteus maximus muscle are identified. The coccygeus and internal obturator muscles are identified at the ischial spine. The levator ani muscles are dissected off the attachments of the coccygeus and internal obturator muscles. This provides access to the supralevator space, allowing for a continuation of the dissection along the internal obturator muscle. This procedure is performed on each lateral aspect of the dissection. The internal pudendal artery is also identified and ligated during the dissection. Anteriorly, the perineal body is identified and dropped posteriorly along the transversus perinei muscle. In male patients, this guides the surgeon during this anterior dissection to the level of the membranous urethra at the insertion of the prostate. At this level and under direct observation and control, the urethra can be transected with the distal aspect remaining exposed for considerations of reconstruction in the case of prostatectomy. The details of a female dissection will be covered below.

### **The Prostate, Seminal Vesicles, and Bladder**

Distal rectal tumors may extend into the prostatic capsule or into the parenchyma of the prostate

gland. Options for partial prostatectomy do exist although this can be difficult to perform, given difficulties understanding and predicting the extent of invasion into the prostate during the intraoperative dissection. Tumors abutting the prostatic fascia can often be approached with an intraparenchymal dissection. This is often more straightforward to perform transabdominally after entering into the plane anterior to the recto-prostatic fascia (Denonvilliers' fascia) allowing for a preservation of the seminal vesicles and the urethra.

When deciding to perform a total prostatectomy as part of the procedure, it is prudent to consult with a urologist in the surgical decision-making process, especially for the purpose of operative planning. The resection will often require removal of the seminal vesicles that is often approached transabdominally and communicated with the transanal dissection. During this process, the vas deferens is identified lateral to the seminal vesicles. The seminal vesicles are identified when the peritoneal reflection anterior to the rectum is incised. This is often performed 10–20 mm anterior to the true reflection. Following the alveolar plane laterally will take the surgical dissection anterior to the seminal vesicles so as to ensure they are included en bloc with the surgical specimen. When the vas deferens is identified, it can often be transected with an energy device. The dissection can then be followed anterior to the seminal vesicles distally to communicate with the transanal dissection. Care must be taken to allow the transanal team to perform the prostatic mobilization.

An additional decision integral to operative planning for taTPE is to determine whether or not the bladder must be excised. Fundamental to this is the assessed involvement of the trigone of the bladder for tumor extension, which mandates en bloc cystectomy. The prostatic dissection can be approached with a combination of a transabdominal and transperineal approach. Transabdominally, after the ureters are identified and isolated as close as possible to the bladder, they are transected with preservation of the peri-ureteric fat for the purposes of maintaining vascularity. The peritoneum is incised lateral to the median umbilical ligaments,

and the space of Retzius is entered with maturation of the plane. Transection of the urachus and median umbilical ligaments should be performed with caution to avoid injury to the inferior epigastric vessels, especially in cases where a vertical rectus abdominus myocutaneous flap will be used for perineal reconstruction.

The plane in the space of Retzius is developed until the endopelvic fascia is reached and opened. The vas deferens is often divided at this level to expose the lateral sidewall and the external iliac vessels and to allow for ligation of the superior and inferior vesicle arteries as well as the vesicoprostatic artery. The superficial dorsal venous complex is exposed and ligated with an energy device when adequate proximal and distal control has been obtained. This later aspect of the procedure can often be performed during the transanal portion of the procedure as well as discussed below.

During the perineal component of taTPE, if sphincter preservation is planned, the surgeon begins with a full-thickness rectotomy at the desired distal margin. The dissection is followed along the presacral plane posteriorly after which, the dissection is advanced further laterally and external to the TME plane to include the visceral pelvic fascia en bloc with the dissection. This will guide the surgical team external to the traditional TME plane when extending the dissection laterally. The prostate is kept pedicled anteriorly to the urethra. The surgical team can follow the extraperitoneal dissection, lateral to the visceral pelvic fascia. This is usually the wrong plane of dissection during a traditional taTME as it takes the surgeon in the extra-TME plane and eventually into the space of Retzius and anterior to the prostate. While entering into this plane when performing an en bloc prostatectomy, care should be taken to avoid the various nerve bundles in the pelvic sidewall which are susceptible to injury. Additionally, when preserving the bladder, limiting the more proximal dissection of the space of Retzius will allow for the bladder to remain adherent anteriorly. As this dissection is continued anteriorly, the membranous (pre-prostatic) urethra is identified. The urethra is next transected along with the urinary catheter; alternatively, the catheter can be left in place for orientation pur-

poses as the remainder of the dissection is continued posterior to the posterior wall of the bladder and into the peritoneal cavity. Care must be taken to identify the dorsal venous complex, which lies anterior and more proximal to the prostate. Once identified the dorsal vein can be divided with a vessel-sealing device, in conjunction with the rest of the urinary sphincter. If unsure of this plane transanally, it may be safer to perform it during the more familiar transabdominal approach. The urethra can then be reconstructed through a bladder advancement to the distal site of transection through the transanal access platform. The bladder-urethra anastomosis is constructed over a urinary catheter (which serves as a stent) and is fashioned with interrupted absorbable sutures. When complete, coloanal reconstruction and anastomosis with an end-to-end, side-to-end, or colonic-j-pouch-configuration utilizing either a stapled or hand-sewn approach is then fashioned.

When a cystoprostatectomy is planned, the lateral dissection discussed in the above section is continued into the space of Retzius and anterior to the prostate and, more proximally, to the bladder. The dissection laterally in the space of Retzius can be continued more proximally such that it facilitates entry into the space anterior to the bladder, thereby dropping it posteriorly for en bloc exenteration. This dissection will have often been performed synchronously with transabdominal dissection during which the two approaches will be communicated at the point of rendezvous. Ileal conduit reconstruction with ureteric reimplantation is then performed during from the abdominal approach.

When anal sphincter preservation is not planned, the approach to the prostate and bladder remains similar – other than the anterior approach to the urethra. As the perineal body is dropped posterior to the transversus perinei muscle, the dissection is brought proximally to the level of the urethra. The remaining steps of the oncologic resection are performed as described above. Perineal reconstruction with biologic mesh or myogenous/myocutaneous flap advancement can be performed when necessary, often in conjunction with plastic/reconstructive surgical team.



## Female Patients and taTPE

As of yet, there are no publications or video reports of an anterior exenteration in a female patient via the taTPE. The approach has been discussed and theorized among authors. Many anterior exenterations in female patients mandate en bloc posterior vaginectomy. Theoretically, the main technical impediment with the taTPE approach is the difficulty in maintaining pneumoperitoneum when the posterior vaginal wall has been excised, because the transanal TAMIS port cannot close the entire perineal defect. As such, the perineal approach, with or without sphincter preservation, can be potentially performed posteriorly and laterally, leaving the tumor and specimen pedicled on the anterior attachments to the posterior wall of the vagina. Additionally, care should be taken to ensure preservation of the autonomic nerves that course along the lateral vagina, if oncologically permissible. Once the perineal dissection is communicated posteriorly and laterally to the abdominal dissection, the abdominal team can also continue the abdominal dissection to the level of the cephalad limit of the intended vaginectomy. The vaginectomy can then be performed transvaginally and transperineally into the vaginal vault and circumferentially around the area of the vagina involved. If the anus is preserved, the posterior wall of the vagina can be closed with or without added reconstruction. If the anus is not preserved, a myocutaneous flap can often be performed to reconstruct the posterior wall of the vagina and the perineum. If an en bloc hysterectomy is intended, a standard approach to hysterectomy can be performed with the anterior dissection continued along and through Morrison's pouch to communicate with the vaginal vault. Care must be taken to avoid injury to the bladder and urethra anteriorly during this dissection.

## Postoperative Considerations

The postoperative course of patients does not differ from patients managed with a standard exenteration. Publications have reported rapid recovery,

when a minimally invasive approach to this radical operation is utilized [7, 11]. Urethral catheters should be managed by the urologic team as should the ureteric stents in cases of ileal urinary conduit creation. Additionally, standard anastomotic assessments should be performed prior to reversing diverting stomas for coloanal anastomoses, assuming an anastomosis has been constructed.

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# TaTME for Abdominoperineal Excision

# 41

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## Introduction

Abdominoperineal excision (APE) is an important operative procedure for patients with low-lying rectal cancer who are not eligible for sphincter-preserving surgery. APE is performed as a combination of abdominal and perineal stages; the perineal stage is usually performed under direct vision. APE has been reported to be associated with poor outcomes, such as higher local recurrence rates or poor overall survival, probably due to the higher rate of positive circumferential margins, especially at the anterior aspect [1, 2]. A wide skin incision in the lithotomy or prone position has been utilized to improve surgical exposure [3], especially on the anterior aspect, even when the skin is spared from tumor invasion. Although recent reports have described division of the levator ani muscle and the ischioanal fossa even from a laparoscopic approach [4], exposure of the anterior aspect is still difficult even with this procedure.

The recent development of the endoscopic bottom-to-top approach in rectal cancer surgery,

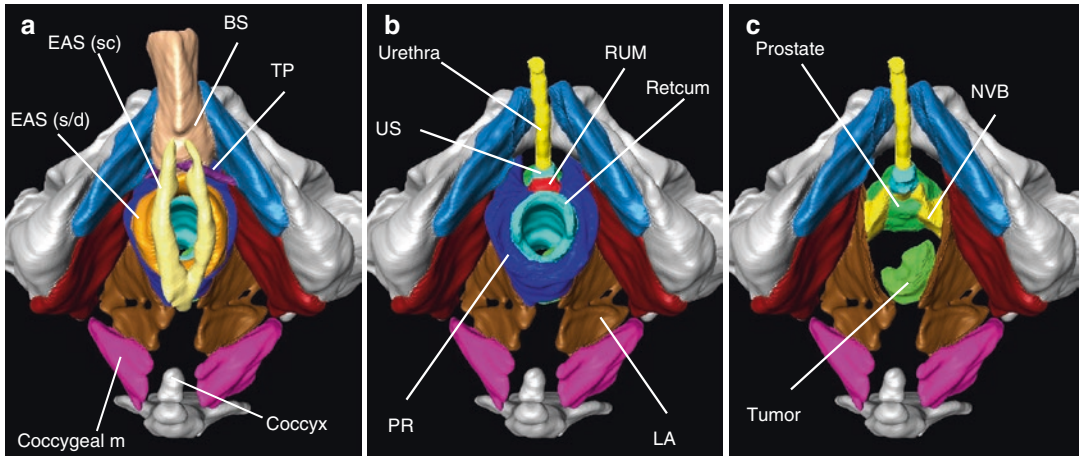
namely, transanal total mesorectal excision (TaTME), has several benefits over laparoscopic surgery. This approach can also be utilized in APE procedures and is also known as transperineal APE (TpAPE). There are several benefits of TpAPE over the conventional method, such as better exposure of the surgical field despite the small skin incision used to gain perineal access. This chapter presents the surgical procedure of TpAPE.

## Anatomical Considerations

There are several important anatomical landmarks specific for APE. In this procedure, it is important to have a thorough knowledge of the anatomy of the striated and smooth muscle complex surrounding the anal canal. The schema of the anatomy around the anal canal from below is shown in Fig. 41.1. The external anal sphincter (EAS) is located at the lower part of the anal canal and is sometimes divided into two or three parts (subcutaneous, superficial, and deep). It is fusiform-shaped and partly extends anteriorly and posteriorly to connect with the bulbospongiosus muscle and the coccyx, respectively. The transverse perineal (TP) muscles sometimes partly intermingle with muscle fibers of the anterior part of the EAS, forming the boundary between the anterior urogenital and rectal compartments. During APE, this muscle is a good landmark for anterior dissection.

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**Fig. 41.1** Anatomy of around the anorectal region. (a) External anal sphincter (EAS) level. (b) Puborectal muscle (PR) level. (c) Prostate level. BS bulbospongiosus

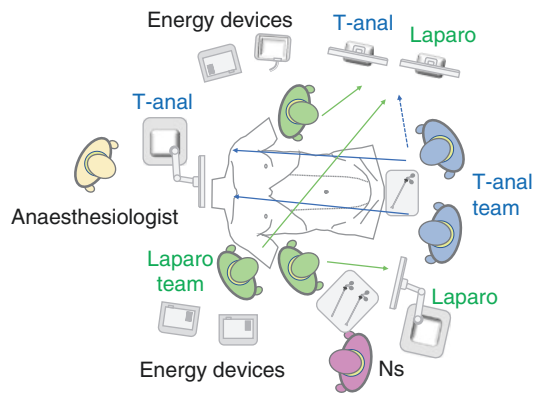
muscle, LA levator ani muscle, NVB neurovascular bundle, RUM rectourethral muscle, TP transverse perineal muscle, US urethral sphincter

The puborectalis muscle is located behind the TP and is U-shaped with two major bilateral slings, pulling the rectum anteriorly to form the anorectal angle. This is the major muscle that contributes to rectal closure. The levator ani is a thin, sheet-like muscle that is anatomically divided into the ischiococcygeus, iliococcygeus, and puborectalis, forming the major part of the pelvic floor.

There are also several important smooth muscle structures that are significant in performing APE. In male patients, the rectourethral muscle (or perineal body) is an anterior extension of longitudinal smooth muscle layer of the rectum extending toward the urethral sphincter just below the prostate. The hiatal ligament, however, is the posterior extension of the longitudinal smooth muscle extending toward the coccyx. These structures must be divided during APE, and it is often difficult to find an appropriate dissection plane here.

**Patient Position and Operative Setup**

The patient is placed in the modified lithotomy position. Because of the small operative field in the transanal/perineal approach, continuous smoke evacuation and maintaining a stable pneumoperi-



**Fig. 41.2** Operative setup (two-team synchronous approach)

toneum are very important for keeping the surgical field stable and clear. Thus, many surgeons prefer to use the AirSeal® insufflation system. We use a two-team synchronous approach, where the laparoscopic and transperineal teams perform surgery simultaneously. The major advantage of this two-team approach is the easier exposure of the surgical field with a shorter operative time. For these reasons, this approach has recently become preferred compared with the one-team approach. The operative setup for the two-team approach is shown in Fig. 41.2. The monitors are placed such that each surgeon can see both operative fields.

## Operative Procedure

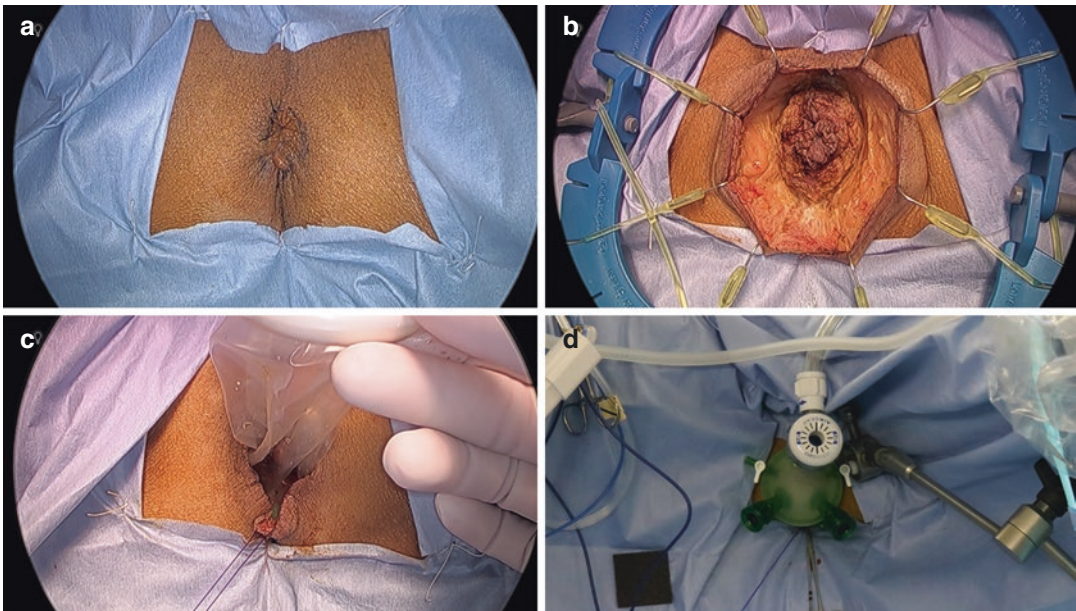
A multimedia manuscript demonstrating our technique for TpAPE has been published previously [5]. After positioning, the operation commences with a circumferential skin incision around the anus, with appropriate margins away from the tumor. Subcutaneous fat tissue is divided using electrocautery so that the ring portion of the GelPOINT-mini® device can be accurately placed. When the skin incision becomes large enough, a purse-string suture is applied, which is beneficial to prevent air leakage during surgery (Fig. 41.3). Following the fixation of the GelPOINT-mini device, pneumoperitoneum is maintained at 8–12 mmHg, and division of the subcutaneous and ischioanal fat is performed (Fig. 41.4).

One can choose from among several dissection planes depending on the extent of tumor invasion. This includes the intersphincteric, the extralevator, or the ischioanal planes (Fig. 41.5). The tip of the coccyx is identified, and the levator ani is widely exposed bilaterally (Fig. 41.6). The levator ani is divided posteriorly just anterior to

the tip of the coccyx. The hiatal ligament, a white fibrous tissue connecting the coccyx and the rectum, is divided with special care so it does not migrate into the mesorectum or posterior rectal wall. Once the mesorectal plane is identified, division of the levator muscle is extended bilaterally, and the endopelvic fascia covering the levator ani is also divided to enter the mesorectal plane (Fig. 41.7).

Posterior dissection is continued until this plane is connected with the laparoscopic dissection. The level of division of the levator muscle can be determined at the surgeon's discretion, mainly depending on the extent of tumor invasion. Here, the roots of the pelvic splanchnic nerves are identified bilaterally, and special care is taken to avoid injury to the autonomic nerves of the pelvis (Fig. 41.8).

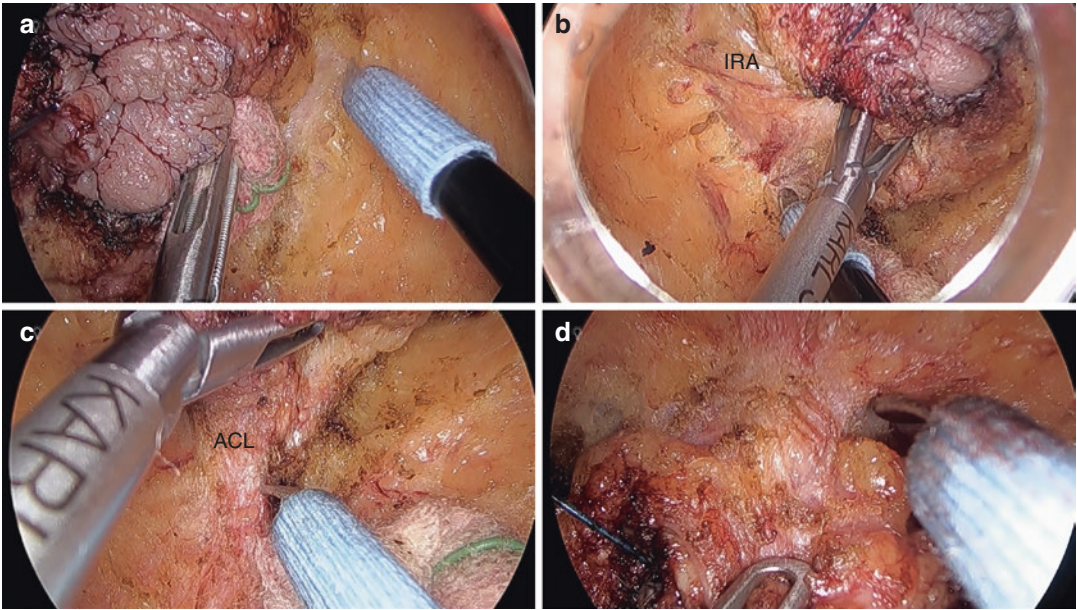
Next, the anterior dissection is addressed. The anterior dissection is more difficult in male patients than in female patients because there is the potential risk of urethral injury in males. Therefore, we describe here the dissection in male patients. The transverse perineal muscle is an important landmark as it divides the anterior



**Fig. 41.3** Skin incision to GelPOINT placement. (a) Skin incision can be minimal when skin is spared from tumor invasion. (b) Subcutaneous fat is divided to some

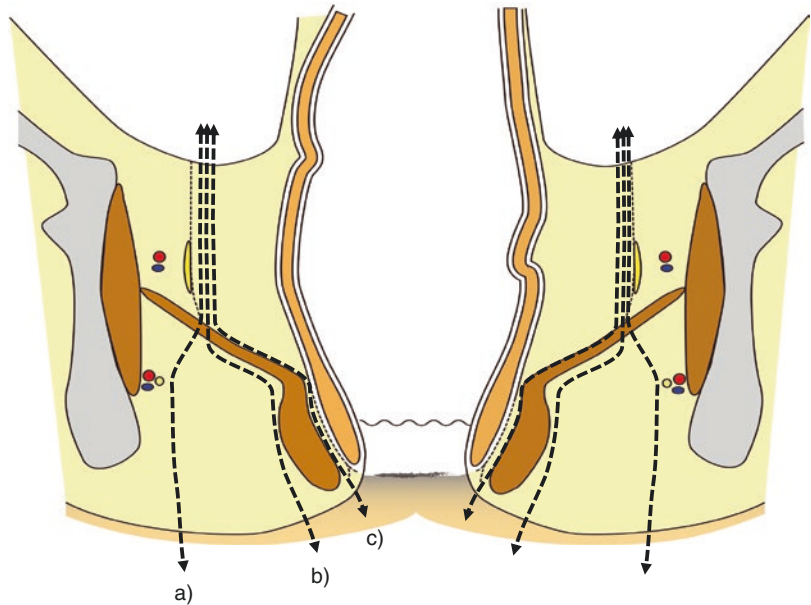
extent to place the GelPOINT device. (c) Purse-string suture is useful to keep the surgical field air-tight. (d) GelPOINT® placement





**Fig. 41.4** Division of the ischioanal fat. (a) Left side. (b) Right side (IRA inferior rectal artery). (c) Posterior side (ACL ano-coccygeal ligament). (d) Anterior side

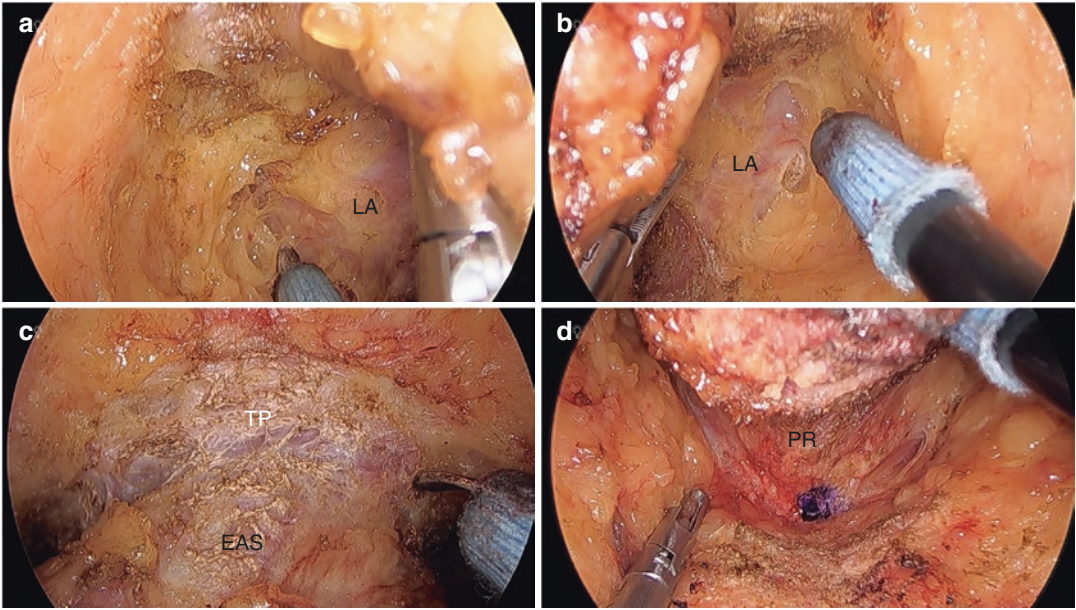
**Fig. 41.5** Perineal dissection planes in APE. (a) Ischioanal APE. (b) Extralevator APE. (c) Intersphincteric APE. (Modified form Holm et al. [7])



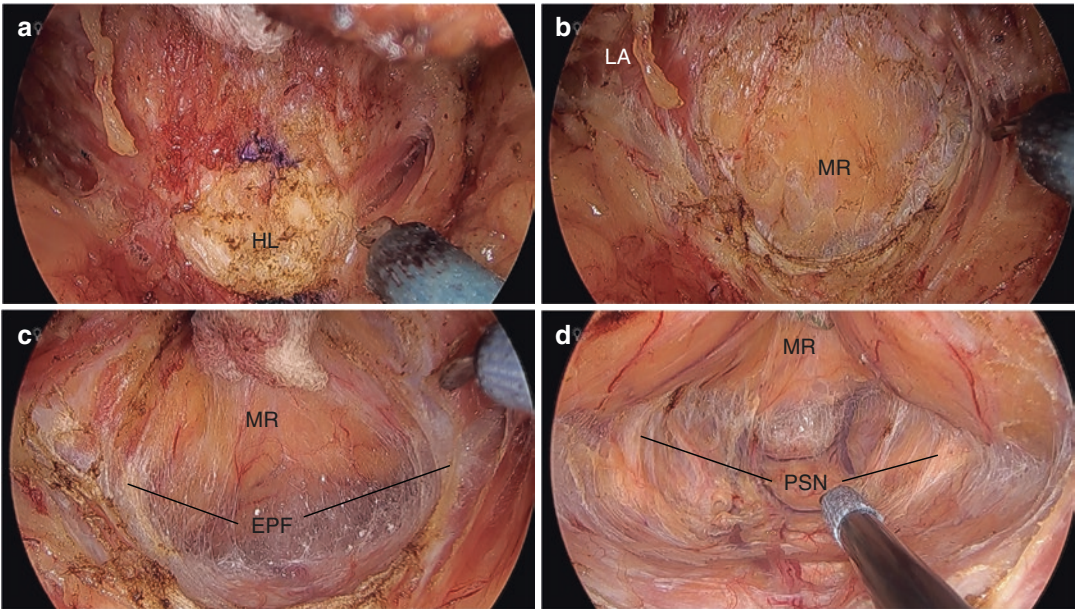
Modified form Holm et al. *Surg Oncol Clin N Am.* 2014

urogenital area and the posterior anorectal area. We dissect just behind the transverse perineal muscle, and here the bilateral puborectal sling, which is oriented along the posterior-anterior axis, is identified. There is no clear anatomical

landmark at this point to divide the puborectalis and levator ani muscles. The dissection line should thus be determined based on the extent of tumor infiltration, from extralevator resection to standard resection (Figs. 41.9 and 41.10).

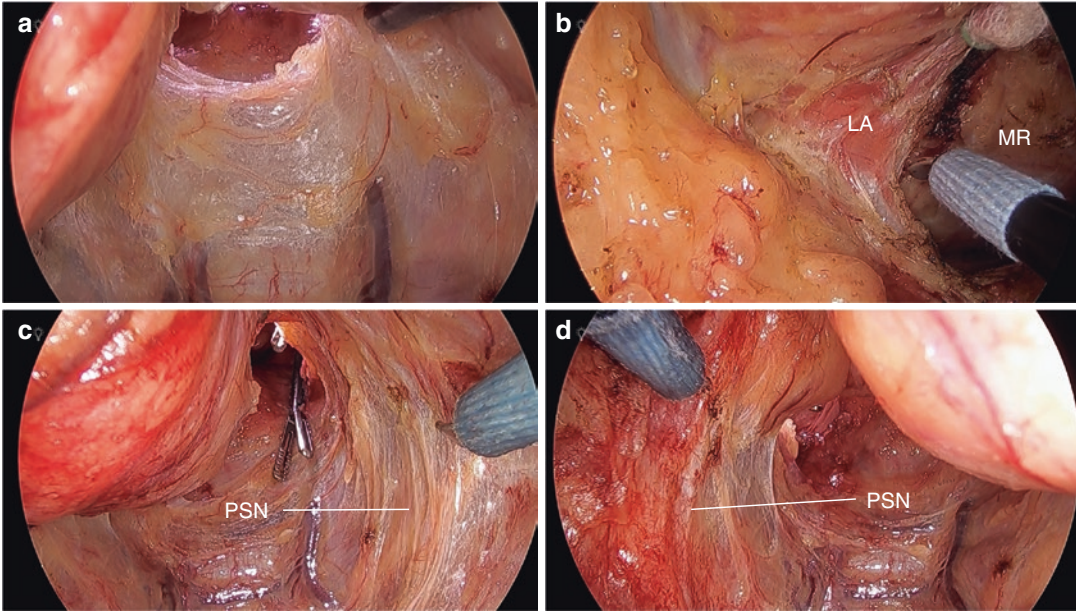


**Fig. 41.6** Exposure of the levator ani muscle and puborectalis muscle. (a) Left side (LA levator ani). (b) Right side (LA levator ani). (c) Anterior side (TP transverse perineal muscle, EA external anal sphincter). (d) Posterior side (PR puborectalis muscle). Blue marker indicates the tip of the coccyx



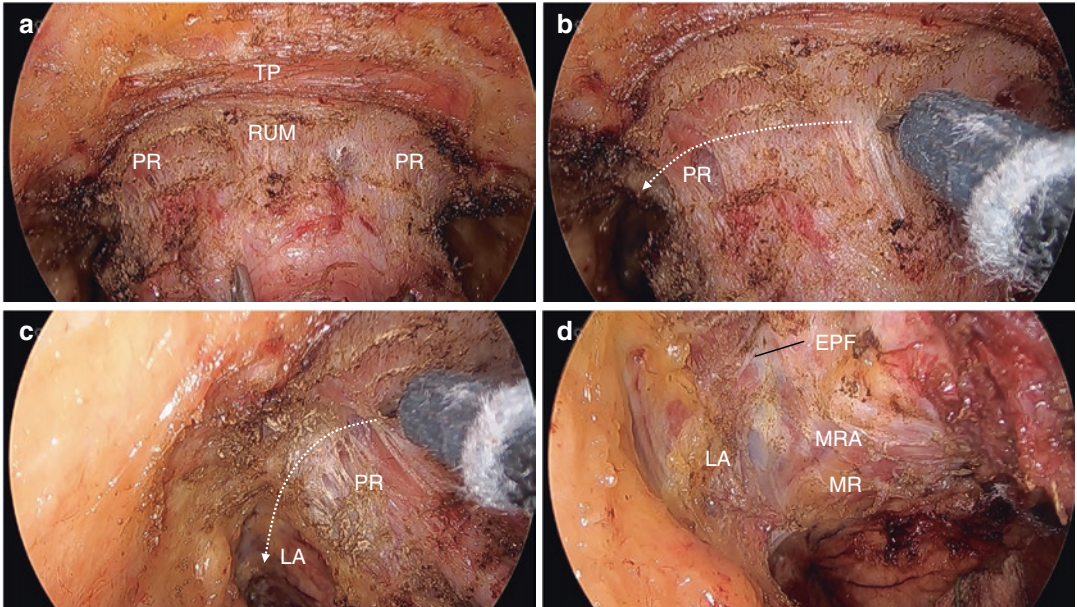
**Fig. 41.7** Division of the levator ani muscle and entering into the posterior TME plane. (a) Division of the levator muscle (HL hiatal ligament). (b) Exposure of the posterior mesorectum (MR) (LA levator ani muscle). (c) Posterior mesorectal dissection (MR mesorectum, EPF endopelvic fascia). (d) Identification of the bilateral pelvic splanchnic nerves (PSN) (MR mesorectum)





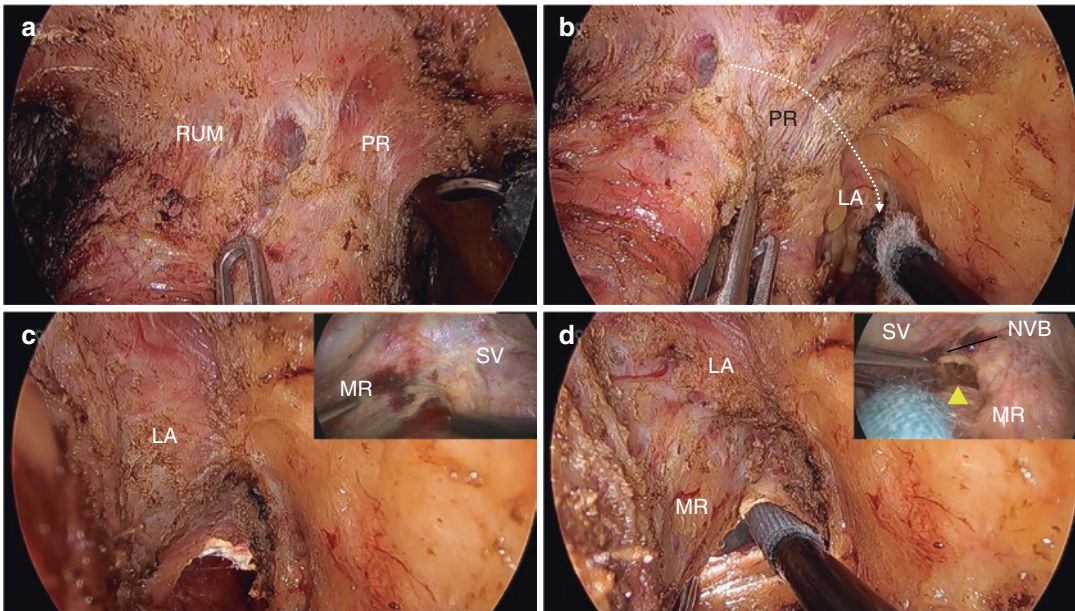
**Fig. 41.8** Lateral extension of the dissection plane. (a) Connection of the dissection plane with laparoscopic team. (b) Extension of the division of the levator ani mus-

cle (LA) to right side (MR mesorectum). (c) Dissection between mesorectum and left pelvic splanchnic nerve (PSN). (d) Dissection between mesorectum and right pelvic splanchnic nerve (PSN)



**Fig. 41.9** Right anterior-lateral dissection. (a) Surgical field after division of behind the transverse perineal muscle. (b) Division of the right puborectal sling (PR). (c) Division of the levator ani muscle (LA).

(d) Surgical field after division of the levator ani muscle (LA) (EPF endopelvic fascia, MRA middle rectal artery, MR mesorectum)



**Fig. 41.10** Left anterior-lateral dissection. (a) Division of the left puborectal sling (PR) (RUM rectourethral muscle). (b) Left puborectal sling (PR) and levator ani muscle (LA). (c) Laparoscopic assistance (right upper window) is helpful for better exposure and identification of the anat-

omy (LA levator ani muscle, MR mesorectum, SV seminal vesicle). (d) After division of the levator ani muscle (LA), dissection between neurovascular bundle (NVB) and mesorectum is performed under laparoscopic assistance (SV seminal vesicle)

Once the puborectal muscle sling is divided, the perineal body or rectourethral muscle, which contains abundant smooth muscle fibers and fibrous connective tissue, is encountered. There is no clear anatomical landmark here, and special care should be taken not to injure the urethra, neurovascular bundle, and prostate (see “How to avoid urethral injury” below). Laparoscopic assistance to identify the contour of the prostate is beneficial to ensure safe and adequate dissection in this area (Fig. 41.10). When the apex of the prostate is identified, the following step is almost identical with that of TaTME. Here, the dissection plane is easy to distinguish between the prostate and the rectum.

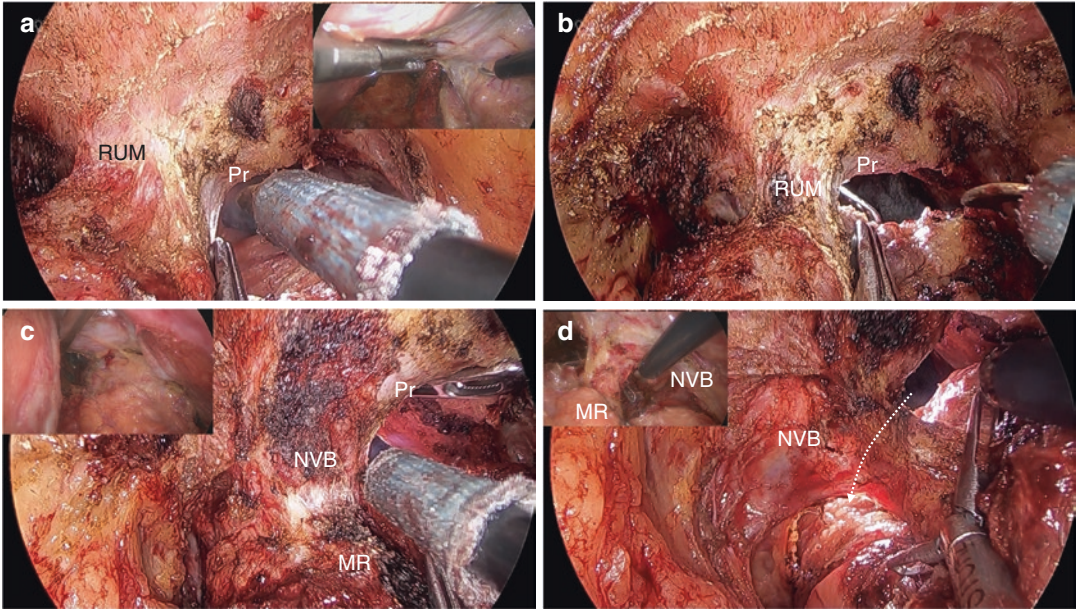
Dissection is widely commenced cranially and connected to the space with laparoscopic dissection. Finally, bilateral mesorectal dissection between the mesorectum and pelvic autonomic nerves is performed with the assistance of the laparoscopic team (Figs. 41.11 and 41.12). The sigmoid mesentery and sigmoid colon are divided laparoscopically. The resected

specimen is extracted from below, and a permanent sigmoid colostomy is fashioned.

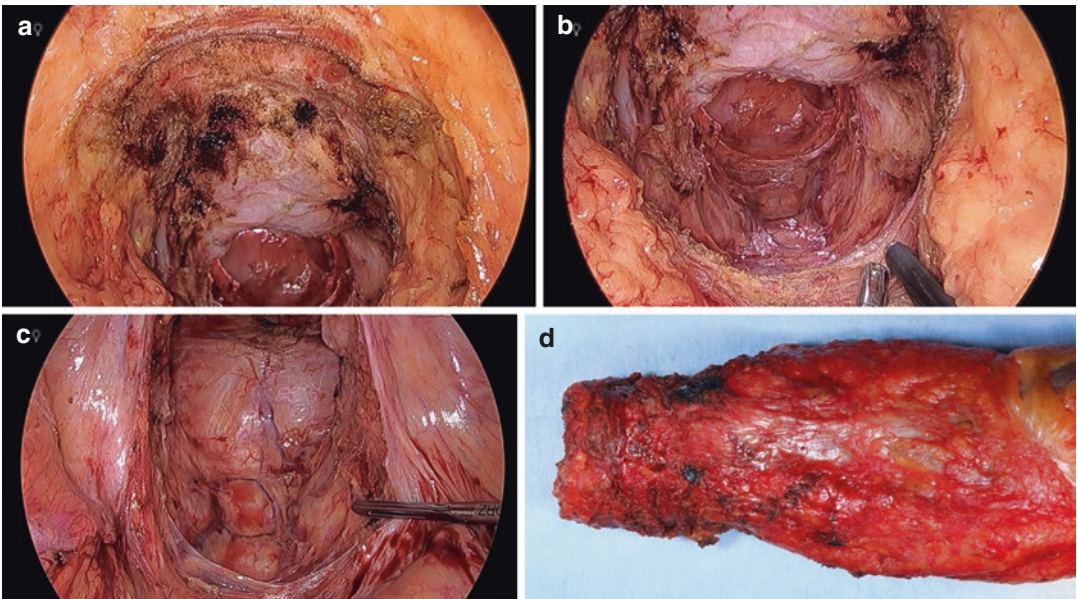
### How to Avoid Urethral Injury During TpAPE

Urethral injury is a very important and serious complication of this procedure. For male patients, the risk of urethral injury is likely increased in TpAPE procedures as compared with TaTME because the dissection plane easily goes more toward the lateral side of the prostate as compared with TaTME. Several methods have been proposed to prevent this serious complication, such as urethral lighted stent placement, intraoperative ultrasonography, and stereotactic navigation [6]. The key anatomic consideration around this area is identification of the apex of the prostate. Assistance with the laparoscopic approach helps to predict the contour of the prostate even if it is just the level of the upper border of the prostate.





**Fig. 41.11** Dissection of the rectourethral muscle and right neurovascular bundle. (a) Dissection between mesorectum and inferior part of the prostate (Pr). Rectourethral muscle (RUM) can be identified as longitudinal whitish fibers. (b) Division of the rectourethral muscle (RUM) (Pr prostate). (c) Dissection between right neurovascular bundle (NVB) and mesorectum (MR). (d) Finally, right lateral attachment is divided, and TpAPE is completed (NVB neurovascular bundle, MR mesorectum)



**Fig. 41.12** Surgical field after specimen extraction. (a) Transanal view. (b) Transanal view. (c) Laparoscopic view. (d) Resected specimen



## Dissection Along the Rectovaginal Septum

For female patients, at the anterior aspect, the perineal body can be divided under direct vision at the most inferior part of the vagina, where there is no clear dissection plane, under the guidance of digital examination and tactile feedback. Once a clear dissection plane between the posterior vaginal wall and rectum is identified, it is relatively easy to maintain this plane toward perineal reflection. This can be assisted by tactile feedback through digital palpation of the vaginal vault during the process of dissection.

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## Pros and Cons of TpAPE

### Pros

- Good exposure of the surgical field, especially along the anterior aspect.
- No air leakage when combined with the laparoscopic approach.
- Skin incision can be minimized if perianal skin is spared from tumor invasion.
- Operative time could be reduced with the two-team approach.

### Cons

- Because the surgical anatomy around the anal canal is relatively complex, it is difficult to identify an appropriate dissection line at the

anterior side, despite good visibility.

- Extra cost and resources are required for the transperineal procedure.

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# Hartmann's Reversal by a Combined Transanal- Transabdominal Approach

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and Antonio M. Lacy

## Introduction

Henri Hartmann first described his eponymous operation in 1921 at the 30th Congress of the French Surgical Association [1]. It was initially proposed for the treatment of rectal cancer, in an attempt to lower the morbidity associated with the abdominoperineal resection, developed by William Ernest Miles at the beginning of the twentieth century. Nowadays, the Hartmann's procedure is still commonly performed in various benign and malignant conditions and both in elective and emergent settings. After this operation, many patients will never undergo colostomy closure (or Hartmann's reversal – HR). In the literature, closure rates range between 28% and 60% [2, 3]. Restoring intestinal continuity is often a technically challenging operation and has significant risks of mortality and morbidity, respectively, up to 10% and 50% [3]. Quality of life is often impaired in patients with a colostomy

for various reasons, and it could be improved with a Hartmann's reversal [4].

Interest in minimally invasive surgery (MIS) has grown significantly in the last decades and is justified by diminished surgical trauma, resulting in better outcomes for many patients who undergo colorectal procedures. Thus, laparoscopic approaches for reversal of Hartmann's procedure using multiport or single-port configurations have been attempted [5–9]. They were shown to be safe in trained hands and are associated with faster postoperative recovery and fewer complications based on recent publications [10–14]. In 2014, a robotic approach to HR was described as a case report [15].

Even with these different MIS approaches, HR remains a challenging operation. The rates of laparoscopic HR remain low (17.6%) according to a study of the ACS-NSQIP data [16]. When a laparoscopic approach is chosen, the conversion rates to an open procedure are as high as 50% [17]. Conflicting data regarding the benefits of laparoscopy for HR was demonstrated by a recent retrospective study of 276 patients: it failed to demonstrate a difference regarding the length of stay and complication rate [18]. Therefore, the search for a different approach for HR remains pertinent.

With the rapid development of advanced transanal procedures, from transanal endoscopic microsurgery (TEM) [19, 20] to transanal minimally invasive surgery (TAMIS) [21], and more

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recently transanal total mesorectal excision (taTME) [22–24], sound proficiency in dissection from a bottom-up approach was gained by various surgeons around the world. In selected cases where visualization from a transanal standpoint would be deemed helpful, a combined transanal-laparoscopic transabdominal Hartmann’s reversal (taHR) was proposed as another approach. It has been previously described by Dr. Antonio Lacy’s team [25–27]. To date, it remains experimental. It should be reserved to medical centers with thorough expertise in transanal surgery.

The expected advantages of this approach include (a) transanal dissection through intact, virgin planes, (b) improved ability to localize the rectal stump (especially when short and covered by peritoneum), (c) optimal visualization during surgery in a narrow pelvis, and, finally, (d) the advantage of performing a double purse-string single-stapled anastomosis with rectal tissues free of fibrosis or staple lines. This chapter is intended to describe taHR and share various technical tips and pitfalls.

## Preoperative Planning

Patients should be well informed on the innovative aspect of this approach for intestinal continuity reconstruction. Also, it is our opinion that every case should be included in a prospective registry to measure outcomes, and, ideally, patients should be part of a study protocol with internal review board approval.

Preoperatively, all patients are evaluated by digital rectal examination and endoscopy of both their rectal remnant and proximal colon. A contrast enema of the rectal stump is also performed to measure its length and visualize its position in the pelvis. Pre-colostomy, baseline anorectal function is determined before proceeding, to provide realistic expectations of functional outcomes after reconstruction and to exclude candidates for whom HR would result in a poor quality of life. A combined transanal-transabdominal approach is considered when the rectal stump appears short (less than 15 cm). Knowledge of the indications for which the initial Hartmann’s procedure was performed and the circumstances of the first oper-

ation is crucial for proper planning. Also, reoperative pelvic surgery can place the ureters at risk for injury; therefore, consideration for preoperative placement of ureteral stents should be given.

## Operative Setup

For the taHR, we favor a two-team approach. It allows for performance of the procedure with assistance of a second team for plane dissection using the two points of view. Thus, two complete teams are operating simultaneously; each one includes a surgeon, one or two assistants, a scrub nurse, and a dedicated set of instruments.

## Technique Description (Table 42.1)

### taHR: Abdominal Aspects

Whenever possible, a laparoscopic approach is favored for the abdominal portion of the taHR operation. It should start with the colostomy take-down, placement of a single-port platform in the

**Table 42.1** Steps of a taHR

Abdominal steps	Transanal steps
1. Colostomy takedown.	1. Placement of the flexible transanal platform.
2. Placement of an EEA stapler anvil in the proximal colon.	2. Evaluation of the rectal stump.
3. Single-port device in stoma site.	3. Choice of the site of rectotomy and mucosa tattooing.
4. Pneumoperitoneum.	4. Rectotomy.
5. Placement of trocars.	5. Dissection and rendezvous. Extraction of the resected portion of rectal stump.
6. Lysis of adhesions.	6. Purse string on the open rectal stump.
7. Mobilization of the left colon and splenic flexure.	7. Tying of the purse string on the EEA anvil.
8. Identification of the rectal stump if possible.	8. Double purse-string single-stapled anastomosis.
9. Anastomosis under laparoscopic guidance.	

colostomy site, and establishing pneumoperitoneum. The mucocutaneous junction is resected, and a purse-string suture is performed on the colon opening and tied around the anvil of an end-to-end anastomosis stapler. The anvil is then delivered back into the abdominal cavity. The platform is secured in place at the former stoma site, and pneumoperitoneum (set to 15 mmHg) is created. A 5 mm or ideally a 10 mm 30° laparoscopic camera is inserted through a trocar in the single-port platform, and the other trocars are then inserted under direct vision as shown in Fig. 42.1. Usually, some degree of lysis of adhesions is necessary to allow for safe placement of trocars. Often, the camera trocar is placed more centrally and away from the instruments trocars to avoid interference with their movements. Alternatively, three trocars (or cannulas) can be introduced through the flexible single-port platform in the colostomy wound to perform a laparoscopic single-port abdominal dissection.

To allow for the performance of a tension-free anastomosis, a mobilization of the left colon is generally necessary. To gain significant reach for the proximal colon, a splenic flexure takedown is achieved if not previously done during the Hartmann's procedure.

Then, attention is directed toward the pelvis. The rectal stump is often identified by blue polypropylene tag sutures placed during the Hartmann's procedure. If the rectal stump is long and easily identifiable, proceeding with a laparoscopic-only HR is recommended. If the rectal stump is short or there are many adhesions in the pelvis, the technique of taHR can be utilized.

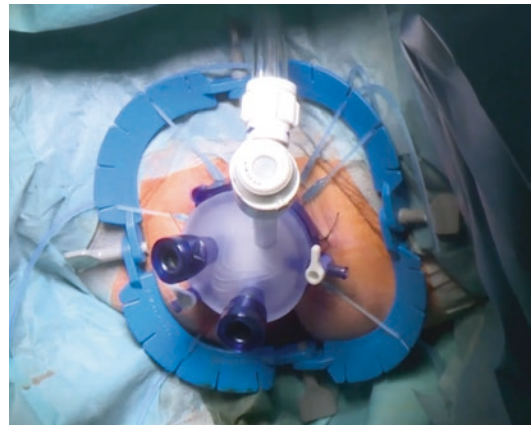
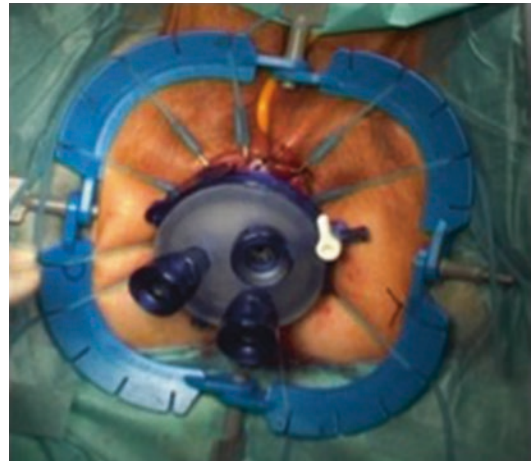


**Fig. 42.1** Proposed single-port platform and trocars placement

## taHR: Transanal Aspects

The transanal steps of taHR are similar to the ones of a taTME. The main differences are that with taHR, less importance is given to obtaining a total mesorectal excision. In addition, the purse-string suture to occlude the lumen prior to the rectotomy with taTME is a step that may be omitted during taHR.

Thus, the first step for the transanal portion of taHR is the positioning of the transanal platform. We favor a flexible (TAMIS) platform (Gelpoint Path Transanal Access Platform; Applied Medical Inc., Rancho Santa Margarita, CA) over a rigid TEM platform (Fig. 42.2). Then, we evaluate the rectal stump under direct vision, looking for the best suitable place for the anastomosis. Often, it is

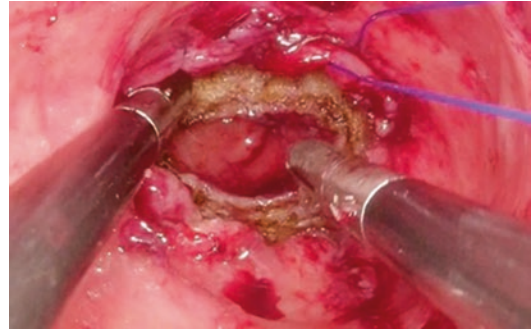


**Fig. 42.2** Transanal flexible platform with an anal retractor





**Fig. 42.3** Rectotomy at the site of stenosis in the rectal stump



**Fig. 42.5** Placement of a purse-string running suture on the open rectal stump (from a transanal perspective)



**Fig. 42.4** Rectotomy reaching the total mesorectal plane (upper right corner)

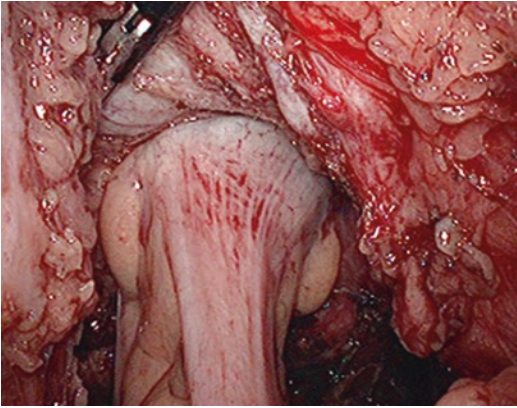


**Fig. 42.6** Another transanal view of the purse-string suturing

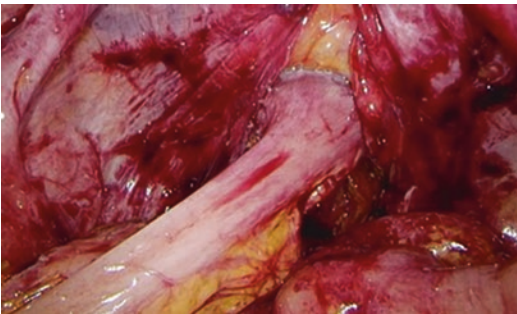
decided to resect the proximal part of the rectum beneath the previous Hartmann's suture/staple line, to avoid creating the anastomosis in a fibrotic or narrowed rectal wall. If a longer segment of the rectum has to be resected, one can close the rectal lumen with a 0 polypropylene purse-string suture. Subsequently, the rectotomy is performed, cutting the rectal wall perpendicularly (Figs. 42.3 and 42.4). Once the perirectal mesorectum fat is reached, dissection is directed cephalad toward the desired point of rendezvous with the abdominal team. Often, dissecting in the total mesorectal plane will help to connect the abdominal and transanal fields and will avoid having parallel planes. In the process, the old staple line on the rectal stump is completely resected and extracted through the transanal platform. Next, a purse-string suture is placed on the open rectal stump

using a 0 or 2–0 polypropylene suture (Figs. 42.5 and 42.6). The proximal colon with the anvil in place is pulled down into the pelvic inlet. The rectal stump purse string is tied around the anvil's long central spike, as is the case of PPH stapler. Alternatively, a drain or a urinary catheter can be used to guide the anvil if a standard EEA stapler is employed. Then, a double purse-string single-stapled anastomosis is created after connecting the anvil to the stapler (Figs. 42.7 and 42.8). An end-to-end or a side-to-end anastomosis can be performed according to the surgeon's preference and colon characteristics. Inspection of the anastomosis is achieved laparoscopically and transanally. An air leak test is also performed. If there exists concern about the appropriate vascularization of the colon or rectum before completing the anastomosis, an intraoperative blood perfusion assessment is performed using indocyanine green (ICG) fluorescence imaging. A temporary diverting loop





**Fig. 42.7** Creation of an end-to-end single-stapled double purse-string anastomosis (EEA anvil still in the proximal colon)



**Fig. 42.8** Final view of a completed anastomosis

ileostomy is created in the case of a low colorectal anastomosis. A closed-suction drain is positioned in the pelvis if deemed necessary by the surgeon, and it is removed before hospital discharge.

## Results

Preliminary results from a pilot study of ten patients showed a 30% complication rate, with no leak and no conversion to an open procedure [27]. There was one conversion to a hand-assisted procedure to help with the lysis of adhesions. Three patients had complications: one patient with surgical site infection (abdominal wall and pelvic) treated with antibiotics and percutaneous drainage and two patients presented with ileus.

## Conclusion

A combined laparoscopic abdominal and taHR is a novel approach to achieve intestinal continuity reconstruction. Further studies are needed to prove the safety of the procedure and to clarify its indications. However, in centers with expertise in transanal surgery, in particular with taTME, it was found to be a valuable additional tool to accomplish Hartmann's reversal by a minimally invasive approach.

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and Chuc Phan Ngoc

## Introduction

At the beginning of the twentieth century, Miles (1906) [1] was the first to propose an oncologic resection in rectal cancer reducing local recurrence rate from 90% to 30%. He defined the benefit to remove “en bloc” all the rectum and the regional nodes with clear margin (R0 resection).

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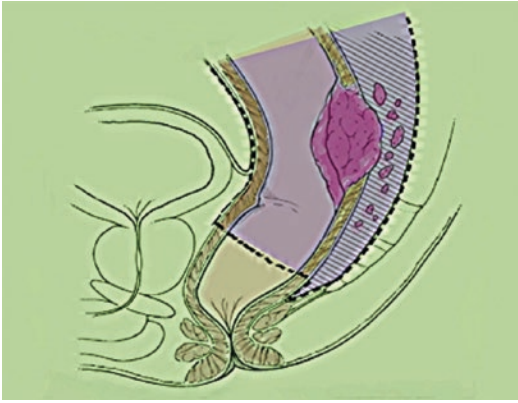
In 1982, Heald et al. published the concept of the total mesorectal excision (TME) for rectal cancer treatment [2]. This procedure remains the gold standard worldwide in the surgical treatment of advanced rectal cancer (Fig. 43.1). Laparoscopic resection has been shown to be oncologically equivalent as compared to open resection in the hands of experts, but TME is a challenging technique particularly for low rectal adenocarcinoma managed by open or laparoscopy even with robotic assistance, useful in obese patient [3].

Transanal TME (taTME) is not a completely new concept [4] but, rather, a mixture of surgical techniques developed during the end of the twentieth century [transanal endoscopy microsurgery (TEM), transabdominal transanal (TATA), and transanal minimally invasive surgery (TAMIS)]. Patricia Sylla and Antonio Lacy (2010) reported their early experience, with transanal video assistance, showing encouraging results in terms of safety and efficacy [5].

In the technique we describe below, oncologic TME is performed exclusively via the pathway using perirectal and retroperitoneal endoscopic dissection. We described it in experimental and clinical settings [6–9].

## Rationale

In advanced rectal cancer, the surgical gold standard is TME performed either by (a) a minimally invasive laparoscopic [without (90%) or with

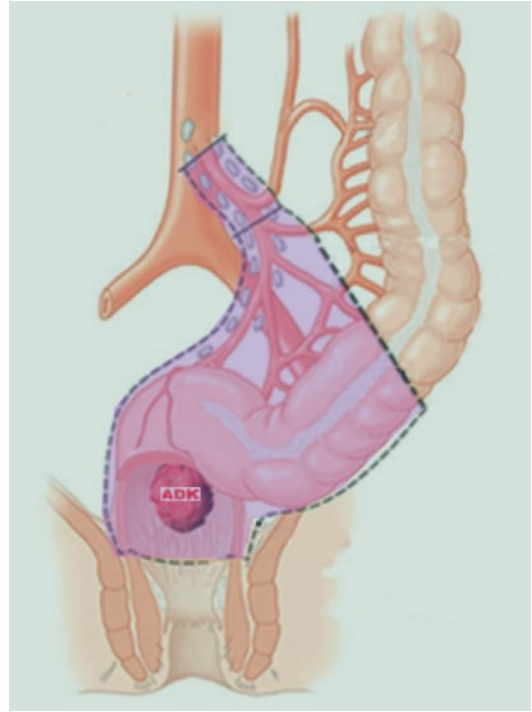


**Fig. 43.1** TME principles for rectal cancer. Meso and its tail are removed respecting fascial envelop

robotic assistance (10%)] resection or, alternatively, (b) by an open, abdominal procedure. To perform a TME, Gerald Marks in the 1980s proposed transanal route for low rectal tumors after radiochemotherapy (RCT) and in fragile patients or patients with a difficult pelvic access (obesity), i.e., narrow space. In the 1990s, his son John Marks updated this approach by combining it with laparoscopy [10]. All these techniques are hybrid techniques that combine two approaches. They called this technique the TATA (transanal-transabdominal) proctectomy [11].

The transanal route was used, by us and most authors, to finish “up-to-down” TME using intersphincteric resection (ISR) in ultra-low rectal tumors and for performing full-thickness resections with TEM platform. Recently surgeons have proposed to begin transanally using video endoscopic platform to facilitate laparoscopic distal step of the TME using the concept proposed by Gerald and John Marks in the TATA. Zorron (2014) named this approach down-to-up TME in opposition of the up-to-down TME [12], but authors performed only a distal or subtotal perirectal dissection, and it is more appropriate to say distal partial or total mesorectal dissection (TMD). Both techniques use combined methods (transanal and laparoscopic). They are well described in other chapters of the book.

Our area of investigation focused on exploring the possibility of performing a pure NOTES (natural orifice transluminal endoscopic surgery)



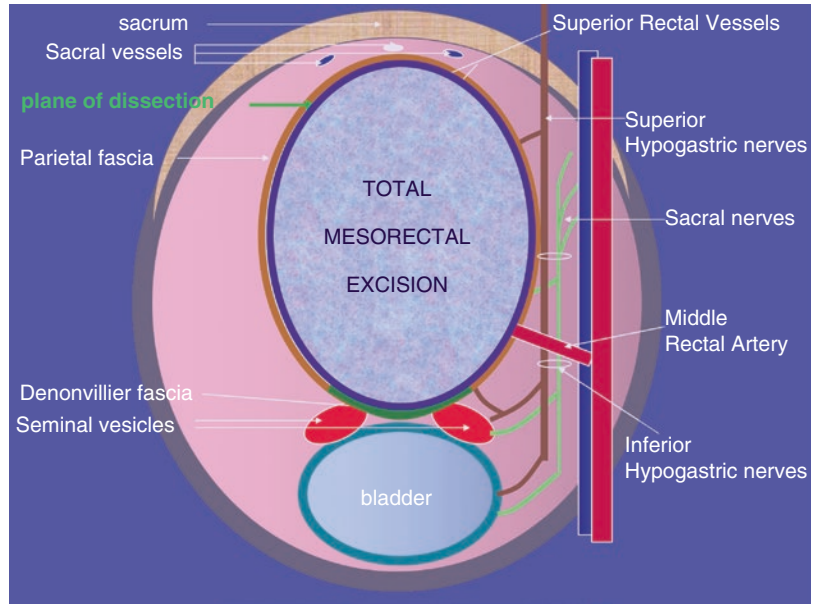
**Fig. 43.2** Gold standard of oncologic rectal resection for cancer with lymphadenectomy

transanal procedure removing the rectum and the mesorectum, dividing the inferior mesenteric vessels with en bloc lymphadenectomy (Fig. 43.2), and doing a transanal colorectal or coloanal anastomosis after removing the specimen transanally. Oncologic resection of the rectum must include rectal resection, mesorectal resection respecting propria fascia with free lateral and distal margin (R0 resection), and en bloc vascular package removal including inferior mesenteric vessels and nodes (Fig. 43.3). Most authors include the mobilization of splenic flexure, but it is only for the purpose of constructing a tension-free anastomosis, and not for any oncologic reason.

In early rectal cancer, different techniques have been described. Local full-thickness resection was introduced using a specifically designed operating apparatus (i.e., TEM) beginning in the early 1980s by Gerhard Buess with success in selected cases [13]. The local recurrence rate was low but not nil. In our opinion, oncologic, curative-intent local excision must include analysis of the nodes in the mesorectum



**Fig. 43.3** Mid-pelvis cross-section view in male. Anatomic landmarks of fasciae



to limit the risk of local recurrence treatment failure – and it is especially crucial to obtain staging that is as accurate as possible, to avoid underestimation of the tumor’s true stage.

Our first complete oncological resection of the rectum together with its mesorectal envelope using a purely transanal approach was performed in June 2010. The patient was a 55-year-old male (in fact, a family doctor) who developed a recurrent mid-rectal lesion after polypectomy with suspected invasive disease, based on morphology (although biopsy revealed only benign neoplasia). He refused standard of care, radical surgery (up-to-down TME), because of the risk of bad functional results, and he preferred to have a transanal local excision. Due to the characteristics of the neoplasm, a pure NOTES transanal TME was performed. Finally pathologic examination revealed invasive adenocarcinoma, pT2N1 (1/15 lymph nodes positive for metastatic disease).

It was a pure NOTES taTME with a long operative time (about 6 h), but – except for diffuse emphysema of the retroperitoneum, mediastinal, and cervical spaces – the postoperative course was uneventful with recovery that was quite rapid. This patient subsequently received adju-

vant RCT. On follow-up, 6 months later, a liver metastatic lesion was detected and promptly resected. Today, the patient is disease-free with good functional results.

For the next patient, we performed another NOTES transanal TME for cancer, but, before doing the anastomosis, a laparoscopic exploration through a single port introduced in the right iliac fossa was performed so as to control the quality of the vascular dissection and, in addition, to aid with bowel mobilization and for creating a diverting ileostomy, as the patient received neoadjuvant radiotherapy. Analyzing our initial experiences, we standardized the procedure that now seemed quite reproducible. As this process improved, the operative time has decreased markedly. Recently, a female (BMI 29) underwent the pure NOTES approach for rectal cancer, she had no previous abdominal or pelvic operations, who had a T2 N0 mid-rectal tumor (Figs. 43.4 and 43.5). The operation was completed in approximately 2 h. Thus, we have refined and standardized the steps of the procedure in a better way; consequently, indications are limited in early-stage tumors for this technically demanding approach.





**Fig. 43.4** CT-scan showing a long compliant sigmoid loop (ideal case for pure NOTES taTME)



**Fig. 43.5** CT-scan of T2 lateral mid-rectal cancer (same patient, ideal case)

## Patient Selection

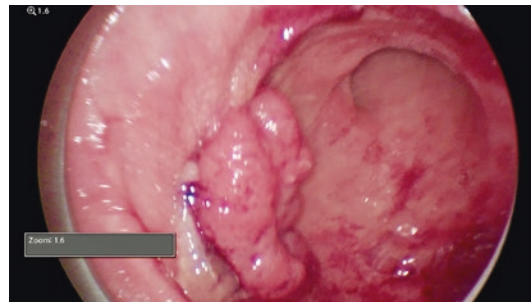
Patient selection is paramount when considering a pure NOTES taTME approach. After a thorough discussion concerning risks, benefits, and alternative approaches, consenting patients are included in our prospective trial for pure NOTES taTME. We select patients with mid-to-low early rectal cancers (T1, T2) (Fig. 43.6). Currently, we exclude patients with locally advanced (T3, T4) disease.

## Surgical Technique

### Armamentarium

Instrumentation is essential to the success of this approach. We use the TEO® platform (Karl Storz, Tuttlingen, Germany) which is a 4 cm diameter operating rectoscope tube (Fig. 43.7). The platform includes 4 cm diameter tubes at the oblique distal extremity (the superior border is the longest) and at the proximal orifice, which allows the connection of cups of different shapes and functions allowing for the introduction and use instruments of various diameters – including fiberscopes up to 2 cm in diameter (each instrument can maintain a seal with the aid of device-specific caps).

For the TEO® apparatus, there are three access channel tube lengths (the “short” one which is 7.5 cm long, the “medium” one is 15 cm long, and the “long” one is 20 cm long). Once introduced into the rectum (after dilating the sphincter with a dilator), the tube is fixed by an articulating support to the operating table. The TEO® can be



**Fig. 43.6** Endoscopic view of the T2 mid-rectal cancer



**Fig. 43.7** TEO® platform from Karl Storz

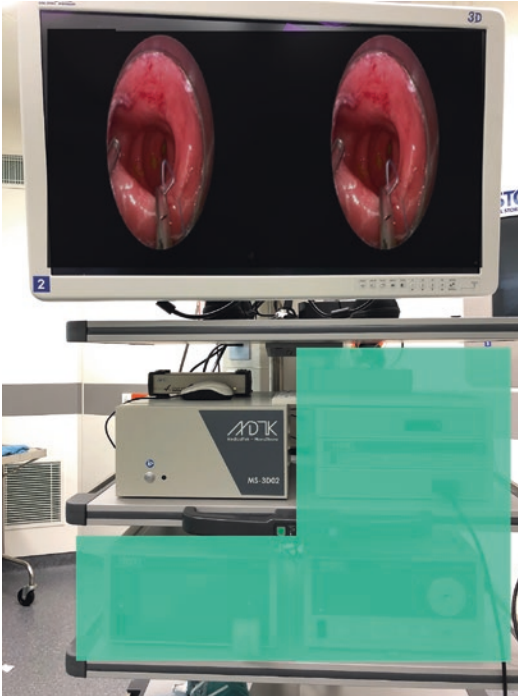
repositioned by adjusting the Martin arm which is mounted to the operating table, and this allows scope movement to more proximal portions of the rectum, which is required during NOTES taTME. This is important, as the working space is a function of the size and length of the operating tube and of the instruments size – since work is done in the axis of the tube. The main advantage of using the TEO® platform is in the concept of circular retraction done by the shape of the tube. It is exactly similar to the endoscopist when he performs a mucosectomy inside a cup exposing the field (Fig. 43.8). Thus, TEO® is used to expose the field doing circular retraction leading to a larger surgical field to dissect safely in the middle and for making a tunnel in the dissection plane without an additional retractor. This allows one to perform the operation autonomously.

Insufflation is performed using CO<sub>2</sub> gas set with continuous high flow (typically in the range of 12–15 mmHg). The platform includes three taps, or access points – two of them are a part of the faceplate connected to the rectoscope (one for the CO<sub>2</sub> insufflation, the other for cleaning the



**Fig. 43.8** Endoscopic cap use for EMR at the extremity of a fiberscope

camera's lens), and the last tap, located in the TEO® scope's handle, is used for evacuating plumes of smoke created during the process of electrocautery dissection. It is very important to have a specialized gas insufflator, with continuous high flow of CO<sub>2</sub>, to clear the operative field and evacuate the smoke (ENDOFLATOR® 40 SCB, Karl Storz, Tuttlingen, Germany). To limit



**Fig. 43.9** MedicalTek® (Taichung, Taiwan). Box for 2D–3D real video conversion (available in 2 K and now in 4 K)



**Fig. 43.10** U-shaped articulating arm fixed to the operating table to maintain TEO® device

the plumes of smoke, we use a low power (20 watts) setting and a modern electronic control energy generator.

The platform includes a 4.5 mm camera lens, fixed to the device, connected itself to a cold light source by a fiber-optic cable. The tip of the scope is a Hopkins® angled 30° downward. There are two camera lens scope lengths, the 21 cm one is adapted to the 7.5 and 15 cm platform and the 28 cm one is for the 20 cm length device. A full-HD 2 K video laparoscopic camera is connected to the scope. Recently we used a 4 K video camera (Olympus) and tested the 2 K/4 K 3D video convector (Fig. 43.9).

For ergonomics, the liquid crystal display (LCD) monitor (minimum 35" diagonal) is positioned above the pubis. The TEO® is fixed to the operating table using a specific holding system, U-shaped, autoclavable, with quick release coupling KSLOCK®, consisting of HR Rotation Socket, to clamp to the OR table, for European

and US standard rails, with lateral clamp for height and angle adjustment of the articulated stand (Fig. 43.10).

The TEO® faceplate is composed of three channels (two 5 mm and one 10 mm) (Fig. 43.11) allowing introduction of operating instrumentation, which can include the same ones used for conventional laparoscopic surgery, and in this fashion, TEO® is similar to TAMIS. There exists specific instrumentation developed for the TEO® and the S-Portal® system (Karl Storz, Tuttlingen, Germany), long instruments and double-curved instruments with a rotating tip as developed by S. Wexner and J. Leroy.

Monopolar electro-surgery can be connected to any type of adapted laparoscopic instrument. In our experience, the monopolar tool with optimal performance characteristics has been the 5 mm HF monopolar spoon electrode with smoke evacuation suction channel, designed by Olympus Company (Tokyo, Japan) (Fig. 43.12). We also recommend





**Fig. 43.11** Cap fixed to the TEO®. Cap with three working channels and one for the camera



**Fig. 43.12** Monopolar spatula with smoke evacuation channel (Olympus™, Japan)

other energy devices (e.g., THUNDERBEAT™ platform or LigaSure Advance™ (Covidien, New Haven, CT, USA) for the safe and durable sealing of vessels. To control local bleeding, we use bipolar coagulation, monopolar coagulation with spatula, and, if necessary, the suction-irrigation-coagulation cannula from Olympus Company designed by J. Okuda (Fig. 43.13).



**Fig. 43.13** Suction, irrigation, and monopolar distal coagulator (useful for pelvic bleeding control)

## Setup

All patients were administered a standard preoperative bowel preparation. Specifically, patients received 3–8 days of a low residue diet, and, upon admission 1 day prior to the operation, cathartic enemas were administered. We have since modified our protocol to include a full mechanical bowel preparation combined with oral antibiotics, based on evolving guidelines supported by recent data [14].

The step-by-step procedure has been previously published and described in detail [28]. Under general anesthesia, the patient is placed supine in a lithotomy/Lloyd-Davies position with urinary catheter placement and padding required around the calves to protect the common peroneal nerve in the lower leg. The patient's buttocks should extend slightly beyond the inferior edge of the table. Thromboprophylaxis is initiated and includes graded compression stockings, intermittent pneumatic compression devices, and venous foot pumps. Operating table with remote control changes in positioning is recommended.

The final control monitoring screen is placed above the pubis in the visual axis of the operator, as described previously.

For safety reasons, the different control panel elements (carbon dioxide pressure, carbon dioxide output, insufflated volume, power of used energies) should be visually and rapidly accessible to the team. The laparoscopic equipment should be prepared in the operating room in case of conversion or should a hybrid technique be required. The patient is draped for both approaches, as well, if the event transabdominal access becomes necessary.



**Fig. 43.14** Team and patient installation for pure taTME



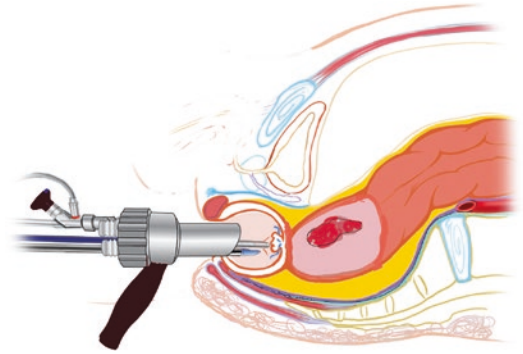
**Fig. 43.15** Perfect purse string closing the distal rectum

The surgeon works in a seated position between the patient's legs with one or two assistants who will manipulate the TEO® in order to change its position during the surgical maneuver (Fig. 43.14).

## Dissection

### Step 1: Closing the Distal Stump of the Rectum Placing a Purse-String Suture

A purse-string suture is placed 1 cm distal to the inferior boarder of the tumor (Fig. 43.15), in order to prevent fecal and cancer cell contamination and to avoid colonic insufflation. The closure must be perfect to avoid insufflation of the proximal rectum and colon (Fig. 43.16). The distal rectum is then irrigated copiously with a povidone-Iodine® solution in an attempt to sterilize the distal anorectum.

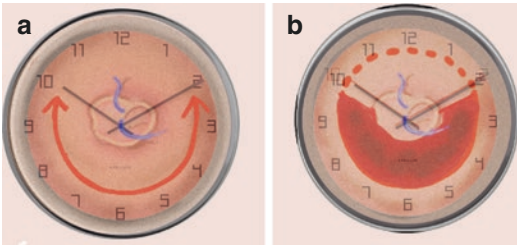


**Fig. 43.16** Purse string minimum 1 centimeter under the tumor

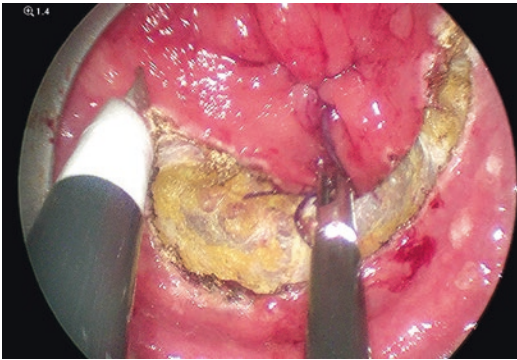
### Step 2: Posterior Rectal Space Opening

The rectal mucosa is initially incised from a 10 to a 2 o'clock position (Fig. 43.17), and then a full-thickness posterior rectotomy is performed (Fig. 43.18). The plane of dissection begins just posteriorly to the rectal fascia and is developed up to the promontory along a plane anterior to the sacral fascia in the posterior midline. The pneumo-dissection performed using insufflation facilitates the identification of this space (Fig. 43.19). In our experience and in the majority of cases, the dissection was performed behind the presacral fascia. Recently, we have successfully dissected along a plane between the presacral fascia and the propria fascia. In so doing, this opens the plane just above their fusion point (i.e., Waldeyer's ligament) leading to entry in the "holy plane" (Fig. 43.1), as described by RJ Heald [2]. This embryonic plane not only provides oncologically precise but also allows for an avascular and thus safe plane which does not encroach upon the pelvic autonomic nerves. As the dissection progresses cephalad beyond the sacral promontory, the retroperitoneal space becomes exposed just inferior to the aortic bifurcation. In the pure NOTES taTME technique, the dissection can be continued from down-to-up by advancing the TEO® rectoscope forward and laterally reaching the level of the sacral promontory. Anterior and medial retraction of the mesorectum is done via the transanal approach by using the TEO® platform's access channel as a circular retractor that "stents open" the operative field.

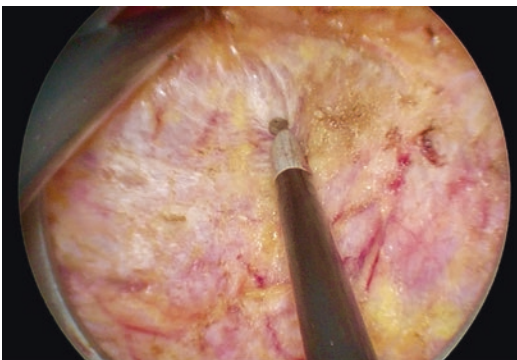




**Fig. 43.17** Drawing of the incision under the purse string (A posterior, B anterior)



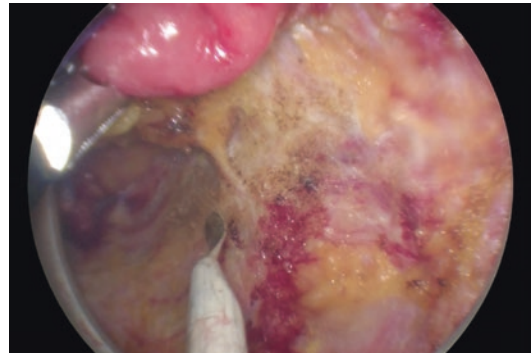
**Fig. 43.18** Full-thickness rectotomy from 2 to 10



**Fig. 43.19** Retrorectal and presacral dissection with monopolar spatula. TEO® is pushed slowly to open the space without another retractor

### Step 3: Cranial and Lateral Progression of the Dissection

If the plane initially entered is not the “holy plane” but the presacral space just posterior to the presacral fascia, care must be taken to avoid dissecting too posteriorly, which can result in injury to the autonomic plexus and presacral veins. While entering the presacral space and not the



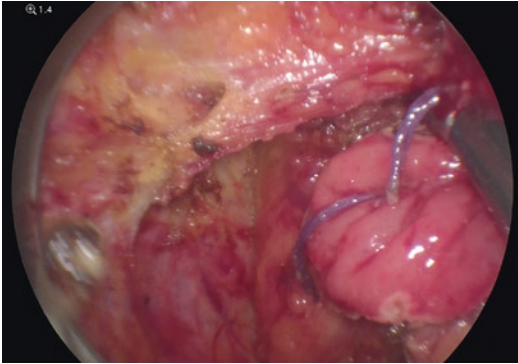
**Fig. 43.20** Left lateral dissection, sliding along the lateral side wall fascia (white structure). Nerve branch crossing the space

“holy plane,” it becomes more challenging as progress is made more cranially and laterally.

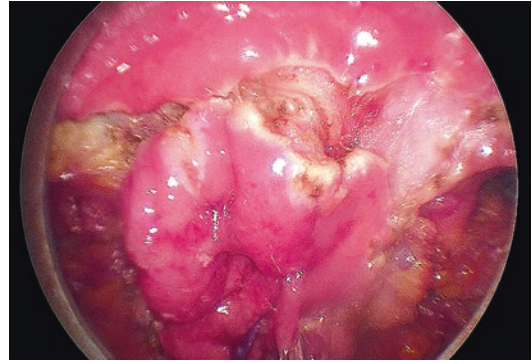
As the lateral dissection progresses, the 15 cm length TEO® rectoscope is advanced to a position between the rectum and the side wall fascia. This will slowly expose the middle rectal vessels and the autonomic branches of the lateral plexus (including the *nervi erigentes*) crossing the lateral side wall pelvic fascia to reach the lateral side of the rectum and mesorectum (Figs. 43.20 and 43.21). It is important to note that until this point in the pure NOTES taTME dissection, the abdominal cavity has not opened as the peritoneal reflection has not been violated. In this technique of dissection, the pressure of the CO<sub>2</sub> gas is not the principle factor in creating the operative exposure, but it is rather the retraction of the TEO® rectoscope shaft. The CO<sub>2</sub> is only used with a low pressure (12–15 mmHg) – with the purpose of clearing the field of view. Landmarks for doing a safe lateral pelvic dissection is to follow the medial side of the side wall pelvic fascia, which appears white. In so doing, iatrogenic injury to anatomical structures including the lateral aspects of the inferior hypogastric plexus can be avoided (Fig. 43.22).

### Step 4: Extending the Perirectal Dissection Anteriorly

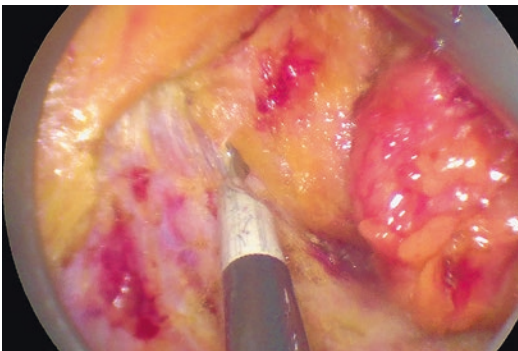
Once the posterior and lateral dissection of the mesorectum has been completed, the remainder of the distal rectal transection is performed anteriorly from a 2 o'clock to a 10 o'clock position



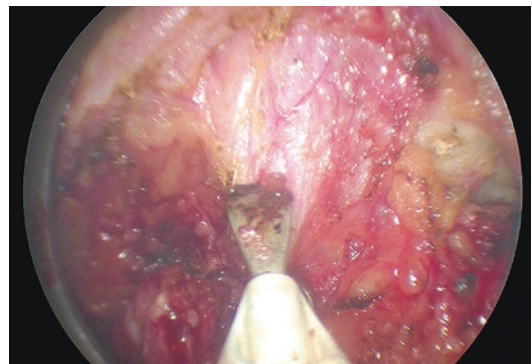
**Fig. 43.21** Right lateral dissection. Visualization of nerves plexus branches



**Fig. 43.23** Full-thickness anterior rectotomy from 10 to 2



**Fig. 43.22** Right side wall fascia (white). Resistant structure which protect laterally the inferior hypogastric plexus

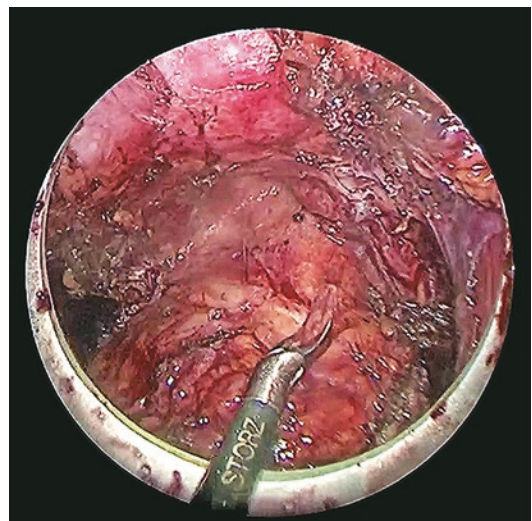


**Fig. 43.24** Female patient: Denonvilliers' fascia (white). Douglas pouch visible

(Figs. 43.17 and 43.23). The rectal wall must be completely dissected to enter into the rectovaginal plane in female patients (Fig. 43.24) and the rectoprostatic plane in males (Fig. 43.25). Dissection is developed until the level of the peritoneal reflection is reached.

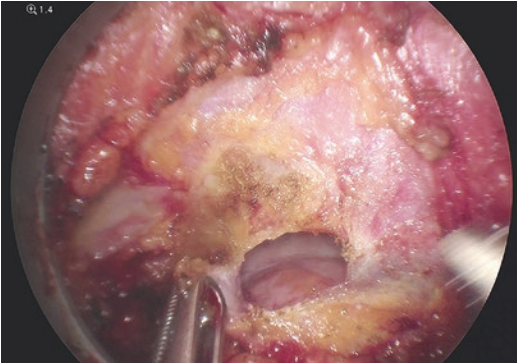
**Step 5: Dividing the Anterior Peritoneal Reflection and Opening the Abdominal Cavity**

This maneuver reveals the rectouterine pouch (Douglas' pouch) in women (Fig. 43.26) and the recto-vesicular pouch in men (Fig. 43.27). As in transabdominal resections, this step is more difficult in men. In men with anterior lesions, the dual-layered Denonvilliers' fascia is kept on the

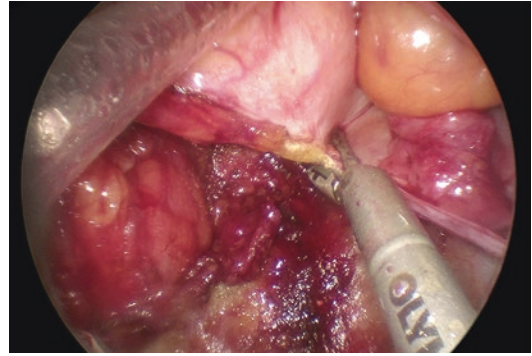


**Fig. 43.25** Male patient: Denonvilliers' fascia anterior, rectum posterior, and Douglas pouch

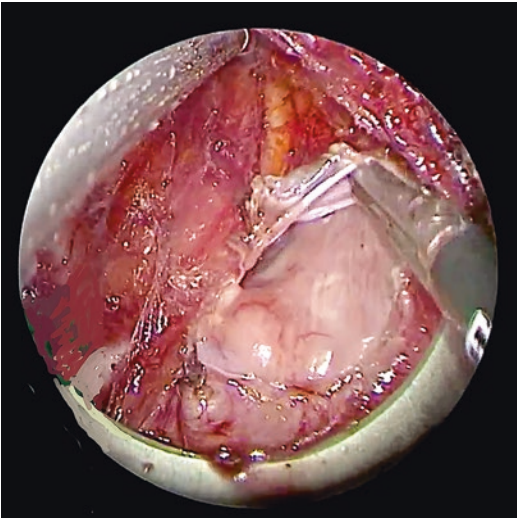




**Fig. 43.26** Female patient: opening the Douglas pouch



**Fig. 43.28** Proximal lateral division on left of the root of the mesorectum



**Fig. 43.27** Male patient: opening of Douglas pouch

mesorectum (to assure oncologic clearance), and care is taken to prevent urogenital tract injuries (prostate, seminal vesicles, and urethra). For these steps, the TEO® platform provides excellent exposure by retracting the fasciae, and this facilitates precise and safe dissection.

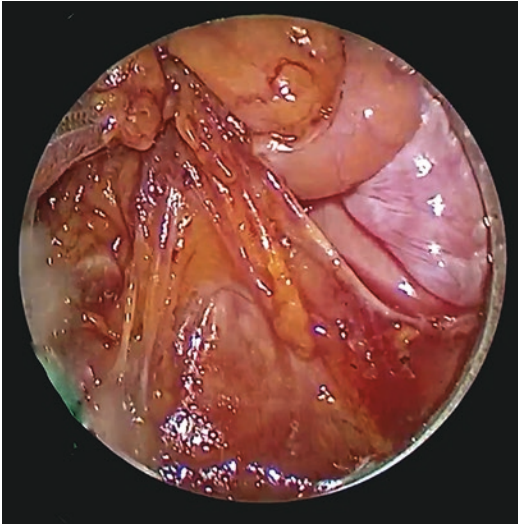
### **Step 6: Proceeding with the Dissection Toward the Root of the Mesorectum and the Retroperitoneal Abdominal Space**

Once the anterior peritoneal reflection has been opened, the rectum is gently distracted downward to expose and divide the lateral attachments of the root of the mesorectum (Fig. 43.28). Next, the rectum is pushed cephalad into the

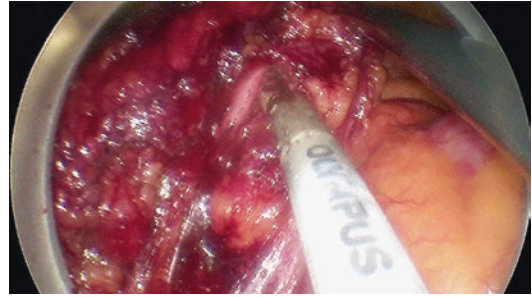
abdominal cavity through the peritoneal entry point along the pouch of Douglas. It is at this moment that the patient is positioned in steep Trendelenburg to obtain retraction of the bowel in the upper part of the abdominal cavity above the pelvic brim, to better expose the upper aspect of the pelvis. The pressure of the intra-abdominal CO<sub>2</sub> gas completes the retraction of the small bowel maintaining it away from the pelvis and operative field, as during classical laparoscopy. Pushing the rectum anteriorly results in tenting of the root of the mesorectum (Fig. 43.29) at the level of the promontory exposing the lateral peritoneal attachments of the mesorectum we divide to open the retroperitoneal space.

### **Step 7: Reaching the Root of the Inferior Mesenteric Vessels**

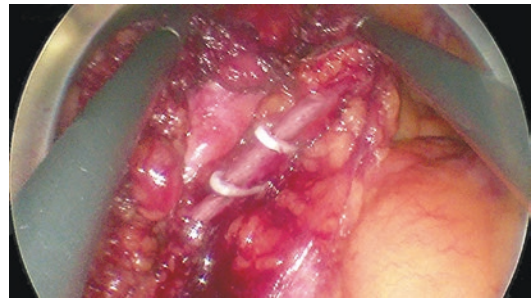
The TEO® long rectoscope (20 cm length) is now utilized. The shaft is advanced behind the rectum toward the promontory by dissecting planes posteriorly with a monopolar spatula electrode. Care is taken to prevent injury to presacral veins posteriorly, to the mesorectal envelope medially, and to pelvic nerves, ureters, and distal branches of iliac vessels coursing laterally. With anterior retraction of the root of the mesorectum, the retroperitoneal space anterior to the aorta is entered, with care to preserve the preaortic fascia and hypogastric plexuses (Figs. 43.30 and 43.31). As stated previously, exposure of the space is maintained by the circular TEO® retractor (Fig. 43.32), which allows for the dissection to be



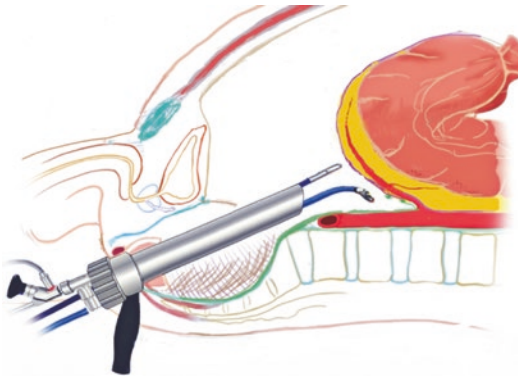
**Fig. 43.29** Root of the mesorectum tented anteriorly exposing the anterior aspect of the promontory



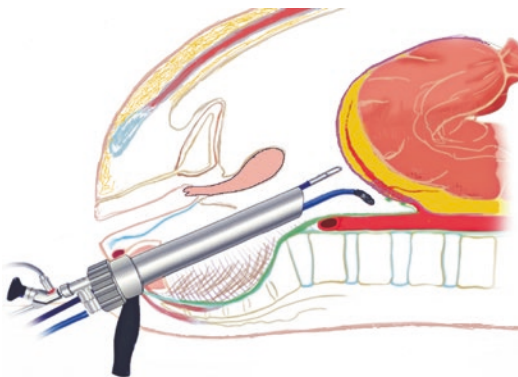
**Fig. 43.32** Vision of a 20 cm TEO® in intra-abdominal position during a pure taTME (view through a right iliac fossa trocar, before doing diverting stoma)



**Fig. 43.33** Dissection origin IMA



**Fig. 43.30** Male patient: 20 cm TEO® pushed above the promontory inside the retroperitoneal space, in front of the aorta

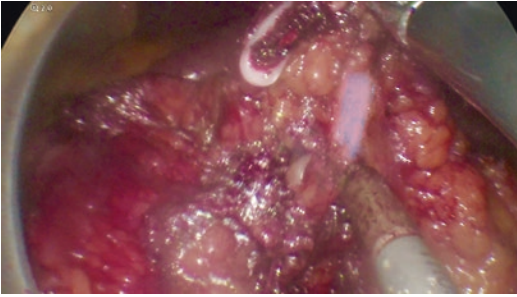


**Fig. 43.31** Female patient: 20 cm TEO® pushed above the promontory inside the retroperitoneal space, in front of the aorta

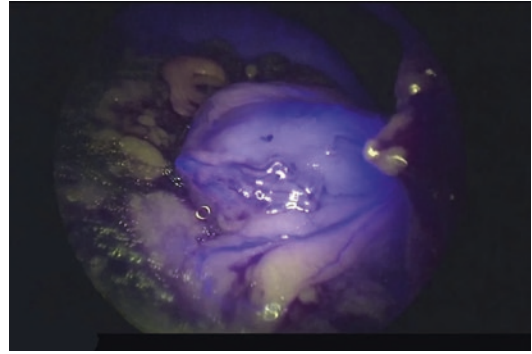
extended toward the root of the sigmoid mesentery, following the dorsal aspect of the vascular sheet of the inferior mesenteric vessels. The retroperitoneal dissection of the sigmoid mesentery is continued to reveal the origin of the inferior mesenteric artery (IMA) (Fig. 43.33). This step may be facilitated by the division of the medial and lateral peritoneal attachment of the sigmoid colon and the ventral lifting of the mesentery. For this step, longer instruments (43 cm) are helpful to achieve better operative angles and improved operative ergonomics.

**Step 8: Dividing the Inferior Mesenteric Vessels and the Sigmoid Mesentery**

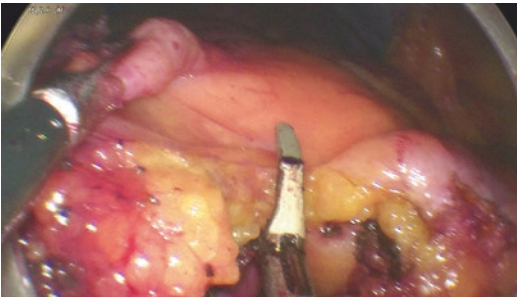
For oncological purposes (as well as to improve conduit reach), a high ligation of the IMA is the standard approach (Fig. 43.34). Otherwise, for early tumor and benign lesions, a distal division of the superior rectal artery may be performed [15–17]. Distal or high divisions of the inferior mesenteric vessels are performed after sealing



**Fig. 43.34** Clipping IMA trunk before division



**Fig. 43.36** Division of the mesosigmoid



**Fig. 43.35** Dissection and division IMV with a sealing device



**Fig. 43.37** Control of the vascularization with ICG®

[with THUNDERBEAT™ Type S (Olympus, Tokyo, Japan) or with LigaSure™ (Covidien, New Haven, CT, USA)] or after clipping. Division of the IMV (Fig. 43.35) is done afterward, and the left colic artery is also divided after high tie of the IMA.

Division of the sigmoid mesentery (Fig. 43.35) is performed intra-abdominally after selecting the best segment (summit of sigmoid loop). One can divide the mesentery first or divide the sigmoid colon first with a linear stapler introduced into the 12 mm operative channel of the TEO® faceplate (stapler access can be obtained removing the silicone obturator). Division of the mesentery is performed with a sealing device (Fig. 43.36). At the end of the division, we observe the quality of the vascularization with visual comparison of the color; alternatively indocyanine green (ICG) can be used to assess bowel perfusion (Fig. 43.37). So as to more easily divide the mesentery, it is useful to retract (by a pushing maneuver) all the rectum mesorectum laterally toward the right iliac fossa.

When the division of the sigmoid mesentery has been completed, the distal extremity of the rectum is grasped and pulled slowly through the TEO® rectoscope; a transanal extraction is then performed at the same time (Fig. 43.38). The specimen is gently exteriorized, with care to maintain the integrity (Fig. 43.39) and quality of the mesorectal envelope, the vascular pedicle, and the mesenteric lymphadenectomy (Fig. 43.40); the proximal margin and distal limit of the resection are determined as well (Fig. 43.41).

Next, the now transanally exteriorized sigmoid colon is divided extracorporeally. To perform this, a suitable portion of sigmoid colon (demonstrating adequate vascularity) is prepared and then divided with a linear Endo-GIA stapler (Fig. 43.42). A suture is fixed on the bowel maintain its orientation.





**Fig. 43.38** Transanal exteriorization of the specimen



**Fig. 43.39** Macroscopic view of rectal specimen

Then, the pelvis is explored and cleansed with irrigation through the anus. A LoneStar™ retractor is positioned transanally to expose the anorectum. Intra-abdominal inspection (e.g., to assess for active sites of bleeding) is done after the TEO® operating

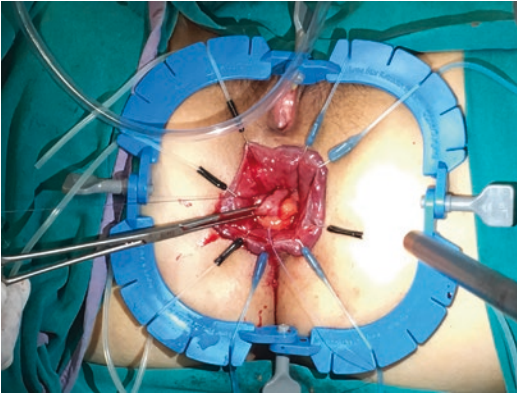


**Fig. 43.40** Control of the quality of oncologic resection and vascular package

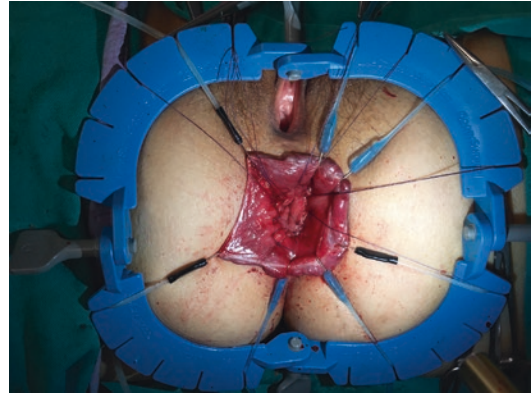


**Fig. 43.41** Resection: distal margin

platform has been reintroduced. If required, further mobilization of the sigmoid and even descending colon can be done at this time.



**Fig. 43.42** Division of the sigmoid with a linear stapler



**Fig. 43.43** Exposure with LoneStar® retractor and preparation of a side-to-end manual low colorectal anastomosis with separated stiches

### Step 9: Construction of Low Colorectal or Coloanal Anastomosis

The anastomosis may be an end-to-end or a side-to-end colorectal or coloanal anastomosis. It can be stapled or hand-sewn, but it may depend on the clinical scenario. The side-to-end hand-sewn anastomosis is the easier technique to perform and is done utilizing either the TEO® platform or the LoneStar® Retractor (Fig. 43.43) depending the level of the anastomosis. Interrupted sutures (preferred) or a running suture may be used.

In a side-to-end stapled anastomosis, a colostomy is performed just distal to a well-vascularized segment of bowel along the antimesenteric border in preparation for the anastomosis [9]. The spike of the anvil is delivered through this colostomy and brought out through the antimesenteric side of the proximal colon. The conduit is then transected with a single firing of a linear stapling device, just distal to the anvil and proximal to the colostomy. A purse-string suture is placed around the spike of the anvil. A catheter is attached over the spike of the anvil to be used as a handle to prevent excessive retraction of the anvil cranially into the abdomen. The anvil is pushed back into the pelvis and the short TEO® is reinserted transanally. The pelvis is inspected for bleeding, and the orientation of the proximal bowel is controlled to ensure that it is not twisted. A purse-string suture is placed to close the orifice around the spike of the anvil. Prior to cinching the purse-string suture, a drain is briefly advanced into the pelvis to evacuate any residual

pneumoperitoneum. The catheter on the anvil's spike is removed, and the spike is grasped with the aid of Kelly forceps. The arm portion of the circular stapler is inserted and mated to the anvil, before performing the anastomosis and controlling it endoscopically.

### Postoperative Care

Patients should follow an enhanced recovery after surgery (ERAS) protocol, and standard analgesia is offered (paracetamol and oral opiates). Sips of fluid are given on the evening of surgery and diet started the next day. Early patient mobilization is encouraged.

### Discussion

#### Why Pure taTME?

Pure NOTES transanal rectal extirpation has attracted our attention. By providing superior visualization and more accurate distal TME dissection (particularly in early rectal cancer), such an approach may improve clinical, oncological, and functional outcomes. In particular, a no-scar radical resection significantly improves healing and recovery after surgery. Thus, not only can patients return to full activity and function

post-operatively, but, when indicated, they can receive adjuvant therapy without significant delay.

Following the Japanese experience in retroperitoneal oncologic right and left colectomies [18] and the experience of pure retroperitoneal lymphadenectomies in gynecologic cancers [19, 20], our center has replicated these approaches for the rectum via a transanal access. Our experimental and clinical experience concluded the feasibility and safety of pure NOTES taTME. In the literature, most of papers report results of hybrid techniques with transanal rectal dissection completed from below, but not above the level of the S2 vertebra [21–30]. Only a few teams have performed pure NOTES taTME [31, 32]. As previously stated, even with proper expertise, only selected patient will benefit of this advanced procedure.

### Why TEO® Platform?

The TEO® platform is not a mere “point-of-access” device equitable to a trocar. When Gerhard Buess develop the revolutionary TEM apparatus, he proposed an automatic gas distension to expose the rectal cavity [13]. Doing only full-thickness excision of rectal neoplasia, he did not, at that time, envision the advantage of using the device’s rectoscope as “tunneling machine” to provide retraction in a circular manner that would enable more radical, en bloc resections. In our opinion, such rigid platforms (TEM or TEO®) provide the advantage to expose the plan of dissection, and CO<sub>2</sub> gas flow aids in clearing the operative field. The TEO® scope can be navigated around the rectum and, subsequently, in the retroperitoneal space, stenting the operative field open, in a similar fashion to how the cap is used to do so by interventional endoscopists during EMR (Fig. 43.8).

Currently at our center, we are exploring the possibility to eventually connect the TEO® platform to a foot pedal or a voice-piloted robotic arm to improve the ergonomic and functional arrangement, allowing a surgeon to operate more autonomously, expeditiously, and without the need for a skilled assistant. Combined, these factors can reduce the cost of the procedure.

### Why a Retroperitoneal Approach?

Decades of experience with conventional, up-to-down TME taught us that the dissection of the

rectum and sigmoid colon is an operation predicated upon embryological planes –

even along the retroperitoneum. All critical blood vessels and relevant autonomic nerves lie within the retroperitoneal space. The main challenges for TME are dissection along this plane, whereby preservation of vital vascular and nerve structures is paramount during the dissection. Today, the pure NOTES down-to-up transanal rectosigmoid dissection is now well standardized at our center and select centers worldwide. With appropriate training and experience, this retroperitoneal approach, particularly for the management and control of the vascular pedicles, appears to be optimal [6, 8, 9]. Confirmatory data reported by other experts subsequent to our published findings are also available [33].

### Is Mobilization of Splenic Flexure Necessary?

For most authors, mobilization of splenic flexure is a step of TME’s procedure. Increasingly, however, there is a growing consensus not to perform mobilization systematically and thus leading most experts to recommend a case-by-case selection. It is one of the techniques available to obtain adequate length, especially for construction of an ultra-low anastomosis, but has little direct effect on blood supply, and splenic flexure mobilization can increase operative and postoperative morbidity. If it is necessary for anatomic reasons (specifically, to gain reach) or because it is otherwise deemed necessary, transanal flexure mobilization is, in fact, feasible with the adaption of long instruments – as John Marks has demonstrated to be successful [34]. An operative fiberscope can be useful as an adjunct, as well [9], and in this manner, pure NOTES taTME including splenic flexure mobilization is possible.

### Teaching and Training

TME procedure for rectal cancer remains a technically demanding operation, whether completed in the open, laparoscopic, robotic, and now via the transanal approach. Through experience, and since the inception of laparoscopic digestive surgery, a standardized methodology of these procedures is essential to reproduce and to teach surgeons so that they may gain proficiency. Thus, a new procedure

should be mastered and perfectly understood before it is taught to delegate surgeons. Today, substantial experience with pure NOTES taTME (in highly selected patients) has been realized and, at our center, has become standardized. Most recently, a pure NOTES taTME for curative-intent rectal resection was completed in 2 h (female patient, T2 mid-rectal tumor, long sigmoid loop, with a virgin abdomen (Figs. 43.4, 43.5, and 43.6). Teaching taTME is not easy. Sam Atallah (2017) demonstrates perfectly in a recent paper how difficult it can be (35). Training in fresh cadaveric model seems for us the best approach. Some advanced programs have been developed worldwide [35–37].

## Conclusion

Performing a pure oncologic transanal TME without abdominal scars is feasible. This concept is based mainly on the objective of providing surgical cure for patients with rectal cancer.

Patient selection is highly important. The best indications for this approach are currently for early rectal cancers of the mid/high rectum, with or without neoadjuvant therapy. The pure NOTES taTME can also be applied for rectal extirpation of carpeting benign rectal tumors for which a complete endoscopic excision is impossible. In our primary experience, a diverting stoma may be avoided in patients in whom there is no neoadjuvant radiochemotherapy.

Its principle limitations seem to be locally advanced rectal cancer and obesity.

Up-to-down or down-to-up TME are surgeries of embryological planes. Before doing down-to-up pure taTME, it is necessary to memorize the technique of up-to-down to perform easier dissection of embryological planes as described above.

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# Totally Robotic taTME: Experiences and Challenges to Date

# 44

Marcos Gómez Ruiz

## Introduction

For the last two decades, total mesorectal excision (TME) has been transforming the outcomes of rectal cancer surgery and is a technique which holds great promise [1].

As in any other oncological surgical technique, TME surgical quality has a direct impact on local control and survival [2, 3]. In the pathological assessment of rectal cancer specimens, the circumferential radial margin (CRM) and the plane of surgery achieved are clear independent predictors of local recurrence [4]. At the same time, not only oncological but also functional outcomes have a significant impact on patients' postoperative quality of life. These results are not always favorable with current surgical techniques for rectal cancer treatment.

Open approach for rectal cancer treatment is the standard of care in most of the centers in the world. This approach is associated with poor postoperative outcomes in terms of patient recovery, pain, lengths of stay, and blood loss [5]. Laparoscopic colorectal surgery started 27 years ago [6] to improve the clinical, oncological, and functional outcomes that open surgery can provide in rectal

cancer surgery. Laparoscopic rectal resection has shown clear advantages in short-term clinical outcomes [7, 8]. However, ALaCaRT and ACOSOG Z6051 trials further questioned the oncologic equivalence of the laparoscopic approach for rectal cancer. These trials failed to establish the oncological noninferiority of laparoscopy compared to open rectal cancer surgery [9, 10].

Robotic-assisted surgery was introduced at the dawn of the new millennium. This new technique appeared to present clear advantages over laparoscopy, with improved stereoscopic visualization, endowristed instrumentation, and superior surgeon ergonomics that diminish fatigue, particularly for long and complex operations. Robotic-assisted surgery has been shown (in single-center series and some meta-analysis reports) to be associated with lower conversion rates, better TME quality, lower positive CRM rates, and earlier recovery of genitourinary functions [11]. Robotic surgery is generally easier to learn than laparoscopic surgery, improving the probability of autonomic nerve preservation and genitourinary function recovery [12, 13]. Furthermore, in very complex rectal cancer, TME procedures such as intersphincteric dissections and transabdominal transections of the levator muscle, the robotic approach is associated with increased performance and safety compared to laparoscopic surgery [14, 15]. Despite these encouraging data, the ROLARR trial failed to establish a clear benefit of robotic-assisted approach when comparing

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postoperative outcomes with the laparoscopic approach [16]. Furthermore, the cost of robotic surgery must also be addressed before it can become the new standard treatment.

There is a close relationship about the rate of CRM involvement and the local recurrence. The impact of robotic-assisted TME on CRM involvement, however, remains controversial. Several studies report no significant differences in CRM involvement as compared to laparoscopic-assisted TME [17, 18]. Nonetheless, a few retrospective case-matched studies found significantly decreased CRM involvement after robotic-assisted TME [19, 20]. Currently, there is limited literature dedicated to assessing the quality of TME in robotic-assisted surgery [20]. Reviewing the current literature on CRM, this is reported as a discrete variable defined as  $<1$  mm [21] or  $\leq 2$  mm [19] rather than continuous variable in mm. Of course, if the tumor (or a positive node) extends to the CRM, this represents not only a positive margin but implies an R1 resection.

Araujo et al. [22] published a large review of the literature in which they reported the oncologic outcomes after robotically performed tumor-specific mesorectal excision for rectal cancer including 1776 patients from 32 reports. The authors reported no significant differences on pathological data such as number of lymph nodes yield and rate of positive CRM. In these series, the mean number of harvested lymph nodes ranged between 10.3 and 20, whereas the total CRM positivity varied between 0% and 7.5%. Nevertheless, although certain heterogeneity among studies is to be acknowledged, a trend toward lower CRM involvement after robotic resections was noted in comparison to both laparoscopy and open standard surgery. It should be noted that, for rectal cancer surgery, the quality of the TME dissection and the CRM status are far more important variables than the number of lymph nodes harvested.

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### Transanal Total Mesorectal Excision

Transanal total mesorectal excision (taTME) was developed to overcome the inherent limits of abdominal approaches, also known as “anterior”

approaches, either open, laparoscopic, or, more recently, robotic. Indeed, a laparoscopic low anterior resection (LAR) remains particularly challenging in adverse anatomical situations, such as male patients with a narrow pelvis, visceral obesity, prostatic hypertrophy, or neoadjuvant chemoradiotherapy. Exposure, rectal dissection, and distal cross-stapling of the rectum can be extremely challenging in these conditions. Starting with dissection from the perineum seems to offer advantages, by avoiding distal cross-stapling in a narrow pelvis. The use of laparoscopic staplers in this situation is difficult as multiple staple firings across the low rectum increase potential for anastomotic leak [23]. The potential anastomotic benefits of a transanal approach have been challenged by the recent publication of the International Registry in which the number of low anastomosis and anastomotic leak rate was concerning [24, 25].

The concept is that a bottom-up (caudal to cephalad) or retrograde dissection technique may provide the surgeon some advantages including the ability to directly visualize and choose the distal resection margin. A transanal purse-string suture below the tumor ensures that an adequate oncological distal margin will be achieved; it also allows using the pneumatic insufflation of the mesorectal plane to facilitate rectal dissection. The optimal close visualization of the mesorectal dissection plane might reduce injury to surrounding structures such as the vagina, prostate, pelvic nerves, and pelvic vessels. Importantly, from the taTME vantage point, conflicts with the adjacent intra-abdominal pelvic structures and viscera are avoided, as they no longer need to be retracted cephalad for rectal mobilization in this unique setting.

The technique itself demands an understanding of pelvic anatomy as well as comfort with currently available surgical equipment including the access platforms and insufflation systems that make this approach possible. These concepts have been challenged by the reported urethral injuries and recent publications in which taTME had a higher positive distal resection margin (DRM) when compared with a robotic low anterior resection [26].

After M. Whiteford first described taTME in a cadaveric model in 2007, P. Sylla and A. Lacy

described the first successful clinical use of taTME in 2010 in a patient with a rectal carcinoma of the middle third [27]. Since 2010, TaTME has had an important impact worldwide, and there has been a significant increase in the number of publications related with taTME over the past 8 years [28]. This concept can be further supported by the fact that national training programs are being developed to ensure that there is safe introduction of taTME across Europe, North America, as well as parts of South America (such as Brazil), and Southeast Asia.

Several cohort series have been published regarding hybrid endoscopic taTME [29–32]. These series suggest that taTME is feasible and safe regarding short-term outcomes and that it delivers high-quality TME specimens in selected patients. Wolthuis et al. [33] reviewed 20 studies where 323 patients were included. Most studies were single-arm prospective studies with fewer than 100 patients. Multiple transanal access platforms were used, and the laparoscopic approach was either a multi- or single-port platform. The procedure was initiated either by transanal or transabdominal. When a simultaneous approach with two operating surgeons was chosen (Cecil approach), the operative time was significantly reduced.

This review clearly demonstrated that taTME is currently performed in a non-standardized way, which reflects surgeons exploring the technical boundaries of ultralow rectal cancer.

The published series that excluded T4 tumors have demonstrated a promising CRM involvement of 0–5.4% [33]. The largest series, including 140 patients, reported CRM involvement of 6.4% [34]; however, T4 tumors were not excluded, and all patients with involvement of CRM were correctly predicted by MRI [35]. Short-term morbidity and oncological results were comparable to other laparoscopic TME series [33].

In the largest published taTME series to date [33], the CRM positivity rates range from 2.5% to 6.4%. When taTME and robotic LAR have been compared in retrospective multicenter studies, similar CRM positivity rates have been found [26]. Long-term follow-up is necessary to assess more accurately these data and validate oncological outcomes.

The significant rate of taTME-related urethral injury occurs at the posterior wall of the pre-prostatic urethra in male patients with a distal anterior rectal cancer (within 3 cm of the anal verge). Atallah [36] has observed in his North American Training Program on taTME that approximately 20% of cadaveric trainees (all with considerable rectal cancer experience) will inadvertently mobilize the prostate and enter the incorrect plane, underscoring the importance of adequate training in this technique, which approaches the rectum from an unfamiliar vantage point. Other cautionary points during taTME include meticulous attention to the autonomic nerve plexi [37] and other anatomic structures detailed in other chapters.

With appropriate training, taTME can be considered a real advancement in the surgical management of rectal cancer surgery. However, it is yet to be seen as to whether or not it will become a real scientifically proven advantage [38, 39]. Randomized trials have been constructed to challenge this issue. There is already an International taTME Registry in place with more than 1500 cases reported so far [24, 25]. In Europe, the GRECCAR 11 trial [40], COLOR III trial [41], and in the near future RESET trial have been designed and are being developed to compare taTME with other existing anterior approaches. In particular, COLOR III and GRECCAR 11 are prospective, multicenter, randomized trials planned to compare taTME with laparoscopic TME. It will take years before robust data will be available. During this period, care must be taken before proposing taTME outside of expert centers.

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## Robotic Transanal Total Mesorectal Excision (Robotic taTME)

Clinical experience of robotic taTME started in 2013 when Atallah et al. [42] reported the first clinical case in a patient with familial adenomatous polyposis and two synchronous tumors. Our group published our robotic taTME experience in a cadaver model [43] using the PAT platform (Developia-IDIVAL, Santander, Spain),

a self-designed platform, and the 80-mm GelPOINT gel cap (Applied Medical, Rancho Santa Margarita, CA, USA). On August 2013, we performed the first clinical case in Europe [44]. To date, very few publications are available on robotic taTME, and all of these only report early experiences [45, 46] or short series of cases concluding that this technique is feasible and safe [47].

Atallah et al. published their initial experience [48] with three patients that underwent curative-intent robotic taTME using the da Vinci Si Surgical System. They performed the abdominal phase of the procedure with a laparoscopic approach and the taTME with robotic assistance. They used a commercially available transanal minimally invasive surgery (TAMIS) port (GelPOINT path transanal access platform) to dock and interface with the robotic arms transanally.

In these three patients, the average age was 45 years (range 26–59) with mean BMI of 32 kg/m<sup>2</sup> (range 21–38.5). The average tumor size was 2.5 cm. All lesions were in the distal 5 cm of the rectum. Mean operative time was 376 min. DRM and CRM were free of tumor, with the closest DRM being 1 cm. The resection quality of the mesorectal envelope was graded for completeness by an independent GI pathologist and was found to be near complete in two cases and completely intact in one case.

We reported the results of our pilot study with our initial five cases of complete robotic taTME [49]. We used a “transanal access port” proctoscope (PAT, Developia-IDIVAL, Santander, Spain). PAT was inserted transanally, and a GelPOINT gel cap was used to occlude the proctoscope and for trocar placement. This platform (which is essentially a hybrid between TEO and TAMIS) allows for optimal lateral docking of the da Vinci Si Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) with unencumbered movements of the robotic arms. All patients underwent a dual-docking procedure with robotic-assisted multiport laparoscopic left colon mobilization, robotic-assisted taTME, ultralow mechanical colorectal or handsewn coloanal anastomosis, and a diverting loop ileostomy. Four patients with stage III disease received preoperative long-course chemoradiation before surgery. In all

cases, pathological examination of the TME specimens showed complete mesorectal excision with negative proximal, distal, and circumferential margins. These preliminary results allowed us to conclude that this technique is feasible, with good pathological results and postoperative outcomes.

Currently, Li-JenKuo et al. [50] have published the largest robotic taTME. Left colon mobilization was performed with a single-site robotic approach. In this series, 15 patients underwent robotic taTME, with two conversions. Morbidity included an injury to the ureter, and one patient presented a Clavien IIIb complication because of a small bowel obstruction.

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## **Totally Robotic taTME: The Santander Experience**

### **Surgical Technique**

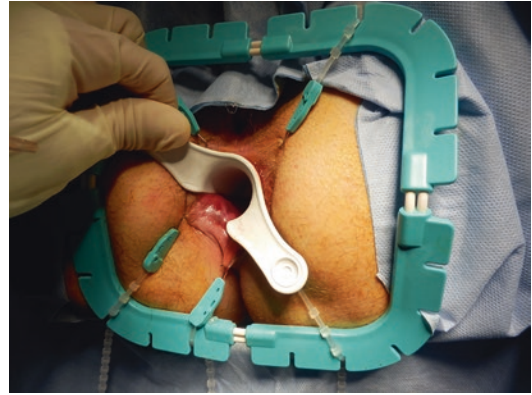
The following section describes the technique used for totally robotic taTME, utilizing the da Vinci Si Surgical System with dual-docking.

With the patient under general anesthesia, a urinary catheter is inserted, and the patient is placed in the lithotomy position with the use of stirrups. Digital examination and rigid proctoscopy are performed to confirm the tumor location. Abdominal access is achieved via Veress needle, which is inserted in the left upper quadrant and the abdomen, and CO<sub>2</sub> insufflation commences to an average pressure of 12 mmHg. Robotic 8-mm trocars are next inserted in the right upper quadrant (12–15 mm and 8 mm), right lower quadrant (two 8-mm trocars), and periumbilical region (12–15 mm). The patient is positioned in a right tilt, and the peritoneal cavity is first inspected through a standard laparoscope. After confirming the absence of significant intra-abdominal adhesions and no evidence of distal tumor extension or cacinomatosis, the da Vinci Si robotic cart is docked from the patient's left side (Fig. 44.1). Monopolar curved scissors are placed in Arm 1, a fenestrated bipolar grasper is placed in Arm 2, and a double-fenestrated grasper is used in Arm 3. A 30° 12-mm endoscope is employed. The splenic flexure is first taken down with dissection and





**Fig. 44.1** Da Vinci Si System docked from the left lateral side of the patient



**Fig. 44.2** Anal exposure for ISR resection or purse-string suture

division of the inferior mesenteric vein and artery at their root. The descending and sigmoid colon are then mobilized, finishing the dissection at the sacral promontory once the ureter and iliac vessels are identified. The robotic surgical system is next undocked, and the patient is repositioned in the Trendelenburg position with a slight right tilt for the next phase of the operation.

Partial intersphincteric resection can be performed for tumors located at  $\leq 3$  cm from the anal verge. A Lone Star retractor (Lone Star Medical Products Inc., Houston, TX) or a PPH anoscope (Ethicon Endosurgery, Cincinnati, OH) is positioned, and the mucosa and internal sphincter muscle are dissected circumferentially beginning at least 1 cm below the distal margin of the tumor. Intersphincteric dissection is extended cephalad for 1–2 cm, and a purse-string suture is then placed to occlude the rectum below the tumor (Fig. 44.2).

Following rectal occlusion, a “transanal access port” proctoscope (Fig. 44.3) is inserted transanally, and a 80-mm GelPOINT gel cap is adapted to this custom-made platform. The robotic trocars are then directly introduced through the gel cap for robotic taTME.

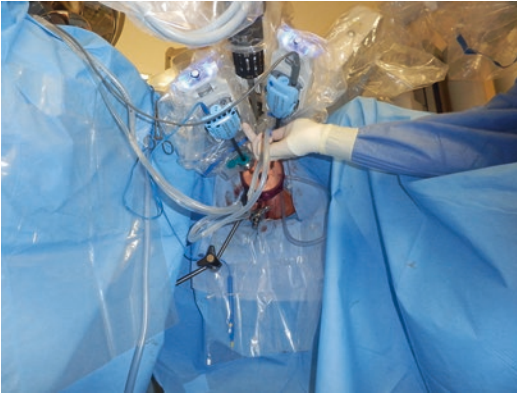
A 12-mm or an 8.5-mm trocar can be used for the optical port. Two 8-mm trocar ports are inserted with a distance of at least 4 cm between robotic instruments, and an accessory 12-mm trocar is inserted for the assistant port. The da Vinci robotic cart is next docked over the left hip of the



**Fig. 44.3** Transanal access port proctoscope. (Developia-IDIVAL, Santander, Spain)

patient. The fenestrated bipolar grasper is then placed in Arm 1 on the left, while monopolar scissors are placed in Arm 2 on the right, and a 30° endoscope is placed through the 12-mm trocar. The assistant trocar is used primarily to assist in tissue countertraction or to apply suction or irrigation (Fig. 44.4). If available, an AirSEAL System (Conmed, Utica, NY, USA) 5-mm or 8-mm valveless trocar can be used for the assistant, thereby stabilizing the pneumatics, as discussed elsewhere.

When partial intersphincteric resection had not previously been done (patients with tumors located higher than 3 cm from anal verge), the rectum is insufflated with CO<sub>2</sub> to a pressure of 8 to 10 mmHg. The rectal mucosa is then scored



**Fig. 44.4** Da Vinci Si System docked transanally using PAT proctoscope

circumferentially with monopolar cautery beginning distal to the purse-string and followed by full-thickness rectal dissection. After rectal wall division, the pelvic space around the remnant anal canal is insufflated to facilitate pelvic dissection and robotic taTME. Anteriorly, the rectum is dissected from the posterior vagina or prostate following Denonvilliers fascia until the peritoneal reflection is reached and divided. Posterior and lateral mesorectal dissection is performed by using a transanal approach with laparoscopic assistance.

Following adequate colonic mobilization, the rectum can be grasped and exteriorized transanally under laparoscopic visualization or through the ileostomy site. An Alexis wound retractor (Applied Medical Inc., Rancho Santa Margarita, CA) can be utilized. A handsewn end-to-end coloanal anastomosis or mechanical end-to-end colorectal anastomosis is performed, depending on case specifics and tumor height. A diverting loop ileostomy is next created, and a pelvic drain can be placed intra-abdominally.

## Clinical Outcomes

Thirty-seven consecutive totally taTME robotic cases have been performed in our unit between 2013 and 2017. Conversion was required in one case (2.70%). Transanal specimen extraction was performed in 56.2% of the patients, and through

**Table 44.1** Clavien-Dindo Complication Distribution

Clavien-Dindo Complications		
	Number	Rate (%)
No complications	28	75.7
I	3	8.1
II	3	8.1
IIIb	2	5.4
IV	1	2.7
Total	37	100.0

the stoma site in 37.8%, Pfannenstiel incision was used in 6% of the patients. Clavien distribution is shown in Table 44.1. Mean hospital stay was 7.54  $\pm$  5.258 days (Table 44.2.). Three patients presented anastomotic leak (8.1%), one of them Grade C.

TNM and UICC distribution of the patients is described in Tables 44.3 and 44.4. The median harvested lymph nodes were 12.6. TME quality assessed by pathologist was complete in 94.6% and almost complete in two cases: 5.4%. DRM and CRM were negative in all cases. Mean tumor height from anal verge was 5.33 cm (2–9 cm). In the follow-up, no patient presented local recurrence.

When analyzing our results and comparing them with the ones published in the International taTME Registry [25], our lower rate of visceral injuries and rectal perforations supports this potential benefit, even though our experience is limited to 37 cases, which is still under the learning curve for taTME [51]. The goal is to achieve the best quality of surgery to obtain the best clinical, oncological, and functional outcomes. To do this, the key points are to obtain an excellent vision and information of the surgical anatomy with the assistance of surgical instruments.

TaTME may provide better results because it improves the vision of the surgical field. The robotic systems facilitate the surgical performance with the endowristed instrumentation. In addition, they can optimize vision and information of the surgical field with the 3D immersive view and with the potential use of augmented reality. The use of stereotactic navigation in the pelvic surgery can be another important step to facilitate the safety as well as oncological quality

**Table 44.2** Mean hospital stay

Hospital stay					
	N	Minimum	Maximum	Mean	Std. deviation
Hospital stay	37	4	30	7.54	5258

**Table 44.3** TNM distribution

		Rate	%
T	0	8	21.6
	1	8	21.6
	2	9	24.3
	3	12	32.4
Total		37	100.0
N	N0	32	86.5
	N1a	5	13.5
Total		37	100.0

**Table 44.4** UICC distribution

		Rate	%
UICC	0	3	8.1
	I	13	35.1
	IIA	9	24.3
	IIIA	1	2.7
	IIIB	6	16.2
	Complete response	5	13.5
	Total	37	100.0

through improved precision [52–54]. The robotic and fully computerized systems can facilitate the implementation of this technology [55].

## Future: New Robotics Platforms

The widespread of the clinical use of the robotic rectal surgery is being limited mainly by the economic costs and access to clinical experience in sufficient number.

Today, the technological progression is exponential. Robotic rectal surgery started less than 10 years ago with the da Vinci Surgical System, and in this period four different systems have progressively been used: S, Si, X, and Xi. SP platform has recently achieved the US Food and Drug Administration (FDA) approval for its use in urological procedures and will probably achieve the same approval for colorectal procedures within the next 2 years. After initial evaluation in cadaver

model [56], preliminary results of its clinical use in three taTME procedures performed by Simon Ng, MD at the Chinese University Hong Kong (Hong Kong), seem promising.

A new wave of robotic platforms specifically designed for single-port and natural orifice surgery is currently under development and evaluation. The main advantage of these systems is the addition of flexible effector arms and/or cameras which can be manipulated in part, or completely, by a master-slave, computer-assisted system [57]. Such systems could change our approach to complex surgical or endoscopic procedures, unique to the field of colorectal surgery, but they first require careful assessment and validation.

In 2017, the Flex® Robotic System and Flex® Colorectal (CR) Drive (MedRobotics, Corp. Raynham, MA, USA), a semi-robotic apparatus for colorectal surgery specifically indicated for transanal endoluminal applications, as well as more radical resection (i.e., taTME), was approved by the US Food and Drug Administration (FDA). This platform has already been used in cadaver model and is currently under evaluation in a clinical trial [58]. The flexible effector arms measure only 3.5 mm, but are not robotic assisted, which is a limitation of the current technology. Other limitations include suturing at ranges beyond 15 cm, needle delivery, and retrieval, and the process of suturing itself can sometimes be encumbered by the Flex® Robot's convolution throughout the sigmoidal bends.

Other single incision platforms such as the SPORT® Surgical System (Titan Medical, Toronto, Canada) [59] or the multi-trocar platforms like the expected robotic systems from Cambridge Medical Robotics, Medtronic, Medcaroid, or Verb Surgical are also in the pipeline for robotic taTME. The latter, a joint venture between Google and Johnson & Johnson, hopes to digitize surgery, thereby providing computer-assisted technology that can ultimately improve surgical precision.

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## Introduction

Although colorectal cancer incidence and death rates have declined over the years, mainly due to advances in early detection and treatment, colorectal cancer still remains one of the most common cancers affecting humans. Further, recent studies have shown an increase in the incidence rates in individuals of a younger age [1]. The goal of rectal cancer treatment remains complete cancer removal while preserving rectal and sphincter function, and, throughout the years, this has undergone various advancements with improved morbidity and mortality rates.

Many surgical techniques have been developed to approach rectal tumors, which are specifically known for their anatomical restrictions and challenges. The nonlinear anatomy hinders visualization and instrumental maneuvering, sometimes resulting in specimen fragmentation and making the attainment of surgically negative margins technically more arduous to achieve. In

1982, Heald's total mesorectal excision (TME) technique [2] was developed, based on the concept that the rectum and mesorectum are of the same embryological origin and thus share lymphatic and venous systems, allowing cancer to spread between them. TME shifted the management of rectal cancers from Dr. Ernest Miles' abdominoperineal resection (1908), with the extraction of the mesorectum and rectum for completeness of oncologic resection. It later became the gold standard of treatment as study results showed improvement of disease-free survival from 68% to 80% at 5 years and 66% to 78% at 10 years [3].

As the laparoscopic era emerged and dominated the surgical spectrum in the 1990s, the introduction of laparoscopy in the management of rectal tumors had conflicting results when compared to open rectal tumor resection. In randomized clinical trials, such as COLOR II, COREAN, and CLASICC, it was shown that laparoscopic TME had better short-term outcomes and comparable long-term outcomes with open TME [4–6]. However, in recent studies, such as AlaCaRT and ACOSOG Z6051, it failed to prove non-inferiority for pathologic outcomes when compared with open approaches [7, 8]. This failure was attributed to the rigidity and straightness of laparoscopic instruments, resulting in poor maneuvering capabilities specifically with low-lying rectal tumors confined within a nonlinear lumen and a narrow, restrictive bony pelvis. The introduction of robotic-

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assisted rectal surgery was a response to the laparoscopic technical limitations for TME. Although the robotic platform is recognized for its improved visualization and ease of maneuvering, this has generally not translated into a measurable improvement in outcomes. Instead, studies reported equivalent oncologic and functional outcomes for both approaches raising the question of cost-effectiveness [9, 10].

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## The Evolution of Transanal Surgery

The classical “top-down” approach to rectal cancer with all its surgical advancements has maintained open TME surgery as the gold standard for rectal cancer treatment. Meanwhile, through experimentation with hybrid approaches, Dr. Gerald Marks explored a “bottom-up” concept in 1984 by introducing the TransAnal Abdominal TransAnal (TATA) proctosigmoidectomy with colo-anal anastomosis as a sphincter-preserving technique for curative-intent rectal cancer resection [11]. In various studies, TATA was successful in avoiding permanent colostomies for patients and provided excellent oncological outcomes for low rectal cancers treated with chemotherapy [12].

The introduction of technological instrumentations began in 1980, with Knight and Griffen introducing the double-stapling technique for low colorectal anastomoses. Two years later, Dr. Gerhard Buess developed transanal endoscopic microsurgery (TEM), a device composed of an optical stereoscope, operating instruments, and a specialized insufflation system. The implementation of TEM in surgical care resulted in better outcomes compared to standard transanal excision as reported in several studies [13]. TEM’s large-scale adoption was hindered, however, by high device cost and steep learning curve.

In the search for the ideal approach that involved a short learning curve, low cost, and equivalent outcomes, transanal minimally invasive surgery (TAMIS) came to the surgical scene in 2009 as an alternative to TEM, promising affordability, accessibility, and perhaps better visibility within the rectal lumen (360 degrees vs.

220 degrees in TEM). It modified the laparoscopic abdominal single port for transanal use, and, as a result, all standard laparoscopic equipment could be used transanally as well [14].

The first human case of transanal total mesorectal excision (taTME) was performed in 2009 by Sylla, Rattner, Delgado, and Lacy [15]. They benefited from the TATA experience and used the TEM platform (TAMIS was still under development at this time). This was followed by a series of 20 rectal cancer patients in 2013 with promising results, showing safety and feasibility of the transanal approach to TME. Although taTME is increasingly being adopted worldwide and preliminary results in case series are encouraging, large-scale studies, such as COLOR III and the taTME trial examining the best surgical approach to rectal cancer, are still underway; further, its indications, standardization, long-term outcomes, and the slope of its learning curve require further elucidation as well. Precise indications and contraindications for taTME have not been established yet, and formalized NCCN guidelines and recommendations for the taTME do not yet exist at the time of this writing.

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## Initial Progress with Transanal Robotics

Given the history of laparoscopy and the transition to robotics in abdominal surgery, it seemed a natural evolution that TAMIS would follow suit and enter the robotic era. The robotic approach to a transanal operation was originally described for local excision of rectal neoplasia by Dr. Atallah and his colleagues using the da Vinci® Surgical System (Intuitive Surgical, Sunnyvale, CA, USA) (Fig. 45.1) [16]. It was a natural step to approach TME of rectal cancers through the robotic platform, which is believed to overcome the limited maneuverability of TAMIS and TEM in transanal operations with these innate and novel properties:

1. Movement of an EndoWrist® instrument
2. Arm crossing
3. Dexterity and precision

**Fig. 45.1** The da Vinci Si® Surgical System. (Photo courtesy of Sam Atallah, MD)



4. Reassigning left–right-hand control in the console
5. 3-dimensional high-definition images, with video magnification

The experimentation with the robotic platform for taTME in the clinical setting has demonstrated feasibility for distal and mid-rectum tumors [17]. In the first human case of RATS-TME (robotic-assisted transanal surgery for TME; synonymous with robotic taTME) procedure in 2012, Dr. Atallah and his team used the da Vinci® Robotic Surgical System–Si (Intuitive Surgical, Inc., Sunnyvale, CA, USA). According to the authors, the Single-Site™ da Vinci® port was not used for RATS-TME because the intraluminal dexterity diminishes with the use of its 5-mm non-wristed straight instruments. The GelPOINT “TAMIS port” was preferred as a platform due to previous team experience, as it offers sphincter protection from the robotic arms by the rigid cylindrical access channel, accommodates an 8.5-mm robotic camera and working arms, and allows the bedside assistant to operate a 5-mm suction-irrigator device. This index case of robotic taTME was performed on a 51-year-old female with a BMI of 35.3 kg/m<sup>2</sup> diagnosed with familial adenomatous polyposis. Her rectal cancer was located 4 cm from the anal verge and complicated by a hepatic flexure tumor. The total operative time was 381 minutes (total proctocolectomy with robotic taTME). All margins

were free, and, based on standard TME grading, the total mesorectal excision was considered near complete due to a 1.5-cm defect in the lower section. The patient was discharged on postoperative day three and remains disease-free 6 years post resection.

Follow-up case reports with a similar operative setup utilizing the GelPOINT TAMIS port and 5-mm instruments have been documented since Dr. Atallah’s group performed the first RATS-TME. Verheijen et al. performed a RATS-TME on a 48-year-old female, with a BMI of 23.6 kg/m<sup>2</sup> and a preoperative colonoscopy demonstrating a circular rectal tumor 8 cm from the anal verge [18]. The operative time was 205 minutes with an estimated blood loss of 50 cc, and there were no intraoperative robotic arm collisions. The patient left the hospital on postoperative day three, and the final pathology report demonstrated a complete mesorectal excision with negative margins and an intact mesorectal fascia. There were no reported postoperative complications.

Additional prospective studies have demonstrated successful use of the da Vinci® Si platform for RATS-TME. In a five patient series including four men and one woman with an average age of 57 years, an average BMI of 28 kg/m<sup>2</sup>, and tumors averaging 5 cm from the anal verge, all margins on mesorectal specimens were negative, and all patients were disease-free at 3-month follow-up [19]. The average operating time was

398 minutes with no intraoperative complications, and the average hospital length of stay was 6 days; postoperatively one anastomotic leak was reported.

Dr. Atallah and his group followed up their initial case report by documenting their experience with four additional RATS-TME operations performed for select, distal rectal cancers [20]. The cohort included three male and one female patient with average age of 44 years and a BMI of 29 kg/m<sup>2</sup>; tumor locations ranged from 1 to 5 cm from the anal verge. The operative times averaged 376 minutes, and estimated blood loss was 200 cc. Patients stayed in the hospital an average of 4 days postoperatively, and all final pathology reports demonstrated a mesorectal specimen that was complete or near complete with an R0 resection in all cases; of note, an average of 27 lymph nodes was contained within each specimen (range 15–39). At 9-month follow-up, one patient experienced a wound hematoma, another patient was found to have an asymptomatic subsegmental pulmonary embolism, and a third was readmitted for dehydration secondary to high ileostomy output. There was no evidence of recurrence within this timeframe. An additional case series in 2015 performed by Dr. Huscher and colleagues demonstrated similar results [21]. In their series, seven patients (three men, four women) underwent RATS-TME with a transabdominal laparoscopic vessel ligation and colonic mobilization. The average age was 63.2 years, average BMI was 29.9 kg/m<sup>2</sup>, and the tumors were located on average 2 cm from the anal verge. The operative time for the transanal portion was 55.5 minutes and resulted in a complete mesorectal excision in six cases with one near complete; the average lymph nodes collected per specimen were 14 (10–20). One patient experienced postoperative rectal bleeding on postoperative day two which required transfusion.

The largest series to date included 15 patients who underwent RATS-TME in combination with transabdominal single-site radical proctectomy [22]. Eight females and seven males with an average age of 60.3 years and an average BMI of 21.97 kg/m<sup>2</sup> with lesions an average of 3.3 cm from the anal verge underwent RATS-TME using

the da Vinci® Si platform with the previously described GelPOINT TAMIS port operative setup. The mean operative time was 473 minutes with an estimate blood loss of 33 cc; mesorectal specimens had an average of 12 nodes (with a range of 8–18), and all margins were clear circumferentially. There were no transanal intraoperative complications; however, there was one left ureteric transection which occurred during a transabdominal portion of the case. One superficial wound infection occurred postoperatively, and there was no mortality at 1-month follow-up. While early data is encouraging displaying continued operative feasibility and satisfactory oncologic outcomes, it is important to note that, given the novelty of this robotic approach, large-scale studies have yet to be conducted, demonstrating improvement in long-term patient outcomes and the enhanced value to patient care.

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## Flex® Robotic System

Within the past few years, new robotic platforms designed for natural orifice surgery equipped with flexible effector arms and cameras have been utilized safely and successfully in otolaryngologic and urologic surgeries. Among the more notable of these platforms is the Flex® Robotic System (Medrobotics, Corp. Raynham, MA, USA) (Fig. 45.2). Since the first application of the platform in transoral robotic surgery (TORS) was reported in 2015, the safety and efficacy have been tested on both benign lesions and carcinomas [23–26]. The utility of an articulating endoscopic robot to accommodate the nonlinear anatomy of the anorectal region was recognized, and, on May 4, 2017, the US Food and Drug Administration (FDA) provided Section 510(k), which added approval for the Flex® Colorectal (CR) Drive, introducing a semi-robotic apparatus for colorectal surgery specifically indicated for transanal endoluminal applications, as well as more radical resection (i.e., taTME). As a transoral oropharyngeal tool, the platform originally lacked a mechanism to maintain a pneumatic seal, but the technology has been modified to accommodate insufflation through adaption of a valveless



**Fig. 45.2** The Medrobotics Flex® System. (Photo courtesy of Sam Atallah, MD)

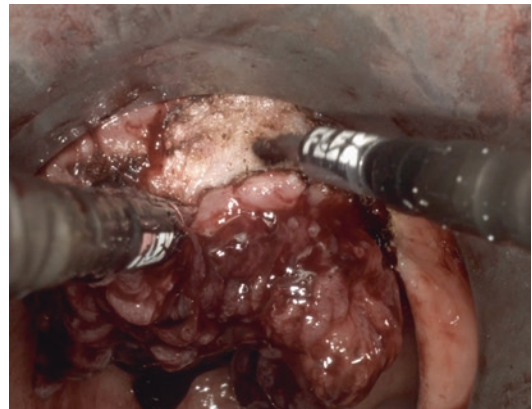


insufflation system (namely, AirSEAL®, Conmed, Inc., Utica, NY, USA).

The Medrobotics Flex® System is an operator-controlled computer-assisted flexible endoscope with remote user manipulation. It utilizes a multi-linked articulating scope with a high-definition display, allowing for navigation through nonlinear anatomy (with near 180-degree mobility) that would otherwise impose significant challenges for traditional laparoscopic and robotic linear cameras and instruments (Fig. 45.3). Through the use of insufflation, the surgeon is able to advance and navigate the endoscope toward anatomic targets from the anus to distal sigmoid colon with ease and clear visualization.

Flexible instruments that accommodate 85-degree articulation are passed through two 3 mm operating ports facilitating dissection and suturing (Fig. 45.4). Currently seven instruments are available for use with the Flex® Robotic System, with optional bipolar and monopolar electro-surgery capabilities. The system accommodates both proprietary and third party instruments.

The Flex® CR Drive has been shown in both cadaveric models and case series to be quite effective given its ease of anatomic access, visualization, and decreased operating room footprint



**Fig. 45.3** The Flex Robotic Platform is utilized to remove a pT1 adenocarcinoma 4 cm from the anal verge anteriorly in a female. (Photo courtesy of Sam Atallah, MD)

when compared to the da Vinci® Si and Xi Surgical System [27–29]. Given the novelty of this technology, large-scale studies have yet to be undertaken; however retrospective reviews are underway and continue to demonstrate the benefits of visualization and nonlinear access to lesions from the anus to distal sigmoid colon with therapeutic intervention potential through the use of articulating surgical instrumentation with tactile feedback [30]. Preclinical cadaveric models have also been used to demonstrate the

**Fig. 45.4** Flex® CR Drive 3-dimensional, high-definition scope and instruments. (Photo courtesy of Sam Atallah, MD)



feasibility of the platform in performance of transanal procedures and have documented a reach of 17 cm along a nonlinear path from the anal verge [31].

platform continues to undergo preclinical studies with FDA approval for clinical use currently pending.

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### SPORT™ Surgical System

Surgical robotic innovation has continued to evolve with a natural combination of articulating instrumentation and single-port surgery. This has recently been demonstrated through the development of the SPORT™ Surgical System (Titan Medical). The robotic system utilizes a single-port site through which multi-articulating instruments with single-use tips are used to address intra-abdominal pathology (Fig. 45.5) [32]. The remote user console includes a work station, equipped with a hand-controlled surgeon interface, operational foot pedals, and a 3-dimensional high-definition screen for improved visualization and ergonomics; a mobile single-arm patient cart is applied at the bedside for a decreased operating room footprint (Fig. 45.6). Currently six instruments with cautery capability are compatible with the platform. Since its initial preclinical trial in September 2017, the SPORT™ Surgical System has demonstrated safe and feasible applications in multiple surgical fields, including general, colorectal, urologic, and gynecologic surgery. The robotic

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### Da Vinci SP® Surgical System

An alternative robotic platform to the SPORT™ Surgical System is the da Vinci SP® Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA, USA). This fourth-generation da Vinci robotic platform utilizes three multi-jointed wristed instruments and a 3-dimensional high-definition endoscope through a single 2.5 cm cannula that can reach 24 cm [33]. The articulation of the instruments allows for 360-degree rotation from a single cannula, and the instruments are triangulated as to avoid operative collision, which has been an obstacle reported in several of the robotic transanal case series mentioned previously. As with all other da Vinci robotic platforms, the surgical console remains the same, allowing for continuity of skills for those surgeons already familiar with the da Vinci platform. However, the da Vinci SP was designed with a navigational aid that displays each of the working arm's positions. This allows the operator to have constant awareness of the orientation of the instrument, especially the portion that is not within direct view of the camera's lens.

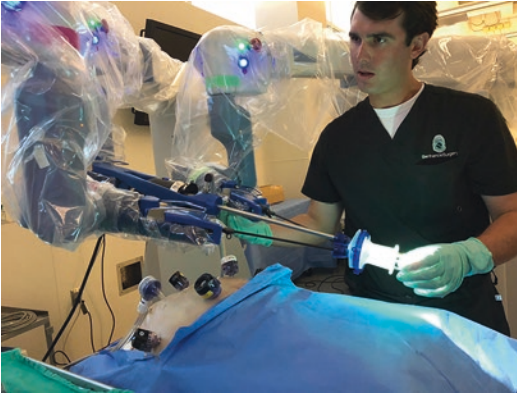
**Fig. 45.5** The CMR modular versus platform allows surgeons to operate in two fields simultaneously to perform two-team taTME. (Photo courtesy of Sam Atallah, MD)



The da Vinci *SP*® has been approved for urologic single-port site procedures since 2014 in Europe, demonstrating both technical feasibility and safety in preclinical cadaveric applications as well as subsequent phase I human trials [34, 35]. Additionally, the platform's ability to access and visualize the oropharynx has been exhibited in cadaveric models [36], and phase I studies performed overseas have demonstrated the

safety and efficacy of the transoral approach to the nasopharynx, oropharynx, larynx, and hypopharynx for benign and malignant lesions [37]. In performance comparisons in cadaveric models to the da Vinci's *Si*® robotic platform, the *SP*® has proven superior in visualization of, access to, and ease of dissection and vessel control of the hypo- and oropharynx [38, 39]. While previously not utilized in the United States, in





**Fig. 45.6** The Senhance modular operation platform is a blend of robotics and laparoscopy which could be utilized for robotic taTME, although this remains experimental. (Photo courtesy of Sam Atallah, MD)

May 2018, the da Vinci *SP*® Surgical System gained FDA approval for single-site port access in urological procedures.

While FDA approval for transanal applications remains pending, the advantages of the new robotic platform designed to reach narrow and deep spaces are clear. Single-port (transanal) access with EndoWrist® three-arm instrumentation, distal triangulation, and 360° articulation extending up to 24 cm, paired with an articulating 3D high-definition endoscope (a new advancement in the da Vinci robotic repertoire) suggests that this version of the da Vinci Surgical System will be able to provide access to lesions well into the proximal rectum and distal sigmoid. An additional advancement in this platform is an extra two degrees of freedom in the EndoWrist® instruments, which provides the surgeon with significantly increased control of the surgical field. Furthermore, the operating boom allows for 360° rotational freedom, which gives the surgeon flexibility when deciding on patient positioning. This level of ergonomic freedom and superior visualization is unprecedented in the da Vinci robotic family, and its clinical transanal application eagerly remains to be awaited in the United States. Already, cadaveric studies have been conducted, demonstrating the utility of the *SP* platform for TAMIS [40], while in 2017, Simon Ng, MD (Hong Kong), has begun live human trials

with the da Vinci *SP* for taTME, as well as other colorectal applications.

Technological advancements in the robotic approach to taTME continue to emerge at an increasingly rapid pace. The ergonomic advantage of articulating instruments through nonlinear anatomy gives a clear advantage over previous approaches, such as seen with TEM and TAMIS, which utilize rigid, linear tools. Given the prevalence of colorectal cancer, and the increasing burden on those of younger age, developing safe and effective approaches to manage this disease process remains an important challenge in colorectal surgery.

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# Video-Based Training Apps and Deferred Live Surgery

# 46

Joep Knol

## Introduction

In the progression of surgical training, whether for a novice surgeon learning a new procedure, or an established surgeon in practice advancing their technical skills with new techniques, many factors are critical to the process of becoming proficient and technically skilled and to be able to perform a safe and effective surgical procedure. The most essential factors are procedural knowledge, cognitive and psychomotor skills training, and direct guidance from a mentor during all steps of the procedure-specific training pathway (Fig. 46.1) [1].

The procedure-specific knowledge acquisition phase should ideally be completed and tested to validate proficiency before advancing along the training pathway. Next, basic technical skills should be practiced in the dry and wet lab setting, before attempting a procedure on live patients and ascending the procedure-specific learning curve [2]. The introduction of minimal invasive surgery (MIS) made this training model more achievable, for both cognitive skills training and mentorship by an experienced surgeon. In MIS, the conduct of the operation is displayed on a screen in real time, the trainer and trainee have the same view to

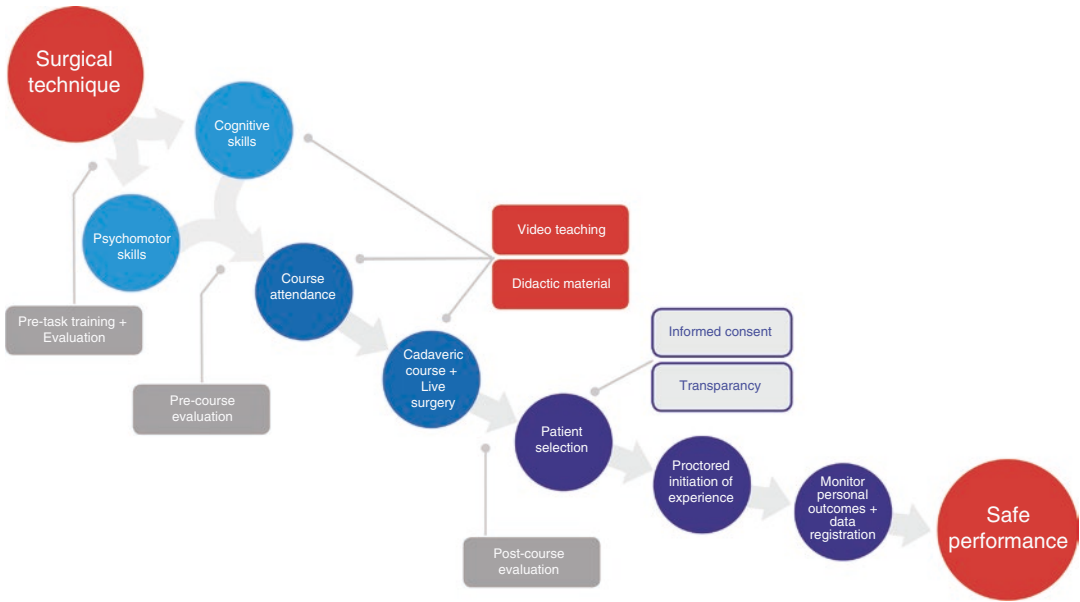
help guide safe dissection and appropriate progression through the case, and procedures can be recorded to audit the case-specific anatomy, to critique the chosen surgical planes, and to assess progression of technical skills for focused learning and improvement. As a result, the MIS revolution forced the surgical community to rethink the ideal surgical training pathway and how to adapt to and incorporate new technologies safely into practice. During the same time, cultural shifts in surgical education emerged, where international duty-hour restrictions limited the time trainees have in the hospital setting to perform live procedures and receive mentorship, and economic realities limited the ability for surgeons in practice to travel and learn new techniques to incorporate more difficult procedures into their practice armamentarium [3–5].

This paradigm shift has driven the search for innovative training solutions, with a greater emphasis on the role of cognitive skills training to accelerate the trainee's understanding of a procedure, formalize the steps being practiced, and reduce the overall training time required to become technically competent [6].

Much focus in cognitive skills training is placed on deliberate practice and simulation. Deliberate practice assumes that improvement and expertise depend on deliberate efforts to change particular aspects of performance [7]. In many domains of professional life, expertise in complex tasks has been described as only

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**Fig. 46.1** The new pathway for surgical skills training

achievable after 10,000 hours of practice – “the 10,000 hour rule” [8]. Surgery fits this rule. In surgery, it seems reasonable that increase in hours of deliberate practice improves performance. Since MIS is performed while watching a video display, optimization of video teaching can contribute to improved surgeon performance. The need to acquire and master the unique skills required for laparoscopic surgery drove the rapid evolution of simulated-based training and assessment of technical skills. As part of the surgical training pathway, dry and wet lab models are most frequently used. Dry labs are working environments that provide training models, such as box trainers and virtual reality (VR) simulators, while wet labs are an animal-based platform [9]. However, in this digital age, procedural videos will play an increasing role in these simulation-based training sessions [10]. Tools continue to be developed to meet these unique training needs and have great promise to meet the changing environment of surgical training.

In this chapter we will discuss the theory and development of novel tools for current surgical training. We will focus on the introduction of cognitive-task simulation applications (apps) and optimization of use of surgical pattern recogni-

tion and images by multi-camera recording that can be made available in a synchronized fashion, known as Deferred Live surgery (dLive).

## Mobile Apps

Mobile apps are applications developed for handheld devices such as smartphones and tablets. While some mobile apps come preloaded with smartphones, users can download others from the mobile app store. In June 2007, Apple, Inc., released the first iPhone at the Macworld Expo. The iPhone scaled computing from an activity previously limited to desktops to one synced with the modern mobile lifestyle and demand for cognitive capability that enables access to the world’s information via the web. In 2008, Google joined the market with Android (operating system)-based smartphones, initially with the HTC Dream phone. During this time period, apps and their associated capabilities continued to grow and scale to meet consumer demand. Now, more than a decade later, global mobile Internet user penetration has exceeded half of the world’s population, with an average daily time spent accessing online content from a mobile device reaching

185, 110, and 43 minutes, respectively, for Millennials (born 1980–2000), Generation X (born 1960–1980), and Boomers (1940–1960) (source: [Statista.com](http://Statista.com), accessed 2018).

Also, among medical trainees and healthcare professionals, the number of mobile Internet users is very high, with an estimated >90% owning a smartphone and having medical smartphone apps installed on their devices [11, 12]. In fact, practicing physicians and medical students are the highest percentage of smartphone users among any single community [13, 14]. An important benefit of mobile resources over traditional methods of accessing relevant medical information lies within their easy, immediate access and ability to update information; reportedly, online resources are more up-to-date than medical textbooks [15, 16].

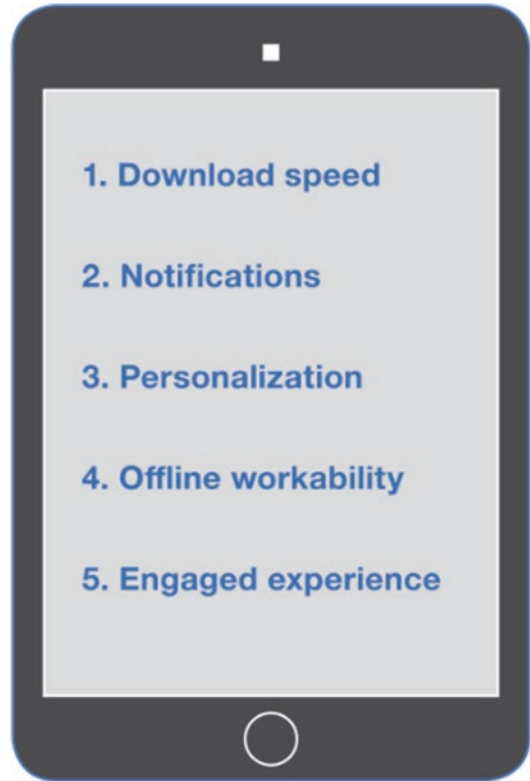
Because of the global accessibility of smart devices and increased availability of apps, there has been a shift in the retrieval method for the online content from use of mobile websites to mobile apps.

Prior surveys have reported that mobile users spend 86% of their online time on mobile apps, with the rest on mobile websites (Flurry Analytics 2014). As they put it: “It’s an App world. The Web Just Lives in it.” The reason for this clear preference is multifaceted, but for users there are several obvious advantages to mobile apps over mobile websites (Fig. 46.2):

1. Download speed
2. Notifications
3. Personalization
4. Offline workability
5. Engaged experience

Mobile apps download content faster than websites and therefore are more convenient to users.

Also, with mobile apps, updates and events can be announced with push notifications, or in-app messages instead of repetitive emails, which often are automatically filtered into “Junk Mail” and are thus never seen or read by the user. As mobile apps can track and observe user engagement, they can provide the user with custom rec-

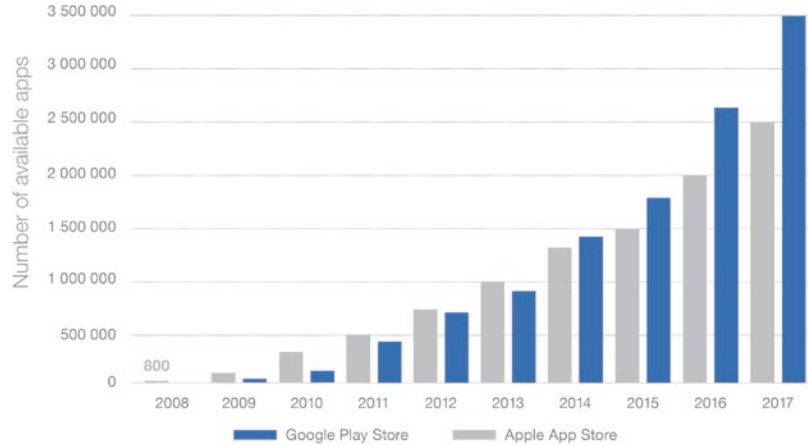


**Fig. 46.2** Benefits of mobile apps over mobile websites

ommendations or meaningful geographically personalized information. In addition, websites can’t be accessed when offline; however, most mobile apps offer a basic functionality to operate with cellular data even if the Internet is not connected.

Currently, the two largest global platforms for app distribution are Apple’s “App Store,” which caters to iOS users, and Google Play, belonging to the eponymous company, which caters to Android OS users. The Apple App Store launched in July 2008, at which time it contained 800 apps. Google originally launched the “Android market” in October 2008; in December 2009 this was rebranded as the “Google Play Store,” containing 6000 apps at that time (source: [Statista.com](http://Statista.com)). Currently (2018), it’s estimated that there are 3.6 million apps in Google Play and 2.2 million apps in Apple’s App Store, but the exact number continues to grow daily with new offerings (Fig. 46.3). Apple’s App Store offers a variety of

**Fig. 46.3** Cumulative number of apps downloadable from Apple and Google store



categories to its users. The most popular apps, as defined by downloads, are games (25.04%), business (9.88%), educational (8.47%), and music (2.49%). Medical apps comprise 1.84% of the total market share for all app users. In a recent study by the Accreditation Council of Graduate Medical Education (ACGME), the most frequently requested medical app types were textbook/reference materials, classification/treatment algorithms, and guides for focused general medical knowledge [17].

While the popularity of medically related apps continues to grow, there is still a lack of high-quality apps available. Payne et al. performed a search on the Apple App Store in 2012, reporting relatively few physician-orientated apps at that time, which did not address or meet the needs of the [British] junior doctors [18]. The authors were convinced that currently high-quality medically orientated apps are scarce both in Apple and Google store.

In a recent survey of medical students, findings were that, after having tried a prototype of an educational app on general practice, students signaled their interest in further development and they highlighted the potential of the app prototype over medical textbooks for both education and medical practice [19]. Advantages associated with the use of smartphones, as listed by medical students and residents, were portability, efficient use of time, flexible communications, powerful applications, access to multimedia resources, and fast access to reliable medical information. In addition, apps

can provide content to allow for a rapid review of critical steps and pearls for surgical procedures shortly before a planned operation [20].

The introduction of minimal invasive surgery (MIS) has furthered the progress of apps for surgical teaching. As MIS is performed utilizing a liquid crystal display, with the increasing ability for video teaching, and increased focus on teaching pathways for more advanced surgical techniques, the time has come to implement video textbooks in a dynamic format. Therefore, the development of apps with an adaptive content, consisting of expert opinions, surgical videos, medical illustrations, 3D animations, and an up-to-date library-like resource, is a logical next step.

## Mobile App Development in Surgery

The use of apps in surgical education and specifically to teach complex surgical procedures is a recent development that is rapidly evolving. Cognitive-task simulation apps currently available include iLappSurgery™ and dLive™ in addition to Touch Surgery™ (Digital Surgery, London, UK), which offer real-time, easy access to facilitate effective learning without traditional bounds.

The health technology app Touch Surgery was the trailblazer. In 2013, the Touch Surgery app was introduced and represented the first high-quality teaching app made globally available to



surgeons, healthcare practitioners, and patients through their smartphones. The Touch Surgery app digitized procedure-specific surgical routes – 3D CGI renderings of patient anatomy and surgical workflows – as a cognitive training tool (further information available at [www.touchsurgery.com](http://www.touchsurgery.com)). This company has recently released their newest product, GoSurgery, a cognitive tool that supports surgical teams in the delivery of coordinated workflows that can help disseminate the right procedural and instrumentation information to the right team member, at the right time – so as to work in a coordinated manner, aiming to produce the most beneficial patient outcomes.

### iLappSurgery and The taTME App

The iLappSurgery Foundation ([www.ilappsurgery.com](http://www.ilappsurgery.com)) was founded in 2015 as a not-for-profit organization with the goal to develop educational material concerning advanced techniques in laparoscopic surgery (Fig. 46.4). In June 2016, iLappSurgery launched the taTME App as a pilot project to explore the need for teaching of a more advanced technique (Fig. 46.5). The iLappSurgery™ Foundation’s freely available downloadable app “taTME” details the history of TME and

all of the technical steps related to this procedure and recognizes its pitfalls and troubleshooting to successfully overcome obstacles.

For a nominal fee, additional content is available to users for further focused learning. Since the inception of the app, Professor RJ “Bill” Heald was one of the mentors of this project and kindly shared his experience on TME, history of rectal cancer surgery, and importance of embryology. His presentations were recorded with a green screen background, and, after keying, his slides were projected in the background to achieve a more dynamic effect. The same kind of recording and keying was done for many other world-known experts who lent their time and expertise for the iLapp initiative. In addition, unique illustrations concerning all the steps and pitfalls of taTME were drawn by a medical illustrator, and 3D animations were developed on patient installation and OR setup. Color grading effects, as first described by our group in a video manuscript on splenic flexure mobilization, were also used in procedural videos of the taTME procedure and included in the app [21].

After launching the iLapp taTME app, there was a steep increase in the number of subscribers, with metrics showing 100, 500, 1500, and 2500 subscribers after 2 weeks, 6 weeks, 6 months, and 24 months after launch, respectively

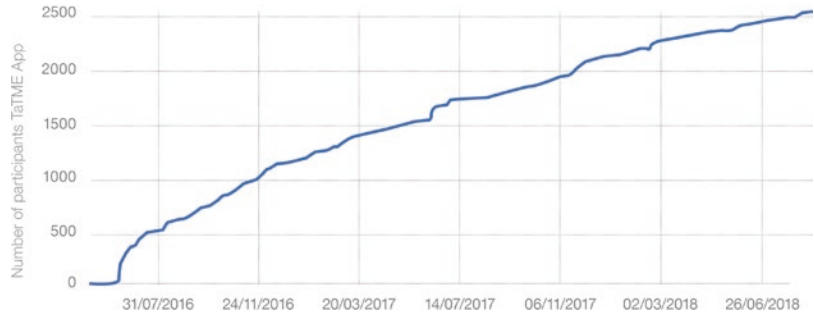


**Fig. 46.4** iLappSurgery logo



**Fig. 46.5** iLapp taTME logo

**Fig. 46.6** Growth of iLappSurgery taTME App after launch



(Fig. 46.6). In many courses the app has become part of the taTME training pathway and didactic curriculum, as it provides a functional pre- and per-course cognitive skills tool for surgeon delegates (UK and Dutch training model as submitted for publication). The library and chapter content is updated on a regular base, and validation as a training tool is pursued.

From the beginning the taTME App was setup as a dynamic text and video book in which some features were crucial:

- *Administration interface*: Easily add content, news, and events and activate directly online
- *Secured and compliant*: General Data Protection Regulation (GDPR) and Health Insurance Portability and Accountability Act (HIPAA) compliant
- *Adaptive learning*: Possibility to apply rules in practical exercises and examinations to allow the content delivery to be adapted to the knowledge level of the user
- *Personalized*: Possibility to personalize content for particular users
- *Evaluations*: Exercises, automated exams, and supervised exams
- *Configurable push notifications*: Notifications to inform the users about new content, events, and news
- *Analytics and reports*: Insights in registration, engagement, and completion rates
- *Copy-Paste structure and concept*: Same format for any future app

As a next project, the iLapp Foundation developed an app for laparoscopic liver surgery. Due to the



**Fig. 46.7** iLappLiver logo

technical complexity of these procedures, fear of compromising the oncological results, and the lack of training opportunities, uptake of laparoscopic liver surgery was initially slow [22]. With the help of experts in the field, a training pathway is presented with focus on cognitive skills training. iLappLiver has the same format as the taTME App and was launched in September 2018 (Fig. 46.7).

As video teaching plays an important role, both in cognitive skills training in general and in the healthcare-related teaching apps, much focus is on improving the images and creating a situation like being in the OR, either by using a multi-camera recording that can be made available in a synchronized fashion (dLive) or by using virtual reality (VR). These images will be added to the available apps in future updates.

## Video-in-Picture

For the iLappSurgery Foundation, there is a specific program developed that can serve as an extension in video teaching and further the interactive learning experience of apps. It is called Video-in-Picture (VIP). The VIP app (VIPicture) has recently been described in a manuscript on Deferred Live surgery and is freely available in Apple and Google store [23].

One can download the app by searching the App Store for VIPicture or by using a QR code (Fig. 46.8). Images that are qualified for use with the application are identified by the presence of the “VIP” logo. After opening the VIPicture application on your smart device, allow your phone to access your camera. This will activate the camera within the application so as to recognize the image within the manuscript, thereby linking you to the appropriate video demonstration.

In the Deferred Live Surgery section below, the VIPicture App can also be used for this purpose.

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## Deferred Live Surgery

The technical nature of surgery necessitates an education for trainees that are based on careful observation of procedures, often in a repetitive



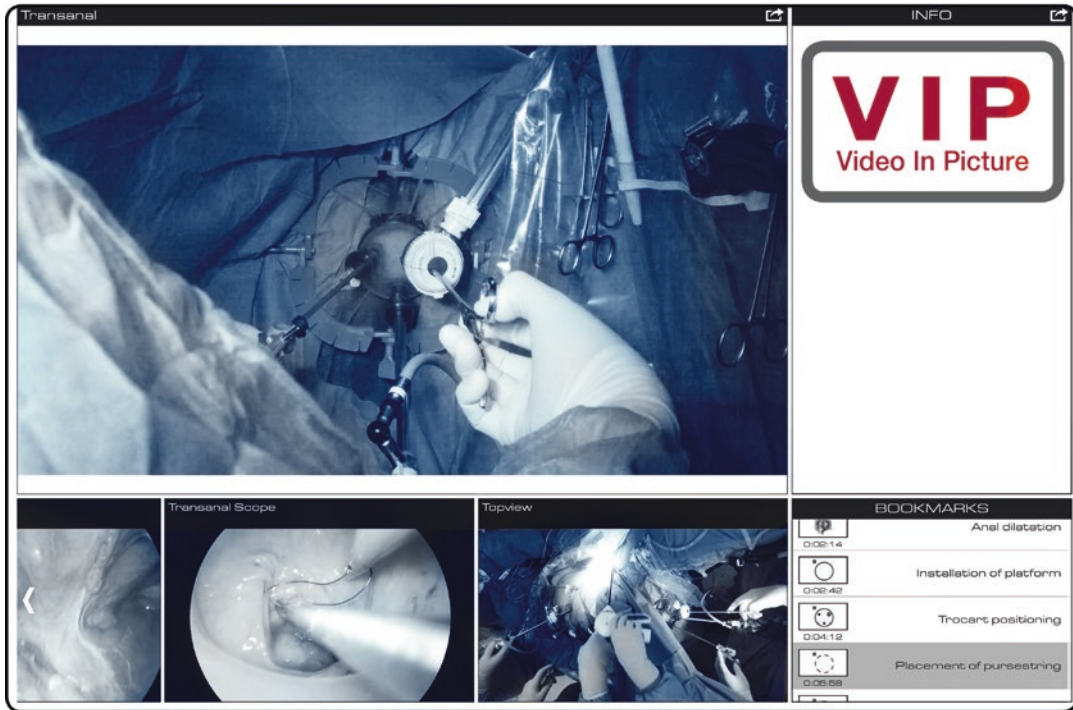
**Fig. 46.8** iLapp VIPicture QR code

fashion. The traditional teaching of new techniques has involved observation of live surgical procedures conducted by experts in the field with specific transferable skillsets.

Unfortunately, live surgery has inherent limitations – primarily centered around the idea that there is significant variability that cannot be predicted, including preoperative indications, physician fitness, intraoperative complexity, and the patient’s overall physiologic fitness. Indications for surgery can often be “loosened” by Live Surgery Course organizers for the purpose of recruitment or may vary between the host institution and that of the surgeon’s home practice environment [24]. Furthermore, patients may be required to wait longer than usual so as to accommodate the conference’s preset timetable [25]; this can be of significant concern in oncologic cases.

In addition, language barriers can affect discussions of informed consent between the treating and hosting surgical teams. A number of factors can also affect the intraoperative performance of surgeons, including operating in an unfamiliar environment with an often unfamiliar team, jetlag (in many cases), operating room traffic, potentially distractive intraoperative questioning from the audience, and the availability of familiar instrumentation and resources, among others. Many reviews on the subject of live surgery have concluded that it is often a number of additive factors, and not one single factor, that result in the potential for adverse events [26, 27].

The presence of these concerns and others led to the development of an alternative method of surgical presentation known as Deferred Live surgery (dLive). In a review of the procedure, our group and colleagues discussed the nature of this technique for surgical education wherein multiple 4K synchronized cameras are used to record the multifaceted aspect of surgical procedures [23]. The synchronized nature of the recording and the dLive mainframe allows the presenter to go through an otherwise unedited full-length surgical procedure, with the ability to toggle between various intraoperative camera views (Fig. 46.9). This provides the audience with the experience of being exposed to all the advantages of the live



**Fig. 46.9** Video-in-Picture (VIP) image of dLive mainframe and aspects of the program

procedure, while mitigating most of the ethical and moral challenges of conventional live presentation techniques. The original procedure can be performed with all the aforementioned recording equipment, without concerns of affecting patient-centered outcomes of surgery. Furthermore, the procedure can be performed at the usual pace of the surgeon without any need for time constraints. Intraoperative adverse events can also be managed, recorded, and subsequently used as an educational tool for members of the audience. Additionally, the high-quality recording and the multiple intraoperative vantage points allow the surgeon to pause, zoom in, and focus on specific parts of the procedure of particular interest to the audience, while being able to switch between the various views in the operating room (Fig. 46.10). This technique also allows the surgeon to narrate various specifics to the audience, without the concern of loss of intraoperative focus or attention during otherwise critical steps of the procedure (the time when questions tend to most commonly be asked during non-deferred live sur-

gical demonstrations). Additionally, users from virtually any point on Earth can have access, with the unique ability to switch between various case presentations to demonstrate specific points in different cases.

The use of dLive technology has been and will continue to be even more advantageous in increasingly complex, multi-team procedures, such as taTME. In such procedures, the entire operating room is of critical importance to demonstrate to the audience. Currently, taTME procedures are recorded with seven synchronized cameras, all in 4K quality, including a 360° camera that provides an overview of the entire operating room. The positions of the various nursing and surgeon teams, the anesthesiologist vantage point, and location of the different intraoperative towers and equipment all contribute to the safe execution of these complex procedures. Furthermore, the coordination between the perineal and transabdominal teams can be presented, providing views of their individual hand motions used to achieve specific intraoperative maneu-





**Fig. 46.10** Video-in-Picture (VIP) image of capabilities of the dLive platform

vers, in addition to the method of communicating the planes of dissection and aiding each other in completing the excision and gastrointestinal reconstruction. The dLiveMed group has been able to also bookmark various procedural landmarks, allowing the presenter to focus on these aspects, if asked by the audience, or to toggle between different cases to demonstrate differences in, for example, lateral or anterior perineal dissection planes in thin and obese patients.

Although there may be a persistent and important role for live surgery sessions, we propose that the dLive concept is an additional tool to demonstrate all aspects of a surgical procedure or intervention in optimal quality, with the maintained advantages of live surgical broadcasts — but also avoiding some of the discussed ethical concerns that are being brought forth. It will form a critical component of the cognitive training pathway for trainees and practicing surgeons alike, further improving the safety of introduction of new techniques such as taTME into practice.

## Conclusion

As novel tools for surgical training are developing quickly, they will allow us to increase the quality and accessibility of cognitive skills training. Video teaching will play an important role in advancing the teaching of MIS techniques. Furthermore, ease of access on mobile devices will further increase the availability to learners. Additionally, using multi-camera synchronized deferred recording, educating large audiences about these surgical skills can be made more easily available in a less controversial fashion, known as Deferred Live surgery (dLive). These new training pathways hold significant value and serve as important adjuncts for the education of complex procedures such as taTME.

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Twitter: @iLappSurgery. Website: [www.ilappsurgery.com](http://www.ilappsurgery.com)



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# Navigation for Transanal Total Mesorectal Excision

# 47

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## Introduction

Functional and oncological outcome after multimodal treatment for rectal cancer could be improved. This can be achieved with a better recognition of anatomical dissection planes, of anatomical landmarks, and of the dissection margin to the tumor to optimize resection margins and to minimize iatrogenic nerve damage. Recently, the performance of stereotactic navigation for minimally invasive transanal rectal surgery has been reported [1, 2]. Additionally, critical challenges related to soft-tissue stereotactic pelvic navigation were assessed [3]. Surgical navigation systems could improve the quality of surgery for rectal cancer as shown when used in other contexts. It is likely to improve the accuracy and efficiency of pelvic surgical procedures in which it is difficult or impossible to identify and dissect along anatomical planes.

Functional and oncological outcome after multimodal treatment for rectal cancer could be improved. Long-term morbidity after multimodal treatment for rectal cancer is reported in up to one third of patients, and it is suggested to mainly originate from nerve injury-related disorders such as urogenital and bowel dysfunctions [4–6]. Additionally, a positive circumferential resection margin (CRM) rate has been reported in a significant number of laparoscopic rectal resections – up to 12% (range 3–12) – being even higher in case of low rectal cancers [7–11]. For this reason, the transanal approach was developed for TME (taTME) [12]. Potential benefits of this approach include a better oncological outcome via a decrease in the positive CRM rate with a better specimen quality and better quality of life through increased sphincter and nerve preservation. On the other hand, taTME is associated with new challenges related to this bottom-up approach to the pelvic anatomy, especially when performing dissection anteriorly. Urethral injuries have been described since the inception of taTME [13, 14]. Additionally, air embolisms were described, probably resulting from venous lesions anterolaterally at the level of the neurovascular bundle of Walsh [13].

The challenges associated with improved oncological and functional outcomes have one thing in common; namely, the importance of the recognition of anatomical dissection planes, of anatomical landmarks, and of the dissection

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**Fig. 47.1** A stereoscopic infrared emitting optical system continuously tracks the patient and instrument by detecting infrared light which is reflected by marker spheres affixed to a patient tracker and an instrument tracker. On

an additional screen which is connected to the navigation platform, the location of the tip of the instrument is displayed in the image data set

margin to the tumor to optimize resection margins and to minimize iatrogenic damage. Consequently, surgical navigation could improve the quality of surgery for rectal cancer as shown for stereotactic navigation, a type of surgical navigation, when used in other contexts.

Stereotactic navigation was developed by neurosurgeons who integrated medical imaging and intraoperative stereotaxy [15]. Stereotactic navigation functions quite similarly to a navigation system in a car. Both systems determine and track the position of an instrument or a car in relation to a patient or the earth, respectively. However, the type of localization technology differs. A stereotactic navigation system does not localize via triangulation similarly to a global positioning system with the help of several satellites. It localizes and tracks reflective marker spheres by means of a stereoscopic infrared emitting camera. Subsequently, by means of a process that is called registration, a point in patient space is assigned to the corresponding anatomical point in image space.

It is reported to increase safety and to minimize the invasiveness of surgical procedures by acting as a real-time guidance tool during the operation using tracked surgical instruments in conjunction with preoperative images. It helps the surgeon to identify anatomical structures, which should be targeted or avoided. These systems are currently mainly used in the brain, skull base, and vertebral surgery, and they have proven to be an essential adjunct to surgical procedures

where anatomical landmarks are obscured and cannot be used for topographic orientation [16].

The first reports of the performance of stereotactic navigation for minimally invasive transanal rectal surgery were published by Atallah et al. in 2015 [1, 2]. The challenges associated with stereotactic pelvic navigation were recently assessed by a study investigating the potential differences in patient anatomy between intraoperative lithotomy and preoperative supine position for imaging [3]. It seems that when several aspects related to patient setup are taken into account, pelvic stereotactic navigation can be performed with accuracy.

## Equipment and Operative Setup

The navigation systems which have been used for stereotactic soft-tissue navigation during transanal rectal surgery rely on several major components (Fig. 47.1):

- A stereoscopic infrared emitting optical system – determines the position of an instrument and the pelvis of the patient in the operation room (OR) by detecting infrared light which is reflected by marker spheres affixed to a patient tracker and an instrument tracker (Fig. 47.1).

- *A patient tracker* – is fixed to the patient or operating table and has marker spheres fixed to it for continuous tracing of the patient by means of the optical system (Fig. 47.2).
- *An instrument tracker* – is fixed to an instrument and has marker spheres fixed to it for continuous tracing by means of the optical system (Fig. 47.3).
- *Skin fiducials* – at least four fiducials are fixed to the skin of the patient during CT scan just before the operation. Initially in the OR, the position of the pelvis is determined by touching the center of these fiducials via a calibrated instrument with marker spheres attached to it (Fig. 47.2).
- *A computer platform* – matches the three-dimensional position of the patient to the CT scan by recognition of the fiducials. The position of the tip of the instrument in the 3D image data set is depicted on a separate screen.
- *Merging software* – merges an MRI or CT scan which was performed well in advance and which relevant anatomical structures and tumor were segmented to the most recent CT scan with fiducials which was used to determine the position of the patient.

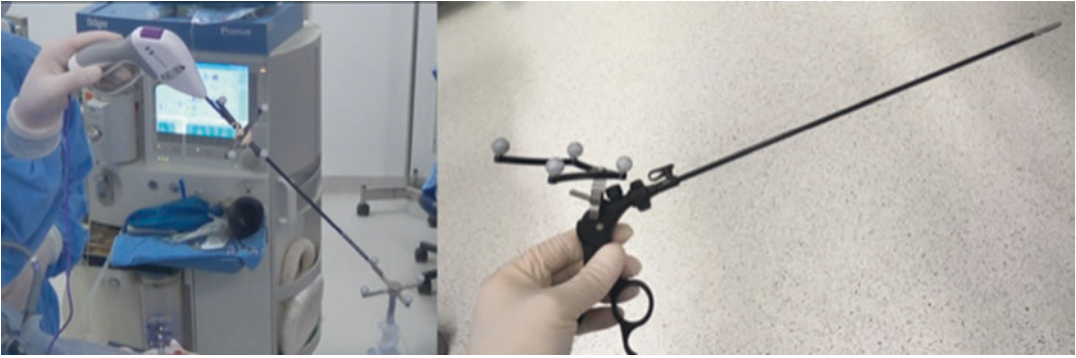
In stereotactic navigation, it is essential to obtain a perfect patient position registration in the OR by means of the infrared optical system. To do so, several skin reference points overlying the area of anatomical interest are marked by means of at least four radiopaque fiducials during preoperative CT scanning, and these fiducials are left in place or changed for sterile fiducials intraoperatively. In the studies, published 12 to 18 fiducials were placed on the skin anteriorly to the pelvic area to optimize the registration process [1–3]. Subsequently, after uploading these preoperative CT scan images to the navigation system, the position of the patient in the operation room (OR) can be determined via recognition and registration of the position of the fiducials by using a calibrated instrument of which the position of the tip is recognized by the infrared optical system (Fig. 47.2). This is the only registration option, which has been described in the literature for stereotactic soft-tissue pelvic navigation [1–3]. After this registration, the patient is tracked by means of optical markers on a patient tracker, which is fixed to the operating table or the patient’s anterior superior iliac spine by Kirschner wires or a screw (Fig. 47.2). Surgical instruments are tracked by means of an instrument tracker, which is fixed to the instrument allowing the position of the tip of the instrument to be determined and visualized in the navigation scans (Figs. 47.3 and 47.4). A computerized process is used to match the



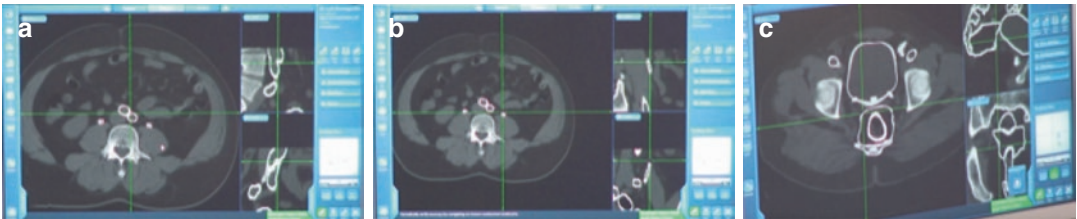
**Fig. 47.2** Several fiducials are placed on the skin anteriorly to the pelvic area. After a CT scan has been made just preoperatively with these fiducials in situ, this image data set is uploaded to the navigation system. These sterile fiducials can then be changed for sterile skin markers after marking. Subsequently, the position of the patient in the OR can be determined via recognition and registration of

the position of the fiducials/markers by using a calibrated instrument (with marker spheres fixed to it) of which the position of the tip is recognized by the infrared optical system. Additionally, the patient tracker (with marker spheres fixed to it) can be recognized which is fixed to the patient or OR table





**Fig. 47.3** The tip of a surgical instrument can be tracked by means of an instrument tracker which is fixed to the instrument. It can be attached to an energy device or a regular surgical instrument



**Fig. 47.4** The position of the tip of the surgical instrument is displayed in the image data set. Using an abdominal approach, the aortic bifurcation (a) and the left ureter

are located (b). During a transanal endoscopic approach, the border of the mesorectum is located (c)

three-dimensional position of the patient in the OR to the preoperative images which will be used for navigation.

Three surgical infrared optical navigation platforms were reported to have been used for stereotactic soft-tissue pelvic navigation (StealthStation®S7 Surgical Navigation System, Medtronic Inc., Louisville, USA; Stryker Navigation, Kalamazoo, MI, USA; CURVE Navigation System, Brainlab, Feldkirchen, Germany) [1, 3, 17]. All systems rely on a stereoscopic camera emitting infrared light, a computer platform, a patient tracker, and an instrument tracker.

### Specific Pelvic Surgery-Related Challenges

Since anatomical structures at risk during rectal surgery are fixed retroperitoneally, they seem to be less affected by pneumoperitoneum and respiratory movements as compared to upper abdomi-

nal organs. However, pelvic surgery is associated with additional challenges as compared to surgical navigation in other contexts such as neurosurgery and orthopedic surgery. Rectal surgery is performed in patients with variable degrees of lithotomy, a position which is different from the supine position used for acquisition of preoperative imaging. This positional change could alter the patient anatomy and subsequently render stereotactic pelvic navigation using preoperative imaging inaccurate. Additionally, the motion of the skin reference points with their fiducial markers by means of positional change may hamper patient position registration in the operating room (OR) to begin with. To assess these challenges, a study was undertaken to determine the difference in patient anatomy, sacral tilt, and fiducial marker position between these different patient positions and to investigate the feasibility and optimal setup for stereotactic pelvic navigation [3]. Four consecutive human anatomical specimens were submitted to repeated CT scans in a supine and



several degrees of lithotomy position. Patient anatomy, sacral tilt, and skin fiducial position were compared by means of an image computing platform. In two specimens, a 10-degree wedge was introduced to reduce the natural tilt of the sacrum during the shift from a supine to a lithotomy position. A simulation of laparoscopic and transanal surgical procedures was performed to assess the accuracy of stereotactic navigation.

An up-to-supracentimetric change in patient anatomy was noted between different patient positions. This observation was minimized through the application of a wedge. When switching from a supine to another position, sacral retroversion occurred irrespective of the use of a wedge. There was considerable skin fiducial motion between different positions. Accurate stereotactic navigation was obtained with the least registration error (1.9 mm) when the position of the anatomical specimen was registered in a supine position with straight legs, without pneumoperitoneum, using a conventional CT scan with an identical specimen positioning.

The authors concluded that the change in patient anatomy is small during the sacral tilt induced by positional changes when using a 10-degree wedge, allowing for an accurate stereotactic surgical navigation when certain prerequisites are taken into account. The following aspects should be considered and included in the protocol for an optimal setup of point-merge stereotactic navigation in pelvic surgery. Patient position registration should be performed without pneumoperitoneum in a patient position which is similar to the position during preoperative CT scanning with fiducials. This is because a changing patient position results in skin fiducial motion, which hampers accurate patient position registration. A supine position with straight legs is the preferred position. The patient tracker should be fixed into the anterior superior iliac spine to integrate the change in the sacral tilt angle into the surgical navigation system, since a change is expected to occur when switching positions. Finally, a forced sacral tilt seems to minimize the change in patient anatomy.

Limitations related to stereotactic navigation include the need for maintaining a direct line of

sight between the infrared camera of the navigation system and the patient and instrument tracker. This line of sight can be hampered by the patient's legs which are placed in lithotomy and the surgeon who is positioned between the patient's legs. Another limitation is that stereotactic navigation relies on preoperative images for accurate navigation. As a result, real-time geometric changes in pelvic anatomy caused by tissue dissection and traction are known to affect the accuracy of stereotactic navigation.

Other factors which should be considered based on earlier studies on pelvic organ motion are the following: rectal and bladder volume should be equal during the scans which are used for registration/ navigation, as well as intraoperatively. Consequently, the bladder should be emptied before scanning as well as intraoperatively via the placement of a urinary catheter. The rectum should be emptied by means of an enema. In case of transanal TME, the rectum should be emptied just before closing the purse string. The pelvic diaphragmatic muscle tension should be equal during the scans, as well as intraoperatively.

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## Clinical Application

Stereotactic soft-tissue pelvic navigation has reported to have been used *in vivo* for laparoscopic and transanal approaches for locally advanced and recurrent rectal cancer cases [2, 17]. Atallah et al. used image-guided real-time navigation in four patients with anteriorly located locally advanced rectal cancer [1, 2]. They used it during the transanal portion of the operation and reported radical resections for all patients without any intraoperative complications. At a median follow-up of 18 months for three patients, there was no evidence of locoregional recurrence of distant metastatic disease [1]. Atallah et al. also used it during a laparoscopic approach for a mixed cystic and solid neoplasm in the left perirectal space of which they performed a complete excision without any perioperative complications [18]. Kawada et al. reported the performance of stereotactic navigation during a laparoscopic Hartmann's operation with distal sacrectomy for a recurrent rectal cancer

[17]. A radical resection was performed without any perioperative complications.

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## Future Directions in Pelvic Stereotactic Navigation

Stereotactic navigation would be more effective when the tumor, relevant anatomical structures, and resection margins are highlighted. MRI is currently the most accurate tool for the depiction of a tumor, mesorectum, and the relationship of the tumor to the surrounding structures. A recent study in which pelvic nerves were manually delineated in 20 volunteers who were scanned with a 3-Tesla MRI reported that even pelvic nerves are usually visible on high-resolution MRI with dedicated scanning protocols (Fig. 47.2) [19]. The advances in medical software facilitating automatic three-dimensional reconstruction from CT scans when performed at an experienced radiological center open the door to new promising opportunities [20]. This is all the more true because the StealthMerge software allows the surgeon to auto-merge the three-dimensional reconstructions with a preoperative CT scan which is used for the registration of the position of the patient. Additionally, it is expected that the combination of a surgical navigation system with robotic-assisted surgery might further improve the precision and accuracy of the navigation system [21]. In sum, such advancements are an important step forward toward the development of digital surgery [22].

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## Conclusions

The application of stereotactic navigation during rectal surgery opens new promising opportunities to increase the precision and quality of surgery. With improved recognition of anatomical dissection planes, anatomical landmarks, and of the dissection margins to the tumor, these margins can be optimized and iatrogenic injuries can be minimized. In the appropriate context, this may improve functional and oncological outcomes. Additionally, it could shorten the learning curve for a technically demanding surgical technique

such as taTME. The challenges related to optimal patient setup combined with the navigation system need to be assessed in in vivo studies.

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# Current Controversies and Challenges in Transanal Total Mesorectal Excision (taTME)

# 48

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## Introduction

Total mesorectal excision (TME) is the requisite method of surgical extirpation for optimizing outcomes of rectal cancer surgery. Components of TME include a complete or near-complete rather than an incomplete mesorectal specimen, tumor-free circumferential resection margins (CRM), a tumor-free distal resection margin (DRM), and the assessment of  $\geq 12$  lymph nodes. Tumor-related characteristics may decrease the potential of achieving these goals. Some adverse prognostic factors noted on pre-treatment thin slice rectal cancer protocol magnetic resonance imaging (MRI) include a threatened CRM and extramural vascular invasion (EMVI). Following the American College of Surgeons (ACS), Commission on Cancer (CoC), National Accreditation Program for Rectal Cancer (NAPRC) standards, all patients with newly diagnosed rectal cancer presenting to an NAPRC center should be discussed in the multidisciplinary tumor (MDT) conference prior to the commence-

ment of any treatment [1]. The standards require MDT attendance by at least one member of each of the following disciplines: surgery, pathology, radiology, medical oncology, and radiation oncology. This group might arrive at a consensus opinion that preoperative neoadjuvant chemoradiotherapy is recommended to help mitigate some of these adverse prognosticators and help meet the surgical goals. However, there is a second set of less modifiable factors that may challenge the surgeon to produce a complete or near-complete TME specimen with tumor-free CRMs and adequate DRM and lymph node extirpation. Such patient-related variables include gender, body mass index (BMI), and prior radiation. Male gender and high BMI associated with overweight, obese, and morbidly obese patients are risk factors for less optimal surgical results which, in turn, pose compromise to clinical outcomes. While robotic surgery was theorized to improve upon these odds for optimal surgery, unfortunately the recently *published Robotic versus Laparoscopic Resection for Rectal Cancer (ROLLAR trial)* [2] showed that this postulate failed. Thus open, laparoscopic, and robotic TME all seem to offer equivalent results as discussed below.

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## Comparison Between Open and Laparoscopic Approach

In the COLOR 2 randomized controlled trial, Van der Pas et al. [3] randomized 1044 patients to laparoscopic ( $n = 739$ ) or open ( $n = 364$ ) resection of rectal cancer. There were no differences in positive CRM and DRM rates and no significant differences in postoperative morbidity and mortality. At 3 years, the locoregional recurrence rate was 5.0% in both groups. Disease-free survival rates were 74.8% in the laparoscopic-surgery group and 70.8% in the open-surgery group. Overall survival rates were 86.7% in the laparoscopic-surgery group and 83.6% in the open-surgery group.

Bonjer et al. [4] reported on 1044 patients, 699 of whom were in the laparoscopic group and 345 in the open group. At 3 years, the locoregional recurrence rate was 5.0% in the two groups. Disease-free survival rates were 74.8% in the laparoscopic-surgery group and 70.8% in the open-surgery group. Overall survival rates were 86.7% in the laparoscopic-surgery group and 83.6% in the open-surgery group.

Boutros et al. [5] reviewed 234 patients underwent resections for rectal cancer, including 118 laparoscopic and 116 open resections. The laparoscopic group had slightly higher lymph node yield in the TME specimen than the open group (26 vs 21,  $p = 0.02$ ), with no differences in CRMs, DRMs, and completeness of TME specimen.

In a Cochrane review from 2006 and update in 2014, Vennix et al. [6] evaluated the differences in short- and long-term results of laparoscopic versus open TME. There was moderate-quality evidence that laparoscopic and open TME had similar effects on local recurrence, 5-year disease-free survival, and overall 5-year survival. There was moderate- to high-quality evidence that the number of resected lymph nodes and surgical margins were similar between the two groups.

Martinez-Perez et al. [7] published in 2017 systematic review and meta-analysis of the pathologic results of laparoscopic compared to open rectal TME. Of 2989 patients, positive CRM was found in 135 (7.9%) of 1697 patients undergoing laparoscopic TME and 79 (6.1%) of 1292 patients undergoing open TME. A noncom-

plete TME (in this study, “noncomplete” was defined as either nearly complete or incomplete) was reported in 179 (13.2%) of 1354 patients undergoing laparoscopic TME and 104 (10.4%) of 998 patients undergoing open TME. The DRM involvement, the mean number of lymph nodes retrieved, the mean distance to the distal margin, and the mean distance to radial margins were not significantly different. The authors concluded that the risk for achieving a noncomplete TME is significantly higher in patients undergoing laparoscopic compared with open TME and thus questioning the oncologic safety of laparoscopy for the treatment of rectal cancer.

Unfortunately, the Martinez-Perez et al. study [7] is critically and fatally flawed in that they erroneously grouped near-complete with incomplete resections. The appropriate internationally accepted standard would have been to correctly group near-complete with complete TMEs and compared that group of oncologically satisfactory specimens to the oncologically unsound group exclusively comprised of incomplete specimens.

Fleshman et al. [8] conducted the ACOSOG Z6051 randomized clinical trial to assess the pathologic results of laparoscopic versus open rectal resection. The primary outcome was to compare successful resection in laparoscopic versus open rectal resections. Successful resection was defined as a composite of CRM greater than 1 mm, DRM without tumor, and completeness of TME. A 6% non-inferiority margin was chosen according to clinical relevance estimation. Successful resection occurred in 81.7% of laparoscopic resection cases and 86.9% of open resection cases and did not support non-inferiority of laparoscopic rectal resection for stage II and III rectal cancer. Moreover, there were no significant differences in three year local recurrence or survival between the laparoscopic and open groups. Thus the problem with the well-intentioned ACOSOG Z6051 study was not a technical problem with laparoscopic technique, but rather a methodologic and statistical problem of using a never before used and un-validated composite score. Unfortunately this score cannot be recommended for use due to its complete lack of correlation with the actual desired oncologic endpoint of recurrence free survival [9].



The CLASICC trial [10] was conducted to assess the long-term results of laparoscopic versus open surgery for colon and rectal cancer. Both the 5-year and 10-year analyses confirmed oncological safety of laparoscopic surgery for both colonic and rectal cancer [11, 12].

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### Comparison Between Laparoscopic and Robotic Approach

In a meta-analysis from 2017, Li et al. [13] reviewed 17 case-control studies, which included 3601 patient, 1726 patients underwent robotic TME, and 1875 laparoscopic TME for rectal cancer. There were no statistically significant differences in oncologic results including positive circumferential resection margins, local recurrence rate, and overall 3-year survival rate.

In a meta-analysis from 2014, Xiong et al. [14] reviewed eight studies, which included 1229 patients in total, 554 in the robotic TME, and 675 in the laparoscopic TME. There were no significant differences in the oncologic radicality of resection or local recurrence between the two groups. Colombo et al. [15] compared 60 laparoscopic TME with 60 robotic TME. There were no significant differences in conversion rate, lymph nodes yield, positive DRM, or positive CRM.

Recently, the results of the ROLARR randomized clinical trial [2] were published. The authors randomized patients to robotic-assisted TME ( $n = 237$ ) or conventional ( $n = 234$ ) laparoscopic TME. There was no significant difference in positive CRM between laparoscopic TME (14/224, 6.3%) compared to robotic TME (12/235, 5.1%).

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### Comparison Between Laparoscopic and taTME Approach

TaTME evolved from a pure NOTES application, initially described by M. Whitford [16] and subsequently P. Sylla [17] to one seen as a gateway to improved access to the distal rectum, thereby overcoming the technical challenges of pelvic surgery and TME. A. Lacy, P. Sylla, S. Atallah, and others [18–25] subsequently popularized this

technique. The benefits of taTME include direct visualization and transection of the DRM and superb visualization of the dissection undertaken to achieve the CRM and complete TME specimen. Some of the results are reviewed in this section.

In a meta-analysis from 2016, Ma et al. [19] reviewed seven studies including 573 patients (taTME group = 270; lap TME group = 303). No differences were observed regarding oncologic results including harvested lymph nodes and positive distal resection margin between the two groups. However, the taTME group showed a higher rate of achievement of complete mesorectal quality, a longer CRM, and less involvement of positive CRM.

In another meta-analysis from 2016, Xu et al. [20] reviewed seven studies including 209 patients who underwent taTME and 257 patients who underwent laparoscopic TME. There were no significant differences in the outcomes of the harvested lymph nodes and distal resection margin. However, compared with laparoscopic TME, taTME showed a longer CRM, lower rate of positive CRM, and higher rate of complete TME.

M. Fernández-Hevia et al. [21] reviewed 140 patients who underwent taTME for low- and mid-rectal cancers. Macroscopic quality assessment of the resected specimen was complete in 97.1% and nearly complete in 2.1%. At a mean follow-up of 15 months, a 2.3% local recurrence rate and a 7.6% rate of systemic recurrence were reported.

On behalf of the International TaTME Registry Collaborative, Penna et al. [26] reported on 720 consecutive patients from 66 registered units in 23 countries, comprising 634 patients with rectal cancer and 86 with benign pathology. Abdominal or perineal conversion was 6.3% and 2.8%, respectively. Intact (complete) TME specimens were achieved in 85%, with minor defects (near complete) in 11% and major defects (incomplete) in 4%. R1 resection rate was 2.7%. Postoperative mortality and morbidity were 0.5% and 32.6%, respectively.

Collectively, these data suggest that taTME is a promising technique which may indeed improve surgical resection quality when performed by

qualified and appropriately trained surgeons. Long-term data is still being collected, and this will remain crucial to the overall success and adoption of this innovative technique.

## Challenges

It is incumbent upon the surgical team wishing to perform taTME to adhere to appropriate training guidelines including cadaver work, viewing videos, watching live surgery, and being proctored. While each one-team and two-team approaches each have advantages, most surgeons prefer the two-team approach both to facilitate mid-rectal dissection and to expedite the length of the procedure. Like any new technology, the results of taTME will be dependent upon appropriate case selection and the judgment and technical prowess of the surgeons performing the procedure. Fortunately, thus far, the results of taTME appear quite laudable, and we expect that, with time, this technique will continue to show increasingly salutary results with expanded worldwide penetration and utilization. The surgical team planning to embark upon the adoption and subsequent practice of taTME should undergo extensive training, as outlined by McLemore and coworkers [23]. Specifically, a staged training including didactic, cadaver, and proctor levels is advisable. Moreover, all data should be captured in a meaningful ultimately externally peer-reviewed registry. At present, both North American and European taTME registries are available for enrollment.

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# Transanal Total Mesorectal Excision: The Next 10 Years

# 49

Ronan A. Cahill

*In a world of change, the learners shall inherit the earth, while the learned shall find themselves perfectly suited for a world that no longer exists.*  
Eric Hoffer

## Reflections on the Evolution to Date of Transanal Total Mesorectal Excision

This book contains many very focused discourses and much expert technical data on specific areas of real relevance to the operative performance of transanal total mesorectal excision (taTME). However, right now, zoom out and look over the table of contents from a highline perspective. What has been achieved over the past decade is the imagination, description, development and validation of an entirely new surgical approach for a common cancer within an existing specialty that had already a clear oncological framework governing its address. This isn't a new disease variant or one that was being poorly treated or neglected imposing little constraint for surgeons

struggling in a field without a clear gold standard. In fact, surgery for colorectal cancer is one of the most standardized and understood areas in all of the areas related to cancer and surgery.

Just before taTME's emergence, the operative approach to this disease had been scrutinized to a higher degree than any other major malignancy or indeed common operation and its common approaches had been the subject of randomized trials with forensic examination of their methodology and results. Nor is taTME the result of any new, cool, breaking technology looking to be applied or indeed one capable of adding extraordinary new technical capability and in doing so opening up a new frontier for surgical intervention. The instruments used, in fact, are often less sophisticated than those commonly employed in open and laparoscopic surgery comprising at core diathermy hook and graspers and sutures. There was no big med-tech industry looking to exploit and profit from a step-advance in excision quality; and no commercial model realized an un-met need. In point of fact, high-end equipment for transanal access has existed for quite some time as part of the catalogue of two major surgical technology companies with global reach (the TEM and TEO devices of Wolf and Storz, respectively). However, these advancements were siloed away from the greater mainstream of laparoscopic access. Furthermore, a highly resourced new company (Intuitive Surgical, Inc.)

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did emerge in the early 2000s with an incredible piece of electromechanical engineering (the da Vinci Robotic Surgical System), but it concentrated its use just as an exact replicator of existing ways to perform total mesorectal excision and it has, to this day, still really failed to provide much advance in patient outcome. Lastly, while the field was opened up through the emergence of Natural Orifice Transluminal Endoscopic Surgery (NOTES), its concepts progressed into reality against the expectations of many – gastroenterologists backed away from the large intestine as a target and no disruptive technology toolboxes were developed (despite considerable investment by all major medical technology companies including Johnson & Johnson /Ethicon and Medtronic). NOTES though didn't disappear (as many indeed thought happened), but its conceptual foundations were realized and, in fact, are central to the technique of taTME. Neither was there any new genomic insight, biomolecular discovery or biological revelation. Simply (although, of course, nothing truly creative is simple), surgeons iterated their surgery knowing that better is always possible and true advancement relates to expert effort not bright, shiny gadgets. The main driver of taTME so has been the intelligent perception of some exceptional surgeon leaders, many of whom are authors in this book, who understood fully the problems of contemporary approaches and who could see the established oncological framework of rectal cancer as an enabling environment rather than a barrier for innovation and who allowed the operative application of their imagination, courage and expertise. The pioneers of this operation individually and collectively have done an incredible job in the realization of an operation that they invented and which now has been delivered to such a standard and indeed steady state that it can now be described in a dedicated textbook. To get here, much use has been made of communicative technologies including video, apps and social media to allow concerted efforts synergize and diffuse widely and to be communicated effectively promoting education and research regarding taTME. Registries have allowed many groups collaborate and share “ownership” of the

technique including in the broad authorship of reports quite different to previous times when single institutions vied to be the first to claim a new procedure. Industry has supported surgery in this effort and watched – with some amazement – to see how their instruments designed for other purposes were creatively applied to a new area and a brand new kind of surgery. So where next can this evolution go?

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### **What's Best When and by Whom?**

Notwithstanding the realization of taTME as a valid operative access that can be safely learnt and performed, further work needs to be done to verify its place in practice and specifically examine if it can displace any of the current approaches to become the preferred approach for the majority. Multicentred trials (including with randomization) are planned (e.g. COLOR III [1], ETAP-Greccar 11 [2] among others) and need to be advanced to conclusion. The role of randomized trials in surgery has long been discussed and indeed continues to be debated [3, 4]. This is perhaps unsurprising, given that previous studies have often been underwhelming in their conclusions related to new technologies and surgical advances. This statement remains valid whether by reason of non-inferiority design or by their performance being undermined by long study times. The latter is an important consideration because surgical procedures are constantly evolving both technically and technologically and so an evolved landscape and practice standard has developed within the time between study design and commencement and publication most especially when oncological follow-up is included making the proposed evaluation somewhat redundant.

More recently some have questioned not the general academic dearth (because this has much improved in terms of quantity and quality) and known pitfalls in construct considerations [5], but actually the applicability of this trial methodology to surgical access examination [6]. As surgical procedures are highly skill and volume dependent, it's difficult for any surgeon to be



truly equally adept and practiced at any two different approaches done for the same disease. While, of course, competency is expected no matter what the access, most if not all surgeons have a preferred approach that works “best” for them. The notion of equipoise has led some to question whether such trials can really be expected to reliably show anything more than equivalence. One suggested proposal to consider is methodological evolution such as randomization to expert in a technique *before*, rather than *after*, selection of surgeon/unit. It is, however, undeniably important for taTME to meet the same burden of proof as the procedures it competes against and also to truly reassure against concerns of new problems related to the new access. Particularly, urethral injury [7] risk, which is specific to this approach, and genitourinary dysfunction whether better, due to more precise dissection, or worse, due to its propensity for excision anterior to Denonvilliers’ fascia [8] need to be defined.

With reassurance of safety, effectiveness and advantage, the next points to clarify relate to which particular patients (including male vs. female but also those with anterior vs. posterior tumours) are best suited for taTME – as well as some consideration as to whether it’s even possible at all to stratify those cancer patients who would best benefit from this novel approach. This has implications not alone for whether rectal surgery might differentiate as a specialty from colon surgery but whether low rectal surgery differentiates from mid-rectal operations, with abdominoperineal resection being perhaps a separate category altogether. If any such strategy can be shown advantageous in very large centres, the onus is naturally for smaller centres to coalesce or refer between each other so that patients, the specialty and society as a whole receive a return on investment in the developmental work related to operative skill and technical advance. Aside from cancer, additional evidence is emerging for the role of taTME in restorative surgery outside of cancer (e.g. ileal pouch-anal reconstruction [9]) and in those suffering complications of colorectal surgery such as anastomotic failure who then later return for reconstruction follow-

ing the subsequent Hartmann’s procedure and in whom the rectal remnant may then be very shrunken and inaccessible in any easy way from above [10]. Additional avenues for specialty advance raised from increasing and improving taTME experience include topics such as whether all colorectal anastomosis should be formed by double purse-string rather than by the double-stapled technique.

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## Educational Advances

The proponents of taTME have adopted new educational formats, including video-based learning and interactive social media, in conjunction with its inclusion in traditional professional congresses. While societies like the European Endoscopic Association of Endoscopic Surgeons (EAES) and its United States counterpart, the Society of American Gastrointestinal Endoscopic Surgeons (SAGES) along with specialty congresses like the European Society of Coloproctology (ESCP) and the American Society of Colorectal Surgery (ASCRS) have included taTME almost from its onset with podium presentations, they also adopted early hands-on skills sessions (including high fidelity models and cadaver training) along with expert-led sessions. In addition, surgical educationalist groups such as IRCAD/EITS have advanced understanding and knowledge of the approach via theoretical sessions and laboratory courses.

Video capture and editing has been a terrific advance and, alongside *WebSurg*, journals such as *Colorectal Disease* have adopted open-access video forum in order for surgeons to investigate, learn and comprehend surgical techniques. The taTME playlist on the YouTube and Vimeo Channels of *Colorectal Disease* has 25 videos of user submitted content ranging from didactic discussion to tips and tricks sessions as well as complication management and advanced technique illustrative case edits (with its most watched video now comprising over 43,000 views totalling over 125 days of watch-time in total). Other journals, including *Techniques in Coloproctology* and *Diseases of the Colon & Rectum*, have also

regularly included open-access videos featuring advancements in taTME. The viewing of live unedited surgery has been taken to new broadcast standards by the Advances in Surgery group who have found and grown a global audience for their outstanding and comprehensive sessions in operative surgery [11]. Furthermore embrace of social media, including Twitter [12], along with dedicated smart phone/tablet technology applications (eg iLAPP [13]), has done much to embed understanding of the technique within the minds of a younger generation surgeons who then can discuss, debate and disseminate material via peer to peer sharing networks. Such broad dissemination has been a great learning support for those interested in transanal access and will go on to further advance the technique of taTME and the application thereof.

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### Platform Advances

There has been little advance in the access equipment now most employed for taTME and indeed perhaps little needed in keeping with the general paradigm of simplicity of approach. Transanal access systems are already simple and neat (even if relatively somewhat over-priced) but could perhaps be better adapted to ensure easy fitting and/or softness against the anal canal. While flexible tubing may allow for a secure fit without risk of overstretch or stercoral injury, other intriguing suggestions due to advanced material manufacturing include the manufacture by 3D printing of the rectal access tube by customizing their length and diameter, based perhaps on measurements from preoperative MRI.

Aside from access capture of the anal canal, insufflation systems are the other means of opening access space both intraluminally and extraluminally. The AirSEAL® Insufflation System (ConMed, Inc., Utica, NY, USA) has been very useful for taTME [14] both in terms of smoke evacuation and continuous pressure maintenance (when compared to traditional laparoscopic insufflation system that only monitor CO<sub>2</sub> rate of flow and pressure intermittently). Today, AirSEAL® remains a niche applica-

tion – principally for transanal and robotic surgery. If a better means of gaseous expansion then fixed volume, variable flow insufflators (similar in concept to neonatal ventilators which need to act similarly to avoid barotrauma but use considerably less sophisticated technology) should become more available and more widespread, including in use for flexible endoscopy and all laparoscopy.

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### Instrumentation Advances

The general trend since the introduction of taTME has been simplification with respect to operating instrumentation with hook diathermy becoming preferred over vessel-sealing devices for the transanal portion of the operation. Most expert taTME surgeons still prefer straight, rigid instrumentation although curved instrumentation is becoming more widely available and may offer some advantages [15]. The main paradigm remains through application of standardized and known laparoscopic techniques (as applied via utilization of the TAMIS platform), since so many surgeons favour the *familiarity principle* over diversity of instruments in their operative tactics.

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### Visualization Advances

Most helpful in the propagation of taTME has been the generally high standard of camera visualization systems. In line optical cabling with respect to the camera head is an advantage in the relatively confined access of the pelvis and, indeed, for the lithotomized patient. Furthermore, some surgeons have found benefit in the use of a bariatric length camera for the transanal portion of taTME, as it can serve to offset instrument shaft lengths, resulting in less camera-to-instrument collisions.

The high-definition quality of most camera optics greatly enables the appreciation of planar access and, of course, provides a quality archive for education and reflective audit. 4K and higher resolution will better the view further, and while

3D seems to have a useful application in this approach [16], its overall relative lack of penetration broadly within theatre systems has hindered its implementation. More truly impactful visualization technology is however likely emerging in the form of image-guided surgery (see below).

### TaTME: A Killer Robot Application or Robot Killer?

Presently, robotic assistance with the Da Vinci series of machines is increasing with proponents advocating improved reach into the male pelvis and better specimen results. taTME conceptually presents the same advantages without the need for multimillion dollar capital investment in trophy technology and subsequent high procedure costs, albeit with the need to learn not just a new approach but also a new perspective on anatomy. Most robotic and taTME experiences however compete with laparoscopic or open experience and not directly with each other (Table 49.1). In general, there hasn't been much published comment to date on the fundamental differences in these technical sets [17]. Practitioners have tended to instead apply the robot to the transanal approach in an effort to improve dexterity and precision alone. The anticipated da Vinci SP system should be better equipped again to enable the

approach transanally, but this still requires complete comprehension of the new environment and new dangers of transgress from below and so we still don't have a robot that can add value to the cognitive interpretation related to plane finding, marginal radicality and normal anatomic structure delineation. These crucial aspects of safe and effective surgery still depend on the surgeon having learnt experientially most often over some considerable timeframe. While clearly only those who can afford robots can use them, the taTME conventional approach has the global market advantage that it can be utilized anywhere with laparoscopic equipment; although, some suggest, this access advantage can be detrimental to progress with taTME, since it allows potentially unskilled practitioners to "give it a go", something much harder to do with a robotic system given their still relative exclusivity and thus general lack of availability.

### Image-Guided Surgery

Where technological progress will really be valuable is in the field of surgical guidance or decision support whether for taTME or other complex endo-laparoscopic intervention. Optical interpretation is a foundational cornerstone of all image-based surgery, and all contemporary systems now create a digital video image on a screen that has been created via fibre-optic energy assimilation that has been passed through a computer before its display. While pixel quality and quantity can add visual clarity, the viewer still has to interpret the meaning of the image and look for visual clues as to the anatomic and pathologic importance of what is being seen.

Confidence and accuracy of interpretation depends to some degree on the individual's eyesight including red-blue-green sensitivity and the catalogue of experience of the observer (surgeon) as much training is still time-based. Assistance in early and accurate identification of structures could help expedite operative flow, improve precision of dissection and increase safety of surgery as well as improve oncological outcomes through accurate, rapid lesion localization, margination and planar

**Table 49.1** Comparison between robotic TME and taTME

	Robotic TME	taTME
Availability	+	+++
Cost	+++	+
Evidence base	++	++
Accuracy	++	+++
Distal margin identification	+++	+++
Circumferential margin identification	-	+++
Anastomotic construction		
Skills transferability versus laparoscopic/open	++	++
Educational opportunity: via industry	+++	++
Educ. via peers and professional bodies	++	+++
Registry opportunity	++	+++
Credentialing opportunity	++	+

identification and preservation as well as shorten learning curves overall. This can improve the variability in surgical performance and outcome known to exist internationally and help elevate standards above simple competence [18].

One example of how this is already happening, and likely to markedly improve in the near-term future, is in the use of near-infrared (NIR) laparoscopy and disclosing dyes. Conventional endoscopes and laparoscopes have used white light alone for tissue illumination. Recently, however, it has been appreciated that broadening the spectral energy into the near-infrared range can add significant information regarding the region of interest under inspection. Within near-infrared wavelengths, energy can penetrate tissues to a depth of several millimetres, and biological tissue lacks back reflectance in this spectral zone. Specific signalling agents placed into the tissue can indicate their presence and thus characterize the tissue, by means of fluorescence emission of detectable energy back to the irradiating source at a different wavelength that can be displayed optically. The only such fluorophores approved for use are indocyanine green (ICG) (Fig. 49.1) and methylene blue (MB), the former being widely available for circulatory mapping of the lymphatic and vascular systems and the latter under specific circumstance can be useful for urinary tract delineation. The mechanisms of action of both dyes depend on normal physiologically processing from which specific information can be inferred.

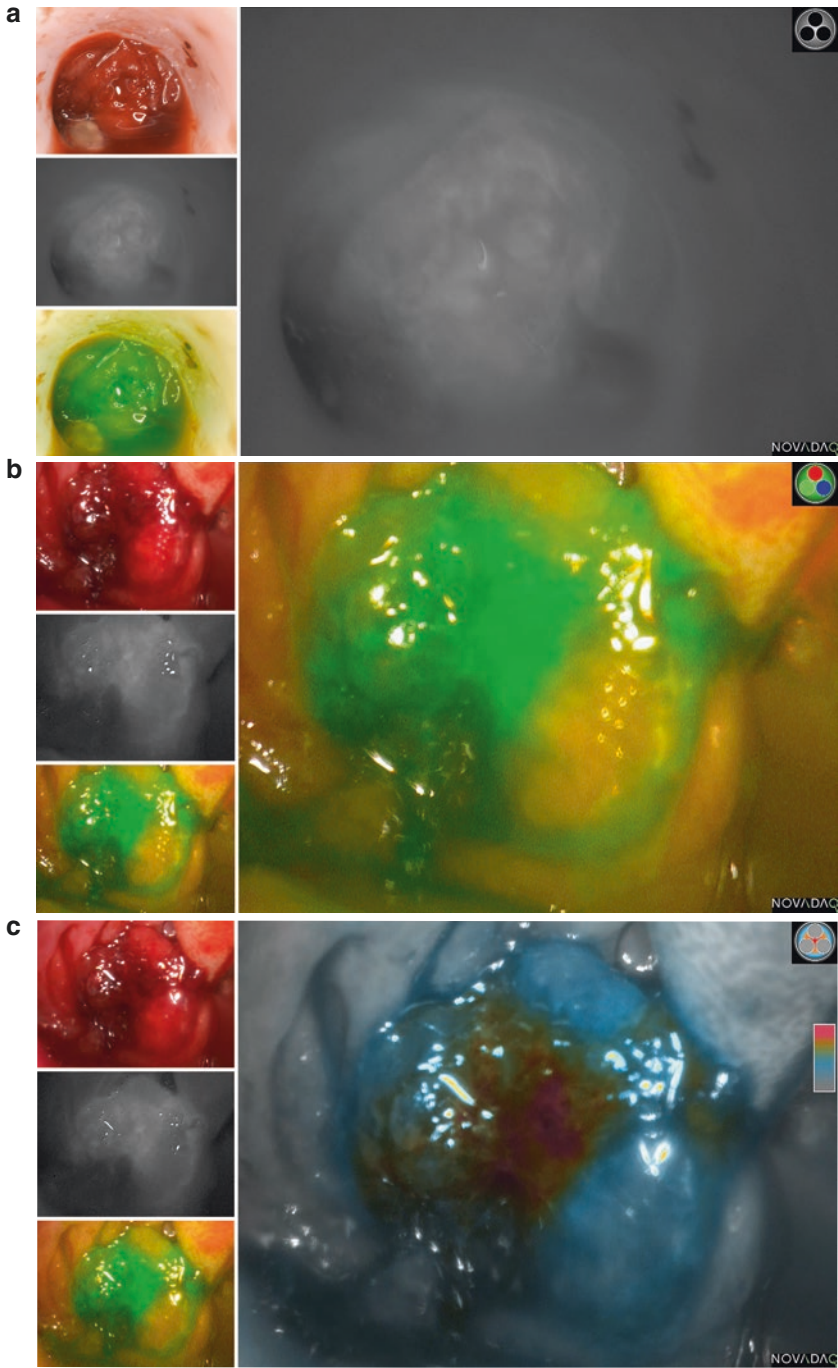
ICG is highly protein-bound, so it remains in the circulation after systemic intravenous administration until its clearance without metabolism by the liver. Therefore, depending on timing it can be used as an indication of perfusion sufficiency and of biliary channel mapping. Its use as an indicator of intestinal perfusion adequacy is already proving beneficial in guiding interpretation of perfusion adequacy before and after anastomotic construction, especially intracorporeally. Prospective studies are showing, quite consistently, a change in operative strategy based on the near-infrared visualized segments in approximately 6% of cases, and that such adjustment is associated with a significant (indeed two thirds)

reduction in significant anastomotic complications (most especially leak) postoperatively [19]. A large international, multicentre randomized trial is under to prove its exact use and is expected to conclude in 2020 [20].

While it also has application in biliary surgery, the use of ICG in this way as a perfusion indicator is appealing as it discloses its information within moments of administration and so can be used easily by surgeons to check or inform decision-making irrespective of duration of procedure or processes beforehand. Biliary mapping needs pre-administration and interpretation is so time-dependent – i.e. meaning earlier then lanned enquiry can give misleading information, such as when a signal is from the vasculature instead of the biliary tree. This can result in misinterpretation if this information is not realised and taken into account by the surgeon.

ICG can also be used as a lymphatic mapping agent. For this, interstitial deposition allows the agent to be taken up by the lymphatic system and the dye concentrated into draining lymph nodes as is normal physiological action. Thus nodal identification is performed, but this is not any indicator of presence of pathology (specifically cancer) within these lymph nodes and further processing, usually by histopathology, is needed for such analysis. MB is cleared renally after its systemic administration and so its near-infrared illumination can display the ureters laparoscopically [21] and this could also be potentially important for identification of the male urethra during taTME [22]. MB is not a perfect dye for this use however, it is not approved for this indication and may act as generator of free radicals on exposure to intense light energy. Notwithstanding, it indicates well that the principles related to NIR-ICG can be broadened with additional dyes. Interestingly also some groups have used NIR energy alone as a means to indicate site of peritoneal connection during taTME [23] and deployed its lymphatic channel marker capability as a means to indicate posterior mesorectal fascial margins [24, 25].

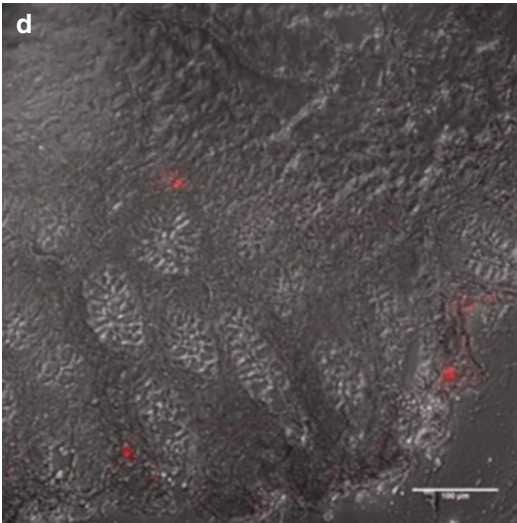
This work shows the application of NIR alongside dye administration and shows it can fit within



**Fig. 49.1** Intraoperative photographs showing rectal cancers identified by fluorescent tagged using indocyanine green (ICG) and near-infrared endoscopic (PINPOINT Endoscopic System, Novadaq/Stryker Corporation) in both (a) near-infrared and (b) false coloured view. Image

(c) shows thresholding capability, assigning different colours to different levels of fluorescence intensity and Image (d) shows a near-infrared microscopic view of the same cancer showing specific depots of fluorescence related to cancer crypts in high-powered views





**Fig. 49.1** (continued)

and add value to operative decision-making and flow. Perhaps most importantly it provides a method of resolving uncertainty in instances of doubt as well as a method for standardizing and enhancing intraoperative decision-making. New agents will allow increased specificity for pathology including cancer-specific targeting and normal anatomy identification including genitourinary nerves and, in combination, can provide a method for determining broadening or narrowing radicality on a personalized basis. Further, in situ identification of nodal disease along with peritoneal or occult liver surface deposits may help improve surgical oncological outcomes and correctly allow fuller disease excision and so great R0 resections and assign postoperative adjuvant and even surveillance strategies.

When considering novel agents, it is important that newer agents allow further stepwise implementation and stick to the fundamental principles of best use as shown by ICG as a perfusion agent (see Table 49.2). The organic dyes should exhibit a high safety profile, be low-cost to implement and widely available. Real-time imaging and assessment is also crucial. Weak signalers needed to be administered long before application – in order to concentrate sufficiently within the region of interest and to wash out of other tissues – will have limited usefulness,

**Table 49.2** Ideal qualities of new disclosing dyes for surgery and artificially intelligent visual processing and feedback systems

Disclosing dyes	Optical feedback systems
Rapid signalling (within moments of administration)	Rapid processing and display (within moments)
High signal to background noise ratios	Applicable to all surgical camera systems, rigid and flexible
Broad applicability	Easy to understand
Easy to include within surgical timescales and work flows	Widely available
Cheap	Decision support rather than instruction
Safe re toxicity and anaphylaxis rates	Machine learning applicable (and so will improve with time)
High sensitivity and specificity	Deployable outside of exclusive platforms

although do show concept and application capability of deep basic science. Agents capable of rapid dissemination along with off-on signalling within the microenvironment of relevance whether ischemia, hypoxia or cancer cell presence are of great interest and are in development. Correct optical delineation of primary and local mesorectal nodes can allow partial mesorectal excision with accuracy from inside the rectum.

### **Cognitive Assistance-Smart Systems Versus Dumb Droids**

Surgery, as the exemplar real-time decision-making specialty, needs its practitioners to be able to comprehend and make sound judgements on the operative landscape in sequence. Adding non-informative extraneous information or data that requires complex cerebral processing is not helpful especially given recent work defining the cognitive burden of operating and its difficulties – especially with non-expert practitioners or in cases when unexpected complexity or complication is encountered. With increased complexity of image presentation, perhaps with multispectral imaging of multiple dyes at different wavelengths simultaneously, there is a need for machine assis-

tance in assigning levels of confidence. This is particular true for NIR given that many agents in development may present high false-positive rates and prolonged timeframes and thus delayed observation windows.

Alongside pixel analysis and feature engineering (such as texture recognition), mathematical algorithms can helpfully provide profiling information regarding the nature of the lesion under observation, most especially if kinetic analysis is built into the profiles in combination with contrast agents and disclosing dyes. Added data, additional dyes, spectra or offset cameras (such as 3D scopes) can allow fluorescence tomography modelling of the lesion to depth (avoiding the predominance of superficial reflectance in current NIR displays). This would allow for rapid lesion recognition by the surgeon as well as a variety of offshoot capabilities such as 3D rendered image presentation. It is interesting that da Vinci robots include a module for fluorescence capacity and Medtronic has recently acquired a specialised fluorescence company (Visionsense) although presently the information is like standard laparoscopic systems, presented for human interpretation alone. That recently an autonomous suturing machine deployed similar technology to reliably perform a tissue anastomosis under hands-off human supervision points the way to an interesting near-term future.

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## Autonomous Operations

With perfect image registration, potentially by highly selective signalling tissue agents in combination with extended or multispectral imaging, in situ tissue reference points can be provided that could allow autonomous target identification as well as defined margination. While widespread use may still be several years into the future – in an era when cars can drive and park themselves, planes can fly themselves and assembly lines can run on the basis of automated manufacture with quality control – straightforward operations such as in situ presentation of an early rectal cancer for excision or even in situ

ablation can easily be envisaged and activated in the near term as a challenge to intraluminal transanal access approaches. Increased accuracy of image and therefore target identification and comprehension allows diagnostic detection of lesions at colonoscopy in addition providing a useful niche for mucosal surveillance and colonic topography mapping.

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## Specializing Specialists

The procedure detailed in this book on taTME has developed to a mature state within about a decade. This has been helped by a variety of technologies that allows surgeons to collaborate and gather evidence more easily than before and disseminate concepts and outcomes both within and without traditional routes rapidly and widely. This broadcast capacity can be equally applied to other areas in clinical practice behoving the clinical expert to update and upskill continuously during a standard career-duration. Techniques and technologically advances can move forward quickly, and patients deserve to be able to benefit from useful advances being applied to their disease without unnecessary experimentalism but equally also without undue delay. This is part of the modern world, and practicing physicians and surgeons must stay abreast of the emerging capabilities in surgical principle and practice. In the words of Stewart Brand, “Once a new technology rolls over you, if you’re not part of the steamroller, you’re part of the road”.

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