Urodynamics, Neurourology and Pelvic Floor Dysfunctions

Salvatore Siracusano · Giuseppe Dodi
Michele Pennisi · Christian Gozzi
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Complications of Surgery for Male Urinary and Fecal Incontinence

Springer

Urodynamics, Neurourology and Pelvic Floor Dysfunctions

Series Editor

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The aim of the book series is to highlight new knowledge on physiopathology, diagnosis and treatment in the fields of pelvic floor dysfunctions, incontinence and neurourology for specialists (urologists, gynecologists, neurologists, pediatricians, physiatrists), nurses, physiotherapists and institutions such as universities and hospitals.

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Series Editor's Preface

Another valuable episode adds to the series of Springer volumes realized under the auspices of the Italian Society of Urodynamics. The aim of the book series is to highlight new knowledge on physiopathology, diagnosis, and treatment in the fields of pelvic floor dysfunctions, incontinence, and neuro-urology for specialists (urologists, gynecologists, colorectal surgeons, neurologists, pediatricians, and physiatrists), nurses, physiotherapists, midwives, and institutions such as universities and hospitals. Our volumes highly cover this variety of interests with an interdisciplinary approach. The present volume adds to our series a precious perspective on complications of surgery with the invaluable merit of involving urological as well as proctological points of view.

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Preface

The decision to plan this book was born from the need to clarify the possible complications of surgery for urinary and fecal incontinence in the male. In fact, to date the attention of most of the texts on this topic is generally addressed to the indications and surgical technique but without reserving particular attention to the complications that this surgery can cause.

In this context as urologists and proctologists we decided to set the diagnosis and treatment of the complications of this surgery by means of an interdisciplinary approach within an integrated vision of the male pelvic floor from the urological and proctological point of view.

Finally, a thank you to all the authors and to the Italian Society of Urodynamics that gave us the opportunity to realize this text.

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Padova, Italy — Giuseppe Dodi
Catania, Italy — Michele Pennisi
Milano, Italy — Christian Gozzi
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Introduction

Urinary and fecal incontinence in the male still represent two pathological conditions that are not fully known in their entirety from the pathophysiological and from the therapeutic point of view. In this context, the evaluation of the complications of this type of surgery is even more problematic, especially in consideration of the fact that frequently they have been evaluated separately for what concerns the anterior or posterior compartment of the pelvic floor. In this text, therefore, we deliberately dealt with each aspect in a transversal way with an integrated urological and proctological approach that allowed the creation of an interdisciplinary point of view for each problem. In my opinion, this represents the winning aspect for the solution of perineal dysfunctions and even more for the deepening of the complications that derive from functional surgery for these patients.

In the future, this type of interdisciplinary approach should represent the standard but it is also true that in order to achieve this objective, the help of all the specialists involved in this area is needed in order to obtain the institutionalization of the professional figure of the perineologist.

Finally, a thank you goes to all members of Pelvic Male Commission and in particular to Prof. Giuseppe Dodi who had the idea of making interdisciplinary comments and to Dr. Alessandro Giammò who was a precious interlocutor with the Italian Society of Urodynamics for the realization of this text.

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Thanks to SIUD for including Colorectal Surgery and Proctology in the Commission that produced this book, and to Professor Siracusano as well for the masterful management of the collaboration with the authors of the chapters on anal incontinence. For them the matter is difficult and controversial, being very dependent on the assessment of the quality of life of the patients. I am confident that those who deal with the pelvic floor in different specialties will appreciate this publication where I had the honor of collaborating thanks to my experience as editor of the journal Pelviperineology where the interdisciplinary assessments and the integral vision of the three compartments are considered the base for training a pelvic floor surgeon.

Giuseppe Dodi

Contents

Part I

General Aspects

Epidemiology of Urinary and Fecal Incontinence

1

Antonio Luigi Pastore, Andrea Ramin, and Angelica Ganss

1.1 Urinary Incontinence

Urinary incontinence (UI) has been defined by the International Continence Society (ICS) as the involuntary leakage of urine [1]. This is subcategorized into different types, including stress urinary incontinence, urge(ncy) urinary incontinence, mixed urinary incontinence, nocturnal enuresis and continuous urinary incontinence. Within the context of overall urinary function, urinary incontinence is often considered to be part of the broader constellation of lower urinary tract symptoms (LUTS). Although the ICS classification of LUTS can be useful, there can be an overlap between symptomatic components, which has led to placing incontinence symptoms into a separate analytic category [2]. Another important issue in the study of urinary incontinence epidemiology is an extensive sexual gap in the published literature. The propensity of published research focuses on urinary incontinence in women, with much less emphasis regarding urinary incontinence in men. One of the reasons may be that most studies on voiding symptoms in men tend to focus on more traditional definitions of LUTS, which do not include urinary incontinence in the conceptual model. Another reason may be the higher prevalence of urinary incontinence in women than in men.

Wide variation exists in prevalence estimates of urinary incontinence in men. Recently, the International Consultation on Incontinence reported that prevalence estimates range from 1% to 39% [3]. The wide span in estimates can be explained by differences in the methods used, including variation in populations (sampling, age range, ethnicity) questions, response options and definitions, as well as participation

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rates [3, 4]. However, clinically relevant estimates are far from 39% in the general population. Using the US National Health and Nutrition Examination Surveys (NHANES) data of the years 2005–2006 and 2007–2008 [5], authors reported that moderate or severe urinary incontinence prevalence was 4.4% [3.6–5.3%] among men. Any urinary incontinence was reported by 12.9%, and corresponding prevalence by urinary incontinence type was 2.5%, 10.3% and 2.7% for stress, urgency and mixed urinary incontinence, respectively. A US Internet-based panel survey examined differences in LUTS between different racial/ethnic groups [6]. Urgency urinary incontinence was reported by 6% of Whites compared with 10% of African-Americans. Authors reported prevalence of stress urinary incontinence was 6% in Afro-American and 2% for Caucasian white males. However, how much these differences really are due to 'racial' or 'biological' differences remain unclear. Overall, all these studies are confirmatory to earlier studies reporting dominance of urgency-type urinary incontinence in men, compared with stress-type urinary incontinence dominance in women [5, 6].

Several earlier studies have shown a significant increase in prevalence of urinary incontinence related to age and comorbidities [3]. An Austrian population-based study assessed prevalence of urinary incontinence in a geriatric cohort (mean age 76 years) of the general population [7]. Any involuntary urine loss at least twice a week was reported by 26% of elderly men. The EpiLUTS study examined rates of urinary incontinence in both men and women in the USA, the UK and Sweden [8]. Prevalence of any urinary incontinence was 46% for men and 68% for women. However, this actually included various forms of urinary symptoms, such as post-micturition dribble was mainly categorized as urinary incontinence, which is questionable and not consistent with current ICS terminology. One more reason for such high estimates was use of only two response options: yes or no. When categorized by type, 5.6% of men reported urgency urinary incontinence, 0.8% stress urinary incontinence and 1.4% mixed urinary incontinence. The 6.3% of these patients had urgency urinary incontinence associated to another form of urinary incontinence, and 1.2% had stress and another form of urinary incontinence.

A number of recent studies have examined the risk factors and other comorbidities most commonly associated with development of male urinary incontinence [3]. Substantial impairments in physical condition are associated with urinary incontinence, particularly in elderly patients. However, the direct influence of walking and other physical activity on continence status can be difficult to assess. A Japanese study on 683 old-aged men and 298 elderly women examined habitual activity levels, including walking and moderate to vigorous physical exercise [9]. The International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) was used to classify degree of incontinence for each individual. Prevalence of urinary incontinence was 7% in men and 28% in women. Individuals who walked regularly had significantly lower rates of urinary incontinence than those who performed less vigorous regular exercise. These findings indicate that regular physical activity appears to reduce risk of urinary incontinence. Other studies have linked urinary incontinence to both falls and physical limitations [10].

Stroke is one of the leading causes of both death and chronic disabilities, particularly in developed nations. Urinary incontinence is extremely common after stroke. An Australian study examined the natural history of urinary incontinence in a group of 1248 patients after stroke [11]. Rates of urinary incontinence after first stroke at 3 months were lower in men (30%) than in women (58%). This trend continued at 12 months, with 25% of men and 51% of women reporting urinary incontinence. Overall, 35% of those who reported de novo urinary incontinence after stroke experienced complete resolution of urinary incontinence by 12 months. Greater stroke severity was associated with higher incidence and lower resolution rates of urinary incontinence.

Rates of comorbidity increase with advancing age, and many conditions can be associated with development of urinary incontinence. A Taiwanese study of 2629 community-dwelling older adults examined associations between diabetes and various geriatric conditions and syndromes [12]. The study examined 1369 men, including 1162 with diabetes and 207 controls. Overall prevalence of urinary incontinence in men with diabetes was 22% compared with 14% of those without. In the multivariate analysis (urinary incontinence as the outcome), the OR was 1.6 (95% CI 1.1–2.5) for diabetes.

Numerous medications have been associated with risk of development of urinary incontinence. A population-based epidemiological study examined this issue using Boston Area Community Health (BACH) survey data [13]. The overall prevalence of urinary incontinence was 4.6% in men and 9.0% in women. Among men, urinary incontinence prevalence was noted to be highest among those who used either an angiotensin II receptor blocker (22%) or a loop diuretic (19%). However, after adjusting for potential covariates, only anticonvulsant medications remained significant (OR 2.5; 95% CI 1.2–5.0).

In men stress urinary incontinence most commonly occurs after prostatectomy for benign or malignant disease. Despite improvements in surgical techniques and implementation of minimally invasive procedures, the reported prevalence of post-radical prostatectomy (RP) SUI varies widely, ranging 4–50% in contemporary series [14, 15]. On the contrary, the prevalence of SUI following transurethral resection of the prostate (TURP) and holmium laser enucleation of the prostate (HoLEP) is much less common (approximately 1%) [16]. However, TURP performed in the setting of prior external beam irradiation or brachytherapy can result in particularly high incontinence rates of up to 18% [17]. The observed discrepancy in the published post-radical prostatectomy SUI rates results from differences in definition of incontinence used by different authors, data collection methodology and evaluation outcomes (patient versus surgeon-reported continence). Although small degree of SUI may not affect patient's well-being, moderate-to-severe post-prostatectomy incontinence negatively impacts men's quality of life [18]. The most common mechanisms of SUI after radical prostatectomy include a direct injury to the urethral sphincter itself as well as to adjacent supportive tissues and nerves [19]. Whereas after TURP urinary incontinence is most likely due to the pre-existing abnormalities of bladder function rather than direct sphincter injury [17]. Improvements in urinary leakage may occur spontaneously or with conservative

measures within the first 12 months after prostatic surgery. However, management of persistent incontinence is often challenging and may be frustrating for both a patient and his doctor, and as a consequence, it can negatively affect doctor–patient relationship.

Epidemiological research has focused less attention on urinary incontinence in men compared with women. This may be due in part to conceptual definitions of lower urinary tract dysfunction in men, which often concentrate on storage and voiding, and may not routinely include urinary incontinence. Ongoing research shows high prevalence of urinary incontinence among elderly people in developed countries, and emerging data indicate that this is a problem in other parts of the world as well. A wide variety of risk factors have been identified, and urinary incontinence can have substantial negative impacts on clinical outcomes and quality of life.

Interdisciplinary Comment
Epidemiology of urinary incontinence in the male has not been investigated to the same extent as for the females. Rates of urinary incontinence continue to be reported in men and women by 1: 2 ratio. In this context it is clear that a pelvic floor surgery involving the sphincter unit is at risk for the development of urinary or faecal incontinence. For a better estimate of the prevalence of urinary and faecal incontinence in the male, a uniformity of the concept of incontinence is essential. Specially in anal and faecal incontinence the range of severity of the dysfunction is so broad, as stated by Ramin and Ganns, that even when episodes of loss of air or stools are quite rare, the quality of life is severely compromised, and both epidemiologic evaluation and therapy are difficult tasks.

1.2 Fecal Incontinence

Fecal incontinence (FI) is defined by the unintentional and recurrent loss of fecal material for at least 1 month's duration in an individual with a developmental age ≥4 years [20], whereas anal incontinence (AI) includes leakage of gas and/or stool [21]. Involuntary passage of flatus alone should not be included in the definition of FI, partly because it is difficult to determine when the gas leakage is abnormal [22]. Major incontinence is defined as soiling of underwear, outer clothing, furnishings, or bedding several times a month or more often [23].

These multiple terminologies have made it difficult to perform an accurate cross-national comparison between studies conducted in the area [24]. Moreover, unless specifically questioned, most people with FI will avoid reporting the condition to a healthcare provider [25]. This has led to an underestimation of the prevalence and consequences of incontinence, to an incomplete knowledge of its biological causes and to limited efforts on disease prevention [21]. Few data are also available on its

economic burden in the United States, whereas FI is associated with substantial economic cost, calling for more attention to its prevention and effective management [26].

Incontinence can lead to both physical (e.g., perianal dermatitis, infections, sores) and psychosocial consequences—the latter being mostly reported as overwhelming. In fact, this condition can have a deleterious impact on personal and social life, affecting self-esteem and potentially leading to social isolation (due to the anxiety of having unexpected episodes), health-related unemployment and even institutionalization [27–29].

A workshop was organized in August 2013 by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), in order to address issues regarding epidemiology, pathophysiology, and management of fecal incontinence [30]. Among the findings of this workshop, a selection bias was encountered in many studies that evaluated the prevalence of this condition, as they were often conducted in selected populations (restricted by age, residence, or underlying disease) [30]. In fact, the prevalence of FI in nursing home residents and in older age groups is known to be considerably higher than in the general population, approaching 47% in a survey of 18,000 nursing home residents in Wisconsin [31]. Three studies in community-dwelling elderly population (≥65 years) reported no difference between men and women [32–34], one a higher prevalence in men [35], and another a higher prevalence in women [36]. However, the true frequency of FI is often underestimated even in this selected population, as healthcare providers seldom investigate the presence of the disease and patients hide the problem from their families, friends, and often their doctors [21, 30].

Population-based studies avoid the referral bias of single-institution-based studies. A review of community-based studies performed between 1992 and 2009 showed a wide difference in prevalence rates [30], ranging from 4.5% to 12.8% [32, 37]. Gross fecal incontinence in the overall male population was reported at a prevalence of 0.4–1.4% [23, 38], while minor incontinence ranges between 6.2% and 9.7% [23, 39]. In a cross-sectional prevalence study in the general population [23], major incontinence was reported in 1.4% of the respondents (0.9% of adults aged 40–64 years and 2.3% of adults aged 65 years), leading to an impaired quality of life in 51.7% of them. In another survey, 33% of patients restricted activities due to incontinence [40].

As stated by Perry et al., the prevalence of FI is strongly associated with age, raising from approximately 4% for any incontinence in men and women aged between 40 and 49 years old to 11.6% in patients aged ≥80 years [23]. A correlation between severity of the disease and older age has also been emphasized: in fact, the oldest age group (80+ years) reported greater soiling than younger age groups [23]. Since FI is strongly associated with age, its incidence will likely increase as the population ages [21].

Data supporting a greater risk of FI in females are still inconclusive [23]. In the population-based study by Perry et al., the frequency of leakage and the prevalence rate of soiling did not differ between men and women, whereas the proportions reporting staining of underwear were higher in men than in women (9.6% vs 7.5%) [23].

In conclusion, fecal incontinence is a relatively common disorder with significant psychosocial implications, often impairing quality of life. Despite the basic understanding of this disease, FI remains an understudied condition, necessitating further clinical research on its epidemiology, pathophysiology, social consequences, and ultimately prevention and management.

Interdisciplinary Comment

The real prevalence of fecal incontinence in the male is lacking due to the absence of an agreement on the grade of incontinence as indeed it happens for urinary incontinence.

Most likely one of the causes is the lack of knowledge of the pathophysiology of fecal continence and of related incontinence symptoms.

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Surgical Anatomy, Physiology and Pathophysiology

2

Maria Angela Cerruto and Benito Ferraro

2.1 Lower Urinary Tract Surgical Anatomy

The lower urinary tract (LUT) consists of urinary bladder, the lower part of both ureters together with the uretero-vesical junction, the urethra and the external urethral sphincter, also referred to as the rhabdosphincter. In men the prostate is considered part of the urethra.

The bladder is a hollow organ that is situated within the pelvis. The bladder wall consists of five layers from inside out: the urothelium, the lamina propria with fibroelastic connective tissue, the muscularis mucosa, the detrusor and the bladder serosa [1]. The muscle of the bladder, named detrusor, is composed of smooth muscle fibres and consists of three layers. The fibres in the middle layer of the detrusor are arranged spiral-circular and form an internal sphincter at the level of the bladder neck. The outer layer is composed of longitudinal fibres that are thickest posteriorly at the bladder base [1].

In men, the internal urethral sphincter (IUS) has its source at the urinary bladder's inferior neck (smooth muscle), continues through the prostatic urethra above the verumontanum and remains under autonomic control. The action of the urethral sphincteric mechanisms consists of an inner smooth muscle layer (longitudinal and circular smooth muscle) and a striated urogenital sphincter muscle (rhabdosphincter), which contribute to the maintenance of urethral closure pressure above the bladder pressure [2].

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The external urethral sphincter (EUS) is located distal to the prostate at the level of the membranous urethra as the secondary sphincter to control the flow of urine [3]. It contains mainly striated muscle and is therefore under voluntary control by the somatic nervous system. The male closing mechanism of the bladder is separated by the prostate. The EUS extends from the prostatic urethra below the verumontanum through the membranous urethra. EUS includes the rhabdosphincter (intrinsic skeletal and smooth muscle) and extrinsic paraurethral skeletal muscle [2]. At the prostate level, the superior part of the striated EUS is largely confined to the anterior side of the urethra and prostate. Inferior to the prostate, the EUS is horseshoe shaped (although named as the rhabdosphincter, omega shaped) with the opening on the dorsal side [3]. The dorsal muscle fibres of the left and right sides approach the midline and sometimes cross the prostate. Rhabdosphincteric muscle fibres insert on the apex and the anterior surface of the prostate and are oriented in vertical and ventrolateral directions with attachments to the subpubic fascia and the medial fascia of the levator ani [2]. They are composed mainly of type 1 (slow-twitch) fibres, which are well suited to maintaining constant tone, as well as allowing voluntary increases in tone to provide additional continence protection.

The EUS is innervated by the autonomic (via the pelvic nerve) and somatic (by the pudendal nerve) nervous systems [3]. Nerve fibres are seen proximally in a dorsolateral position (5–7 o'clock), while more distally, they are located primarily laterally [3]. The intrinsic smooth muscle of the proximal urethra receives parasympathetic innervation from pelvic nerve branches of the inferior hypogastric plexus [3]. The rhabdosphincter may also receive somatic innervation. 'Putative continence nerves' have been described as branches of the pelvic nerve travelling under the endopelvic fascia picking up intrapelvic branches of the pudendal nerve, given off before it enters the pudendal canal [3]. It has also been proposed that somatic innervation from the pudendal nerve after it exits the pudendal canal is primarily sensory in origin, facilitating reflex contraction of the sphincter complex to maintain continence [3]. The pudendal nerve supplies innervation to the urethral sphincter complex [4]. The pudendal nerve, according to most anatomists, mainly follows an extrapelvic course via Alcock's canal [4]. Anatomic studies have shown a partially intrapelvic route for the pudendal nerve branches that go on to innervate the urethral sphincter [5–7]. There is debate about the role and extent of the contribution of the neurovascular bundles (NVBs) in the innervation of the external urethral rhabdosphincter. Some authors state that it has never been demonstrated that the NVB might contain any somatic nerve supply and therefore should merely have a functional role in the continence function of the rhabdosphincter [8]. However, others state that the internal urethral sphincter has dense autonomic fibres [9]. Newly elucidated anatomic dissections point to the cavernous nerves providing at least a small portion of the innervation to the membranous urethra [10, 11]. The functional meaning of this is still unclear. However, Nelson et al. [12], measuring changes in intraurethral pressure caused by intraoperative NVB stimulation, noted a consistent increase in pressure on stimulation in eight consecutive patients. Furthermore, there is clinical evidence that NVB preservation during RP leads to earlier recovery of urinary continence [13, 14].

The bladder neck and urethral sphincteric mechanisms have a close relationship but are independent of the pelvic floor. In the male, the major components of the supporting system are the Denonvilliers' fascia, puboprostatic ligament, endopelvic fascia, levator ani muscle and arcus tendineus fascia pelvis in the male. These components might not play a significant role in determining continence in healthy males, because the prostate itself can prevent stress urinary incontinence. However, as the prostate is removed by RP, these components might be impaired. Therefore, preservation, reconstruction and reinforcement of these components can recreate a new supporting system and ensure urethrovesical pressure dynamics, and thus improve recovery of urinary continence after RP.

2.1.1 Continence Control and Physiology

An ancient Chinese proverb of 2000 years ago says that: 'the bladder is the mirror of the soul'. Actually, the bladder reflects our feelings and well-being, and we can all recognize that increased anxiety and stress may lead to subjective changes in voiding behavioural. Psychological influences on voiding may be responsible for increased frequency and urgency also in healthy individuals.

In normal conditions, the LUT relies on intact neuronal innervations that are under the control of a complex supraspinal network. In a pathological state, this network does not work correctly, resulting in lower urinary tract symptoms (LUTS).

Bladder control during the storage phase can be switched to the voiding phase voluntarily. Although there are several working models regarding the brain–bladder control network in normal conditions, the pathophysiological mechanisms remain largely unknown.

A recent working model of brain–bladder control during urine storage identified three forebrain circuits able to generate sensation and control voiding by suppressing the voiding reflex at the periaqueductal grey (PAG) [15]. The circuit 1, frontal, involves the lateral prefrontal cortex (lPFC), the medial prefrontal cortex (mPFC) and the insula; it is the circuit of contextualization of bladder sensory information with preconscious and conscious control over bladder filling and voiding; it is the seat of the void/no void decision [15, 16]. The circuit 2, the midcingulate level, involves the dorsal anterior cingulate cortex (dACC) and the adjacent supplementary motor area (SMA). It has the task of registering bladder sensory information and preparing the motor responses. The circuit 3 is directly linked to the circuit 3 via mPFC. The circuit 3, subcortical, involves regions such as the hippocampal complex; it corresponds with the limbic system, pattern/environmental recognition and relating urinary status to emotional state. These forebrain circuits are connected with each other through the PGA.

2.1.2 Pathophysiology of Urinary Incontinence

Incontinence in the male as in the female can be broadly divided into causes related to bladder and/or sphincter dysfunction [3]. The pathophysiology of incontinence as

it relates specifically to the male is fairly well described; however, advances in science and anatomy will undoubtedly provide better understanding in the future. For example, the causes of sphincter insufficiency are known (i.e. damage to muscle, nerve and/or supporting structures) but clinicians are not able to accurately assess the exact cause of sphincter insufficiency in any given patient.

Therefore, much of our understanding of post-treatment incontinence 'pathophysiology' is derived from reports of incontinence (incidence/prevalence) after surgery or radiation. In addition, investigators have not done an adequate job in defining the incidence of incontinence related to interventions for prostatic disease, whether benign or malignant. Some work has been provided to understand and discriminate the issue of pre- and post-operative incontinence, but as an issue of shortened hospitalization those prospective investigations, which are mandatory for the understanding of the physiological functioning and the pathophysiology, which might become clinically significant after the intervention this doesn't make sense. Problems have been twofold: first in defining incontinence and what is bothersome/significant and second in accurately reporting data.

Benign prostatic hyperplasia (BPH) and benign prostatic obstruction (BPO) and their treatments have long been associated with incontinence in men [3]. Detrusor overactivity (DO), impaired compliance and urgency incontinence are prevalent in men with BPO. The prevalence of OAB ranges in adult males from 10% to 26% and in adult females from 8% to 42%. It increases with age and often is associated with other LUTS [17]. In men undergoing urodynamic testing detrusor overactivity is present in 40–80% of patients with obstruction [18–20]. In addition, impaired compliance, another potential cause of incontinence, has been shown to have a high correlation with outlet obstruction in men [21, 22]. Thus, even before treatment of BPH and BPO there is a notable incidence of bladder dysfunction and incontinence.

The aetiology of urinary incontinence after radical prostatectomy (RP) is complex and multifactorial. Not only surgical technique and surgeon's skill, but also patient characteristics can affect continence status after RP [3].

Neuromuscular anatomic elements and pelvic support are known to influence post-prostatectomy incontinence (PPI) as evidenced by multiple publications. A number of non-anatomic and surgical elements have been postulated as contributing factors to PPI. Biological factors and preoperative parameters include: functional bladder changes, age, body mass index (BMI), pre-existing LUTS, prostate size and oncologic factors [23]. Multiple studies reported the impact of specific anatomic/surgical factors, including fibrosis, shorter membranous urethral length (MUL), anastomotic stricture, damage to the neurovascular bundle and extensive dissection, all of which have a negative impact on the continence status of patients following radical prostatectomy (RP). Investigation of the impact of techniques to spare the bladder neck and additional procedures to reconstruct the posterior or anterior support structures (e.g. the Rocco stitch) on continence status is ongoing.

The development of de novo post-RP DO is a biological risk factor that has been suggested to be associated with PPI [23]. Functional changes including DO and reduced compliance may develop after RP due to denervation or devascularization of the urinary bladder [24]. DO has been observed in up to 51% of patients after RP at the

3-year follow-up. However, DO already existed in 38% of patients before surgery, with a persistence of DO up to 74% at the 3-year follow-up. The deterioration in storage symptoms could be related to a reduction in maximum cytometric capacity – possibly involving the absence of urethral-detrusor inhibition – and sphincteric incompetence. In the literature, DO has been reported as the sole cause of PPI in only 4% of cases and was associated with sphincteric incompetence in up to 42% of cases [25].

Increasing age is an important predictor of incontinence, because atrophy of the rhabdosphincter and neural pathway degeneration would occur with increasing age although data from the literature are conflicting. Matsushita et al. [26], analysing 2849 patients, confirmed that greater age was an independent predictor of worse continence outcomes at 6 and 12 months after prostatectomy. Conversely, Kadono et al. [27] revealed that age was not related to post-RP continence recovery. In addition, Catalona and Basler found no correlation between regaining continence after RP and age in a series of 784 patients [28].

Body mass index (BMI) is associated with poor post-prostatectomy continence outcome. It has been reported that PPI was more prevalent among physically inactive, obese men (BMI >30 kg/m^2) with previous RP [29]. Among patients who underwent robot-assisted radical prostatectomy (RARP), urinary continence outcomes were significantly lower for patients with BMI >30 kg/m^2 at the 1- and 2-year follow-up [30]. Conversely, Kadono et al. observed that BMI did not predict the post-RP continence outcome [27]. Hsu et al. [31] observed no statistically significant relation between body weight and postoperative continence. In one of the larger series to date to evaluate preoperative predictors of urinary continence, Matsushita et al. noted that among 2849 patients who underwent prostatectomy, higher BMI was an independent predictor of worse continence outcomes at the 6- and 12-month follow-up.

Data on the impact of TURP before RP on PPI are scarce and conflicting [32, 33]. However, waiting at least 4 months after TURP before performing RP may help to decrease the risk of incontinence among such patients [32].

Preoperative LUTS is one of the most critical factors for PPI, and pre-RP baseline continence represents a significant predictor of post-RP continence [34].

Membranous urethral length (MUL) preservation during RP improves continence outcomes [35]. In patients with a large prostate, RP is theoretically associated with excision of relatively longer parts of the urethra, which might impact continence outcomes in such patients [36]. Matsushita et al. [26], evaluating multiple preoperative factors among 2849 men, confirmed that longer MUL was strongly associated with improved continence rates at 6 and 12 months after prostatectomy.

Urethral fibrosis and the occurrence of anastomosis strictures may play an important role in the development of PPI because they may have a negative effect on external urethral sphincter function [37, 38].

Anatomic support and pelvic innervation are important factors in the aetiology of PPI. Damage to the urethral sphincter complex, the surrounding structures or their innervation leads to higher rates of PPI. Some preoperative biological factors and parameters, such as greater age, higher BMI, pre-existing LUTS, lower MUL and functional bladder changes, have a negative impact on continence rates after RP. Among the many surgical and technical factors proposed in the literature as

contributing to the development of UI following RP, extensive dissection during surgery, damage to the NVBs and the development of postoperative fibrosis have a substantial negative impact on the continence status of men undergoing RP. According to the basic concept to improve early return of urinary continence after RP maintaining normal anatomical and functional structures in the pelvis as much as possible, three steps can be carried out to reduce PPI: preservation (bladder neck; nerves, puboprostatic ligaments, pubo-vesical complex sparing, urethral length), reconstruction (posterior rhabdo-sphincter, anterior retropubic suspension, total reconstruction of vesico-urethral junction, reattachment of the arcus tendinous to the bladder neck) and reinforcement (bladder neck plication, bladder neck sling suspension) of anatomical structure in the pelvic. Although many intraoperative technical modifications to prevent PPI have been reported, the establishment of an accurate measure to assess postoperative continence and the validation of the usefulness of these modifications by prospective, randomized controlled studies carried out at multiple centres is required. Robotic surgery has provided a revolutionary advance for RP and greatly benefits patients and surgeons.

Interdisciplinary Comment

A multidisciplinary approach for the management of pelvic functional diseases in men requires an adequate cultural background. This must be based on continuous education in theory and practice; thus, a clinical research is very important in this field. The relationship between mind and body is an every present issue into the male pelvic dysfunction towards a holistic view of the male pelvic medicine. Understanding the mechanisms of faecal continence and of defecation and consequently the physiopathology of many conditions in which these two functions may be compromised is often quite difficult. The main aspects of anorectal and bowel functions are described in Ferraro's chapter. In an interdisciplinary view of the pelvic floor, both in male and female, it must be well kept in mind that while bladder and urethra must be able in human to contain and expel just urine, that is a liquid always similar to itself, the anorectum and the anal sphincters are continuously challenged by gas, solid stools, mucus and, with diarrhoea, liquid stools. Peristalsis furthermore may be quite active and a satisfactory continence may be lacking even in normal subjects.

2.2 Terminal Tract of the Large Intestine Anatomy

2.2.1 Anatomy and Physiology

The terminal tract of the large intestine includes the rectum and the anal canal, with a different embryological origin. The *rectum* extends from the sigmoid–rectal junction at the level of the third sacral vertebrae, 10–15 cm distally, down to the anorectal junction.

The peritoneum that covers the anterior wall of the rectum in the male is reflected in the space between the rectum and the bladder (recto-vesical space), and in the female between the rectum and the uterus (recto-uterine cavity, Douglas pouch). The depth of these reflections varies: the average distance from the anal margin is about 8 cm in the male and 4 cm in the female. The anterior wall of the rectum is substantially straight, and it follows closely a line parallel to the posterior axis of the vagina in the female, and to the recto-genital septum in the male. The posterior wall of the rectum is retroperitoneal, and it runs along the front of the last 3 sacral segments, up to the sacrococcygeal joint. The rectal lumen has 3 semi-lunar folds, the *Huston valves*: superior, middle (the largest, placed on the right front wall), and inferior, inconstantly located on the left side, about 2.5 cm from the one above. The valves are formed by thickening of the rectal wall, in particular by the circular muscle bundles of the internal muscular layer.

The *submucosa* is a layer of loose connective tissue, containing the terminal vascular ramifications and the Meissner plexus. The rectal mucosa with columnar epithelium is similar to that of the colon, but is thicker, raised at the folds, darker in color, more vascularized, and more loosely connected to the muscular layer. The *anal canal* connects the rectum with the perianal skin. It is included, proximally, between the sphincter portion of the rectum, clinically palpable at the upper edge of the puborectalis muscle sling, and distally, the anal orifice, which opens at the posterior triangle-shaped perineum, anteriorly from the bisischiatic line and posteriorly from the tip of the coccyx. The average length is about 5 cm, longer in men than women. The *surgical anal canal*, between anorectal passage and the *dentate or pectinate line* (irregularly wavy demarcation of the rectal mucosa placed at about 2 cm from the external anal orifice), is distinguished from the distal portion between the dentate line and the anal orifice, named *anatomical anal canal*. The line between the two parts differs histologically and embryologically.

The proximal part of the anal canal, extended for about 15 mm, is lined with a cylindrical epithelium similar to that of the rectal mucosa; it covers the *internal hemorrhoidal plexus* rising in vertical reliefs, 6–12 columns of Morgagni. Between the column small longitudinal depressions called rectal sinuses. The lower extremities of the rectal columns are connected by the rectal valves, small semi-lunar folds of the mucosa that delimit the so-called anal crypts; these are small recesses where the rectal glands open. The rectal valves form a so-called dentate line, between the entodermal part of the anal canal derived from the cloaca and the ectodermal part derived from the proctodeum, the transition zone or pecten. In this area, which is 15 mm wide below the line, the epithelium is of a non-keratinized layered type. The transition zone covers the external hemorrhoidal plexus; it is bounded inferiorly by the *Hilton white line* that marks both the passage to the perianal epidermis which is the border between the inferior margin of the internal sphincter and the subcutaneous portion of the external sphincter [39, 40].

The muciparous *anal glands* [41] in number varying from 6 to 12 are located in the area covered by colorectal epithelium and in the transition zone, as the typical crypts of the colonic mucosa secrete mucin. The anal ducts are tubular structures penetrating the submucosa and in some cases the internal sphincter muscle, ending

in the intersphincteric space [42]. Their branches may extend beyond the external sphincter to the ischiorectal fossa. The epithelium varies from squamous in the transition zone to cylindrical in the middle and columnar in the deep part. They are characterized by the presence of intraepithelial microcysts.

The *internal anal sphincter* (IAS) represents a gradual thickening of the internal circular muscular layer of the rectum and is composed of smooth musculature innervated by myenteric and submucosal nerve plexuses. The IAS has a thickness of 2–4 mm and a length of 2–4 cm. It ends with a rounded edge at the level of the dentate line about 1.5 cm from the outer contour of the anus, immediately above the lower portion of the external sphincter muscle, with which it forms an easily palpable shower for digital exploration [43].

The *longitudinal muscular layer* of the rectum continues downwards and, at the level of the pelvic diaphragm, connects to fibromuscular expansions coming from the pubococcygeal and puborectalis portions of the levator ani muscle and pelvic fascia fibers to become the *longitudinal muscle* consisting of three layers. The middle layer is the continuation of the rectal longitudinal muscle, the intermediate is the suspension strip of the levator ani. The lateral layer is the longitudinal extension of the upper ring of the external anal sphincter. The longitudinal muscle ends at the lower edge of the internal anal sphincter constituting a fascial fusion called "central tendon" which is divided into multiple fibrous septa. The middle septum is still in the rectal neck, the lateral goes through the external anal sphincter, forming the septum of the ischioanal fossa; the intermediate penetrates the superficial external sphincter anchoring to the dermis and perianal skin and constituting the corrugating muscle of the anus [44]. Some fibers of the longitudinal muscle pass through the internal anal sphincter forming the suspensory ligament of the mucosa [45].

The *external anal sphincter* (EAS) is a striated muscle shaped like an elliptical cylinder that surrounds the anal canal. According to Shafick [46], the EAS is a triple ring system (three loops theory), superior, middle, and lower. Each ring would be separated from the other by a fascial septum and would have its own individual attachment, its own direction of the muscular bundle and its innervation. The upper portion of the EAS comprises the deep part of the EAS and the puborectalis, fused together; the middle portion is formed by the superficial external sphincter surrounding the internal anal sphincter; the lower portion develops below the inferior margin of the internal sphincter muscle with which it forms a palpable groove. The subcutaneous SAE is crossed by the fibers of the longitudinal muscle that attach it to the perianal skin. Posteriorly the superficial portion of the EAS contributes to the formation of the anococcygeal ligament. Anteriorly the fibers of the EAS are inserted in the perineal body, where they merge and continue with the transverse muscle of the perineum.

The *levator ani muscle* is a large, thin muscle and is an essential part of the pelvic floor, innervated by the fourth sacral nerve, formed by *iliococcygeus*, *pubococcygeus*, and *puborectalis* muscle. According to Shafick, the latter would be an integral part of the deep portion of the external sphincter muscle with which it is fused). The iliococcygeus muscle originates from the ischial spine and from the posterior part of the obturator fascia reaching the sacrum and the anococcygeus rafis. The pubococcygeus muscle originates from the anterior part of the obturator fascia and

from the pubis; the fibers are directed back downwards and medially, where they cross with the fibers of the opposite side. The puborectalis muscle originates from the posterior surface of the pubic symphysis and from the fascia of the urogenital diaphragm; along the anorectal junction it rejoins the muscle of the opposite side, surrounding, U-shaped, the rectum, and projecting it toward the pubic bone.

The arterial vascularization is supported by the *superior rectal arteries*, branches of the inferior mesenteric, *middle and low hemorrhoidal arteries*, branches of the hypogastric and the pudendal artery. The superior, middle, and lower hemorrhoidal *veins* terminate corresponding to the arteries: inf. mesenteric, hypogastric, and pudendal veins.

The intestine has an intrinsic innervation consisting of two neuronal networks located in the thickness of the wall [47]. The myenteric plexuses of Auerbach and submucosal of Meissner are present in the rectum and in the anal canal, extending to the area of passage of the cylindrical epithelium to the flat epithelium. Ganglion cells disappear into the dentate line and are completely absent beyond the Hilton's white line. The myenteric plexus of Auerbach is located between the longitudinal and circular muscular layers of the muscular layer and plays a fundamental role in the control of motor function (peristalsis and intestinal transit). The submucosal plexus of Meissner is involved in the reflexes that regulate the blood flow and the cellular function of secretion and absorption. The intrinsic nervous system responds to mechanical, osmotic, and chemical stimuli coming from the intestinal lumen. The innervation of rectum and anal canal comes from the upper and lower hypogastric plexuses. The superior hypogastric plexus (presacral nerves) originates from the lower edge of the third lumbar vertebra and terminates at the upper part of the sacrum. The inferior hypogastric plexuses are located on each side of the rectum, of the prostate, of the seminal vesicles and at the lower posterior part of the bladder in the male, in the uterus and vaginal surfaces in the female. In the two sex there is s rectal, bladder, vaginal, and uterine innervation. Nerves are connected to the upper hypogastric plexus. Hypogastric nerves carry most of the orthosimpatic fibers to the pelvic plexuses. Parasympathetic fibers enter the plexus as pelvic spinal nerves. The rectum is innervated bilaterally, but the nerves of the opposite sides are anastomosed into the wall through the enteric plexus. In addition to the lower hypogastric plexus, the walls of the rectum receive branches directly from the splanchnic nerves, and from the terminal branches of the inferior mesenteric plexus. The voluntary external sphincter muscle of the anus is innervated by the lower branches of the lower hemorrhoidal nerve, a collateral joint branch of the pudendal plexus, together with branches coming from the perianal branch of the fourth sacral nerve and the perineal nerve, terminal branch of the pudendal nerve. The levator ani muscle receives innervation directly from the sacral roots S2–S4 or from the muscular branches of the pudendal plexus. The group of motoneurons (about 625 from both sides of the medulla) from which the motor fibers originate is located in the ventral horn of S2 and also from S1 to S3 [39]. The motoneurons are the origin of the pudendal nerve and are involved in the urinary continence, defecation, and contraction during orgasm (Onuf's X nucleus, 1899) [48]. The internal sphincter muscle of the anus, involuntary, is regulated in its function by the intrinsic autonomous plexuses of the intestine. It is innervated by the branches of the pelvic plexus, whose

sympathetic component determines its contraction, the parasympathetic one ensures its release. It is controlled by the myenteric plexus through local reflex mechanisms. The sensory component of innervation has different characteristics above and below the dentate line. The epithelium of the anal canal up to about 15 mm above the dentate line is rich in free and corpuscular nerve endings, particularly close to the anal valves, while at the perianal level there are only free terminations. At the level of the pecten and in the region of the crypts and of the anal valves there are corpuscles of Golgi Mazzoni, Meissner of Krause, and genital corpuscles. They are responsible for critical sensitivity for the discriminative capacity between solid, liquid, and gaseous material. In the colorectal mucosa, the sensory terminations abruptly disappear. The corpuscles of Pacini, at the intramucosal level and in the intersphincteric space, together with the neuromuscular spindles and the tendon organs of Golgi are proprioceptive terminations sensitive to changes in neuromuscular tension [45]. Sensory afferences reach through the lower hemorrhoidal nerve, branch of the pudendal nerve, II, III, and IV sacral segment. The area below the transition zone has somatic innervation. The area beneath the transition zone has somatic innervation resulting from the branches of the pudendal nerve (S2-S3-S4), which exiting the small pelvis through the large ischial foramen and passing between sacrospinous and sacrotuberous ligament (Alcock's canal) it reaches the ischiorectal space and it ends in the superficial innervation of the skin of the perineum, penis, clitoris, prepuce, and glans [49]. The tactile, thermal, and pain sensitivity at this level is remarkable for the presence of numerous free nerve endings.

2.2.2 Continence and Defecation

The functions of the anorectum are to maintain fecal continence and to allow defecation at the desired time and place [50].

The rectal *compliance* is the property of tonic adaptation of the bowel by volume increase without pressure increase (relationship between the intrarectal pressure and volume of distension). Compliance is influenced by both the elasticity of the bowel and the reflex regulating smooth muscle activity. From the point of view of motility, the rectum has a periodic activity of contracting at the sigmoid–rectal junction (PRMA). These are contractions of amplitude >8 mm/Hg, 2–3 min. frequency and >3 min duration. The reverse pressure gradient that is created determines a barrier resistant to the progression of feces during sleep. At the anal level, the different pressure between the distal and proximal part of the anal canal determines a vector force in the direction of the rectum, which is important in the control of liquid stools and gases.

The recto-anal sensory aspect is important for continence. We distinguish two types of sensitivity related to the mechanism of defecation: (1) the perception of rectal distension; (2) the ability to discriminate the characteristics of rectal content. Sensitivity to distension is related to the presence of extrinsic receptors in the rectum, located in the puborectalis muscle and around the pelvic muscles. As the receptors that determine proprioceptive reflex mechanisms are external to the walls of the rectum, the reflexes

remain intact even after low resection of the rectum. The anal canal, unlike the rectum, is full of tactile, thermal, and painful receptors. When the arrival of the fecal bolus determines the distension of the ampulla and the reflected dilatation of the internal anal sphincter, these receptors come into contact with the fecal content and discriminate its characteristics so that the subject can decide whether to evacuate or not.

In the anal canal there is a high pressure area which extends for 3–5 cm from the anal margin with values between 25 mm/Hg and 120 mm/Hg and which constitutes an effective barrier to the rectal pressure (5–20 mm/Hg). This pressure regimen is maintained essentially by the activity of the internal anal sphincter regulated by the sympathetic and parasympathetic innervation and by the intrinsic enteric one. The tone is permanent, its action escapes voluntary control and is decisive for the automatic maintenance of continence. A further function of the IAS is represented by the Inhibitory Rectal Anterior Reflex (RIRA) which consists in a temporary inhibition of the IAS resulting from the distension or contraction of the rectum. It is a local reflex supported by intramural, lacking in patients suffering from Hirschsprung disease, and extramural at the puborectal level. The SAE also contributes to the maintenance of the basal tone with a voluntary mechanism. Its striated musculature differs from others in that it presents an electromiographically demonstrable basic tonic activity. According to the "three loop theory" of Shafick, a hermetic closure of the anal canal is obtained by the opposite direction of the three groups of fibers forming the EAS: the contraction of the upper and lower parts brings the posterior wall of the anal canal toward the anterior wall; the contraction of the intermediate part brings the front wall toward the back. The combined action of opposing forces contributes to the closure of the anal canal by direct mechanical action and kinking.

The puborectalis muscle sling determines the occlusion of the lumen of the anal canal together with the basal tone of the internal and external sphincters. The anorectal angle (about 90° at rest) due to the tonic contraction of the rectal pubis muscle is the most important mechanism for the preservation of continence. According to Parks' flap advanced theory, the mucous flap of the anterior wall is applied to the upper extremity of the anal canal, leading to occlusion of the lumen thanks to the anterior puborectalis stretching which keeps the walls collapsed so that each sudden increase in intra-abdominal pressure (coughing, stress) discharges to the anterior wall while keeping the distal rectus closed.

In the subcutaneous tissue of the anal canal, there are structures bearing, vascular, connective tissue and muscle-elastic, the so-called corpus cavernosum recti. These structures with their ability to expand strengthen the closure of the anal canal contributing to the maintenance of continence for 10–15%.

The volume and consistency of feces vary in the same individual and from individual to individual and between different geographical areas [51]. The consistency of feces can play an important role in colonic transit time. When the colonic content is liquid, transit is accelerated since the left colon does not store fluids. The consistency of feces is a factor conditioning continence. Some patients may be continents to solid stools but incontinent to gases and liquid stools. This is important in the orientation on the type of treatment of incontinence since in these cases it may be sufficient to operate to change the consistency of the feces and thus recover fecal control.

The stimulus to defecation is caused by the distension of the rectum, induced by the propulsive activity of the colon [51]. Mass movements of the colon, which occur 3–4 times a day, are triggered by the intake of adequate volumes of food and at least 650 calories. The defecation is regulated by several factors in balance between them: environmental factors, conditioned reflexes, colonic content. The defecatory urgency can be suppressed by cortical inhibition of anorectal reflexes, favored according to patterns of behavior acquired (in the morning after breakfast, after food or liquid intake), suppressed by change of habits (hospitalization, change of eating habits). Normally the distention of the rectum induces the reflexes of the internal sphincter (RIRA) and contraction of the external sphincter (RAER). In this way continence is determined and discrimination of fecal content is permitted. If it is decided to evacuate the internal sphincter inhibition reflex remains, the external and puborectal reflex is released with consequent opening of the anorectal angle [52]. At this point the pressure of the rectal ampulla exceeds the pressure in the anal canal with expulsion of feces. Defecation requires an increase in intra-abdominal pressure caused by the contraction of the abdominal wall muscles. To prevent the viscera from ascending to the thorax, the glottis remains closed and the diaphragm contracted (Valsalva maneuver). The intersphincteric longitudinal muscle with its contraction determines a shortening and widening of the anal canal which compensates the stretching due to the passage of the feces, thus resulting in a preventive mechanism against the onset of rectal prolapse. If it is decided to postpone defecation, the voluntary contraction of the external sphincter and puborectalis muscle is maintained, the rectal ampoule adapts its tone to the increased content, and the inhibitory anal rectum reflex is exhausted allowing again the contraction of the internal sphincter.

2.2.3 Pathophysiology of Incontinence and Disorders of Defecation

The resistance to the loss of feces and gas is due to the dynamic barrier function exerted by the sphincters (internal, external, and puborectalis) to the changes of the intrarectal pressure at rest, and intra-abdominal during the mass peristaltic movements. Puborectalis muscle dysfunction determines complete incontinence; the dysfunctions of the SAE determine an altered voluntary control (urge incontinence) [53]; the dysfunctions of the IAS are associated with an altered control of the basal tone at rest (passive incontinence). Hemorrhoids under normal conditions contribute to the closure of the anal canal by 10–15% [54]. Removal of the hemorrhoids may result in an alteration to their closure function [55]. The configuration of the anal canal is important in maintaining its closure, as it exerts an adequate and concentric pressure, transmitted and distributed over the entire length of the anal canal (*high pressure zone*). An alteration or deformation of the ano-perianal configuration may cause significant symptoms such as fecal leakage or incontinence to liquids despite an apparent normal blood pressure profile. This occurs as a result of surgical trauma. The quality and propulsive force of feces are at the root of possible

continence dysfunction. In particular, the increase in fecal mass (as in the case of fiber supplement) and in the production of gas can cause episodes if fecal loss and a reduction in conscious control. The increase in the propelling axial force as in diarrhea (as for example in the IBS or IBD) is associated with an unfavorable change in the consistency of the faces and is a further threat to the sphincter complex. The reservoir function is guaranteed: (1) by the ability of the rectum to store feces, even if an excessive capacity, as in the megarectum, can lead to an ineffective emptying; (2) from the rectal compliance which reflects the distensibility of the rectal wall. The prolapse of pelvic organs, a degenerative pathology, mainly affects women. The instability of the pelvic structures and the ineffectiveness of completing fecal and urinary emptying can lead to a reduction in the reservoir function with frequent, unwanted stimulation to evacuation over time. The reservoir function is also altered when there is a reduction in compliance following surgery on the rectum [56], irradiation of the pelvis (neoplasms of the rectum, uterus, prostate); in the presence of tumors, narrowing of the lumen, or inflammation of the rectal wall (IBD, abscess, proctitis, etc.). The central nervous system creates a network of information coming from the unconscious and unconscious nature, necessary for adequate control. Possible central neurological deficits include focal stroke lesions, tumors, trauma, multiple sclerosis; or widespread brain alterations (dementia, infections, drugs). Peripheral innervation ensures adequate somatic and visceral nerve transmission to the intestine, pelvic floor, and sphincter complex. Peripheral neuropathy may be localized (multiparity, pudendal nerve neuropathy, pelvic irradiation, after-effects of surgery) or be widespread as in diabetes mellitus, drug neurotoxicity, chemotherapeutic agents (oxaliplatin). Functional alterations in the absence of morphofunctional correlation (hypersensitivity, spasticity, increase in propulsive movements) are the basis of inflammatory bowel syndrome (IBS) disorders [57].

Within the framework of the functional constipation abscess, groups of patients with symptoms related to the difficulty of expulsion are identified in which anatomical/functional changes of the anorectal region and pelvic floor are involved. The paradoxical contraction of puborectalis muscle during the evacuative thrust is also known as anism [58]. Pelvic floor dysfunction may indicate both functional alterations of the anal sphincters and the remaining musculature of the perineal plane [59] and also include structural alterations such as rectal mucous prolapse, intussusception, rectocele, lack of relaxation of the perineal plane or its poor coordination [60], and also, according to other authors, the consequence of structural pelvic changes [61–63]. This set of functional and structural anomalies are included under the term of defecation disorders [64].

Interdisciplinary Comment
The physiology of fecal continence shows analogies with urinary continence due to anatomical and functional similarities.

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Urinary and Fecal Incontinence: Preoperative Considerations

3

Michele Pennisi and Alvise Frasson

3.1 Urinary Incontinence

Male urinary incontinence (UI) is a multifactorial disease. Details of the type of UI as severity and voiding symptoms usually allow to define whether the patients are affected by stress urinary incontinence (SUI), urgency urinary incontinence (UUI), or mixed urinary incontinence (MUI). Furthermore, patients with associated pain, hematuria, recurrent urinary tract infection (UTI) or with a history of prostate surgery or radiotherapy or suspected neurological disease need rapid referral to an appropriate specialist. In this way the patient should also be asked about medications and other diseases that may impact on symptoms of UI and medical history should be collected with the help of a voiding diary recording as follows:

- the amount of liquid he drinks
- frequency of micturition
- micturition volume
- frequency and amount of the leaks
- whether he felt a strong urge to go before leaking
- whether the leak occurred after a strain, or, coughing or sneeze
- how long the symptoms have been occurring

Symptom scores, symptom questionnaires and health-related quality of life (HRQoL) measures, validated for the language in which they are being used, may be useful to measure outcomes, but in men ICIQ-UI-SF score does not differentiate

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UI types, evidence on their sensitivity is inconsistent and there is no evidence that use of QoL or condition specific questionnaires have an impact on outcome of treatment. The European Association of Urology (EAU) recommends to use a validated and appropriate questionnaire when standardized assessment is required (Grade B).

Clinical examination is an essential part of assessment of men with UI. Abdominal examination allows us to detect a bladder overdistension or other abdominal mass, and perineal and rectal digital examination an enlarged prostate, changes in sensitivity and perineal and anal tone, a perineum descending, alterations of anal and bulbocavernosus reflexes. A cough test may reveal SUI if the bladder is sufficiently full.

Urinalysis and urine culture should be included in males with UI to rule out a urinary tract infection that may be asymptomatic or aggravate the symptoms.

Post-void residual, measured by catheterization or ultrasound, also if it is recommended the latter, is important because residual worsens symptoms and can cause urinary infections.

Urodynamic tests like multichannel cystometry with pressure/flow study, urethral pressure profilometry, Valsalva leak point pressure and videourodynamics, usually are performed to confirm diagnosis and predict treatment outcome. In spite of the widespread of use, these invasive tests, there are no RCTs, confirming their usefulness to predict outcome of surgery for incontinence after a radical prostatectomy. It is also uncertain if urodynamics will distinguish causes of incontinence, but can be used to rule out pure detrusor dysfunction, identify poor bladder compliance and confirm the diagnosis of intrinsic sphincteric deficiency.

The recommendations of EAU on the use of urodynamic examinations in patients are:

- Advise patients that the results of urodynamics may be useful in discussing treatment options, although there is limited evidence that performing urodynamics will predict outcome of the treatment for uncomplicated urinary incontinence.
- Perform urodynamics if the findings may change the choice of invasive treatment (GR B).
- Do not use urethral pressure profilometry or leak point pressure to grade severity of incontinence or predict the outcome of treatment (GR C)
- Clinicians should:
  - ensure that the test replicates the patient's symptoms;
  - interpret results in the context of the clinical problem;
  - check recordings for quality control;
  - remember there may be physiological variability within the same individual.

Pad test is usefulness in quantifying severity of urinary incontinence and selecting the ideal candidate for periurethral bulking agents. Furthermore, change in leaked urine volume on pad test can be used to measure treatment outcome. There are two versions of pad test, the short-term, performed for 1 h in clinic and the long-term pad test, performed for 24 h at home. There is no evidence that one type is superior to another, but 24-h pad weights have been shown to be superior and are considered the gold standard for objective measurement of urinary incontinence. Previous authors have categorized incontinence into three categories: mild if <100 g/24 h, moderate if 100–400 g/24 h and high-grader if >400 g/24 h. Variation in activity level can lead to

significant differences in 24-h pad weights: changes greater than 100 g can be seen in patients who have different physical activity during the day.

Urethrocystoscopy can be useful to verify the state of the sphincter, the ability to contract it voluntarily and its occlusion compressing and lifting the perineum.

There is a general consensus that magnetic resonance imaging (MRI) provides good global pelvic floor assessment; however, there is a large variation in MRI interpretation between observers and little evidence to support its clinical usefulness in the management of urinary incontinence.

De Lancey and coworkers in a pilot study on functional and anatomical differences between continent and incontinent men post-radical prostatectomy on urodynamics and 3T MRI conclude that men with PPI were not able to increase urethral pressure with a Kegel maneuver despite similar resting urethral pressure profiles. Additionally, incontinent men had shorter urethras and were more likely to have distortion of the sphincter area. All suggesting that the sphincter in men with PPI is both diminutive and poorly functional. However, De Lancey and coworkers in an evaluation with dynamic MRI of urethral hypermobility post-radical prostatectomy assert that there are no statistically significant differences in bladder neck and urethral position or mobility on dynamic MRI evaluation between continent and incontinent men.

The evidences of the EAU guidelines on the use of imaging (ultrasound and MRI) in the diagnosis of urinary incontinence in men are:

- Imaging can reliably be used to measure bladder neck and urethral mobility, although there is no evidence of clinical benefit for patients with urinary incontinence (LE 2b).
- There is no consistent evidence that bladder (detrusor) wall thickness measurement is useful in the management of urinary incontinence (LE 3).

So the EAU guidelines recommendation is: "Do not routinely carry out imaging of the upper or lower urinary tract as part of the assessment of urinary incontinence (GR A).

Interdisciplinary Comment

The steps that constitute the diagnosis of urinary incontinence in the male are indispensable and in this context the videourodynamics represents an inalienable investigation that allows us to objectivate the presence of the sphincter insufficiency.

As described by Frasson, clinical conditions leading to anal (when the patient is incontinent just to gas, and is able to contain liquid and solid stool) and fecal incontinence are very numerous. Any of the factors that allow continence and defecation may be involved in the disease. The diagnosis is therefore extremely important: sphincters, rectal compliance, anorectal sensitivity, colonic transit time, characteristics of the stool, mental attention, manual and walking capabilities, and so on, must be evaluated together with his quality of life. There is not, like for urodynamics, a single diagnostic test suggesting us the best treatment: the patient must be fully investigated and really considered a person before just a patient.

3.2 Fecal Incontinence

Faecal incontinence is a debilitating disease with an enormous impact on quality of life, and with several social, economic and medical implications [1]. The International Continence Society stated that 'anal incontinence (AI) is the involuntary loss of flatus, liquid or solid stool that is a social or hygienic problem', while faecal incontinence is 'the involuntary loss of liquid or solid stool that is a social or hygienic problem'. The reluctance of patients to admit symptoms of AI or FI makes it difficult to establish their true prevalence, which in the literature is reported at about 2–17% in the general population [2]. It is likely that this wide range can be linked to a mis-classification of the most important etiological factor of incontinence. The aetiology and pathophysiology of incontinence in men are different than in women [3], while the severity of symptoms and their impact on quality of life are almost comparable between the genders. Faecal continence is a multifactorial function that involves anal sphincters, anal and rectal sensitivity, rectal compliance, faecal consistency, anal and rectal innervation. Commonly, AI and FI are caused by more than one pathophysiological alteration at the same time [4]. The pathogenic factor could be a simple or complex structural defect or disruption of the anal sphincter, although a weak but intact sphincter due for example to diabetes, denervation of pudendal nerves or other neurological disorders, spinal trauma, inflammatory bowel disease, rectal prolapse, primary muscle degeneration, could cause the same symptoms. This variety of etiological factor (Table 3.1) makes a misdiagnosis

Table 3.1 Causes of faecal incontinence [6]

Structural abnormalities	
Anal sphincter	Haemorrhoidectomy, anal dilation, radiation, inflammatory bowel disease
Rectum	Prolapse, hypersensitivity/hyposensitivity, neoplasms, congenital abnormalities, excessive perineal descent
Puborectalis muscle	Trauma
Pudendal nerve	Surgical injury, excessive perineal descent
Central nervous system, spinal cord, autonomic nervous system	Spinal cord injury, head injury, stroke, back surgery, diabetes mellitus, multiple sclerosis, tabes dorsalis, cauda equina injury or tumour
Functional abnormalities	
Anorectal sensation	Central nervous system/autonomic nervous system injury, diabetes mellitus, inflammatory bowel disease
Faecal impaction	Dyssynergic defecation
Stool characteristics	
Volume and consistency	Inflammatory bowel disease, irritable bowel syndrome, medications, infections
Irritants	Bile salt malabsorption, laxatives
Hard stools and retention	Dyssynergic defecation, faecal impaction, medications
Other	
Physical mobility and cognitive function	Aging, disability, dementia, sedation
Psychosis	Wilful soiling

easy, as it is, for example, reported with incontinence due to childbirth since the inability of a proper diagnosis occurs in 87% of midwives, 28% of young doctors, 14% of physicians, compared to 1% of experienced clinicians [5].

The diagnosis of the true cause of incontinence is of the greatest importance in the planing of an appropriate medical therapy, thus a proper training is critical to allow an undiagnosed or misclassified etiological factor to be correctly diagnosed. Moreover, equally essential is the differential diagnosis of incontinence and pseudoincontinence, which is a medical condition that mimics incontinence symptoms [6–8].

It is mandatory that physicians perform a full assessment of patients including medical history, general physical examination and proctological examination, instrumental studies, with the aim to fully outline incontinence's characteristics and thus provide important tips about future therapies (Table 3.2).

A thorough history represents the first step of the clinical evaluation. The medical history must not be focused only on AI, but rather on retrieving all of the patient's medical information concerning systemic disorders and co-morbidities as urinary incontinence, previous surgery (urological surgery, proctological surgery or oncological surgery), spinal injuries, trauma, drugs and lifestyle [3, 4, 6]. Furthermore, the patient should be interviewed on bowel habit and on bowel care including diet, fluid intake and laxatives, and how these influence AI. Until recently, incontinence was underreported in men, as it was thought to be mainly a childbirth-related dysfunction. Literature's data have actually shown that the incidence of incontinence and its impact on quality of life are quite similar between the genders. Nevertheless, women are more likely to talk about this topic and seek help for symptoms, as incontinence causes severe restriction both in sexuality and in sexual activity mostly in women [3]. The symptoms experienced by the patient must be deeply investigated to rule out every other condition that causes soiling or incontinence (e.g. fistulas, external haemorrhoids, anal or low rectal tumours). If the patient describes an

Table 3.2 History and physical examination for faecal incontinence [6]

History	Onset, duration and pattern of symptoms
	Stool consistency
	Associated symptoms: Urgency, lack of sensation of stool passage, urinary incontinence
Medical history	Diabetes mellitus, multiple sclerosis, radiation treatment, dementia
Surgical history	Haemorrhoidal surgery
	Perianal surgery
	Bowel resection
	Cole
Medications	Psyllium fibre, antibiotics, proton pump inhibitors, etc. (see text)
Physical examination	Perianal scars, fistulae, fissures, skin irritation
	Haemorrhoids, anal skin tags, prolapse
	Anocutaneous reflex (anal wink)
	Digital rectal examination—resting and squeezing anal sphincter tone, masses
	Sensation intact? (i.e. aware of urge to defecate on rectal examination; anal sensation)

Table 3.3 Types of anal incontinence

Type	*Description*	*Defect*
Flatus incontinence	Incontinence of flatus due to inability to differentiate gas from solid or liquid	Internal anal sphincter
Passive leakage	Involuntary soiling or discharge of liquid or solid stool without patient awareness	Internal anal sphincter
Urge incontinence	Inability to retain faeces as long as needed to find a toilet once the need to defecate is perceived	External anal sphincter

Table 3.4 The Wexner Score [9]

	Frequency				
Type of incontinence	Never	Rarely	Sometimes	Usually	Always
Solid	0	1	2	3	4
Liquid	0	1	2	3	4
Gas	0	1	2	3	4
Wears pad	0	1	2	3	4
Lifestyle alteration	0	1	2	3	4

Never, 0; rarely, <1/month; sometimes, <1/week; ≥1/month; usually. <1/day, ≥1/week; always, ≥1/day
0, perfect; 20, complete incontinence

AI only for liquid stool, then a colonic cause of diarrhoea should be excluded. If an AI is present, it must be differentiated as a flatus incontinence, passive leakage or urge incontinence (Table 3.3), never forgetting that an overlapping between these conditions is always possible.

Keeping a daily incontinence diary is essential to clarify the characteristics of incontinence such as the timing, amount, pattern, duration and need of pads. Hence, the severity of AI can be graduated as (a) minor, if incontinence happens less than once a month; (b) moderate, if incontinence to solids happens more than once a month or to liquids more than once a week; and (c) severe, when incontinence to solids and/or liquids happens daily or several times a week. All these characteristics can be better classified with grading systems such as the Wexner score system (Table 3.4) or the American Medical Systems (AMS) score (Table 3.5), which allow one to use an objective parameter to evaluate AI, to verify the response to therapy and to follow up its evolution.

It is also important to interview the patient on the impact of incontinence on the quality of life, satisfaction, needs, restrictions, anxiety and/or decreased mood, sexual dysfunction and on how AI influences them. Questionnaires such as the SF-36, FIQoL or others are critical to outlining these characteristics [4, 7, 11–13].

The proctological examination should start from the inspection of the perineum and anus, checking their integrity and looking for scars from previous surgery, a keyhole deformity of the anus suggesting a sphincter defect, or just for irritation or

Table 3.5 The American Medical Systems (AMS) score [10]

Over the past four weeks, how often	*Never*	*Rarely*	*Sometimes*	*Weekly*		*Daily*	*Several times daily*
Did you experience accidental bowel leakage of gas?	0	1	7	13	19	25	
Did you experience minor bowel soiling or seepage?	0	31	37	43	49	55	
Did you experience significant accidental bowel leakage of liquid stool?	0	61	73	85	97	109	
Did you experience significant accidental bowel leakage of solid stool?	0	67	79	91	103	115	
Has this accidental leakage affected your lifestyle?	0	1	2	3	4	5	

Several times daily, >1 episode a day; daily, 1 episode a day; weekly, 1 or more episodes a week but <1 a day; sometimes, >1 episode in the past four weeks but <1 a week; rarely, 1 episode in the past four weeks; never, 0 episodes in the past 4 weeks

excoriation of the skin due to soiling. Moreover, during the inspection one should ask the patient to strain in order to check the presence of a descending perineum or of mucosal, haemorrhoidal or full-thickness rectal prolapse. Then, the digital rectal examination verifies the sphincter tone at rest (indicative of internal anal sphincter function), in contraction (indicative of external anal sphincter function) and during squeezing, the latter to check the function of the puborectalis muscle, which with squeezing should push the examiner's finger anteriorly. Moreover, the rectal examination can highlight a rectal mass, which can suggest a cancer. Asking the patient to cough will result in an external sphincter contraction, thus checking the anal sphincter reflex. The rectal examination may show an asymmetry of the sphincter suggesting a regional defect. Finally, a proctoscopy and a rectosigmoidoscopy with a rigid instrument must be done to complete the proctological visit.

(a) *Transanal ultrasonography* [14]: Transanal ultrasonography is central to the study of the ano-rectal canal, the internal and external sphincter, the puborectalis muscle and the levator ani muscle, their morphology and any damage, if present, in order to plan therapies. Usually, the assessment of the anorectum is completed with a tridimensional endoanal ultrasound (*3D-EAUS*) and a perineal ecography. Specific scores define the severity of the sphincter damage (Table 3.6). The endoanal ultrasound can recognize and sharply describe many of the following parameters such as the presence of damage of the internal or of the external anal sphincter or of a combined lesion of both, the presence of dam-

Table 3.6 Ultrasonographic scoring system to define the severity of sphincter lesion [14]

Defect characteristic	Score 0	Score 1	Score 2	Score 3
Internal sphincter defect				
Length	None	Half or less	More than half	Whole
Depth	None	Partial	Total	–
Size	None	≤90°	91–180°	> 180°
External sphincter defect				
Length	None	Half or less	More than half	Whole
Depth	None	Partial	Total	–
Size	None	≤90°	91–180°	>180°

Table 3.7 Anorectal manometry parameters

1	Resting anal sphincter pressure
2	Rectal sensory thresholds for first sensation, urge and maximum tolerated threshold
3	Rectal pressure on strain and concomitant anal relaxation or paradoxical contraction
4	Maximum anal sphincter squeeze pressure and duration of maximum anal squeeze pressure (sustained squeeze)
5	Anal pressure on cough
6	Balloon expulsion recorded as time taken to expel a party balloon tied at the end of a section of intravenous tubing and inflated with 50 mL of warm water, from the rectum, while seated on a private toilet

age of the puborectalis muscle, the number and site of damages if these are more than one, the presence of scars, the characteristics of the muscles and of all the other layers (echogenicity, thickness, vascularisation).

To note, sometimes patients have a sphincter lesion without any clinical symptoms of AI, while other patients with AI have no evidence of any damage to the muscle but actually have an atrophic sphincter or the manifestation of a pudendal neuropathy.

(b) *Electromyography (EMG)*: The integrity of or damages to the external sphincter, if present, can be studied by both the single and the concentric needle EMG. Moreover, EMG shows the changes in the electrical activity of the sphincter and of the levator ani muscle due to contraction. Nowadays, its role in the diagnosis of AI's aetiology has been replaced by ultrasound.

(c) *Pudendal nerve terminal motor latency (PNTML)*: Its aim is the study of the time to contraction due to a stimulation to the pudendal nerve. Usually PNTML is prolonged in patients with AI, but the symptoms are not directly proportional to its value. Nowadays, it is rarely used in the diagnostical setting because of this low correlation with symptoms [11, 12].

(d) *Anal manometry*: This exam is a diagnostic test with high specificity and sensitivity in AI diagnosis. It shows many characteristics of the sphincters and of the rectum (Table 3.7). First, it shows the anal sphincters' pressure at rest. Second, it studies the rectal perception of the faecal mass that is distending its wall. This is pointed out by the following parameters: (a) the lowest volume that evocates the first sensation, (b) the volume at need to defecate, and (c) the maximum volume

Fig. 3.1 Multi-Functional Anoscope (MFA—Courtesy of Sapi Med, Alessandria, Italy): an anoscope with a balloon that can be used to measure rectal sensitivity and compliance

tolerated. Third, it describes the rectoanal inhibitory reflex—RAIR—which is the inhibition of the internal anal sphincter tone due to a distension of the rectum. Fourth, it studies the rectal compliance, which is the adaptation of rectum to the incoming stool. This is pointed out by the analysis of the value at rest (showing the tonic function of both the internal and external anal sphincters), or the value during voluntary contraction, Valsalva or cough (external anal sphincter function). Usually, patients with AI have a low resting pressure (defect of the internal anal sphincter), a low squeeze pressure and a low duration of squeezing time (external anal sphincter dysfunction → inability to suppress defecation). Looking at men, the literature describes a longer sphincter length and on the contrary a higher anal squeeze pressure. These data are likely to be link to sexual differences. Moreover, men if compared to women have higher anal resting and squeezing pressures, and the likelihood of a shorter duration of sustained squeeze is lower than in women [3]. An alteration of the rectal sensation may contribute to AI by a misunderstanding of the presence of stool and of the need to defecate. Urge AI could be linked to a decrease in rectal compliance, which may cause an increased frequency of defecation and a rapid transit of stool through the rectum.

Even if manometry is a test with high specificity and sensitivity in AI diagnosis, its clinical utility is limited by the low standardisation of the procedure and because in the differential diagnosis of continent and incontinent patients, it is not as much sensible and specific [1, 11, 12, 15].

(e) *Balloon rectal test*: It is a useful test to check rectal sensitivity and compliance quickly. A balloon (Fig. 3.1) is placed in the rectum to mimic the presence of

Table 3.8 Values of the parameters checked with the inflation of an endorectal balloon

Parameters	Normal value
First sensation	30–60cc of air or fluid
Defaecatory desire volume	60–160cc of air or fluid
Maximum tolerable volume	160–270cc of air or fluid
Pain	>270

Fig. 3.2 Digital dynamometer PRAP2000 with solid disposable sphere (Courtesy of Sapi Med, Alessandria, Italy)

Table 3.9 Normal value checked with the solid sphere test

Parameters	Normal value
Voluntary contraction	1000–1200 g
Baseline	200–400 g
Ejection	Ideally 0 g or anyway less than at baseline

stool by its gradual inflation. The inflation of air or fluid allows to measure the volume of the following items (Table 3.8): (1) first sensation; (2) desire to defecate; (3) urgency to defecate; and (4) pain. Usually, in incontinent patients, these values are lower than in the general population (rectal hypersensitivity). Higher values indicate rectal hyposensitivity.

(f) *Solid sphere test* [16–18]: This test studies the rectal sensitivity on outpatients. A solid sphere attached to a digital dynamometer (Fig. 3.2) is introduced into the anorectum. The withdrawal of this sphere out of the anorectum made the dynamometer quantify which is the resistance of the sphincters to sphere's extraction. As the sphere is pulled out, the dynamometer will check the following parameters: (a) first, the patient will contract the sphincter trying to stop the ball extraction → voluntary contraction phase; (b) second, the patient is asked to strain to eject the sphere as quick as possible → ejection phase; (c) third, the sphere is pulled out with the patient at rest → baseline phase (Table 3.9). This test allows us to differentiate the internal sphincter's activity at rest from the external sphincter's activity during contraction. Moreover, it allows for the evidence of a paradoxical contraction or a failure of relaxation of the puborectalis muscle when the patient is asked to strain and the dynamometer shows a value as high as that on voluntary contraction or near to this.

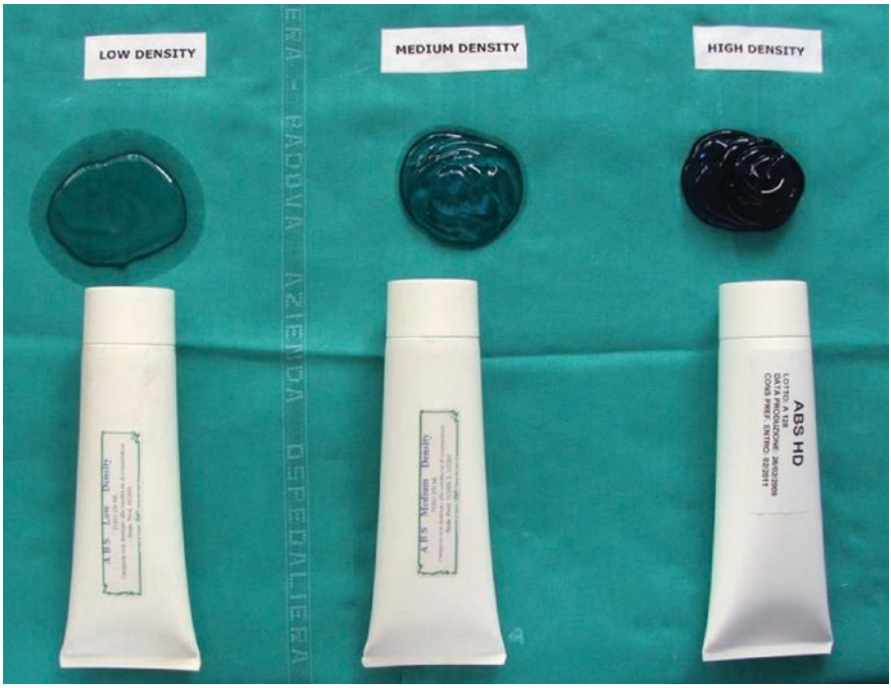

Fig. 3.3 Artificial Blue Stool (ABS): from left to right the low, the medium and the high density blue gel (Courtesy of Sapi Med, Alessandria, Italy)

(g) *Artificial Stool*: The aim of this test is to check the patient's ability to retain faeces by filling the rectum with a blue gel that mimics stool (Fig. 3.3). This gel is available in three different densities: high, medium and low density. The exam is started with the high-density gel. Once the rectum is filled with this gel, the patient is asked to do some physical activity (e.g. walk or climb stairs) and then checked for any incontinence: if the result is negative, the patient undergoes a stress test with a small enema. If no incontinence happens, the patient will be checked with the medium-density gel as described earlier and, if needed, with the low-density one. The test is useful to compare the results after therapy.

Interdisciplinary Comment

The aetiology of faecal incontinence is multifactorial. An accurate patient evaluation is necessary to individualise the dysfunction. In this way, medical history, general physical examination and proctological examination and instrumental studies may help plan the correct treatment.

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Part II

Surgical Procedures and Intraoperative Complications

Artificial Urinary (AUS) and Anal (AAS) Sphincter

4

Salvatore Siracusano, Luigi Fondacaro, and Enrico Melega

4.1 Artificial Urinary Sphincter (AUS)

4.1.1 AMS 800

Artificial urinary sphincter (AUS) is the only mechanical device that closely simulates the function of a biological urinary sphincter. Over the past four decades, advances in mechanical design, applications of new technology and lessons learned from clinical experience have made the AMS 800 device the standard of care in post-prostatectomy urinary incontinence.

It was designed by F.B. Scott, W.E. Bradley and G.W. Timm in 1973. The original model underwent a number of modifications, but the basic principle remained the same. It consists of a fluid-filled hydraulic system with a cuff around the urethra, a pressure-regulating balloon and an activating device, the pump, placed in the scrotum. In this context, clinicians should consider AUS placement no earlier than six months after prostatectomy if patients are incontinent and not improving (Grade of recommendation C).

The device is usually implanted at the level of bulbar urethra by the transperineal approach because the trans-scrotal approach appears particularly useful for simultaneous placement of an AUS and inflatable penile prosthesis through a single incision [1]. Following an adequate antibiotic prophylaxis, the patient is placed in the dorsal lithotomy position. A size 12 catheter is early inserted. A midline perineal

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Fig. 4.1 Bulbar urethral measurement to choice an adequate cuff

incision is made centred on the point at which the catheter makes its bulbar prominence. The dissection is carried down to the bulbospongiosus muscle through subcutaneous fat and superficial fascia. The bulbospongiosus muscle is split in its midline. A lateral dissection of the urethra is carried out sharply and, when complete, the Buck's fascia is visualized. Using Metzenbaum scissors oriented away from the urethra, the Buck's fascia is opened exposing the underlying corpora and the Buck's fascia on the dorsal aspect of the urethra. Same steps are repeated on the contralateral side. So, under direct vision, the circumferential access between the urethra and the corporal bodies is obtained. A right-angle clamp is passed dorsal to the Buck's fascial layer. A tape is passed to allow for further retraction of the urethra for dissection and for ultimate measurement of the urethral diameter and to obtain adequate space for cuff placement. The urethral calibre is measured by a bespoke AMS calibration sling in order to choose an adequate cuff size (Figs. 4.1 and 4.2). Most cases will either for or four and half centimetres.

An isotonic contrast medium is used to fill the whole circuit. This allows for future troubleshooting in case of device malfunction. First, the cuff is prepared: air bubbles are aspirated out of the cuff. The pressure-regulating balloon is squeezed of all air. Routinely a 61–70 cm H_2O pressure-regulating balloon is used. Next, the

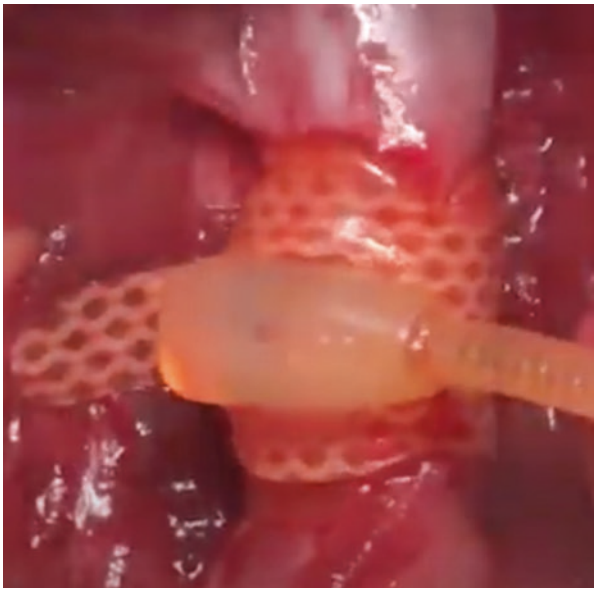

Fig. 4.2 Placement of the cuff around bulbar urethra

pump is prepared: both the inflow and outflow tubing are kept in a basin with medium contrast, and the pump and the deactivation button are squeezed several times so that the air bubbles are expelled from the device.

The cuff is passed around the urethra using a right-angle clamp and the tab is secured to the cuff: care must be taken to ensure that the tab seats well since a common cause of device failure is inadvertent device uncoupling due to a poorly seated tab. A second incision is performed two fingers above the symphysis pubis in a line along the access to the anterior superior iliac spine. Dissection is carried down to the fascia and the fascia is opened, then a Kelly clamp and scissors are used to split the rectus muscle and to develop a pre-purchased space of Retzius for pressure-regulating balloon placement that is performed. 20–25 ml of dilute contrast medium are placed into the balloon. It is important to be sure that the tubing is non-kinked under the balloon since this can be a common source of device malfunction. Next, the scrotal subdartos pocket for the pump is made: a curved sponge stick is passed above the fascial level (subcutaneous space) to the appropriate hemiscrotum. Care must be taken to ensure that the testicle remains posterior to the passage so that the future site of the pump will be anterior and lateral to the testicle. The deactivation button must be pointed anteriorly. The pump is allocated into the previously created subdartos pouch. Tubing from the urethral cuff is then passed superiorly to the pressure-regulating balloon, in subcutaneous space, using a clamp (Fig. 4.3). Care is taken to avoid the spermatic cord during the passage. Then, secure connections are completed using the Quick Connect System provided in the kit (Fig. 4.4). An urethroscopy is performed to exclude urethral injuries and to visualise good coaptation of mucosa. Incisions are sutured in a multilayer fashion using absorbable sutures.

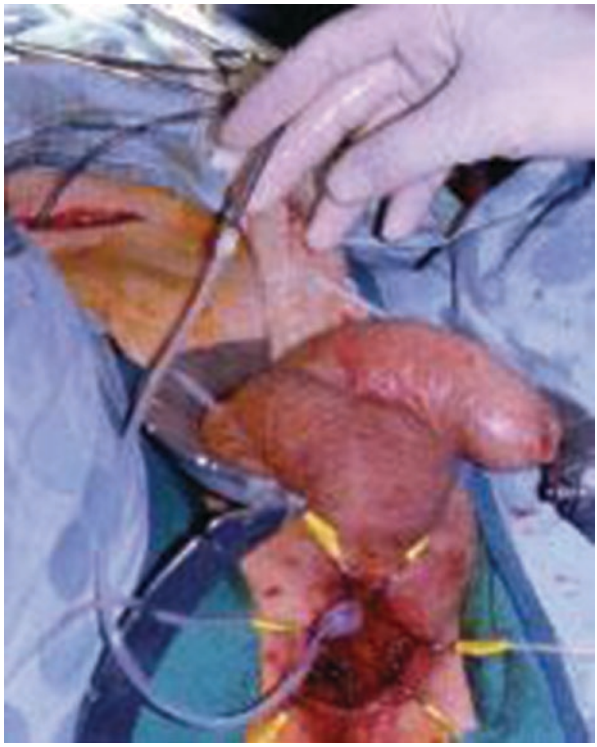

Fig. 4.3 Passage of tubing cuff superiorly

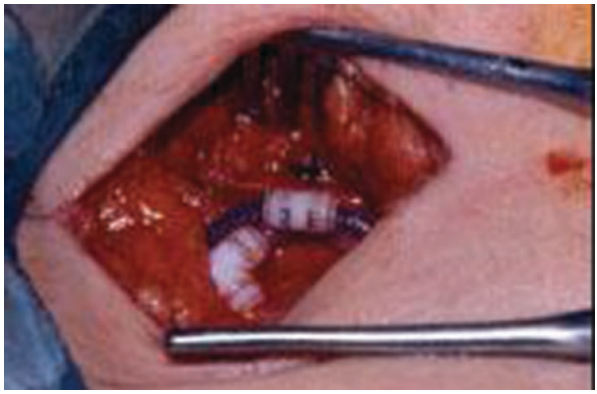

Fig. 4.4 Tubing connecting system

Intraoperative complications are closely related to an incorrect isolation of the urethra, with the perforation of the latter, or due to an incorrect positioning of the pump in the scrotum or the reservoir itself in the Retzius or inside the peritoneum. From a mechanical point of view, it is mandatory to correctly perform all the steps required for the assembly of the prosthesis as it could be the cause of malfunction,

with the need for a surgical revision when the prosthesis is activated. Fortunately, these drawbacks mentioned above rarely occur because the procedure is routinely performed. However, it is recommended that the implant always be carried out by surgeons trained in this surgery.

4.1.2 ZSI 375

ZSI 375 (Zephyr Surgical Implants, Geneva, Switzerland) is a one-piece artificial urinary sphincter (Fig. 4.5) manufactured from medical-grade silicone rubber. It was designed to facilitate AUS insertion because this structure theoretically facilitates implantation and minimises mechanical failures. It has no abdominal reservoir so as to reduce the operating time and to avoid abdominal incision and dissection in scarred retroperitoneum. It comprises two components, a circular urethral cuff (Fig. 4.6) and a pressure-regulating tank (Fig. 4.7) placed in the scrotum. These components are connected by flexible, kink-resistant tubing.

The cuff consists of a moulded curved silicone rubber and comes in a range of different diameters from 3.75 to 5 cm and three different pressure ranges—60–70, 70–80 and 90–100 cm H_2O [2]. It is adjustable around the urethra and pre-connected, and the pressure can be increased in a postoperative setting to improve the patient's continence. The pressure-regulating tank consists of an activation button, a hydraulic circuit and a compensation pouch. At rest, a piston mechanism, under spring-loaded tension, exerts pressure on the fluid in the hydraulic chamber. When

Fig. 4.5 ZSI 375

Fig. 4.6 circular urethral cuff

Fig. 4.7 pressure regulating tank

the activation button is pressed (Fig. 4.8a), the piston descends, forcing fluid from the cuff into the hydraulic circuit and the compensation chamber. So the cuff deflates and the patient can empty the bladder (Fig. 4.8b). Auto-inflation of the cuff (Fig. 4.8c) occurs within 2–3 min, restoring the continence status. The theoretical advantage of the Zephyr device is that it is possible to adjust the pressure of the device by injecting or removing fluid from the compensating pouch, and the lack of a third component to be placed in the retropubic space thereby decreasing the risk of bladder injury and device migration. Two versions of the sphincter manufactured by ZSI are available: a version (ZSI 375) that is initially provided dry and must be filled with a saline solution before insertion: the sphincter must be filled and air bubbles removed; and a pre-filled version (ZSI 375 PF) ready to be implanted.

A size 16 Foley catheter is placed in the urethra for guidance. A perineal incision is performed and the bulbospongiosus muscle is dissected and opened. About 2 cm of urethra are dissected. There is no real cleavage space between the corpus spongiosum and the cavernous corpus: the urethra is gently pulled and the passage is carefully created by a blunt dissection. An inguinal incision is performed because

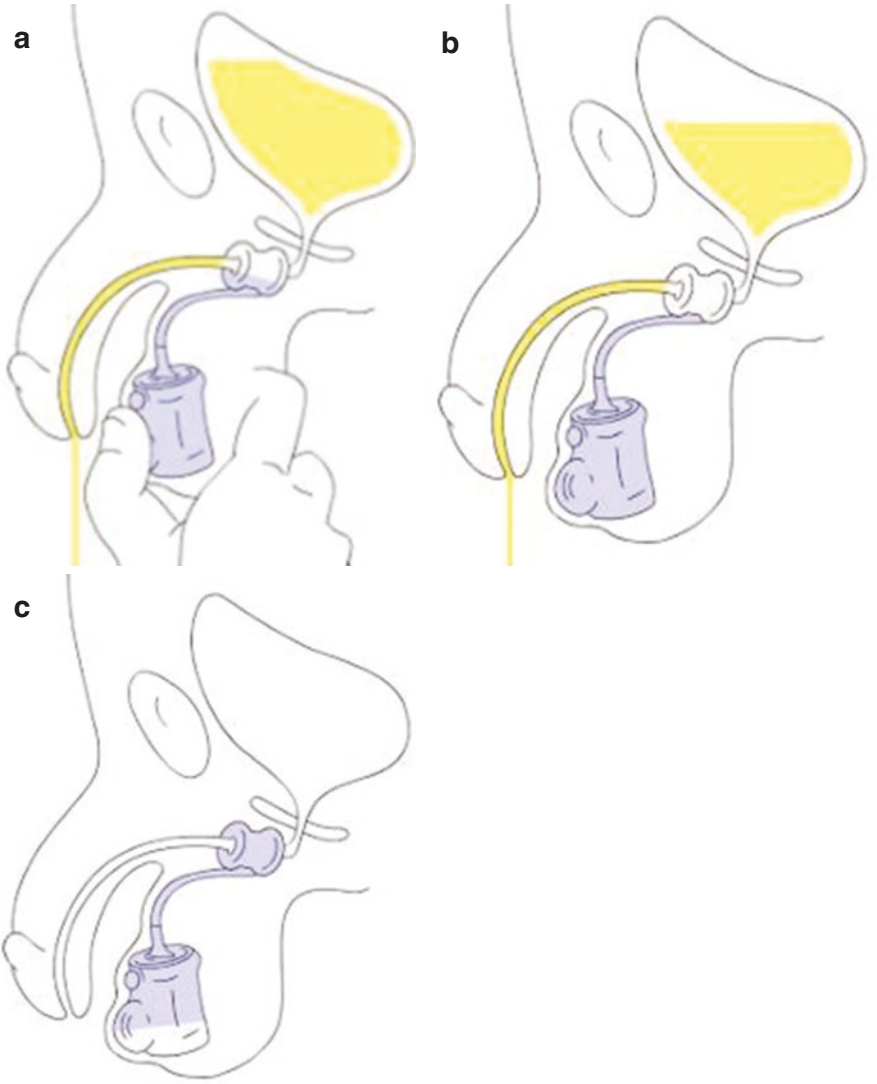

Fig. 4.8 (**a**, **b**, **c**) operating sequences during voiding

finding the subdartos space from an inguinal incision is believed easier than a scrotal incision. A subdartos pouch for the pump unit is prepared by scissors and clamp and enlarged by finger. Then the passage between the perineal and inguinal incisions is created maintaining the subdartos space behind the spermatic cord of the testis and between the dartos of scrotum posteriorly and the cremaster muscle previously.

The blister contains one 5 ml syringe and two Huber needles. First, it is recommended to place the device as soon as possible into a normal saline solution with antibiotics, thereby minimising the time the device is in open air. The preparation of cuff and hydraulic circuit includes performing a vacuum in the device with a 20 ml syringe and injecting 4.5 ml of saline solution with a 5 ml syringe. All air bubbles have to be congregated and gathered into one single bubble, then any remaining air is aspirated from the cuff and the whole hydraulic circuit. Likewise, the preparation of the compensation pouch involves similar steps. Then proceed to the deactivation of the device: the pump button is pressed and released 3–4 times to empty the cuff. The spring of the compensation pouch is stressed below the minus sign. By pressing the deactivation button firmly, the cuff is kept deflated. Pulling the collar tape through the loop, the pillow of the cuff is positioned in contact with the urethra. A non-absorbable suture is placed between the collar tape and the shoulder of the loop. To control the pressure in the hydraulic circuit, the Foley catheter is removed and the activation button is pressed. Finally, the cuff is emptied by pressing the deactivation button of the pump. A size 12 Foley catheter is inserted and a passage of the pump unit is performed from the perineal to the inguinal incision positioning the pump unit in the scrotal subdartos pouch. The wings of the pump unit's butterfly are sutured to the internal scrotal tissue to avoid rotation of the pump unit. Closing the perineal and inguinal incisions completes the procedure.

After the procedure, a 12 Ch Foley catheter is inserted into the bladder. On average, it is maintained for 2.4 days (1–4 days) [3]. The device is activated 8 weeks later.

The patient will be easily able to locate the sphincter pump in the scrotum. On voiding, the patient presses the bulb-shaped pump button. Pressure from the spring refills the cuff via a restriction flow filter over 2–3 min. This allows the patient to empty his/her bladder before the urethra is closed again by the cuff.

Another theoretical advantage is the chance of modulating the cuff's pressure around the urethra: the sphincter pressures can be adjusted via a trans-scrotal approach to improve continence rates. The insertion of 1 ml of saline increases the pressure by 10 cm H_2O.

Are not reported intraoperative complications. Perioperatively, is reported related pain assessed by the use of VAS, with an intensity value of 0.82 (range 0–4) [4]. The early infection rate ranged from 2.2% to 11% [5–7].

Interdisciplinary Comment

As clearly reported by Melega, the implant of the artificial anal sphincter in females and in a smaller number of males has been a short experience between the end of the 1990s and the first few years of this century. The main problem faced by the colorectal surgeons with this initially quite promising procedure (due to the success of the urinary artificial sphincter) is represented by the physiology of continence and defecation. The anus, when needed, must retain gas, solid or liquid stool; solid stool must be easily expelled as well. Actually

the anal artificial sphincter is only partially dynamic. Furthermore, also due to the fibrosis induced by the foreign body in the surrounding tissues, its relaxation and opening, while perfect for urine, requires great efforts with solid or hard stool. This, in our female population in cases with a frail pelvic floor caused genital prolapse.

4.2 Artificial Anal Sphincter (AAS)

In the late 1990s, Christiansen [8] published the results of a series of anal sphincter implantations beginning with an Artificial Urinary Sphincter (AMS 800, manufactured by American Medical Systems, Inc., Minnetonka, MN) for intractable faecal incontinence. AMS Company, after this experience, developed the Artificial Bowel Sphincter (ABS), followed by Acticon Neosphincter (Fig. 4.9), enlarging the length and width of the cuff, and this device was considered an option for severe or otherwise intractable faecal incontinence [9].

Acticon is a dynamic device composed by an inflatable cuff, which is implanted around the anal canal, a pressure-regulating balloon, implanted in the preperitoneal retropubic space, and a control pump, which is placed in major labia in women and in the scrotum in male patients [10]. The inflatable cuff is placed around the upper anal canal through a transverse or bilateral vertical perineal skin incision. Another skin incision is made in the iliac fossa region for implanting the regulating balloon. Each artificial sphincter component is connected by subcutaneous antikinking tubes and filled by isotonic radio-opaque fluid. The inflatable cuff, at rest, is full of fluid in order to close the anal canal. When defecation occurs, the patient manually squeezes and releases several times the pump, permitting fluid transfer from the cuff to the balloon. The cuff is therefore emptied and the anal canal is opened. Due to different pressures between the regulating balloon and the cuff, the fluid is slowly forced back to the cuff and the anal canal is closed again.

Following implantation, the device remains deactivated for at least 6 weeks, allowing for complete wound healing and anal cuff adaptation. Then, the device is activated by pressing the pump.

At the beginning, surgeons enthusiastically welcome the artificial anal sphincter believing that a dynamic device could be an effective option for severe or end-stage anal incontinence. Therefore, mild faecal incontinence and faecal incontinence due to diarrhoea were considered unsuitable for artificial anal sphincter implantation. Other contraindications considered were destroyed or severely scarred perineum, perineal radiation-induced lesions, pelvic sepsis, pregnancy, receptive anal intercourse, inflammatory bowel diseases [10].

In the years 2001–2010, several centres implanted the Acticon anal sphincter for more than 400 procedures [11]. Intraoperative complications were rare, and no intraoperative deaths were reported in the literature [12]. Only Melenhorst [13] reported intraoperative rectal perforation, in one patient from a series of 34, and the

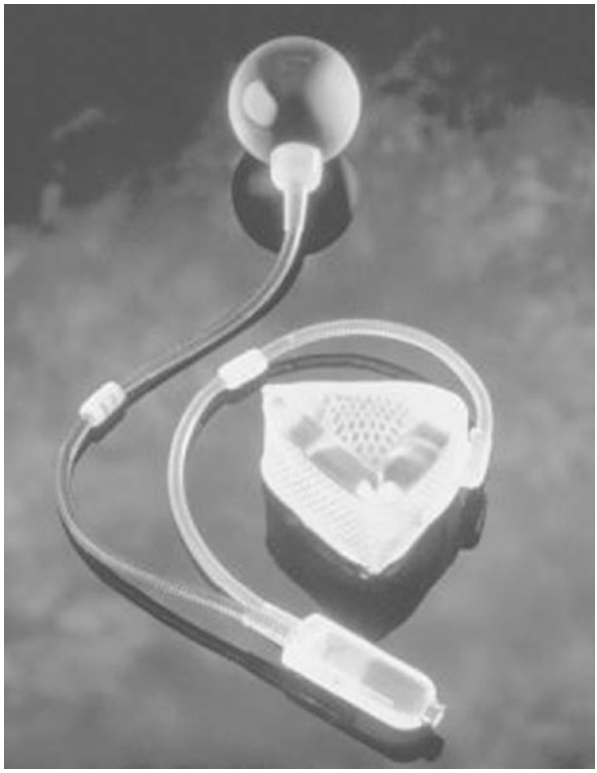

Fig. 4.9 Acticon Neosphincter (Courtesy of American Medical Systems, Inc., Minnetonka, MN)

implantation of the artificial anal sphincter was abandoned and the procedure was delayed until after complete healing of the rectal wound.

In our institution, a series of 17 artificial anal sphincter implantations, in 16 patients, were performed from 1999 to 2003 [14, 15]. The experience was also included in a multicentre Italian study [16]. No postoperative deaths and intraoperative complications occurred.

Interdisciplinary Comment

It represents the replacement of the sphincteric unit by a device highly tested for urinary incontinence. The indications for this device are related to the severity of incontinence and to the compliance of the patient to self-manage this system.

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Slings for Urinary and Fecal Incontinence

5

Christian Gozzi, Salvatore Siracusano, and Filippo La Torre

5.1 Slings for Urinary Incontinence

5.1.1 AdVance: AdVance XP

For the implant of AdVance sling with tension under endoscopic control, we recommend a type of anesthesia that doesn't relax the pelvic floor muscles. This is achieved by laryngeal mask anesthesia without use of curare. In cases of intubation a short-term muscle relaxant should be used, which loses its effect at the time of tension. In case of contraindications to a general anesthesia, a peridural anesthesia is possible only if it keeps intact the motor part of the pelvic musculature. In motivated patients the implant can also be performed under local anesthesia, possibly accompanied by light sedation. A curarization or spinal anesthesia compromises a real endoscopic monitoring because a floppy pelvic floor alters the endoscopic picture of the effect of sling traction.

Positioning of the patient is standardized in a lithotomy position with moderate opening of the legs, knees in width corresponding to the width of the shoulders. Flexion of the hips and knees is about 100°–110°, it must not reach a right angle. The perones are directed towards the respective opposite shoulder.

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Local anesthesia of the perineal incision and transobturator (TO) pathway simplifies both the development of anesthesia and the awakening phase, which is delicate due to involuntary slipping of the sling in the phase of awakening, caused by pain.

A small incision (3–5 cm) is made at the root of the scrotum, avoiding the area near the perineum (Fig. 5.1).

To facilitate implantation the bulbospongiosus muscle can be dissected, but muscle-sparing preparation is recommended to preserve anatomy and to reduce postoperative pains, mainly in a sitting position. Proceed with mobilization of the urethra spongy bulb by section medial raphe until reaching tendon center for a tension free repositioning (Fig. 5.2).

Otherwise in case of prolapse, elevation with the sling is counteracted by the deep insertion of the central tendon with reduced efficiency and danger of erosion.

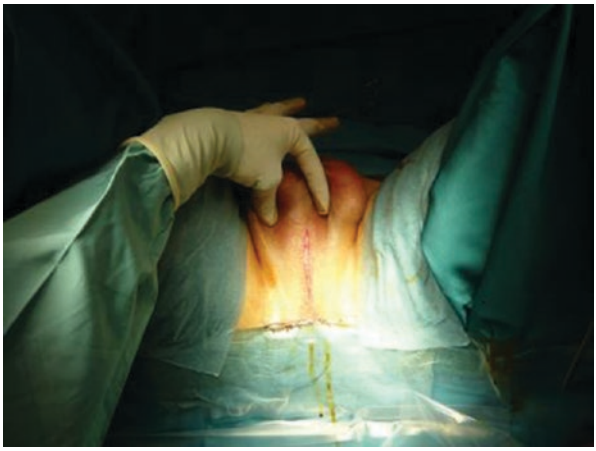

Fig. 5.1 Perineal incision

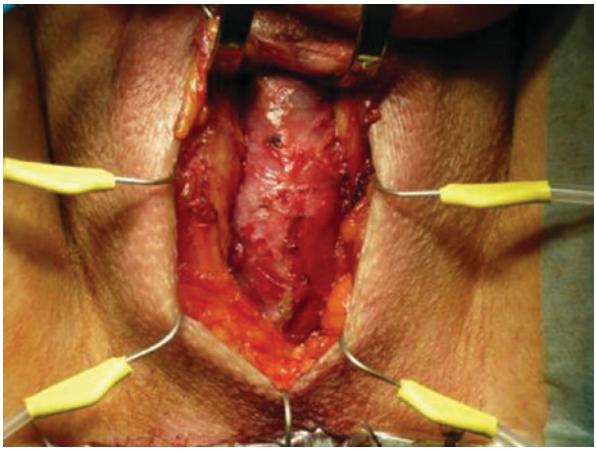

Fig. 5.2 Preparation of the tendon center for the positioning of the sling

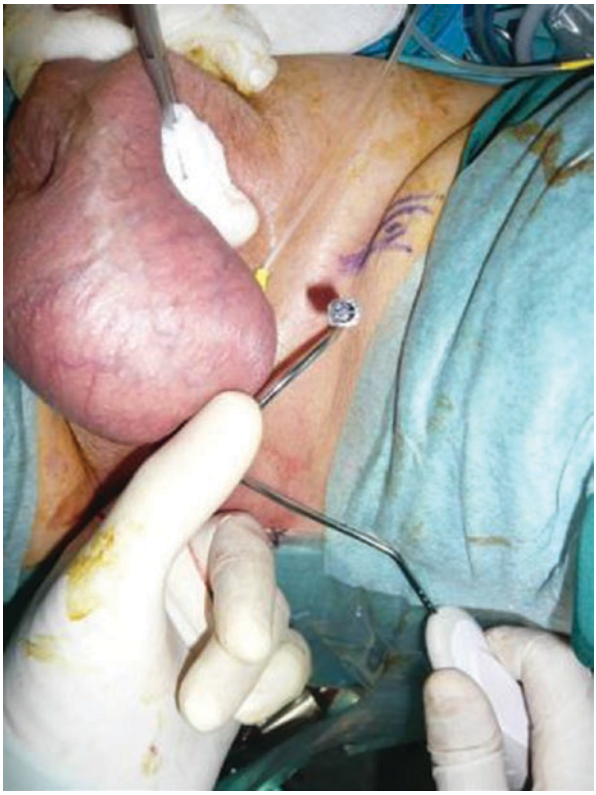

Fig. 5.3 Passage with the helical needles

Place a marking suture (we use 4-0 Vicryl) at the site of the distal extent of the central tendon as soon as you have dissected this part of the central tendon off the corpus spongiosum. The site of this marking suture will be the future site where the distal edge of the broad part of the sling will lay and be secured.

Subsequently the passage with the helical needles will be performed. This should start in the superomedial quadrant of the obturator foramen, at the corner of the pubic branches, near the bone, circumventing it, and emerging between the urethra and os pubis more cranially possible, directly against the urethra (Fig. 5.3). Throughout the maneuver the needle has to be maintained at 45° until it reaches the finger of the hand that awaits the blunt tip of the needle in the corner between the pubic branch and the urethra (Fig. 5.4). Then the end of the sling has to be inserted to the tip of the needle until hear the click (Figs. 5.5 and 5.6).

At this point, the sling through the reverse rotation of the needle will be placed in the right position. We will proceed contralaterally in the same way (Fig. 5.7).

The sling now has to be fixed to the spongy bulb in the medial raphe, previously dissected. This fixation can take place by means of either two distal parallel stitches or with four stitches, two parallel distal and two proximal parallel ones. We recommend to use long-absorption thread such as PDS 4-0 or 4-0 Prolene with atraumatic needle.

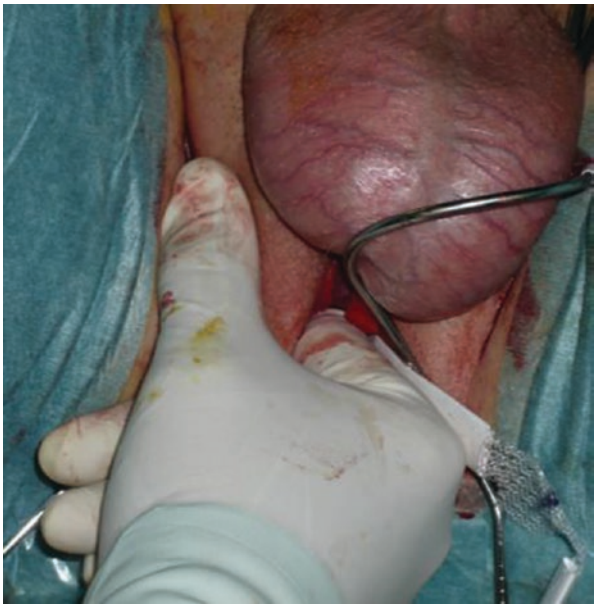

Fig. 5.4 Passage with the helical needles

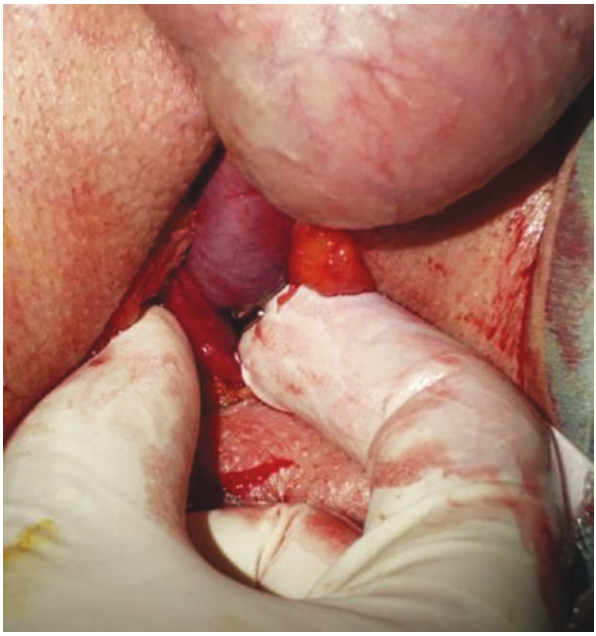

Fig. 5.5 Passage with the helical needles

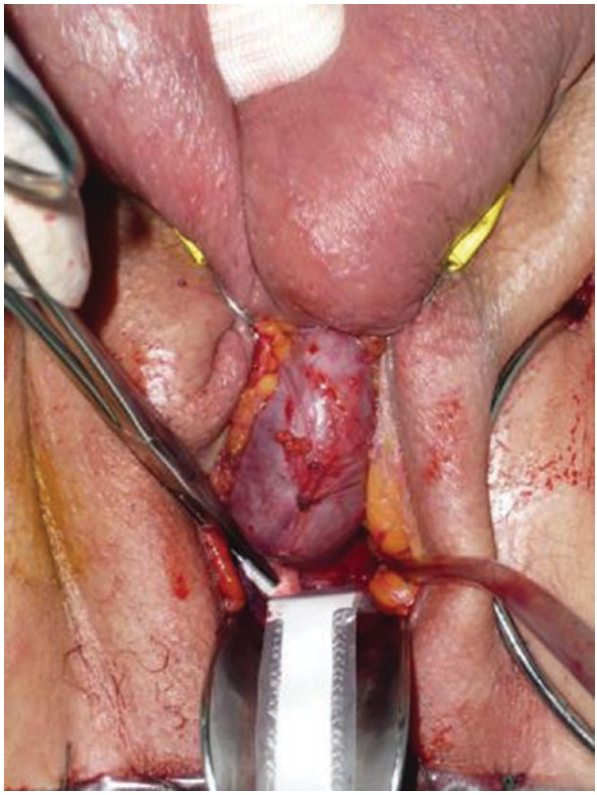

Fig. 5.6 Passage with the helical needles

However, in order to avoid the curling of the sling during the traction, it is advisable to fix the bulb on the sling with more points (4–6) in the longitudinal direction along the raphe (Fig. 5.8).

In this way also the prolapsed spongy bulb of the urethra is fixed on the sling and 90° rotated (from horizontal to vertical) (Fig. 5.9), thus facilitating the function of the sphincter and therefore the continence.

The degree of repositioning, anteriorization and concentric contraction is controlled endoscopically by 17 cm ureteroscope with 0° optic positioned in the proximal bulbar urethra. A lace around the penis prevents contamination of the operative field. The removal of the sling sheaths is performed under cystoscopic guidance to avoid hypertensioning, by positioning between urethra and sling a surgical instrument (scissors tip, pean, pincer). Due to the inherent characteristics of the AdVance XP sling (mini anchors) it is essential to avoid excessive tension.

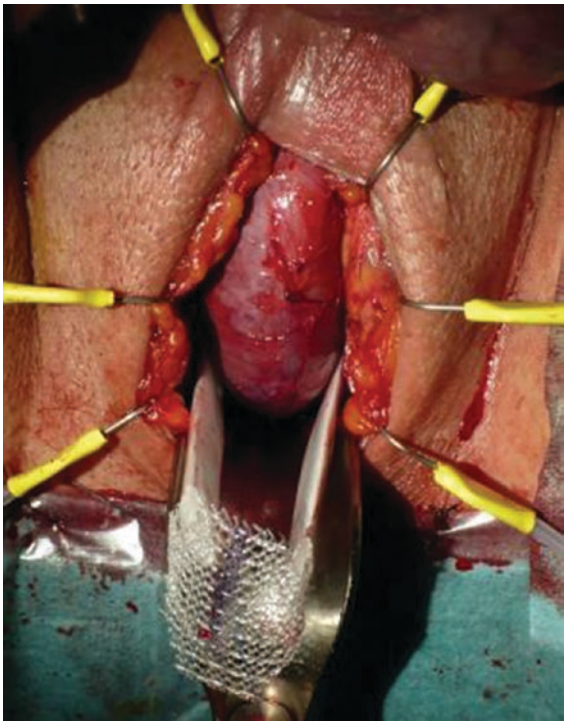

Fig. 5.7 Positioning of the sling

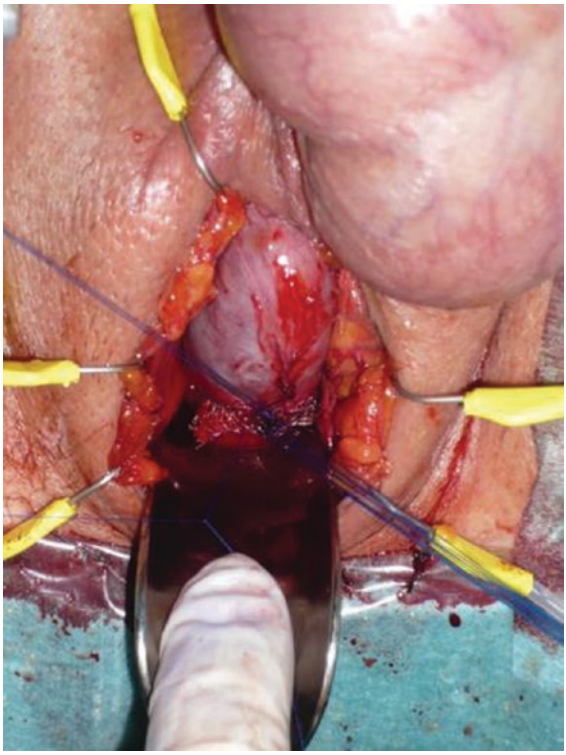

Fig. 5.8 Fixation of the sling to spongy bulb in the medial raphe

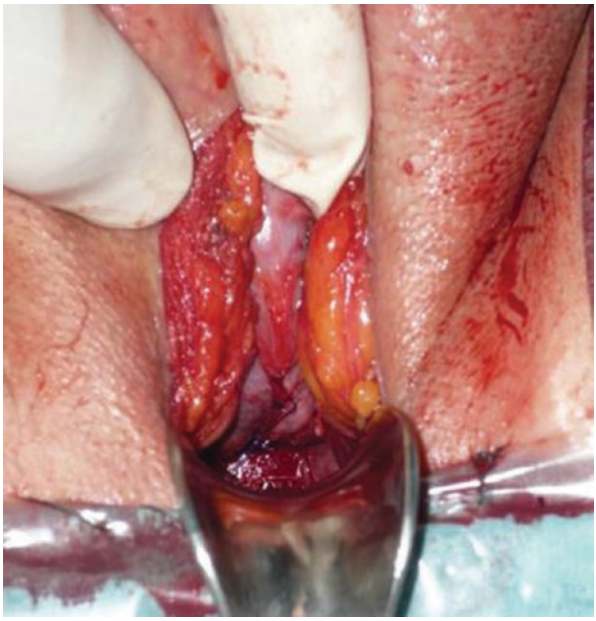

Fig. 5.9 Restoration of continence by rotation of the spongy bulb

The counter-incision and the subcutaneous tangential passage of the sling is purely for comfort purposes (Figs. 5.10, 5.11, and 5.12).

In case of muscle sparing the wound closure is reduced to subcutaneous and skin suture.

Severe complications, both intraoperative and postoperative, are rare. The main potential intraoperative complication is urethral injury during trocar passage. Bauer et al. [1] reported in 115 patients no intraoperative complications and no patient required pain medication for >4 weeks postoperatively. There was no postoperative Clavien–Dindo grade IV or V complications.

In another study that compared AdVance and AdVance Xp in 294 patients, Husch et al. [2], no intraoperative complication occurred in either of the groups. There were no significant differences in the postoperative complication rates except for higher rates of urinary retention in patients with AdVance XP and no significant postoperative bleeding occurred.

In the paper of Lima et al. [3], in a total of 11 patients, two patients in the AdVance® group experienced pain, which was relieved with analgesics; one had dehiscence of the surgical incision.

5.1.2 I-Stop TOMS

Implantation has to be performed with the patient under spinal or general anesthesia, and a Foley urethral catheter has to be inserted. The patient is placed in the lithotomy position, and a 6-cm median vertical perineal incision below the inferior border of the pubic symphysis is performed to expose the bulbospongiosus muscle. The perineal aponeurosis at the top of the triangular space is delimited laterally by each ischiocavernosus muscle and medial to the bulbospongiosus. A short 2-mm

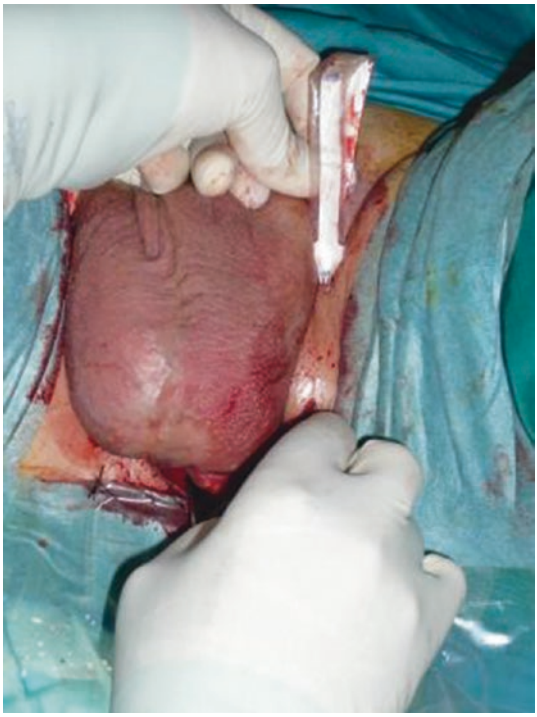

Fig. 5.10 Counter incision and the subcutaneous tangential passage of sling

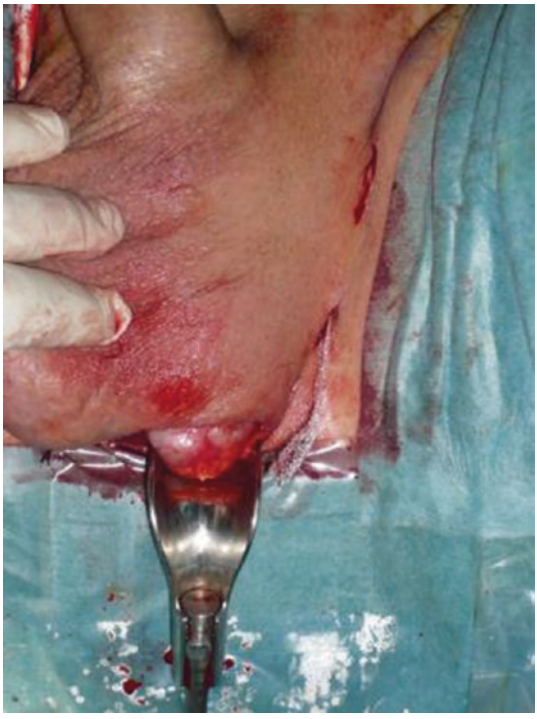

Fig. 5.11 Counter incision and the subcutaneous tangential passage of sling

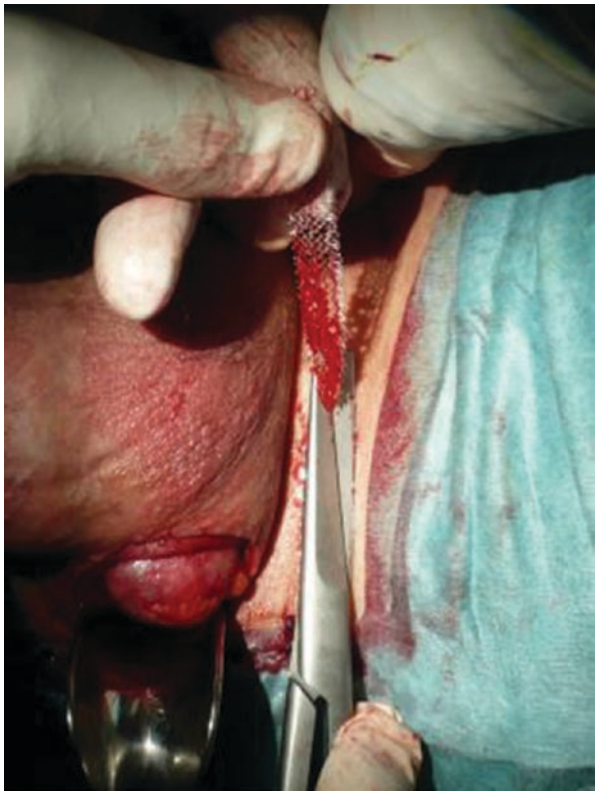

Fig. 5.12 Counter-incision and the subcutaneous tangential passage of sling

incision through the pelvic fascia afforded access to the obturator muscle just under the ischiopubic ramus bone. A stab incision is made at the top of the thigh, 4 cm from the median line and 4 cm below the major adductor longus muscle. The transobturator puncture is preferentially outside–inside using a Hemet needle. The endpoint of the puncture is the opening of the pelvic fascia. After sling attachment to the needle, pulling back the needle implanted the two arms of the sling in the same passage. The same procedure is repeated on the other side. The sling is sutured to the bulbospongiosus muscle with non-absorbable sutures and then pulled firmly from each side to obtain a 2-mm visible mark on the bulbospongiosus muscle. The perineal body is not dissected. The incision is closed without drainage, and the urethral catheter was left indwelling for 2 days.

In literature no complications, such as bladder perforation, intraoperative bleeding (>200 mL), or nerve, bowel, or vascular injury occurred during the intervention. The only complication was wounding of the corpus cavernosum (4.0% of the patients [4]). In the results presented by Griese et al. [4] micturition at removal of the catheter 48 h after surgery occurs in 98.9% of the patients. Hematoma and wound infection were very rare, and the mean perineal pain visual analog scale score was low. Of the patients, 97.3–100% were free of urinary tract infection at the different follow-up visits, and 96.5–100% of the patients had not experienced urinary tract infection in the month before the visits. The maximal urinary flow rates

were similar before and after surgery. The post-void residual (PVR) urine volume was increased after surgery and was normal at 30 days; a low stream was reported by some patients. Acute urinary retention (AUR) did not occur.

5.1.3 Virtue

The Virtue Quadratic male sling is a four arm polypropylene mesh with two transobturator arms and two prepubic (PP) arms (Figs. 5.13 and 5.14). After inserting a urethral catheter, a 5-cm perineal incision is made, exposing the bulbous urethra and pubic rami. The bulbospongiosus muscle has to be let intact, and the urethra is detached from the perineal body. On each side, the inferior sling extension is attached to the curved introducer, passed from the medial aspect of the descending ramus, through the obturator foramen, and through the ipsilateral groin crease, just inferior to the adductor longus tendon. The sling is withdrawn from medial to lateral. Through two stab incisions 4 cm apart and 2 cm above the pubic symphysis, the curved introducer is passed from superior to inferior, anterior to the pubis and

Fig. 5.13 The sling with the four arms

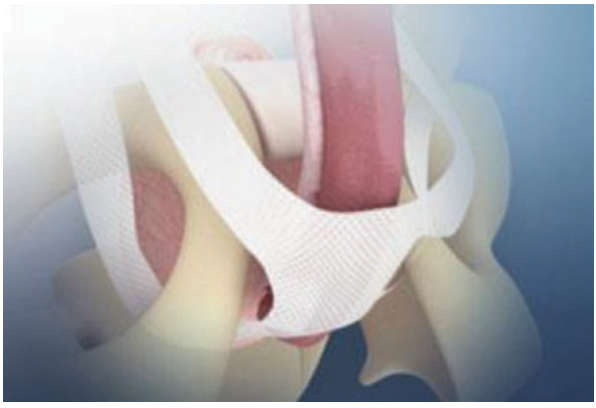

Fig. 5.14 Reconstruction of sling placement

out perineally, lateral to the urethra. The superior sling extension is attached to the introducer and pulled up through the stab incision. In relation to sling tensioning the TO extensions were pulled laterally until the bulbar urethra moved 2–3 cm proximally. The plastic sleeves were removed, and the TO arms were tunneled back medially to the midline. The PP arms were manipulated upward to provide visual compression of the sling against the bulbar and perineal urethra. Retrograde leak point pressure (RLPP) was measured via perfusion sphincterometry with a 14Fr catheter in the penile urethra, and PP sling tension was adjusted sufficiently to increase the RLPP to 60- to 70-cm water. The plastic sleeves were removed, and the mesh was cut flush to the skin. The perineal incision and stab wounds were irrigated and closed. The urethral catheter was removed the following morning.

After analysis of the 12-month data, a second cohort of 31 patients was enrolled in a Virtue "fixation" trial, whereby the surgical device was secured in position via a straightforward technique. Inclusion and exclusion criteria were similar to the primary trial, as were efficacy and safety measures.

Complications—all grade I—occurred in 17/29 patients (58.6%). The most frequent complication was scrotal pain, occurring in five (17.24%) patients; nevertheless, all five were discharged with a mean VAS of 6.0 (+0.54), that after 1 month decreased to 1.2 (+0.96) [5, 6].

5.1.4 Remeex System

It is an adjustable suburethral sling that provides a soft compression of the bulbar urethra, leading to subvesical obstruction by an effective regulation of the suburethral pressure at any time during everyday life [7]. The magnetic resonance spectroscopy (MRS) is composed of a monofilament suburethral sling connected to a suprapubic mechanical regulator with two monofilament traction threads. The mechanical regulation part, the varitensor, is a subcutaneous permanent implant, which is placed over the abdominal rectum fascia 2 cm above the pubis. The implant allows adjustment of suburethral pressure from outside the body by means of an external manipulator. A special screwdriver called the uncoupler is used to disconnect and separate the external manipulator from the varitensor once the desire continence level is achieved, allowing the removal of the manipulator from the body. The varitensor is a small cubic device with an internal never-ending axis to wind the traction threads. The threads are passed through into the varitensor through two lateral holes and emerge through the central hole at the varitensor midline, where the threads are secured with a fixing screw (Fig. 5.15). The varitensor has a mechanical connecting point for the external manipulator on its upper side. By rotating the manipulator clockwise or counterclockwise, suburethral pressure may be increased or decreased. The suburethral support is a 3 × 4 cm suburethral polypropylene sling mesh joined to the varitensor through two non-reabsorbable Prolene threads (Fig. 5.16). The patient is placed in the lithotomy position and prepared by shaving the abdomen and perineum. An 18Fr Foley catheter is placed per urethra. A 4-cm transverse incision is made just above the upper side of the pubic symphysis dissecting the subcutaneous tissue until the anterior rectal muscle

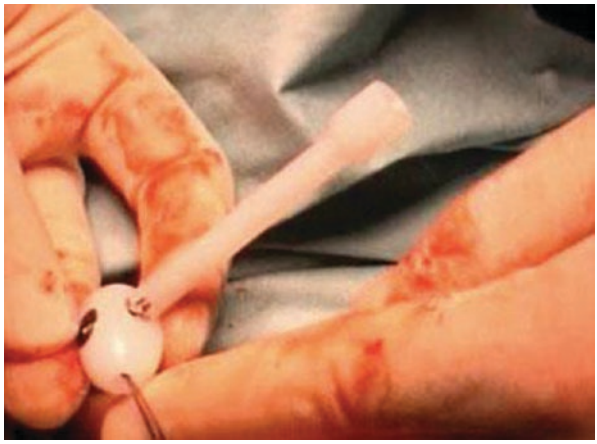

Fig. 5.15 The transfer of threads into varitensor

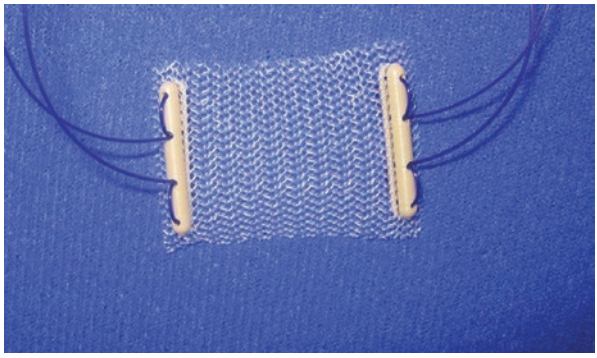

Fig. 5.16 3 × 4 cm suburethral polypropylene through two non-reabsorbable Prolene threads

fascia or the scar tissue is seen. A vertical incision of 4–5 cm long is made in the perineum. The urethra, surrounded by the bulbocavernosus muscle, is carefully dissected by using a Scott perineal retractor. The interior edge of the ischiopubic ramus is dissected, and the urogenital diaphragmatic fascia is sharply penetrated very close to the bone. Then the hole is enlarged with scissors to permit introduction of the index finger. Digital ascending dissection of the retropubic space is performed, in an attempt to reach the highest possible position to minimize the space between the fingertip and the anterior rectal fascia.

A small suprapubic incision is performed and fat tissue is dissected until the fascia is reached.

A modified Stamey needle is placed at the retropubic space guided by the tip of the finger to avoid urethral or bladder perforation (Fig. 5.17). The needle, with the traction threads attached, is then pushed up until it reaches the suprapubic incision. The same maneuver is performed contralaterally. A cystourethroscopy is used to confirm urethrobladder integrity. If there is no perforation, the traction threads are pulled up until the polypropylene sling mesh is in full contact with the bulbocavernosus muscle without exerting pressure (Fig. 5.18). The sling is then fixed and fully

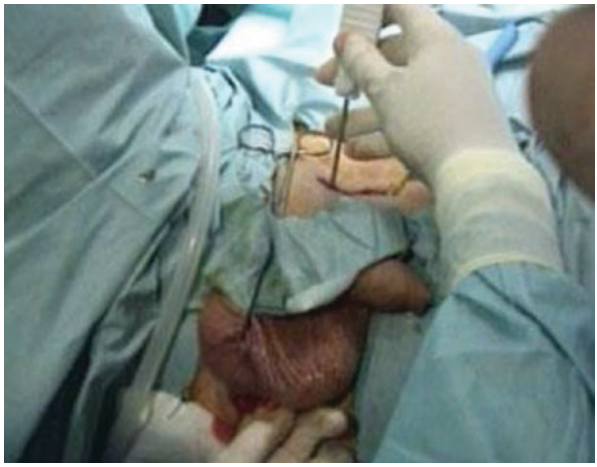

Fig. 5.17 Passage of Stamey needle through the retropubic space

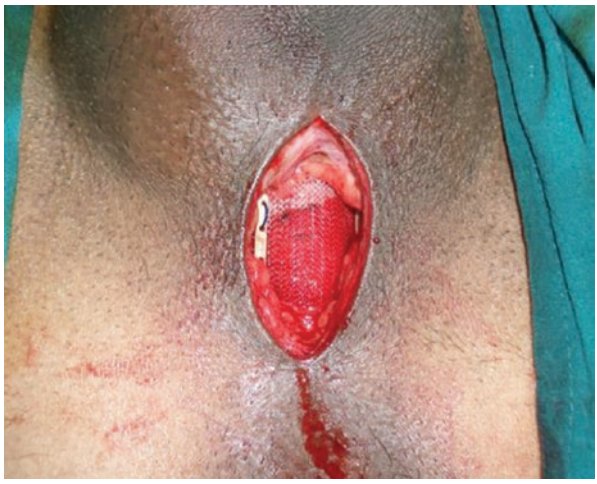

Fig. 5.18 Contact of mesh with bulbocavernosus muscle without tension

extended by placing four reabsorbable stitches. The perineum is closed in layers with reabsorbable sutures without leaving drains.

Suprapubically, the traction thread tips are introduced into the varitensor through the corresponding lateral hole, appearing through the central varitensor hole. Then both thread ends are fixed with a security frontal screw, and the traction threads are wounded into the varitensor by rotating the manipulator clockwise until the varitensor rests freely over the abdominal rectal fascia or the previous scar (Fig. 5.19). The operation is completed by closing the abdominal incision, leaving the external manipulator connected to the varitensor and protruding through the center of the abdominal incision (Fig. 5.20). If there was no perforation during surgery, the morning after the operation the bladder is filled with 250–300 mL of saline through the urethral catheter. The patient is then asked to stand up and perform Valsalva

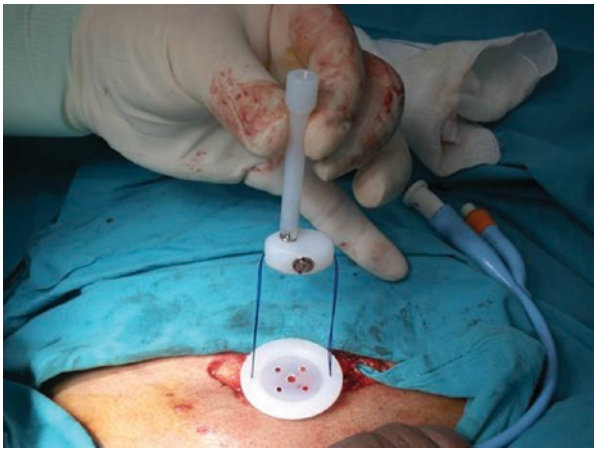

Fig. 5.19 Placement of varitensor

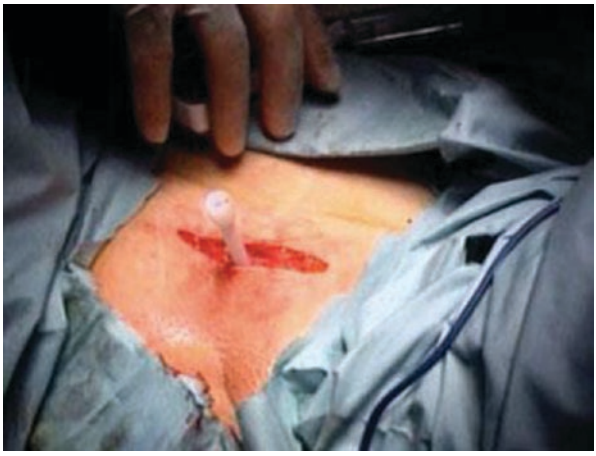

Fig. 5.20 Protrusion of external manipulator

maneuvers (cough) and if incontinence appears, the external manipulator is rotated four complete turns clockwise, and continence is checked again. If the patient is still incontinent, additional turns are applied to the manipulator; this maneuver is repeated until leakage disappears. If residual urine is under 100 mL and the patient is able to void well, the uncoupler is used to remove the manipulator from the varitensor and the patient is discharged.

On a total of 51 patients are reported five (9.8%) uneventful intraoperative bladder perforations discovered during surgery, all cases being solved by performing a new function [8].

5.1.5 ATOMS

The ATOMS system consists of a mesh implant with an integrated adjustable cushion, protection sheet and titanium port for adjustment of cushion volume (Fig. 5.21) [9].

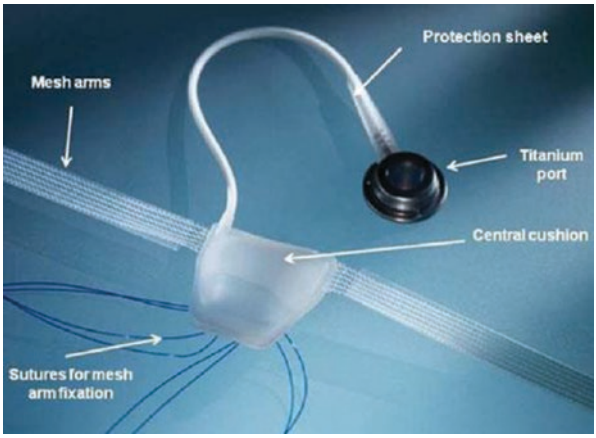

Fig. 5.21 Components of the atoms system

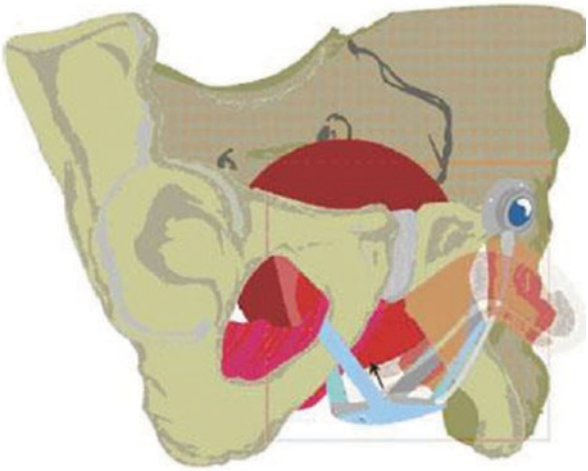

Fig. 5.22 Reconstruction of ATOMS placement

A vertical perineal incision is made with sharp dissection of Colles fascia and exposure of the bulbospongiosus muscle. Subsequently space was created between the bulbospongiosus and ischiocavernosus muscles. The system is implanted using an outside-in technique, whereby the obturator foramen was passed subcutaneously with a helical tunneller. The mesh arms were drawn back to the central part of the cushion and sutured, thereby anchoring the ATOMS device to the inferior pubic ramus like a backpack (Fig. 5.22).

The titanium port is placed subcutaneously deep in the left symphysis region and secured with two non-absorbable sutures. The initial adjustment is made by puncturing the port intraoperatively (1–2 mL demineralized aqua-iopamiro 1:1 solution). The 14Fr silicone catheter is removed during the first day postoperatively. Uroflowmetry and post-void residual are performed before discharging of patient.

On total of 137 patients there were no intraoperative injuries to the urinary tract or bladder as reported by the two major papers on this system [9, 10]. The

placement of the sling is surgically safe although the surgical procedure requires a higher learning curve than the slings are now reported.

5.1.6 Argus and Argus-T

This system is designed for retropubic and transobturator access (Figs. 5.23, 5.24, 5.25, and 5.26). The surgical approach for the implant of retropubic system (ARGUS) was described for the first time by Romano [11]. The sling includes a silicone 3 × 4 cm cushion, two silicone columns and silicone rings/washers. The rings are positioned on the columns, resting on the rectus fascia to regulate the tension of the silicone cushion on the bulbar urethra. The coned structure of the columns allows adjustment of sling tension by tightening or releasing the two silicone rings. A 7 cm perineal incision is made up to the bulbospongiosus muscle. The lateral borders were carefully dissected to reveal the perineal membrane on both sides. The urethra and the inferior border of the symphysis pubis are palpable. A transverse

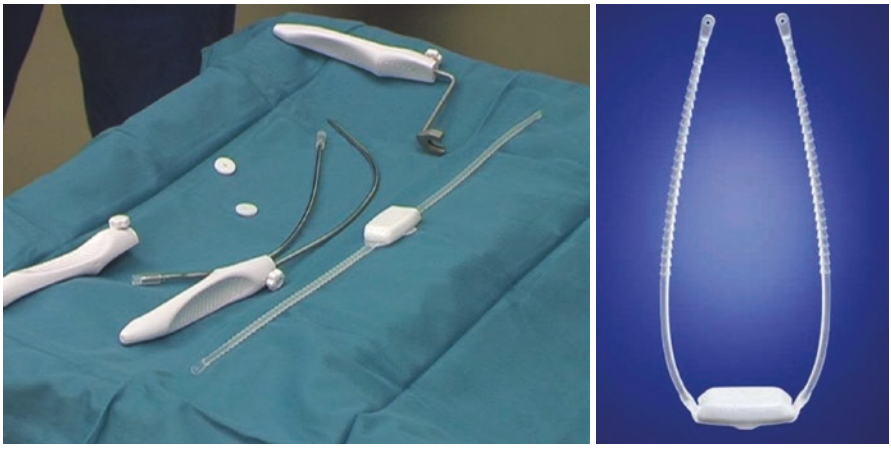

Fig. 5.23 ARGUS device composition kit and direction of columns after implantation

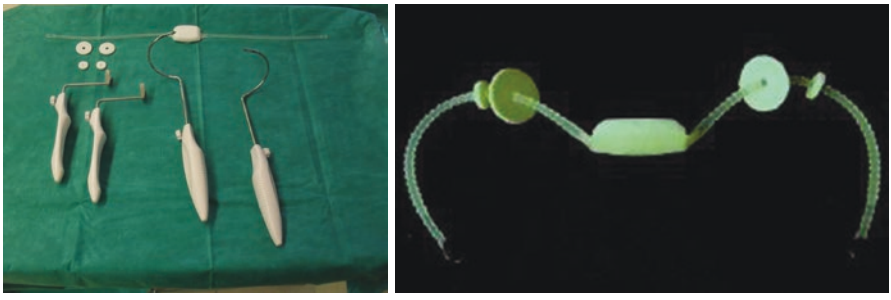

Fig. 5.24 ARGUS-T device composition kit and direction of columns after implantation

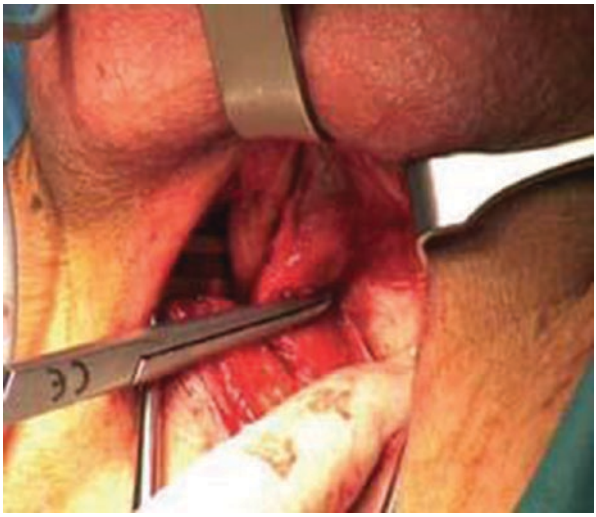

Fig. 5.25 Isolation of bulbar urethra with bulbocavernosus muscle left in situ

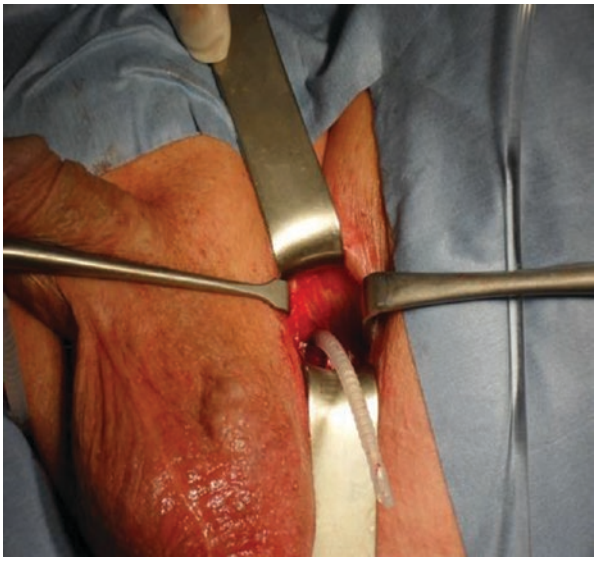

Fig. 5.26 Placement of column laterally

suprapubic incision of 7 cm is made and rectus fascia is exposed bilaterally to accommodate placement of the silicone rings. Guided by the operator's index finger, a 90° crochet needle was carefully introduced, perforating the perineal membrane in the space between the bulbar urethra and the ischiopubic bone. The needle was then advanced just posterior to the pubic bone in the direction of the ipsilateral shoulder, toward the suprapubic incision. The same maneuver is done on the other side. The needle handles are relocated to the suprapubic ends of the needles. The columns of the Argus device are attached and pulled toward the suprapubic incision. The silicone cushion is positioned around the bulbar urethra. The Foley catheter is

removed and cystoscopy is performed to exclude bladder perforation. At this point the two silicone rings are placed over the coned columns and positioned on the rectus fascia to regulate sling tension. The tension was adjusted to achieve a retrograde leak point pressure of 40 cm H_2O. Sling tension is judged to be correct if cystoscopy showed coaptation of the bulbar urethra. The silicone columns were then positioned crosswise deep to the suprapubic subcutaneous fat and both wounds were closed in layers. The Foley catheter is reinserted at the end of the procedure and removed 24 h postoperatively. Instead with regards to the transobturator approach (ARGUS-T) a 6 cm median perineal incision is executed and the tissues are dissected until the exposure of the bulbocavernosus muscle. The muscle is left in situ and the urethra is not mobilized from the central tendon (Fig. 5.25). In order to access the obturator foramen, the lateral borders of the muscle are dissected free until the perineal aponeurosis are identified bilaterally so it can be detached to the muscle fibers. A bilateral small incision below the insertion of the adductor magnus muscle is executed in correspondence of the inguinal fold. A transverse suprapubic incision until the exposure of the muscle rectus fascia is then made. The helical needle is introduced bilaterally with a movement "out-in" from the lateral entries until the perineal one. During this procedure the surgeon had to perforate the obturator aponeurosis so, with an opposite movement, it is possible to allocate the columns laterally (Fig. 5.26) and the cushion on the ventral surface of the bulbar urethra (Fig. 5.27). Then the washers are introduced on the end of the columns bilaterally so the surgeon can adjust the tension of the sling.

At this point it is performed a cystoscopy to control and to correct the tension. The adjustment is carried out until a RLPP (retrograde leak point pressure) of 30–40 cm H_2O is obtained. This procedure can also identify any urethral trauma related to the needle crossing. When the tension of the sling is achieved the cushion is fixed to the bulbocavernosus muscle. Finally, the end of the columns are positioned crosswise deep the suprapubic subcutaneous fat and both wounds are closed in layers. The Foley catheter is repositioned at the end and it is left in pace for 24–48 h. Finally, an important characteristic of both devices is represented by the possibility to perform a revision procedure in spinal anesthesia to improve

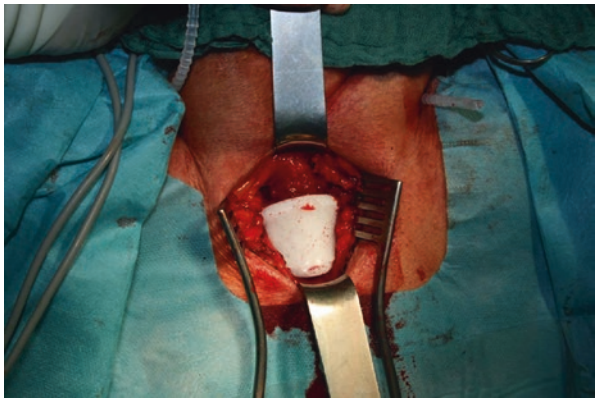

Fig. 5.27 Placement of cushion on the ventral surface of the bulbar urethra

continence. In this way suprapubic and inguinal incisions are opened and the sling tightened by pulling the coned columns through the washers over 1 or 2 cones bilaterally. Cystoscopy was performed as previously described. During the retrograde urethromanometry we aimed for an optimal retrograde leak point pressure (between 40 and 50 cm H_2O), generally 10 cm H_2O higher than the previous condition.

Schrier [12] and Siracusano [13] do not reported intraoperative complications, for the retropubic and transobturator approach respectively, in their patient series. However, during needle passage the only possible complication could be represented by bladder perforation with the retropubic approach while a lesion of the bulbar urethra with the transobturator access.

Interdisciplinary Comment

The experience of the Urologists with the slings for the male urinary incontinence may be interpreted as the consequence of their planetary success in the female patients where the sling is not a static closure, but rather a reinforcement of the pubourethral ligaments. The Integral System Theory by Peter Petros tries to find, through the pelvic ligaments failure, an explanation also for fecal incontinence. Unfortunately, we do not have at the moment the equivalent of the pathophysiology of the utero-sacral ligaments in the male. Therefore, we are basically stuck in the belief of fecal incontinence being due to the damage of the pudendal nerve, which is probably true only in some cases.

5.2 Slings for Fecal Incontinence

The initial first-line therapy for faecal incontinence (FI) remains the conservative management with dietary modification, anti-diarrheal agents and rehabilitative pelvic floor muscle protocols. Patients who fail this approach might be offered a surgical procedure. The actual gold standard is the sacral nerve stimulation or the posterior tibial nerve stimulation [14], provided that the stimulation test is positive. Otherwise, in case of anal lesions or disrupted external sphincter, alternative strategies could be bulking agents [15, 16], placement of anal slings, anal sphincter repair, dynamic graciloplasty and artificial anal sphincter [17]. Except for the first two possibilities, the other techniques require a good expertise, and consist of major surgical procedures, with high morbidity rates and costs.

The rationale of placing a sling for this pathological condition is based on Parks' theory. According to him, an adequate anorectal angle (ARA) plays an essential role in the maintenance of continence [17], explaining why different surgical procedures have experimented in order to support the pubo-rectalis muscle, preventing from both rectal prolapse and incontinence episodes. Indeed, firstly described as a modified Thiersch procedure for rectal procidentia, it has been widely proved that the mesh implant gave excellent results in resolving the faecal incontinence when present [18–20].

Furthermore, all procedures consist of a minimal-invasive, perineal approach, applicable to a large number of elderly or debilitated patients, which normally are the main target of the population suffering from faecal incontinence. The procedures usually can be held in one-day surgery, under spinal or general anaesthesia, placing the patient in a lithotomic position, giving perioperative prophylactic antibiotics.

According to FDA-approved investigational protocol conducted by Mellgren et a1. [21], the few exclusion criteria for anal sling placement are limited to neurogenic faecal incontinence, intolerance to prosthetic materials, stage IV prolapse, pregnancy, IBD, recent pelvic surgery and rectal resection. New perspectives are opened by the group of Ducháč et al. [22] who recently conducted a pilot study regarding the correction of the elevator hiatus using an anal sling in idiopathic, neurogenic FI.

Among the different techniques proposed, we can classify the placement of anal sling in three main procedures, regardless of sex, age, comorbidities and FI aetiology: anal encirclement, retro-pubic anal sling and trans-obturator pubo-rectal sling, differing for the final implantation site and the anatomical route of mesh insertion.

The anal encirclement was the first application of a sling in coloproctology in 1891, by Thiersch [23] who described a simple method of anus encirclement by a silver wire as a treatment of rectal prolapse, functioning as an obstruction situated at the anal outlet under the perianal skin. Since then, numerous authors proposed technical modifications, mainly regarding the shape and type of material used for encircling the anus. Despite the technological advances of the recent years [24, 25], this technique has been progressively abandoned, likely due to the frequent mild-term adverse reactions, and the poor outcomes.

Deriving from the gynaecological experience, the retropubic sling was first reported in 1974 by O'Rourke [26] as an alternative to the abdominal approach of rectal prolapse repair. The sling is fixed to the inferior aspect of the pubic rami and passes behind the rectum below the level of the elevators. By reproducing the sphincteric effect of the pubo-rectalis, following the patient muscle contractions and distensions, it resulted in a more physiological approach compared to the anal encirclement. According to the author, control of both prolapse and faecal incontinence was estimated around 60%, but 50% of the followed-up patients required a re-operation for failure or adverse events.

In the last 15 years, it has been introduced a new self-fixating type I polypropylene, monofilament device positioned via a trans-obturator route, passing behind the ano-rectum through two small incisions in the buttocks, similarly to a trans-obturator urinary sling. The TOPAS pelvic floor repair system (American Medical Systems, Minnetonka, Minnesota, USA) described by Rosenblatt et al. [26], has gained a large consensus because of its poor adverse reactions, compared to the retropubic route and its good potential in restoring faecal continence (success rate is estimated around 69% at 12 months) [20]. Depending on the fixating system, some surgical variants have been proposed by Brochard [27] who fixes the mesh with polyglycolic acid sutures, and La Torre [28] who describes a tension-free technique without applying any traction of the surrounding tissues. In all cases the central body of the

mesh suspends and pulls the rectum anteriorly, replacing the function of the pubo-rectalis muscle and external anal sphincter which frequently show a partial or complete denervation in pelvic floor disorders.

Interdisciplinary Comment

The positioning of sling to restore the function of the pubo-rectalis muscle and external anal sphincter is an interesting application of the anatomical relocation of sphincteric unit. This functional concept is applied to restore urinary continence by suspensive sling as the Advance device or by Virtue sling.

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ProACT for Urinary Incontinence

6

Alessandro Giammò and Enrico Ammirati

ProACT is an extra urethral bulking system made of a silicone balloon connected with a dual lumen tubing (12–14 cm) to a titanium scrotal port that allows the postoperative adjustment (Fig. 6.1). It was introduced in the European market in 2000 as the first non-circumferential compressive device. The continence mechanism is guaranteed by a bilateral compression of the urethra, augmenting maximum urethral closure pressure (MUCP). In a study by Reuvers et al. this mechanism was demonstrated in a cohort of 23 successfully implanted patients in which a significant increase in MUCP from 58 cmH_2O to 79 cmH_2O was observed [1].

The surgical technique is performed under general or spinal anesthesia in lithotomic position with ankle flexion of around 100°. The procedure begins with a cystoscopy with the aim to evaluate the quality of the urethra, and through the instrument, the bladder is filled with 50 mL of radiopaque contrast medium. The contrast medium helps to identify the bladder neck under radioscopic control. The access is made through two 1.5 cm perineal incisions, laterally to the bulbous of the urethra. The superficial tissues are dissected with blunt scissors. Using a dedicated introduction set (Fig. 6.1) that combines a trocar and a "U-shaped" cannula, the pelvic floor and the deep transverse perineal muscle are perforated. Under radioscopic control, the trocar proceeds lateral to the urethra until the tip reaches the vesicourethral anastomosis, in case of implant after radical prostatectomy. The tip reaches the membranous urethra, in case of presence of the prostate after TURP. If a correct plane parallel to the urethra has been reached, the lateral mobilization of the trocar moves the urethral plane identified by the cystoscope. Then the ProACT is inserted through the "U-shaped" cannula and its correct placement is verified by fluoroscopy. The tip of the balloon is identified by a radiopaque marker. The device is filled with 1 mL of isotonic contrast medium solution

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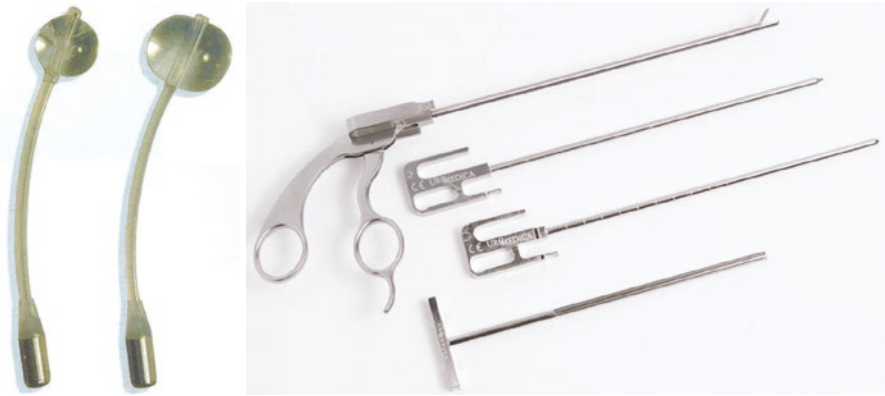

Fig. 6.1 ProACT device and dedicated introduction set

(recommended solution) using a non-traumatic needle (Huber needle). At the end of the placement, the radioscopic control verifies the correct symmetric periurethral position. The filling of the device is also important to recognize a flattening of the medial border of the balloon, representing a good urethral compression. Furthermore, the bulking effect and the absence of injuries is verified by cystoscopy. Finally, the two ports are allocated into a subcutaneous scrotal position. This allows future postoperative adjustments using a Huber needle. The incisions are closed with re absorbable sutures and a 14Ch Foley catheter is left in place overnight [2]. A tissue expander device (TED) is also available (Fig. 6.1) to facilitate the dissection of more fibrotic and resistant tissues [3]. However, in these cases, such as in radiotreated patients, the quality of the tissues interferes and reduces the compressive effect of the device with worse continence results; thus the TED has been underused as there is a relative contraindication to the placement of ProACT device in fibrotic and radiotreated tissues.

To overcome the limits of the fluoroscopic control (radiation exposure, lack of direct visualization of structures, and long learning curve), in 2006 an alternative technique by using ultrasound guidance was proposed. A 7.5 MHz linear and convex 3.5 MHz ultrasound transrectal probe is used to guide the procedure. Instead of the cystoscope, a 14Ch catheter is left in place to fill the bladder with saline solution. The skin incisions are the same as the fluoroscopic technique. A 20-gauge spinal needle is inserted through the skin incisions and directed bilaterally to the vesicourethral anastomosis under multiplanar TRUS guidance. The linear probe monitors the advancement of the spinal needle towards the bladder neck, while the convex probe is used to monitor the distance from the urethra. The tissues are then dissected using saline solution injection. Finally, the trocar is inserted and the balloons are positioned similarly as the fluoroscopic technique. A good balloon positioning should be around 5–10 mm distal to the bladder neck and 2–5 mm lateral from the urethra. The couple of balloons should be positioned at 9 o'clock and 3 o'clock in relation to the urethra to achieve a triangular urethral compression between the two balloons and the symphysis pubis. This technique allows to have,

in experienced hands, a good balloon placement with similar surgical times compared to the fluoroscopic technique [4, 5].

The main advantages of this device are the minimal invasiveness, the out-office adjustment of the balloons and the easy management of complications. The procedure requires monthly adjustments, using 0.5–1 mL of isotonic solution medium until continence is reached. These steps allow the development of a fibrotic capsule around the balloons, which prevents the risk of erosion and migration.

In case of complications, it is possible to easily remove the devices in outpatient office. This procedure is performed in local anesthesia, after deflating the balloons, though small scrotal incisions and it does not provoke pain or significant bleeding.

This device gives good results for the treatment of non-neurogenic postoperative male stress urinary incontinence, with dry rates that vary from 52% to 68% and improved continence rates (>50%) that vary from 8% to 26% [4–6]. The continence results, in a large cohort of patients presented at the International Continence Society 2017 annual meeting, were 38.7–39.5% dry and 37.2–39.6% improved >50% [7, 8]. Mean operative time ranges from 19 to 23 min [4–6]. The mean number of postoperative balloon filling ranges between 2.33 and 5 and mean final balloon volume ranges from 3.1 mL to 4.46 mL [3–6, 9, 10]. The maximum volume of the balloon is 8 mL.

Filling the balloons with isotonic contrast medium solution allows to evaluate their postoperative position at subsequent fillings by conventional X-ray. When done in anterior–posterior and latero–lateral orthogonal projection, conventional X-ray gives the spatial relationships between the devices and the bony structures so that only gross dislocation or deflated balloons can be seen. In the absence of radiological abnormalities, continence would be attempted only by progressive filling of the devices up to the maximum 8 mL volume allowed. Other than patients with irradiation and fibrotic tissues, it is not easy to predict at an early stage, which will not have a successful outcome despite adjustment. In a study conducted by Giammò et al., multidetector computed tomography (CT) was applied to reveal any incorrect device positioning, even when conventional X-rays show correct positioning. In dry patients, the balloons at multidetector CT scan were placed paraurethrally at the bladder neck, in patients after radical prostatectomy, or adjacent to the residual prostatic tissue, in patients after TURP, and all above the urogenital diaphragm. In four dry patients, only one of the balloons was placed above the urogenital diaphragm in a correct position, while the other was displaced more caudally: in these patients, the continence result was achieved by adequate monolateral compression of the well-positioned balloon. In patients not achieving dryness with further refilling of the balloons, multidetector CT scan evidenced that the balloons were both placed more caudally. In half of these cases, conventional X-ray and scout CT scan could not evidence an incorrect position below the urogenital diaphragm, highlighting the difficulty to judge a correct positioning during routine fillings with conventional X-ray control. In one case the balloons were correctly positioned, but the patient did not achieve continence; multidetector CT scan evidenced homogeneous tissue of hypodensity at the level of the implant, suggesting sclerosis in a radiotreated patient. Thus, they concluded that a correct surgical position of the balloons in a periurethral position above the urogenital diaphragm is essential to achieve dryness.

Radiotherapy and the consequent sclerosis and periurethral fibrosis could represent a relative contraindication to the positioning of this device [11].

The most frequent intraoperative complications are represented by bladder and urethral perforation during the dissection maneuvers with the trocar. The incidence of bladder perforation varies between 2.3% and 18%, whereas the incidence of urethral perforation varies between 4% and 8% [3–8]. In case of a small bladder perforation, it is possible to extract the trocar and create a different dissection plane to allocate the ProACT. A bladder perforation is not a contraindication to the placement of balloons, it just requires to keep a Foley catheter for a few days to guarantee a prompt healing of the bladder infraction. The case of a urethral perforation (Fig. 6.2) is a contraindication to the placement of balloon. In this situation, it is advisable to leave a Foley catheter for a few days and postpone the implant on that side for at least 4 weeks.

Intraoperative balloon ruptures are described [3] but are uncommon. The use of isotonic contrast medium solution is mandatory to evaluate the morphology of each balloon and promptly identify the damage of the device. The surgical technique does not carry a significant bleeding risk, there may be minor and self-limiting bleeding during dissection and that stops with temporary tamponade (Fig. 6.3).

The surgical technique is easy and well standardized but surgical expertise is required. A good ProACT positioning is related to better functional outcomes and lower incidence of complications as referred by Hubner et al. They compared the results of the first 50 implants to the consequent 50 ones. The surgical time reduced (range 14–56 min during the first 50 surgeries; 12–24 min during the last 50 cases) reflecting operative refinement and practice. Continence results improved in the second group indicating a learning curve of about 50 cases (in the first group 52% dry or using 1 pad/day, 8% >50% improvement, 40% failed; in the second group 60% were continent, 22 > 50% improved, 16% failed). In the first group, 38 of 50 implants had no complications, whereas in the second group 42 of 50 (84%) implants were uneventful. In the first group, intraoperative complications were urethral perforations (8%), bladder-neck perforations (8%), immediate balloon ruptures (4%), and balloon migrations (4%). In the second group, they had no urethral

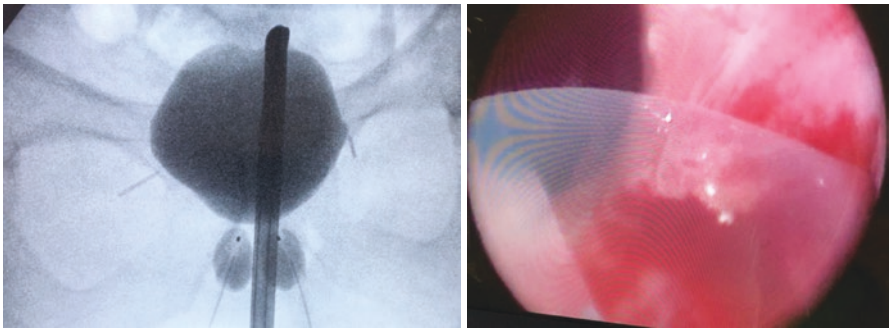

Fig. 6.2 Urethral perforation: X-ray and corresponding endoscopic view

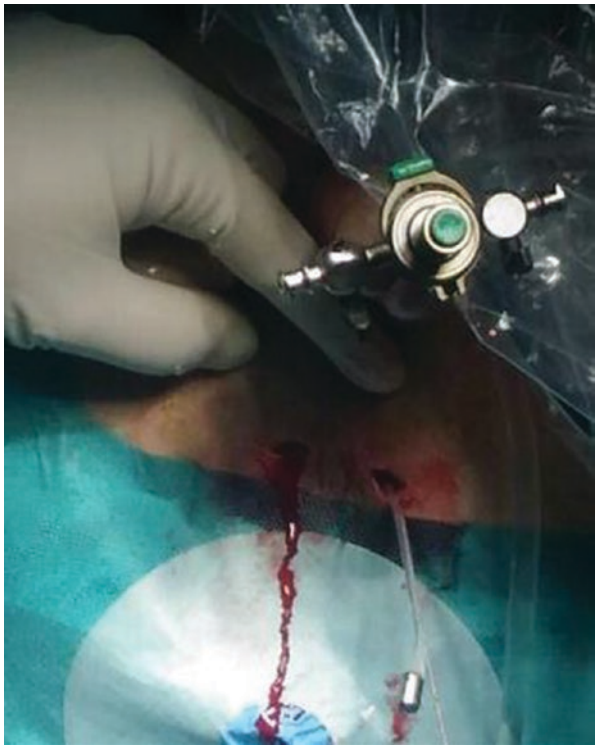

Fig. 6.3 Minor bleeding does not represent a significant complication of this device

perforations, balloon ruptures, or intraoperatively migrations. This means that with experience and following the standard technique, this device appears to be safe to implant. Of notice in the second group, they had 18% of bladder-neck perforations but all in patients with densely scarred bladder necks, such as after radiotherapy; these complications could be avoided with a better selection of the patients, being radiotherapy a relative contraindication. Also, the management of intraoperative perforations changed between the two groups [3].

Interdisciplinary Comment

ProACT is conceptually able to recover the compressive action of urethral sphincter which is mostly represented at membranous urethra with typical omega shape. The placement of balloons laterally to the membranous urethra must be coaxial to make the coaptation of the membranous urethra more effective. Similar positioning of balloons is necessary when they are placed around the anal sphincter.

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Bulking Agents for Urinary and Fecal Incontinence

7

Michele Pennisi, Antonio Luigi Pastore, and Filippo La Torre

7.1 Bulking Agents for Urinary Incontinence

Male stress urinary incontinence (SUI) is most commonly a consequence of prostatic surgery except when symptoms are driven by a neurological concomitant condition. Hence, compared to what urologists know about current clinical practice in female SUI, the diagnostic phase in men is a very particular and important step in the management of the disease, with accurate evaluation of the clinical context, SUI cause, quality of life assessment, and patient complaints [1, 2]. Improvements in urinary leakage after prostatic surgery (RP and TURP) may occur spontaneously or with conservative measures within the first 12 months after surgery. However, management of persistent incontinence is often challenging and may be frustrating for both a patient and his doctor, and as a consequence, it can negatively affect patients' quality of life and doctor–patient relationship [3]. Urinary incontinence causes problems, such as poor hygiene and loss of self-confidence that directly affect the quality of life of patients. The mechanism for male SUI after prostate surgery appears to be internal sphincter deficiency. The probable mechanism for internal sphincter deficiency after prostate surgery includes rhabdo-sphincter injury during apical dissection, large and deep sutures during vesico-urethral anastomosis, or injury of the neurovascular bundles [3].

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Initial management of male SUI consists of pelvic floor muscle training, biofeedback, and electrical stimulation. Should conservative approach fail, surgical interventions become inevitable. Currently, there have been several competitive products available for operative treatment of male SUI. The surgical armamentarium has completely changed during the past 15 years with the introduction of new generation male slings, new bulking agents, stem cell therapy, and the minimally invasive devices [3–5].

Intramural urethral bulking agents (synthetic or autologous) injections are one of the first treatment methods used for the treatment of male SUI [6–10]. The aim of this approach is to increase the intraurethral pressure and thus enhance the continence. The agents currently used are mainly bovine collagen (Contigen), cross-linked polyacrylamide hydrogel (Bulkamid), dextranomer/hyaluronic acid copolymer (Deflux), pyrolytic carbon particles (Durasphere), and (polymethylsyloxane Macroplastique) [2]. The use of Bulkamid has mostly been reported in women. The basic principle of this technique is to inject the product under the urethral mucosa just under the area of the sphincter to get a better coaptation of the urethral wall and increase urethral resistance to decrease the occurrence of leakage.

Injection procedures are usually performed in the lithotomy position by using intraurethral lidocaine jelly injection. A 0-degree 24-Fr urethroscope is used. A syringe containing 5 mL of bulking agent is attached to a 5-Fr injection catheter with a 20-gauge needle. The bulking agent is delivered to the 3, 6, 9, and 12 o'clock points of the urethra in the proximal position of the remnant urethral sphincter, creating a bleb under the urethral mucosa that protruded into the urethral lumen. Special care was taken to not inject the material into the external urethral sphincter because this can produce pudendal nerve irritation, resulting in sphincter spasm and discomfort. After injection, the urethral lumen was confirmed to be coaptated (Fig. 7.1). When proper coaptation was achieved, residual urine was evacuated with

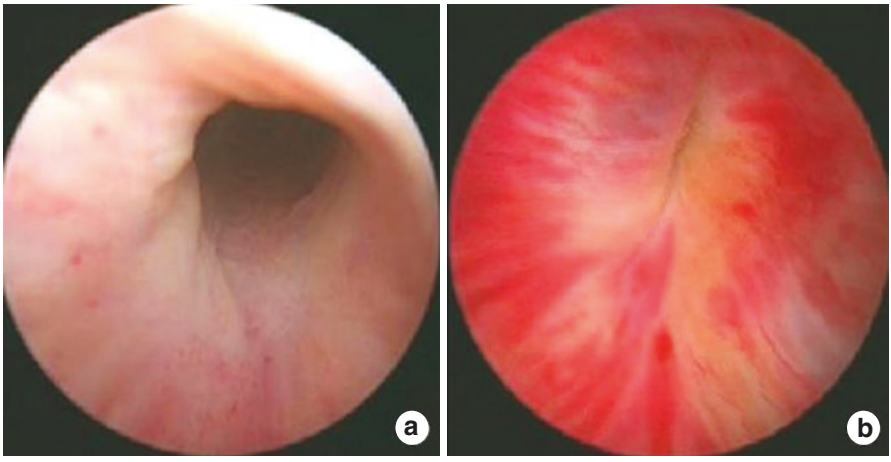

Fig. 7.1 Pre- and post-injection endoscopic view (0° lens) of the urethral sphincter. (**a**) Pre-injection: the urethral lumen is wide open. (**b**) Post-injection: the urethral lumen is coaptated

a thin urethral catheter to avoid displacement of the implant. Patients were discharged after successful voiding without significant residual urine (≤100 mL).

The U.S. Food and Drug Administration (FDA) has approved the use of bovine glutaraldehyde cross-linked collagen (Contigen; CR Bard, Covington) in 1993. It was generally well tolerated by patients and had relatively low complication rates [6, 8–10]. However, the long-term treatment outcomes of this method proved unfavorable [9, 10]. Moreover, in order to maintain the therapeutic effect, several repeat injections are often required. The most commonly used bulking agent substances have generally small volume of distribution, and, do not migrate to other organs [7, 10]. However, the use of Teflon was withheld after animal studies found that it migrated into the lymph nodes, the brain, the spleen, and the lungs [10]. The early treatment failure rates with bulking agents approach 70% and increase even further with time despite repeat treatments [6–10]. Another complication of this technique is the development of local inflammation, which can lead to so-call frozen urethra [7, 10]. In the past 10 years, multiple reviews and consensus reports have stated that, based on the available literature, periurethral injection of bulking agents should not be proposed as a first line therapy for SUI in men because of its relatively low short-term success rate and high risk of recurrence of symptoms [2–5]. Two interesting studies analyzing the practice of north American surgeons have shown that periurethral injections of bulking agents had still a significant—although decreasing—market share [11, 12].

Kim et al. used the data of the Surveillance Epidemiology and End Results cancer registry data linked with Medicare claims to analyze the type of surgeries done over the last decade (2000–2007) for post-prostatectomy SUI management [12]. They found that 6% of the 16,348 patients who underwent radical prostatectomy (all aged more than 65) in the database had at least one anti-incontinence procedure. Among all the surgeries done, periurethral injection of bulking agents was the most common (38%), followed by artificial urinary sphincter implantation (36%), and male sling (26%). Patients who had injection of bulking agents often finally underwent artificial urinary sphincter implantation (39%). Moreover, repeated injections were needed in 60% of cases, and finally only 18% of patients had a single injection with no other subsequent procedure. Although limited to a particular dataset, these data directly reflecting clinical practice reflect the low efficacy and the relatively high recurrence rate after injection in male SUI. The study conducted by Poon et al. also shows, through another dataset, that the popularity of periurethral injections of bulking agents remains relatively high in the United States [11]. The authors analyzed the anti-incontinence procedures in men in the case logs submitted by urologists to the American Board of Urology for certification purposes from 2004 to 2010. The number of procedures overall increased over the study period. The share of endoscopic injections remained relatively high decreasing from 80% in 2004 to 60% in 2010.

Bulking agents, although the least invasive, were reported to have low success rates and rapid deterioration, and thus were only considered to be beneficial in the short term. Furthermore, re-intervention is common particularly after bulking procedures, and at least 50% of patients need a second procedure. Bulking procedures

also had a higher tendency to be converted to another device after original treatment. Interestingly, the success rates of urethral bulking agents as a treatment for male SUI is reported to be between 17% and 38% [13, 14].

Interdisciplinary Comment
The purpose of the urethral coaptation procedure is to recover the sphincter function of the urethra. In this context, the optimization of the urethral coaptation depends on the distribution of the bulking agent in the sphincteric tissue as on the other hand it occurs during the bulking agent injection at the level of the anal sphincter. The correct injection procedure is fundamental for achieving urinary and fecal continence.

7.2 Bulking Agents for Fecal Incontinence

In the last 25 years, the injection of bulking agents (BA) has been adopted to treat mild to moderate faecal incontinence (FI) with promising results [15]. The treatment with BAs is a minimally invasive procedure that aims to augment the anorectal wall in order to increase the resistance to involuntary bowel emptying. The use of perianal BA proves especially useful in those patients at higher risk for comorbidity for whom more invasive surgical procedures should be avoided. Different injectable bulking agents have been described in the literature but the most frequently used were PTQ® or silicone biomaterial, NASHA and Durasphere® [16–19]. Seven different techniques have been described in the literature.

These differ in two main aspects: final site of implantation and route of insertion of the needle used to deliver the bulking material (trans-anal, trans-mucosal, transsphincteric or inter-sphincteric). Also, local, regional or general anaesthesia are used to perform the injection procedure. However, the majority of injections were carried out under general anaesthesia. In addition, patients were placed in a variety of positions to facilitate the injection of the bulking agents, including the prone, jack-knife, left lateral and traditional lithotomy positions. Agent used route of injection type of anaesthesia and position of patient at time of injection and use of postoperative laxatives had an impact on the likelihood of postoperative complications. In ideal terms, a filling agent should be non-compatible and non-immunogenic and it should induce a minimal inflammatory and fibrotic response [20].

The agent particles should be large enough to avoid migration away from the injection site (i.e. a diameter >80 mm) and they should be sufficiently durable. Animal studies have shown that there is distant migration of particles with diameters of 4–80 mm, with particulate material found in lymph nodes, the lungs, the kidneys, the spleen and the brain [21]. With migration comes poor durability and, more seriously, the possibility of chronic granuloma formation at the migration site. In general, most of the current materials consist of particles suspended in an excipient, which is usually in the form of a biodegradable gel. Moreover, the carcinogenic

potential of implanted prosthetic materials has been examined in animals but it has yet to be established in humans [22, 23]. It was found that especially route of injection may have an impact on the likelihood of postoperative complications. Tjandra et al. [24] demonstrated in a randomized trial that inter-sphincteric injection of PTQ® under ultrasound guidance was associated with significantly better short- and long-term results compared with digital/manual guidance with a finger placed in the anal canal. The increased risk of complications associated with the intersphincteric route of injection was related largely to the puncture site/site of needle insertion. In trans-mucosal injection, the mucosal surface heals faster and demonstrates a diminished inflammatory reaction in response to trauma, like a surgical wound. A further factor may be a high degree of vascularity in the inter-sphincteric space with susceptibility of vessels to trauma during injection. This may lead to haematoma formation and eventually infection. The review of Hussain et al. [17] suggests that injections of bulking agents are best performed under general anaesthesia, probably related to the better exposure achieved for injection. Poor exposure may explain the poor short-term results associated with injection of bulking agents under local anaesthesia. Surprisingly the only predictor of longer-term efficacy seems to be the postoperative use of laxatives. Straining in the most vulnerable immediate postoperative period may cause significant displacement and/or leakage of injectable agents, resulting in a large volume loss over a short interval and a shorter period of symptomatic control. Avoiding straining in the postoperative period by using laxatives may reduce the displacement and/or leakage, and improve medium-term efficacy. Patients may, therefore, benefit from routine postoperative laxatives after the injection of bulking agents.

Interdisciplinary Comment

The purpose of this procedure is to recover anal sphincter function. In this context, the optimization of the anal coaptation depends on the distribution of the bulking agent in the sphincteric tissue as on the other hand it occurs during the bulking agent injection at the level of the urethral sphincter. The correct injection procedure is fundamental for achieving faecal continence.

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Sacral Neuromodulation for Urinary and Fecal Incontinence

8

Maria Angela Cerruto and Alessandra Masin

8.1 Sacral Neuromodulation for Urinary Incontinence

Sacral neuromodulation (SNM), also termed sacral nerve stimulation (SNS), is an established treatment modality for patients with chronic lower urinary tract dysfunction (LUTD). Since the late 1980s, this therapy has evolved in an effective but mainly empirical way, and the precise mechanism of its action is still unknown. The United States (US) Food and Drug Administration (FDA) has approved the following indication for patients with chronic LUTD, refractory to appropriate conventional treatments: urge urinary incontinence, urgency-frequency syndrome and dysfunctional voiding with non-obstructive urinary retention. SNM has become an established therapy also for anorectal disorders such as faecal incontinence.

Despite its overall success, the therapy fails in a proportion of patients [1–3]. This may be partially due to suboptimal electrode placement. In 2017, Matzel et al. published a report on the standardized electrode placement technique [4].

8.1.1 Peripheral Nerve Evaluation (PNE)

The first step of sacral nerve stimulation (SNS) is the peripheral nerve evaluation (PNE), a test needed to determine whether SNS is appropriate for a given patient [5]. It is a temporary application of SNM both as a therapy and a diagnostic test, yielding information about location, integrity and function of the sacral nerves, the

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nature of patients' symptoms and the likelihood that SNS will ultimately improve symptoms and quality of life.

The PNE can reasonably be performed in an office or hospital setting; this will depend on individual concerns such as space, equipment, cost and personal preference. It is essential to have an assistant to operate the hand-held screener and to tend to the patient's comfort. Necessary materials are included in the Medtronic PNE kit (Fig. 8.1).

In order to prepare and position the patient correctly, the following equipments are required: a standard operating-room table, multiple (usually minimum four) pillow/rolls for extra support of chest and pelvis and to compensate for lumbar lordosis, a ground pad and an external test stimulator (ENS, Verify) (Fig. 8.2).

The patient should be positioned in the prone position with the head, thorax, and hips well supported. Feet and toes should be lifted off the table (usually with a

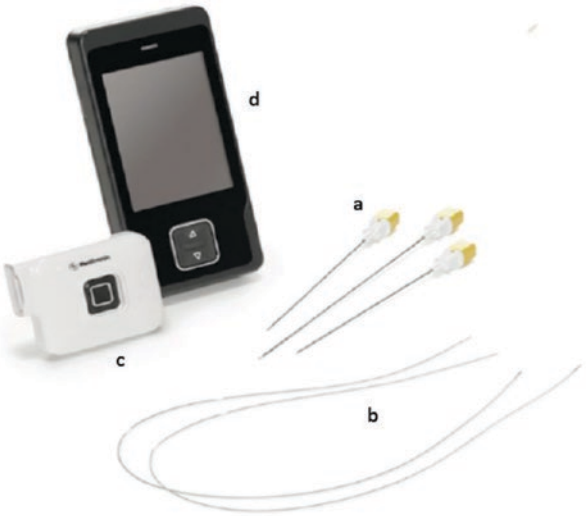

Fig. 8.1 PNE kit: (**a**) foramen needle; (**b**) temporary electrode; (**c**) external test stimulator (ENS), verify; and (**d**) controller 3537

Fig. 8.2 External test stimulator (ENS), verify

pillow under the shins) to ensure verification of toe and foot response upon stimulation. The main purpose of correct positioning is to be able to achieve the correct angle from which to enter the foramen. Therefore, lumbar lordosis should be reduced as much as possible. For X-ray, the aim is for a straight line between the spinal process of the sacrum and lumbar spine in the lateral plane. In obese patients, surface anatomy may blur the position of the bones. The patient's buttocks can be taped apart so that the cheeks are open for observation of the anus during electro-stimulation.

An antiseptic solution is used to sterilize the skin of the sacral region and the immediately surrounding area (including the posterior superior iliac crests, between the lateral edges of the greater sciatic notches, and above the crease between the buttocks and upper thighs). Sterile drapes are placed to delimit a rectangle enclosing the surgical site and anus. A transparent adhesive sterile drape can be used; this will allow direct observation of the anal response without any contamination of the operating field. Sterility is of utmost importance because the procedure involves implantation of foreign material, and infection will necessitate removal. The draping should allow the surgeon to observe the anal bellows response and the feet to control for stimulation-induced movement and to monitor the potential of sacral nerve stimulation.

In order to identify the S3 foramen, several ways may be used by bony landmarks, such as:

- Greater sciatic notches and central spinous process
- Crest or high point of sacrum
- Measure up 9 cm from tip of coccyx
- Fluoroscopy (alternatively, only for PNE, it is possible to use ultrasound)

Using the X-ray to mark S3, we need a C-arm ad antero–posterior (A-P) and lateral imaging of the sacrum with continuous fluoroscopy. The procedure starts with an A–P view of the sacrum, provided the patient is ideally positioned (no lordosis) on an X-ray table. X-ray landmarks are the medial edges of the foramina. The medial edges are marked with a vertical line on each side (this line is marked on the skin and usually runs almost parallel to the midline although not always and may vary side to side if there is some degree of scoliosis) and a line connecting the lower edges of the sacroiliac joint. All are marked on the skin producing an 'H' figure (Fig. 8.3).

The intersecting points of this 'H' represent the upper medial part of the third sacral foramen, the ideal site for lead entry. After marking with an A-P view, the C-arm is rotated laterally for imaging of the entire sacrum for the electrode insertion.

The skin over S3 is infiltrated with 1–2 mL of local anaesthetic (e.g. 1% lignocaine), using a fine-gauge needle. Adequate skin analgesia is shown by 'peau d'orange'. Apart from skin, the sensitive posterior sacral periosteum must be anaesthetized. Once the anaesthesia has been performed, a correct orientation of the needle relative to skin surface is crucial. Actually it is important to pay attention to the orientation of the foramen needle relative to the skin surface: usually, the correct

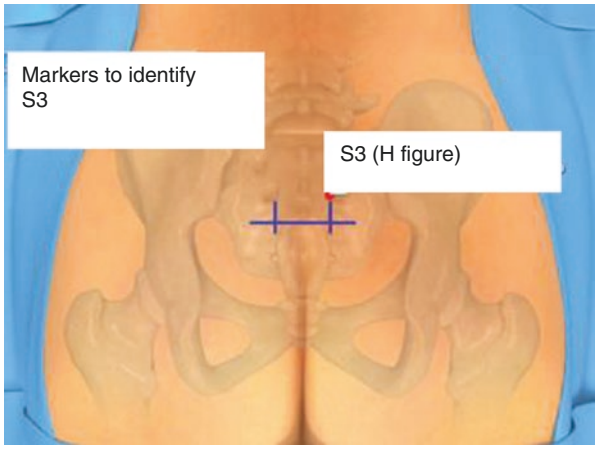

Fig. 8.3 The medial edges of the foramina are marked with a vertical line on each side and a line connecting the lower edges of the sacroiliac joint. All are marked on the skin producing an 'H' figure

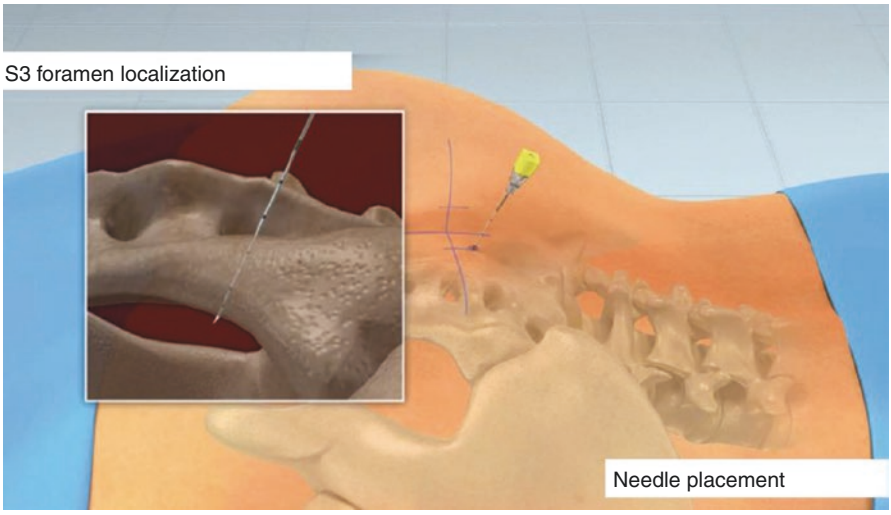

Fig. 8.4 Needle placement at S3 level

needle/skin angle is 60° in S3, less in S2, and almost 90° in S4. Two standard-length 'Foramen' needles (length 9 cm, 20 Gauge) are available. Further 12.5 cm 20 Gauge foramen needles are available for obese patients. Once the needle is entered (Fig. 8.4), fluoroscopy can be used to advance the needle to the inner table of the sacrum. Usually, the entry into the foramen is felt as a penetrating movement through a ligamentous structure as opposed to hitting the bone.

Once the needle has been positioned within the foramen, the patient screener cable should be attached to the uninsulated portion of the foramen needle, which is located immediately beneath the hub (Fig. 8.5).

The hand-held screener (controller) needs to be operated by an un-scrubbed assistant. A grounding pad to the patient is fixed where it can be easily checked (e.g.

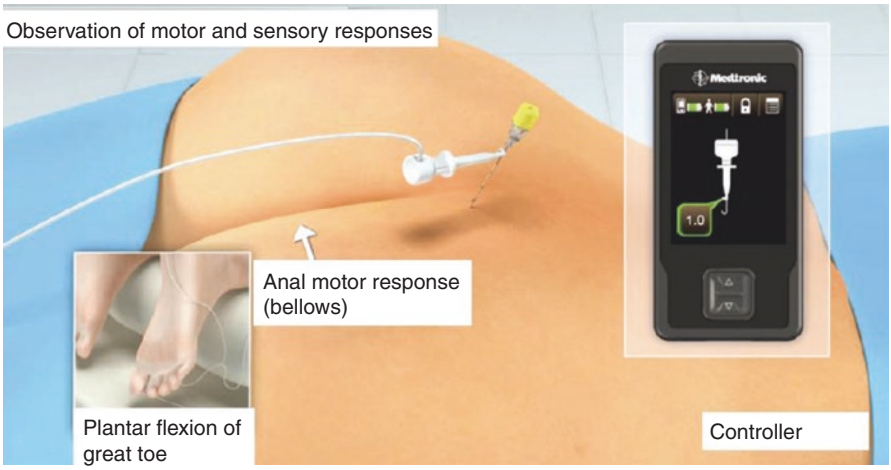

Fig. 8.5 The needle is connected to the external screener using a screener cable. A controller is used to modulate the electrical stimulation in order to observe motor and sensory responses

Table 8.1 Responses of patient to stimulation according to the foramen penetrated

Nerve innervation	Response: pelvic floor	Response: foot/calf/leg	Sensation
S2: primary somatic contributor of pudendal nerve for external sphincter, leg and foot	'Clamp'[a] of anal sphincter	Leg/hip rotation, plantar flexion of entire foot and contraction of calf	Contraction of base of penis and vagina
S3: virtually all pelvic autonomic functions and striated muscle (levator ani)	'Bellows'[b] of perineum	Plantar flexion of great toe, occasionally other toes	Pulling in rectum, extending forward to scrotum or labia
S4: pelvic, autonomic and somatic. No leg or foot	'Bellows'[b]	No lower-extremity motor stimulation	Pulling in rectum only

[a]Clamp: contraction of anal sphincter and, in males, retraction of base of penis. Move buttocks aside and look for anterior/posterior shortening of the perineal structures.
[b]Bellows: lifting and dropping of pelvic floor. Look for deepening and flattening of buttock groove

the patient's heel) and connects the patient's screener to it and the screener cable. The aim is to achieve an anal motor response (bellows) toe/forefoot response at a low current, that is, <2 mA. It is then common practice to reduce the stimulation amplitude to a lower level (e.g. 1 mA) and make small adjustments to the depth of the needle to maximize the motor response. The amplitude of stimulation must be increased slowly until perceived as strong, not painful. Ideally, the patient should perceive stimulation as comfortable and soothing. If pelvic pain is a part of clinical presentation, it is encouraging if the patient feels the stimulation as paraesthesia in the area of the pain.

Responses to stimulation differ according to the foramen penetrated (see Table 8.1).

The site giving an S3 response is usually best for sub-chronic stimulation. The temporary electrode is placed once S3 has been well identified by acute stimulation. The depth of the electrode is marked on the surface for both 7 and 12 cm foramen needles. The foramen needle stylet is removed and the temporary electrode is gently threaded into the lumen until the point marked on the electrode just disappears into the hub, or when resistance from the tissue beyond the needle tip is met. Patient monitoring/electrode stimulation ensures correct electrode depth.

If the electrode has been inserted too deeply after needle withdrawal, it is possible to stimulate and withdraw the temporary electrode simultaneously while its stylet is still in place, until the appropriate responses are seen again. Once responses are confirmed, the electrode is grasped and stabilized while the foramen needle and electrode stylet are completely removed.

If the acute stimulation responses cannot be duplicated, it is usually necessary to remove the temporary electrode, replace the foramen needle and reposition the temporary electrode. When the stylet has been removed, a new electrode must be used if replacement is needed. Records of responses and X-ray confirmation of electrode position are essential. The temporary electrode is secured to the skin using a breathable membrane dressing supplied in the kit. The ground pad is positioned on the patient's back, near the site of the lead placement and the connections are made to the appropriate patient screener cable. All redundant portions of the electrode and the connection to the ground pad are covered with a dressing (Fig. 8.6).

It is advisable to remind patients that accurate diaries and reports of screener–user problems are important. The response to the sub-chronic phase of PNE is used

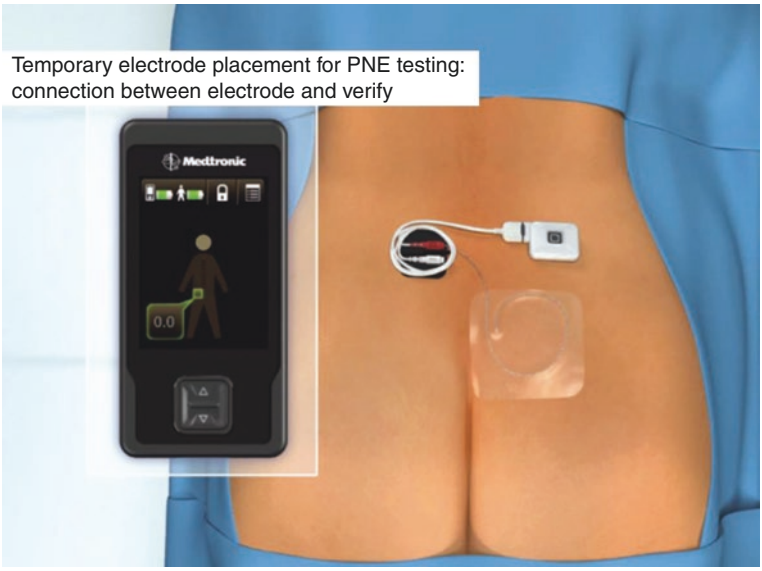

Fig. 8.6 The temporary electrode is secured to the skin using a breathable membrane dressing supplied in the kit

to determine whether a patient's symptoms are sufficiently altered by neuromodulation, and whether the patient should go on to the implantation phase.

A medial orientation of the needle tip may stimulate the nerve mechanically. This gives patients a painful shock and mandates needle repositioning. If the needle is pushed back along the temporary electrode, the tip may shear off. Unfortunately, there is a high rate of lead migration and in several centres the sub-chronic phase of PNE is substituted by the quadripolar tine lead electrode placement.

8.1.2 Quadripolar Electrode Placement

Patient's position and S3 identification are the same used for the PNE test as well as the foramen needle placement.

Once a perfect approach has been determined by adjustment, the needle can be advanced. When using local anaesthesia, the syringe attachment (after removal of the stylet) can be used for deeper infiltration. Care should be taken not to infiltrate within the sacral foramen, as this risks abolishing the response to stimulation testing. With minor adjustments in angle, but avoiding significant deviation from the central axis it should be possible to advance the needle into the upper and most medial section of the sacral foramen. At this stage, the needle stylet can be removed and the directional guide can be inserted. It is critical not to advance the directional guide beyond the depth of the needle (by using the markings provided on the wire or X-ray control). This is emphasized because it is very easy inadvertently to push the needle in with the guidewire such that both advance considerably beyond the inner table of the sacrum and thus penetrate the fascia. (N.B.: This is an even greater risk when the introducer is inserted: see below.) Once the directional guide is placed, the skin at the point of introduction is incised for 0.5 cm in order to comfortably permit the introducer to be inserted. The needle is then removed, leaving the guidewire in situ. The guidewire in place has two marks at each end corresponding to the 9 and 12 cm foramen needle. These markers correspond to the different lengths of the needle electrodes (9 or 12.5 cm) and the length of the introducer. It helps to identify the depth of insertion. The incision for the introducer can be extended in cranial direction because it will allow at a later stage to bury the inserted electrode underneath the skin. When the dilator is inserted, it is crucial to avoid inadvertent deep placement of the introducer that may create a false path for the tined lead electrode. It is also very easy to push the guidewire further into the pelvis while pushing the introducer. Thus, continuous or intermittent fluoroscopy is advised to control advancement of the dilator. The radiopaque marker on the sheath of the introducer at the border of the plastic part should no longer be used as a reference for the depth of the introducer placement. Rather, the reference point for depth of introduction is now the tip of the introducer (distance between the radiopaque marker of the introducer sheath and the plastic tip of introducer sheath is around 4 mm). The risk of creating a false tract for electrode placement must be avoided. The operator should heed the following steps:

1. To leave the metallic directional guide free to avoid forcing the tract during dilator positioning.
2. To push the dilator carefully with both hands, handling the top part of it.
3. To use continuous (or at least intermittent) fluoroscopy to ensure that the tip of the dilator is located in the deep limit of the sacral foramina and not ventral to the ventral opening of the foramen.
4. To monitor the potential migration of the directional guide during insertion of the dilator. If two hands are used during the insertion (see Step 2, above) and the direction of the metallic guide is respected, usually the dilator runs down through the guide. However, it is best to get an assistant to firmly hold the directional guide while you advance the introducer. In case of guide migration, it should be retracted.

The tined lead electrode (usually 28 cm, also available in 33 and 41 cm for obese patients) carries four electrode contacts measuring 3 mm each with spacing of 3 mm (Fig. 8.7). The distance between the most proximal electrode and the most distal set of tines is 10 mm. At the top of the tined lead electrode four contacts, each 2.2 mm correspond to the four contacts on the electrode tip. Electrode contacts are termed '0' (most distal), '1,' '2' and '3' (most proximal).

Once the introducer is in place, with the radiopaque marker inside the sacral foramen, introduction of the electrode follows. The electrode comes pre-packaged with a stiff, straight stylet. With the modified technique described here, this is exchanged for a softer stylet with a flexible and curved tip. The insertion of the electrode into the introducer should orient the curved tip in the direction of the

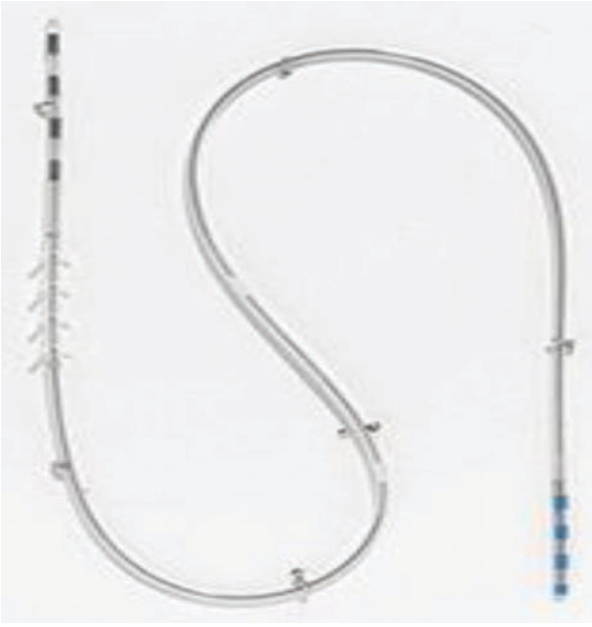

Fig. 8.7 The tined lead electrode

natural path of the target nerve: into a caudo-lateral direction. The aim of electrode placement is to position the four contacts in close proximity to the target sacral spinal nerve. This is achieved if low-intensity stimulation results in an adequate motor/sensory response (depending on whether the procedure is performed under general or local anaesthesia). An optimally placed electrode has specific appearance on A–P and lateral fluoroscopic views. This can best be achieved if the foramen is entered at its medial and upper edge (hence optimized needle placement above) and by avoidance of a false track (see 'Introducer Placement'). The electrode will subsequently follow the natural course of the foraminal lumen. In general, intermittent stimulation and fluoroscopic control are advised throughout the procedure at any step that can result in a change of the electrode position. For its placement, the electrode is pushed through the introducer until the first white marker reaches the introducer's upper edge. This indicates that the entire electrode is still covered by the introducer. If the electrode is pushed in further gently and without force, up to the second marker, the four contacts exit off the introducer, the tines still being inside the introducer and not deployed. The electrode follows the path of least resistance, usually the course of the target nerve. Pushing of the electrode is done under fluoroscopy to ensure adequate entry direction and movement into the pelvis. Once the electrode is positioned, test stimulation is applied to each of the four contacts at the external top of the electrode, which correspond to the contacts at the tip of the electrode. Ideal placement is achieved when an adequate stimulation response is evoked with $\leq$2 mA at each contact. This may require revision/optimization of the initial placement: the position can be altered by rotating the bent electrode or by gentle withdrawal or pushing in (or a combination of these movements), all preferably done with intermittent low-intensity stimulation and imaging. During movements, it is important to hold the introducer sheath and lead together when adjusting lead position. Obtaining a correct position is imperative because withdrawing the introducer sheath will deploy the tines and anchor the lead.

The highest likelihood to be close to the nerve is at its exit at the ventral opening of the foramen because distal to that level the path of the nerve may vary. If the most distal electrode contact '0' gives a good response to stimulation throughout electrode positioning it is indicative that the electrode lead follows the path of the nerve.

While holding the lead in place, the operator can now retract the introducer sheath. This must be done gently as this outward pulling may result in a dislodgement of the electrode either dorsally or ventrally. As with electrode placement, this step should be performed under fluoroscopy that adjustments can be made to prevent movement. To accomplish this it may be useful to exert a turning or wobbling movement on the sheath without compressing it, as some resistance may be present that can pull on the lead.

After and during the removal of the introducer sheath, the position of the lead can be tested by stimulating the four electrode contacts (0, 1, 2 and 3). If the evoked responses are the same as previously, the introducer lead stylet can be removed, again keeping the lead itself fixed. Intermittent fluoroscopy helps to confirm the stable position of the electrode.

Once the introducer is removed the electrode position is confirmed by fluoroscopy and stimulation, again at each single electrode contact. The introducer can only be fully removed if the electrode stylet is removed, which results in an even more flexible electrode. Documentation of the final electrode position with fluoroscopy is advised. Ideally, in a lateral view, the distances between the more distal electrode contacts appear to be less than between the more ventral ones based on the fact of a lateral deviation of the electrode from the midline, which can be confirmed by an A-P view.

Once the tined lead is positioned the next step is to tunnel the electrode to a pocket in the buttock and then to tunnel the percutaneous extension that will be used for the external stimulation during the test-period (up to 2 months).

A felt tip marker marks the final placement of the IPG in the buttock, preferably on the side of the tined lead. The final placement should allow the patient to sit, lie flat on the back and lie on that side without discomfort. Also the IPG must be accessible for the patient to activate/de-activate with the patient's programmer (Medtronic Patient Programmer 3037 Icon). Depending on patient's stature positioning of the pocket 3–4 cm lateral to the sacral bone, 4–6 cm inferior iliac crest avoids contact with bony structures.

This is especially important in thin patients. Preoperative marking of the IPG position is advisable. Local anaesthetic with norepinephrine is injected along the designed tracts if under local anaesthesia. The incision should be long enough to ensure safe dissection to the subcutaneous fascia (Scarpa's fascia). A small pocket is prepared under Scarpa's fascia, large enough to contain the connector of percutaneous extension but superficial to the epimysium of the gluteal muscles.

From the newly created pocket, the percutaneous extension is tunnelled subcutaneously across the midline to the opposite side. This allows reducing the risk of infection during the test period. The route is marked with a felt tip and local anaesthetic with norepinephrine (if the procedure is done under local anaesthesia) is injected. A small stab wound is made and the tunnelling tool with tube is inserted and care is taken to secure the tip enters the pocket in buttock. The tunnelling tool is removed leaving the tube in place.

The percutaneous extension lead is then inserted through the tube from the pocket side.

The tunnelling tool is bent to allow a curved route from the sacral bone to the buttock. The route is marked with a felt tip and local anaesthetic with norepinephrine is injected if under local anaesthesia. The tunnelling tool with tube is inserted at the incision over the sacral bone where the lead protrudes through the skin and targeted to the pocket in buttock. The tunnelling tool is removed leaving the tube in place and the lead is passed through the tube. The electrode is placed in the set screw connector so far that the blue tip of the electrode end is visible. The four screws are tightened with a torque wrench and the silicone boot—which was placed before the connection—is pulled over the connector and secured with a non-absorbable suture at each end of the connection. The pocket and stab wounds are closed.

Fig. 8.8 The equipments required for SNM: (**a**) needles; (**b**) introducer sheath; (**c**) directional guide; (**d**) tined lead electrodes; (**e**) external test stimulator, verify; (**f**) controller for verify; (**g**) InterStim II 3058; (**h**) InterStim patient programmer iCon; and (**i**) N'Vision programmer

When a chronic SNM is decided following a positive test-period, a subcutaneous pocket is created as described above, large enough to hold the IPG tight. The electrode is then connected to a Medtronic Interstim II 3058 implantable impulse generator (IPG): the electrode is connected (in case of a two-staged procedure after disconnection of the extension lead) by insertion into the IPG until the blue tip of the electrode is visible in the transparent connection head of the IPG and fixed by closing the screw (Fig. 8.8).

8.1.2.1 Antibiotic Prophylaxis

These recommendations are based on expert opinion and not based on evidence [6, 7]. Antibiotic prophylaxis in SNM comes with standard measures of prevention of the infectious risk that include detection of infectious risk factors (skin disease for instance), careful preoperative skin preparation and operative setting of high standard regarding aseptic conditions of the procedure. Careful intraoperative skin prep (iodine solutions or similar) and sterile draping are mandatory. The entire procedure either for implantation of the tined-test lead or IPG is conducted in strictly sterile conditions. During the test-phase whatever its duration instructions have to be given to the patient to keep clean and well covered the exit point of the lead extension. The other wounds are treated as usual.

Protocol may vary with regard to infectious risk in patient's special conditions (diabetic or immuno-compromised) or due to environmental bacterial pressure and/or general recommendations in institutions or countries.

It is recommended to give one dose of intravenous prophylactic antibiotics before the implantation of a tined lead as well as an IPG implantation. Recommended drugs cover cutaneous and enteric flora and commonly used drugs are Augmentin 625 mg iv, Cephazolin 2 g slow IV and in case of allergy: Vancomycin 15 mg/kg/60 min or Clindamycin 600 mg slow IV. This has to be done approximately 30 min before a procedure done under local anaesthesia and at induction in case of general anaesthesia.

There is no consensus regarding the benefit of antibiotic-impregnated sheet use, wound irrigation with antibiotic solution, or local gentamicin-collagen sponge implantation. In general, no routine antibiotics are needed post-operatively. Some experts recommended broad-spectrum oral antibiotics for a period of 5–7 days.

8.1.2.2 Intraoperative Problems and Troubleshoots [4]

After needle placement, it is possible to have no response to electrical stimulation. If no response is detected at all (even at high amplitude), it is mandatory to re-check the equipment. In case of poor response to needle electrical stimulation (i.e. anal motor/toe response only at high amplitude), it advisable to repeat needle insertion on the contralateral side at S3. If this is not successful, repeat the manoeuvre targeting S4. If an abnormal motor response (e.g. ipsilateral buttock contraction or foot rotation) occurs, we can re-perform needle insertion and check radiological landmarks again: usually, the needle is not in the foramen or not at the correct level (usually S2 if foot rotation).

During introducer placement, the directional guide slips through the foramen into the pelvis. In that case, it must be withdrawn under fluoroscopy. If the insertion of the introducer at skin level requires pressure, the skin incision needs to be enlarged. If the introducer is positioned too far in, exiting the foramen ventrally, it must be withdrawn under fluoroscopic guidance.

During the tined lead electrode placement, it is possible that only one or two contacts of the electrodes are in proximity to the target nerve resulting in adequate motor/sensory response. In that case it is advisable to rotate the electrode and reinsert into the introducer with the curved tip pointing in a different direction. As a second step, it may become necessary to remove and reposition the needle electrode with subsequent reinsertion of the introducer.

It is advised to reposition the electrode also if concomitant motor response of the forefoot/toe occurs prior—with less stimulation intensity—to the pelvic floor response.

Interdisciplinary Comment

Regardless the indications, surgical procedures as well as intraoperative complications that may occur during SNS implant are the same. Sharing information within the experts in this field is mandatory in order to manage the patient at best.

As clearly reported in Masin's chapter, the best results with sacral neuro stimulation in proctologic dysfunctions are obtained in patients with faecal incontinence rather than with constipation and pelvic pain. Should the financial resources be good enough, it would always be worthwhile the attempt with this procedure.

8.2 Sacral Nerve Modulation for Fecal Incontinence

Sacral nerve modulation (SNM) is an established therapy for functional pelvic disorders, including both urinary and anorectal indications [4]. SNM has been advocated as a minimally invasive and safe treatment for functional urinary and anorectal diseases because of its relatively simple surgical procedure and absence of life-threatening adverse effects, particularly no intraoperative complications are reported [8].

An international multidisciplinary group of highly experienced surgeons in performing SNM standardized the main operative steps to optimal electrode lead placement. They identify key elements of the surgical technique in order to avoid the most frequent intraoperative troubles and the post-operative therapy failure [4].

Troubleshooting key elements during the procedure were listed, considering the procedural stages.

8.2.1 Patient Position and Preparation

The patient should be placed in the prone position; feet and toes should lean out of the table (usually with a pillow under the shins) to ensure verification of toe and foot response upon stimulation. The correct position allows to achieve the correct angle from which to enter the foramen. Therefore, lumbar lordosis should be reduced as much as possible [4].

8.2.2 Use of X-Ray (C-Arm) and Marking

The procedure starts with an anteroposterior (A–P) view of the sacrum, provided the patient is ideally positioned. The C-arm is then rotated lateral for imaging of the entire sacrum during the electrode insertion. Difficulty in identifying the relevant sacral reference structures is related to position of the patient (not perpendicularly for the lateral fluoroscopy) or to overlying bowel gas. Repositioning of patient or operating table and pre-operative enema is advised [4].

Shakuri-Rad reported the first use of ultrasound for placement of sacral neuromodulation. Using ultrasound, the guidance of the needle into the S3 foramen was easy and the number of initial punctures was reduced. Radiation exposure time was also reduced for patient, surgeon, and the operating room staff [9].

8.2.3 Foramen Needle Placement

With the introduction of percutaneous lead placement, the procedure became more “blinded” and required the use of reliable bone landmarks that usually can be easily identified. Fluoroscopy can be used to check the needle position to the inner table of the sacrum. Once at this indicative level, testing stimulation can start [4].

To ameliorate the percutaneous technique, Hellstrom reported the use of the O-arm for surgical navigation for the implant in a patient needing the third revision. The O-arm (Medtronic Inc., Louisville, CO, USA) is a mobile 2D/3D X-ray imaging system optimized for bony structures in spinal and orthopedic surgery. In that case, the bony sacral structures were clearly visualized and the applied method was useful to help the surgeon. The method is slightly more invasive than the usual technique but could be an option in anatomically challenging cases and reoperations [10].

Poor response to needle electrical stimulation (i.e., anal motor and/or toe response only at high amplitude) or an abnormal motor response (e.g., ipsilateral buttock contraction or foot rotation) is relating to wrong needle placement (outside the foramen or not at the correct level). Re-performing needle insertion at the same or in the contralateral side and checking radiological landmarks again are advisable [4].

8.2.4 Introducer and Tined Lead Electrode Placement

It is crucial to avoid inadvertent deep placement of the introducer that may create a false path for the tined lead electrode. The directional guide can slip through the foramen into the pelvis or the introducer could be too far in, exiting in the foramen ventrally. Continuous or intermittent fluoroscopy is advised to control advancement of both the introducer and the dilator.

Gumber reported a case of a 50-year-old man with intractable anal pain who underwent insertion of a sacral nerve stimulator via the right S3 vertebral foramen with good symptomatic relief. Thirteen months after the implant, he presented signs of sepsis. Computed tomography (CT) and magnetic resonance imaging (MRI) showed a large presacral abscess. MRI demonstrated increate enhancement along the pathway of the stimulator electrode, indicating that the abscess was caused by leptomeningeal infection introduced at the time of sacral nerve stimulator placement. The patient was treated with antibiotics, sacral nerve implant removal, and TC- and endoscopy-guided drainage. In view of the progressive presacral sepsis, a laparotomy was performed with drainage of the abscess, closure of the upper rectum, and formation of a defunctioning end sigmoid colostomy. Following this, the presacral infection resolved [11].

Once the introducer is in place, with the radiopaque marker inside the sacral foramen, introduction of the electrode follows. The electrode must be placed with

the four contacts in close proximity to the target sacral spinal nerve. This is achieved if low-intensity stimulation (<2 mA at each contact) results in an adequate motor/sensory response.

This may require revision/optimization of the initial placement: the position can be altered by rotating the electrode or by gentle withdrawal or pushing in (or a combination of these movements), all preferably done with intermittent low-intensity stimulation and imaging. During movements, it is important to hold the introducer sheath and lead together when adjusting lead position [4].

The highest likelihood to be close to the nerve is at its exit at the ventral opening of the foramen because distal to that level the path of the nerve may vary. If the most distal electrode contact "0" gives a good response to stimulation throughout electrode positioning, it is indicative that the electrode lead follows the path of the nerve [4].

In case of only one or two contacts of the electrodes are in proximity to the nerve with inadequate motor/sensory response or if concomitant motor response of the forefoot/toe occurs prior to the pelvic floor response with less stimulation intensity: repositioning the electrode is advised. The significance of a correct position intraoperatively achieved has been reported in a recent review on patients with OAB. The authors concluded that with a higher number of intraoperative electrodes, responses were at significant lower risk for SNM implant revision, particularly for patients with greater toe responses [12].

If the electrode bends in the wrong direction outside the foramen ventrally, this may be due to the incorrect positioning or increased tissue resistance (e.g., after surgery in the pelvis): repositioning of the electrode is advised.

8.2.5 Tunneling, IPG Pocket, and Percutaneous Extension Lead

Pre-operative marking of the IPG position is advisable. Depending on the patient's stature, the best site of the pocket is 3–4 cm lateral to the sacral bone, avoiding contact with bony structures. This is especially important in thin patients and will reduce the post-operative pain [4].

The IPG placement is the last stage, but it is important to be accurate. Myer in a recent study on 1930 patients underwent to SNM definitive implant found two factors related to pocket creation and independently associated with an increased risk of infection requiring explant: hematoma formation and pocket depth of >3 cm. These factors remained significant also with multivariate analysis [13].

8.2.6 Conclusions

Standardization of stages for SNM implant may ensure close electrode proximity to the target nerve providing an optimal effect, more programming options, and reduced likelihood of side effects and complications.

Interdisciplinary Comment

The indications for this surgical procedure are not yet completely defined. The intraoperative complications that may occur during SNS implant are not frequent. In this scenario, it is mandatory that patients are treated by experts in this field.

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Anal Sphincter Reconstruction and Graciloplasty

9

Enrico Melega

9.1 Sphincter Reconstruction

9.1.1 Sphincteroplasty

Sphincter repair (sphincteroplasty) is indicated in patients with symptomatic FI caused by sphincter defect. Obstetric and iatrogenic aetiologies are the most common causes implicated [1]. From 75% to 100% of patients in reported series are female patients [2]. Sphincteroplasty aims to restore the anatomical integrity in order to re-create a barrier for faecal continence and with that the high-pressure zone.

Transanal ultrasound or transanal MRI is the gold standard imaging examination for detecting the presence, the site and the extent of anal sphincter damage [3].

The skin over the anal defect is incised and the ends of damaged muscles are identified. Avoiding excessive lateral dissection sparing muscle and preserving scare tissue are recommended [4].

The repair of interrupted end of external anal sphincter can be direct (end to end) or by overlapping, both surgical techniques resulted equal to an extensive review analysis [5]. A temporary protective colostomy does not influence morbidity and functional results [6].

9.1.2 Postanal Repair

In case of intact but weak anal sphincter, the postanal repair was proposed to restore the anorectal angle, the length of the anal canal and the high-pressure anal zone.

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Surgical technique consists in posterior incision that allows the proceeding into the intersphincteric space between the external and internal sphincters until the puborectalis muscle. The retrosacral fascia is divided to access the levator ani muscles. The ischiococcygeus, the pubococcygeus and then the puborectalis muscle, part of the levator ani, are approximated in layers, in order to create sharpened the anorectal angle and to enhance the passive closure at the upper anal canal. Anterior levator ani muscle plication was associated in some experience for improving functional results. The surgical procedure was identified as total pelvic floor repair.

Poor early functional results further deteriorate over time and this surgical approach was rarely used [4].

9.2 Dynamic Graciloplasty

In cases of extensive sphincter disruption or heavily impaired sphincter, techniques of muscle transposition aim to replace anal sphincters.

Pickrell et al. described the use of gracilis transposition around the anal canal to construct a neosphincter in 1952 [7]. Bilateral graciloplasty and bilateral gluteus maximus transposition were also used for muscle neosphincters but soon abandoned.

Non-stimulated gracilis muscle is unable to maintain tonic contraction over prolonged periods, therefore muscle gracilis transposition technique evolved with the addiction of electrical muscle stimulation (dynamic graciloplasty—DGP) [8]. The gracilis muscle is a fatigue-prone muscle composed by fast-twitch fibres. Adequate electrical stimulation training, according to alternation of stimulation and resting periods, produces a muscle conversion from fast-twitch, fatigue-prone (type II) to slow-twitch, fatigue-resistant (type I) muscle fibres. Following this conversion training, muscle fibre can sustain a continuous muscle contraction electrically controlled by implanted pulse generator. Electrical pulse generator is an implantable pacemaker, placed in the inferior part of abdominal wall, subcutaneously, and wired connected with the gracilis muscle. Amplitude, frequency, voltage and cycle (stimulation on—off) of stimulation can be controlled via a remote unit [9].

Through an upper thigh incision, the gracilis muscle is identified, the distal tendon is detached at its insertion on medial site of the knee. The tendon and muscle body are mobilized up to its neurovascular bundle, which must be preserved. Close to neurovascular bundle, two wire electrodes are inserted inside the muscle fibres and, after tested muscle contraction through electrical stimulation, fixed to epimysium. Electrodes are tunnelled subcutaneously to the lower abdominal wall, where the stimulator is implanted.

Tendon and muscle body are tunnelled and transposed to perianal region through two incisions, which are made lateral to the anus. The muscle and tendon are wrapped around the anal canal. The distal end of gracilis muscle tendon is then sutured to the ipsilateral or contralateral ischiatic bone spine or to the skin, depending on the length of tendon and the accommodation of muscle body in the perianal space.

Most configuration shape can be obtained: a gamma, epsilon and alpha loop [10].

A protective colostomy is not needed but sometimes created.

Patients should deambulate as soon as possible, and antithrombotic prophylaxis is made as well as wearing elastic stocks for several weeks, to prevent swelling leg and deep venous thrombotic complication.

The pacemaker is switched off for 4–6 weeks, and then muscle stimulation can start cyclically, with resting period longer than muscle contraction. Subsequently, the contracting time is increased in a stepwise manner, reducing the resting period, in order to achieve a continuous stimulation.

After muscle training period, gracilis muscle is able to maintain a continuous contraction and create a high-pressure zone in anal canal. Through a remote unit control, the patient can switch off the pacemaker, to permit defecation, and switch on, after defecation, to achieve continence.

At our institution, from 1996 to 2000; 13 (three male patients) dynamic graciloplasties were performed, 1 following abdominal perineal rectal resection for rectal adenocarcinoma and 2 for severe iatrogenic faecal incontinence; in the remaining ten female patients, dynamic graciloplasty was performed for severe faecal incontinence, three of those as salvage treatment following artificial anal sphincter explantation.

No mortality and intraoperative complication were recorded [11].

Interdisciplinary Comment

The outcome of sphincter reconstruction does not allow a functional activity of the sphincteric unit. Dynamic graciloplasty represents a surgical technique able to replace the activity of sphincteric unit, which is composed by slow and fast muscle fibres contraction. The indications for this surgical operation are rare and are related with the extent of the loss of sphincteric activity.

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Radiofrequency (SECCA) for Fecal Incontinence

10

Marco Frascio

Fecal incontinence has been defined as the unintentional passing of stool in an inappropriate place or time, more than two times a month [1]. Fecal incontinence is not a life-threatening disease; however, it can seriously impair quality of life in affected patients and frequently results in disability [2, 3]. It is a worldwide problem affecting 8–12% of the general population, often under-diagnosed, under-reported, and poorly managed. Fecal incontinence morbidity increases with age and can be frequent occurring in up to 45% of the elderly population [1].

Treatment of fecal incontinence starts conservatively through a fiber-enriched diet, physiotherapy of the pelvic floor and medications inducing constipation. When unsuccessful, patients presenting an anal sphincter defect can be offered a sphincter repair. New surgical options for patients with or without a sphincter defect are dynamic graciloplasty [4] or sacral neuromodulation [5] or artificial bowel sphincter [6].

Yet, all these treatments have success percentages defined as substantial improvement varying around 70%, carry some side effects, demand specific expertise and are not generally available.

Data obtained in randomized trials are currently limited, and there still appear to be no reliable guidelines for the optimal treatment of fecal incontinence. Current practice guidelines for the treatment of fecal incontinence are based on expert opinions, clinical experience, and case studies [7]. Several less-invasive approaches to the treatment of fecal incontinence have been developed recently.

The SECCA procedure consists in the application of radiofrequency energy to the internal anal sphincter. For the last two decades this energy has been used to

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treat gastroesophageal reflux disease, prostatic hypertrophy, sleep apnea syndrome, ablation of hepatic tumors, spinal lesions, renal tumors, and joint capsule instability [8].

In theory, radiofrequency-induced modification of the internal anal sphincter should cause collagen deposition and fibrosis with the potential effect of tightening of the affected area. In an animal model, non-ablative radiofrequency appeared to induce morphological changes in the internal and external anal sphincters leading to an anatomical state reminiscent of normal sphincter structure [9]. When delivered to tissue in the frequency range of 200 kHz–3.3 MHz, radiofrequency energy results in vibration of water molecules and subsequent frictional heating [9–12]. The SECCA procedure entails delivery of temperature- and impedance-controlled radiofrequency energy to the sphincteric complex of the anal canal extending up to 2.5 cm above the dentate line. The device is rotated 90° and the next anal quadrant is treated. The radiofrequency energy hand piece is an anoscopic device with four nickel–titanium-curved needle electrodes (22 gauges, 6 mm in length) that are deployed through the mucosa of the anal canal and into the internal sphincter muscle [11].

Results reported in literature are referring to good to moderate clinical effects, in some experience declining over time. The SECCA procedure might be valuable also in combination with other interventions for fecal incontinence. Results of randomized, sham-controlled trials are awaited [12–14]. No intraoperative complications are described in the literature. Few and mild post-operative complications are described in literature [13].

Contraindications to SECCA procedure are inflammatory bowel diseases [15, 16] and previous radiotherapy.

Interdisciplinary Comment

Radiofrequency is a mini-invasive surgical technique employed in other surgical fields as treatment of liver tumor and of renal cancer. However, the indications for this type of treatment are few and in selected patients. New clinical data are needed to define the outcomes and the exact role of this mini-invasive surgery.

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Part III

Short, Intermediate and Long-Term Postoperative Complications

Artificial Urinary (AUS) and Anal (AAS) Sphincter (AUS)

11

Salvatore Siracusano, Luigi Fondacaro, and Enrico Melega

11.1 Artificial Urinary Sphincter (AUS)

For the preparation of this chapter, we have decided to take into account the complications of the AUS without reference to one of the two specific devices as the only experiences available with more than 20 years of experience mainly refer to the AMS 800.

Complications following implantation of the AUS can be divided into the categories of incontinence, erosion and/or infection, and unusual complications.

In this setting, the total number of procedures done in a given center does not seem to be a determining risk factor for complications. This suggests that erosion and infection may be more closely related to the physiologic state of the host rather than the experience of the surgical team, provided standard precautions are strictly applied. Nevertheless, as experience with the AUS has grown, the overall revision rate has reportedly decreased.

In this context, incontinence following implantation of an AUS can result from:

- Alteration in bladder function
- Atrophy of the urethra
- Mechanical failure of the device

These causes may co-exist.

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11.1.1 Alteration in Bladder Function

It is based on post-operative patient symptoms because 23% of men undergoing AUS for PPI can develop de novo OAB [1]. Alteration in bladder function has been reported principally in patients with neurogenic bladder dysfunction, especially in children. These changes include de novo involuntary detrusor contractions, a decrease in bladder compliance, and the development of a high-pressure system, causing incontinence, hydronephrosis and ultimately renal failure. In this way the ideal candidates for sphincter implantation are those with a low-pressure, relaxed, and compliant bladder.

11.1.2 Atrophy of the Urethra

Urethral atrophy may occur at the cuff site secondary to long-term mechanical compression of the periurethral and urethral tissues (Fig. 11.1). However, some authors do not mention it as a possible cause of AUS failure. About 4 months following implantation, cuff efficiency diminishes, presumably because pressure atrophy occurs in every patient to some extent. The incidence of urethral atrophy leading to revision varies from 3% to 9.3% [1]. Atrophy can be lessened with nocturnal deactivation of the cuff.

However, sometimes some conditions may mimic a urethral atrophy. In fact, we hypothesize that material failure of the cuff or balloon, likely because of age and the resulting inability to generate the appropriate pressure, is the cause of failure and that urethral atrophy does not exist.

11.1.3 Mechanical Failure

This includes perforation of one of the components with loss of fluid from the system, air bubbles or organic debris within the system causing inadequate function of

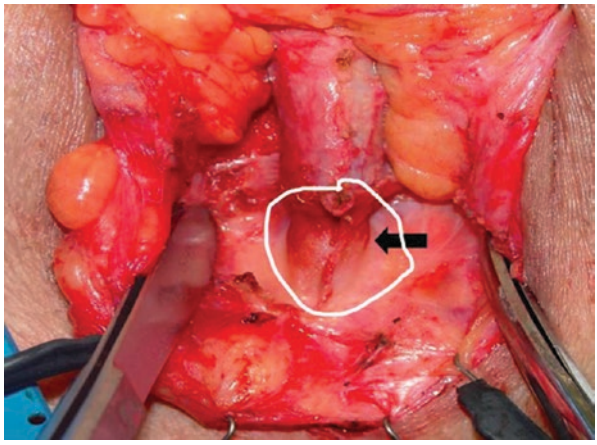

Fig. 11.1 Urethral atrophy

the pump, disconnection of the tubes or kinking of the tubes. Introduction of "kink-free" tubing has virtually eliminated this last complication. The incidence of this complication varies widely and ranges from 0% to 52.5% with the longest follow-up [1]. In this context the cuff seemed to be the most vulnerable part of the system followed by pump failure. Blockage is an exceptional event. At this regard Baylor, chronicling a 13-year experience with the AUS, mechanical failure occurred at an average of 68.1 months post-operatively [1].

11.1.4 Erosion and/or Infection or Extrusion of Components

Erosion and infection are two major complications that necessitate removal of the prosthesis (Fig. 11.2). Their incidence may be reported separately, or more commonly as a single complication. The incidence of these complications varies from 0% to 24.6% [1].

Most recent large series report an incidence of infection and erosion generally <8%. As would be expected, the highest incidence has been reported with the longest follow-up (10–15 years).

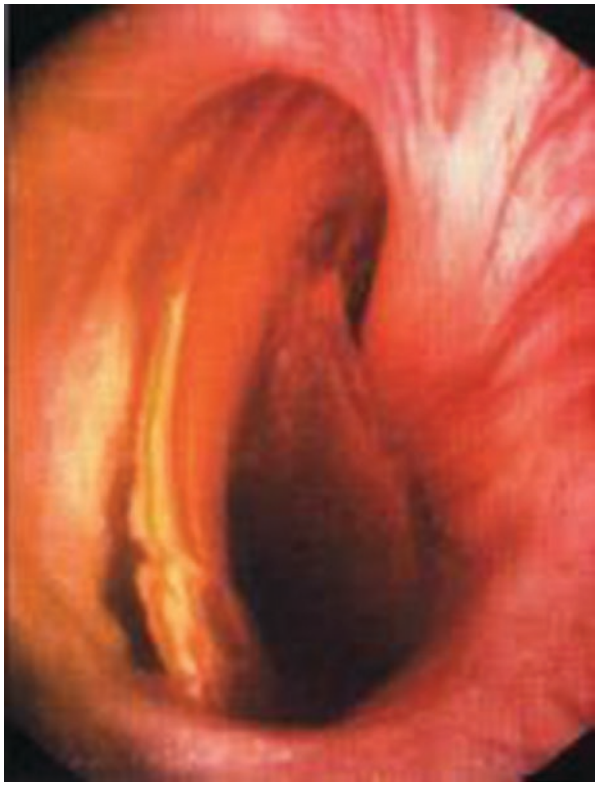

Fig. 11.2 Urethral erosion by urethroscopic view

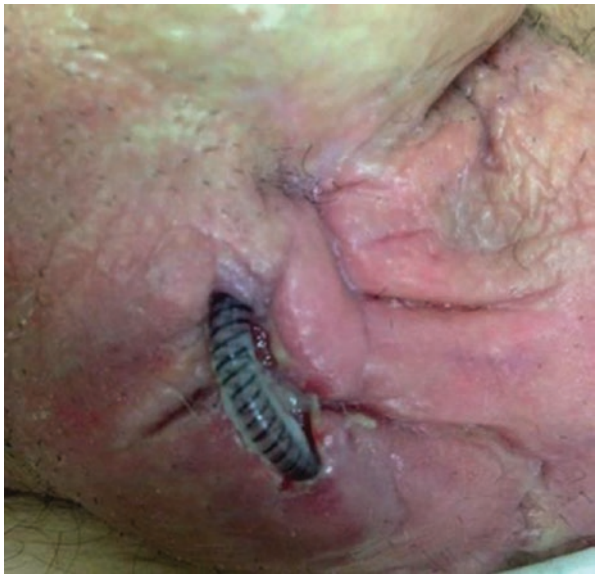

Fig. 11.3 Extrusion tubing connections

Lai and colleagues reported that erosion occurred at an average of 19.8 months post-operatively rather than in the peri-operative period. Previous surgery at the site of cuff placement increases the risk of erosion. This, however, may be decreased by delayed cuff activation. A study noted that patients undergoing a "secondary" implant (after a prior explant for erosion of infection) had a fourfold higher erosion rate compared to "virgin" cases.

Other risk factors include urethral catheterization and urethral endoscopic manipulations with an activated sphincter in place. This point is important, and it is crucial that patients with an AUS understand that if they are to have a catheter placed, they should ask their physician to have a urologist deactivate the AUS first.

A likely etiology of early erosion is intra-operative laceration of the urethra when dissecting it from the corpora cavernosa, where a difficult anatomical plane exists. Intra-operative recognition of urethral injury can be facilitated by retrograde perfusion sphincterometry using a flexible cystoscope. Finally, another complication may be represented by extrusion (Fig. 11.3) of tubing connections following decubitus with subcutaneous tissues and skin. In these cases, a conservative surgical attempt can be undertaken.

11.1.5 Rare Complications

Several unusual and rare complications have been reported in the literature, such as the intravesical migration of the reservoir with secondary stone formation in the

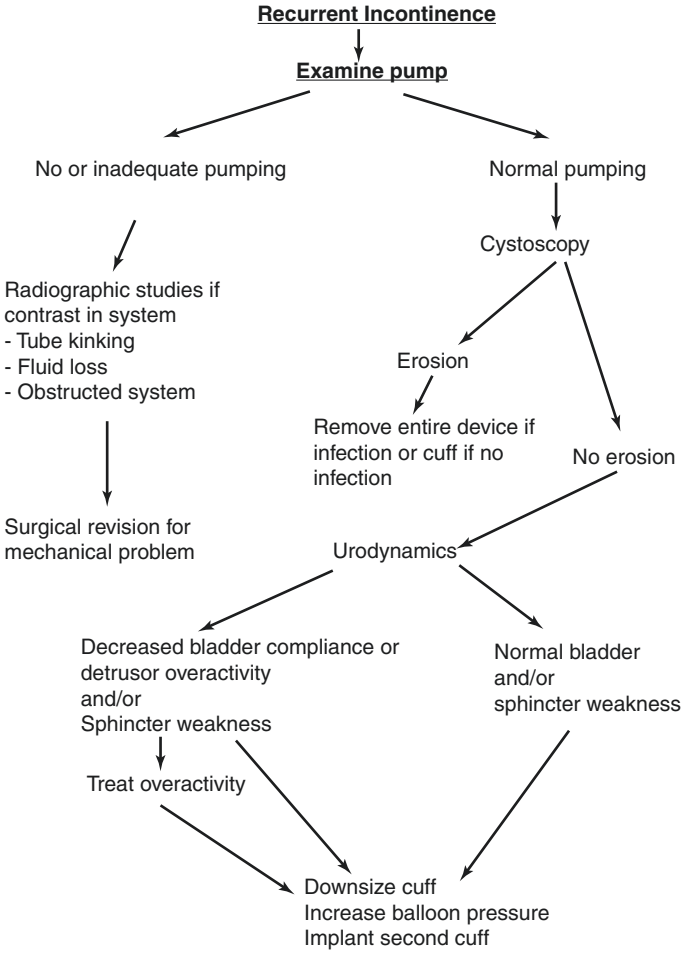

Fig. 11.4 Diagnostic algorithm to individualize the cause of AUS failure

bladder, or a giant urethral diverticulum at the site of a previously removed cuff because of erosion and urinary extravasation.

In this context it is evident that post-operative complications may be multifactorial and sometimes they are not easy to identify. Recently the ICI proposed a structured decision algorithm aimed at this purpose as reported in Fig. 11.4.

Interdisciplinary Comment

A comparison between artificial urinary and anal sphincters regarding long-term complications is impossible due to the fact that when implanted in the anus the device never reached an adequate follow-up.

11.2 Artificial Anal Sphincter (AAS)

The implantation of artificial anal sphincter was considered safe and technically easy, but eventually an unexpected high explantation rate and the adverse events rate were recorded [2].

Early and late complications were distinguished mainly in complications occurring before or after the artificial anal sphincter activation.

Infections, erosions or ulcerations were the most common adverse events recorded in the early or intermediate post-operative period. Post-activation infections varied between 6% and 33% [3].

The risk of infection is increased in comparison to other surgical procedures, partly due to the implantation of a foreign body in the anorectal region. Early infections, before activation of the device, involved mainly the perineum or abdomen, and are probably due to intra-operative or peri-operative device contamination despite meticulous surgical technique, asepsis, and intra- and peri-operative use of antiseptic solution, wound cares and the routine administration of post-operative antibiotics.

In our experience, early post-operative infections occurred in three cases and perianal skin erosions in other three patients. Infections were treated with explantation of the device and after wound healing patients were offered to have a dynamic graciloplasty; one case of skin erosion was explanted and successfully reimplanted with artificial anal sphincter; one refused other treatment and last case was successfully resutured [4–6].

Wexner [7], analyzing his experience on 50 patients, found that early first post-operative bowel movement and history of perianal infection were significant factors for early post-operative infection at both univariate and logistic regression analysis. It is possible that stool contamination of the wound in the early post-operative period predisposes to failure, but routinely bacterial culture from wound fluid in cases of device explantation found significant bacterial growth only in few cases, suggesting a multifactorial pathogenesis of wound and artificial anal sphincter infection. In fact, other risk factors could be considered such as wound tension, or the presence of diabetes mellitus, immunodepression, radiation-induced lesions on perineal skin [8] and history of perianal infection. In some series, artificial anal sphincter implantation was reported in patients with stoma for anal incontinence; even in this sub-group of patients, post-operative infections were recorded leading to the conclusion that stoma does not prevent post-operative device infection.

Late infections, following activation of the device, were caused mainly by erosion of the anal canal or perineal skin or rectum. Repeated straining during defecation, too tight anal cuff, elevated pressure inside the anal cuff, due to inappropriate pressure regulating balloon, tissue damage were the causes of tissue erosions and ulcerations. Erosions or ulcerations of the skin covering the pump and pressure balloon dislocations were reported less frequently. Infections and erosions resulted in explantation of the infected component or the complete device.

We recorded, in the follow-up following device activation, skin erosion with subsequent infection in two cases, one of these experienced anal pain for long time before skin erosion. In both cases the artificial anal sphincter was explanted.

Mechanical failure or evacuation difficulties were reported as causes of explantation or surgical revision.

Mechanical failure included rupture of the cuff, loss of fluid from the system, disconnection of any component, and malfunction or migration of the control pump and these are reported in percentage that varies from 8% to 26% [2]. In case of mechanical malfunction, a replacement of the damage component is possible; however it can be a cause of complete explantation. In our experience, cuff rupture occurred in two cases, due to excessive straining efforts. The cuff was successfully replaced in both cases. One patient had pump malfunction, which was replaced.

Obstructed defecation is a frequently reported adverse event following device activation that is usually managed with diet, stool softening, laxatives, enemas, and even with the device deactivation. A too tight anal cuff, a high pressure balloon, and a short opening time of the device are supposed to be the cause of difficulties in rectal evacuation. In some cases, the anal cuff replacement with wider one or the balloon replacement with one of lower pressures can be considered in order to face obstructed defecation [8].

The artificial anal sphincter implantation can worsen a previously undiagnosed outlet evacuation disorder due to colonic dysmotility or pudendal neuropathy or previous rectal prolapse surgery. Therefore, even facing with an incontinent patient, a careful attention has to be paid for evacuation dysfunction history.

We recorded obstructed defecation with several episodes of fecal impaction in four cases associated with anal pain in two. One case was unsuccessfully treated with implantation of a wider cuff, another patient had pressure balloon replacement with one with lower pressure without benefit, and the remaining had the device deactivated. Explantation was required in two cases [4–6].

High explantation rate, ranging from 14% to 65%, is reported in the literature. The risk of explantation was evaluated with the Kaplan–Meier survival curve. The cumulative risk of artificial bowel sphincter explantation increased with the time: 9.7% of the cumulative risk of artificial bowel sphincter explantation at first year; 13% at second year; 43%, 48%, and 57% at the third, fourth, and fifth years, respectively [7]. Therefore, more than at least half of artificial anal sphincter has to be removed within 5 years.

Fecal incontinence score and quality of life for fecal incontinence indexes significantly ameliorate in those patients with functional device, but when the results of artificial anal sphincter implantation are analyzed on the intention-to-treat basis, the outcome is disappointing.

The high complication and explantation rates, the poor level of study design and the cost of device reduce the indication of artificial anal sphincter (Acticon) implantation in favor of minimally invasive therapies and new designed artificial sphincter.

Interdisciplinary Comments

The high rate of mechanical complications and explantations rates, along with the cost of device, reduce the indication of this device implantation. In urologic surgery this device is highly used from 1973 with wide experience by many authors and in this context, it is considered a gold standard in the treatment of post-prostatectomy incontinence. Further clinical experiences are needed in proctologic surgery to define the role of this device in this field.

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Complications of Anal Sphincter Reconstruction and Graciloplasty

12

Enrico Melega

12.1 Sphincter Repair

Wound infection, ranging from 6% to 35%, is the most common reported complication that may cause suture dehiscence and influence the long-term outcome [1]. As previously said, temporary colostomy does not prevent infections; otherwise, colostomy can be required to control the anal infection.

Bleeding, urinary retention and urinary tract infection, fecal impaction, and wound hematoma are reported less frequently [2]. Early post-operative impaction is considered a threatening event for the risk of suture breaking, due to the excessive straining or manual fecal evacuation.

Occasional fecal impaction or obstructed defecation or digital assisted evacuation or frequent use of enema is also described in long-term follow-up as poor functional outcome.

Fecal continence is reported to improve in more than 75% of patients in the short-term follow-up. A progressive decline in continence is reported as proceeding with follow-up. The explanation of impairment of continence remains uncertain: early breakdown of the repair, aging, scarring, and progressive pudendal neuropathy can be considered as concomitant causes [3].

12.2 Dynamic Graciloplasty

Complications of the procedure are common and occur in more than 50% of cases. They include surgical site infections and hematoma at both perineal and thigh sites, perineal and thigh pain, rectal injury, anal and rectal erosion and skin erosion of the

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skin covering the pacemaker [4]. Two patients of our series developed adverse events in thigh site, deep venous thrombosis, in one, and hematoma requiring blood transfusion, in the other [5]. Muscle ischemia and tendon detachment are also reported, in literature [6]. Rectal and anal erosion, involving the muscle tendon, can be managed with antibiotics and surgical repair without explantation, as occur in case of artificial anal sphincter implantation.

Procedure-related complications are those involving electronic circuitry and stimulation. Amplitude of muscle stimulation may increase with time for muscle denervation or tissue atrophy or electrode displacement or electrode fracture. In case of electrode malfunction displacement or fracture, electrodes can be reimplanted, as occurred in two of our patients [5]. Pacemaker dislocation may cause loss of remote control as reported in few cases; patients are not more able to switch off and on the device and surgical replacement is required. Moreover, pulse generator battery exhausts with time; it has been calculated that battery can last from 7 to 10 years of life, depending on the amplitude of stimulation. Pulse generator substitution is easy to perform but is expensive.

Following the stimulation onset, few patients experienced perianal and thigh pain, requiring the reduction of amplitude of electrical stimulation or even the permanent switch-off of the stimulation.

As reported for artificial anal sphincter implantation, even in case of dynamic graciloplasty, constipation and obstructed defecation are frequently reported [7].

Despite the high morbidity and adverse event rate, dynamic graciloplasty remains efficient on anal incontinence over time with improving quality of life, but the indications are significantly reduced with the advent of new minimally invasive therapies.

Interdisciplinary Comments

Sphincter reconstruction and graciloplasty represent two surgical solutions with a high rate of complications. The main problem is related to the absence of predictive factors of failure. Ideally the graciloplasty is a fascinating solution because, at difference of compressive or suspensive slings used for urinary incontinence, the "new sphincter" is electrically activated. Further experiences are needed to evaluate the real role of this surgical technique.

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Slings for Urinary and Fecal Incontinence

13

Christian Gozzi, Salvatore Siracusano, and Filippo La Torre

13.1 Slings for Urinary Incontinence

13.1.1 AdVance/AdVance XP

In a study between February 2006 and April 2009, of 230 consecutive patients treated with the AdVance sling, 21.3% (49 patients) had acute urinary retention after removal of the catheter. One patient (0.4%) had urinary infection with fever 10 days after sling implantation, treated with antibiotics, and one patient (0.4%) showed local wound infection 8 days after surgery and was treated with oral antibiotics. No further treatment was necessary. One patient (0.4%) suffered chronic perineal pain and five patients (2.2%) reported mild perineal discomfort for 4–6 weeks, but these patients did not need any pain medication. One patient showed pubic symphysitis 4 months after sling implantation. During explantation there were no local signs of inflammation. Further diagnostics revealed the Guillain–Barrè syndrome as the causative pathology [1].

In another study 80 patients were treated with the AdVance and AdVance XP (39–41, respectively). No peri-operative complications were reported. There were a total of 9 and 12 device- or procedure-related complications in AdVance and AdVance XP arms. There were two serious AEs (adverse events) in the AdVance

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group. One was symphysitis, which occurred at day 54 post-implantation. The patient underwent catheterization and received antibiotics and symptoms resolved at 8 weeks of treatment. The second AE was an infection of tendon adductor longus 41 days post-operation. The event resolved with the antibiotic treatment.

In the AdVance XP group, there were three serious AEs. One patient with an urge of urinary incontinence received medication with several anticholinergics for 6 months followed by transection of one arm of the sling (urgency symptoms disappeared). Two patients with persistent urinary retention underwent transection of one arm of the sling. In both cases, the symptoms were resolved and continence improved. No sling explantation was required in either treatment group [2].

The most frequent complication that occurs after implantation of AdVance is urinary retention. This usually resolves spontaneously in few days after surgery, or at most in few weeks. These patients require therefore to be adequately cared for in the post-operative period. If there is a minimum residual, the first therapeutic approach will be pharmacological with the administration of anticholinergics. The association between high-dose anticholinergics and intermittent self-catheterization or derivation by suprapubic or transurethral catheter (4–5 times/day) is recommended in cases of severe residual urine.

It is necessary to pay special attention during catheterization; in fact in several patients, urethral perforations were found caused by the maneuver itself (Fig. 13.1a, b).

If, therefore, self-catheterization appears to be difficult to perform, it will be advisable to place a small indwelling catheter or suprapubic derivation for the time necessary to resolution of urinary retention.

Very rarely (<1%) could be a retention that persists over time that can be settled by bilateral or unilateral section of the sling under endoscopic surveillance, which should be performed at least after 3–4 months of the device implantation.

In case of failure of the Advance implant, if indications to the implant were correct, it has to be considered an improper placement of the sling. The passage too lateral or dorsal of the needles can in fact cause a worsening of incontinence.

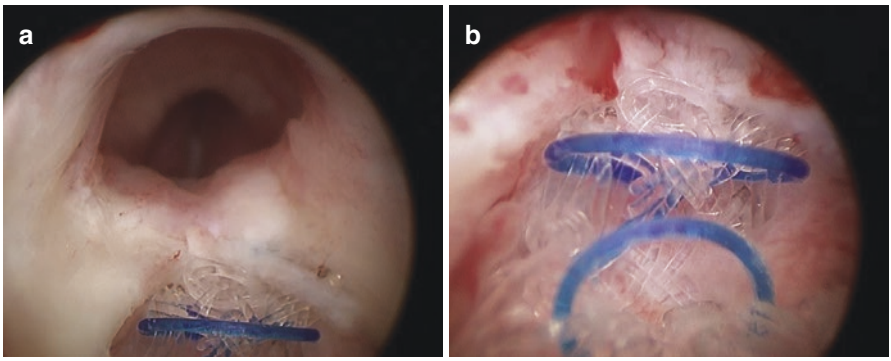

Fig. 13.1 (**a**, **b**) Three months after Advance implant. Radiotreated patient with urethral erosion due to traumatic catheterization for urinary retention

This condition is due to dorsal traction of the urethra that will keep it pervia, getting worse the sphincter functionality. In this case you will need to intervene through section of the two side arms and the new Advance implant in the correct position.

13.1.2 I-Stop TOMS

Not many data are available in the literature about this device. In two prospective case series, 143 patients were included with 1-year follow-up and the reported success rates (>50% improvement) were excellent [3]. Yiou et al. recently described the prospective results of 40 patients treated with the TOMS™ with a 2-year follow-up; seven patients required additional treatment between the first year and the second year after implantation (five PRO-ACT balloons, two artificial urinary sphincter [AUS]). No post-operative complications were reported after 12 months [4].

A total of 103 patients were followed up for 12 months. The surgical procedure was considered easy to perform. Treatment satisfaction was >90%. The post-void residual urine volume did not increase substantially, and acute urinary retention did not occur. The perineal pain scores were very low at follow-up. Wound infection was seen in two patients at the 1-month follow-up [5].

One of the complications can be the infection occurring in both the early and post-operative late stages. The problem of infection after surgery can be attributed to a placement of the sling, which is more superficial than other devices. The treatment of the infection consists of antibiotic therapy.

Being positioned more distally and more superficially than Advance, it is possible to treat any failure by positioning an Advance implant correctly considering that the indications for placement of TOMS are similar to those of Advance (residual sphincter function).

13.1.3 Virtue

McCall [6] identified 32 consecutive male patients who were implanted with the Virtue Quadratic (VQ) sling over the study period. One patient was excluded due to no follow-up. Median follow-up was 55 months. Median pre-operative and post-operative pads per day were 3 (interquartile range: 1–3) and 2 (1–2.5). There were 21 (68%) patients who were considered procedure failures. Two (7%) patients reported chronic pain following placement and seven (22%) underwent subsequent sling explant due to pain or for failure (1 vs. 6). Six (20%) patients underwent subsequent AUS placement. Failure was more likely in patients with external beam radiation therapy (6; 19%) ($P = 0.02$). There was no association between procedure failure with age ($P = 0.65$) or severity of incontinence ($P = 0.17$). The results shown in this study demonstrated a significant procedure failure and complication rate. The authors do not recommend the use of the VQ sling and have abandoned all further implantation of the device.

Opposite results have been described by Ferro et al. [7], where 72.4% of patients had pre-operative mild incontinence (1–2 pads/day), while nine patients used 3–5 pads/day. There were a total of 17 complications, which occurred in 29 patients (58.6%); all were Clavien–Dindo grade I. At 12-month follow-up, patients showed a significant improvement in 24-h pad test (128.6 vs. 2.5 g), the number of pads per day (2 vs. 0), ICIQ-SF score (14.3 vs. 0.9) and USP score for SUI (4 vs. 0), and outcomes remained stable at 36 months. At the last follow-up, the median score on the PGI-I questionnaire was 1 (very much better).

13.1.4 Reemex

The first results of this system were published by Sousa-Escandò et al. in 2004. In a multicenter European study with 51 patients with a mean follow-up period of 32 mo, 33 patients were cured (64.7%). Almost all patients needed at least one readjustment of the sling under local anesthesia. The sling had to be removed in three cases: in one case urethral erosion occurred, and three mild perineal hematomas were seen. Perineal discomfort or pain was very common and was treated with oral pain medication [8, 9].

Considering the various interventions to which patients should be subjected for further adjustments, there is a high risk of infection. The risk of infection is increased by the presence of a foreign body located at a subcutaneous level (variotensor) that has to be reached through an incision to obtain a re-tension. To treat this frequent complication, is not always enough antibiotic therapy, but in most cases it has to be removed the device. This maneuver is made difficult by the incorporation of the network in the subcutaneous tissue that forms a fibrosis around the mesh component and complicates removal. The infection, associated with the mechanical pressure and the chronic stimulation on the urethra, especially if atrophic, may cause erosion of the urethra itself. This ulceration will give rise to continuous infections with high risk of abscess and, if not treated, to erosion. In case of erosion of the urethra, the first treatment must be the removal of the device and the placement of a urinary catheter to facilitate the spontaneous healing of the urethral mucosa, or recut the wound borders and make a direct suture in more severe cases.

Since Reemex is a treatment that causes an obstruction on the urethra to prevent the leakage of urine, in some cases it can cause urinary urgency. To improve this problem, it is possible to proceed or with the loosening of the cords, to reduce the pressure of the network on the urethra, or through conservative treatment with administration of drug therapy (anticholinergics), which could however cause an increase in the post-void bladder residual.

Referred pain in a large percentage of treated patients is due to compression and irritation of the mesh on the superficial perineal nerves. This symptom is often treatable with painkillers and anti-inflammatories, but sometimes leads to the patient's request to remove the device. In case of failure of Reemex, it is possible to implant a functional sling or an artificial urinary sphincter (AUS). If the residual

sphincter function is valid and the membranous urethra shows hypermobility or prolapse, then you can choose for a functional sling (Advance) that has to be positioned more cranially than Reemex. In the remaining cases, the gold standard is represented by AUS. In case of damage of the urethral bulb, the positioning of AUS should be trans-cavernous or it should be placed more proximally, where the urethra appears intact.

13.1.5 ATOMS

The long-term results (2 years' follow-up) of the ATOMS® have been described in two prospective cohort studies including 137 patients. The success rate (<50% reduction in pad use) varies from 72% to 91%. Sling was performed in 4–35%. The most important reasons for sling removal were erosion and infections (47–40% of cases). Sixty-eight percent of cases present transient pain, which disappears within the first 3 months, but in three cases sling removal following persistent serious pain was reported [9, 10].

Being ATOMS a combined device, there is a high risk of infection due to the silicone parts. There is a great difficulty in removing the trans-obturator mesh that anyway, if infected, must be completely removed (Fig. 13.2a, b).

As well as for the other devices that cause obstruction of the urethra, ATOMS can determine atrophy for chronic stimulation and consequent erosion, especially considering the presence of an inflatable cushion placed on the mesh, on which the patient may cause further compression and recumbency, causing a worsening local condition (Fig. 13.3a, b).

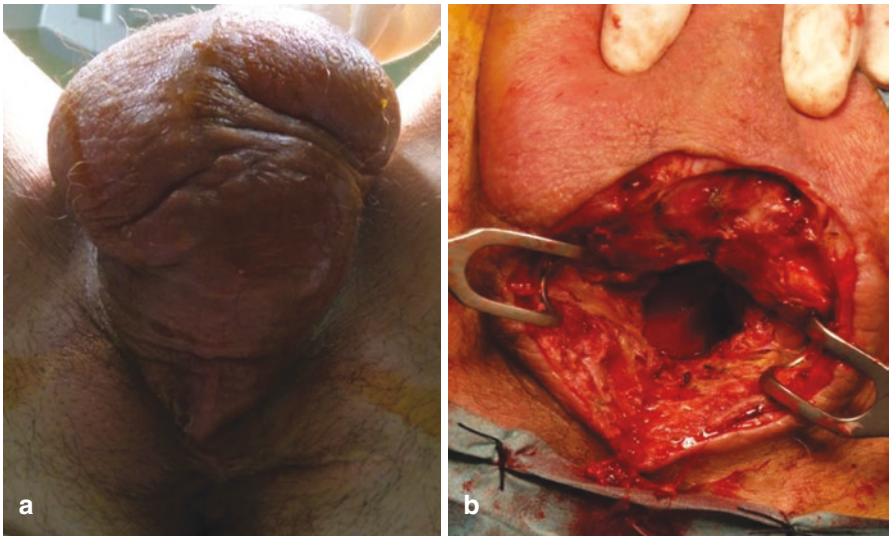

Fig. 13.2 (**a**) Perineal–scrotal abscess after ATOMS implant. (**b**) Post-abscess drainage

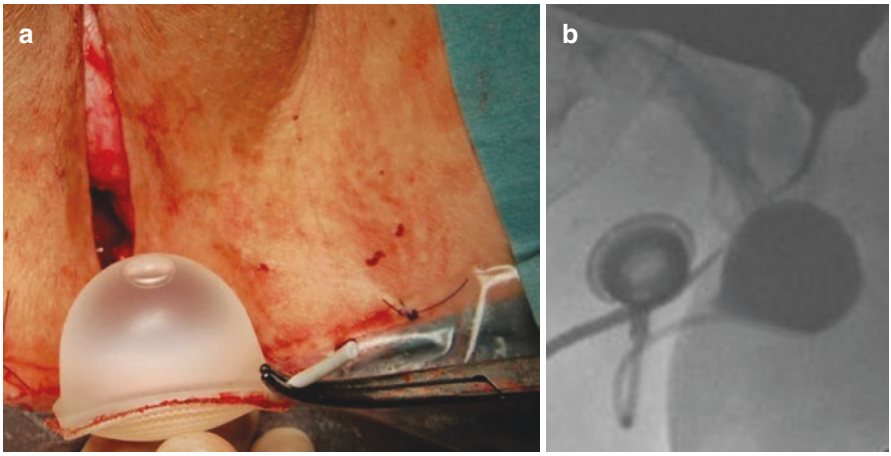

Fig. 13.3 (**a**) Extrusion of inflatable cushion that is the cause of recumbency. (**b**) Cystourethrography shows recumbency of urethra that is the cause of pain for the patient

Even for the ATOMS, in case of erosion, it will be necessary to remove the device and subsequently to implant an AUS, distally to the ATOMS site.

13.1.6 Argus and Argus-T

Regarding ARGUS sling by retropubic approach in a cohort of 48 patients with a mean follow-up of 7.5 months, Romano showed a cure rate of 73% [11]. Three urethral perforations during surgery were reported, and the sling had to be removed in five patients (10.4%). Seven patients had acute urinary retention, and, except for one patient in which the sling needed to be loosened, it resolved spontaneously.

Dalpiaz [10] revaluated 29 male patients who received an Argus® and reported a complication rate of 35%. Overall 24 patients (83%) experienced a total of 37 complications at a median follow-up of 35 months, including 10 (35%) in acute urinary retention. The sling was removed in ten patients (35%) due to urethral erosion (three patients), infection (two patients), system dislocation (two patients), urinary retention (two patients), and persistent pain (one patient). Eight men (27%) complained of significant perineal pain, necessitating continuous oral analgesics. In one patient, ureteral reimplantation was done due to ureteral erosion from a dislocated sling. As regards the displacement of the sling, the mechanism is probably due to the retro-pubic positioning of the Argus, which through a continuous tensioning determines the rotation and migration of the device.

Recently Bochove-Overgaauw [12], in 100 consecutive patients, reported an overall success rate (defined as patients who were cured and improved) of 92% at the first evaluation 6 weeks after surgery and 72% (68 of 95) after a median FU of 27 months (range 14–57). A revision procedure to tighten the sling via the suprapubic incision was done in 24 patients once, in seven twice and in one patient three

times. Regarding complications they occurred in 55 patients. In 11 patients, the sling had to be removed due to infection refractory to antibiotic treatment [6], erosion through the bladder/urethra [3], sling rupture [1], and hypersensitivity/pain [1]. Of these patients, three had been treated previously with radiotherapy for local recurrence of prostate cancer, and two had been diagnosed and treated with incision of urethral strictures or bladder neck stenosis before Argus implantation. Regarding ARGUS-T, Siracusano [13] reported an overall successful rate of 86.2% (157/182 patients) at the median follow-up of 22 months. In particular, analyzing the patient who underwent a previous radiotherapy, only the 61.2% of patients (30/49) obtained a successful result. None complication occurred intra-operatively while in 26 of 182 patients (14.2%), a post-operative complication, such as infection in 9 of 182 patients (4.9%), urethral erosion in 1 of 182 patients (0.5%) and hypercontinence in 16 of 182 patients (8.8%), was observed. The overall removal rate was 9.3% (17/182 patients). Transient inguinal or perineal pain was reported by 72 of 182 (38.5%) patients. The pain disappeared within 1 month with the administration of analgesics.

Over the last few years ARGUS system was replaced by ARGUS-T device, which is certainly advantageous when the sphincter function is anatomically compromised. In fact, this device is certainly less invasive than the AUS and at the same time does not preclude a subsequent implant of the artificial sphincter as the bulbocavernosus muscle has remained intact.

Interdisciplinary Comment

Slings as a support of the puborectalis muscle have been an attempt to improve the anal sphincteric function in fecal incontinence, but they did not work despite an initial interest. Luckily, in the small sample of patients, no relevant complications have been described in the short and long terms. Slings failure can be attributed to our persisting ignorance of the physiology of anal continence.

13.2 Slings for Fecal Incontinence

Firstly proposed as treatment of stress urinary incontinence [14], the use of Anal Slings has gained popularity and this mini-invasive technique has opened new possibilities in the field of faecal incontinence. Therefore, it is not exempt from adverse reactions. Depending on the surgical technique and the material of the implanted mesh, we can observe mild-to-moderate side effects such as post-operative pain, infection, faecal retention, incontinence recurrence, de novo urgency and rectal erosion. The majority of them appeared in the short-term follow-up (within 12 months), and resolved spontaneously or with medical treatment, but still there is a non-predictable, inter-individual variability.

Slings differ in their composition, going from the adynamic Thiersch silver wire (now completely abandoned) to Dacron-reinforced Silastic sling, Mersilene mesh,

Polypropylene mono/multifilament implants or partially/completely readsorbing nets. Unfortunately, none of them have proved to be the ideal material, in terms of resistance, tolerance, tissue integration and costs. Although the polypropylene is considered by many authors the material of choice, a report by Clavé et al. [14] proved that the PP is not inert, and processes like haematomas in the site of implantation alter the physical and mechanical properties of the polymer, because of the accumulation of blood-derived fatty acids and radical oxidative products. This mechanism explains the reason why multifilament PP, non-knitted non-woven PP and composite implants are more frequently associated with infection and subsequent degradation. On the contrary, monofilament PP and re-adsorbing nets are involved in a fibrous reaction, which leads to a complete disappearance of fibroblasts and maturation of collagen, with better integration of the mesh.

Different outcomes have also been observed depending on the different routes of mesh implantation.

The anal encirclement is definitely the most hazardous technique, associated with a large variety of side effects. The subcutaneous implant is at high risk of skin or mucosal erosion with subsequent infection or rectal ulcer. In addition, it acts as an obstruction causing constipation and faecal impaction if too tightened [15]. Devesa et al. [16], using a silicon band like the Flat Drain Jackson-Pratt® and suturing the hollow ends with a small piece of a Marlex® mesh, reported good controls of symptoms, but a high index of complications. Among these, early side effects included spontaneous break of the sling in 6% of patients probably due to the inadequate method of closing the device. Late complications regarded skin erosion and consequent infection in 6% of patients and breaking of the sling in 23% of cases, requiring, for half of them, the sling removal and its eventual re-implantation.

The retropubic access has proved to be superior in terms of adverse events, which, though, are still consistent as demonstrated in the very limited series of eight patients who underwent the procedure by Yamana et al. [17]. In one patient the polyester mesh caused a wound infection in the early post-operative period, while another patient developed a rectal ulcer, necessitating the sling explant. Incontinence recurrence, combined de novo urinary urgency or urinary retention is also advocated to be a potential side effect in this peculiar route, probably due to the proximity of the mesh to the bladder, thus also interfering with urinary continence.

The trans-obturator approach reduces the risk of bladder, bowel and vascular and vaginal injures with the needle passage, and has shown a low rate of complications [18, 19]. The Food and Drug Administration (FDA)-approved protocol for TOPAS system [20] demonstrates the safety and feasibility of this technique applied in a series of 152 patients. None of them reported skin extrusion or exposure of the material, nor rectal ulcer, being the central core of the sling pre-attached to a porcine dermis in order to protect the rectum. The most common adverse event was a mild post-operative pelvic and groin pain/discomfort (27%), which resolved spontaneously (36%) or required a non-surgical treatment (62%). A very low rate of serious AEs included faecal incontinence recurrence that needed a re-operation, incision site infection treated by oral antibiotics and other systemic disorders in fragile patients.

In conclusion, trans-obturator anal sling placement is a safe, effective procedure if correctly performed, provided a good knowledge of the implanted material. However, care should be taken in case of mild-to-severe adverse reactions such as pain, infection and faecal incontinence recurrence [21].

Interdisciplinary Comments

The perineal pain is the main complication of this procedure as well as the risk of infection. The surgical technique needs to be improved in terms of long-term outcomes as it happened for trans-obturator approach for the treatment of post-prostatectomy urinary incontinence.

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14 ProACT for Urinary Incontinence (Early, Intermediate, and Long-Term Complications)

Alessandro Giammò

According to the most recent version of the *European Association of Urology (EAU) Guidelines on urinary incontinence*, there is very limited short-term evidence suggesting that the non-circumferential compression device (ProACT) is an effective treatment of post-prostatectomy stress urinary incontinence. The European guidelines give cautious recommendations because the implant of ProACT is associated with a high failure and complication rates, leading to frequent explantation. For this reason they recommend that the implantation of artificial compression device (ProACT) for men should only be offered in expert centers. Nevertheless, they advise to warn men receiving ProACT that, even in expert centers, there is a high risk of complications, mechanical failure, or a need for explantation. They warn, furthermore, to avoid the implant of ProACT in men who have had pelvic radiotherapy, at higher risk of failure [1].

The EAU guidelines refer to a prospective study by Rupret et al. on 128 patients implanted with ProACT with mean follow-up of 56.3 months describing a "good" functional outcome in 68% of patients with explant of the device in 18%. They reported the following incidence of complications: 8.5% urethral erosion/infection, 5.4% migration, 13.3% revision surgery [2]. At the end of the follow-up 18% ($n = 23$) of the balloons were explanted, but 74% ($n = 17$) of them were successfully re-implanted; so only 6 implants (4.7%) should be considered absolute failure. In the same article the author found a significant correlation between radiotherapy and the occurrence of complications (failure, urethral erosion, migration, intraoperative perforation). If we analyze the population treated in this cohort, 25% of patients had undergone adjuvant radiotherapy, that is considered a relative contraindication to ProACT placement for the fibrotic quality of periurethral tissues. It is our opinion that there may be a bias in the guidelines, that refer to a study with a high prevalence

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of radiotreated patients, a population at higher risk of complications, and without considering successful reimplantation as therapeutic success, even if with the expense of a secondary surgical procedure.

In another study by Hubner et al. he demonstrated in a cohort of 117 consecutive cases that continence results are durable over 2 years. There were complications in 54 patients, but mostly were minor and decreasing with increasing expertise. They had 6% of temporary urinary retention requiring only partial deflate of the balloon; 10% balloon rupture, that were replaced after 1–2 months; 7% migration without erosion, requiring reimplantation; 6.4% urethral/bladder erosion, requiring removal and replacement 6 weeks later; 26% explanted for no response. Reimplantations for complications were required in 32 patients, with 75% success rate [3]. It is remarkable that the lack of response, and thus the consecutive removal of the device—that is an out-office minimally invasive procedure—is considered a complication and not a failure of the technique. Complications should be regarded as unlucky events that deviate from the standard follow-up, whether a failure of the technique is the lack of therapeutic success. It is our opinion that in this study there is a bias due to over-rating of complications.

Gilling et al. followed up a cohort of 32 patients for 12 months after successful ProACT placement. They had only one case of intraoperative bladder injury; they describe wound infections in three patients requiring unilateral (two cases) or bilateral (one case) removal of the balloons: in the case of unilateral removal, the device was replaced in one case, in the other the patient was dry with only one balloon. Device migration, and subsequent removal, occurred in only two patients. Overall two patients (5%) required unilateral removal and three required bilateral removal (8%). Minor and self-limiting complications were: transient pain (6), temporary urinary retention (2), UTI (2), and de-novo urgency (2) [4].

Martens in a series of 29 implants reported 10 cases of perioperative complications, 20 cases of postoperative complications, and 12 revisions. Among the perioperative complications only 2 of 6 bladder perforations required a secondary surgical repositioning (in the other 4 cases implantation of balloons was possible, despite the bladder infraction); there were only 1 unilateral and 1 bilateral cases of balloon defect; one case of scrotal hematoma and one case of urinary retention represented temporary and self-limiting complications; an allergic reaction to iodine and a case of atrial fibrillation were not related to the device. Among the postoperative complications the dislocation of the device was the most frequent, but in 10 of 14 cases it happened only once. The most worrisome complication—i.e., erosion—happened in only two cases. Among surgical revision in 8 of 12 cases it was needed only once [5].

The latest version of the international guidelines of the *International Consultation on Incontinence* only mentions ProACT without giving indications on its use, and indicates only the artificial urinary sphincter and male slings as possible treatments of male stress urinary incontinence in the specialized management of incontinence table [6]. The device was present in the previous version of the guidelines, even if it had not a specific recommendation. It is strange that it has not been included in the 2017 guidelines, in particular with reference to the concomitant 2017 FDA approval that allowed the use and reimbursement of ProACT implant in the USA.

At the 47th annual meeting of International Continence Society attended in Florence in 2017, the Italian Group presented results and complications at short and medium term in a large cohort of patients. In a multicenter retrospective study involving 7 centers in Italy, data on 486 consecutive patients were collected with a short-term follow-up of 6 months. This study is one of the largest and most recent cohorts available in medical literature. Most of the interventions (301) were done under fluoroscopic control, the rest (184) with ultrasound guidance. Only 77 patients (15.8%) had undergone adjuvant radiotherapy. Perioperative complications were found only in 42 patients (8.6%): most of them were bladder perforations ($n = 25$; 5.1%), the others urethral perforations ($n = 11$; 2.2%) and bleeding ($n = 6$; 1.2%). All complications were classified as grade I (8.3%) or II (0.2%) according to the Clavien-Dindo Classification of Surgical Complications [7].

The same working group analyzed data from 9 Italian centers on 515 consecutive patients treated with ProACT implant for postoperative stress incontinence. Of them 230 patients had a follow-up >24 months, with mean follow-up of 77.5 months (SD 37, range 24–174). They assisted 46 complications in 44 patients (19%): ProACT device rupture ($n = 22$, 9.5%) (Fig. 14.5); recurrent urinary tract infection ($n = 1$, 0.4%); acute urinary retention ($n = 2$, 0.8%); ProACT infection ($n = 7$, 2.8%); ProACT migration ($n = 9$, 3.6%) (Figs. 14.1, 14.2, and 14.3); and urethral erosion ($n = 5$, 2%). Thirty-one complications (67.4%) were considered grade I, 3 complications (1.2%) grade II, and 12 grade III according to the Clavien-Dindo Classification of Surgical Complications. They had no grade 4 or higher complications. Fifteen patients (6%) underwent monolateral ($n = 12$, 4.8%) or bilateral ($n = 3$, 1.2%) reimplant of ProACT balloons. Three of these patients were dry, nine improved [9] (Figs. 14.4 and 14.5).

The rate of complications in this cohort of patients is 19% with a mean follow-up of 77.5 months in a large cohort of patients. It is important to underline that most of complications are self-limiting and do not require major surgical procedures (Clavien-Dindo grade I and II). Also most of grade III complications are managed in an out-office setting, not requiring major surgery (Fig. 14.6).

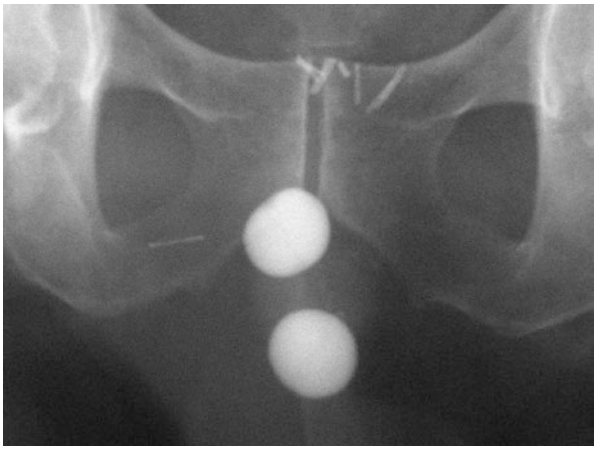

Fig. 14.1 Caudal dislocation of balloon

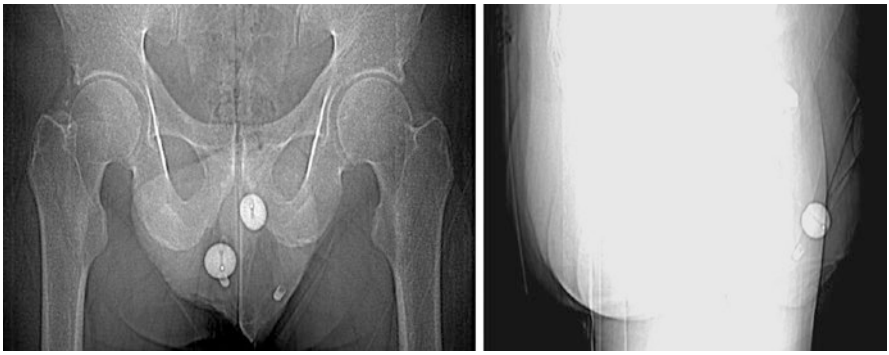

Fig. 14.2 Caudal and anterior dislocation of the balloon with antero-posterior and latero-lateral view

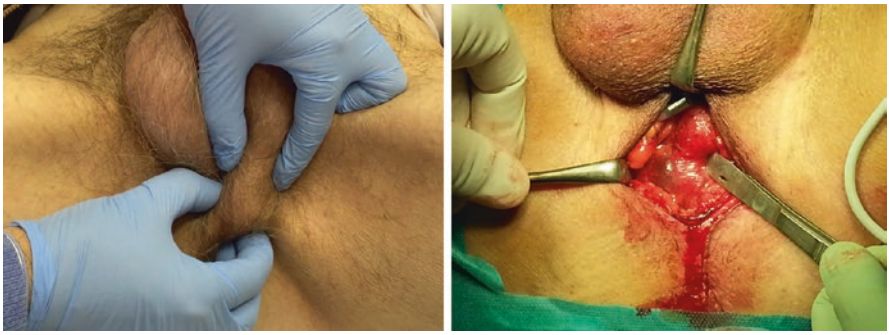

Fig. 14.3 Perineal dislocation of the balloon, palpable though the skin, and its surgical exploration

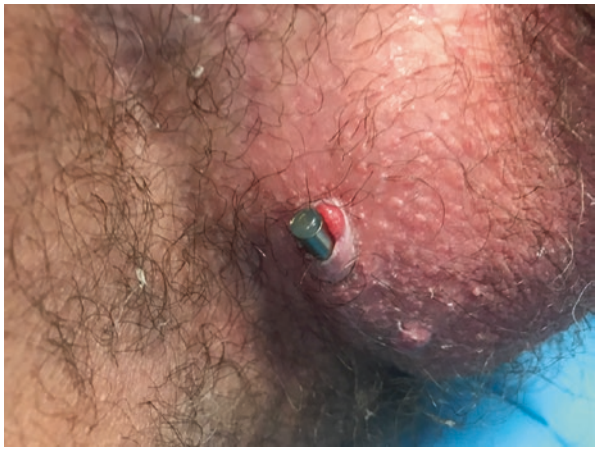

Fig. 14.4 Infection and scrotal skin extrusion of the titanium port

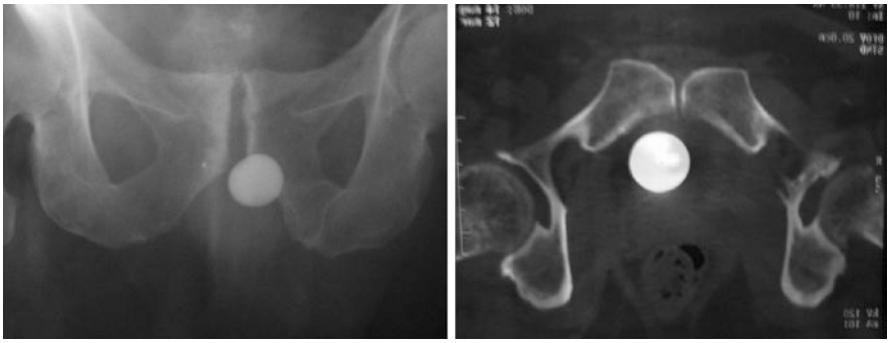

Fig. 14.5 Deflate of the balloon, radioscopic (right) and CT (left) view [8]

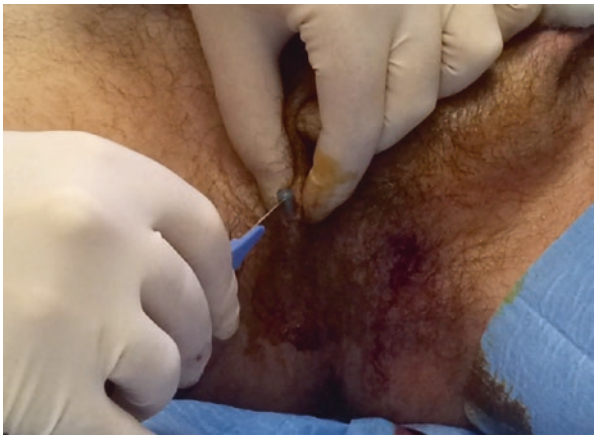

Fig. 14.6 Simplicity of device removal in out-office setting and local anesthesia

We can conclude that complications are described in various good quality studies, but when examining the results most of them appear minor and transient. Furthermore, we have to consider that several studies refer to the first generation of the device that was subsequently replaced by a newer generation with a lower risk of rupture.

The most severe complications require only minor surgical procedures (e.g., out-office device removal or reimplantation), so it appears that the ProACT device is correlated with mainly minor complications. Complications seem to be the strength of this device: even when things go the wrong way, complications are well tolerated by the patient and are easy to be solved. (With the contribution of Dr. Enrico Ammirati.)

Interdisciplinary Comment

ProACT is conceptually able to recover the compressive action of urethral sphincter which is mostly represented at membranous urethra with typical omega shape. The placement of balloons laterally to the membranous urethra must be coaxial to make the coaptation of the membranous urethra more effective. Similar positioning of balloons is necessary when they are placed around anal sphincter.

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Bulking Agents for Urinary and Fecal Incontinence

15

Michele Pennisi, Antonio Luigi Pastore, and Filippo La Torre

15.1 Bulking Agents for Urinary Incontinence

The incidence of SUI after radical prostatectomy has been reported to range from 8% to 47% [1–4], whereas the incidence of SUI after benign prostatic surgery has been reported to be 0.5% [5]. When conservative treatment fails, surgical treatment should be considered. AUS is considered the gold standard treatment for male SUI, with a success rate ranging from 59% to 90% and a patient satisfaction rate of 76% [6, 7]. However, the revision rate for AUS is relatively high (20% to 29%) owing to infection, urethral erosion, and mechanical failure [6, 7]. Compared with AUS, a male sling operation has several advantages, including the absence of mechanical problems, no need for device training, immediate efficacy, and an overall reduced revision rate. The success rate of a male sling operation ranges from 54% to 83% [8, 9]. However, urinary retention, erosion, infection, system dislocation, and persistent pain are possible complications of a male sling operation, whereas technical difficulty is another problem in patients who have undergone radical pelvic surgery [10].

Compared with other surgical treatments, bulking agent injection is less invasive but has a lower success rate, and multiple injections are usually needed to maintain continence [11]. The therapeutic mechanism of bulking agent injection therapy in male SUI patients is urethral sphincter obstruction or the sealing effect afforded by the bulking agent. Histologically, the bladder neck and posterior urethra consist of

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four layers, namely the mucosa, lamina propria, muscle layer, and adventitia. Of the four layers, the lamina propria has the potential space for bulging. If the bulking agent is inserted into the lamina propria, dissecting and urethral bulging between the mucosa and muscle layer can occur and result in sealing [10]. A variety of bulking agents have been used to treat male SUI. Polytetrafluoroethylene (Teflon) was widely used in the past, but was shown to cause several problems, including urethral irritation and perineal discomfort; small particle migration to the regional lymph nodes, lungs, and brain; and in animal experiments, polytetrafluoroethylene sarcoma formation [12]. Therefore, polytetrafluoroethylene is not currently in use. One of the most commonly used materials is collagen, which does not migrate to other sites. Collagen implant is well tolerated, has low complication rates, and has been recommended for mild-to-moderate incontinence in male SUI [13, 14]. It has been reported that best results can be obtained in patients with mild degrees of incontinence and with a preoperative Valsalva leak point pressure (VLPP) greater than 60 cmH2O. Similarly, eliminating poor prognostic factors such as postoperative radiation therapy, adjuvant cryotherapy, and bladder neck incisions might improve the outcome of collagen injection [10]. Aboseif et al. reported treatment results in 88 patients with collagen injection. A total of 48% of patients in their series were dry and 22% showed significant improvement [15]. In another study, collagen injection revealed dry/improved rate of 58% in patients with post-radical prostatectomy UI at a mean follow-up of 10.4 months [16]. However, clinical results regarding the efficacy of collagen injection are not consistent. Griebling et al. treated 25 men with incontinence after RP and transurethral resection of prostate and obtained minimal improvement and significant improvement in eight (32%) and two (8%) patients, respectively [17]. However, collagen is rapidly resorbed, so repeated injections are needed to maintain continence. A hypersensitivity reaction can also occur during collagen use [18]. Similar to collagen, autologous fat shows rapid resorption and is associated with a relatively low success rate. An adequate blood supply is essential for the maintenance of autologous fat; thus, the success rate is low when periurethral vascular injury is present after prostate surgery [19]. The Macroplastique is composed of textured silicon particles (polydimethylsiloxane) in a liquid gel. These particles have a low migration rate because they are larger than 100 μm, the injection material is encapsulated by nearby tissue, and there is a quiescent foreign body reaction that is maintained for 9 months [20]. Compared with other bulking agents, Macroplastique has more stable characteristics. Studies that have investigated transurethral injection treatment for male SUI have reported widely different success rates [17, 20–24]. This wide variation in success has several possible explanations. First, there is no common definition of success across studies. Studies also differed in terms of patient characteristics, injected materials, number of injections, and length of the postoperative follow-up period. Taking together all published studies indicate that treatment with an injection agent has a lower success rate than does AUS or a male urethral sling. Several factors may affect the success rate of bulking agents injection. During radical prostatectomy, extensive scarring owing to multiple anastomotic incisions and scarring of the mucosal layer after radiation therapy can cause tight adhesion of the mucosa and muscle layer, or a “rigid urethra.” Rigid

urethra interferes with bulging and causes extravasation of materials [13]. The long length of the male urethra compared with the female urethra and technical failure owing to bulking agent migration may also contribute to the lower success rate of injection treatment [22].

The injection volume of the bulking agents (range, 7.1–11.9 mL) may represent another cause of lower success rate with a possible relationship between low injection volume and reduced success rate. In addition, the success rate is related to the number of bulking agent injections and repeated injections report an overall higher success rate. Several risk factors have been identified that could influence the success of injection treatment. Increasing age is associated with problems such as low tissue quality, loss of ureter dexterity, and increased overactivity of the bladder [22]. Radiation therapy is associated with long-term consequences, such as obliteration of small vessels with subsequent endarteritis resulting in fibrosis, tissue ischemia, necrosis, and aberrant tissue repair [23].

Risk factors for complications of urethral bulking agents have not been fully characterized, but may include biomechanical properties of the material used, host tissue activity, and the volume of agent injected [25].

A literature review has stated that the complication rates with commercially available agents are acceptably low [26]. Safety concerns may occur that are generic to all substances (e.g., suburethral swellings, hematuria, urinary retention) or are agent specific (e.g., particle migration, granuloma formulation, hypersensitivity). Reports of suburethral swellings are rare, and have been observed with collagen [27], PTFE [28], carbon-coated zirconium beads [29], and NASHA/Dx gel [30]. Their etiology in SUI is unclear, but is presumably related to an increased risk of a tissue reaction to the injectable agent that has been placed outside the urethral wall, and they appear to resolve in many cases with simple needle drainage. Particle migration was a major concern with PTFE. Among current materials, it is much less of a concern with biodegradable agents (e.g., collagen, NASHA/Dx gel) than non-biodegradable agents (e.g., silicone, carbon-coated zirconium beads). Indeed, permanent accumulation of non-biodegradable agents may be a problem, particularly where there is a risk of granuloma formulation or other potential adverse effects (e.g., carcinogenicity).

Among agents more commonly used today, particle migration has been observed with silicone in dogs, though it has been stated that this agent does not migrate to vital organs [31], and with carbon-coated zirconium beads [32]. Migration has been attributed to small particles within the injectable agent [33]. Therefore, given that carbon-coated zirconium beads are relatively large (251–300 μm), the migration may be due to technical problems rather than being a property of the agent. Particle migration has not been reported for collagen, NASHA/Dx gel, or calcium hydroxylapatite.

In summary, few of the early agents were free from safety concerns. The “ideal” urethral bulking agent, with excellent tissue bulking, host immunocompatibility, and minimal migration, has yet to be identified. Nonetheless, when used judiciously and appropriately, these materials can play an important role in the treatment of stress urinary incontinence. Patients and providers must be made aware of potential complications, including pseudoabscess or migration.

Interdisciplinary Comment
The purpose of the urethral coaptation procedure is to recover the sphincter function of the urethra. In this context the optimization of the urethral coaptation depends on the distribution of the bulking agent in the sphincteric tissue as on the other hand occurs during the bulking agent injection at the level of the anal sphincter. The correct injection procedure is fundamental for achieving urinary and fecal continence.

15.2 Bulking Agents for Fecal Incontinence

Injection of bulking agents (BA) for fecal incontinence is a safety mini-invasive procedure but not clear of adverse events. Generally, the complications of bulking agents include [34] ecchymosis, inflammation, anal ulceration, persistent pruritus ani, perianal abscess, and sepsis. They may also include displacement and migration of prosthesis and general symptoms such as abdominal pain, postoperative proctalgia, fever, diarrhea, and constipation. Due to the characteristics of the implanted materials, a progressive resorption process is to be expected and a reduction in the volume of the injected implants is theoretically taken into account. Guerra et al. report a migration and fragmentation rates calculated as percentages: 16% of patients had one bolus migrated to the external sphincter layer and in 11% there was a fragmentation of one implant [35]. Eight variables (agent used, site of injection, route of injection, use of preoperative and postoperative antibiotics, use of postoperative laxatives, type of anesthesia, and position of patient) had a significant impact on short-term and long-term efficacy and adverse events [36]. A clinical trial about comparison between PTQ and Durasphere shown morbidity recorded in only one patient. This was a perianal abscess in a patient who was given PTQ, which resolved with surgical drainage [37]. A multicenter observational study on implantation of Gatekeeper® reported:

(a) Six percent of spontaneous extrusion of a single prosthesis immediately after placement requiring replacement.
(b) Thirteen percent of patients experienced anal discomfort or pain for 4·4(3·8) days, requiring administration of non-steroidal anti-inflammatory drugs.
(c) Dislodgement of a single prosthesis was documented in three patients 6%, but replacement was not required.

At the 1- and 3-month, and 1-year follow-up, EAUS confirmed that neither acute nor chronic peri-prosthesis inflammation was present. No patient perceived a significant dislodgement [38]. Al-Ozaibi reported a case of man presented with perianal pain and swelling and was diagnosed to have a perianal abscess, for which incision and drainage were done and one of the gatekeeper prosthesis popped out of the abscess cavity 2 years later the implantation of bulking agent [39]. A case series

reported by de La Portilla et al. on ultrasonographic evidence of migration of Gatekeeper® showed the occurrence of displacement of 24 out of 42 prostheses, in five of the seven patients treated. Of these, 15 prostheses had migrated to a lower level, while 9 had migrated to an upper level of the anal canal and rectum. The ultrasound performed 1 year post-procedurally showed no migration of the other prostheses, but six of the implants that had already been noted as displaced at 3 months had undergone further migration in the interim [40]. Injection of bulking agents as treatment of fecal incontinence is a safe and effectiveness mini-invasive procedure but there is no type of bulking agent with no rate of complication as migration, dislocation, or infection neither short nor long term.

Interdisciplinary Comment

The recovery of fecal continence by injection of bulking agents represents the mechanical recovery of sphincteric unit as it happens at urethral level. The loss of coaptation of the sphincter due to the reabsorption of the injected material represents a common occurrence because the "ideal bulking agent" does not exist.

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Sacral Neuromodulation for Urinary and Fecal Incontinence

16

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16.1 Sacral Neuromodulation for Urinary Incontinence

Overactive bladder (OAB), both wet and dry, is a common and widely recognized syndrome, being part of the so-called lower urinary tract dysfunction (LUTD). It causes a spectrum of morbidity and decreased quality of life for patients. The classic treatments of LUTD and OAB comprise different strategies. When patients have tried behavioral modifications and oral medical therapy, without experiencing adequate relief of their symptoms, the next step is to consider minimally invasive therapies. Sacral neuromodulation (SNM), otherwise termed sacral nerve stimulation (SNS), has been approved by the Food and Drug Administration (FDA) for the treatment of refractory voiding dysfunction since the late 1990s, urge incontinence (UI) since 1997, and OAB since 1999 [1].

The main limitations for more extensive use of SNM include relatively high cost, implantation of a device, and possibly reoperation secondary to adverse events (AE).

The most common technique for SNM is started with percutaneous access of the S3 foramen using landmarks such as the sacral notches and fluoroscopy. An insulated needle is first placed in the foramen and electrical stimulation is gently applied. Ideally, both sensory and motor responses are achieved. The sensory response is a pulling or vibration sensation in the vaginal and rectal areas in women and in the genital and rectal areas in men, while the motor response is a bellows like movement of the levator musculature and dorsiflexion of the big toe. If there is significant movement of all the toes at S3 and appropriate sensation is obtained at S4 with a good levator response, S4 placement should be considered. The implantable pulse

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generator (IPG) is placed in the lateral upper buttock area 4–6 cm below the posterior superior iliac crest. The lead is tunneled to the IPG with a tunneling device and connected with a screwdriver provided in the kit. Broad-spectrum antibiotics should be given prior, and appropriate precautions observed as for any prosthetic case.

16.1.1 Complications after SNS

In medicine, a complication or AE is an unanticipated problem that arises following, and is a result of, a procedure, treatment, or illness. A complication is so named because it complicates the situation. Complications associated with the use of SNS can be stratified into the following categories:

1. Hardware-related complications: the commonest being lead-related complications such as lead migration or fracture, extension-related complication, disconnection or misconnection, and IPG-related complications such a battery depletion, flipping, and recharging difficulties.
2. Biological complications: the commonest of which were infections, deep and superficial; the development of hematoma or seroma over the device; or more commonly pain over the implanted hardware. Less frequent biological complications include nerve injury.

MDT-103 was the first prospective, randomized, multicentre trial on the treatment of voiding dysfunction by SNS. It involved a total of 633 patients with different types of LUTD with 210 UI and 229 OAB dry (urgency-frequency) [2].

Table 16.1 shows AE after test stimulation in the MDT-103 trial, before the development of the quadripolar tine lead. Of 581/914 stimulation tests, 76.8% had no AE; 180 AE required no (92) or non-surgical (88) intervention; 1 required surgery. All 181 AE were fully resolved, and 50.8% of AE resolved without medical intervention. Most AE involved suspected migration of the test lead.

Table 16.1 AE after test stimulation in the MDT-103 trial

Type of AE	Number of AE	Incidence (%) on 914 pts
Suspected lead migration	108	11.8
Technical problem	24	2.6
New pain	19	2.1
Suspected device problem	10	1.1
Persistent skin irritation	6	0.7
Change in bowel function	4	0.4
Infection at test stimulation lead site	3	0.3
Change in voiding function	3	0.3
Other	3	0.3
Transient electric shock	1	0.1
Total	181	19.8

AE adverse events, *pts* patients

Table 16.2 Post-implant AE in the MDT-103 trial

Post-implant AE (157/250 pts	Number of AE	No intervention	Non-surgical intervention	Surgical intervention
Pain at IPG site	60	4	13	43
New pain	50	13	25	12
Suspected lead migration	39	4	7	28
Infection	28	4	9	16
Pain at lead site	18	3	4	7
Transient electric shock	23	7	15	3
Suspected device problem	28	5	9	15
Change in bowel function	12	4	4	6
Technical problem	10	2	0	8
Persistent skin irritation	3	2	3	0
Others	97	12	62	23

AE adverse events, *pts* patients

Table 16.2 presents AE after implantation in the MDT-103 trial, before the development of the tine lead. Post-implant AE (368) occurred in 157/250 patients. Most needed surgical intervention; 329/368 (89.4%) AE had been resolved at last follow-up. Repositioning of lead/extension was the most frequent surgical treatment (24.2%). Next was surgical repositioning of IPG (21.1%). Buttock IPG placement reduced revision surgery.

The two most recent systematic reviews [3, 4] found a reoperation rate of 33% and explantation rate of 9%. Common reported side effects were pain at the implant or lead site in 25%, lead migration in 16%, replacement and repositioning of the IPG in 15%, wound problems in 7%, and infections in 5% [5]. Table 16.3 presents the AE of SNS in prospective trials.

Figure 16.1 shows infection in the site of IPG (a) and electrode (b) implant. Fig. 16.2 shows quadripolar tine lead migration after implantation.

Rarely an IPG extrusion due to allergic reaction to the device may occur. In that case, it is possible to re-implant the IPG in a gluteal pocket using covering the device in a Dacron envelope.

The most common types of surgical intervention to solve AE after SNS implant are as follows:

1. Repositioning of the lead/extension: due to suspected lead migration, a change in bowel function, foot or leg movement, new pain, lack of efficacy, pain in the lead side, a technical problem, a change in stimulation sensation, transient electric shock, strong anal sensation, urinary hesitancy, or numbness or tingling.

Table 16.3 AE of SNS in prospective trials

Study	Stimulation/ implantation	Device-related AE after implantation	Re-intervention (Re-int) Explantation (Expl)	Follow-up
Siegel [6]	340/272	22% undesirable change in stimulation 15% pain 13% ineffective	33.5% re-int for battery 30.9% re-int for AE 19.1% Expl	5 years (183 completers)
Peeters [7]	382/217	11.5% ineffective 1.8% malfunction 1.8% infection	41% re-int 18% Expl	Mean of 46.88 months
Al-Zahrani [8]	196/96	37.5% ineffective 16.6% pain 0% infection	39% re-int 20.8% Expl	Median of 50.7 months
Van Kerrebroeck [9] MDT-103 post-approval study	163/152	28.2% undesirable Change in stimulation 27.6% pain 7.9% infection	39.4% re-int 10.5% Expl	5 years
Jonas [10] MDT-103 study group	177/68	29.7% pain 8.4% lead migration 6.1% infection	Not reported	6 months
Siegel [11], and Das, 2004 [12] MDT-103 long-term follow-up	581/219	29.7% pain 8.4% lead migration 6.1% infection	33% re-int 10.5% Expl	1.5–3 years
Hassouna [13] MDT-103 study group	51/51	29.7% pain 8.4% lead migration 6.1% infection	33.3% revision 2% Expl	6 months (50 completers) 6 months 50 completers
Schmidt [5] MDT-103 study group	155/98	35% pain 7% lead migration	32.5% revision 6.3% Expl	6 months (58 completers)

AE adverse events, *SNS* sacral nerve stimulation

2. Temporary explant/re-implantation: due to suspected lead migration, a suspected device problem, infection, chronic pelvic pain, device rejection, lack of efficacy, end of battery life, technical problems, IPG movement, or a change in bowel sensation.
3. Repositioning of the IPG: due to pain at the IPG site, new pain, or a superficial connection.
4. Device exchange: due to suspected lead migration, a suspected device problem, technical problems, lack of efficacy, pain at the IPG and lead site, new pain, transient electric shock, or infection.

A possible limitation of SNS is the lack of rechargeable IPG. Since battery life remains a significant limitation and also increases costs, a rechargeable IPG would be a welcome addition [5]. Again, the technology for externally rechargeable devices that may need to be charged every 2–3 weeks, but which may not require

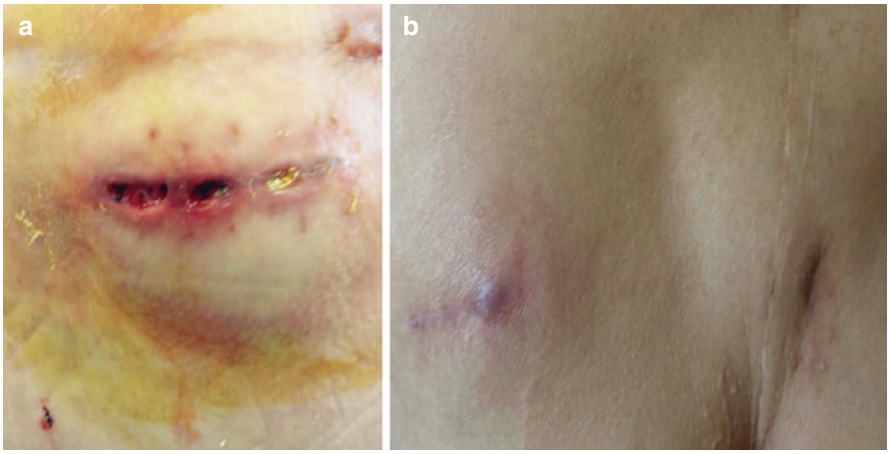

Fig. 16.1 (**a**) Infection in the site of IPG. (**b**) Infection in the site of both IPG and electrode implant

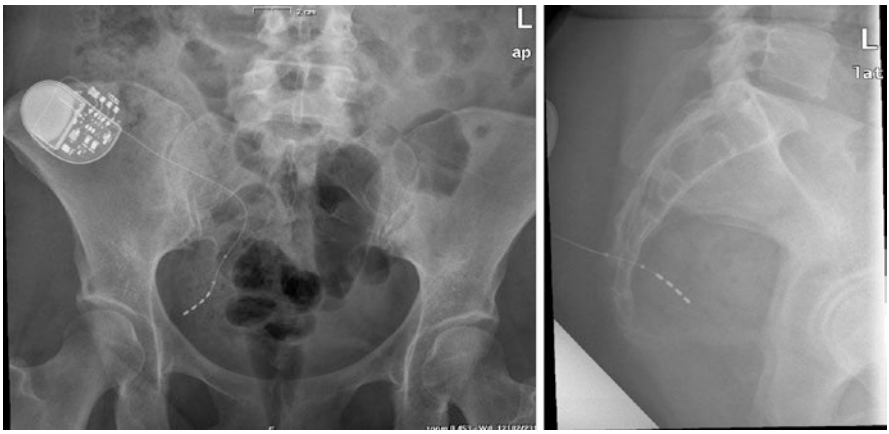

Fig. 16.2 Migration of the quadripolar tine lead after implantation

replacement for up to 10 years, already exists and it is only a matter of time before it becomes available.

16.1.2 Conclusions

SNS does require a minimally invasive surgical procedure to place the IPG once a PNE/test stimulation or stage 1 lead placement shows adequate subjective and objective symptom improvement. For patients with refractory OAB, these modalities represent acceptable treatment options if behavioral therapies are unsuccessful and pharmaceutical management is suboptimal or leads to intolerable side effects. Revisions of SNS due to lead migration, pain, and battery depletion (expected after 2–4 years) are common but well-tolerated minimally invasive procedures.

Interdisciplinary Comment
Regardless of the indications, surgical procedures as well as intraoperative complications that may occur during SNS implant are the same. Sharing information within the experts in this field is mandatory in order to manage the patient at best.

16.2 Sacral Neuromodulation for Fecal Incontinence

16.2.1 Introduction

Fecal incontinence (FI) is a functional problem with a strong impact on patients' quality of life, leading to isolation and withdrawal to avoid embarrassing situations. Lifestyle, medical, and surgical intervention fail often to reach a complete resolution.

In the late 1990s, sacral nerve stimulation (SNM) became in Europe a valid option to treat patients after failure of conservative or surgical treatments, according to the positive urological experience. The clinical use in patients suffering from fecal incontinence was first reported by Matzel in 1995 [14] and afterward several centers in Europe included SNM as option for unresponsive FI. SNM use was somewhat limited because of its cost, but in 2004 the NICE guidance inserted this treatment in the guidelines for mild, moderate, and severe FI [15, 16]. In 2011 also FDA approved in USA the use of SNM for FI [17].

In 2015, the Italian Society of Colorectal Surgery and the Italian Association of Hospital Gastroenterologists published a Consensus statement, regarding diagnosis and treatment of fecal incontinence. The expert panel recommendations included SNM for FI have a wide range of indications; however, there is limited evidence for which is the best indication (4C) [18].

Fecal incontinence is a problem that affects between 1.4% and 15.3% of the general population [19]. Classically, it has been considered that FI affects mainly women; above age 50 years the rates increase to 11% in men and 26% in women. Studies on large population underwent sacral nerve modulation reported percentages of male implanted patients ranging from 5% to 9.7% [20].

16.2.2 Complications of SNM

Following SMN implant, the patients reported adverse events. Many of them surface early after definitive implant and respond to changes in stimulation parameters. Events as leg cramp, pain, or mild infection in the site or implant, painful or slight stimulation and poor efficacy can be resolved with non-surgical approach. The most common resolutive actions are reprogramming and medications [21]. These events may thus be considered a part of the routine maintenance of this treatment.

In cases of lead migration, lead fracture, severe pain in IPG site, severe implant infection or battery depletion surgical management must be considered to resolution [21].

In the literature, the surgical revision rate ranges from 16% to 41% [21]. In a recent review by Bielefeldt, reoperation rate was 18.6% (14.2–23.9). The total number of patients was 1,953 followed for a median time period of 27 months (range: 1–117 months). Detailed information was found in two studies that prospectively monitored a total of 201 patients and recorded 828 incident adverse events over a period 5 years, most of which were related to loss of benefit. This chapter reported also the data of adverse events (AE) from FDA during a 3 months period in 2015: complaints led to secondary surgery in 29.7% of the AE [17].

All the same rates of surgical revisions are high and increase over time [17].

16.2.3 Lack or Loss of Benefit

Most of the concerns focused on lack or loss of benefit, which are accountable for up to 50% of the primary problems described in the narrative [17] (Table 16.4). Conceptually, it is questionable whether lack or loss of benefit is truly an adverse event [22].

Adjustment of stimulation parameters, more frequently in the first period after implant, effectively tends to ameliorate the clinical outcome. This occurrence can be accepted as adverse event, as it is related to additional and repeated contacts with hospital and physicians.

The main causes of unsatisfactory benefit are lead-related. This is usually a result of a suboptimal location of the permanent lead or excessive peri-lead fibrosis over time, as well as progression of the actual cause of FI, particularly if there is an underlying neurological condition [23].

Abnormal measurements of impedance between the electrodes are likely to be due to a fractured lead or from damage to the insulation coating around the lead.

Table 16.4 Incidence rate of lack/loss of benefit

Authors	No. patients	FU median (range) (months)	Lack/Loss of efficacy	Incidence rate %
Altomare (2009)	60	75 (60–122)	13	22
Govaert (2009)	155	28.1 (1–93.6)	9	6
Hollingshead (2011)	91	22 (1–138)	14	16
Melenhorst (2007)	100	25.5 (2.5–62.2)	21	21
Michelsen (2010)	142	24 (3–72)	29	20
Wexner (2010)	120	28 (2.2–69.5)	6	5
Kamm (2010)	45	28 (1–55)	1	13
Zeiton et al. [21]	125	45.8 (1–99)	22	17
Altomare (2016) (European SNS Outcome study Group)	228	84 (70–113)		28.7

However, in cases with normal impedance, but patients continue to lack sensation of stimulation or require very high stimulation amplitudes, migration or misplacement of the permanent lead must be suspected. Even the most minimal of migrations, such as 2 mm, have been reported to significantly alter the therapeutic effects of SNS [21].

Mechanical factors can occur with electrode migration, broken leads, dislodged, and loose connections [23].

16.2.4 IPG Related and Programming Problems

Battery and IPG-related problems are frequently reported in the literature, accounting for 27% of the unplanned procedures in Zeiton article and regarding a third of patients [21].

In the FDA reports 4.6% described programming problems, which were related to the patient programmer in 43.3% of the cases. The percentage was 46.7% in the first year after implant, decreasing in the following years to 3.3% at year 5 [17].

Battery depletion is another device-related problem. The rate of battery depletion is determined by the set stimulation parameters of the device, such as the amplitude and mode of stimulation. The approximate battery life ranges from 7 to 5 years, depending on the model of the Medtronic IPG implanted. Unless the need for battery replacement surfaces very early after stimulator implantation, it may also be considered not routine maintenance of electrotherapy but also as adverse event [23].

16.2.5 Pain and Infection

Pain is also a common complaint (in about 15% of cases) and may be due to local factors as well as stimulation-related [23], with 35.1% of FDA reports specifically referring to the generator site as affected area. The incidence tends to reduce along the time (from 78.4% in the first year to 5.1% at fourth) [17].

To differentiate between stimulation and device pain, the IPG should be switched off. Alternatively, changing the electrode configuration or reducing the stimulation amplitude may alleviate symptoms [24].

The IPG may have associated infection, hematoma, cellulitis, local allergic reaction, or erosion, causing pain. Infection is recognized as a common adverse effect following SNS implantation, reportedly affecting between 2% and 10% of patients with 50% of these cases requiring full explantation [21]. In the Bielefeldt literature review on 44 studies with 1953 patients, the pooled rate of infection was 5.1% [17].

Most infections will tend to occur early and will be secondary to staphylococcal spp. [23].

16.2.6 Secondary Surgery

Findings from FDA report with descriptions of reoperation accounting for 25% of the reports highlight the potentially significant burden of SNS. Re-interventions were

Table 16.5 Adverse events

Author	Sample	Follow-up (months)	Infection	Explant	Reoperation
Altomare (2009)	58	74	0	6	15
Matzel (2009)	12	117	0	3	14
Browner (2010)	55	37	1	1	11
Faucheron (2010)	87	48.5	4	12	36
Lim (2011)	41	51	0	0	6
Uludag (2011)	50	74	4	11	24
George (2012)	23	114	2	3	5
Hull (2013)	120	60	12	30	72
Damon (2013)	101	62	1	10	39
Maeda (2014)	101	60	2	20	20
Moya (2014)	50	55.5	2	6	11
Gorissen (2015)	61	13	0	1	2
Johnson (2015)	145	12	5	6	15
Bielefeldt [17]	278	–	5	31	65
Zeiton et al. [21]	125	45.8	2	6	30

nearly equally split between explants (39.3%) and replacements (41.7%). Considering the literature review (39 studies covering 1810 patients) device explants were largely due to infection, but were also caused by generator erosion through the skin or other local complications at the pocket site and lack of benefit, thus leading to a higher rate of reoperation (Table 16.5). During the follow-up period, with of an average of 10.0% (7.8–12.7) and a significant increase with the duration of follow-up [17].

Isolated lead replacement accounted for only 4.3% of the FDA reports. Pocket revisions were responsible for 14.1%, and minor operative revisions in 0.6% [17].

While the majority of adverse events occur within the first 2 years after the original implant, the relative likelihood of secondary surgery increases significantly over time [17].

16.2.7 Case Report

This book is dedicated to the complications of the surgical procedures for fecal incontinence in the male patients. However, significant complications are quite rare and furthermore it is difficult to imagine a gender difference in this type of therapy; therefore, the case of this woman may be quite interesting and deserving to be presented, showing how many body functions may be involved in SNM.

A female patient had a first diagnosis of chronic urinary retention at 43 years and treated with self-catheterization and subsequently with permanent urinary catheter. Urodynamic test showed detrusor contractility, bladder sensitivity absence, and increased bladder compliance. The patient complained also chronic pelvic pain, partially resolved with mesotherapy and acupuncture.

At 45 years, she underwent permanent SNM implant in two stages. Neuromodulation failed to resolve both urinary disturbances and pelvic pain, but compared severe constipation, central abdominal pain, amenorrhea, and dysphagia.

Two years later had new surgery because of equine cauda syndrome, with anchorated terminal filum in S1. Neurosurgical operation resolved the legs sensitivity disturbances, but other symptoms remained unchanged. After 5 years from SNM implant, it was removed: dysphagia and mesogastric pain disappeared.

16.2.8 Conclusions

SNM is a minimally invasive and safe treatment for fecal incontinence. The findings highlight the rate of adverse events after SNS with common need for several visits or reoperations. This matter should be clearly discussed with patient considering that the potential improvement has to be weighed against a high likelihood of residual symptoms and adverse events requiring secondary surgeries. Every adverse event must be recognized and managed according to a standardized protocol, in order to avoid wrong recognition and/or mistreatment [23].

Interdisciplinary Comment

This mininvasive technique shows interesting results as in urologic field.

Therefore, this treatment is at risk of different possible reoperations as in urologic patients. This event should be discussed and focused with the patients before the beginning of the procedure.

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A Complication in SECCA Procedure: Case of Anal Abscess

17

Marco Frascio

With the SECCA procedure patients evidenced few complications: local hematoma, laxative-associated diarrhea, fever, and anal pain. The majority of the reported complications were not severe and resolved spontaneously in a few weeks; severe complications such as deep anorectal ulcers may develop occasionally after the procedure [1].

17.1 Presentation of the Case

A 66-year-old woman presented with gas and fecal incontinence for 20 years. She had one daughter born in 1970 by cesarean section after a long labor without pelvic lesions or lacerations.

She takes the following home therapy:

- Telmisartan 40 mg, 1 tablet at 12 h and 1 tablet at 20 h;
- Levothyroxine 75 μg, 1 tablet at 8 h;
- Bromazepam 1.5 mg, 1 tablet at 8 h and 1 tablet at 20 h;
- Clomipramine 10 mg, 1 tablet at 8 h;
- Nebivolol 5 mg, 1 tablet at 8 h.

She refers fecal incontinence of liquid or solid stool and gas incontinence two to three times per day, which had a marked negative impact on her social life.

She is suffering from anxiety-depressive syndrome that worsened because of incontinence. She has changed her lifestyle, her behavior, and she is very embarrassed of her incontinence.

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Physical examination: nothing to report.
Rectal exploration: anal sphincter hypotonia.
Anorectal manometry was performed with detection of:

- Low median basal pressure: 20 mmHg (normal range 40–60 mmHg),
- The lower limit of normal pressure after maximal voluntary contraction: 93 mmHg,
- Duration of maximal voluntary contraction 15 s (normally more than 1 min),
- Sensitivity threshold to 30 mL (normally 40–60 mL),
- Threshold of subjective reflection to 40 mL (normal value 50–70 mL),
- Normal threshold of the inhibitory objective reflex: 40 mL (normal value 30–50 mL) (Fig. 17.1).

She did not perform any medical therapy for incontinence, but she has performed three cycles of rehabilitation with anorectal biofeedback with poor benefit.

We proposed to the patient to undergo SECCA procedure

Gynecological position, general anesthesia was performed. A dose of 500 mg of metronidazole was administered intravenously to induction of anesthesia. Then, 20 applications of radiofrequency through the four nickel needles of the device were performed from the dentate line and proceeding cranially every 5 mm to 2.5 cm total. The same procedure was performed on the four quadrants of the internal anal sphincter, including the recto-vaginal wall (which is often the thinnest area and for this reason not always surgically treatable). The entire procedure lasted 40 min.

The day after surgery she was discharged in good health. After 10 days, she presented intermittent hyperpyrexia, leak of purulent material through the anus, and anal pain. We performed general physical and proctological examination with

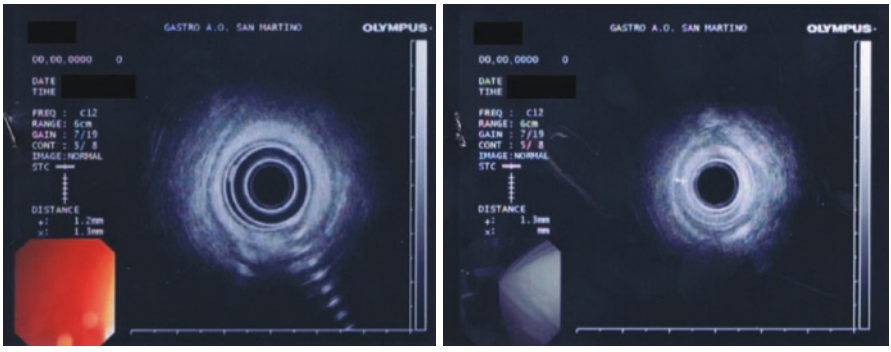

Fig. 17.1 Transrectal endoscopic ultrasonography. "External anal sphincter echo structural normal. Internal anal sphincter without interruption of continuity, but of reduced thickness, (about 1.3 mm measured at about 9 o'clock and three in correspondence of the middle part of the anal canal)"

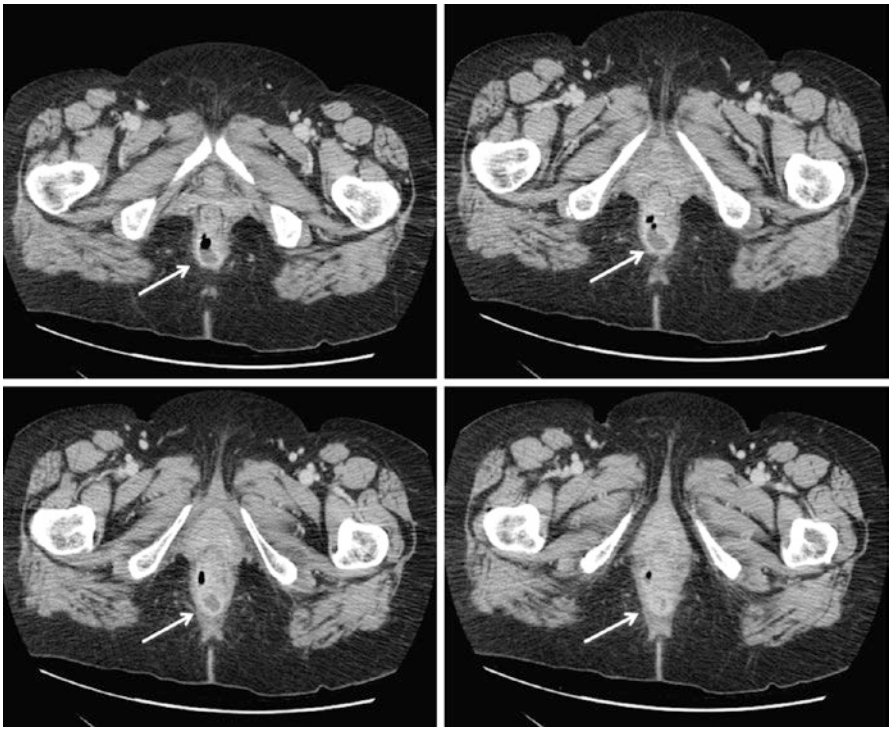

Fig. 17.2 Abdominal CT scan. Small perianal lesion (32 × 30 × 28 mm approx) in the right posterior–lateral wall with hyperemic wall and partial gas content, probably an abscess (arrows). Not free fluid in the pelvis

anoscope and found evidence of abscess of the right posterior–lateral anal wall at 2 cm from the anal verge (Fig. 17.2). We have sent the purulent material for bacterial culture and antibiogram: "Escherichia Coli multi resistant." The patient has performed blood tests without indices of inflammation replaying.

The authors administered antibiotic therapy with metronidazole and ciprofloxacin without satisfactory improvement of the symptoms.

Surgery has been organized to remove the abscess after 20 days from SECCA procedure. The patient was in gynecological position. Metronidazole 500 mg was administered intravenously. The authors explored the anal canal finding about 2 cm from the anal verge, a recess of about 2–3 cm in diameter, undermined for about 1 cm in cranial direction (Fig. 17.3). Opening and deroofing with curettage of the fundus treated the abscess (Fig. 17.4).

The day after surgery she was discharged in good health. Four days after the procedure, the patient was in good conditions. At 6 months follow-up, the patient was in good health and during the anal exploration it was possible to feel a rectal depression in the wall with a smooth consistence. In spite of the complication and subsequent surgical treatment, the procedure has been able to ameliorate the patient incontinence.

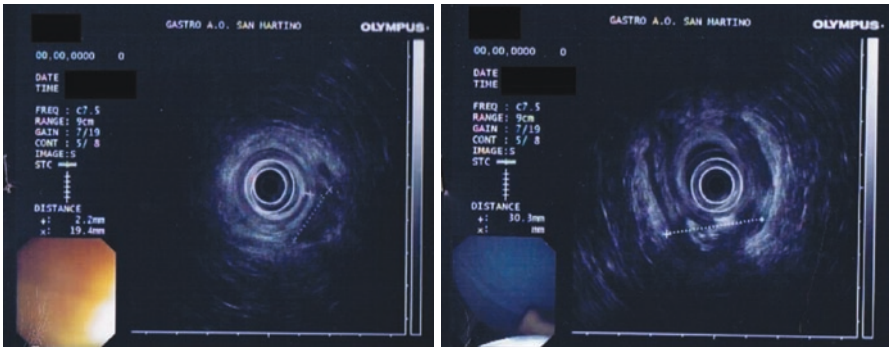

Fig. 17.3 Transrectal EUS to assess the extent of the abscess: "Normal endoscopic appearance of the rectal mucosa. Internal anal sphincter appears seamless continuity but a thickness of about 2.2 mm. It was confirmed, in the right posterior-lateral area, the presence of known abscess 30 × 15 mm hypoechoic with hyperechoic images in to report a gas content"

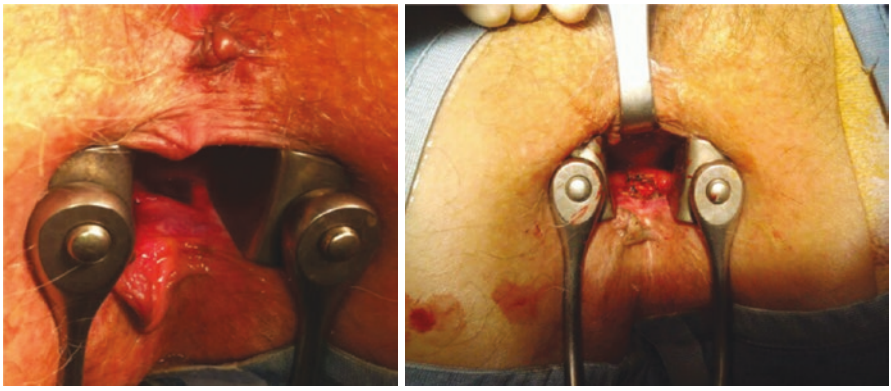

Fig. 17.4 Surgical removal of the abscess

17.2 Conclusions

Among complications post-SECCA procedure, the finding of an anal abscess is rarely described in the literature. Antibiotic therapy was not sufficient to treat the abscess, but it was a necessary surgical treatment to cure this complication.

This case seems to consolidate the importance of administering antibiotic therapy to patients treated with SECCA procedure. We propose to run a full course (at least 6 days) rather than a short induction therapy, with the aim to minimize the incidence of complications.

Informed Consent Written informed consent was obtained from the patient for publication of this case report and any accompanying images.

Interdisciplinary Comment

This clinical case emphasizes the need for an antibiotic therapy with a wide antibacterial spectrum also in patients that must be treated in mini-invasive way as reported here. Similarly, also in patients who have to undergo a prostatic biopsy, a wide antibacterial spectrum should be done as suggested by international guidelines.

Reference

1. Kim DW, Yoon HM, Park JS, Kim YH, Kang SB. Radiofrequency energy delivery to the anal canal: is it a promising new approach to the treatment of fecal incontinence? Am J Surg. 2009;197(1):14–8.