Female Pelvic Surgery

Farzeen Firoozi
Editor

Second Edition

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Foreword

The field of female pelvic medicine and reconstructive surgery (FPMRS) continues to evolve, and this second edition of *Female Pelvic Surgery* serves to mirror that evolution. Each chapter and author has been carefully selected to further the mission that the combined boards of urology and gynecology sought to develop with collaborative experiences to serve the best needs of our patients.

A few things have transpired since the last version of this book. The continual reassessment of the role for vaginal mesh use certainly adds more questions to our ever-changing practices. Still, complications with pelvic reconstructive surgery do occur, and this book serves as a fantastic reference piece to how best to avoid complications but also how to correct them should they occur. Gender confirmation surgery is coming into a specialty of its own, and a dedicated chapter to this has been added to keep the readers current on some of the latest concepts in this field.

While FPRMS surgeons have to adapt to our changing landscape, patients should be reassured that the trainees graduating now are in possession of excellent skills and wide experiences that keep them at the cutting edge of the art and science of surgery.

Sandip P. Vasavada, MD
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Preface

The subspecialty of female pelvic medicine and reconstructive surgery, while still in its infancy by name, has grown in leaps and bounds over the last two decades. There have been significant innovations in the fields of research and treatment of female pelvic floor disorders. This growth has been due in large part to the collaboration of urologists and gynecologists.

Technology and regulatory requirements are constantly evolving; thus, this book was envisaged to provide a compendium of information for the practicing urologist, gynecologist, female urology specialist, and urogynecologist. It draws from all these areas of medicine, with experts from varied training backgrounds, and truly represents a collaborative effort. The goals of this book are twofold: to report an updated account of the current literature and to provide the basic and advanced surgical techniques for the management of common and uncommon diseases within the domain of female pelvic medicine and reconstructive surgery.

It is my hope that the internationally recognized contributors to this book have created a text that is both accessible and integral to readers. I genuinely believe that this second edition is a significant and valuable addition to the library of those who aspire to or practice in the field of female pelvic medicine and reconstructive surgery.

Lake Success, NY, USA — Farzeen Firoozi, MD

Acknowledgments

To my wife, Kelly, for her love and support. It is with her constant encouragement that I can accomplish all the goals in my life, both personal and professional.

To my three sons, Sam, Alex, and Jack, whose daily enthusiasm and indefatigable inquisitiveness serve as a primer for my own motivation to be the best father and physician.

To my students, residents, and fellow whom I learn from every day.

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Anatomy of the Female Pelvis

1

Michael G. Funaro and Sonia Bahlani

Introduction

The anatomy of the female pelvis is a complex network of organs, muscles, ligaments, nerves, and blood vessels that are essential for reproduction, micturition, and defecation. This chapter serves as an overview of the relationships between these structures and how they relate to these vital bodily functions. Additionally, we will consider the blood supply, innervation, and embryological underpinnings of these structures.

Abdominal Wall

Embryology

The musculoskeletal structures comprising the abdominal wall are formed initially in the fourth through eighth weeks of development. The musculoskeletal system develops from the paraxial and lateral plate mesoderm. Through the subsequent migration of myoblasts, the right and left rectus abdominal muscles are formed. The developing mesoderm of the future abdominal wall divides into three layers which give rise to the internal oblique, external oblique, and transversus abdominis muscles [1, 2].

Anatomy

The abdominal wall is comprised of skin, subcutaneous tissue (fascia), muscles, deep fascia, extraperitoneal fascia, and parietal peritoneum. The superficial fatty layer of fascia is called Camper's fascia; this layer is continuous over the inguinal ligament with the superficial fascia of the thigh and similar fascia in the perineum. The deeper membranous layer of superficial fascia is called Scarpa's fascia. This layer is thin and membranous. It continues into the thigh, fusing with the deep fascia of the thigh just below the inguinal ligament [3]. Medially, this layer attaches to the pubic symphysis and linea alba, and continues into the pelvis where it is attached to the ischiopubic rami and the perineal membrane.

Deep to the superficial fascia lie the anterolateral muscles, which are oriented in a woven network that provides a flexible but strong abdominal wall. These muscles assist in respiration, micturition, defecation, childbirth, as well as ambulation. Three flat muscles begin with posterolateral fibers which pass anteriorly, and then aponeurose as the fibers course toward the midline—the external oblique, internal oblique, and transversus abdominis muscles (Fig. 1.1). Two vertically oriented muscles exist near the midline—the rectus abdominis and pyramidis muscles. The external oblique is the most superficial flat muscle, the

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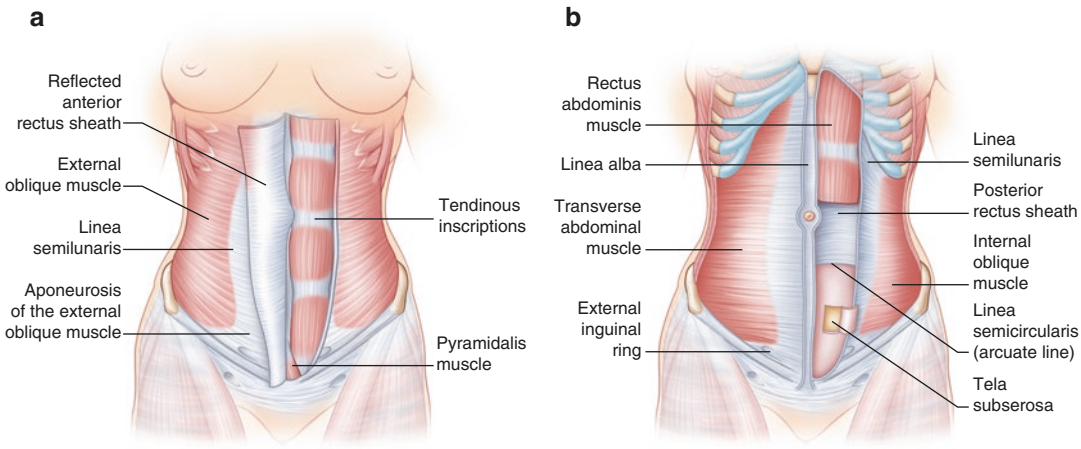

Fig. 1.1 (**a**, **b**) The muscular attachments to the bony pelvis

lower border of which forms the inguinal ligament. The internal oblique, deep to the external oblique, is smaller and thinner. The transversus abdominis fibers run across the abdominal wall, ending in an anterior aponeurosis at the midline with the linea alba. The rectus abdominis runs from the pubic crest and symphysis to insert on the costal cartilages of ribs V through VII and the xiphoid process (Fig. 1.1b) [4]. The pyramidalis originates at the front of the pubis and pubic symphysis, and inserts onto the linea alba. The rectus abdominis and pyramidalis are enclosed in the rectus sheath, a layering of the aponeuroses of the internal and external oblique and transveralis muscles. The upper three-quarters of the rectus are enclosed by this sheath, with no sheath covering the lower quarter of the rectus abdominis, where it is in contact with the transveralis fascia [5]. The transveralis fascia overlies the extraperitoneal fascia, which serves to separate the former from the peritoneum. Deep to this fascia is the peritoneum, which lines the walls of the abdominal cavity, reflecting onto the viscera, forming a semi-closed sac known as the peritoneal cavity.

Innervation

The skin, muscles, and parietal peritoneum of the abdominal wall are innervated by the T7 to T12 and L1 spinal nerves. Anterior rami from these roots give off a lateral cutaneous branch and end as an anterior cutaneous branch as they proceed from posterior to anterior. Intercostal nerves from T7 to T11 leave their intercostal spaces and course to the anterolateral abdominal wall between the internal oblique and transversus abdominis muscles; they then enter the rectus sheath and pass posterior to the lateral aspect of the rectus abdominis muscle. T12 and L1 nerves join to form the iliohypogastric nerve, dividing into an iliac branch which innervates the lower internal and external oblique muscles, and a hypogastric branch, which innervates the inferior transversus and internal oblique muscles, the external oblique aponeurosis, and the pubic symphysis [5, 6].

Blood Supply

The superficial abdominal wall is supplied by branches of the musculophrenic artery, a terminal branch of the internal thoracic artery superiorly, and by the superficial epigastric artery and superficial circumflex iliac artery, both branches of the femoral artery, inferiorly [7]. More deeply, the superior epigastric artery (terminal branch of internal thoracic artery supplies the superior deep abdominal wall, while the inferior wall is supplied by the inferior epigastric artery and deep circumflex iliac arteries, both branches of the external iliac artery [8].

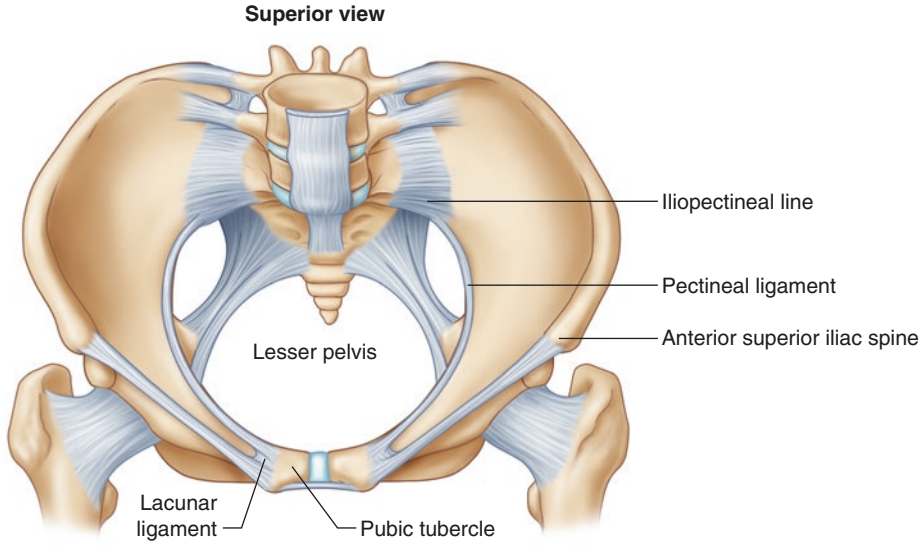

Fig. 1.2 The bony pelvis, divided into two compartments by the iliopectineal line: the greater (false) pelvis and the lesser (true) pelvis

Bony Pelvis

Embryology

The bony pelvis is derived from the mesoderm; the mesoderm is formed during the third week of gestation where the trilaminar disc develops into the ectoderm, mesoderm, and endoderm. The mesodermal cells further separate into clusters—the paraxial mesoderm, lateral plate mesoderm, and intermediate mesoderm. The paraxial mesoderm gives rise to the axial skeleton, while the lateral plate gives rise to the pelvic and shoulder girdles and long bones of the limbs [9].

Anatomy

The pelvis is comprised of the right and left pelvic bones, the sacrum, and the coccyx. It is divided into two regions; the superior region is the false (greater) pelvis and anatomically is part of the abdominal cavity; and inferiorly, the true (lesser) pelvis encloses the pelvic cavity (Fig. 1.2). The pelvic cavity is continuous with the abdominal cavity superiorly. The inferior border of the pelvis is the pelvic floor. The false pelvis contains portions of the small intestine and the sigmoid colon. The true pelvis contains the rectum, bladder, reproductive organs, and the anus.

The pelvic bones are each comprised of the ilium, ischium, and pubis; these bones are initially connected by cartilage and then subsequently fuse and ossify by early adulthood (Fig. 1.3) [10].

The ilium is the most superior component and is divided by a ridge known as the arcuate line. This is significant insofar as it forms the pelvic brim and helps define the true and false pelvis. The superior margin of the ilium is prominent and forms the iliac crest, which serves as the site of attachment for muscles and fascia of the abdomen, back, and lower limb. The pubis is the anterior and inferior part of each pelvic bone. Medially, the left and right pubis meet to form the pubic symphysis. Additionally, there is both a superior and inferior pubic ramus; the former joins the ilium and ischium at its base, forming the obturator groove. The ischium is the posterior and inferior component of the pelvic bone; it has a large body that joins with the superior pubic ramus and ilium, and also a ramus which projects to join the inferior ramus of the pubis anteriorly. The ischial tuberosity is on the posterior aspect,

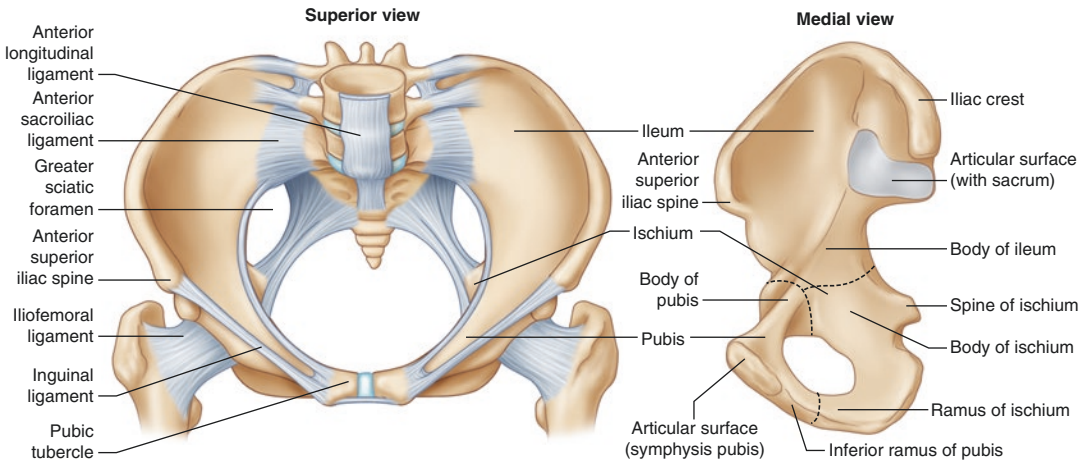

Fig. 1.3 The bony pelvis is composed of three bones: the ilium, the ischium, and the pubis

and serves as an attachment site for muscles of the lower extremity [5].

The sacrum is comprised of five fused sacral vertebrae, and articulates with the terminal lumbar vertebra and the coccyx. The lateral aspects of the sacrum have L-shaped facets which facilitate attachments of ligaments which serve to support the sacroiliac joint. The coccyx is formed by four fused coccygeal vertebrae, with the shape of an inverted triangle. The superior surface has a facet for articulation with the sacrum.

Numerous joints with tough ligamentous junctions join these various bony structures (Fig. 1.4). The sacrum articulates with the vertebral column, reinforced with strong iliolumbar and lumbosacral ligaments. The sacroiliac joints join the ilium and the sacrum, allowing for transfer of forces to the vertebrae. These joints interlock to resist movement, and may become fibrous and/or ossified with age.

Blood Supply

The internal iliac artery supplies most blood to the pelvis; it arises from the common iliac artery anterior to the sacroiliac joint. The iliolumbar artery, a branch of the posterior division of the internal iliac artery, supplies bone and muscle tissue in the iliac fossa. The lateral sacral branches of the posterior division of the internal iliac supply the sacrum and coccyx.

Nerves

The pelvic bones are innervated by the superior hypogastric plexus. Nerve fibers are derived from the inferior mesenteric and lumbar sympathetic ganglia. This then divides into the left and right hypogastric nerves. The inferior hypogastric plexuses are formed when the left and right hypogastric nerves are joined by preganglionic sympathetic fibers derived from the pelvic splanchnic nerves. These plexuses are located bilaterally on the rectum and bladder base [5, 11].

Pelvic Muscles

Embryology (Fig. 1.5)

Skeletal muscle originates from the paraxial mesoderm. Somites form from the paraxial mesoderm, subsequently forming a dermamyotome and a myotome. Myoblasts then undergo frequent divisions and form myotubes [12].

Anatomy of the Muscular Pelvic Wall

The lateral walls of the pelvis are formed by two muscles, the obturator internus and the piriformis muscles (Fig. 1.6b). The obturator internus muscle is a flat muscle which spans from the deep surface of the obturator membrane and inserts on the greater trochanter of the femur. The

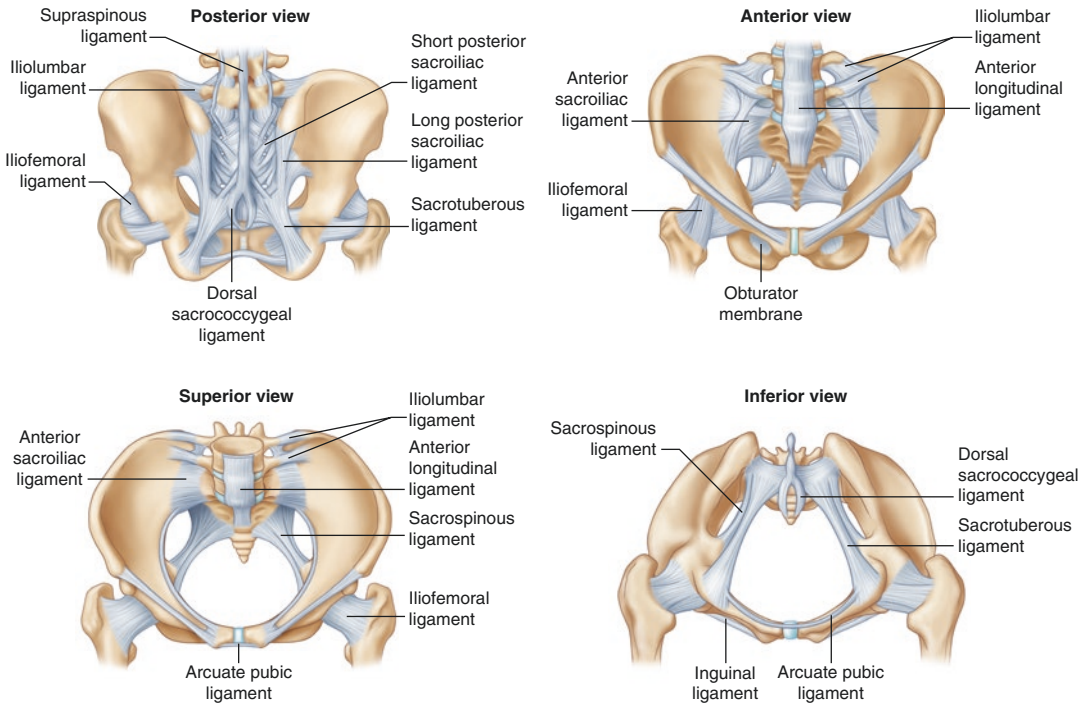

Fig. 1.4 The ligaments of the bony pelvis

obturator internus forms much of the anterolateral wall of the pelvic cavity. The piriformis forms much of the posterolateral wall of the pelvis, separating the greater and lesser sciatic foramen. The priformis muscle originates at the anterior surface of the sacrum and inserts on the superior border of the greater trochanter of the femur (Fig. 1.7) [3].

Anatomy of the Pelvic Floor

The pelvic floor is essential to most of the pelvic functions—it supports and retains abdominal and pelvic organs, and allows for micturition and defecation. The pelvic floor is comprised of the pelvic diaphragm, the perineal membrane, and muscles in the deep perineal pouch. The pelvic diaphragm is the muscular portion of the pelvic floor. It is comprised of the levator ani and coccygeus muscles. It is shaped much like a bowl and attaches to the pelvic walls superiorly. The pelvic diaphragm attaches on the pelvic wall between the greater sciatic foramen and the lesser sciatic foramen, allowing for communication between the lower limb and gluteal region, and lower limb and perineum, respectively.

The levator ani muscles originate from either side of the pelvic wall and course medially and inferiorly, joining one another in the midline, surrounding the anal aperture and meeting one another posterior to the vagina (Fig. 1.6a). The levator ani consists of the iliococcygeus muscle, the pubococcygeus muscle, and the puborectalis muscle. The pubococcygeus originates at the body of the pubis and courses posterior to attach to the coccyx with further divisions associated with the structures to which it attaches—the pubovaginalis and puboanalis muscles. The puborectalis forms a sling around the terminal part of the gastrointestinal tract. The iliococcygeus originates from fascia that covers the obturator internus muscle, joining on the other side of the midline to form the tendinous arch (Fig. 1.7). The contraction of these muscles serves to oppose intrabdominal pressures exerted on pelvic organs. The coccygeus muscles overlie the sacrospinous ligaments, forming the posterior aspect of the

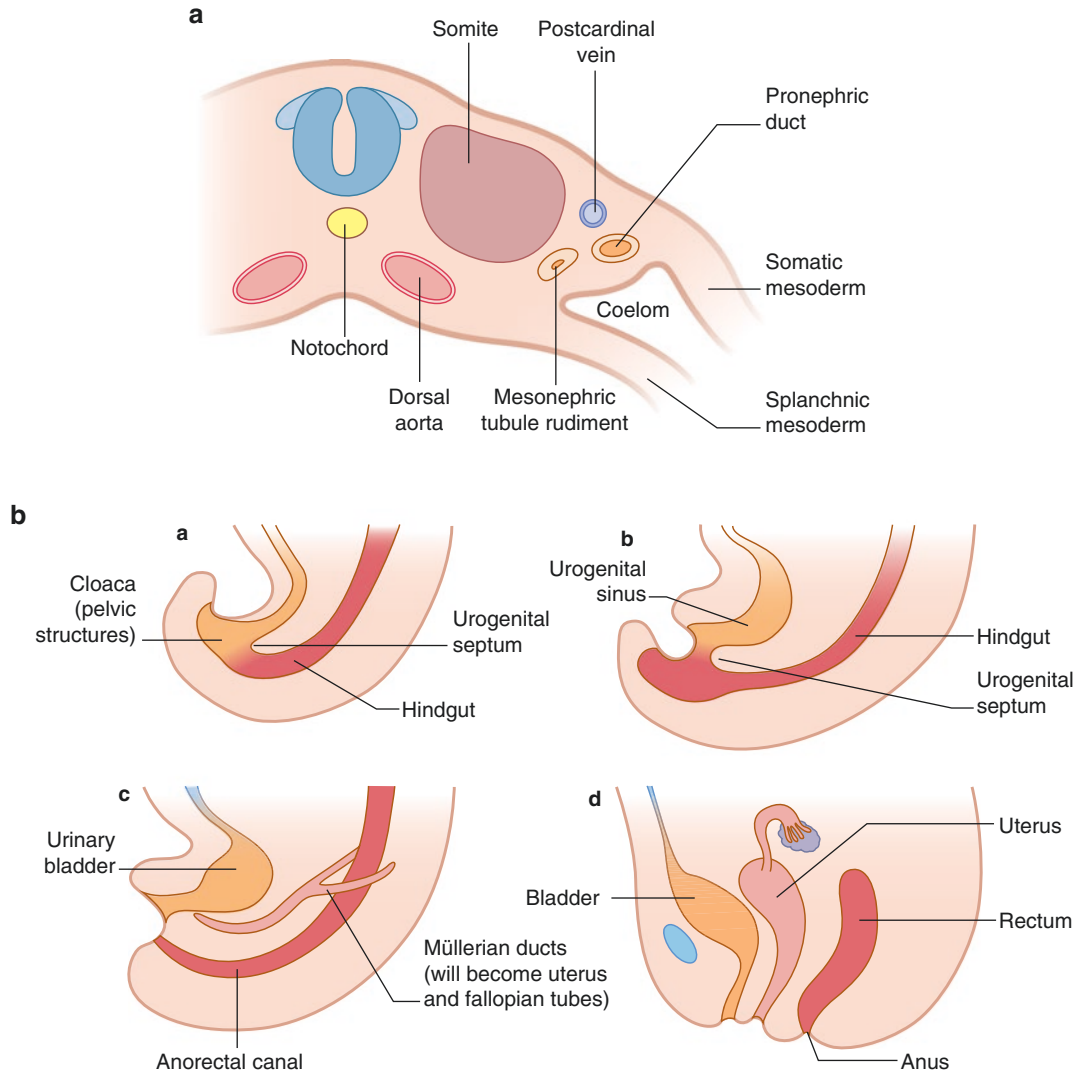

Fig. 1.5 (**a**) Embryology of the pelvis muscles. (**b**) (1–4) Embryology of the pelvic floor musculature

pelvic diaphragm. The coccygeus stems from the ischial spine sacrospinous ligament, inserting on the lateral margin of the coccyx and sacrum. The coccygeus serves to form the pelvic floor and also pulls the coccyx anteriorly after defecation.

The perineal membrane is a fascial structure, shaped like a triangle, which attaches to the pubic arch. This membrane serves to provide support for the external genitalia and muscles which are directly associated with them (Fig. 1.8). Superior to the perineal membrane lies the deep perineal pouch, which contains skeletal muscle that functions mainly as a urethral sphincter and also supports the posterior edge of the perineal membrane. The external urethral sphincter is formed by a series of muscle fibers that surround the urethra. In women, there is a sphincter urethrovaginalis, which surrounds the urethra and vagina as a unit. There is also a group of muscles called the compressor urethrae, which originate on both sides of the ischiopubic rami and fuse anterior to the urethra. These three groups of muscle work to pro-

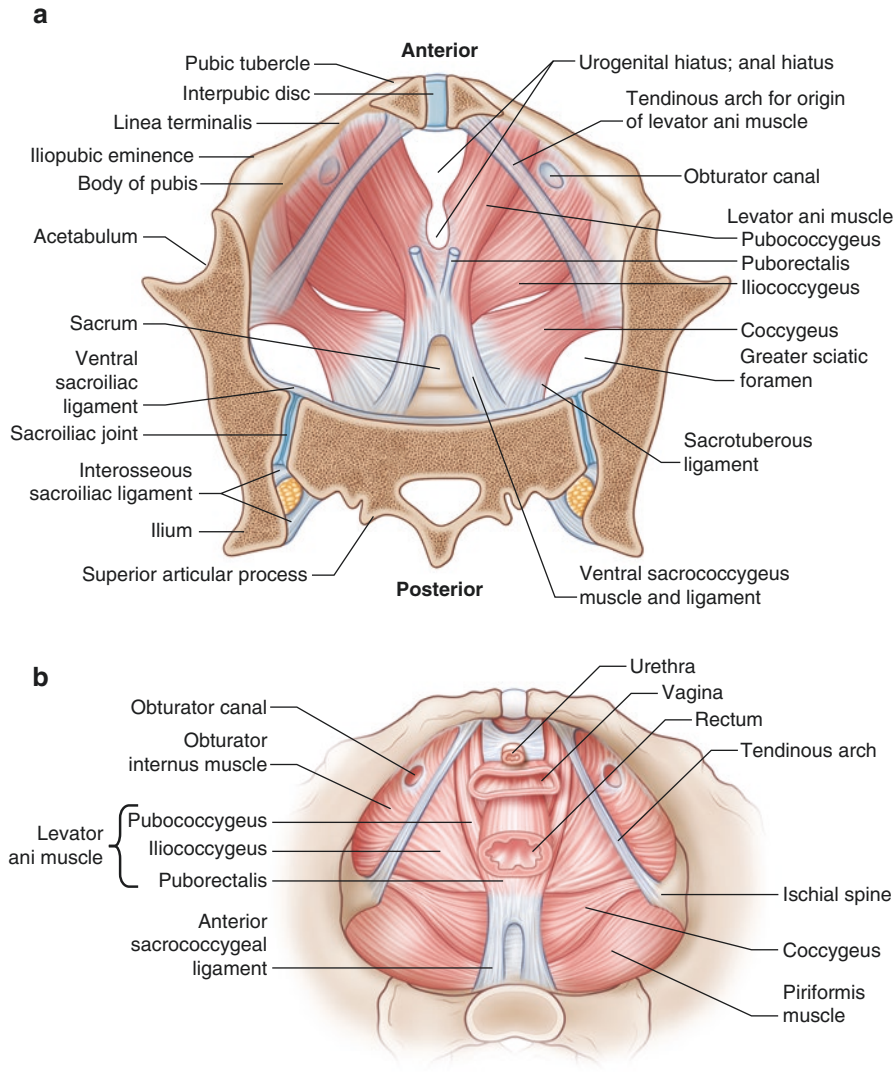

Fig. 1.6 (**a**) The musculature of the bony pelvis, (**b**) with an abdominal view

mote continence through external compression of the urethra. The deep transverse perineal muscle follows the free margin of the perineal membrane [3, 5].

Blood Supply (Fig. 1.9)

The internal iliac artery supplies most of the blood to the structures of the pelvis. The internal iliac arises from the common iliac artery, and then divides into anterior and posterior divisions. The course and exact arrangements are variable between individuals, though the division between anterior and posterior is generally conserved. The posterior division gives rise to the superior gluteal, iliolumbar, and lateral sacral arteries. The anterior division gives rise to many more branches, including the obturator artery, the inferior gluteal artery, umbilical artery, uterine artery,

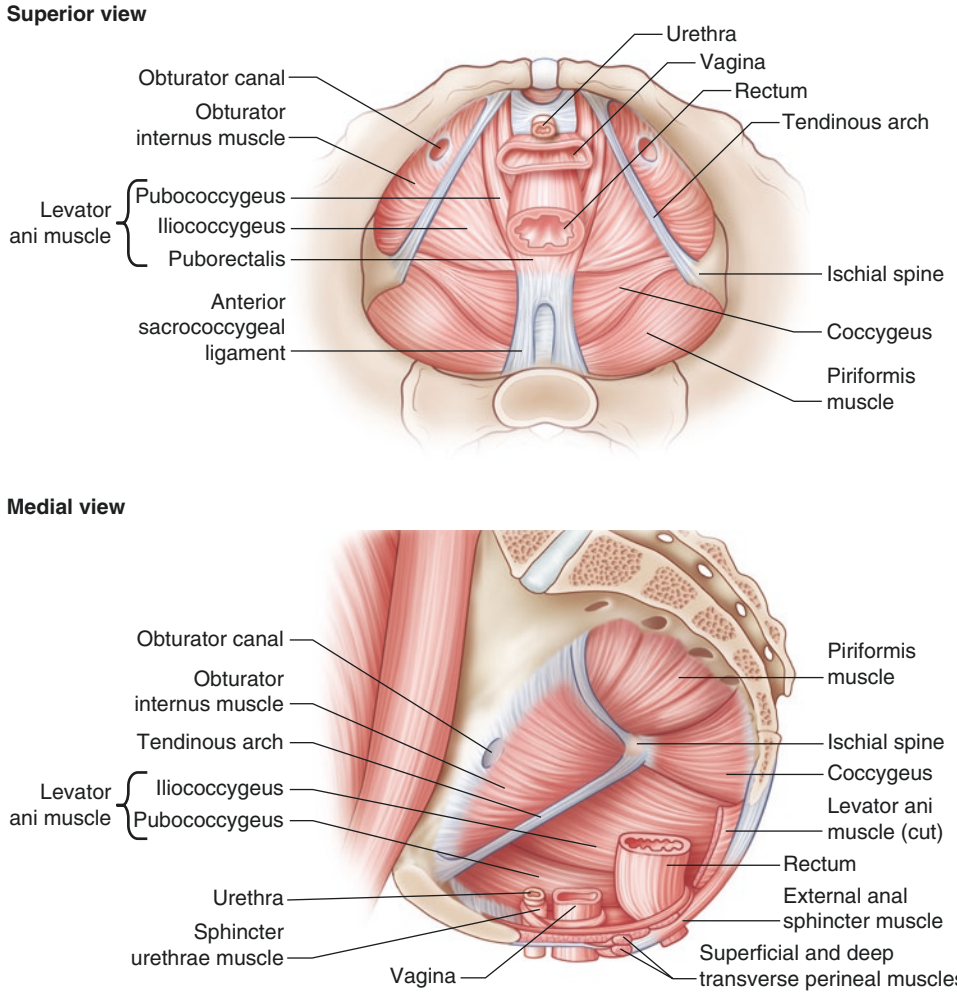

Fig. 1.7 Pelvic muscles groups and their attachments

vaginal artery, inferior vesical artery, middle rectal artery, internal pudendal artery, and superior vesicular artery [13].

Nerve Supply (Fig. 1.10)
The sacral plexus supplies the buttocks, lower limb, and structures of the pelvis. The ventral rami of S1–S3 and the upper division of S4 form the sacral plexus. The pudendal nerve (S2–S4) supplies most of the perineum and muscles of the pelvic diaphragm. The pudendal nerve contains motor and sensory fibers, and also sympathetic fibers [14]. The pudendal nerve crosses the greater sciatic foramen below the piriformis, entering the perineum through the lesser sciatic foramen. It passes through the pudendal canal in the ischiorectal fossa, giving off branches to the inferior rectal nerve and the perineal nerve. The perineal nerve divides into a deep branch which innervates the perineal muscles, and a superficial branch, which innervates the labium majus in women [14]. A coccygeal plexus supplies skin over the coccyx.

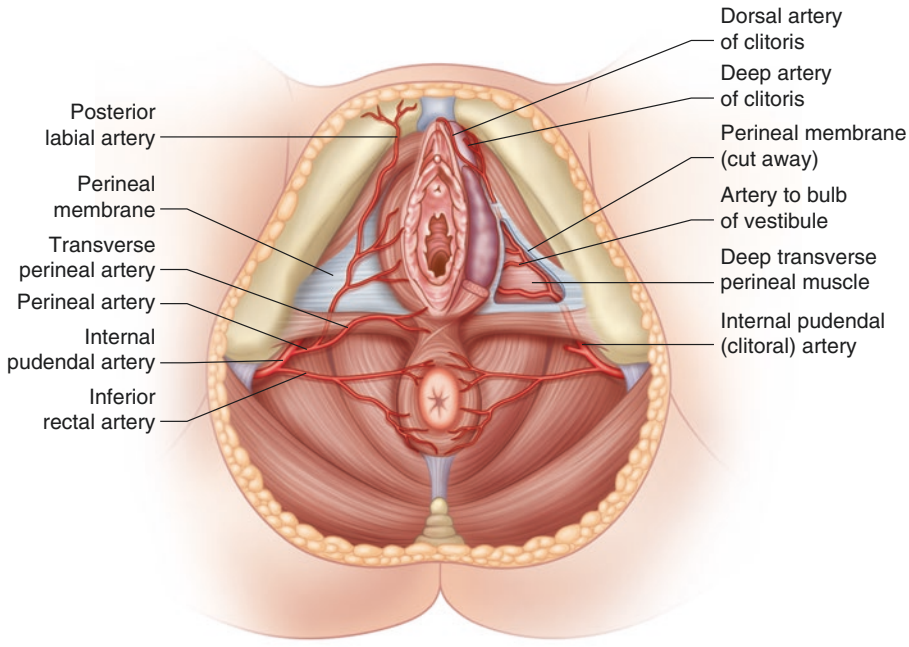

Fig. 1.8 Posterior vaginal support structures

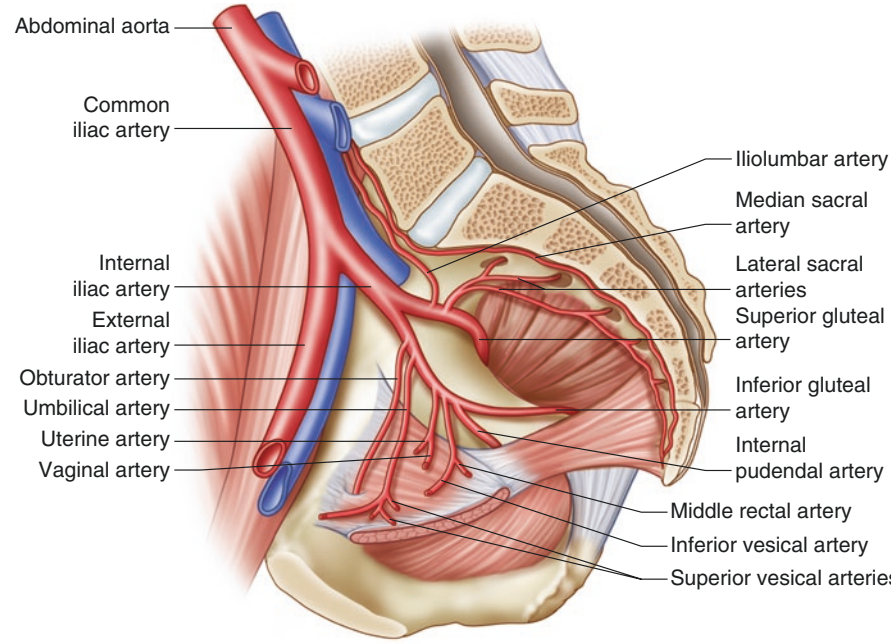

Fig. 1.9 Branches of the internal iliac artery (hypogastric artery)

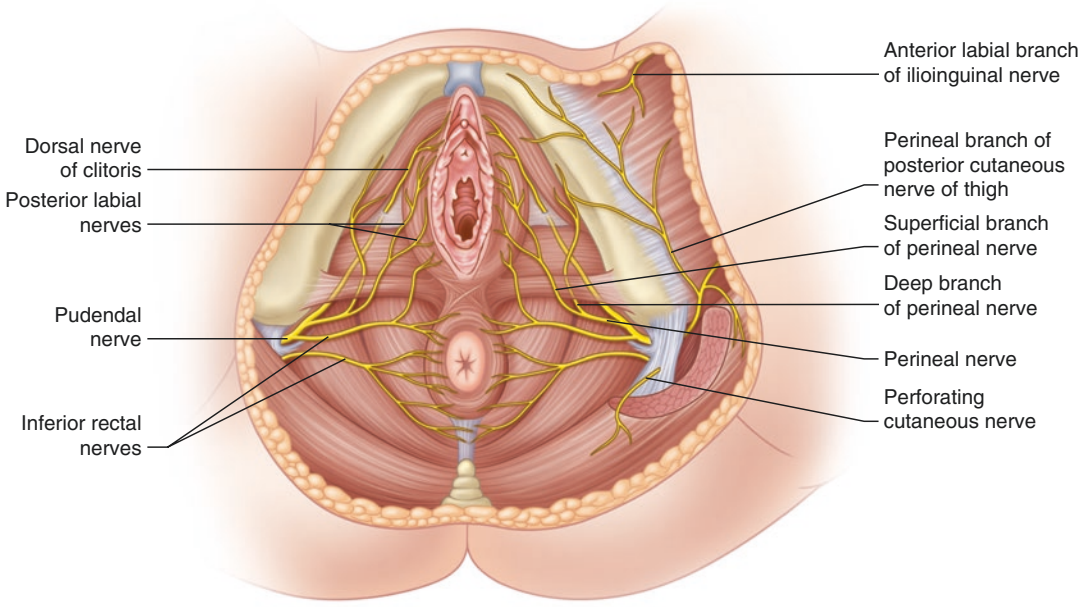

Fig. 1.10 Nerve supply to the pelvis

The Urinary Tract

Embryology (Fig. 1.11)
The urogenital ridge gives rise to the urogenital system in the fourth week of development. The urogenital ridge contains a nephrogenic ridge that is responsible for the formation of the urinary system. The development of the kidneys is sequential; three sets develop in the development of the fetus; however, only the final set is maintained after birth. The pronephros is a rudimentary structure that regresses completely. Subsequently, a mesonephros is formed, which functions only for a short period of time. The caudal portion of the mesonephric duct gives rise to the ureteric bud. The elongated stalk of the ureteric bud forms the ureter [15]. The cranial end of the ureteric bud forms the collecting duct system of the kidney, the major and minor calices, and the renal pelvis. A portion of mesoderm in contact with the ureteric bud—the metanephrogenic blastema—is induced by signals released by the former to form the renal tubules [2].

In the 4th–7th weeks of development, the cloaca is divided into two parts by the uro-rectal septum. The anterior portion is the urogenital sinus; it consists of an upper part, which forms the bladder, and a pelvic portion, which forms the entire urethra in females [9]. The urinary bladder is continuous with the allantois during development, though this is subsequently obliterated and forms the median umbilical ligament. The trigone of the bladder is derived from the caudal ends of the mesonephric ducts. The remainder of the bladder forms from the endoderm [2].

Kidneys

Anatomy
The kidneys are bean-shaped organs that are retroperitoneal, located in the posterior abdominal region. They are immediately adjacent to the vertebral column, and range from T12 to L3, with the left kidney sitting slightly higher than the right, secondary to its relationship with the liver. The right kidney is in contact with the suprarenal

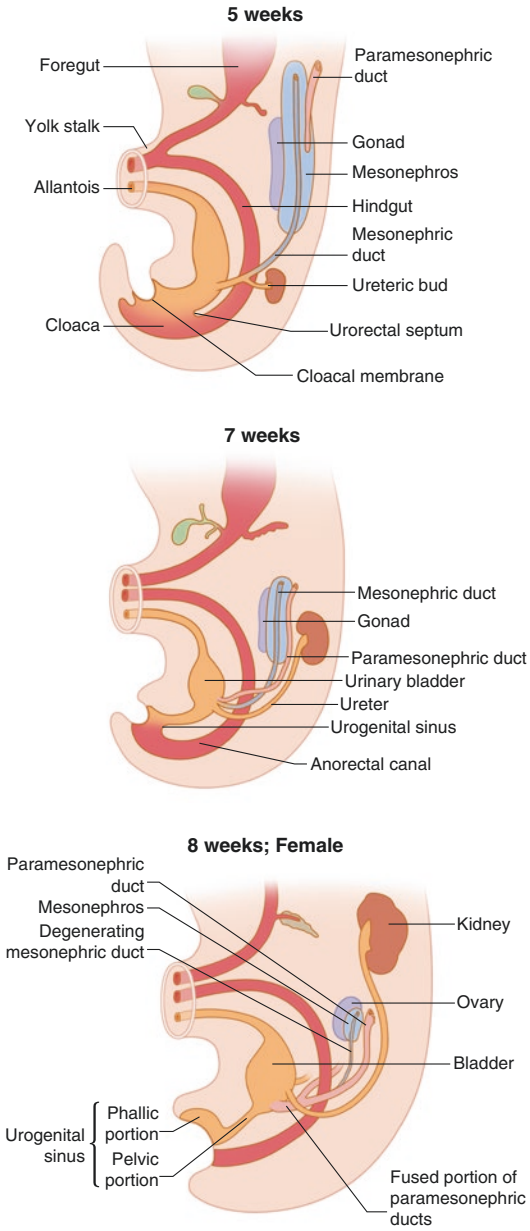

Fig. 1.11 Embryology of the urinary tract

gland superiorly, the liver anteriorly, the descending duodenum medially, the right colic flexure laterally, and the small intestine medially. Note that these structures are variably in direct contact or separated by peritoneum, depending on whether they are intraperitoneal or retroperitoneal structures. The superior pole of the left kidney is covered by the suprarenal gland; the stomach and spleen also contact the superior pole. The lateral aspect of the kidney contacts the left colic flexure and descending colon, while the jejunum covers much of the inferior pole. Posteriorly, the kidneys are bordered by the diaphragm superiorly and the psoas major, quadratus lumborum, and transversus abdominis muscles inferiorly. The kidney is immediately surrounded with perinephric fat, the renal fascia, and then further layered with paranephric fat. Medially at each kidney, there is a hilum, which contains renal vessels, lymphatics and nerves, as well as the ureteropelvic junction.

Blood Supply (Fig. 1.12)
A single renal artery supplies each kidney. These vessels arise off the abdominal aorta, just inferior to the origin of the superior mesenteric artery, between L1 and L2. The right renal artery is longer than the left typically, and also commonly passes posterior to the inferior vena cava.

Nerves
The kidney receives innervation from the renal plexus. The renal plexus includes input from the sympathetic and parasympathetic nervous system. The sympathetic innervation serves to trigger vasoconstriction. Parasympathetic innervation derives from the vagus nerve. Visceral afferents convey pain as visceral pain by traveling back to the spinal cord.

Ureters

Anatomy
The ureters are muscular tubes which convey urine from the kidneys to the bladder. The major calyces of the kidney coalesce to form the ureteropelvic junction, which narrows and becomes continuous with the ureter. The ureters descend in the retroperitoneal space, crossing over the distal common iliac or proximal external iliac artery to enter the pelvis. Of note, ureters are constricted at the ureteropelvic junction, at their entrance to the pelvic brim,

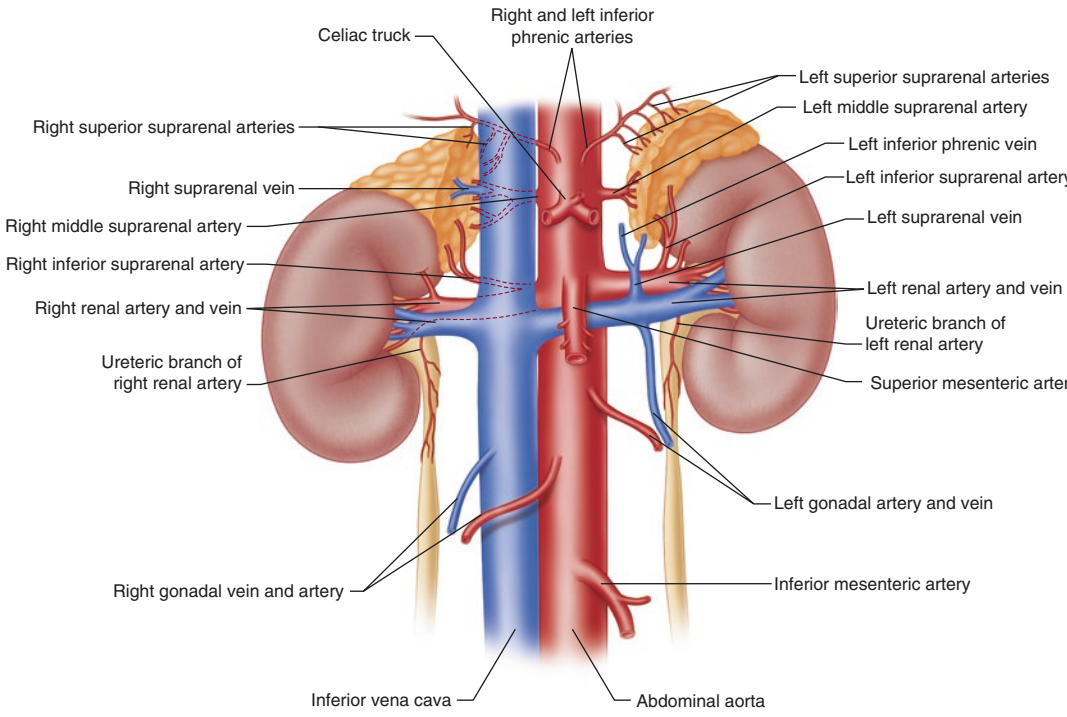

Fig. 1.12 Blood supply to the kidneys

and at the wall of the bladder; these are likely locations for obstruction [16].

Blood Supply

The ureters receive blood supply from adjacent structures as they course to the bladder. The proximal portion of the ureter receives blood from the renal artery (Fig. 1.12). The middle section of the ureter receives blood variably from the branches of abdominal aorta, common iliac arteries, and the ovarian arteries. The distal portion is supplied by branches of the internal iliac arteries.

Innervation

Ureteric innervation is derived from renal, aortic, superior hypogastric and inferior hypogastric plexuses, through nerves which course alongside the vasculature. Of note, pain from the ureters are referred to cutaneous areas which are supplied by T11–L2, leading to flank, abdominal, pelvic, and genital pain in the event of an obstruction and/or distension [17].

The Bladder (Fig. 1.13)

The bladder is the most anterior pelvic organ and is fully situated in the true pelvis when empty. As the bladder distends, it extends superiorly, crossing the pelvic brim into the abdomen. The apex of the bladder is directed toward the top of the pubic symphysis and maintains an attachment with the median umbilical ligament. The base of the bladder faces posteroinferiorly, with the two ureters entering the upper corners of the bladder base, and the urethra draining from the inferior corner of the base. The bladder is further cradled inferiorly and laterally by the levator ani muscles of the pelvic diaphragm. The neck of the bladder is the inferior most part, anchored by the pubovesical ligaments, which along with the pelvic floor, help to support the bladder (Fig. 1.14).

Blood Supply

The primary blood supply of the bladder comes from the superior and inferior vesical arteries,

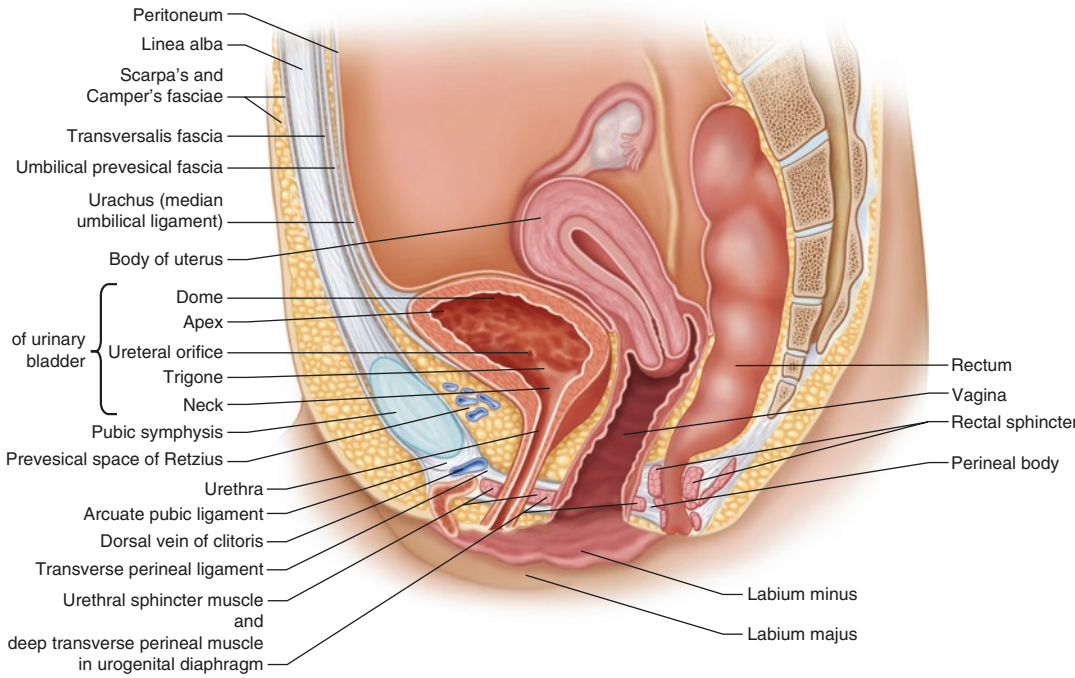

Fig. 1.13 Relationship of bladder to neighboring organs

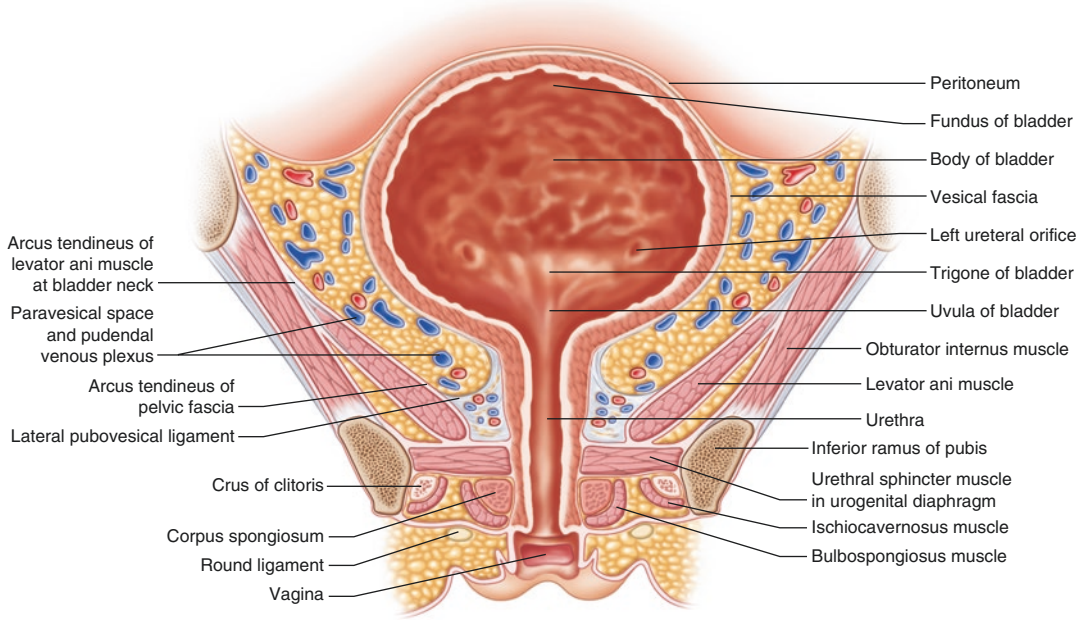

Fig. 1.14 Anatomy of the urethra

which arise from the internal iliac artery. These vessels may arise directly or indirectly from the internal iliac artery. In females, the inferior vesical artery may commonly arise as a branch of the uterine artery [16].

Innervation
The bladder is innervated by branches of the vesical and prostatic plexuses. These plexuses are extensions of the inferior hypogastric plexuses. Parasympathetic fibers serve to innervate the detrusor muscle, helping in urination. Sensory fibers sense bladder distension and create the sensation of bladder fullness.

The Urethra

Anatomy
The urethra is approximately 4 cm long in women, running from the neck of the bladder under the pubic symphysis, passing through the pelvic floor and into the perineum [13]. It then passes through the deep perineal pouch and perineal membrane before opening between the labia minora. Two small paraurethral mucous glands are present at the lower end of the urethra. The urethra consists of the mucosa, submucosa, and an outer fibromuscular layer. The fibromuscular layer consists of inner longitudinal muscle fibers and outer circular muscles; these meet with the bulbocavernosus and ischiocavernosus muscles distally, creating the external urethral sphincter.

Blood Supply
The blood supply to the urethra comes from the vaginal and internal pudendal arteries. The inferior vesical branches of the vaginal artery also supply the proximal urethra.

Innervation
Parasympathetic and sympathetic fibers from the hypogastric plexus innervate the urethra. The pudendal nerve innervates the external urethral sphincter.

The Female Reproductive System

Ovaries

Embryology (Fig. 1.15)
From the intermediate mesoderm, the urogenital ridge arises. Within the urogenital ridge, coelomic epithelium and mesoderm proliferate, forming the gonadal ridge. The gonadal ridge forms primary sex cords, which develop into rete ovarii. Secondary sex cords then develop and absorb in primordial germ cells. These break apart into primordial follicles and subsequently undergo follicular development. The ovaries develop higher on what will become the posterior abdominal wall and then descend prior to birth. As these structures move inferiorly, they are followed by the vessels which will supply them.

Anatomy
The ovaries lie immediately below the pelvic brim and are 2.5–5 cm in length. The ovaries are suspended my mesovarium, a portion of mesentery which is the posterior extension of the broad ligament. The ovaries receive support from the mesovarium, the ovarian ligament, and the suspensory ligament of the ovary. The ovarian ligament affixes the ovary to the lateral surface of the uterus. The suspensory ligament of the ovary extends out from the ovary to the wall of the pelvis. The suspensory ligament of the ovary contains the ovarian artery.

Blood Supply
The ovarian arteries are the primary blood supply of the ovary. These vessels emerge from the abdominal aorta, cross the common iliac artery, and then pass over the ureter and into the pelvis, traveling to the ovary within the suspensory ligament of the ovary.

Nervous Innervation
Nerves to the ovaries run within the suspensory ligament, alongside the vessels. The supply stems from the ovarian, hypogastric, and aortic plexuses.

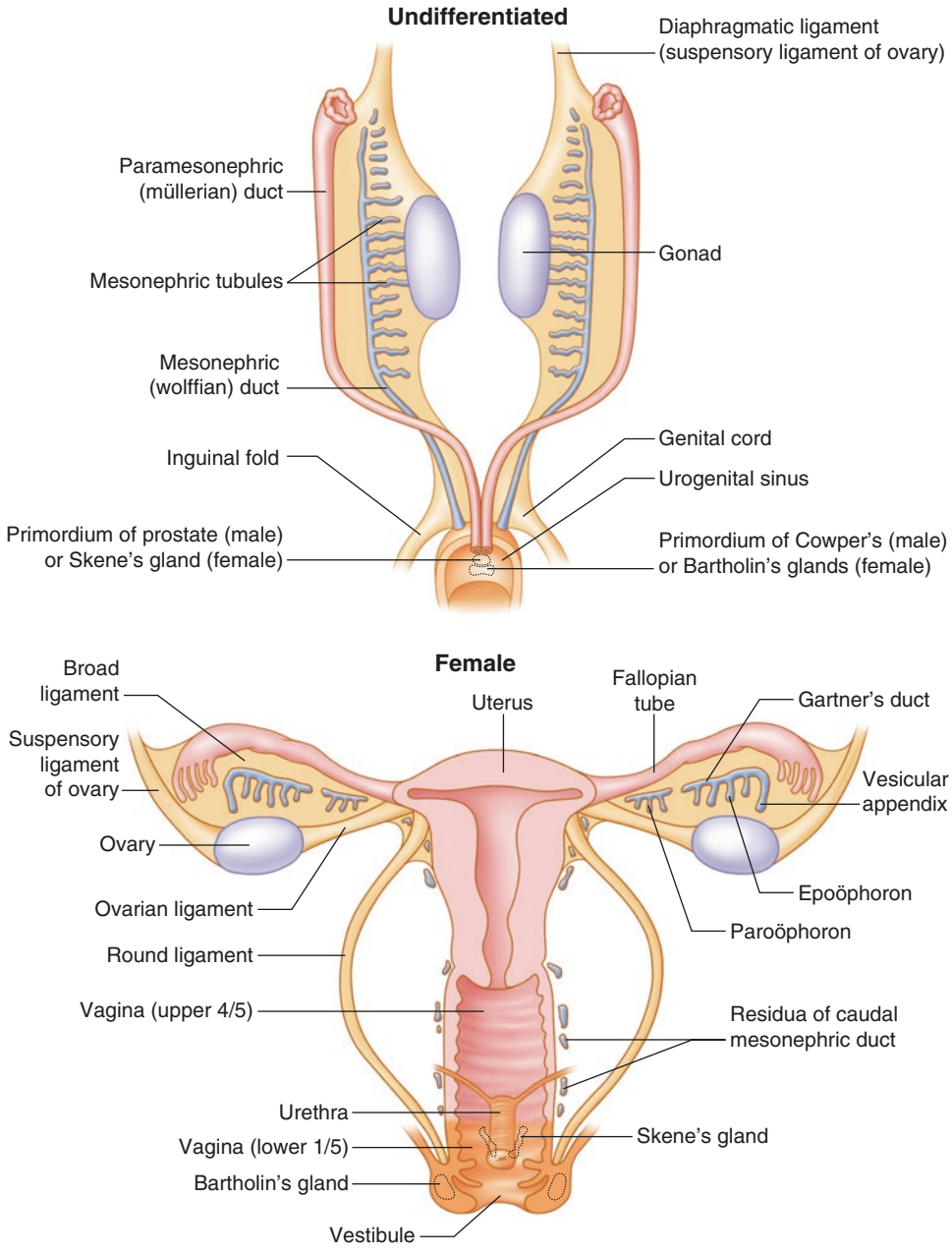

Fig. 1.15 Embryology of the female genital tract

Fallopian Tubes

Embryology

The mesoderm gives rise to the urogenital ridge, which forms the mesonephric (Wolffian) and paramesonephric (Mullerian) ducts. The Mullerian ducts give rise to the fallopian tubes, the uterus, and the upper portion of the vagina.

Anatomy

The fallopian tubes extend from each side of the superior aspect of the uterus and run to the lateral

pelvic wall. They are enclosed within the mesosalpinx portions of the broad ligaments, passing over the ovaries superiorly and then terminating laterally. The fallopian tubes have an infundibulum or a funnel-shaped, hollow section distally; the distal portion of the infundibulum is lined with fimbriae—finger-like projections. The narrow portion that comes from the uterus is called the isthmus, and this is connected to the infundibulum by the ampulla (Fig. 1.16).

Blood Supply

Like other tubular structures in the pelvis, the fallopian tubes derive their blood supply from adjacent organs. The upper portion is supplied by tubal branches of the ovarian artery, while the lower portion proximal to the uterus is supplied by a tubal branch of the uterine artery.

Nervous Supply

Sympathetic and parasympathetic nerve fibers innervate the fallopian tubes, with fibers coming from the ovarian plexus and the uterovaginal plexus for the segments distal and proximal to the uterus, respectively.

Uterus

Embryology

Until week 8, primordial for male and female internal genitalia coexist in the embryo. The lack of exposure to testosterone and the absence of a Y chromosome result in fusion and canalization of the paramesonephric (mullerian) ducts in the midline pelvis. The mesonephric ducts regress. The mullerian ducts become the uterine tubes and uterovaginal promordia. After a series of fusions, the uterovaginal primordial degenerates, creating the fundus, body, and isthmus of the uterus. The endometrial stroma and smooth muscle of the uterus are derived separately from splanchnic mesenchyme.

Anatomy

The uterus is a muscular organ with thick walls. It sits midline between the bladder and the rectum. The uterus consists of the body of the uterus and the cervix, with uterine tubes projecting laterally from the superior aspect. Inferiorly, the uterus joins the vagina. The rounded superior end of the uterus is called the fundus. The body of the

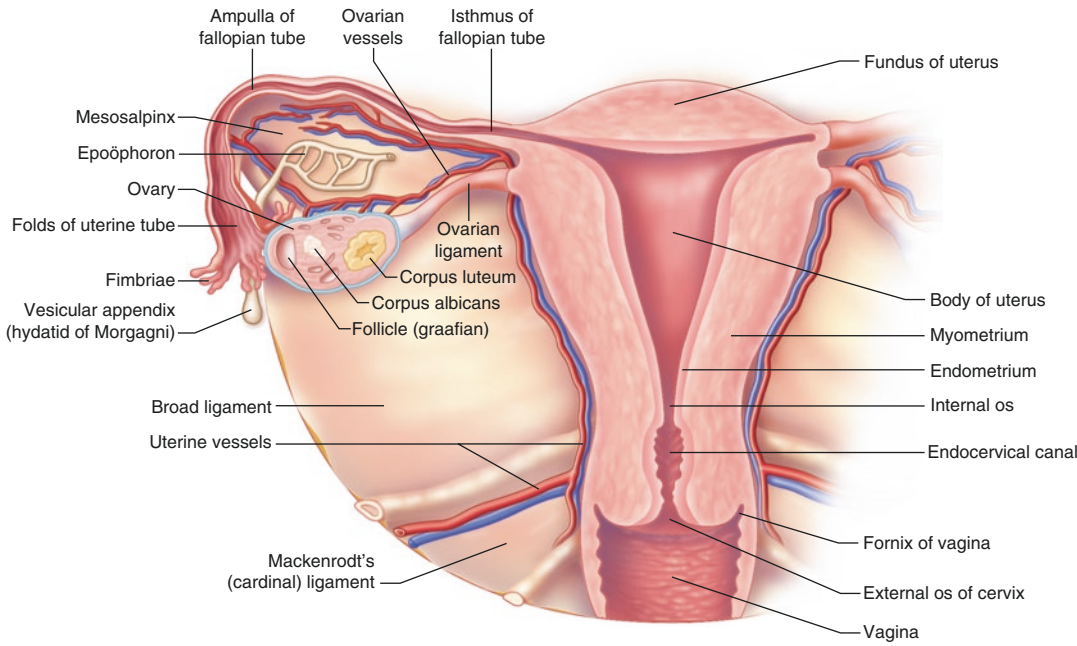

Fig. 1.16 Uterine ligaments and relationships to ovaries and fallopian tubes

uterus is covered by the broad ligament. The cervix has an opening allowing for communication between the vagina and the uterus. The external os is the opening into the vagina, and the internal os is the opening from the cervix into the uterus.

The bladder is separated from the uterus by the uterovesical pouch, which is formed by peritoneum. The rectum is also separated from the uterus by a deep fold of peritoneum, which creates the pouch of Douglas. Small bowel sits on the uterus and can extend into the pouch of Douglas. The uterine vessels cross over the ureter approximately 1.5 cm from the lateral fornix of the vagina [18].

The uterus is held in place by several ligaments which offer stability and support. The uterosacral ligament runs from the posterior cervix to the anterior sacrum. The cardinal ligaments run from the sides of the cervix to the ischial spines. The pubocervical ligament runs from the side of the cervix to the pubic symphysis.

Blood Supply (Fig. 1.17)

The uterus receives blood from the uterine artery and the ovarian artery. The ovarian artery is a direct branch of the aorta, while the uterine artery is a terminal branch of the internal iliac artery. The uterine artery crosses anterior to the ureter and travels to the uterus in the cardinal ligament, and commonly anastomoses with the ovarian artery. The uterine artery serves as the main blood supply to the uterus and enlarges during pregnancy.

Nervous Supply

The uterovaginal plexus, a division of the inferior hypogastric plexus, supplies sympathetic, parasympathetic, and visceral afferents to and from

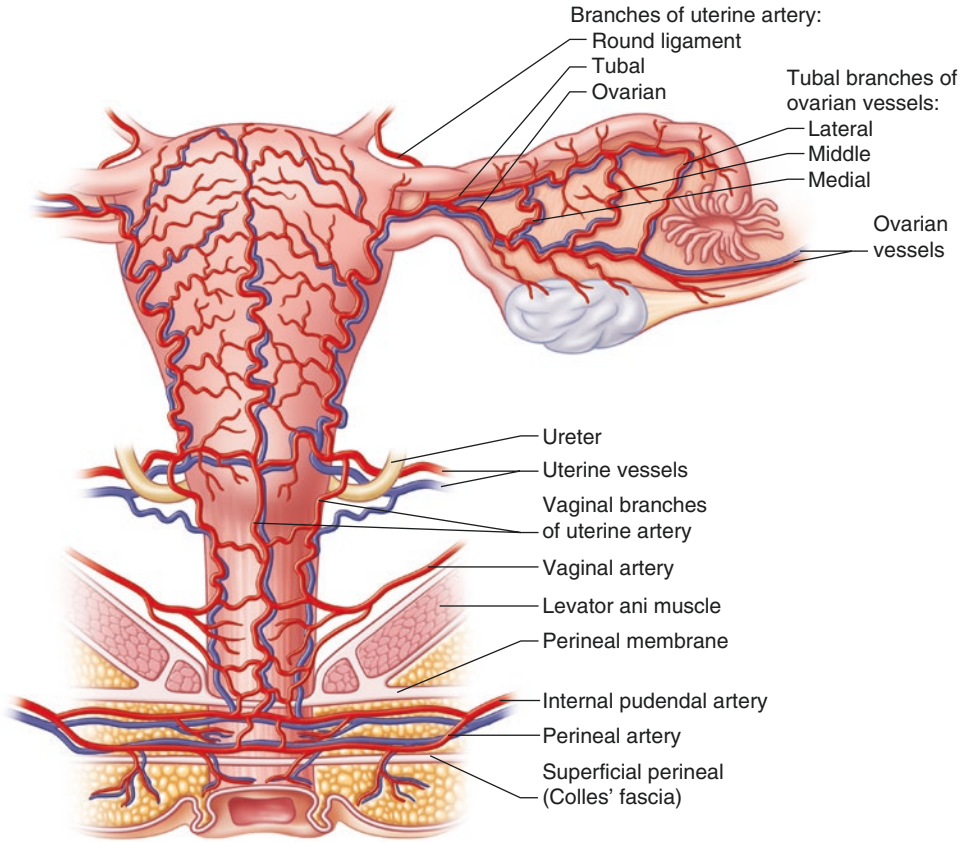

Fig. 1.17 Blood supply to the uterus

the uterus. The parasympathetic fibers are derived from the pelvic splanchnic nerves (S2–S4). The cervix receives most of its innervation by inferior fibers of the uterovaginal plexus. The afferent fibers ascend through the pelvic plexus and enter the spinal cord via T10–L1 nerve fibers.

Vagina

Embryology

The paramesonephric duct is the precursor of the uterus, fallopian tubes, cervix, and upper vagina. The caudal end of the fused paramesonpehric ducts forms the upper two-thirds of the vagina. The lower third of the vagina is formed with the canalization of the sinovaginal node. Vertical fusion occurs in the 8th week of development where the fused paramesonephric ducts which form the upper vagina fuse with the sinovaginal bulb [19].

Anatomy

The vagina is a fibromuscular tube which extends from the pelvic floor, into the pelvic cavity. The internal end of the vagina forms the vaginal vault. The anterior wall of the vagina is adjacent to the bladder and urethra; the urethra is fused to the anterior vaginal wall. The vagina opens into the vestibule of the perineum posterior to the external urethral opening. The vaginal fornix is a recess that is formed between the cervix and the vaginal wall; the fornix is subdivided into the anterior fornix, posterior fornix, and two lateral fornices. The distal vagina abuts the levator ani muscles.

Blood Supply

Blood supply to the vagina is provided largely by the vaginal artery. The vaginal artery is a branch of the internal iliac artery. The vagina also receives blood supply from the middle rectal artery and the internal pudendal artery.

Nerve Supply

The upper vagina receives sympathetic and parasympathetic innervation from the pelvic plexus. The lower vagina receives somatic innervation from the pudendal nerve. The pudendal nerve branches into the perineal nerve as it passes through Alcock's canal [20].

Vulva

Embryology

At around 8 weeks of gestation, the external genitalia of females develop from the urogenital sinus. The corpora cavernosa of the clitoris and glans are formed from the phallus. The vaginal vestibule, vestibular bulbs, and female corpus spongiosum are formed from the pelvic and phallic part of the urogenital sinus. In the female, labioscrotal swellings give rise to the labia majora and do not fuse as they do in males [9].

Anatomy

The vulva is formed by the clitoris and the vestibular apparatus (Fig. 1.18). Also termed the erectile apparatus, it consists of the labia minora, clitoris, and vestibular bulbs. Two thin folds of skin on either side of the midline are called the labia minora. The region bound by the labia minora is called the vestibule and contains the vagina and the urethra. Skene's ducts, which are paraurethral ducts along the external orifice of the urethra, are found in the anterior portion. The labia minora both converge on the clitoris to form the frenulum of the clitoris with a set of medial folds, and the prepuce of the clitoris with a set of lateral folds. Additionally, Bartholin's glands sit along the sides of the vaginal opening; these glands are thought to secrete fluids preceding orgasm.

The clitoris is formed by the two corpora cavernosa and the glans, covered with the aforementioned prepuce. The corpora cavernosa become engorged with arousal. The glans itself contains cavernous tissue and is in direct contact with the skin. The glans is particularly rich in nerve endings.

Blood Supply

The blood supply to the clitoris includes a deep artery of the clitoris, which supplies the corpus cavernosum, the artery of the bulb, which sup-

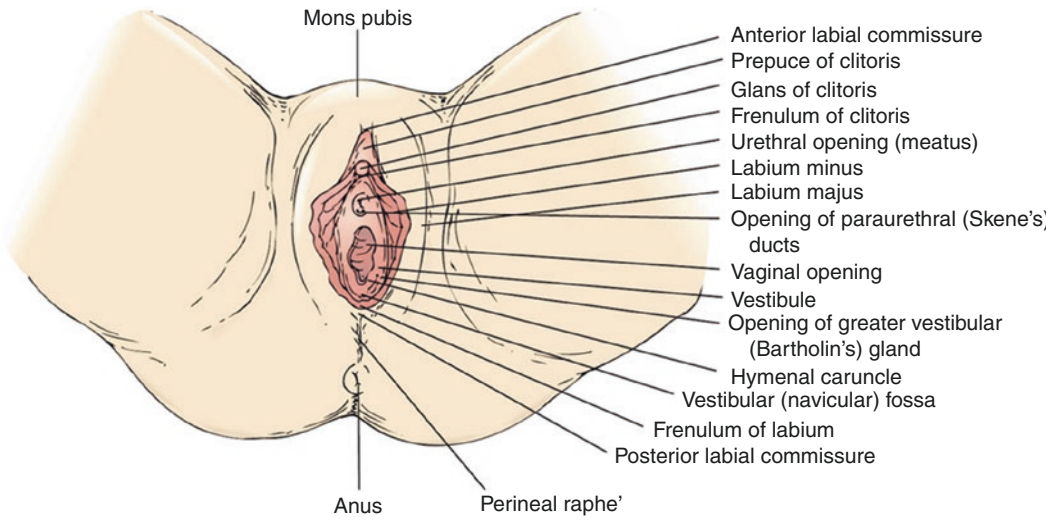

Fig. 1.18 Anatomy of the vulva

plies the bulb of the vestibule, and the dorsal artery of the clitoris, which supply both the glans and the prepuce of the clitoris. These vessels are branches of the pudendal artery. The more external and lateral portions of the vulva receive supply from the deep external pudendal artery.

Nerve Supply

The vulva is densely populated with nerves. The major somatic nerve to the vulva is the pudendal nerve, originating from S2 to S4 by way of the sacral plexus. The pudendal nerve first leaves the pelvis through the greater sciatic foramen and then enters through the perineum, passing medially and entering through the lesser sciatic foramen. The pudendal nerve has three terminal branches; the dorsal nerve of the clitoris innervates the clitoris. It enters through the deep perineal pouch and courses through the perineal membrane. The erectile tissues also receive innervation from visceral nerves; postganglionic sympathetic nerves reach this area by accompanying the pudendal nerve.

Conclusion

The female pelvis facilitates the process of micturation, defecation, and reproduction, while allowing for stability and locomotion and serving as an interface between the abdomen and the lower extremities. Accordingly, it houses a diverse collection of visceral, neurovascular, and musculoskeletal structures. A sound appreciation of these structures and their relationships forms a necessary foundation for the assessment and treatment of disease in the female pelvis.

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2 Instrumentation for Female Pelvic Surgery

Omar Al Hussein Alawamlh, Ramy Goueli, and Richard K. Lee

Introduction

Female pelvic surgery is unique in that interventions can be performed using vaginal, open abdominal, laparoscopic, and/or robotic approaches. Regardless of the selected modality, proper instrumentation is imperative for a successful operation. The instruments listed in the following sections represent a sampling of all that are available, but which we have found most useful for female pelvic surgery. This section has been divided based on the type of female pelvic surgery (open/vaginal, laparoscopic, or robotic). A representative image as well as a brief description of each instrument has been provided. For a full listing, see Table 2.1.

Table 2.1 List of instruments and devices for female pelvic surgery

Open surgery	Catheters Diluted indigo carmine Stirrups Cystoscope weighted vaginal speculum Uterine tenaculum Allis forceps DeBakey forceps Metzenbaum scissors Mayo scissors Deaver retractor Vaginal handheld retractors Self-retaining retractors Raz double-pronged needle Heaney needle holder Capio© device Phaneuf clamp surgical sutures Vaginal packing Mid-urethral sling trocars vaginal dilators
Laparoscopic surgery	Veress needle Laparoscopic trocars Ligasure™ (Covidien, Dublin, Ireland); Harmonic® scalpel (Ethicon Endo-Surgery, Inc., Johnson & Johnson, New Brunswick, NJ) Laparoscopic Maryland forceps Laparoscopic scissors
Robotic surgery (Da Vinci® Surgical System) (Intuitive Surgical, Inc., Sunnyvale, CA)	Monopolar scissors Bipolar cautery Tenaculum Ligasure Prograsp forceps Needle drivers

Instruments Used for Open/Vaginal Surgery

Uterine Tenaculum (Fig. 2.1)

Tenacula are useful instruments for grasping and holding tissue. The piercing hooks of a tenaculum can be anchored onto areas such as the cervix. The term tenaculum is derived from the Latin word "tenere" which means "to hold or grasp."

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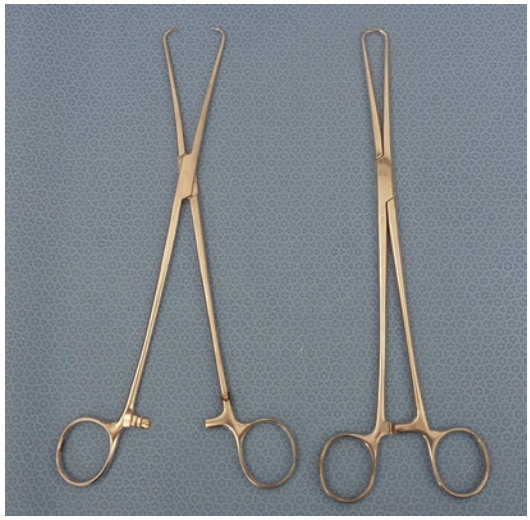


Fig. 2.1 Uterine tenaculum

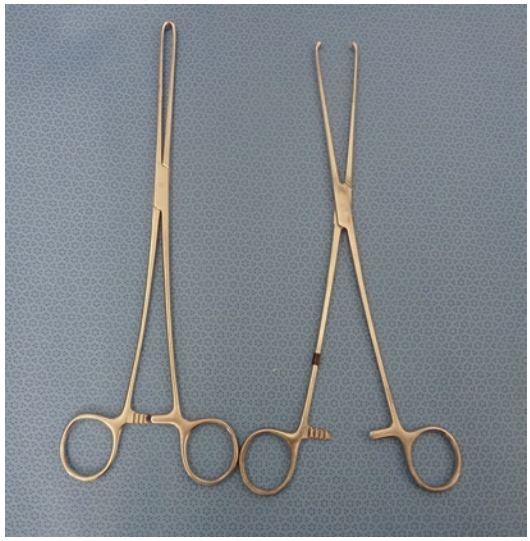


Fig. 2.2 Allis forceps

Uterine tenacula can be made of stainless steel, which makes them reusable after sterilization, or of plastic for use as disposable devices.

Allis Forceps (Fig. 2.2)

Allis forceps are instruments designed to grasp and hold structures in an atraumatic fashion. Their serrated jaws contain a tooth-like structure,

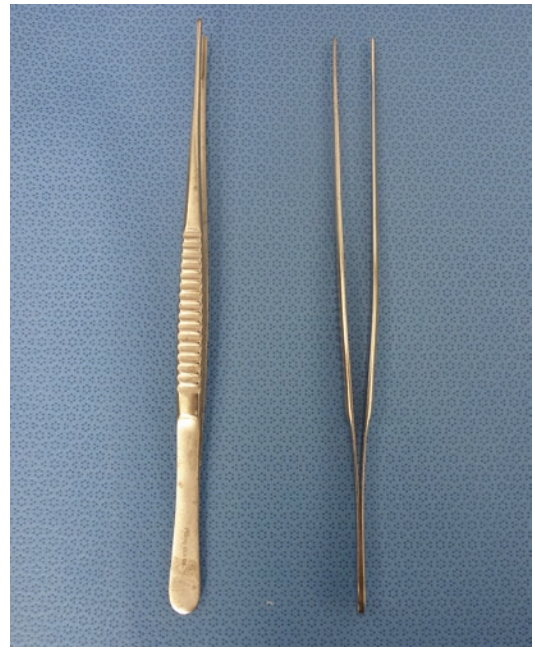


Fig. 2.3 DeBakey forceps

which enables the surgeon to hold on to delicate structures. Both self-locking and non-self-locking forceps are available according to the surgeon's preference.

DeBakey Forceps (Fig. 2.3)

DeBakey forceps are atraumatic forceps meant to grasp delicate tissues. The inner aspect of the tips contains microscopic, atraumatic teeth while the outer side of the instrument is normally ridged providing a better grip while handling delicate structures. DeBakey forceps are normally straight with curved variants available for special utilization. The size can range up to 9.5 in.

Metzenbaum Scissors (Fig. 2.4)

Metzenbaum scissors are mostly known as dissecting scissor, which is an excellent tool to perform fine cuts. Models with tungsten carbide cutting edges are the most precise, while cheaper models are made of stainless steel. Regardless if

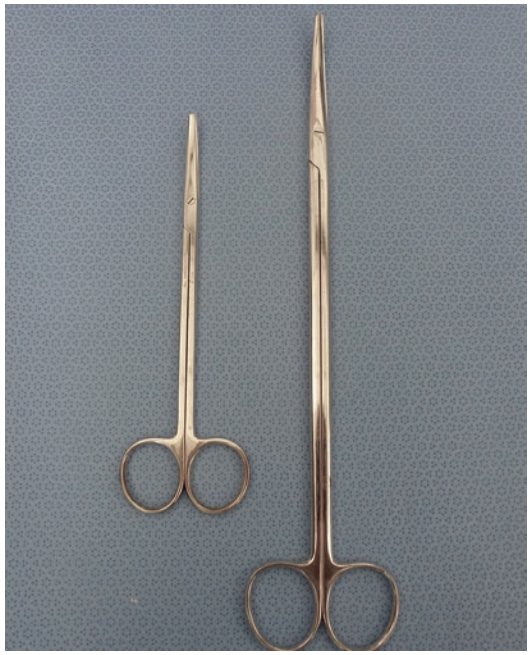


Fig. 2.4 Metzenbaum scissors

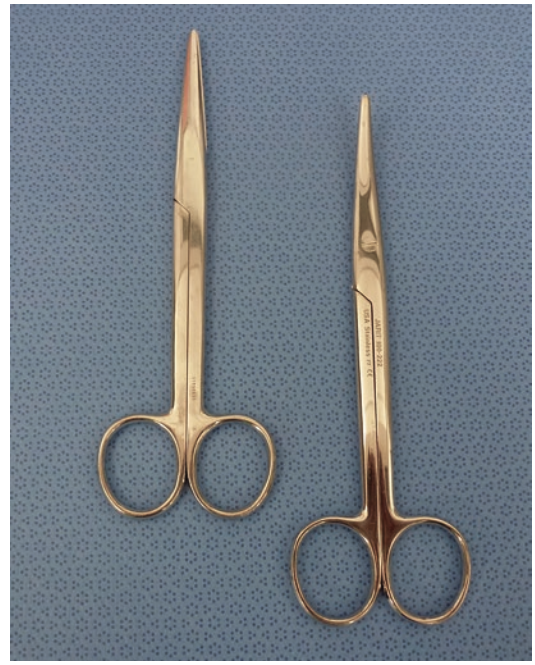


Fig. 2.5 Mayo scissors

the blades are curved or straight, if small (4.5 in.) or large (14 in.), they typically possess a long shank or handle with a blunt-tipped scissor sorter blades. Metzenbaum scissors should not be used to cut regular sutures as they can be dulled easily.

Mayo Scissors (Fig. 2.5)

In contrast to the Metzenbaum scissor, the Mayo scissor is designed to cut tougher structures. It can be used for dissecting but it is not as precise as Metzenbaum scissor. Mayo scissors can have either straight or curved blades, although they typically have semi-blunt ends. Straight-bladed Mayo scissors are also called "suture scissors," as they are amenable to cutting sutures since they do not dull as easily as other types of scissors. Curved Mayo scissors are usually used for cutting deeper thick tissue like the uterus as they allow deeper penetration into the wound. Mayo scissors can be made of titanium or stainless steel and normally range from 6 to 6¾ inches.

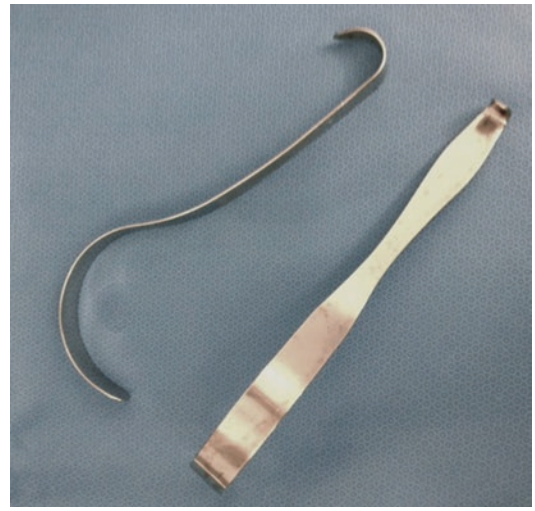


Fig. 2.6 Deaver retractors

Deaver Retractor (Fig. 2.6)

Deaver retractors are flat, thin devices with curved ends. Models can vary according to length, width, and angle of curvature. The edges of the Deaver retractor are smoothed to avoid damage to surrounding tissues.

Vaginal Handheld Retractors (Fig. 2.7)

Normally, vaginal retractors consist of a handle and a curved blade with varying lengths, widths, and angles. One of the most commonly used retractors is the Breisky–Navratil retractor, which has a ridged handle and a notch for good retraction and comfortable handling. Lighted vaginal retractors, like the Heaney–Simon or the Miyazaki retractors, have also been proposed for use in the deep pelvic surgery.

Self-Retaining Retractors (Fig. 2.8)

The Scott retractor© is a self-retaining retractor commonly used in vaginal surgery. Multiple piercing or nonpiercing hooks can be used to optimize exposure of the surgical field. It can be used in tandem with a weighted vaginal speculum to maximize visualization during vaginal surgery. This retractor can be either disposable or non-disposable.

Weighted Vaginal Speculum (Fig. 2.9)

A weighted vaginal speculum contains a weight at one end, utilizing gravity to help retract the posterior aspect of the vagina. Two main types of weighted specula exist: the traditional and the articulated device. Traditional specula have a rounded heavy end and a hollow groove, which is positioned at a 90° angle to the blade of the retractor. Articulated specula can be adjusted by altering angles and lengths and can be made of plastic as well. There are several types of weighted specula, such as the Hardy-Duddy, Auvard, or Steiner variants.

Mid-Urethral Sling Trocar (Fig. 2.10)

The choice of using mesh versus autologous fascia for slings is largely practitioner- and situation-specific. Depending on the choice of sling, a

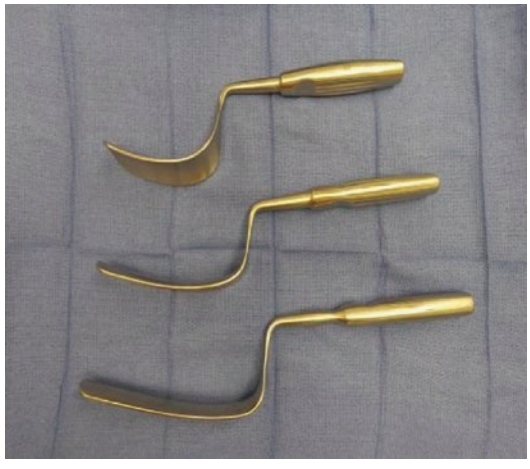


Fig. 2.7 Vaginal handheld retractors (Breisky retractors)

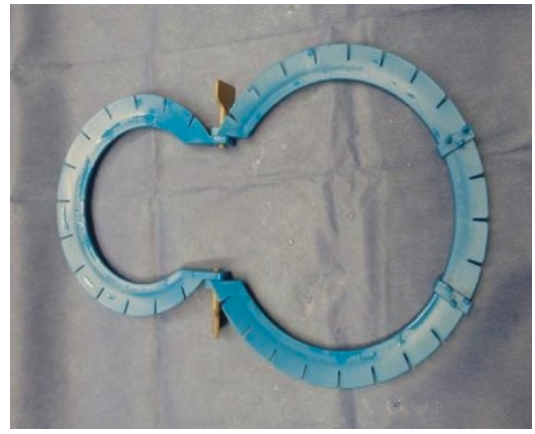


Fig. 2.8 Self-retaining retractor (Scott retractor)

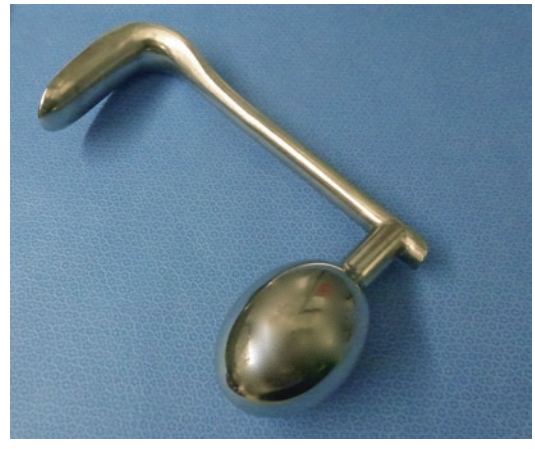


Fig. 2.9 Weighted vaginal speculum

specific trocar is required to position the mesh in its proper location. Included is a representative image of a trocar used to place a transvaginal tape sling.

Raz Double-Pronged Needle (Fig. 2.11)

This device is a double-pronged ligature carrier, which can be used for bladder neck suspension or sling placement. The tip of the needle is placed under finger guidance to the desired position. The inner segment of the device can be slid over the external support, extending the tip of the needle to place the suture in the desired position.

Heaney Needle Holder (Fig. 2.12)

The Heaney needle holder is a curved needle holder, which can be useful in situations where the use of a straight needle holder is difficult due to nearby anatomic structures.

Capio® Device (Fig. 2.13)

The Capio® (Boston Scientific, Marlborough, MA) device is designed to throw, catch, and retrieve sutures. It is supposed to extend the surgeon's reach into deep areas while ensuring precise suture placement in difficult-to-reach areas. It consists of a head that can be angled, a needle driver component, as well as alignment indicator. Available suture materials include both absorbable and nonabsorbable sutures.

Phaneuf Clamp (Fig. 2.14)

The Phaneuf clamp can be either straight or curved-bladed. With single teeth at its blunt tip and serrated inner blades, it represents a solid instrument to clamp bigger and thicker structures like the cardinal, uterosacral, and broad ligaments during hysterectomy.

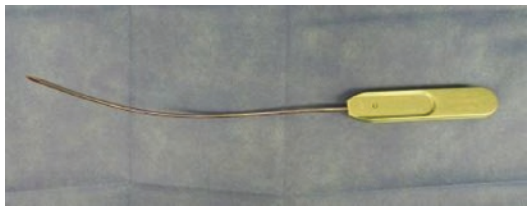


Fig. 2.10 Mid-urethral sling trocar

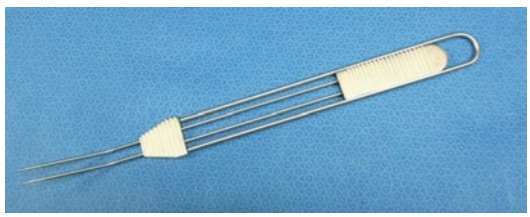


Fig. 2.11 Raz double-pronged needle

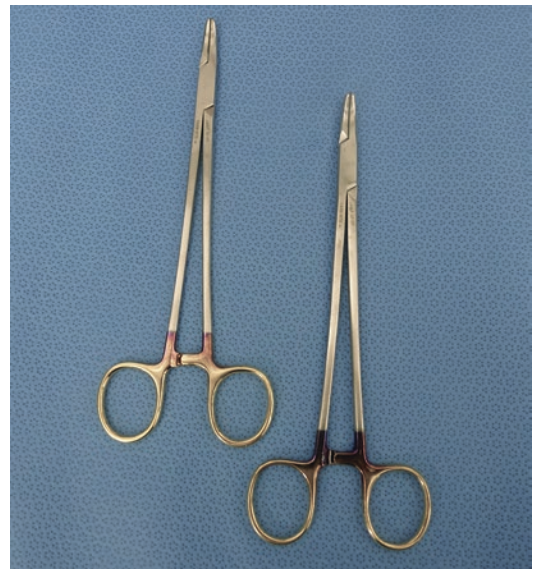


Fig. 2.12 Heaney needle holder

Fig. 2.13 Capio® device

Cystoscope (Fig. 2.15)

Urethrocystoscopy is an endoscopic procedure of the urethra and the bladder performed with a cystoscope. Cystoscopy is a routinely performed diagnostic as well as therapeutic procedure and can be done with flexible or rigid devices. Most cystoscopes have one or two ports allowing delicate instruments to be inserted like graspers, biopsy forceps, or ureteral stents.

Catheters (Fig. 2.16)

Indwelling urinary catheters are commonly used during surgery and in the perioperative period in order to guarantee emptying of the urinary bladder. Catheters can be made of many different types of materials with silicone being most common. The size of catheters is measured in Charrière (in English-speaking countries, the term "French" is mostly used), with one Charrière being approximately 0.3 mm.

Diluted Indigo Carmine Solution

Diluted indigo carmine solution is primarily excreted by the kidneys within a few minutes after intravenous injection. The blue color can be very useful during surgery either to evaluate the exact position of the orifices under cystoscopy or simply to ensure the integrity of the bladder.

Surgical Sutures

Two main types of surgical sutures exist in terms of durability: absorbable and nonabsorbable. Surgical sutures may come in monofilament vs. braided (woven) forms.

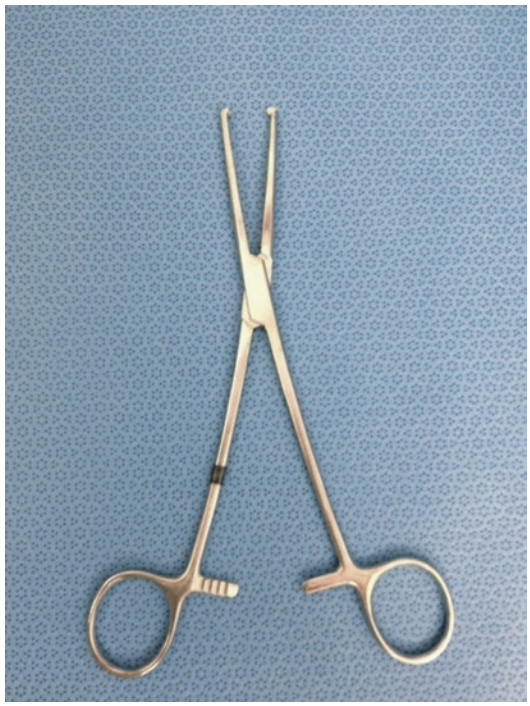


Fig. 2.14 Phaneuf clamp

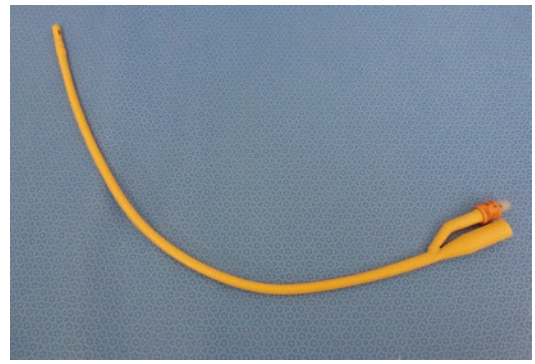
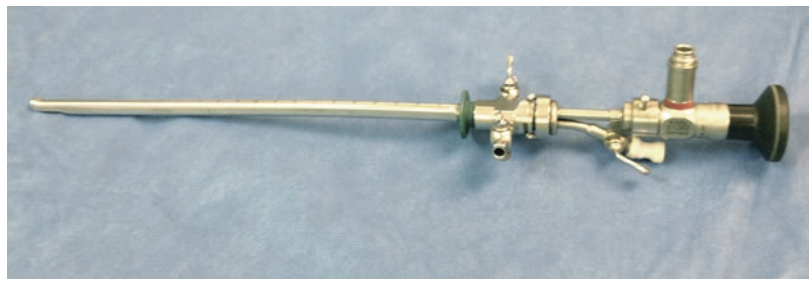


Fig. 2.16 Catheter

Fig. 2.15 Cystoscope



Stirrups (Fig. 2.17)

Stirrups are used to hold legs in position while surgery is positioned. Depending on surgeon preference and surgical requirement, there are a number of different options for the type of stirrups one can use. Two representative types are the Yellofin® stirrups (Allen Medical Systems, Hill-Rom Company, Batesville, IN) and the Candy Cane Stirrups.

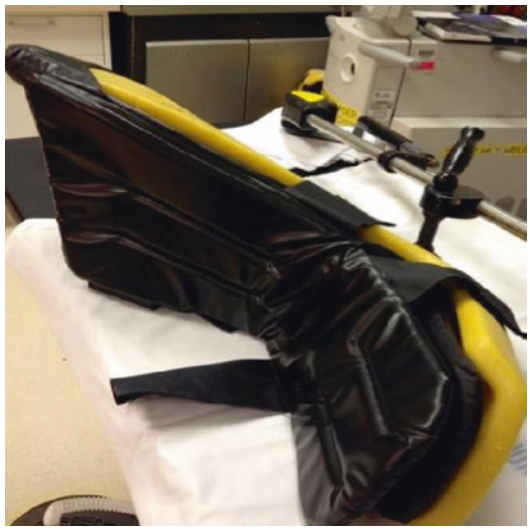


Fig. 2.17 Yellofin® stirrup

The fin design of the boot of the Yellofin® stirrups reduces the likelihood of peroneal nerve injury, which might occur otherwise if the patient is not positioned in a proper way. The Candy Cane stirrups provide more leg clearance while firmly preventing slippage with their height-adjustable clamps and straps. A drawback to the use of Candy Cane stirrups is the lack of proper foot and leg support that is offered by boot-type stirrups, such as the Yellofin®, that can evenly distribute pressure and prevent its localization to a single area.

Vaginal Packing

Vaginal packing typically refers to cotton-woven gauze placed into the vagina to absorb bleeding and to provide pressure for tamponade.

Instruments Used for Laparoscopic Procedures

Veress Needle and Laparoscopic Trocars (Fig. 2.18)

Instruments for laparoscopy are introduced into the body via trocars. Although blunt trocars exist, most possess a sharp tip to penetrate tissue. Most

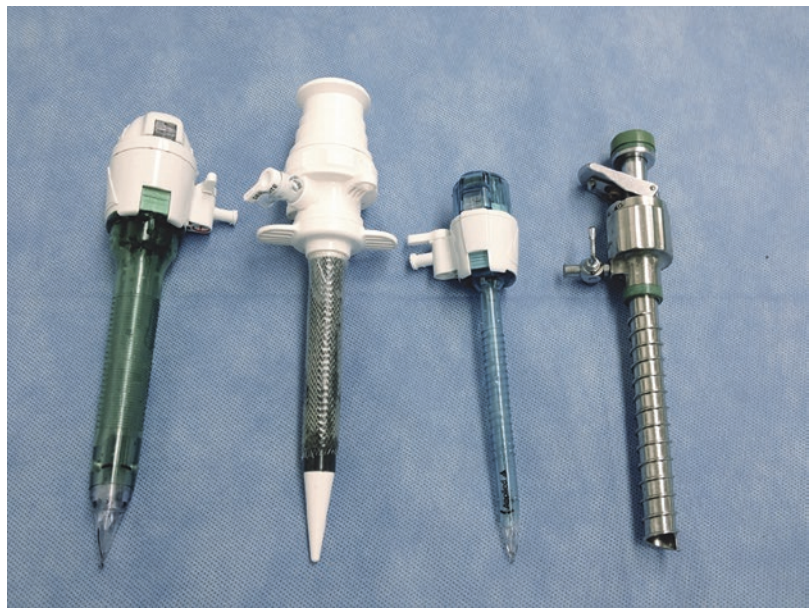


Fig. 2.18 Laparoscopic trocars

trocars have two openings: a primary port for inserting devices into the body and a secondary gas port. Trocars come in different sizes (e.g., 5 French for laparoscopic forceps, 10 or 12 French for cameras and larger instruments) and lengths. Trocars may be reusable or disposable.

It is possible to place the trocars under direct vision (Hassan technique) or blindly. If a blind technique is to be utilized, the desired surgical field should be first insufflated with gas. A Veress needle can be used to first penetrate the skin and underlying tissues to gain access to the desired surgical compartment. Gas is insufflated through the hollow core of the needle, after which the needle is removed and the trocar inserted.

LigaSure™ (Fig. 2.19)

LigaSure™ (Covidien, Dublin, Ireland) is an electrothermal bipolar tissue-sealing system, which can be used for both open and laparoscopic procedures. It provides a combination of pressure and energy to seal and cauterize blood vessels and tissue. Vessels up to and including 7 mm in diameter as well as tissue bundles can be fused permanently without dissection or isolation. The seals can withstand up to three times normal systolic blood pressure. In contrast to ultrasonic devices, the LigaSure™ device is able to coagulate larger vessels and tissue structures but at the cost of a larger device size.

Harmonic® Scalpel (Fig. 2.20)

In contrast to the Ligasure™ device, the Harmonic® scalpel (Ethicon Endo-Surgery, Inc., Johnson & Johnson, New Brunswick, NJ) is a cutting and sealing instrument using ultrasound vibratory energy. It is often used in laparoscopic procedures, as it can be directed either to cut tissue (with a vibration of 55.5 kHz) or to coagulate smaller vessels and tissue by sealing them through protein denaturization.

Laparoscopic Maryland Forceps and Laparoscopic Scissors (Fig. 2.21)

The Maryland forceps has a 10 mm diameter and a 33 cm length (with up to 45 cm available on request). It has a serrated semi-blunt tip, which can be rotated by 360° at the handle, and can be used to grab and secure tissue. Additionally, tissue can be cauterized using electrocautery. As with laparoscopic forceps, the laparoscopic scissors can also be rotated and used to cauterize tissue.

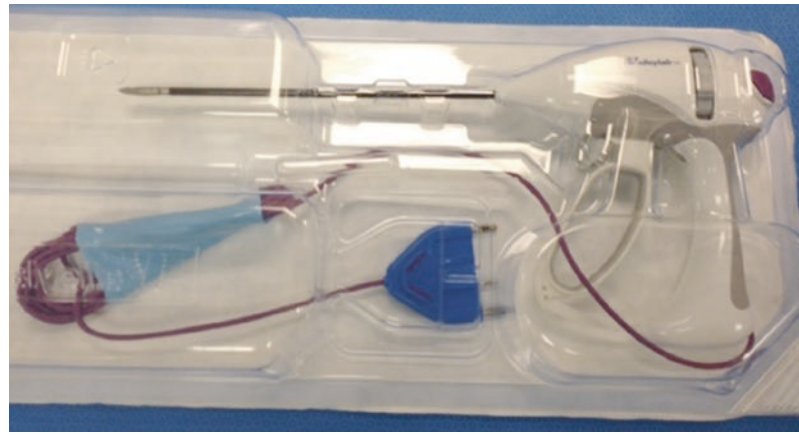


Fig. 2.19 Ligasure™

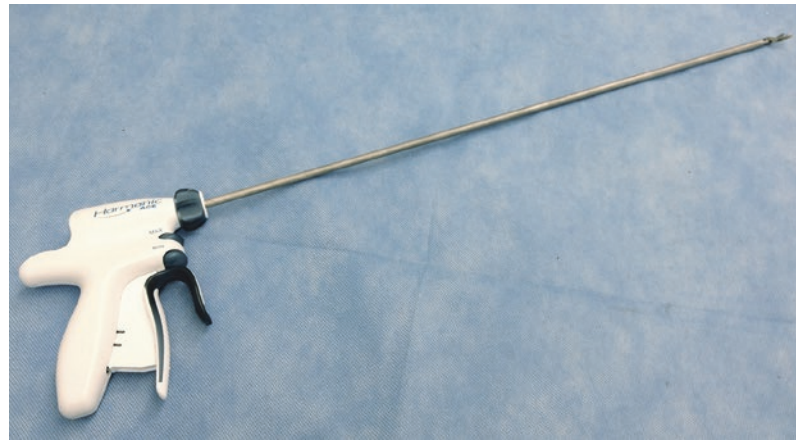


Fig. 2.20 Harmonic® scalpel

Fig. 2.21 Laparoscopic scissors

Instruments Used for Robotic Surgery: Da Vinci® Surgical System (Figs. 2.22, 2.23, 2.24, 2.25, 2.26, 2.27, 2.28a, b)

The da Vinci® Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA) has been approved by the Food and Drug Administration (FDA) for laparoscopic surgical procedures. The system consists of a patient-side cart or an overhead arrangement with four robotic arms and an accompanying command console. While one robotic arm is utilized for the endoscopic camera, which enables full stereoscopic three-dimensional high-definition vision for the surgeon, the other arms are used to manipulate laparoscopic instruments. The robotic arms can be moved with hand controllers and foot pedals. One of the advantages of the Da Vinci® Surgical System is that it has been designed to maximize flexibility of movements and to minimize human tremor.

There are three systems in widespread usage:

- *Da Vinci Si:* This second-generation Da Vinci® Surgical System is the first to be introduced among the three systems. It was the second system to feature the fourth robotic

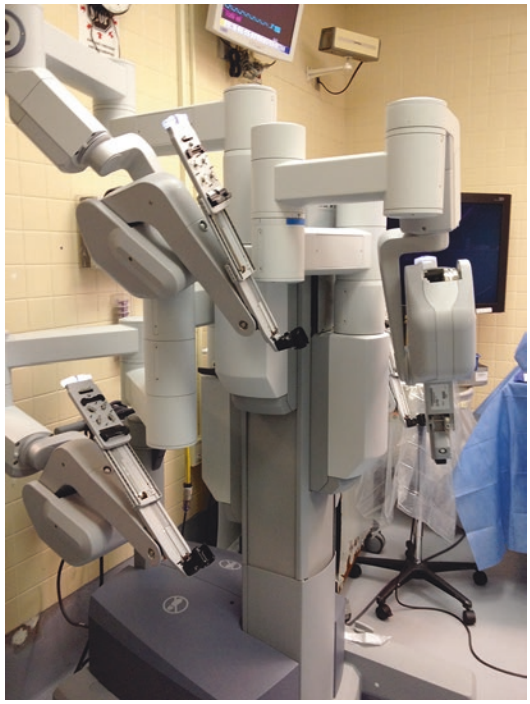


Fig. 2.22 Da Vinci® Si robot

arm allowing the use of an extra instrument by the surgeon following the S System. The most significant advantage that this model possesses compared to the earlier Da Vinci® Systems is the dual console feature, making the Si the first system to present the concept of collaborative robotic-assisted minimally invasive surgery, which has also enabled real-time mentoring. Other noteworthy upgrades include enhanced high-definition vision, fluorescence imaging, and overall control precision.

- *Da Vinci Xi*®: This is the flagship robotic Da Vinci® System. In addition to all the capabilities that the Xi retains from the Si System, there are several significant upgrades. The Xi features an overhead arrangement of thinner and smaller hinged robotic arms that provide greater anatomical access, compared to the earlier systems, and minimizes the need for robotic arm or patient repositioning. The newer system permits the placement of the

Fig. 2.23 (**a**) Da Vinci® robot needle driver. (**b**) Tip of Da Vinci® robot needle driver

Fig. 2.24 Tip of Da Vinci® robot suture-cut needle holder

Fig. 2.25 Tip of Da Vinci® robot single-tooth tenaculum

Fig. 2.26 (**a**) Da Vinci® robot precise bipolar forceps. (**b**) Tip of Da Vinci® robot precise bipolar forceps

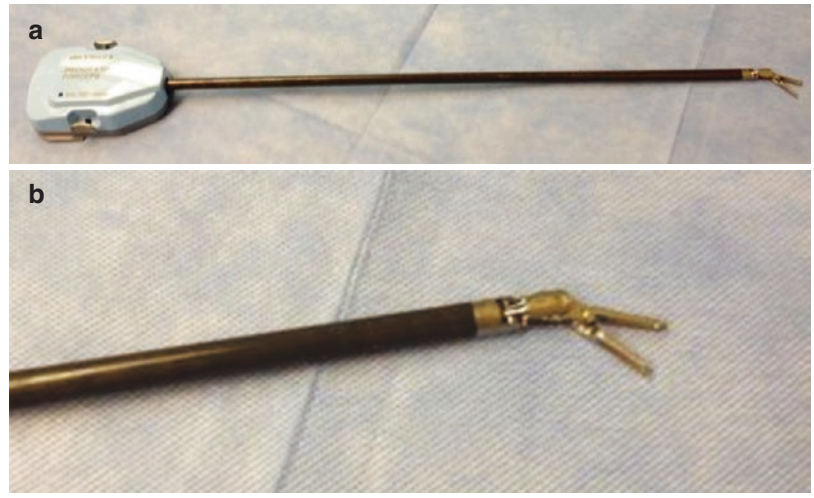


Fig. 2.27 (**a**) Da Vinci® robot prograsp forceps. (**b**) Tip of Da Vinci® robot prograsp forceps

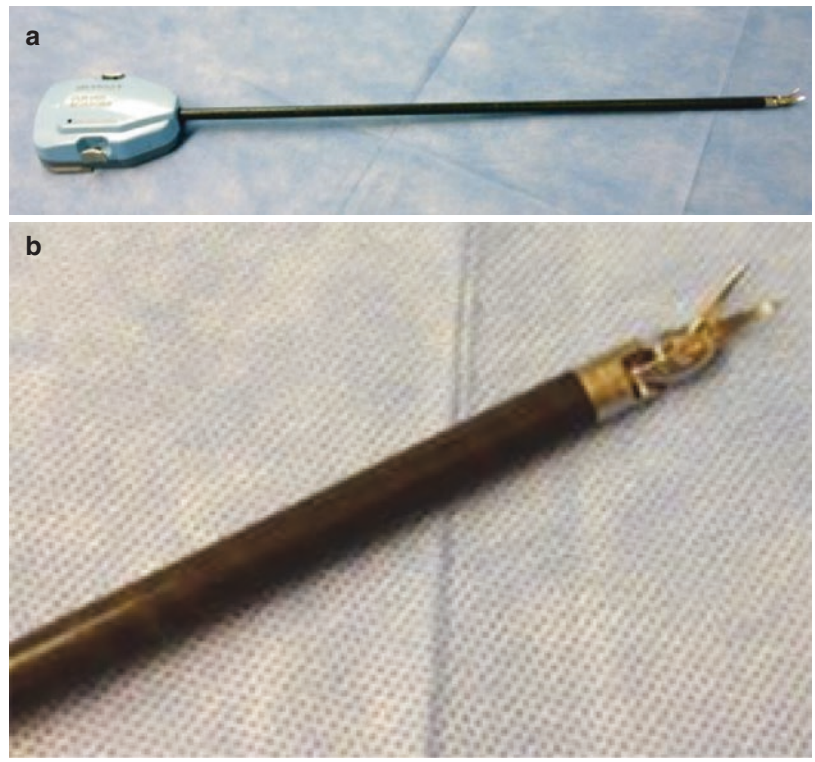


Fig. 2.28 (**a**) Da Vinci® robot curved scissors. (**b**) Tip of Da Vinci® robot curved scissors

scope on any of the four arms and, along with the further advanced high-definition vision, provides optimal visual clarity to the surgeon.

- *Da Vinci X*®: This latest Da Vinci® System was developed as a budget-friendly alternative to the more advanced flagship Xi System. Although this system possesses thinner and more flexible arms like the Xi System, it has less anatomical reach and retains the patient-side cart featured in the Si System. It, however, possesses some of the higher end technological advancements seen in its older sibling, like voice and laser guidance and similar visual capabilities.

3 The Surgical Management of Stress Urinary Incontinence

Kai-Wen Chuang and Farzeen Firoozi

Introduction

Stress urinary incontinence (SUI) has a reported prevalence between 12.8% and 46% [1]. There is no doubt that SUI has been clearly shown to negatively impact the everyday quality of life (QOL) of the women who suffer from this dysfunction [2]. The economic burden for the treatment of urinary incontinence has been estimated to be approximately 19 billion annually in the United States [3]. Risk factors for the development of UI include age, obesity, previous pelvic surgery, and childbirth [4].

Surgical management of SUI is the standard of care once conservative options, such as behavioral modification, pelvic floor exercises, fluid modification, and scheduled voiding, have been exhausted [5]. The surgical options have evolved over the last few decades to include the Burch colposuspension, periurethral bulking agents, pubovaginal slings, and the newest multitude of approaches for midurethral synthetic slings [6]. The synthetic slings include retropubic, transobturator, and the newest additions which include the so-called single-incision slings. The aims of this chapter include the evaluation and management of SUI and review each of the surgical techniques currently available to pelvic floor surgeons.

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Evaluation

Surgical Options

Burch Colposuspension

In 1961, Burch reported a series of retropubic uretropexies for the management of SUI [7]. The surgery today can be performed via laparotomy, laparoscopy, or robotic assistance. Although the approaches have become more minimally invasive, the basic surgical tenets remain unchanged.

The surgical selection for the Burch colposuspension includes patients with genuine UI and hypermobility of the urethra. This specifically includes patients who have low leak point pressures with urethral hypermobility as well as those with low urethral closure pressures. Patients with intrinsic sphincteric deficiency (ISD)—defined as SUI despite complete support of the urethra—are not good candidates for the Burch colposuspension. Nowadays, most pelvic surgeons would agree that the Burch colposuspension is a safe and effective surgical option for SUI, largely considered for women undergoing a concomitant open or laparoscopic procedure such as pelvic organ prolapse repair.

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Surgical Technique

There have been some modifications to the techniques of the Burch colposuspension described in the literature since its inception in 1961. The majority of open Burch colposuspensions performed today are closest in technique described by Tanagho [8]. The laparoscopic/robotic Burch colposuspensions adopt essentially all the same surgical steps but differ in that these are minimally invasive options with equivalent outcomes.

Open

The patient is placed in a dorsal lithotomy position with legs in stirrups. A 16 Fr. Foley catheter is placed at the beginning of the procedure. A 5 cm transverse suprapubic incision is made to expose the rectus fascia. The rectus fascia is then opened with a similar-length incision. The fascia is then mobilized from underlying rectus muscle with electrocautery. The space of Retzius is then entered bluntly and dissected laterally in both directions. A self-retaining retractor (e.g., mini-Bookwalter or Balfour retractor) is placed followed by entry into the dome of the bladder. The surgeon's nondominant hand is placed into the vagina. Two No. 1 nonabsorbable sutures are placed on each side of the urethra. The sutures are thrown with double bites, almost including full thickness of the vaginal wall. The initial suture is at the urethrovesical junction and the second suture is approximately 1 cm caudal. Care is taken to place these sutures at least 4 mm lateral to the urethra. The sutures are then placed through Cooper's ligament (Fig. 3.1). The interior of the bladder is then examined to rule out injury, and bilateral efflux from the ureteral orifices is noted. A cotton swab test is performed, after the Foley catheter is removed, demonstrating a 0–10° angle to the horizon by loosening or elevating the sutures. Once this is established, the sutures are tied down. The bladder is then closed with 2-0 absorbable suture in standard 2-layer fashion. A Foley catheter is left indwelling at the end of the procedure.

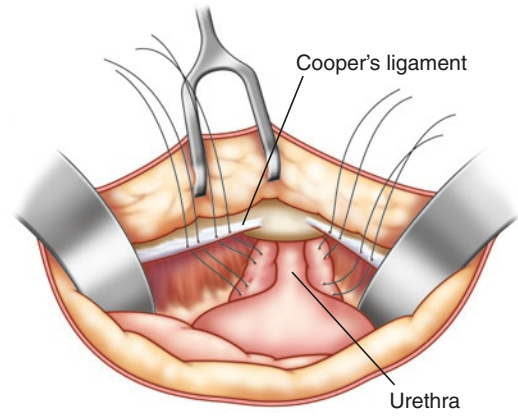

Fig. 3.1 Burch colposuspension. The initial suture is at the urethrovesical junction and the second suture is approximately 1 cm caudal. Care is taken to place these sutures at least 4 mm lateral to the urethra. The sutures are then placed through Cooper's ligament

Laparoscopic/Robotic

The patient is placed in a dorsal lithotomy position with legs in stirrups. A 16 Fr. Foley catheter is placed at the beginning of the procedure. Monitors, typically two for the surgeon and assistant surgeon, are placed at the patient's feet. The two midline trocars are for both introduction and extraction of curved needles and passage of the laparoscope. The 5 mm trocars are placed laterally at the border of the rectus muscles, at the level of the suprapubic 12 mm trocar (the distance between the pubic symphysis and 5 mm trocars would be no less than 4 fingerbreadths). This distance allows for adequate access to the space of Retzius.

Once any concomitant procedures are completed (e.g., hysterectomy, prolapse repair) the space of Retzius is entered. Blunt and sharp dissection is used to expose the pubic symphysis and Cooper's ligament. Also dissected out and exposed are the lateral pelvic sidewall, obturator neurovascular canal, ischial spine and arcus tendinius, arcus of the levator ani, and the paravaginal fascia. If indicated, a paravaginal repair can be performed if there is a lateral cystocele defect.

At this point, Ethibond No. 0 sutures are placed in the same fashion as described for the

open approach. After the sutures are tied down, cystoscopy is performed after indigo carmine is injected intravenously to check for ureteral efflux, ruling out any obstruction. The 12 mm trocars are closed in standard fashion with 2-0 absorbable suture. The 5 mm trocar fascia does not need to be closed. The patient may undergo a voiding trial in the recovery room according to individual surgeon preference.

Outcomes

The Burch colposuspension has been shown to outperform pharmacotherapy, conservative management, needle suspensions, Marshall–Marchetti–Krantz procedure, and anterior colporrhaphy [9]. A recent Cochrane review of open Burch colposuspensions reported an overall success rate of 69–88%. This same meta-analysis had separately reviewed 12 trials comparing open approach versus laparoscopic approach and found no statistically significant difference in patient-reported incontinence and the 1-year and 5-year follow-up periods.

There have been studies that have evaluated the long-term success rates of the open Burch colposuspension. Sivaslioglu et al. reported an 84% success rate at 7 years in their series of 262 patients [10]. The Burch colposuspension is a safe and effective surgical option for SUI, largely considered for women undergoing a concomitant open or laparoscopic procedure such as pelvic organ prolapse repair [11].

Complications

As any open or laparoscopic abdominal procedure, there are common risks including bleeding, infection, erosion of materials involving the bladder, injury to abdominal organs, and hernias [12]. The main long-term issues at hand center around voiding dysfunction and pelvic organ prolapse postoperatively. These pelvic floor issues include detrusor overactivity, urinary retention, and formation of enterocele/rectocele.

Detrusor Overactivity

Many studies have reported differing rates of de novo detrusor overactivity. The mechanism of the dysfunction is widely thought to be secondary to increased elevation of the vagina, and ostensibly the bladder trigone at urethropexy. This therapy further emphasizes the importance of stabilization versus elevation as an important factor in the success of the Burch colposuspension. One of the earlier reports that came from Stanton et al., whose group reported postoperative urodynamic-proven de novo detrusor overactivity, demonstrated a rate of de novo detrusor overactivity at 18.5% [13]. In Langer et al.'s 10-year follow-up study, the incidence of de novo detrusor overactivity was 16.6%. Voiding dysfunction appeared within the first year in 70.5% of the patients ultimately diagnosed with de novo detrusor overactivity [14].

Urinary Retention

In reviewing the literature on the incidence of long-term urinary retention, the authors acknowledge that there is not a great deal reported. Alcalay et al. reported four of the 366 patients who underwent the Burch colposuspension required urethrolysis postoperatively [15]. Although Feyeriesl reported a 16% rate of residual >60 ml in their patient population at 5–10-year follow-up, the authors do not report on any patients with residuals greater than 150 ml. Suffice it to say, there is a risk of urinary retention in the Burch colposuspension technique, albeit most likely a low risk.

Enterocele/Rectocele Formation

As discussed in the technique section, the goal of Burch colposuspension is stabilization, not elevation. In early series, the risk of enterocele or rectocele formation is widely thought to be secondary to over-elevation of the vaginal wall [16]. Keeping this in mind, more recent series

have lower rates of these anatomic sequelae by avoiding excessive elevation.

Periurethral Bulking Agent

The first description of the injection of a periurethral agent for the management of stress urinary incontinence came from Murless in 1938. The substance used was sodium morrhuate. Following that, many others published experiences with a wide variety of injectables, including paraffin wax, sclerosing agents, polytetrafluoroethylene, collagen, autologous fat, silicone, and stem cells. Despite the significant presence of injectable agents in urologic practice, there have been very few well-designed published studies evaluating the efficacy of this therapy.

The patient selection for this procedure consists of patients with ISD and normal detrusor function. The urodynamic cutoff for Leak Point Pressure (LPP) is typically 60 cm H_2O [17]. The success in ISD patients is thought to be secondary to the mechanism of action which is thought to be a result of increased area and pressure transmission ratio. This would ostensibly prevent the bladder neck or proximal urethra from opening under stress. Patients may also have hypermobility of the urethra, and still have their ISD component addressed with an injectable agent [18]. In this section, we will review the technique and outcomes of this therapeutic modality. In addition to these indications, urethral bulking agents are also indicated in patients who are young and desire more children, poor surgical candidates, persistent SUI after anti-incontinence procedure, and SUI with poor bladder emptying.

Surgical Technique

The most common environment for this procedure is under local anesthesia in an outpatient basis. There are two main approaches—transurethral and periurethral. The agent is typically placed submucosally or into the lamina propria. The injectable can be placed at the bladder neck or the proximal urethra. The typical sites of implant are the 3 and 9 o'clock positions. The size of the needle is dependent on the injectable agent. The proposed mechanism of action is to achieve coaptation of the urethra during the storage phase, with maintenance of this coaptation when there is an increase in abdominal pressure transmitted to the bladder with a Valsalva maneuver.

Periurethral

The patient is placed in dorsal lithotomy position. Local anesthesia is injected in the 3 and 9 o'clock positions 3 mm lateral to the urethral meatus. A 30° cystoscope is introduced after local anesthesia is injected. The periurethral needle is then placed lateral to the urethral meatus (same site as local injection) and advanced to the bladder neck/proximal urethra. The agent is injected in the 3 o'clock position on the right, followed by 9 o'clock position on the left. The goal is to create blebs that meet in the midline, akin to prostatic lateral lobes (Fig. 3.2). If there is any mucosal leakage of the injectable agent from a rent in the mucosa, which can be seen with a transurethral

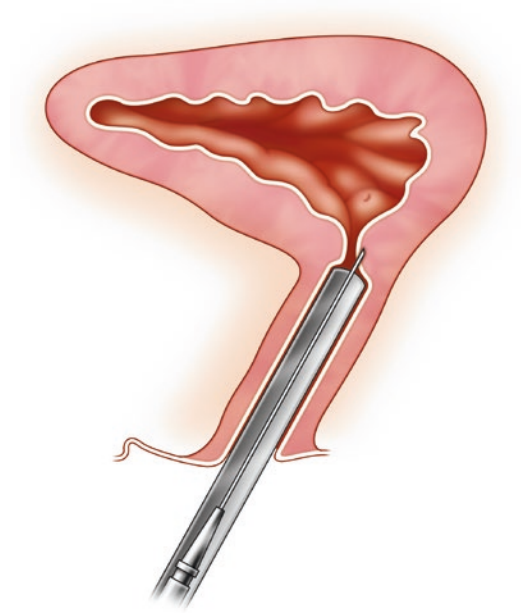

Fig. 3.2 Bulking agent injection for SUI. The agent is injected in the 3 o'clock position on the right, followed by 9 o'clock position on the left. The goal is to create blebs that meet in the midline, akin to prostatic lateral lobes

technique, the needle can be repositioned and agent reinjected. At this point, the patient is asked to valsalva to evaluate for SUI. If there is still SUI, more of the injectable agent may be injected. Once completed, the patient is asked to void and residual is checked. If in urinary retention, a small-caliber catheter, 8 or 10 Fr., is inserted. A theoretical benefit of the periurethral technique is the avoidance of mucosal leakage and local bleeding that may occur with transurethral needle injection.

Transurethral

The setup is quite similar to the periurethral approach. Local anesthesia may be instilled via the urethra. Needles specific to the injectable agent or generic needles may be used to inject transurethrally in the same locations described in the above section. A proposed advantage of this technique is better visualization of the injected material compared to the periurethral technique.

Outcomes

There have been many agents that have been used over the years as periurethral bulking materials. For the purposes of remaining current, the authors will review outcomes of bulking agents that are available at the time of publication of this text.

Macroplastique® (Uroplasty Inc., Minneapolis, MN) is a nonbiodegradable hydrogel composed of vulcanized polydimethylsiloxane elastomer suspended in a water-soluble carrier gel (polyvinylpyrrolidone). The agent does not require preadministration testing. The bulking agent can be administered with an 18-gauge endoscopic needle or a proprietary nonendoscopic transurethral injection device called the MIS (Macroplastique® Implantation System, Uroplasty Inc., Minneapolis, MN). The device is a mutichanneled needle-positioning tool angled needle entry points with 6, 2, and 10 o'clock positions. The typical volumes of injection are 2.5 ml, 1.5 ml, and 1.5 ml, respectively. There have been many studies reporting the success rates of Macroplastique. Most recently, there was a multicenter trial of 247 patients randomized to Macroplastique or Contigen® (collagen) (Bard Medical, Murray Hill, NJ). At 12 months follow-up, improved and dry/cure rates were 61.5% and 36.9% in patients injected with Macroplastique versus 48% and 24.8% in patients injected with Contigen.

Durasphere® (Boston Scientific, Natick, MA) is made of pyrolytic carbon-coated zirconium beads suspended in a water-based carrier gel composed of 2.8% glucan. Due to concern for the potential of migration, Durasphere was designed with large-caliber particles (>80 m) in order to obviate this issue. There are 1 ml and 3 ml formulations. That having been said, there have been reports published on local periurethral and local lymphatic migration [19]. The first generation of Durasphere was plagued by issues of difficulty with injection using a proprietary 18-gauge needle with standard endoscopic instruments. Dusrasphere EXP was developed, which included a reformulated carbon bead size and carrier gel to be injected with a customized, side-firing 18-gauge or 20-gauge needle. One of the larger randomized trials with 355 women compared Durasphere to bovine collagen. The study showed no significant difference in outcomes: 80.3% treated with Durasphere and 69% treated with collagen were improved by one or more continence grade at 12 months [20].

Coaptite® (Boston Scientific, Natick, MA) is composed of particles of calcium hydroxylapatite ranging in diameter from 75 to 125 μ suspended in an aqueous gel carrier composed of sodium carboxymethylcellulose and glycerin. There is a 1 ml formulation. The injection can be performed with standard endoscopic instruments with a supplied 21-gauge rigid injection needle, available in end-firing and side-firing capability. One of the largest multicenter randomized trials compared Coaptite to cross-linked collagen in 296 women. Patients treated with Coaptite had 63.4% versus 57% of those treated with collagen, with a rate of improvement of 1 Stamey incontinence grade or more; this was statistically significant. The study also demonstrated that fewer patients treated with Coaptite required repeat injections compared to collagen patients, 62% versus 74% [21].

Complications

Complications have been reported in all injection agents currently available in the US market. Macroplastique adverse events have included dysuria (short-lived, self-limited), frequency, and hematuria in many patients. Urinary retention has been reported in 6–10% of patients injected with Macroplastique [22]. In addition to the common adverse events listed above for Macroplatique, Dursaphsere has been shown to result in noninfectious periurethral abscess formation and urethral prolapse [23]. There have also been case reports of urethral prolapsed after Coaptite injection [24].

Pubovaginal Sling

First introduced at the beginning of the twentieth century, the pubovaginal sling procedure has remained an excellent, viable option for the management of SUI. The materials used include both synthetic and biologic options. A common synthetic described in the literature is polypropylene. Biologics have included autografts (rectus fascia, fascia lata, and vaginal wall), allografts (fascia, dermis, and dura mater), and xenografts (porcine or bovine). Although there are many published studies evaluating all of these options, autologous rectus fascia is the most commonly used approach and represents the greatest body of literature (this will be the focus of this section). Before the widespread application of the synthetic midurethral sling, pubovaginal slings were largely considered the gold standard of care for the management of SUI.

Surgical Technique

The patient is placed in a dorsal lithotomy position and the abdomen and vagina are prepped and draped in standard fashion. A transverse lower abdominal incision is made 2 cm above the pubic symphysis approximately 7 cm in length. Dissection is carried down to the rectus fascia, which is cleared of overlying fat. A 2 × 8 cm portion of the fascia is marked. The fascia is then harvested with either sharp or electrocautery dissection (Fig. 3.3a, b). Once the fascia is harvested, the defect is closed with 0 delayed absorbable suture. With a Foley catheter in place, the bladder neck is identified. A midline, vertical incision is made after the anterior vaginal wall is hydrodissected with a mixture of 1% lidocaine with 1:200,000 epinephrine solution. A tunnel is then created to the retropubic space using sharp and blunt dissection. The dissection is carried to the level of the posterior rectus abdominis fascia. Pereyra needles are then passed suprapubically 2 cm on either side of the midline into the vaginal incision. A cystoscopy is performed with both 30 and 70° lenses to rule out injury to the urethra or bladder.

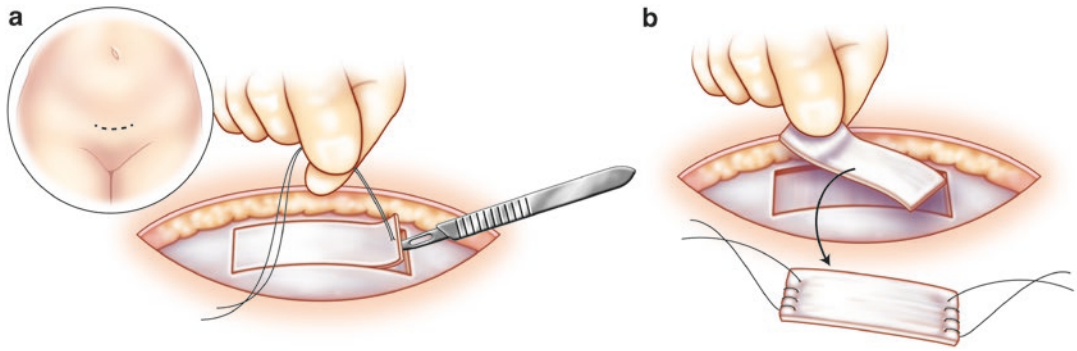

Fig. 3.3 Pubovaginal sling. A 2 × 8 cm portion of the fascia is marked (**a**). The fascia is then harvested with either sharp or electrocautery dissection (**b**)

The harvested fascia is then prepared for implantation. 0 prolene sutures are placed on either side. The sutures are then placed through the eyelet of the Pereyra needles and brought through the abdominal wall bilaterally (Fig. 3.4a, b, c). The sutures are then tied over the abdominal wall (on top of one finger to avoid overtensioning). The anterior abdominal subcutaneous layer is closed with 2-0 absorbable suture and skin with 4-0 absorbable suture. The vaginal wall is closed with 2-0 absorbable suture. A vaginal packing is placed along with a 16 Fr. Foley catheter. The patient will have a voiding trial in 5–7 days. If there are elevated residuals (>150 ml), the patient will perform intermittent straight catheterization until her residuals return to normal.

Outcomes

The SISTeR trial was the largest randomized control trial reported in the literature evaluating the efficacy of autologous rectus fascia pubovaginal sling. The Urinary Incontinence Treatment Network (UITN) designed and executed this multicenter trial. The study, which consisted of 655 women, compared outcomes of patients randomized to autologous rectus fascial pubovaginal sling and Burch colposuspension. The success rates, defined as no self-reported symptoms of SUI, was higher in the pubovaginal sling group than the Burch colposuspension group, 66% and 49% respectively. This reached statistical significance with a $P < 000.1$. The same group went on to publish their 5-year follow-up data on 482 patients. The authors found that there were significant declines in continence in both groups. However, there were higher continence rates in the pubovaginal sling group compared to the Burch colposuspension group, 30.8% and 24% respectively ($P = 0.002$). Although patient satisfaction decreased for both groups, rates of patient satisfaction were still higher in the pubovaginal sling group compared to the Burch colposuspension group after 5 years, 83% and 73% respectively ($P = 0.03$) [25].

There are 14 other published RCTs looking at pubovaginal slings, a majority utilizing autologous rectus fascia. All consistently demonstrated the efficacy of the pubovaginal sling in the management of SUI. The pubovaginal sling has also seen another indication in light of recent complications noted with midurethral synthetic slings, namely lower urinary tract erosion [26]. In addition, pubovaginal slings have become the trans-

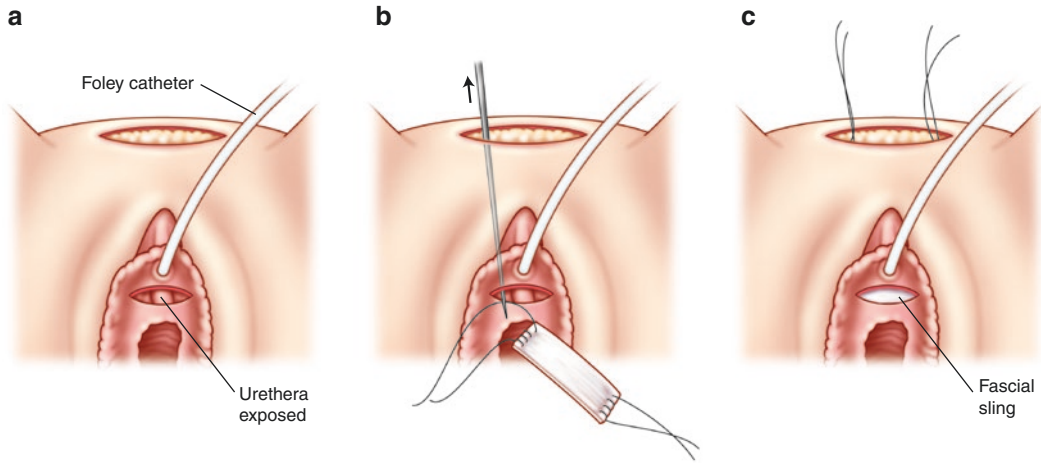

Fig. 3.4 Pubovaginal sling. The anterior vaginal wall dissection is performed (**a**). 0 prolene sutures are placed on either side (**b**). The sutures are then placed through the eyelet of the Pereyra needles and brought through the abdominal wall bilaterally (**c**)

vaginal anti-incontinence procedure of choice for concomitant repairs of urethral diverticula and urethrovaginal fistulas [27].

Complications

There are known complications related to pubovaginal slings. Some common adverse events include urinary tract infections (UTI) (48%), voiding dysfunction (14%), and postoperative urge incontinence requiring treatment (27%) [25]. Of note, adverse events were more common in studies which used synthetic material for pubovaginal slings.

Midurethral Synthetic Slings

In 1995, Ulmsten first introduced the synthetic midurethral sling procedure [28]. In the last three decades, this procedure has become the most commonly employed for the treatment of SUI [29]. Proponents of this surgical option would argue the reason for this overwhelming popularity is due to short learning curve, brevity of the procedure, and low morbidity. In addition, there have been many studies that have demonstrated the excellent long-term durability and success rate of the procedure.

The first iteration of the technique was retropubic placement. This approach was based on the integral theory proposed by Ulmsten and Petros [30]. The theory postulates that there are three structures (the pubourethral ligament, the suburethral vaginal hammock, and the pubococcygeus muscles) that, as a group, control the opening and closing of the bladder neck and urethra (Fig. 3.5). The goal of the technique was the retropubic placement of a synthetic sling to reconstitute the suburethral vaginal support and the pubourethral ligament. A top-down approach and a bottom-up approach are described in the next section.

The transobturator approach was introduced in 2001 in an attempt to reduce the risk of bladder, bowel, and vascular injury experienced with the retropubic approach. The mechanism of action of the procedure is based on Delancy's "hammock theory" of SUI. The hammock theory postulates that a combination of urethral support and constriction is necessary for continence. It is the layers of fascia, muscles, and vaginal wall that comprise this support and construction, according to the theory (Fig. 3.6). The transobturator synthetic sling placed in a horizontal plane provides the same support for the urethra during

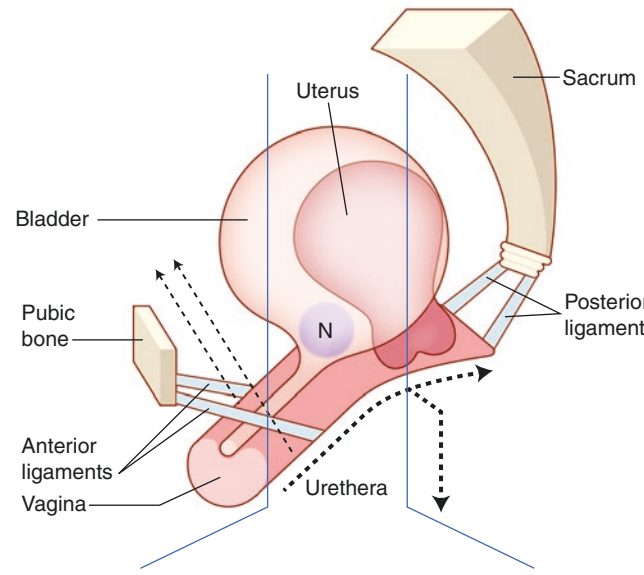

Fig. 3.5 Integral theory

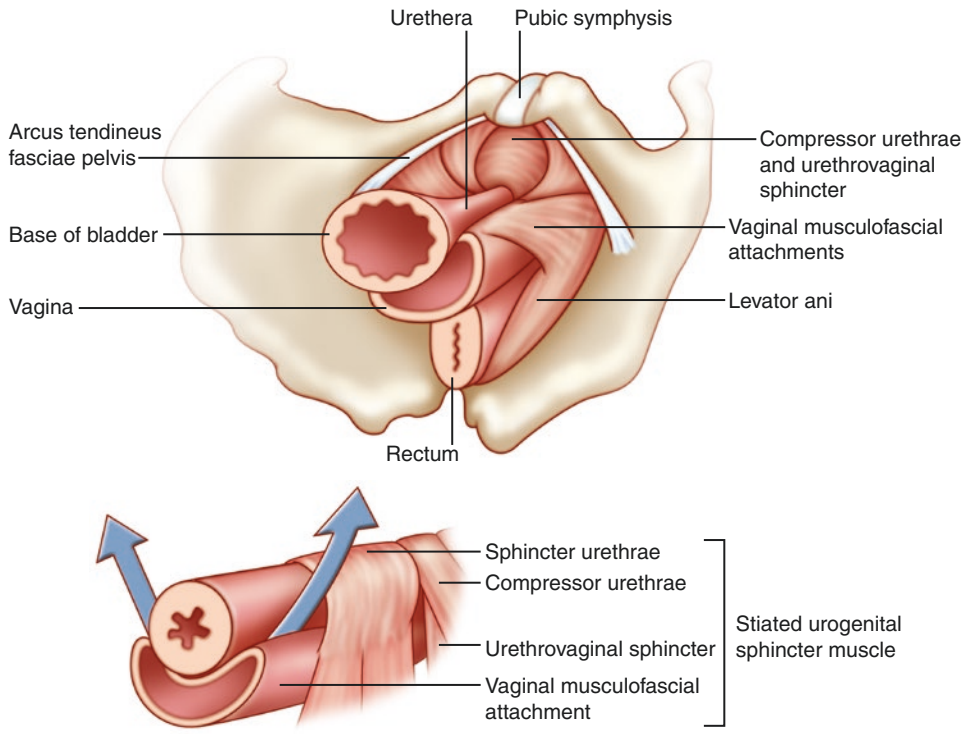

Fig. 3.6 Hammock theory

moments of increased abdominal pressure, thereby preventing incontinence. An out-in and in-out technique has been designed and utilized for the transobturator synthetic sling, also described in the following section.

Retropubic

Surgical Technique

Top-Down

Some examples of the top-down retropubic slings available in the United States include the Lynx® (Boston Scientific, Natick, MA) and SPARC® (American Medical Systems, Minnetonka, MN). The technique below applies for all top-down approaches, regardless of specific brand.

The patient is placed in a dorsal lithotomy position with legs in stirrups. The abdomen and vagina are prepped and draped in standard fashion. A 16 Fr. Foley catheter is placed and the bladder is drained. The anterior vaginal wall over the midurethral complex is hydrodissected using 1% lidocaine diluted with 1:200,000 epinephrine. A 2 cm vertical midline incision is made in the anterior vaginal wall, approximately 1 cm from the urethral meatus. Suburethral pockets are created with sharp and blunt dissection, carried to the retropubic space. The trocars are placed bilaterally through stab incisions directly above the pubic symphysis, each one fingerbreadth lateral to the midline. The trocars are advanced into the vaginal incision (Fig. 3.7). The vaginal wall is evaluated for any perforation by the trocar. The Foley catheter is removed and a rigid cystoscopy is performed with 30 and 70° lenses. Once injury is ruled out, the 16 Fr. Foley catheter is replaced. The mesh is then attached to the trocars and the mesh is placed under the midurethral complex which is covered by a Kelly clamp. This prevents any tension while placing the mesh. Excess mesh is then excised. The stab incisions may be closed with a skin adhesive or 4-0 absorbable suture.

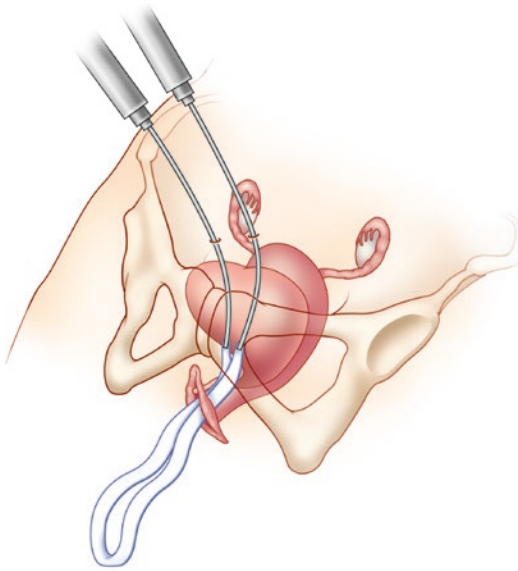

Fig. 3.7 Retropubic sling: top-down

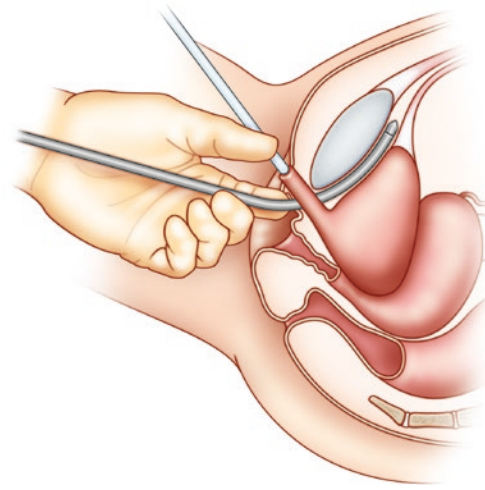

Fig. 3.8 Retropubic sling: bottom-up

The vaginal wall is then closed using 2-0 absorbable suture. A vaginal packing is placed. The patient can undergo a voiding trial in the recovery room.

Bottom-Up

Some examples of the bottom-up retropubic slings available in the US market include the TVT and TVT Advantage (Boston Scientific, Natick, MA). The technique below applies for all bottom-up approaches, regardless of specific brand.

The patient is placed in a dorsal lithotomy position with legs in stirrups. The abdomen and vagina are prepped and draped in standard fashion. A 16 Fr. Foley catheter is placed and the bladder is drained. The anterior vaginal wall over the midurethral complex is hydrodissected using 1% lidocaine diluted with 1:200,000 epinephrine. A 1 cm vertical midline incision is made in the anterior vaginal wall, approximately 1 cm from the urethral meatus. Metzenbaum scissors are used to sharply dissect a tract in the direction of the retropubic space. Stab incisions are made 2.5 cm on either side of the midline at the level of the pubic symphysis (some surgeons will choose to hydrodissect through these incisions to aid with trocar placement). The Foley catheter is replaced with the catheter guide in the direction of the contralateral side to where the trocar will be placed. The trocars are placed one at a time through the vaginal incision into the suprapubic stab incision. The trocar is aimed towards the patient's ipsilateral shoulder (Fig. 3.8). The vaginal wall is evaluated for any perforation by the trocar. The Foley catheter is removed and a rigid cystoscopy is performed with 30° and 70° lenses. Once injury is ruled out, the 16 Fr. Foley catheter is replaced. The mesh is then placed under the midurethral complex which is covered by a Kelly clamp. This prevents any tension while placing the mesh. Excess mesh is then excised. The stab incisions may be closed with a skin adhesive or 4-0 absorbable suture. The vaginal wall is then closed using 2-0 absorbable suture. A vaginal packing is placed. The patient can undergo a voiding trial in the recovery room.

Transobturator

Surgical Techniques

Out-In

Some examples of the out-in transobturator slings available in the US market include the Monarc® (American Medical Systems, Minnetonka, MN)

and Aris® (Coloplast, Humblebaek, Denmark). The technique below applies for all out-in approaches, regardless of specific brand.

The patient is placed in a dorsal lithotomy position, legs in stirrups. The lower abdomen and vagina are prepped and draped in standard fashion. The anterior vaginal wall over the midurethral complex is hydrodissected with 1% lidocaine diluted with 1:200,000 epinephrine. A vertical midline incision is made 1 cm from the urethral meatus 2 cm in length. Suburethral pockets are created with sharp and blunt dissection carried to the level of the obturator internus. Stab incisions are made in the inguinal groin crease at the level of the clitoral hood (two fingerbreadths inferior to the adductor longus tendon). The helical trocars are placed through the stab incision and advanced to the vaginal incision on both sides. The vagina is inspected for any sign of perforation. The Foley catheter is removed and a rigid cystoscopy is performed with 30° and 70° lenses to rule out any injuries. The Foley catheter is then replaced, and the mesh is then attached and placed under the midurethra. A Kelly clamp is placed between the urethra and mesh to prevent tension. Excess mesh is excised. The stab incisions are closed with a skin adhesive or 4-0 absorbable suture. The vaginal wall is closed with 2-0 absorbable suture. A vaginal packing is placed. The patient undergoes a voiding trial in the recovery room.

In-Out

Some examples of the in-out transobturator slings available in the US market include the TVT-O and Abbrevo® (Ethicon, Blue Ash, OH). The technique below applies for all in-out approaches, regardless of specific brand.

The patient is placed in a dorsal lithotomy position, legs in stirrups. The lower abdomen and vagina are prepped and draped in standard fashion. The anterior vaginal wall over the midurethral complex is hydrodissected with 1% lidocaine diluted with 1:200,000 epinephrine. A vertical midline incision is made 1 cm from the urethral meatus 1 cm in length. Stab incisions are made 2 cm lateral to the inguinal groin crease and 2 cm superior to the level of the clitoral hood. The helical trocars with mesh attached are placed with a guide and advanced to the groin incisions on both sides. The vagina is inspected for any sign of perforation. The Foley catheter is removed and a rigid cystoscopy is performed with 30° and 70° lenses to rule out any injuries. The Foley catheter is then replaced, and the mesh positioned under the midurethra. A Kelly clamp is placed between the urethra and mesh to prevent tension. Excess mesh is excised. The stab incisions are closed with a skin adhesive or 4-0 absorbable suture. The vaginal wall is closed with 2-0 absorbable suture. A vaginal packing is placed. The patient undergoes a voiding trial in the recovery room.

Outcomes

There have been many meta-analyses and systematic reviews reported in the literature evaluating outcomes of the different synthetic midurethral slings. In 2010, Novara et al. performed a systematic review and meta-analysis of the comparative data on Burch colpopsuspensions, pubovaginal slings, and midurethral synthetic slings. They found that patients with retropubic slings had higher continence rates compared to those treated with Burch colposuspensions. Retropubic slings and pubovaginal slings were similarly effective. Although objective cure rates were higher in retropubic slings compared to transobturator slings, there was no difference in subjective cure rates between the two [31].

Another meta-analysis conducted by Ogah et al. in 2009 reviewed 62 trials involving 7101 patients who underwent synthetic midurethral sling for SUI. A subanalysis of eight RCTs comparing pubovaginal slings to synthetic midurethral slings demonstrated an equivalent subjective cure rate at 12 months follow-up (RR 1.03, 095% CI 0.94–1.13). Six trials evaluated in this meta-analysis compared laparoscopic Burch colposuspensions to synthetic midurethral slings and found no difference in subjective cure rates at 12 months follow-up (80% vs. 74%) [4].

In terms of comparing retropubic versus transobturator, there have also been meta-analyses describing the outcomes based on these two different approaches. Novara et al. discovered that retropubic synthetic slings were associated with a higher objective cure rate when compared to transobturator synthetic slings (OR 0.8, 95% CI 0.65–0.99) [31]. However, the same analysis found that the subjective cure rates were equivalent in both approaches. Ogah et al. also compared retropubic and transobturator slings and reported that subjective cure rates in both approaches were 83%. In addition, even though the objective cure rates were statistically significantly greater in the retropubic versus transobturator groups, 88% and 84% respectively, the clinical significance could be argued [4].

There have also been RCTs comparing retropubic synthetic slings and transobturator slings. Richter et al. published their RCT of 587 women randomized to retropubic or transobturator synthetic sling for SUI. The retropubic group did demonstrate higher subjective performance compared to the transobturator group at 12 months follow-up. In addition, the objective success rate for the retropubic group was 80.8% compared to 77.7% in the transobturator group (3% difference, 95% CI 3.6–9.6).

The author continued this study with a 5-year longitudinal follow-up and found that long-term treatment success and satisfaction with retropubic and transobturator midurethral slings declined over time. They also reported that complications continued to rise. They demonstrated that women who underwent transobturator midurethral slings had more sustained improvement in urinary symptoms, quality of life, and sexual function despite lower treatment success rates [32].

Taken in aggregate, the data suggest that retropubic synthetic slings have a slight edge on transobturator synthetic slings in terms of success rates. Of course, the complications do differ as will be discussed in the next section.

Complications

Complications stemming from placement of synthetic midurethral slings range from minor to major. Similar to vaginal mesh for prolapsed complications, these issues are typically codified to timing of complication: intraopertaive, early postoperative, or delayed postoperative.

Intraoperative complications include injury to the urethra, bladder, bowel, vascular structures, or vagina. Urethral injuries have been shown to be equivalent in retropubic and transobturator synthetic slings, 0.88% and 1.09%, respectively [33]. Bladder injuries have been reported as more common in retropubic synthetic slings compared to transobturator synthetic slings. In terms of bowel and vascular injury, no differences have been reported between retropubic and transobturator slings [4].

Early postoperative complications include voiding dysfunction, UTI, groin pain, and urinary retention. Retropubic synthetic slings have been shown to have higher rates of voiding dysfunction and urinary retention compared to transobturator synthetic slings. Voiding dysfunction requiring surgical intervention has also been reported greater in retropubic versus transobturator synthetic slings, 2.7% and 0%, respectively. Groin pain is a complication more common in transobturator synthetic slings, reported as high as 8.2% in some studies. Although suprapubic pain is more common in retropubic synthetic slings, the rates are low (1.7%) [4].

Late postoperative complications include de novo voiding dysfunction and mesh extrusion/erosion. Similar to early voiding dysfunction, late de novo voiding dysfunction has also been reported to be more common in retropubic synthetic slings. Mesh extrusion/erosion rates have been equivalent for retropubic and synthetic slings [31].

Single Incision

Single-incision slings, or sometimes referred to as mini-slings, were introduced into the market with the purpose of minimizing morbidity and anesthetic requirements. There has been a paucity of literature on outcomes of this procedure. Some of the initial publications reported on devices that are no longer available in the market [34]. The basic tenet of the procedure involves use of no external trocar, with the sling deployed

with transvaginal trocar. This section discusses the current available devices and outcomes published on these currently practiced procedures.

Surgical Technique

Some examples of the SISs available in the US market include the MiniArc™ (American Medical Systems, Minnetonka, MN), Altis® (Coloplast, Humlebaek, Denmark), and Ajust® (Bard Medical, Covington, GA). The technique below applies for all SIS approaches, regardless of specific brand.

The patient is placed in a dorsal lithotomy position, legs in stirrups. The lower abdomen and vagina are prepped and draped in standard fashion. The anterior vaginal wall over the midurethral complex is hydrodissected with 1% lidocaine diluted with 1:200,000 epinephrine. A vertical midline incision is made 1 cm from the urethral meatus 1.5 cm in length. Suburethral pockets are created with sharp dissection carried to the level of the obturator internus. Push the first slip tip onto the curved needle. Advance the needle at a 45° angle on one side. Advance the needle into the obturator internus until the midline of the sling is over the midline of the urethra. Release the sling tip and remove the needle. Perform the same maneuver to place the other end of the sling into the contralateral obturator internus. Tension appropriately. (Some devices do differ with respect to method and device-specific aspects for this portion of the procedure.) Check both vaginal sulci to rule out mesh perforation. The Foley catheter is removed and a rigid cystoscopy is performed with 30° and 70° lenses to rule out any injuries. The vaginal wall is then closed with 2-0 absorbable suture.

Outcomes

There have been varying results reported for single-incision slings. Although the TVT-Secure (Gynecare) were among the first published, due to the fact that it is no longer available in the market, the outcomes are not discussed here. The MiniArc™ (American Medical Systems, Minnetonka, MN) has had success rates reported between 77.8% and 94% at 12 months follow-up. A meta-analysis published by Abdel-Fattah in 2011 compared SIS to standard synthetic slings. A total of nine RCTs with 758 women were reviewed. In this review, although operative times and pain scores were significantly lower in the SIS group, the subjective and objective success rates were significantly lower when compared to standard synthetic slings (RR 0.83, 95% CI 0.70–0.99 and RR 0.85, 95% CI 0.74–0.97, respectively). There were also significantly higher rate of repeat continence surgery in the SIS group (RR 6.72, 95% CI 2.39–18.89). Even though the SIS were found safe and somewhat efficacious, the conclusion was that they were inferior to standard synthetic slings.

Complications

The same approach to evaluation of complications that applies to standard slings applies to SIS. Adverse events include UTI (4.3%), urinary retention (3.2%), dyspareunia (2.1%), and vaginal extrusion (1.6%) [35]. Despite the fact that complication rates for SIS have been comparable to standard slings, the FDA has requested post-marketing surveillance data from manufacturers of these devices to ensure safety and efficacy.

Conclusion

The surgical management of SUI options has evolved over the past few decades. The modern era of SUI management started with Burch colposuspensions and has slowly followed a path of less invasive options including periurethral bulking agents, pubovaginal slings, and the newest multitude of approaches for midurethral synthetic slings. The synthetic slings include retropubic, transobturator, and the newest additions which include the so-called single-incision slings. As a result of this evolution, there are now many surgical procedures in the armamentarium of pelvic floor surgeons for treating SUI.

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4 Neuromodulation for Voiding Dysfunction

Justina Tam, Wai Lee, and Jason Kim

Introduction

Voiding dysfunction, including urinary frequency, urinary urgency, urge urinary incontinence, and urinary retention, can have a significant adverse effects on quality of life, with 64.3% of adults reporting at least one symptom of lower urinary tract symptoms, and increasing symptom prevalence with age [1]. According to the AUA guidelines, first-line treatment for overactive bladder (OAB) and LUTS includes conservative treatment including lifestyle and behavioral modifications, and pelvic floor physical therapy, while second-line treatments include oral antimuscarinic or β3-adrenoreceptor agonist or therapies [2]. Subjects who fail first- and second-line therapies may be offered third-line therapies including peripheral tibial nerve stimulation (PTNS), and sacral neuromodulation. Neuromodulation may be defined as the use of electrical stimulation to modulate the nerves controlling pelvic floor and bladder function. This therapeutic technique has been used to treat various ailments, from pain to voiding dysfunction. This chapter details the indications, patient evaluation, surgical techniques, outcomes, and adverse effects of PTNS and sacral neuromodulation.

Background

Neuromodulatory techniques can be traced back as far as 46–47 AD when Scribonus Largus treated headaches with electric eels [3–5]. However, the roots of neuromodulation can be traced back to the 1800s, when spinal nerve root experiments were performed and uncovered their function [6]. Building on this new knowledge, studies to evaluate the control of bladder function were initiated, and efforts to stimulate or prevent voiding with electrical stimulation commenced with a variety of stimulators and stimulation sites [6] including intravesical stimulation by the Danish surgeon M.H. Saxtoroph in 1878 [7, 8], spinal cord [9], and sacral root stimulation [10], with the first sacral anterior root implant performed in 1978 by Brindley et al. to induce bladder emptying [11]. The first implant to manage urinary incontinence was performed by Caldwell in 1963 [12], and the sacral implant currently used for sacral neuromodulation has its roots in the work performed by Tanagho and Schmidt in 1981 in dogs with spinal cord injury and neurogenic urinary retention. Their work has formed the basis for modern neuromodulatory techniques [13].

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Normal Physiology of Voiding

In order to understand voiding dysfunction, an understanding of normal voiding must be established. Normal voiding requires the coordination of urine storage and voiding to maintain continence until it is deemed socially acceptable to void, which is managed by the brain, spinal cord, and peripheral ganglia [14]. Afferent signaling from the bladder via the sacral nerves (S2–S4) during filling is relayed to the periaqueductal gray (PAG), which is activated during bladder filling [15, 16]. The coordination of bladder filling and suppression of voiding is managed by communication between the PAG, the insula, the anterior cingulate cortex (ACC), the pons, the thalamus, and the prefrontal cortex [17]. The ACC is also thought to promote continence by increasing motor output to the urethral sphincter and reflexively suppresses detrusor contraction [18, 19] via the hypogastric nerve (T11-L2) [20]. Additionally, urine storage is promoted by the pontine storage center, alternatively known as the L-region of the pontine micturition center [16, 21], and the prefrontal cortex, which generates inhibitory signals to prevent voiding and is involved with the voluntary decision to void [22]. Voiding is permitted by the disinhibition of the pontine micturition center, which leads to urethral relaxation and bladder contraction to allow voiding [16]. Bladder contraction is regulated by the parasympathetic sacral nerves originating from S2 to S4 of the spinal cord, while urethra is primarily innervated via the pudendal nerve (S2–S4) [20]. It should be noted that pudendal nerve mapping has shown that the S1, S2, and S3 nerve roots do not have equal distribution to the pudendal nerve, and thus a lack of effect from S3 stimulation may be expected [18, 23]. It is believed that once micturition is initiated at higher brain centers, voiding is maintained at the level of the spinal cord [24].

Normal voiding clearly requires a complex set of interactions to function appropriately, and is therefore susceptible to derangements resulting in voiding dysfunction [20]. Neuromodulation, which is a widely used in the management of voiding dysfunction including refractory nonneurogenic overactive bladder and urinary retention, may function by modulating these effects [8, 20, 25].

Indications for Treatment and Patient Selection

Prior to consideration of treatment of voiding dysfunction with neuromodulation, a thorough patient evaluation should be completed. Overactive bladder (OAB) is defined by the International Continence Society as the presence of "urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of UTI or obvious pathology." Therefore, a complete history and physical exam should be performed on all patients presenting with voiding symptoms to evaluate for underlying pathologic conditions. A thorough history of the patient's voiding complaints may allow symptoms to be traced back to a specific event, for example, trauma or surgery. Incomplete bladder emptying and urinary tract infection should be evaluated with a bladder scan to evaluate postvoid residual, urinalysis, and urine culture. A physical exam should be performed including a pelvic exam to evaluate for pelvic floor dysfunction, pelvic organ prolapse, vaginal atrophy, or other identifiable pathology on exam. Cystoscopy may be considered for evaluation of intravesical pathology if history of malignancy, hematuria, tobacco use, or prior pelvic surgery is present. A voiding diary to document the number of voids per day, volume of void, fluid intake, and number of episodes of urgency or incontinence may provide objective information about patient symptoms which may be used to evaluate symptom improvement after treatment. Further evaluation with urodynamics may be considered if the clinical picture is not consistent with straightforward OAB, including mixed urinary incontinence, incomplete bladder emptying, or history of neurologic disease. After appropriate evaluation, patients with OAB or nonobstructive urinary retention who have not achieved improvement with conservative therapies are candidates for treatment with neuromodulation. Further considerations for appropriate patient selection for specific neuromodulatory techniques are discussed.

PTNS

Tibial nerve stimulation was first introduced by McGuire et al. in 1983, who applied transcutaneous electrical nerve stimulation (TENS) to the common peroneal and posterior tibial nerves and found that TENS at these points suppresses reflex detrusor activity on urodynamics [26]. However, the technique of peripheral tibial nerve stimulation (PTNS) was first described by Stoller et al. in 1987 [27, 28], which became known as "Stoller afferent nerve stimulation" or "SANS" [29]. Interestingly, the insertion point for PTNS corresponds with a traditional acupuncture point (SP6) to relieve pelvic floor and pelvic organ dysfunction [30, 31]. The technique is now known as percutaneous tibial nerve stimulation, peripheral tibial nerve stimulation, or posterior tibial nerve stimulation (PTNS) [30, 32]. PTNS is a technique of neuromodulation which is performed by percutaneous stimulation of the posterior tibial nerve (originating from nerve roots L4–S3) [33]. PTNS is believed to function by modulating afferent and efferent nerve stimulation through the sacral plexus [31] possibly resulting in reflex-mediated inhibition of the detrusor to treat bladder overactivity [13, 29, 34]. Stimulation of the posterior tibial nerve is recommended as a third-line therapy for overactive bladder (OAB) [2] and is FDA-approved as an official therapy for the treatment of OAB [33].

Patient Selection, Contraindications, and Treatment Side Effects

Patients who prefer a less invasive neuromodulatory treatment, and who may require frequent imaging with MRIs, may be better candidates for treatment with PTNS than with SNM, as PTNS does not require permanent device implantation. PTNS is contraindicated in patients prone to excessive bleeding, those with pacemakers or implantable defibrillators, patients with nerve damage that could impact either percutaneous tibial nerve or pelvic floor function, and patients who are pregnant or planning to become pregnant. No antibiotics or lab work are required prior to treatment with PTNS. Side effects of PTNS are generally minor, including transient pain, numbness, or tingling at the simulation site, diarrhea, headache, low back pain, hematuria, vasovagal response to needle placement, minor bleeding, bruising, and calf cramping [30, 33, 35].

PTNS (Fig. 4.1)

Technique

During therapy with PTNS, a fine needle is placed 4–5 cm (3 fingerbreadths) cephalad to the medial malleolus and 2–2.5 cm posterior to

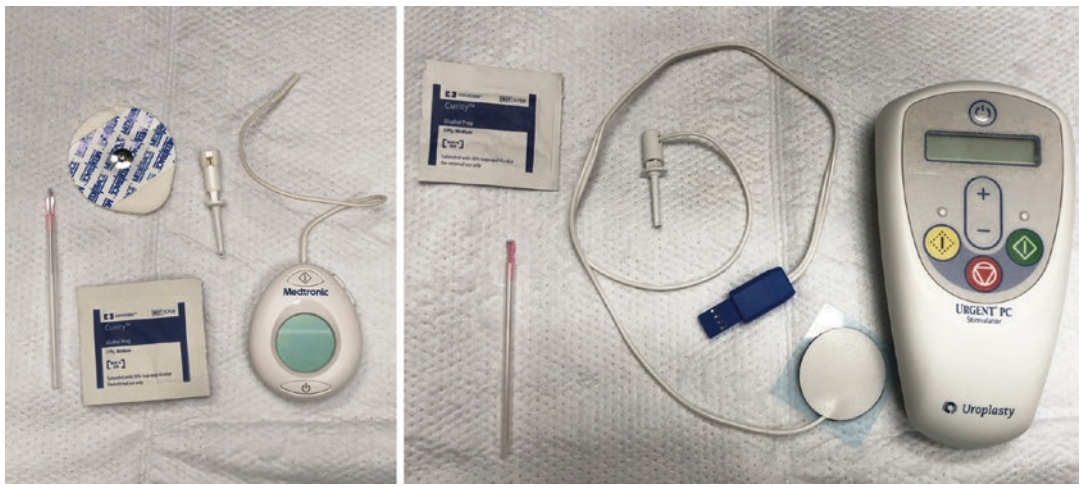

Fig. 4.1 PTNS kits. Left—Medtronic® NURO with stimulator, needle, and cable with J-hook and grounding sticker. Right—Cogentix® Urgent PC with stimulator, needle, and cable with J-hook and grounding sticker

the tibia [30, 31]. The needle has two parts, the distal end which is finer and inserted into the skin, and the proximal end which is thicker and may be used as a handle when inserting the needle. Prior to insertion of the needle, the site is cleaned with an alcohol pad. The needle is packaged within a clear plastic guide tube with a stop plug at one end. The needle with its guide tube should be positioned over the insertion location at a 60-degree angle from the ankle, with the tip of the needle pointing cephalad (Fig. 4.2). Once the needle and guide tube are positioned appropriately, the stop plug should be removed. With the guide tube still in place, the top of the needle is gently tapped to pierce the skin. The tube is then carefully removed to prevent dislodging the needle. The needle is then advanced until approximately 2 cm of the needle is inserted. A surface electrode lead is then placed on the arch of the ipsilateral foot. The lead wire is connected to the stimulator device, and then the needle electrode clip is attached to the distal, finer end of the needle. The stimulator device is then turned on and the current setting is slowly increased while observing for motor response and assessing the patient's sensation. Motor response is a toe flexion, toe fan, or twitch. The sensory response is described as a mild pulsing sensation traveling away from the insertion site, toward the heel, arch, toes, or up the leg [29–31]. Once the patient has an appropriate response, the current setting should be reduced by one increment prior to beginning the treatment to avoid potential patient discomfort during the treatment session. The current range used for treatment is between 0 mA and 9 mA. If the patient is uncomfortable during stimulation, the current setting may be reduced, or the treatment may be applied to the contralateral ankle. If the sensation is localized only to the area surrounding the needle, the needle may need to be inserted further. If there is neither motor nor sensory response the needle position may be adjusted, or the needle may be removed, and an attempt may be made at the contralateral ankle.

Treatment sessions last 30 minutes and occur once weekly for 10–12 weeks. Although the treatment is intermittent, prior experiments on cats have demonstrated that a 5 -minute stimulation results in effects lasting longer than 1 hour [36]; however, cessation of treatment results in return of symptoms [30], indicating a need for maintenance therapy [29]. Studies suggest that longer or more frequent treatment sessions may achieve the same results in less time [37, 38]. After the 12 weekly treatment sessions, continuation of therapy with monthly treatment sessions has been reported; however, the best regimen for PTNS maintenance treatment remains unclear. Variable maintenance rates ranging from single treatments based on patient-reported symptom recurrence [39–41], monthly treatments [42], and fixed schedule tapering protocols followed by tailoring to patient symptoms [43] have been reported.

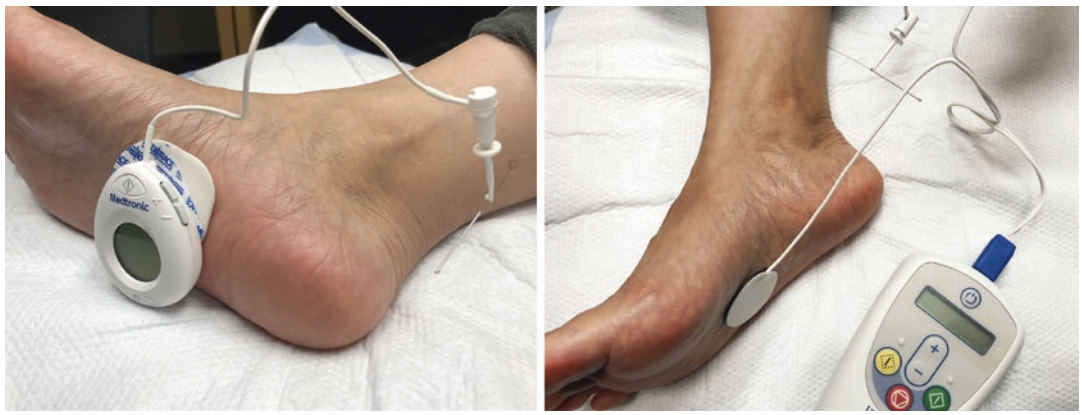

Fig. 4.2 PTNS with needle placed and connected to pulse generator. Left—Medtronic® NURO and Right—Cogentix® Urgent PC

Success Rates and Future of PTNS

Peters et al. performed the SUmiT trial, a multicenter, double-blind, randomized, controlled trial comparing the efficacy of percutaneous tibial nerve stimulation to sham, and they found that 54.5% of PTNS subjects reported moderately or markedly improved global response assessments (GRA) compared to baseline, which is higher than 20.9% of sham subjects who demonstrated improvement [44]. Long-term efficacy of PTNS after 3 years have been reported by Peters et al. in the STEP trial, where participants of the SUmiT trial were recruited to evaluate sustained therapeutic effects of PTNS [43]. After completing the initial 12 weekly treatments, subjects received a fixed schedule of a 14-week tapering protocol, and the frequency of PTNS was adjusted based on patient reporting of symptom recurrence. Subjects ultimately received an average of 1 PTNS treatment per month. They estimated that 77% of patients maintained marked or moderate improvement in OAB symptoms at 3 years. In addition, all quality-of-life measures remained markedly improved through 3 years. There are also promising results for PTNS in the treatment of pediatric patients with voiding dysfunction, nonobstructive urinary retention, neurogenic lower urinary tract dysfunction, chronic pelvic pain/bladder pain syndrome, interstitial cystitis, and fecal incontinence. Further study may provide insight into additional therapeutic options for these patients. In addition, efforts to improve patient compliance with PTNS including an implantable tibial nerve stimulator have demonstrated encouraging results and more are currently in progress [45, 46].

Sacral Neuromodulation

Sacral neuromodulation (SNM) is a technique in which the S3 nerve root is stimulated through a tined electrode that is placed percutaneously through the S3 foramen, and is typically performed using the Interstim device® (InterStim, Medtronic Inc. Minneapolis, MN) which was FDA-approved in 1997 for the treatment of urinary urge incontinence, in 1999 for nonobstructive urinary retention and urgency-frequency, and in 2011 for the treatment of fecal incontinence [8, 47]. SNM is believed to function by stimulating both afferent and efferent spinal nerves to affect urine storage and emptying [13], possibly resulting in reflex-mediated inhibition of the detrusor to treat bladder overactivity [13, 34]. Activation of efferent nerves to the striated urethral sphincter is believed to result in detrusor relaxation, and activation of afferent nerves inhibits the voiding reflex [18]. Stimulation of the afferent nerves is also believed to reduce abnormally elevated afferent activity to the urethral sphincter, restore the sensation of bladder filling, and reduce the inhibition of detrusor muscle contraction to allow spontaneous voiding in the treatment of nonobstructive urinary retention; essentially inhibiting the inappropriate activation of the "guarding reflex" [13, 18, 48, 49].

Patient Selection

Prior to proceeding with SNM, the patient must be evaluated for possible contraindications to the therapy. The patient must be evaluated for a history of prior spine surgery or spinal pathology such as scoliosis which may make lead placement difficult. A neurologic exam and history of neurologic disorder such as multiple sclerosis are also necessary as subjects who may require frequent imaging with MRI should not receive SNM, as electromagnetic interference may cause injury to the patient or damage the device. Patients who require an MRI after the device is implanted must have all components of the device removed prior to the MRI; however, the InterStim II device is FDA-approved for 1.5 Tesla MRI head scans [50]. Chermansky et al. suggested that although MRI is not recommended for patients who have Interstim devices, subjects who underwent MRIs with their device turned off, including lumbar and pelvic MRIs, had no adverse effects [51]. Guzman-Negron et al. demonstrated that subjects with implanted Interstim devices which were turned off were able to undergo lumbosacral MRI at 1.5 Tesla with few patients recalling mild warmth or discomfort. In addition, patients were able to maintain therapeutic efficacy with

unchanged device settings up to 1 month after their scans [52]. Patients with other implanted devices such as cardiac pacemakers and defibrillators may be considered for SNM; however, clinicians involved with both devices should discuss possible interactions with the device. Of note, defibrillation therapy may damage the SNM device, and electrical pulses from SNM may interact with the cardiac device and trigger an inappropriate response from the device such as a defibrillation. Generally, these devices should be placed as far away as possible from each other. Patients should be assessed for risk of bleeding, as there has been a report of perioperative death after permanent SNM lead placement from a retroperitoneal hematoma in a patient receiving anticoagulation therapy. Laboratory evaluation for coagulation abnormalities such as elevated INR, history of bleeding disorder, and medications such as anticoagulation therapy should be noted. Patients who have not demonstrated an appropriate response during test stimulation or are unable to operate the neurostimulator should not receive SNM.

Risks of Therapy

Risks of therapy include adverse changes in voiding or bowel function, allergic response to implanted materials, infection, lead erosion or migration, new pain, pain at the neurostimulator site or lead site, seroma, hematoma, bleeding, nerve injury, transient electric shock, nerve injury, and need for reintervention for the above side effects. Sacral neuromodulation has reported rates of reintervention of 13.7% within 1 year, 26.3% within 3 years, and 38% within 5 years of SNM placement. The most common reasons for reintervention are treatment failure and device malfunction [53]. Other reasons include pain, lead breakage or migration, infection, pocket revision, and need for battery replacement [13, 54]. Predictors for reoperation after SNM include female gender, lower mean body mass, more reprogramming events, longer median follow-up, use of hormone replacement therapy, and having a complication [54]. Future work to decrease reoperation rates, including efforts to improve the device and battery, techniques of implantation, and patient selection, is warranted [55].

Technique

The Interstim device is placed in a two-stage process. The first stage is the placement of a lead into the S3 foramen either in the office, called a percutaneous nerve evaluation (PNE) in which a temporary unipolar lead is placed, or in the operating room as a first-stage lead implant where the permanently implanted tined quadripolar lead is placed [8, 13, 47, 56]. During the second stage of the procedure, if the patient has undergone a PNE, both the permanent lead implant and the implantable nerve stimulator (INS) are placed at the same time. If the patient received a first-stage lead implant, the second stage involves placement of the INS and connecting it to the existing lead. No antibiotics are given prior to PNE; however, antibiotics may be given after a first-stage lead implant and after placement of the INS at the discretion of the surgeon. It is the authors' preference to give 24 hours of perioperative antibiotic coverage.

Technique: Percutaneous Nerve Evaluation (PNE)

The patient is evaluated in the office setting and placed in the prone position. Pillows are placed under the patient's abdomen to flatten the sacrum and shins to dangle the toes. Socks are removed and the grounding pad is placed on the heel. The lower back and buttocks are then prepped and draped with the feet exposed. C-arm is positioned in the AP view over the sacral region. The medial edge of the sacral foramina is marked bilaterally using the directional guidewire as a marker (Figs. 4.3 and 4.7c).

The C-arm is then moved into the lateral position with care taken to drape the lower arm. This view allows identification of the hillocks with their respective fusion planes and the iliac shadow. The iliac shadow is formed from the fusion of the sacroiliac joints at the S2 foramen and it angles toward the S3 foramen (Fig. 4.4).

The projected skin approach through the S3 foramen is approximated by using a blunt-tipped metal instrument such as a hemostat or smooth pickup. This is placed at the skin level angled downwards approximately 60 degrees and perpendicular to the dorsal plane of the sacrum on lateral view. Once the ideal vertical level of entry is determined, it is marked (Fig. 4.5).

Local injection of lidocaine or bupivacaine is administered at the same point and angle bilaterally. The foramen needle is then used along this trajectory and at the medial edge of the foramina.

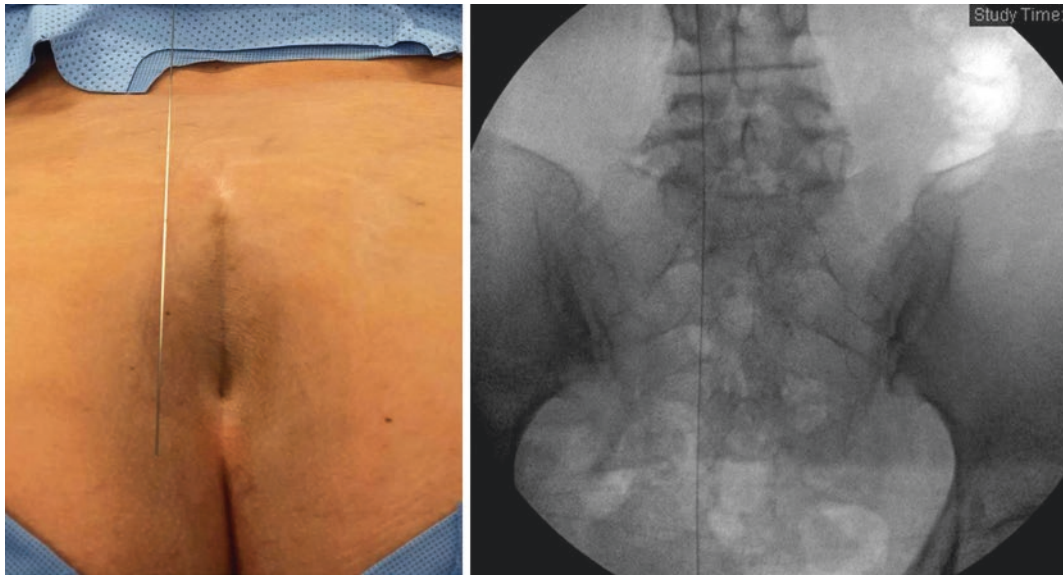

Fig. 4.3 Left—directional guidewire over skin, and Right—on A-P view. Once the guidewire is aligned with the medial edge of the sacral foramina, the skin is marked. This is performed bilaterally

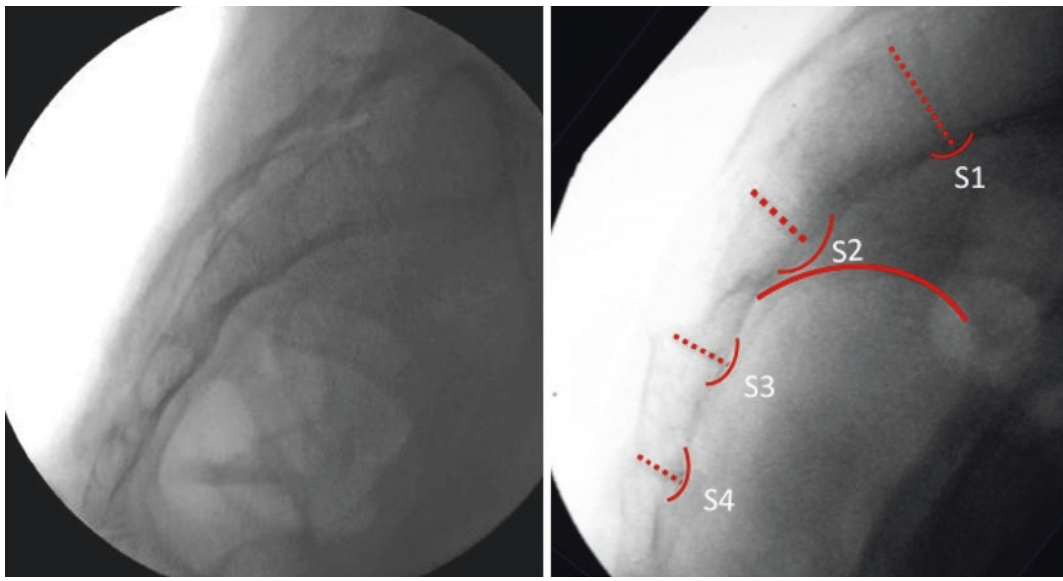

Fig. 4.4 Left—lateral view of sacrum. Right—sacral foramina (dotted lines), hillocks (curved lines), and iliac shadow (curved line) are marked in red (Reprinted with permission from Medtronic)

There are 3.5″ and 5″ needles that can be used, depending on the patient's body habitus (Fig. 4.7). During initial insertion of the needle, hitting the sacral periosteum can be expected and intermittent fluoroscopy can help guide appropriate angling. The needle can then be repositioned with care taken not to bend the needle. When the needle reaches the S3 foramen, it should advance quite easily at a further depth. Repeat fluoroscopy in both the lateral and A-P views can help confirm ideal positioning—the needle should be parallel with the medial edge of the sacral foramina on A-P views and parallel with the S3 fusion plane on lateral view (Fig. 4.6).

At this point, the S3 needle can be tested for optimal placement by attaching the external test

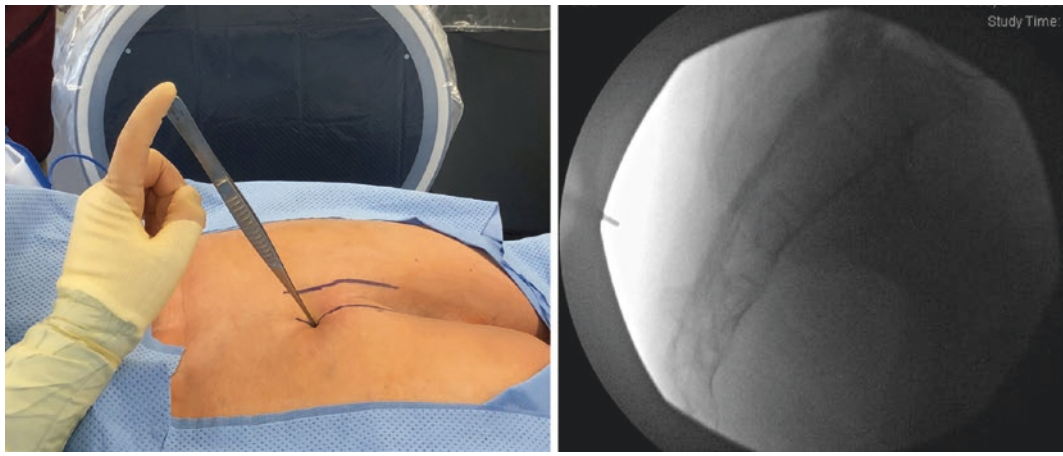

Fig. 4.5 Left—Debakey placed at skin level 60 degrees from skin at the line drawn along the medial edge of the sacral foramina. Right—lateral view of the instrument perpendicular to the dorsal plane of the sacrum. Tip of instrument can be seen on the left side of the image

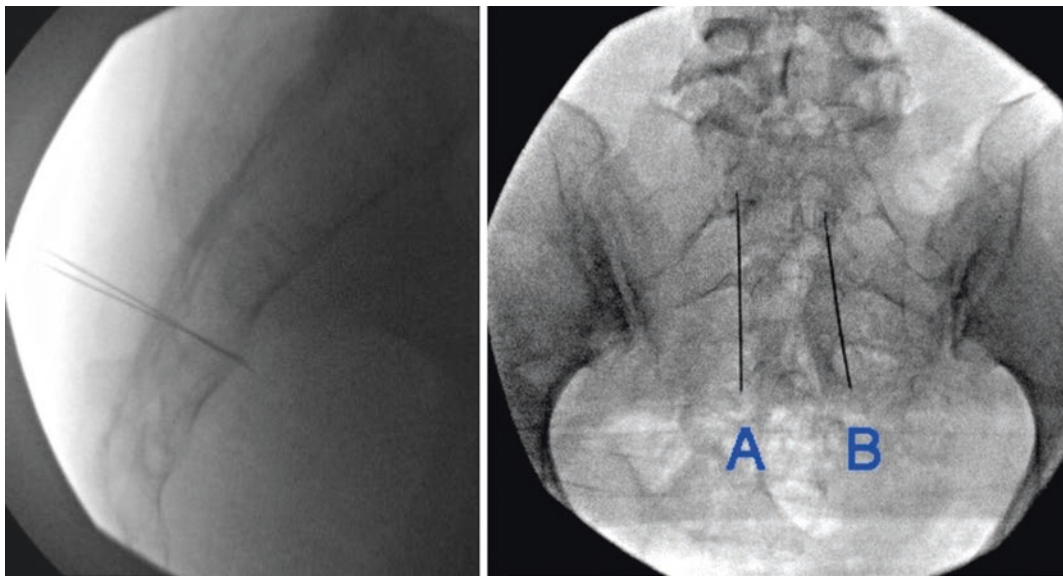

Fig. 4.6 Left—Lateral view of bilateral foramina needles in the S3 foramina. Right—A-P view of the same needles. Needle A demonstrates ideal needle placement. Needle B deviates laterally as it runs caudally. This is suboptimal placement

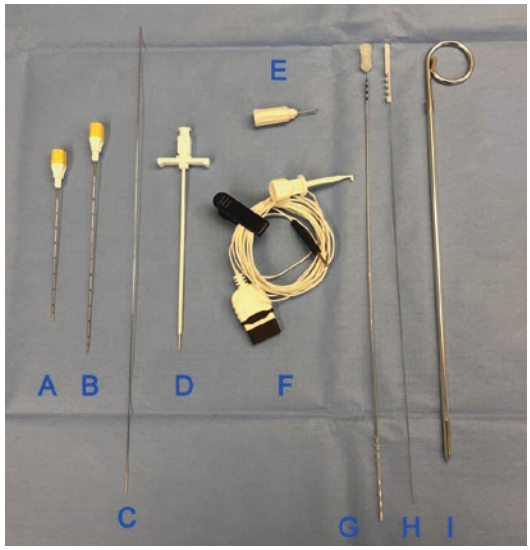

Fig. 4.7 Stage 1 assembly kit. (**a**) 3.5″ foramen needle, (**b**) 5″ foramen needle, (**c**) directional wire guide, (**d**) lead introducer and sheath/dilator, (**e**) torque wrench, (**f**) cable for external test stimulator with J-hook, (**g**) tined lead with straight stylet, (**h**) curved stylet, and (**i**) tunneling device

stimulator to the needle. Upon stimulation, the patient can be asked about sensory responses (tingling in the genital, perineal, or anal regions) or observed for direct responses (lifting of the perineum from levator contraction or "bellowing," and observation of plantar flexion of the ipsilateral great toe). It should be noted that if "bellows" are observed without plantar flexion of the great toe, the needle may be in the S4 foramen. Furthermore, movement of the great toe without "bellows" may be from medial rotation of the leg or calf cramping with S2 stimulation (Table 4.1). At this point, the contralateral foramen should be tested with a second foramen needle. Upon stimulation of the bilateral needles, the preferred side tends to elicit responses at lower amplitudes.

Once the side and correct position are determined, the foramen needle stylet is removed and a test simulation lead is advanced to proper depth—the first marker on the PNE lead corresponds to a 3.5″ needle and the second marker corresponds to a 5.0″ needle. The needle is then removed taking great care to keep the lead in place.

Table 4.1 Motor and sensory responses

Foramen	Motor	Sensory
S2	Medial rotation of leg, calf cramping	Genital
S3	Bellows, great toe plantar flexion	Genital, perineal, anal
S4	Bellows	Anal

The leads are then connected to the test stimulator and a large tegaderm is used to cover the lead site. The patient device is then programmed to the optimal sensation. The device can be trialed for 3–7 days to see if the patient experiences improvement and satisfaction. Patients keep a voiding diary during this period to assess for greater than 50% improvement in their urinary symptoms. If the patient wishes to proceed with implantation of the neurostimulator, the patient can be brought back to the operating room for permanent lead and stimulator placement.

Technique: First-Stage Lead Implant

During a first-stage lead implant, the previously described technique for PNE is followed with sedation in the ambulatory surgery setting. This procedure is generally performed with conscious sedation and local anesthesia without paralyzing agents in order to allow evaluation of both sensory and motor responses during lead stimulation. Patient positioning is identical.

After optimal foramen needle placement, the foramen needle stylet is removed. The directional wire guide is passed through the needle to the mark corresponding to the appropriate needle length—the first marker corresponds to a 3.5″ needle and the second marker corresponds to a 5.0″ needle. The foramen needle is then removed, leaving the directional wire guide in place. A skin incision is then made on either side of the needle with an 11 blade, to allow passage of the lead introducer sheath over the directional wire guide. The lead introducer sheath and dilator are then passed over the directional guide under fluoroscopy until the radiopaque marker at the tip of the sheath is half way through the foramen. The tip of the dilator should not be advanced beyond the anterior surface of the sacrum (Fig. 4.8). The dilator is then twisted to unlock and removed

from the introducer sheath along with the directional guide, leaving only the introducer sheath in place. The tined lead comes preloaded with a straight stylet. The straight stylet should be removed and replaced with the curved stylet at the beginning of the procedure. This allows for lead placement along the natural path of the nerve, which is lateral and caudal [57].

Advance until the marker C on the lead aligns with the top of the introducer sheath handle. The lead should then be advanced under fluoroscopic guidance until electrodes 2 and 3 straddle the anterior edge of the sacrum. Care should be taken not to advance the lead beyond marker D until optimal placement is confirmed. Advancing the lead past marker D will deploy the tines and will not allow further positioning of this lead (Fig. 4.9). Fluoroscopy should be used to confirm ideal lead placement. Repeat testing of the 0, 1, 2, and 3 leads is performed with the external test stimulator. A promising goal for each lead is motor and/or sensory response at amplitudes less than 2 mA. Once satisfactory positioning is confirmed, the introducer sheath is carefully retracted under fluoroscopic guidance to deploy the tined leads. On lateral view, the unequal spacing between the leads may suggest an optimal curve toward the viewer. On A-P view, the lead should clearly follow a caudal and lateral direction, similar to a hockey stick (Fig. 4.10).

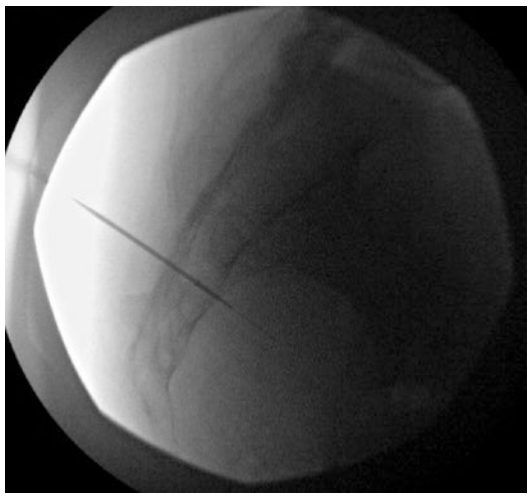

Fig. 4.8 Lateral view of the sheath and dilator advanced over the directional guidewire. Note the radiopaque marker approximately halfway through the foramen

At this point, an incision is made where the eventual neurostimulator pocket will be made. Generally, the subcutaneous tissue lateral to the sacrum over the upper gluteal region is selected. A 2 cm incision is made through the skin and subcutaneous tissues. Blunt dissection with a finger is used to open a small pocket. The tunneling tool with attached tube is used to create a subcutaneous tunnel from the lead insertion site toward the neurostimulator pocket. The tunneling tool may be bent to suit the patient's body habitus. The tunneling tip is removed leaving the straw in place. The lead is then fed through the straw and out the pocket site. The lead is carefully wiped with a wet gauze, and then with a dry gauze. A protective booty is placed over the lead wire and the lead is inserted into the temporary external quadripolar lead with the metal bands aligned. This end is attached to the percutaneous extension. The torque wrench is used to tighten each

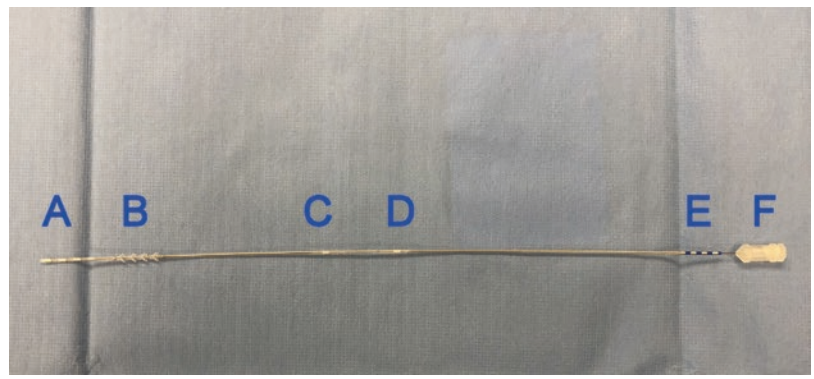

Fig. 4.9 Tined lead with stylet. (**a**) Distal electrodes 0, 1, 2, and 3, (**b**) tines, (**c**) marker band (**c**, **d**) marker band, (**d**, **e**) proximal electrodes 0, 1, 2, and 3, and (**f**) stylet handle

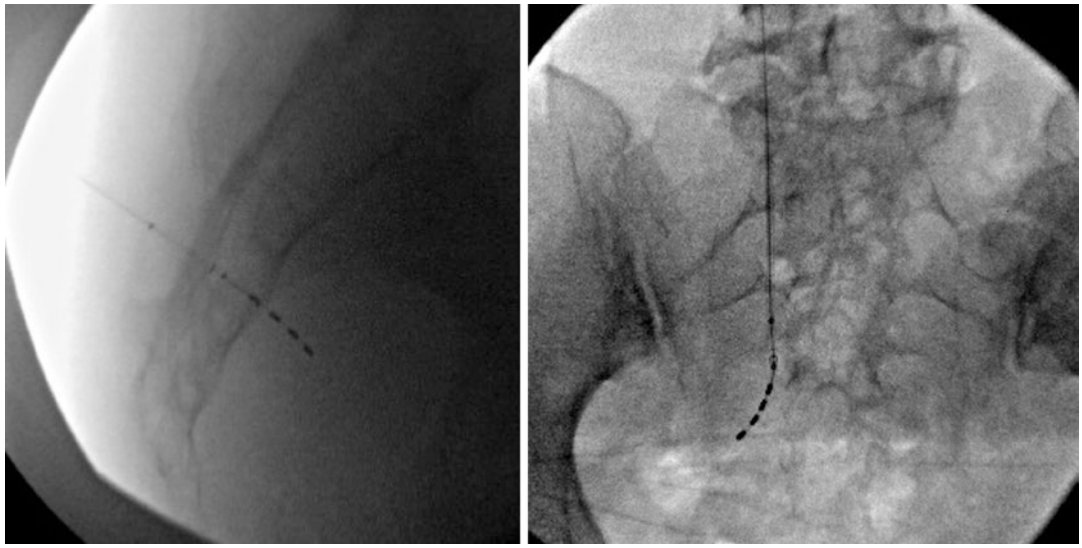

Fig. 4.10 Left—Lateral view of lead placement. Right—A-P view of lead placement. Notice the lateral orientation of the lead in a hockey-stick manner

screw one click. The protective booty is then advanced over this area and a 0-silk tie is used to tie off the boot grove on the booty.

Another subcutaneous tunnel is then made from the pocket site to the contralateral buttocks. The wounds are irrigated with antibiotic solution and the pocket site closed in two layers. The percutaneous extension is placed through the straw and tunneled out of a separate skin site. The straw is removed. The percutaneous extension is connected to the twist lock gray cable, which is attached to an external lead extension for a test stimulation trial for 1–2 weeks.

Technique: Placement of Neurostimulator

The patient is brought back to the operating room in 1–2 weeks for the implantation of the neurostimulator or stage 2 if the trial is successful. Identical positioning and sedation is performed. Fluoroscopy is not needed. After the patient is prepped and draped, the area overlying the prior incision site over the buttocks is infiltrated with local analgesia. Skin incision is made and electrocautery used to enter the subcutaneous tissues, avoiding the use of coagulation. The lead wire is located with blunt dissection. The end leading to the percutaneous extension cable can be identified by its protective clear cover and is cut with heavy scissors, leaving the protective booty behind. An assistant off the field can pull on the nonsterile end to remove it from the field.

The suture securing the protective booty is cut and the boot removed. The setscrews are loosened with the torque wrench and the lead is removed. This is wiped with a wet gauze, then dried with a dry gauze. The lead is then inserted into the neurostimulator device, aligning the blue tip through the device window. Torque wrench is used to tighten the lead in the neurostimulator until a single audible click is heard. At this point, a pocket is made subcutaneously with blunt dissection until the neurostimulator device is properly fitted. The device should lay flat in the pocket without any notable bulge. At this point, impedances are measured and confirmed to be in the appropriate range of 50–4000. The wound is then irrigated and closed in two layers. Dressings are placed over the buttocks incision as well as the skin puncture site for the percutaneous extension cable.

Technique: Device Removal

Device removal may be performed at bedside in the hospital or in the office with local analgesia or in the operating room using sedation. Patient is

positioned in the prone position and the area overlying the lead and neurostimulator is prepped and draped. A 4–5 cm incision is made over the neurostimulator site. Electrocautery is used to dissect down to the neurostimulator. Older devices may have a well-formed capsule. Once the device is isolated, the lead is placed on traction to help palpate the lead entry site into the S3 foramen. A second incision is then made over the lead site near its entry point into the S3 foramen. Dissection into the subcutaneous tissues is performed with electrocautery. Further palpation can confirm the lead site with the neurostimulator on traction. A right angle can be used to hook the lead and deliver a loop of the cable out of the incision site. Once this is accomplished, the cable can be cut with heavy scissors near the neurostimulator. The cable is then delivered near the incision by the S3 foramen. A heavy pickup such a Kelly clamp is then used to twist the cable around it two to three times and then to apply upwards traction until the tined leads are removed. Irrigation of the incisional sites is performed. The neurostimulator pocket is closed in two layers. The incision near the S3 foramen is closed superficially with absorbable monofilament suture. Dressings are placed over both incision sites.

Success Rates and Future Direction of SNM

A systematic review reported that the improvement of >50% in leakage episodes ranges widely between 29 and 76%, and the overall dry rate ranges between 43 and 56% [58]. A 5-year follow-up study by Siegel et al. reported that the overall success rate for overactive bladder (OAB) treated with SNM was 85% at 1 year and 82% at 5 years after device implantation. Subjects with urge urinary incontinence and urgency-frequency had significantly decreased leakage episodes and voids per day, respectively. Additionally, at 5 years, continence was achieved in 45% of subjects with urge urinary incontinence, and 84% of subjects reported an improved or greatly improved urinary symptom interference score [59]. The literature suggests that treatment with SNM yields in sustained clinical benefit in voiding dysfunction [60].

SNM is also FDA-approved for the treatment of nonobstructive urinary retention. Studies have suggested that the commonly used 2-week trial period may be too short for this patient population and a trial period of up to 4 weeks may ensure the best chance for treatment response [61], and studies evaluating the use of bilateral leads have demonstrated that some subjects were only able to void with bilateral leads [62]. The efficacy of SNM in idiopathic nonobstructive urinary retention has been demonstrated with reported success rates of approximately 70% [63, 64]. A randomized control study demonstrated that of subjects who received SNM, 69% no longer required catheterization, and 14% had 50% or greater reduction in catheterization volume, resulting in 83% success in the implant group compared to 9% success in the control group receiving conservative therapy at 6 months [63]. A prospective worldwide study by van Kerrebroeck et al. demonstrated that 71% of subjects with urinary retention had successful outcomes 5 –s after implantation [64]. A meta-analysis demonstrated a mean decrease in postvoid residual of 236 mL, and mean voided volume increase by 299 mL [65]. These results suggest that SNM is an effective treatment for nonobstructive urinary retention.

Although neurogenic bladder disease due to MS, spinal cord injury, spinal surgery, stroke, and diabetes is not an FDA-approved indication for SNM, studies have evaluated its use in this patient population. Previously, it was believed that a dysfunctional neurologic pathway would prevent SNM from working properly [66]; however, current literature has demonstrated promising results [18, 66–70]. A meta-analysis by Kessler et al. revealed a pooled success rate of 68% for the test phase of SNM, and 92% for permanent SNM with a mean follow-up of 26 months [69]. However as the majority of studies are retrospective, there is enormous heterogeneity between studies, and patient populations are small, further prospective studies with longer follow-up are needed [66, 71]. A randomized placebo-controlled, double-blind

clinical trial investigating sacral neuromodulation for neurogenic lower urinary tract dysfunction is currently underway [72].

Future Direction/Conclusion

Overactive bladder is a chronic condition that affects millions of people worldwide, with significant impairment in quality of life and substantial financial burden [64, 73–76]. Many patients do not have symptomatic improvement with conservative therapies such as pelvic floor physical therapy and anticholinergics, and move on to third-line therapies such as neuromodulatory techniques including PTNS and InterStim. Advances in these therapies are currently underway, including implantable PTNS modalities such as Urgent-SQ [77], and Axonics rechargeable [78] and conditional labeled full-body MRI compatible [79] sacral neuromodulation device which is currently only available in Europe. Durable success with both therapies in the treatment of voiding dysfunction has been reported in the literature, and studies to evaluate the use of these neuromodulatory techniques for other indications including pelvic pain and neurogenic voiding dysfunction are currently underway. New techniques of neuromodulation have also been reported, including pudendal nerve stimulation, which has demonstrated promising results [80, 81].

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Transvaginal Prolapse Repair

5

Nitya E. Abraham and Howard Brian Goldman

Introduction

Transvaginal pelvic floor reconstruction can be divided by compartment: anterior repair, posterior repair, and apical repair. Approaches can be restorative, compensatory, and obliterative. Restorative repairs utilize native tissue to fix defects, while compensatory repairs utilize biologic or synthetic graft material to fix defects. It is critical to recognize that the presence of prolapse alone is not an indication for treatment. Up to half of women who have had a vaginal delivery will have prolapse to the hymen. Many, especially as they get older, will have prolapse beyond the hymen [1]. For a significant proportion of these patients, the prolapse is asymptomatic and does not require intervention. *Only symptomatic patients should be treated.*

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Anterior Repair

Background

Anterior compartment prolapse is herniation of pelvic organs into the anterior vaginal wall, including urethrocele (herniation of the urethra), cystocele (herniation of the bladder), and anterior enterocele (herniation of the small bowel) [2]. The prevalence and incidence of anterior compartment prolapse is not well described. In the Women's Health Initiative, the prevalence of cystocele was 34% in women aged 50–79 years [3]. Risk factors for anterior compartment prolapse include increasing age, body mass index, and number of vaginal deliveries. Other possible risk factors include pregnancy, forceps delivery, young age at first delivery, prolonged labor, high infant birth weight, smoking, elevated intraabdominal pressure (due to constipation, chronic cough, or occupations requiring heavy lifting), estrogen deficiency, previous hysterectomy, connective tissue disorders (e.g., Ehlers–Danlos syndrome, Marfan's syndrome), muscular disorders (e.g., multiple sclerosis, muscular dystrophy), low socioeconomic status, ethnicity, family history, and history of prior prolapse repair [2, 4, 5]. The strongest risk factor is vaginal delivery with one study noting a 2.2 (1.8–2.7) times increased risk of cystocele after a single childbirth compared to nulliparity [4].

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Evaluation

The first and most important step in the evaluation of anterior compartment prolapse is a history and physical examination. Women with symptomatic anterior compartment prolapse may complain of a sensation of a vaginal bulge, pressure, or heaviness. They may visualize the protrusion. Urinary symptoms may include incontinence, frequency, urgency, obstructive voiding symptoms, or the need to manually reduce the prolapse to void. Patients may also complain of dyspareunia [4]. General symptoms can include low back pain, generalized pelvic pain, or bloody discharge due to ulceration of the prolapsed vaginal skin [2]. The history should thus elucidate the presence of risk factors and symptoms as listed above.

Physical examination is standardized by utilizing the Pelvic Organ Prolapse Quantification (POP-Q) system, which involves the measurement of 9 points (Fig. 5.1):

Aa—anterior vaginal wall 3 cm proximal to the hymen
Ba—most distal position of the remaining upper anterior vaginal wall
C—most distal edge of cervix or vaginal cuff scar
D—posterior fornix (not applicable if post-hysterectomy)
Ap—posterior vaginal wall 3 cm proximal to the hymen
Bp—most distal position of the remaining upper posterior vaginal wall
Genital hiatus (gh)—middle of external urethral meatus to posterior midline hymen
Perineal body (pb)—posterior margin of gh to middle of anus
Total vaginal length (tvl)—depth of vagina with prolapse reduced

The POP-Q can be categorized into stages:

Stage 0—No prolapse.
Stage 1—The most distal point of the prolapse is at least 1 cm above the level of the hymen.
Stage 2—The most distal point of the prolapse is between 1 cm proximal and 1 cm distal to the level of the hymen.
Stage 3—The most distal point of the prolapse is between 1 cm distal to the level of the hymen and 2 cm less than the tvl.
Stage 4—The most distal point of the prolapse is equal to or beyond 2 cm less than the tvl, from the level of the hymen.

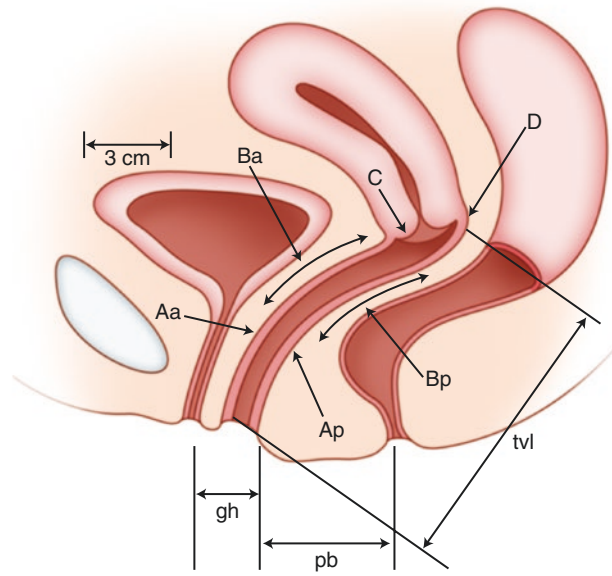

Fig. 5.1 POP-Q exam. Aa point A anterior, Ap point A posterior, Ba point B anterior, Bp point B posterior, C cervix or vaginal cuff, D posterior fornix (if cervix is present), gh genital hiatus, pb perineal body, tvl total vaginal length

Some clinicians simplify the POP-Q exam and do not routinely measure Aa or Ap. Other staging systems generally utilize the relationship of the leading edge of the prolapse to the hymenal ring or introitus.

Imaging is not routinely used in the evaluation of pelvic organ prolapse. However, it has been argued that clinical examination assesses surface anatomy and is more limited in assessing structural abnormalities [6]. Underestimation or misdiagnosis of the compartment that is prolapsed can occur in 45–90% of the cases [7]. What appears to be a cystocele could in rare cases be a urethral diverticulum, Gartner duct cyst, or anterior enterocele [6]. Thus, in ambiguous cases, translabial ultrasound or dynamic MR imaging can be utilized. However, this is not routine, requires trained personnel to interpret the imaging, and may be cost-prohibitive.

Surgical Repair

The patient is placed in the dorsal lithotomy position. The external genitalia is prepped and draped in the usual sterile fashion. Some choose to shave the perineum but it is not required. One dose of intravenous antibiotics is administered for prophylaxis prior to incision. As per the 2011 American Urological Association Best Practice Policy Statement on Antibiotic Prophylaxis, the antibiotics of choice for vaginal surgery are a first-/second-generation cephalosporin or an aminoglycoside (aztreonam if the patient has renal insufficiency) plus metronidazole or clindamycin. Alternative antibiotics are ampicillin/sulbactam or fluoroquinolone [8]. A foley catheter is placed to drain the bladder. A weighted speculum is placed in the vagina. A Scott retractor or translabial sutures are used to retract and expose the prolapse. The anterior compartment prolapse repair is then performed using one of the following techniques: traditional anterior colporrhaphy, mesh-augmented colporrhaphy, or paravaginal defect repair.

Traditional Anterior Colporrhaphy

1. An Allis clamp is placed 1 cm distal to the vaginal cuff or cervix. A second Allis clamp is placed just proximal to the bladder neck.
2. While pulling the anterior vaginal wall outward with the Allis clamps, the vaginal wall is infiltrated superficially with a dilute solution of lidocaine mixed with epinephrine (Fig. 5.2).
3. A midline incision is made between the two Allis clamps (Fig. 5.3).
4. Allis clamps are placed on the edges of the vaginal skin on both sides of the incision.
5. While retracting the Allis clamp outward, the assistant should provide countertraction on the pubocervical fascia thus delineating the plane between the vaginal skin and pubocervical fascia. (Note, the more appropriate term is

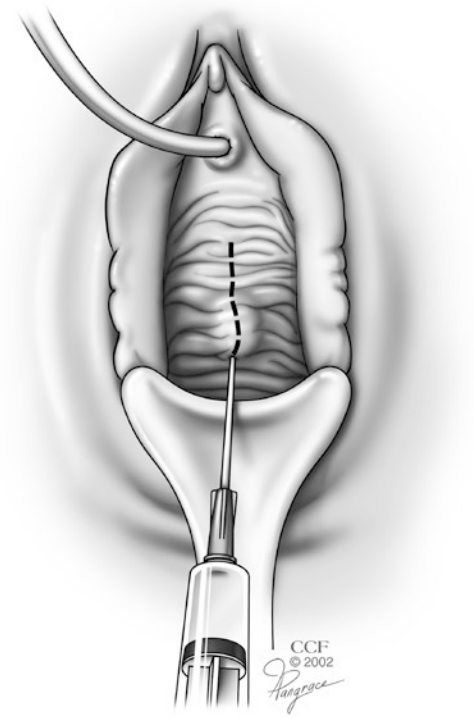

Fig. 5.2 Hydrodissection with a dilute solution of lidocaine mixed with epinephrine. (Reprinted with permission, Cleveland Clinic Center for Medical Art and Photography © 2002–2013. All Rights Reserved)

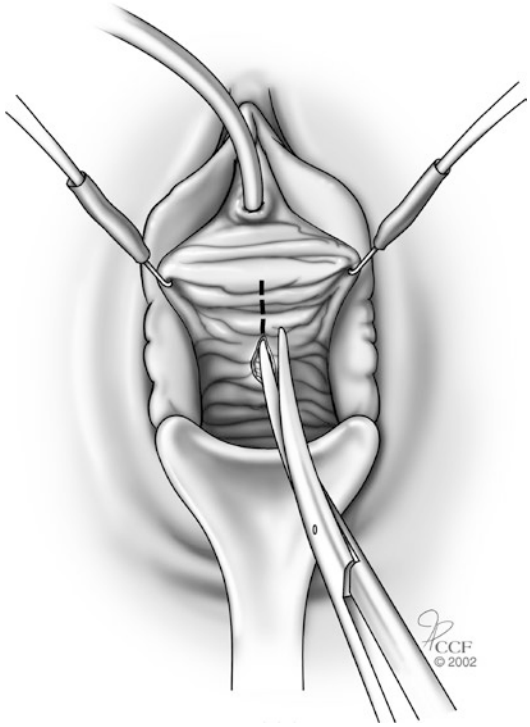

Fig. 5.3 Midline incision for anterior colporrhaphy. (Reprinted with permission, Cleveland Clinic Center for Medical Art and Photography © 2002–2013. All Rights Reserved)

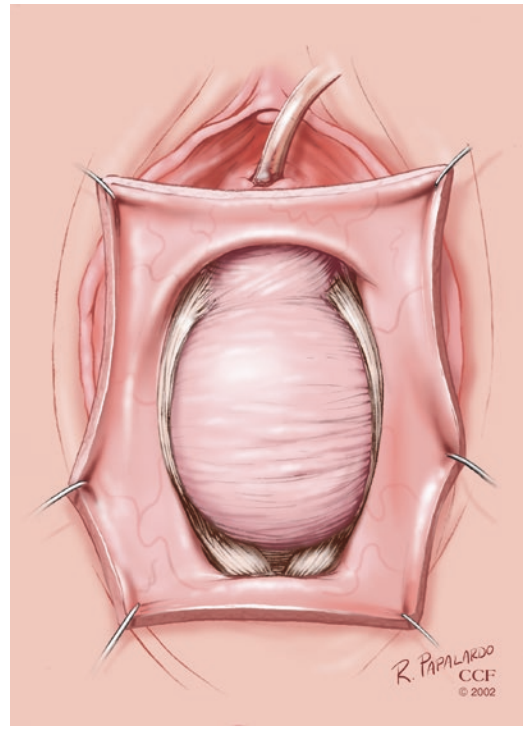

Fig. 5.4 Dissection between vaginal skin and pubocervical fascia. (Reprinted with permission, Cleveland Clinic Center for Medical Art and Photography © 2002–2013. All Rights Reserved)

vaginal muscularis and not pubocervical fascia, since there is no actual fascial layer.) A combination of sharp and blunt dissection is used to dissect the vaginal skin off the underlying pubocervical fascia (Fig. 5.4).

6. The pubocervical fascia is then plicated in the midline with 2-0 absorbable interrupted sutures (Fig. 5.5).
7. Many surgeons perform a cystoscopy at this point to evaluate for ureteral efflux ensuring that they have not caused ureteral obstruction, and to verify there are no sutures in the bladder.
8. Excess vaginal skin is excised and the incision is closed with a running, locking absorbable suture—it is important not to overtrim the vaginal skin.
9. If a concomitant mid-urethral sling (MUS) is being placed, it should be done after the cystocele repair through a separate more distal incision. This is done to prevent possible migration of the MUS proximally if a large area of dissection is in continuity with the sling. Typically, the minimal dissection needed for an MUS limits the chance of migration proximally.

Mesh-Augmented Colporrhaphy

Mesh placement for mesh-augmented anterior colporrhaphy can be performed using self-tailored biologic or synthetic mesh, a transobturator and/or transgluteal trocar-guided synthetic mesh kit, or a non-trocar synthetic mesh kit [9]. (The objective outcome data are better for macroporous polypropylene synthetic mesh compared to biologic mesh. See section on Recent Randomized Trials on Outcomes)

1. An Allis clamp is placed 1 cm distal to the vaginal cuff or cervix. A second Allis clamp is placed 1–2 cm proximal to the bladder neck.

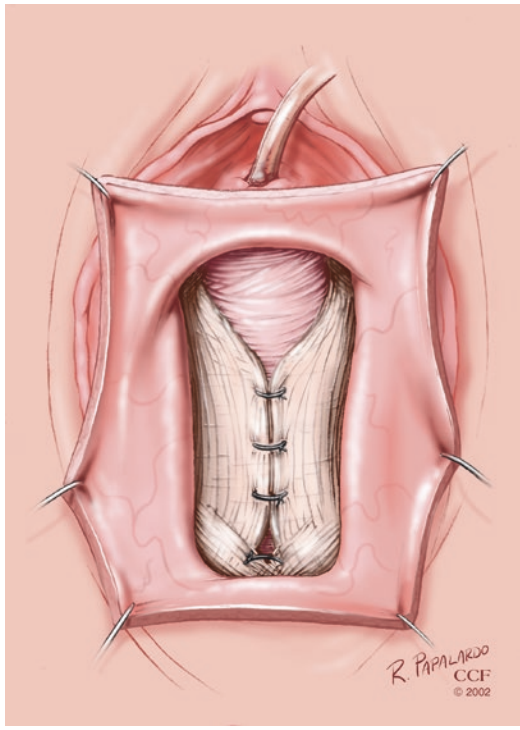

Fig. 5.5 Plication of pubocervical fascia for anterior colporrhaphy. (Reprinted with permission, Cleveland Clinic Center for Medical Art and Photography © 2002–2013. All Rights Reserved)

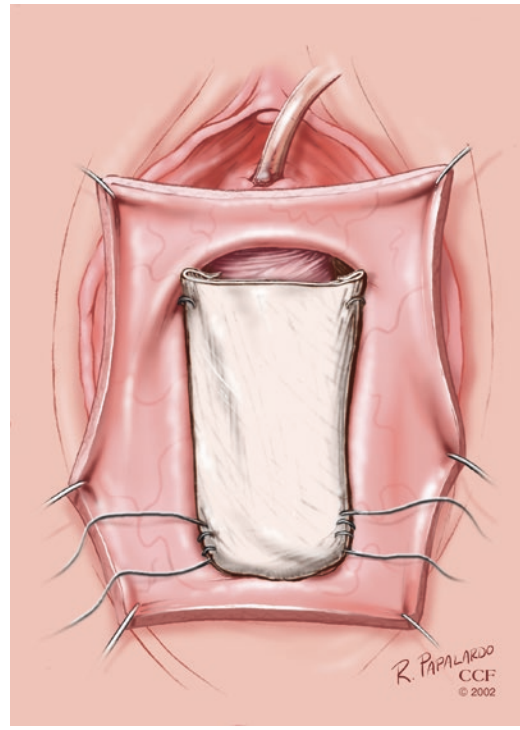

Fig. 5.6 Biologic mesh-augmented anterior colporrhaphy. (Reprinted with permission, Cleveland Clinic Center for Medical Art and Photography © 2002–2013. All Rights Reserved)

2. While pulling the anterior vaginal wall outward with the Allis clamps, the vaginal wall is infiltrated *deeply* and hydrodissected with a dilute solution of lidocaine mixed with epinephrine, thus developing a plane between the pubocervical fascia and the bladder adventitia.
3. A midline incision is made between the two Allis clamps.
4. Allis clamps are placed on the edges of the vaginal skin on both sides of the incision.
5. A combination of sharp and blunt dissection is used to dissect the vaginal skin with the underlying pubocervical fascia off the bladder adventitia, thus developing the vesicovaginal space. The dissection to achieve this plane is very different from the traditional colporrhaphy dissection. The correct plane for mesh placement is critical to ensure that mesh extrusion does not occur.
6. The mesh is placed loosely to allow for possible scarring and tightening of the mesh.
7. The mesh is secured to the arcus tendineus fascia pelvis (ATFP), iliococcygeus muscle, or sacrospinous ligament depending on the technique used (Fig. 5.6).
8. Cystoscopy is performed to verify there are no sutures or mesh in the bladder.
9. The vaginal skin is not trimmed and is closed with a running absorbable suture [9].
10. A vaginal pack is left in place overnight

Paravaginal Defect Repair

1. The pubocervical fascia is exposed in the same manner as detailed above for traditional anterior colporrhaphy. However, the dissection is extended further so that the anterior border of the developed space is the ischiopubic rami, the medial border is the pubic symphysis, and the lateral border is the ischial spine.

2. The pubocervical fascia is then plicated in the midline with 2-0 absorbable interrupted sutures.
3. The lateral defect is then repaired by placing nonabsorbable suture through the avulsed lateral edge of the pubocervical fascia, ATFP, and muscularis of the lateral vaginal wall. Transvaginally, the exposure and suture placement on the arcus tendineus can be challenging but is made easier by use of a device that allows for suture placement based on palpation (Capio®, Boston Scientific Company). A series of four to six stitches are placed along the ATFP from the ischial spine toward the level of the urethrovesical junction.
4. The same is performed on the contralateral side.
5. The sutures are tied sequentially from one side to the other starting from the urethrovesical junction heading toward the ischial spine. This technique can also be performed transabdominally. Transabdominal paravaginal defect repair is currently often performed with a minimally invasive laparoscopic or robotic approach.
6. Cystoscopy is performed to evaluate for ureteral efflux and to verify there are no sutures in the bladder.
7. Excess vaginal skin is excised and the incision is then closed with a running, locking absorbable suture.

Recent Randomized Trials on Outcomes [10]

Several prospective trials have compared outcomes between these approaches. The first randomized trial comparing anterior colporrhaphy techniques was published by Weber et al. in 2001 [11]. Chmielewski et al. reanalyzed the data using a more clinically relevant definition of success, which included no prolapse beyond the hymen, absence of prolapse symptoms, and absence of re-treatment. One hundred fourteen women were randomized to standard anterior colporrhaphy, ultralateral colporrhaphy, or anterior colporrhaphy with (absorbable) mesh, and were followed at 6 months, 1 year, and 2 years after repair. Eighty-eight percent of women with sufficient follow-up data at 1 year met the definition of surgical success. There was no difference between repair groups. The authors concluded that standard anterior colporrhaphy is appropriate for primary cystocele repair at 2-year follow-up [12]. Some have criticized this study as a reanalysis years after the original with changing definitions and relatively short follow-up given the length of time from the original study [13].

Several more recent randomized controlled trials have compared anterior colporrhaphy with mesh-augmented colporrhaphy. Anatomical success rates for anterior colporrhaphy were 41–72% versus 81–91% for self-tailored synthetic mesh-augmented colporrhaphy and 87–91% for synthetic mesh-kit-augmented colporrhaphy at 1-year follow-up. Vaginal mesh extrusion rates were 4–7%. Rates of de novo dyspareunia were not significantly different between groups [14–17].

The randomized controlled study with the longest follow-up, 3 years, reported 59% anatomical success in the traditional colporrhaphy group versus 87% in the synthetic mesh-augmented colporrhaphy group ($p < 0.0001$). Symptomatic outcomes and rates of de novo dyspareunia were similar in both groups. The mesh extrusion rate was 19% [18].

A criticism of several studies has been that anterior colporrhaphy has had worse anatomic outcomes compared to mesh-augmented colporrhaphy due to not addressing concomitant apical prolapse. Nguyen et al. performed a randomized trial comparing anterior colporrhaphy with synthetic mesh-augmented colporrhaphy. The majority of these women underwent uterosacral vault suspension. At 1-year follow-up, anatomic success (no stage 2 or greater anterior prolapse) was 55% and 87% in the traditional and synthetic mesh-augmented groups, thus demonstrating the superiority of mesh-augmented repairs even after addressing apical prolapse in both groups [16].

Given the risk of extrusion with synthetic mesh, three randomized trials have compared traditional colporrhaphy with biologic graft-augmented colporrhaphy (Pelvicol®, Bard

Medical; Tutoplast®, Davol). There was no difference in objective and subjective outcomes in any of these studies [19, 20] suggesting no functional or symptomatic advantage with the use of a biologic graft for colporrhaphy.

A randomized controlled trial comparing traditional colporrhaphy, xenograft-augmented, and synthetic mesh-augmented colporrhaphy was conducted with 2-year follow-up. Anatomic failure rate was 58%, 46%, and 18% in each respective group ($p < 0.05$). Symptomatic failure rates were not statistically different between groups. The mesh extrusion rate was 14%. The authors concluded that synthetic mesh-augmented repair had the best anatomic outcome but symptomatic outcomes were similar between all groups [21]. These findings were further validated in a recent two parallel group, multicenter, randomized controlled trials (PROSPECT) comparing traditional colporrhaphy, xenograft-augmented, and synthetic mesh-augmented colporrhaphy in 1352 women with 2-year follow-up. The primary outcomes were patient-reported prolapse symptoms and quality of life scores. There was no difference in outcomes between groups, however, the mesh extrusion rate was 12% (51/434) [22].

Finally, a recent Cochrane review concluded that the use of biologic graft or absorbable mesh for augmenting anterior colporrhaphy does not improve outcomes. Traditional colporrhaphy results in higher recurrence and risk of repeat surgery for prolapse compared to synthetic mesh-augmented repair, but decreased risk of de novo stress urinary incontinence, bladder injury, and repeat surgery (including mesh exposure). Given the higher complication rate after synthetic mesh-augmented repair, traditional colporrhaphy is preferred [23].

See Table 5.1.

Table 5.1 Success rates for pelvic organ prolapse repair

	Objective success (%)	Subjective success (%)[a]
Anterior repair		
Traditional	41–89	81–100
Paravaginal	83	93
Synthetic mesh-augmented	81–96	81–91
Biologic mesh-augmented	54–82	
Posterior repair		
Traditional	75–91	80–93
Site-specific	78	88
Synthetic mesh-augmented	78–96	79–96
Biologic mesh-augmented	54–88	97
Apical repair		
USVS	86–97	94
SSLF	69	91
Transvaginal mesh-augmented	43	79
Open ASC	76–94	94
Laparoscopic ASC	77–91	87
Robotic ASC	88–94	
Uterine-sparing ASC	68	
Hysterectomy and A–P repair	87	
Colpocleisis	85–100	

[a]Subjective outcomes not reported as a percentage for robotic ASC, uterine-sparing ASC, hysterectomy and A–P repair, and colpocleisis, and thus not listed

Summary

The randomized controlled trials comparing colporrhaphy with and without mesh are heterogeneous. However, the consensus seems to be that mesh repair provides superior anatomic outcome but equivalent symptomatic outcome. While subjective outcomes appear similar in the short run, one cannot know at this point if that will remain so in the long run. Specifically, will those patients with asymptomatic anatomic recurrences now become those that have symptomatic recurrences in the future? Rates of de novo dyspareunia are not significantly increased with mesh repair, but mesh exposure rates and the increased surgical complication rates are not negligible. As of January 2018, synthetic vaginal mesh for prolapse repair is banned in Australia, New Zealand, and the United Kingdom because there is inadequate evidence showing the benefit outweighs the risk [24]. Given the risk of mesh extrusion, the FDA safety update on transvaginal mesh for pelvic organ prolapse [25], the ban of its use in other countries [24], surgeons must use caution when utilizing transvaginal mesh. Unfortunately, the

PROSPECT trial demonstrated that 81–85% of women in both the traditional and mesh-augmented repair groups reported symptomatic prolapse at 2 years, suggesting that we need better treatment options than what is currently available [22].

Key Points

- Anatomic cure after traditional colporrhaphy is as high as 72% compared to as high as 91% after synthetic mesh-augmented colporrhaphy, even after addressing apical prolapse.
- Biologic graft-augmented colporrhaphy is not superior to traditional colporrhaphy.
- Early subjective outcomes and rates of de novo dyspareunia are similar for all types of colporrhaphy.
- Synthetic mesh extrusion rates are 4–19%.
- Long-term anatomic durability and subjective outcomes (>3 years) are unknown.

Posterior Repair and Perineorrhaphy

Background

Posterior compartment prolapse is herniation of pelvic organs into the posterior vaginal wall, including rectocele (herniation of the rectum) and posterior enterocele (herniation of the small bowel) [2]. The prevalence and incidence of posterior compartment prolapse is also not well described. In the Women's Health Initiative, the prevalence of rectocele was 19% in women of age 50–79 years [3]. Risk factors for posterior compartment prolapse are similar to those for anterior compartment prolapse (see above). The strongest risk factor is vaginal delivery with one study noting a 1.9 (1.7–2.2) times increased risk of rectocele after a single childbirth compared to nulliparity [4].

Evaluation

The first step in the evaluation of posterior compartment prolapse is a history and physical examination. Women with symptomatic posterior compartment prolapse may complain of a sensation of a vaginal bulge, pressure, or heaviness. They may visualize the protrusion. Bowel symptoms may include incontinence of flatus or stool, feeling of incomplete emptying, straining to defecate, fecal urgency, digital evacuation of stool from rectum, splinting or manual reduction of prolapse to defecate, and feeling of obstruction during defecation. Patients may also complain of dyspareunia [4]. General symptoms can include low back pain, generalized pelvic pain, or bloody discharge due to ulceration of the prolapsed vaginal skin [2]. The history should thus elucidate the presence of risk factors and symptoms as previously described.

Physical examination is standardized by utilizing the POP-Q system as detailed in the previous section.

Imaging is not routinely used in the evaluation of pelvic organ prolapse. However, transperineal ultrasound or MR defecography can differentiate a rectocele from an enterocele.

Surgical Repair

The patient is placed in the dorsal lithotomy position. The external genitalia is prepped and draped in the usual sterile fashion. One dose of intravenous antibiotics is administered for prophylaxis prior to incision. As per the 2011 American Urological Association Guidelines on Antibiotic Prophylaxis, the antibiotics of choice for vaginal surgery are a first-/second-generation cephalosporin or an aminoglycoside (aztreonam if the patient has renal insufficiency) plus metronidazole or clindamycin. Alternative antibiotics are ampicillin/sulbactam or flouroquinolone [8]. A foley catheter is placed to drain the bladder. A weighted speculum is placed in the vagina. A Scott retractor or translabial sutures are used to retract and expose the prolapse. The

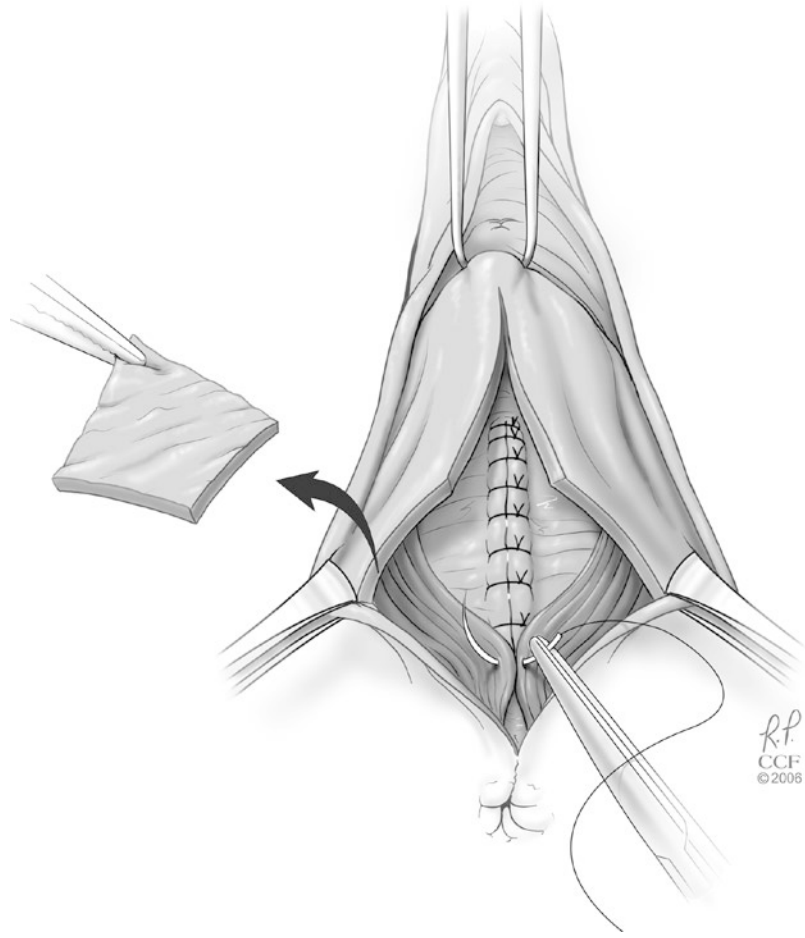

Fig. 5.7 Plication of rectovaginal fascia for posterior colporrhaphy. (Reprinted with permission, Cleveland Clinic Center for Medical Art and Photography © 2002–2013. All Rights Reserved)

posterior compartment prolapse repair is then performed using one of the following techniques: traditional posterior colporrhaphy, site-specific posterior repair, or graft-augmented posterior colporrhaphy. Perineorrhaphy is often performed at the same time. The goals of posterior compartment prolapse repair are plication of the prerectal and pararectal fascia, narrowing of the levator hiatus, and repair of the perineal body [26].

Traditional Posterior Colporrhaphy

1. The posterior vaginal wall is infiltrated superficially with a dilute solution of lidocaine and epinephrine.
2. A transverse incision is made at the hymen and a midline incision made extending toward the cervix, creating an inverted T (some prefer a triangle instead).
3. The vaginal skin is carefully dissected off the rectovaginal fascia using sharp and blunt dissection. (Note, the more appropriate term is vaginal muscularis and not rectovaginal fascia, since there is no actual fascial layer.)
4. The lateral rectovaginal fascia is plicated together in the midline with interrupted 2-0 absorbable stitches, starting proximally and progressing distally toward the perineal body (Fig. 5.7).
5. A perineorrhaphy is typically performed by placing deep plication sutures in the puborectalis muscle.

6. Excess vaginal skin is excised after which the posterior vaginal wall is closed with running locking absorbable suture. It is important to not over plicate the perineum and to leave adequate skin so the incisions are not closed under tension. Too much narrowing of the vagina can lead to dyspareunia. It is the author's practice to leave the introitus large enough to accommodate three fingers (Fig. 5.8).

Site-Specific Posterior Colporrhaphy

1. The posterior vaginal wall is not hydrodissected in order to better identify defects in the rectovaginal septum.
2. A transverse incision is made at the hymen and a midline incision made extending toward the cervix, creating an inverted T (some prefer a triangle instead).
3. The vaginal skin is carefully dissected off the rectovaginal fascia using sharp and blunt dissection.
4. A finger from the nondominant hand is placed in the rectum and pushed upward to identify fascial defects, which are then repaired with interrupted stitches (Fig. 5.9).
5. Excess vaginal skin is excised, a perineorrhaphy is performed if needed, and the vaginal skin is then closed.

Graft-Augmented Posterior Colporrhaphy

1. A plane deep to the rectovaginal fascia is developed (usually after copious hydrodissection).
2. The mesh is sutured proximally to the cervix, uterosacral ligaments, or sacrospinous ligaments, distally to the perineal body or distal

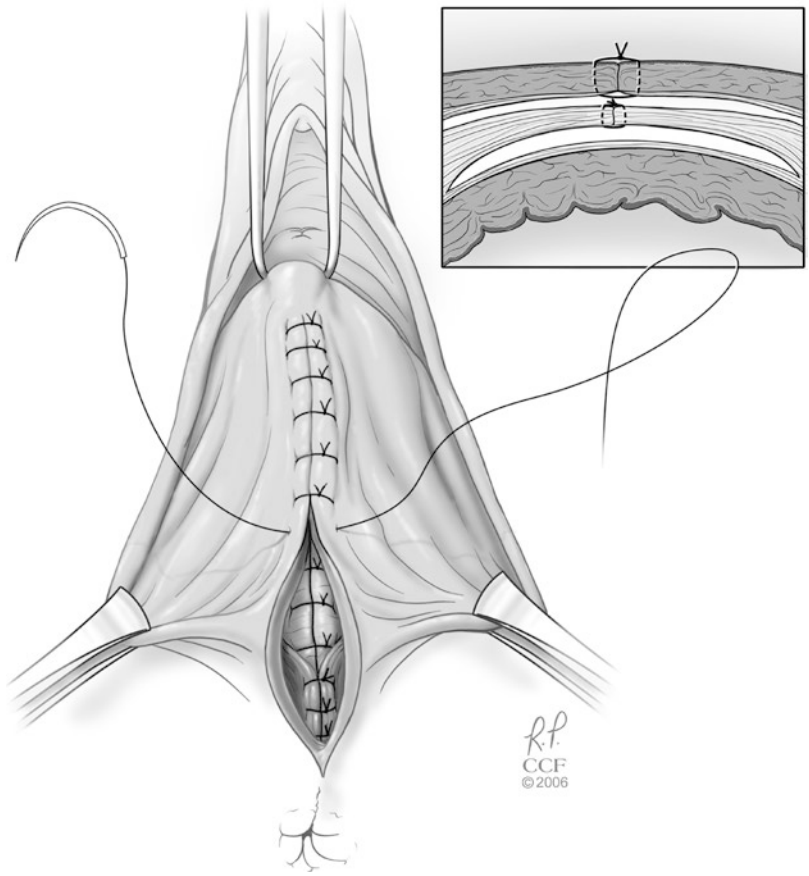

Fig. 5.8 Closure for posterior colporrhaphy. (Reprinted with permission, Cleveland Clinic Center for Medical Art and Photography © 2002–2013. All Rights Reserved)

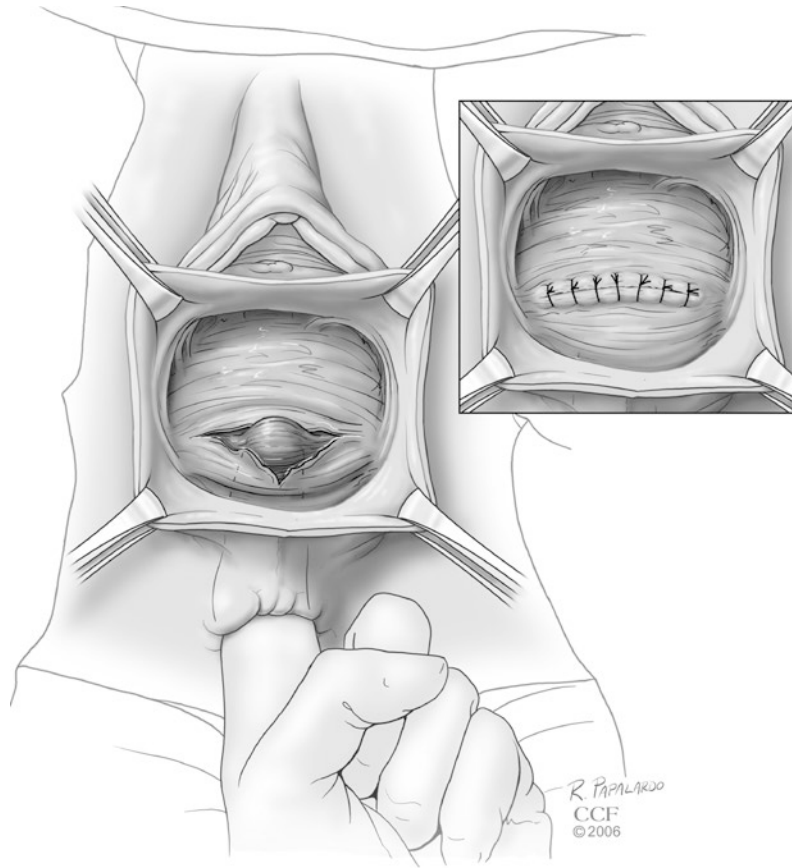

Fig. 5.9 Site-specific posterior colporrhaphy. (Reprinted with permission, Cleveland Clinic Center for Medical Art and Photography © 2002–2013. All Rights Reserved)

rectovaginal septum, and in some techniques laterally to the pelvic sidewall. Alternatively, if a smaller patch of the mesh is used, it is sutured laterally to the pararectal fascia and proximally and distally to the rectovaginal fascia.

3. The vaginal skin is not trimmed and is subsequently closed over the mesh.

Recent Randomized Trials on Outcomes

A 2018 Cochrane review evaluated 10 trials on various approaches to posterior colporrhaphy [27]. There were four trials comparing biological graft-augmented posterior colporrhaphy with traditional repair. There was no difference in recurrence of posterior compartment prolapse. However, the complication rate was higher after biologic graft-augmented repair. There is one randomized controlled study comparing synthetic mesh-augmented posterior colporrhaphy with traditional repair (191 patients in the PROSPECT trial), which found no difference in anatomic or subjective outcomes at 1 and 2 years respectively. The mesh complication rate was 14% (for anterior and posterior compartment mesh) [22]. Site-specific repair (n = 37) was compared with traditional colporrhaphy (37) by Paraiso et al. Anatomic cure was defined as POP-Q point Bp less than or equal to −2 at 12 months follow-up. Patients also completed validated questionnaires to assess subjective outcomes. At 1-year follow-up, the rate of anatomic cure was 86% in the posterior colporrhaphy group and 78% in the site-specific group. There was no significant difference in subjective outcomes or rates of de novo dyspareunia [28]. There are four randomized trials comparing

transvaginal and transanal rectocele repair [27]. Compared to transvaginal repair, women who underwent transanal repair were more likely to be aware of prolapse (RR 2.78, 95% CI 1.00–7.70), have recurrent posterior vaginal wall prolapse (RR 4.12, 95% CI 1.56–10.88), and experience postoperative obstructed defecation (RR 1.67, 95% CI 1.00–2.79). There was no significant difference in repeat surgery for any prolapse, postoperative dyspareunia, postoperative complications, and operating time [27].

See Table 5.1.

Summary

Transvaginal repair is preferred over transanal repair of rectocele. Given the risk of mesh extrusion and the overall similar objective and subjective outcomes for mesh-augmented versus traditional repair noted in most studies, posterior compartment repair with native tissue is currently the gold standard [29].

Key Point

- The gold standard for rectocele repair is transvaginal traditional posterior colporrhaphy.

Apical Repair

Background

Apical compartment prolapse is herniation of the cervix, uterus, or vaginal cuff into the apical vaginal wall [2]. In the Women's Health Initiative, the prevalence of uterine prolapse was 14% in women of age 50–79 years [3]. Risk factors for apical compartment prolapsed are similar to those for anterior compartment prolapse (see above). The strongest risk factor is vaginal delivery with one study noting a 2.1 (1.7–2.7) times increased risk of uterine prolapse after a single childbirth compared to nulliparity [4].

Evaluation

The first step in the evaluation of apical compartment prolapse is a history and physical examination. Women with symptomatic apical compartment prolapse may complain of a sensation of a vaginal bulge, pressure, or heaviness. They may visualize the protrusion. They may report urinary and bowel symptoms as detailed previously. Patients may also complain of dyspareunia [4]. General symptoms can include low back pain, generalized pelvic pain, or bloody discharge due to ulceration of the prolapsed vaginal skin [2]. The history should thus elucidate the presence of risk factors and symptoms previously described.

Physical examination is standardized by utilizing the POP-Q system as detailed previously.

Imaging is not routinely used in the evaluation of pelvic organ prolapse. Transperineal ultrasound is least useful in the apical compartment [6, 7].

Surgical Repair

The options for transvaginal apical repair can be divided into restorative, compensatory, and obliterative procedures. The restorative techniques include transvaginal sacrospinous ligament fixation (SSLF), transvaginal iliococcygeus suspension, or transvaginal uterosacral suspension.

The patient is placed in the dorsal lithotomy position. The external genitalia is prepped and draped in the usual sterile fashion. One dose of intravenous antibiotics is administered for prophylaxis prior to incision. As per the 2011 American Urological Association Guidelines on Antibiotic Prophylaxis, the antibiotics of choice for vaginal surgery are a first-/second-generation cephalosporin or an aminoglycoside (aztreonam if the patient has renal insufficiency) plus metronidazole or clindamycin. Alternative antibiotics are ampicillin/sulbactam or flouroquinolone [8]. A foley catheter is placed to drain the bladder. A weighted speculum is placed in the vagina. A Scott retractor or translabial sutures are used to retract and expose the prolapse.

Restorative Apical Prolapse Repair

Transvaginal Sacrospinous Ligament Fixation (SSLF)

SSLF can be performed unilaterally or bilaterally, using an anterior or posterior approach. SSLF is preferred if there is coexistent posterior prolapse. However, anterior prolapse can be exacerbated by SSLF.

1. If the patient has previously undergone hysterectomy, the location on the apex of the vagina that will be secured to the sacrospinous ligament is marked with a stitch. Otherwise, the cervix is secured to the sacrospinous ligament.
2. The posterior vaginal wall is infiltrated with a dilute solution of lidocaine and epinephrine.
3. A midline incision is made extending toward the apex/cervix.
4. The right pararectal space is bluntly dissected to reach the right sacrospinous ligament (Fig. 5.10).
5. Three Breisky–Navratil retractors are used to expose the sacrospinous ligament, one retracting the rectum medially, another retracting the vaginal wall upward, and the third retracting laterally thus exposing the ligament. The full extent of the ligament is exposed such that the ischial spine and sacrum are palpable. A Kittner can be used to bluntly expose and clean off any tissue overlying the sacrospinous ligament.
6. Two adjacent stitches, using permanent or delayed absorbable suture, are placed through the sacrospinous ligament under direct visualization using the Deschamps needle driver 2 cm medial to the ischial spine to avoid the pudendal neurovascular complex. Alternatively, a Miya hook or automatic suture-capturing device like the Capio® device (Boston Scientific, Natick, MA) can be used to pass the suture through the ligament. A 1 × 1 cm segment of macroporous polypropylene mesh can be placed through the suture and placed on top of the ligament to aid in apical scarring (Fig. 5.11).

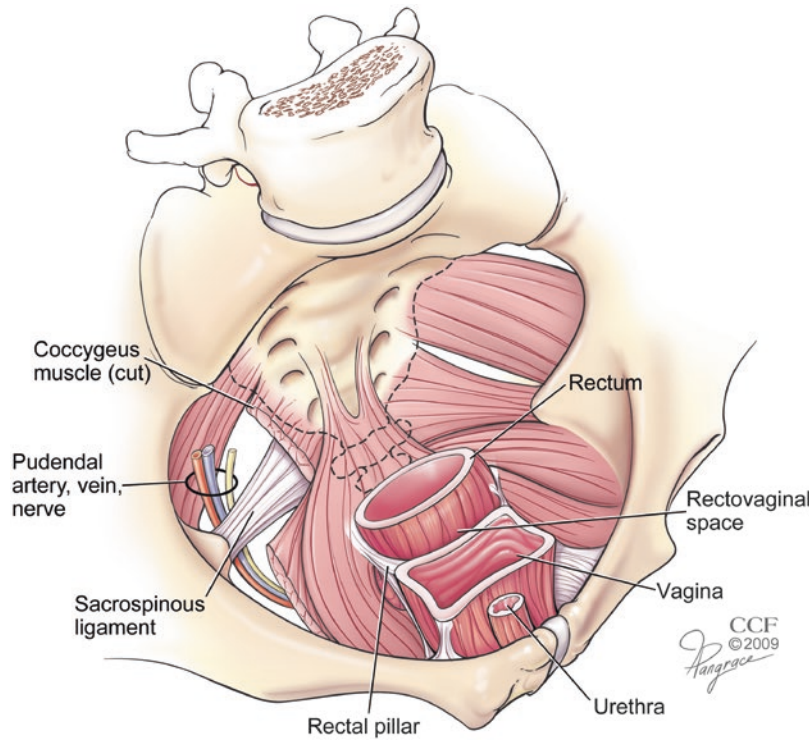

Fig. 5.10 Anatomical location of sacrospinous ligament. (Reprinted with permission, Cleveland Clinic Center for Medical Art and Photography © 2002–2013. All Rights Reserved)

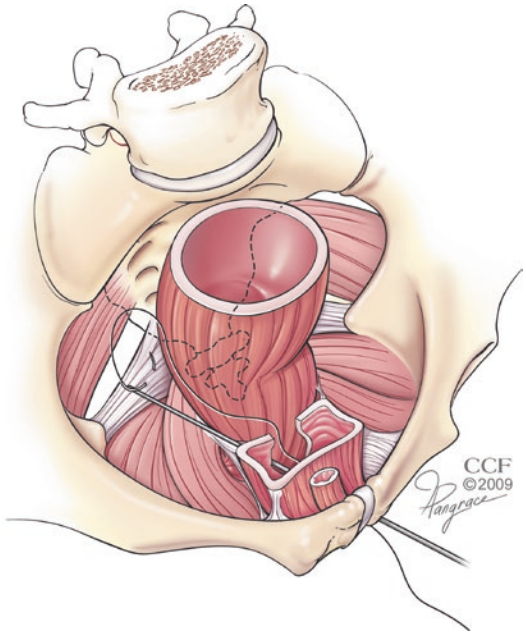

Fig. 5.11 Pathway for placement of suture in transvaginal sacrospinous ligament fixation. (Reprinted with permission, Cleveland Clinic Center for Medical Art and Photography © 2002–2013. All Rights Reserved)

7. The posterior vaginal wall is then closed.
8. If the sacrospinous ligament is attenuated or if the vagina is foreshortened and the apex cannot reach the sacrospinous ligament, the sutures can be placed through the right iliococcygeus muscle. When performing an iliococcygeus suspension, bilateral sutures are often placed.

Transvaginal Uterosacral Ligament Suspension (USLS)

Transvaginal uterosacral ligament suspension is preferred if concomitant hysterectomy is being performed and the vaginal cuff is open since uterosacral ligament suspension is best performed intraperitoneally. This may also be the preferred technique post-hysterectomy in the presence of a significant enterocele.

1. After the hysterectomy is performed, pack the bowel away with a moistened laparotomy sponge and lift the bowel upward with a Deaver, Heaney, or Breisky–Navratil retractor to expose the uterosacral ligaments (USL). In the post-hysterectomy patient, it is helpful to place a suture at each USL dimple at the apex after which the peritoneum can be entered via a diamond-shaped incision and with tension on the sutures the USL can be palpated.
2. Palpate the ischial spines and sacrospinous ligaments bilaterally. An Allis clamp is placed on the distal uterosacral ligament and placed on traction to allow palpation of the uterosacral ligament. The USL approaches the sacrospinous ligament and then takes a medial course to insert into the sacrum.
3. The more cephalad the sutures are placed on the USL, the more medial the sutures will be, thus minimizing ureteral injury. Two or three permanent or delayed absorbable sutures are placed through the proximal uterosacral ligaments and vaginal apex bilaterally. Note the suture through the USL should not be too deep so as to avoid injury to sacral nerve roots (Fig. 5.12).
4. If an anterior colporrhaphy is required, it should be performed at this time. The anterior vaginal wall incision and vaginal cuff should be closed.
5. Indigo carmine or flourescein should be administered intravenously. It is the authors' practice to place the uterosacral ligament fixation sutures on traction and then perform cystoscopy to ensure efflux from both ureteral orifices, thus confirming patency. The sutures are tied down and cystoscopy is performed again. If there is no efflux, the sutures on that side are sequentially removed starting with the most distal stitch, until efflux is seen.

Compensatory Apical Prolapse Repair

Compensatory techniques for apical repair entail the utilization of mesh to augment the repair. Mesh can be used via a transvaginal or transabdominal approach. Hysterectomy can be performed concomitantly or the procedure can be uterine-sparing.

There are a few remaining transvaginal mesh kits for apical repair including the following:

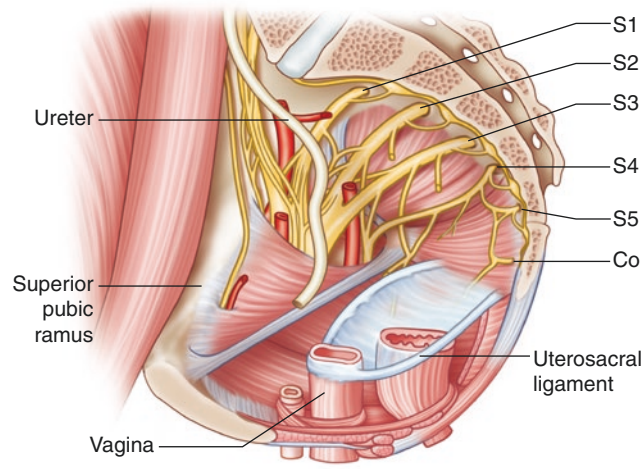

Fig. 5.12 Anatomical location of uterosacral ligament and proximity of sacral nerves

Boston Scientific Uphold LITE and Coloplast Restorelle Direct Fix. The mesh kits utilize fixation to the SSL and/or ATFP with a Capio® (Boston Scientific, Natick, MA) needle driver (Uphold LITE™) or with another anchoring system (StatTack®, Coloplast) [30].

Sacral colpopexy is performed transabdominally in women who have undergone hysterectomy. Two strips of polypropylene mesh or a preformed Y-shaped mesh is secured to the anterior and posterior vaginal wall with permanent or delayed absorbable sutures. The cranial ends are secured to the anterior spinous ligament on the sacral promontory. If uterine-sparing is desired, only a posterior mesh strip is utilized or a Y-shaped strip of mesh is tunneled through the broad ligament bilaterally and secured anterior to the uterus. Abdominal sacral colpopexy (ASC) or hysteropexy can be performed open or more commonly today via a laparoscopic or robotic approach. These procedures are described in further detail in Chaps. 7 and 8.

Obliterative Apical Prolapse Repair

For women who are not sexually active or who have multiple comorbidities warranting a less complicated procedure, colpocleisis is a simple obliterative procedure that can be utilized for significant apical prolapse (anterior and posterior prolapse is needed as well to technically perform colpocleisis). Success rates are 85–100% [26]. These procedures will be discussed in Chap. 6.

Recent Randomized Trials on Outcomes (Table 5.1)

Transvaginal Repair With Versus Without Mesh

Six randomized controlled trials including 598 patients were evaluated in a recent Cochrane review. There was little or no difference in risk of awareness of prolapse (RR 1.08, 95% CI 0.35–3.30), repeat surgery for prolapse (RR 0.69, 95% CI 0.30–1.60), recurrent prolapse (RR 0.36, 95% CI 0.09–1.40), or dyspareunia (RR 1.21, 95% CI 0.55–2.66) between these two groups [31]. The authors therefore concluded that there is insufficient evidence to support the use of mesh for vaginal apical prolapse repair.

Transvaginal USLS Versus SSLF

The OPTIMAL trial compared USLS versus SSLF for apical prolapse repair. Three hundred seventy-four women were randomized and followed for 2 years [32]. An extended trial included 244 women who completed 5 years of follow-up

[33]. The primary outcome was surgical failure defined as a combination of objective and subjective failure (apical descent greater than one-third into vaginal canal or anterior or posterior vaginal wall beyond the hymen, or re-treatment) or bothersome vaginal bulge symptoms. At 5-year follow-up, the surgical failure rates were not significantly different (61.5% USLS and 70.3% SSLF) [33]. The serious adverse event rates were also similar (16.5% USLS, 16.7% SSLF) [32]. Therefore, USLS and SSLF are both good options in the short term.

Transvaginal Versus Transabdominal Approach

A Cochrane review of six randomized controlled trials including 583 women favored the transabdominal approach for apical repair. Awareness of prolapse (RR 2.11, 95% CI 1.06–4.21), recurrent prolapse (RR1.89, 95% CI 1.33–2.70), repeat surgery for prolapse (RR 2.28, 95% CI 1.0–4.32), and dyspareunia (RR 2.53, 95% CI 1.17–5.5) were all more common after vaginal repair [31].

Summary

There are many options for apical repair including restorative, compensatory, or obliterative, transvaginal versus transabdominal, concomitant hysterectomy versus uterine-sparing, and open versus endoscopic repairs. The literature demonstrates that the use of transvaginal mesh for apical prolapse repair is not supported by improved outcomes, transvaginal apical repairs (USLS and SSLF) have similar outcomes, and abdominal sacrocolpopexy performs better than transvaginal apical repairs, subjectively and objectively. Robotic and laparoscopic ASC is gaining popularity as patients seek minimally invasive surgery. Women with predominantly anterior and vault prolapse may benefit more from an abdominal sacrocolpopexy, whereas women with predominantly posterior and vault prolapse may benefit from vaginal sacrospinous or uterosacral colpopexy. For elderly women who no longer desire to be sexually active, colpocleisis is a suitable repair option. There is no gold standard repair; the surgical approach must be customized to each patient.

Key Points

- The procedures for apical repair are restorative, compensatory, or obliterative.
- Use of transvaginal mesh for apical prolapse repair does not result in better outcomes.
- USLS and SSLF have similar outcomes, with about 60% success at 2 years.
- The transabdominal approach to apical prolapse is superior to the transvaginal approach both subjectively and objectively.
- Colpocleisis is the least invasive repair option and has an 85–100% cure rate, but is only feasible for women who no longer desire to be sexually active and have very significant prolapse.

Conclusion

Transvaginal prolapse repair should be tailored to the individual patient, making sure to factor in the degree of prolapse, risk for recurrence, and patient expectations. More prospective, randomized trials with longer follow-up are needed to determine the gold standard of care.

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6 Female Pelvic Surgery: Obliterative Vaginal Procedures

Ryan M. Krlin, Barry Hallner Jr., Nia Thompson, and J. Christian Winters

Background

Pelvic organ prolapse (POP) is a common condition among women, and its prevalence increases with age [1–3] Approximately 4.1% of women aged 80 years or older have symptomatic POP [3], and an estimated 11.1% of women will undergo at least one surgery for POP repair or stress urinary incontinence by 80 years of age [4].

As the population of older women expands, there will be increasing numbers of patients suffering from and seeking care for POP. The U.S. Census Bureau estimates indicate that starting in 2056, the population, age 65 and over, will outnumber the population under age 18 [5]. Additionally, Census calculations project that the population age 65 and older will double between 2012 and 2060, from 43.1 million to 92.0 million [5]. Using population projections and age-specific prevalence of POP, Wu et al. estimated that between 2010 and 2050, the number of women with POP will increase 46% from 3.3 to 4.9 million [6]. In a second study, Wu et al. predict that between 2010 and 2050, there will be a 47% increase in women undergoing procedures for POP (166,000 in 2010 and 245,970 in 2050) [7].

Surgical repair of POP is challenging and has been fraught with a high reoperation rate of up to 29% [4]. Pelvic tissues that are either weakened or damaged are thought to predispose these women to failure. The mean time to first reoperation for recurrent prolapse after primary surgical correction has been reported to be between 3 and 4 years [8, 9]. Each additional repair appears to be less robust, with the time between surgeries decreasing with each successive repair [4]. Johnson et al. looked at patient-reported outcomes and found a high rate of early recurrence with 35.4% of patients experiencing recurrent prolapse within 3 months of a primary surgical repair. Furthermore, they found a much higher overall recurrence rate of 64.6% with 30% of patients not reporting recurrences to their primary surgeon [10]. This low reporting rate could account for an underestimation of failure rates in any given physician's practice.

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Colpocleisis

Colpocleisis is simply a closure of the vagina with reduction of the prolapse back into the pelvis. Replacement of the pelvic organs into their anatomic position allows for the relief of the symptoms caused by prolapse. Closure of the vagina is permanent, and it precludes future vaginal intercourse, a point which should be stressed to the patient. Obliteration may be performed in the setting of a prior hysterectomy or with the uterus still in place. The LeFort modification of the procedure is utilized when leaving the uterus in situ. Additionally, hysterectomy may be performed concurrently with colpocleisis in those patients that require removal of the uterus and or cervix. Removal of the vaginal epithelium followed by apposition of the anterior and posterior fibromuscularis layers achieves obliteration of the vaginal space.

Colpocleisis is an effective and durable procedure for the treatment of prolapse. Anatomical success rates range from 97% to 100% in most series [11–18]. The procedure can be, likely than other pelvic organ prolapse procedures to be performed under local or general anesthesia broadening availability to patients with comorbidities or poor surgical candidates [19]. Historically, this procedure has been an appropriate choice for elderly patients >70 years old who do not wish to preserve vaginal function for intercourse [20, 21]. Patients with symptomatic prolapse commonly experience other pelvic floor symptoms including lower urinary tract symptoms, incomplete bladder emptying, and various bowel complaints. Significant improvements have been seen in these additional domains in several studies.

Hullfish and colleagues looked at symptom relief via postsurgical attainment of patient goals that were set preoperatively. In this format, 91% of patients reported improvement of urinary urgency and frequency following colpocleisis [22]. In a series of 324 women who underwent colpocleisis, Zebede and colleagues reported preoperative urgency symptoms in 54% of patients. Following surgical repair, there was a statistically significant reduction in these urgency symptoms by 50% ($p < 0.001$) [18].

Again, looking at postoperative attainment of patient goals, Hullfish and colleagues found a 76.4% subjective improvement in bladder emptying following colpocleisis [22]. In a cohort of women with POP and a postvoid residual (PVR) greater than 100 cc, Fitzgerald and colleagues reported 89% resolution of incomplete bladder emptying after surgical prolapse repair [23]. Similarly, in a series of 64 women who underwent colpocleisis, 36% had elevated preoperative PVR volumes all of which normalized postoperatively [15]. A retrospective cohort by Song and colleagues found that 11.4% of their 35 women studied had postoperative urinary retention that resolved within 4–7 days [24].

The resolution of bowel symptoms is equally encouraging. In a prospective study by Gutman and colleagues, bothersome bowel symptoms resolved in the majority of patients after colpocleisis. Specifically, all obstructive symptoms (digital assistance, straining, and incomplete emptying) and the majority of incontinence symptoms (anal (fecal) incontinence with stress and urge, anal incontinence of flatus and liquid stool) were significantly decreased 1 year after surgery [25]. Likewise, in their large case series, Zebede and colleagues found a significant resolution of bowel symptoms including the following: constipation, obstructed defecation, and fecal incontinence [18].

Patients report a high rate of satisfaction after colpocleisis ranging from 90.3% to 100% [12, 14, 17, 18, 24, 26–28]. In most studies, women urinary retention or urgency was the cause for "neither satisfied nor dissatisfied" [24, 29]. Barber and colleagues reported that patients had significant improvements in multiple quality-of-life measures including the following: bodily pain, vitality, social functioning, and mental health measures [26]. Also, in this study of women of age 65 or older with Stage 3 or 4 prolapse, there were no differences found between the reconstructive and obliterative groups as both demonstrated significant improvements in health-related quality of life [26]. A study of 278 women by Wang and colleagues reported a significant improvement in the total body image scores approximately 3 years post procedure [30].

Correspondingly, Murphy and colleagues also found that the quality of life and patient satisfaction was similar between groups of women who had reconstructive versus obliterative prolapse repairs [31].

Evaluation/Workup

Preoperative evaluation for colpocleisis should include a thorough history of the prolapse complaint including prior reconstructive procedures and associated pelvic floor symptoms. Details should be obtained regarding pain and pressure symptoms, urinary incontinence, voiding dysfunction, fecal incontinence, and defecatory dysfunction. A detailed vaginal exam, bimanual and speculum, is required with evaluation of all compartments. A quantitative scoring of the prolapse, assessment of uterine size when applicable, measurement of post void residual, and assessment of urine for infection and hematuria should be included. Colpocleisis is most easily completed in patients with Stage 3 or greater prolapse (Fig. 6.1). In patients with less severe support defects, or asymmetric compartment prolapse, the dissection required may be more challenging.

Some type of preoperative evaluation for stress urinary incontinence (SUI), even in patients who report continence, is recommended due to the high rate of occult SUI in women with POP. The rate of occult stress urinary incontinence in the setting of Stage 2 prolapse or greater ranges from 33.5% to 67.9% [18, 32–35]. A simple cough stress test with a full bladder and the prolapse reduced is often sufficient in patients with uncomplicated, demonstrable SUI. Patients with voiding dysfunction, mixed incontinence, incomplete bladder emptying, or prior urologic surgery undergo a more thorough investigation with urodynamics in our practice.

The data are varied and the true predictive value of preoperative urodynamics remains unclear. Reena and colleagues studied women both before and after they underwent prolapse repairs without anti-incontinence procedures and found that 64.2% of patients with documented occult SUI also demonstrated SUI postop [33]. In a small series of patients, Chaikin and colleagues reported that no patients with negative preoperative testing developed postoperative SUI [29]. Similarly, Hafidh and colleagues found a very low rate of postoperative SUI (4%) in patients with no SUI demonstrated on preoperative urodynamics [36]. In contrast, studies by Wei and Al-Mandeel found a high incidence of postoperative SUI, 38% and 42% respectively, in patients with preoperative testing that was negative for SUI [35, 37]. What is clear, however, is that it is reasonable to place a midurethral sling at the time of prolapse repair in women with clinical SUI or documented occult SUI. A study by Davenport et al. reported that the stage of preoperative cystocele in accordance with the POP quantification system was directly related to de novo stress urinary incontinence after prolapse repair [38]. Specifically, they reported a 41.3% rate of de novo incontinence for women with Stage 2 prolapse, 52.5% for Stage 3, and 66.1% for women with advanced Stage 3 and Stage 4 prolapse. This study only included women undergoing

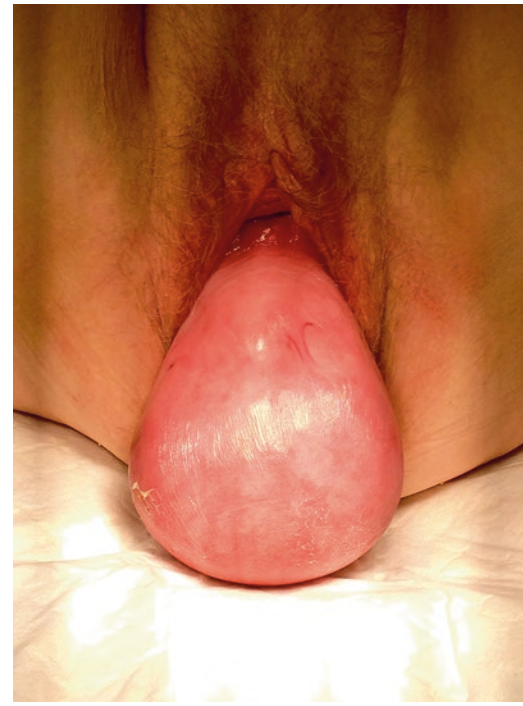

Fig. 6.1 Stage 4 vaginal vault prolapse

abdominal sacrocolpopexy and may not be generalizable to obliterative procedures. In 100 women with occult SUI who underwent TVT, Croutz and colleagues report an 83% success rate for absence of postoperative SUI and only 2% of patients with persistent SUI were symptomatic [32]. Meschia and colleagues also reported high rates of postoperative continence (objective 92%, subjective 96%) in patients who underwent TVT placement for occult SUI [39]. Jelovesk and colleagues validated a model that predicts de novo stress incontinence after prolapse repair, and may be useful in counseling patients about concomitant anti-incontinence procedures [40].

Management of the Uterus

In women with a uterus, it is prudent to confirm that there is no cervical or endometrial pathology which would be a contraindication to leaving the uterus in situ. A decision analysis by Jones et al. reported that colpocleisis without hysterectomy is preferred and most common among practicing surgeons [41]. Closure of the vagina will severely limit the ability to perform future surveillance via the traditional routes (pap smear, endometrial biopsy). A complete history should be taken regarding any history of abnormal pap smears as well as any episodes of postmenopausal bleeding. Benign cervical cytology should be documented in a patient with a history of any abnormal pap smears or a previous treatment for cervical intraepithelial neoplasia (CIN). The most recent guidelines from the American College of Obstetricians and Gynecologists (ACOG) recommend that women with a history of CIN2, CIN3, or adenocarcinoma in situ should have 20 years of negative screening following treatment prior to discontinuation of cervical cancer screening [42]. Therefore, it is recommended that any woman who would need continued surveillance based on her history should have a hysterectomy at the time of colpocleisis.

The incidence of endometrial cancer in the general population is 3.5% [43]. While the risk of endometrial cancer is low, women with a history of endometrial hyperplasia or any episodes of postmenopausal bleeding should have a preoperative assessment of the endometrium. This can be accomplished via endometrial sampling via endometrial biopsy or dilation and curettage of the uterus. Alternatively, the least invasive approach is to evaluate the endometrial thickness via transvaginal ultrasound. In women with postmenopausal bleeding, endometrial sampling is not required if an endometrial thickness of less than or equal to 4 mm is found on transvaginal ultrasound [44]. The decision to screen asymptomatic women with transvaginal ultrasound for assessment of the endometrial thickness may be left to the discretion of the surgeon. Approximately 68% of surgeons in a survey published by Jones et al. reported sampling the uterus before the time of surgery [45]. As reported by ACOG, the significance of an endometrial thickness greater than 4 mm in a postmenopausal woman without bleeding has not been established and does not routinely need evaluation in the absence of risk factors [46]. Concurrent hysterectomy is recommended and appropriate for women with the finding of endometrial hyperplasia and those with numerous risk factors [47]. Patients with the diagnosis of atypical endometrial hyperplasia should be referred to a gynecologic oncologist for surgical management due to the high rate (42.6%) of concurrent carcinoma [48].

Adverse Perioperative Events

Major perioperative adverse events after colpocleisis are rare regardless of age [19, 20, 49–51]. Failure with need for reoperation, wound infection, atrial fibrillation, and vaginal vault hematoma are among the most serious documented adverse outcomes. Vaginal evisceration after colpocleisis is a very rare surgical emergency and only two cases have been documented in the literature [52]. Urinary tract infection and mild urinary retention are the most common adverse events [53]. A retrospective review by Catanzarite and colleagues reported an 8.1% complication rate with urinary tract infection as the most common adverse event occurring in 6.4% of patients. Accordingly, the study also reported similar rates

of urinary complications in women who underwent colpocleisis alone and colpocleisis with a sling. Age less than 75, COPD, and hemiplegia, have been identified as risk factors for increased complications. Similarly, a 10-year study by Hill and colleagues, UTI was the most common side effect occurring in 34.7% of women [20]. This retrospective study compared rates of adverse outcomes in women who underwent colpocleisis alone versus concurrent hysterectomy. The study examined 19 different end points and found no differences in overall rates but did identified a statistically significant difference ($p < 0.0001$) in longer operative times and greater blood loss with concurrent hysterectomy [20].

Regret and Recurrence

Rates of regret following colpocleisis are low typically ranging from 3% to 9% [22, 54, 55]. In a series by von Pechmann and colleagues, a higher rate of regret (12.9%) was reported; however, half of those patients also stated that they still would have the surgery again. There are concerns that closure of the vagina may negatively affect a patient's body image, but most patients report improved body image following surgery and no regret over the loss of sexual function [17, 19, 29, 44, 56]. In their series of 40 patients with self-created goals, Hullfish and colleagues found a 96.9% improvement in self-image after surgery [22]. Utilizing questions regarding body image and perception, Koski and colleagues found that 50% of patients felt that their body looked better after colpocleisis and 82% reported their body felt better after the procedure [17]. Overall, colpocleisis is associated with a high satisfaction rates and low rates of regret.

Because colpocleisis eliminates the possibility of future vaginal intercourse, preoperative counseling is extremely important and patient selection is key. There is no identified minimum age requirement for consideration of the procedure. With colpocleisis, as in all cases of prolapse repair and reconstruction, the treatment plan must be individualized for each patient. Preoperative counseling should be specific and thorough including information on potential pessary management, alternative options for repair, possibility of postoperative urinary incontinence and recurrence risk.

A retrospective cohort by Krissi and colleagues found that in women with Stage 3 or 4 prolapse the greatest risk factors for recurrence were longer vaginal length and wider genital hiatus. Objective recurrence was defined as Stage 2 prolapse or greater in any compartment and subjective recurrence was defined by patient perception [57]. Medical comorbidities, BMI, length of menopause and number of vaginal deliveries did not affect recurrence. Furthermore, one study of 107 women found that there was a higher rate of recurrence in women who delayed surgery after onset of prolapse (24.6 ± 22.8 years) versus those who did not (8.0 ± 12.9 years $p = 0.02$) [58].

In the carefully selected patient, these results demonstrate that an obliterative procedure remains a particularly good option following a thorough informed discussion.

Concurrent Procedures

Concurrent Hysterectomy

It is important to note that hysterectomy with concurrent colpocleisis does not improve success rates over colpocleisis alone [14, 41, 57], and has been associated with an increased blood loss and patient transfusion requirements [14]. The American College of Surgeons national surgical quality improvement program reported more occurrences of major postoperative complications with concomitant hysterectomy, but no difference in the rate of overall complications [19, 59]. A similar review of colpocleisis versus colpocleisis with hysterectomy by Bonchenska and colleagues reported that 87% of women opted for colpocleisis alone and had shorter operative times [60]. Due to these concerns, exceptions to the above recommendations may be reasonable in patients who are of advanced age or debilitated and should be a joint decision between the patient and the surgeon.

Concurrent Midurethral Sling

The option for concurrent midurethral sling placement should also be discussed with patients, specifically, in the situation of demonstrated SUI in the setting of incomplete bladder emptying as well as patients with no preoperative urinary incontinence. The addition of a midurethral sling does not appear to cause a high risk of urinary retention and preoperative incomplete bladder emptying seems to resolve in most patients [34, 61]. In a series of 38 women who underwent colpocleisis and midurethral sling placement, Abbasy and colleagues reported a 2% rate of elevated PVR postoperatively. Additionally, they saw a 90% postoperative resolution of preoperative incomplete bladder emptying (defined as PVR greater than 100 ml) [61]. In a much larger series of 210 women, Smith and colleagues found a de novo voiding dysfunction rate of 1.9% in women who underwent colpocleisis and midurethral sling. Similarly, they found a 91% resolution of preoperative incomplete emptying [34]. An alternative, nonpermanent approach is to offer periurethral bulking injections to patients for whom the risk of retention is thought to be particularly high.

The decision whether to offer a midurethral sling to continent patients at the time of colpocleisis remains controversial. As detailed above, the risk for de novo SUI may be quite significant; however, midurethral slings are not without complications or sequela. A large randomized controlled trial by Wei and colleagues specifically addressed this question by randomizing women without SUI who were undergoing vaginal prolapse repair to either have a midurethral sling or sham sling incisions. The sling group had significantly decreased rates of urinary incontinence at both 3 (23.6% vs. 49.4% ($p < 0.001$)) and 12 months (27.3% vs. 43.0% ($p = 0.002$)) [35]. However, the sling group did have significantly higher rates of complications including the following: bladder perforation, urinary tract infection, major bleeding complications, and incomplete bladder emptying for up to 6 weeks following surgery. Also, of note 5% of patients in the sham group had a sling placement within the first year after surgery, but only 2.4% of patients in the sling group required sling revision for voiding dysfunction. A detailed discussion of all the possible risks and benefits should be carried out with patients when making the determination of whether to place a sling in this population.

Surgical Procedures

All patients receive a preoperative prophylactic broad-spectrum antibiotic. Additionally, all patients have DVT prophylaxis; our standard is to use compression stockings and sequential compression devices on the lower extremities (Table 6.1).

For a patient in whom the uterus is to remain in situ, a LeFort colpocleisis is performed. To begin, outward traction is placed on the cervix using a tenaculum or Allis clamp. Two rectangles (anterior and posterior) are outlined with a surgical marker starting approximately 2 cm distal to the cervix and extending to the bladder neck anteriorly and mirroring this posteriorly. This will aid in maintaining orientation during removal of the vaginal epithelium. Laterally, there should be at least 2 cm of epithelium separating anterior from posterior rectangles in order to allow adequate tissue for creation of the drainage channels. Starting with the posterior wall 1% lidocaine with a 1:200,000 dilution of epinephrine is infiltrated in to the subepithelial space to aid in hemostasis and hydrodissection. The demarcated areas are circumscribed with knife and sharp dissection is performed to start the removal of the vaginal epithelium from the underlying fibromuscularis. It can be helpful to refrain from making all incisions initially but rather to proceed in a systematic fashion (posterior to anterior) in order to decrease blood loss and improve visualization during dissection. Typically, a combination of sharp and blunt finger dissection with a sponge can be employed to facilitate removal of the epithelium once the appropriate plane is achieved. Hemostasis is maintained with meticulous use of monopolar cautery throughout the dissection. With the LeFort procedure, only the areas of anterior and posterior rectangles are denuded.

Table 6.1 Risk classification for venous thromboembolism

Level of risk	Definition	Prevention strategies
Low	Surgery less than 30 min in patients younger than 40 years with no additional risk factors	No specific prophylaxis, early mobilization
Moderate	Surgery lasting less than 30 min in patients with additional risk factors	Low-dose unfractionated heparin: (5000 units every 12 h) OR Low molecular weight heparin: (2500 units dalteparin or 40 mg enoxaparin daily) OR Graduated compression stockings OR Intermittent pneumatic compression device
	Surgery lasting less than 30 min in patients aged 40–60 years with no additional risk factors	
	Major surgery in patients younger than 40 years with no additional risk factors	
High	Surgery lasting less than 30 min in patients older than 60 years or with additional risk factors	Low-dose unfractionated heparin: (5000 units every 8 h) OR Low molecular weight heparin: (5000 units dalteparin or 40 mg enoxaparin daily) OR Intermittent pneumatic compression device
	Major surgery in patients older than 40 years or with additional risk factors	
Highest	Major surgery in patients older than 60 years plus prior venous thromboembolism, cancer, or molecular hypercoagulable state	Low-dose unfractionated heparin: (5000 units every 8 h) OR Low molecular weight heparin: (5000 units dalteparin or 40 mg enoxaparin daily) OR Intermittent pneumatic compression device/ graduated compression stockings + low-dose unfractionated heparin or low molecular weight heparin Consider continuing prophylaxis for 2–4 weeks postop

Based on data from Refs. [62, 63]

To continue the LeFort procedure, channels are created after the removal of the epithelium and prior to starting closure of the vagina. Absorbable suture is used to tubularize the lateral strips of epithelium by suturing the epithelial edges together superior to inferior. This may be done with an interrupted or running stitch. Our preference is to use 2-0 polyglycolic acid suture on a CT2 needle and run this closure toward the cervix, thus allowing the surgeon to sew toward herself. These channels will allow the drainage of cervical and uterine secretions. Care should be taken to continue to identify the location of the channels throughout the rest of the procedure in order to avoid inadvertently suturing them closed.

Following creation of the channels, imbricating sutures are placed in the fibromuscularis to begin reduction of the prolapse. Successive anterior to posterior imbricating sutures in either an interrupted or figure-of-eight fashion are the most effective when reducing the epithelialized cervix. Once the cervix has been fully reduced, it is usually most straightforward to continue with anterior to posterior imbrication until the prolapse has been reduced to the level of the levator plate. Cystoscopy is then carried out following administration of Indigo Carmine to ensure ureteral efflux. From this point onward, the procedure is completed with a levator plication and perineorrhaphy in the same fashion as a complete colpocleisis is performed without the uterus in situ.

As addressed above, concomitant hysterectomy should be performed for patients with a contraindication to retention of the uterus. This combined procedure can have increased morbidity due to inherent risk of entry into the peritoneal cavity, increased operative time, and increased blood loss. Following vaginal hysterectomy, the

cuff should be closed to protect the intraperitoneal structures at which point removal of the epithelium is then started.

In the patient with a prior hysterectomy, a complete colpocleisis requires the removal of entire vaginal epithelium. A surgical marker is used to outline the lateral borders of dissection along the perineum, vaginal sidewalls, and anterior vaginal wall proximal to the urethra. This may be further demarcated into quadrants in order to aid in maintaining orientation, which can be easily lost, during dissection with severe prolapse (Figs. 6.2 and 6.3). Injection of 1% lidocaine with a 1:200,000 dilution of epinephrine into the subepithelial space may be utilized to aid in hemostasis and hydrodissection [64]. The demarcated areas are circumscribed with a knife and sharp dissection is used to initiate removal of the vaginal epithelium from the underlying fibromuscularis. Similarly to the LeFort, it is best to proceed in a systematic fashion in order to maintain orientation, decrease blood loss, and preserve visualization. The authors would recommend posterior to anterior (Fig. 6.4). Again, once the appropriate plane is entered, a combination of sharp and blunt dissection can be used to separate the epithelium from the fibromuscularis (Fig. 6.5a–c). Attention should be given to maintaining hemostasis throughout the dissection with judicious use of the monopolar cautery. Significant blood loss can be encountered when performing extensive dissection on severe prolapse, so all efforts toward hemostasis will help to decrease the need for transfusion.

It is not uncommon to encounter an enterocele during removal of the vaginal epithelium. An attempt should be made to avoid entering the enterocele. However, these dissections can be challenging and with some severe defects, there may be peritoneum directly abutting vaginal epithelium. If an enterocele is entered, the sac should be meticulously mobilized circumferentially from the surrounding tissue with special care taken to avoid small bowel injury. The enterocele sac should then be tied off using an absorbable suture and a circular purse-string stitch. For large defects in the peritoneum, 2–3 full purse-string sutures are required to ensure adequate closure. If there is an excessive amount of redundant, prolapsing enterocele sac, the peritoneum can be trimmed circumferentially for a more proximal and effective closure.

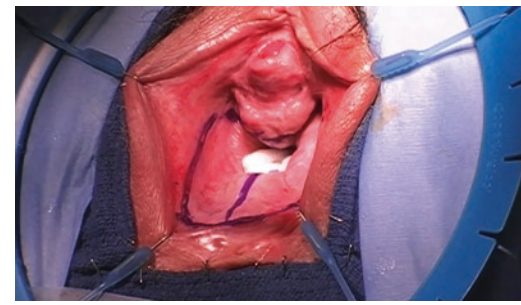

Fig. 6.3 Boundaries of perineal dissection

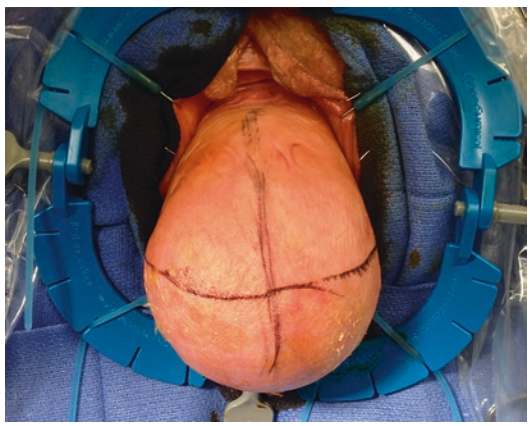

Fig. 6.2 Demarcated quadrants for dissection

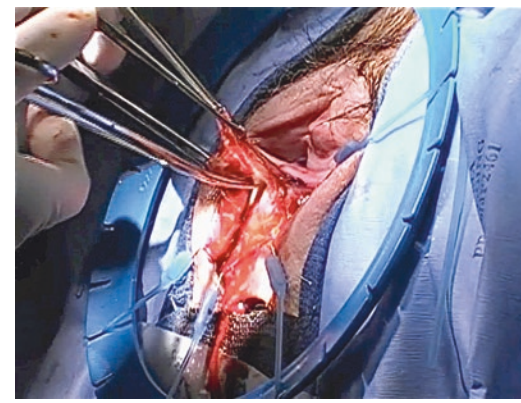

Fig. 6.4 Posterior dissection of vaginal epithelium from fibromuscularis

Following removal of the vaginal epithelium, reduction of the prolapse can be performed with one of two techniques or a combination of both. One option is to use successive anterior to posterior imbricating sutures in either an interrupted or figure-of-eight fashion. Alternatively, sequential, circular purse-string stitches are an effective technique for reduction of the prolapse (Fig. 6.6). The authors favor using 2-0 polyglycolic acid suture on a CT2.

Several centimeters of vaginal epithelium should be retained on the distal, anterior vaginal wall underneath the urethra. This is recommended for all patients whether they are having a concomitant sling placement or not. Maintenance of this distal epithelium prevents excessive traction on the urethra and leaves room for immediate or future sling placement. Placement of a midurethral sling is most easily achieved after the prolapse has been reduced to or above the levator plate and before levator plication.

Cystoscopy with IV indigo carmine administration is performed at this point to rule out bladder injury and ureteral obstruction. If ureteral obstruction is diagnosed on cystoscopy, a prudent first step is to remove the anterolateral sutures, as this is often the location where the ureters are

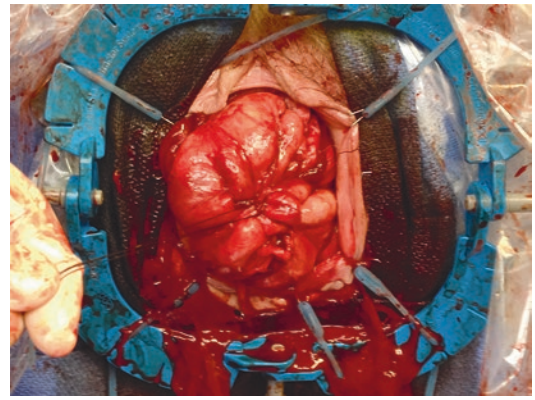

Fig. 6.6 Purse-string reduction of prolapse

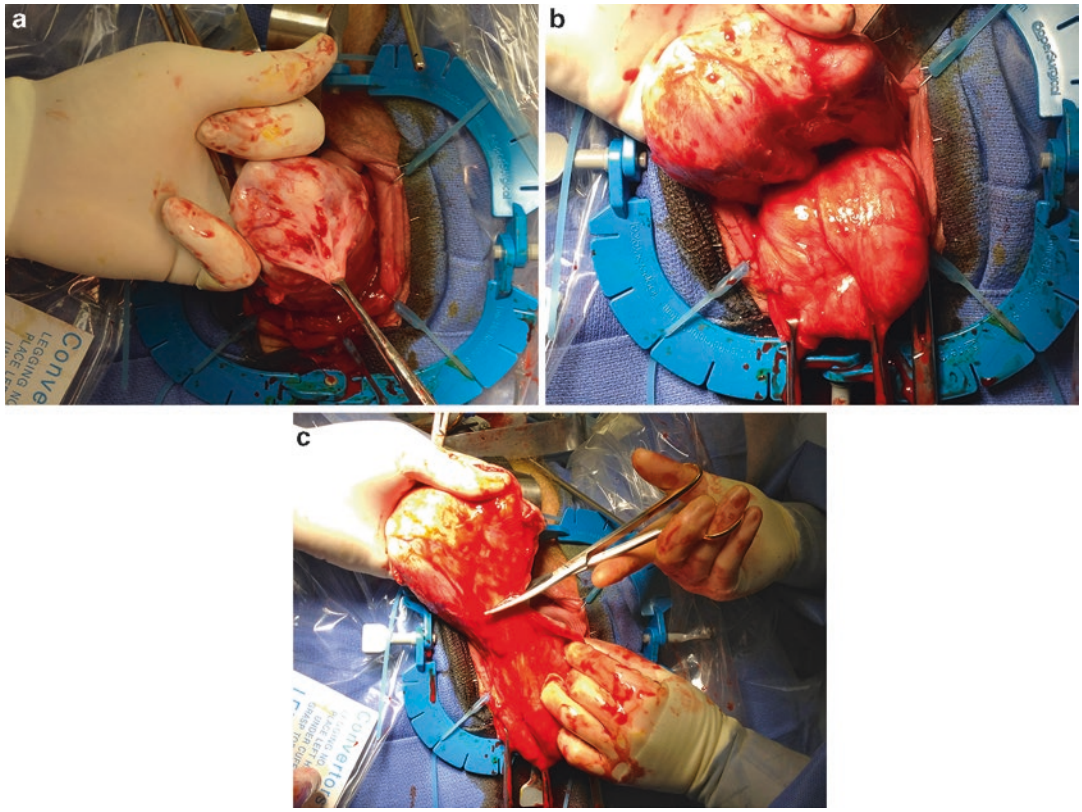

Fig. 6.5 (**a**–**c**) Dissection and removal of vaginal epithelium

encountered. Cystoscopy is then repeated to ensure ureteral patency.

Next, a levator plication is performed to close the genital hiatus and buttress the repair. Using 2-0 polyglycolic acid suture on a CT 2, interrupted or figure-of-eight sutures are performed pulling the muscles together in the midline (Fig. 6.7). Initially, excessively lateral bites of tissue can cause undue tension and may make it difficult to achieve approximation in the midline. Following levator plication, the perineorrhaphy should include reapproximation of the transverse perineal and bulbocavernosus muscles at the introitus. Finally, the vaginal epithelium is reapproximated in 1–2 layers with a subcutaneous and a subcuticular stitch or a running through and through stitch (Fig. 6.8).

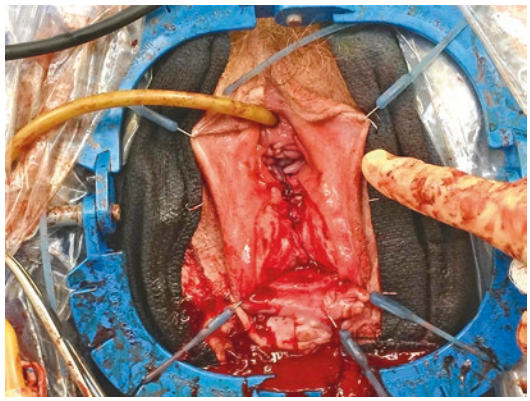

Fig. 6.7 Completed levator plication

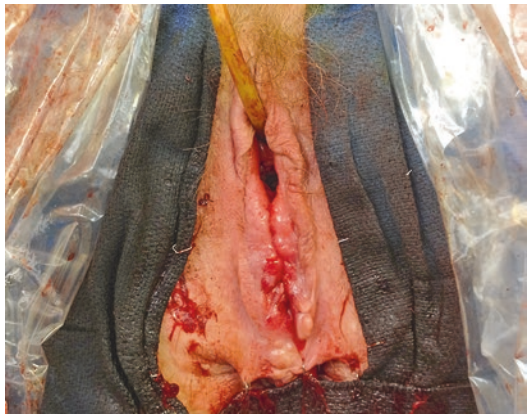

Fig. 6.8 Completion of perineorrhaphy

Summary

Colpocleisis is a successful operation with few complications, and postoperatively patients report minimal regret and significant improvement in quality of life. SUI should be evaluated preoperatively but may warrant postoperative reassessment based on patient symptoms. Concurrent procedures are associated with more risks and should be carefully chosen. Urgency urinary incontinence after these surgeries can be problematic and may require additional medical treatment. Overall, the procedure is an effective option in the properly selected patient.

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7 Open Transabdominal Sacrocolpopexy

Christopher F. Tenggardjaja, Tyler A. Kern, and Sandip P. Vasavada

Introduction

Pelvic organ prolapse (POP) is a common condition with an estimated 19% lifetime risk for undergoing a surgical procedure for treatment. Although transvaginal and minimally invasive techniques have been developed, transabdominal sacrocolpopexy (ASC) remains the gold standard for the treatment of apical prolapse. Surgical preparation for ASC begins with a thorough history and physical examination culminating in an earnest discussion between the patient and the surgeon regarding treatment options and goals of therapy. Open ASC requires the pelvic surgeon to have technical prowess in abdominal surgery and a familiarity with pelvic anatomy. Long-term surgical outcomes for ASC are durable and efficacious with acceptably low rates of complications and recurrence. Although ASC has been around since the 1960s in its modern form, the technique has continued to evolve, and controversies such as concomitant anti-incontinence procedures are addressed in this chapter.

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Background

POP affects nearly 50% of parous women and is a common finding on pelvic examination [1, 2]. Despite its high anatomic prevalence, a 3% symptomatic prevalence was noted in the 2005–2006 National Health and Nutrition Examination Survey and other studied populations demonstrate an 11–19% lifetime risk of undergoing surgery for treatment of POP [3–5]. Traditionally, management of the patient with POP depends on several different factors including the patient's preferences, comorbidities, and the surgeon's expertise. Treatment options vary from pelvic floor physical therapy to pessary usage to surgical correction. Surgical treatment options depend on the compartment which has prolapsed. Regarding apical prolapse, surgical treatment consists of either an obliterative or a restorative approach. Patients who are no longer sexually active are candidates for an obliterative approach with a colpocleisis. For those who prefer a restorative approach, the gold standard for apical POP after hysterectomy is transabdominal sacrocolpopexy (ASC) [6].

History

Treatment of POP has been described by various cultures throughout history. An Egyptian papyrus from 1550 B.C. described the treatment of a "displaced womb" using oil, manure, and honey [7].

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During the Hippocratic era (400 B.C.), treatment options ranged from irrigating a displaced uterus with wine to succussion, a practice in which a woman was hung upside down for several minutes [8]. Pessary usage has been described since the middle ages with dipping linen and wool cloth into different potions [9]. While there are various techniques for the surgical management of apical prolapse, the gold standard of ASC was developed as a counterpart to the transvaginal techniques for addressing apical vault prolapse. Huguier and Scalin in 1958 and Lane in 1962 described using a graft to attach the vaginal cuff to the sacrum [10–12]. The S3–S4 graft placement was subsequently described by Birnbaum but was later revised to the S1–S2 level by Sutton after hemorrhage [13, 14]. Although different biologic and artificial grafts have been used in surgical correction/augmentation of POP repair, ASC continues to be the gold standard.

Patient Evaluation

All patients referred for POP undergo a complete history and physical examination at their initial visit. Quality of life and baseline symptoms are documented with various questionnaires such as the Urinary Distress Inventory (UDI) and Incontinence Impact Questionnaire (IIQ). A focused history of present illness can elicit symptoms of prolapse including obstructive emptying, bulging sensation toward the end of the day, vaginal soreness/bleeding, and splinting with voiding or defecation. A thorough review of systems also evaluates for any urinary incontinence related to urgency or stress, defecatory issues, and comorbidities (such as neurologic disease) that may affect continence and bladder function. Prolapse surgery remains an elective surgery that has the ability to greatly improve a patient's quality of life. A careful evaluation of medical and surgical history may change the approach or rule out surgery as an option for those patients with multiple exclusionary comorbid conditions. A vaginal approach for prolapse correction may be associated with less morbidity in a patient who has had multiple abdominal surgeries and is at risk for adhesive disease. Parity, method of delivery, and family history are taken into account, as these are risk factors for POP [15–17]. For all patients, we believe it is paramount to address the patient's goals at the first visit. If they are not interested in sexual intercourse, obliterative procedures, such as colpocleisis become a viable surgical option for prolapse. For those who wish to spare their uterus, the discussion may include sacrospinous hysteropexy or sacrohysteropexy.

A routine pelvic examination is performed in the office with a half speculum. Visual examination can assess for vaginal atrophy, abnormal discharge, rashes, or masses. Urethral tip angulation suggesting hypermobility is assessed with a cotton tip applicator in the urethra. Measurements are obtained and recorded using the POP-Q classification (Fig. 7.1) [18]. Stress urinary incontinence (SUI) is elicited with a supine stress test and occult SUI is tested for with reduction of the prolapse.

Given the results of the Colpopexy and Urinary Reduction Efforts (CARE) and Outcomes Following Vaginal Prolapse Repair and Midurethral Sling (OPUS) trials, all our patients are counseled on the advantages of a concomitant anti-incontinence procedure at the time of POP surgery [19, 20].

Subsequently, all patients who have comorbidities such as coronary artery disease, obstructive sleep apnea, uncontrolled hypertension, diabetes, or symptoms suggesting undiagnosed medical problems are referred to anesthesia for preoperative clearance. Prior to surgery, all patients are instructed to refrain from taking NSAIDs/anticoagulation medications for up to 1 week prior to surgery, and to perform a bowel preparation to decrease stool content in the pelvic region. For patients who routinely smoke, we advise them to stop smoking to aid with recovery, wound healing, and improve their overall health. An informed consent is performed in conjunction with the patient and operating surgeon. Given the FDA announcements regarding transvaginal mesh, numerous questions can be expected given that ASC is most successfully performed using an artificial synthetic graft material. It is important to note that the FDA announcement focuses

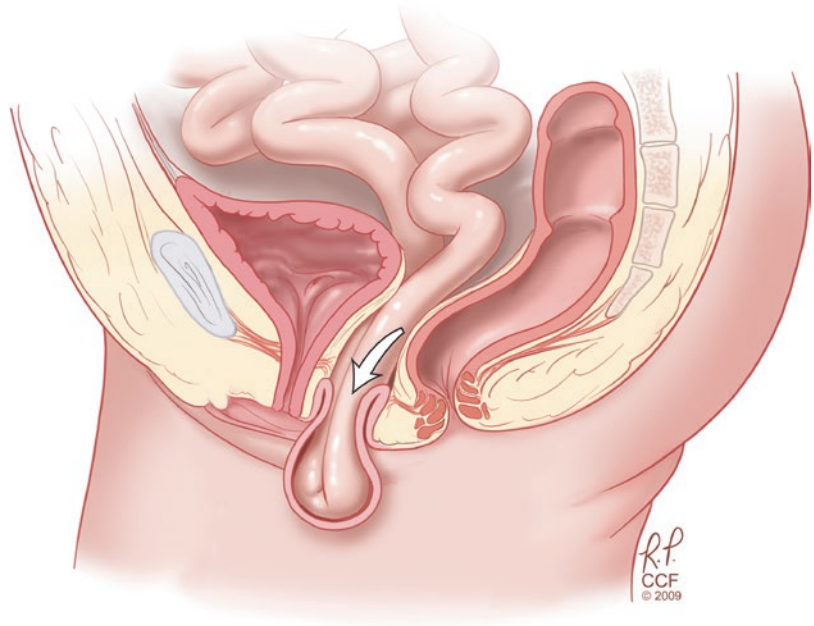

Fig. 7.1 Sagittal view of enterocele in post-hysterectomy patient. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2009–2019. All Rights Reserved)

on transvaginal mesh placement rather than ASC (Table 7.1). We do not routinely correct anterior/posterior compartment defects at the time of ASC, but this should be individualized to each patient depending on goals and symptoms. Concomitant anti-incontinence procedures are typically performed with a mid-urethral sling utilizing synthetic macroporous polypropylene mesh, with efficacy and safety previously demonstrated in long-term studies [21, 22].

Complications of ASC are discussed with all patients and include the risk of infection (UTI 10.9%, wound infection 4.6%), blood transfusion (4.4%), bladder/bowel or ureteral injury (1–3%), and DVT or PE (3.3%) [23]. Ileus and small bowel obstruction requiring reoperation are quoted at 6.9% and 1.2%, respectively [24]. Extrusion rates with polypropylene mesh from 0.5% to 10.5% are quoted [23, 25, 26]. Subjective improvement based on global assessment is quoted upwards of 85% [27]. Rates of reoperation for POP are expected to be less than 5% in modern series but can be as high as 29% [3, 23, 27]. Of note, the rate of reoperation for POP following ASC is likely due to persistent or de novo anterior or posterior POP rather than recurrent apical POP [28, 29].

Technique

The day of surgery, patients arrive in the preoperative care unit where an intravenous line is started by anesthesia. Perioperative antibiotics are administered within 60 minutes of the surgical incision. Given the intra-abdominal nature of the case, we prefer using cefazolin or clindamycin and gentamycin in patients who have a severe penicillin allergy or allergy to cephalosporins [30]. Subsequently, the patient is positioned in the lithotomy position with a slight amount of flex to open the pelvis. We routinely utilize yellow fin stirrups for the legs. All pressure points are padded. Sequential compression devices are placed. The patient's vagina and abdomen are prepped. Preoperatively a dose of prophylactic subcutaneous 5000 units of heparin or 40 mg enoxaparin is administered.

The patient is then prepped and draped. A 16 fr Foley catheter is placed to empty the bladder. One may choose to make either a Pfannenstiel or lower midline incision. Camper's and Scarpa's fascia are dissected through with electrocautery. The rectus is split in the midline. The transversalis fascia and peritoneum are opened close to the umbilicus. Any adhesions encountered are taken

Table 7.1 FDA safety communication

FDA safety communication: serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse
The FDA first released a notice in 2008 regarding the complications of transvaginal mesh placement for POP. In July 2011, an update was provided regarding transvaginal mesh usage in POP. Given the additional 2874 reports of complications received from January 1, 2008, to December 31, 2010, they concluded that serious complications are not rare. While open ASC utilizes artificial synthetic mesh, this FDA notification does not apply specifically to transabdominal mesh placement for pelvic organ prolapse (see below). Although not specific to transabdominal mesh placement, this notice highlights the need for patient education and a thorough informed discussion process between the surgeon and the patient regarding the realistic goals of treatment and the complications stemming from any surgery. The following is a summary of the recommendations for healthcare providers:
Obtain specialized training for each technique; be aware of the risks
Be vigilant for potential adverse effects
Watch for complications associated with tools used for mesh placement
Inform patients of the permanency of mesh and that some complications may need additional surgery
Inform patients that complications can affect their quality of life due to dyspareunia, scarring, and narrowing of the vagina
Provide patients with a patient labeling from the mesh manufacturer
POP can be treated without mesh
Choose mesh after weighing the risks and benefits of all alternative options
Consider the following before placing mesh:
Mesh is permanent making further surgery difficult
Mesh may put the patient at risk for further surgery and the development of new complications
Removal of mesh is difficult and may require multiple surgeries and poorer quality of life due to complications
Mesh placed abdominally for POP repair may result in lower rates of mesh complications compared to transvaginal mesh
Inform the patient about all options for POP including nonsurgical and nonmesh including the likely success of the alternatives
Notify the patient if mesh will be used and what specific type
Ensure the patient understands the risks and complications including the limited long-term data

down sharply with Metzenbaum scissors. Pelvic exposure is improved by using a self-retaining Bookwalter retractor and packing the rectum to the patient's left side. The anterior plane of the vagina is dissected away from the bladder. We find that utilizing an end-to-end anastomotic (EEA) sizer or sponge stick in the vagina helps in exposing the vagina and aiding with dissection. Only in extreme cases of scarring do we find it appropriate to backfill the catheter to find the bladder. Once the bladder has been dissected free from the vagina, the posterior vagina is addressed. The vagina is dissected free from the rectum. Again, in conditions of extreme adhesion or uncertainty do we find an additional EEA sizer useful for rectal delineation.

Once the anterior and posterior walls of the vagina are free, dissection of the anterior longitudinal ligament is performed. Care is taken to incise the peritoneum overlying the sacral promontory at the midline in a longitudinal fashion and avoid the iliac vessels. Bleeding in this area can be attributed to any number of vessels in the area including the middle sacral vessels, superior and inferior hypogastric plexus. In cadaveric studies, on average, the left common iliac vein was the closest major vessel (2.2–2.7 cm) to the mid-sacral promontory while the middle sacral artery and vein were closer at less than a centimeter (Fig. 7.2) [31]. After the sacral promontory at the level of S1 is cleared off, two pieces of 3 × 15 cm macroporous synthetic polypropylene mesh are used for grafting. While many different biologic (fascia lata, rectus fascia, and porcine dermis) and artificial synthetic grafts (polytetrafluoroethylene, polyester, polyethylene, and silicone coated) have been used, we prefer to use polypropylene mesh given its efficacy and decreased rate of exposure/erosion (Fig. 7.3a, b) [32–36]. The polypropylene mesh

is attached to the anterior and posterior vaginal wall using non-braided delayed absorbable suture such as polydioxanone. Alternatively, several permanent monofilament sutures can be utilized away from the anterior bladder dissection. The mesh is fixated at approximately 5 points along both the posterior and anterior vaginal walls. These are preferentially tied down with multiple knots given the location deep in the pelvis (Fig. 7.4). We have also utilized non-absorbable braided suture for graft fixation, but patients may occasionally complain about continued vaginal discharge from suture exposure. Multiple studies have suggested a higher rate of

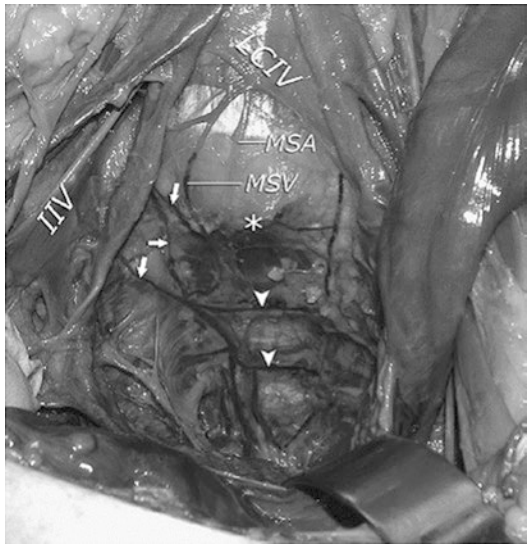

Fig. 7.2 Cadaver pelvic vascular anatomy dissection. Sacral venous plexus. Left common iliac vein (LCIV), internal iliac vein (IIV), middle sacral artery (MSA), middle sacral vein (MSV), mid-sacral promontory (asterisk), lateral sacral veins (arrows), and sacral venous plexus anastomoses (arrowheads). (Reprinted from Wieslander et al. [31]. With permission from Elsevier)

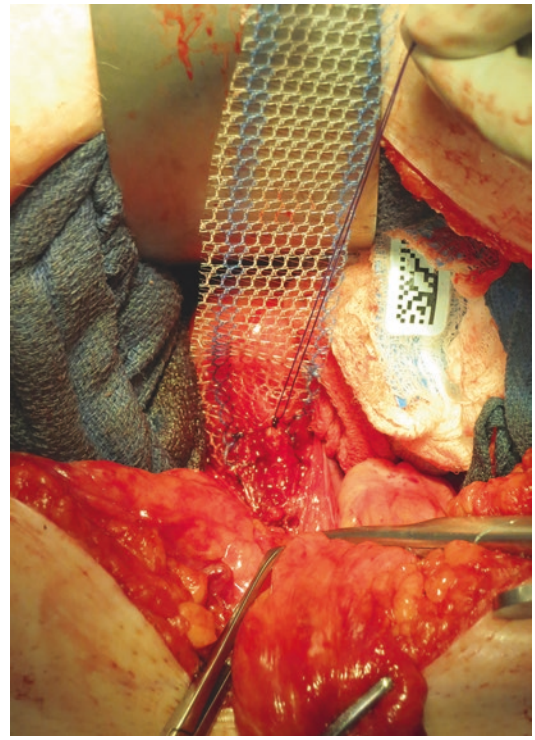

Fig. 7.4 Placement of mesh over the anterior portion of the vagina. We prefer to suture the mesh onto the anterior vagina with absorbable monofilament suture with multiple knots to secure the mesh deep in the pelvis

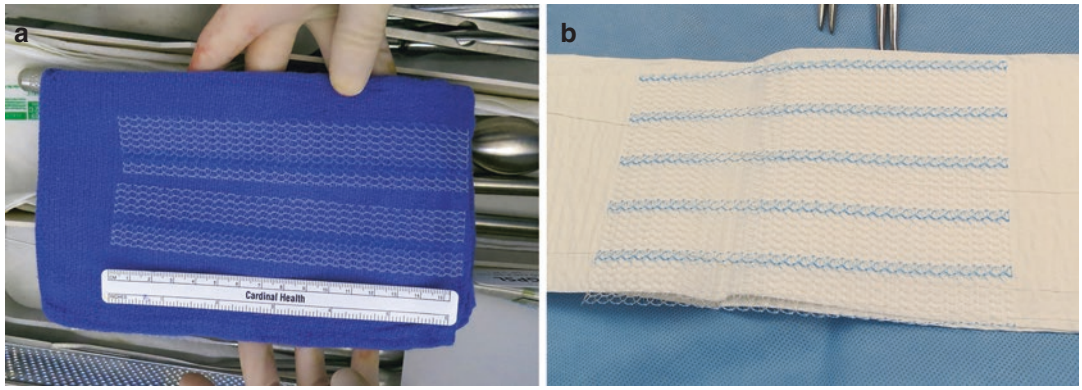

Fig. 7.3 Macroporous polypropylene synthetic mesh used for sacrocolpopexy. (**a**) Cut mesh. (**b**) Whole mesh

exposure/extrusion correlated with the use of braided suture material but they are limited by their small sample sizes, heterogeneous use of graft material and retrospective nature. No prospective trial exists evaluating the risk associated with monofilament absorbable suture and braided suture on polypropylene mesh extrusion/erosion in ASC [33, 37, 38].

With an EEA sizer in the vagina to reduce the prolapse, the mesh tails are tensioned appropriately and fixated to the anterior longitudinal ligament. Tensioning should be done to assure at least mobility to the bladder neck and avoid undue tension to keep the vaginal axis straight, avoiding upwards deviation. The excess mesh is then trimmed. Our suture of choice for fixation to the sacral promontory is a non-braided permanent suture (Fig. 7.5). Two sutures are placed in a horizontal fashion on the anterior longitudinal ligament. In a cadaveric study utilizing female non-embalmed specimens, horizontal versus vertical suture placement was not found to be statistically significant in regards to pull out strength in sutures placed at or 1 cm above the level of S1 [39]. Care should also be taken to place the suture in the anterior longitudinal ligament and not through the disc space which could lead to increased risk for infection or discitis. In an MRI study evaluating the lumbosacral spine in women, the L5-S1 disc was identified as the true sacral promontory rather than the S1 vertebrae in the majority of cases [40]. Risk can also be minimized by ensuring that the vaginal fixation sutures are not through the vaginal epithelium [41–43].

At this time, the peritoneum is reapproximated over the mesh. Although retroperitonealization of the mesh does not necessarily lead to fewer complications, re-approximation of the peritoneum adds little time and morbidity to the surgery [44]. If a large defect in the posterior cul-de-sac is seen, culdoplasty can be performed at this time. Anecdotally, given the advent of minimally invasive sacrocolpopexy there has been a decrease in concomitant culdoplasty with minimal change seen in objective results. From below, the apical prolapse is reassessed to ensure the defect has been corrected. The anterior and posterior compartments are reassessed after ASC. Any anterior or posterior vaginal repairs are performed at this time. We do not routinely offer a posterior colporrhaphy to all prolapse patients and concomitant posterior colporrhaphy is based on the patient's preferences and symptoms (Fig. 7.6).

If an anti-incontinence procedure is to be performed, an assistant can begin with the vaginal dissection and exposure for a retropubic midurethral sling while the abdomen is being closed. Hemostasis is confirmed by visualization. The pelvis is irrigated with body temperature saline. All surgical counts are verified. The abdominal closure is done in a sequential fashion using #1 looped polydioxanone for fascial closure. In obese patients, we prefer to re-approximate Scarpa's fascia to avoid dead space. The skin is addressed with a running subcuticular stitch using polyglactin suture. Cyanoacrylate skin adhesive is used for the skin. A vaginal pack soaked in povidone–iodine solution is placed. The patient is woken up from anesthesia and monitored in the postanesthesia recovery unit. Patients are then transitioned to an acute surgical floor. Intravenous fluids are continued at maintenance rates until the patient is tolerating a diet. All patients are started on a prophylactic deep vein thrombosis regimen including early ambulation and subcutaneous heparin. On postoperative day 1, the vaginal pack is removed and a trial of void is performed. Postoperative labs are not routinely checked after surgery unless bleeding occurred or a patient is symptomatic [45]. The patient is transitioned to oral pain medication when they are tolerating a diet. All patients receiving narcotics receive a stool softener to reduce the incidence of constipation. Postoperative length of stay is usually 2–4 days.

Patients are discharged from the hospital with postoperative instructions. All patients are told to refrain from heavy lifting greater than 10 lbs. during this time period, avoid strenuous activity (although avoidance of any activity such as walking is contraindicated), and avoid vaginal instrumentation/sexual intercourse. Follow-up is scheduled at 6 weeks. At the patient's follow-up visit, we routinely perform a physical examination to assess for POP recurrence and graft exposure/extrusion.

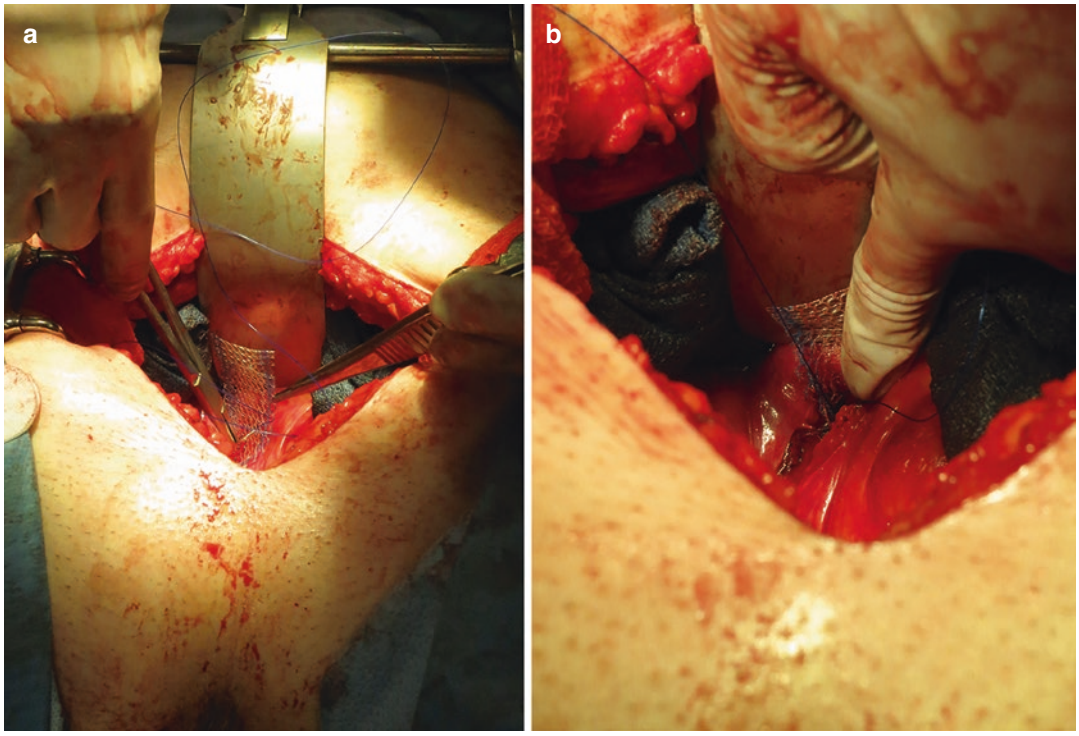

Fig. 7.5 The tails of the mesh are sutured to the anterior longitudinal ligament using nonabsorbable monofilament suture

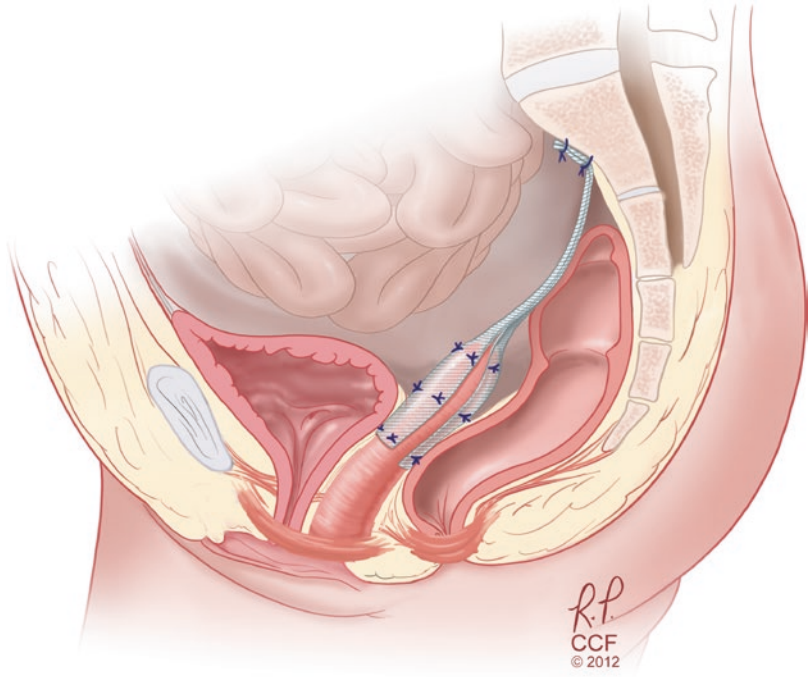

Fig. 7.6 Sagittal view of ASC repair with synthetic mesh. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography © 2009–2019. All Rights Reserved)

Outcomes

Definition of Success

Success of ASC encompasses a heterogeneous definition of outcomes. Anatomic success, defined by lack of apical prolapse on an objective POP-Q measurement at postoperative evaluation, ranges from 78% to 100%. Subjective success, including patient satisfaction, can range from 85% to 100% [23]. In a randomized controlled study comparing ASC to vaginal sacrospinous colpopexy, subjective success based on prolapse symptoms and satisfaction of ASC using a visual analog scale was 94% and 85%, respectively, at an average of 2 years [46]. In one of the longest follow-ups at a mean of 13.7 years, Hilger et al. demonstrated a 74% success rate with ASC. Success in this study was defined by either no reoperation for POP or a negative answer to question 5 on the Duke Pelvic Floor Distress Inventory ("Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?"). Of the 38 patients included in this study, 4 patients (10.5%) underwent reoperation and 6 patients (15.8%) answered "yes" to question 5 on the Duke Pelvic Floor Distress Inventory. Twelve of the original 38 women included in the study were available for physical examination. Of the 12 women who were examined, including 6 patients who had failed by their criteria, no patients had greater than stage II prolapse on examination [47]. The CARE trial was a multicenter randomized controlled trial that randomized continent women undergoing ASC to receive a Burch colposuspension at the same time of surgery [19]. This was designed to evaluate whether postoperative SUI symptoms were reduced by concomitant Burch colposuspension during ASC in continent women. Long-term follow-up of this cohort evaluated rates of anatomic and symptomatic failure. Anatomic failure was defined as reoperation or pessary for POP where the vaginal apex descends below the upper third of the vagina or the anterior/posterior vaginal wall descends past the hymen. Symptomatic failure was defined as a positive response to one or more questions on the POP distress inventory referring to seeing or feeling a bulge or reoperation or pessary for POP. At a follow-up of 7 years, the anatomic failure rate was 27% and the symptomatic POP failure rate was 29% in the urethropexy arm [26].

Attempting to address this obtuse definition of success in ASC patients, Barber et al. evaluated the data from the CARE trial and applied 18 different surgical success definitions. Among their objectives was to describe how using different definitions affect estimates of treatment success and compare different definitions of surgical success by examining their relationship to patient's subjective assessments of improvement. At 2 years, 94% of patient's achieved surgical success when it was defined by the absence of prolapse beyond the hymen. When applying National Institutes of Health definitions of outcomes such as optimal (POP-Q stage 0) or satisfactory (support higher than 1 cm proximal to hymen), the rates of success were lower at 19% and 57%, respectively [27].

Rates of reoperation for prolapse in the CARE trial were low at 2.8% over 2 years which rose to 5.1% over the course of 7 years [26, 27]. This is comparable to the 4.4% (0–18.2%) median reoperation rate observed in summarized published studies. The most common reason for reoperation was prolapse of the anterior or posterior compartment [23]. As previously discussed, Hilger et al. identified a 10.5% rate of reoperation at a mean follow-up of 13.7 years.

Genitourinary/Gastrointestinal/Sexual Function Outcomes

In regards to system-specific genitourinary, gastrointestinal, and sexual function after ASC, most studies in the past did not evaluate complaints with standardized validated questionnaires or in prospective fashion thereby making a generalization on outcomes difficult to assess. In a case–control study, evaluating women who had undergone ASC versus women who had solely undergone hysterectomy, patients were evaluated using a bowel function questionnaire and the Cleveland Clinical Incontinence Score (CCIS).

While those undergoing ASC had more significant obstructive defecatory symptoms (splinting, incomplete evacuation, and use of enemas), anal incontinence rates were not different. Incontinence was noted to be higher in patients who had obstetric anal injury. Unfortunately, results from this study are difficult to extrapolate without the context of preoperative symptom scores. On average, time from surgery to questionnaire was 8.1 years for the ASC group [48]. Grimes et al. evaluated the progression of posterior compartment prolapse over 5 years following ASC in CARE trial participants. Of the 36 women without posterior POP (Ap <0) prior to ASC, 2 patients (9%) subsequently developed posterior POP with obstructive defecatory symptoms; one of these patients went on to have a posterior repair. Of the 24 patients with evidence of baseline posterior POP (Ap >0) prior to ASC who did not undergo concomitant posterior repair, 23 patients (96%) had resolution of posterior POP with ASC alone. Of the 29 patients with posterior POP who underwent concomitant posterior repair at the time of ASC, 4 patients (14%) underwent subsequent posterior repair within 5 years and 3 patients developed recurrent posterior POP [49]. Evaluating 1-year bladder symptoms based on UDI changes in patients who participated in the CARE trial, de novo irritative voiding was reported in 12/131 (9.2%) women. For those with obstructive voiding symptoms before surgery, improvement was noted in 85.1%. A statistically significant mean reduction of PVR of 31 mL was observed postoperatively [50]. A 1-year follow-up was also evaluated in regards to sexual function in patients who participated in the CARE trial. Using the Pelvic Organ Prolapse/Urinary Incontinence Sexual Functioning Questionnaire (PISQ-12), patients who had a sexual partner before and after surgery were evaluated at 1 year for effects of surgery on sexual function. There was a statistically significant rise in the amount of women who were sexually active compared to prior to surgery (76.3% vs. 66.1%, p <0.001). Fewer women after ASC avoided sexual activity due to pelvic or vaginal symptoms, fear of incontinence, bulge in the vagina, or being limited by pain. It was noted that 11/148 (7.4%) women became sexually inactive after surgery. There was a higher proportion limited by pain, but this was not statistically significant (26% vs. 22% $p = 1.0$). The authors did note that there was a higher incidence of infrequent sexual desire among those who were inactive after surgery (70% vs. 22.1%, p <0.001) [51].

Open ASC Versus Laparoscopic/ Robot-Assisted ASC

Although ASC has been recognized as the gold standard surgery for apical POP repair, increased hospital stay, blood loss, and length of recovery have all been listed as drawbacks of open ASC compared to other approaches [52, 53]. Minimally invasive surgery and robot-assisted laparoscopic surgery decrease the convalescence associated with transabdominal surgery. Siddiqui et al. evaluated robotic ASC outcomes at 1 year compared to patients in the CARE trial and found no significant difference in surgical failures as defined by bothersome vaginal symptoms or repeat surgery for prolapse (8% vs. 4%, $p = 0.16$). Operative characteristics that were significantly different between robotic versus open ASC include estimated blood loss (90 mL vs. 228 mL, p <0.01), concomitant hysterectomy (49% vs. 28%, p <0.01) and posterior repair at time of ASC (8% vs. 22%, p <0.01). Complications that were significantly different included wound disruption (0 vs. 4.3%, p = 0.01), febrile morbidity (4.8% vs. 10.9%, p = 0.04), and ileus (5.6% vs. 11.6%, p = 0.05) [54]. Rozet et al. similarly found laparoscopic sacral colpopexy to be efficacious in treating POP. The retrospective review evaluated 363 patients who underwent a laparoscopic sacrocolpopexy. 25% of patients had undergone a previous hysterectomy and only 4% had a concomitant hysterectomy. Complications were low with 2% requiring open conversion. Average hospital stay was noted to be 3.7 days. On average follow-up of 14.6 months, anatomic cure rate, which was not defined on postoperative visit, was noted to be 96% with a similar 96% satisfaction rate [55]. These rates are similar to those reported in a laparoscopic sacrocolpopexy review article

[56]. A retrospective cohort study evaluating laparoscopic sacrocolpopexy and ASC found that although mean operating time (269 vs. 218 minutes p <0.0001) was longer in the laparoscopic cohort, mean hospital stay was significantly shorter (1.8 vs. 4 days, p <0.0001). Clinical efficacy was difficult to assess because not all patients had preoperative and postoperative POP-Q standardized scores [57]. The LAS trial was a randomized controlled equivalence trial comparing anatomic and subjective outcomes in 53 post-hysterectomy patients with vaginal vault prolapse that were randomized to undergo open or laparoscopic sacrocolpopexy. At 1-year follow-up, there was no significant difference in point C measurements using the POP-Q system (−6.63 cm for open approach vs. −6.67 cm for laparoscopic approach). There was no significant difference in subjective outcome assessed with the Patient Global Impression of Improvement (PGI-I) questionnaire, with 90% and 80% of patients endorsing a current condition of at least "much better" than prior to the open and laparoscopic intervention, respectively. The laparoscopic cohort had less blood loss (56.15 vs. 240.4 mL, p <0.01) and shorter length of hospital stay (3.2 vs. 4.1 days, p = 0.02) compared to the open cohort [58]. Coolen et al. similarly compared the outcomes of laparoscopic and open abdominal sacrocolpopexy in a randomized controlled multicenter study evaluating 74 women. At 1-year follow-up, there was no significant difference in POP-Q evaluation or disease-specific quality of life measured with UDI. The laparoscopic cohort had less blood loss [86 (IQR 10–100) versus 200 (100–300) mL (p <0.001)] and a shorter length of hospital stay [(2 (IQR 2–3) vs. 4 (IQR 3–5) days (p <0.001)] compared to the open cohort [59]. To date, no prospective randomized trial has been done to compare robotic ASC to open ASC [60].

Controversial Topics in Open ASC

Open ASC has been constantly evolving since being first described in the 1960s. The subjects of uterine sparing, concomitant hysterectomy at the time of ASC and concomitant anti-incontinence procedures are briefly discussed here.

Uterine Sparing

The surgical approach of ASC assumes that POP has occurred in the setting of the post-hysterectomy patient. For those with apical prolapse and an intact uterus, there continues to be a debate on whether to preserve the uterus. Proponents of uterine sparing would argue that keeping the uterus intact preserves sexual function, decreases the morbidity associated with hysterectomy, and maintains the body as a whole [61]. Detractors from uterine sparing point out that after parturition, the uterus no longer serves a useful function and that sexual function is not diminished after hysterectomy [62]. In a long-term randomized controlled study evaluating sacrocolpopexy with uterus preservation versus vaginal hysterectomy with colporrhaphy for the correction of prolapse, 8-year outcomes were not statistically different between the two groups in regards to reoperation rate and Incontinence Impact Questionnaire (IIQ) or POP-Q (Pelvic Organ Prolapse Quantification) scores [63]. Dietz et al. performed a multicenter randomized controlled study evaluating sacrospinous hysteropexy versus vaginal hysterectomy with uterosacral vault suspension and found increased rates of apical recurrence at 1-year after sacrospinous hysteropexy but no significant difference in IIQ or other functional outcomes and quality of life questionnaires [64]. Patient surveys indicate that 36–60% of women would decline hysterectomy and elect for uterine preservation if outcomes were equivalent. However, only 21% of women would elect for uterine preservation if superior outcomes were associated with concomitant hysterectomy [65, 66].

Concomitant Hysterectomy

After counseling a patient on the options, our preference in the patient with apical POP and an intact uterus is to perform a transvaginal

hysterectomy with vault suspension at the time of the procedure to address the prolapse along with a possible anterior or posterior repair if needed. Given the theoretical risk of cuff infection and mesh extrusion, we do not routinely perform ASC in the setting of a hysterectomy. Mattox et al. in a retrospective study found a higher rate of mesh infection in patients who underwent hysterectomy versus those who did not (27% vs. 1.3%) [67]. Markinkovic evaluated abdominal hysterectomy at the time of abdominal sacrocolpopexy. In a retrospective review of 67 patients who underwent total abdominal hysterectomy and sacrocolpopexy with two pieces of polypropylene mesh, no exposures/extrusions were noted at a median of 26 months follow-up [68]. This is in contrast to other series which included patients who had concomitant hysterectomies and erosion rates from 1.5% to 27% thought to be related to mesh type versus how the cuff was addressed during the time of hysterectomy [69–71]. Siddiqui et al. noted no mesh erosions at 1-year follow-up in any patients who underwent robotic ASC with supracervical hysterectomy [54]. Thus, an ideal patient for sacrocolpopexy is the patient with a prior hysterectomy and now has symptomatic vaginal vault descent and desires a reconstructive operation.

Concomitant Anti-incontinence Procedure

During the patient's initial visit and assessment of POP, her symptoms may or may not include stress urinary incontinence. Despite provocative testing maneuvers, SUI and occult SUI may not be unmasked. Regardless, all patients are counseled of the probability of a concomitant anti-incontinence procedure at the time of ASC.

As previously discussed, the CARE trial was designed to evaluate whether postoperative SUI symptoms were reduced by concomitant Burch colposuspension during ASC. Continence was defined as answering "never" or "rarely" to the SUI portion of the Medical, Epidemiological, and Social Aspect of Aging (MESA) questionnaire. The trial was stopped after the first interim analysis as there was a significant difference between postsurgical SUI symptoms in patients undergoing concomitant Burch colposuspension and those who did not (23.8% vs. 44.1% p <0.001). The difference was also significant when evaluating those without evidence of SUI on preoperative UDS (reduction of postoperative SUI from 38.2% to 20.8% $p = 0.007$) [19].

Though these results are compelling to offer an anti-incontinence procedure to all our patients regardless of preoperative symptoms of SUI, we counsel patients on possible mid-urethral sling placement but ultimately give the patient the option in making the final decision. Studies have advocated a more conservative approach of offering anti-incontinence procedures to patients with occult SUI or symptomatic SUI [72, 73]. Our standard anti-incontinence procedure is a mid-urethral sling performed at the time of ASC. The CARE trial evaluated Burch colposuspension as their anti-incontinence procedure which may suggest that their results are not wholly applicable to our patient population. The Outcomes Following Vaginal Prolapse Repair and Mid-urethral Sling (OPUS) trial evaluated stress urinary incontinence at 3 months and 12 months after prolapse surgery with either concomitant mid-urethral sling placement versus a sham procedure. The rates of urinary incontinence were significantly higher in the sham group at 3 months (49.4% vs. 23.6%, p <0.001) and 12 months (43% and 27.3%, $p = 0.002$). The rates of incontinence demonstrated by a cough stress test at 12 months were significantly higher in the sham group (20.5% vs. 3.5% p <0.001). Occult SUI was observed in preoperative testing in 33.5% of the women in the study even though women included in this study did not report SUI symptoms [20]. These results are similar to the CARE trial and suggest that any anti-incontinence procedure at the time of prolapse surgery will significantly reduce SUI symptoms afterward. Whereas the CARE trial involved an anti-incontinence procedure which we do not typically perform, the OPUS trial had a patient population who underwent transvaginal prolapse correction, thus, these results also may not be applicable to patients who undergo ASC with a

concomitant retropubic mid-urethral synthetic sling placement.

Borstad et al. evaluated concomitant anti-incontinence surgery in women with SUI at the time of prolapse surgery versus reassessing at 3 months. Utilizing tension-free vaginal tape (TVT) as their anti-incontinence procedure, they found no significant difference in SUI cure rate between either groups. They did note that of those randomized to wait 3 months postoperatively for their TVT procedure; only 53 out of the original 94 patients required an additional surgery [74]. The CUPIDO trials were two multicenter randomized controlled trials that evaluated women with at least Stage 2 POP and either SUI (CUPIDO I trial) or occult SUI (CUPIDO II trial). Women were randomized to transvaginal prolapse surgery combined with mid-urethral sling placement versus prolapse surgery alone. The primary outcome of these trials was to evaluate absence of SUI 12 months after surgery using the Urogenital Distress Inventory (UDI). The CUPIDO I trial included 134 women and identified a higher rate of absence of postoperative SUI in women that underwent concomitant mid-urethral sling placement compared to prolapse surgery alone (78% vs. 39%, RR 1.97, 95% CI 1.44–2.71). Of the women that had prolapse surgery alone, 12 women (17%) eventually underwent mid-urethral sling placement [75]. The CUPIDO II trial included 91 women and identified a higher rate of absence of postoperative SUI in women who underwent concomitant mid-urethral sling placement compared to prolapse surgery alone (86% vs. 48%, RR 1.79, 95% CI 1.29–2.48) [76]. Of the women who had prolapse surgery alone, 6 women (13%) eventually underwent mid-urethral sling placement. Given the significant difference in postoperative SUI between the two treatment groups but relatively low reoperation rate, the authors encourage having a detailed risk–benefit discussion with the patient. This discussion should cover possible complications of mid-urethral sling placement including intraoperative urethral/bladder perforation and bleeding, as well as postoperative voiding dysfunction, overactive bladder, recurrent urinary tract infections, dyspareunia, and sling extrusion, with the possibility of sling incision for issues not resolved with conservative management [77, 78].

Summary

Given the aging population, the number of women who will undergo POP surgery will substantially increase in the next 40 years [79]. Although POP can be approached transvaginal or with a minimally invasive approach with robot assistance, transabdominal ASC remains the gold standard operation for apical POP repair. Patients should be evaluated thoroughly including the use of standardized symptom questionnaires on their initial visit as well as POP-Q measurements to objectively evaluate their POP. Comorbid conditions should be medically optimized prior to surgery. Most importantly, the patient's goals should be identified from the beginning given that the majority of women with POP are not symptomatic nor do they require an invasive procedure.

For those undergoing a corrective operative procedure, an informed discussion regarding the use of synthetic mesh graft is paramount. Patient's expectations are aligned with the surgeon's goals of surgery. The expected postoperative course is discussed with the patient to minimize any chance of misunderstanding. During surgery, techniques that optimize success include perioperative antibiotics, DVT prophylaxis, obtaining exposure, and recognizing pelvic anatomic landmarks to allow for precise dissection and avoidance of neurovascular structures. We advocate the use of a macroporous polypropylene synthetic graft and non-braided suture.

Successful transabdominal ASC outcomes are high but depend on the definition used, which is still not standardized in current literature. While minimally invasive approaches to ASC have been developed and decrease perioperative morbidity and length of hospital stay, there is no evidence to support superior outcomes (anatomic or subjective) in the minimally invasive approach when compared to the traditional transabdominal approach.

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8 Robotic/Laparoscopic Sacrocolpopexy

Wesley M. White and Michael Polin

Introduction

Pelvic organ prolapse (POP) is expected to impact nearly half of all females during their lifetime [1]. POP can be severely lifestyle limiting and is of particular concern given our aging population [2]. Management of POP has traditionally come in the form of cautious observation, pessary fitting and use, myriad vaginal repairs, and abdominal sacrocolpopexy (ASC). Definitive correction of POP is surgical, accomplished through vaginal or abdominal-based reconstruction. The optimal treatment is predicated not only on patient-derived factors – including the degree and nature of pelvic relaxation, comorbidities, patient preferences and expectancies, and the integrity of the individual patient's tissue – but also on the experience and expertise of the operating surgeon, and taken in the context of evidence-based outcomes.

Among those patients with severe apical relaxation and/or multicompartment prolapse with an apical component that desire, and are considered good candidates for, definitive surgical reconstruction, the superiority of abdominal sacrocolpopexy (ASC) is well established [3]. Indeed, the chief precept of surgical correction for pelvic prolapse is the durable restoration of the vaginal apex in a manner that provides for improved urinary, sexual, and bowel function [4]. Sufficient high-quality evidence exists to contend that open ASC offers consistently higher objective success rates and lower rates of dyspareunia when compared to sacrospinous-based vaginal repair [3, 5]. However, open ASC is considered disproportionately invasive, and these favorable results have traditionally come at the expense of increased short-term morbidity and prolonged convalescence [3].

The application of laparoscopy and robotics during ASC has significantly improved morbidity associated with the procedure while continuing to offer durable and satisfactory outcomes [6]. Coupled with the climate of fear surrounding mesh-augmented vaginal repair, laparoscopic/robotic ASC has become the preferred corrective procedure for POP among many patients and providers [7]. This chapter will focus on the indications and patient evaluation for laparoscopic/robotic ASC, describe the surgical technique with the aid of intraoperative photographs, and discuss the outcomes and economic ramifications of minimally invasive ASC.

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Patient Evaluation and Preparation

Candidates for laparoscopic/robotic ASC include women with symptomatic stage II or multicompartment prolapse with a significant apical component, those with recurrent prolapse following primary vaginal repair, and those with POP and the need for concomitant abdominal surgery. Women with an in situ uterus may be considered for uterus-sparing sacrohysteropexy or may elect to undergo concomitant supracervical hysterectomy at the time of sacrocolpopexy. Prior abdominal surgery is common among this patient population and is not considered a contraindication. While patients should be counseled on the risk of a hostile abdomen and the potential need for extensive lysis of adhesions, we have encountered very few women for which a minimally invasive approach to ASC is prohibitive.

All patients should undergo a thorough history and physical examination, and particular effort should be made to reconcile the patient's symptoms with their examination findings. Our center employs a multidisciplinary team of urologists and urogynecologists that offers patients a complete range of diagnostic and therapeutic options. We find that this cooperative approach is ideal for both our patients and our providers.

The most common presenting symptoms include urinary, sexual, and bowel bother in addition to classic complaints of vaginal heaviness, pressure, or protrusion. Women with advanced-stage prolapse may report the need for manual reduction or the ability to palpate or directly visualize the vaginal apex or uterus. Concomitant urinary incontinence is frequent. The majority of patients exhibit mixed urinary incontinence and occult stress urinary incontinence should be considered. A voiding log and postvoid residual measurement can be helpful, and quality-of-life questionnaires are useful to establish a baseline for later reference. Urodynamics may be judiciously employed, especially among women with advanced-stage prolapse. Some women with severe POP have an element of detrusor underactivity owing to prolonged overdistention. Patients should be counseled on the possibility of persistent and/or de novo postoperative voiding dysfunction or hesitancy. Reflexive placement of a concomitant midurethral sling is discouraged, but occult stress incontinence should be assessed. Dyspareunia should be discussed as a rare but possible adverse event. Finally, many women with multicompartment POP will report chronic constipation and attention must be paid to bowel function postoperatively to avoid repetitive stress on the integrity of the reconstruction.

Physical examination should be systematic and thorough. The abdomen should be examined for the presence of prior surgical intervention as patient reported histories are not infallible. As previously stated, prior abdominal surgery may create a comparatively hostile field that, while not prohibitive, should be factored into the decision to approach reconstruction abdominally versus vaginally. A bimanual examination should be performed to assess for the presence and size of a uterus (if present) and the presence of any adnexal pathology. A bivalve speculum should be inserted to assess the vaginal apex and/or cervix. The speculum is then disarticulated to evaluate the anterior and posterior compartments independently. The presence and stage of prolapse in the anterior, apical, and posterior compartments should be quantified utilizing the pelvic organ prolapse quantification (POP-Q) system [8]. Estrogen status and the integrity of the levator musculature and perineal body are likewise assessed.

A cough stress test and/or cotton swab test may be performed in the office to address potential urethral hypermobility and stress urinary incontinence. In-office cystoscopy can be selectively performed. Although published studies suggest that women without existing complaints of stress incontinence may benefit from midurethral sling owing to the presence of occult leakage, our practice is to individualize our approach to sling placement based on preoperative evaluation for occult stress urinary incontinence [9]. As stated, the degree of detrusor underactivity should not be underestimated in this patient population and voiding dysfunction and obstructive symptoms can be preexisting or result from indiscriminate sling placement.

Preoperative preparation includes selective medical clearance and a comprehensive explanation of surgical risks. Informed consent for laparoscopic/robotic ASC should include a thorough account of the surgical steps of the procedure and well as its risks including, but not limited to, injury to the bladder or ureters, mesh-related complications including erosion or extrusion, inadvertent vaginal entry (vaginotomy), vaginal foreshortening, dyspareunia, postoperative voiding dysfunction including retention, discitis, and sacral osteomyelitis, and other imponderables. Obtaining a separate and dedicated consent form regarding the placement of polypropylene mesh is left to the discretion of the surgeon, and it is largely dictated by the regulatory and legal expectations of the practice setting. Refers to need for blood products/transfusion. Venous thromboembolism prophylaxis is employed with either sequential compression devices or subcutaneous heparin [10]. A first- or second-generation cephalosporin is ordered for administration on call to the operating room and redosed throughout the case, if indicated based on procedure length and drug half-life. We have found the use of pre- and perioperative intravenous acetaminophen to be effective in reducing postoperative opioid requirements.

Laparoscopic/Robotic Sacrocolpopexy: Technique

The patient is brought to the operating room and placed in the supine position. General endotracheal anesthesia is administered, and the patient is then converted to the low lithotomy position in Allen stirrups. We prefer to tuck the patient's arms, and a foam back pad is used to prevent movement while in Trendelenburg position. The patient's perineum should approach the edge of the bed to facilitate external manipulation of the vagina during the case as well as access to the vagina for subsequent midurethral sling or distal rectocele repair, as needed. A Foley catheter and vaginal manipulator are placed.

The abdomen, vagina, and perineum are widely prepped and draped into a sterile field. We prefer to use a one-piece laparoscopic gynecology drape (prefabricated service pockets and Velcro straps) that offers dual access to the both abdomen and vagina. The relevant pelvic landmarks are identified and a periumbilical incision is made. For laparoscopic ASC and robotic ASC using an older generation robot, an approximate 12-mm incision is made. An approximate 8-mm incision is made in the same location if using a newest generation robotic platform. Access to the peritoneum is achieved with either a Veress needle or a Hasson trocar. If a Veress needle is used (our preference), it is inserted into the peritoneal cavity, and confirmation of access is achieved with the use of a saline drop test. The abdomen is insufflated with CO_2 gas to a maximum pressure of 15 mmHg. If a Veress needle is used, it is exchanged for a standard 8-mm or 12-mm operative trocar. We often employ a balloon-tipped cannula to prevent inadvertent slippage of the trocar that is commonly encountered in the very obese or the very petite. A laparoscopic/robotic 0-degree camera is introduced, and the abdomen is widely inspected. The patient is then placed in steep Trendelenburg position, and the table is maximally lowered.

Under direct vision, two additional working trocars (5–8 mm) are placed approximately 10 cm lateral and just caudad to the umbilicus. If laparoscopic ASC is planned, an additional trocar may be placed in the left lower quadrant to facilitate manipulation and retraction of the sigmoid colon by an assistant. If robotic ASC is planned, an additional 8-mm left lower quadrant port is placed as well as a right lower quadrant 12-mm assistant port in a standard sawtooth configuration. The robot is then positioned with its base either between the patient's legs (standard docking common with older generation robots) or at an acute perpendicular angle near the base of the operative table (side-dock). Many urologists will feel more comfortable with a standard docking approach given its ubiquity during male pelvic surgery. However, side docking, commonly employed during benign gynecologic procedures, offers several distinct advantages during ASC including unfettered access to the vagina for manipulation and anatomic guidance.

Side-docking is common and recommended with the use of the daVinci® Xi system (Fig. 8.1).

Once the robot has been docked, we insert "right-handed" 8-mm monopolar shears and "left-handed" ProGrasp forceps. The accessory (most lateral 8-mm robotic trocar on the left side) robotic port is provided Cadiere forceps. We prefer Cadiere forceps for manipulation and retraction of the sigmoid mesentery as the closing force/crushing potential of the Cadiere is significantly less than that of the ProGrasp. If a laparoscopic approach is chosen, a right-angle dissector/hook cautery or hot shears is used in the operating surgeon's right hand and a nonlocking atraumatic grasper is used in the surgeon's left hand. Likewise, an atraumatic grasper is used by the surgical assistant to manipulate and retract the sigmoid colon. Alternatively, a percutaneously placed 0-silk suture placed in a figure of 8 fashion through the redundant pedunculated fat of the sigmoid colon or taenia coli may be used to obviate an assistant trocar.

Identification of relevant pelvic anatomy ensues including adhesiolysis as needed. The Foley catheter is manipulated to clearly demarcate the limits of the bladder, and the vaginal manipulator is employed to define the apex of the vagina. The bladder can also be backfilled if needed to help delineate its boundaries at the vaginal apex. The peritoneum is incised at the vaginal apex, and the avascular plane between the posterior aspect of the bladder and the anterior aspect of the vagina is developed in patients who had previously undergone hysterectomy. Dissection is carried onto the anterior surface of the cervix and vagina following concomitant supracervical hysterectomy (Fig. 8.2). In general, blunt dissection with directed pinpoint cautery nicely sweeps the bladder off the anterior surface of the vagina. This dissection is carried down to the approximate level of the trigone. Again, manipulation of the urinary catheter can help reconcile these landmarks. In some cases, identifying the appropriate plane of dissection can be challenging, especially among women who have undergone prior hysterectomy or transvaginal reconstruction. Inadvertent entry into the bladder or vagina may occur and should be immediately recognized. Although less than ideal, vaginotomy or cystotomy may ultimately afford the surgeon with a clearer understanding of the patient's anatomy and the limits and contours of the bladder and vagina. These entries should be utilized to direct the remaining dissection and then closed in

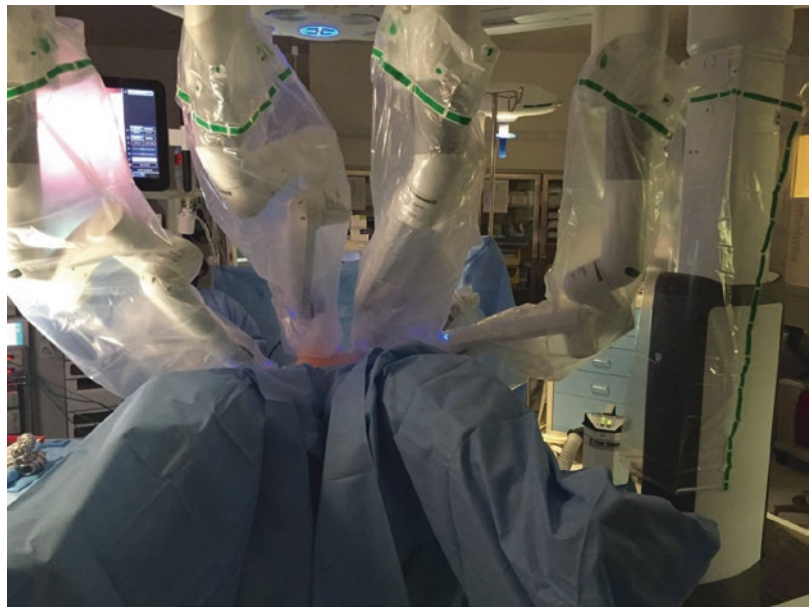

Fig. 8.1 Intraoperative photograph demonstrating patient positioning and representative port placement during robotic sacrocolpopexy. With use of the daVinci Xi® robotic platform, the base of the robot is positioned at the patient's side. This affords unencumbered access to the vagina for manipulation, backfilling of the bladder, etc.

multiple layers using absorbable suture. Mesh overlying any such defects should be trimmed and removed.

The posterior peritoneum is then dissected off the cervical stump/posterior vagina and carried distally toward the recto-vaginal pouch. In general, the initial dissection can be very indistinct (Fig. 8.3) but with further progress, a very nice areolar plane avails itself down to at least the level of peritoneal reflection and perhaps farther to the presumed level of the perineal body. An EEA sizer placed in the rectum can help delineate the rectal boundaries if needed. Again, a savvy bedside assistant can help confirm the approximate level of posterior dissection.

The sigmoid colon is reflected to the patient's left side, and the sacral promontory is then identified (Fig. 8.4). The retroperitoneum opened at the level of its "drop off" to expose the anterior longitudinal ligament (Fig. 8.5). A 30-degree down scope can aid in visualizing this dissection. Typically, the promontory is readily apparent in all but the most obese of patients. With laparoscopic ASC, the promontory is generally easily

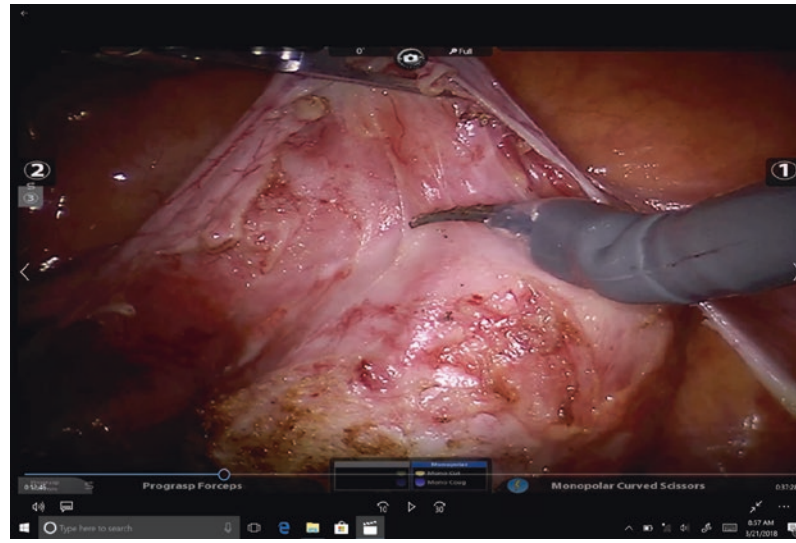

Fig. 8.2 Dissection is initiated at the vaginal apex and carried over the anterior aspect of the vaginal/posterior aspect of the bladder within the areolar plane

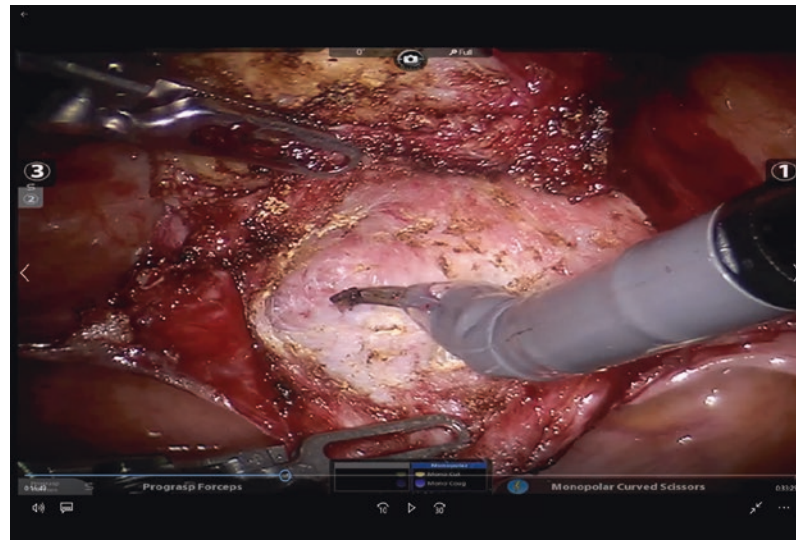

Fig. 8.3 The posterior dissection is started at the vaginal apex or posterior aspect of the cervical stump

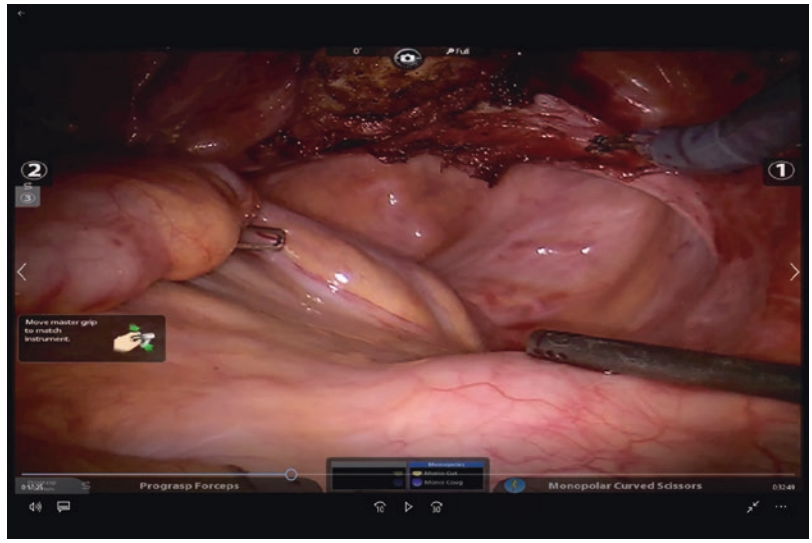

Fig. 8.4 The accessory robotic arm is used to atraumatically reflect the sigmoid colon to the patient's left side. The bedside assistant is using the suction/irrigator to palpate the sacral promontory

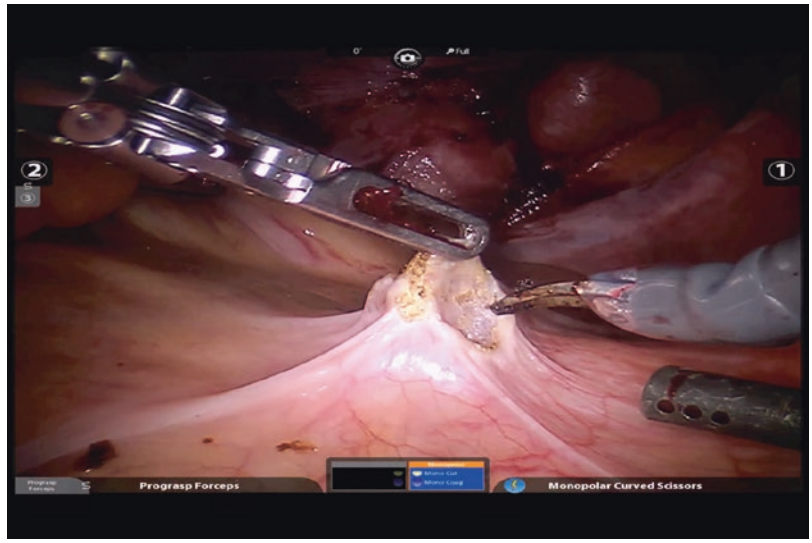

Fig. 8.5 The retroperitoneum is incised at the level of the sacral promontory. The anterior longitudinal ligament is exposed

palpated. Lacking tactile feedback during robotic ASC, the operating surgeon can elect to have the bedside assistant directly palpate the sacrum using a laparoscopic suction/irrigator to ensure its location. However, in our experience, "learned tactile feedback" with the robot makes identification straightforward.

A retroperitoneal tunnel is created from the level of the sacral promontory down the length of the posterior cul-de-sac to meet with the previously created peritoneal opening over the posterior aspect of the vagina (Fig. 8.6a, b). Alternatively, the retroperitoneum can be opened down the length of the posterior pelvis. While creating a retroperitoneal tunnel hastens reconstruction later in the case, the availability of barbed suture has made reconstruction of the incised peritoneum fairly straightforward. If a tunnel is not created, one

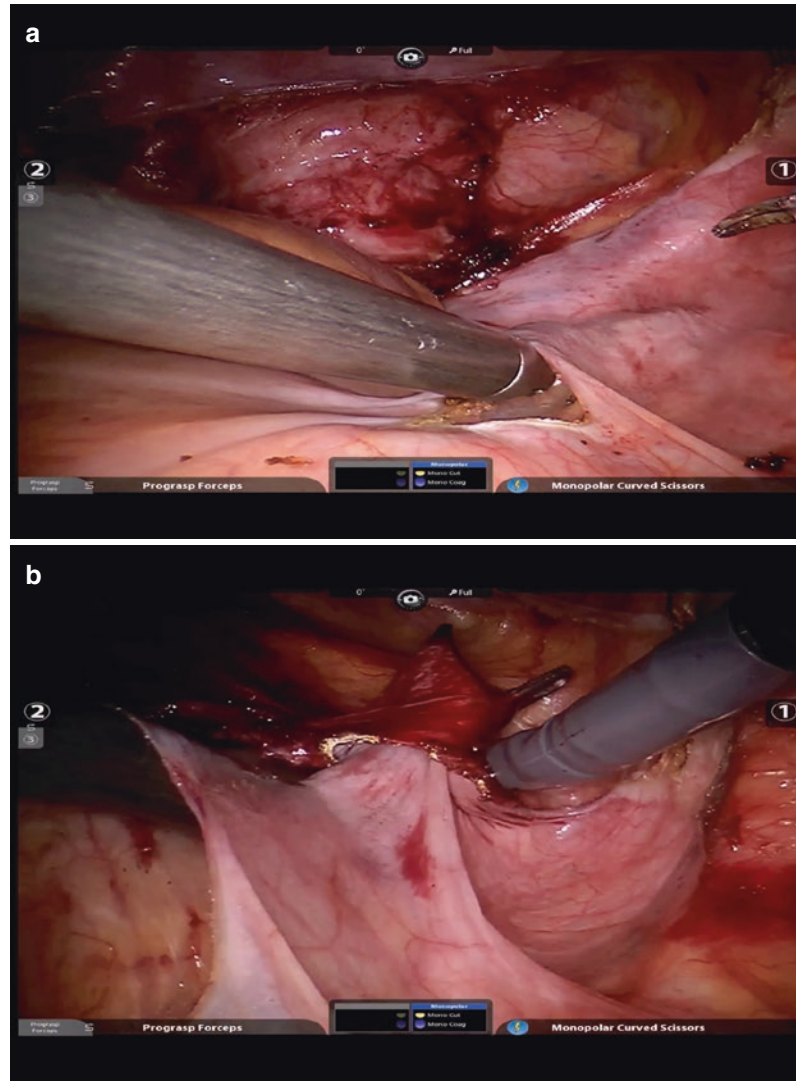

Fig. 8.6 (**a**) A retroperitoneal tunnel is created using the blunt tip of the ProGrasp forceps. (**b**) Intraoperative photograph demonstrating the fully developed retroperitoneal tunnel

must be cognizant of the right ureter and must avoid its entrapment during closure.

A prefashioned Y-shaped polypropylene mesh is trimmed to approximately 6–10 cm anterior/posterior. This length is highly dependent on patient-specific anatomy and must be individualized. The mesh is rolled up and introduced. The Y-shaped graft is unrolled and laid flatly over the anterior aspect of the vagina and/or cervical stump and vagina (Fig. 8.7). It is fixed to the anterior aspect of the vagina and/or cervical stump using a series of 0-Vicryl sutures or 2-0 PDS sutures (Fig. 8.8). Typically, 6–12 sutures are placed both anteriorly and posteriorly in multiple rows of 2 sutures each. We prefer to take robust bites of the vagina/cervical stump but not enough to "bunch" the graft (Fig. 8.9). Suture fixation posteriorly can be tedious and one should be comfortable throwing sutures at a variety of angles to best seat the graft in a flat fashion (Figs. 8.10 and 8.11). If performed robotically, we prefer to use a MegaCut or "suture cut" nee-

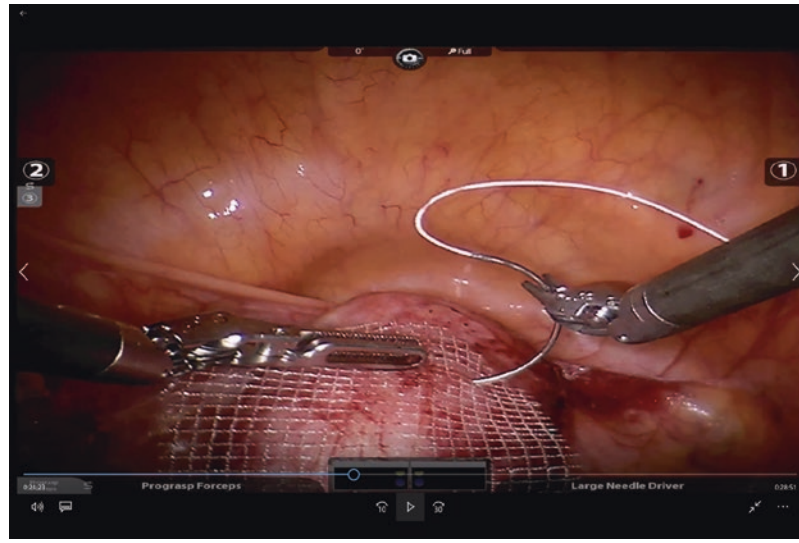

Fig. 8.7 The graft is laid flat against the anterior aspect of the vagina/cervical stump and the posterior leaflet of the graft "tucked" within the peritoneal "pocket"

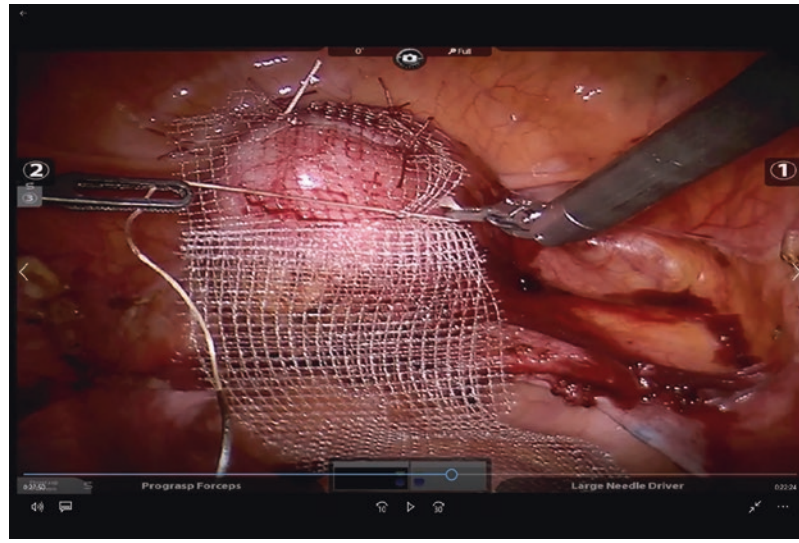

Fig. 8.8 The anterior leaflet of the graft is affixed to the vagina/cervical stump using interrupted, dyed 0-Vicryl suture on a CT-2 needle

dle driver in the right hand to expedite this step through conservation of motion. One may also consider fixing the graft to the vagina using a barbed suture in a "switchback" fashion. The flexibility of the barbed suture avoids repetitive suture exchange.

The tail of the graft is brought out through the retroperitoneal tunnel (or up to the level of the promontory if the retroperitoneum was split) (Fig. 8.12). The tail of the graft is fixed to the anterior longitudinal ligament using two or three interrupted 0-Ethibond sutures or CV-2 Gore-Tex sutures (Fig. 8.13). We prefer to throw a "right forehand, left forehand" slip-knot stitch that allows the graft to be securely affixed to the ligament. Care must be taken to apply appropri-

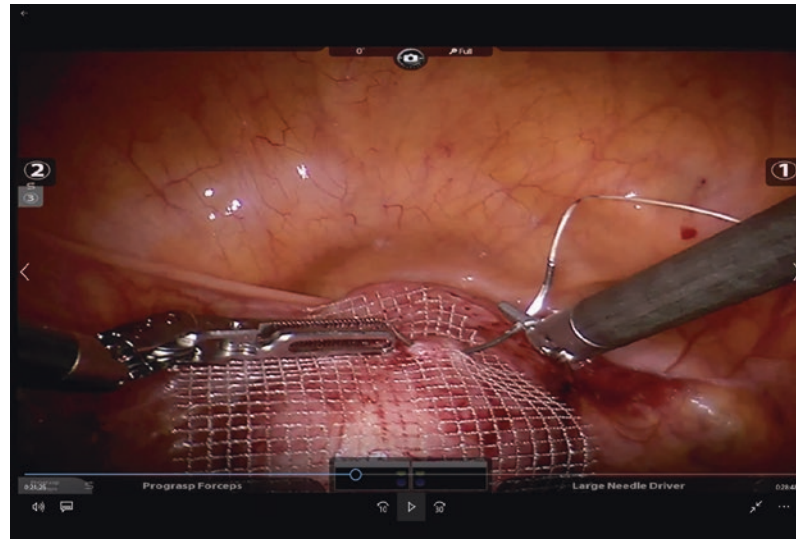

Fig. 8.9 We prefer to take a robust purchase of the vaginal wall that spans "4 pores" on the graft. This technique affords secure fixation of the graft without bunching

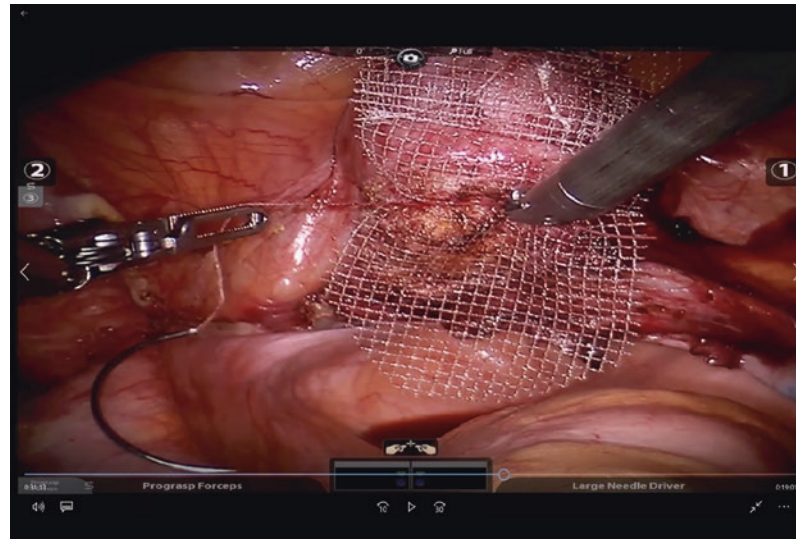

Fig. 8.10 The posterior leaflet of the graft is affixed in a similar fashion

ate but not undue tension when reducing the vaginal apex externally. Over tightening of the graft fails to account for potential mesh contracture.

Once the graft has been adequately positioned and prolapse reduction confirmed transvaginally, the retroperitoneum is closed over the vagina and sacrum using a running barbed suture of choice (Figs. 8.14 and 8.15). We find this technique again provides secure and efficient coverage of the graft. Caution must be exercised during closure of the retroperitoneum to avoid incorporation and/or kinking of the right ureter. In certain rare circumstances, the graft may be left exposed should the retroperitoneum be attenuated and/or risk ureteral entrapment. However, to forego cov-

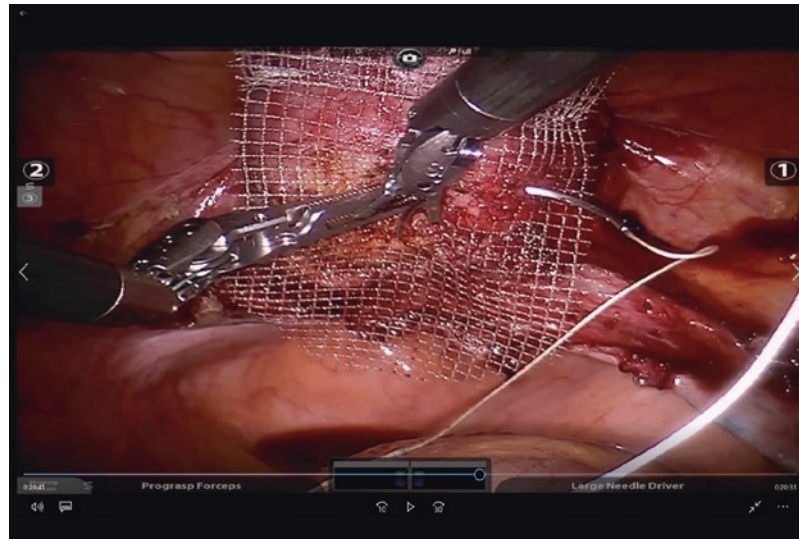

Fig. 8.11 In certain circumstances, the surgeon must use a backhand/forehand/forward/backward throw to achieve a suitable approach for mesh fixation on the posterior leaflet

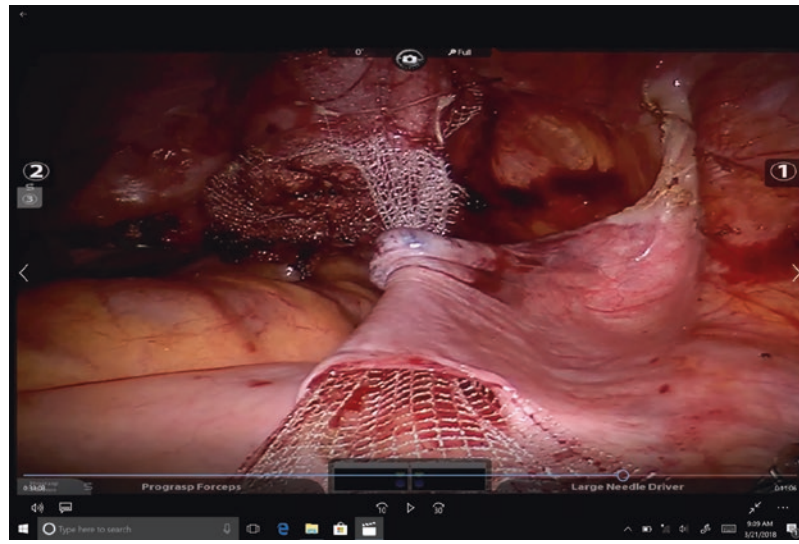

Fig. 8.12 The tail of the graft is brought up through the retroperitoneal tunnel. The vagina is reduced from below, and the graft is tensioned appropriately

erage of the graft may place the patient at risk for an internal hernia. While our preference is graft coverage, each circumstance should be individualized.

The abdomen is desufflated following removal of all ports under direct vision. The midline 12-mm incision is closed using a 0-Vicryl suture in a meticulous fashion. Skin incisions are then closed in a subcuticular fashion.

The patient is converted to the exaggerated lithotomy position, and a thorough vaginal examination is again performed to assess for apical support. Often, a distal rectocele will be inadequately addressed abdominally and will require primary vaginal repair at this stage. Cystoscopy is performed to ensure ureteral efflux and integrity of the bladder. If a midurethral sling is planned, it is performed at this time. A Foley

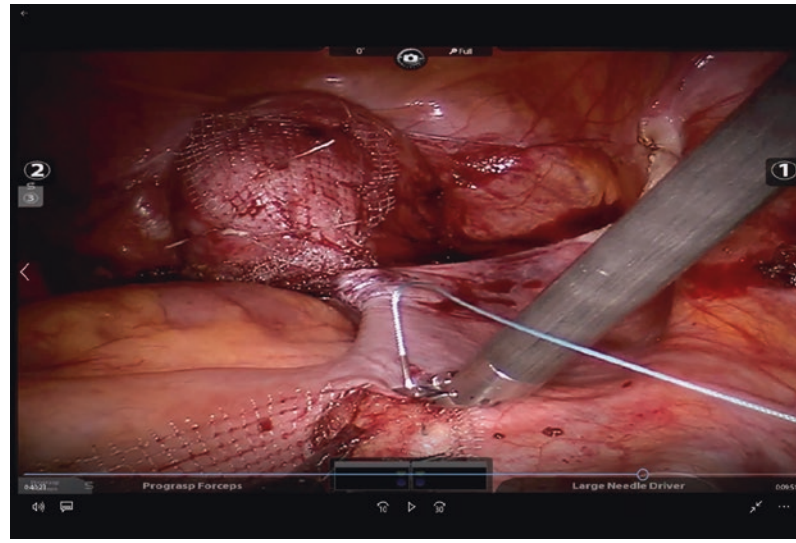

Fig. 8.13 The graft is affixed to the anterior longitudinal ligament using two interrupted 0 Ethibond sutures on an SH needle (tapered). A "slip-knot" stitch affords secure apposition of the graft the promontory

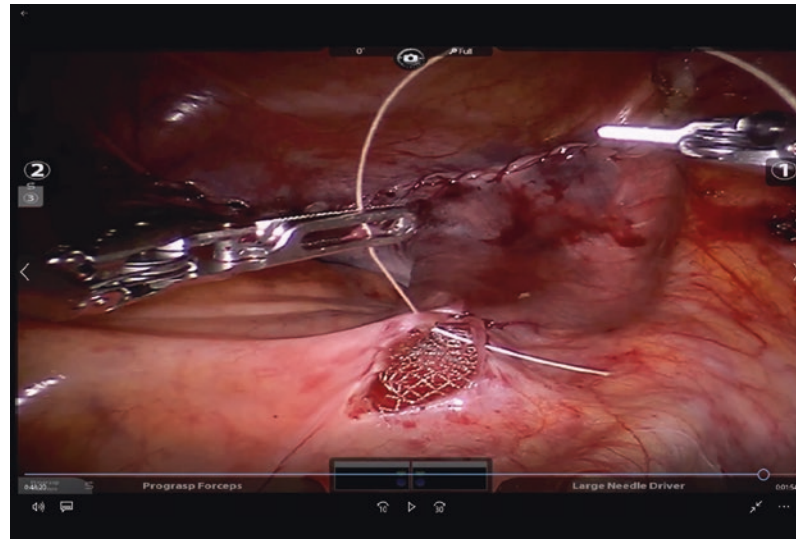

Fig. 8.14 The peritoneal defect is closed using a running barbed suture, and a 2-0 Vicryl suture is used to close the defect at the level of the promontory

catheter is replaced as well as an estrogen-soaked vaginal pack.

The patient is admitted to the hospital for 23-hour observation and ambulated that evening. A regular diet is ordered. Laboratory testing is not necessary. Venous thromboembolism prophylaxis is provided in the form of sequential compression devices or heparin versus enoxaparin. The vaginal pack and catheter are removed the next morning, and the patient is discharged by noon the day following surgery. Same-day discharge may be considered in appropriate patients. Patients are instructed to avoid sexual intercourse for a minimum of 4 weeks. Weight restrictions are evolving and trending toward encouragement of increased activity in the immediate postoperative period.

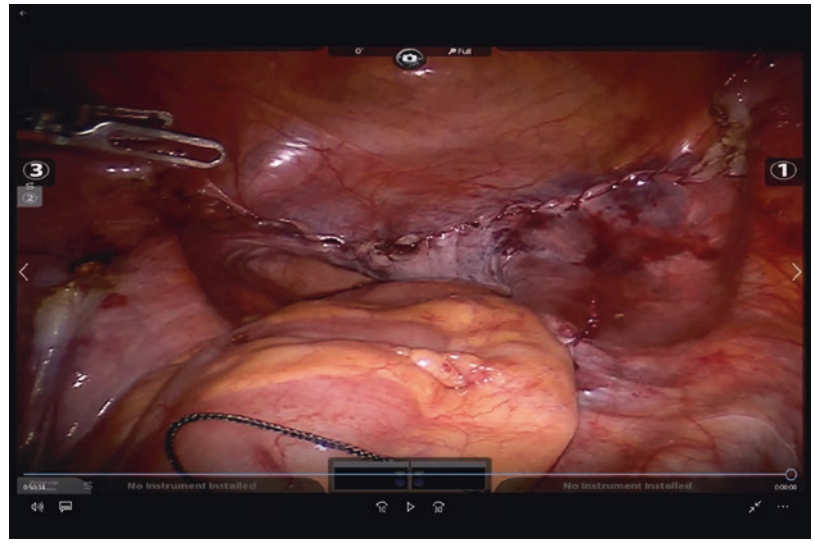

Fig. 8.15 The entire graft should be fully retroperitonealized to avoid bowel entrapment and mesh exposure to the abdominal contents

Outcomes of Laparoscopic/Robotic ASC

Certainly, laparoscopic/robotic ASC offers the promise of decreased morbidity when compared to its open counterpart. Objective outcomes have likewise been reassuring with multiple published studies demonstrating comparable durability without discordant risk or surgical complexity [11–13].

Serati and colleagues published a systematic review and meta-analysis of 1488 patients who underwent robotic-assisted ASC at 27 centers and explicitly focused on efficacy and perioperative complications [13]. The authors then compared robotic ASC to both open and laparoscopic ASC. Functional objective/subjective outcomes with robotic ASC were excellent with success/"cure" rates reported to be as high as 84–100%. Subjective cure/patient satisfaction rates based on validated questionnaires were scarce in the aforementioned meta-analysis and are admittedly scarce in the literature as a whole. However, available numbers suggest a high level of patient satisfaction. Conversion to open ASC occurred in less than 1% of cases. Intraoperative complications occurred in 3% of cases and included 14 vaginotomies, 26 cystotomies, 1 ureteral injury, and 4 bowel perforations. Postoperative complications were primarily low grade in nature (Clavien Class 3 or lower) and occurred in 11% of cases. Mesh erosion was reported in a total of 2% of patients with no further information available regarding means of correction. It was noted that mesh erosions occurred more frequently in the setting of vaginotomy and when ASC was performed at the time of total hysterectomy. For this reason, we do not routinely perform ASC at the time of total hysterectomy, favoring supracervical hysterectomy or, in some cases, interval reconstruction. Rates of urinary, sexual, and anorectal dysfunction are low among patients treated with laparoscopic/robotic ASC. Urinary complications and dysfunctions are likely from concomitant anti-incontinence procedures. Vaginal elongation is among the distinct advantages of ASC with dyspareunia rates of less than 5% reported. Bowel complications are unusual though not impossible with laparoscopic/robotic ASC even with concomitant rectocele repair. Comparative objective/subjective "success" rates and complication rates were comparable among the open, laparoscopic, and robotic approaches.

Despite its clear ability to be "effective" in accomplishing its task, it remains speculative about whether robotic ASC can be "efficient." Data on the cost-effectiveness of robotic ASC have thus far largely consisted of retrospective studies and/or cost-minimization analyses [14–

16]. Results have been conflicting with the majority of studies detecting increased costs with the robotic approach as compared to either open or laparoscopic ASC. And while the sunk cost of the robot is an expected cost driver, prolonged operative time with robotic ASC appears responsible as well [17].

One randomized controlled trial was conducted to specifically assess financial outcomes between laparoscopic and robotic ASC [18]. A total of 78 women with symptomatic stage II or greater POP, including significant apical support loss, were randomized to either laparoscopic (n = 38) or robotic (n = 40) ASC. Primary outcomes focused on cost and readmission rates with secondary outcomes centered on anatomic outcomes and quality of life results. As expected, no differences were noted in the two groups with respect to these secondary outcomes or readmission rate. Robotic ASC was found to be more expensive than laparoscopic ASC by nearly $1000 ($12,586 vs. $11,573), but this difference was not statistically significant. The authors cited the robot purchase price and maintenance costs as the primary difference makers with respect to cost.

Critics of these aforementioned studies (both pro-robot and pro-lap) cite the difficulty in defining "cost" vs. "charges" and the relative lack of uniformity with which charges are calculated. Still others point out the inherent bias in many of these newer prospective studies, namely the authors' lack of experience and/or volume with robotic ASC when compared to laparoscopic ASC. Specifically, the authors define proficiency as a surgeon who had completed greater than 10 robotic ASCs [17, 18]. In our experience and that of others, with greater experience comes reduced operative times, reduced disposable waste, the need for fewer robotic surgical instruments, and less surgical variability. These surgical refinements translate into reduced costs.

Conclusion

The volume of patients with symptomatic prolapse is growing, and the demand for durable surgical correction is likewise expected to grow. ASC represents the surgical approach with the highest degree of durability. Laparoscopic/robotic sacrocolpopexy is poised to become the preferred treatment approach for women with moderate-to-severe prolapse of the apical component. Aversion to transvaginal mesh repair by patients, coupled with increasing comfort with robotics and abdominal-based reconstruction by providers, is expected to drive this shift. Ultimately, we must seek to offer patients a tailored treatment algorithm that balances consistent and durable effectiveness with fiscal responsibility, minimizes risk to the patient, and marries the goals of the patient to the experience and purview of the surgeon.

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9 Transvaginal Urethrolysis for Urethral Obstruction

Kevin Cwach and Justin S. Han

Background

Urethral obstruction or bladder outlet obstruction (BOO) represents a rare urologic condition among women. Its incidence has been reported to range from 2.7% to 8.3% [1, 2]. Causes of female BOO may be classified into either functional or anatomic etiologies. Functional causes include primary bladder neck obstruction, dysfunctional voiding, or detrusor-external sphincter dyssynergia. Anatomic causes include extrinsic compression resulting from pelvic organ prolapse, prior prolapse repair, pelvic tumor, and most commonly, prior stress urinary incontinence (SUI) surgery.

Stress urinary incontinence is a common and bothersome condition that affects up to 10% of the female population [3]. While there are a number of treatment options for SUI, including urethral bulking agents and bladder neck suspensions, nearly 80% of female incontinence procedures performed in the United States are mid-urethral slings [4]. Iatrogenic urethral obstruction following incontinence surgery is by far the most common cause of female urethral obstruction/BOO, with the incidence of BOO after anti-incontinence surgery ranging from 2.5% to 24%, depending on the type of repair [3, 5].

A meta-analysis was published by the American Urological Associated Stress Urinary Incontinence Panel (AUA SUI) assessing outcomes and complications from various female SUI surgeries [6]. For patients undergoing synthetic mid-urethral sling, retention (defined as patients requiring an additional procedure or lasting longer than 1 month) was found in 3%. Rates of retention were similar in patients undergoing Burch colposuspension (1–3%) and Marshall–Marchetti–Krantz procedures (MMK, 2–4%), and slightly higher for patients undergoing autologous fascial pubovaginal sling (5–8%). Rates of de novo urge incontinence were also relatively similar across procedure types, from 6% following synthetic mid-urethral sling, to 8% after Burch colposuspension and 9% after autologous pubovaginal sling.

In addition to extrinsic causes, less common intrinsic etiologies for BOO include female urethral stricture disease, urethral diverticulum, benign urethral polyps, or urethral malignancies. Urethral stricture disease will be addressed elsewhere in this book.

Evaluation and Diagnosis

The diagnosis of female bladder outlet obstruction is challenging, as there are no standardized definitions or criteria within the literature [7].

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While some women present with more obvious obstructive symptoms of urinary retention, Valsalva voiding, weak urinary stream, or incomplete emptying, the majority of women with BOO have more subtle symptoms. Most often, these women present with new onset lower urinary tract symptoms (LUTS) of urinary urgency, frequency, suprapubic fullness, and urge incontinence, probably secondary to the bladder's response to new obstruction [3, 5]. Carr and Webster noted that 75% of female BOO presented primarily with these irritative voiding symptoms [8]. Other clues to diagnose female outlet obstruction include an elevated postvoid residual (PVR) or recurrent urinary tract infections. Oftentimes, the most critical part of the history is the temporal relationship between incontinence or prolapse surgery and new symptom onset [5]. Many times the symptoms arise immediately after surgery and persist beyond an acceptable several week duration. Even so, some patients may present years after their initial surgeries; therefore, clinicians must be vigilant and maintain a high suspicion for the possibility of urethral obstruction in patients with prior pelvic surgeries and persistent, refractory symptoms.

The physical exam of females with BOO is often unremarkable. Abnormal findings may include hypersuspension of the urethra, in which the urethra and urethral meatus appear retracted upward or "fixed" toward the pubic bone [3]. Another potential exam finding is a urethral ridge that is felt with introduction of a Q-tip or catheter into the urethra. Nevertheless, a negative physical exam does not rule out female bladder outlet obstruction and is often the norm [5].

Important diagnostic testing for female BOO include urinalysis, urine culture, uroflowmetry, postvoid residual measurement, cystoscopy, and urodynamics. Cystoscopic examination may reveal abnormal urethral angulation or kinking, trabeculation of the bladder, or bladder diverticulae suggestive of chronic BOO. The use of pressure-flow studies (PFS) or urodynamics (UDS) in the diagnosis of female BOO have been investigated and reported in several studies in the literature. Despite multiple studies, there is no consensus on UDS criteria for diagnosing female outlet obstruction [7]. Chassagne et al. first proposed parameters to define BOO in women [9]. They compared UDS from 35 obstructed patients to 124 controls with stress incontinence and formulated a definition of female BOO as having maximum flow rate (Q_{max}) less than 15 mL/s and detrusor pressure at maximum flow rate ($P_{det}Q_{max}$) greater than 20 cm H_2O. In 2000, Lemack and Zimmern proposed cut-offs of a Q_{max} less than 11 mL/s and $P_{det}Q_{max}$ greater than 21 cm H_2O in their updated cohort of obstructed women with SUI women as controls. Finally, the same group updated their criteria in 2004 with greater numbers but using asymptomatic controls. Defreitas et al. compared UDS reports of 169 women with clinical BOO to 20 asymptomatic female controls and found that cut-offs of Q_{max} less than 12 mL/s and $P_{det}Q_{max}$ greater than 25 cm H_2O yielded the highest area under the receiver operating characteristic curves [10].

Others, however, have found that these cut-offs can miss potential instances of BOO. In a study by Nitti et al. where videourodynamics was performed and compared to standard UDS, the addition of voiding cystourethrography identified further cases of obstruction (as determined by fluoroscopic evidence of obstruction at the bladder neck/urethra) that were missed with the cut-offs proposed by Chassagne et al. [11]. Nitti et al. found that using the criteria of Q_{max} <15 mL/s and $P_{det}Q_{max}$ >20 cm H_2O, 11.8% and 10.5% of 76 radiographically obstructed patients would not be properly identified. The authors, however, did confirm the general concept of reduced maximum flow rates, higher detrusor pressures at maximum flow rate, and elevated postvoid residuals in obstructed patients. Cormier et al. later determined that the single most discriminating UDS parameter for female BOO was the area under the curve of detrusor pressure during voiding adjusted for voided volume, rather than simply detrusor pressure at maximum flow or maximum flow rate [12].

Perhaps most comprehensively, Blaivas and Groutz developed a BOO nomogram for women that combined uroflowmetry, UDS, and voiding cystourethrography and categorized obstruction as none, mild, moderate, or severe. Their

nomogram was noted to correlate with the American Urological Association Symptom Index score previously developed for male BOO [13]. The applicability of the Blaivas–Groutz nomogram for female BOO was subsequently examined by others, who found poor correlation with symptoms based on the Urogenital Distress Inventory [14]. Later, Akikwala et al. compared the five different abovementioned definitions of BOO and found significant over-estimation of obstruction with the Blaivas–Groutz nomogram and underestimation with the 2004 Defreitas criteria [15]. They concluded that there was no single standard definition for female BOO, although the original 1998 Chassagne and videourodynamic definitions were most correlative.

Repair Techniques for Urethral Obstruction

Timing of Repair

Even in the relatively straightforward case of immediate and persistent postoperative urethral obstruction following incontinence surgery, the optimal timing of urethrolysis or sling incision/excision is somewhat controversial. There is general consensus that surgical intervention should not be significantly delayed beyond 1 year. However, studies differ on the exact time frame. South et al compared early intervention (defined as less than 1 year) to late intervention for outcomes following sling incision [16]. They noted that early incision within 1 year was associated with greater symptomatic improvement (91% vs. 71%, $p = 0.01$) on multivariate analysis. Others have also demonstrated that delayed intervention is associated with permanent bladder dysfunction and overactive bladder (OAB) symptoms [17]. In their study, Leng et al. noted that of 15 patients reviewed after urethrolysis, 7 patients had complete resolution of symptoms, while the remaining 8 patients required continued anticholinergic medications. The two cohorts had significant different mean times from initial incontinence to intervention, with the complete resolution group having a mean period of 9.0 months as compared to 31.3 months in the persistent group. However, Starkman et al. determined in their study of urethrolysis patients who delayed time to repair was not associated with a difference in outcomes with OAB symptoms [18]. Both the persistent and resolved OAB symptom groups had a mean delay of 22 months. The authors found that the resolution of obstructive voiding symptoms was broadly observed, but noted that resolution of OAB symptoms was more variable. These somewhat conflicting findings may be related to the difficulty in assessing pre-existing OAB symptoms prior to urethrolysis or sling incision and the variability in the study cohorts and methodologies.

Ideal timing of early intervention within 1 year is even less clear. Some advocate for a waiting period of approximately 3 to 4 months to reduce the potential risk of recurrent incontinence, while others feel that persistent symptoms beyond 4 weeks postoperatively are unlikely to further resolve. In our experience, allowing for a period of approximately 4 to 6 weeks is sufficient to allow for spontaneous resolution of symptoms and maintain a low risk of recurrent incontinence, which reflects the experience of other institutions [19]. In a long-term follow-up study, Thiel et al. performed simple sling incision at mean of 65 days (range 36–225) postoperatively from pubovaginal sling surgery and noted long-term maintenance of continence after intervention at mean 5 years of follow-up.

Sling Incision/Excision

Perhaps the simplest approach for repair of urethral obstruction after sling surgery is sling incision/excision. This approach is considered first-line for patients who develop obstruction after any sling placement, whether synthetic or autologous fascia. The surgical technique is generally reproducible and successful. The patient is first positioned in the dorsal lithotomy position with Trendelenburg and a Foley catheter is placed. Often with simple traction of the Foley catheter, the sling is palpable as a ridge or a rigid cystoscope or urethral sound may be torque angle

of the urethra thereby elucidating the sling for palpation. We prefer to perform a midline incision, ideally over the previous incision scar if visible, to begin our surgical dissection. Others have described inverted U or transverse incisions. The healthy urethra is then identified distal to the sling and careful sharp dissection is carried proximally until the sling is identified. Often the sling can only be identified as a fibrotic thickened band of tissue (Fig. 9.1). We then proceed to sharply dissect the sling off the underlying urethra. The plane between the urethra and the sling is frequently not well delineated and not amenable to blunt dissection; therefore, we prefer sharp dissection primarily. Counter-traction on the sling with a clamp is a key surgical maneuver that allows for this sharp dissection (Fig. 9.2a). Once the sling has been freed partially from the urethra, we place a right-angled clamp behind the sling for further retraction which allows for easy simple incision, or for further lateral dissection for excision (Figs. 9.3 and 9.4). When the sling is incised, the cut ends typically spring open or retract apart (Fig. 9.2b). Some have suggested that for pubovaginal slings simple incision will suffice, while for synthetic slings, more extensive excision of the suburethral portion should be conducted [2]. In the event that the sling ends do not appear to spring apart, we advocate extension of the dissection and excision as possible.

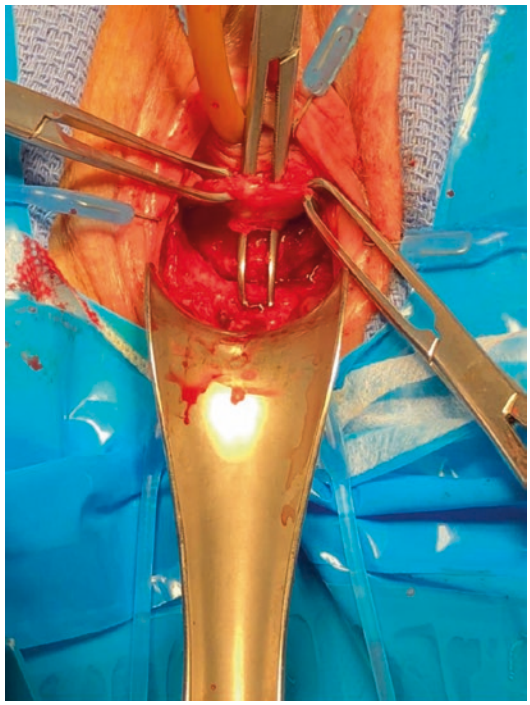

Fig. 9.1 Once an inverted U incision is made, sharp dissection is carried down to the sling. Often, the sling can only be identified as a fibrotic thickened band of tissue. (Courtesy of Ricardo Palmerola, MD, MS)

There are instances where the sling cannot be readily separated from the underlying periurethral tissue or has involved/eroded into the urethra itself. In this difficult scenario, it may be necessary to incise into the urethra and create a urethrotomy to remove the offending sling. Once this has occurred, the urethral defect should be closed primarily if possible and we typically introduce a Martius flap for additional coverage prior to closure of the vaginal incision. It is also critical in this instance, particularly for synthetic slings, to remove the entire vaginal portion of the sling (Fig. 9.5). For instances where the sling cannot be readily identified from an initial midline approach, taking a more lateral approach to dissecting the urethra beginning at the distal urethra can allow for identification of the sling.

Urethrolysis

Urethrolysis surgery is generally reserved for patients who are at risk of significant periurethral scarring. These patients typically have undergone multiple prior urethral or bladder neck surgeries, including prior failed sling incision/excision, prior urethrolysis, Burch colposuspension, Marshall–Marchetti–Krantz (MMK) or other bladder neck suspension/urethropexy procedures. It is best performed by experienced surgeons due to its inherent technical challenges and lack of a well-defined endpoint. Clinical judgment is key to determining the extent of adequate dissection and mobilization of the urethra for urethrolysis, as well as the proper surgical approach. The goal of urethrolysis is to restore some but not excessive mobility to the urethra. A Q-tip intermittently inserted into the urethra during surgery is a good tool to judge progress,

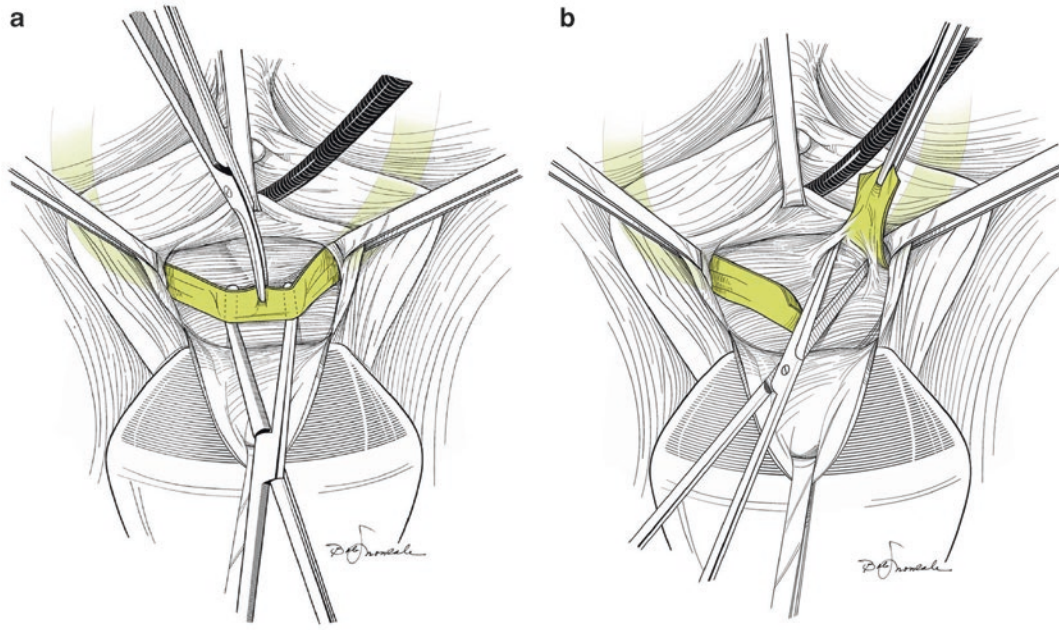

Fig. 9.2 (**a**) Once the sling is identified and dissected off the urethra, counter-traction with a right-angle clamp allows for the sling to be incised in its midline. (**b**) The cut ends often then spring apart, and further dissection can be performed sharply laterally. (Reprinted from Nitti et al. [29]. With permission from Elsevier)

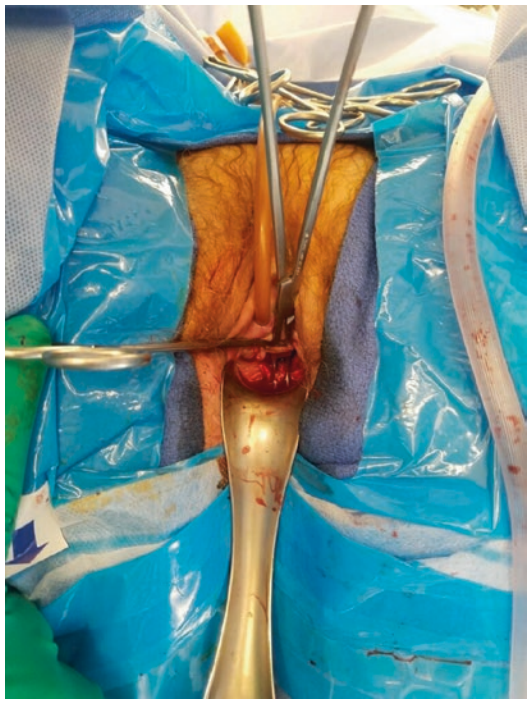

Fig. 9.3 The sling can be grasped with an Allis clamp for retraction and dissection, however, once freed, a right-angle clamp is useful in providing additional retraction and tension in order to dissect free the lateral arms of the sling. (Courtesy of Ricardo Palmerola, MD, MS)

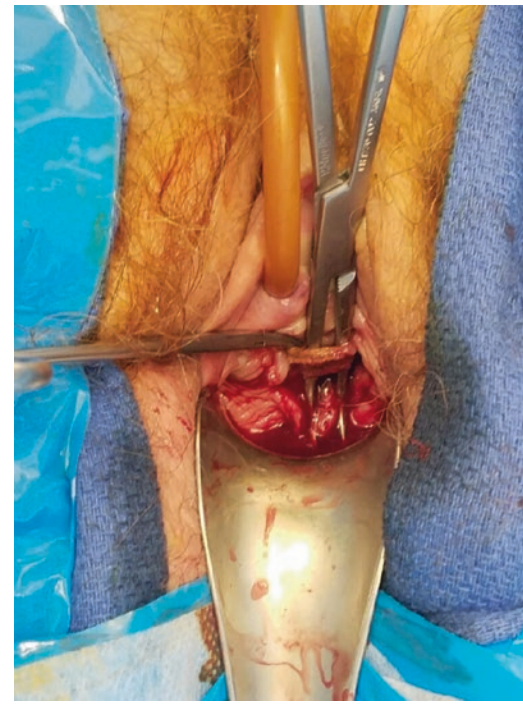

Fig. 9.4 The sling can be grasped with an Allis clamp for retraction and dissection, however, once freed, a right-angle clamp is useful in providing additional retraction and tension in order to dissect free the lateral arms of the sling. (Courtesy of Ricardo Palmerola, MD, MS)

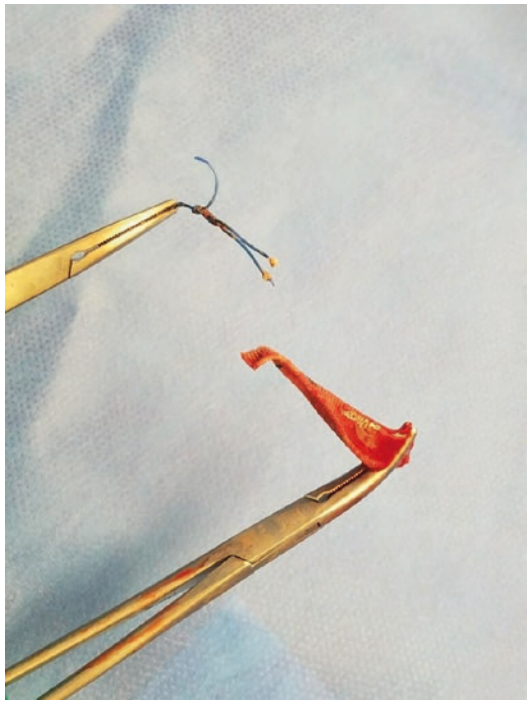

Fig. 9.5 Entire vaginal portion of the sling removed. (Courtesy of Ricardo Palmerola, MD, MS)

although there is no standardized angle/degree of improvement to follow. Two main approaches for urethrolysis have been described, retropubic and transvaginal. Variations on the transvaginal approach include the suprameatal and transvestibular techniques. More recently, with the wide availability of robotic surgical systems, minimally invasive robotic-assisted approaches have also been reported. Nonetheless, in each of these varied techniques, the original incontinence surgery can often guide the most appropriate urethrolysis approach.

Retropubic Approach

In 1990, Webster and Kreder described the retropubic approach to urethrolysis, which is best used for prior retropubic suspensions or pexy procedures [20]. A Pfannenstiel or low midline incision is made to enter into the retropubic space, wherein the urethra, bladder neck, and anterior vagina are dissected sharply off and freed anteriorly from the pubis. Once the urethra, bladder neck, and anterior vagina are freed, an omental flap can be brought down to wrap around the freed structures to prevent future adhesions. For particularly scarred instances, the dissection can be carried more laterally toward the ischial tuberosities. This more extensive dissection can lead to paravaginal defect and thus should be avoided unless absolutely necessary. In certain instances, a combined transvaginal and retropubic approach may be taken for particularly challenging cases of failed/repetitive prior transvaginal urethrolysis or altered vaginal/pelvic anatomy.

Transvaginal Approaches

Transvaginal urethrolysis for urethral obstruction was first described by Zimmern et al. in 1987 [21]. A midline or inverted U incision is made over the mid-urethra and sharp dissection is then performed to the urethra, taking care not to enter or injure the urethra (Fig. 9.6a–d). Oftentimes, a plane within the periurethral tissue is difficult to identify, and particular care should be taken to sharply develop this space. At this point, dissection is then carried out along the urethra proximally toward the bladder neck and/or distally to the meatus depending on the degree of scarring, as well as laterally through to the endopelvic fascia. Once the endopelvic fascia is entered, blunt dissection with a right-angle clamp or a finger or sharp dissection can be used to free up the urethra further from its attachments anteriorly to the pubic symphysis and to the sidewalls. This lateral approach is generally more successful for treating urethral obstruction following pubovaginal slings or needle suspensions. For repeat urethrolysis, it is crucial to completely free and mobilize the urethra circumferentially and to place a Martius flap circumferentially around the urethra to prevent future scarring and adhesions [22].

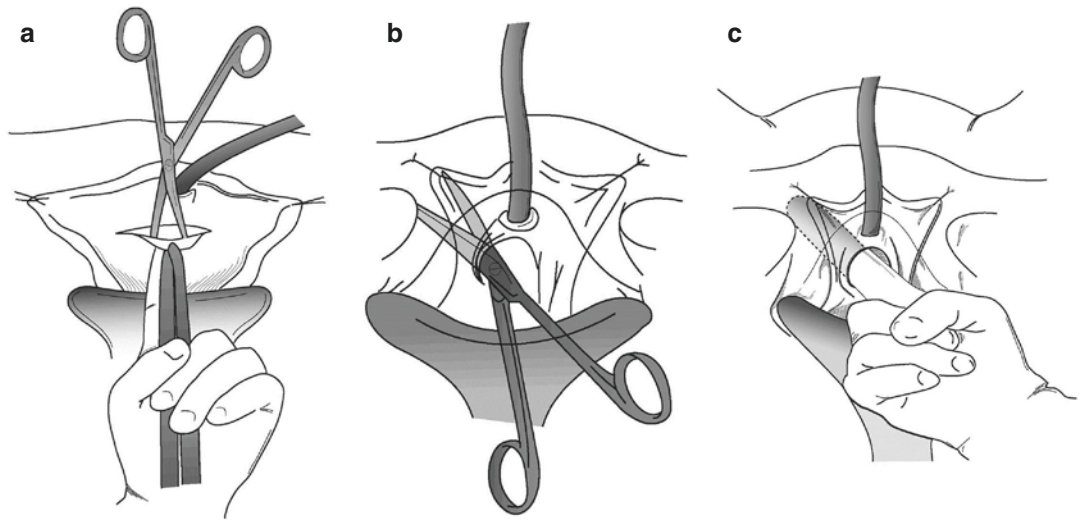

Fig. 9.6 (**a**) A midline or inverted U incision is made over the mid-urethra and sharp dissection is then performed to the urethra, taking care not to enter or injure the urethra. (**b**, **c**) Once the endopelvic fascia is entered, blunt dissection with a right-angle clamp or a finger or sharp dissection can be used to free up the urethra further from its attachments anteriorly to the pubic symphysis and to the sidewalls. This lateral approach is generally more successful for treating urethral obstruction following pubovaginal slings or needle suspensions. (Reprinted from Blaivas and Chaikin [43]. With permission from Elsevier)

For a transvaginal approach to prior retropubic procedures such as the Burch or MMK retropubic suspensions, the suprameatal variation can be quite useful [23]. An inverted U incision is made between the clitoris and the urethral meatus anteriorly (Fig. 9.7a–d]. The dissection is then carried proximally dorsally over the urethra toward the bladder neck underneath the pubic symphysis. Lateral perforation of the endopelvic fascia can be avoided in this way as described by Petrou et al. Visualization, however, can be quite challenging and bleeding can be encountered proximally. Once the retropubic sutures or sling is encountered, they are then cut under either direct visualization or by feel. This anterior suprameatal approach can also be combined with the lateral approach for better visualization and dissection, which is particularly useful for instances where a Burch or MMK procedure is performed and a sling subsequently placed. A Martius flap can also be placed via the suprameatal approach [24].

A transvestibular urethrolysis has also been described, although to our knowledge it has not gained widespread practice [25]. Carmignani et al. report their technique where a circummeatal incision is made and the urethra is then circumferentially freed proximally. Once the urethra had been adequately mobilized to the bladder neck and freed from its surrounding adhesions, the urethral meatus was then repositioned with interrupted circumferential sutures to the vaginal mucosa.

Robotic/Laparoscopic Approach

Pure laparoscopic and robot-assisted laparoscopic techniques for urethrolysis have also been reported in the literature [26]. Orasanu et al. reported on a series of six patients who underwent robotic-assisted urethrolysis after abdominal hysterectomy and Burch colposuspension [27]. The surgical technique mirrors the open retropubic approach, with perhaps the added benefit

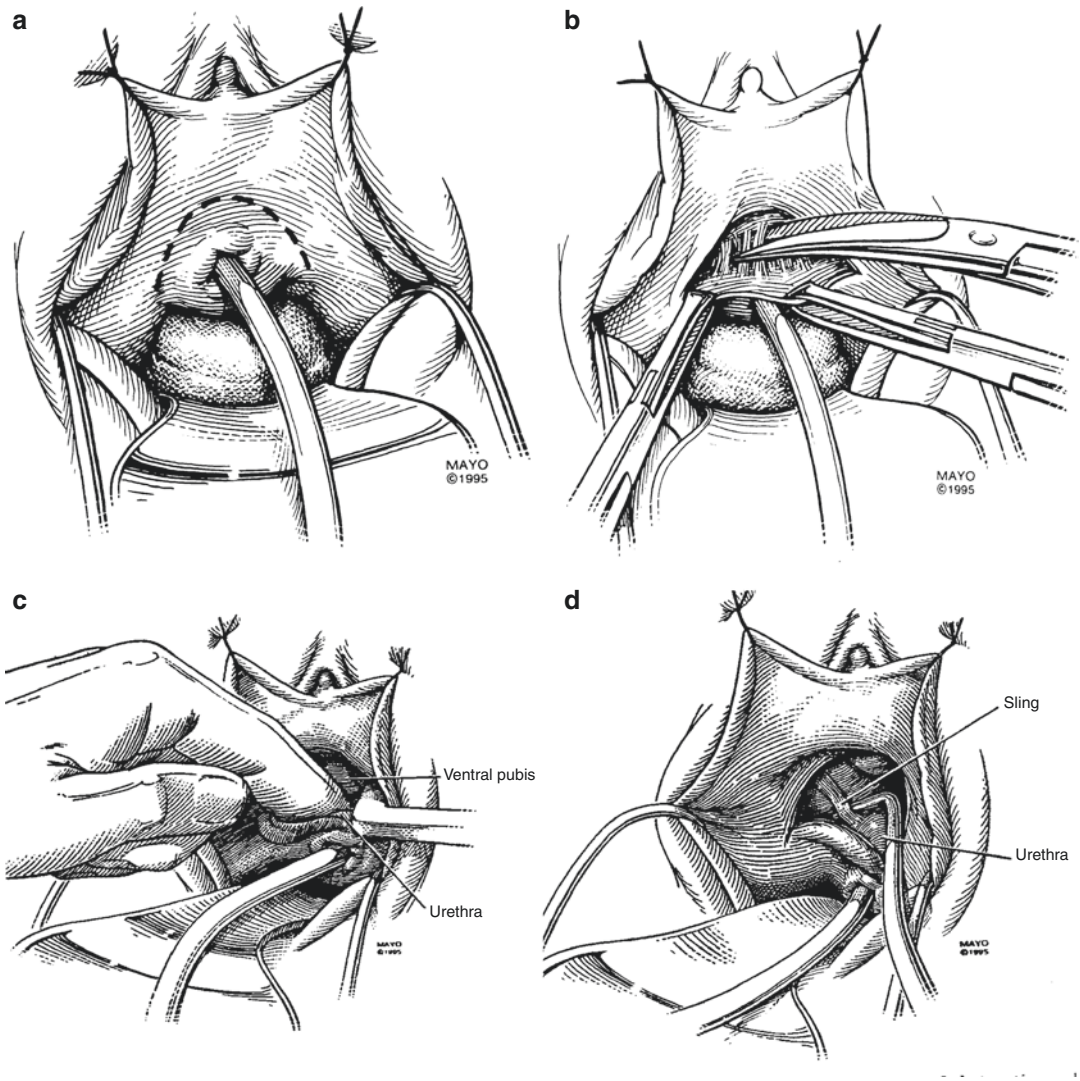

Fig. 9.7 (**a**) An inverted U incision is made between the clitoris and the urethral meatus anteriorly. (**b**) The dissection is then carried proximally dorsally over the urethra toward the bladder neck underneath the pubic symphysis. (**c**) Lateral perforation of the endopelvic fascia can be avoided in this way. (**d**) The sling or retropubic sutures are identified laterally to the urethra and incised. (Reprinted from Petrou et al. [23]. With permission from Elsevier)

of minimally invasive surgery with decreased recovery time and easier surgical maneuverability and exposure.

Clinical Outcomes

Outcome measures following sling incision/excision or urethrolysis have ranged greatly in the literature. This is due in part to limitations of the published studies and data. Most studies are small series and have varying inclusion criteria combining different incontinence surgeries. Additionally, there is lack of standardization with regard to the definition of success and the outcomes measured. Some have used subjective measures such as global patient satisfaction scores, patient-reported outcomes, and quality-of-life questionnaires or unvalidated assessments of symptoms to report success. Others describe

specific objective urodynamic parameters, such as postvoid residuals, flow rates, and voiding pressures. Urinary retention with the need for chronic or intermittent catheterization is also a commonly reported outcome measure. As a result of this variability, it is difficult to truly assess the comparative effectiveness of each approach.

Sling Incision/Excision

Sling incision/excision generally has the highest rates of success reported in the literature, although perhaps in part due to more uniform patient study cohorts. Goldman reported on simple sling incision for urethral obstruction in 14 women, 11 who had undergone autologous fascial pubovaginal sling and 3 who had synthetic mid-urethral sling [28]. He determined that at a mean follow-up of 1 year there was a 93% success rate. Of the 14 women, 11 had complete resolution of symptoms and 2 had significant improvement. One patient required further urethrolysis. Nitti et al. described their series of 19 patients who underwent simple incision of pubovaginal sling (18/19 were autologous biologic slings) [29]. Twelve patients presented in urinary retention with catheterization and the other 7 presented with LUTS. They found at mean of 1-year follow-up 84% of patients had either complete resolution or improvement of symptoms, with 3 women going on the formal urethrolysis. In larger study combining both simple sling incisions and transvaginal urethrolyses, Amundsen et al. examined their cohort of 32 patients with urethral obstruction following pubovaginal sling procedure and administered postoperative quality-of-life and disease-specific questionnaires [30]. Voiding diaries were also performed. Twenty-six of the 32 patients were catheter-dependent preoperatively, and postoperatively, 94% of these patients resumed efficient voiding. Thirty of 32 patients (94%) had preoperative urge incontinence, and in 20 of the 30 patients (67%) urge incontinence completely resolved postoperatively. In the largest reported series, South et al. retrospectively reviewed 112 patients who underwent sling incision for irritative or obstructive voiding symptoms after pubovaginal or mid-urethral sling [16]. The authors found a success rate of 84% in the entire cohort in terms of improvement of symptoms, with 91% of patients improved in the early invention (<1 year) group as compared to 71% in the delayed (>1 year) group.

Retropubic Urethrolysis

In a small series of 12 patients, Petrou and Young examined the success rates of women who had undergone retropubic urethrolysis only [31]. Ten of the 12 patients reported satisfactory improvement in their urinary symptoms, while 2 patients experienced subjective mild improvement. Basu et al. reported changes in urodynamic parameters in a series of six patients with obstructive or irritative symptoms after Burch colposuspension treated with retropubic urethrolysis [32]. Mean Q_{max} improved from 11.2 mL/s to 16.4 mL/s and mean $P_{det}Q_{max}$ decreased from 43.2 cm H_2O to 34.7 cm H_2O. Although this was a small study of 16 patients, the authors found that 43% of patients following transvaginal urethrolysis had resolution of their symptoms while 78% did so after retropubic urethrolysis. In their series of 51 consecutive patients with BOO undergoing 54 urethrolyses, Carr and Webster found no significant differences in between retropubic and transvaginal approaches [8]. They noted success, defined as complete resolution or significant improvement, occurred in 86% of the retropubic cohort and 73% of the transvaginal cohort. However, when examining a more uniform patient cohort, Anger et al. have suggested that retropubic urethrolysis is superior to the transvaginal approach for BOO after Burch colposuspension [33]. Anger et al. reported that only 43% of patients had resolution of urinary symptoms as compared to 78% who underwent a retropubic approach in this cohort.

For robotic-assisted retropubic urethrolysis, the success rates are similar to the open approach. Orasanu et al. reported complete symptom resolution in five of six patients (83%) of patients undergoing robotic-assisted urethrolysis and a mean improvement in emptying of 46.5 mL on postvoid residual (range: 0–176 mL) [27].

Transvaginal Urethrolysis

In addition to the abovementioned studies, several studies have presented outcomes following transvaginal urethrolysis. Cross et al. reviewed a cohort of 39 women with urethral obstruction and urge incontinence following various incontinence procedures [34]. All patients underwent transvaginal urethrolysis, and 85% had complete resolution of urge incontinence. In another review of 31 women undergoing transvaginal urethrolysis without bladder neck resuspension, Goldman et al. found that 84% of patients were improved/cured. In their cohort, irritative voiding as a presenting symptom was less common (55%), and most patients had obstructive voiding, incomplete emptying, or urinary retention (71%) [35]. Six of the 26 improved patients did develop recurrent stress urinary incontinence; all treated successfully with bulking agents. Another small series by Carey et al. examined 23 patients who underwent transvaginal urethrolysis with Martius flap wrapping [22]. In this series, 87% of patients had complete resolution of symptoms at mean 16 months of follow-up, with three patients continuing with clean intermittent catheterization.

Studies of transvaginal suprameatal urethrolysis exhibited similar success rates. Petrou et al. examined 32 patients with urethral obstruction, of which 20 were in urinary retention and 12 had primarily irritative voiding or urge incontinence symptoms [23]. Following suprameatal urethrolysis, 65% of retention patients were able to void well and 67% of irritative voiding patients had complete resolution of their symptoms. Following transvestibular urethrolysis, Carmignani et al. noted symptomatic improvement and decreased postvoid residuals in all 18 patients treated [25].

Repeat Urethrolysis

While some of the previous studies included prior urethrolysis in their cohorts, Scarpero et al. specifically examined a cohort of repeat urethrolysis and reported their outcomes [36]. Their cohort of 24 patients included 23 prior transvaginal and 1 prior retropubic urethrolyses. Redo urethrolysis was performed via the retropubic approach in 12, transvaginal in 10, and combined in 2. Success was noted in 91% of catheter-dependent patients, who were able to eliminate catheterization postoperatively. Irritative voiding symptoms resolved completely in 12% of patients, improved on anticholinergic medication in 69%, and remained same in 19%. There were no instances of de novo irritative symptoms. Mean postvoid residual volume improved from 334 mL preoperatively to 44 mL postoperatively (p <0.001).

More recently, Oliver and Raz presented their series of 11 patients undergoing suprameatal urethrolysis with Martius flap after failed transvaginal urethrolysis [24]. At a mean follow-up of 10.8 months, they noted a success rate of 82%. Two of the 11 patients continued to require catheterization and went on to additional surgical intervention.

Complications of Repair

Surgical complications following sling incision/excision or urethrolysis are uncommon and usually of low morbidity. In published reports, complications following these procedures are rarely described in a standardized fashion, such as with the Clavien-Dindo classification system. Reported complications generally relate to the recurrence or de novo occurrence of voiding symptoms. Scant literature exists describing the rates of urethral injury following urethrolysis and sling incision/excision, presumably because their occurrence is so infrequent in expert hands or conversely necessary in a controlled fashion for completion of the procedure.

Recurrence of Stress Urinary Incontinence

One of the most common complications after sling incision/excision for bladder outlet obstruction is the recurrence of stress urinary

incontinence. In the case of simple sling incision, Clifton et al. reported on 93 women who were treated with sling lysis for obstruction or retention after sling placement. With a median follow-up of 32 months, they found that 14% of these patients required a repeat anti-incontinence procedure after sling incision at an average of 3 months postrevision [37]. Agnew et al. found that more extensive sling revisions such as partial sling excision resulted in a higher proportion of patients requiring reoperation for recurrent stress urinary incontinence (23%) when compared to simple sling incision (6%) [38]. Shaw et al. validated these results in a cohort of 102 women. In the study, 88% of patients had undergone prior sling incision and 10% prior sling excision for voiding dysfunction or retention. The remaining two patients underwent sling excision for mesh erosion or pain. At mean follow-up of 36 months, 4.4% of sling incision patients required reoperation for SUI recurrence as compared to 29% of patients for sling excision [39].

For these patients who develop persistent or recurrent incontinence following sling incision/excision, autologous fascial pubovaginal or retropubic sling (for prior mid-urethral sling) are potential treatment options [40]. Sparse literature exists on the incidence of repeat urethral obstruction in patients undergoing repeat sling procedures after urethrolysis. Parker et al. compared autologous fascial pubovaginal sling placement in redo cases to virgin cases and noted a significantly higher rate of retention (8.5% vs. 3.1%, $p < 0.001$). Interestingly, he found that—despite a higher rate of CIC use—those with prior failed sling placement reported a lower rate of obstructive symptoms based on UDI-6 questionnaire compared to patients undergoing initial sling placement (6.8% versus 10.9%). The authors hypothesized that these women with prior failed sling placement may have a higher tolerance of bothersome bladder symptoms given their long-standing symptoms [41]. These patients must therefore be counseled appropriately regarding the higher potential risk of pubovaginal slings in these circumstances.

Overactive Bladder

New onset overactive bladder symptoms and urge incontinence after sling insertion are among the most common complaints that lead women to undergo sling revision. Unfortunately, the resolution of these symptoms is far from guaranteed and highly unpredictable. The persistence of these symptoms following sling incision/excision or urethrolysis ranges from 10% to 76% in the literature [18, 42]. The study by Nitti et al. involved 19 women undergoing midline sling lysis for obstruction. With a mean sling revision time of 10.6 months, they found that 11 of the 13 women with irritative symptoms had resolution or improvement in their symptoms [29]. A recent study by Crescenze et al. of 107 patients examining urge incontinence following revision of sling found a persistence of urge incontinence in 76% of the cohort. Of note, this cohort had a mean time to revision of 21 months [42]. Not surprisingly, patients with postrevision urgency incontinence had higher Urogenital Distress Inventory-6 scores than women with no symptoms or resolution of symptoms.

Starkman et al. looked at a cohort of 40 women, who were divided into two groups with either persistent overactive bladder or resolved overactive bladder symptoms following urethrolysis. They found that 56% of their cohort had persistent overactive bladder symptoms with a mean time to revision of 22 months. Those with persistent overactive bladder symptoms had higher rates of detrusor overactivity on urodynamics, but similar rates of clean intermittent catheterization and elevated postvoid residuals. The authors noted that they did not routinely perform postoperative urodynamics, but had uniformly high success rates for the resolution of obstructive voiding symptoms in both cohorts [18].

Conclusion

Female urethral obstruction is a rare clinical entity and typically occurs iatrogenically after incontinence surgery. While many cases present

in the immediate postoperative period, there is a certain percentage of patients who may demonstrate a delayed presentation. Maintaining a high suspicion based on clinical history is often key for initial diagnosis, as physical examination can often be unrevealing and presenting symptoms can vary greatly. The presence of urethral obstruction can be confirmed on noninvasive uroflowmetry, cystoscopy, voiding cystourethrography, and urodynamics. Urethrolysis and sling incision/excision are two approaches for surgical repair, with urethrolysis typically reserved for more complex cases or suspension procedures. Outcomes after urethrolysis and simple sling incision/excision are quite favorable, but a small portion of patients do continue to experience persistent obstruction. Recurrent stress urinary incontinence, overactive bladder symptoms, and urge incontinence are potential significant, albeit relatively uncommon, sequelae following sling lysis or urethrolysis. There exists a high degree of unpredictability with the resolution of OAB symptoms. Further study is necessary for delineating long-term validated patient-reported outcomes and examining comparative effectiveness of the various repair techniques.

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Vaginal Fistula Repairs

10

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Introduction

A urinary fistula is defined by extra-anatomic communication between two contiguous organs. This communication in the lower urinary tract may involve the ureters, bladder, or urethra, which makes an abnormal connection with the rectum, vagina, uterus, or skin. A complex urinary fistula might involve several different abdominal and pelvic organs, emphasizing the importance of a complete workup before attempting a repair.

A urinary fistula negatively affects an individual's quality of life, and prompt repair is suitable in most patients that are properly selected. There are many surgical approaches to repair a urinary fistula. The best repair centers on the first procedure being the most effective. However, there is a lack of high-quality comparative studies to guide the surgeon. When selecting the initial surgical approach, the surgeon should consider their expertise and experience after a thorough evaluation to determine the etiology and location of the fistula. In this chapter, we will focus on the etiology, diagnosis, evaluation, and surgical repair of vesicovaginal, urethrovaginal, ureterovaginal, and rectovaginal fistula.

General Principles of Fistula Repair

This chapter provides an overview of the principles for successful repair including the evaluation, timing, condition of the patient, vaginal access, surgical approach, and use of adjuvant procedures. The majority of fistulas encountered in developed countries are iatrogenic and will be the focus of this chapter.

Evaluation

History and Physical Examination

Women with vesicovaginal fistula (VVF) and urethrovaginal fistula most often present with constant urinary incontinence shortly after a pelvic surgery. Questioning about the degree of difference voided and the amount leaked may give clues to the size and location of the VVF. If leakage is small volume and continuous, a small fistula may be anticipated. If minimal voiding occurs, a larger fistula should be suspected. Timing of the onset of leakage and whether there is stress incontinence or urge incontinence with overactive bladder symptoms before the VVF is important to consider in selecting treatment options and patient counseling. A patient with a

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urethrovaginal fistula in the distal third of the urethra may remain continent and asymptomatic or they will commonly describe a splayed urinary stream. They may additionally complain of urinary leakage after vaginal voiding. When the fistula is in the mid-urethra and part of the external sphincter, the patient may have positional intermittent leakage of urine. Patients may have constant, large amounts of urine leaking indicating there is a large fistula that is located proximal to the mid-urethra in the proximal urethra or bladder neck. Gathering information to determine the etiology and prior surgical attempts to repair the fistula can affect the treatment plan.

On physical examination, there should be careful inspection of the fistula size, location, and quality of the surrounding tissue. The location of VVF after hysterectomy is usually a single fistula at the vaginal cuff, although it may present as a complex VVF with multiple fistulas. Evidence of the fistula site is found with surrounding inflammation with granulation and tissue defect. Adequate vaginal access and the degree of mobility of the tissue surrounding the fistula are revealed by the amount of vaginal prolapse. Nulliparous patients or with a history of radiation may be challenging due to a lack of vaginal access and mobility because of narrow vaginal width. On examination, the integrity of the vaginal epithelium, urethral mobility, and assessment of stress incontinence with provocative maneuvers should be performed.

It is important to differentiate the origin of the vaginal drainage and not to make any assumptions as the fluid may be from the fallopian tube, vaginal secretions, peritoneum, lymph, or urine. The differential diagnosis of VVF is urethrovaginal fistula, ureterovaginal fistula, uterovaginal fistula, ectopic ureter, or vaginal infection. The presenting symptoms may be recurrent urinary tract infections with chronic perineal changes exhibited by poor healing and irritated skin. A complete vaginal examination will guide the surgeon to the diagnosis, but this may be indeterminate and other tests may be needed to make the diagnosis.

Patients with rectovaginal fistula (RVF) often present with clinical symptoms of gas, stool, and purulent vaginal discharge. The physician should be aware that colonic or enteric fistula may present with similar symptoms as a rectovaginal fistula. History should focus on causes of the fistula, most commonly obstetric trauma, but also includes pelvic surgery, malignancy, history of radiation, pelvic abscess, and inflammatory bowel diseases. Occasionally, small or intersphincteric rectal vaginal fistula may be asymptomatic. Vaginal and bimanual examination should be performed taking note of the location, number, tissue quality, and size of the fistula. On examination, the fistula is normally clearly visualized, and instilling dye into the rectum may be of assistance. The location of the fistula is important in deciding the operative approach and is classified into high and low in relation to the anal sphincter. High fistula may need to be approached abdominally and low fistula transvaginally. Occasionally examination under anesthesia is indicated for a more thorough evaluation. During physical examination, anal sphincter tone should be evaluated, as this may need concomitant repair.

Diagnosis

The diagnosis of a urinary or rectovaginal fistula can most often be made upon a vaginal examination. A urethral catheter with retrograde filling of the bladder or rectum with dye may demonstrate the fistula on examination. A urinary fistula can be confirmed after administering phenazopyridine once it is excreted in the urine. By placing gauze or a tampon in the vagina, the gauze should turn orange in color in the presence of a fistula. A double-dye tampon test can further delineate the origin and location of the fistula by giving the patient phenazopyridine followed by retrograde instillation of dye, methylene blue, or indigo carmine, into the bladder through a catheter. A ureterovaginal fistula should be orange in the proximal part of the packing while a VVF or urethrovaginal should be blue in the mid or distal packing. A negative tampon test does not rule out a fistula and clinical suspicion is often required to make the diagnosis.

There are varying opinions and no consensus on the imaging required in the evaluation of a

VVF or urethrovaginal fistula. Many patients have a complex history with postoperative complications and there are medico-legal implications that should be considered [1]. Our practice is to completely evaluate the patient to attempt to address all problems at the initial repair. A voiding cystogram during filling may demonstrate the fistula; however, the intradetrusor pressure may need to be increased during voiding to visualize small fistulas with the patient positioned in the lateral and oblique position. The lateral views may best demonstrate the fistula when it has a direct connection between the bladder and vagina or when the connection is indirect and enters a collection/sinus tract before draining into the vagina. The VCUG can identify additional findings of a urethrovaginal fistula which can be found concomitantly with VVF, the degree of vaginal prolapse, and stress incontinence [2]. Demonstration of preoperative stress incontinence may change the treatment plan by the addition of an anti-incontinence procedure or it may alter patient expectations so it will not be a surprise if they leak postoperatively. Upper tract involvement should be evaluated for obstruction or fistula.

While retrograde studies were in the past most important to rule out concomitant ureteric fistula, CT urogram with 3-dimensional reconstruction can demonstrate the integrity of the ureters. Cystoscopically, 0- or 15-degree lenses are used for visualizing urethral fistulas and finger compression of the bladder neck helps to fill the urethra. It is our routine practice to perform a cystoscopy to evaluate for a urethral fistula and consider it mandatory when there is a history of hematuria or radiation. Cystoscopy is different from urethroscopy. A urethroscopy should be performed with a short-beaked rigid cystoscope (urethroscope or hysteroscope) or flexible cystoscope to allow full visualization of the urethra. The light and the irrigant are at the same level allowing direct vision and expansion of the urethral wall. A 30- and 70-degree optic lens allow identification of bladder or urethral foreign bodies or lesions that would need to be biopsied. The fistula size and location in relation to the bladder neck, trigone, and ureteric orifice are determined on cystoscopy. If the fistula involves the bladder neck, it should be discussed with the patient, as it may affect continence after repair. Findings on a cystoscopy can determine if ureteral stents are necessary and if a combined vaginal and abdominal approach is appropriate when there is ureteric involvement.

It is important to document preoperative sexual function and discuss potential postoperative complications. Vaginal stenosis is a potential complication that can be corrected with a subsequent vaginoplasty in most cases. Vaginal shortening may result when a Martius flap has insufficient length for a proximal fistula or as a result of Latzko partial colpocleisis. The peritoneal flap is better situated for proximal fistula repair to prevent vaginal shortening. Patients should be counseled and encouraged that sexual function may improve following fistula repair [3].

Upper tract evaluation to assess for abnormal findings of hydronephrosis or urinary extravasation with CT urogram should be performed, although there are no formal recommendations to guide the surgeon. There is a 12% risk of upper tract injury with VVF [4]. Should there be further questions regarding ureteric involvement, a retrograde pyelogram would be justified, as it is the most sensitive in the detection of upper tract injury, although a CT urogram with reconstructions may be adequate in our experience [5]. Urine cytology is recommended for those with a history of malignancy or pelvic radiation.

Further radiologic evaluation with a CT of the abdomen and pelvis should be performed in cases of prior malignancy or in patients without other risk factors for RVF. Gastrografin enema may identify the location of the rectovaginal fistula. Proctosigmoidoscopy and colonoscopy may establish the diagnosis and evaluate for malignancy, especially in the case of radiation-induced fistula where about a third are malignant [6]. If there is any concern for malignancy, the fistula should be biopsied.

Anal sphincter tone should be evaluated preoperatively with physical examination. Nearly 50% of patients have fecal incontinence which should be discussed and potentially treated

simultaneously with fistula repair [7]. Our practice is to routinely obtain endoanal ultrasound when the cause of the fistula is from trauma after vaginal delivery. Endoanal ultrasound and anal manometry testing can provide valuable information regarding sphincteric function and defects preoperatively.

Timing

Timing of repair begins with an assessment of risk factors for poor healing (malnutrition, radiation, immunosuppression, or vaginal atrophy) that should be corrected when possible before proceeding with repair. The timing of repair depends mostly on the etiology of the fistula and the experience and comfort level of the surgeon. The surgical approach is individualized for every patient and depends on the experience of the surgeon. The first repair should be the most successful. Most fistulas are found after the acute period and traditionally it was thought that a period of about 6 months was required for tissue swelling and infection to resolve so that an optimal repair could be performed. However, we now know that there are similar outcomes with early or delayed repair with several reports where fistula repair can be performed successfully after 2 weeks [8–10]. The prerequisites for early repair are no obvious infection and the absence of an ischemic fistula from radiation or obstructed labor which can impede healing from the viability of tissue margins that vary with time.

In the cases of radiation-induced fistula, it is advisable to allow for tissue stabilization, although many fistulas present late when there is no active progression. Assuming there is no infection and the tissue has stabilized, the patient could proceed to surgical reconstruction. Radiation results in extensive tissue ischemia and the reported failure rates can be up to nearly 50% [11]. Due to high failure rates, adjuvant procedures involving tissue interposition should be performed. Consideration of temporary fecal diversion or in severe cases permanent urinary or fecal diversion may be warranted. Additional findings of diminished bladder capacity are common with the fistula typically located in the immobile region of the bladder trigone and may involve the ureteric orifices requiring an abdominal approach to perform bladder augmentation and/or ureteral reimplant.

Special consideration should be given to RVF from Crohn's disease by first contemplating medical therapy before proceeding to surgical repair. Medical therapy with anti-tumor necrosis factor therapy has a reported success rate of 60% at 1 year, but this declines to 36% at long-term follow-up with similar unsatisfactory results from other studies [12–16]. Other medical treatments include 6-mercaptopurine, and cyclosporine with limited success. Even with advances in medical therapy, surgical repair is the primary basis for long-term cure.

Abdominal or Vaginal approach

The goal of surgical repair is to have a durable repair with the least morbidity and to preserve continence. In deciding the surgical procedure, consideration is made to the location of the fistula, size, etiology, quality of the surrounding tissue, and vaginal access all of which could limit or change aspects of the surgery. Principles of repair regardless of approach include non-overlapping sutures, tension-free approximation of tissue, avoid devitalizing of the tissue, removal of foreign bodies, good hemostasis of the surgical field, a watertight, multilayer closure with or without the interposition of tissue, and postoperative bladder and urethra drainage or fecal diversion. An infratrigonal VVF is typically approached vaginally. While a supratrigonal fistula may be considered difficult to approach vaginally by some surgeons, in our experience, the non-irradiated high fistula that is not complex can be repaired by the vaginal approach. Other options include the abdominal approaches (open, laparoscopic, or robotic) [17–19]. An indication for an open or minimally invasive abdominal is based on surgeon preference or when there is a need for concomitant bladder augmentation, ureteral reimplant, intraperitoneal pathology, or bowel diversion.

Both abdominal and vaginal repair of VVF are well established and have excellent success rates with each approach having its advantages [20]. Laparoscopic and robotic repairs are being used more routinely at centers of excellence with encouraging results, but further study may be

warranted before wide-scale adoption [18, 19, 21–23]. There are some data to suggest shorter hospital stay and reduced morbidity in patients treated with a minimally invasive compared to open abdominal approach [18]. There are currently no studies directly comparing the vaginal approach to a minimally invasive abdominal approach. The advantages of a vaginal approach over open abdominal approach are decreased morbidity, shorter hospitalization, and decreased complications due to avoidance of intraperitoneal injury and a large bladder incision. In deciding the approach, a surgeon has to consider their experience, comfort, and familiarity with each approach. The first repair is the most important in establishing long-term successful outcomes from either approach.

Urethrovaginal fistula repair is tailored by the location, size, and symptoms. A fistula located in the distal urethra may only need an incision of the distal urethra or observation if asymptomatic. If the fistula is large in size (>1–2 cm), radiation induced, or tissue is necrotic and inflamed, the use of an interpositional tissue flap is recommended. Interposition with a Martius flap is the preferred method due to the location to the urethra and ease in dissection with minimal complications. More complex urethral damage may require more complex procedures like rotational vaginal or labial flaps, neo-urethral reconstruction, autologous fascia sling, or bladder neck reconstruction.

As in other fistula, there are no formal guidelines for rectovaginal fistula repair. Most urologists or gynecologists repair RVF vaginally, while colorectal surgeons are more familiar with transanal or abdominal repair. Most rectovaginal fistulae are easily accessed by the vaginal route, while the abdominal approach is used for sigmoid colon and proximal rectal fistulae. There is limited experience with minimally invasive treatment with fibrin glue or endoscopic management [24]. We will focus on vaginal repair, which avoids the morbidity of an abdominal surgery.

Before embarking on vaginal repair, there should be consideration to the fistula location, sphincteric function, quality of the tissues due to radiation or prior surgeries, concomitant abdominal pathology or the need for a diverting colostomy. A high fistula is not an absolute indication for an abdominal repair. A vaginal approach allows for simultaneous anal sphincter reconstruction. The surgeon's expertise and familiarity should be considered for each case.

Concomitant Procedures

Stress incontinence after successful VVF repair may cause distress and lead the patient to believe their surgery was a failure. Preoperative evaluation and education is important so patients understand their surgical options. Concomitant anti-incontinence procedures can be performed with fistula repair and do not increase the risk of recurrence, although it may be better to stage the anti-incontinence procedures [25]. In select instances, we would consider placement of a fascial sling at the time of VVF repair, but in the majority of cases, the procedure is staged because even temporary outlet obstruction can lead to fistula recurrence. A synthetic sling is not recommended, as it is a foreign body and may lead to fistula recurrence. Our preference is to stage an anti-incontinence procedure to prevent the risk of high-pressure voiding that may result in fistula recurrence.

The approach is similar with urethrovaginal fistula, in which the majority of cases the procedure is staged to prevent the development of urethral obstruction and increased risk of fistula recurrence. The condition where there is less controversy about placing a fascial sling is when the fistula involves the mid-urethra sphincteric complex or distal third of urethra and there is suspicion that the patient will be incontinent postoperatively. The sling would be placed proximal to the repair at the bladder neck. Some have successfully reported concomitant autologous fascial sling at the time of a fistula repair, while we have not placed a sling distal to our urethral repair due to the risk of the sling creating obstruction and high-pressure voiding that may result in fistula recurrence.

Ureteral Reimplant and Bladder Augmentation

Diagnostic evaluation can determine the need for additional bladder or ureteral surgery which would require an abdominal approach. An

abdominal approach is indicated when there is ureteric obstruction or fistula which would require reimplantation. Placement of preoperative ureteral stents when a vesicovaginal fistula is located near the ureteric orifice may avoid reimplant. In cases of a small and contracted bladder capacity, an augmentation should be performed. The need for concomitant procedures can typically be assessed with urodynamic studies that assess bladder capacity and compliance.

Fecal Diversion

The decision to perform a temporary diverting colostomy or ileostomy is made on an individual basis, as there are no absolute indications. The surgeon may elect to divert stool with complex fistula that are radiation induced, recurrent, large, or a result of malignancy. The diversion is taken down 3–6 months postoperatively after a successful repair.

Tissue Interposition: Peritoneal, Martius, Labial, Gluteal Flaps (Inner Thigh Rotational Flaps Based on the Internal Pudendal Artery)

Urinary repair and reconstruction is complex and requires many techniques to be in the surgeon's armamentarium. Successful repair consists of several layers in the closure of the fistula. The use of interpositional tissue is advised when the fistula is complex, large, a history of radiation, tissue is inflamed, or closure is suboptimal. There are differing opinions when tissue interposition is necessary, as there are no definitive indications. Evan et al. in a retrospective study showed improved success rates of VVF repair with interpositional flap [26]. There are several described flaps that can be used for interposition. After a hysterectomy, the location of the VVF is often at the vaginal cuff and we routinely use a peritoneal flap due to its ideal location, ease of dissection, and it maintains a reliable vascular supply. The results have been excellent with a peritoneal flap with 96% success rate [17]. A peritoneal flap is an appropriate choice for supratrigonal fistula and in the case of a distal fistula, it should be repaired with a Martius flap due to its location. Successful repair has been reported at 97% with a Martius flap [17]. The Martius flap is well vascularized with the blood supply superiorly by the external pudendal artery, laterally by the obturator artery, and inferiorly by the posterior labial branches of the internal pudendal artery by which it is usually based. The Martius flap is mobilized by transection of the superior and lateral pedicles and its blood supply is based on the inferior pedicle in the majority of cases. Successful repair is subject to adequate mobilization so that the flap is off tension without compromising its blood supply. Disadvantages are that it may not reach a proximal fistula without compromising its viability or resulting in vaginal shortening [17].

Rotational labial and inner thigh rotational flaps are selected for specific conditions – large vaginal defects, difficult vaginal access requiring a relaxing incision subsequent need for vaginal coverage, large, recurrent, or radiation-induced fistula. When there is a large vaginal defect, these flaps can provide fibroadipose tissue and skin coverage with a well-vascularized blood supply. Full-thickness rotational labial flaps for anterior vaginal wall or gluteal flaps for posterior or proximal vaginal wall are chosen depending on the location of where the flap is needed. A full-thickness rotational labial flap is the same fatty tissue of a Martius flap with its overlying skin that is rotated to cover an anterior vaginal defect. The fistula is first repaired and then a U-shaped incision is made lateral to the labia majora with the apex located at the posterior fourchette. The flap's blood supply is from the superior pedicle which is based on the external pudendal artery. This flap is dissected free from the fascia of the pubic bone so that it can be rotated medially to achieve repair. In a small series, there has been a successful report of this technique [27].

A full-thickness gluteal inner thigh rotational flap is reserved for complex refractory fistula. With the patient in the lithotomy position, a mediolateral episiotomy is made at 5 o'clock extending from the introitus to the vaginal apex. Dissection is continued into the pararectal space. A 4 × 12 cm inner thigh flap is prepared by making an inverted U-incision lateral to the labia major extending from the ischial tuberosity inferiorly, and to the pubic rami superiorly. This incision preserves the blood supply from the internal pudendal artery and innervation from the labial

branches of the internal pudendal nerve and perineal branches of the posterior cutaneous nerve of the thigh. Dissection is carried to the level of the fascia. The episiotomy is extended to the inferomedial aspect of the flap to allow complete mobility. This creates a lateral gluteal rotational inner thigh flap and a medial labial flap. The labial and gluteal rotational inner thigh flaps are crossed; the inner thigh flap medially and the labia flap laterally. The inner thigh flap is transferred and sutured to the vaginal defect. This is a functional full-thickness flap that provides good sensation, and adequate vaginal width and depth. A variation of the full-thickness inner thigh flap is the Singapore island flap [28]. The dissection of the flap is similar except that the episiotomy is avoided and the flap is tunneled to the defect. The epithelium of the flap is removed except for the area that is covering the fistula. This flap is used in complex fistula repair and may be preferred to the full-thickness rotational inner thigh flap when there is already adequate vaginal access.

There are several reports of gracilis myocutaneous flap for radiation-induced fistula in which it is used for vaginal reconstruction [29, 30]. We seldom find it necessary to perform this technique because the rotational gluteal flap can duplicate many of the same functions of this gracilis graft without the associated morbidity and cosmetic defects.

The most well-described interposition is the omental flap which has increased success rates for abdominal repair in retrospective studies [26, 31]. The omentum is based on the right or left branch of gastroepiploic artery, although typically it is based on the right, which is usually larger and more caudal. In cases of bowel resection, the mesentery can be preserved and serve as a useful interposition which has similar properties as the omentum with a well-vascularized blood supply and lymphatic drainage to decrease inflammation and promote healing. Other tissue interposition flaps that have been reported are bladder flaps [32], free bladder mucosal flaps [33], peritoneal flaps [34], urachal flaps [35], and rectus myofascial flaps [36].

Selection of closure and reconstruction of the urethra after urethrovaginal fistula requires expertise and experience due to its complexity. Urethral reconstruction centers on different techniques, primarily urethral closure, vaginal and bladder flap advancement which includes pedicle flap (labia minora and anterior or posterior bladder), and use of grafts [37]. Surgical planning of the urethra reconstruction technique may influence vaginal incision location. In a complex fistula resulting in damage of nearly the entire urethra that can extend potentially to the bladder neck, a urethral reconstruction using vaginal or bladder flap construction with interposition of tissue would be preferred to a primary closure. It would be advised to place ureteral stents as the fistula may distort the anatomy and ureteral injury may be avoided during the repair.

Vesicovaginal Fistula

Background

Vesicovaginal fistula is an abnormal, extra-anatomic connection between the bladder and vagina. Women with VVF suffer enormous amounts of physical, social, and psychological limitations. Though uncommon in Western countries, it remains a widespread problem in underdeveloped countries due to obstructed labor [38]. In developed countries, VVF is most often a complication of pelvic surgery (hysterectomy), where we will direct the majority of our attention. VVF can be associated with urethrovaginal fistula and/or rectovaginal fistula [17, 39]. In this section, we will cover the etiology, diagnosis, and repair (both vaginal and abdominal approach) of VVF.

Etiology

VVF in the USA and developed countries are the result of gynecologic pelvic surgery in over 80% of cases, with the remaining causes being comprised from radiation, malignancy, trauma, and obstetric instrumentation during childbirth [2]. Hysterectomy accounts for 91% of the gynecologic pelvic surgeries that resulted in VVF [17]. A total of 600,000 hysterectomies are performed annually in the USA and nearly a third of women have hysterectomies for benign disease [40–42]. The reported incidence of fistula after hysterectomy for benign disease is reported to be 0.1% to

0.4%. The risk of fistula increases about tenfold to 1–4% after radical hysterectomy [43]. The majority of hysterectomies in the USA are performed abdominally, with a Cochrane review reporting the risk of fistula formation is similar regardless of the approach, although there is increased risk of injury of the urinary tract with laparoscopic hysterectomy [44, 45]. A national database registry study in Sweden found that abdominal and laparoscopic surgery had the highest fistula rate [46]. Fistula formation after hysterectomy is thought to be the result of unrecognized injury to the urinary tract at the time of surgery. The injury may be directly to the bladder itself, or from inadvertently placed sutures that result in tissue necrosis. These injuries result in a urinoma that accumulates and drains through the vaginal cuff [43]. Preoperative risk factors for fistula formation after hysterectomy for the benign and malignant disease are diabetes, smoking, history of cesarean section, endometriosis, pelvic inflammatory disease, and radiation [47–49]. Intraoperative findings of pelvic adhesions, bladder injury, extensive surgery, and higher stage cancer have higher risk of fistula [47–49]. Performing a subtotal hysterectomy with preservation of the cervix decreased the fistula rate which may be the result of a less extensive surgery [46]. Attention to avoiding injury to the urinary tract and performing a cystoscopy during difficult dissections where bladder injury is suspected may prevent a fistula [1]. It may be helpful to retrograde fill the bladder with dye or saline in these select cases to detect injury. Observation of the urine draining from the Foley during hysterectomy should be clear and if there is question further investigation is indicated.

Pelvic surgery with mesh-augmented repair can be is another cause of fistula. There are reports of transvaginal mesh causing VVF at low rates 0.29% [50]. A mid-urethral sling may inadvertently injure the bladder and cause a VVF [51]. This reinforces the importance of a cystoscopy at the time of sling placement to prevent urinary fistula. As the number of transvaginal mesh surgeries has been increasing, there may have been a rise in the number of urinary fistula from mesh complications [52]. This trend may reverse as a result of decreased transvaginal mesh-augmented repairs due to the FDA safety communication in July 2011 regarding complications related to transvaginal mesh for POP. Radiation-induced fistula represents a minor portion of VVF. The mechanism of injury is due to obliterative arteritis, resulting in ischemia which also produces inflammation of encompassing tissue that must be taken into account [53]. Presentation of radiation fistula can occur acutely or be delayed for several years. Suspicion of recurrent cancer or secondary malignancy must be considered with a history of radiation fistula.

Diagnosis

VVF commonly presents with constant urinary incontinence that is distressing and may be intensified as a result of a surgical complication, usually total abdominal hysterectomy, which remains the most common approach in the USA. Usually, fistulae appear between the 7th to 12th postoperative day [54]. As previously noted, the diagnosis of a vesicovaginal fistula can most often be made upon a vaginal examination. The location of VVF after hysterectomy is usually a single fistula at the vaginal cuff, although it may present as a complex VVF with multiple fistulas.

A urethral catheter with retrograde filling of the bladder with dye (dilute methylene blue), with a tampon or gauze in the vagina, may demonstrate the fistula on examination. A urinary fistula can also be identified after administering phenazopyridine once it is excreted in the urine. A negative tampon test however does not rule out a fistula, and clinical suspicion, in many cases, is required to make the diagnosis. Evidence of the fistula site is commonly found with surrounding inflammation, granulation, and tissue defect.

There are many different opinions and no consensus on the imaging required during the evaluation of VVF. As mentioned previously, our practice is to completely evaluate the patient to attempt to address all problems at the initial repair which may require a voiding cystogram and additional position changes (lateral and oblique) to increase intradetrusor pressure during voiding to visualize small fistulae. Of note, the lateral views may best demonstrate the fistulae when there is a direct connection between the bladder and the vagina, or when the connection is indirect, and enters a collection/sinus tract before draining into the vagina (Fig. 10.1). In addition, VCUG will demonstrate concomitant urethro-

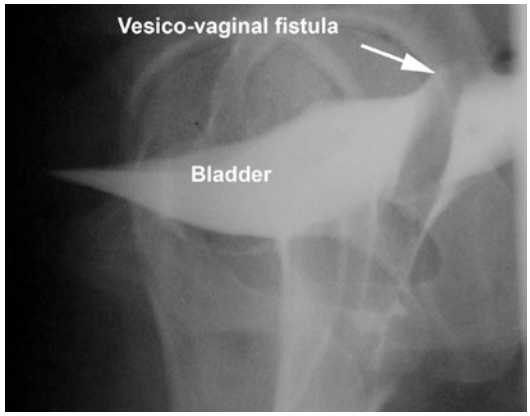

Fig. 10.1 A VCUG of vesicovaginal fistula

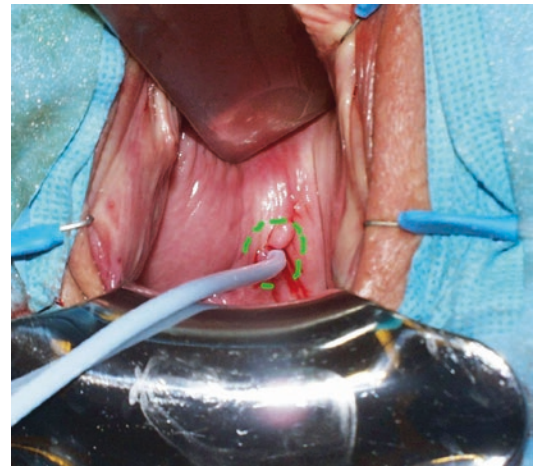

Fig. 10.2 The fistula is identified with a probe

vaginal fistulae, the degree of vaginal prolapse, and stress incontinence [2]. Prior to surgery, a dedicated physical examination, urine analysis, culture if required, cystoscopy, and VCUG are performed with selective CTU and tridimensional reconstruction in selected cases. In addition, we place bilateral urethral stents preoperatively, when the fistula is noted/discovered to be near the ureteric orifices.

Timing of Repair

Classical teaching advocates waiting for 2–4 months before closure. This allows for spontaneous healing while the bladder is under continuous drainage, but this is only useful for small fistulas (<5 mm). Others advocate a delay of 4–6 weeks before attempting repair; however, a successful repair can be done as early as 2 weeks after diagnosis under certain conditions: if there is no evidence of infection, there is no history of radiation to the area, and if it is not an ischemic fistula.

Treatment

Conservative Treatment

The goal of surgical repair is to have resolution of the fistula with the least morbidity. In select circumstances, it is reasonable to attempt a trial of catheter for about 4 weeks [55]. There are reports of spontaneous resolution of fistulas that are simple and small with the overriding principle that there should be no delay in definitive repair [56–58]. Consideration of endoscopic treatment with fulguration and fibrin glue has been successfully reported in small case series when fistulas are less than 3.5 mm in size [59, 60]. This is a reasonable approach when patients meet these defined criteria; however, few patients are candidates for these conservative or minimally invasive procedures and require surgical repair. Patients with a history of complex, large, or radiation-induced fistulae should proceed with a definitive repair, as minimally invasive treatment is futile.

Trans Vaginal Repair

In this section, we describe our basic technique and adjuvant procedures done in complex cases. With the patient in lithotomy position, surgical repair begins with vaginal exposure with a ring retractor and vaginal speculum. The key to performing this repair is the identification of the fistulous tract. A cystoscopy is performed to identify the fistula and a wire is placed through it. A 16–18 Fr catheter is inserted into the bladder. The vaginal cuff is grasped with Allis clamps to expose the fistulous tract. The tract is then dilated with hollow or Goodwin sounds or over a guidewire to allow passage of an 8–10- Fr catheter (Fig. 10.2). The catheter is an important aid in the exposure of the fistula and retraction of the bladder during the repair. A circumferential incision is made less than 1 cm from the fistula track. An inverted U-incision is made on the anterior vaginal wall and it is mobilized 3–4 cm to create the anterior vaginal flap (Fig. 10.3a–d). An inverted U posterior vaginal wall flap is created from the cuff to expose the prerectal fascia, the vesico-

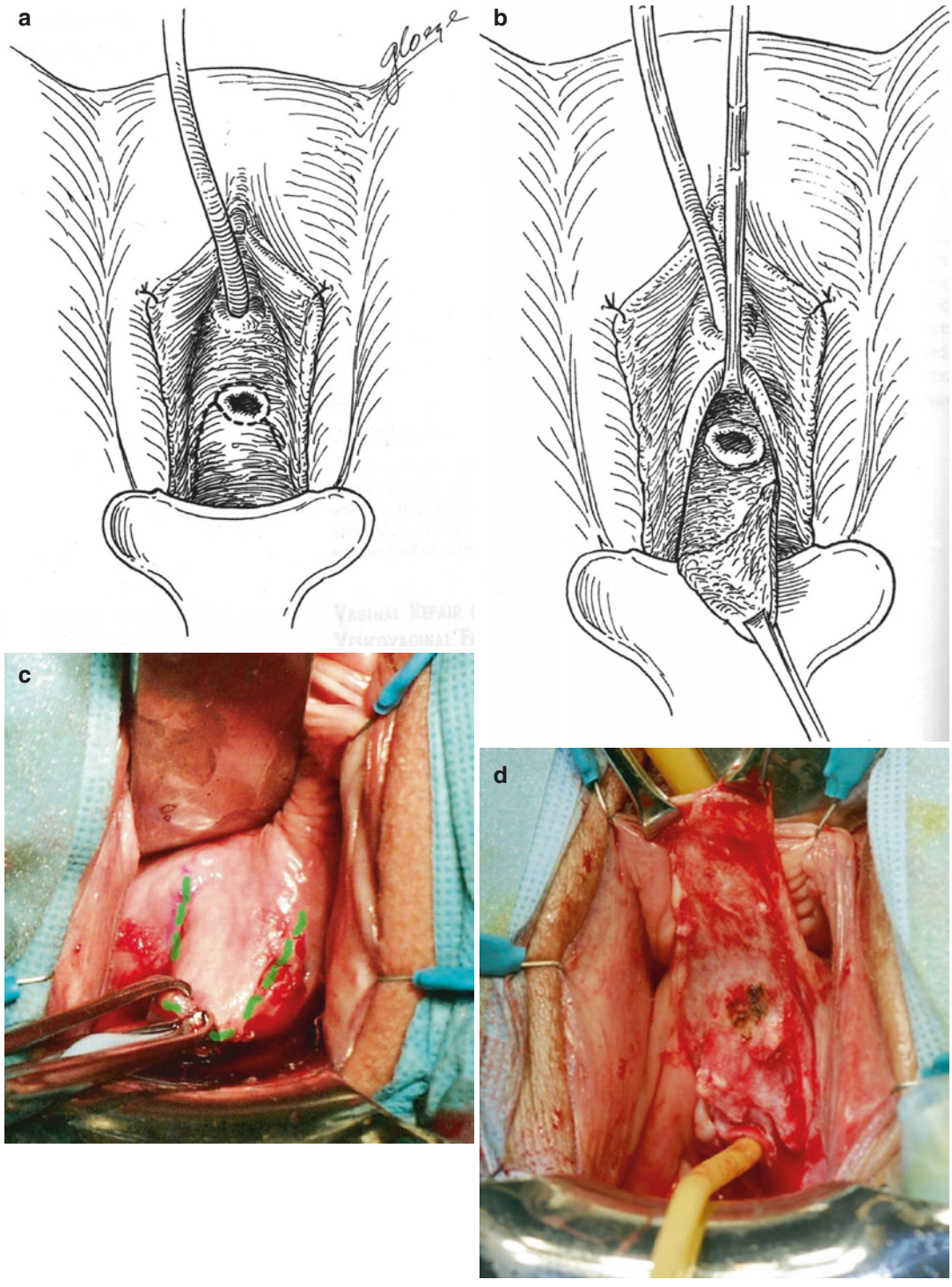

Fig. 10.3 (**a**–**d**) The vaginal epithelium is then incised in a U-shaped fashion and separated the vaginal epithelium from the underlying bladder

rectal space, and the posterior cul-de-sac, where the peritoneal flap can be retrieved.

The fistula tract is isolated and closed with 2-0 or 3-0 delayed absorbable interrupted sutures (Figs. 10.4, 10.5, 10.6, 10.7, and 10.8). Care is taken to incorporate all the fistulous tract and the bladder wall into the closure. We omit excision of tract unless there is a concern of malignancy or extensive necrotic tissue. We do not excise the fistulous tract because a small fistula stays small, but excision of the margins may turn a small fistula into a very large defect.

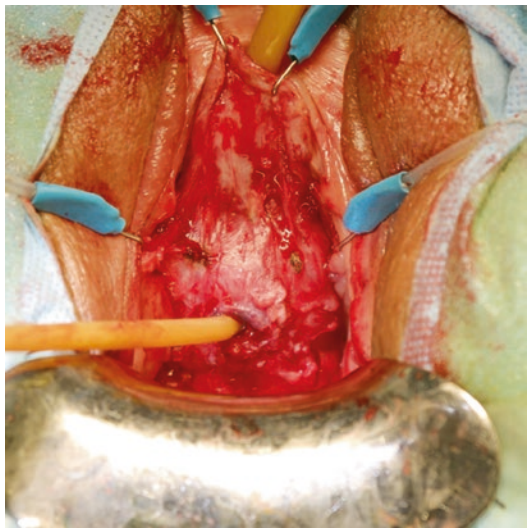

Fig. 10.4 A Foley is then placed into the opening in the bladder

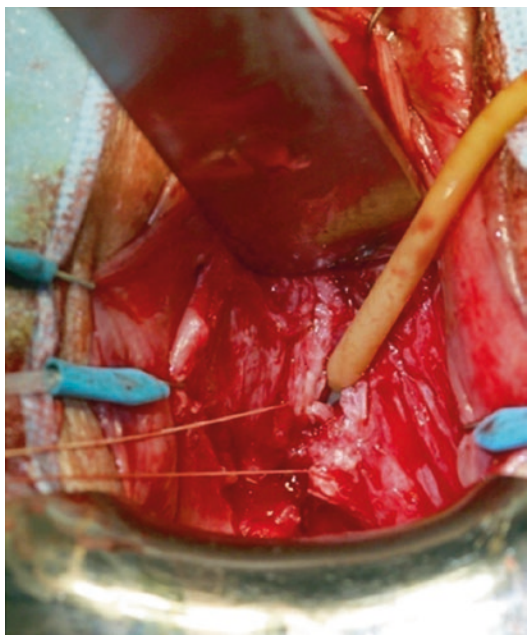

Fig. 10.5 Traction is placed on the Foley to bring the fistulous opening forward. Several sutures are placed across the opening, around the Foley

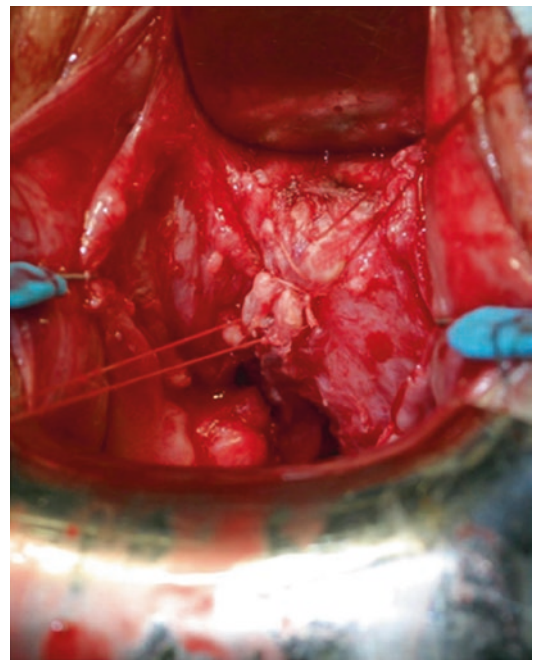

Fig. 10.6 The Foley is then deflated and removed

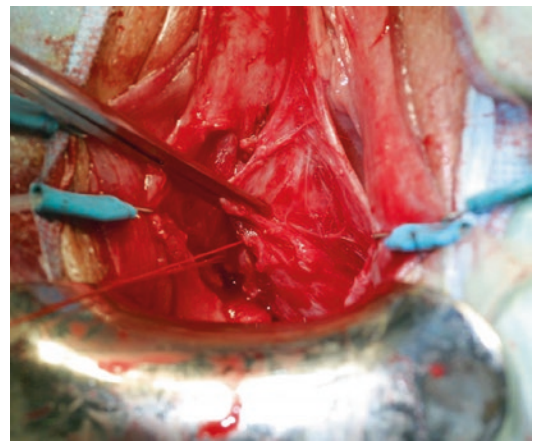

Fig. 10.7 The sutures are tied closing the opening in the bladder

Excision of the tract may also lead to bleeding, which may necessitate coagulation of the margins, impairing the repair. The fistulous tract is excellent anchoring tissue for protecting and reinforcing the closure. If the fistula is next to the ureteric orifice, there is no need for reimplantation, a stent is simply inserted under direct visualization. Once the closure is complete, the bladder is then filled with dilute indigo carmine to ensure there is no extravasation, thereby testing the integrity of the repair. A second layer of sutures, 1 cm from the fistula, are then imbricated over the tract with 2-0 or 3-0 delayed absorbable interrupted suture for the second layer of closure. A double-layer peritoneal flap is then dissected from the vesico-rectal space, mobilized, and advanced 2–3 cm distal to the fistula closure. The flap is sharply dissected and mobilized from the cul-de-sac so that it can be advanced 2–3 cm distal to the fistula. This flap is approximated with 3-0 absorbable interrupted sutures. A small segment of the distal flap is excised and the posterior flaps, advanced, and closed beyond the fistula side with absorbable, 2-0 interrupted suture, resulting in a 4-layer closure. A Martius flap may also be used if the fistula location is more distal (Figs. 10.9, 10.10, 10.11, 10.12, 10.13, and 10.14).

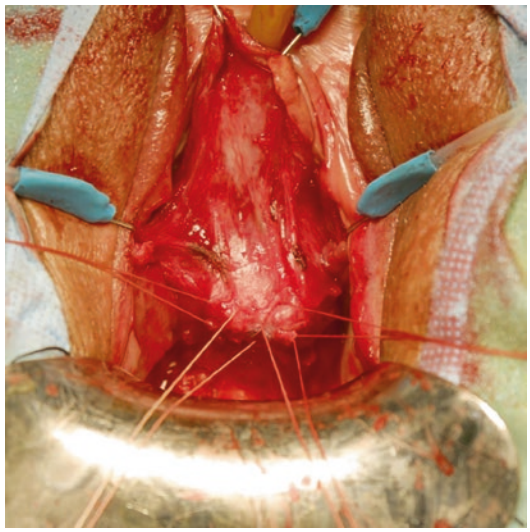

Fig. 10.8 After bladder closure

Latzko Partial Colpocleisis

The Latzko partial colpocleisis is the traditional technique for VVF repair. The Latzko technique is usually utilized to repair proximal post-hysterectomy fistulae. It involves a circumferential elliptoid incision around the fistula with wide

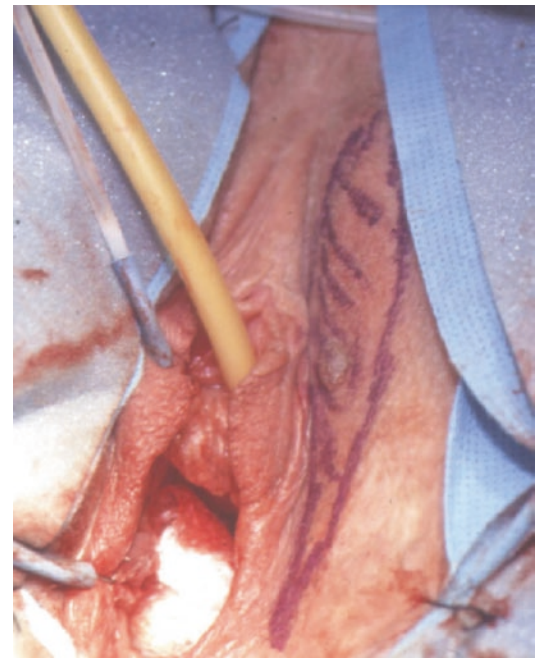

Fig. 10.9 Location of the Martius flap is marked on the skin

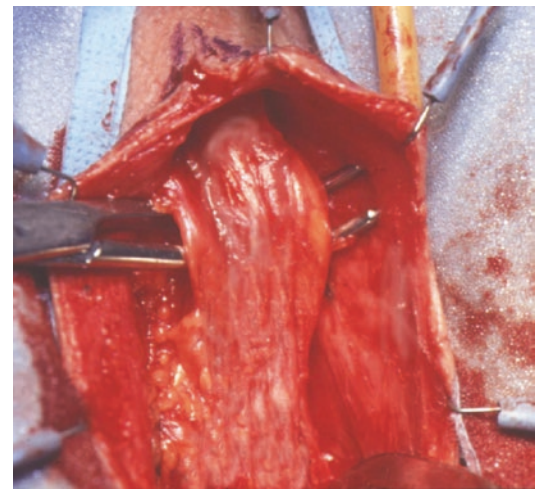

Fig. 10.10 The Martius flap is then isolated

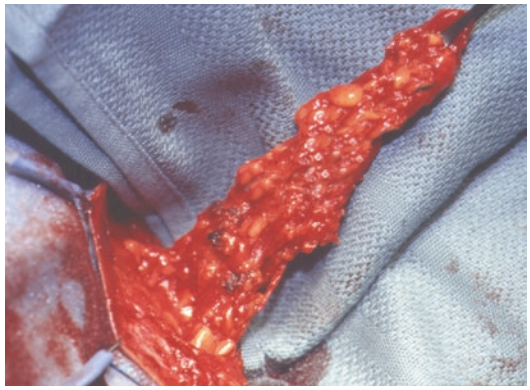

Fig. 10.11 The proximal end of the flap is ligated

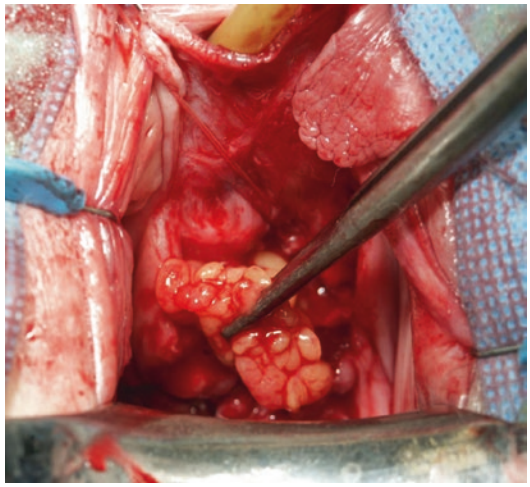

Fig. 10.12 The Martius flap is placed over the closed defect in the bladder

mobilization of the vaginal epithelium in all directions. The fistula tract is closed and the repair is reinforced by an inverted layer of the perivesical tissue. The suture lines are overlapping in this repair. Potential advantages of this approach are decreased morbidity from less blood loss and shorter operating time. We prefer our approach as described above, as it avoids vaginal shortening and an overlapping suture line which may result in recurrence. It is worth noting, however, that some authors report low recurrence rates with the traditional Latzko repair, and that there is vaginal shortening only when there is an already shortened vagina [61].

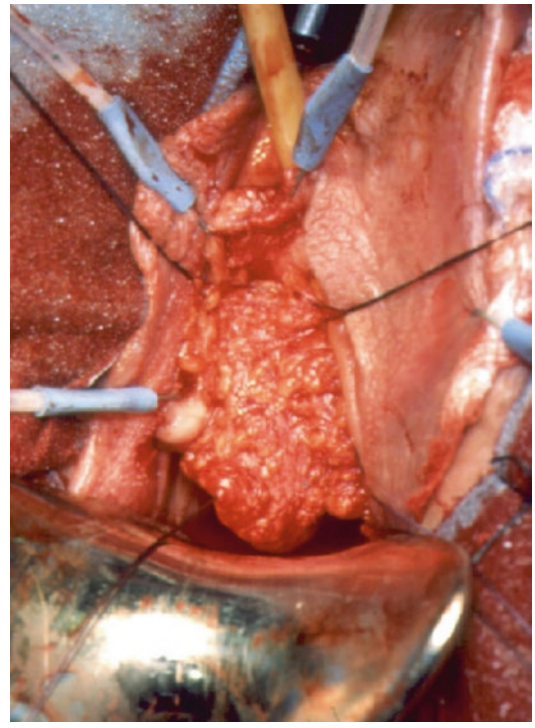

Fig. 10.13 The flap is sutured into place

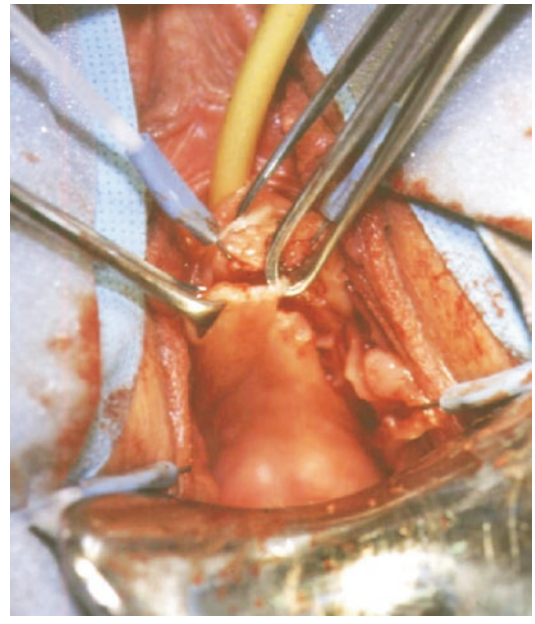

Fig. 10.14 Flap of vaginal epithelium is advanced

Abdominal Repair

This may include open, laparoscopic, or robotic approaches. An absolute indication for the abdominal approach is a contracted bladder capacity and/or the need for ureteric reimplantation. Abdominal repair is typically done via the O'Conor technique. In instances of intraperitoneal pathology, concomitant ureteric reimplant, or bladder augmentation, or the need for bowel diversion, this is the preferred technique. Our approach begins with a midline incision that extends from the umbilicus to the pubic bone. Once the peritoneum is entered, the bladder is identified by retrograde filling via the catheter. A probe is then inserted into the vagina, and the vaginal wall retracted superiorly. The bladder is then dissected free from the vaginal wall until the fistulous tract is encountered. The fistulous tract is then opened and no bi-valving of the bladder is required. The vagina is then dissected free from the bladder for a distance of 3–4 cm surrounding the area of the fistula. The bladder is then closed in layers, with indigo carmine injected to assure the integrity of the closure. The vaginal incision is then closed with a segment of omentum, or free peritoneum is interposed between the bladder closure and the vaginal closure. Alternatively, the bladder can be bi-valved (which is the traditional O'Conor approach), extending the incision to include the fistula, which can be biopsied if there is concern for malignancy. The bladder is dissected and mobilized away from the vagina so that it is prepared for later closure. The bladder and the vagina are closed in two layers with interposition of tissue flap for added security. The most described interposition is the omental flap which has increased success rates in retrospective studies [26, 31]. In cases of bowel resection, the mesentery can be preserved and serve as a useful interposition material, which has similar properties similar to omentum, with a well-vascularized blood supply and lymphatic drainage to decrease inflammation, and promote healing.

Laparoscopic/Robotic

The first description of a laparoscopic VVF repair was by Nezhat in 1994 [62]. The robotic repair was first described in 2005, which is a platform that allows more surgeons to perform the technical aspects of this surgery of suturing and knot tying that are technically demanding with laparoscopic surgery [63]. The success rates are about 90% or greater in the few case series reporting on these techniques [21–23, 64, 65]. There is one study comparing open to robotic repair of VVF with similar outcomes [21]. As in open repair, the robotic approach allows the surgeon to perform ureteric reimplant when indicated. In another study, Bora et al. performed robotic-assisted VVF repair in 30 patients: 11 with complex fistulas, 9 had failure of a previous repair, and 27 were found to have a supratrigonal VVF [19]. No recurrence was seen in 28 patients and the mean duration of follow-up was 38 weeks. These emerging technologies appear to be promising for the surgeon skilled in robotic or laparoscopic surgery; however, the vaginal approach is a still faster, minimally invasive outpatient surgery that allows for excellent exposure of the fistula with good functional and anatomical results.

Complications

Complications include infection, bladder spasm, and vaginal bleeding. These complications should be treated, as they raise the risk of recurrence. Postoperative antibiotics are routinely given for about 2 weeks postoperatively, anticholinergics, or B & O suppositories may be needed to prevent bladder spasms, and patients should be advised to have pelvic rest for 3 months postoperatively. The most common complication is UTI (8%) regardless of the approach [66]. The most significant complication is fistula recurrence, and every attempt should be made to prevent it. Recurrent fistula should be treated with a tissue interposition, and at least a 3-month delay in repair. Rare complications include injury to the ureters, bowel, and rectum, and should be discussed with the patient during the preoperative informed consent process.

Urethrovaginal Fistula

Background

A urethrovaginal fistula is an abnormal connection between the urethra and the vagina that may

be the result of obstetric, iatrogenic, neoplasm, trauma, or infection. This should not be confused or grouped together with vesicovaginal fistula because the etiology, surgical repair, and potential complications of urethrovaginal fistula differ. Urethrovaginal fistula is a rare condition due to the female urethra being seldom involved in injury because of its short length and protection from the pubic bone [67, 68]. The majority of urethrovaginal fistulas in developed countries are iatrogenic and arise from pelvic surgery or radiation and less often from obstetric procedures during childbirth [2, 38, 69]. Increasingly, these fistulas are seen as the result of mesh mid-urethral sling placement [70].

Etiology

Urethrovaginal fistulas in developed countries are the main focus and can be divided into two main categories: causes from vaginal/pelvic procedures which make up the majority and less often from radiation. Currently, with the increased use of mesh, mesh exposure or erosion into the urethra needs to be considered as a source of fistula. There are case reports of synthetic mid-urethral slings causing urinary fistulas [51, 71]. This mechanism of injury is likely unrecognized iatrogenic injury of the urethra from urethral perforation which increases the risk of fistula formation [72–74]. Urethral diverticulectomy surgery is the most common surgical cause of urethrovaginal fistula [2]. This may be the result of incomplete excision of the diverticulum or inadequate urethral closure without sufficient tissue interposition.

Radiation fistula formation can present immediately or can occur years after exposure and may contribute to 15% of urethrovaginal fistulas [2, 10]. There should be consideration of malignancy when patients have a history of pelvic cancer or radiation treatment. Rare cases of urethrovaginal fistula in the USA may be the result of trauma, injury during childbirth, malignancy, or infection. As childbirth techniques have improved, there are less injuries and trauma contributing to urethrovaginal fistula [38]. The use of forceps or instruments may result in laceration of the urethra that if not identified and repaired can lead to urethrovaginal fistula. Blunt trauma with pelvic fracture rarely can cause an avulsion of the urethra or develop into a urethrovaginal fistula with an incidence range of 0–6% [75]. Instrumentation of the urethra is another unusual cause of fistula [76, 77]. Chronic indwelling Foley can cause pressure necrosis of the bladder neck and distal urethral which can form a hypospadic urethra and urethrovaginal fistula [78–80].

The majority of urethrovaginal fistulas in undeveloped countries originate from prolonged obstructed labor and are not iatrogenic as in western countries. These urethrovaginal fistulas are due to ischemia and commonly involve the bladder and urethra with extensive tissue loss. The mid-urethral sphincteric complex may be irreversibly damaged making for a tenuous repair with unwanted outcomes [75, 81].

Treatment

Vaginal Surgical Repair

This is a description of a urethrovaginal fistula that is closed primarily (Figs. 10.15 and 10.16). Surgical repair begins with vaginal exposure with a ring retractor and vaginal speculum. A Foley catheter is inserted into the urethra. A small Foley catheter is inserted in the fistula with dilation of the tract if necessary. Injection of retrograde dye

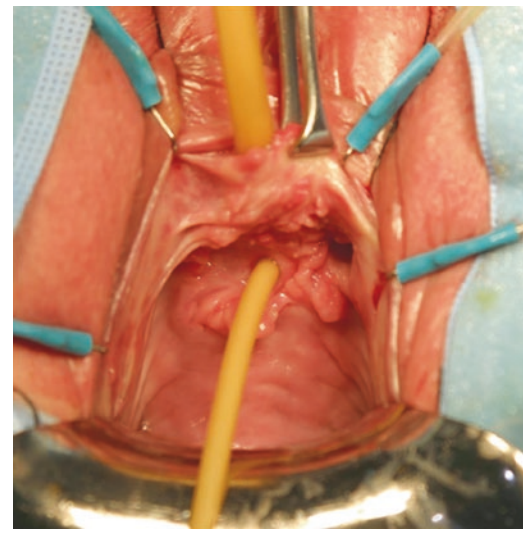

Fig. 10.15 Urethrovaginal fistula with a Foley catheter used as a retractor

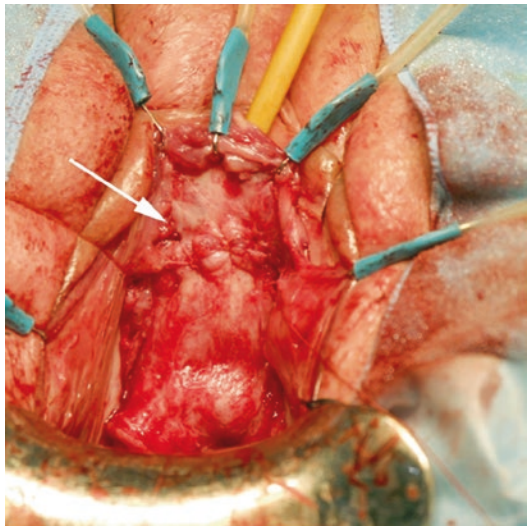

Fig. 10.16 Closure of the periurethral fascia

in the urethral meatus may help to identify a small fistula. An inverted U-incision is made on the anterior vaginal wall. The anterior vaginal wall flap is dissected and freed so that it has mobility to advance 2 cm distal to the fistula. The anterior vaginal wall flap is dissected lateral and proximal to the fistula which facilitates creation of the flap by avoiding scarring and friable tissue. Lateral and distal vaginal flaps are dissected which expose the fistula tract and the periurethral fascia. Once the vaginal wall is separated and is adequately mobilized, a transverse incision of the periurethral tissue is made at the level of the fistula as in a urethral diverticulectomy repair. Superior and inferior flaps of the periurethral fascia are created, isolating the urethral wall with the catheter in place. The fistula is closed in 2 layers with the urethra as the first layer closed transversely like a Heineke-Mikulicz technique. The periurethral fascia is closed in a transverse fashion to cover the area of reconstruction. The fistula tract is not routinely excised because it provides excellent anchoring tissue for closure, avoids creating a larger defect to repair, and prevents bleeding from the fistula tract edges that can become devitalized from electrocautery during the control of bleeding [10, 82]. Optionally, creation of a Martius flap to cover the periurethral fascia (radiation, multiple surgeries, large defects, and poor tissue quality) is performed. The vaginal wall flap is advanced to cover the area of reconstruction. The Foley catheter for is left for 2–3 weeks and removed with a negative voiding trial or VCUG. Success rate has been reported at 95% [83].

Complications

Complications should be discussed preoperatively so the patient has realistic expectations after repair. Patients may develop obstructive voiding due to urethral stenosis in 5–20% of cases [69, 84]. There is a 33–50% chance that they will develop stress incontinence symptoms requiring an anti-incontinence procedure [68, 83]. Patients requiring extensive urethral reconstruction or a history of radiation with an immobile poorly vascularized urethra may fail fistula repair necessitating a bladder neck closure and urinary diversion.

Ureterovaginal Fistula

Background

Ureterovaginal fistula is an abnormal communication between the ureter and the vagina. It can result from inflammation, malignancy, exposure to radiation, or prior pelvic surgery. It is a relatively uncommon site for fistula disease and a high degree of suspicion is needed to pursue appropriate diagnosis and treatment. Urinary incontinence is a common presenting complaint – often continuous in nature. Distinction should be made between continuous urinary leakage that has been lifelong vs new onset, as the former suggests a congenital defect such as ectopic ureter while the latter lends more suspicion toward acquired fistula disease.

Etiology

Iatrogenic injury during pelvic surgery is the most common cause of ureterovaginal fistula [85], with ureteral injury rates up to 2% following gynecologic surgery [86]. Ureterovaginal fistula can be present with fistula disease in other locations; for example, it can be seen in up to

12% of patients with VVFs [4]. In addition to continuous urinary leakage, some patients will present with symptoms of flank pain or nausea if upper tract obstruction proximal to the fistula is present. Upper tract imaging plays in important role in diagnosis by potentially providing information about presence and location of fistula as well as define features of adjacent anatomy that can be important in planning treatment, CT or MR urography are particularly helpful for this (Figs. 10.17 and 10.18) [87]. Diagnosis can be facilitated by the double-dye tampon test discussed earlier in this chapter. Another clinical feature that distinguishes this from the continuous leakage of VVF is that patients will generally report continued normal voiding cycles because bladder filling is maintained by the contralateral ureter.

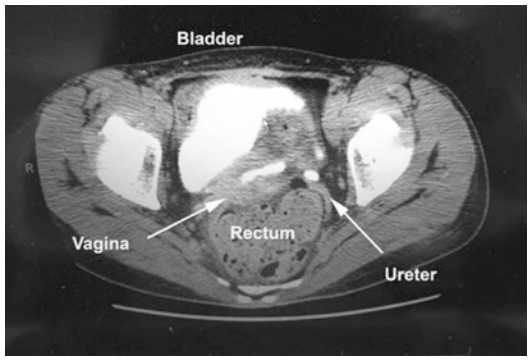

Fig. 10.17 Axial CT image showing contrast extravasation into vaginal cuff in the region of the distal ureter, contrast has also drained into the bladder

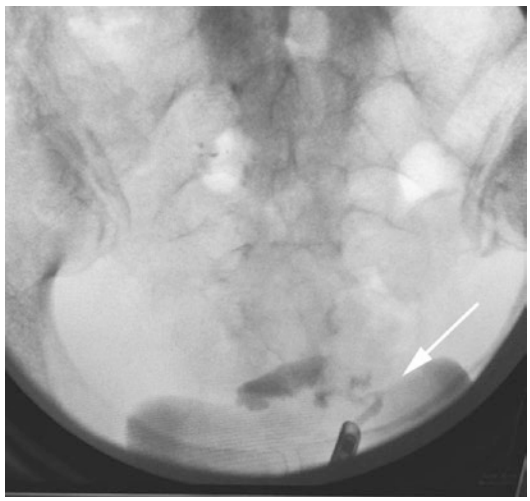

Fig. 10.18 Patient with urine leakage per vagina following vaginal hysterectomy and cystocele repair, cystoscopy and cystogram were unremarkable. Retrograde injection of contrast into left ureter reveals extravasation of contrast into vaginal cuff, confirming the presence of ureterovaginal fistula

Surgical Repair

The goals of treatment are to preserve upper tract function and to resolve urinary leakage, with the latter being the more urgent priority [88]. In some cases, endoscopic management alone may be successful. Antegrade stent placement can be pursued if attempts at retrograde stent placement are not successful. Endoscopic decompression with the use of a temporary stent has been reported to be successful in approximately 50% of cases [89]. If ureteral obstruction precludes successful stenting, or if leakage persists in spite of stenting, then surgical repair can be pursued. While there has been some debate about the value of surgical timing with immediate vs. delayed repair, current opinion favors immediate repair with no benefit seen to delaying surgery [10].

Since the fistula is usually located in the distal ureter in a region of scarring/inflammation from the original inciting cause of the fistula, ureteral reimplantation (ureteroneocystostomy) is generally favored over attempts at primary repair. Surgical technique involves mobilization of the ureter proximal to the fistula, taking care to avoid excessive skeletonization of the ureter to preserve blood supply and reduce postoperative risk of stenosis or stricture. A refluxing (non-tunneled) anastomosis is generally preferred to reduce the risk of obstruction or high pressures in the upper tract that could impair success of the surgery. If needed to reduce tension, additional interventions such as a psoas hitch and/or Boari flap can be made (Fig. 10.19). Reimplantation can be accomplished using open, laparoscopic, or robotic-assisted approaches based on surgeon preference [90]. Fortunately, success rates for treatment of ureterovaginal fistula with surgical ureteral reimplantation are very high, consistently >90% in contemporary series [85, 91].

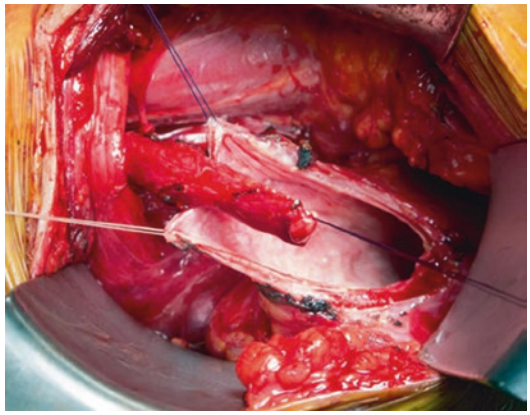

Fig. 10.19 Use of Boari flap to reduce tension on anastomosis in ureteral reimplantation

Complications

Complications similar to the above urinary fistulas (i.e., bleeding, infection, bladder spasms) can be seen with ureterovaginal fistula repair. Complications specific to this type of fistula include damage to the involved ureter, which may present late after the repair. Fistula persistence or recurrence can happen as a result of obstruction, ischemia, or tension on the anastomosis if reimplantation is performed. Ureteral stricture can also occur due to ischemia from excessive skeletonization during mobilization, or as a sequela of the original underlying cause (i.e., inflammation, prior radiation). For this reason, upper tract imaging, such as renal sonography, should be done 4–6 weeks after stent removal to assess for hydronephrosis. If a patient presents earlier with flank pain then more urgent upper tract imaging should be done to assess for obstruction. In some patients who had chronic obstruction prior to fistula repair, there may be some residual hydroureteronephrosis that persists even after a successful repair. In these cases, a nuclear medicine renogram can help determine whether or not obstruction is present. If this test is done in a patient who had a refluxing reimplant, then a catheter should be placed in the bladder during the study to prevent erroneous reporting of delayed drainage time from the affected side.

Rectovaginal Fistula

Background

Rectovaginal fistula is an extra-anatomic epithelial connection between the rectum and vagina. It is a disabling disease that severely devastates and impacts an individual's social life and self-esteem.

Etiology

RVF is most often a complication after a traumatic vaginal delivery that occurs in about 0.1% of vaginal deliveries in modern developed countries [92, 93]. Fistula formation is the result of high-grade rectal lacerations, grade 3 and 4, involving the perineal body and rectum that is unrecognized or becomes infected after repair. They may also develop as a result of prolonged or obstructed labor, causing pressure necrosis of the rectovaginal septum [94]. Risk factors for high-grade rectal lacerations at the time of vaginal delivery include midline episiotomies, use of forceps, first vaginal delivery, and increased birth weight of the fetus [95]. Investigation should be given to additional causes of RVF from pelvic surgery including low anterior resection, synthetic mesh for POP, hysterectomy [96], pessary [97], colorectal or gynecologic malignancy, history of radiation, pelvic abscess, and inflammatory bowel diseases which include Crohn's disease, ulcerative colitis, and diverticulitis [98].

Surgical Repair

Tissue Interposition

The majority of RVF repairs involve interposition of tissue to prevent recurrence with little added morbidity. Interposition of a Martius flap after a transvaginal repair of low fistula is our preference. We typically reserve gluteal rotational inner thigh flaps for high fistulas, difficult vaginal access, large defects, or fibrotic vaginal tissue that is suboptimal for fistula closure.

Vaginal Repair

Routine administration of broad-spectrum antibiotics and mechanical bowel preparation are given preoperatively. The transvaginal repair is performed with a multilayer closure with routine use of tissue interposition. Fecal diversion is performed selectively. The patient is positioned in high lithotomy position and the fistula is exposed with a ring retractor. A Foley is inserted into the fistula tract and can be used as a retractor. A U-incision is made on the posterior vaginal wall and it is mobilized 3–4 cm to create a vaginal flap. The vaginal wall is dissected free on the lateral wall and the prerectal fascia is dissected to create a flap that will be cover the fistula at the end of the procedure. The fistula tract is closed in 2 layers with interrupted delayed 3-0 absorbable suture that results in a watertight closure. The first layer includes the rectal and vaginal wall. The second layer includes the perirectal fascia that is advanced 2–3 cm over the fistula repair. A Martius flap that had been previously prepared is placed for additional coverage. A vaginal flap is advanced for a 4-layer closure (Figs. 10.20, 10.21, 10.22, 10.23, 10.24, 10.25, 10.26, 10.27, 10.28, 10.29, 10.30, 10.31, 10.32, and 10.33). There have also been descriptions of biological material used to reinforce the fistula repair [99].

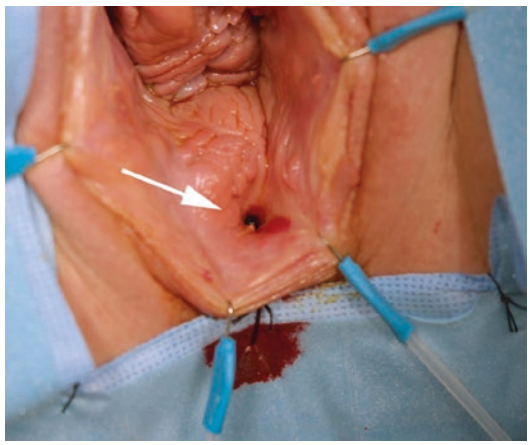

Fig. 10.20 A small, distal rectovaginal fistula (white arrow)

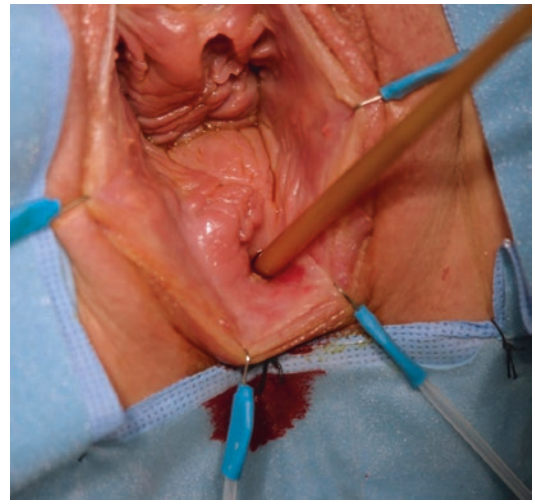

Fig. 10.21 A Foley catheter is inserted into the fistula tract. The catheter is used to facilitate the dissection of the fistula tract

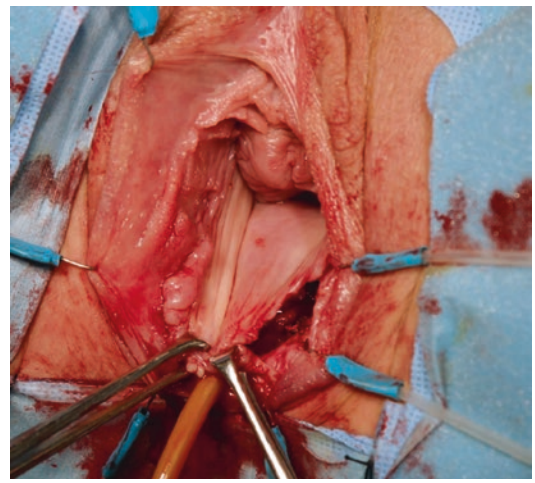

Fig. 10.22 A U-incision is made in the posterior vaginal wall and a flap is developed with the distal tip in the area of the fistula. The flap is extended proximally 5–8 cm. If prerectal fascia is present, it is used to create another flap, which is later used to reinforce the closure of the fistula. Distal to the fistula, a flap of vaginal wall is developed to the posterior fourchette, or distal vagina 3–4 cm from the fistula

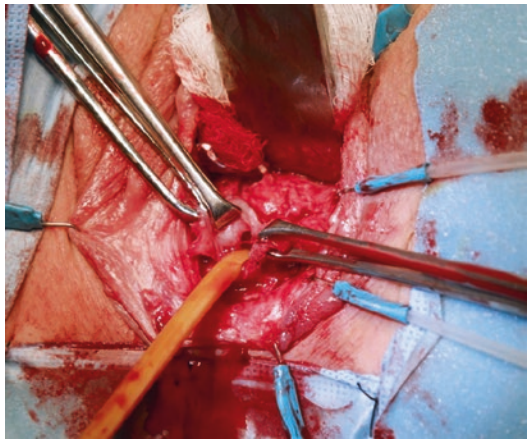

Fig. 10.23 The Foley catheter remains in the fistulous tract while the anterior rectal wall is exposed

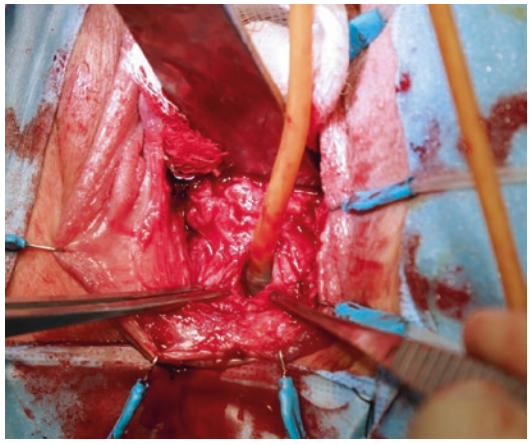

Fig. 10.24 Wide exposure of the fistula is obtained for several centimeters around the fistula, leaving a small ring of fistulous tract in place

Transanal Repair

The transanal approach is most commonly used for a low fistula. It begins with the patient in a prone jackknife position. A rectal advancement flap is created that includes the mucosa, submucosa, and the circular muscular fibers (internal sphincter). The flap is dissected 5 cm proximal to the fistula with its proximal base being twice the width of the apex. The fistula tract is excised and the rectal side of the fistula is closed leaving the vaginal side open.

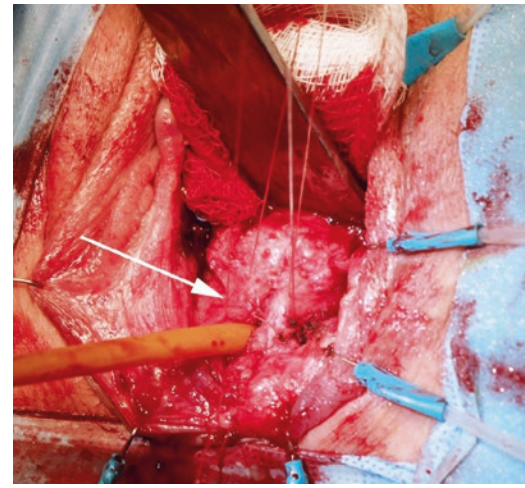

Fig. 10.25 The rectal wall and margins of the fistula tract are incorporated in the closure of the fistula tract (white arrow)

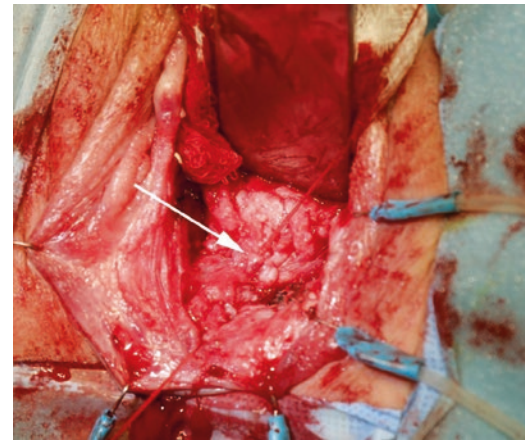

Fig. 10.26 Two layers of delayed absorbable sutures are used to close the fistula (white arrow). The rectum is irrigated with a diluted iodine solution. The absence of extravasation confirms the integrity of the closure

Perineal Repair

The perineal approach involves a 2-step procedure which is more morbid than a transvaginal repair. Perineal repair is used primarily for perineal fistulas, which many times involve the anal sphincter. First, a catheter is inserted into the fistula and the overlying tissue is incised creating a perineoproctotomy. The fistula tract

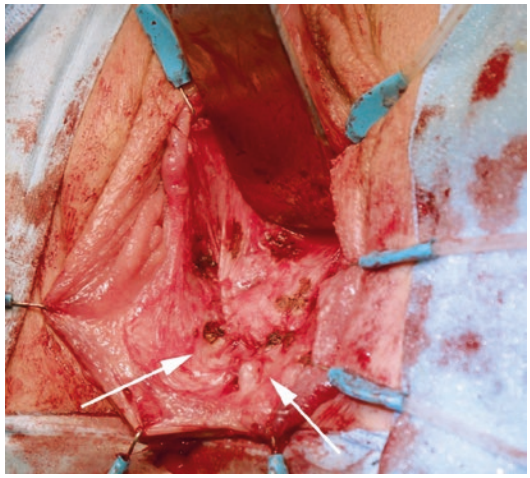

Fig. 10.27 The flap of prerectal fascia previously developed is advanced distally to cover the area of the fistula repair

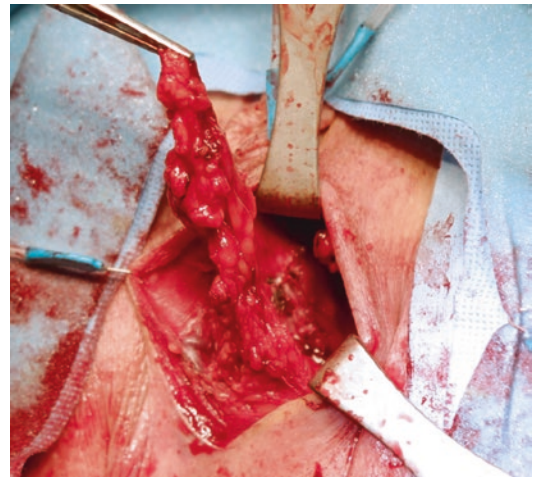

Fig. 10.29 The superior pedicle of the Martius flap is tied and cut anterior to the pubic bone to allow mobilization of the flap

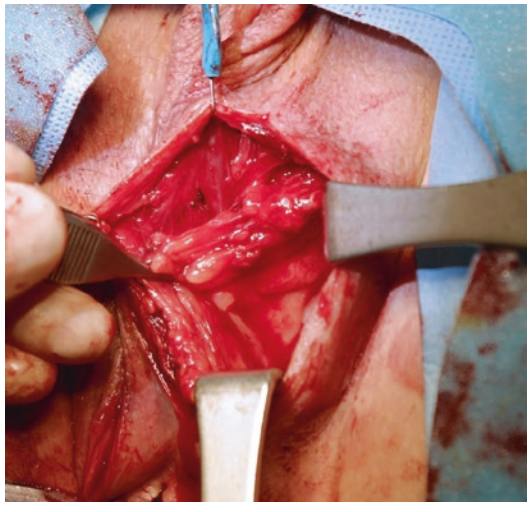

Fig. 10.28 A Martius flap is created using a vertical incision in the left labia majora. The inferior pedicle of the flap is preserved

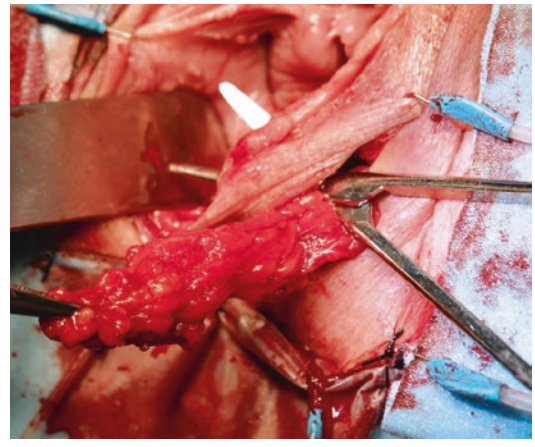

Fig. 10.30 A tunnel under the labia is created toward the anterior rectal wall

can be excised and then the layers that were divided are approximated without tension. The vaginal and rectal mucosa are separated and closed in 2 layers. The second step is a sphincteroplasty and rebuilding of the perineal body. The internal and external sphincters are approximated and the perineal body is rebuilt.

In our experience, we perform adjuvant procedures to improve the repair by making the incision asymmetric and excising only the epithelium so the subcutaneous fat can be crossed over and interposed to provide an additional layer.

Complications

Complications of hematoma and infection increase the risk of recurrence of the fistula.

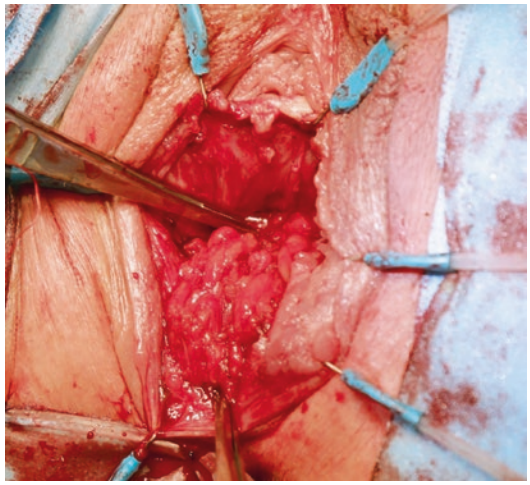

Fig. 10.31 The Martius flap is transferred to the vaginal canal and placed over the anterior rectal wall. The flap should provide coverage to the area 3 cm around the closed fistulous tract. Interrupted, delayed absorbable sutures are used to secure the flap in place

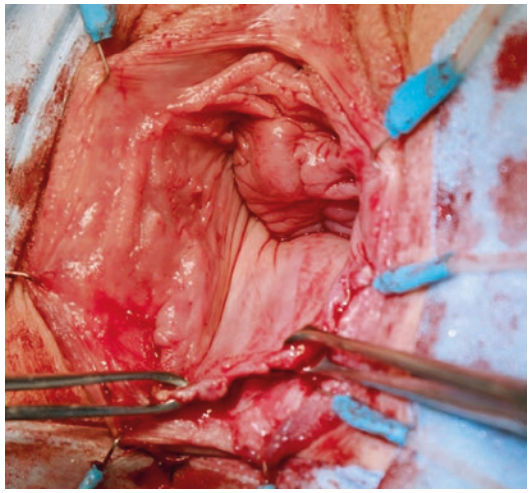

Fig. 10.32 The flap of posterior vaginal wall is advanced distally to provide new tissue coverage to the site of the fistula closure

Preoperative broad coverage antibiotics are given in an attempt to prevent infections. In cases of recurrent fistula, the patient should have a fecal diversion before exploration and repair. The repair should include interposition of tissue. Additional causes of RVF recurrence include foreign bodies or non-absorbable sutures used in the repair, recurrence of malignancy or IBD, poor tissue quality, inflammation, ischemia, dead space that was not obliterated during the initial repair, and significant constipation [100].

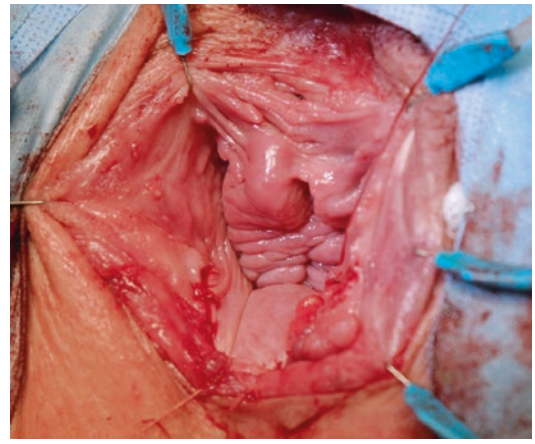

Fig. 10.33 A final image of the closure of a rectovaginal fistula using a Martius flap

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Repair of Urethral Diverticula

11

Jennifer Rolef and Eric Rovner

Introduction

The diagnosis and surgical approach to female urethral diverticulum (UD) can be an extremely challenging aspect of female urology. UD is known for a complex variety of presentations, ranging from asymptomatic, incidentally found lesions on examination or on imaging, to painful vaginal masses associated with lower urinary tract symptoms, dyspareunia, incontinence, stones, or tumors. Each case poses a unique challenge due to variations in anatomy, as well as the location, size, and complexity of these lesions.

Development of imaging modalities, such as ultrasound and MRI, in the past 30 years has greatly contributed to our advanced understanding of UD. With the expanding use of such imaging techniques, the diagnosis and evaluation of UD continue to evolve. Once confirmation of the diagnosis is achieved, definitive therapy typically consists of surgical excision and reconstruction. Successful operative excision and reconstruction requires advanced knowledge of the relevant surgical anatomy, as well as creativity and occasionally improvisation in the operating room.

Prevalence and Risk Factors

UD has been reported to occur in as many as 1%–6% of adult females [1]. However, the true incidence is unknown as many patients are either asymptomatic or misdiagnosed [2]. Most patients with UD present between the third and seventh decades of life, but presentation can occur at any age [3–7], and no specific risk factors have been identified. Previously multiparity and traumatic childbirth were thought to be associated with increased risk. However, a more recent study showed that 31% of patients with UD were nulliparous [8]. Some series suggest a definite racial predilection, with African American women being six times more likely to develop UD compared to their white counterparts. The reasons for this racial disparity are not well understood [9].

Pathophysiology and Etiology

UD represents an epithelialized cavity dissecting within the fascia of the urethropelvic ligament [10] (Figs. 11.1 and 11.2). This defect is often an isolated cyst-like appendage with a discreet connection to the lumen of the urethra, called the neck or ostia. Complicated anatomical patterns are possible, and in certain cases, the UD may partially extend ("saddlebag" UD) around the urethra, anterior [11], or circumferentially all around the urethra [12].

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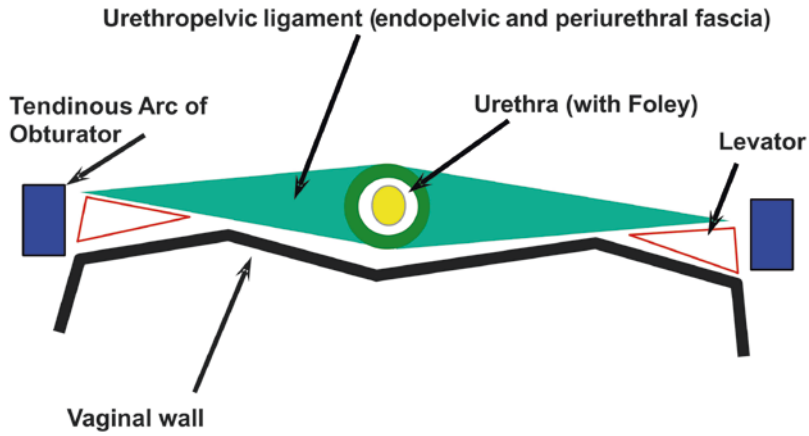

Fig. 11.1 Representative anatomy of the mid urethra in a coronal plane. (Reprinted from Rovner [10]. With permission from Elsevier)

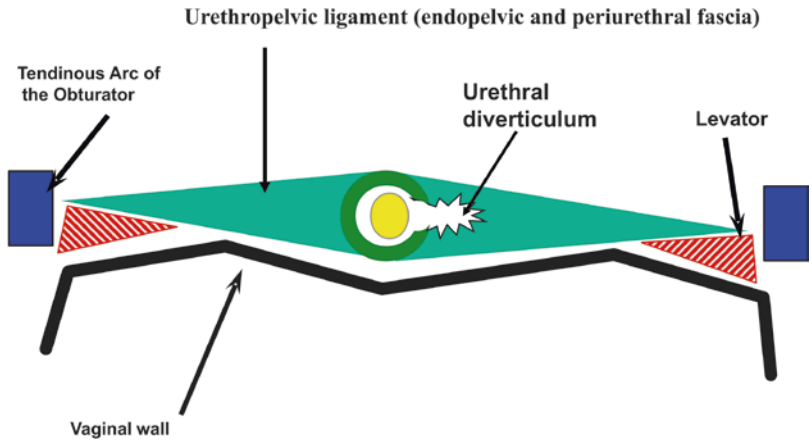

Fig. 11.2 Diagram of urethral diverticulum. The urethral diverticulum forms within and between the layers of the urethropelvic ligament. (Reprinted from Rovner [10]. With permission from Elsevier)

The periurethral glands are the probable site of origin of acquired UD [10]. Huffman characterized the periurethral glands as being located mostly dorsolateral to the urethra, arborizing proximally along the urethra, but also draining into ducts located in the distal one third of the urethra [13]. Importantly, he noted that periductal and interductal inflammation was also commonly found. In support of his observations and an infectious or acquired etiology of UD, in over 90% of cases, the ostia is located posterolaterally in the mid to distal urethra which corresponds anatomically to the location of the periurethral glands [14, 15].

Peters and Vaughn found that there was a strong association with concurrent or previous infection with *Neisseria gonorrhea* and UD [16]. However, the initial infection and subsequent reinfections might also originate from a variety of sources, including *E. coli*, and other coliform bacteria, as well as flora within the vagina. Nevertheless, UD has been classically attributed to recurrent infection of the periurethral glands with obstruction, suburethral abscess formation, and consequent rupture of these infected glands into the urethral lumen. Continual filling and collection of urine in the resultant cavity may result in stasis, recurrent infection, and eventual epithelialization of the cavity forming a permanent diverticulum [17]. Reinfection, inflammation, and recurrent obstruction of the neck of the cavity are hypothesized to result in patient symptoms and enlargement of the diverticulum. However, it should be noted that Daneshgari and colleagues have also reported noncommunicating urethral diverticula diagnosed by MRI [18]. Whether this represents a unique form of UD or UD with an obstructed ostium is unknown.

Diverticular Anatomy

Typically, UD represents an epithelialized cavity with a single connection to the lumen of the urethra. The size of the lesion may vary from just a few millimeters to several centimeters. In addition, the size may vary over time due to inflammation, intermittent obstruction of the ostia, and subsequent drainage into the urethral lumen.

The epithelium of UD may consist of columnar, cuboidal, stratified squamous, or transitional cells. In some cases, the epithelium is absent and the wall of the UD consists only of fibrous tissue. These lesions are found within the periurethral fascia, bordered by the anterior wall of the vagina ventrally. In the sagittal plane, UD is most often centered in the middle third of the urethra with the luminal connection or ostia located posterolaterally. The sac may extend distally along the urethra and vaginal wall, almost to the meatus or proximally to the level of the bladder neck, and sometimes extending underneath the trigone of the bladder (Fig. 11.3). An array of configurations can be noted on imaging and at surgical exploration. In the axial plane, the UD cavity may extend laterally along the urethral wall and in some cases around the dorsal side of the urethra or wrap circumferentially around the entire urethra (Fig. 11.4). UD may be bilobed (dumbbell shaped) extending across the midline. Multiple loculations can be common, and at least 10% of patients have multiple UD at presentation. Varying degrees of sphincteric compromise may exist due to the location of diverticulum relative to the proximal and distal urethral sphincter mechanisms resulting in clinical stress urinary incontinence. This is especially important to note when considering surgical repair and the possibility of concomitant repair of the stress urinary incontinence.

Evaluation/Workup

The diagnosis and complete evaluation of UD can be made with a combination of a thorough history, physical examination, urine culture and analysis, cystourethroscopy, and selected imaging studies. A urodynamic evaluation may also be utilized in select cases.

Presentation

The classic presentation has been historically described as the "three Ds": dysuria, dyspareunia, and dribbling (postvoid). However, none of

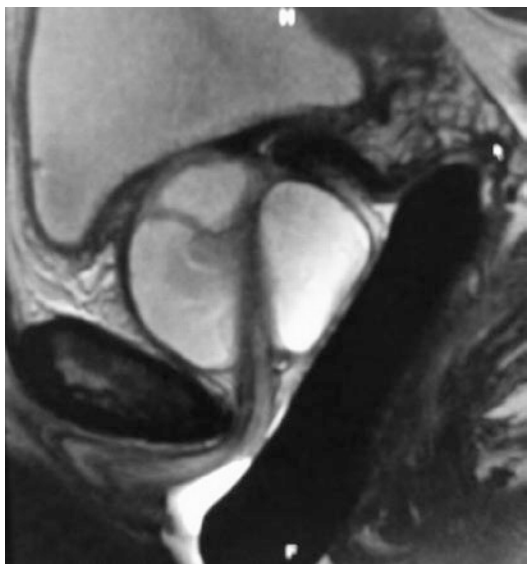

Fig. 11.3 Urethral diverticulum extending under bladder neck, sagittal MRI. (Courtesy of Dr. Travis Bullock)

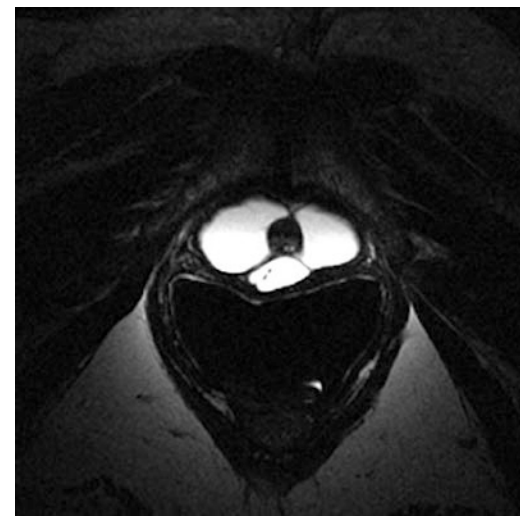

Fig. 11.4 Multiloculated circumferential urethral diverticulum, axial MRI

these symptoms are sensitive or specific for UD [19]. Although the presentation is quite variable, the most common symptoms are irritative (frequency, urgency, etc.) lower urinary tract symptoms (LUTS), pain, and infection [8, 16, 20, 21]. Dyspareunia will be noted by 12–24% of patients [8, 20]. Approximately 5–32% of patients complain of postvoid dribbling [4, 8]. Recurrent cystitis or urinary tract infection is also a frequent presentation in one third of subjects [4, 8] likely due to stasis of urine in the UD. Multiple bouts of recurrent cystitis should alert the physician to the possibility of a UD. Other complaints include vaginal pain or mass, hematuria, vaginal discharge, obstructive symptoms, urinary retention, and incontinence (stress or urge). Some patients may present with a tender or nontender anterior vaginal wall mass, which upon gentle compression may reveal retained urine or purulent discharge per the urethral meatus. Although spontaneous rupture of UD is extremely rare, urethrovaginal fistula may result under these circumstances [22]. The size and complexity of the diverticulum do not correlate with symptoms [23]. Finally, symptoms may wax and wane, and even resolve for long periods of time. This may be related to periodic and repeated episodes of infection and inflammation.

As many symptoms associated with UD are not specific, patients often can be misdiagnosed and treated for years before the diagnosis of UD is made. In one series of 46 consecutive women eventually diagnosed with UD, the mean interval from onset of symptoms to diagnosis was 5.2 years [24]. This underscores the importance of a baseline level of suspicion and a thorough pelvic examination in patients complaining of LUTS or other symptoms potentially associated with UD.

Physical Examination

During physical examination, the anterior vaginal wall should be palpated for masses and tenderness. The location, size, and consistency of a suspected UD should be noted. Most UD are located ventrally over the middle and proximal portions of the urethra, corresponding to the area of the anterior vaginal wall 1–3 cm inside the introitus (Fig. 11.5). Configuration of the UD may have significant implications when undertaking surgical excision and reconstruction. UD may also extend proximally toward the bladder neck. Such UD may produce distortion of the bladder outlet and trigone on cystoscopy or on radiographic imaging, and special care should be taken during surgical excision and reconstruction due to concerns for bladder and ureteral injury as well as the potential development of postoperative voiding dysfunction and incontinence. Distal vaginal masses or perimeatal masses may represent other lesions, including Skene's glands abnormalities. The differentiation between these lesions often cannot be made by physical examination alone and may require additional radiological imaging. A particularly hard anterior vaginal wall mass may indicate a calculus, vagi-

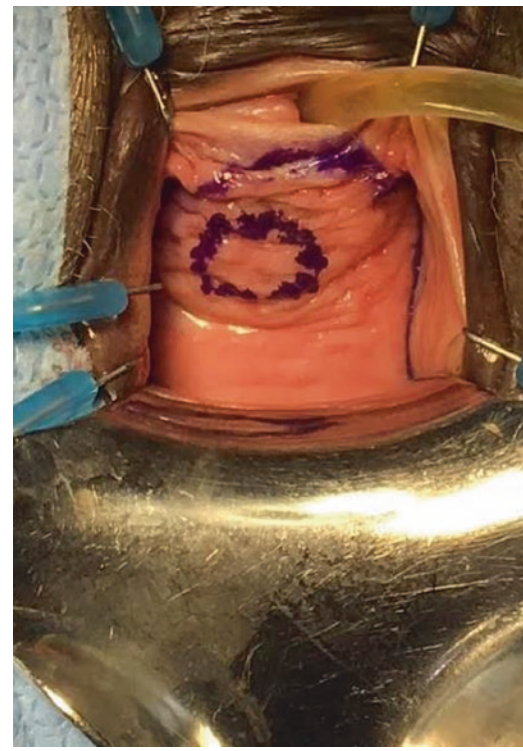

Fig. 11.5 Intraoperative image of a urethral diverticulum marked on the anterior vaginal wall. A Foley catheter is in the urethra, and weighted speculum is used for downward retraction of the posterior vaginal wall

nal wall fibroid, or cancer within the UD and mandates further investigation. During physical examination, the urethra may be gently "stripped" or "milked" distally in an attempt to express purulent material or urine from within the UD cavity. Although often described for the evaluation of UD, this maneuver does not produce the diagnostic discharge per urethral meatus in the majority of patients [25].

Vaginal walls should be assessed for atrophy, rugation, and elasticity. Poorly estrogenized, atrophic tissues are important to note if surgery is being considered. These tissues are often surgically mobilized and may be used for flaps during excision and reconstruction. The distal vagina and vaginal introitus are also assessed for capacity. These factors may impact surgical planning, as a narrow introitus can make surgical exposure difficult and may mandate an episiotomy. Finally, during physical examination, a provocative maneuver to elicit stress incontinence should be performed as well as an assessment of any vaginal prolapse.

Urine Studies

Urinalysis and urine culture should be performed. The most common organism isolated in patients with UD is *E. coli*. However, other gram-negative enteric flora and *N. gonorrhea*, *Chlamydia*, *Streptococcus*, and *Staphylococcus* are often present [20, 26]. A sterile urine culture does not exclude infection, as these patients are often on antibiotic therapy at presentation. In patients with irritative symptoms or where there is suspicion of malignancy, a urine cytology can be checked.

Cystourethroscopy

Cystourethroscopy is performed in an attempt to both visualize the UD ostia and evaluate for other potential causes of the patient's lower urinary tract symptoms. A flexible cystoscope or a specially designed rigid female cystoscope is most helpful in evaluating the female urethra. The short beak on the sheath of a specially designed rigid female cystoscope maintains the flow of the irrigation solution immediately adjacent to the lens and, thus, aids in distention of the relatively short (as compared to the male) urethra, permitting improved visualization. It may also be advantageous to compress the bladder neck while simultaneously applying pressure to the diverticular sac with an assistant's finger. Luminal discharge of purulent material can often be seen with this maneuver or with digital compression of the UD during urethroscopy. Again, the UD ostia is most often located posterolaterally at the level of the midurethra, but it can be very difficult to identify in some patients. The success in identifying a diverticular ostia on cystourethroscopy is quite variable, and reported to be between 15% and 89% [4, 8, 25]. Failure to visualize an ostia on cystourethroscopy should not influence the decision to proceed with further investigations or surgical repair.

Urodynamics

For patients with UD and urinary incontinence or significant voiding dysfunction, a urodynamic study may be helpful. Approximately 50% of women with UD will demonstrate SUI on urodynamic evaluation [4, 27]. However, many patients with UD will have paradoxical incontinence, which is the loss of urine from the UD itself. This is different from genuine SUI, and it is important to distinguish between these two conditions as the repair of genuine SUI can be considered in select patients at the time of UD repair. In cases where urinary incontinence is present, urodynamics may be helpful to better characterize and document the presence of genuine SUI as well as assess for the presence of detrusor dysfunction.

A videourodynamic study combines both a voiding cystourethrogram and a urodynamic study, thus consolidating the diagnostic evaluation and decreasing the number of required urethral catheterizations during the patient's workup. For patients undergoing surgery for UD with coexistent bothersome stress urinary incontinence demonstrated on physical examination, or urodynamically demonstrable SUI, or those

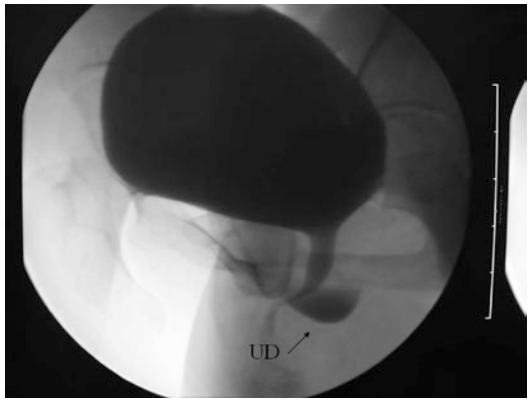

Fig. 11.6 A voiding cystourethrogram demonstrates a urethral diverticulum. (Reprinted from Rovner [10]. With permission from Elsevier)

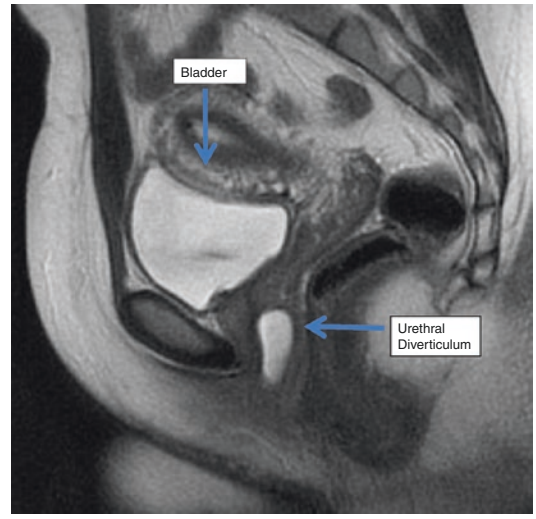

Fig. 11.7 Sagittal MRI demonstrating a urethral diverticulum in the most common location

found to have an open bladder neck on preoperative evaluation, a concomitant anti-incontinence surgery can be offered. Multiple authors have described successful concomitant repair of urethral diverticula and stress incontinence in the same operative setting [4, 27–29]. However, it should be noted that not all patients with postoperative SUI, whether it be de novo or preexisting, will be bothered postoperatively, and this should be a consideration in patient counseling [30, 31].

A small number of patients may have evidence of bladder outlet obstruction due to the obstructive or mass effects of the UD on the urethra. It should be noted that SUI may coexist with obstruction [32] but nevertheless, both conditions can be treated successfully with a carefully planned operation.

Imaging

A number of imaging techniques have been applied to the study of female UD. Currently available techniques for the evaluation of UD include double-balloon positive-pressure urethrography (PPU), voiding cystourethrography (VCUG) (Fig. 11.6), intravenous urography (IVU), ultrasound (US), and magnetic resonance imaging (MRI) (Fig. 11.7), with or without an endoluminal coil (eMRI).

US was introduced in the 1970s for many indications and has been applied to the identification of UD. US is readily available, inexpensive, with minimal discomfort to the patient, and does not require radiation. However, it is highly operator dependent and, in some cases, has been shown to have poor sensitivity. For example, in one study of 27 patients with UD, US was positive in only 10 patients [31]. MRI, on the other hand, with its superb soft-tissue contrast allows for accurate delineation of urethral anatomy and its supporting structures and has become the gold standard for UD diagnosis [33–35]. In addition, MRI has the unique ability of reliable identifying the location of the diverticula ostia in 85% of cases [34].

Surgical Repair

Indications for Repair

Although often highly symptomatic, not all urethral diverticula mandate surgery. Some patients may be asymptomatic at presentation, with the lesion diagnosed incidentally. Whether these lesions will progress in size, symptoms, or complexity over time is not known. For these reasons, and due to the lack of symptoms in selected cases, some patients may not desire surgical therapy. However, it should be noted that there are multiple reports in the literature of carcinomas

arising in UD [36–44], which may be asymptomatic and may not be prospectively identified on radiological imaging [45].

Symptomatic patients, including those with dysuria, refractory bothersome postvoid dribbling, recurrent UTIs, dyspareunia, and pelvic pain, may be offered surgical excision. Those with UD and symptomatic bothersome stress urinary incontinence can be considered for a concomitant anti-incontinence procedure at the time of UD excision [30].

Techniques for Repair

Alternative Techniques

A variety of surgical interventions for urethral diverticula have been reported since 1805 when Hey described transvaginal incision of the UD and packing of the resulting cavity with lint [10]. Approaches have included transurethral and open [46, 47] marsupialization, endoscopic unroofing [48, 49], fulguration [50], or polytetrafluoroethylene [51], coagulation, and excision with reconstruction. Most commonly, a complete excision and reconstruction is performed. However, for distal lesions, a transvaginal marsupialization as described by Spence and Duckett may reduce operative time, blood loss, and recurrence rates [46, 47, 52]. During this procedure, care must be taken to avoid aggressively extending the incision proximally which could result in vaginal voiding or potentially damage the proximal and distal sphincteric mechanism, resulting in postoperative stress incontinence. Therefore, this approach is probably only applicable to UD in very select cases involving the distal one third of the urethra, and as such, it is not commonly performed.

Excision and Reconstruction

Excision with reconstruction is the most common surgical approach to UD in the modern era. The principles of the urethral diverticulectomy operation have been well described. There are only a few minor issues about which some surgeons may disagree including the type of vaginal incision (midline vs. inverted "U" vs. inverted "T"), whether it is necessary to remove the entire epithelialized portion of the lesion, and finally, the optimal type of postoperative catheter drainage (urethra only versus urethra and suprapubic).

Complex urethral reconstructive techniques for the repair of UD have been described. Fall described the use of a bipedicled vaginal wall flap for urethral reconstruction in patients with UD and urethrovaginal fistula [53]. Laterally based vaginal flaps have also been utilized as an initial approach to UD [54, 55]. Complex anatomical configurations may exist, and many novel approaches have been described for complicated anterior or circumferential lesions [11, 12, 55]. The technique described herein is similar to that described by Leach and Raz [21] based on earlier work by Benjamin et al. [56] and Busch and Carter [57].

Preoperative Preparation

Prophylactic antibiotics can be utilized preoperatively to ensure sterile urine at the time of surgery. Patients can also be encouraged to strip the anterior vaginal wall following voiding, thereby consistently emptying the UD and preventing urinary stasis and recurrent UTIs. This may not be possible in those with noncommunicating UD or in those who have significant pain related to the UD. Application of topical estrogen creams for several weeks prior to surgery may be beneficial in some patients with postmenopausal atrophic vaginitis in improving the quality of the tissues with respect to dissection and mobilization. Preoperative parenteral antibiotics are often administered, especially for those with recurrent or persistent UTIs.

Patients with symptomatic stress urinary incontinence can be offered simultaneous anti-incontinence surgery. Preoperative videourodynamics may be helpful in evaluating the anatomy of the UD, assessing the competence of the bladder neck, and confirming the diagnosis of stress incontinence. In patients with SUI and UD, Ganabathi and others have described excellent results with concomitant needle bladder neck suspension in these complex patients [4, 58]. More

recently, pubovaginal fascial slings have been utilized in patients with UD and stress urinary incontinence with satisfactory outcomes [28–30]. According to the AUA Stress Urinary Incontinence Guidelines, synthetic slings should not be used synchronously at the time of the surgical repair of UD [58]. There may be an increased risk of sling erosion in such circumstances.

Further complicating these cases may be associated pain, dyspareunia, voiding dysfunction, urinary tract infections, and urinary incontinence. These associated symptoms are often, but not always, improved or eliminated with surgery. Therefore, the importance of appropriate preoperative patient counseling regarding surgical repair and postoperative expectations of cure cannot be overemphasized.

Procedure

The patient is placed in the lithotomy position with all pressure points well padded. The use of padded adjustable stirrups for the lower extremities greatly enhances operative access to the perineum. A standard vaginal antiseptic preparation is applied. A weighted vaginal speculum and Scott retractor with hooks aid in exposure. A posterolateral episiotomy may be beneficial in some patients for additional exposure although the midurethral (and, therefore, somewhat distal in the vaginal canal) location of most UD usually preclude the need for this. A Foley catheter is placed per urethra, and a suprapubic tube may be utilized for additional postoperative urinary drainage if desired. An inverted "U" is marked out along the anterior vaginal wall with the base of the "U" at the level of the distal urethra and the limbs extending to the bladder neck or beyond (Fig. 11.8). Care is taken to ensure that the limbs of the "U" are wider proximally (toward the bladder neck) to ensure adequate vascularity at the distal lateral margins of the anterior vaginal wall flap. As opposed to the inverted "T" incision, the inverted "U" incision provides excellent exposure laterally at the level of the midvagina and can be extended proximally as needed for lesions that extend beyond the bladder neck. Injectable saline can be infused along the lines of the incision to facilitate dissection. It is oftentimes helpful, especially for saddlebag UD, to initially dissect lateral to the limbs U-shaped flap. An anterior vaginal wall flap is created by careful dissection with Metzenbaum scissors in the potential space between the vaginal wall and the periurethral fascia. The use of sufficient countertraction during this portion of the procedure is important in maintaining the proper plane of dissection. Care is taken to preserve the periurethral fascia and avoid inadvertent entry into the UD.

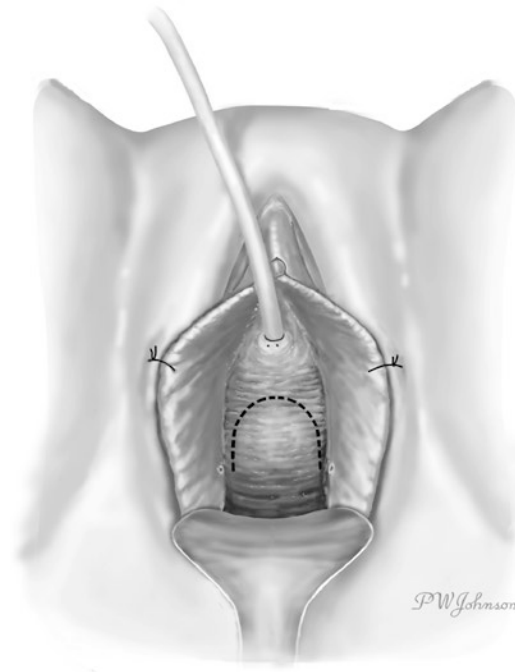

Fig. 11.8 An inverted U-shaped incision (*dashed line*) on the anterior vaginal wall (Reprinted from Rovner [10]. With permission from Elsevier)

A distinct layer of periurethral fascia is usually interposed between the vaginal wall and the UD. Preservation and later reconstruction of this layer are of paramount importance to prevent recurrence, close dead space, and avoid urethrovaginal fistula formation postoperatively. Pseudodiverticula have been described where this layer of tissue is considerably attenuated or even absent [59]. In these patients, an interpositional flap or graft such as a pubovaginal sling may be utilized for reconstruction.

The periurethral fascia is incised transversely (Fig. 11.9). Proximal and distal layers of peri-

urethral fascia are carefully developed using Metzenbaum scissors, avoiding entrance into the UD. The UD is then grasped and dissected back to its origin on the urethra within the leaves of the periurethral fascia (Fig. 11.10). In many cases, it is necessary to open the UD to facilitate dissection from the surrounding tissues. The ostia or connection to the urethra is identified, and the walls of UD are completely removed. Every effort should be made to remove the entire epithelialized surface of the UD in order to prevent recurrence [4, 60]. This may involve removing small adherent or inflamed portions of the urethral wall, especially in the area of the ostia. All abnormal tissue in the area of the ostia should be removed if possible to ensure that no mucosal elements of the UD wall remain, which could result in postoperative urine leakage and recurrence. Elaborate methods of identifying the full extent of the UD cavity have been described, including catheterization of the UD with urinary [5, 60] and Fogarty [61] catheters, packing the UD with gauze [62], infusing and staining the UD with methylene blue, and the use of silicone [63] or cryoprecipitate [64] to create a solid mass and ease dissection.

The Foley catheter is usually seen following complete excision of UD (Fig. 11.11). The urethra can be reconstructed over as small as a 12F Foley catheter without long-term risk of urethral stricture [10] and should be closed in a watertight fashion with running or interrupted 4.0 synthetic absorbable suture. The closure should be tension free and watertight (Fig. 11.12). In rare circumstances, a UD may extend circumferentially around the urethra and require segmental resection of the involved portion of the urethra and complex reconstruction [12, 23, 65].

The periurethral fascial flaps are reapproximated with interrupted 3.0 synthetic absorbable suture in an orientation perpendicular to the urethral closure line to minimize overlap and the risk of postoperative urethrovaginal fistula formation

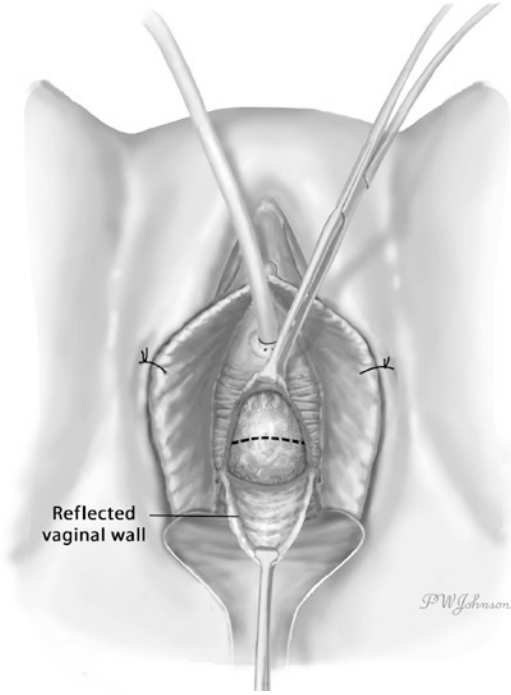

Fig. 11.9 After reflection of the anterior vaginal wall, a transverse incision is made in the periurethral fascia. The *dotted line* represents the intended incision line. (Reprinted from Rovner [10]. With permission from Elsevier)

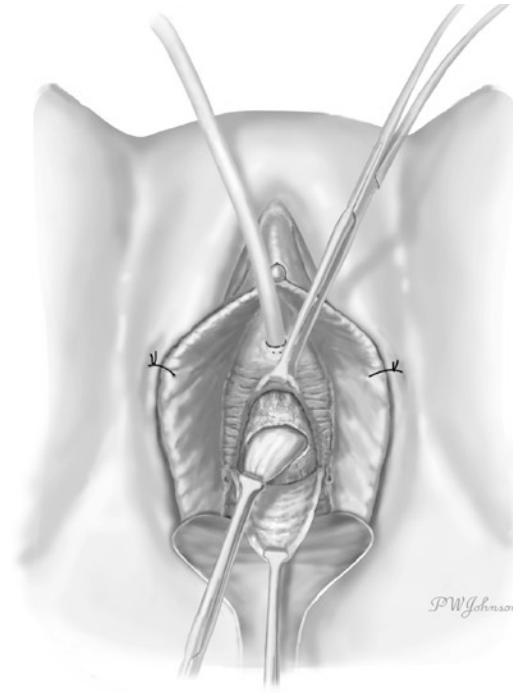

Fig. 11.10 The UD sac is freed from the periurethral fascia. (Reprinted from Rovner [10]. With permission from Elsevier)

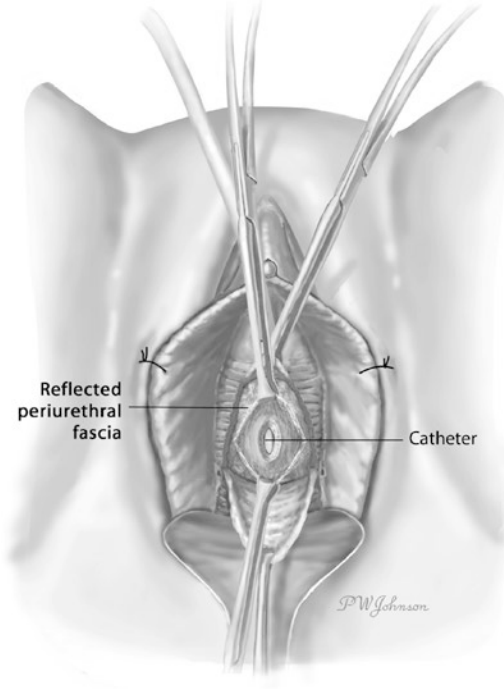

Fig. 11.11 The urethral catheter is seen after complete excision of the UD sac. (Reprinted from Rovner [10]. With permission from Elsevier)

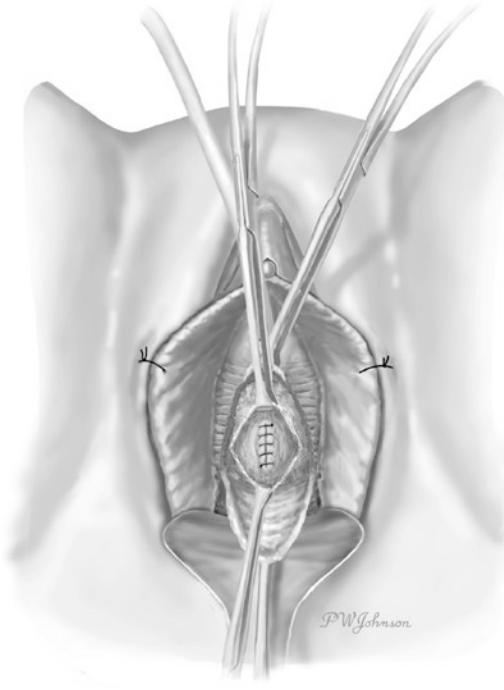

Fig. 11.12 The urethra is closed with absorbable suture. (Reprinted from Rovner [10]. With permission from Elsevier)

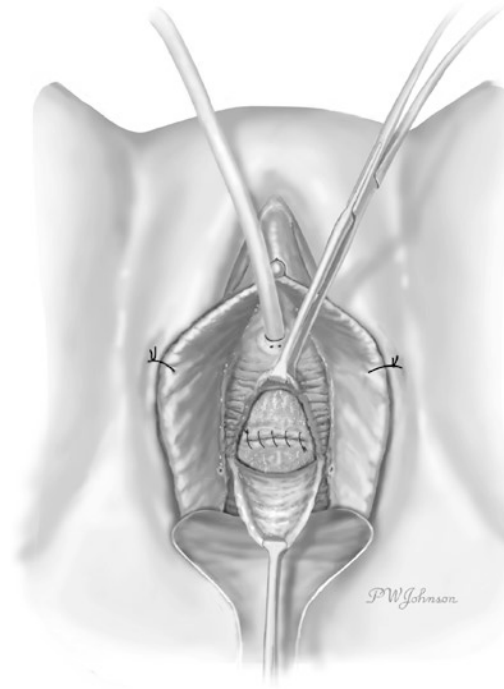

Fig. 11.13 The periurethral fascia is closed with care to obliterate any dead space. (Reprinted from Rovner [10]. With permission from Elsevier)

(Fig. 11.13). Care is taken to secure the periurethral fascial flaps in order to close all the dead space.

If desired, a fibro-fatty labial (Martius) flap can be harvested at this point and placed over the periurethral fascia as an additional layer of closure [65]. In patients with poor-quality tissues, attenuated periurethral fascia, or in whom significant inflammation is encountered intraoperatively, a well-vascularized adjuvant flap such as a Martius flap may reduce the risk of wound breakdown and subsequent complications such as urethrovaginal fistula.

The anterior vaginal wall flap is then repositioned and reapproximated with running 2.0 synthetic absorbable suture. This completes a three-layer closure consisting of the urethra, periurethral fascia, and vaginal wall (four layers if a Martius flap is utilized). An antibiotic impregnated vaginal pack is placed.

Postoperative Care

Antibiotics are continued for 24 h postoperatively. The vaginal packing is removed, and the patient

discharged home with closed urinary drainage. Antispasmodics are used to reduce bladder spasms. A pericatheter VCUG is obtained at 10–14 days postoperatively. If there is no extravasation, the catheters are removed. If extravasation is seen, then repeat pericatheter VCUGs are performed weekly until resolution is noted. In the vast majority of cases, extravasation will resolve in several weeks with this type of conservative management [66]. Persistent extravasation may indicate surgical failure or alternatively another cause for delayed wound healing, such as a retained foreign body or poorly functioning postoperative catheter drainage. If surgical failure is suspected resulting in either urethrovaginal fistula or persistent UD, then surgical repair is indicated after a sufficient waiting period of 3–6 months if the patient is symptomatic.

Complications

Careful adherence to the principles of transvaginal urethral diverticulectomy should minimize postoperative complications. Nevertheless, complications may arise. Large diverticula (>4 cm) or those associated with a lateral or horseshoe configuration may be associated with a greater likelihood of postoperative complications [66]. Common complications include recurrent UTIs (up to 31.3%), urinary incontinence (1.7–16.1%), or recurrent UD (1–25%). Urethrovaginal fistula (0.9–8.3%) is a devastating complication of urethral diverticulectomy [67]. A fistula located beyond the sphincteric mechanism should not be associated with symptoms other than, perhaps, a split urinary stream or vaginal voiding. As such, an asymptomatic distal urethrovaginal fistula may not require repair, although some patients may request repair. Conversely, a proximal fistula located at the bladder neck or at the midurethra in patients with an incompetent bladder neck will likely result in considerable symptomatic urinary leakage. These patients should undergo repair with or without the use of an adjuvant tissue flap such as a Martius flap to provide a well-vascularized additional tissue layer. The actual timing of the repair relative to the initial procedure is controversial although a delay of 3–6 months is generally an acceptable balance between patient discomfort and optimal tissue quality. Rare complications include urethral stricture (up to 5.2%), hypospadias, distal urethral necrosis, bladder injury, urethral injury, and vaginal scarring or narrowing with consequent dyspareunia [67]. Meticulous attention to surgical technique, good hemostasis, avoidance of infection, preservation of the periurethral fascia and a well-vascularized anterior vaginal wall flap, and multilayered closure with nonoverlapping suture lines should minimize the potential for postoperative urethrovaginal fistula formation.

Persistence of Symptoms Following Urethral Diverticulectomy

Some patients will have persistence or recurrence of their initial symptoms postoperatively. The finding of a UD following a presumably successful urethral diverticulectomy may occur as a result of a new medical problem (e.g., UTI), a new UD, or alternatively, as a result of recurrence of the original lesion. Recurrence of UD may be due to incomplete removal of the UD, inadequate closure of the urethra or residual dead space, or other technical factors. Lee noted recurrent urethral diverticulum in 8 of 85 patients at follow-up of between 2 and 15 years from the initial UD resection [67]. Repeat urethral diverticulectomy surgery can be challenging due to altered anatomy, scarring, and the difficulty in identifying the proper anatomic planes.

Summary

Urethral diverticulectomy surgeries are often challenging but ultimately very satisfying for the patient and the surgeon. Many of these patients are highly symptomatic and experience relief of their symptoms with successful surgery. Adherence to principles of reconstructive surgery including careful dissection and preservation of the vascular supply of flaps, avoidance of overlapping suture lines, and watertight closure is important to ensure a satisfactory result.

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Augmentation Cystoplasty

12

Annie Chen, Brian S. McIntyre, and Elise J. B. De

Introduction

Persons with decreased bladder storage or impaired detrusor compliance can benefit from augmentation cystoplasty (AC) in both the pediatric and adult settings. Augmentation cystoplasty, also known as bladder augmentation, is the process of surgically enlarging the bladder with ileum, colon, or gastric tissue in order to increase storage capacity or improve compliance parameters. In most contemporary cases, AC is offered to patients who have failed trials of anticholinergics and botulinum toxin, with or without self-catheterization. Although AC has moved to third-line therapy somewhat with the advent of sacral neuromodulation (idiopathic dysfunction) and botulinum toxin (both idiopathic and neurogenic), it is still practiced as second-line therapy in the pediatric population especially in the context of spina bifida and bladder exstrophy [1]. An argument could be made that AC should be second line in the younger adult population given the projected timeline for bladder management and the desire to avoid repeat injections of botulinum toxin. This chapter reviews patient presentation and management, surgical techniques, postoperative concerns, and complications, with a focus on the female population.

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Background

AC was first used by Tizzoni and Foggi in 1888 in a canine model as a two-stage operation in which an ileal segment was anastomosed to the prostatic urethra [2]. It was used in a human model in 1889 by Von Mikulicz [3], and later, it was used to treat a small, contracted end-stage tuberculous bladder by Couvelaire in 1950 [4]. Different segments have been used in AC, including colon in 1912 by Charghi [5], sigmoid in 1943 by Bisgard [6], cecum in 1950 by Couvelaire [4], and stomach in 1978 by Leong [7]. Ileocystoplasty was introduced by Goodwin in 1959 and is the most common organic tissue used in AC [8]. On occasion, the ureter has been used, particularly in children with congenital anomalies; however, other indigenous organic tissues have not been found to be particularly useful, including peritoneum, omentum, pericardium, skin, and gallbladder [9].

Presentation

Severe bladder dysfunction can be neurogenic (congenital or acquired) or nonneurogenic in nature, as summarized in Table 12.1. It is essential

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Table 12.1 Indications for augmentation cystoplasty

Neurogenic causes	
Congenital	Spina bifida
	Posterior urethral valves
	Bladder exstrophy
	Cloacal exstrophy
	Sacral agenesis
	Caudal regression
	Myelodysplasia
Noncongenital	
Spinal cord	Trauma
	Tumors
	Idiopathic
	Tethered cord
Multiple sclerosis	
Nonneurogenic causes	
Cystitis	Interstitial cystitis
	Radiation induced
	Chemotherapy induced
Infection	Tuberculosis
	Schistosomiasis
Other	Iatrogenic bladder injury
	Idiopathic detrusor instability
	Pelvic floor dysfunction
	Defunctionalized bladder

to fully investigate the extent of dysfunction with urodynamics (UDS) and comprehensive neurological evaluation prior to proceeding to such a definitive intervention as AC. Severe voiding dysfunction, tethered cord, multiple sclerosis, herniated disc, sacral tumor, schistosomiasis, and bladder outlet obstruction are examples of treatable contributors that should be addressed prior to committing to permanent alterations in bladder management. Repeat UDS can assess the outcome of intervention where relevant.

In the pediatric population, congenital anomalies comprise the most common causes of neurogenic bladder – and by extension frequency of AC. Concerns about malignancy, potential bladder perforation, and decreased bone growth due to metabolic derangements in acid-base status are likely contributors to an almost 25% decrease in rates of AC in the United States in the 2000s [1, 10–13]. It is likely that improved medications, the newer option of bladder chemodenervation (with botulinum toxin), and unfavorable reimbursement patterns for cystoplasty play a more recent role in this change [14, 15].

About 25% of patients with myelomeningocele and 50% with bladder exstrophy will undergo AC [1, 16]. There are some considerations in special populations. Cloacal exstrophy is a rare developmental defect in which the abdominal wall structures form abnormally, causing the abdominal organs to protrude outside of the abdominal cavity. This leads to splitting of the bladder and genitalia and an imperforate anus. These patients will likely require a series of surgeries in order to achieve urinary continence with half achieving continence by age 11 [17]. This history as well as the underlying anatomy will render AC more complex. Patients with bladder exstrophy will have had closure of the abdominal wall leading to thin overlying tissues and scarring. Those with myelodysplasia may have had a vesicostomy early in life, followed by closure and variable success with interval bladder management. For patients with severe end-stage renal disease, AC is sometimes necessary in order to achieve a lower pressure system with acceptable capacity prior to renal transplantation. The augmentation should be accomplished at least several months prior to transplantation [18]. Patients with MS should be carefully counseled regarding AC because the loss of muscle coordination may make it hard to self-catheterize if the MS progresses. A catheterizable cutaneous stoma may help with access to the bladder, especially in females, either due to impaired hand function or due to difficulty with legs (spasticity or positioning in the chair). AC was originally intended to treat sequelae from infections like tuberculosis and schistosomiasis, but these etiologies are now increasingly rare [19].

About 77% of adult patients who undergo AC have a primary urodynamic (UDS) diagnosis of reduced compliance and 22% have detrusor overactivity [20]. Many will have detrusor external sphincter dyssynergia. Patient presentations can vary. Those with decreased bladder capacity typically present with incontinence, urgency, frequency, nocturia, or enuresis. The upper urinary tract can also be affected by high ureteric

pressures or long-term reflux manifesting in possible renal scar formation, recurrent urinary tract infections (UTIs), hydronephrosis, pyelonephritis, urolithiasis, renal insufficiency, or overt renal failure [21–23].

Evaluation, Initial Treatment, and Workup Prior to Augmentation Cystoplasty

A full clinical history including timing, severity, frequency of voiding, associated pain, or any other symptoms should be elicited. A sample intake form regarding prior treatments is included in Table 12.2. Validated symptom scores can be helpful adjuncts and important for tracking improvement of symptoms after therapy. The authors are not aware of one that is validated for both neurogenic and idiopathic LUTS.

AC is not without risks, so it is important to start with a trial of conservative therapies. The European Association of Urology (EAU) has recommended that cystoplasty be offered to patients with overactive bladder or low compliance bladder who have failed conservative therapy [24]. Behavioral modification such as bladder training or pelvic floor muscle training with or without biofeedback can be used as first-line management depending on idiopathic versus neurogenic etiology [25]. Behavioral training can also include timed voiding with limitation of excessive fluid intake and avoidance of potential bladder irritants, including caffeine and alcohol. Behavioral management can be combined with antimuscarinics or B3 agonists.

Cystoscopy and UDS should be performed in adults with idiopathic etiology who are refractory to these interventions for frequency, urgency, and urge incontinence. Once tumor and stones are ruled out, treatment can focus more aggressively on detrusor overactivity or an overly sensate bladder. Interventions progress through medications, sacral neuromodulation, or botulinum toxin with or without clean intermittent self-catheterization (CISC). In patients with

Table 12.2 Sample treatment map/intake form from the Massachusetts General Hospital Pelvic Floor Disorders Service

Bladder history			
We would like to give you a tool to communicate and map treatment over time. Please help us understand what you have tried in the past and keep a copy so we can map a plan over time.			
The primary symptoms are:			
Medication	**Tried?**	**Relief?**	**Still using?**
Bladder relaxing medications			
Ditropan (Oxybutynin)			
Gelnique (Oxybutynin gel)			
Oxytrol (Oxybutynin patch)			
Detrol (Tolterodine)			
Toviaz (Fesoterodine)			
Sanctura (Trospium)			
Enablex (Darifenacin)			
Vesicare (Solifenacin)			
Myrbetriq (Mirabegron)			
Levsin (Hyoscyamine)			
Amitriptyline (Elavil)			
Nortryptiline (Pamelor™)			
Imipramine (Tofranil)			
Bladder instillations			
Medications to open bladder outlet			
Terazosin (Hytrin)			
Flomax (Tamsulosin)			
Cardura (Doxazosin)			
Alfuzosin (Uroxatral)			
Rapaflo (Silodosin)			
Muscle relaxants			
Lioresal, Kemstro (Baclofen)			
Zanaflex (Tizanidine)			

(continued)

Table 12.2 (continued)

Bladder history			
Benzodiazepines (Valium, Xanax, Ativan)			
Infection management			
Vaginal estrogens			
Hormones by mouth, injection, or patch			
Cranberry supplements			
D Mannose			
Methenamine and vitamin C			
Oral or IV antibiotics (doses and # days)			
Antibiotic instillation in the bladder			
Other medications:			
Surgery:	**Tried?**	**Relief?**	**Details**
Hysterectomy (removal of uterus)			
Ovary removal			
Prolapse surgery			
Incontinence surgery			
Incontinence injection (e.g., collagen, coaptite)			
Urethral diverticulum or fistula surgery			
Urethral dilation			
Bladder hydrodistention			
Sacral nerve stimulation (Interstim)			
Botox to:			
☐ Bladder detrusor muscle			
☐ Bladder exit (sphincter)			
☐ Pelvic muscles			
☐ Skin surface			
Procedures and treatments	**Tried?**	**Relief?**	**Details**
Pelvic physical therapy			
Pelvic biofeedback			
Bladder management	**Tried?**	**Relief?**	**Details**
☐ Bladder empties naturally			
☐ Timed voids by the clock			
☐ Intermittent catheterization __ times per day			
☐ Indwelling tube changed every __ weeks			
☐ Supply info:			
Other treatments:			
Type of test	**Number of tests**	**Date, location**	**Results normal?**
Urinalysis and culture			
Urine cytology			
Documentation of a voiding diary			
Blood tests			
CT scan of abdomen and pelvis			
Ultrasound of kidneys			
MRI of:			
☐ Spine			
☐ Head			
☐ Abdomen/pelvis			
Spine X-ray (type)			
Cystogram			
Cystoscopy			
Urodynamic testing			
EMG			

neurogenic etiology, UDS will be part of routine evaluation for the overwhelming majority. A fluid/voiding/cath diary can direct and confirm urodynamic investigation and rule out fluid intake outside the norm (type and volume). Behavioral therapy is less likely to be effective but can be offered to those with incomplete loss of function. Sacral neuromodulation is not part of the algorithm, but medications, botulinum toxin, and AC form the mainstays of therapy, usually in that order.

Botulinum toxin is injected cystoscopically through the body of the detrusor muscle in an effort

to increase the volume of onset and decrease the amplitude of detrusor contractions. The higher the dose, the more likely that emptying will be impaired. For many of our patients with neurological disease, self-catheterization is often already part of the bladder management. For those who must transition to self-catheterization after botulinum toxin or AC, there will be a learning curve and psychological adjustment. It is essential to (1) counsel the patient about this possibility, including the need to irrigate mucus after AC, (2) assess psychological and physical ability to self-catheterize, (3) consider self-catheterization teaching prior to botulinum toxin, and (4) confirm definite ability to self-catheterize and irrigate prior to augmentation cystoplasty with nursing and/or occupational and physical therapy.

In sum, patients with refractory OAB, a poorly compliant bladder with high filling pressures (over 40 cm H_2O), low bladder capacity, detrusor instability, or in very select cases of refractory interstitial cystitis (IC) who have failed conservative management may be candidates for AC [20]. An ultrasound should be ordered to check for hydronephrosis, stone disease, pyelonephritis, obstruction, or any other suspected urinary tract abnormality unless there is indication for CT scan (hematuria or stones). Renal mass protocol imaging and cytology should be performed for the same indications as any patient (i.e., gross hematuria or ≥3 red blood cell per high-power field in the absence of infection) [26]. Urine studies such as urinalysis and cultures should be ordered to evaluate for UTI. Because metabolic acidosis and renal failure are relative contraindications, a serum chemistry panel should be ordered and referral arranged if abnormal. These parameters may improve with indwelling catheter while the work up is underway. A colonoscopy should be considered – especially if the colon will be harvested for augmentation, and definitely if due for screening. The patient should be given a full bowel preparation prior to surgery [27]. In patients with neurogenic bowel, this usually includes a clear liquid diet and mechanical bowel preparation initiating 48 hours preoperatively. In women with a history of pelvic radiation secondary to malignancy such as cervical cancer, a complete evaluation for possible fistula (continuous incontinence), urethral incompetence, detrusor areflexia, and fibrosis is recommended [28].

There are also special considerations in transplant patients. Augmentation cystoplasty is an absolute last resort as is the use of bowel in the urinary tract for any reason in transplant patients. Most candidates for transplantation produce urine and void allowing one to assess their bladder function with a careful history and PVR. All anuric transplant candidates should be considered for cycling beginning at least several months before they are placed on the transplantation list. This is also true for those who have a history of severe bladder dysfunction. There are at least three reasons to do this: (1) to increase capacity and evaluate detrusor activity during filling, (2) to access continence and ability to void to completion, and (3) to teach the patient intermittent catheterization in the event it becomes necessary in the posttransplant period. Cycling is accomplished by instilling saline until capacity is reached, removing the catheter, and having the patient void to completion. Restoration of normal volume and voiding occurs very quickly in most patients, and there is then no need to continue. The bladder can be very difficult to evaluate in these patients on UDS – hence, the cycling exercise which over time provides a great deal of information and need not be continued once the appropriate course has been determined.

Contraindications to AC include inflammatory bowel disease, history of irradiated bowel, bladder tumors, severe radiation cystitis, liver disease, or severe renal insufficiency (Table 12.3). Some of these are not absolute. Patients who are not

Table 12.3 Relative contraindications to augmentation cystoplasty

Inflammatory bowel disease
Short gut syndrome
History of irradiated bowel
Bladder tumors
Severe radiation cystitis
Significant renal insufficiency (GFR <40 ml/min)
Liver disease
Pelvic irradiation (enterocystoplasty)
Inability or unwillingness to self-catheterize

amenable to CISC should not undergo AC, as intermittent catheterization can be required, including irrigation of mucus.

For patients who are unable to perform CISC because of loss of dexterity (MS or higher level spinal cord injury patients), destruction of urethral anatomy, body habitus (intravaginal urethra or redundant mons pubis tissue), leg spasticity rendering perineal access difficult, urethral pain, or unwillingness or aversion due to some other cause (a subset of trauma patients), a cutaneous catheterizable stoma might be suitable to render AC an option.

Surgical Techniques

Catheterizable Cutaneous Stoma Techniques

A catheterizable cutaneous stoma can make AC a suitable option for patients who are unable to perform CISC per urethra due to anatomic or neurological considerations (Fig. 12.1). The catheterizable stoma needs to be a vascularized, tubularized structure with a continence mechanism. Continence will be achieved by mild resistance along the channel (e.g., a reimplantation tunnel into the bladder or augment or less commonly the valve mechanism of the terminal ileum) as well as ensuring low filling pressures in the augmented bladder. Appendix or ileum is most commonly used at present. The Mitrofanoff principle involves an appendicovesicostomy. The distal end of the appendix is implanted onto the posterior wall of the bladder, and the proximal end is brought out through the umbilicus or a small stoma (rarely, patients anticipate the umbilicus would be too uncomfortable, but usually the decision is intraoperative based on what will reach most easily) [29, 30]. Alternatively, ileum can be used in an ileovesicostomy using the Yang-Monti principle. This 2.5- to 3.5-cm segment of ileum is detubularized along the antimesenteric border and then retubularized in the long direction, allowing ends free of the mesentery, and an appropriate diameter for catheterizing with a 12–14 French catheter. Single, double, or spiral Monti can be constructed based on the needed length [31, 32]. The continent stoma should be easily catheterizable during surgical construction with the bladder full to avoid reoperation. The Monti ileovesicostomy used in catheterizable cutaneous stoma should be distinguished from the incontinent ileovesicostomy, in which a chimney of ileum is applied to a small bladder with neurogenic detrusor overactivity and brought to the skin as an incontinent stoma to protect the upper urinary tracts [33, 34]. Continent vesicostomy was first introduced in the pediatric population to treat congenital bladder anomalies, and studies indicate a satisfactory continence rate of over 90% [35–37]. In the adult study population, continence rates are about 74% in one study [38]. Failure rates range from 8% to 57% for stomal stenosis and 11–25% for leakage in adults with a revision rate of up to 50% [38–40]. It is the author's experience that tunneling the distal end of the cutaneous stoma (appendix or Monti retubularized ileum) can be more difficult in the adult population. The bladder may be severely thickened and scarred, deeper in the pelvis, and the abdominal wall may contain challenging amounts

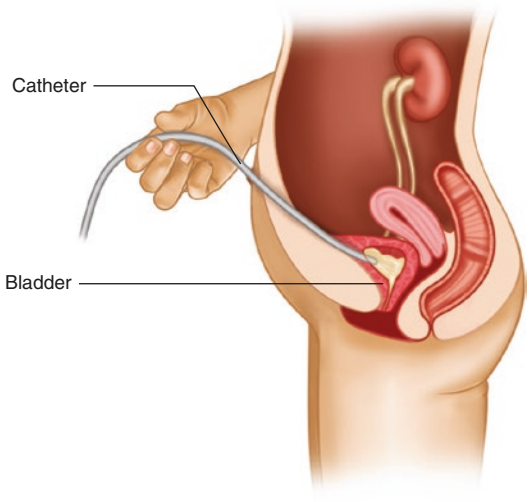


Fig. 12.1 Illustration of self-catheterization via stoma

of adipose tissue. In these cases, tunneling is made into the augment itself without the benefit of a detrusor tunnel.

Augmentation Cystoplasty Techniques

The purpose of AC is to increase bladder capacity or decrease detrusor filling pressure, increasing compliance (patients understand well when one uses the analogy of an easy to inflate balloon for the kidneys to push the urine forward). The basic goals are to improve symptoms of frequency, urgency, incontinence, dysreflexia, and infections and to prevent deterioration of the upper urinary tract. AC can be performed using various segments of the GI tract. Rarely, a composite augmentation will be performed. The ileum, colon (sigmoid colon or cecum), or gastric tissue is opened up to expose the lumen (detubularization, Fig. 12.2). The successful use of the ureter [30] and fallopian tube [41] has also been described, but it has never gained wide favor. The ureter may be used in highly selective situations where a dilated ureter exists and is not needed for urinary drainage. Often, this happens in the case of megaureter in children. Theoretically, it might be possible that ureter and fallopian tube would dilate over time, but anecdotally, it has only happened rarely. The detubularized piece of intestine will be reconfigured in the opposite orientation to improve the geometry of the volume held and interrupt peristalsis, and it is sutured to the clamshelled bladder. The most commonly used segment is the ileum due to ease of handling and constant blood supply, followed by the sigmoid colon [42].

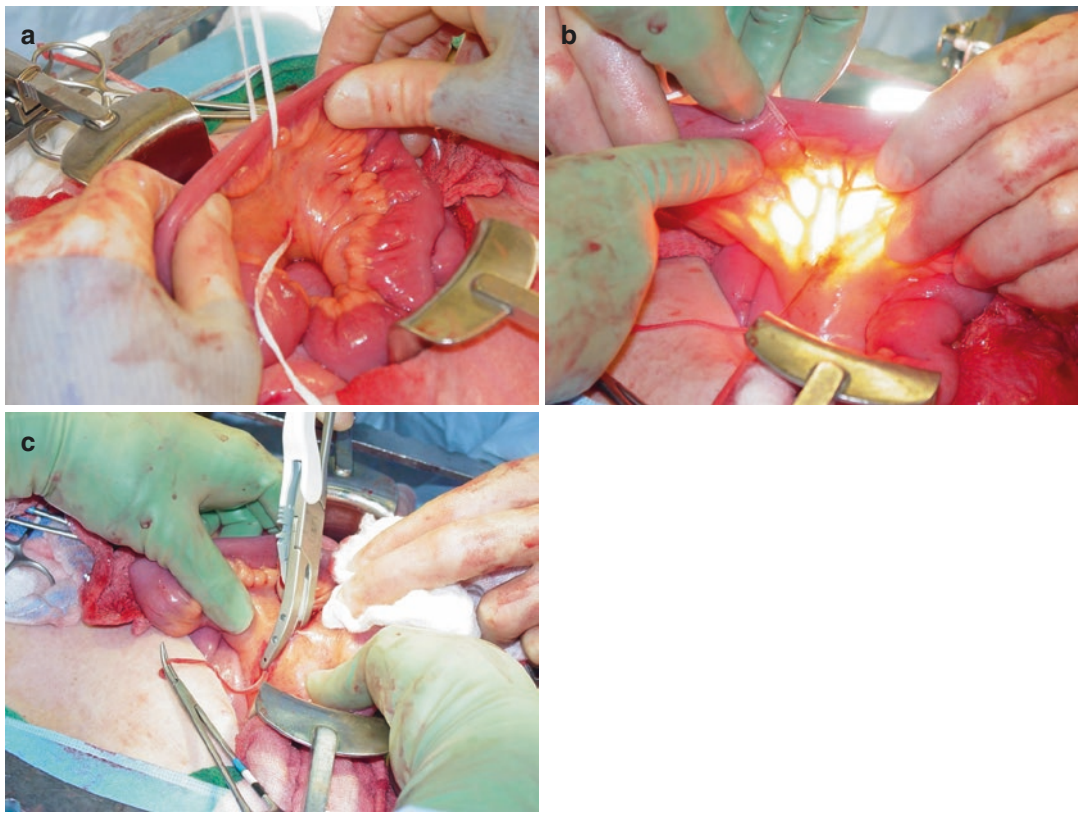
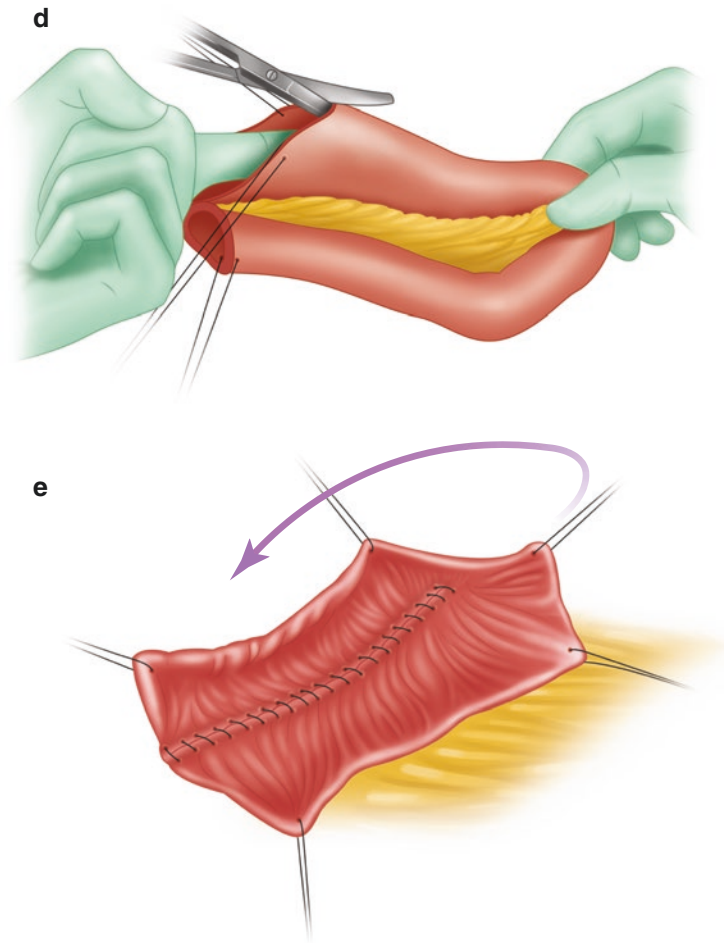


Fig. 12.2 (**a**, **b**, **c**, **d**, **e**): The ileum is harvested detubularized, and reconfigured for augmentation cystoplasty

Fig. 12.2 (continued)



Generally, ileum or colon is preferred for augmentation cystoplasty as stomach and jejunum have a number of complications which are more difficult to manage than those which arise from the use of the ileum or colon (Tables 12.4 and 12.5). There are, however, rare circumstances when one of these two segments may be preferred. When the ileum or colon is not suitable, such as in the case of Crohn's or a history of pelvic radiation, the stomach can be used (gastrocystoplasty). However, recent studies have cited higher rates of malignancy particularly in gastrocystoplasty, which may make it a less favorable choice [43]. Acid hematuria (hematuria–dysuria) syndrome due to helicobacter pylori [44, 45], stones, the syndrome of severe metabolic alkalosis [46], and higher rates of reoperations are also associated specifically

Table 12.4 General complications from augmentation cystoplasty

Metabolic derangements (depending on the segment of bowel used)	
	Metabolic acidosis
	Metabolic alkalosis
	Hyperchloremia
	Hypokalemia
	Hyperkalemia
	Hypocitraturia
	Hypercalciuria
	Hyperoxaluria
Lithiasis	
Malignancy	
Bladder perforation	
Osteomalacia, impaired healing of fractures	
Growth retardation in children	
Short bowel syndrome	
Altered bowel function	
Infections (UTI, pyelonephritis)	

Table 12.5 Tissue-specific complications

	Advantages	Disadvantages
Gastrocystoplasty	Reliably vascularized	Higher rates of reimplantation than ileocystoplasty
	Alternative to ileum in patients with Crohn's, short gut, or other ileal disease	Vitamin B12 deficiency
	Lower incidence of bacteriuria	High mucus accumulation Stones UTI
		Metabolic derangements Acid hematuria syndrome Hypokalemic, hypochloremic metabolic alkalosis Syndrome of severe metabolic alkalosis
		Malignancy
		Risk of bladder ulcers and perforation
Ileocystoplasty	Reliably vascularized	Malabsorption of fat-soluble vitamins (A, D, E, K)
	Easily manipulated	Bile salts
	Low mucus accumulation	Vitamin B12 deficiency
		Metabolic derangements Hyperchloremic metabolic acidosis Poor bone growth in pediatric population
		SBO
Jejunocystoplasty	Reliably vascularized	Highest rates of metabolic derangements Hyponatremic, hyperkalemic metabolic acidosis Iron and calcium deficiency Poor bone growth in pediatric population
		Severe dehydration
Colon	Alternative to ileum in patients with prior pelvic radiation, Crohn's, short gut, or other ileal disease	Metabolic derangements Hyperchloremic metabolic acidosis (Gough DCS) Poor bone growth in pediatric population
	Redundant in spina bifida patients	Incontinence (15% in one study Gough DCS)
	Antireflux tunnels easily made	High mucus accumulation
	Fewer nutritional issues	Higher mucus accumulation than ileum Stones UTI
Ureterocystoplasty	Advantageous in neurogenic bladder or posterior urethral valves	High rates of reimplantation
	Ideal when megaureter is available	
	No mucus accumulation	

Based on data from Refs. [27, 112, 113]

with gastrocystoplasty [47]. Patients should be counseled on the importance of long-term follow-up with cystoscopy. In patients with cloacal exstrophy and short gut, a composite bladder augmentation using both stomach and bowel can be advantageous as very few patients develop metabolic derangements or malignancies even at an interval follow-up of 13 years [48]. Finally, in situations in which the colon and ileum have been significantly compromised due to pelvic radiation, a segment of jejunum can be an acceptable option.

AC can be performed via open, laparoscopic, and robotic transperitoneal approach. Laparoscopic and robotic approaches have been reported to take almost twice as long as the open approach in most hands [49]. When performed laparoscopically or robotically, four trocars are placed intraperitoneally radiating from the umbilicus with one in the umbilicus and the abdomen insufflated. The rest of the operation is similar to the open approach.

If the ileum is used, the cecum is an important landmark. For the augment, a 25-cm segment of ileum in adults (20–25 cm in children) is harvested at least 15 cm from the ileocecal valve, with careful attention to the configuration of vessels serving it. If a Monti is to be created, an additional 2- to 3.5-cm segment can be harvested on its own vessel [50]. If one is planning on using an appendicovesicostomy, it should be harvested and evaluated now. If the lumen is of insufficient caliber or the blood flow tenuous, a Monti will be needed. The appendix will need to be harvested with its mesoappendix and appendiceal blood supply. Some recommend taking a corner of the cecum in order to facilitate length if the appendix itself is too short. Catheterization with a 10-French feeding tube indicates sufficient caliber, as it should be expected to dilate over time. The segment(s) should be evaluated for reach to the site of planned anastomosis to the bladder prior to harvesting, as one can either travel more proximal on the bowel or change to a sigmoid augment in the event of a short mesentery. The mesentery can sometimes be striated superficially to release the parietal peritoneum and allow stretch. Once the ileal segment is harvested, bowel continuity should be reestablished cephalad to the planned augment. If established caudad, there will be a site of relative obstruction as the augment is pulled down toward the bladder. Staplers of 3.5 cm are typically used to harvest the segment (GIA) and reanastomose the bowel (TA and GIA), although a hand-sewn anastomosis can certainly be used. One must always double check the surgical technician has not handed vascular 2.5-mm staples into the field, as these will lead to delayed necrosis and bowel anastomotic breakdown. After bowel continuity has been reestablished, attention is directed to the ileal segment. A triple-antibiotic-soaked blue towel is placed underneath, and the stapled ends of the segment are removed sharply. Triple antibiotic is irrigated into one end and the other positioned over a kidney basin, paying attention to avoid too much stretch on the mesentery. Once the efflux is clear, a chest tube or disconnected suction tip is threaded into the segment. If a Monti had been planned, its 2- to 3.5-cm segment will be separated at this point depending on single, double, or spiral configuration. The end used will depend on blood supply and the best choice for mesenteric positioning, usually the proximal end of the ileal segment. The catheterizable channel should be created prior to the augment in order to work on this finer piece prior to onset of edema. Selection of single versus spiral Monti will depend on the length needed to catheterize. It is the authors' experience that the double Monti can be difficult to catheterize at the juncture between the two retubularized 16- to 20-mm ileal pieces. The single Monti will be 2 cm and will simply be opened at the antimesenteric border. The spiral is opened as a right angled Z as pictured in Fig. 12.3. We recommend bringing a drawing to the operating room for reference. For the spiral, a 3.5- to –4-cm section of ileum is isolated on its mesentery and divided into two equal segments with each segment opened and unfolded in opposite directions [51]. The mesentery is left intact. This effectively doubles the length of ileum. The angled segment at the mid-portion will need to be smoothed and the lumen narrowed in order to prevent pocket formation at the mid-tunnel. Suture material for any of the above will be a delicate delayed absorbable 4-0 or 5-0 with

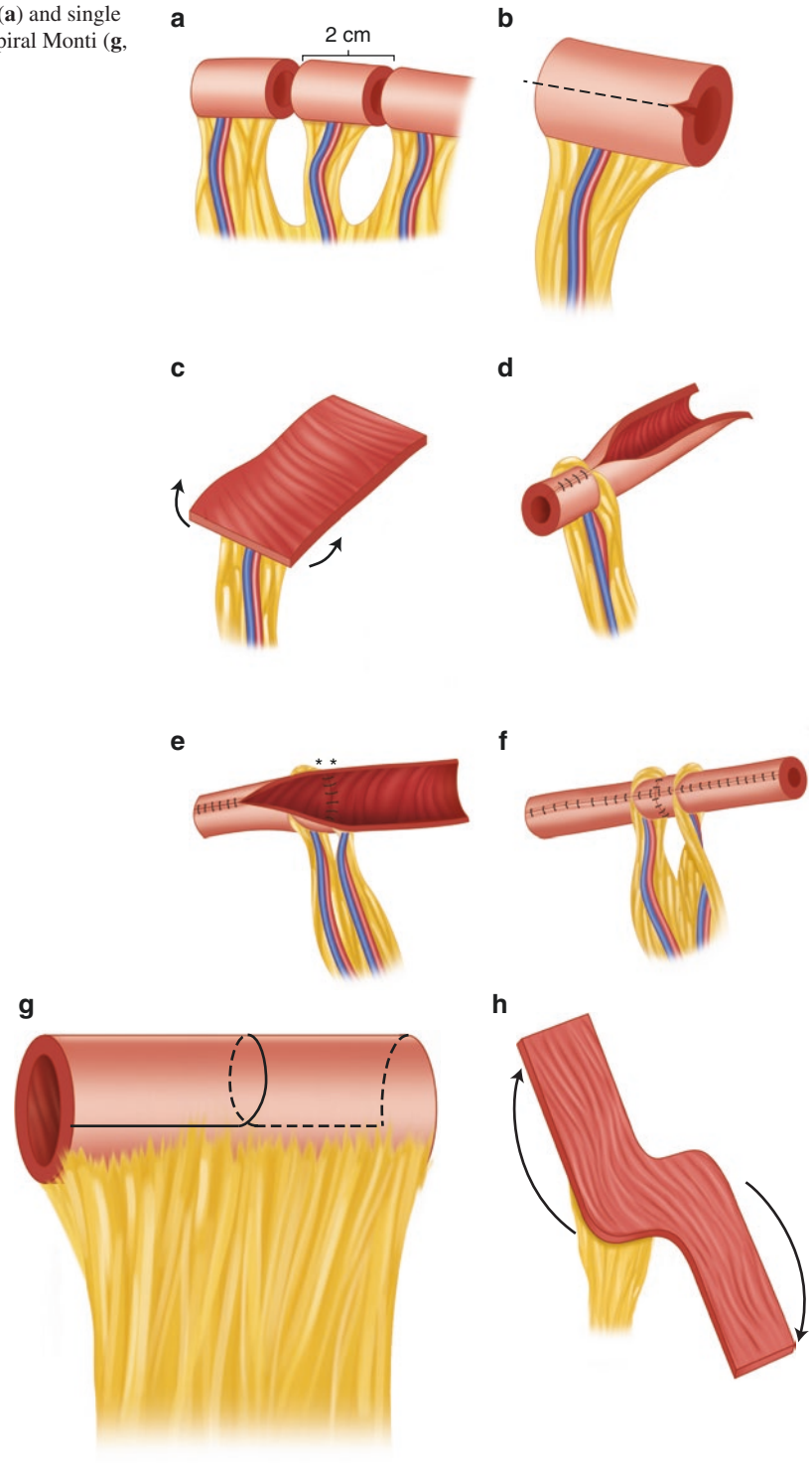


Fig. 12.3 Segment harvest (**a**) and single (**b**, **c**, **d**), double (**e**, **f**), and spiral Monti (**g**, **h**, **i**, **j**, **k**) technique

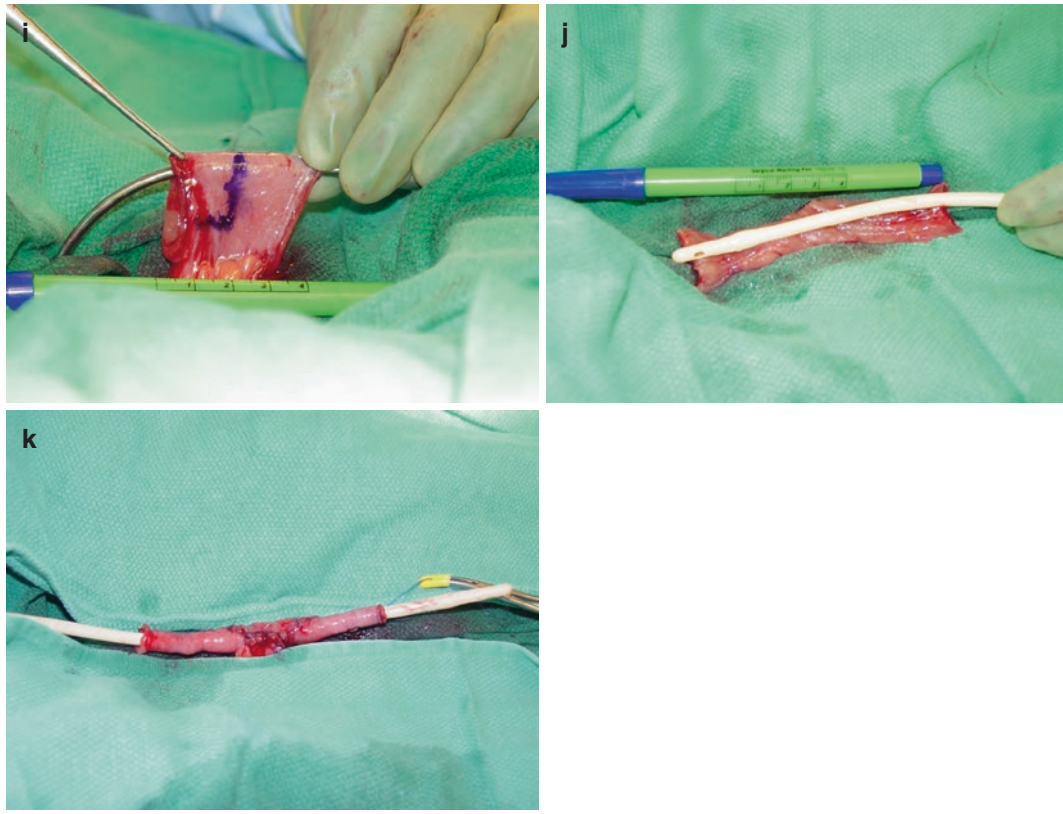


Fig. 12.3 (continued)

2-3 interrupted at each end, the last with a tail, and the mid-portion running watertight.

If the cecum is used to lengthen the appendix, both the appendix and the base of the cecum are harvested using a stapling device for detubularization in order to create the conduit. The ileocecal valve is preserved for stool continence along with the appendiceal mesentery. The ileocecal valve is reliable, durable, and very adaptable. However, one must remember that in myelodysplasia patients and those with extreme detrusor instability, rectal fecal incontinence may be a consequence. A Barium Enema is a must on all patients in whom the colon is used for any reconstruction. If the ileocecal valve is to be used as a continence mechanism, consider consulting a radiologist under fluoroscopy to assess its competence. This does not guarantee success, but if it is incompetent, the valve needs to be reinforced. Some advocate for its reinforcement in all cases. The main part of the continence mechanism is really due to the coaptation of the terminal ileum, and great care needs to be directed to this portion of the operation. Again, when finished, it must be easily catheterizable when full in the operating room. The native cecum is closed and the donor cecal base is tubularized over a 12- or 14-French catheter doubling the appendix length [52].

For the augment itself, needle tip Bovie cautery on cutting current is used to open the antimesenteric border. A plastic Yankauer suction tip within the lumen serves as a useful stent here. Remaining succus is irrigated from the surface without too much sponge manipulation. The ileum is reconfigured as an upside-down "U" shape with the free ends pointing toward the patient's feet. Running interlocking absorbable suture is placed in watertight fashion – the authors use 2-0 vicryl. Ideally, the knot is excluded, but it is the author's experience that suture stones are rare in this setting, given the bladder irrigation

that is prescribed as routine management. The assistant should follow the suture and gently tighten it without strangulating the tissue during the reconfiguration.

Sigmoid: A 30-cm segment of sigmoid colon is usually used as an alternative to the ileum, and it is generally detubularized as a straight or cup patch for a straightforward substitution to the bladder [27]. The sigmoid is a good alternative also because it lies directly next to the dome of the bladder. The stomach can also be used, albeit as a last resort usually because of complications (see complications section). A wedge-shaped gastric segment along the greater curvature is harvested. Either the right or left gastroepiploic artery can be harvested along with the segment, but the nonharvested artery should be transected, and each of the branches either transected or tied. The stapler is used to close the conduit [53].

Next will be the anastomosis to the bladder. The bladder is bivalved using either a coronal or a sagittal approach down to the level of the ureteral orifices bilaterally or the bladder neck and trigone sagittally (Fig. 12.4). The authors find the sagittal incision easiest as one need not worry about encountering vesicular blood supply. The important technical detail is to open the bladder as generously as possible in order to prevent future anastomotic narrowing with difficulty emptying. The detubularized segment of bowel or stomach is anastomosed to the clamshelled bladder using a freehand running absorbable suture [54, 55]. The authors use 2-0 vicryls in running fashion locking every third. The anastomosis is initiated at the most posterior aspect of the bladder in the midline, close to the trigone. The two tails are tied together (Fig. 12.5). This will be the most difficult location to reach for additional suturing if the anastomosis is not found to be watertight, so very careful attention is paid here. It will also typically involve the suture line of the reconfigured ileal segment. The sutures are placed closely abutting this suture line. The bladder is irrigated and a pelvic drain placed (Fig. 12.6a).

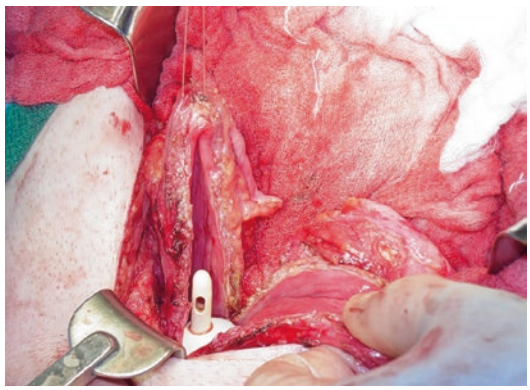


Fig. 12.4 The bladder is bivalved in the sagittal plane

AC has been performed without enterocystoplasty or gastrocystoplasty by using an existing dilated ureter in a process called ureterocystoplasty, primarily in the pediatric population. This procedure is advantageous in the setting of neurogenic bladder or posterior urethral valves (PUV) and dilated ureters or in the setting of megaureter. The lumen of the ureter is nonsecretory, unlike the lumen of the gastrointestinal system, and protects the patient from metabolic derangements [56–58]. Outside of renal impairment which would require this quality, ureterocystoplasty is not ideal due to high rates of reoperation [59].

If a Monti or appendicovesicostomy is part of the plan, the right lower portion of the anastomosis will be performed last. Ideally, the catheterizable channel will be reimplanted into the bladder detrusor aiming for a 4:1 or 5:1 tunnel. Often, this same principle will need to be applied to the augment, with less favorable results. A technique by Karsenty et al. involves implanting the catheterizable cutaneous stoma into a posterolateral bladder wall flap to achieve continence. Removal of the dysfunctional detrusor muscle via supratrigonal cystectomy is first done. A full-thickness 2.5- to 3-cm posterolateral bladder wall flap is preserved. A catheterizable tube is then implanted in the flap with maximal flap length of about 16.5 cm. The excised portion is then replaced with a 55-cm piece of detubularized ileum harvested about 30 cm from the ileocecal valve and anastomosed to the trigone. The cutaneous catheterizable channel is implanted into the detrusor flap and sutured to the skin with a

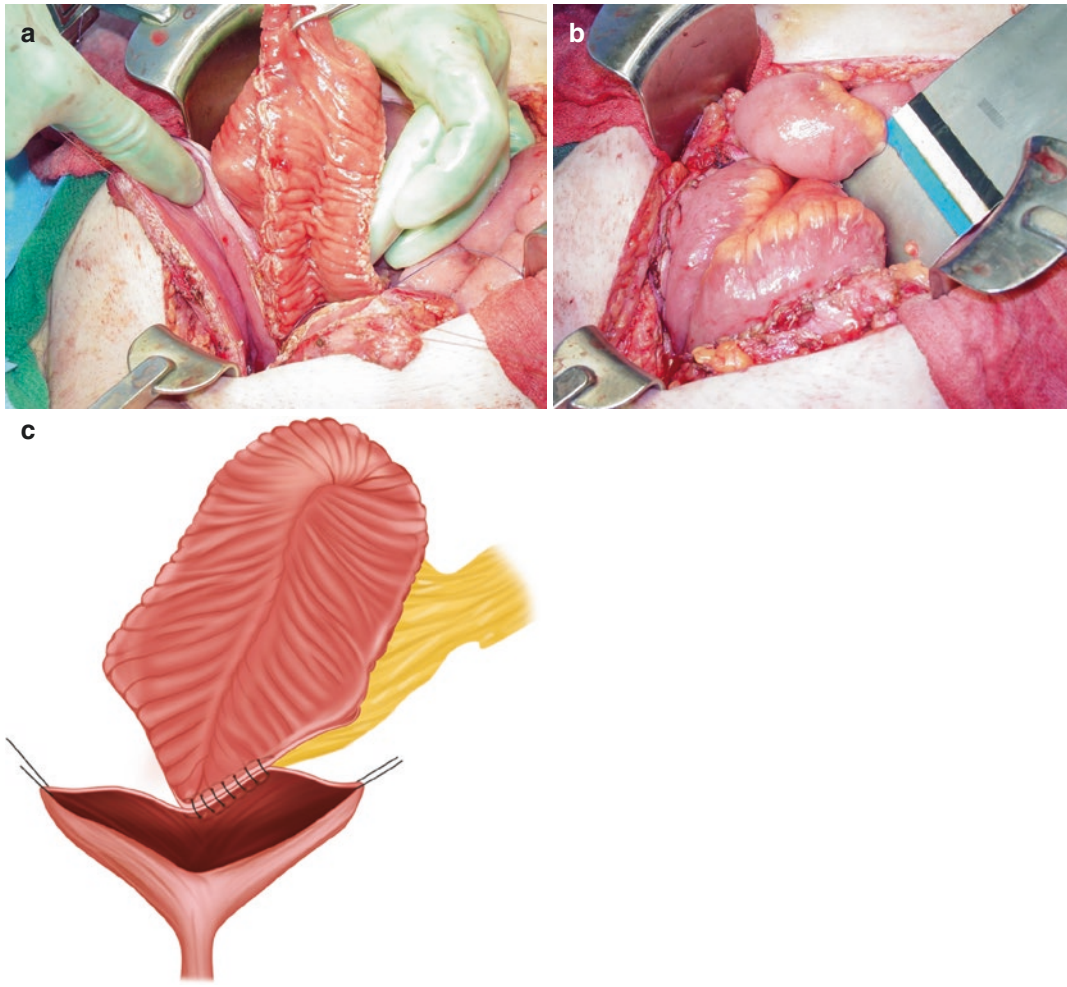


Fig. 12.5 (**a**, **b**, **c**) The ileum is sutured to the bladder in AC

V-shaped skin flap. We have tried this technique with success without performing the cystectomy and with a shorter segment of ileum. The posterior bladder wall flap was quite satisfactory for reimplantation [60].

Prior to the completed anastomosis and throughout these final steps, the channel's reach to the umbilicus or planned right lower quadrant stoma site should be evaluated for the planned path of catheterization. The authors almost always suture the bladder and/or augment to the anterior abdominal wall using Kocher clamps to approximate fascial position. Now attention will be directed to the skin surface. An upside-down V approximately ½ inch on either side is created using an 11 blade. If the umbilicus is used, it should be separated from the stalk attaching it to the fascia underneath. With Kocher clamps holding the fascia in the midline, a fascial incision is created on the trajectory of the planned catheterization toward the bladder. It should be at least 2 cm from the fascial edge and large enough to allow a fingertip. A Babcock is placed from the skin incision into the abdomen and the channel gently pulled to the surface; 1–2 of its interrupted sutures can be opened up to spatulate the end. After ensuring it is not twisted, the end will be anastomosed with approximately 8 interrupted 4-0 or 5-0 interrupted delayed absorbable sutures. This stoma will be flush with the skin surface. Holding the abdominal wall in place, ease of

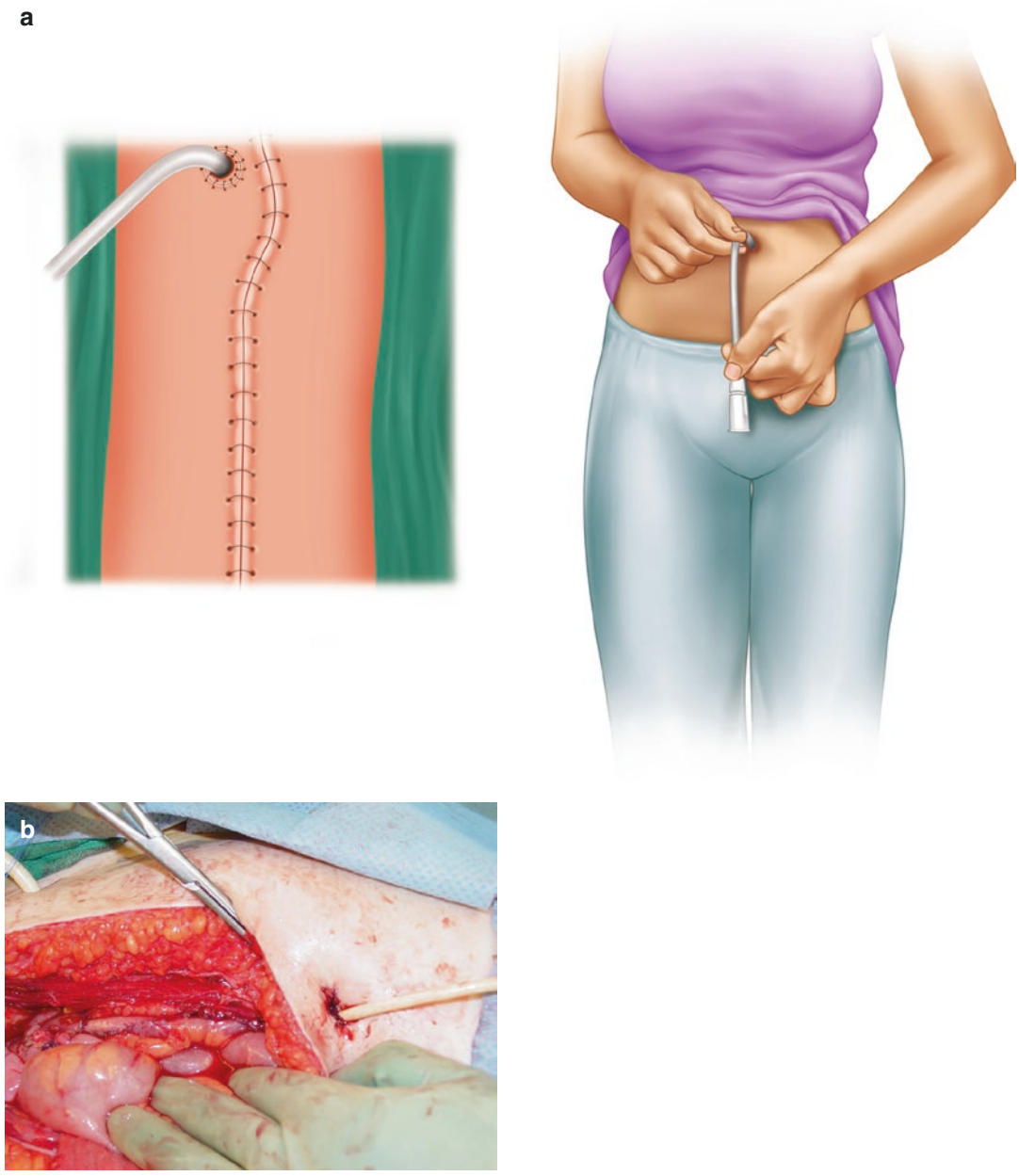


Fig. 12.6 (**a**) Final appearance. (**b**) Safe preservation of a catheterizable stoma can be achieved with palpation of the tunnel and gentle retraction using the fascial edge as a guide/handle

catheterization should be tested and adjustments made as necessary. A 12-French catheter should be left in place, sutured to the skin 2 cm from the stoma, and capped with the balloon deflated.

A 22-French Foley should be introduced into the bladder – preferably via the wall of the native detrusor through the left lower quadrant. A urethral catheter, suprapubic catheter, and, if present, a cutaneous stomal catheter should be left in place, although the balloon on the latter should be left uninflated in the event that it is dislodged. Of note, large loops in the drainage tubing should be avoided at the bedside because centimeter per

centimeter these will increase the pressure needed to empty the bladder.

Postoperative Management

Routine postoperative management includes anticholinergics, maximal continuous drainage as above, and saline bladder irrigations daily (60-cc saline in and out of each catheter withdrawing mucus, repeat until clear, every 8 hours) to prevent mucus accumulation and to promote healing. For particularly aggressive bladders (severe early detrusor overactivity or history of poor tolerance of catheters), the authors will inject botulinum toxin in the detrusor at the time of augment to minimize stress on the suture lines. There are no published data to support this practice. Prior to discharge, patients should be educated about the importance of follow-up and symptoms of bladder perforation in the immediate postoperative period. At 3 weeks postoperatively, a cystogram is performed. If a cutaneous catheterizable stoma is present, catheterization will be initiated in teaching with the surgeon at this point. The postoperative catheter is removed, the bladder filled with 200 cc of saline via the suprapubic tube, and a 12–14 French soft catheter gently attempted by the surgeon. An olive tip or coude tip may be necessary. It is helpful to make notes of the route of catheterization during the actual surgery in preparation for this moment. Once the surgeon can pass easily, the patient attempts. He or she is sent home with the proper supplies and the suprapubic tube capped, with instructions to uncap the tube if unable to catheterize. In all cases, the urethral catheter will be removed at this visit if it has not been removed due to intolerance prior. Patients who usually self-catheterize per urethra will return to this management. Follow-up after this visit will be in 2–5 days. Serum chemistry panels should be ordered to evaluate renal function and to watch out for development of acidosis in the immediate postoperative period.

In the post-AC transplant patient, filling the bladder and irrigating out any retained mucus periodically until transplantation occurs would be a good idea. Again, this allows an assessment of voiding and whether there will be a need for intermittent catheterization following transplantation. Augmentation is only considered when cycling has failed to produce a bladder with an acceptable, low-pressure bladder volume. In the United States, those who are candidates usually have had multiple bladder surgeries which have resulted in a very low capacity, rigid, scared detrusor which when filled results in low volume and high pressure. Infections, mostly in other parts of the world, have also been implicated as etiologic. With respect to the ureter, at our institution, the native ureter has been routinely used in transplantation where the ipsilateral kidney needs to be removed.

Outcomes

Success rates of AC are high with one study of all etiologies ($n = 40$) noting a bladder capacity percentage increase of 130% postoperatively (283 ± 151 to 492 ± 123 mL [$p < 0.01$]), an increase in compliance by 87%, and a decrease in detrusor overactivity by 54% at 10-year follow-up with no significant changes in glomerular filtration rate (GFR) [61]. Continence rates in AC range from 67% to 89% under CISC [62, 63].

Patients are generally highly satisfied with AC and greater than 90% of patients report better quality of life [16, 64, 65]. Success in non-neurogenic indications is variable. IC patients with Hunner's ulcers have a 63% rate of complete pain relief initially, but it can recur in the newly augmented bladder [66–68]. Patients with underlying infectious etiology can also benefit from AC. One study shows 25 patients with chronic tuberculous cystitis status post-AC with average follow-up of about 11 years, 80% attained diurnal frequency of more than 2 hours with normal sensation ($p = 0.03$), greater capacity ($p < 0.01$), and greater compliance ($p < 0.01$) than the 20% of patients who had poor results. Poor results statically occurred in cases using tubularized sigmoid and in patients with prostatitis [69].

Complications

A list of complications from AC can be found in Tables 12.4 and 12.5. This section will expand on irrigation concerns, calculi formation, bladder rupture, UTI, malignancy, upper tract deterioration, and concerns related to pregnancy.

Irrigation

Mucus production following augmentation cystoplasty can lead to stones, infection, and BOO [70]. The average mucus production from ileum and colon when used as a cystoplasty segment is 35–40 g per day when used as an augment, which does not decrease over time despite villous atrophy [27]. Bladder irrigation is helpful in preventing mucus-associated stone formation and recurring urinary tract infections in patients who have undergone ileocystoplasty and is usually sufficient [71]. Patients need to be instructed to intentionally withdraw the saline via the catheter and to repeat until the saline returns clear [72]. Initial instillation of 120 mL will elevate the bladder/augment off the ports of the catheter. If 60 mL are removed and reinserted until clear, then this will prevent suctioning the tissue and interference with mucus clearance at lower cycling volumes. Ranitidine has been shown to decrease mucus production from 1.38 ± 0.18 mg/mL to 0.39 ± 0.04 mg/mL [73] and bladder irrigation with N-acetylcysteine and urea can dissolve mucus and has been used to treat mucus accumulation [74]. However, the efficacy of N-acetylcysteine and ranitidine in treating mucus production was questioned in a 2001 study in which neither muco-regulatory drug resulted in a reduction [75].

Calculi

Stone formation has been theorized to result from seeding on the mucus secretion within the augmented bladder [70, 76–78]. In spina bifida patients specifically, bladder calculi were the most common complication following AC, which can be alleviated in part by high-volume bladder irrigations of ≥240 mL with daily bladder washout [79]. Metabolic abnormalities may also play a role in stone development with many studies showing hypocitraturia, low urinary volumes (<1600 mL in 24 hours), hypercalciuria, and hyperoxaluria to be associated with recurrent bladder calculi. Hypocitraturia was demonstrated almost universally [80–82].

Bladder Rupture

Bladder perforation is a potentially life-threatening complication that has been reported in up to 13% of patients with prior augmentation cystoplasty [83]. Bladder perforation should be considered in all patients who have undergone augmentation cystoplasty who present with fever, abdominal pain, or sepsis, taking note of impaired sensation in many of these patients [84]. Metcalf et al. reported a significant increased risk of spontaneous perforation in patients who had undergone outlet resistance increasing bladder neck surgery (other than bladder neck sling) compared to no bladder outlet procedure, as urethral leakage can be protective when the system is challenged (28% risk of perforation in those with outlet surgery versus 4% without). Bladder neck slings had a 20-fold decrease in relative risk for spontaneous bladder perforation when compared to other types of bladder neck surgeries like artificial urinary sphincters, Kropp procedure, Pippi Salle bladder neck repairs, and Young-Dees-Leadbetter reconstruction. There were no differences in relative risk among the other types of bladder neck surgeries [85]. This study also revealed a 20-fold lower risk of perforation in patients who had a sling procedure prior to augmentation compared to those who underwent other surgery aiming to increase bladder outlet resistance prior to augmentation. Perforation may also be associated with substance abuse or patient noncompliance with catheterization [86]. The choice of tissue used for augmentation may have an impact on the incidence of perforation. Metcalf et al. reported a 3.5-fold increased risk of perforation associated

with the use of sigmoid colon (19%) compared to ileum (8%), stomach (5%), and cecal (5%) tissue [85]. There was no significant difference among ileum, stomach, or cecal segments. Perforation in the first few months following surgery usually occurs at either the anastomosis or through the augmenting bowel segment [87]. However, there is a 5–13% annual risk of perforation throughout the life of the augment [83, 88, 89]. The site of perforation in the years following augmentation is consistent with the immediate postoperative period, and usually, it occurs in the bowel segment with early perforations at the anastomotic line [89]. Prompt exploratory laparotomy is the gold standard for treatment of bladder perforation and can be diagnosed using abdominal and pelvic CT with a cystogram [90].

UTI

Bacteriuria is common following AC and should not be treated with antibiotics if the patient is asymptomatic [91]. Asymptomatic cultures may be treated in preparation for diagnostic procedures or surgery. A 2018 study by Wang and Liao reviewed 173 patients who underwent AC and found that more than 70% of patients had postoperative asymptomatic bacteriuria, but symptomatic UTI only developed in eight patients (4.7%) [92]. A 2015 study of 40 patients with neurogenic bladder who had undergone AC demonstrated a 67.5% cumulative incidence of UTI with a median follow-up period of 13 years, and 7.5% of patients with more than one episode of UTI per year [61]. Large postvoid residual volumes, mucus production by the bowel segment, and the need for CISC are the main factors contributing to clinically relevant UTI following augmentation cystoplasty [27]. The presence of UTI in patients with a history of enterocystoplasty is associated with an increase in urinary nitrosamine levels. There is some evidence that Nitrosamine has been associated with the development of cancer in patients status post enterocystoplasty [93]. Use of prophylactic antibiotics and treatment of UTI has been shown to significantly decrease mean nitrosamine levels (1.3 μmol/L in patients taking prophylactic antibiotics versus 1.9 v μmol/L), with the greatest decrease seen in patients taking trimethoprim, ampicillin, or cefadroxil [93]. There is no evidence that long-term antibiotics reduce the risk of cancer, and certainly, the risk of antibiotic resistance speaks against this application, so more research is needed. In spina bifida patients, high-volume bladder irrigations were also demonstrated to reduce the rate of symptomatic UTI [79].

Malignancy

In a systematic review of 57 articles published since 2014, the probability of developing a malignant tumor after AC ranged from 0% to 5.5% at an incidence of 0–272.3 per 100,000 patients per year. The most common malignant tumor histologically was adenocarcinoma (51.6%) predominantly occurring at the enterourinary anastomosis site (50%). There does not seem to be a significant difference in incidence of malignant tumors among gastro-, ileo-, or colocystoplasty. Patients were usually in advanced stages of malignancy at time of diagnosis. The most common presentation was urinary tract symptoms with gross hematuria being the most common, acute renal failure, recurrent UTI, hydronephrosis, lumbar pain, and nonspecific lower urinary tract symptoms. The mean latency period was 19 years postoperatively. There are no official recommendations for long-term screening cystoscopy after AC, nor do the authors have specific recommendations – our practice is to offer patients surveillance cystoscopy, citing that there are no clear data that this improves outcomes, and to allow them to make the decision. Treatment for malignancy in this setting is usually surgical with radical cystectomy being the most common (69%), and partial cystectomy or transurethral resection following next (14.1%). Other treatments include adjuvant therapy, chemotherapy, radiotherapy, and radiochemotherapy [64]. Treatment of these tumors is beyond the scope of this chapter.

Patients with congenital bladder anomalies (CBA) have higher risk of bladder cancer over the general population. Historically, AC was thought of as an independent risk factor for

malignancy but that theory has been disproven [94]. Cystoscopy and cytology are ineffective tools for screening in the pediatric population because of low incidence rates of malignancy and high costs in the pediatric population with CBA [94, 95]. The role of interval biopsy has been contentious with some recommending biopsy if there is clinical suspicion of malignancy and others advocating for annual biopsy [96, 97]. Some reports have determined that both cystoscopy and cytology are not cost-effective for detecting malignancies given low incidence rates in patients with congenital bladder anomalies [94, 98]. In adults, there is emerging evidence that cystoscopy after 5 years of neurological disease may identify cancer (usually squamous cell carcinoma) early enough to impact prognosis [99]. These data are not specific to AC.

Upper Tract Deterioration

The upper tract is usually stable in patients status post AC even at 12-year follow-up with preserved or better renal function versus presentation [100, 101]; 0–15% of patients reported renal function deterioration after AC. Deterioration seems to depend on baseline creatinine clearance: 15% patients with greater than 15 mL/min had deterioration, while only 4.1% of patients with a creatinine clearance of greater than 40 mL/min had deterioration [27, 102, 103]. Children with CBA should generally receive treatment within the first year of life depending on UDS starting, where relevant, with catheterization to preserve the upper urinary tracts [104]. In spina bifida patients, substance abuse and noncompliance were also the most common reasons for upper tract deterioration [79].

Pregnancy

Pregnancy and successful deliveries in women who have undergone augmentation cystoplasty have become more common, but they are associated with increased rates of complications and morbidity. The goal in managing these patients is the safe delivery of the baby while maintaining urinary tract integrity and renal function in the mother [105]. Common complications contributing to increased morbidity include pyelonephritis, renal deterioration, UTI, ureteric dilation, obstruction, and premature labor [27]. Regular bacteriological analysis of urine should be performed in order to aggressively treat UTI at an early stage [106]. Pyelonephritis may also be associated with premature delivery, as seen in a 1990 study by Hill and Kramer in which 3/4 patients with prior cystoplasty developed pyelonephritis and had premature deliveries [107]. Renal function should be monitored by monthly serum creatinine levels. If creatinine levels are increased, evaluation by renal ultrasonography should be used to assess hydronephrosis [106, 108]. Unless there is an obstetric indication, Cesarean section should be avoided due to possible injury to the bladder and to the pedicle of the augmenting bowel [27]. In a 2003 study by Greenwell et al., vaginal delivery was not associated in adverse outcomes in 91% of patients when Cesarean section was not indicated [109]. Elective Cesarean section is recommended in patients who have undergone a combination of AC and either vesical neck reconstruction or placement of an artificial urinary sphincter to avoid disrupting the continence mechanism during vaginal delivery [27, 28, 54, 107]. If Cesarean section is indicated, care should be taken to avoid injury of the vascular pedicle to the cystoplasty [110]. This becomes challenging when a cutaneous catheterizable stoma is involved especially in neurogenic bladder. A paramedian skin incision contralateral to the catheterizable stoma has been shown to be a successful approach to Cesarean section in bladder exstrophy patients after catheterizable stoma; the uterine incision can still be in the midline [111]. In general, pregnancy in neurogenic bladder is complicated by higher chances of UTI, obstruction, and preeclampsia, but has not been correlated with prohibitive long-term consequences [54].

The urologist and less often urogynecologist or colorectal surgeon should be prepared to offer intraoperative assistance during Cesarean section. It is good practice to provide the patient and/

or family with a drawing of the anatomy and a copy of the operative note at the first postoperative visit, advising them to keep track of the file for later complications or surgeries. As usually, these consults are not on one's own construction, one should attempt to acquire and read the original operative note(s). Often, a young female adult with a history of pediatric reconstruction can find a copy in her parents' files if the original hospital has purged the records. One can then create a visual of the anatomy for the team, placing one in the chart and asking the patient to tape another copy to the wall in her delivery room. In the event of expedited decision making and on-call night coverage uncertainties, there is a quick reference with pointers highlighted. Once in the operating room, the incision should slow as soon as the peritoneum is entered. The mesentery will either be low overlying the lower uterine segment and out of the way, or stretched almost imperceptibly thin overlying the entire gravid uterus. In the latter case, a high classical Cesarean section incision will allow the safest access. This possibility must be counseled prior to the event, as it will limit delivery options in the future. Conversations about future pregnancy should have included the offer of a tubal ligation concurrent with the Cesarean as well, given the higher risk pregnancy and the likelihood of scarring. In the setting of a catheterizable cutaneous stoma, the surgeon should ask the patient specifics about the direction of the channel prior to induction, and then place a 12-French Foley for identification intraoperatively once prepped and draped. A urethral catheter should also be in place for maximal drainage. Palpation of the tunnel (Fig. 12.6b) and gentle retraction using the fascial edge as a guide/handle will almost always allow safe preservation.

Summary

AC is an effective surgical technique for modification of the bladder in order to increase capacity or improve detrusor compliance/overactivity and protect the upper urinary tract in refractory storage impairments. As with any surgical procedure, appropriate candidates must be chosen carefully with consideration for the patient's history, clinical picture, and trials of alternative management. Adequate renal function, availability of segments, and the ability to self-catheterize and to irrigate mucus are prerequisite to the operation. Patients are usually satisfied with AC and report improved quality of life [16, 64]. Common complications such as calculi, infection, bladder rupture, or rarely malignancy can occur. Patients should be monitored longitudinally postoperatively.

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Urethroplasty for Female Urethral Stricture Disease

13

Zachery Chad Baxter

Introduction

Female urethral stricture disease has been historically treated with urethral dilation, which has demonstrated high recurrence rates. There is growing evidence that formal urethroplasty should be pursued early in the care of female urethral stricture disease as surgery can provide durable results [1]. This chapter presents the various techniques for female urethroplasty that are presented in the recent literature.

Background

Urethral stricture disease, while sometimes idiopathic, is commonly iatrogenic. Urethral dilations, catheterization, urinary tract endoscopy, urethral surgery, and radiation are all implicated. Urethral strictures may occur as a consequence of urethral infection, urethral diverticulum, atrophy with subsequent fibrosis, primary urethral carcinomas, leiomyomas, teratomas, and trauma [2–8].

Female urethral stricture disease is rarely diagnosed and rarely reported in the contemporary urological literature. All causes of bladder outlet obstruction have an estimated incidence of 3–8% of women presenting with obstructive symptoms [9].

Of these women with obstruction, even fewer have proven urethral stricture. Estimates range between 4% and 13%. Thus, the true incidence of urethral stricture appears to lie between 0.1% and 1% [10–12].

Despite the low incidence of urethral stricture disease, urethral dilation and urethrotomy have historically been employed to manage a wide variety of lower urinary tract symptoms in women [11, 13–15]. McLean and Emmett reported the first urethral dilation in 1923, and by the 1960s, series with as many as 800 patients were reported [15]. Dilation of the female urethra has been advocated to treat recurrent urinary tract infections, bladder pain syndromes, urinary urgency, urinary frequency, overactive bladder, and interstitial cystitis symptoms [13, 14]. Contemporary literature has demonstrated that urethral dilation has no benefit and may be harmful for patients in the absence of demonstrable urethral stricture disease [16].

Santucci and the Urologic Diseases in America Project reported in 2008 that urethral dilation for various lower urinary tract symptoms appears ineffective, common, costly, and mostly unnecessary [16]. They note that while there were less than 40 reports of true female urethral strictures in the contemporary literature at that time, more than 1.2 million office visits for female urethral stricture occurred in the United States between 1992 and 2000 at a cost of $61 million per year. Since

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the first case report in 1828 [17], no more than 200 cases have been reported in the English language literature. The majority of reports describe small, single-surgeon series and lack objective preoperative or postoperative measures of success.

Given the low number of reported urethroplasties, there exists no consensus for surgical treatment and several different surgical techniques have been reported and will be reviewed here.

Evaluation

As Blaivas et al. note the diagnosis of urethral stricture in women requires a high index of suspicion. Similar to other forms of bladder outlet obstruction such as prolapse, bladder neck dysfunction, and detrusor external sphincter dyssynergia, symptoms of urethral stricture may include urinary frequency, dysuria, weak or dribbling stream, and recurrent urinary tract infections. Cystoscopy provides the most reliable assessment, though some experts advocate urethral calibration as well. Urethral calibration may offer information of scar density through haptic feedback [1]. Periurethral fibrosis may also be measured by translabial or transvaginal ultrasound, though the efficacy of ultrasound for this purpose in women is not well defined. Detrusor pressure-flow studies allow determination of bladder outlet obstruction and may be graded according to the Blaivas-Groutz nomogram [11] and voiding cystourethrogram or cystoscopy allows one to determine the location of obstruction.

Preoperative Considerations

Female urethroplasty can be categorized by the surgical approach, nature of any needed tissue graft, and whether to perform concomitant bladder outlet procedure. The urethra is approached either dorsally or ventrally. A dorsal approach is perhaps less familiar to many urologists and care must be taken to avoid injury to the crura and body of the clitoris. A dorsal approach may also facilitate later anti-incontinence procedures, prevent sacculation of the reconstructed urethra, minimize risk of urethrovaginal fistula, or hypospadias [18]. A ventral approach, conversely, is familiar to urologists experienced in many of the transvaginal anti-incontinence procedures and allows for easier visualization of the urethra to the level of the bladder neck.

Graft tissue may be either a local rotational flap, pedicle flap, or free flap harvested from vaginal, labial, or oral mucosa. Free or pedicle flaps may minimize distortion of local tissue compared to rotational flaps but are also associated with harvest site morbidity including paresthesia, anesthesia, and altered cosmesis.

The decision to perform a concomitant anti-incontinence procedure should be based on preoperative evidence of stress incontinence, or in the opinion of some experts, in the presence of contrast entering the urethra to the level of the stricture during fluoroscopic imaging while performing a Valsalva maneuver and cough [1]. Many experts advocate dorsal, as opposed to ventral, urethroplasty techniques to facilitate concomitant or delayed placement of ventral urethral sling [18].

Given the infrequent occurrence of urethral strictures and more infrequent reports of their repair in the literature, there is a paucity of data precluding a recommendation of one approach or graft over another.

Postoperative Care

Duration of catheterization, use of imaging, and antibiotic therapy differs among reported series of urethral reconstructions. Many surgeons advocate leaving a catheter indwelling for 2–4 weeks, obtaining a voiding cystourethrogram at the time of catheter removal, and maintaining antibiotics, usually low-dose ciprofloxacin or trimethoprim-sulfamethoxazole, for the duration of catheterization.

Surgical Techniques

Ventral Incision and Anastomosis

Short strictures located primarily on the ventral aspect of the urethral lumen may be incised longitudinally with transverse closure consistent

with the Heineke-Mikulicz principle. Long or circumferential dense scar may be recalcitrant to this technique.

1. In dorsal lithotomy position, prepare the vagina with betadine, drape, and facilitate exposure with a Lone Star or similar retractor.
2. Place a Foley catheter or under cystoscopic guidance, intubate urethra, and stricture with a guide wire.
3. Develop an anterior vaginal wall flap exposing the underlying periurethral fascia.
4. Transversely incise the periurethral fascia to expose the underlying urethra.
5. Incise the urethra longitudinally through the stricture.
6. Calibrate urethra preferably to 28 French, place 20 French catheter.
7. Repair urethra with transverse closure using absorbable suture, such as 4-0 poliglecaprone, in an interrupted fashion.
8. Close periurethral fascia with interrupted absorbable suture, such as 3-0 polyglactin.
9. Advance the anterior vaginal wall flap beyond the underlying suture line of the periurethral fascia.
10. Close vaginal wall with running, locking 3-0 polyglactin.

Excision and end-to-end anastomosis is not often used due to the risk of urethral ischemia distal to the excision. Rovner reported that this approach was useful in treating complex urethral diverticulae [19].

Vaginal Inlay Flap

Vaginal inlay flaps have been separately reported by several investigators [20, 21].

1. After intubated the urethra with a catheter, wire, or guide, an anterior vaginal wall flap is created with an inverted-U incision, the apex of which is at the urethral meatus (Fig. 13.1).
2. The ventral aspect of the urethra is incised in the midline from the meatus, through the stricture, to a point of normal caliber urethra proximal to the stricture.
3. The dorsal aspect of the urethra may need to be incised in the midline to facilitate approximation of the flap.
4. The apex of the vaginal wall flap is then approximated with absorbable suture, such as 4-0 poliglecaprone, to the proximal extent of the urethral incision.
5. A large caliber urethral catheter is then placed.
6. The vaginal wall flap is approximated with running, locking absorbable suture to the urethra along either side of the flap until the urethra has been reconstructed distally to the urethral meatus.

Free Labia Minora Skin Flap

The free labia minora skin flap is an alternative to the vaginal inlay flap and is well described by Rehder et al. [22].

1. The vagina is prepped and draped in the usual surgical fashion.
2. An anterior vaginal wall flap or midline anterior vaginal wall incision beneath the urethra may be performed to expose the urethra.
3. The urethra, intubated with urethral sound, catheter, or wire, is incised in the midline to level proximal to the stricture.
4. Donor tissue site is selected from medial aspect of the labia minora.
5. An elliptical graft is sharply harvested, its size corresponding to the length and width of the urethral defect.
6. The graft donor site is repaired with interrupted absorbable suture.
7. The graft is anastomosed to the urethra with running, locking absorbable 4-0 polyglyconate, or poliglecaprone over a catheter.
8. Vaginal wall is then closed with running, locking absorbable suture.

Consideration should be given to placing a Martius flap harvested through either a separate vulvar incision or from the lateral aspect of the anterior vaginal wall flap incision.

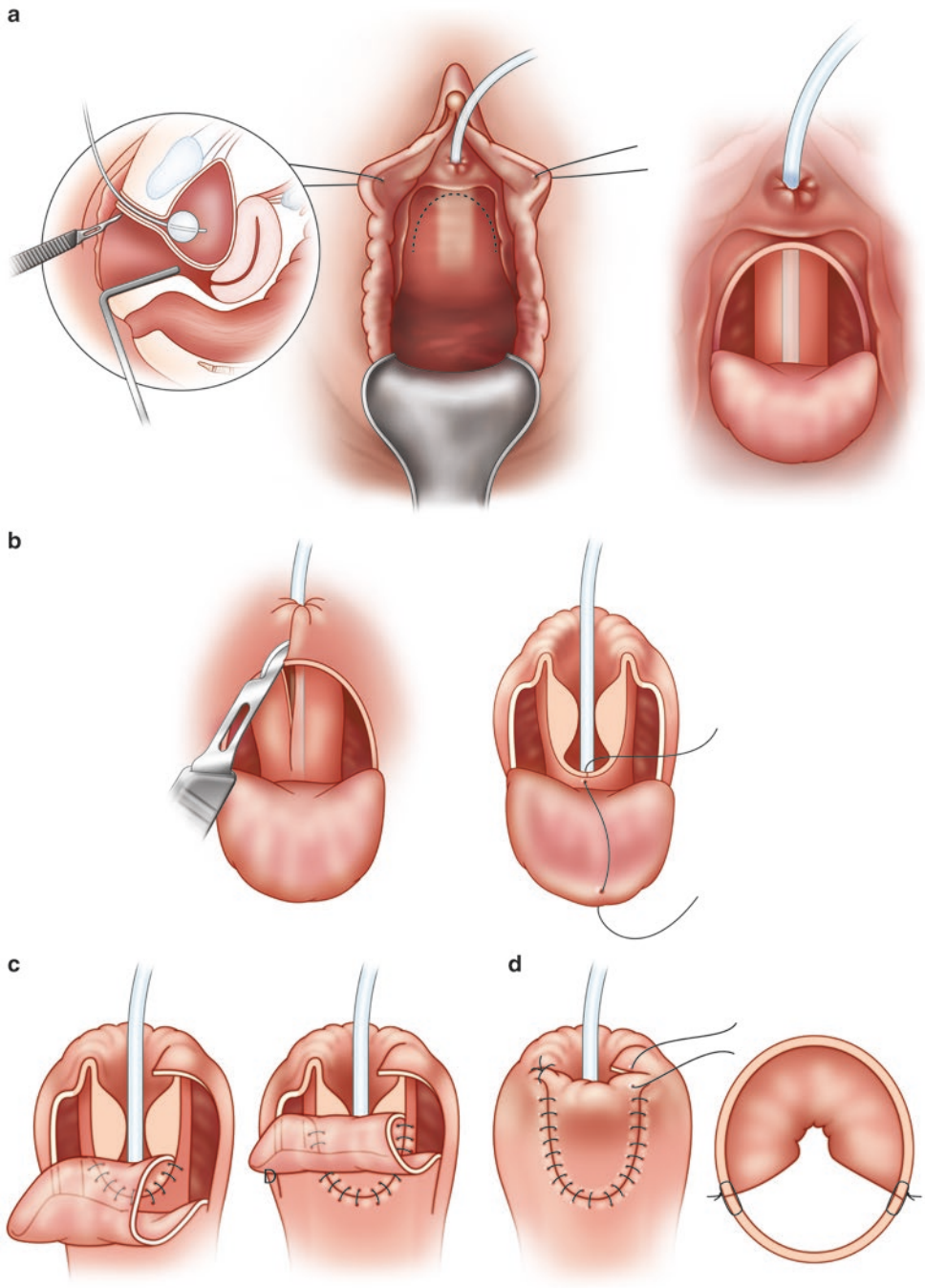

Fig. 13.1 Vaginal inlay flap. (**a**) Anterior vaginal wall is exposed with labial retraction and weighted speculum. Foley catheter is placed per urethra to guide dissection. An anterior vaginal wall, inverted-U vaginal wall flap is dissected superficial to the periurethral fascia. (**b**) Periurethral fascia is opened sharply and the urethra incised longitudinally from distal to proximal traversing the stricture. (**c**) The anterior vaginal wall flap is folded upon itself and the apex of the flap affixed to the proximal extent of the urethrotomy. Repair is continued with running, locking absorbable suture (e.g., 4-0 poliglecaprone). (**d**) The final repair thus consists of vaginal wall as the inferior portion of the urethra

Pedicle Flap from the Labia Minora

This procedure is similar to the free labial graft, except that the donor tissue is isolated on a pedicle and tunneled under the vulvovaginal wall to the site of urethral dissection (Fig. 13.2). The remainder of the urethroplasty is similarly performed [23].

Ventral Buccal Graft

Buccal grafts, widely used in male anterior urethral reconstruction, are well described for female urethral reconstruction by Bergland et al. [24]. Mukhtar and team recently reported their series of 22 women receiving ventral-onlay buccal graft since 2012. Median 21 months of follow-up revealed >95% stricture-free rate with corresponding improvement in Qmax from 7 to 18 mL/s ($P < 0.05$) and post-void residual decreasing from mean of 100 mL to 15 mL ($P < 0.05$) [25].

1. Prior to the buccal graft harvest, the urethra is exposed via an anterior vaginal wall flap. The intubated urethra is incised from the meatus through the stricture to healthy tissue proximally.
2. A suprapubic catheter can be placed at this time so that postoperative manipulation of the urethra may be minimized.
3. The buccal graft is harvested as described by Morey and McAninch [26] with a width of

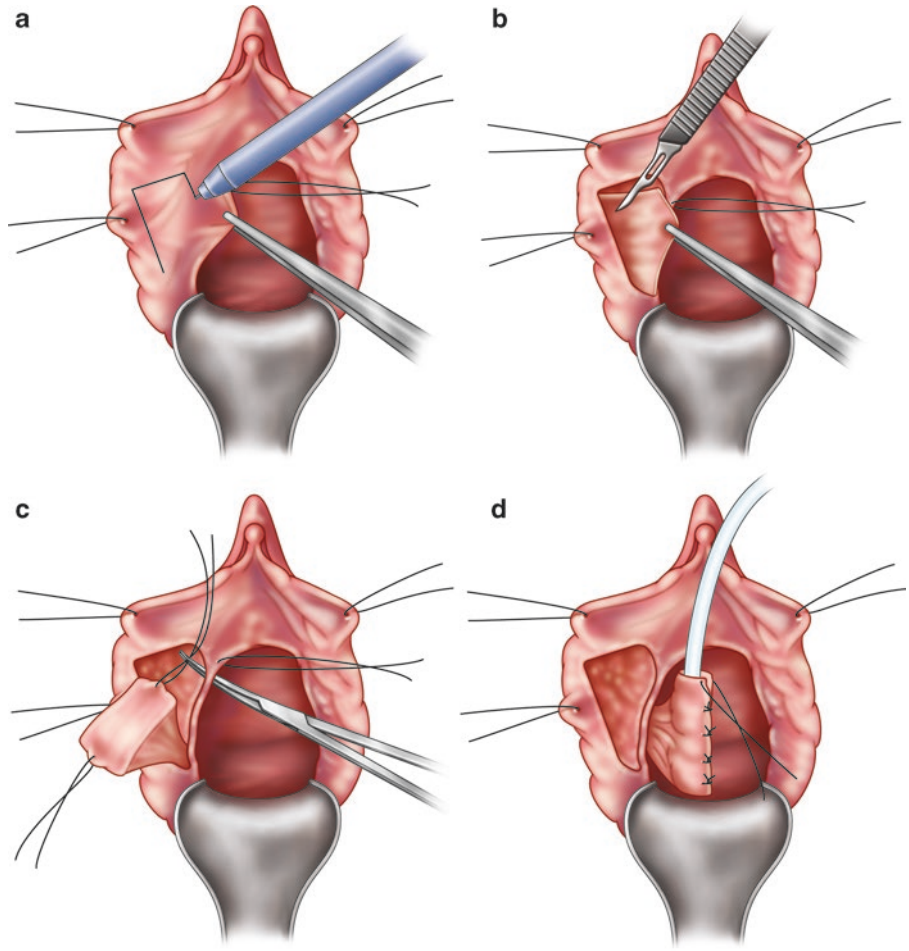

Fig. 13.2 (**a**) Graft site is marked. (**b**) The graft is harvested taking care to preserve the pedical. (**c**) (**d**) The graft is tunneled and affixed to the urethra

2–2.5 cm and tailored to fill the length of the urethral defect.
4. The graft is then approximated to the urethrotomy defect with running, locking absorbable suture. Berglund et al., reported using 5-0 polyglyconate.
5. A 28 French sound is used to calibrate the urethra. An 18 French Foley catheter is then placed, as well as a suprapubic catheter.
6. The graft is covered with periurethral soft tissue or Martius flap if periurethral soft tissue is inadequate.
7. The vaginal wall is closed with running, locking absorbable suture.

Dorsal Buccal Graft [18]

1. Suprameatal incision is made from 9 o'clock to 3 o'clock position between the urethra and the clitoral cavernous tissue.
2. The urethra is dissected to the level of the bladder neck, with the anterior component of the striated urethral sphincter mobilized from the urethral wall.
3. The bladder neck is marked with an absorbable suture, such as 4-0 polyglyconate.
4. An incision is made in the midline over the intubated urethra, full thickness through spongiosal and mucosal tissues, from bladder neck to meatus.
5. The buccal graft is harvested, 6 cm × 2.5 cm
6. The graft is sewn to the mucosa of the urethrotomy with absorbable 4-0 polyglyconate suture.
7. The urethra is quilted to the clitoral body to cover the grafted urethra.
8. A Martius flap may be deployed to facilitate blood supply and prevent fixation of urethra to the posterior aspect of the pubis.
9. The vulvar incision is then closed with running, locking absorbable suture.

Dorsal Vestibular Flap Urethroplasty [27]

1. Midline incision anterior to the urethra between the meatus and the clitoris is performed sharply (Fig. 13.3).
2. The dorsum of the urethra is exposed and anterior component of sphincter reflected from urethra.
3. The urethra is incised in the midline.
4. If a Martius flap is needed, it is now harvested and rotated into position between the urethra and the pubis.
5. The vestibular flap is dissected free and rotated into the urethrotomy.
6. Urethral reconstruction performed with running, locking 4-0 polyglyconate suture, calibrated to 28 French.
7. Vestibular incisions closed with absorbable suture.

Free Vaginal Wall Inlay Graft [28]

1. A transverse segment of anterior vaginal wall measuring as large as 6 cm × 2.5 cm is harvested. The harvest site is then closed with running, locking absorbable 4-0 polyglyconate suture.
2. Urethral dissection is performed, either dorsal or ventral, and urethrotomy is performed.
3. The free graft is then anastomosed within the urethrotomy to a calibrated lumen of 28–30 French.
4. Vaginal wall is then closed.

Lateral-Based Anterior Vaginal Wall Flap [29]

"Inspired by the Orandi technique," Romero-Maroto and colleagues describe well this technique and recently reported results in 9 patients over 22 years. Qmax improved from 6.8 to 21 mL/s and they reported no stricture recurrence nor de novo stress urinary incontinence in this small cohort.

1. The anterior vaginal wall is incised in the midline from the urethral meatus to the bladder neck.
2. The urethra is cannulated with either a catheter or guide wire as its strictured lumen permits and is spatulated in the midline from meatus proximally through the area of stricture as high as the bladder neck.

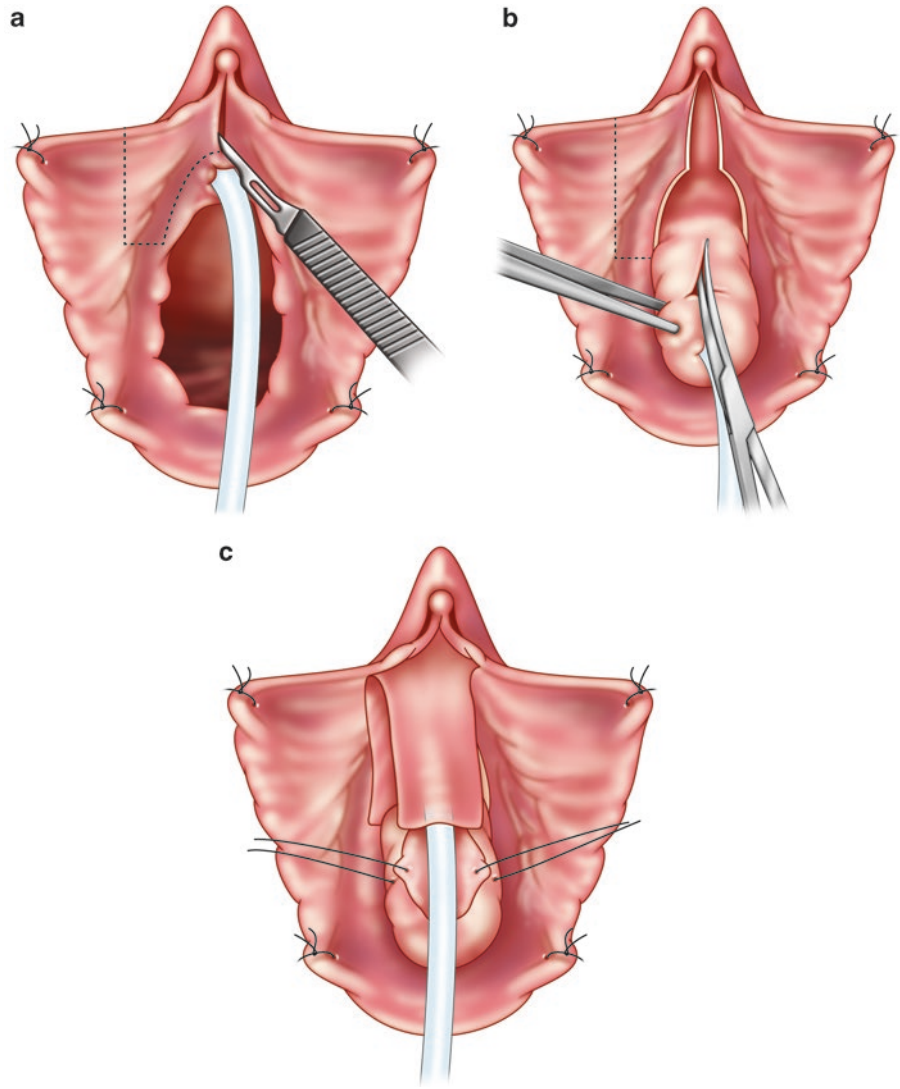

Fig. 13.3 (**a**) With labia retracted, a suprameatal incision is performed. (**b**) The dorsal urethra is incised through the stricture. (**c**) The vestibular flap is harvested and mobilized to the proximal extent of the urethrotomy. Repair is accomplished with running, locking poliglecaprone, or polyglyconate suture

3. A unilateral margin of the vaginal wall epithelium is then mobilized to match the urethral defect. The medial edge of the vaginal wall flap is anastomosed to the ipsilateral edge of spatulated urethra with poliglecaprone or polyglyconate suture. The lateral edge of the vaginal wall flap is then rotated and secured to the contralateral edge of the spatulated urethra with similarly absorbable suture, thus forming the ventral aspect of the urethra.
4. Finally, the vaginal wall is closed.

Summary

Female urethral stricture disease is an infrequently reported entity despite more than 100,000 physician office visits each year in the United States for symptoms mimicking the condition. The vast majority of female patients with obstructive voiding symptoms have a dynamic dysfunction as opposed to a fixed urethral stricture. Presumed fixed urethral obstruction has been historically managed by urethral dilation and rarely endoscopic urethrotomy. In patients

with proven urethral stricture disease, minimally invasive treatments including dilation and endoscopic incision generally fail with early recurrence and the need for additional procedures or intermittent catheterization. Urethroplasty appears to be a viable and preferred option for definitive therapy. Given the low number of reported urethral strictures, small series in even the most specialized urology practices, and variety of surgical techniques, the optimal treatment is not yet known. The dorsal approach to the proximal female urethra may be associated with a greater postoperative incidence of stress urinary incontinence when compared to ventral approaches, but this remains to be proven. Anti-incontinence procedures such as urethral sling placement or suspensions are not routinely performed concomitant to urethroplasty, but again evidence for this recommendation is lacking. Local tissue flaps, when available, appear to be very effective. When local tissue is inadequate, distal grafts, for example, buccal mucosa, appear efficacious.

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Excision of Vaginal and Vulvar Cysts

14

Diana El-Neemany and Harvey Winkler

Introduction

Benign vaginal and vulvar cysts are fairly common with an estimated prevalence of 1 in 200 [1]. They typically are present among adolescent and premenopausal women, and rarely are seen in prepubertal children and postmenopausal women. Vaginal and vulvar cysts can originate from embryologic remnants or are acquired. While they anatomically appear within the vagina, vaginal cysts can be a manifestation of disease processes from other nearby structures, such as urethral diverticula, Gartner duct cysts, and Skene's gland cysts. The most common embryologic vaginal cysts are Müllerian cysts, while the most common acquired cysts are epidermal inclusion cysts [2].

Embryology

A rudimentary understanding of embryology of the genital tract is useful when evaluating vaginal and vulvar cysts. The urogenital system is divided into the urinary tract, which consists of the kidneys, ureters, bladder, and urethra, and the genital tract which consists of the gonads, ductal system, and external genitalia. The formation of the urogenital system in an embryo begins when a fold of intermediate mesoderm forms along each side of the abdominal aorta in early development. These folds are termed the urogenital ridges, each of which then separates into a nephrogenic ridge and a genital ridge [2].

The Urinary Tract

The urinary tract begins to form between 20 and 22 days gestational age, prior to the formation of the genital tract. There are three stages of development of the urinary tract: the pronephric, mesonephric, and metanephric stage. The pronephros begins developing at the cranial end of the embryo and proceeds in a caudal direction. Though the pronephric ducts do not have an excretory function, they stimulate the nephrogenic portion of intermediate mesoderm to form mesonephric tubules. The nephrogenic ridges give rise to the mesonephric kidneys and ducts, also known as the Wolffian ducts. These ducts connect the mesonephric kidneys to the cloaca, a distal pouch where the urinary, genital, and alimentary tracts culminate. By the 5th week of fetal life, each mesonephric duct gives rise to a ureteric bud. Subsequently, the ureteric bud becomes a metanephric duct, developing into the ureter. The ureter initiates formation of the metanephros, which becomes the adult kidney.

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Concomitantly, the mesonephric kidney degenerates by the 10th week of life [2].

The Genital Tract

At 5 weeks of gestation, the gonads are undifferentiated and have the capability of becoming either ovaries or testes. After differentiation into ovaries, the formation of the genital tract begins. The paramesonephric ducts, also known as the Müllerian ducts, develop bilaterally from an invagination of the coelomic epithelium between the gonad and the mesonephric duct at 6 weeks of gestation. Both the Müllerian and mesonephric ducts end at the posterior aspect of the cloaca. The cloaca divides to form the urogenital sinus anteriorly and the rectum posteriorly. The urogenital sinus is composed of three parts, including the vesicle portion that develops into the bladder, the middle portion that develops into the urethra, and the caudal portion that develops into the distal vagina including the Bartholin (greater vestibular), urethral, and Skene's (paraurethral) glands (Fig. 14.1). The most inferior aspects of the mesonephric and metanephric ducts enter the trigone of the bladder. At 12 weeks of gestation, the inferior portion of the Müllerian ducts fuses to create the uterovaginal canal. By 20 weeks, the uterovaginal canal develops into the uterus and upper vagina. The superior aspects of the Müllerian ducts do not fuse and instead become the fallopian tubes [2].

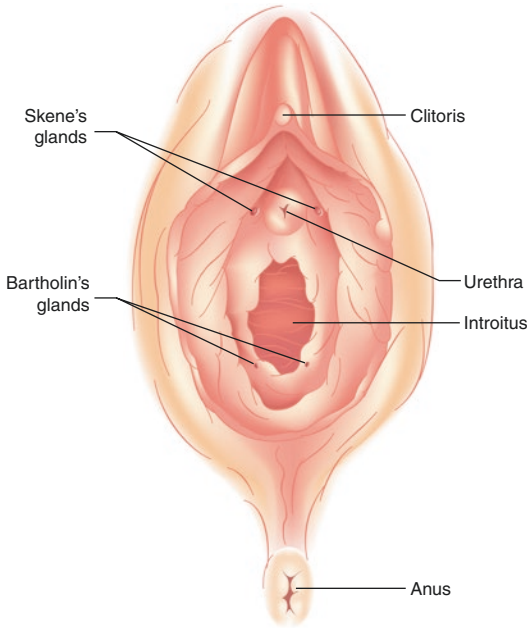

Fig. 14.1 Bartholin gland and Skene's/paraurethral gland duct openings within the vagina

The Vagina

The formation of the vagina starts with the development of two solid sinovaginal bulbs in the superior aspect of the vaginal portion of the urogenital sinus. These bulbs grow distally and form a solid vaginal plate. As the central aspect of the vaginal plate disintegrates, the lumen of the lower vagina is created and is completed by 20 weeks. This lower vaginal lumen is separated from the more superior urogenital sinus and uterovaginal canal by the hymenal membrane. This membrane usually disintegrates centrally before birth, leaving behind a circumferential tissue band within the distal vagina and proximal to the vaginal introitus [2].

Anatomy

Vaginal Structure and Histology

Knowledge of pertinent normal lower genital tract anatomy is also useful when identifying vaginal and vulvar cysts. The vagina is an empty tubular structure with a lumen that is held in place by its surrounding muscular and connective tissue support structures and sits between the bladder and the rectum. The most proximal aspect of the vagina, the vaginal apex, heads posteriorly toward the ischial spines. Normal vaginal length in the adult female is generally between 7 and 10 cm with the cervix present at the vaginal apex. The outer portion of the cervix (the ectocervix) is made of nonkeratinized stratified squamous cells and the inner portion and canal of the cervix (the endocervix) is comprised of simple columnar cells. Where these two different cell

types meet is termed the transformation zone. Histologically, the vaginal walls consist of four layers [3]. The first layer in direct communication with the vaginal lumen is the vaginal epithelium composed of nonkeratinized stratified squamous epithelium. The next layer is the lamina propria which is composed of fibrous connective tissue that is heavily vascularized and full of lymphatic channels. Engorgement of these vascular plexuses produces a transudate that allows for vaginal lubrication during sexual intercourse. Deep to the lamina propria is the muscularis that contains smooth muscle. The deepest layer is the adventitia that is made of collagen and elastin connective tissue and contains a large plexus of blood vessels. The muscularis and adventitia together are referred to as the fibromuscular layer. The fibromuscular layer separating the bladder from the anterior vagina is termed the pubovesicocervical fascia. The fibromuscular layer directly underneath the posterior vaginal wall separating it from the rectum is termed the rectovaginal or Denonvillier's fascia.

Vaginal Neurovasculature

Blood is supplied to the vagina from the descending cervical branch of the uterine artery and branches of the internal iliac artery including the vaginal, middle rectal, and internal pudendal arteries. Lymphatic drainage of the upper two-thirds of the vagina is to the obturator nodes as well as the external and internal iliac nodes, while the lower third of the vagina drains to the inguinal nodes. Portions of the inferior hypogastric plexus are responsible for sympathetic innervation of the vagina [4].

The Urethra

The female urethra averages 3 cm in length. The distal two-thirds of the urethra is fused with the anterior vaginal wall and the proximal one-third of the urethra courses through the bladder base, also known as the bladder neck. The anterior vaginal wall supports the proximal urethra in a sling-like fashion [5]. The urethra is comprised of four layers: mucosa, submucosa, internal urethral sphincter made of smooth muscle, and striated external urethral sphincter made of skeletal muscle. The inner surface of the urethra is lined by hormonally sensitive stratified squamous epithelium that becomes transitional as it nears the bladder base [4]. Paraurethral glands open into the urethral lumen within this layer in the dorsal or vaginal side of the distal urethra. The most pronounced of these paraurethral glands are the Skene's glands that can be visible on the inner surface of the external urethral meatus.

Blood supply to the urethra arises from the internal pudendal, vaginal, and inferior vesical arteries, while nerve supply comes from the pudendal nerve for somatic control and portions of the inferior hypogastric plexus for autonomic control [4]. The lymphatics of the distal third of the urethra drain into the superficial or deep inguinal nodes, whereas the proximal two-thirds drain into the external iliac, internal iliac, and obturator nodes.

The Vulva

The vulva is the term for the female external genitalia and includes the mons pubis, labia majora, labia minora, clitoris, vestibule, vestibular bulbs, greater vestibular (Bartholin) and lesser vestibular glands, paraurethral glands, external urethral meatus, and vaginal orifice. The epithelium overlying the mons pubis and labia majora has hair growth. Underneath this epithelium is a fatty subcutaneous layer composed of a superficial fatty and a deep membranous layer. The obliterated processus vaginalis, or canal of Nuck, and the round ligament exit the inguinal canal and terminate within the fat or skin of the labia majora. The epithelium over the labia minora does not have hair and its subcutaneous tissue is devoid of fat.

The vaginal vestibule is an area in between the labia minora. The boundaries include the clitoris anteriorly, fourchette posteriorly, Hart line laterally, and hymen medially. The Hart line is a demarcation where the skin on the labia minora distally becomes mucous membrane proximally.

The vestibule also contains the urethral, vestibular, Bartholin, and Skene's gland openings.

The Bartholin glands are the female equivalent of the male bulbourethral, or Cowper, glands. The glands are situated at the 5 o'clock and 7 o'clock positions, and each gland possesses a duct that opens into the vaginal vestibule. The inner surfaces of these glands are lined by columnar cells that secrete mucus to provide lubrication [4].

History and Physical Examination

A thorough history and physical examination is important to distinguish different types of vaginal/vulvar cysts. Symptoms include the presence or absence of vaginal or vulvar pain, dyspareunia, urethral versus vaginal discharge, spotting, post-void dribbling, leakage of urine, dysuria, incomplete voiding, or palpable mass. A history of recent urologic or gynecologic surgery, vaginal trauma, or vaginal insertion of a foreign body into the vagina should also be obtained. Pertinent aspects in the past medical history include age, known congenital urogenital tract anomalies, obstetrical history including vaginal trauma and repair, sexual activity, recurrent urinary tract infections, prior vaginal surgery, and history of pelvic radiation therapy. Gynecological history including menstrual cycles, prior vaginal infections, endometriosis, fibroids, and exposure to diethylstilbestrol (DES) in utero may be specifically applicable to the patient's presenting condition.

A targeted physical examination should include bimanual and speculum exams. Special attention should be taken to palpation of the anterior vaginal wall; a compressible bulge and discharge per urethra should raise suspicion for urethral diverticulum. Vaginal discharge should be evaluated. Masses such as cystic-appearing bulges should be examined for the size, location, and tenderness of the cyst.

Further evaluation with a transvaginal ultrasound, voiding cystourethrogram (VCUG), computerized tomography (CT), or magnetic resonance imaging (MRI) can assist with diagnosis. MRI has the advantage of distinguishing tissue planes more precisely and thus differentiating between urethral diverticulum, Gartner duct cysts, and other vaginal pathologies [6]. Additionally, radiographic information regarding cyst characteristics and its proximity to neighboring structures can be helpful prior to performing surgery.

Differential Diagnosis

A summary of the differential diagnosis of vaginal and vulvar cysts is listed in Table 14.1. The differential diagnosis for vaginal cyst includes the following: epidermal inclusion cysts, Müllerian cysts, Gartner duct cysts (mesonephric remnants), urethral diverticulum (Fig. 14.2), and mucous inclusions (adenosis). Deppisch studied the classification of 64 surgically excised vaginal cysts and found that Gartner duct cysts were uncommon, Müllerian cysts made up 1/3 of cases, and epithelial inclusion cysts were the most common type of vaginal cyst [7]. Less common types of vaginal cysts include endometriotic cysts, adenosis, and vaginitis emphysematosum. Vaginal endometriotic cysts are infrequently encountered, as the vagina is a rare location for endometriotic implants to manifest [8]. Although the etiology remains unclear, the benign and self-limited condition of multiple gas-filled cysts lining the vaginal wall (vaginitis emphysematosa) has also been described [9].

Table 14.1 Differential diagnosis of vaginal and vulvar cysts

Vaginal cyst	Vulvar cyst
Epidermal inclusion cyst	Epidermal inclusion (sebaceous) cyst
Müllerian cyst	Bartholin (greater vestibular) gland cyst
Gartner duct cyst (mesonephric remnant)	Skene's (paraurethral) gland cyst
Adenosis (mucous inclusions)	Cyst of the canal of Nuck (hydrocele)
Endometriotic cyst	Leiomyoma
Vaginitis emphysematosum	
Urethral diverticulum	

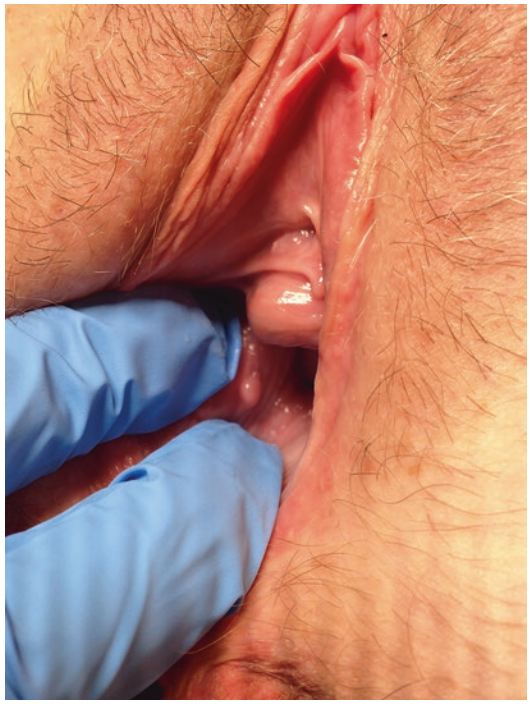

Fig. 14.2 Urethral diverticulum

The differential diagnosis of vulvar cysts includes vulvar epidermal inclusion (sebaceous) cysts, Bartholin (greater vestibular) gland cysts, Skene's (paraurethral) gland cysts, cysts of the canal of Nuck (hydroceles), and leiomyoma.

Presentation with a vaginal cyst is uncommon and is usually an incidental finding on physical examination as most patients are asymptomatic. However, vulvar cysts, like the Bartholin gland cyst, usually presents with discomfort and erythema. Kondi-Pafiti et al. reviewed 40 cases of benign vaginal and vulvar cysts, which included 12 cases of Müllerian cysts (30%), 11 cases of Bartholin gland cysts (27.5%), 10 epidermal inclusion cysts (25%), 5 cases of Gartner duct cysts (12.5%), one endometrioid cyst (2.5%) and one unclassified cyst (2.5%). The majority of patients were asymptomatic (31 cases, 77.5%). The cyst type which was most frequently associated with symptoms was Bartholin duct cysts [10]. Due to the symptomatology associated with vulvar cysts, such as pain, pressure, and inflammation, they are reported more frequently.

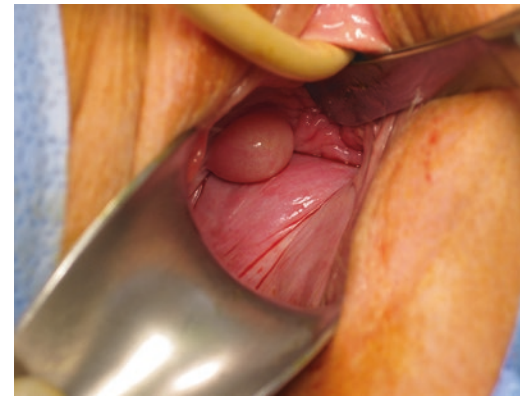

Fig. 14.3 Epidermal inclusion cysts arising from right lateral vaginal wall

Vaginal Cysts

Vaginal Epidermal Inclusion Cysts

Epidermal inclusion cysts are the most common non-embryological type of vaginal cysts [7]. These cysts can appear anywhere on the body and can also present as vulvar cysts. They are often asymptomatic and discovered during routine gynecological exam. They can be associated with previous surgery where squamous epithelium is entrapped when closing an incision. Thus, epidermal inclusion cysts are usually located in the vicinity of a previous incision, such as an episiotomy, or vaginal cuff from a hysterectomy [11]. They appear round, pinkish-white in color, and vary in size (Figs. 14.3, 14.4, 14.5, and 14.6). The fluid content can be viscous. Histopathology confirms the diagnosis and reveals epithelial cells lined by a cyst wall made of nonkeratinized stratified squamous epithelium. Asymptomatic cysts can be observed while symptomatic epidermal inclusion cysts require surgical excision. In order to reduce rates of recurrence, it is essential to ensure removal of the entire cyst wall.

Gartner Duct Cysts

During male embryogenesis, the mesonephric (Wolffian) ducts form the seminal vesicles, vas deferens, and epididymis. In females, after the

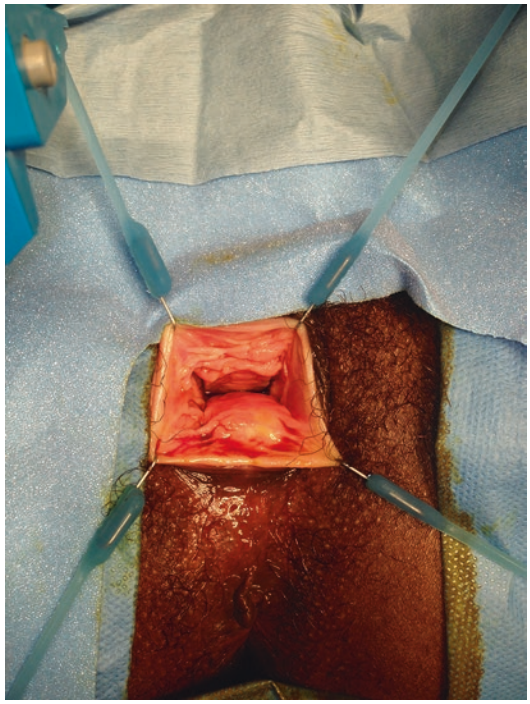

Fig. 14.4 Epidermal inclusion cysts arising from posterior vaginal wall

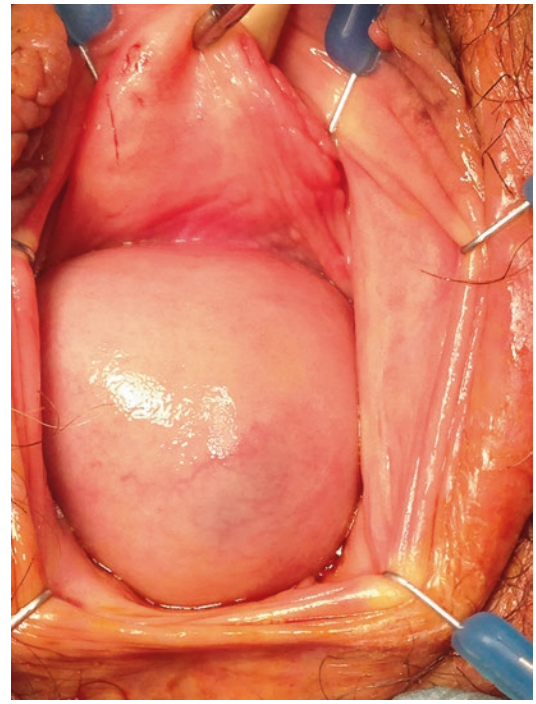

Fig. 14.6 Base of epidermal inclusion cyst shown on Fig. 14.5 arising from mid-portion of anterior vaginal wall

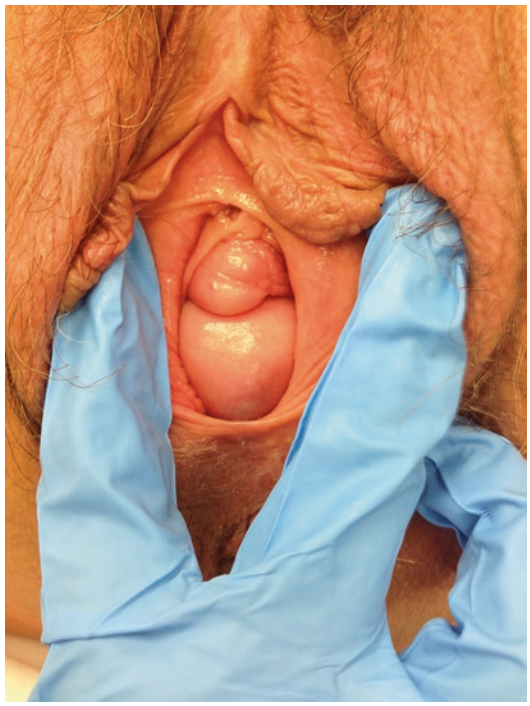

Fig. 14.5 Epidermal inclusion cyst visually difficult to distinguish from pelvic organ prolapse

fundamental urinary system is created, the mesonephric ducts regress due to the absence of testosterone. Remnants of mesonephric ducts may develop into Gartner duct cysts.

Gartner duct cysts are usually asymptomatic. However, patients who present with symptoms report vaginal pain, dyspareunia, vaginal bulge, or urinary incontinence. On examination, Gartner duct cysts are usually small averaging approximately 2–3 cm and are located within the anterolateral walls of the vagina. Sometimes, Gartner duct cysts can enlarge and be mistaken for an anterior vaginal prolapse or urethral diverticulum [12]. Additionally, due to the close interaction between the development of the genital and urinary tract during embryogenesis, Gartner duct cysts can be associated with congenital anomalies of the urinary tract [13]. Several case reports have noted findings of ectopic ureter, renal agenesis, and abnormalities of Müllerian structures associated with Gartner duct cysts [14, 15]. In a retrospective chart review of 29 patients with Gartner duct cyst, 10% were found to have other

genitourinary anomalies, including bladder cyst, urethral diverticulum, and a solitary kidney with uterine didelphis and septate vagina [16]. Therefore, if a Gartner duct cyst is suspected, an MRI should be obtained to determine the origin of the mass and if any associated urinary system abnormalities coexist [17] (Figs. 14.7 and 14.8).

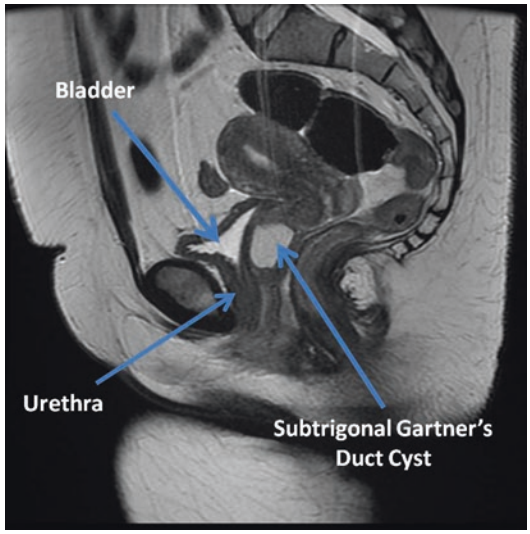

Fig. 14.7 MRI sagittal view of Gartner duct cyst. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

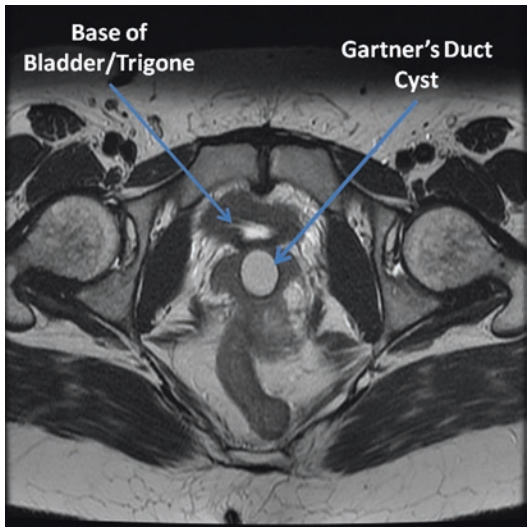

Fig. 14.8 MRI transverse view of Gartner duct cyst. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

Surgical excision of Gartner duct cysts is warranted if the patient is symptomatic. Otherwise, asymptomatic cysts can be observed. Marsupialization of Gartner duct cysts may be indicated if infection develops. Histologically, these cysts are lined with cuboidal or columnar epithelium.

Adenosis

Vaginal adenosis is a condition where endocervical or uterine columnar epithelial cells implant into the ectocervix or vagina. The etiology can be spontaneous, but many affected patients have a history of exposure to diethylstilbestrol (DES) in utero. DES is an orally active nonsteroidal estrogen that was approved by the Food and Drug Administration for vaginitis, menopausal symptoms, postpartum lactation suppression, and prevention of preterm deliveries and miscarriages. During the 1940s to 1960s, pregnant women with high-risk pregnancies were prescribed to take DES between 5 and 6 weeks gestational age, though some were prescribed DES later in pregnancy [18].

During the 1970s, case reports of vaginal clear cell adenocarcinoma (CCAC) were identified in women below the age of 40. The etiology of clear cell adenocarcinoma in this population of women was determined to be in utero exposure to DES. Additionally, several retrospective studies showed an association between vaginal and cervical adenoses with DES exposure, specifically in women exposed at an earlier gestational age and at higher dosages. Some have hypothesized DES-exposed vaginal adenoses as a precursor to the development of clear cell adenocarcinoma. However, more studies are required to confirm this relationship.

Clinically, women who present with vaginal adenosis should be questioned regarding a history of DES exposure in utero due to the increased risk of CCAC. Annual colposcopic examination with vaginal and cervical cytology is usually required in women with DES exposure in utero and biopsy should be obtained upon presentation with vaginal adenosis [18]. Symptoms of vaginal adenosis

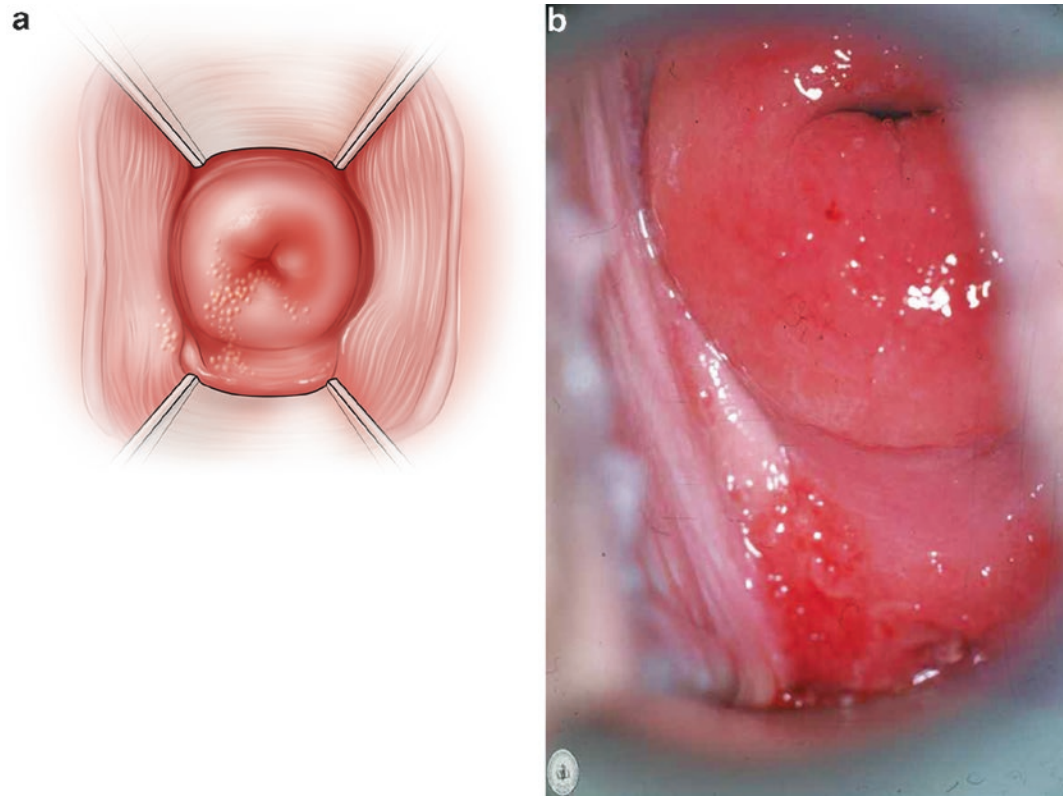

Fig. 14.9 (**a**, **b**) Vaginal adenosis

include vaginal discharge, irritation, pruritus, dyspareunia, and postcoital spotting. The area of affected vaginal wall appears erythematous and grainy or possibly with multiple small cysts (Fig. 14.9). Histology displays normal vaginal stratified squamous mucosa containing regions of columnar epithelium. The condition is usually benign and self-limited; however, if persistent or symptomatic, treatment with carbon dioxide laser coagulation or excision can be considered.

Vaginitis Emphysematosum

Vaginitis emphysematosum is an uncommon abnormality that produces multiple subcentimeter gas-filled cysts within small connective tissue spaces in the vaginal wall giving it a corrugated appearance. The condition is often discovered in gravid or immunocompromised patients [19, 20]. The etiology of this pathology is unclear, but treatment of infectious organisms such as *Trichomonas vaginalis* and *Gardnerella vaginalis* have been found to be curative [9, 21]. Patients usually do not present with symptoms. However, when present, symptoms may include vaginal discharge and pruritus. The condition can be observed on imaging such as ultrasound or CT scan as submucosal structures appearing as echogenic dots in a pattern similar to pneumatosis of the small bowel [20, 22]. Histology reveals gas spaces beneath the vaginal epithelial pegs that are lined by inflammatory multinucleated giant cells. Vaginitis emphysematosum is benign and self-limiting, and treatment with metronidazole when *T. vaginalis* and *G. vaginalis* are identified is appropriate [9].

Müllerian Cysts

Müllerian cysts are the most common congenital vaginal cysts. Müllerian cysts originate from persistent Müllerian epithelium that is not replaced with squamous epithelium of the urogenital

sinus. These cysts can occur anywhere along the vaginal wall, although it is typically located in the anterolateral wall [6]. Patients who are symptomatic complain of dyspareunia and presence of a palpable mass. They appear round, smooth, pink, vary in size, and the fluid content feels gelatinous when palpated. On exam, it is not possible to distinguish Müllerian cysts from inclusion or Gartner duct cysts and instead is diagnosed histologically with a finding of columnar epithelium. Once again, asymptomatic cysts can be observed whereas incision and drainage or excision can be performed for symptomatic or infected cysts.

Vulvar Cysts

Vulvar Epidermoid Cysts

Vulvar epidermoid cysts are also known as sebaceous cysts. They form on areas where hair follicles or sebaceous glands are present and are caused by obstruction of the pilosebaceous duct which leads to buildup of secretions and consequently cyst formation. They most commonly present on the labia majora, however, there have been case reports of epidermoid cysts presenting on the clitoris. Clitoral epidermoid cysts can present as a long-term complication from female circumcision. Rouzi et al. [23] reported on 21 females presenting 2–20 years after having a type I female genital mutilation procedure, and Birge et al. [24] presents two cases of clitoral epidermoid cysts in type II female circumcision. There are also several case reports of clitoral epidermoid cysts occurring spontaneously in prepubertal and adolescent females [25, 26].

Symptoms associated with vulvar inclusion cysts include tenderness and bothersome appearance. On examination, they appear firm, are often mobile, and contain caseous material. Epidermoid cysts can become infected and develop into an abscess. Treatment includes warm compresses to drain the obstructed duct. Recurrent, persistent, or enlarging cysts can be treated with incision and drainage, punch biopsy with subsequent drainage, or excision.

Bartholin Gland Cysts

Bartholin gland cysts develop from obstruction of the gland and subsequent accumulation of glandular fluid. Abscess formation is usually caused by anaerobic and aerobic bacteria, and rarely *Neisseria gonorrhoeae* or *Chlamydia trachomatis*. To this end, Bhide et al. [27] found that 74% of 78 cases revealed a positive microbial culture, and aerobes were the most common organisms involved. None of the cases contained *N. gonorrhoeae* or *C. trachomatis*. Mechanical trauma can be a risk factor for cyst formation and stimulation from sexual activity can lead to cyst enlargement.

Bartholin gland cysts are most commonly found in premenopausal women, though presentation in postmenopausal women can occur. Bartholin gland cysts that present in women above the age of 40 should be evaluated with biopsy of the cyst wall to exclude malignancy as primary carcinoma of the Bartholin gland accounts for approximately 5% of all vulvar cancers. In a retrospective chart review of 429 cases of vulvar cancer by Bhalwal et al., 7.7% had invasive vulvar carcinoma of the Bartholin gland with 87.9% ($n = 29$) of patients having squamous cell histology and 12.1% ($n = 4$) of patients having adenocarcinoma [28].

Bartholin gland cysts are usually asymptomatic; however, infection and abscesses can cause pain and appear erythematous. The glands are usually unilaterally affected and rarely have simultaneous bilateral gland involvement (Figs. 14.10 and 14.11).

The high rate of recurrence of Bartholin gland cysts should be taken into consideration when choosing the method of surgical intervention. Several modalities have been studied, including incision and drainage with Word catheter placement, marsupialization, and full excision of the Bartholin gland. Other procedures such as silver nitrate gland ablation [29], excision with CO_2 laser [30], and alcohol sclerotherapy [31] have also been described but are not commonly employed. A recent review by Wechter et al. [32] looked at the recurrence rates after various treatment modalities of Bartholin gland cysts and abscesses and found

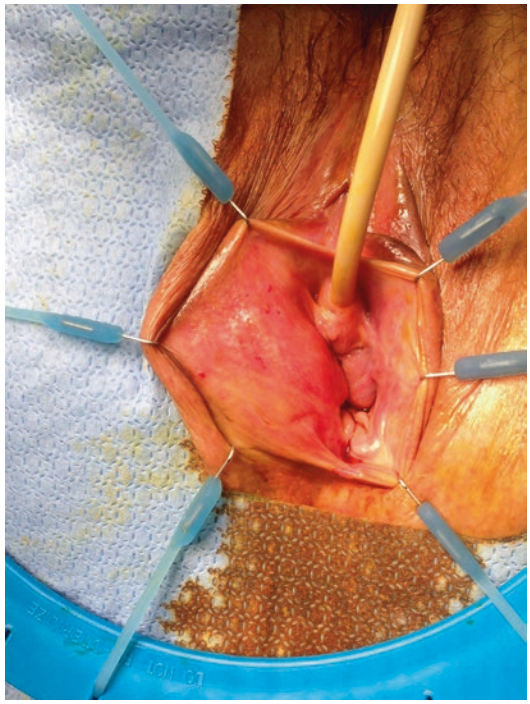

Fig. 14.10 Bartholin gland cyst

recurrence rates varied from 0% to 38% and were highest after incision or aspiration alone. There were no recurrences noted after marsupialization; however, no best treatment approach was identified. In the WoMan-trial [33], recurrence rates for both Word catheter placement and marsupialization were comparable with recurrence rates between 10% and 12%. Patients experienced more pain during treatment with Word catheter, though more analgesia was required during marsupialization. After treatment, there was no difference in pain scores between both techniques.

Based on the above studies, simple incision and drainage is not sufficient treatment and surgical intervention should include fistulization with either Word catheter placement or marsupialization. Gland excision can also be performed for recurrence; however, this method is associated with an increased risk of significant bleeding. Antibiotic treatment is not necessary when draining a Bartholin gland cyst unless there are signs of infection. Again, presentation of Bartholin cysts after the age of 40 warrants a biopsy due to the possibility of malignancy.

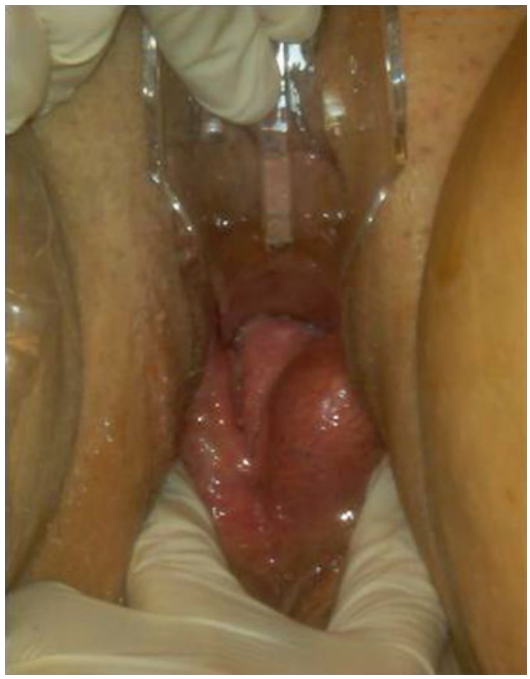

Fig. 14.11 Bartholin gland cyst. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

Skene's Gland Cysts

Skene's glands are located at the distal urethra and are the largest paraurethral glands. Skene's gland cysts occur after gland ductal occlusion (Fig. 14.12). Similar to other vulvar gland pathology, the cyst can become infected and form an

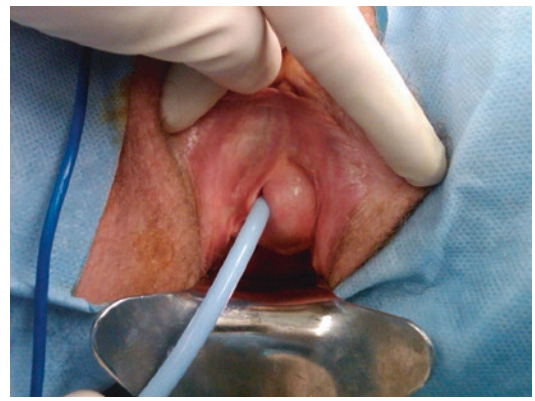

Fig. 14.12 Skene's gland cyst. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

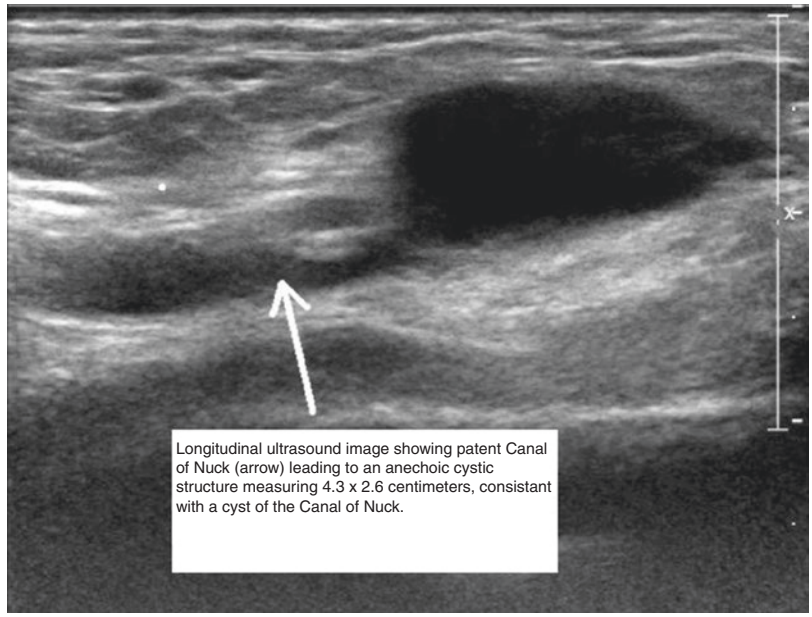

Fig. 14.13 Longitudinal ultrasound image of cyst of the Canal of Nuck. (Used with permission from Jagdale et al. [34]. www.jrcr.org/916)

abscess. Risk factors may include local infection or trauma. Symptoms include dyspareunia, localized pain, voiding dysfunction, and urinary obstruction. Skene's gland cysts can be observed if asymptomatic or excised if infected or symptomatic. Abscesses should be treated with antibiotics prior to excision to decrease the risk of spreading infection.

Cysts of the Canal of Nuck

The canal of Nuck, the male equivalent of the processus vaginalis, is a protrusion of parietal peritoneum that extends through the inguinal canal and terminates on the labia majora. Failure of the canal to close can lead to a hydrocele or herniation of pelvic contents, such as the ovary. A canal of Nuck cyst is a fluid-filled hernia of the peritoneum. It presents with inguinal swelling with or without unilateral labia majora pain and swelling. On examination, these cysts can be confused with an inguinal hernia; however, intestinal contents should not be present and is irreducible if the mass is truly a cyst of the canal of Nuck. Transillumination can be used to evaluate for a cystic versus a solid mass. Ultrasound or MRI are the imaging modalities of choice to aid in diagnosis and exclude an inguinal hernia (Fig. 14.13). Both ultrasound and MRI would reveal an ovoid tubular structure within the inguinal canal or labia majora. Treatment is excision of the cyst and correction of any herniation that may be present. Diagnosis is confirmed with histopathology after excision.

Surgical Intervention

Operative Technique

Surgical management options for vaginal and vulvar cysts include incision and drainage, marsupialization, and definitive management with excision.

Incision and Drainage

Incision and drainage can be performed as an outpatient to provide temporary, symptomatic relief. However, once the incision edges heal, secretions may recollect within the cyst. Therefore, after an incision and drainage, attempt should be made to create a new epithelialized tract for continued drainage. This can be achieved with placement of a Word catheter, for Bartholin

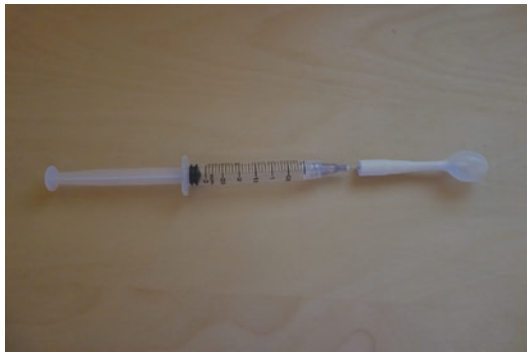

Fig. 14.14 Word catheter

gland cysts, or marsupialization, which will be further described below.

To perform an incision and drainage, the patient is placed in dorsal lithotomy position and the area overlying the cyst is cleaned with an antiseptic agent. A local anesthetic, such as 1% or 2% lidocaine, is infused into the overlying vaginal epithelium where the incision is to be made. An incision is made through the vaginal epithelium and cyst wall. The tips of a hemostatic or tonsil clamp may be placed within the cyst and used to lyse adhesions, thereby facilitating drainage. If an abscess is suspected, a culture can be obtained. The incision can be kept patent with a device such as a Word catheter. The tip of a Word catheter (Fig. 14.14), which has a diameter of a number 10 French Foley catheter, is placed within the cyst cavity. The balloon tip is inflated with sterile saline until it is large enough to prevent the catheter from falling out (about 3 mL). As there are openings on both ends of the catheter, this device allows drainage of cyst contents into the vagina. The catheter should remain in situ for 4 weeks during which time nothing should be placed in the vagina. Broad-spectrum antibiotics to cover aerobes and anaerobes are only warranted in the case of an abscess.

Marsupialization

Marsupialization is a technique that was devised due to the high recurrence rates following incision and drainage without epithelialization of the tract. It is a technique to create a new duct drainage tract without the use of an external device, such as a Word catheter. The procedure is most commonly performed in an ambulatory operating room setting but can also be done in an office or emergency room. The patient is placed in dorsal lithotomy position. Analgesia can be achieved with local anesthesia, sedation plus local anesthesia, regional anesthesia, or most commonly general anesthesia. The vagina and vulva are prepped and draped. An incision with a 15- or 10-blade scalpel is made in the vaginal epithelium overlying the cyst while taking care not to rupture the cyst wall (Fig. 14.15). The cyst wall is then incised, the contents drained, and the cyst incision extended to the same size as the vaginal epithelial incision (Fig. 14.16). Allis clamps are then used circumferentially to evert the cyst wall with the vaginal epithelium edges. A hemostat is used to lyse adhesions within the cyst and the cyst is irrigated (Fig. 14.17). The cyst wall edges are circumferentially sutured to its overlying vaginal epithelium within an interrupted fashion with either a 2-0 or 3-0 delayed-absorbable suture, such as polyglactin 910 (Fig. 14.18). Generally, by 4–6 weeks after the procedure, the opening of the duct decreases in size to less than 1 cm.

Risks of marsupialization include cyst recurrence and abscess formation. Compared to incision and drainage, marsupialization requires more surgical site exposure, a larger incision,

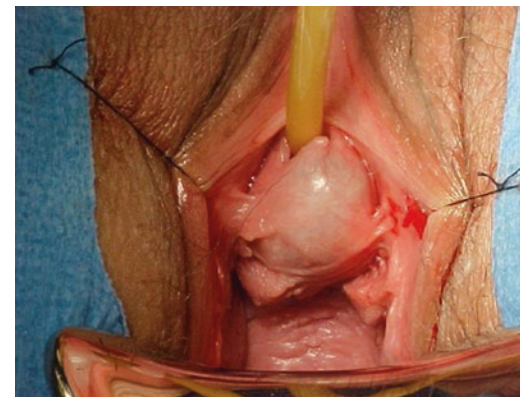

Fig. 14.15 Skene's gland cyst. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

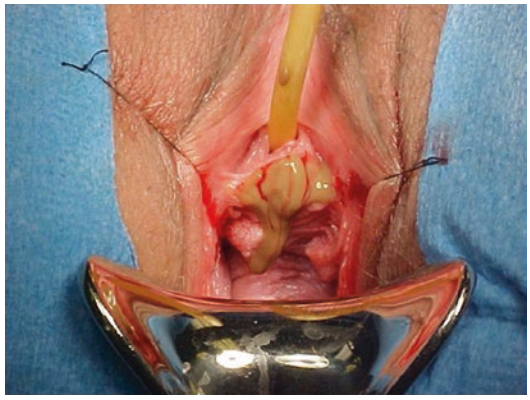

Fig. 14.16 Cyst wall incision. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

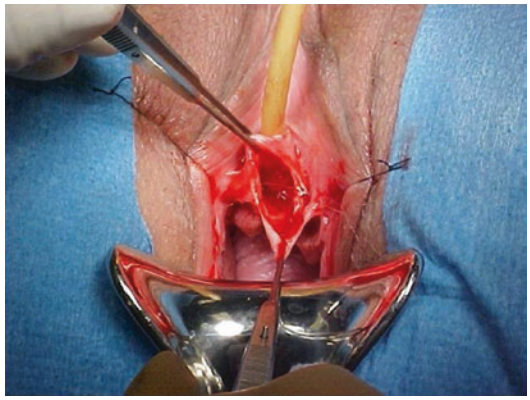

Fig. 14.17 Lysis of adhesions within cyst wall. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

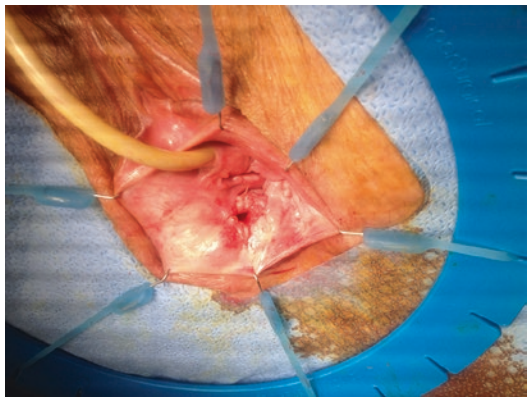

Fig. 14.18 End result after marsupialization of cyst wall to vaginal epithelium

more suturing, greater levels of analgesia, and more time. Additionally, compared to marsupialization, Word catheter placement is an easy, outpatient procedure with low cost [35]. As a result, the use of marsupialization has decreased since the introduction of the Word catheter.

Excision

The procedure for excision of a vaginal cyst is similar regardless of the type of cyst. When performing an office physical examination, one should inspect the size of the cyst and consideration should be taken to perform excision in the operating room for larger cysts. Although there is no cutoff as to what size cyst is unlikely to be successfully excised in the office setting, cysts greater than 2 cm generally require dissection that may be too extensive for an office procedure. In addition, preoperative assessment may be performed with imaging to evaluate the relationship of the cyst to surrounding structures depending on its vaginal location on exam. If preoperative evaluation reveals the cyst to be in close proximity to the bladder or ureters, the procedure should take place under general anesthesia with consideration of placing ureteral catheters prior to cyst excision. Integrity of the urethra and bladder can be evaluated intraoperatively with the use of cystourethroscopy.

Surgical intervention in the operating room may be performed under local or general anesthesia. The patient is placed in dorsal lithotomy position and prepped and draped in the usual sterile fashion. Adequate exposure and visualization of the cyst can be achieved with vaginal retractors or a Lone Star Retractor System™ (Cooper Surgical, Inc., Stafford, Texas) (Fig. 14.19). Stay sutures may be placed to keep orientation above and/or below the cyst. The vaginal epithelium may be infused with a dilute vasopressin solution using a 22 or 25-gauge needle. It is our practice to dilute 20 units of vasopressin in 100 mL of normal saline and use this solution for hydro-dissection and hemostasis. A scalpel is used to make a longitudinal superficial incision through the vaginal epithelium overlying the cyst wall. The vaginal

wall is then dissected circumferentially off the cyst until the base is reached and the cyst is entirely freed (Fig. 14.20). Dissection is performed with a combination of sharp and blunt technique, while using electrocautery sparingly to avoid rupture of the cyst. As the cyst is dissected from its base, brisk bleeding may be encountered. This base should be sutured with a 2-0 delayed-absorbable suture, such as, polyglactin 910, in a figure-of-eight fashion or in a running-locking technique until hemostasis is achieved. The vascular supply to the cyst can also be clamped with a hemostat and suture ligated with a 2-0 or 3-0 polyglactin-910 suture. Electrocautery may be used during the procedure with careful consideration of underlying structures. Complete removal of the cyst (Fig. 14.21) is essential to prevent recurrent cyst formation. If a potential space (Fig. 14.22) is present in the fibromuscular layer deep to the vaginal epithelium after the cyst is excised, this space can be re-approximated with 2-0 or 3-0 delayed-absorbable sutures in an interrupted fashion. The overlying vaginal epithelium is then sutured in a running-locking fashion with 2-0 polyglactin 910 (Fig. 14.23).

Larger cysts sometimes impede proper visualization and require intentional drainage prior to

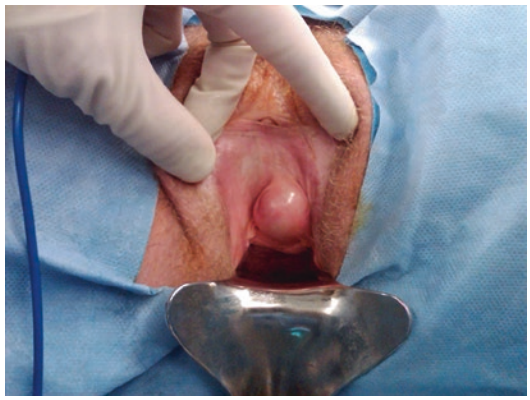

Fig. 14.19 Skene's gland. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

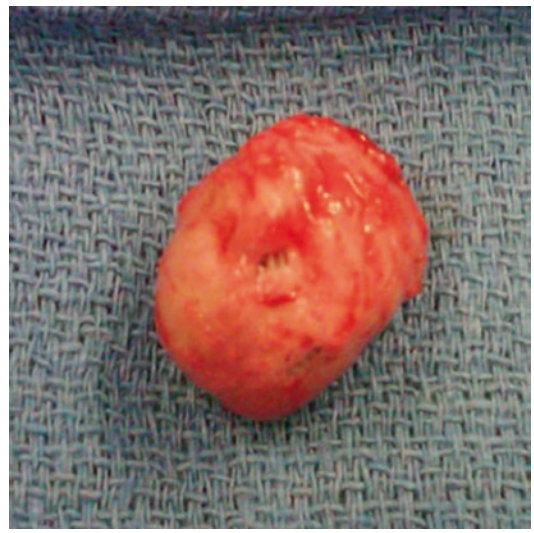

Fig. 14.21 Skene's gland cyst. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

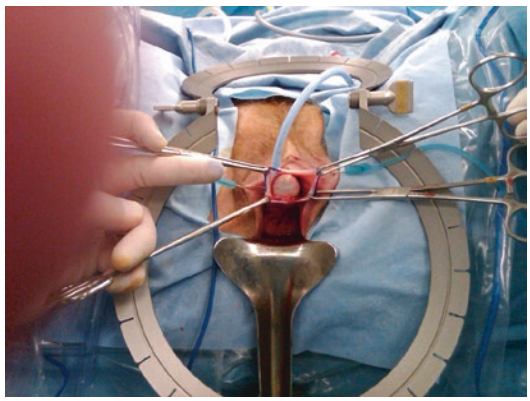

Fig. 14.20 Vaginal wall dissection off the underlying cyst. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

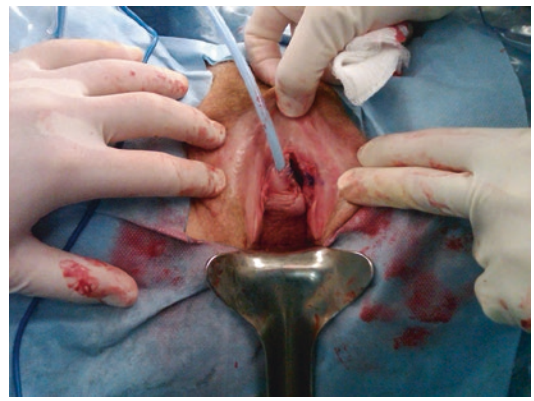

Fig. 14.22 Potential space after excision of cyst. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

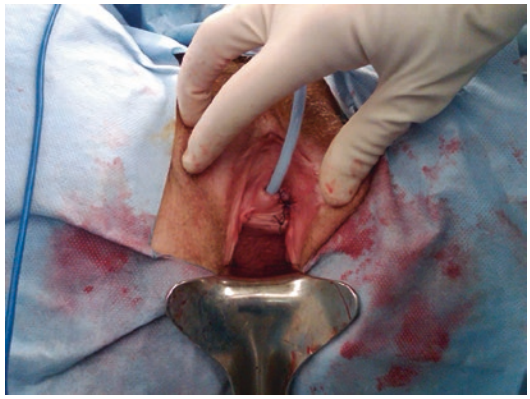

Fig. 14.23 Closure of vaginal epithelium. (Courtesy of Howard Goldman, MD, Department of Urology, Cleveland Clinic, Cleveland, OH)

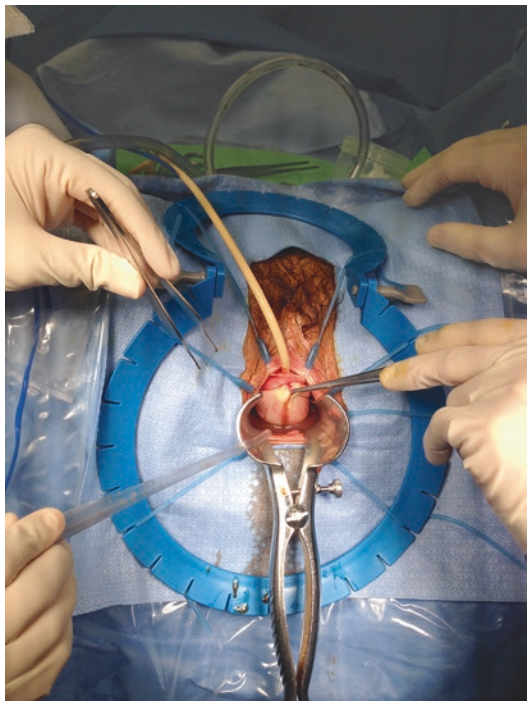

Fig. 14.24 Cyst rupture during dissection of anterior vaginal wall cyst

removal (Figs. 14.24 and 14.25). With cyst rupture, the cyst wall can be dissected from the underlying vaginal epithelium (Figs. 14.26, 14.27, and 14.28) or it can be fulgurated. The potential space and the vaginal epithelium should be closed in the aforementioned manner (Figs. 14.29, 14.30, and 14.31). The excised cyst

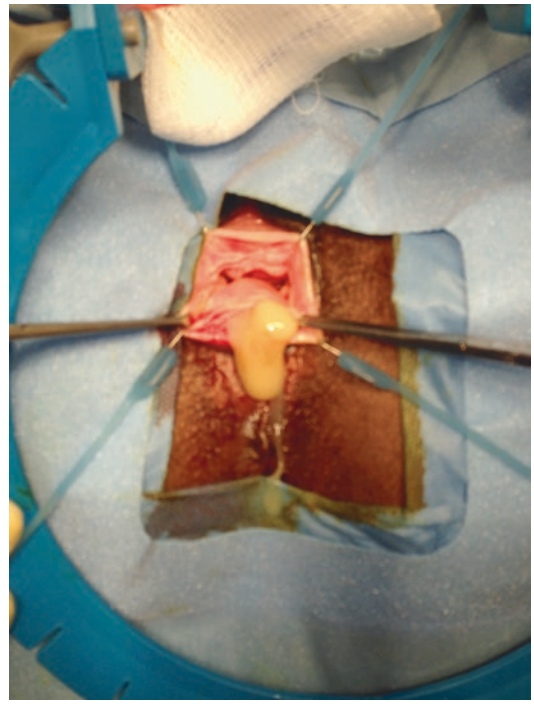

Fig. 14.25 Drainage of a posterior vaginal cyst contents

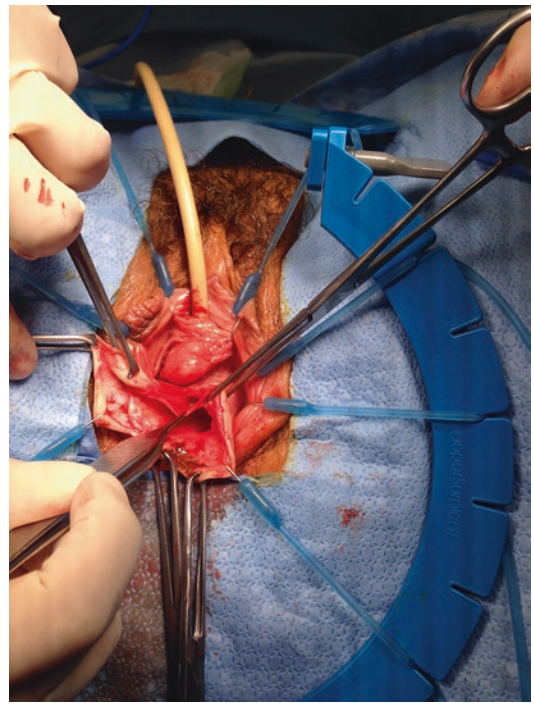

Fig. 14.26 Dissection of posterior vaginal cyst wall off of vaginal epithelium and underlying endopelvic fascia

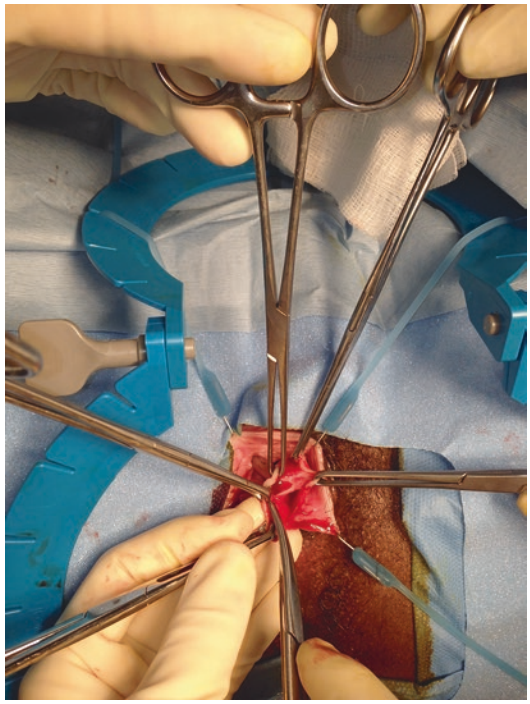

Fig. 14.27 Dissection of posterior vaginal cyst wall off ofvaginal epithelium and underlying endopelvic fascia

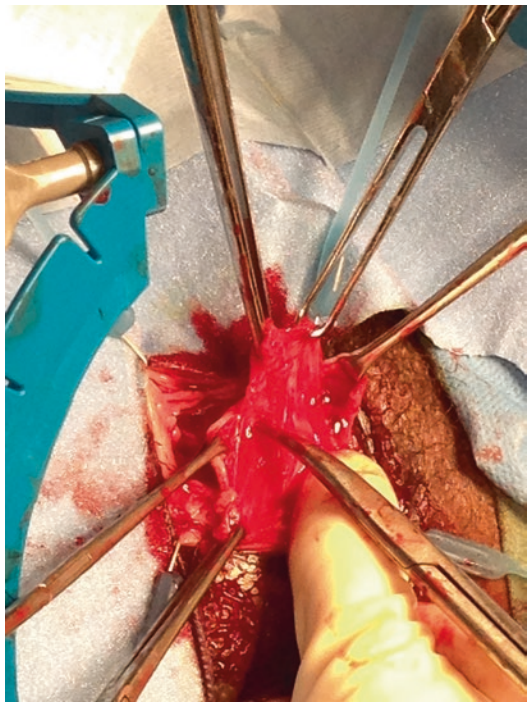

Fig. 14.28 Allis clamps lifting posterior vaginal cyst wall

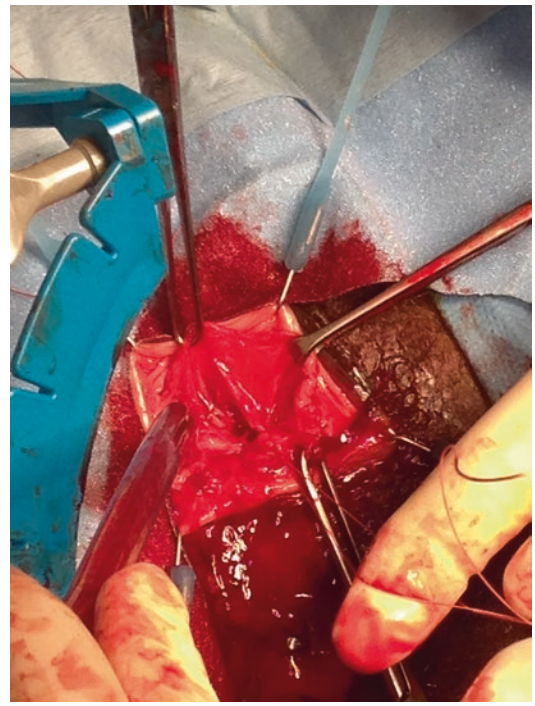

Fig. 14.29 Closure of potential space after removal of posterior vaginal cyst

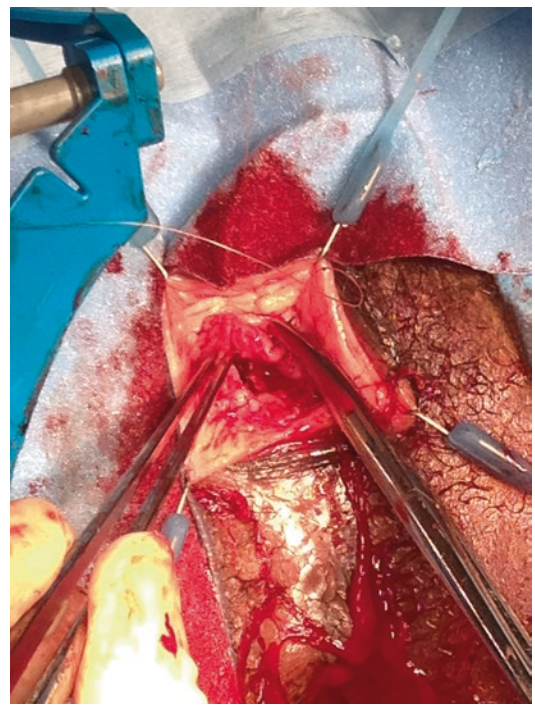

Fig. 14.30 Closure of posterior vaginal epithelium after excision of cyst

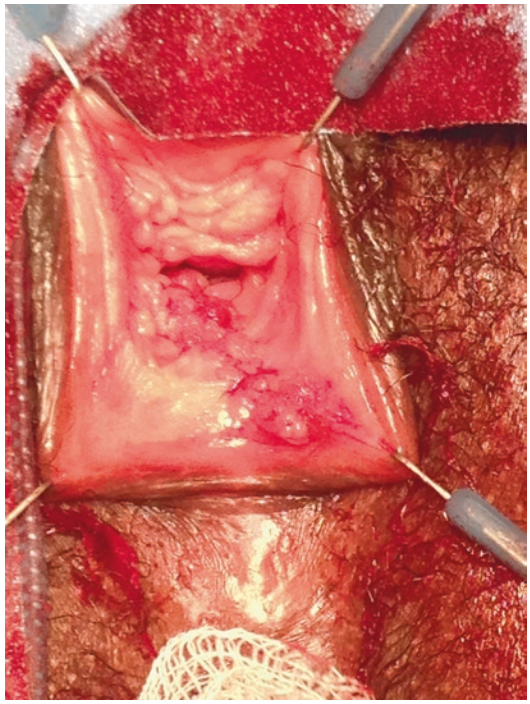

Fig. 14.31 Completed closure of posterior vaginal wall

or a portion of the cyst wall should be sent to pathology for examination. We recommend cystourethroscopy be performed at the end of any anterior vaginal cyst excisional procedure to evaluate for urinary tract injury. Risks of excision include bleeding, hematoma formation, cellulitis, cyst recurrence, pain, dyspareunia, and damage to deep and surrounding anatomical structures.

Vulvar Considerations

The techniques for surgical management of vulvar cysts such as incision and drainage, marsupialization, and excision are similar to that of vaginal cysts, with a few variations based on the type of vulvar cyst that is present.

Vulvar Epidermal Inclusion Cysts

Symptomatic vulvar epidermal inclusion cysts can be treated with surgical excision. Cysts that are 1 cm or smaller can be excised utilizing a wedge incision technique. A wedge-shaped specimen removes its encompassing skin, subcutaneous tissue, and the cyst in its entirety. Cysts larger than 1 cm can be excised as described for vaginal cysts above, starting with the incision on the vulvar epithelium overlying the cyst, sharp dissection of the epithelium off the underlying cyst wall, and complete removal of the cyst. The skin can be held with Adson forceps while fine dissection is carried out with Stevens tenotomy scissors. The wound is closed in layers and excess skin is cut as needed for the skin to realign properly. After excision of vulvar cysts, the vulvar epithelium is closed in an interrupted or subcuticular running fashion with 4-0 delayed-absorbable sutures. A pressure dressing can be applied to prevent hematoma formation.

Bartholin Gland Cysts

Bartholin gland cysts are fairly common and have high recurrence rates if not treated appropriately. While there is no consensus regarding which method is best, Word catheter has been shown to be a low-cost outpatient procedure with treatment costs seven times lower than for marsupialization [35]. Patients also need to be made aware that gland function and ability to form vaginal secretions may be reduced if the gland is removed in its entirety.

The technique for Bartholin gland cyst incision and drainage is similar to that described above for vaginal cysts. However, the initial incision should be made on the medial aspect of the vestibule overlying the cyst roughly 1 cm distal and parallel to the hymen, and on the vaginal mucosa and not on the vulvar skin. After drainage, a Word catheter should be placed and remain in situ for at least 4 weeks. Patients must be counseled regarding the risk of cyst re-accumulation when any portion of the gland is left in situ.

If marsupialization is performed, a 2 cm vertical skin incision is first made over the cyst remaining parallel with the hymen to prevent creating a fistulous tract to the labia majora. The cyst wall is then incised and contents drained. The contents may be cultured if an infection is suspected. Additionally, in patients over the age of

40, a biopsy should be obtained to exclude adenocarcinoma. As described above, the cyst wall is sutured to the adjacent vulvar epithelium with 2-0 or 3-0 delayed-absorbable sutures. Generally, antibiotics are not necessary after drainage of the cyst. However, if drainage is purulent and an infection is suspected, antibiotics such as trimethoprim-sulfamethoxazole, doxycycline, or cephalexin may be used for 7–10 days [36].

Most Bartholin gland cysts resolve with incision and drainage, Word catheter placement or marsupialization. In patients whom Bartholin gland cysts recur frequently, excision of the gland may be performed. For this procedure, the surgeon should be aware that the rectum is located just posterior to the Bartholin gland. A finger may be placed in the rectum during dissection to differentiate between the rectum and the cyst. Dissection of the cyst from the vaginal epithelium should be directed toward the posterosuperior aspect of cyst, where the blood supply to the gland arises. To prevent hematoma formation, the potential space from where the Bartholin gland cyst was excised should be re-approximated in multiple layers. In addition to suture ligation techniques, direct pressure should be applied and a drain may be placed intraoperatively if needed. Although rare, there have been case reports of rectovaginal fistula developing as a complication to Bartholin gland excision.

Postoperative care includes ice packs initially to decrease swelling and pain from scarring. Nothing should be placed per vagina for at least 4 weeks, at which time the site should be inspected. Warm sitz baths and proper hygiene should be encouraged during recovery. Broad-spectrum antibiotics need only be given when treating abscesses with accompanying cellulitis or if postoperative cellulitis develops.

Cysts of the Canal of Nuck

Surgical treatment of a cyst of the canal of Nuck begins with a vertical incision into the labia majora to expose the underlying cyst. If blood vessels are encountered while dissecting in the subcutaneous tissue, they can be suture ligated with 3-0 absorbable suture. The cyst is then grasped with Allis clamps and freed using sharp dissection on all sides except the superior attachment. Metzenbaum scissors utilizing the flash technique are used to ensure there is no underlying intestine and subsequently the cyst is entered. A finger is placed into the cyst to palpate the external inguinal ring. Any peritoneal lining is excised from the cyst, and the external inguinal ring is closed. The superior portion of the cyst is then closed with a purse-string suture and the cyst is excised and freed. The vulva including the skin is then closed in layers with 2-0 or 3-0 absorbable sutures. If an inguinal hernia is present, an inguinal hernia repair should be performed.

Summary

In conclusion, both vulvar and vaginal cysts are often asymptomatic and discovered on routine gynecological examination. The evaluation of these cysts includes a detailed history, thorough physical examination, and possibly imaging. Asymptomatic cysts can be observed, while symptomatic or infected cysts should be actively managed. Patient demographics and cyst characteristics should guide the clinician as to what surgical procedure to employ. Techniques include incision and drainage, marsupialization, and excision. Incision and drainage with epithelialization of the drainage tract as well as marsupialization have good outcomes with low complication and recurrence rates. Definitive treatment is achieved by cyst excision. Clinicians should have a low threshold to biopsy of any concerning or recurrent lesion.

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Transvaginal Closure of Bladder Neck

15

Teresa L. Danforth, Evgeniy I. Kreydin, and David A. Ginsberg

Abbreviations

BNC	Bladder neck closure
CIC	Clean intermittent catheterization
SBO	Small bowel obstruction
SPT	Suprapubic catheter
TP	Transperineal
TPN	Total parenteral nutrition
TV	Transvaginal

Background

Transvaginal closure of the bladder neck in the female patient is indicated for those with a devastated outlet, usually caused by chronic indwelling urethral catheter placement. Many of these patients have a neurogenic etiology for either urinary retention or urinary incontinence. Chronic catheterization leads to urethral erosion and destruction, ultimately resulting in a patulous urethra that cannot be maintained in the bladder. Management is limited, as many of these patients are debilitated due to their comorbid conditions. There is often an inadequate amount of residual urethra to allow for placement of a pubovaginal sling, and many of these patients are unwilling or unable to undergo urinary tract reconstruction. Therefore, the best option is often bladder neck closure with suprapubic tube (SPT) placement. Transvaginal closure is an outstanding option that does not require an abdominal incision, making it a viable minimally invasive option; however, vaginal techniques can be technically challenging for inexperienced vaginal surgeons. Primary complications include fistula formation, bladder stones, SPT site leakage or stenosis, and wound infection. Transvaginal closure of the bladder neck carries less morbidity but may require more than one procedure to achieve continence.

Indications for Transvaginal Closure of the Bladder Neck

Transvaginal closure of the bladder neck in a female patient is indicated for the devastated bladder outlet, usually caused by chronic indwelling urethral catheter placement. Chronic urethral catheters are placed for a variety of indications, including urinary incontinence refractory to other treatments and urinary retention. Many patients with indwelling urethral catheters have a neurogenic etiology (i.e., multiple sclerosis, spinal cord injury, spinal dysraphism, or stroke) as the cause of their lower urinary tract dysfunction. However, as the population ages and treatment of

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incontinence in the debilitated aging patient continues to be a challenge, chronic indwelling catheter usage may be seen with increasing frequency in this patient population as well.

The typical clinical situation would be one in which a patient undergoes placement of a urethral catheter as she is unwilling or not medically able to undergo any more invasive form of treatment for urinary incontinence or retention. These patients are generally not optimal candidates for clean intermittent catheterization (CIC) for reasons such as physical debilitation, poor hand function, or simply unwillingness to catheterize. In addition, most skilled nursing facilities are unable to maintain patients on a regular CIC program; indwelling catheter placement is a much easier initial option for both the patient and the nursing staff. Male patients with urinary incontinence have the option of using a condom catheter; unfortunately, there is not a similar alternative for female patients. Chronic indwelling catheters are known to have complications including urinary tract infections, urinary tract calculi, catheter plugging, cellular toxicity, and malignancy [1]. Furthermore, pressure from the catheter, balloon, and poor management of catheter by the patient or ancillary staff all contribute to urethral erosion and destruction (Fig. 15.1) [2]. With urethral erosion, further leakage around the catheter can occur which frequently leads to upsizing of the catheter or the balloon, resulting in even further damage to the urethra over time. The urethra become patulous and catheters are frequently pulled out or cannot be maintained in the bladder leading to a decreased bladder capacity, as the bladder can no longer fill and cycle. The damage can lead to traumatic hypospadias and/or anterior urethral erosion to the level of the pubic symphysis.

Management options for these patients are limited. Unfortunately, many of these patients are debilitated secondary to their medical comorbidities and poor nutritional status. The use of pads or diapers can be problematic for management of pressure ulcers and wounds, which are commonplace in this subset of patients. Suprapubic catheters have been successfully used in some patients; however, many patients will still have significant leakage per urethra due to the damage caused by the initial indwelling urethral catheter. Transvaginally placed slings, although theoretically are useful as they allow for continued access to the bladder through the native urethra, do not usually give enough support to achieve continence. In addition, there may not be an adequate amount of residual urethral length to allow for sling placement if the urethral damage is severe enough.

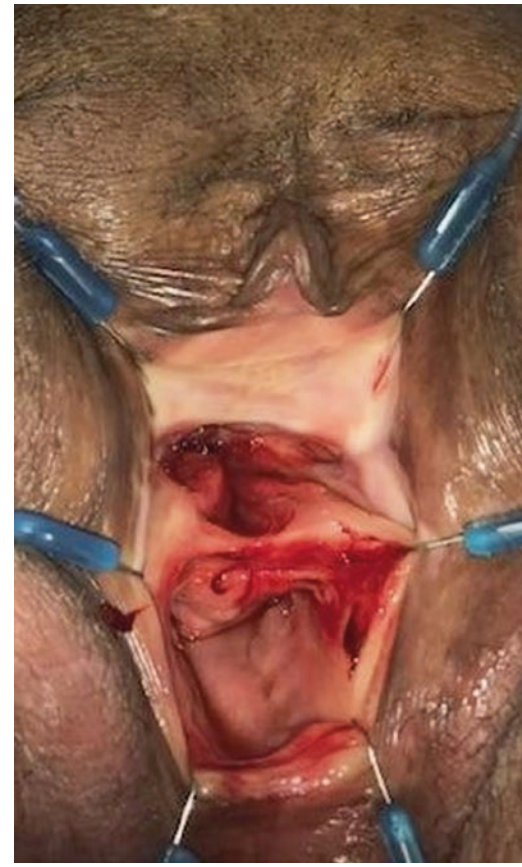

Fig. 15.1 Devastated urethra in a chronically catheterized patient with a spinal cord injury

Reconstruction of the lower urinary with various methods have been described but many patients are not willing or medically appropriate to undergo such procedures. In patients who are willing and able to undergo urinary tract reconstruction, closure of the bladder neck is usually achieved transabdominally at the same time as

their reconstruction. This type of closure is more invasive but has been reported to have lower rates of fistula formation postoperatively compared to transvaginal repair.

Transvaginal bladder neck closure (BNC) with SPT placement is reserved for those patients whom are not candidates for more invasive reconstruction. The primary concern with this procedure is fistula formation between the closed bladder neck and the vagina and may be more technically challenging for inexperienced pelvic surgeons.

Preoperative Evaluation

Preoperatively, the most important decision is which approach to take in managing the patient's incontinence. Andrews et al. described a series of 57 patients with long-term indwelling catheters of which 39 were managed successfully with SPT alone [1]. Similarly, Eckford et al. reported that 11 of 50 women with multiple sclerosis managed with indwelling catheters were happy with an SPT alone even with a small degree of intermittent leakage from the urethra [3]. It is important to recognize that some patients, depending on the degree of urethral destruction, may have enough improvement in their incontinence with an SPT alone that they may not need further surgical intervention. If this fails due to a poor outlet, then treatment will likely focus on an obstructing sling versus bladder neck closure. Wantanabe et al. reported that candidates for pubovaginal sling must have an intact bladder neck with 1 cm of proximal urethral tissue in order to obtain effective compression of the urethra, which may or may not be the case in patients with a chronic indwelling catheter [4]. If bladder neck closure is to be done, then the decision between transvaginal versus transabdominal approach needs to be resolved.

When considering abdominal versus vaginal approaches, various factors must be considered: morbidity of the procedure, planned concomitant procedures, prior surgeries, surgeon experience [1, 5]. Certainly, avoiding an abdominal incision allows for decreased morbidity. While one recent study from the University of Alabama demonstrated equivalent continence rates between abdominal (29 patients) and vaginal approaches (35 patients), most preceding studies found the transvaginal approach to be associated with higher rates of fistula and/or failure [1, 2, 5, 6]. Surgeon experience should be taken into account, as less experienced vaginal surgeons may not fare as well with this approach. Levy et al. reported on a series of 12 patients, 4 of whom underwent transvaginal closure of the bladder neck alone with a 50% success rate [5]. The two patients who failed and the subsequent 8 patients underwent combined abdominal and transvaginal approach with 100% success. Levy suggests that surgeons without significant experience operating vaginally should consider an abdominal approach to achieve higher success. Ginger et al. also reported an 11% leakage rate in 26 patients undergoing abdominal BNC as opposed to a 100% leakage rate in 2 patients who underwent transvaginal approach [2].

As already discussed, patients with chronic indwelling catheters are often debilitated and malnourished. Poor preoperative nutrition status is associated with poor wound healing, increased infection rate, higher pulmonary complication rate, prolonged hospitalization, and higher mortality rates [7]. Hebbar et al. reviewed studies looking at the use of total parenteral nutrition (TPN) or enteral feeds preoperatively and the rates of complications. From the VA TPN Cooperative Study which used 7–15 days of preoperative TPN, patients with severe malnourishment were found to have a dramatic drop in complication rate from 42.9% to 5.3% with the use of TPN; however, pooled data of all patients did not show any significant difference. There was no difference between the use of TPN versus enteral feeds. Therefore, one could consider using preoperative nutrition in the severely malnourished patient.

Procedure

Various techniques have been described to perform a transvaginal closure of the bladder neck [1–3, 8–11]. The patient is placed in dorsal lithotomy position with adequate exposure to the anterior vaginal wall using labial retraction sutures and/or a self-retaining retractor, with or without a posterior weighted speculum. If an SPT is not already present, one can be placed with various techniques. Eckford et al. describe a two-stage technique in which an SPT is placed during the first procedure (percutaneously or open) followed by a second procedure for transvaginal BNC if the patient continues to leak [3]. A Lowsley suprapubic tractor may be used to aid in SPT placement if desired [6, 8].

The anterior vaginal wall is infiltrated with injectable saline to aid in the dissection of the vaginal wall from the urethra and bladder. Two incisions are made along the anterior vaginal wall: one circumferentially around the urethral meatus and the second as an inverted wide-based anterior vaginal wall flap beginning from the urethral meatus extending past the bladder neck (Fig. 15.2a–f) [10]. The urethra is dissected laterally over the periurethral fascia to the retropubic space and off of the urethropelvic ligaments followed by transection of the urethra off of the urethropelvic ligament dorsally to the inferior margin of the pubic symphysis. This allows for complete mobilization of the remaining urethra and bladder neck (Fig. 15.2b). The necrotic urethral tissue is then removed, which may in fact be the entire urethra, thus making bladder neck mobility extremely important. If there is viable urethral tissue, one can utilize a technique described by Rovner et al. in which the anterior urethra is divided toward the bladder neck and the bivalved urethra is rotated in an anterior and cephalad direction and secured to the anterior bladder wall with two layers of absorbable suture (Fig. 15.2d). This rotates the suture line anteriorly, toward the retropubic space and underneath the pubic symphysis, minimizing overlying suture lines during closure of the vaginal wall flap (Fig. 15.2e, f). In addition, if possible, we also try to then secure the sutures used to close the bladder neck to the undersurface of the pubic symphysis, further placing the bladder neck closure anteriorly. Mobilization of the closure upward should minimize the risk of postoperative fistula formation. The vaginal wall flap is closed with absorbable suture and packing is placed.

Nielson et al. describe a technique in which two chromic sutures are passed through the SPT site via the Lowsley tractor and used to tag the edges of the urethral closure [8]. These sutures are then later used to invaginate the urethral mucosa and pull the urethra away from the vaginal closure.

Flaps or graft placements are generally not necessary in primary repair. In cases where the perivesical tissues may be compromised or in patients with history of prior pelvic radiation, one can consider using a Martius flap for interposition [9]. In patients who have failed prior attempts, a combined abdominal and vaginal approach with omental, peritoneal, or Martius flaps have been described [3, 10].

Postoperative Management

Appropriate postoperative management is critical to the success of abdominal or transvaginal closure of the bladder neck. Ginger et al. found an association with poor postoperative catheter care and leakage [3]. They found that 13 of 29 patients had documented poor catheter management by their caregivers which included poor securing of the SPT, inadequate catheter irrigation, clogging, kinking, and dislodgement; 7 of 8 patients with persistent leakage postoperatively (6 urethral and 2 around SPT) were associated with poor catheter care. This stresses that not only an adequate catheter size should be used but also that catheters need to be appropriately secured at all times and irrigated if necessary to ensure that it is draining appropriately.

Equally important to adequate catheter drainage is management of detrusor overactivity. Ginger et al. demonstrated detrusor overactivity in 12 of 23 patients preoperatively [2]. Stoffel et al. also showed that 10 of 12 neurogenic patients had poorly compliant bladders on fluo-

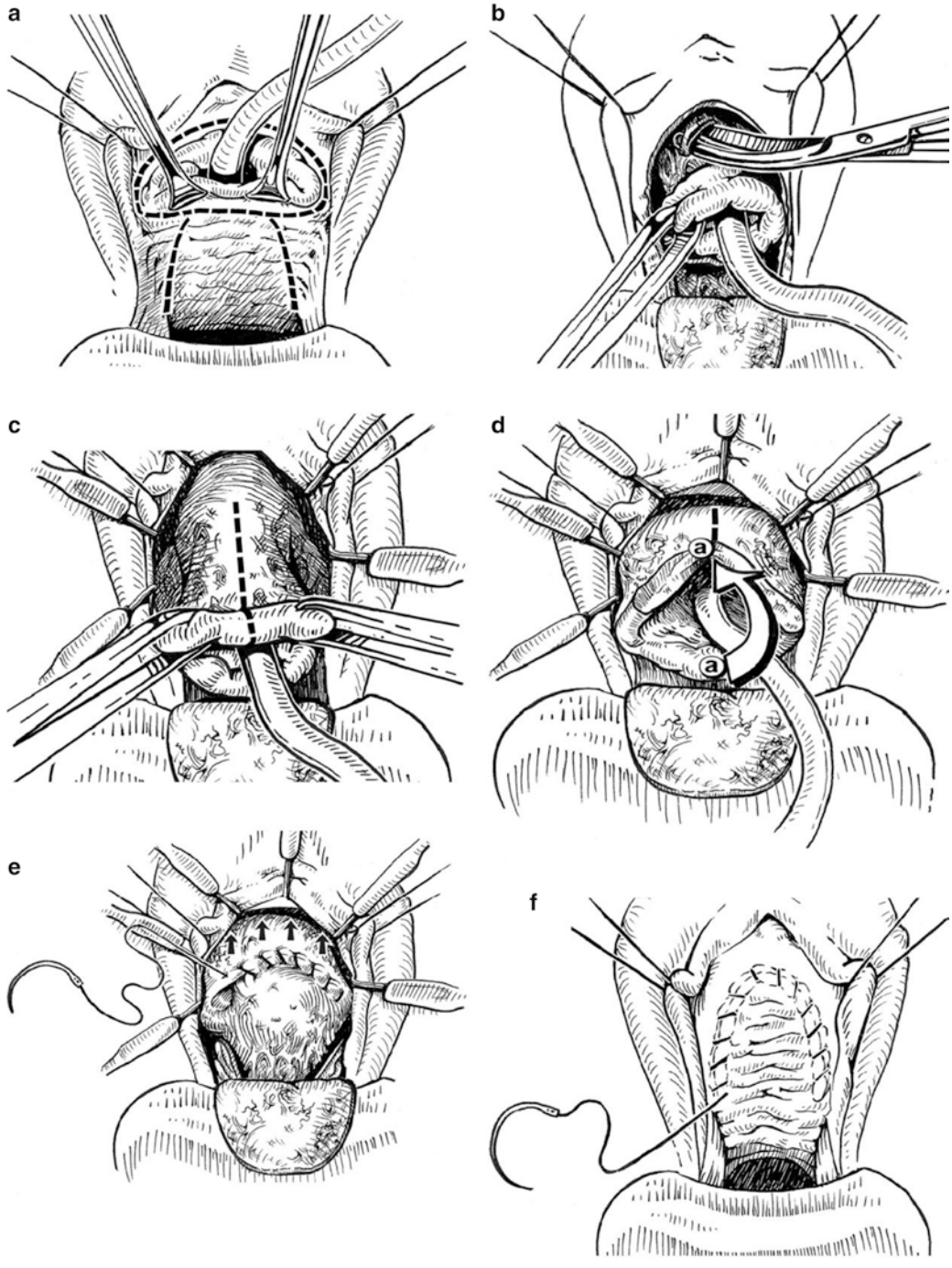

Fig. 15.2 (**a**–**f**) TV BNC with posterior urethral flap. (**a**) Vaginal wall flap developed and dorsal semilunar incision is made above the urethra. (**b**) Dissection continued above urethra into retropubic space. Pubourethral and urethropelvic ligaments taken down, mobilizing urethra and anterior bladder neck. (**c**) Dorsal urethra bivalved and incision carried onto anterior bladder neck for 2–3 cm. (**d**) Dorsally bivalved urethra then rotated cephalad toward anterior bladder wall incision. (**e**) Ventral urethral flap affixed high on anterior bladder wall, such that when bladder rotates into anatomic position, suture line rotates under symphysis pubis. (**f**) Vaginal wall closed as second layer with no overlapping suture lines. (Reprinted from Rovner et al. [10]. With permission from Elsevier.)

rourodynamics prior to BNC with urinary diversion [11]. Although an SPT should allow for continuous bladder drainage, physiologically, an open bladder neck prompts a bladder contraction. Higher pressures in the bladder put stress on the suture line, thus increasing the risk of postoperative fistula formation. Administration of anticholinergics will potentially decrease this risk and should be used postoperatively (or continued if patient is already on them) [12]. The use of onabotulinumtoxinA at the time of BNC has not yet been studied, but presumably would allow for lower bladder pressures and higher success rates.

There are various complications associated with transvaginal closure of the bladder neck, the most important of which is continued leakage of urine and development of a vesicovaginal fistula. A postoperative cystogram should be performed 2–3 weeks following the procedure to assess the integrity of the repair. If a leak is suspected but cannot be identified on cystogram, often, it can be identified on examination. Methylene blue or indigo carmine irrigation in the bladder can be used to easily identify the site of leakage if it cannot be identified.

If there is a leak, continued catheter drainage can be attempted with the hopes of eventual closure. No study has looked at conservative management of leakage after an attempted transvaginal BNC. In uretero-ileal anastomosis or abdominal BNC with fistula, it has been suggested that conservative management with continued drainage for several weeks with frequent catheter irrigations and placement of bilateral percutaneous nephrostomy tubes may lead to resolution of a fistula [12]. If a patient has a leak on cystogram with bladder filling, but is clinically dry, these patients can usually be managed with regular SPT changes monthly and do not require further intervention unless the fistula progresses and becomes clinically relevant. For a matured fistula tract, repeat surgery may be considered. The choice of transvaginal versus transabdominal versus combined approach is at the discretion of the surgeon. Those surgeons with more vaginal experience may consider a repeat transvaginal approach with or without a Martius flap. Less experienced vaginal surgeons may consider an abdominal approach or combined abdominal and transvaginal approach. If the repair is not salvageable, more invasive measures for urinary diversion may be considered including cystectomy with continent or incontinent diversion.

Complications

Fistula rates for transvaginal BNC are variable, ranging from 0% to 100% (Table 15.1) [1–3, 5, 6, 8, 10–13]. After revision, fistula rates drop to 0–25% [1, 3, 10–12]. Abdominal BNC fistula rates are notably lower with both primary repair (0–18%) and after revision (0–6%) [1, 2, 11, 12, 14, 15].

Other complications of transvaginal BNC surgery include bladder stones, SPT site leakage, SPT dislodgement requiring open SPT placement, SPT site stenosis, leakage around SPT, and wound infection. If associated bladder augmentation procedures are performed, further complications can arise including intestinal fistulae, stomal stenosis, small bowel obstruction (SBO), and poor bladder compliance.

Summary

Overall, transvaginal closure of the bladder neck is well tolerated and carries less morbidity than an abdominal approach; however, patients may require more than one procedure to achieve continence.

Table 15.1 Comparison of complication rates of transvaginal and transabdominal BNC

Author	Approach (number of patients)	Follow-up	Complications	Fistula rate
Zimmern et al. [13]	Transvaginal (6)			TV 0%
Nielsen et al. [8]	Transvaginal (5)	35 months (10–78)	SPT site stenosis 20%	TV 20%
Eckford et al. [3]	Transvaginal (50)	6.5 years (2–17)[a]	Bladder stones 42% Catheter blockage 79% Redo SPT 11%	TV 22% 8% after 2nd revision
Levy et al. [5]	Transvaginal (4) Combined (10)[b]	15.6 months (6–40)		TV 50% Combined 0%
Andrews et al. [1]	SPT (39) Urethral Recon (6) Transvaginal (8) Abdominal with augment(4)	4.6 years (0.5–9.5)	Bladder stones 6% SPT site leakage 6%	Urethral Recon 33% TV 50% 25% after revision Abdominal 0%
Shpall et al. [12]	Abdominal with augment (39)	36.9 months (7–173)	Stomal dysfunction 15% Wound infection 3% Retained sponge 3% Stones 13%	Abdominal 15% 3% after revision[c]
O'Connor et al. [14]	Abdominal with SPT (15) Abdominal with continent stoma (12) Abdominal with ileovesicostomy (5)	78.6 months (12–164)	Vesicocutaneous fistula 6% Enterocutaneous fistula 3% SBO 3% Stomal stenosis 9% Bladder stone 6%	Abdominal 17% 6% after revision
Stoffel et al. [11]	Transperineal (4)[d] Transvaginal (8)[d]	20 months (9.2–27)	Poor bladder compliance 8%	75% (all patients 1 procedure) TV 12.5% after revision TP 0% after revision
Spahn et al. [15]	Abdominal with continent diversion (17)	68 months (12–129)	Vesico-intestino-cutaneous fistula 6% Stomal Stenosis 24% Stones 12%	Abdominal 18% 0% after revision
Ginger et al. [2]	Transvaginal (2) Abdominal (26) Perineal (1)	38.2 months (0.9–104)	SPT dysfunction 24% Wound infection 21% SPT leakage 3% SBO 3% Urosepsis 3% Stones 10%	TV 100% Abdominal 12% Perineal 100%
Rovner et al. [10]	Transvaginal (11)	9.6 months (1–36)	Cellulitis 9%	9% 0% after revision
Willis et al. [6]	Transvaginal (35) Abdominal (29)	21 months (1–187)	Urinary stones 19% SPT obstruction 9% SPT dislodgement 5% SPT leakage7%	TV 14%, 40% after revision Abdominal 10%[e]

[a]Only 19 patients had data for review
[b]Two patients were failed transvaginal BNC
[c]One patient had spontaneous resolution of fistula
[d]Patients underwent concomitant bladder augmentation
[e]Two of three patients underwent urinary diversion with bowel interposition

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Surgical Therapy for Fecal Incontinence

16

Kelly A. Garrett

Introduction

Fecal incontinence is defined as the involuntary passage or the inability to control the elimination of stool or fecal material from the anus [1]. Incontinence can be characterized as being passive—the involuntary discharge of stool or gas without awareness, urge—the discharge of stool in spite of active attempts to retain bowel contents, or seepage—the leakage of stool following an otherwise normal evacuation. In addition, symptoms can range from mild leakage to complete loss of control of both liquid and solid stools. Nevertheless, this problem can be socially devastating and can have significant emotional and psychological impact on quality of life. Fecal incontinence is one of the most common causes of institutionalization in the elderly, and it accounts for significant expense. There is limited information regarding the economic burden of this disease, and the total costs remain difficult to measure. In a study following 63 patients with fecal incontinence, it was estimated that the average lifetime cost associated with treatment and follow-up was $17,166 per patient in 1996 with average facility charges associated with sphincteroplasty to be $8555 per procedure [2].

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The prevalence of fecal incontinence is difficult to estimate, as it is frequently underreported due to embarrassment and reluctance of patients to discuss symptoms with their physicians. In a recent study, more than two-thirds of women with symptoms of incontinence had never discussed their condition with a physician. The lack of care-seeking for this symptom was hindered by embarrassment, perception that symptoms are a normal part of aging, development of personal coping skills, and the perception that there is no treatment available, among other reasons [3]. Nonetheless, quoted prevalence rates vary from 1.4% to 19% with higher rates in nursing home residents, parous females, patients with cognitive impairment or neurologic disorders, and the elderly [3–6]. Even though it is primarily a problem in the elderly population, younger groups are affected as well. Obstetric factors can be implicated in this latter group as the incidence of temporary or permanent fecal incontinence after vaginal delivery can reach 3% or more [7]. This population, however, is complex because although we know that anal sphincter injury is an important factor, it has been shown that mode of delivery does not affect the prevalence of fecal incontinence [8].

Although it is difficult to estimate the exact incidence and prevalence of this condition, we know that the causes are many times multifactorial. Continence depends on many elements such as colonic transit, stool consistency, rectal reservoir function, anorectal sensation, muscle

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innervation, and internal and external sphincter muscle function. Interfering with one or more of these factors can lead to issues with incontinence.

Etiology

Obstetric Injury

Obstetric injury is the most commonly cited cause of incontinence in females [9]. At 3–6 months after delivery, as many as 13–25% of women report fecal incontinence [10, 11]. However, the prevalence falls to 1–6% by 12 months postpartum [12, 13]. Sphincteric injury is clinically recognized in approximately 10% of all vaginal deliveries but many other women may have unrecognized damage to the sphincter. Risk factors for sphincteric disruption include forceps delivery, occipitoposterior position, a prolonged second stage of labor, mediolateral episiotomy, and primiparity [14–16]. Additionally, as touched upon previously, women who give birth vaginally and do not suffer a sphincter laceration, and even those who undergo cesarean delivery, may also develop fecal incontinence [8, 17]. This may be related to pelvic floor denervation resulting from compression or traction injury to the pudendal nerves.

Congenital

Anorectal malformations represent a spectrum of defects that are characterized by absence of an external anal orifice. They are categorized as being low (perineal fistula, vestibular fistula) or high (rectourethral fistula, rectovesical fistula, anal atresia without fistula, rectal atresia, or persistent cloaca). Anorectal malformations occur in approximately 1 in 5000 live births. Operative procedures depend on the type of deformity but the goal is to create a perineal opening with adequate sensory and motor control [18]. Even with adequate surgical repair, it is well known that these patients have many issues with pelvic floor dysfunction characterized by constipation and fecal incontinence as well as urinary and sexual dysfunction [19, 20]. Reported rates of incontinence vary, but in a large retrospective study from Germany, complete continence was found in only 27% of patients and 74% of patients had some degree of soiling. Only approximately 50% of this cohort followed a bowel management program consisting of enemas, suppositories, and/or anal plugs and still more than 80% of these patients had persistent soiling [20].

Iatrogenic

Fecal incontinence is a common sequela of anorectal surgery. The most common procedures to cause symptoms of incontinence are those for anal fissure and for fistula-in-ano. Although both of these procedures involve cutting some degree of sphincter muscle, the mere use of an anal retractor can cause damage to the internal sphincter muscle with resultant postoperative seepage or leakage of stool.

The theory behind treatment for anal fissure is reduction of elevated sphincter tone. The first line of treatment is usually medical treatment such as topical nitroglycerin, topical calcium channel blocker, or botulinum toxin injection. When conservative treatment fails, surgical treatment is usually indicated. The most common surgical procedure to treat this condition is lateral transection of the internal sphincter muscle or lateral internal sphincterotomy. This procedure is highly effective for treatment of anal fissure but fecal incontinence is a reported complication. In a study from Brazil, it was noted that the rates of incontinence were decreased depending on the amount of internal sphincter muscle that was divided. When less than 25% (<1 cm) of the sphincter muscle was divided, there were no patients who suffered from postoperative fecal incontinence [21].

Perianal infections or abscesses are one of the most common benign anorectal disorders treated by colon and rectal surgeons. Of all patients who present with an initial perianal abscess, up to one-third will develop a chronic or recurrent anal fistula [22]. Although the principal goal is to

eradicate the fistula and minimize the risk of recurrence, it is also important to preserve continence. There are many different surgical procedures available to treat anal fistulas. The most effective procedure is fistulotomy which entails division of a variable degree of anal sphincter muscle. Although the success rate for this procedure can approximate 90%, postoperative incontinence has been noted in up to 40% of patients. Patients who are predisposed to incontinence include those with baseline incontinence, patients with a history of anal operations, women with anterior-based fistulas, and patients with high tracts involving a significant amount of sphincter muscles [23–25].

Procedures other than anorectal surgery can result in incontinence. Although the vast majority of patients with rectal cancer can now be treated with sphincter sparing procedures, there is still frequently postoperative compromise of anorectal function. While sphincter function may be preserved, capacity of the neo-rectum, maximum tolerable volume, and rectal compliance may be reduced resulting in an increased stool frequency and episodes of incontinence. Postoperative continence is even poorer if treatment with radiation and chemotherapy is used [26].

Neurogenic

Denervation of the pelvic floor muscles, specifically the puborectalis and the external anal sphincter, has been described in up to 80% of patients with idiopathic fecal incontinence. Descending perineal syndrome has been implicated in this denervation. Similar to the mechanism causing postpartum pudendal neuropathy, chronic straining for stool can also cause traction injury to the perineal branches of the pudendal nerve. A vicious cycle then results in further weakness of the pelvic floor and the subsequent need for more straining. This theoretically leads to denervation causing incontinence [7, 27].

Spinal cord injuries and neurologic conditions can also cause incontinence. The pathophysiology leading to incontinence in these patients is complex. Colonic transit time is prolonged leading to constipation and often fecal impaction. The ability to voluntarily contract or relax the external anal sphincter is absent or reduced while the function of the internal sphincter muscle is normal. When the rectum is full the internal sphincter will relax; however, the patient may be unable to completely relax the external anal sphincter. This may contribute to constipation and impaction. This, in combination with an intact rectoanal inhibitory reflex (RAIR), leads to leakage of liquid stool around hard impacted stool in the rectum and incontinence [28].

Rectal Prolapse

Rectal prolapse can be associated with constipation or incontinence. Approximately 50–75% of patients with rectal prolapse report fecal incontinence [29]. The pathophysiology causing incontinence is multifactorial. The prolapsed rectum causes chronic stretching of the anal sphincter muscles, inhibition of the internal anal sphincter muscle due to constant stimulation of the RAIR, mechanical disruption of the sphincter, impairment of anorectal sensation, and denervation of the pelvic floor muscles [7]. Improvement of continence after surgical correction of prolapse occurs in approximately two-thirds of patients [29, 30].

Assessment

As with any diagnosis, a proper and complete history and physical examination is necessary. In the case of fecal incontinence, concentration is mainly toward the perineal exam. Patients are examined in the left lateral decubitus or the prone jackknife position. First external inspection is performed. Observation should be made if the patient wears a pad, what is on the pad, and if there is stool externally on the skin. Documenting the presence of previous surgical scars or evidence of a previous obstetric injury is necessary. Inspection should be made for fistulous openings or any other significant deformities. Notation should be made if the anus is patulous or open when the buttocks are separated.

With the patient bearing down, the physician should inspect for hemorrhoidal, mucosal, or full-thickness rectal prolapse. While straining, if the perineum balloons down, this indicates weakness of the pelvic floor or in more severe cases descending perineum syndrome.

Digital rectal exam should assess resting anal sphincter tone which is a function of the internal sphincter. With the finger in the rectum, the patient should be asked to squeeze simulating their ability to hold in a bowel movement. Assessment can be made if the squeeze is normal, decreased, poor, or absent which will determine external sphincter function. The examiner can feel the amount and consistency of stool in the rectum or if the patient is impacted with hard stool. Digital exam may reveal a rectocele by pushing the anterior wall of the rectum anteriorly and downward into the vagina. By performing a bimanual exam with a finger in the vagina and the rectum, the thickness of rectovaginal septum can be evaluated. By asking the patient to squeeze and then bear down, one can determine for the presence of anismus or paradoxical contraction.

Anoscopy, proctoscopy, or flexible sigmoidoscopy can be performed in the office to look for inflammation or proctitis. This can explain symptoms of diarrhea or significant mucus production. Other pathologies can cause significant mucus production such as a solitary rectal ulcer which can frequently be found in patients with rectal prolapse or internal intussusception or large villous adenomas. Findings during physical examination should be described and recorded properly. Other studies can be ordered or added as adjuncts to physical examination on an as-needed basis.

Physiologic Testing

Anorectal Manometry

Anorectal manometry provides an objective assessment of anal sphincter resting and squeeze pressures as well as an evaluation of rectal sensation, rectoanal reflexes, and rectal compliance. There are different types of systems available including a water-perfused probe with multiple closely spaced sensors or a solid-state probe with micro-transducers. The latter tend to be easier to calibrate and possibly more accurate [31–33]. Although manometry gives a reliable, reproducible, and objective assessment of anal sphincter function, the findings do not consistently correlate with severity of fecal incontinence. Anal pressures in normal individuals have a large range and vary with age and gender. Patients with low values may be continent whereas high pressures do not guarantee continence. Nevertheless, the test may influence management decisions, but it may not reliably predict postoperative results.

Pudendal Nerve Terminal Motor Latency

Pudendal Nerve Terminal Motor Latency (PNTML) measurement is an assessment of pudendal nerve function. This test can be performed in conjunction with anal manometry and specifically measures neuromuscular integrity between the terminal portion of the pudendal nerve and the anal sphincter (Fig. 16.1) [1].

This test employs a disposable electrode that is placed around the gloved fingertip and inserted into the rectum. Transrectal stimulation of the pudendal nerve is performed while measuring the time from electrical stimulus of the pudendal nerve to the onset of the electrical response in the muscles of the pelvic floor. Prolonged PNTML indicates pudendal neuropathy. Unfortunately, normal latencies do not exclude nerve injury as only the fastest remaining conducting fibers are recorded [34]. In addition, there can be anatomic overlap of the pudendal innervation on both sides of the external anal sphincter [35].

Endorectal Ultrasound

In women with suspected obstetrical injury or patients who have a history of anorectal procedures, endorectal ultrasound is a simple test for defining defects in the internal and external anal sphincter muscles. The most frequently used instruments have a 360° rotating transducer and

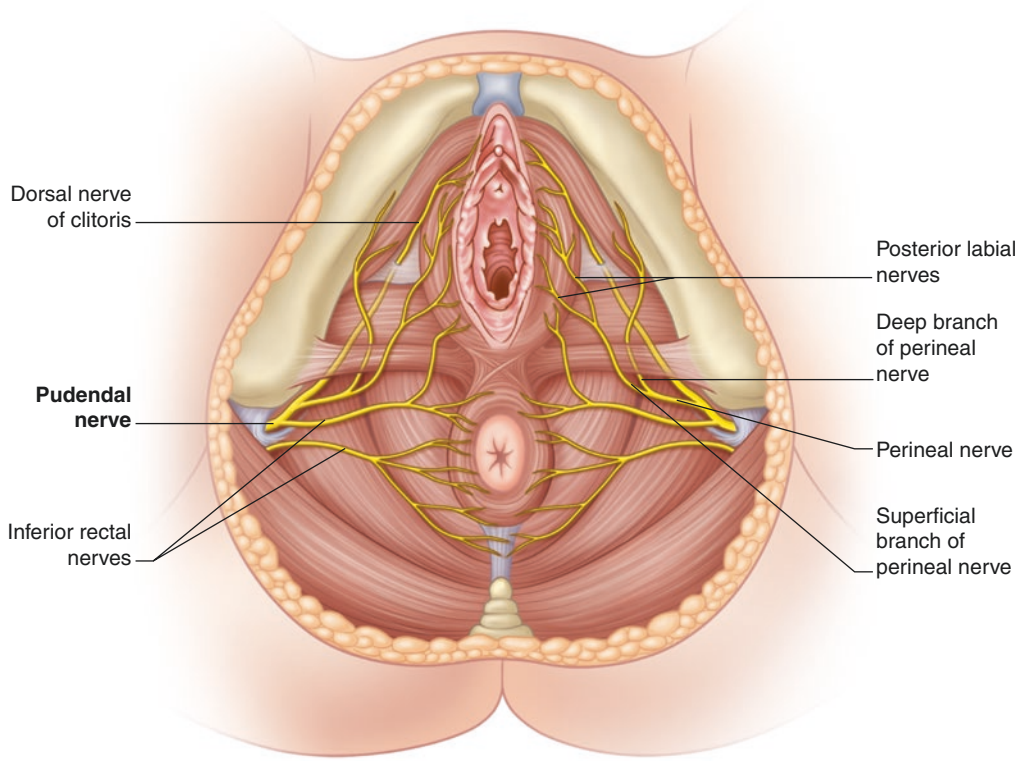

Fig. 16.1 Anatomy of pudendal nerve

work with 7 or 10 MHz. More recently, three-dimensional probes have become popular. Both sphincters can be visualized and length and width can be determined. Atrophy, scar tissue, and defects in the sphincters can also be seen [18] (Fig. 16.2). This technique, similar to ultrasound in other areas of the body, is operator dependent and requires training and experience. However, when performed by an experienced clinician, this test approaches 100% sensitivity and specificity in identifying sphincter defects [36–38].

Defecography

Defecography can be performed under fluoroscopy or using magnetic resonance imaging (MRI). Both techniques involve filling the rectum with either a barium paste in the case of fluoroscopic imaging or ultrasound gel in the case of MRI. Static images at rest and during squeezing and pushing allow measurement of the anorectal angle (Fig. 16.3a, b), perineal descent, and anal canal length. It has been demonstrated that the anorectal angle is increased in pelvic floor denervation as a sign of pelvic floor weakness. However, there is wide interobserver variation in the measurement of the anorectal angle which perhaps makes quantification of limited clinical value [18]. Rectal intussusception, full-thickness prolapse, rectoceles, and enteroceles can also be observed. Fluoroscopic defecography tends to be a better test in some cases since the patients are sitting up in the actual position in which one normally defecates, whereas during MR defecography the patient is lying supine and it is often difficult to evacuate the gel in this nonphysiologic position. In addition, although both tests can detect a number of abnormalities, these abnormalities can also be seen in otherwise asymptomatic individuals and their presence often correlates poorly with impaired evacuation [39, 40].

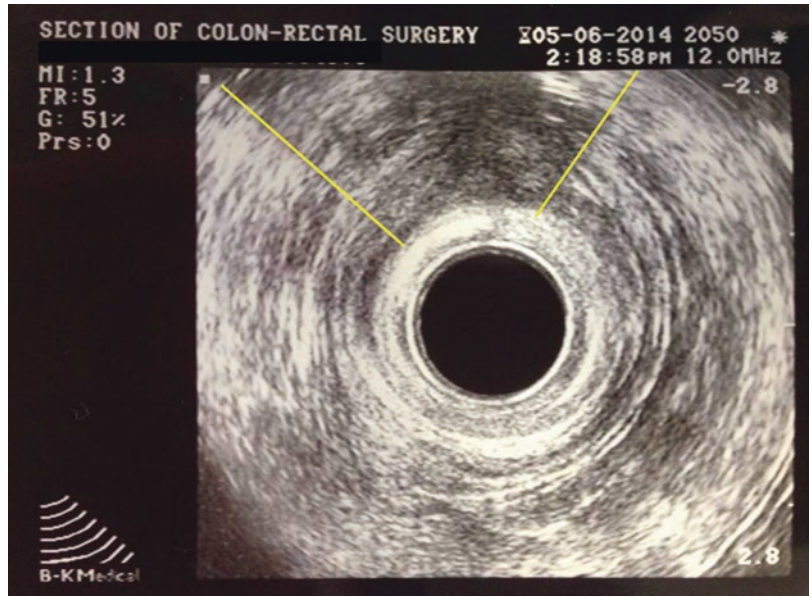

Fig. 16.2 Endorectal ultrasound demonstrating an external sphincter defect

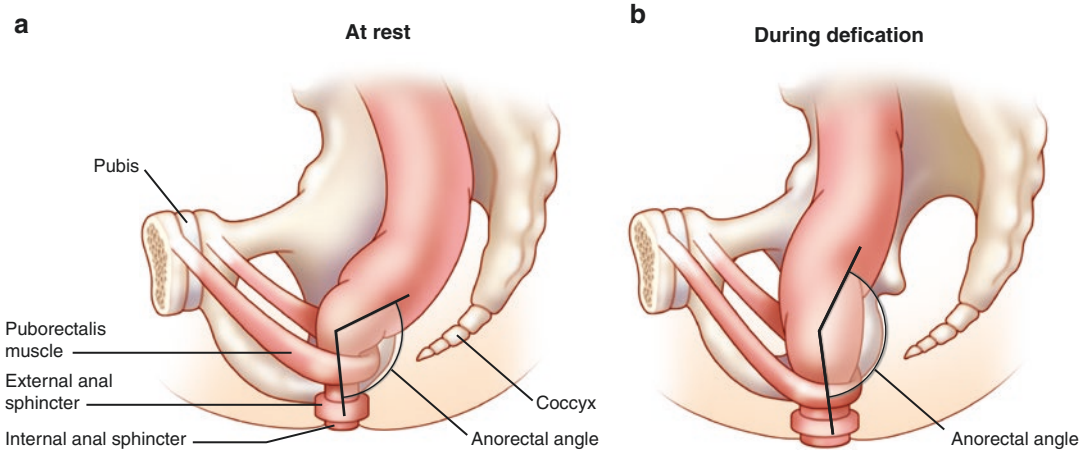

Fig. 16.3 (**a**, **b**) Normal anorectal angle at rest (**a**) and with straining (**b**)

Treatment

Medical

After a complete history and physical examination with the addition of necessary physiologic tests, supportive measures are frequently the first approach. It is recommended for patients to keep a bowel and food diary to try and identify offending agents. For patients with diarrheal stool, one would have patients cut lactose and dairy out of the diet to evaluate for possible triggers. Trying to promote a regular ritualized bowel habit is also important. Oftentimes, patients will not empty their rectum completely and residual stool in the rectum may seep or leak out. In these cases, bowel management programs and a regular enema may be useful to promote more complete evacuation. This type of regimen is especially helpful in patients with spinal cord injuries. In patients with loose or segmented stools, a fiber supplement is often recommended. Fiber helps to bulk the stool and promote complete emptying all at once as opposed to having to go back and forth

to the bathroom several times. Unfortunately, fiber supplements can potentially worsen diarrhea by increasing colonic fermentation.

For patients with liquid or even mushy stools, Loperamide (Imodium®—McNeil Consumer & Specialty Pharmaceuticals, Fort Washington, PA) and diphenoxylate/atropine (Lomotil®—Pfizer, New York, NY) can produce modest improvement in symptoms related to fecal incontinence. A placebo-controlled study of loperamide 4 mg TID has been shown to reduce the frequency of incontinence, improve stool urgency, increase colonic transit time, reduce stool weight, and interestingly, increase anal resting sphincter pressure [41–43]. Other medications that can be used are Codeine sulfate, which can cause drowsiness and addiction, or Cholestyramine (Questran®—Par Pharmaceuticals Inc., Spring Valley, NJ), which is a bile acid–binding agent (Table 16.1).

Biofeedback

Behavioral therapy using "operant conditioning" techniques has been shown to improve bowel function and incontinence [44]. The main principle is that patients acquire new and better behaviors through a process of trial and error. The goals of biofeedback are to improve the strength of the anal sphincter muscles, improve the coordination between the abdominal, gluteal, and anal sphincter muscles, and enhance the anorectal sensory perception [1]. The benefit is variable, but improvement in as many as 64–89% of patients has been reported [45, 46]. Careful selection of patients is crucial and includes factors such as motivation, ability to understand instruction, some rectal sensation preservation, and ability to contract the external anal sphincter voluntarily [47].

Anal Plugs

The anal plug enables controlled evacuation and helps reduce skin complications by temporarily occluding the anal canal. The plug is attached to the perineum using tape and can easily be retrieved. It is effective in controlling incontinence in a minority of patients who can tolerate its use [14].

Surgical Modalities

Surgery should be considered in selected highly symptomatic patients who have failed conservative measures.

Table 16.1 Classification of antidiarrheal medications

Category	Mechanism of action	Medication
Adsorbents		
Fiber supplements	Adsorbs water	Psyllium husk (Metamucil®)
	Reduces fecal water content	Methylcellulose (Citrucel®)
	Increases consistency of stool	Guar gum
		Calcium polycarbophil (FiberCon®)
		Wheat dextrin (Benefiber®)
Bile acid sequestrant	Forms insoluble complexes with bile acid	Cholestyramine (Questran®)
	Makes bile acids osmotically inactive	
Antispasmodics	Decreases motility	Opioids (Codeine sulfate)
	Slows passage of stool	Diphenoxylate/atropine (Lomotil®)
	Allows more time for salt and water to be absorbed	Diphenoxin/atropine (Motofen®)
		Loperamide (Imodium®)
	Inhibits hormonal secretion	Octreotide acetate (Sandostatin®)
	Decreases motility	
	Decreases secretion	
Anti-inflammatory	Stops expulsion of fluid into the bowel lumen by coating the mucosa	Bismuth subsalicylate (Pepto-Bismol® and Kaopectate®)
	Reduces inflammation/irritation of the intestinal mucosa	
	Antibacterial	

Anal Encirclement Procedures

Anal encirclement was originally described by Thiersch in 1891 for the treatment of complete rectal prolapse. This was later adopted for the treatment of fecal incontinence. A variety of materials have been used for this procedure including nylon, silk, strips of fascia, silver wire, silastic bands, and bioabsorbable materials [18, 48] (Fig. 16.4a–d). The goal of the procedure is to create a rigid barrier to the passage of stool. In general, the perioperative morbidity rate is high with a variety of complications described including fecal impaction, infection, breakage of the encircled material,

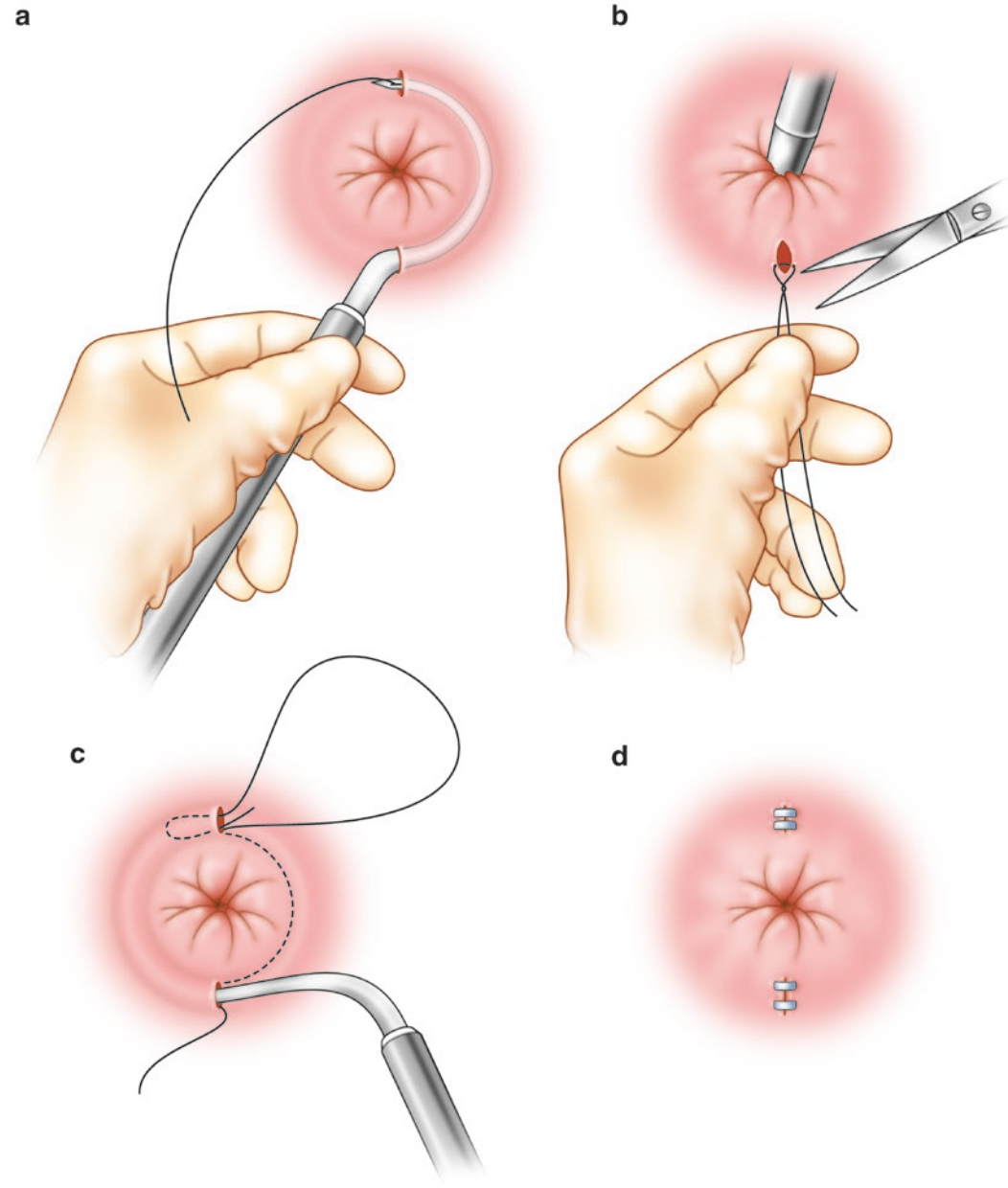

Fig. 16.4 (**a**–**d**) Anal encirclement (Thiersch) procedure

or erosion through the skin [14, 49]. This procedure has largely been abandoned because of poor results and high postoperative complication rate.

Radiofrequency

Radiofrequency energy or the Secca® procedure (Curon Medical Inc., Sunnyvale, CA) uses heat generated by a high-frequency alternating current that flows from four electrodes causing frictional movements of ions and tissue heating. This procedure is done under sedation and local anesthetic. The device is placed under direct vision into the anal canal and needles are deployed into the tissue and into the sphincter muscles. The generator then delivers energy (465 kHz, 2–5 W) at each needle electrode for 90 s or until the temperature reaches 85 °C. The mucosa is constantly cooled by chilled water at the base of each needle. There is constant temperature monitoring and feedback to control the amount of energy delivered to tissue. The therapeutic goal is to create thermal lesions or a controlled scar in the muscle while preserving mucosal integrity. There are variable results in the literature. In a study by Ruiz et al., of 24 patients who underwent the procedure, 16 were available for follow-up. The mean treatment time was 46 min and the number of radiofrequency lesions in the anal canal varied from 31 to 80. Four patients (25%) experienced minor complications including bleeding, diarrhea, and constipation. Four patients (25%) had worsening of their incontinence and two patients (12.5%) had no improvement. Overall, 10 of 16 patients (62.5%) had improvement but still had moderate incontinence at 1-year follow-up [50]. The exact mechanism of this procedure is not known. No consistent changes in anal manometry or anorectal ultrasound have been reported [51–53]. More studies are needed to determine which patients would benefit from this minimally invasive treatment.

Bulking Agents

Injection of bulking agents has emerged as a new treatment for fecal incontinence following success that has been reported in treating urinary incontinence. Many different injectable materials have been used including autologous fat, Teflon, bovine glutaraldehyde cross-linked collagen, carbon-coated zirconium beads (Durasphere®), polydimethylsiloxane elastomer, dextranomer in nonanimal stabilized hyaluronic acid (NASHA™ Dx), hydrogel cross-linked with polyacrylamide hydrogel (Bulkamid), porcine dermal collagen (Permacol), silicone biomaterial (PTQ™), synthetic calcium hydroxylapatite ceramic microspheres, and polyacrylonitrile in cylinder form. These materials can be injected in different ways including through the perianal skin into the intersphincteric space or through the anal mucosa into the submucosa. Injection can be guided digitally or can be done under ultrasound guidance [54].

The goal of injection is to bulk up the tissue inside the anal canal in order to approximate the anal mucosa. In doing so, this should close the anal canal or raise the pressure inside the anal canal to prevent leakage of stool. Studies looking at the results of this treatment are limited. There is lack of information regarding the volume of injection, ideal site of injection, and the route it should be injected. One large randomized trial comparing NASHA™ Dx to sham injections demonstrated that NASHA™ Dx is efficacious in the treatment of fecal incontinence with a follow-up of 12 months [55]. There are no studies looking at long-term benefit. In a review of all the studies published to date, the injection of bulking agents appears relatively safe; however, minor adverse events are relatively common (discomfort, pain, bleeding, abscess, and leakage of injected material) [54, 55].

Overlapping Sphincteroplasty

Overlapping sphincteroplasty is offered to highly symptomatic patients with an anterior external anal sphincter defect secondary to an obstetric or iatrogenic trauma. The procedure typically involves a full mechanical bowel preparation and pre-procedure intravenous antibiotics. A transverse incision is made over the perineum. Dissection is carried up to the level of anorectal ring and the anal mucosa is separated from the sphincter complex. Care is taken not to carry the dissection too far laterally as

the nerve supply to the external anal sphincter enters posterolaterally. The fibrous remnant of the external anal sphincter is then divided. End-to-end repair has been described but retraction of the ends of the muscle and lack of a bulking effect because of excision of the scar tissue have been implicated in the suboptimal results [56].

For overlapping repair, the scar at the ends of the sphincter is preserved to aid in anchoring the sutures. The ends of the mobilized external sphincter are overlapped and sutured together with absorbable mattress sutures. Plication of the internal anal sphincter may be concurrently performed. Anterior levatorplasty and closure of the perineal incision in a V–Y manner can help to bulk up the perineal body and increase the anovaginal distance. Typically, the wound is left partially open to promote drainage [18]. Satisfactory results, which are defined as continence for solid and liquid stools, have been reported in 70–100% of patients [7]. However, the majority of patients will not have perfect continence, and many patients will have residual symptoms. Some patients may even develop new evacuation problems [57]. The most important factor in the return of normal sphincter function seems to be an increase in squeeze pressures [58]. Poor outcome is usually associated with pelvic floor denervation or a residual sphincter defect [59, 60].

In a study looking at functional results of sphincter repair after a median of 10 years, none of the patients were fully continent to flatus or stool [61]. Reasons for failure or decline of continence can be explained by weakening of the muscle because of normal aging, repair breakdown, or a combination of these factors [62]. Repeat sphincter repair can be performed in patients with recurrent symptoms, especially if breakdown of the repair is verified on endoanal ultrasound. It has been demonstrated that the long-term results of a repeat sphincter repair are approximately equivalent to those for primary overlapping sphincter repair [63].

Postanal Repair

Postanal repair was first described by Sir Alan G. Parks in 1975 [64]. This technique was described specifically for idiopathic or neurogenic incontinence and for incontinence following surgery for the repair of rectal prolapse. These conditions are associated with lengthening of the anorectal angle and shortening of the anal canal as a consequence of sphincter denervation [7]. The procedure is also advocated for patients with "weak" sphincters but no anatomic sphincter defect [14].

The procedure is performed through a curved incision posterior to the anus with dissection through the intersphincteric space, through Waldeyer's fascia, and into the pelvis. The iliococcygeus, pubococcygeus, and puborectalis muscles are plicated using a series of polypropylene sutures. Further plicating sutures can be placed in the deep and superficial parts of the external anal sphincter muscle using polyglactin suture [18]. The goals of the procedure are to restore the anorectal angle and to tighten the anal sphincter muscle. Although Parks reports successful outcome in approximately 80% of patients, these results have not been reproduced [7]. The mechanism of restoration of continence is unclear as the anorectal angle does not change significantly following this procedure and the manometric evaluation of sphincter function is variable [65, 66]. Improvement after this procedure may be caused by creation of a local stenosis or a placebo effect rather than improvement of muscle function [18].

Muscle Transposition

The most common skeletal muscle used in transposition techniques is the gracilis. Gracilis muscle transposition was first described by Pickrell in 1952 [67]. The muscle is freed from its insertion, completely mobilized, and subcutaneously tunneled to the perineum. It is then wrapped around the anus and anchored with sutures to the contralateral ischial tuberosity or the inferior ramus of the pubic bone. The gracilis muscle is mostly composed of type two muscle fibers that are short-acting and fast-twitch fibers. Therefore, the muscle is fatigable and only contracts by will. Dynamic graciloplasty combines gracilis muscle transposition with an implantable electrical stim-

ulator. This applies chronic low-frequency stimulation which functions to change the composition of the muscle to long acting, slow twitch, nonfatigable, type one muscle fibers. The procedure has a variable success rate with reports as high as 72%. Given the steep learning curve of this technique, there is a high complication rate. Most complications are minor, but infection and rectal perforation are described [68]. Unfortunately, this has not been approved for use in the United States. Other muscles that have been transposed include the gluteus maximus muscle [69], pubococcygeus [70], transverse perineal muscle [71], and even the antropylorus [72]. Free muscle transplantation has also been described [73].

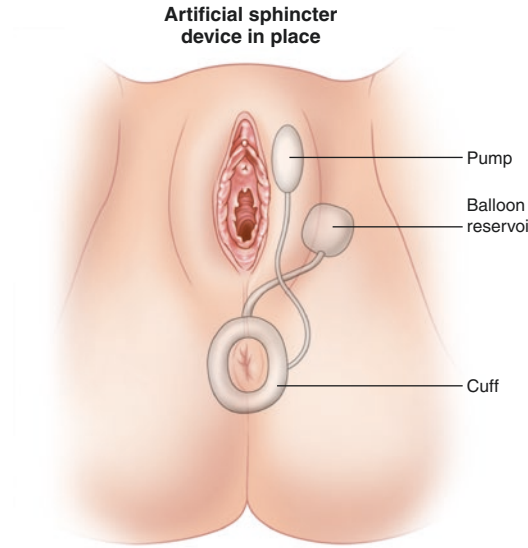

Fig. 16.5 Illustration of the implantation of the artificial bowel sphincter

Artificial Bowel Sphincter

The artificial bowel sphincter (ABS) was adapted from the artificial urinary sphincter which was introduced in 1972 by American Medical Systems (AMS). In 1987, the first description of the use of the artificial urinary sphincter was reported for fecal incontinence. The patient had an excellent result with no complications at a follow-up of 3 months [74].

Since then, modifications have been made to the artificial urinary sphincter to make it more applicable for use around the anus which culminated in the development of the Acticon Neosphincter™ (AMS, Minnetonka, Minnesota). The procedure involves encirclement of the anus with an implantable fluid-filled, silicone, elastomer cuff that is connected by tubes to a control pump and a pressure-regulating balloon. Cuff lengths range from 7 to 14 cm with three cuff widths of 2, 2.9, and 2.4 cm. The control pump is implanted in the labia or the scrotum and the balloon is implanted in the space of Retzius. The inflated cuff compresses the anus all the time. When the patient has to defecate, the fluid is manually pumped from the cuff to the balloon by using the control pump. The empty cuff allows the passage of stool and then the pressure in the balloon sends the fluid back into the cuff (Fig. 16.5).

In a multicenter, prospective, nonrandomized clinical trial looking at 115 patients, 6 patients were aborted because of perforation. Device-related complications were reported in 86% of enrolled patients. Forty-six percent of patients required device revisions to treat major adverse events including infection or erosion and 36% required explantation. At the end of the follow-up period of 1 year, 75 of 112 patients (67%) had functioning devices [75].

The magnetic anal sphincter (MAS) (FENIX™; Torax Medical Inc., Shoreview, MN) is a novel artificial sphincter mechanism which was recently described. This was originally used in the treatment of gastroesophageal reflux disease. This device is composed of a series of titanium beads with magnetic cores inside. The beads are interlinked with titanium wires to form a flexible ring that is implanted around the external sphincter in a circular fashion. The device is manufactured in different lengths based on the number of beads (14–20) [76].

One major advantage of this device in contrast to the ABS is that it works immediately once implanted without the need for further manipulation by the patient or the surgeon. The device is passively activated by the passage of stool and it automatically retracts back to its closed size after evacuation. In a study comparing ten patients

implanted with the ABS and ten patients implanted with the MAS, there was similar 30-day complication rate but the procedure for MAS was shorter in duration with a shorter length of hospitalization [77]. Of note, this device has received European CE Mark approval for the treatment of fecal incontinence but is not available in the United States and is only limited to investigational use.

Sacral Nerve Stimulation

In 1988, Tangaho and Schmidt described the use of electrical stimulation for the treatment of neurogenic bladder [78]. Following that in 1995, Matzel et al. described its use in three patients for the treatment of fecal incontinence [79]. Since then, sacral nerve stimulation (SNS) has been advocated as a safe and effective treatment for severe fecal incontinence with minimal morbidity [80–82]. SNS has been shown to be more effective than optimal medical therapy and a placebo effect has been eliminated [83, 84]. The device has also proven to be beneficial in patients with idiopathic fecal incontinence as well as those with sphincter defects and also pudendal neuropathy [83, 85].

After a prospective multicenter study, SNS was FDA approved in the United States in 2011 for the treatment of fecal incontinence. This study looked at 120 patients who received an implant. After a mean follow-up of 28 months, 85% of patients were improved and 40% had perfect continence [86]. Although no studies have been done in the United States with regard to cost, the procedure has been shown to be cost-effective in other countries [87–89].

Diversion

Although considered as the last option in the surgical strategy, construction of an end diverting colostomy may be indicated in certain patients in whom available treatments have failed, are inappropriate because of other comorbidities, or when preferred by the patient [14]. A stoma may be successful in controlling symptoms of incontinence but it may also be associated with significant psychosocial issues and stoma-related complications. As a stoma in this instance will most likely be permanent, it is important for the patient to be marked preoperatively by an enterostomal therapy (ET) nurse and also receive teaching and counseling prior to undergoing the procedure.

In patients with severe fecal incontinence, a stoma will improve quality of life in the majority of patients. In a survey, 83% of patients with a permanent colostomy for incontinence reported a significant improvement in lifestyle and 84% would choose to have the stoma again [90].

Conclusion

Fecal incontinence is an underreported condition for many reasons including embarrassment and unawareness of both physicians and patients to the available treatments. A detailed medical surgical, obstetric, and bowel history should be obtained. A thorough rectal exam combined with appropriate physiologic, endoscopic, and radiologic tests should be performed. Treatments are individualized to the particular patient. Emerging therapies for the treatment of fecal incontinence are promising and may avoid or even supplant traditional surgical procedures such as overlapping sphincteroplasty. The majority of patients can avoid a diverting stoma.

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Botulinum Toxin Therapy for Voiding Dysfunction

17

Ricardo Palmerola and Benjamin Brucker

Introduction

Botulinum toxin is a neurotoxin which is produced by the gram-positive bacteria *Clostridium botulinum* and has been utilized therapeutically since the 1980s. Botulinum toxin exerts its effects at the presynaptic nerve terminals by inhibiting the release of the neurotransmitter acetylcholine. There are numerous subtypes of the toxin used in clinical practice; however the subtype most familiar to urologists and urogynecologists is onabotulinumtoxinA. Botulinum toxin is available in different commercial forms which are molecularly distinct and thus differ in their pharmacologic properties. As such, they are not interchangeable in terms of potency and dosage. Three readily available commercial products used globally include onabotulinumtoxinA (BOTOX®, Allergan, Inc., Irvine, CA, USA) (Fig. 17.1), incobotulinumtoxinA (Xeomin®, Merz Pharma GmbH & Co KGaA, Frankfurt am Main, Germany), and abobotulinumtoxinA (Dysport®, Ipsen Biopharmaceuticals, Inc., Basking Ridge, NJ, USA). The following chapter will discuss the use of onabotulinumtoxinA (BOTOX®) as it relates specifically to the field of urology and female pelvic medicine and reconstructive surgery.

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Mechanism of Action

Botulinum toxin is a molecule consisting of a heavy chain and a light chain which are bound by a disulfide bond. The heavy chain of onabotulinumtoxinA binds to the secretory vesicle protein SV2, which is active and exposed to the synaptic cleft during exocytosis [1] (Fig. 17.2). The molecule is then internalized by the process of receptor-mediated phagocytosis. The two chains' disulfide bonds are broken down, and the light chain is released into the neuron's cytosol where it disrupts the fusion of the presynaptic vesicles from releasing the neurotransmitter acetylcholine. Several proteins are involved in vesicle-mediated neurotransmission and collectively form the SNARE complex. OnabotulinumtoxinA specifically targets and cleaves the synaptosomal nerve-associated membrane protein 25 (SNAP-25), which ultimately defunctionalizes the protein complex. By the disruption of the SNARE complex, onabotulinumtoxinA prevents the docking of vesicles transporting acetylcholine to the nerve ending, therefore preventing its release into the synaptic cleft. Interestingly, both molecular targets for onabotulinumtoxinA, SNAP-25 and SV2, are located ubiquitously throughout the parasympathetic nerves [2, 3]. In the lower urinary tract, parasympathetic stimulation of the detrusor muscle by acetylcholine stimulation of M2–3 receptors is largely responsible for detrusor contraction (Fig. 17.3). Therefore, acetylcholine release inhibition by onabotulinumtoxinA is thought to contribute to the

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Fig. 17.1 OnabotulinumtoxinA 100 unit and 200 unit vials (BOTOX®). (Courtesy of Allergan, Inc., Irvine, CA, USA)

desired clinical effects (in the case of detrusor overactivity) of "calming" the contraction of the bladder.

OnabotulinumtoxinA also plays a role in modulating the handling of afferent stimuli in the bladder thought to be central to the pathophysiology of overactive bladder. This is accomplished by several pathways, one of which is onabotulinumtoxinA inhibiting the SNARE complex-dependent exocytosis of neuropeptides (substance P, CGRP) by the sensory nerves [4–8].

Additionally, onabotulinumtoxinA has been shown in rat models to inhibit purinergic transmission (stimulatory effect on the afferent nerves), while increasing nitric oxide release from the urothelial cells (inhibitory effect on the afferent nerves) [9]. Although evidence for these mechanisms is not as robust as the evidence supporting its role as a chemical denervating agent, clinical evidence with onabotulinumtoxinA bladder instillation has supported its effect on afferent pathways [10, 11].

Indications for Use of OnabotulinumtoxinA

Numerous medical conditions are treated with onabotulinumtoxinA, in addition to its applications in urology and female pelvic medicine (Table 17.1). Although there are several off-label uses for onabotulinumtoxinA in urology and female pelvic medicine, onabotulinumtoxinA is currently the only FDA approved for the use in adults for neurogenic detrusor overactivity (NDO) and non-neurogenic overactive bladder (OAB).

Use in Neurogenic Detrusor Overactivity (NDO)

Neurogenic detrusor overactivity (NDO) is a urodynamic observation characterized by involuntary detrusor contractions during filling cystometry in a patient with associated neuro-

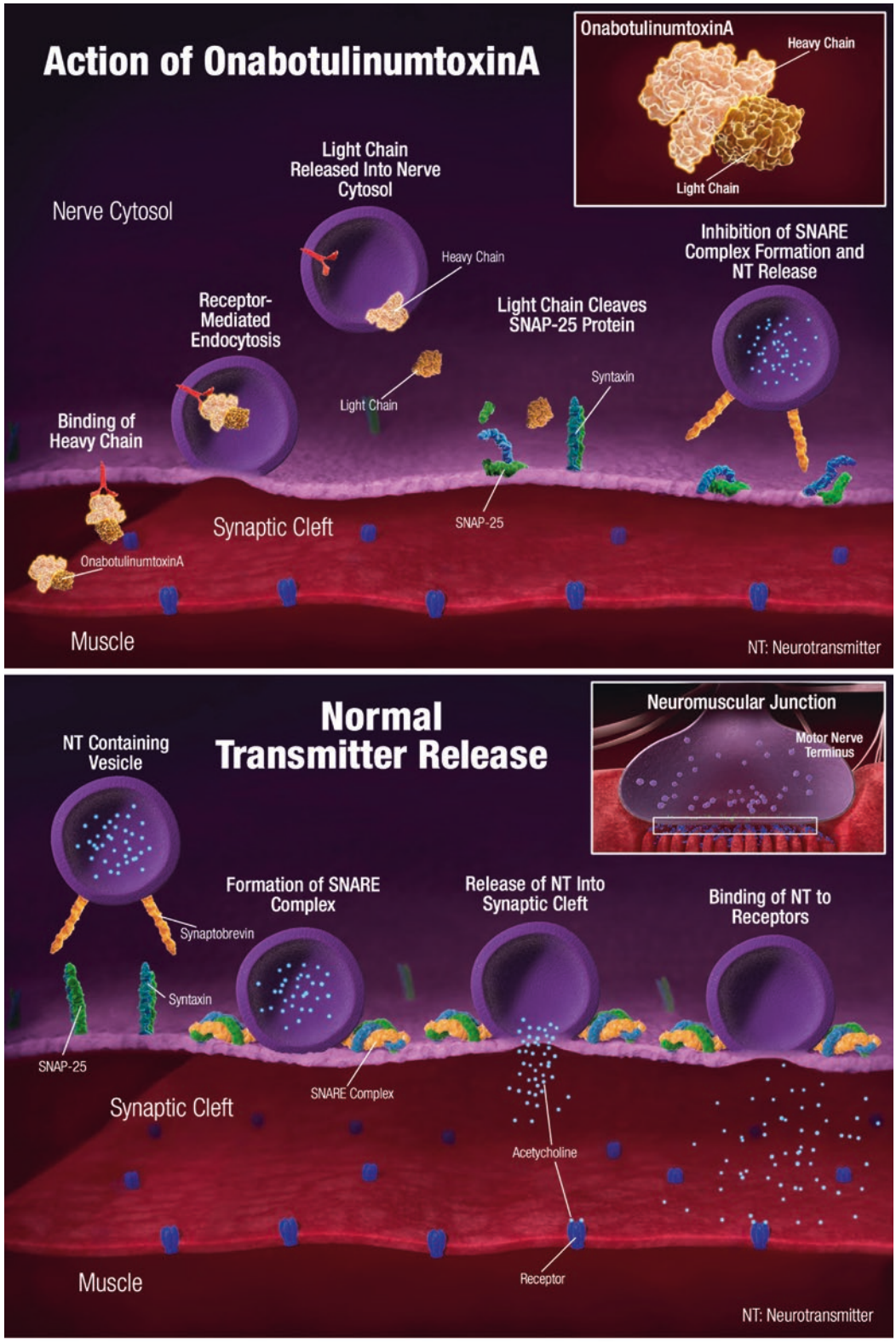

Fig. 17.2 Botulinum Toxin Mechanism of Action. (Courtesy of Allergan, Inc., Irvine, CA, USA)

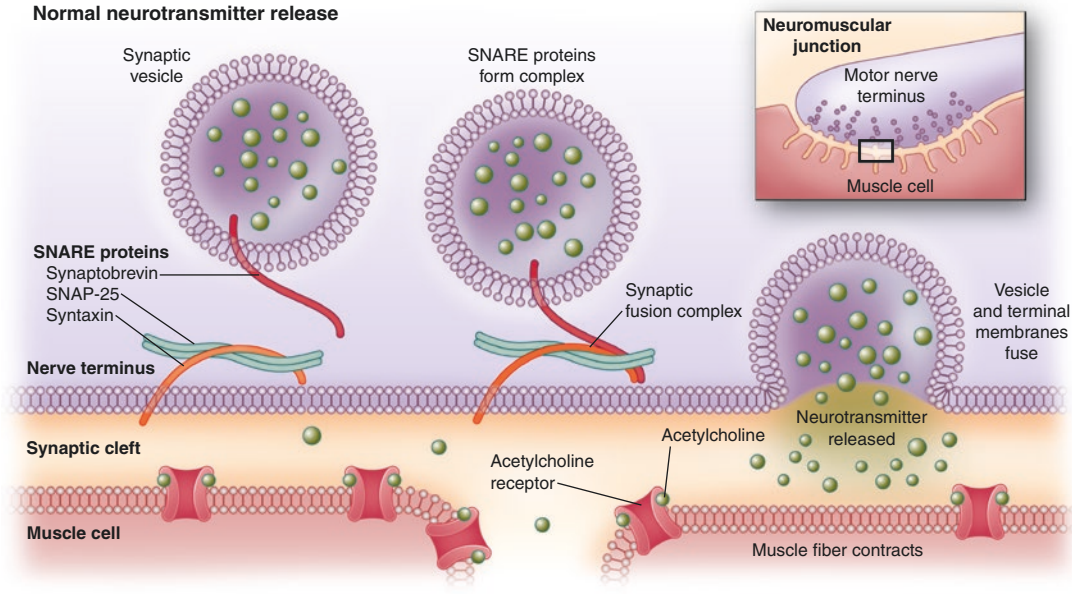

Fig. 17.3 Normal cholinergic-mediated neurotransmission at neuromuscular junction. (Courtesy of Allergan, Inc., Irvine, CA, USA)

Table 17.1 Approved conditions treated with onabotulinumtoxinA injection and recommended dosing

Condition	Dose (Units)[a]
Overactive bladder	100 U
Neurogenic detrusor overactivity	200 U
Chronic migraine	155 U
Upper limb spasticity	75–400 U[b]
Lower limb spasticity	300–400 U
Cervical dystonia	198–200 U
Axillary hyperhidrosis	100 U
Blepharospasm	3.75 U–7.5 U per affected eye
Strabismus	Variable[c]
Cosmetic	4–40 U

[a]One should not exceed injecting 400 units for any indication within a 3-month period

[b]Dose may vary depending on the muscle group injected and electromyographic (EMG) response

[c]Dose varies based on prism diopter correction and ongoing treatment response. Communication with treating physician is recommended as redosing occurs in up to half of patients

logical disease and plays a central role in the development of adult neurogenic lower urinary tract dysfunction (NLUTD) [12]. This observation is thought to be responsible for the bothersome lower urinary tract symptoms experienced by patients with various neurological diseases and includes urinary urgency, urgency urinary incontinence (UUI), frequency, and nocturia. Common neurological conditions that are associated with NDO include multiple sclerosis (MS), spinal cord injury (SCI), Parkinson's disease, and cerebrovascular accident. Up to 52% of patients with SCI or MS have urgency urinary incontinence. NDO and the associated urinary incontinence may play a deleterious role in a patient's quality of life and preservation of hygiene [13, 14]. Initially one may consider behavioral therapy in the treatment plan; however many patients will require additional forms of therapy including oral pharmaceuticals, clean intermittent catheterization (when incomplete bladder emptying is also present), botulinum toxin injection, and urinary diversion in more severe cases [15].

Initial pharmacologic therapy for patients with NDO includes anticholinergic therapy with oral medications that preferentially competitively antagonize muscarinic receptors in the bladder [15]. Various anticholinergic medications have been used to treat patients with NDO, as there is no conclusive evidence to suggest one medication over the other. However, oxybutynin is FDA

approved in pediatric patients with NDO. In general, most patients with neurogenic bladder will need high doses of anticholinergic medications in order to achieve the greatest therapeutic benefit [16, 17]. As a result, these patients may experience high rates of bothersome side effects associated with this class of medications, namely, xerostomia (dry mouth), constipation, and central nervous system-related side effects (i.e., dizziness, cognitive impairment). As is common with other medications, drug efficacy is reliant upon adherence to therapy. Various studies have investigated that drug compliance is poor with antimuscarinic therapy for idiopathic overactive bladder, and thus one must consider a similar problem in the neurogenic population [18, 19]. Alternatively, clinicians may consider the use of a beta 3 agonist for initial or second-line oral pharmacotherapy in patients with NDO. In a recent prospective, randomized, double-blind placebo-controlled study by Krhut et al., patients with SCI and MS were randomized to mirabegron 50 mg or placebo. A total of 66 patients were included in the study and the authors reported significant increases in bladder compliance, cystometric capacity, and reduced leakage as measured by a pad weight test [20]. Furthermore, patients in the treatment arm experienced a low risk of adverse effects when compared to the placebo group (6.25% v. 2.94%). These results are promising for patients with NDO; however, data are still limited. If side effects are not tolerated/acceptable or efficacy is inadequate with oral medication then one considers more advanced therapies.

The first published report on the use of onabotulinumtoxinA in the urinary tract was put forth by Dykstra et al. in 1988, where the toxin was used to treat detrusor sphincter dyssynergia in patients with spinal cord injuries [21]. After a successful nonrandomized trial using intradetrusor botulinum toxin in SCI patients, Schurch et al. published their results from the first phase 2 randomized, double-blind, placebo-controlled trial utilizing onabotulinumtoxinA injections in the bladder [22, 23]. The group randomized 53 patients with SCI and 6 with MS to receive 200 U or 300 U of onabotulinumtoxinA or placebo. Patients were followed clinically up to 24 weeks including urodynamic studies occurring 2 weeks prior to injection and then at 2, 6, and 24 weeks postinjection. Comparable to their initial trial, the investigators found significant improvements in urodynamic parameters including increased mean cystometric capacity (174 mL in 200 U group, 92 mL in 300 U group), increased reflex detrusor volume (volume at first involuntary detrusor contraction; of note, 23 patients did not demonstrate involuntary detrusor contraction on at least one follow-up visit), and decreased mean detrusor pressure during involuntary detrusor contractions (−38 cmH_2O for 200 U; − 35 cm H_2O for 300 U). Of note, the changes in baseline in cystometric capacity were higher than the placebo group at every follow-up interval with the exception of 24 weeks in the 300 U cohort. Most importantly, the investigators found that both treatment groups had significant improvements in incontinence episodes, and 49% of the treatment group (14 patients in 200 U and 10 patients in 300 U group) reported resolution of incontinence for at least 1 week. Furthermore, clean intermittent catheterization (CIC) rates remained constant throughout the study period and comparable to placebo [23]. One limitation of this study is that no clear difference between 200 U and 300 U injections was demonstrated. Subsequently, Hershorn et al. performed a multicenter phase 2 randomized, placebo-controlled trial also demonstrating efficacy in reducing incontinence episodes and improving quality of life in patients with NDO [24].

Two multicenter, placebo-controlled, phase 3 randomized controlled trials spearheaded by the DIGNITY (Double blind InvestiGation of purified Neurotoxin complex In neurogenic detrusor overactivitY) clinical research program solidified the evidence in support of the use of onabotulinumtoxinA for NDO and ultimately led to FDA approval [25, 26]. Both trials included patients with urodynamically proven NDO and a history of SCI or MS. Inclusion criteria for SCI were a history of an injury occurring at T1 and below at least 6 months prior to screening. MS patients screened had to score ≤6.5 on the Expanded Disability Status Score (the ability to walk must

be demonstrated) [25–29]. The primary endpoint for both studies was the degree in change in weekly urinary incontinence episodes from baseline to week 6. Secondary endpoints included changes in Urodynamics, Quality of Life, and adverse effects. In 2011, Cruz and colleagues performed a multi-institutional double-blind randomized controlled trial comparing 200 U and 300 U of onabotulinumtoxinA to placebo in a cohort that included 154 patients with MS and 121 patients with SCI [25]. Patients in the treatment arm had statistically significant decreases in urgency incontinence episodes as noted on 7-day bladder diaries in both the 200 U (−21.8. incontinent episodes) and 300 U (−19.4 incontinent episodes compared to placebo). Furthermore, patients in the study achieved significant dry rates in comparison to patients in the placebo arm when stratified by underlying neurological condition and dose [MS, 43%, 200 U; 41%, 300 U; SCI, 31% for 200 U, 37% for 300 U]. The study also reported on rates of urinary tract infection (UTI) and urinary retention. UTI incidence was similar across all groups in the study (placebo, 200 U, and 300 U) in the SCI population, while patients in the MS population UTIs were more common in the patients receiving onabotulinumtoxinA injections. Although the rate of UTI was high (53% for placebo, 60% for treatment group), the study did not distinguish between symptomatic and asymptomatic infections. Furthermore, roughly half of patients included in the study were performing clean intermittent catheterization (CIC) upon recruitment (52% overall, 50% in treatment group) contributing to a high rate of bacteriuria that was regarded as a UTI. Urinary retention requiring CIC increased with treatment dose (12% placebo, 30% 200 U, 42% 300 U in the first treatment cycle) and was initiated at the treating physician's discretion which may have led to higher rates of CIC than would be seen in clinical practice.

In 2012 Ginsberg et al. reported on the second trial for DIGNITY which included 416 patients, of which 227 had MS and 189 had SCI [26]. Both treatment groups achieved a statistically significant reduction in incontinent episodes documented on a 7-day bladder diary (−21 episodes for 200 U, −23 episodes for 300 U), and a significant number of patients were reportedly dry by week 6 (36% of 200 U cohort, 41% of 300 U cohort). Urodynamic diagnoses and quality of life also improved significantly in treatment groups in comparison to placebo [26]. Adverse effects were similar to the prior phase 3 trial by Cruz and colleagues, notable for de novo CIC in 35% of patients receiving 200 U and 42% receiving 300 U. UTI was the most common adverse effect, but as was observed in the aforementioned study this must be interpreted within the context of the patient population. For example, patients in the placebo arm with a history of SCI had a UTI rate of 42%, while 50% of the SCI patients with active treatment developed UTI. The high rate of UTI in this group is reflective of the prevalent use of CIC in this population. Furthermore, in the MS patient population approximately 50% of the treatment arm developed UTI in comparison to 28% of patients in the placebo arm. This, however, was likely driven by de novo incomplete bladder emptying requiring CIC and how the investigators defined "UTI." For example, applying the definition described in the study, patients developing asymptomatic bacteriuria after beginning a CIC regimen would be considered to have a UTI regardless of symptoms and subsequently influence this adverse event's rate. Data from both of these pivotal trials have been pooled by Ginsberg et al. who found significant differences in the reduction of urinary incontinence episodes, improvements in urodynamic parameters (increased cystometric capacity, reduction in detrusor pressure during involuntary detrusor contractions), improved quality of life, and patient satisfaction with both treatment doses. Interestingly, no significant difference in reduction of urinary incontinence episodes or dry rate was noted between 200 U and 300 U injections. Despite similar improvements in incontinence between both treatment doses, patients receiving 300 U injections did have a higher rate of urinary retention as well as a statistically significant difference in satisfaction after initiating CIC [30]. In addition to reporting the aforementioned common adverse events, there were no reports of respiratory compromise, MS

exacerbation, and development of neutralizing antibodies to the injected toxin.

Long-term data for onabotulinumtoxinA in NDO were reported by Kennelly et al. who published the results of a multicenter prospective trial recruiting 396 patients who had completed 1 year of the phase 3 randomized controlled trials [31]. The endpoint was the change in the mean number of incontinence episodes per week, 6 weeks after each injection. Initially patients were randomized to placebo, 200 U, and 300 U injections; however after FDA approval in 2011, all patients in the treatment arm received 200 U. Over the 4-year treatment period, daily incontinence episodes decreased (−3.2 to −4.1 per day in 200 U group) while 43–56% of patients were dry across six treatments. Similarly, the majority of patients reported greater than 11-point increases in the I-QOL (incontinence quality of life) questionnaire score, and this was consistent across time. In terms of adverse effects, de novo CIC use was 29.5% after the first treatment, while this number dropped to 3.4% with the second injection. Another important observation made in this study is the small percentage of patients who developed antibodies; 2.1% of patients were enrolled. Interestingly, the patients who developed antibodies were retreated sooner than their counterparts, undergoing repeat injection at a mean of 5 months (4 months sooner than median retreatment time or 9 months) [31]. Other groups have also reported on the long-term use of onabotulinumtoxinA including Joussain and colleagues who performed a retrospective study including 292 patients with MS, SCI, and spina bifida [32]. Their primary endpoint was failure and withdrawal rate at intervals of 3, 5, and 7 years after the initial treatment. After 3 years, 80% of the cohort continued treatment, while 71% and 60% continued treatment after 5 and 7 years, respectively. Overall the treatment remained safe throughout the study period, but one case of pseudo-botulism was reported. Leitner and colleagues also reported on the long-term use of onabotulinumtoxinA in patients with NDO [33]. Their cohort consisted of 52 patients with SCI, MS, or spina bifida who had begun onabotulinumtoxinA treatment over 10 years prior to publication. They found that despite having a 40% discontinuation rate, as one could expect over an extended follow-up period, treatment efficacy was maintained after multiple repeat injections. Of the patients who discontinued treatment, half were patients who did not respond clinically and/or urodynamically. Three patients (all had SCI) developed antibodies to onabotulinumtoxinA, which occurred after the 4th, 7th, and 8th injections.

Approximately 32% of patients with NDO fail to respond to onabotulinumtoxinA injection [34]. This presents a treatment dilemma to patients and physicians alike as alternatives, such as urinary diversion, may be undesirable options. Peyronnet et al. performed a retrospective study comparing repeated use with the same toxin versus using a different botulinum toxin A after a patient had failed to respond [35]. For patients who had received onabotulinumtoxinA initially, they were switched to receive 750 U abobotulinumtoxinA. If patients received 750 U abobotulinumtoxinA, they were switched to 200 U onabotulinumtoxinA. The authors noted a successful result in 51% of patients who had a switch, in comparison to 24% success in those who remained on the same dose and toxin. A similar study by Bottet and colleagues studied a cohort of 57 onabotulinumtoxinA failures which were all switched to 750 U abobotulinumtoxinA [36]. The authors found significant improvements in daily incontinence episodes in 52% and improved urodynamic parameters (cystometric capacity and reduction in maximum detrusor pressure) in all patients. Most importantly, 87% of patients who were switched to 750 U abobotulinumtoxinA continued to have a therapeutic response after 21-month follow-up, suggesting a long-term option for nonresponders. Although these early studies show promising results for abobotulinumtoxinA, ongoing research is underway and contributes to the growing body of evidence showing its benefits in this population [37].

Although most large trials investigating the use of onabotulinumtoxinA for NDO included patients with MS, SCI, or myelomeningocele, one must note that this therapy may be used

successfully for voiding dysfunction associated with other neurological conditions [38]. One particular example is Parkinson's disease (PD). Approximately half of PD patients may experience urgency urinary incontinence in addition to bothersome storage symptoms (urgency, frequency, nocturia) and obstructive lower urinary tract symptoms [39]. Botulinum toxin injection in PD has been studied in several small series with success in treating urgency incontinence and a relatively low rate of urinary retention (0–12.5%) [40–45]. Given the lack of randomized controlled trials in the literature, there is a paucity of data in the best dosing regimen for patients with PD. Despite this limitation, onabotulinumtoxinA has the potential to alleviate symptoms associated with NDO and carries little to no risk of interacting with medications being administered for PD (particularly anticholinergics).

In conclusion, patients with NDO resulting in adult neurogenic lower urinary tract dysfunction (ANLUTD) may be treated successfully with intradetrusor onabotulinumtoxinA injections. Treatment may result in significant improvements in urinary urgency, urgency urinary incontinence, and improvements in quality of life. Although repeated injections are necessary, efficacy is maintained during the treatment course and alternatives are being investigated for those patients with suboptimal response.

Use in Overactive Bladder

Overactive bladder is a condition characterized by urinary urgency, with or without UUI, urinary frequency, and nocturia [46]. Approximately 16% of the US population is affected by this condition, and about 1/3 of patients affected by this condition have associated urgency urinary incontinence [47]. Furthermore, the prevalence is expected to continuously increase, reaching 20% prevalence by 2018 [48]. Patients with OAB are usually treated in a stepwise fashion as suggested by the AUA/SUFU (American Urological Association/Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction) guideline for OAB in adults [49]. These steps are referred to as first-, second-, and third-line therapies. First-line therapies consist of behavioral therapies (i.e., pelvic floor exercises, diet/fluid manipulation), and pharmacologic therapies form the mainstay of second-line treatments (although they may be introduced along with behavioral therapies). Oral pharmacologic options consist of antimuscarinic medications and oral beta 3 receptor agonists. Although both medication classes have been shown to be effective in treating OAB symptomatology and improving quality of life, they are limited by poor long-term persistence on the medication regimen. Studies suggest most patients discontinue therapy with beta 3 agonists or antimuscarinic medications 1 year after initiating therapy (62% and 80%, respectively) [18, 50, 51]. For patients who are refractory to first- and second-line therapies and/or cannot tolerate medication side effects, intradetrusor onabotulinumtoxinA injection is considered a "standard" third-line therapy in the appropriately counseled patient [49].

Initial small series composed of noncontrolled and randomized placebo-controlled studies were performed to demonstrate the efficacy of botulinum toxin injection for OAB [52–55]. Two subsequent phase 2 multicenter, randomized controlled trials assessed the safety and efficacy of various dosing ranges and compared them to placebo [56, 57]. Both studies included patients with refractory OAB with eight or greater UUI episodes daily. Dmochowski et al. utilized 50, 100, 150, 200, and 300 U injections of onabotulinumtoxinA, whereas Denys et al. utilized 50, 150, and 200 unit onabotulinumtoxinA injections. Both studies found substantial improvements in UUI for injections greater than 100 U; however doses higher than this were observed to place patients at additional risk of incomplete bladder emptying requiring CIC.

Two multicenter randomized controlled trials investigated the use of 100 U of onabotulinumtoxinA in patients with idiopathic OAB [58, 59]. Nitti et al. investigated the use of a 100 U dose of intradetrusor onabotulinumtoxinA injection in patients with refractory OAB versus placebo [58]. Included patients had a baseline of 3 or

more UUI episodes over a 3-day period and 8 or more voids daily. Patients included also needed to discontinue their anticholinergic medications and demonstrated adequate bladder emptying (PVR <100 mL). Follow-up occurred regularly (2, 6, 12 weeks, then every 6 weeks) until study exit at 24 weeks. If patients had greater than 2 incontinent episodes in a 3-day period or requested a repeat injection at the 12-week interval, they were offered retreatment. Outcome measures included daily UUI episodes, positive response to treatment benefit scale (TBS) at 12 weeks, number of voids, and urgency episodes. The investigators found that onabotulinumtoxinA injection produced a statistically significant difference in the reduction of daily UUI episodes when compared to placebo (2.65 v. 0.87, $p < 0.001$) and significant positive response on TBS which was sustained from week 2 to 12 (60.8% with positive response at week 12 v. 29.2%, $p < 0.001$). Furthermore, patients receiving onabotulinumtoxinA injection benefited from a significant reduction in OAB symptoms including urgency, number of daily voids, and nocturia. Total continent rates ("dry rate") were also affected by botulinum toxin injection and approximately 23% in the onabotulinumtoxinA group and 6.5% in the placebo arm were dry at the completion of the study. Quality of life improvements as measured by I-QOL and King's Health Questionnaire (KHQ) also favored patients in the onabotulinumtoxinA group versus placebo. The most common adverse effects were UTI (24.5% onabotulinumtoxinA v. 9.25% placebo) and incomplete bladder emptying requiring CIC (6.1% onabotulinumtoxinA v. 0%). Of note, the number of patients who developed UTI increased in both groups from 12 weeks to 24 weeks, likely reflecting the inherent risk in developing UTI when instrumenting the urinary tract. Interestingly, only one additional patient required CIC after 12 weeks. Chapple and colleagues used a similar study protocol in Europe and found a comparable decrease from baseline UUI in patients undergoing onabotulinumtoxinA injection versus placebo at 12 weeks (−2.65 v. 1.03, $p < 0.001$) [59]. Improvements following injection were also reflected by 62.8% of patients reporting a positive treatment response on TBS scale. The most common adverse effects were also echoed in this study, with UTI (24% onabotulinumtoxinA v. 9.6% placebo) and incomplete bladder emptying requiring CIC (6.9% onabotulinumtoxinA v. 0.7% placebo) being reported at similar rates. Of note, both trials' CIC threshold dictated that patients with a PVR greater than 350 mL begin CIC or those with symptoms of incomplete bladder emptying and a PVR of 200–350 mL. Other groups have used less stringent CIC guidelines safely and found a de novo CIC rate as low as 1.6% [60].

Sievert and colleagues performed a pooled analysis of both of the aforementioned trials [61]. This group found a statistically significant reduction in UUI episodes in the treatment arm compared to placebo (−2.8 v. −0.95, $p < 0.001$) as well as decreased number of daily voids and urgency episodes. Furthermore, the dry rate significantly favored the treatment arm compared to placebo (27.1% v. 8.4%, $p < 0.001$). Furthermore, a systematic review and meta-analysis performed by Ramos and colleagues focused primarily on randomized placebo-controlled trials also found significant reductions in UUI, urgency, and number of micturitions for patients treated with onabotulinumtoxinA [62]. Overall, there are robust level one data in support of using onabotulinumtoxinA injections for OAB.

Long-term follow-up was also reported by Nitti and colleagues for patients who completed one of the phase 3 randomized controlled trials [63]. This was an open-label extension study that concluded after 3.5 years or 6 treatment cycles. A total of 839 patients enrolled in the study and 829 patients received 1 or more onabotulinumtoxinA injections. Patients were permitted to request for retreatment in order to replicate daily clinical practice (retreatment criteria: PVR <200 mL, ≥2 episodes UUI in 3 days, ≥12 weeks since last injection). After a 3.5-year study period, 51.3% of patients completed the study and significant reductions in daily UUI episodes were sustained in both the overall population and subgroups corresponding to number of treatments the patient received (−3.1 to 3.8 in overall population; −2.9 to −4.5 in individual subgroups). Similarly,

overactive bladder symptoms and quality of life were significantly improved, while patient satisfaction remained high as measured by the TBS. Overall the median time to retreatment was 7.6 months, and almost a third of patients had sustainable effects up to 1 year. Of the patients who withdrew from the study, only 5.7% of patients reported lack of efficacy and 5.1% reported bothersome side effects. Most patients who withdrew during the study period reported personal reasons, study burden, and site closure impeding their participation in the study. This long-term study also clarifies concerns over long-term adverse events including UTI, urinary retention, and antibody formation. Overall there were no changes in adverse effects with each additional treatment, for example, the development of UTI ranged between 13.5% and 17.5% of patients. The study protocol dictated that CIC be initiated if PVR was >350 mL regardless of symptoms or 200–350 mL with symptoms of incomplete bladder emptying. After the first injection, merely 4% of patients required CIC which decreased with each subsequent injection. There were no patients developing toxin neutralizing antibodies when receiving 100 U of onabotulinumtoxinA; however 3 patients developed antibodies after receiving 150 U (this part of the protocol was amended in 2012). Overall, this study provides support for the use of onabotulinumtoxinA as a suitable long-term option for OAB patients who are refractory to first- and second-line therapies.

Few studies have compared intradetrusor onabotulinumtoxinA injections to oral second-line therapies for OAB. One study by Drake and colleagues used a method known as network meta-analysis in order to compare treatments for OAB using data from published clinical trials [64]. They included studies evaluating the efficacy of onabotulinumtoxinA, mirabegron, and several anticholinergics used in clinical practice. Their results showed that all of the interventions were more efficacious than placebo in multiple outcomes studied (urgency incontinence episodes, micturition, and urgency episodes) at 12 weeks. OnabotulinumtoxinA showed the greatest reduction in all OAB symptoms investigated. Furthermore, onabotulinumtoxinA had the highest odds in achieving 100% resolution of UUI as well as the greatest mean reduction in urgency incontinence episodes and micturition and urgency episodes when comparing the treatments with each other. Despite the ability to compare a large number of trials and interventions, using network meta-analysis is subject to certain limitations inherent to the biases and quality of the studies included. Visco and colleagues performed a multicenter randomized controlled trial comparing the oral anticholinergic solifenacin with a single injection of onabotulinumtoxinA [65]. A study population composed of women with ≥5 UUI episodes (recorded on 3-day diary) was randomized to a cohort receiving oral solifenacin and a placebo injection (normal saline) or a second group receiving 100 U of onabotulinumtoxinA and placebo oral medication. Patients in the oral anticholinergic arm were started at 5 mg of solifenacin; however dose escalation to 10 mg could occur at 2 months. Additionally, patients in this arm could also change medication to trospium 60 mg daily if their symptoms were refractory to oral solifenacin by 4 months. After a 6-month follow-up, the authors concluded there was similar reduction in UUI episodes when comparing the patients receiving oral anticholinergics versus onabotulinumtoxinA. More patients in the onabotulinumtoxinA group enjoyed complete resolution of UUI (27% v. 13%, $p = 0.003$); however they also had higher rates of UTI (33%) and incomplete bladder emptying (5%).

Few well-designed studies are available that compare botulinum toxin injection to sacral neuromodulation. Recently, investigators for the ROSETTA trial reported their outcomes when comparing onabotulinumtoxinA injection and sacral neuromodulation for women who had refractory urgency urinary incontinence [66]. Eligible patients were randomized to receive 200 U onabotulinumtoxinA injection (higher than the FDA-approved dose for idiopathic OAB), and a second group was randomized to undergo sacral neuromodulation. Furthermore, only the patients who had greater than a 50% improvement in the onabotulinumtoxinA group were compared to the patients who underwent

stage 2 sacral neuromodulation implantation. After a period of 6 months, the patients in the onabotulinumtoxinA group had a greater mean reduction in incontinence episodes (−3.9 v. −3.3), as well as a higher rate of complete resolution of urgency urinary incontinence (20% v. 4%). Despite the greater reduction in incontinence episodes in the botulinum toxin group, there was no difference in the patient's overall perception in overall improvement; thus it is unclear whether this improvement is clinically relevant.

Patient Selection and Workup

Patients who are considered for intradetrusor onabotulinumtoxinA injection are typically refractory to initial therapies for NDO and OAB [49]. However, patient treatment plans should be individualized to optimize convenience for the patient, compliance with therapy, minimize side effects, and optimize quality of life. In addition to considering the patients' lower urinary tract condition, one must consider the patients' overall medical condition, current medications, and a realistic assessment of goals of therapy.

In patients refractory to first- and second-line therapies including behavioral modification and oral medications (antimuscarinics and beta 3 agonists), a detailed history and physical examination should be performed in order to select the appropriate third-line therapy and screen for contraindications to receiving onabotulinumtoxinA injections (Table 17.2). When obtaining a history, it is critical to ask specifically about the duration of prior treatments, side effects experienced, and whether dose escalation was attempted. Furthermore, modifiable behaviors and fluid intake should be addressed prior to considering injection with onabotulinumtoxinA (i.e., excessive caffeine). In patients referred with refractory OAB, details about previous therapies the patient has tried should be obtained. Details about duration of therapy, medication dose and frequency, and side effects encountered should be obtained from the patient. Similarly, prior urological history is needed for patients with neurogenic bladder. In some neurological conditions, there is a higher risk of concomitant upper tract dysfunction, and attention needed to be paid to ensuring an appropriate evaluation has been carried out.

Table 17.2 Contraindications and warnings for botulinum toxin

Active urinary tract infection
Urinary retention
Patient unwilling to perform CIC if necessary (even after counseling and education)
Patient or caretaker unable to perform CIC
Hypersensitivity to botulinum toxin or components in drug
Planned injection will surpass 400 U dose in 3-month interval
Pregnancy
Drug interactions
Active anticoagulation or antiplatelet therapy[a]
Lactation[b]
Myasthenia gravis, Lambert-Eaton syndrome[b]
Immunosuppressed (renal, liver transplant recipients)[b]

[a]Patients should be counseled to hold anticoagulation for 3 days prior to the procedure with consultation with prescribing physician. Dual antiplatelet therapy (aspirin and clopidogrel) should be discussed with the patient's cardiologist. Low dose aspirin (81 mg) may be continued through the time of procedure; however full dose aspirin (325 mg) or clopidogrel should be discontinued at least 5 days prior

[b]Data are limited in guiding treatment in these populations. One must weigh the risk of treatment versus any benefit the patient may gain. Consideration must be given to postpone treatment until the condition is resolved (lactation) or the patient is optimized medically with close follow-up postinjection

There are currently seven FDA-approved indications for onabotulinumtoxinA. Therefore, it is important to determine whether the patient is receiving onabotulinumtoxinA (or other neurotoxin) for any other indication prior to performing intravesical injection. A total of 400 U of onabotulinum toxin is suggested in any one 3-month period, and when possible injections should be performed within 24 hours of each other to minimize the potential risk of antibody formation.

Although botulinum toxin injection is not contraindicated in OAB patients without UUI ("OAB Dry"), one must counsel patients that the highest level of evidence from drug trials included patients with UUI. However, very often patients

may be classified as dry because they have modified behaviors to prevent leaks. Detailed history and close questioning may help elucidate this information. Further, onabotulinumtoxinA, though not FDA approved for PBS/IC, is considered as a fourth-line therapy in the AUA guidelines [67]. This suggests that there is perhaps a role of the therapy on the sensory input from the bladder to the CNS, perhaps more of a factor in some "dry" patients where frequency is driven by sensory urgency. Finally, in some complex cases, the clinician may consider performing urodynamic studies (complex cystometry, pressure flow study, PVR, electromyography) or videourodynamics in OAB patients with refractory symptoms that have failed prior drug therapies and in patients with neurogenic bladder [68].

Some OAB patients experience frustration when primary and secondary therapies are not effective and they are unaware that advanced therapies are available. To prevent this, it is now much more common to present the entire treatment paradigm for OAB to a patient upfront. To do this, many physicians have used clinical care pathways to help the patient navigate to effective therapies. This means that the onabotulinumtoxinA injection as a treatment option may come early in conversations with patients. Either at that point or perhaps more appropriately when the use of onabotulinumtoxinA is being considered, the discussion about the therapy needs to become more intense. Very often this discussion considers other third-line therapies including sacral neuromodulation and posterior tibial nerve stimulation.

When counseling patients about the use of onabotulinumtoxinA for voiding dysfunction, it is important to use terminology that will allow the patient to understand the efficacy and alleviate concerns or anxiety concerning the treatment. Very often we rush beyond the key point of explaining the efficacy of the treatment to discuss uncommon side effect. This is something that needs to be addressed, but the timing in the conversation matters. Additionally, after discussing the success rates and efficacy to be expected, reviewing the duration of drug effect is important. The message of retreatment being a normal part of the therapy should be explained.

The next key message that the patient wants to know about is how the therapy is administered. The patients should be informed that this is a treatment done using a cystoscope, most often with a local anesthetic as an office-based procedure. The "how to" is detailed in the section below.

After explaining the therapy and how it works, the safety of onabotulinumtoxinA injection should be addressed. Urinary tract infection is one of the common adverse events that can occur. Prevention of infection can be reviewed, and treatment of infection can be explained. As an injector, care should be taken to avoid injection when patients are actively infected. Pre-procedure urine analysis is very often sufficient to rule out infections. In patients with a history of recurrent urinary tract infection, indwelling catheter, bacteriuria, or those that are currently performing CIC obtaining a pre-procedure urine culture can allow for culture-specific antibiotics prior to the procedure and avoid last minute cancellation. Many clinicians routinely administer antibiotics prophylaxis periprocedurally. This may be largely due in part to the manufacturer's recommendation to administer periprocedural antibiotics (1–3 days prior to injection, day of injection, and 1–3 days postinjection); however there is no general consensus on periprocedural antibiotic regimens [69, 70]. In our experience, we pretreat based on a recent positive urine culture (see above for specific populations) for at least 3 days prior to injection, treatment day, and 3 days following injection. For uncomplicated patients at low risk of bacteriuria, we shorten the antibiotic course to 1 day of pretreatment, treatment on the day of injection, and postinjection day 1. Ideally, the antibiotic chosen for periprocedural prophylaxis has adequate penetration into the genitourinary system and is cross-referenced with the local antibiogram to cover most anticipated uropathogens. The use of aminoglycoside antibiotics should be avoided as the effect of onabotulinumtoxinA can theoretically be potentiated [69].

The other adverse effect of the procedure is the risk of incomplete bladder emptying. In some cases, this may require transient use of clean intermittent catheterization. Patients should be

counseled about the possibility and must be willing to accept the risk prior to utilizing the therapy. As we gain more experience with onabotulinumtoxinA, we can consider risk stratifying the risk of incomplete bladder emptying and potentially counsel patients accordingly. Elevated PVR, detrusor underactivity, and increasing age may be risk factors for needing CIC after treatment with onabotulinumtoxinA. The authors do not think it is necessary to pre-teach CIC to most patients. In some very select cases where the ability of CIC is questioned and the risk of retention is high, teaching CIC prior to an intervention can be considered. Additionally, clinicians should inform patients that this adverse effect is temporary (on average about 6 weeks in the pivotal trials) and does not affect the overall quality of life improvement.

Off-Label Uses for OnabotulinumtoxinA

There are several "off label" uses for onabotulinumtoxinA that have been used by clinicians in treating various lower urinary tract symptoms and voiding dysfunction. One of the first uses of onabotulinumtoxinA in urological conditions was put forth by Dykstra et al. in the management of detrusor sphincter dyssynergia (DSD) in patients with SCI [21]. Most studies since that time have used onabotulinumtoxinA injections into the external sphincter and have included patients with neurogenic bladder; however, the toxin has been injected into the bladder neck for patients with primary bladder neck obstruction [71, 72]. High-quality evidence is limited for the use of onabotulinumtoxinA for sphincter dyssynergia; however, there is one randomized controlled trial that included 86 patients with DSD and history of MS [73]. Patients in this study were randomized into a group receiving 100 U of onabotulinumtoxinA or placebo (normal saline) injected using a transperineal technique. Both groups were also prescribed an alpha blocker for 4 months. The primary outcome of the study included post void residual (PVR) at 1 month, and secondary outcomes included the International Prostate Symptom Score (IPSS), filling detrusor pressure, and voided volumes. Although no significant improvement was seen in PVR, the patients receiving onabotulinumtoxinA did increase their voided volumes by 54% and decreased their filling detrusor pressure. Despite the apparent improvement noted, one must weigh the benefits highlighted in this study against the potential limitation, and this intervention can place on a neurogenic bladder patient receiving onabotulinumtoxinA for other indications. The procedure is also limited by the dosing frequency every 3 months and discomfort to sensate patients as the urethra is difficult to anesthetize. Furthermore, there are no long-term data on how these improvements translate into better outcomes in terms of quality of life, continence, and upper urinary tract deterioration.

Another application that has been investigated for onabotulinumtoxinA is in the treatment of bothersome lower urinary tract symptoms as a result of Benign Prostatic Hyperplasia (BPH). Several groups have reported on the use of botulinum toxin for BPH with limited success after Maria et al. initially reported improvement in urinary flow rate (Qmax) and AUA symptom score [74, 75]. Despite their enthusiastic findings, subsequent investigators did not find appreciable differences between intraprostatic onabotulinumtoxinA and placebo including two multicenter phase 2 randomized controlled trials performed in the United States and Europe [76, 77]. Overall, both studies found a significant placebo response which compared to responses in the cohorts receiving active treatment. Based on these results, intraprostatic onabotulinumtoxinA injection is not routinely performed.

Interstitial cystitis/bladder pain syndrome (IC/BPS) is a syndrome whereby patients present with an unpleasant sensation perceived to be related to the bladder and associated with lower urinary tract symptoms for more than 6 weeks without a clear etiology to explain symptoms [78]. Several studies have investigated the use of intradetrusor onabotulinumtoxinA injection for the pain and bothersome lower urinary tract symptoms associated with IC/BPS with modest improvements in pain scores, nocturia, and urinary frequency [79–

81]. As described earlier in the chapter, onabotulinumtoxinA works primarily by inhibiting acetylcholine neurotransmission producing a state of chemodenervation. It also exhibits analgesic activity by inhibiting afferent nociceptive signaling thus warranting investigation for its use in patients with IC/BPS [81, 82]. In order to maximize the analgesic effect of onabotulinumtoxinA, certain authors have proposed limiting injections to the trigone of the bladder as this area contains the highest concentration of nociceptive afferent fibers [2, 83, 84]. The published studies available have been limited by small study populations, heterogeneity in patient symptom severity, number and location of injections, utilization of hydrodistention, dose, and follow-up [85]. The largest study population was investigated by Kuo et al. when 67 patients were randomized to receive 100 U or 200 U suburothelial onabotulinumtoxinA injection or hydrodistention alone [86]. All patients were followed up in 2 weeks for hydrodistention, regardless of the intervention they were randomized to. After 3 months, the authors reported statistically significant improvements in cystometric bladder capacity, as well as improved bladder pain as measured by the visual analog scale. The authors reported no additional benefit in using 200 U in comparison to the 100 U dose and found a higher incidence of adverse effects in the patients receiving 200 U injections. Long-term follow-up was reported by Giannantoni et al. where 15 patients underwent submucosal injections in the lateral walls of the bladder and trigone [81]. After 1 year, there was no beneficial effect in pain relief from the intervention, and at 5 months only 26% of patients had pain improved from baseline. The most recent study was a phase 2 double-blind randomized controlled trial performed by Pinto and colleagues where patients were injected with 100 U of onabotulinumtoxinA or normal saline within the trigone (Fig. 17.4) [83, 87]. In contrast to other studies reviewed, the author's protocol did not utilize hydrodistention and the patients had to discontinue other intravesical or oral treatments for IC/BPS (with the exception of nonsteroidal anti-inflammatory drugs, gabapentin, pregabalin, and paracetamol) prior to the study. At week 12, 60% of patients who received onabotulinumtoxinA injections had >50% improvement in pain compared to 22% who received placebo. Patients also demonstrated improvements in quality of life and reduction in micturition frequency. Furthermore, the procedure posed minimal risk with regard to urinary retention as the mean PVR was minimal (5 ± 13 mL). The current guidelines on IC/BPS from the American Urological Association include onabotulinumtoxinA injection as a fourth-line therapy [78]. This therapy should be reserved for patients who have undergone extensive counseling on the risks of urinary retention requiring CIC. This adverse effect may preclude treatment in many patients with IC/BPS as bladder distention, and performing CIC may be particularly painful, thus limiting any efficacy from the treatment. Future advances in the delivery method of onabotulinumtoxinA may serve to benefit patients with IC/BPS. Chuang and colleagues recently published their results of a prospective randomized controlled trial evaluating the use of liposomal formulated onabotulinumtoxinA (lipotocin) in patients with refractory IC/BPS [88]. Unfortunately, the study failed to demonstrate efficacy in this population and improvements from baseline symptoms were largely driven by placebo effect.

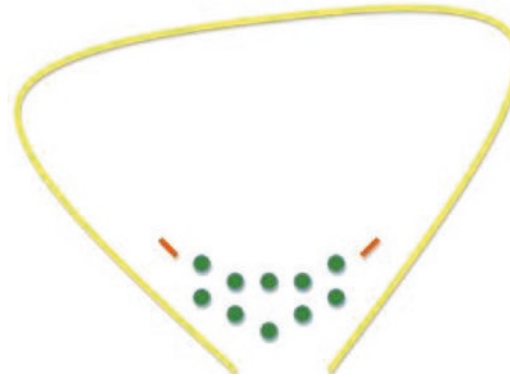

Fig. 17.4 Trigonal injection sites. Green circle marks site of injection. Orange dash indicates location of ureteral orifice. (Reprinted from Pinto et al. [87]. With permission from Elsevier)

Chronic pelvic pain due to pelvic floor muscle dysfunction is a common disorder encountered in many urologic and urogynecologic practices and

has been estimated to affect roughly 15% of adult women [89]. The pathophysiology is not well defined; the condition has been labeled high-tone pelvic floor dysfunction (or levator myalgia) as it is thought to be the effect of hypertonicity of the levator ani complex. Patients may present with myriad of symptoms including bothersome lower urinary tract symptoms, pelvic pain, dyspareunia, and tenesmus. The cornerstone of therapy includes pelvic floor physical therapy; however, other therapies including biofeedback, antidepressants, intravaginal anxiolytics, and trigger point injections have been investigated [90–93]. OnabotulinumtoxinA has been used successfully in relieving pain and function in conditions also characterized by increased resting muscle tone (cervical dystonia, limb spasticity) [94]. Thus, investigators hypothesized botulinum toxin injection into trigger points in the pelvic floor musculature (puborectalis, pubococcygeus for example) would lead to similar symptom control. Abbott and colleagues performed a randomized clinical trial where patients were randomized into cohorts receiving injections of 80 U of onabotulinumtoxinA or placebo (normal saline) and followed for 6 months. The authors found that patients in the onabotulinumtoxinA group had significant improvement in dyspareunia and nonmenstrual pelvic pain measures by visual analog scale. Additionally, there was also a significant reduction in pelvic floor pressure (measured by vaginal manometry) compared to baseline in the onabotulinumtoxinA group. Higher doses of onabotulinumtoxinA in the pelvic floor muscles have been used by Adelowo et al. in a retrospective series including 29 women [95]. Doses administered during the study period varied between 100 and 300 U, and pain improvement was seen in 79% of the study population within 6 weeks. The median time to patient requested retreatment was 4 months, and half of the patients included requested repeat injections. The authors did report adverse effects including urinary retention ($n = 3$) and fecal incontinence ($n = 2$), which occurred in patients receiving 300 U injections and resolved between 12 and 20 weeks postinjection.

Transperineal and transvaginal injections have been described in prior reports [95, 96]. For women, a transvaginal route is preferred as one can elicit trigger points in the levator ani complex and direct injections as dictated by examination. The procedure can be performed under anesthesia however, adequate pain relief can be provided by performing a pudendal nerve block using an Iowa trumpet guide. Injections should pierce the vaginal epithelium at least 1 cm and enter the levator muscles. Prior to injecting, one must withdraw on the syringe in order to prevent intravascular injection. At this point the trigger point injection can begin by directing injections to individual findings on physical exam (Figs. 17.5 and 17.6). After injecting, one may use digital pressure or place a vaginal pack for 5–10 minutes to ensure hemostasis.

Adverse Effects of OnabotulinumtoxinA

Intradetrusor injection of onabotulinumtoxinA for idiopathic OAB and NDO has proven to be a safe and effective treatment with an acceptable risk profile for routine clinical practice. There are important safety considerations clinicians must be aware of to prevent adverse effects as well as a working familiarity with both common and rare side effects. In general, most of the adverse effects that impact patients are localized to the lower urinary tract and easily treated.

As discussed above, the most commonly reported adverse effects with botulinum toxin injection are localized to the lower urinary tract and include UTI and incomplete bladder emptying. The most common adverse effect reported after intradetrusor onabotulinumtoxinA injection is UTI. The rate of UTI is variable in the literature and ranges between 3.6% and 54.5%. Compared to 0–10% incidence of symptomatic UTI following diagnostic cystoscopy, this rate appears to be discordant with the higher rates of UTI after injecting sterile botulinum toxin [97]. This wide range may be due to several factors including a lack of consistency across studies about criteria defining a UTI after injection. For example, in two randomized controlled trials, UTI was based on laboratory data rather than

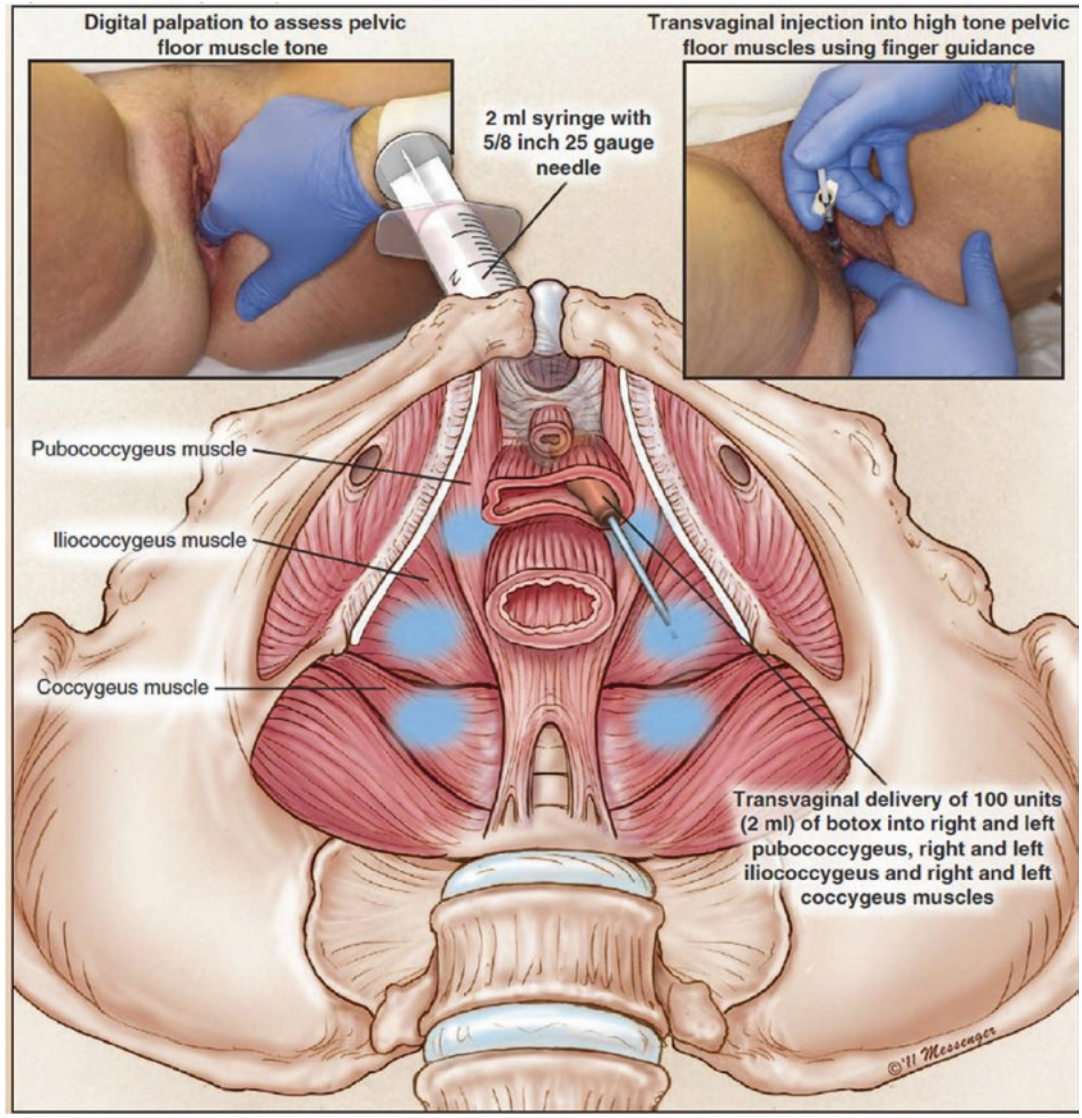

Fig. 17.5 Transvaginal injection of onabotulinumtoxinA into levator ani muscles. (Reprinted from Goldstein et al. [96]. With permission from Elsevier)

relying on patients' symptoms and objective data [26, 58]. This incidence may certainly be influenced by patients with asymptomatic bacteriuria, transient pyuria following cystoscopy, and performing CIC. Additionally, patients receiving this treatment will have bothersome urinary tract symptoms at baseline and persistence or exacerbation of these symptoms can mimic UTI symptoms and thus prompt a workup including urinalysis and urine culture. In one recent systematic review, Stamm et al. evaluated the definition of UTI used by investigators performing cystoscopy with onabotulinumtoxinA injection and compared them with published guideline statements defining UTI [98]. They found that only 54% of the studies that met inclusion criteria reported their UTI criteria. They concluded that future studies must adhere to clearly defined criteria to better understand the incidence of UTI following botulinum toxin injection. In order to prevent this adverse effect, many clinicians administer concurrent antibiotic prophylaxis as

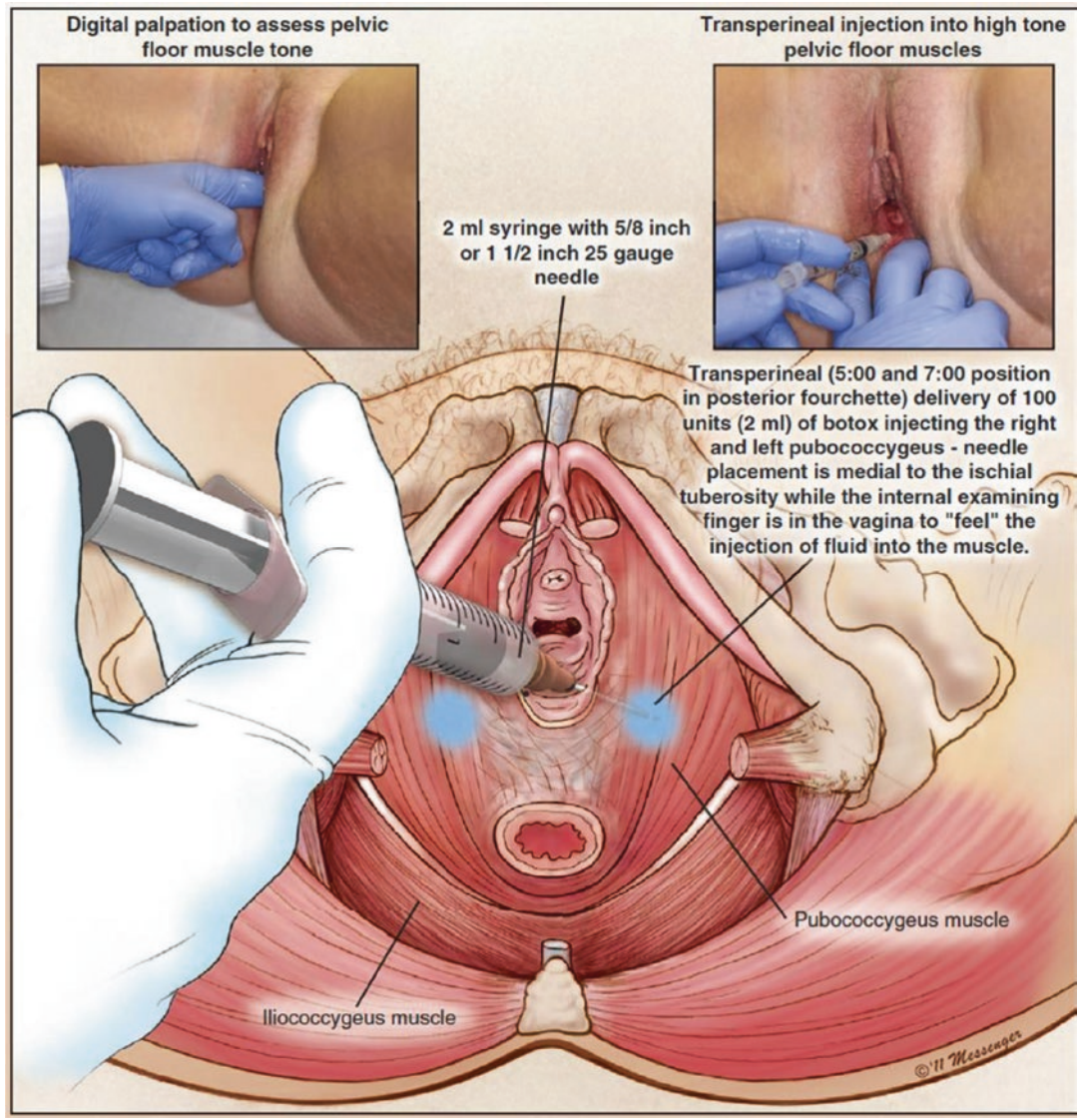

Fig. 17.6 Transperineal onabotulinumtoxinA injection into levator ani muscles. (Reprinted from Goldstein et al. [96]. With permission from Elsevier)

recommended by the AUA clinical guidelines on antibiotic prophylaxis for cystoscopic procedures [99].

Incomplete bladder emptying resulting in elevated post void residual may occur after onabotulinumtoxinA injection; however many patients may remain asymptomatic as a result of this adverse effect. Although this adverse effect can occur at all indicated doses, it seems to occur in a dose-dependent manner. Studies including patients with NDO (specifically MS and SCI) did not have a predetermined volume at which CIC would be initiated, and the decision to begin CIC was largely at clinician's discretion [26]. Approximately half of the patients receiving onabotulinumtoxinA injections that did not perform CIC at the time of recruitment began catheterizing after injection. There was also a significant number of patients (22%) in the placebo arm of the study who began catheterizing, suggesting

that perhaps many patients may have benefited from CIC prior to enrollment. Nevertheless, patients who do not catheterize prior to injection should be counseled appropriately on their risk of incomplete bladder emptying. One must be able to assess the patient's ability to realistically perform CIC and consider teaching CIC prior to injection. In non-neurogenic OAB randomized controlled trials, patient symptoms (difficulty voiding, bladder fullness) were taken into account in addition to the post void residual [58, 59]. When the results of both phase 3 randomized controlled trials were pooled by Sievert et al., CIC was initiated in 5.8% of patients receiving 100 U of onabotulinumtoxinA. Prior to injection, patients who do not perform CIC already should be advised on the potential risk of urinary retention. Discussion can be individualized based on comorbidities and functional status. For example, hand and upper extremity strength, coordination, and tactile sensation should be assessed. Many patients, particularly those with NDO, may also benefit from learning how to catheterize prior to injection. Furthermore, the patient's body habitus and genitourinary tract anatomy should be considered when deciding between CIC and an indwelling catheter should the patient develop urinary retention.

Less common side effects resulting after botulinum toxin injection were also localized to the urinary tract and include hematuria (3–7%), increased incontinence (7%), and bladder pain (1–6%) [26, 58]. However, there is a risk of side effects resulting from distant spread of the toxin to other parts of the body. Symptoms associated with distant side effects can include muscle weakness, difficulty with breathing or respiratory depression, dysphonia, dysphagia, and ptosis. Although rare, these complications have been reported and may occur immediately following the procedure, or in a delayed fashion (weeks) [100, 101]. Furthermore, patients with a history of myasthenia gravis should be counseled on the increased risk of distant effects including muscle weakness. Close follow-up should be performed along with the patient's treating neurologist in order to adjust home medications and monitor for flares in symptoms.

Long-term use from onabotulinumtoxinA injection appears to be safe and effective for both NDO and non-neurogenic OAB [63, 102]. Patients receiving multiple injections in both studies continued to have improvements in UUI and quality of life that were sustained throughout the study periods. Furthermore, the risk of CIC in both studies seemed to diminish with repeat injections, even in those patients who had developed urinary retention with their first treatment. Most importantly, there was no increase in adverse effects with repeat injections, and there were no significant treatment-related side effects outside the urinary tract. Antibody-mediated degradation of botulinum toxin did occur in 2% of NDO patients (all had SCI). No patients receiving the FDA-approved dose (100 U) for onabotulinumtoxinA developed antibodies. Overall, botulinum toxin injection is an efficacious and safe procedure for both neurogenic detrusor overactivity and non-neurogenic OAB.

Injection Technique

Intradetrusor injection with onabotulinumtoxinA can be performed in an office setting or as an ambulatory surgery (sample protocol summarized in Fig. 17.7). In the author's experience, performing botulinum toxin injection in the office is well tolerated in both men and women. Additionally, the procedure is more efficient for both patient and physician as the office setting allows for a controlled workflow without impedance from delays inherent to operating rooms and hospitals (presurgical testing, operating room delays, untrained staff, etc.). In both settings, it is critical to ensure the proper equipment is available and the medication has been properly stored. OnabotulinumtoxinA vials should be stored in a refrigerator (2–8 °C) or freezer (≤ −5 °C). The product in the vial has a fine white grainy appearance and needs to be reconstituted with sterile injectable saline prior to usage. Once it is reconstituted, it can be stored in a refrigerator for 24 hours, and unused medication should be discarded. For OAB, a 100 U dose is recommended, divided into 20 injection sites (0.5 mL per site)

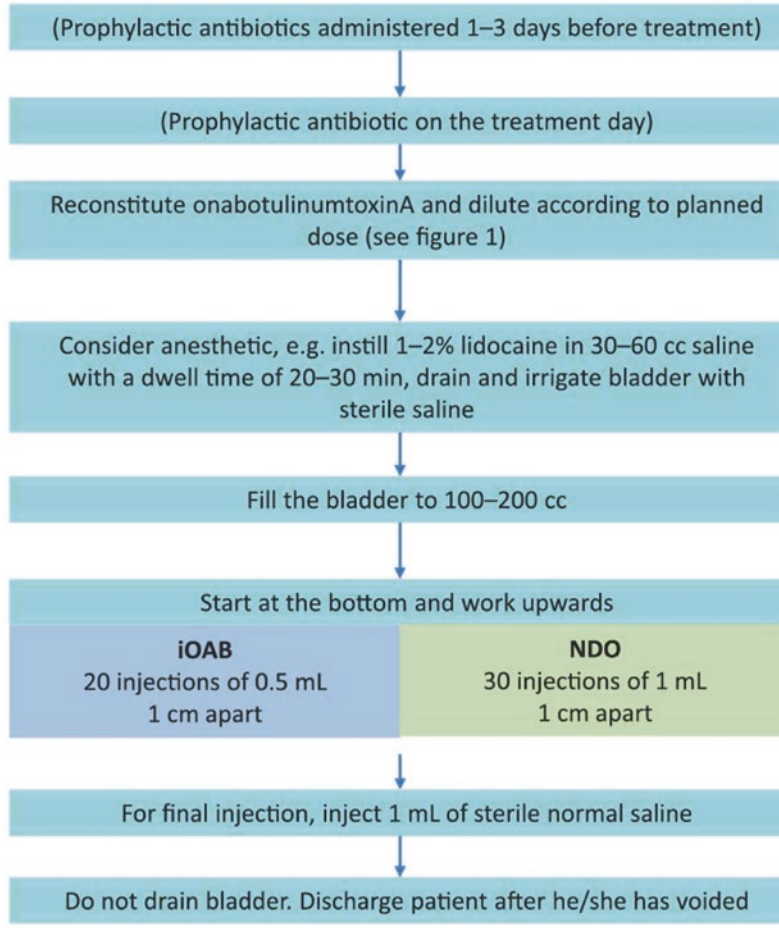

Fig. 17.7 Summarized protocol for onabotulinumtoxinA administration in office setting. (Reprinted from Rovner [105]. With permission from John Wiley & Sons, Inc.)

after reconstituting in 10 mL of injectable normal saline. Proper technique for reconstitution of the drug is demonstrated in (Fig. 17.8). It is critical to avoid shaking or mixing the toxin aggressively as this may disrupt the toxin's disulfide bonds and render it ineffective. For patients with NDO, a 200 U dose is the approved dose; however it is important to note that 100 U injections have been used in NDO patients who are not catheterizing prior to injection therapy (e.g., Parkinson's disease) [45]. The 200 U dose, the reconstituting instructions recommended by Allergan, is paraphrased in the following statements [69]. If using a 200 unit vial, the drug is reconstituted with 6 mL of injectable normal saline and then 2 mL is drawn into three 10 mL syringes. Next, 8 mL of injectable saline is added to each of the 10 mL syringes and mixed gently for a total of 10 mL of reconstituted botulinum toxin. Alternatively, one can use two 100 unit vials and add 6 mL of injectable normal saline into each. Next, 4 mL of reconstituted toxin is drawn into two 10 mL syringes, and the remaining 2 mL from each vial is drawn up into a third syringe. Finally, 6 mL of injectable saline is added to each of the syringes for a total of three 10 mL syringes containing reconstituted botulinum toxin.

In order to perform the procedure in an office setting, the authors prepare the patient to arrive approximately 45 minutes prior to injection with a comfortably full bladder. After the patient voids, he/she is allowed for a urinalysis. After instilling 2% viscous lidocaine, a catheter is used to drain the bladder and instill intravesical local anesthetic. A post void residual can also be recorded at the time the bladder is drained. This

Using the reconstitution needle, draw up the correct amount of saline in the appropriately sized sterile syringe. A 21-gauge, 2-inch needle is recommended for reconstitution. Reconstituted onabotulinumtoxinA should be clear, colourless, and free of particulate matter

Insert the needle straight into the vial, then tilt the vial at a 45° angle and slowly inject the saline into the onabotulinumtoxinA vial. Vacuum is present in the vial, which demonstrates that the sterility of the vial is intact. Do not use the vial if the vacuum does not pull the saline into the vial

Release the vacuum by disconnecting the syringe from the needle and allowing air to flow into the vial. Gently mix onabotulinumtoxinA with the saline by moving vial side to side or rotating the vial

Draw the fluid into the injection syringe by placing the needle into the bottom corner of the vial for full extraction. Do not completely invert the vial

Disconnect the injection syringe from the vial and attach an appropriate needle for injection

Fig. 17.8 Reconstitution of onabotulinumtoxinA. (Reprinted from Rovner [105]. With permission from John Wiley & Sons, Inc.)

is left in situ for approximately 30 minutes. The anesthetic used may vary; however, the author's preference is 30 mL of 1% lidocaine diluted in 50 mL of normal saline. In select patients, sedation or general anesthesia can be used.

Special precautions should be in place for patients with NDO and a history of autonomic dysreflexia or those with high spinal cord injuries (injuries affecting levels at or above T6). These patients may benefit from performing onabotulinumtoxinA injection in a monitored setting. Furthermore, in some cases these patients may benefit from preoperative alpha receptor blockade to prevent unopposed sympathetic stimulation [103].

Injections can be performed through a flexible or a rigid cystoscope using a long injection needle ranging from 21 to 25 gauge. The needle depth can be variable as well as typically ranging between 4 and 8 mm. In the author's practice, a rigid injecting cystoscope is used in female patients. In male patients a flexible scope with a long needle that fits through the working channel is used. When utilizing a flexible cystoscope for botulinum toxin injection, one must be careful to avoid injury to the working channel that can occur from the sharp needle tip. Most needles used with flexible scopes have an outer sheath or a retractable tip to facilitate.

The procedure should begin with an anatomical assessment of the bladder neck, trigone, position of the ureteral orifices, and assessment of the urothelium. Bladder should be partially filled to about 200 mL. Avoiding overdistention reduces the risk of patient discomfort, may prevent perforation, and minimizes inducing an involuntary bladder contraction. Traditionally injections of 0.5 mL of reconstituted medication are per-

formed systematically and under direct vision in 20 separate sites for OAB patients and 1 mL injections in 30 separate locations for NDO. Sites selected should be 1 cm apart and 2 mm deep into the detrusor while avoiding any obvious blood vessels. Through the package insert state 1 cm, most clinicians likely evenly distribute injection throughout the bladder. Some clinicians may opt to inject the afferent laden trigone, while others may elect to follow the pattern used during the registration trials and avoid injecting the trigone.

Proper injection depth can be assessed visually while the drug is being injected and optimized using the proper length needle. For example, if a superficial bleb rises at the injection site, the injection may be too shallow (submucosal), or if there is no change, the drug may be too deep. Ideally, one should visualize a subtle rise in the mucosa underneath the injection site. Minor bleeding may be seen after an injection and may impair visualization; thus we follow an injection template that proceeds from the base of the bladder and work ventrally can be helpful (Fig. 17.9). We begin injecting approximately 1–2 cm cephalad to the right or left ureteral orifice on the posterior wall and continue laterally for the subsequent injections. Once the contralateral side of the bladder is reached (~5 injections), the next column begins a few cm cephalad to the last injection and proceeds laterally. In order to clear the needle of unused toxin and ensure the full dose is administered, the final injection should consist of a small volume of normal saline that matches the volume of the needle used. Bleeding localized to injection sites is typically self-limiting and resolves without intervention. However, if bleeding persists, one may apply direct pressure using the beak of the cystoscope. Alternatively, one can retract the injection needle into the sheath and apply pressure using the blunt tip of the injection sheath. In a minority of patients, monopolar electrocautery using a bugbee electrode is necessary.

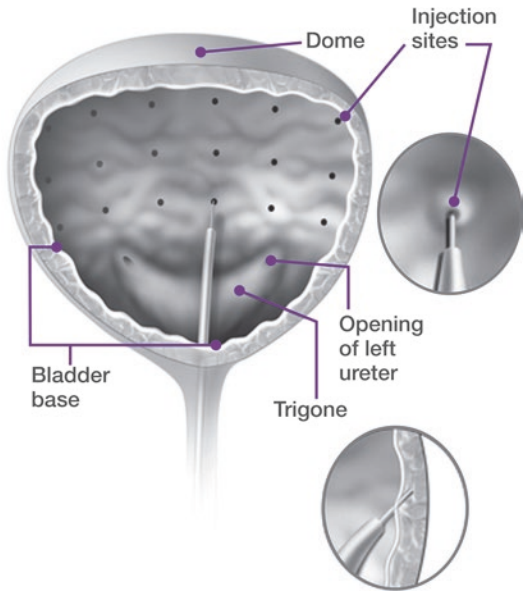

Fig. 17.9 Standard injection template for OAB/NDO. (Courtesy of Allergan, Inc., Irvine, CA, USA)

After the procedure, patients should be monitored and demonstrate the ability to void. For patients performing CIC, they can be instructed to empty their bladder after the procedure. Prophylactic antibiotics are administered to minimize the risk of UTI. Patients are usually given postprocedure expectations and instructions on follow-up. Dysuria and mild hematuria can be expected after most transurethral procedures. They should also be informed that the onabotulinum toxin will not start to show clinical efficacy right way. They should expect about 2 weeks to appreciate an improvement. Furthermore, they should be counseled to contact the clinician if they experience fevers, chills, respiratory symptoms, and generalized muscle weakness. Patients should be scheduled for a follow-up appointment approximately 2 weeks postinjection in order to reevaluate their symptoms, and measure a post void residual and consider a urinalysis if needed. The registration trials for idiopathic OAB CIC were initiated if the PVR was 200 mL or greater, or less than 350 mL with associated symptoms (e.g., difficult voiding or a sensation of bladder fullness), or PVR was 350 mL or greater regardless of symptoms. These cutoffs now can serve as a framework, but more liberal thresholds have also been described [60].

Good practice includes arranging a follow-up a few months after injection to assess symptoms and if needed arrange for a repeat injection.

Closer follow-up may be needed if patients experience suboptimal efficacy or if elevated residuals need to be followed more closely.

For patients with idiopathic OAB who do not respond to 100 U injection, we initially consider reinjection with 100 U of onabotulinumtoxinA 3 months following their initial injection. A higher dose (200 U) may be considered for this patient population, but a higher risk of incomplete bladder emptying must be discussed prior to injection. Furthermore, idiopathic OAB patients with symptoms refractory to chemodenervation may be counseled on other third-line therapies as an adjunct or alternative.

Patients with NDO follow a similar algorithm where reinjection can be performed after 3 months. However, one may consider off-label use of abobotulinumtoxinA as an alternative or consider repeat injection with 300 U of onabotulinumtoxinA [35, 104].

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Construction of the Neovagina

18

Tonya N. Thomas and Cecile A. Ferrando

Introduction

Creation of a neovagina is usually necessary in the following cases: congenital absence of the vagina, vaginal contracture and stenosis, reconstruction following neoplastic resective surgery or radiotherapy, and gender affirmation surgery. While there is no standard procedure for neovaginal reconstructive surgery, there exist many surgical and nonsurgical techniques that are often used to create the vagina. These techniques include vaginal dilation methods, the McIndoe vaginoplasty procedure with the use of split-thickness skin grafts, modified McIndoe procedures using full-thickness skin and mucosal grafts, transpositional skin graft techniques, laparoscopic techniques including the Davydov and Vecchietti operations, myocutaneous and fasciocutaneous pedicled flap surgeries, and intestinal flap surgeries. The ideal reconstructive method should provide a patent vaginal canal of adequate length, width, and texture that will allow for sexual intercourse, provide a cosmetically appealing appearance with minimal morbidity of both the recipient and donor surgical sites, and have a low incidence of overall complications. Construction of the neovagina can be very complex and challenging. Each method of repair has its advantages and disadvantages, which should be carefully weighed with the desired treatment goals as well as the surgeon's experience with various surgical techniques.

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Indications

Creation of a neovagina is usually necessary in the following cases: congenital absence of the vagina, vaginal contracture and stenosis, reconstruction following neoplastic resective surgery or radiotherapy, and gender affirmation surgery.

Approximately 1 in 4000 to 1 in 10,000 female newborns are born with congenital absence of the vagina [1]. The most common cause of this congenital malformation is Mayer–Rokitansky–Kuster–Hauser syndrome (MRKH). The anomaly results from hypoplasia or agenesis of the mullerian duct system. The phenotype of this anomaly exists on a wide spectrum and may include partial or total vaginal agenesis with a hypoplastic or rudimentary uterus and fallopian tubes. Patients have a normal 46,XX karyotype, normal female phenotype, and normal ovarian hormonal and oocyte function. On exam, patients have normal external genitalia with a normal-appearing hymenal ring and a small vaginal pouch with a dimple. These patients often present in the setting of primary

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amenorrhea or once sexual intercourse proves to not be possible. Up to 10% of patients have a functional endometrium, which can lead to cyclic pain and associated hematometra [2]. These adolescent patients most often present in the setting of primary amenorrhea and painful hematocolpos. Concomitant urologic anomalies such as unilateral renal agenesis, pelvic or horseshoe kidney, and anomalies of the collecting duct system occur in up to 50% of patients, while 10–15% of patients also have skeletal anomalies [3].

A shortened vagina, or blind vaginal pouch, is also found in genetic syndromes such as Morris syndrome and Turner's syndrome [4], as well as disorders of sex development including androgen insensitivity syndrome (AIS) and congenital adrenal hyperplasia (CAH). These conditions often require sex assignment surgery in either childhood or adolescence. AIS is an X-linked disorder caused by a mutation in the androgen receptor gene that leads to peripheral androgen resistance [5]. The complete form of AIS occurs in approximately 1:20,000 of individuals who are born 46,XY with normal-appearing female genitalia but with sparse pubic hair and a blind vaginal pouch [6]. CAH is a result of several different inherited defects of the steroid synthesis pathway. In cases of 17 α-hydroxylase deficiency, 46,XY individuals will present with normal-appearing female external genitalia, a blind short vaginal pouch, no uterus or fallopian tubes, and intra-abdominal testes [6]. This phenotype is referred to as "complete male pseudohermaphroditism." These patients frequently have abnormal-appearing external genitalia in addition to a shortened vagina, and their reconstructive surgical needs may be extensive.

An immediate partial or total vaginal reconstruction is frequently necessary in cases of extirpative or extensive radical pelvic surgery for cancer treatment. Anterior exenteration procedures are commonly performed for invasive bladder carcinoma [7], while total exenteration procedures are considered salvage operations for recurrent gynecologic cancers such as cervical, uterine, vulvar, and vaginal cancer [8]. Exenteration procedures involve removal of the pelvic organs en bloc and result in significant tissue defects that cannot be closed primarily. While there is no standard procedure for neovaginal reconstructive surgery, there exist many surgical and nonsurgical techniques that are often used to create the vagina. These techniques include the following:

1. Vaginal dilation methods with and without physical therapy
2. McIndoe vaginoplasty procedure with the use of split-thickness skin grafts
3. Modified McIndoe procedures using full-thickness skin and mucosal grafts
4. Transpositional skin graft techniques
5. Laparoscopic techniques including the Davydov and Vecchietti operations
6. Myocutaneous and fasciocutaneous pedicled flap surgeries
7. Intestinal flap surgeries

All of these techniques will be described in detail in this chapter.

Preoperative Assessment and Planning

Patient evaluation begins with a detailed physical exam. In adolescence and young adulthood, office examination with pelvic and/or rectal exam is the first step of evaluation. In the pediatric population, vaginoscopy is the diagnostic standard for evaluating the lower reproductive tract and is usually performed in the operating room. Patients who are suspected of having a congenital anomaly or disorder of sex differentiation should have a karyotype and hormonal evaluation. Additionally, imaging is important to help elucidate which mullerian structures are present and which are absent. T2-weighted magnetic resonance imaging (MRI) of the vagina can show a high-intensity central mucosa surrounded by a low-intensity submucosal layer [9]. With a marker on the perineum, the distance of an obstructed vagina from the perineum can be determined [10], delineating the length of the agenesis, which is helpful for preoperative planning. MRI is also helpful in determining the presence of the uterus, cervix, and ovaries. MRI has

been shown to have 100% sensitivity and specificity in diagnosing MRKH syndrome in patients who are suspected of having vaginal agenesis on physical exam [9]. Transabdominal ultrasonography is useful for evaluating the presence of pelvic organs as well as detecting associated urologic anomalies. Transperineal ultrasound can be used to measure the length of the agenesis as well, especially in the setting of hematocolpos. Understanding the anatomy is the key to successful neovagina reconstruction, which is why the preoperative assessment is so important.

Goals of Therapy

Timing for nonsurgical or surgical creation of a neovagina is elective; however, it is best planned when the patient is emotionally mature. Many of these surgeries are performed in adolescence or in young adulthood. Additionally, it is important to ensure that the patient has a strong support system. The best predictor of favorable emotional outcomes after diagnosis and surgery is a positive relationship between the patient and her guardians and the patient's feeling of self-efficacy with regard to being able to share her feelings with family and friends [11].

The ideal reconstructive method should provide a durable, stable vaginal canal of adequate size and texture that will allow for sexual intercourse, provide a natural aesthetic appearance while simultaneously minimizing morbidity of both the recipient and donor sites, and have a low incidence of overall complications. The most preferable methods also preclude the need for subsequent long-term dilation or need for stents or obturators, as well as lubricants, and can be done in a single-stage fashion [6]. Conservative management is an option for most patients and should strongly be considered as first-line therapy. There are also several surgical procedures that are indicated for neovaginal reconstruction. There is currently no consensus in the literature about the best approach for this type of surgery. The approach should be based on the experience of the surgeon performing the surgery, taking into consideration that the initial surgery is the most likely to be effective and that repeat surgeries may become more challenging with less successful outcomes over time [12].

Conservative Management

Conservative approaches to the creation of a neovagina can be attempted in patients with congenital absence of the vagina. When vaginal development fails, a soft, pliable span of skin is usually left between the urethral meatus and the anus [13]. Nonoperative creation of a vagina can be achieved through progressive dilation and invagination of the perineal epithelium. To achieve this, the patient must have a shallow vaginal pouch that can be stretched to lengthen the canal [14]. Conservative therapy becomes most challenging in patients with no vagina or only a small vaginal dimple, but should still be attempted as success has been demonstrated in these patients as well [15]. The American Congress of Obstetrics and Gynecology recommends dilation as first-line therapy for vaginal lengthening in patients with agenesis of the vagina, as it is the least invasive approach, is very safe with significantly less morbidity than surgical alternatives, is not associated with disfiguring scarring, and has highly favorable outcomes [16]. In 1938, Frank [17] was the first to formally describe vaginal formation with progressive dilation by using Pyrex glass molds and applying persistent pressure to the perineum. Today, Frank's method includes the use of silicon dilators to invaginate the vaginal pouch with the progression of dilator size until a functional vagina is created. Daily dilation, usually performed in lithotomy position, is required for at least 30 minutes each day [6]. The Ingram [18] modification of Frank's technique involves having the patient sit on a bicycle seat stool for progressive dilation, using body weight to maintain adequate dilator pressure. This method has also showed very favorable outcomes [19], but is associated with more discomfort and less patient compliance. Patients should be counseled on the need for good compliance, as well as the anatomic and functional expectations once the process is complete. Anatomic and functional success rates are

Fig. 18.1 Vaginal dilators. Vaginal dilators come in variable lengths and sizes. (Reprinted from Ridgeway and Attaran [89] with permission from Elsevier)

as high as 90% if there is good compliance with dilator use [20]. Roberts et al. [19] followed 51 patients, finding 92% success in those adhering to a vaginal dilation regimen using Frank's technique. Mean time to successful dilation was 11.8 months, with a range of 3–33 months. Younger patients have been found to have the poorest compliance with dilator use [17] as the technique is time-intensive and uncomfortable, especially at the beginning of the process. These patients especially must be counseled about the commitment required for this technique, as well as the projected length of time it will take to achieve a vagina of adequate length and caliber. Figure 18.1 is an image of vaginal dilators, showing that they come in variable lengths and sizes.

Physical therapy can also be used as an adjunct to vaginal dilators in the creation of the neovagina. Vaginal dilators are widely used by physical therapists for the treatment of pelvic floor disorders such as pelvic floor hypertonicity causing pelvic pain, vaginismus, vulvodynia, and dyspareunia [21]. They are used in desensitization therapy using graded exposure with a progressive increase in the size of the dilator in order to treat dyspareunia [22]. Physical therapy using various heat modalities to make the tissues more pliable in conjunction with manual stretching by a therapist while the patients continue to use dilators on her own is associated with a shorter length of treatment to attain a functional vagina [23] and may be a good option for some patients and should be considered.

Surgical Management

Surgery is indicated for patients who are unsuccessful with dilators or patients who opt for surgical management after they have been thoroughly counseled about the risks and the benefits of surgery. The patient should be counseled that surgical management with vaginoplasty is not necessarily a "quick fix" and that she will need to use vaginal dilators postoperatively to maintain her surgically created vagina. Again, the goals of therapy involve the creation of a vaginal canal that is of adequate length and caliber, in the correct axis, with some secretory capacity that will allow for sexual intercourse to occur without the need for lifelong dilation. The timing of the surgery depends on the patient and the type of procedure planned. Surgeries often are performed in late adolescence when the patient is more mature and better able to adhere to postoperative dilation or instructions [24].

McIndoe Procedure

The most common surgical procedure performed in the United States to create a neovagina is the McIndoe operation, which is commonly used to treat patients with congenital absence of the vagina. The primary goal is the creation of a functional vagina. The technique involves creating a canal within the connective tissue between the bladder and the rectum and using a mold to line the vagina with a split-thickness skin graft (STSG) obtained from the patient's thigh, inguinal region, or buttocks [25] followed by progressive vaginal dilator use to achieve maximal vaginal length and caliber. In order to perform this technique, the patient is placed in the dorsal supine lithotomy position. Laparoscopy may be performed first, even in cases when an intra-abdominal graft is not used, in order to delineate organs such as the bladder and rectum prior to commencing the rectovesical dissection from below. Next, the vaginal dimple or foreshortened vagina is identified, and a 3 cm transverse incision is made across it. Dissection is then done, using a mostly blunt technique, first creating two channels on either

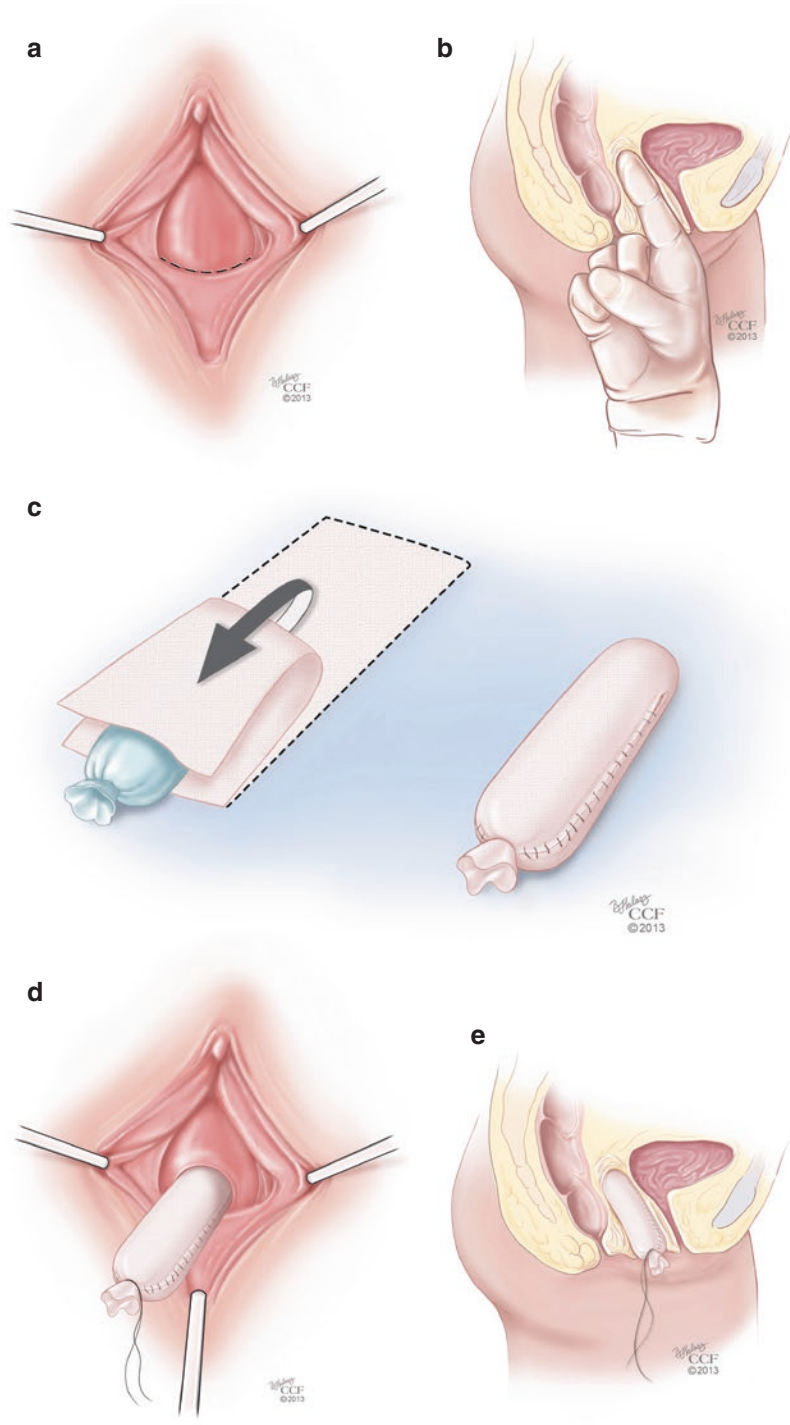

Fig. 18.2 McIndoe procedure. (**a**) The initial step of the McIndoe procedure involves the identification of the vaginal dimple and the creation of a 3 cm transverse incision across it. (**b**) Blunt dissection can be done in the space between the rectum and the bladder in order to create the canal with a goal depth of approximately 10–12 cm. (**c**) Once dissection is complete, the graft is placed over a dilator-like mold in an "inside-out" fashion so that the external portion of the skin lies against the mold. (**d**) The mold is then placed inside the dissected vaginal canal. (**e**) Sagittal view of the mold inside the vaginal canal. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved)

side of the median raphe of the perineum (Fig. 18.2a). Gentle pressure is applied cephalad during dissection to create the canal with a goal depth of approximately 10–12 cm (Fig. 18.2b). Care should be taken during the dissection to avoid entry into the bladder, rectum, and posterior cul-de-sac. An EEA sizer may be used in the rectum to help with dissection. Prior to dis-

section, a split-thickness graft is harvested and should be approximately 10 × 20 cm in size and kept moist using normal saline during the canal dissection. The graft is passed through a skin mesher, which perforates the tissue, expanding the surface area of the graft while permitting egress of blood and fluid from the surgical site postoperatively. Once dissection is complete, the graft is placed over a dilator-like mold in an "inside-out" fashion so that the external portion of the skin lies against the mold (Fig. 18.2c). Placement should be symmetric so that the tip of the mold is at the middle of the graft with the long axis of the graft draped along the long axis of the mold on both sides. The mold is then placed inside the dissected vaginal canal and the edges of the graft are then everted and sutured in an interrupted fashion to the distal opening of the neovagina using 3-0 or 4-0 delayed absorbable suture (Fig. 18.2d, e). Patients are advised about modified or complete bed rest to avoid having the mold or stent fall out and placing tension on the distal sutures. The labia majora are often sewn together over the stent to keep it in place. A Foley catheter is left in place for 5–7 days postoperatively and is removed at the time of mold or stent removal, which is done carefully during an exam under anesthesia so as to not avulse the graft from the underlying connective tissue. Patients subsequently undergo a dilation process that can last several months to a year depending upon patient and tissue compliance.

Studies have shown excellent results after the McIndoe operation. After 12 months, Seccia et al. [4] found that out of 32 patients, 90% of patients presented with complete skin graft take, and 84% reported normal sexual activity with good sensitivity. The most common postoperative complications were anxiety (~6% of patients) related to possible pain during the insertion of the dilator and keloid scarring on the donor site of the skin grafts (~3% of patients). Klingele et al. [20] looked at patient satisfaction with the McIndoe procedure and reported that 79% believed that the procedure improved their quality of life, and 91% were sexually active. Other potential complications reported in the literature include graft rejection, contraction of the graft, hematoma, infection, fistula formation, and excess granulation tissue [26–28].

Modifications of the McIndoe

A modification to the McIndoe procedure is the technique used to open the perineum prior to dissection. A triangular-shaped inferiorly based flap approximately 3–4 cm in size can be created as the initial incision, which can then be sutured to the graft placed on the stent [29]. This method of opening can provide additional length to the neovagina and also help create a tension-free reapproximation of the graft to the neointroitus.

A second modification to the standard McIndoe procedure is the addition of a laparoscopic intraperitoneal repair. Laparoscopically, the bladder is retrograde filled to facilitate visualization of its margins. The peritoneum is grasped at the superior edge of the bladder margin and opened and then dissected off the underlying bladder muscularis. Dissection can be facilitated with injection of normal saline to create a hydrodissection plane. A retropubic dissection is sometimes necessary to further mobilize the peritoneum and to release the bladder from the pubic symphysis, which brings the peritoneum closer to the graft implant site. After the rectovesical dissection is complete and the mold is placed with the graft in its desired location, the peritoneal flap can be used to cover the mold. Bowel epiploica as well as the omentum, if it can be mobilized, can also be used to cover the mold.

The McIndoe procedure also has several modifications related to the type of tissue or material that is used to line the neovagina. While the split-thickness skin graft has been described as a safe and low-morbidity technique [25, 27], it has significant disadvantages. The use of a STSG can be associated with a high contracture rate, even when patients are compliant with vaginal dilation, and this can lead to inadequate vaginal length and caliber [19, 30]. Reported modifications of the McIndoe technique include replacement of the STSG with various alternatives, including autol-

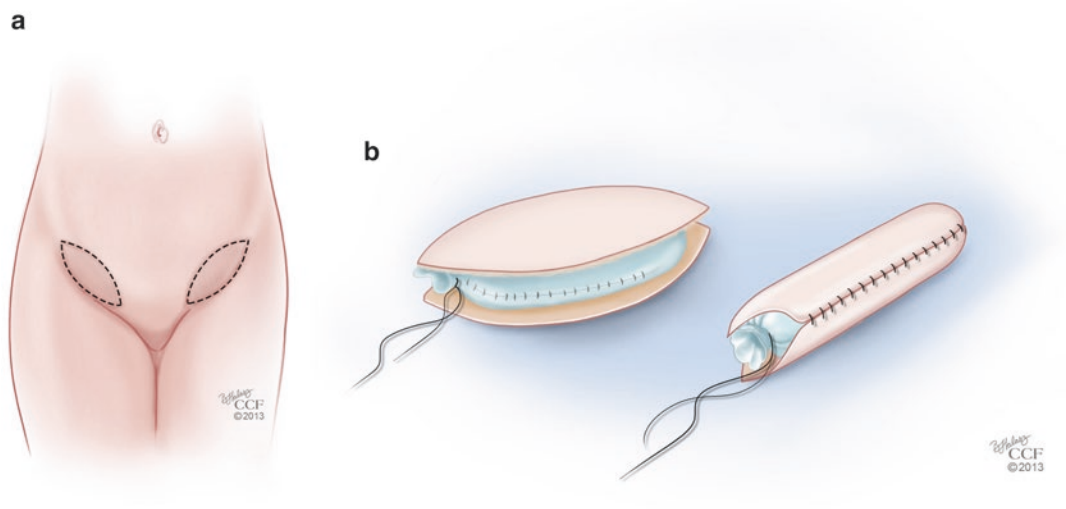

Fig. 18.3 Modification of the McIndoe procedure. (**a**) Technique using full-thickness skin grafts (FTSG) from the inner groin. (**b**) FTSG placed over a mold. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved)

ogous full-thickness skin grafts (FTSG), human amnion, peritoneum, bladder mucosal grafts, xenografts, and synthetic graft material [28, 31–33]. Techniques using FTSG are less likely to lead to neovaginal contracture and stenosis and do not require prolonged stenting [33, 34]. In addition, sebaceous and sweat glands are better preserved in these grafts, which can help with lubrication of the neovagina in some patients [35]. Akin describes a technique using a FTSG from the inner groin areas [29] (Fig. 18.3a). These grafts are used in a similar fashion to the STSG used with the traditional McIndoe procedure (Fig. 18.3b). Younger patients who require neovagina reconstruction may have limited potential graft sites for FTSG harvesting. Techniques such as tissue expander placement in sites such as the bilateral groins have been described with good outcomes and limited morbidity to the donor sites [36]. While FTSG confers many advantages when compared to STSG, the disadvantages of these grafts include skin texture mismatch and unwanted hair growth. Additionally, donor-site morbidity is slightly higher than with STSG and short-term dilation is still required with this technique.

The ideal lining for the vagina is a moist mucosa; however, there are limited donor sites for this type of graft. An option includes lining the neovaginal cavity with multiple full-thickness buccal mucosal grafts. The advantage of this type of grafting is that the neovagina is lined with mucosa, which is moist and may facilitate pleasurable intercourse. Additionally, the donor site heals well with virtually no morbidity [37]. The use of autologous buccal mucosa to reconstruct the vagina was presented in 2003 in two separate publications. Lin et al. [38] used complete pieces of full-thickness harvested mucosal grafts (approximately 6–7 cm × 2–3 cm) from both cheeks to line the neovagina; each graft was expanded in size by making stab incisions throughout the grafts, which were sutured over a stent and then placed in an inside-out fashion into the dissected vesicorectal space. The stent is removed once the graft takes to the underlying tissue. Ozgenel et al. [30] described a similar technique of harvesting the same mucosal grafts, expanding them with stab incisions, but then dividing them into several smaller pieces to cover a larger area over the stent. Another technique involves harvesting two buccal grafts, expanding them and then mincing the grafts into tiny pieces and then spreading the micromucosa graft onto the surfaces of gelatin sponge strips which are then placed over a stent and introduced into the

dissected cavity, left in place until the graft takes to the underlying tissue [37]. Biologic grafts may also be used to line the neovagina and obviate the need for autologous tissue, which confers many advantages in terms of donor-site morbidity. Acellular dermal allografts such as Alloderm® (LifeCell Corps., Woodlands, TX), porcine dermal grafts such as Permacol® (Covidien, Mansfield, MA), and porcine intestinal submucosa grafts such as Surgisis® (Cook Medical Inc., Bloomington, IN) may be options in neovagina reconstruction. All these grafts are composed of an acellular collagen scaffold that provides a bridge for tissue incorporation and neovascularization. Research on the role of these materials for reconstruction is sparse, with the exception of Alloderm®, which has yielded successful outcomes in vulvovaginal reconstructive cases [39].

Tissue engineering to generate vaginal cells is being studied as an alternative approach to lining the neovagina at the time of the McIndoe procedure. Construction of a functional vagina using autologous cells expanded from a small vaginal biopsy was successful in a rabbit model [40]. And, in 2007, Panici et al. [41] reported the first case of neovaginal construction using autologous in-vitro cultured vaginal tissue. A small skin biopsy can be used to culture vaginal tissue, which can be used as a graft at the time of McIndoe vaginoplasty. Early results demonstrate a vagina with normal length and depth with vaginal tissue present on biopsy [41]. Further research is needed in tissue engineering, in its use for vaginoplasty, and long-term outcomes associated with this type of procedure.

Williams Procedure

The Williams Procedure is a vaginoplasty technique that has been employed in vaginal agenesis patients that involves creating a vulvar skin flap that is then sutured in place to create a neovagina. Williams [42] describes placing Allis clamps on the vulvar tissue and applying gentle traction. A U-shaped incision is made extending across the perineum and up to the medial side of the labia (Fig. 18.4a). The upper edge of the incision is made 4 cm laterally and up to the level of the external urethral meatus. The skin flap is sharply dissected off the underlying tissues creating a flap that can be mobilized inward, creating a vaginal pouch (Fig. 18.4b). Once the tissues are mobilized, a first layer of sutures is placed between the inner skin margins using interrupted 0 delayed absorbable sutures, starting posteriorly and moving anteriorly (Fig. 18.4c). A second layer of sutures of the same material is used to approximate the subcutaneous fat and the perineal muscles (Fig. 18.4d). Lastly, the external skin is sutured with interrupted stitches (Fig. 18.4e). The Creatsas modification of the Williams vaginoplasty involves using electrocautery to open the hymen at the 3, 6, and 9 O'clock positions, which further opens the introitus and helps to create adequate vaginal caliber and prevents hemorrhage due to rupture of hymenal vessels during the first sexual intercourse [43]. Follow-up of these patients reveals overall subjective satisfaction with vaginal lengths of 10–12 cm and widths of 4–5 cm [44]. This procedure is considered to be superior to the McIndoe procedure as it is can be performed in less time and there is less need for postoperative vaginal dilators, which reduces the psychological impact of the treatment [43].

Laparoscopic Procedures

The Vecchietti and Davydov techniques for vaginal reconstruction were first performed as open procedures, but advances in minimally invasive surgery have allowed these procedures to be performed laparoscopically. The main advantage of a laparoscopic approach is the ability to bridge the need to perform an indicated abdominal procedure with the ease of recovery for the patient. The postoperative phase of these surgeries is usually very involved, and therefore, length of hospital stay is usually not significantly shortened, as is seen with most laparoscopic operations. However, once discharged from the hospital, patient recovery is easier as postoperative pain is less and patients are able to return to their daily activities faster.

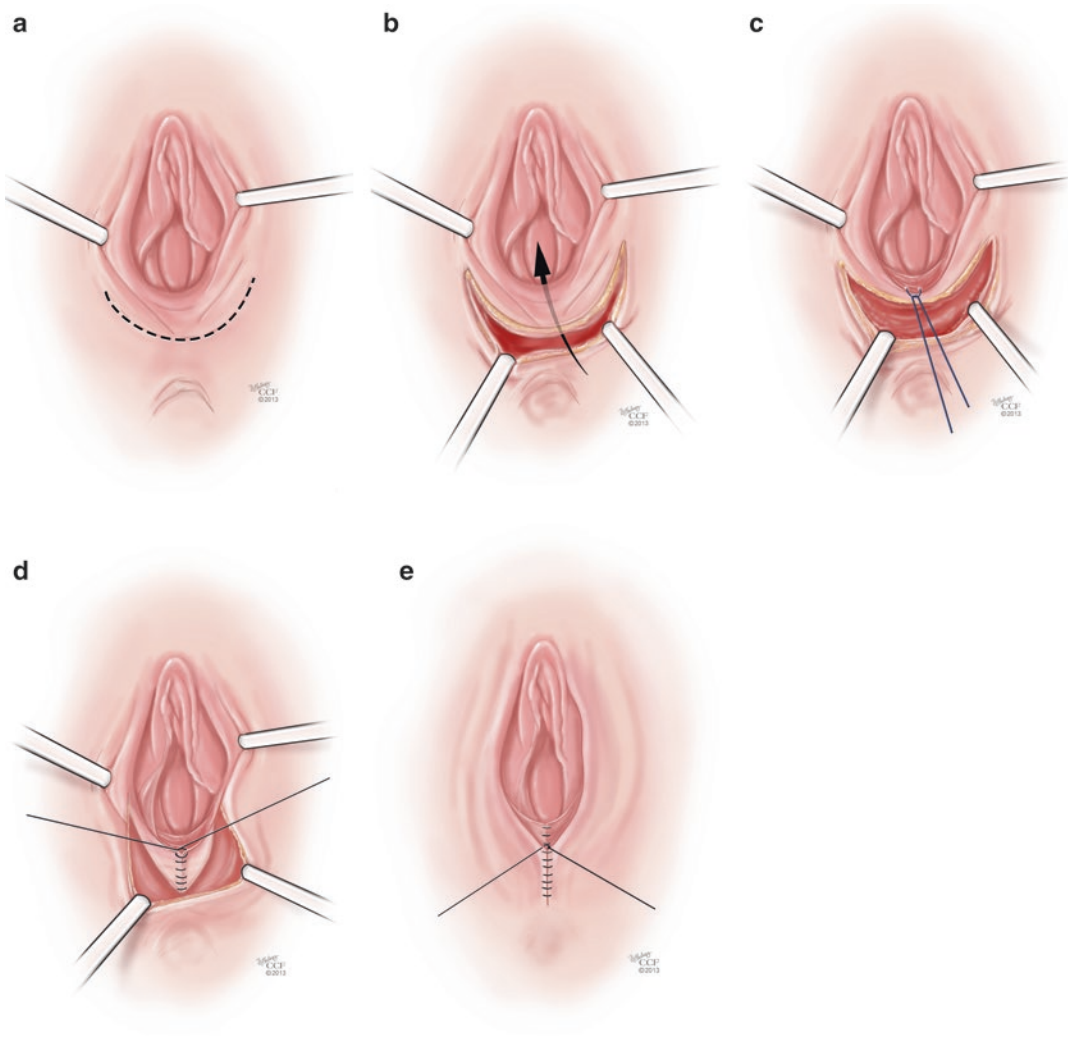

Fig. 18.4 Williams procedure. (**a**) The initial step of the Williams procedure is a U-shaped incision extending across the perineum and up to the medial side of the labia. (**b**) The skin flap is sharply dissected off the underlying tissues creating a flap that can be mobilized inward, creating a vaginal pouch. (**c**) Once the tissues are mobilized, a first layer of suture is placed between the inner skin margins using interrupted 0 delayed absorbable sutures. (**d**) A second layer of sutures of the same material is used to approximate the subcutaneous fat and the perineal muscles. (**e**) The external skin is sutured with interrupted stitches. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved)

Vecchietti Procedure

The Vecchietti procedure involves gradual mechanical stretching of the patient's vaginal skin to create a full-length vagina. This procedure is most appropriate for patients presenting with vaginal agenesis and no prior reconstructive surgery [45]. In this procedure [46], the vesicorectal space is carefully dissected laparoscopically to reflect the bladder anteriorly. An EEA sizer can be placed inside the rectum for mobilization and visualization of the rectovesical space in order to avoid entry into the rectum at the time of dissection. A 2 cm olive-like acrylic bead is placed on the vaginal dimple and is sutured in place to the perineum. Under direct visualization with the laparoscope, a guide needle is used to pass permanent sutures through

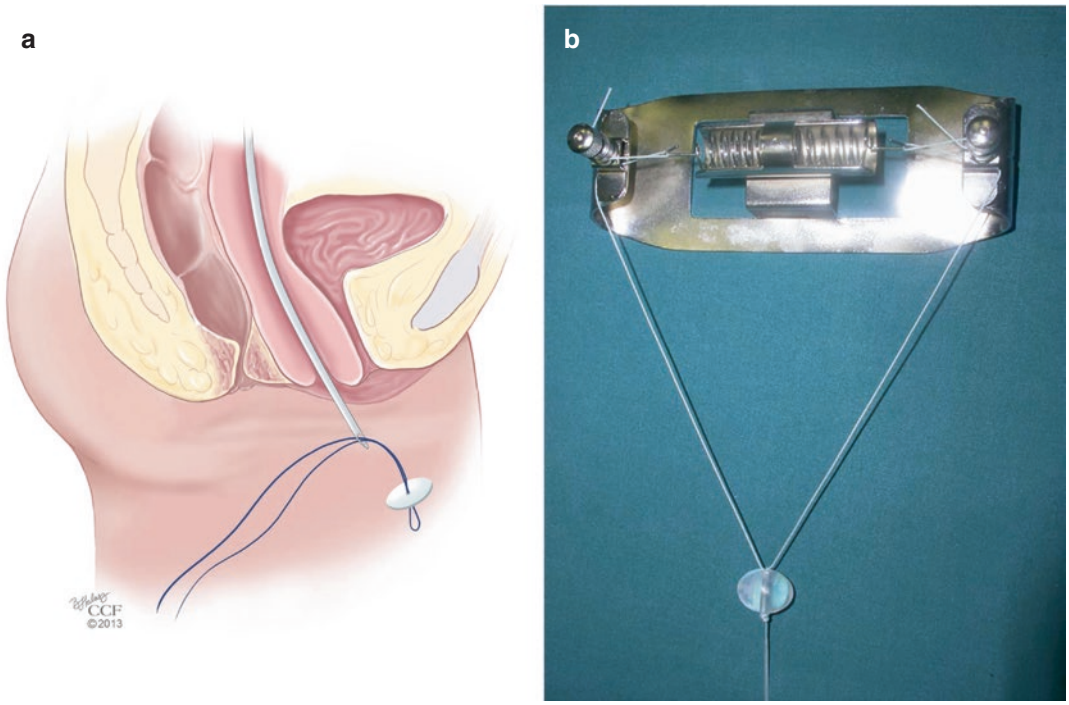

Fig. 18.5 Vecchietti procedure. (**a**) Under direct laparoscopic visualization, a guide needle is used to pass permanent sutures through the acrylic bead and vagina and into the dissected rectovesical space in the pelvis. A guide needle is then inserted suprapubically and used to pull the sutures out of the body. (**b**) Sutures are connected to a traction device that is secured to the patient's abdomen. ((**a**) Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved; (**b**) Reprinted from Fedele et al. [90] with permission from Elsevier)

the acrylic bead and vagina and into the dissected rectovesical space in the pelvis. A guide needle is then inserted suprapubically and used to pull the sutures out of the body (Fig. 18.5a). The sutures are connected to a traction device that is secured to the patient's abdomen (Fig. 18.5b). Sutures are tightened on a regular schedule, placing traction on the vaginal epithelium, and gradually increasing the length of the vaginal canal. Once adequate vaginal length is achieved, the traction device is removed and the sutures are cut and freed from the body. Patients are advised to practice daily dilation in order to help stretch the vaginal epithelium and maintain vaginal caliber and length during the traction phase of the procedure, and for a limited amount of time once the device is removed. As with the Frank dilation method, patient compliance with vaginal dilation and routine follow-up of the traction device are paramount to the success of the surgery. Data on long-term anatomic outcomes as well as sexual health and quality of life outcomes are favorable with this procedure [47].

Davydov Procedure

The Davydov procedure [48] is a technique used to create a neovagina using the patient's own peritoneum. Good candidates for this procedure include patients with disorders of sex differentiation, such as XY females, who have undergone prior feminizing genitoplasty procedures, but have had poor outcomes, or are not satisfied with vaginal length or caliber. Several modifications of the procedure exist. We recommend first making a U-shaped perineal incision to serve as a landmark for where the peritoneal edges are to be sutured later in the case.

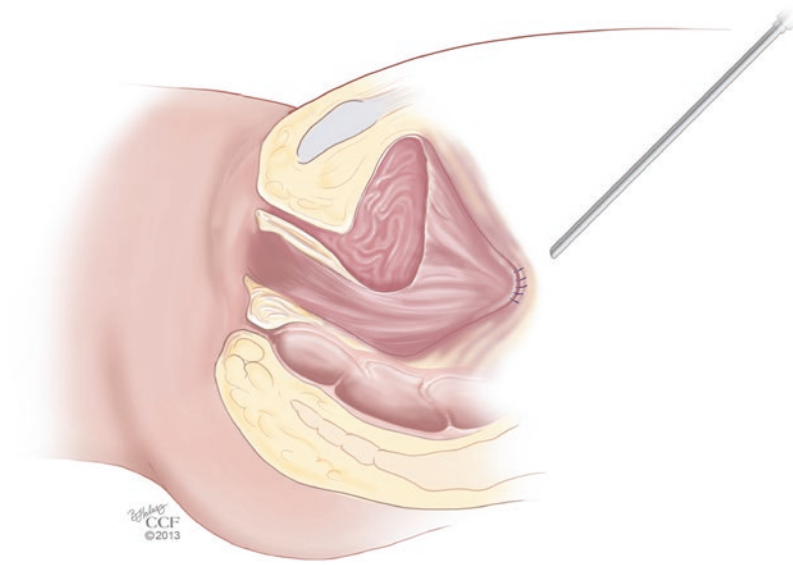

Fig. 18.6 Davydov procedure. The mobilized peritoneum is sutured to the perineal incision and closure of the abdominal end of the neovagina is done laparoscopically with a purse string suture. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved)

Laparoscopic dissection is then done in the rectovesical space, similar to the technique described for the Vecchietti procedure. This is also done using an EEA sizer in the rectum, to delineate the correct dissection plane. Releasing peritoneal incisions in the pouch of Douglas are then made either laparoscopically or transvaginally, freeing and mobilizing the peritoneum caudally so that it can be sutured to the previously made perineal incision. Closure of the abdominal end of the neovagina is done laparoscopically with a purse string suture (Fig. 18.6). A vaginal mold is left in place for several weeks and, once removed, it is replaced with daily dilation until maximal vaginal length is created [45].

There are significant advantages to these two laparoscopic procedures when compared to nonsurgical dilation methods. Lengthening of the vagina is accomplished at the time of the procedure, and does not require long-term dilation that can be very uncomfortable initially and time-consuming. The dilation that is then required postoperatively is usually much easier as the vagina has already been created and the main goal of dilation is the maintenance of length and caliber. Patients tend to be very compliant with these steps. The main disadvantage is that both techniques require surgical intervention, and while they are performed in a minimally invasive fashion, require extensive dissection into the rectovesical space, which can be associated with rectal, bladder, nerve, and vascular injury. Therefore, the meticulous technique requires an experienced surgeon.

Myo- and Fasciocutaneous Flap Procedures

The principle of a myo- and fasciocutaneous flap is the creation of an island flap that depends on the underlying muscle or fascia for its vascular supply. The flap is made up of muscle with or without fascia or fascia alone and the overlying subcutaneous and cutaneous tissues.

Two main techniques can be described when reconstructive surgery is performed using flaps: (1) the standard local or regional flap technique which is based on a vascular pedicle that remains intact while the flap is being mobilized and (2) the more sophisticated microvascular free flap, which involves ligation of the vascular pedicle and reanastomosis to the vasculature of the recipient site. With a few exceptions, the pedicled flap is the most commonly employed flap technique for reconstruction of the neovagina and is usually used after extirpative pelvic surgery or when initial skin-graft techniques have failed in patients with congenital anomalies.

Flap orientation and dimensions of the skin paddle harvested are designed to achieve adequate perfusion through the muscular portion of the flap while achieving adequate skin for vaginal reconstruction, as well as primary donor-site closure. All pedicled flaps have their limitations in terms of the arc of rotation, the size, the tissue volume, and the restriction of mobility. These factors sometimes make it difficult to tailor the flap to the defect that needs repair [49]. Advantages of myo- and fasciocutaneous flaps include the mobilization of a substantial amount of tissue to repair pelvic dead space while providing a source for revascularization for the surrounding tissues. The disadvantages of these flaps are that they can sometimes be very bulky which can affect cosmetic outcome and make the neovaginal cavity narrow, the skin paddles that line the vagina do not provide any lubrication for intercourse, and there can be significant morbidity from the donor site [50].

Rectus Abdominis Flap

Rectus abdominis musculocutaneous flaps are based off the deep inferior epigastric vessels and can be harvested in two different orientations: transverse (TRAM) and vertical (VRAM). The VRAM flap is usually the preferred method of harvesting for exenteration procedures when stomas are created for bowel and urologic reconstruction [49, 51]. The VRAM flap can be taken from either the patient's left or right side and is developed above the level of the arcuate line (Soper) (Fig. 18.7a). The skin paddles typically measure 12 × 8 cm in size, which is usually sufficient for the creation of a functional vagina [52]. The horizontal dimension is usually limited by the ability to close the skin primarily; a flap width extending 2 cm lateral to the palpable edges of the rectus can be closed easily in most cases [53]. Once the course of the deep inferior epigastric vessels is identified with Doppler, the flap is elevated from the costal margin to the level of the inguinal fold. Dissection is carried down to the rectus sheath and the lateral border is opened sharply. The skin island with the underlying subcutaneous tissue is mobilized off the anterior rectus fascia, and the fascia is incised in a slightly smaller ellipse mirroring the skin island in order to leave a smaller fascial defect [51]. The muscle is elevated off the posterior fascia after the intercostal neurovascular bundles are ligated. The flap is freed superiorly by dividing the muscle at the costal margin. The superior epigastric vessels are identified and ligated. The deep inferior epigastric vessels remain as the vascular supply to the flap, and are identified inferiorly on the posterolateral surface of the muscle, crossing the lateral border of the muscle at approximately the level of the arcuate line. The flap is then elevated carefully so as to not shear the underlying branches of the pedicle. Interrupted absorbable sutures can be used to secure the muscle edges to the overlying subcutaneous tissue to prevent shearing during flap transfer [53] (Fig. 18.7b, c). TRAM flaps are raised in an elliptical fashion as well, below the umbilicus, from one anterior superior iliac spine to the contralateral iliac spine (Fig. 18.8a). In a similar fashion, the dissection is made underneath the anterior rectus fascia, which is preserved in a transverse orientation. The epigastric vessels are identified, and the superior vessels are ligated to allow for mobilization of the pedicled flap in a similar method used for the VRAM (Fig. 18.8b, c).

Once the flap is raised, it is folded into a tube by approximating the edges in a 2-layer closure using absorbable sutures. VRAM flaps are folded into a tube such that the proximal and distal ends of the flap form the introitus once placed in a proper position [52]. TRAM flaps are folded such that the lateral border is approximated to the medial border and the cranial edge of the flap is used to form the introitus [51]. The tube is then mobilized into the pelvis through an opening in the posterior rectus fascia, and then brought beneath the pubic ramus, without placing tension on the pedicle. Closed suction drains are placed in the abdomen and pelvis to prevent hematoma and seroma formation. The rectus fascia at the donor site is closed with heavy running sutures and the overlying skin is closed in a manner that limits the distortion of the umbilicus.

A modification to the VRAM flap is the inferior-based VRAM flap. This flap has been

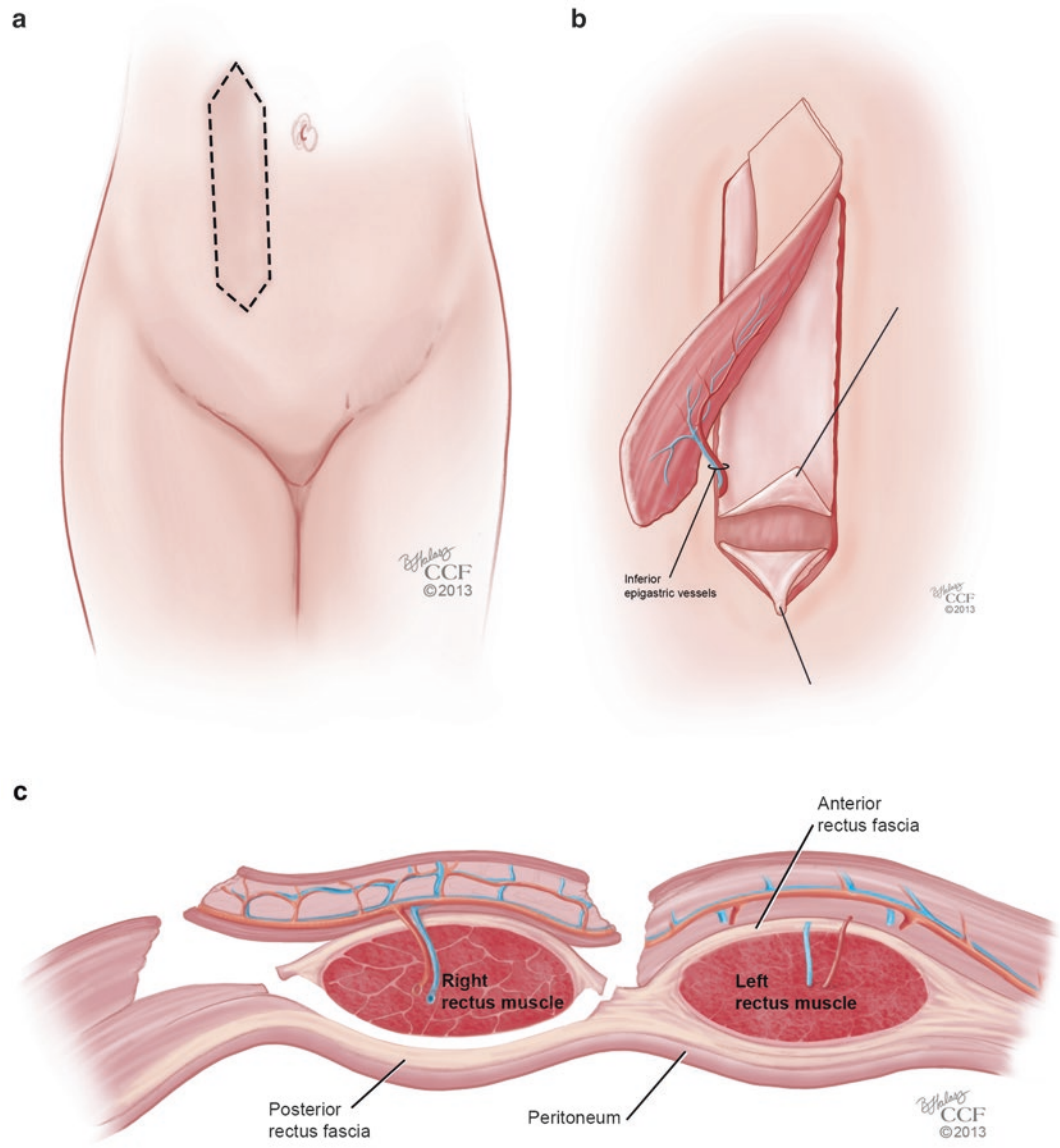

Fig. 18.7 VRAM flap. (**a**) Orientation of the vertical rectus abdominis musculocutaneous (VRAM) flap. (**b**) Mobilization of the VRAM flap on its vascular pedicle. (**c**) Coronal view of the mobilization of the VRAM flap on its vascular pedicle. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved)

shown to meet reconstructive needs in cases of vulvar and perineal defects after resective surgery. Traditional myocutaneous flaps used for reconstruction following radical vulvectomy can cover the large perineal defects but do not provide a "functional" reconstruction that can preserve anal and vaginal patency. The inferior-based VRAM flap is marked and raised in a similar fashion to the standard VRAM flap. The muscle is then split distally in the midline with care taken to avoid transection of the muscular branches of the superior epigastric artery that anastomose with the deep inferior epigastric artery, and supply important perforators to the muscle and skin of the flap. These muscular branches can easily be identified and separated

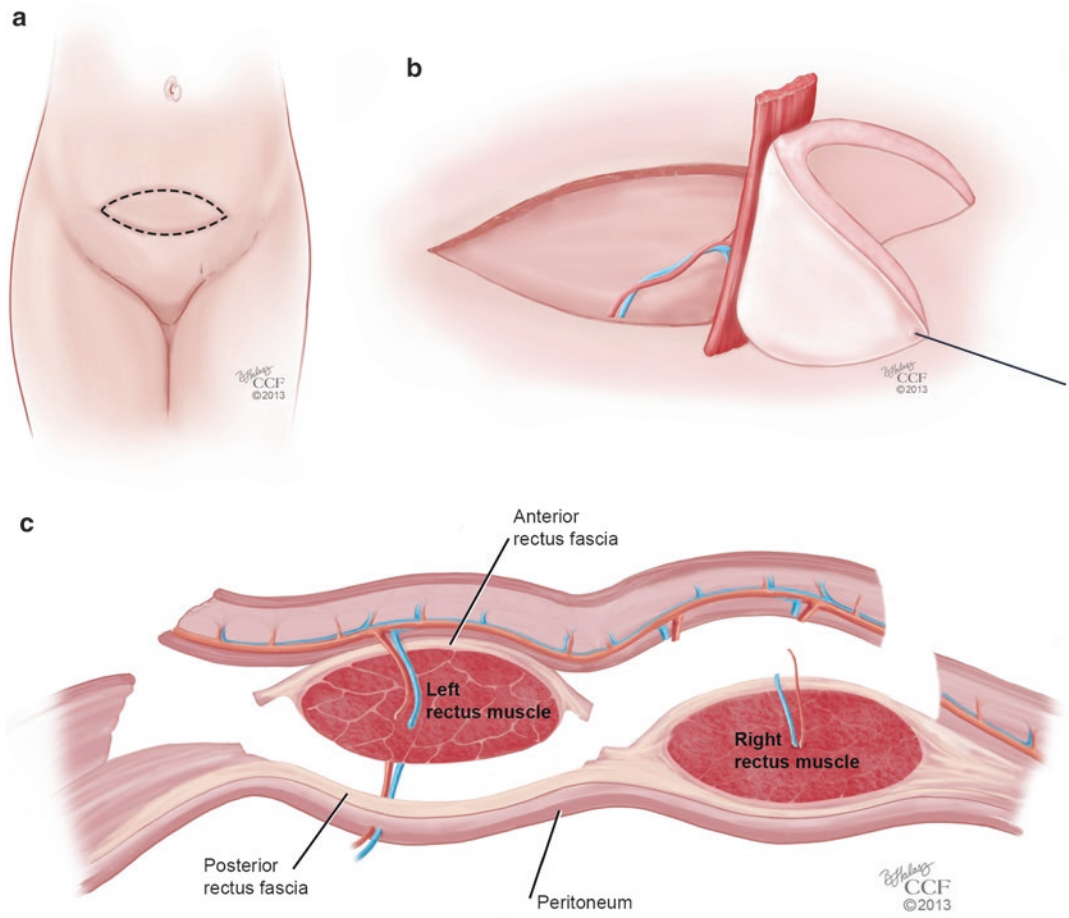

Fig. 18.8 TRAM flap. (**a**) Orientation of the transverse rectus abdominis musculocutaneous (TRAM) flap. (**b**) Mobilization of the TRAM flap on its vascular pedicle. (**c**) Coronal view of the mobilization of the TRAM flap on its vascular pedicle. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved)

on the underside of the muscle by using spreading dissection, each supplying a tongue of overlying skin and subcutaneous tissue [53]. Division of the distal flap produces well-vascularized myocutaneous fork flaps that can be draped around the vaginal cuff and crossed inferiorly over the perineal body to create a fourchette. This also provides a skin edge for attachment of anal mucosa if extensive perianal dissection was performed.

Several series have looked at the complication rates and outcomes of rectus abdominis myocutaneous flaps [50, 52, 54, 55]. One of the larger series found that 38% of patients developed flap-specific complications including stricture/stenosis (13%), pelvic abscess or hematoma (6%), and rectovaginal fistula (6%), while only two (6%) patients experienced complete flap loss [51]. Donor-site complications included fascial dehiscence (5%) and superficial separation (13%). A major criticism of the VRAM flap is that synthetic mesh is often necessary to repair the fascial defect to prevent the risk of ventral wall hernia [56]. However, the VRAM orientation is often preferable for certain exenteration procedures, as it allows for easier stoma and conduit creation on the contralateral side. Additionally, techniques that focus on reducing the size of the fascial defect to less than 4–6 cm in comparison to the entire flap size can significantly reduce the risk of

future hernia. In their case series, Soper et al. [51] found that there were no significant differences between the TRAM and VRAM groups in the distribution of donor-site, recipient-site, or overall flap-specific complications; VRAM flaps were not more likely to be complicated by ventral wall hernia.

Gracilis Flap

Gracilis musculocutaneous flaps are based off the medial circumflex femoral artery. A skin flap matching the dimensions of the defect is outlined on the proximal two-thirds of the inner thigh overlying the gracilis muscle, the most superficial muscle of the inner thigh (Fig. 18.9a). Once the course of the medial circumflex femoral artery has been identified with Doppler, a full-thickness elliptical island of skin and subcutaneous tissue approximately 14–20 cm in length and 8–10 cm in width is raised. The proximal skin incision and the arc of rotation are based approximately 6–8 cm from the pubic tubercle, at the point of entry of the neurovascular bundle into the gracilis muscle [57]. Using sharp and blunt dissection, the underlying gracilis muscle is mobilized with care taken to identify and preserve the dominant neurovascular pedicle [58] (Fig. 18.9b, c). Incising the fascia over the adductor magnus muscle and dissecting this fascia medially with a blunt instrument facilitates identification of the bundle. Once the muscle is completely dissected out and separated from the surrounding inner thigh muscles, it is transected proximally close to the ischial pubic ramus and then sutured to the overlying subcutaneous tissue using 3-0 or 4-0 absorbable sutures in an interrupted fashion [58]. The raised flap is then rotated posteriorly through a subfascial perineal tunnel. If complete vaginal reconstruction is necessary, bilateral flaps are raised. Flaps are then formed into tubes by approximating the skin edges such that the distal edge of each flap becomes the apex

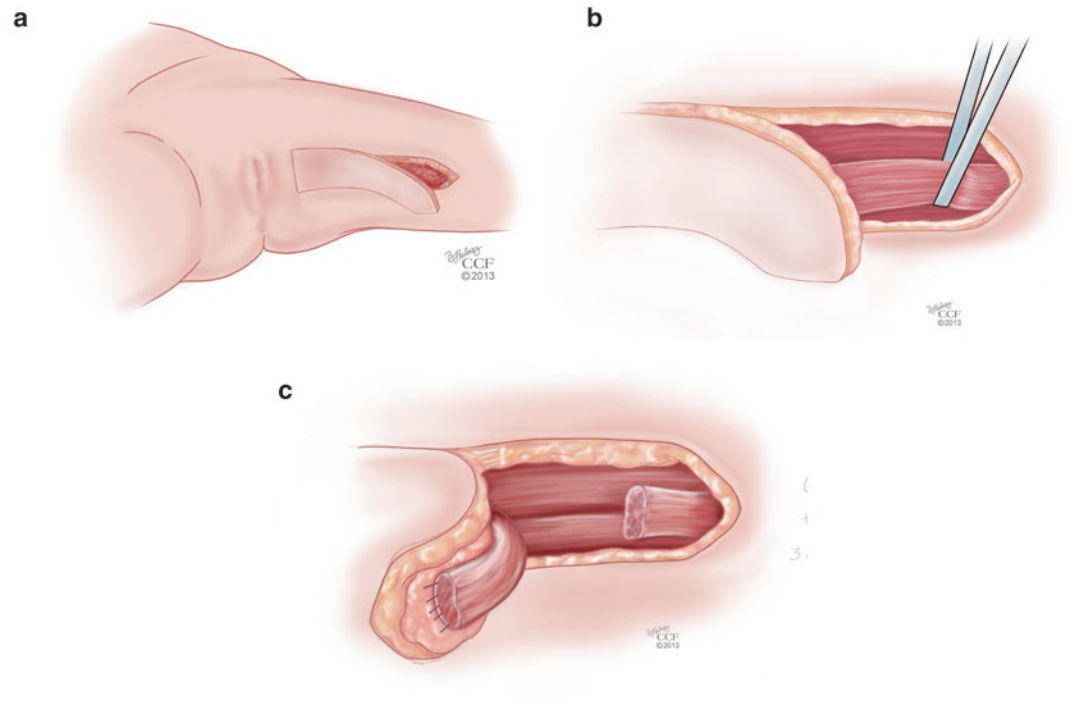

Fig. 18.9 Gracilis flap. (**a**) Orientation of the gracilis musculocutaneous flap. (**b**) Identification of the gracilis muscle. (**c**) Mobilization of the gracilis muscle. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved)

of the neovagina. The neovaginal tube is then rotated posteriorly into the pelvic defect and the proximal skin edges approximated to the introitus. The donor site is closed in layers with synthetic absorbable suture, and a closed-end drain is left in place at this site.

The gracilis musculocutaneous flap is commonly used to repair vaginal defects after extirpative surgery. The main advantage of the flap is that, with proper technique, it is easy to raise and also less difficult to tunnel to the vaginal or vulvar defect. However, when compared to rectus abdominis flaps, the gracilis flap has been associated with a higher rate of flap loss (14% versus 3%) [57]. Casey et al. [50] performed one of the largest outcome studies evaluating myocutaneous flaps. They compared 41 VRAM, 13 gracilis, and 45 pudendal thigh flaps. They determined that the VRAM had the lowest overall and flap-related complication rates following complete vaginal reconstruction. However, the flap and donor-site complication rates for the gracilis and pudendal thigh flaps were acceptable enough to consider these flaps good alternatives if a VRAM flap is not possible. They also found that patient age and preoperative sexual activity were good predictors of postoperative sexual activity following vaginal reconstruction; therefore, this should be assessed preoperatively and considered when deciding upon vaginal reconstruction methods.

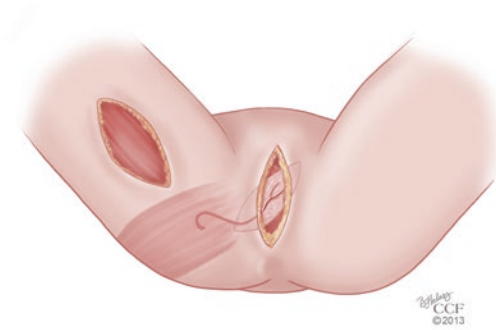

Fig. 18.10 Posterior thigh flap. Mobilization of the posterior thigh flap, based off the inferior gluteal artery. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved)

Posterior Thigh Flap (Fig. 18.10)

An alternative to the gracilis flap is the posterior thigh flap, based off the inferior gluteal artery. The posterior femoral cutaneous nerve of the thigh is usually preserved at the time of this flap dissection; therefore, a portion of the flap is usually partially sensate. Friedman et al. [59] describe this technique. The course of the inferior gluteal artery is confirmed with Doppler and the skin island is centered over the vascular pedicle along the length of the posterior thigh. Flap dimensions are marked according to the defect needing repair. The distal most aspect of the flap should be marked a few centimeters superior to the popliteal crease, to avoid potential scar contracture deformity and wound-healing problems. Dissection is first begun at the distal aspect of the flap and carried out laterally and medially until the distal portion of the flap is reached. The flap is then elevated in continuity with the underlying fascia of the posterior compartment of the thigh, from a distal to proximal direction. Absorbable sutures are placed through the fascia and dermis to prevent shearing of the vascular pedicle and to facilitate mobilization of the flap. The flap is completely raised once it is dissected proximally to the inferior border of the gluteus maximus muscle. The flap is mobilized to the pelvis through a subcutaneous tissue tunnel, above the underlying fascia, between the posterior thigh and the adjacent defect. Bilateral flaps are usually raised and mobilized for creation of the neovagina. Once mobilized, they are tubularized and positioned in a similar fashion as the gracilis flap. Drains are placed in the pelvis and at the donor site, which is usually closed primarily. The advantages and disadvantages of the posterior thigh flap reflect those of the gracilis and rectus abdominis flaps [59]. It remains a good alternative in cases that do not allow for the use of more common reconstructive procedures.

Pudendal Thigh Flap

The pudendal thigh flap is a vulvoperineal fasciocutaneous flap and is also known as the *Singapore* or *Malaga flap*, and can also be used for recon-

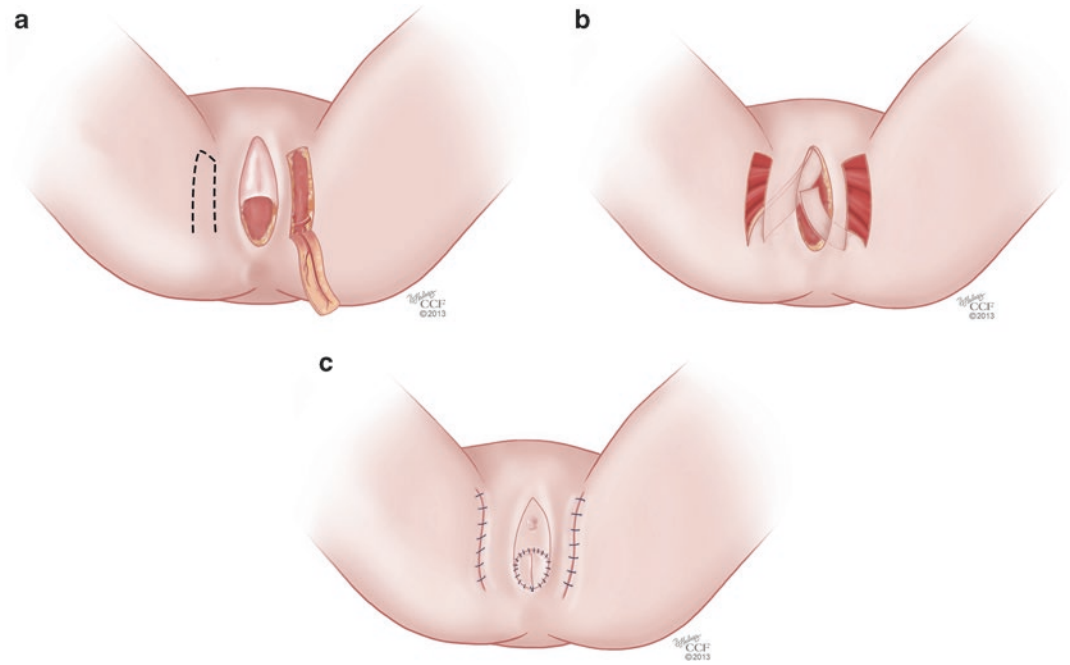

Fig. 18.11 Pudendal thigh flap. (**a**) Pudendal thigh flap based off the posterior labial arteries. (**b**) The strip of flap that passes under the labia is de-epithelialized and sutured to the overlying tissue. (**c**) The medial, distal, and lateral margins of the flaps are approximated, creating a tubular pouch, and the skin edges are sutured to the neointroitus and cutaneous edges of the labia majora. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved)

struction of the vagina. The pudendal thigh flap is based off the posterior labial arteries, which are a continuation of the perineal vessels, which are the terminal vessels of the internal pudendal artery. These arteries anastomose with branches of the deep external pudendal artery, the medial circumflex femoral, and the anterior branch of the obturator artery over the proximal portion of the adductor muscle. The posterior portion of this flap is innervated by the posterior labial branches of the pudendal nerve. As a result, the proximal portion of the flap often times maintains some degree of sensation. The superficial perineal nerve is often preserved as well with this flap, which adds additional sensation. The vulvoperineal skin island is marked vertically in a rectangular shape with the longitudinal axis overlapping the lateral limit of the labia majora; the base of the flap is inferior to the posterior border of the neovaginal introitus, extending from the labia majora across the groin crease to the medial thigh and measures up to 12 × 6 cm [60] (Fig. 18.11a). Sharp dissection is done to raise the flap starting at the superior most margins where the deep external pudendal artery branches with the superficial perineal artery. This anastomosis is ligated and the superficial perineal artery is preserved with the flap. The flap is dissected down to the level of the adductor muscles, the fascia over the muscles is raised with the flap, and the superficial perineal muscles can be identified [61]. The flap is detached medially by transecting the insertion of the adductor aponeurosis, which inserts into the ischiopubic ramus. Bilateral flaps are usually raised and then tunneled subcutaneously under the labia majora into the previously dissected rectovesical space. The strip of flap that passes under the labia is de-epithelialized and sutured to the overlying tissue. Lastly, the medial, distal, and lateral margins of the flaps are approximated, creating a tubular pouch, and the skin edges are sutured to the neointroitus and cutaneous edges of the labia majora (Fig. 18.11b, c). The donor site is then closed primarily in several layers. Long-term follow-up of these patients shows positive anatomic and functional outcomes [61].

Martius Bulbocavernosus Flap

The Martius bulbocavernosus flap was first described in 1928 by Martius [62] and has been used frequently in the repair of complex vaginal fistulas. It can also be a useful source for the construction of a partial or complete neovagina [63–65]. For larger defects such as complete vaginectomy in the setting of total pelvic exenteration, bilateral Martius flaps can be used by tubularizing the flaps to create a complete, full-length vagina with normal caliber. When marking and mapping these flaps, the primary goal should be to create flaps that are as large as possible with the ability to close the donor site primarily without tension. This technique has been described by Green et al. [63]. The Martius flaps should extend from the level of the clitoris superiorly to a level just above the perineal body inferiorly. The medial margin is the sulci between the labia majora and minora. The lateral margin is the lateral edge of the labia majora. The flap is sharply developed and raised, preserving the vascular pedicle, which is the posterior labial branch of the internal pudendal artery. The flaps are tunneled through the paravaginal windows into the abdomen. The portion of the flap that is to become the posterior vagina is sewn to the top of the vagina. The two flaps are joined on the posterior aspect with interrupted sutures. The anterior aspects are sewn to the vaginal cuff and then joined anteriorly, creating a tube with vulvar epithelium lining the neovagina. This method of reconstruction is an excellent choice for patients who have vulvar anatomy that is conducive to creating large flaps that can be easily mobilized. In the appropriate patient, this procedure for neovaginal reconstruction is associated with minimal blood loss, short operative time, decreased pain, and less disfigurement than other types of flaps and has very favorable anatomic outcomes [63].

Omentum-Pedicled Flap

While the greater omentum-pedicled graft is not a musculocutaneous flap, it has been extensively used for coverage of perineal and other soft-tissue defects but has also been used successfully in vaginal reconstruction [66]; for these reasons, it is worth mentioning. Case series have shown that the flap can be used in conjunction with an absorbable graft such as a Vicryl mesh that is first positioned into proper location using a vaginal stent and sutured to the remaining edges of either the posterior or anterior vagina. The omentum-pedicled graft is based off the left gastro-epiploic artery, which is mobilized down along the left paracolic gutter, and then draped over all parts of the mesh and sutured to the graft [67] (Fig. 18.12). While this type of flap is not commonly used for vaginal reconstruction, it may confer important benefits. The omentum has a rich vascular supply and it unlikely to necrose, even after mobilization. Additionally, it is easily mobilized without significant morbidity. Lastly, the flap itself is much less bulky than other commonly used myocutaneous flaps and may have better cosmetic results. Its major disadvantage is that a mesh graft may be necessary for placement as there are no reported cases of omental flaps used for vagi-

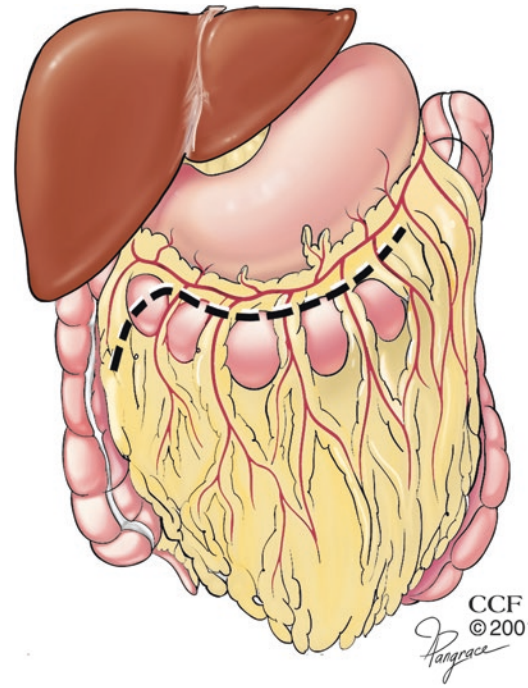

Fig. 18.12 Omentum-pedicled flap. Based off the left gastro-epiploic artery, which is mobilized down along the left paracolic gutter to the site of reconstruction. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved)

nal reconstruction without the use of a mesh graft. There are currently no studies examining the safety of synthetic nonabsorbable grafts in neovaginal reconstruction with omentum-pedicled flaps.

Intestinal Flaps

Different bowel segments, including the ileum, jejunum, cecum, and sigmoid colon, have been used for neovaginal reconstruction. The procedure involves resecting a segment of the bowel approximately 10–12 cm in length with its vascular pedicle intact, reanastomosing the bowel, mobilizing the resected segment into the pelvis, suturing the edges to the obliterated vagina after creation of a proper space, and suturing to close the proximal end of the segment, forming a pouch [68] (Fig. 18.13a–d). The main advantages of intestinal flaps are that the risk of contracture and stenosis is significantly reduced, molds or stents are not required to ensure patency, and lubrication is not a problem, facilitating intercourse [69]. Procedures are usually performed via a laparotomy; however, there are some case reports and series describing laparoscopic techniques [70]. The most significant disadvantages of intestinal flaps include the morbidity of laparotomy such as infection and wound dehiscence, shrinkage with intestinal stenosis, anastomotic dehiscence, possible need for colostomy, and persistent copious secretion of colonic mucus. These procedures are more complicated than other neovaginal procedures and are limited to surgeons with a very unique skill set.

Sigmoid Flap

The sigmoid is the most commonly used piece of colon for neovaginal reconstruction because of its location in the pelvis and ease of mobilization [6]. Its vascular supply consists of the sigmoidal arteries that branch off the inferior mesenteric artery. In a large series, Kwun Kim et al. [71] showed that the sigmoid neovagina achieved a very low contraction rate, was able to maintain adequate vaginal length and width without the use of stenting, mucous secretion helped with sexual intercourse, there was low incidence of malodor, and patients were satisfied with the cosmetic appearance of the reconstruction. Additionally, sexual satisfaction has been reported to be as high as 78% after sigmoid vaginoplasty [72]. While these cases have been done laparoscopically [70], the vast majority are performed via laparotomy, which has its risks and associated comorbidities. In addition, there are reports of diversion colitis, ulcerative colitis, patient dissatisfaction with copious malodorous neovaginal discharge, prolapse, flap failure, and defecatory dysfunction [70]. While very rare, primary adenocarcinoma of the colon has been reported in the sigmoid neovagina as well [73].

Ileocecal Flap

The ileum and cecum have both been used successfully in the creation of the neovagina and are based off the ileal branches of the superior mesenteric artery (SMA). The main advantage of these flaps is that there is excellent blood supply to those portions of the bowel and the vascular pedicle is long enough to be mobilized to the pelvis. Additionally, reports show that there is the least mucous production of all of the intestinal flaps and therefore, there is less vaginal discharge [69]. The main disadvantage of the ileal flap is that compared to the jejunum and sigmoid, the ileum wall is much more fragile and delicate and more likely to sustain trauma with subsequent bleeding at the time of mobilization and is also associated with a higher rate of stenosis and intestinal obstruction [6]. Similar to the sigmoid flaps, there are reported cases of laparoscopic ileal vaginoplasty, which have been successful and confer the advantage of less morbidity [69].

Jejunal Flap

This pedicled flap is also based off a branch of the SMA. The jejunum has a smaller lumen than the rectosigmoid and can provide favorable cosmetic and functional outcomes [6]. Another significant advantage over the sigmoid flap is that

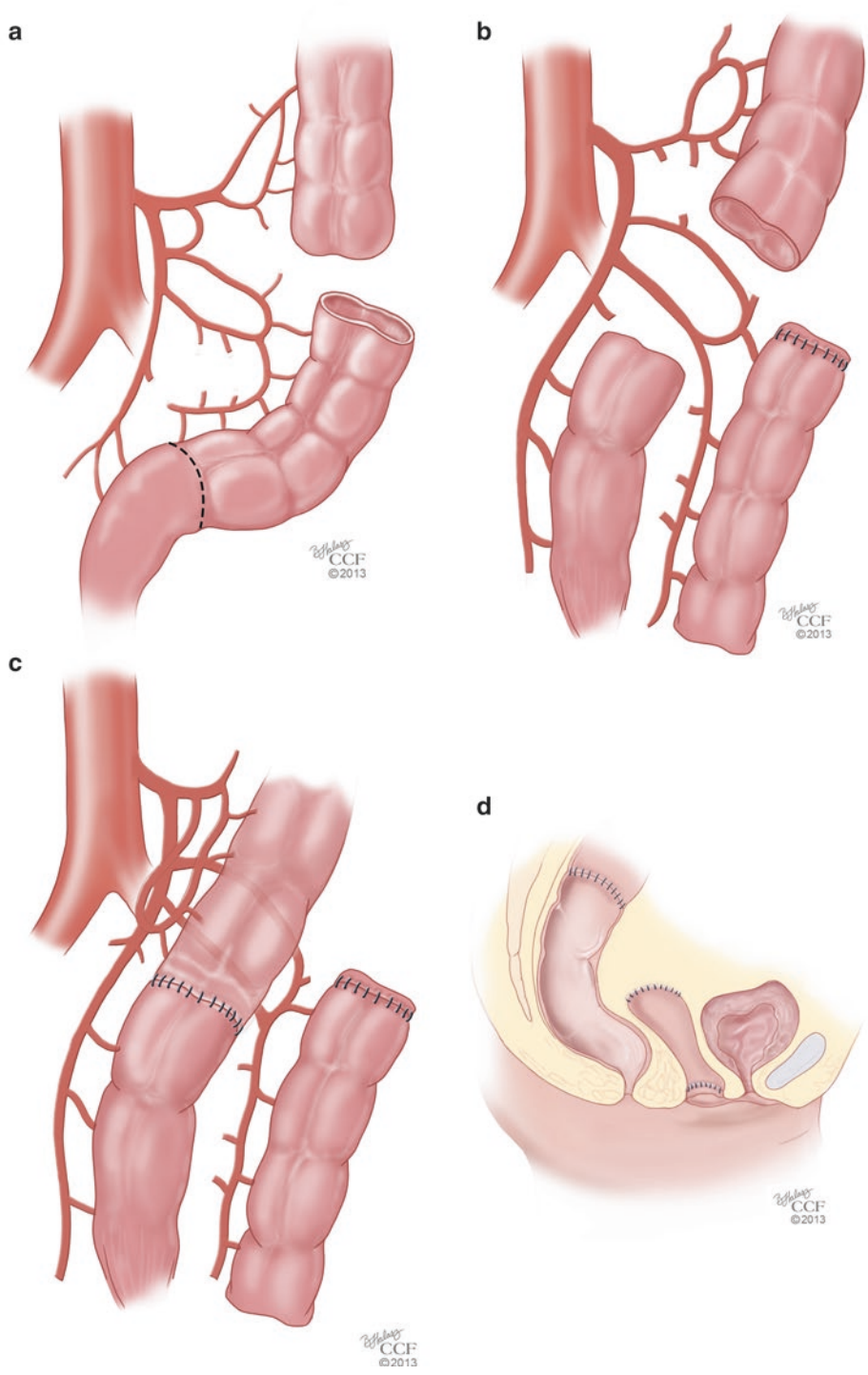

Fig. 18.13 Creation of a neovagina with an intestinal flap. (**a**, **b**) A segment of the bowel is resected with its vascular pedicle intact. (**c**) The bowel is reanastomosed and the resected portion is mobilized into the pelvis. (**d**) A sagittal view of the bowel flap sutured to the obliterated vagina, creating a neovaginal pouch. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2013–2019. All Rights Reserved)

there is less dissection needed for mobilization and patients report significantly less defecatory dysfunction [74]. A disadvantage of the flap is copious intestinal secretion but this can be rectified by performing the surgery as a free flap procedure with anastomosis rather than as a pedicled flap procedure, as temporary ischemia of the flap during mobilization leads to decreased mucous production [6]. When a free flap procedure is performed, the SMA branches that are mobilized with the flap are anastomosed using a microvascular technique to the inferior epigastric vessels. There are fewer laparoscopic cases that have been reported, as mobilization of the jejunum is done most easily via a laparotomy, and is obligatory when a free flap technique is employed.

Vaginoplasty for Transgender Women

Transgender patients experiencing gender dysphoria, defined as distress caused by an incongruence between an individual's natal sex and gender identity, may seek gender affirmation surgery [75]. Male-to-female transgender patients who meet the criteria for surgery according to the World Professional Association for Transgender Health guidelines may choose to undergo gender affirmation surgery to create an aesthetic and functional neovagina, vulva, labia, and clitoris [75]. In addition to two referral letters from qualified mental health professionals, patients desiring to undergo vaginoplasty must have persistent, well-documented gender dysphoria, be of the age of majority and have capacity to consent and make an informed decision, and have well-controlled medical and mental health comorbidities. Furthermore, 12 months of hormonal therapy is recommended unless the patient is unable or unwilling to take hormones, and 12 months of living in their affirmed gender role is strongly recommended [75]. The most common technique for creating a neovagina is the penile inversion vaginoplasty technique, which uses local flaps and grafts from the penis and scrotum to create the neovagina. Other less common techniques which may be used in secondary surgeries or in cases of insufficient local skin, such as penoscrotal hypoplasia in patients on puberty blockers, include the use of bowel segments (most commonly ileum or sigmoid) or other non-local cutaneous flaps. The procedure for bowel vaginoplasty and the use of non-local flaps and grafts for vaginoplasty is similar to the procedure as described in natal women, with the addition of penectomy, orchiectomy, vulvoplasty, clitoroplasty, and labiaplasty to create aesthetic and functional feminine external genitalia.

Our technique for performing penile-inversion vaginoplasty begins by marking the scrotal graft which will be used to line the neovagina. The anterior margin is marked at the base of the penile shaft, the lateral margins are 2 cm medial to the groin creases bilaterally, and the posterior margin is the perineum 4–5 cm anterior to the anus (Fig. 18.14). After the graft is harvested, an orchiectomy is performed to remove the testes if not performed previously (Fig. 18.15). The penis is then degloved, separating the epithelium from the underlying penile structures and creating a

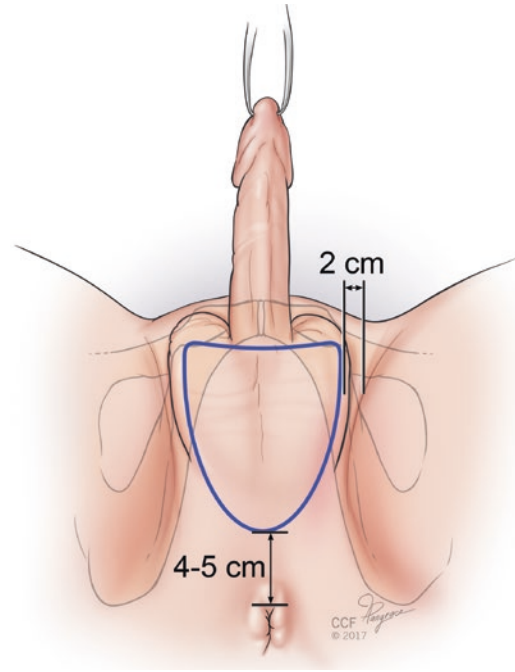

Fig. 18.14 The scrotal graft is marked and harvested. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

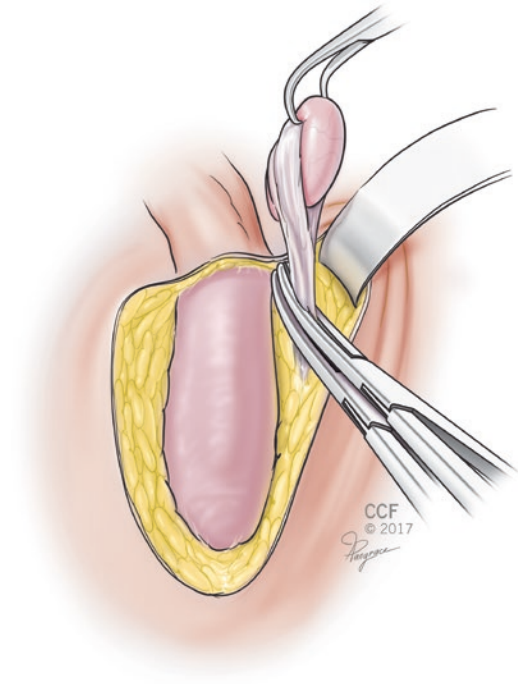

Fig. 18.15 Orchiectomy is performed. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

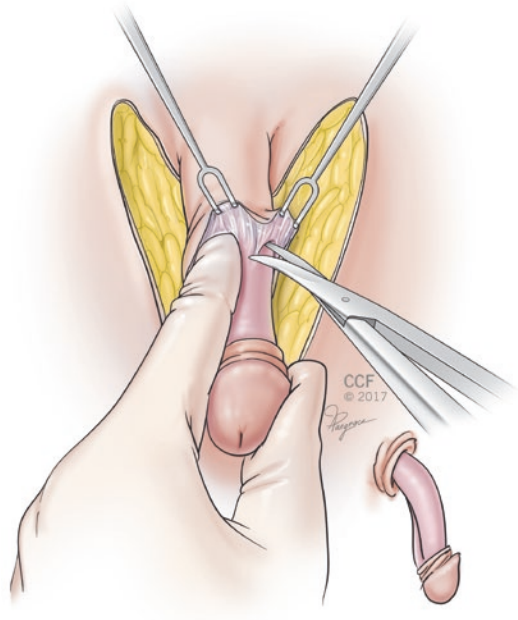

Fig. 18.16 The penis is degloved and a penile skin tube is created. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

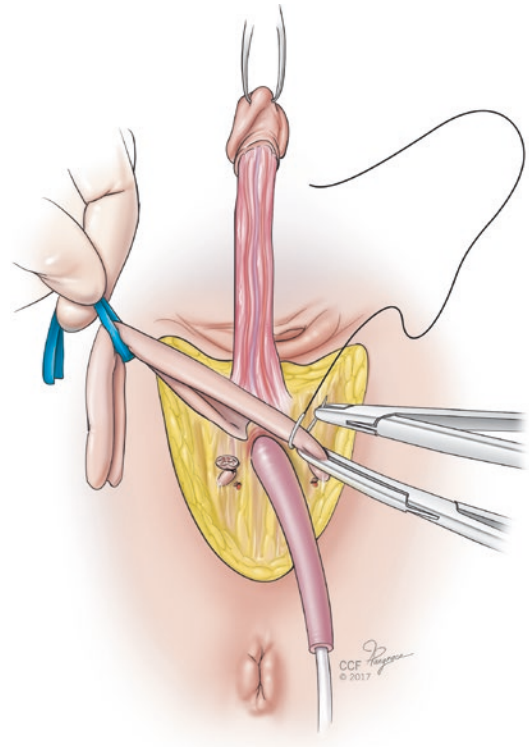

Fig. 18.17 A dorsal neurovascular flap and a ventral urethral flap are created. The corpora cavernosa are excised. The dorsal flap will later form the neoclitoris. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

penile skin tube (Fig. 18.16). The penile structures are then separated into a dorsal neurovascular flap which will later be used to create the neoclitoris, and a ventral urethral flap. The corpora cavernosa are excised and discarded (Fig. 18.17). The excess glans is excised, and the dorsal flap is folded on itself and secured to the fascia overlying the pubis, positioning the neoclitoris in the midline at approximately the level of the insertion of the adductor longus tendons. Interrupted sutures are used to shape the neoclitoris. If sufficient distal penile skin is available, it may be left intact and later used to create a labia minora (Fig. 18.18a–d). The ventral urethral flap is then spatulated and trimmed to create a moist mucosal bridge between the neourethral meatus and the neoclitoris. The edges are secured, and the neourethral meatus is positioned at the level of the pubis, allowing for a downward urinary

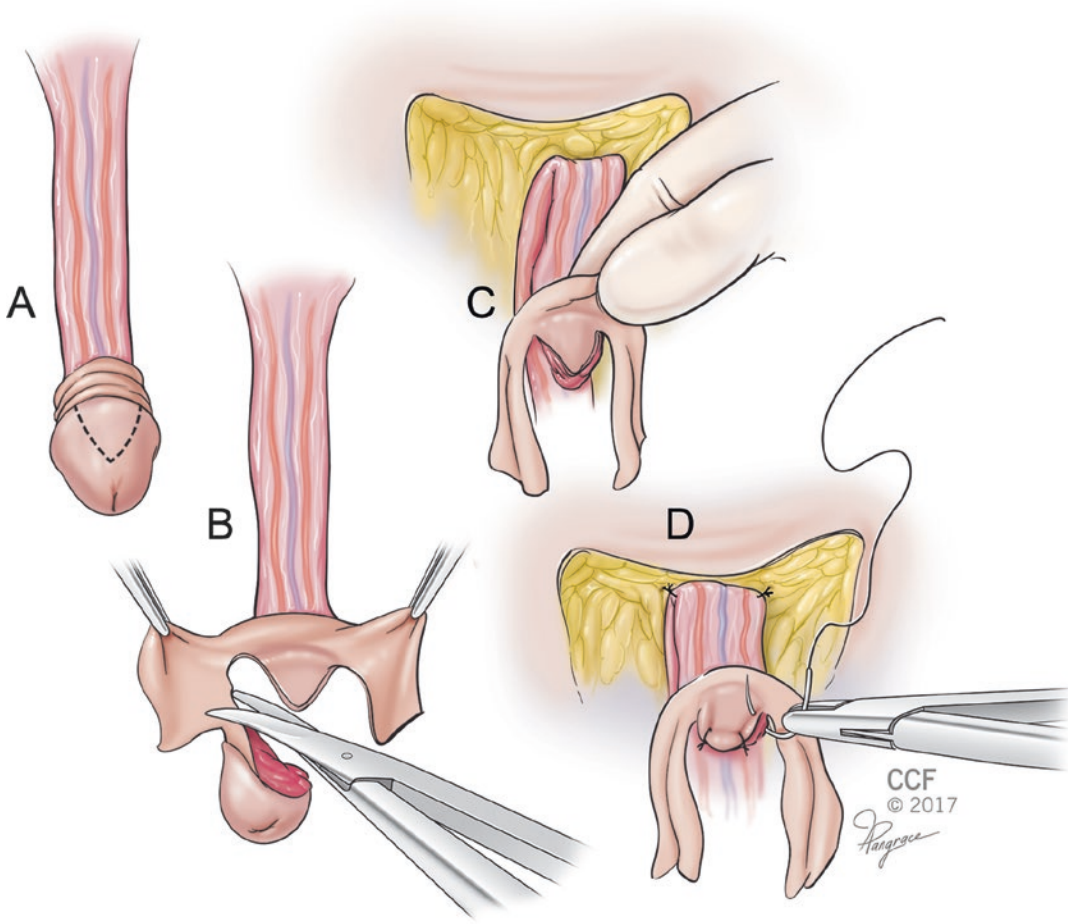

Fig. 18.18 Creation of the neoclitoris. (**a**) The neoclitoris is marked on the glans. (**b**) Excess glans is excised. Distal penile skin is left intact to later create labia minora. (**c**) The flap is folded on itself and positioned. (**d**) The neoclitoris is shaped. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

stream (Fig. 18.19). The perineal tendon is incised sharply, and then, a combination of sharp followed by blunt dissection is used to dissect the vesicorectal space until the peritoneal reflection is encountered. Great care must be taken during this portion of the procedure to avoid injury to the rectum and bladder. Dissection with one finger in the rectum is used to demarcate the borders of the rectum, and gentle traction on the urinary catheter allows for palpation of the balloon inside the bladder. A total vaginal length of 10–15 cm is achieved (Figs. 18.20, 18.21, and 18.22).

The scrotal graft is prepared to create a full-thickness skin graft, which is sewn onto the vaginal stent (Fig. 18.23). Permanent depilatory procedures are recommended prior to surgery to avoid hair growth in the neovagina. Remaining hair follicles may be electrosurgically coagulated at the time of graft preparation. The graft and stent are then passed through the penile tube and anastomosed. The stent with overlying penoscrotal flap and graft is then placed into the previously dissected neovaginal cavity, and the skin edges are secured. The stent is removed and vagi-

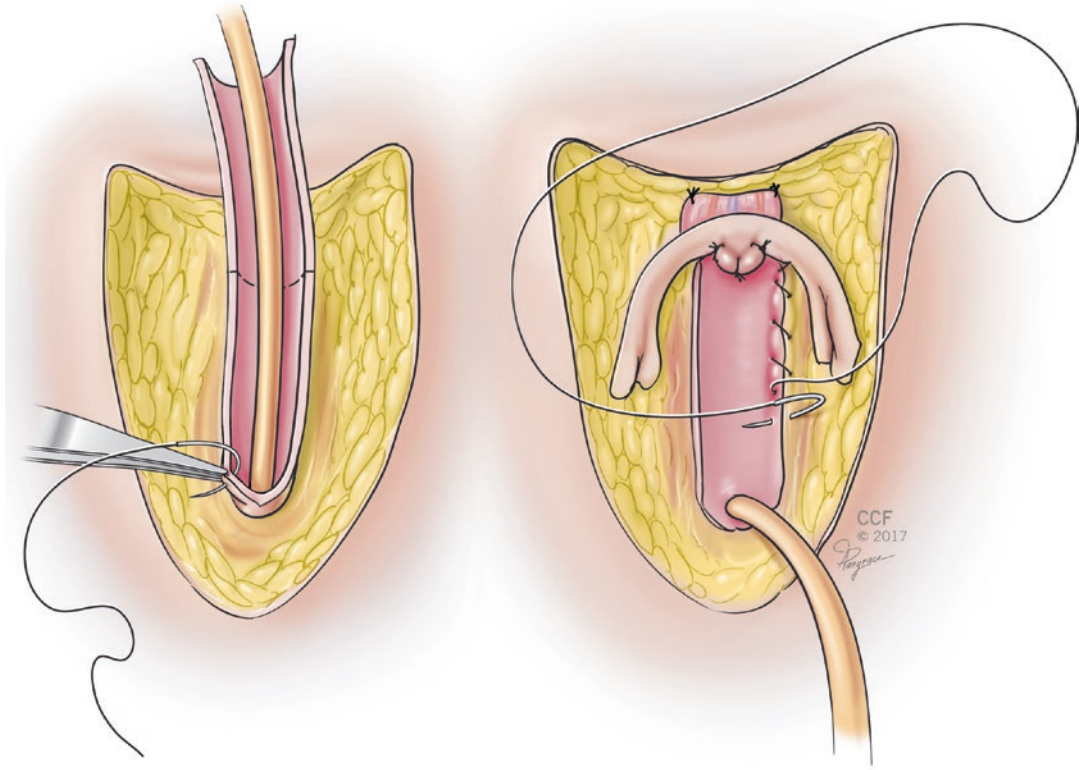

Fig. 18.19 The urethral flap is spatulated, trimmed, and secured to create a mucosal bridge between the neourethral meatus and the neoclitoris. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

nal pacing is placed (Fig. 18.24). An incision is made in the midline through the anterior penile flap, exposing the underlying neoclitoris and neourethral meatus. The reserved distal penile skin is then used to create labia minora, or alternatively labia minora may be created from the edges of the penile skin flap. Drains are placed in the labia majora, and the incisions are closed (Figs. 18.25 and 18.26). A vulvar pressure dressing is applied and left in place until postoperative day two, during which time patients are kept on bed rest. Drains are left in place for 2–3 days postoperatively, and the vaginal packing and Foley catheter remain in place for 6–7 days. After removal of the vaginal packing, patients begin vaginal dilation. Some surgeons fix the apex of the neovagina to the levator ani musculature and connective tissue; however, there are no studies that have evaluated the safety and efficacy of performing concurrent prophylactic prolapse surgery at the time of vaginoplasty. Furthermore, the incidence of neovaginal prolapse in the transgender woman has not been very well delineated, as studies are lacking, but it is thought to be low.

Complications of Neovaginal Construction

Vaginal dilation is recommended as first-line therapy for vaginal elongation in patients with congenital vaginal agenesis due to its safety, cost-effectiveness, and high success rate [76]. Surgical creation of a neovagina may be considered in those patients who are unable or unwilling to dilate, or in whom vaginal dilation has failed. A careful discussion of the risks, benefits, and alternatives of the various methods of surgery should

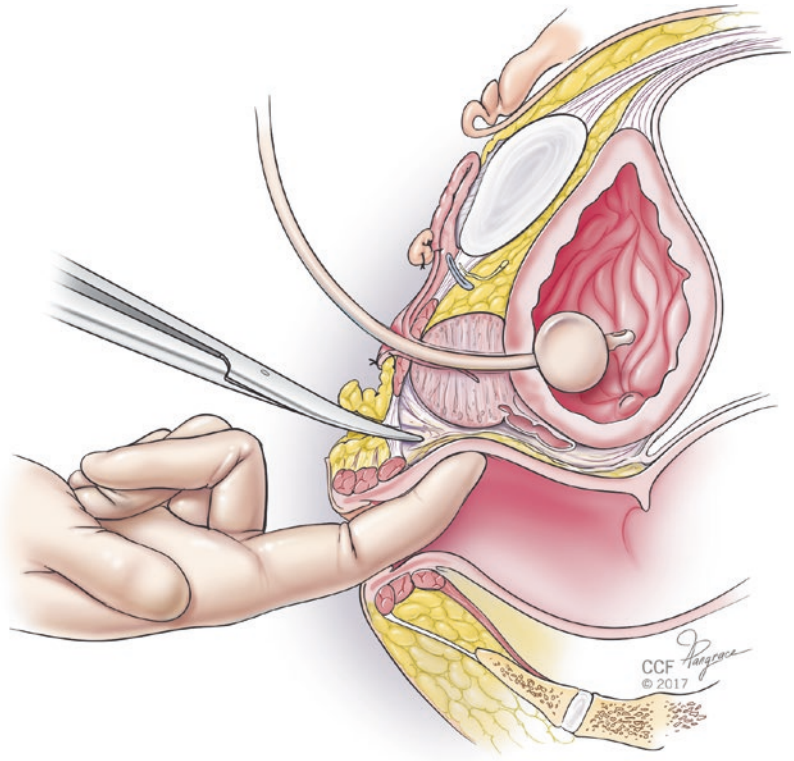

Fig. 18.20 The perineal tendon is incised sharply, and careful dissection is carried out with a finger in the rectum to avoid injury. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

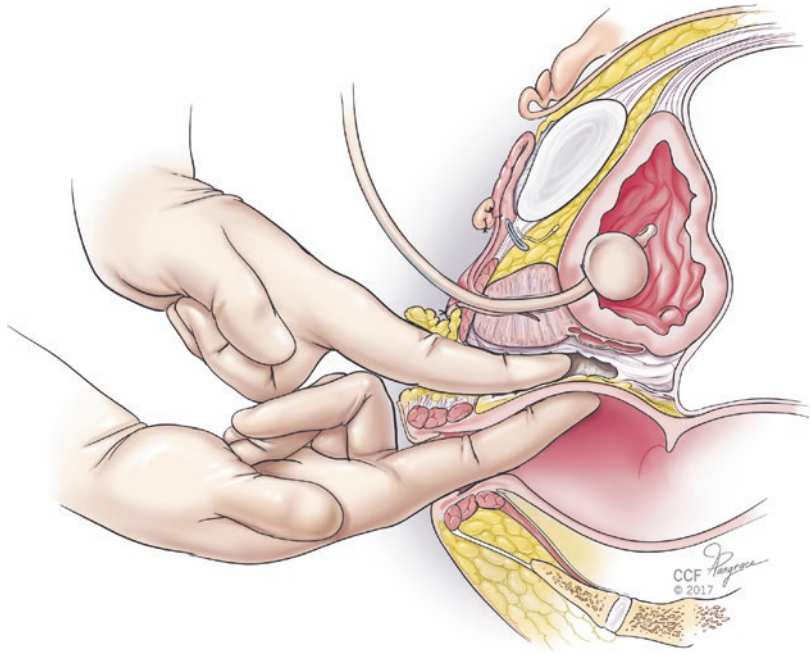

Fig. 18.21 Blunt dissection is used to dissect the vesicorectal space until the peritoneal reflection is encountered. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

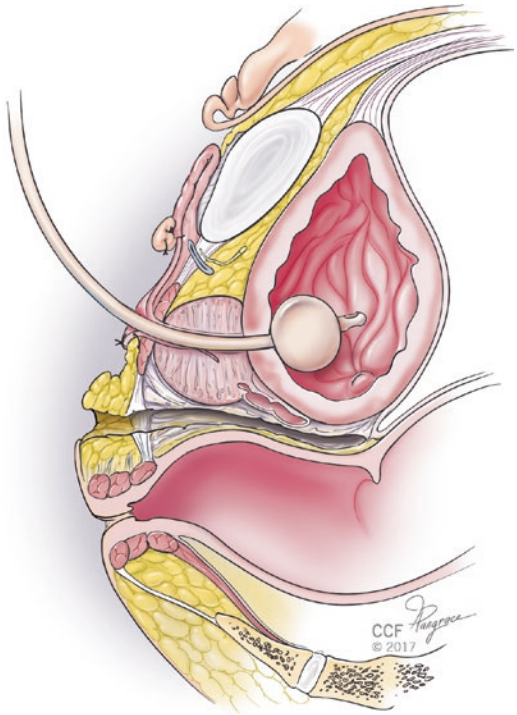

Fig. 18.22 The fully dissected rectovesical space. A total vaginal length of 10–15 cm is achieved. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

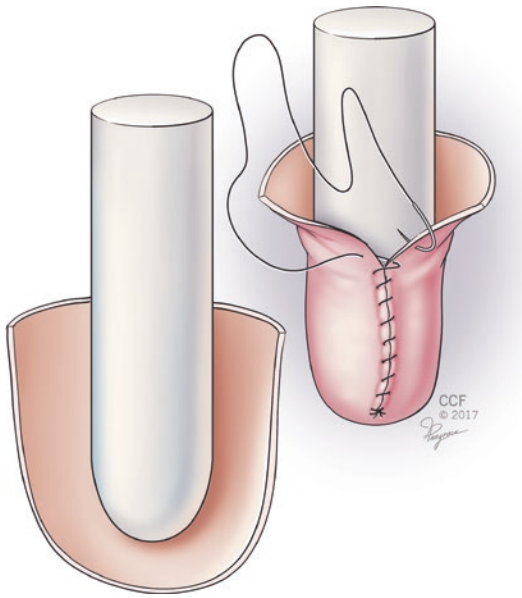

Fig. 18.23 The scrotal graft is sewn onto the vaginal stent. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

be had with the patient [76]. Intraoperative complications of neovaginal construction include bleeding, infection, and injury to surrounding organs including the rectum, bowel, and bladder. In the case of bowel segment vaginoplasty, additional complications inherent to bowel resection and anastomosis may occur. Postoperative complications include hematoma or seroma formation, wound infection, graft failure or flap necrosis, neovaginal stenosis or narrowing, urogenital or rectovaginal fistula formation, and neovaginal prolapse. Medical, anesthetic, and venous thromboembolic complications may also occur.

In two older retrospective series reviewing the complications and outcomes following McIndoe vaginoplasty in 50 and 26 patients, intraoperative and early postoperative complications included urethral injury and fistula formation, rectal injury and fistula formation, hematoma formation, stent-related complications, and graft failure [27, 77]. Late complications included vaginal stricture or contracture, granulation tissue formation, and scarring at the donor site [27, 77]. In the long term, 45 out of 47 patients available for follow-up in one study were able to have intercourse, and in the other study, 18 out of 23 available for follow-up were sexually active, with two patients reporting that their vaginas were too short for intercourse [27, 77].

In appropriately selected patients, the laparoscopic modification of the Vecchietti procedure is thought to be a less invasive and relatively rapid technique for construction of a neovagina. Comparative studies of different vaginoplasty techniques for vaginal agenesis are lacking, likely due to the rarity of the procedures. In a comparison of the McIndoe and modified laparoscopic Vecchietti techniques in 11 MRKH patients with a pelvic kidney, two patients underwent the McIndoe procedure, and nine underwent the Vecchietti procedure [78]. There were no perioperative complications in the study. The Vecchietti procedure was shorter (32 ± 6 minutes) in comparison to the McIndoe (190 ± 14.1 minutes). At long-term follow-up, both patients who underwent the McIndoe procedure had adequate vaginal depth and width and reported normal satisfactory sexual functioning. Eighty-nine percent

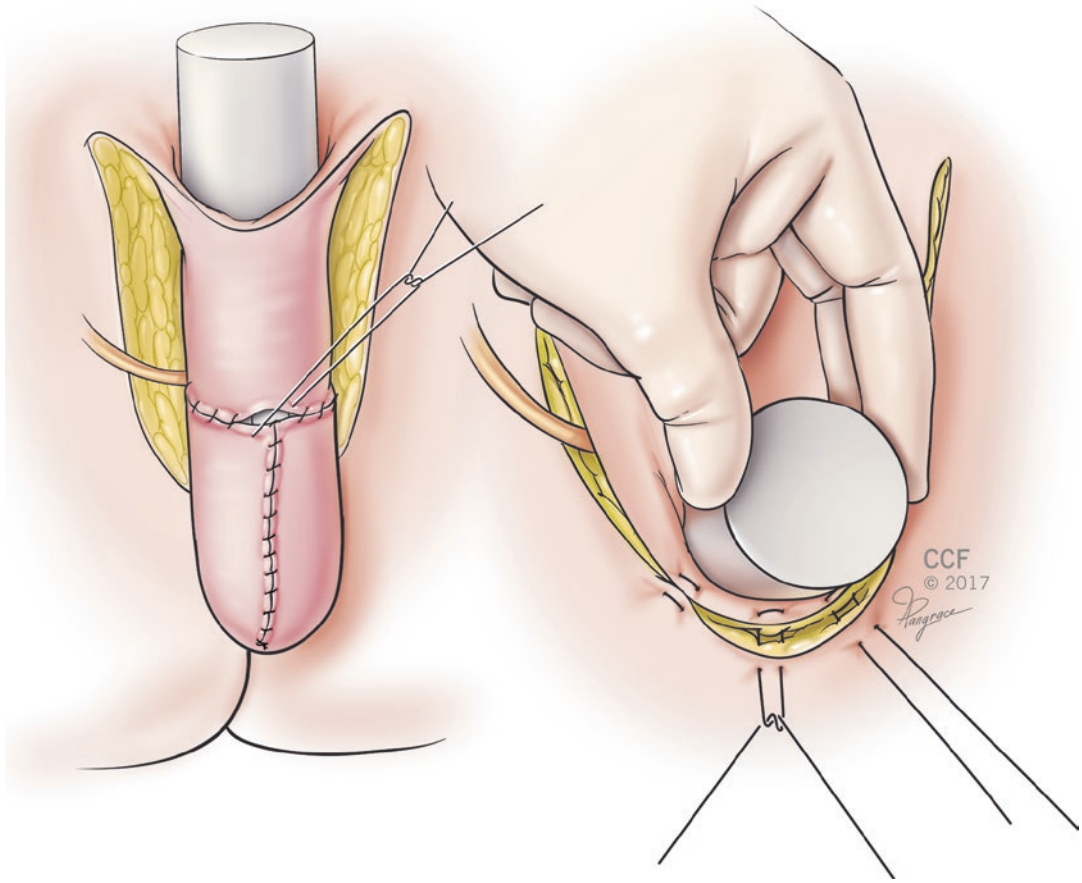

Fig. 18.24 The graft and stent are passed through the penile tube and anastomosed, then placed into the previously dissected neovaginal cavity and secured. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

of those that had the Vecchietti procedure showed anatomic and functional success, with the exception of one patient who was not compliant with vaginal dilation.

In a recent large systematic review and meta-analysis of outcomes and complications following male-to-female vaginoplasty by penile inversion or bowel vaginoplasty techniques, complications specific to the penile inversion vaginoplasty technique included fistula (1%, range 0–5%), stenosis or stricture (10%, range 7–15%), tissue necrosis (2%, range 0–8%), and prolapse (3%, range 1–8%; 77% neovaginal, 23% urethral) [79]. Complications of bowel vaginoplasty included fistula (6%, range 2–20%), stenosis or stricture (17%, range 9–16%), and prolapse (3%, range 1–8%; 81% neovaginal, 29% urethral). In both groups combined, the ability to have an orgasm was 76% (range 60–90%). Overall satisfaction was high (92%, range 75–100%) with low reports of regret (1%, range 0–3%) [79].

Prolapse of the Neovagina

While neovaginal prolapse appears to be a rare complication, there are several reported cases of vaginal vault prolapse in women who have undergone neovaginal reconstruction or vaginal dilation for vaginal agenesis. The vagina is composed of three segments: upper, middle, and lower. The

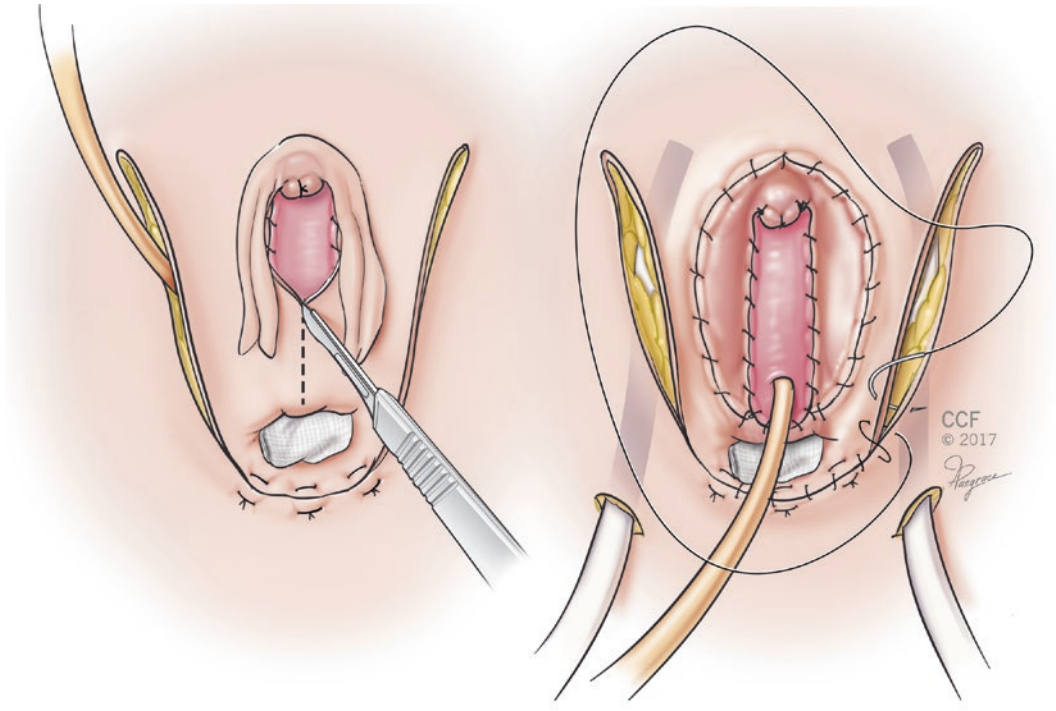

Fig. 18.25 The anterior penile flap is incised exposing the neoclitoris and neourethral meatus. Labia minora, or alternatively labia minora may be created from the edges of the penile skin flap. Drains are placed in the labia majora and the incisions are closed. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

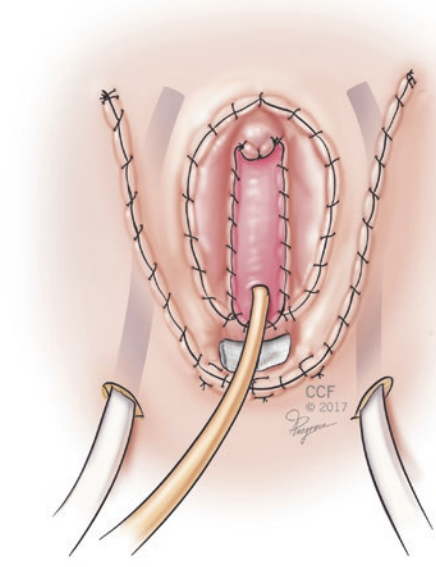

Fig. 18.26 Completed modified penile inversion vaginoplasty. (Reprinted with permission, Cleveland Clinic Center for Medical Art & Photography© 2017–2018. All Rights Reserved)

upper and middle segments are derived from the mullerian ducts and are suspended to the surrounding structures by connective tissue fibers to the sacrum and fascia of the pelvic sidewall, respectively. The lower segment of the vagina is derived from the urogenital sinus and is fused to the perineum as well as the fascia of the levator ani muscles and perineal body. Patients with mullerian agenesis are born without the fibrous connections of the upper and middle segments of the vagina. In these patients, the vagina is a blind pouch that opens at the introitus. A mechanically created neovagina or a surgically constructed one lacks the fibrous supports that suspend the vagina to the bony pelvis, and as a result, are at risk for prolapse of the vaginal apex and its lateral supports. Based on existing published case reports, successful outcomes can be achieved with vaginal vault prolapse surgeries. The prevalence of vaginal vault prolapse in vaginal agenesis patients who have undergone neovaginal construction is

not known. However, as we continue to perform reconstructive neovaginal procedures for these patients, prolapse procedures for some patients will continue to be necessary.

In cases where the neovagina that has been created through vaginal dilation has prolapsed, repair has been described by both sacrospinous ligament fixation and by sacrocolpopexy. While sacrospinous ligament fixation is performed through a vaginal approach and avoids abdominal surgery, the often short neovagina may not successfully reach the sacrospinous ligament for fixation. In the case of one MRKH patient, the vagina was not long enough to be directly sutured to the sacrospinous ligament, and so, a fascia lata allograft was sutured to the anterior and posterior vaginal walls and then secured to the right sacrospinous ligament to help bridge the gap between the vaginal apex and ligament [80]. Sacrospinous ligament fixation has also been described in a case using vaginal mesh augmentation; however, this case was complicated by postoperative vaginal mesh exposure, requiring excision and repair using a biologic graft [81]. Notably, in one case of a patient with MRKH, the patient was able to continue vaginal dilation to increase her total vaginal length from 5 cm to 8 cm preoperatively, allowing for sacrospinous ligament colpopexy [82]. In women with foreshortened vaginas, sacrocolpopexy is often the procedure of choice for prolapse repair when the vagina cannot reach the sacrospinous ligament, and has been described in cases of patients with MRKH. Thoughtful tensioning of the mesh in the case of a patient with MRKH with a preoperative total vaginal length of 7.5 cm allowed for vaginal lengthening and a postoperative total vaginal length of 9 cm [83]. In one case describing neovaginal prolapse after McIndoe vaginoplasty, sacrocolpopexy resulted in successful repair of the prolapse [84].

Cases of prolapse involving the sigmoid neovagina may be treated by suspension of the apex if full thickness prolapse is present, or if prolapse is limited to the mucosa only, local excision of the prolapsed mucosa may be considered. In a patient who had previously undergone multiple unsuccessful prolapse repair procedures, repair was able to be successfully performed by suspending the neovaginal apex to the left sacrospinous ligament, which best corrected the patient's left-side predominant prolapse consisting mostly of adipose tissue of the sigmoid mesentery on MRI [85]. During the procedure, no mesenteric bleeding was encountered. In another case, the sigmoid neovagina was suspended to the right sacrospinous ligament [86]. Laparoscopic promontofixation using mesh fixed to the anterior neovaginal wall and anterior longitudinal ligament of the sacral promontory was performed to successfully treat sigmoid neovaginal prolapse in the case of a woman with MRKH who had previously undergone several unsuccessful prolapse repair procedures [87]. While prophylactic suspension of the neovaginal apex is not a routinely performed portion of the procedure by all surgeons, in cases of laparoscopic sigmoid vaginoplasty for the creation of the neovagina in transwomen, Bouman et al. describe prophylactic fixation of the sigmoid apex to the sacral promontory using permanent suture [88]. Prophylactic suspension of the neovagina to the sacrospinous ligament could also be considered.

Summary

Patients with congenital anomalies of the vagina usually present in adolescence while children with sex differentiation disorders present with an intersex phenotype in the early period of life. Once these disorders are identified, proper evaluation is required in order to identify all anatomic abnormalities and to help with accurate diagnosis. Evaluation includes all or some of the following: office physical exam and exam under anesthesia if necessary, karyotype, hormonal panel, and imaging with MRI and/or ultrasonography. Once this information is obtained, proper management planning can be done. Treatment takes place once the patient is mature enough to understand their disorder, to commit to the treatment plan, and as long as adequate social supports are in place. First-line management for patients with vaginal agenesis is any version of Frank's method of progressive vaginal dilation. It should be the first therapeutic procedure because

it is the least invasive and has fewer serious complications.

If this method fails to create a proper vagina, or patients decline this method, surgical neovaginal construction can be performed. The surgical option often depends on the experience and preference of the surgical team, and sometimes requires a multidisciplinary approach with gynecologists, pediatric surgeons, urologists, and plastic surgeons. The technique most often employed for patients with vaginal agenesis or disorders of sex differentiation is the McIndoe operation, a modification of this surgery, or the Williams vaginoplasty. Laparoscopic techniques such as the Vecchietti and Davydov operations are also minimally invasive options for patients and have yielded favorable outcomes. For failed procedures or more complex reconstruction, various flap procedures can be performed. Many factors direct the type of flap that is used. These include the size and type of defect that needs to be repaired, the availability of certain flaps, the morbidity associated with flap harvesting and repair of the donor site, and the number and types of prior reconstructive procedures the patient has already had. Patients with vaginal agenesis or disorders of sex differentiation require construction of a patent vaginal tube that is functional and cosmetically appealing. Patients who have undergone resective surgeries or have undergone radiation therapy for malignancy have these same requirements, in addition to larger vulvar and perineal defects that require repair. Many different flaps have been described in this chapter, including those that are musculo- and fasciocutaneous and intestinal. The majority of these flaps are pedicle-based and rotational in nature and do not require microvascular surgery. Additionally, the use of biologic allografts and tissue engineering to create the neovagina was briefly discussed and may be promising minimally invasive techniques for the future, but need to be investigated further. More recently, there has been an increase in transgender patients seeking gender affirmation surgery, and familiarity with and surgical training in male-to-female vaginoplasty techniques is needed. The most common technique used for vaginoplasty is the penile inversion technique. Less commonly, bowel vaginoplasty or non-local flaps or grafts may be used in certain circumstances such as penoscrotal hypoplasia. The ideal reconstructive method should provide a patent vaginal canal of adequate length, width, and texture that will allow for sexual intercourse, provide a cosmetically appealing appearance with minimal morbidity of both the recipient and donor surgical sites with a low incidence of overall complications.

Reconstruction of the neovagina can be very complex and challenging. Each method of repair has its advantages and disadvantages, which should be carefully weighed with the desired treatment goals as well as the surgeon's experience with various surgical techniques.

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19 Surgical Management of Interstitial Cystitis/Bladder Pain Syndrome

Samir Derisavifard and Robert Moldwin

Introduction

Interstitial cystitis/bladder pain syndrome (IC/BPS) is a chronic condition associated with urinary urgency, frequency, and pelvic pain or discomfort. Symptoms from comorbid conditions such as irritable bowel syndrome, vulvar pain syndrome, and fibromyalgia often complicate the clinical picture. Given that its etiology is likely multifactorial, there exists a range of options regarding treatment. Severe cases may fail conservative measures and intravesical therapy; and then more aggressive approaches such as endoscopic or open surgery may become viable options. The presence of Hunner lesions (HL), focal regions of inflammation seen in approximately 10–15% of patients, may play a significant role in the choice of intervention. For example, those patients with HL may achieve good, albeit usually temporary, symptom relief with fulguration or triamcinolone injection while those without HL are unlikely to benefit. In contrast, botulinum toxin injection and sacral neuromodulation have a more general application, as do surgical reconstructive options. In this chapter we will review these indications and the treatment options for those patients requiring endoscopic and surgical management of IC/BPS.

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Hunner Lesions

Formerly known as a Hunner "ulcer," Hunner lesions were first described by Dr. Guy Hunner a century ago. They are defined by an area of inflamed and reddened mucosa with a central blanched scar and a confluence of capillaries [1, 2]. The prevalence of this classic finding is highly variable within the literature; it has been quoted presently as low as 5–10% and up to 50% in patients with IC/BPS. Patients with HL are likely to be older, exhibit a decreased bladder capacity, and suffer from higher levels of urinary frequency [3, 4].

Upon gross examination, Hunner lesions are usually wedge-shaped, focal regions of inflammation often associated with edema. Histologically, they demonstrate acute and chronic inflammation with central fibrin deposition and may or may not have an intact urothelial surface [5–8]. Inflammatory disease may be present in the lamina propria and detrusor as well, where it causes edema and fibrosis [5]. Historically, it was believed the presence of mast cells in classic IC bladders led to histamine secretion and local inflammatory effect that caused symptoms of pain, frequency, and neovascularization [9]. However, recent histopathologic assessment of HLs has shown evidence of pancystitis with a significant population of B cells undergoing clonal expansion instead, perpetuating a local inflammatory response, urothelial injury, and denudation [10]. IC without HL, on the other hand, is histopathologically a noninflammatory disorder and should be considered as

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a separate entity. The fact that the urothelium is not denuded in all cases is specifically why the finding was renamed a nonspecific "lesion" rather than an "ulcer."

The presence of a HL classifies a patient as having the "classic" variant of IC/BPS, the form of the condition originally described by Hunner. Severe pain and even bleeding appear to occur with bladder filling, often to volumes which would not even provoke the need to void in the average individual. HL can be identified with office cystoscopy or with narrow band imaging in the setting of focal inflammation that develops during the process of hydrodistension [11]. HL should not be confused with glomerulations. Glomerulations are a product of bladder hydrodistension. They are rarely seen on routine cystoscopy without over-distending the bladder, and unlike the defined centralized appearance of a HL, they are characterized by multiple, nonspecific punctate, submucosal bleeding points (Fig. 19.1).

Attempts to identify clinical features or surrogate markers to predict the presence of HL in classic IC patients without the use of cystoscopy have been unsuccessful [6]. There are no lower urinary tract symptoms or demographic parameters that have been linked to classic IC. Additionally, no link has been found between classic IC and Sjogren's syndrome, Lyme dis-

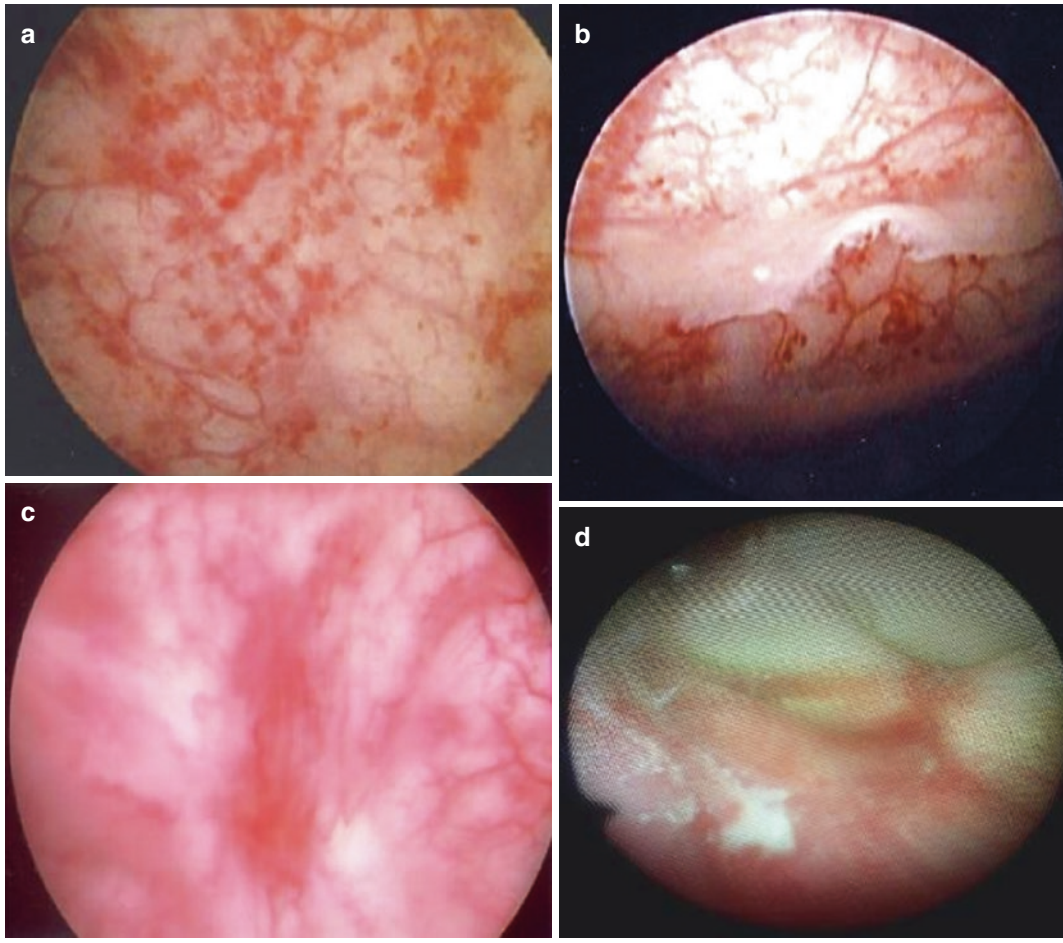

Fig. 19.1 (**a**) Glomerulations seen during hydrodistension during anesthesia. (**b**) Glomerulations and mucosal tears seen during hydrodistension. These tears commonly occur at the bladder neck. (**c**) Hunner lesion with diffuse hyperemia. Note the difficulty differentiating this from a malignancy. (**d**) Hunner lesion with bladder wall scarring. This can cause a loss of bladder capacity

ease, multiple sclerosis, fibromyalgia, migraine headaches, or temporomandibular joint dysfunction [12]. It has been noted, however, that the incidence of pyuria is higher in classic IC patients [6, 12].

Hydrodistension: Is There a Role for It?

Historically, hydrodistension has played an important role as a diagnostic and therapeutic tool in IC/BPS; however, its use has been questioned in the modern era. The procedure involves distending the bladder under anesthesia using a fluid irrigant to a level that would be uncomfortable for the patient had they been awake. The technique for the procedure varies, and there is no standard accepted method [13–15]. Hydrodistension was first described in the 1920s and later incorporated into the definition of IC espoused by Messing and Stamey in 1978 [1]. Initially it was viewed as the "gold standard" for the diagnosis of IC, but as knowledge of the nuance and complexity of IC/BPS grew, hydrodistension's lack of sensitivity and specificity became painfully obvious. One study reported that 45% of women who were found to have cystoscopic evidence consistent with IC/BPS after hydrodistension were completely asymptomatic [16–18]. Furthermore, the finding of glomerulations is often inconsistent in any given patient [18].

Although its diagnostic ability remains in question, hydrodistension may still be used as a treatment option for IC/BPS [15, 19]. The most current guidelines of the American Urological Association (AUA) at the time of this publication state that low-pressure hydrodistension (Table 19.1) may be used as a third-line treatment option in the setting of severe symptoms that have failed less invasive treatment methods. It is also noted that high-pressure or long-duration hydrodistension should be avoided at all costs [13]. It is our practice to perform office cystoscopies for diagnostic purposes, especially if there is a concern for the presence of a Hunner lesion. However, we do not routinely perform hydrodistension for diagnostic purposes.

Table 19.1 Technical pearls regarding hydrodistension

1. Anesthesia is required, either general or spinal.
2. Perform for a short duration (2–4 minutes) until a pressure of 60–80 cm H_2O is reached.
3. Visualize the bladder mucosa at all times. If mucosal tearing is noted, discontinue the filling process or proceed with extreme caution.
4. Have electrocautery equipment on hand at the onset of the case in the event that it is needed for focal bleeding.
5. Avoid hydrodistension in the presence of a Hunner lesion. If present, biopsy the lesion to rule out carcinoma in situ (CIS).
6. For patient comfort, utilize a local intravesical anesthetic (i.e. 2% lidocaine) postprocedure

The use of hydrodistension as a therapeutic option dates back to the original description of the condition [1, 20–22], although reports of its success are highly variable and dependent on the duration of follow-up and the metrics used to define success. In modern series, hydrodistension has been found to be effective in 56–100% of cases. Additionally, it may be effective in controlling symptoms of pain for up to 6 months [17, 23, 24]. Our experience suggests that only one third of patients derive a meaningful improvement in bladder-based pain and/or urinary frequency. Furthermore, the clinician and patient should understand a symptom flare may occur postoperatively, often lasting three or more weeks. It is not clear which patients would benefit the most from the use of hydrodistension. No significant relationship has been identified between postprocedural outcomes and anesthetic capacity or the presence of glomerulations [24]. A paucity of strong evidence to support the use of low-pressure hydrodistension even as a therapeutic option has led to a grade C recommendation by the AUA [25]. Similarly, the European Association of Urology (EAU) reiterates its limited role [13]. Despite concession that little evidence exists to strongly support hydrodistension for treatment, the Japanese Urologic Association gives it a grade B recommendation [19]. Lastly, it is important to consider that although it is minimally invasive, low-pressure hydrodistension is not a completely benign procedure. We suggest caution if performing hydrodistension on a patient with HL as the distension may produce significant bleeding and potential perforation. Cases of

bladder necrosis and ensuing urine extravasation have been reported even in non-HL patients, and care should be taken to tailor each procedure individually based on a patient's clinical findings [22, 26, 27].

Endoscopic Management

Resection

The idea of removing a HL as a method of symptom control has been around since it was first proposed by Hunner himself. Historically, however, the use of partial cystectomies proved to be less effective in the long term and carried a high complication rate [7]. The development of sophisticated endoscopic instrumentation ultimately provided a less-invasive approach to HL resection. Compared to more invasive, open procedures, transurethral resection (TUR) provides local peripheral denervation and as such does not cause any undesired motor effects. A few series have retrospectively reported their experience using TUR as a method of treating classic IC/BPS [7, 28]. Technically, the key is to focus on generous resection of the HL and the surrounding edematous tissue. The depth of resection should not exceed more than half of the detrusor layer. The electrical setting should be on the lowest intensity that allows for effective resection, and coagulation should be limited to pinpoint spotting of bleeding vessels as to minimize the incidence of fibrosis [29].

Peeker et al. demonstrated HL TUR to be extremely effective. In their study, 90% of participants noted an increase in the duration of symptom relief as compared to treatment with hydrodistension for an average of 23 months [7]. They also reported on these patients separating into four distinct groups. Groups 1 and 2 involved patients with excellent responses to treatment who exhibited long and short periods of remission, respectively. Groups 3 and 4 encompassed patients who progressed toward end-stage disease, with group 3 taking more than 2 years and group 4 less than 2 years to reach that point. Group 3 patients suffered from bladder contracture and low capacities before reaching end-stage disease [7]. Symptomatic improvement after TUR was also reported by Chennamsetty et al. in which 89.6% of participants reported improvement after Hunner lesion TUR. Additionally, they found that on follow-up, TUR did not affect a patient's bladder capacity [28]. The reasoning as to why HL TUR is an effective treatment is hypothesized to be due to its downstream effect of decreasing the local production of inflammatory mediators responsible for a patient's symptoms. This is in addition to removing the hypersensitive nerve endings within the lesion [7].

Despite satisfactory functional results of TUR, it still remains a surgical procedure and thus is not without risk. One of the aforementioned series reported an 11% risk of hematuria requiring clot evacuation and fulguration under anesthesia [7]. Reports of bladder perforation after resection have also been made [29]. As such, within the current AUA guidelines, HL resection is not listed as a recommended treatment option. Less invasive methods detailed below, including electrocautery fulguration, laser ablation, and steroid injection, have been found to be equally effective but less morbid in treating HL. With grade C evidence, they are recommended for use in classic IC/BPS as third-line agents [13].

Fulguration

Due to the theoretically lower risk of bladder perforation and scarring, HL fulguration has become a common, preferred method of treatment. Here, thorough fulguration of the area in question is performed with a bugbee electrode or a TUR rollerball. Salient technical aspects for fulgurating HLs are detailed in Table 19.2. Most patients see relief within 24–48 hours of their procedure, but the reoperation rate is quoted as high as 98% in one study [28]. Hillelsohn et al. examined classic IC patients treated with HL fulguration and stated that 54.2% of patients necessitated a single procedure at 33 months of follow-up, of which 78% expressed symptom improvement or stability. On the other hand, the remaining 45.8% necessitated further treatment with repeat fulguration [30].

Table 19.2 Technical aspects of Hunner lesion fulguration

Biopsy HL before proceeding to rule out neoplasia; lesions may be indistinguishable from carcinoma in situ.
1. Presence of a HL does not mandate surgical intervention. Consider other conservative measures.
2. Counseling should emphasize that fulguration is for symptomatic control and does not provide a cure; HL are likely to recur.
3. Patients with diffuse inflammatory disease are poor candidates for lesion ablation. Consider other methods of treatment in these cases, i.e. intravesical instillations or cyclosporine.
4. Avoid hydrodistension at the time of fulguration. Our experience suggests that this frequently leads to significant bleeding from the friable lesions. They are more likely to tear during the filling process. Additionally, the edema caused by bladder overdistension often extends the area of hyperemia making identification of the lesion(s) difficult to assess when fulgurating.
5. For patient comfort, strongly consider use of an intravesical anesthetic agent postprocedure.
6. Consider a 3–4-week postprocedure bladder retraining protocol in an attempt to optimize bladder capacity

Those requiring repeat procedures on average needed 4.3 procedures with a mean time of 20.3 months between interventions. Forty-eight months after the initial procedure, the repeat fulguration rate stabilized, suggesting that the natural lifespan of classic IC may have an active phase that over time becomes quiescent [30]. These findings were echoed by Ryu et al. who stated the durability of the procedure to be 94%, 70%, and 33% at 2, 5, and 10 months of follow-up, respectively [31]. Neither series found a clinical characteristic that could predict the need for repeat fulguration, but those who did require it exhibited no differences in success rates or functional bladder capacity compared to those who required fewer fulgurations [30, 31].

Laser Ablation

An alternative to HL fulguration is endoscopic laser ablation. An experimental study in the 1980s first reported that the neodymium:YAG (ND:YAG) laser was an effective means of ablating HL with a response rate of 50–65% [32]. That same series, however, reported two cases of delayed small bowel perforation, questioning the safety of this treatment modality. A more modern series from 2001 by Rofeim et al. revisited the issue with increased success. Here, the researchers more carefully chose laser settings to only allow for a 5 mm depth of penetration and a low degree of tissue heating to a range of 60–70 °C. This minimizes damage to underlying elastic fibers and thus has minimal negative impact on bladder capacity [33]. As compared to the newer trial, the older one differed procedurally as well. The patients in the older study underwent hydrodistension before proceeding with laser ablation. Additionally, the entire trigone with the exception of the ureteral orifices was ablated. Alternatively, in the newer trial, the bladder was minimally filled with sterile water for no more than 3 seconds, and the laser power never exceeded 15 W. As soon as the targeted tissue blanched, treatment was discontinued in that area. With these more stringent parameters, laser ablation was not only well tolerated, but no complications were noted. Results showed that pain scores significantly improved, falling on a visual analog scale from 9.1 to 1.2. Subjective complaints of lower urinary tract symptoms including urgency, frequency, and nocturia also showed sizable improvement. Improvement was noted as soon as 2–3 days postoperatively, but like fulguration, 11 (45.8%) patients required a repeat procedure.

Steroid Injection

Endoscopic HL steroid injection is an alternative treatment that has recently become more commonly performed as it has the theoretical advantage of minimizing bladder scaring. As can be seen with hypertrophic scars and keloids, local injection of steroids may result in regression of local scarring and subsequent tissue contraction.

Injections are performed under direct vision during cystoscopy with an endoscopic needle (Fig. 19.2). A target depth of injection is 2–3 mm, which can be appropriately adjusted given the angle of needle penetration. Just like any ablative

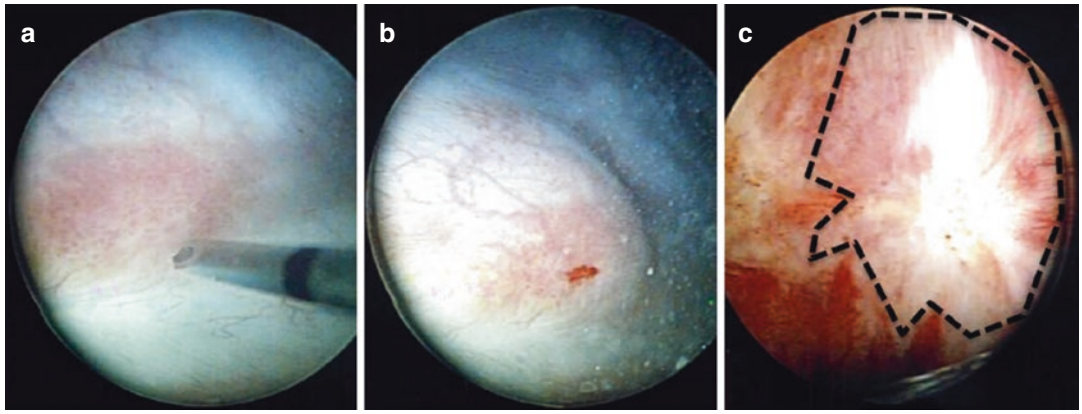

Fig. 19.2 (**a**) Small HL prior to injection. (**b**) Same patient after injection. Note the raised mucosa. (**c**) Different patient with recurrent symptoms 16 months after initial injection. Note region of previous injection devoid of inflammatory disease (inside dashed line), but peripheral region of recurrent inflammation. (Reprinted from Gurram and Moldwin [73] with permission from Springer Nature)

procedure, we advocate that bladder filling be kept to a minimum in order to prevent bleeding from the lesions. At the same time, the bladder must be distended enough to allow the needle to pass through the mucosa with ease. Given IC/BPS patients are highly sensitive to bladder filling and poorly tolerate any form of endoscopic manipulation, we advocate performing steroid injections or fulguration under anesthesia. In this manner, the bladder can be appropriately distended in order to visualize the operative field, allowing for precise and safe injections. We suggest having electrocautery at hand in the event that the needle puncture into inflamed tissue produces significant bleeding.

One series has evaluated the use of triamcinolone acetonide as an agent injected into HLs [34]. Triamcinolone was selected because of its prolonged duration of action spanning several weeks in addition to its common use in treating postop inflammation. A 40 mg/mL solution of triamcinolone acetonide was injected into the center and periphery of Hunner lesions in 0.5 cc aliquots totaling no more than 10 mL. Twenty-eight of the 30 study participants (93%) experienced some level of pain improvement, whereas 21 of the 30 (70%) participants reported significant improvement. IPSS scores fell from 21.1 to 11.3 at 4 weeks postoperatively, a significant improvement. No complications were reported in this series. These findings have been corroborated by another more recent series as well. Funaro et al. noted that triamcinolone injections into HLs at 3–6 month follow-up resulted in an improvement in Likert pain scale scores and nocturia bother score, 8.3 (preprocedure) to 3.8 (postprocedure) and 7.5 (preprocedure) to 5.1 (postprocedure), respectively [35].

OnabotulinumtoxinA Injection

OnabotulinumtoxinA (BTA) inhibits the release of acetylcholine from neurons at the neuromuscular junction, causing a state of flaccid paralysis [36]. Intradetrusor BTA is currently FDA approved for use within the bladder to induce smooth-muscle relaxation to treat neurogenic detrusor overactivity and overactive bladder syndrome (OAB) [37, 38]. As such, it was initially overlooked in the treatment of bladder pain. Used as an off-label treatment option, Smith et al. first published on the use of BTA in treating IC/BPS pain [39]. In a proof-of-concept study from 2004, they reported a 69% improvement in pain with the use of BTA injected in the bladder wall and trigone. Further assessments of this treatment method ensued. Currently two meta-analyses have been published assessing BTA use in IC/BPS. They first assessed both the efficacy and

safety of BTA compiling data from five randomized-controlled studies. With a total of 252 participants (133 experimental and 119 control), the study reported significant improvements in lower urinary tract visual analog scale (VAS) scores and O'Leary Sant voiding and pain scores as compared to placebo. Relatively low rates of adverse events were also reported: large post void residual (8.3%), urinary retention (6%), urinary tract infection (6%), and hematuria (3.6%) [40]. These findings were corroborated by a second meta-analysis including 183 experimental and 134 control patients with similar efficacy and safety results [41]. Acceptable protocols typically use 100 units of BTA trademarked as BOTOX® (Allergan, Dublin, Ireland) injected in equally spaced aliquots within the bladder trigone taking care not to involve the ureteral orifices. This protocol was designed to affect the sensory neurons that were concentrated in the trigone in contrast to the supratrigonal injections typically employed for bladder overactivity.

Despite its effectiveness in treating IC/BPS, further work is needed to define which patients would most benefit from its use and how to optimally deliver the medication. The goal is to maximize the effect of BTA on sensory afferent nerve fibers while minimizing adverse effects of voiding difficulty and retention. As BTA has little to no effect on bladder function as an instillation, methods to enhance absorption through the urothelial surface have been sought. To that end, a liposome-encapsulated BTA has shown some efficacy [42].

Currently bladder BTA for IC/BPS is seen a relatively safe, effective treatment option. Both American and European guidelines recommend its use before proceeding to more invasive treatments [13, 25].

Bladder Wall Incision

Despite our best efforts, some patients with HL progress to develop severe chronic pain in the setting of a severely contracted, small-capacity bladder resulting from chronic bladder wall fibrosis and inflammation. These patients, labeled as suffering from an "end-stage bladder," have limited minimally invasive surgical options. A case report from Bahlani and Moldwin catalogued the use a novel bladder incision technique on two patients who were poor candidates for urinary diversion [43]. Both patients suffered from severe bladder scaring causing decreased bladder capacities, 30 and 120 cc, respectively. Both bladders showed evidence of severe tethering causing decreased compliance. A holmium laser was used to incise the bands at multiple points along their length down to the level of the perivesical fat. Following the procedure, a Foley catheter was left in place for a week and then a cystogram was performed to ensure proper bladder healing before its removal. A bladder training protocol was initiated thereafter in which the patients were encouraged to hold their urine for 15–20 minutes following the urge to urinate in order to improve their bladder capacity. At a mean follow-up of 4.2 years, both patients exhibited a bladder capacity increase nearing 50%. Significant improvements in pain and time between voids were noted with bladder filling postprocedure.

The advantageous mechanism of utilizing the holmium laser include the precision with which the laser can be used to target the scar tissue minimizing injury to any other surrounding tissue while concomitantly providing a hemostatic effect. The method of endoscopic bladder scar lysis can be an effective method to consider especially in patients who are either hesitant about or are poor candidates for any further invasive surgical measures.

Surgical Management

Sacral Neuromodulation

The complexity of IC/BPS and broad spectrum of symptoms it encompasses cannot be emphasized enough. While in some it may be considered a primary bladder disease, in others it encompasses a diffuse pelvic pain syndrome that may not appropriately respond to targeted bladder or other end-organ therapies [44]. In some patients, their symptoms may be due to the pathologic upregu-

lation of pelvic nerves causing pelvic floor dysfunction. Sacral nerve stimulation has been FDA approved for the treatment of refractory urinary retention and urinary frequency, urgency, and urge incontinence. Currently it is listed as a fourth-line agent in the AUA guidelines, on par with bladder BTA, for patients with symptoms refractory for less invasive therapies [13]. Although it has not been approved for treatment of IC/BPS per se, its use can be justified based on patient's symptoms of urgency and frequency. Peters et al. [45] assessed the use of the InterStim® (Medtronic Inc., Minneapolis, MN) implantable neuroprosthetic device to treat chronic pain in IC/BPS resistant to more conservative measures. Twenty-one patients were enrolled who all had undergone at least six pervious treatments for IC/BPS. At 15.4 mean months of follow-up, 20 of 21 (95.3%) of patients reported moderate to significant improvement in their pain symptoms. In addition, patients' morphine dose equivalent of pain medication decreased by 36% from an average of 81.5 to 52 mg/day; 22% of patients who used opioids stopped taking them all together. Another study followed up 22 patients at 3-month intervals for 2 years and reported on the durability of treatment and outcomes. In their series, 9% of patients required explanation for infection. In the remaining 20 patients, 20% reported a loss of efficacy at the end of the study period, but the remaining 80% were satisfied with their level of symptom control [46]. Although the evidence in support of sacral neuromodulation in this patient population is limited, the literature suggests there may be a role for its off-label use.

Neurological Procedures

Since the 1940s, researchers have postulated that the pain and urgency of IC/BPS is in part secondary to altered function of those nerves innervating the bladder. Attempts were made to denervate the parasympathetics supplying the bladder with mixed results. An early case report cataloged the use of S3 sacral blocks with procaine in three patients. All patients improved after the injection and subsequently underwent bilateral S3 neurectomy. All three patients experienced postoperative improvement in symptoms as well as an increase in bladder capacity reported years later [47, 48]. Similar positive results were seen by a later series of 6–10 patients with an average of 15 months of follow-up [49, 50].

Bohm and Franksson focused on the dorsal sacral roots in their study testing this technique [51]. Previously they had established that sensory afferents of the bladder would be carried through the dorsal nerve roots where they felt would be the source of pathology. In a series of eight patients, they divided the dorsal root of IC/BPS patients either unilaterally or bilaterally in up to three segments. Surprisingly, however, the results were lackluster. Only one patient reported complete pain relief, and one other patient exhibited measurable improvement. All others continued to suffer postoperatively. Bladder volumes and the frequency of developing HL remained unchanged in all patients. Compounding this, complications and side effects that have been documented included the following: postoperative wound infections, bladder atony, hyperalgesia, perineal numbness, and loss of the Achilles reflex [52].

Another neurosurgical option that has been historically explored is anterolateral chordotomy. This is the most central form of denervation that has been attempted in order to treat IC/BPS. There are only two published reports of the technique in the literature. Frazier et al. first reported this method in a case report in a 33-year-old female with symptoms of radiating vaginal and bladder pain associated with bladder lesions. The initial procedure performed on this patient involved a unilateral chordotomy of the fifth thoracic segment, resulting in 1 year of pain relief. A second procedure was performed on her left third thoracic segment for a recurrence of right-sided pain. The patient's pain resolved during the subsequent 8 years of follow-up. Unfortunately, the patient also suffered from transient lower extremity weakness, urinary retention, and permanent loss of temperature sensation below the umbilicus [53]. Despite confirming its ability to relive pain, other attempts to explore the procedure have been limited [54, 55].

Given the level of invasiveness and the lack of strong supportive evidence, neurosurgical proce-

dures, including rhizotomy and anterolateral chordotomy, are not currently recommended as viable treatment options for IC/BPS.

Surgical Reconstruction

If a patient fails to respond to the aforementioned minimally invasive treatment options, surgical reconstruction is available as a sixth-line treatment [13]. Multiple clinical factors need to be recognized before making the recommendation to perform a urinary diversion or augmentation cystoplasty. Consideration of renal function and comorbid medical illnesses are crucial to note given downstream metabolic consequences [56] and the elevated risk of malignancy after bowel has been incorporated into the urinary system [57]. As opposed to urothelium, bowel mucosa easily resorbs ammonium chloride, leading to chronic hyperchloremic metabolic acidosis. In patients with a glomerular filtration rate less than 40 cc/min/1.73 m^2 body surface, this can cause severe electrolyte abnormalities [58]. In addition, the patient must be prepared to cope with the ramifications of surgery socially. Discussions of body image and the risk of complications and need for re-operation should be discussed with patients on multiple occasions in order to set realistic expectations. Patient cooperation, manual dexterity, and cognitive ability are paramount in the setting of a continent cutaneous diversion, which requires routine clean intermittent catheterization. Pain relief is never guaranteed, as many patients may have other associated pelvic pain generators, i.e., pelvic floor myalgia, or have centralized pain [44]. Accordingly, one might expect the *most reliably successful results in those patients with Hunner lesions and a small, noncompliant bladder*.

Cutaneous Urinary Diversion

Cutaneous urinary diversions with bowel segment conduits are the most radical treatment options for IC/BPS. There can be either an incontinent urostomy (ileal conduit) or continent pouch (Indiana pouch), although they are associated with more issues related to body image than other forms of surgical reconstruction. Formation of an ileal conduit remains the most commonly performed diversion with the lowest complication rate. Advantages of this technique are that it utilizes the smallest bowel segment and requires the least amount of maintenance and patient cooperation. When performing an ileal conduit, it was initially deemed acceptable to leave the bladder intact based on early observations that as long as urine was not stored in the bladder, patient's symptoms improved [2]. Leaving the bladder in situ also reduces the surgical morbidity associated with its removal. Others have advocated for cystectomy reporting that it leads to improved quality of life, sexual function, patient satisfaction [59], and minimizes the risks of reoperation if symptoms persist or if patients develop pyocystis [60]. The major disadvantage of this technique is the exposed urostomy may not be suitable for many patients because of its effect on body image both for its appearance and because a patient will remain incontinent.

Comparatively, a continent cutaneous diversion allows for the patient to remain continent without a urostomy of exposed external urine reservoir. But this comes with a price. As noted previously, the patient must be willing and able to catheterize and care for the pouch. In addition, the use of longer bowel segments may lead to malabsorptive disorders and/or diarrhea. Moreover, continent cutaneous diversions are plagued by a higher complication rate and frequently require revision or follow-up surgery. These are all factors a patient must buy into to be an acceptable candidate [52].

Supratrigonal Cystectomy With Augmentation

Although simple bladder augmentation will increase the bladder's capacity, it is likely to result in poor clinical outcomes, perhaps because it does not excise pain-generating tissue [61]. On the other hand, supratrigonal cystectomy with bladder augmentation has the advantage of

removing a probable source of pain (particularly in the patient with Hunner lesions) while eliminating the need for ureteral reimplantation. The procedure is aesthetically acceptable to many patients as there is no need for an ostomy or catheterizable channel. Supratrigonal cystectomy with augmentation has, however, produced mixed clinical outcomes, with "success" rates ranging between 25% [62] and 100% [63, 64]. Surgery has the potential to improve urinary frequency, functional bladder capacity, and measures of patient satisfaction [65]. Nielsen et al. noted that a marked reduction in preoperative anatomic bladder capacity was related to better outcomes [62]. This group assessed the outcomes of supratrigonal cystectomies in eight IC/BPS patients. The two patients who reported successful outcomes both had cystoscopic bladder capacities of 200 cc or less. The remaining six patients, with an average bladder capacity of 534 cc (range 400–675 cc), reported no resolution of symptoms. This finding was echoed by other similar series that noted reduced bladder capacity as a positive predictor of augmentation and bladder substitution success [66–68] (Table 19.3).

A prime surgical dictum when performing supratrigonal cystectomy and bladder augmentation (particularly in the face of inflammatory disease) is that the supratrigonal bladder should be completely resected, as this area is implicated as a root cause of symptoms. Hunner reported that all significant lesions in classic IC patients occurred in the free portion of the bladder, whereas the trigone (or the fixed bladder) was unaffected [2]. Another series reported that all advanced HL either involved the either free bladder or just the dome. When the trigone was involved, it was much less affected [69]. In instances where the detrusor was not completely resected, patients' symptoms continued postoperatively [66, 70]. In these cases, revisions may be considered. This involves secondary resection of the bladder remnant to the level of the trigone [71] or to the bladder neck [68], both of which have been reported as effective treatment options. Another revision option is secondary supravesical urinary diversion [52].

The presence of urethral pain should be considered a relative contraindication for supratrigonal cystectomy and bladder augmentation as these patients will often continue to endorse symptoms despite the cystectomy. The clinician must bear in mind that not all patients will empty their augmented bladders effectively and may need to be placed on a CIC protocol. This, of course, would be problematic for the patient who remains with urethral pain. In these settings, a radical cystectomy with a continent or incontinent diversion should be considered to provide the optimal chance for a complete recovery without residual bladder or urethral pain symptoms.

Table 19.3 Preoperative bladder capacity in IB/BPS predicts postoperative outcomes

	Mean preoperative bladder capacity (cc)	
Study	Successful outcome	Failure
Goodwin [72]	50	0
Kontturi [66]	186	300
Nielsen [62]	200	524
Von Garrelts [67]	<100	n/a
Webster [68]	192	362

Conclusions

Although treating IC/BPS is difficult and requires trial and error as well as a multi-disciplinary approach, a range of minimally invasive and reconstructive surgical treatment options are available. Patients are good candidates for minimally invasive procedures if they have failed more conservative measures and suffer from well-documented bladder-based pain symptoms. These tools are continuously evolving, and as we better understand the disease process of IC/BPS, we hope that these techniques improve and render the use of more invasive higher order surgical options obsolete. In the meantime, if major surgical reconstruction is necessary, patient selection is key. Patient counseling regarding lifestyle changes and body image is of paramount importance to optimize patient satisfaction.

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The Use of Mesh in Pelvic Floor Reconstruction

20

Michael Ingber and Laura Dhariwal

Introduction

Pelvic organ prolapse is a highly prevalent condition, and surgery for prolapse is performed twice as common as continence surgery [1]. The prevalence of prolapse surgery varies widely among women from 6% to 18% [1]. There is no standard approach for surgical management of pelvic organ prolapse, and techniques include abdominal approaches, native tissue vaginal repairs, and surgeries which incorporate the use of surgical implants or synthetic or biological graft material. With the introduction of trocar-guided transvaginal "mesh kits," worldwide usage of vaginal mesh for prolapse surgery has increased [2]. Although multiple studies now address the subjective and objective outcomes with the use of vaginal mesh for prolapse repair, inherent limitations to surgical studies as well as the limited number of randomized control trials evaluating these meshes require an intimate understanding of mesh qualities, knowledge of relevant anatomy, and risk factors associated with these surgeries. Because of previously unknown risks to these procedures, a detailed review of the official statements made by the Food and Drug Administrations (FDA) and specialty societies is crucial in order to better counsel patients on available therapies.

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Mesh Properties and Characteristics

The role of the synthetic implant is to support the prolapsed organs, restore physiological anatomy, and to strengthen the pelvic floor support with minimal host response [3]. However, in order to produce a successful outcome, there are certain desired characteristics of the ideal mesh. It must be biocompatible, sterilizable, resistant to infection and mechanical strains, and be cost-effective [4].

Synthetic meshes are widely used for surgical repair of abdominal wall defects and hernias and in the light of the experience of general surgeons, similar implants are currently used in the pelvis to treat pelvic organ prolapse. Therefore, similar to The American Hernia Society standardizing guidelines in describing mesh products, the International Urogynecological Association (IUGA) has proposed similar standards for describing implants used for pelvic floor surgery [5].

Due to the wide array of available mesh implants and lack of standardization, comparing synthetic mesh properties can be confusing to both the surgeon and the patient. Therefore, it is essential to implement an accurate and more standardized product description consisting of data on the biological properties gathered in animal experiments, anatomical cadaveric studies,

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and upfront clinical studies followed by a compulsory registry on the first 1000 patients implanted. IUGA suggested to provide material and structural data that includes terminology and concepts derived from those used in the textile industry which can be applied to synthetic implants. These data include (1) the nature of the composing polymer(s) and filament(s), (2) resistance of polymer(s) to degradation (permanent or reabsorbable), (3) weaving type (knitted or woven), (4) filament diameter, (5) pore dimensions and density, (6) exact dimensions and weight, (7) total area of all filaments in the graft to be implanted, and (8) the uniaxial stress–strain plot, in the plane of and perpendicular to the material, determining tensile stress and stiffness, distentional stiffness, and bending stiffness (functional rigidity) [5].

Synthetic surgical meshes used in the repair of pelvic organ prolapse most commonly comprised nonabsorbable polymeric fibers which may be composed of multiple filaments organized into a complex knitting pattern [6]. Knitting implants are, in general, more porous and flexible, but are typically less strong primarily due to its decreased filament density [7]. Knitted meshes for prolapse repair are often designed on textile schemes with four main unit cells: octagonal, rhombic, square, and multiple pore shapes [5, 7].

Relative weight (or density) of synthetic mesh is expressed in grams per meter squared. Heavyweight implants (HW) describe densities above 80 g/m^2, medium weight (MW) are densities between 40 and 70 g/m^2, and low weight (LW) are densities below 40 g/m^2 [7, 8].

Pore size is the key factor in determining inflammatory response, fibrocollagenous tissue ingrowth, angiogenesis, flexibility (or stiffness), and strength. Pore size plays an important role in mesh infection prevention and fibrous ingrowth of surrounding tissues. Mesh pore size is typically calculated as the pore area to total area and described in micrometers. The best mechanical anchorage with collagen infiltration occurs with pore sizes between 50 and 200 micrometers [7]. When pore size is too small, the implant becomes susceptible to infection. This propensity to infection is due to the bacteria, typically 1 μm in size, being able to enter and proliferate while larger macrophages and neutrophils cannot reach to fight off the infection [9]. Therefore, all nonabsorbable grafts used for pelvic organ prolapse repair are considered "macro-porous" and classified as type I based on pore size greater than 75 μm. Macroporous implants allow for tissue incorporation and ingrowth of vessels and fibroblasts, whereas microporous mesh is more prone to being encapsulated rather than infiltrated by host tissue [10]. In a study comparing the influence of pore size for the treatment of abdominal wall defects in dogs, Greca et al. found that although the mesh with smaller pore size had a greater burst strength prior to implantation, the strengths were similar after implantation. Furthermore, the larger pore mesh had a significantly higher proportion of type I collagen incorporation, greater biocompatibility, and a more adequate scar formation to prevent recurrent, as compared to the more microporous mesh [11]. Classification of synthetic mesh based on pore size is further described in (Table 20.1) [12].

Mesh stiffness is the main parameter affecting functionality and support provided by the implant. Stiffness is defined as the ratio of a force applied on an elastic medium resulting in changes in shape or size of the material [5, 7]; tensile stiffness is related to the deformation of the product due to a uniaxial or "in-plane" loading. Perpendicular loads to the implant determine distentional stiffness, and bending stiffness represents the functional rigidity of the product [7, 13]. High-stiffness meshes may have implications in the rate of mesh-related complications [14, 15]. Liang et al. demonstrated that implantation of high-stiffness mesh resulted in a negative tissue response including thinning of the smooth muscle layer, increased cell apoptosis, increased collagenase activity, decreased collagen and elastin content, and increased GAG content [16]. Therefore, the structural integrity of vagina is negatively correlated with high-stiffness mesh.

In recent times, absorbable meshes have also reached the market in an effort to reduce host response and increase biocompatibility. Polyglycolic acid (Dexon) is an example of an absorbable synthetic material. Dexon requires

Table 20.1 Classification of synthetic mesh based on pore size

Classification	Description	Pore size	Characteristics
Type I	Macroporous	>75 μm	Allows fibroblastic cell infiltration for tissue ingrowth Reduced inflammation Reduced infection rates
Type II	Microporous	<10 μm	High infection rates High foreign body reaction
Type III	Macroporous with multifilamentous or microporous components		High infection rates Poor tissue ingrowth Less surface tension
Type IV	Submicronic	<1 μm	Often associated with type I mesh for adhesion prevention in intraperitoneal implantation

90 days for absorption and results in mesh absorption and subsequent recycling of by-products into new collagen fibers. Polyglactin 910 (Vicryl) is another absorbable option. It hydrolyzes during the third week after implantation and loses the majority of its mechanical value after 30 days. Absorbable materials help to promote postoperative fibroblast activity, have low infection rates and no host rejection, and are known not to be harmful to the viscera [6, 9].

Physiological Response to Polypropylene Mesh

Biocompatibility is the ability of a material to perform with an appropriate host response. As such, biomaterials should be physically and chemically inert. The ideal biomaterial used in pelvic floor reconstruction is yet to be determined; however, the most widely used polymeric material in pelvic organ prolapse repair is monofilamentous, macroporous polypropylene (PP). This is due to its durability and inert characteristics [17–19].

After biomaterial implantation, the host tissue reaction begins with an immediate immune response followed by an acute inflammatory response. This ultimately leads to collagen production and scar formation [20, 21]. First, an influx of blood flows toward the synthetic material produces a transient matrix rich in cytokines, chemoattractants, and growth factors. This matrix lays the scaffolding for subsequent immune responses [19, 22, 23]. Next, histamine-mediated phagocyte recruitment occurs, and increased neutrophil activity along with histamine and interleukin release from mast cells produces an acute inflammatory response [24]. Chronic inflammation initiates when monocytes and lymphocytes are recruited to the implant site [25, 26]. Finally, cytokine and growth factor-mediated macrophage activation and fibroblast proliferation result in tissue growth into the mesh implant [27]. The timeline of the physiological response to lightweight mesh is depicted in (Table 20.2).

Table 20.2 Physiologic response to lightweight mesh

Day 3	Inflammation: exudative, then cellular
Day 10	Fibroblastic ingrowth
Week 6	Complete ingrowth
Weeks 3–12	Prosthetic strength doubles

Current Vaginal Mesh Products

The perfect synthetic mesh product is yet to be determined. Due to the many variations of mesh products based on characteristics described above, there had been a number of commercially available mesh products that have been used throughout the past decade. At the time of this chapter's publication, there are only three commercially available vaginal mesh kits used for pelvic floor reconstruction for pelvic organ prolapse. These include Uphold™ LITE vaginal mesh system (Boston Scientific, Marlborough MA), Novasilk™ mesh, and Restorelle® DirectFix (Coloplast, Minneapolis, MN). All three are lightweight macroporous polypropylene meshes.

Table 20.3 Commercially available synthetic vaginal mesh kit products

Commercial name	Manufacturer	Chemical composition	Density (g/m^2)	Pore size (μm)	Unit Cell Structure	Thickness (mm)	Membrane stiffness (N/mm)
Intepro®	American Medical System	MW PP	52.4	159x114	Octagonal	0.53	N/A
Intepro Lite®	American Medical System	LW PP	25.2	>100	Octagonal	N/A	N/A
Gynecare	Ethicon	MW PP	42.4	240	Octagonal	0.42	2.97
Gynemesh PS®	Ethicon	MW PP	44	247x168	Octagonal	0.41	0.29
Alyte®	Bard Davol	LW PP	17.7	278x133	Multiple pore shapes	0.29	0.29
Restorelle® DirectFix	**Coloplast**	**LW PP**	**20**	**240**	**Square**	**0.31**	**N/A**
Novasilk™	**Coloplast**	**LW PP**	**18.7**	**110**	**Rhombic**	**0.26**	**0.1-0.5**
Uphold™	Boston Scientific	LW PP	40	160	Rhombic	0.20	N/A
Uphold™ LITE	**Boston Scientific**	**LW PP**	**25**	**280**	**Rhombic**	**0.20**	**N/A**
Artisyn®	Ethicon	PP/ Absorbable layer	28	240x160	Rhombic	0.53	N/A
Intemesh®	American Medical System	PET/Silicone	N/A	N/A	N/A	0.70	N/A
Dynamesh PR soft®	American Medical System	PVDF	N/A	N/A	Square	N/A	N/A

Black text depicts the three currently commercially available mesh kits. Blue font depicts products no longer in the market

Table 20.3 describes a list of synthetic mesh kits and their descriptive properties. Black text depicts the three currently commercially available mesh kits. Blue font depicts products no longer in the market [9, 28, 29].

Figures 20.1, 20.2, 20.3, and 20.4 depict pelvic constructive surgery involving Uphold™ LITE vaginal mesh system. First, a self-retaining retractor is placed into position, and Allis clamps are applied in a horizontal fashion approximately 4 cm apart and proximal to the bladder neck to demarcate the place of vaginal incision (Fig. 20.1). After the bladder and surrounding connective tissue are separated from the anterior vagina and extended to the vaginal/cervical junction, the dissection is then extended to the sacrospinous ligaments bilaterally. The Uphold™ LITE mesh is then brought onto the surgical field (Fig. 20.2). The arms of the Uphold™ LITE mesh are anchored to the mid-portion of the sacrospinous ligaments bilaterally with the assistance of the Capio™ SLIM Suture Capturing Device (Fig. 20.3). The Uphold™ LITE vaginal mesh is then advanced into position under the

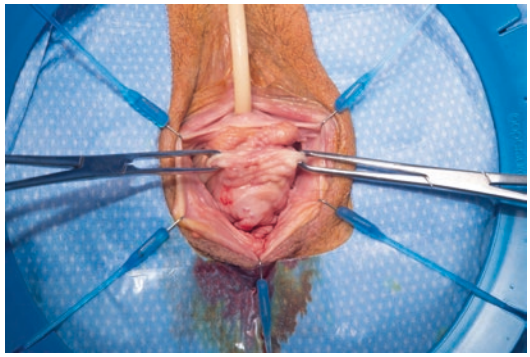

Fig. 20.1 Uphold™ LITE mesh kit system placement: preparation for vaginal incision

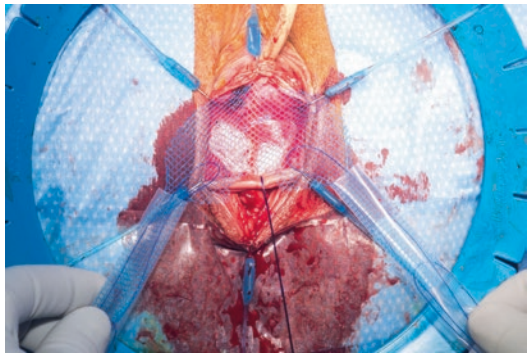

Fig. 20.2 Uphold™ LITE mesh kit system placement: anterior wall dissection

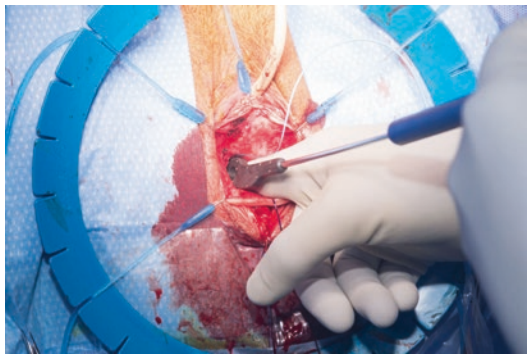

Fig. 20.3 Uphold™ LITE mesh kit system placement: sacrospinous ligament fixation using Capio™ SLIM Suture Capturing Device

bladder without tension, and the distal end of the mesh is attached to the surrounding connective tissue (Fig. 20.4).

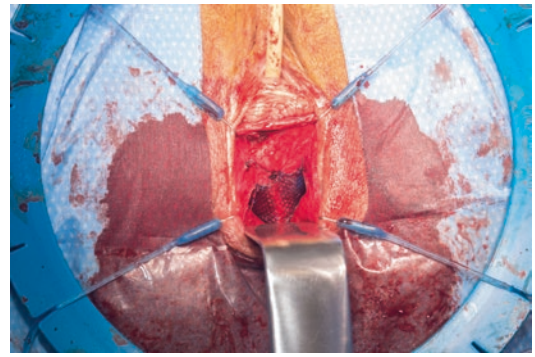

Fig. 20.4 Uphold™ LITE mesh kit system placement: after tensioning

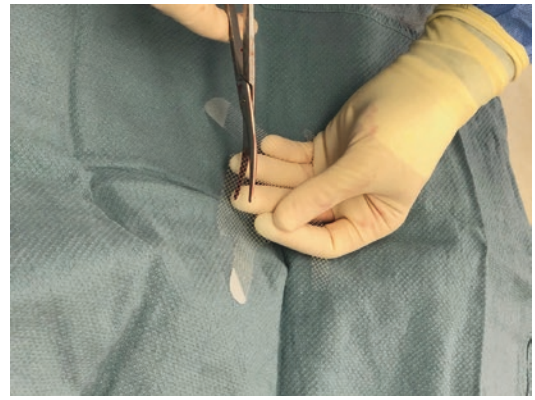

Fig. 20.5 Restorelle® DirectFix mesh product

Figure 20.5 depicts the Restorelle® DirectFix mesh product with a similar surgical placement shown in Fig. 20.6.

Outcome Data

Studies involving vaginal mesh for pelvic organ prolapse are limited by the inherent shortcomings of surgical studies, as well as the lack of randomized controlled trials (RCTs). Studies evaluating vaginal mesh for pelvic organ prolapse repair are mostly case series and retrospective reviews that evaluate both commercial mesh kits as well as surgeon-fashioned mesh surgeries. Furthermore, even while evaluating randomized controlled studies on transvaginal mesh, many transvaginal polypropylene meshes have been voluntarily

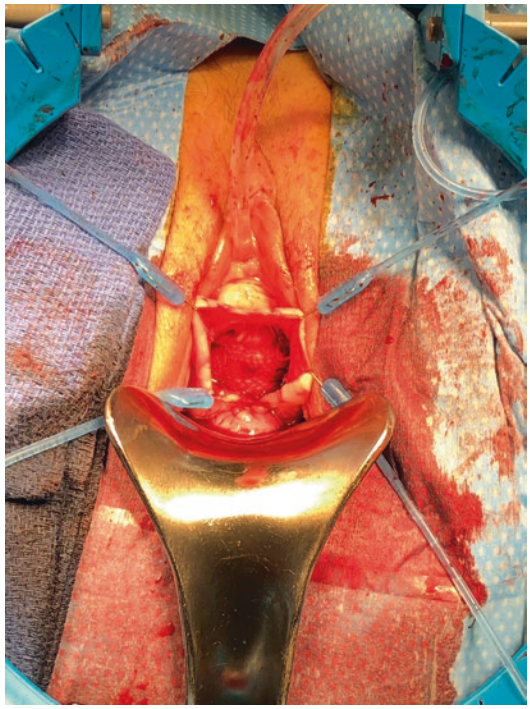

Fig. 20.6 Restorelle® DirectFix mesh product placement: after tensioning

removed from the market, and newer lightweight transvaginal meshes that are available have not been assessed by RCTs. Therefore, clinicians and patients should be cautious when utilizing these products, as their safety and efficacy have not been established.

In a 2013 Cochrane Review, Maher et al. evaluated 21 trials that compared a variety of surgical procedures for anterior compartment prolapse (cystocele). Ten compared native tissue repair with graft repair (absorbable and permanent mesh, biological grafts) for anterior compartment prolapse. The authors concluded that native tissue anterior repair (AR) was associated with a greater risk of recurrent anterior compartment prolapse than when supplemented with a polyglactin (absorbable) mesh inlay (RR, 1.39; 95% CI, 1.02–1.90) or porcine dermis mesh inlay (RR, 2.08; 95% CI, 1.08–4.01). There was no difference in postoperative awareness of prolapse after absorbable mesh (RR, 0.96; 95% CI, 0.33–2.81) or a biological graft (RR, 1.21; 95% CI, 0.64–2.30). Additionally, AR was associated with more anterior compartment prolapse on examination than for any mesh repair (RR, 3.15; 95% CI, 2.50–3.96). Awareness of prolapse was also higher after the anterior repair as compared with polypropylene mesh repair (28% versus 18%; RR, 1.57; 95% CI, 1.18–2.07) [30].

In 2011, Altman and colleagues produced a multicenter randomized control trial that evaluated traditional colporrhaphy versus colporrhaphy with Gynecare Prolift Anterior Pelvic Floor Repair System kit. The primary outcome was POPQ stage 0–1 and absence of vaginal bulge symptoms assessed at 12 months. At 1 year, the primary outcome was significantly more common in the women treated with transvaginal mesh repair (60.8%) than in those who underwent colporrhaphy (34.5%) ($p < 0.001$; RR, 3.6; 95% CI, 2.2–5.9). Anterior mesh was associated with greater OR time (20 min), increased blood loss (50 cc), more postop SUI (12.3% versus 6.3%), increased bladder perforations (3.5% to 0.5%), and a 3.2% risk of surgery for mesh exposure. There was no difference noted in sexual function. Therefore, the transvaginal mesh kit produced higher short-term rates of successful treatment but also higher rates of surgical complications and postoperative adverse events [31].

In a 2012 retrospective cohort study evaluating patients who underwent pelvic reconstruction using Uphold™ Vaginal Support System from November 2008 to October 2010, Vu and colleagues reported a combined anterior–apical recurrence rate of 1.89%. The rate of mesh exposure was 2.6%, including two women who underwent concurrent hysterectomy. Self-reported dyspareunia was more common preoperatively (13.4%) than postoperatively (9.3%), and PFDI scores improved in all domains. The vast majority of women (93%) reported that they were satisfied and would choose the surgery again [32].

In another cohort study, Su et al. compared Elevate™ anterior and posterior prolapse repair system with traditional vaginal native tissue repair. The primary outcome was anatomical success 1 year after surgery. They found that the anatomical success rate of the anterior compartment was significantly higher in the Elevate™ repair group than in the traditional repair group (98%

versus 87%), but not for the apical or posterior compartment. Both groups showed significant improvements in the quality of life after surgery with no statistical difference. Mesh-exposure rate was 3% and need for revision of the vaginal wound occurred in 1% of patients. The mesh repair group had a longer hospital stay, increased operative time, and greater estimated blood loss when compared to the traditional vaginal native tissue repair [33].

More recently in 2016, Maher et al. reported a Cochrane Review of 33 randomized controlled trials evaluating 3332 surgeries to compare traditional native tissue anterior repair versus biological grafts (eight trials), absorbable mesh (three trials), permanent (polypropylene) mesh (16 trials), and abdominal paravaginal repair (two trials). Four trials compared a transvaginal graft versus another transvaginal graft, and four trials evaluated native tissue repair of anterior and/or posterior compartments of the vagina versus graft repair. They concluded that biological graft repair or absorbable mesh provides minimal advantage compared with native tissue repair. Native tissue repair was associated with increased awareness of prolapse and increased risk of repeat surgery for prolapse and recurrence of anterior compartment prolapse compared with polypropylene mesh repair. However, native tissue repair was associated with reduced risk of de novo SUI, reduced risk of bladder injury, and reduced rates of repeat surgery for prolapse, stress urinary incontinence, and mesh exposure (composite outcome). Therefore, the current evidence does not support the use of mesh repair compared with native tissue repair for anterior compartment prolapse owing to increased morbidity [34].

At the time of publication, we await the data from the Study of Uterine Prolapse Procedures – Randomized Trial (SUPeR) which compares the efficacy and safety of native tissue repair with vaginal hysterectomy and suture apical suspension versus uterine conservation with mesh hysteropexy using Uphold™ LITE transvaginal mesh kit. Patients were followed through 36–60 months postoperatively after primary repair of uterovaginal prolapse. Participants and evaluators were masked to their surgical intervention in an effort to decrease bias. The primary purpose of the study is to compare the effectiveness and safety of two transvaginal apical suspension strategies for uterovaginal prolapse: a mesh-augmented hysteropexy versus vaginal hysterectomy and uterosacral ligament suspension (USLS) [35]. We anticipate that the results of this study will contribute meaningfully to the literature on the safety and efficacy of transvaginal mesh for pelvic organ prolapse.

The Food and Drug Administration (FDA) on transvaginal mesh

In 2008 after receiving over a thousand voluntary reports from nine surgical mesh manufacturers of serious complications associated with pelvic mesh use, the FDA released a public health notice regarding complications and adverse events associated with the use of synthetic mesh in prolapse and stress urinary incontinence surgery. In July of 2011, the FDA released a safety communique entitled "UPDATE on Serious Complications Associated with Transvaginal Placement of Surgical Mesh for Pelvic Organ Prolapse." The stated purpose of this advisory was to inform surgeons and patients that serious complications with placement of this mesh are not rare and that it is not clear that these repairs are more effective than nonmesh repair. In January of 2016, the FDA issued two final orders to manufacturers and the public to strengthen the data requirements for transvaginal mesh to repair pelvic organ prolapse: (1) to reclassify transvaginal mesh from class II (moderate-risk devices) to class III (high-risk devices) and (2) an order that requires manufacturers to submit a premarket approval (PMA) application to support the safety and effectiveness of surgical mesh for the transvaginal repair of pelvic organ prolapse [36].

Using an electronic survey of the American Urogynecologic Society (AUGS) members between December 2011 and January 2012, Clemons and colleagues evaluated the rate of mesh usage before and after the FDA statement. They found that 40% of AUGS members reported decreased use of transvaginal mesh, and 12% had

stopped completely [37]. Skoczylas et al. also found that fewer vaginal mesh procedures and more native tissue repairs and minimally invasive sacrocolpopexies were being performed at their large institution as a result of the FDA warning [38].

In a manuscript published in 2012, 600 members of the Pelvic Surgeons Network endorsed a response to the 2011 FDA communication with evidence-based criticisms. Recognizing the FDA's mission to patients' safety and advocacy and agreeing with several portions of the 2011 FDA statement, the authors of this manuscript had four main rebuttals to the published advisory. The first is the statement that "mesh used in transvaginal pelvic organ prolapse repair introduces risks not present in traditional non-mesh surgery for pelvic organ prolapse repair." While this is true for mesh-specific complications such as mesh erosion, there are other risks that are common to both modes of prolapse repair. Some of these risks include bleeding, pelvic pain, and urinary complaints. The statement is therefore misleading, implying that multiple mesh-specific risks exist that do not apply to nonmesh repairs. Second, the FDA states that "mesh placed abdominally for pelvic organ prolapse repair appears to result in lower rates of mesh complications compared to transvaginal pelvic organ prolapse repair with mesh." While most surgeons do agree that transvaginal mesh erosion rates are higher, it is important to keep in mind that (1) published rates of mesh erosions after transvaginal mesh surgery vary greatly are and likely surgeon-specific, and (2) there are risks of the abdominal approach (other than mesh erosion) that must also be taken into account. Just as any other medical intervention, a thorough risk-benefit analysis must be made before any recommendation can made for the patient. Next, the statement that there is "no evidence that [apical repair] or [posterior repair] with mesh provides any added benefit compared to traditional surgery without mesh" is arguable. As mentioned previously in this chapter, data regarding transvaginal mesh repair for pelvic prolapse is limited, and therefore this, along with the FDA's statement "transvaginal [anterior repair] may provide anatomic benefit, but may not result in better symptomatic results," is inaccurate and lacks adequate supporting data [39].

Not only have the members of the Pelvic Surgeons Network voiced their opinion on the FDA communiques on transvaginal mesh, but also the American College of Obstetricians and Gynecologists (ACOG), the American Urologic Association (AUA), and the International Urogynecological Association (IUGA) have all made statements regarding this advisory. Reconstructive pelvic surgeons unanimously agree that a thorough informed consent should be conducted prior to the use of mesh products for pelvic organ prolapse and that patient selection for its use is an integral part of decision-making. This has led to the development of patient selection guidelines and informed consent recommendations intended to maximize patient safety in patients undergoing surgical repair of pelvic organ prolapse. Davila et al. provided key points to consider when deciding to use transvaginal mesh for prolapse repair. These include individual host factors such as age, site and stage or prolapse, history of collagen deficiencies, presence of chronic and/or repetitive increased of abdominal pressure, chronic pain, and co-morbidities such as diabetes, atrophy, immunosuppression, smoking status, and BMI. Patient's fertility plans should also be addressed. There are technical factors that also affect rates of mesh complications including performance of concurrent hysterectomy, tensioning, depth of implantation, management of excess vaginal epithelium, choice of materials, and surgeon experience [40].

In February 2019, the FDA ordered the two remaining manufacturers of surgical mesh intended for transvaginal repair of anterior compartment prolapse to stop selling and distributing their products. This seemingly abrupt decision was made prior to the completion of the companies' ongoing 522 studies; however, it was done based on a congressionally mandated timeline for the most stringent device review pathway. With several of the studies at or near complete enrollment, the FDA does require the completion of these 522 studies. Once the 36-month follow-up is complete, companies can resubmit this data for FDA review.

The Future of Mesh

In light of the FDA advisories against transvaginal mesh and its order to discontinue transvaginal mesh kits, the remaining three commercially available products were removed from the market. This withdrawal has left surgeons with the option of free-cut mesh as their only available transvaginal mesh option for prolapse repair. The current data is sparse and varies greatly in the type and characteristics of the meshes used. Using free-cut mesh will only further skew this data. AUGS encourages providers pursuing this approach to "1) employ a detailed shared-decision-making model and robust consent process and documentation, 2) engage in registry or other data collection process." The future of transvaginal mesh repair for pelvic organ prolapse depends on the final outcome data proving that these mesh kits provide a safe and efficacious means of treating pelvic prolapse and that its benefits outweigh the known risks of mesh erosion and potential postoperative complications.

As time goes on, we are learning more and more about the types of meshes which will not only provide good support but also carry low risk. Ongoing studies involving newer synthetic products are underway that aim to provide safe and efficacious alternatives for pelvic reconstruction surgery. One such example includes an electrospun 17-β-estradiol-releasing polyurethane (PU) scaffold that would potentially provide anatomical support as well as stimulate new extracellular matrix (ECM) production and angiogenesis [41]. Clinical trials in the United Kingdom are still pending; however, the increased elasticity of polyurethane as well as the estrogen-releasing property of the product may provide a promising alternative to traditional polypropylene.

Materials of the future will be lightweight, flexible, and impregnated with factors geared toward decreasing a host response. These may include stem cells or growth factors. Personalized medical therapy is the wave of the future, whether it is by individual gene therapy or computation of individual pelvic anatomy and concomitant use of 3D printing for implant processing.

We are a long way from prospect of the perfect synthetic implant, but the work starts with investigations and well-designed research to prove to safety, efficacy, and cost-effectiveness of our current synthetic products.

Conclusion

With the current data, the decision to proceed with the use of transvaginal mesh will rely heavily on an open, transparent discussion between the surgeon and the patient regarding the risks and benefits of synthetic mesh. As for the surgeon, adequate surgical training, meticulous technique, and careful patient selection are imperative to ensure successful use of transvaginal mesh for pelvic reconstruction surgery.

At the time of publication, postmarket surveillance studies evaluating the safety and efficacy of transvaginal mesh are ongoing. We expect outcome data to further guide the practitioner on when using a transvaginal mesh is warranted. Until this data is available, however, careful understanding of the mesh properties, surgical technique, and patient's needs and history will allow for a safer implantation of transvaginal mesh.

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Gender Confirmation Surgery

21

Miroslav L. Djordjevic

Introduction

Gender dysphoria represents a condition where a person's gender assigned at birth and the gender with which they identify are incongruent. Hence, these individuals can be very uncomfortable with their biological sex, primary and secondary sex characteristics, and social gender roles, and they experience various levels of distress. Presence of public figures who are openly transgender, their appearance in mainstream media, and political and social climate lead to more individuals coming out in the open as to their state. Prevalence rate cannot be correctly estimated and, according to DSM-5, ranges between 0.005–0.014% and 0.002–0.003% for adult natal males and natal females, respectively [1]. Medical treatment requires a team of experienced experts, and it usually includes mental health professionals, endocrinologists, and surgeons. Psychiatric assessment is the first step and is very complex because it is necessary to exclude other conditions that might mimic gender dysphoria. The next step is hormonal treatment, under the care of an endocrinologist, which is then followed by "a real-life trial." Some individuals decide to stop here, while others continue to gender confirmation surgery. Surgical transition is the last step in an individual's transition to the preferred gender. It comprises surgical procedures that will reshape the individual's body into a body with the appearance of the desired gender. The last edition of the Standards of Care of the World Professional Association of Transgender Health (WPATH) offers flexible guidelines for the treatment of people experiencing gender dysphoria and describes the criteria for surgical treatment [2]. Patients undergoing surgery of their choice are required to provide two recommendation letters from certified psychiatrists and a gender specialist, as well as a confirmation of having been on hormonal therapy prescribed by an endocrinologist for a period of a minimum of 1 year.

Since the reconstruction of genitalia presents the last step in an individual's transition, the transgender person must consider the preferred postoperative result they wish to achieve and the surgical options available to them. At this point, it is essential that the patient undergoes a detailed preoperative consultation and examination by the surgeon, as well as a discussion with a psychologist/psychiatrist about the surgical outcome, to prevent a possible disappointment or regret following surgery. In male-to-female gender confirmation surgery, the main goal is the creation of a vagina with external genital organs that are as feminine as possible in appearance, with no scars or traumatic postoperative neuromas [3, 4]. The most commonly performed surgeries in female-to-male transsexual patients are bilateral mastectomy with male chest contouring and genital

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reconstructive surgery which includes total hysterectomy with bilateral oophorectomy, vaginectomy, reconstruction of the neophallus, urethral reconstruction, and scrotoplasty with the implantation of testicular prostheses. Concerning neophallic reconstruction, two options are available: metoidioplasty and phalloplasty [5].

Male-to-Female Gender Confirmation Surgery

The main goal of gender confirmation surgery in female transgenders is to create the vagina and external genital organs to be as feminine as possible in appearance. However, the optimal surgical technique has not yet been decided. The neovagina should be ideally moist, elastic, and hairless, no less than 10 cm in depth and about 3–4 cm in diameter, without introital stenosis. The new clitoris should be small and hidden, but sensitive, offering, together with neovaginal sensation, acceptable erogenous stimulus during sexual intercourse. The urethra should be shortened so the urinary stream is pointed downward in the sitting position without fistulas or strictures. Labia minora and majora should not be bulky but resemble as much as possible the anatomically female vulva [3, 6–8].

A variety of surgical options exists for vaginal reconstruction with the same goals: creation of functional and aesthetically acceptable vagina and vulva, with a normal voiding function and satisfactory sexual function. Although several different surgical procedures in vaginal reconstruction are published, two most widespread techniques are (1) penile skin inversion, optionally combined with scrotal flaps, and (2) intestinal vaginoplasty. Surgery includes removal of testicles, reduction of the glans penis to proper dimensions for the creation of a new clitoris, vaginoplasty with inverted penile skin flap, and vulvoplasty. If the patient has been previously circumcised, the penile skin available for neovagina may be insufficient. In these cases, or in cases with failed vaginoplasty, a vaginal lining can be created either from hairless skin grafts or from an intestinal segment. These procedures may not provide the same sensate qualities and general outcomes such as after penile inversion method, but the vaginal opening is identical, and the degree of sensation is approximately the same as that of most women so pleasure should not be less.

The use of other different tissues, such as buccal mucosa, amnion grafts, or acellularized tissues, is based on experimental models with temporary outcomes that have never been compared.

Penile inversion technique remains the method of choice for vaginoplasty in male-to-female transsexuals. In this technique inverted penile skin, with or without the scrotal skin, is used for flap tubularization [7]. The key for success lies in preserved vascularization of the penile skin, its mobility and versatility, thin connective tissue, sensation, as well as hairlessness. One of the main disadvantages of this technique could be the insufficiency of penile skin in circumcised patients or in patients with short penises, which results in exposure of the neoclitoris and widening of the anterior commissure [8]. Refinements of the initially described techniques were published by several authors with the combination of the penile skin flap and urethral flap in order to overcome these problems. They also reported better outcomes in vaginal moisture and its self-lubricating due to a well-vascularized urethral flap. Preoperative hair epilation is advised to all patients to avoid hair-bearing neovagina. Postoperative neovaginal dilation is advised for at least 1 year to prevent introital stenosis and neovaginal shrinkage. Neovaginal prolapse can be prevented by its fixation to the sacrospinous ligaments giving a better aesthetic appearance [9].

Intestinal vaginoplasty represents probably the second most used vaginoplasty procedure in male-to-female transsexuals, which is primarily indicated after a failed penile inversion technique or as a primary procedure in cases with insufficient penile skin. The technique results in a self-lubricating and well-sized neovagina, which does not require postoperative dilatation for extended periods of time. Use of rectosigmoid colon as a pedicled flap for the creation of a neovagina is effective since sufficient length may be obtained with excellent blood supply of the segment. This segment is thick-walled and large in diameter and

can tolerate trauma better than small bowel, bladder, or skin grafts. Postoperative management is simple and easy. Mucus production decreases dramatically after 3–6 months regardless of the sigmoid segment length. Although sufficient to provide adequate lubrication, it was neither excessive nor irritating to our patients. Dilation or calibration of the introital anastomosis is temporary and well tolerated. However, there are disadvantages as well, including the need for laparotomy and bowel anastomosis, which increases the risk of postoperative ileus. In addition, certain disadvantages such as prolonged mucus production, persistent odor, introital stenosis, bleeding after sexual intercourse, or diversion colitis prevent this technique from being seen as the number one choice in the majority of centers throughout the world [10–12].

Penile Inversion Technique

Several subprocedures are required to form the new vagina. After the usual bilateral orchidectomy, the penis is disassembled into its anatomical components, i.e., the corpora cavernosa, the glans cap with the urethra and the neurovascular bundle, and the vascularized penile skin (Fig. 21.1a). The corpora cavernosa are dissected up to their attachments to the pubic bones. Crural arteries are ligated, and then corpora are completely detached from the bones. The glans cap is divided into two parts, ventral and dorsal; the dorsal part of the glans is reduced by excising the central ventral tissue, leaving the sides of the glans intact. Lateral excisions on the glans are not recommended, to avoid injuring the neurovascular bundle which enters the glans cap lateroventrally. However, the sides are deepithelialized and sutured, to obtain a conical shape for the neoclitoris. The bulbospongiosus muscle is removed from the bulbous part of the urethra; the dissection of the bulbar urethra must be precise to avoid injury to the fascial sheath. The urethra is then spatulated, including the bulbar part, and used to create the mucosal part of the neovagina. A female type urethra is then formed and the neoclitoris fixed above the new urethral meatus. In reconstructing the new vagina, the skin of the penile body and prepuce (if present) are fashioned into a vascularized island tube flap. It is important to obtain a long, vascularized pedicle for the tube, and therefore, the level of the incision is no more than 2 cm above the base of the mobilized penile skin. A hole is made at the base of the pedicle to transpose the urethral flap (Fig. 21.1b). A superficial longitudinal incision is made on the dorsal skin tube, preserving vascularized subcutaneous tissue remains. Skin is mobilized to create a bed for urethral flap. The urethral flap, which is transposed through the pedicle hole, is embedded into the skin tube and sutured. The bottom of the tube is closed with the distal part of the urethra and/or the remaining ventral half of the glans cap after the deepithelialization of its inner side. The tube, consisting of skin and urethral flap, is inverted, thus forming the new vagina.

In cases of insufficient penile skin (a small and/or circumcised penis), the neovagina can be created in two ways: (a) the short penile skin flap is used together with a vascularized scrotal skin flap, with or without long urethral flap, and (b) using the vascularized urethral flap and free penile skin grafts, where the vascularized urethral flap plays the key role.

Space for the new vagina is created in the perineum. Two tunnels are made on both sides of the tendineus center allowing access to the deep and wide perineal cavity between the urethra, bladder, and rectum. Special care should be taken to avoid injury of the rectum. The right pararectal space is opened by penetrating the right pararectal fascia (rectal pillar), and the right ischial spine is palpated. After exposing the sacrospinous ligament, a long-handled Deschamps ligature carrier is used to pierce the ligament medially to the ischial spine. Care must be taken to prevent injury of the pudendal nerve and internal pudendal vessels. Both ends of the suture are brought out; one is passed through the skin part and the other is passed through the urethral part of the distal third of the neovagina, and the fixation stitches are firmly tied. Vaginopexy to the sacrospinous ligament is performed, and the neovagina is placed deep in the perineal cavity. This provides good

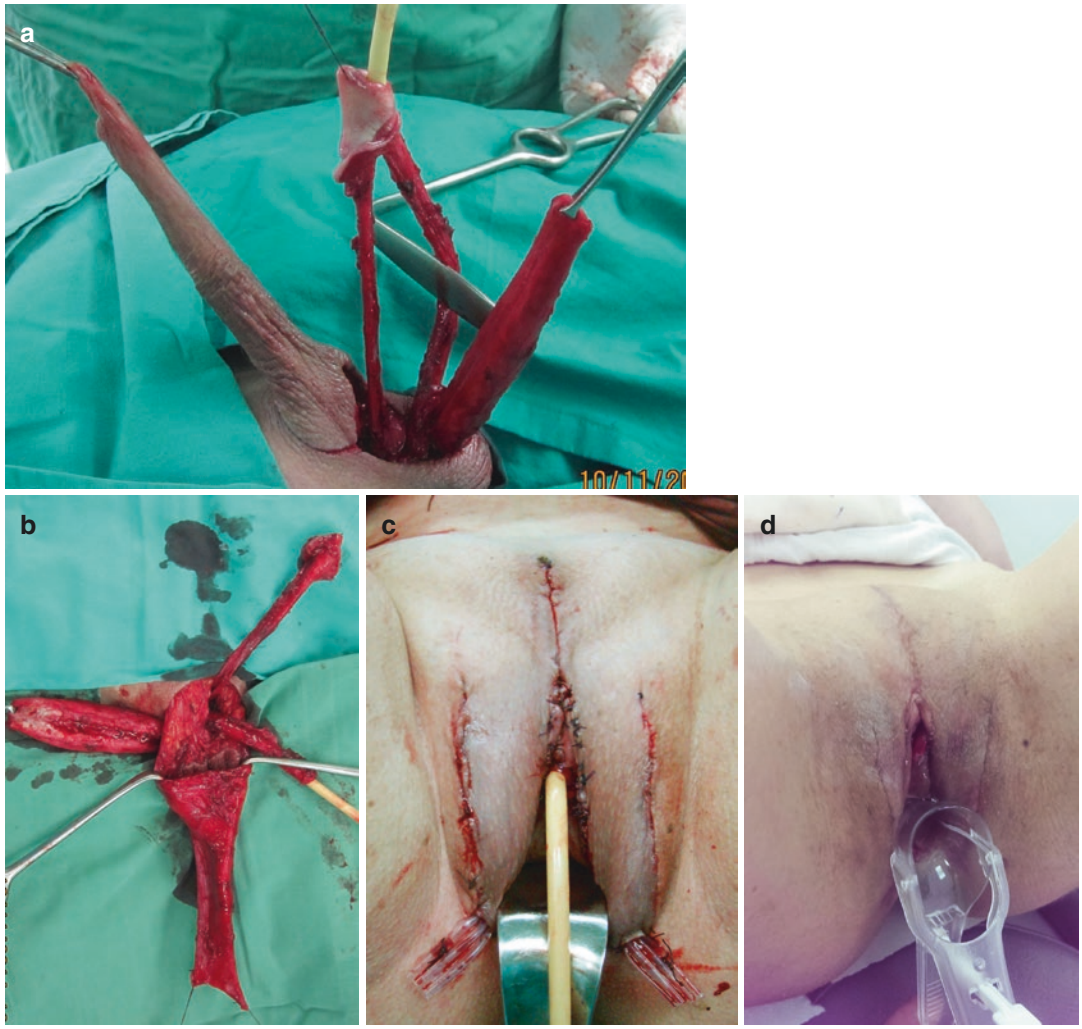

Fig. 21.1 Penile inversion vaginoplasty. (**a**) Penile disassembly is done. Penis is separated into its anatomical parts, corpora cavernosa, urethra with glans cap, and neurovascular bundle; (**b**) neovagina is created from inverted penile skin. Clitoris is made after reduction of the glans; (**c**) appearance after surgery; and (**d**) outcome 6 months later with good depth of the neovagina

placement of the neovagina preventing its prolapse, postoperatively. Vulvoplasty involves creation of the labia minora and majora. The remaining parts of the penile skin and scrotal skin are used to form the labia minora and majora (Figs. 21.1c, d.).

Sigmoid Vaginoplasty

The patient is placed in an extended lithotomy position as for a synchronous combined abdominoperineal approach (Fig. 21.2a). Through a Pfannenstiel incision, the sigmoid colon is mobilized from its lateral retroperitoneal attachment, as far as possible. Before making the final selection of the segment of sigmoid colon, one should assess the length of the sigmoid and its mesentery to determine whether it can easily reach the perineum. Usually, the isolated segment of rectosigmoid ranges from 8 to 11 cm in length with the aim to avoid excessive mucus production postoperatively. Sigmoid segment is harvested with the blood supply originating from sigmoidal

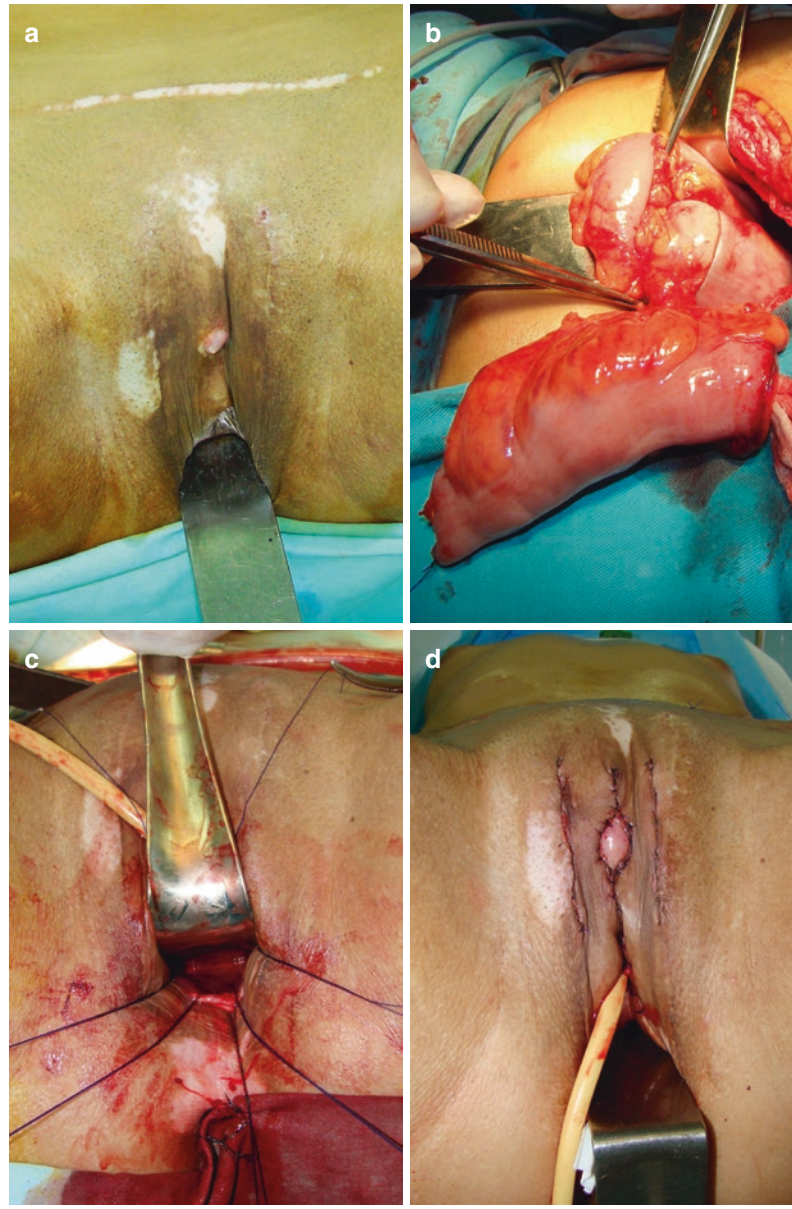

Fig. 21.2 Sigmoid vaginoplasty. (**a**) Appearance of female genitalia after failed male-to-female surgery. Vagina is absent; (**b**) small segment of the sigmoid colon is dissected for neovagina. Colonic anastomosis is done by stapler device; (**c**) anastomosis of the sigmoid vagina with perineal flaps is done deeply into the space preventing its prolapse; and (**d**) outcome after reconstruction of genitalia

arteries or/and superior hemorrhoidal vessels. Preferably, it should be divided distally first in order to check its mobility and determine the correct site for its proximal division. The proximal portion of the sigmoid is closed in two layers with absorbable suture. Bowel continuity is achieved using an intraluminal stapling device (Fig. 21.2b). Perineal cavity for vaginal replacement is created using simultaneous approach through abdomen and perineum. Dissection is performed very precisely, to avoid injury of the rectum, bladder, and urethra. In failed vaginoplasty, scarred and nonfunctional vagina should be completely excised allowing adequate space for positioning of the sigmoid loop. Isolated sigmoid flap is brought down to the perineal canal without tension to create a tension-free coloperineal anastomosis. Usually, "U" shaped incision is made posterior to the urethra, creating two lateral vascularized introital flaps. The flaps are completely mobilized

and joined with sigmoid flap into the perineal channel as deep as possible to prevent mucosal prolapse and to give better aesthetic results with the anastomosis deeply hidden (Fig. 21.2c, d).

The aesthetic, sensational, and functional results of vaginoplasty vary greatly. Surgeons vary considerably in their techniques and skills, patients' skin varies in elasticity and healing ability, previous surgery in the area can impact results, and surgery can be complicated by problems such as infections, blood loss, or nerve damage. However, in cases with proper and complete recovery, it is often very difficult for anyone, including gynecologists, to detect transwomen who underwent vaginoplasty. Supporters of colovaginoplasty state that this method is better than the use of skin grafts for the reason that colon is already mucosal, whereas skin is not. However, many post-op transwomen report that the skin used to line their vagina develops mucosal qualities from months to years post-op. For others, lubrication is needed when having sex, and occasional douching is advised so that bacteria do not start to grow and give off odors. Since the human body treats the new vagina as a wound, all current techniques for vaginoplasty require some long-term maintenance of volume (depth and width). Vaginal dilation, using medical graduated dilators, dildos, or suitable substitutes, is highly recommended to maintain the vaginal volume. It is very important to note that sexual intercourse is not always an adequate method and substitute for dilation.

Reconstruction of female genitalia in male transsexuals generally presents a safe and reasonable choice with acceptable complications and satisfactory results. When patients remain sexually active, vaginal intercourse without discomfort is possible. Although a consensus on the ideal method of vaginoplasty may never be reached, efforts should be made on selecting the optimal method of long-term follow-up for these patients. Psychological and psychosocial recovery should definitely be considered in evaluating their quality of life. Only through continuous improvement of previous techniques can we continue our quest to evolve new and better techniques [13–15].

Female-to-Male Gender Confirmation Surgery

The current management of female-to-male gender confirmation surgery is based on the advances in neophalloplasty, perioperative care, and the knowledge of the female genital anatomy, as well as the changes that occur to this anatomy with preoperative hormonal changes in transgender population. Reconstruction of the neophallus is one of the most difficult elements in surgical treatment of female transsexuals. Despite the variety of available surgical techniques, their results are not equally acceptable to all patients. The preference for a particular surgical technique mostly depends on the patient's desires and expectations. Nevertheless, the surgeon's duty is to fully inform the patient about all advantages and disadvantages, as well as all complications that might occur after the surgical procedure – and even to talk them out of a desired surgical technique if there are contraindications.

Metoidioplasty is a technically demanding surgical procedure used in female-to-male transsexuals who desire a gender reassignment surgery without undergoing a complex, multi-staged surgical creation of an adult-sized phallus. Metoidioplasty is viable in cases where the clitoris seems large enough after androgen hormonal treatment. Since the clitoris plays the main role in female sexual satisfaction, its impact on the outcome of female-to-male transgender surgery is predictable [16–18].

Various free flaps have been reported for total phalloplasty, such as radial forearm flap, latissimus dorsi flap, anterolateral tight flap, different abdominal wall flaps, free deltoid flap, scapular free flap, sensate osteocutaneous free fibula flap, tensor fasciae latae, deep epigastric artery perforator flap, and dorsalis pedis flap [19–21]. The fact that there are so many techniques for penile reconstruction in cases of penis absence proves that none of the abovementioned techniques succeeded in achieving the goals of an ideal penis reconstruction. We will emphasize the most commonly used surgical techniques in genital confirmation in FTM transsexuals with reference to respective eligibility criteria for each procedure.

Finally, reconstruction of the neophallus in FTM patients is a great challenge because no optimal replacements are available to recapitulate erectile, fascial, or urethral tissue. Desired outcomes of metoidioplasty include voiding in the standing position, creation of an aesthetically pleasing phallus, and preservation of clitoral sensation. Additional goals of total phalloplasty include development of erogenous and tactile phallus sensation, minimization of donor-site morbidity, and the ability to engage in penetrative sexual intercourse.

Metoidioplasty

Metoidioplasty is one of the most popular surgical techniques for creating neophallus in female transsexuals. The main goal of metoidioplasty is to give the patient "male-looking genitalia" and the possibility to void in standing position. In the first procedure described, the hormonally enlarged clitoris was used to create a small neophallus. The scrotum was created from the labia majora with insertion of two testicular prostheses. As the urethral plate remained intact, the neophallus was usually small and curved. Later modifications were based on urethral lengthening. New urethra was created from the urethral plate and a labia minora skin flap. The urethral plate was divided at the level of the urethral opening. Since the dissection was in the proximal-to-distal direction, there was a risk of compromising the vascularization of the mobilized plate. This type of dissection resulted in a high complication rate [22]. Recently, Belgrade center reported their original technique of neophalloplasty/metoidioplasty, based on the repair of most severe forms of hypospadias with the goal to improve the results of urethral reconstruction and minimize complication rate in one-stage repair. This work later resulted in many modifications of this original technique, aimed at changing the feminine appearance of the external genitalia to a more masculine morphology and at allowing voiding while standing. The novel technique is based on the similarity in penile and clitoral anatomy, and the statement first introduced by Williams states that the clitoris is thus in many details a small version of the penis, but that it differs basically in being entirely separate from the urethra [23–25].

This one-stage procedure includes the removal of internal female genitalia, comprising hysterectomy, adnexectomy, and vaginectomy, the creation of a neophallus from the clitoris, and the reconstruction of the urethra and scrotum. The approach is based on great experience in the treatment of severe hypospadias associated with penoscrotal transposition [26].

Clitoral dissection starts with a circular incision beneath the glans, at the border between the inner and outer layer of the clitoral prepuce, and continues around the urethral plate and native urethral orifice. Clitoral degloving continues with the division of the fundiform and suspensory clitoral ligaments including detachment from the pubic bones (Fig. 21.3a). Additional lengthening and straightening are achieved by dissection of the short urethral plate positioned ventrally between glans and female urethral opening. Dissection should be performed carefully to prevent injury of the spongiosal tissue around the urethral plate and extreme bleeding. It includes the mobilization of the bulbar muscles that will be used for the upcoming urethral reconstruction. Since the urethral plate is short and causes ventral chordee, it has to be divided. All of these maneuvers enable a complete straightening and lengthening of the clitoris.

Urethral reconstruction presents the most difficult procedure in metoidioplasty. Reconstruction of the neourethra begins with the reconstruction of its bulbar part. One of the main advantages of the novel technique lies in the simultaneous removal of the vaginal mucosa and use of the periurethral vaginal tissue for the reconstruction of the bulbar urethra. As the urinary stream is the strongest at this location, this site presents with a high risk of fistula formation in the postoperative period. Joining the two bulbar muscles over the lengthened urethra and additional covering with surrounding tissue can successfully prevent fistula formation. Further urethral reconstruction is based on the formation of a new urethral plate. Buccal mucosa graft presents a gold standard in

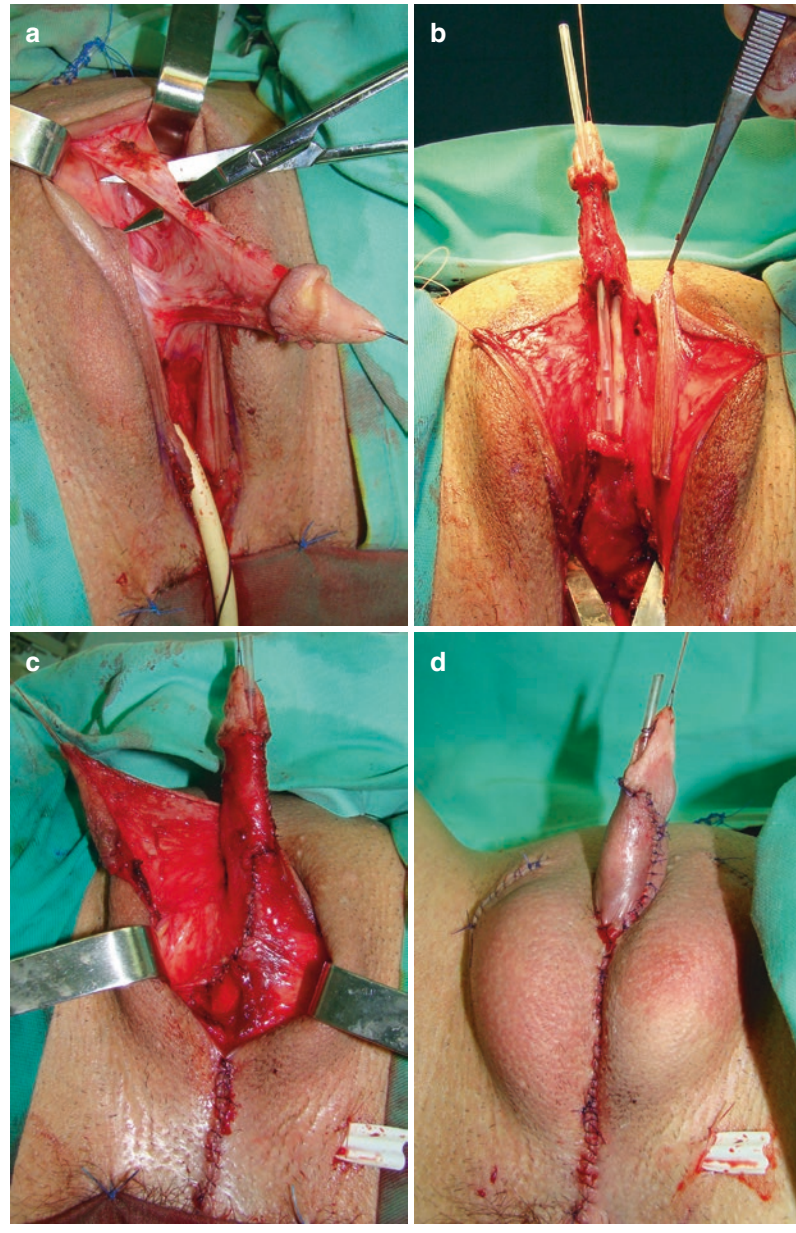

Fig. 21.3
Metoidioplasty. (**a**) Clitoral lengthening by division of all clitoral ligaments; (**b**) urethral lengthening with buccal mucosa graft and left labial skin flap; (**c**) long neourethra is completely covered by surrounding vascularized subcutaneous tissue; and (**d**) appearance at the end of procedure. Neophallus is created from enlarged clitoris. Scrotum with testicular implants lies above the neophallus in proper position

urethral reconstruction in the recent decades. The graft is tough, elastic, easy to harvest, easy to handle, and leaves no visible scar at the donor site. The size of the graft depends on the size of the defect between the newly created bulbar urethra and the glans. The graft is placed as a dorsal inlay on corporal bodies and quilted, enabling better graft survival. Additionally, a well-vascularized recipient site provides a good blood supply and prevents contractions of the graft. Urethral reconstruction can be accomplished by using either a longitudinal dorsal clitoral skin flap button-holed ventrally or a flap harvested from the inner surface of the labia minora. Recent studies confirmed smaller complication rate using such a labial flap combined with buccal mucosa graft [25] (Fig. 21.3b, c).

Scrotoplasty is performed by joining both labia majora in the midline and inserting two silicone testicle implants of appropriate volume.

Considering that this technique uses a large portion of clitoral skin, the remaining labia minora is always available for covering of the lengthened neophallus. Reconstruction of the skin with well-defined penoscrotal angle offers a real masculine appearance of the external genitalia (Fig. 21.3d). Postoperative use of the vacuum device is advised to prevent retraction of the neophallus, for a period of at least 6 months, combined with a phosphodiesterase type-5 inhibitor treatment.

One-stage metoidioplasty has been recognized as a method of choice for genital confirming surgery in FTM transsexuals who wish to have a male-like appearance of their genitals, without undergoing complex and multistage procedures. The main disadvantage of metoidioplasty is that the created neophallus is mostly inadequate in length to allow vaginal penetration, and all patients should be informed of this fact prior to surgery. However, this does not present a limitation for further total phalloplasty.

Phalloplasty

Phalloplasty, in female-to-male transsexual patients, still presents one of the most difficult surgical procedures in genital reconstructive surgery. Moreover, the procedure poses considerable challenges for all surgeons performing gender confirmation surgery due to the particular psychological implications and patients' demands. Phallic reconstruction should ideally create an aesthetically pleasing phallus with sufficient length for vaginal penetration, which has tactile and erogenous sensibility and enables voiding in standing position and with acceptable donor-site morbidity.

Since total penile reconstruction was first reported, there have been constant endeavors to develop an ideal technique for phalloplasty that can fulfill all the desired objectives. In the past, many authors described their experience with variants of local flaps, generally based on the inferior epigastric vessels, but during the 1980s, different microsurgical free flaps became very popular and entered into common use for female-to-male confirmation surgery [19–21, 27–29]. Despite the fact that various phalloplasty techniques were described in recent decades using pedicle or free transfer flaps, the most commonly used flaps in FTM transsexuals are radial free forearm and free musculocutaneous latissimus dorsi flap that will be discussed in detail.

Forearm phalloplasty involves the construction of a neophallus from forearm tissue and its attachment in the appropriate position to approximate a male penis. The neophallus is generally formed from tissue taken from the inner forearm skin (on the patient's nondominant side) as well as vaginal tissue to form the neourethra. The use of the radial forearm free flap is well described by a great number of different authors in genital reconstructive surgery [19, 20]. This flap is supplied by the radial artery and by the paired vena comitantes. Sensation of the flap is based on medial or lateral antebrachial cutaneous nerves. The skin is thin, pliable, and usually hairless, while the vascular pedicle may be up to 18 cm in length, and the vessel diameters are usually large (2–4 mm).

Recently, the most popular approach is "tube within a tube" phalloplasty. Part of the flap along the ulnar border of the forearm, free of hair, is tubed inward around a Foley catheter, creating the neourethra. The remaining part of the flap is wrapped around the neourethra, creating a tube. The pedicle, which consists of radial artery, venae comitantes, lateral cutaneous nerve, and cephalic vein, is dissected carefully and left attached, while a second surgical team prepares the recipient groin vessels. Once the recipient site is ready, the radial artery flap is transferred to the groin. Vascular anastomosis of the radial artery end-to-side with the femoral artery and that of the cephalic vein end-to-end with the long saphenous vein are performed. The lateral cutaneous nerve of the forearm is joined to the ilio-ingunal nerve. The neourethra is anastomosed to the advanced female urethra. The clitoris remains undisturbed at the base of the new phallus, retaining its sensation [20, 29].

Advantages of this procedure include the creation of a sensate neophallus with complete urethral lengthening at the same stage. Consistent arterial anatomy and long vascular pedicle with

good diameter of the vessels enable easier microsurgical anastomoses. Disadvantages of this technique include the small size and circumference of the neophallus, as well as visible donor site scar. Additionally, smaller volume of the neophallus presents a limitation for insertion of two cylinders of the penile prostheses (Fig. 21.4a, b).

The musculocutaneous latissimus dorsi flap has a reliable and suitable anatomy (good size, volume, and length of neurovascular pedicle) to meet the aesthetic and functional requirements of phallic reconstruction [21]. The Belgrade Center has published first results with this technique in phallic reconstruction in boys with epispadias, micropenis, and intersex disorders [30]. In gender confirmation surgery, the technique includes the removal of internal female genitalia such as hysterectomy, adnexectomy, and vaginectomy, followed by the creation of a neophallus from the latissimus dorsi musculocutaneous flap, fixation at the pubic region, anastomosis with the blood vessels at the recipient site, and scrotoplasty. Additional stages include neophallic urethral lengthening and penile prosthesis implantation and can be performed several months after the first stage. Preoperatively, the donor, nondominant, site region needs to be treated by a professional massage which will improve skin elasticity and thus enable direct closure of the donor site after harvesting of the flap. The massage is performed continuously for at least 3 months before the surgery [21, 30–32].

Clitoral lengthening and repositioning is performed in the same way as previously described for metoidioplasty. Urethral reconstruction begins with the reconstruction of the bulbar part of the urethra. Remaining part of the anterior vaginal wall is anastomosed with the remaining urethral plate, forming the bulbar part of the urethra. Further urethral reconstruction includes using all available genital tissue, both labia minora, and hairless clitoral skin. The inner surface of both labia minora is dissected to create a flap with appropriate dimensions without detachment from the outer labial surface. Flaps are joined to create a tube and to lengthen the urethra from its bulbar part. The urethra is lengthened further using available clitoral skin. Both varieties of flaps, clitoral and labial, have fine supportive tissue that prevents fistula formation. Vaginal space is approximated and perineum is fashioned to resemble the male perineum. Both labia majora are joined in the midline over the neourethra creating the one-sac scrotum. Silicone testicle prostheses are inserted in the newly formed scrotum, completing scrotoplasty (Fig. 21.5a).

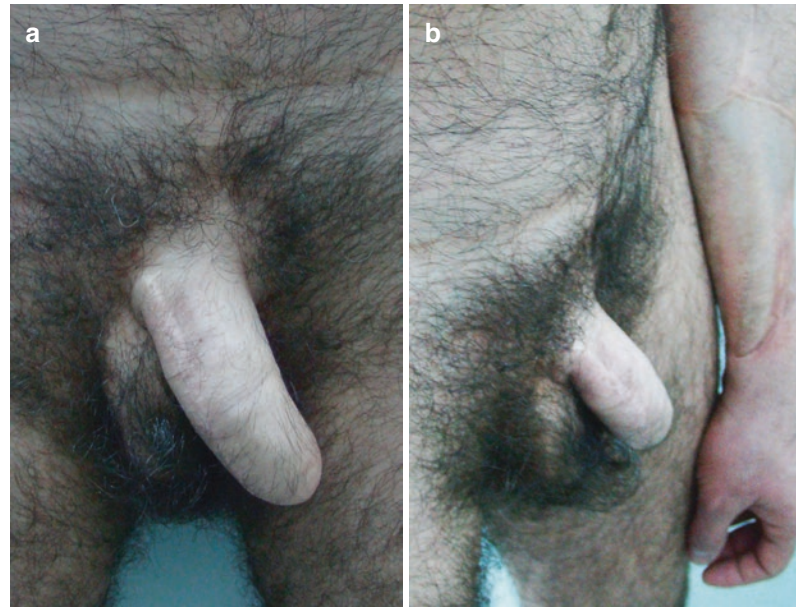

Fig. 21.4 Total phalloplasty – radial forearm free flap procedure; (**a**) appearance after radial forearm flap phalloplasty, (**b**) huge scar formations on the left arm in comparison with modest phallic size and volume

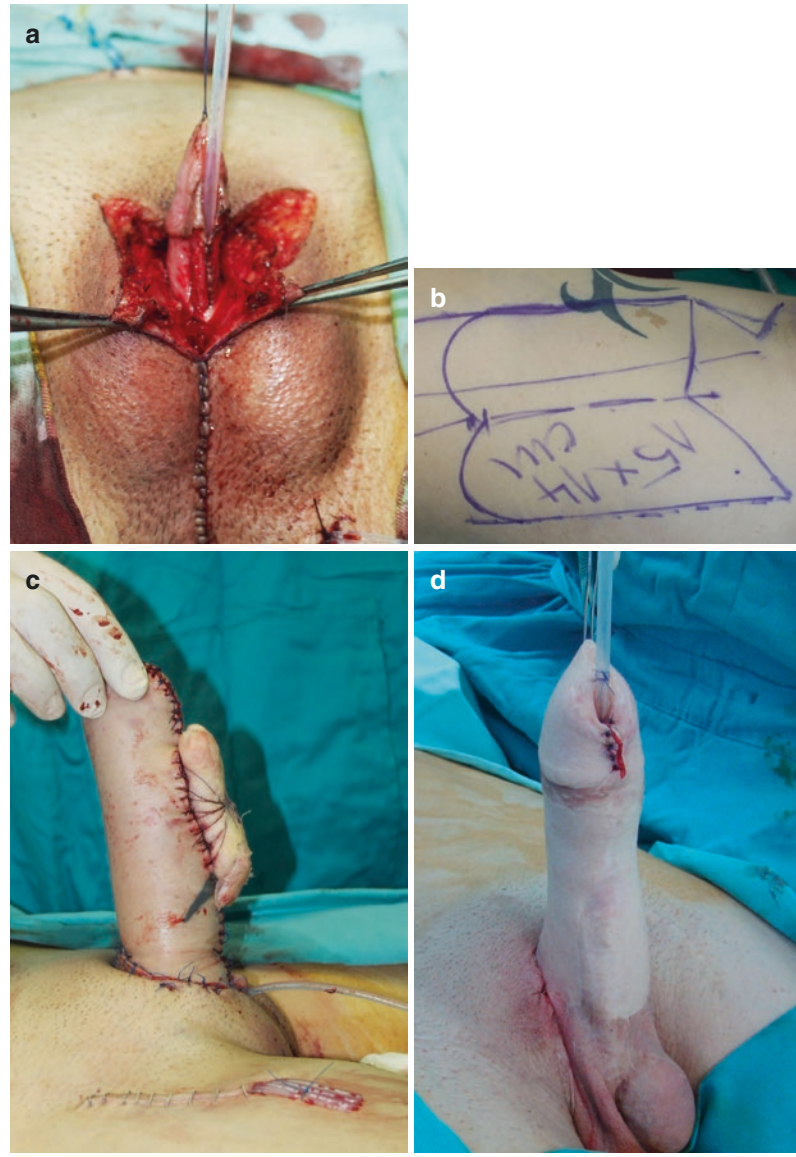

Fig. 21.5 Total phalloplasty – musculocutaneous latissimus dorsi flap. (**a**) Vascularized genital flaps, created from both labia minora and clitoral skin, are used for urethral lengthening. Scrotum with testicular implants is created; (**b**) design of the musculocutaneous latissimus dorsi flap with appropriate dimensions; (**c**) appearance at the end of surgery. A good-sized neophallus is created; and (**d**) final outcome after insertion of inflatable penile prosthesis

The patient is placed in the lateral position for harvesting the latissimus dorsi musculocutaneous flap from the nondominant side (Fig. 21.5b). Flap elevation starts with an incision of the anterior skin margin down to the deep fascia, and the plane is developed between the latissimus and anterior serratus muscle, using sharp and blunt dissection. The flap is divided inferiorly and medially, cauterizing the large posterior perforators of the intercostal vessels, and then lifted to expose the neurovascular pedicle. The pedicle, surrounded by fatty tissue, is identified and dissected proximally up to the axillary vessels. The flap is completely elevated except for the neurovascular bundle, which is not transected until the recipient vessels and nerve have been prepared for micro-anastomosis. Latissimus muscle is fixed at several points to the edges of the skin to prevent layer separation during further dissection. The flap is tubularized creating the neophallus and closed distally to form the glandial part. Entirely constructed neophallus is detached from the axillary region after clamping and dividing the subscapular artery, vein, and thoracodorsal

nerve at their origin, in order to achieve maximal pedicle length. The donor site is approximated and closed directly after adjacent undermining. In case of significant tension, presented skin defect is covered by split thickness skin grafts.

After identifying all neurovascular structures at the recipient site, the thoracodorsal vessels and nerve are divided, the neophallus is transferred to the pelvic region, and a microsurgical vascular anastomosis is performed immediately. The neophallic base is fixed to the skin at the recipient site (Fig. 21.5c).

Further stages include urethral lengthening and insertion of penile prosthesis. Staged urethral reconstruction, i.e., neophallic urethroplasty, is performed by using buccal mucosa grafts. The grafts are placed and quilted on the ventral side of the neophallus starting from the advanced urethral meatus to the tip of the glans. Three or more months later, newly created urethral plate is tubularized to form the distal part of the new urethra. Two types of penile prostheses, semirigid or inflatable, can be inserted into the neophallus, enabling penetrative sexual intercourse. A semilunar incision is made at the dorsal side of the neophallus. Hegar dilators are used to create space for the prosthesis to be inserted. The prosthesis is covered with vascular grafts imitating tunica albuginea to prevent protrusion through the glans. Additional fixation to the periostium of the inferior pubic rami is also recommended (Fig. 21.5d).

Finally, metoidioplasty or phalloplasty - that is the question for transmen. The choice lies in satisfying the patient's desires and understanding their needs. Transgender surgeon plays a very important role in explaining the pros and cons of each procedure, considering each individual as unique case and presenting the best surgical option.

Gender Confirming Surgery and Bioethics

Treatment of gender dysphoria always raised numerous and different bioethical issues, and with rapid acknowledgment and recent achievements, new complex issues in medical management have emerged. The most prominent challenges and ethical questions pertain to the treatment of underage individuals, fertility after gender confirmation surgery, and possibility of later regret [33]. Main ethical principles are autonomy, beneficence, nonmaleficence, and informed consent. The individual must have autonomy of thought and intention when making decisions about their medical treatment. This is an especially sensitive field in the treatment of gender dysphoria, because sometimes the individual's desires, hopes, and expectations might not correlate with reality. Experts must be very straightforward regarding specific possibilities, risks, and benefits of medical treatment, especially considering that the last step in medical transition, genital confirming surgery, is irreversible. Beneficence implies doing only good, only what is in the patient's best interest. However, some may consider that mutilation of healthy organs, in case of surgery, is not in line with this principle. Nonmaleficence must ensure that the treatment does not harm the individual, either in an emotional, social, or physical sense. Always keeping these principles in mind, WPATH Standards of Care and criteria for diagnosis might not be enough to be certain that we are doing the right thing. Although it may seem that an individual fulfills all these criteria on paper, sometimes, we can observe their personal disadvantages, youth, impairment, or desperation. It seems that even with the reassurance and recommendation from a mental health professional, ethical unease cannot be entirely erased because treatment guidelines have preceded the answers to vitally relevant questions [34, 35].

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