



Slings for Urinary and Fecal Incontinence

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5.1 Slings for Urinary Incontinence

5.1.1 AdVance: AdVance XP

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

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

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

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

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

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

Fig. 5.1 Perineal incision

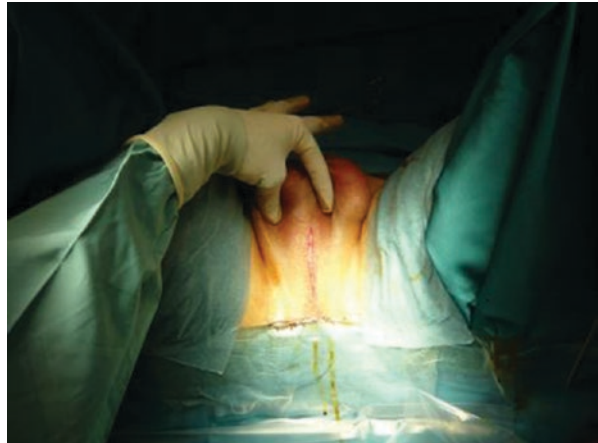


Fig. 5.2 Preparation of the tendon center for the positioning of the sling

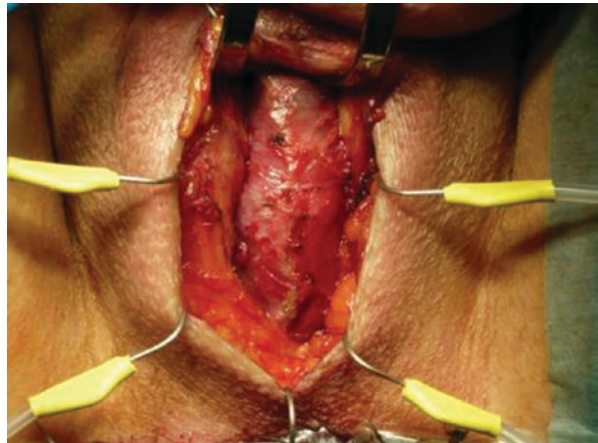


Fig. 5.3 Passage with the helical needles



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

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

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

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

Fig. 5.4 Passage with the helical needles



Fig. 5.5 Passage with the helical needles

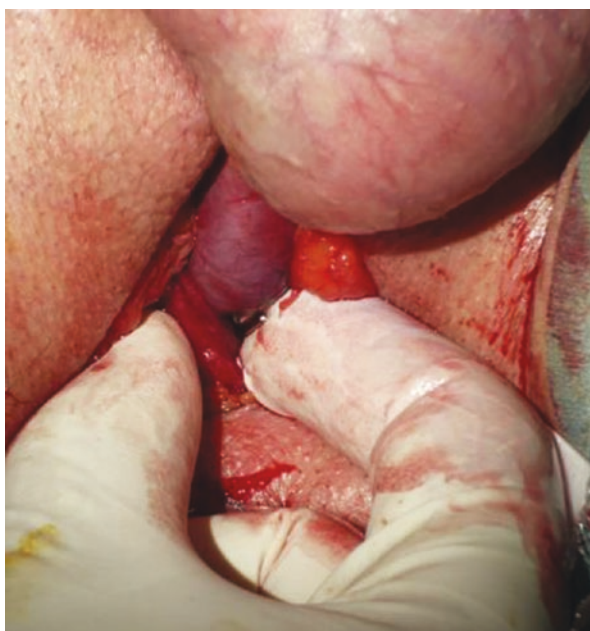
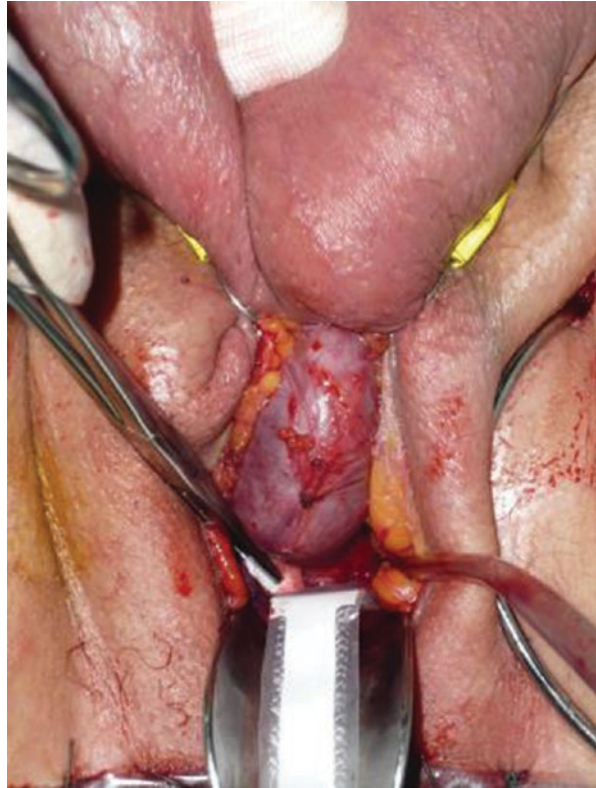


Fig. 5.6 Passage with the helical needles



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

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

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

Fig. 5.7 Positioning of the sling

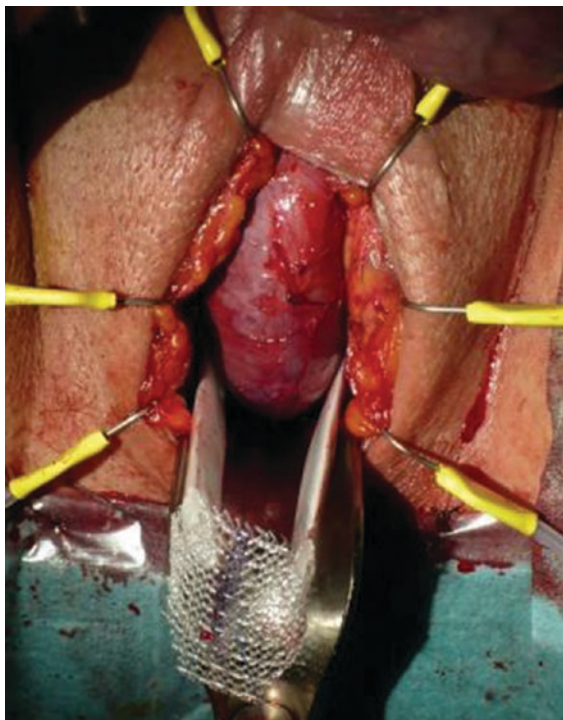


Fig. 5.8 Fixation of the sling to spongy bulb in the medial raphe

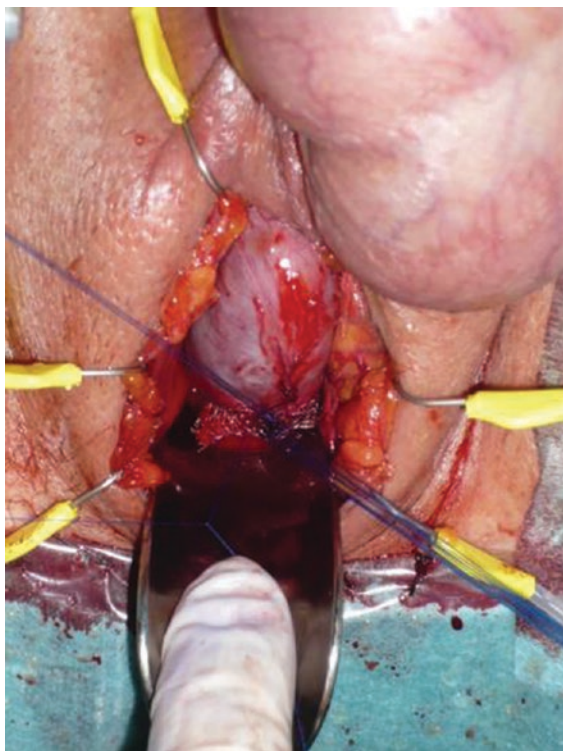


Fig. 5.9 Restoration of continence by rotation of the spongy bulb



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

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

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

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

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

5.1.2 I-Stop TOMS

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

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



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



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



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

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

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

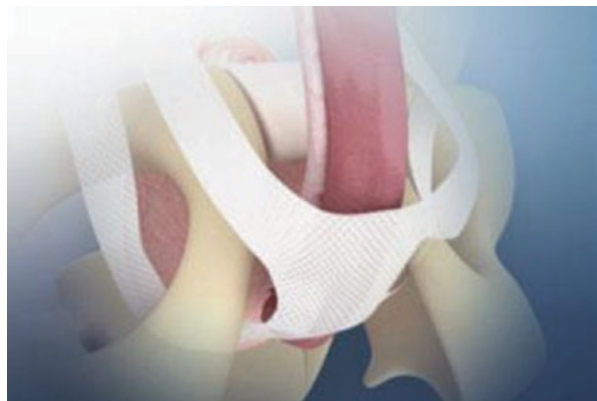
5.1.3 Virtue

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

Fig. 5.13 The sling with the four arms



Fig. 5.14 Reconstruction of sling placement



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

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

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

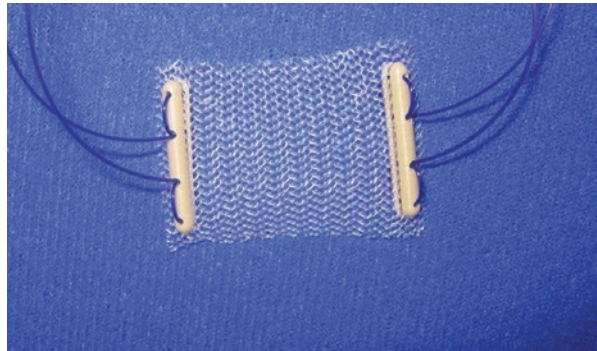
5.1.4 Remeex System

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

Fig. 5.15 The transfer of threads into varitensor



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



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

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

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

Fig. 5.17 Passage of Stamey needle through the retropubic space



Fig. 5.18 Contact of mesh with bulbocavernosus muscle without tension



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

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

Fig. 5.19 Placement of varitensor



Fig. 5.20 Protrusion of external manipulator



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

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

5.1.5 ATOMS

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

Fig. 5.21 Components of the atoms system

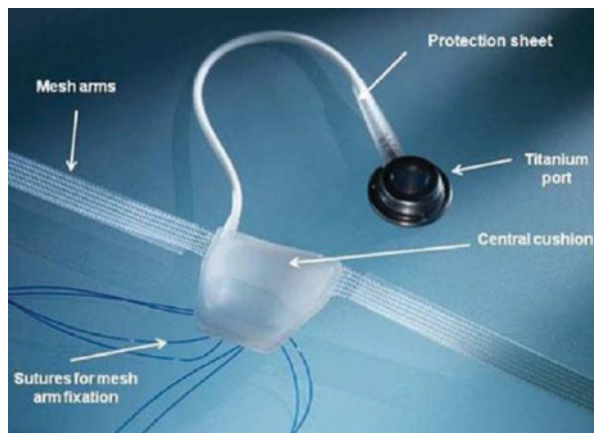
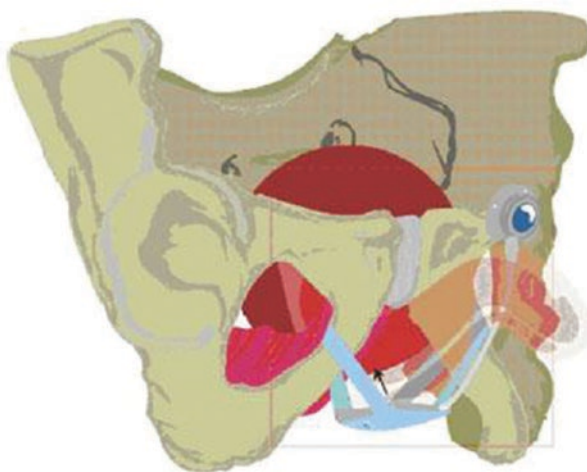


Fig. 5.22 Reconstruction of ATOMS placement



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

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

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

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

5.1.6 Argus and Argus-T

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



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

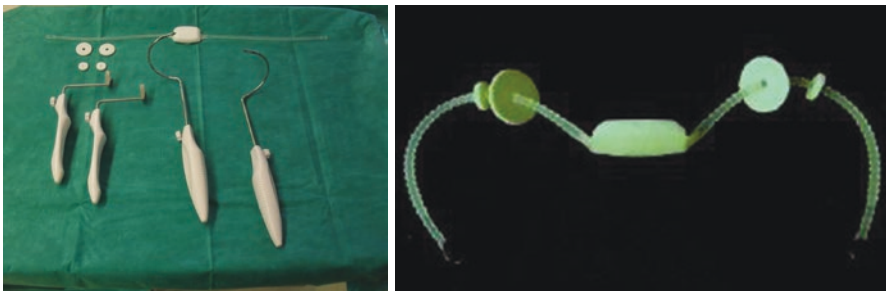
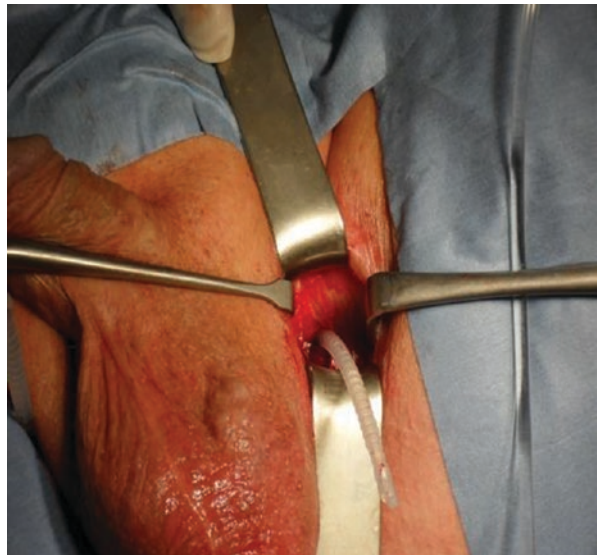


Fig. 5.24 ARGUS-T device composition kit and direction of columns after implantation

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



Fig. 5.26 Placement of column laterally

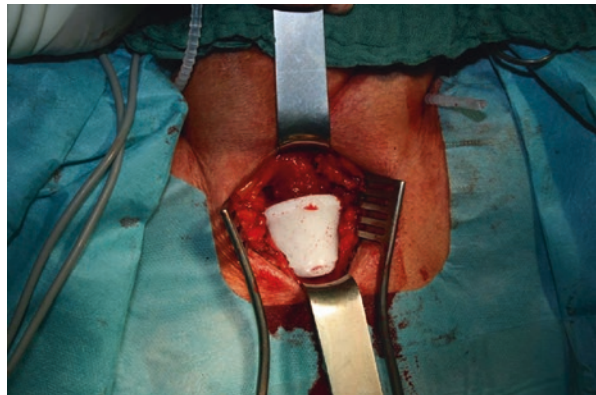


suprapubic incision of 7 cm is made and rectus fascia is exposed bilaterally to accommodate placement of the silicone rings. Guided by the operator's index finger, a 90° crochet needle was carefully introduced, perforating the perineal membrane in the space between the bulbar urethra and the ischiopubic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

removed and cystoscopy is performed to exclude bladder perforation. At this point the two silicone rings are placed over the coned columns and positioned on the rectus fascia to regulate sling tension. The tension was adjusted to achieve a retrograde leak point pressure of 40 cm H₂O. Sling tension is judged to be correct if cystoscopy showed coaptation of the bulbar urethra. The silicone columns were then positioned crosswise deep to the suprapubic subcutaneous fat and both wounds were closed in layers. The Foley catheter is reinserted at the end of the procedure and removed 24 h postoperatively. Instead with regards to the transobturator approach (ARGUS-T) a 6 cm median perineal incision is executed and the tissues are dissected until the exposure of the bulbocavernosus muscle. The muscle is left in situ and the urethra is not mobilized from the central tendon (Fig. 5.25). In order to access the obturator foramen, the lateral borders of the muscle are dissected free until the perineal aponeurosis are identified bilaterally so it can be detached to the muscle fibers. A bilateral small incision below the insertion of the adductor magnus muscle is executed in correspondence of the inguinal fold. A transverse suprapubic incision until the exposure of the muscle rectus fascia is then made. The helical needle is introduced bilaterally with a movement “out-in” from the lateral entries until the perineal one. During this procedure the surgeon had to perforate the obturator aponeurosis so, with an opposite movement, it is possible to allocate the columns laterally (Fig. 5.26) and the cushion on the ventral surface of the bulbar urethra (Fig. 5.27). Then the washers are introduced on the end of the columns bilaterally so the surgeon can adjust the tension of the sling.

At this point it is performed a cystoscopy to control and to correct the tension. The adjustment is carried out until a RLPP (retrograde leak point pressure) of 30–40 cm H₂O is obtained. This procedure can also identify any urethral trauma related to the needle crossing. When the tension of the sling is achieved the cushion is fixed to the bulbocavernosus muscle. Finally, the end of the columns are positioned crosswise deep the suprapubic subcutaneous fat and both wounds are closed in layers. The Foley catheter is repositioned at the end and it is left in pace for 24–48 h. Finally, an important characteristic of both devices is represented by the possibility to perform a revision procedure in spinal anesthesia to improve

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



continence. In this way suprapubic and inguinal incisions are opened and the sling tightened by pulling the coned columns through the washers over 1 or 2 cones bilaterally. Cystoscopy was performed as previously described. During the retrograde urethromanometry we aimed for an optimal retrograde leak point pressure (between 40 and 50 cm H₂O), generally 10 cm H₂O higher than the previous condition.

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

Interdisciplinary Comment

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

5.2 Slings for Fecal Incontinence

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

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

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

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

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

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

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

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

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

Interdisciplinary Comment

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

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