

# Male incontinence and trans-obturator approach: where we are

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**Abstract:** Surgery is the mainstay for treating postprostatectomy stress urinary incontinence. Although the artificial urinary sphincter (AUS) remains a gold standard treatment option, a decade worth of innovations have expanded the role of male sling surgery. The sling appears to have a low risk of infection, erosion, and urethral atrophy. Recent changes in male sling surgery may improve efficacy in men with moderate or mild incontinence. Transobturator slings are currently promoted for the treatment of stress urinary incontinence (SUI) after radical prostatectomy (RP), but data on the outcome remain still limited.

**Key words:** Male; Suburethral sling; Postoperative male incontinence; Transobturator male sling.

## INTRODUCTION

Although surgical techniques for radical prostatectomy have been refined significantly during the last 20 years, a significant number of patients still suffer from persisting post-prostatectomy stress urinary incontinence.<sup>1,2</sup> Post-prostatectomy urinary incontinence is a disorder that often has an important impact on the quality of life of those who suffer from it. The artificial urinary sphincter has become the gold standard for the treatment of this disorder but it is expensive and associated with mechanical failure. Despite the success of the artificial urinary sphincter there has been a renewed interest in male slings.

Current male sling devices are based on the early concepts described by Berry,<sup>3</sup> Kaufman,<sup>4</sup> and Kishev<sup>5</sup> in the 1960s early 1970s. Most notable were Kaufman procedures which included a crural crossover<sup>6</sup> and then modified to use a synthetic mesh tape that brings crural together in midline<sup>4</sup> by a silicone gel device attached to the corpora cavernosa that compresses the ventral urethra. Based on the Kaufman principles, Clemens<sup>7</sup> reported a bulbourethral sling procedure in 64 men with severe PPI with a series of tetrafluoroethylene bolsters placed beneath the bulbar urethra, through which a suture is passed and then transferred suprapubically using Stamey needle lateral to the urethra and bladder neck, in this way providing the compression of the bulbar urethra. At a mean follow-up of 18 months, 56% of patients became dry and 8% improved significantly. However, despite the encouraging results, sling revision was required in 21% of patients and bolster removal was necessary secondary to infection in 6%. Moreover, 52% of patients had perineal numbness or pain with 26% rating this problem as moderate or severe. This discomfort is most likely due to the high pressure entrapment of pudendal nerve branches during blind suprapubic suture or passage.

Therefore, in order to avoid discomfort, some special sling systems have been realized to make this surgical approach procedure even less invasive and safer.

All currently marketed slings for a minimally invasive treatment of male incontinence induce compression or suspension of the bulbar urethra as recently described by Gozzi and co-workers.<sup>8</sup> At present a long term follow-up of these procedures is lacking even if EAU guidelines assign a Grade of recommendation C with level of evidence 3.<sup>1</sup>

In this overview we report the results of transobturator non-adjustable and readjustable sling systems through a review of the literature using MEDLINE and PubMed database for original articles published using the terms "postoperative male incontinence, transobturator male sling and male sling from 2002 to 2011. Most relevant current publications and data were evaluated.

## METHODS

### Non-adjustable slings

#### a) *Outside in*

#### AdVance

Different compressive sling systems were evaluated for many years and Advance is the first sling with a functional therapeutic approach. This new sling merely repositioned the lax and descended supporting structures of the sphincter to the former preoperative position.<sup>8</sup> The retrourethral transobturator sling offers a noncompressive functional therapeutic approach. It exerts its function on the membranous urethra by fixing it into the normal anatomic position, thus allowing the function of the sphincter and has been shown to be not efficacious in patients with intrinsic sphincter deficiency.<sup>8</sup> The urodynamic studies show an increase of the membranous urethral length and an improvement of the urethral closure pressure without obstruction.<sup>8</sup>

#### *The surgical procedure*

The AdVance system is an outside-in trans-obturator sling. A midline perineal incision is made, exposing the bulbospongiosus muscle, which is then split centrally and retracted laterally. The dissection is extended to the perineal body. After exposure of the urethral bulb, blunt-finger dissection is used to identify the space between the corpora cavernosa laterally and the corpus spongiosum medially. A small skin incision is made in the leg fold on the lateral side of the scrotum, 1 cm below and lateral to the insertion of the adductor longus tendon at the medial border of the obturator foramen. The index finger of the surgeon is then placed between the urethral bulb medially and the proximal corpus cavernosum laterally, just inside the bulbospongiosus muscle. The helical curved introducer needle is placed over the skin incision and mild force is used to perforate the subcutaneous tissue and obturator fascia, maintaining a constant axis of rotation at 45°. The needle is passed towards the tip of the finger and the tape is then positioned through both obturator fossae. With 2 absorbable sutures the middle part of the polypropylene tape is then fixed distally onto the bulb and proximally onto the perineal body. The tape is then pulled at both ends to its final position, and the ends are cut at skin level.<sup>8-10</sup>

#### *Outcomes*

Short-term results of this technique have shown to be effective in 70% of patients as reported in Tab.1 at median follow-up of 29 months.

The first results were reported by Rehder and confirmed by Gozzi, who showed cure and improvement rates of 52% and 38% respectively with low morbidity after 6 months

follow-up.<sup>8,12</sup> These results were confirmed in a large prospective single-armed study by Bauer<sup>13</sup> who reported a cure rate of 51.4% (defined as 0 pads or security pad), an improved rate of 25.7% and a failure rate of 22.9% in 70 men followed for 12 months. Improvement was defined as one or two wet pads a day or a reduction in pad use by 50%. HRQL measures were significantly improved at 6 months, but these improvements were not sustained at 12 months. There was no difference in outcome according to severity of preoperative post-prostatectomy urinary incontinence (PPUI). Men with severe PPUI fared as well as those with milder forms, although this definition is based on pad usage rather than urodynamic data, which were not included in the study.

Cornel<sup>14</sup> reported efficacy of the AdVance sling in 36 men with PPUI, with unimpressive results: the cure rate (0 pad use and <20 g urine loss/day) was only 9% at 12 months, with improvement in 45.5%. There was no effect on cure of PPUI in 36.5% of men.

Gill in a retrospective chart review and phone interview of 35 men treated with placement of the AdVance sling<sup>15</sup> showed satisfactory results, although there are obvious study limitations. The success rate was 51.4% while the objective success, defined as cure or improvement (0 pads or 1-2 pads/day), occurred in 60% of men. The mean pad use was significantly decreased, from 3.7 to 1.4 pads/day, with a pad-free rate of 28.5% at 9 months.

In a prospective evaluation conducted by Cornu on 136 patients with a median follow-up of 21 months, an overall success rate of 62% is reported.<sup>16</sup>

The urodynamic changes observed by Davies in 13 patients after AdVance sling surgery with a show a significant improvement in the 24-h pad test (779.3 vs 67.6 g) at 6 months.<sup>17</sup>

In most series, urinary retention is rare, and usually transient. Cornel<sup>14</sup> had one of 36 men with transient retention, while Gill<sup>18</sup> had three men with retention and two who needed to catheterize for 3 and 6 months. By contrast, Bauer,<sup>19</sup> in a paper specifically examining complications of AdVance sling surgery, reported a postoperative retention rate of 21.3%. All but one man had returned to normal voiding at 3 months. This study of 230 men described also a need to remove the sling in 0.9% and one case requiring sling division due to obstruction. In the Cornel<sup>14</sup> study, 17% of men had severe postoperative pain that settled at 3 months, but otherwise pain is rarely reported. Recently Hanhan<sup>20</sup> and Rehder<sup>21</sup> reported interesting results at 2 and 3 year follow-up respectively. In particular Hahan showed a success of 53.6% in 66 patients concluding that the majority of them reported an improvement in post-prostatectomy incontinence but with a decrease of the benefit with time. However these results were not confirmed by Rehder in a multicentric study describing a success of 76.6% at 12 months that was maintained at 3 year at 75.7%. This trend reported by Rehder was also described by Bauer with a success rate of 75.4% in 137 patients at median follow-up of 27 months.<sup>22</sup>

### Trans-obturator slings (TOMS)

In 2006 Grise developed a new transobturator bulbar male sling<sup>23</sup> that works by compressing the urethra in a more distally position than AdVance sling.

#### The surgical procedure

The surgical technique was performed under spinal or general anesthesia, the patients were placed in the lithotomy position and a 6 cm median vertical perineal incision below the inferior border of the pubic symphysis was carried out in order to expose the bulbospongiosus muscle, then to expose

TABLE 1. – Outcomes of AdVance trans-obturator sling systems.

Author	N° of Patients	Mean follow-up	Cure,	improved
Bauer et al. (2009)	70	12	51.4%	25.7%
Cornu et al. (2009)	102	13	62.7%	17.6%
Rehder et al. (2009)	20	24,3	65.0%	20.0%
Bauer et al. (2010)	126	27,2	51.6%	23.8%
Rehder et al. (2010)	118	12	73.7%	16.9%
Cornel et al. (2010)	35	12	9.0%	45.5%
Cornu et al. (2010)	136	21	62.0%	16.0%
Gill et al. (2010)	35	2.9	60.0%	-

the perineal aponeurosis at the top of the triangular space delimited laterally by each ischiocavernosus muscle and medial to the bulbospongiosus. A short 2 mm incision through the pelvic fascia afforded access to the obturator muscle just under the ischiopubic ramus bone. A stab incision was 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 was an outside inside with a Hemet needle. The end point of the puncture was the opening in the pelvic fascia. After sling attachment to the needle, it was pulled back in order to correctly implant the sling. The same procedure was repeated on the other side. The sling was sutured to the bulbospongiosus muscle with non-absorbable sutures. The graft was then constructed as a circle around the inferior pubic branch on each side and was self-anchoring with the necessary compression of the urethra.

#### Outcomes

Grise reported at three months and at 12 months follow-up a reduction of pad use in 30% of cases within a concomitant improvement of QoL.<sup>24</sup>

#### b) Inside-out de Leval sling

In 2008 de Leval reported on a new transobturator polypropylene sling,<sup>25</sup> with two arms passed inside out through the obturator foramen, pulled for compressing the urethral bulb, and tied to each other across the midline. Conceptually this approach was designed to minimize the risk of pelvic space penetration and urethra perforation by the trocars and mesh arms, lessen the possibility of urethra erosion by using a large mesh entirely covering the bulbospongiosus muscle and by avoiding fixation of the mesh to the urethra with suture material and sustain sling tension by tying up the mesh arms to prevent mesh slippage.

#### The surgical procedure

A 6-cm sagittal skin incision is made at the median raphe of the perineum ending 2 cm above the anal margin. Transection of the subcutaneous fat and Colles superficial perineal fascia allows access to the bulbospongiosus muscle, which is freed ventrally to the pubic symphysis and dorsally to the central body of the perineum. Further dissection is conducted laterally to expose the ischiocavernosus muscles. Together with the transverse muscles, the bulbospongiosus and ischiocavernosus muscles delineate, on either side of the urethral bulb, a triangular space. The inferior layer of the median perineal aponeurosis, which is located in depth of this space, is carefully dissected. Starting with the right side, the bulbar urethra is reflected on the left side using a retractor, thus providing access to the median perineal plane. Scissors are used to open up the inferior layer of the median perineal aponeurosis in the anterior portion of the triangular space, just lateral to the bulb. The guide is inserted through the scissors-initiated dissection path with a 45° angle rela-

tive to the urethral sagittal plane to come into contact with the upper part of the ischiopubic branch. The guide is introduced further and perforates the right internus obturator muscle and obturator membrane. The distal linear segment of the passer is slipped along the gutter of the guide so as to pass through the obturator membrane.

The tape was then clipped to the extremity of the needle and was pulled out laterally outside the skin. This procedure was then repeated on the other side, and the central part of the mesh was fixed by a resorbable suture to the ventral part of the urethra.

#### Outcomes

In 2008 de Leval showed, at 24 months mean follow-up, cure and improvement rates of 49% and 35%, respectively. The failure rate was of 16%. No sling infection, persistent pain, bladder, urethra, bowel, or nerve complications were encountered.<sup>25</sup> Recently the same author published the midterm results on 173 consecutive patients.<sup>26</sup> After a median follow-up of 24 months 49% were cured, 35% improved and 16% not improved. The QoL was enhanced and 72% of patients were moderately to completely satisfied with the procedure.

#### Adjustable slings

##### ArgusT

ArgusT is readjustable suburethral sling devices which permit an effective regulation of the sling tension not only during surgery but also in the first postoperative days. This possibility of suburethral pressure control should represent the main advantage of this procedure in order to cure incontinence avoiding urinary retention.

The Argus® system is composed of a radiopaque cushioned system with silicone foam for soft bulbar urethral compression, two silicone columns formed by multiple conical elements, which are attached to the pad and allow system readjustment, and two radiopaque silicone washers which allow regulation of the sling tension.

#### The surgical procedure

A 7 cm vertical perineal incision is made in order to open the interbulbar urethral cavernous space until it reaches the inside edge of the ischial pubic branch of the pubic bone, and the helicoid needles are inserted from outside inward. The point of the skin puncture is established at the intersection of a line beginning with the pubic insertion at the adductor muscle, crossing 3 cm below the inguinal plies (this point corresponds to the middle portion of the obturator orifice) where a 3 cm vertical incision is made until it reaches the facial tissue separating the fat tissue. Using the index finger, the crochet tip of the needle is retrieved from behind the ischial pubic bone, where the same finger simultaneously protects the urethra by pushing it to the other side. The pelvic floor is perforated and the cone column snapped into place and spread out bilaterally.

The symmetric adjustment of the washers with the positioner will be controlled by measuring the adjustment retrograde pressure with a water column connected to the Foley catheter, which will be located in the navicular fossa. The objective is to achieve urethral wall coaptation and stop the drip, indicating that a retrograde LPP of 45 cmH<sub>2</sub>O has been achieved.

#### Outcomes

In patients with mild to moderate incontinence, dry rates of up to 70% was achieved after a median follow-up of 6 months in 37 patients.<sup>27</sup> In this study Romano reported a 73% cure rate and 13.5% of improvement. The treatment failed in five patients (13.5%).

#### ATOMS

This sling was developed in 2005<sup>28</sup> and introduced in Europe in 2008 to be implanted for the first time in March 2009. The advantages of this device are the postoperative adjustment without surgical reintervention and the low possibility of dislocation.

The ATOMS system consists of a mesh implant with an integrated adjustable cushion, protection sheet and titanium pot for adjustment of cushion volume. The silicon cushion is located in the middle of the mesh type and filled via the port and catheter intraoperatively and postoperatively. The adjustment is performed by puncturing the port percutaneously and is possible at any time in an outpatient setting to counteract continued incontinence or urinary retention.

#### The surgical procedure

It is performed under spinal or general anesthesia with the patient in lithotomy position. A medial vertical perineal incision is made to exposure the bulbospongiosus muscle. A space is created between the bulbospongiosus and ischiocavernosus muscle. The system is implanted using an outside-in technique whereby the obturator foramen is passed subcutaneously with an helical tunneller. The mesh arms are drawn back to the central part of the cushion and sutured, thereby anchoring the device to the inferior pubic branch like a backpack.

#### Outcomes

At present are available only results in the short-term as reported by Seweryn.<sup>29</sup> At mean follow-up of 16.9 months the overall success rate was 84.2%. Of these cases 60.5% were considered dry and 23.7% improved. In 15.8% of the patients the treatment was considered failed.

#### CONCLUSION

Advances in surgical management of incontinence have led to new alternatives in the management of post-prostatectomy incontinence. It is generally accepted that patients with mild to moderate incontinence are appropriate candidates for a male sling and probably patients with severe incontinence should be treated with AUS although there is not a specific recommendation in this context.

Although there was a lack of prospective randomized studies concerning the different anti-incontinence surgical procedures, the AUS represented the gold standard by which other surgical managements were compared (Grade 2. Level of recommendation B). However, technical problems related to the AUS management are the long-term complications as well as expensiveness.

In this way sling procedures are quicker and less invasive than AUS. In particular the use of a trans-obturator approach seems to be safer and easier than the retropubic approach with a lower incidence of intraoperative complications. At present we have long term results for transobturator sling AdVance only. The use of new trans-obturator sling models is still under clinical investigation and further clinical experience are needed to compare the trans-obturator approach with the retropubic approach.

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