Surgery in Motion

The Inside-Out Trans-Obturator Sling: A Novel Surgical Technique for the Treatment of Male Urinary Incontinence

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Abstract

Objectives: To describe a new sling procedure for treating stress urinary incontinence (SUI) after radical prostatectomy (RP) and prospectively evaluate its short-term safety and efficacy.

Methods: The sling technique uses specific instruments and a polypropylene mesh with two arms that are passed inside to outside through the obturator foramens, pulled for compressing the bulbar urethra upward, and tied to each other across the midline. Patients with detrusor overactivity were excluded. Baseline and follow-up evaluations included uroflowmetry and continence and quality of life (QoL) questionnaires. Cure was defined by no pad use and improvement by a number of pads/d ≥2 and reduced by at least 50%. Complications were recorded.

Results: From April 2006 through February 2007, 20 consecutive patients suffering from post-RP SUI underwent the sling procedure using the same operative protocol. Preoperatively, 3 (15%), 11 (55%), and 6 (25%) patients were using 2, 3–5, and >5 pads/d, respectively. The procedure was preceded by an endoscopic urethrotomy in four patients. No perioperative complication was noted; three patients required suprapubic catheterization. At 6 mo, nine (45%) patients were cured and eight others (40%) were improved (1 pad/d). QoL was significantly enhanced and 80% of patients were moderately to completely satisfied with the procedure. Preoperative and postoperative maximum flow rate and postvoid residual values were not statistically different. No sling infection, urethra erosion, persistent pain, or neurologic complications were observed.

Conclusions: The inside-out trans-obturator sling procedure appears to be safe and efficient at short term. Further studies are warranted to determine long-term outcome.

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1. **Introduction**

Male stress urinary incontinence (SUI) that occurs as a result of sphincter dysfunction after radical prostatectomy (RP) is a devastating adverse event for patients and a frustrating problem for urologists [1]. The incidence of this clinical condition ranges between 3% and 45% [2]. Initial management is usually conservative and includes the use of diapers or pads, penile clamps, or various collecting systems (eg, condom catheter). Mild degrees of SUI in the early postoperative period may be improved by pelvic muscle exercises, physiotherapy, and pharmacotherapy. In many cases, SUI improves considerably within the first 12–18 mo after surgery; surgical treatments are therefore generally not recommended within this time interval. When conservative therapies fail to alleviate SUI, patients are usually offered one of the following surgical alternatives: injections of bulking agents, artificial urinary sphincter (AUS) placement, or sling insertion. Use of urethral or bladder-neck balloon compression devices has also been reported by a few groups [3–5]. Transurethral injections of various bulking materials have been used for decades and are minimally invasive, safe, and well tolerated. Nevertheless, effectiveness is usually temporary, requiring multiple injections, and long-term results have been disappointing so far, with cure rates reaching only 20–40% [6,7].

Pioneered by Foley 50 yr ago [8] and largely developed by Scott in the early 1970s [9], the AUS has culminated in the hydraulic AMS-800 final version commercialized by American Medical Systems. Currently, the AUS remains the gold standard for treatment of incontinence after prostatectomy. Numerous reports with medium- to long-term follow-up of this procedure exist in the literature, with 61–96% success rates as defined by variable criteria [2,10]. The results are generally lower among patients with radiation-induced or -associated incontinence [11]. Despite its attractiveness, the AUS is an expensive mechanical device that can fail and requires manual opening to empty the bladder and therefore the dexterity or mental capacity to use it. In addition, surgical revision or replacement may be required due to mechanical failure, infection, or cuff erosion. The 5-yr reoperation rate ranges between 17% and 57% [2,10,12,13].

Sling procedures are conceptually attractive in that they are inexpensive and not mechanical and allow for physiologic voiding without significant obstruction [11,14]. The use of fixed urethral compression for the treatment of male SUI began in 1961 with Berry who used acrylic prostheses to compress the ventral urethra against the urogenital diaphragm; this was followed by the different sling procedures developed by Kaufman in the 1970s [15]. Since then, various techniques of bulbar urethra compression using synthetic or biologic materials have emerged. Sling devices are usually secured either over the rectus abdominis fascia/muscles after retropubic passage [16] or at each inferior pubic ramus with the use of bone screws to avoid a separate suprapubic incision [17]. Results from clinical series assessing the intermediate- and long-term outcome of sling procedures indicate that success rates may compare favorably with those obtained after placement of an AUS [18,19]. Yet, no randomized studies comparing the results of both procedures are currently available.

In this report, we present the preliminary results of a prospective study of a novel trans-obturator sling for treatment of post-RP SUI.

2. **Patients and methods**

2.1. **Preoperative evaluation**

Since April 2006, men with SUI after RP and who were offered a surgical treatment were candidates for inclusion in this prospective, observational study. All patients had undergone an adequate trial of nonsurgical treatment such as pelvic muscle exercises and physiotherapy without success. The Ethical Committee of the University Hospital of Liège approved the protocol used in this trial. Patients were invited to participate in the trial only if the following inclusion criteria were met: clinical and urodynamic diagnoses of SUI and positive bulbar urethra compression test. Patients with urodynamically proven detrusor overactivity or active urinary infection were excluded from the study. Informed consent was obtained from all patients.

Preoperative evaluation included detailed history, physical examination with a bulbar urethra compression test, urinalysis, multichannel urodynamics, 2-d voiding diary, administration of self-questionnaires assessing urinary continence (questions 1–3 of the urinary section of the UCLA Prostate Cancer Index-Short Form (PCI-SF) questionnaire [20]; Appendix A) and quality of life (QoL; Ditrovie questionnaire [21]), flexible urethrocystoscopy, and urethrocystography. The latter two investigations were systematically performed to evaluate the degree of opening of the bladder-urethra anastomosis, the quality of the urethral mucosa (radiation therapy sequelae), and the length and degree of occlusion of the urethral sphincter, to rule out or confirm the presence of urethral stenosis, and to exclude a bladder tumor or other bladder abnormalities.

The degree of incontinence was arbitrarily categorized as mild (using 1–2 pads/d), moderate (using 3–5 pads/d), or severe (using >5 pads/d), as previously described [22].

2.2. **Surgical procedure**

The surgical procedure used specifically designed instruments allowing, via an inside-out trans-obturator approach,
Fig. 1 – (A) General principle of the inside-out trans-obturator sling procedure. The mesh bears two lateral arms that are initially passed from either side of the urethral bulb through the obturator foramina, then rotated around the inferior pubic rami, and finally pulled and bound to each other across the midline so that the central portion of the mesh exerts an upward bulbar urethra compression. (B) Specific instruments used for the inside-out trans-obturator sling procedure. The passers are pairs of stainless steel instruments that are specific for the left and right sides and comprise a handle, a vertical segment, and a flat curved segment. The latter is perpendicular to the handle’s axis and has three segments: a proximal, linear segment, an intermediate, open circular segment with a 3-cm radius, and a terminal, open circular segment having a shorter radius and ending with a conic section formed by curled segments that enable the intraoperative attachment of a hollow polyethylene tube. The guide is a stainless steel device that has a semicircular gutter with a blunt end. Its proximal portion bears two small wings that are parallel to the gutter’s plane and hold the device. (C) The polypropylene mesh used for the sling procedure comprises a 3 cm large central portion. Its ventral extremity is linear and its dorsal end is rounded. The mesh bears two lateral arms that arise mainly from the dorsal aspect of the mesh. The width of the proximal portion of each arm progressively decreases from 4 cm to 2 cm over a 2.5-cm distance.
Fig. 2 – Sling procedure: part 1. (A and B) After the patient is placed in the lithotomy position, legs on stirrups, with thighs in hyperflexion (110° angle) and slight abduction, the surgical area is prepared and draped in a sterile fashion. A 16F Foley catheter is inserted and the scrotal skin is temporarily pulled upward with two stitches fixed at the inner side of both thighs, to facilitate access to the perineum. A 6-cm sagittal skin incision is made at the median raphe of the perineum ending 2 cm above the anal margin. Transsection 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 ischiocavernous muscles. Together with the transverse muscles, the bulbospongiosus and ischiocavernous 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. Cautious hemostasis of the small perforating vessels of the urethral bulb is done by electrocauterization. (C and D) 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. Metzenbaum 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. Scissors transsect the muscular plane and then perforate
placement of a compressive polypropylene mesh at the level of the bulbar urethra; its general principle is shown in Fig. 1A. In case of associated urethral stenosis, classic endoscopic urethrotomy was performed first. Antibiotic prophylaxis was systematically carried out by intravenous administration of third-generation cephalosporin.

2.2.1. Specific surgical instruments

The passers are pairs of stainless steel instruments that are specific for the left and right sides. They comprise a flat curved segment ending with a conic section formed by curled segments that enable the intraoperative attachment of a hollow polyethylene tube (Fig. 1B). As detailed below, the hollow plastic tubes are used to ease the passage of each arm of the mesh through the obturator foramens.

The guide is a stainless steel device with a bayonet shape intended to avoid any traumatic compression of the bulbous urethra during insertion of the passers (Fig. 1B). It is intended to act both as a shoehorn for slipping in each passer alongside the gutter and as a barrier for preventing entry of the passers into the pelvic cavity.

A monofilament, macroporous, low-density polypropylene mesh (Gynemesh PS®, Ethicon, Somerville, NJ, USA) is cut in the operating room according to a preset frame. The mesh comprises a central portion and two lateral arms (Fig. 1C).

2.2.2. Surgical technique

The surgical technique is detailed in Figs. 2–4 and is also presented in the video accompanying this report. Intraoperative urodynamic evaluations were performed with the use of a dual-channel urodynamic urethral catheter to record the urethral pressure profile (UPP) and to measure abdominal leak-point pressure (ALPP) and maximal urethral pressure (MUP; Fig. 4).

2.3. Perioperative and postoperative evaluation

Perioperative information was recorded during and immediately after surgery. Urethral catheter was left in situ for 24–48 hours. After catheter removal and a trial of voiding, urinated volume, maximum flow rate \(Q_{\text{max}}\), and postvoid residual (PVR) were measured and the patient was discharged. In case of complete retention or important PVR volumes, a suprapubic catheter was inserted and left for 2 wk and the patient was asked to complete a voiding diary in the interval. No specific threshold was used for defining PVR volume as important. Clinical relevance of PVR volumes was judged by the surgeon. Other immediate postoperative complications were also recorded during the hospital stay of the patients.

Follow-up evaluation at 1, 6, and 12 mo, and yearly thereafter included physical examination, urinalysis, uroflowmetry with PVR measurement, 2-d voiding diary, and administration of the self-questionnaires assessing urinary continence and QoL. All patients were also asked to self-evaluate their satisfaction with the treatment (graded on a scale of 1 = completely dissatisfied to 5 = completely/considerably satisfied) and whether it met their expectations (graded on a scale of 1 = did not meet expectations at all to 5 = completely met expectations; Appendix B) [22]. To perform uroflowmetry and PVR measurements, patients were invited to present to the follow-up visits with a full bladder.

Postoperative complications were recorded, including bleeding; hematoma; urinary retention; need for suprapubic catheter placement; bladder, bowel, urethra, or nerve damage; urethral erosion; sling infection; or persistent pain.

2.4. Definitions used

Patients were classified as “cured” of SUI if they were using no pads. SUI was arbitrarily considered as improved when the number of pads used by the patient daily was both ≤2 and reduced by at least 50%. Treatment was considered as failed when the number of pads per day was >2 or not reduced by at least 50%.

2.5. Statistical analyses

Comparisons between preoperative and postoperative pad numbers, QoL scores, \(Q_{\text{max}}\), and PVR volumes were performed with the use of the paired Student t test. Statistical tests were two-tailed and \(p < 0.05\) was considered statistically significant. The analyses were performed with the Statview statistics software package (SAS Institute, Cary, NC, USA).

3. Results

3.1. Baseline characteristics of the patients

Between April 2006 and February 2007, 20 consecutive patients with post-RP SUI who fulfilled the inclusion and exclusion criteria underwent the inside-out trans-obturator male sling procedure without any modification of the surgical technique. Baseline characteristics of the patients are summarized in Table 1.

Three (15%), 11 (55%), and 6 (30%) patients complained of mild, moderate, and severe incontinence, respectively, as defined by the number of pads used daily. Flexible urethrocystoscopy and urethrocystography demonstrated urethral stenosis at the bladder–urethra anastomosis or membranous urethra in four patients. One of these patients had undergone radiation therapy and the membranous urethra appeared white and rigid.

the upper layer of the median perineal aponeurosis. (E and F) The guide is inserted through the scissors-initiated dissection path with a 45° angle relative 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 open side of the guide must be facing the operator. (G and H) The distal linear segment of the passer is slipped along the gutter of the guide so as to pass through the obturator membrane.
Fig. 3 – Sling procedure: part 2. (A and B) The guide is removed and, thanks to a rotational movement of the passer’s handle, the tip of the passer appears at the outer edge of the ischiopubic ramus, at its junction with the body of pubis. (C and D) A hollow plastic tube is attached to the tip of the passer and the device assembled with the tube is rotated backward. The plastic tube becomes externalized at the perineal level and is subsequently freed from its supporting passer. At this stage, the tube bridges the perineum with the right outer aspect of the obturator foramen. The same technique, using the left passer and a second plastic tube, is applied to the left side. (E and F) The dorsal extremity of the mesh is attached to the central body of the perineum using a 2-0 nonabsorbable suture. (G and H) A nylon wire is passed through the tip of the left arm of the mesh; both ends of the wire are introduced into the left hollow tube (at the perineal level).
3.2. Perioperative data

Surgery was performed under general and spinal anesthesia in 10 and 10 cases, respectively. The sling procedure was carried out independently of the patient’s size and weight in all case subjects and was preceded by an endoscopic urethrotomy in the four patients with associated urethral stenosis. Mean operative time was 60 ± 21 min (range: 40–80 min). No complication was encountered during surgery. Estimated blood loss was <200 ml in all patients.

The results of intraoperative urodynamic studies were available for 18 of the 20 patients; technical problems were encountered during recording and saving of the data for 2 patients (Table 2). Mean increase of MUP and ALPP between post- and pre-tensioning of the sling was 40 ± 21 cm H2O (range: 10–85 cm H2O) and 46 ± 21 cm H2O (range: 20–93 cm H2O), respectively. After sling tensioning, UPP consistently showed an initial peak followed by a plateau (Fig. 5A).

3.3. Postoperative data

3.3.1. Objective and subjective SUI cure rates

At the time this manuscript was written, a minimum follow-up of 6 mo was available for all patients; according to the flowchart of the study, only 7 of the 20 patients were seen at the 1-yr visit. Hence, follow-up data presented hereafter are those collected at the 6-mo visit. The sling procedure significantly reduced the number of pads used daily ($p < 0.0001$). Nine of the 20 (45%) patients were pad free, whereas 8 others (40%) were improved (wearing only 1 pad/d), giving a global cure/improvement rate of 85% (Table 3). It is noteworthy that in the seven patients with 1-yr follow-up, numbers of pads used were similar to those at the 6-mo visit.

The three failures included the patient who had undergone post-RP radiation therapy. This man later developed an almost complete urethral anastomotic closure and underwent cystectomy with trans-ileal ureterostomy 9 mo after the sling procedure. The second patient was 79 yr old and had been using 8 pads/d for the past 10 yr. He had previously undergone polydimethylsiloxane transurethral injections and also had developed an anastomotic stricture. He was given an AUS implant 11 mo after the sling procedure. After cutting the mesh arms laterally to the bulb, the AUS cuff was placed without difficulty around the bulbar urethra. The third patient had a history of two previous endoscopic urethrotomies and required another urethrotomy at the bladder–urethra anastomosis level before sling insertion. This patient is unwilling to receive any additional therapy.

On evaluating the responses to question 1 of the urinary function section of UCLA PCI-SF auto-questionnaire, whereas preoperatively all patients (100%) stated that they experienced urinary leakage every day, only nine patients (45%) leaked every day

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**Table 2 – Perioperative urodynamic results**

<table>
<thead>
<tr>
<th>Before tensioning of the mesh</th>
<th>After tensioning of the mesh</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean MUP, cm H2O</td>
<td>42 ± 16 (40; 16–69)</td>
</tr>
<tr>
<td>Mean ΔMUP, cm H2O</td>
<td>40 ± 21 (36; 10–85)</td>
</tr>
<tr>
<td>Mean ΔLPP, cm H2O</td>
<td>56 ± 18 (58; 25–91)</td>
</tr>
<tr>
<td>Mean AALPP, cm H2O</td>
<td>46 ± 21 (42; 20–93)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>82 ± 24 (83; 45–137)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>102 ± 25 (97; 75–165)</td>
</tr>
</tbody>
</table>

Values are given as mean ± SD (median; range).
MUP = maximal urethral pressure; ALPP = abdominal leak-point pressure; AMUP = difference between post- and pre-tensioning MUP; AALPP = difference between post-and pre-tensioning ALPP.
Fig. 4 – Sling procedure: part 3. (A) By pulling on both wire ends (at the external obturator level), the left arm of the mesh is attracted into the tube. Pulling of the wire is stopped just before the proximal, larger portion of the arm enters the tube. Hemostatic forceps are used to grasp and lock the wire's ends at their exit from the tube and the same maneuver is applied to the right arm of the mesh. (B) The most ventral portion of the mesh is then fixed to the aponeurosis of the ischiocavernous muscles by one separate stitch of 2-0 nonabsorbable suture to either lateral side of the mesh. (C and D) Unfolding of the mesh is achieved by slightly pulling on the plastic tubes; the mesh then appears to cover the bulbous urethra. At this stage, a urodynamic evaluation is performed and the bladder is filled with 300 ml normal saline. Thanks to a dual-channel urodynamic urethral catheter, the urethral pressure profile (UPP) is recorded and the abdominal leak-point pressure (ALPP) and maximal urethral pressure (MUP) are measured. (E and F) The nylon wires and plastic tubes are grasped on either side and pulled toward the operator, thus attracting both the mesh and the urethral bulb cranially. (G) The tubes and then the wires are removed and both arms of the mesh are crossed and temporarily bound to each other with forceps over the bulb. Urodynamic measurements are repeated until tension on both arms of the mesh increases ALPP to approximately 100 cm H₂O. (H) At this stage, the two arms of the mesh are tied to each other by a triple knot; the latter is
after the sling procedure. Responses to question 2 showed improvement in urinary control reported by the patients postoperatively (Table 4). Responses to question 3 were consistent with the numbers of pads used daily by the patients, as assessed by interview (compare Tables 3 and 4).

3.3.2. QoL and satisfaction
QoL scores were significantly improved postoperatively \((p < 0.0001; \text{Table 4})\). Moreover, 16 patients (80%) were moderately to completely satisfied with the procedure and 2 of them (10%) stated they were halfway satisfied with the procedure (Fig. 5B). Treatment moderately or completely met the expectations of 16 of the 20 patients (80%; Fig. 5B).

3.3.3. Voiding parameters
Preoperative and postoperative \(Q_{\text{max}}\) and PVR values (Table 4) were not different \((p = 0.71\) and \(p = 0.83\), respectively).

sutured to the mesh covering the urethral bulb and excess arm ends are cut off. The urodynamic urethral catheter is removed and the Foley catheter is reintroduced into the bladder. Insertion of the catheter should be easy, ideally without resistance. Hemostasis is completed when necessary, and the different tissue layers (Colles fascia, subcutaneous fat, and skin) are closed plane by plane using polyglactin suture.

Fig. 5 - (A) Intraoperative urodynamic measurements of abdominal leak-point pressure (ALPP) and maximal urethral pressure (MUP) before and after applying tension to the sling. Urethral pressure profiles (UPPs) are also shown. ALPP and MUP values are expressed in cm H\(_2\)O. (B) Responses to the questions assessing the degree of satisfaction of the patients with the sling procedure and whether the latter met their expectations.
3.3.4. Complications

In the immediate postoperative period, three patients developed moderate perineal hematoma not necessitating any therapy. Three patients required the placement of a suprapubic catheter because of complete retention or important PVR volumes after urethral catheter removal. Of these three patients, two resumed voiding with PVR volumes ≤20 ml and the catheter was withdrawn. The remaining patient, who had a very poor quality urethra due to radiation therapy, presented persistent important PVR volumes and severe leakage; he underwent urinary diversion. Median hospital stay for the 20 patients was 4 d (range: 3–6 d). No mesh infection, persistent pain, or bladder, urethra, bowel, or nerve complications were encountered.

Table 3 – Pad usage preoperatively and at 6 mo after the sling procedure

<table>
<thead>
<tr>
<th>Daily pad usage</th>
<th>No. of patients (%) reporting pad use at baseline</th>
<th>No. of patients (%) reporting pad use at 6 mo follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>—</td>
<td>9 (45%)</td>
</tr>
<tr>
<td>1</td>
<td>—</td>
<td>8 (40%)</td>
</tr>
<tr>
<td>2</td>
<td>3 (15%)</td>
<td>—</td>
</tr>
<tr>
<td>3–4</td>
<td>9 (45%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>5–6</td>
<td>6 (30%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>7–8</td>
<td>1 (5%)</td>
<td>1 (5%)</td>
</tr>
<tr>
<td>9–10</td>
<td>1 (5%)</td>
<td>—</td>
</tr>
<tr>
<td>Mean ± SD (median)</td>
<td>4.4 ± 2.1 (4)</td>
<td>1.3 ± 2.2 (1)</td>
</tr>
</tbody>
</table>

Arrows represent the evolution of the three patients in whom the sling procedure failed.

Table 4 – Preoperative and 6-mo postoperative incontinence severity scores, voiding parameters, and QoL scores

<table>
<thead>
<tr>
<th>Preoperative</th>
<th>Postoperative</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCLA PCI- Short Form</td>
<td>n (%)</td>
</tr>
<tr>
<td>Q1: Leakage frequency</td>
<td></td>
</tr>
<tr>
<td>Every day</td>
<td>20 (100)</td>
</tr>
<tr>
<td>About once a week</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Less than once a week</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Not at all</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Q2: Urinary control</td>
<td></td>
</tr>
<tr>
<td>No control whatsoever</td>
<td>5 (25)</td>
</tr>
<tr>
<td>Frequent dribbling</td>
<td>14 (70)</td>
</tr>
<tr>
<td>Occasional dribbling</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Total control</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Q3: Daily pad use</td>
<td></td>
</tr>
<tr>
<td>≥3 pads/d</td>
<td>17 (85)</td>
</tr>
<tr>
<td>1–2 pads/d</td>
<td>3 (15)</td>
</tr>
<tr>
<td>No pad</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Ditrovie QoL form (Scale from 10 [best condition] to 50 [worst condition])</td>
<td>Median (range) [mean ± SD]</td>
</tr>
<tr>
<td></td>
<td>35 (19–42) [32.3 ± 5.9]</td>
</tr>
<tr>
<td>Voiding parameters:</td>
<td></td>
</tr>
<tr>
<td>PVR, ml</td>
<td>Median (range) [mean ± SD]</td>
</tr>
<tr>
<td></td>
<td>10 (0–160) [30.5 ± 40.1]</td>
</tr>
<tr>
<td>Qmax, ml/s</td>
<td></td>
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<tr>
<td></td>
<td>14 (6–37) [16.2 ± 8.5]</td>
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Urinary section of the UCLA Prostate Cancer Index-Short Form.
QoL = quality of life; PVR = postvoid residual; Qmax = maximum flow rate.
4. Discussion

The trans-obturator approach has gained wide popularity for the treatment of SUI in women and accumulating clinical evidence indicates that synthetic trans-obturator tapes (TOTs) are associated with excellent success rates and minimal complications [23]. In theory, the trans-obturator route could also be used for sling placement in men. However, two relevant dissimilarities need be considered to adapt this route for sling insertion in men. First, from an anatomic standpoint, inferior pubic rami are thicker and the angle formed by these rami is less opened in men than in women. Hence, it is anticipated that the surgical instruments currently used for inserting TOTs in women would require some modifications to accommodate male anatomy. Second, at the physiopathologic level, whereas suburethral tapes placed without tension are effective to treat female SUI, considerable pull-up forces must be reliably applied to male slings to prevent urinary leakage. It may thus be suspected that the self-anchoring system ("Velcro effect") of synthetic TOTs may not be able to sustain sling tension.

Our primary experience with the inside-out trans-obturator sling involved studies conducted on cadavers. These studies allowed us to design specific instruments enabling two mesh arms to be (1) easily passed around the inferior pubic rami, (2) pulled downward for compressing the bulbar urethra upward, and (3) tied to each other for maintaining sling tension. In addition, in agreement with the male cadaver dissection results obtained by Bauer [24], who described an inside-out trans-obturator route, and those related to the tension-free vaginal tape (TVT-O) technique for treating female SUI [25,26], we found that the inside-out trans-obturator approach for male sling insertion bears a minimal risk of harming any sensitive structure in the male pelvis (unpubl. data, J. de Leval et al.). It was also felt that, for the purpose of circumventing the inferior pubic rami, an inside-out route, as compared with an outside-in one, would carry a lower risk of penetrating the pelvic space.

The clinical results of our first 20 consecutive procedures appear to corroborate these anatomic data. In total, 40 mesh arms were passed around 20 left and 20 right inferior pubic rami and no serious complication was encountered during or after surgery. This is important because the trans-obturator approach is expected to minimize the risk of bladder, bowel, and vessel injuries, which can be observed during the blind, retropubic passage of a needle through the pelvic space, particularly in men after RP. In addition, our approach allows for avoidance of bone anchors and related issues including osseous infection and pain.

One group previously reported on the use of a trans-obturator sling for treating male SUI. Indeed, an outside-in trans-obturator approach was recently proposed by Rehder and Gozzi for the placement of a polypropylene tape under the proximal part of the urethral bulb via one perineal incision and two small skin incisions at the thigh folds, in a manner similar to that of the TOT procedure used to treat female SUI [27]. The tape was described as self-anchoring due to the woven nature of the polypropylene tape and the main anchor point was reported to be the obturator muscles and fascia [27]. At 6 wk postoperatively, the incontinence cure rate (no pad usage) was 40% (8 of 20 patients) and the improvement rate (1–2 pads/d) was 30% (6 of 20 patients). Our trans-obturator sling technique differs in several aspects from that described by Rehder and Gozzi. Of special note, our technique allows us to tie the two trans-obturator mesh arms to each other, thus preventing any risk of mesh slippage. Such slippage causing relapse of incontinence has been suspected in one patient who underwent the self-anchoring outside-in procedure [27].

Recently, evidence became available as to the long-term effectiveness of abdominal wall-secured or bone-anchored male slings for treating post-RP SUI, with cure rates after a mean or median follow-up of 4 yr comparing fairly well with those obtained after AUS implantation [18,19]. However, the literature related to these procedures clearly shows outcome variability, which may be dependent on a number of parameters including the definition of success, the technique used, the severity of incontinence, comorbidities such as irradiation, and the surgeon’s experience [20]. In our series, 85% of the patients were using at least 3 pads/d preoperatively. At 6 mo postoperatively, 45% required no pad for protection (cured) and 40% were wearing only 1 pad/d (improved), giving an overall cure/improvement rate of 85% patients (≤1 pad/d). This experience is similar to reported short-term rates of sling efficacy [22,27–32]. Most importantly, the procedure was associated with a significantly improved QoL and a high satisfaction rate (≥80%), and from the patients’ perspective, treatment expectations were met in most of them (≥80%). Yet, the outcome of our small cohort of patients clearly shows that the inside-out trans-obturator sling may not be ideal for all men with post-RP SUI. Interestingly, the three patients in whom the procedure failed had undergone prior...
radiation therapy or had associated urethral stenosis requiring urethrotomy. Strictures and radiation-related lesions of the urethra reduce tissue compliance and are suspected risk factors for lower success rates after incontinence surgery [16]. Patients with such morbid factors remain very difficult to cure with any intervention. It is also noteworthy that our trans-obturator sling does not appear to compromise further AUS implantation, which was successful in one of our patients who had an initial failure.

Various methods have been used to intraoperatively set the degree of sling tension, the latter being empirically determined either preoperatively or during the procedure. Several groups have used intraoperative urodynamic measurements of MUP [16,32], ALPP [16], or retrograde leak-point pressure (RLPP) [31,33,34] to determine adequacy of tension. Others relied on the cough test [22,35], the observation of a 3–4-cm elevation of the bulbar urethra above the level of the central body of the perineum [36], or the increase of urethral resistance [17]. No standardized, commonly accepted sling tensioning method or threshold is currently available. Similarly to other groups [22,32], we believed that a RLPP or MUP of 60 cm H2O intraoperatively may not be sufficient to achieve complete urinary continence, especially in patients with severe incontinence. We chose an ALPP of approximately 100 cm H2O to set the sling tension. With this threshold, post-tensioning MUP increased to a mean of 82 cm H2O, a pressure in the same range as that used by Xu et al to adjust tension on their suprapubically secured bulbourethral sling. Hence, our trans-obturator–opened V-shaped sling allowed us to generate similar degrees of urethra compression (as measured by MUP) as those obtained with retropubic U-shaped suspensions. Yet, we obviously cannot make any definite claims regarding specific pressures required for tension adjustment.

To date, despite achieving fairly high urethral pressures, none of our patients have developed urethral erosion. This type of complication is in fact uncommon after male sling placement [32]. In contrast, significant erosion rates, ranging from 5% to 15%, were reported after AUS placement [2]. By compressing the ventral aspect of the bulbar urethra over a relatively large surface, our V-shaped sling may better preserve arterial and venous circulation than the AUS with its cuff encircling the entire circumference of the urethra on a smaller contact surface. Accordingly, the risk of urethral atrophy and subsequent erosion is likely to be minimized.

Another concern after sling placement relates to the threat of causing obstructive voiding. In our study, this was addressed by comparing preoperative and postoperative mean $Q_{\text{max}}$ and PVR values, which were not statistically different. However, temporary urinary retention was observed postoperatively in three patients, of whom two resumed normal voiding within 2 wk. The unique patient who had long-standing retention had radiation-induced urethral stricture and ultimately underwent urinary diversion. Although no repeat urodynamic study was performed postoperatively in our patients, follow-up flowmetry data are consistent with previous studies of other bulbourethral male slings showing unobstructed voiding patterns despite significant increases in Valsalva leak-point pressures [14].

We realize that our study is limited by the short follow-up of only 6 mo in a small cohort of patients. Nevertheless, the outcome based on both the objective and subjective assessment of urinary function and continence following surgery was evaluated prospectively. We have additionally assessed the patient’s satisfaction and QoL after the procedure, an important consideration in patients who are incontinent after RP.

5. Conclusions

Early experience indicates that the inside-out trans-obturator sling technique for treating post-RP SUI is associated with a very low morbidity and high rates of SUI cure/improvement and patient satisfaction. Longer follow-up in larger series of patients is needed to confirm these encouraging results.

Conflicts of interest

The authors have no conflicting interest to disclose. They declare that no funding or other agreement has limited their ability to fairly complete and publish this research study. There has been no extramural funding for this study.

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Appendix A. Specific items of the urinary section of the UCLA Prostate Cancer Index-Short Form (UCLA PCI-SF)

This section is about your urinary habits. Please consider ONLY THE LAST 4 WEEKS.

**Over the LAST 4 WEEKS, how often have you leaked urine?**

1. Every day  
2. About once a week  
3. Less than once a week  
4. Not at all

**Which of the following best describes your urinary control during the LAST 4 WEEKS?**

1. No control whatsoever  
2. Frequent dribbling  
3. Occasional dribbling  
4. Total control

**How many pads or adult diapers per day did you usually use to control leakage during the LAST 4 WEEKS?**

1. $\geq 3$ pads/d  
2. 1–2 pads/d  
3. No pad

Appendix B. Specific questions used to assess patient’s satisfaction with the surgical treatment

1. How would you categorize your overall satisfaction with the operation for treating incontinence?

1. Completely dissatisfied  
2. Moderately dissatisfied  
3. Halfway satisfied  
4. Moderately satisfied  
5. Completely/considerably satisfied

2. Did the treatment meet your expectations?

1. Did not meet expectations at all  
2. Did not meet expectations moderately  
3. Met expectations halfway  
4. Met expectations moderately  
5. Completely/considerably met expectations
Appendix C. Supplementary data

Supplementary data associated with this article can be found, in the online version, at doi:10.1016/j.eururo.2007.11.025 and via www.europeanurology.com. Subscribers to the printed journal will find the Surgery in Motion DVD enclosed.

References


