Male Stress Urinary Incontinence
A 2015 SPRINGER PUBLICATION: Chapter 9 Functional Devices
A review of all male slings shows the TOMS to be superior in many respects to the alternatives – the surgical technique is the least invasive

G. Del Popolo et al. (eds.), Male Stress Urinary Incontinence, Urodynamics, Neurourology and Pelvic Floor Dysfunctions, DOI 10.1007/978-3-319-19252-9_9

STATMENTS REGARDING TOMS:
Continence rate remains stable at 2 year follow-up in a single centre study, 57% patients being cured and overall 90% experiencing improvement (0 or 1 pad per day) [36] which compares positively with artificial sphincter.

At 1-year follow-up, cure rate (0 pad) is 59.4% and overall improvement is 87%; 13% patients have no improvement. All selected patients have mild or moderate incontinence and no history of radiation. The procedure is safe with very few complications: no urinary retention, no severe perineal pain (mean 2.7 on VAS in early postoperative stage), wound infection is very rare [33]. Interestingly for a “compressive” sling, maximum urinary flow rates are similar before and after surgery. These results are very close to those of AdVance® at 1-year follow-up, with less postoperative complications and show a trend toward superiority when used in difficult cases with urethral damage [35].

STATMENTS REGARDING ADVANCE:
In the first long-term results publication [18], the overall success rate at 3-year follow-up is 75.7% including dry and improved patients (with no indication of continence definition, but success appreciation is based on daily pad use). Cure rate at 3 years shifts from 58.6% in case of mild or moderate incontinence to 42.3% in case of severe incontinence. Failure rate jumps from 18.2 to 32.7% respectively. At that time, radiotherapy history seemed to have no impact on results.

Complications are rare and they occur in the early postoperative period: sling explantation and infection are among the most severe and urinary retention the lightest. Urinary retention is a pretty common complication (up to 46%) and resolves spontaneously.

Urology Vol 79 No 2 Feb 2012
I-STOP TOMS Trans Obturator Male Sling, a Minimally Invasive Treatment for Post prostatectomy Incontinence: Continence Improvement and Tolerability

► 103 patients in multi-centre study at 1+ year follow-up
► 59.4% completely dry, and 20.3% on one pad.
► Patient satisfaction over 90%
► No retention compared to 12.9% acute retention for the Advance
► Mean operating time 36.3 minutes
► TOT out-in or in-out
The CL Medical I-STOP TOMS sling for male stress urinary incontinence was developed in France where it is widely used and is the market leader. It is constructed with the patented non-stretch I-STOP tape.

It uniquely has a double arm which can be an advantage in certain circumstances. There are just the usual two incisions for accommodating the tape through the obturators.

To date over 2000 I-STOP TOMS have been implanted since its introduction. The momentum is increasing with current sales running at well over 100 per month. There are an increasing number of users in several countries including the UK and USA. Results have been consistently excellent.

The procedure is quite straightforward, and easily learned.

There has been no reported case of erosion.

The incidence of post operative pain persisting for more than 24 hours is low. The reported post-operative VAS pain score after 24 hours is 2, reducing to 0 - to 0.2 at one month.

The indication is for cases of mild to moderate incontinence and merits serious consideration as a less invasive alternative to an artificial sphincter.

Enclosed are:
- Description of the steps for the procedure,
- A multi-centre study in Urology Vol 79 No2 February 2012.

*DVDs showing the procedure are available from Genesis Medical on request.*

Genesis Medical will be pleased to arrange for training at one of the regular sessions or for a surgeon to work with you to treat one or more patients in your hospital. Please call Robin Penberthy for details.
1. - Carry out a preoperative perineal scrub
   - General or spinal anesthesia
   - A medial perineal incision in the sagittal plane: 5-7 cm

2. - Bulbospongiosus muscle is exposed but left in place
   - Then a dissection is made laterally in the space between the urethra and corpora cavernosa covered by ischiocavernosus muscle.
   - A short incision in the perineal fascia (i.e. perineal aponeurosis) affords deeper access towards the obturator muscle just above ischiopubic ramus bone

3. - A stab incision is made at the top of the thigh, 4 cm from the medial line and 4 cm below the major adductor longus muscle.

4. - Palpate the medial aspect of the ischiopubic ramus with finger to acquire a landmark for needle rotation.
   - The needle is inserted to puncture the obturator foramen in order to reach the tip of the finger on the inside landmark

5. - The tape is clipped to the needle tip....
6. and withdrawn rotating the needle back through the stab incision.

... repeat step 3, 4, 5, and 6 on the contralateral side

7. Position the tape without tension

8. A non-resorbable suture is used at 4 corners to avoid the tape migrating down and to prevent any cheese wire effect when tension is applied. There is no need to push the sling backwards to adjust tension. A curved depression is obtained by slight compression on the bulbospongiosus muscle.

9. Cut off the tape ends at skin level
- The sling should rest on the area where the urethral catheter is located.
- The wound is closed in two layers using resorbable sutures

10. The closed wound without surgical drain (recommended)
Prostatic Diseases and Male Voiding Dysfunction

I-Stop TOMS Transobturator Male Sling, a Minimally Invasive Treatment for Post-prostatectomy Incontinence: Continence Improvement and Tolerability

Philippe Grise, Renaud Vautherin, Bertin Njinou-Ngninkeu, Ghislain Bochereau, Jean Lienhart, and Christian Saussine, for the HOMme INCon tinence Study Group*

OBJECTIVE
To prospectively evaluate the efficacy and tolerability of the I-STOP TOMS transobturator male sling in patients with post-prostatectomy stress urinary incontinence. Minimally invasive techniques, such as slings, are becoming the standard of care for mild to moderate post-prostatectomy incontinence.

METHODS
From March 2007 to June 2009, 122 patients with post-prostatectomy stress urinary incontinence were treated with the I-STOP TOMS sling and followed up for 1 year in the Phase IV HOMme INCon tinence trial. The preoperative and postoperative evaluation included daily pad use, pad test, questionnaires evaluating urinary function and bother (University of California, Los Angeles, Prostate Cancer Index–urinary function short form, and International Consultation on Incontinence Modular Questionnaire–urinary incontinence short form) and uroflowmetry, including the post-void residual urine volume. Patient satisfaction and perineal pain were also assessed.

RESULTS
A total of 103 patients were followed up for 12 months. The surgical procedure was considered easy to perform. The mean daily pad use decreased significantly from 2.4 to 0.6 at 12 months of follow-up; 87.0% of the patients reported improved continence (59.4% completely dry, 20.3% 1 pad/d, 7.3% >1 pad/d), and 13.0% reported no improvement. All quality-of-life scores (University of California, Los Angeles, Prostate Cancer Index–urinary function short form, and International Consultation on Incontinence Modular Questionnaire–urinary incontinence short form) improved significantly after sling implantation. Treatment satisfaction was >90%. The post-void residual urine volume did not increase substantially, and acute urinary retention did not occur. The perineal pain scores were very low at follow-up. Wound infection was seen in 2 patients at the 1-month follow-up visit.

CONCLUSION
The I-STOP TOMS is a good treatment option for patients with post-prostatectomy stress urinary incontinence. With follow-up ≤12 months, most patients were continent or had improved continence. The intervention was well tolerated, with few infections. UROLOGY xx: xxx, xxxx. © 2011 Elsevier Inc.

*A complete list of the HOMme INCon tinence Study Group can be found in the Appendix.

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Stress urinary incontinence (SUI) is common after prostatectomy, although the reported prevalence of this condition is highly variable (0.8%-87.0%) owing to the numerous definitions of post-prostatectomy continence.1,2 Male SUI is mainly caused by sphincter deficiency; however, urethral support deficiency and increased mobility of the bulbar and membranous urethra can also be involved. Even mild post-prostatectomy SUI can strongly affect patients’ quality of life. The initial treatment consists of pelvic floor muscle training and behavioral therapy, although the evidence on the efficacy of these treatments is rather weak. The artificial urinary sphincter remains the reference standard for severe SUI, which is often related to major sphincter deficiency.3
This procedure involves high costs, carries the risk of erosion and infection, and patients can be hesitant to have a mechanical implant or be unable to use it.

Therefore, other minimally invasive treatment options could be an alternative for patients with mild to moderate post-prostatectomy SUI. These include sling procedures, implantation of compressive adjustable balloons, or injection of bulking agents. The current guidelines from the International Consultation on Incontinence (ICI) do not recommend the latter 2 options, for which multiple sessions are often required. Slings are becoming the standard of care for mild and moderate male SUI. Although all available slings are placed under tension to occlude the urethra at rest and during stress maneuvers, they differ in the materials used, the methods of fixation and the position of the support. The 4-arm I-STOP TOMS transobturator male sling (CL Medical) is an adapted version of the 2-arm TOMS bulbar sling (CL Medical). It is a monofilament polypropylene (macropores >75 μm) nonextensible 4-arm large sling (Fig. 1). The dimensions are 45 cm × 1.4 cm, with a 2.8-cm central part placed over the urethra. The aim of the present trial was to evaluate the improvement in continence and quality of life and the tolerability of patients with post-prostatectomy SUI treated with the I-STOP TOMS transobturator male sling.

**MATERIAL AND METHODS**

**Patients and Study Design**

The eligible patients had SUI related to prostatectomy (radical or transurethral resection of the prostate) performed >6 months before study entry. In addition, they were unresponsive to, or refused, urinary physiotherapy, and had a urinary incontinence score of 4-16 using the ICI Modular Questionnaire—urinary incontinence short form (score range 0-21). Patients with bladder outlet obstruction, bladder overactivity (assessed urodynamically), low compliance, or urethral or anastomotic stenosis (assessed by urethrocystoscopy or urethrography) were excluded. Furthermore, patients were excluded if they had progressive prostate cancer as assessed by the prostate-specific antigen level, a history of prostate radiotherapy, neurologic disorder, or chronic urinary retention with overflow incontinence. Current urinary tract infection resulted in temporary exclusion until the infection had resolved.

Patients were asked to stop any urinary incontinence medication, in particular anticholinergic agents, during the study.

In the present prospective, multicenter, interventional, open-label, nonrandomized, Phase IV study, data were obtained at inclusion, just after sling implantation, and 1, 3, 6, and 12 months after implantation. Longer patient follow-up could be decided by each center. The present study, the HOMme INContinence study, was approved by the local research ethics committee (Comité Consultatif de Protection des Personnes se présentant à des Recherches Biomédicales, Haute-Normandie, May 4, 2006, extended to increase the number of patients and centers on November 8, 2007) and conducted in compliance with good clinical practice guidelines and the Declaration of Helsinki. All patients provided written informed consent. The study was registered at ClinicalTrials.gov (trial registration number NCT00442078).

**Implantation Procedure**

The sling was attached at each end to a clip to connect it to a Hemet or helical needle, according to surgeon preference. All surgeons were experienced in transobturator sling procedures. Implantation was performed with the patient under spinal or general anesthesia, and a 16F Foley urethral catheter was inserted. The patient was placed in the lithotomy position, and a 6-cm median vertical perineal incision below the inferior border of the pubic symphysis was performed to expose the bulbospongius muscle. Next, the perineal aponeurosis at the top of the triangular space was delimited laterally by each ischiocavernous muscle and medially 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 preferentially outside-inside using a Hemet needle. The endpoint of the puncture was the opening of the pelvic fascia. After sling attachment to the needle, pulling back the needle implanted the 2 arms of the sling in the same passage. The same procedure was repeated on the other side. The sling was sutured to the bulbospongiosus muscle with nonabsorbable sutures and then pulled firmly from each side to obtain a 2-mm visible mark on the bulbospongiosus muscle. The perineal body was not dissected. However, in the case of rolling of the inferior edge of the sling on the bulb, the bulb was dissected just enough to place it under the sling and then sutured to the sling. No retrograde urethral pressure adjustment was performed. The incision was closed without drainage, and the urethral catheter was left indwelling for 2 days.

**Patient Assessments**

All patients completed their continence status and 2 validated questionnaires to evaluate urinary function and bother at baseline and 1, 3, 6, and 12 months after implantation. The urinary function short form (Prostate Cancer Index, University of California, Los Angeles) consists of 4 questions on urinary function (range 0-100) and 1 on urinary bother (range 0-100, with a low score indicating a worse outcome). The second questionnaire, the urinary incontinence short form (ICI Modular Questionnaire), has a score range of 0-21, with a low score indicating mild incontinence. A short-term pad test was assessed at...
baseline and 3 and 12 months after implantation. The test measured the weight of the pads after bladder filling with 200 mL saline and after a short set of exercises of leakage provocation, as recommended by the ICI guidelines.\textsuperscript{9,10} In addition, postoperatively, at 1, 3, 6, and 12 months, the patients indicated their satisfaction with the intervention and their new health status (1 question for each item, with 4 answer options, from 'not satisfied at all' to 'very satisfied') and evaluated the perineal pain (visual analog scale; range 0-10). The maximal flow rate and post-void residual (PVR) urine volume, low stream, urination, and adverse events were also assessed at these points.

The primary endpoint evaluated was the number of pads used at 12 months of follow-up. The secondary efficacy endpoints included changes in the number of pads used, a change in the pad test outcome, improvements in continence and urinary bother scores, and changes in the satisfaction with the intervention and the new health status.

**Statistical Analysis**

The statistical analysis included the efficacy and tolerability results for those patients with 12 months of follow-up. The surgical and tolerability results were descriptively reported per event. A comparison of between-group baseline and efficacy outcomes was performed using a Kruskal-Wallis test. Within-group comparisons were analyzed using the Wilcoxon matched-pairs signed-ranks test. Secondary analyses of the number of pads used within 24 hours were also performed, taking into account the SUI level at baseline (i.e., mild SUI [1-2 pads/d], moderate SUI [3-5 pads/d], and severe SUI [>5 pads/d]).\textsuperscript{11,12} $P < .05$ was considered statistically significant for all comparisons. The statistical analyses were performed using SAS software (SAS Institute, Cary, NC).

**RESULTS**

A total of 122 patients were included from 30 centers in France from March 2007 to June 2009. The duration of follow-up was 12 months for 103 patients (84.4%), and 19 patients were lost to follow-up, 8 (6.6%) at 6 months, 6 (4.9%) at 3 months and 5 (4.1%) at 1 month. The additional results reported included only those patients with 12 months of follow-up. Of the 122 patients, 72.9% had undergone open radical prostatectomy, 22.2% laparoscopic radical prostatectomy, and 5.1% transurethral prostate resection. The mean interval from previous prostate surgery was 41.5 months, and 94.8% had undergone prostate surgery >12 months before sling implantation. The mean patient age was 69.4 ± 6.1 years. The rate of urinary infection in the previous 3 months before study inclusion was 4.9%. Implantation was performed with the patient under general anesthesia in 83.7% of the patients and locoregional anesthesia was used in 13.3%. The mean intervention time was 36.3 minutes. In 75.7% of the procedures, an outside-inside transobturatore puncture was used; in 24.3%, it was an inside-outside puncture. For 93.9% of the procedures, the surgeon indicated that the perineal dissection was easy to perform. Performing the left puncture, the right puncture, and passing the sling were indicated as easy in 89.9%, 94.9%, and 97.0% of the procedures, respectively.

**Efficacy**

The number of pads used daily at baseline and at 12 months was available for 69 patients. At 12 months, 60 (87.0%) of the 69 patients had improvement in the number of pads used daily: 41 (59.4%), 14 (20.3%), and 5 (7.3%) patients reported 0, 1, and >1 pad/d, respectively. However, 9 patients (13.0%) had no improvement, with 7 (10.1%) and 2 (2.9%) reporting 1 and >1 pad/d, respectively. Pad use at 12 months had decreased significantly compared with that at baseline (mean 0.6 vs 2.4, $P = .001$; n = 69). In patients with improved continence status, the mean decrease in daily pad use at 12 months was 2.1, 2.1, and 3.0 in patients with 0, 1, and >1 pad/24 h, respectively (Fig. 2A). Comparing the patients with different SUI levels at baseline, the decrease in the number of pads used daily was statistically significant compared with at baseline for both patients.
Table 1. Improvement in self-reported incontinence rate/bother (questionnaires) at 12 months of follow-up

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>Endpoint</th>
<th>Difference</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCLA-PCI-specific HRQOL (n = 101)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leakage</td>
<td>1.0 ± 1.1</td>
<td>37.2 ± 7.9</td>
<td>35.3 ± 8.1</td>
<td>.0001</td>
</tr>
<tr>
<td>Urinary control</td>
<td>41.5 ± 3.9</td>
<td>71.0 ± 4.4</td>
<td>29.3 ± 5.6</td>
<td></td>
</tr>
<tr>
<td>Pads used daily</td>
<td>36.1 ± 4.6</td>
<td>80.4 ± 6.0</td>
<td>43.3 ± 6.9</td>
<td></td>
</tr>
<tr>
<td>Problem of urine dripping</td>
<td>14.9 ± 3.8</td>
<td>72.3 ± 5.9</td>
<td>56.9 ± 6.6</td>
<td></td>
</tr>
<tr>
<td>Problem of urine function</td>
<td>19.6 ± 5.0</td>
<td>75.0 ± 5.9</td>
<td>55.0 ± 6.8</td>
<td></td>
</tr>
<tr>
<td>ICIQ UI (n = 102)</td>
<td></td>
<td></td>
<td></td>
<td>.0001</td>
</tr>
<tr>
<td>Frequency of leakage</td>
<td>3.9 ± 0.1</td>
<td>2.0 ± 0.3</td>
<td>−1.9 ± 0.3</td>
<td></td>
</tr>
<tr>
<td>Quantity of leakage</td>
<td>3.3 ± 0.2</td>
<td>1.5 ± 0.2</td>
<td>−1.8 ± 0.3</td>
<td></td>
</tr>
<tr>
<td>Bother</td>
<td>6.6 ± 0.4</td>
<td>2.1 ± 0.4</td>
<td>−4.5 ± 0.5</td>
<td></td>
</tr>
</tbody>
</table>

UCLA-PCI, University of California, Los Angeles, Prostate Cancer Index; HRQOL, health-related quality of life; ICIQ UI, International Consultation on Incontinence Modular Questionnaire—Urinary Incontinence.

Data presented as mean improvement ± standard error.

UCLA-PCI: question 1, leakage (answer, ‘everyday’, ‘once a week’, ‘less than once a week’, ‘not at all’ [score 0, 33, 66, 100, respectively]); question 2, urinary control (answer, ‘no control’, ‘frequent dribbling’, ‘occasional dribbling’, ‘total control’ [score 0, 33, 66, 100, respectively]); question 3, pads used daily (answer, ‘3 pads/d’, ‘1-2 pads/d’, ‘no pads/d’ [score 0, 50, 100, respectively]); question 4, how big a problem is dripping urine or wetting pants (answer, ‘no problem’, ‘very small problem’, ‘small problem’, ‘moderate problem’, ‘big problem’ [score 100, 75, 50, 25, 0, respectively]); question 5, how big a problem is your urine function (answer, ‘no problem’, ‘very small problem’, ‘small problem’, ‘moderate problem’, ‘big problem’ [score 100, 75, 50, 25, 0, respectively]).

ICIQ UI: question 1, frequency of leakage (answer, ‘never’, ‘once a week maximum’, ‘2-3 times a week’, ‘about once daily’, ‘several times daily’, ‘always’ [score 0-5]); question 2, quantity of urinary leakage (answer, ‘none’, ‘small’, ‘median’, ‘important quantity’ [score 0-6]); question 3, bother about leakage (answer, ‘not at all’ to ‘important bother’ [score 0-10]).

with mild and moderate SUI and those with severe SUI (Fig. 2B). The absolute difference in pad use between baseline and follow-up tended to be larger in patients with severe SUI (Fig. 2B). The mean daily pad use at 12 months of follow-up was 0.4, 0.7, and 1.8 for mild, moderate, and severe SUI, respectively. The outcomes in pad weight of the short-term pad test were only available for 36 patients. No patients were able to report the pad test results. The results were significantly improved at 12 months compared with at baseline (mean 11.3 g vs 105.1 g; P < .01).

At 12 months of follow-up, all symptoms and bother scores, as assessed by the urinary function short form (Prostate Cancer Index, University of California, Los Angeles, CA) and the urinary incontinence short form (ICIQ Modular Questionnaire), were significantly improved statistically compared with at baseline (Table 1). The functional scores improved from ‘everyday’ or ‘frequent problem’ to ‘once a week’ or ‘occasional’. The bother scores improved from ‘big’ or ‘moderate problem’ to ‘very small problem’. In addition, 91.2% of the patients were ‘satisfied’ or ‘very satisfied’ with the treatment and 87.8% with their new health status from the post-operative period to the end of follow-up at 12 months. The satisfaction was stable over time.

Perioperative Complications and Tolerability

No complications, such as bladder perforation, intraoperative bleeding (>200 mL), or nerve, bowel, or vascular injury occurred during the intervention, except for wound of the corpus cavernosum (4.0% of the patients).

Micturition at removal of the catheter 48 hours after surgery occurred in 98.9% of the patients. Hematoma and wound infection were very rare, and the mean perineal pain visual analog scale score were low (Table 2). Of the patients, 97.3%-100% were free of urinary tract infection at the different follow-up visits, and 96.5%-100.0% 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 PVR urine volume was increased after surgery and was normal at 30 days; a low stream was reported by some patients (Table 2). Acute urinary retention (AUR) did not occur.

COMMENT

This is the first study presenting prospective data on the efficacy and tolerability of the 4-arm large I-STOP TOMS male sling. Prospective studies on sling implantation for post-prostatectomy SUI in series including 100 patients are exceptional.

In the present study, 87.0% of the patients reported improved continence, with 39.4% completely dry at 12 months of follow-up; 13% reported no improvement but the absence of worsening. The quality of life had improved significantly at early follow-up, and the improvements were maintained through the follow-up period. The patients were highly satisfied with the intervention and with their new health status. Tolerability was high. Some patients experienced a low stream but in the absence of an increased PVR urine volume and without additional risks.

One limitation of the present study was the length of follow-up, which was 12 months. Long-term data on the efficacy and tolerability are needed. In addition, a short pad test was used instead of a 24-hour pad test; however, the test was performed according to the recommendations of the ICI.10 The combination of regular follow-up visits with patient-reported outcomes using validated patient-completed questionnaires is a strong point of the present study.7,8 We observed that safety reporting was
Table 2. Tolerability of the sling procedure

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>Immediate Postoperatively</th>
<th>Follow-Up Visit (mo)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hematoma (n)</td>
<td>—</td>
<td>8/92</td>
<td>2/96</td>
</tr>
<tr>
<td>Wound infection (n)</td>
<td>—</td>
<td>0/97</td>
<td>0/96</td>
</tr>
<tr>
<td>Current UTI (n)</td>
<td>0/103</td>
<td>—</td>
<td>0/96</td>
</tr>
<tr>
<td>UTI in previous 30 days (n)</td>
<td>—</td>
<td>2/85</td>
<td>2/89</td>
</tr>
<tr>
<td>Difficulty voiding low stream (n)</td>
<td>5/101</td>
<td>3/89</td>
<td>2/73</td>
</tr>
<tr>
<td>Perineal pain (VAS)</td>
<td></td>
<td></td>
<td>22/97</td>
</tr>
<tr>
<td>Patients (n)</td>
<td>99</td>
<td>94</td>
<td>102</td>
</tr>
<tr>
<td>Mean score ± SD</td>
<td></td>
<td>2.7 ± 1.9</td>
<td>1.2 ± 1.8</td>
</tr>
<tr>
<td>Qmax (mL/s)</td>
<td>0.4 ± 1.2</td>
<td>2.7 ± 1.9</td>
<td>0.4 ± 1.0</td>
</tr>
<tr>
<td>Patients (n)</td>
<td>90</td>
<td>60</td>
<td>74</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>23.4 ± 10.7</td>
<td>20.1 ± 8.7</td>
<td>21.4 ± 12.4</td>
</tr>
<tr>
<td>PVR urine volume (mL)</td>
<td>84</td>
<td>63</td>
<td>71</td>
</tr>
<tr>
<td>Patients (n)</td>
<td></td>
<td>60</td>
<td>60</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>6.0 ± 14.7</td>
<td>14.0 ± 28.3</td>
<td>11.7 ± 21.1</td>
</tr>
</tbody>
</table>

UTI, urinary tract infection; VAS, visual analog scale; Qmax, maximal flow rate; PVR, post-void residual.

lower compared with efficacy reporting with longer follow-up. We believe this is a common situation in the case of good tolerability.

Male slings have been used for a few decades; however, the slings developed in recent years are not comparable to those from earlier years. The study inclusion criteria for patients and the outcomes definitions, such as the success rate have varied highly, making it difficult to compare trials quantitatively. The published success rates of studies, with a mean follow-up of 6-24 months using male slings of all types, have ranged from 38% to 76%, depending on the outcome measures used, with the best results achieved in patients with low to moderate incontinence who had not undergone radiotherapy.

The most common complications are infection, erosion, and urinary retention. If the sling is placed with insufficient pressure, incontinence will remain. However, if the pressure on the sling is too high, it could result in obstruction, leading to AUR, although other factors, such as the sling location, could also be involved. This could explain the significant proportion of patients developing AUR in some studies. In our study, none of the patients had experienced AUR at ≤1 year after implantation. Indicative of obstruction is a decrease in the maximal urinary flow rate and/or an increased PVR urine volume. Both outcomes remained similar to the baseline measurements in the present trial.

The occurrence of adverse events can also correspond with the fixation technique used during implantation. The retrofix fixation procedure has raised concerns regarding the risk of bladder perforation or erosion. Using the perineal route, a sling can be fixed by bone screws to the pubic bone or using the transobturador technique. The latter approach gained wide popularity for the treatment of SUI in women and was first described for male sling implantation in 2005. Generally, the transobturador technique is perceived as being easier to perform and reproducible, with a low rate of complications. Data on 4 transobturador male slings are available.

The male perineal sling InVance™ is implanted in the same position as the 1-STOP TOMS; however, the former is anchored to the pubic bone with bone screws. InVance™ study with 50 patients showed that about half of the treated patients reached complete continence; however, an AUR rate of 12% and persistent perineal pain rate of 12% were reported at a median follow-up of 6 months. In a representative study of 62 patients with the InVance™ sling, the infection rate was 4.8% and the urinary retention rate was 3.2%.

Adjustable slings typically require reinsertion (38.6% for Argus, >80% for the Male Reemex System), and complications have been relatively common. Sling removal because of urethral erosion or infection was described in 5.9%-15.8% of patients.

The bulbomembranous Advance™ sling is positioned deeper than the 1-STOP TOMS and more posterior to reposition the membranous urethra. However, the urethral wall is thin in this location, and the location of the sling is close to the sphincter. Comparing our results with those from a study of 124 patients with mild to moderate SUI after radical prostatectomy treated with the transobturador Advance™ sling, the efficiency rates were comparable, with 59.4% completely dry at 12 months of follow-up in our series compared with 55.7% at 12 months in their study. However, the postoperative complication rate, in particular AUR, was greater than in our series (12.9% with the Advance™ sling). A recently published Advance™ series reported 2.8%-5.7% of patients with posturinary retention (mean follow-up of 35 weeks vs follow-up of 12 months). In addition, the mean interval needed to implant the Advance™ sling was 97 minutes, longer than that required in our series (36.3 minutes). Overall, the results of the present study have shown that the 1-STOP TOMS achieves adequate suburethral
positioning to obtain good continence in most patients without causing obstruction or other adverse events.

CONCLUSIONS
The I-STOP TOMS is an appropriate choice for nonradiated patients with mild to moderate post-prostatectomy SUI. At ≤12 months, most patients were continent or had improved continence. The operation time was short, and the intervention was well tolerated, with minimal postimplantation pain and few cases of infection.

Acknowledgements. To CL Medical, who provided the I-STOP TOMS male slings; and to Ismar Healthcare for their assistance in writing the report, with thanks.

References

APPENDIX
The HOMme INContinence study group consisted of the following participants: I. Bah-Clozel, Clinique Pasteur, Guiler-and Oranges; O. Bochereau, Clinique Saint-Augustin, Nantes; B. Chavrier, Clinique de la Sauvagende, Lyon; P. Coeurdamier, Polyclinique Sévigné, Cesson Sévigné; F. Collet, Clinique Trénel, Sainte-Colombe; E. David, Polyclinique du Grand Sud, Niames; A. Delannoy, Centre Hospitalier Avranche-Granville, Avranche; O. Delbos, Clinique du Millénaire, Montpellier; L. Drelon, Clinique des 2 Caps, Coquelles; D. Dupuy, Clinique Ambrose Paré, Toulouse; R. Faye, Clinique de l’Anjou, Angers; J. Graill, Clinique de Fontaine, Dijon; E. Gremmo, Polyclinique Synergia, Carpentras; P. Grise, Hôpital Charles Nicolle, Rouen; O. Lan, Polyclinique Synergia, Carpentras; B. Le Portt, Clinique Océane, Vannes; F. Levigne, Centre de l’Hospitalisation Privée de la Loire, Saint-Étienne; J. Lienhart, Clinique Trénel, Sainte-Colombe; P. Lille, Clinique Saint Odilon, Moulins; A. Manunta, CHU Pontchaillou, Rennes; B. Marc, Polyclinique Saint-Privat, Boujon-sur-Libran; O. Marecaux, Clinique Sainte-Catherine, Sainte-Catherine-lez-Arras D. Miane, Clinique de Provence, Orange; B. Nijniou, Clinique des Ormeaux, Le Havre; C. Olivier, Polyclinique du Sidober, Castres; P. Paulhac, Clinique des Émailleurs, Limoges; Y. Perraud, Centre de l’Hospitalisation Privée de la Loire, Saint-Étienne; O. Rousseau, Clinique du Cédre, Beis-Guillaume; J. Serkissian, Hôpital Jean Mermoz, Lyon; C. Sausanne, Centre Hospitalier Universitaire-Hôpital Civil, Strasbourg; J. Vannier, Clinique Saint-Augustin, Tours; R. Vautherin, Clinique Trénel, Sainte-Colombe; and G. Ybert, Clinique Chirurgicale Marie Immaculée, Bourges.
TRANS-OBTURATOR MALE SLING TOMS FOR THE TREATMENT OF URINARY STRESS INCONTINENCE IN MEN.

Aims of study
Despite improvement in the surgical technique of radical prostatectomy, stress urinary incontinence (SUI) remains a problem that affects the quality of life of many patients. The prevalence of post-prostatectomy depends on the definition of incontinence. In order to minimize surgical morbidity and cost of the artificial sphincter, sling procedures were described with or without bone anchor. With the experience of the female trans-obturator polypropylene sling, a new trans-obturator male sling (TOMS) was developed, the first results with minimal one year experience are reported.

Material and methods
A prospective multicenter clinical study was conducted on male patients suffering from post prostatectomy incontinence and failure of physiotherapy. Patients with minor or moderate SUI were included with minimal 12 month follow-up. Exclusion criteria were pre or post-operative radiation, less than one year interval from surgery, bladder outlet obstruction, bladder overactivity or hyponephrosis. Pre operative assessments included clinical study questionnaire, urodynamics (urocystometry, uroflowmetry, bladder residual), a pad test short form, ICIQ and SF36 questionnaire, Visual analogic pain scale (VAS). Post-operative evaluations were at 1, 6, 12, 18 and 24 months using the same evaluation except urocytostomanometry. Per and post-operative hazards were recorded on a case report form. The sling was made of polypropylene macroporous non extensible, 1 cm large, connected at each end to a needle attachment device. Hemotic or helicoidal needle was used according to surgeon preference. The surgical technique was done under spinal or general anaesthesia, a 16 F Foley urethral catheter was inserted then a median perineal incision exposed the angle between each corpus cavernosum and corpus spongiosum. The trans-obturator puncture was outside similar to the female procedure. The sling was applied to the urethra then pulled firmly from each side to have a visible mark on the corpus spongiosum. No retrograde pressure adjustment was realized. The urethral catheter was left for 1 day. Before hospital discharge, an uroflowmetry, a residual, and a pelvic pain evaluation on VAS were obtained.

Results
A total of 14 patients, age 70.8 (57-87) years old underwent surgery. Mean follow-up was 18 (12-23) months. The surgery was easy to perform in all the cases. No per-operative complications were reported, no significant intra-operative bleeding (+200ml) occurred or nerve, bowel or vascular injury. One patient experienced temporary urinary retention, one a low stream, and residual was always less than 100 ml. Mean pad use modified from 2.4 to 0.9, and 50% of them used no pad. Pad test mean weigh decreased from 62g to 8 g. The SF36 score improved from a median of 120 (57-325) to 317 (92-500), the Mann-Whitney test was significant with p < 0.001. The ICI-Q score improved from 13 (6-16) to 7 (0-15). The pain mean value was 2.5 post-operatively, 0.9 at one month and 0.1 at one year.

Interpretation of results
Patients with minimal and moderate incontinence are demanding of improvement and even only one pad a day affects their quality of life. Many new minimal invasive techniques (injectable biomaterials, balloons, sling with bone screw attachment or with retropubic puncture) have been proposed for managing SUI in males but they had adverse side effects or poor results. The artificial sphincter remains the gold standard technique, but the cost and the erosion or infection rate limit the indication for severe incontinence. The transobturator sling has no screw fixation and minimal well tolerated polypropylene biomaterial, this may explain the good tolerance and minimal pain. This route is an alternative to retropubic puncture that limit the risk of bladder perforation. This short series demonstrate the feasibility, the good tolerance, and marked improvement in continence.

Concluding message
The trans-obturator male sling (TOMS) is a new attractive surgical procedure for moderate or minor post-prostatectomy SUI. The implanted biomaterial is non mechanical, easy to insert and well tolerated. Most of the patients are improved or continent with one year follow-up. In properly informed patients, this sling may afford an improvement in their quality of life.

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TRANSOBTURATOR DOUBLE ARM MALE SLING TOMS FOR MALE URINARY INCONTINENCE

Author Block: Philippe Grize*, Rouen, France; TOMS Study Group

Abstract: Introduction and Objective: Sling procedures are an attractive alternative to the artificial sphincter for postprostatectomy stress urinary incontinence (SUI) in order to minimize surgical morbidity and cost of the surgery. With the experience of the female trans-obturator polypropylene sling, a new double arms trans-obturator male sling (TOMS) was developed, the results with minimal one year experience are reported.

Methods: A prospective multicenter study was conducted on patients suffering from mild or moderate SUI. Exclusion criteria were pre or post-operative radiation, bladder overactivity or hypocompliance. Evaluation included clinical study questionnaire, urodynamics, ICIQ and SF36 questionnaire. Visual analogic pain scale (VAS). The sling was made of polypropylene macroporous non extensible, 1 cm large, connected at each end to a needle attachment device. Hemet or helicoidal needle was used according to surgeon preference. The trans-obturator puncture was outside-inside similar to the female procedure. The sling was applied to the urethra then pulled until to have a visible mark on the corpus spongiosum. No retrograde pressure adjustment was realized. Before hospital discharge at day 2, a residual and a pelvis pain evaluation were obtained.

Results: A total of 14 patients, age 70.8 (57-87) years old underwent surgery with minimal 12 months year follow-up. The surgery was easy to perform in all the cases. No per-operative complications were reported, no significant intra-operative bleeding (>200 ml) occurred or nerve, bowel or vascular injury. Residual was always less than 100 ml except 1 urinary retention and 1 low stream. Mean pad use modified from 2.4 to 0.9, and 50% of them used no pad. The SF36 score improved from a median of 126 (57-325) to 317 (92-500), the Mann-Whitney test was significant with p < 0.001. The ICI-Q score improved from 13 (6-16) to 7 (0-15). The pain mean value was 2.5 post-operatively, 0.9 at one month and 0.1 at one year. Conclusions: The trans-obturator male sling (TOMS) is a new attractive surgical procedure for moderate or minor post-prostatectomy SUI for patients demanding of improvement on their daily life comfort. The implanted biomaterial is non mechanical, easy to insert and well tolerated, has no screw and no retropubic puncture. Most of the patients are improved or continent with one year follow-up.

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Incontinence after Prostatectomy — The Transobturator I-STOP™ Male Sling as a New Treatment Option

a report by

Philippe Grise

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A new minimally invasive sling technique has been developed for the management of post-prostatectomy incontinence as a simple and well-tolerated alternative to artificial sphincter, using the latest improvements in female transobturator sling with specific adaptation for males. Early results are encouraging and this technique seems to be a valuable alternative to the artificial sphincter in moderate incontinence and could also be proposed to patients with minor, but annoying, incontinence.

Stress urinary incontinence (SUI) following prostatectomy is a very distressing complication. The rate of persistent post-radical prostatectomy incontinence, despite active conservative measures, varies widely at 2–65% depending on continence definition, method of assessment and surgical procedure. Prostatectomy is the curative surgery of a localised prostate cancer, particularly for men with a long life expectancy. The prevalence of prostatectomy has increased due to early detection by prostate-specific antigen of adenocarcinoma, which is the most common cancer in men. After prostatectomy for benign prostatic hyperplasia, incontinence is less common but still has devastating effects on the patient’s quality of life.

The gold standard in severe cases is still the implantation of an artificial hydraulic urinary sphincter; however, the materials are expensive and may expose the patient to urethral erosion or infection, leading to explantation. In moderate incontinence, a variety of alternative minimally invasive techniques have been proposed, such as injection or sling. Endo-urethral bulking-agent injection may initially improve minimal incontinence, but the injections must be repeated in the majority of cases and the results often dramatically decrease with time.

These considerations have more recently led to developments in the field of sub-urethral male sling. Initial reports were compressive bulbo-urethral slings with silicone material and retropubic suspensions. These showed efficacy, but retropubic puncture may expose the patient to bladder perforation. Moreover, the tension of the sling was intentionally compressively adjusted using retrograde urethral pressure. An alternative procedure has been proposed using the bone-anchored male sling attached to the pubic bone, with the sling biomaterial being a large-surface silicone mesh. Although efficacy was reported in approximately 70% of cases, prolonged perineal pain was frequent and some patients experienced biomaterial infection leading to explantation.

The transobturator I-STOP™ male sling was developed to provide moderate compressive support to the bulbo-urethra via a well-tolerated biomaterial using a simple technique. Clinical experience of female transobturator I-STOP sling in routine practice has been the cornerstone to extending this material for male incontinence specificity and adapted to the male pelvic anatomy. The prosthetic implant is placed under the bulbo-urethra and passes through the obturator foramen as the sole lateral fixation.

Initial Experience

An anatomical cadaveric study was conducted to validate the transobturator route in males and to validate the point and direction of the puncture. A preliminary human implantation was then carried out in four cases with the same material as that used for women, but with a specific male transobturator puncture and a perineal incision. The results were encouraging, with three patients totally dry and one improved for incontinence. A pilot, prospective multicentre study of 50 patients with moderate post-prostatectomy incontinence has been in progress since June 2006.

Technique

Material

The I-STOP sling, developed by CI. Médical, has the following characteristics:

- exclusively monofilament polypropylene mesh;
- macropores over 75 micrometres;
- no-string effect as the width (15mm) is
maintained despite sustained traction;
- no shape memory;
- non-aggressive edges;
- low weight per area obtained by fine thread; and
- specific knit weave.

**Delivery System**

The sling is attached at each end to a chip. Two long, curved needles with special handles are supplied with the implantation kit.

**Surgical Technique**

Implantation was performed under general anaesthesia with patients placed in the dorsal lithotomy position. A 16-French urethral catheter was inserted at the beginning of the procedure and removed on day two.

A perineal sagittal incision was made and the bulbocavernous muscle exposed but left in situ. The dissection was then conducted laterally in the space between the urethra and each corpus cavernosa covered by ischiocavernosal muscle. A short incision of the perineal fascia (i.e. perineal aponeurosis) affords access more deeply towards the obturator muscle just above the ischio-pubic ramus bone. This allows palpation of the inside landmark using the tip of the finger.

**Outcome**

Prospective multicentre studies have confirmed that this new technique is easy to perform. Results have been evaluated on validated questionnaires and pad tests. While the one-year outcome is still awaited, the preliminary results at three months in the operated-on patients have demonstrated either cure or incontinence improvement. Moreover, the patients did not suffer any perineal pain and no biomaterial infection or urinary retention was observed.

Lessons from clinical experience underline the fact that the male pelvic anatomy is different from the female and the transobturator technique must take into account male specificity. The direction of the puncture needle is deeper and in a narrow area to reach the right place close to the inferior pubic ramus through the obturator foramen. The perineal dissection beyond the fascia is also deeper than that for the female, but this step is quickly performed and with little or no bleeding. The biomaterial implanted has no silicone, with a surface close to the urethra large enough to support it with no string effect. The amount of biomaterial is limited in order to minimise the risk of prosthetic infection. The transobturator route is also a major step in avoiding the risk of retropubic bladder perforation or the risk of osteitis or pain from bone-anchor fixation.

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**The preliminary results of the transobturator I-STOP male sling are sufficiently encouraging to consider it as a new treatment option of choice for moderate post-prostatectomy incontinence...**

A puncture of the root of the thigh, 4cm from the median line and 4cm below the major adductor muscle, is performed. The specific needle is inserted to puncture the obturator foramen in order to reach the tip of the finger on the inside landmark. The tape is clipped to the needle tip and exteriorised inside-outwards to the thigh. After puncturing the opposite side, the sling is adjusted with a pressure on the bulbocavernous muscle and a four-corner non-resorbable suture is carried out to avoid any sliding of the tape and to prevent any string effect. No retrograde pressure is performed in order to adjust the sling pressure, however, a visible curved depression is obtained on the muscle in order to afford only a slight compression. The wound is closed in two layers with an absorbable suture.

Pressure of the male sling is adjusted using only visual control, with no retrograde pressure. This approach is advocated as many anatomical and functional structures providing continence must be considered as well as standing position and SUI factors.

Another consideration is that of cost-effectiveness — the I-STOP male sling is far less expensive than an artificial sphincter or bone-anchor sling.

**Conclusion**

The preliminary results of the transobturator I-STOP male sling are sufficiently encouraging to consider it as a new treatment option of choice for moderate post-prostatectomy incontinence and also in patients with minor, but troubling, incontinence.
Four-arm Transobturator Male Sling for Post-prostatectomy Urinary Incontinence
Philippe Grise

Professor of Urology, Rouen University
Incontinence post-prostatectomy remains a problem, even when minor or moderate. In order to minimise surgical morbidity and costs, sling procedures have been proposed. The authors have developed a new transobturato male sling (TOMS) procedure and reported their results after one-year experience. Materials and Methods: A prospective multicentre study was conducted in 96 patients suffering from minor or moderate post-prostatectomy incontinence. Evaluation of the I-Stop™ two-arms bulbar TOMS was based on clinical form assessment using the Incontinence Questionnaire-Short Form 36 (IQ-SF 36) questionnaire pre-and post-operatively and at three, six, nine and 12 months. Results: The surgical procedure was considered easy to perform and no post-surgery complications were reported except for one retention. The median number of pads per day decreased significantly from two pads before surgery to one during the follow-up period. The SF-36 continence and quality of life scores improved from a median of 117 to 308, and the median ICIQ and quality of life score decreased from 15 to 5 one year after the intervention. Conclusion: The I-Stop TOMS is an attractive, simple surgical technique for moderate or minor post-prostatectomy stress incontinence and offers an improvement in the quality of life.

Keywords
Urinary incontinence, sphincter deficiency, prostatectomy surgery, sling

Disclosure: Philippe Grise is the main investigator of the I-Stop™ TOMS sling (DC Medical), in which he has no financial interest.
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The number of patients suffering from post-prostatectomy incontinence is increasing. Despite improvement in surgical techniques, the number of such patients has increased with the progression of early-detected localised prostate cancer in men. Depending on the study and definition of incontinence, the incidence of post-prostatectomy incontinence is estimated to be from 1 to 55% of men.1 The wide range of reported rates of incontinence early after surgery decreases during the one-year post-surgery period and with physiotherapy sphincter exercises. Incontinence that persists after one year is estimated to affect fewer than 5% of patients.2 Quality of life is strongly affected, and even a minor leakage requiring one pad a day may be highly bothersome.3 Transurethral prostatectomy or high-frequency ultrasounds are rarely causes of incontinence.

Clinical symptoms are stress urinary incontinence (SUI) that increases with physical effort during the day, but for some patients urine may be expressed mainly during the afternoon. Initial assessment includes a urinary diary; a questionnaire in order to gauge the precise type of incontinence and severity and number of pads used or, optimally, a pad test. The International Consultation on Incontinence Questionnaire-Short Form (IQ-SF) questionnaire is a very simple and useful tool recommended by the European Urological Association. Urgo incontinence may be associated with an overactive detrusor. The severity of incontinence affects quality of life. According to Stamey, the grading of SUI can be mild (incontinence only with severe stress, such as coughing or sneezing), moderate (incontinence with minimal stress, including walking or severe (major incontinence and incontinence during the night). Practically, severe incontinence is suspected when the number of totally wet pads used is more than four per day, or when there is over 200ml of urine during the 24-hour pad test.

After first-line treatment with pelvic floor exercises, the persistence of incontinence requires complementary examinations. Ultrasound evaluates residual urine and a urethrocystoscopy evaluates the sphincter and anatomy. Urodynamic is indicated before surgery to determine bladder capacity and activity. However, a sphincter deficiency is difficult to determine. Low maximal urethral closing pressure suggests a sphincter deficiency, but a normal value may be associated with a weak sphincter. An associated evacuative bladder or anatomosis structures must be ruled out and treated before incontinence surgery. The pathophysiology of male stress SUI is mainly a sphincter deficiency, but an excess of mobility of the bulb and membranous urethra may be an associated factor.

A transobturato sling is the logical progression in minimally invasive treatment for mild or moderate male incontinence. For severe SUI, an artificial sphincter remains the gold standard technique for severe incontinence due to sphincter deficiency, with an 80% continence rate, despite a high cost and risk of erosion or infection.
These factors and the need for patients to press a pump for each micturition make many patients reluctant to have this type of surgery for moderate incontinence. In order to minimize surgical morbidity and cost, for mild or moderate incontinence minimally invasive options have been proposed, i.e. sling procedures and balloons, bulking agents and stem cell therapy.

As regards urethral bulking agents, many agents have been used but they are often disappointing. Short-term results are good, but long-term success is poor even with reinjections. Stem cell therapy is a research treatment that involves a complicated laboratory procedure. An adjustable balloon is an alternative to the sling procedure and is based on a mechanism of lateral compression from the proximal urethra. Patients who use up to one pad a day were reported in 60% of cases, but the high rate of complications during and post-surgery and several adjustments were of some concern. Slings are the more commonly proposed treatment for mild to moderate female SUI.

The concept of minimally invasive surgery with perineal bolsters acting as a sling on the urethra was described by Schaeffer et al.1 The initial results were excellent for continence with no significant outlet obstruction, but the outcome was complicated by balanitis removal due to pain, infection or erosion. Efficacy was demonstrated in an average of four years with a 42% cure rate. In order to improve tolerance and by using a retropubic puncture, John used a bidimensional composite suspension with porcine dermis and polypropylene sling, and Xu et al.5 used a sling made of polyester plus polypropylene. There is concern regarding the retropubic route due to a risk of a bladder puncture or erosion, and the adhesions from the prostatectomy may increase the risk of using this route.

A new concept of a large perineal sling on the bulbar urethra was introduced with the in Vancore bone-anchored male sling, which is made of a large triangular silicone-coated biomaterial. Comparing et al.15 reported 65% cured and pad-free patients at minimum two-year follow-up with a polypropylene or polyester mesh using bone anchor fixation. However, up to 10% of patients reported perineal pain or numbness that persisted for many weeks. These adverse effects might possibly be due to irritation in the area of the bone screws or a lesion to the perineal nerves during ischial tuberosity dissection. In addition, infection of the biomaterial frequently occurred due to the use of a large silicone-coated membrane instead of macroscopically mesh tape and biomaterial, characteristics that may explain morbidity, including istheseals from bone screws. After radiation, patients had a significantly lower cure rate.

Different biomaterials were also used for the sling (allograft, porcine xenograft, synthetic and composite mesh), but a poor outcome resulted from the non-synthetic graft.6 The successful tolerance of polypropylene is widely accepted. A prodynamic study revealed that the bulbar urethral sling had no significant effects on voiding function. Nevertheless, post-surgery retention may occur, possibly due to an excess in sling tension or an incompressibility bladder reflex. A decision should be discussed with the patient about the possibility of immediate re-operation to release the tension on the tape or to wait a few weeks with self-catheterization.

The transobturator route was usually used for female incontinence, but in males this route was initially reported by Bauer et al.16 in a cadaver study of three males using a holocutaneous puncture from inside to outside. We conducted a cadaver study that confirmed this approach, and added the feasibility of outside-inside puncture in male patients. A prospective study with Ethical Committee approval then followed and was conducted using a polypropylene sling on the bulbar urethra and a transobturator puncture. Other bulbar slings have also been described recently. The Argus sling, adjustable and made of silicone that is exposed to erosion or infection. The De Laval sling is a polypropylene sling but with an additional subcutaneous lateral route to tie the two lateral arms to each other. The stronger attachment must be evaluated in respect of potential complications due to a larger amount of biomaterial and a wider dissection. The AdVance male sling system is located more proximally on the bulbar-membranous urethra in order to modify mobility and to act as a hammock-like support of the posterior sphincter complex, but tension is also applied on the sling. A proximal dissection close to the sphincter is a potential risk for a major deficiency. In addition, the membranous urethra is thin and fragile, which exposes it to urethral erosion.

There is concern regarding the retropubic route due to a risk of a bladder puncture or erosion, and the adhesions from the prostatectomy may increase the risk of using this route.

There have been encouraging results with the transobturator male sling (TOMS) on continence and good tolerance with minimal pain and no infection. The initial TOMS with two arms showed the following results on continence. After surgery, 50% of patients used no pads per day, and 32% used one pad per day. Sling failure was the result of the sling having slipped and not being close to the urethra. A new larger four-arm TOMS using the same biomaterial was studied using the same criteria in a prospective study conducted from May 2006.

The Transobturator Male Sling Procedure

The sling (developed by CL Medical) (see Figure 1) has four arms (two arms on each side) made of monofilament polypropylene, with macro pores over 75 micrometres, is non-extendable, 45cm long and 1.4cm wide, and has a central part that is 2.8cm wide over the urethra. The sling is attached at each end to a clip in order to
Incontinence

The surgical technique is performed under spinal or general anaesthesia, and a 16-F Foley urethral catheter is inserted. The patient is placed in the lithotomy position and a 6cm median vertical perineal incision is made below the inferior border of the pubic symphysis to expose the bulbospongiosus muscle. The perineal space is then dissected laterally by each ischiocavernosus muscle and medially to the bulbospongiosus. A 2cm incision through the rectal fascia enables access to the obturator muscle just under the ischiopubic ramus bone. A stab incision is made at the top of the hymen, 4cm from the median line and 4cm below the major adductor longus muscle. The transobturator puncture is preferably outside-in with a Hemostat needle. The end-point of the puncture is the opening in the pelvic fascia. After the slings are attached to the needle, pulling back the needle implants 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 bulbocavernosus muscle with non-absorbable sutures and then pulled firmly from each side in order to obtain a 2mm visible mark on the bulbospongiosus muscle. The perineal body is not dissected, but in case of rolling of the inferior edge of the sling on the bulb, the bulb is dissected just enough to apply it under the sling, until sutured to the sling. No retrograde urethral pressure adjustment is necessary. The incision is closed without drainage and the urethral catheter left for two days. Before hospital discharge, a post void residual and pelvic pain evaluation on the visual analogue scale (VAS) should be obtained.

Clinical Results with the Four-arm Transobturator Male Sling

A prospective multicentre study was conducted on 94 male patients suffering from mild or moderate post-prostatectomy incontinence after a failure of physiotherapy and a minimum of one year after surgery without radiation. The study received Ethical Committee approval.

Pre- and post-surgery assessments included previous medical history, physical examination, a clinical study questionnaire about urological symptoms and number of pads used per day and urodynamics (cystometrogram and post-void residual urine). The patients completed the IQ-C-SC and the SF-36 questionnaire and a VAS before and after surgery. The number of patients studied at follow-up visits at one, three and six months, respectively, was 93, 82, and 81.

Changes on SF-36 and IQ-C were found not to follow an approximate normal distribution. Accordingly, changes in these endpoints were analysed using Winconsin’s sign rank test. Changes in flowmetry more closely followed an approximate normal distribution and were analysed using Student’s t-test. Both tests examined departures from the null hypothesis of no overall change from baseline. All analyses were performed using the univariate procedure in SAS v9.1. P-values of less than 0.05 were considered statistically significant, and those less than 0.01 were considered to be highly statistically significant.

Results

The surgery was considered by the surgeon to be easy to perform in all cases. The median operative time for the procedure was 30 minutes (25-45 minutes). No surgery complications were reported, no significant intra-operative bleeding (>200ml) occurred and there was no nerve, bowel or vascular injury. On the VAS, the median pain value the day after surgery was 2, then decreased significantly to 1.2 at one month and remained at 0.4 for all further visits. After catheter removal, residual urine was less than 50ml for all patients. The maximum flow rate median value was 23ml/sec before surgery and 17.5ml/sec at one month, 19ml/sec at three and six months. The change was significant one month post-surgery but not for the three- and six-month follow-up period. Overall, median pad use decreased significantly from two pads per day before surgery to one pad per day for all the visits thereafter. At one, three and six months the number of pad-free patients was, respectively, 60, 51 and 51.

Continence rate of use of no or one pad per day was, respectively, 74, 82 and 83%. The SF-36 score of continence, measured on a scale ranging from 0 to 100, improved highly significantly (p<0.001) from a median score of 117 before the TCMS was inserted to 350 at one month, 338 at three-month and 308 at six-month follow-up. The IQ-C incontinence median score decreased highly significantly (p<0.001) from 14 before the TCMS was inserted to 5 at one- and three-month follow-up and to 6 at six-month follow-up.

Conclusion

The new four-arm TCMS is an attractive, simple and safe sling for mild or moderate post-prostatectomy incontinence in non-radiated patients. Most of the patients are cured and have improved quality of life.
Transobturator Male Sling TOMSTM for the Treatment of Stress Post-Prostatectomy Incontinence, Initial Experience and Results with One Year’s Experience

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ABSTRACT

Purpose: Post-prostatectomy incontinence remains a problem, even in minor or moderate degrees. In order to minimize surgical morbidity and costs, sling procedures have been proposed. The authors have developed a new transobturator male sling procedure and report their results after one-year experience.

Materials and Methods: A prospective multicenter study was conducted in 50 patients with minor or moderate post-prostatectomy incontinence. Evaluation of TOMSTM two arms bulbular sling was based on clinical form assessment, The International Consultation on Incontinence Questionnaire (ICIQ) and short-form (SF) 36 questionnaire pre and postoperatively and at 3, 6, 9 and 12 months.

Results: The surgical procedure was considered easy to perform and no post-surgery complication was reported except for one retention. The median number of pads per day decreased significantly from 2 pads before surgery (95% CI: 2 - 3) to 1 during the follow-up period (95% CI: 0 - 2 at 360 days), and at 3 months patients using none or one pad per day were 30% and 32% respectively. The SF 36 continence and quality of life score improved from a median of 100 (95% CI: 83 - 133) to 300 (95% CI: 167 - 375), and the median ICIQ incontinence and quality of life score decreased from 15 (95% CI: 14 - 16) to 8 (95% CI: 5 - 12) one year after surgery.

Conclusion: The transobturator perineal male sling TOMSTM is an attractive simple sling technique for moderate or minor post-prostatectomy stress incontinence and offers an improvement in the quality of life.

Key words: urinary incontinence; male; urinary sphincter; prostatectomy; surgery; sling Int Braz J Urol. 2009; 35: 706-15

INTRODUCTION

Despite improvement in surgical technique of radical prostatectomy, incontinence remains a bothersome problem. The prevalence of post-prostatectomy depends on the definition of incontinence and evaluation methods; however, studies indicate that 5% to 55% of patients are concerned (1). Even only one pad a day affects the quality of life (2).

For major stress urinary incontinence (SUI), the artificial sphincter remains the gold standard technique despite a risk of erosion or infection. As regards urethral bulking agents, they are often disappointing even with re-injections.
In order to minimize surgical morbidity and cost, bulbar sling procedures have been proposed of which the most common sling used is bone-anchor fixation. Good results without significant obstruction were obtained but concern remains regarding perineal pain and infection of the material. Based on our experience of the female transobturator polypropylene sling (3) we developed a new transobturator bulbar male sling (TOMSTM) (4) in order to minimize the adverse effects of bulbar slings. Other male transobturator slings (5-8) have also recently been reported in the bulbar location (5,7,8) or in membranous location (6). The benefits and our clinical results were studied in a prospective multicenter series. The results with one year’s experience are reported.

MATERIALS AND METHODS

In a preliminary study (4) on six male cadavers in the lithotomy position, the surgical technique was performed using a vertical perineal incision. The bulbospongiosus muscle was dissected, then the ischiocavernous muscles, in order to expose the perineal aponeurosis close to the ischiopubic ramus bone and the obturator foramen situated just above the ramus. The surgical procedure was evaluated concerning outside-inside and inside-outside transobturator puncture in male pelvis using respectively Hemet and helical needle.

Therefore, a prospective multicenter clinical study was conducted from May 2006 to August 2007 on 50 male patients suffering from post prostatectomy incontinence and after a failure of physiotherapy. Our study received Institutional Ethics Committee approval.

All surgeons were experienced in transobturator procedure for female stress incontinence and followed the same instructions for surgery. The number of surgeons involved was ten and their first patients were included in this series.

A total of 50 patients were included with minimal 12 months follow-up. Exclusion criteria were pre or post-surgery radiation, less than one year before surgery, bladder outlet obstruction from anastomotic or urethral stricture, bladder overactivity or bladder hypocompliance. Only minor or moderate SUI patients according to the Stamey definition were enrolled based on the urologist’s evaluation and 5 or less pads per day.

Pre-surgery assessments included previous medical history, physical examination, clinical study questionnaire for urological symptoms and number of pads per day, urodynamics (urethrocystometry, uroflowmetry, post-void residual urine) according to the recommendations of the International Continence Society, and cystourethroscopy to rule out any anatomical abnormality.

The patients completed the International Consultation on Incontinence Questionnaire – Short Form (ICIQ-SF) (9) and the Short-Form (SF) 36 (10) questionnaire, and a visual analog pain scale (VAS) before and after surgery.

The physician recorded post-surgery evaluations at 1, 3, 6 and 12 months using the same evaluation except for urothrocystometry. As regards safety assessments, potential per and post-operative hazards were recorded on a case report form.

The sling was a monofilament polypropylene, with macro pores over 75 micrometers, non-extensible, 45 cm long x 1.4 cm large, developed by CL Medical (4). The sling is attached at each end to a clip in order to connect it to a specific needle. Hemet or helical needle was used according to the surgeon’s preference.

The surgical technique was performed under spinal or general anesthesia, and a 16F Foley urethral catheter was inserted. 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 the perineal aponeurosis at the top of the triangular space delimited laterally by each ischiocavernous 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 bulbous spongiosus muscle with non-absorbable sutures, and then pulled firmly from each side in order to obtain a 2 mm visible mark on the bulbous spongiosus muscle. The perineal body was not dissected, but in cases of rolling of the inferior edge of the sling on the bulb, the bulb was dissected just enough to apply it under the sling, then sutured to the sling. No retrograde urethral pressure adjustment was performed. The incision was closed without drainage and the urethral catheter left indwelling for 2 days. Before hospital discharge, an uroflowmetry, a post void residual, and a pelvic pain evaluation on VAS were obtained.

Statistical analysis - The description of the population at baseline was done using the median, the first and the third quartile (Q1 - Q3). As regards the trend over time, the results of each visit were summarized using the median and a 95% confidence interval (CI). For the graphical illustration of these trends, box-plots, as described by Tukey (11), were used. In order to test the hypothesis of no change between consecutive visits against the alternative that there was a change, rank based methods were applied. As the power of these tests depends among others on the proportion of tied observations, Wilcoxon’s test for dependent samples was used for all tests relating to the same variable if the first quartile at any visit was larger than zero. For all other variables, the sign test was used in order to verify whether changes between consecutive visits were significant. Admitting for each variable a global level of 0.05 for answering the question whether a change occurred between any two consecutive visits, Holm’s method was used to control for the inflation of the risk of a Type-I error.

RESULTS

In the cadaveric procedures, the perineal approach to the bulbar urethra and the outside-inside or inside-outside puncture of the obturator foramen were easily performed.

Concerning the clinical study, a total of 50 patients with a median age of 72 years (Q1 - Q3: 64 - 77) underwent TOMS™ surgery. Incontinence was a problem for all the patients. At least half of them wore 2 pads per day (Q1 - Q3: 1 - 3). History of prostatic surgery was radical prostatectomy for 48 and transurethral prostatectomy for 2 patients, the median time between prostatectomy and surgery for SUI was 35 months (Q1 - Q3: 22 - 50).

The surgery was considered by the surgeon as easy to perform in all the cases. The median operative time for the procedure was 30 minutes (Q1 - Q3: 25 - 45).

No per-surgery complication was reported, and no significant intra-operative bleeding (> 200 mL) occurred or nerve, bowel or vascular injury.

On the VAS, the median pain value the day after surgery was 2 (95% CI: 1 - 3), then decreased significantly to 0 (95% CI: 0 - 0) at one month and remained similar for all further visits until the end of the study.

After urethral catheter removal, residual was less than 100 mL for all the patients except one patient who experienced urinary retention. This patient was reopened (day 2) to release the tension on the tape, and then a good result on micturition and continence was obtained. A low stream was reported for one patient but this was not bothersome. Maximal flow rate was 20 mL/sec on the median (95% CI: 17 - 24) before surgery and 16 (95% CI: 8 - 26) when evaluated after catheter removal; the values (Figure-1) did not change significantly during the follow-up period.

Overall median pad use decreased significantly (p-value used sign test and is reported in Figure-2) from 2 pads per day (Q1 - Q3: 2 - 3) before discharge and at one month, to 1 pad for all the visits thereafter (Figure-2). At three months and during the follow-up period to 12 months, patients using none or one pad per day were 30% and 32% respectively.

The SF36 continence scores, measured on a scale ranging from 0 to 500 (Figure-3), improved significantly from a median score of 100 (95% CI: 83 - 133) to 300 at one year (95% CI: 167 - 375). During the follow-up period, the median scores were 242, 217 and 267 at 1, 3 and 6 months respectively.

The ICIQ incontinence score (Figure-4) decreased significantly from 15 (95% CI: 14 - 16) before the TOMS sling to 8 (95% CI: 5 - 12) at one year, and the median score was 9 for all other visits at follow-up.
Figure 1 – Maximum flow rate evaluated before being operated (OP) and after catheter removal (AC) and during the follow-up period. After correction for multiple testing, no significant change between visits was observed.

<table>
<thead>
<tr>
<th>consecutive visits</th>
<th>before OP, AC</th>
<th>AC, day 30</th>
<th>day 30, day 90</th>
<th>day 90, day 180</th>
<th>day 180, day 360</th>
</tr>
</thead>
<tbody>
<tr>
<td>p Value (Wilcoxon)</td>
<td>0.4258</td>
<td>0.0527</td>
<td>0.7574</td>
<td>0.6625</td>
<td>0.0391</td>
</tr>
</tbody>
</table>

Figure 2 – Overall median pad use was evaluated after being operated (OP) and on follow-up after surgery. It decreased significantly from 2 pads after surgery to 1 pad at 3 months and remained at 1 pad at 12 months.

<table>
<thead>
<tr>
<th>consecutive visits</th>
<th>before OP, day 30</th>
<th>day 30, day 90</th>
<th>day 90, day 180</th>
<th>day 180, day 360</th>
</tr>
</thead>
<tbody>
<tr>
<td>p Value (sign test)</td>
<td>0.8506</td>
<td>0.0094</td>
<td>0.5078</td>
<td>0.0391</td>
</tr>
</tbody>
</table>
Figure 3 – The SF36 continence score (0 to 500 scale) was evaluated before patients were operated (OP) and on days after surgery. It improved significantly after surgery, and during the one year follow-up period.

<table>
<thead>
<tr>
<th>consecutive visits</th>
<th>before OP, day 30</th>
<th>day 30, day 90</th>
<th>day 90, day 180</th>
<th>day 180, day 360</th>
</tr>
</thead>
<tbody>
<tr>
<td>p Value (Wilcoxon)</td>
<td>&lt; 0.0001</td>
<td>0.1211</td>
<td>0.1414</td>
<td>0.0681</td>
</tr>
</tbody>
</table>

Figure 4 – The ICIQ score of incontinence (0 to 21 scale) was evaluated before patients were operated (OP) and on days after surgery. It decreased significantly during the one year follow-up period.

<table>
<thead>
<tr>
<th>consecutive visits</th>
<th>before OP, day 30</th>
<th>day 30, day 90</th>
<th>day 90, day 180</th>
<th>day 180, day 360</th>
</tr>
</thead>
<tbody>
<tr>
<td>p Value (Wilcoxon)</td>
<td>&lt; 0.0001</td>
<td>0.4862</td>
<td>0.4063</td>
<td>0.4971</td>
</tr>
</tbody>
</table>
A number of minimal invasive techniques have been proposed for managing SUI in male patients but some of them have adverse side effects or minimal outcome measurements. Among them, the adjustable balloon is an alternative to the sling procedure based on a mechanism of lateral compression of the proximal urethra. Patients with none and one pad a day were reported in 60% (12), but the high rate of peri and post-surgery complications and several adjustments were of some concern.

The artificial sphincter remains the gold standard technique for severe incontinence due to sphincter deficiency although the cost, the erosion or infection rate as well the need to press the pump for each micturition, make many patients reluctant to have this type of surgery for moderate or minor incontinence.

The concept of minimal invasive surgery with perineal bolsters acting as a sling on the bulbar urethra was described by Schaeffer et al. (13). Initial success rate was excellent for continence with no significant outlet obstruction but outcome was complicated with bolster removal due to pain, infection or erosion. The efficacy was demonstrated on an average of four years (14) with a 42% cure rate.

In order to improve tolerance, John (15) reported a bulbourethral composite suspension with porcine dermis and polypropylene sling through the retropubic space. This author reported 69% continence patient with a 14-month mean follow-up. Using a retropubic sling made of polyester plus polypropylene Xu et al. (16) achieved successful treatment in 85% of 26 patients at 28 months.

There is a concern regarding the retropubic route due to a risk of bladder puncture or erosion (7), and the adhesions due to the prostatectomy may increase the risk of using this route.

A new concept of a large perineal sling on the bulbar urethra was subsequently introduced with the InVance™ bone anchored male sling made of a large triangular silicone coated biomaterial. Comiter (17) had 65% cured and pad free patients at minimum 2 year follow-up with a polypropylene or polyester mesh using bone anchor fixation, however up to 16% of patients reported perineal pain or numbness that persisted during many weeks. These adverse effects might possibly be due to irritation in the area of the bone screws or lesion to the perineal nerves (18) during ischiopubic rami dissection. Moreover, infection of the biomaterial frequently occurred due to a large silicone coated membrane instead of macroporous mesh tape, and biomaterial characteristics may explain the morbidity including osteomyelitis from bone screws.

Different biomaterials have been used for the sling (allograft, porcine xenograft, synthetic, composite mesh) but a poor outcome resulted from the non-synthetic graft (19), and the good tolerance of polypropylene is now widely accepted. The TOMS™ polypropylene tape is macroporous, non-extensible and the procedure is considered to be easy. No complication was reported and tolerance was good, particularly concerning perineal pain.

As other authors during peri-surgery we did not adjust the tension of the sling with the use of urethral pressure value as this measurement was retrograde, not standardized in technique and threshold. The sling was not clinically compressive for most of the patients as confirmed on clinical records, post-void residual and uroflowmetry, although a pressure-flow study was not conducted to document a possible urodynamic compressive effect. Urodynamic study in 22 men by Comiter (17) revealed that the bulbar urethral sling had no significant effects on voiding function. Nevertheless, in our series, one patient experienced postoperative complete retention possibly due to excess in tension or to an acontractility bladder reflex. The decision between immediate reoperation to release the tension on the tape, or after few days of self-catheterization should be discussed with the patient.

The data on continence confirmed the interesting results of the other retropubic and bone anchor bulbar urethral male slings. As in the reported series, about 60% of the patients used none and one pad per day at three months and during the follow-up period to 12 months.

An explanation why pad use did not change at 30 days follow-up could be that the patients were still anxious about leakage and used a safety pad.

Evaluation based on SF 36 scale and ICI-Q scale showed that the continence and the quality of life improvement was significant on both scales, and the results were maintained at one year.
Radiation was an exclusion criterion in order to present a homogenous series as this factor adversely affects male sling outcomes.

The transobturator route in male was initially reported by Bauer et al. (5) in a three male cadaver study using a helical puncture, our study confirmed this approach and added the feasibility of outside-inside puncture. In male patients, the transobturator tape was reported either on membranous urethra (6) using Advance sling, or on bulbar urethra using Argus sling (7) or De Leval sling (8) or TOMSTM sling (4). Argus sling (7) is made of silicone and is an adjustable sling. De Leval and Waltremy (8) used a polypropylene transobturator sling at the same position as our sling on the bulbar urethra; they obtained continence in 45% of their patients at 6 months. The difference between our techniques is that they performed an additional subcutaneous lateral dissection to tie the two lateral arms to each other, but more biomaterial and a larger dissection were risk factors for a potential infection or perineal pain. However, attachment of each arm to each other was probably stronger than to rely only on the transobturator route.

The mechanism of action may need further studies on the precise location and degree of male urethral mobility. The AdVanceTM male sling system (6) is located more proximally on the bulbar-membranous urethra in order to modify the mobility and to act as a hammock-like support of the posterior sphincter complex, but tension is also applied on the sling. A proximal dissection close to the sphincter is a potential risk for a major deficiency; moreover, the membranous urethra is thin and more fragile which may explain a reported case (20) of urethral erosion.

These results using TOMSTM sling remain encouraging but the continence results should be improved and a study is currently ongoing with a four arm larger sling using the same biomaterial and transobturator route.

CONCLUSION

The transobturator perineal male sling TOMSTM is an attractive technique for moderate or minor post-prostatectomy stress incontinence.

The implanted biomaterial is non-mechanical, and easy to insert and well tolerated. Most of the patients were improved or continent with a one year follow-up.

CONFLICT OF INTEREST

Philippe Grise is the main investigator of the TOMSTM study (CL medical company). No financial support was provided for the study and the authors received no funding for the study. Philippe Grise received funding as an invited speaker at a symposium by Ipsen and from CL Medical companies.

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Beyond the Abstract - Male stress urinary incontinence: The place of alternatives to an artificial urinary sphincter, by Philippe Grise, MD

Tuesday, 16 March 2010

BERKELEY, CA (UroToday.com) - The number of patients suffering from postprostatectomy incontinence is increasing despite improvements in surgical techniques. Quality of life is strongly affected, even in minor or moderate leakage. Pathophysiology of male stress urinary incontinence is mainly a sphincter deficiency, but a deficit in urethral support and an excess of mobility of the bulbar and membranous urethra may also be involved. After a first line treatment with pelvic floor exercises, the persistence of incontinence requires the assessment of the absence of an associated overactive bladder or an anastomosis stricture.

For severe stress urinary incontinence (SUI) due to major sphincter deficiency, the artificial sphincter remains the gold standard technique with 80% continence rate despite a high cost and a risk of erosion or infection. These factors and the need to press the pump for each micturition make many patients reluctant to have this type of surgery for moderate incontinence.

In order to minimize surgical morbidity and cost, for mild or moderate incontinence, minimally invasive options were proposed, i.e. sling procedures and balloon or bulking agents.

The results of urethral bulking agents on continence are disappointing. Adjustable balloon is a minimally-invasive procedure based on a mechanism of lateral compression of the proximal urethra. The rate of dry patients was only 30%, but patients with none and one pad a day were reported in 60%. Moreover, the high rate of pre and post-surgery complications (more than 50% in series) and several inflations of the balloons were of concern.

Slings are the more commonly proposed treatment for mild and moderate male stress incontinence. The concept of minimally invasive surgery with perineal bolsters acting as a sling on the bulbar urethra was described more than 10 years ago. The initial success rate was excellent for continence with no significant outlet obstruction, but outcome was complicated with bolster removal due to pain, infection or erosion. However the efficacy was demonstrated with a 42% cure rate.

Other slings were proposed but there was a concern regarding the retropubic route
due to a risk of a bladder puncture or erosion.

The concept of a large perineal sling made of silicone applied on the bulbar urethra and a bone anchor fixation was proposed with the InVance™ male sling. Many cases of infection of the silicone biomaterial and a 16% rate of patients suffering from perineal pain led to this sling being progressively abandoned despite good results with 65% of patients pad-free at two-year follow-up.

The transobturator route was first used for female incontinence, then applied to male patients and reported in 2006 by Grise. Two types of polypropylene transobturator male slings are proposed, depending of the location on the urethra: bulbar or membranous site. The AdVance™ male sling system is located proximally on the membranous urethra in order to modify the mobility and to act as a hammock-like support of the posterior sphincter complex, and a tension is applied on the sling. A proximal dissection close to the sphincter is a potential risk for increasing the patient’s deficiency; moreover the membranous urethra is thin and fragile which exposes it to urethral erosion. The sling is made of a large central part and 1 arm on each side.

The TOMS male sling (Figure 1) is located more distally, on the bulbar and post-bulbar urethra, which is covered with the bulbospongiosum muscle. The sling is made of a large central part with 2 arms on each side. The transobturator puncture was preferentially an outside-inside with Hemet needle but an inside-outside puncture may be performed with a helical needle.

Clinical results of four arms male sling TOMS

A prospective multicenter study was conducted on 96 male patients suffering from mild or moderate post prostatectomy incontinence and after a failure of physiotherapy and minimally one year post-surgery; radiated patients were excluded. The study received Ethical Committee approval.

Pre- and post-surgery assessments included previous medical history, physical examination, clinical study questionnaire for urological symptoms and number of pads per day, and urodynamics (uroflowmetry, post void residual urine). The patients completed the ICIQ-SF and the SF36 questionnaires, and a visual analog pain scale (VAS) before and after surgery. The number of patients studied at follow-up visits was at 1, 3 and 6 months respectively 93, 80, 54. The surgeon considered the surgery easy to perform in all the cases. The median operative time for the procedure was 30 minutes (25 - 45). No pre-surgery complication was reported, no significant intra-operative bleeding (>200ml) occurred or nerve, bowel or vascular injury.

On the VAS, the median pain value the day after surgery was 2, then decreased significantly to 1.2 at one month and remained at 0.4 for all further visits. After urethral catheter removal, residual volume was less than 50 ml for all the patients. Maximal flow rate median value was 23 ml/sec before surgery and 17.5 at 1 month then 19 at 3 and 6 months, the change was significant between pre-surgery and 1 month post-surgery but not at 3 and 6 month follow-up period. Overall median pad
use decreased significantly from 2 pads per day (2 - 3) before surgery and at one month to 1 pad for all the visits thereafter. At 1, 3, and 6 months, the number of pad-free patients was respectively 60%, 51%, 51%. The continence rate, using 0 to 1 pad per day, was respectively 74%, 82%, and 83%.

The SF36 score of continence, measured on a scale ranging from 0 to 500, improved highly significantly (p < 0.001) from a median score of 117 before the TOMS sling to 350 at 1 month, 338 at 3 months, and 308 at 6 months follow-up. The ICIQ incontinence median score decreased highly significantly (p < 0.001) from 14 before the TOMS sling to 5 at 1 and 3 months, and to 6 at 6 months follow-up.

In male stress urinary incontinence, there is a place for alternatives to an artificial urinary sphincter in mild or moderate incontinence. The artificial sphincter remains the gold standard for severe stress urinary incontinence, and male sling may be now proposed in mild or moderate incontinence in non-radiated patients. More than 50% of patients were completely continent and more than 70% of the patients were improved in their continence and their quality of life. TOMS bulbar sling is a safe procedure.

Figure 1. The sling is inserted by a perineal incision. The central part is on the bulbar urethra, and laterally the two arms are on each side.

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Written by:
Philippe Grise, MD as part of Beyond the Abstract on UroToday.com. This initiative offers a method of publishing for the professional urology community. Authors are given an opportunity to expand on the circumstances, limitations etc... of their research by referencing the published abstract.