Adjustable bulbourethral male sling: experience after 101 cases of moderate-to-severe male stress urinary incontinence

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INTRODUCTION

The estimated incidence of stress urinary incontinence (SUI) after prostate surgery ranges widely from 3% to 60% of men [1–3]. Although SUI is rare after TURP, open prostatectomy and even radical prostatectomy (RP) it can nevertheless have devastating effects on postoperative health-related quality of life. Current surgical therapies for SUI in men include the artificial urinary sphincter (AUS, AMS 800®; American Medical Systems, USA) as the proposed ‘gold standard’ for post-prostatectomy SUI [4–6], the minimally invasive ProACT® (Uromedica, Plymouth, MN, USA) adjustable balloons [7] and the adjustable REMEEX® sling (Neomedic International, Barcelona, Spain). Bulking agents and the bone-anchored slings are also considered minimally invasive techniques for post-prostatectomy SUI, although neither technique is adjustable [8]. In 2007, Rehder and Gozzi [9,10] published the first reports with short-term follow-up data on the Advance® transobturator sling system (American Medical Systems, Minnetonka, MN, USA), which attempts to re-establish the preoperative anatomical position of the external sphincter.

PATIENTS AND METHODS

Between April 2005 and April 2009, 101 men with a mean (range) age of 69.6 (51–84) years with moderate (2 pads/day) to severe SUI received later successful treatment (seven with an artificial urinary sphincter, five with re-implantation of the sling). Four of these patients were lost for follow-up.

• After a median (mean) follow-up of 2.2 (2.1) years, 80/101 (79.2%) patients were considered dry, with a pad test of 0–1 g (70 patients, 0 g; 10 patients, 1 g). The I-QoL score improved from a mean of 28.8 (14.5–61.8) to 63.2 (16.4–115) points after sling placement.

• Both the 20-min pad-weight tests and I-QoL responses improved significantly compared with baseline ($P < 0.001$).

CONCLUSION

• We think that the Argus male bulbourethral sling system is an excellent first- or second-line treatment for moderate-to-severe male SUI, even after external beam radiation treatment.

KEYWORDS

radical prostatectomy, male urinary incontinence, stress urinary incontinence, adjustable male sling

O B J E C T I V E S

• To report our experience using an adjustable bulbourethral sling since April 2005 for male stress urinary incontinence (SUI) after prostate surgery.
• To evaluate the safety, efficacy and health-related quality of life in recipients of the Argus® (Promedon SA; Cordoba, Argentina) adjustable bulbourethral sling.

P A T I E N T S  A N D  M E T H O D S

• Between April 2005 and April 2009, 101 men with moderate-to-severe SUI after prostatic surgery were implanted with the Argus sling.
• The radio-opaque Argus system comprises a thick silicone-foam pad for soft bulbar urethral support. The pad is attached to silicone columns that, after being passed with needles from the perineum to the abdominal wall, are adjusted with silicone washers to maintain the desired position.
• Between prostatic surgery and Argus sling placement, most patients (74.3%) had undergone various procedures for SUI or bladder neck pathologies: 22 had undergone secondary irradiation therapy after surgery (19 after retropubic radical prostatectomy [RP], one after perineal RP and two after transurethral resection of the prostate).
• All patients were evaluated before and after sling placement with 20-min pad tests, the Urinary Incontinence Quality of Life Scale (I-QoL), cystoscopy and uroflowmetry.

R E S U L T S

• The mean (range) follow-up was 2.1 (0.1–4.5) years. The mean (range) sling surgery duration was 49 (28–105) min.
• Adjustment was necessary in 39 cases (38.6%), either loosening (10/101; 9.9%) or tightening (29/101; 28.7%) at a mean of 104.3 (14–910) days after the initial implantation.
• The sling had to be removed in 16/101 patients (15.8%) at a mean of 371.1 (20–1260) days after implantation due to urethral erosion or infection. However, six of the 16 patients were within the first 22 placements and probably represent the ‘learning curve’. In all, 13 of these patients received later successful treatment (seven with an artificial urinary sphincter, five with re-implantation of the sling). Four of these patients were lost for follow-up.
• After a median (mean) follow-up of 2.2 (2.1) years, 80/101 (79.2%) patients were considered dry, with a pad test of 0–1 g (70 patients, 0 g; 10 patients, 1 g). The I-QoL score improved from a mean of 28.8 (14.5–61.8) to 63.2 (16.4–115) points after sling placement.

• Both the 20-min pad-weight tests and I-QoL responses improved significantly compared with baseline ($P < 0.001$).
(>2 pads/day), were implanted with an Argus® sling (Promedon SA; Cordoba, Argentina) (Fig. 1) in our department; however, no patient with mild SUI received an Argus sling at our clinic. Of these 101 men, 87 (86.1%) were incontinent after RP (retropubic RP, perineal RP, endoscopic RP), 13 (12.9%) were incontinent after surgery for BPH (10 patients after TURP, three after open prostatic surgery) and one (1%) had become incontinent after receiving first-line irradiation for prostate cancer. In all, 22 patients (21.8%) had been treated before implantation with the Argus sling with pelvic irradiation after their RP or TURP, one of them, as mentioned above, with first-line irradiation. Overall, 30 patients (29.7%) had required bladder neck incisions or an urethratomia interna after their initial RP for bladder neck contracture or urethral stenosis. In total, between RP and Argus sling placement, most patients (74.3%) had undergone various procedures for SUI or bladder neck pathologies (Table 1). All patients were evaluated before and after sling implantation with a 20-min pad test and the Urinary Incontinence Quality of Life Scale (I-QoL) questionnaire [11], as well as a cystoscopy and an uroflowmetry where accomplished.

SURGICAL TECHNIQUE

The surgical technique was first described by Romano et al. [12] in 2006. Under spinal or general anaesthesia, a 12 F Foley catheter is passed transurethrally whilst the patient is placed in the position for a standard TURP. A 7-cm medial skin incision is made in the perineum to expose and prepare the posterior urethra. The crura of the cavernous bodies are clearly identified whilst ensuring that the central tendon and the bulbospongious muscle remain intact (Fig. 2). A transverse incision is carried out in the suprapubic region to expose the rectus fascia. An insertion needle is directed between the urethra and the cavernous body. The pelvic floor is perforated using the leading hand to push the insertion needle and the other hand to control the depth of penetration. The needle is orientated about 2–3 cm laterally and then upwards, passed through to the suprapubic incision, ensuring that it is in close contact with the posterior surface of the pubic bone. The same procedure is repeated now on the left side. The insertion needle handles are moved from below to above (Fig. 3). Columns are then connected to the end of the needles and transferred to the suprapubic incision (Fig. 4) and the sling pulled in to place to snugly fit the posterior urethra (Fig. 5). The presence of clear urine and cystoscopy

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TABLE 1  

<table>
<thead>
<tr>
<th>VARIABLE</th>
<th>N (%)</th>
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<tr>
<td>Prostatic surgery or EBRT leading to SUI</td>
<td></td>
</tr>
<tr>
<td>Retropubic RP</td>
<td>73 (72.3)</td>
</tr>
<tr>
<td>Perineal RP</td>
<td>7 (6.9)</td>
</tr>
<tr>
<td>Endoscopic RP</td>
<td>7 (6.9)</td>
</tr>
<tr>
<td>Open prostatic surgery-BPH</td>
<td>3 (3)</td>
</tr>
<tr>
<td>TURP</td>
<td>10 (9.9)</td>
</tr>
<tr>
<td>First-line irradiation</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Irradiation second-line</td>
<td>22 (21.8)</td>
</tr>
<tr>
<td>Surgery prior to Argus implantation</td>
<td></td>
</tr>
<tr>
<td>Bladder neck incision or urethratomia interna</td>
<td>30 (29.7)</td>
</tr>
<tr>
<td>Bulking agents</td>
<td>11 (10.9)</td>
</tr>
<tr>
<td>ProACT®</td>
<td>27 (26.7)</td>
</tr>
<tr>
<td>AUS</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Invance®</td>
<td>2 (2)</td>
</tr>
<tr>
<td>Remeex®</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Argus®</td>
<td>2 (2)</td>
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confirm that the urethra and bladder are intact. Washers are then put in place by laying them over the rectus fascia (Fig. 6). To establish the retrograde leak-point pressure (RLPP) [13] a cystoscopic sheath is used. The Argus sling is progressively adjusted by tensioning the silicone columns through the washers to achieve a RLPP measurement ranging within 20–48 cmH\textsubscript{2}O (Fig. 7) and then subsequently the perineal incision is closed. Before closing the suprapubic incision, the ends of the columns are crossed over each other and fixed with a nonabsorbable suture to facilitate postoperative adjustments if necessary. A Foley catheter is generally left in situ for 2 days.

RESULTS

The sling was positioned with a mean (range) RLPP of 37 (20–48) cmH\textsubscript{2}O. The mean (range) operative duration was 49.4 (28–105) min. The response data reported represent the results obtained from the last follow-up visit of each patient. The median (mean) follow-up was 2.2 (2.1; 0.1–4.5) years. SUI decreased after sling implantation, with the 20-min pad test decreasing from a mean (range) of 30.9 (1–117) g to 2.2 (0–90) g after sling placement (\(P < 0.001\)). A third adjustment to the position of the columns and washers was necessary in three patients (3%) due to migration of the washers or rupture of a column after an average of 313 days. One patient required a fourth adjustment after 760 days (tightening after 5, 7, 670 and 760 days). Within the whole series five intraoperative bladder perforations occurred (5%). In these cases, similar to the classic tension-free vaginal tape implantation, the needle was simply re-positioned and the Foley catheter left in situ for 4 days. One primary perineal infection was treated conservatively. In all, 16 patients (15.8%) had complications requiring device removal due to urethral erosion (13) or infection (five, two of whom had erosion and infection) after a mean (range) of 371.1 (20–1260) days. However, six of those 16 patients were within the first 22 placements and probably represent the ‘learning curve’. In the following 79 cases, nine explantations (11.4%) were required. In all, 15 patients (14.9%) had transient perineal discomfort or moderate pain that resolved after a maximum of 3 weeks with the use of NSAIDs.

SUBGROUP ANALYSIS

Index patients

As the present cohort included a lot of previously operated and/or irradiated patients that were implanted with other devices to treat the SUI before Argus placement, we evaluated a subgroup of ‘index patients’ (32 patients), defined as:

I >1 year follow-up
II No external beam radiotherapy (EBRT)
III No previous surgery for SUI except for urethratomia interna
IV SUI only after RP (25) or TURP (seven).

The median (mean) follow-up in this subgroup was 2.3 (2.3) years. The 20-min pad test decreased from a mean (range) of 31.5 (5–117) g to 0.9 (0–10) g after sling placement. In all, 87.5% in this subgroup were considered as ‘dry’ at the time of the last follow-up. Within this group only two urethral erosions and three infections occurred. In four of these cases (12.5%) the sling had to be explanted. The I-Qol within this subgroup was raised to a mean of 58.3 points from a preoperative mean of 29.7 points. A separation of patients after TURP and RP did produce statistically significant difference relating to 20-min pad-test, erosion rate, infection or the I-Qol-questionnaire.

EBRT subgroup

Patients in this subgroup where incontinent after RP (20 patients) or TURP (two) and only two had another device implanted before
implantation of the Argus sling (one ProACT and one InVance®; American Medical Systems, USA). The median (mean) follow-up in this group was 1.5 (1.8) years. Of these 22 patients who had received their irradiation therapy before implantation of the sling, only two erosions and one infection emerged. In two cases, the sling had to be explanted and this occurred 22 and 430 days after implantation. The remaining 20 irradiated patients all were dry at their last follow-up.

Follow-up analysis

The comparison of patients of the whole cohort with a shorter follow-up of 1–2 years (23 patients; median follow-up 1.6 years, mean 1.5) and those with a follow-up of 2–3 years (21 patients, median and mean follow-up 2.5 years) showed constant results for the 20 min pad-test, erosion rates and I-QoL questionnaire as shown in Fig. 8.

RLPP differentiation

As we initially attempted to tension the sling to 45 cmH₂O and later preferred a RLPP of a mean of 37 cmH₂O, we split our total cohort in two groups of RLPPs: one group with an intraoperative RLPP of >40 cmH₂O and the other with a RLPP of <40 cmH₂O. The follow-up in the group with the higher RLPP was not surprisingly longer with a mean of 3.2 years, the mean follow-up in the group with the now preferred RLPP was 2 years. The intraoperative higher RLPP (>40 cmH₂O) lead to slightly better results for the postoperative pad test, with a mean of 0.6 g vs mean 3.4 g for the <40 cmH₂O RLPP group; however, the erosion rate was 33% (21 patients) in contrast to 5.1% (59) in the latter group.

Explantations

Reflecting on the 16 cases in which an explantation due to urethral erosion (13), infection (three) or both (two) was necessary, these complications where treated by implantation of an AUS (six AMS 800, one Flow Secure®, Sterilin Ltd, Abergoed, Bargoed, UK) in seven cases or re-implantation of an Argus sling at a later date after complete healing of the erosion in five cases. As the full silicone Argus sling can be removed completely to allow healing of the urethra, the re-operations were not excessively challenging. Four of the 16 cases were lost to follow-up. In fact, all patients who had an explantation of the sling were finally treated successfully, if not lost to follow-up.

DISCUSSION

Unlike female slings that are placed as a tension-free support under the mid-urethra, male slings need to generate a slight, permanent urethral resistance to achieve continence. To avoid overcorrection and obstruction, and to enable the sling to adapt to developing functional or anatomical changes in the patients, adjustable systems are preferable. For many years, the AUS has been considered the ‘gold standard’ for the treatment of SUI in men. High rates of continence and patient satisfaction have been reported with the use of the AUS; however, up to 30% of corrective operations, that are considered as ‘adjustment operations’ are needed [14–16]. Compressing the bulbourethra in an attempt to provide urinary continence was first suggested by Marshall et al. [14] in 1946; they proposed that with compression and elevation of the perineal area, sphincter support could be provided, thus improving its function. Very few authors had previously reported on the use of bulbourethral sling procedures whereby the sling is transferred to the abdomen using needles [15–18] until Schaeffer et al. [19] in 1998 published a series of 64 patients. They reported a 64% cure/improvement rate (0–2 pads/day) after a median follow-up of 18.1 months and a 75% success rate after adjustment-operations were made in 27%. However, longer term results were less satisfactory with 24 patients (42%) considered cured, 17 (30%) wearing 1–2 pads/day and 16 patients (28%) requiring ≥2 pads/day after a mean follow-up of 48 months. After the report from Schaeffer et al. [19], other centres considered bulbourethral sling procedures as a realistic alternative for the treatment of SUI after RP. In addition, the sling is much less expensive than the AUS. Subsequently, various slings were marketed for post-prostatectomy SUI, constructed from various synthetic and autologous materials [20]. A different technique based on the concept originally proposed by Kaufman et al. (1970) [21–23], which compresses the bulbous urethra in the perineum without entering the abdomen, was later applied by Madjar et al. [24] in 2001 and subsequently by Comiter [25]. This technique used bone anchors to fix a polypropylene mesh for urethral compression and produced very encouraging results in the short term, with a 90% cure/improvement rate after a mean follow-up of 12 months. Subsequently, Castle et al. [8] reported their medium-term experience in 38 patients treated with the bone-anchored Invance sling with a mean follow-up of 18 months and a success rate (defined as no more than 1 pad/day) of only 39.5%. The success of Invance seems to depend on the preoperative incontinence grade as well as the duration of the follow-up. Rehder and Gozzi [9,10] introduced the Advance transobturator sling in 2007 as a new non-obstructive tape for the treatment of SUI after radical prostatectomy. This first clinical series included 20 patients, with reports that 40% of the patients were cured and 30% had improved incontinence. However, their follow-up was only 6 weeks. Gozzi et al. [26] recently published a further report on the Advance sling in a series of 67 patients with a follow-up of 3 months. The cure rate was 52% with further 38% improved. Their re-operation rate was 11%. The present results in 101 patients after a median follow-up of 2.2 years are promising despite the complicated presentation of patients, where 33.7% of patients had previous failed implantations with other devices for their SUI and a significant proportion had undergone adjunctive procedures, i.e. irradiation (21.8%), repeated bladder neck incisions or urethrotomia interna (29.7%) which tend to further complicate efforts to produce a satisfactory outcome after any treatment for SUI (Table 1). Despite this difficulty, the Argus sling achieved high continence rates (79.2% dry, pad test 0–1 g) with relatively low complication rates (15.8% device removals). As shown in the comparison of different follow-ups it appears that Argus sling result are durable. Nevertheless, in patients who have not previously undergone and failed other SUI surgeries, better results...
may be possible. As such, our learning curve is represented by the first 22 cases, where accumulated experience established a suitable initial degree of tension to apply, based on an appropriate intraoperative adjustment of the RLPP during the initial implant procedure. Initially, we attempted to tension the sling to 45 cmH₂O. However, our early experience with erosions in the first 22 cases showed that this was too high. A RLPP of an average of 37 cmH₂O is now preferred intraoperatively, which is typically 10–15 cmH₂O higher than the reference RLPP measured initially, before sling placement. We found that this RLPP measurement prevented erosion and made adjustments easier. The rationale for these numbers is the fact, that the vast majority of patients are able to interrupt their stream using the somatic striated sphincter, still being clinically incontinent due to an insufficient resting pressure secondary to the compromised innervations and function of the smooth muscle as well as the slow twitch portion of the striated sphincter. This slight increase of the urethral resistance (10–15 cmH₂O) leads to full continence in most patients. As shown above an intraoperative higher RLPP lead to slightly better results for the postoperative pad test; however, erosion rates where higher within this subgroup. The relatively high revision rate in this patient group was probably primarily due to our ‘learning curve’; however, the total cohort did not include patients with mild SUI and 74.3% of patients had undergone previous surgery before the implantation of the Argus sling. Of the 16 patients with urethral erosion or infection, 12 where treated as mentioned before with an AUS or re-implantation of the sling. In fact, these surgeries where uncomplicated, as the silicone-foam pad of the Argus sling can, even after a long time, easily be removed leaving normal tissue behind.

In conclusion, the Argus male sling used for the treatment of post-prostatectomy SUI is an easy, straight-forward approach. It may be used even in irradiated patients and in those with severe leakage. If needed, the Argus male sling allows adjustments, either under local or general anaesthesia at any time after implantation. We think that the Argus male sling system is an excellent first- or second-line treatment option for patients who have previously undergone and failed other SUI surgeries for moderate-to-severe post-prostatectomy SUI and is suitable for patients after irradiation therapy.

CONFLICT OF INTEREST
None declared.

REFERENCES

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**Abbreviations:** SUI, stress urinary incontinence; RP, radical prostatectomy; AUS, artificial urinary sphincter; RLPP, retrograde leak-point pressure; EBRT, external beam radiotherapy.