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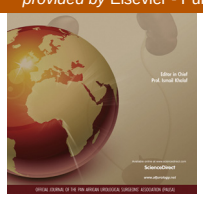

Voiding dysfunction
Original article

Use of the adjustable trans-obturator male sling system for the treatment of male incontinence. An initial experience

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Abstract
Objective: To evaluate the safety and efficacy of the "Adjustable Trans-Obturator Male Sling System (ATOMS)" as a new surgical technique for the treatment of different types of male urinary incontinence.
Subjects and methods: Between March 2012 and December 2013, 9 patients with a mean age of 56 (range 15–74) years were operated for urinary incontinence using the ATOMS system. Incontinence had developed following bladder exstrophy repair in 2, after radical cystectomy with construction of an orthotopic neobladder in 3, after transvesical open prostatectomy in one and after radical prostatectomy in 3 patients. Preoperative evaluation included a detailed medical history, physical examination, 24-h pad tests, urodynamic assessment and sonography.
Results: The mean number of pads used preoperatively was 4.6 (range 3–6). The mean operative time was 45 (range 36–50) min. No intraoperative complications were encountered. The mean hospital stay was 3.8 (range 3–6) days. Transient perineal/scrotal pain was observed in 6 patients (66.7%) and controlled with non-opioid analgesics. There were no perineal infections; however, two port infections occurred (22.2%) and repositioning of the port was done in these cases. At a mean follow-up of 9 (range 6–12) months, the overall success rate was 100% with 77.8% of the patients being completely dry (0 pads per 24 h) and 22.2% using less than 2 pads per 24 h.
Conclusions: Our early experience demonstrated that the ATOMS system may be a safe and effective procedure for the treatment of male urinary incontinence. It has the advantage of being feasible any time after an operation when necessary. However, long-term follow-up on a large number of cases is required to ensure its long-term efficacy and safety.

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Introduction

Male stress urinary incontinence (SUI) is a devastating complication mainly occurring after prostatectomy and having a significant impact on the patient's quality of life [1]. The incidence of post-prostatectomy SUI has been reported to be as high as 1–48% [2].

Treatment options include minimally invasive procedures such as electrical stimulation and bio-feedback. However, a poor outcome and their limitation to mild cases have prevented their popularity [3]. Despite the high success rate of the artificial urinary sphincter (AUS), its high cost and the risk of mechanical failure are major drawbacks. The concept of using sling material for the treatment of male SUI has been recently introduced with many advantages and promising results on short and intermediate-term follow-up [4]. However, a lack of postoperative adjustment and the risk of dislocation of the device due to insufficient anchorage which, in turn, compromise cure rates have been reported to be the main drawbacks of sling procedures.

The ATOMS system was developed to overcome these difficulties with the option of simple, minimally invasive postoperative adjustment. Using this system, a success rate of 80% has been reported in patients with post-prostatectomy incontinence [5]. Since its effectiveness in treating male SUI due to causes other than post-prostatectomy SUI has never been addressed, this study was designed to investigate the versatility of ATOMS for the treatment of male SUI due to different etiological factors.

Subjects and methods

Between March 2012 and March 2013, 9 men with a mean age of 56 (range 15–74) years were operated using the ATOMS system. They were suffering from mild to severe SUI which had developed following radical prostatectomy in 3, open prostatectomy in one, bladder exstrophy repair in two and radical cystectomy with orthotopic neobladder construction in 3 patients (Table 1).

All patients underwent preoperative evaluation including a detailed medical history, physical examination and gray-scale ultrasonography for the evaluation of the upper urinary tract as well as the assessment of the post-void residual (PVR) urine volume. Urinalysis and culture were carried out. All patients were subjected to retrograde urethrography in order to exclude concomitant strictures. A pressure flow study was carried out in accordance with the International Continence Society (ICS) guidelines. A 24-hour pad test was carried out and the number of pads used was recorded. Urinary incontinence was considered mild, moderate or severe depending on the number of pads used per day.

Table 1 Types of patients.

Cause of incontinence	Number of patients
Post radical prostatectomy	3
Post transvasical prostatectomy	1
Post bladder extrophy repair	2
Post radical cystectomy with orthotopic neobladder	3

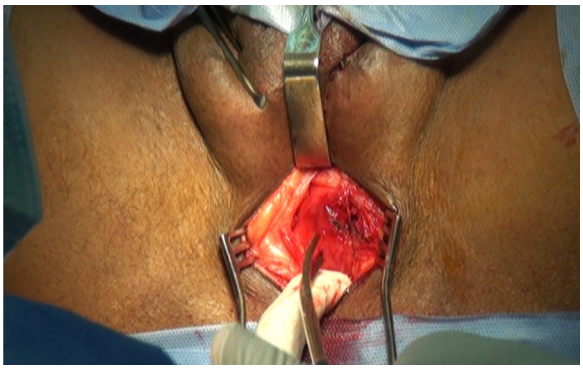

Fig. 1 Operative picture showing exposure of bulbospongiosus muscle, to create a space between the bulbospongiosus and ischiocavernosus muscles.

Surgical technique

All surgical procedures were carried out under spinal anesthesia. The patients were positioned in a modified lithotomy position. The skin was washed with a povidone–iodine solution. All patients were given a 3rd generation cephalosporine prior to surgery. After draping the patient with a sterile covering, an 18Fr Foley catheter was inserted. A medial vertical perineal incision of approximately 5 cm was made, with sharp dissection of the Colles fascia and exposure of the bulbospongiosus muscle, and a space was created between the bulbospongiosus and ischiocavernosus muscles (fossa ischiorectalis) (Fig. 1).

Application of ATOMS

The ATOMS system consists of a mesh implant with an integrated adjustable cushion, protection sheet and titanium port for the adjustment of the cushion volume. The silicone cushion is located in the middle of the mesh tape and filled intra- and postoperatively via the port and catheter (Fig. 2).

The system was implanted in all patients using an outside-in technique. The obturator foramen was passed subcutaneously with a helical tunneller. The mesh arms were drawn back to the central part of the cushion and sutured, thus anchoring the ATOMS device to the inferior pubic ramus. The titanium port was placed subcutaneously deep in the inguineal region and secured with two non-absorbable sutures. The perineal and suprapubic wounds were rinsed with saline solution and closed in multiple layers (Figs. 3 and 4).

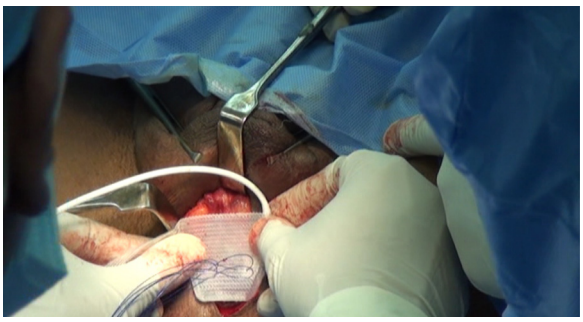

Fig. 2 Operative picture of application of the silicone cushion to measure if the dissected space is appropriate for its size or not.

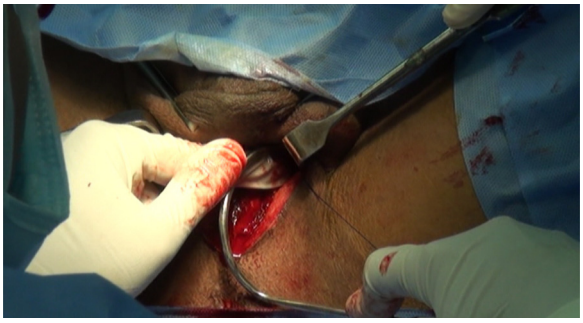

Fig. 3 The system was implanted using an outside-in technique using helical passer through the obturator foremen.

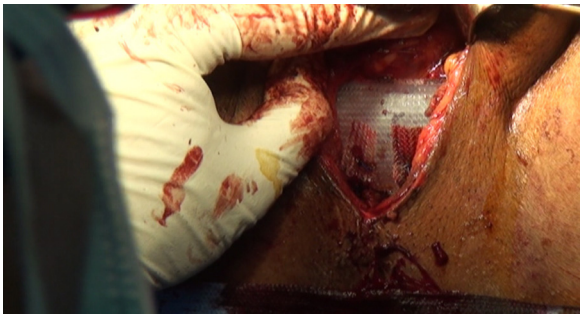

Fig. 4 The mesh arms were drawn back to the central part of the cushion and sutured, thus anchoring the ATOMS device to the inferior pubic ramus.

The urethral catheter was removed the next day. Prior to discharge from the hospital, the patients were subjected to uroflowmetry and assessment of PVR urine with a PVR urine volume <100 cc considered safe.

Follow up

The patients were first seen one week after surgery. The first adjustment, where necessary, was made no earlier than 3 weeks postoperatively with an average volume ranging from 2 to 5 ml. If required, further adjustments can be made with smaller volumes to minimize the risk of urinary retention. The amount of residual urine and a maximum urine flow <10 ml/s determined the maximum adjustment volume.

Follow-up at 1, 3 and 6 months included physical examination, uroflowmetry, the assessment of PVR urine and a 24-hour pad test. The patients were considered continent when they used 0 to 1 pads with less than 15 ml urine loss daily. Their condition was considered improved when the daily pad use was reduced by more than 50% with a urine loss of less than 100 ml daily. All other cases were considered treatment failures.

Statistical analysis

Statistical analysis was performed using SPSS® for Windows 10.5.1. The paired t test and Pearson's Chi-square test were used, with significance defined as $p < 0.05$.

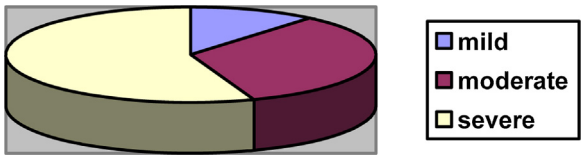

Fig. 5 Degree of incontinence.

Results

In total, 9 patients with a mean age of 56 (range 15–74) years were included in the study. The median preoperative pad use was 4.6 pads daily (range 3–6) and the mean 24-hour pad test weight was 747 (range 230–1600) g. One patient (11.1%) was suffering from mild (1–2 pads), three (33.3%) from moderate (3–4 pads) and five (55.56%) from severe incontinence (5 or more pads) (Fig. 5). The mean Q max ± SD was 17.8 ± 8 (range 9.5–33.1) ml/s, while the mean PVR urine ± SD was 45 ± 35 (range 0–80) ml.

The mean operative time ± SD was 45 ± 15 (range 36–50) min. No intraoperative complications were encountered. Transient urinary retention after removal of the transurethral catheter seen in one patient resolved spontaneously after 24 h. Six patients reported perineal or scrotal pain (66.7%). Early wound infection at the site of the titanium port developed in two (22.2%) patients and was controlled with proper antibiotics. After an initial intraoperative adjustment with 1–2 ml solution, all patients were dry and further adjustments were not required.

At a mean follow-up of 6 (range 3–6) months, the overall success rate was 100%. 77.8% of the patients were considered dry (0–1 pad per 24-hour) and in 22.2% the condition had improved (more than 1 pad per 24 h). Compared to the preoperative evaluation of urine flow, there was no case of significant obstruction. The mean QMax was 18.89 (range 9–30) ml/s, while mean PVR urine ± SD was 50 ± 35 (range 0–90) ml (Table 2).

Discussion

Male urinary incontinence which mainly occurs after radical prostatectomy is a highly feared complication due to its negative effect on the quality of life. There are several treatment options for the correction of the problem. The AUS is considered the gold standard for the treatment of moderate to severe SUI. The overall success rates are very high with 75–78% of the patients being dry [4]. However, its high cost, the difficult manipulation and the risk of complications such as erosions and infections varying from 6% to 27% are major drawbacks. Furthermore, the necessity for surgical revision due to mechanical failure of AUS occurs in 12–53% [4]. One of the first male sling devices which was an acrylic device placed beneath the bulbocavernosus muscle was described by Berry with a 45% success rate [5]. Several years later, Kaufman proposed several techniques of urethral compression achieved by crossing the crura over the

Table 2 Comparison between pre and post operative Qmax and PVR.

	Preoperative	Postoperative
Mean Qmax	17.8	18.89
Mean PVR	45	50

bulbar urethra and implanting a prosthetic perineal implant with bone anchors [6]. The advantage of male slings compared to the AUS lies in the fact that slings are not prone to mechanical failure and subsequent revision surgery, and voiding is possible without device manipulation. The success rates reported for non-adjustable slings vary from less than 40% up to 80% [7,8]. However, since almost all these slings are not adjustable, they may lead to urinary obstruction with excessive pressure or they may provide insufficient pressure, thus preventing cure of incontinence. The ATOMS system which provides the possibility of postoperative adjustment was developed to resolve this problem. The surgical approach and the anatomical findings achieved when using this system were reported by Bauer et al. in 2005 [7]. The low risk of urethral erosion compared to that encountered with the AUS is due to the lack of circumferential compression [8]. Also, there is no risk of mechanical failure due to the absence of mechanical parts. Unlike other implants such as balloons where erosion rates account for up to 8% [9] or adjustable slings with an erosion rate up to 15.8% [10], the more distal positioning of the ATOMS cushion on the bulbospongiosus muscle minimizes the incidence of erosion.

In the current study, the success rate was 100%. Of the 9 patients, 77.8% were considered dry and 22.2% improved. Also, there was a significant decrease in pad use from 5 (range 3–6) daily preoperatively down to 1 (range 0–3) daily postoperatively. Other adjustable suburethral slings have shown an 83% success rate which is similar to our results but with a higher incidence of obstruction (15% of acute urinary retention versus 0% in our study) [11]. Interestingly, none of our cases developed complications such as urine retention or significant urinary flow obstruction, not even those with orthotopic bladder substitution.

Pain and numbness of the perineum and scrotum were the most frequent side effects in our study which resolved within 2 months after surgery following treatment with non-opioid analgesics.

Infection rates after suburethral sling procedures have been reported to range from 1.8% to 16% [8,10,12,13]. In our study, there were no cases of primary device infection. However, two cases of early postoperative infection at the port site were observed.

We are aware of the fact that the current study has many limitations, e.g. the small number of patients, the heterogeneity of the studied population and the short follow-up. However, this initial experience with promising results will open the door for better designed studies on a larger scale.

Conclusions

ATOMS is a safe and effective method to treat male SUI with very low complication rates.

Ethical committee approval

Minia university (354/1078).

Conflict of interest

There is no conflict of interests for any of the authors.

Source of funding

None.

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