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### ORIGINAL ARTICLE

# The role of synthetic slings in male stress incontinence

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#### KEYWORDS

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#### ABBREVIATIONS

MUP, maximal urethral pressure; DO, detrusor over-activity; BAMS, bone-anchor male sling; TOMS, transobturator male sling; PGII, Patient Global Impression of Improvement; (S)UI, (stress) urinary incontinence; UBA, urethral bulking agent; AUS, artificial urinary sphincter; UDS, urodynamic study

**Abstract Objective:** Our primary aim was to compare the outcomes of synthetic bone-anchored male slings (BAMS) and transobturator male slings (TOMS), to identify preoperative risk factors for failure, and to evaluate patient satisfaction with each procedure.

**Patients and methods:** Charts were reviewed retrospectively of patients who underwent synthetic BAMS or TOMS from 2000 to 2011. Data were categorised into groups based on outcomes of 'dry', 'improved' and 'failure'. Success was defined as completely dry or an improvement by > 50% in daily pad use. The data analysed included demographics, daily pad use before and after surgery, previous urethral insult, type of prostatectomy, and urodynamic study variables. Data were analysed using logistical regression, the *t*-test and chi-square analysis, where appropriate.

**Results:** Sixty-eight men were analysed (30 in each group; eight patients were excluded). Daily pad use for the TOMS group changed from 3.5 before to 1.5 after surgery ( $P = 0.001$ ), whilst the BAMS group was unchanged from 3.9 to 3.5 ( $P = 0.747$ ). The TOMS group had a success rate of 23/30 (77%) and a mean (SD) patient global impression of improvement score of 1.67 (0.90), whilst the BAMS group had a success rate of 11/30 (37%) and mean (SD) score of 2.64 (1.12). Urethral insult ( $P = 0.001$ ) and preoperative pad use ( $P = 0.047$ ) were significant predictors of failure.

**Conclusion:** TOMS gave better outcomes than BAMS in both performance and patient satisfaction. Patients with a greater severity of incontinence and evidence of urethral insult before surgery should be counselled about the likelihood of suboptimal outcomes with any type of sling placement.

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#### Introduction

Stress urinary incontinence (SUI) is a condition that affects many men after prostate surgery, and it negatively impacts their



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health, both physically and emotionally. SUI is most commonly a result of treatment for prostate cancer, and less commonly from surgical treatment of benign prostatic hypertrophy (BPH). In reviewing post-prostatectomy urinary continence rates at six months post-operative status, robotic assisted laparoscopic prostatectomy achieved continence rates ranging from 82% to 97%, laparoscopic prostatectomy achieved 73–96%, and open prostatectomy achieved 58–98.5% [1].

Several treatment options exist to facilitate the achievement of urinary continence. Non-surgical methods include Kegel exercises and pelvic floor biofeedback to strengthen the pelvic floor musculature. Injection of urethral bulking agents (UBA), a minimally invasive procedure, can also be used alone or to augment urethral bulk after male perineal sling placement. However, this has proven to have widely varying, and often times disappointing, results from 2.5% to 87% efficacy [2,3]. Male perineal sling and artificial urinary sphincter (AUS) are the more invasive surgical options that exist with AUS remaining the “gold standard”. Many patients with only minimal or moderate SUI after prostatectomy find any leakage unacceptable and seek AUS placement whilst others shy away from AUS placement secondary to its invasive nature and potential for mechanical malfunction over time. These same patients may also only show minimal benefit from injection of UBA’s or non-pharmacologic means of SUI treatment. It is in these patients that the male perineal sling is the most supportive to the urethra and effective in its results. Synthetic male slings are minimally invasive, boast a shorter operative time, hospital stay, and recovery period. Additionally, patients suffer fewer complications. Simply stated, it is a procedure that is a quick and relatively simple treatment modality for the treatment of post-prostatectomy male SUI [4].

The male sling offers a treatment option for male SUI that requires little from the patient except compliance with the healing period requiring limited activity and lifting [5]. The greatest challenge is to find the most effective treatment method for SUI that simultaneously meets or exceeds patient expectations. The aim of this study is to compare the outcomes of two synthetic male sling types, bone anchored male sling (BAMS) and transobturator male slings (TOMS). Secondly, we aim to evaluate patient satisfaction with each type of sling procedure.

### Patients and methods

Following Internal Review Board approval, a retrospective chart review was conducted of all male patients having undergone synthetic BAMS or TOMS placement for the treatment of male SUI from 2000 to 2011. Follow-up time was calculated from the date of surgery to the last follow up visit. Any patient with a follow up time of <6 weeks or with biological sling placement was excluded from this study.

The data analysed included pre-operative and post-operative daily pad usage, history of previous urethral disease or insult (i.e. urethral stricture disease, brachytherapy, external beam radiation therapy, etc.), urodynamic study (UDS) parameters, adverse events, and pre-operative presence of detrusor overactivity (DO) as found on UDS prior to sling placement. Each patient was asked to complete the validated patient global impression of improvement (PGII), a seven-point Likert scale, at each post-operative visit (Fig. 1) [6].

As a primary outcome, failure was defined as no change or an increase in daily pad usage post-operatively. An improved outcome was defined as greater than 50% improvement in daily pad usage post-operatively without having complete dryness. Complete dryness required no pad usage. A successful outcome was defined as complete dryness post-operatively or improved condition.

Statistical analysis was performed using paired and two-sample *t*-tests, chi-square, and logistical regression analysis where appropriate. A *p*-value of <0.05 determined statistical significance.

### Results

A total of sixty-eight patients underwent male sling placement from 2000 to 2011 by one surgeon. Thirty patients remained in each group after exclusions. Eight total patients were excluded. Five patients were excluded from the BAMS group for having biological sling placement and three patients were excluded from the TOMS group for inadequate follow up. The mean age for the BAMS and TOMS groups were 68.9 years ( $\pm 10.80$ ) and 70.4 years ( $\pm 7.94$ ), respectively Table 1. demonstrates the pre-operative characteristics for each patient group. The mean follow up time was 43.2 months (2–95) for the BAMS group and 14.6 months (3–33) for the TOMS group with statistically significant difference ( $p = 0.001$ ). Pre-operatively, only maximal urethral closure pressure (MUP) and urethral insult demonstrated statistically significant difference with  $p = 0.014$  and  $p = 0.010$ , respectively.

When analysed, change in pad usage from pre- to post-operatively was found to be significantly decreased in the TOMS group from 3.5 pads per day to 1.5 pads per day ( $p = 0.001$ ) as compared to the BAMS group at 3.9 pads per day to 3.5 pads per day ( $p = 0.747$ ).

Upon analysis of pre-operative risk factors, urethral insult ( $p = 0.001$ ) and pre-operative pad use ( $p = 0.047$ ) were the only factors found to demonstrate significance and pre-dispose patients to sling failure (Table 2).

Table 3 demonstrates the outcomes for each group. Using our definition of failure, analysis revealed a failure rate of 63.3% (19/30) in the BAMS group, compared to

Circle the number that best describes how your condition is now, compared with how it was before you had the treatment intervention.
1. Very much better
2. Much better
3. A little better
4. No change
5. A little worse
6. Much worse
7. Very much worse

**Figure 1** Patient global impression of improvement.

**Table 1** Pre-operative patient characteristics.<sup>a</sup>

	BAMS ( <i>n</i> = 30)	TOMS ( <i>n</i> = 30)	<i>p</i> -Value
Age (years)	68.9 (39–84)	70.4 (54–86)	0.947
Follow-up (months)	43.2 (2–95)	14.6 (3–33)	0.001
Pad use	3.9 (1–10)	3.5 (1–12)	0.501
BMI	27.7 (21.11–39.43)	28.4 (21.44–37.56)	0.668
ALPP (cm H <sub>2</sub> O)	75.0 (5–150)	91.2 (22–152)	0.214
MUP (cm H <sub>2</sub> O)	64.8 (5–143)	99.4 (13–255)	0.014
FL (cm)	3.3 (1.5–6)	3.7 (2–7)	0.306
Urethral insult	19 (63.3%)	9 (30.0%)	0.010
DO	9 (30.0%)	7 (23.3%)	0.559

<sup>a</sup> BMI = body mass index, ALPP = leak point pressure, MUP = maximal urethral pressure, FL = functional length, DO = detrusor overactivity.

**Table 2** Pre-operative risk factors for sling failure.<sup>a</sup>

Risk factor	<i>p</i> -Value
Age	0.180
BMI	0.339
Pre-operative pad use	0.047
ALPP	0.083
MUP	0.670
FL	0.627
Urethral insult	0.001
DO	0.094

<sup>a</sup> BMI = body mass index, ALPP = leak point pressure, MUP = maximal urethral pressure, FL = functional length, DO = detrusor overactivity.

23.3% (7/30) in the TOMS group. Analysis of the PGI-I for both groups as a whole after sling placement demonstrated a mean of 3.64 in the BAMS group and 2.25 for the TOMS group. This shows a statistically significant difference in favour of the TOMS group ( $p = 0.004$ ). The trend in PGI-I amongst the dry, improved, success, and failed groups is further demonstrated in Table 3.

Of the patients who underwent BAMS, 22 (73%) patients had an open prostatectomy with 14 of those 22 patients (63.6%) having been failures and 8 of the 22 patients (36.4%) either dry or improved. None (0%) of the BAMS group underwent a laparoscopic prostatectomy, 3 (10%) underwent an endoscopic prostatectomy, and 5 (17%) patient charts contained no data regarding previous prostatectomy procedure. In the TOMS group, 15 (50%) patients had an open prostatectomy and only 3 (20%) were failures leaving 12 of the 15 patients (80%) as dry or improved. Eight (27%) patients underwent prostatectomy by laparoscopic approach, five (17%) underwent endoscopic approach, and two (7%) patient charts contained no data regarding previous prostatectomy procedure.

In our cohort of BAMS patients, three patients had bone anchor dislodgement (10%) requiring revision, one patient (3.3%) had no change in SUI after sling placement, one patient (3.3%) had medication-refractory urgency with urge incontinence effectively treated with sacral neuromodulation, and three patients (10%) had scrotal/groynne pain or numbness that resolved within three months. In the TOMS cohort, four patients (13.3%) had post-operative acute urinary retention that resolved with 3–5 days of catheter placement, one

(3.3%) patient had recurrent SUI that was treated with a urethral bulking agent, and four patients (13.3%) had post-operative scrotal/groynne pain or numbness that resolved within three months.

## Discussion

The treatment of post-prostatectomy incontinence (PPI) remains a challenge for urologists. Not only must a surgeon consider the most appropriate treatment modality for each patient, but consideration must be given to patient motivation and expectation of treatment. In some instances, the patient may choose an AUS even with minor leakage secondary to the desire to be completely dry. Therefore, thorough discussion with each patient regarding treatment options and patient expectation should not be underestimated.

Whilst this cohort demonstrates that the amount of pad usage and urethral insult to be pre-disposing factors for sling failure, our previous study demonstrated all analysed pre-operative risk factors to be significant for sling failure regardless of the type of sling used [5]. Based on the results of both studies, it seems that the most important risk factors to discuss with each patient and consider prior to choosing a treatment modality is the severity of pre-operative incontinence and the presence of prior urethral insult.

Based on prior studies, severe pre-operative incontinence, urodynamic proven detrusor instability, and treatment with radiation therapy were predisposing factors for sling failure in those receiving BAMS [7]. Our results mirror this study and further conclude that these factors are predisposing not just to BAMS failure but to TOMS failure as well. Of course, the best case scenario for any patient would be minor pre-operative incontinence without the presence of urethral insult. Whilst this is idealistic, the reality is that few patients present with such optimal circumstances. Based on the results in this study, favour is demonstrated by TOMS to be a better choice when treating male SUI. However, these results may be secondary to a variety of factors and not just exclusively for reasons of product superiority. It must be considered that there may be a bias in favour of TOMS given the shorter follow up interval.

To factor out material differences, all slings analysed were of the synthetic variety. Therefore, questions of biologic material failure are of no concern when considering superiority of treatment outcomes. The only characteristics demonstrating pre-operative significance were MUP and urethral insult.

**Table 3** Group outcomes.<sup>a</sup>

Groups	Dry	Improved	Success	Failed
BAMS ( <i>n</i> = 30)	4 (13.3%)	7 (23.3%)	11 (36.6%)	19 (63.3%)
TOMS ( <i>n</i> = 30)	12 (40.0%)	11 (36.7%)	23 (76.7%)	7 (23.3%)
BAMS PGI-I (mean and SD)	1.75 (±0.83)	3.14 (±0.83)	2.64 (±1.12)	4.29 (±0.89)
TOMS PGI-I (mean and SD)	1.08 (±0.28)	2.32 (±0.86)	1.67 (±0.90)	4.14 (±0.35)

<sup>a</sup> BAMS = bone anchor male sling, TOMS = transobturator male sling, PGI-I = patient global impression of improvement, SD = standard deviation.

Therefore, these factors may have had a bearing on treatment outcome initially. Whilst demonstrating pre-operative significance, MUP did not further demonstrate significance as a risk factor for failure. Interestingly, those patients in the BAMS group had lower pre-operative MUP values (64.8 cm H<sub>2</sub>O) than did the TOMS group (99.4 cm H<sub>2</sub>O).

Sphincteric incompetence secondary to direct neurological injury is the primary contributing factor to the development to PPI [8,9]. Winters et al., found that >90% of males having had radical prostatectomy by the retropubic approach had sphincteric incompetence during UDS after surgery [10]. Since MUP is a measure of external urethral sphincteric function, one can be left with the inference that TOMS is better in patients who have undergone radical prostatectomy by the open approach or who have a lower MUP. This inference is supported in our cohort by the analysis of the type of prostatectomy procedures in the TOMS group. This better outcome may be explained by the ability of a properly placed TOMS to better support the external urethral sphincter through the design of the mesh. A BAMS is tensioned by the surgeon to support the urethra and can be limited. The configuration of the patient's bony pelvis with subsequent loose configuration of the sling can render the BAMS as ineffective as if there were bone anchor dislodgement. The TOMS applies tension directly to the bulbar urethra and there remains a smaller window of error.

Many of the patients in this cohort had urethral insult secondary to neoadjuvant or adjuvant treatment with brachytherapy, external beam radiotherapy, cryotherapy, or urethral insult through stricture disease. This may have also had a bearing on the treatment outcomes with sling placements as these are difficult parameters with which to deal. These findings are further supported by previous studies demonstrating that increased pre-operative incontinence and prior pelvic radiation therapy negatively impacted treatment success with male slings [5,11–13]. Whilst these treatment modalities can directly cause scarring and strictures, they can also cause compromised blood supply/fibrosis of the urethra, and decrease the tissue compressibility of the urethra that inhibits coaptation of the external sphincter. These inherent complications can make treatment of any variety a challenge and may further explain the success of the TOMS group alone. It goes without saying that patients with more severe incontinence in the face of urethral/sphincteric injury should be directed toward the placement of an AUS.

We demonstrated an overall success rate of TOMS to show a trend toward a better outcome than BAMS. This is supported by the change in pad usage from pre to post-operatively. Of those who had TOMS placement, 76.7% of patients experienced total dryness or improvement versus only 36.7% of BAMS. This directly contradicts a study reported by Schaffer

in which BAMS demonstrated 64% success rate of dry or improved over 18 months follow up [12]. This is also in direct correlation with the findings of our previous study comparing BAMS and TOMS in which BAMS and TOMS demonstrated a 31.7% and 69.6% success rate respectively [5]. In this cohort, TOMS patients revealed significance in decrease in overall pad usage post-operatively from 3.5 pads per day to 1.5 pads per day. Disregarding the group outcome breakdown, the TOMS group demonstrates an overall decrease in pad usage by half as opposed to BAMS (3.9 pads per day to 3.5 pads per day). This is further supported by a TOMS study that revealed a decrease in pad usage pre to post-operatively from 4.52 to 1.04 at six months [14]. Although pad weight was not factored in, a study by Cornel et al, demonstrated no significance when pad weight was used [15]. Our patients were allowed to use their own pads pre and post operatively and can infer a decrease in pad weight with the reporting of less pad usage.

Even though our results demonstrate a trend toward a better outcome of the TOMS group in the treatment of PPI, it is reasonable to mention that technical differences and inherent complications with each sling type exist. Whilst BAMS may not demonstrate superiority in this or even other studies, there are studies in which BAMS have a favourable and durable outcome even with shorter follow up times [16]. However, BAMS carry the inherent potential for bone anchor dislodgement that may be responsible for failure both immediately and after years of implantation [4,17]. This was seen in our cohort of BAMS patients in 10% of patients. This should prompt pelvic imaging if patients experience a return of symptoms. Conversely, TOMS carry the risk of proximal migrational patterns and placement rendering it ineffective. Each type of sling carries complication potentials that are similar. Each sling type has the potential for erosion, infection, acute urinary retention, recurrent SUI, urgency with urge incontinence, perineal/scrotal numbness, post-void dribbling, and persistent pain [18–20]. Our results concerning adverse events do not differ in the types. However, the adverse events experienced by our patients were easily treatable and did not include infection or sling erosion. Moreover, each patient should be thoroughly counselled on the potential for complications both unique to each sling type and those in common.

To further strengthen this retrospective study, patients completed the PGI-I as is our protocol with any surgery. This study demonstrates an overall significantly better satisfaction rate with TOMS as is evidenced by an overall mean PGI-I of 2.25 versus 3.64 for the BAMS group (*p* = 0.004). This is comparable to a similar study by Crites et al., in which the PGI-I was superior in the TOMS group [5]. In analysis of the PGI-I trend with both groups, the PGI-I remained consistently stronger with the TOMS group in all outcome arms. Keeping this in

mind, the follow up time for each group was significantly different. Therefore, the PGI-I values for each group may have differed if analysed at similar points in time.

The strengths of this study lie in the gathering of validated PGI-I results to factor in patient satisfaction, the results of one surgeon, and the ability to measure outcome based on complete dryness, improvement, and frank failure. However, the inherent weakness of this study lies in its retrospective nature, the inequality of follow up time evaluated, and possibly improved patient selection in the TOMS group.

Areas of further study would be to analyse the superiority of sling types within the same group (i.e. different types of TOMS), evaluation of sling outcomes based on patients having had the same type of prostatectomy, and to further analyse UDS parameters to determine potential factors for sling failure. Prospective, multi-centre studies of new male slings are also critically needed to better evaluate their best role in treating male SUI.

## Conclusions

TOMS demonstrates a trend toward better outcomes when compared to BAMS, in a shorter follow up time, in patients who have undergone any type of prostatectomy, and by patient satisfaction. Patients with pre-operative risk factors such as severe incontinence or those who have had pelvic radiation therapy, brachytherapy, or cryotherapy, with or without concomitant urethral stricture disease, should be counselled as to the likelihood of a poor outcome with any type of male sling placement. These patients will be more difficult to treat and may be more appropriate candidates for AUS or urinary diversion.

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## Editorial comment

The authors in this retrospective study have evaluated 2 types of male slings: the perineal bone-anchored and transobturator. Each arm comprised 30 patients. A point of strength in the study was that all cases were performed by one surgeon.

Important to note: 73% of those having bone-anchored and 50% of those with transobturator slings had open prostatectomy, presumably for symptomatic BPH.

However, what is more important is the conclusion the authors made that Transobturator route is better than bone anchored one, regarding cure of incontinence as a primary outcome measure.

Looking at table 1, the length of follow up is significantly different. Those with transobturator tapes were seen much earlier than those with bone anchored slings (14.6 months vs. 43.2 months).

Urethral function was considered poorer in those with the bone-anchored sling. Maximum urethral pressure was significantly lower than transobturator slings. 19 patients in the bone-anchored group were having urethral damage (stricture, irradiation...). This is much higher than the comparable group in the bone-anchored arm (9 only).

It is well documented in the literature that success rate of male slings<sup>1</sup>; like female slings<sup>2</sup>; is inversely proportional to

<sup>1</sup> Wadie, B. S.: Retropubic Bulbourethral Sling for Post-Prostatectomy Male Incontinence: 2-Year Followup. *J Urol.*184, 2446-2451, 2010

<sup>2</sup> Albo, M.E., Richter, H. E, Brubaker L. et al: Burch Colposuspension versus Fascial Sling to Reduce Urinary Stress Incontinence. *N Engl J Med.* 356:2143-55, 2007.

time. Cure rate with such devices usually follows a de-  
crescendo pattern. This intuitively means that a sling performs  
better at shorter follow up without being truly superior.

Urethral function in the group of bone-anchored slings was  
significantly worse than in the transobturator group and this  
also implies that the latter may do better just because of the  
better urethra it is applied to.

Based on these facts, I feel the difference of cure/improve-  
ment between the 2 slings subject matter of the study is not  
truly significant and I would rather stick to the Null hypothe-

sis: the difference between the 2 slings might be entirely attrib-  
uted to chance!

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