

Analyzing outcomes of the adjustable transobturator male system (ATOMS) for post-prostatectomy incontinence and its relationship with detrusor overactivity and radiotherapy with the help of urodynamics

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ABSTRACT

Introduction: The adjustable transobturator male system (ATOMS) has recently garnered attention for its surgical simplicity and suitability for mild post-prostatectomy incontinence (PPI). This retrospective study investigated the outcomes of patients who received ATOMS, including subgroup analyses of individuals with overactive bladder (OAB) or previous radiotherapy.

Methods: A retrospective cohort study was conducted on 104 patients who received ATOMS. To classify mild, moderate, and severe incontinence, preoperative severity was defined as <2 pads per day (PPD), 2–4 PPD, and >4 PPD, based on the 24-hour pad count and/or <200 g, 200–400 g, and >400 g, based on the 24-hour pad-test (24h-PT).

Postoperative “dry” status referred to ≤1 pad/day, while “improved” or “very much improved” indicated a pad reduction of ≥50% or ≥75%,

KEY MESSAGES

- This is among the first studies to incorporate comprehensive preoperative urodynamic findings, thereby uniquely assessing the impact of OAB on ATOMS outcomes.
- Although ATOMS is typically indicated for mild to moderate SUI, our extended followup data show its efficacy in moderate to severe cases as well.
- Our extended followup period provides valuable insights into device durability, highlighting a low explantation rate (5.5%).
- OAB does not significantly affect ATOMS effectiveness, supporting its suitability for broader PPI patient populations.

respectively. Patients who reported “much better” or “very much better” on the Patient Global Impression of Improvement-Incontinence (PGI-I) questionnaire were considered “satisfied.”

Results: Thirteen patients were excluded for insufficient followup, leaving 91 patients (mean age 70 years, mean followup 42 months). Most were classified as moderately (44%) or severely (55%) incontinent, with a median of four pads/day and a mean 24-hour pad test of 351 g preoperatively. At final followup, the median pad count was 0.5; 89% improved overall, 58% became dry, and 91% were satisfied. Complications occurred in 27% (five grade III). Patients with prior radiotherapy (n=29) exhibited lower dryness (55% vs. 79%) and improvement (83% vs. 92%), alongside more adjustments and higher total instilled volume. There were no other significant subgroup differences.

Conclusions: ATOMS appears to be a safe and effective device for PPI, including for moderate to severe incontinence, though radiotherapy may affect efficacy.

INTRODUCTION

The most common cause of male stress urinary incontinence (SUI) is radical prostatectomy, earning it the title of post-prostatectomy incontinence, or PPI (2). The prevalence of PPI is estimated to range from 1% to 40% of patients after surgery (3) and is widely recognized as one of the most serious complications of prostate cancer treatment, severely impacting patient quality of life (QoL) (4,5).

As a result, there has been an increased demand for development of surgical techniques aimed preserving the sphincter and reducing PPI prevalence. In modern medicine, the initial PPI typically involves conservative treatments, such as pelvic floor muscle training, as well as lifestyle modification for at least the first 6 to 12 months (6). Improvement from these non-invasive techniques tends to plateau over this timeframe, and if continence is not achieved, conservative treatment is considered to have failed. During this period, patients may benefit from penile clamps, condom catheters, or other devices to manage their continence. These devices may also be used long-term, if proven helpful and acceptable for some patients. If conservative treatment fails, surgical treatment is then offered as the next course of action.

Among surgical treatments, the artificial urinary sphincter (AUS) is known to be the “gold standard” surgical PPI treatment (3,5,7,8). However, since its development in 2008, the *Adjustable Male Transobturator System* gained popularity among the male slings (9) due to its post-operative adjustability without need for invasive surgery. Although the exact number of overall ATOMS implantations since its introduction remains unknown, a recent meta-analysis published in 2023 pooled data from over 1,500 patients who received the most-recent generation of the device (10). The device can be easily adjusted in the clinical setting by injecting or withdrawing isotonic contrast solution, or sterile saline.

The concept of the ATOMS device was initially introduced via a cadaveric study in 2005. The first-generation of the publicly available device goes back to 2008, where a titanium circular port was to be placed in the inguinal region. This device necessitated both a perineal and an inguinal incision.

In 2013, a second-generation version relocated the port into the scrotum and introduced a membrane covering — therefore avoiding the inguinal incision but still requiring a tube connection. This change from an inguinal to a scrotal port has significantly facilitated the procedure, reduced infection risk, postoperative pain, and the time required for postoperative sling volume adjustments.

Subsequently, the third generation, introduced in 2014, the port was pre-attached and covered with silicone (SSP), eliminating the need for a separate connection. The pre-attached port was proven to shorten operative time and avoids possible serum leakage through a tube connection, while the silicone reduced any rare titanium-related complications observed with earlier versions (10).

The aim of this study is to analyze outcomes of ATOMS in patients suffering from post-prostatectomy incontinence. Outcomes are measured by post-operative reduction in pad count, postoperative dryness rates, and patient-reported satisfaction. The secondary objectives are to assess the incidence and severity of device-related complications, and to evaluate the impact of overactive bladder and radiotherapy on device effectiveness, with the assistance of pre-operative urodynamics.

Based on the literature review, we hypothesize that the ATOMS device is a safe and effective treatment for PPI. However, we anticipate that its effectiveness will be lower in patients with more severe incontinence. Additionally, we suspect that both prior pelvic radiotherapy and the presence of overactive bladder, defined by clinical symptoms and urodynamic evidence of detrusor overactivity, will negatively impact the devices outcomes.

METHODS

Study design and participants

The present retrospective cohort study included all patients who received implantation of the third-generation ATOMS device between June 2015 and March 2021.

Outcomes

Prior to the surgery, all patients underwent a comprehensive evaluation, which included various assessments such as questionnaires, 24-hour pad test and pad count, cystoscopy and urodynamics. To classify the severity of incontinence as mild, moderate or severe, preoperative incontinence severity was defined as <2 pads per day (PPD), 2-4 PPD and >4 PPD regarding 24h pad-count and/or <200g, 200-400g, and >400g regarding 24h pad-test (24h-PT). A patient was considered "Dry" if they had 0 or 1 pad post-operatively. Improvement rates were determined by the reduction in pre- versus post-operative pads per day. Patients who experienced a decrease in

PPD by $\geq 50\%$ or $\geq 75\%$ were defined as "Improved" or "Very much improved", respectively. With regards to satisfaction, significant patient satisfaction was defined as having "Much better" and "Very much better" results from the PGI-I questionnaire.

Complications were classified under the Clavien-Dindo classification system. Grade I complications involved any deviation from the normal postoperative course that did not necessitate treatment beyond those for supportive care. Grade II complications required treatment that exceeded the scope of Grade I, which indicated a more significant deviation from the expected recovery. Lastly, Grade III complications were characterized by the need for surgical intervention, thereby representing a higher degree of severity.

For the purposes of this study, an overactive bladder was defined as the presence of both clinical symptoms (urinary urgency, with or without urge incontinence) and urodynamic evidence of detrusor overactivity during pre-operative testing. Patients with either isolated symptoms or isolated urodynamic findings were not classified as having OAB.

One experienced surgeon at our center implanted all the devices. Patients were then followed up as needed every two weeks for device adjustments. After optimal adjustment, all patients underwent a 24-hour pad count test and a PGI-I questionnaire. One year after optimal device adjustment, patients' pain was measured using the visual analogue scale (VAS). During retrospective analysis of medical records, any patient with a follow up inferior to 12 months was excluded from the study.

Statistical analysis

Descriptive statistics were presented as frequencies and percentages for categorical, mean, and standard deviation (SD; [min-max]) or median and interquartile range (IQR; [min-max]). Variables distributions were validated visually by histograms. No imputation methods were used. Listwise deletion was applied for concerned analyses. All statistics were analysed with a two-sided α of 0.05. Statistical analyses were performed with SPSS v.28.

Pre-post outcomes were compared using Wilcoxon signed-rank test for non-parametric data. Association with radiotherapy were evaluated using unpaired Student's t-tests (or Mann-Whitney) for continuous variables and Chi-squared χ^2 (or Fisher's exact test) for categorical variables.

RESULTS

The medical records of 104 patients were analysed, and 13 patients were excluded due to a follow-up inferior to 12 months. The demographic data for the 91 patients included in the study can be found in *Table 1*. The patients included had a mean age of 70 years (6.6; [55-88]) and a mean follow-up of 42.3 months (1.9; [12-78]). Among the 91 patients, 21 had previously undergone incontinence surgeries. The breakdown of prior treatments can be found in *Table 1*.

Pre-operatively, patients had a median PPD of 4 (3-6; [1-12]) with a mean 24h-PT of 351 g (178-484; [30-1174]). Most patients were therefore classified as being moderately (n=40, 44%) to severely (n=50, 54.9%) incontinent (*Table 2*).

At final follow up, we observed a significant decreased in median PPD (3 [2.5 - 5] vs 0.5 [0 - 1.5]; $p<0.001$). Eighty-one (89.0%) patients noted overall improvement, with 67 (76.0%) of them being “very much improved”, and 65 (97%) being “dry”. Eighty-three (91.2%) patients were satisfied. Twenty-five (27.4%) patients experienced complications of any Clavien-Dindo grade, of which 5 were grade III. Among the grade 3 complications, three patients presented device leakages, and two patients presented device migrations. In our group comparison (*Table 2*), patients having received prior radiotherapy (n=29, 32%) had a lower dryness rate (55% vs 79%; $p=0.02$) than those having not received radiotherapy. Radiotherapy recipients also required more post-operative device adjustments (median 3 [2-4] vs 1 [1-3]; $p=0.001$) and had a higher total instilled volume (median 18.5mL [13.5-22] vs 13mL [10-16]; $p=0.01$). Despite the statistically significant difference in instilled volumes, it is noteworthy that patient satisfaction rates were not significantly different between the two groups, indicating that both cohorts were comparably satisfied with the procedure. There were no other statistically significant differences of interest found. Notably, we could not conclude any differences in complication rates at any Clavien-Dindo grade, as well as that of the patient satisfaction rate (*Table 3*).

Among the included patients, 23 (25.2%) of patients presented with detrusor overactivity with clinical symptoms of overactive bladder alongside their stress-urinary incontinence proven on pre-operative urodynamic testing. This group of patients had no statistically significant difference pre-operatively or post-operatively than patients who did not present with detrusor overactivity alongside their PPI. Findings for this association analysis can be found in *Table 3*. Furthermore, patients who were classified only symptomatically as having overactive bladders, regardless of pre-operative urodynamic testing, were found to have no statistically significant differences than those who did not.

DISCUSSION

The ATOMS device has been made available in Canada in 2014 and is not yet available in the United States. It is a self-anchoring adjustable system that supports the bulbar urethra using the trans-obturator approach (9). In the treatment of PPI, the Artificial Urinary Sphincter is known as the “Gold Standard” procedure. However, the ATOMS device has gained popularity, and it has been suggested by some to consider it among modern PPI treatments. Our article shows that the ATOMS is a relatively safe and effective procedure in the resolution of PPI.

Esquinas et al. published a meta-analysis in 2018 analyzing results of over 1300 patients who have undergone the ATOMS surgery (11). When comparing our results to theirs, our findings are similar. Nonetheless, our study has a slightly higher success rate (71% vs 67%) and lower explantation rates (4.4% vs 5.75%). Satisfaction rates are comparable (90% in the meta-analysis

vs 91% in the present study). With study findings similar to that of the meta-analysis, the present study demarcates itself from the rest of the literature because of three main reasons: long patient follow-ups, incontinence severity, and pre-operative urodynamics testing.

Another study comparing the ATOMS sling versus the Artificial Urinary Sphincter was recently published. Their study found that explants rate was earlier for AUS than for ATOMS, and their Kaplan-Meier analysis showed that device durability was higher in ATOMS. In their study, the lower explanation rates were attributed to the single incision procedures and shorter learning curves for medical professionals to implant (12). The mean follows up for the said study was 34.9 months. In contrast, the mean follow-up of our patients was longer (42.33 months), which allowed us to thoroughly investigate device durability. Among our 91 patients, 5 patients (5.5%) required device explantation. These 5 patients all requested reimplantation of the same device afterwards. Device removal was performed by removing the main ATOMS device and by following up the pubic rami to remove as much of the polypropylene mesh as possible. Due to fibrotic tissue growing over the mesh, it was deemed unsafe to completely remove all of the mesh, and extreme measures would have been needed to do so. Thus, the mesh was removed as much as possible, and the new ATOMS device was placed on top of the previous devices' mesh in a second surgery.

The study by *Redmond et al.* concludes that prior radiotherapy, diabetes, and severe incontinence significantly reduce the likelihood of ATOMS success, with radiotherapy associated with higher explanation rates and complications. In radiated patients, their findings align with our results, which also demonstrate lower dryness rates and higher adjustment volumes. Comparatively, the AUS, has historically been considered the gold standard for severe PPI, including in radiated patients. This device in radiated individuals is also associated with worse outcomes, such as higher rates of device erosion, mechanical failure, and explantation. While our findings indicate that ATOMS is less effective in radiated patients than in non-radiated ones, its post-operative adjustability may explain why it still achieves acceptable efficacy and patient satisfaction. Our findings could suggest that ATOMS remains a strong alternative for radiated patients, though careful patient selection and expectation management are essential.

On top of this, with a high population of severely incontinent patients in our study, we demonstrated that they were treated efficaciously with ATOMS implantation, which contrasts the findings of *Redmond et al.*. This raises the question of whether ATOMS could begin to be considered for use in moderately to severely incontinent patients, expanding its indications beyond what is currently recommended.

Future studies with direct comparisons between ATOMS, AUS in severely incontinent radiated populations would be valuable in further defining optimal treatment strategies. New surgical techniques are continually being developed to enhance the effectiveness of this device. In a 2023 article, *Queissert et al.* detailed the modification of the installation technique of

this system, aiming to improve its effectiveness (16). Their study reported on four patients who required reimplantation of the ATOMS device due to initial misplacement. Following reimplantation using the novel surgical approach, all four patients experienced significant improvement in their symptoms. These findings are promising, suggesting potential advancements in the management of explantation and device migration in ATOMS.

One reason for hesitancy to increase use of ATOMS in PPI is due to its lack of effectiveness in severely incontinent patients. Today's literature reserves the ATOMS device for mild-to-moderately severe stress urinary incontinence, and less severe incontinence (13). In fact, a negative correlation has been found between the ATOMS device's effectiveness and urinary incontinence severity. The more severe the incontinence, the less effective the device. To quantify, it was stated that the chances of continence were 6-fold greater in patients with < 423g 24h-PWT than in those with higher than 423g (1). Additionally, another study states that injection of over 15-20CC's into the device post-operatively rarely improves continence status (9). Despite the majority of our population being moderately or severely incontinent, our findings show high continence rates. Therefore, ATOMS may potentially be considered in severely incontinent patients.

4 men included during revision

Kielb & Clemens found that the presence of detrusor overactivity did not affect the results of bulbourethral slings. However, to our knowledge, no other study has evaluated the impact of OAB or detrusor overactivity on effectiveness and satisfaction of the ATOMS device specifically. By systematically performing pre-operative urodynamic studies on all of our patients, our findings support those of Kielb & Clemens in that OAB does not impact ATOMS effectiveness. Lai et Boone reported similar findings for the AUS device, indicating that OAB does not negatively impact its effectiveness (15).

One limitation of the present study is of its subjective nature. Some individuals may change their pads more frequently than others due to personal preference, for example. As a result, the 24-hour pad count may not be a fully accurate representation of the level of incontinence experienced by an individual, and relying solely on this metric may lead to inaccurate conclusions about the effectiveness of the ATOMS device. Therefore, it would be important in future studies to consider other measures in addition to the 24-hour pad count when evaluating the effectiveness of urinary incontinence devices.

Another limitation of the present study is its retrospective design, which can limit the ability to draw definitive causal inferences. The retrospective nature may affect the consistency and completeness of the data, since it depends on the accuracy and consistency of medical records and patient recall.

Additionally, it is important to note that the present study is limited by its relatively small sample size and single-center design. Larger prospective, multicenter studies with longer follow-up periods could further evaluate the effectiveness and safety of the ATOMS device in PPI

treatment. Nonetheless, the present study provides valuable insights into the use of the ATOMS device in a real-world clinical setting.

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CONCLUSIONS

The utilization of the ATOMS device in the treatment of post-prostatectomy incontinence appears to be safe and effective, with negative effects on device effectiveness noted in patients with prior history of pelvic radiotherapy but not those with overactive bladders or detrusor overactivity. The findings of this study highlight the need for more robust research and support the opportunity to undertake a prospective, non-inferiority pilot project that directly compares the effects of the Artificial Urinary Sphincter and the Adjustable Trans Obturator Male System in the treatment of male urinary stress incontinence.

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FIGURES & TABLES

Table 1. Patient demographics	
Age, years, mean \pm SD (range)	70.4 (6.6) [55–88]
Previous prostate surgeries, n (%)	91 (100)
Radical prostatectomy	90 (98.9)
Open	5 (5.5)
Laparoscopic	80 (87.9)
Robotic	4 (4.4)
Transurethral resection	1 (1.1)
History of pelvic radiation, n (%)	29 (31.9)
History of urethral stenosis, n (%)	32 (35.2)
Previous incontinence surgery, n (%)	21 (23.1)
Pro-ACT	8 (38.0)
Virtue	5 (23.8)
ATOMS	5 (23.8)
AUS	3 (14.3)

ATOMS: adjustable transobturator male system; AUS: artificial urinary sphincter; SD: standard deviation.

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Table 2. Comparison of ATOMS outcomes in patients having received prior radiotherapy vs. those who have not on several parameters					
	No prior radiotherapy (n=61, 68.1%)		Prior radiotherapy (n=29, 31.9%)		p ^a
Median preoperative 24-h pad-test, g (SE)	434	(37.3)	320	(42.9)	0.50 ¹
Preoperative incontinence severity					
Mild incontinence (%)	1	(1.6)	0	(0)	0.77 ²
Moderate incontinence (%)	26	(41.9)	14	(48.3)	0.77 ²
Severe incontinence (%)	35	(56.5)	15	(51.7)	0.77 ²
Median preoperative PPD (IQR)	4	(5–3)	4	(6–3)	0.39 ¹
Median postoperative PPD (IQR)	0.5	(1–0)	1	(2.5–0.25)	0.005¹
Median pad change (IQR)	3	(5–2.5)	3	(4.75–2)	0.45 ¹
Dryness after final adjustment (%)	49	(79)	16	(55.2)	0.02²
Improvement after final adjustment (%)	57	(93.1)	23	(82.8)	0.30 ²
Very much improved after final adjustment (%)	50	(81.9)	17	(58.6)	0.09 ²
Patient satisfaction (%) ^d	58	(93.5)	25	(86.2)	0.26 ²
Median number of adjustments (IQR)	1 ^b	(3–1)	3.0 ^c	(4–2)	0.001¹
Median total volume instilled, mL (IQR)	12.75 ^b	(16–10)	18.5 ^c	(22–13.5)	0.001¹
Median months from surgery to 1 st adjustment (IQR)	0.21 ^b	(0.7–0.1)	0.20 ^c	(0.4–0.2)	0.73 ¹
Postoperative complication of any grade (%)	15	(24.2)	9	(31.0)	0.49 ²
Grade I (%)	12	(80)	5	(55)	–
Grade II (%)	0	(0)	2	(22)	–
Grade III (%)	3	(20)	2	(22)	–
Explantation rates (%)	3	(4.9)	2	(6.7)	0.26 ²

^ap < 0.05 are considered statistically significant. ^bIncludes the 54 patients (88.4%) who required ≥1 adjustments. ^cIncludes the 29 patients (100%) who required ≥1 adjustments. ^dSignificant patient satisfaction was defined by “Much better”, and “Very much better” PGI-I results. ¹p-value calculated using the Mann-Whitney test. ²p-value calculated using the Fisher exact test. ATOMS: adjustable transobturator male system; IQR: interquartile range; PPD: pads per day; SE: standard error.

Table 3. Comparison of ATOMS outcomes in patients presenting with detrusor overactivity with clinical symptoms versus those who do not on several parameters					
	Absence of DO (n=68, 75%)		Presence of DO (n=23, 25%)		p
Median preoperative 24-h pad-test, g (SE)	504	(37.3)	337	(42.9)	0.26 ¹
Preoperative incontinence severity					
Mild (%)	1	(1.5)	0	(0)	0.08 ²
Moderate (%)	34	(50)	6	(26.1)	0.08 ²
Severe (%)	33	(48.5)	17	(73.9)	0.08 ²
Median preoperative PPD (IQR)	4	(5–3)	4	(6 - 3)	0.12 ¹
Median postoperative PPD (IQR)	0.5	(1.4–0)	0.5	(2-0)	0.89 ¹
Median pad change (IQR)	3	(4–2.5)	4	(5.5–3)	0.07 ¹
Dryness after final adjustment (%)	49	(72)	16	(69.6)	0.82 ²
Improvement after final adjustment (%)	60	(88.2)	21	(91.3)	1.00 ²
Very much improved	50	(73.5)	16	(69.6)	0.93 ²
Patient satisfaction (%) ^d	61	(89.7)	22	(95.7)	0.67 ²
Median number of adjustments (IQR)	2 ^b	(4–1)	2 ^c	(3–1)	0.52 ¹
Median total volume instilled, mL (IQR)	14 ^b	(18–11)	15 ^c	(19–11)	0.60 ¹
Median months from surgery to 1 st adjustment (IQR)	0.20 ^b	(0.6–0.1)	0.20 ^c	(0.4–0.2)	0.58 ¹
Postoperative complication of any grade (%)	16	(23.5)	8	(34.8)	0.29 ²
Grade I	13	(81)	5	(55)	–
Grade II	0	(0)	1	(11)	–
Grade II	3	(19)	2	(22)	–

^ap < 0.05 are considered statistically significant. Includes the 68 patients (100%) who required ≥1 adjustment. ^cIncludes the 23 patients (100%) who required ≥1 adjustment. ^dSignificant patient satisfaction was defined by “Much better”, and “Very much better” PGI-I results. ¹p-value calculated using the Mann-Whitney test. ²p-value calculated using the Fisher exact test. ATOMS: adjustable transobturator male system; DO: detrusor overactivity; IQR: interquartile range; PPD: pads per day; SE: standard error.