# Analyzing outcomes of the adjustable transobturator male system 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%, 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, although 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 (PPI).[1,2] The prevalence of PPI is estimated to range from 1–40% 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 the development of surgical techniques aimed at preserving the sphincter and reducing PPI prevalence. In modern medicine, initial PPI treatment typically involves conservative treatments, such as pelvic floor muscle training, as well as lifestyle modification for at least the first 6–12 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

## 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.

Adjustable Male Transobturator System (ATOMS) gained popularity among the male slings due to its postoperative adjustability without the need for invasive surgery.[9] Although the exact number of overall ATOMS implantations since its introduction remains unknown, a recent meta-analysis published in 2023 pooled data from over 1500 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, thereby avoiding the inguinal incision, but still requiring a tube connection. This change from an inguinal to a scrotal port has significantly facilitated the procedure, as well as reduced infection risk, postoperative pain, and the time required for postoperative sling volume adjustments.

Subsequently, in 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 avoid 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 was to analyze outcomes of ATOMS in patients suffering from PPI. Outcomes were measured by postoperative reduction in pad count, postoperative dryness rates, and patient-reported satisfaction. The secondary objectives were to assess the incidence and severity of device-related complications. and to evaluate the impact of overactive bladder (OAB) and radiotherapy on device effectiveness, with the assistance of preoperative urodynamics (UDS).

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 OAB, defined by clinical symptoms and urodynamic evidence of detrusor overactivity, will negatively impact the device 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 UDS. 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 <200 g, 200–400 g, and >400 g regarding 24h pad-test (24h-PT). A patient was considered "dry" if they had 0 or 1 pad postoperatively. Improvement rates were determined by the reduction in pre- vs. postoperative PPD. Patients who experienced a decrease in PPD by ≥50% or ≥75% were defined as "improved" or "very much improved," respectively. Significant patient satisfaction was defined as having "much better" and "very much better" results from the Patient Global Impression of Improvement-Incontinenc (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 OAB was defined as the presence of both clinical symptoms (urinary urgency, with or without urge incontinence) and UDS evidence of detrusor overactivity during preoperative testing. Patients with either isolated symptoms or isolated UDS 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 followup 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]). Variable 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 $\alpha$ 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 was evaluated using unpaired Student's t-tests (or Mann-Whitney) for continuous variables and Chi-squared $\chi^2$ (or Fisher's exact test) for categorical variables.

## RESULTS

The medical records of 104 patients were analyzed, and 13 patients were excluded due to a followup 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 followup 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.

Preoperatively, 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).

**Table 1. Patient demographics**

| | |
|---|---|
| Age, years, mean ± 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) |

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

At final followup, we observed a significant decrease 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 five were grade III. Among the grade III complications, three patients presented with device leakages and two with device migrations.

In our group comparison (Table 2), patients who had received prior radiotherapy (n=29, 32%) had a lower dryness rate (55% vs. 79%, p=0.02) than those who had not received radiotherapy. Radiotherapy recipients also required more postoperative device adjustments (median 3 [2–4] vs. 1 [1–3], p=0.001) and had a higher total instilled volume (median 18.5 mL [13.5–22] vs. 13 mL [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

**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) | 0.501 |
| 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) | 0.005[1] |
| Median pad change (IQR) | 3 | (5–2.5) | 3 | (4.75–2) | 0.45[1] |
| Dryness after final adjustment (%) | 49 | (79) | 16 | (55.2) | 0.02[2] |
| 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) | **0.001**[1] |
| Median total volume instilled, mL (IQR) | 12.75[b] | (16–10) | 18.5[c] | (22–13.5) | **0.001**[1] |
| Median months from surgery to 1st 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] |

[a]p<0.05 are considered statistically significant. [b]Includes the 54 patients (88.4%) who required ≥1 adjustments. [c]Includes the 29 patients (100%) who required ≥1 adjustments. [d]Significant patient satisfaction was defined by "Much better", and "Very much better" PGI-I results. [1]p-value calculated using the Mann-Whitney test. [2]p-value calculated using the Fisher exact test. ATOMS: adjustable transobturator male system; IQR: interquartile range; PPD: pads per day; SE: standard error.

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%) presented with detrusor overactivity with clinical symptoms of OAB alongside their SUI proven on preoperative UDS. This group of patients had no statistically significant difference preoperatively or postoperatively 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 OAB, regardless of preoperative UDS, were found to have no statistically significant differences from those who did not.

## DISCUSSION

The ATOMS device was available in Canada in 2014 and is not yet available in the U.S. It is a self-anchoring adjustable system that supports the bulbar urethra using the transobturator approach.[9] In the treatment of PPI, AUS is considered the gold-standard procedure; however, the ATOMS device has gained popularity. 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 ATOMS surgery.[11] Our findings are very similar to theirs. Nonetheless, our study has a slightly higher success rate (71% vs. 67%) and lower explantation rate (4.4% vs. 5.75%). Satisfaction rates are comparable

**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 1st 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) | – |

[a]$p<0.05$ are considered statistically significant. [b]Includes the 68 patients (100%) who required ≥1 adjustment. [c]Includes the 23 patients (100%) who required ≥1 adjustment. [d]Significant patient satisfaction was defined by "Much better", and "Very much better" PGI-I results. [1]p-value calculated using the Mann-Whitney test. [2]p-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.

(90% in the meta-analysis vs. 91% in the present study). With study findings similar to that of the meta-analysis, the present study distinguishes itself from the literature for three main reasons: 1) long patient followups; 2) incontinence severity; and 3) preoperative UDS.

Another recent study comparing the ATOMS sling to AUS found that the explant 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 followup for the study was 34.9 months, in contrast to our mean followup of 42.33 months, which allowed us to thoroughly investigate device durability.

Among our 91 patients, five (5.5%) required device explantation. These five 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.

A 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.[13] In radiated patients, their findings align with our results, which also demonstrate lower dryness rates and higher adjustment volumes. Comparatively, 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 postoperative 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, although careful patient selection and expectation management are essential.

Further, with a high population of severely incontinent patients in our study, we demonstrated that they were treated effectively 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 and 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.[14] 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 ATOMS use in PPI is its lack of effectiveness in severely incontinent patients. Today's literature reserves the ATOMS device for mild to moderately severe SUI and less severe incontinence.[15] 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 six-fold greater in patients with <423 g 24h-PT than in those with higher than 423 g.[1] Additionally, another study states that injection of over 15–20 cc into the device postoperatively 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.

Kielb and Clemens found that the presence of detrusor overactivity did not affect the results of bulbourethral slings;[16] however, to our knowledge, no other study has evaluated the impact of OAB or detrusor overactivity on the effectiveness and satisfaction of the ATOMS device specifically. By systematically performing preoperative UDS on all of our patients, our findings support those of Kielb and 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.[17]

### Limitations

One limitation of the present study is 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 for future studies to consider other measures in addition to the 24-hour pad count when evaluating the effectiveness of urinary incontinence devices.

Another limitation is the study's 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 followup 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.

## CONCLUSIONS

The use of the ATOMS device in the treatment of PPI 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 OAB 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 AUS and ATOMS in the treatment of male SUI.

COMPETING INTERESTS: Dr. Ismail has received honoraria from Astellas. The remaining authors do not report any competing personal or financial interests related to this work.

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