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## LONG-TERM OUTCOME AFTER IMPLANTATION OF THE ATOMS CONTINENCE DEVICE: 7 YEAR MULTI-CENTER DATA

### Hypothesis / aims of study

Male stress urinary incontinence (SUI) is one of the major complications after prostate treatment (radical prostatectomy [RPE], transurethral resection of the prostate [TURP], radiotherapy [RT]) and incontinence surgery should be recommended to patients after failed conservative therapy options. Beside the use of the artificial urinary sphincter (AUS) the last few years have been marked by the rapid development of several continence systems (male slings), of varying designs and usually implanted via a minimally-invasive approach.

The Adjustable Transobturator Male System (ATOMS), one of these novel devices, is now in its third generation with a pre-attached fully silicon covered port system (SSP) and shows promising outcomes in short and mid-term studies (1, 2, 3) of the precursor generations (inguinal port [IP], simple scrotal port [SP]). This study presents the first long-term results with the largest follow-up period and largest patient database. It provides new findings on the efficacy, tolerability and durability of the three ATOMS generations.

### Study design, materials and methods

In a total of 287 male patients with mild (1-2 pads/24h), moderate (3-5 pads/24h) and severe (>5 pads/24h) SUI after RPE, TURP and RT were treated with the ATOMS device in 5 international high volume continence centers between 11/2009 and 3/2016. Surgical technique as well as peri-operative procedure was standardized. Ethics committee approval and patient consent were obtained.

Patient characteristics (age, body mass index [BMI], minimal mental state [MMS], time from prostate treatment to ATOMS implantation) and patient performance status was determined using the Charlson Comorbidity index (CCI) and the American Society of Anesthesiologists (ASA) physical classification.

Clinical outcome parameters were overall success rate ([OSR]; improvement in daily pad test and pad use), dry rate ([DR]; <10ml in daily pad test and 0-1 pad use), quality of life ratings (ICIQ-SF, PGI-I), urodynamic measurements (uroflowmetry [Qmax], post void residual urine [PVR], bladder capacity [Vol]), device removal, device durability and complications (Clavien-Dindo scale). Surgery outcome parameters were operation time (OT), number of days catheterized and admission days. Subgroup analysis was done between port types, former ineffective incontinence procedures [primary (PI; no previous surgery), secondary (SI; 1 previous surgery), tertiary implantation (TI; >1 previous surgery)] and history of radiotherapy and urethral surgery.

### Results

At implantation mean patient age was 69.7 years and 77% were over 65 years old. Average BMI was 27.8, MMSE was 28.7 and time from prostate treatment to ATOMS implantation was 5.5 years. Mean age at the start of prostate treatment was 65.9 years. RPE, TURP, TURP+RPE, RT and RPE+RT were done in 61.8%, 9.3%, 0.8%, 1.6% and 15.8% respectively. Mean CCI/ASA was 7.3/2.2 and 8.5%/15.5% had additionally urge incontinence and urethral surgery in their preoperative history. 19.9% of patients had had previous incontinence surgery or bulking agents (AdVance, AdvanceXP, AMS 800, Argus, Deflux, InVance, ProAct, ZSI 375 in alphabetical order) and 4.9% had had at least two failed devices before.

59.2% of patients had the IP (2009-2013), 28.2% the SP (2013-2015) and 12.6% the SSP (2014-2016) at implantation. After mean follow-up at 32.5 months (range 0.1-75.0) and after a mean of 3.0 adjustments daily pad test and pad use decreased from 539.5g/4.4 to 86.1g/1.3 (both p<0.001), concomitantly all quality of life parameters (ICIQ-SF 16.8 to 4.9 and PGI-I 4.4 to 1.6; both p<0.001) improved and urodynamic measurements changed (Qmax 16.2 reduced to 14.7 ml/s and voiding volume 159.4 increased to 203.8 ml; both p<0.001). PVR was marginal higher in the follow-up (3.5 to 8.1 ml). Pain perception scales declined slightly after implantation (VAS 0.1 to 0.6 and LANSS 0.1 to 0.9; both p<0.001). Percentage of SUI grade varied significantly between baseline and follow-up (severe SUI from 24% to 2%; moderate SUI from 65% to 11%; mild SUI from 11% to 60%; no SUI from 0% to 26%).

In all generations OSR and DR was 91.6% and 67.1% respectively. Mean OT was 46.1 minutes and average number of catheterization/admission days was 1.2/3.5 days. No intraoperative complications occurred in any procedures. The majority of post-operative complications were Clavien Dindo 1-3 (6 early infections, 7 urinary retentions, 6 hematomas), 4 and 5 did not occur. At present 80.5% of all implanted ATOMS devices are still working. In contrast 19.5% (n=56) got removed due to local titanium intolerance (8.0%), leak/dysfunction (6.6%), early infection (≤30 days; 1.4%), late infection (>30 days; 1.4%), dislocation (1.4%) persistent pain (0.7%) with a mean time to explantation of 17.9 months. Of removals, 10.1% received an ATOMS re-implantation and 3.8% an AUS implantation after completed wound healing. A solitary port-system change (IP to SP) was carried out in 4.9% due to malrotation or port dysfunction.

In subgroup analysis the SSP generation has the shortest OT (IP/SP/SSP 52.4/40.1/29.3 minutes) and best tolerability (76.0/82.7/97.2% of devices are still working) even though the follow-up period is shorter (mean 6.0 months) compared to the IP/SP (mean 42.8/22.8 months). However, the continence outcome parameters OSR and DR (91.7%/80.6%) are superior to the IP (88.1%/67.9%) and SP (86.3%/51.3%) group.

Patients with PI or without RT in history showed greater durability (85.2%/85.5%) over time compared to SI (67.5%)/TI (78.9%) and patient with previous RT (64.2%).

### Interpretation of results

Similar to former reports and to the present literature the ATOMS continence device also confirms good effectiveness in large scale follow-up of up to 7 years if standardized perioperative procedure is implemented. Patient satisfaction is high and complication rates are low post-operatively. Intra-operative complications did not occur and the surgical approach is safe. ATOMS re-implantation is possible, although the risk of a re-removal is higher. OT and time of admission are short. Clinical outcome varies between port types and between PI/SI/TI and treatment failure is higher in patient with a history of RT. The latest generation (SSP) shows best results in effectiveness and tolerability.

### Concluding message

The ATOMS shows good continence outcome, device durability and high patient satisfaction in the largest presently known follow-up. The third generation with its pre-attached SSP is superior to the precursors in OT, continence outcome and device tolerability. In all generations, enhanced results are possible with PI and without RT in the patient history.

### References

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### Disclosures

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