# Sexuality and erectile function after implantation of an Adjustable Transobturator Male System (ATOMS) for urinary stress incontinence. A multi-institutional prospective study

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#### **Summary** Objectives: To investigate erectile function and sexuality before/after implantation of the ATOMS device including continence outcome, pain perception and co-morbidities.

Materials and methods: We collected data from 34 patients (2010-2014) who were provided with an ATOMS implant due to mild or moderate stress urinary incontinence (SUI) after radical prostatectomy (RPE), transurethral resection (TURP) or radiotherapy. Previous failed implants were no contraindication. Sexuality was evaluated with the International Index of Erectile Function (IIEF-5). The Visual Analog Scale (VAS) and Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) were used to analyse pain perception. Results regarding continence, influence of co-morbidities and drug intake were interpreted.

Results: IIEF-5 score increased 6 months after ATOMS implantation with a mean difference of 2.18 (Cl: 1.22, 3.14), p < 0,001). Non-sexually active patients had the greatest benefit. However, 50% of patients achieved a mean IIEF-5 of 10.1 and 38% of patients reported a new onset of sexual activity at follow up (mean IIEF-5 score of 12.9). This is in accordance with reduced SUI and absence of persistent pain syndrome. Overall success rate regarding 24h pad-use was 88% (no pad rate 38%). Previous failed implants did not influence results but diabetes, obesity and drug intake (beta-blockers, antidepressants) led to poorer outcomes.

Conclusion: Sexuality and erectile function improves significantly 6 months after ATOMS implantation. We postulate that reduced SUI (also during sexual activity) and absence of chronic pain are the improving factors. ATOMS should be offered to men with mild to moderate SUI who are interested in regaining their erectile function and sexual activity.

**KEY WORDS:** Stress urinary incontinence; Sexual activity; Erectile function.

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## INTRODUCTION

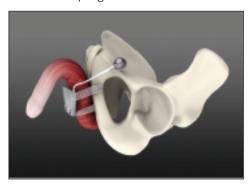
Male stress urinary incontinence (SUI) continues to be the most common complication after radical prostatectomy (RPE). 27% to 38% of patients are incontinent two years after RPE (1). An urodynamic study with 3 Tesla MRI was able to identify functional and anatomical changes causing post prostatectomy incontinence (PPI). A decrease in urethral length (31-35%), sphincter distorsion (85.7%), lacking build-up of urethral pressure and an increased angle of the neo-bladder neck funnel (28.9°) were recognised and associated with PPI (2).

Equally pre- and postoperative psychological stress has a negative effect on the development of PPI (3), especially if patients expect urinary symptoms after prostate treatment the Hospital Anxiety and Depression Scale (HADS) shows poor values (18). The fear of urinary leakage during sexual intercourse affects 44.4% of patients 3 months after surgery and 36.1% after 2 years (4). An American study (n = 15) demonstrated an improved sexual quality of life (QoL) after implantation of an artificial urinary sphincter (AUS) or a sling device in PPI patients (5). We thus found out that the erectile function can be posi-

tively affected by the reduction of urinary leakage and lack of permanent pain syndrome as well as by the anatomical location and placement of the implant. We have an unproven assumption that the ATOMS device, with its central cushion directly placed on the bulbospongiosus muscle is probably able to improve erectile function by changing the behaviour of the nearby spongious body of the penis (Figure 1). Therefore further studies have to prove this hypothesis. Incontinence implants vary greatly from non-adjustable/non-anchored systems, nonadjustable/anchored systems or adjustable/non-anchored systems to artificial urinary sphincteric (AUS) systems with on-off cuff function. Sling systems are preferable to AUS systems for mild and moderate SUI (6). Erosion rates of 3-13% and wound infection rates of 3-11% vary between studies and may lead to explanation (7). The ATOMS, which is characterized by firm anchoring and adjustability, has the advantage that its position at the distal bulbospongiosus muscle allows it to be applied even prior to and following radiotherapy.

## Figure 1.

The ATOMS implant placed on the bulbospongiosus muscle.



The central cushion is placed on the bulbospongiosus muscle and indirectly on the spongious body. The ATOMS implant is characterized by firm transobturatoric anchoring and easy adjustability by transdermal punction of the inguinal or scrotal port. The position at the distal bulbospongiosus muscle allows further radiotherapy.

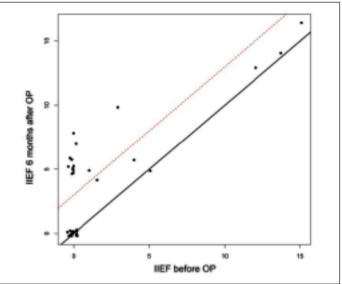
It has been constantly established on the market for about 5 years (8). The overall success rate after 18 months lies at 92%, whereby 63% of patients are continent and 29% report an improvement of SUI in terms of a reduced paduse. An average pad-use reduction from 7.1 to 1.3/24h was recognised (9). Erosions are rare due to the lack of contact with the urethra and transient perineal/scrotal dysesthesia can be avoided by intraoperative lateralization of the neurovascular bundle including the posterior scrotal nerves.

# **MATERIALS AND METHODS** *Patients*

In this prospective, non-randomized, single center study a total of 34 men with mild (1 to 2 pads per day) to moderate (3 to 5 pads per day) SUI were provided with an ATOMS implant between January 2010 and March 2014 after urodynamic investigation. A valid approval from the ethics committee and written consent from all patients were obtained. 30 of the patients had a previous RPE (76% retropubic RPE (RRPE) 24% endoscopic RPE (ERPE)), 4 patients had got a transurethral resection of the prostate (TURP) only, and 9

# Figure 2.

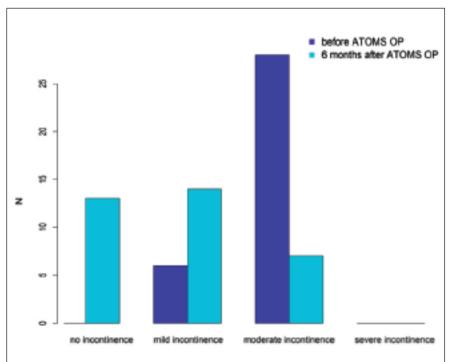
IIEF-5 score pre- and postoperatively.



Every patient is represented by his IIEF-5 score preand postoperatively. Points above (below) the black line indicate an improvement (decline) of erectile function. For points above the dotted red line, the IIEF-5 score increased for at least 3 score points after 6 months. A significant improvement appeared only to patients with IIEF-5 = 0 preoperatively.

## Figure 3.

SUI classification pre- and postoperatively.



SUI classification regarding 24h pad-use: 0 = no incontinence, 1-2 = mild incontinence, 3-5 = moderate incontinence, > 5 = severe incontinence. The number of patients with moderate incontinence could be considerably reduced. A no pad-rate of 38% was achieved; hence 13 out of 34 patients did not suffer from incontinence at follow up. patients had received adjuvant radiotherapy after RPE or TURP. In 6 patients the bladder neck had to be opened intraoperatively by Sachse urethrotomy to enable the placement of a transurethral indwelling catheter.

Twenty-seven patients received the recent ATOMS generation with a scrotal port, seven patients received an inguinal port which requires an additional inguinal incision.

# Pre- and postoperative assessment

The patients were questioned regarding their erectile ability and pain condition the day before surgery and 6 months after surgery via an anonymous questionnaire. The Visual Analogue Scale (VAS) (20) with numeric description and Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) (19) were used to evaluate pain. A LANSS score of bigger than 12 points describes the existence of neuropathic pain syndrome in the tested skin area. The erectile function was elicited via the International Index of Erectile Function (IIEF-5) and was categorized correctly by the number of points (< 5 no sexual intercourse, 5 to 7 severe ED, 8 to 11 moderate ED, 12 to 16 moderate to weak ED, 17 to 21 weak ED, 22 to 25 no ED).

PSA level, 24h pad-use as well as co-morbidities (diabetes mellitus (DM), arterial hypertension, coronary heart disease (CHD) and obesity (body mass index > 30) were recorded. The long-term use of antidepressants and beta-blockers was also taken note of. Erectogenic aids or sexual stimulating drugs were not taken by patients during the observed period.

Six patients had anastomotic stricture at time of implantation which were corrected in the same setting. Exclusion criteria for implantation were none or severe SUI, a recent PSA increase, an acute febrile urinary tract infection, detrusor overactivity and pronounced dementia/cognitive disorders. All patients were anesthetically evaluated preoperatively and internal medical risk was assessed. The implantation was carried out under dual antibiotic therapy (amoxicillin 825 mg clavulanic acid 125 mg for 7 days with gentamicin and 240 mg for 3 days) and thrombosis prophylaxis.

The transurethral indwelling catheter was removed after one day, wound checks and physical examination were performed daily. The implant cushion was filled intraoperatively with 7-9 ml saline solution, the first readjustment was carried out after 6 weeks in the outpatient setting, when required with 1-2 ml saline. Before discharge (3 to 5 days postoperatively) residual urine was measured sonographically and oral pain medication (metamizol or non-steroidal anti-inflammatory drugs) were prescribed if required.

# Outcome variables

The primary outcome measure was whether patients sexuality and erectile function (IEFF-5) vary before and after ATOMS implantation.

Change of 24h pad-use (e.g. overall success, no pad rate) and change of the pain perception (VAS + LANSS pain scale) was also noted over time. Subgroup analysis including operation type (inguinal/scrotal port), co-morbidities, age, time from prostate treatment to ATOMS implantation, previous implants, as well as complications (infections, explantation) were provided.

# Statistical analysis

Data were descriptively analysed through mean values and standard deviation for continuous variables, and absolute values and percentages for categorical variables. Descriptive analysis was stratified for the operation method (scrotal port/inguinal port). A t-test for paired data was used to test for improvement in erectile function and reduction in pads use before and after implantation. Also paired t-tests were calculated for the difference in LANSS and VAS score. Additionally 95% confidence intervals were estimated for all comparisons. Pearson's correlations were calculated for age, IIEF-5 score, 24h pad-use and time from prostate operation to ATOMS implantation.

P-values of 0.05 or less were considered to be statistically significant. All calculations were performed in R 3.0.2.

# RESULTS

A total of 34 men with a mean age of 70.7 years (range 54.9 to 82.9) were registered at the time of ATOMS implantation. The average age at the time of the RPE, TURP or radiotherapy was 64.5 years (range 52.2 to 78.8). The mean time from prostate treatment to ATOMS implantation was 75.1 months. 24% of patients had a history of previous unsuccessful incontinence implants (ProAct, InVance). The average observation period was 5.7 months. Mean preoperative PSA was 0.137 ng/ml and 0.163 ng/ml at follow up. During the stated period no patient received androgen deprivation therapy (ADT), chemotherapy, or adjuvant radiotherapy. The following comorbidities were recorded according to frequency: DM (12%), arterial hypertension (56%), CHD (9%) and obesity (12%). Regular antidepressant and beta-blocker intake was noted in 21% and 26% of patients respectively. Descriptive data are summarized in Table 1.

# Sexuality

The average IIEF-5 score increased from 1.6 (+/-0.7) before ATOMS implantation to 3.8 (+/-0.8) after 6 months. The mean difference was 2.18 (CI: 1.22, 3.14), p < 0.001). However figure 2 indicates that mostly patients with no sexual intercourse benefited from ATOMS implantation and many patients achieved a 3 points higher IIEF-5 score than at baseline, which can be definitely interpreted as not just a theoretically improvement. For patients with moderate or weak ED, the IIEF-5 score has increased marginally or not at all.

Preoperatively, 88% of patients had rarely tried to be sexual active (IIEF-5: < 5 points), 12% of patients reported sexual activity with spontaneous erections and the ability to penetrate with a mean IIEF-5 score of 11.5.

Of these, 3 patients had moderate to weak ED and 1 patient had severe ED. Six months postoperatively, 17 (50%) continued to have not the ability for sexual intercourse (IIEF-5: < 5 points). Their mean IIEF-5 score was 3.8 and however, higher than preoperatively. Seventeen (50%) were sexually active postoperatively with a mean IIEF-5 score of 10.1. Of these, 12 patients had severe ED,

## Table 1.

Descriptive analysis according to operation method.

	Total (n = 34)	Inguinal port (n = 7)	Scrotal port (n = 27)
Age ATOMS implantation	70.7 (+/-1.2)	72.3 (+/-2.1)	70.3 (+/-1.4)
Previous implants	10 (29%)	2 (29%)	8 (30%)
TURP	4 (12%)	1 (14%)	3 (11%)
RRPE	26 (76%)	4 (57%)	22 (81%)
ERPE	4 (12%)	2 (29%)	2 (7%)
Radiotherapy	9 (26%)	0 (0%)	9 (33%)
CHD	3 (9%)	2 (29%)	1 (4%)
Arterial hypertension	19 (56%)	3 (43%)	16 (59%)
DM	4 (12%)	0 (0%)	4 (15%)
Obesity (BMI > 30)	4 (12%)	0 (0%)	4 (15%)
Beta-blocker intake	9 (26%)	3 (43%)	6 (22%)
Antidepressant intake	7 (21%)	0 (0%)	7 (26%)
Preoperatively			
PSA value (ng/ml)	0.137 (+/-0.1)	0.208 (+/-0.1)	0.119 (+/-0.1)
IIEF-5 score	1.6 (+/-0.7)	0 (+/-0)	2.1 (+/-0.8)
24h pad-use	3.5 (+/-0.2)	3.6 (+/-0.5)	3.4 (+/-0.2)
VAS pain scale	0.5 (+/-0.2)	0.4 (+/-0.4)	0.5 (+/-0.2)
LANSS pain scale	1 (+/-0.6)	1.1 (+/-1.1)	1 (+/-0.7)
Follow up			
PSA value	., ,	0.224 (+/-0.1)	0.147 (+/-0.1)
IIEF-5 score	3.8 (+/-0.8)	2.6 (+/-1.2)	4.1 (+/-0.9)
24h pad-use	1.5 (+/-0.3)	0.7 (+/-0.4)	1.7 (+/-0.3)
VAS pain scale	0.6 (+/-0.2)	0.1 (+/-0.1)	0.7 (+/-0.3)
LANSS pain scale	1.3 (+/-0.5)	0.7 (+/-0.7)	1.5 (+/-0.6)
Time to ATOMS	75 4 (1/40 4)	EZ (1/14 0)	70.0 (+ / 10.1)
implant (months) Overall success	75.1 (+/-10.1)	57 (+/-14.2)	79.9 (+/-12.1)
(pad-use reduction)	30 (88%)	7 (100%)	23 (85%)
No pad rate	13 (38%)	4 (57%)	9 (33%)
Follow up (months)	5.7(+/-0.5)	7.3(+/-1.6)	5.3 (+/-0.5)
Wound infection	6 (18%)	0 (0%)	6 (22%)
Explantation	4 (12%)	0 (0%)	4 (15%)

Descriptive analysis was stratified according to operation method (inguinal port/scrotal port). Mean values and standard deviation were calculated for continuous variables, and absolute values and percentages for categorical variables.

2 had moderate ED and 3 had moderate to weak ED. 44% of all patients had an improved IIEF-5 score (from 2.3 to 7.1) at 6 months. 38% of all patients had new onset of sexual activity postoperatively with an average IIEF-5 score of 12.9.

Subgroup analysis showed that diabetics (4 patients) had worse outcomes compared to non-diabetics regarding pre- and postoperatively IIEF-5 and 24h pad-use (mean values; preoperatively: 0.0/3.8 vs. 1.9/3.4 and postoperatively: 2.0/2.8 vs. 4.1/1.3). Patients with arterial hypertension showed no differences when compared to others without arterial hypertension regarding 24 pad use, IIEF-5, VAS and LANSS score.

Patients under continuous antidepressant intake had a lower mean IIEF-5 score (2.1) at follow up then others. Patients with beta-blocker intake had a poor improvement of IIEF-5 score (+1.0) at follow compared to others.

## Pain perception

Results of the t-tests showed that none of both pain scores significantly increased after 6 months. The mean differences were 0.32 (CI: -0.76, 1.41), p = 0.5484) and 0.11 (CI: -0.36, 0.59), p = 0.6187) for LANSS score and VAS score, respectively. Nobody got a fully developed perineal neuropathic pain syndrome (LANSS > 12) after 6 months but postoperatively wound pain was mostly existing for a few days. Compared to others, diabetics had less pain pre- (VAS: 0.0 vs. 0.5; LANSS: 0.0 vs. 1.1.) and postoperatively (VAS: 0.0 vs. 0.7; LANSS: 0.0 vs. 1.5).

#### Pad-use

The average 24h pad-use significantly decreased from 3.5 (+/-0.2) preoperatively to 1.5 (+/-0.3). The mean difference was -2.0 (CI: -2.5, -1.5), p < 0.001). Thirty patients reduced their daily pad-use after 6 months, resulting in an overall success rate of 88%, 38% were completely dry (no pad rate) and 18% used one pad daily (one pad rate). Twelve percent of implantations were unsuccessful, of these four implants were explanted prematurely due to uncontrolled wound infection. For no patient, the daily pad-use increased after 6 months. Figure 3 shows the shift of incontinence groups pre- and postoperatively. Obese patients had a poor improvement regarding daily pad-use (3.3 to 2.0) then patients of normal weight.

#### DISCUSSION

This study is the first to examine potency and erectile function after implantation of ATOMS, an adjustable implant cushion firmly anchored transobturatorally and indirectly attached to the spongious erectile tissue. The series was an unselected patient group, men who had been treated with RRPE, ERPE, radiotherapy or TURP and had partly previous implants in history.

While other studies observe long term pain syndromes after implantation of transobturatoric devices (17), persistent pain rate was low in our study because implantation was done with full protection of the neurovascular bundle next to the bulbospongiosus muscle. However, wound pain was existing for a few days postoperatively. In general, VAS and LANSS score differ slightly between pre- and postoperative situation because of further implants as you can see in table 1 but there is no significant comparison.

All the men were suffering from SUI which had been urodynamically confirmed and was resistant to conservative therapy. While preoperative selection of patients is significant to treatment outcome (10), we deliberately selected patients with SUI of different aetiologies, which also had significant co-factors for the formation of an ED (e.g. DM).

The overall success rate of 88% and the no to one padrate of 56% at follow up is in accordance with previous reports and studies (8, 9). Male urinary incontinence is not a new problem, but it is still taboo in many countries and is a social and economic problem. An aging society also contributes to the increase of neurogenic bladder dysfunction, thus incontinence therapy has increasingly moved into the spotlight. The wish for better quality of life, sustaining body image and reintegration into everyday life are common reasons for patients to opt for surgical incontinence interventions. Access to incontinence centres with implant surgery depends on area of residence (*rural vs. urban*), ethnicity and age, according to a large American study (11, 12). Only 6% of all patients receive incontinence surgery after RPE (median 20 months). This low rate may reflect the underused situation of potentially beneficial procedures (11).

In addition to tumor follow up sexual rehabilitation and incontinence therapy are important components of post-RPE care. In 35% of cases sexual dissatisfaction, increase of PPI, depression and loss of ability to work are the cause of poor generic quality of life after implantation of an AUS (13). The improvement of erectile function and SUI with the same implant could significantly enhance the quality of life and keep the body image undisturbed. A recent study shows that 15% of the men (n = 1729 of 11 726) opt for active surveillance and after 5 years follow up 64% of these continue with this. This data shows that a decrease in the RPE due to the introduction of active surveillance, including age at diagnosis and tumor risk/stage, can be expected. A high number of unreported cases of patients with PPI (> 59%) such as those after TURP (> 10%) will always be present (14), and therefore incontinence surgery is still a legitimated therapy option. A large number of studies, some of which with small case numbers, report the successes and failures of incontinence implants. The majority of studies have been on AUS surgery. It has been shown that the learning curve for AUS surgery is very long and with increasing surgeon experience the re-operative rates slowly decrease (reoperative rate: 24.0% vs. 18.1% after 5 and 100 cases) (15). Incontinence surgery with its large variety of available implant is in a constant state of flux and very dynamic. New implants are constantly being designed, improved, copied, but also rejected (16). A small study of 15 evaluable patients after anti-incontinence surgery with AUS/male sling surgery (between 2000 and 2007) showed a beneficial effect of anti-incontinence surgery on PPI during sexual activity (100% undergoing AUS and > 50% undergoing sling procedure reported marked improvement in sexuality) (5). PPI during sexual activity is seen as a disturbance in 44.4% after 3 months and 36.1% after 24 months. Bother from incontinence during sexual activity and from SUI were strongly associated at all times. Therefore it is expected that with reduction of PPI, an improvement of sexual satisfaction can be achieved (4).

This was demonstrated in the current study.

There are some limitations to the present study which should be pointed out. First, the number of subjects included may not be sufficient to achieve statistically significance. Some patients attended other hospitals for care and adjustment after implantation. There is currently no standard for use of implants in incontinence surgery, thus there is variation between departments and their implant expertise.

Second, it is not a randomized study and follow up was short (5.7 months). Third, the IIEF-5 score is limted to evaluate erectile function. Thus the current situation with family partner in connection with libido and sexual behaviour pre- and postoperatively could not be elicited.

## CONCLUSION

Within the limitation of this study, we conclude that 6 months after ATOMS implantation sexuality and erectile function, measured with the IIEF-5, improve significantly. We postulate that reduced SUI (also during sexual activity) and absence of chronic pain are the improving factors.

ATOMS should be offered to men with mild to moderate SUI who are interested in regaining their erectile function and sexual activity.

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