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Long-term efficacy and safety of the Adjustable Transobturator Male System (ATOMS): 6-year results of a European multi-institutional study

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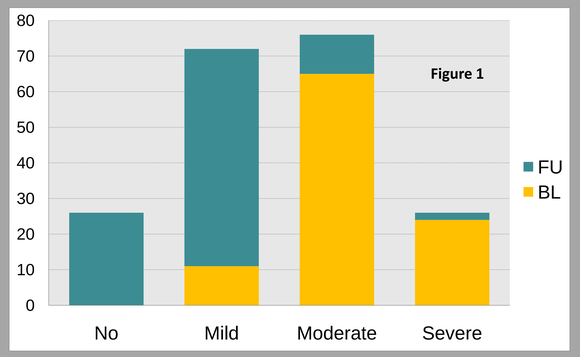
OBJECTIVES

Male stress urinary incontinence (SUI) remains a common problem after prostate surgery with a reported wide range prevalence of 17-80%.[1] After ineffective conservative treatment (pelvic floor muscle training, life style modification) incontinence surgery is a justified option to reduce SUI.[2] The Adjustable Transobturator Male System (ATOMS; A.M.I., Feldkirch, Austria) was designed 2004 and first implanted in 2009. This device, with its compressing cushion on the bulbospongious muscle is now in its third generation with the full silicone covered scrotal port system. Initial experiences[3], temporary results[4] and recently risk factor analysis regarding treatment failure[5] were found in literature. However long-term follow-up trials are missing.

The present study focuses on long-term clinical efficacy, safety and durability of the ATOMS device and between port generations.

Table 1

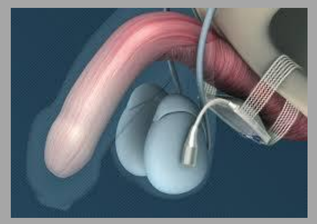
	BL	FU ≤ 18 mo	FU	p-value (BL/FU)
24h pad count	4 (3-5)	1 (1-2)	1 (0-2)	<0.0001
24h pad test (ml)	400 (300-770)	50 (5-150)	28 (0-110)	<0.0001
ICIQ-SF	17 (15-18)	6 (3-8)	6 (1-7)	<0.0001
PGI-I	4 (4-4)	2 (1-2)	1 (1-2)	<0.0001
Qmax (ml/s)	17 (15-19)	14 (13-16)	15 (13-16)	<0.0001
Voiding vol. (ml)	154 (108-200)	187 (155-233)	193 (155-260)	<0.0001
PVR	0 (0-0)	0 (0-10)	0 (0-10)	<0.0001
VAS	0 (0-0)	0 (0-1)	0 (0-1)	<0.0001
LANSS	0 (0-0)	0 (0-3)	0 (0-0)	<0.0001

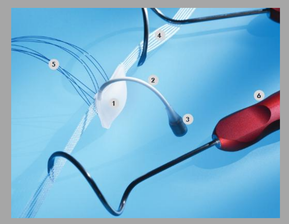


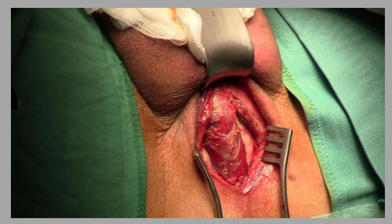
METHODS

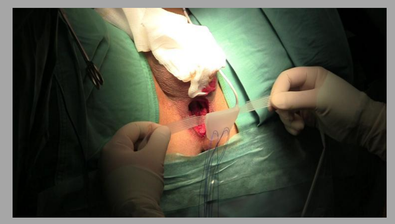
257 men were treated with an ATOMS device (including inguinal [IP], scrotal [SP], silicon scrotal port [SSP]) in 4 European continence centers between 2008 and 2015. Surgical technique and perioperative procedure was based on the studies of Hoda and Seweryn et al. Through a small perineal incision the central cushion (1) of the ATOMS is directly placed on the bulbospongious muscle and fixed with two mesh arms (4) going around the obturator foramina using the helical tunneller (6). Ethics committee approval and patient consent was obtained.

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 (Kaplan Meier survival curve) and complications (Clavien-Dindo scale). 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.







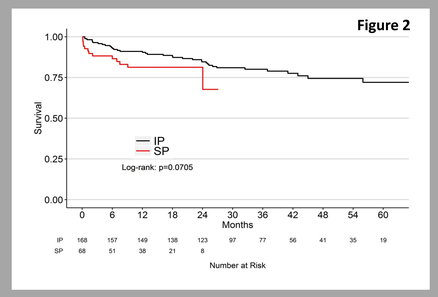


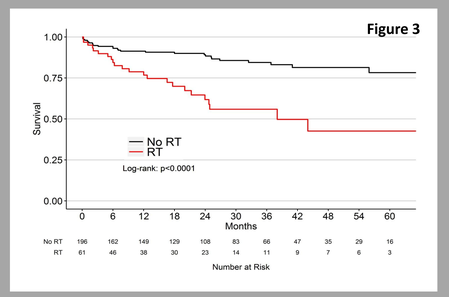
RESULTS

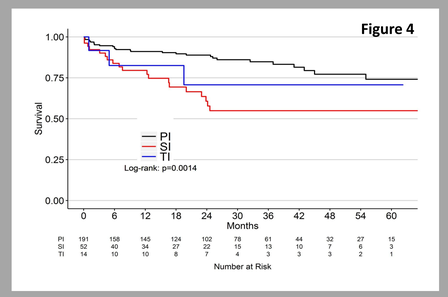
Mean time from prostate treatment to ATOMS implantation was 4.4 years. After a mean of 2.7 adjustments mean daily pad test and pad use decreased, concomitantly all quality of life parameters and urodynamic measurements improved (table 1). SUI grade changed between baseline and follow-up from moderate/severe SUI to no/mild SUI as illustrated in figure 1. OSR, DR, surgery time and removal rate vary between port types,. The latest SSP achieves best results in spite of short follow-up (table 2). In total device removal was due to local titanium intolerance (8.2%), leak/dysfunction (6.2%), early infection (2.7%), dislocation (1.6%) or persistent pain (0.8%). Mean time from implantation to removal was 14.2 months. The majority of complications were Clavien Dindo 1-3 (4 early infections, 4 urinary retentions, 2 hematoma), 4 and 5 did not occur. In subgroup analysis patients with primary ATOMS implantation (figure 4) and without a history of radiotherapy (figure 3) had better clinical outcome and greater durability. To date all ATOMS with the SSP are still working (zero removals; figure 2) without minor or major complications.

Table 2

	ALL Ports	IP	SP	SSP
N (%)	257	65%	27%	8%
max. FU (mth)	71,0	71,0	27,1	3,12
OSR (%)	90,2	91,2	67,5	94,7
DR (%)	63,7	89,4	50,0	73,7
OP time (min)	47,0	52,5	37,9	32,9
Removal (%)	19,5	20,8	22,1	0







CONCLUSIONS

The ATOMS device shows good efficacy, durability and high patient satisfaction in long-term follow-up. Best results are achieved with primary implantation (no previous ineffective continence surgery). The 3rd generation with its pre-attached, fully silicon covered scrotal port is presently superior to the precursors in clinical outcome and tolerability.

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