THE ATOMS DEVICE FOR MALE STRESS URINARY INCONTINENCE: 5 YEAR RESULTS OF A PROSPECTIVE-MULTICENTER STUDY

Hypothesis / aims of study
The effectiveness and safety of the Adjustable Transobturator Male System (ATOMS) with inguinal or scrotal port (IP, SP) for treatment of male stress urinary incontinence (SUI) has been described multiple times in short and medium term studies. This prospective multicenter study is the first to report functional long term results in 5 year follow-up (FU).

Study design, materials and methods
A prospective multicenter study was carried out from 11/2009 to 2/2015 including 222 male patients with mild (<150ml/24h) to severe (>500ml/24h) SUI after radical prostatectomy (RPE), transurethral resection (TURP) and single or adjuvant radiotherapy (RT). Patient performance status was determined using the Charlson Comorbidity Index (CCI) and the ASA classification. Baseline (BL) and FU measurements included 24h pad-usage and pad-weight test, uroflowmetry (Qmax), post void residual urine (PVR), VAS/LANSS for pain analysis and quality of life scores (ICIQ-SF, PGI-I). Complications of surgery were assessed using the Clavien-Dindo classification. Failure rate and reasons of explantation were shown and postoperative device adjustments were recorded. Cure was defined as zero to one pad-use in 24h or urine loss of 0-5 g in the 24h pad-weight test.

Results
All patients (mean age 64.4 [39-94] yr) underwent urodynamic investigation before implantation. At BL 75.7% of patients were older than 65 yr. Reasons for SUI were RPE (86.9%), TURP (10.8%), TURP+RPE (2.3%) and single/adjuvant RT (26.2%). 26.6% had previous implants or bulking agents (ProAct, AMS800, Advance, Deflux, Argus, InVance, Zephyr). Previous implant count of 1/2/3 was seen in n=44/9/3 patients respectively. Mean BMI was 27.4 [20.1-40.0] and average CCI/ASA was 7 [4-12]/2 [1-3]. 7.6% of patients had urgency pre implantation. Mean time from primary prostate treatment to ATOMS implantation was 4.7 years. 22% of patients had urgency pre implantation. Mean time from primary prostate treatment to ATOMS implantation was 4.7 years. At implantation 67.1% (n=149) got the IP and 32.9% (n=73) the SP.

At FU (median 39.1 [4.4-63.9] months), after a mean number of 3.1 adjustments, 24h pad-usage/pad-weight test decreased significantly from 4.5 [2-11]/539g to 1.5 [0-8]/106g (p<0.05). Mean Qmax showed a reduction from 20.3ml/s (169ml filling) to 15.1ml/s (177ml filling). The mean VAS/LANSS increased from 0.1/0.1 to 0.9/1.4 and the ICIQ-SF/PGI-I improved significantly from 16.5/3.9 to 5.9/1.7 (p<0.05). Zero to one 24h pad-rate was 62.6% (=cured); 90.1% of patients had an overall benefit (=24h reduction of pad-use).

There was marginal PVR at BL/FU, however 19.4% (n=43) required an urethrotomy for catheterization during implantation. No intraoperative complications occurred. Average operation time was 47.1 minutes (IP/SP = 51.3/36.6; p<0.05). Postoperative infection rate was 21.5% (n=45) (IP/SP). Explantation rate was 62.6% (=cured); 90.1% of patients had an overall benefit (=24h reduction of pad-use).

Interpretation of results
Similar to initial experiences (1) and early results (2), the ATOMS device shows good effectiveness in long term FU of up to 5 years, high patient satisfaction and low complication rates (table 1). Operating time is short and secondary implantation is possible after failure. Infection prevention is the key to long implant endurance and to best functional outcomes.

Table 1. Short and long term results of the ATOMS device

<table>
<thead>
<tr>
<th>Authors</th>
<th>n</th>
<th>Age (mth)</th>
<th>FU (%)</th>
<th>Prev. Impl. (%)</th>
<th>IP/SP (n)</th>
<th>Mean OP time (min)</th>
<th>Mean pad-use (BL/FU)</th>
<th>Mean pad-weight (BL/FU) (g)</th>
<th>Dry rate (%)</th>
<th>Overall success rate (%)</th>
<th>Infect. Rate (%)</th>
<th>Expl. Rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Seweryn et al., 2012</td>
<td>38</td>
<td>70.0</td>
<td>16.9</td>
<td>28.9</td>
<td>38/0</td>
<td>52.0</td>
<td>6.8/1.4</td>
<td>747/115</td>
<td>60.5</td>
<td>84.2</td>
<td>10.5</td>
<td>7.0</td>
</tr>
<tr>
<td>Hoda et al., 2012</td>
<td>99</td>
<td>70.4</td>
<td>17.8</td>
<td>34.3</td>
<td>99/0</td>
<td>47.4</td>
<td>7.1/1.3</td>
<td>681/80</td>
<td>63.0</td>
<td>92.0</td>
<td>4.0</td>
<td>4.0</td>
</tr>
<tr>
<td>Friedl et al., 2015</td>
<td>222</td>
<td>64.4</td>
<td>39.1</td>
<td>26.6</td>
<td>149/73</td>
<td>47.1</td>
<td>4.5/1.5</td>
<td>539/106</td>
<td>62.2</td>
<td>90.1</td>
<td>21.5</td>
<td>17.1</td>
</tr>
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</table>
Concluding message
The ATOMS is a safe, effective and well tolerated device for the treatment of persistent male SUI in FU of up to 5 years.

References

Disclosures
Funding: None Clinical Trial: No Subjects: HUMAN Ethics Committee: EC Barm. Brüder Hospital Vienna Helsinki: Yes Informed Consent: Yes