Adjustable Trans-Obturator Male System (ATOMS) for Stress Urinary Incontinence: A Multi-centre New Zealand Experience

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Abstract

To evaluate the New Zealand clinical experience with the Adjustable Trans-Obturator Male System (ATOMS), a novel continence device in the management of all degrees of stress urinary incontinence (SUI), focusing on efficacy and safety outcomes.

Introduction

Designed and introduced in Europe in March 2009, the ATOMS (AMI, Vienna, Austria) or Adjustable Trans-Obturator Male System is a self-anchoring, non-mechanical system composed of mesh arms and an adjustable volume silicone cushion. A number of studies have been published in the recent literature, with positive outcomes both in meta-analysis (1) and multicentre studies performed in Europe and Canada (2-5).

Unlike the Artificial Urinary Sphincter (AUS), which compresses the urethra circumferentially thereby interfering with venous blood flow predisposing to urethral atrophy and erosion, the ATOMS® device compresses only the ventral aspects of the bulbar urethra, leaving the dorsal and lateral blood flow intact. Additionally, the ability for patients to spontaneously void without manipulation of the device is a distinct advantage over the AUS.

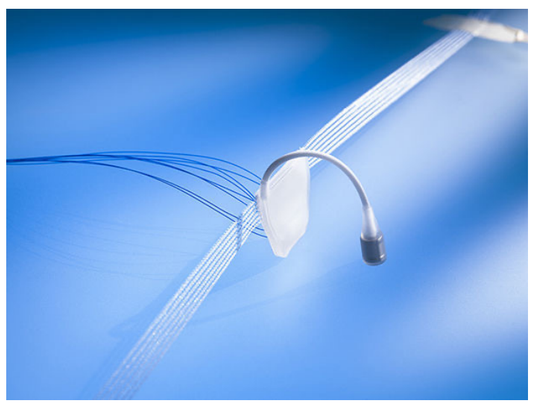

Figure 1. ATOMS Device

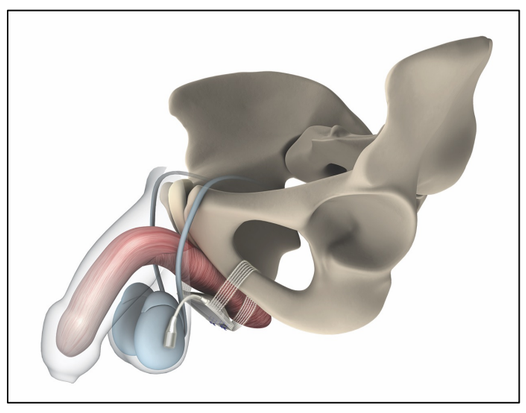

Figure 2. Implanted Device in profile

Methods and Materials

Data from 140 men who underwent an ATOMS implantation at 2 institutions from May 2015 to November 2020 were retrospectively and prospectively collected.

All patients were evaluated pre-operatively with a complete history and physical examination by the treating surgeon. Video urodynamics was used selectively to evaluate abdominal leak point pressure (ALPP) and detrusor function. Patient demographics and baseline information was recorded, including age, co-morbidities, salvage or adjuvant radiotherapy (RT), previous incontinence surgery, previous urethral stenosis, modality of prostatectomy and degree of incontinence.

Incontinence was defined as mild (1 to fewer than 3 pads per day), moderate (3 or more to 5 pads per day) or severe (greater than 5 pads per day).

The primary outcome measures considered were the overall success rate (improvement in continence outcome) and the dry rate (with dry defined as either no or 1 safety pad/day). The number of outpatient adjustments and total filling volumes were also documented in each case.

Incidence and severity of device complications and an analysis of treatment failures, with specific attention to the radiotherapy and previous incontinence surgery cohorts was also completed.

Results

Median patient age was 70 year old with a median pre-operative pad usage of 4 pads/daily. In our cohort, 53 (37.9%) had previous radiotherapy with 26 (18.6%) patients having had a previous continence procedure performed

Patients were followed up for a median of 11 months and the median post- operative pad usage reduced to 1 pad per day. 96 patients (68.6%) required a median of 2 outpatient adjustments and a median cushion volume of 13mls to achieve these outcomes. In our cohort, 116 patients (82.9%) reported an improvement in their continence status and were considered successful with 107 (76.4%) patients reporting themselves as dry.

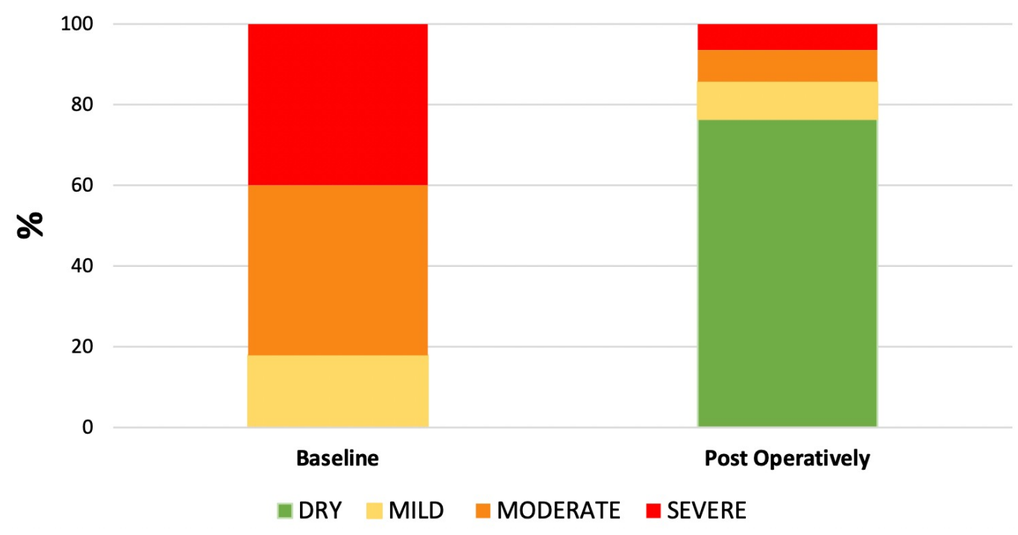

Figure 3: Severity of Stress Incontinence – pre and post surgery

Complications and Sub-Group Analysis

Men with a history of radiation treatment or previous incontinence surgery had poorer outcomes (Table 1). This is likely due to micro-vascular tissue trauma due to irradiation and previous inflammation, promoting fibrosis and impairing healing.

Complications within the first 90-days post-surgery occurred in 20 (14.3%) of patients. These were Clavien-Dindo (6) grade I in 16 (11.4%), grade II in 1 (0.7%) and grade III in 3 (2.1%) patients. All grade III complications were related to the scrotal port site.

A total of 22 devices (15.7%) were explanted, the majority being due to ongoing urinary incontinence (16 patients). Chronic infection was seen in 5 patients (related to scrotal port) and one patient had the device removed due to persistent perineal discomfort. 18 patients proceeded to have a second procedure, with the majority having an Artificial Urinary Sphincter (AUS) and 2 patients having a re-do ATOMS procedure. All AUS devices placed had a successful outcome with regards to continence.

	Improvement in Continence (%)	p-value	Dry Rate (%)	p-value
Overall Cohort	82.9	-	76.4	-
Previous Radiotherapy	75.4	0.07	64.2	0.008
Prior Incontinence Surgery	57.7	0.001	53.8	0.003

Table 1: Post Operative Outcomes: Subgroup Analysis

Conclusions

Our study confirms that the ATOMS device is an highly efficacious, safe and acceptable modality of SUI treatment in a complex patient cohort.

The option of minimally invasive adjustment to respond to patient needs is a significant advantage.

References

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