

## EVALUATION OF THE FLOWSECURE™ ARTIFICIAL SPHINCTER: PRELIMINARY RESULTS

### Hypothesis / aims of study

Whilst the Artificial Urinary Sphincter (AMS Medical Systems) is widely accepted as the gold standard for the treatment of male Urodynamic Stress Urinary Incontinence, it has a number of limitations. Patient dexterity is an essential component to success. The risk of erosion and mechanical failure necessitating revision surgery can be both costly and inconvenient for the patient. We aimed to evaluate the use of a new alternative sphincter which has been developed.

### Study design, materials and methods

The FlowSecure™ a new silicone hydraulic urinary sphincter that has an extra pressure transmission balloon to transfer increased intra abdominal pressure directly to the cuff. Intraabdominal pressure peaks will be transferred to the cuff thus providing stress continence by passive pressure transmission. The pressure of the urethral cuff is low (<30cm H<sub>2</sub>O) to maintain continence at rest.

Furthermore it provides the possibility of adjusting the volume and thus the pressure within the system post operatively.

As the pressure around the urethral sleeve changes according to the intra abdominal pressure, the risk of erosion may be reduced. We evaluated male patients who presented with Stress Urinary Incontinence following prostate surgery to establish feasibility and short term efficacy of the procedure in this group of patients. Patients were assessed at baseline using 20 minute pad testing which was repeated post operatively. Perioperative details were recorded. Any complications were noted.

### Results

Fifteen male patients have been implanted to date. Median age 71.5 (range 61- 80) years with a mean follow up of 5.2 months. Previous prostate surgery included: retropubic Prostatectomy (7); TURP (3), Perineal Prostatectomy (2); Radiotherapy (2) and brachytherapy (1). All patients had failed conservative therapy. Most patients had undergone a previous surgery for their incontinence including injectable bulking agent (4): ProACT (6) and Argus Sling (1).

Mean operative time was 80 mins (54-116) with all procedures being completed uneventfully. Four patients required 5 adjustments. Incontinence based on the 20min pad test decreased from 64 - 4g post operatively. At last follow up, 10 patients were dry, 3 patients continued to wear 1 safety pad per day, and 1 patient underwent explantation arising from infection. Seven patients use the pump whilst 6 patients use it as an adjustable cuff. Post void residual was 4ml (0-30).

Complications included 1 device destroyed by the surgeon, with no other per operative complications noted. Post operative complications included wound infection in one 1 patient which was managed conservatively; one explantation was undertaken due to MRSA despite 2 months good function; One patient went into retention, but was managed by deflation of the cuff and 1 pump was inadvertently destroyed by the urologist at adjustment.

### Interpretation of results

Implantation of the FlowSecure™ artificial sphincter is technically feasible and would appear to be safe and effective in the short term for the treatment of male Urodynamic stress Urinary Incontinence arising from a number of aetiologies. Prior anti incontinence surgery does not appear to be an impediment to implantation.

### Concluding message

Further controlled evaluation of the use of the FlowSecure™ is warranted.

**FUNDING:** Nil

**CLINICAL TRIAL REGISTRATION:** This clinical trial has not yet been registered in a public clinical trials registry.

**HUMAN SUBJECTS:** This study was approved by the Korneuburg and followed the Declaration of Helsinki. Informed consent was obtained from the patients.