

## LONG TERM FOLLOW-UP OF THE MALE REMEEEX SYSTEM FOR THE SURGICAL TREATMENT OF MALE INCONTINENCE

### Hypothesis / aims of study

Male Slings for the treatment of urinary incontinence (UI) have been in use as the primary surgical method of treatment. Traditionally these are implanted retro-pubically, or via the Trans-Obturator approach. Success relies heavily on the tissue ingrowth into the mesh interstices and upon fibrotic response, further tensioning is inhibited. A review of recent literature cites many situations whereby patients have either an excess or lack of tension which produces voiding difficulty or persistent urinary leakage postoperatively.

In 2000 we included an adjustable component to traditional slings via the Male Remeex™ System (Neomedic, Ltd)) into our surgical algorithm. Our primary patient population were those that required increased urethral compression without compromising normal voiding function. The aim of this study was to evaluate safety, efficacy and durability of the Male Remeex™ System (MRS) with seven (7) year follow up to include how many postoperative adjustments were required to achieve full continence

### Study design, materials and methods

20 male patients with moderate to severe UI were prospectively operated on using an adjustable sling (MRS®). The etiology of incontinence was status post radical prostatectomy in 18 cases, TURP in one case, and open prostatectomy in one case. Average follow-up was at 82 months. Long term cure rates and number of adjustments were recorded.

### Results

All patients were adjusted within 1-3 days post-op. 19 patients required a second adjustment between 1 to 4 months after surgery, completed under local anesthesia. 15 patients required more than one delayed adjustment. The longest time interval from placement of the MRS and adjustment was 100 months under the same conditions as those that were adjusted between 1-4 months.

A total of 14 patients (70%) reported no pad utilization. Three (3) patients (15%) demonstrated an overall resolution. Three (3) patients (15%) remained incontinent. Of these three patients, one suffered a CVA unrelated to the operation but was disqualified for further adjustments; and, one patient was disqualified for further adjustments due to tumor progression.

No mesh or varitensor required removal and there was no evidence of mesh erosion or reported infections. In 6.5% of cases, uneventful intraoperative bladder perforations occurred and healed on their own. Two (2) mild perineal hematomas were reported and some patients reported perineal discomfort or pain, all of which were successfully resolved via oral medications.

### Interpretation of results

The benefit of postoperative adjustability, with the patient conscious and in normal anatomic position offers a new level of therapeutic options in the treatment of male UI.

### Concluding message

Follow up data of seven (7) years revealed that greater success rates are achievable solely due to the ability to adjust the tension of the device, externally, and subsequently for at least 100 months after surgery. Postoperative complications were insignificant and certainly within the limits of the those reported on patients with traditional mesh sling placements.

<b><i>Specify source of funding or grant</i></b>	<b>None</b>
<b><i>Is this a clinical trial?</i></b>	<b>Yes</b>
<b><i>Is this study registered in a public clinical trials registry?</i></b>	<b>No</b>
<b><i>Is this a Randomised Controlled Trial (RCT)?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>Yes</b>
<b><i>Specify Name of Ethics Committee</i></b>	<b>Ethics Committee of the Sociedad Gallega de Urologia.</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>