Incontinence

Adjustable Suburethral Sling (Male Remeex System®) in the Treatment of Male Stress Urinary Incontinence: A Multicentric European Study

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Abstract

Objective: To evaluate the effectiveness of a readjustable sling for the treatment of male stress urinary incontinence (SUI).

Materials and methods: Between October 2002 and August 2005, 51 male patients with mild to severe SUI were prospectively operated with the use of a readjustable sling (MRS®) at seven different European hospitals: Spain (2), Italy (2), Greece (1), Germany (1), and Portugal (1). The origin of incontinence was radical prostatectomy in 43 cases, TUR in 4, and open prostatectomy in another 4. Duration of incontinence ranged from 1 to 10 yr with an average of 3.5 yr.

Results: All patients but 5 were regulated during the early postoperative period; 44 patients (including all 5 not regulated during the early period) required a second regulation under local anaesthesia between 1 to 4 mo after surgery, and 17 other patients required more than one delayed regulation. After that, 33 patients (64.7%) were considered cured (25 of them wore no pads at all, and 8 used small pads or sanitary napkins for security but normally remained dry); another 10 cases showed important improvement (19.6%); and only 8 patients remain unchanged (15.7%). The average follow-up time was 32 mo (range: 16–50). The mesh was removed in 1 case owing to urethral erosion and the varitensor in 2 cases owing to infection. There were five (9.8%) uneventful intraoperative bladder perforations at the postoperative period, and there were three mild perineal haematomas (5.9%). Most patients felt perineal discomfort or pain, which was easily treated with oral medications.

Conclusions: The MRS® allowed postoperative readjustment of the suburethral sling pressure at the immediate or midterm postoperative period, which allowed the achievement of good midterm results in almost 85% of patients without significant postoperative complications.

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1. Introduction

Moderate to severe SUI is a devastating complication that occurs in 5–12% of patients after radical prostatectomy and occasionally after surgery for benign prostatic diseases [1,2]. In terms of quality of life, its consequences are dramatic to patients; a surgical treatment to solve it is always required [3].

Pharmacotherapy, electrical stimulation, pelvic floor exercises, and injections of bulking agents are usually ineffective in the treatment of moderate to severe SUI. Only the artificial sphincter and slings have shown good results in the treatment of this condition [4].

The Male Readjustable System® (MRS) from Neomedic International, Barcelona, Spain, is an adjustable suburethral sling that permits effective regulation of the suburethral pressure at any time during the patient’s life. This possibility of control is always an advantage in incontinence surgery but is especially important in male SUI because of the narrow error margin between urinary retention and leakage persistency.

2. Patients and methods

From October 2002 to August 2005, 51 male patients with mild to severe SUI were prospectively operated with the use of a readjustable sling (MRS) at 7 different hospitals: Spain (2), Italy (2), Greece (1), Germany (1), and Portugal (1). The origin of incontinence was radical prostatectomy in 43, transurethral resection of the prostate in 4, and open prostatectomy in another 4. Ten patients had a past history of radiotherapy. The preoperative duration of incontinence ranged from 1 to 10 yr with an average of 3.5 yr.

Ages ranged from 58 to 81 yr (median: 69) and postoperative follow-up ranged from 16 to 50 mo (median: 32). Preoperative assessment included clinical evaluation, basic urodynamic study, cystoscopy to exclude patients with urinary obstruction, severe vesical instability, or very reduced bladder capacity. Prostate-specific antigen level and urine analysis were also done to exclude tumor recurrence or urinary infection. All patients had undergone prostate surgery at least 1 yr before and used geriatric pads or external urine collectors. Those patients who used pads needed between 2 to 8 pads per day (average: 4.25).

Urinary incontinence was considered mild, moderate, or severe by the number of pads used per day. Nine patients (17.6%) showed mild incontinence (1–2 pads), 10 (19.6%) showed moderate incontinence (3–4 pads), and another 32 (62.7%) were considered to have severe incontinence (5 or more pads). Postoperative results were considered a success if patients wore no pads or used small security pads but remained dry most days, improved if the number of pads needed diminished more than 50%, and a failure when reduction in the number of pads diminished less than 50%. The Incontinence Impact Questionnaire (short form, IIQ-7) was self-administered to 35 patients (68.6%) after a median follow-up of 24 mo.

2.1. Surgical technique

The MRS is composed of a monofilament suburethral sling connected to a suprapubic mechanical regulator with two monofilament traction threads (Fig. 1.1). The mechanical regulation part, the varitensor, is a subcutaneous permanent implant, which is placed over the abdominal rectum fascia 2 cm above the pubis; the implant allows adjustment of suburethral pressure from outside the body by means of an external manipulator (Fig. 1.4). A special screwdriver called the uncoupler (Fig. 1.5–1.7) is used to disconnect and separate the external manipulator from the varitensor once the desired

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continence level is achieved, allowing the removal of the manipulator from the body.

The varitensor is a small (1 × 1 × 2.5 cm) cubic device with an internal never-ending axis to wind the traction threads. The threads are passed through into the varitensor through two lateral holes and emerge through the central hole at the varitensor midline, where the threads are secured with a fixing screw (Fig. 1.2 and 1.3). The varitensor has a mechanical connecting point for the external manipulator on its upper side. By rotating the manipulator clockwise or counterclockwise, suburethral pressure may be increased or decreased (Fig. 1.4). The suburethral support is a short (3 × 4 cm) suburethral polypropylene sling mesh joined to the varitensor through two non-reabsorbable prolene threads.

Under spinal anaesthesia and antibiotic prophylaxis, the patient is placed in the lithotomy position and prepared by shaving the abdomen and perineum. An 18F Foley catheter is placed per urethra. A 4-cm transverse incision is made just above the upper side of the pubic symphysis dissecting the subcutaneous tissue until the anterior rectal muscle fascia or the scar tissue is seen.

A vertical incision of 4–5 cm long is made in the perineum. The urethra, surrounded by the bulbocavernous muscle, is carefully dissected by using a Scott perineal retractor (Fig. 2.1 and 2.2). The interior edge of the ischiopubic ramus is dissected, and the urogenital diaphragmatic fascia is sharply penetrated very close to the bone. Then the hole is enlarged with scissors to permit introduction of the index finger. Digital ascending dissection of the retropubic space is performed, in an attempt to reach the highest possible position to minimize the space between the fingertip and the anterior rectal fascia. A small suprapubic incision is performed and fat tissue is dissected until the fascia is reached (Fig. 2.3). A 60° modified Stamey needle is placed at the retropubic space guided by the tip of the finger to avoid urethral or bladder perforation (Fig. 2.4). The needle, with the traction threads attached, is then pushed up until it reaches the suprapubic incision (Fig. 2.5 and 2.6). The same manoeuvre is performed contralaterally. Cystourethroscopy is used to confirm urethrobladder integrity.

If there is no perforation, the traction threads are pulled up until the polypropylene sling mesh is in full contact with the bulbocavernous muscle without exerting pressure (Fig. 2.7). The sling is then fixed and fully extended by placing four reabsorbable stitches (Fig. 2.8). The perineum is closed in layers with reabsorbable sutures without leaving drains. Suprapubically, the traction thread tips are introduced into the varitensor through the corresponding lateral hole, appearing through the central varitensor hole. Then both thread ends are fixed with a security frontal screw, and the traction threads are wound into the varitensor by rotating the manipulator clockwise until the varitensor rests freely over the abdominal rectal fascia or the previous scar (Fig. 2.9). The operation is completed by closing the abdominal incision, leaving the external manipulator connected to the varitensor and protruding through the centre of the abdominal incision (Fig. 3.1).

If there was no perforation during surgery, the morning after the operation the bladder is filled with 250–300 ml of saline through the urethral catheter. The patient is then asked to stand up and perform Valsalva manoeuvres (cough) and all those movements that usually produce urinary leakage.

If incontinence appears, the external manipulator is rotated four complete turns clockwise, and continence is checked again. If the patient is still incontinent, additional turns are applied to the manipulator; this maneuver is repeated until leakage disappears (Fig. 3.2). Then the patient is invited to urinate, and the postvoiding volume is measured by sonogram or with a urethral catheter. If residual urine is under 100 ml and the patient is able to void well, the uncoupler is used to remove the manipulator from the varitensor (Fig. 3.4) and the patient is discharged. If the bladder was penetrated during surgery, the urethral catheter was left for 4–5 d and no early regulation of the suburethral tension was performed.

In the remaining patients or those who become newly incontinent after hospital discharge, a delayed regulation is done just by reopening the suprapubic area under local anaesthesia. The external manipulator is rejoined to the varitensor by using the uncoupler, and the adjustment is repeated in the same way.

3. Results

All patients but 5 (those who had intraoperative problems) were regulated during the early postoperative period; 44 patients (including the 5 not regulated during the early period) required a second regulation under local anaesthesia between 1 to 4 mo after surgery; and another 17 patients required more than one delayed regulation under local anaesthesia. After that, 33 patients (64.7%) were considered dry: 25 wore no pads and 8 used only one “security” pad/day (which was frequently dry at night except for those days when they performed physical efforts). Ten cases showed important improvement (19.6%) and the remaining eight patients remain unchanged (15.7%). One very improved patient voluntarily rejected a new regulation, and another nonimproved patient was rejected for regulation because of a cerebrovascular accident. The average of pads needed diminished from 4.25 to 1.4 pads per day after a follow-up time of 32 mo (range: 16–50). No patient presented urinary retention during immediate postoperative period or after delayed regulations. No cases of de novo urgency were seen. The IIQ-7 scores from the 35 patients interviewed diminished from a preoperative value of 52.8 to 7.6 postoperatively. All patients cured or improved were satisfied with the procedure, which represented an 84.3% subjective success rate.

The rates of satisfied patients (cured or improved) in cases with mild, moderate, or severe incontinence were, respectively 100% (9 of 9), 90% (9 of 10), and 78.1% (25 of 32). On the other hand, the success rates (cured or improved) in patients with or without radiotherapy were 60% (6 of 10) and 90.2% (37 of 41), respectively.

There was one urethral erosion of the mesh, which was removed; the patient remains incontinent. There were two infections of the varitensor, which was removed, and the prolene threads were tied to each other without changing the suburethral pressure. After that, one patient was incontinent but the other was highly improved. There were five (9.8%) uneventful intraoperative bladder perforations discovered during surgery, all cases being solved by performing a new puncture. There were
three mild perineal haematomas (5.9%) that needed no aggressive treatment; most patients felt transient pain or perineal discomfort, which was treated with oral medications.

4. Discussion

Male urinary incontinence due to sphincteric insufficiency, which occurs after radical prostatectomy or transurethral resection of the prostate, is a highly feared complication because of its effect on the patient’s quality of life. Surgical attempts to correct this problem are not recent. In the 70s, along with the development of the artificial sphincter, Kaufman [5,6] proposed several techniques with discouraging long-term results.

Among the techniques currently accepted to treat this condition, the injection of periurethral bulking agents is expensive and has shown a very low 1-yr success rate. For these reasons it has been excluded from most international guidelines [4]. Another “bulking” treatment, the ProACT system has shown higher success rates in mild to moderate incontinence, but only 65.2% achieved continence (including those using 1 pad per day). This system is not recommended for severe cases of SUI [7].

The artificial sphincter AMS-800 [1] is considered the gold standard for treatment of moderate to severe SUI. Global success rates are very high with 75–87% of patients being dry or “almost dry” [4]. However, it is very expensive, results in an abnormal micturition, and requires manual dexterity to be used; surgical revisions due to mechanical failures occur in 12–53% of cases; and the incidence of erosion and infection varies from 6% to 27% [4].

Various surgical techniques are used to improve continence, but no evidence overwhelmingly supports any specific technique [8]. Suburethral sling surgery for treating male SUI was initially described 34 yr ago by Salcedo [9]. Since that time several hundred patients have been treated worldwide with many different suburethral slings; those which were published have achieved patient cure or improvement in 58% and 13% of cases, respectively (Table 1) [10–27]. However, almost all these slings are not adjustable, which means that, if slings are placed with an excessive suburethral pressure, a urinary obstruction will be produced. Nonetheless, to place it with insufficient pressure will not cure the incontinence.

In fact, studies performed with suburethral mesh anchored to the pubic bone with screws showed that, if high pressure was applied to the mesh, high success results might be achieved but a postoperative urinary retention would occur in one third of patients, 20% of whom would require medication due to de novo urge incontinence, which indicates an obstructive urinary pattern [15]. Urodynamic studies confirm this obstructive pattern with a decrease in maximal urinary flow of 6.5 ml/s [28]. However, other authors who applied a lower tension to the mesh had to retighten the mesh in 22% of patients to improve their lower success rates [18].

Table 1 - Worldwide experience with non-readjustable suburethral slings in male stress urinary incontinence

<table>
<thead>
<tr>
<th>Author/Year</th>
<th>No</th>
<th>Etiology</th>
<th>Material</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mizuo [10]</td>
<td>3</td>
<td>TUR</td>
<td>Goretx</td>
<td>100% cured</td>
</tr>
<tr>
<td>Schaeffer [11]</td>
<td>64</td>
<td>Radical prostatectomy</td>
<td>Goretx</td>
<td>67% cured + 8% improved</td>
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<tr>
<td>Ghoneim [12]</td>
<td>10</td>
<td>Radical prostatectomy</td>
<td>Fascia</td>
<td>70% cured + 10% improved</td>
</tr>
<tr>
<td>Céspedes [13]</td>
<td>9</td>
<td>Radical prostatectomy</td>
<td>Fascia/skin</td>
<td>66.6% cured + 11.1% improved</td>
</tr>
<tr>
<td>Kapoor [14]</td>
<td>8</td>
<td>Adenom/TUR</td>
<td>Dacron</td>
<td>100% “dry”</td>
</tr>
<tr>
<td>Franco [15]</td>
<td>15</td>
<td>Radical prostatectomy</td>
<td>Polypropilene</td>
<td>86.6% cured + 6.6% improved</td>
</tr>
<tr>
<td>Xu [16]</td>
<td>12</td>
<td>Radical prostatectomy</td>
<td>Polypropilene</td>
<td>83% cured + 8.3% improved</td>
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<tr>
<td>Migliari [17]</td>
<td>9</td>
<td>Radical prostatectomy</td>
<td>Polypropilene</td>
<td>55.5% cured + 22% improved</td>
</tr>
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<td>Herschorn [18]</td>
<td>18</td>
<td>Radical prostatectomy</td>
<td>Polypropilene</td>
<td>89% cured or improved</td>
</tr>
<tr>
<td>Dikranian [19]</td>
<td>36</td>
<td>Radical prostatectomy</td>
<td>Dermis/silicone</td>
<td>63.8% cured + 19.4% improved</td>
</tr>
<tr>
<td>Onur [20]</td>
<td>46</td>
<td>Radical prostatectomy</td>
<td>Polypropilene</td>
<td>41.3% cured + 34.7% improved</td>
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<tr>
<td>John [21]</td>
<td>16</td>
<td>Radical prostatectomy</td>
<td>Dermis + polypropilene</td>
<td>68.8% cured + 6.3% improved</td>
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<tr>
<td>Schaal [22]</td>
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<td>Radical prostatectomy/TUR</td>
<td>Polypropilene</td>
<td>66.7% cured + 13.3% improved</td>
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<tr>
<td>Cetiné [23]</td>
<td>12</td>
<td>Radical prostatectomy/TUR Adenom/Neur</td>
<td>Polypropilene</td>
<td>75% cured or improved</td>
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<tr>
<td>Cerqueira [24]</td>
<td>10</td>
<td>Radical prostatectomy/Adenom TUR/Cistoproct</td>
<td>Polypropilene</td>
<td>85% cured + 20% improved</td>
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<td>Fassi-Fehri [25]</td>
<td>22</td>
<td>Radical prostatectomy/TUR Ablaterm</td>
<td>Polypropilene</td>
<td>50% cured + 22.7% improved</td>
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<tr>
<td>Queipo [26]</td>
<td>4</td>
<td>Radical prostatectomy</td>
<td>Polypropilene</td>
<td>50% cured + 25% improved</td>
</tr>
<tr>
<td>Comiter [27]</td>
<td>48</td>
<td>Radical prostatectomy</td>
<td>Polypropilene</td>
<td>65% cured + 15% improved</td>
</tr>
<tr>
<td>Romano [32]</td>
<td>48</td>
<td>Radical prostatectomy/TUR</td>
<td>Silicone foam pad</td>
<td>73% cured + 10% improved</td>
</tr>
</tbody>
</table>

Total 420 59% cured + 12% improved
Some studies comparing slings and artificial urinary sphincters (AUS) have been performed and showed that, after intermediate follow-up, 85–89% of patients treated with slings were cured or improved, whereas only 75–79% treated with AUS showed good results. These results were obtained with mild to intermediate SUI patients; however, in the severe incontinence group (more than 3 pads a day), AUS was more effective (65%) than a bone-anchored sling (50%) [18,29]. In fact, the bone-anchored sling is only recommended for mild to moderate degrees of incontinence [30,31].

Other adjustable suburethral slings [32] have demonstrated an 83% success rate (patients cured or improved), which is very similar to our own results but with higher problems of obstruction (15% of acute urinary retention vs. 0% in our study). These results clearly show that male MRS permits achievement of adequate suburethral pressure to avoid urine leakage without causing obstruction.

Initial good results with the MRS have been previously published [33]; this multicentric study confirms these high success rates in the treatment of moderate to severe SUI after a mean of 2 yr of follow-up (range: 16–50 mo). Immediate and delayed readjustment of suburethral pressure were both safe and effective, increasing these positive results (dry or very improved patients) close to 85% and showing no voiding problems.

Satisfactory results were a little lower in patients with severe incontinence (78%) than in those with mild to moderate incontinence (100% and 90%, respectively). On the other hand, satisfactory results were also lower in irradiated patients (60%) than in those who did not receive this kind of treatment (90%).

The urethral erosions of the mesh detected in one patient were probably due to an inadvertent urethral perforation during surgery because the problem occurred during the learning curve period. Moreover, the varitensor was removed in two cases owing to infection that occurred during delayed reopening of the suprapubic skin. After that, we do not recommend reopening the scar until 2 mo after the last manipulation and maintaining the external manipulator in place more than 3 d. Postoperative pain was easily controlled with oral medication, probably because local pain is directly related to the tension applied to the suburethral mesh and this system allowed us to apply the minimum pressure needed to achieve continence.

New prospective studies, with the improved model of the MRS (which has lateral reinforcement of the suburethral mesh and improved support for the suprapubic prosthesis) are currently in progress.

5. Conclusions

As a take-home message, we think that the MRS suburethral sling has been shown to be a simple method to treat postprostatectomy stress urinary incontinence with very low complication rates. This readjustable bulbourethral sling obtains satisfactory and long-lasting results in almost 85% of patients.

Conflicts of interest

None of the authors has any commercial relationship with Neomedic International that might be in any way considered related to a submitted article.

References

The method to treat a specific pathology provides some indications about the physiopathology of the condition. In women, it is now clear that two conditions drive stress urinary incontinence. Hypermobility of the urethra and bladder neck seems to play a major role because its correction by supporting the middle portion of the urethra in a tension-free manner with either retropubic or trans-obturator tape results in about 80% of patients becoming dry. The other 20% remain wet because they have exclusive or additional intrinsic sphincter deficiency, which could be treated by bulking agents (injections or balloons) or by an artificial urinary sphincter.

In men, the situation seems apparently a bit different. For a long time, an artificial urinary sphincter was considered the gold standard treatment for stress urinary incontinence in men. Intrinsic sphincter deficiency was thought to be the major condition involved [1].

Despite some former disappointments with slings, the literature now seems to indicate that pulling strongly on the bulbar portion of the male urethra with an artificial mesh can restore continence in mildly to moderately incontinent patients [2]. Various slings have been described but none have applied the tension-free concept, which seems not to be adaptable in men. On the contrary, it seems of high importance to apply...
strongly the mesh on the bulbar portion of the urethra. For the moment it is not clear if the mesh has to be applied directly on the urethra [3] or without opening the bulbocavernous muscles [4]. A trans-obturator approach is also expected to give promising results [5]. We need to clarify the pathophysiology of continence in men compared to what we know in women. Moreover, despite no available long-term results, some data indicate that progressive failure will occur with time [6]. Therefore, a device allowing adjustment of the tension of the mesh with time as described in the paper of Sousa-Escandon is of high interest [7].

But in awaiting further data with a longer follow-up, one should clarify how to evaluate the results after treating stress urinary incontinence in men. Should we use a questionnaire on symptoms or quality-of-life questionnaire or both and, then, which questionnaires? Is a pad test mandatory? One should also establish what constitutes a successful result. Does wearing no pads or wearing only a security pad have the same clinical meaning? A patient who wore eight pads a day before treatment and who after treatment needs only three pads a day has a significant decrease in number of pads used. But is this patient satisfied with his continence? Probably he is not. An international consensus should be established on all these subjects. Otherwise we will continue to read, as in the Sousa-Escandon article, that the Remeex[TM] device gives 85% of patients good results including, in fact, not only dry patients but also 20% of patients with significant improvement but not cured, and 15% of patients who continue to wear a security pad.

References


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