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The suburethral tension adjustable sling (REMEEX system) in the treatment of female urinary incontinence due to 'true' intrinsic sphincter deficiency: results after 5 years of mean follow-up

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OBJECTIVE

To retrospectively report the objective and subjective outcomes of suburethral tension adjustable sling (Remeex system) implantation for stress urinary incontinence (SUI) caused by 'true' intrinsic sphincter deficiency (ISD) with fixed urethra.

PATIENTS AND METHODS

Thirty female patients with severe SUI, mainly because of iatrogenic ISD, underwent Remeex system positioning between May 2002 and July 2008 (mean follow-up 60.6 months, range 22–96 months). Before surgery, patients were evaluated by physical examination, translabial ultrasonography, flexible cystoscopy, urodynamics, 1-hour pad test and compilation of a quality-of-life questionnaire. Postoperatively, based on the physical examination and pad test, patients were stratified into three groups: (i) Cured: perfectly dry patients at stress test, pad weight 0–1 g; (ii) Improved: patients with mild to moderate incontinence, pad weight 2–50 g; and (iii) Failed: unchanged or worsened patients, pad weight >50 g.

RESULTS

At the final follow-up visit, 26 (86.0%) patients were cured, 2 (7.0%) were improved and 2 (7.0%) had failed. In particular, the total mean pad weight decreased to 33.2 ± 15.6 (71%) and the total mean questionnaire score significantly increased to 86.9 ± 6.7 (74.0%). Sling tension readjustment was needed during follow-up in two patients (7%). Among the complications, persistent urinary retention (10%), seroma formation (3%) and *de novo* urgency (7%) were easily treated.

CONCLUSION

The Remeex system produced remarkable 5-year results with a low complication rate. These outcomes have also been confirmed in a worse prognosis patient group as reported in the present study.

KEYWORDS

urinary incontinence, stress, therapeutics, suburethral slings

INTRODUCTION

The treatment of female stress urinary incontinence (SUI) caused by intrinsic sphincter deficiency (ISD) still remains a very difficult target for urologists [1,2]. As recommended by both European and American guidelines, past and current treatment options for ISD mainly included urethral bulking agents, suburethral slings and artificial urinary sphincters [3,4]. The comparison between the outcomes reported by these different procedures is very difficult because of the different criteria used to assess ISD and the lack of long-term, randomized, multicentre trials with specific definitions of cure and failure. However, several papers have revised the roles of bulking agents because of their reported low long-term cure rates (<50%), and of artificial urinary sphincters because of their high rates of revision, explantation (20–50%) and costs [5–8]. In this setting, the pubovaginal sling emerged as the most feasible procedure for the treatment of SUI caused by ISD with acceptable efficacy and safety profiles [1,2,9].

Many types of sling materials and procedures have been proposed to obtain adequate sling tension and avoid the risk of postoperative complications. In particular, the use of synthetic slings has gained a new popularity based on the good results reported with the tension-free procedure in the treatment of urethral hypermobility [9–11]. In fact, urethral hypermobility and ISD often coexist and this aspect may explain the good results reported for the tension-free procedures [1,10,11]. In cases of ISD with fixed urethra or after anti-incontinence and surgical procedures, which could produce neurological damage of the pelvic plexuses (hysterectomy), tension-free slings are more likely to fail, which has produced an interest in alternative less invasive but more effective techniques [2,11–13].

The suburethral tension adjustable sling (Remeex system; Regulation Mechanical External; Neomedic International, Terrassa, Spain) combines the advantages of a less invasive approach with the opportunity of a synthetic sling re-adjustment, which seems to

produce better results in terms of continence rate and morbidity [14–16].

We report our subjective and objective results after Remeex system implantation in a particular group of patients who reported urinary incontinence mainly because of iatrogenic ISD with a 'lead pipe' and fixed urethra.

PATIENTS AND METHODS

In May 2010 we retrospectively assessed 30 consecutive female patients, aged from 28 to 81 years (mean age 66.3 years), who had undergone suburethral tension adjustable sling (Remeex system) implantation for SUI due to ISD, between May 2002 and July 2008 (mean follow-up 60.6 months, range 22–96 months).

All patients presented with severe SUI due to ISD with a 'lead pipe' and fixed urethra for at least 1 year.

TABLE 1 Patient characteristics before the Remeex procedure

Patient characteristics	Value
Number, *n*	30
Age, mean years (range)	66.3 (28–81)
Body mass index, mean (range)	24.5 (23–29)
Parity, mean (range)	2.1 (0–4)
Postmenopausal, no. of patients (%)	29/30 (97)
Associated prolapse, no. of patients (%)	6/30 (20)
Previous anti-incontinence surgery, no. of patients (%)	
Prolapse repair	7/15
Tension free suburethral sling positioning	5/15
Burch colposuspension	2/15
Bulking agents injection	3/15
Total, *n* (%)	15/30 (50)
Previous gynaecological surgery (hysterectomy), no. of patients (%)	5/30 (17)
Detrusor overactivity, no. of patients (%)	0/30 (0)
Pad weight (g), mean ± range	114.6 ± 45.3
Maximal urethral closure pressure (cmH_2O), mean ± range	14.6 ± 2.5
Abdominal leak point pressure (cmH_2O), mean ± range	41.1 ± 11.6
Total quality-of-life questionnaire score, mean ± range	25.7 ± 8.5

Preoperative evaluation included history, routine laboratory tests, physical examination with stress test (cough provocation), translabial ultrasonography [17], flexible cystoscopy and multichannel urodynamic measurement of the filling and voiding phases [18]. In particular, history and physical examination showed severe SUI (more than four pads/day) for at least 1 year with no urethral hypermobility. The translabial ultrasonography confirmed the presence of a fixed urethra. The cystoscopy showed a wide open bladder neck at rest and a 'lead pipe' urethra. The urodynamic measurement reported maximal urethral closure pressure and abdominal leak point pressure values ≤20 cmH_2O and 60 cmH_2O, respectively, and no instance of detrusor overactivity in all the patients.

Patients also underwent a 1-hour pad test, in accordance with the International Continence Society's guidelines [19], and filled in a quality-of-life (QoL) questionnaire with the help of a non-partisan healthcare provider; the physician and questioner had no knowledge of each other. It was a specific incontinence QoL questionnaire that contained 22 items, each with a five-point Likert-type scale (from 1 to 5), yielding a total score ranging between 22 and 110 [20].

Twenty (67%) of the patients had already undergone previous gynaecological (hysterectomy) or anti-incontinence (prolapse repair, tension-free suburethral sling positioning, Burch colposuspension, bulking agents injection) surgery.

Among the patients who had already undergone a prolapse repair, six patients (20%) presented SUI with an associated recurrent stage I–II pelvic organ prolapse. In these cases, sling positioning was combined with prolapse repair using the vaginal approach. The pelvic organ prolapse was scored according to the Pelvic Organ Prolapse Quantification classification [21].

Patients' characteristics are summarized in Table 1.

The suburethral suspension was performed using the Remeex system. The composition of this device has already been reported in the literature [16].

The surgical procedure was performed, under spinal anaesthesia, with the patient placed in the dorsal lithotomy position. A 16 French Foley catheter was passed and inflated. The anterior vaginal wall was incised from the middle urethra to the urethrovesical junction for about 2 cm and dissected from the underlying periurethral and perivesical tissues. In cases of previous suburethral sling surgery, the sling material was completely removed before positioning the Remeex system. A 3- to 4-cm lower abdominal incision was then made and a Stamey carrier needle holder was passed through the retropubic space, from the abdominal to the vaginal plane, reaching the tip of the index finger introduced in the periurethral tissue, which had been previously prepared. A no. 1 polypropylene monofilament suture attached to a polypropylene mesh of 1.25 × 2.5 cm was then 'clipped' to the needle tip and pulled up until it appeared at the abdominal incision. The same procedure was carried out on the opposite side. With the varitensor 10 cm above the fascia of the abdominal rectus, the ends of the suture were inserted into the varitensor and knotted together. The mesh was then placed at the proximal urethra and the manipulator was wound clockwise until the varitensor was about two fingertips above the rectus aponeurosis (1–2 cm). The vaginal and abdominal incisions were closed, leaving the manipulator in place. Cystoscopy was performed during this procedure and the urethral catheter was left to gravity drainage.

The day after surgery, the bladder was filled with about 250 mL saline, the catheter was removed and the patient was invited to stand up and cough; the sling support was then adjusted by turning the manipulator until the patient was completely dry. The patient was then invited to go to the toilet to verify a spontaneous micturition and the residual

TABLE 2 Outcomes of the Remeex procedure regarding physical examination, pad test and quality of life (QoL) score after a mean of 60.6 months of follow-up

Patients	No. of patients (%)	Mean pad weight ± SD (g) (% improvement; *P* value)	QoL score ± SD (% improvement; *P* value)
Cured	26 (86.0)	0.6 ± 0.3 (99.0; <0.05)	102.0 ± 6.2 (98.0; <0.05)
Improved	2 (7.0)	27.6 ± 12.1 (76.0; <0.05)	89.3 ± 7.6 (74.0; <0.05)
Failed	2 (7.0)	111.5 ± 39.6 (0.02; ns)	26 ± 0.8 (2.0; ns)
Total	30 (100)	33.2 ± 15.6 (71.0; <0.05)	86.9 ± 6.7 (74.0; <0.05)

The values are reported in accordance with the respective units of measurement. Percentages of improvement compared with the respective preoperative values are also included. The P value is reported when the parameter is significantly different before and after the Remeex procedure. In all other cases the difference is not significant (ns).

urine was checked. In the event of residual urine ≥100 mL the sling tension was decreased but if it was <100 mL the disconnector was rotated 90° in relation to the manipulator, either clockwise or counterclockwise, and the disconnector–manipulator was easily removed from the varitensor, which stayed buried in the fat above the rectus aponeuoris as a permanent regulation mechanism, to be used to readjust the sling whenever necessary during follow-up.

Postoperative follow-up included an initial visit 7 days after surgery. Further visits were scheduled at 1, 6 and 12 months, then every year for 5 years. During the visits, patients underwent history, physical examination with stress test, 1-h pad test and abdominal ultrasonography for the evaluation of post-void residual urine and also filled in the self-assessment QoL questionnaire [20]. Urodynamic examination was only repeated in uncured patients.

After the physical examination and the pad test, patients were stratified into three groups: (i) Cured: perfectly dry patients at stress test, pad weight 0–1 g; (ii) Improved: patients with mild to moderate incontinence, pad weight 2–50 g; and (iii) Failed: unchanged or worsened patients, pad weight >50 g. Questionnaire data were collected from each group of patients.

Mean values concerning pad weight and questionnaire score data before and after surgery were compared using Student's *t* test and a commercially available software ($P < 0.05$ was considered significant).

RESULTS

Before surgery all 30 patients reported severe incontinence with positive pad tests (mean pad weight 114.6 ± 45.3 g). The mean maximal urethral closure pressure and abdominal leak point pressure were 14.6 ± 2.5 cmH_2O and 41.1 ± 11.6 cmH_2O, respectively. The mean total score of the QoL questionnaire was 25.7 ± 8.5 (Table 1).

Table 2 shows the clinical outcomes of the Remeex procedure and the improvement rates of mean pad weight and questionnaire score data compared with the respective preoperative values.

At the last follow-up visit in May 2010, 26 patients (86%) were completely cured, 2 (7%) had improved and 2 (7%) failed. With regard to the total mean pad weight, it decreased to 33.2 ± 15.6 g with a significant mean improvement of 71%. In particular, in cured and improved patients it decreased significantly to 0.6 ± 0.3 g and 27.6 ± 12.1 g, corresponding to an improvement of 99% and 76%, respectively.

Concerning the mean total score of the QoL questionnaire, it significantly increased up to 86.9 ± 6.7 with a mean improvement of 74% ($P < 0.05$). In particular, in cured and improved patients it significantly increased up to 102.0 ± 6.2 and 89.3 ± 7.6, corresponding to improvements of 98% and 74%, respectively. Significant variations in mean pad weight and QoL score were not recorded in failed patients.

A readjustment of sling tension was needed under local anaesthesia, 1 month after surgery, in two patients (7%) but was refused by the two improved patients (7%) because of their satisfaction with the improvement of continence. The two failed patients (7%) also refused any other treatment that we proposed.

No variation of the clinical and QoL results was assessed during the follow-up. No association has been detected between treatment failure and combined prolapse repair during the Remeex procedure.

Among the complications, three cured patients (10%) reported persistent urinary retention, which was successfully treated in two cases, 3 days after surgery, by reducing the sling tension and descending the urethra with a Hegar dilator. The remaining patient (3%) who continued to report a partial urinary retention after this procedure needed to perform self-catheterization.

One cured patient (3%) developed seroma formation, approximately 15 days after surgery, which required a reduction of the sling tension and surgical revision with drainage of the seroma. Sling tension was then increased 1 month later, restoring complete continence.

Two cured patients (7%) with *de novo* urgency and no residual urine were successfully treated with anticholinergic drugs. These two patients previously underwent injection of bulking agents and showed severe fibrosis of the periurethral tissues, which made the surgical dissection very difficult.

None of the patients complained of pain after surgery or discomfort from feeling the Varitensor under the skin.

Overall, no association has been assessed between complications and combined prolapse correction during the Remeex procedure.

DISCUSSION

The goal of treatment for ISD is to correct incontinence without creating outlet obstruction. To date, there is no consensus in the literature on the best treatment to choose and various options may be considered, mainly represented by bulking agents, artificial urinary sphincters and slings [1–4]. The role of bulking agents, which is surely the

least invasive technique with an acceptable short-term cure rate (60–80%) [22,23], was revised recently, because of the dramatic decrease in continence rate during the mid-term follow-up (25–40%) [5,23]. Also, the use of artificial urinary sphincters in women has been limited and is usually reserved for those patients with ISD caused by multiple failed anti-incontinence procedures or congenital abnormalities. In fact, in spite of the good continence rate after 4 years of follow-up reported in the largest series by Costa *et al.* [7] (88.7% and 81.7% in patients with non-neurogenic and neurogenic bladders, respectively), the problems related to the abdominal approach, the life expectancy of the device, the revision or explantation rates (overall 50–60%) and the higher costs, required a strict patient selection process to identify potential candidates for artificial urinary sphincter implantation [7,24].

In this scenario, pubovaginal sling procedures have been considered the first choice of therapy because of their appreciable outcomes. In fact, continence rates greater than 75%, with a significant improvement of QoL, have been shown by many authors [9–11]. Regarding pubovaginal sling morbidity, urinary retention and urgency, which are the most frequent complications and probably secondary to the obstructive nature of the device, were reported by 0–25% of patients in the early postoperative period, although they spontaneously disappeared or could be successfully cured with drugs during follow-up. The development of more serious conditions, such as urethral erosion, have rarely been reported after sling procedures [9–11,13,25]. In the last few years, many types of sling materials, sutures and surgical techniques have been proposed to obtain complete continence while minimizing the risk of complications. Recently, good results were reported using tension-free vaginal tape procedure showing a cure rate ranging between 74 and 91.4% [13,26,27]. However, the results of tension-free slings are not always promising, especially in cases of recurrent ISD or fixed urethra [13,26,27]. In particular, Haliloglu *et al.* [11] found that patients with fixed urethra were associated with the lowest success rates indicating that the presence of a fixed urethra was a risk factor for failure in tension-free procedures [11,13].

Accordingly, the aim of our study was to assess the outcomes of a Remeex procedure in a group of patients with worse prognosis affected by 'true' ISD (mainly iatrogenic ISD with 'lead pipe' urethra and fixed urethra). In fact, in patients who failed tension-free procedures, or in situations where tension-free slings are more likely to fail, such as ISD with fixed urethra, an adjustable tension sling procedure should provide many opportunities to reach an appropriate and durable sling tension avoiding the risk of complications [14–16]. Our outcomes confirmed this expectation, showing a cure rate of 86%, in accordance with the success rates reported in literature, which ranged between 55.5 and 98.9% [28–30]. Moreover, our data provided a longer follow-up than those reported in literature, confirming the durability of the Remeex technique up to 5 years after surgery.

In terms of QoL, these clinical improvements were supported by higher satisfaction rates, most probably because of the patient's well being for the regained health condition. Furthermore, among cured and improved patients, the significant improvement of quality of life regarded all the aspects assessed by the questionnaire including physical and mental health, psychosocial impact and intimate relationships.

As regards sling tension adjustment, it was easily and successfully performed under local anaesthesia, also showing the efficacy of this procedure during follow-up. The adjustability of the system allowed the patient to regain continence in cases that would have required additional surgery if they had been treated with non-adjustable techniques. Interestingly, as reported by other authors and also in our experience, some potentially curable patients refused to undergo sling re-adjustment because they felt improved enough [16,30].

Concerning morbidity, our outcomes also reported an acceptable complication rate (20%), mainly because of minor events, which were easily resolved [14–16,28–30]. With regards to urinary retention, the ability to loosen the sling tension was an interesting option, which allowed a normal flow to be regained immediately with no residual urine in two out of three patients. Surgical revision was only needed in one patient (3%), because of sling infection, who was successfully cured; there were no cases of urethral erosion. None of the patients reported any complication in the mid-term follow-up.

In our experience, the Remeex system produced remarkable 5-year results that showed the effective role of this device in attaining an adequate sling tension as well as regaining the patient's continence and minimizing the risk of complications. These outcomes have also been confirmed in a worse-prognosis patient group, as reported in the present study.

The design limitations of this study, which was based on a retrospective and not comparative analysis, highlight the need for randomized prospective studies comparing the Remeex procedure with other anti-incontinence techniques.

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CONFLICT OF INTEREST

None declared.

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Abbreviations: **SUI**, stress urinary incontinence; **ISD**, intrinsic sphincter deficiency; **QoL**, quality of life.