Mid- to Long-Term Results of the Remeex System for the Treatment of Female Incontinence Due to Intrinsic Sphincter Deficiency: A Retrospective Analysis of the First 50 Patients

Claudio Giberti, Fabrizio Gallo,* Pierluigi Cortese, and Francesco Visalli
Department of Urology, San Paolo Hospital, Savona, Italy

Aims: To retrospectively report our mid- to long-term results following suburethral tension adjustable sling (Remeex system) implantation for stress urinary incontinence (SUI) due to intrinsic sphincter deficiency (ISD). **Methods:** Fifty female patients with severe SUI due to ISD underwent Remeex system positioning between May 2002 and March 2013 (mean follow-up 83.8 months, median follow-up 85.4 months). Before surgery, patients were evaluated by physical examination, translabial ultrasonography, cystoscopy, urodynamics, 1 hr pad test and compilation of 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 7-years mean follow-up, 45 (90.0%) patients were cured, three (6.0%) were improved, and two (4.0%) had failed. Concerning the mean total score of the quality-of-life questionnaire, it increased significantly up to 87.1 ± 5.9 with an improvement of 76.9%. Sling tension readjustment was needed in three patients (6%). The incontinence-free survival curve showed that, after sling positioning and tension readjustments, all the cured patients remained continent during all the follow-up. Complications were represented by bacterial cystitis (6%), de novo urgency (10%), persistent urinary retention (6%), and seroma formation (2%). **Conclusions:** Our 7-year results showed the efficacy of the Remeex procedure in the treatment of SUI due to ISD. These outcomes tended to be confirmed in the mid- to long-term follow-up which would highlight the durability of this technique. *Neurourol. Urodynam.* © 2016 Wiley Periodicals, Inc.

Key words: stress urinary incontinence; suburethral slings; therapeutics

INTRODUCTION

Today, the surgical treatment of female stress urinary incontinence (SUI) is substantially based on the positioning of mid-urethra slings which provide remarkable outcomes with a less invasive approach in uncomplicated patients.[1] However, the majority of tension-free anti-incontinence devices have been shown to be less or not effective for the treatment of SUI due to intrinsic sphincter deficiency (ISD), especially in cases of iatrogenic ISD with fixed urethra.[2–4] Other options proposed for the treatment of this worse-prognosis group of patients include mainly urethral bulking agents and artificial urinary sphincters (AUS). The role of bulking agents, which is surely the least invasive technique with an acceptable short-term cure rate (60–80%), was revised recently, due to the dramatic decrease in continence rate during the mid-term follow-up (25–40%).[5–7] The diffusion of AUS has also been limited, despite a reported cure rate >85%, by the risk of device revision or explantation due to mechanical complications (13.6%) and the relevant costs.[8] In this scenario, the suburethral tension adjustable sling (Remeex system) was proposed as a new device which combined the advantages of a less invasive approach with the opportunity of sling re-adjustment in order to increase the success rate and overcome the complications generally reported after the positioning of other compressive pubovaginal slings.[9] In the last few years, some authors, including our team, have published their experience of the Remeex procedure for the treatment of ISD showing remarkable results in terms of cure and complication rates. However, these outcomes were based mainly on a small number of patients with limited follow-up periods and should be confirmed by a larger series with longer follow-ups.[10–13]

The aim of this article is to report our results following Remeex system implantation in the first 50 patients affected by urinary incontinence due to ISD with mid- to long-term follow-up.

MATERIALS AND METHODS

In October 2015, we retrospectively assessed 50 consecutive female patients, from 28 to 81 years (mean age 67.8), who had undergone suburethral tension adjustable sling (Remeex system) positioning for SUI due to ISD, between May 2002 and March 2013 (mean follow-up 83.8 months, range 30–160, median follow-up 85.4 months). The characteristics of the patients are detailed in Table I.

All patients were affected by SUI due to ISD diagnosed with the following findings:

1. History and physical examination with stress test (cough provocation) showed severe SUI (more than four pads/day) for at least 1 year with no urgency or urethral hypermobility.
2. Translabial ultrasonography confirmed the presence of a fixed urethra.

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*Correspondence to: Dr. Fabrizio Gallo, Department of Urology, San Paolo Hospital, Via Genova 30, 17100 Savona, Italy. E-mail: fabriziogallo.sv@gmail.com
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TABLE I. Patient Characteristics Before the Remeex Procedure

Patient preoperative characteristics	Value
Number	50
Age (mean years ± range)	67.8 (28–81)
BMI (mean Kg/m^2 ± range)	23.8 (23–29)
Parity (mean ± range)	1.9 (0–4)
Postmenopausal (number of patients -%-)	49/50 (98%)
Associated grade 1-2-prolapse (number of patients -%-)	8/50 (16%)
Previous anti-incontinence surgery (number of patients -%-)	
Prolapse repair	9/50
Tension free suburethral sling positioning	5/50
Burch colposuspension	2/50
Bulking agents injection	3/50
Total	19/50 (38%)
Previous gynaecological surgery (hysterectomy) (number of patients -%-)	11/50 (22%)
Detrusor overactivity (number of patients -%-)	0/50 (0%)
Pad weight (mean ± range) (g)	121.4 ± 42.8
MUCP (mean ± range) (cmH_2O)	15.1 ± 2.3
ALPP (mean ± range) (cmH_2O)	43.5 ± 12.1
Total QoL questionnaire score (mean ± range)	28.3 ± 7.9

BMI, body mass index; MUCP, maximal urethral closure pressure; ALPP, abdominal leak point pressure; and QoL, quality of life.

3. Cystoscopy showed a wide open bladder neck at rest and a "lead pipe" urethra.
4. Urodynamic measurements reported abdominal leak point pressure values ≤ 60 cm H_2O and no instances of detrusor overactivity. Urethral pressure profilometry showed maximal urethral closure pressure values ≤ 20 cm H_2O.[14–15]

Patients also underwent a 1 hr pad test, in accordance with the International Continence Society's guidelines, and filled in Wagner's quality of life (QoL) questionnaire with the help of an unmasked health care provider; the physician and questioner had no knowledge of each other. It was a specific incontinence QoL questionnaire which contained 22 items, each with a five-point Likert-type scale (from 1 to 5), yielding a total score ranging between 22 and 110.[16–18]

Before surgery, all the patients signed a specific informed consent form.

The composition of the Remeex device (Regulation Mechanical External; Neomedic International) has already been reported in literature.[11] The surgical procedure has also been described previously.[13]

Sling tension readjustment was performed under local anesthesia in case of recurrent SUI with no urgency.

In the event of associated pelvic organ prolapse, the sling positioning was combined with prolapse repair using the vaginal approach.

All the procedures have been performed by the same experienced surgeon in anti-incontinence procedure (C.G.).

The postoperative follow-up included an initial visit 7 days after surgery. Further visits were scheduled at 1, 6, and 12 months, then yearly. During the visits, patients underwent history, physical examination with a stress test, a 1 hr pad test and abdominal ultrasonography for the evaluation of post void residual urine as well as filling in the self assessment QoL questionnaire. Urodynamic examination was only repeated in uncured patients. Complications were defined and graded according to the Clavien–Dindo classification.[19] We considered complication as any deviation from the ideal postoperative course that was not inherent in the procedure and did not comprise a failure to cure. The complications were assessed by the medical doctor during the follow-up visits.[19]

Following 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 was collected from each group of patients.

Statistical Analysis

Mean values concerning pad weight and questionnaire score data before and after surgery were compared using the paired Student's t-test. The Chi-squared test was used to compare the clinical outcomes between the different groups of patients. A P-value < 0.05 was considered significant.

RESULTS

As reported in the Table I, before surgery all 50 patients reported severe incontinence (mean pad weight: 121.4 ± 42.8 g). Among this group, 30 patients (60%) had experienced previous anti-incontinence or gynaecological procedures while 8 patients (16%) reported an associated grade 1–2 pelvic organ prolapse which needed a combined prolapse repair using the vaginal approach.[20]

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

At 7-years mean follow-up, 45 patients (90%) were completely cured, three (6%) improved, and two (4%) failed. With regard to the total mean pad weight, it decreased to 6.3 ± 24.2 with a significant mean improvement of 91.1%. In particular, in cured and improved patients it decreased significantly to 0.5 ± 0.4 g and 24.2 ± 13.6 g, corresponding to an improvement of 99.3% and 78.2%, respectively. Concerning the mean total score of the QoL questionnaire, it increased significantly up to 87.1 ± 5.9 with a mean improvement of 76.9% ($P < 0.05$). In particular, in cured and improved patients it increased significantly up to 104.1 ± 4.6 and 91.1 ± 4.7, corresponding to an improvement of 98.9% and 74.0%, respectively which regarded all the aspects assessed by the questionnaire including physical and mental health, psychosocial impact and intimate relationships.

Significant variations in mean pad weight and QoL score were not recorded in failed patients.

TABLE II. Outcomes of the Remeex Procedure Regarding Physical Examination, Pad Test, and Quality of Life (QoL) Score After 83.8 Months Mean Follow-Up

Outcomes	Number of patients (%)	Mean pad weight ± S.D. (g) (% improvement [P-value])	Mean QoL score ± S.D (% improvement [P-value])
Cure	45 (90.0)	0.5 ± 0.4 (99.3% [$P < 0.05$])	104.1 ± 4.6 (98.9% [$P < 0.05$])
Improvement	3 (6.0)	24.2 ± 13.6 (78.2% [$P < 0.05$])	91.1 ± 4.7 (74.0% [$P < 0.05$])
Failure	2 (4.0)	119.5 ± 28.9 (0.04.% [n.s.])	25.3 ± 1.3 (2.0% [n.s.])
Total	50 (100)	6.3 ± 24.2 (91.1% [$P < 0.05$])	87.1 ± 5.9 (76.9% [$P < 0.05$])

The percentages of improvement of the pad weight and the QoL score are reported compared to the respective preoperative values.

Sling tension readjustment was needed under local anesthesia, 1 month after surgery, in three patients (6%). In particular, a single readjustment produced a new complete recovery of continence in two patients while a second readjustment was needed in the remaining patient. Despite the repeated procedure, this patient did not achieve complete continence (1 pad/daily) and refused to undergo any other treatment. A readjustment was refused by the two other improved patients (4%) due to their satisfaction in the improvement of continence. The two failed patients (4%) also refused all of the other treatments we proposed.

As reported in Figure 1, the patients with incontinence (failed or improved) were assessed during the first 6 months after surgery. The incontinence-free survival curve showed that 90% of patients remain continent during the follow-up.

Regarding the complications, they occurred in 12 cured patients (24%), as reported in Table III. Grade II complications were due to bacterial cystitis, which required antibiotic therapy in three patients (6%), and mild to moderate de novo urgency, which were treated successfully with anticholinergic drugs in four patients (8%). Grade IIIa complications were due to persistent urinary retention, severe de novo urgency and seroma formation. The persistent urinary retention, which occurred in three patients (6%), was successfully treated in two cases, 3 days after surgery, by descending the urethra with a Hegar dilator. The remaining patient who continued to report partial urinary retention needed to perform self-catheterization. A severe de novo urgency, which was resistant to the anticholinergic drugs, only occurred in one patient (2%) who required section of the sutures without removing the sling. After this procedure, the patient reported a remarkable improvement of the urgency and maintained complete continence. Seroma formation, which developed in another patient (2%), was treated with surgical drainage approximately 15 days after surgery. The sling tension was decreased during the surgical revision and then increased 1 month later, restoring complete continence. No intraoperative complications were assessed. No cases of grade I, IIIb, IV, and V complications were reported. No association was assessed between complications and combined prolapse correction during the Remeex procedure.

TABLE III. Description of Complications and Types of Treatment in Accordance With the Clavien–Dindo Classification

Grade	Complication (number of patients) (%)	Treatment (number of patients) (%)
I	None	None
II	Bacterial cystitis (3) (6%)	Antibiotic therapy (3) (6%)
	De novo urgency (4) (8%)	Anticholinergic drugs (4) (8%)
IIIa	Persistent urinary retention (3) (6%)	Hegar dilator descending (2) (4%)
		Self-catheterization (1) (2%)
	Severe de novo urgency (1) (2%)	Suture section (1) (2%)
	Seroma (1) (2%)	Drainage (1) (2%)
IIIb	None	None
IV–V	None	None

DISCUSSION

The aim of this paper was to evaluate the role of the suburethral tension adjustable sling procedure for the treatment of urinary incontinence due to ISD in a larger series of patients with a longer follow-up than previously reported in literature. In fact, although the latest papers regarding the Remeex technique, including our experience, have reported cure rates higher than 80%, the small number of patients studied (mainly between 20 and 30 cases) or the rather limited follow-up periods (not more than 5 years) tended to downsize the importance of these outcomes.[21–23] A larger series of patients was only published by Errando et al., who showed a cure rate of 86% in 70 patients. However, the reported follow-up was less than 3 years.[24] In this setting, a longer-term evaluation on a similar number of patients remains important in order to confirm the efficacy and verify the durability of the Remeex procedure with respect to different treatments for SUI due to ISD.

Our results, which were assessed in 50 patients with 7 years of mean follow-up, showed cure and overall improvement rates of 90% and 96%, respectively. These data are consistent with the better 5-year outcomes reported to date using this device in smaller number of patients.[13,22] In terms of quality of life, these clinical improvements were also supported by similar satisfaction rates, due to the patient's well-being for the regained health condition. These results are based on the technical characteristics of the Remeex device which allowed both an early and a late adjustment of the sling tension favoring a more effective recovery of continence at any time. In fact, the possibility of reconnecting the manipulator to the varitensor whenever necessary during the follow-up period also allowed re-adjustment of the sling tension in cases of recurrent incontinence. In our experience, the adjustability of the system allowed continence to be regained in 4% of patients who would have required additional surgery if they had been treated with non-adjustable techniques.

Interestingly, some improved and potentially curable patients refused a sling re-adjustment. This aspect, which has already been reported in literature, is due to the patients' satisfaction with the new degree of incontinence (1 pad) with respect to the severe preoperative condition. In fact, although the need of pad still impacted negatively on the patients' QoL, producing a slightly lower improvement rate of the mean QoL score than the mean pad weight, a significant improvement rate of the mean questionnaire score was also confirmed among the improved patients.[12,24]

Regarding the durability of the Remeex system, the incontinence-free survival curve showed that, after sling positioning and tension readjustments, all the cured patients remained continent during all the follow-up. However, these results, which did not show a deterioration of the continence status representing a remarkable finding given the natural history of incontinence, will have to be confirmed in a longer term follow-up.

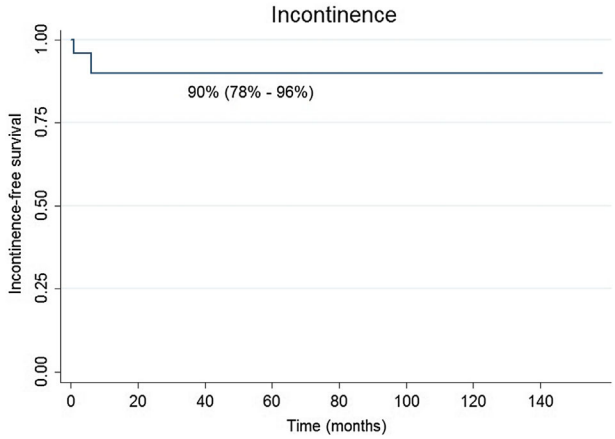

Fig. 1. Incontinence-free survival rate during the follow-up.

Concerning morbidity, our outcomes showed an acceptable complication rate (24%), mainly due to mild to moderate de novo urgency (8%), and bacterial cystitis (6%) which were easily resolved with an oral therapy. The development of these complications has been widely demonstrated following anti-incontinence surgery and the rate observed in our series was similar to those reported with other sling procedures.[25] On the other side, some grade IIIa complications (persistent urinary retention, severe de novo urgency, and seroma), which occurred in 10% of patients of our series, could be related more specifically to the Remeex procedure. However, the ability to loosen the sling tension was similarly an effective option for the treatment of the persistent urinary retention. Furthermore, the severe de novo urgency and sling infection, which occurred in only 4% of patients, were successfully managed with a surgical revision. No complications developed after the re-adjustment procedures.

The present study has a main limitation due to its nonblinded and retrospective design. Furthermore, our data derived from the experience of a single skill surgeon and did not provide additional informations regarding the reproducibility of this technique. These aspect highlights the need for randomized prospective multicenter studies comparing the Remeex procedure with the other anti-incontinence techniques.

CONCLUSIONS

Our results show the efficacy of the Remeex procedure in the treatment of SUI due to ISD. The cure rate and the low morbidity confirm the effective role of this device in order to reach an adequate sling tension as well as regaining the patient's continence and minimizing the risk of complications. These outcomes tended to be confirmed in the mid- to long-term follow-up which would highlight the durability of the Remeex technique.

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