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A re-adjustable sling for female recurrent stress incontinence and intrinsic sphincteric deficiency: Long-term results in 205 patients using the Remeex sling system

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Aims: To evaluate the outcomes and complications at long-term follow-up after a Remeex re-adjustable sling for recurrent stress urinary incontinence (rSUI) and intrinsic sphincteric deficiency (ISD) in women.

Methods: Two hundred thirty women with SUI were evaluated after undergoing a re-adjustable sling operation. Twenty-five patients were lost to follow-up, 205 were classified by Q-tip, urodynamic, and clinical criteria into ISD (109) and rSUI (96). Outcome measures included number of pads, 1 h pad-test, urodynamics and subjective satisfaction index with the procedure.

Results: After a mean follow-up of 89 months (26-159), 165 patients were cured of SUI (71.7% in the intention to treat analysis (itt), 80.5% in per protocol analysis (pp)). Forty patients remained incontinent (17.4% in itt, 19.5 in pp). Thirty-one patients (15.1%) had detrusor overactivity (DH) incontinence, 21 (10.2%) with de-novo DH and 10 with previous urodynamic mixed incontinence. Eighty-eight patients required re-adjustment of the sling during the follow-up. The tension was increased in 82 cases due to recurrence of SUI and reduced in six due to outlet obstruction. The overall complications rate was 28.8%, (3.4% clavien III).

Conclusions: The Remeex re-adjustable sling provides a good cure rate for rSUI and ISD at long-term follow-up. The complications rate is acceptable since most complications are clavien II. The ability to re-adjust the sling tension during the follow-up allowed us to achieve cure for recurrence after the initial procedure, and to relieve obstruction in every case attempted.

KEYWORDS
disease management, humans, stress/surgery, suburethral slings, urinary incontinence, urodynamics/physiology

1 | INTRODUCTION

The approach to female stress urinary incontinence (SUI) has changed since the advent of tension-free mid-urethral slings (MUS), being the most frequently used surgical intervention in Europe.[1] EAU guidelines recommend offering the MUS to

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women with uncomplicated SUI as the preferred surgical intervention. However, there are no clear recommendations for the management of recurrent SUI (rSUI) or Intrinsic Sphincteric Deficiency (ISD).[1–3]

Several studies have shown the usefulness of the Remeex re-adjustable sling in rSUI[4–8] and ISD[4–9] in small number of women at short follow-up. The initial outcome of this procedure had been previously reported by our group showing good results with a low complication rate.[8] The data presented here represents a larger series with longer follow-up (89 months).

2 | MATERIALS AND METHODS

The results of a single center experience were retrospectively reviewed in order to determine the outcomes and complications of the Remeex re-adjustable sling in the treatment of women with rSUI or ISD. All operations were performed by three surgeons (CE,CG,PA) with no significant difference in results between them. The procedure was included in our management protocol for SUI since 2000, being presently our standard clinical practice in these indications. The preliminary results of the first 125 women had been already published.[8]

Data collection and database use was approved by our institutional review board. All eligible patients complained of SUI and provided an informed consent. Of the 230 women included, 25 were lost to follow-up (10,8%). The results of the remaining 205 women were analysed after a mean follow-up of 89 months (26-159). The baseline patient characteristics are shown in Table 1. The only difference between the indications subgroups is in the rate of previous sui surgeries. In the rSUI subgroup by definition all patients had a previous intervention, with a significantly higher number of tension-free procedures than in the ISD subgroup. The preoperative workup consisted of a standard urogynecological history and physical examination including Q-tip test. All patients underwent full urodynamic evaluation consisting of uroflowmetry, post-void residual measurement, cystometry, pressure/flow study (P/F), and urethral pressure profile.

Inclusion criteria were the presence of SUI on examination or urodynamics. The patients were classified into two groups: rSUI and ISD. All 107 patients (46.5%) classified as rSUI had a hypermobile urethra and at least one previous surgery due to SUI (pubovaginal sling, TVT, TOT). The 123 patients (53.5%) in the ISD group met all of the following criteria: leak at rest or minimal stress (walking), Q-tip test of less than 20° and maximal urethral closure pressure of less than 20 cm of H2O.[10] Most patients in the ISD group (65%) had recurrent SUI after an average of three previous surgeries. This cohort was nevertheless classified as ISD if the criteria mentioned above were fulfilled considering that ISD has a worse prognosis than rSUI.

Exclusion criteria were the presence of pelvic organ prolapse, history of neurogenic disorders, radical pelvic surgery, radiotherapy, bladder outlet obstruction or pure detrusor overactivity incontinence without SUI. Ten patients (4.3%) had detrusor overactivity incontinence plus SUI (urodynamic mixed incontinence).

The Remeex re-adjustable device and the surgical procedure had been previously described.[8] Briefly, the Remeex device consists of a $30 \times 15\,mm^2$ polypropylene mesh, with two pre-attached non-absorbable sutures (Figure 1). It is placed under the mid-urethra through a vaginal incision. A second transverse incision is made in the suprapubic region. The sutures are passed to the suprapubic field with needles, and then fixed to the Varitensor with a

TABLE 1 Baseline patient characteristics

	Total $N = 205$		rSUI $N = 96$		ISD $N = 109$		p*t Student, +Chi-square
Age (mean,sd)	65.3	10	63.2	10	66	8	*0.09
BMI (mean,sd)	29	5	29	5	30	6	*0.6
Parity (mean,sd)	2.2	1	2.2	0.9	2.1	1	*0.9
C-section (mean,sd)	0.1	0.4	0.2	0.5	0.07	0.3	*0.1
Diabetes Mellitus (*N*,%)	31	15.1	12	12.5	19	17.4	+0.3
Abdominal Hysterectomy (*N*,%)	36	17.5	16	16.6	20	18.3	+0.8
Vaginal Hysterectomy (*N*,%)	26	12.6	12	12.5	14	12.8	+0.5
Previous SUI surgery (*N*,%)	167	81.4	96	100	71	65.1	+< 0.001
Retropubic (Burch/MMK) (*N*,%)	73	35.6	40	41.6	33	30.3	+0.11
TensionFree (tvt/tot) (*N*,%)	69	33.7	43	44.8	26	23.9	+< 0.001
PVS (*N*,%)	25	12.2	13	13.5	12	11	+0.67

rSUI, recurrent stress urinary incontinence; ISD, instrinsic sphincteric deficiency; Sd, standard deviation. MMK, Marshall Marchetti Kranz; tvt, tension-free vaginal tape; tot, transobturator sling; PVS, Pubovaginal sling.

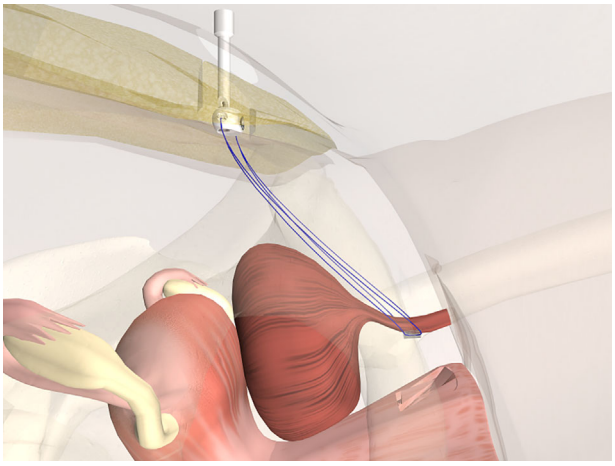

FIGURE 1 Detail of the Remeex sling system

screw to a rotating reel. The reel can be turned by using a stick (called Manipulator) that temporarily protrudes through the skin, allowing post-operative sling tension adjustment (Figure 2). After the adjustment, the Manipulator is withdrawn, leaving the Varitensor in the subcutaneous tissue over the rectus fascia. The re-adjustment procedure consists of a subsequent access to the Varitensor achieved via a minimal incision under local anaesthesia, locking a sterile Manipulator in place to re-adjust the tension up or down when necessary during follow-up.

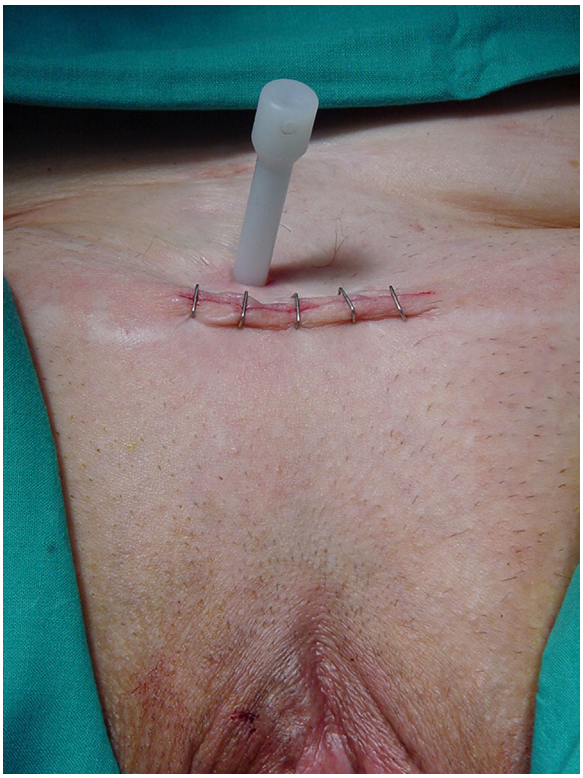

FIGURE 2 Appearance at the end of surgery, with the manipulator appearing through the skin

The operation was performed under spinal anaesthesia in most cases (82%). The Foley's catheter was removed one day postoperatively after filling the bladder with 300 mL of saline. Immediately after, the sling tension was adjusted by asking the patient to cough in the standing position. If leakage was evident, the tension was increased by rotating the Manipulator clockwise until continence was achieved. Regardless of being continent with coughing, a 1-h pad-test was subsequently performed and the sling tension was increased if leakage was evident. The voiding diary, uroflowmetry and post-void residual were assessed. A pressure/flow study was performed when the peak urine flow was lower than 15 mL/s and the post-void residual higher than 50% of voided volume. According to Chassagne,[11] obstruction was defined if Qmax was <15 mL/s and detrusor pressure at maximum flow was >20 cm H_2O. In these cases, the sling tension was reduced by rotating the Manipulator counter-clockwise and facilitating the descent of the urethra by placing a Hegar's dilator inside the urethra and tilting it downward. This made the patient incontinent again. Then the tension was increased up to the continence state as in the initial procedure. Once the correct tension was achieved, the Manipulator was detached from the Varitensor and the patient discharged. In patients with residual volumes >50% without obstruction, intermittent self-catheterisation was prescribed.

Follow-up evaluation was carried out at 8 weeks, 6 to 9 months, and annually thereafter. At follow-up, all patients had urodynamic evaluation within 12 and 24 months after the surgery and completed the satisfaction questionnaire ("How satisfied are you with the outcome of your treatment?" in an ordinal scale from zero to 10). The criteria used for therapeutic success were continence during the cough test, pad test, and urodynamics as well as no complaint of wet pads. Continuous variables were assessed with the mean, standard deviation, median, and range and analyzed with the Student *t*-test. Categorical variables were assessed with number (n) and proportion (%) of patients per category, and analyzed with the chi-squared, Kruskall-Wallis or Fisher exact tests. Methods, definitions and units conformed to the standards of the International Continence Society except where specifically noted.[12]

3 | RESULTS

After a mean post-operative follow-up of 89 months (26-159), 165 women (71.7% itt, 80.5% pp) are continent with stress. Forty patients (17.4% itt, 19.5 pp) have some degree of SUI, wetting >1 pads per day (Table 2). Eighteen of these patients refused to be have further re-adjustment concerned about the theoretical possibility of infection of a prosthetic material that was

TABLE 2 Stress urinary incontinence (SUI) results

	rSUI ($n = 107$)	ISD ($n = 123$)	Total ($n = 230$)
Intention to treat analysis. $N = 230$. Lost of follow-up: 25 patients			
No SUI	81 (75.7%)	84 (68.2%)	165 (71.7%)
SUI	15 (14%)	25 (20.3%)	40 (17.4%)
	chi-square test, $P = 0.8$ (ns)		
Lost follow-up	11 (10.2)	14 (11.4)	25 (10.9%)
	rSUI ($n = 96$)	**ISD ($n = 109$)**	**Total ($n = 205$)**
Per protocol analysis: $N = 205$ patients			
No SUI	81 (84.4%)	84 (77.1%)	165 (80.5%)
SUI	15 (15.6%)	25 (22.9%)	40 (19.5%)
	chi-square test, $P = 0.8$ (ns)		

rSUI: recurrent SUI. ISD, intrinsic sphincteric deficiency.

producing some benefit, because they felt improved enough. Thirteen patients are on the waiting list for re-adjustment. Nine are failures after several re-adjustments. Thirty-one patients (15.1%) have urge incontinence, with no further SUI. All those patients were evaluated with urodynamics showing de-novo DH incontinence in 21 cases (10.2%) whereas in 10 patients DH was already present on preoperative cystometry. Twenty patients were managed by anticholinergic therapy, and 11 needed a botulinum toxin injection, however 19 of them still have some degree of DH incontinence.

Eighty-two cases (40%) had recurrence of incontinence during follow-up. After ruling out DH by urodynamic evaluation, 65 patients (31.7%) underwent re-adjustment of the sling after an average of 34 months (3-94). Thirteen (6.3%), 3 (1.5%) and 1 (0.5%) patients required 2, 3, and 4 further re-adjustments to achieve continence. The details of number and time of all re-adjustments during the follow-up period in rSUI and ISD groups are given in Table 3. The re-adjustment procedure was performed under local anaesthesia. During follow-up, six patients (2.9%) underwent re-adjustment to reduce the sling tension due to outlet obstruction after a mean period of 32 months (Table 3).

Three patients (1.5%) had difficulty voiding due to detrusor underactivity, defined according to the definition of the ICS (13). Therefore, the tension was not changed in this group and the patients were instructed to do self-catheterisation that lasted for an average of 3 months (1-3).

The cure rate of SUI (Table 2) and the rate of sling re-adjustment during follow-up (Table 3) were not statistically different between rSUI and ISD groups.

The amount of pads used reduced significantly from 3.6 to 0.7 ($P < 0.001$). The overall average satisfaction index was 8.5/10, being significantly better in patients with cure (8.5) than in those with failures (5.8) (chi^2, $P < 0.000$). The mean satisfaction index was however similar in the rSUI (8.4) and ISD (8) groups. Patients with DH incontinence showed less satisfaction (7.3) than non-DH incontinence patients (8.3) ($P = 0.03$).

Complications following Clavien classification are described in Table 4. De novo DH incontinence occurred in 21 women (10.2%). Two cases had urethral erosion that required mesh removal and urethroplasty. Two cases had vaginal erosion with extraction of the prosthesis due to infection in one case. The other case was managed by partial resection of the mesh and vaginal closure. Three patients had infection in the hypogastric field resulting in total prosthesis removal.

4 | DISCUSSION

The results of MUS in rSUI or ISD are not as promising as in uncomplicated cases. In fact, Cochrane and Figo reviews did not find any data to recommend a therapeutic strategy for rSUI[3,13] and the EAU guidelines provide recommendations based on low-grade evidence in complicated SUI.[1] However, two recent metaanalysis showed a similar continence rate of around 75% after retropubic or transobturator MUS[14,15] in rSUI. A recent metaanalyses of MUS in ISD[16] based on only eight trials showed a 12% higher cure rate in women undergoing a retropubic procedure. The reported cure rate after pubovaginal sling in ISD ranges from 73% to 92%[17] taking into account that the heterogeneity of diagnostic criteria used for ISD makes comparison difficult.[13] The main reason for poor results, however, has been attributed to excessive tension on the sling, obstruction, urgency and DH where urgency incontinence was the explanation for incontinence in up to 76% of cases after surgery.[17] This observation highlights the importance of avoiding too much tension on the sling.

The ability of Remeex re-adjustable sling to treat rSUI and ISD has been previously reported in small series with different follow-up periods.[4–9] Park had a 90% cure in rSUI after MUS in 40 patients, at 2.3 years of follow-up[6] and Barrington in a prospective study of 19 patients had a 53% of cure and a 35% of improvement at 17 months using subjective

TABLE 3 Details of number and time to Re-adjustment

Average time from surgery to re-adjustment (m, in brackets)	Total $N = 205$		rSUI $N = 96$		ISD $N = 109$		P
1 Re-adjustment (34 m) (*N*,%)	71	(34.6)	32	(33.3)	39	(35.8)	$^{+}P = 0{,}8$
Increase tensión (*N*,%)	65	(31.7)	30	(31.3)	35	(32.1)	$^{+}P = 0{,}9$
Decrease tensión (*N*,%)	6	(2.9)	2	(2)	4	(3.7)	$^{+}P = 0{,}5$
2 Re-adjustments (60 m) (*N*,%)	13	(6.3)	6	(6.2)	7	(6.4)	$^{++}P = 1$
3 Re-adjustments (99 m) (*N*,%)	3	(1,5)	3	(3.1)	0		
4 Re-adjustments (106 m) *N*,%)	1						
Total Re-adjustments (*N*,%)	88	(42.9)	40	(41.6)	48	(44)	$^{+}P = 0{,}5$
Nr. Re-adjustments/patient (mean,sd)	0,4	(0,7)	0,4	(0,8)	0,5	(0,7)	$^{*}P = 0{,}6$

rSUI: recurrent SUI. ISD, intrinsic sphincteric deficiency; sd, standard deviation; m = months. +Chi-square, *t-Student, ++Kruskal-Wallis.

criteria.[5] Giberti published a 90% cure rate in ISD at 7 years in 50 patients.[9] Although direct comparison of cure rates between various studies is difficult because of the difference in measuring postoperative outcomes, the similar results obtained by different groups support the reproducibility of the Remeex procedure. The initial results of our series showed a cure rate of an overall 87%.[8] When a bigger number of cases are analyzed at extended follow-up period (mean 7.4 years, and 57% of patients with a follow-up longer than 60 months) the continence rate fell to a more realistic overall rate of 71.7% itt (80.5% in pp analysis), without a significant difference between ISD (68.2% itt, 77.1% pp) and rSUI (75.7% itt, 84.4% pp). The re-adjustability of the sling tension during follow-up was fully utilized as 42.9% of our patients took advantage of this option and most patients (34.6%) required only one re-adjustment. Other adjustable slings like Ajust® system (Bard Inc., NJ) only provide this adjustment facility at surgery, but not during the postoperative period.[18]

The relatively high number of re-adjustment procedures in our study compared to other studies of re-adjustable sling[7] is probably due to our conservative protocol of adjustment. In order to avoid obstruction, we usually perform minimal tension on the sling to achieve continence during coughing and pad testing. We hypothesize that when patients return to their normal daily activity, after 6 weeks of resting, they do much more effort that during pad testing. Some degree of incontinence (hidden during cough and pad-test) can therefore appear later thus requiring further re-adjustments during follow-up.

Outlet obstruction and de-novo DH are a source of great concern in the surgical treatment of SUI. The re-adjustability of Remeex provides the opportunity to decrease the sling tension when obstruction is suspected which was the cause in our series of new onset of mixed voiding and storage symptoms. In cases of fixed urethra, *the minimal tension to get continence* can be very close to obstruction. Therefore, it is our practice to minimize the sling tension during the adjustment in order to avoid obstruction. In agreement, only six patients needed re-adjustment to reduce the tension of the sling during follow-up. These patients had a low peak flow on

TABLE 4 Complications

Complication	Clavien	*N*	%
De novo DH dry	II	28	13,7
De novo DH incontinence	II	21	10,2
Urinary retention (Self Catheterisation)	II	3	1,5
Total Clavien II		**52**	**25,4**
Infection and prosthesis withdrawal	III	3	1,5
Urethral erosion: withdrawal and urethroplasty	III	2	1
Vaginal erosion:	III	2	1
Partial resection of the mesh		1	
Infection and prosthesis withdrawal		1	
Total Clavien III		**7**	**3,4**
Total Complications		59	28,8

DH: detrusor hyperactivity.

uroflowmetry after surgery although the initial diagnosis was impaired contractility because of very poor or no contraction during the P/F study that did not fulfil obstruction criteria. The patients then developed proper contractility after some time (up to 9 months) that allowed observing the high pressure/low flow pattern and the diagnosis of obstruction. The down regulation of the sling tension consisted of turning the manipulator gently counter clockwise (average of 20 turns) and tilting down the urethra with a Hegar's dilator in situ. This manoeuvre caused reappearance of SUI and proceeding to re-adjust from incontinence to continence again by increasing the tension slowly as in the initial procedure. The possibility to reduce the tension even at the long term could be explained by the very circumscribed fibrosis produced by the small size of the mesh sling (3×2 cm) that it is localized only below the mid urethra with minimal fibrosis at the lateral tunnels where there are only two monofilament non-knitted traction threads.

The complications rate increased from 12% in our initial paper[8] to 28.8% at longer follow-up (Table 4). This consisted mainly (25.4%) of clavien II complications that included DH and self-catheterisation. Four cases of vaginal or urethral erosions and three cases of infection required further surgery to remove the prosthesis and perform urethroplasty, which produced a 3.4% clavien III complications rate. However, the overall satisfaction index observed (8.5/10) suggests that the patients do not perceive the complications too negatively.

A limitation of the present study is lack of comparison with a randomized control group. Further studies are definitely needed to determine the best surgical treatment for rSUI and ISD since unfortunately as yet, there are no clear data regarding which surgical technique should be the gold standard.[19]

5 | CONCLUSIONS

Re-adjustable sling system provides a good cure rate with a low complication rate, for both ISD and rSUI subgroup of women with SUI. The ability to increase or decrease the sling tension allows treating both incontinence and obstruction in every case when needed. The design limitations of the present non-controlled study highlight the importance of conducting further randomised trials comparing the Remeex system with other midurethral sling techniques. This study, however, reports good outcome of a promising new procedure that has been performed in a large number of women with long term follow-up.

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CONFLICTS OF INTEREST

Dr. Errando-Smet reports personal fees from Boston Scientific and Neomedic International, outside the submitted work. Dr. Gutierrez, Dr. Arañó and Dr. Villavicencio has nothing to disclose.

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