Neurourology and Urodynamics

A Re-Adjustable Sling for Female Recurrent Stress Incontinence and Sphincteric Deficiency: Outcomes and Complications in 125 Patients Using the Remeex Sling System

Carlos Errando,[1]* Fernando Rodriguez-Escovar,[1] Cristina Gutierrez,[1] Carlos Baez,[1] Pedro Araño,[1] and Humberto Villavicencio[1]

[1]*Department of Female and Functional Urology, Fundacio Puigvert, Barcelona, Spain*

Aims: To evaluate the outcomes, complications, and quality of life of patients after a Remeex re-adjustable sling for recurrent stress urinary incontinence (SUI) and intrinsic sphincteric deficiency (ISD) indications. **Methods:** One hundred twenty-five patients with SUI were prospectively evaluated following a re-adjustable sling in a single tertiary academic Center. Patients were classified by Q-tip, urodynamic and clinical criteria into ISD (70) and recurrent SUI (55). All patients underwent a re-adjustable sling placement. Outcome measures included pad-test, urodynamics, and the King's Health Questionnaire. **Results:** After a mean follow-up of 38 months (26–72), 109 patients (87%) are cured of SUI based on pad-test, clinical, and urodynamic criteria. Sixteen patients (13%) remain incontinent. Nine of those (7%) are satisfied to the point that they decline re-adjustment of the sling, and seven (6%) are on the waiting list for re-adjustment. Nineteen patients show urge incontinence (9 with previous urodynamic mixed incontinence, 10 (8%) with de novo detrusor overactivity). Twenty-one patients benefited from a re-adjustment of the sling during the follow-up. The tension was increased in 17 cases (continent at discharge) due to recurrence of SUI, and reduced in 4 due to obstruction. The Varitensor was removed in 1 case due to infection. No other complications were seen. **Conclusions:** The Remeex re-adjustable sling system provides a good cure rate for recurrent SUI and ISD with a low complication rate. The ability to increase or decrease sling tension allowed us to achieve cure in patients who were not initially dry, and to relieve obstruction in every case attempted. *Neurourol. Urodynam.* © 2010 Wiley-Liss, Inc.

Key words: intrinsic sphincteric deficiency; stress incontinence; surgical treatment

INTRODUCTION

The approach to stress urinary incontinence (SUI) has changed since the advent of tension free slings, which provide good long-term success rates in uncomplicated cases.[1–3] However, many series report failures as well as bladder outlet obstruction, which often correlate to not enough or too much tension in the sling system.[4,5] Consequently, a new concept providing the minimal tension to render the patient continent is arising, replacing the literal sense of "tension-free," or without any tension at all.[3] Specifically directed to manage this issue, the Remeex re-adjustable sling allows the regulation of the sling tension not only at the moment of placement but also at any time during follow-up, as suggested by previous reports at shorter follow-up.[5–7] The objective of this study is to evaluate prospectively the outcomes and complications of a technique already included in our protocol of treatment of recurrence after previous anti-incontinence surgeries, such as Burch or tension-free slings, or cases of intrinsic sphincter deficiency (ISD).

MATERIALS AND METHODS

Between October 2000 and November 2006 we conducted a prospective study in order to determine the outcomes with the Remeex re-adjustable sling in the treatment of SUI in the aforementioned complicated patients. In this single institution study, 130 patients with an average age of 63 years (40–84) were included. Five were lost of follow-up. All of them had stress incontinence on exam or urodynamics. The preoperative workup consisted of a standard urogynecological history, inspection for pelvic floor disease (using the modified POP-Q grading system), Q-tip test, and completion of the King's Health Questionnaire (KHQ). All patients underwent a full urodynamic evaluation consisting of uroflowmetry, post-void residual volume measurement, cystometry, pressure/flow voiding test. Nine patients had detrusor overactivity incontinence plus stress incontinence. According to the recommendations of the European Association of Urology guidelines in the specialized management of SUI, the urethral function was evaluated with urethral pressure profile.[8] Patients presenting any pelvic organ prolapse were not included in this protocol. The patients enrolled were classified into two groups; recurrence and ISD. The 55 patients (44%) classified in the recurrent SUI group had a hypermobile urethra and at least one previous tension-free vaginal tape or trans-obturator vaginal tape surgery (43 cases) or retropubic urethropexy (12 cases). The 70 patients (55%) classified in the ISD group met all of the following criteria: leakage at rest or minimal stress (walking), Q-tip angle by straining of less than 20° and maximal urethral closure pressure (MUCP) of less than 20 cm of H_2O.[9] Most of the patients in the ISD group (95%) were as well recurrences after an average of three previous surgeries, nevertheless they were

Conflicts of interest: none.
Linda Brubaker led the review process.
*Correspondence to: Dr. Errando Carlos, Cartagena 340-350, Barcelona 08025, Spain. E-mail: 26466ces@comb.cat
Received 22 September 2009; Accepted 25 November 2009
Published online in Wiley InterScience
(www.interscience.wiley.com)
DOI 10.1002/nau.20879

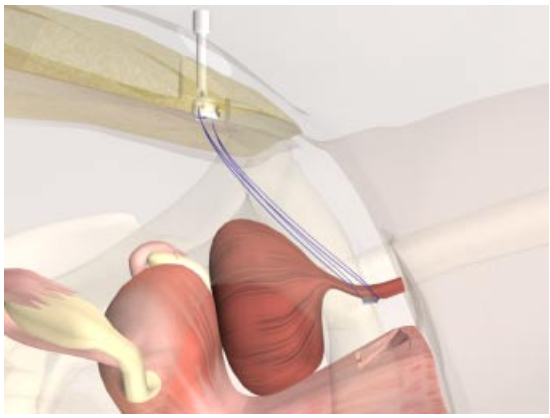

Fig. 1. Detail of the Remeex device placement.

classified in the ISD group if accomplished the criteria mentioned above, because we considered ISD a worse prognosis group than recurrence. Preoperative post-void residuals were less than 100 ml in all patients.

The Remeex device consists of a $30 \times 15\ mm^2$ polypropylene mesh, with two preattached non-absorbable sutures (Fig. 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 screw to a rotating reel. The reel can be turned by using a stick ("Manipulator") that temporarily protrudes through the skin, allowing post-operative sling tension adjustment (Fig. 2). After the adjustment, the Manipulator is withdrawn, leaving the Varitensor in the subcutaneous tissue over the rectus fascia. Subsequent access to the Varitensor is achieved via a minimal incision under local anesthesia, locking a sterile Manipulator in place to re-adjust the tension up or down when necessary during follow-up.

The surgery was performed under spinal anesthesia in most cases. The Foley catheter was removed the day after the surgery after filling the bladder with 300 ml of saline. Immediately, the adjustment of sling tension was accomplished by asking the patient to cough in the standing position. If leakage was evident, the tension was increased by rotating the Manipulator clockwise, two turns each time, until continence was reached. Regardless of being continent with cough, a 1-hr pad-test is performed, again increasing sling tension if leakage was evident under stress. This was necessary in 40% of the patients continent with cough. Voiding diary and post-void residual was controlled, and a videourodynamic study was done when it was higher than 50% of voided volume. If there was obstruction, the sling tension was reduced by rotating the Manipulator counter clockwise. In addition, descent of the urethra is facilitated by placing a rigid catheter or Hegar dilator inside and tilting it downward. This leads the patient to incontinence again, increasing then the tension up to continence as in the initial procedure. The diagnosis of obstruction was confirmed by videourodynamic evaluation and according to the following criteria proposed by Nitti[11] fluoroscopic evidence of obstruction between bladder neck and distal urethra, maximum flow rate of less than 15 ml per second and a detrusor pressure at maximum flow of more than 20 cm of water. Some patients had trouble voiding due to detrusor underactivity, defined according to the definition of the ICS.[10] When there was detrusor underactivity the tension was not changed and the patient was instructed on self-catheterization. Once the correct tension was achieved the Manipulator was unlocked and detached from the Varitensor and the patient discharged.

Follow-up evaluation was carried out at 8 weeks, 6–9 months, and annually thereafter. At follow-up, all patients had an urodynamic evaluation within 6 and 9 months after the surgery and completed the KHQ and a satisfaction questionnaire ("How satisfied are you with the outcome of your treatment?" in a ordinal scale from 0 to 10). The criteria for therapeutic success were complete continence during the cough test, pad-test and urodynamics, and no necessity of pad usage. Other outcomes were classified as failures. Methods, definitions and units conform to the standards of the International Continence Society except where specifically noted.[10]

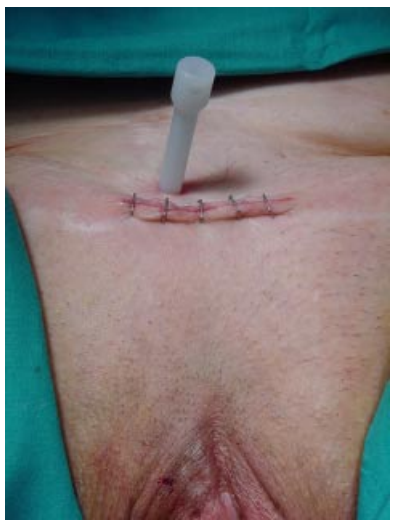

Fig. 2. Final appearance, with the manipulator appearing through the skin.

RESULTS

After a mean follow-up of 38 months (26–72) 109 patients (87.2%) are continent under stress (Table I). Of those, 92 (84%) were continent after the initial surgery, 17 (14%) benefited from a subsequent re-adjustment due to persistence of leakage, and 2 (2%) required a second re-adjustment to achieve continence (Table II). Sixteen patients (13%) presented some degree of SUI, using one or more pads per day. Nine of these patients refused to be further re-adjusted reporting enough improvement in their continence, whereas seven patients are on the waiting list for re-adjustment. Nineteen patients (15.2%) presented urge incontinence, although are cured of SUI. All those patients were evaluated with urodynamics

TABLE I. Results

	Recurrent SUI, n = 55	ISD, n = 70	Total, n = 125
Cured	49	60	109 (87%)
Failed			
Refuse re-adjustment	4	5	
Pending re-adjustment	2	5	
Total failed	6	10	16 (13%)

SUI, stress urinary incontinence; ISD, intrinsic sphincteric deficiency.

TABLE II. Re-Adjustments

	n	Time at re-adjustment (months), median (range)
One re-adjustment	17	9 (1–18)
Two re-adjustments	2	11 (9–13)

TABLE IV. Complications

	n	%
Infection and withdrawal	1	0.8
De novo detrusor overactivity	10	8
Overall	11	8.8

(Table III) showing in 10 patients (8%) de novo detrusor overactivity. Nine patients were diagnosed as mixed urodynamic incontinence in the preoperative workup, and even though they are cured of SUI and have persistent detrusor overactivity incontinence, they are not considered de novo cases.

Twenty-one patients (17%) underwent a long-term re-adjustment under local anesthesia at an average of 12 months after the surgery (1–18 months). The placement of the manipulator was done in the operating room to assure a sterile condition. The patients stayed 1 day performing the pad and cough tests and measuring residuals. Two of those patients were adjusted twice. In 17 cases the re-adjustment consisted of increasing the tension due to recurrence of SUI, adding an average of seven turns clockwise. A total of four patients (3.2%) with mixed filling and voiding symptoms were diagnosed as obstructed after the initial procedure. They were successfully re-adjusted by reducing the sling tension turning an average of 16 turns counter clockwise and descending the urethra with a Hegar dilator. This procedure was done after a mean period of 16 months because two patients with initial urodynamic findings consistent with poor detrusor contractility made the diagnosis of obstruction difficult.

Forty-nine out of 55 recurrent patients and 60 of the 70 patients with ISD are presently continent, representing 89% and 86% cure rates respectively. Eight patients (14%) of the recurrent group and 13 (19%) of the ISD group needed re-adjustment during the follow-up. The two patients re-adjusted twice had ISD and one is a failure.

Mean operative time was 55 min (SD 12). Hospital stay was 3 days (2–4). The prior mesh did not produce any problem intra-operatively since in most of the cases it was almost impossible to identify it during the surgery. Vaginal exams shown no urethral or vaginal erosion, defect healing or tape rejection. One patient presented a seroma in the subcutaneous tissue around the Varitensor that was drained three times with a syringe, obtaining sterile cultures. Finally, it became iatrogenically infected. The Varitensor was then removed, knotting the sutures together over the rectus fascia, leaving the sling in place and maintaining continence. This case plus the 10 cases of de novo detrusor overactivity means an overall complication rate of 8.8% (Table IV). Four patients (3.2%) did self-catheterizations after the surgery. Two patients required self-catheterization during less than 30 days after regaining normal balanced voiding. Other two patients with detrusor underactivity in the post-operative urodynamic evaluation, did self-catheterization during 16 months after regaining a normal contractility. At this point, they were diagnosed as obstructed and re-adjusted.

The preoperative mean KHQ score was 52 (SD 22) and changed to 21 (SD 18) after the surgery representing a change in the total score of −34 points as an average.

TABLE III. Urodynamic Results

	Before the surgery	After the surgery
Leakage during cistometry	125	16
Detrusor overactivity	9	19
Obstruction	0	4[a]

[a]These four patients were re-adjusted, and subsequent urodynamics ruled out obstruction.

DISCUSSION

Both midurethral tension-free slings provide a good success rate in uncomplicated cases.[1–3] However the results of tension-free slings in recurrent cases or ISD are not as promising. Different authors[3,12] present cure rates of 79–82% in recurrent cases. In patients who fail tension-free procedures, or in situations where tension-free slings are more likely to fail,[3] such as ISD, the Remeex re-adjustable sling provides the valuable ability to precisely alter sling tension to render the patient continent. Thus we have selected these two groups of complicated patients in order to evaluate the efficacy of the re-adjustable system in the treatment of SUI.

Data relating to cure of ISD patients is difficult to evaluate due to the wide variety of diagnostic criteria used to describe the condition. Hence, Soulié et al.[3] have a 77.8% cure rate with TVT in cases with MUCP <30 cm H_2O as single criteria of ISD. Rezapour et al.[13] reported a 74% cure rate in ISD patients presenting MUCP <20 cm H_2O considering the immobile urethra as a bad prognostic factor. A recent article link the function of the sphincteric mechanism with the function of the levator ani muscle.[14] They suggest that the function of the urethral sphincter depends on the proper function of the levator ani muscle producing a simultaneous bend at the midurethra.[14] In this sense, Lo et al.[12] suggest that the immobile urethra (less than 30° in the Q-tip-test) is a risk factor for failure in tension-free slings. Similarly, the AUA guidelines for SUI recommend that the presence of hypermobility and ISD are basic factors to be evaluated in SUI management.[15] They suggest that when there is incontinence with minimal stress activities, leak with minimal or no hypermobility in the physical exam, and low valsalva leak point pressure, ISD should be considered as an etiology. They recommend that a measure, or estimate of sphincteric strength and urethral hypermobility, such as leak point pressure and cottonswab test, should be performed in order to assess for the relative contribution of urethral hypermobility and intrinsic sphincteric deficiency. However, they recognize that the leak point pressure needs further validation regarding reproducibility, variables affecting the measurement and standardization of technique.[15]

Taking into account the different criteria used to diagnose ISD, a trend toward lower success rates of this subset of patients seems clear if treated with tension-free techniques.[3,9] On the other hand, it is currently accepted that incontinence due to either ISD or hypermobility are not sharply separated entities. Moreover, it is proposed that both overlap in the same patients more frequently than suspected.[15,16] Accordingly, our inclusion criteria for the ISD group were intended to detect the cases with worse prognosis for tension-free techniques, and

thereby challenge the Remeex system in treating the most difficult cases to cure.

An initial report on 21 cases at 12 months of follow-up reported a subjective cure rate of 90%[4] and later Araco et al.[6] published a 94% of success in 38 patients evaluated after an average of 28 months. The long-term cure rate obtained in our study of 86% has been possible using the late re-adjustment in 17 patients to achieve continence. The possibility of reconnecting the Manipulator to the Varitensor whenever necessary during follow-up allows the re-adjustment of the sling tension in cases of recurrence or obstruction. This procedure can be easily done in an ambulatory setting under local anesthesia. The adjustability of the system allowed the patients to regain continence in cases that would have required another surgery if they had been treated with non-adjustable techniques. Interestingly, some patients potentially curable, refused to undergo a sling re-adjustment concerned about the theoretical possibility of infection of the prosthetic material that is currently producing some benefit, because they felt improved enough. Infection occurred in one patient in our series associated with a seroma requiring multiple aspirations. There were no infections caused by the re-adjustment of the device, however the possibility exists and the patients should be so informed of that possibility. This fact was already mentioned by Iglesias and Espuña[4] that presented a 9.5% of failures that refused the possibility of a new re-adjustment because they were subjectively satisfied with their degree of incontinence.

The risk of rendering a patient obstructed after anti-incontinence procedures is well known from the literature, resulting in 4–8% surgical revision by either cutting the sling or urethrolysis.[17,18] The potential ability to loosen a sling at a time remote from surgery is an excellent and novel option.[19] The possibility to reduce the tension even at long term is due to the very circumscribed fibrosis by the small mesh sling that it is localized only in the lower portion of the urethra and the minimal fibrosis at the lateral tunnels where there are only two monofilament non-knitted traction threads.[20] In all cases, the patients regained a normal flow rate with low detrusor pressure and no residuals. Detrusor overactivity on repeat urodynamic testing disappeared in two cases after successful re-adjustment for outlet obstruction. However, in one patient the filling phase symptoms persisted.

Taking all the precautions common to prosthetic surgeries, such as prophylactic antibiotics, rinsing the surgical wound with saline, etc., we had just one case of infection after a seroma drainage. The concern about the possibility of infect the Varitensor during the re-exposure on adjustments is addressed by performing this procedure in a sterile environment and using standard antibiotic chemoprophylaxis. Thus, we had no case of infection acquired as a consequence of the re-adjustment procedure. Some very thin patients can feel the Varitensor under the skin. However, complain due to pain in the Varitensor placement or dyspareunia were not reported.

The development of de novo detrusor overactivity has been widely demonstrated after every anti-incontinence procedure. The rate observed in this study (8%) is similar to those described with other sling procedures.[18,19,21,22]

CONCLUSIONS

The results presented herein allow us to conclude that the re-adjustable sling system provides a good cure rate with a low complication rate, either in the ISD or in recurrent hypermobile subset of incontinent patients analyzed in the present study. The ability to increase or decrease sling tension allowed us to cure incontinence or obstruction in every case whenever necessary. However, the evolution of urinary continence must be reviewed at longer follow-up. The design limitations of a non-controlled study highlight the importance for future prospective and randomized investigations comparing with other sling techniques. Meanwhile, this study reports a good outcome of an interesting new technique, based on a remarkable number of cases followed at mid term.

REFERENCES

1. Tsivian A, Mogutin B, Kessler O, et al. Tension-free vaginal tape procedure for the treatment of female stress urinary incontinence: Long-term results. J Urol 2004;172:998–1000.
2. Nilsson CG, Falconer C, Rezapour M. Seven-year follow-up of the tension-free vaginal tape procedure for treatment of urinary incontinence. Obstet Gynecol 2004;104:1259–62.
3. Soulie M, Cuvillier X, Benaissa A, et al. The tension-free transvaginal tape procedure in the treatment of female urinary stress incontinence: A French prospective multicentre study. Eur Urol 2001;39:709–14.
4. Iglesias X, Espuña M. Surgical treatment of urinary stress incontinence using a method for postoperative adjustment of sling tension (Remeex System). Int Urogynecol J Pelvic Floor Dysfunct 2003;145:326–30.
5. Nguyen JN. Tape mobilization for urinary retention after tension-free vaginal tape procedures. Urology 2005;66:523–6.
6. Araco F, Gravante G, Dati S, et al. Results 1 year after the Reemex system was applied for the treatment of stress urinary incontinence caused by intrinsic sphincter deficiency. Int Urogynecol J Pelvic Floor Dysfunct 2008;19:783–6.
7. Campos-Fernandes JL, Timsit MO, Paparel P, et al. REMEEX: A possible treatment option in selected cases of sphincter incompetence. Prog Urol 2006;16:184–91.
8. Schröder A, Abrams P, Andersson KE, et al. EAU Guidelines on Urinary Incontinence. Available at http://www.uroweb.org/fileadmin/tx_eauguidelines/2009/Full/Incontinence.pdf. Accessed May 2009.
9. Sand PK, Bowen LW, Panganiban R, et al. The low pressure urethra as a factor in failed retropubic urethropexy. Obstet Gynecol 1987;69:399–402.
10. Abrams P, Cardozo L, Fall M, et al. The standardisation of terminology of lower urinary tract function: Report from the Standardisation Sub-committee of the International Continence Society. Neurourol Urodyn 2002;21:167–78.
11. Nitti VW, Tu LM, Gitlin J. Diagnosing bladder outlet obstruction in women. J Urol 1999;161:1535–40.
12. Lo TS, Horng SG, Chang CL, et al. Tension-free vaginal tape procedure after previous failure in incontinence surgery. Urology 2002;60:57–61.
13. Rezapour M, Falconer C, Ulmsten U. Tension-free vaginal tape (TVT) in stress incontinent women with instrinsic sphincter deficiency (ISD)—A long-term follow-up. Int Urogynecol J Pelvic Floor Dysfunct 2001;12:S9–11.
14. Wallner C, Dabhoiwala NF, DeRuiter MC, et al. The anatomical components of urinary continence. Eur Urol 2009;55:932–44.
15. AUA Clinical Practice Guidelines. Report on The Surgical Management of Female Stress Urinary Incontinence. Available at http://www.auanet.org/content/guidelines-and-quality-care/clinical-guidelines/main-reports/fsuimainrpt.pdf. Accessed May 2009.
16. Kayigil O, Iftekhar Ahmed S, Metin A. The coexistence of intrinsic sphincter deficiency with type II stress incontinence. J Urol 1999;162:1365–6.
17. Abouassaly R, Steinberg JR, Lemieux M, et al. Complications of tension-free vaginal tape surgery: A multi-institutional review. BJU Int 2004;94:110–3.
18. Doo CK, Hong B, Chung BJ, et al. Five-year outcomes of the tension-free vaginal tape procedure for treatment of female stress urinary incontinence. Eur Urol 2006;50:333–8.
19. Bujons A, Errando C, Prados M, et al. Low obstruction tract by system Remeex. Actas Urol Esp 2007;31:43–8.
20. Chu CC, Von Fraunhofer JA, Greisler HP. Wound closure biomaterials and devices. Boca Raton FL: CRC Press LLC; 1997. pp 237–9.
21. Kershen RT, Appell RA. De novo urge syndrome and detrusor instability after anti-incontinence surgery: Current concepts, evaluation, and treatment. Curr Urol Rep 2002;3:345–53.
22. Tsivian A, Kessler O, Mogutin B, et al. Tape related complications of the tension-free vaginal tape procedure. J Urol 2004;171:762–4.