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SURGICAL TECHNIQUE

ReMeEx device (External Mechanical Regulator) for female stress urinary incontinence: a critical review of a single-operator, long-term experience on implants and readjustments

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ABSTRACT

Objective: A single-operator, long-term (15 years) experience on a sling technique that allows a postoperative adjustment of its tension is presented to retrospectively report the objective and subjective outcomes in the treatment of female stress urinary incontinence (SUI). The readjustment option prevents the need of a reoperation in case of relapse with great compliance of the patients.

Materials and methods: Indications for surgical tratment of SUI by ReMeEx included patients affected with not only true intrinsic sphyncteric deficency (ISD) and fixed urethra but also mild urethral hypermobility, previous incontinence surgery and relapsing conditions such as diabetes and obesity. Fifty-five female patients with severe SUI underwent ReMeEx system positioning between 1998 and 2013. Before surgery, patients were evaluated by physical examination, translabial ultrasonography, urodynamics, pad-test and compilation of a specific incontinence quality of life questionnaire.

Results: Out of 55 patients treated, 50 were cured with readjustment in 10; in one case, the device was removed for infection. Complications as one transitory retention, two de novo urgency and one sovrapubic varitensor seroma were easily treated.

Discussion: In our experience, the ReMeEx system produced remerkable long-term results that showed the effective role of this device in obtaining an adequate sling tension, also confirmed in a worse prognosis patient group, as reported in the present study. The limitation of this study, based on a retrospective and not comparative analysis, suggests the need for randomized prospective studies comparing the ReMeEx procedure with other similar anti-incontinence techniques.

Conclusions: ReMeEx system offers the possibility to modify the sling support whenever needed during patients' life. By this device, we can improve the outcomes of these patients leaving them completely dry without reoperations. The system produced remarkable 15 years 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: Female stress urinary incontinence, Long-term experience, ReMeEx device, Worse prognosis

Introduction

Treatment of female stress urinary incontinence (SUI) mainly due to intrinsic sphincter deficency or similar conditions still remains a very difficult target. As recommended by both European and American guidelines, past and current treatment options included urethral bulking agents, suburethral slings and artiphicial urinary sphincters (1). 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 rate and of artiphicial sphincters because of their high rates of revision, explantation and costs (2). Pubovginal slings emerged as the most feasible procedure for the treatment of SUI with acceptable efficacy and safety profiles. The suburethral tension adjustable sling (ReMeEx system) combines the advantages of a less invasive approach with the opportunity of a synthetic sling readjustment, which seems to produce better results in terms of continence rate and morbidity. Here, we

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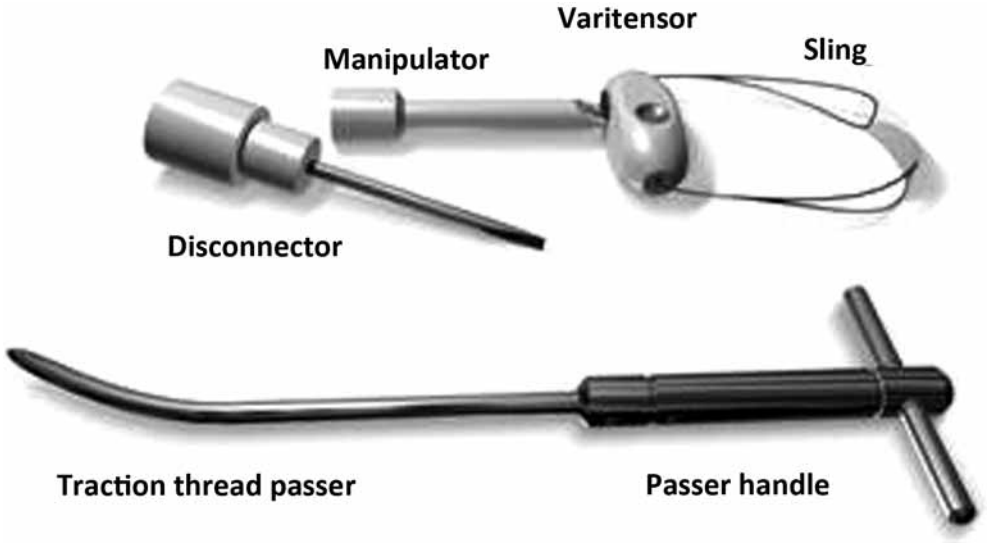

Fig. 1 - Composition of ReMeEx system.

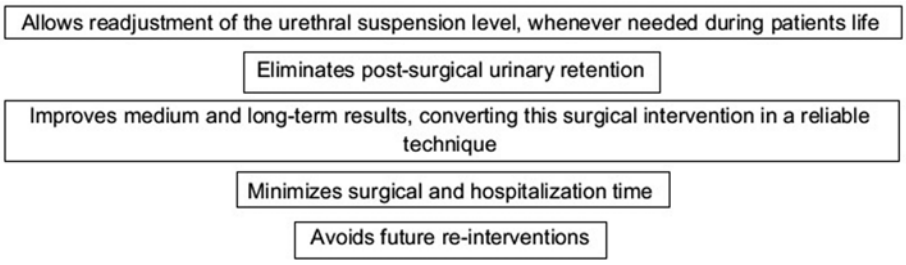

Fig. 2 - ReMeEx characteristics.

presente a long-term experience in the treatment of female SUI by ReMeEx device (NEOMEDIC International – Barcelona – Spain). External Mechanical Regulation is a microdevìce for incontinence made up by a varitensor, like an endless screw, moved by a special miniscrewdriver (manipulator) (Fig. 1).

The polypropilene sling is connected to a regulator so that it can be stressed or relaxed, adjusting the tension of the suspension. The opportunity of the regulation prevents retention, being adjustable, never needs to be removed and moreover it makes no more necessary a reoperation in case of relapse because the regulation can always be performed simply reconnecting the manipulator to the varitensor by means of a little incision in local anaesthesia and just in the office (Fig. 2).

Materials and methods

Fifty-five female patients, aged from 30 to 70 years (mean age 50) who had undergone ReMeEx system implantation between 1998 and 2013, were retrospectively assessed. Preoperative evaluation included history, physical examination with stress test, routine laboratory tests and urodynamics to exlude detrusor overactivity and translabial ultrasonography (3). Patients also underwent a 1-hour pad-test in accordance with ICS guidelines and filled in a specific incontinence quality of life (I-QoL) questionnaire with 22 items, each with a five-point Likert-type scale (from 1 to 5), yielding a total score ranging between 22 and 110 (4). Thirty patients had already undergone previous antincontinence surgery (Tab. I). Indications for surgical treatment of female SUI by ReMeEx included patients with not only intrinsic sphincteric deficency mainly because of iatrogenic ISD with a “lead pipe” and fixed urethra but also mild urethral hypermobility, previous incontinence surgical interventions and relapsing conditions as diabetes or obesity. Operation steps are here detailed: a soprapubic icision will receive the varitensor. By a fingerguided percutaneous-vaginal approach, two needles are inserted to take the sutures of the sling to be transferred in the retropubic region where the device is located. A cystoscopic check follows to exclude transfictions. The sutures are inserted into the varitensor. Epidural anaesthesia allows to perform an intraoperative stress test just followed by the suspension regulation to obtain continence. The day after, completely without anaesthesiological effects, the last regulation can be assessed, just by standing, under real effort and not laying and simulating as in operatory room. Patient is then invited to go to the toilet to verify spontaneous micturition and the residual of urine is checked to decrease the suspension if necessary. The manipulator is then easily removed from the varitensor that remains buried in the fat above rectus aponeurosis as a permanent regulation mechanism for readjusting the sling whenever needed. Postoperative follow-up included an initial visit after 1 month, then after 6 and last after 12 months (5).

TABLE I - Patient characteristics

Patient characteristics	Value
Number	55
Age, mean years (range)	50 (30-70)
Parity, mean (range)	2(0-4)
Body mass index, mean (range)	27.5 (25-30)
Mean pad weight (g) ± range	115.5 ± 45.5
Postmenopausal patients	35
Diabetics	8
Previous anti-incontinence surgery:	30
Bulking agents injection	4
Tension free suburethral sling positioning	15
Prolapse repair	8
Burch colposuspension	3
Previous hysterectomy	12
Total quality-of-life questionnaire score, mean ± range	24.8 ± 7.9

TABLE II - Outcomes of ReMeEx procedure after a mean of 60 months follow-up

Patients	No. of Patients	Mean pad weight ± SD (g) (% improvement; p value)	QoL score ± SD (% improvement; p value)
Cured	50/55	0.7 ± 0.2 (99.0; <0.05)	104.8 ± 5.6 (98.0; <0.05)
Readjustments	10/55		
Complications	4/55		
Failed	1/55		

Cured = perfectly dry patients at stress test, pad weight 0-1 g.
Failed = unchanged or worsened patients, pad weight >50.
p value = Student's *t* test.

Results

Clinical outcomes of the ReMeEx procedure and the rates of mean pad weight and questionnaire score compared with the respective preoperative values were significantly improved (Tab. II): before surgery, patients reported severe incontinence with positive pad-test (130 g) and total questionnaire score (28). At the last follow-up visits, out of the 55 patients, 50 were cured, but 10, including diabetic individuals and obese, required a readjustment in the follow-up. They were performed at the office, in local infiltrative anaesthesia around the device, opening shortly the skin and the varitensor fibrotic copsule by skalpel, then reconnecting the manipulator to increase sling tension (1 mm every four rounds) according to the necessity required to restore complete continence. Four patients were cured but with complications: one reported persistent retention resolved decreasing urethral suspension by Hegar dilator; two presented transitory de novo urgency resolved with antimuscarinics; and one developed sovrapubic seroma formation treated by percuteneous echoguided needle drainage and corticosteroid injection. Patients previously underwent bulking agent injections reporting fibrosis of periurethral tissues, making surgical dissection more difficult. Failed previous slings were left inside (6).

Discussion

In the last years, many types of sling materials, sutures and surgical techniques have been proposed to obtain complete continence while minimizing the risk of complications. Good results were reported using tension-free vaginal tape procedures showing a high cure rate. However, the results of tension-free slings are not always promising, especially in case of recurrent ISD or fixed urethra. Accordingly, the aim of our study was to assess the outcomes of ReMeEx procedure in a group of patients with worse prognosis affected by true ISD, mainly iatrogenic, with lead pipe urethra and fixed urethra. In fact, in patients who failed tension-free procedures, or in situations where tension-free sligs are more likely to fail, such as an 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: our outcomes confirmed this expectation. In our experience, the ReMeEx system produced remerkable long-term results that showed the effective role of this device in obtaining an adequate sling tension, also confirmed in a worse prognosis patient group, as reported in the present study. The limitation of this study, based on a retrospective and not comparative analysis, suggests the need for randomized prospective studies comparing the ReMeEx procedure with other similar anti-incontinence techniques.

Conclusions

The aim of this study was to assess the outcomes of ReMeEx procedure at long-term follow-up in patients with rather worse prognosis owing to aetiology of SUI, relapse rate and comorbidities where simple tension-free slings are more likely to fail. An adjustable tension sling procedure should provide many opportunities to reach an appropriate and durable tension avoiding the risk of complications and failure. Personal outcomes confirm this expectation, showing a high cure rate in accordance with the success rate reported in literature. In terms of QoL, clinical improvements were supported by high satisfaction rate, most probably because of the patients' well being for the regained health condition. Concerning morbidity, outcomes also reported a very low complication rate mainly because of minor events easily resolved. With regard to sling tension adjustment, it was easily and successfully performed under local infiltrative anaesthesia, showing the efficacy of the procedure whenever needed. The up-to-date series and follow-up of this experience allow to report definitive comments on the safety and effectiveness of the device. Just a positive comment can be expressed on the functional features of the suspension significantly reducing

retention, complications or other defects and above all making it no more necessary a reoperation in case of recurrence; therefore, it seems ideal for patients already relapsed, to whom maximum care must be given to prevent other relapses. Therefore, ReMeEx can reasonably be considered the most suitable cure for worse prognosis incontinence in female patients.

Disclosures

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Conflict of interest: The authors declare that there are no conflicts of interest.

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