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ORIGINAL ARTICLE

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Surgical treatment of urinary stress incontinence using a method for postoperative adjustment of sling tension (Remeex System)

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Abstract We present a technique that allows postoperative adjustment of the sling tension in female patients with urinary stress incontinence (USI). Twenty-one female patients with urodynamically proven USI were prospectively evaluated. Subjective and objective evaluation was made preoperatively, 6 months postoperatively and yearly thereafter. Mean age was 63.5; mean parity was 2.3. All patients were postmenopausal and 13 (62%) had had previous surgery for USI. The operating time was 32 minutes (range 25–45). At a mean follow-up of 12 months (6–25), 19 patients (90.5%) were very satisfied. Two patients (9.5%) were considered failures but subjectively were satisfied and refused readjustment. One patient (4.7%) developed 'de novo' detrusor instability. In conclusion, this is a sling procedure for patients with previous failed surgery and those with intrinsic sphincter deficiency (ISD) with the peculiarity that the sling tension can be regulated postoperatively. The readjustment can be made in the office, months or even years after the procedure.

Keywords Readjustable sling technique · Urinary stress incontinence

Abbreviations *USI* Urinary stress incontinence · *ISD* Intrinsic sphincter deficiency · *MUCP* Maximum urethral closure pressure · *VLPP* Valsalva leak-point pressure

Introduction

Surgical procedures to treat urinary stress incontinence (USI) generally aim at lifting and supporting the urethrovesical junction. Suburethral slings serve this purpose well. Several materials, either biological or synthetic, have been used to create slings.

Unfortunately, no method is available that will provide adequate support or elevation of the urethrovesical complex and achieve good continence while avoiding urinary obstruction. This results in some patients with continence failures and some with postoperative voiding dysfunction.

We present a new technique that allows postoperative adjustment of the sling tension the following morning, or months or even years after the procedure. The aim of our study was to assess this method.

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Materials and methods

Twenty-one women with urodynamically proven urinary stress incontinence were prospectively evaluated. A symptom questionnaire, physical examination, 1-h pad test and urodynamic studies were performed preoperatively. Objective outcomes were assessed by clinical examination and stress testing at maximum cystometric capacity during the urodynamic evaluation 6 months postoperatively, and thereafter annually by physical examination and 1-h pad test. Subjective outcomes were assessed by interviewing the patients about their postoperative urinary symptoms and asking them to classify their level of satisfaction with the outcome of the surgery by selecting one of five grades (very satisfied, moderately satisfied, neither satisfied nor unsatisfied, a little unsatisfied and very unsatisfied).

The status of the patients is illustrated in Table 1. Mean age was 63.5 (53–78), mean parity was 2.3 (0–6). All the patients were postmenopausal and 13 (62%) had had previous surgery for USI. The preoperative 1-hour pad test was 63 g (16–170). According to the preoperative urodynamic study, 19 (90.4%) of the patients had pure stress incontinence and 2 (9.5%) had mixed incontinence). A urodynamic diagnosis of stress incontinence was made if visual loss of urine was demonstrated during cystometry, on coughing in the sitting position, with the bladder at maximum capacity in the absence of a bladder contraction. Urethral pressure profile at rest was measured with the patient in the sitting position with an empty bladder. Eleven (52%) patients were considered to have ISD on the basis of a maximum urethral closure pressure (MUCP) < 20 cmH_2O or Valsalva leak-point pressure (VLPP) < 60cmH_2O.

Table 1 Patient characteristics

Variable	($n = 21$)
Age (mean years)	63.5 (53–78)
Parity (mean)	2.3 (0–6)
Postmenopausal	21 (100%)
Previous incontinence surg.	13 (62%)
1 h pad test (g)	63 (16–170)
Pure stress incontinence	19 (90.4%)
Mixed incontinence	2 (9.6%)
ISD	11 (52%)

VLPP < 60 cmH_2O/MUCP < 20 cmH_2O

The system is called Remeex (Mechanical External Regulation; Neomedic International) and the components can be seen in Figure 1. The system is composed of:

- A polypropylene mesh of 1.25 × 2.5 cm attached to a no. 1 polypropylene monofilament (traction thread);
- *Varitensor:* which is the regulation mechanism. Made of Chirulen (ultrahigh molecular weight polypropylene) and titanium.
- *Manipulator:* Attached to the varitensor to manipulate the regulation mechanism. Rotating the manipulator clockwise or counterclockwise elevates or lowers the level of the sling.
- *Disconnector*: To connect and disconnect the manipulator to the varitensor. Will help in removing the manipulator once the proper adjustment has been made, usually the day after the operation.

The traction threads can be placed with any suspension needles (vaginal to abdominal or abdominal to vaginal direction). The manufacturer has vaginal to abdominal needles that can be attached to a manipulator to help them pass through the space of Retzius.

The procedure is performed as follows. Sodium cefminox 2 g i.v. is given prophylactically. Under spinal anesthesia the patient is placed in the dorsal lithotomy position and the lower abdomen, genitalia and perineum are prepared and draped. An 18 FrFoley catheter is inserted and inflated with 5 ml saline; the urine is drained and a clamp placed at the end of the catheter and dropped over the lower abdomen. A 3–4 cm lower abdominal incision is made and the aponeurosis of the rectus muscles is exposed (Fig. 2). The anterior vaginal wall is incised at the urethrovesical junction for about 3–4 cm and dissected off the underlying periurethral and perivesical tissues. The needle, with the help of the handle, is passed lateral to the urethra to the posterior aspect of the pubic bone, very close to it and piercing the rectus aponeurosis at the lower abdomen. The same is done on the other side (Fig. 3). A cystoscopy

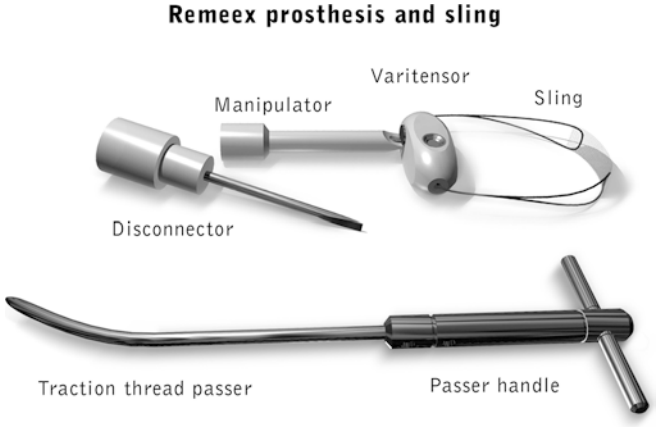

Fig. 1 Remeex components

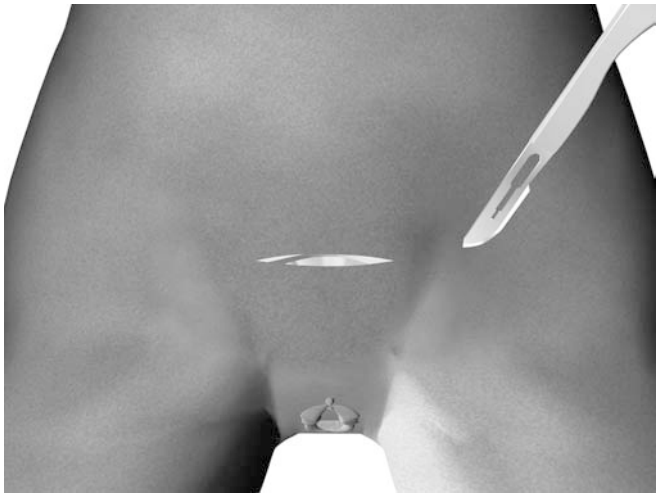

Fig. 2 Abdominal incision 3–4 cm wide and dissection until the rectus aponeurosis is exposed

is performed. If there is evidence of bladder perforation (Fig. 3) , the needle is removed and reinserted in the correct place. The polypropylene sutures are passed through the needles holes and pulled up until they appear at the abdominal incision (Fig. 4). With the varitensor at 10 cm above the fascia of the abdominal rectus, the ends of the sutures are inserted into the varitensor and knotted with each other using five or more knots (Fig. 5). Before adjusting the sling tension, the mesh should be well located at the urethrovesical angle. The fixation of the mesh to the urethrovesical tissues is within the discretion of the surgeon ('potestative'). While the varitensor is maintained in horizontal position the manipulator is wound clockwise until the varitensor is about two fingertips above the aponeurosis (3 cm) (Fig. 6). The vaginal and the abdominal incisions are closed in the usual manner. The urethral catheter is left to gravity drainage.

The day after the procedure the bladder is filled with about 300 ml of saline, the Foley catheter is removed and the patient is invited to stand up (this part of the procedure can be delayed some hours or a few days if there have been any complications, such as bladder perforation, hematoma etc.). The patient is asked to make Valsalva maneuvers, cough, bear down etc.; if there is leakage of urine we will adjust the sling support by making four complete turns of the manipulator and repeat this maneuver again until the patient is completely dry. The patient will then go to the toilet to

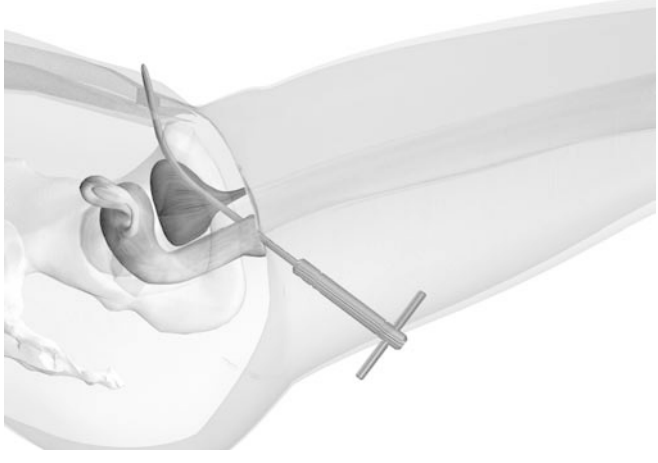

Fig. 3 The needle is passed up lateral to the urethra through the space of Retzius

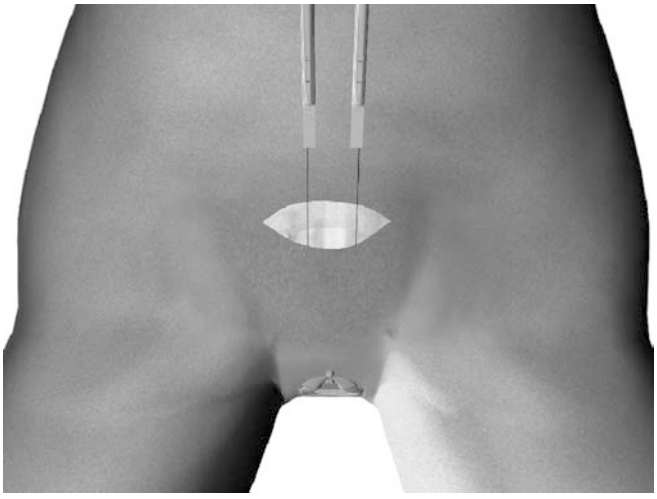

Fig. 4 The prolene sutures have been inserted into the needle holes and recovered at the abdominal incision

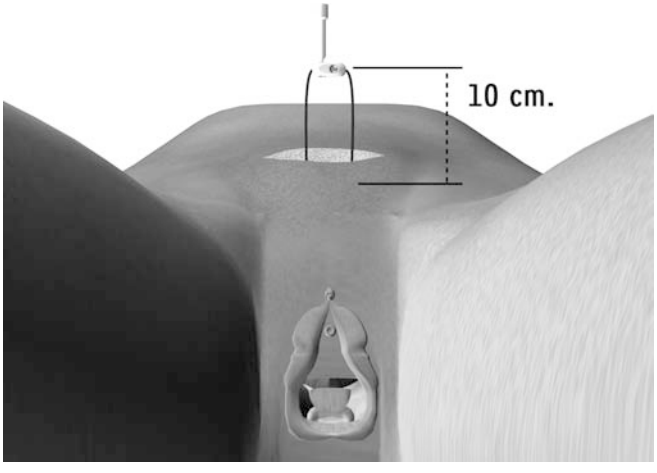

Fig. 5 The prolene sutures from both sides are tied together with at least five knots. The varitensor is maintained horizontal about 10 cm above the skin

prove that she can void spontaneously, and the residual urine is checked. If the residual is more than 100 ml the sling tension will be decreased. If the residual is less than 100 ml the disconnector is rotated 90º in relation to the manipulator, either clockwise or counterclockwise, and the disconnector–manipulator is easily removed from the varitensor, which stays buried in the fat above the aponeurosis of the rectus abdominis as a permanent regulation mechanism (Fig. 7), to be used if ever needed to readjust the sling.

Results

The results are illustrated in Table 2. The operating time for the procedure was 32 min (25–45), and 4 (19%) of the patients had some added surgery for prolapse. There have been no intraoperative complications. The mean duration of the postoperative urethral catheterization was 1.3 days (1–2). No patient needed catheterization for longer than 2 days. Immediate postoperative regulation (the day after surgery) was necessary in 10 of 21

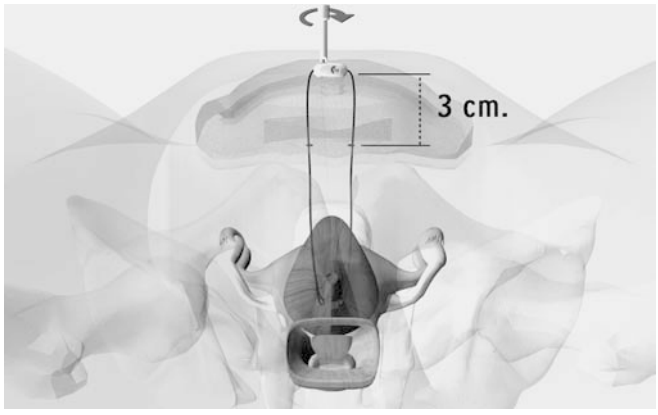

Fig. 6 Winding the varitensor clockwise until the prosthesis is about 3 cm from the aponeurosis so that a fingertip can pass easily between the prosthesis and the aponeurosis

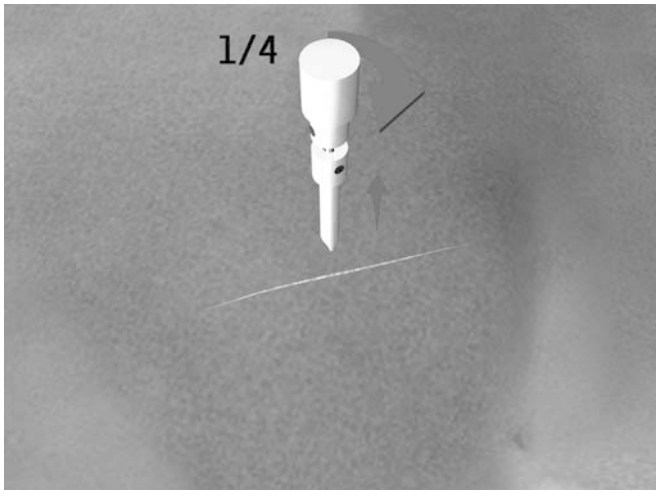

Fig. 7 With a quarter of a turn the manipulator and the disconnector are withdrawn

patients. The sling tension had to be increase by rotating the manipulator of the varitensor clockwise a mean of 5 mm (min 1, max 9) in those patients. With a mean follow-up of 12 months (6–25), the postoperative 1-hour pad test (<2 g) was observed in 13 patients (62%) and 6 patients (28%) had a 1-hour pad test <10 g. Subjectively all these 19 patients (90.5%) were very satisfied with the outcome of the surgery. Two patients (9.5%) had a 6-month postoperative pad test more than 10 g and were considered objective failures, although subjectively the patients were satisfied to the point that they refused the option of being readjusted by an easy ambulatory maneuver. One patient (4.7%) developed de novo detrusor instability.

Comments

The suburethral sling has traditionally been considered a procedure of last resort for previous surgical failures and

Table 2 Results

Variable	($n=21$)
Added prolapse surgery (*)	4 (19%)
Operating time for the procedure (mean min)	32 (25–45)
Duration catheter (mean days)	1.3 (1–2)
Postop voiding difficulty (> 7 days)	0
Subjective cure rate (very satisfied)	19 (90.4%)
Postop 1 h pad test (< 2 g)	13 (62 %)
Post-op 1 h pad test (< 10 g)	6 (28%)
Post-op 1 h pad test (> 10 g) - failures	2 (9.5%)
De novo detrusor instability	1 (4.7%)

for those patients with severe ISD [1]. There is now a tendency to increase its use as a primary procedure for USI. Published reports suggest a continence rate of 93.9% according to the update of Appell [2], although a recent Cochrane review states that evidence that suburethral slings may be better or worse than other surgical or conservative management is lacking [3].

We present a new suburethral sling technique which allowspostoperative readjustment of the sling tension whenever needed during the patient's life.

The overall goal of sling placement is to produce adequate urethral resistance to prevent stress incontinence while allowing voluntary and complete bladder emptying. The most common problem of sling surgery has been excess tension, and concern over postoperative bladder outlet obstruction has led to the development of a number of methods to determine the proper tension. To date there has been no universally accepted, objective and easily reproducible technique for this critical step in sling surgery. The REMEEX system (Mechanical External Regulation) allows the readjustment to be performed under physiological conditions 24 h after the operation in a standing position, with a predetermined bladder volume and without anesthesia. As a general rule the sling is left without tension; of these 21 patients postoperative readjustment was necessary in 10, and the sling tension had to be increased by rotating the manipulator of the varitensor clockwise: the mean rotation was 5 mm (min 1, max 9). No postoperative urinary retention was observed in this series of 21 patients and we think this is because the sling is left without tension. The regulation is made after surgery, thereby avoiding postoperative bladder obstruction.

We wish to emphasize that the severity of the urinary stress incontinence in our population was important: 62% had had previous incontinence surgery; 52% had urodynamic evidence of an ISD with a mean preoperative pad test of 63 g; and yet 90.4% of patients had a subjective cure. Sixty-two percent of our patients had a 1 h pad test less than 2 g and, interestingly enough, the 2 patients with objective failure refused the postoperative readjustment as they considerer themselves much improved compared with before the operation. Our results agree with Black et al.'s [4] study on the impact of surgery for stress incontinence on the social lives of 442 women: they demonstrated that the extent of the improvement was related to the preoperative severity, that is, that the women who benefited most were those more severely affected by the stress incontinence. All of this suggests that the technique can be adequate for patients with severe incontinence and with failures in previous operations. Moreover, we can offer them the possibility of a readjustment several months after surgery. This is performed under local anesthesia, in the office; the manipulator with the disconnector will be inserted and, after the readjustment, both the manipulator and the disconnector will be withdrawn (Fig. 8).

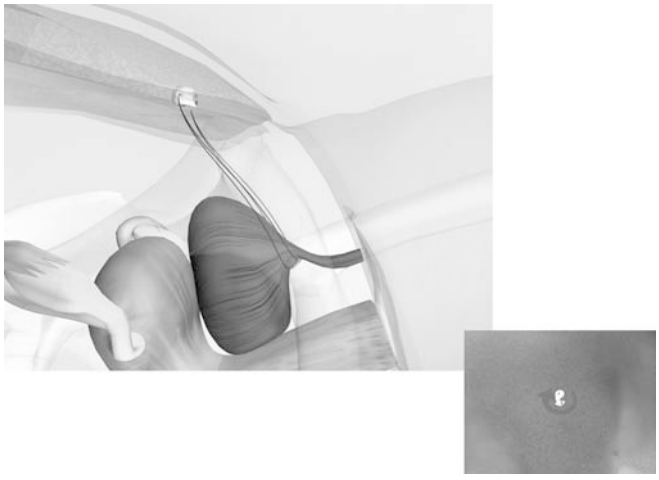

Fig. 8 The varitensor remains in place. The sling support level can be modified if needed by replacing the manipulator and the disconnector under local anesthesia

We have so far had no rejection of the material in these 21 patients, and according to the information from the manufacturers (Neomedic International), in a group of 750 patients with the Remeex inserted, 5 had the varitensor removed. Once the varitensor was removed the polypropylene sutures were tied together, ensuring good continence in 4 patients.

In summary, we believe that this is a sling procedure suitable for patients with previous failed surgery and for patients with ISD, with the peculiarity of being able to regulate the sling tension easily after the operation. As this is a very simple procedure under local anesthesia, the readjustment can be made in the office months or even years after the procedure.

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Editorial comment

Adjusting the sling tension of a bladder neck sling at the time of surgery is diffucult and not very scientific. Slings that are too tight are associated with voiding dysfunction and De Novo urge incontinence. Slings that are too loose may still allow stress incontinence. This sling system allows the surgeon to leave very loose at the time of surgery with the ability to tighten or loosen the sling easily in the post-operative period to achieve continence and still maintain adequate voiding function. Data on long term success or need for surgical removal is not available. The ability to tighten or, more importantly, loosen this sling at a later time in the post-operative period when scarring has occured is not known at present.