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The TRT Female Remeex System® for recurrent female stress urinary incontinence: A 5-year follow-up study

J. Barrington, R. Archer, M. Kulkarni & A. Forrest

Department of Gynaecology, Torbay Hospital, Torquay, UK

Conventional surgery for female stress incontinence is usually successful but recurrent cases are difficult to treat. This study of 20 such cases treated by the Remeex TRT system shows symptomatic benefit up to 5 years following insertion of the device. The benefit of this procedure is that the sling can be adjusted to the correct tension in the optimum leak position and circumstances, and anytime thereafter without the need to repeat the entire operation. As a result, the voiding dysfunction rate and need to intermittent self-catheterise is reduced, even with a low pressure urethra. The cost per procedure and complication rate is higher that standard TVT, and the device may occasionally need removal due to persistent seroma. However, the improved quality of life makes this operation an attractive option in recurrent cases of female stress incontinence.

Keywords: Recurrent female stress incontinence, TRT Remeex, TVT

Introduction

Mid-urethral slings or tapes have revolutionised the management of stress incontinence in women. Although sling operations were first described over a century ago, it was the invention of the tension-free vaginal tape (TVT) procedure by Ulmstem in 1996 (see Ulmstem et al. 1999) that led to its popularity today, and why it is considered the 'gold standard' by many surgeons. The success rate of TVT is variously quoted as between 85% and 92% (Martinez et al. 2003) but a dilemma still exists as to what is the optimum treatment for the small number of operative failures and/or patient dissatisfaction. The options mainly lie between a repeat sling or bulking agent procedure or reversion to a more traditional operation such a Burch colposuspension. However, it is well known that the success rate for a secondary procedure is lower than for a primary procedure, which is often due to difficulty in adequately gauging the correct tension, especially if there is a low urethral closing pressure (Lose and Brostrom 2002). As a result, there is a higher rate of voiding dysfunction in repeat procedures and a need for intermittent self-catheterisation (ISC). The Remeex tension-free readjustable tape (TRT) system (Neomedic) is an adjustable device allowing the suburethral tension to be altered at any time postoperatively to increase the success rate of incontinence surgery and to overcome the complications of over-tightening. Previous studies (Iglesias and Espuna 2003; Araco et al. 2008) have shown a subjective cure of 90–95% using this technique but the follow-up period is short term only and usually limited to 12–24 months. This study describes our long-term 5-year experience of the device in refractory stress urinary incontinence (SUI).

Materials and methods

Ethical approval was granted by the local research ethics committee for this prospective observational study. A total of 20 parous women (age range 32–81 years; mean 52 years) were recruited into the study. All the women had undergone previous incontinence surgery (TVT $n = 17$: colposuspension $n = 3$) and four of these women had undergone two previous incontinence procedures. Preoperative urodynamic (non-videocystourethrography) studies were carried out in each case, which revealed detrusor overactivity in three cases that were treated with anticholinergics prior to surgery. A low urethral closing pressure (< 20 cm H_2O) was revealed in eight women (range 8–18; mean 14 cm H_2O). In addition, the average daily pad usage was calculated, and all the women asked to complete a Kings College Hospital Quality of Life Questionnaire (KCHQOL) together with a Visual Analogue Scale (VAS) to score the personal degree of incontinence. The procedures were all carried out under general anaesthetic with antibiotic cover. A 4 cm transverse skin incision was made 2 cm above the symphysis pubis and the dissection was continued until the rectus sheath was exposed. The suburethral vaginal epithelium was then incised and dissection made onto the endopelvic fascia, which was perforated using the supplied needles (traction thread passer). The needles were passed retropubically and upward, with the needles perforating the rectus sheath at the lateral margins of the initial suprapubic incision. The Remeex System consists of a 4×1 cm type 2 macroporous polypropylene sling attached to nylon sutures, and a variotensor with an adjustable handle or manipulator (Figure 1); the nylon sutures were passed through an eyelet on the needles and drawn upwards on each side. A cystoscopy was carried out to ensure no bladder perforation had occurred; no case of bladder injury occurred in this study. The nylon sutures were then placed in the variotensor and secured in place. The handle was then rotated and the excess suture was taken up so that the variotensor lay on the rectus sheath without tension. The vaginal and abdominal incisions were then closed leaving the handle protruding through the skin incision. The following day, the bladder was retrograde filled and the women asked to perform a cough test or any activities that would generally result in urinary incontinence. The handle was then rotated to tighten the sling suburethrally until no further leakage was demonstrated. The handle was then disconnected from the variotensor and the small skin defect closed. The women were discharged with a week's course of antibiotics, and were followed-up at 3, 6, 12 months and 5 years. At each visit, the degree of incontinence was assessed using the same criteria as before. If the patient was not satisfied, the handle was reattached to the variotensor

Correspondence: J. Barrington, Department of Gynaecology, Torbay Hospital, Torquay, Devon TQ2 7AA, UK. E-mail: julian.barrington@nhs.net

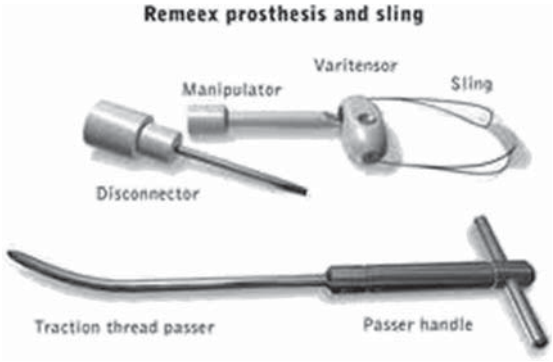

Figure 1. The Remeex System.

via a minor outpatient procedure under local anaesthetic and the tension readjusted.

Results

The system required adjustment in three cases to regain continence: 1 each at 1, 2 and 4 years postoperatively. These were carried out under local anaesthesia with antibiotic cover in the outpatient department. A small incision was made over the palpable variotensor in the suprapubic area and routine dissection performed onto the device. The device was usually encapsulated in fibrous tissue. An incision was made in this capsule and the handle easily reattached and the tension adjusted. The handle was then disengaged and the incision closed in layers. No recorded cases of infection were recorded. All 20 women were followed-up to 12 months. By 5 years, one woman had died and two were lost to follow-up: two systems had to be removed due the development of chronic seromas around the variotensor that failed to respond to antibiotics and aspiration/drainage. However, the sling was left *in situ* and the nylon sutures were tied together with the same tension as the variotensor, and continence was maintained in each case. No suture breakage was observed at any point during the follow-up period and no urethral erosions were observed. Voiding was spontaneous in 18 women; two women intermittently self-catheterised. De novo overactive bladder had developed in a further three cases. The KCHQOL results are shown in Table I. There was no statistical improvement in the General Health domain but all other domains of the KCHQOL at both 1 and 5 years were statistically improved ($p < 0.05$). There was a statistical difference between preoperative VAS scores ($p < 0.0001$) and 1 and 5 years (preop range 4–10, mean 8.3, median 8.3; 1-year range 0–6, mean 1.2, median 1.0; 5-year range 0–9, mean 3.0, median 2.0). There was also a statistical reduction ($p < 0.0001$) in the number of pads used daily (preop range 0–10, mean 3.8, median 3.0; 1-year range 0–3, mean 0.3, median 0.0; 5-year range 0–5, mean 0.7, median 0.0). At 1 year, nine women considered their incontinence had been cured by the Remeex procedure; 11 women felt their symptoms had improved, while no women considered their incontinence has remained the same or worsened as a result of the operation. By 5 years, nine women were still cured; six were still improved; two women felt the system had failed but declined any further tightening of the sling due to concerns regarding ISC. A total of 19 out of the 20 women at 1 year and 16 out of 17 at 5 years would recommend the operation to a friend or relative if they needed it.

Discussion

The management of recurrent female SUI is a difficult clinical problem. The results of a repeat TVT procedure are approximately 80% and are therefore slightly lower than that for primary surgery. A Burch colposuspension may have a slightly higher success rate but this is at the expense of major invasive surgery that carries a higher morbidity due to marked retropubic fibrosis. Long-term results of urethral bulking procedures are disappointing with a subjective improvement of 25–30%. This study has therefore shown that the TRT Remeex System is a useful adjuvant in the treatment of continued incontinence that has not been cured by conventional surgery. The results do decline slightly over time but this deterioration is not statistically significant and can easily be adjusted rather than resorting to a repeat of the entire sling procedure. In our opinion, it should not be used in primary surgery except in low urethral closing pressure cases where the reported cure rates are generally lower. The procedure is more expensive than a standard TVT due to the increased price of the device, but when compared with repeated surgery, it becomes cost-effective. There are potentially more postoperative problems but these are offset by a major improvement in quality of life and self-esteem.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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Table I. Kings College Hospital Quality of Life Questionnaire (KCHQOL) results.

	Mean			Median			*p* value	
	Pre	1-year post	5-years post	Pre	1-year post	5-years post	1-year post	5-years post
General health	20.0	18.1	25.0	25.0	12.5	25.0	0.6823	0.8026
Incontinence impact	93.4	22.1	37.7	100.0	33.0	33.0	0.0001	0.0001
Role limitations	81.7	10.2	12.2	100.0	0.0	0.0	0.0001	0.0001
Physical limitations	76.8	13.8	22.3	83.0	0.0	17.0	0.0001	0.0001
Social limitations	55.8	9.1	13.3	58.5	0.0	0.0	0.0001	0.0001
Personal relationships	55.2	5.5	21.6	67.0	0.0	0.0	0.0001	0.0001
Emotions	73.8	24.6	28.1	78.0	22.0	22.0	0.0001	0.0011
Sleep/energy	57.5	34.2	31.1	58.5	33.0	17.0	0.0085	0.0049
Severity measures	80.4	26.9	31.7	83.0	25.0	25.0	0.0001	0.0001

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