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Barrington J[1], Hogg S[2]
1. *Torbay Hospital,* ***2.*** *Torbay Hospital*

THE REMEEX SYSTEM FOR REFRACTORY FEMALE STRESS URINARY INCONTINENCE.

Hypothesis / aims of study

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 Ulmstein in 1996 that has led to it's 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% but a dilemma 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. As a result there is higher rate of voiding dysfunction in repeat procedures. The Remeex System (Neomedic) is an adjustable device allowing the suburethral tension to be altered at any time post-operatively to increase the success rate of incontinence surgery and to overcome the complications of over-tightening. This study describes our initial experiences of the device in refractory stress urinary leakage.

Study design, materials and methods

Twenty women (age range 32 -81 years: mean 52 years) were recruited into the study. All the women were parous and had undergone previous incontinence surgery (TVT n=17: Colposuspension n=3). All the women had undergone pre-operative urodynamics, which had excluded detrusor overactivity and revealed a low urethral closing pressure (<20 cmH20) in 8 women. In addition a pad test was performed, 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 in the lithotomy position under general anaesthetic with antibiotic cover. A 4cm transverse skin incision was made 2cm 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. The needles were passed retropubically and upward with the needles perforating the rectus sheath at the lateral margins of the initial incision. The Remeex System consists of a 4x1cm polypropylene sling attached to nylon sutures, and a variotensor with an adjustable handle: the nylon sutures were passed through an eyelet on the needles and drawn upwards on each side. A cystoscopy was carried out to ensure the bladder had not been perforated. 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 on the variotensor 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 then discharged with a week's course of antibiotics.

The women were followed up at 3, 6 and 12 months: at each visit the degree of incontinence was assessed and if the patient was not satisfied the handle was reattached to the variotensor via a minor outpatient procedure under local anaesthetic and the tension readjusted. A follow up pad test and usage, KCHQOL and VAS was carried out in each case. Nonparametric (Mann-Whitney) tests were used to determine statistical significance.

Results

There were no operative problems and no bladder perforations occurred. The average length of stay was 2 days. The system was readjusted in the outpatient clinic in 3 cases to regain continence. One system had to be removed due the development of a chronic seroma 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. Voiding was spontaneous in 18 women: 2 women intermittently self catheterised. The results are shown in the table below:

	Min		Max		Mean		Median		Std Dev		p
	Pre	Post	Pre	Post	Pre	Post	Pre	Post	Pre	Post	
General Health	0	0	50	50	20.00	18.06	25.00	12.50	17.40	20.66	0.6823
Incontinence Impact	33	0	100	100	93.35	22.11	100.00	33.0	17.45	22.87	0.0001
Role Limitations	17	0	100	83	81.70	10.17	100.00	0.00	26.39	21.40	0.0001
Physical Limitations	33	0	100	100	76.75	13.83	83.00	0.00	20.49	25.67	0.0001
Social Limitations	11	0	89	67	55.83	9.12	58.50	0.00	28.08	18.12	0.0001
Personal Relationships	0	0	100	33	55.15	5.50	67.00	0.00	38.16	12.85	0.0001
Emotions	0	0	100	100	73.75	24.61	78.00	22.00	26.77	26.86	0.0001
Sleep / Energy	17	0	100	67	57.50	34.22	58.50	33.00	23.31	23.87	0.0085
Severity Measures	33	0	100	75	80.35	26.89	83.00	25.00	18.24	24.16	0.0001
VAS Score	4	0	10	6	8.25	1.22	8.25	1.00	1.50	1.40	0.0001
Pad Test (mls)	12	0	750	8	84.17	0.56	40.50	0.00	168.63	1.92	0.0001
No. of Pads	0	0	10	3	3.78	0.33	3.00	0.00	2.58	0.84	0.0001

Interpretation of results

There was no statistical improvement in the General Health domain but all other domains of the KCHQOL were statistically improved ($p<0.05$). There was also a statistical difference in VAS scores, urine loss on pad testing and reduction in the number of pads used daily. 9 women considered their incontinence had been cured by the Remeex procedure: 11 women felt their symptoms had improved whilst no women considered their incontinece has remained the same or worsened as a result of the operation despite the fact only 9 women continued to do pelvic floor muscle exercises. In fact 19 out of the 20 women would recommend the operation to a friend or relative if they needed it.

Concluding message

This study has shown that the adjustable Remeex System is a useful adjuvant in the treatment of female stress urinary incontinence that has not been cured by traditional surgery. 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. There are potentially more postoperative problems but these are offset by a major improvement in quality of life and self esteem.

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What were the subjects in the study?	**HUMAN**
Was this study approved by an ethics committee?	**Yes**
Specify Name of Ethics Committee	**South Devon Local Research Ethics Committee**
Was the Declaration of Helsinki followed?	**Yes**
Was informed consent obtained from the patients?	**Yes**