

## DOES THE REMEEEX RE-ADJUSTABLE SLING OFFER LONG-LASTING RESULTS IN RECURRENT STRESS INCONTINENCE AND SPHINCTERIC DEFICIENCY?

### Hypothesis / aims of study

Evaluate the safety and efficacy of the Remeex re-adjustable sling procedure after 60 months of follow-up. This study intends to confirm the clinical and quality of life results of re-adjustable systems in the treatment of ISD and recurrent stress urinary incontinence already presented.

### Study design, materials and methods

Sixty patients with stress incontinence were classified by cough stress test, Q-tip, and urodynamics into two groups: ISD (31 cases), and recurrent hyper-mobility SUI (29 cases). All patients underwent the Remeex procedure. The patients were evaluated with cough test, standardized pad-test and urodynamic evaluation before and after the surgery.

The quality of life was evaluated by means of the Kings Health Questionnaire (KHQ) that was administered at baseline and a minimum of 36 months after the Remeex implantation.

### Results

After a mean follow up period of 60 months (42-74), 51 patients (85%) achieved cure of stress incontinence (defined as negative cough and pad testing). Nine patients (15%) are not objectively cured (3 satisfied patients refuse re-adjustment, and 6 are in the waiting-list for re-adjustment). Eleven patients (18%) show urge incontinence and detrusor overactivity. Five of the 11 patient with urge incontinence post-operatively had urodynamic evidence of mixed incontinence pre-operatively while 6 (10%) patients developed de-novo detrusor overactivity. Twenty-one patients (35%) required a total of 24 adjustments of the sling at 25 months after the initial procedure as an average. The tension was increased in 18 cases due to recurrence of SUI and reduced in 3 cases due to obstruction. Fifty patients (83%) shown an improvement in quality of life based on the KHQ scores. The implanted adjustment device has been removed in 2 cases due to infection with preservation of continence in one. Bladder perforation during the needle passage was noted intra-operatively in 7 patients and was managed with foley catheter drainage for 48 hours. No other adverse events or complications happened.

### Interpretation of results

The cure rate obtained after a long-term assessment can be considered satisfactory, taking into account the specially challenging subset of patients that we are dealing with. The King's Health Questionnaire results confirm as well the correlation between the clinical results and the incontinence-related quality of life in those patients.

### Concluding message

The Remeex adjustable sling system provides a good cure rate for recurrent SUI and ISD with a low complication rate based on 60 patients at 60 months of follow-up thus confirming the previously reported results at short-term. Re-adjustment of the sling tension either increasing or decreasing has been possible whenever necessary.

<b><i>Specify source of funding or grant</i></b>	<b>None</b>
<b><i>Is this a clinical trial?</i></b>	<b>No</b>
<b><i>What were the subjects in the study?</i></b>	<b>HUMAN</b>
<b><i>Was this study approved by an ethics committee?</i></b>	<b>No</b>
<b><i>This study did not require ethics committee approval because</i></b>	<b>It is a prospective study that doesn't require any change in clinical practice.</b>
<b><i>Was the Declaration of Helsinki followed?</i></b>	<b>Yes</b>
<b><i>Was informed consent obtained from the patients?</i></b>	<b>Yes</b>