

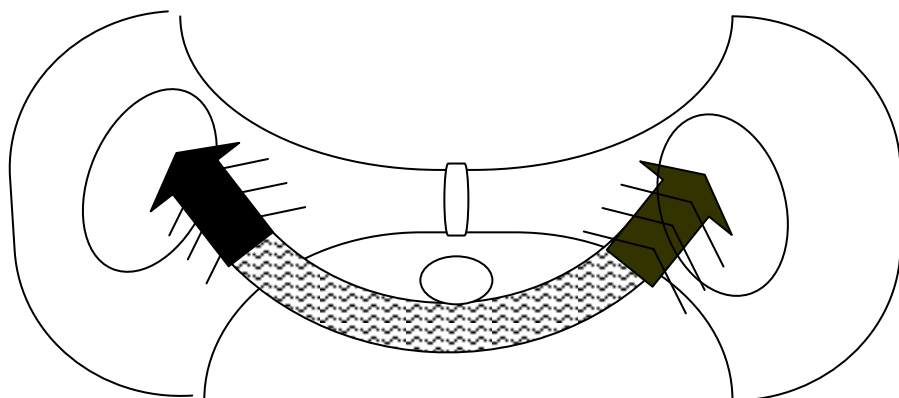
PRELIMINARY RESULTS OF TREATMENT OF STRESS URINARY INCONTINENCE WITH OPHIRA MINI-SLING

Hypothesis / aims of study

Since last decade mid-urethral slings became a standard treatment for female patients suffering stress urinary incontinence. Nowadays there is a general tendency to minimize even minimally invasive procedures. During last years many mini slings were presented to the market. Preliminary data on these procedures showed low cure rate and poor reproducibility.

The aim of the study was to evaluate preliminary results of Ophira mini sling. Unlike to other slings, Ophira has an unique edge fixation system, which is fishbone like. It allows the sling to be fixed well in the tissues, even when the margins of the harpoons are not penetrating obturator membranes.

Figure 1. Ophira mini sling positioning in mid-urethra



Study design, materials and methods

Thirty female patients suffering stress urinary incontinence (SUI) were operated with Ophira minisling. Mean age of the patients was 62 +-8.6 years (from 44 to 81). Eight women (26.67%) had a history of previous genital surgery. Three of them (10%) developed SUI after prolapse repair. Stress urinary incontinence confirmed by positive cough test during physical examination was inclusion criteria for this study. Associated urgency symptoms were present in 29 patients from 30 before surgery (96.67%). Urodynamic observation was done for all patients. Urodynamic stress urinary incontinence was proved in all cases. 12 patients (40%) showed terminal detrusor overactivity during cystometry.

Results

Follow up visits were done in 1 month and 12 months after surgery. Two patients were lost for follow up (6.67%). Visual analog scale (0 to 10) was utilized for evaluation of patients' subjective response to the treatment. Cough test was negative in all patients after first month and in 26 patients from 28 (92,86%) after 2 months following surgery. In twelve months after the surgery the urgency symptoms were resolved in 40,74% of patients (11 patients from those 27 with pre-operative urgency, who were available for follow ups). Other patients were managed with anti-muscarinic medications.

Table 1. Follow up of 28 from 30 patients

	First month visit (28 pts.)	Twelve months visit (28 pts)		
Objective cure rate % (negative/positive cough test)	26/2	92.86%	26/2	92.86%
Subjective cure rate % (VAS > 3 from 10)	25/3	89.29%	23/5	82.14%
Pain	2/26	7.14%	28/1	3.57%
UTI	3/25	10.71%	1	3.57%
Residual urine >100 cc	2/26	7.14%	2	7.14%

Subjective cure rate was evaluated via visual analog scale (VAS). Only three patients were not satisfied with results of their treatment. Two of them have a recurrence of stress urinary incontinence and one with urgency urinary incontinence.

Interpretation of results

Objective and subjective cure rates for Ophira remains at 92,86% and 82.14% respectively within 12 months after surgery. Urgency symptoms disappeared in almost 40% of patients.

Concluding message

Ophira mini sling is an effective and safe method for treatment of SUI in female patients. It has unique fixation system that results to high efficacy rate in short term follow up. This method may be used effectively for treatment of patients suffering stress urinary incontinence with urgency symptoms. Further investigations are necessary for evaluation of long term efficacy.

<i>Specify source of funding or grant</i>	Nothing to disclose
<i>Is this a clinical trial?</i>	Yes
<i>Is this study registered in a public clinical trials registry?</i>	No
<i>Is this a Randomised Controlled Trial (RCT)?</i>	No
<i>What were the subjects in the study?</i>	HUMAN
<i>Was this study approved by an ethics committee?</i>	Yes
<i>Specify Name of Ethics Committee</i>	Ethics Committee of Moscow State Medical Stomatological University (MSMSU)
<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes