

THE IMPROVEMENT OF QOL AFTER MID-URETHRAL TFS SLING OPERATIONS FOR URODYNAMIC SUI IN OUTPATIENT CLINIC – 1YEAR RESULTS-

Hypothesis / aims of study

The TFS (Tissue Fixation System) is a new "minisling" device with a one-way tightening system.¹ We reported 1year results of mid-urethral TFS sling operations for 44 SUI (stress urinary incontinence) patients in outpatient clinic on 2009.² We reported the results which were increased the number of men and were described of QOL in detail so as to test the feasibility of using the TFS to perform a mid-urethral sling for urodynamic SUI in a free-standing outpatient facility this time.

Study design, materials and methods

Materials and methods :We performed 72 mid-urethral TFS sling operations between December 2006 and March 2009 at Yokohama Motomachi Women's Clinic LUNA. All patients had urodynamic SUI proven by pre-operative urodynamic testing. All patients had a positive cough stress test, and residual urines were less than 10 ml. We evaluated the patients at 12 months after the operations. Mean age was 61.3±11.6. All patients were Japanese. Average BMI is 23.9±3.74. Menopause rate was 76.3%. They had no previous urogynecologic surgery, no pelvic organ prolaps and no severe psychiatric disease.

Preoperating data: Mean 24 hours pad test result was 53.0±64.8ml. The mean abdominal leak point pressure (ALPP) was 79.4± 32.0 cm of water and mean maximum urethral closure pressure (MUCP) was 29.9± 14.2 cm of water. There was no detrusor overactivity recorded on urodynamic testing. We defined intrinsic sphincter deficiency (ISD) when ALPP was less than 60 cm of water or MUCP less than 20 cm of water. According to this definition, 25 patients (34.7%) out of 72 were diagnosed as having ISD.

Operating data: All operations were performed as described in the manual³ on a day-surgery basis. Average operating time included local anesthesia was 24.1± 7.1 minutes. Average blood loss was 12.0± 14.7 ml.

Five patients could not void spontaneously within 8 hours of the operation. They were discharged with a special indwelling catheter with attached DIB capTM. DIB capTM is a magnetic plug made by DIB international co.ltd. in Japan which allows the patient to urinate and dispenses with a urine bag. All 5 patients voided with no difficulty within 2 days.

Results

Success was defined as no patient reports of leakage during coughing, a negative cough stress test performed with a full bladder, and 24 hour pad test results less than 3gm, 3gm being an average loss from normal vaginal discharge. All patients were followed for at least one year. Success cases were 65 out of 72, that is 90.2 %. Failure cases were 7 out of 72, that is 9.8%. The average total score of International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) of all cases changed from 12.4±4.2 to 2.82±3.31. The average total score of International Incontinence Questionnaire 7(IIQ-7) of all cases changed from 9.55 ±4.51 to 0.66 ±1.11. The average total score of Overactive Bladder Symptom Score (OABSS) changed from 4.30 ±3.00 to 2.26 ±1.64. And the average total score of EuroQol (EQ-5D) of all cases changed from 6.61±1.53 to 5.36±0.68. We re-operated on 5 out of 7 patients with another TFS midurethral sling on 6 months. All 5 patients became continent after re-operation. Eight patients (11.1%) had experienced overactive bladder symptoms post-operatively at 12 months. And there occurred 1 erosion of tape out of 72 cases. This patient had kept continence on 1 year follow up nevertheless the erosive tape was cut.

Interpretation of results

Our results indicate that the TFS mid-urethral sling operation is a simple, safe, and effective operation to improve the QOL of patients who suffer from SUI.

Concluding message

TFS mid-urethral sling operation can be done without difficulty in a free standing clinic as an outpatient procedure.

References

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Is this a clinical trial?	Yes
Is this study registered in a public clinical trials registry?	No
Is this a Randomised Controlled Trial (RCT)?	No
What were the subjects in the study?	HUMAN
Was this study approved by an ethics committee?	Yes
Specify Name of Ethics Committee	Medical Corporation Leading Girls Ethics Committee

<i>Was the Declaration of Helsinki followed?</i>	Yes
<i>Was informed consent obtained from the patients?</i>	Yes
