

## Efficacy of Mini Sling System in the Management of Stress Incontinence: 1 Year Follow-Up Data

<sup>1</sup>Asuman Ozkan, <sup>2</sup>Yakup Kumtepe and <sup>3</sup>Ilhan Bahri Delibas  
<sup>1</sup>Department of Biochemistry, Regional Research and Education Hospital,  
Erzurum, Turkey  
<sup>2</sup>Department of Obstetrics and Gynecology, Faculty of Medicine,  
Ataturk University, Erzurum, Turkey  
<sup>3</sup>Nenehatun Obstetrics and Gynecology Hospital, Erzurum, Turkey

**Abstract:** The objective of this study was to evaluate the 1 year success of the Mini Sling System in the treatment of Stress Urinary Incontinence (SUI). The subjects were 22 patients who had been treated with the Mini Sling system between July 2009 to January 2010 in the clinic. After diagnosis of genuine SUI by history, physical examination, cough stress pad test and urodynamics. The patients were evaluated at postoperative 1st, 3rd, 6th and 12th months, in terms of urinary incontinence, dyspareunia and lower urinary tract infection and symptoms. The mean operation time was 7 min. There were no intraoperative complications. At the 1st week of surgery, the Mini Sling System was totally removed from a patient due to confirmation of treatment failure. One patient had tissue reaction manifested by a palpable right inguinal nodularity at the postoperative 6th month and treated with partial mesh excision following antibiotherapy. The patient remained continent throughout the follow-up period. There were no other procedure-related complications detected within 1 year of follow-up. Objective cure and failure rates at 1 year follow-up were 95% (21/22) and 5% (1/22), respectively. In conclusion, the Mini Sling System is easy to use and effective minimally invasive method in the treatment of genuine stress incontinence.

**Key words:** Mini Sling System, stress urinary incontinence, success rate, follow-up, Turkey

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### INTRODUCTION

From the 1st operation for stress incontinence in the early 1900s to until the early 1990s, treatment of Stress Urinary Incontinence (SUI) remained essentially unchanged. Treatment of SUI was by vaginal repair or major abdominal surgery, broadly termed bladder neck elevation surgery. Enhorning's 1961 Pressure Transmission Theory became widely accepted as a rational anatomical explanation for the bladder neck elevation technique and the most popular operation of this genre was the Burch colposuspension which gradually became accepted as the gold standard (Burch, 1968). Between 1990 and today there has been an exponential change in the surgical treatments offered for USI. Petros and Ulmsten described the Tension free Vaginal Tape (TVT) operation which was revolutionary because it was a minimally invasive day-care operation (Petros and Ulmsten, 1990). This technique has minimal pain no significant post-operative urinary retention and high success rate. However, reports of small bowel and

external iliac artery perforations were major causes of concern. Delorme's transobturator approach has significantly decreased such complications with an almost equivalent cure rate (Delorme, 2001). However, the Transobturator Tape (TOT) has its own major complications such as obturator nerve and artery damage, groin pain even bladder perforation.

A more recent development is the Mini Sling System to avoid the complications inherent to the TVT and TOT procedures. In this study researchers aimed to evaluate the Mini Sling System in terms of its efficiency and lower urinary tract infections and symptoms.

### MATERIALS AND METHODS

The study was carried out in the Gynecology Department of Ataturk University Faculty of Medicine. Twenty two patients with urodynamically proven SUI were operated with the Mini Sling System (Ophira<sup>®</sup>, Promedon<sup>™</sup>) between June 2009 to January 2010 (Fig. 1). The patients were evaluated with a full clinical history,

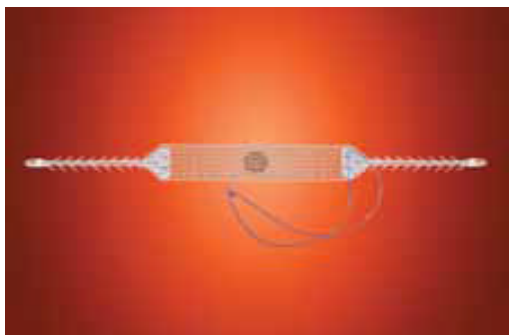


Fig. 1: The Mini Sling System

pelvic and urogynecologic examination, pelvic ultrasound, Urinary Distress Inventory-6 (UDI-6) questionnaire (Cam *et al.*, 2007), urodynamics before the operations and Cough Stress Pad Test (CSPT). All patients were checked for urinary infections using urinalysis. If it was necessary, urinary culture was done. A preweighed pad was placed on the vulva. The patient coughed 10 times with a full bladder, the pad was reweighed and the increased amount was noticed as leaked urine. A urine loss >1 g was regarded as positive for SUI and a loss <1 g was regarded as a negative result. Exclusion criteria were:

- Concomitant pelvic organ prolapse
- Residual volumes >100 cm<sup>3</sup>
- Acute urinary tract infection
- Recurrent stress urinary incontinence
- Overflow incontinence
- Neurological lesions
- Overactive bladder

All patients participated to the study after informed consents were taken and the local ethics committee of the hospital accepted the study.

The patients were evaluated at 1st, 3rd, 6th and 12th months. The primary outcome measures were objective cure rate and failures 1 year after the anti-incontinence surgeries. Secondary outcome measures were duration of procedure, dyspareunia, postoperative urinary retention, the impact of SUI on quality of life and mesh extrusion.

If CSPT was negative after the operation and the patient reported restoration of urinary continence then it was regarded as objective cure. If CSPT was positive or no change in the incontinence complaint was noted after the operation then it was regarded as failure.

The operations were performed as described by Palma (2011). After injection of 10 mL of 2% lidocaine solution at the midurethra towards the vaginal fornix, advancing 2 cm in the obturator internus muscles,

provided adequate local anesthesia, a vertical 1 cm incision was performed at 1 cm from the urethral meatus. Minimal vaginal dissection was performed laterally towards the ascending ramus of the ischiopubic bone, preserving the endopelvic fascia. The delivery trocar was introduced through the small vaginal incision, guided by the surgeon's index finger previously introduced at the vaginal fornix to avoid vaginal wall perforation. Once the needle was felt at the fornix, the tip was introduced towards the obturator internus muscle, 1 cm above the vaginal fornix. When half of the mesh was within the incision, the deploying bottom at the handle of the mini trocar was retracted, deploying the sling in place, allowing for the self-anchoring fishbone columns to provide strong primary fixation. The same maneuvers were repeated on the other side. Total follow-up period was 18 months (29±12 months).

All the data were recorded using standard forms. Data were analyzed using SPSS 11.5 (Statistical Package for Social Sciences) for Windows and the results were presented as mean±standard deviation and frequency distribution.

## RESULTS

The demographic characteristics of the patients who were operated due to stress urinary incontinence were given in Table 1. Excluding time for anesthesia, the mean operative time was 7 min. There were no intraoperative complications such as injury of bladder and urethra or profuse bleeding, encountered in any of the patients. Twenty patients were discharged at the day of surgery while two patients in whom urinary retention developed were discharged 2 days after the operation.

Patients were questioned 1, 3, 6 and 12 months after the operation in terms of urinary incontinence, lower urinary tract symptoms and dyspareunia. Neither early complications (i.e., bleeding, pelvic pain and severe urinary obstruction necessitating loosening or removal of the Mini Sling System) nor late complications (i.e., mesh exposure and sexual dysfunction) were developed. Laboratory analyses confirmed free of urinary tract infections. Two patients experienced postoperative urinary retention which resolved spontaneously 48 h after urinary Foley catheter remained in place. At the 1st week of surgery in one patient who reported no change in symptoms of incontinence, the Mini Sling System was totally removed under local anesthesia after confirmation of treatment failure by a positive CSPT. One patient had tissue reaction around the tip of the right fixation arm located within the obturator internus muscle which was

Table 1: Some demographic characteristics of the patients

Mean of age (years)	50.5
Average of parity (range)	3.66 (2-7)
Average number of vaginal birth (range)	3.16 (2-7)
Average of incontinency period (months)	40.08 (0-0)

manifested by a palpable right inguinal nodularity at the postoperative 6th month and treated with partial excision of the right fixation arm following antibiotherapy. The patient remained continent throughout the follow up period. There were no other procedure-related complications detected within 1 year of follow up. While all patients had positive CSPT and had UDI-6 scores between 9 and 14 preoperatively, at the end of postoperative 1st year except for the patient who had total mesh removal and regarded as failure at the 1st week, all patients had negative CSPT and UDI-6 score detected as 0. Objective cure and failure rates at 1 year follow-up were 95% (21/22) and 5% (1/22), respectively.

## DISCUSSION

In recent years, introduction of new concepts concerning the pathophysiology of stress urinary incontinence and in particular integral theory has led to emergence of many surgical techniques in the treatment. Today, Mini Sling meshes are being applied with well standardized techniques. Moreover, they can be applied with local anesthesia that lead to less postoperative pain and quicker return to daily activities (Palma, 2011).

There is controversy in the literature on the efficacy of Mini Sling System. Lim *et al.* (2010) halted their study recruitment due to high number of early failures. Moreover, Basu and Duckett (2010) reported that the Mini Sling System was associated with a higher failure rate than a retropubic TVT. On the other hand, Sekiguchi *et al.* (2009) noted a 91% cure rate after Mini Sling (Tissue Fixation System, TFS®) surgery. In the study researchers achieved 95% objective cure rate at 1 year follow up. Groin and lower extremity neuropathy, a specific complication associated with the full length transobturator mesh procedures was reported to occur in 15-24 and 4.75% of the patients in short and long term, respectively (Lim *et al.*, 2006; Roth, 2007). Such a complication is not expected to occur following mesh procedures like Mini Sling which does not involve application of persistent material within or near the obturator foramen.

There has been continuing evolution within Mini Sling Systems. The 1st Mini Sling clinical series was presented by Smith and Hilton (2008) with 2 years follow up data. Their data showed well tolerance of local anesthesia, reduced recovery period and low complication

rate. However, in further studies short-term effectiveness of those early Mini Sling Systems, in which mesh ends were not stabilized within the tissue were reported to be as low as 60%, significantly lower than full length mesh systems thus their routine use became unjustified (Bacarat, 2008). These results were attributed to the failure of stabilizing the mesh to the tissue at the very time of surgical procedure thus maintaining tissue fixation was thought to increase effectiveness. With this aim, the Mini Sling System removing the possibility of early sling slippage was developed. The system that researchers used in this study was a stabilized Mini Sling System thanks to the multiple fixation points along its fishbone shaped self-anchoring arms made up of biosynthetic material.

Except for the patient in which Mini Sling System failed to cure SUI and removed at the postoperative 1st week, no sign of sling loosening or incontinence in any of the patients was detected within 12 months after surgery. In addition to early failure of the mesh to cure SUI in one patient at the 1st week of surgery, maintenance of continence in the patient with right inguinal nodular reaction despite excision of 60% of the right fixation arm at the 6th month after surgery, confirms the importance of early fixation that researchers mentioned before. Researchers think that development of shorter and lighter fixation arms which reduce foreign body load without impairing fixation will reduce long term mesh complications such as translocation and erosion.

## CONCLUSION

Although, size of the study population was small, results were exciting for the success of Mini Sling System in the treatment of stress incontinence. Accumulation of data from randomized controlled studies with larger numbers and longer follow up periods are needed to determine long-term success rates. Consequently, researchers suppose that the Mini Sling System is easy to use and effective minimally invasive method in the treatment of genuine stress incontinence and researchers believe that its use will increase gradually.

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