

## ORIGINAL ARTICLE

# The Evaluation of Long-Term Outcomes of Outside-in Transobturator Tape Procedure in the Treatment of Stress Urinary Incontinence

 Alim Gökhan Kuşgöz<sup>1</sup>,  Ertugrul Can Tüfekçi<sup>2</sup>,  Fisun Vural<sup>2</sup>,  Ayşe Deniz Ertürk Coşkun<sup>2</sup>

<sup>1</sup>Department of Obstetrics and Gynecology, Special Izmiryolu Sevgi Hospital, Balıkesir, Türkiye

<sup>2</sup>Department of Obstetrics and Gynecology, Haydarpaşa Numune Training and Research Hospital, University of Health Science, İstanbul, Türkiye

## Abstract

**Introduction:** The objective of the study was to investigate the objective-subjective success rates and complications of outside-in transobturator tape (TOT) surgery with urinary distress inventory (UDI)-6 questionnaire and subjective assessment after 5 years follow-up.

**Methods:** We analyzed 60 women with stress urinary incontinence who underwent outside-in TOT procedure by the same surgeon and mesh, and were followed up after 5 years. All patients' gynecological examination findings, stress test, Q-tip test, pad test, residual urinary volume, UDI-6 questionnaire, and duration of operation and complications were recorded. 3 years and 5 years after surgery, all patients were evaluated for anatomic-functional outcomes and subjective patient satisfaction.

**Results:** The mean age of the population was  $51.92 \pm 7.31$  years, and 50% of the women were postmenopausal. Two patients (3.3%) had intraoperative bladder injury. Among long-term complications, one patient had (1.6%) de novo urge incontinence. There was no mesh erosion in the 5 years follow-up. When we compared the pre-operative and 5-years post-operative Q-tip test angles, a significant decrease was observed ( $63.92 \pm 14.17$ ;  $25.08 \pm 9.68$ ) ( $p=0.001$ ). UDI-6 question 3,4 survey scores were also significantly lower in the 5th year follow-up ( $p=0.001$ ). At the end of 5 years, we observed an objective success in 82.9% of the patients. The patients also reported a subjective improvement of 82.9%.

**Discussion and Conclusion:** If proper surgical technique is used, outside-in TOT procedure is an efficient and safe method with high objective and subjective cure rates and low complication rates after a 5 year follow-up.

**Keywords:** Mesh; stress incontinence; transobturator tape; urinary incontinence.

International continence society (ICS) defines urinary incontinence (UI) as involuntary loss of urine which can be shown objectively and causes a social or hygienic problem. Stress urinary incontinence (SUI) was defined as an involuntary incontinence pattern that occurred with the intravesical pressure exceeding the urethral pressure and without an increase in detrusor activity. The prevalence among

women of age 15–64 is reported as 10–30% in the literature<sup>[1,2]</sup>. SUI prevalence in Turkey has been reported as 4.7% among women of ages 15–24, 21.6% among ages 35–44, 25.15% among ages 55–64, and 21.9% among women aged 65 and older<sup>[3,4]</sup>. Women are 4–5 times more likely to have SUI compared to men, and multiparity, advanced age, and menopause are the prominent risk factors<sup>[4]</sup>.

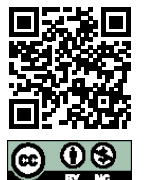
**Correspondence (İletişim):** Alim Gökhan Kuşgöz, M.D. Özel İzmiryolu Sevgi Hastanesi, Balıkesir, Türkiye

**Phone (Telefon):** +90 535 855 08 27 **E-mail (E-posta):** agkusgoz@yahoo.com

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Considering the longer life expectancy of today a better quality of life at older ages is a reasonable wish. Therefore, surgical correction with its high success rates is a preferred option for this condition that can cause a significant decrease in the quality of life and restrict social life.

Stress incontinence patients are most likely to benefit from surgery among different types of incontinence. Surgical procedures work on the principle of raising and supporting the urethrovesical junction<sup>[5,6]</sup>. These procedures can be grouped into 4 main groups as; colposuspension, colporaphy anterior, needle suspensions, and sling procedures<sup>[6]</sup>.

Sling surgery has been used for incontinence surgery since the beginning of the 20<sup>th</sup> century. The surgical procedure for SUI should make the patient continent and improve her quality of life while being minimally invasive. The tension free vaginal tape (TVT) was the first alternative to burch colposuspension. Transobturator tape (TOT), later developed by Delorme avoided the retropubic space and related complications<sup>[4]</sup>.

There is no clear consensus on the type of surgery a certain type of patient is likely to benefit from. Studies on the long-term success and complications of different techniques will eventually lead to a consensus. The long-term outcomes of TOT surgery have recently started being reported in literature. This study aims to research the success rates, subjective satisfaction and quality of life changes 5 years after TOT surgery for SUI.

## Materials and Methods

The study was done in the Gynecology clinic of Haydarpaşa Numune Training and Research Hospital. Ethical approval was obtained from Haydarpaşa Numune Institutional Board. The hospital records between January 2008 and June 2011 were scanned. Patients who had TOT surgery for stress incontinence by the same surgeon were included in the study. Those with incomplete records, those who had repeated incontinence surgery, different surgical technique, diabetes, and steroid use were excluded from the study. The study was completed with 60 patients eligible to participate in the study. The out-in-technique with a multifilament mesh was used for surgery. The same reusable ergonomically designed custom made instrument was used for each operation keeping the costs at minimum.

Patients with diabetes, collagen diseases, neurological problems and those receiving immunosuppressive treatment were not included in the study. Patients, who had missing data in their files, were operated by a different surgeon, and those who could not be reached with the available contact

number were also excluded. The history of all patients taken before TOT surgery; their age, parity, weight, height, medical conditions, treatments, hormone replacement usage, incontinence type, and duration was examined.

All patients had pelvic and gynecological examination including transvaginal pelvic ultrasound. They filled the Turkish version of urinary distress inventory (UDI) – 6, pre-operative Q- tip test angle and post void residual urine volume measurement was recorded. Pre-operative complete blood count and urine analysis was done and a negative urine culture was affirmed. All patients were called at post-operative 1<sup>st</sup> and 3<sup>rd</sup> months and evaluated for early complications and continence, and the results were recorded.

Sixty patients that could be contacted were invited and evaluated 3 and 5 years postoperatively. For a more objective evaluation examination, Q-tip test, stress test, and pad test was done by another researcher (AGK) other than the one performing the surgeries. Subjective satisfaction was evaluated with a Likert test with three questions. A short questionnaire with choices “better, same as before, worse” was asked to be filled. The “better” response indicated that the patient’s condition improved with surgery, “same as before” response indicated no improvement with surgery, whereas “worse” response indicated a worsening of the condition after surgery. Objective success was evaluated with stress test.

Patients with objective incontinence were considered not successful. Patients with a negative stress test and no incontinence complaint were considered as “objectively cured.” If the patient had a positive stress test but did not complain of incontinence, she was considered “subjectively cured.” If the patient had a negative stress test and a dry pad test but had complaints of incontinence they were considered “subjectively not successful.”

Number Cruncher Statistical System (NCSS) 2007 and Power Analysis and Sample Size (PASS) 2008 Statistical Software (Utah, USA) was used for statistical analyses. Data were analyzed with descriptive statistical methods (mean, standard deviation, median, frequency, ratio, minimum, and maximum) and Wilcoxon Signed Ranks test was used for comparison of quantitative data with non-normal distribution.  $P < 0.05$  was considered significant.

## Results

The woman in the study population was aged between 40 and 66 years, the mean being  $51.92 \pm 7.31$  years. Half of the patients were postmenopausal (50%,  $n=30$ ). All patients had vaginal deliveries (Table 1).

**Table 1.** Sociodemographic and clinical characteristics of surgical cases

	Min-Max	Mean±SD
Age (year)	40–66	51.92±7.31
Height (m)	1.50–1.70	1.59±0.05
Weight (kg)	47–105	78.30±11.02
BMI (kg/m <sup>2</sup> )	19.56–41.02	31.14±4.72
Parity	2–15	4.15±2.52

### Surgical and Perioperative Complications

Operation times varied between 10 and 40 min, 20.15±8.39 min being the mean. Patients who had other surgery had an extra operation time of 5–70 min, 19.09±16.51 being the mean. Hospital stay times varied between 1 and 7 days, 1.63±0.94 being the mean. Patients without extra operations were discharged on the 1<sup>st</sup> post-operative day. Only one patient stayed until the 7th post-operative day for post-operative fever.

About 55% (n=33) of the patients had an additional operation. About 82% (n=27) of these 33 patients had colpo-raphyanterior-posterior (CAP), 3.03% (n=1) had hystero-scopic polyp resection(H/S), 3.03% (n=1) had conization and CAP, 3.03% (n=1) had laparoscopic tubal ligation (L/S), 3.03% (n=1) had total abdominal hysterectomy and bilateral salpingoopherectomy (TAH + BSO) 3.03% (n=1) had vaginal hysterectomy (VH), and CAP. 46.7% (n=28) of the patients had general anesthesia, 53.3% (n=32) had spinal anesthesia. About 3.3% (n=2) of the cases had bladder injury, 1.7% (n=1) needed cystoscopy. One patient required longer hospitalization for fever with unidentified cause. Urinary retention, de novo urge incontinence and de novo dysuria was not seen.

### Post-Operative Results

1. Surgical success and subjective satisfaction: Three years after the surgery 85% (n=51) of participants evaluated the subjective result of their operation as “better,” 11.7% (n=7) as “same as before” and 3.3% (n=2) as “worse.” One patient who reported worsening of her symptoms was questioned further to reveal a story of urge incontinence starting much later than surgery (de novo urge incontinence) and was successfully treated with an anticholinergic drug. Objective evaluation was done with stress test, pad test, and Q-tip test. The 3 years and 5 years success rates and subjective satisfaction rates were 85% and 82.9% for the 3rd year and 82.9% and 82.9% for the 5th year, respectively (Table 2).

**Table 2.** 3 year and 5 year success rates

	3 year results	5 year results
Objective success	85%	82.9%
Subjective success	82.9%	82.9%
Failure	15%	17.1%

2. Anatomic results and quality of life questionnaire: Comparing the pre-operative Q-tip angles (63.92±14.17) and post-operative Q-tip angles (25.08±9.68) resulted in an average of 25.08±9.68 degree reduction in the angle which is statistically significant (p<0.01) (Table 3). The evaluation of the pre-operative and post-operative UDI-6 quality of life questionnaires reveals statistically significant changes in all question groups (Table 4).

### Discussion

Urinary incontinence is a sociocultural and medical problem with high prevalence. SUI surgery should aim maximum success and satisfaction with minimally invasive procedures and low complication rates. TOT surgery is preferred for easy application, short surgery time, and short hospital stay. This study aimed to assess the long-term outcomes of TOT surgery. The study shows that TOT surgery done by the same surgeon using the same technique (out-

**Table 3.** Evaluation of Q-tip test before and after the surgery

	Q-tip			p
	Min-max. (median)	Average±SD	Change	
Preop	35–90 (62.5)	63.92±14.17	38.83±12.12	0.001**
Postop	5–45 (27.5)	25.08±9.68		

<sup>a</sup>Wilcoxon signed ranks test. p<0.01\*\*.

**Table 4.** Evaluation of pre-operative and 5-year follow-up UDI-6 measurements

	Preoperative	5 <sup>th</sup> year	Variation	p
UDI-6 Question 1–2				
Mean±SD	2.32±1.23	1.83±1.14	0.48±0.89	0.001
Min-Maks. (median)	0–4 (2)	0–5 (2)		
UDI-6 Question 3–4				
Mean±SD	3.80±0.58	1.63±0.86	2.17±0.96	0.001
Min-Maks. (median)	3–5 (4)	1–4 (1)		
UDI-6 Question 5–6				
Mean±SD	1.17±0.69	1.02±0.79	0.15±0.58	0.047
Min-Maks. (Median)	0–4 (1)	0–4 (1)		

<sup>a</sup>Wilcoxon signed ranks test. p<0.05\*. p<0.01\*\*.

in) and using the same multifilament mesh has given secure and successful long-term results.

TVT introduced in 1996 by Ulmsten et al.<sup>[7]</sup> was the first alternative to traditional incontinence surgeries and has been performed as a successful minimally invasive surgery for 20 years. Even though success rates are as high as 84–88%, injuries of bladder, intestine or major vessels, development of de novo urge incontinence and postoperative voiding dysfunction has necessitated the search for a different technique. Delorme has developed the TOT technique through the obturator foramen in 2001 and the technique has been widely accepted since. A total of 7101 women have been included in a meta-analysis of 62 randomized controlled studies. Both techniques have high subjective and objective cure rates (TOT: 84%, TVT: 88%). Perioperative complications such as bladder perforation, voiding dysfunction, and blood loss are less frequent with TOT technique. However, this comparison involves short-term results. Long-term results recently started being published. The results indicate that TOT is successful, however with more long-term complications<sup>[8,9]</sup>.

Arrabal-Polo et al.<sup>[10]</sup> reported their complication rate as 12%. Kaelin-Gambirasio et al.<sup>[11]</sup> have reported similar complication rates. In our study, early complication rate was 4.9%, 2 patients had bladder injury (3.3%) and 1 patient required longer hospitalization (1.6%). Vaginal injury, voiding dysfunction, or bleeding was not observed. Even though perineal pain has been reported in literature up to 16%, we did not observe a case which required unusual amounts of analgesia or a steroid injection for obturator nerve neuropathy<sup>[12]</sup>.

The 3 year and 5 year objective and subjective cure rates are similar in our study (3 year: 85%, and 5 year: 82.9%). These rates are higher than the 74% reported by Groutz et al.<sup>[13]</sup> in their 61 patient study, and the 72% reported by Angioli et al.<sup>[14]</sup> in their 32 patient study<sup>[14,15]</sup>. The cure rates of Cheng and Liu<sup>[15]</sup> in their 103 patient study (87.4%) and Yonguc et al.<sup>[16]</sup> in their 126 patient study (87.3%) is similar to our rates. Comparison of preoperative Q tip test values and UDI-6 scores to post-operative values show significant improvement. These results are similar to those of Sopalı et al.<sup>[17]</sup> Considering patients who had mixed urinary incontinence preoperatively and were operated for the stress incontinence component, there are studies in the literature which show improvement in the urge component postoperatively<sup>[18,19]</sup>. Looking at the first and second questions of UDI-6 questionnaire which measure urge incontinence, there is statistically significant postoperative decrease in urge incontinence in our study group.

The most frequent long-term complications of TOT surgery are de novo urge incontinence and mesh erosion. Now that long-term results have started being published the long-term complications can be evaluated more clearly. In our study one patient had de novo urge incontinence (1.6%) which is similar to the results in literature. Ballert et al.<sup>[12]</sup> reported de novo urge incontinence rates as 0.2–15% after TVT operation and 2.1–13.9% after TOT operation. Another undesired complication after TOT surgery is early or late mesh erosion. Deval et al.<sup>[20]</sup> reported vaginal erosion rates of 0.7% for TVT and 13.8% for TOT. A meta-analysis by Latthe et al.<sup>[21]</sup> reported the vaginal mesh erosion rates of TOT surgery to be twice that of TVT surgery. Most of the mesh erosions are asymptomatic and are not diagnosed unless the patient is examined. Our patients all had a vaginal examination on the fifth post-operative year, and no mesh erosions were diagnosed. It is stated in the literature that surgical technique and mesh type are the main factors leading to mesh erosion<sup>[8,12]</sup>. Erosion is less frequent with monofilament macropore meshes<sup>[12]</sup>. The lack of erosion in our patients even though multifilament meshes have been used may be due to our patient selection criteria (diabetic and immunosuppressed patients were excluded from the study) and that the operations were performed by the same surgeon using the same technique.

The most important restriction of our study is the retrospective design. However, the regular recordings of patient data are an advantage. Another aspect which makes our study strong is that all surgeries have been performed by the same surgeon, with the same technique and the same material (out-in and multifilament mesh) with low cost. Not including patients with recurrent incontinence surgery, patients with diabetes and those using steroids and performing additional surgeries for pelvic organ prolapse if needed may explain our success rates similar to those in the literature and our low complication rates.

## Conclusion

TOT surgery is a safe procedure for stress urinary incontinence with low complication rates and high long-term success and subjective satisfaction rates. This study emphasizes that surgical technique and patient selection are the main factors effecting TOT surgery success. To reach a clear consensus on the long-term results and complications of TOT surgery prospectively designed studies following the patients for longer periods such as 10 years are needed.

**Ethics Committee Approval:** Institutional review board approval was taken.

**Peer-review:** Externally peer-reviewed.

**Authorship Contributions:** Concept: A.G.K.; Design: A.G.K., E.C.T.; Data Collection or Processing: A.G.K.; Analysis or Interpretation: A.G.K., A.D.E.C.; Literature Search: A.G.K., F.V.; Writing: A.G.K., A.D.E.C.

**Conflict of Interest:** None declared.

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