

# Modified Autologous Transobturator Mid-urethral Sling Surgery for the Treatment of Female Stress Urinary Incontinence: Initial Results

## Kadın Stres Üriner İnkontinans Tedavisinde Modifiye Otolog Transobturator Midüretal Askı Cerrahisi: İlk Sonuçlar

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Received: 19.12.2018

Accepted: 26.12.2018

Available online: 28.12.2018

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**ABSTRACT Objective:** The goal of this study is describe mid-urethral sling surgery without mesh usage to avoid mesh related complications. For this purpose our modified transobturator mid-urethral sling technique with the short-term results was evaluated. **Material and Methods:** The data of 20 patients performed modified transobturator mid-urethral sling with autologous tissue were recorded. The primary endpoints of this study were improvements in The International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS) scores and quality of life scores, one-hour pad test measurements, and cough stress tests rates as an objective cure, and Patients Global Impressions of Improvements (PGI-I) scale as a subjective cure. Categorical variables were compared using a paired Student's t-test. **Results:** Twenty patients with a mean age of 50.5±3.3 years and mean body mass index of 28.9±3.9 kg/m<sup>2</sup>, were enrolled in the study. The mean follow-up time was 3.9±0.8 months. Mean operation time was 42.7±7.5 minutes, and complication rates were 1/20 (5%). The mean PGI-I score was 2 postoperatively which means much better than preoperatively. The positive cough test rate and one-hour pad weight gain were statistically lower postoperatively. The decreases of subscores and quality of life scores of the incontinence section were statistically significant. The total ICIQ-FLUTS score and quality of life scores were significantly reduced in the postoperative period. **Conclusion:** To avoid mesh related complications of mid-urethral sling surgeries, our modified transobturator mid-urethral sling technique is a feasible option for patients and surgeons with its short-term effectiveness and safety profile.

**Keywords:** Stress urinary incontinence; autograft; midurethral sling surgery; mesh; autologous fascial sling

**ÖZET Amaç:** Bu çalışmada, stres üriner inkontinans tedavisinde sentetik meşlerle ilişkili komplikasyonlardan kaçınılabilmek için sentetik meş kullanmadan midüretal askı cerrahisi tanımlanmak istenmiştir. Bu amaçla modifiye otolog transobturator midüretal askı cerrahisi (m-OTOT) tekniğimizin kısa dönem sonuçları sunulmuştur. **Gereç ve Yöntemler:** m-OTOT uygulanan 20 hastanın preop ve postop "The International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS)" skorları, 1 saatlik ped testi ölçümleri, stres testi sonuçları, yaşam kalitesi ölçeği (QoL) ve postop "Patients Global Impressions of Improvements (PGI-I)" skalasını içeren datalar toplandı. Kategorik değişkenler, eşleştirilmiş bir Student t-testi kullanılarak karşılaştırıldı. **Bulgular:** Yaş ortalaması 50,5±3,3, beden kitle endeksi 28,9±3,9 kg/m<sup>2</sup> olan 20 hastanın ortalama takip süresi 3,9±0,8 aydır. Ortalama ameliyat süresi 42,7±7,5 dakika ve komplikasyon oranı 1/20 (%5) (lokal tedavi ile iyileşen vajinal erozyon)'dir. PGI-I skoru 2 olarak belirtilmiştir ve ameliyat öncesine göre daha iyi olma durumunun karşılığıdır. Pozitif stres test oranı ve 1 saatlik ped testinde ağırlık artışı oranları postoperatif dönemde anlamlı olarak düşüktü. ICIQ-FLUTS formunda inkontinans bölüm skoru ve inkontinans bölümü yaşam kalitesi skoru postop dönemde anlamlı iyileşme göstermiştir, ayrıca toplam ICIQ-FLUTS skorü ve toplam yaşam kalitesi skoru da anlamlı olarak iyileşmiştir. **Sonuç:** Stres üriner inkontinans cerrahisinde mesh ile ilişkili komplikasyonlarından kaçınmak için, modifiye transobturator orta üretal sling tekniğimiz, kısa süreli etkinliği ve güvenlik profili ile hastalar ve cerrahlar için uygun bir seçenektir.

**Anahtar Kelimeler:** Stres üriner inkontinansı; otogreft; midüretal askı cerrahisi; mesh; otolog fasiyal askı

Mid-urethral sling surgeries (MUSS), transobturator-tape (TOT) or tension-free vaginal tape (TVT) with non-absorbable synthetic material are the most common surgery for stress urinary incontinence (SUI).<sup>1</sup> MUSS procedures have been supported by literature with its advantages such as short operation time, less morbidity, lower postoperative voiding dysfunction, outpatient characteristics, and good long-term results.<sup>2</sup> The use of synthetic tape materials causes mesh-specific complications such as bladder or urethral erosion, mesh migration, mesh site infections, and vaginal erosion.<sup>3</sup> These complications cause surgical interventions aiming to revise or remove the meshes, and reduce irreversible symptoms and the emotional distress on patients.<sup>4</sup> The complication rates caused by meshes have been reported to be up to 7.3% after MUSS.<sup>5</sup>

In the last decade, the United States Food and Drug Administration (FDA) released public health notifications about meshes and classified meshes as class 3 devices (highest risk devices) for pelvic organ prolapse (POP) surgery and class 2 for SUI surgery.<sup>6</sup> In these reports, it was stated that mesh sling surgeries were similarly effective to non-mesh surgeries, and caused complications that were not present in non-mesh surgeries. Although these reports were not directly about mesh use in SUI surgery, after these reports patients, surgeons, and legal communities have been increasingly questioning the mesh use for SUI.<sup>7</sup> Television advertisements have been the most common source of public knowledge about mesh complications and patients have been unwilling to undergo mesh surgeries, and litigation related with mesh complications has increased since the FDA reports. Currently, patients are increasingly reporting symptoms while complication rates have remained stable after MUSS.<sup>8</sup>

Although current guidelines still recommend MUSS, sling surgeries with autologous tissues are being discussed in the current literature.<sup>1,9</sup> The pubovaginal sling procedure, which has been known for almost a century and is traditionally reserved for intrinsic sphincter deficiency and failure of MUSS and concomitant periurethral surgery,

has been re-popularized for SUI.<sup>9,10</sup> Linder et al. modified the TOT procedure without synthetic mesh by using autologous tissue and published good short-term outcomes.<sup>1</sup> El-Gamal et al. described a hybrid TOT sling to reduce the total mesh amount in MUSS.<sup>11</sup>

Nowadays, the optimal surgical technique for SUI in patients who are unwilling to undergo mesh surgery is unknown. In this study, we present the initial results of a modified transobturator mid-urethral sling with autologous tissue.

## MATERIAL AND METHODS

After Institutional Review Board approval (Haseki Training and Research Hospital, 2017/599), 20 patients underwent modified autologous transobturator mid-urethral sling surgery (MATOMS) for SUI between December 2017 and February 2018. Patients were evaluated through a detailed history, pelvic examination including urethral hypermobility test, cough stress test in the lithotomy and standing position, POP examination, urine culture, and measurement of post-void residual volume (PVRV). The International Consultation on Incontinence Questionnaire-Female Lower Urinary Tract Symptoms (ICIQ-FLUTS), which is a validated form used for the evaluation of lower urinary tract symptoms and quality of life in three sections (frequency, voiding, and incontinence) was administered to all patients. To assess SUI objectively, the one-hour pad test, which is standardized by the International Continence Society (ICS) by briefly measuring weight gain of pads after a standard protocol, was used. A 1 g weight gain was the threshold value for mild incontinence, 10 g for moderate, and 50 g for severe incontinence. POP greater than grade 2 according to the Pelvic Organ Prolapse Quantification (POPQ) system, pregnancy, previous history of pelvic radiation, previous history of SUI surgery, increased PVRV (more than 150 cc) and history of neurologic disease were the exclusion criteria.

Patients who were reluctant for conservative management or were not satisfactorily informed about the surgical options for SUI. In this study, all

patients were aware about the current concerns related with non-autologous synthetic mesh surgeries and they were disposed to non-mesh surgical options.

### SURGICAL TECHNIQUE

After induction of general anesthesia, a Foley catheter was inserted for drainage of bladder and a weighted vaginal speculum was used. Following hydrodissection of the anterior vaginal wall, a 2-cm longitudinal incision was performed through the midurethra with the patient in the lithotomy position. Simultaneously, 5 cm of rectus fascia was harvested via a 3-cm suprapubic incision. Two non-absorbable 2-0 polyester (Ethibond®, Ethicon) stay sutures were placed on the corners of the fascial graft. Two separate punctures were performed on both sides over the medial aspect of the obturator foramen at the level of the clitoris and the dissection continued to the foramen. A TOT needle was passed twice through the foramen and transferred the stitches from the vaginal incision to the skin. A bridge was performed on the obturator membrane by separate stitches. Graft was positioned to midurethra without tension and sutures were tied. Vaginal and thigh incisions were closed separately. Vaginal packing was placed and removed when the patient was discharged.

### FOLLOW-UP

Perioperative data regarding operative time, estimated blood loss (total number of gauze pads used during the surgery), and complications were evaluated and classified in accordance with the Clavien system. Visual analogue scores (VAS) for pain at the postoperative 8<sup>th</sup> and 24<sup>th</sup> hours was noted. All patients were discharged on the first postoperative day after they spontaneously voided at least two-thirds of total bladder volume, which was documented using ultrasonography. Patients were seen after the first postoperative week to evaluate the surgical wound and ask about any surgery-related problems.

At the postoperative third month, all patients were evaluated with a stress test, one-hour pad test, ICIQ-FLUTS, and the PGI-I scale. Requirement for

further surgery due to complications or failure were also noted. The primary endpoints of this study were improvements in ICIQ-FLUTS subscores and quality of life scores, one-hour pad test measurements, and cough stress tests as an objective cure, and PGI-I as a subjective cure.

### STATISTICS

The Statistical Package for the Social Sciences for Windows (SPSS) version 20 was used for statistical analysis. Categorical variables are presented as numbers and percentages. Continuous variables are presented as means and standard deviations and were compared using a paired Student's t-test. Statistical significance was considered when a two-tailed p value was <0.05.

### RESULTS

Twenty patients with a mean age of 50.5±3.3 years and mean body mass index of 28.9±3.9 kg/m<sup>2</sup> were enrolled in the study. The mean follow-up time was 3.9±0.8 months. All patients were in the premenopausal period. The patients' mean parity was 3.3±1.3 and they had not undergone any previous pelvic surgery. Preoperatively, 15 patients were pure SUI, and 5 had stress-dominant mixed urinary incontinence (MUI). All patients had a positive cough test (20/20). Urethral hypermobility was detected in 20/20 patients. The mean weight gain of pads was 55.7±14.0 g in the one-hour pad test; according to this test, 4/20 (20%) patients had moderate and 16/20 (80%) had severe incontinence. Subscores and quality of life subscores of the frequency, voiding, and incontinence sections on ICIQ-FLUTS were 8.4±3.2, 4.9±2.1, 17.4±5.4, and 18.7±8.2, 10.5±3.5, 41.1±3.8, respectively. The total scores and total quality of life of scores of ICIQ-FLUTS were 29.7±4.5 and 70.4±10.9, respectively (Table 1).

The mean operation time was 42.7±7.5 minutes, and complication rates were 2/20 (10%), Clavien grade 1. The mean VAS scores 8 hours and 24 hours postoperatively were 6.3±0.7 and 2.5±1.2, respectively (Table 2).

Positive cough tests were 0/20 at the postoperative third month. The mean weight change of pads was <1 g in the one-hour pad test, and the

TABLE 1: Demographic data.	
Age (year)*	50.5±3.3
Body Mass Index*	28.9±3.9
Parity*	3.3±1.3
Vaginal*	3.0±1.7
C/S*	0.3±0.6
Pelvic Surgery History	0
Menopausa	10 (%50.0)
Incontinence (Pur stress / Mixt)	15/5
DM	1 (%5.0)
ICIQ Frequency*	8.4±3.2
ICIQ Frequency QoL*	18.7±8.2
ICIQ Voiding *	4.9±2.1
ICIQ Voiding QoL*	10.5±3.5
ICIQ Incontinance*	17.4±5.4
ICIQ Incontinance QoL*	41.1±3.8
ICIQ Total Score*	29.7±4.5
ICIQ Total QoL Score*	70.4±10.9

\*: mean+standard deviation.

TABLE 2: Operative data.	
Operation Time*	42.7±7.5
Blood Loss (Sponge)*	5.5±1.4
VAS Score (Post op 8. hours)*	6.3±0.7
VAS Score (Post op 24. hours)*	2.5±1.2
Complication	
Grade 1	1 (%5.0)
Grade 2	0
Grade 3	0

\*: mean+standard deviation.

TABLE 3: Comparison of preoperative and postoperative data.			
	Preoperative	Postoperative	p
ICIQ Frequency*	8.4±3.2	8.7±2.6	0.688
ICIQ Frequency QoL*	18.7±8.2	17.4±5.4	0.380
ICIQ Voiding *	4.9±2.1	5.5±1.9	0.170
ICIQ Voiding QoL*	10.5±3.5	11.3±3.0	0.299
ICIQ Incontinance*	17.4±5.4	7.5±1.6	0.001
ICIQ Incontinance QoL*	41.1±3.8	14.0±3.0	0.001
ICIQ Total Score*	29.7±4.5	21.7±4.3	0.001
ICIQ Total QoL Score*	70.4±10.9	42.7±7.5	0.001

\*: mean+standard deviation.

mild, moderate or severe incontinence rate was 0/20. Subscores and quality of life scores of the frequency, voiding, and incontinence sections on ICIQ-FLUTS were 8.7±2.6, 5.5±1.9, 7.5±1.6 and 17.4±5.4, 11.3±3.0, 14.0±3.0, respectively. The total scores and quality of life scores of ICIQ-FLUTS were 21.7±4.3 and 42.7±7.5, respectively (Table 3).

The mean PGI-I score was 2 postoperatively. The positive cough test rate and one-hour pad weight gain were statistically lower postoperatively ( $p<0.001$  and  $p<0.001$ ). The decreases of subscores and quality of life scores of the incontinence section were statistically significant ( $p=0.001$  and  $p=0.001$ ). The total ICIQ-FLUTS score and quality of life scores were significantly reduced in the postoperative period ( $p=0.001$  and  $p=0.001$ ).

## DISCUSSION

After FDA warnings about mesh use in transvaginal surgeries, although it was not directly about MUSS surgeries, there has been great fear and confusion among patients and surgeons about MUSS.<sup>10</sup> In the study of Rice et al., in which symptoms and complication rates related to mesh were evaluated after the FDA warnings, the complication rates of patients treated with MUSS remained stable, but mesh-related symptoms were significantly increased.<sup>12</sup> After the FDA warnings, the number of MUSS procedures and surgeons performing MUSS decreased in Canada.<sup>13</sup> According to new studies after the FDA warnings, pubovaginal sling and colposuspension surgeries have been re-popularized

and new non-mesh surgical techniques for SUI have been described.<sup>1,2,7-11</sup> As a result of the controversies, we recently started to perform non-mesh surgeries in our patients.

To date, the use of autologous tissue in MUSS has been discussed in the literature in small series with short-term results.<sup>1,8,11</sup> Firstly, El-Gamal et al. described a hybrid mesh, which was an elongated rectus fascia with synthetic non-absorbable mesh on both edges. It was used in TOT procedures of 44 patients.<sup>11</sup> The resulting cure rates were high (92%) and complication rates were comparable with other conventional sling surgeries. The important different of our technique from this technique is their technique did not totally met the concept of non-mesh surgery.

Linder et al. described an autologous transobturator (ATO) urethral sling placement and published their initial results with 10 patients, and early results with 33 patients.<sup>1,8</sup> Retreatment-free survival was 75% at 18 months and it was lower than the current literature rates. The authors noted that inappropriate sling tension or failure to have an adequate bridge between sutures was the reasons for repeat surgery requirements. The basic mechanism of autologous fascial slings is to provide urethral coaptation, urethral compression, and sub-urethral support during effort. Adequate permanent fixation and tension of autologous fascia is crucial for these goals. In our opinion, the use of absorbable polyglactin 910 sutures may decrease the tension on an autologous fascia due to early relaxation and might be reason of their treatment failure. Non-absorbable (polypropylene, polyester) or late absorbable (polydioxanone) sutures are used in pubovaginal sling surgery, which is very similar to ATO.<sup>9,10,14</sup> In our present study, in the absence of long-term results, the higher rates of objective and subjective cure rates than in previous studies is probably related with non-absorbable suture material, and the appropriate and permanent tension provided by its use.

Erosion of periurethral tissues is the most unique and feared complication of MUSS, which is reported in the literature with a range of 0.7-24%.<sup>15</sup> The aetiology of erosions has multiple factors such

as inadequate vaginal closure, wound infection, early sexual intercourse, and synthetic mesh use. Mesh erosion rates have been reduced, but not eradicated, along with improvements in mesh production. In contrast, pubovaginal sling surgeries have no mesh erosions due to their autologous structure. El-Gamal et al. reported that periurethral erosion was not seen due to their hybrid mesh, which has the autologous part in the periurethral area.<sup>11</sup> In our study, only 1 patient had a minimal vaginal exposure smaller than 1 cm, which was treated successfully with estradiol cream.

The objective and subjective cure rates of MUSS, pubovaginal sling, and colposuspension surgeries vary from 62 to 98% in different studies.<sup>16</sup> For midurethral sling surgeries with autologous tissues Linder et al. reported retreatment recurrence-free survival as 92% at 12 months and 75% at 18 months and El-Gamal et al. reported subjective cure rate according to the PGI-I scale was 92.9%, and the objective cure rate, according to a positive cough stress test and one-hour pad test, was 85.7%.<sup>1,11</sup> In the present study, the early objective cure rate detected with the stress test and one-hour pad test was 100%, and subjective cure rate according to PGI-I was 100%. The presented early results of autologous midurethral sling surgeries are comparable with conventional sling surgeries however a one to one comparison of autologous tissue methods is impossible due to absence of comparable data. In the future comparison of these methods in terms of effectivity might be an object for new trials.

Although pubovaginal sling and MUSS have similar cure rates, voiding dysfunction is a common problem after pubovaginal sling. According to a meta-analysis by Schimpf et al., 7.5% of patients who underwent pubovaginal sling and 3% who had sling release operations had urinary retention.<sup>17</sup> In the literature, de novo urgency and urge incontinence were seen in up to 20% of cases.<sup>10</sup> Linder et al. reported that voiding dysfunction was not seen after autologous transobturator urethral sling.<sup>1</sup> In our study, voiding dysfunction was not detected; a tension-free mid-urethral position of the autologous material is crucial for this result.<sup>1,11,15,18-21</sup>



In the literature, there is a little knowledge about the ideal autologous sling material. A Cochrane review stated that participant-reported improvement rates within the first year favoured the traditional autologous material rectus fascia over other biologic materials such as porcine dermis, lyophilized dura mater, fascia lata, vaginal wall, and autologous dermis.<sup>22,23</sup> In accordance with the literature, we used rectus fascia in the present study and the size was dependent on the measurement of the distance between both inferior ischiopubic rami. In our opinion, it is easy to harvest this fascia and usually patients have an incision secondary to previous cesarean or other surgical interventions; therefore, it can be performed via this incision to avoid a new incision and scar on patients. It is not surprising that patients have morbidity due to this incision, which does not occur in MUSS. However, the comparison of VAS scores between postoperative 8 and 24 hours showed a statistically significant decrease 24 hours postoperatively ( $p < 0.001$ ). This incision also has some minor unique complications such as surgical site infection or seroma; however, we had only one patient with seroma in our series, which did not require any additional surgical intervention, similar to the literature.<sup>17</sup>

Although this study contributes to the literature of surgical modifications, it has some limitations such as the short follow-up period and low patient volume.

## CONCLUSION

Patients and surgeons are abstaining from MUSS surgery with non-absorbable mesh because it has

some unique complications. Alternative surgical options must be discussed with patients, especially without mesh use. Relatively more morbid surgeries such as colposuspension and pubovaginal slings have regained popularity; however, the minimally invasive nature of MUSS should not be disregarded. At this point, our MATOMS technique is a feasible option for patients and surgeons with its short-term effectiveness and safety. Studies with long-term follow-up and larger patient volumes are needed.

### Source of Finance

*During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.*

### Conflict of Interest

*No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.*

### Authorship Contributions

**Idea/Concept:** Alkan Çubuk, Mehmet Fatih Akbulut; **Design:** Alkan Çubuk, Metin Savun, Ali Erdem Ayrancı, Akif Erbin; **Control/Supervision:** Fatih Yanaral, Şeref Başal, Ömer Sarılar; **Data Collection and/or Processing:** Alkan Çubuk, Metin Savun, Ali Erdem Ayrancı, Özgür Yazıcı; **Analysis and/or Interpretation:** Alkan Çubuk, Fatih Yanaral, Mehmet Fatih Akbulut; **Literature Review:** Ömer Sarılar, Şeref Başal, Mehmet Fatih Akbulut, Alkan Çubuk; **Writing the Article:** Alkan Çubuk, Fatih Yanaral, Mehmet Fatih Akbulut; **Critical Review:** Şeref Başal, Ömer Sarılar, Özgür Yazıcı; **References and Fundings:** Akif Erbin, Metin Savun, Ali Erdem Ayrancı, Özgür Yazıcı; **Materials:** Alkan Çubuk, Ömer Sarılar.

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