

Female Stress Urinary Incontinence Treatment by Forming an Uretro-Vesical Angle with or without Mesh

Mehmet Kilinc, Yunus Emre Göger

Department of Urology, Meram Medical Faculty, Necmettin Erbakan University, Konya, Turkey
Email: mehmkilinc@hotmail.com

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Abstract

Objective: To evaluate, in a comprehensive way, mesh and mesh free SUI treatment results obtained in a single center. The present study addresses the efficacy and safety of a novel surgical technique. **Material & Methods:** Adult female SUI patients, 184 in total, were divided within a sequential manner into two groups to be treated for SUI either with or without mesh insertion during a surgical intervention. In this novel procedure, a vertical vaginal incision from the urethra towards the bladder bottom is made and closed transversely. After the intervention the patients revisited the clinic at the 6th month. **Results:** 81 patients in mesh and 83 in the mesh free group completed the 2-year follow up. Based on the pad tests conducted at the end of 24-month follow up, 82% of the patients in the mesh free group and 85% in the mesh group were considered as successful if the pad test resulted with ≤ 2 gram. Cystocele of Grade I or II was also treated in 69 patients within the same single surgical procedure. **Conclusion:** The surgical outcomes of the mesh and mesh-free group were almost the same. However, though the cure rate of the mesh group was higher, it was not statistically significant. Adverse events were more frequent in the mesh group due to mesh presence.

Keywords

Female Incontinence, Stress Urinary Incontinence (SUI), Cystocele, Mesh, Treatment

1. Introduction

Worldwide women, with a prevalence of 25% - 57%, suffer from varying degrees of stress urinary incontinence (SUI) [1] related complaints leading to the emergence of varying surgical techniques [2]. Possible underlying mechanisms are

increasing urethral resistance [3] and/or relocating the proximal urethra to a more intra-abdominal position in order to optimize urethral pressure [4]. Recent procedures favor mid-urethral support rather than bladder repositioning to increase urethral resistance [5].

Conflicting reports on the impact of Burch colposuspension (BC) and pubo-vaginal slings (PVS) on urethral resistance have been published [4] with contradictory success rates such as similar discussions about the efficacy of mid-urethral sling (MUS) [6]. Tension vaginal tape (TVT) has been associated with some peri and post operative complications such as bladder perforation, temporary or persistent urinary retention, urinary infection, and de novo instability [7]. In order to avoid these complications, Transobturator tape (TOT) was proposed yielding roughly similar continence rates compared to retro-pubic TVT [8] [9] [10] [11] [12]. Besides, a needle suspension procedure for genuine stress incontinence and anterior vaginal wall prolapse was developed and applied during vaginal hysterectomy for anterior vaginal wall relaxation correction [13]. In the present study, we describe a novel vaginal technique to treat female SUI and if present also cystocele Grade I - II, regardless being symptomatic, within the same surgical intervention. In this procedure the urethra-vesical junction (UVJ) angle, much larger before the operation, is narrowed with a surgical intervention. Sub-urethral incision is continued to sub-vesical vaginal vertically and closed transversely either with or without mesh according to the patient groups. This surgical technique, with or without mesh, is feasible, accurate, quick, and simple while preserving the urethra and bladder.

2. Material & Method

Throughout April 2002 to May 2012, 184 women were in a sequential manner into two cohorts as propylene mesh (2.5×2.5 cm) or mesh-free groups after obtaining their informed consent about their participation in writing. According to their groupings, patients were intervened within a sequence after obtaining the permission of the local ethic committee (Nr.2002). The mean age of the participants was 46.8 years old ranging between 32 and 78. They were evaluated preoperatively with pad test, coughing test, urodynamic (multichannel) test made using urethral pressure profilometry (UPP) voiding pressure study, and clinical examination. Exclusion criteria were former pelvic and vaginal surgery history within the last 6 months, urethral and/or bladder pathologies, active urinary tract infection (UTI), refractory overactive bladder, and grade 3, 4, and 5 anterior and/or posterior prolapse.

The degree of pelvic organ prolapse was evaluated using Baden Walker *et al.* criteria [14] during the physical examination. In the present study, SUI patients with Grade I & II anterior cystocele were treated for cystocele within the same surgical intervention. The one hour pad test was a routine evaluation process for SUI. An increase of less than 2 gram in the total pad weight is considered as normal, 2 - 10 gram as mild, 10 - 50 gram as middle, and above 50 gr as severe incontinence in the pre- and postoperative SUI evaluation. This test, used while

determining the success of the intervention, is considered to be practical and useful in determining the leakage amount [15].

Urogenital Distress Inventory (UDI-6) and Incontinence Impact Questionnaire (IIQ-7) short form symptom scores in SUI patients and urodynamic evaluation were a part of the total evaluation process. Invasive Urodynamic test was performed using double lumen catheter. Rectal tube was used to record abdominal pressure while voiding in sitting position with the catheter. Incontinence was graded according to McGuire *et al.* [16] test conducted at 200 ml, as I if the abdominal pressure was leak point pressure (LPP) > 90 cm H₂O, as II if LPP was 60 - 90 cm H₂O, and as III if LPP was <60 cm H₂O. The patients were asked to strain during cystometry until leakage was detected.

3. Surgical Technique

The aim of the surgical procedure was to decrease the urethra-vesical junction (UVJ) (bladder neck) angle either with or without mesh in 184 selected patients according to their grouping. Patients were examined in dorsal lithotomy position and were tested for incontinence under general or regional anesthesia by injecting 400 ml Saline solution into the bladder via a 16 Foley catheter. After the removal of the catheter, first Boney-Marchetti test was applied. Subsequently Q-tip test was made. Finally, in order to determine urinary leakage the self designed technique in which suprapubic abdominal pressure on the bladder using fingers was applied. This test was designed by the researcher to determine urinary leakage before and after the beginning of the surgical intervention.

Foley catheter is reinserted and a balloon is inflated both to empty the bladder and to initiate the procedure. Upon emptying bladder, a small transverse incision is made 5 mm below the urethral meatus to prevent meatus perforation with electrocautery at small doses. Then the bladder UVJ is marked using electrocautery if this part yields in with pressure. Female urethra is hard and does not yield in with pressure. A vertical suburethral vaginal incision about 2.5 cm is made from the small transverse incision until UVJ. Later on an incision of the same size is made from the UVJ to the vaginal bladder bottom. In the presence of cystocele of Grade I - II, the vaginal bladder bottom incision is continued downwards up to 1 - 1.5 cm. In this technique only the vaginal tissue is incised until periurethral and perivesical fascia.

First 2/0 vicryl absorbable sutures 3 - 4 mm approximately above and under of UVJ (bladder neck) are passed and thus the first line is formed transversely (about 5 sutures one in the urethral middle and 2 to both left and right) (**Figure 1(a)**).

If folded propylene mesh (2.5 × 2.5) is to be used, it is placed under the first line (**Figure 1(b)**). Then the second line is formed using 4/0 non-absorbable prolene sutures (**Figure 2**) and the third line with 2/0 vicryl absorbable sutures in the same way (**Figure 3(a)**). The vaginal tissue incised vertically until urethral and vesical fascia is finally closed transversely (**Figure 3(b)**).

Following the intervention, the bladder is filled with 400 ml saline solution

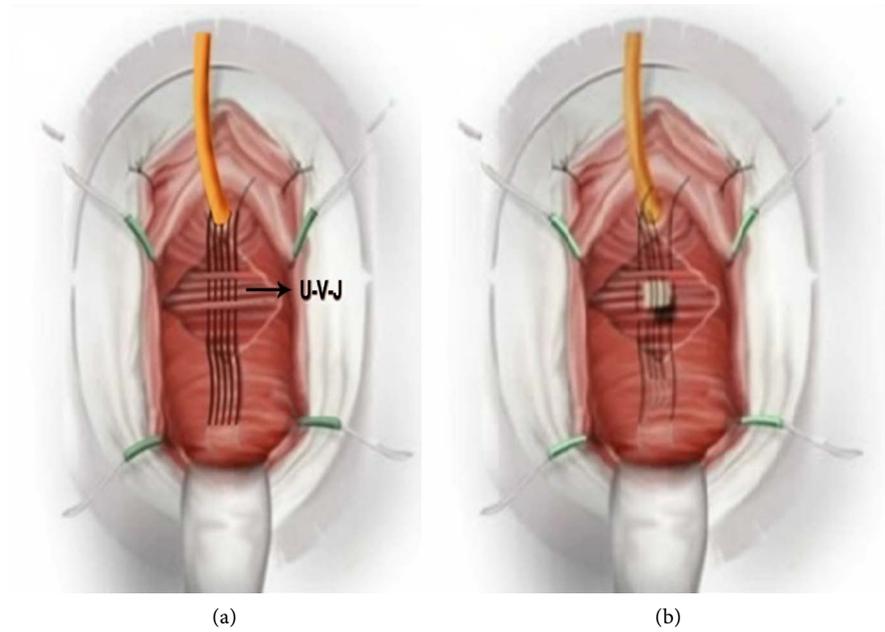


Figure 1. Urethro-vesical junction angle-formation: (a) First-line vicryl sutures (no mesh), (b) First-line mesh then vicryl sutures.

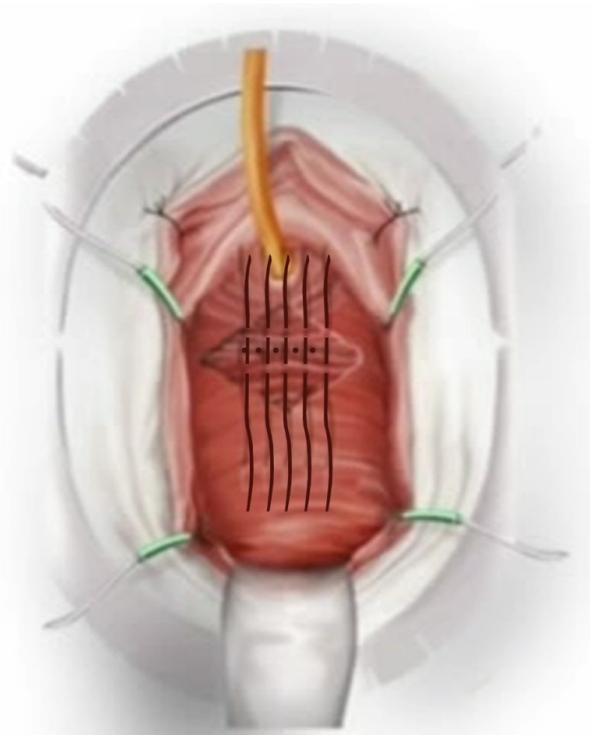


Figure 2. Urethro-vesical junction angle-formation: second-line 1 prolene sutures.

and the Foley catheter inserted earlier is removed. Boney-Marchetti test, Q-tip test, and suprapubic abdominal pressure (to the upper bladder area) to determine urethral leakage by using fingers are made upon surgical intervention. The surgical intervention is considered successful if there is no leakage in the Boney-Marchetti test and abdominal pressure test. Whether the Q-tip test may be

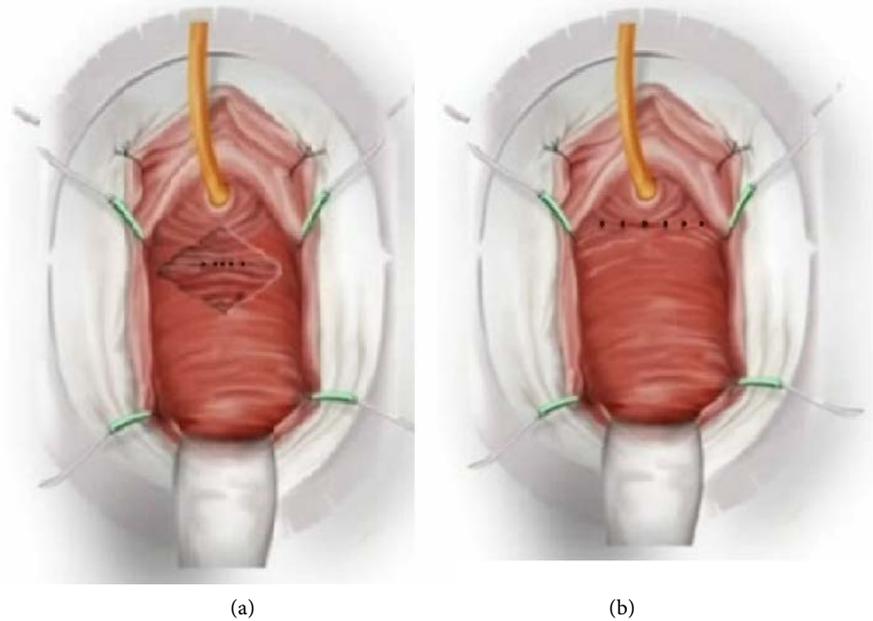


Figure 3. Urethro-vesical junction angle-formation: (a) Third-line vicryl sutures, (b) Transverse vaginal closure.

positive or not, incontinence may not be present in all cases. Q-tip test can be positive in bladder neck elevation and urethral mobility. Later on, during cystoscopic examination the bladder neck is seen to be as elevated and closed.

The 16-Foley is reinserted and totally removed during the 1st or 2nd post operative day. Following catheter removal, patients are discharged. In the comparison of mesh and mesh free groups, Chi-square test was used. Independent t-test, Mann Whitney U-test and Fischer exact test were employed to evaluate patient parameters and urodynamic results of both groups. In all statistical analyses, $p \leq 0.05$ was considered as the threshold level for statistical significance. For statistical analyses Statistical Package for the Social Sciences (SPSS) (version 15, Chicago Illinois) package program was used.

4. Results

The mean age of the 81 patients in the mesh and 83 patients were in the mesh-free group was 46.8 (32 - 78). These participated in the 24 month postoperative follow up period throughout April 2002 to May 2012 period. During the post-operative follow up period 9 patients in the mesh and 11 in the mesh-free group were lost. There was no statistically significant difference in terms of mean age and Body Mass Index (BMI) (**Table 1**).

Total prolapse (anterior/posterior) (POP) prevalence was 83. In 34 patients out of 81 patients in the mesh group was anterior Grade I - II, and in 35 out of the 83 patients in the mesh free group it was anterior Grade I - II. Posterior POP number was in total for both groups 14 (**Table 1**). None of the patients who underwent surgical intervention required concomitant procedures for additional vaginal repair surgery such as pelvic organ prolapse as this technique repairs

Table 1. Demographics and baseline evaluation of two groups.

	Mesh	Mesh free	p Value
Patients	81	83	
Age	46.8 (33 - 75)	46.08 (32 - 78)	0.4
BMI	34.01 ± 5	31.99 ± 5	0.4
POP Total Number	42	41	
	34	35	0.3
Anterior POP Grade I Grade II	6	7	0.3
	26	28	0.3
Posterior POP	8	6	0.3
Abdominal LLP	90 ± 23	81 ± 27	
	20	23	0.5
Grade of SUI Grade I Grade II Grade III	42	39	0.5
	19	21	0.5

cystocele Grade I - II together with SUI. The patients were divided preoperatively according to their abdominal LLP in different SUI grades as SUI Grade I, II, and III. Patients with SUI Grade II were more common (**Table 1**). Pad test is employed to determine surgical outcomes and to determine success throughout the 24 month postoperative period.

In none of the patients, intra-operative urethral and/or bladder perforations emerged. This is an advantage of the present technique. Among sexually active women, none experienced dyspareunia and felt suture or mesh related discomfort except for mesh and/or prolene extrusion and erosion. Intra-operative blood loss was less than 100 ml. Urinary tract infection (UTI) was the same for both groups and was treated with antibiotics disregarding urine culture. A further advantage of this surgical intervention is that both SUI and cystocele Grade I - II are treated within the same session. This fact makes this technique superior to MUS, PVS, BC, and the other surgical interventions in SUI treatment.

Mesh related early and late adverse events included erosion and/or prolene suture (4 patients) exposure and/or prolene suture (3 patients). Prolene suture visibility of non-absorbable prolene suture was seen in 4 patients in each group. Mesh extrusion and vaginal erosion, especially prolene suture was felt mostly through the anterior vaginal wall by the patients within the 3 - 6 months of the postoperative period. These conditions do not have an impact on SUI treatment.

Vaginal epithelium perforation occurred in 2 patients in each group. Post-operative catheter use for more than 3 days was necessary in 3 patients in the mesh group and in 2 patients in the mesh-free group. Novo urgency was seen in 3 patients in the mesh group and 2 patients in the mesh free group. All these 5 novo urgency cases responded to medical treatment.

Baseline and post operative 6th month urodynamic parameters of SUI patients

were evaluated. Although the abdominal leak point pressure (LLP) is higher in the mesh group, this difference between two groups is not statistically significant. On comparing the baseline level and at postoperative 6th month data, post-voiding residual urine (PVR) levels had slightly increased (mesh group 4 ± 5 ml and mesh free group 3 ± 5 ml); however, cystometric capacity, compliance, Q-max results had, as a result of the treatment modality, decreased (**Table 2**). Yet, these outcomes were not statistically significant ($p \leq 0.05$). In the two groups, 4 patients in total had de novo urgency and were therefore treated with anticholinergics.

Preoperative and postoperative Short Incontinence Impact Questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6) results for both groups are presented as baseline and postoperative 6 months results. During the 6 months follow up, mesh and mesh free groups showed statistically significant decreases compared to the pre intervention levels ($p \leq 0.05$) (**Table 3**).

Pad test results indicated that at the end of 24 month follow up, 82% of the patients in the mesh free group and 85% in the mesh group were cured. However, based on the 1-hour pad test (≥ 2 mg) 13 patients in the mesh group and 14 patients in the mesh free group were considered as failures. Comparing the mesh free and mesh group in terms of the data obtained in the present study, there differences among the both groups were not of utmost importance. Hence, due to the limited number of complications and simplicity of the surgical intervention the mesh free technique should be preferred.

Table 2. Comparison of postoperative urodynamic variables.

	Mesh	Mesh Free	p Value
PVR	4 ± 5 ml	3 ± 5 ml	0.5
P Detrusor filling cm H₂O			
Baseline	9 ± 4	8, 5	0.5
6 months	9 ± 4	8 ± 4	0.5
Compliance ml/cm H₂O			
Baseline	84 ± 50	70 ± 49	0.4
6 months	67	75	0.4
MCG (ml)			
Baseline	381 ± 100	377 ± 110	0.3
6 months	335 ± 100	309 ± 100	0.3
P Detrusor Q max cm H₂O			
Baseline	25 ± 11	28 ± 13	0.3
6 months	27 ± 14	28 ± 11	0.4
Q max			
Baseline	20.5 ± 8	19.6 ± 7	0.5
6 months	18 ± 8	18 ± 8	0.5

Independent t-test, Mann Whitney U-test, Fischer exact test.

Table 3. Pre and postoperative values of short incontinence impact questionnaire (IIQ-7) and Urogenital Distress Inventory (UDI-6).

	Mesh	Mesh Free	p Value
UDI-6			
Baseline	45 ± 13	42 ± 11	0.04
Postop. 6 months	14 ± 11	14 ± 12	0.04
IIQ-7			
Baseline	43 ± 12	41 ± 12	0.04
Postop. 6 months	16 ± 11	16 ± 12	0.04

5. Discussion

The main objective of SUI surgical treatment is to render patients completely continence without significant morbidity. Following the first report of Ulmsten *et al.* [17] on a new SUI surgical treatment modality, Gynaecare's TVT gained global diffusion due to minimal invasive and high success rates. Many other devices are now on the market. In order to minimize retropubic space injury, TOT has been used to place the sling both with outside-in and inside-out approaches as proposed by Delorm [10] [18] and by Leval [2]. Many retrospective studies have shown that the difference between inside-out TOT and outside-in TOT approaches was insignificant [19]. The authors concluded that both of these approaches were equally safe and clinically effective. Another randomized prospective study, [20] compared TVT and TOT patients, and did not determine a significant difference in terms of objective cure rate [21]. In our study, no significant difference in the objective cure rates of the patients in both groups (objective cure rate of the mesh group 85% and of the mesh free group 82% at the end of 24 month follow up). Teo *et al.* [22] found that cure rates for TVT patients at 1 year 85.4% and for TOT 89.7% at the same time interval. Accumulating reports have indicated the efficacy of tension-free sub-urethral tapes which are currently widely utilized [2].

Kraus *et al.* [22] compared SUI treatment using BC and PVS. Only patients with fascial sling had significant increase in detrusor pressure at maximum flow, suggesting increased outlet resistance. Zullo *et al.* [23] have found no significant decrease in non invasive urine flow rates, PVR, and P detrusor Q max. In the present study, except mesh originating problems, there were no significant complications in both groups. The results of randomized prospective multi-center studies trial comparing retropubic TVT with colposuspension, have recently shown that continence rates were similar at 6 month follow up [18] [24]. TVT procedure required much less operative time, short hospitalization, less post operative pain, faster return to normal daily activities than BC. The current procedure, with a mean operative time about 30 minutes, aims to narrow UVJ angle with plication sutures in order to achieve natural hammock effect.

The position of TOT, TVT tape, and PVS is similar to that of the natural hammock supporting the urethra [25] and the natural hammock supporting the

bladder neck in PVS. Our technique forms an angle in the urethra-vesical junction in both the mesh and mesh free patient with plication sutures. This condition increases the hammock effect in the bladder neck as described by De Lansey [25] [26].

Boustead [7] have reported serious complications such as vascular and bowel injuries, in addition to bladder perforation, de novo urgency in 2.5% - 25%, urinary retention in 1.5% - 12%, and hematoma. In the present surgical technique major complications were not observed; yet, de novo urgency developing were cured using anti-muscarinic drugs yielding satisfactory responses. Urine retention and PVR in both groups was less than 100 ml. However, the difference between the two groups was not significant. In the present study vaginal erosion and/or prolene suture visibility, and vaginal mesh exposure and/or prolene suture visibility are the most common complications in patients with folded mesh SUI treatment. Whereas, prolene suture visibility is common in the mesh free group, mesh related problems arouse in the folded mesh group. We did not observe any cases of urethral and/or bladder perforation.

6. Conclusions

In conclusion, the comparison of the mesh and mesh free group indicated that the mesh free SUI treatment is safer because of the missing mesh related complication.

The surgical procedure described is safe, simple, accurate, as it preserves the bladder and urethra. Moreover, in the presence of cystocele Grade I - II, it is treated within the same session.

The findings of the present study propose an alternative to various mid urethral slings in female SUI treatment. However, the necessity for prospective studies with higher patient series in female SUI treatment constitutes a limitation of the present study.

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Ethical Standards

The present study has been conducted according to decision of the local ethics committee of Selçuk University enumerated 2002.

Conflict of Interest

The author declares no conflict of interest.

Authors' Contributions

The present study is conducted by a single author. The minor contributions of the colleagues are expressed in the acknowledgment section.

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