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FEMALE UROLOGY
Original Article

Use of polyvinylidene fluoride in treatment of female stress urinary incontinence: Efficacy and safety of midurethral slings: 24-month follow-up results

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ABSTRACT

Objective: To evaluate the safety and efficacy rate of polyvinylidene fluoride (PVDF) slings in the treatment of female stress urinary incontinence (SUI).

Material and methods: A prospective pilot study was conducted with women with SUI who underwent PVDF slings. Data regarding subjective (International Consultation on Incontinence Questionnaire - Urinary Incontinence [ICIQ-UI] and International Consultation on Incontinence Questionnaire - Overactive Bladder [ICIQ-OAB]) and objective (stress test and bladder diary) outcomes and complication rates were evaluated. Primary outcomes were objective (negative pad and stress test) and subjective (no leakage episodes) success after a median follow-up of 24 months.

Results: PVDF slings demonstrated a high level of satisfaction with objective cure (transobturator 90% compared with retropubic 100%, P = .90), urgency to urinate, frequency *of de novo* incontinence (transobturator 90% compared with retropubic 80%, P = .85), ability of physical and sexual activity (transobturator 90% compared with retropubic 100%, P = .90). The multivariate logistic regression model for satisfaction was associated with overall treatment success (odds ratio [OR] = 3.55, 95% confidence interval [CI] 2.32–6.1), greater reduction in ICIQ-UI (OR = 0.85; 95% CI 0.78–1.85) and ICIQ-OAB (OR =0.99; 95% CI 0.89–1.78). The total Female Sexual Function Index (FSFI) score for both groups was 19.3 ± 1.2 and 20.7 ± 1.8, statistically significant when compared with perioperative FSFI score 16.7 ± 1.1 and 17.6 ± 1.4 (P < .001).

Conclusion: PVDF mid-urethral slings are safe with clinically efficacies at 3, 6, 12, and 24-month follow-up for the treatment of SUI. The high level of satisfaction seen after PVDF sling procedures is associated with objective improvement of SUI and fewer slings related complications. Further studies using larger sample sizes with longer and comparative clinical follow-up are required.

Keywords: Midurethral slings, urinary incontinence, overactive bladder, dyspareunia

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Introduction

Urinary stress incontinence (SUI) is a problem, increasingly common in women, affecting their quality of life (QoL) and that of their loved ones. The prevalence of UI increases with old age, with a typical rate in young adults (20%–30%), a peak around middle age (30%–40%), and a steady increase during old age (30%–50%).[1] The treatment of female SUI with alloplastic slings seems to have short-term effectiveness. The overall reported success rate of clinical trials ranges from 86% to 99%.[2, 3] The most common implants used in these surgeries, owing to *the* disadvantages of being *non-biodegradable* in nature, has been polypropylene (PPL) mesh, which is used to support either the urethra for SUI and pelvic organs. Despite the high success rates of PPL mid-urethral slings, a growing number of complications and adverse effects have been reported.[4, 5] The Food and Drug Administration (FDA) modified the risk class in 2016 from II (moderate risk) to III (high risk) for alloplastic implants because of serious erosion and complications related to mesh insertion,[6] and in 2019 ordered manufacturers of all remaining transvaginal alloplastic implants devices for pelvic organ prolapse (POP) repair to stop distributing and selling these products imme-

diately. The implantation of alloplastic implants in fascia and muscle tissue is known to cause fascial implant related infections and surgical complications, such as the erosion of adjoining organs or vesicovaginal, urethrovaginal, or ureterovaginal fistula formation.[7-10] Klinge et al.[11] identified long-term signs of foreign body reaction and chronic inflammation surrounding the alloplastic implants, and there was extensive foreign body reaction (inflammation, infection, and/or rejection) with fibroses and shrinkage (30%–50%) during the first month following surgery. Alloplastic implants potentially add to these complications. These also include trauma of insertion, contraction of the mesh (causing pain), and the stability of the prosthesis over time.[12] Recognized implant-related complications of the mid-urethral sling include *de novo* with urge incontinence, dyspareunia, postoperative pain, mesh erosion, and the potential for bladder, vaginal, and vascular injury.[13, 5] A material's biocompatibility and ability is an important requirement for the perfect ingrowth of the implant. It is determined by inflammatory foreign body reactions and depends on parameters such as the type of polymer, material weight, and pore size.[15, 14] PVDF is a relatively new polymer with improved textile and biological properties and biocompatibility with tissues, which means less mesh shrinkage.[15, 16] Although it has been introduced in orthopedics, general and vascular surgery for years, it has never been used for the construction of surgical meshes. The open question is whether PVDF is fundamentally safe and effective for the treatment of female SUI. Therefore, in this study, we aimed to evaluate objective and subjective success (primary endpoints) and complication rates (secondary endpoint) of PVDF mid-urethral sling after a median follow-up of 18 months.

Material and methods

Study design

A prospective pilot study of women with SUI was conducted from January 2018 to January 2019. Patients affected by SUI were prospectively evaluated for the retropubic and transobturator mid-urethral slings with PVDF mesh. The regional ethics committee for medical research approved the PVDF 17-002 study in August 2018. The study protocol was registered at the "2017229" medical association in Nordrhein-Westfalen before the start of the study. All the participants gave their written consent after receiving all the information about the study. Study methods were applied according to recommendations by the International Urogynecological Association (IUGA) and the International Continence Society (ICS).[17, 7] The primary outcomes were objective (negative pad and stress test) and subjective (no self-reporting of SUI symptoms and no leakage episodes on bladder diary) success after 12 and 24 months. Two surgeons, experienced in both the surgical techniques, performed one approach each. We enrolled 20 women who complained of SUI symptoms with urodynamically proven SUI. Eligibility requirements included at least a three-month history of SUI that was predominantly or solely associated with urethral hypermobility according to the recommendations by ICS. Exclusion criteria were a history of previous sling procedure, overactive bladder (OAB), urodynamically proven detrusor overactivity, a postvoid residual volume > 100 mL, and the desire for future childbearing. All included patients underwent preoperative urodynamic studies with Valsalva leak-point pressure measurement, and the pressure/flow study using a standardized protocol in accordance with good urodynamic practice guidelines of the ICS.[18] Twenty patients completed three validated questionnaires on quality of life (QoL): the International Consultation on Incontinence Questionnaire (ICIQ-UI), International Consultation on Incontinence Questionnaire overactive bladder (ICIQ-OAB), and the Female Sexual Function Index (FSFI). QoL was assessed using the ICIQ-UI, with possible scores of 0 to 21.[19]

Main Points:

- Polyvinylidene fluoride (PVDF) is a new type of mid-urethral sling for the treatment of female stress urinary incontinence (SUI).
- PVDF mid-urethral slings are safe with clinically efficacies at 3, 6, 12, and 24-month follow-ups.
- PVDF was associated with significant improvement in other lower urinary tract symptoms such as urgency, frequency, and sexual activity.
- Further studies using larger sample sizes with longer and comparative clinical follow-up are required.

Study procedures

All the women kept a bladder diary for three days and underwent pelvic floor ultrasound and urodynamic cystometry, which included urethral profilometry. Finally, the Valsalva leak point pressure (VLPP) was determined at vesical volumes of 150 and 200 cc. Mid-urethral sling procedures were performed by two surgeons according to the surgical technique described by Ulmsten et al.[20] All the patients were placed in the lithotomy position, with thighs flexed at approximately 90°, and the surgical procedures were performed under general anesthesia. The peri and postoperative assessments were done using the same protocol. Postoperative lower urinary tract dysfunctions, storage symptoms, and obstructive symptoms were defined by ICS.[18]

Outcomes

The objective and subjective outcomes (primary endpoints) were assessed at 3, 6, 12, and 24 months after treatment. Objective success was described as a negative pad test, a negative cough stress test at a bladder volume between 200 and 300 cc, and no retreatment for SUI. Subjective success was described as no self-reporting of SUI symptoms on the validated ICIQ- UI questionnaire and no urine leakage in the bladder diary (three days).

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We also used sexual questionnaires (FSFI) postoperatively at 3, 6, 12, and 24 months after surgery to determine any impairment in sexually active women. Secondary outcomes included postoperative implant-related complications and the difference between transobturator and retropubic slings, postoperative pain, change in QoL as assessed by SF-12,[21] and a change in sexual function. Additional urodynamic testing was performed when women complained of the onset of irritative urinary symptoms. For women with OAB, anticholinergic drugs were administered for at least 8–12 weeks. The reporting of implant-related complications and the classification of the severity of events were documented across the Clavien-Dindo classification.[22]

Statistical analysis

Statistical analysis was performed using IBM Statistical Package for Social Sciences v.19 for Windows (IBM Corp, Armonk, NY, USA). Descriptive statistics were used for the evaluation of complication rates and analysis of the questionnaire. We used the chi-squared test for trends to evaluate the success of the surgical procedure at the different follow-up visits (3, 6, 12, and 24-month follow-ups). Changes in number of used pads and incontinence episodes were recorded by the ICIQ UI and ICIQ OAB questionnaires, whereas the bladder diary and pain scores were analyzed using the repeated, measured analysis of variance or the Friedman test as appropriate. The Mann-Whitney U and Wilcoxon tests were used to compare ordinal and non-normally distributed continuous variables. Univariate and multivariate logistic regression analyses were performed with each variable of 20 patients. The t-test was utilized for a comparison of the complications between the groups. A P value below .05 was considered statistically significant.

Results

Twenty women with proven SUI were enrolled, who met the inclusion criteria and signed informed consent. Tables 1 and 2 shows the demographic and preoperative measures and urodynamic parameters of the patients in each group. Patient characteristics, intraoperative data, postoperative clinical outcomes, and incontinence severity data were similar in the two groups. The severity of incontinence at baseline and objective (as measured by cough stress test and pad test) and subjective (as measured by the ICIQ-UI and ICIQ-OAB questionnaires) measures were not statistically different between the satisfied and unsatisfied patients. Preoperative urodynamic parameters were similar in the two groups. The median (IQR) age of the patients included in these studies was 59.3 ± 10.51 years for the transobturator group and 55.90 ± 11.17 for the retropubic group. None of the

Table 1. Demographic, preoperative measures, and urodynamic parameters of patients in both study groups (continuous parameters)

	Sling type	Mean	Median	SD	Lower quartile	Upper quartile	Min	Max	p
Age (years)	Transobturator	59.30	58	10.51	46.0	64.3	26.0	84.1	0.9
	retropubic	55.90	54	11.17	48.0	63.6	25.1	85.2	
Parity, n	Transobturator	2.76	2.0	1.17	2.0	3.0	0.0	5.0	0.9
	retropubic	2.62	2.0	1.2	2.0	3.0	0.0	6.0	
PVR, mL	Transobturator	14.2	6.5	23.54	4.0	15.0	0.0	153.0	0.93
	retropubic	13.54	7.1	22.54	5.0	14.0	0.0	168.0	
MUCP, cmH_2O	Transobturator	25.41	28.4	17.23	20.0	62.0	5.0	97.0	0.76
	retropubic	27.07	29.2	19.89	22.0	63.0	6.0	91.0	
FUL, mm	Transobturator	21.2	25.0	4.9	21.0	27.0	13.0	51.0	0.56
	retropubic	23.3	23.0	4.7	20.0	29.0	12.0	48.0	
ICIQ - OAB	Transobturator	8.0	9.0	4.0	5.0	13.0	6.0	12.0	0.77
	retropubic	9.0	10.0	3.0	4.0	12.0	7.0	14.0	
ICIQ -UI	Transobturator	15.0	14.0	2.0	13.0	19.0	13.0	20.0	0.83
	retropubic	17.0	14.0	4.0	14.0	20.0	15.0	21.0	
FSFI	Transobturator	12.0	11.0	3.0	9.0	15.0	4.0	15.0	0.78
	retropubic	13.0	12.0	5.0	8.0	14.0	5.0	14.0	

SD: standard deviation; Min: minimum; Max: maximum; PVR: postvoid residual volume; MUCP: maximal urethral closure pressure; FUL: functional urethral length; ICIQ-OAB: international consultation on incontinence questionnaire overactive bladder; ICIQ UI: international consultation on incontinence questionnaire-urinary incontinence; FSFI: Female Sexual Function Index.

Table 2. Demographic and urodynamic parameters of patients in both study groups (categorical parameters)

Parameter		Transobturator	Retropubic	p
BMI, kg/m^2	18.0–25-0	40 (22.9)	42 (20.9)	0.85
	25.0–30.0	78 (40.1)	80 (41.4)	0.78
	≥30.0	81 (40.4)	79 (39.6)	0.79
Valsalva maneuver	negative Valsalva	95 (76.1)	101.3 (80.1)	0.58
	maneuver and VLPP>60	42 (25.5)	39 (26.5)	
	cmH_2O			
	VLPP<60 cmH_2O			
Incontinence score	Grade 1	3 (30)	1 (10)	0.6
	Grade 2	5 (50)	6 (60)	
	Grade 3	2 (20)	3 (30)	
Pads (n)		3 (1-6)	3 (2-7)	0.89

BMI: body mass index; VLPP: Valsalva leak point pressure

Table 3. Primary outcome measures at 24 months

	Transobturator	Retropubic	p
Follow-up (mon), mean; IQR	24±2.2	24±1.5	0.83
ICIQ - OAB	4.6±2.79	3.7±1.66	0.71
ICIQ -UI	7.2±2.54	7.9±3.5	0.88
FSFI increase	19.32±1.24	20.70±1.84	0.81

ICIQ-OAB: international consultation on incontinence questionnaire overactive bladder module; ICIQ UI-SF: international consultation on incontinence questionnaire-urinary incontinence short form; FSFI: Female Sexual Function Index

Table 4. Odds ratios with 95% confidence interval and p values for univariate and multivariate logistic regression models associated with patient satisfaction at 24 months

	Univariate OR (95% CI)	p	Multivariate OR (95% CI)	p
Objective outcome	3.5 (2.35–4.1)	0.05	3.55 (2.32–6.1)	<0.001
Subjective cure	3.6 (0.9–5.2)	0.05	4.9 (1.9–6.2)	<0.001
de novo urgency incontinence	1.65 (0.84–2.05)	0.032	1.43 (0.28–1.85)	0.05
ICIQ-UI	1.4 (0.83–2.4)	0.05	0.85 (0.78–1.85)	0.05
ICIQ-OAB	1.54 (0.85–1.95)	0.05	0.91 (0.89–1.78)	0.01
FSFI	3.4 (1.3–4.7)	0.02	3.1 (1.3–3.9)	<0.001

ICIQ-OAB: international consultation on incontinence questionnaire overactive bladder module; ICIQ UI-SF: international consultation on incontinence questionnaire-urinary incontinence short form; FSFI: Female Sexual Function Index; OR: Odds ratio; CI: Confidence interval

patients had previously undergone unsuccessful anti-incontinence procedures or had a history of previous pelvic surgery. The mean (IQR) for maximal urethral closure pressure was 27 (5–25) cmH_2O. All the women underwent mid-urethral slings under general anesthesia, with a mean anesthesia plus operative duration of 32 (24± 66) min. The blood loss was < 100 mL in all the patients. Nineteen (95%) women resumed immediate spontaneous voiding. The mean (IQR) length of hospital stay was 2 (1–5) days following surgery. The follow-up was conducted at a mean (IQR) interval of 24 ± 2.2 (IQR 24–26) months for the transobturator group and 24 ± 1.5 (IQR 24–27) months for the retropubic procedure; the overall median was 24 months.

Outcome data

The primary outcome data for our study is shown in Table 3. Twenty women completed eht ICIQ- UI and ICIQ-OAB satisfaction questionnaires, and no leakage were recorded in the bladder diary questionnaire at 3, 6, 12, and 24 months in both groups. After 24 months of follow-up, 20 patients were available for clinical check-up. Clinical effectiveness was estimated based on subjective and objective outcomes. PVDF mid-urethral slings (transobturator, retropubic) demonstrated a high level of satisfaction with objective cure (transobturator 90% and retropubic 100%, P = .90), urgency to urinate, frequency of *de novo* incontinence (transobturator 90% and retropubic 80%, P = .85), ability of physical, and sexual activity (transobturator 90% and retropubic 100%, P = .90). In the last follow up, the majority of patients were highly satisfied, according to the ICIQ-OAB and QoL questionnaire, specifically with the urgency and frequency to urinate and ability of physical and sexual activity. There was no significant difference between the two treatment groups (Table 3). The multivariate logistic regression model for satisfaction was associated with overall treatment success (odds ratio [OR]

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Table 5. Complications of PVDF midurethral slings

Type of complications	Transobturator	Retropubic	p
Bladder injury, n (%)	0.0 (0)	0.0 (0)	-
Vaginal injury, n (%)	1 (10)	0.0 (0)	0.05
Urinary retention (> 500 mL) n (%)	0.0 (0)	1 (10)	0.05
Postoperative *de novo* overactive bladder, n (%)	0.0 (0)	2 (20)	0.02

PVDF: polyvinylidene fluoride

= 3.55, 95% confidence interval [CI] 2.32–6.1), greater reduction in ICIQ-UI (OR = 0.85; 95% CI 0.78–1.85) and ICIQ-OAB (OR = 0.91; 95% CI 0.89–1.78) (Table 4). In addition, there was no statistically significant difference in clinical efficacy between these two groups ($\chi^2 = 1.76$, P = 0.49). The total FSFI score for both groups was 19.3 ± 1.2 and 20.7 ± 1.8, statistically significant when compared with perioperative total FSFI score 16.7 ± 1.1 and 17.6 ± 1.4 (P < .001).

Peri and postoperative complications

There was one intraoperative vaginal perforation in the transobturator group; this was managed by the removal and repositioning of the needle. The rate of postoperative urinary retention was 1/20 (5%) in the retropubic group. Urinary retention was successfully treated by placement of a transurethral catheter for two days. Three months after the surgery, two women of our cohort 2/20 (10%) had *de novo* detrusor instability with urinary leakage. They were treated with anticholinergics for five weeks and were symptom-free in the last follow-up. After completing their final outcome, there were no long-term effects. Table 5 shows peri and postoperative complications.

Discussion

Alloplastic implants have produced highly variable outcomes, causing implant-related infections and surgical complications in some cases, whereas providing others with safe and effective treatment. The risk-benefit ratios for the use of urogynecological meshes to treat SUI and POP is a complex issue, caused by inherent incompatibility and increased inflammatory and fibrotic tissue reaction of the mesh.[23] The new implants for the pelvic floor should be clearly biocompatible and not produce an intense inflammatory reaction or extensive foreign body reaction. Furthermore, they should be strong enough to withstand dynamic distention, yet not so rigid as to cause erosion or foreign body reaction through a patient's native tissue. In 2002, PVDF abdominal mesh was developed as a new polymer for the construction of surgical meshes.[24] PVDF was introduced in vascular surgery years ago.[25] Klinge presents in their textile analysis that the tensile intensity, surface roughness, surface roughness, bending stiffness, and resistance fabric have equivalent properties as observed with common PPL material.[24] Recent studies of PVDF mesh application for the reconstruction of pelvic floor are available.[25-27] These studies have shown a greater impact on functional outcome and a significant improvement in symptoms with manageable complications.[25-27] In these studies, the authors present a good level of mechanical stability with less complications than the existing literature.[28, 29] Implant-related complications and erosion is reported to be about 10% after anterior mesh application.[28, 29] Our study on incontinence treatment with PVDF mid-urethral slings focuses on objective outcomes and subjective cures to define success. To the best of our knowledge, this is the first prospective study comparing the retropubic with the transobturator PVDF mid-urethral slings for SUI treatment. All the women included had high expectations about the success of PVDF mid-urethral slings, as well as incontinence related issues. The results of this work show a high level of satisfaction in terms of SUI improvement (transobturator 90% compared with retropubic 100%, P = .90). At the same time, a significant improvement in lower urinary tract symptoms (such as frequency, urgency, and sexual activity) was reported by most women too. Satisfaction with symptom improvement was associated with both objectively measured and patient-perceived improvement of SUI. The complications, as categorized according to the Clavien-Dindo classification, were not significant. *De novo* urgency after surgery and incontinence related QoL scores (ICIQ-OAB) were present in relatively small number of patients 2/20 (10%). Although there are an increasing numbers of trials with PPL mid-urethral slings, comparing the efficacy and subjective cures, the rate of *de novo* urgency in published reviews is higher (5%–35%).[20, 30] Generally, thigh pain is one of the most frequent transobturator complications.[31] In the transobturator group, we did not re-treat patients with thigh pain. Several studies have assessed sexual function in women following surgery for SUI, and these studies have suggested that sexual function can be negatively affected because of the alloplastic mesh.[31, 32] Maaita completed a retrospective study, using a validated questionnaire evaluating the effects of mid-urethral slings surgery on sexual function. A recently published study with a follow-up of 12 months reported about improvement in postoperative continence.[33] However, they used only the transobturator slings, and sexual function postoperatively was not reported.[33] In this study, 72% of the women reported no change in sexual function after surgery, but 14% reported a worsening of sexual function.[24] In another study comparing sexual function pre- and postoperatively using FSFI, they found no difference in terms of sexual activity.[34] However, Yeni et. al. [34] reported a statistically significant worsening of sexual function, dyspareunia, and satisfaction after mid-urethral slings compared with controls. Our study findings showed no postoperative dyspareunia in sexual function. The sexually active women reported that postoperative sexual function related to the elimination of

"coital urinary incontinence" was strongly associated with an improvement in sexual activity. Finally, our testing of various approaches of mid-urethral slings have shown no significant difference between the groups.

A major limitation of our pilot study was the small sample size. This was owing to the nature of all pilot studies. The inclusion of objective and subjective outcomes is strength of our study, particularly given the increasing recognition of these measures, which are likely to be useful in improving patient outcomes. It is possible that the results were overestimated or underestimated using the overall effects of mid-urethral slings on SUI.

PVDF is a new type of mid-urethral sling for the treatment of SUI. PVDF mid-urethral slings are safe with clinically efficacies at 3,6,12, and 24-month follow-ups after surgery for the treatment of SUI. PVDF was associated with significant improvement in other lower urinary tract symptoms such as urgency, frequency, and sexual activity. Satisfaction with symptom improvement was associated with both objectively measured and patient-perceived improvement of SUI. Further studies using larger sample sizes with longer and comparative clinical follow-up are required.

Ethics Committee Approval: Ethics Committee approval for the study was obtained from the the regional ethics committee for medical research (PVDF 17-002, August 2018).

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept - B.B.; Design - B.B.; Supervision - T.A.V.; Resources - B.B., S.H.; Materials - B.B., S.H.; Data Collection and/or Processing - B.B., S.H.; Analysis and/or Interpretation - B.B.; Literature Search - B.B.; Writing Manuscript - B.B.; Critical Review -T.A.V.

Conflict of Interest: The authors have no conflicts of interest to declare.

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References

1. Hunskaar S, Lose G, Sykes D, Voss S. The prevalence of urinary incontinence in women in four European countries. BJU Int 2004;93:324–30. [Crossref]
2. Novara G, Ficarra V, Boscolo-Berto R, Secco S, Cavalleri S, Artibani W. Tension-free midurethral slings in the treatment of female stress urinary incontinence: a systematic review and meta-analysis of randomized controlled trials of effectiveness. Eur Urol 2007;52:663-78. [Crossref]
3. Ogah J, Cody JD, Rogerson L. Minimally invasive synthetic suburethral sling operations for stress urinary incontinence in women. Cochrane Database Syst Rev 2009;4:63-75. [Crossref]
4. Rehman H, Bezerra CC, Bruschini H, Cody JD. Traditional suburethral sling operations for urinary incontinence in women. Cochrane Database Syst Rev 2011;1:CD001754. [Crossref]
5. Daneshgari F, Kong W, Swartz M. Complications of mid urethral slings: important outcomes for future clinical trials. J Urol 2008;180:1890-7. [Crossref]
6. FDA. Public health notification: serious complications associated with transvaginal placement of surgical mesh in repair of pelvic organ prolapse and stress urinary incontinence. 2008. Available from: www.fda.gov/cdrh/safety/102008- surgicalmesh.html.
7. Schneider R, Herrington JL Jr, Granda AM. Marlex mesh in repair of a diaphragmatic defect later eroding into the distal esophagus and stomach. Am Surg 1979;45:337-9.
8. Hume RH, Bour J. Mesh migration following laparoscopic inguinal hernia repair. J Laparoendosc Surg 1996;6:333-5. [Crossref]
9. DeGuzman LJ, Nyhus LM, Yared G, Schlesinger PK. Colocutaneous fistula formation following polypropylene mesh placement for repair of a ventral hernia: diagnosis by colonoscopy. Endoscopy 1995;27:459-61. [Crossref]
10. Schumpelick V, Kingsnorth G. Incisional Hernia. 1st ed. Berlin: Springer; 1999. [Crossref]
11. Klinge U, Klosterhalfen B, Müller M, Schumpelick V. Foreign body reaction to meshes used for the repair of abdominal wall hernias. Eur J Surg 1999;165:665-73. [Crossref]
12. Haylen BT, Freeman RM, Swift SE, Cosson M, Davila GW, Deprest J, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint terminology and classification of the complications related directly to the insertion of prostheses (meshes, implants, tapes) and grafts in female pelvic floor surgery. Neurourol Urdoyn 2010;29:4-20.
13. Deng DY, Rutman M, Raz S, Rodriguez LV. Presentation, and management of major complications of midurethral slings: are complications under-reported? Neurourol Urodyn 2007;26:46-52. [Crossref]
14. Gomelsky A, Dmochowski RR. Biocompatibility assessment of synthetic sling materials for female stress urinary incontinence. J Urol 2007;178:1171-81. [Crossref]
15. Gerullis H, Georgas E, Eimer C, Goretzki PE, Lammers BJ, Klosterhalfen B, et al. Evaluation of biocompatibility of alloplastic materials: development of a tissue culture in vitro test system. Surg Technol Int 2011;21:21-27.
16. Gerullis H, Georgas E, Borós M, Klosterhalfen B, Eimer C, Arndt C, et al. Inflammatory reaction as determinant of foreign body reaction is an early and susceptible event after mesh implantation. Biomed Res Int 2014;2014:510807. [Crossref]
17. Abrams P, Cardozo L, Fall M, Griffiths D, Rosier P, Ulmsten U. The standardisation of terminology of lower urinary tract function: report from the Standardisation Sub-committee of the International Continence Society. Neurourol Urodyn 2002;21:167-78. [Crossref]
18. Schafer W, Abrams P, Liao L, Mattiasson A, Pesce F, Spangberg A, et al. Good urodynamic practices: uroflowmetry, filling cystometry, and pressure-flow studies. Neurourol Urodyn 2002;21:261-74. [Crossref]

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DOI: 10.5152/tud.2021.21059

19. Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P. ICIQ: a brief and robust measure for evaluating the symptoms and impact of urinary incontinence. Neurourol Urodyn 2004;23:322-30. [Crossref]
20. Ulmsten U, Henriksson L, Johnson P, Varhos G. An ambulatory surgical procedure under local anesthesia for treatment of female urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 1996;7:81-5. [Crossref]
21. Melville MR, Lari MA, Brown N, Young T, Gray D. Quality of life assessment using the short form 12 questionnaire is as reliable and sensitive as the short form 36 in distinguishing symptom severity in myocardial infarction survivors. Heart 2003;89:1445-6. [Crossref]
22. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004;240:205-13. [Crossref]
23. Huang W, Wang T, Zong H, Zhang Y. Efficacy and safety of tension-free vaginal tape-secur mini-sling versus standard midurethral slings for female stress urinary incontinence: a systematic review and meta-analysis. Int Neurourol J 2015;19:246-58. [Crossref]
24. Klinge U, Klosterhalfen B, Öttinger AP, Junge K, Schumpelick V. PVDF as a new Polymer for the Construction of Surgical Meshes. Biomaterials 2002;23:3487-93. [Crossref]
25. Barski D, Arndt C, Gerullis H, Yang J, Boros M, Otto T, et al. Transvaginal PVDF-mesh for cystocele repair: a cohort study. Int J Surg 2017;39:249-54. [Crossref]
26. Joukhadar R, Meyberg-Solomayer G, Hamza A, Radosa J, Bader W, Barski D, et al. A novel operative procedure for pelvic organ prolapse utilizing a MRI-visible mesh implant: safety and outcome of modified laparoscopic bilateral sacropexy. Biomed Res Int 2015;2015:860784. [Crossref]
27. Noe KG, Schiermeier S, Alkatout I, Anapolski M. Laparoscopic pectopexy: a prospective, randomized, comparative clinical trial of standard laparoscopic sacral colpocervicopexy with the new laparoscopic pectopexy-postoperative results and intermediate-term follow-up in a pilot study. J Endourol 2015;29:210-5. [Crossref]
28. Barski D, Otto T, Gerullis H. Systematic review and classification of complications after anterior, posterior, apical, and total vaginal mesh implantation for prolapse repair. Surg Technol Int 2014;24:217-24.
29. Maher C, Feiner B, Baessler K, Schmid C. Surgical management of pelvic organ prolapse in women. Cochrane Database Syst Rev 2013;4:CD004014. [Crossref]
30. Molden S, Bracken J, Nguyen A. Harvie HS, White A, Hammil SL, et al. A retrospective multicenter study on outcomes after midurethral polypropylene sling revision for voiding dysfunction. Female Pelvic Med Reconstr Surg 2010;16:340-4. [Crossref]
31. Hinoul P, Vervest HA, den Boon J, Venema PL, Lakeman MM, Milani AL, et al. A randomized, controlled trial comparing an innovative single incision sling with an established transobturator sling to treat female stress urinary incontinence. J Urol 2011;185:1356-62. [Crossref]
32. Maaita M, Bhaumik J, Davies AE. Sexual function after using tension-free vaginal tape for the surgical treatment of genuine stress incontinence. BJU Int 2002;90:540-3. [Crossref]
33. Sabadell J, Pereda-Núñez A, Ojeda-de-los-Santos F, Urbaneja M, González-García C, Camps-Lloveras N, et al. Polypropylene and polyvinylidene fluoride transobturator slings for the treatment of female stress urinary incontinence: 1-year outcomes from a multicentre randomized trial. Neurourol Urodyn 2021;40:475-82. [Crossref]
34. Yeni E, Unal D, Verit A, Kafali H, Ciftci H, Gulum M. The effect of tension-free vaginal tape (TVT) procedure on sexual function in women with stress urinary incontinence. Int Urogynecol J Pelvic Floor Dysfunct 2003;14:390-4. [Crossref]