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CLINICAL ARTICLE

Gynecology

The impact of partially absorbable midurethral slings in stress urinary incontinence surgery: A cohort study

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Abstract

Objective: To evaluate the performance of retropubic midurethral slings (MUS) for the treatment of female stress urinary incontinence (SUI) at a certified continence center and to identify risk factors for sling failure.

Methods: This was a single-center cohort study including women who underwent a retropubic MUS procedure for SUI between 2012 and 2019 with a follow up of 12 months. Primary end point was cure of SUI assessed using the validated questionnaire International Consultation of Incontinence Questionnaire—Urinary Incontinence—Short Form. Univariate and multivariate analyses were applied to identify risk factors for sling failure. Wilcoxon signed-rank tests were used as paired samples tests. The significance level was set at 5%.

Results: A total of 662 women with a median age of 65 years (interquartile range 19 years) were included in the investigation; 523 (79.0%) presented with complicated SUI. Cure was reported by 213 (32.2%) women. Independent predictors for failure were obesity, pharmacotherapy for overactive bladder, postoperative sling adjustment, and use of partially absorbable mesh, which was correlated with a 56% decrease in the odds for achieving cure.

Conclusion: This investigation questions the role of partially absorbable mesh for stress urinary incontinence procedures and scrutinizes the use of implants with inadequate clinical evidence.

KEYWORDS
absorbable implants, stress, suburethral sling, surgery, urinary incontinence

1 | INTRODUCTION

Stress urinary incontinence (SUI) in women is a common condition with a prevalence between 28% and 65%.[1] The reference standard for surgical treatment of SUI is the synthetic midurethral sling (MUS).[2] Since its introduction by Ulmsten and Petros[3] in 1995, a large body of evidence for its efficacy and safety has been collected.[4] However, there are still limited data regarding risk factors for MUS failure.[5] Moreover, the efficacy and safety of MUS are commonly investigated in well-controlled clinical trials and highly selected patients. In contrast, evidence for heterogeneous patient cohorts are scarce.

Recently, the use of synthetic polypropylene mesh in pelvic organ prolapse (POP) repair has been steeped in controversy due to numerous adverse events.[6] In certain countries, not only transvaginal

mesh implants for POP repair, but also MUS were prohibited.[7] This increased the demand for improved quality control mechanisms to ensure the safe use of implants in POP and SUI surgery. The German societies of Continence, Gynecology and Obstetrics, Coloproctology, General and Visceral Surgery, and Urology, and the Surgical Working Group for Coloproctology recently established a new joint certification system for continence and pelvic floor centers, which requires the evaluation of the effectiveness of the procedures.[8]

This study was performed in a certified German continence center, providing insights into the success rates of retropubic MUS procedures in a patient cohort from daily clinical practice, using a validated questionnaire as primary endpoint of MUS procedures. In addition, predictors for MUS failure were investigated.

2 | MATERIAL AND METHODS

This was a single center, single-arm cohort study of a certified continence center, which required no ethical approval. As the collected data are part of the quality assurance system for certified continence centers, the present investigation is exempted from ethical approval according to § 15 paragraph 1 of the professional code of conduct of the State Medical Association. The results of such an evaluation may be published without the consent of the person concerned, if the data were previously anonymized as stated by the local ethics committee. The research was conducted in accordance with relevant guidelines/regulations.

Women who underwent a retropubic MUS procedure for the treatment of SUI between 2012 and 2019 were considered for analysis. Indication for the procedure was SUI and mixed urinary incontinence (UI)[9] after failed conservative therapy. In women with mixed UI, the urge component was treated primarily. Exclusion criteria were the absence of the International Consultation of Incontinence Questionnaire—Urinary Incontinence—Short Form (ICIQ-UI-SF) at baseline and/or follow up. Complicated SUI was defined as the presence of a history of previous incontinence surgery, neurogenic voiding dysfunction, history of radiation therapy, or bothersome POP.[2] Baseline evaluation included an anamnesis, a vaginal examination, a pelvic ultrasound, an urodynamic study, a cough stress test, and the ICIQ-UI-SF. The decision for MUS procedure was at the surgeon's discretion and in accordance with the patient's decision. Retropubic MUS procedure was performed in inside-out technique. Surgeons had different levels of experience. As part of the quality assessment for continence centers, the ICIQ-UI-SF was sent to each patient 12 months after surgery. Patients completed the questionnaire voluntarily and returned it at no charge. The evaluation of the questionnaire and the collection of perioperative data are an integral part of quality control in certified continence centers.

Treatment success was evaluated according to the validated and standardized questionnaire ICIQ-UI-SF.[10] The score of the ICIQ-UI-SF includes four items with a sum score ranging between 0 and 21 points. The higher the score, the higher the impact of symptoms. Severity classification was defined according to the sum score as no UI (0), slight UI (1–5), moderate UI (6–12), severe UI (13–18), and very severe UI (19–21).[11]

Cure was the absence of UI defined by an ICIQ sum score of 0 at follow-up. Improvement was defined by a decrease in the sum score such that the severity decreased at least one level of classification, e.g. from moderate to slight. No change was defined as no change in the sum score or involving a change in the sum score, as long as the change remained within the same severity grade, e.g. an improvement in the sum score from 10 to 7, which is still considered moderate. Worse UI was defined by an increase in the sum score, such that the severity of UI increased at least one level of classification, e.g. from moderate to severe UI. The primary end point was cure and secondary end point was cure or improvement (COI) of UI.

The material properties of all MUS (Serrag Wiessner, AMI, PFM medical, Neomedic, Dima) consisted of biocompatible type 1 polypropylene and were either non-absorbable or partially absorbable. Partially absorbable slings (PAS) were coated with a polyglycolic acid-caprolactone, which hydrolyzes over a period of 90–120 days.

The surgical technique was performed in inside-out technique for all retropubic MUS procedures with an indwelling Foley catheter. A 10-mm midline incision was made over the midurethral portion of the anterior vaginal wall. Two small incisions were made above the pubic symphysis to allow trocar passage. Subsequently, trocar passage in inside-out technique was performed and the sling was positioned in a tension-free fashion. Urethrocystoscopy was then performed, followed by wound closure.

Descriptive statistics were applied and presented as median (interquartile range) or numbers and frequencies. Wilcoxon signed-rank tests were used as paired samples tests. A chi-squared test or Mann–Whitney *U* test was performed to identify variables correlating with the end points. The following variables were investigated: age, obesity classification, urethral closure pressure, functional urethral length, nycturia, pharmacotherapy for overactive bladder (OAB), local estrogen therapy, surgeon, concomitant procedures, history of urogynecology surgeries, number and type of deliveries, number of pads, diabetes mellitus, chronic obstructive pulmonary disease, apoplexy, neurologic diseases, menopause, smoking, sling manufacturer, complicated SUI, baseline ICIQ sum score, baseline ICIQ severity classification, and PAS. A multivariate logistic regression analysis was conducted to predict failure using significant variables from the univariate analysis as predictors. Missing data were handled using an available case analysis approach. Age was grouped into the categories up to 60, 61–70, 71–80, and 81–90 years. Number of pads was grouped into more than two pads/day and up to two pads/day. Body mass index (BMI; calculated as weight in kilograms divided by the square of height in meters) was categorized according the World Health Organization[12] into the obesity classes I (BMI 30.0–34.9), II (BMI 35.0–39.9), and III (BMI >40). The significance level was set at 5%. Statistical analysis was performed using SPSS version 26 (IBM Corp., Armonk, NY, USA).

3 | RESULTS

Out of a total of 1298 women who underwent MUS surgery, 662 (51.0%) completed the ICIQ-UI-SF at baseline and follow up and were included in the analysis. Of these, 523 (79.0%) women were defined as suffering from complicated SUI. Baseline characteristics are presented in Table S1. Primary surgery was performed in 560 (84.5%) patients and PAS were used in 130 (19.6%) patients. Postoperative sling adjustment was performed in 135 (20.4%) patients.

After a follow-up time of 12 months, COI was achieved in 506 (76.3%) women; 213 (32.2%) were cured, 128 (19.3%) reported no change, and 28 (4.2%) reported worse UI. Improvement across four severity gradings (very severe to no UI) was reported by 28 (4.2%) patients, across three severity gradings by 131 (19.8%), across two severity gradings by 185 (27.9%), and across one grade by 162 (24.4%). The median ICIQ sum score (median 5, interquartile range 10; $P < 0.001$) and ICIQ severity grading ($P < 0.001$; Figure 1) improved significantly in comparison between baseline and follow-up.

Postoperative urge symptoms, defined by question 4 of the ICIQ-SF, were reported by 312 (47.1%) patients. Adjusted for patients without urge symptoms, cure and COI were reported by 209/350 (60.1%) and 311 (89.4%) patients, respectively.

Cure and COI correlated with several baseline variables in the univariate analysis (Table S2). In particular, age 81–90 years, obesity, pharmacotherapy for OAB, nycturia, and the use of PAS were significantly associated with a lower probability for cure and COI.

Adjusted for the presence or absence of urge symptoms, PAS still correlated with significantly lower success rates for both cure and COI.

No correlation with cure or COI could be identified for the following: surgeon, urethral closure pressure, local estrogen therapy, concomitant procedures, number and type of deliveries, chronic obstructive pulmonary disease, apoplexy, neurologic disease, menopause, sling manufacturer, or complicated SUI.

In the multivariate analysis, pharmacotherapy for OAB, obesity classification, postoperative sling adjustment, nycturia, secondary surgery, and the utilization of PAS were identified as independent variables for decreased cure rates (Table 1). Importantly, there was a 56% decrease in the odds of achieving cure by using PAS.

Patients, who underwent postoperative sling adjustment were statistically more frequently obese ($P = 0.015$), aged 61 years or older ($P = 0.009$), presented with recurrent SUI ($P = 0.033$), received pharmacotherapy for OAB more frequently ($P = 0.018$), and reported nycturia more frequently ($P = 0.007$). Patients with nycturia received medication for the treatment of OAB significantly more often ($P < 0.001$).

Smoking was associated with a 2.3-fold increase in probability of cure. However, women who smoked were also significantly younger than non-smoking women (55.8 vs 64.2 years; $P < 0.001$).

Independent predictors for decreased COI were age 81–90 years, diabetes mellitus, obesity classification, pharmacotherapy for OAB, lower ICIQ severity classification, lower functional urethral length, postoperative sling adjustment, and use of PAS (Table 1). The use of PAS was associated with a 46% decrease in the odds for COI.

4 | DISCUSSION

In this large heterogeneous cohort of women who underwent retropubic MUS, cure of SUI was achieved in 32.2% of women, and COI was reported by 76.3%. Importantly, most women (79.0%) were categorized as having complicated SUI. Independent risk factors for decreased cure and COI were obesity, pharmacotherapy for OAB, postoperative sling adjustment and the use of PAS. There was a 2.3-fold and 1.8-fold increase in the odds for cure and COI, respectively, if non-absorbable mesh was used.

COI rate was 76.3%, which is consistent with the literature. A Cochrane meta-analysis reported subjective cure rates between

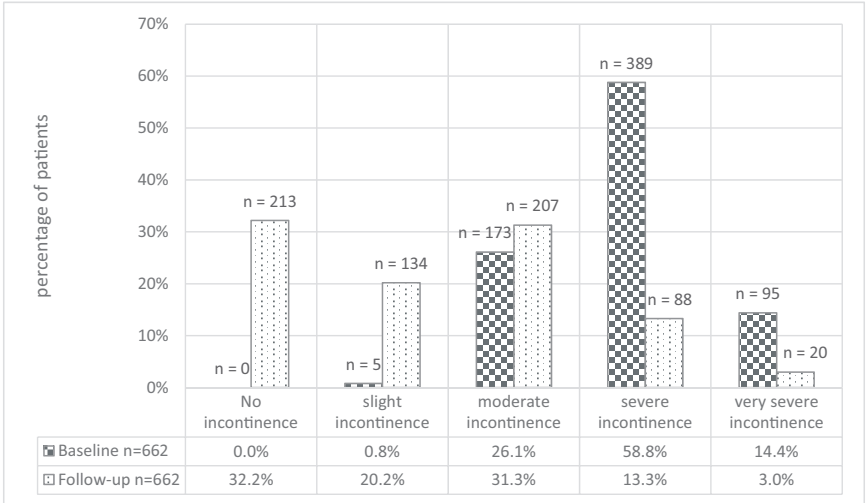

FIGURE 1 International Consultation Of Incontinence Questionnaire–Short Form severity classification in comparison between baseline and follow up

TABLE 1 Independent variables correlated with "cure" or "cure and improvement" after stress urinary incontinence surgery

Variable	*P* value	OR	95% CI
Cure			
Primary surgery	0.041	1.73	1.02–2.93
Pharmacotherapy for overactive bladder	<0.001	0.36	0.21–0.63
Obesity classifications	0.013	0.70	0.53–0.93
Smoking	0.003	2.32	1.34–4.04
Nycturia	<0.001	0.51	0.36–0.74
Sling adjustment	0.023	0.57	0.35–0.93
Partially absorbable mesh	0.001	0.44	0.27–0.71
Cure and improvement			
Age 81–90 years	0.016	0.29	0.11–0.80
Diabetes mellitus	0.026	0.48	0.25–0.92
Obesity classifications	<0.001	0.58	0.44–0.76
Pharmacotherapy for overactive bladder	0.014	0.53	0.32–0.89
Higher ICIQ severity classification	<0.001	5.43	3.75–7.85
Functional urethra lengths	0.012	1.04	1.00–1.08
Sling adjustment	0.050	0.59	0.35–1.00
Partially absorbable mesh	0.019	0.54	0.32–0.91

Abbreviations: CI, confidence interval; ICIQ, International Consultation of Incontinence Questionnaire; OR, odds ratio.

71% and 97% for retropubic mid-urethral sling operations.[4] This meta-analysis defined cure as being dry, improved, or cured and improved. However, cure rate, defined as the absence of UI, was 32.2% in the present study. A recent retrospective analysis of MUS in a real-world setting reported a dry rate of 47.5%; however, this was limited by a response rate of 38.4%.[13] Patient selection has a great impact on success outcome; two prospective randomized trials, including solely women with uncomplicated SUI reported dry rates of 84.0% and 62.2%, respectively.[14,15] The present study, however, reflects the performance of MUS in a heterogeneous patient population from daily clinical practice.

Several independent risk factors for decreased odds of cure and COI have been identified in this clinical investigation. Importantly, there was a 56% and 46% decrease in the odds of achieving cure or COI, respectively, by using PAS. Partially absorbable mesh has become increasingly popular in the last decade.[16] It aims to reduce foreign-body load and mesh-related complications, such as mesh exposure.[17] In urogynecology, the efficacy and safety of partially absorbable mesh have been investigated for POP repair; no significant differences in mesh-related complications or efficacy in comparison to non-absorbable meshes were found.[17] In contrast, in the present study, there were significantly lower cure (20.8% vs 35.0%) and COI (70.0% vs 78.0%) rates if PAS were used for the treatment of SUI. To our knowledge, this is the first clinical study investigating the efficacy of PAS in MUS procedures. Further studies are necessary to evaluate PAS for the treatment of SUI.

Obesity has been identified as an independent risk factor for decreased cure and COI rates in this investigation. The relationship between obesity and UI is well established. A recent meta-analysis reported an increase of 20% in the relative risk of the development of UI per five BMI units.[18] Regarding the impact of obesity on sling surgery, the risks for subjective and objective failure are increased by 1.69- and 1.62-fold, respectively, according to a recent meta-analysis.[19] Our results are consistent with existing literature.

Pharmacotherapy for OAB was associated with both decreased cure and COI rates. The Effect of Surgical Treatment Enhanced with Exercise for Mixed Urinary Incontinence (ESTEEM) trial also identified OAB medication as an independent risk factor for treatment failure,[20] so confirming the findings of the present study. In this investigation, nycturia was a predictor for decreased cure rates and also positively correlated with medication for OAB. This suggests that the underlying cause of nycturia may, in most cases, be an OAB syndrome.

Some manufacturers offer the possibility of postoperative adjustment of retropubic MUS by leaving the suture ends temporarily outside the body. However, adjustability has not demonstrated significant advantages for treatment success.[21] In the current investigation, postoperative sling adjustment was performed predominantly in women with multiple risk factors for MUS failure. This might explain the independent correlation with decreased success rates in this investigation. Furthermore, there is missing information about whether or not the results would have been even less favorable without an adjustment. Further clinical trials are necessary to investigate the benefit of adjustability in patients at risk for sling failure.

Advanced age (81–90 years) has been identified as an independent predictor for decreased odds for COI. This result is consistent with the literature, confirming the negative impact of advanced age on cure rates in prospective clinical trials.[22,23] However, the results in the current investigation are limited because of the low number of women with advanced age, and therefore should be considered

cautiously. Indeed, women aged between 60 and 80 years were not associated with decreased success rates.

Functional urethral length was an independent predictor for COI in the current investigation. However, the mean difference was only 1.5 mm, which questions the clinical importance of this statistical outcome. In contrast, maximum urethral closure pressure has been identified as a risk factor for MUS failure in the literature.[24] In this study, however, it did not correlate with the outcome.

Diabetes was identified as an independent risk factor for reduced COI rates and showed a negative correlation with cure in the univariate analysis. This is consistent with a retrospective analysis of 1225 women who underwent MUS procedure, demonstrating an independent correlation with sling failure.[5] An explanation may be a pre-existing neuropathy, which causes sphincter incompetence.[5]

Interestingly, higher ICIQ severity classification correlated with a significant increase in COI. Severe SUI has a higher impact on quality of life than lower classifications, so the effect of treatment may be rated better. Furthermore, women with more severe SUI often witnessed an improvement across several severity classifications, hence, the change in improvement was more significant than for women with lower classifications, which might explain these results.

Smoking was an independent predictor for increased odds for cure in the current investigation. The impact of tobacco consumption on MUS outcome is contradictory. Bohlin et al.[25] did not identify a correlation between tobacco and MUS success in a review of a national register with more than 5000 patients. In an investigation of more than 15 000 patients, tobacco was associated with an increased risk for treatment failure.[26] On the contrary, the current investigation identified an increased odds for cure. However, smokers were significantly younger than non-smokers, which may explain the discrepancy in these results.

Several patients underwent concomitant POP surgery. The risks of short-term voiding difficulties and adverse events have been identified as increased in combination surgeries in a meta-analysis from 2014.[27] However, there is an ongoing debate whether to include sling surgery during POP repair. A Cochrane meta-analysis[28] concluded that a concurrent sling surgery might reduce postoperative SUI but also a two-stage strategy is feasible. However, complications were not assessable. A recent analysis of a US registry identified a risk for reoperation and venous thromboembolism if sling surgery was performed concurrent with vaginal POP repair.[29] Hence, the time point of sling surgery in women with POP is still debatable and currently depends on the surgeons' and patients' preferences.

We acknowledge the limitations of this investigation because of its retrospective design, therefore some pertinent data are not available. Furthermore, no objective criteria, such as the pad test, were available. The patient population was heterogeneous, including patients with complicated and/or mixed UI and various patients underwent concomitant procedures during sling surgery. However, the aim of this study was to investigate the performance of MUS in a real-life setting, using a validated questionnaire. Furthermore, some results may be associated with a type II error, because some risk groups lack adequate patient numbers.

In conclusion, the present study provides success rates using the ICIQ-UI-SF as quality control tool, as required by certified continence centers in Germany. Cure rates of UI were lower in comparison with the literature involving controlled prospective trials including highly selected patient populations. This highlights the impact of a heterogeneous patient population from daily clinical practice on the success rates of SUI surgery. In addition, several independent risk factors for decreased cure and improvement rates have been identified, including the use of partially absorbable slings, obesity, and pharmacotherapy for OAB.

Importantly, this is the first study identifying PAS as an independent risk factor for decreased cure and improvement rates in the treatment of SUI. Prospective comparative studies need to further investigate the role of PAS in SUI surgery.

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DATA AVAILABILITY STATMENT

Research data are not shared.

CONFLICTS OF INTEREST

TH declares personal fees from Photocure GmbH outside the submitted work. CF declares honoraria and expenses from pfm medical, Serag-Wiessner, AMI, and Promedon outside the submitted work. NN-S has nothing to disclose.

AUTHOR CONTRIBUTIONS

TH: project development, data management, analysis and interpretation, manuscript writing. CF: project development, data interpretation, manuscript editing. NN-S: project development, data collection, manuscript editing. All authors reviewed and approved the final version of the manuscript.

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SUPPORTING INFORMATION

Additional supporting information may be found in the online version of the article at the publisher's website.

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