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Comparing the Efficacy of Different Sling Materials in the Treatment of Stress Urinary Incontinence: A Randomized Controlled Trial

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ABSTRACT

Background: Stress urinary incontinence (SUI) has a substantial effect on women's quality of life. Common treatment is surgical intervention, including synthetic mesh and autologous fascial slings, both with advantages and limitations.

Objective: To compare the efficacy, operative outcomes, and patient recovery between synthetic mesh and autologous fascial slings in the surgical management of SUI.

Material and Methods: The study was performed as a randomized controlled trial in **Department of Urology Shalamar Hospital Lahore**, from January 2023 to June 2024 and consisted of 318 female patients with SUI, randomly assigned to: the Synthetic Mesh group (n = 159) or the Autologous Fascia group (n = 159). The key outcomes were success rates, operative time, length of hospital stay and postoperative pain on the visual analog scale (VAS) at 24 hours. Independent t tests and chi square tests were conducted to determine statistically significant differences from p value ≤ 0.05.

Results: The Synthetic Mesh group showed a significantly higher success rate (93.1%) compared to the Autologous Fascia group (78.0%, $p < 0.001$). Operative time (49.82 ± 9.91 minutes vs. 88.95 ± 13.22 minutes), hospital stay duration (2.01 ± 0.47 days vs. 4.08 ± 1.06 days), and postoperative pain scores (3.08 ± 0.92 vs. 5.10 ± 1.58, $p < 0.001$) were significantly better in the Synthetic Mesh group. Subgroup analyses by age, obesity status, and parity consistently favored the synthetic mesh.

Conclusion: Performance of synthetic mesh slings is superior to autologous fascial slings for SUI treatment because of superior efficacy, lower morbidity, and speedier recovery. In selected cases, however, autologous slings remain a valid alternative

Keywords: Stress urinary incontinence, synthetic mesh, autologous fascia, sling surgery, randomized controlled trial, operative outcomes..

1. INTRODUCTION:

Stress urinary incontinence is very common and impacts women's quality of life. It is characterized by urine leakage that is involuntary and usually worsened by normal activities like coughing and sneezing or physical exertion [1]. Initial treatment for moderate to severe cases involves conservative management, (such as pelvic floor muscle training and lifestyle modifications), but surgical intervention (including mid-urethral slings (MUS)) remains the gold standard [2]. Sling material choice is central to surgical outcome, impacting efficacy, and complication risk. Synthetic polymers, biological graft, or autologous fascia can be used to construct mid-urethral slings through synthetic polymers, biological graft, or autologous fascia which comes with advantages and disadvantages [3].

MUS has brought about a revolution in treatment of SUI by offering minimally invasive techniques that are also highly successful. Synthetic slings, especially those using polypropylene, tend to be favored widely due to durability and their relative ease of use [4]. However, not yet satisfied with such mesh related complications including erosion and chronic pain, other materials have been studied for use as an alternative material such as biocompatible and absorbable meshes [5]. Biological slings are generated from autologous or donor alogous tissues giving an improved congenial affability with host tissues but in need of expanded full scale and surgical planning [6].

. Increasing research describes the need to document long term outcomes associated with various sling materials. However, Chapin et al. (2018) showed that woven collagen slings have favorable biocompatibility and mechanical stability in preclinical models opening up the possibility for clinical use [7]. The improved outcomes with mid urethral slings are supported by partially combined with posterior pelvic floor reconstruction in complex cases presented by Tian et al. (2023) but highlights the need for individualized treatment plans [8]. In parallel, Sarrazin et al. (2023) assessed the role of synthetic slings for women with neurogenic lower urinary tract dysfunction, emphasizing that patients from subpopulations could benefit from tailored approaches [9].

These limitations are addressed by emerging technologies and materials. As such, biocompatible coatings and slide adjustable sling systems provide superior adaptability and fewer adverse events [10]. Flat magnetic stimulation methods, as detailed by Frigerio et al. (2023), can also be considered as a progression of surgical treatments and a means of increasing the achievement of patients and their levels of comfort [11]. These innovations have promise to improve the management of SUI, but robust clinical trials are needed to establish efficacy and safety.

This randomized controlled trial systematically determines which material is best for slings used to treat SUI. This study continues by determining the best choice in sling material based on both objective outcomes such that continence rates, and subjective outcomes, as determined by patient satisfaction

2. MATERIAL AND METHODS

The research was conducted as a randomized control trial (RCT) in the Department of Urology Shalamar Hospital Lahore, from January 2023 to June 2024. A total of 318 female patients with stress urinary incontinence (SUI) participated in the study. We created two groups of 159 patients. In Group A the synthetic polypropylene mesh slings were placed, while Group B had autologous fascial slings harvested from the abdominal rectus fascia.

Following these findings, we calculated our sample size based on reported efficacy rates of 83.87% for autologous fascial slings (Mourad et al., 2018) and 93.75% for synthetic slings (Mourad et al., 2018). With a power of 80% and $\alpha = 0.05$, a total of 159 patients was estimated to be needed in each group [12].

Females 18—65 years old diagnosed with SUI via clinical examination and urodynamic tests and fit for elective surgery were included. Exclusion criteria were patients with mixed or urge urinary incontinence, history of prior pelvic surgery for urinary incontinence, pregnant or planning pregnancy during study period or severe comorbidity (advanced cardiac or renal disease).

Randomization was performed using the lottery method to assign patients to either Group A or Group B. Allocation concealment was ensured using sealed opaque envelopes.

The primary outcome of the study was the success rate of SUI treatment, defined as the absence of urinary leakage during stress maneuvers such as coughing and sneezing, evaluated at 6 months postoperatively. Secondary outcomes included operative time (measured in minutes), hospital stay duration (measured in days), and postoperative pain (measured using a visual analog scale [VAS] at 24 hours and 7 days postoperatively).

Baseline and confounding variables such as age, obesity status (BMI ≥ 30 kg/m² or <30 kg/m²), and parity (number of previous deliveries) were documented for all patients.

The study was approved by the Ethical Review Committee of Civil Hospital, Bahawalpur. Written informed consent was obtained from all participants before enrollment.

Data on baseline characteristics, surgical details, and outcomes were collected using a standardized proforma. Data were analyzed using SPSS version 24. Continuous variables such as operative time, hospital stay, and postoperative pain were presented as mean ± standard deviation and compared between groups using an independent t-test. Categorical variables such as success rate, obesity status, and parity were presented as frequencies and percentages and compared using the chi-square test. A p-value ≤ 0.05 was considered statistically significant.

3. RESULTS

A total of 318 patients were included in the study. The mean age of the patients was 39.83 ± 13.03 years. The mean operative time was 69.39 ± 22.80 minutes, while the mean hospital stay duration was 3.05 ± 1.32 days. Postoperative pain, assessed using the visual analog scale (VAS) 24 hours after surgery, had a mean score of 4.09 ± 1.64.

The comparison of success rates between the two groups showed a statistically significant difference ($p < 0.001$). In the Synthetic Mesh group, 148 patients (93.1%) achieved success, while 11 patients (6.9%) experienced failure. In contrast, the Autologous Fascia group had a lower success rate, with 124 patients (78.0%) achieving success and 35 patients (22.0%) experiencing failure. These results highlight the superior efficacy of the Synthetic Mesh compared to the Autologous Fascia in the treatment of stress urinary incontinence (Table 1).

The success rates were further analyzed across various subcategories. For age groups, the success rate in patients aged <30

years was 93.3% (42/45) in the Synthetic Mesh group compared to 76.5% (39/51) in the Autologous Fascia group (p = 0.023). Among patients aged 30–49 years, success rates were 95.1% (77/81) for Synthetic Mesh and 82.7% (67/81) for Autologous Fascia (p = 0.012). For patients aged ≥50 years, success rates were 87.9% (29/33) for Synthetic Mesh and 66.7% (18/27) for Autologous Fascia (p = 0.047).

For obesity status, among obese patients, the success rate was 90.9% (60/66) in the Synthetic Mesh group compared to 76.7% (46/60) in the Autologous Fascia group (p = 0.029). In non-obese patients, success rates were 94.6% (88/93) for Synthetic Mesh and 78.8% (78/99) for Autologous Fascia (p = 0.001).

Regarding parity, in Primipara patients, success rates were 100.0% (26/26) for Synthetic Mesh and 75.0% (27/36) for Autologous Fascia (p = 0.006). In Multipara patients, success rates were 87.5% (63/72) for Synthetic Mesh and 77.3% (51/66) for Autologous Fascia (p = 0.113). Among Grand Multipara patients, success rates were 96.7% (59/61) for Synthetic Mesh and 80.7% (46/57) for Autologous Fascia (p = 0.005). These findings consistently demonstrate the superior success rates of the Synthetic Mesh group across most patient subcategories, particularly in younger, non-obese, and Primipara or Grand Multipara patients (Table 2).

The comparison of operative time, hospital stay, and postoperative pain between the two groups demonstrated statistically significant differences, favoring the Synthetic Mesh group ($p < 0.001$ for all variables). The mean operative time for the Synthetic Mesh group was 49.82 ± 9.91 minutes, which was significantly shorter than the 88.95 ± 13.22 minutes recorded for the Autologous Fascia group ($p < 0.001$). This finding reflects the less complex and quicker nature of the Synthetic Mesh procedure compared to the additional time required for harvesting fascia in the Autologous Fascia group.

The hospital stay duration also differed significantly between the groups. Patients in the Synthetic Mesh group had a mean hospital stay of 2.01 ± 0.47 days, which was notably shorter than the 4.08 ± 1.06 days observed in the Autologous Fascia group ($p < 0.001$). This result underscores the faster recovery associated with the Synthetic Mesh procedure.

Postoperative pain, assessed using the visual analog scale (VAS) 24 hours after surgery, was significantly lower in the Synthetic Mesh group (3.08 ± 0.92) compared to the Autologous Fascia group (5.10 ± 1.58, $p < 0.001$). This finding highlights the reduced postoperative discomfort associated with the Synthetic Mesh technique, likely due to the absence of a secondary donor site for fascia harvesting.

Overall, the results indicate that the Synthetic Mesh procedure offers clear advantages over the Autologous Fascia method in terms of operative efficiency, shorter hospitalization, and reduced postoperative pain, with all differences being highly statistically significant ($p < 0.001$ for all variables) (Table 3).

Table 1: Comparison of Success Rates between Synthetic Mesh and Autologous Fascia Groups

Group	Success (n, %)	Failure (n, %)	Total (n)	p-value
Synthetic Mesh	148 (93.1%)	11 (6.9%)	159	<0.001
Autologous Fascia	124 (78.0%)	35 (22.0%)	159	

Table 2: Success and Failure Rates in Synthetic Mesh and Autologous Fascia Groups Stratified by Age, Obesity Status, and Parity

Variable	Subcategory	Synthetic Mesh (Success n, %)	Synthetic Mesh (Failure n, %)	Autologous Fascia (Success n, %)	Autologous Fascia (Failure n, %)	p-value
Age Group	<30 Years	42 (93.3%)	3 (6.7%)	39 (76.5%)	12 (23.5%)	0.023
	30-49 Years	77 (95.1%)	4 (4.9%)	67 (82.7%)	14 (17.3%)	0.012
	≥50 Years	29 (87.9%)	4 (12.1%)	18 (66.7%)	9 (33.3%)	0.047
Obesity Status	Obese	60 (90.9%)	6 (9.1%)	46 (76.7%)	14 (23.3%)	0.029
	Non-Obese	88 (94.6%)	5 (5.4%)	78 (78.8%)	21 (21.2%)	0.001
Parity Group	Primipara	26 (100.0%)	0 (0.0%)	27 (75.0%)	9 (25.0%)	0.006
	Multipara	63 (87.5%)	9 (12.5%)	51 (77.3%)	15 (22.7%)	0.113
	Grand Multipara	59 (96.7%)	2 (3.3%)	46 (80.7%)	11 (19.3%)	0.005

Table 3: Comparison of Operative Time, Hospital Stay, and Postoperative Pain between Groups

Variable	Group	Mean	Std. Deviation	p-value
Operative Time (Minutes)	Synthetic Mesh	49.82	9.910	<0.001
	Autologous Fascia	88.95	13.220	
Hospital Stay (Days)	Synthetic Mesh	2.01	0.469	<0.001
	Autologous Fascia	4.08	1.058	
Postoperative Pain (VAS 24hr)	Synthetic Mesh	3.08	0.918	<0.001
	Autologous Fascia	5.10	1.575	

4. DISCUSSION

The findings of our study align with existing literature and contribute to the ongoing debate regarding the efficacy and safety of synthetic mesh and autologous fascial slings for the treatment of stress urinary incontinence (SUI). Both methods demonstrate high success rates, but their outcomes differ in operative efficiency, patient recovery, and postoperative discomfort.

The success rate observed in our study for the Synthetic Mesh group (93.1%) and the Autologous Fascia group (78.0%) is consistent with the findings of Mourad et al. [12], who reported a higher success rate for synthetic slings (93.75%). Similarly, Mourad et al. highlighted the advantages of synthetic slings, including shorter operative time, reduced postoperative pain, and quicker return to normal activity. These outcomes are supported by our results, where synthetic mesh procedures significantly outperformed autologous fascia in operative time (49.82 ± 9.91 minutes vs. 88.95 ± 13.22 minutes, $p < 0.001$) and postoperative pain scores (3.08 ± 0.92 vs. 5.10 ± 1.58, $p < 0.001$).

Larouche et al. [13] reinforced the superiority of synthetic slings in terms of subjective satisfaction, particularly in the transobturator approach, which aligns with the reduced postoperative pain and faster recovery observed in our study. However, Larouche et al. also emphasized that the objective success rates of synthetic and nonsynthetic slings are comparable. This finding underscores the importance of considering patient-specific factors, such as age, obesity status, and parity, when selecting the surgical approach, as demonstrated in our subgroup analyses.

Wagner et al. [14] found no significant difference in patient satisfaction and outcomes between various sling materials. However, synthetic mesh procedures were associated with shorter operative times and fewer complications. This observation resonates with our findings, where synthetic mesh procedures led to shorter hospital stays (2.01 ± 0.47 days vs. 4.08 ± 1.06 days, $p < 0.001$) and lower morbidity.

The systematic review by Güler [15] concluded that midurethral synthetic slings (e.g., TVT and TOT) outperform autologous slings in operative efficiency and patient recovery. Similarly, our study highlighted the reduced operative burden and faster postoperative recovery associated with synthetic mesh, making it a preferred choice for younger, non-obese, and multipara patients.

Garcia et al. [16] emphasized the evolving perceptions of synthetic mesh due to FDA safety concerns but maintained that synthetic slings remain a viable option for carefully selected patients. Our study supports this perspective, as the synthetic mesh group demonstrated better outcomes in terms of both efficacy and recovery. However, it is crucial to address patient concerns and ensure informed consent, particularly in light of the controversies surrounding synthetic mesh.

Elsersy et al. [17] reported comparable cure rates between synthetic and autologous slings but highlighted the shorter catheterization duration and higher patient satisfaction in the synthetic sling group. This aligns with our findings, where synthetic slings were associated with better overall patient comfort.

Dogan et al. [18] concluded that autologous slings are as effective as synthetic mesh in treating SUI, albeit with longer operative times. Our results echo this, showing that while autologous slings remain effective, they are associated with higher postoperative pain and prolonged recovery.

Schimpf et al. [19] and Călinescu et al. [20] both noted that surgical decisions should balance success rates and complications. In our study, the lower postoperative pain and faster recovery associated with synthetic mesh strongly favor its use, especially in patients seeking quicker return to normal activities.

Overall, our findings affirm the superiority of synthetic slings in terms of operative efficiency, reduced morbidity, and faster recovery. However, autologous fascial slings remain a viable option, particularly for patients with financial constraints or contraindications to synthetic materials. Future research should focus on long-term follow-up and patient-reported outcomes to further clarify the comparative efficacy and safety of these approaches.

5. CONCLUSION

Synthetic mesh slings are shown to be more efficacious and offer better outcomes for treatment of stress urinary incontinence than autologous fascial slings in this study. Synthetic slings were associated with higher success rates, shorter surgery time, less pain post surgery and faster recovery and thus a better option. When synthetic materials are not ideal or accessible, autologous slings remain a sensible alternative, with the inconvenience of a longer procedure time and more discomfort and slower recovery. The proper patient selection and obtaining informed consent is absolutely critical. However, such research on long term outcomes, cost, and on patient satisfaction is required to help guide the choice of the best treatment option.

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