



Original Article



Comparison of Prolene Sutures Versus Skin Staples for Mesh Fixation in Lichtenstein Inguinal Hernioplasty: A Randomized Controlled Trial

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ABSTRACT

Chronic postoperative groin pain following Lichtenstein inguinal hernia repair is commonly attributed to nerve irritation during mesh fixation. Alternative fixation methods, such as skin staples, have been proposed to reduce postoperative pain. **Objectives:** To compare postoperative pain outcomes following mesh fixation with Prolene sutures versus skin staples in Lichtenstein inguinal hernioplasty. **Methods:** This randomized controlled trial was conducted at Mayo Hospital, Lahore. 132 adult male patients undergoing elective unilateral Lichtenstein inguinal hernioplasty were randomized to mesh fixation using either Prolene sutures or stainless-steel skin staples. Postoperative pain was assessed using the Visual Analogue Scale (VAS) on postoperative days 1, 14, 30, and 90. Statistical analysis included the Mann-Whitney U test, chi-square test, and logistic regression. **Results:** Baseline characteristics were comparable between groups. Median VAS on day 1 was higher in the Prolene group compared to the staple group, but pain scores declined significantly in both groups over time. By day 90, 37.9% of patients were pain-free, with no significant difference in pain-free rates between fixation methods ($p=0.858$). No independent predictors of persistent pain were identified. **Conclusions:** Mesh fixation with Prolene sutures and skin staples results in comparable postoperative pain outcomes. Fixation choice may therefore be guided by surgeon preference and operative considerations.

INTRODUCTION

Inguinal hernia repair is among the most frequently performed procedures in general surgery, with the Lichtenstein tension-free mesh technique widely regarded as the standard open approach due to its simplicity, reproducibility, and low recurrence rates [1]. Despite these advantages, chronic postoperative groin pain (inguinodynia) remains a significant complication. It continues to be a major cause of patient dissatisfaction and impaired quality of life following inguinal hernia repair

[2]. The aetiology of chronic post-herniorrhaphy pain is multifactorial, with nerve irritation, nerve entrapment, and excessive fibrosis during mesh fixation being the most commonly implicated mechanisms [3]. Traditionally, polypropylene mesh is secured using non-absorbable Prolene sutures. While effective, suture fixation has been associated with increased tissue handling and the potential for nerve involvement, which may contribute to early postoperative pain and the development of chronic



symptoms [4]. To address these concerns, alternative mesh fixation techniques have been explored, including absorbable sutures, tissue adhesives, self-gripping meshes, and skin staples. Skin staples offer potential advantages, including reduced operative time, standardized depth of fixation, and decreased tissue trauma. Several studies have reported lower early postoperative pain with staple fixation compared to suture fixation in open Lichtenstein repair; however, findings regarding long-term pain outcomes remain inconsistent [5,6].

Most existing evidence comparing fixation techniques originates from small trials or heterogeneous study populations, and regional data from low- and middle-income settings remain limited. Furthermore, while early postoperative pain has been evaluated in many studies, fewer have assessed pain trajectories over an extended follow-up period using standardized pain scales. The present randomized controlled trial was therefore conducted to compare postoperative pain outcomes following mesh fixation with Prolene sutures versus skin staples in Lichtenstein inguinal hernioplasty. In addition, this study aimed to evaluate the pattern and trajectory of postoperative pain reduction over a 90-day follow-up period to determine whether the choice of fixation technique influences both early and longer-term pain outcomes.

METHODS

This randomized controlled trial was conducted at the East Surgical Ward, Mayo Hospital, Lahore, over six months, following institutional ethical approval (IRB No. 511/RC/KEMU; dated 28th June 2025) and clinical trial registry number: NCT07210424. The study was conducted from July 2025 to December 2025. Although both sexes were eligible, only male patients presented to us with the condition during the study period. After obtaining informed consent, 132 adult male patients aged 18–65 years undergoing elective unilateral Lichtenstein inguinal hernia repair were included and randomly assigned to two groups. Patients were excluded if they had chronic obstructive pulmonary disease, were immunocompromised (including HIV, hepatitis B or C positivity, or diabetes mellitus), had obstructive uropathy, or suffered from chronic constipation. The study was conducted and reported in accordance with CONSORT guidelines. A CONSORT flow diagram illustrating participant enrolment, allocation, follow-up, and analysis is presented (Figure 1).

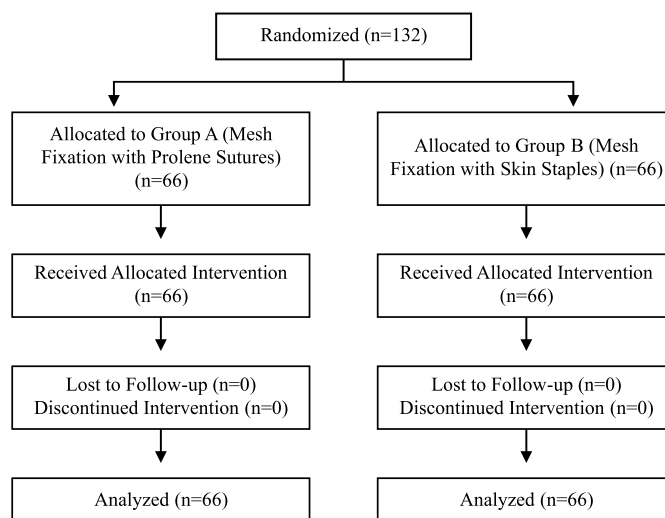


Figure 1: CONSORT Flow for Participant Enrolment, Allocation, Follow-Up, and Analysis

Patients were randomized using a lottery method into Group A: Mesh fixation with Prolene sutures and Group B: Mesh fixation with stainless-steel skin staples. Postoperative pain was assessed using a 10-point Visual Analogue Scale (VAS) on postoperative days 1, 14, 30, and 90 by a blinded assessor. A VAS score >3 was considered clinically significant pain. Data distribution for continuous variables (VAS pain scores at each postoperative time point, age, and BMI) was assessed using histograms, Q-Q plots, and the Shapiro-Wilk test. Because VAS scores demonstrated significant deviation from normality ($p < 0.050$), nonparametric statistical methods were used for continuous data analysis. Continuous variables are presented as median and interquartile range (IQR). Between-group comparisons of pain scores at each follow-up time point (postoperative days 1, 14, 30, and 90) were performed using the Mann-Whitney U test. Categorical variables were analyzed using the chi-square test or Fisher's exact test where appropriate. For long-term outcomes, pain at day 90 was analyzed both as a dichotomous variable (pain-free vs pain present; VAS = 0 vs >0) and as clinically significant pain (VAS >3). Associations between baseline variables and persistent pain at day 90 were explored using univariate and multivariable logistic regression models. Variables entered into the multivariable model included age, body mass index (BMI), treatment group, and baseline postoperative VAS score. Odds ratios (ORs) with 95% confidence intervals (CIs) were reported. Longitudinal trends in pain reduction within each group were evaluated descriptively across follow-up intervals using serial non-parametric comparisons. A p -value ≤ 0.050 was considered statistically significant. Statistical analyses were performed using SPSS version 25 (IBM Corp., Armonk, NY).

RESULTS

A total of 132 male patients were included in the dataset. Participants were evenly distributed between Group A (Prolene Fixation) and Group B (Staples) (66 in each group). All individuals were male, so gender differences could not be evaluated. The pain outcomes were assessed using the Visual Analogue Scale (VAS). The study summarizes baseline demographic and clinical characteristics of both groups. The median age was 48 years in both groups, and BMI distributions were comparable. The median body mass index (BMI) of participants was 22.9 kg m^{-2} (IQR 3.3), with slightly higher values in Group B (median 23.15 kg m^{-2} , IQR 3.05) than in Group A (median 22.6 kg m^{-2} , IQR 3.48). Baseline pain level (VAS Day 1) was higher in Group A (median 3.55, IQR 2.40) compared with Group B (median 2.80, IQR 1.95), indicating that individuals in Group A reported more severe pain at the start of the study (Table 1).

Table 1: Baseline Characteristics of Study Population (Median [IQR])

Variable	Group A, (n = 66)	Group B, (n = 66)
Age (years)	48 (21.75)	48 (23.00)
BMI (kg m^{-2})	22.6 (3.48)	23.15 (3.05)
VAS day 1	3.55 (2.40)	2.80 (1.95)
VAS day 14	1.70 (1.08)	1.20 (0.98)
VAS day 30	0.40 (0.50)	0.40 (0.80)
VAS day 90	0.20 (0.40)	0.20 (0.50)

Median VAS scores declined in both groups. In Group A and Group B, respectively, median VAS scores were 3.55 and 2.80 on day 1, 1.70 and 1.20 on day 14, 0.40 and 0.40 on day 30, and 0.20 and 0.20 on day 90. By days 30 and 90, the median scores were similar between groups (Figure 2).

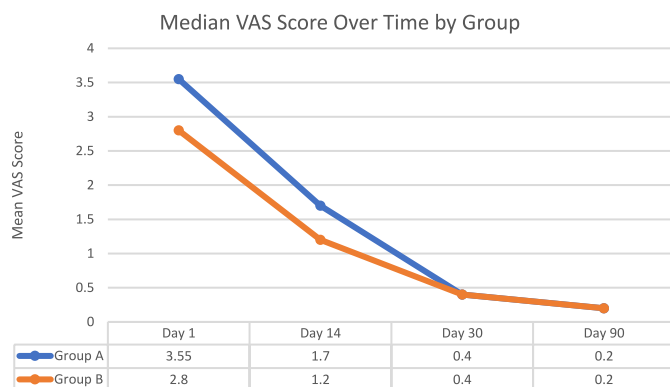


Figure 2: Median Visual Analogue Scale (VAS) Scores at Each Follow-Up for Group A and Group B

To explore long-term pain outcomes, VAS Day 90 scores were dichotomized into "no pain" (VAS = 0) and "pain present" (VAS > 0). At day 90, 50 patients (37.9%) were pain-free. Longitudinal trends were described using serial median comparisons. Pain-free rates did not differ significantly between groups ($p=0.858$). The median age

and BMI were similar between pain-free and pain-present patients. Baseline pain tended to be slightly lower among patients who were pain-free by day 90, but the difference did not reach statistical significance ($p=0.156$). Overall, there was no evidence that demographic factors, BMI, or baseline pain predicted pain-free status at three months. At day 90, clinically significant pain (VAS > 3) was uncommon and did not differ significantly between the Prolene and staple groups ($p>0.050$) (Table 2).

Table 2: Pain-Free Status at Day 90 by Baseline Variables

Variable (Categories)	Pain-Free	Pain Present	p-value
Group, n(%)	A: 26 (39.4%), B: 24 (36.4%)	A: 40 (60.6%), B: 42 (63.6%)	0.858
Age (Median [IQR])	45.0 (21.0)	49.0 (22.0)	0.184
BMI (Median [IQR])	23.0 (3.1)	22.8 (3.3)	0.341
VAS Day 1 (Median [IQR])	3.0 (2.2)	3.4 (2.1)	0.156

Mann-Whitney U test used for continuous variables. Chi-square test used for categorical variables

To identify factors associated with persistent pain at day 90, both univariate and multivariable logistic regression models were fitted with pain present as the dependent variable. Predictor variables included age, BMI, treatment group, and baseline VAS score. The univariate analysis showed that none of the variables was significantly associated with persistent pain. For example, the odds ratio (OR) for group (reference = Group A) was 1.14 (95 % CI 0.56 – 2.30; $p=0.720$), indicating that assignment to Group B did not significantly alter the odds of pain at day 90. In the multivariable model, which adjusted for all predictors simultaneously, the associations remained nonsignificant. The pseudo- R^2 of the multivariable model was 0.006, and the likelihood ratio test was not significant ($p=0.903$), suggesting that the model explained little of the variation in pain outcomes (Table 3).

Table 3: Logistic Regression Predicting Pain at Day 90

Predictor	OR (95 % CI)	p-value
Univariate Models		
Age (Per 1-Yr Increase)	1.01 (0.99 – 1.04)	0.390
BMI (per 1- kg m^{-2} Increase)	1.02 (0.88 – 1.17)	0.820
Group (B vs A)	1.14 (0.56 – 2.30)	0.720
Baseline VAS (Per 1-Unit Increase)	0.96 (0.79 – 1.18)	0.710
Multivariable Model†		
Age	1.01 (0.99 – 1.04)	0.370
BMI	1.01 (0.88 – 1.17)	0.860
Group (B vs A)	1.07 (0.51 – 2.24)	0.870
Baseline VAS	0.96 (0.77 – 1.18)	0.680

†The multivariable model simultaneously adjusted for age, BMI, group, and baseline VAS score

DISCUSSION

This randomized controlled trial compared postoperative pain outcomes following mesh fixation with Prolene sutures versus skin staples in open Lichtenstein inguinal hernia repair. The principal finding of our study is that although staple fixation was associated with lower pain scores in the immediate postoperative period, this early difference did not persist beyond the first few weeks. By 30 days and continuing through 90 days of follow-up, pain scores and pain-free rates were comparable between the two fixation techniques. These findings suggest that the choice of mesh fixation method does not significantly influence long-term postoperative pain outcomes. In the early postoperative period, patients in the Prolene suture group reported higher pain scores compared to those in the staple group. Wani *et al.* reported that staple fixation significantly reduced operative time while maintaining postoperative outcomes similar to those with polypropylene sutures [5]. Ali *et al.* observed a slightly lower incidence of postoperative pain in the stapler group, although the difference was not statistically significant [6]. In addition, the systematic review by Alabi *et al.* found no consistent superiority of one fixation technique over another regarding chronic pain outcomes [7]. These findings are broadly consistent with our observation of lower early pain with staple fixation. Suture fixation requires multiple needles passes through the inguinal tissues, which may increase tissue trauma and transient nerve irritation. In contrast, skin staples allow rapid fixation with less tissue handling, which may explain the lower early pain scores observed in our staple group. Alabi *et al.* in a systematic review of fixation techniques, reported no consistent superiority of mechanical fixation methods for chronic pain outcomes, although some techniques may influence postoperative pain profiles [7]. Khulique *et al.* reported lower surgical site infection rates with staple fixation while observing comparable rates of other postoperative complications [8]. Additionally, Hassan *et al.* demonstrated that variations in suture techniques can significantly influence postoperative pain following Lichtenstein repair [9]. The clinical importance of early postoperative pain has also been highlighted by Sultana *et al.* who showed that reductions in early pain significantly improve patient satisfaction during recovery [10]. Despite this early difference, pain trajectories in both groups showed a steady and parallel decline over time. By one month postoperatively, pain levels were low and no longer significantly different between the two groups. This convergence suggests that early postoperative pain related to fixation technique is largely transient and diminishes as tissue healing progresses. By the 90-day follow-up, approximately one-third of patients in both

groups were completely pain-free, and the proportion of patients reporting any residual pain did not differ significantly between fixation methods. The relatively high proportion of patients reporting some degree of pain at 90 days should be interpreted with caution. In our study, pain was dichotomized into "no pain" versus "any pain," which may capture even mild or intermittent symptoms. Cirocchi *et al.* reported that the incidence of chronic postoperative inguinal pain varies widely across studies, reflecting differences in definitions, surgical techniques, and follow-up periods [11]. Similarly, Calderon *et al.* observed that chronic pain rates at three months after hernia repair are generally low and often associated with improved quality of life [12]. Earlier work by Poobalan *et al.* also showed that although many patients report some postoperative discomfort, clinically significant pain affecting daily activities occurs in a much smaller subset [13]. These observations suggest that the residual pain seen in our cohort likely represents mild symptoms during the late healing phase rather than disabling chronic pain. Importantly, our multivariable analysis identified no independent predictors of persistent pain at 90 days, including fixation method, age, body mass index, or baseline pain intensity. Aziz *et al.* reported differences in early postoperative pain between fixation techniques in laparoscopic TAPP repair, although other early complications were comparable between groups [14]. In contrast, Zhou *et al.* found that patient-related factors such as younger age, obesity, and smoking were associated with higher perioperative pain levels [15]. Similarly, Van Den Dop *et al.* identified several patient and surgical factors, including surgical technique and nerve handling, as contributors to chronic postoperative inguinal pain [16]. These variations across studies may reflect differences in study design, follow-up duration, and patient populations. From a clinical perspective, our results suggest that both Prolene sutures and skin staples are acceptable options for mesh fixation in open Lichtenstein hernioplasty. Matikainen *et al.* reported that different fixation techniques, including sutures and less-penetrating methods, showed no significant differences in long-term pain or recurrence rates after Lichtenstein repair [17]. Similarly, Matikainen *et al.* found that fixation type did not independently predict chronic postoperative groin pain [18]. In contrast, Sharma *et al.* demonstrated that modified fixation techniques may reduce operative time and postoperative discomfort [19]. Expert consensus recommendations have also highlighted the potential advantages of alternative fixation approaches while emphasizing the need for further evidence [20]. These findings support our observation that fixation choice can be guided by surgeon preference and operative considerations without compromising long-term patient

comfort.

This study has several limitations. First, the follow-up period was limited to 90 days, which captures the transition from acute to early chronic postoperative pain but does not allow assessment of longer-term pain persistence. Second, although both sexes were eligible, only male patients were enrolled during the study period, limiting generalizability to female patients. Third, formal longitudinal modelling and group-by-time interaction testing were not performed; pain trajectory comparisons were therefore based on serial assessments at predefined time points using non-parametric methods. Additionally, operative time, recurrence rates, nerve handling, and postoperative analgesic use were not analyzed, which may partly explain the regression model's limited explanatory power. Despite these limitations, the randomized design, standardized surgical technique, blinded pain assessment, and structured follow-up strengthen the study's internal validity. Within these constraints, our findings suggest that the mesh fixation technique, whether Prolene sutures or skin staples, does not significantly influence long-term postoperative pain following Lichtenstein inguinal hernia repair.

CONCLUSIONS

This study demonstrates that both Prolene sutures and skin staples are effective options for mesh fixation in Lichtenstein inguinal hernia repair, with comparable long-term pain outcomes. While staple fixation showed lower pain scores in the immediate postoperative period, this difference resolved by one month. By day 90, pain-free rates were comparable between groups, and no clinical predictors of chronic pain were identified. These findings suggest that the choice of fixation technique can be guided by surgeon preference and operative considerations without compromising long-term patient comfort.

Authors' Contribution

Conceptualization: AA

Methodology: AA, SM, AS

Formal analysis: SM, AS

Writing and Drafting: MHJ, FE, MZS

Review and Editing: AA, MHJ, SM, AS, FE, MZS, MYN

All authors approved the final manuscript and take responsibility for the integrity of the work

Conflicts of Interest

All the authors declare no conflict of interest.

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