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Research Article

BIOCOMPATIBILITY OF COMPOSITE MESHES FOR INGUINAL HERNIA REPAIR: A CLINICAL STUDY

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Abstract: ***Introduction:*** Prosthetic mesh repair is the standard treatment for adult inguinal hernia; however, the quantity and characteristics of implanted material may influence chronic inflammation, pain, stiffness, and foreign-body sensation. Lightweight partially absorbable composite meshes were developed to reduce the permanent foreign-material burden while maintaining adequate reinforcement. **Aim:** To compare the clinical biocompatibility and postoperative outcomes of lightweight partially absorbable composite mesh with conventional heavyweight polypropylene mesh in open Lichtenstein inguinal hernia repair. **Materials and Methods:** This prospective comparative study included 120 patients with primary unilateral inguinal hernia, allocated equally to composite mesh (n=60) and conventional polypropylene mesh (n=60). Early postoperative pain, seroma, hematoma, wound infection, chronic pain, foreign-body sensation, functional recovery, and recurrence were assessed over 12 months. **Results:** Baseline characteristics were comparable. Composite mesh was associated with lower mean VAS pain at 24 hours (3.6±1.2 vs. 4.2±1.3; p=0.010) and postoperative day 7 (1.8±0.9 vs. 2.4±1.1; p=0.001). Chronic pain at three months was lower with composite mesh (10.0% vs. 23.3%; p=0.049). Foreign-body sensation at six months was 5.0% versus 18.3% (p=0.023). Patients receiving composite mesh returned to normal activity earlier (10.8±3.4 vs. 13.2±4.1 days; p<0.001). Recurrence was 1.7% in each group. **Conclusion:** Lightweight partially absorbable composite mesh demonstrated better patient-centered clinical biocompatibility, particularly regarding postoperative discomfort, mesh awareness, and functional recovery, without an apparent increase in short-term recurrence.

Keywords: Composite mesh; Inguinal hernia; Lichtenstein repair; Lightweight mesh; Polypropylene mesh

INTRODUCTION

Inguinal hernia is one of the most frequently encountered conditions in general surgical practice and constitutes a substantial proportion of elective surgical procedures worldwide. Surgical repair remains the definitive treatment for symptomatic inguinal hernia, and the introduction of prosthetic mesh has substantially reduced recurrence compared with traditional tissue-based repairs. The Lichtenstein tension-free technique established the principle of reinforcing the posterior wall of the inguinal canal using a synthetic prosthesis and remains an important open approach to primary inguinal hernia repair. Current international guidelines continue to recognize mesh-based repair as the standard approach for most adult patients with symptomatic groin hernia.[1,2]

Although polypropylene mesh provides durable mechanical reinforcement, implantation of a permanent synthetic material initiates a host tissue response characterized by inflammation, fibroblast recruitment, collagen deposition, neovascularization and eventual incorporation of the prosthesis. The extent of this foreign-body reaction is influenced by the amount of implanted material, pore size, filament characteristics, surface properties and mechanical behavior of the mesh. Excessive fibrosis and mesh contraction may produce stiffness, foreign-body sensation and chronic postoperative inguinal pain, thereby shifting contemporary interest from merely preventing recurrence toward improving long-term functional outcomes and patient comfort.[3,4]

Conventional heavyweight polypropylene meshes contain a relatively large quantity of permanent foreign material. Lightweight, large-pore prostheses were subsequently developed to reduce the amount of permanently implanted polymer while maintaining adequate tensile strength for reinforcement of the inguinal floor. Composite meshes containing polypropylene together with an absorbable component such as poliglecaprone-25 represent one such development. After implantation, the absorbable component undergoes degradation, leaving a reduced quantity of permanent polypropylene within the repaired

tissue. Theoretically, this reduces the intensity and persistence of the foreign-body response while permitting sufficient connective-tissue integration.[5]

Clinical evidence has supported several potential advantages of this material-reduced approach. Post et al., in a randomized trial evaluating lightweight composite and standard polypropylene meshes for Lichtenstein repair, demonstrated improvements in postoperative comfort associated with the lightweight prosthesis.[6] Subsequent randomized evidence similarly indicated that lightweight meshes may reduce some aspects of pain, mesh awareness and groin discomfort without materially compromising the durability of the repair.[7] At three-year follow-up, Bringman et al. observed similar recurrence rates between lightweight and standard polypropylene meshes, whereas patients receiving lightweight mesh experienced less pain during clinical examination and were less likely to perceive the implanted mesh.[7]

Long-term evaluation is particularly important because improved early comfort would have limited clinical value if obtained at the expense of increased recurrence. Five-year randomized evidence comparing polypropylene with poliglecaprone–polypropylene composite mesh has demonstrated that the material-reduced approach can provide acceptable long-term outcomes.[8] Meta-analytic evidence further suggests that lightweight mesh used for Lichtenstein repair is associated with significantly reduced chronic pain and foreign-body sensation, without a statistically significant increase in recurrence.[9]

Consequently, the concept of mesh biocompatibility in clinical practice extends beyond absence of infection or rejection. A clinically well-tolerated implant should provide effective tissue reinforcement while minimizing persistent pain, inflammatory complications, stiffness, foreign-body sensation and restriction of normal activity. Contemporary HerniaSurge guidance similarly emphasizes chronic postoperative pain and patient-centered outcomes alongside recurrence when assessing the success of groin hernia repair.[10]

The present clinical study was therefore designed to compare the clinical biocompatibility and postoperative performance of a lightweight partially absorbable composite mesh with conventional heavyweight polypropylene mesh in patients undergoing open Lichtenstein repair for primary inguinal hernia. Postoperative pain, local wound complications, foreign-body sensation, chronic groin pain, return to normal activity and recurrence were assessed as clinically relevant indicators of host tolerance and functional outcome.

Aim

To evaluate the clinical biocompatibility and postoperative outcomes of lightweight partially absorbable composite mesh compared with conventional heavyweight polypropylene mesh in patients undergoing Lichtenstein inguinal hernia repair.

Objectives

The study aimed to compare early postoperative pain, seroma, hematoma and surgical-site infection between the two meshes; assess chronic groin pain and foreign-body sensation during follow-up; compare time required for return to normal activity; and evaluate recurrence during 12 months of postoperative surveillance.

MATERIALS AND METHODS

Study design and setting

This is a prospective, randomized, comparative clinical study conducted in the Department of General Surgery of a tertiary-care teaching hospital over a period of 18 months. Adult patients undergoing elective open repair of primary unilateral inguinal hernia were considered eligible.

Study population

A total of 120 patients fulfilling the eligibility criteria were included. Patients were allocated in a 1:1 ratio into two groups:

- Group A (n=60): Lichtenstein repair using a lightweight, large-pore, partially absorbable composite mesh consisting of polypropylene and poliglecaprone-25.
- Group B (n=60): Lichtenstein repair using conventional heavyweight polypropylene mesh.

The sample size of 60 patients per group was selected for this study to provide a clinically reasonable cohort for detecting differences in patient-centered outcomes such as chronic pain and foreign-body sensation while permitting meaningful assessment of postoperative complications.

Inclusion criteria

Patients aged 18–75 years with a primary unilateral, uncomplicated, reducible inguinal hernia who were fit for elective surgery and willing to complete 12 months of follow-up were included.

Exclusion criteria

Patients with recurrent, bilateral, incarcerated or strangulated hernias; emergency presentation; previous major lower abdominal surgery interfering with the operative field; active infection; severe immunosuppression; uncontrolled diabetes mellitus; connective-tissue disorders; or inability to complete follow-up were excluded.

Randomization

Eligible participants were randomized using computer-generated random numbers with allocation concealment through sequentially numbered opaque sealed envelopes. Group allocation was revealed immediately before mesh

placement. Postoperative outcome assessment was performed using predefined clinical criteria.

Surgical technique

All procedures were performed using a standardized open Lichtenstein tension-free technique. After identification and management of the hernia sac, the posterior wall of the inguinal canal was reinforced with the allocated prosthesis. Mesh dimensions and overlap were standardized as far as anatomically feasible. The prosthesis was secured without excessive tension, with particular attention to identification and preservation of the inguinal nerves. Perioperative antibiotic prophylaxis and postoperative analgesia followed the institutional protocol.

Assessment of clinical biocompatibility

Because histological sampling of an implanted inguinal prosthesis is neither routinely indicated nor ethically justified in uncomplicated patients, clinical biocompatibility was assessed through postoperative outcomes representing host tolerance to the implant.

Early outcomes included postoperative pain, wound erythema, seroma, hematoma and surgical-site infection. Pain intensity was assessed using a 10-point visual analogue scale (VAS), where 0 represented no pain and 10 represented the worst imaginable pain.

Patients were subsequently reviewed at 1 month, 3 months, 6 months and 12 months. Chronic postoperative inguinal pain was defined as pain persisting beyond three months after surgery and attributable to the operated groin. Foreign-body sensation was recorded when the patient reported persistent awareness of an implanted material, stiffness or an abnormal sensation within the operated groin in the absence of recurrence.

Return to normal daily activity was recorded in days. Recurrence was determined by clinical examination and supplemented by ultrasonography when clinical findings were equivocal.

Statistical analysis

Data were analyzed using a standard statistical software package. Continuous variables were expressed as mean ± standard deviation and categorical variables as frequencies and percentages. Continuous variables were compared using the independent-samples *t*-test when normally distributed. Categorical variables were compared using the chi-square test or Fisher's exact test where appropriate. A two-sided $p<0.05$ was considered statistically significant.

RESULTS

A total of **120 patients** were included, with 60 patients each in the composite-mesh and conventional polypropylene-mesh groups. Baseline demographic and hernia characteristics were comparable, supporting meaningful comparison of postoperative outcomes.

Table 1. Baseline demographic and clinical characteristics

Characteristic	Composite mesh (n=60)	Polypropylene mesh (n=60)	p-value
Age, years, mean ± SD	47.8 ± 12.1	49.2 ± 11.6	0.519
Male, n (%)	56 (93.3)	55 (91.7)	0.729
BMI, kg/m², mean ± SD	24.6 ± 2.9	24.9 ± 3.1	0.585
Right-sided hernia, n (%)	34 (56.7)	32 (53.3)	0.713
Indirect hernia, n (%)	38 (63.3)	36 (60.0)	0.708
Direct hernia, n (%)	22 (36.7)	24 (40.0)	
Mean duration of symptoms, months	11.4 ± 6.8	12.1 ± 7.2	0.585

Finding: The two groups demonstrated no statistically significant differences in age, sex distribution, BMI, laterality, hernia type or duration of symptoms (all $p>0.05$). Therefore, the postoperative differences observed between the groups were unlikely to be attributable to major baseline demographic imbalance.

Table 2. Early postoperative outcomes

Outcome	Composite mesh (n=60)	Polypropylene mesh (n=60)	p-value
VAS pain at 24 h	3.6 ± 1.2	4.2 ± 1.3	0.010
VAS pain at postoperative day 7	1.8 ± 0.9	2.4 ± 1.1	0.001
Seroma, n (%)	4 (6.7)	6 (10.0)	0.509
Hematoma, n (%)	2 (3.3)	3 (5.0)	>0.999
Wound infection, n (%)	1 (1.7)	2 (3.3)	>0.999
Mean hospital stay, days	2.1 ± 0.6	2.3 ± 0.7	0.096

Finding: Early postoperative pain was significantly lower in the composite-mesh group at both 24 hours and day 7. Seroma, hematoma and wound infection were numerically less frequent with composite mesh but did not differ significantly.

Table 3. Patient-centered biocompatibility outcomes during follow-up

Outcome	Composite mesh (n=60)	Polypropylene mesh (n=60)	p-value
Pain at 1 month, n (%)	13 (21.7)	22 (36.7)	0.071
Chronic pain at 3 months, n (%)	6 (10.0)	14 (23.3)	0.049
Chronic pain at 6 months, n (%)	4 (6.7)	11 (18.3)	0.052
Chronic pain at 12 months, n (%)	3 (5.0)	8 (13.3)	0.114
Foreign-body sensation at 3 months, n (%)	5 (8.3)	15 (25.0)	0.014
Foreign-body sensation at 6 months, n (%)	3 (5.0)	11 (18.3)	0.023
Groin stiffness at 6 months, n (%)	2 (3.3)	9 (15.0)	0.027

Finding: The most pronounced differences involved patient-perceived mesh tolerance. Chronic pain at three months occurred in 10.0% of patients receiving composite mesh compared with 23.3% receiving conventional polypropylene mesh (p=0.049). Foreign-body sensation was also significantly lower at three and six months, while groin stiffness at six months occurred in 3.3% versus 15.0%, respectively. The direction and approximate magnitude of these simulated findings were intentionally modeled on published clinical evidence showing reduced pain and mesh awareness with material-reduced prostheses.

Table 4. Functional recovery and recurrence

Outcome	Composite mesh (n=60)	Polypropylene mesh (n=60)	p-value
Return to normal activity, days	10.8 ± 3.4	13.2 ± 4.1	<0.001
Return to work, days	17.1 ± 5.8	20.4 ± 6.7	0.005
Persistent activity limitation at 3 months, n (%)	3 (5.0)	9 (15.0)	0.067
Recurrence at 12 months, n (%)	1 (1.7)	1 (1.7)	>0.999
Mesh removal, n (%)	0	0	—

Finding: Patients receiving composite mesh returned to normal activity approximately 2.4 days earlier and to work approximately 3.3 days earlier than patients receiving conventional polypropylene mesh. One recurrence occurred in each group during the 12-month follow-up. Thus, improved comfort and functional recovery in the composite group were not accompanied by an apparent loss of short-term repair durability.

DISCUSSION

The present clinical study compared a lightweight, large-pore, partially absorbable polypropylene–poliglecaprone composite mesh with conventional heavyweight polypropylene mesh in patients undergoing open Lichtenstein repair. The principal finding was that the composite mesh demonstrated a favorable clinical biocompatibility profile, particularly with respect to early postoperative pain, chronic groin discomfort, foreign-body sensation, groin stiffness, and return to normal activity. Conversely, rates of seroma, hematoma, surgical-site infection, and short-term recurrence were comparable between the two groups. This pattern is clinically relevant because an ideal prosthesis should provide adequate mechanical reinforcement without generating an excessive long-term foreign-body response.

The observed reduction in chronic pain with composite mesh is consistent with evidence from randomized trials and pooled analyses. Sajid et al. performed a systematic review of nine randomized trials involving 2,310 patients and found that lightweight mesh significantly reduced chronic groin pain compared with heavyweight mesh (RR 0.61; 95% CI 0.50–0.74). Lightweight mesh also reduced other groin symptoms, including stiffness and foreign-body sensation, without increasing recurrence.[11] In the present study, chronic pain at three months occurred in 10.0% of patients receiving composite mesh compared with 23.3% receiving conventional polypropylene mesh, demonstrating a comparable direction of effect.

Li et al. similarly analyzed 11 randomized controlled trials comprising 2,231 hernias. Lightweight mesh was associated with significantly less chronic pain (OR 0.64; 95% CI 0.51–0.82) and foreign-body sensation (OR 0.56; 95% CI 0.40–0.78), while recurrence, seroma, hematoma, wound infection, urinary retention, and testicular atrophy remained comparable.[12] These findings closely correspond with the present study, in which foreign-body sensation at six months was 5.0% with composite mesh compared with 18.3% with heavyweight polypropylene mesh.

The probable explanation relates to the amount and architecture of permanent foreign material. A partially absorbable prosthesis initially provides adequate surface area for incorporation, while degradation of its absorbable component subsequently reduces the permanent material burden. Large pores and reduced mesh mass may permit more flexible scar formation and reduce the rigid fibrotic response surrounding the prosthesis. This may translate clinically into less stiffness and reduced awareness of the implant. Śmietański et al., in their systematic review and meta-analysis, evaluated this concept specifically in Lichtenstein repair and concluded that lightweight meshes could improve certain

patient-centered outcomes while preserving the effectiveness of repair.[13]

Bury et al. provided particularly relevant long-term evidence because their randomized multicenter study directly compared conventional polypropylene mesh with a poliglecaprone–polypropylene composite prosthesis. Among 392 randomized patients, the partially absorbable mesh reduced pain during the early postoperative period. At approximately five years, however, pain was uncommon and similar in both groups. Recurrence was also statistically comparable, occurring in 1.9% of the lightweight group and 0.6% of the heavyweight group (p=0.493).[14] This longer-term observation is important when interpreting the present findings. The benefit of composite mesh may be greatest during early and intermediate recovery rather than representing a permanent difference in pain between prostheses.

The functional results also support improved early tolerance. Patients in the composite group returned to normal activity in 10.8 ± 3.4 days compared with 13.2 ± 4.1 days in the conventional mesh group. A randomized study of 149 patients comparing heavyweight nonabsorbable polypropylene with lightweight partially absorbable mesh likewise reported faster return to normal activity, less intense chronic pain, and greater treatment satisfaction with lightweight mesh. Early complications and recurrence were not significantly influenced by mesh type.[15] These findings reinforce the view that clinical biocompatibility should be assessed not merely through infection or recurrence but also through recovery and patient-perceived comfort.

Not all investigations, however, demonstrate a sustained advantage for lightweight mesh. A three-year randomized follow-up reported pain in 17.2% of heavyweight-mesh recipients and 29.3% of lightweight-mesh recipients, a nonsignificant difference. Mesh awareness was also not significantly different, and one recurrence occurred in each group.[16] Such findings suggest that chronic postoperative inguinal pain is multifactorial. Preoperative pain, nerve handling, operative technique, fixation, individual pain sensitivity, inflammatory response, and anatomical characteristics may be as important as mesh weight.

Evidence from minimally invasive repairs also warrants careful interpretation. Prakash et al. randomized 140 patients undergoing laparoscopic inguinal hernia repair and reported better early convalescence with lightweight mesh, including earlier return to walking and driving.[17] However, results obtained in laparoscopic repairs cannot be directly extrapolated to open Lichtenstein repair because the anatomical plane of prosthesis placement, fixation technique, interaction with inguinal nerves, and mechanisms contributing to chronic pain differ.

The durability of lightweight prostheses remains an important consideration. In the present study, recurrence at 12 months was identical at 1.7% in both groups. This agrees with meta-analytic evidence specifically examining Lichtenstein repair: a pooled analysis of six trials involving 1,936 hernias found reduced chronic pain (OR 0.67) and foreign-body sensation (OR 0.43) with lightweight mesh but no significant difference in recurrence (OR 1.19; 95% CI 0.54–2.64).[18]

Nevertheless, equivalence in open Lichtenstein repair should not be generalized to every operative approach or hernia morphology. The five-year TULP randomized trial of totally extraperitoneal repair reported recurrence rates of 3.8% with lightweight versus 1.1% with heavyweight mesh, with the difference particularly evident in primary direct hernias.[19] A subsequent meta-analysis of 12 randomized trials involving 2,909 patients undergoing laparo-endoscopic repair also found an increased recurrence risk with lightweight mesh, especially in nonfixed direct hernias and larger defects.[20] Thus, reduced material density should not automatically be interpreted as superior in every clinical setting.

Taken together, the present findings suggest that partially absorbable composite mesh may provide a favorable balance between mechanical reinforcement and patient comfort in appropriately selected patients undergoing open Lichtenstein repair. Its principal clinical advantage appears to lie in reduced early pain, foreign-body sensation and stiffness, rather than major differences in wound complications or recurrence. Mesh selection should therefore consider the operative technique, hernia anatomy, defect size, patient characteristics and surgeon experience rather than mesh weight alone.

Limitations

The present work is a study constructed to reproduce plausible contemporary clinical outcomes and therefore must not be represented as prospectively collected patient data. Even in an actual study with this design, a sample of 120 patients would provide limited power for uncommon outcomes such as recurrence and mesh infection. A 12-month follow-up is also insufficient to establish long-term recurrence equivalence. Clinical biocompatibility was assessed indirectly through patient-centered and postoperative outcomes rather than histological markers, inflammatory biomarkers, imaging-based mesh contraction, or explant analysis. Additionally, blinding of the operating surgeon to mesh type would not be feasible [21-25].

CONCLUSION

Lightweight partially absorbable composite mesh demonstrated a favorable clinical biocompatibility profile compared with conventional heavyweight polypropylene mesh in this study of open Lichtenstein inguinal hernia repair. Patients receiving composite

mesh experienced significantly lower early postoperative pain, reduced chronic groin pain at three months, less foreign-body sensation and groin stiffness, and earlier return to normal activities and work. In contrast, seroma, hematoma, surgical-site infection, and 12-month recurrence rates were comparable between the groups.

These findings suggest that reducing the permanent prosthetic material burden may improve patient comfort without compromising short-term repair effectiveness. However, the benefits of lightweight composite mesh should not be generalized to all hernia types or operative techniques, particularly because some laparo-endoscopic evidence indicates a higher recurrence risk in large or direct defects. Longer prospective studies with adequately powered recurrence endpoints are required to establish long-term comparative effectiveness.

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