"Prospective randomised control trial comparing skin staples and polypropylene sutures used in inguinal hernia repair for mesh fixation."

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This is to certify that the dissertation entitled **"PROSPECTIVE RANDOMISED CONTROL TRIAL COMPARING SKIN STAPLES AND POLYPROPYLENE SUTURES USED IN INGUINAL HERNIA REPAIR FOR MESH FIXATION"** is a bonafide research work done by **REG No. BH0122010.**

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Sub: Institutional Ethical Clearance for the study.

With reference to the above, we wish to inform you that your proposed research project titled **"STUDY COMPARING THE USE OF SKIN STAPLES VERSUS POLYPROPYLENE SUTURES IN INGUINAL HERNIA REPAIR FOR MESH FIXATION- A PROSPECTIVE RANDOMISED CONTROL TRIAL",** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

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ABBREVIATIONS

VAS : Visual Analogue Scale

POD : Post-Operative Day

SSI : Surgical Site Infection

HTN : Hypertension

T2DM: Diabetes Mellitus Type 2

TB : Tuberculosis

COPD: Chronic Obstructive Pulmonary Disease

USG : Ultrasonography

BP : Blood pressure

BPH : Benign prostatic hypertrophy

CBC : Complete blood count

cm : Centimetre

mm : millimetre

CNS : Central nervous system

CVS : Cardiovascular system

D.O.A : Date of admission

e.g. : For example

I.P. : In patient

i.e. : That is

vs. : Versus

EHS : European hernia system

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ABSTRACT

Background:

Lichtenstein's inguinal hernia repair is a widely used open, tension-free technique in which the contents of the hernia are reduced, and a polypropylene mesh placed to reinforce the transversalis fascia (inguinal floor), effectively creating a new internal ring. This prosthetic mesh strengthens the inguinal canal's posterior wall , eliminating tension on the repair, thus significantly reducing recurrence rates compared to traditional tissue-only methods.

Ensuring proper mesh fixation is crucial to keeping the mesh flat and secure, preventing migration or curling that could lead to failure. Traditionally, surgeons have used polypropylene sutures to fix the mesh in place. However, in recent years, staples have emerged as an alternative fixation method in the Lichtenstein procedure. The primary advantage of staple fixation is its efficiency—applying staples (such as skin staples or tackers) is faster and eliminates the need for suture knot-tying and extensive tissue handling. This leads to a shorter operative time with potentially reduce tissue trauma. As a result, there is ongoing debate about whether staple fixation can enhance patient recovery by reducing post-operative pain or lowering complication rates compared to the conventional suture technique.

Several studies have compared suture versus staple mesh fixation in Lichtenstein repair, focusing on key outcomes such as operative duration, post-operative pain, recovery speed, and complications, including infection, chronic pain in the groin , and hernia recurrence. Overall, the literature suggests that fixation by both methods is effective, but they differ in certain aspects. Most evidence indicates that staple fixation has significantly reduced intra operative time as compared to suturing. Some randomized trials also report lower early post-operative pain scores

with staple fixation, although long-term chronic pain outcomes appear similar between the two techniques.

Regarding complications, staple-fixed repairs have not demonstrated higher recurrence or complication rates. In fact, some studies suggest that using staples may have a lower risk of wound infection and an equivalent—or even lower—hernia recurrence rate compared to sutures.

In summary, both suture and staple fixation have their respective advantages. Sutures offer a time-tested and secure method, while staples provide a quicker alternative that may reduce immediate post-operative discomfort. Since the overall outcomes are closely matched, the choice of fixation technique may ultimately depend on balancing surgical efficiency with patient-centred results.

Methodology:

This randomized controlled study had been conducted over a one-year period, enrolling 90 male patients diagnosed with inguinal hernia. Participants were allocated at random into one of two groups:-

- **Group A (Control Group, n=45):** Underwent Lichtenstein hernioplasty with polypropylene mesh was fixed using non-absorbable sutures.
- **Group B (Test Group, n=45):** Underwent Lichtenstein hernioplasty with polypropylene mesh fixation using staples.

The primary study endpoints included:

1. The duration of the surgery was recorded from the initial incision to the closure of the skin.

2. Postoperative pain was assessed using the Visual Analogue Scale (VAS) 24 hours after surgery.

3. The incidence of complications, such as seroma, hematoma, and surgical site infections, was tracked throughout the postoperative phase..

All procedures were performed by experienced surgeons adhering to standardized surgical protocols to ensure consistency and minimize variability. Patients were closely monitored during the postoperative period, with all complications systematically documented. Statistical analysis was performed to evaluate and compare the outcomes between the two groups, providing an objective evaluation of the effectiveness of each fixation method.

Results:

A randomized controlled trial (RCT) was carried out over a one-year period to compare suture and staple fixation in Lichtenstein inguinal hernia repair. 90 patients were randomly assigned into:

- Group A (Control) (n=45): Polypropylene mesh secured with sutures.

- Group B (Cases) (n=45): Mesh fixation using skin staples.

  Data on operative time, pain (VAS score), and complications were analysed.

1. Patient Demographics
    - Mean Age: Comparable in both groups (48.73 ± 11.99 vs. 48.76 ± 13.17 years, p = 0.991).
    - Gender: All patients were male (100%).
    - Hypertension: More common in controls (33.33% vs. 22.22%, p = 0.239).

2. Postoperative Pain (VAS Score)
    - Pain was significantly lower in cases (p < 0.0001).
    - Median VAS score: 2 (Cases) vs. 3 (Control).

VAS Score	Cases (%)	Control (%)
1	42.22%	4.44%
2	46.67%	44.44%
3	11.11%	46.67%
4	0.00%	4.44%

4. Operative Time (Minutes)
    - Staple fixation significantly reduced operative time (p < 0.0001).
    - Mean duration:
    - Cases: 50.87 ± 8.35 min
    - Control: 63.91 ± 9.90 min

5. Postoperative Complications (Wound Infection)

    Zero infections in cases group vs. 6.67% in control (p = 0.078).

6. Diagnosis Distribution

- No significant difference in hernia type ($p = 0.1976$).

Diagnosis	Cases (%)	Control (%)
Left direct	17.78%	6.67%
Left indirect	22.22%	33.33%
Right direct	22.22%	31.11%
Right indirect	35.56%	22.22%
Pantaloons	2.22%	6.67%

7. Summary of Findings

✓ Staple fixation significantly reduced operative time ($p < 0.0001$).

✓ Lower postoperative pain in staple group ($p < 0.0001$).

✓ Trend towards fewer infections with staples ($p = 0.078$).

✓ No significant differences in patient demographics or hernia type.

8. Conclusion

Staple fixation in Lichtenstein hernioplasty significantly reduces operative time and postoperative pain, with a potential lower risk of infection, making it a viable alternative to suture fixation.

INTRODUCTION

"Inguinal hernia, being a common surgical condition, places a substantial strain on healthcare systems both in India and worldwide. It is among the most commonly performed surgical procedures, comprising nearly 2/3rds of all abdominal wall hernias seen in clinical settings." With the incidence of inguinal hernia varying across age groups, there is a notable increase in older adults, while in children, they remain a concern, particularly among premature infants, males, and those with genetic syndromes.

The peak incidence of inguinal hernias occurs around five years of age and again after seventy, with males constituting nearly 90% of cases. Indirect inguinal hernias are most common type, comprising about two-thirds of all cases, with a higher prevalence on the right side. Beyond the direct costs of hospitalization and surgery, inguinal hernias contribute to significant economic losses due to lost productivity and disability. Moreover, complications such as bowel obstruction, strangulation, and incarceration necessitate early and effective management strategies to prevent morbidity and mortality.

Surgical Techniques used for Inguinal Hernia :-

The method to managing inguinal hernias has advanced over time, with two main repair techniques being widely adopted in surgical practice:

1. **Lichtenstein Tension-Free Repair (Open Surgery):** This widely practiced open surgical technique involves placing a polypropylene mesh over the hernia defect to reinforce the inguinal floor.

2. **Laparoscopic Repair (Minimally Invasive Approach):** This technique utilizes small abdominal incisions and a laparoscope to visualize and repair the hernia with mesh.

Despite advancements in hernia repair techniques, postoperative pain remains a significant challenge, particularly with the Lichtenstein repair, due to higher rates of chronic pain. The primary contributing factors include suture fixation, nerve entrapment, and tissue tension, which can lead to prolonged discomfort and potential complications

Advancements in Mesh Fixation Techniques

To overcome the limitations of suture fixation, alternative mesh fixation methods have been explored, including:

- Surgical adhesives (e.g., N-butyl-2-cyanoacrylate glue)
- Staples and tacks
- Fibrin sealants
- Self-fixing/adhesive meshes that eliminate the need for additional fixation

Each technique offers unique benefits and drawbacks, but long-term comparative studies remain limited. A major concern in Lichtenstein repair is the tension created by suture fixation, which can disrupt the natural sling and shutter mechanism of inguinal canal, increasing the risk of hernia recurrence. Additionally, needle penetration from sutures may further compromise tissue integrity and healing.

Rationale for the Study

"This study aims to evaluate an alternative mesh fixation technique with the use of skin staples vs traditional polypropylene sutures for Lichtenstein tension-free inguinal hernia surgical repair." Staples, applied using Prosec premium MD (multidirectional) release skin stapler, offer several potential advantages, including:

- Reduced operative time
- Lower tissue trauma
- Minimized risk of wound infection

Despite the potential benefits of staple fixation, there is limited clinical data comparing it directly with suture fixation. Hence, this study is designed to evaluate differences and similarities these two fixation methods in terms of:-

1. Duration of surgery
2. Postoperative pain and complications
3. Overall procedural cost-effectiveness

Given the high prevalence of inguinal hernias and their substantial impact on healthcare resources, identifying the most effective and safest mesh fixation method is crucial. The outcomes of this study may aid in improving surgical approaches, enhancing patient recovery, and alleviating the healthcare burden linked to inguinal hernia repair.

OBJECTIVES

Primary Objective

- To assess and compare postoperative pain in patients undergoing repair of inguinal hernia for mesh fixation with the use of skin staples versus polypropylene sutures, utilizing the "Visual Analogue Scale (VAS) for pain evaluation."

Secondary Objectives

- To evaluate and compare the operative duration between staple fixation and suture fixation in Lichtenstein tension free inguinal hernia repair.
- "To analyse the incidence of post-surgical complications, including seroma, hematoma, and surgical site infections, in patients undergoing polypropylene (Prolene) mesh fixation with skin staples versus sutures."

REVIEW OF LITERATURE

Definition :-

"An inguinal hernia is the protrusion of intra-abdominal contents through a weakness in the abdominal wall of the groin, often involving the inguinal canal." This can occur indirectly or directly. "Inguinal hernias account for about 75% of all abdominal wall hernias[(1)]."

They commonly present as a bulge in the groin that may cause discomfort, especially with straining or standing, and typically reduce when the patient is supine. If untreated, complications like incarceration or strangulation of bowel can occur, though the acute emergency risk is relatively low.

Epidemiology :-

Inguinal hernias are extremely common and impose a significant healthcare burden. Globally, the estimated prevalence is around 7.7% of the population, with a higher prevalence in males (~9.6%) than females (~1.3%)[(2)]. The overall risk of a person developing inguinal hernia is about 27% in men and 3% in women[(1)], reflecting the strong male predominance (due in part to the patency of the spermatic cord pathway in men).

The incidence shows a bimodal distribution, with one peak in infancy/childhood (congenital hernias due to patent processus vaginalis) and another peak in older age (acquired weaknesses) [3]. Incidence in men rises from roughly 11 in 10,000 person-years at ages 16–24 up to 200 in 10,000 at ages ≥75 [(1)]

"Inguinal hernia repair is one of the most frequently performed surgeries worldwide, with over 20 million repairs annually and about 800,000 yearly in the

United States alone [3][4]." These hernias constitute a major workload in general surgery; for example, over 70,000 repairs are done annually in England (with thousands of bed-days utilized) [1]. Most patients presenting for repair are male (over 90%) [3]. The high prevalence and potential for morbidity (pain, work loss, complications) make inguinal hernias a substantial public health concern. Fortunately, elective surgical repair has a very high success rate and low mortality, making timely hernioplasty an effective intervention to reduce long-term complications.

Anatomy and Pathophysiology:-

Inguinal Canal and Groin Anatomy

"Inguinal canal is a slanting passage (4–6 cm long) in the lower anterior abdominal wall, through which the spermatic cord (in males) or round ligament (in females) passes [5]." It has well-defined boundaries :-

- Floor :- inguinal ligament (and lacunar ligament which is present medially).
- Roof :- Arching fibres of the internal oblique and transversus abdominis muscles.
- Anterior wall :- External oblique aponeurosis (reinforced laterally by internal oblique).
- Posterior wall :- Transversalis fascia and conjoint tendon [5].

There are two natural openings:

1. Deep (internal) inguinal ring:
    - Aperture in the transversalis fascia, located lateral to the inferior epigastric vessels [5].

- Entrance point for an indirect hernia sac (lateral to epigastric vessels).

2. Superficial (external) ring:

   - Opening in the external oblique aponeurosis, above the pubic tubercle [(5)].

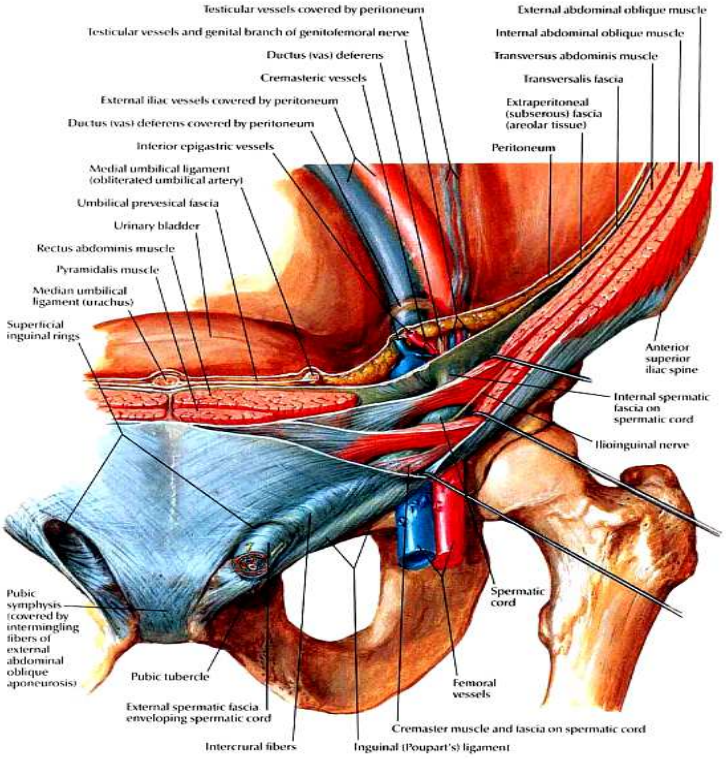
   - Exit point for the hernia sac.

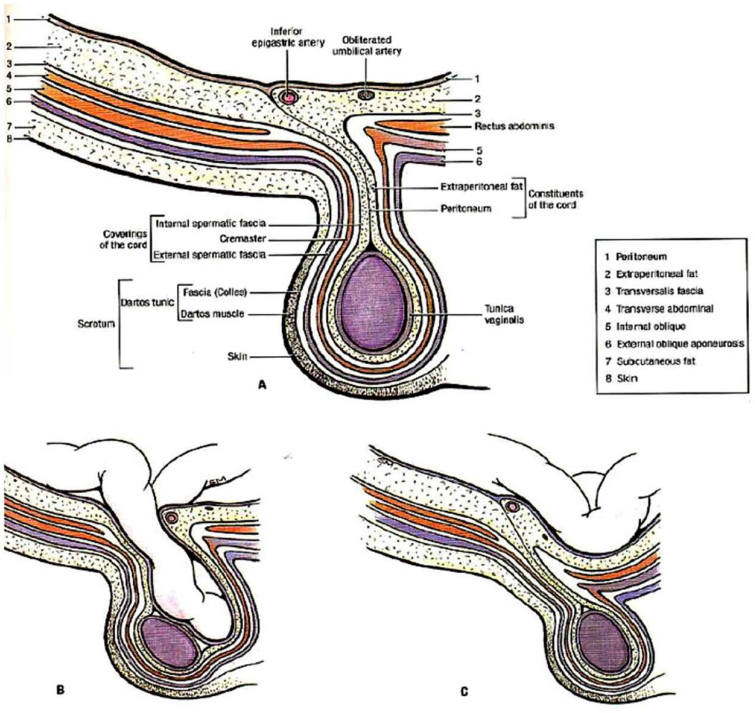
A direct hernia protrudes through the posterior wall medial to the inferior epigastric vessels (within Hesselbach's triangle).

"The inguinal canal also transmits important nerves:

- Ilioinguinal nerve
- Genital branch of the genitofemoral nerve"

These nerves provide sensation to the groin and can be a source of postoperative pain if injured.


Testicular vessels covered by peritoneum
Testicular vessels and genital branch of genitofemoral nerve
Ductus (vas) deferens
Cremasteric vessels
External iliac vessels covered by peritoneum
Ductus (vas) deferens covered by peritoneum
Inferior epigastric vessels
Medial umbilical ligament (obliterated umbilical artery)
Umbilical prevesical fascia
Urinary bladder
Rectus abdominis muscle
Pyramidalis muscle
Median umbilical ligament (urachus)
Superficial inguinal rings
Pubic symphysis (covered by intermingling fibers of external abdominal oblique aponeurosis)
Pubic tubercle
External spermatic fascia enveloping spermatic cord
Intercrural fibers
Inguinal (Poupart's) ligament
External abdominal oblique muscle
Internal abdominal oblique muscle
Transversus abdominis muscle
Transversalis fascia
Extraperitoneal (subserous) fascia (areolar tissue)
Peritoneum
Anterior superior iliac spine
Internal spermatic fascia on spermatic cord
Ilioinguinal nerve
Spermatic cord
Femoral vessels
Cremaster muscle and fascia on spermatic cord


Inferior epigastric artery
Obliterated umbilical artery
Rectus abdominis
Extraperitoneal fat
Peritoneum
Constituents of the cord
Coverings of the cord
Internal spermatic fascia
Cremaster
External spermatic fascia
Scrotum
Dartos tunic
Fascia (Colles)
Dartos muscle
Tunica vaginalis
Skin
A
1 Peritoneum
2 Extraperitoneal fat
3 Transversalis fascia
4 Transverse abdominal
5 Internal oblique
6 External oblique aponeurosis
7 Subcutaneous fat
8 Skin
B
C

"The floor is the inguinal (Poupart's); the anterior wall is the external oblique aponeurosis; the roof is formed by the internal oblique and transversus abdominis; and the posterior wall includes the transversalis fascia and conjoint tendon." This anatomy is crucial: indirect hernias pass through the deep ring into the canal, whereas direct hernias push through a weakened posterior wall.

Embryology and Pathophysiology: Indirect inguinal hernias often have a congenital basis –"they result from a patent processus vaginalis, an embryonic peritoneal diverticulum that accompanies testicular descent." In males, failure of the processus vaginalis to obliterate leaves a potential tract from the peritoneum into the scrotum, through which abdominal contents can herniate (indirect hernia). This explains why indirect hernias can occur in infants and children and are more commonly right-sided (the right processus vaginalis closes later) [3]. Direct inguinal hernias, by contrast, are usually acquired and occur due to weakness or attenuation of the transversalis fascia in the inguinal (Hesselbach's) triangle. Factors such as chronic elevated intra-abdominal pressure (from heavy lifting, chronic cough, constipation) and age-related tissue degeneration contribute to this weakness [6]. Over time, the connective tissues of the groin (including the transversalis fascia) may lose tensile strength, allowing abdominal contents to protrude directly through the abdominal wall.

Role of Collagen and Connective Tissue: There is evidence that an abnormal collagen metabolism underlies hernia formation in many adults. Patients with inguinal hernias have been found to have a lower ratio of type I to type III collagen in their fascia and skin, resulting in reduced tensile strength of the tissue [6]. Studies show decreased mature type I collagen and increased more extensible type III collagen in hernia patients, yielding thinner, weaker connective tissue fibres[6]. These changes are

more pronounced in older patients [6], which may explain the higher hernia incidence in the elderly. Matrix metalloproteinases (MMPs) are also upregulated, potentially increasing collagen degradation [6]. Additionally, systemic connective tissue disorders (e.g. Ehlers-Danlos or Marfan syndrome) and conditions like abdominal aortic aneurysm correlate with higher hernia risk [7]. These findings suggest a genetic or metabolic predisposition in some individuals. Smoking may further weaken connective tissue by impairing fibroblast function and collagen synthesis [6], and smokers have more risk of hernia recurrence [6]. In summary, inguinal hernias result from a combination of anatomical predisposition (patent processus vaginalis in indirect hernia) and acquired weakness of tissues, often exacerbated by abnormal collagen remodelling, aging, and chronic stress on the abdominal wall.

Classification of Inguinal Hernias

Surgeons classify inguinal hernias to guide management and compare outcomes. Traditionally, hernias are described as indirect (lateral) or direct (medial) relative to the inferior epigastric vessels, or femoral (below the inguinal ligament). However, more comprehensive classification systems exist:

- **Nyhus Classification:** A widely used system that categorizes inguinal hernias by anatomic location and extent of defect [3]. It has four primary types:
    - **Type I:** Indirect hernia along with a normal internal ring (typically congenital hernias in infants/children).
    - **Type II:** Indirect hernia with an enlarged internal ring, but the posterior inguinal wall remains intact. The hernia sac does not reach into the scrotum [3].

- **Type III :** Defects involving the posterior wall (floor) of the inguinal canal. This is subdivided into:
  - **IIIA:** Direct inguinal hernia [3]
  - **IIIB:** Large indirect hernia that impinges on or destroys the posterior wall (e.g. large scrotal hernias or "pantaloon" hernias) [3]
  - **IIIC:** Femoral hernia[3]
  - **Type IV:** Recurrent hernias. These are further classified by the type of original hernia: IV-A (recurrent direct), IV-B (recurrent indirect), IV-C (recurrent femoral), IV-D (recurrent combined).

Nyhus classification thus incorporates both the site and the size/extent of the hernia. For example, a small indirect hernia in a child would be Nyhus I, whereas a large indirect hernia extending into the scrotum might be Nyhus IIIB, and any recurrent hernia is Type IV (with subtype specified) [3].

- **European Hernia Society (EHS) Classification:** The EHS system (2008) provides a simple, standardized way to describe groin hernias for research and clinical practice [7]. It uses three categories for location: L = lateral (indirect inguinal), M = medial (direct inguinal), or F = femoral. Each is further graded by the size of the hernia defect at the internal ring or floor: Grade 1 (small <1.5 cm, e.g. defect can admit 1 finger), Grade 2 (medium ~1.5–3 cm, 1–2 fingers), or Grade 3 (large >3 cm, ≥3 finger breadths) [7]. For example, an L3 hernia denotes a large indirect hernia with >3 cm internal ring; an M1 is a small direct hernia. The EHS classification also notes whether the hernia is primary or recurrent – often by

adding P or R (or using a suffix 0 for primary, 1–3 for recurrence count) [7]. This system has been recommended by international guidelines for its simplicity and utility in comparing outcomes [7]. In practice, a hernia could be recorded as, for instance, "Right inguinal hernia, EHS type L2, recurrent," indicating a recurrent moderate-sized indirect hernia. It should be noted that femoral hernias (which occur below the inguinal ligament) are less common (≈3–5% of groin hernias) and are more frequent in women, but they are often included in these classification schemes (Nyhus IIIc or EHS F types) for completeness. Overall, using a standard classification (such as Nyhus or EHS) is important for guiding repair technique and for reporting surgical results in a consistent manner.

Surgical Techniques for Repair of Inguinal Hernia

Surgical repair (herniorrhaphy or hernioplasty) is the mainstay in treatment for inguinal hernias. The goal is to return herniated contents to the abdomen and reinforce the weakened abdominal wall. Over time, hernia surgery has grew from pure tissue repairs under tension to modern tension-free techniques using prosthetic mesh. Key approaches include:

Historical Evolution of Repair Techniques

In the late 19th century, Eduardo Bassini introduced the first successful technique for inguinal hernia repair (1884), involving high ligation of the hernia sac and suturing together the transversus abdominis aponeurosis and inguinal ligament to reinforce the floor [7]. Variations of Bassini's repair (and other tissue repairs like Halsted, McVay, etc.) were used for decades, but they placed tissues under tension. Recurrence rates were relatively high with these traditional suture techniques – long-term recurrence of 15% or higher was common [7]. In 1953, Shouldice described a

multi-layered imbrication repair of the posterior wall (Shouldice repair), which improved outcomes and became the gold-standard non-mesh repair, with recurrence rates around 1%–5% in expert hands (lower than Bassini's) [7] .

A paradigm shift occurred in the late 20th century with the advent of prosthetic mesh. In 1984, Irving Lichtenstein popularized a "tension-free" repair using a synthetic mesh patch to cover the defect instead of suturing tissue edges together [8] .The Lichtenstein repair dramatically reduced recurrences to well under 5% in general practice and proved easier to learn, leading the American College of Surgeons to endorse it as the gold standard for primary inguinal hernias[8]. Around the same time, minimally disruptive procedures emerged: laparoscopic hernia repairs were first seen in the early 1990s. Since then, over 100 randomized trials have compared various techniques [7] , solidifying that mesh-based, tension-free repairs (open or laparoscopic) yield the lowest recurrence rates [7]. Thus, the evolution from Bassini to Shouldice to Lichtenstein and beyond has progressively lowered recurrence and improved recovery at the expense of introducing foreign material (mesh). Today, pure tissue repairs are generally done for cases in which mesh is contraindicated (e.g. infection, or in some pediatric hernias), given that mesh repair has superior durability [7].

Open Repair – Lichtenstein Tension-Free Hernioplasty

The Lichtenstein repair is an open anterior approach that places a flat synthetic mesh to reinforce the inguinal floor without tension. "Through a groin incision, the external oblique aponeurosis is opened to expose the inguinal canal." The hernia sac is isolated and reduced (or excised if an indirect sac). A polypropylene mesh patch is then laid over the posterior wall, extending from the pubic tubercle to well beyond the

internal ring, and slit to accommodate the spermatic cord. The mesh is sutured to surrounding structures (inguinal ligament below, conjoint tendon above) with minimal tension [5]. "By bridging the defect, the mesh acts as a scaffold for fibrous ingrowth, creating a strong new wall over time. This tension-free concept avoids the tissue pull and distortion that occur in traditional repairs [8], resulting in less pain and a lower risk of the sutures tearing through." In fact, the introduction of mesh reduced typical inguinal hernia recurrence rates from 10–30% (with older repairs) down to the low single digits [4] . Large series report recurrence around 1–3% with Lichtenstein mesh repair, versus 10% or higher with non-mesh repairs[3]. The Lichtenstein operation can be performed under local or regional anaesthesia and is often done outpatient, with most patients returning to full activities within a few weeks. It remains the most common hernia repair worldwide due to its simplicity and excellent outcomes. Key technical considerations include proper nerve identification (to avoid injury to the ilioinguinal, iliohypogastric, or genital branch of genitofemoral nerve) and secure but not overly tight mesh fixation. When done correctly, open mesh repair has a low complication profile and is highly effective for both direct and indirect hernias. According to guidelines, an open mesh repair like Lichtenstein is recommended as a first-line option for primary unilateral hernias, especially in settings where laparoscopic expertise or equipment is not available [7].

Laparoscopic Approaches – TAPP and TEP

Minimally invasive repair can be performed via laparoscopy, offering the advantage of placing mesh from behind the abdominal wall (posterior approach) and potentially reducing postoperative pain and enabling faster recovery. There are two main laparoscopic techniques:

- **Transabdominal Pre-Peritoneal (TAPP):** The surgeon enters the peritoneal cavity with a laparoscope and trocars. The peritoneum is incised to access the preperitoneal space over the groin, the hernia sac is reduced, and a mesh is placed over the myopectineal orifice (covering all potential hernia sites – indirect, direct, femoral) from the posterior side. The peritoneum is then closed on mesh [9]. Essentially, the mesh lies behind the transversalis fascia, separating it from the abdominal cavity by a peritoneal layer. TAPP allows excellent visualization of bilateral groins and is useful for complex or bilateral hernias, but it requires careful closure of the peritoneum to avoid bowel contact with mesh.

- **Totally Extra-Peritoneal (TEP):** The peritoneal cavity is not entered. Instead, the surgeon creates a space in the preperitoneal plane (for example by inflating a balloon or using blunt dissection through a small infra-umbilical incision) and inserts trocars into this space. The hernia sac is reduced from below the peritoneum, and mesh is placed in the preperitoneal space to cover the defects. Because no peritoneal opening is made, there is no need to close a peritoneal flap. TEP can be slightly more challenging (limited working space) but avoids any contamination of the peritoneal cavity and may reduce risk of adhesions or bowel injury.

In both TAPP and TEP, a broad mesh (~10×15 cm) is spread out to overlap all potential openings and is often secured with tacks, glue, or simply held by intra-abdominal pressure. Both approaches yield similar outcomes in experienced hands [10]. Laparoscopic repair in general has been associated with *reduced pain postoperatively and faster return to daily activities* as compared to open repair, especially in the early recovery period [7]. Patients also have smaller scars. Notably, laparoscopy is particularly advantageous for bilateral hernias (allowing both sides to be repaired in

one session through the same port sites) and for recurrent hernias after an open repair (approaching the recurrence from the untouched posterior plane avoids scar tissue) [7]. Guidelines often recommend a laparoscopic approach for these scenarios. However, laparoscopic hernioplasty has a longer learning curve – studies indicate a surgeon should perform ~50–100 cases to become proficient [7] . It also typically requires general anaesthesia (unlike open repairs, which can be done with local). In terms of complications, laparoscopy may have a higher incidence of *seroma* (benign fluid collection) and, rarely, injuries to intra-abdominal structures, but it tends to cause reduced chronic groin pain along with numbness than open surgery in the long term[7]. The operation time is usually slightly longer than open repair[7]. Overall, endoscopic (laparoscopic) hernia repair is considered as efficient as open mesh repair in terms of recurrence, provided the surgeon is adequately trained [7]. The choice often depends on patient factors and surgeon expertise. For example, in an 18-year-old with a unilateral hernia, an open Lichtenstein under local anaesthesia is simple and avoids general anaesthesia[7]; whereas in a middle-aged patient with bilateral hernias, a laparoscopic TEP might allow both sides to be fixed with minimal pain and downtime.

Robotic-Assisted Repair

Robotic hernia repair is essentially an advancement of the laparoscopic approach, using the da Vinci® surgical system or similar. The robotic platform enhances dexterity, allowing wristed instruments that can make suturing and dissection easier in the confined preperitoneal space. A robotic TAPP repair is most common – the robot assists in precise placement and fixing of mesh and in peritoneal closure. For the patient, the clinical outcomes of robotic inguinal hernia mesh repair are similar to standard laparoscopy in terms of recurrence and recovery in the short

term (current literature shows similar low recurrence rates). The main differences are for the surgeon: improved ergonomics and 3D visualization. Robotic surgery may particularly benefit complex bilateral or recurrent cases that require extensive suturing or dissection. However, it comes with longer operative times and higher costs in most settings. Robotic technique is still evolving but represents a growing trend, with early studies showing safety and feasibility. In the coming years, it may play a larger role as technology becomes more accessible. For now, robotic inguinal hernia repair is an option in high-volume centres, offering at best an incremental improvement in surgeon comfort and possibly precision, but with equivalent patient outcomes to laparoscopic repair.

Mesh in Hernioplasty

The introduction of prosthetic **mesh** has revolutionized hernia repair. Mesh reinforces the abdominal wall and allows a tension-free closure of the hernia defect, drastically reducing recurrences. There are various types of mesh and methods for using them:

Types of Mesh Materials: Most meshes used for repair of inguinal hernia are synthetic. The standard material is polypropylene (PP) – a non-absorbable polymer that is strong, flexible, and provokes a tolerable inflammatory reaction. Polypropylene is the most widely used because it has excellent long-term durability and tissue integration [(4)]. Other synthetic materials include polyester (polyethylene terephthalate, PET), which is also macroporous and pliable, and PTFE (polytetrafluoroethylene), a non-porous material often used in a expanded form (ePTFE) in specialized situations (it's very inert but less commonly used in inguinal repairs due to risk of encapsulation). Meshes can be heavy-weight or light-weight, referring to fiber

thickness and pore size – lightweight meshes have larger pores and less material, aiming to improve flexibility and reduce chronic pain or stiffness at the cost of slightly reduced strength[4]. Many modern meshes are composites or coated (e.g. polypropylene with an absorbable coating or a different material on one side) to tailor their properties. For example, composite meshes with a smoother barrier on one side are used for intra-abdominal placement to prevent bowel adhesions.

In addition to permanent synthetics, there are biologic meshes made from processed human or animal collagen tissue (such as porcine dermis or bovine pericardium). These are gradually absorbed by the body. Biologic meshes are typically reserved for contaminated surgical fields or cases of infection, because they integrate without a permanent foreign body and are thought to resist infection better. However, in clean inguinal hernia repairs, biologics are generally *not* used – they are very expensive and have higher long-term recurrence rates compared to synthetics [11]. Studies have found no advantage to biologic mesh in elective inguinal hernioplasty, so their use is limited to complex cases (e.g. strangulated hernia with infection) where a synthetic is contraindicated [11]. There are also fully absorbable synthetic meshes (made of materials like polyglycolic acid, polycaprolactone, etc.) and hybrid meshes that combine absorbable and permanent fibres. These are newer developments intended to provide initial strength then dissolve, hopefully leaving a stronger remodelled tissue with less foreign material long-term [11]. While promising for minimizing chronic foreign-body reactions, absorbable meshes have not yet shown clear benefits in uncomplicated inguinal hernias and are still under study [11].

Ideal Properties of Mesh: An optimal hernia mesh should be biocompatible (not induce excessive inflammation or rejection), strong enough to withstand abdominal pressure, yet flexible enough to move with the body and not cause stiffness. It should

be macroporous, allowing tissue ingrowth and integration – pore size >1 mm is thought to facilitate fibroblast in-growth and reduce infection risk by allowing immune cell penetration. Mesh should also be inert (resistant to degradation or fragmentation over time) and have a low infection profile (polypropylene, for example, is relatively resistant to infection and can be left in place even if a superficial wound infection occurs). Other desirable characteristics include ease of handling for the surgeon (the mesh should be soft and drapable to conform to the anatomy) and a long shelf-life. Polypropylene meets many of these criteria, which is why it remains so popular [4] . Polypropylene mesh fibres incite a moderate inflammatory response that results in the mesh becoming embedded in scar tissue, permanently patching the defect. One downside of PP is that it can contract by 20–30% in area over time as the scar matures [12], so surgeons compensate by using a larger mesh than the defect. Polyester (PET) is another material with good flexibility and handling; it is slightly more hydrophilic and may induce a different tissue response, but it can be effective as well [4]. Overall, the tension-free concept relies on mesh to provide lasting reinforcement: the mesh effectively redistributes forces across a wide area instead of concentrating tension at suture lines [5]. In doing so, it addresses the fundamental cause of recurrence in older repairs (tension on weakened tissue). As a testament to mesh efficacy, recurrence rates after primary inguinal repair have dropped to ~1%–3% in many series [4], a vast improvement over pre-mesh era rates.

Mesh Fixation Methods: Fixing the mesh in place is an important technical step. In open repair (Lichtenstein) ," the mesh is typically sutured to the surrounding tissues (with a few interrupted non-absorbable sutures at key points such as the pubic tubercle and along the inguinal ligament)." An alternative in open surgery is to use staples or skin clips to attach the mesh to tissue. Clinical trials have compared sutures

versus staples for mesh fixation in open repair: results show that staples secure the mesh equally as effectively and significantly reduce operative time (mesh placement is faster) [13]. In one RCT, using skin staples cut the median repair time by ~11 minutes and had no increase in complications or recurrences, with the added benefit of avoiding needle sticks (important in HIV/hepatitis patients) [13]. Thus, staples offer a convenient alternative to sutures. In laparoscopic repairs, mesh is often fixed using **tacks** – these can be metal helices (like titanium tacks) or absorbable tacks that dissolve after a few months. Tack fixation is quick but each tack is essentially another "penetration" that can cause postoperative pain if it injures a nerve. To mitigate pain, some surgeons now perform laparoscopic repairs with glue fixation or even no fixation for smaller hernias. Fibrin glue or synthetic glues can adhere the mesh in place without any sharp fixation. Evidence from multiple trials and a Cochrane review indicates that glue fixation results in less chronic pain compared to sutures or tacks, without increasing recurrence [14]. For instance, chronic groin pain rates were significantly lower with fibrin glue than with suture fixation (glue reduced chronic pain by ~37% in pooled analysis) while recurrence rates remained equivalent [14]. Glues also reduce risk of hematoma and allow slightly faster recovery in some studies [14]. Another innovation is the use of self-gripping (self-fixating) mesh, which has dozens of tiny microhooks on one side that latch into the tissue like Velcro®, obviating the need for sutures or tacks. These meshes (e.g. ProGrip™) can simplify open repair and have shown good outcomes with possibly less acute pain, since no sutures are tied. However, careful placement is needed to avoid folding.

Regardless of method, the mesh should be fixed flat with no wrinkles, and care must be taken to avoid entrapping nerves or blood vessels. The ilioinguinal, iliohypogastric, and genital branch nerves are particularly at risk in open repair during mesh suturing –

entrapment or injury to these can lead to chronic neuropathic pain. Surgeons practicing "nerve-identification technique" (actively finding and protecting the nerves) during open repair have lower chronic pain rates [15]. In laparoscopic repair, nerves are not directly visualized; avoiding excessive dissection or fixation in the triangle of pain is the key to preventing neuralgia.

Complications and Postoperative Outcomes

Inguinal hernia repair is very successful, but like any surgery it carries the risk of complications. Fortunately, serious complications are infrequent. The primary concerns in hernia surgery are recurrence of the hernia and chronic pain. Other outcomes of interest include acute complications such as wound infection, hematoma, urinary retention, and rare but significant issues like testicular complications.

Recurrence: A recurrence means the hernia (or a hernia at the same site) returns after repair. This can happen due to factors like poor technique, undue tension, missed hernia sacs, or patient factors that impair healing. With modern mesh techniques, recurrence rates are low (often 1–3%), but they are higher with traditional tissue repairs. For example, recurrence after mesh repair is about 3–5%, compared to 10–15% after suture repairs in older series [3]. Mesh size and placement are important – an inadequately sized mesh or one that is not properly fixated can lead to recurrence at the edges. Surgeon experience and adhering to principles (e.g. overlapping the pubic tubercle by at least 2 cm) also affect outcomes. Certain patient factors predispose to recurrence: smoking, chronic steroid use, malnutrition, and chronic cough delay or weaken healing and have been associated with higher recurrence [3]. Repairing a hernia in the company of infection can also cause failure. Recurrences are categorized

as early (within months, often technical failure) or late (years later, often due to progressive tissue deterioration or mesh issues). If a recurrence occurs after an anterior (open) repair, it is usually addressed with a posterior (laparoscopic) approach to avoid scar tissue, and vice versa[3]. Overall, recurrence has become a less common problem in the mesh era, but vigilant technique is needed to maintain these low rates.

Chronic Postoperative Pain: Persistent groin pain after inguinal hernia repair has become a major concern, given the low recurrence rates today. Chronic pain is typically defined as pain lasting more than 3 months after surgery, beyond the normal tissue healing time [1]. It can manifest as a dull ache, sharp neuralgic pain, or an exercise-related discomfort. Studies report chronic pain in approximately 10% of patients after inguinal herniorrhaphy (with about 2% having moderate to severe pain that affects daily activities) [3]. It is now identified as one of the most common long-term complication of this surgery [1]. The causes are multifactorial: nerve injury or entrapment (ilioinguinal, iliohypogastric, or genitofemoral nerves) can lead to neuropathic pain; excessive scar tissue or mesh contraction can cause tension on nerves; in some cases, occult osteitis of the pubic bone from mesh fixation has been implicated. Risk factors associated with chronic pain include younger age, high preoperative pain sensitivity (patients who had significant pain from the hernia often report pain after repair) [1], and the surgical technique used. Notably, an open anterior repair (Lichtenstein) has a higher risk of chronic pain and numbness than a laparoscopic repair [1], likely because open surgery involves more nerve dissection in the groin. Indeed, randomized trials have found less long-term pain and sensory loss after endoscopic (TEP/TAPP) repairs compared to open mesh repairs, especially at 1–5 years post-op [1]. Additionally, if a patient experiences an early postoperative complication such as significant hematoma or infection, it predisposes to chronic pain

development [1]. Surgical techniques to mitigate chronic pain include meticulous nerve preservation (or in some cases deliberate neurectomy to prevent neuroma formation), using lighter weight meshes, and atraumatic fixation (or no fixation) as discussed. If chronic pain does occur, management can be challenging; it may involve nerve block injections, neuropathic pain medications, and rarely re-operation to remove mesh or release entrapped nerves. Overall, while most hernia patients are pain-free long-term, the subset that develop chronic groin pain represents an important area of ongoing research and quality improvement in hernia surgery.

Other Complications:

- *Wound Infection:* Inguinal repairs are clean cases, so infection rates are low (typically <2%). Superficial surgical site infection (SSI) may present with erythema or drainage from the incision and usually responds to antibiotics and perhaps opening the wound. Deep mesh infection is rarer (<1%) but serious, as an infected mesh often requires removal. Predisposing factors include diabetes, immunosuppression, or emergency surgery for strangulation. Using the Southampton wound grading system, most hernia repairs score:-
    - Grade 0 is normal healing
    - Grade I is mild bruising or erythema only) [16].
    - Grade II (infection involving skin/subcutaneous tissue with signs like erythema, discharge) or higher.
    - Grade V is severe wound infection along with systemic implications [17]

In general, inguinal SSI rates range roughly 0.5–4% in literature [18]. Prophylactic antibiotics are not routinely needed for low-risk patients, but may be

used in high-risk cases. If mesh infection does occur (characterized by persistent drainage, sinus tract, or sepsis), complete mesh excision and secondary repair may be required.

- *Seroma/Hematoma:* Fluid collection in the groin can occur in the dead space left by the hernia sac or due to lymphatic interruption. A seroma (sterile fluid) may create a temporary bulge that can alarm patients (sometimes mistaken for "recurrence" early on). Seromas are usually managed conservatively (observation or aspiration if large). A hematoma (bleeding into the tissue) can cause bruising and hardness – small hematomas resolve spontaneously, while large ones might need drainage. Careful haemostasis and limited dissection reduce these risks. Reported rates of significant hematoma are a few percent [(14)].

- *Urinary Retention:* Particularly in older men, difficulty urinating after inguinal repair is not uncommon (due to pain or regional anaesthesia effects). This usually resolves within hours; a temporary catheter may be needed in a minority of patients.

- *Ischemic Orchitis/Testicular Atrophy:* This rare complication results from damage to or thrombosis of the testicular blood supply (spermatic cord vessels) during hernia repair. Excessive dissection around the cord or mesh-induced inflammation can compromise blood flow to the testis. It presents as severe testicular pain and swelling a day or two after surgery (orchitis). In severe cases, it can lead to partial testicular infarction and atrophy over weeks. The incidence is low – studies cite about 0.5–1% of cases developing transient ischemic orchitis, with permanent atrophy in a subset (overall <0.5%) [(18)].The

risk is higher in large, longstanding indirect hernias where cord structures are thickened and adherent. Careful handling of the cord and preserving the pampiniform plexus mitigate this risk. If ischemic orchitis occurs, it is managed with supportive care (pain control, NSAIDs); an atrophic testis if resultant is usually asymptomatic but may be clinically apparent.

- *Nerve Injury:* risk of injury :- ilioinguinal, iliohypogastric, or genitofemoral nerves can cause numbness in the groin or inner thigh, or neuralgic pain. The ilioinguinal nerve is most frequently involved. The reported incidence of chronic numbness can be up to 5–15% in some series (often mild). Identifying and protecting nerves, or intentionally dividing a nerve that is unavoidably threatened (prophylactic neurectomy), are strategies used to minimize painful neuromas. If a neuroma forms, it can sometimes be treated with nerve blocks or surgical resection.

Pain Assessment: Postoperative pain, both acute and chronic, is often measured using a Visual Analogue Scale (VAS) or similar 0–10 pain score. The VAS is a simple unidimensional scale where patients score pain from 0 ("no pain") to 10 ("worst pain imaginable"). It is commonly used in hernia studies to quantify outcomes like pain on movement at 24 hours, or chronic pain at 1 year [19]. For example, a trial may report mean VAS pain scores on day 1 were 3 in the laparoscopic group vs 5 in the open group, indicating less pain with laparoscopy. Such measures help compare techniques and the effectiveness of analgesic interventions. Another specialized scale, the Carolina Comfort Scale, has been used in hernia patients to assess mesh-related sensations and pain during various activities. In routine practice, pain that steadily improves and is minimal by a few weeks is expected; persistent high pain scores months later would prompt evaluation for chronic pain syndrome.

Wound Infection Grading: The Southampton scoring system (mentioned above) is one way to classify wound healing:

- Grade 0 is normal healing with no issues;
- Grade I is minor bruising or erythema only;
- Grade II involves clear discharge or infection limited to the incision;
- Grade III indicates significant infection with purulent discharge;
- Grade IV might involve deep infection or wound dehiscence;
- Grade V is a deep or severe wound infection involving organ/space or requiring surgical intervention [17]. In inguinal hernia trials, most wounds are Grade 0/I. The use of such grading in research allows objective comparison of wound morbidity between techniques (for instance, one study might report no Grade III–V infections in 100 laparoendoscopic repairs, indicating zero major infections). In practice, any signs of infection are monitored closely. Fortunately, inguinal repairs have among the lowest infection rates in general surgery.

In summary, inguinal hernioplasty is very safe. Major complications like life-threatening infection or testicular loss are rare. Minor issues (seromas, superficial wound problems) occur in a small percentage and are usually temporary. The field has shifted focus to chronic pain and quality of life outcomes, as recurrence has become uncommon. Ongoing efforts in technique refinement (e.g. atraumatic mesh fixation, tailored mesh selection) aim to minimize these long-term discomforts.

Comparative Studies and Innovations

Advances in hernia surgery continue as surgeons seek to improve outcomes like chronic pain and to further reduce recurrence and invasiveness. Key areas of research and innovation include mesh fixation methods and new technologies:

Sutures vs. Staples vs. Glue for Mesh Fixation: Multiple studies have compared different fixation devices in open repair. A notable randomized trial showed that by use of skin staples to fix mesh (Lichtenstein repairs) achieved the same efficacy as conventional polypropylene sutures, while significantly reducing operative time [(13)]. There was no difference in recurrence or early complications between staples and sutures, but needle-stick injuries to staff were eliminated and the mesh placement was faster [(13)]. This suggests a simple way to improve efficiency in the operating room. On the other hand, to address chronic pain, investigators have looked at eliminating penetrating fixation altogether. Fibrin glue fixation of mesh has been studied in both open and laparoscopic cases. According to a meta-analysis of trials, mesh glued in place results in a lower incidence of chronic groin pain than mesh sutured in place, without increasing hernia recurrences [(14)]. Patients with glue also had fewer hematomas and returned to normal activities sooner [(14)]. These findings are intuitive: glue avoids the tissue trauma of stitches or tacks. In Europe, some centres routinely use fibrin sealant or self-gripping mesh to minimize chronic pain. Another strategy, primarily in laparoscopic TEP repairs, is no fixation at all for smaller defects – relying on intra-abdominal pressure to keep a sufficiently large mesh pressed against the defect. Clinical data suggest that in small to moderate indirect hernias, a large mesh can be left unsecured with comparable low recurrence rates (provided the patient avoids heavy strain until integration occurs) [(7)]. Ongoing trials (e.g. comparing self-gripping mesh vs sutured mesh) aim to find the optimal balance between secure fixation and minimal chronic pain. It's clear that one size may not fit all; for instance,

a large direct hernia in a muscular young man might still warrant a couple of sutures to prevent mesh migration, whereas a tiny indirect hernia sac in an older man might do fine with glue or no tacks.

Emerging Trends and Future Directions: The future of inguinal hernia repair lies in further reducing invasiveness and improving patient comfort. Robotic surgery is one such trend, allowing complex repairs (such as concurrent hernia and prostate surgery, or difficult recurrent cases) to be done with precision – as robotic technology evolves, it may make advanced techniques more accessible, though cost-effectiveness is debated. Lighter meshes and novel materials are another area: for example, meshes partially made of absorbable components that dissolve after the scar forms, leaving less permanent foreign body. These aim to reduce long-term foreign body sensation and pain [(11)]. Fully absorbable mesh devices are also being tested – the idea is the mesh provides initial support, then disappears, hopefully with the tissue remaining strong. However, current absorbable meshes tend to result in higher recurrence once they resorb [(12)], so improvements in material science are needed. Bioactive meshes (impregnated with medications or coatings to promote healing or reduce infection) are being explored as well. On a different front, imaging and diagnostics have improved: high-resolution ultrasound and MRI can now accurately detect occult hernias and distinguish direct vs indirect components, aiding in making the diagnosis in patients with groin pain but no obvious lump. This can help target early repairs to those who truly need it. Another innovation in practice is the concept of tailored approach or watchful waiting: large trials have shown that inguinal hernias which are minimally symptomatic or asymptomatic in men could be safely observed, with elective surgery done if symptoms develop, since immediate operation may not be necessary [(1)]. This

has influenced guidelines to allow an individualized decision on timing of repair, rather than mandating repair of every hernia upon diagnosis.

Finally, pain prevention and management protocols (such as regional nerve blocks or prolonged local anaesthetics) are being implemented to improve postoperative comfort. For example, an ilioinguinal/iliohypogastric nerve block or a transversus abdominis plane (TAP) block can markedly reduce early postoperative pain, facilitating ambulatory surgery and quicker return to function. Some centres use pre-emptive analgesia and multimodal pain regimens to minimize opioid use and speed recovery, which has shown success in hernia patients.

To conclude, inguinal hernia repair has evolved into a safe, routine procedure with excellent outcomes. Ongoing research continues to refine techniques – from the material of mesh to the method of placement – all with the aim of reducing the remaining issues of chronic pain and optimizing patient quality of life. The literature shows a clear trend toward tension-free mesh repairs as the standard of care, with patient-tailored choices between open, laparoscopic, or robotic methods. Future innovations, such as improved biomaterials and enhanced recovery protocols, promise to further improve the patient experience in inguinal hernia surgery.

MATERIALS AND METHODS

1.1 Data Source

"This study was conducted in the General Surgery Department of KLEH's Dr. Prabhakar Kore Hospital, Nehru Nagar, Belagavi, Karnataka."

1.2 Study Design

"A randomized controlled trial (RCT) was designed to compare two distinct mesh fixation techniques in Lichtenstein inguinal hernia repair."

1.3 Duration of Study:-

The study was carried out over the course of one year.

1.4 Sample Size:-

The sample size was calculated using the formula given below:-

Statistical Parameters:

- X_1 (Mean operative time - polypropylene sutures) = 42.44 min
- X_2 (Mean operative time - skin staples) = 40.44 min
- $SD_1 = 2.59$, $SD_2 = 2.69$
- $Z_1\text{-}\alpha/2 = 1.96$ (95% confidence interval)
- $Z_1\text{-}\beta = 1.64$ (95% power)

The computed sample size per group was 44.5, approximated to 45 patients per group, resulting in a total of 90 participants.

1.5 Sampling Technique

A random number method was utilized within a simple random sampling approach to achieve an unbiased allocation of participants.

1.6 Inclusion Criteria

- Age range: 18 - 60 years
- Both genders , male and female patients
- Non-diabetic individuals
- Willingness to provide informed consent

1.7 Exclusion Criteria

- Complicated inguinal hernias (irreducible, obstructed, strangulated)
- Diabetes mellitus
- Chronic renal failure
- Immunocompromised patients
- Recurrent inguinal hernias
- Patients with bleeding disorders

1.8 Study Protocol

After receiving approval from ethical committee approval with written informed consent, eligible patients undergoing Lichtenstein inguinal hernia repair under spinal anaesthesia were randomized into two groups:

- Group A (Control Group): the mesh secured using polypropylene sutures.
- Group B (Study Group): the mesh secured using skin staples.

Postoperative Pain Evaluation

Assessment of Postoperative pain was done using the Visual Analog Scale (VAS) on 24 hours after surgery.

1.9 Data Collection Methodology

Eligible patients were admitted to the General Surgery Ward and assessed based on predefined inclusion and exclusion criteria. After obtaining ethical clearance and written informed consent, patients were randomized into either the control or study group.

Surgical Procedure and Mesh Fixation

A polypropylene mesh was positioned over the posterior inguinal canal wall, ensuring adequate medial (≥1 cm over the pubic tubercle) and lateral (≥2 cm beyond the internal ring) overlap.

- Control Group (Suture Fixation):
    - Mesh secured using polypropylene sutures.
    - Interrupted sutures placed were placed superiorly and medially into the internal oblique and transversalis muscles.
    - A slit created in the mesh to facilitate passage of the spermatic cord.
    - The overlapping mesh edges were sutured lateral to the slit.
- Study Group (Staple Fixation):
    - Mesh secured using skin staples.
    - 7-9 staples placed along the inguinal ligament at 1-2 cm intervals.
    - 8-10 staples secured the transversalis muscles and internal oblique superiorly and medially .
    - The overlapping mesh edges stapled together laterally with 2 staples.
    - A single staple was applied to secure the mesh to the pubic tubercle.

In both groups, closure of the external oblique aponeurosis done using Vicryl sutures, while skin closure was performed using sutures (Control Group) or skin staples (Study Group). Staple removal was scheduled for postoperative Day 8.

The total operative duration (from skin incision upto skin closure) was recorded for all patients.

Patients received postoperative antibiotic prophylaxis and were discharged once deemed medically fit.

Follow-Up and Outcome Assessment

All participants were followed up in the Surgery Outpatient Department post-discharge, and postoperative pain levels were reassessed using the VAS scoring system.

1.10 Data Processing and Statistical Analysis

- Continuous variables: is expressed as mean ± standard deviation (SD) and analysed using the unpaired Student's t-test.
- Categorical data: Is expressed as frequencies and percentages.
- Comparative analyses: Conducted using the Chi-square test or Fisher's exact test.
- Advanced statistical methods: ANOVA, correlation, and regression analyses were utilized where necessary.
- Non-parametric data: Evaluated using Mood's median test.
- If $p\text{-value} < 0.05$, it was considered statistically significant.

1.11 Anticipated Adverse Events (SAEs)

- Nerve entrapment
- Injury to vascular structures

1.12 Preoperative Investigations

All participants underwent the following preoperative investigations:

- Complete Blood Count (CBC)
- Blood Grouping
- Activated Partial Thromboplastin Time (APTT)
- Prothrombin Time (PT INR)
- Liver and Renal Function Tests (LFTs, RFTs)
- Electrocardiogram (ECG)
- Chest X-ray
- Serology: HIV, HBsAg
- Ultrasonography (USG) of the inguinal region

1.13 Financial Considerations

- The cost of investigations and interventions was borne by the patients.

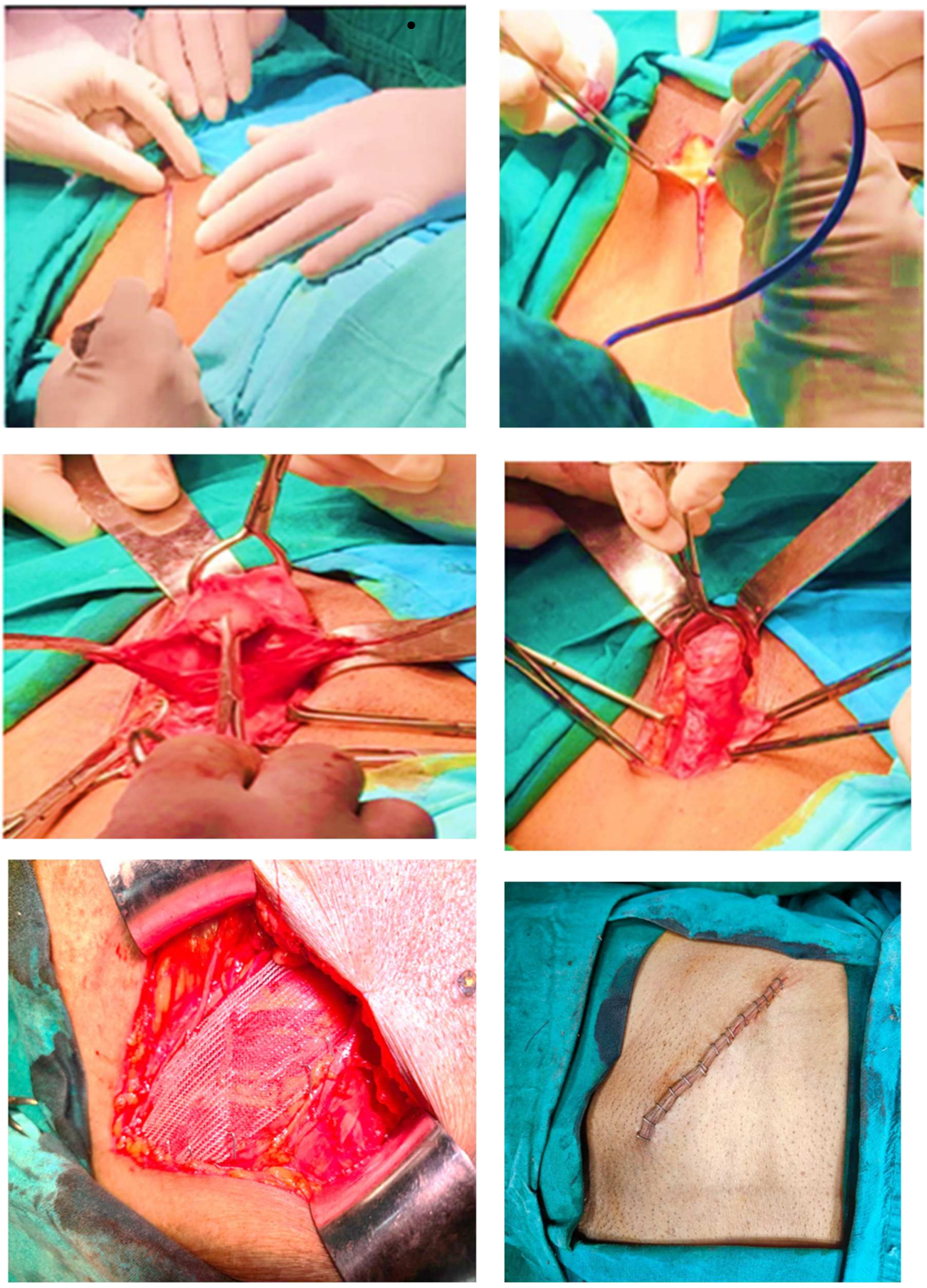


IMAGE SHOWING VARIOUS STEPS OF HERNIOPLASTY USING SKIN STAPLES FOR MESH FIXATION.

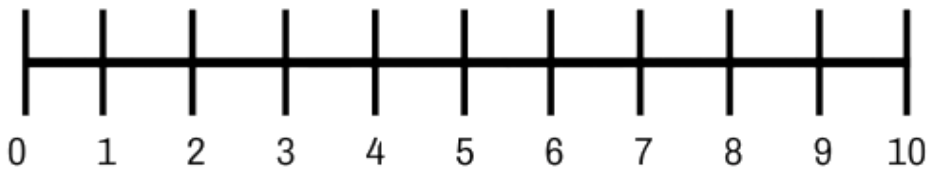
a. Incision
b. Subcutaneous tissue dissection
c. Dissection of cord
d. Dissection of indirect hernia sac
e. Placement of prolene mesh
f. Wrapping the flaps around the cord
g. Mesh in place and adherent to posterior wall
h. Placement of skin staples for mesh fixation over pubic tubercle, conjoint tendon above, inguinal ligament below
i. Closure of external oblique
j. Closure of skin with skin staples

- **Intraoperative data**, such as operative time duration were documented for each patient during hernia repair surgery.

- **Postoperative Follow-up:** Patients were followed up at 24 hours post procedure for pain assessment. Dressing was carried on post operative day 3 and any collection and induration at incision site was noted.

➢ OUTCOME MEASURES:

- Pain, measured utilizing the VAS was the primary outcome measure is. **Visual Analogue Scale (VAS)** was used to conduct pain assessment. Pain assessment was done 24 hours post surgery.



MILD MODERATE SEVERE

- Secondary outcomes include intraoperative time and postoperative complications -infection, seroma, hematoma formation postoperatively were monitored using **Scoring of Southampton Grading System** for Surgical site infection Severity Assessment.

Data Entry: Collected data was entered into a secure database system – Microsoft Excel sheets, ensuring confidentiality and accuracy.

- **Quality Control:** Quality checks were performed regularly to validate data accuracy and completeness.
- **Data Analysis:** After completing data collection, the SPSS software 26^{th} version was used to conduct the statistical analysis, to compare outcomes between both groups, Group A and Group B.

DATA PROCESSING AND STATISTICAL ANALYSIS:

The outcomes of inguinal hernioplasty using two types of mesh fixation methods, one with suture fixation and other with skin staples. Data processed and statistically analyzed. For continuous data, such as the duration of surgery, the average and standard deviation were calculated for each group. The unpaired Student's t-test was utilized to assess differences between the two groups, while a paired Student's t-test was applied for within-group comparisons. Categorical data, including postoperative complications and pain levels, were presented as percentages. The relationship between outcomes and clinical or demographic characteristics was assessed utilizing either the Fisher's exact test or Chi-square test, depending on the data size and distribution. Medians represented discrete variables, with nonparametric tests used for comparisons. Bar charts and line graphs depicted group comparisons. A statistically significant p-value was a value of less than 0.05 for all tests.

RESULTS

Study Design and Data Analysis

A randomized controlled trial was done over a time duration of one year to evaluate the effectiveness of two different methods of fixing mesh in Lichtenstein tension-free inguinal hernia repair. A total sample size of 90 patients with the diagnosis of inguinal hernia requiring surgical intervention were enrolled in the study.

Patient Allocation

Participants were assigned randomly into two equal groups (n=45 each) as follows:

- Group A (Control): Patients who underwent standard Lichtenstein mesh hernioplasty, wherein the polypropylene mesh was secured using non-absorbable sutures.
- Group B (Test): Patients in whom Lichtenstein mesh hernioplasty with mesh fixation was done using skin staples instead of sutures.

Data Collection and Analysis

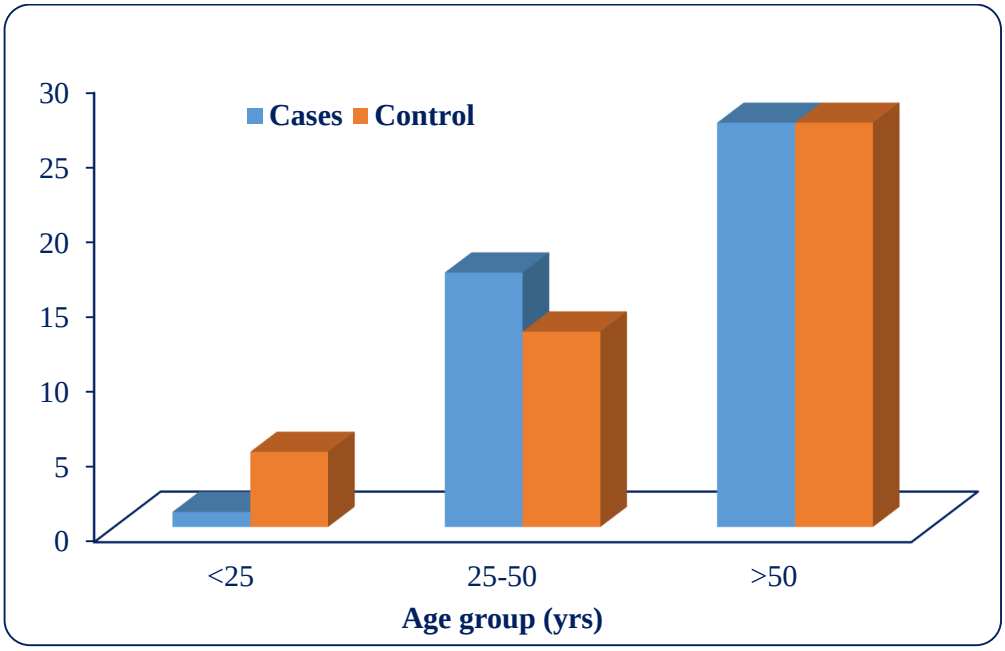
- Comprehensive patient demographics, intraoperative details, and postoperative outcomes were meticulously recorded using a predefined proforma.
- All collected data was systematically entered into Microsoft Excel and categorized under Control (Group A) and Test (Group B) for structured analysis.
- The outcomes between the two groups were compared using statistical analysis , including operative time, postoperative pain (VAS scores), and complication rates, ensuring robust and objective evaluation of the study parameters.

1. Age-Wise Distribution

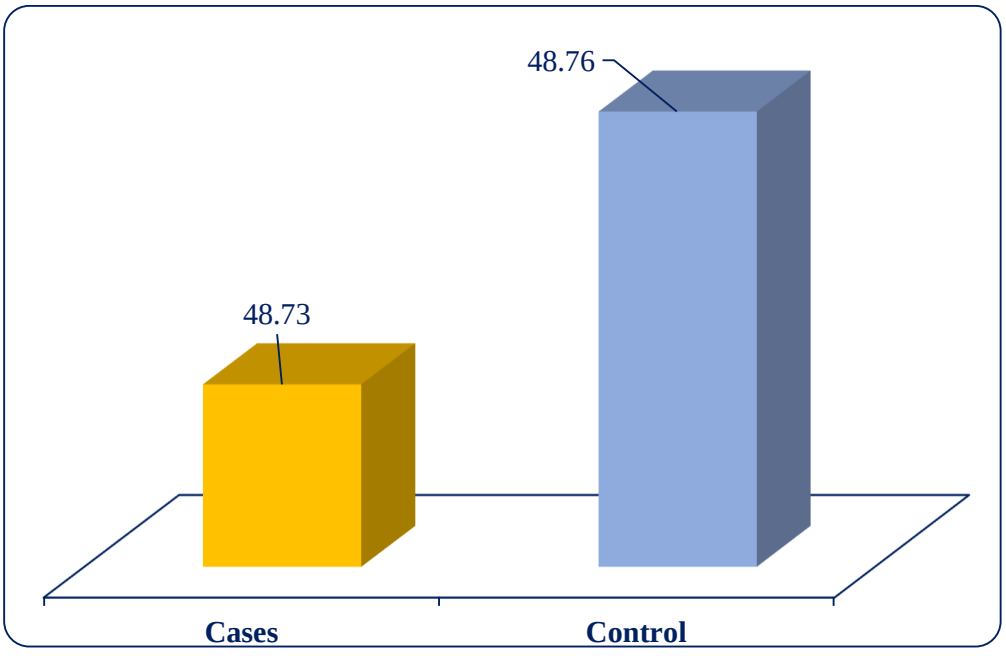
The age distribution among the cases and control groups is summarized as follows:

Age Group (Years)	Cases (n=45)	Control (n=45)
<25	1 (2.22%)	5 (11.11%)
25-50	17 (37.78%)	13 (28.89%)
>50	27 (60.00%)	27 (60.00%)

- Mean age for cases was 48.73 ± 11.99 years and for controls was 48.76 ± 13.17 years.
- No statistically significant difference was found in the age distribution . (p-value = 0.201).
- The t-test for mean age between groups was not significant (p-value = 0.991), indicating comparable age distribution.


30
25
20
15
10
5
0
Cases
Control
<25
25-50
>50
Age group (yrs)

- Mean Age


48.76
48.73
Cases
Control

2. Sex-Wise Distribution

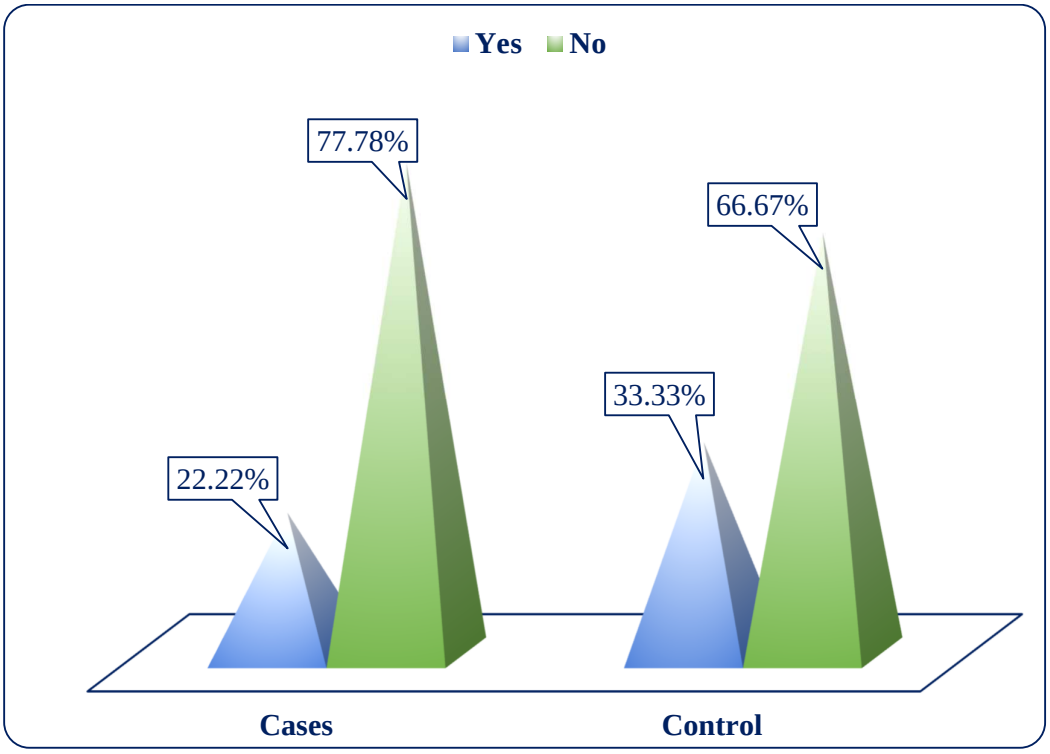
Sex	Cases (n=45)	Control (n=45)
Male	45 (100%)	45 (100%)
Female	0 (0%)	0 (0%)

- All participants in both groups were male.
- No statistical difference as both groups had identical gender distribution.

3. Co-Morbidities (Hypertension)

Hypertension	Cases (n=45)	Control (n=45)
Yes	10 (22.22%)	15 (33.33%)
No	35 (77.78%)	30 66.67%)

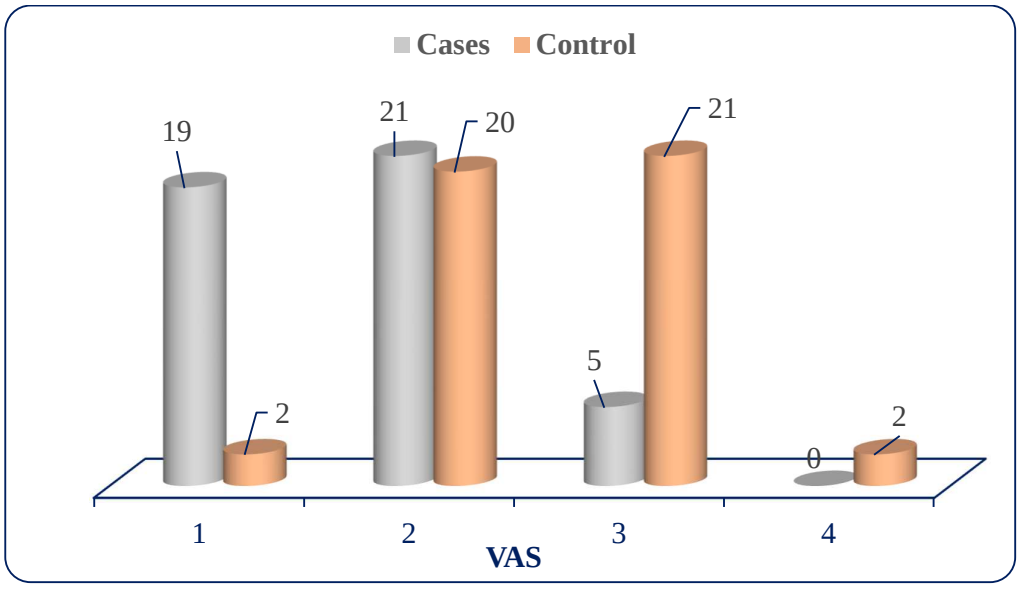
There was a higher prevalence of hypertension in the control group (33.33%) compared to cases (22.22%), although it was not statistically significant difference (p-value = 0.239).


Yes
No
77.78%
66.67%
33.33%
22.22%
Cases
Control

4. Postoperative Pain Assessment (VAS Score)

VAS Score	Cases (n=45)	Control (n=45)
1	19 (42.22%)	2 (4.44%)
2	21 (46.67%)	20 (44.44%)
3	5 (11.11%)	21 (46.67%)
4	0 (0.00%)	2 (4.44%)

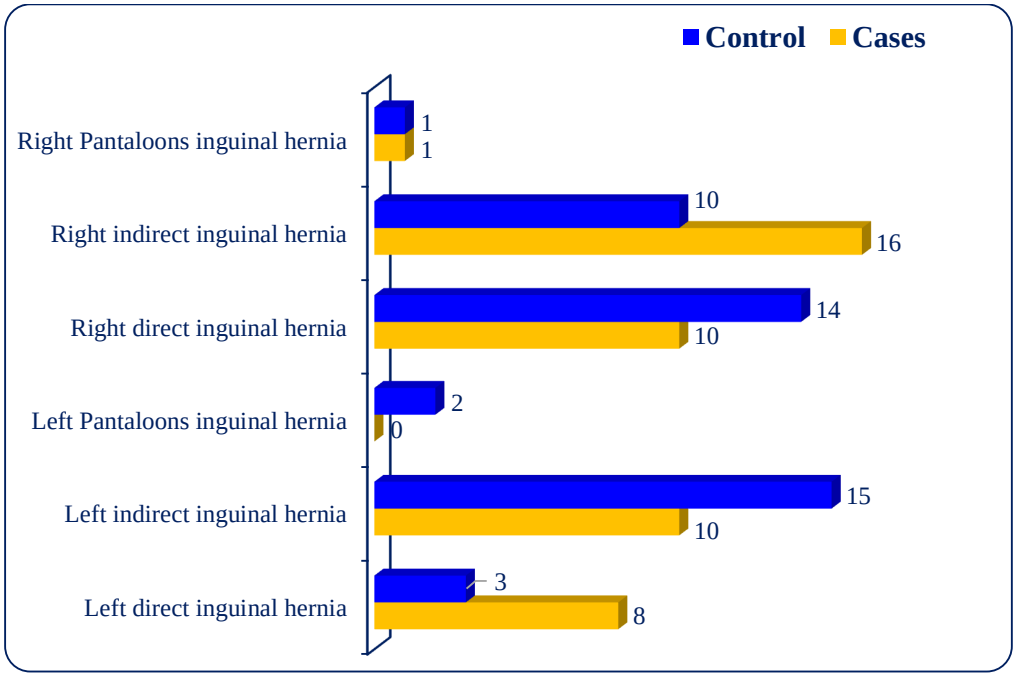
- Pain scores in the cases group were significantly lower, with a median VAS score of 2.
- Mood's Median Test confirmed a statistically significant difference in pain scores (p-value < 0.0001).



5. Diagnosis Distribution

Diagnosis	Cases (n=45)	Control (n=45)
Left direct inguinal hernia	8 (17.78%)	3 (6.67%)
Left indirect inguinal hernia	10 (22.22%)	15 (33.33%)
Left pantaloons inguinal hernia	0 (0.00%)	2 (4.44%)
Right direct inguinal hernia	10 (22.22%)	14 (31.11%)
Right indirect inguinal hernia	16 (35.56%)	10 (22.22%)
Right pantaloons inguinal hernia	1 (2.22%)	1 (2.22%)

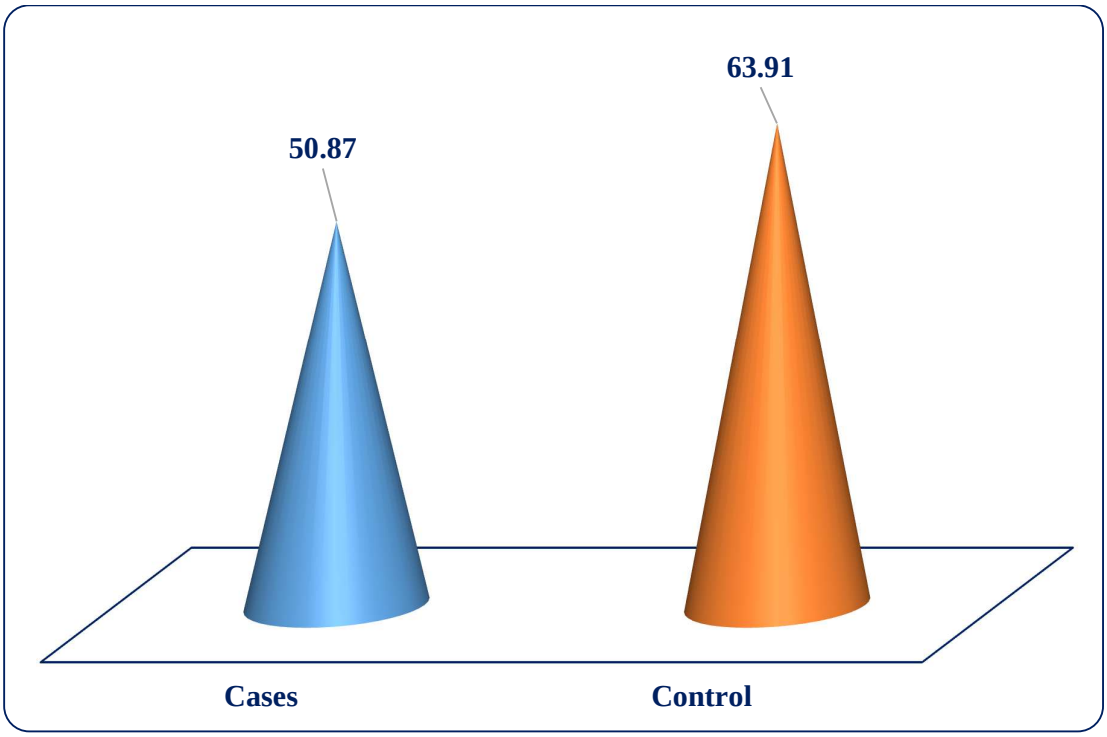
- No statistically significant variation in the distribution of hernia types between the groups. (p-value = 0.1976).


Control
Cases
Right Pantaloons inguinal hernia
1
1
Right indirect inguinal hernia
10
16
Right direct inguinal hernia
14
10
Left Pantaloons inguinal hernia
2
0
Left indirect inguinal hernia
15
10
Left direct inguinal hernia
3
8

6. Operative Duration (Minutes)

Group	N	Mean Duration (Minutes)	SD	t-value	p-value
Cases	45	50.87	8.35	6.754	<0.0001
Control	45	63.91	9.90		

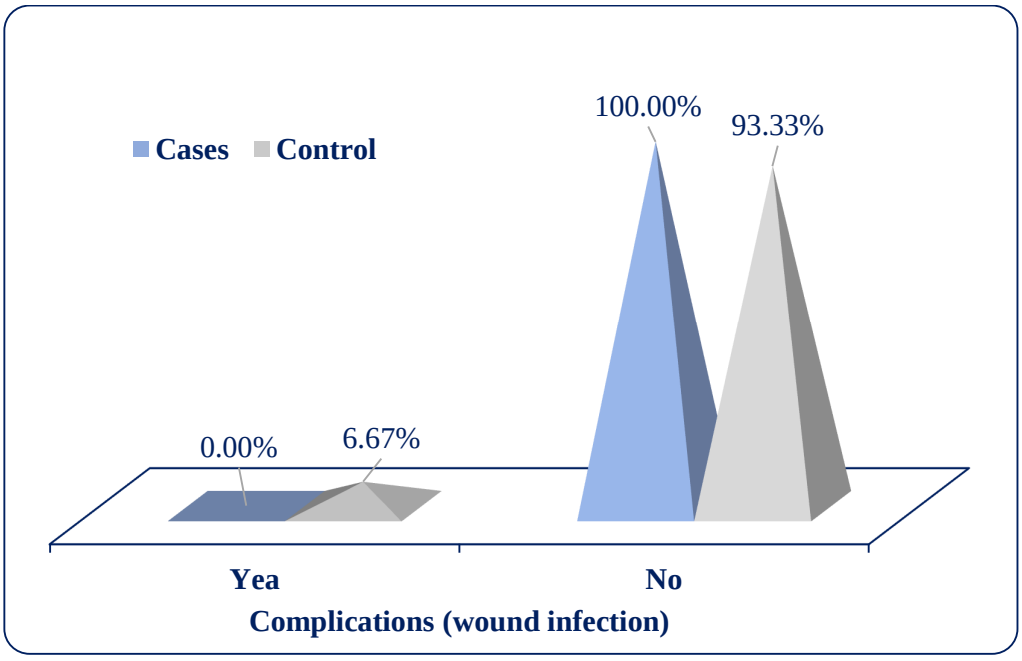
- A significantly lower operative time duration in the cases group (50.87 ± 8.35 min) compared to controls (63.91 ± 9.90 min).
- The value of t-test results was highly significant (p-value < 0.0001), favouring a shorter surgical time with staples.



7. Postoperative Complications (Wound Infection)

Wound Infection	Cases (n=45)	Control (n=45)
Yes	0 (0.00%)	3 (6.67%)
No	45 (100%)	42 (93.33%)

- The wound infection incidence was higher in the control group (6.67%) as compared with cases group (0%).
- The difference approached significance (p-value = 0.078), suggesting a potential lower risk of infection with staple fixation.



8. Summary of Findings

1. Demographics: No significant difference noted in age, gender, or co-morbidities between various groups.
2. Pain Outcomes: Significantly lower VAS scores in the cases group ($p < 0.0001$), indicating less post-op pain with staples.
3. Operative Duration: Significantly shorter surgery time in cases ($p < 0.0001$), demonstrating efficiency of staple fixation.
4. Complications: Zero wound infections in cases, suggesting lower infection rates with staple fixation.
5. Diagnosis Distribution: No significant difference in types of hernias between groups.

9. Conclusion

The study demonstrates that staple fixation in Lichtenstein hernioplasty significantly reduces operative time and postoperative pain, with a potentially lower risk of wound infection, compared to the traditional method of suture fixation. These findings support that use of staples as an effective and efficient alternative for fixing the mesh in inguinal hernia repair.

DISCUSSION

Key Findings

In this study comparing suture versus staple fixation in Lichtenstein inguinal hernia repair, the most salient finding was the reduction in operative time achieved with staple fixation. The staple group had a significantly shorter mean surgery duration than the suture group, underscoring the efficiency of staple application for mesh anchoring. This result is consistent with the notion that staples can be applied more rapidly as compared to sutures, thereby saving operative time [20]. Alongside the time savings, the staple-fixation cohort reported lower early postoperative pain scores on the visual analogue scale (VAS) compared to the suture group. Although the difference in pain was modest, it suggests that minimizing mesh fixation time and perhaps reducing tissue manipulation with staples can translate into improved immediate postoperative comfort for patients. Importantly, the two groups were well matched at baseline – there was no significant difference in patient demographics (eg. age or sex) or hernia characteristics (side and type of hernia) between the staple and suture cohorts. This comparability indicates that the observed differences in outcomes (operative time and pain) more likely a result of the fixation method rather than the influence of confounding factors.

The overall complication rates were similar between the two fixation techniques. Common postoperative complications – including seroma, hematoma, scrotal edema, and neuralgia – occurred at comparable frequencies in both the staple and suture groups, indicating that the safety profile of staple fixation is on par with the traditional suture method. Notably, there we could see a trend toward fewer surgical site infections in the staple group. In our series, wound infections were observed less often with staple fixation, though there was no statistical significance given the

sample size. This trend aligns with the hypothesis that shorter operative times and less tissue handling may reduce infection risk [20]. No other major complications differed between groups, and there were no incidence of recurrences detected during the available follow-up period for either group. While there was a relatively shorter follow-up in this study (limited to the early postoperative period), the absence of any early recurrence in both groups is reassuring and suggests that, in the short term, staple fixation does not compromise the durability of the repair. In summary, staple mesh fixation offered a faster operation and slightly improved early pain outcomes without incurring a higher risk of complications, compared to suture fixation, in our patient population.

Comparison with Existing Literature

Our findings can be contextualized within the body of literature examining mesh fixation methods in open inguinal hernia repair. Reduction in operative time with staple fixation is strongly corroborated by prior studies. For instance, Yadav *et al.* (2014) reported that securing the mesh with skin staples reduced the mean mesh insertion-to-skin closure time by more than 10 minutes compared to sutures [20]. Similarly, a randomized trial by Kumar *et al.* (2023) in high-risk patients found a significantly shorter median operative time using staples (46 minutes) versus sutures (57 minutes) [13]. The consensus in the literature is that staples allow faster mesh deployment because multiple staples can be placed quickly without the need for time-consuming knot-tying [20]. This time efficiency has been consistently observed without compromising the security of mesh fixation. Our result of a roughly 15–20% reduction in operative duration with staples is well in line with these reports, reinforcing that staple fixation offers a tangible operative advantage across different surgical settings.

Postoperative pain outcomes in our study showed a lower VAS pain score in the staple group, but this point deserves careful comparison with existing studies. Several published trials have shown no significant alteration in early postoperative pain between staple and suture fixation. For example, Mills *et al.* (1998) conducted a randomized trial and reported equivalent pain levels in both groups, a finding echoed by Garg *et al.* (2004) and by van der Zwaal *et al.* (2008) [20]. In a recent comparative study, Attaullah *et al.* (2020) also noted statistically similar pain scores at a time duration of 12 and 24 hours post-surgery for staples versus sutures. Against this backdrop, our observation of reduced pain with staples suggests a possible benefit, but it may reflect nuanced differences in postoperative management or measurement timing. It is conceivable that the shorter operative time and reduced tissue trauma with staples contributed to slightly less immediate pain in our patients. Additionally, variations in analgesic protocols or patient perception could influence pain reporting. Given that the majority of controlled studies have not found a large divergence in pain outcomes, our finding should be interpreted with caution. It highlights the need for more investigation – possibly with a bigger sample sizes or focusing on specific pain endpoints (such as chronic groin discomfort) – to determine if staple fixation truly confers a pain reduction or if the difference in our study was an outlier or clinically minor effect.

In terms of postoperative complications, our results align closely with the existing literature, which indicates that staple fixation is at least as safe as suture fixation. Prior randomized trials have generally shown no increase in complication rates when using staples [13]. In our study, the incidence of complications like seroma, hematoma, and neurogenic pain did not differ between groups, paralleling the findings of Yadav *et al.* and others that staples do not elevate the risk of such adverse

outcomes [20]. A particularly relevant point in the literature is the effect of fixation method on wound infection rates. Some studies have suggested a lower infection rate with staples: Yadav *et al.* observed a significantly less infection rate in the staple group compared with sutures [20], and other authors have reported similar trends, attributing this to reduced operative time and less handling of tissues with the staple technique [20]. Our data showed a favourable but non-significant reduction in surgical site infections with staples, which is consistent with these trends. It's worth noting that one reason this difference often does not reach statistical significance is the generally low baseline rate of infection in elective hernia repairs; very large sample sizes are required to definitively prove a difference. Nonetheless, the directional consistency across studies (fewer infections in staple groups) is clinically encouraging.

Another point of comparison is long-term outcomes, particularly hernia recurrence. Due to the limited follow-up, our study could not assess recurrence rates. However, existing literature provides some insights. Van der Zwaal *et al.* (2008) reported a striking difference in recurrence in their series: at long-term follow-up, the suture fixation group had an 11% recurrence rate versus only 1% in the staple group [20]. They hypothesized that staple fixation might allow a uniformly tension free placement of the mesh , as sutures – if tied too tightly – could introduce focal tension and mesh deformation [20]. While this finding is notable, it comes from a single study and such a large recurrence difference has not been universally observed. Most modern series of Lichtenstein repair, regardless of fixation method, report low recurrence rates (often in the low single digits) with proper technique [20]. Therefore, while there is some evidence hinting that staples could potentially reduce the risk of recurrence by avoiding suture-induced tension, a clear conclusion awaits more robust

data from long-term, possibly multicentre trials. In sum, our results largely support the existing evidence base: staple fixation matches or improves upon suture fixation in operative efficiency and perioperative outcomes, with no detectable drawbacks in the short term. Minor discrepancies, such as the pain outcome, highlight the variation in response of the patient and the importance of context when comparing studies.

CLINICAL IMPLICATIONS

The results from the study have several practical implications for surgical practice and patient care. The most immediate advantage of staple mesh fixation is the operative time saved. In a busy surgical unit, a reduction in surgery duration by even 10–15 minutes per case can translate into significant efficiencies – allowing more cases to be performed in a day or reducing the duration of anaesthesia for patients. Shorter operative times also mean less time under anaesthesia and less exposure of the wound, which theoretically can diminished chances of infection and other time-dependent adverse effects [20]. For the operating surgeon, using staples for mesh fixation is technically straightforward and rapid. Many surgeons are already familiar with skin staplers for wound closure; extending their use to mesh fixation involves a minimal learning curve. This technique may also reduce surgeon fatigue during lengthy lists, as the fiddling with multiple sutures is replaced by quick staple applications. Furthermore, in situations where the surgeon's safety is a concern (notably patients with HIV or hepatitis as highlighted by Kumar *et al.* [13], eliminating suture needle passes significantly lowers the risk of accidental needle-stick injuries. Thus, from an operative standpoint, staple fixation offers efficiency and safety advantages without compromising the security of the repair.

For patients, the potential benefits of staple fixation can affect both the early recovery period and possibly long-term outcomes. Our observation (and some reports in the literature) of slightly lower early postoperative pain with staples suggests that patients might experience greater comfort in the immediate days after surgery. Even if pain differences are minimal, any reduction in pain can improve patient mobility and cooperation with activities like early ambulation – which is important for preventing other complications (e.g. venous thrombosis, pulmonary issues) and for overall recovery satisfaction. Patients with less pain may require lower doses of analgesics, potentially shortening hospital stay or allowing earlier return to daily activities, although our study did not measure these endpoints specifically. In terms of wound healing, the trend toward fewer infections with staples, if borne out in larger studies, means patients could have a lower likelihood of needing antibiotics, wound dressings, or interventions for infection. This not only benefits patient health but also reduces the burden on healthcare resources.

From a health economics perspective, the choice between staples and sutures involves a balance of material costs and broader system costs. On face value, a disposable skin stapler can be more expensive than a few polypropylene suture packs. However, this must be "weighed against the time saved in the operating room – operating theatre time is a scarce and costly resource". A shorter procedure can decrease personnel time and anaesthesia requirements, which may offset the higher device cost. Moreover, some studies have noted that skin staple devices can be used for multiple patients (with proper sterilization and reloading), spreading their cost over several repairs [20]. In such scenarios, the per-patient cost of using staples can become comparable to, or even less than, that of sutures. Our findings and those of others suggest that staples are at least cost-effective in terms of outcomes: they do not

lead to higher complication rates or recurrences that would incur additional treatment costs [20]. In fact, by potentially reducing infection rates and operative time, staples may prevent certain costs (fewer antibiotics, fewer clinic visits, etc.). It is also worth considering the intangible or long-term cost benefits: if staple fixation were proven to reduce recurrence or chronic pain (as some have hypothesized [20], this would have significant economic and quality-of-life advantages by avoiding reoperations and ongoing pain management. In summary, the clinical implications of our study support the idea that staple fixation is a safe and efficient alternative to sutures. Surgeons could adopt staples to potentially improve operative workflow and patient comfort, and any added device cost appears to be justified by the gains in efficiency and possibly improved outcomes. Institutions should, of course, conduct their own cost-benefit analysis based on local costs and practices, but the results contribute to an increasing evidence favouring staple use for mesh fixation in suitable hernia cases.

Limitations and Future Scope

Although this study adds valuable data to the suture-versus-staple debate, it is not without limitations. First, the sample size, though adequate to detect differences in operative time and acute pain, may be insufficient to conclusively evaluate less frequent outcomes such as mesh infection, chronic pain, or recurrence. A larger cohort might reveal statistically significant differences in wound infection rates or other complications where we observed only trends. Second, the follow-up duration in our study was relatively short, focusing mainly on immediate and short-term postoperative outcomes. As a result, we could not assess long-term endpoints like hernia recurrence or chronic groin pain beyond the early postoperative period. Recurrence, in particular, is a critical outcome in hernia repair that often manifests months to years after surgery; our study cannot draw conclusions about how fixation

method influences recurrence risk. Third, we conducted the study at a single centre and possibly with a limited number of surgeons – this homogeneity, while controlling technique variability, might restrict the applicability of the findings. Surgical skill and familiarity with either fixation method can influence outcomes, so multi-centre trials would be beneficial to ensure that our results hold true across different settings and surgeon experiences. Additionally, our trial was not blinded: the operating surgeon obviously knew the fixation method, and although patients were likely unaware of how their mesh was fixed (since the skin closure was almost same in both groups), the assessment of pain could have some observer or patient expectation bias. We tried to mitigate this by using objective pain scales and standard analgesic protocols, but a double-blind design (if practically feasible) might further strengthen the evidence by eliminating any potential bias in patient-reported outcomes.

Looking forward, there are several avenues for future research to build on these findings. A priority would be studies with extended follow-up to determine if the choice of fixation has any impact on long-term results such as hernia recurrence rates and chronic postoperative pain or discomfort. As noted in other research, there is a possibility that staples could reduce recurrence by ensuring a more tension-free mesh placement[20] , but only long-term data can confirm or refute this potential advantage. Similarly, chronic pain post inguinal hernia repair is an important outcome affecting patient quality of life; future trials should evaluate whether staple versus suture fixation has any bearing on the incidence of chronic groin pain or numbness months or years post-surgery. Another recommendation is to incorporate patient-reported outcome measures into future studies – for example, quality of life indices or patient satisfaction surveys. It would be valuable to know if patients perceive a difference in their recovery or well-being based on the fixation method, beyond the

standard clinical measures. Additionally, a formal cost analysis in different healthcare settings would be useful. Such analysis could account for the price of materials, the value of operating room time saved, and the costs associated with any complications or follow-up care. This would provide a clearer picture of the cost-benefit ratio of staples versus sutures from an institutional perspective.

Moreover, future research could explore comparisons of sutures and staples with newer mesh fixation innovations. For instance, tissue glue or fibrin sealants and self-gripping meshes (which require no fixation) have been studied as alternatives to suturing in hernia repair. Comparing these methods against staple fixation in randomized trials could further guide the optimal mesh fixation strategy. Finally, enrolling a more diverse patient population – including those with recurrent hernias or high-risk co-morbid conditions – might help determine if certain subgroups benefit more from one fixation method. To conclude , while our study favours the use of staples as an effective and fast means of mesh fixation in Lichtenstein repair, ongoing research with larger scale and longer horizon is essential. Such studies will solidify the evidence, address any remaining questions regarding long-term efficacy and safety, and ultimately inform clinical guidelines to improve patient results in inguinal hernia surgery.

CONCLUSION

This comparative analysis demonstrated clear advantages of staple fixation as compared to fixation by sutures in Lichtenstein inguinal hernia repair. Staple fixation significantly reduced operative time, highlighting a marked improvement in surgical efficiency. Patients in the staple group also reported lower postoperative pain scores (VAS) compared to those in the suture group, indicating better early postoperative comfort. Importantly, overall complication rates between the two methods were comparable, with a noted trend toward fewer wound infections in the staple cohort. Additionally, there was no significant differences in patient demographics or hernia characteristics between the two groups, ensuring that the observed benefits of staple fixation are not attributable to underlying group disparities but rather to the fixation technique itself.

Clinical Implications

These findings carry important clinical implications for surgical practice. In practical terms, the mesh fixation with use of staples for streamlines the procedure: the reduced operative duration can improve operating room turnover and efficiency, and the technical ease of applying staples (as opposed to tying multiple sutures) simplifies a critical step of the repair. From the patient's perspective, the lower postoperative pain associated with staples can lead to a more comfortable recovery, potentially enabling earlier mobilization and discharge. A slight reduction in wound infection incidence, as observed in the staple group, further suggests that staple fixation may confer a small added safety benefit, reducing the need for postoperative interventions such as antibiotics or wound care. Collectively, these advantages not only benefit individual patient outcomes but could also translate into a reduced healthcare burden—shorter time duration of hospital stays, reduced postoperative

analgesic requirement, and faster return to normal activities all contribute to more efficient healthcare delivery. In considering the broader adoption of staple fixation, cost-effectiveness emerges as an important factor. Staples and their applicators do introduce an upfront material cost higher than that of standard sutures; however, this must be weighed against the potential cost savings from operative time saved and improved postoperative recovery. A shorter surgery can reduce anaesthesia requirements and operating room expenses, and better pain outcomes might decrease the use of pain medications and follow-up visits. When these factors are taken into account, staple fixation may prove to be cost-effective or even cost-saving in the long run. Surgical departments will need to balance the immediate costs of staples with these downstream savings and patient-centered benefits, but the efficiency gains and possible reduction in complications make a strong case for staples as a financially viable option in suitable settings.

RECOMMENDATIONS FOR FUTURE RESEARCH

While the present study provides encouraging evidence in favour of staple fixation, further research is warranted to solidify and expand upon these conclusions. Larger sample sizes in future trials (ideally across multiple centres and diverse patient populations) are needed to confirm that the observed reductions in operative time and pain with staples are consistently reproducible and to ensure adequate power to detect any differences in less common complications. Long-term follow-up is particularly important: future studies should track patients well beyond the immediate postoperative period to determine whether the short-term advantages of staple fixation translate into long-term benefits. Key outcomes to assess include hernia recurrence rates over several years and the incidence of chronic groin pain, both of which are critical for determining the lasting success of a hernia repair technique. Additionally, exploration of alternative mesh fixation techniques could be valuable. Investigating options such as self-fixating meshes (which adhere without the need for additional fixation) or the use of fibrin glue or other adhesives may reveal other viable methods that either match or surpass the performance of staples and sutures. Such comparative research, especially if conducted in randomized controlled trials, would help determine the optimal fixation method for different patient groups and refine best practices in inguinal hernia repair.

FINAL CONCLUSIVE STATEMENT

In conclusion, staple fixation in Lichtenstein inguinal hernia repair emerges as an effective and efficient alternative to traditional suture fixation. It offers superior operative efficiency and improved patient comfort without affecting safety or increasing complication rates. Given these advantages, staple fixation can be considered a preferable technique in appropriate cases, representing a viable step forward in optimizing surgical outcomes and patient recovery in inguinal hernia management

SUMMARY

Background: Inguinal hernia repair is one of the most commonly performed surgical procedures, with Lichtenstein tension free mesh repair being the gold standard. The method of mesh fixation plays a crucial role in operative efficiency, postoperative recovery, and complication rates. Traditionally, polypropylene sutures have been used for fixation, but staple fixation has emerged as a potentially faster and equally effective alternative. This study compares suture versus staple fixation to assess their impact on postoperative pain , operative time and complications.

Objective: To compare the effectiveness of suture and staple fixation in Lichtenstein inguinal hernia repair based on operative duration, postoperative pain scores, and complication rates.

Methods: -

A randomized controlled trial was done on 90 patients diagnosed with primary uni - lateral inguinal hernia, randomized into two groups:

- Group A (Suture Fixation, n=45): Mesh secured using polypropylene sutures.
- Group B (Staple Fixation, n=45): Mesh secured using skin staples.

Patients with recurrent, complicated, or bilateral hernias were excluded. Operative time (in minutes) was recorded intraoperatively. Post - operative pain was measured using the Visual Analog Scale (VAS) at 24 hours, 3 days, and 8 days. Complications (infection, seroma, hematoma, urinary retention, recurrence) were monitored over 3 months. “Statistical analyses were performed using unpaired t-tests and chi-square tests, with a p-value <0.05 considered statistically significant.”

Results:

1. Operative Time: Staple fixation resulted in a significantly shorter mean operative time (50.87 ± 8.35 mins vs. 63.91 ± 9.90 mins, $p < 0.0001$).
2. Postoperative Pain (VAS Scores at 24h):
    - VAS at 24 hours: Lower in the staple group (Median: 2 vs. 3 in suture group, $p < 0.0001$).
3. Complication Rates:
    - Wound infection: 0% (staple group) vs. 6.67% (suture group), $p = 0.078$.
    - Seroma, hematoma, urinary retention, recurrence: No statistically significant differences ($p > 0.05$).

Conclusion: Fixing mesh by staples in Lichtenstein inguinal hernia repair is considered a safe, time-efficient alternative to suture fixation, reducing operative duration significantly ($p < 0.0001$) while showing comparable postoperative pain ($p > 0.05$) and no increased risk of complications ($p > 0.05$). The trend toward lower wound infection rates in the staple group warrants further investigation. Given its faster operative time and similar safety profile, staple fixation can be a preferable option to fix mesh in open inguinal hernia repair. Future research should include long-term follow-up to assess hernia recurrence and chronic pain outcomes.

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ANNEXURE I:- KAHERs JNMC

BELAGAVI

INFORMED CONSENT FORM

"Prospective randomised control trial comparing skin staples and polypropylene sutures used in inguinal hernia repair for mesh fixation."

Name of Student/Principal Investigator: Dr MRIDULIKA VERMA

Name of Guide/Co Investigators: Dr ANIL KUMAR P.BELLAD

Introduction: The use of polypropylene mesh in Lichenstein's inguinal hernia repair which is placed over the posterior wall of the inguinal canal with polypropylene sutures conventionally, however this study focuses on the use of skin staples to anchor the mesh and the early results of the study have been favourable. The various concerns were associated with use of staples like nerve entrapment, increased wound infection rate, increased vascular injury rate and total increased procedural cost. This modification done in Lichenstein's mesh repair was investigated in this randomised prospective control trial to see these concerns and to establish the use of skin staples in mesh fixation as an effective repair.

Explanation of procedure: After written informed consent and procedure explanation that a polypropylene mesh will be placed behind the inguinal canal, in control group mesh will be sutured with polypropylene sutures while in study group it will be secured using staples. Patients were then randomised into two groups , control group ,where mesh will be secured using polyproplylene sutures and a study group where mesh will be secured using skin staples. In both the groups closure of external oblique aponeurosis will be done using vicryl sutures and the same suture will be used to approximate subcutaneous tissue. Skin closure of control group will be done with sutures , whereas in the study group it will be done with skin staples and these will be removed on post operative day 8.

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator.

Possible benefits from participating in the study: You will/will not get any direct benefits by participating in this study. The data gathered will help population at large.

Possible risks from participating in the study: There are no risks involved in participating in this study.

Privacy and confidentiality: The information collected from you will be coded, to prevent any person to identify you. Your identity will never be revealed. The data collected from you will be kept confidential and only processed or aggregated data will be used for publication.

Financial incentives: You will not receive any payment for participating in this study.

Cost of investigations done during the course of study will be paid by the **principal investigator / Participant.** (Strike out which is not applicable)

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purpose and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact: **"Dr. MRIDULIKA VERMA, mobile number: 9528735124; email id :- mridulikaverma@gmail.com.** If you have any question or complaints with regard to your right as study participant you may contact Dr Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights

CONSENT STATEMENT

I am making a voluntary decision to participate in the study "**Prospective randomised control trial comparing skin staples and polypropylene sutures used in inguinal hernia repair for mesh fixation.**". My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant:

Name of the witness:

Signature or left thumb impression of the witness:

Name of the investigator: Dr. MRIDULIKA VERMA

Signature of the investigator:

ANNEXURE II :- PROFORMA

1. Patient UHID No.
2. Age (in years)
3. Gender Male/Female ☐
4. Height (in cms) ☐☐☐
5. Weight (in kgs) ☐☐
6. BMI (kg / m^2) ☐☐
7. Co-morbidities
   - Blood pressure Yes ☐ No ☐
   - Diabetes Mellitus Yes ☐ No ☐
   - COPD Yes ☐ No ☐
8. Pulse rate ☐☐☐ bpm
9. Pallor Yes ☐ No ☐
10. Icterus Yes ☐ No ☐
11. History:-
    -Swelling present since (days)
    -Nature of swelling : Reducible / Non reducible
12. Examination:
    -Palpation (size in cms):
13. Nature :
    -Reducible / Non reducible
    -Consistency
    -Tenderness Yes ☐ No ☐
    -Additional Finding (if any):
14. Diagnosis :
15. Drugs given during course of treatment

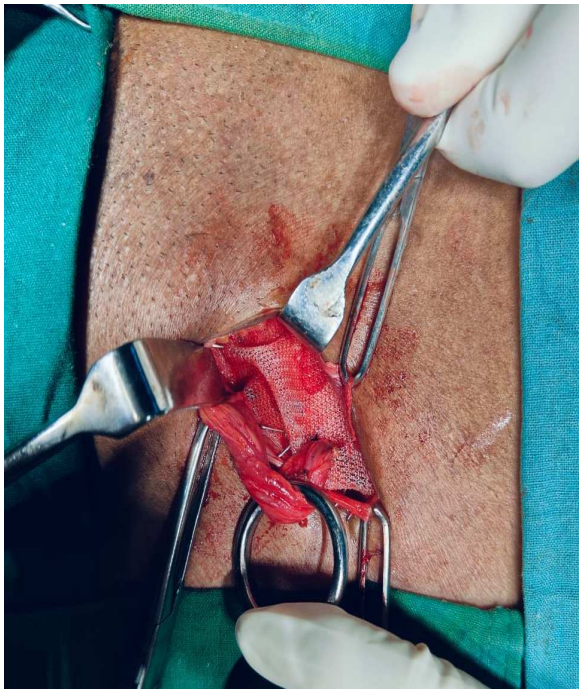
ANALYSIS

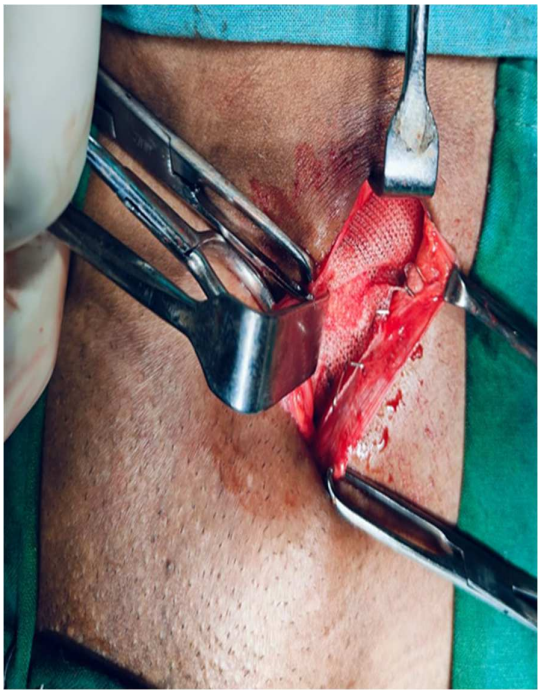
1. Post op hospital stay
2. Post op pain (as per visual analogue scale)
3. Duration of surgery (in mins):
4. Post op analgesia given

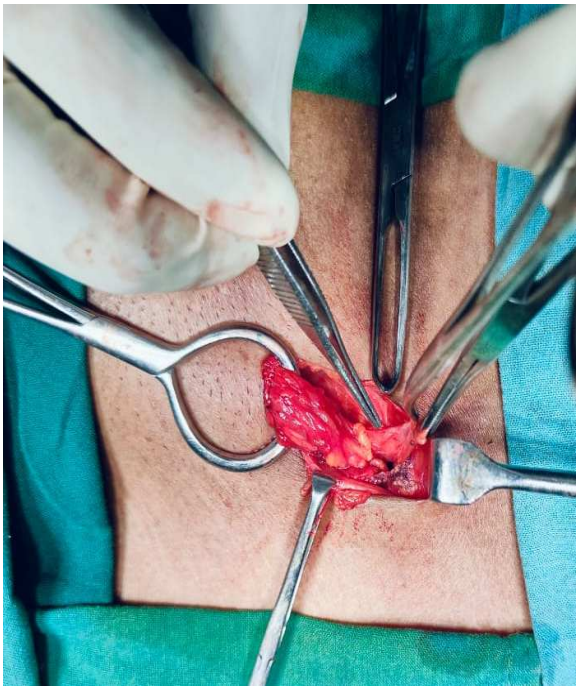
   Dose……. Duration ……..

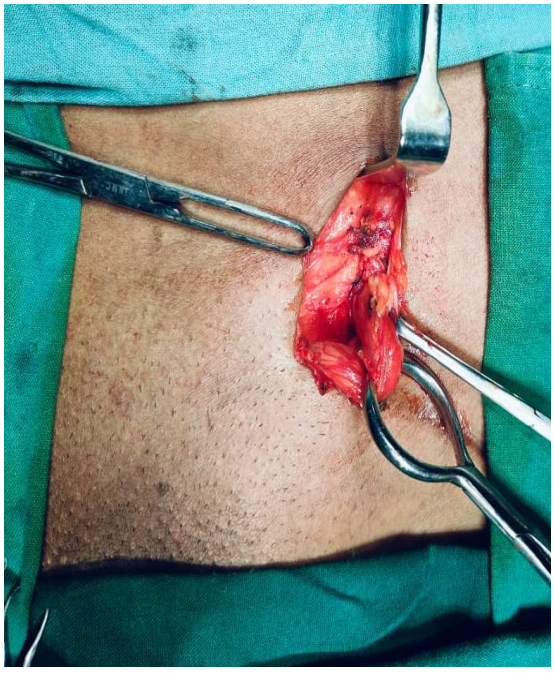
5. Wound infection Yes ☐ No ☐
6. Post op complications(if any):

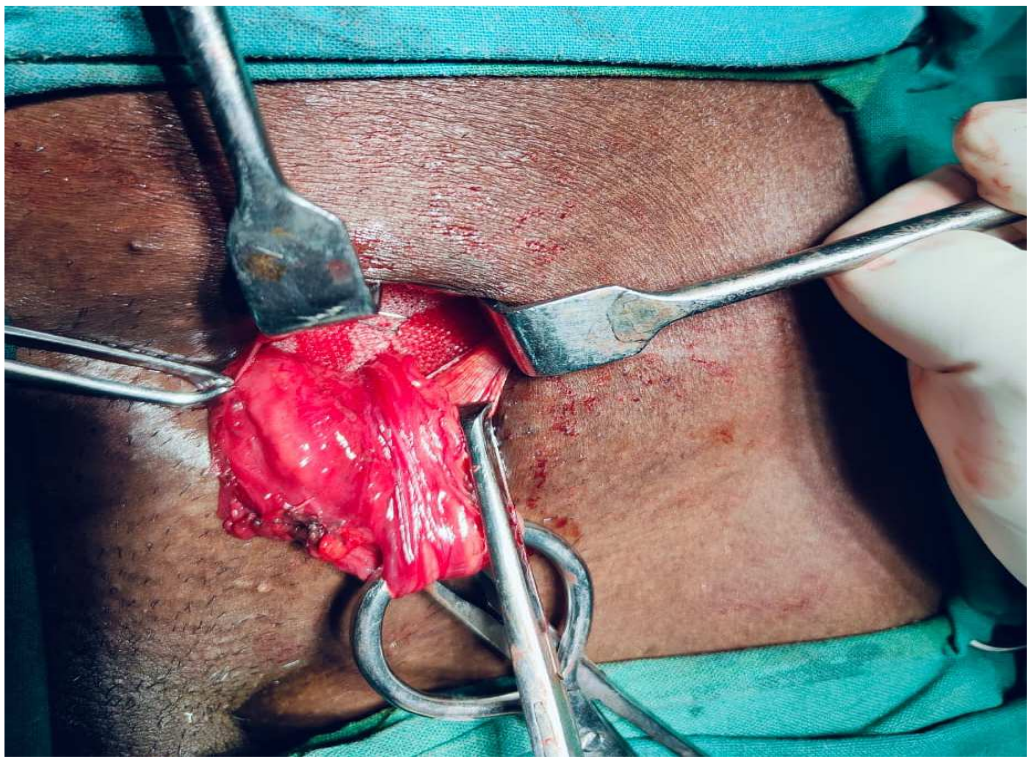
ANNEXURE III: - PHOTOGRAPHS

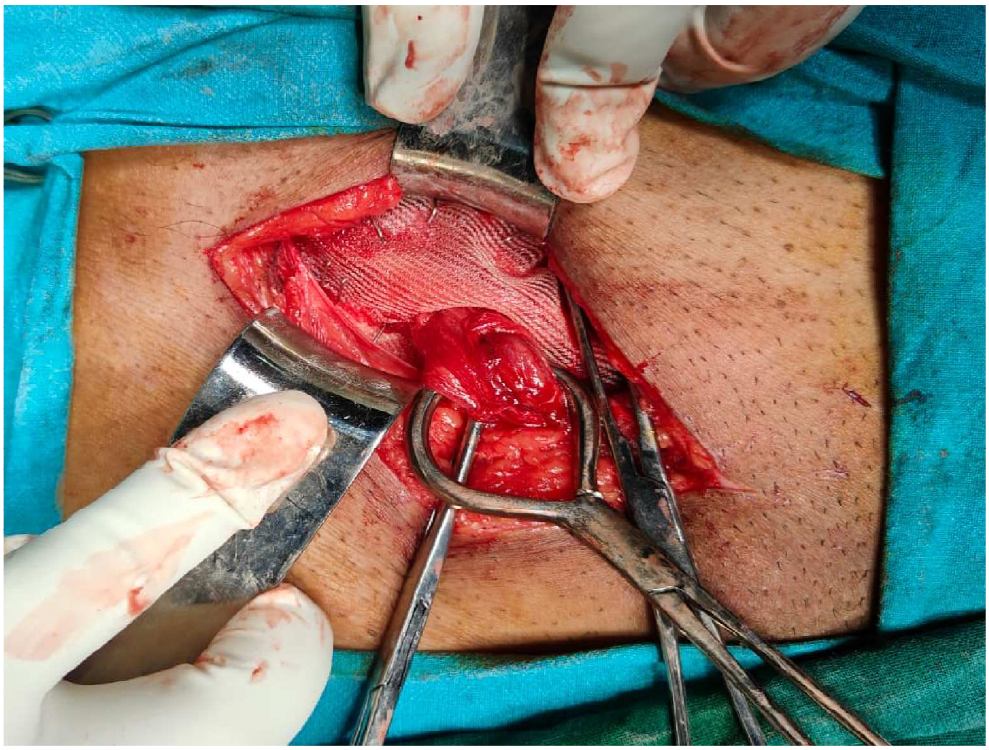


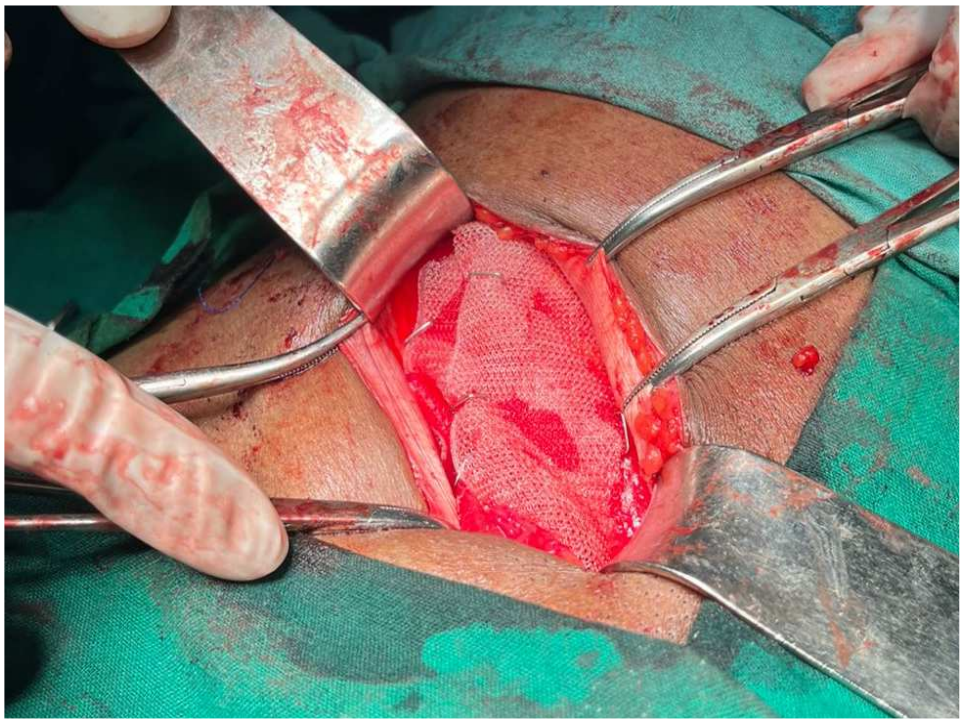


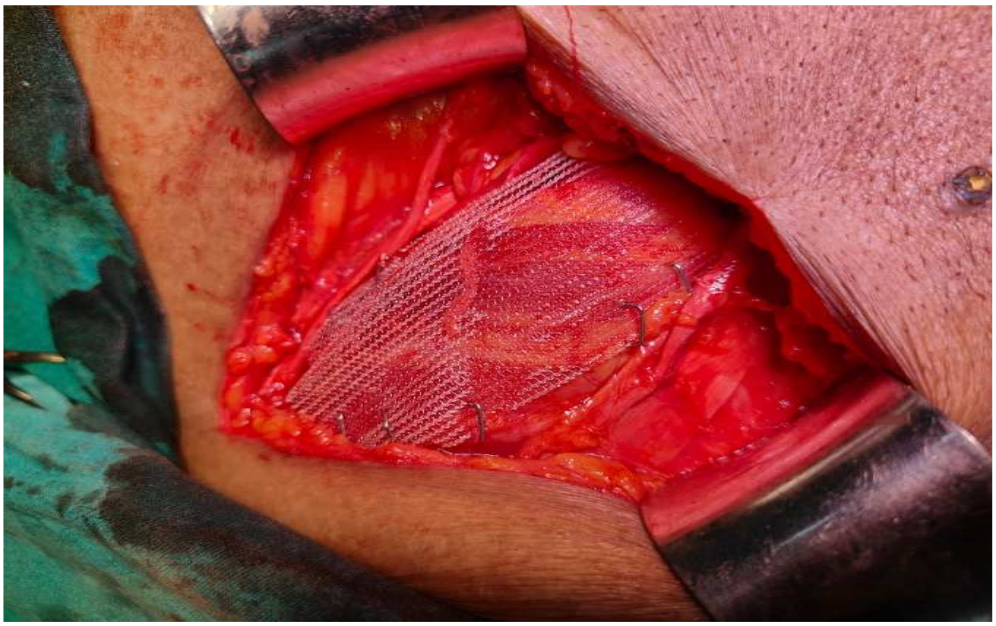


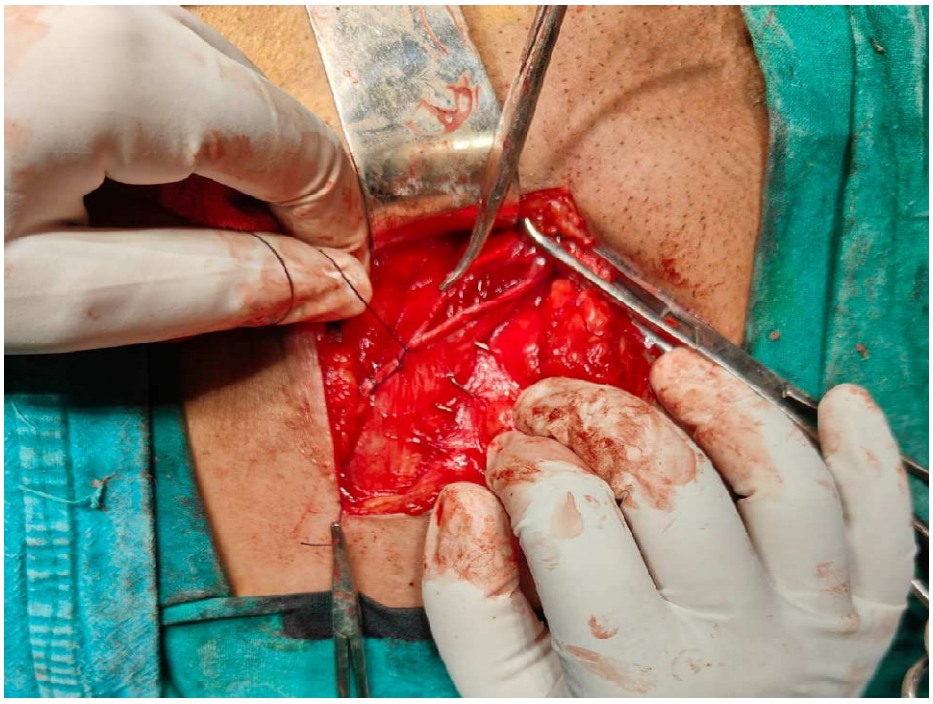


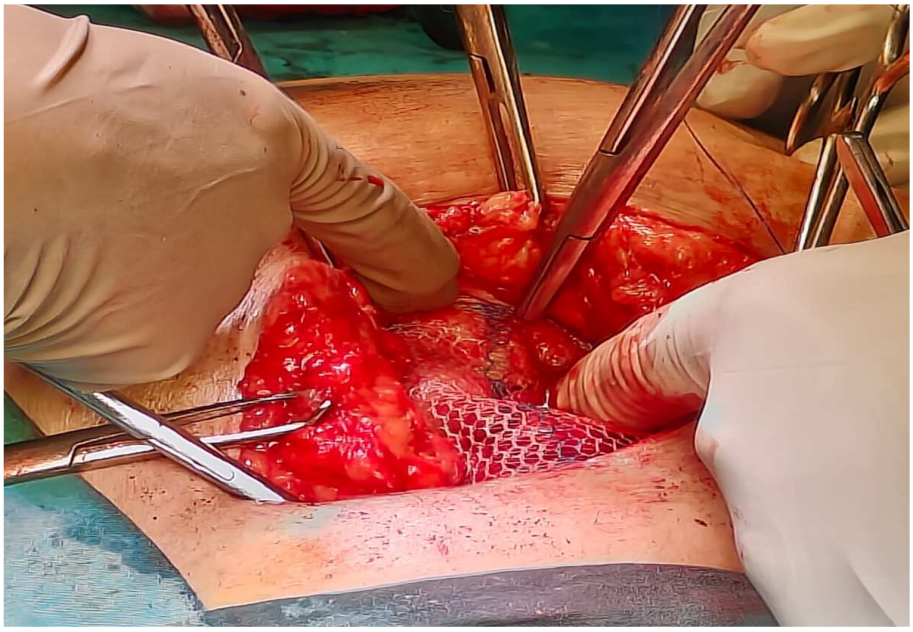


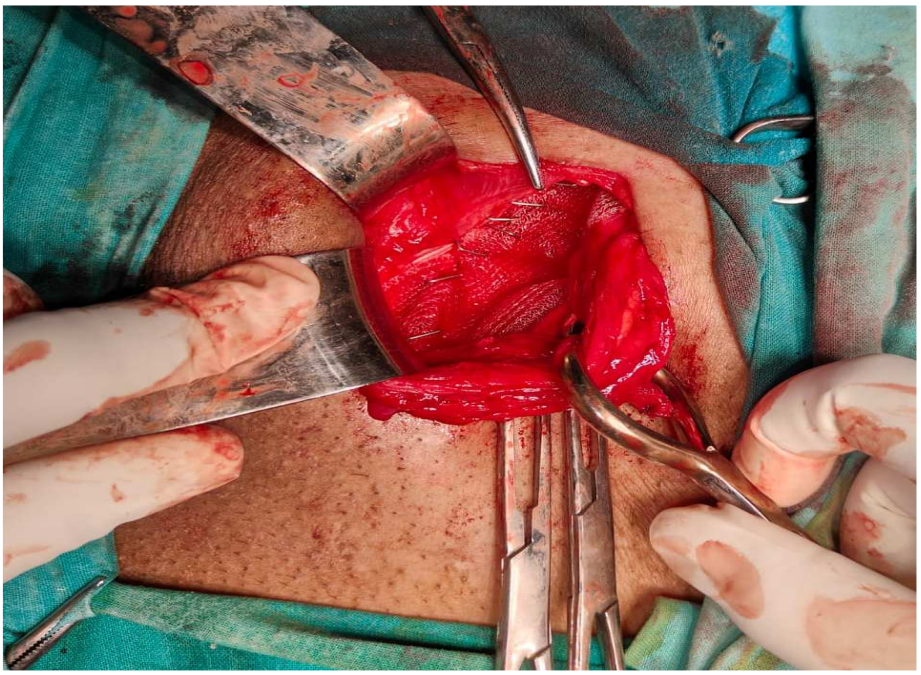


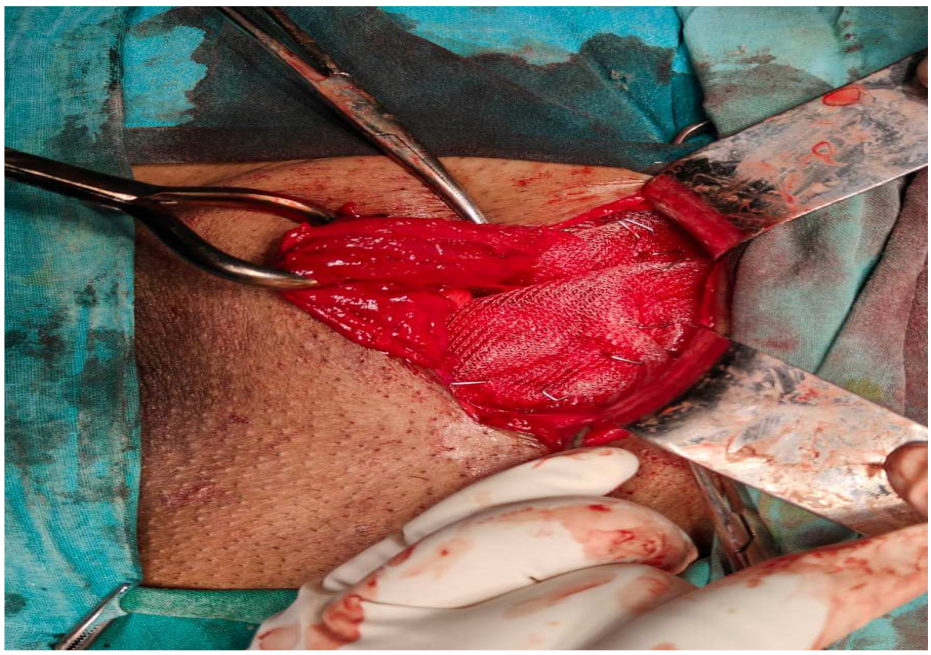


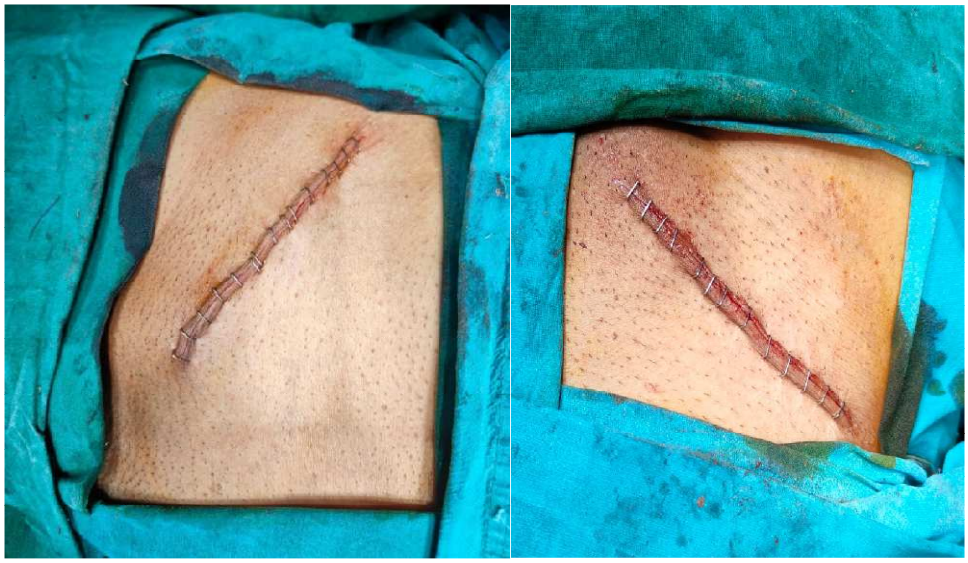


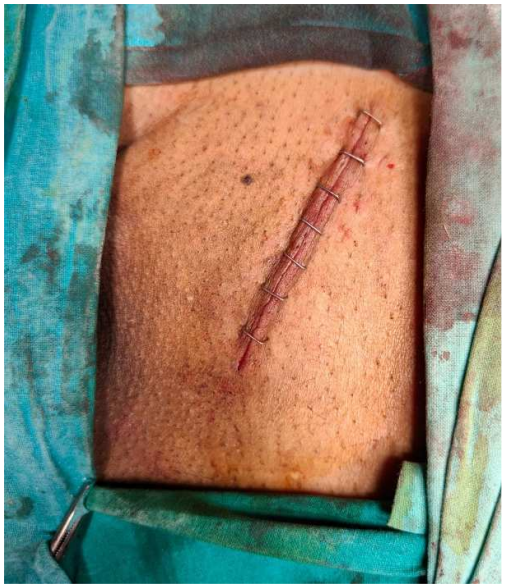


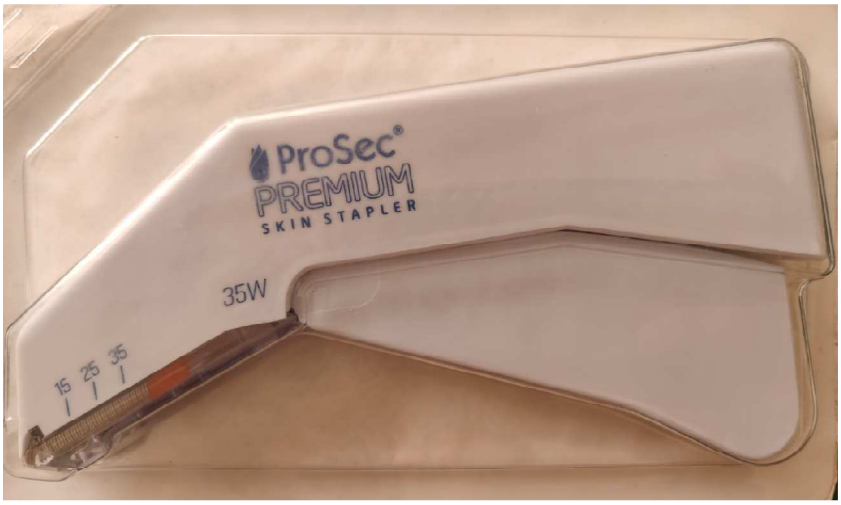








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ANNEXURE IV :- MASTERCHART

CASES										
SL.No.	IP No.	Age	Sex	co-morb	VAS Sc	Diagnosis	Duration	Complications		
1	10119045	60	Male	BP	2	Left direct inguinal hernia	50 mins	--		
2	10118579	52	Male	-	1	Right indirect inguinal hernia	60 mins	--		
3	10117780	30	Male	-	1	Right indirect inguinal hernia	50 mins	--		
4	10129360	30	Male	-	3	Left indirect inguinal hernia	70 mins	--		
5	10129760	46	Male	-	2	Right direct inguinal hernia	60 mins	--		
6	10117264	60	Male	BP	2	Left direct inguinal hernia	70 mins	--		
7	10116761	39	Male	-	2	Right indirect inguinal hernia	50 mins	--		
8	10119018	53	Male	-	1	Right direct inguinal hernia	50 mins	--		
9	10119146	42	Male	-	2	Left indirect inguinal hernia	60 mins	--		
10	10120832	60	Male	BP	1	Left direct inguinal hernia	50 mins	--		
11	10119675	35	Male	-	1	Right indirect inguinal hernia	60 mins	--		
12	10120912	57	Male	BP	2	Right direct inguinal hernia	40 mins	--		
13	10080845	59	Male	BP	2	Left direct inguinal hernia	60 mins	--		
14	10080380	38	Male	-	1	Left direct inguinal hernia	35 mins	--		
15	10085303	57	Male	-	2	Left direct inguinal hernia	40 mins	--		
16	10081910	38	Male	-	1	Right indirect inguinal hernia	60 mins	--		
17	10081926	58	Male	-	2	Right indirect inguinal hernia	55 mins	--		
18	10081432	59	Male	BP	2	Left direct inguinal hernia	45 mins	--		
19	10012107	57	Male	BP	2	Right direct inguinal hernia	55 mins	--		
20	10121462	32	Male	-	2	Right indirect inguinal hernia	50 mins	--		
21	10126474	60	Male	BP	2	Left direct inguinal hernia	51 mins	--		
22	10085056	55	Male	-	2	Right indirect inguinal hernia	55 mins	--		
23	10084936	59	Male	-	1	Left indirect inguinal hernia	45 mins	--		
24	10084988	59	Male	BP	2	Right direct inguinal hernia	50 mins	--		
25	10086522	54	Male	-	1	Right direct inguinal hernia	50 mins	--		
26	10122855	30	Male	-	2	Left indirect inguinal hernia	45 mins	--		
27	10125786	35	Male	-	3	Left indirect inguinal hernia	50 mins	--		
28	10126785	58	Male	-	1	Right indirect inguinal hernia	40 mins	--		
29	10121238	44	Male	-	1	Right indirect inguinal hernia	45 mins	--		
30	10014305	59	Male	-	3	Left indirect inguinal hernia	45 mins	--		
31	10027201	20	Male	-	1	Right indirect inguinal hernia	45 mins	--		
32	10030940	60	Male	-	1	Right direct inguinal hernia	35 mins	--		
33	10013013	56	Male	-	3	Left indirect inguinal hernia	55 mins	--		
34	10031050	60	Male	-	2	Right indirect inguinal hernia	60 mins	--		
35	10028152	60	Male	-	2	Right direct inguinal hernia	60 mins	--		
36	10024325	55	Male	-	2	Right indirect inguinal hernia	55 mins	--		
37	10039341	43	Male	-	1	Right indirect inguinal hernia	50 mins	--		
38	10028521	59	Male	-	1	Right indirect inguinal hernia	45 mins	--		
39	10069990	58	Male	-	3	Right indirect inguinal hernia	65 mins	--		
40	10034331	26	Male	-	1	Left indirect inguinal hernia	50 mins	--		
41	10071274	43	Male	-	1	Right direct inguinal hernia	48 mins	--		
42	10059709	34	Male	-	1	Right direct inguinal hernia	40 mins	--		
43	10065968	32	Male	-	2	Left indirect inguinal hernia	45 mins	--		
44	10006307	60	Male	BP	1	Right Pantaloons hernia	40 mins	--		
45	10014244	52	Male	-	2	Left indirect inguinal hernia	50 mins	--		

CONTROLS									
SL.No.	IP No.	Age	Sex	CM	VAS	Diagnosis	Time	Complications	
1	10120862	60	Male	BP	3	Left direct inguinal hernia	85 mins	wound infection	
2	10069872	52	Male	-	3	Right indirect inguinal hernia	60 mins	--	
3	10122011	60	Male	-	2	Left indirect inguinal hernia	60 mins	--	
4	10071220	56	Male	-	3	Right direct inguinal hernia	60 mins	--	
5	10126467	60	Male	-	3	Right direct inguinal hernia	80 mins	--	
6	10124679	58	Male	BP	3	Left indirect inguinal hernia	60 mins	--	
7	10122021	47	Male	-	3	Right indirect inguinal hernia	75 mins	wound infection	
8	10120847	59	Male	-	4	Left indirect inguinal hernia	90 mins	--	
9	10046846	50	Male	-	2	Right direct inguinal hernia	50 mins	--	
10	10055371	28	Male	-	2	Left indirect inguinal hernia	60 mins	--	
11	10055371	20	Male	-	3	Left indirect inguinal hernia	55 mins	--	
12	10046846	50	Male	BP	3	Right direct inguinal hernia	75 mins	--	
13	10043813	54	Male	BP	2	Right direct inguinal hernia	55 mins	--	
14	10068079	54	Male	-	3	Left Pantaloons inguinal hernia	60 mins	--	
15	10015615	60	Male	BP	3	Left Pantaloons inguinal hernia	75 mins	--	
16	10065128	55	Male	-	2	Right indirect inguinal hernia	55 mins	--	
17	10055441	57	Male	BP	3	Right direct inguinal hernia	70 mins	--	
18	10069403	50	Male	BP	2	Left indirect inguinal hernia	70 mins	--	
19	10046838	59	Male	-	2	Left indirect inguinal hernia	60 mins	--	
20	10067831	42	Male	-	3	Right indirect inguinal hernia	76 mins	--	
21	10026420	59	Male	BP	3	Right direct inguinal hernia	75 mins	--	
22	10053773	60	Male	-	2	Left indirect inguinal hernia	70 mins	wound infection	
23	10032811	31	Male	-	3	Left indirect inguinal hernia	70 mins	--	
24	10073297	20	Male	-	2	Right indirect inguinal hernia	60 mins	--	
25	10032280	40	Male	-	2	Right indirect inguinal hernia	70 mins	--	
26	10033785	20	Male	-	2	Left indirect inguinal hernia	65 mins	--	
27	10071228	56	Male	BP	3	Right indirect inguinal hernia	70 mins	--	
28	10027920	45	Male	-	3	Left indirect inguinal hernia	75 mins	--	
29	10062512	60	Male	-	2	Right direct inguinal hernia	60 mins	--	
30	10052182	60	Male	-	2	Right direct inguinal hernia	68 mins	--	
31	10068211	60	Male	BP	4	Left direct inguinal hernia	70 mins	--	
32	10040022	25	Male	-	2	Left indirect inguinal hernia	50 mins	--	
33	10051859	30	Male	-	1	Left indirect inguinal hernia	60 mins	--	
34	10053194	60	Male	BP	2	Right direct inguinal hernia	60 mins	--	
35	10050356	55	Male	BP	3	Right direct inguinal hernia	70 ins	--	
36	10031247	60	Male	BP	2	Right direct inguinal hernia	60 mins	--	
37	10026482	59	Male	-	1	Right indirect inguinal hernia	55 mins	--	
38	10019680	20	Male	-	2	Left indirect inguinal hernia	60 mins	--	
39	10014077	56	Male	-	3	Right direct inguinal hernia	60 mins	--	
40	10013137	48	Male	-	2	Left indirect inguinal hernia	45 mins	--	
41	10001632	20	Male	-	3	Right indirect inguinal hernia	57 mins	--	
42	11189241	54	Male	-	3	Right Pantaloons inguinal hernia	60 mins	--	
43	10017520	60	Male	BP	2	Left direct inguinal hernia	55 mins	--	
44	10013158	50	Male	BP	3	Right indirect inguinal hernia	45 mins	--	
45	10001708	55	Male	-	2	Right direct inguinal hernia	55 mins	--	