"INGUINAL HERNIOPLASTY USING BIO COMPONENT MESH (POLYESTER MONOFILAMENT AND POLYLACTIC ACID) VS. POLYPROPYLENE MESH: A ONE YEAR RANDOMIZED CONTROL STUDY"

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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 **"INGUINAL HERNIOPLASTY USING BIO COMPONENT MESH (POLYSTER MONOFILAMENT AND POLYLACTIC ACID) VS POLYPROPELENE MESH: A ONE YEAR RANDOMIZED CONTROL STUDY, AT KAHER'S DR. PRABHAKAR KORE CHARITABLE HOSPITAL AND MEDICAL RESEARCH CENTRE, BELGAVI-590010"** is ethical and justifiable. The proposed research project has been cleared by the JNMC Institutional Ethics Committee.

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LIST OF ABBREVIATIONS

PLA	:	Polylactic Acid
VAS	:	Visual Analogue Scale
POD	:	Post-Operative Day
SSI	:	Surgical Site Infection
HTN	:	Hypertension
T2DM	:	Type 2 Diabetes Mellitus
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
e-PTFE:		Expanded polytetraflouroethylene
EHS	:	European hernia system

ABSTRACT

Background:

Inguinal hernia repair is a prevalent surgical procedure, and advancements in mesh materials and fixation techniques aim to optimize patient outcomes by reducing operative time, postoperative pain, and complications. This study aims to compare the outcomes of self-adhesive bio-component mesh (Polyester Monofilament and Polylactic Acid) Vs. a traditional polypropylene mesh fixed with sutures in inguinal hernia repair.

Methodology:

A randomized controlled study was conducted over one year, involving 70 male patients who were divided into two groups. Group A / Control group (n=35) underwent Lichtenstein hernioplasty using a polypropylene mesh fixed with non-absorbable sutures, while group B / Test group (n=35) received a self-adhesive bio-component mesh. The primary endpoint included operative time, postoperative pain measured by the visual analogue scale (VAS). Pain levels were assessed at multiple postoperative intervals: immediately after surgery (postoperative day 0), on the third day (postoperative day 3), the fifth day (postoperative day 5), at one month, and at three months. Complication rates (seroma, hematoma, infection) were monitored on postoperative day 3, postoperative day 5, postoperative day 7 and Southampton grading score noted.

Results:

The study found a significant difference in operative times between the two groups. Group B demonstrated a significantly reduced operative time, averaging 68.77 ± 15.13 minutes, compared to 82.80 ± 12.86 minutes in Group A (p=0.001). This reduction is attributed to the elimination of suturing time required for mesh fixation in the traditional method.

Pain levels were assessed using the Visual Analogue Scale (VAS) at multiple post-operative intervals. On postoperative day 0, pain scores were similar between both groups, with Group A recording an average score of 6.628 ± 2.590 and Group B recording 6.485 ± 2.671 (p=0.821). However, by postoperative day 3, Group B reported significantly lower pain scores (3.942 ± 2.325) compared to Group A (p=0.001).

This trend continued on postoperative day 5, with Group B scoring 1.742 ± 1.421 against Group A's 3.11 ± 1.5 (p=0.001). At one month, Group B's pain scores further decreased to 1.428 ± 1.786 compared to Group A's 2.4 ± 2.0 (p=0.012). Although pain scores at three months were lower in Group B (1.31 ± 1.2) than in Group A, the difference was not statistically significant (p=0.348) due to an outlier in Group B.

The incidence of complications, including seroma, hematoma, and infections, did not differ significantly between the groups, underscoring the safety of the self-fixing mesh. For instance, seroma rates at postoperative day 3 were 3 in Group A and 2 in Group B (p=0.614), while hematoma rates were 1 in Group A and 0 in Group B (p=0.731). Both groups demonstrated comparable wound healing as assessed by the Southampton scoring system (p=0.089).

A significant reduction in chronic groin pain was observed in Group B at the 3-month follow-up. No hernia recurrences were reported in either group throughout the 3-month follow-up period.

Conclusion:

The self-adhesive bio-component mesh offers significant advantages over the traditional polypropylene mesh fixed with sutures. These benefits include reduced operative time and lower short-term postoperative pain, enhancing patient recovery and comfort. The comparable complication rates and absence of hernia recurrences within the study period further support the efficacy and safety of the self-adhesive mesh. These findings suggest that the self-adhesive bio-component mesh could be a superior alternative to traditional methods, though further long-term studies are recommended to confirm these benefits over extended follow-up periods.

Keywords: *Inguinal hernia, hernioplasty, self-adhesive mesh, polypropylene mesh, postoperative pain.*

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INTRODUCTION

Inguinal hernia poses a considerable burden on healthcare system in India and worldwide, and is one of the most common surgeries performed. According to epidemiological data, inguinal hernias account for a substantial proportion of all hernias diagnosed annually, constituting roughly 3/4th of all abdominal wall hernias encountered in clinical practice[1]. The incidence varies across different age groups, with a notable increase observed in older adults. While inguinal hernias are less common in children, they remain a significant concern, particularly in premature infants and males[2].

The incidence of inguinal hernias peaks around the age of 5 and after the age of 70, with males accounting for approximately 90% of cases. Indirect hernias are the most common type of groin hernia, comprising two-thirds of all cases, and are more prevalent on the right side. The economic burden of inguinal hernias includes direct costs related to hospitalization and surgery, as well as indirect costs from lost productivity and disability. Complications such as bowel obstruction, strangulation, and incarceration highlighting the need for effective management strategies.[3, 4]

Two primary techniques dominate the arena of inguinal hernia repair – the traditional Lichtenstein repair and the more contemporary laparoscopic repair. The former, an open surgical procedure, involves the strategic placement of a mesh over the hernia defect to fortify the weakened area. On the other hand, laparoscopic repair, a minimally invasive approach, utilizes small abdominal incisions and a laparoscope to visualize and repair the hernia with mesh. Despite these strides, post-operative pain continues to be a notable complication, with the Lichtenstein repair, though widely practiced, being particularly associated with higher rates of chronic pain, notably due to suture fixation and nerve entrapments. [5, 6]

In order to eliminate sutures and in search of alternatives, new methods and techniques of mesh (prostheses) evolved over time during the 20th and 21st centuries. Some notable and research proven methods are: N-butyl-2-cyanoacrylate glue (surgical glue), staplers, tacks, fibrin sealant, etc. which have their own advantages and disadvantages and with fewer long term studies on most of these fixation methods available in the current scenario. Also, along with them came the novel meshes such as the self fixing/adhesive meshes which do not need any form of the fixation methods/ devices and have micro hooks within the mesh serving the purpose of fixation. [2, 3]

The rationale of the study on comparing inguinal hernioplasty using bio-compatible mesh (Polyester Monofilament and Polylactic Acid) which is self adhesive/ self fixing Vs. Polypropylene mesh which uses sutures stems from the need to address ongoing concerns regarding the optimal choice of mesh material in hernia repair. In the past decade, there has been growing interest in bio-compatible mesh materials that offer potential advantages over traditional synthetic meshes such as polypropylene. While polypropylene (prolene) mesh has been used very frequently and demonstrated efficacy in hernia repair, it is associated with certain drawbacks, including a foreign body response, chronic inflammation, and a risk of mesh-related complications such as infection, adhesion formation, and chronic pain.[7]

The emergence of the novel biocompatible mesh composed of Polyester Monofilament and Polylactic Acid (PLA) presents a promising alternative, as it is designed to be self adhesive, more biocompatible, promote tissue integration, and potentially reduce the risk of long-term complications. Polyester Monofilament provides strength and durability, while PLA is a bio-absorbable material that gradually degrades over time, allowing for tissue regeneration and remodelling. However, despite the theoretical advantages of bio-compatible mesh, there is limited clinical evidence comparing its outcomes and complications[7, 8].

Therefore, the rationale for conducting a detailed randomized control study lies in the need to systematically evaluate and compare the operative time, clinical outcomes, including complication rates, and patient-reported VAS results associated with the use of this new mesh Vs. the old polypropylene (Prolene) mesh.

Furthermore, given the prevalence and impact of inguinal hernias on patient morbidity and healthcare costs, identifying the most effective and safest mesh type and fixation method is of paramount importance. The findings from this study have the might aid in contributing to advancements in hernia surgery practices, improve patient outcomes, and reduce the overall healthcare burden associated with inguinal hernia repair.

OBJECTIVES

Primary Objective:

To evaluate post-operative pain in inguinal hernia repair patients with polypropylene (Prolene) mesh (suture fixation) Vs. self-fixing bio-component monofilament Polyester + Polylactic acid mesh.

Secondary Objective:

To evaluate operative time and post-surgical complications (seroma, hematoma, infections) in inguinal hernia repair patients with polypropylene (Prolene) mesh (suture fixation) Vs. self-fixing bio-component monofilament Polyester + Polylactic acid mesh.

REVIEW OF LITERATURE

General surgeons execute about 8 lakhs inguinal hernia repairs each year, making it one of the most often done surgeries[5]. An inguinal hernia is a condition characterized by the protrusion of abdominal contents via a weak spot in the inguinal canal, which is located in the groin area.[6, 7]

RELEVANT SURGICAL ANATOMY OF INGUINAL REGION:

Extent of the Anterior Abdominal Wall: [8-11]

- **Superiorly:** The Xiphoid process as well as the costal margins.
- **Inferiorly:** Extends to the pubis, pubic symphysis, and bilateral iliac crests.
- **Groin Region:** Situated below the anterior superior iliac spine level.

Inguinal Canal: [12-16]

- **Function:** Serves as a conduit between the abdominal cavity and the labia majora in females or the scrotum in males.
- Oblique- Situated directly above the inguinal ligament - medial side.
- **Length:** Approximately 4-5 cm.
- Extends from the superficial to the deep inguinal ring.

External/Superficial Inguinal Ring:

- **Location:** The external oblique aponeurosis contains a triangular opening that is located lateral to and above the pubic crest.

- **Structure:**

a. Apex: directed along the aponeurosis's deep fibres.

b. Base: In the pubic crest region.

c. Sides: Formed by 2 crura.

- **Lateral Crus:** Reinforced by inguinal ligament fibres, forming a groove for the spermatic cord in males.

- **Medial Crus:** Thinner; connected to the pubic symphysis; fibres from the other side are interconnected with it.

d. Intercrural Fibres: They arch over the "apex.

Deep Inguinal Ring:

- **Location:** An opening in the transversalis fascia that is shaped like an oval and is located 1.25 centimetres above the inguinal ligament. This aperture is situated between the anterior superior iliac spine and the symphysis pubis.

- **Boundaries:**

- **Above + Laterally:** The transversalis fascia's arched inferior margin.

- **Below + Medially:** Inferior epigastric vessels.

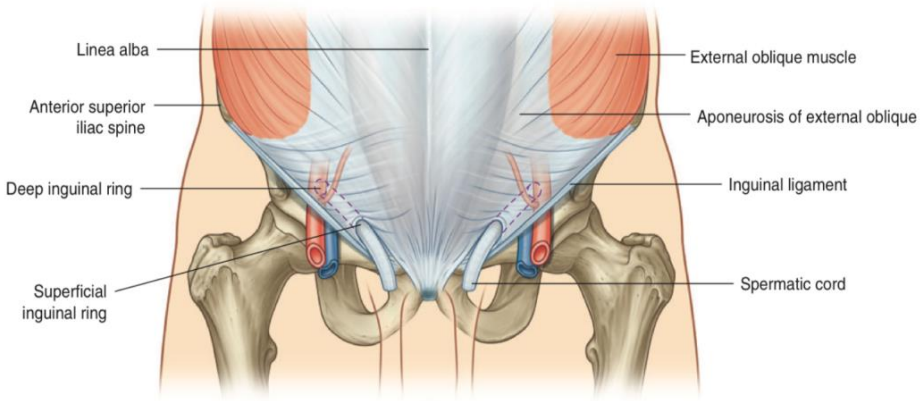


FIGURE 1. SHOWS THE ANATOMY OF INGUINAL REGION FROM THE ANTERIOR REGION [11]

Boundaries of the Inguinal Canal: [12-16]

- **Anterior Wall:**

➢ Skin. Superficial fascia. Aponeurosis of external oblique.

➢ Lateral 1/3rd: Internal oblique fibres.

- **Posterior Wall:**

➢ **Medial:** Conjoint tendon (internal oblique as well as transverses abdominis muscles.)

➢ **Lateral:** The transversalis fascia, the reflected portion of inguinal ligament.

It strengthens the interfoveolar ligament, which is made up of tendinous fibres from the transverses abdominis muscle.

- **Roof:**

➢ Arched fibres - internal oblique + transverse abdominis muscle.

➢ Internal oblique fibres continue as an aponeurosis attached to the pubic crest and pectineal line.

- **Floor:**

➢ The Transversalis fascia + the inguinal ligament.

➢ A significant triangle band that is continuous with the pectineal fascia and is situated posterior to the medial end of the inguinal ligament, on the medial side, is referred to as the lacunar ligament.

- Apex attached to the pubic tubercle.

Contents of the Inguinal Canal:

➢ **In Males:** The spermatic cord consists of the testicular artery, lymphatic vessels, autonomic nerves, and the pampiniform plexus of veins.

➢ **In Females:** The genitofemoral nerve's genital branch and the uterine round ligament.

➢ **In Both genders:** Ilioinguinal nerve, which transverses through the canal but not through the deep inguinal ring.

Hesselbach's Triangle (Inguinal Triangle) [12-16]:

- **Boundaries:**

➢ **Medial:** The rectus abdominis muscle's lateral edge.

➢ **Lateral:** Inferior epigastric vessels.

➢ **Inferior:** Inguinal ligament.

➢ **Clinical Relevance:** The most common location for direct inguinal hernias, in which different abdominal contents emerge through a transversalis fascia weakening.

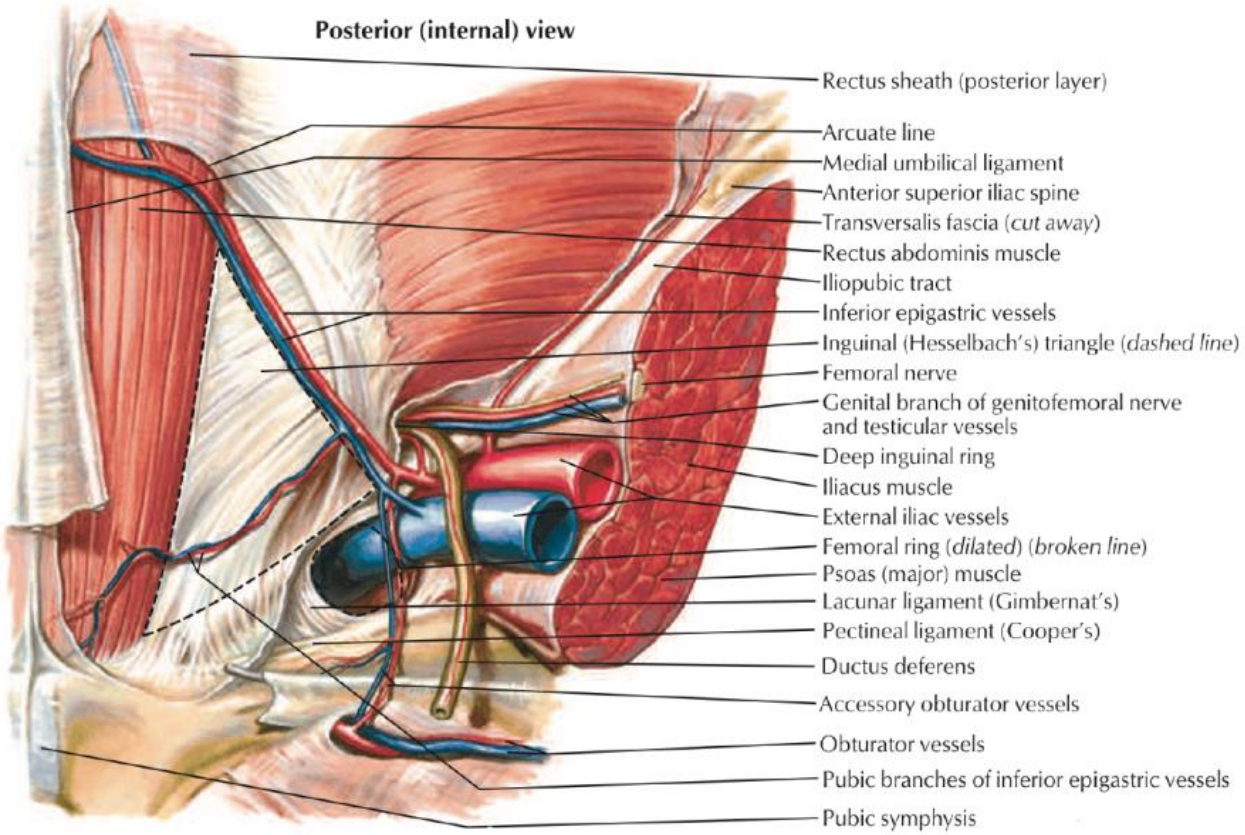


FIGURE 2. ANATOMY FROM THE INTERNAL/POSTERIOR VIEW OF THE GROIN REGION WITH HESSELBACHS TRIANGLE [11]

Myopectineal Orifice of Fruchaud: [12-16]

- **Boundaries:**

➢ **Superior:** TransVs. abdominis muscle. Internal oblique muscle.

➢ **Inferior:** Pectineal ligament/Cooper's ligament.

➢ **Medial:** The rectus abdominis muscle's lateral edge.

➢ **Lateral:** Iliopsoas muscle.

Clinical Significance: Location of inguinal hernias, both direct and indirect, and femoral hernias; consequently, a crucial location to identify during laparoscopic surgery.

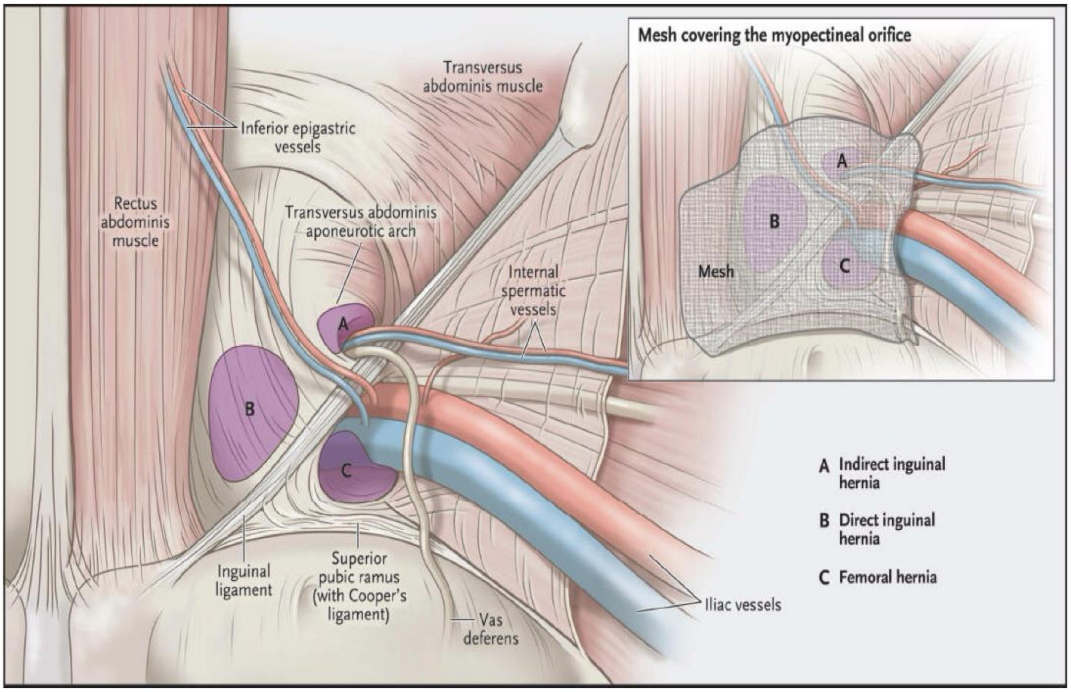


FIGURE 3. MYOPECTINEAL ORIFICE. SHOWING THE MESH PREVENTS THE FORMATION OF ALL 3 TYPES OF HERNIA: INDIRECT, DIRECT, AND FEMORAL[17]

Nerves in the region: [11]

In this region, several important nerves transverse or innervate structures, contributing to both motor and sensory functions. These nerves include:

Ilioinguinal Nerve:

- Origin: L1
- Supply:
  - **Sensory:** Medial thigh, root of penis/mons pubis, upper scrotum/labia majora
  - **Motor:** Anterior abdominal wall muscles

Iliohypogastric Nerve:

- Origin: L1

- Courses along with ilioinguinal nerve
- Supply:
  - **Sensory:** Lateral gluteal region, lateral pubic area, upper inguinal region
  - **Motor:** Abdominal wall muscles

Genito femoral Nerve:

- Origin: L1-L2
- Branches:
  - **Genital branch:** Supplies anterior scrotum/ mons pubis
  - **Femoral branch:** Supplies anterior thigh

Lateral Femoral Cutaneous Nerve:

- Origin: L2-L3
- Courses through inguinal ligament
- **Sensory supply:** Lateral thigh
- Compression may cause meralgia paresthetica

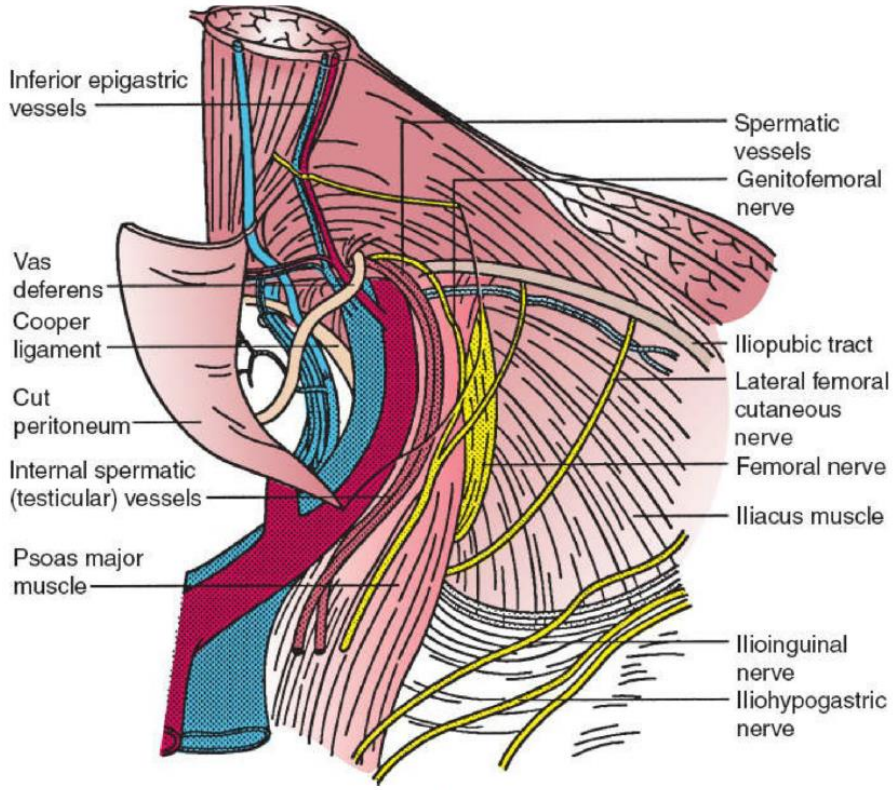


FIGURE 4. IMPORTANT NERVES AND VESSELS IN THE REGION FROM AN INTERNAL/POSTERIOR VIEW[17]

PATHOPHYSIOLOGY OF HERNIA: [8]

- Studies indicate a correlation between inguinal hernias and collagen types[5]. Past research studies have concluded that individuals with inguinal hernias had elevated quantities of **type III collagen** in comparison to type I collagen.[5]

- **A prolonged processus vaginalis** is another possible component that might influence the development of inguinal hernia [6, 7]. In the event of closure failure of the processus vaginalis, children may develop an indirect inguinal hernia and also elevated probability of the same during adulthood too[9]. It should be emphasized that the presence of a patent processus vaginalis does not ensure the occurrence of a hernia [9].

AETIOLOGY AND PREDISPOSING FACTORS FOR THE FORMATION OF HERNIA: [8]

Although the majority of adult hernias are classified as acquired, genetics also contribute to their development.

Predisposing factors:

- Familial predisposition[5].
- Chronic obstructive pulmonary disease (COPD),
- Ehlers-Danlos syndrome
- Marfan syndrome [6, 7].
- Increased intra-abdominal pressure (obesity, persistent coughing, excessive physical exertion, smoking, and, exertion caused by constipation or prostatomegaly) [8,9].

EPIDEMIOLOGY OF THE OCCURRENCE OF INGUINAL HERNIA: [8]

- Demographically, inguinal hernias exhibit a male predominance. Epidemiological studies have consistently reported a male-to-female ratio of incidence ranging from 8:1 to 10:1 for inguinal hernias. This gender disparity is attributed to anatomical differences in the inguinal canal and associated risk factors.

- Inguinal hernias are the most prevalent type of hernia in both males and females, whereas femoral hernias are more common among the latter.

- The risk rises with advancing age, reaching its highest point around 5 years old and beyond 70-75years.

- Geographically, the prevalence of inguinal hernia demonstrates variability across regions and populations. While inguinal hernias are prevalent globally, their incidence tends to be higher in certain geographic regions, including parts of Africa, Asia, and Latin America[18,19].

➢ CLASSIFICATION OF INGUINAL HERNIAS:[20]

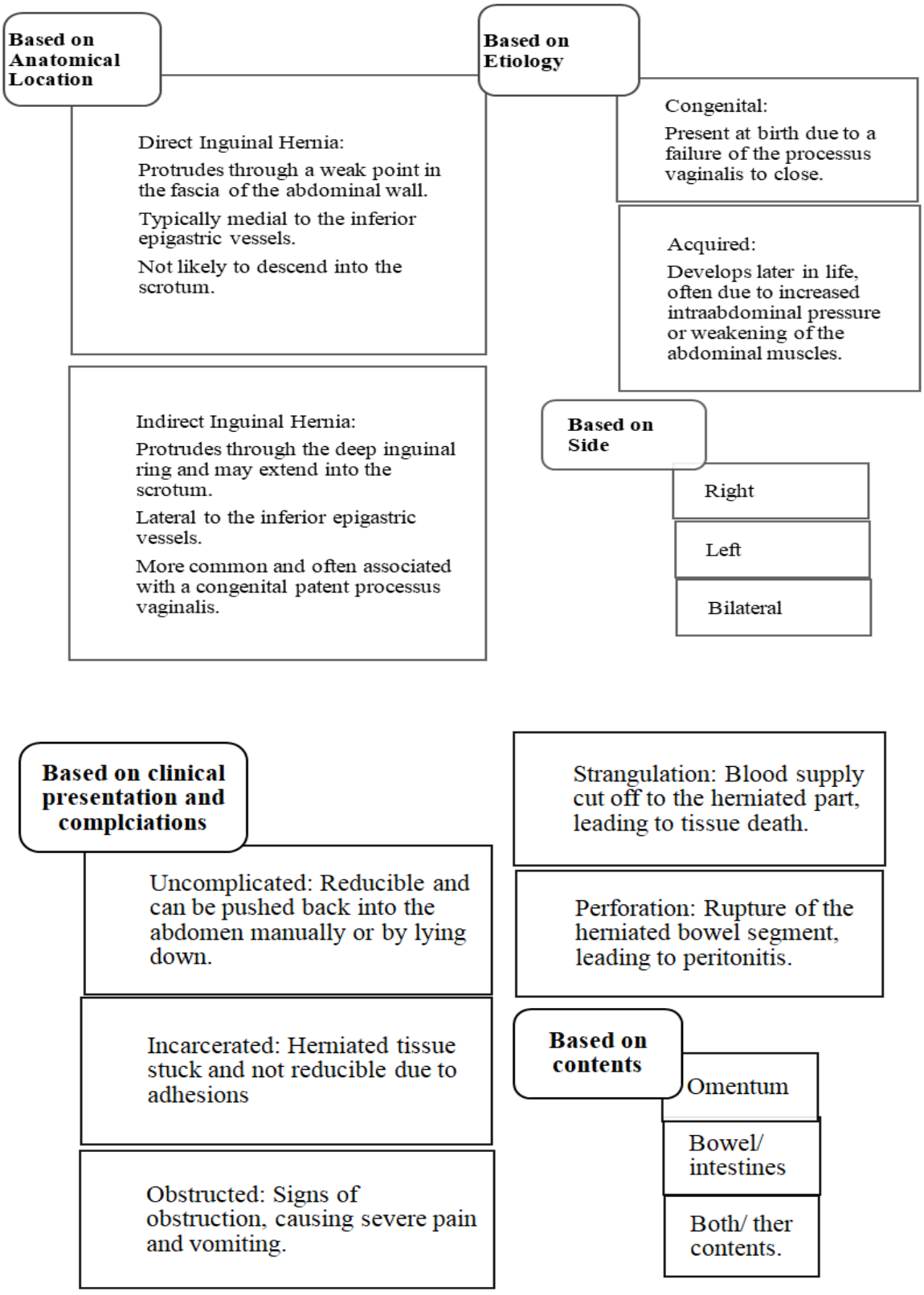


FIGURE 5. FLOWCHART: DEPICTING CLASSIFICATION BASED ON VARIOUS CLINICAL EXAMINATION FINDINGS AND COMPLICATIONS

Groin hernia is classified based on various classification systems over the years in history:

- Lichtenstein classification, Schumpelick-Arit Wantz, Halverson-McVay, Zollinger classifications, Ruthkow and Robbins classification, Kingsnorth classification, Gilbert classification, Nyhus classification and EHS classification[21-24].

Following are the 2 major classification systems currently in practice and accepted worldwide:

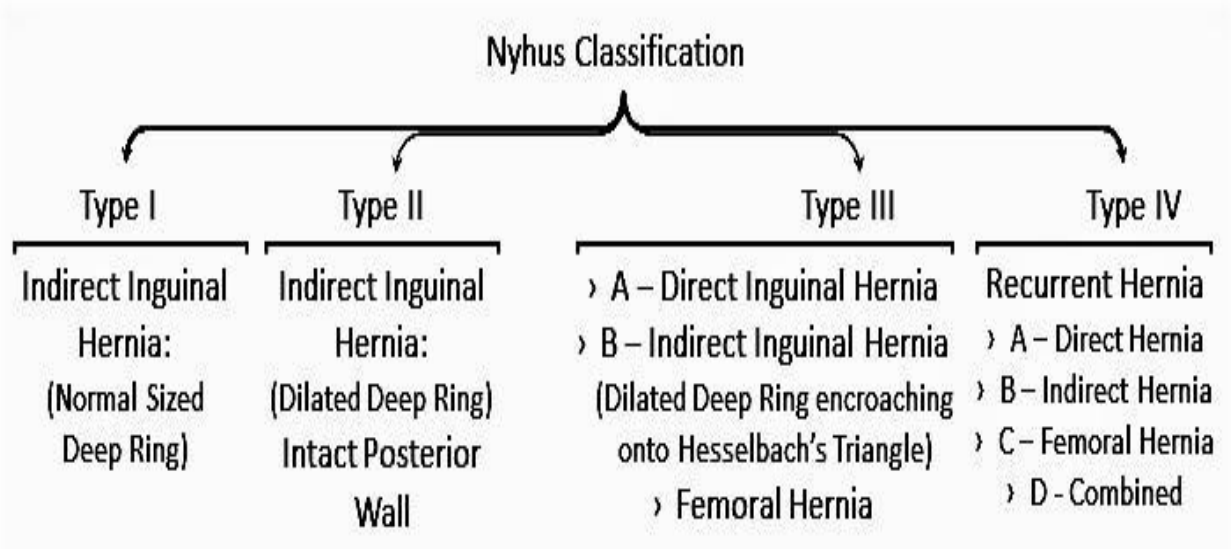


FIGURE 6. TYPES OF HERNIA BY NYHUS CLASSIFICATION[25]

P = primary hernia
R = recurrent hernia

0 = no hernia detectable
1 = < 1,5 cm (one finger)
2 = < 3 cm (two fingers)
3 = > 3 cm (more than two fingers)
x = not investigated

L = lateral/ indirect hernia
M = medial/ direct hernia
F = Femoral hernia

		P	R		
	0	1	2	3	x
L					
M					
F					

FIGURE7. EUROPEAN HERNIA SYSTEM (EHS) INGUINO-FEMORAL CLASSIFICATION [26]

Indications for hernia repair:

Surgical intervention is often necessary for hernias that result in persistent pain, discomfort, or the potential for exacerbation of symptoms.

- Symptomatic hernias.
- Complicated hernias (obstructed hernias, incarcerated hernias, and strangulation).
- Patient preference.
- Recurrent hernias.

Although not all hernias need urgent surgical intervention, the majority will ultimately necessitate treatment due to their tendency to increase in size over time.

EVOLUTION OF HERNIA REPAIR AND HISTORICAL PERSPECTIVE: [8]

Hernia repair has undergone a process of evolution, shifting from conventional open procedures to minimally invasive treatments using the use of mesh [27].

Traditional Techniques:

Historically, hernia repair relied on conventional methods such as primary tissue approximation or herniorrhaphy. These techniques, dating back centuries, involved the closure of hernia defects using sutures without the use of prosthetic mesh reinforcement (Kingsnorth, 2007). While effective in some cases, traditional hernia repairs were linked to high instances of recurrence and complications as a consequence the reliance on tension-bearing sutures and the inability to address underlying weaknesses in the abdominal wall.[28]

The Bassini Repair, developed in the late 19th century, is a surgical method that involves closing the inguinal canal using sutures thereby reinforcing the back/posterior wall with conjoined tendon[29]. It has greater chances of recurrences and hence not practiced routinely in modern world.

The Shouldice Repair developed in the mid-20th century, involves using sutures to strengthen different components, leading to a low risk of recurrence [30, 31]. It is often regarded as a standard for repairing inguinal hernias.

Birth of Tension-Free Repair: [8]

The paradigm shift in hernia surgery occurred by introduction of tension-free repair techniques, championed by Dr. Irving Lichtenstein in the 1950s (Lichtenstein, 1989). Lichtenstein advocated for the use of prosthetic mesh to reinforce the weakened abdominal wall without subjecting tissues to tension. His landmark study demonstrated superior

outcomes with tension-free mesh repair compared to traditional methods, leading to widespread adoption of this approach (Lichtenstein et al., 1990). The principle of tension-free hernioplasty laid the foundation for subsequent innovations in hernia surgery[32, 33, 34]. The Lichtenstein procedure provides a dependable and economical approach for repairing inguinal hernias. The simplicity of learning, minimal complication rates, and ability to send patients on the same day contribute to its popularity among both experienced and trainee surgeons. In conclusion, The Lichtenstein surgery continues to be a widely used and efficient option for repairing inguinal hernias.

Alternative Mesh Repairs:

The Prolene Hernia System mesh features a unique, bi-layered polypropylene design with an underlay patch for posterior wall support and an on-lay patch for anterior wall reinforcement. It has been shown to result in shorter hospital stays and less post-operative discomfort. Consequently, it is a feasible substitute for the Lichtenstein technique [35, 36].

The Plug and Patch procedure, which was made famous by Ruthkow and Robbins, employs a cone-shaped plug and mesh patch to achieve a comparable level of efficiency as the Lichtenstein repair[37].

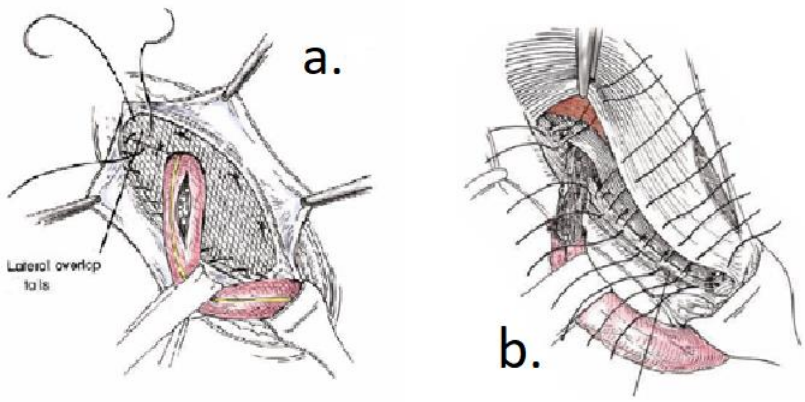


FIGURE8. SHOWING: A. LICHTENSTEIN REPAIR, B. BASSINI REPAIR PROCESS[35]

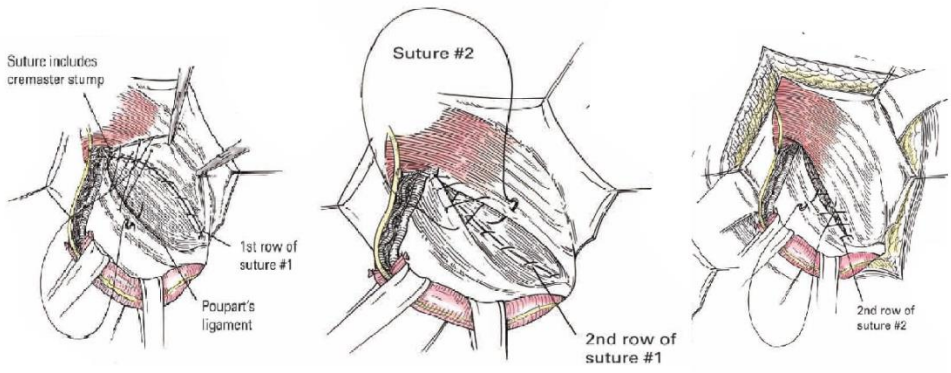


FIGURE 9. SHOWING THE SHOULDICE REPAIR PROCESS[35]

Minimally invasive procedures: [8]

In the 1990s, laparoscopic techniques emerged as a minimally invasive alternative to open hernia repair, offering many perks such as lesser postoperative pain, lesser hospital stays, and speedy recovery. Early studies demonstrated comparable outcomes between laparoscopic and open approaches, prompting increased utilization of laparoscopy in hernia surgery.[36,37]

The Transabdominal Preperitoneal (TAPP) Repair is a laparoscopic method that provides a quicker recovery time and less discomfort [38]. The procedure entails gaining entry to the abdominal cavity, establishing a preperitoneal space, and introducing mesh for strengthening [39]. This approach offers repairs on both sides simultaneously, if necessary. The total extra peritoneal repair (TEP) is a surgical procedure that is similar to TAPP. However, TEP differs in that it does not include entering the peritoneum and abdominal cavity [40]. Alternatively, dissection takes place in the extra peritoneal area, resulting in a clear division between the mesh and the organs in the abdomen [41]. This technique is very well-suited for hernias that have recurred [42].

Robotic-assisted surgery has revolutionized hernia repair by providing enhanced accuracy and three-dimensional imaging [43]. Robotic systems offer exceptional performance, delivering precise motions despite the possibility of extended surgical durations. While evidence supporting the superiority of robotic-assisted hernia repair remains limited, ongoing research aims to elucidate its comparative effectiveness and long-term outcomes. [43].

Single Incision Laparoscopic Surgery (SILS) is a novel technique that reduces scarring and discomfort by using just one incision [44].

The field of hernia repair has significantly advanced, moving from classic open procedures such as Bassini, Shouldice, and other more current techniques that use various types of mesh and less invasive methods like TAPP and TEP [45, 46]. The ongoing advancement is motivated by the aspiration to enhance patient outcomes and reduce problems [46].

Outpatient hernia repair/ Day care hernia repair: Recent advancements in minimally invasive methods and recovery regimens have made it possible to do hernia repairs on an outpatient basis. This can save expenses, speed up the healing process, return to the everyday activities more quickly [47, 48].

The future of hernia repair is positive, as breakthroughs in mesh technology (such as biological meshes and 3D printing) and surgical procedures continue to improve, offering enhanced patient experiences [49,50,51].

Mesh in Hernioplasty: [9]

Meshes used in hernioplasty are prosthetic materials, either synthetic or biologic implants designed to reinforce the weakened abdominal wall and prevent hernia recurrence.

Ideal mesh qualities: [8, 9]

An ideal hernia repair mesh achieves a harmonious equilibrium among several crucial attributes:

- Chemically inert and biocompatible.
- Non-carcinogenic
- Avoid mechanical and physical strains
- Can be sterilized easily
- Flexibility
- Minimal Shrinkage
- Low Risk of Infection
- Ease of Handling and placement
- Cost-effectiveness
- Should not cause hypersensitivity, and should not induce foreign body reaction or react with tissue fluids.

Role of Mesh Materials[52, 53, 54]:

- Reinforce the weakened abdominal wall.
- Distribute intra-abdominal pressure to prevent hernia recurrence.
- Provide structural support during healing.
- Minimize postoperative complications (recurrences/failure of repair).
- Act as a barrier between visceral contents and surrounding tissues to prevent adhesion formation and visceral injury.
- Promote tissue adherence and integration post-surgery.

Types of meshes: [8, 9]

A. Synthetic mesh materials commonly used in hernia repair include polypropylene, polyester, poly tetra fluoro ethylene (PTFE), and polyethylene terephthalate (PET). These can be non absorbable or partially absorbable.[52,53,54]

B. Biologic mesh materials derived from human or animal tissues, such as porcine dermis or human acellular dermal matrix, offer an alternative option for patients with complex hernias or a history of mesh-related complications.[52,53,54]

A. Synthetic mesh: [8, 9]

[1] Polyester (Dacron) Mesh: Made from polyethylene terephthalate (polyester).

Advantages:

- High tensile strength.
- Good flexibility.
- Relatively low cost.

Disadvantages:

- Higher risk of infection.
- Potential for foreign body reaction.
- Less biocompatible.

[2] Expanded Polytetrafluoroethylene (ePTFE) Mesh[8, 9]: Porous form of PTFE used in hernia repairs.

Advantages:

- Highly biocompatible.
- Low risk of adhesion formation.
- Minimal tissue reaction.

Disadvantages:

- Less flexibility.

- More expensive.
- Challenging tissue integration.

[3] Dual Mesh

Combines ePTFE with another material (e.g., polypropylene).

Advantages:

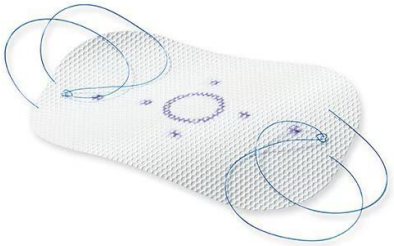
- Combines strengths of both materials.
- Reduced adhesion on one side.
- Good mechanical strength.

Disadvantages:

- More complex and expensive.
- Varying integration rates.

[4] Parietex Composite Mesh[8,9]

Composition: polyester + collagen barrier coating.



Advantages:

- Enhanced tissue integration.
- Reduced adhesion formation.
- Can be put intraperitoneal.

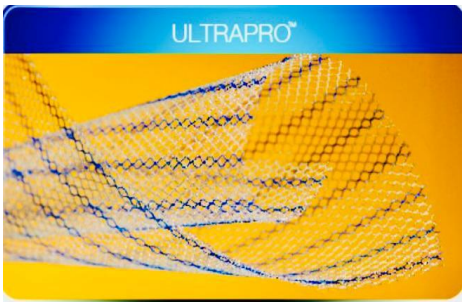
- Good mechanical strength.

Disadvantages:

- Higher cost.
- Coating can degrade over time.
- Difficult handling.

[5] Ultrapro Mesh[8,9]

Made from polypropylene and poliglecaprone (Monocryl).



Advantages:

- Lightweight.
- Promotes good tissue in-growth.
- Partially absorbable, reducing long-term foreign body load.

Disadvantages:

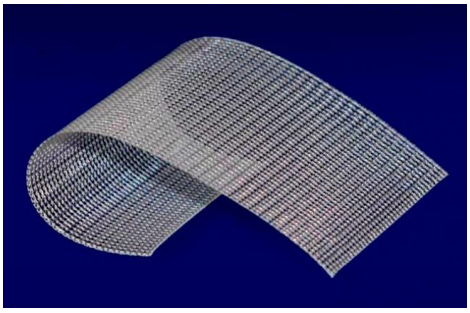
- Less durable over time.
- Potential for early mechanical failure

[6] Traditional Polypropylene Mesh in Inguinal Hernioplasty:[55,56,57]

Polypropylene (prolene) mesh has been the standard material utilized for open hernia repair surgeries for decades and remains widely utilized due to its favourable mechanical properties and established track record in clinical practice. [8, 55]

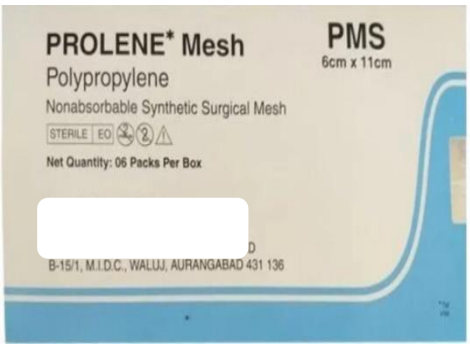
Composition: Polypropylene is a synthetic polymer typically composed of knitted or woven polypropylene fibres [53, 54]

Properties:



- High tensile strength and durability.
- Maintains its structural integrity over time.
- Porosity: Allows for tissue in growth.
- Biocompatibility: Polypropylene is biocompatible, but not biodegradable.
- Flexibility and Conformability: Polypropylene mesh is flexible and conformable,.(53,54)

Disadvantages: [55, 56, 57]



- Potential for chronic pain
- Foreign body reaction.
- Mesh erosion and complications.
- Infection: Even though very rare, Polypropylene mesh is susceptible to colonization by bacteria.

Modifications of the polypropylene (prolene) mesh:

6-a. Lightweight Mesh: [58]

Advantages:

1. Reduced chronic pain and discomfort
2. Lower complication rates

3. Improved quality of life

Disadvantages:

1. Potential for higher recurrence rates

2. Higher cost

6-b. Macro porous mesh: Macro porous meshes are characterized by larger pore sizes, typically greater than 1-1.5 mm, which allows for better tissue integration and vascularisation.

Advantages:

- ❖ Enhanced tissue integration
- ❖ Reduced risk of infection
- ❖ Improved patient comfort
- ❖ Decreased risk of seroma formation

Disadvantages:

- ❖ Potential for mesh shrinkage
- ❖ Cost considerations
- ❖ Technical challenges

B. Biologic Meshes

It is made from processed human or animal tissue, leaving a collagen matrix.

Examples: Strattice (porcine), AlloDerm (human), SurgiMend (bovine)

Advantages:

- Excellent biocompatibility
- Reduces chronic inflammation risk
- Integrates well with host tissue
- Remodels into functional tissue

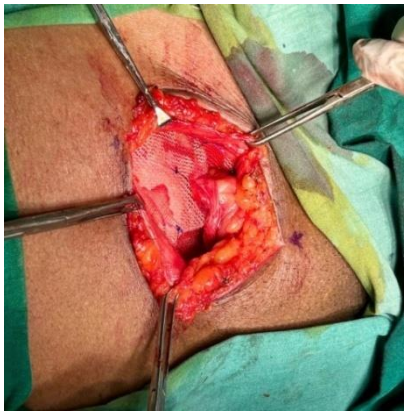
Disadvantages:

- Higher cost
- Variable strength and durability
- Potential for minimal risk of disease transmission
- Potential for quicker degradation

➢ **METHODS OF FIXATION OF MESHES**

a) Suture fixation: Mesh is sutured/stitched to the surrounding tissue.[59,60]

Advantages:



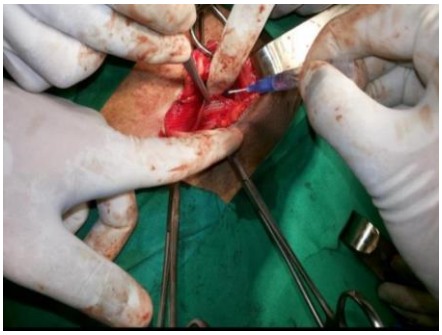
- Strong and secure fixation
- Well established technique

Disadvantages:

- Longer operative time
- Risk of chronic pain due to nerve damage

b) Glue fixation[60, 61]: Glue fixation in inguinal hernioplasty involves using adhesive substances instead of sutures to secure the mesh in place.

Advantages:

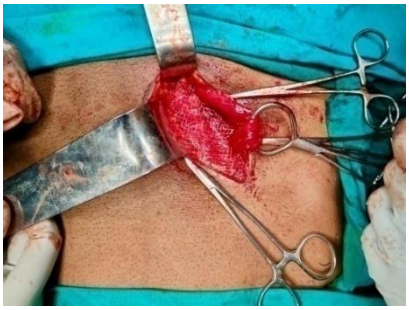


- Less Chronic Pain
- Comparable Efficacy in short term studies.
- Improved Recovery
- Minimized Tissue Trauma

Disadvantages: Weaker fixation, moisture interference, limited adhesion in certain tissues, allergic reactions (hypersensitivity), higher expense, limited long-term data, may not be suitable for all cases.

c) Stapler fixation: Stapler fixation involves the use of surgical staplers to attach the mesh to the surrounding tissues[59, 60].

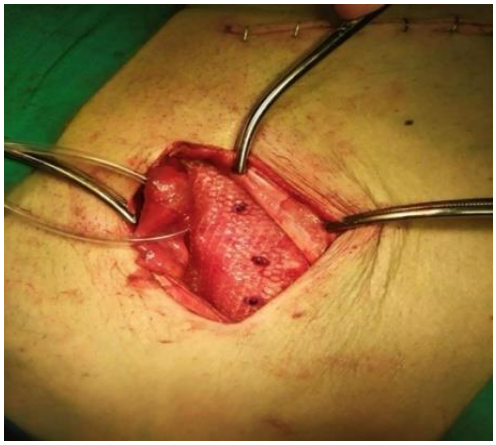
Advantages:



- ❖ **Speed:** Quicker fixation compared to sutures
- ❖ **Consistency:** Uniform and secure attachment of the mesh.
- ❖ Reduced Tissue Handling

Disadvantages: Postoperative pain, nerve injury, high cost, interference with imaging, difficult removal and limited flexibility, migration of mesh and higher risks of infection, limited long term data[61,62,63].

d) Tacks: Metal or absorbable tacks are used to attach the mesh.[59,60]



Advantages:

- Faster than sutures
- Provides strong fixation

Disadvantages:

- Potential for chronic pain
- Possible migration or dislodgement

e) Fibrin sealant: [8, 9]A biological adhesive made from fibrinogen and thrombin used to fix the mesh.

Advantages:

- Reduces operative time
- Lower risk of chronic pain
- Promotes natural tissue healing

Disadvantages: May not provide as strong fixation as sutures or tacks and higher cost compared to traditional methods.

f) Self Fixing Mesh in Inguinal Hernia[64-71]:

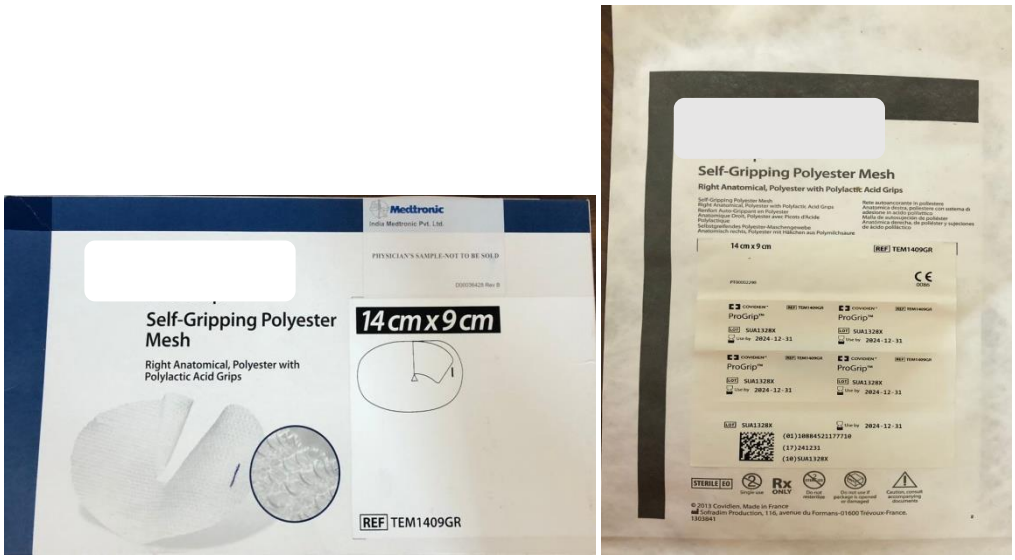


FIGURE 10. BIO COMPONENT SELF RETAINING MESH (POLYESTER MONOFILAMENT AND POLYLACTIC ACID) [72]

Composition:

- **Polyester Monofilament:** Used in medical devices for its biocompatibility and mechanical properties. Its single-strand structure provides strength, flexibility, reduces infection risk, and enhances tissue integration.
- **Polylactic Acid (PLA):** A biodegradable polymer absorbed by the body, reducing long-term complications. PLA promotes tissue in growth, fibrosis, and remodelling[72,73].

Properties:

- Self-Fixing: With the help of micro hooks.
- Biocompatibility
- Flexibility and Good Tensile Strength
- Tissue Integration

- Biodegradability: PLA is biodegradable.[73]

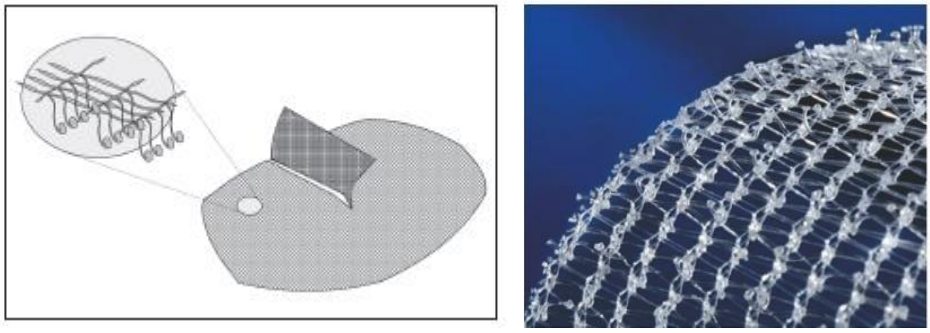


FIGURE 11. SCHEMATIC REPRESENTATION OF MICRO HOOKS IN THE MESH[73]

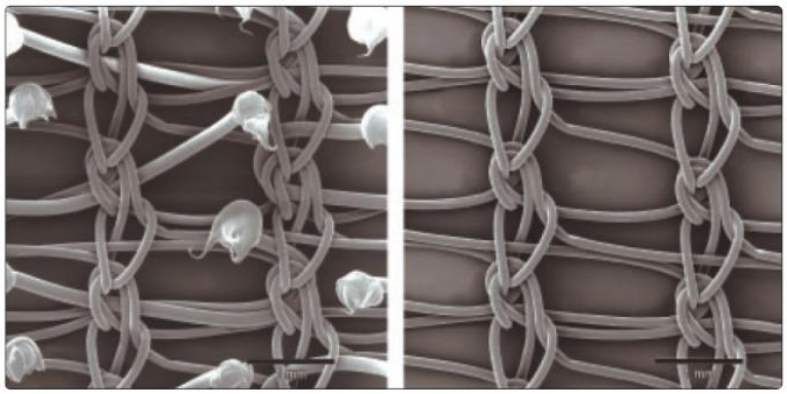


FIGURE 12. SCHEMATIC REPRESENTATION OF MESH BEFORE AND AFTER THE PROCEDURE OF PLA DEGRADATION[74]

Advantages: [75-78]

- Reduced Risk of Long-Term Complications (Chronic pain, mesh erosion, and mesh infection).
- Enhanced Tissue Integration: Due to biodegradability of PLA.
- Improved Biocompatibility
- Versatility
- Reduced Postoperative Pain

Further research and clinical studies are warranted to validate its (self fixing mesh) efficacy and long-term outcomes in inguinal hernioplasty.

- In a study by Cucuk and Barbaros et al., on 40 patients, self-gripping mesh demonstrated advantages over staple fixation mesh in laparoscopic inguinal hernia repairs. The researchers found that using self-gripping mesh resulted in significantly shorter operative times and lower pain scores in the immediate postoperative period and lesser recurrences in long term follow up. This study was conducted on small sample size.[79]

- Kirov et al. in a study, explored the potential of self-adhesive mesh in 52 patients to address chronic postoperative inguinal pain. Their preliminary data suggest that the utilization of self-adhesive mesh can significantly decrease early postoperative pain and potentially eliminate chronic pain by avoiding the need for mesh fixation. The study design was prospective, without a control group and with small sample size.[80]

- A study by Fan, J. et al. aimed to assess the long-term benefits and impacts in open inguinal hernioplasty of using a self-gripping semi re-absorbable mesh (PROGRIP) Vs. traditional polypropylene (prolene) mesh. Through a randomized trial involving 45 patients, the research sought to evaluate various parameters, over a follow-up period of up to 6 years. The study found significant reductions in the time for mesh placement and total operative time in the PROGRIP group, with comparable long-term surgical outcomes, chronic pain levels, and recurrence rates to those observed in the traditional polypropylene mesh group. Though the study was conducted for a long term, the sample size is small, which may not give accurate results.[81]

- A study by Del Papa et al. conducted a study on 204 open inguinal hernia repairs and evaluated the effectiveness and safety of using self-gripping Parietex Progrip mesh. The

study highlighted minimal postoperative chronic pain and a low recurrence rate over a 2-year follow-up period. It was a retrospective study without any control group.[82]

- A study by Guerron et al. evaluated the technical feasibility and short-term outcomes of single-site laparoscopic TEP herniorrhaphy using self-fixating mesh. The results from 34 patients indicated that this approach is safe and effective for managing inguinal hernias in the short term, with minimal postoperative complications. The study suggests that single-site TEP with self-fixating mesh is a viable surgical option for inguinal hernia repair. The study had a small sample size and no control group.[83]

As the above mentioned studies have various limitations as described, and there is limited literature available on this topic, hence this study was conducted in an effort to fill in those gaps from previous studies and hence deduce a structured, statistically relevant result.

Complications of hernia repair[84, 85, 86]:

Similar to any surgical intervention, hernia repair includes problems/complications. Below are a few possible issues that may arise with hernia repair:

- Discomfort in the groin area
- Pain
- Hematoma
- Adhesions
- Seroma
- Infection
- Mesh migration and erosion
- Urinary Retention
- Hernia Recurrence
- Fistula formation
- Sexual Dysfunction

➢ **CHRONIC PAIN AFTER INGUINAL HERNIA REPAIR:**

Definition: Persistent groin pain lasting over three months post-hernia repair.

Postoperative pain is a frequent occurrence. Following inguinal hernia repairs, 10% to 15% of individuals may continue to suffer mild pain or discomfort even one year after undergoing the procedure. Affects daily activities and wellbeing and becomes a clinical challenge.

❖ **Causes:**

- Nerve Injury
- Nerve Entrapment/ Neuroma
- Mesh Related Issues
- **Inflammatory Reactions:** Chronic inflammation, foreign body reaction.
- **Psychological Factors:** Anxiety, depression, catastrophizing can worsen pain.

❖ **Management:** Chronic inguinodynia needs a holistic multidisciplinary approach.

- **Conservative Measures:**
- **Therapies:** Physical therapy, neuropathic medications, nerve blocks.
- **Support:** Psychological counseling.

- **Surgical Interventions:** Has variable outcomes.
- **Procedures:** Neurectomy.

Visual Analogue Scale (VAS)

The Visual Analogue Scale is a subjective measure which is used to quantify patients' pain intensity or other subjective experiences. VAS allows patients to point out their discomfort or pain on a scale as shown in Figure 13[87, 88].

Patients are asked to rate their pain on a horizontal line, typically 10 centimetres in length, with endpoints labelled as "no pain" (0) and "worst imaginable pain" (10). The following scoring method is commonly used:

- **0:** Represents no pain or discomfort experienced by the patient.
- **1-3:** Indicates mild pain or discomfort, which is tolerable
- **4-6:** Signifies moderate pain or discomfort
- **7-9:** Reflects severe pain or discomfort
- **10:** Represents the worst imaginable pain or discomfort

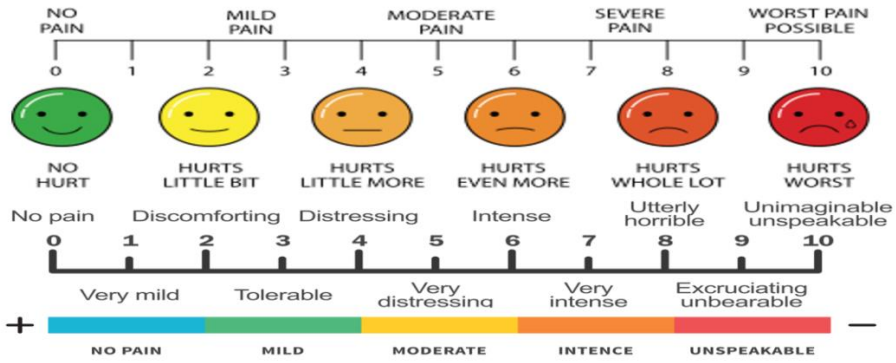


FIGURE 13. VAS SCORING SYSTEM

Surgical Site Infection in postoperative Open Inguinal Hernia Repair:

Incidence: Surgical site infections occur in 1% to 5% of open inguinal hernia repairs.

Risk Factors:

- **Patient-related:** Advanced age, diabetes, obesity, immune suppression, and smoking.
- **Surgery-related:** Extended operative time, suboptimal surgical techniques, and absence of prophylactic antibiotics.

Postoperative care: Poor wound management and substandard hospital conditions.

Prevention Strategies:

- **Preoperative:** Timely administration of antibiotics, patient health optimization, and management of co morbidities.
- **Intraoperative:** Strict aseptic techniques, appropriate mesh utilization, reduced surgery duration.
- **Postoperative:** Proper wound care, vigilant monitoring, and patient education on infection indicators.

Management:

- **Superficial Surgical site infections:** Regular wound cleansing, dressing changes, and antibiotics.
- **Deep Surgical site infections:** Surgical drainage or removal of infected mesh, combined with targeted antibiotic therapy.

Surgical site infections Severity Assessment:

The Southampton Grading System offers a structured approach to categorizing the severity of surgical site infections (SSI) following surgery. This system assigns grades ranging from Grade 0 to Grade 5 based on clinical parameters indicative of infection severity[89]. The following scoring method is typically used:

Grade	Definition
0	Normal healing
I	Normal healing with mild bruising or haematoma
II	Erythema plus other signs of inflammation
III	Clear or haemoserous discharge
IV	Pus
V	Deep or severe wound infection with or without tissue breakdown; haematoma requiring aspiration

FIGURE 14. SOUTHAMPTON SCORING SYSTEM[89]

Recurrence of hernia: Hernia recurrence, also known as the reappearance of a hernia at or near the location of a prior repair, can occur due to various factors, including wound infection, insufficient healing, or poor repair during the first surgery. The rates of recurrence might range from 1% to 10% [90].

METHODOLOGY

Study Design: This study adopted a **randomized controlled study** design to compare the outcomes of inguinal hernioplasty using two different types of mesh materials: conventional polypropylene mesh with suture fixation and self fixing bio component polyester + polylactic acid mesh. Randomization allocated patients into 2 groups: GROUP-A (control group) and GROUP-B (test group) ensuring unbiased assignment.

Source of Data Collection: The study was conducted at: **KAHER'S Dr.Prabhakar Kore Charitable Hospital and Medical Research Centre, located in Nehru Nagar, Belagavi, and KLES Dr.Prabhakar Kore Hospital and Medical Research Centre.**

Study Duration: 1 Year.

Sample Size: 70. The sample size calculation is based on the minimum sample size formula for two proportions. With a desired power of 80% and a significance level of 5%, the sample size is determined to be **35 for each group,** considering an expected sample loss during follow-up.

The minimum sample size formula calculation based on the two proportions:

$$n = \frac{(z_\alpha + z_\beta)^2 \bar{p}(1-\bar{p})}{d^2}$$

Where p_1 and p_2 are the proportions of the two groups.

$$p = \frac{p_1 + p_2}{2} \text{ and } d = p_1 - p_2$$

z_α is related with the level of significance and z_β is related with the power of the test. For 5% level of the significance $z\alpha = 1.96$ and $z_\beta = 0.84$ for 80% power of the test.

The parameter considered in the calculation was the percentage of cases having grade 2 pain score after 3 months[91].

By taking, p_1 = 10.0% and p_2 = 43.3% the sample size obtained was 28.

There would be two groups with size of 28.

Due to expected sample loss during follow up, sample size of 35 for each group was decided.

- **STUDY PARTICIPANTS**

Inclusion Criteria:

- Patients with uncomplicated inguinal hernia.
- Patients aged 18 years and above.
- Patients presenting to surgery OPD with indirect inguinal, direct inguinal or congenital inguinal hernia (adults).
- All elective cases.

Exclusion Criteria:

- Patient < 18 years.
- Patients with other hernias: (femoral or sliding hernia).
- Patient presenting with complicated hernias such as obstruction, strangulation, or incarceration.
- Patients with associated surgical disorders.
- Patients unable to follow up.

SAMPLING TECHNIQUE: Simple random sampling using the computerised SPSS software was utilised.

- **GROUP ALLOCATION**

Group allocation was performed using simple random sampling, ensuring that each patient had an equal chance of being assigned to either Group A or Group B. This randomization process helped to minimize selection bias and ensure that the groups were comparable at baseline.

- **Group A (Control group):** Group A (control group) consisted of patients undergoing inguinal hernia repair using conventional polypropylene mesh using suture for fixation
- **Group B (Test group):** Group B (test group) comprised patients undergoing hernioplasty with bio component polyester + polylactic acid mesh which is self adhesive.

- **STUDY PROTOCOL**

The study protocol involved the enrolment of 70 patients with inguinal hernia. Written informed consent was obtained from all participants prior to their inclusion in the study and before undergoing the operative procedure.

➢ DATA COLLECTION AND PROCEDURE

Data collection for this study involved several steps to ensure comprehensive and accurate gathering of information related to inguinal hernioplasty outcomes using different mesh fixation methods.

❖ **Preoperative Data Collection:** Detailed patient histories and physical examinations were recorded, including demographic information, hernia characteristics, and medical co morbidities, etc. in the predefined proforma after taking consent from the participants to take part in the study.

❖ **Investigations:** Patients underwent preoperative imaging studies – Ultrasound of abdomen and pelvis (CT Abdomen+Pelvis as and when indicated) and routine blood investigations with 2d ECHO as and when necessary. The fitness taken from the physician and other necessary departments for anaesthesia. The patient was then taken up for procedure depending upon randomisation.

❖ **Operative steps: (IMAGE 1)**

- **Informed Consent and Preparation:**

o Written consent was obtained, and anaesthesia was administered using spinal, epidural, or regional block techniques. The patient was prepped and draped under stringent sterile conditions.

- **Incision:**

o A 6 to 7 cm curvilinear incision was made 2-2.5cms above the inguinal ligament. Dissection proceeded through the subcutaneous tissue and Scarpa's fascia facilitated by

electro-cautery. The external oblique aponeurosis was exposed, incised, and opened, avoiding the iliohypogastric and ilioinguinal nerves.

- **Dissection of the cord structures:**

  - The external oblique aponeurosis was cleared of soft tissue by thorough dissection, and the spermatic cord was mobilized and hernia ring forceps applied.

- **Indirect Hernia:**

  - The cremaster muscle fibres were separated carefully from the cord structures, and the cord was isolated. Skeletonisation of the cord structures done.

  - The indirect hernia sac was ligated, and excised.

- **Direct Hernia:**

  - The hernia sac was reduced without excision.

- **Control Group:**

  - A polypropylene mesh was tailored and positioned over the pubic tubercle, under the cord, and affixed using polypropylene 1-0 sutures. On the medial side the mesh was sutured just above the pubic tubercle (avoiding periosteum) to the soft tissue and then sutured on both sides to inguinal ligament and the conjoined tendon. The two tails of mesh was sutured lateral to the cord, extending few centimetres beyond the deep inguinal ring.

- **Test Group:**

  - Pre-tailored mesh structured separately for right and left side with flaps was wrapped around the cord structures and adhered to the inguinal floor with micro hooks (present only on one side of the mesh, palpable and felt by the hand of the surgeon), then trimmed as needed.

- **Final Steps:**

  - Nerves were preserved, and haemostasis was ensured.
  - The external oblique aponeurosis sutured with non-absorbable (polypropylene 2-0) continuous sutures.
  - Scarpa's fascia and subcutaneous layer were closed with absorbable (vicryl 2-0) sutures.
  - The skin was closed with subcuticular sutures/ vertical mattress sutures using Ethilon 3-0/ staples followed by a sterile dressing.

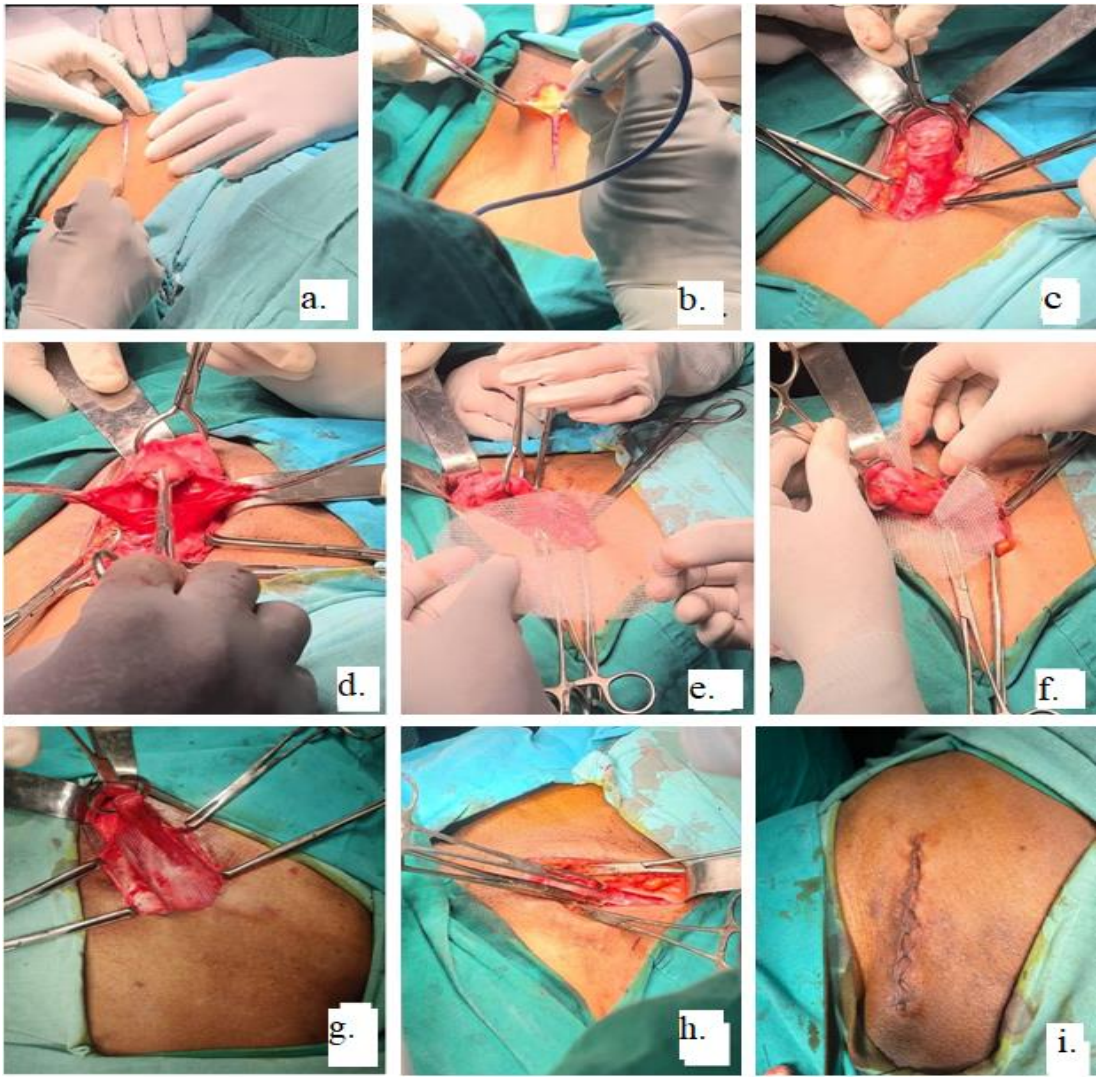


IMAGE 1. SHOWING VARIOUS STEPS OF HERNIOPLASTY USING SELF FIXING MESH

a. Incision

b. Subcutaneous tissue dissection

c. Dissection of cord

d. Dissection of indirect hernia sac

e. Self fixing mesh

f. Wrapping the flaps around the cord

g. Mesh in place and adherent to posterior wall

h. Closure of external oblique

i. Closure of skin.

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

- **Postoperative Follow-up:** Patients were followed up at specified intervals postoperatively, including on postoperative day 0, postoperative day 3, postoperative day5, at one month, and three months visits.

- **OUTCOME MEASURES:**

- The primary outcome measure is pain, measured utilizing the VAS. Pain assessment was conducted using the **Visual Analogue Scale (VAS)**. Pain assessment was performed on postoperative day 0, postoperative day 3, postoperative day 5, at one month, and three months visits.

- 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 were 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, statistical analysis was conducted using the SPSS software 26th version, to compare outcomes between Group A and Group B.

DATA PROCESSING AND STATISTICAL ANALYSIS:

The outcomes of inguinal hernioplasty using two types of mesh conventional polypropylene mesh with suture fixation and self-fixing bio-component polyester + polylactic acid mesh. Data processed and statistically analyzed. For continuous data, such as the duration of surgery, the average and standard deviation were calculated for each group. Differences between groups were compared using an unpaired Student's t-test. Comparisons within each group were conducted using a paired Student's t-test.

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 p-value of less than 0.05 was considered statistically significant for all tests.

RESULTS

A 1 year RANDOMISED CONTROL STUDY was conducted, and the results analyzed as required.

A total of 70 subjects admitted with inguinal hernia requiring mesh repair were a part of the study. These patients were further randomized and divided into two groups of 35 each, categorized as follows:

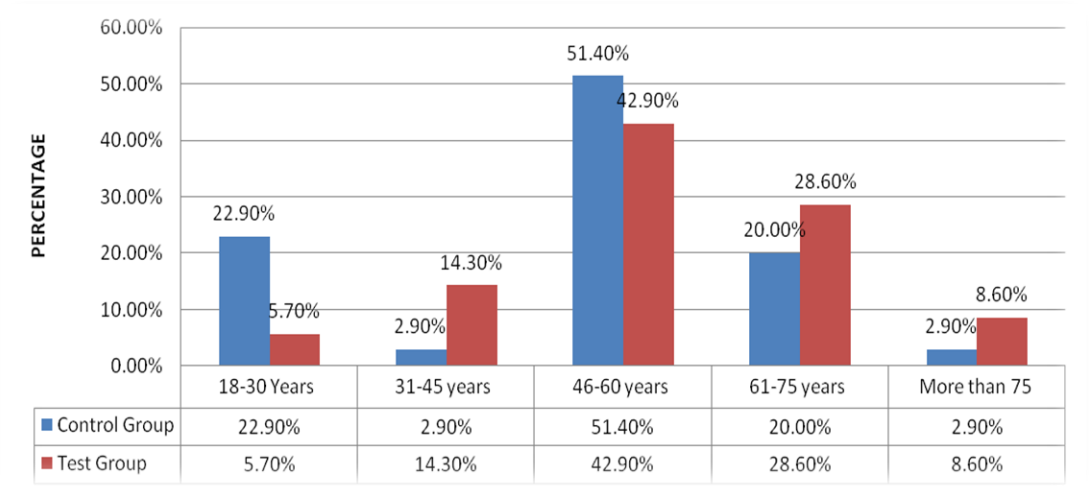
- **The group A/ Control group:** Patients who underwent hernia repair by conventional method i.e. Lichtenstein mesh hernioplasty with polypropylene mesh sutured with non-absorbable sutures.
- **The group B/ Test group:** Patients who underwent hernia repair using the novel self fixing bio component mesh of polylactic acid with polyester monofilament.

The details and all the relevant data were noted in predefined proforma. The collected data was then put in the Microsoft Excel spreadsheets, divided into two sheets as control group and test groups, and compared with each other for further analysis of the results.

1. AGE DISTRIBUTION:

TABLE 1. SHOWING CATEGORIZATION OF AGE INTO VARIOUS AGE GROUPS

Age (In years)	Control group		Test group	
	Number	Percentage	Number	Percentage
18-30 Years	8	22.90%	2	5.70%
31-45 years	1	2.90%	5	14.30%
46-60 years	18	51.40%	15	42.90%
61-75 years	7	20.00%	10	28.60%
More than 75	1	2.90%	3	8.60%
Total (100%)	**35**	**50%**	**35**	**50%**

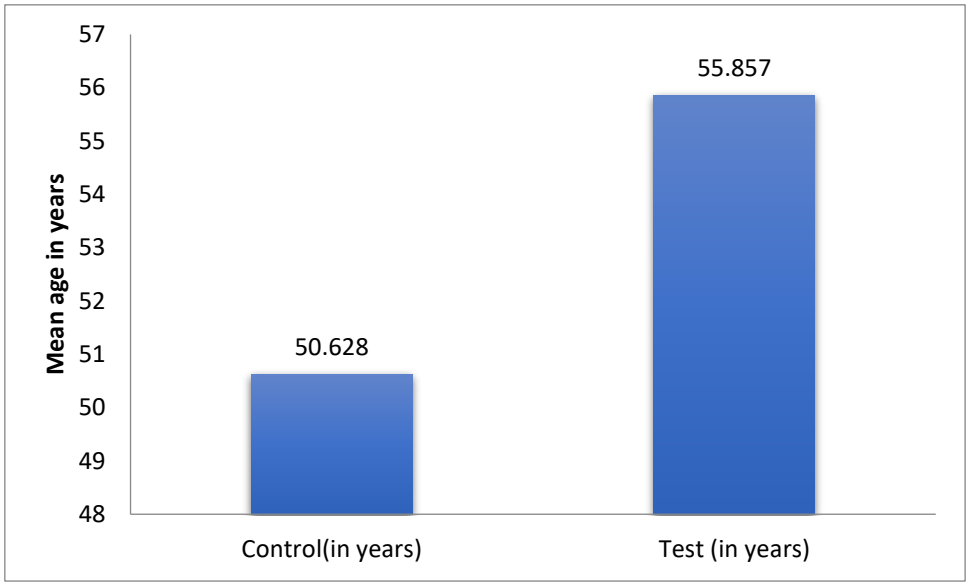


GRAPH 1a. SHOWING CATEGORIZATION OF AGE INTO VARIOUS AGE GROUPS

The above table and graph shows the age distribution among control and test groups and the most common age group affected is 46-60 years followed by 61-75 years. This suggests that hernia is more common between 46-75 years of age.

TABLE 2. COMPARISION OF MEAN AND MEDIAN AGE IN BOTH GROPUS

Study group	Mean	Median	Maximum	Minimum
Control(in years)	50.628	54	76	23
Test (in years)	55.857	58	84	19



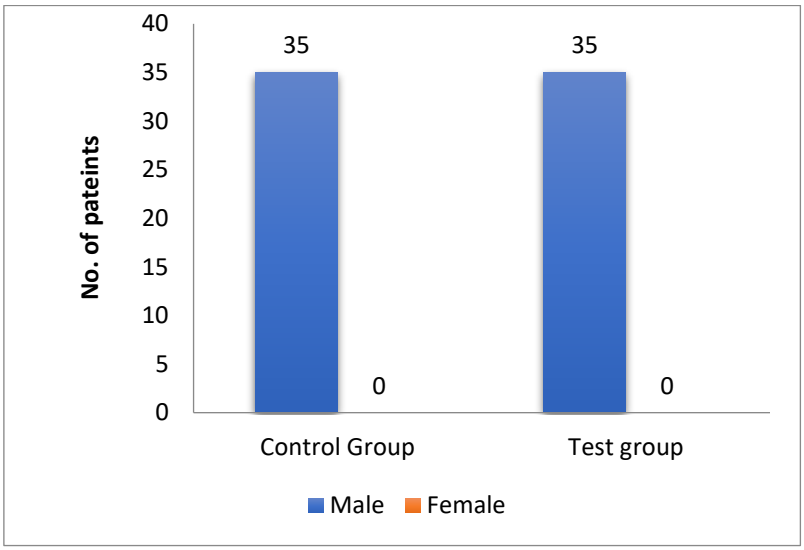
GRAPH 1b: MEAN AGE IN YEARS BETWEEN THE STUDY GROUPS

The above table and graph suggest that mean age in control group is 50 years and 55 years in test group, though slightly more in test group, the age distribution among the groups seems consistent.

2. GENDER DISTRIBUTION:

TABLE 3. GENDER DISTRIBUTION OF CONTROL AND TEST GROUP

Gender	Control Group		Test group		Total (Number, Percentage)
	Number	Percentage	Number	Percentage	
Male	35	50%	35	50%	70(100%)
Female	0	0%	0	0%	0



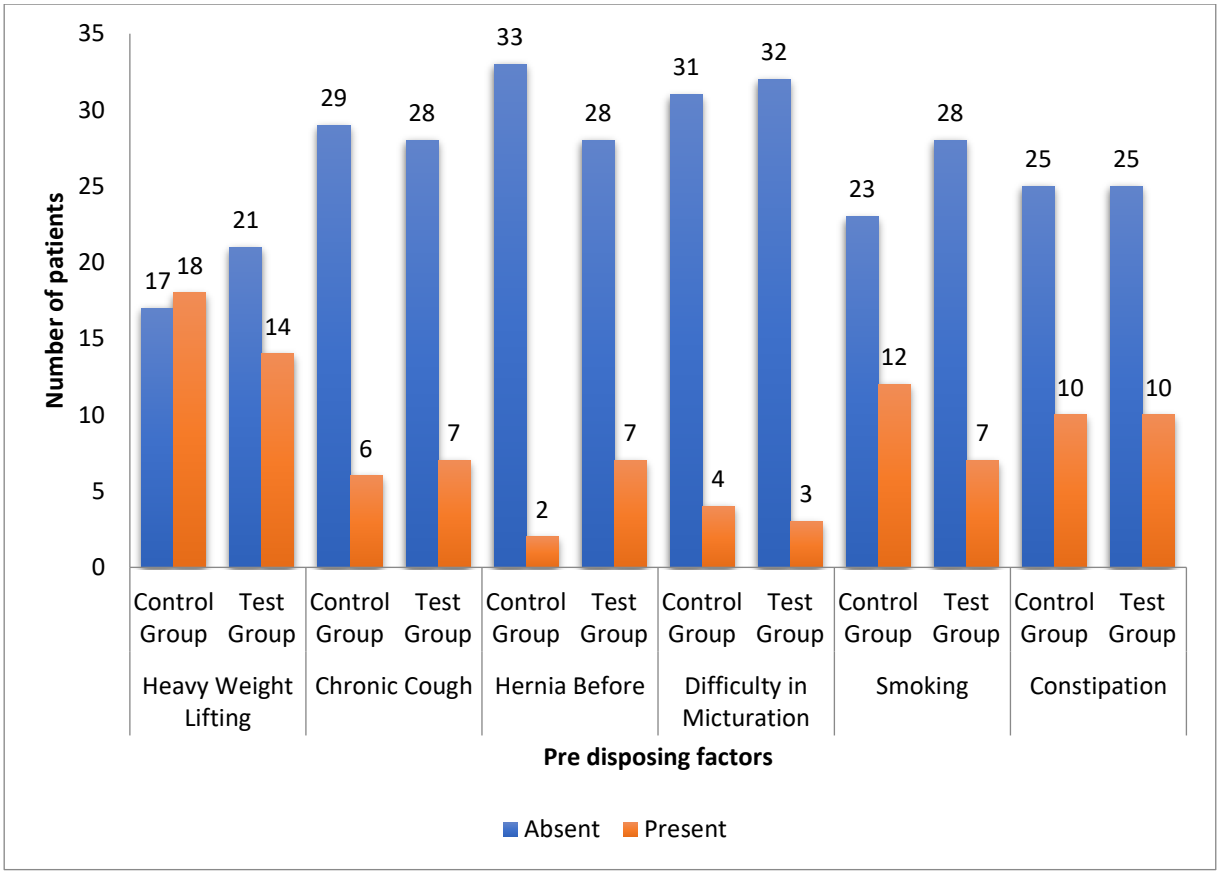
GRAPH 2. GENDER DISTRIBUTION BETWEEN CONTROL AND TEST GROUP

The above table and graph suggests that both groups the participants were male, 35 males in each group with no female participants in either groups. This indicates that hernia is more common in males.

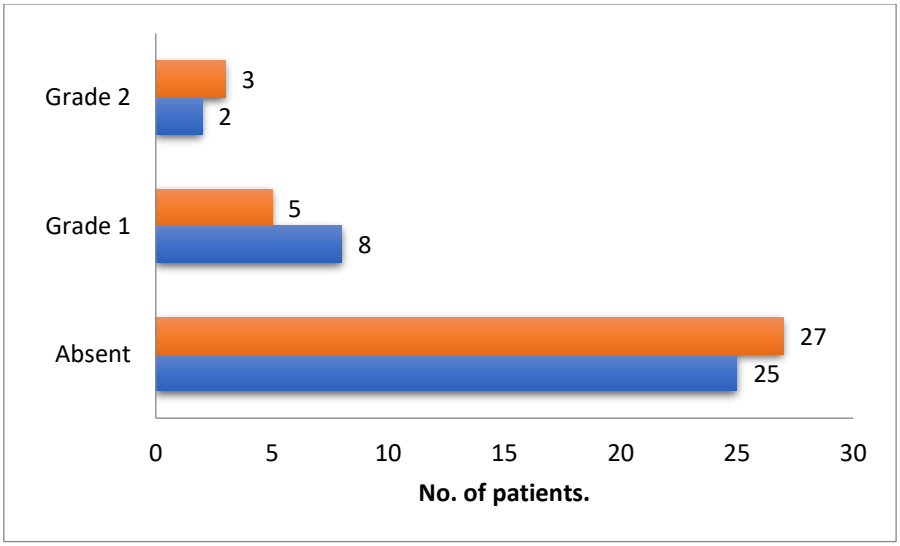
3. PRE-DISPOSING FACTORS:

TABLE 4. DISTRIBUTIONS OF THE VARIOUS PREDISPOSING FACTORS

Factors	Study group	Absent (Number and percentage)	Present (Number and percentage)	Chi Sq value	p value	Significance
Heavy Weight Lifting	Control Group	17 (48.6%)	18 (51.4%)	0.921	0.472	Non-Sig
	Test Group	21 (60.0%)	14 (40.0%)			
Chronic Cough	Control Group	29 (82.9%)	6 (17.1%)	0.094	0.992	Non-Sig
	Test Group	28 (80.0%)	7 (20.0%)			
Hernia Before	Control Group	33 (94.3%)	2 (5.7%)	3.151	0.040	Non-Sig
	Test Group	28 (80.0%)	7 (20.0%)			
Difficulty in Micturation	Control Group	31 (88.6%)	4 (11.4%)	0.150	0.910	Non-Sig
	Test Group	32 (91.4%)	3 (8.6%)			
Smoking	Control Group	23 (65.7%)	12 (34.3%)	1.909	0.382	Non-Sig
	Test Group	28 (80.0%)	7 (20.0%)			
Constipation	Control Group	25 (71.4%)	10 (28.6%)	0.000	1.000	Non-Sig
	Test Group	25 (71.4%)	10 (28.6%)			
		Absent	Grade 1	Grade 2	Chi Square	P value
Prostatomegaly (Per rectal examination)	Control Group	25 (71.4%)	8 (22.9%)	2 (5.7%)	0.969	0.616 (Non-Sig)
	Test Group	27 (77.1%)	5 14.3%	3 (8.6%)		



GRAPH 3. COMPARING THE PREDISPOSING FACTORS IN CONTROL AND TEST GROUP



GRAPH 4. SHOWING PROSTATOMEGALY BASED ON PER-RECTAL EXAMINATION

- Around 51.1% in control group and 40% in test group were heavy weight lifting history which is a known risk factor associated with hernia.

- 34.3% among control and 20.0% among test were smokers which is also another known predisposing factor.

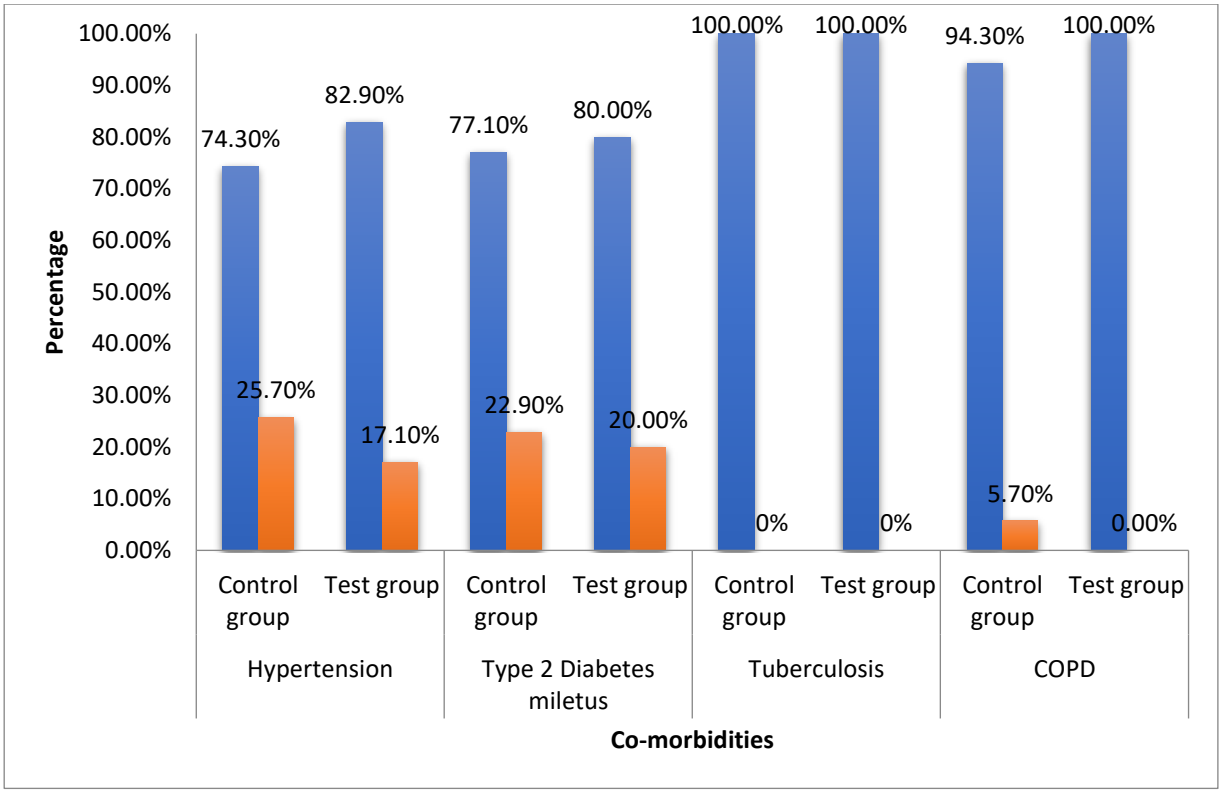
- Difficulty in micturition was there in 11.4% and 8.6% of control and test groups respectively which is relatively less compared to other risk factors. On per rectal examination – prostatomegaly was found in 10 subjects in control and 8 subjects in test with grade 1 – 29.9% in control and 14.3% in test, grade 2- 5.7% in control and 8.6% in test.

- Other predisposing factors such as constipation and chronic cough were comparable in either group.

4. COMORBIIDITIES:

TABLE 5. SHOWING THE VARIOUS COMORBIDITIES BETWEEN GROUPS

Co-morbidity	Study group	Absent	Present	Chi Sq value	p value	Significance
Hypertension	Control Group	26	9	0.754	0.581	Non-Sig
		74.3%	25.7%			
	Test Group	29	6			
		82.9%	17.1%			
Type 2 Diabetes Miletus	Control Group	27	8	0.094	0.992	Non-Sig
		77.1%	22.9%			
	Test Group	28	7			
		80.0%	20.0%			
Tuberculosis	Control Group	35	0	0.000	1.000	Non-Sig
		100.0%	0%			
	Test Group	35	0			
		100.0%	0%			
Chronic obstructive pulmonary disease	Control Group	33	2	1.056	0.493	Non-Sig
		94.3%	5.7%			
	Test Group	35	0			
		100.0%	.0%			



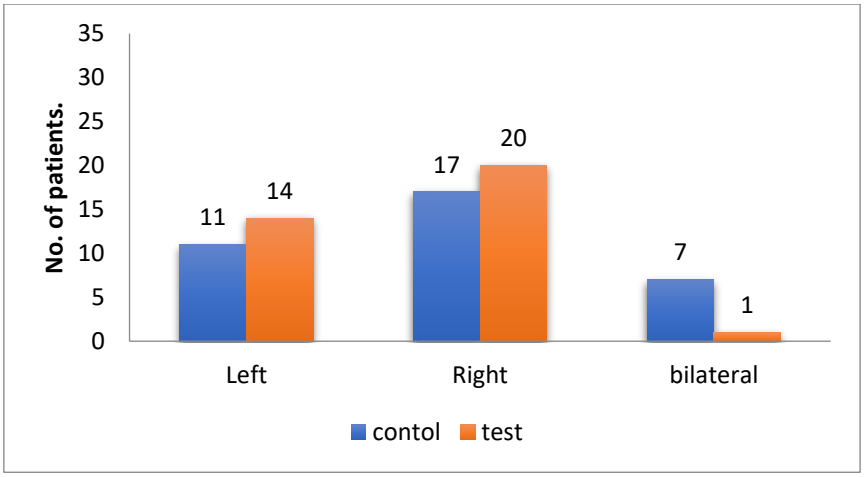
GRAPH 5. SHOWING THE COMORBIDITIES IN TEST AND CONTROL GROUPS

Patients with hypertension were 9 (25.70%) in control and 6 (17.10%) in test, type 2 diabetes Miletus 8(22.90%) in control and 7(20%) in test, no patients presented with Tuberculosis or history of Tuberculosis, 2(5.70%) patients had Chronic obstructive pulmonary disease in control whereas none in test group.

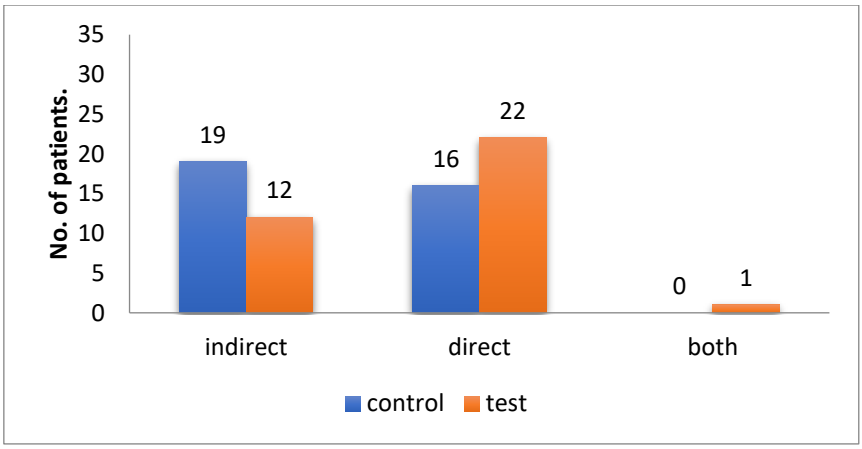
5. CLINICAL DIAGNOSIS:

TABLE 6. SHOWING CHARACTERISTICS OF HERNIA BASED ON CLINICAL EXAMINATION

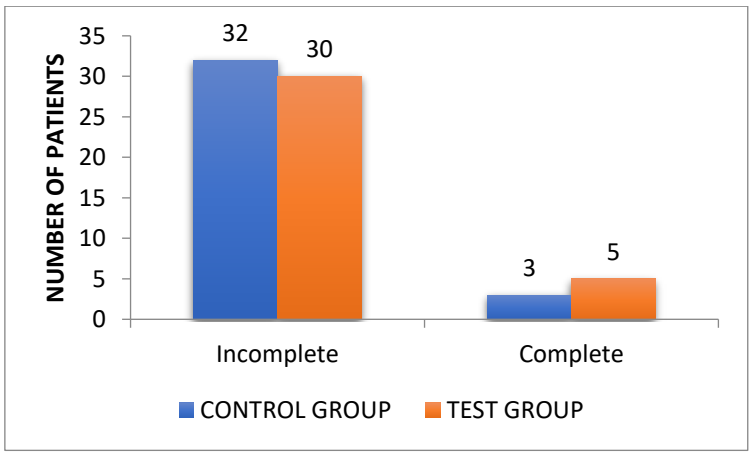
Clinical examination	Study group	Left	Right	Bilateral	Chi Sq value	p value	Significance
Side	Control Group	11	17	7	4.081	0.081	Non-Sig
		31.4%	48.6%	20.0%			
	Test Group	14	20	1			
		40.0%	57.14%	2.86%			
		Indirect	Direct	Indirect+ Direct			
Type of hernia	Control Group	19	16	0	2.302	0.348	Non-Sig
		54.3%	45.7%	0%			
	Test Group	12	22	1			
		34.3%	62.85%	2.85%			
		Incomplete	Complete	-			
Completeness	Control Group	32	3		0.594	0.710	Non-Sig
		91.4%	8.6%				
	Test Group	30	5				
		85.7%	14.3%				
		Bowel	Omentum				
Content	Control Group	7	28		1.801	0.382	Non-Sig
		20.0%	80.0%				
	Test Group	12	23				
		34.3%	65.7%				



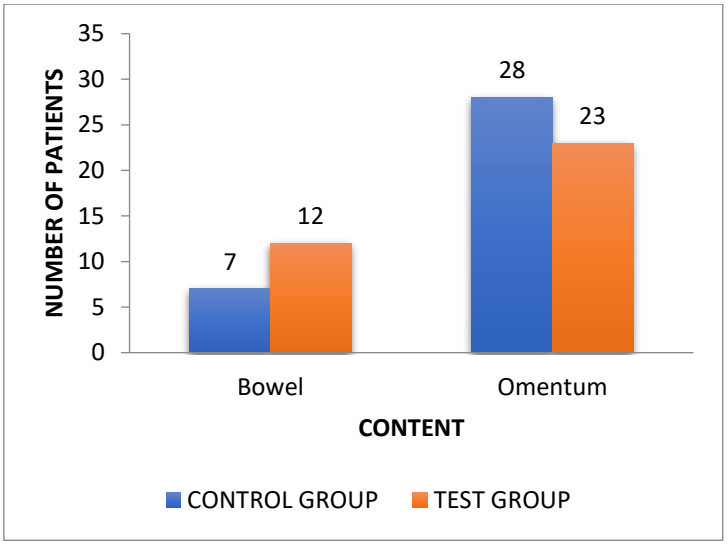
GRAPH 6. SHOWING THE SIDE OF HERNIA (RIGHT, LEFT OR BILATERAL)



GRAPH 7. SHOWING THE TYPE OF HERNIA: DIRECT, INDIRECT OR BOTH



GRAPH 8. SHOWING COMPLETE VS. INCOMPLETE HERNIAS



GRAPH 9: SHOWING CONTENT OF HERNIAS (BOWEL AND OMENTUM)

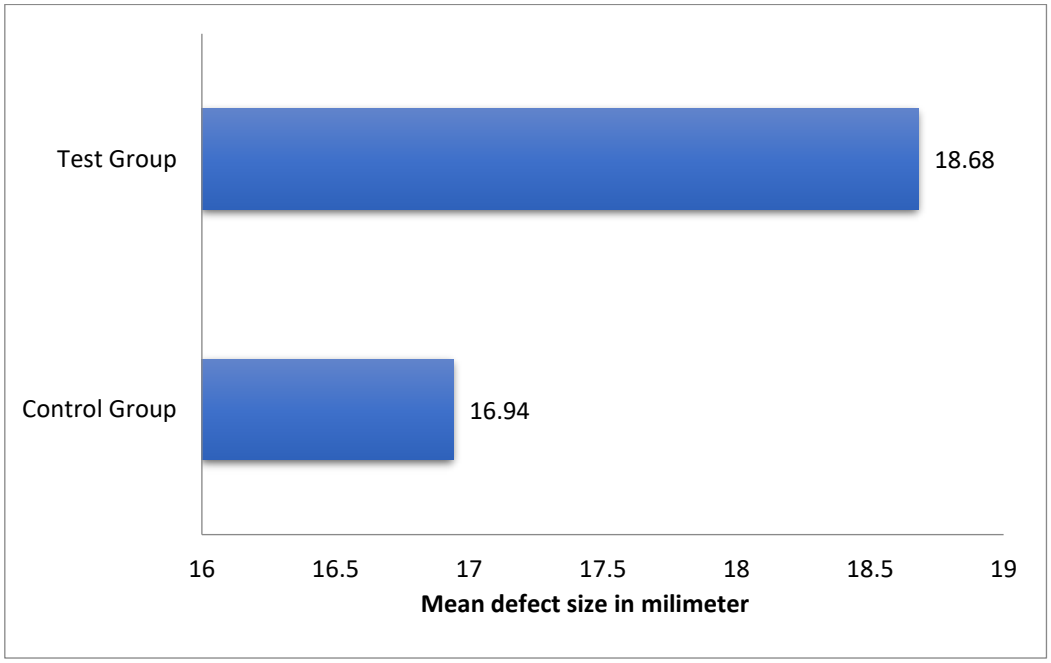
- All hernias in control and test study group are uncomplicated and reducible.
- 11(31.4%) in control and 14(40%) in test group had left sided hernia, 17(48.6%) in control and 20(57.14%) in test had right sided hernia, 7(20.0%) in control and 1(2.86%) in test had bilateral hernia but operated only on one side.
- 19(54.3%) in control and 12(34.3%) in test had indirect hernia, 16(45.7%) in control and 22 (62.85%) in test had direct hernia, 1(2.85%) in test and none in control group had pantaloons or indirect+direct hernia.
- 3(8.6%) in control 5(14.3%) in test had complete hernia reaching till base of scrotum and rest of them had incomplete hernia.
- 7(20.0%) in control and 12(34.3%) in test had bowel as content of hernia and resonant on percussion, the remaining in both groups had omentum as content based on clinical diagnosis

6. ULTRA SONOGRAPHY-FINDINGS:

DEFECT SIZE IN ULTRASONOGRAPHY (in millimetre)

TABLE 7. SHOWING COMPARISON OF MEAN DEFECT SIZES IN TEST AND CONTROL GROUP

Study group	Mean (in mm)	Std. Deviation	Std. Error Mean	p value	Significance
Control Group	16.94	6.47	1.094	0.465	Non- Sig
Test Group	18.68	12.32	2.114		



GRAPH 10: SHOWING MEAN DEFECT SIZE (IN MILIMETER) BETWEEN THE GROUPS

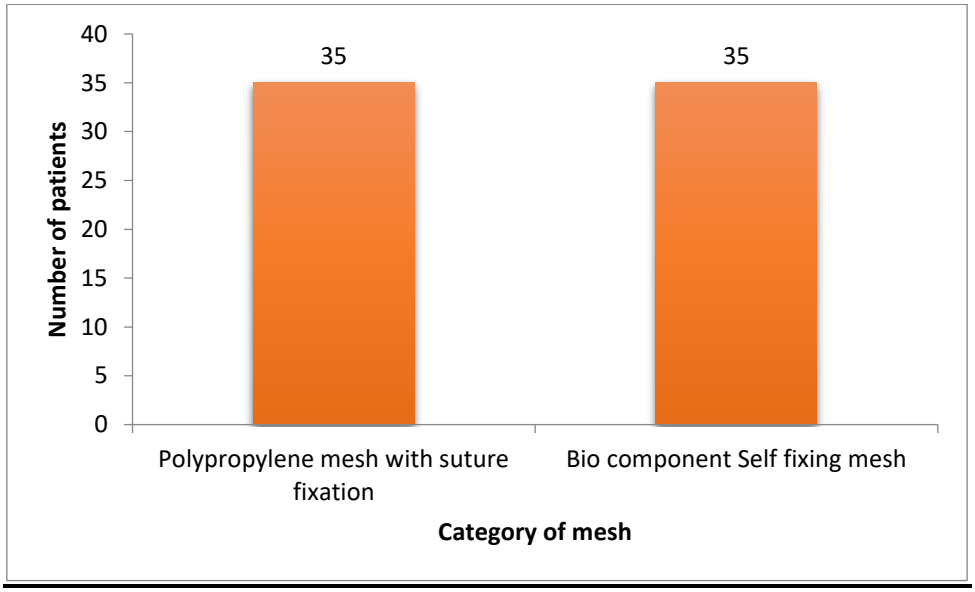
Defect size based on ultrasound in control group: 16.94±6.47 mm and in test group: 18.68±12.32 mm which was not significant but slightly larger in test group. P value is 0.465 and non-significant.

7. TREATMENT (LITCHENSTEIN TENSION FREE MESH HERNIOPLASTY):

a. Category of Mesh Used:

TABLE 8. CATEGORY OF MESH USED

Category of mesh used	Number	Percentage
Polypropylene mesh with suture fixation (CONTROL GROUP / GROUP A)	35	50%
Bio component Self fixing mesh (TEST GROUP / GROUP B)	35	50%
Total	70	100%



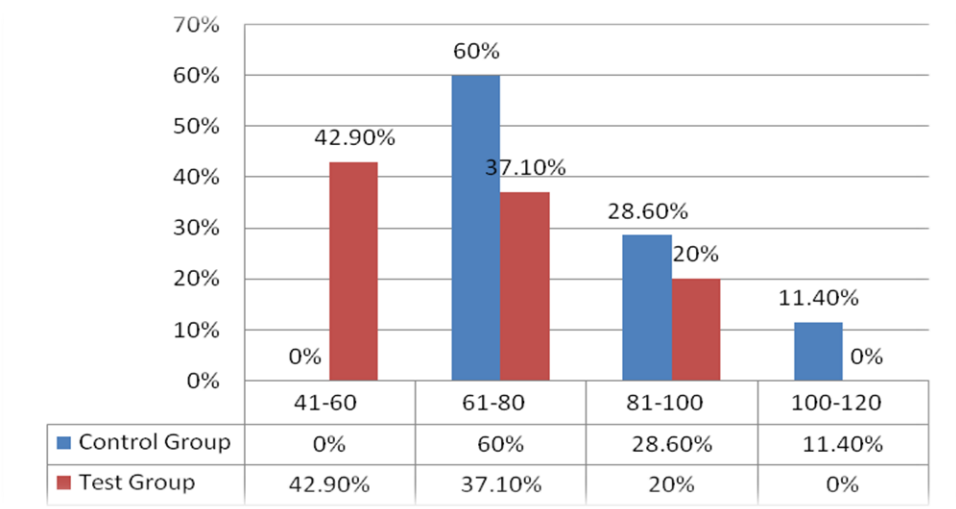
GRAPH 11. SHOWS CATEGORY OF MESH USED

- Control group consisted of 35 patients who underwent hernia repair by conventional method i.e. Lichtenstein mesh hernioplasty with polypropylene mesh sutured with non-absorbable sutures and test group consisted of 35 patients who underwent hernia repair using the novel self fixing bio component mesh of polylactic acid with polyester monofilament.

b. Operative time:

TABLE 9. DISTRIBUTION OF OPERATIVE TIME IN MINUTES IN CONTROL GROUP AND TEST GROUP

Time in minutes	Control Group	Test Group	p value
41-60	0 (0%)	15 (42.9%)	0.001 (Sig)
61-80	21 (60.00%)	13 (37.1%)	0.001 (Sig)
81-100	10 (28.6%)	07 (20%)	0.041 (Sig)
100-120	04 (11.4%)	00 (0%)	0.01 (Sig)



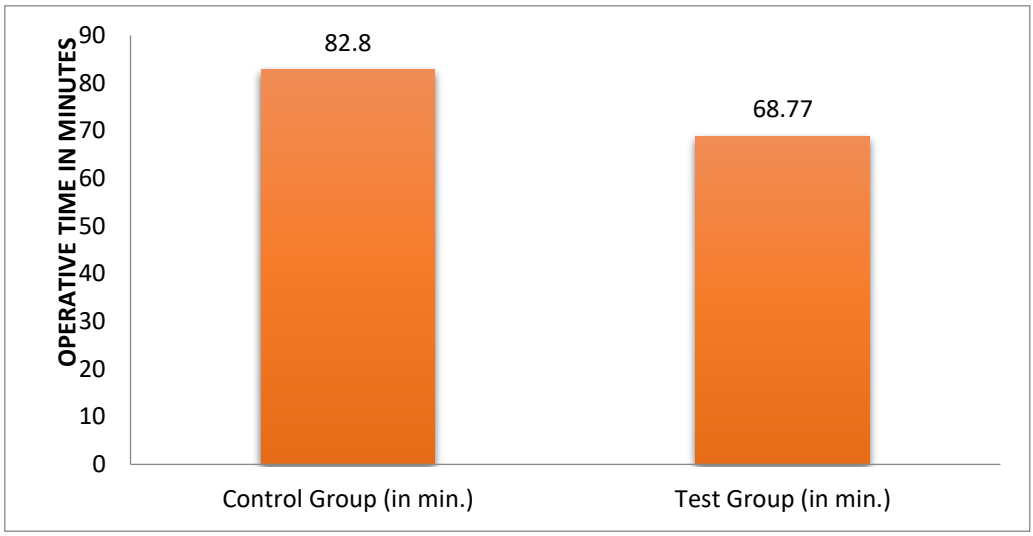
GRAPH 12. DISTRIBUTION OF OPERATIVE TIME IN MINUTES IN CONTROL GROUP AND TEST GROUP

The above table and graph depict operative time (in minutes) distribution ranging from 41 minutes to 120 minutes with each interval of 20 minutes. In control group majority of the operations fall under 61-80 minutes i.e. 21(60%) patients followed by 81-100 minutes 10(28.6%) patients. Whereas in test group the majority of operations fall under 41-60 minutes i.e. 15(42.9%) patients followed by 61-80 minutes 13(37.1%).

The p value of each group is <0.05 showing significance in distribution of operative time in each group

TABLE 10. MEAN OPERATIVE TIME (IN MINUTES)

Study group	Mean	Std. Deviation	Std. Error Mean	p value
Control Group (in minutes)	82.80	12.860	2.173	0.001 (significant)
Test Group (in minutes)	68.77	15.132	2.557	



GRAPH 13. MEAN OPERATIVE TIME IN MINUTES

In the above table and graph with mean operative time's comparison, control group – 82.80±12.860 minutes and test group 68.77 ± 15.132 minutes and **p value of 0.001** which is significant.

8. ANALGESIC DOSES:

TABLE 11. COMPARISION OF ANALGESIC DOSES RECIEVED THROUGH VARIOUS ROUTES IN CONTROL AND TEST GROUPS

Route of analgesia	Study group	Mean	Std. Deviation	Std. Error Mean	p value	Significance
Intra venous (Doses)	Control Group	9.257	2.604	0.440	0.011	Sig
	Test Group	7.600	2.692	0.455		
Oral (Doses)	Control Group	9.628	1.941	0.328	0.436	Non-Sig
	Test Group	10.114	3.716	0.628		
Patch (Number of Days)	Control Group	0.428	1.420	0.240	0.808	Non-Sig
	Test Group	0.514	1.482	0.250		
Epidural (Top Ups)	Control Group	0.057	0.338	0.057	0.112	Non-Sig
	Test Group	0.314	0.900	0.152		

- **Intravenous route:** control group 9.257±2.604 doses and test group 7.600±2.692 doses and **p value of 0.011** which was significant as control group received more doses of intravenous analgesia compared to test group patients.
- **Oral route:** control group 9.628±1.941 doses and test group 10.114±3.716 with p value of 0.436
- **Transdermal patch:** control group 0.428±1.420 days and test group 0.514±1.482 days and p value : 0.808
- **Epidural top ups:** control group 0.057±0.338 and test 0.314 ± 0.9 with p value 0.112. Analgesic doses received through oral route, epidural topups, transdermal patches were insignificant.

9. PAIN SCORES AT POSTOPERATIVE DAY ZERO:

TABLE 12. PAIN SCORES BASED ON SEVERITY AT POSTOPERATIVE DAY ZERO

Severity	Control Group	Test Group	Total	p value
No Pain	0	0	0	0.413 (Non-Sig)
	0%	0%	0%	
Mild Pain	4	8	12	
	11.4%	22.86%	17.14%	
Moderate Pain	14	8	22	
	40.0%	22.86%	31.43%	
Severe Pain	10	16	26	
	28.57%	45.71%	37.14%	
Very Severe Pain	7	3	10	
	20.0%	8.57%	14.29%	

Table shows distribution of pain on Postoperative day zero in both groups and shows that most patients had moderate to severe pain and p value 0.413 which is non significant

TABLE 13. MEAN AND MEDIAN VAS SCORE AT POSTOPERATIVE DAY ZERO

	Study group	Mean	Median	Std. Deviation	Std. Error Mean	p value
POSTOPERATIVE DAY ZERO	Control Group	6.628	6.00	2.590	0.437	0.821
	Test Group	6.485	7.00	2.671	0.451	

Table shows mean and median with p value for mean being 0.821 which is not significant.

10. PAIN SCORES AT POSTOPERATIVE DAY THREE:

TABLE 14. PAIN SCORES BASED ON SEVERITY AT POSTOPERATIVE DAY THREE

Severity	Control Group	Test Group	Total	p value
No Pain	0	2	2	0.029 (Sig)
	.0%	5.71%	2.86%	
Mild Pain	1	12	13	
	2.86%	34.28%	18.57%	
Moderate Pain	21	16	37	
	60%	45.72%	52.86%	
Severe Pain	13	5	18	
	37.14%	14.29%	25.71%	
Very Severe Pain	0	0	0	
	0%	0%	0%	

Table shows the severity of pain on postoperative day three, most patients had moderate to severe pain with **p value of 0.029** which is significant.

TABLE 15. MEAN AND MEDIAN VAS SCORES AT POSTOPERATIVE DAY THREE

	Study group	Mean	Median	Std. Deviation	Std. Error Mean	p value	Significance
Postoperative day three	Control Group	6.114	6.00	1.728	0.292	0.001	Sig
	Test Group	3.942	4.00	2.325	0.393		

Table shows mean and median with **p value of 0.001** which is significant meaning pain on postoperative day 3 was significantly lowered in test patients compared to control group.

11. PAIN SCORES AT POSTOPERATIVE DAY FIVE:

TABLE 16. PAIN SCORES BASED ON SEVERITY AT POSTOPERATIVE DAY FIVE

Severity	Control Group	Test Group	Total	p value
No Pain	0	4	4	0.001 (Sig)
	.0%	11.4%	5.7%	
Mild Pain	23	29	52	
	65.7%	82.8%	74.3%	
Moderate Pain	12	01	13	
	34.3%	2.9%	18.6%	
Severe Pain	0	1	1	
	.0%	2.9%	1.4%	
Very Severe Pain	0	0	0	
	.0%	0%	0%	

Table shows the severity of pain on postoperative day five with p value of 0.001 which is significant

TABLE 17. MEAN AND MEDIAN VAS SCORES AT POSTOPERATIVE DAY FIVE

	Study group	Mean	Median	Standard Deviation	Standard Error (Mean)	p value	Significance
POSTOPERATIVE DAY FIVE	Control	3.114	3.00	1.078	1.078	0.001	Sig
	Test	1.742	1.00	1.421	1.421		

Table shows mean and median at postoperative day five with **p value of 0.001** implying that difference in pain reduction in test group is significant compared to control group.

12. **PAIN SCORES AT ONE MONTH:**

TABLE 18. PAIN SCORES BASED ON SEVERITY AT ONE MONTH

Severity	Control Group	Test Group	Total	p value
No Pain	3	11	14	0.001 (Sig)
	8.6%	31.43%	20.0%	
Mild Pain	24	23	47	
	68.57%	65.71%	67.14%	
Moderate Pain	8	0	8	
	8.57%	0%	11.43%	
Severe Pain	0	0	0	
	0%	0%	0%	
Very Severe Pain	0	1	1	
	.0%	2.9%	1.43%	

Table shows severity of pain at 1 month with **p value = 0.001** implying it is significant.

TABLE 19. MEAN AND MEDIAN VAS SCORES AT ONE MONTH

	Study group	Mean	Median	Standard Deviation	Standard Error Mean	p-value
1 Month	Control	2.400	2.00	1.376	0.232	0.012 (significant)
	Test	1.428	1.00	1.786	0.302	

Table shows mean and median at 1 month postoperative and **p value is 0.012** which is significant.

13. **PAIN SCORES AT THREE MONTH:**

TABLE 20. PAIN SCORES BASED ON SEVERITY AT THREE MONTHS

Severity	Control Group	Test Group	Total	p value
No Pain	8 (22.86%)	16 (45.71%)	24 (34.28%)	0.031 (Sig)
Mild Pain	27 (77.14%)	18 (51.43%)	45 (64.29%)	
Moderate Pain	0 (0%)	0 (0%)	0 (0%)	
Severe Pain	0 (0%)	0 (0%)	0 (0%)	
Very Severe Pain	0 (0%)	1 (2.86%)	1 (1.43%)	

Table shows severity of pain at three month with **p value of 0.031** which is significant

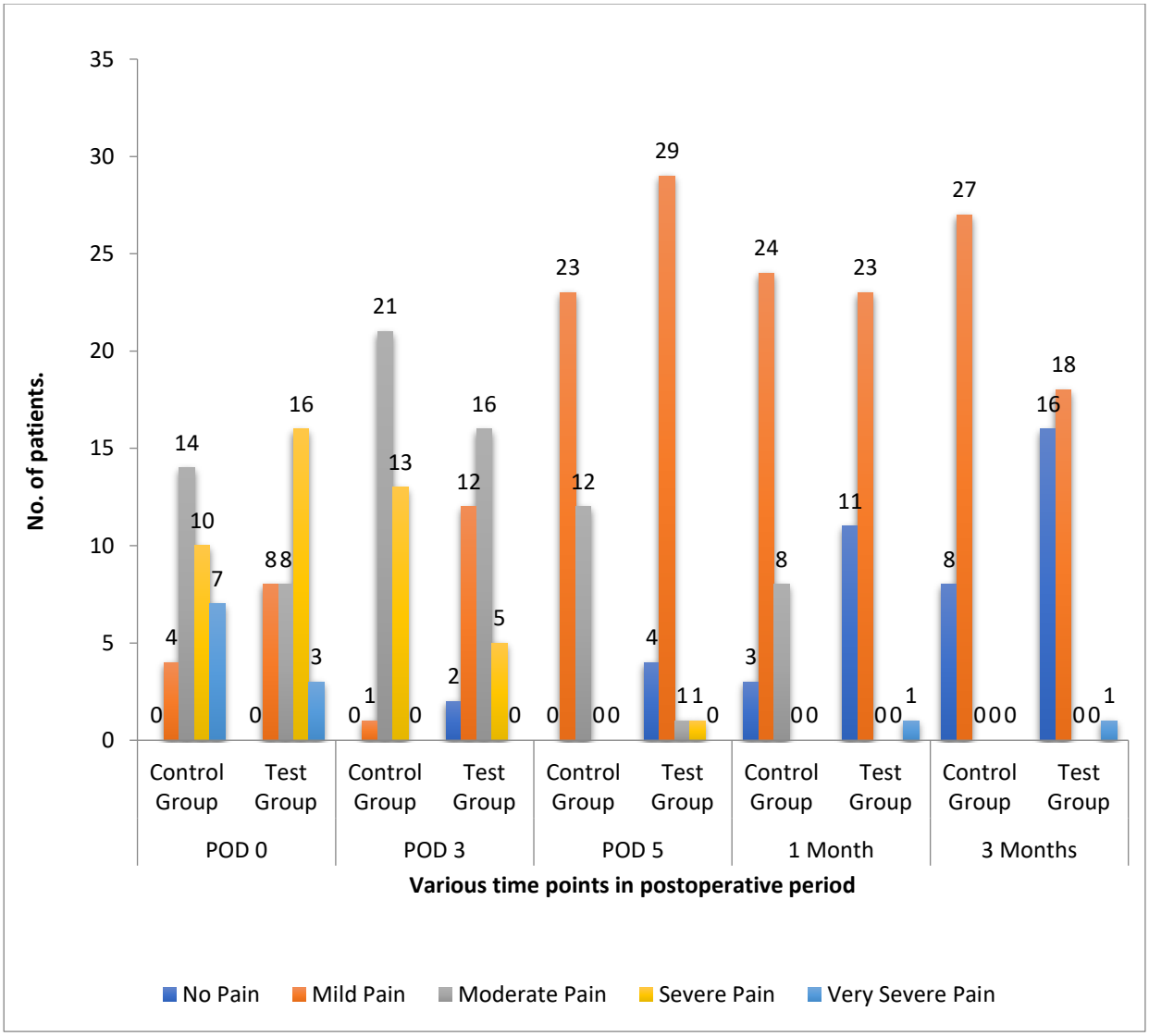
TABLE 21. MEAN AND MEDIAN VAS SCORES AT THREE MONTHS

	Study group	Mean	Median	Std. Deviation	Std. Error Mean	p value	Significance
THREE Months	Control Group	1.314	2.00	0.866	0.146	0.348	Non-Sig
	Test Group	1.000	1.00	1.765	0.298		

Table shows mean and median at three month postoperative and **p value is 0.348** which is non-significant.

As there are outlier VAS score 10 in one patient in test group, on applying Mann Whitney U test for the medians: The test statistic (U value) is 783.5, **p value is** approximately **0.0175**. Since the p value is less than 0.05, implies that there is a statistically significant difference between the control group and the test group. The mean pain score at 3 month was not significant, but if we exclude the outlier or use non parametric tests like Mann Whitney U the results appear significant.

14. DISTRIBUTION OF PATIENTS AT VARIOUS TIME POINTS BASED ON THE SEVERITY OF PAIN:



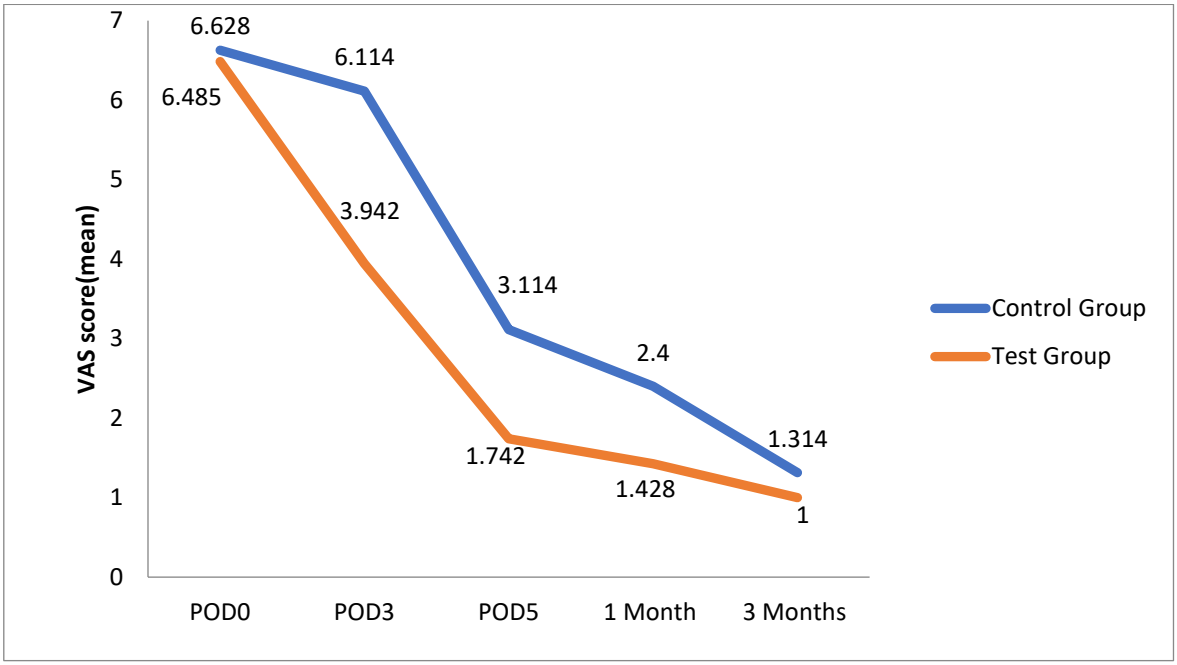
GRAPH 14: DISTRIBUTION OF PATIENTS AT VARIOUS TIME POINTS BASED ON THE SEVERITY OF PAIN

The above graph depicts distribution of the patients based on severity of pain. On postoperative day zero, both groups had majority of patients with severe to very severe pain. At postoperative day three the severity shifted to moderate to severe in control group and mild to moderate in test group. Whereas, at postoperative day five and one month the majority of patients had mild to moderate pain in control group and no pain to mild pain in test group. At three months majority patients had mild pain in control group, but had mild pain to no pain in test group.

15. DECREASE IN MEAN VAS SCORES AMONG THE TWO GROUPS:

TABLE 22. SHOWING THE DECREASE IN MEAN VAS SCORES FROM POSTOPERATIVE DAY ZERO TO THREE MONTHS

Day	Study group	Mean
POSTOPERATIVE DAY ZERO	Control Group	6.628
	Test Group	6.485
POSTOPERATIVE DAY THREE	Control Group	6.114
	Test Group	3.942
POSTOPERATIVE DAY FIVE	Control Group	3.114
	Test Group	1.742
ONE Month	Control Group	2.4
	Test Group	1.428
THREE Months	Control Group	1.314
	Test Group	1



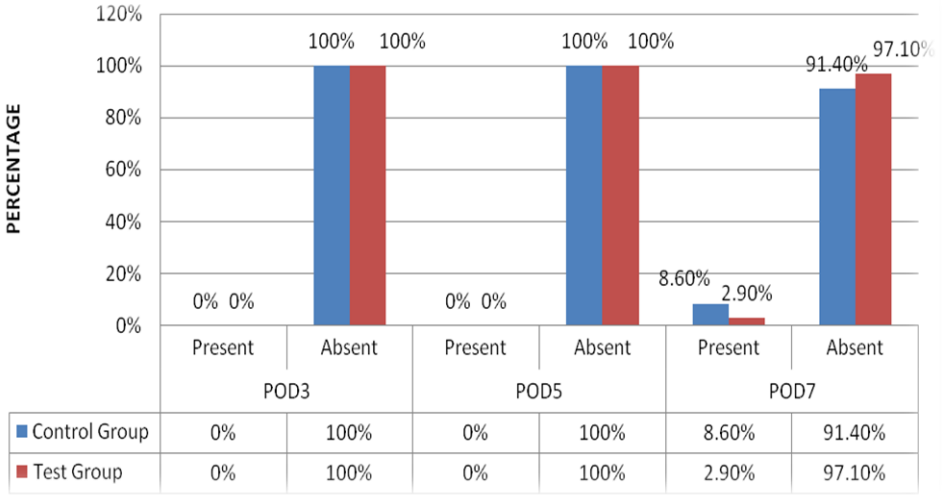
GRAPH 15. SHOWING THE COMPARISON OF DECREASE IN MEAN VAS SCORES

16. COMPLICATIONS (Surgical site infection):

a. Seroma:

TABLE 23. SEROMA ON POSTOPERATIVE DAY THREE, POSTOPERATIVE DAY FIVE, POSTOPERATIVE DAY SEVEN

Day		Control Group (number and %)	Test Group (number and %)	Chi Sq value	p value	Significance
POSTOPERATIVE DAY THREE	Present	0 (0%)	0 (0%)	0.000	1.000	Non-Sig
	Absent	35 (100%)	35 (100%)			
POSTOPERATIVE DAY FIVE	Present	0 (0%)	0 (0%)	0.000	1.000	Non-Sig
	Absent	35 (100%)	35 (100%)			
POSTOPERATIVE DAY SEVEN	Present	3 (8.6%)	1 (2.9%)	1.061	0.614	Non-Sig
	Absent	32 (91.4%)	34 (97.1%)			



GRAPH 16. SEROMA ON POSTOPERATIVE DAY THREE, POSTOPERATIVE DAY FIVE, POSTOPERATIVE DAY SEVEN

The above graph and table depict the complication seroma after surgery at surgical site. Seroma was absent on postoperative day three and postoperative day five in either group.

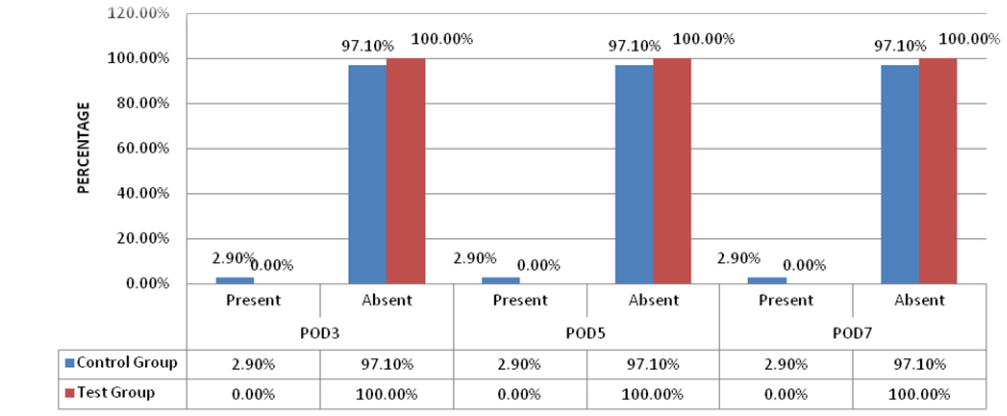
On postoperative day seven, control 3(8.6%) and test 1(2.9%) patients had seroma which was aspirated or managed conservatively.

p value of 1 on postoperative day three and postoperative day five, **p value of 0.614** on postoperative day seven which is not significant.

b. Hematoma:

TABLE 24: HEMATOMA ON POSTOPERATIVE DAY THREE, POSTOPERATIVE DAY FIVE, POSTOPERATIVE DAY SEVEN

Day		Control Group (number and %)	Test Group (number and %)	Chi Sq value	p value	Significance
POSTOPERATIVE DAY THREE	Present	1 (2.9%)	0 (0%)	1.014	0.731	Non-Sig
	Absent	34 (97.1%)	35 (100.0%)			
POSTOPERATIVE DAY FIVE	Present	1 (2.9%)	0 (0%)	1.014	0.731	Non-Sig
	Absent	34 (97.1%)	35 (100.0%)			
POSTOPERATIVE DAY SEVEN	Present	1 (2.9%)	0 (0%)	1.014	0.731	Non-Sig
	Absent	34 (97.1%)	35 (100.0%)			



GRAPH 17. HEMATOMA ON POSTOPERATIVE DAY THREE, POSTOPERATIVE DAY FIVE, POSTOPERATIVE DAY SEVEN

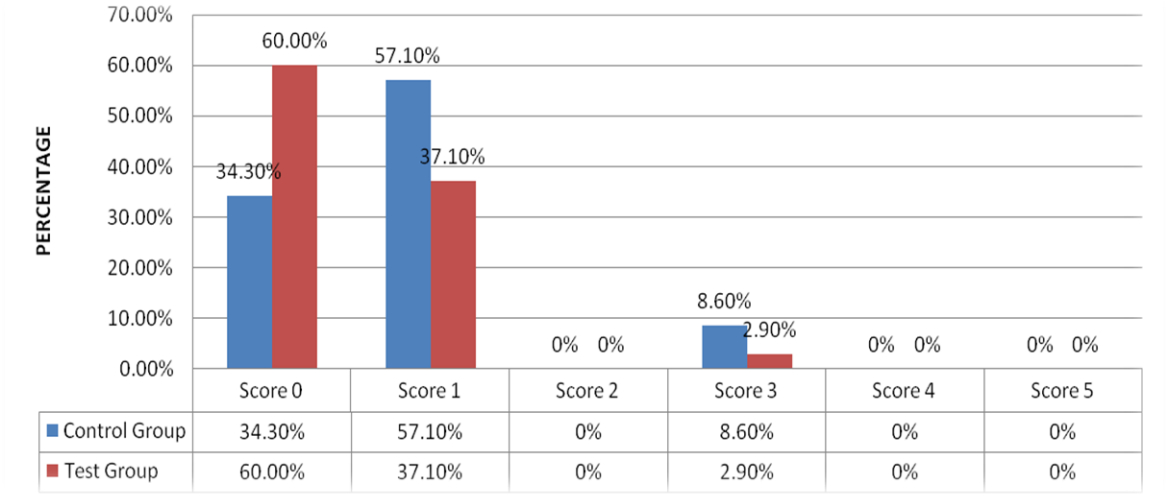
The above graph and table depict the complication hematoma after surgery at surgical site. Hematoma was absent on postoperative day three, postoperative day five and postoperative day seven in test group. In control group 1(2.9%) patient had hematoma and treated conservatively and recovered completely. **P value: 0.731** which was not significant.

c. Infection: None of the patients in either group experienced infection.

17. SOUTHAMPTON SCORING:

TABLE 25. SOUTHAMPTON SCORING FOR SURGICAL SITE INFECTION

Score	Control Group	Test Group	Total	p value
Score 0	12	21	33	0.089 (Non-Sig)
	34.3%	60.0%	47.1%	
Score 1	20	13	33	
	57.1%	37.1%	47.1%	
Score 2	0	0	0	
	0%	0%	0%	
Score 3	3	1	4	
	8.6%	2.9%	5.7%	
Score 4	0	0	0	
	0%	0%	0%	
Score 5	0	0	0	
	0%	0%	0%	



GRAPH 18. SHOWING THE COMPARISON OF SOUTHAMPTON SCORING IN BOTH GROUPS

The above graph and table depicts the Southampton scoring system in control and test based on postoperative wound.

- Score 0: control 12(34.3%) and test 21(60%) with a total of 47.1% with score 0
- Score 1: control 20 (57.1%) and test 13(37.1%) with a total of 47.1% with score 1
- Score 3: control 3(8.6%) and test 1(2.9%) patients with a total of 5.7%

No patient had score 2, score4 or score 5 in either group.

DISCUSSION

Surgical intervention for inguinal hernias is a frequently conducted procedure, utilizing a range of techniques and materials to achieve the best possible results.

This study examines the effectiveness of two types of meshes: the traditional polypropylene mesh with sutures and a self-fixing bio-compatible mesh made of polyester monofilament and polylactic acid (PLA) [91].

Our randomized controlled study focused on assessing postoperative pain, operative time, and postoperative complications between these two groups over one year. This study is significant because it thoroughly examines different factors that can affect the results of hernia repair surgeries. It takes into account pre-existing conditions, other health issues, surgical techniques, pain management after surgery, and potential complications. This study provides valuable insights into the impact of various factors on surgical outcomes in hernia surgery. The findings have the potential to facilitate in treatment decision-making and improve the patient care protocols, leading to more effective treatments and increased patient satisfaction.

This study involved 70 cases of inguinal hernia and aimed to compare the effectiveness and results of two different types of hernia repair. Control group underwent the conventional polypropylene mesh repair with sutures, while Test group received the innovative bio component polyester + polylactic acid self-retaining mesh repair.

The age distribution in the control group ranged from 23 to 76 years, with a mean age of 50.63 years, while in the test group, the ages ranged from 19 to 84 years, with a mean age of 55.86 years [92,93]. The age distribution in our study reveals a notable presence of older adults receiving inguinal hernia repair, with the majority of patients in both the control and test groups being over 46 years old [91,93]. This trend aligns with the results of comparable studies.

As an example, a study conducted by Jose et al. [91] revealed that the majority of inguinal hernia surgeries are performed on older individuals, specifically those who are 50 years old or above. Similarly, a study conducted by Fang et al. [92] revealed that the frequency of inguinal hernia repairs tends to rise as individuals grow older, reaching its highest point during the fifth and sixth decades of life.

The gender distribution in our study, which exclusively consisted of male participants, is consistent with previous research that has demonstrated a greater incidence of inguinal hernias among men. Research conducted by Gunasekaran et al. [93] and Chastan et al.[94] has found that there is a notable chance of increased occurrence of inguinal hernia cases in males. The lack of female participants in the study is due to the lower occurrence rates among women, as pointed out by Sanders et al. [95]. Our findings are relevant to the primary affected demographics.

In our study, factors that could potentially contribute to the condition were examined, including heavy weight lifting, chronic cough, smoking, and constipation. However, no significant differences were observed between the control and test groups [96,97]. These results align with previous research conducted by Batabyal et al. [96] and Karthikeyan and Rajasekar et al. [97] have also found that heavy lifting and chronic coughing are frequently associated with inguinal hernia. The lack of significant differences in our study emphasizes that both groups were similar in terms of risk factors, which allows for a fair comparison when evaluating different types of mesh. This highlights the importance of our findings in the wider scope of evaluating and treating inguinal hernias.

In our study, the occurrence of other health conditions like high blood pressure, diabetes, tuberculosis, and chronic lung disease did not vary significantly between the control and test groups [97,92]. These results are consistent with previous research conducted by Karthikeyan and

Rajasekar et al.[97] and Fang et al. [92]. These studies also found no significant differences in the distribution of co-morbidities among patients who underwent inguinal hernia repair. This balance guarantees that other health conditions did not influence the results, strengthening the credibility of our comparison of different mesh types. The consistency observed across studies highlights the strength of our methodology and findings in the field of inguinal hernia surgery.

Our study found no statistically significant differences in clinical examination parameters between the control group and the test group [91]. Both studies found a comparable distribution of unilateral and bilateral hernias, with a higher prevalence of indirect hernias. The consistent findings observed in these studies highlight the impartial patient selection and validate our comparative analysis of different mesh types for inguinal hernia repair. These similarities improve the applicability of our study's results.

Our study found that the defect sizes observed in both the control and test groups were similar, and there was no significant difference in the average defect size.

In terms of management, conventional mesh and self-retaining mesh were evenly distributed, highlighting the fair allocation of treatment options.

Nevertheless, there were noticeable disparities in the duration of the procedures among the groups. Operating time was significantly lower in the test group, averaging 68.77 ± 15.13 minutes, compared to 82.80 ± 12.86 minutes in the control group [91]. This is in line with other studies conducted by Batabyal et al. [96] and Sanders et al. [95] which have demonstrated reduced operating time while using self fixing mesh. This reduction is attributed to the elimination of the suturing time required for mesh fixation in the traditional method.

The present study's findings are consistent with previous research, confirming the effectiveness of self-retaining mesh in reducing postoperative pain and severity when compared to the conventional mesh type [92]. This consistency highlights the idea that

improvements in mesh fixation technology can have a significant effect on patient outcomes, supporting similar findings from previous studies (Fang et al., 2017) [92]. Pain levels were assessed using the Visual Analogue Scale (VAS) at multiple post-operative intervals: immediately after surgery (postoperative day 0), on the third day (postoperative day 3), the fifth day (postoperative day 5), at one month, and at three months. The test group consistently reported lower pain scores across all time points compared to the control group. On postoperative day 0, pain scores were similar between both groups, with the control group recording an average score of 6.628 ± 2.590 and the test group recording 6.485 ± 2.671. However, by postoperative day 3, the test group reported significantly lower pain scores (3.942 ± 2.325) compared to the control group. This trend continued on postoperative day 5, with the test group scoring 1.742 ± 1.421 against the control group's 3.11 ± 1.5. At one month, the test group's pain scores further decreased to 1.428 ± 1.786 compared to the control group's 2.4 ± 2.0. At three months, although pain scores were lower in the test group (1.31 ± 1.2) than in the control group, the difference was not statistically significant due to an outlier in the test group.

Our research findings align with previous studies Avinash Jose et al. and Dr. Karthikeyan et al.[91,97], further strengthening the evidence for the effectiveness of self-retaining meshes in hernia repair procedures. These findings highlight the importance of widely implementing these meshes and fixation methods for better outcomes.

The incidence of complications, including seroma, hematoma, and infections did not differ significantly between the groups [94]. This underscores the safety of the self-fixing mesh. Seroma rates at postoperative day 3 were 3 in the control group and 2 in the test group, while hematoma rates were 1 in the control group and 2 in the test group.

TABLE 26. COMPARATIVE ANALYSIS OF PRESENT STUDY WITH PREVIOUS SIMILAR STUDIES

Parameter	**Present Study**		**Avinash Jose et al.**		**Dr. Karthikeyan et al.**		**Pikli Batabyal et al.**	**Gautham Gunasekaran et al.**	
Type of study	**Randomised control study**		**Prospective observational study**		**RCT**		**RCT**	**RCT**	
Number of participants	**n= 70**		**n=120**		**n=40**		**n=540**	**n= 50**	
Study groups	**Test group**	**Control group**	**Test group**	**Control group**	**Test group**	**Control group**		**Test group**	**Control group**
Age Distribution	55.86 years	50.63 years	50 and 60 years		35.7 years	29.15 years	63 years.	55 years	48 years
Gender	Male (100%)		Male (93.3%)	Male (96.7%)	Predominantly male		Male (89%)	Predominantly male	
Predisposing Factors	Heavy weight lifting and chronic cough		Heavy weight lifting and chronic cough		Not mentioned		Not mentioned	Not mentioned	
Clinical examination	No significant differences		Not mentioned		No significant differences		No significant differences	Right side >left side with no significant differences	
Operative Time	68.77 minutes	82.8 minutes	31.17 minutes	41.75 minutes.	40-45 minutes	50-70 minutes	40 minutes test group, 50 minutes control group	Significantly lower (p value: 0.005)	
Postoperative Pain	Pain was higher among the Conventional Mesh group ($p<0.05$) on POD 3, POD 5, 1 month and 3 months.		Pain scores were significantly lower at 15 days, 3 months and 6 months, p value= 0.01		Pain was higher among the Conventional Mesh group ($p<0.05$).		P =04	Not statistically significant (p value: 0.114, 0.07 on POD 0, POD1, POD2)	
Complications	Seroma: 3 in control, 2 in test groups. Hematoma: 1 in control group. Infection: Nil		Nil		n=2, 10%	n=5, 25%	7.4%.	Seroma in 1 patient in control group, not statistically significant	

This indicates a low occurrence of these complications in our study, which aligns with previous research findings (Chastan et al., 2012)[94]. Our findings are consistent with previous research, which also documented low rates of these complications after hernia repair surgeries. These findings suggest that the new mesh is comparable to conventional mesh in terms of surgical site complications and suggest that this new method can be a very good alternative to conventional mesh.

Both groups demonstrated comparable wound healing as assessed by the Southampton scoring system, suggesting that their postoperative recovery paths were comparable. This emphasises the trustworthiness of our findings and highlights the significance of ongoing monitoring of postoperative complications to improve patient care and surgical outcomes in the long run.

There were no recurrences noted in either group over the follow up period of three months.

Limitations: Though our study was conducted in rigorous and meticulous ways and is a randomised control study, there are a few limitations to be noted. Small sample size, heterogeneity of surgical expertise of surgeons, short follow-up period and single centre study to be noted.

CONCLUSION

In conclusion, this study examined the effectiveness of two different types of mesh in the surgical treatment of inguinal hernias. One was a traditional polypropylene mesh, while the other was a self-fixing bio-compatible mesh composed of polyester monofilament and polylactic acid (PLA).

There was a notable decrease in immediate pain in the novel self-gripping bio component mesh group, accompanied by a quicker resumption of daily activities because of the same.

There was a notable decrease in operative time in the self fixing mesh group.

Regarding perioperative outcomes, though statistically insignificant, there is a decrease in the incidence of seroma and hematoma, with similar rates of infection indicating it is a good alternative to the conventional methods.

The self-gripping mesh group also experienced a substantial decrease in chronic groin pain after 3 months, leading to an enhanced quality of living in these patients.

Additional follow-up studies could provide more insight into the impacts of self-gripping bio component mesh over polypropylene sutured mesh in the future.

SUMMARY

The study conducted a thorough comparison between two types of meshes used in inguinal hernia repair: the traditional polypropylene mesh fixed with sutures and the self-adhesive bio-component mesh (Polyester Monofilament and Polylactic Acid). This comparison involved 70 patients, divided equally into two groups. The control group underwent hernioplasty with the polypropylene mesh fixed with sutures, while the test group used the self-adhesive bio-component mesh. Several metrics were evaluated to determine the effectiveness and benefits of each mesh type, including operative time, post-operative pain, and complications such as seroma, hematoma, and infections.

The age distribution in the control group ranged from 23 to 76 years, with a mean age of 50.63 years, while in the test group, the ages ranged from 19 to 84 years, with a mean age of 55.86 years.

Both groups were entirely male. The distribution of hernia types (indirect and direct) was similar between the groups (p=0.348), ensuring a balanced comparison.

Operative time was significantly reduced in the test group, averaging 68.77 ± 15.13 minutes, compared to 82.80 ± 12.86 minutes in the control group (p=0.001). This reduction is attributed to the elimination of suturing time required for mesh fixation in the traditional method.

The test group consistently reported lower pain scores across all time points compared to the control group. On postoperative day 0, pain scores were similar between both groups, with the control group recording an average score of 6.628 ± 2.590 and the test group recording 6.485 ± 2.671 (p=0.821). However, by postoperative day 3, the test group reported significantly lower pain scores (3.942 ± 2.325) compared to the control group (p=0.001). This trend

continued on postoperative day 5, with the test group scoring 1.742 ± 1.421 against the control group's 3.11 ± 1.5 (p=0.001). At one month, the test group's pain scores further decreased to 1.428 ± 1.786 compared to the control group's 2.4 ± 2.0 (p=0.001). At three months, although pain scores were lower in the test group (1.31 ± 1.2) than in the control group, the difference was not statistically significant (p=0.348) due to an outlier in the test group. On applying non-parametric tests, results at 3 months were significant (p=0.0175) .

The incidence of complications, including seroma, hematoma, and infections, did not differ significantly between the groups, underscoring the safety of the self-fixing mesh. Seroma rates at postoperative day 3 were 3 in the control group and 2 in the test group (p=0.614), while hematoma rates were 1 in the control group and nil in the test group (p=0.731).

Both groups demonstrated comparable wound healing as assessed by the Southampton scoring system.

No hernia recurrences were reported in either group throughout the three month follow-up period.

The self-fixing bio-component mesh offers significant advantages over the traditional polypropylene mesh fixed with sutures. These benefits include reduced operative time and lower short-term postoperative pain, enhancing patient recovery and comfort. The comparable complication rates and absence of hernia recurrences within the study period further support the efficacy and safety of the self-adhesive mesh. These findings suggest that the self-adhesive bio-component mesh could be a superior alternative to traditional methods, though further long-term studies are recommended to confirm these benefits over extended follow-up periods.

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ANNEXURE 1- INFORMED CONSENT FORM

"**Inguinal Hernioplasty using bio component mesh (Polyester monofilament and polylactic acid) Vs. Polypropylene mesh: A one year Randomized control study,**"

Name of Student/Principal Investigator: _____

Name of Guide/Co Investigators: _____

- **INTRODUCTION**

Inguinal hernia is one of the most commonly performed surgeries in the world. Since the beginning of the modern surgery, the hernia repair has undergone several modifications. Currently Lichtenstein repair remains the gold standard next to laparoscopic repair. Post-operative pain is a disabling complication of inguinal hernia repair. Sutures that are used to anchor the mesh are blamed for tissue tension and nerve entrapment leading to postoperative pain i.e. inguinodynia. This has led to the replacement of traditional suture based repair with the newer modifications such as non absorbable sutures, absorbable sutures, and usage of glue and has today come to self-fixating systems.

Self retaining mesh is known to offer better comfort after surgery. It also gives the surgeons the ability to accurately position and secure the mesh within a short span of 60-120 seconds. This may help in the reduction of overall surgery time. The polyester mesh is macro porous and contains resorbable polylactic acid (PLA) micro-grips on one side. This helps to quickly secure the mesh without the need for sutures, fibrin glue, tacks or any form of fixation. Hence this hypothesis needs to be tested that return to normal activities would be shortest and postoperative pain would be lesser after inguinal hernia repair when there are no permanent sutures fixing the mesh.

Objective: To evaluate the postoperative pain in inguinal hernia repair patients with prolene mesh repair Vs. biocomponent polyester + polylactic acid self fixing mesh repair.

Explanation of procedure: This prospective randomized control study comprised of 70 cases of inguinal hernia which will be randomly divided into two groups of 35 each named group A and group B. Group A includes Lichtenstein's repair using conventional mesh and group B includes Lichtenstein's repair using self- retaining mesh . Written and Informed Consent will be obtained for taking part in study and for operative procedure. Patient's history and examination will be recorded in detail. Time period for surgery in each patient will be noted for comparison. Each group will be compared postoperatively for pain and complications.

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 have nor get any benefits by participating in this study. The data gathered will help the 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 from identifying 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.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes 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:"_____" If you have any question or complaints with regard to your right as study participant you may contact Dr _____

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 **"Inguinal Hernioplasty using bio component mesh (Polyester monofilament and polylactic acid) Vs. Polypropylene mesh: A one year Randomized control study,**".

1. I confirm that I have read and understood the information sheet for the above study and have had the opportunity to ask questions.
2. I understood that my participation in the study is voluntary and that I am free to withdraw any time, without giving any reason, without my medical care or legal rights being affected.
3. I understood that sponsor and others working on the sponsor's behalf, The Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of current study and at any further research that may be conducted in relation to it, even if I withdraw from the study. I agree to this. However I understood that my identity will not be revealed in any information released to third parties or published.
4. I agree to restrict the use of any data or results that arise from this study provided such a use for scientific purposes.
5. I agree to take part in the above study.

Signature or left thumb impression of the participant

Name of the participant:

Signature or left thumb impression of witness

Name of the witness:

Signature of the investigator

Name of the investigator

ANNEXURE 2- PROFORMA

SCREENING

Screening No. ☐☐

Enrollment No./IP No. ☐☐☐☐☐☐☐☐

Date of Screening ☐☐ ☐☐ ☐☐☐☐

First Name ☐☐☐☐☐☐☐☐

Middle Name ☐☐☐☐☐☐☐

Last Name ☐☐☐☐☐☐☐☐

Age (Years) ☐☐

Address

House No. ☐☐☐☐☐

Street ☐☐☐☐☐☐☐☐☐

Taluka ☐☐☐☐☐☐☐☐☐

District ☐☐☐☐☐☐☐☐☐

Phone No.1 ☐☐☐☐☐☐☐☐☐☐

Phone No.2 ☐☐☐☐☐☐☐☐☐☐

Patient with uncomplicated inguinal hernia:

- Yes ☐
- No ☐

Patient age above 18:

- Yes ☐
- No ☐

Applicant is willing to give consent

- Yes ☐
- No ☐

Patient undergoing open inguinal hernia repair:

- Yes ☐
- No ☐

Patient has no associated illness or complications:

- Yes ☐
- No ☐

FINAL RESULT

- Ineligible
- Eligible but refused
- Eligible and participating

PROFORMA

Name:

DOA:

Age: YEARS

Sex:

Occupation:

Address:

H No.

Street

Taluka

District

Phone No.1

Phone No.2

CHIEF COMPLAINTS

Swelling – ☐

Pain – ☐

Duration-months ☐

H/O PRESENT ILLNESS:

Swelling-☐

Does it disappear spontaneously on lying down-? ☐

Pain – 1.dragging ☐ 2.aching ☐

Systemic symptoms - colicky abdominal pain ☐

Vomiting/nausea- ☐

Abdominal distension- ☐

Absolute constipation- ☐

Chronic cough- ☐

Frequency/difficulty in micturition- ☐

H/o heavy weight lifting- ☐

PAST HISTORY:

H/O Similar episodes before- ☐

H/O DM / HTN / BA / TB ☐

H/O previous surgery - ☐

h/o inguinal hernia repair done on same/opposite side- ☐

PERSONAL HISTORY:

Smoker - ☐

Alcoholic- ☐

Bowel – 1.NORMAL ☐ 2.CONSTIPATED ☐

GENERAL PHYSICAL EXAMINATION:

Nutritional status- 1.WELL BUILT ☐ 2.POORLY BUILT ☐

Pallor - ☐

Icterus- +/- ☐

Cyanosis/ clubbing/ oedema- ☐

Generalized/ regional lymphadenopathy - ☐

Pulse rate- ☐☐☐ BPM

Blood pressure- ☐☐☐/☐☐☐

LOCAL EXAMINATION:

Inspection -

o Swelling – ☐

o Impulse on coughing ☐

Central penis- ☐

Palpation – Position_____ and extent_____ ☐

Impulse on coughing - zieman's technique- ☐

Reducibility ☐

Ring occlusion test ☐

Percussion - dull ☐ resonant ☐

Auscultation – for bowel sounds - ☐

P/R – Prostatomegaly- ☐

PER ABDOMEN-

SOFT ☐

NON TENDER ☐

BOWEL SOUNDS

CARDIO VASCULAR SYSTEM – normal- ☐

RESPIRATORY SYSTEM – normal- ☐

CENTRAL NERVOUS SYSTEM –normal ☐

DIAGNOSIS:

INVESTIGATIONS: routine- ☐

USG/CT- ☐

TREATMENT:

IV broad spectrum antibiotics- ☐

TYPE OF ANAESTHESIA: 1.spinal ☐ 2.general anaesthesia ☐

THERAPEUTIC PROCEDURE:

- 1.PROLENE MESH WITH SUTURES ☐
- 2.POLYLACTICACID SELF GRIPPING MESH ☐

Operative time- ☐☐☐ minutes.

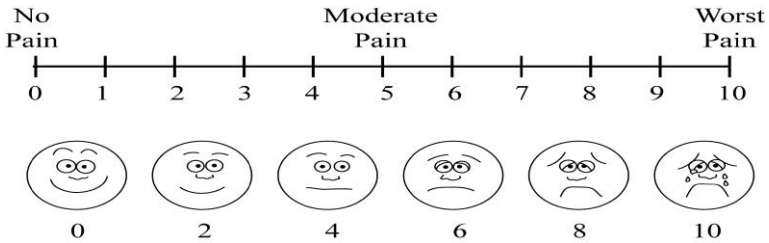
IV fluids- ☐

OUTCOME EVALUATION IN THE POSTOPERATIVE PERIOD:

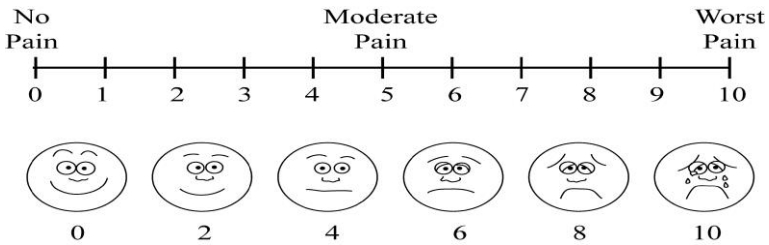
Pain:

1. IV analgesics ☐☐
2. ORAL analgesics ☐☐
3. EPIDURAL topups ☐☐
4. TRANSDERMAL PATCH in days ☐☐

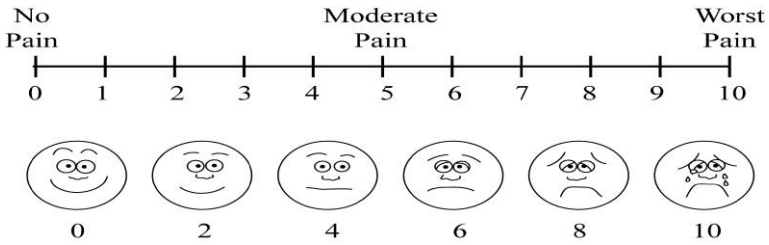
a. Acute pain: immediate post op: VAS on POSTOPERATIVE DAY ZERO



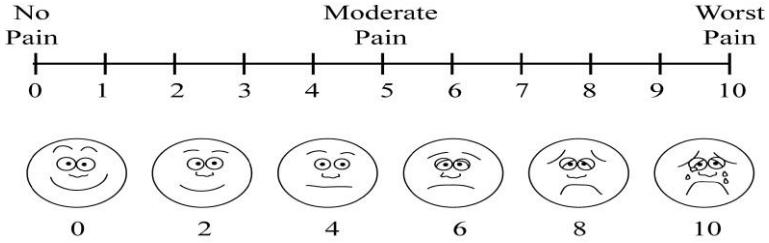
c. VAS on POSTOPERATIVE DAY THREE:



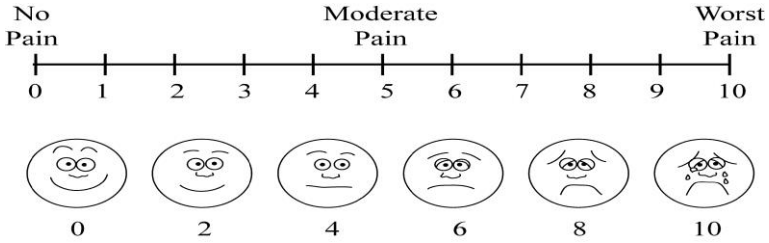
d. VAS on POSTOPERATIVE DAY FIVE:



e. VAS at one month visit:



f. VAS at three months visit :



COMPLICATIONS/ Surgical site infections:

	POSTOPERATIVE DAY THREE	POSTOPERATIVE DAY FIVE	POSTOPERATIVE DAY SEVEN
HEMATOMA			
SEROMA			
INFECTION			

SOUTHHAMPTON GRADING SCORE:

ANNEXURE 3 - PHOTOGRAPHS

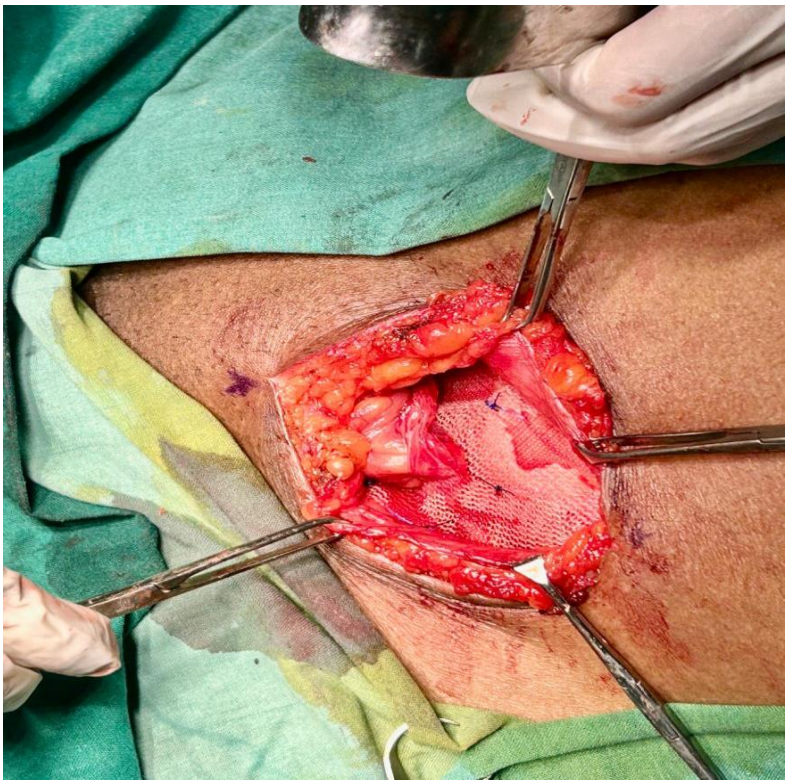


IMAGE 2. PLACEMENT OF POLYPROPYLENE MESH WITH PROLENE 1-0 SUTURES ON THE LEFT SIDE INGUINAL HERNIA REPAIR:

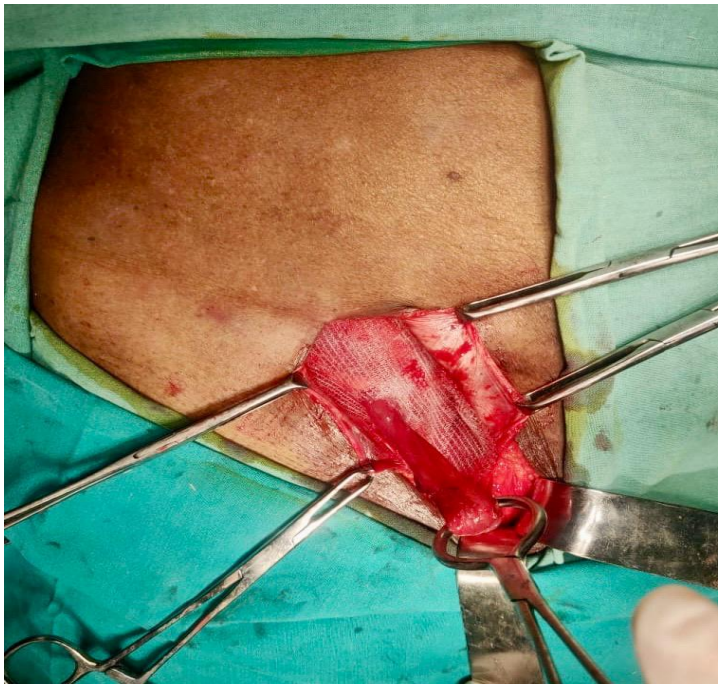


IMAGE 3. PLACEMENT OF SELF FIXING BIO COMPONENT POLYLACTIC ACID + POLYESTER MESH IN RIGHT INGUINAL HERNIA

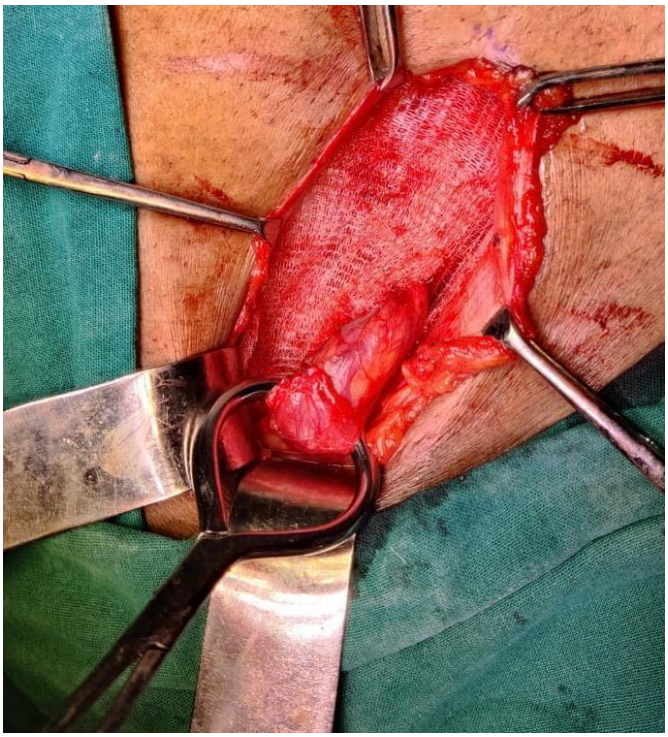


IMAGE 4. PLACEMENT OF SELF FIXING BIO COMPONENT POLYLACTIC ACID + POLYESTER MESH IN LEFT INGUINAL HERNIA

CONTROL GROUP **TEST GROUP**

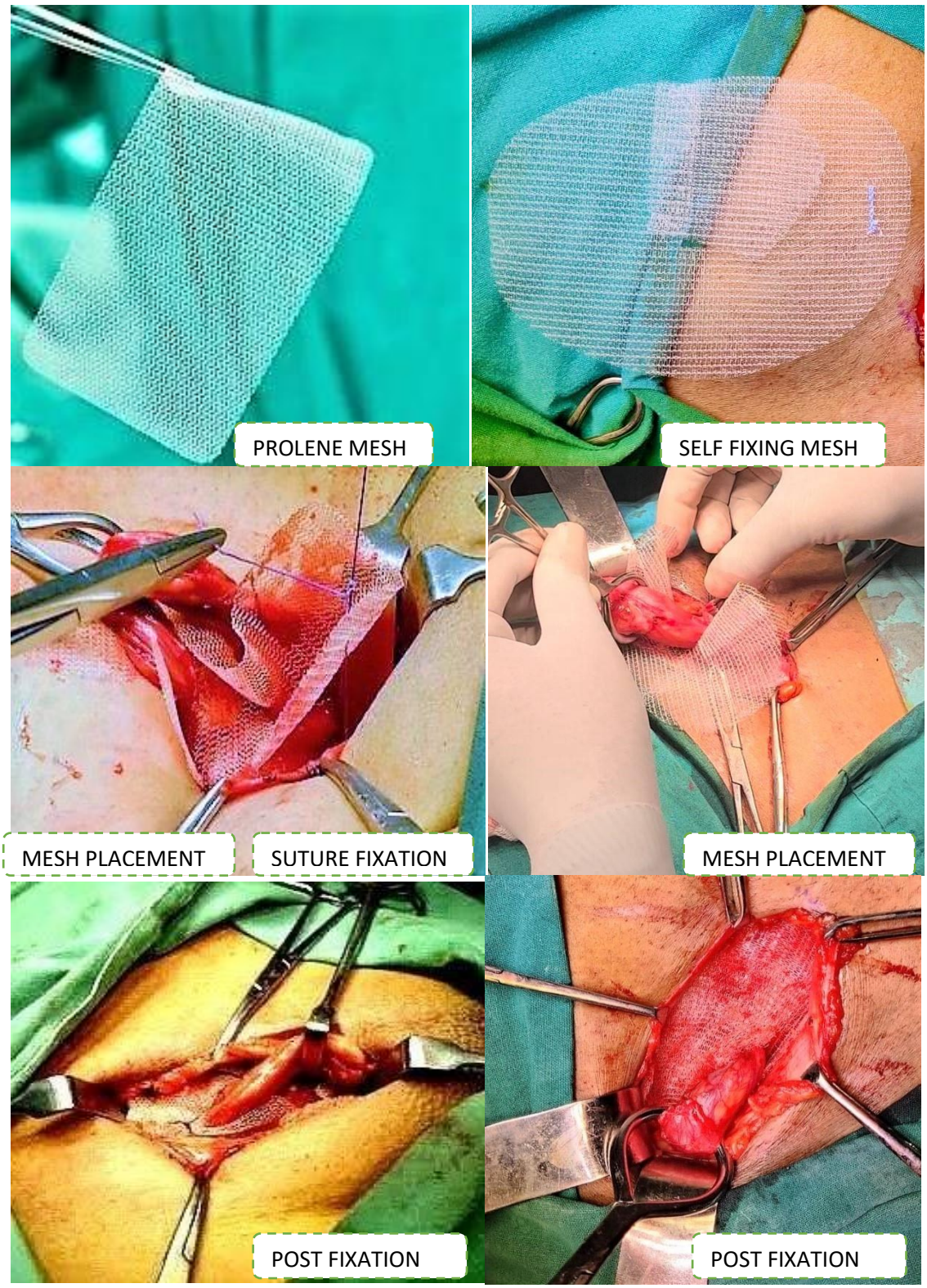


IMAGE 5. COMPARISION OF CONTROL GROUP AND TEST GROUP: MESHES, MESH FIXATION AND POST FIXATION PHOTOGRAPHS.

ANNEXURE 4- KEY TO MASTER CHART

- ✓ Sl. No. –Serial number
- ✓ Age: in years
- ✓ M- Male
- ✓ F- Female
- ✓ I – Present
- ✓ II – Absent
- ✓ H/O – History of
- ✓ T2DM – Type 2 Diabetes mellitus.
- ✓ HTN – Hypertension
- ✓ TB – Tuberculosis
- ✓ BA- Bronchial Asthma
- ✓ COPD – Chronic obstructive pulmonary disease.
- ✓ R- Right sided
- ✓ L- Left sided
- ✓ i – Indirect inguinal hernia
- ✓ d – Direct inguinal hernia
- ✓ mm- Millimetre
- ✓ IV- Intravenous
- ✓ VAS- Visual analogue score
- ✓ POD– Postoperative Day
- ✓ C – Complete
- ✓ IC – Incomplete
- ✓ B – Bowel
- ✓ O – Omentum
- ✓ M – Mesentery
- ✓ OT time - Operative time
- ✓ BL – Bilateral
- ✓ USG – Ultrasonography

ANNEXURE 5 - MASTER CHART

TEST GROUP:

SL. NO	DEMOGRAPHIC DATA				RISK FACTORS						PROSTATOMEGALY	COMORBIDITIES			
	IP NO.	AGE	GENDER	OCCUPATION	H/O HEAVY WEIGHT LIFTING	CHRONIC COUGH	H/O HERNIA BEFORE	DIFFICULTY IN MICTURITION	SMOKER	CONSTIPATION		HTN	T2DM	TB	BA/COPD
1	1158129	60	M	Farmer	I	II	II	II	II	II	II	II	II	II	II
2	1162342	79	M	Unemployed	II	II	II	II	II	II	Grade I	II	II	II	II
3	1163941	60	M	Farmer	I	II	II	II	II	II	Grade I	II	II	II	II
4	1165031	48	M	Tailor	I	II	II	II	I	II	Grade II	I	I	II	II
5	1171128	48	M	Driver	II	II	II	II	II	II	II	II	II	II	II
6	1172525	38	M	Electrician	I	II	II	II	II	I	II	II	II	II	II
7	1175288	62	M	Wine shop	I	I	II	II	II	I	II	II	II	II	II
8	1209331	52	M	Shopkeeper	II	II	I	II	II	II	II	II	II	II	II
9	10009225	60	M	Farmer	II	II	II	II	II	II	II	II	II	II	II
10	10007443	69	M	Poultry	I	II	II	II	II	II	Grade II	II	II	II	II
11	1163742	48	M	Labourer	II	II	II	II	I	II	II	II	II	II	II
12	10013890	56	M	Teacher	I	II	II	I	II	II	II	II	II	II	II
13	10020584	84	M	Farmer	I	I	II	II	II	I	Grade II	I	II	II	II
14	10031247	70	M	Shopkeeper	II	II	II	II	II	II	II	II	II	II	II
15	10038905	67	M	Tailor	II	II	I	II	II	I	II	II	II	II	II
16	10043813	74	M	Labourer	I	I	II	II	II	II	Grade I	II	II	II	II
17	10043763	55	M	Farmer	II	II	II	II	II	II	II	I	I	II	II
18	10046797	19	M	Student	II	II	II	II	II	II	II	II	II	II	II
19	10046728	38	M	Teacher	II	II	II	II	II	II	II	II	II	II	II
20	10046838	59	M	Farmer	I	I	I	I	I	I	II	II	II	II	II
21	10046846	50	M	Clerk	II	I	II	II	II	II	II	II	II	II	II
22	10048507	62	M	Factory worker	II	II	II	II	II	I	II	II	II	II	II
23	10049836	58	M	Auto repair	I	II	II	II	II	I	II	II	II	II	II
24	10050468	64	M	Unemployed	I	II	II	I	I	II	II	II	I	II	II
25	10050979	52	M	Goldsmith	II	II	I	II	I	II	II	II	I	II	II
26	10055371	20	M	Policeman	I	II	I	II	II	II	II	II	II	II	II
27	10011720	45	M	Officer	II	II	II	II	I	II	II	II	II	II	II
28	10032280	40	M	Dairy	II	II	II	II	II	II	II	II	II	II	II
29	10038830	58	M	Auto driver	II	II	II	II	II	I	Grade I	II	I	II	II
30	10041918	63	M	Security	II	II	II	II	II	II	II	II	II	II	II
31	10044243	73	M	Textile shop	II	I	II	II	I	I	II	I	I	II	II
32	10044237	79	M	Unemployed	II	I	I	II	II	II	Grade I	I	I	II	II
33	10049836	37	M	Barber	II	II	II	II	II	II	II	I	II	II	II
34	10052699	46	M	Technician	I	II	II	II	II	II	II	II	II	II	II
35	10028182	62	M	Painter	II	II	I	II	II	I	II	II	II	II	II

SL. NO	CLINICAL DIAGNOSIS					USG		OT TIME	ANALGESIC DOSES				VISUAL ANALOGUE SCALE					SEROMA			HEMATOMA			INFECTION			SOUTHHAMPTON SCORING SYSTEM
	SIDE(R/L/BL)	TYPE(d / i/ d+i)	COMPLETE	REDUCIBILE	CONTENT	DEFECT SIZE (IN MM)	CONTENT		IV	ORAL	PATCH	EPIDURAL	POD0	POD3	POD5	1MONTH	3MONTH	POD3	POD5	POD7	POD3	POD5	POD7	POD3	POD5	POD7	
1	R	i	C	I	B	33	B	60	6	6	0	0	6	5	2	2	1	II	II	II	II	II	II	II	II	II	0
2	L	i	IC	I	B	18	B	70	6	4	0	0	6	1	1	1	1	II	II	II	II	II	II	II	II	II	0
3	BL	i	C	I	B	41	B	78	4	4	0	0	7	7	4	3	1	II	II	II	II	II	II	II	II	II	1
4	R	d	IC	I	O	18	O	68	15	25	5	3	8	8	8	10	10	II	II	I	II	II	II	II	II	II	3
5	L	d	IC	I	O	11	M	75	4	9	0	0	1	1	0	0	0	II	II	II	II	II	II	II	II	II	0
6	L	i	IC	I	O	##	##	60	7	8	0	0	10	4	2	2	2	II	II	II	II	II	II	II	II	II	1
7	R	i	IC	I	O	20	M	78	6	8	0	0	8	5	3	3	0	II	II	II	II	II	II	II	II	II	0
8	R	d	IC	I	O	10	O	90	8	10	0	0	3	4	2	2	0	II	II	II	II	II	II	II	II	II	1
9	L	i	IC	I	O	15	M	60	7	10	0	0	7	6	2	2	2	II	II	II	II	II	II	II	II	II	1
10	L	d	IC	I	O	7	O	69	8	6	0	0	3	2	2	2	1	II	II	II	II	II	II	II	II	II	1
11	L	i	IC	I	B	22	B	76	12	10	0	0	9	7	2	1	0	II	II	II	II	II	II	II	II	II	0
12	R	i	IC	I	B	##	##	75	12	12	0	0	2	4	2	2	0	II	II	II	II	II	II	II	II	II	0
13	L	i	IC	I	B	72	B+O	70	8	8	0	0	9	6	2	1	0	II	II	II	II	II	II	II	II	II	0
14	R	i+d	IC	I	B	18	B	80	9	12	0	0	8	4	1	0	0	II	II	II	II	II	II	II	II	II	0
15	L	i	IC	I	B	23	B+O	60	6	10	0	0	9	5	1	1	1	II	II	II	II	II	II	II	II	II	0
16	R	i	IC	I	B	20	B+O	58	8	10	0	0	9	6	1	0	0	II	II	II	II	II	II	II	II	II	1
17	L	d	IC	I	O	8	O	65	10	10	0	0	9	8	1	0	0	II	II	II	II	II	II	II	II	II	1
18	L	i	IC	I	O	##	##	45	6	10	0	0	3	3	1	0	0	II	II	II	II	II	II	II	II	II	0
19	R	i	IC	I	O	18	M	50	6	10	0	0	5	4	1	1	1	II	II	II	II	II	II	II	II	II	0
20	L	d	IC	I	O	12	O	50	6	10	3	0	9	0	0	0	0	II	II	II	II	II	II	II	II	II	1
21	R	d	IC	I	B	18	B+O	45	6	10	0	0	8	5	3	3	3	II	II	II	II	II	II	II	II	II	0
22	R	d	IC	I	O	18	M	60	12	12	0	3	9	2	2	2	1	II	II	II	II	II	II	II	II	II	1
23	R	i	C	I	B	35	B	60	8	12	0	0	10	9	2	1	1	II	II	II	II	II	II	II	II	II	0
24	R	i	IC	I	O	13	B+O	56	8	12	0	0	5	1	1	0	0	II	II	II	II	II	II	II	II	II	1
25	R	i	IC	I	O	23	O	50	12	12	0	0	2	4	1	0	0	II	II	II	II	II	II	II	II	II	0
26	L	d	IC	I	O	7	O	90	4	14	5	0	10	4	2	2	2	II	II	II	II	II	II	II	II	II	0
27	R	i	IC	I	O	10	M	86	10	14	0	0	6	3	0	0	1	II	II	II	II	II	II	II	II	II	0
28	L	i	IC	I	O	12	O	88	8	12	0	3	4	5	1	1	1	II	II	II	II	II	II	II	II	II	1
29	R	i	IC	I	O	15	O	90	4	10	0	0	8	2	2	1	0	II	II	II	II	II	II	II	II	II	1
30	R	d	IC	I	O	10	M	95	4	12	0	0	9	3	2	2	2	II	II	II	II	II	II	II	II	II	1
31	R	d	IC	I	O	9	O	60	10	14	5	0	6	2	1	1	1	II	II	II	II	II	II	II	II	II	0
32	L	i	C	I	B	25	B+O	50	8	10	0	0	6	1	1	0	0	II	II	II	II	II	II	II	II	II	0
33	R	i	IC	I	O	18	O	75	6	6	0	0	3	0	0	0	0	II	II	II	II	II	II	II	II	II	0
34	R	d	IC	I	O	14	O	70	6	6	0	0	3	5	3	2	1	II	II	II	II	II	II	II	II	II	0
35	R	i	IC	I	O	12	O	95	6	6	0	2	7	2	2	2	2	II	II	II	II	II	II	II	II	II	0

CONTROL GROUP:

SL. NO	DEMOGRAPHIC DATA				RISK FACTORS						PROSTATOMEGALY	COMORBIDITIES			
	IP NO.	AGE	GENDER	OCCUPATION	H/O HEAVY WEIGHT LIFTING	CHRONIC COUGH	H/O HERNIA BEFORE	DIFFICULTY IN MICTURITION	SMOKER	CONSTIPATION		HTN	T2DM	TB	BA/COPD
1	1156238	24	M	Driver	I	II	II	II	II	I	II	II	II	II	II
2	1156720	68	M	Carpenter	I	I	II	II	I	I	Grade I	I	II	II	II
3	10034518	59	M	Vendor	I	I	II	II	I	II	Grade I	II	II	II	II
4	1159140	59	M	Farmer	I	II	II	II	II	I	II	I	I	II	II
5	10011520	72	M	Unemployed	II	II	II	I	II	II	Grade II	II	II	II	II
6	10020567	53	M	Labourer	I	II	I	II	II	II	II	II	II	II	II
7	10031034	50	M	Buisiness	I	II	I	I	II	II	II	II	II	II	II
8	10031126	49	M	Teacher	II	II	II	II	II	II	II	II	II	II	II
9	10030796	58	M	Autoshop	I	II	II	II	I	I	II	II	I	II	II
10	10035518	69	M	Carpenter	I	I	II	II	I	II	Grade I	II	II	II	II
11	10030957	47	M	Farmer	I	II	II	II	II	II	II	II	I	II	II
12	1141256	56	M	Farmer	I	II	II	II	I	II	II	II	II	II	II
13	1135298	65	M	Salesman	I	I	II	II	I	I	II	II	I	II	II
14	1135423	60	M	Farmer	I	II	II	II	II	II	II	I	II	II	II
15	1135277	73	M	Unemployed	I	II	II	II	I	II	Grade I	I	I	II	II
16	1175131	23	M	Student	II	II	II	II	II	II	II	II	II	II	II
17	1173750	48	M	Buisiness	II	II	II	II	II	II	II	II	II	II	II
18	1186688	29	M	Engineer	II	II	II	II	II	II	II	II	II	II	II
19	10048269	57	M	Office	II	II	II	I	II	I	Grade I	I	I	II	II
20	10046534	58	M	Vendor	I	I	II	II	I	II	II	II	II	II	II
21	10049619	60	M	Security	II	II	II	II	II	I	Grade I	II	II	II	II
22	10034056	50	M	Plumber	I	II	II	II	II	I	II	II	II	II	II
23	10034040	25	M	Cook	II	II	II	II	II	II	II	II	II	II	II
24	1187892	32	M	Shopkeeper	II	II	II	II	I	II	II	II	II	II	II
25	10009547	29	M	Farmer	I	II	II	II	II	I	II	II	II	II	II
26	1009771	46	M	Weight	I	II	II	II	II	II	II	II	II	II	II
27	10010937	76	M	Carpenter	I	II	II	II	I	II	Grade I	I	I	II	II
28	10011169	26	M	Student	II	II	II	II	II	II	II	II	II	II	I
29	10013580	60	M	Unemployed	II	II	II	I	II	I	Grade II	II	II	II	II
30	10016355	54	M	Shopowner	II	II	II	II	II	II	II	I	I	II	I
31	10020333	29	M	Teacher	II	II	II	II	II	II	II	II	II	II	II
32	10003498	67	M	Farmer	II	II	II	II	II	II	II	I	II	II	II
33	10041302	47	M	IT	II	II	II	II	II	II	II	II	II	II	II
34	10003234	25	M	Clerk	II	II	II	II	I	II	II	II	II	II	II
35	10046908	69	M	Unemployed	II	I	II	II	I	II	Grade I	I	II	II	II

SL. NO	CLINICAL DIAGNOSIS					USG		OT TIME	ANALGESIC DOSES				VISUAL ANALOGUE SCALE					SEROMA			HEMATOMA			INFECTION			SOUTHHAMPTON SCORING SYSTEM
	SIDE(R/L/BL)	TYPE (d/i/d+i)	COMPLETE	REDUCIBILE	CONTENT	DEFECT SIZE (IN MM)	CONTENT		IV	ORAL	PATCH	EPIDURAL	POD0	POD3	P0D5	1MONTH	3MONTH	POD3	POD5	POD7	POD3	POD5	POD7	POD3	POD5	POD7	
1	L	i	C	I	B	22	B	100	8	4	0	0	10	6	4	4	2	II	II	II	II	II	II	II	II	II	0
2	R	d	IC	I	O	##	##	96	9	6	0	0	10	5	4	4	0	II	II	II	II	II	II	II	II	II	1
3	R	d	IC	I	O	15	O	110	10	10	5	0	10	9	5	2	2	II	II	II	II	II	II	II	II	II	1
4	R	i	IC	I	O	##	##	90	8	12	0	0	6	4	4	4	2	II	II	I	II	II	II	II	II	II	3
5	BL	d	IC	I	O	13	M	100	12	8	0	0	10	7	3	2	2	II	II	II	II	II	II	II	II	II	1
6	L	d	IC	I	O	26	M	98	12	10	0	0	9	4	3	3	3	II	II	II	II	II	II	II	II	II	0
7	L	i	IC	I	B	16	B	102	14	8	0	0	9	4	2	2	0	II	II	II	II	II	II	II	II	II	1
8	R	i	IC	I	O	22	M	104	12	8	0	0	9	5	3	2	2	II	II	I	II	II	II	II	II	II	3
9	BL	i	IC	I	O	23/25	O	95	16	8	0	0	10	8	6	5	0	II	II	II	II	II	II	II	II	II	0
10	R	d	IC	I	O	15	O	110	10	10	5	0	10	9	2	0	0	II	II	II	II	II	II	II	II	II	1
11	BL	d	IC	I	O	##	O	80	10	12	0	0	5	8	4	3	2	II	II	I	II	II	II	II	II	II	3
12	L	d	IC	I	O	8	O	80	4	8	0	0	8	9	3	2	2	II	II	II	II	II	II	II	II	II	1
13	BL	i	IC	I	O	10/6	O	90	6	10	0	0	7	7	4	4	1	II	II	II	II	II	II	II	II	II	1
14	R	i	C	I	B	18	B	70	6	10	0	0	8	8	1	1	1	II	II	II	II	II	II	II	II	II	0
15	R	d	IC	I	O	8	O	80	8	12	0	0	8	7	4	3	0	II	II	II	II	II	II	II	II	II	0
16	L	i	IC	I	O	10	O	68	8	10	5	0	6	7	3	2	1	II	II	II	II	II	II	II	II	II	1
17	L	i	IC	I	O	12	O	72	8	10	0	0	8	9	3	3	2	II	II	II	II	II	II	II	II	II	0
18	R	i	IC	I	B	20	B	76	4	6	0	0	6	5	2	0	0	II	II	II	II	II	II	II	II	II	1
19	BL	d	IC	I	O	8/7	O	70	10	10	0	0	10	3	3	3	1	II	II	II	II	II	II	II	II	II	1
20	L	d	IC	I	B	21	B	72	5	15	0	2	5	4	2	1	1	II	II	II	II	II	II	II	II	II	1
21	BL	d	IC	I	O	18/16	O	78	10	10	0	0	9	9	3	2	2	II	II	II	I	I	I	II	II	II	1
22	R	i	IC	I	O	##	##	82	6	8	0	0	6	4	2	0	0	II	II	II	II	II	II	II	II	II	0
23	R	i	IC	I	O	8	O	70	10	10	0	0	6	6	2	1	1	II	II	II	II	II	II	II	II	II	0
24	R	i	IC	I	O	8	O	76	10	10	0	0	3	6	2	1	1	II	II	II	II	II	II	II	II	II	0
25	R	i	IC	I	O	20	O	70	12	10	0	0	2	5	2	1	1	II	II	II	II	II	II	II	II	II	1
26	L	d	IC	I	O	17	O	72	12	10	0	0	3	5	3	2	2	II	II	II	II	II	II	II	II	II	0
27	L	d	IC	I	O	21	O	82	8	12	0	0	4	6	3	3	2	II	II	II	II	II	II	II	II	II	1
28	BL	d	IC	I	O	16/26	O	68	10	10	0	0	4	6	3	3	2	II	II	II	II	II	II	II	II	II	0
29	R	d	IC	I	B	28	B	75	8	10	0	0	4	6	4	4	2	II	II	II	II	II	II	II	II	II	1
30	L	i	IC	I	O	12	O	68	10	10	0	0	4	6	4	4	2	II	II	II	II	II	II	II	II	II	0
31	R	i	C	I	B	33	B	86	10	10	0	0	6	4	3	3	2	II	II	II	II	II	II	II	II	II	1
32	R	d	IC	I	O	29	O	80	8	10	0	0	4	7	5	5	2	II	II	II	II	II	II	II	II	II	1
33	R	d	IC	I	O	10	O	80	10	10	0	0	4	5	4	3	2	II	II	II	II	II	II	II	II	II	1
34	L	d	IC	I	O	20	B	70	10	10	0	0	7	6	2	1	1	II	II	II	II	II	II	II	II	II	1
35	R	d	IC	I	O	20	O	78	10	10	0	0	2	5	2	1	0	II	II	II	II	II	II	II	II	II	1