
“COMPARISON OF MODIFIED PROLENE HERNIA SYSTEM
REPAIR VERSUS CONVENTIONAL LICHTENSTEIN MESH
REPAIR FOR POST-OPERATIVE PAIN IN INGUINAL
HERNIAS - A RANDOMISED CONTROL TRIAL”.

REGISTRATION NO. : BH0108002

Dissertation

**SUBMITTED TO THE KLE UNIVERSITY BELGAUM,
KARNATAKA
IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR
THE DEGREE OF**

**MASTER OF SURGERY (M.S.)
IN
GENERAL SURGERY**

DEPARTMENT OF GENERAL SURGERY
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELGAUM-590010, KARNATAKA

MAY – 2011

**KLE UNIVERSITY BELGAUM,
KARNATAKA.**

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LIST OF ABBREVIATIONS

PHS = Prolene Hernia System

MPHS = Modified Prolene Hernia System

CLMR = Conventional Lichtenstein Mesh Repair

CGP = Chronic Groin Pain

VAS = Visual analogue score

ABSTRACT

Introduction

Inguinal hernioplasty is an evolving surgical solution to an age old problem. The most important criteria for the choice of method are safety (morbidity and mortality), recurrence rates and convenience for the patient and post-operative pain. The Lichtenstein “tension-free” mesh repair is currently the gold standard to which all other repairs are compared. The introduction of prolene hernia system has further revolutionised the field.

Objective

The aim of the study was to compare post-operative pain following Modified Prolene Hernia System repair against the conventional Lichtenstein’s mesh repair in repair of inguinal hernias. The post-operative pain is assessed on the basis of Visual Analogue Scale.

Methodology

The present one year randomized controlled trial was conducted in the Department of Surgery, KLES Dr. PrabhakarKore Hospital and Medical Research Centre, Belgaum on 60 patients with inguinal hernias during the period of December 2008 to December 2009. The patients were divided into two different groups by number randomization (Group 1 Modified Prolene Hernia System and Group 2 conventional Lichtenstein mesh repair). Post-operative pain was assessed at 2 weeks and then every 15 days upto 12 weeks by the Visual Analogue Scale.

Results

There was no statistical difference in the baseline characteristics like age distribution and side of hernia between the two groups. The pain in MPHS repair at 2 weeks was 5.7 ± 0.56 and at 12 weeks it was 1.0 ± 0.30 . In conventional Lichtenstein mesh repair mean pain score at 2 weeks was 5.9 ± 0.69 and at 12 weeks it was 1.1 ± 0.35 . P value was insignificant for every assessment of both groups.

Conclusions

The Modified Prolene Hernia System provides the benefits of both an anterior repair and posterior repair with the incidence of post-operative pain being same as the conventional Lichtenstein repair.

Key words : Prolene Hernia System, Lichtenstein tension-free repair, Modified Prolene Hernia System, Groin pain.

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INTRODUCTION

Inguinal hernioplasty is an evolving surgical solution to an age old problem. It is one of the most frequently performed operations in general surgery and so even modest improvements in clinical outcomes are important. The most important criteria for the choice of method are safety (morbidity and mortality), recurrence rates and convenience for the patient and post-operative pain.

The use of prosthetic meshes for open surgical repair of inguinal hernia has become increasingly popular in western countries as well as in India. Prosthetic meshes were first introduced in 1958 and have since evolved over the years. The Lichtenstein “tension-free” mesh repair is currently the gold standard to which all other repairs are compared. The Prolene Hernia System introduced in 1998 further revolutionized the field by providing a combined anterior and posterior repair with results similar to Lichtenstein’s repair. The only drawback of the Prolene Hernia System was the high cost involved especially in the setting of developing countries. This can be overcome by a few modifications in the technique such as the one proposed in this study.

For decades, long-term analysis of results of hernia repair concentrated on post operative pain and recurrence rates. More recently however, several studies have focused on aspects of chronic pain and quality of life after hernia repair. This technique differs from the Lichtenstein’s repair in only a few steps. Hence the study has been taken as an initiative to compare the post-operative pain after conventional Lichtenstein’s meshplasty against Modified Prolene Hernia System repair.

AIM OF THE STUDY

The aim of the study was to compare post-operative pain following Modified Prolene Hernia System repair against the conventional Lichtenstein's mesh repair in repair of inguinal hernias in KLES DR PRABHAKAR KORE HOSPITAL, BELGAUM. The post-operative pain is assessed on the basis of Visual Analogue Scale.

REVIEW OF LITERATURE

History¹

Since the dawn of surgical history, hernias have been the subject of interest and their treatment has evolved through distinct stages.

“The history of hernia is the history of surgery”.

I. Ancient times:-

The earliest reference to hernia has appeared in “Egyptian Papyrus of Ebers” (Circa 1552 BC).

II. Greeko Roman Medicine:-

Hippocrate has mentioned about hernia in the “Corpus Hippocraticum”. Herophilus, Erasstratus, Aulus Cornclius and Leonardo gave description of hernia operation with hemostasis by ligature of vessels and careful efforts to preserve the testicles. Later Galen of Pergamum, recommended the operation which consists of ligature of sac and cord with amputation of testicle.

III. The Middle Age (AD476 to 5th century)

Paulus Aegineta, Albucasis and Salerno gave accurate description of the operation for hernia. While William, rejected mutilation of testicle as essential part of the operation for the cure of hernia.

IV. The Renaissance (15th to mid 17th century)

Ambroise Pare in his book “The Apologic and Treatise” mentioned about treatment of rupture of hernias and described about diverse trusses for control of hernias. Pierre Franco gave the description of a radical operation which included original technique that left unharmed, the spermatic vessels and testis and also a

description of an operation for strangulated hernia. Kaspar Stromayer established the distinction between direct and indirect hernias.

V. Post Renaissance Era

Antonio Scarpa described about sliding hernia. Astely Paston Cooper of Norfolk, described about superior pubic ligament and fascia transversalis, with their role in pathogenesis of hernia.

VI. Nineteenth and Twentieth century

Edoardo Bassini, revolutionized the treatment of inguinal hernia by introducing the ‘Bassini’s repair’ while Marcy described about transabdominal approach and La Roque about the intrabdominal approach of inguinal hernia repair. George Loeithessen and Chester Mcvay described about the Cooper’s ligament repair.

VII. Contemporary times

Local anesthesia for the repair of hernias was reported by Harry Cushing who used field block anesthesia by cocaine infiltration. Shouldice, Obney and Ryan described about the Canadian experience in the repair of hernia in 1950, which was a layered reconstruction of posterior wall of inguinal canal. Concept of tension free repair was first introduced by Lichtenstein and colleagues in 1989 which is a prosthetic hernioplasty. Condon described the anterior iliopubic track repair using anterior approach through the inguinal canal.

During the 1990’s, with advances in laparoscopic technology, the laparoscopic inguinal hernia repair was introduced. Benefits from this repair included less pain and quicker return to activity. But the initial enthusiasm has recently subsided because of associated high cost, steep learning curve, more serious complications and necessity for general anesthesia.

In 1998, the Prolene Hernia System (PHS) mesh was introduced as an option for tension free open repair of inguinal hernias. In theory, this repair combines the benefit of a posterior and an anterior repair from an open approach. PHS mesh has been touted for the repair of direct, indirect and femoral hernias with extremely low recurrence rates.

Further advances in mesh technology have led to the introduction of Vypro, Ultrapro meshes with their own distinct advantages and disadvantages.

ANATOMY OF GROIN^{2,3}

The groin or inguinal region is a transitional area in which the thigh and the abdomen are joined.

The pelvic skeleton

The pelvic bones include the iliac bones, pubic bones and ischial bones which with sacrum forms a complete circle. These pelvic bones attached to the lumbar vertebral column via sacrum at approximately 60°.

Superficial fascia of anterior abdominal wall

The superficial fascia above umbilicus is single layer and contains fat. Below umbilicus, it divided into

- 1) Superficial fatty layer (fascia of Camper).
- 2) Deep membranous layer (fascia of Scarpa) which is continuous below with Colle's fascia and above umbilicus it merges with fatty layer.

The Fasciae contain -

- (a) Variable quantity of fat
- (b) Cutaneous nerves

- (c) Cutaneous vessels
- (d) Superficial lymphatics

Cutaneous nerves of anterior abdominal wall

- 1) Lower six thoracic nerves
- 2) First lumbar nerve (iliohypogastric)
- 3) Ilioinguinal nerve

Cutaneous arteries

- 1) Anterior cutaneous arteries, branches of superior and inferior epigastric arteries
- 2) Lateral cutaneous arteries, branches of lower intercostal arteries
- 3) Superficial inguinal arteries which supply lower abdomen,
 - a) Superficial epigastric artery
 - b) Superficial external pudendal artery
 - c) Superficial circumflex iliac artery

Cutaneous veins:

These veins accompany the arteries and the superficial inguinal veins drain into great saphenous vein.

Lymphatics

Lymphatics above the umbilicus, drain into the axillary lymph nodes and those below the umbilicus, drain into the superficial inguinal lymph nodes.

Anterior abdominal wall musculature

The muscle bundles and fibrous tissues are arranged in layers and each muscle is covered by fascia. The flat lateral abdominal muscles are inserted via a laminated aponeurotic sheet which further enhances integrity of abdominal wall. These laminae contribute to rectus sheath. Ultimately, it inserts in the midline, thereby forming the linea alba.

Muscles

- (1) External oblique muscle
- (2) Internal oblique muscle
- (3) Transverse abdominis
- (4) Rectus Abdominis
- (5) Cremaster muscle
- (6) Pyramidalis muscle

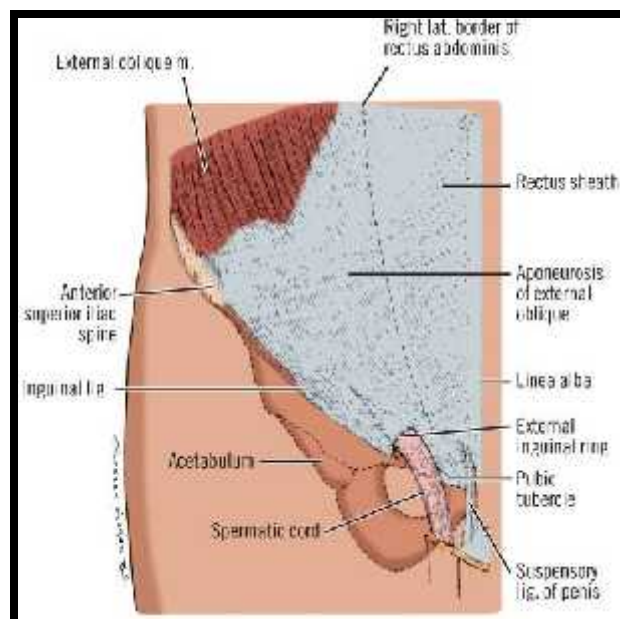


FIGURE 1 : MUSCLES OF ANTERIOR ABDOMINAL WALL

Ligaments And Fasciae

I. Inguinal Ligament -

Formed by lower border of the external oblique aponeurosis, is thickened and folded backward on itself which extends from anterior superior iliac spine to pubic tubercle. The lateral half is rounded and oblique, medial half is grooved upward and horizontal.

Extensions form:

- 1) Lacunar ligament
- 2) Ligament of Cooper
- 3) Lateral crus of superficial inguinal ring

II. Fascia Transversalis

It lines the inner surface of transverses abdominis and separates the anterior abdominal muscles from the peritoneum

Consists of 2 laminae:

- 1) Posterior Lamina
- 2) Anterior Lamina

Rectus Sheath

This is an aponeurotic sheath covering the rectus abdominis muscle. It has 2 walls, anterior and posterior.

a) Above the costal margin

Anterior wall -- External oblique aponeurosis

Posterior wall – Deficient, rectus rest directly on costal cartilage

b) Between costal margins and the arcuate line

Anterior wall – Aponeurosis of external oblique

Anterior lamina of the aponeurosis of internal oblique

Posterior wall – Posterior lamina of the aponeurosis of internal oblique

Aponeurosis of transverses muscle

c) Below the arcuate line (semi-lunar line of Douglas)

Anterior wall – Aponeurosis of all the three flat muscles of abdomen

Posterior wall – Deficient, rectus rests on fascia transversalis

Contents of rectus sheath

(A) Muscles – 1) Rectus abdominis

2) Pyramidalis muscle

(B) Arteries – 1) Superior epigastric artery

2) Inferior epigastric artery

(C) Vein – 1) Superior epigastric vein

2) Inferior epigastric vein

(D) Nerves – Terminal parts of lower six thoracic nerves.

INGUINAL CANAL

This is an oblique passage in the lower part of the anterior abdominal wall situated just above the medial half of inguinal ligament. It is about 4 cm (1.5 inches) long and is directed downwards, forwards and medially which extends from the deep inguinal ring to superficial inguinal ring.

Deep inguinal ring is an oval opening in the fascia transversalis situated half an inch (1.5 cms) above the midinguinal point.

Superficial inguinal ring is a triangular gap in the external oblique aponeurosis. It is shaped like an obtuse angled triangle. The base of triangle is formed by pubic crest. The two sides of the triangle forms lateral and medial margins of the opening. At and beyond the apex of the triangle the two crura unite by intercrural fibres.

Boundaries

A) Anterior wall – formed by

In its whole extent by - (1) skin (2) superficial fascia (3) external oblique aponeurosis

In its lateral 1/3 by - fleshy fibers of the internal oblique muscle.

B) Posterior wall – formed by

In its whole extent by - (1) The fascia transversalis (2) extra peritoneal tissue (3) The parietal peritoneum.

In its medial 2/3 by - conjoint tendon and reflected part of inguinal ligament

In its lateral 1/3 by - the interfoveolar ligament.

C) **Roof** – It is formed by the arched fibers of the internal oblique and transversus abdominis muscle.

D) **Floor** – It is formed by the grooved upper surface of the inguinal ligament and medial end by the lacunar ligament.

Structures passing through the canal

- 1) The spermatic cord in males or round ligament of uterus in females enters the inguinal canal through deep inguinal ring and passes out through superficial inguinal ring.
- 2) The ilioinguinal nerve enters the canal through the interval between external and internal oblique muscles and passes through superficial inguinal ring.

Constituents of spermatic cord

- 1) The ductus deferens
- 2) The testicular arteries, cremasteric arteries and artery of the ductus deferens
- 3) The pampiniform plexus of veins
- 4) The genital branch of genitofemoral nerve
- 5) The plexuses of sympathetic nerves around artery to Ductus deferens
- 6) Remnants of processus vaginalis

Coverings of spermatic cord

From within outwards –

- 1) Internal spermatic fascia derived from fascia transversalis and it covers the cord in its whole extent.
- 2) The cremasteric fascia consists of the muscle loops of cremasteric muscle and the intervening areolar tissue. It is made up of internal oblique and transverses abdominis muscles and covers the cord below the level of these muscles.
- 3) The external spermatic fascia is derived from external oblique aponeurosis and covers the cord below the superficial inguinal ring.

Hesselbach's triangle - It is a weak spot in the anterior abdominal wall through which the direct inguinal hernia protrudes. It is bounded

- 1) Medially by outer border of rectus abdominis muscle
- 2) Laterally by inferior epigastric vessels
- 3) Inferiorly by medial part of inguinal ligament.

The floor of this triangle is formed by fascia transversalis. This triangle is bisected by median umbilical fold which is formed by obliterated umbilical artery.

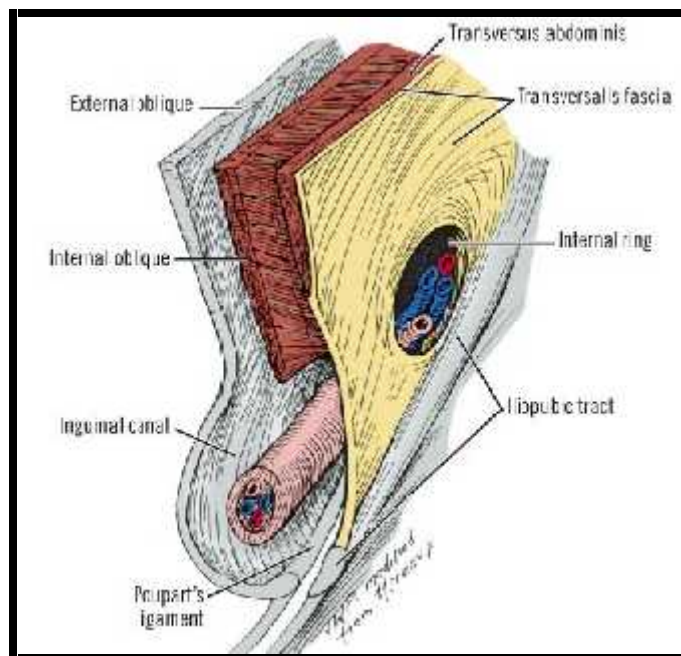


FIGURE 2 : CROSS SECTION OF INGUINAL CANAL

Mechanisms which prevent hernia in inguinal region⁴

The defensive mechanisms which prevent hernia to occur are -

- 1) The obliquity of the inguinal canal - When there is rise in intrabdominal pressure, the posterior wall is apposed against the anterior wall and thus prevents coming out of the abdominal content, through inguinal canal.

- 2) The shutter mechanism - The arched fibers of the internal oblique and the transverse abdominis will bring down these muscles towards the floor, when they contract during the rise of intra abdominal pressure.
- 3) The ball valve action of cremaster muscle - Cremaster pulls up the spermatic cord into the canal, which plugs it during a rise in intra abdominal pressure.
- 4) In floor of deep inguinal ring, there are strong fibers of internal oblique muscle; these prevent entry of the any abdominal contents through deep inguinal ring.
- 5) The strong conjoint tendon in front of Hesselbach's triangle prevents direct inguinal hernia.

INGUINAL HERNIA

An Inguinal hernia is the protrusion of part of the contents of the abdomen through the inguinal region of the abdominal wall.

Aetiology⁴

Mainly 2 factors play in the causation of a hernia

(I) Weakness of the abdominal musculature –

- This can be
- (a) Congenital
 - (b) Acquired.
 - (c) Primary fascial pathology

(a) Congenital weakness

- 1) Persistence of the processus vaginalis causes indirect complete inguinal hernia.
- 2) Patent canal of Nuck in the female causes indirect inguinal hernia.

(b) Acquired weakness

- 1) Excessive fat in the abdomen causes weakness of the abdominal musculature
- 2) Surgical incisions may lead to division of nerve fibers and thus causes muscle weakness.
- 3) Muscle weakness may follow repeated pregnancy.

(c) Primary fascial pathology

Abnormal collagen metabolism was an early biological metabolism in patients with inguinal hernias. Immature collagen defects were present in the skin biopsies remote from hernia site, supporting a genetic basis for hernia formation. Acquired collagen defects were ascribed to cigarette smoking or nutritional deficiencies.

(II) Increased abdominal pressure⁴ – Examples

- 1) Whooping cough in children
- 2) Chronic cough in bronchitis, Tuberculosis etc.
- 3) Bladder neck obstruction or urethral stricture
- 4) Benign prostatic hyperplasia
- 5) Constipation
- 6) Repeated pregnancy.

Composition of hernia

- Hernia consists of 3 parts –
- (1) Sac
 - (2) Coverings
 - (3) Contents

- (1) The sac – is a diverticulum of the peritoneum consisting of
 - i) The Mouth is the opening of the sac through which content enter the sac.
 - ii) The Neck is the most constricted part of the sac and strangulation of bowel is likely to occur at a narrow neck.
 - iii) The Body is the main portion of the sac.
 - iv) The Fundus is the most redundant part of the sac.
- (2) Coverings are derived from the layers of the abdominal wall through which the sac passes.
- (3) Contents – These can be
 - Omentum – omentocele
 - Intestine – enterocele
 - A portion of circumference of intestine – Richter’s hernia
 - A portion of bladder – sliding inguinal hernia
 - A Meckel’s diverticulum – Littre’s hernia

Classification (NYHUS) ⁵

Type I – Indirect hernia with an internal ring of normal size, configuration, and structure. The hernial sac is contained within the inguinal canal and the floor is intact.

Type II – Indirect hernias characterized as having an enlarged and distorted internal ring, without disruption or encroachment into the direct floor of the inguinal canal. The sac can occupy the entire inguinal canal but does not extend into scrotum.

Type III

III A – contains all direct hernias wherein “the protrusion does not herniate through the internal ring”.

III B – Large indirect hernias where the defect has expanded medially and encroaches on posterior inguinal wall or direct floor. The sac is inguino-scrotal in size.

III C – Hernias consist of femoral hernia that emerges through the femoral ring.

Type IV – Recurrent hernias

IV A – Direct

IV B – Indirect

VI C – Femoral

VI D- Combination of A , B and C.

Other Classifications

A Bendavid / TSD

Type (T) – Anterolateral (indirect)

Antero medial (direct)

Posteromedial (femoral)

Posterolateral (Perivascular)

Stage (S) - Stage I Sac in canal

Stage II Sac outside external ring

Stage III Sac in scrotum

Dimension (D) – orifices maximum in centimeter

B Gilbert classification⁶

Indirect

Small I

Medium II

Large III

Direct

Entire floor IV

Diverticular V

Combined

Indirect and direct VI

Femoral VII

C Halverson and MCVAY classification

Small indirect

Medium indirect

Large indirect & direct

Femoral

Combined – any mixture of above

Clinical features

(A) Symptoms

- 1) Many hernias present as an asymptomatic swelling in the groin.
- 2) Pain – The patient complains of a dragging or aching type of pain in the groin. This is often noticed when there is a tendency for a hernia to develop, so the pain appears long before lump is noticed. When a hernia becomes very painful and tender, it is probably strangulated.
- 3) Systemic symptoms – If the hernia is obstructing the lumen of the bowel (incarcerated hernia), the cardinal symptoms of intestinal obstruction will appear, colicky abdominal pain, vomiting, abdominal distension and absolute constipation.
- 4) Other Complaints – the causes of hernia may be present like, whooping cough or chronic bronchitis, dysuria due to BPH or urethral stricture.
- 5) Past history – History of Appendicectomy, previous hernia repair (recurrent hernia etc)

Local examination – The patient should be first examined in the standing position and then in the supine position.

- 1) **Position and Extent** – When the hernia is confined to the groin, it should be differentiated from femoral hernia. An inguinal hernia is positioned above the inguinal ligament and lateral to the pubic tubercle, whereas femoral hernia lies below the inguinal ligament and lateral to pubic tubercle.
- 2) **To get above the swelling** – This examination differentiates a scrotal swelling from an inguino-scrotal swelling. In case of inguinal hernia one cannot get above

the swelling, whereas in case of pure scrotal swelling one can get above the swelling.

- 3) **Consistency** – If the inguinal hernia contains omentum the swelling feels doughy and granular. If it contains intestine it feels elastic. A strangulated hernia feels tense and tender.
- 4) **Impulse on coughing** – This is a classical sign of an uncomplicated hernia.
- 5) **Reducibility** – This is another classical sign of an uncomplicated hernia.
- 6) **Invagination test** – After reduction of hernia one can perform this test. If the palpable impulse is felt on the pulp of the finger then it is a direct hernia and if impulse is felt on the tip it is an indirect hernia.
- 7) **Ring occlusion test** – This is done after occlusion of the deep inguinal ring ,the direct hernia will show a bulge medial to occluding finger but an indirect hernia will show no bulge on coughing.

Investigations

- 1) Routine investigations like complete blood counts, urine examination, blood sugars and renal function tests.
- 2) Ultrasonography – Inguinal hernias are found by placing the transducer over the inguinal ligament. The reference structures are the rectus sheath medially and internal oblique and transverse abdominis muscle laterally. Epigastric vessels are identified by color – coded duplex scan. It helps in identifying the defect (size and location) and also the nature of the contents.

Treatment of inguinal hernia

(A) **Conservative treatment** – Operation is undoubtedly the treatment of choice.

Treatment is divided into 2 groups.

- 1) **Watchful waiting** – in cases of small direct hernias watching waiting can be done.
- 2) **TRUSS** – A truss is used to prevent hernia to come out of superficial inguinal ring.

Indications⁷

- 1) Those who refuses operation and those who are not fit for surgery
- 2) In old patient suffering from diseases like chronic bronchitis, enlarged prostate and constipation where surgery even if performed runs the risk of recurrence.

Contraindication

- 1) When the hernia is irreducible
- 2) When the patient does strenuous job or suffer from chronic bronchitis
- 3) When the hernia is associated with an undescended testis
- 4) If there is an associated huge hydrocele
- 5) If the patient is not intelligent enough to position the truss properly and to clean the hernial area.

Mode of action

- 1) A truss acts by pressing the anterior wall against posterior wall. It also presses on deep inguinal ring and prevents hernia from coming out.

- 2) Adhesions gradually develop in the inguinal canal so that hernia may not find access to come out.

Method of use

- 1) A truss should be used in lying down position after reducing the hernia completely
- 2) Truss should be used throughout the day.

(B) Operative treatment – 3 types of operations are performed

(a) Herniotomy

(b) Herniorrhaphy

(c) Hernioplasty

- a) **Herniotomy** – In this operation the neck of sac is transfixed and ligated, then the hernial sac is excised. No repair of inguinal canal is performed. It is indicated.

(a) In infants and children in whom there is preformed sac

(b) In case of young adults with very good inguinal musculature

- b) **Herniorrhaphy** – It consists of herniotomy and repair of the posterior wall of inguinal canal by opposing conjoint tendon to inguinal ligament. The suture materials which are used for such repair are usually non absorbable material example- prolene or silk.

Indications

- 1) In all cases of indirect hernia except in children below 18 years
- 2) In adult patients whose muscle tone is quite good.

Types

(1) The modified Bassini's repair⁸

The main aim is to strengthen the posterior wall of the inguinal canal by stitching (3 to 5 interrupted sutures) the lower margin of the muscles (internal oblique and transversus) and the conjoint tendon to the inner margin of the inguinal ligament behind the cord. And the most medial suture should be passed through periosteum of pubic tubercle.

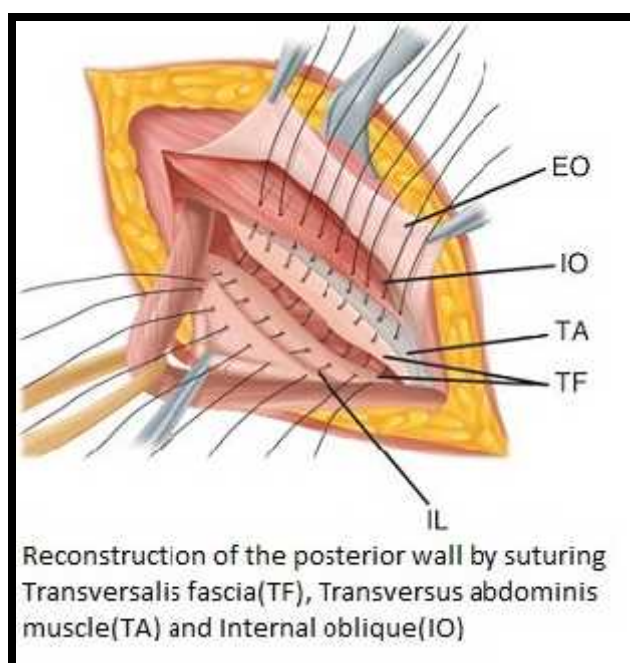


FIGURE 3 : MODIFIED BASSINI'S REPAIR

(2) The Shouldice repair^{9, 10}

The Shouldice technique is commonly used for open repair of inguinal hernias and is the most popular pure tissue hernia repair. It is in essence the modern evolution of the Bassini repair performed in a multilayered fashion. In this technique the transversalis fascia is incised from the deep inguinal ring to medially as far as possible near pubic tubercle. The deep inferior epigastric vessels are safe guarded. The first

layer of repair begins at the pubic tubercle where the iliopubic tract is sutured to the lateral edge of the rectus sheath, then progressing laterally. The inferior flap of the transversalis fascia, which includes the iliopubic tract, is sutured continuously to the posterior aspect of the superior flap of the transversalis fascia until the internal ring is encountered. The suture is not tied here, but rather is continued back upon itself in the medial direction. At the internal ring, the second layer is the re-approximation of the superior edge of the transversalis fascia to the inferior fascial margin and the shelving edge of the inguinal ligament. The suture is then tied to the tail of the original stitch. A third suture is started at the tightened inguinal ring, joining the internal oblique and transversus abdominis aponeuroses to external oblique aponeurotic fibers just superficial to the inguinal ligament. This layer is continued to the pubic tubercle where it reverses upon itself to create a fourth suture line. Unique to this operation is the routine division of the genital branch of the genitofemoral nerve. The repair is performed using monofilament continuous suture of polypropylene or stainless steel.

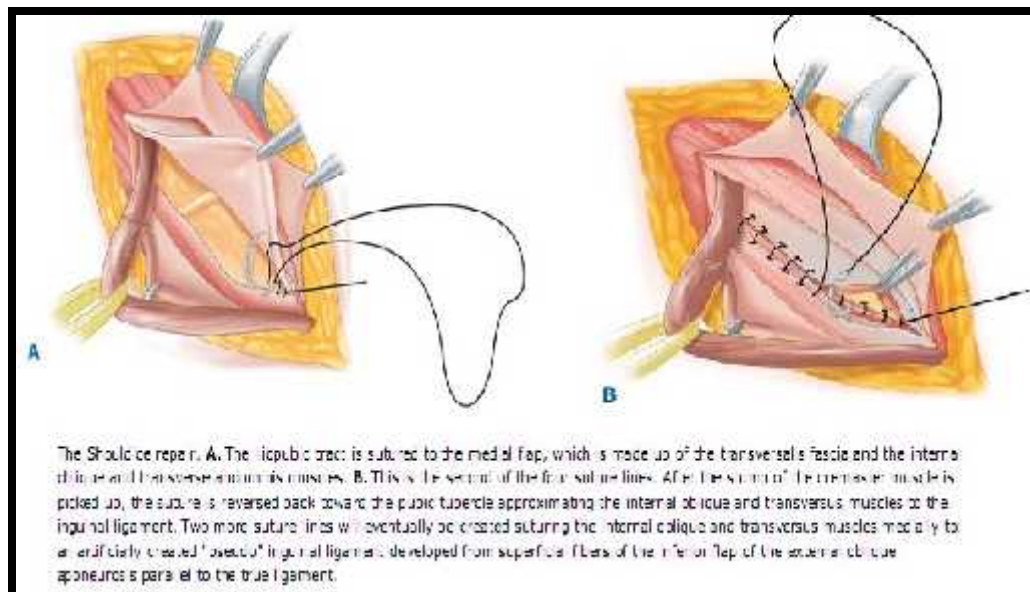


FIGURE 4 : SHOULDICE REPAIR

- (3) **The Marcy repair**
- (4) **Halsted operation with subcutaneous transplantation of cord
(Halsted I)**
- (5) **The Ferguson operation**
- (6) **The Andrews operation**
- (7) **Halsted II (Ferguson – Andrews operation)**
- (8) **Nylon darn inguinal hernia repair**

HERNIOPLASTY

Earlier in the 1960, techniques using biocompatible meshes were introduced. Later in the 1980's and 1990's amazing spread of prosthetic methodologies took place and in 1984 Lichtenstein introduced tension free hernioplasty.

It is herniotomy and reinforced repair of post wall of the inguinal canal by filling the gap between the conjoined tendon and inguinal ligament by either autogenous material or heterogeneous material.

Indications of hernioplasty-

- (1) Cases of indirect hernia – in patients with poor muscle tone
- (2) All cases of direct hernias
- (3) All cases of recurrent hernias
- (4) Patient who do strenuous jobs or suffering from chronic bronchitis, enlarged prostate etc

(1) LICHTENSTEIN TENSION – FREE HERNIOPLASTY^{11, 12, 13}

A 5cm skin incision which starts from the pubic tubercle and extends laterally within Langer's line is made. External oblique aponeurosis is opened and its lower leaf freed from spermatic cord and upper leaf from underlying internal oblique muscle. The cord with its cremasteric covering is separated from the floor of inguinal canal and pubic bone. Cremasteric sheath is incised longitudinally and indirect hernial sac is freed from the cord to a point beyond the neck of sac and inverted into the abdomen. In complete non-sliding scrotal hernia, the sac is transected at the midpoint of the canal leaving the distal section in place and anterior wall of distal sac is incised to prevent postoperative hydrocele. In case of direct hernias, the large sacs are inverted with absorbable suture. A thorough exploration of groin is necessary to rule out co-existing femoral hernia.

A sheet of 6 x 11 cm of mesh is used. The medial end of the mesh is cut to the shape of the medial corner of inguinal canal. The rounded corner is sutured with non absorbable monofilament suture material to the anterior rectus sheath above the pubic bone and overlapping the rectus sheath by 1 to 1.5 cm. This is a crucial step in the repair, because failure to cover this bone with the mesh can result in recurrence. This suture is continued to attach the lower edge of the mesh to the inguinal ligament up to a point just lateral to internal ring by a continuous suture. If there is a concurrent femoral hernia, the mesh is also sutured to Cooper's ligament 1 to 2 cm below its suture line with the inguinal ligament to close the femoral ring. A slit is made at the lateral end of the mesh, creating two tails, a wide (2/3) one above and a narrower (1/3) below. The upper wide tail is grasped with hemostat and passed underneath the spermatic cord, this positions the cord between two tails of the mesh. The wider upper tail is crossed and placed over the narrower one and held with hemostat and sutured to

the inguinal ligament lateral to the deep ring. The upper edge of the patch is sutured in place with two interrupted absorbable suture, one to rectus sheath and other to the internal oblique aponeurosis just medial to the internal ring. Upward retraction of upper leaf of external oblique during this phase of repair is important because it results in the appropriate amount of laxity in giving a dome like configuration for the patch when the retraction is released. This laxity assures a true tension free repair.

The lower edges of each of the two tails are fixed to inguinal ligament just lateral to completion knot of the lower running suture. This creates new internal ring. The excess mesh on lateral side is trimmed, leaving at least, 5cm beyond the internal ring. This is tucked underneath the external oblique aponeurosis which is then closed over the cord with an absorbable suture.

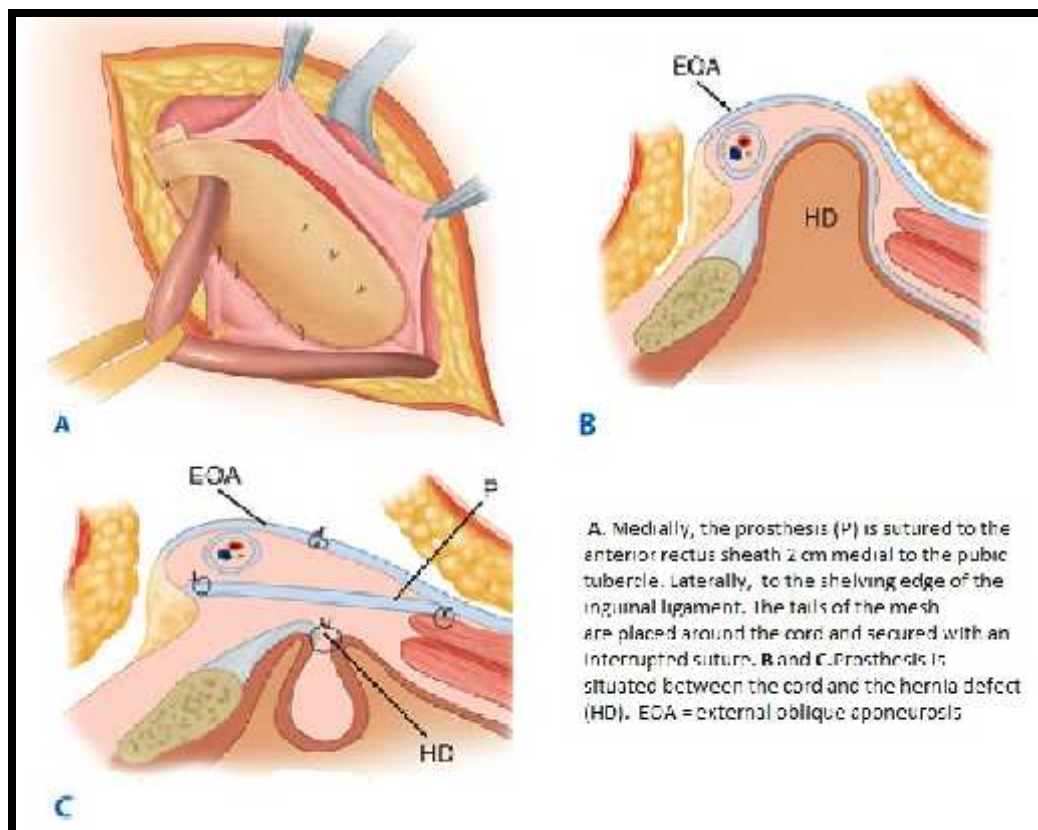


FIGURE 5 : LICHTENSTEIN TENSION – FREE HERNIOPLASTY

Advantages

- 1) It is easier to perform, teach and learn.
- 2) Postoperative pain is less compared to other inguinal hernia repairs.
- 3) Return to work after tension free hernioplasty is earlier between 2 to 14 days.

Complication

Infection, hematoma and seroma occur in approximately 1% of cases.

Technical consideration

Using a wide piece of mesh to overlap tissue beyond the boundary of Hasselbach's triangle for 3 to 4 cm is important in order to reduce the chance of recurrence. After incorporation is complete, this overlap results in uniform distribution of intra-abdominal pressure over the much wide surface of the overlapped area. It compensates for future shrinkage of mesh.

Placement of mesh over inguinal floor and behind the external oblique aponeurosis uses the intra-abdominal pressure in favour of repair. Contraction of the external oblique keeps the mesh tightly in place by acting as an external support when intra-abdominal pressure rises with straining.

2) Plug Repair of Inguinal Hernia¹⁴

Indication – Recurrent inguinal hernias and femoral hernias are primary indication for a mesh umbrella.

Under local anesthesia a small incision is made above the hernial orifice. With the patient actively straining to demonstrate the hernia the external aponeurosis is exposed only in the region of the location where hernia can be seen. Spermatic cord is dissected only to the extent that is necessary for detaching the hernial sac. Hernial sac

is pushed back through the hernial orifice into the preperitoneal tissue. The plug is then prepared by coiling one or two polypropylene strips with a dimension of 20x 2cm. It must fit into the hernial orifice so tightly that it cannot push it out even before the suture is fixed. The cylinder is fixed in hernial annulus by six prolene sutures placed above cylinder, the external aponeurosis, the subcutaneous tissue and the skin is closed in a conventional manner.

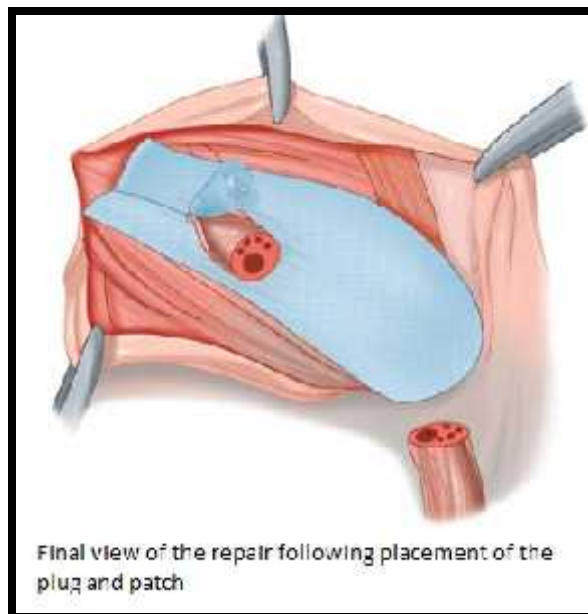


FIGURE 6 : PLUG REPAIR OF INGUINAL HERNIA

3) Tension – free hernioplasty using a bilayer prosthesis^{16,17,18}

The bi-layer polypropylene device is known as prolene hernia system (PHS), introduced in 1998 and is constructed in a three in one model. The inguinal canal is approached from an anterior approach after dividing the skin, Scarpa's fascia and the external oblique aponeurosis. The cord is examined for any indirect sac. In indirect hernias, sac is inverted and pocket created in the pre-peritoneal space. The underlay of the PHS is then deployed in the pre-peritoneal space. The onlay is secured by using 3 interrupted sutures to pubic tubercle, the conjoint tendon and the shelving edge of the

inguinal ligament. A lateral slit is made in the mesh to accommodate the cord structures and to recreate the internal ring.

For direct hernias the attenuated transversalis fascia of the floor of the inguinal canal is opened and the hernia sac and contents reduced. The underlay of the PHS mesh is placed in the pocket created in the pre-peritoneal space and the onlay is sutured to the pubic tubercle, conjoint tendon and the shelving edge of the inguinal ligament.

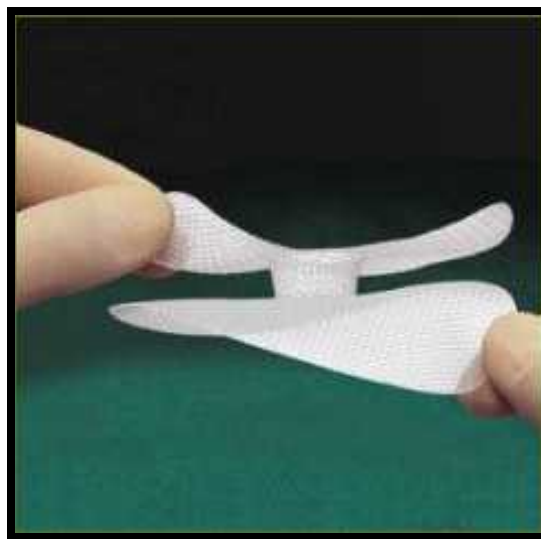


FIGURE 7 : PROLENE HERNIA SYSTEM

Its underlay component is designed to protect the canal's posterior wall. Inferiorly it reaches beyond Cooper's ligament to protect the femoral triangle and superiorly it reaches well above the transverse arch, medially it reaches behind the pubic ramus and laterally it reaches to well beyond the internal ring. It is flat and pliable, and it covers and protects the entire myopectineal orifice. Its 2cm diameter connector will sit within the defect or internal ring. The onlay component of the device covers and protects the entire posterior wall. Laterally, it is positioned between the internal and external oblique muscles, and medially, it extends over the transverse arch and the pubic bone. It extends along the shelving edge of the inguinal ligament,

protecting the entire Hasselbach's triangle. The onlay patch makes it wide enough and long enough to cover the full width and breadth of the vulnerable posterior wall.

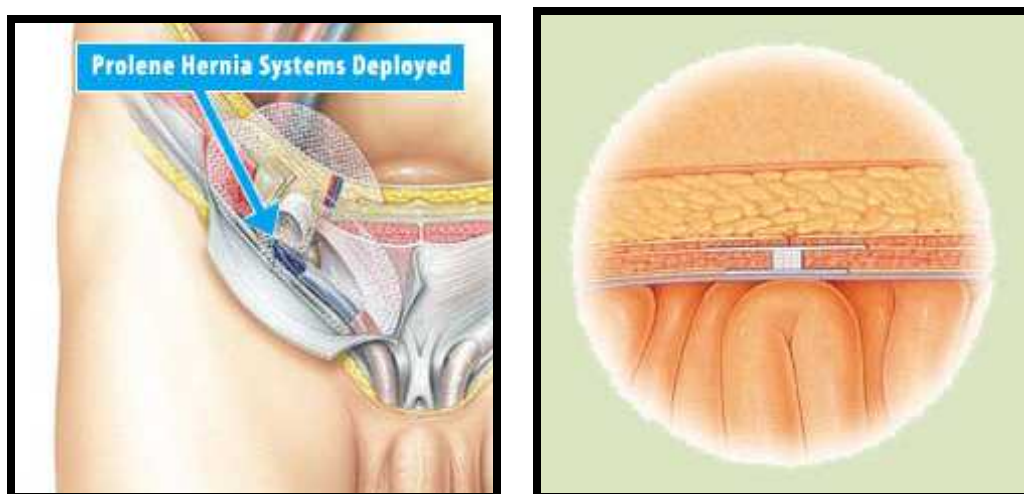


FIGURE 8 : PROLENE HERNIA SYSTEM DEPLOYED

4) Preperitoneal hernia repair^{19,20}

It is the most anterior approach of hernial repair. After opening the inguinal canal, an incision is made to enlarge the transversalis fascia defect both laterally and medially. In case of incarceration and strangulation the peritoneum is opened and the sac is reduced from within. Peritoneum is closed after the sac is reduced. The sac is then amputated and distal end left open. Access to peritoneal cavity and its content is excellent with this approach. In case of direct hernia non-absorbable, running or interrupted suture is done and in case of indirect hernia, the defect in the internal ring is repaired. Then transversalis arch to iliopubic tract is repaired with or without mesh reinforcement.

Advantages-

- 1) It provides exposure of the entire groin area, thus visualization of all areas of inguinal herniation as well as the confounding structures including the element of sliding hernias are possible.
- 2) This method minimizes potential for injury to bowel and bladder, and contents of hernial sac.

Laparoscopic Inguinal Hernia Repair^{21,22,23}

The use of laparoscopic or minimal access surgery has become the trend of the day and it has added an exciting and highly controversial dimension to hernial repair.

The first report of laparoscopic hernia repair was in 1982, when Ger et al²¹ used a Michel staple applied with a Kocher clamp to close the peritoneal opening of a hernia sac under laparoscopic guidance. In 1989, filling of an indirect hernia defect with a plug of polypropylene mesh followed by laparoscopic suture closure of the internal ring was tried.²² In 1990 closing of an indirect hernia with extra corporeally tied sutures and closure by placing a 4x5 cm dural patch over the area was reported.²³

Two techniques are used.

1. TAPP – Transabdominal preperitoneal repair
2. TEP– Totally extraperitoneal approach.

The main hernial repair technique is same in both these methods; the difference lies in the manner in which access to the preperitoneal space is achieved. In TAPP intra peritoneal approach is made and the peritoneal flap over the posterior inguinal area is incised to reach the preperitoneal space. In TEPP the preperitoneal space is reached without entering the peritoneal cavity.

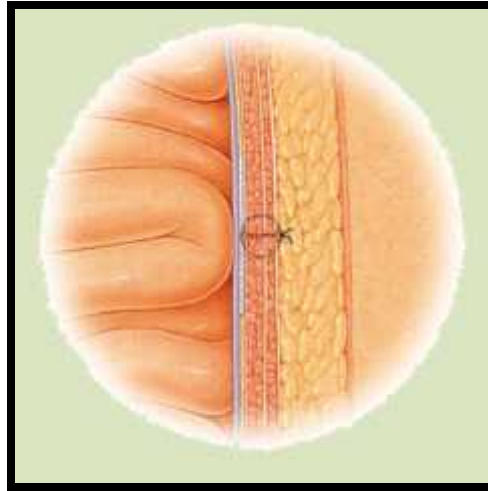


FIGURE 9 : LAPAROSCOPIC HERNIA REPAIR

Advantages-

- 1) Reduces post operative pain and resultant disability
- 2) Entire myopectineal orifice can be inspected bilaterally allowing for repair of any unexpected contra-lateral hernia.
- 3) For patients with a previous anterior herniorrhaphy laparoscopic repair avoids the previous operative site in patient with recurrent hernia.

Modified Prolene Hernia System

This is performed by placing 2 polypropylene meshes (after dividing a single mesh into 2 pieces) after trimming them to required sizes. The initial procedure of dissection is the same as in conventional Lichtenstein repair. Additionally transversalis fascia is dissected. The direct or the indirect sac is dealt with after reducing the contents. A pre-peritoneal space is created. The Modified Prolene Hernia System is first created outside by taking 3 connecting sutures between the two pieces of mesh with non-absorbable prolene sutures. The system is then deployed with the underlay mesh being placed in the preperitoneal space. The onlay mesh is fixed by

sutures to the pubic tubercle, conjoint tendon and the shelving edge of the inguinal ligament by continuous sutures with a proper slit for the cord. The onlay mesh in the Modified Prolene Hernia System is of the same size as the conventional Lichtenstein repair.

This technique is being proposed by us for the first time. It involves a minor deviation from the existing PHS repair. But it provides the same repair of the PHS but at a much lesser cost equivalent to the conventional Lichtenstein's repair.

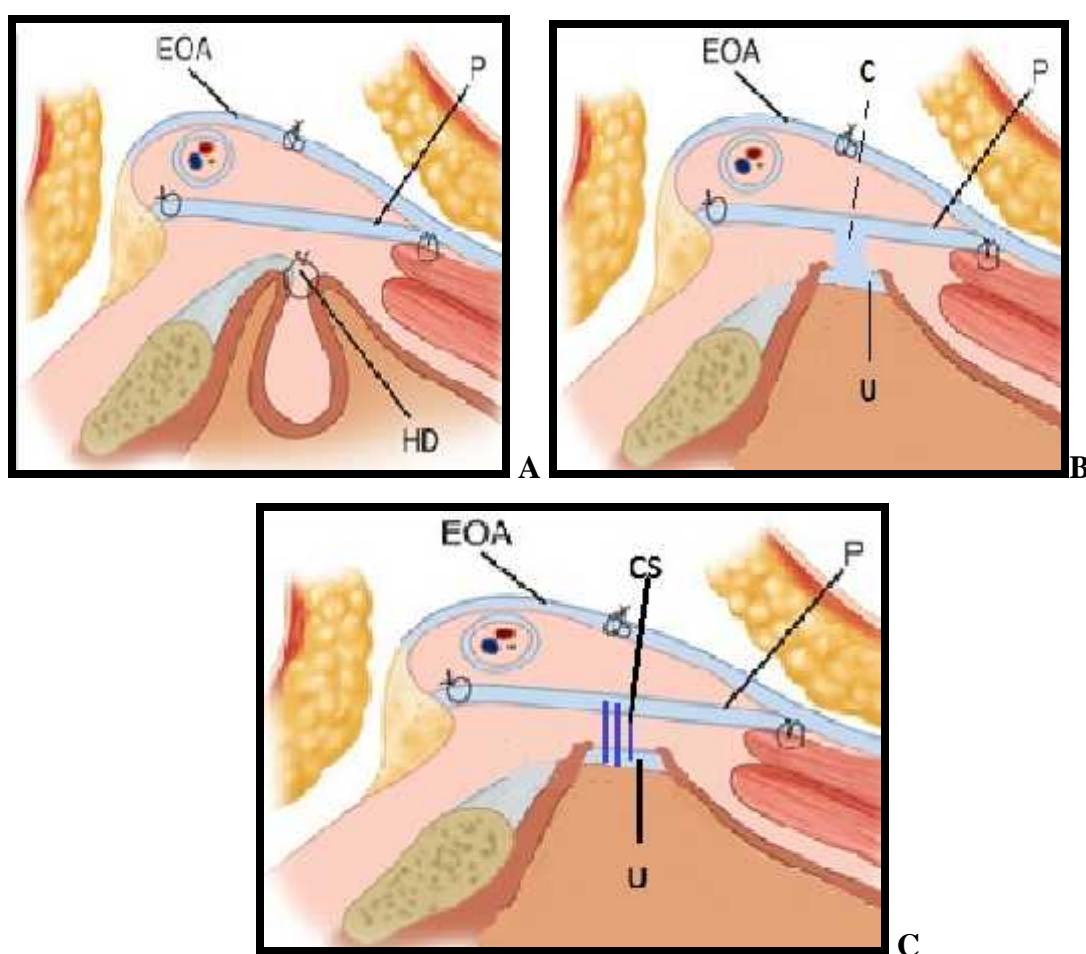


FIGURE 10 : COMPARISION OF LICHTENSTEIN REPAIR. PHS REPAIR AND MODIFIED PHS REPAIR

Fig. comparing the 3 repairs. A shows Lichtenstein repair. B shows PHS repair with connector and C shows Modified PHS repair with the 3 connecting sutures and onlay mesh as the same size as Lichtenstein repair and underlay in pre-peritoneal space. EOA = External Oblique Aponeurosis, P = Prosthetic mesh, HD = Hernial defect, U = Underlay mesh C = Connector and CS = Connecting Sutures.

Materials used in hernioplasty^{12,24}

- (a) Autogenous materials –these are patients own tissue. The materials used are:
- 1) Strip of fascia lata from the lateral side of the thigh.
 - 2) A strip of external oblique aponeurosis
 - 3) A flap of anterior rectus sheath which is turned down to cover inguinal canal
 - 4) Skin flap may be used in two ways, an elliptical portion of skin is tensely sutured to conjoined tendon and inguinal ligament to cover posterior wall (dermoplasty) or the skin is made into a ribbon (skin ribbon) which is now used as strip.
- (b) Heterogeneous material - Prolene or a stainless steel wire has been used for darning. Prolene mesh or stainless steel mesh has also been used.

COMPLICATIONS OF INGUINAL HERNIA REPAIR

(I) Chronic groin pain after inguinal herniorrhaphy^{25,26,27,28}

Postoperative pain is an extremely important consideration in that many primary hernias present without pain as a symptom. Postoperative pain can be sub classified into short term and chronic. Chronic post herniorrhaphy pain lasts beyond 3 months.

There are many causes for this persistent, post-operative hernia-area pain (also called inguinodynia) including

- 1) Nerve damage (at time of surgery).
- 2) Nerve entrapment in scar tissue, mesh or sutures.

- 3) Scar tissue itself or tissue damage.
- 4) Misplaced mesh.
- 5) Contracted, scarified and hardened mesh plugs (Meshomas).
- 6) Infection.
- 7) Recurrent (or persistent) hernia.
- 8) Constriction or narrowing of internal inguinal ring around the cord.
- 9) Periosteitis at pubic tubercle.

Post herniorrhaphy pain is classified into 3 syndromes

- 1) Somatic
- 2) Visceral
- 3) Neuropathic.

Somatic pain is secondary to damage to ligaments and muscles. Pain that results from these injuries usually is reproduced with exertion or movement of the abdominal wall. Visceral pain refers to pain experienced during a visceral function such as ejaculation and may result from injury to a sympathetic nerve plexus. Neuropathic pain is usually a localized sharp pain, that may impart a sensation of burning or tearing and indicates direct nerve damage or entrapment. Neuropathic pains may present as early as in the recovery room, where patients may complain of significant sharp pains.

Treatment:

Somatic pains are usually treated with rest, NSAIDs, and reassurance. Neuropathic pains also are amenable to NSAIDs, but there is also a role for nerve-

directed injections of steroids and anesthetics. Failing conservative management, neurectomy may be undertaken.

(II) Wound infection in hernia repair^{10,29}

Bacterias commonly involved are – Staphylococcus aureas

Staphylococcus epidermidis¹²

Group A streptococcus¹⁵

Clinical presentation– Fever, pain and signs of inflammation around infected area.

Treatment –

- 1) If a localized area of infection- drainage of pus.
- 2) If extensive area of infection- requires opening of wound / debridement with antibiotics depending on culture sensitivity.

(III) Cord and testicular complications¹⁰

- 1) Hydrocele
- 2) Hematocele
- 3) Complications involving vas deference
 - (a) Dysejaculation syndrome
 - (b) Transsection of vas
- 4) Nerve injuries - Commonly genitofemoral and ilioinguinal nerve involved.
- 5) Damage to blood vessels of testicles
- 6) Ischemic orchitis and testicular atrophy
- 7) Testicular pain
- 8) Infertility

BIOMATERIALS

History of surgical meshes

More than 160 years ago Belams used the air bladders of fish to close the gap of an inguinal hernia. He intended to provoke “an adhesive inflammation” and applied this technique on 30 dogs and then in three patients with success. In 1886, Macewan used gathered hernial sac to seal the internal hernial ring, a year later Trendelenburg proposed the implantation of a 4 x 4 cm² strip of periosteum.

Artificial material was introduced in 1889 by Witzel who used a mesh of silver wire for abdominal wall hernias. Busse in 1901 used meshes made of gold wire. In 1931 Fiescher proposed the implantation of rubber sponges. In 1949 Preston took meshes of metallic wire to treat hernial patients.

The triumphant progress of meshes had its beginning after World War II with the development of synthetic polymer for medical purposes.

Principles of mesh repair

The mesh induces an inflammatory foreign body reaction with a consecutive intense fibrosis, resulting in a compound of non absorbable mesh filaments as a mechanical – sealing mechanism and embedding collagen rich scar tissue. Both components form a mechanical stable artificial abdominal wall.

Mesh materials^{24,30,31,32}

Meshes used for hernia repair are-

(I) Nonabsorbable

(a) Polypropylene

(b) Polytetrafluoroethylene

- (c) Polyvinyl
- (d) Polyamide
- (e) Polyethylene terephthalate

(II) Absorbable

- (a) Polyglactin 910
- (b) Polyglycolic acid

(a) Polypropylene(PP)³³ :

PP ($-\text{CH}_2 - \text{CH}(\text{CH}_3) -$)_n is a thermoplast based on propane with a molecular wt of 100,000. It is supposed to resist physical decay even after years of being implanted PP meshes shows a considerable shrinkage of about 20% in length and 40% of original area.

Disadvantages

- 1) High bending stiffness of the monofilaments, being susceptible to increase even during incorporation.
- 2) Direct contact with intestine, tend to form intense adhesions and later fistulas.
- 3) Intense fibrosis entirely embedding the mesh into scar plate is frequently followed by a restriction of abdominal wall mobility.
- 4) Formation of fibrinous seroma.

Polyethylene Terephthalate(PE) :

PE is a macromolecular compound made by polycondensation of polybasic carbonic acids usually of ethylene glycol and terephthalic acid.

Disadvantages

- 1) PE undergoes obligate degradation with an entire loss of mechanical stability.
- 2) Durable strength is less than PP.
- 3) Complications like infection, recurrence, fistula formation are more with PE.

Polytetrafluoroethylene (PTFE)

It is made up of a hydrophobic PTFE. They have comparatively small pores, with a size of 1 to 6 um. The PTFE material is mainly encapsulated by fibrous tissue and not embedded into a scar plate. This material shows an increased rate of eventration, so for a sufficient mechanical strength it requires a tight and durable fixation of the mesh in the surrounding tissue.

Absorbable meshes

In principle all absorbable materials whether synthetic or natural, cannot provide a sufficient strength of repair and is followed by a high rate of recurrence. These materials have a mean time of 2 to 3 weeks to halve their mechanical strength and 6 to 8 weeks for complete absorption. These meshes are preferred for temporary wounds or peritonitis. The temporary implantation as an inlay permits daily revision and reduces the intra-abdominal pressure, promoting the blood supply to bowel, kidney etc. These also used to cover the non absorbable meshes to prevent direct contact with the intestine until the peritonealization is finished.

Influence of the mesh weight³³

Connective tissue formation are closely related to amount of material implanted, type of filament (multi/ monofilament) and proportion of pores that define the surface area with the recipient tissues. Larger amount of the material with huge

surface induce a strong and active inflammatory tissue reaction, resulting in a mesh completely embedded in a scar plate with a domination of neutrophils, whereas the reduction of the material and diminishing of the plane area support chronic macrophage controlled tissue response, thus low weight meshes with large pores permits the formation of fibrous tissue just around the mesh filament with mainly fat tissue filling up the pores, preserving most of its flexibility.

Mesh related tissue reaction^{34,35}

- 1) Foreign body reaction with typical foreign body granuloma, including epitheloid cells and giant cells.
- 2) Persistent acute inflammation with varying amount of CD 15 positive neutrophils and focal fibrinoid necrosis.
- 3) Perifilamentous fibrosis with extensive amount of deposited collagen fibers. In periphery connective tissue with numerous collagen fibers form a thick capsule in which the whole mesh is integrated and complete penetration of connective tissue into the pores. As result, mesh and the newly formed connective tissue around the mesh forms a complex unit.

Tissue response of the host³⁴

The tissue response mainly determines the biocompatibility and suitability of the mesh. The type of material, the amount, the surface area and the mesh structure all affect the extent of inflammation and the level of the persisting foreign body reaction. The histological picture of implant bed is different for different material which are decisive for the estimation of inertness and biocompatibility of surgical meshes.

Following are some common histological changes shown by all type of meshes.

- 1) A persisting inflammation over the year after implantation.
- 2) Continuous cellular stress response to the presence of polymer fibers characterized by the induction of heat shock.
- 3) Consistent tissue damage with features of apoptosis, DNA strand breaks and necrosis.
- 4) Persistent and compensating tissue repair indicated by proliferating cells in the interphase.

MATERIALS AND METHODS

Patients

This is an randomised control study done in our hospital over period of one year between Dec 2008 to Dec 2009..

All the patients (60 patients) scheduled for inguinal hernia repair using the modified Prolene Hernia System repair and conventional Lichtenstein mesh repair technique and who met the inclusion criteria were considered for the study.

Inclusion_criteria-

1. All patients requiring mesh repair for inguinal hernias.
2. Unilateral or bilateral inguinal hernias.

Exclusion criteria-

1. Immunocompromised individuals.
2. Patients with tuberculosis.
3. Patients with post-op cough & wound infection (redness & purulent discharge).
4. Patients with pantaloon hernia.
5. Patients with recurrent hernia.
6. Patients with complicated hernia.

Randomization was done by computerized randomization table into 2 groups, group A (Modified Prolene Hernia System repair) and group B (conventional mesh repair)

Group A patients underwent Modified Prolene Hernia System repair using standard polypropylene mesh and group B patients underwent conventional mesh repair.

1) **Modified Prolene Hernia System** This is performed by placing 2 polypropylene meshes (after dividing a single mesh into 2 pieces) after trimming them to required sizes. The initial procedure of dissection is the same as in conventional Lichtenstein repair. Additionally transversalis fascia is dissected. The direct or the indirect sac is dealt with after reducing the contents. A pre-peritoneal space is created. The Modified Prolene Hernia System is first created outside by taking 3 connecting sutures between the two pieces of mesh with non-absorbable prolene sutures. The system is then deployed with the underlay mesh being placed in the preperitoneal space. The onlay mesh is fixed by sutures to the pubic tubercle, conjoint tendon and the shelving edge of the inguinal ligament by continuous sutures with a proper slit for the cord. The onlay mesh in the Modified Prolene Hernia System is of the same size as the conventional Lichtenstein repair.

This technique is being proposed by us for the first time. It involves a minor deviation from the existing PHS repair. But it provides the same repair of the PHS but at a much lesser cost equivalent to the conventional Lichtenstein's repair.

2) **Conventional Lichtenstein Mesh Repair** :- The contents of the sac are reduced and sac inverted. The floor is reinforced with a piece of flat polypropylene mesh and is sutured to the pubic tubercle and a continuous suture is taken to fix the mesh to the reflected part of the inguinal ligament. Mesh is fixed to the conjoint tendon by interrupted sutures. A slit is created for the cord structures and an internal ring is recreated.

All patients will undergo routine pre-operative investigations including

1. Blood investigations:
 - i) Complete blood counts.
 - ii) Blood urea and serum creatinine.
 - iii) BT and CT.
2. Urine routine and microscopy
3. Ultrasonography of the abdomen.

All patients received the same analgesics ie Diclofenac Sodium 50mg intramuscularly post-operatively.

Blinding:- Informed consent was taken from the patient after explaining the pros and cons of both the procedures, but the patient was blinded to the operative procedure followed. The pain grading charts obtained from the patient were received and analysed by another post graduate student in the Department of General Surgery who was unaware of the operative technique followed in each patient.

Method of study

The criteria for the study is described below:

Groin pain – This was measured on a Visual Analogue Scale ranging from 0 (no pain) to 10 (unbearable pain) from 2wks to 12wks post operatively every 15 days. Patients were explained that a scoring of 1-3 constituted minimal pain, 4-7 was moderate pain and 8-10 was severe unbearable pain.

RESULTS

The present study was conducted in KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum and the findings are tabulated as below.

During the study year from December 2008 to December 2009, 60 patients with inguinal hernias were randomized into study (Modified Prolene Hernia System) and control (Conventional Lichtenstein mesh repair) group. These groups were studied for groin pain post-operatively. The pain was assessed by Visual Analogue Score of 0-10. Patients were explained that 1-3 constituted mild pain, 4-7 moderate pain and 8-10 was severe pain.

TABLE 1: SEX DISTRIBUTION

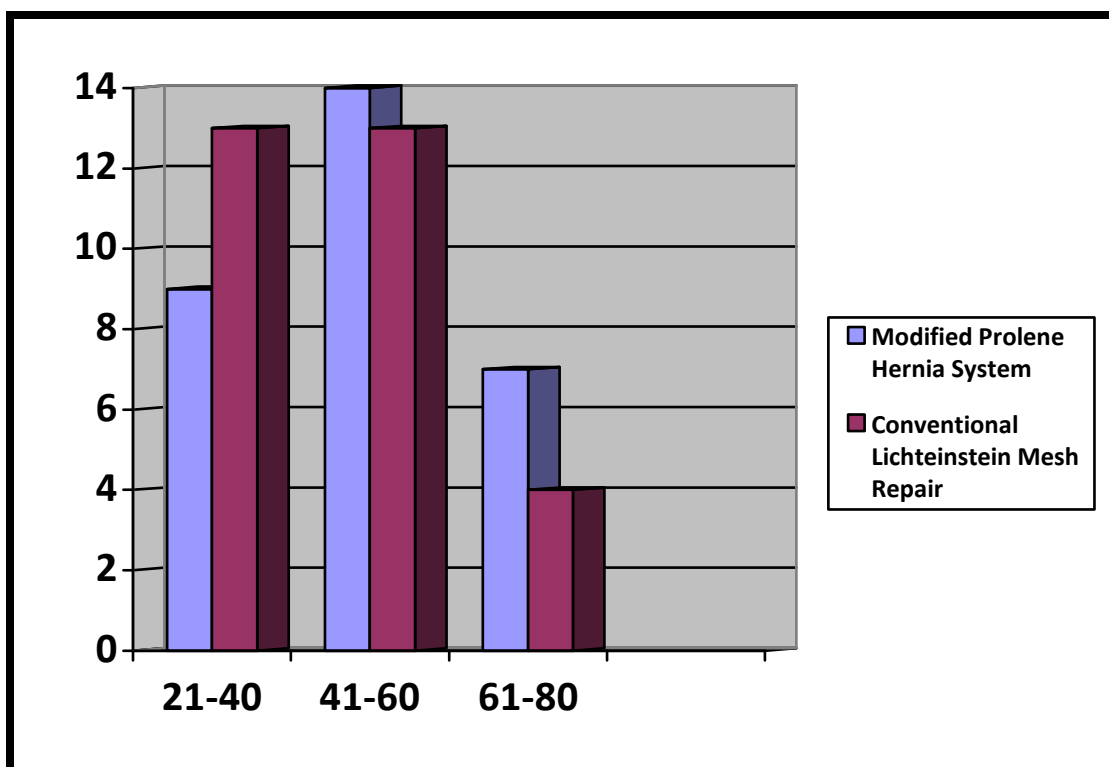
Group	Male	Female	Total
Modified Prolene Hernia System Repair	30	0	30
Conventional Lichtenstein Mesh Repair	30	0	30

In this study all patients in both groups were male patients.

TABLE 2: AGE DISTRIBUTION OF THE PATIENTS

	21-40	41-60	61-80
Modified Prolene Hernia System Repair	9	14	7
Conventional Lichtenstein Mesh Repair	13	13	4

GRAPH 1 : AGE DISTRIBUTION OF THE PATIENTS



In this study it was noted that most of the patients were in the middle aged group of 41-60 years in both the groups.

TABLE 3: MEAN AGE OF THE PATIENTS

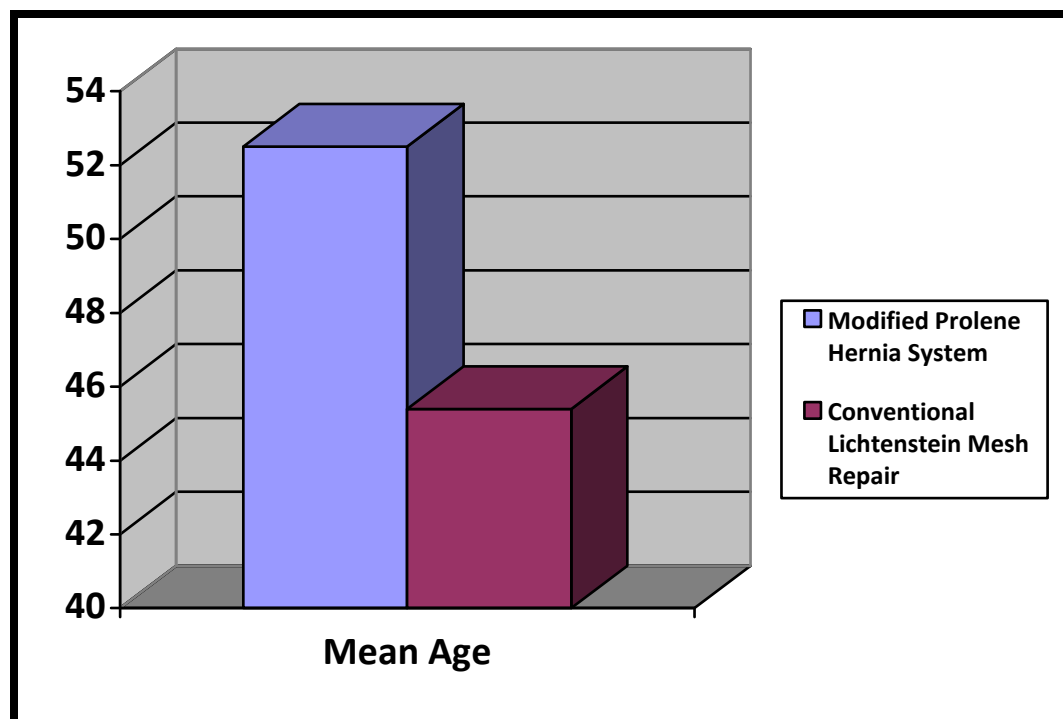
Group	Male
Modified Prolene Hernia System Repair	52.5 \pm 15.26
Conventional Lichtenstein Mesh Repair	45.4 \pm 16.21

t = 1.590

DF = 48

P = 0.118

GRAPH 2 : MEAN AGE OF THE PATIENTS

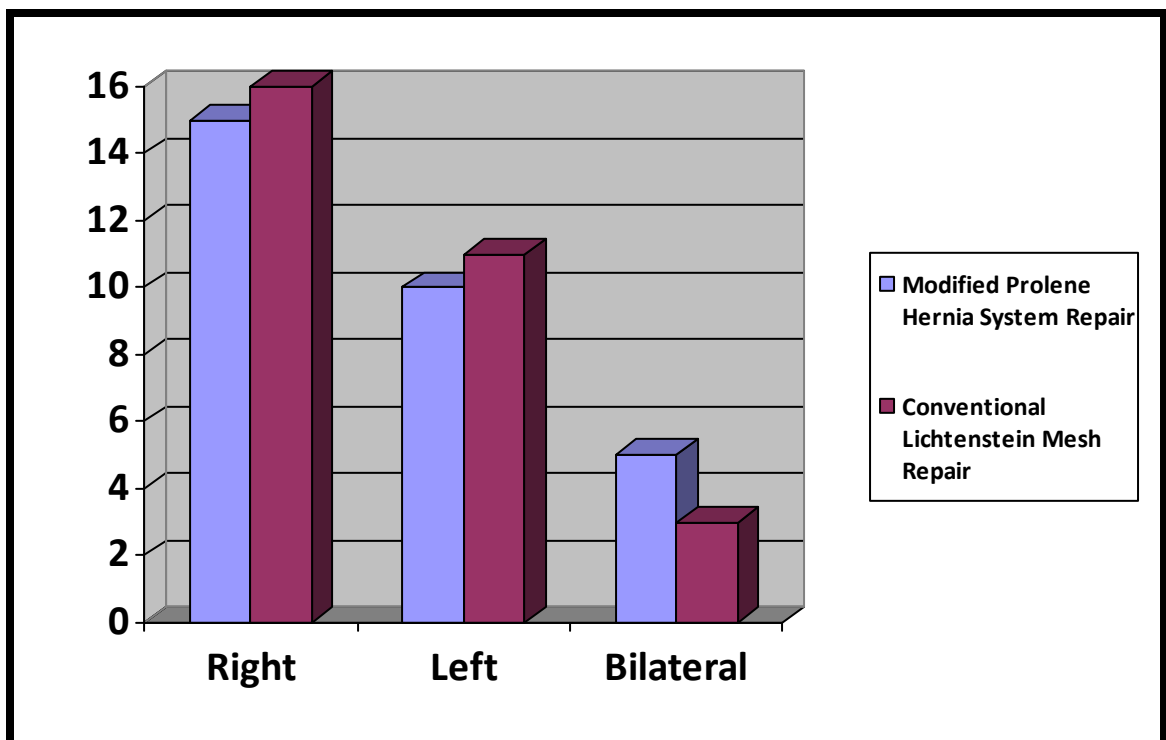


There was no significant statistical difference between the two groups.

TABLE 4: COMPARISION OF SIDE OF HERNIA

	Right	Left	Bilateral
Modified Prolene Hernia System Repair	15	10	5
Conventional Lichtenstein Mesh Repair	16	11	3

GRAPH 3: COMPARISION OF SIDE OF HERNIA

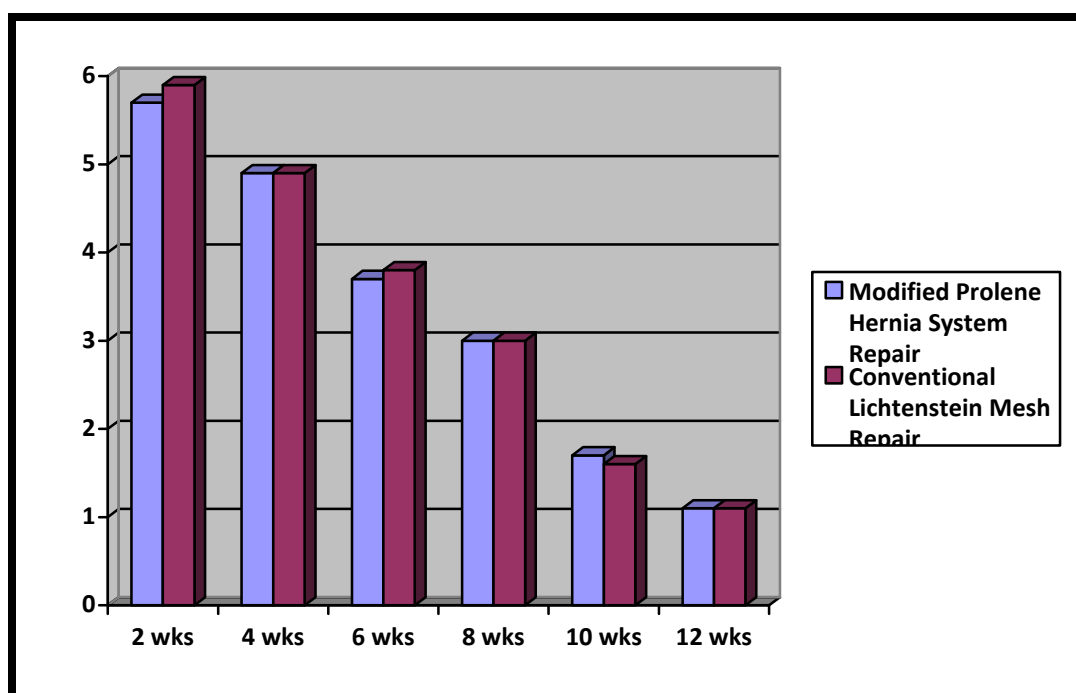


In this study, majority of the hernias were of the right side. Again no significant statistical difference was seen between the two groups.

TABLE 5: COMPARISION OF GROIN PAIN

Group	2 wks	4 wks	6 wks	8 wks	10 wks	12 wks
A	5.7 \pm 0.56	4.9 \pm 0.63	3.7 \pm 0.53	3.0 \pm 0.61	1.7 \pm 0.53	1.0 \pm 0.30
B	5.9 \pm 0.69	4.9 \pm 0.71	3.8 \pm 0.74	3.0 \pm 0.74	1.6 \pm 0.62	1.1 \pm 0.35
Mann whitney U test	Z = 0.939 P = 0.347	Z = 0.172 P = 0.863	Z = 0.585 P = 0.558	Z = 0.354 P = 0.723	Z = 0.809 P = 0.419	Z = 0.471 P = 0.683

GRAPH 4: COMPARISION OF GROIN PAIN



As noted in the above table and chart, maximum pain score was seen at 2 weeks and minimum pain at 12 weeks. It was also observed that the pain score in both groups were comparable at all weeks with no statistically significant difference noted as per Mann Whitney U Test.

Pain at 2 wks was 5.7 ± 0.56 in MPHS group and 5.9 ± 0.69 in CLMR group. At 12 weeks it was 1.0 ± 0.30 and 1.1 ± 0.35 respectively in both groups.

TABLE 6: MEAN REDUCTION OF PAIN FROM 2ND WEEK TO 12TH WEEK

Group	Pain score
Modified Prolene Hernia System Repair	4.8 ± 0.47
Conventional Lichtenstein Mesh Repair	4.7 ± 0.70
Mann whitney U test	Z = 0.944 P = 0.345

The mean reduction of pain from 2nd to 12th week was 4.8 ± 0.47 in MPHS group and 4.7 ± 0.70 in CLMR group. No statistical significant difference was noted as demonstrated by Mann Whitney U test.

TABLE 7: WILCOXON SIGNED RANKS TEST

Modified Prolene Hernia System Repair	Z = 4.412	P = 0.000
Conventional Lichtenstein Mesh Repair	Z = 4.093	P = 0.000

Wilcoxon Signed Ranks Test also demonstrated that there was no statistically significant difference between the 2 groups.

DISCUSSION

Inguinal hernia surgery is the most frequently performed operation in general surgery and so even modest improvements in clinical outcomes are important. The most important criteria for the choice of method are safety (morbidity and mortality), recurrence rates and risk of chronic groin pain.

Chronic groin pain has been reported to be 25-30% in literature. It is not only described as pain but also as stinging, nipping or itching etc. Considering the large number of inguinal hernia surgeries performed every year, this chronic groin pain is a serious problem.

The causes for chronic groin pain put forward are

- Tissue handling
- Foreign body reaction
- Sutures for fixing the mesh
- Nerve entrapment.

The use of mesh has become well established in inguinal hernia surgery. The stability of the mesh must match the physiological forces exerted on the abdominal wall.

The ideal mesh is selected on important characteristics like:

- Minimal foreign body response.
- Tensile strength.
- Pore size.
- Biocompatibility.
- No degradation.

- Tissue integration.
- No adhesion/ fistula formation.

The aim of the present study was to compare the post-operative pain using Modified Prolene Hernia System repair against the conventional Lichtenstein's mesh repair.

The groin pain was assessed by Visual Analogue Scale on a scale of 1 to 10 with 1-3 being mild pain, 4-7 being moderate pain and 8-10 being severe pain.

All the patients presented with groin swelling in both groups. All patients in both groups were male. The mean age and standard deviation in group A and group B is 52.5 ± 15.26 and 45.4 ± 16.21 respectively. In group A mean pain score at 2 weeks was 5.7 ± 0.56 and at 12 weeks it was 1.0 ± 0.30 . In group B mean pain score at 2 weeks was 5.9 ± 0.69 and at 12 weeks it was 1.1 ± 0.35 . P value was insignificant for every assessment of both groups.

In this study, no patients experienced severe pain in either group at 2 weeks, only mild to moderate pain was reported. Though not included in the aims of this study it is worthwhile to mention that most patients resumed their full activities by 4 weeks.

The Prolene Hernia System is known to confer the benefits of both an anterior repair (Lichtenstein's mesh repair) and a posterior repair (Laparoscopic repair). The PHS covers the entire myopectineal orifice of Fruchad thus providing a complete repair whereas the Lichtenstein's repair does not cover for femoral hernia and there is always a possibility of hernia recurrence between the posterior wall and the mesh.

The downside of the PHS is the high cost involved (approximately Rs. 9000) compared to conventional mesh repair (approximately Rs. 2000). This is especially a

big problem in developing countries with already over-burdened medical and healthcare systems.

But in this novel technique proposed by us in this study, we can give the benefits of a PHS bi-layer repair at the same cost of the conventional mesh repair. This is so because we use a single mesh (divided in 2 pieces) and the same suture material provided in the hernia kit without any need for extra material.

This present study is only limited to post-operative pain following hernia surgery by both methods. Further studies need to be done to assess other factors such as quality of life and recurrences.

CONCLUSION

This study showed that with the use of Modified Prolene Hernia System mesh repair, pain is comparable to the conventional Lichtenstein mesh repair while providing a more complete repair to the patient at the same cost.

In a conclusion, there is apparent advantage in the use of Modified Prolene Hernia System repair over other conventional mesh repairs. The short term follow up of the study did not allow any conclusion regarding recurrence of hernia, thus larger cohorts with longer follow up are needed.

SUMMARY

“COMPARISON OF MODIFIED PROLENE HERNIA SYSTEM REPAIR VERSUS CONVENTIONAL LICHTENSTEIN MESH REPAIR FOR POSTOPERATIVE PAIN IN INGUINAL HERNIAS - A RANDOMISED CONTROL TRIAL”.

In this study out of 60 patients who underwent mesh repair 30 underwent Modified Prolene Hernia System repair and 30 underwent conventional Lichtenstein mesh repair. With standard inclusion and exclusion criteria all patients were given spinal anesthesia

Mean age group in Modified Prolene Hernia System repair group was 52.5 while in conventional Lichtenstein mesh repair group was 45.4. Most of the patients had symptoms of inguinal swelling from within 20 months in both the groups. In Modified Prolene Hernia System repair left sided hernias were in 6 patients, Right sided hernias were in 11 patients, bilateral in 8 patients. In conventional mesh repair group left sided hernias in 5 patients, right sided hernias in 14 patients, bilateral in 6 patients. In both groups all were male patients.

In both the groups postoperative pain was observed by VAS from 2week to 12 week daily. Postoperative pain measured by visual analogue score (VAS) pain was assessed both at rest and after exercise. In this study in group A mean pain score at 2 weeks is 5.7 and at 12 weeks it is 1.0, where as in group B at 2 weeks is 5.9 and at 12 weeks it is 1.1. Analysis showed there was no significant statistical difference present between the two groups. Most significantly 100% of patients had resumed full recreational activities by 4 weeks.

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ANNEXURE – I

PROFORMA

PROFORMA OF CLINICAL EXAMINATION OF INDIVIDUAL PATIENT

Name of the patient

Age

Sex

Address

Occupation

Socioeconomic

IP.No

Date of admission

Clinical diagnosis

Clinical details

HISTORY

- 1) Pain
- 2) Lump
- 3) Systemic symptoms
- 4) Other complaints
- 5) Past history of operation
- 6) Personal history

GENERAL PHYSICAL EXAMINATION

- 1) Vitals
- 2) Appearance
- 3) Attitude

LOCAL EXAMINATION

Position of patient

- 1) Standing
- 2) Supine

Local examination

Inspection

- 1) Swelling
- 2) Skin over the swelling
- 3) Impulse on coughing
- 4) Position of penis

Palpation

- 1) Impulse on coughing
- 2) Reducing

Percussion

Auscultation

Tone of muscle

R.S.Examination

CVS Examination

INVESTIGATION

- 1) CBC
- 2) Urine routine
- 3) Serum urea and creatinine

POST OPERATIVE PERIOD: Evaluation of pain on VAS.

Post-operative pain	2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
Visual Analogue Score						

ANNEXURE – II

CONSENT FOR PARTICIPATION IN RESEARCH

Mr./Mrs. _____ we are requesting you to enroll yourself in study titled “**COMPARISON OF MODIFIED PROLENE HERNIA SYSTEM REPAIR VERSUS CONVENTIONAL MESH REPAIR IN POST-OPERATIVE PAIN IN INGUINAL HERNIAS – A RANDOMISED CONTROLLED TRIAL**” conducted by **Dr.** _____, postgraduate student in MS GENERAL SURGERY under the guidance of **Dr.** _____ at J. N. Medical College, Belgaum.

Objective / purpose of this study:

You have been requested to participate in research because we find your profile matching with our study group. Your participation in the research is absolutely voluntary. Your decision to participate in the study or otherwise will not affect your relationship with J.N.M.C. If you decide not to participate, you are free to withdraw at any time.

This study is being done to compare two techniques used in repair of inguinal hernia viz. Modified Prolene Hernia System Repair and the Conventional Mesh Repair and assess the post-operative pain in both the techniques.

Procedure:

Two techniques used in repair of inguinal hernia viz. Modified Prolene Hernia System Repair and the Conventional Mesh Repair are compared in this study.

Risk and benefits:

There is no increased risk involved in becoming a part of this study and the complications are those which are normally anticipated. This study will help us to estimate the incidence of post operative pain in comparison with the two techniques involved. The results derived at the end of study will benefit all similar patients admitted in this hospital.

Withdrawing / Removal from the study:

The participant has full freedom to withdraw from the study whenever he/she wishes and without prior notice. . Even if you decline to participate, there will not be any change in the line of your management or the relationship with your doctor. You will be told about all the new information that may affect your decision to participate in the study. The Investigator may also exclude a participant from the study at anytime.

Privacy and Confidentiality:

The only people to know that you are a research subject are the members of research team. No information about you or provided by you during the research will be disclosed to others without your written permission except:

1. In emergency to protect your rights and welfare.
2. If required by law.

Institutional / Sponsors policy:

If any unforeseen complications or injury occurs during the period of study the participant will be given treatment within the limitations of KLE's Prabhakar Kore Hospital General ward.

Financial incentives for participation:

The participant will neither get any financial incentives during the period of study nor will be asked to pay for the purpose of this study.

Contact details :

The participant can contact me any time during the study period for clarification of doubts or any questions.

Dr. _____,

J.N.M.C , Belgaum.

Phone no.

Authorization to Publish Results:

When the results of the research are published or discussed in a conference, no information will be displayed that would disclose your identity. Any information that is obtained in connection with this study and that can be identified with you will remain confidential

CONSENT STATEMENT:

I, the undersigned, have been explained in my own vernacular language about the study. I am aware that my participation in this study is voluntary and I could withdraw at any time. Also I had been given enough time to comprehend and clarify my doubts about the study and my rights as a study participant.

In case you have any questions related to the study, please feel free to contact the Principal investigator Dr. _____ at anytime (Phone no. _____).

Signature or the left thumb impression of the participant or legally authorized representative

Participant's name _____ Signature _____

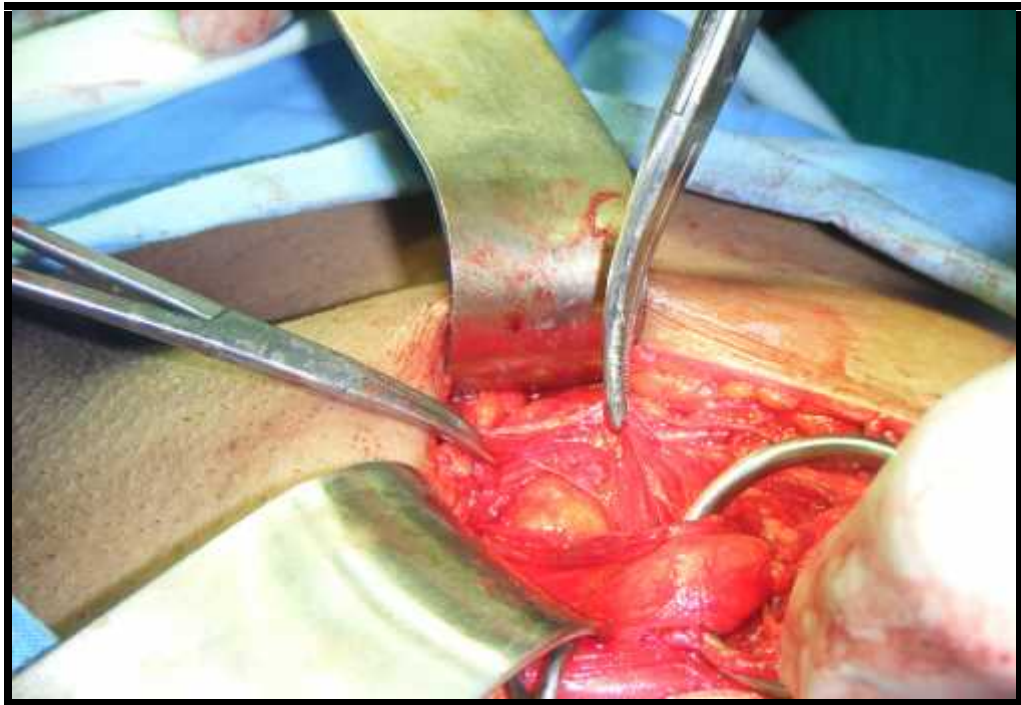
Witness's name _____ Signature _____

Investigator's name _____ Signature _____

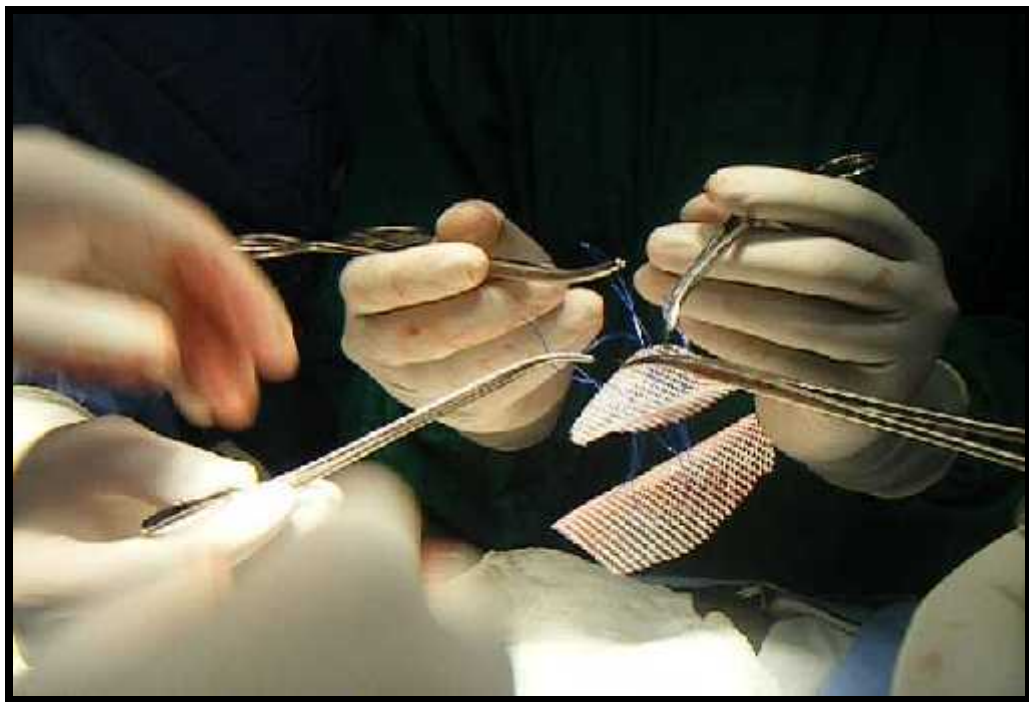
Place _____

Date _____

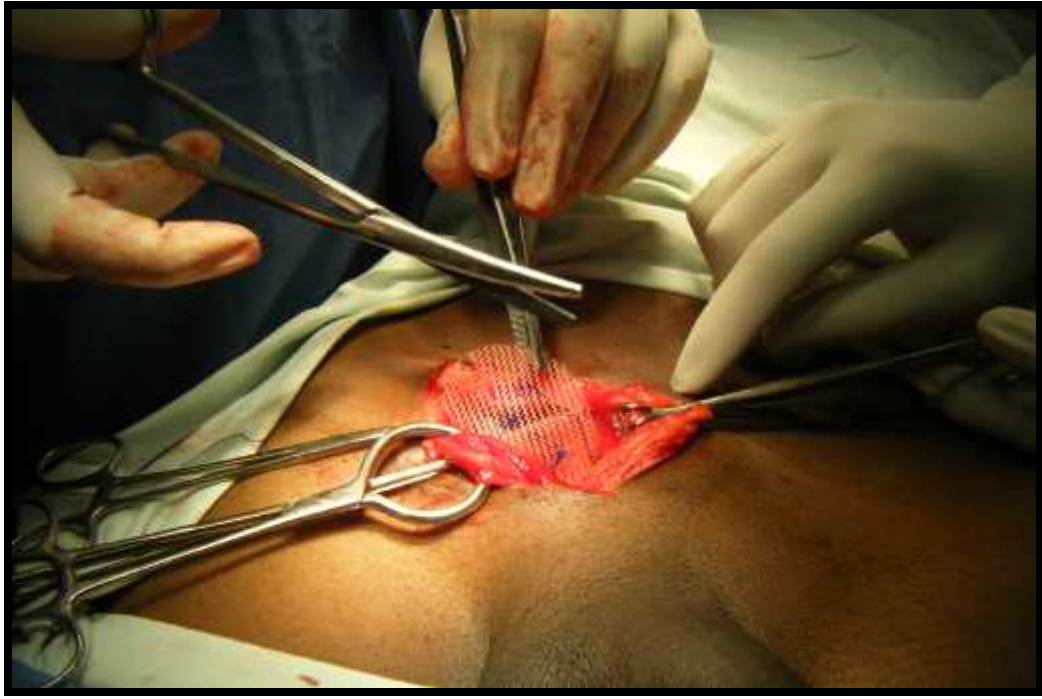
ANNEXURE – III
PHOTOGRAPHS



PHOTOGRAPH 1: DISSECTION OF TRANSVERSALIS FASCIA



**PHOTOGRAPH 2: CREATION OF MODIFIED PROLENE HERNIA
SYSTEM**



PHOTOGRAPH 3: DEPLOYMENT OF MODIFIED PROLENE HERNIA SYSTEM



PHOTOGRAPH 4: FIXATION OF MODIFIED PROLENE HERNIA SYSTEM



PHOTOGRAPH 5: FINAL POSITION OF MPHS

**ANNEXURE – IV MASTER CHART
MODIFIED PROLENE HERNIA SYSTEM**

SL NO	IP NO	NAME	AGE/SEX	DIAGNOSIS	PAIN SCORE AT DIFFERENT WEEKS					
					2 wks	4 wks	6 wks	8 wks	10 wks	12 wks
1	292818	SB	48/M	RDH	6	5	4	3	1	
2	296716	SM	70/M	RDH	6	6	4	3	2	1
3	302660	BP	26/M	LIH	6	5	4	3	2	1
4	304885	KH	70/M	BDH	7	6	5	4	3	2
5	305184	DP	35/M	RIH	6	5	4	3	2	1
6	304856	SG	45/M	RIH	6	5	4	3	2	1
7	304339	RJ	40/M	RDH	6	5	4	3	2	1
8	304332	RP	52/M	RDH	5	4	3	2	1	
9	308437	PD	65/M	BDH	6	5	4	3	2	1
10	309465	VK	70/M	BDH	6	5	4	3	2	1
11	310108	BJ	70/M	BDH	5	4	4	2	1	
12	320412	BK	65/M	RDH	6	5	4	3	2	1
13	312814	BK	53/M	LDH	5	4	3	2	1	
14	314112	TM	23/M	LIH	6	5	4	3	2	1
15	320797	HB	57/M	LDH	6	5	4	3	2	1

SL NO	IP NO	NAME	AGE/SEX	DIAGNOSIS	PAIN SCORE AT DIFFERENT WEEKS					
					2 wks	4 wks	6 wks	8 wks	10 wks	12 wks
16	320941	AS	40/M	RDH	6	5	4	3	2	1
17	320833	AR	21/M	RIH	5	4	3	2	1	
18	321614	IP	25/M	RIH	6	5	3	3	2	1
19	321978	PP	65/M	RDH	6	5	4	3	2	1
20	321331	NA	38/M	LDH	5	4	3	3	1	
21	321614	AT	22/M	LIH	5	4	3	3	1	
22	323673	VO	60/M	BDH	5	4	3	3	1	
23	324168	BG	60/M	RDH	6	5	3	4	2	1
24	325052	AK	60/M	RDH	6	5	4	4	2	1
25	325290	SM	56/M	LDH	6	5	4	4	2	1
26	325670	PM	45/M	RDH	7	6	4	3	2	
27	325980	RF	50/M	LDH	5	5	3	2	1	2
28	326112	RG	53/M	LIH	6	6	3	3	2	1
29	326178	SG	48/M	RIH	5	6	4	4	1	1
30	326645	TG	49/M	LIH	6	5	4	4	2	1

CONVENTIONAL LICHTENSTEIN MESH REPAIR

SL NO	IP NO	NAME	AGE/SEX	DIAGNOSIS	PAIN SCORE AT DIFFERENT WEEKS					
					2 wks	4 wks	6 wks	8 wks	10 wks	12 wks
1	299998	GH	56/M	RDH	5	4	5	4	2	1
2	300530	AB	29/M	RIH	6	5	4	4	1	2
3	300598	CP	33/M	LIH	6	5	5	3	2	1
4	298608	BH	58/M	RDH	6	4	5	3	1	
5	301923	IB	42/M	LDH	7	6	4	3	3	
6	302919	SH	62/M	RDH	6	5	4	3	2	1
7	303170	RV	78/M	LDH	5	6	3	3	2	1
8	303966	KT	66/M	LDH	6	5	3	3	2	2
9	303741	ND	40/M	RIH	5	6	3	2	1	1
10	305484	VR	60/M	RDH	6	5	4	2	1	1
11	307399	SS	31/M	RIH	6	5	5	4	3	1
12	306866	SM	52/M	RDH	6	4	4	3	2	
13	305058	NS	75/M	LDH	7	4	3	3	2	
14	308905	AK	40/M	RIH	6	4	4	2	1	1
15	312483	BD	45/M	RDH	5	4	5	2	1	1

SL NO	IP NO	NAME	AGE/SEX	DIAGNOSIS	PAIN SCORE AT DIFFERENT WEEKS					
					2 wks	4 wks	6 wks	8 wks	10 wks	12 wks
16	314138	SP	22/M	LIH	5	5	5	3	1	
17	316376	AK	35/M	LDH	6	5	4	2	1	1
18	316324	DK	52/M	LDH	7	5	3	3	2	
19	317194	SP	23/M	RIH	6	6	3	3	2	1
20	317345	IH	53/M	RDH	6	6	3	2	2	
21	320168	DK	50/M	RDH	6	5	4	5	1	1
22	323778	NS	60/M	BDH	5	6	4	3	1	
23	324567	SH	36/M	RDH	6	5	3	3	1	1
24	298127	SK	50/M	LDH	7	4	4	3	2	1
25	299342	SD	30/M	LIH	6	5	3	2	2	2
26	299416	VP	63/M	RDH	5	4	3	3	2	
27	303956	BK	60/M	RDH	5	5	4	3	2	1
28	305439	AC	40/M	LDH	6	6	4	4	1	1
29	308132	RP	45/M	BDH	7	5	3	4	1	1
30	310445	AB	40/M	BDH	7	5	4	3	1	1