"A ONE YEAR RANDOMISED CONTROLLED TRIAL TO COMPARE PROLENE HERNIA SYSTEM REPAIR VERSUS LICHTENSTEIN MESH REPAIR FOR REDUCTION IN POST-OPERATIVE PAIN IN INGUINAL HERNIAS"

By

Dr. VASANT KUMAR V. TEGGIMANI

(REG.NO. BH0109008)

Dissertation

Submitted to the
KLE University, Belgaum, Karnataka

In Partial Fulfillment
of the requirements for the degree of

M. S.
in
GENERAL SURGERY

Under the Guidance of

Dr. A. S. GOGATE MS
Professor

DEPARTMENT OF SURGERY,
JAWAHARLAL NEHRU MEDICAL COLLEGE,
BELGAUM, KARNATAKA

MAY - 2012

KLE UNIVERSITY, BELGAUM, KARNATAKA

DECLARATION BY THE CANDIDATE

I hereby declare that this dissertation entitled **"A ONE YEAR RANDOMISED CONTROLLED TRIAL TO COMPARE PROLENE HERNIA SYSTEM REPAIR VERSUS LICHTENSTEIN MESH REPAIR FOR REDUCTION IN POST-OPERATIVE PAIN IN INGUINAL HERNIAS"** is a bonafide and genuine research work carried out by me under the guidance of **Dr. A. S. GOGATE** **MS** Professor, Department of Surgery, Jawaharlal Nehru Medical College, Nehru Nagar, Belgaum-590 010.

Date:

Place:

Dr. VASANT KUMAR V. TEGGIMANI
REG. NO. BH0109008

KLE UNIVERSITY, BELGAUM, KARNATAKA

CERTIFICATE BY THE GUIDE

This is to certify that the dissertation entitled **"A ONE YEAR RANDOMISED CONTROLLED TRIAL TO COMPARE PROLENE HERNIA SYSTEM REPAIR VERSUS LICHTENSTEIN MESH REPAIR FOR REDUCTION IN POST-OPERATIVE PAIN IN INGUINAL HERNIAS"** is a bonafide research work done by **Dr. VASANT KUMAR V. TEGGIMANI (REG. NO. BH0109008)** in partial fulfillment of the requirement for the degree of **M. S. in GENERAL SURGERY.**

Date:

Place:

Dr. A. S. GOGATE **MS**
Professor,
Department of Surgery,
J. N. Medical College,
Nehru Nagar, Belgaum – 10

KLE UNIVERSITY, BELGAUM, KARNATAKA

ENDORSEMENT BY THE HOD/PRINCIPAL/ HEAD OF THE INSTITUTION

This is to certify that the dissertation entitled **"A ONE YEAR RANDOMISED CONTROLLED TRIAL TO COMPARE PROLENE HERNIA SYSTEM REPAIR VERSUS LICHTENSTEIN MESH REPAIR FOR REDUCTION IN POST-OPERATIVE PAIN IN INGUINAL HERNIAS"** is a bonafide research work done by **Dr. VASANT KUMAR V. TEGGIMANI (REG. NO. BH0109008)** under the guidance of **Dr. A. S. GOGATE** $_{MS}$ Professor, Department of Surgery, Jawaharlal Nehru Medical College, Nehru Nagar, Belgaum-590010.

Dr. V. M. UPPIN $_{MS}$
Professor and Head,
Department of Surgery,
J. N. Medical College,
Nehru Nagar, Belgaum – 10

Date:
Place: Belgaum

Dr. V. D. PATIL $_{MD,DCH}$
Principal,
J. N. Medical College,
Nehru Nagar, Belgaum – 10

Date:
Place: Belgaum

KLE UNIVERSITY, BELGAUM, KARNATAKA

COPYRIGHT

DECLARATION BY THE CANDIDATE

I hereby declare that the KLE University, Belgaum, Karnataka shall have the rights to preserve, use and disseminate this dissertation in print or electronic format for academic / research purpose.

Date :

Place :

Dr. VASANT KUMAR V. TEGGIMANI
(REG. NO. BH0109008)

ACKNOWLEDGEMENT

I take this opportunity to express my respect and heart felt gratitude to all my teachers.

I gladly utilize this opportunity to express my deep sense of gratitude and indebtedness to my respected teacher and guide **Dr. A. S. Gogate**$_{M.S.}$ Professor, Department of Surgery without whose everlasting inspiration, incessant encouragement and criticism, with valuable suggestions for improvement, the completion of this study would not have been possible.

I am extremely grateful and indebted to **Dr. V. M. Uppin**$_{M.S.}$ Professor and Head of the Department of surgery, J. N. Medical College, Belgaum, for his valuable advice and guidance in completing this dissertation.

I also wish to express my deepest gratitude to **Dr. V. D. Patil** $_{MD, DCH}$ Principal, J. N. Medical College, Belgaum, for allowing me to conduct this study.

I am thankful to **Dr. M. V. Jali**$_{M.D.}$ Medical Director, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum, for allowing me to carry out the dissertation work.

I express my sincere gratitude to **Dr. V. B. Dhaded**$_{MS,FICS.,}$ **Dr. A. S. Godhi**$_{MS, FICS}$ **Dr. Shashi. M. Uppin**$_{MS,FICS}$ **Dr. M. S. Sangoli**$_{MS,}$ **Dr. S. S. Shimikore**$_{MS,}$ **Dr. I. V. Uppin**$_{MS,}$ **Dr. A. C. Pangi**$_{MS,FAIS,}$ **Dr. S. C. Metgud** $_{MS,}$ **Dr. P. S. Pattanshetti**$_{MS,}$ Professors who have encouraged me during the course of study. I thank them for their inspiration and moral support.

I thank **Dr. R. R. Rao**$_{MS,}$ **Dr. Basavaraj Kajagar**$_{MS.}$ Associate Professors, Department of Surgery, for their valuable guidance throughout the course of this study.

I express my sincere gratitude to **Dr. R. S. Koujalagi**$_{M.S.,}$ **Dr. V. M. Pattanshetti** $_{M.S.,}$ **Dr. S. N. Halabhavi**$_{M.S.,}$ **Dr. Manoj Togale** $_{M.S.,}$ **Dr. Rahul. K** $_{MS.}$ **Dr. Aman Mahajan** $_{MS,}$ **Dr. Pushpa S Kumar**$_{MS}$

Dr. Prashant Hombal$_{MS}$ Assistant Professors, Department of Surgery, who have provided me with moral support during the study.

I sincerely thank my post graduate colleagues **Dr. Chetan Hoskatti, Dr. Chintan Soni, Dr. Manohar S, Dr. Sidharth Chacko, Dr. Abhay Agrawal, Dr. Chandrashekar, Dr. Rohit Muvva, Dr. Yogesh J K, Dr. Manoranjan U. D., Dr. Pramod S., Dr. Amit Katti, Dr. Sunil Reddt, Dr. Amit Nagpure, Dr. Shawn Thomas, Dr. Akhay Metgud, Dr. Meghana, Dr. Allamprabhu** and **Dr. Aditya** for their kind help rendered throughout the course of my study.

I am thankful to **Mr. M. D. Mallapur**$_{M.Sc.}$ Statistician, for his help in statistical analysis.

From the bottom of my heart I convey my heartfelt gratitude to **All Patients** without whose co-operation this study would have been incomplete.

No amounts of words can measure up my deep sense of gratitude and fullness that I feel towards my parents **Dr. Virendra. V. Teggimani** and **Sadhana. V. Teggimani ,** my sister **Leelavati** and other friends and family members.

I express my sincere thanks to my friends for their constant help, support, encouragement and cooperation in designing my dissertation.

Date:

Place: Belgaum

Dr. VASANT KUMAR V. TEGGIMANI
REG No. BH0109008

LIST OF ABBREVIATIONS USED

BPMD	-	Bilayer polypropelene mesh device
CGP	-	Chronic Groin Pain
CLMR	-	Conventional Lichtenstein Mesh Repair
EOA	-	External oblique aponeurosis
PHS	-	Prolene Hernia System
PTFE	-	Poly tetra flouroethylene
VAS	-	Visual analogue score

ABSTRACT

Background and Objectives

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 present study was planned to compare the incidence of reduction in postoperative pain following hernia repair with PHS versus Lichtenstien mesh repair.

Methodology

The present one year randomized control trial was conducted in the Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2010 to December 2010 on 60 patients with inguinal hernia undergoing mesh repair. Based on computer generated blocked random numbers patients were divided into two groups that is, group A (Patients undergoing PHS) and Group B (Patients undergoing conventional mesh repair).

Results

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 51.4±15.69 and 53.47±17.18 respectively. During the second week pain score in group A were significantly less compared to group B (5.87±0.78 vs 6.67±0.61). Similarly during fourth and sixth week also significant less pain score was noted in group A (4.67 ± 0.76 and 3.60 ± 0.77) compared to group B (5.43 ± 0.57 and 4.17 ± 0.79). However the pain score during eighth, tenth and twelfth

week were less in group A compared to group B ($p>0.05$). No patients experienced severe pain in either group at 2 weeks, only mild to moderate pain was reported.

Conclusion and interpretation

In conclusion, pain scores with the use of Prolene Hernia System mesh repair, were comparable to the conventional Lichtenstein mesh repair while providing a more complete repair to the patient.

Keywords

Conventional Lichtenstein Mesh Repair; Inguinal hernia; Hernia repair; Prolene hernia system;

CONTENTS

LIST OF TABLES

LIST OF GRAPHS

LIST OF FIGURES

LIST OF PHOTOGRAPHS

Introduction

Objectives

Review of Literature

Methodology

Results

Discussion

Conclusion

Summary

Bibliography

Annexure-I

Annexure-II

Annexure-III

Annexure-IV

INTRODUCTION

Several different types of abdominal wall hernias have been identified, along with a larger number of associated eponyms. Groin Hernias are one of the most common surgical condition faced by surgeons over the years and it still continues, to excite the interest of surgeons and patients. Surgeons are more interested in the techniques available, in recurrence rates, and in short term complications of hernia surgery whereas patients are most interested in return to work and full social activity, pain-free convalescence, and a well-healed wound.

In late 18th century, Edorado Bassini revolutionized the treatment of inguinal hernia by the technique designed "to restore those conditions in the area of the inguinal orifice which exists under normal circumstances".[1] Since then numerous methods of repairs were developed for inguinal hernias namely, Halstead, Shouldice, McVay and regardless of modification they shared a common disadvantage that is suture line tension, being prime etiologic factor in hernia recurrence.[2] These repairs are limited by the shortcomings of their respective techniques.

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.[3]

Various types of tension-free mesh repairs have been described, but with incidence of recurrence of about 0.1% - 0.4% and wound complications.[4]

Prosthetic meshes were first introduced in 1958 and have since evolved over the years. The use of prosthetic meshes for open surgical repair of inguinal hernia has become increasingly popular in western countries as well as in India. 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. Surgeons have related success by using a prolene hernia system, which gives a double advantage of combining an anterior repair (as in conventional mesh repair) and a posterior repair (as in Laparoscopic repair).

This latest tension-free Prolene Hernia System mesh technique has been introduced by Dr. Arthur Gilbert in 1999 and has been used in North Penn Hernia institute since a decade with least complications and recurrence rate of less than 0.5%. This method utilizing the prolene hernia system mesh is a "3-in-1 device" made of polypropylene, incorporating an "underlay patch" that is positioned in the pre-peritoneal space, a "connector" that is placed through the hernia defect, and an "onlay patch" that is placed on the inguinal floor, also with minimal fixation.[5]

This device combines all the benefits of the Lichenstein's,[6] mesh plug and Kugel techniques.[7] It is the only tension-free device that covers the entire hernia

prone area called “The Myopectineal Orifice”, while the other techniques leave areas of this region of abdominal wall vulnerable.

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. Developments in the non-tension mesh repairs have led to the on going debate as to the best hernioplasty procedure.

There are many studies comparing the efficacy of the prolene hernia system with the litchenstien mesh repair. Though one or two studies have been done in India but similar study has not been done in our centre. Despite the advantages of PHS the procedure is not being adapted at our centre in the past. Hence the present study was planned to compare the incidence of reduction in postoperative pain following hernia repair with PHS versus Lichtenstien mesh repair.

OBJECTIVES

The objective of the present study was to compare the incidence of postoperative pain following hernia repair with PHS versus Lichtenstien mesh repair.

REVIEW OF LITERATURE

EMBROYLOGY[8]

During the sixth week of gestation, mesoderm from the myotomes which lie on either side of the vertebral column invades the somatopleura (primitive wall of the abdomen). The mesoderm forms a Sheet like embryologic entity. After migrating laterally and ventrally, it differentiates to form the right and left rectus. Around 12th week, they approximate in the midline, closing the body wall.

The lower abdominal wall is formed by a mesodermal layer, the so-called "secondary mesoderm". It envelops and invades the cloaca, thereby separating ectoderm from endoderm cranial to the cloaca. The embryology of inguinal canal is peculiar. In a highly synergistic way, the skin, parietal peritoneum, and embryologic and anatomic entities between them produce the future pathway of the testes. The skin will form the scrotum (scrotal folds) in male and labia (labial folds) in the female. The parietal peritoneum will produce the processes vaginalis. This peritoneal diverticulum is more important to the male fetus as it will permit the descent of the testes.

The embryologic entities between skin and peritoneum permit the processes vaginalis to penetrate them and form the inguinal canal, so the downward journey of the testicle to the scrotum is allowed. In girls, the descent of the ovary outside the peritoneal cavity is forbidden. The processes vaginalis finally closes to obstruct ovarian exodus but leaves the formation of the inguinal canal in-situ.

The vaginal process caries extensions of the layers of the abdominal wall before it, which form the walls of the inguinal canal. In males, these layers also form the coverings of the spermatic cord and testes. The opening in the transversalis fascia, produced by the vaginal process becomes the deep inguinal ring and the opening created in External oblique aponeurosis forms the superficial inguinal ring.[9]

SURGICAL ANATOMY[9-14]

The anterior abdominal wall extends from the costal margins and xiphoid process superiorly to the iliac crests, pubis and pubic symphysis inferiorly. The groin is that portion of the anterior abdominal wall below the level of the anterior superior iliac spines and has been the subject of great interest to surgeons and anatomists for centuries. A three dimensional mental conception of structural relations must be acquired if one is to understand the groin anatomy and the fundamental features of a groin hernial repair. Anterior abdominal wall tissues form the inguinal canal that connects the abdominal cavity to the scrotum in men, or the labia majora in women and also form the umbilicus; both of these sites being of clinical importance.

The groin or inguinal repair, is most often defined as a transitional area in which the thigh and abdomen are joined.

Soft tissue of the anterior abdominal wall

Superficial fascia

The superficial fascia of the abdominal wall consists mostly of a single layer that contains variable amount of fat. It lies between the skin and muscles of anterior abdominal wall. In the lower part, the fascia differentiates into superficial and deep layers between which lie superficial vessels and nerves and, in the groin region, superficial inguinal lymph nodes.

a) Superficial layer (Camper's fascia) being thick, areolar in nature and contains variable amount of fat and is often greatly thickened in obese individuals. Inferiorly, it lies superficial to inguinal ligament and is continuous with superficial fascia of thigh, and the outer layer of fascia covering the perineum, penis and scrotum. In this region, it is generally thin with very little adipose tissue and in the scrotum contains smooth muscle fibres, which form the dartos muscle. In females, it continues from the suprapubic skin of the abdomen into the labia majora and perineum.

b) Deep membranous layer (Scarpa's fascia) This layer contains more elastic fibres and is loosely connected by areolar tissue to the aponeurosis of external oblique, but in the midline it is intimately adherent to linea alba and public symphysis. In male, it extends to form superficial ligament of the penis and continues medially and inferiorly over penis and scrotum where it becomes continuous with membranous layer of the superficial fascia of the perineum.

Transversalis fascia

A thin layer of connective tissue lying between the inner surface of transverse abdominis and extraperitoneal fat. In the inguinal region, it is thick and dense, and augmented by the aponeurosis of transverses abdominis muscle. Medial to the femoral vessels it is thin and fused to pubis behind conjoint tendon. Some fibres spread laterally towards the anterior superior iliac spine, some fibres run medially behind rectus abdominis, and some descend to pubis behind conjoint tendon, forming deep crural arch. The curved fibres of this arch thicken the inferomedial part of the rim of the deep inguinal ring. The spermatic cord in male, or the round ligament of uterus in female, pass through the transversalis fascia at the deep ring. The transversalis fascia is prolonged onto these structures as the internal spermatic fascia surrounding the testes and blends with areolar tissue on the parietal layer of tunica vaginalis.

Superficial vessels

The anterior abdominal wall receives its blood supply from paired superior epigastric artery (terminal branch of internal thoracic artery), and inferior epigastric artery (from the external iliac artery posterior to inguinal ligament) running vertically through the tissues, and from paired posterior intercostal, subcostal and lumbar vessels running obliquely around the anterolateral aspects of the abdomen.

Other vessels namely are the superficial circumflex iliac and external pudendal vessels arising from femoral artery. All the arteries are accompanied by their respective veins and form tributaries to the femoral vein.

Lymphatic drainage

The lymphatic vessels of the anterior abdominal wall lie both superficial and deep to the deep fascia. Superficial lymphatics from the infra-umbilical skin run with the superficial epigastric vessels and vessels from lumbar and gluteal regions run with the superficial circumflex iliac vessels and drain ultimately into the superficial inguinal nodes.

Deep lymphatic vessels accompany the deep arteries. The vessels from the posterior portion of the abdominal wall pass with the lumbar arteries to drain into lateral aortic and retro-aortic nodes. Vessels from upper abdominal wall run with superior epigastric vessels to the parasternal nodes. Vessels of the lower abdominal wall drain into circumflex iliac, inferior epigastric and external iliac nodes.

Innervation

The 7^{th} to be 12^{th} lower thoracic ventral rami continue anteriorly from the intercostals spaces into the abdominal wall. The rectus muscle and external oblique are both supplied by lower intercostal and subcostal nerves (T7 – T12), and the internal oblique and transverses by those same nerves with the addition of iliohypogastric and ilio inguinal nerves (L1). The 11th nerve supplies the skin below the umbilicus. The ilio-inguinal nerve accompanies the spermatic cord through the external inguinal ring. It goes on to supply the medial thigh proximal to the inguinal ligament, the root of the penis and upper anterior scrotum. In the female, the nerve exits the external ring to supply the mons pubis and labium

majus. Iliohypogastric nerve has some fibres in common with subcostal and ilioinguinal nerve.

The genitofemoral nerve emerges onto the anterior surface of psoas major muscle and its genital branch exits the pelvis via the deep inguinal ring and courses with the spermatic cord, supplying the cremaster muscle. The femoral branches of the genitofemoral nerves (L1, L2) pass under or pierce the inguinal ligament, travel across the thigh lateral to the saphenous hiatus, and then travel a short distance in the femoral sheath to supply the skin over the femoral sheath.

Inguinal canal

The inguinal canal is an oblique intermuscular slit about 4 cm long lying above the medial half of inguinal ligament. Its size varies with age, and although present in both sexes, is well developed in males. It commences at the deep inguinal ring, ends at the superficial inguinal ring, and transmits the spermatic cord in males, the round ligament of the uterus in females, and the ilionguinal nerve in both sexes.

Its anterior wall is formed by the external oblique aponeurosis, assisted laterally by the internal oblique muscle. Its floor is the inrolled lower edge of the inguinal ligament, reinforced medially by the lacunar ligament. Its roof is formed by the lower edges of the internal oblique and transverses muscle, which arch over from in front of the cord laterally to behind the cord medially, where their conjoined aponeurosis, constituting the conjoint tendon, are inserted into the pubic crest and the pectineal line of the pubic bone.

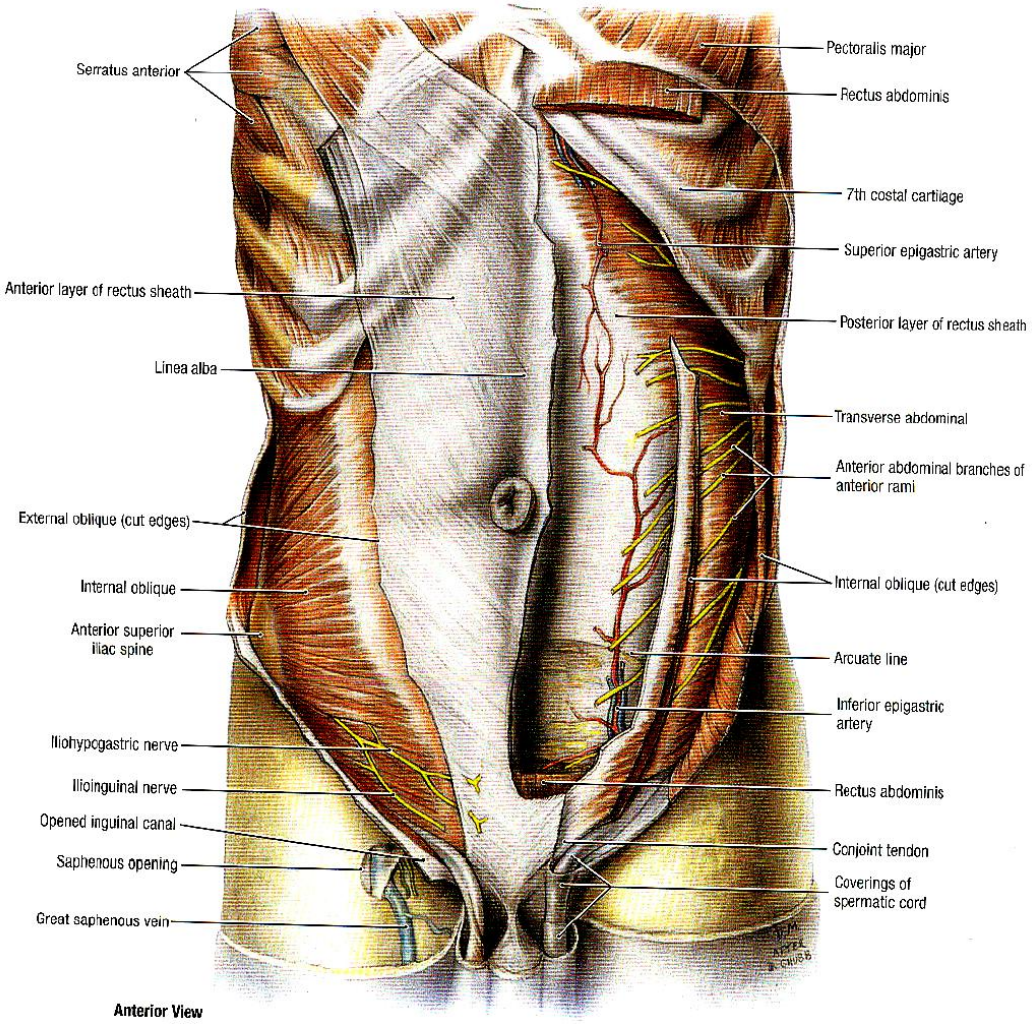
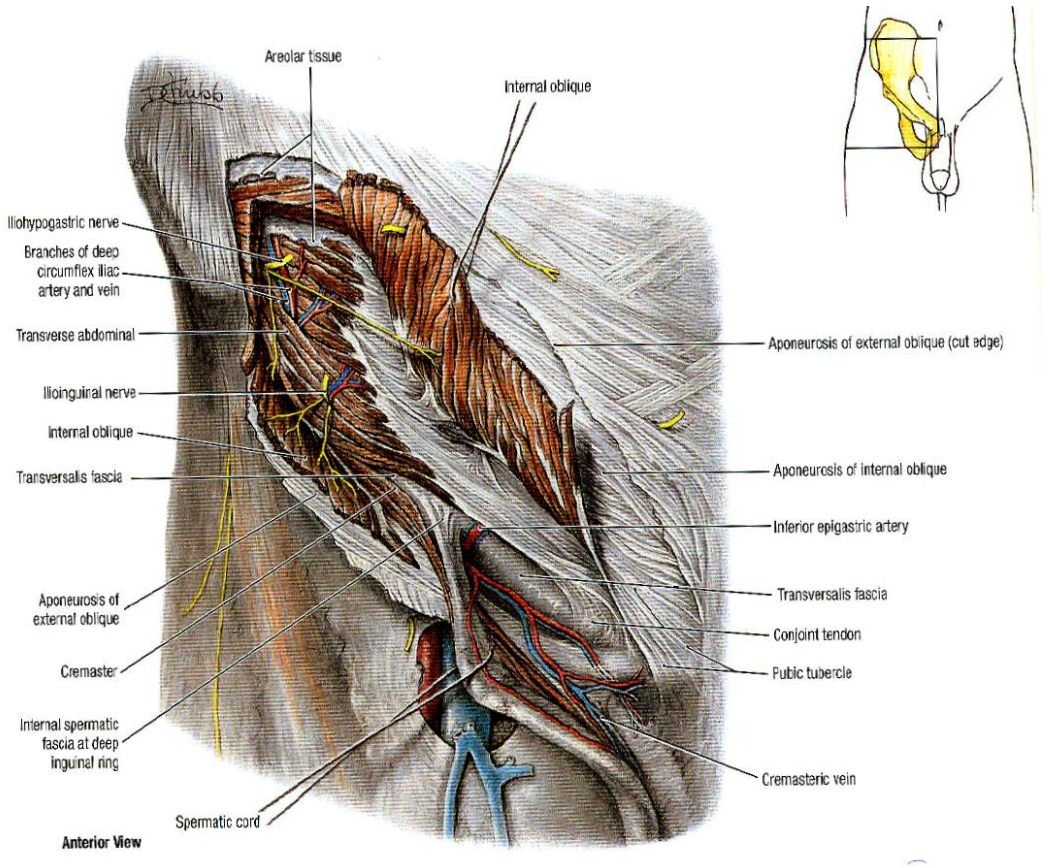


Figure 1. Vessels and nerves of the anterior abdominal wall



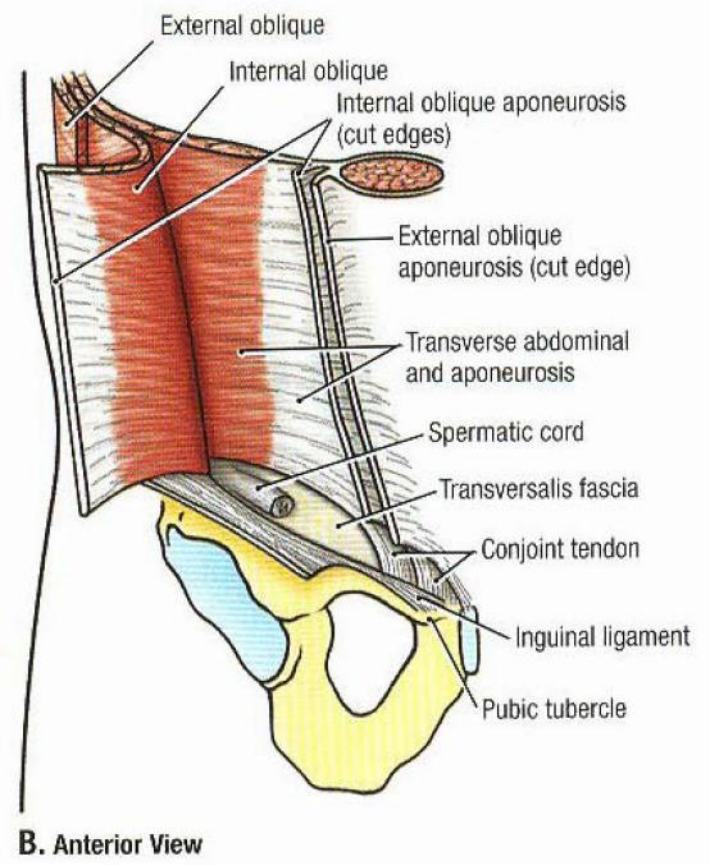


Figure 2. Inguinal canal in the male

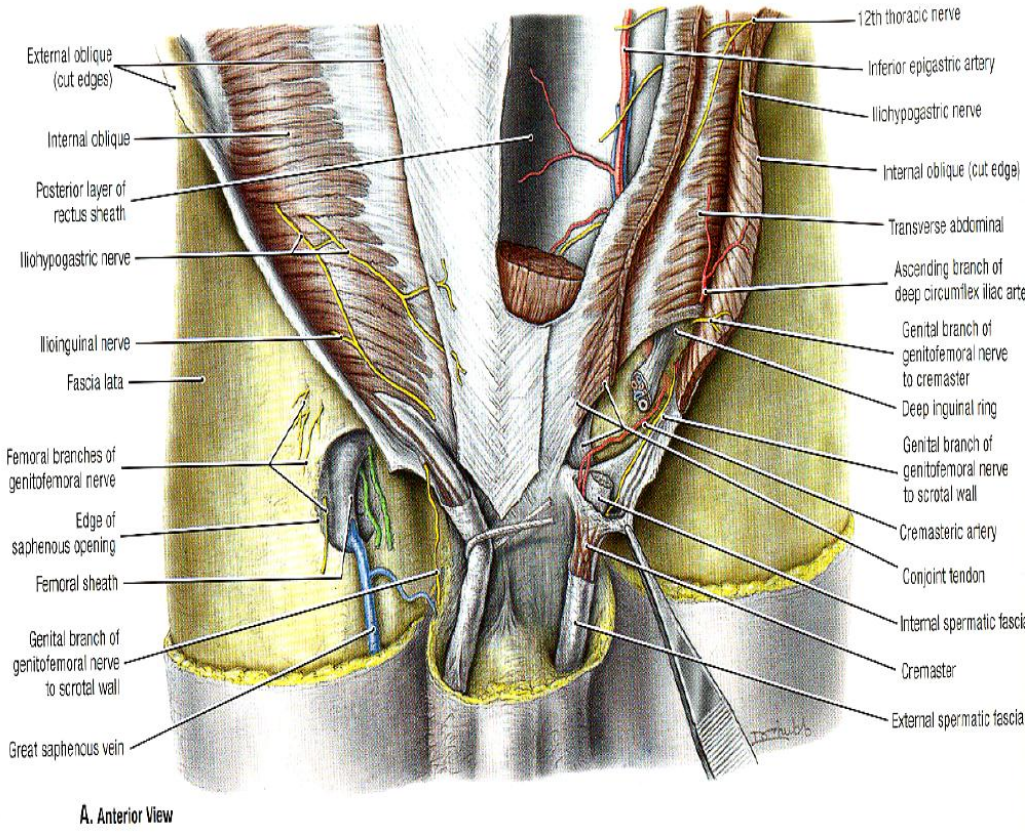


Figure 3. Inguinal region of the anterior abdominal wall in the male

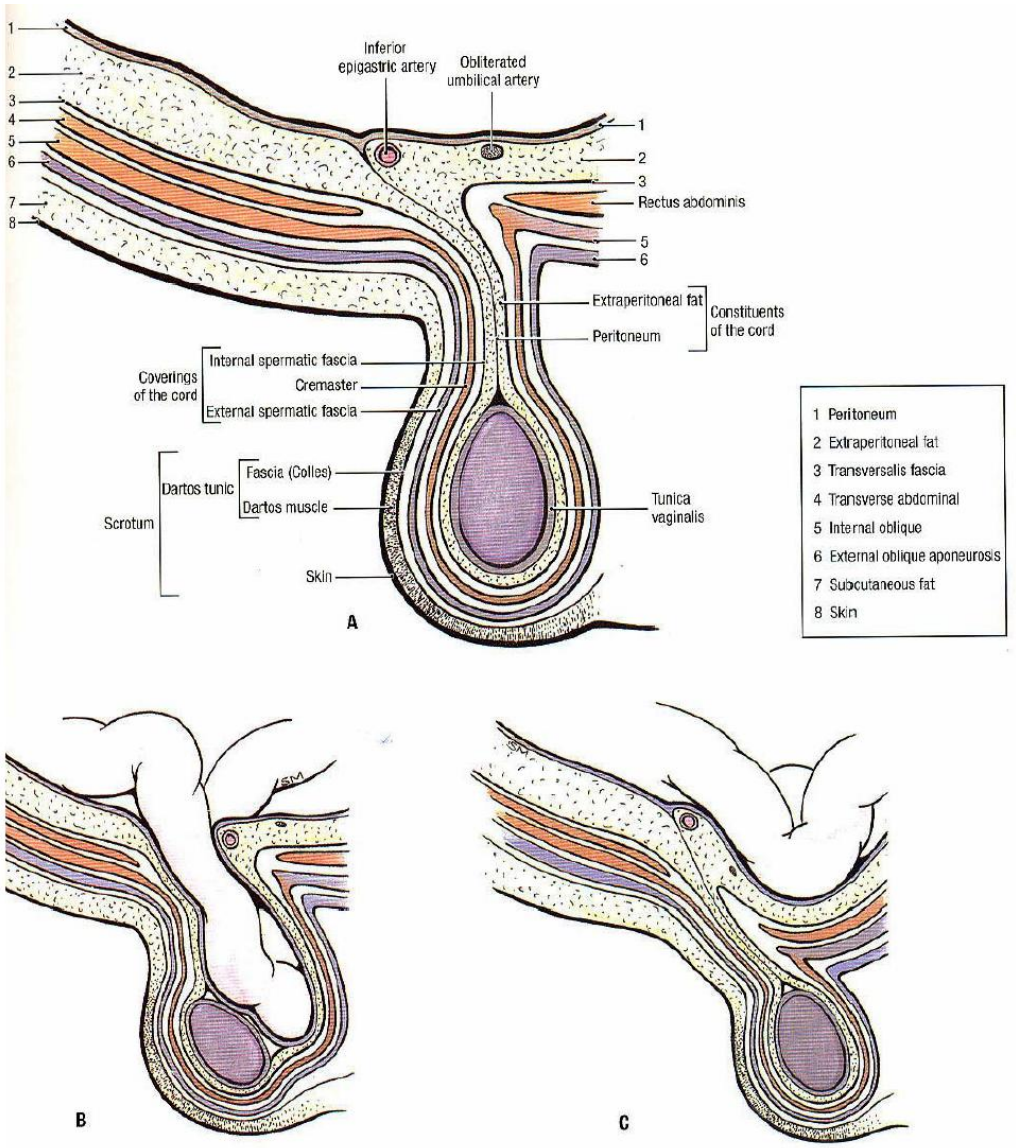


Figure 4. Labelled diagrams: A-Coverings of spermatic cord and testes; B-Indirect inguinal hernia; C-Direct inguinal hernia.

The posterior wall of the canal is formed by the strong conjoint tendon medially and weak transversalis fascia throughout.

Superficial inguinal ring

It is a hiatus in the external oblique aponeurosis, just above and lateral to the public crest. The ring is actually triangular with its apex pointing along the line of the deep fibres of the aponeurosis. The base lies along crest of the pubis and its sides are the crura. The lateral crus is stronger and is reinforced by fibres of the inguinal ligament inserted into the public tubercle. The medial crus is thin and attached to the front of pubis symphysis and interlace with fibres from the opposite side. A few fibres arch above the apex of the ring as intercrural fibres. In males, the lateral crus is curved to form a groove in which the spermatic cord vests. Fibres from external oblique aponeurosis continue downward as a tubular fibrous tissue around the spermatic cord and testes as the external spermatic foscia.

Deep inguinal ring

It is a oval slit in the transversalis fascia, midway between the anterior superior iliac spine and symphysis pubis approximately 1.25 cm above the inguinal ligament. It is related above to the arched lower margin of transverses abdominis, and medially to the inferior epigastric vessels and the interfoveolar ligament. Traction on this fascial ring exerted by internal oblique may constitute a valve – like safety mechanism when intra-abdominal pressure is increased.

Boundaries

Anterior wall

The inguinal canal is bounded anteriorly by the skin, superficial fasica and the aponeurosis of the external oblique. In its lateral one-third, the anterior wall is reinforced by the muscular fibres of internal oblique just above their origin from the inguinal ligament.

Posterior wall

Medially the posterior wall consists of a strong conjoint tendon, as already explained. Lateral to the conjoint tendon, lies the transversalis fascia and reflected part of the inguinal ligament, which separate the inguinal canal from extraperitoneal connective tissue and peritoneum. Laterally the transversalis fascia in the posterior wall is strengthened by the presence in front of it of tendinous, and sometimes muscles fibres derived from transverse abdominis muscle constituting the interfoveolar ligament. The integrity of the inguinal canal mainly depends upon the strength of the anterior wall in its lateral part and of the posterior wall in the medial part, and provided the abdominal muscles are of good tone and their aponeurosis unyielding, no direct herniation of viscera can take place.

Roof of the canal

This is formed by the arched fibres of internal oblique and transverse abdominis. The fleshy fibres of internal oblique arise from lateral two thirds of the inguinal ligament and in the groin region, its fibres are nearly transverse. The

fibres that arise from the inguinal ligament are continued into an aponeurosis that is attached to the crest of the public bone, and more laterally, to the pectineal line.

Throughout much of its course in the groin, the internal oblique muscle is intimately attached to the underlying fibres of transverses abdominis aponeurosis. The internal oblique has a free lower border, which arches over spermatic cord: laterally the margin consists of muscle fibres in front of the cord; medially the margin consists of tendinous fibres in front of the cord; medially the margin consists of tendinous fibres behind the cord. These lower most fibres of internal oblique and transversus are supplied by iliohypogastric and ilioinguinal nevers (L1). Their contraction tightens the conjoint tendon and lowers the roof of the canal, like pulling down a shutter. Thus division of ilioinguinal nerve above this level (as in a muscle-splitting incision of appendectomy) leads to a direct inguinal hernia-the conjoint tendon bulges when intra abdominal pressure rises.

Note that damage to the ilioinguinal nerve within the canal does not paralyse these fibres; at this level the nerve is purely sensory, having already given off its motor fibres, and injury here will only cause some sensory loss over anterior part of scrotum (labium majus) and adjacent thigh.

Floor

It is formed by the union of the transversalis fascia with the inguinal ligament and, at the medial end, the lacunar ligament. The lacunar ligament is a thick triangular band of tissue lying mainly posterior to medial end of inguinal ligament. It is formed from fibres of medial inguinal ligament and fibres from the fascia lata of thigh. The inguinal fibres run posteriorly and laterally to the medial

end of the pectineal line and are continuous with the pectineal fascia. The apex of the triangle is attached to the pubic tubercle.

A strong, fibrous band, the pectineal ligament of Astley cooper extends laterally along the pectineal line. Fibres from the fascia lata join the inferior posterior border of the inguinal ligament; the latter, in combination with fibres from the transversalis fascia, fuses with the pectineal fasica as it joins the thickened periosteum of the pectineal line.

Relations

The inferior epigastric vessels are important posterior relations of the medial end of the canal. They lie on the transversalis facia as they ascend obliquely behind the conjoint tendon into the posterior portion of the rectus sheath.

The inguinal triangle/Hesselbach's triangle is bounded inferiorly by medial half of inguinal ligament, medially lower lateral border of rectus sheath and laterally inferior epigastric artery. By definition a hernial sac passing lateral to the artery (i.e. through the deep ring) is an indirect hernia, one passing medial to the artery through the inguinal triangle is a direct hernia.

Fruchaud's myopectineal orifice

Fruchaud believed that all hernias of the groin begin within the groin, in an area he named the "Myopectineal orifice". This area in the groin is bounded as follows

Superior: Arch of internal oblique muscle and transverses abdominis muscle

Lateral: Iliopsoas muscle

Medial: Lateral border of rectus muscle and its anterior lamina

Inferiorly: Pecten pubis

The inguinal ligament spans and divides this framework.

Spermatic cord

It has three covering and six constituents. It begins in the preperitoneal space with the confluence in the region of the deep ring of testicular artery and vein and ductus deferens. Three coverings of spermatic cord from inside outwards are:

1. Internal spermatic fascia – derived from the transversalis fascia at the deep inguinal ring.
2. Cremaster muscle and cremasteric fascia – This is a loosely arranged layer consisting of striated muscle bundles united by areolar tissue and arises from the internal oblique and transverse abdominis muscle. The fibres spiral down the cord and loop back to get attached to public tubercle.
3. External spermatic fascia – acquired from the external oblique aponeurosis as the cord passes between the crura of the superficial ring.

The cremaster muscle can elevate the testes forwards or even into the inguinal canal; although the fibres are skeletal the action is reflex rather than voluntary. This cremasteric reflex is particularly active in infants and children

and must be borne in mind when examining the scrotum in young to avoid a misdiagnosis of an undescended testis.

The constituents of the cord;

1. The Ductus deferens, which usually lies in the lower and posterior part of the cord.
2. Arteries – Testicular artery (from the aorta), artery to ductus (from inferior vesical artery), and the cremasteric artery (from inferior epigastric artery).
3. Veins – pampiniform plexus of veins, cremasteric veins, veins of ductus deferens.
4. Lymphatics – especially those from the testis draining to para-aortic and interaortocaval lymphnodes, but some from the coverings of the cord draining into external iliac nodes.
5. Nerves – genital branch of genitofemoral nerve supplying the cremaster muscle. Other nerves are sympathetic twigs which accompany the arteries.
6. Processes vaginalis – the obliterated remains of the peritoneal connection with the tunica vaginalis of the testis. When patent it forms the sac of an indirect inguinal hernia.

EPIDEMIOLOGY[15,16]

- 75% of all abdominal wall hernias are found in the groin, making it the most common location for an abdominal wall hernia.
- Of all groin hernias, 95% are hernias of the inguinal canal.

- Inguinal hernias are nine times more common in men than in women in ratio of 7:1 or 12:1 in different series.
- Indirect hernias outnumber direct hernias by about 2:1
- Right sided groin hernias are more common than those on the left.
- The overall lifetime risk of developing a groin hernia is 15% in males and less than 5% in females.
- The lifetime risk for development of bilaterality is around 39%
    i. Age 25 to 34 - 31%
    ii. Age 65 to 74 - 45%
    iii. Age 75 + - 59%

ETIOLOGY[17-20]

Congenital

Patent processes vaginalis

It is the prime cause of indirect inguinal hernia in infants and children. The same probably holds true for adults in whom the processes vaginalis may be completely patent / only partially obliterated. The development of the processes, its migration into the scrotum, and its final obliteration are intimately linked to the descent of the testis from the abdominal cavity into the scrotum. These processes are initiated and controlled by the calcitonin gene – related peptide (CGRP) released by the genito-femoral nerve under the influence of fetal androgens. The presence of a patent processes vaginalis does not necessarily indicate that an indirect inguinal hernia is present, nor does it mean that one will

necessarily develop in the future. Therefore, additional factors must be present to produce an indirect inguinal hernia besides a patent processes vaginalis.

Hereditary

Hereditary also plays part in development of groin hernias, as evidenced by the high incidence of hernias in several generation of a family above that of the general population. It is however not clear whether in these families there is a higher incidence of patent processes vaginalis / defect in the structure of fascia transversalis or both.

Connective tissue disorders

Marfan's Syndrome, Ehlers Danlos Syndrome, Hurler – Hunter syndrome, and certain mesenchymal metabolic defects causing a deficiency of collagen and structural abnormalities of the collagen fibres, predispose to groin hernias.

The ability of fascia transversalis to withstand physiologic and pathologic elevations in the intra-abdominal pressure is dependant on the state of the collagen fibres that make up its tissues and give it its strength. Collagen is an active, live tissue maintained by a constant balanced state of production and absorption. The fasica transversalis may be attenuated by factors that interfere with normal collagen production / cause its increased destruction.

Hydroxylation of proline and lysine plays an important role in stabilizing collagen as this process produces inter and intra-molecular cross-linking and glycosylation of collagen. Significantly lower levels and hydroxylated proline

and lysine seem to be present in fascia samples from direct hernia patients. The collagen showed altered salt precitibility with a decreased amount of mature, insoluble, thick (polymeric) forms. On electron microscopy, collagen fibrils showed irregular periodicity and variable width, with same intracellular fibrillar positioning. These changes in ultrastructure were later confirmed by Peacock (1974), Berliner (1978), Nikolov and Beltshev (1990) and Pans et al (1997).

They later concluded, "The collagen framework was modified, mainly in the direct hernia group, associated with increased vascularity and cellularity. Similar changes were observed on the non herniated sided, suggested that connective tissue pathology play a role in the genesis of groin hernias.

In surgical patients with diseases other than hernia, increased persistent postoperative concentrations of MMP2 and MMP-1 (matrix metalloprotenases) has been found and furthermore, reduced levels of tissue inhibitor of MMP have been found in elderly. These findings explain why hernia is associated with high patient age.

Acquired weakness

The ability of the abdominal wall in the groin to withstand the forces in favour of herniation may be reduced by the weakening of the muscle and fascia with,

- Advancing age
- Lack of physical exercise
- Adiposity

- Multiple pregnancies
- Loss of weight and body fitness (after an illness, operations or prolonged bed rest).

Certain "cosmetic" operative incisions, such as very low and unduly long transverse abdominal incisions for gynecologic or urologic procedures or "cosmetic" appendectomy, may be followed by appearance of groin hernia caused by cutting into the myoaponeurotic arch cutting across the motor or sensory nerves of the groin, causing, atrophy of the muscles.

Cigarette smoking

In a few studies it has been said that substances in the cigarette smoke such as active proteases and elastase are circulating in the blood stream and upset the protease - antiprotease system in the blood and bring about destruction of elastin and collagen of rectus sheath and fascia transverses and so cause their attenuation and pre-dispose to herniation.

Increased intra-abdominal pressure

- Whooping cough in children / chronic bronchitis or TB in adults.
- Bladder neck obstruction or urethral stricture.
- Enlarged prostate.
- Powerful muscular effort or straining during lifting heavy weights.
- Pregnancy, obesity
- Chronic constipation.

PATHOPHYSIOLOGY OF HERNIAS[17,18,20,21]

As a rule, a hernia consists of three parts – the sac, the coverings of the sac, and the contents of the sac.

1. **The sac** is a diverticulum of peritoneum which comes out through the abdominal musculature, consisting of mouth, neck, body and fundus.
    a. The mouth i.e. the opening of the sac through which the contents enter the sac.
    b. The neck of the sac is usually well defined but in some direct inguinal hernias and in many incisional hernias there is no actual neck. The diameter of the neck is important because strangulation of bowel is a likely complication when the neck is narrow especially in indirect and femoral hernias.
    c. The body, which varies greatly in size and is not necessarily occupied.
    d. The fundus which is the redundant part of the sac. In infancy and childhood, the sac is gossamer thin. In long standing cases the wall of the sac may be comparatively thick, associated with hypertrophy of cremaster muscle, which encompasses the whole of cord.
2. **The contents** : These can be:
    a. Omentum = Omentocele (synonym : epiplocele) ;
    b. Intestine = Enterocele ; more commonly small bowel but may be large intestine / appendix ;
    c. A portion of the circumference of the intestine = Ritcher's hernia.

d. A portion of the bladder (or a diverticulum) may constitute part of or be the sole content of a direct inguinal, a sliding inguinal or a femoral hernia.

e. Ovary with or without corresponding fallopian tubes;

f. A Meckel's diverticulum = a Littre's hernia.

g. Fluid, as part of ascitis / as a residuum there of.

3. **The coverings** are derived from the layers of abdominal wall through which the sac passes. In long standing cases they become atrophied from stretching and so amalgamated that they are indistinguishable from each other. Coverings in case of an indirect inguinal hernia are, from inside out, as follows:

   a. Extraperitoneal fatty tissue

   b. Internal spermatic fascia

   c. Cremasteric fascia

   d. External spermatic fascia

   e. Two layers of superficial fascia and Skin

   Coverings in case of a direct hernia, from inside out, are as follows:

   a. Extraperitoneal fatty tissue.

   b. Fascia transversalis

   c. Conjoint tendon

   d. External oblique aponeurosis

   e. Two layers of superficial fascia and skin

   Differential diagnosis of Inguinoscrotal swellings:

a. Encysted hydrocele of the cord
b. Varicocele
c. Lymph varix or lymphagiectasis
d. Funiculitis
e. Diffuse lipoma of the cord
f. Inflammatory thickening of the cord
g. Malignant extension of testis
h. Torsion of testis
i. Retractile testis

Evolution of primary groin hernia

Groin hernias all share the common feature of emerging through the myopectineal orifice of Fruchaud, the opening in the lower abdominal wall as explained earlier. This unfortunate evolutionary defect in humans – the absence of the posterior rectus sheath below the arcuate line and a rather insubstantial transversalis fascia, unsupported by muscle or aponeurosis, resisting the intra abdominal pressure and holding the breach between the abdomen and thigh – is compounded by humans having adopted the upright posture and changed from quadrupedal to bipedal locomotion. It is believed that this change has opened up and stretched the groin region and brought about alterations in the functional anatomy in man, such as a reduction in efficiency of the shutter mechanism, which led to the greater propensity to develop hernias.

In humans, the upright posture causes the gravitational stress to pass down to the lower abdominal wall, which structurally is not designed for it, nor

has evolution suited it for its new role. Furthermore, the inguinal canal is directed downward, and the weight of the intra abdominal contents pressing on its internal opening tends to dilate it and allow loops of bowed to enter the canal.

Physiology of Inguinofemoral area

The integrity of the normal inguinal canal depends upon:

1. Sphincter action of the transversus abdominis and internal oblique muscles acting at the internal ring.

2. Shutter action of the transversus abdominis aponeurosis, which forms the transversus abdominis arch. This action reinforces the posterior wall of the canal. When the arch fails to reach the inguinal ligament area, the patient is a candidate for herniation.

3. Ball-valve action of cremaster muscle which pulls the spermatic cord into the canal and plugs it during rise in intra-abdominal pressure.

4. Obliquity of the inguinal canal – with rise in intra-abdominal pressure the posterior wall is apposed to the anterior wall and prevents the abdominal contents from entering in canal.

CLINICAL FEATURES[17,20-23]

Age

Inguinal hernia can occur at any age. Indirect inguinal hernias occur in children in first few months of life / in late teens and young adults. Direct hernia is seen in older subjects.

Occupation

People involved in strenuous work or heavy work especially, lifting weight, are prone to develop hernia as a great strain is put on the abdominal muscles which may already have an underlying weakness. Patient may relate onset of hernia to particular event, like lifting a heavy weight / sudden severe strain.

Symptoms

Pain

Type of discomfort / dragging / aching sensation may be the chief complaint, gets worse as the day passes. Pain may appear long before the lump is noticed and may continue so long as the hernia is progressing, but ceases when it is fully formed. Pull on the mesentery may cause pain in epigastrium.

Lump

Patient notices swelling in the groin in absence of pain, but usually he will have some sort of discomfort.

Systemic symptoms

Features of intestinal obstruction (colicky abdominal pain/vomiting / abdominal distension absolute constipation) may be present if the hernia is obstructing the lumen of the bowel.

Associated symptoms

Persistent coughing, constipation, dysuria due to be benign enlargement of prostate or stricture urethra.

Past history

Whether the patient had any previous abdominal operations especially appendectomy or any other operation confined to lower abdomen as incisions associated with these procedures may cause subcostal / ilioinguinal nerve division and that leads to weakness of the abdominal muscles. This usually predisposes to direct inguinal hernia.

Signs

Clinical examination usually reveals a bulge / swelling in the region of the groin which may or may not extend down into the scrotum. Two classical signs of an uncomplicated hernia are;

- Impulse on coughing
- Reducibility.

Position and extent

If the swelling descends into scrotum / labia majora it is obviously an inguinal hernia. An inguinal hernia is positioned above the inguinal ligament and medial to the public tubercle whereas femoral hernia lies below inguinal ligament and lateral to public tubercle.

To get above the swelling

In case of inguinal hernia one cannot get above the swelling.

Consistency

If the hernia contains omentum the swelling feels doughy and granular. If it contains intestine (enterocele) it feels elastic. A strangulated hernia feels tense and tender.

Invagination test

It is done to know size and patency of the superficial inguinal ring, to know tone of the ring, to differentiate direct from indirect hernias based on direction of finger and impulse on cough.

Ring occlusion test

After reducing the hernia, a thumb is pressed on the deep inguinal ring and patient is asked to cough. A direct hernia will show a bulge and an indirect hernia will show no bulge.

Zeimann's technique

When there is no obvious swelling or after the hernia has been reduced, the examiner places his corresponding index, middle and ring fingers on the indirect, direct and femoral hernial sites. The patient is asked to hold nose and below out. A peculiar gliding motion of the walls of an empty sac or typical pushing sensation will be felt beneath the fingers, if a hernia is present in any one of these corresponding sites.

A tympanic percussion note may be heard over an enterocele and impaired dull note in case of omentocele. Bowel sounds may be heard in cases where loops of bowel is present in the hernial sac. The last few tests are at times inconclusive and differentiation is only of academic interest. The true nature of the hernia is sometimes revealed at operation and is handled accordingly. Other relevant examinations include the complete external genital examination essentially the scrotum for a thickened spermatic cord, absent or atrophic testis or presence of a hydrocele. The penis is examined for phimosis, pinhole meatus, presence of stricture urcthra, deviation of penis. Per rectal examination is done to rule out benign prostatic enlargement and should be done routinely. The abdomen is examined to note the tone of abdominal muscles and respiratory system to rule out any cause of chronic cough (Tuberculosis / chronic bronchitis).

DIFFERENTIATION OF DIRECT AND INDIRECT INGUINAL HERNIA[17,21]

Features	Indirect	Direct
Age	At any age commonly infants and young adults	Usually in elderly
Sex	Mostly males, rarely females	Almost always in males
Profession	Usually no relation	More in sedentary workers
Obstruction	May be present	Usually absent
Site	Unilateral or may be bilateral	Bilateral usually
Shape	Pyriform	Globulr
On coughing	Emerges obliquely	Emerges directly
On lying down	May persist or reduce gradually	Usually disappears immediately
Malgaignes bulges	Usually absent	Usually present
Mode of reduction	Upwards, backwards and laterally	Backwards
Internal ring occlusion	Hernia does not reappear	Reappears
Direction of finger in invagination test	Upwards, backwards and laterally	Directly backwards
Cough impulse	Felt on tip of finger	Felt at the pulp of fingers
Development	May be congenital	Acquired
Performed sac	Present	Absent
Entrance	Internal inguinal ring	Hasselbach's triangle
Passage	Entire length of inguinal canal	Rarely medial third of canal
Exit	External inguinal ring	Very rarely external ring
Entry into scrotum	Very common	Rare
Relation of sac to cord	Within cord	Outside the cord

CLASSIFICATION SYSTEM OF INGUINAL HERNIAS[20,24,25]

Clinical classification

Irrespective of site, a hernia can be classified into five different types.

Reducible hernia

The hernia either reduces itself when the patient lies down or can be reduced by the patient / the surgeon. A reducible hernia imparts an expansile impulse on coughing.

Irreducible hernia

In this case the contents cannot be returned to the abdomen but there is no evidence of other complications. It is usually due to adhesions between the sac and it's contents or overcrowding within the sac. Note that any degree of irreducibility predisposes to strangulation.

Obstructed (Syn. Incarcerated hernia)

Irreducible hernia + features of intestinal obstruction, but there is no interference to the blood supply of the bowel. The features are;

- Irreducible hernia.
- The sac is lax, not tender.
- Cough impulse usually absent, may be present.
- Features of intestinal obstruction (Abdominal distension / colicky abdominal pain / vomiting / constipation).

Usually there is no clear distinction clinically between obstruction and strangulation and the safe course is to assume that strangulation is imminent and treat accordingly.

Strangulated hernia

Irreducible hernia + features of intestinal obstruction + when the blood supply of its contents is seriously impaired, rendering contents ischaemic. Gangrene may ensue as early as five to six hours after onset of first symptom the features are;

- Irreducible hernia.
- Sac is tense, tender; inflammed and edematous skin.
- Cough impulse absent.
- Features of intestinal obstruction

Inflammed hernia

A rare condition which mimics a strangulated hernia and occurs when its contents like a appendix / a salpinx / a meckel's diverticulum becomes inflamed. The features are;

- Overlying skin becomes red and oedematous.
- It is not tense and not associated with intestinal obstruction.
- Swelling becomes painful, swollen, tender
- Cough impulse usually absent

Lichtenstein's classification, 1987

- Indirect Femoral.
- Direct Combined.
- Whole floor any two or more.
- Lateral ½ of floor others.
- Medial ½ of floor.
- Diverticular.

Gilbert's classification with additions by Rutkow and Robbins

- Type I – Snug internal ring
- Type II – Opening 2 finger breaths in width + direct flow intact
- Type III – Indirect hernias with enlarged internal ring of > 2 finger breadths
- Type IV – Large direct hernias + intact internal ring
- Type V – Diverticular defects + intact internal ring
- Type VI – Pantaloon / combined indirect and direct hernia
- Type VII – Femoral hernia

Nyhus classification, 1993

- Type I Indirect, small Stoppa Modification 1998
- Normal int. ring Aggravating factors
- Sac in canal Local / systemic
- Type II indirect, medium Upstage type by 1
- Enlarged internal ring

- Sac not in scrotum
- Type III A direct – floor only
- B combined – Indirect large
- Encroaching into direct floor
- C femoral
- Type IV Recurrent A direct
- B indirect
- C femoral
- D combination A-B-C

Classification as per the contents of hernia

- Enterocele
- Omentocele
- Entero-omentocele
- Cystocele
- Meckel's diverticulum in Littre's Hernia.

As per the patency of processes vaginalis

- Bubonocele: Hernia limited to the inguinal canal
- Funicular: Processes vaginalis is closed just above the epididymis. The
- contents can be felt separately from the testis.
- Complete: Processes vaginalis patent upto bottom of scrotum. Testis appears to lie within the lower part of the hernia.

Anatomical classification (Ferguson type)

Bendavid classification (TSD- Type, Stage, and Dimension classification)

- Type I Anterolateral (Indirect)
- Type II Anteromedial (Direct)
- Type III Posteromedial (Femoral)
- Type IV Posterolateral (Prevascular)
- Stage 1 Sac in canal
- Stage 2 Sac beyond external ring – not in scrotum
- Stage 3 Sac in scrotum
- Dimension Max diameter defect in cm

Alexandre classification, 1998

- Type Indirect / direct/ femoral / others
- Orifice Max diameter in cm
- Sac Length in cm
- Modifiers I Incarcerated
- B Bilateral
- R Recurrent

Zollinger RM proposed a unified classification attempted to build upon previous ideals of Gilbert, Rutkow, Robbins, Nyhus, Alexandre, Bendavid and others. It builds upon the traditional indirect, direct and femoral anatomic locations, while recognizing the defect size, competence of the internal ring, and the integrity of the direct floor.

Proposed modified traditional classification

- I Indirect, small
- II Indirect, medium
- III Indirect, large
- IV Direct, small
- V Direct, medium
- VI Direct, large
- VII Combined
- VIII Femoral

Others

- Any not classified by number above
- Femoral + indirect / direct
- Femoral + indirect / direct
- Massive > 8 cm (4 fingers) inguinal defect
- Prevascular

Principles of tension-free prolene hernia system mesh technique

This three-dimensional mesh device such as the prolene hernia system have revolutionized the repair of hernias by building upon the advantages of the earlier tension – free techniques and making them even more effective.

It is a "3 – in – 1" design (meaning that it incorporates three of the most widely used and accepted repair techniques into one single device) consisting of three components integrated into one device:[26]

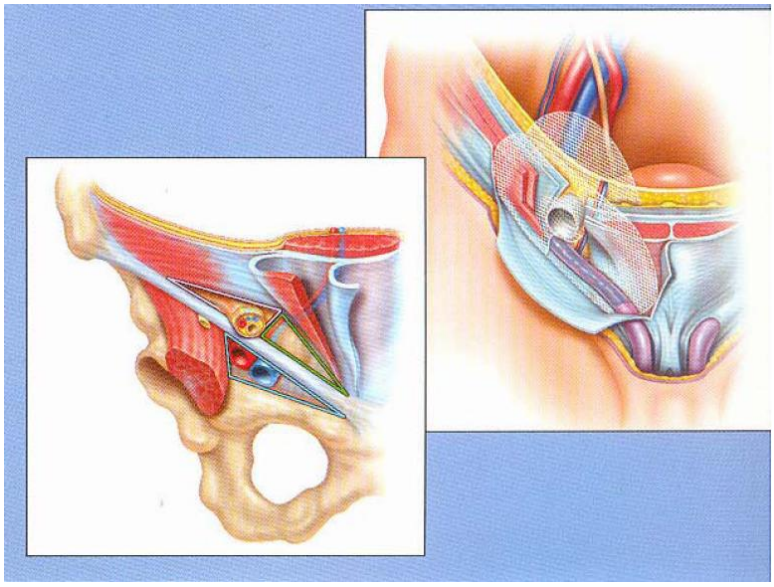


Figure 5. Underlay mesh covers both inguinal and femoral regions, protecting the entire myopectineal orifice

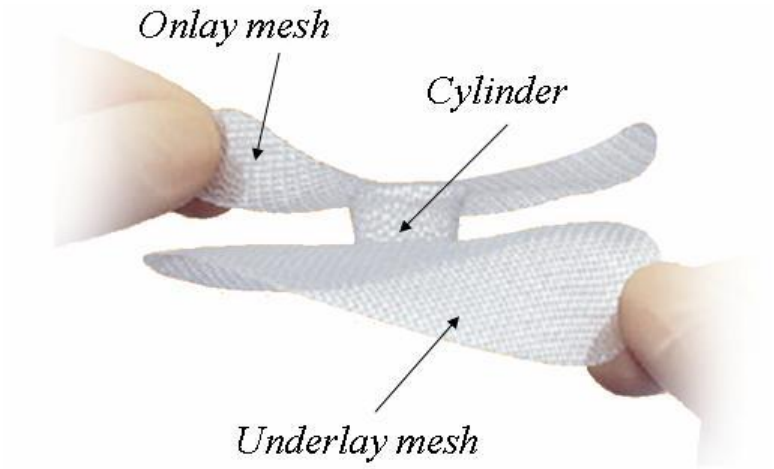


Figure 6. Prolene hernia system

Onlay mesh: Like Lichenstein technique, flat mesh repair covers and protects the entire floor of the inguinal canal, the system provides protection at the pubic tubercle for added support (Figure 6).

Cylinder: Provides the simplicity of a plug repair while securing the underlay patch to virtually eliminate the incidence of migration (Figure 6).

Underlay mesh: Like a laparoscopic repair, delivers posterior support (Figure 6).

An Underlay patch (similar to that used in Gilbert's suture less repair)[27] that provides effective posterior repair on the inside of the abdominal wall much like laparoscopic repair, covering all of the myopectineal orifice.

An Onlay patch (similar to that used in the Lichtenstein's repair)[28] that lays over the posterior inguinal wall, much like a flat mesh repair.

A Connector that connects the underlay to the onlay patch, which is not as bulky as the plug described by Rutkow,[29] and not as hard as the rolled plug described by Lichtenstein. This connector, virtually eliminates the possibility of the device from moving, or migrating, thus significantly reducing the potential for recurrence. The system sandwiches tissue between two layers of mesh, which supplements potentially weak areas of the abdominal wall and minimizes the changes of getting another hernia in the same area.

Advantages

- Patient comfort
- Virtually zero chance of migration
- Little suturing, reducing the risk of nerve damage that could lead to groin pain.
- Can be done under local / regional anaesthesia
- Takes typically about 30 – 40 minutes.[30]
- Quick recovery and return to normal activities.
- Extremely low recurrence rates.[31]

Technique of operation[32]

Usually with local / regional anesthesia, a low two inch transverse incision is made in the groin. The incision is deepened through the superficial Camper's and deep Scarpa's fascia and external oblique aponeurosis exposed. The external oblique aponeurosis (EOA) is opened.

The first important space is created by dissecting beneath the medial and lateral flaps of EOA creating the anterior space then down the inguinal ligament clearing its shelving edge to the public tubercle. This anterior space will eventually house the onlay patch of the device.

Indirect inguinal hernia

Sharp dissection is used to separate the sac from the cord, and from the investing fibres of the transversalis fascia at its neck. This is followed by high dissection of the neck of the hernial sac to utilize the potential of the preperitoneal space.

To actualize the posterior space, the peritoneum is freed from its attachments to the posterior wall by inserting a soft gauze sponge through the internal ring. Cooper's ligament can be visualized after completion of dissection through the posterior wall. The deep epigastric vessels are not disturbed unless the hernia has a pantaloon presentation, in which case, they are divided and the two defects are converted to one. Attempts to actualize the posterior space using the prosthetic device, or by using the gloved finger, will be usually frustrating and ineffective. In all types of indirect and direct hernias the posterior space is created using a gauze

sponge to do the dissection. This is the key element for ease and success of the operation.

Using the Insertion Manouevre, with a finger in the internal ring, pulsations of the iliac artery can be felt laterally. The circular underlay portion of the P.H.S. is folded and inserted through the internal ring, allowing the mesh to expand to the underlay position. Surgical manipulation may be used to facilitate the expansion of the device to the underlay position. No sutures are necessary in the underlay patch.

The onlay patch, which is designed to cover the posterior wall (floor of canal), is then modified as needed to accommodate the cord structures. As one end of the oval onlay patch is longer than the other, the mesh is positioned so that the longer end covers the posterior wall and overlaps the public tubercle. Sutures may be used to secure the onlay patch in place at two or three sites. The cord structures then lie on top of the medial portion of the onlay patch after making a slit to accommodate it, and connector fits snugly in internal ring.

Direct inguinal hernias

The defect is circumscribed at its base, the contents fully reduced, and the preperitoneal space is actualized as explained above prior to the insertion of the P.H.S. The circular underlay patch is folded and inserted as explained earlier and the oval onlay patch is secured to the posterior wall and the connector site in the defect.

When this device is used in infants or children, pregnant women or women planning future pregnancies with future growth potential, the surgeon should be aware that this product will not stretch significantly as the patient grows.

HISTORICAL PERSPECTIVE AND CURRENT LITERATURE

History of surgical meshes[33,34]

Zimmerman wrote, "Prostheses, whatever their values, cannot replace a full knowledge of underlying anatomy and pathology of hernia, or substitute for the exercise of time-honoured principles of surgical technique".

From the beginning of modern anatomic hernia surgery, the problem of recurrences have plagued and frustrated surgeons and during this past century, it has become clear even to the most recalcitrant devotee of autologous tissue repairs that prosthetic biomaterials are sometimes required to bridge / reinforce natural and unnatural defects in the integrity of abdominal wall.

The earliest use of manmade prosthetic reinforcements was the use of silver filigrees, silver wire coils and stainless steel wires in late 18th century.

In 1940, But the introduced tantalum gauze and described its reaction and tolerance to human tissues. At this time in surgical history metallic meshes was the best available synthetic prosthetic for hernia repair.

Then, in 1959, Koontz and Kimberly introduced non-metallic, non-absorbable materials like Dacron fabric, nylon cloth, fiberglass, Mylar nylon mesh, Orlon cloth, polyethylene polyvinyl sponge, Teflon mesh and Vinyon-N cloth. However none of these materials withstood infection. Despite some success, original Teflon (PTFE) mesh is not incorporated into body tissues, it is not tolerant to infection and had a wound complication rate too high to allow this mesh to be recommended for routine use in hernia repair.

In 1952, Usher et al. introduced a new polyethylene plastic mesh called Marlex 50 which was more pliable and readily inserted into any size defect without disadvantages of fragmentation of metal meshes. In 1963, an improved version of Marlex was introduced based on a new Knitted mesh of polypropylene monofilament fibre, and this remains the prosthesis in use today. Polyglycolic acid (Dexon70) and polyglactin 910 (Vicryl) absorbable meshes have been developed recently in combination with non-absorbable polypropylene as the most suitable prosthetic replacement.

Commercially available newer products include ULTRA-PRO MESH, PROCEED MESH, VYPRO MESH. These are light weight meshes, having an inner absorbable and outer non absorbable layer, with wider pore size showing good tissue in growth into them. These meshes are known to cause less discomfort to the patient and improved durablity.[35]

Properties of ideal prosthetic material[36,37]

In 1950's Cumberland and Scales developed 8 still pertinent criteria for ideal implantable biomaterial. They have been enumerated more recently by Homes Hodges and Scott. The material should be;

- Not be physically modified by tissue fluids.
- Be chemically inert.
- Not excite inflammation / Foreign body reaction.
- Be noncarcinogenic.
- Not produce a state of allergy / hypersensitivity.
- Be capable at resisting mechanical strains.

- Be capable of being fabricated in the form required.
- Be capable of sterilized.

Future biomaterials must meet three additional criteria to more nearly match the above requirements for an ideal prosthetic material

- They must be resistant to infection.
- They must provide better barrier to adhesions on the side of the material placed adjacent to the abdominal viscera.
- They must respond in vivo more like autologous tissue allowing tissue incorporation for good fixation and a strong lasting repair without encouraging scarring and encapsulation problems seen with many of today's prosthesis.

The latest Vypro II (polyglactin / polypropylene meshes) and Ultrapro light weight meshes are being used and seem to have less foreign body sensation in patients.

Properties of polypropylene mesh[34]

Polypropylene (–CH2 – CH (CH3) – is a thermoplast based propane with molecular weight of 100,000. This material is readily available, strong and nonabsorbable.

It is a monofilament that is inert, porous, thin and firm, but pliable. Polypropylene mesh is not rejected by the body and is able to withstand infection. A disadvantage is the high bending stiffness of the monofilaments. Nevertheless, most of the current meshes are built of monofilaments.

Microscopically, it initiates an intense foreign body inflammatory reaction, its interstices are infiltrated completely by fibroblasts, with subsequent dense fibrous scar formation. Direct contact with the intestine has to be prevented very carefully because polypropylene meshes tend to form intense adhesions and later fistulas.

As a consequence of physiologic wound contraction, depending largely on the extent of inflammation, the polypropylene meshes show considerable shrinkage of about 20% in length, and 40% of the original area, sometime folding and forming shaggy edges.

The induction of an intense fibrosis entirely embedding the mesh into a scar plate is frequently followed by a restriction of the abdominal wall mobility as complained by the patient. This problem is being tackled by the introduction of new light weight polypropylene meshes.

History of prolene hernia system tension free mesh technique

The use of tension free techniques has demonstrated the effectiveness in inguinal hemias. In 1984, Lichtenstein addressed the issue of tension by popularizing routine use of mesh, coining the term "tension free hernioplasty."[38]

Tension-free hernia repairs utilize a patch to fill/cover the defect. Again, a variety of methods and patches have been utilized. Native tissue like fascia lata from the thigh has been removed and used as a patch, saphenous vein has been rolled into a plug. In addition, a variety of synthetic materials such as silver filigrees, tantalum gauze, stainless steel, polyvinyl sponge, Fortisan fabric,

Nylon, silastic, teflon, polyester, polypropylene and expanded polytetrafluoroethylene (ePTFE) have been used for reinforcement.[33]

In 1997, a connected Bilayer polypropylene Mesh Device (BPMD) was designed to repair every type of inguinal hernia. It was manufactured and introduced into the surgical community early in 1998 as the Prolene Hernia System by Dr. Arthur Gilbert. The design incorporates the concept of simultaneous posterior and anterior mesh repairs. The circular shaped underlay patch is sufficiently large to cover the entire myopectineal orifice. The on lay patch provides a coverage equal to Lichtenstein's tension free repair. The under lay patch is connected to the oblong shaped anterior patch that provides the anterior repair. A one half inch mesh connector stabilizes the two flat mesh patches. While the design itself virtually eliminates migration, a few vicryl or prolene sutures in the anterior patch secure the entire device and eliminate any opportunity for migration. The connector seats itself in the internal ring of an indirect hernia or through the posterior wall defect of a direct hernia similar to a short rolled mesh plug.

This technique is literally a true physiologic repair since the posterior patch is secured in place, against the inside of the abdominal wall by the patient's own intraabdominal pressure – "the same forces that created the hernia are used to repair it".

The overall concept of its design was to include the best features of all currently available techniques while eliminating their undesirable features. It was

anticipated that its failure rate would be as low or lower than other popular products and techniques.

Since 1998, BPMD has grown in acceptance by surgeons, especially those who trained to use it. Initially, surgeons expressed concern that using this device required opening the posterior wall, a step they thought foreign to anterior open hernia repair. Opening into the pre-peritoneal space is a basic step in the Bassini, Halsted, McVay, Shouldice, Kugel and Per Fix plug operations.

Surgeons also expressed concern about not being able to make the underlay patch as flat as seen with laparoscopic/ Kugel patch. When the patient increased his / her own intraabdominal pressure the mesh will became flattened against the inside contour of the abdominal wall.

Single layer anterior and posterior repairs have recurrence rates in one to three percent ranges; occasionally even higher. Years have transpired since the BPMD was introduced and sufficient time and follow-up opportunity have passed to make more confident statements about its performance.

The failure rate for the BPMD repair by surgeons of all levels of expertise is less than one tenth of all other current techniques including plug and single-layer patch repairs by open / laparoscopic approaches. The apparent answer to this dramatic improvement rests in the synergy between the two patches separated by the canal's posterior wall.[39-42]

In 1999, Dr. Arthur Gilbert introduced this latest tension free Prolene Hernia system mesh technique and it has been used in North Penn Hernia

Institute, Florida, USA since a decade with least complications and recurrence rate less than 0.5%.[32]

From March 1998 – October 2002, 125 patients were retrospectively reviewed for early and late complications with PHS mesh. Only two patients had complications (1.6%) and no recurrences were reported.[43]

In 2002, a randomized double blind study on PHS was carried out for short term and medium – term outcomes in primary inguinal hernia. Immediate postoperative pain was significantly low. Operating time was significantly shorter. There were no recurrences.[44]

Between February 2002 through April 2003 prospective study using P.H.S. in 47 patients was done. There was no post-operative mortality. 4 patients developed mild self-limiting neuralgias. There was no wound complications reported. Average duration of post-operative hospitalization was 3.5 days. No recurrences reported so far.[45]

In a study between Sept. 2001 – Jan 2004, PHS mesh was used on 150 patients with follow up at one month and one year. Wound hematoma / swelling was seen in 1.3% of patients ; infection in 2%, hydrocele / scrotal swelling in 2.7%, testicular pain in 0.7% and prolonged pain in 12% of patients. No residual hernia was noted (within 30 days post-operatively). Recovery and return to full normal activity was rapid.[46]

In 2004, a randomized clinical trial using P.H.S. was used in 111 patients. Wound hematoma was reported in 4 patients and superficial wound infection in

12 patients. Recurrent hernia was seen in1 PHS group. VAS pain score showed an inverse correlation with increasing age ($p< 0.001$).[47]

In 2006, a prospective study on the long term outcome and symptoms in 367 patients with total of 395 hernias were evaluated. Post-operative complications developed in 5.1% of the patients and 1.8% suffered recurrence. Long term moderate pain and discomfort was reported by only 1.9% and 0.8% of patients, respectively.[48]

METHODOLOGY

The present study was conducted in the Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2010 to December 2010.

Study design

A one year randomized control trial.

Place

The present study was conducted in the Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum attached to Jawaharlal Nehru Medical College, Belgaum.

Study period

One year from January 2010 to December 2010.

Source of data

Patients admitted with inguinal hernia undergoing mesh repair in the wards of Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the study period.

Sample size

A total of 60 patients with inguinal hernia undergoing mesh repair were studied.

Sampling method

The sample size was calculated considering 80% of the average for last three years of patients with inguinal hernia undergoing surgery at KLES Dr. Prabhakar Kore Hospital Medical Research Centre, Belgaum.

Selection criteria

Inclusion

- All patients with inguinal hernia requiring mesh repair.

Exclusion

- Immunocompromised individuals.
- Subjects with pulmonary tuberculosis.
- Subjects with chronic cough & wound infection (redness and purulent discharge).
- Subjects with recurrent hernia.
- Subjects with Pantaloon hernia.

Randomization

Computer generated blocked random numbers was used to assign the type of surgery to the patients that is, group A (Patients undergoing PHS) and Group B (Patients undergoing conventional mesh repair).

Procedure

Ethical clearance for the study was obtained from Institutional Ethics Committee, Jawaharlal Nehru Medical College, Belgaum. Based on the selection criteria patients admitted with inguinal hernia at Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum were screened for eligibility. The eligible patients were briefed about the nature of the study and a written informed consent (Annexure I) was obtained from the selected patients. Thorough history was taken and clinical examination was done for all patients and findings were recorded on predesigned and pretested proforma (Annexure II).

Further, all the patients underwent routine pre-operative investigations including complete blood counts, blood urea, serum creatinine, bleeding time, clotting time and urine routine and microscopy.

Surgical procedure

Group A

This was performed by using prolene henia system. The initial procedure of dissection is the same as in conventional Lichtenstein repair. Additionally transversalis fascia was dissected. The direct or the indirect sac was dealt with after reducing the contents. A pre-peritoneal space was created. The Prolene Hernia System was then deployed with underlay mesh being placed in the preperitoneal space. The onlay mesh was fixed by sutures to the pubic tubercle, conjoint tendon and the shelving edge of the inguinal ligament with a proper slit

for the cord. The onlay mesh in the Prolene Hernia System was of the same size as the conventional Lichtenstein repair.

Group B

The contents of the sac were reduced and sac was inverted. The floor was reinforced with a piece of flat polypropylene mesh and was sutured to the pubic tubercle and a continuous suture was taken to fix the mesh to the reflected part of the inguinal ligament. Mesh was fixed to the conjoint tendon by interrupted sutures. A slit was created for the cord structures and a internal ring was recreated.

Post-operatively patients of both the groups were given the same analgesics that is Inj. Diclofenac 75 mg IM.

Further the patients were monitored for pain by Visual Analogue Scale (VAS) ranging from 0 to 10 considering 0 as no pain and 10 as maximum pain from post-operatively from second week to 12^{th} week at the interval of every two weeks. The pain grading charts were obtained from 2 to 12 weeks from the patients and analyzed by another resident who was unaware of the operative techniques followed in each patient.

Statistical Analysis

Data obtained was tabulated and expressed as rates, ratios and percentages. Comparison was done using by chi-square test and student ‘t’ test. A probability value (‘p’ value) of less 0.05 was considered as statistically significant.

RESULTS

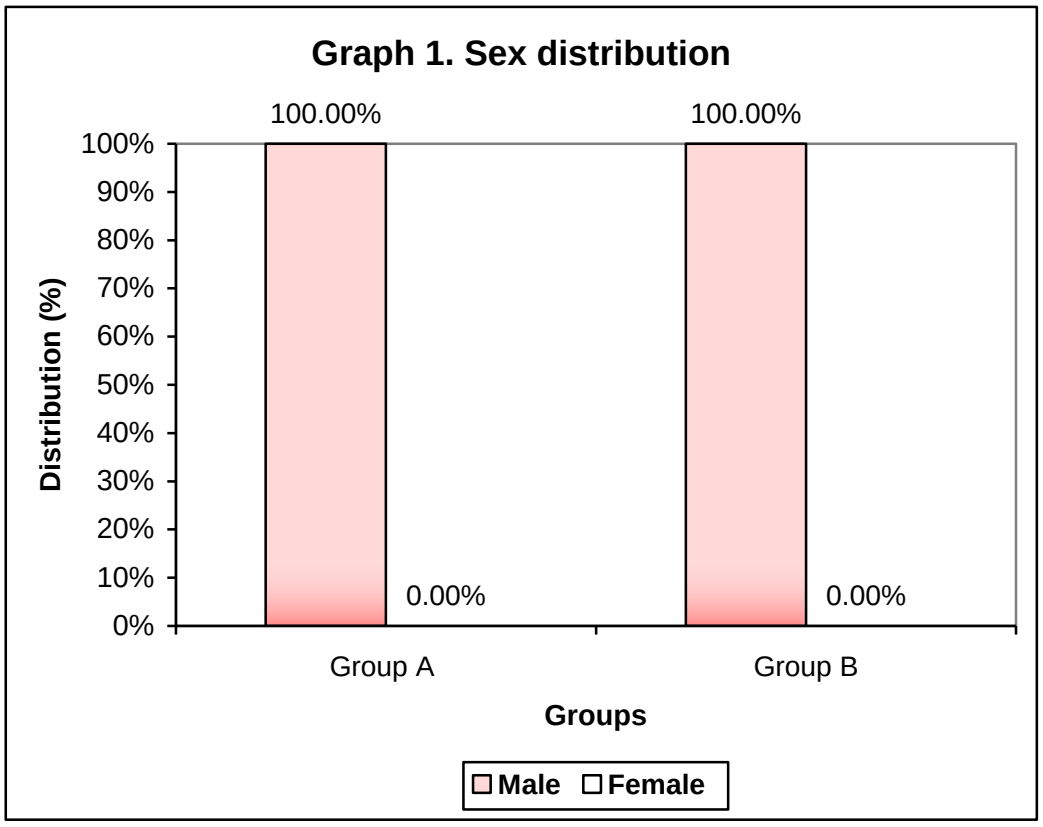
The present one year randomized control trial was conducted in the Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2010 to December 2010 on 60 patients with inguinal hernia undergoing mesh repair.

Based on computer generated blocked random numbers patients were divided into two groups that is, group A (Patients undergoing PHS) and Group B (Patients undergoing conventional mesh repair).

Data obtained was tabulated and analysed as below.

Table 1. Sex distribution

Gender	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Male	30	100.00	30	100.00
Female	0	0.00	0	0.00
Total	**30**	**100.00**	**30**	**100.00**

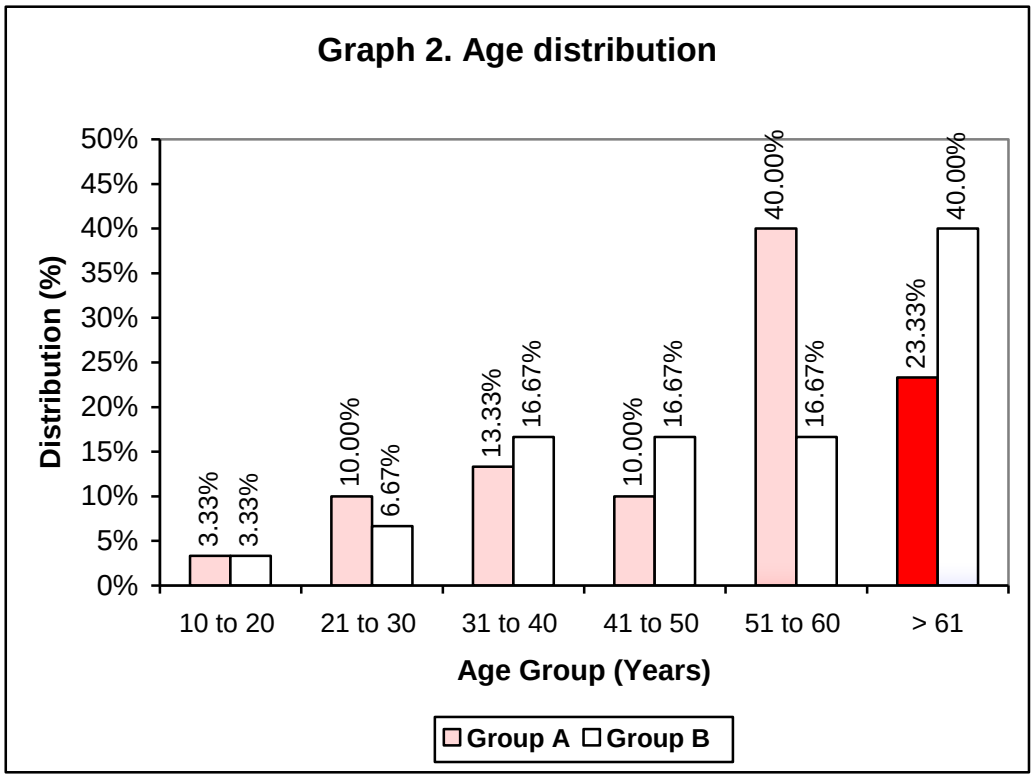


In this study all patients (100%) in both groups were males.

Table 2. Age distribution

Age group (Years)	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
10 to 20	1	3.33	1	3.33
21 to 30	3	10.00	2	6.67
31 to 40	4	13.33	5	16.67
41 to 50	3	10.00	5	16.67
51 to 60	12	40.00	5	16.67
>61	7	23.33	12	40.00
Total	**30**	**100.00**	**30**	**100.00**

x^2=4.365 p=0.113

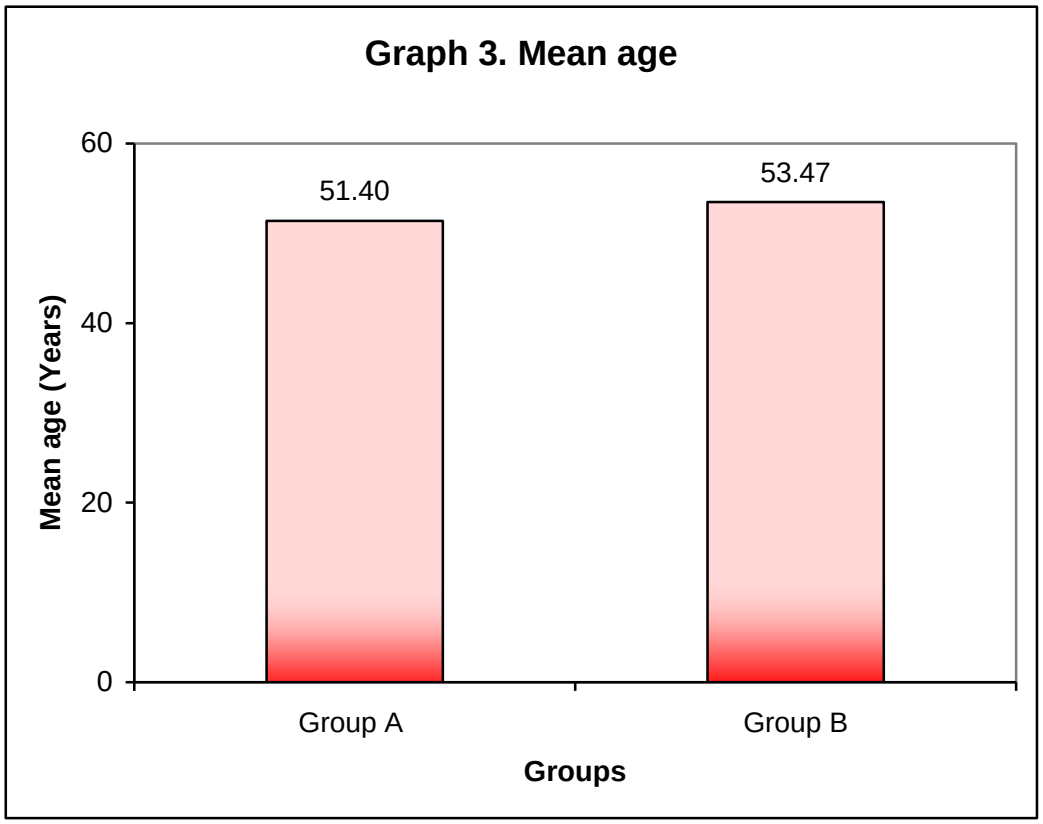


In this study it was noted that most of the patients were in the middle aged group of 51-60 years in both the groups.

Table 3. Mean age

Groups	Mean age (Years)		Range (Years)	
	Mean	**SD**	**Minimum**	**Maximum**
Group A	51.40	15.69	19	80
Group B	53.47	17.18	13	74

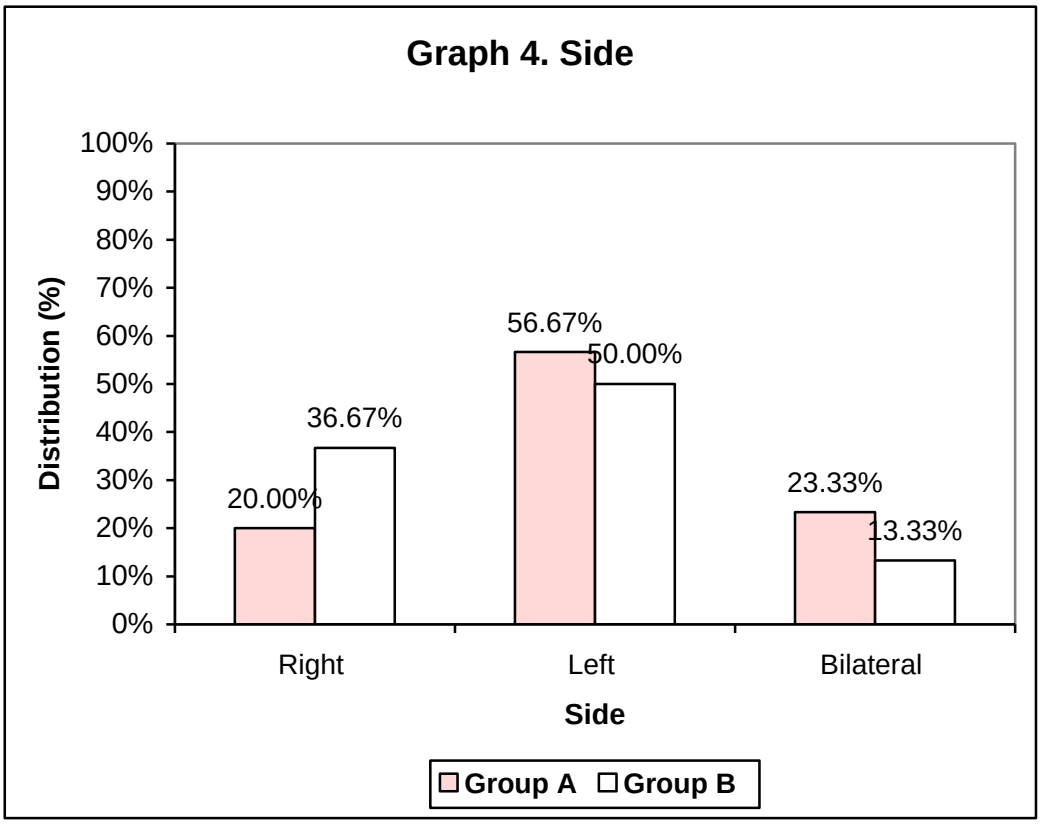
t=0.487 DF=58 p=0.628



There was no significant statistical difference between the two groups.

Table 4. Side

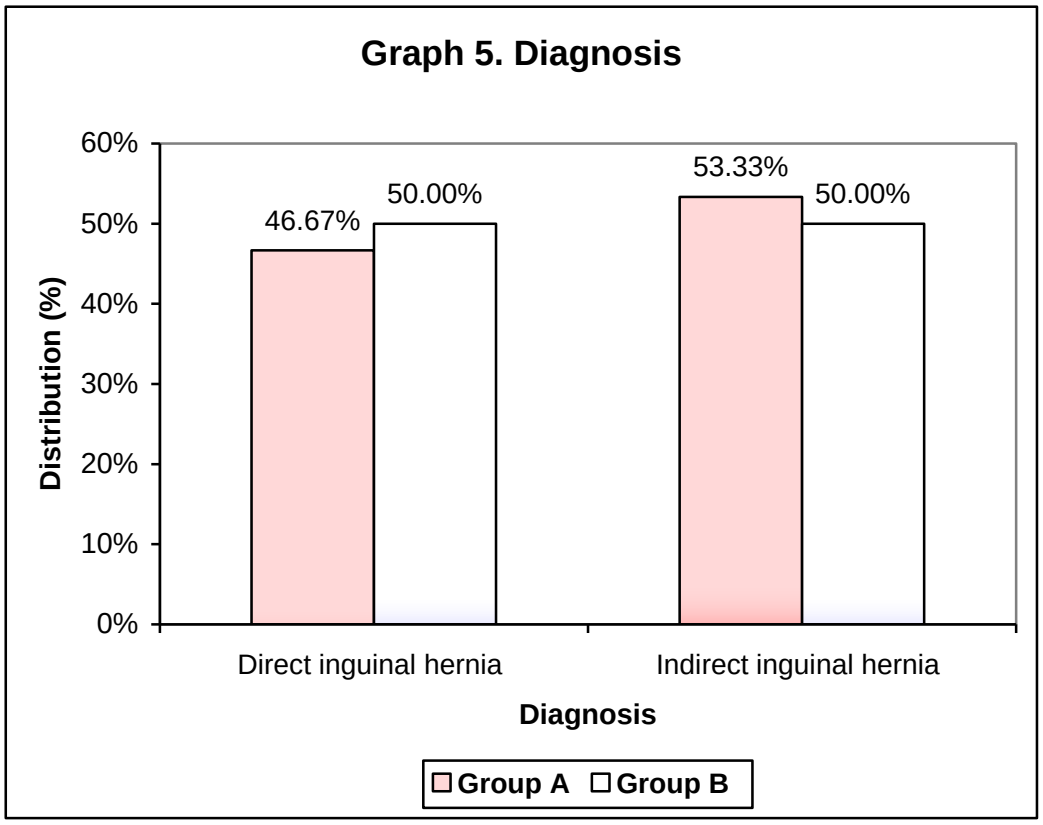
Side	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Right	6	20.00	11	36.67
Left	17	56.67	15	50.00
Bilateral	7	23.33	4	13.33
Total	**30**	**100.00**	**30**	**100.00**



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

Table 5. Diagnosis

Diagnosis	Group A (n=30)		Group B (n=30)	
	Number	**Percentage**	**Number**	**Percentage**
Direct inguinal hernia	14	46.67	15	50.00
Indirect inguinal hernia	16	53.33	15	50.00
Total	**30**	**100.00**	**30**	**100.00**

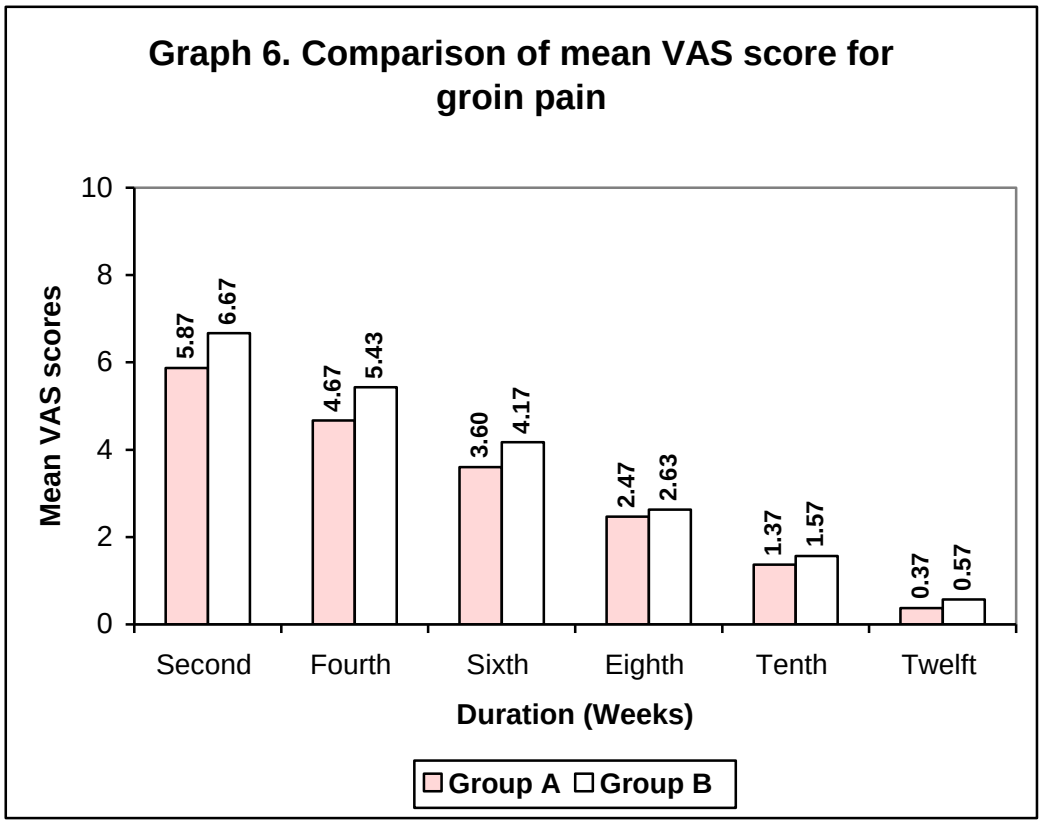


There was no significant statistical difference between the two groups.

Table 6. Comparison of mean VAS score for groin pain

Duration (Weeks)	Group A		Group B		Mann Whitney U Test	
	Mean	SD	Mean	SD	Z	p
Second	5.87	0.78	6.67	0.61	3.76	<0.001
Fourth	4.67	0.76	5.43	0.57	3.85	<0.001
Sixth	3.6	0.77	4.17	0.79	2.72	0.007
Eighth	2.47	0.68	2.63	0.67	1.12	0.262
Tenth	1.37	0.56	1.57	0.57	1.48	0.139
Twelfth	0.37	0.56	0.57	0.57	1.48	0.139
Intragroup*	z=4.92; p<0.001		z=5.06; p<0.001			

*Wilcoxon Signed Ranks Test



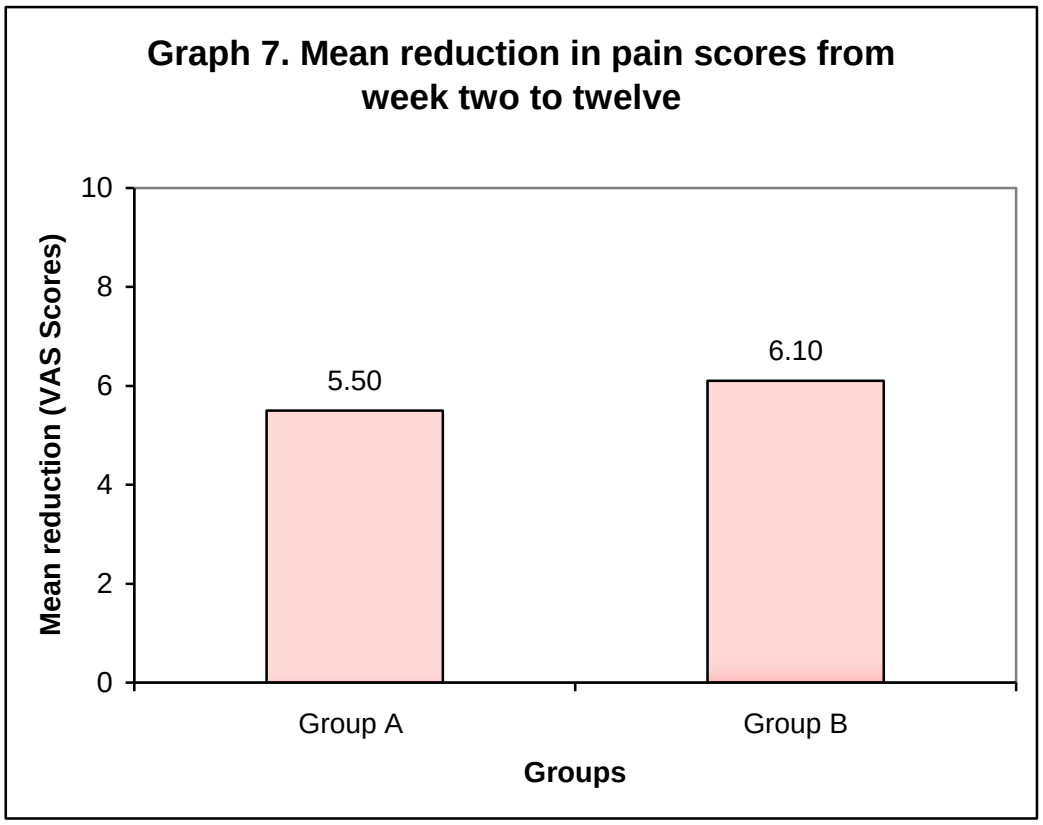
In this study, the intergroup comparison of pain scores from week two to twelve in both the groups showed significant reduction in pain score at every next consecutive weeks ($p<0.001$).

Maximum pain score was seen at second week and minimum pain at 12 weeks. During the second week pain score in group A were significantly less compared to group B (5.87±0.78 vs 6.67±0.61). Similarly during fourth and sixth week also significant less pain score was noted in group A (4.67 ± 0.76 and 3.60 ± 0.77) compared to group B (5.43 ± 0.57 and 4.17 ± 0.79). However the pain score during eighth, tenth and twelfth week were less in group A compared to group B but, this difference was statistically not significant.

Table 7. Mean reduction in pain scores from week two to twelve

Groups	Mean reduction in pain scores (VAS)	
	Mean	**SD**
Group A	5.50	0.57
Group B	6.1	0.48

z=3927 p=<0.001



The mean reduction of pain in group A was 5.50 ± 0.57 and in group B it was 6.1 ± 0.48. This difference was statistically significant (p<0.001).

DISCUSSION

Since the dawn of surgical history, hernias have been a subject of interest, and their treatment has evolved through distinct stages. The history of hernia is the history of surgery. Inguinal hernia surgeries are one of the most frequently performed operations in general surgery and as such even minor alterations in the outcome have appreciable impact. As surgeons we want techniques with short learning curves, but we still want to attain results comparable to the specialist hernia surgeons. Our patients on the other hand want their period of convalescence and rehabilitation to be uncomplicated in both short and long term outcome so as to return to their normal daily activities.

The modern era of hernia surgery developed in late 1880's by Bassini before which, a truss was the preferred treatment for an inguinal hernia. Currently, two major techniques of hernia repair exist

1. Pure tissue repairs
2. Tension-free / mesh repairs

At present, tension-free preshaped mesh hernioplasties have become a gold standard for most operating surgeons and over the last decade several types of meshes have evolved, and are used as single flat meshes or used in conjuction with threedimensional plugs.

In 1984, Lichtenstein addressed the issue of tension by popularizing routine use of mesh (monofilament polypropyelene meshes) which was laid on

posterior wall of the inguinal canal, and a slit made at the lateral end of the mesh, creating two tails, 69 which pass around the cord as it emerges from the internal ring. He then later on, introduced the use of hand-rolled polypropylene plugs for direct and femoral hernias.[49]

This technique was borrowed by Dr. Arthur Gilbert later in 1984, and he introduced this plug into the internal ring. Until 1998, for indirect hernias, Dr. Arthurs Gilbert used prolene umbrella plug and onlay patch repair, and for direct hernias he continued to use shouldice repair protecting it with a prolene underlay patch.[49]

The repair for direct hernias was not tension-free until 1998 when he began using the latest generation of repair, the Prolene Hernia System, a bilayer one-piece mesh device. Incorporated in this new one-piece device are all of the components of previous generations of techniques, while it most notably eliminates surgeons concern about migration of the underlay patch and ensures coverage of the entire myopectineal orifice affording protection against the occurrence of femoral hernias also.[49]

Dr. Arthur Gilbert became the clinical surgeon – consultant to Ethicon and developed this device and designed its shape and the dimensions of its patches and connector for the 3 sizes that are currently available (Medium, large and extended).[49]

Large sized PHS mesh was used for all 30 patients studied. Chronic groin pain following inguinal hernia repair is a recognized long-term complication, but the precise incidence is still unknown. Well conducted, large unselected

epidemiological studies suggest that about 20% of patients are affected and that in about 12% the intensity of pain is sufficient to impair some aspects of daily activity. Patients are classified as having chronic pain if postoperative pain lasts for more than three months.[50]

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 51.4±15.69 and 53.47±17.18 respectively.

In this study, the intergroup comparison of pain scores from week two to twelve in both the groups showed significant reduction in pain score at every next consecutive weeks ($p<0.001$).

Maximum pain score was seen at second week and minimum pain at 12 weeks. During the second week pain score in group A were significantly less compared to group B (5.87±0.78 vs 6.67±0.61). Similarly during fourth and sixth week also significant less pain score was noted in group A (4.67 ± 0.76 and 3.60 ± 0.77) compared to group B (5.43 ± 0.57 and 4.17 ± 0.79). However the pain score during eighth, tenth and twelfth week were less in group A compared to group B but, this difference was statistically not significant. No patients

experienced severe pain in either group at two weeks, only mild to moderate pain was reported.

A recent Canadian study reported 12% of patients suffered moderate to severe pain 2 years after operation.[51] Another study[48] with follow up of 19.3 months reported 1.9% patients with pain whereas another study[52] with 41 months reported 2.8% patients with pain. These findings were contradictory to the present study wherein no pain was reported with followup period of one year.

The downside of the PHS is the high cost involved compared to conventional mesh repair. This is especially a big problem in developing countries with already over-burdened medical and healthcare systems.

The limitation of the present study was only limited to post-operative pain following hernia surgery by both methods. Furthermore, the short term follow up of this study did not allow any conclusion regarding recurrence of hernia.

Further studies with larger cohorts with longer follow up, assessing other factors such as quality of life and recurrences would help surgeons to determine the right procedure to be performed.

CONCLUSION

This study showed that, the pain scores with the use of Prolene Hernia System mesh repair, were significantly less compared to the conventional Lichtenstein mesh repair while providing a more complete repair to the patient showing apparent advantage in the use of Prolene Hernia System repair over other conventional Lichenstein's mesh repair.

SUMMARY

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 present study was planned to compare the incidence of reduction in postoperative pain following hernia repair with PHS versus Lichtenstien mesh repair.

The present one year randomized control trial was conducted in the Department of Surgery, KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Belgaum during the period of January 2010 to December 2010 on 60 patients with inguinal hernia undergoing mesh repair. Based on computer generated blocked random numbers patients were divided into two groups that is, group A (Patients undergoing PHS) and Group B (Patients undergoing conventional mesh repair).

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 51.4±15.69 and 53.47±17.18 respectively. In this study, the intergroup comparison of pain scores from week two to twelve in both the groups showed significant reduction in pain score at every next consecutive weeks ($p<0.001$). Maximum pain score was seen at second week and minimum pain at 12 weeks. During the second week pain score in group A were significantly less compared to group B (5.87±0.78 vs 6.67±0.61). Similarly during fourth and sixth week also significant less pain score was noted in group A (4.67 ± 0.76 and 3.60 ± 0.77)

compared to group B (5.43 ± 0.57 and 4.17 ± 0.79). However the pain score during eighth, tenth and twelfth week were less in group A compared to group B but, this difference was statistically not significant. No patients experienced severe pain in either group at two weeks, only mild to moderate pain was reported.

In conclusion, pain scores with the use of Prolene Hernia System mesh repair, were comparable to the conventional Lichtenstein mesh repair while providing a more complete repair to the patient.

BIBLIOGRAPHY

1. Patino JF. A history of the treatment of hernia. In: Fitzgibbons R, Greenburg G, eds. Nyhus and Condon's Hernia, 5th ed. Philadelphia, USA: Lippincott Williams and Wilkins; 2002. p. 22.

2. Singh SB, Bhola H, Gupta D. Tension free hernioplasty under local anaesthesia – Gilbert's repair. Indian J Surg 1999; 61(5): 310.

3. Vironen J, Nieminen J, Eklund A, Paovolainen P. Randomised clinical trial of Lichenstein's patch or prolene hernia system for inguinal hernia repair. Br J Surg 2006; 93: 33-9.

4. Mayagoitia J. Inguinal hernioplasty with the prolene hernia system. Hernia 2004; 8(1): 64-6.

5. Gilbert AI, Graham MF, Voigt WJ. A bilayer patch device for inguinal hernia repair. Hernia 1999; 3:161-6.

6. Kurzer M, Belsham PA, Kark AE. The Lichtenstein repair for groin hernias-surgical clinics of North America 2003; 83: 1099-117.

7. Rutkow MI. A selective history of hernia surgery in the late eighteenth century. Surg Clin North America 2003; 83: 1021-44.

8. Skandalakis JE, Gray SW, Ricketts R, Skandalakis LT. The Anterior Abdominal Wall. In Skandalakis JE, Gray SW, Editors. Embryology for Surgeons – The Embryological Basis for the treatment of congenital anomalies: Maryland, USA: Williams and Wilkins 2004.p54.

9. Standring S. Anterior abdominal wall. In: Gray H. eds. Textbook of Gray's Anatomy. 14th ed. Philadelphia: Lee and Fabiger; 1985. p. 1055.

10. Last RJ. The anterior abdominal wall. In: McMinn RMH, Editor, Last's Anatomy Regional and Applied 11th edition London. Churchill Livingstone; 1994. p. 229.

11. Kux M. Anatomy of the Groin: A view from the surgeon. In: Fitzgibbons R, Greenberg G, editors. Nyhus and Condon's Hernia, 5th ed. Philadelphia USA: Lippincott Williams and Wilkins; 2002. p. 45.

12. Quinn TH. Anatomy of the Groin: A view from the Anatomist. In: Fitzgibbons R, Greenberg G, editors. Nyhus and Condon's Hernia, 5th ed. Philadelphia USA: Lippincott Williams and Wilkins, 2002. p 55.

13. Boffard KD. The Groin and Scrotum. In: Decker GAG, du Plessis DJ. Lee McGregor's Synopsis Of Surgical Anatomy. Bristol, Great Britain: John Wright and Sons Limited; 1986. p 118-37.

14. Snell RS. Clinical Anatomy for Medical Students. 3rd ed. Boston: Little, Brown and Company; 1986.

15. Fitzgibbons RJ, Flipi CJ, Quinn TH. Inguinal Hernias. In: Brunicards FC, Anderson DK, Billiar TK, Dunn DL, Hunter JG, Pollock RE, eds. Schwartz's Principles of Surgery. USA: McGraw-Hill; 2005. p. 1353.

16. Javid PJ, Brooks DC. Hernias. In: Zinner MJ, Ashley SW, editors. Maingot's Abdominal operations 11th edn. USA: McGraw Hill; 2007. p. 103.

17. Das S. A Concise Textbook of Surgery. 1st ed. Calcutta: Dr. S. Das; 1994.

18. Abrahamson J. Etiology and pathophysiology of primary and recurrent groin herniaformation. Surg Clin North Am 1998; 78(6): 953.

19. Read RC. Why do Human Beings Develop Groin Hernias? In: Fitzgibbons R, Greenberg G, eds. Nyhus and Condon's Hernia: Philadelphia USA: Lippincott Williams and Wilkins; 2002. p. 3.

20. Kingsnorth AN, Bennet DH, Hernias, Umbilicus and abdominal wall. In: Russell RCG, Williams NS and Bulstrode CJK, eds. Bailey and Love's Short Practice of Surgery. 25th edn. London: Arnold; 2008. p. 968.

21. Das S. A. Manual on Clinical Surgery. 6th ed. Calcutta : Dr. S. Das; June 2004.

22. Das SA. A Textbook on Surgical Short Cases. 1st ed. Calcutta: Dr. S. Das; 1990.

23. Gupta RL, Textbook of Surgery. 2nd ed. New Delhi: Jaypee Brothers Medical Publishers; 2003.

24. Zollinger RM. Classification of ventral and Groin Hernias. In: Fitzgibbons R, Greenberg G, eds. Nyhus and Condon's Hernia: Philadelphia USA: Lippincott Williams and Wilkins; 2002. p. 71.

25. Zollinger RM. Classification Systems for Groin Hernias. Surg Clin of N Am 2003; 83: 1053.

26. Divilio LT. FACS Director Medical Affairs ETHICON, Inc. Inguinal hernias and the prolene hernia system. 1997.

27. Gilbert AI. Inguinal hernia repair: Biomaterials and sutureless repair. Persp Gen Surg 1991; 2: 113-29.

28. Kurzer M, Belsham PA, Klark AE. The lichtenstein's repair for groin hernia. Surg Clin North Am, 2003; 83(5): 1099-117.

29. Robins AW, Rutkow IM. The mesh plug hernioplasty. Surg Clin North Am 1993; 73: 501-12.

30. Murphy JW. Use of the Prolene hernia system for Inguinal hernia repair: Retrospective, comparative time analysis vs other inguinal hernia repair systems. Am Surg 2001; 67: 919-23.

31. Gilbert AI. Combined anterior and posterior inguinal hernia repair: Intermediate recurrence rate with 3 groups of surgeons. Hernia 2004; 8: 203-7.

32. Gilbert AI, Graham MF, Voigt WJ. A bilayer patch device for inguinal hernia repair. Hernia Institute of Florida, Miami, USA, Hernia 1999; 3: 161-6.

33. Debord JR. The historical development of prosthetics in Hernia surgery. Surg Clin North Am 1998; 78(6): 973.

34. Schumpehck V, Klinge U, Klosterhalfen B. Biomaterials for the repair of abdominal wall hernia; structural and compositional considerations. In: Fitzgibbons R, Greenberg G, editors. Nyhus and Condon's Hernia. 5th ed. Philadelphia USA: Lippincott Williams and Wilkins; 2002. p 551-65.

35. Holste JL. Are meshes with light weight construction strong enough? Int Surg 2005; 90(3 Suppl): S10-2.

36. Martin K, Belsham PA, Klark AE. The Lichenstein's repair. Surg Clin North Am 1998; 78(6): 1025-46.

37. Klinge U. Mesh for hernia repair. Br J Surg 2008; 95: 539-40.

38. Amid PK. Licthenstein's tension free hernioplasty for repair of primary and recurrent inguinal hernia. In: Fitzgibbons R, Greenberg G, editors.

Nyhus and Condon's Hernia. 5th ed. Philadelphia USA: Lippincott Williams and Wilkins; 2002. p. 149.

39. Gilbert AI, Young J, Graham MF, Divilio LT, Patel B. Combined anterior and posterior inguinal hernia repair: intermediate recurrence rates with three groups of surgeons. Hernia. 2004; 8(3): 203-7.

40. Pozzi HA, Hamilton RL. New surgical procedures; can we minimize the learning curve. Br Med J 2000; 320: 171-3.

41. Gilbert AI. The lateral triangle of the groin. Hernia 2000; 4: 234-7.

42. Kurzer M, Kark A, Hussain T. Inguinal hernia repair. J Perioper Pract. 2007; 17(7): 318-21, 323-6, 328-30.

43. Mayagoitia J. Inguinal hernioplasty with the prolene hernia system. Hernia 2004; 8(1): 64-6.

44. Kingsnorth AN, Wright D, Porter CS, Robertson G. Prolene hernia system compared with Lichtenstein patch : a randomized double blind study of short-term and medium-term outcomes in primary inguinal hernia repair. Hernia 2002; 65(6): 488-91.

45. Chandiramani VA, Katara AN, Pandya SM, Nair NS. Prolene hernia system in the tension-free repair of primary inguinal hernias. Indian J Surg 2003; 65(6): 488-91.

46. Vironen J, Nieminen J, Eklund A, Paovolainen P. Randomised clinical trial of Lichenstein's patch or prolene hernia system for inguinal hernia repair. Br J Surg 2006; 93: 33-9.

47. Nienhuijs SW, Oort IV, Keemers-Gels ME, Strobbe LJA, Rosman C. Randomized clinical trial comparing the prolene hernia system, mesh plug repair and Lichtenstein method for open inguinal hernia repair. Br J Surg 2005; 92: 33-8.

48. Hasegawa S, Yoshikawa T, Yamamoto Y, Ishiwa N, Morinaga S, Noguchi Y, Ito H, Wada N, Inui K, Imada T, Rino Y, Takanashi Y (2006) Long-term outcome after hernia repair with the prolene hernia system. Surg Today 36(12):1058–62.

49. Gilbert AI, Graham MF. Tension free hernioplasty using a bilayer prosthesis. In: Fitzgibbons R, Greenberg G, eds. Nyhus and Condon's Hernia. Philadelphia USA: Lippincott Williams and Wilkins; 2002. p. 173.

50. Aasvang E, Kehlet H. Surgical management of chronic pain after inguinal hernia repair. Br J Surg 2005; 92: 795-801.

51. Poobalan AS, Bruce J, King PM, Chambers WA, Krukowski ZH, Smith WCS.Chronic pain and quality of life following open inguinal hernia repair. Br J Surg 2001; 88: 1122-6.

52. Huang CS, Huang CC. Lien HH. Prolene hernia system compared with mesh plug technique: a prospective study of short-to mid-term outcomes in primary groin hernia repair. Hernia. 2005; 9(2): 167-71.

ANNEXURE I – CONSENT FORM

CONSENT FOR PARTICIPATION IN RESEARCH

Mr./Mrs._____ we are requesting you to enroll yourself in study titled **"A ONE YEAR RANDOMISED CONTROLLED TRIAL TO COMPARE PROLENE HERNIA SYSTEM REPAIR VERSUS LICHTENSTEIN MESH REPAIR FOR REDUCTION IN POST-OPERATIVE PAIN IN INGUINAL HERNIAS"** conducted by **Dr. Vasant Teggimani**, postgraduate student in MS GENERAL SURGERY under the guidance of **Dr. A. S. GOGATE** **MS** Department of General Surgery, Jawaharlal Nehru 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. 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. 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. In case of any queries, you can contact the following:

Dr. V. D. Patil $_{MD, DCH}$**,**
Chairperson, College Ethical Dissertation
And Research Committee,
J. N. Medical College,
KLE University, Belgaum –10.

Dr. A.S.GOGATE
Professor,
Department of Surgery
J. N. Medical College,
KLE University,Belgaum-10

Dr.VASANT TEGGIMANI
Postgraduate student,
Department of General surgery
J. N. Medical College,
KLE University, Belgaum – 10.

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 II – 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 III – PHOTOGRAPHS

ANNEXURE IV - KEY TO MASTER CHART

b	-	Bilateral
DH	-	Direct hernia
F	-	Female
IH	-	Inguinal hernia
IP No.	-	In patient number
l	-	Left
LMR	-	Lichenstein mesh repair
M	-	Male
r	-	Right
Sl No.	-	Serial Number
VAS	-	Visual analog score

ANNEXURE IV MASTER CHART - GROUP A PROLENE HERNIA SYSTEM

Sl. No.	IP No.	Sex	Age (Years)	Diagnosis	Side	Pain (VAS) score at different weeks					
						2 weeks	4 weeks	6 weeks	8 weeks	10 weeks	12 weeks
1	323673	M	60	DH	b	7	5	4	3	2	1
2	328855	M	60	DH	b	7	4	3	3	2	1
3	312644	M	80	DH	b	7	6	5	3	2	1
4	312641	M	60	DH	b	6	5	4	3	2	1
5	350298	M	60	DH	b	6	6	5	4	2	1
6	370972	M	38	IH	r	6	5	3	2	1	0
7	367950	M	44	IH	l	6	4	3	2	1	0
8	369092	M	52	IH	r	6	5	4	3	1	0
9	369539	M	26	DH	r	7	4	3	2	1	0
10	314113	M	23	IH	r	5	4	3	2	1	0
11	312814	M	53	IH	b	7	6	5	3	2	1
12	331774	M	60	IH	l	5	4	3	2	1	0
13	339916	M	36	DH	r	6	4	3	2	1	0
14	330058	M	55	IH	r	5	4	3	2	1	0
15	346446	M	19	IH	r	6	5	3	2	1	0
16	346453	M	65	DH	l	6	5	4	3	2	1
17	347318	M	32	IH	l	5	4	3	2	1	0
18	364597	M	25	DH	r	6	5	4	2	1	0
19	365169	M	62	IH	r	5	4	3	2	1	0
20	365950	M	72	DH	b	7	6	5	4	3	2
21	330814	M	60	IH	r	5	4	3	2	1	0
22	381585	M	70	DH	r	6	5	4	3	2	1
23	381308	M	52	IH	r	5	4	3	2	1	0
24	380810	M	49	IH	r	5	4	3	2	1	0
25	379649	M	60	DH	l	6	5	4	2	1	0
26	379087	M	38	DH	r	5	4	3	2	1	0
27	377650	M	61	IH	l	6	5	4	2	1	0
28	385139	M	70	IH	r	5	4	3	2	1	0
29	385532	M	55	DH	r	7	6	5	4	2	1
30	385807	M	45	IH	r	5	4	3	2	1	0