

Original Research Article

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Clinical study of prolene hernia system in inguinal hernia repair

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ABSTRACT

Background: Lichtenstein was first to coin the term "tension-free hernioplasty" in his book "Hernia repair without disability". All direct, indirect and recurrent adult hernias can be repaired by this procedure. The objective of this study was to determine the feasibility of using the prolene (polypropylene) hernia system for open tension-free repair on inguinal hernias.

Methods: During period of 2 years, 42 patients were subjected to prolene hernia. Of these 42 patients, 3 patients underwent bilateral repair. Thus, in all 45 inguinal hernias were repaired. The median age of patients in our study was 57 years. In our study majority hernias were indirect inguinal hernias (47.61%). Nineteen (45.23%) hernias were of direct type while 2 (4.76%) pantaloan and 1 recurrent inguinal hernias. Out of the 42 patients, 16 were operated under local anesthesia while 17 patients operated under spinal anesthesia. Maximum hernias were Gilbert's type III hernias.

Results: The duration of surgery averaged 35 min (range 20-90 min). There were no postoperative deaths. Two out of 42 patients developed local infection at wound site. Wound seroma was found in 3 patients but subsided by giving antibiotics and patients were discharged as per routine protocol. 2 patients (4.76%) developed mild pain in testicular region which subsided with non-steroidal anti-inflammatory drugs. One patient (2.38%) in our series had pain in operative region that lasted for more than one month, only non-steroidal analgesics sufficed to deal with this problem and no patient complained of pain after 2 months of surgery. No patient in our series developed late infection or testicular atrophy. No recurrence was noted during the period of follow-up. This was consistent with the result of other series performed worldwide. Most of the patients in our study (18 patients i.e. 42.87%) were discharged on 3rd postoperative day. One patient had mild neuralgia up to maximum of 2 months in the follow up period which subsided with analgesics. No recurrence was seen in the follow up period.

Conclusions: The prolene hernia system is a novel approach in the management of inguinal hernias, with encouraging initial results. Its long-term efficacy needs to be studied with larger, prospective double-blind randomized trials, with longer follow-up.

Keywords: Prolene hernia system, Tension-free inguinal hernioplasty

INTRODUCTION

Lichtenstein was first to coin the term "tension-free hernioplasty" in his book "Hernia repair without disability".¹ All direct, indirect and recurrent adult hernias can be repaired by this procedure. The most important of all advantages of the Lichtenstein repair is the dramatically low recurrence rate, ease of operative

technique and low infection rate.² But Wantz warns in his study titled as "Experience with tension-free hernioplasty for primary inguinal hernias in men" that though this procedure produces excellent results, the prolene mesh does not cover the entire myopectineal orifice (MPO) and therefore is inadequate to prevent a femoral hernia. He also states that incomplete covering of MPO by the mesh may in future predispose to direct herniation from below

the mesh edges and presence of a slit in the mesh may permit indirect peritoneal protrusions.³ The prolene hernia system is a sterile, pre-shaped device constructed of knitted non-absorbable polypropylene filaments.⁴ The benefits of the open tension-free method (placing a prosthetic mesh anterior to the muscle) and those of laparoscopic approach (placing the mesh posterior to the muscle) are exploited in this repair.⁴ This repair covers entire myopectineal orifice (MPO). We report our initial experience with the PHS.

METHODS

The duration of our study 'study of prolene hernia system in surgical treatment of inguinal hernia' was spread over a period of 2 years. During this period, 42 patients were subjected to prolene hernia system repair for their inguinal hernias after taking informed consent. Of these 42 patients, three patients underwent bilateral repair. Thus, in all 45 inguinal hernias were repaired. All patients in our study were males. This finding was consistent with the fact that inguinal hernias are more common in males. The youngest patient in the study was 27-year-old male while the oldest was 75-year-old male. Maximum numbers of patients were found in the age group of 61-70 years (19 patients i.e. 45.23%). The median age of patients in our study was 57 years. In our study majority hernias were indirect inguinal hernias (20 hernias i.e. 47.61%). Nineteen (45.23%) hernias were of direct type while 2 (4.76%) pantaloon and 1 recurrent inguinal hernias. Out of 45 operated hernias 31 (66.66%) were incomplete and 14 hernias were complete (33.33%). Out of the 42 patients 16 were operated under local anesthesia, 17 patients under spinal anesthesia, 6 under epidural and 3 patients under general anesthesia. To all the patients advantages and disadvantages of spinal and local anesthesia were briefed and choice was left to them regarding the type of anesthesia. Out of the three patients who required general anesthesia one had h/o prolapsed intervertebral disc and one had irreducible hernia and the third one had hepatomegaly with deranged PT. 3 doses of cefuroxime 500mg were given as Prophylactic antibiotic.

Study classified the hernias by Gilbert's method due to its simplicity. Maximum hernias (16 i.e. 35.55%) were Gilbert's type III hernias whereas Gilbert's type IV and type II constituted 9 (20.00%) and 7(15.55%) hernias respectively. The least common were Gilbert's type VI (pantaloons) hernias that were 3 (6.66%) in number.

RESULTS

The duration of surgery averaged 35 min (range 20-90 min). There were no postoperative deaths.

Out of the 42 patient only 2 (4.76%) patients developed local infection at wound site. Out of which one patient developed wound gape and required secondary suturing for the same. Wound seroma was found in 3 patients which subsided by giving antibiotics and were discharged

routinely. 2 (4.76%) developed mild pain in testicular region which subsided with non-steroidal anti-inflammatory drugs.

Table 1: Early postoperative complications (<1 month).

Complication	No.	Percentage
Fever	1	02.38%
Cord edema	4	09.52%
Hematoma	0	0
Seroma	3	07.14%
Wound infection	2	04.76%
Thromboembolism	0	0
Testicular pain	2	04.76%

Table 2: Late postoperative complications (>1 month).

Complication	No.	Percentage
Pain		
a) < 2months	1	2.38%
b) > 2months	0	0
Late infection	0	0
Testicular atrophy	0	0
Recurrence	0	0

Out of 45 hernia repairs in 42 patients only one patient (2.38%) in our series had pain in operative region that lasted for more than one month. Only non-steroidal analgesics sufficed to deal with this problem and no patient complained of pain after 2 months of surgery. No patient in our series developed late infection or testicular atrophy. No recurrence was noted during the period of follow-up. This was consistent with the result of other series performed worldwide.

Duration of stay in hospital

Most of the patients in our study (18 patients i.e. 42.87%) were discharged on 3rd postoperative day. One patient had to stay in hospital for 25 days, which was the longest hospital stay in our series had developed wound gape and required secondary suturing after 15days.

Follow up

In our study patients were followed upto a minimum of 3 months and maximum of 24 months. Maximum number of patients (12, i.e 28.57%) were followed upto a period of 12 months. One patient out of 42 lost to follow up as he absconded from the ward. One patients had mild neuralgia upto maximum of 2 months in the follow up period which subsided with analgesics. No recurrence was seen in the follow up period.

Surgical technique

A standard inguinal incision was deepened down to the external oblique aponeurosis. Inguinal canal was opened

by incising external oblique aponeurosis upto the superficial inguinal orifice resecting the iliohypogastric and ilioinguinal nerves. Both flaps of the fascia of external oblique muscle must be dissected at either end, particularly at the bottom, since the PHS on lay is expanded and fixed in this area. The spermatic cord was mobilized and hernial sac separated from the cord by blunt dissection. The hernial sac located and dissected. Indirect sacs are transfixated and excised. For indirect hernia repair, a high dissection of the neck of the hernia sac is done to utilize the potential of the preperitoneal space to insert the prolene hernia system. For direct hernia, the defect is circumscribed at its base, the contents fully reduced, and the preperitoneal space is actualized prior to the insertion of the prolene hernia system. If a pantaloan hernia is encountered, the inferior epigastric vessels are ligated and cut thus converting the two areas into one large defect. If a femoral hernia is encountered, the hernia is reduced through the inguinal approach, and the PHS is deployed, which effectively covered the hernial defect, as well as the potential inguinal hernial sites. The prosthesis size is choosing according to patient's morphology. In the vast majority of patients, the medium size prosthesis is sufficient. The most delicate point is the implantation and expansion of the underlay in Bogros's space. Two methods are important here, firstly it is necessary to detach the peritoneum extensively from Bogros' space in all directions downward beyond cooper's ligament and outward beyond the deep inguinal orifice. Secondly it is necessary to inspect the expansion of the underlay visually.

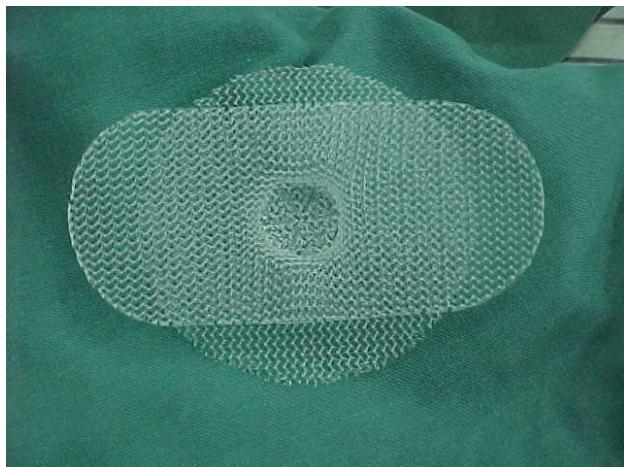


Figure 1: Prolene hernia system.

The circular, or bottom underlay portion of the prolene hernia system is folded and is inserted through the defect or the internal ring allowing the mesh to expand to the underlay position. The underlay portion should expand under the defect in the floor of the inguinal canal. Surgical manipulation may be used to facilitate the expansion of the device to the underlay position. During this procedure, it is necessary to ensure that the on lay will be oriented correctly in the axis of inguinal canal

after deployment. The on lay is deployed anterior to the abdominal fascia and anterior to internal oblique muscles. An external slit is incised to allow the components of spermatic cord to pass. Both ends of prosthesis are joined by using non-absorbable suture outside the deep inguinal orifice. Two or three sutures or clips may be used to secure the top on lay patch in place. The procedure is completed by closing the external oblique by using non-absorbable sutures and skin closed with ethilon or dermabond.

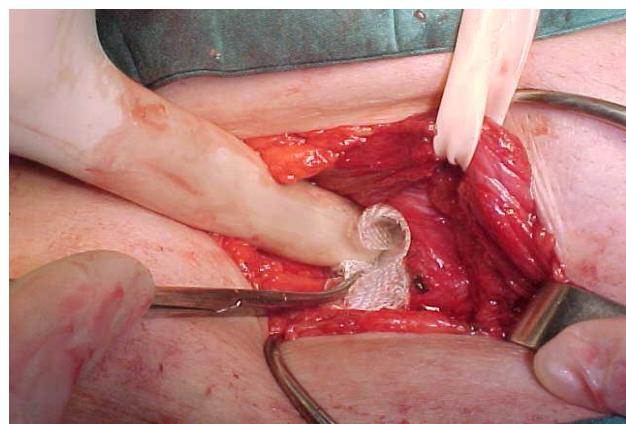


Figure 2: Insertion of underlay portion of PHS.

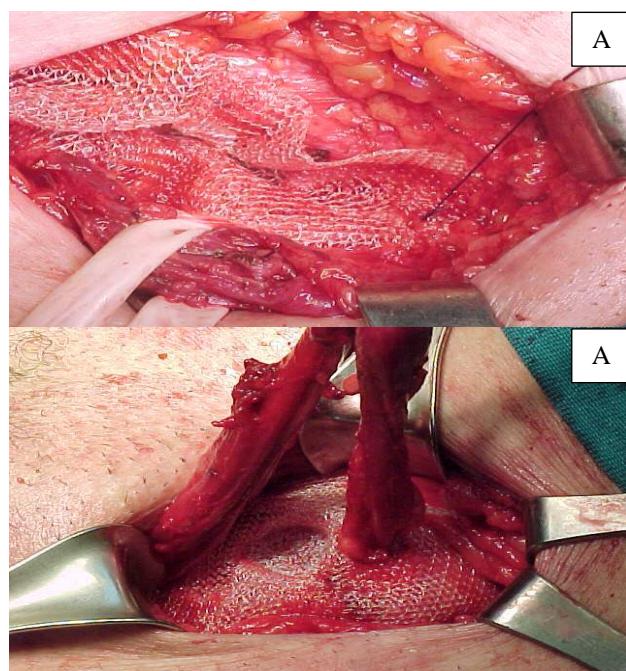


Figure 3: A) and B) Completed PHS repair.

DISCUSSION

Repair of hernia is the most common surgery performed in general surgery and, as such, even minor alterations in outcome has an appreciable impact. Preperitoneal placement of mesh as advocated by Cheatle and later approved by Stoppa was further explored by Ger by laparoscopic approach.⁵ The concept of preperitoneal

approach to repair especially for groin hernia was described by Annadale, Stopa implanted an impermeable mesh barrier around the entire peritoneal bag demonstrating that the repair does not require closure of the defect *per se*. In stoppa procedure, the mesh is held in place by intra-abdominal pressure an application of hydrostatic principle of Pascal. Lichtenstein was the first to describe the patch repair.⁶ Lichtenstein and Shore were the first to describe the plug repair and Read was the first to describe the preperitoneal repair.^{7,8} Gilbert was the first to use something similar to the PHS.⁹ He placed 2 meshes, one preperitoneal and another in the inguinal canal. He did not use any sutures to fix them together or in place. The PHS has all types of repairs incorporated in a single mesh. It provides the advantages of the preperitoneal repair that blocks the myopectineal orifice completely, and is pushed by the abdominal pressure against the abdominal wall and hence the abdominal pressure fixes the mesh rather than tends to dislodge it. This preperitoneal mesh is placed via a simple inguinal exposure that is familiar to the surgeon unlike the laparoscopic, midline or supra-inguinal approach. The PHS also provides the plug repair, but with a simple sutureless technique.⁹

Amid described that one of the complications of the plug repair was it assuming a cartilage-like consistency and eroding into the bladder. This is not expected to happen in the PHS as the deep edges of the plug merge with the preperitoneal mesh which will prevent it from migration. The PHS also provides the patch repair which is familiar to most surgeons. In addition, all these 3 repairs, being incorporated in a single mesh mechanism offers safety and there is no chance that one repair will disrupt from the other, parts of the mesh offer stability to one another. The prolene hernia system has been developed for a tension free repair of groin hernia. It combines the virtues of both the anterior and posterior prosthetic mesh and covers the potential deficiencies in the myopectineal orifice. The PHS theoretically provides all the advantages of a tension-free repair, including less patient discomfort, rapid return to normal activity and lower recurrence rates. These benefits have been observed in the limited time period of case studies so far. In addition, it is easy to use, requires fewer sutures for fixation and is more comfortable for the patient in the postoperative period, in our experience. It provides a stable anterior repair with the added benefits of a posterior repair and plug repair. The higher cost of the PHS as compared to the conventional polypropylene mesh makes its widespread use difficult. There are patients undergoing conventional tension-free hernioplasties who develop recurrence. These 'high-risk' group of patients may be a good target to analyze the role of the PHS as a superior primary repair. Even recurrences should be tackled with the PHS where an area on the posterior wall with relatively fewer adhesions, usually on the medial half, can be used as an approach to create the preperitoneal plane. Many other studies comparing prolene hernia system with Lichenstein repair and other repairs have been done

which prove improved outcomes of prolene hernia system.¹¹

The PHS is constructed of high-porosity polypropylene for optimum tissue ingrowth. It can be used to repair all types of inguinal hernias, including femoral hernias. The PHS has many theoretical advantages over the other conventional forms of repair. It provides a larger allowable surface for effective tissue ingrowth and fibrosis. The underlay patch lies in the preperitoneal space and provides a double-layered reconstruction of the transversalis fascia. The PHS protects both the femoral and inguinal regions from recurrence. The underlay component secures the myopectineal orifice and the onlay component secures the posterior wall of the inguinal canal. Placement of the underlay component in the preperitoneal plane has theoretical advantages. It employs Pascal's principle of hydrostatic pressure to allow the intra-abdominal pressure to keep the mesh secure in place. It has all the advantages of a secure posterior repair from a simple anterior approach. It is a versatile prosthesis that can be used for other abdominal wall hernia repairs. Most of our patients were operated under local anesthesia. Apart from averting all the complications of general anesthesia, it allowed patients to cough and strain during the procedure to identify additional hernias. We were able to test competency of the repair on table, and patients were able to walk and void immediately after surgery.

The average hospitalization for our patients was 3.5 days. Most of our patients who underwent surgery under local anesthesia became ambulatory very soon after surgery. Most of them were fit for discharge 1 or 2 days after surgery, and returned to work in 7-10 days. Some patients stayed longer for medical reasons. The average hospital stays of our patients also increased because 4 patients underwent other procedures simultaneously (2 cystoscopies with internal urethrotomies, 1 orchidectomy, 1 TURP with cystolithotomy). In addition, on account of logistical reasons such as outstation residence and comorbidity factors, a few patients wished to stay until suture removal. Few of our patients were well motivated and undertaken as day care patients. Early reports of this device are encouraging. Operating time is shorter and there is quicker recovery.⁵⁻⁷

The PHS theoretically provides all the advantages of a tension-free repair, including less patient discomfort, rapid return to normal activity and lower recurrence rates. These benefits have been observed in the limited time period of case studies so far. In addition, it is easy to use, requires fewer sutures for fixation and is more comfortable for the patient in the postoperative period, in our experience. It provides a stable anterior repair with the added benefits of a posterior repair and plug repair. The higher cost of the PHS as compared to the conventional polypropylene mesh makes its widespread use difficult.

CONCLUSION

The prolene hernia system is a novel approach in the management of inguinal hernias, with encouraging initial results. The cost factor may be a major drawback, especially in developing countries. Its long-term efficacy needs to be studied with larger, prospective double-blind randomized trials, with longer follow-up.

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Ethical approval: The study was approved by the institutional ethics committee

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