Original Article

# Polyglactine/Polypropylene Mesh vs. Propylene Mesh: Is There a Need for Newer Prosthesis in Inguinal Hernia?

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## ABSTRACT

**Background/Aim:** To compare outcomes of light and heavy weight mesh for repair of inguinal hernia. **Materials and Methods:** This study was conducted at the Department of Surgery; Lady Reading Hospital, Peshawar from January 1, 2007 to December 31, 2008. Patients were divided into two groups based on the type of mesh implanted for inguinal hernia repair. Group 1 included patients in whom light weight composite (VyproII®) mesh is implanted: Group 2 included patients in whom polypropylene (Prolene®) mesh is implanted. Data concerning the complications and post operative pain in the perioperative and postoperative period were collected and analyzed. Categorical data were presented as percentages with 95% confidence intervals and compared using a $\chi^2$ test and $P < 0.05$ were considered significant. **Results:** Following allocation and exclusion of violating cases, 111 patients in group 1 and 138 patients in group 2 were analyzed. The mean age in group 1 was 38.20 ± 13.34 years and in group 2 was 39.55 ± 13.70 ($P = 0.434$). In group 1, hematoma formation was observed in four cases (3.6%), while it was observed in six cases (4.2%) in group 2 ($P = 0.766$). During the entire study, ten patients in all developed urinary retention, three of which required transient catheterization. One year post operation, there was a recurrence in only five cases overall, while only two patients complained of pain ($P = 0.826$). **Conclusion:** The frequency of postoperative pain and complications in patients was similar in both groups.

**Key Words:** Light weight mesh, heavy weight meshes, Lichtenstein technique, inguinal hernia

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Inguinal hernia, regardless of type, is one of the most common diseases in a surgeon's daily workload.[1] The traditional suturing techniques include Bassini's, Darning, and Shouldice repairs. Bassini's repair in its modified versions continues to be widely practiced in this part of the world.[2,3] Traditional suture repair of inguinal hernia is fast giving way to routine tension-free mesh repair. In many countries, mesh repair is now more common than suture repair.[4] Lichtenstein presented his open mesh repair technique for inguinal hernia in 1986.[5,6] Tension-free mesh repair is nevertheless associated with complications such as foreign body reaction, infection, pain, fistula formation, migration, shrinkage, and recurrence.[7]

Lists of techniques and prosthetic materials to repair the defect have been attempted with variable success.[8] The meshes used are typically made from polypropylene. The original first generation of meshes described for the treatment of hernias were of the heavy type with a smaller pore size, greater weight/area, lesser elasticity and higher burst pressure. The latter generation of meshes included the light weight meshes with larger pore size resulting in smaller interface between the mesh and surrounding tissues, low weight per area, greater elasticity and a lower burst pressure.[9] It has been surmised that the inflammatory reaction to the foreign material is correlated with the amount and structure (i.e., pore size) of the synthetic material inserted.[10] Tension-free repair with non-resorbable mesh (polypropylene) has been used in a higher number of cases during the past few years.

Typically, the new mesh has lower weight when compared to the conventional heavy weight meshes. The elasticity of the new generation composite mesh being in the range of 20-35% (at 16 N/cm).[11,12] It is made by 50% resorbable suture (polyglactine) and 50% non-resorbable suture (polypropylene). The polyglactine fibers are resorbed in 56-70 days. The remaining fibers of polypropylene are incorporated by collagen in-growth and the abdominal wall is reinforced.

The idea of introduction of the heavy weight meshes was to guarantee maximum mechanical stability, based on closing the hernia gap with a stiff, non flexible device and induce a strong scar tissue.[13,14] Flexible light weight meshes with similar elasticity to the abdomen, demonstrate their superiority with respect to a physiologic hernia repair.[15] Modern biomaterials, including polymers, are physically and chemically inert and stable, non-immunogenic and

non-toxic. In contradiction to their physical and chemical stability, the biomaterials trigger a variety of adverse responses *in vivo* including inflammation, fibrosis, calcification and thrombosis. The quality of inflammatory reaction is surprisingly constant characterized by a rapid accumulation of huge numbers of phagocytic cells in particular blood monocytes and tissue derived macrophages.[16,17]

It is not clear how these inert materials induce an immunogenic reaction. The 'protein hypothesis' suggests the early incorporation of degraded material within the inert mesh that triggers the attachment of phagocytes. The amount of fibrosis and inflammatory reaction varies with the physiochemical properties of the mesh, the surface area and the type of protein absorbed.[18,19]

Regardless of the mechanism involved in the formation of a thick scar plate, most patients following mesh repair still present in the long term with complaints of chronic pain.[20] It is now believed that most of these symptoms are related to the type of material used as mesh for the repair rather than the technique employed.[21] In the past decade, with the introduction of mesh repair for groin hernia the incidence of recurrence following the procedure was found lower than 3% in most studies.[22]

The argument of a low recurrence rate, frequency of postoperative pain and the chance of infection with the application of different materials (meshes) with a similar technique is the emphasis of this study. In this study, we compare the postoperative outcome of repair of inguinal hernia using the light weight composite (VyproII®) mesh and the conventional heavy weight (Prolene®) mesh by the Lichtenstein technique of mesh repair.

## MATERIALS AND METHODS

This study was conducted at the Department of Surgery, Postgraduate Medical Institute, Lady Reading Hospital, Peshawar from January 1, 2007 to December 31, 2008, as a part of a single center randomized clinical trial. The study was undertaken to compare the outcome in patients following Lichtenstein's technique of tension free mesh repair using polypropylene and light weight composite (VyproII®) mesh. The study was approved by the institutional review board of the hospital.

It was an analytical (prospective) clinical trial. Over a period of one year, three hundred patients, diagnosed clinically with the presence of inguinal hernia presenting at the outpatient department were included in the study. They were divided into two groups. Group 1 included patients in whom the light weight composite (VyproII®) mesh was incorporated and group 2 with patients in whom the Propylene (Prolene®) mesh was used by the Lichtenstein's technique of tension free mesh repair. The method of simple randomization was undertaken before the surgery.

Inclusion criteria were clinical diagnosis of inguinal hernia; age 16-80, consent, the will to abide by the proposed duration of follow-up. Patients with a history of immunosuppression, prevailing malignant condition or other medically co-morbid conditions and violation of visit schedule were excluded from the study. Part of the preoperative collection of data also included a visual analogue scale to assess the severity of pain, if present in patients before the surgery.

Patients included in the study were all admitted a day before surgery. Following admission a detailed history and physical examination was performed. Investigations performed were blood hemoglobin%, blood urea, serum creatinine, blood glucose, blood coagulation profile, screening tests for hepatitis viruses and AIDS. All patients over the age of 40 were advised a chest roentgenogram and patients above 50 were also advised an electrocardiogram. Further relevant investigations were advised by the attending surgeon. All surgeons undertaking the procedure were un aware of the inclusion of the patients in this particular study.

### Operative technique

Under general anesthesia, a suprainguinal incision was given and the external oblique was approached. Preservation of iioinguinal nerve was done where possible and the spermatic cord lifted. The hernia sac was dissected and relevant steps taken based on the type of hernia and dealt accordingly. In both groups, respective meshes were trimmed to fit the space, with a slit cut laterally to accommodate the spermatic cord following the dissection of the spermatic cord from the hernial sac. The mesh was laid with the medial edge 1-2 cm medial to the pubic tubercle. After moving the mesh with further trimming if necessary until it was laid in the ideal position, it was fixed inferiorly first starting at the medial end with continuous 2/0 polypropylene suture. Three or four interrupted sutures were used to fix the mesh superiorly. The two tails were then overlapped lateral to the deep ring and secured by two or three interrupted sutures making sure that the cord is not constricted.

An intravenous antibiotic was administered three hours pre-operatively in all cases. Analgesics were initially given through the parenteral route and increments done according to the severity of pain, as analyzed by a visual analogue score. The quantity of prescribed analgesic (Diclofenac sodium) during the first 24-hour duration postoperatively was noted. The proforma contained the development of complications from the perioperative period till the final visit at 12 months from surgery. These included development of hematoma, seroma, wound infection and urinary retention. Visual analogue scores (numerical rating score) were recorded at all

visits as was the amount of prescribed analgesics used by the patient in the postoperative period. Patients with pain during the first six months were labeled as "acute pain" whereas pain persisting greater than duration of one year was considered 'chronic'.[23]

Testing the hypothesis of the latter generation of modern day lightweight meshes with greater pore size, patients were accordingly advised follow up over a period of one year and the examining surgeon was blinded from the type of mesh used in the operative procedure. The sequence of follow-up at the outpatient department was at seven days, three months, six months and one year. These visits were taken note of on a proforma that was being carried throughout the perioperative period.

### Statistical analysis

Assuming a significant fall from previous equivocal studies the size of sample was decided with a confidence interval of 95%. Each group contained 150 patients. So a total of 300 patients would be needed to allocate to both groups. The Department of Surgery at Postgraduate Medical Institute, Lady Reading Hospital, Peshawar, had the capacity for the specified sample and was supported by experienced surgeons. Sampling was done by consecutive non-probability.

Patients failing to abide by the visit protocols were excluded from the study. Descriptive statistics were used for characteri zation of patient groups, presented as mean (SD) or median (range) depending on the type of data and distribution. The data was compared using Student's *t test*. Categorical data was presented as percentages with 95 per cent confidence intervals and compared using an $\chi^2$ test. A value of $P<0.050$ was considered significant. Data was analyzed using SPSS[R] For Windows version 13.0.

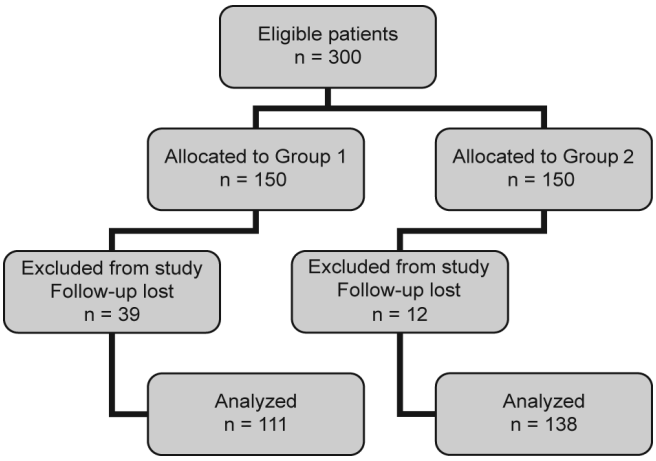


**Figure 1:** Allocation of patients into groups

## RESULTS

A total of 300 patients were enrolled at the department of Surgery in the period from January 1, 2007 to December 31, 2008. They were randomized into the two groups [Figure 1]. Group 1, included patients who would receive the placement of a light weight composite (VyproII®) mesh whereas in group 2 the patients would receive a Polypropylene (Prolene[R]) mesh for placement in the treatment of inguinal hernia. Due to violation of follow-up protocol or death, 39 patients from group 1 were lost whereas 12 patients from group 2 were lost. Thus a total of 111patients were analyzed in group 1 whereas 138 patients were analyzed in group 2.

The mean age in group 1 was 38.2 ± 13.34 and mean age in group 2 was 39.55 ± 13.7. Both groups, which were randomly allocated, showed no significant difference and only one female was part of the entire study that was allocated to the prolene® group (group 2). In both the groups six patients had exhibited pain before surgery and in one case it was excruciating. This was statistically not significant between the two groups ($P = 0.699$). The duration of presentation from the time of occurrence till surgery was delayed in group1 which was 10.23 ± 6.3 and was 8.92 ± 5.72 in group 2 that was statistically not significant ($P = 0.732$).

The data regarding the type of hernia was confirmed peroperatively and was grouped according to the Nyhus classification of groin hernias. Majority of the hernia in both groups were of the indirect type (Nyhus I and II) followed by the direct type (Nyhus IIIB). These findings were also statistically not significant ($P = 0.648$).

The operating time in cases of both groups was similar. The minimum recorded time was 26 min and another case took

**Table 1: Baseline data of patients (n = 249)**

| | Group 1 N=111 (%) | Group 2 N=138 (%) | *P* value |
|---|---|---|---|
| Age (years) | 38.2 ± 13.34* | 39.55 ± 13.7* | 0.434[T] |
| Sex ratio (M:F) | 111 male | 137:1 | 0.367[χ] |
| Pain before surgery | 6 (5.4)[a] | 6 (4.34%)[a] | 0.699[χ] |
| Time from occurrence of hernia till surgery (months) | 10.23 ± 6.3* | 8.92 ± 5.72* | 0.732[χ] |
| Type of hernia (Nyhus classification) | | | |
| • Type I | 44 (39.6)[a] | 67 (48.5)[a] | 0.648[χ] |
| • Type II | 42 (37.8)[a] | 43 (31.1)[a] | |
| • Type IIIA | 03 (2.7)[a] | 02 (1.4)[a] | |
| • Type IIIB | 18 (16.2)[a] | 22 (15.9)[a] | |
| • Type IV | 04 (3.6)[a] | 04 (2.8)[a] | |
| Operative time (min) | 49.61 ± 11.6* | 49.8 ±11.59* | 0.672[χ] |

Percentages within group - [a]; Student *t* test - [T]

**Table 2: Perioperative and postoperative complications (n = 249)**

| Complication | Group 1 N=111 (%)[a] | Group 2 N=138 (%)[a] | *P* value[χ] |
|---|---|---|---|
| Ilioinguinal nerve injury | 5 (4.5) | 4 (2.8) | 0.50 |
| Hematoma formation | 4 (3.6) | 6 (4.2) | 0.766 |
| Seroma formation | 4 (3.6) | 5 (3.5) | 0.993 |
| Urinary retention | 6 (5.4) | 4 (2.8) | 0.317 |
| Wound infection | 2 (1.8) | 4 (2.8) | 0.575 |
| Recurrence at 12 months | 2 (1.8) | 3 (2.1) | 0.835 |

Percentages within group - [a]; Chi square test - [χ]

as long as 80 min. The mean time in group 1 and 2 was 49.6 min and 49.8 min, respectively [Table 1].

Amongst the list of complications there was no statistically significant difference between the heavy weight and light weight groups [Table 2]. Clinical or operative evidence of nerve injury to the Ilioinguinal nerve was observed in five cases (4.5%) of group 1 and four cases (2.8%) of group 2. More importantly the number of cases of hematoma formation and seroma formation in both the groups was similar.

During the entire study 10 patients in all went into urinary retention; three of them required transient catheterization. Six patients (5.4%) were in group 1 and four (2.8%) were from group 2. These findings were not significant ($P = 0.317$). Recurrence was in five cases overall at one year duration. Two patients (1.8%) were from group 1 and three patients (2.1%) were from group 2. ($P$ value $\geq 0.05$).

The most important variable studied during the course of this study was the incidence of pain perceived by the patient in the postoperative period. Using the visual analogue chart patients were described to have discomfort with incorporation of different meshes. No statistically significant differences were observed in the outcomes in both groups. Following surgery, on the seventh day post operatively, majority of the patients in both groups presented with complaints of pain. In group 1 a larger percentage of patients had complaints of pain as compared to group 2 but this was not significant ($P = 0.523$). There was a dramatic improvement by the third month. Although the percentage of complaints in group 1 was higher, this was also not significant ($P = 0.831$). By the end of one year two patients in either group had complaints of pain [Table 3].

**Table 3: Perioperative and postoperative pain (n = 249)**

| Duration of study | Group 1 N=111 (%)[a] | Group 2 N=138 (%)[a] | *P* value[χ] |
|---|---|---|---|
| Before surgery | 6 (5.4) | 6 (4.2) | 0.699 |
| At 7 days post-op | 56 (50.4) | 64 (46.3) | 0.523 |
| 3 months post-op | 8 (7.2) | 9 (6.3) | 0.831 |
| 6 months post-op | 3 (2.7) | 5 (3.5) | 0.682 |
| 12 months post-op | 2 (1.8) | 2 (1.4) | 0.826 |

Percentages within group - [a]; Chi square test - [χ]

## DISCUSSION

In this study, following the implantation of light weight composite (VyproII®) mesh the incidence of pain in patients undergoing Lichtenstein technique of mesh repair was similar to the placement of conventional heavy weight polypropylene mesh. The notion that modern day light weight meshes leaves a lower quantity of unabsorbed propylene in the scar tissue over time would support patient comfort and fewer incidences of chronic pain.[24] The incidence of discomfort, chronic groin pain, and sensations of numbness after prosthetic inguinal hernia repair is as high as 40%; this is an unacceptable level, and in some circumstances even exceeds the preoperative subjective symptoms caused by the inguinal hernia itself.[25]

The implantation of nonabsorbable polymeric "biomaterials" induces activation of cytokine cascades and proteases that exhibit characteristics of a chronic inflammatory reaction. The inflammatory reaction and the accompanying fibrosis are prerequisites for mesh fixation within the tissue and the reinforcement of the abdominal wall. However, the mesh-induced inflammatory reaction frequently causes complications, including seroma formation, mesh shrinkage and migration, adhesion, infection, and pain.[26]

Recent studies suggest that there is some correlation between the polypropylene amount and structure of mesh and postoperative quality of life. Schmidbauer *et al*. showed that large pore-sized low weight polypropylene meshes composed of multifilament's, e.g., Vypro II, had better abdominal wall compliance and caused less chronic pain than large pore-sized, monofilament heavy-weight polypropylene meshes, e.g., Prolene.[27] These finding were not observed in the present study. The incidence of pain at all times during the study revealed a higher percentage of patients in the light weight mesh group (group 1) complaining of pain. In a recently published randomized trial comparing the same meshes in laparascopic extra-peritoneal inguinal hernia repair (TEP) of recurrent unilateral hernias the light weight composite (VyproII®) mesh group had a significantly better pain score.[28] The results from a similar study conducted by Agarwal *et al*.,[29] where placement of lightweight Polypropylene mesh was associated with significantly better pain scores, patient comfort, and sexual function.

Apart from the incidence of postoperative pain, the concern of surgeons regarding the handling of various meshes has been dismayed in this study as there are no values to support the notion.[30] In this study, the operative time, varies very little between the use of the light weight composite (VyproII®) mesh and the conventional polypropylene mesh.

Light weight composite (VyproII®) mesh is knitted from polyfilament fibers, which increase the mesh's surface and can expose the implant to infection. A risk of infection has not been observed in clinical trials, but experimental studies have confirmed this relationship.[31] In this study the incidence of infection was similar in both groups.

A common postoperative complication in the present trial was urinary retention. This is less than in some studies.[32] Ideally, it should occur in less than 1 per cent.[33] Although spinal anesthesia is useful in clinical trial settings to prevent bias from using various types of anesthesia, in routine practice other types of anesthesia should also be considered.[34]

The mesh technique may decrease the risk of postoperative pain, but the problem is still a great challenge. The possible risk of nerve injury in Lichtenstein's operation has been well established. In addition, postoperative fibroblastic ingrowths and shrinkage of the mesh may cause entrapment of the nerves. The entrapment syndrome causes neuralgia, and is associated with secondary injury from mesh-associated inflammation (chronic inflammatory demyelinating peripheral neuropathy).[35]

The incidence of nerve injury in this study was comparably higher than in other studies[36] and could be associated with the fact that there were a fair proportion of patients with recurrent hernia and long standing hernias included in the study.

Earlier studies have revealed that the extent of a foreign body reaction largely depends on the type of alloplastic material introduced.[37] Absorbable meshes have been designed, e.g., polyglactin 910, which lose 50% of their mechanical stability within three weeks and are degraded within three months. A compromise taking advantage of both material properties has been developed in a composite mesh. These optimized meshes exhibit a diminished foreign body reaction with improved biocompatibility.

Previous studies have noted higher recurrence rates when the lightweight meshes were used, even reaching more than five per cent as in a study conducted by O'Dwyer *et al*.,[20] Part of the study was to assess the recurrence rate in cases of both meshes. The follow-up period of 12 months should be extended to observe the tendency in the following years. Only one study by Bringman *et al*.,[24] has reported a follow-up longer than 1 year, without increased recurrence rate for lightweight composite meshes. The rate was found to be higher in the heavy weight mesh group (group 2) but this was not significant ($P = 0.835$) and further evaluation for a five year recurrence rate will define superiority of either mesh in due course.

## CONCLUSION

Modern day light weight meshes do not promise the prospects of a comparatively reduced incidence of chronic pain in patients undergoing Lichtenstein technique of tension free mesh repair for inguinal hernia. Neither do they exhibit a higher incidence recurrence nor infection following repair of inguinal hernia when compared to polypropylene meshes.

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