

Original Research Article

A study of short and long term complications of prolene hernia system

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ABSTRACT

Background: Prolene hernia system was introduced in 1999, and was thought to be a revolutionary type of mesh in preventing recurrence. But studies regarding long term results and complications were sparse. Our study is one such type which sheds light into the complications of prolene hernia system and its significance in Indian scenario.

Methods: 30 patients with inguinal hernia in Karnataka institute of medical sciences, Hubli, were included in the study. All of them were operated with prolene hernia system. Patients were assessed in the post-operative period and during follow-up for any complications. Appropriate statistical tests were applied.

Results: 1 (3.3%) patient each had seroma and superficial surgical site infection in the post-operative period. 2 (6.7%) patients had chronic groin pain symptoms and none of them had recurrence till date.

Conclusions: Based on the observations, we conclude that PHS is an effective method for open inguinal hernia repair with minimal complications. It has comparable results with lichenstein repair and other types of repairs available.

Keywords: Chronic groin pain, Inguinal hernia, Prolene hernia system

INTRODUCTION

A hernia is defined as a protrusion of a viscus or part of the viscus through an abnormal opening in the walls of its containing cavity.¹ While the definition of hernia is straightforward, the terminology is often misinterpreted. It should be clear that hernia refers to the actual anatomic weakness or defect, and hernia contents describe those structures that pass through the defect.

Groin hernia repair does not have the glamour of a Whipple or of a heart transplant, but in terms of preserving years of useful life, in sheer volume, is one of the most important surgical procedures. Repair of inguinal hernia is one of the commonest surgical procedures worldwide, irrespective of the country, race or socio-economic status and constitutes a major health-care drain in every country.²

There are innumerable types, shapes, and components of mesh. Each carries a unique profile of benefits and risks.

It would seem that surgeons should select a mesh which they feel comfortable placing, place these meshes consistently to improve their comfort with the devices, and follow these patients prospectively for outcomes. It is likely that in this complex field, there is not one right mesh for each patient.³

Prolene Hernia System (Ethicon; Somerville, NJ, USA) is a novel device developed for tension-free repair of inguinal hernia by Gilbert and colleagues in 1999. It is made from high porosity polypropylene for optimum tissue ingrowth. It comes in three sizes: medium, large and extended. According to the need appropriate size was selected so as to get maximum protection. It consists of two layers of polypropylene mesh joined by the connector, which provides three-point protection.⁴⁻⁷

- An 'underlay' mesh which is a round disc placed in the pre-peritoneal space of Bogros, like in Kugel or Nyhus pre-peritoneal repair.

- An 'onlay' mesh which is oblong shaped placed over the floor of the inguinal canal, similar to that used in Lichtenstein repair.
- A 'connecting' cylinder between the two plugging the deep ring, like in Robbin & Rutkow's plug repair (Figure 1).

Though it was thought to be a revolutionary breakthrough in open mesh repair, it has not reached the expectation, mostly due to its cost, and partly due to surgeons fear of complications. Here we try to evaluate PHS open mesh repair, its short and long term complications, and its feasibility in Indian scenario.

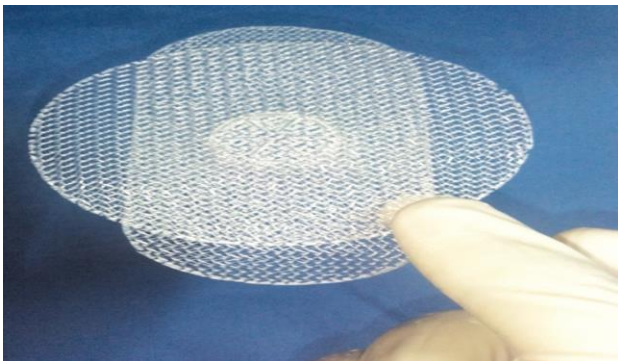


Figure 1: PHS mesh.

METHODS

The study is a prospective study of patients admitted in Karnataka Institute of Medical Sciences, Hubli, India from November 2013 to January 2014, with the diagnosis of inguinal hernia. 30 patients with inguinal hernia were included in the study.

All patients were operated under spinal anesthesia. The incision and exposure were like the conventional mesh repair. Intraoperatively, if an indirect sac is present, it is invaginated through the internal ring. If a posterior wall hernia is present (direct hernia), the defective tissue is circumscribed. In both the cases the preperitoneal sac is dissected free with the sponge. Separating the peritoneum from the transversalis fascia develops its shoulders. The PHS is inserted through either of these defects. If a pantaloon hernia exists, the deep epigastric vessels are divided, and the two defects get converted into a single defect. The entire PHS is inserted through the posterior wall defect or the internal ring.

The underlay component is deployed so that the edge of the graft is at complete distraction from the connector and is placed in preperitoneal space of Bogros. The onlay graft is extracted and placed against the posterior wall into the anterior space beneath the external and internal oblique muscles and laid against the transversus arch down to and over the pubic tubercle. A few sutures are placed on the onlay graft. One is placed at the pubic tubercle, one at the mid-portion of the transversus arch

and one at the mid-portion of the inguinal ligament. The spermatic cord is accommodated with the central or a lateral slit in the onlay component.

In the immediate post-operative period, patients were assessed for complications like seroma and infection. All the patients are still under follow up and are being evaluated for long term complications like recurrence and chronic groin pain.

Statistical analysis

Statistical analysis was done using IBM SPSS Statistics 20 software. Results on continuous measurements were presented on Mean+_{SD}. Significance was assessed at 5% level of significance.

Unpaired Student t test was used to find the significance of study on continuous scale between two groups (Intergroup analysis). Chi-square and Yates corrected Chi-square test were used to find homogeneity of samples on categorical scale. Wilcoxon matched pairs test was used to find the significance of study within the group (intragroup analysis).

RESULTS

Mean age group of the study was 49.9 years. 29 (96.7%) of the patients in the study were males. 1 (3.3%) out of 30 patients had seroma in the post-operative period. The seroma settled with conservative management. Those which are symptomatic and resistant to conservative management warrant evacuation.

1 (3.3%) out of 30 patients had surgical site infection. wound infection was superficial, did not concern implanted material or fascia and was successfully cured with antibiotic coverage in the post-operative period. A suppurative collection may need evacuation.

2 (6.67%) out of 30 patients had features of chronic groin pain in our study. The incidence of chronic groin pain decreased with time. Such patients were treated with analgesics and reassured in present study.

None of the patients in the study had recurrence in the follow up period till now. All patients were followed up for a period of 3 years. The authors would like to continue follow-up of these patients to evaluate long term efficacy of PHS with respect to recurrence.

DISCUSSION

Inguinal hernia repair is probably the most common procedure in general surgery. It is also one of the earliest operations in a junior surgical resident's postgraduate period.⁸

Usher first introduced polypropylene prosthetics for inguinal hernia in the late 1950s, however, the wide

acceptance of them took place in 80's following Lichtenstein's report of very successful results. Meshes have decreased the rate of recurrence significantly, but some problems related to meshes have been reported. As a foreign body, mesh theoretically may increase the risk of infection and seroma formation.⁸ In the complex field of hernia repair, there is not one right mesh for each patient.³

The localized accumulation of serum is common with the use of synthetic mesh in hernia repairs, and is probably a physiologic reaction to the foreign body. This seroma in many cases act as the nidus for infection. Although a sound concept, mesh placement underneath the transversalis fascia in the preperitoneal space (via open or laparoscopic approach) requires unnecessary dissection of this highly complex anatomical space and leads to obliteration of the spaces of Retzius and Bogros.⁹ This so called unnecessary dissection may also cause injury to nerves in the region and can lead to chronic groin pain. Various groin pain syndromes may develop, usually from scar tissue, reaction to prosthetic material, or involvement of a nerve in staples or suture material during repair of the hernia PHS mesh needed more dissection and had an extra layer of mesh. Hence theoretically, PHS mesh were supposed to have higher chances of seroma, infection and chronic groin pain. This was probably one of the reasons why PHS did not gain popularity. Historically, the recurrence rate has been the exclusive yardstick for comparing different types of hernia repairs. However, two factors have surfaced that have served to decrease the importance of recurrence. The first is the better ability to measure quality of life, which has resulted in a realization

by surgeons that the incidence of post herniorrhaphy sequelae such as chronic groin pain occurs more frequently than one might have anticipated. The second factor decreasing the importance of the recurrence rate is the development of the newer tension-free approaches that have brought the recurrence rate down to an essentially irreducible number (i.e., <1%) in experienced hands. Nevertheless, hernia recurrences will continue to be seen because a recurrence rate of 1% still translates into a relatively large number because of the size of the denominator.

A French study found that all 206 recurrences in their series were located at the Myopectineal Orifice and that the choice of mesh must take this into account.¹⁰ There is also evidence suggesting that development of an ipsilateral femoral hernia after inguinal mesh repair may be more common place than previously thought; a study has found a 15-fold incidence of femoral hernia repair after previous inguinal hernia surgery than in the general population.¹¹ PHS has the added advantage of strengthening the whole of myopectineal orifice, and virtually eliminating any risk of recurrence as well as femoral hernia.⁴

Various studies in the past have evaluated the efficacy of PHS mesh for inguinal hernia.^{6,12-14} Many studies have compared PHS with Lichtenstein repair and various other repairs available.^{4,15-20} All these studies have concluded independently that PHS is an effective method for open inguinal hernia repair. It has comparable results with lichtenstein repair and other types of repairs available (Table 1).

Table 1: Complication rates of PHS in various studies.

Study	Seroma %	Infection %	Chronic pain %	Recurrence %
Gohel J et al	0	0	8	0
Mottin C	2.1	1.0	2.1	1.0
Yener O	10	3.3	6.7	3.3
Faraj D	-	-	1.8	2.3
P Study	3.3	3.3	6.7	0

Present study shed light into the complications which had hindered the widespread usage of PHS. It may help in alleviating some of the apprehensions associated with PHS mesh repair. In contrast to the above theories, PHS is associated with minimal complications. Seroma and infection rate in the early post-operative period is acceptable.

Chronic groin pain which was dreaded to become the most common complication of PHS hernia repair due to more dissection and two-layered mesh, is also manageable with low incidence. By covering the entire

myopectineal orifice, PHS virtually eliminates inguinal and femoral hernias.

CONCLUSION

Study conclude that PHS mesh for inguinal repair is a feasible option with comparable complication rates with existing meshes for the repair of inguinal hernia.

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