Experience in Day Surgery with prolene hernia system (PHS)

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Abstract

Aim: The aim of this study was to evaluate the outcomes of inguinal hernia repair with prolene hernia system (PHS) mesh under local anaesthesia with sedation as a day surgery procedure within a surgical training programme.

Patients and Methods: 5450 patients with inguinal herniae were admitted for hernia repair between 1997 and 2005 in our day surgery unit. 1840 inguinal hernias were repaired with PHS during this time, 1002 patients were operated by residents (54,54%) under staff supervision. Patients were followed-up at five years post-operatively and the outcome measures of pain and complications recorded. Trainees and staff surgeons were assessed by an evaluation of both knowledge and technique.

Results: Local anaesthesia with sedation was used in 97.4% (1793) of patients; regional anaesthesia in 45 (2.49%): conversion from local to general anaesthesia was required in two patients (0.2%). Mean operation time was 40 min, including t anaesthesic preparation. Mean hospital stay for all patients was 6 hours. The evaluation of hernia repair with the PHS system was similar between the staff members and residents.

Conclusion: Inguinal hernia repair using the PHS tech¬nique under local anaesthesia with sedation is feasible on a day case basis and is a suitable procedure for training in a residency programme.

Keywords: inguinal hernia, prolene hernia system, local anaesthesia, day case surgery, training programme.

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Introduction

Inguinal hernia is one of the most common surgical procedures performed worldwide. Many surgical techniques have been implemented for inguinal hernia repair, using both the open and laparoscopic approaches. In the early 1990s, tension-free techniques became the gold standard for hernia repair. Learning the inguinal hernia approach is very important to the resident training in general surgery. In our training centre, the trainee starts learning the PHS technique, and once mastered, progresses to other procedures. The bilayer polypropylene mesh device and the prolene hernia system (PHS) for inguinal hernia repair (so-called '3D' meshes) were introduced in 1998. The PHS system combines many of the advantages of the earlier tension-free repair techniques while offering anterior and posterior reinforcement of the hernia defect. This is attributed to its three components comprising the underlay patch (for preperitoneal placement), the onlay patch (for subfascial placement) and the connector which joins thet two patches and acts as a plug.

We present a retrospective study of 1840 cases treated in our Ambulatory Unit of both primary and recurrent inguinal hernia repair using 3D mesh. Inclusion criteria included: patients ASA I, II, or stable III patients, absence of recent upper respiratory tract infection, absence of significant past or family history of problem with anaesthesia, age less than 80 years, body mass index <40, availability of responsible adult to escort home with care for 24 hrs, easy access to a telephone and indoor toilet.

Patients and Methods

1840 patients with inguinal hernia were included (147 women [8%] and 1693 men [92%]), who attended the ambulatory day surgery unit from 1997 to 2005. All patients were operated on an elective basis and follow up at 5 years.

Preoperative routine laboratory tests and electrocardiography were conducted in the outpatient clinic. Patients were questioned regarding other systemic diseases, allergic reactions particularly to anaesthetic agents, and current drug history.

Informed consent was obtained before surgery and included patients' approval for performing the hernia repair using the PHS mesh under local anaesthesia with sedation. All patients were admitted on the morning of surgery. Patients were discharged between six and eight hours post-operatively.

One hour before surgery, oral midazolam (0.5–2.0 mg) was administered.

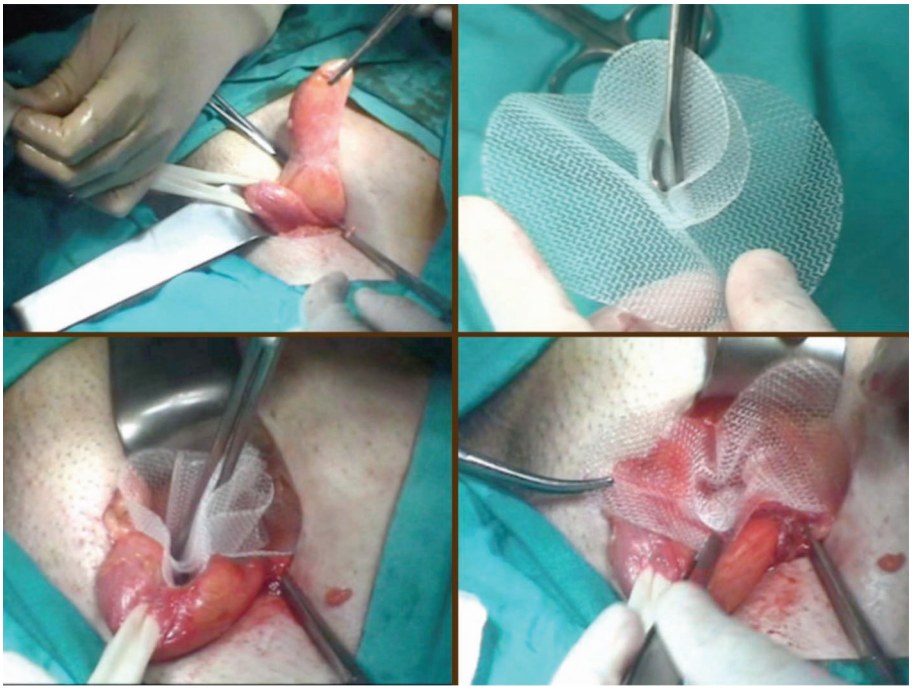
Local anaesthesia was performed by the operating resident. Conversion to general anaesthesia was indicated for failure of local anaesthesia after maximal sedation had been administered.

Local anaesthesia and sedation technique

Patients were sedated with propofol (0.5 ml/kg) before the local anaesthesia by the surgical trainee. For local anaesthesia, the residents used a combination of bupivacaine with 1:200,000 adrenaline (1% solution) and lidocaine (5%) up to 60ml. Twenty ml of physiological saline solution, 10 ml of lidocaine (5%) and 10ml of bupivacaine with Adrenaline were mixed. Standard anaesthetic monitoring of vital signs was maintained during the injection of the local anaesthetic agents and throughout the procedure. The iliohypogastric and ilioinguinal nerves (T12 and L1) were blocked by the injection of 10 ml of local anaesthetic into the oblique muscles medial to the anterior superior iliac spine; another 10ml was injected around the external ring, a further 10 ml lateral to the pubic tubercle, 10 ml in the other side of the inguinal ring, and the final 10 ml are injected in the line of the incision. During surgery, local anaesthetic can be injected into the hernia sac and/or the muscle layers. (Figure 1)

Hernia repair technique: PHS was used for all repairs. This 3D mesh comprises two layers; an ellipsoid onlay layer, and an inferior circular

Figure 1 Inguinal Hernioplasty with PHS. There is a big direct hernia treated with PHS hernioplasty. In the picture we introduce the mesh directly in the hernia defect, expand the circular inferior layer in preperitoneal space. Finally the superficial layer is fixed with a cardinal point.



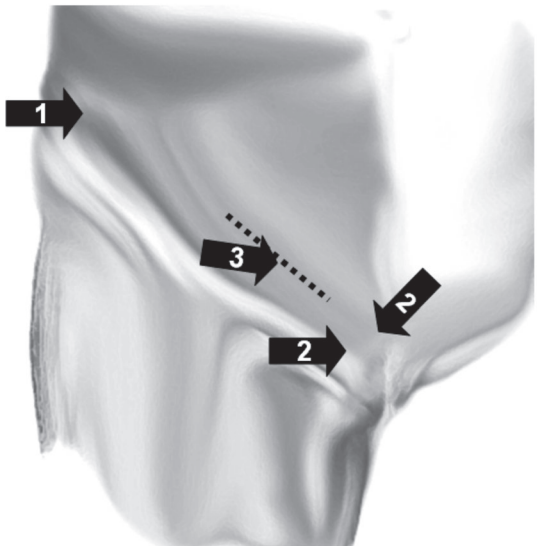
layer introducing into the preperitoneal space; both layers are joined by a connecting cylinder of mesh acting as a plug into the internal ring.

In both direct and indirect hernia repair, the hernia sac was dissected and reduced into the abdominal cavity. A preperitoneal space was then created behind the transversalis fascia for the placement of the deep layer of the PHS mesh. The dissection was done with the finger and with gauze separating the preperitoneal space. The superior layer was trimmed laterally to create an opening for the spermatic cord and fixed with a suture.

A critical step of the PHS mesh technique was the fixation of the superficial onlay layer to the pubis by a 2/0 prolene suture, with a maximum of 4 further sutures fixed at the cardinal points of the inguinal ligament and the conjoined tendon. Care was taken to avoid entrapping nerves in the stitches. (Figure 2) Postoperative pain was assessed using a visual analogue scale pain rating scale. Mild and moderate postoperative pain was managed with simple analgesics (metamizol) with or without non-steroidal anti-inflammatory drugs (NSAID).

Figure 2 Local anaesthesia technique

1. First point: antero superior iliac spine, two-three centimeter to midline.
2. *Second actuation (I):* infiltration of external inguinal ring in midline face. *Second actuation (II):* infiltration of external inguinal ring in outside face.
3. *Final point:* superficial infiltration in the line of the incision, and direct through this line to the subcutaneous fatty tissue midline.



Assessment of knowledge and surgical skill

Participants

Members of the staff: 6 senior surgeons experimented in inguinal hernia repair, working full-time in the ambulatory day surgery centre.

Residents: 25 residents (3 months of their surgical rotation).

Assessment: To compare the differences between residents and surgeons trained in this technique we used a scale designed by the tutors in our Ambulatory Centre (1).

A) Knowledge about the mesh:0–5

B) Knowledge about the sutures: 0–5

C) Surgical technique: 0–5

1. Dissection of inguinal hernia: 1
2. Dissection of the hernia sac: 1
3. Identification of structures (Inguinal cord, Cooper's ligament, fascia transversalis,etc.): 1
4. Ability to accurately place the mesh (introduction and placement of the two layers of the mesh): 1
5. Sutures (fixation and knotting): 1

D) Surgical advice discharging the patient: 0–5

E) Follow-up: 0–5

Table I Comparative method to evaluate and compare the result of the resident and the staff members.

Comparative Method						
A) Knowledge about the PHS mesh	0 Nothing	1 Materials	2 1 and Parts of the mesh	3 1,2 and Sizes	4 1,2,3 and Placement of the layers	5 1–4 and Integration of the materials
B) Knowledge about the sutures	0 Nothing	1 Types of sutures Reabsorbables-Non reabsorb-ables	2 1 and Knotting	3 1,2 and Placement of the sutures	4 1,2,3 and Correct Suture in simulators	5 1–4 and Integration and duration of the materials
C) Surgical technique	0 Nothing	1 Dissection of inguinal hernia	2 Skelitization of hernia sac	3 Identification of structures	4 Facility and skill to place the mesh	5 Sutures in the mesh
D) Surgical advice discharging the patient	0 Nothing	1 Simple information	2 Basic information: result	3 1,2 and Anesthesic and surgical technique	4 Advance infor-mation: About the mesh	5 Complete information
E) Follow-up	0 Nothing	1 Follow-up on discharge of the patient	2 1 and Telephone Follow-up	3 1,2 and Follow-up 1 month in clinic	4 1,2,3 and Follow-up 3 month in clinic	5 1–4 and Follow-up 6 month in clinic

The results were recorded as follows:

Each surgeon received a combined score ; (A+B+C+D+E)=F.

The sum of *"F"* was averaged among the participating surgeons whether trainees or experienced surgeons with a maximum score per participant available.

The range was: 0–5 (poor result), 5–10 (normal result), 10–20 (good result), and 20–25 (very good result).

The assessment was performed at the end of the resident's rotation by the tutor. Staff members were evaluated by the centre's chief of staff.

Results

1840 patients with inguinal hernia, 147 women (8%) and 1693 males (92%), admitted in the criteria of day surgery. Mean age of the patients was of 56 years (range 18-82 years).

Herniae were classified according to Gilbert's classification: type I n=15 (0.81%), type II n= 49 (2.7%), type III n=736 (40%), type IV n=939 (51.3) and type V n=101 (5.5%). Primary hernias comprised 92.0% (1692) of patients while recurrent hernias accounted 148 (8.0%).

Anaesthesia: Local with sedation n=1793 (97.4%); Regional block n=45 (2.5%); General anaesthesia n=2 (0.1%).

PHS Sizes: Normal: n=376 (20.4%); Large:n=801 (43.5%); Extra-large: n=663 (36.0%).

Mean operation time was 40 mins (range 30–80 mins), including time to anaesthetise.

The overall hospital stay was 5-8 hours, with a mean of 6 hours; 1748 (95%) had a stay less than five hours, 81 (4.4%) had a stay less than 23 hours, and a 11 patients (0.59%) stayed overnight.

Staff surgeons performed 838 repairs (45.5%) and residents 1002 (54.5%) supervised by trained surgeons.

Postoperative pain management

At 3 months follow-up: B) 6 (0,3 %)

Recovery without complications n=1830 (99.4%)

Post-operative complications (pain, haematoma, seroma, infection) n=6 (0.3%) Chronic pain or hernia recurrence n=4 (0.2%)

Postoperative pain intensity of was mild (2–4 points) in 31.5%, moderate (4–6 points) in 54% and severe (6–8 points) in 14.5% of cases in the day of surgery. All cases were alleviated with a NSAID with or without paracetamol. On the first postoperative day all patients were managed with simple analgesics (metamizol) with or without non-steroidal anti-inflammatory drugs (NSAID).

Comparison of trainees and experienced surgeons

Surgical outcomes comparing trainees and experienced staff were similar

Staff members: A(4.5)+B(4)+C(5)+D(5)+E(4)= 22.5

Residents: A(3.5)+B(4.5)+C(5)+D(4.5)+E(3)= 20.5

Discussion

The results of inguinal hernia repairs performed with the PHS 3D technique in our unit are comparable to those achieved with a standard Lichtenstein hernia repair. Inguinal hernia repair using the PHS technique under local anaesthesia could be mastered by most of the surgeons in our hospital with minimal morbidity and short hospital stay with a minimal recurrence [1,2]. This is one of the principal reasons to teach this technique in our training resident programme. Once the trainee has mastered the PHS technique, they can advance to the other common surgical techniques such as Lichtentein, Stoppa, McVay, Rutkow-Robbins, etc.

In a randomized clinical trial of Lichtenstein patch vs Prolene Hernia System for inguinal hernia repair in 20063 the median duration of operation for unilateral primary hernia was 37 min for the Lichtenstein operation and 27 min for the PHS procedure ($P < 0{\cdot}001$). Postoperative pain was similar after both operations. Median sick leave was 7 days in both groups. Time to driving a car was 4 versus 3 days, and time to return to sporting hobbies 13 versus 11 days, in the Lichtenstein and PHS groups, respectively. Beside a residual femoral hernia after Lichtenstein repair, no recurrent inguinal hernias were detected [3] but the PHS procedure takes significantly less time to perform [1,4]. Hence our rationale for using the PHS technique as our standard technique for teaching hernia repair.

There are only a few data regarding the long-term outcomes of prolene hernia system (PHS) mesh in the published reports. When we compare the short-term and long-term outcomes of the PHS mesh with the Lichtenstein mesh technique in two studies there is no significant difference in the early and long-term outcomes between PHS and Lichtenstein hernia repairs [5,6].

PHS technique involving preperitoneal dissection is well tolerated and easy to carry out under local anaesthesia [7]. Local anaesthesia lends itself to ambulatory surgery and is especially useful in patients with severe co-mobidities, where general anaesthesia would be high risk. It also provides four-five hours postoperative analgesia which can be easily administered by the surgeon [2,7]. The PHS technique can also be applied to other types of hernia repair such as epigastric and umbilical hernia; with good results in all cases [8].

In a study of efficacy of Bilayer Mesh Device compared with the gold standard Lichtenstein onlay mesh for inguinal hernias , there were significantly lower recurrence rates for the PHS technique in early results. Additionally, in the PHS mesh group, there was a trend toward decreased overall complication rates with significantly less seroma/ hematoma rates. Therefore, the PHS mesh repair may represent a superior alternative for the repair of inguinal hernias [4]. It is a safe and effective technique for inguinal hernia training for trainees, with similar results to staff surgeons with less operative time that with other inguinal hernia techniques [7,9]. We have therefore concluded that the PHS technique is a safe and reliable procedure with low rates of complication, recurrence, and late symptoms in both early and long-term follow-up [10].

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