

A Two-centre Double Blinded Randomised Control Study Comparing the Lichtenstein Patch, Perfix® Plug and Proloop® Plug in the Repair of Primary Inguinal Hernia

DL Sanders, DH Samarakoon, SW Ganshirt, CS Porter AN Kingsnorth

Plymouth Hernia Service, Derriford Hospital, Plymouth, UK

And

Dept of Surgery, Lake Forest Hospital, Illinois, USA



Introduction

The use of prosthetic mesh in the repair of inguinal hernia was first introduced fifty years ago. Since that time there have been several modifications in terms of the mesh itself and the techniques for positioning the mesh.

The aims of these modifications are twofold, firstly to create readily reproducible repairs with low risk of recurrence and secondly to minimise patient post operative discomfort.

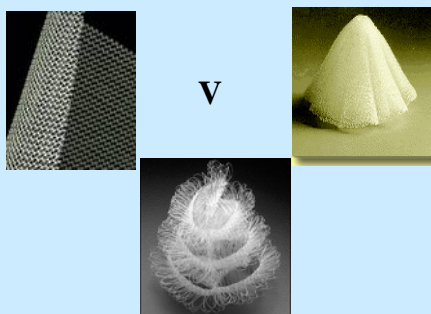
Perhaps the most significant of these modifications was the introduction of the concept of tension free repairs by Lichtenstein, which within the last decade has been adopted widely as the 'gold standard' for repair of inguinal hernia.

Techniques of mesh plug repair have also been adopted by some centres. The technique of choice remains a subject of ongoing debate.

One of the main complaints about the mesh plug has been report of plug hardening resulting in groin pain. The incidence of groin pain is reported as 8.6% in one series, whilst others report 5.6% of patients requiring plug removal secondary to groin pain. To address this issue the ProLoop® plug (Atrium) has been developed. It has a lightweight configuration to reduce bulk and increase conformability.

At 2 week, 6 month and 12 month follow up patients were assessed for postoperative pain, using a Visual Analogue Scale (VAS). Any postoperative complications were also noted.

For each clinical endpoint the PL plug was compared to the LTFM repair and PF plug.



Aim

This prospective double blind randomised control trial compares the early and medium term outcomes following repair of adult primary inguinal hernia by Lichtenstein tension free mesh (LTFM) repair, Perfix® plug (Bard) (PF), and ProLoop® plug (Atrium) (PL) repair.

Method

Consecutive patients, between March 2003 and January 2006, over the age of 18 years with primary unilateral inguinal hernia were randomised to receive a LTFM, PF plug or PL plug repair. Follow up was at 2 weeks, 6 months and 12 months.

Patients were excluded if they were under 18 years, failed to consent to inclusion or were already participating in other medical studies. Irreducible and recurrent hernias were also excluded.

Preoperative And Intraoperative Details

All patients received outpatient preoperative anaesthetic assessment. Patients were admitted on the day of surgery and reviewed by the research hernia nurse and consented by the operating surgeon. Analgesia in the form of 100mg Diclofenac suppository was given 1 hour preoperatively.

Randomisation was computer generated, using sealed numbered envelopes, which were opened, in theatre. All repairs were performed under local anaesthetic and patients under 60 years received additional sedation with Midazolam 3 mg.

Standard procedure techniques for LTFM repair, PF plug and PL plug repairs were used. External oblique closure, skin closure and local anaesthetic infiltration were uniform for all mesh types.

Data Collection And Analysis

Data was collected on standardised questionnaires and report forms. Intraoperative data was collected by the operating surgeon on operating time. To ensure blinding these forms were placed in sealed envelopes and sent to the data management unit for processing.

Results

295 consecutive patients with unilateral primary inguinal hernia were recruited to the study.

93 patients were randomised to receive PL plug repairs, 101 PF plug repairs and 101 LTFM repairs. There was no significant difference between the 3 groups in terms of age, sex or BMI.

Bodily Pain Scores

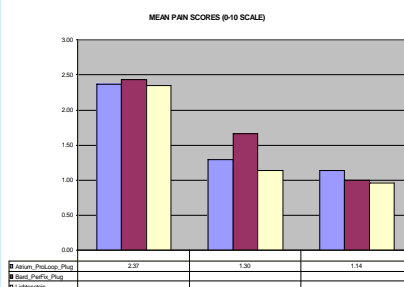


Figure 1: Mean pain scores at 2 weeks, 6 months and 12 months

There was no significant difference between the groups at 2 weeks, 6 months or 12 months.

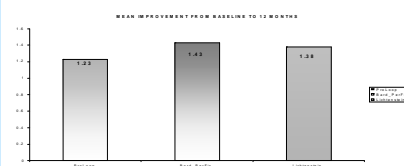


Figure 2: Mean improvement in pain from 2 weeks to 12 months

Operative Time

To complete the repair, the PL plug took a mean of 32.9 minutes (range 19-76 minutes), the PF plug a mean of 31.05 minutes (range 17- 54 minutes) and the LTFM repair a mean of 32.8 minutes (range 20-62 minutes). There was no statistical difference between the groups (PL V PF P=0.92; PL V LTFM P=0.52).

Hospital Stay

The mean hospital stay for the PL plug was 8.7 hours (range 3.6 – 52.03 hours), for the PF plug a mean of 8.1 hours (range 4.08 – 30 hours) and for the LTFM repair a mean of 8.9 hours (range 4.6 - 32 hours). There was no significant difference between the groups (PL V PF P=0.74; PL V LTFM P=0.44).

Complications

There was no significant difference between the groups.

ROSE-OF-OUTCOME	COUNT	RANDOMISATIME
Wound Healing Problem	0	4 - Atrium_ProLoop_Plug 3 - Bard_Perfix_Plug 1 - Lichtenstein
Signs of Infection	5	2 - Atrium_ProLoop_Plug 2 - Bard_Perfix_Plug 1 - Lichtenstein
Herniation	4	1 - Atrium_ProLoop_Plug 1 - Bard_Perfix_Plug 2 - Lichtenstein
Recurrence	5	2 - Atrium_ProLoop_Plug 1 - Bard_Perfix_Plug 2 - Lichtenstein
Numbness	109	40 - Atrium_ProLoop_Plug 69 - Bard_Perfix_Plug 60 - Lichtenstein
Testicular Atrophy	0	

Table 1: Postoperative complications

Return To Daily Activity

272 patients (PL total = 87, PF total = 94, LTFM total = 91) were assessed for return to normal daily activity. There was no significant difference between groups.

Conclusion

- This study provides evidence that the PL plug is comparable with the PF plug and LTFM repair at early, 6 month and one year follow up.
- The overall complication rates including groin pain were similar for all three procedures. As were length of operation, hospital stay and return to normal daily activity.
- The recurrence rate for the PL plug in this study was 2.0% as comparable with the largest non-randomised collective study of 2060 primary mesh plug repairs, which quoted the recurrence rate as less than 0.02% at 6 years. The recurrence rate in the LTFM repair group (2.0%) compares very favourably to other studies where recurrence ranges from 1.6% to 4.9%. This discrepancy may be due to the length of follow up being only one year in this study.
- The shape and design of mesh plugs are different. A number of 'pre-formed' mesh plugs are available on the market. Some of these are conical in shape and although are easy to site may not completely fill the defect. Others require more extensive tissue dissection, to site attached underlay and onlay patches.
- It concludes that the PL plug offers comparable results to the PF plug and LTFM repair. It may be that at longer-term follow-up, the lightweight nature of the PL mesh resists 'mesh hardening', which may reduce groin pain.

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