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

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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.

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.

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 if age, sex or BMI.

Bodily Pain Scores

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.

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.

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 the 2.0% 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 overlay 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.

References