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Mesh-Plug Hernioplasty in Over 2,000 Patients**

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Hernia 2007:Online First

Distribution as Reprints Only

A long-term evaluation of the modified mesh-plug hernioplasty in over 2,000 patients

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Received: 14 June 2007 / Accepted: 27 November 2007
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Abstract

Background A modified technique for mesh-plug hernioplasty is a long-term, safe and efficacious treatment for primary unilateral inguinal herniorrhaphy.

Methods Prospective analysis of 2,038 patients who underwent primary unilateral hernioplasty from 1997 to 2005 at a private university medical center. A modified technique using a mesh-plug was performed under local anesthesia with intravenous sedation. The modified technique consisted of placing the mesh plug into the preperitoneal space and suture fixation of the plug using the inner petals. The main outcome measures were Surgical morbidity, postoperative recovery, hernia recurrence, and chronic pain.

Results There were 1,265 indirect and 773 direct hernias. Mean operative time was 28 min; mean recovery room time, 47 min. A total of 1,936 (95%) returned to normal activities within 3 days. Only 367 patients (18%) required prescription pain medication. Nine patients (0.4%) have been treated for chronic pain. No mesh infections or mesh migration have occurred. Three recurrences (0.15%) have been detected with a 99% follow-up over 2–10 years (mean 72 months).

Conclusion The modified mesh-plug hernioplasty is a safe and efficacious treatment option for the primary unilateral inguinal hernia patient.

Keywords Inguinal hernia · Modified plug technique

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Introduction

Inguinal hernia repair is one of the most common procedures performed by general surgeons in the United States with more than 50,000 performed annually [1]. The pursuit of increasing efficacious and lasting repairs for this common affliction has brought about the evolution of a broad spectrum of procedures [2–11]. During the last two decades, mesh repairs have become accepted because they result in a tension-free repair with a low recurrence rate [12, 13].

Mesh-plug hernioplasty was first introduced in the 1970s and then promoted as a repair for all varieties of inguinal hernias in the 1990s [9–14]. Rutkow and Robbins have reported the short and long-term safety and efficacy of the traditional mesh-plug hernioplasty [15]. We have previously reported a modified mesh-plug hernioplasty technique with excellent short-term results [16, 17]. We have now accumulated a series which confirms the long-term safety and efficacy of the modified mesh plug hernioplasty for unilateral initial presenting inguinal hernias.

Materials and methods

A prospective analysis of 2,038 patients with unilateral inguinal hernias undergoing mesh-plug hernioplasty was conducted between 1 May 1997 and 1 May 2005 at Rush University, Chicago, USA. Patient demographic data and data regarding operative findings, operating room time, recovery room time, postoperative pain medication used, and recovery time to normal activities were all recorded into a data registry. All patients were required to return after 1 week postoperatively for evaluation and between 1 and 2 years postoperatively. Telephone interview was

conducted every 6 months after 2 years to inquire about recurrence and chronic pain.

Chronic or significant groin and/or leg pain was defined as pain that persisted more than 6 months after the procedure which caused the patient to not be able to perform an activity which the patient considered important. Pain which resolved prior to 6 months postoperatively or pain which the patient only considered to be a nuisance was not counted as chronic or significant pain.

All procedures were performed by the authors. The operative technique used has been previously described in two reports [16, 17]. For indirect hernias, the inside petals of a large plug are sutured to the internal oblique muscle and the shelving edge of Poupart's ligament portion of the internal ring allowing for the outer surface of the plug to form an underlay preperitoneal patch of the indirect defect. For direct hernias, the inside cone of an extra large plug is sutured to the conjoint tendon or, if not present, the lateral edge of the rectus muscle, Cooper's ligament, and the shelving edge of Poupart's ligament allowing for the outer surface of the plug to form an underlay preperitoneal patch of the direct defect. The PerFix Plug[®] (Davol, Cranston, R.I., USA; a division of C.R. Bard, Murray Hill, N.J., USA) was used exclusively for all hernia repairs. Local anesthesia, 1% lidocaine hydrochloride (Xylocaine; Astra Pharmaceutical Products, Westborough, Mass., USA) with intravenous sedation was used for all repairs. Ketorolac tromethamine (Toradol[®]; Roche Laboratories, Nutley, N.J., USA) was given at the conclusion of the procedure for postoperative pain before discharge.

Results

Patient demographic data are listed in Table 1. There were 1,265 indirect and 773 direct hernias. Classification of the hernias as described by Gilbert are listed in Table 2 [18]. Mean operative time was 33 min (range 20–39 min). Mean recovery room time was 47 min (range 25–64 min). All patients were discharged as outpatients. Of the 2,038 patients, 1,671 (82%) required only over-the-counter pain medication postoperatively, 367 (18%) required prescription pain medication ranging from 2 to 14 days in duration, and 1,006 (49%) were able to perform normal activities without prescription pain medication within 3 days. The

Table 1 Demographic data

Men	1,962
Women	76
Age (mean)	48 years (range 15–96 years)
Manual laborer	872

Table 2 Hernia classification

Indirect	1,265
Type I	143
Type II	1,035
Type III	87
Direct	773
Type IV	721
Type V	52

remaining 5% of patients returned to normal activities within 14 days. Ninety-nine percent (862) of manual laborers returned to work without restriction on postoperative day 14.

We recorded a total of 52 postoperative complications (2.6%). Thirty-seven postoperative hematomas were non-expanding and were treated by observation. Fifteen patients returned with urinary retention and required catheterization. Three of these patients subsequently required transurethral resection of the prostate for significant benign hypertrophy of the prostate. No wound or mesh infections, orchitis, sinus tracts or plug migration occurred.

Between 1 and 2 years postoperatively, 2,018 patients (99%) have been examined, and two recurrences have been detected for an early recurrence rate of 0.1%. Another recurrence was detected at 65 months postoperatively for an overall long-term recurrence rate of 0.15%. Mean follow-up by telephone interview is 72 months (range 2–10 years) with only 20 patients (1%) being lost to follow-up.

Nine patients (0.4%) returned from 6 to 38 months postoperatively with significant groin and/or leg pain. Seven of these patients responded to a series of local steroid injections. Two patients required radiofrequency ablation of the ilioinguinal and iliohypogastric nerves. Both patients have some residual pain that is related to position. However, both patients are able to maintain full-time employment. At present, no patient has required re-exploration for mesh removal or nerve transection.

Discussion

The evolution of inguinal hernia repair has progressed dramatically from the mid-1980s until the present day [2–11]. Mesh repairs for primary inguinal hernias have reduced the recurrence rate from greater than 10% in tissue-to-tissue herniorrhaphy to approximately 1% or less [7–13, 15–17]. There are numerous types of mesh, techniques and approaches without adequate documentation as to their long-term safety and efficacy. We have previously reported the early results of a modified mesh-plug hernioplasty that achieved 0.1% early recurrence rate, a 3-day recovery, minimal perioperative complications and few chronic pain

outcomes [16, 17]. This series confirms with 99% follow-up over a 10-year span, a 0.15% long-term recurrence rate and less than a 1-in-200 treatable chronic pain rate.

We modified the Rutkow and Robbins technique by using the inner petals to fixate the plug with sutures to the anatomical structures used in most hernia repairs [16, 17]. For indirect hernias, the inner petals are sutured to the shutter mechanism (internal oblique muscle) medially and to the inguinal ligament laterally. This allows for the outer cone to open and flatten out in the preperitoneal space. For direct hernias, the inner cone is sutured to the conjoined tendon medially and to Cooper's ligament and the shelving edge of the inguinal ligament laterally, again allowing for the outer cone to flatten out in the preperitoneal space. These modifications eliminate the possibility of plug migration or of the inner petals from protruding into the inguinal canal. The sutured plug is completely preperitoneal in an almost flat configuration, with its structure allowing it to spring open and close so that no tension is placed across the inguinal floor. Since polypropylene has memory when groin musculature contracts, the structure of the cone allows it to open or spread out like a flower blossoming and, when the groin musculature relaxes, the polypropylene returns to its original configuration of a cone. We believe this tension-free modification reduces medially-induced rectus muscle spasm, which accounts for most pain after inguinal mesh hernioplasty or tissue-to-tissue herniorrhaphy. Our 95%, 3-day return to normal activities and only an 18% use of postoperative prescriptions pain medication gives us proof of this hypothesis.

The procedure is performed with the patient under local anesthesia with intravenous sedation, which avoids general anesthesia. The fact that all patients leave the ambulatory facility in approximately 1 h after surgery confirms the minimal effect of the anesthesia and surgical procedure on the patients. Also, 99% of manual laborers returned to work without restriction in 2 weeks. Patients are not restricted from any activities except heavy lifting of greater than 50 lb (22.7 kg) for 2 weeks. Workman's compensation patients were excluded from the study in an effort to remove the bias of requiring 6–8 weeks off work after hernia repair.

Deploying the plug directly into the hernia defect through an anterior approach simplifies preperitoneal placement which is much more difficult with laparoscopic, Stoppa or Kugel repairs. Performing the repair in approximately 30 min with basic instruments keeps the operating room cost to a minimum. Utilizing a 4- to 5-cm incision on the vast majority of patients keeps the repair in the realm of minimally invasive surgery. Overall, this procedure should be described as a simple, minimally invasive, cost effective, open approach to inguinal hernia repair.

Our complication rate is minimal. Hematomas are expected in small numbers after hernia repairs and in this

series they resolved without intervention. A less than 1% urinary retention rate is evidence of the minimal trauma to the groin that results after this repair. A less than 0.5% long-term pain rate is an indication that nerve entrapment is unlikely when the plug position is entirely preperitoneal. A 0.1% nerve ablation rate for the treatment of chronic pain is further evidence that nerve entrapment is highly unlikely or non-existent with this modified repair. Positioning or placing the plug in the preperitoneal space as an underlay technique seems to have the plug become a Tugel bolt in the groin which has seemed to eliminate plug migration and also minimizes the contact that the plug has with the cord structures which should also minimize the chance of spermatic cord scarring occurring.

A long-term recurrence rate of 0.15% with overall 99% follow-up is outstanding. A comment about follow-up and patient selection should be noted. The patient population came from a private practice and a private university. This was a compliant and reliable population with regard to their health care. Also, all patients were offered free screening for colon cancer, prostate cancer, hypertension and cardiac disease if they participated in follow-up. Medical students from ten consecutive classes worked diligently each week over 10 years with the authors to document follow-up. We believe this is the only study in the literature that can accurately measure long-term recurrence.

The modified mesh-plug hernioplasty technique is simple and should be able to be mastered by all general surgeons. Operating room and recovery room times are kept to a minimum. Pain and its required medication are reduced to a few days. Recovery and return to physical labor are at most extended for only 2 weeks. Cost is kept to a minimum. Early and late recurrence as measured by the results of physical exam and telephone interview are less than 0.15%. Chronic pain requiring nerve ablation is less than 0.1%.

Conclusion

The modified mesh-plug hernioplasty uses a minimum of medical resources, is associated with an early return to normal activities and manual labor, and has minimal complications with a low recurrence and chronic pain rate. We believe that this procedure is a safe and efficacious treatment modality for unilateral primary inguinal hernias as evidenced by the results of this study.

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