

# Laparoscopic Prosthetic Reinforcement of Hiatal Herniorrhaphy

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## Key Words

Laparoscopic Nissen fundoplication · Prosthetic · Polytetrafluoroethylene · Hiatal hernia, recurrence · Recurrent hernia

## Abstract

**Background/Aims:** Primary repair of a large hiatal hernia is associated with a published recurrence rate of up to 10%; anecdotal rates even higher than this have been reported to the authors. The use of prosthetic material in the repair of other abdominal wall defects has often produced better results than primary repair. We wanted to compare laparoscopic primary repair of large hiatus hernias with laparoscopic primary repair reinforced with prosthetic. **Methods:** Thirty-one patients with symptomatic gastroesophageal reflux and a hiatal defect 8 cm or greater were randomized to Nissen fundoplication with posterior cruroplasty (n = 16) or Nissen cruroplasty, and onlay of polytetrafluoroethylene (PTFE) mesh (n = 15). All patients underwent preoperative esophagogastroduodenoscopy (EGD) and barium esophagography. After posterior cruroplasty with interrupted nonabsorbable suture, the mesh reinforcement group had an onlay of PTFE placed around the hiatus. A radial slit with 3 cm

'keyhole' (to accommodate the esophagus) was cut into the PTFE. The prosthetic was stapled to the diaphragm, and the two leaves of the slit were stapled to each other. All patients underwent EGD at 3 months and all had esophagrams every 6 months postoperatively. Follow-up ranged from 12 to 36 months. **Results:** Length of hospital stay was equal in both groups (2 days). The average cost to the patient with PTFE was USD 1,050 higher than to the patient with primary repair. There were 2 complications (1 pneumonia, 1 urinary retention) in the PTFE group, and 1 complication (pneumothorax) in the primary repair group. There were 3 recurrences (18.8%) in the primary group (p = 0.08,  $\chi^2$  test). **Conclusion:** The use of PTFE reinforcement for primary repair of large hiatal hernias may result in a lower rate of recurrent herniation compared to primary repair alone.

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## Introduction

The results of laparoscopic antireflux surgery performed by experienced surgeons appear to be equivalent to that of open surgery, i.e. a success rate in the range of 90% [1, 2]. Failure of an antireflux procedure can commonly be attributed to: disruption of the wrap; construction of a wrap which is too tight or misplaced, or recurrent hiatal herniation [3]. The incidence of this last sequela

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ranges from 0 to 10% in series of primary antireflux procedures (both open and laparoscopic), but generally is about 1% [4–11]. Recurrent hiatal herniation was the operative indication in up to 70% of reoperations in series of failed antireflux procedures [3, 12–15].

An enlarged hiatus traditionally is closed with interrupted large gauge sutures (primary closure; simple cruroplasty) [3]. However, any closure method is prone to disruption since the diaphragm is under repetitive stress. Closure of large fascial defects elsewhere in the body (e.g. inguinal or ventral hernia) under similar stress has been performed using prosthetic patches with salutary results [16]. We were interested in applying the use of prosthetic to the hernia of the esophageal hiatus; the first several cases have been published elsewhere [17]. We have since undertaken a randomized control trial comparing laparoscopic primary repair of the large hiatal defect versus repair buttressed with polytetrafluoroethylene (PTFE), and report the results here.

## Patients and Methods

This study was approved by our institutional review process. Patients under consideration for laparoscopic Nissen fundoplication for gastroesophageal reflux disease underwent preoperative evaluation which included a barium esophagram and an esophagogastroduodenoscopy (EGD). If a hiatal hernia was detected, the patient was advised of the study; informed consent was obtained from those wishing to participate. All procedures were done at one hospital with the same senior surgeon in attendance. Final enrollment required a hiatal defect of 8 cm or greater, measured intraoperatively.

The technique of laparoscopic Nissen fundoplication with prosthetic-reinforced hiatal hernia repair follows a previous description [17]. Cefazolin (2 g i.v.) is given with induction of anesthesia. Pneumoperitoneum is established with an Optiview trocar (Ethicon EndoSurgery). Abdominal contents which have herniated into the mediastinum are reduced with gentle traction. The hernia sac is entered anteriorly and sharply dissected out of the mediastinum; the sac ultimately is excised. The crura are dissected posterior to the esophagus. The hiatal defect is measured using a laparoscopic hernia patch spreader (discontinued, Cabot Medical), and the patient is randomized.

Short gastric vessels are divided with a harmonic scalpel (Ethicon EndoSurgery). Preserving the vagi, the distal esophagus is mobilized so that at least 5 cm is intra-abdominal without tension. A posterior cruroplasty is performed around a 50-french esophageal bougie with nonpledged interrupted sutures of 2-0 polyester. An oval sheet of fenestrated PTFE (15 × 10 cm, 1 mm thickness; MycroMesh, W.L. Gore and Associates) with a 3-cm defect cut in the center along with a radial slot ('keyhole') is placed over the repair as an onlay; the esophagus passes through the cut defect. The PTFE is fixed to the diaphragm and crura with a hernia stapler; staples are placed at the mesh periphery and around edges of the defect cut for the esophagus. The leaves on either side of the radial slot are stapled to each other.

A floppy 3-stitch Nissen fundoplication is then performed. The cephalad stitch incorporates a bite of the prosthetic, anchoring the fundoplication (the origin of said maneuver is based in clinical practice).

Patients were seen postoperatively in clinic at 1 and 2 weeks, 1 and 3 months, and then every 6 months. An EGD was performed at 3 months and an esophagram was done every 6 months routinely, and as needed if symptoms developed. Data were compared with the unpaired t test and the  $\chi^2$  test, and the level of significance was set at  $p = 0.05$ .

## Results

Thirty-five patients (mean age 54, range 36–68 years) with a defect of 8 cm or greater were randomized to repair with or without PTFE. Fifteen patients had hiatal reconstruction with PTFE onlay, and 16 patients had reconstruction with cruroplasty only. There were no emergency procedures. Operative time was longer in the PTFE group compared to the cruroplasty-only group ( $3.2 \pm 0.3$  vs.  $2.5 \pm 0.2$  h, respectively;  $p < 0.05$ ). The cost of the procedure in the PTFE group was USD 1,050  $\pm$  135 more than in the cruroplasty-only group ( $p < 0.05$ ), which reflects the cost of the prosthetic and the increased operating room time.

Hospitalization time was equivalent (= 2 days) between the 2 groups. There were 2 complications (1 pneumonia, 1 urinary retention) in the PTFE group (13%) and 1 complication (pneumothorax) in the cruroplasty-only group (6%). Follow-up ranged from 12 to 36 months. There were 3 recurrences (19%) in the cruroplasty-only group and none in the PTFE group ( $p = 0.08$ ), all recognized in the first 6 months. Two of the patients with recurrence underwent reoperation (both were symptomatic); one was done laparoscopically with PTFE and the other was done open. The posterior cruroplasty was disrupted in both reoperative cases, with herniation of the fundoplication into the mediastinum.

## Discussion

Thirty-one patients with gastroesophageal reflux disease and an esophageal hiatus of 8 cm or greater were treated in a randomized fashion with laparoscopic Nissen fundoplication and posterior cruroplasty with or without PTFE onlay. The operation required about 45 min and USD 1,000 more in the PTFE group. There were no prosthetic-related complications. The recurrent hernia rate tended to be higher in the group without PTFE, but this did not reach significance.

The choice of defect size, prosthetic, and technique used in this study was based on practice habits and available data. A minimum diameter of 8 cm was the requirement for prosthetic because we considered an 8 cm defect 'large', in that closure would result in excessive tension. Incidentally, this requirement eliminated most of the patients referred to us with reflux disease/hiatal hernia for consideration of mesh placement. PTFE was chosen as the prosthetic because there is no evidence that PTFE erodes into neighboring hollow viscera like other prosthetics (e.g., polypropylene mesh) [18, 19]. PTFE is also the prosthetic of choice for repair of congenital diaphragmatic hernia (if primary closure is undesirable) [20].

Our technique of hiatal herniorrhaphy with PTFE involves primary closure of the crura followed by prosthetic onlay. The mesh in this situation functions as a buttress, protecting the cruroplasty sutures from the intra-abdominal forces. Some authors who have described laparoscopic hiatus hernia repair with prosthetic have utilized a 'tension free' repair, in which the defect is left open and the prosthetic bridges the gap [21–24]. Another group reporting a laparoscopic tension-free technique cut a relaxing incision in the diaphragm to the right of the hiatus [25]. Cruroplasty is then performed, and the defect created by the relaxing incision is patched with polypropylene. The theoretical advantages and disadvantages of the above procedures may be argued, but we have no hard evidence to demonstrate the superiority of our or someone else's technique. We employed the onlay technique secondary to our previous clinical experience; we have used polypropylene onlay in the open repair of large paraesophageal hernia in 44 patients from the prelaparoscopic era [26]. There were no recurrences in that series.

A difficult question to answer is whether prosthetic material is needed in the repair of any hiatal hernia; there is evidence suggesting that a prosthetic is not needed and may be harmful. Some authors do not have a problem with recurrence after simple cruroplasty [3, 9, 27]. Previously there has been negative experience with a silastic prosthesis (Angelchik) used at the hiatus for treatment of reflux disease [28]. There have also been cases of mesh erosion into the esophagus after paraesophageal hernia repair with prosthetic (not PTFE) [26, 29, 30]. So why consider prosthetic?

Our experience with primary hiatal hernia repairs, like many other authors' (see Introduction), has not been recurrence free. We noted in the literature the improvement in the results of incisional and inguinal hernia repair as prosthetic utilization became more common, and we also were cognizant of our own success with open hiatal

hernia repairs reinforced with polypropylene mesh (see above). The extension of prosthetic use to include the large hernia of the esophageal hiatus seemed logical, and the accumulated experience with PTFE indicated that it may be safer to use in this location than polypropylene. It may be argued that placement of prosthetic at the hiatus of every large defect would not be necessary in at least 90% of patients, given what is known about primary recurrence. A similar statement could be made regarding inguinal hernia; however, this fact has not prevented the current widespread usage of prosthetic in inguinal herniorrhaphy. Surgical practice would seem to indicate that a recurrence rate in the range of 5–10% is justification for trying an intervention such as prosthetic to improve results.

We undertook this study to determine if prosthetic use at the hiatus is justified; there are not any previous comparative studies. We acknowledge that this study does not have the statistical power to provide an irrefutable statement regarding prosthetic use. The number of patients required to do that would best be accumulated in a multi-institutional trial, so that enrollment may be completed in reasonable time. The present study should provide impetus for such a trial.

Laparoscopic herniorrhaphy with PTFE onlay reinforcement for large (8 cm or greater) hernias of the esophageal hiatus is feasible and safe. There have been no mesh-related complications or sequelae in our follow-up period. The recurrence rate is at least as good as simple cruroplasty and may be better. It would be reasonable to consider PTFE onlay reinforcement when confronted with a large hiatal hernia.

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