

# Ελάχιστα επεμβατική θολοπλαστική κατά Nissen με πλαστική διαφραγματοκήλης

## Minimally invasive Nissen fundoplication with hernia repair

*Constantine T. Frantzides, Mark A. Carlson*

**Background:** Open Nissen fundoplication has been shown to be an effective treatment for gastroesophageal reflux disease. Short term results with minimally invasive Nissen fundoplication have been promising. The presence of hiatal hernia in the patient with reflux is an indication for herniorrhaphy at the time of fundoplication. Unfortunately, hiatal hernia repair generally is predisposed to disruption, which can reduce the effectiveness of the fundoplication. We have reviewed our

results with the laparoscopic Nissen operation over a 6 year period, and also present a preliminary trial examining the use of prosthetic in hiatal herniorrhaphy during laparoscopic Nissen fundoplication. **Methods:** A review of the medical records of 362 patients undergoing laparoscopic Nissen fundoplication during the period 1991-1997 was performed. All patients were symptomatic and had objective evidence of reflux disease. Follow up after fundoplication ranged from 6 months to 6 years, and included endoscopy and/or esophagography in all patients. In a prospective trial conducted within this patient population, 31 patients with a hiatal defect of 8 cm or greater were randomized to Nissen fundoplication with posterior cruroplasty (N=16) or Nissen, cruroplasty, and onlay of polytetrafluoroethylene mesh (N=15). Follow up in this group was 12-36 months. **Results:** None of the patients had severe esophageal

*Division of Surgery, University of Chicago Hospital,  
Chicago IL, USA*

*Ανάρτυρα: C.T.Frantzides, MD, PhD, FACS,  
Professor and Chairman, Division of Surgery,  
Director, Minimally Invasive Surgery Center,  
University of Chicago Hospitals, Louis A. Weiss  
Memorial Hospital, 4646 North Marine Drive,  
Chicago, IL 60640, USA. Phone 001-773-5645926,  
Fax: 001-773-5645991*

shortening. There were 359 (99.2%) operations completed with laparoscopic technique. Complications included 3 gastric perforations, 2 pneumothoraces, 1 pneumonia, 1 postoperative bleed, and 1 abdominal wall hematoma. A good to excellent result was obtained in 344 (95.0%) patients; 13 (3.6%) had postoperative symptoms beyond 2 months. The procedure failed in 5 (1.4%) patients. In the polytetrafluoroethylene trial, there were 3 hernia recurrences (18.8%) in the primary repair group and none in the prosthetic group ( $p=0.08$ , chi squared test). **Conclusions:** Minimally invasive Nissen fundoplication has proved to be an effective and durable treatment for gastroesophageal reflux disease. The use of prosthetic reinforcement of primary repair of large hiatal hernia may result in a lower rate of recurrent herniation compared to primary repair alone.

**Key words:** Minimally invasive surgery, laparoscopy, Nissen, fundoplication, prosthetic, polytetrafluoroethylene, PTFE, hiatal hernia, recurrence, recurrent hernia.

## INTRODUCTION

Gastroesophageal reflux disease (GERD) affects approximately 40 million people in the United States<sup>1</sup>. The indications for an antireflux procedure for GERD during the era of open surgery were limited chiefly to complications of the disease, such as stricture, aspiration, or other failure of medical treatment<sup>2</sup>. It seems that with the advent of minimally invasive surgery more patients are being referred earlier for surgical intervention<sup>3,4</sup>. The early results of laparoscopic antireflux surgery, especially Nissen fundoplication, appear to be equivalent to that of open surgery, with a success rate in the range of 90%<sup>5-7</sup>. Studies with intermediate follow up are beginning to accrue, and confirm the early results<sup>8,9</sup>.

Failure of an antireflux procedure commonly can be attributed to: disruption of the wrap, construction of a wrap which is too tight or

misplaced, or recurrent hiatal herniation<sup>10</sup>. The incidence of this last sequelae ranges from zero to 10% in series of primary antireflux procedures (both open and laparoscopic), but generally is about 1%<sup>11,18</sup>. Recurrent hiatal herniation was the operative indication in up to 70% of reoperations in series of failed antireflux procedures<sup>10,19-22</sup>. An enlarged hiatus traditionally is closed with interrupted large gauge sutures (primary closure; simple cruroplasty)<sup>10</sup>. Any primary closure method, however, is prone to disruption since diaphragm is under repetitive stress. In an attempt to address this problem, we previously have reported the use of prosthetic reinforcement of hiatal herniorrhaphy during laparoscopic Nissen fundoplication<sup>23</sup>.

We were interested in reviewing the results of our minimally invasive Nissen fundoplications to determine the efficacy at intermediate follow up. We also during this time period performed a prospective randomized trial of prosthetic reinforcement of hiatal hernia repair in patients with a large hiatal defect. Herein we report the results.

## METHODS

### Patients

Three hundred sixty-two consecutive patients (173 men, 189 women, mean age: 48 yrs, range 11-78) with symptomatic reflux were scheduled for laparoscopic Nissen fundoplication. Preoperative evaluation in all patients included esophagogastroduodenoscopy (EGD) and esophagography. Individuals without evidence of esophagitis underwent 24-hour ambulatory pH monitoring to determine if acid reflux was the cause of their symptoms. Patients with evidence of dysmotility on esophagogram or who reported symptoms of dysphagia or odynophagia underwent manometry ( $n=58$ ). There were 128 (35.3%) patients with associated hiatal hernia and 114 patients (31.5%) had a previous abdominal operation. Additional procedures (cholecystectomy, adhesiolysis, inguinal herniorrhaphy, liver biopsy, gastrostomy, or lymph node biopsy) were performed

at the time of fundoplication in 41 (11.3%) patients.

### Minimally invasive Nissen fundoplication

All operations were performed with the same surgeon (CTF) in attendance. We have described our surgical technique previously<sup>24</sup>; an updated description is given here. The patient is placed in a modified lithotomy position. The abdomen is entered with an Optiview trocar (Ethicon Endosurgery; Cincinnati, OH), a 15 mm Hg CO<sub>2</sub> pneumoperitoneum is established, and a total of five 10-11 mm trocars are placed (left subcostal mid-clavicular line, left subcostal anterior axillary line, right upper quadrant, supraumbilical, and subxiphoid). The laparoscope is introduced through the supraumbilical port, and the left lobe of the liver is retracted with an inflatable balloon retractor (Soft Wand Retractor, Circon; Santa Barbara, CA) placed through the subxiphoid port.

A Babcock forceps with atraumatic inserts (Pilling Wck, Inc.; Research Triangle Park, NC) is used through the left lateral port to retract the stomach inferolaterally, and the gastrohepatic ligament is incised anterior to the caudate lobe of the liver up to the esophageal hiatus. The phrenoesophageal ligament is divided, exposing the anterior esophagus. Identification of the esophagus is facilitated by an intraesophageal lighted bougie (Bioentrics Corp.; Carpinteria, CA). The esophagus is mobilized with a palpation probe, and the right crus and posterior vagus (left attached to the esophagus) are identified.

The stomach is retracted medially with an atraumatic Babcock forceps, and the short gastric vessels are taken with a Harmonic scalpel (Ultracision Ethicon Endosurgery; Cincinnati, OH). Visualization of the splenic pole during this step is facilitated with a 30° laparoscope. A window posterior to the esophagus is created and, in patients with hiatal hernia (and in most other cases), a posterior cruroplasty with interrupted 2-0 polyester sutures is performed over a 50 Fr intraesophageal bougie.

The fundus is brought posterior to the esophagus with a Babcock forceps, and a 2 cm, 360° fundoplication is created loosely around the 50 Fr bougie with 3 interrupted 2-0 polyester sutures, sewing fundus to fundus. The anterior arch of the crus is incorporated in the upper stitch to prevent slippage of the wrap. The port defects are closed with a fascial closer (Carter-Thomason; Eden Prairie, MN).

### Postoperative care

Postoperative pain was managed with acetaminophen/oxycodone or ketorolac. Postoperatively, patients were instructed to chew their food well, to avoid red meat for 1 week, to eat small meals for the first few weeks, and to avoid carbonated beverages, alcohol, citrus juices, spicy foods, and gas-producing foods (e.g., beans, peas, broccoli, and onions) for 2 months. Postoperative evaluation included esophagography and EGD at 2-3 months with an esophagogram yearly thereafter. Patients with Barrett's esophagus underwent yearly EGD with biopsy.

### Trial of prosthetic use in hiatal hernia repair

This study was approved by our institutional review process. A patient with a hiatal hernia detected preoperatively was advised of the study, and informed consent was obtained. Final enrollment required a hiatal defect 8 cm or greater, measured intraoperatively with a hernia patch spreader (discontinued, Cabot Medical). The technique of laparoscopic Nissen fundoplication with prosthetic-reinforced hiatal hernia repair follows the above description, but including the following. Cefazolin (2 g IV) is given with induction of anesthesia, and pneumoperitoneum is established. 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, and the patient is randomized.

After the posterior cruroplasty is performed, an oval sheet of fenestrated polytetrafluoroethylene (PTFE MycroMesh; 15x10 cm, 1 mm thickness; W.L.Gore and Associates; Flagstaff, AZ) with a 3 cm defect cut in the center along with a radial slot ("keyhole") is placed over the repair as an onlay<sup>23</sup>. The esophagus passes through the "keyhole". 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. The fundoplication is then performed. The cephalad stitch incorporates a bite of the prosthetic, anchoring the fundoplication.

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 was compared with the unpaired t-test and the chi-squared test, and the level of significance was set at  $p=0.05$ .

## RESULTS

### Minimally invasive Nissen fundoplication

There were 3 conversions to an open procedure (0.8%), all of which were secondary to gastric perforation (these occurred prior to the availability of the atraumatic Babcock forceps described in the Methods section). Operative time decreased from  $2.7\pm 0.4$  hr during the period 1991-1994 to  $1.8\pm 0.3$  hr during 1994-1997, and hospitalization time decreased from 2.2 to 1.5 days within the same time frame. There were 8 major complications (2.2%), including the 3 aforementioned gastric perforations, 2 pneumothoraces, 1 pneumonia, 1 postoperative bleed, and 1 trocar site hematoma (the latter 5 complications were managed nonoperatively). Early postoperative gastrointestinal symptoms are summarized in Table 1. The vast majority of these problems were resolved after 2 months; symptoms that persisted beyond this time are summarized in Table 2. Lower esophageal sphincter pressures were  $4.0\pm 1.2$  mm

( $n=58$ ) and  $14.6\pm 1.8$  ( $n=39$ ) mm Hg, pre- and postoperative respectively. Fifty-one patients had Barrett's esophagus at the time of operation. One of these patients progressed to severe dysplasia postoperatively (asymptomatic), and was treated with ablative photodynamic therapy.

**Table 1.** The frequency of postoperative symptoms occurring within 2 months after minimally invasive Nissen fundoplication.

Symptom	n	%
Early satiety	263	72.6
Bloating/flatulence	147	40.6
Dysphagia	75	20.7
Constipation	28	7.7
Diarrhea	15	4.1
Odynophagia	13	3.5
Nausea	7	1.9
Dry heaves	6	1.6

**Table 2.** The frequency of postoperative symptoms which persisted for more than 2 months after minimally invasive Nissen fundoplication.

Symptom	n	%
Bloating/flatulence	8	2.2
Dysphagia	2	0.5
Diarrhea	3	0.8

A good to excellent outcome (minimal to nil persistent postoperative symptoms) was obtained in 345 patients (95.3%) during the follow up period, which ranged from 6 months to 6 years. One patient with persistent dysphagia (Table 2) had a cruroplasty that was too tight; evaluation in the other dysphagic patient did not reveal a cause. Evaluation of the patients with diarrhea also revealed no cause; one of these individuals had preoperative diarrhea that became worse after operation. Twelve of the 13 patients described in Table 2 were categorized as having a fair outcome (3.3%); the patient with the over-tight cruroplasty had dysphagia severe enough to be classified as a having a poor outcome (treatment failure). There

were 5 treatment failures (1.4%): 3 in patients with large hiatal hernia defects who disrupted their cruroplasty (see below), 1 secondary to persistent dysphagia as mentioned, and 1 because of a slipped wrap (repaired with laparoscopic reconstruction).

### Trial of prosthetic use in hiatal hernia repair

Thirty-five patients (mean age 54, range 36-68) with a defect 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±0.3 hours vs 2.5±0.2 hours, respectively;  $p<0.05$ ). The cost of the procedure in the PTFE group was US\$ 1050±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 two 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

The results of laparoscopic Nissen fundoplication in 362 consecutive patients were reviewed. There was no mortality and few (2.2%) major complications. Operative time averaged a little over 2 hr. A good to excellent result was obtained in 95.3% of patients. Postoperative symptoms were common, but resolved in the vast majority of

patients by 2 months (3.6% had persistent symptoms). A fair to poor result was obtained in 4.7% of patients, including 3 disrupted cruroplasties, 1 slipped wrap, and 1 constrictive wrap. Follow up was up to 6 years.

We would like to attribute the 95% success rate in this series in part to proper patient selection. The importance of a correct preoperative diagnosis of GERD in the outcome of an antireflux procedure cannot be overemphasized. The details of an adequate work up for GERD have been well described<sup>25,26</sup>, and will not be repeated here. Interestingly, we did not see a patient with esophageal shortening that required an esophageal lengthening procedure. We believe that this observation is secondary to a trend, alluded to in the Introduction, for early referral of GERD patients for minimally invasive intervention prior to development of the classic GERD complications.

We believe that proper surgical technique also is responsible for the success rate in this series<sup>27-29</sup>. Specifically, the stomach and lower esophageal segment must be mobilized out of the chest so that the completed wrap will lie intraabdominally with minimal to no tension. Complete mobilization of the gastric fundus (that is, take down of the short gastric vessels) allows the construction of a floppy wrap, which is thought to prevent reflux while avoiding the sequela of dysphagia. The wrap is kept short, which also aids in the creation of a floppy wrap.

A trial of prosthetic use in hiatal herniorrhaphy was performed in a subset of the 362 patients. Thirty-one patients with GERD and an esophageal hiatus >8 cm were treated with laparoscopic Nissen fundoplication and posterior cruroplasty with or without PTFE onlay. The operation required about 45 min and \$ 1000 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 minimum defect size, prosthetic, and technique used in this "subset" trial were based on practice habits and available data. A

minimum diameter of 8 cm was the requirement for prosthetic usage because we considered an 8 cm defect "large", in that closure would result in excessive tension. Incidentally, this requirement eliminated most of 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) are able<sup>30,31</sup>. PTFE is also the prosthetic of choice for repair of congenital diaphragmatic hernia (if primary closure is undesirable)<sup>32</sup>.

Our technique of hiatal herniorrhaphy with PTFE involves primary closure of the crura followed by prosthetic only<sup>23</sup>. The mesh in this situation functions as a buttress, protecting the cruroplasty sutures from the intraabdominal 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<sup>33-36</sup>. Another group reporting a laparoscopic tension-free technique cut a relaxing incision in the diaphragm to the right of the hiatus<sup>37</sup>. A cruroplasty then is 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 pre-laparoscopic era<sup>38</sup>. 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 prosthetic is not needed and may be harmful. Some authors do not have a problem with recurrence after simple cruroplasty<sup>10,16,39</sup>. Previously there has been a negative experience with a silastic prosthesis (Angelchik) used at the hiatus for treatment of reflux disease<sup>40</sup>. There also have been cases of mesh

erosion into the esophagus after paraesophageal hernia repair with prosthetic (non PTFE)<sup>38,41,42</sup>. So why consider prosthetic?

Our experience with primary hiatal hernia repairs, like many other authors' (see Introduction), has not been recurrence free. We have noted the improvement in the published results of incisional and inguinal hernia repair as prosthetic utilization has become 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 trial to determine if prosthetic use as the hiatus is justified; there are not any previous comparative studies. We acknowledge that this trial 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 could be completed in reasonable time. Our preliminary trial might provide the impetus for such a larger study.

The intermediate results of minimally invasive Nissen fundoplication in this review of 362 patients confirm the early results, in that the procedure is effective treatment for GERD in over 90% of referred patients. In addition, laparoscopic herniorrhaphy with PTFE onlay reinforcement for the large (8 cm or greater) defect of the esophageal hiatus is feasible and safe. 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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