



and Other Interventional Techniques

## Prosthetic closure of the esophageal hiatus in large hiatal hernia repair and laparoscopic antireflux surgery

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Received: 28 June 2005/Accepted: 26 October 2005/Online publication: 19 January 2006

### Abstract

**Background:** Laparoscopy has become the standard surgical approach to both surgery for gastroesophageal reflux disease and large/paraesophageal hiatal hernia repair with excellent long-term results and high patient satisfaction. However, several studies have shown that laparoscopic hiatal hernia repair is associated with high recurrence rates. Therefore, some authors recommend the use of prosthetic meshes for either laparoscopic large hiatal hernia repair or laparoscopic antireflux surgery. The aim of this article was to review available studies regarding the evolution, different techniques, results, and future perspectives concerning the use of prosthetic materials for closure of the esophageal hiatus.

**Methods:** A search of electronic databases, including Medline and Embase, was performed to identify available articles regarding prosthetic hiatal closure for large hiatal or paraesophageal hernia repair and/or laparoscopic antireflux surgery. Techniques and results as well as recurrence rates and complications related to the use of prosthetics for hiatal closure were reviewed and compared. Additionally, recent experiences and recommendations of experienced experts in this field were collected.

**Results:** The results of 42 studies were analyzed in this review. Some techniques of mesh hiatal closure were evaluated; however, most authors prefer posterior mesh cruroplasty. The type and shape of hiatal meshes vary from small angular meshes to A-shaped, V-shaped, or complete circular meshes. The most frequently utilized materials are polypropylene, polytetrafluoroethylene, or dual meshes. All studies show a low rate of postoperative hernia recurrence, with no mortality and

low morbidity. In particular, comparative studies including two prospective randomized trials comparing simple sutured hiatal closure to prosthetic hiatal closure show a significantly lower rate of postoperative hiatal hernia recurrence and/or intrathoracic wrap migration in patients who underwent prosthetic hiatal closure.

**Conclusions:** Laparoscopic large hiatal/paraesophageal hernia repair with prosthetic meshes as well as laparoscopic antireflux surgery with prosthetic hiatal closure are safe and effective procedures to prevent hiatal hernia recurrence and/or postoperative intrathoracic wrap migration, with low complication rates. The type of mesh, particularly the size and shape, is still controversial and is a matter for future research in this field.

**Key words:** Laparoscopic paraesophageal hernia repair — Laparoscopic antireflux surgery — Prosthetic — Hiatal closure — Mesh — Hiatal hernia recurrence — Intrathoracic wrap migration

Paraesophageal hernia is a rare condition associated with a high incidence of complications. Therefore, most authors recommend surgical management of paraesophageal hernia, even in patients without symptoms. The minimally invasive approach to paraesophageal hernia repair has become the standard of care for surgical management of this problem. Athanasakis et al. [3] have shown that laparoscopic paraesophageal hernia repair is associated with a lower incidence of morbidity, a shorter hospital stay, and a shorter recovery period compared to open repair. Additionally, most authors agree that the laparoscopic approach allows better visibility and higher dissection of the intrathoracic esophagus. However, whether performed open or

laparoscopically, paraesophageal hernia repair is associated with a high recurrence rate. Hashemi et al. [25] have shown that the laparoscopic approach in particular has a higher recurrence rate than the open approach, with recurrence rates for the former up to 42%. Due to this high recurrence rate, several technical details have been considered to minimize the rate of recurrent hiatal herniation. Some operative details are still a matter of controversy; for example, the complete removal of the hernia sac, the need to perform an antireflux procedure, or the performance of a gastropexy are frequent topics of discussion [35, 45]. However, one of the main questions is whether to perform the hiatoplasty with simple interrupted sutures or with prosthetic material.

During the past few years, hiatal closure has also become a central point in laparoscopic antireflux surgery for gastroesophageal reflux disease (GERD) [30]. The causes of failure of an antireflux procedure are multiple, but the most frequent cause has proven to be the recurrent hiatal hernia with consecutive intrathoracic herniation of the fundic wrap into the mediastinum [51]. Typical symptoms of an intrathoracic wrap herniation are persistent or recurrent reflux, dysphagia, or both. The combination of these symptoms and this anatomic complication leads to reoperation in most patients [22]. In a large review of more than 10,000 laparoscopic antireflux procedures, it was documented that postoperative intrathoracic wrap herniation was the most common intraoperative finding during redo-surgery for the failed antireflux procedure [8].

Some possible patient-related and procedure-related mechanisms for postoperative intrathoracic wrap migration include inappropriate postoperative activities of the patients immediately after surgery, inadequate mobilization of the esophagus, inadequate crural closure secondary to widely spaced crura sutured under tension, or a postoperative rupture of the cruroplasty due to continuous excursion of the diaphragm.

Crural closure has become a relevant problem in laparoscopic antireflux surgery as well as during laparoscopic paraesophageal hernia repair. To solve this problem, some authors have advocated the use of prosthetic material for crural closure in both laparoscopic paraesophageal hernia repair and laparoscopic antireflux surgery. The concept of using prosthetic meshes is based on the lessening of tension on the hiatal crura or the reinforcement of simple sutured crura to prevent postoperative hiatal disruption. Since the first description of prosthetic hiatal closure by Kuster and Gilroy in 1993 [35], a number of techniques have been published. There has been debate regarding the shape of the mesh, the material of the mesh, the placement of the mesh, and especially whether a prosthetic hiatal reinforcement has to be tension free. Additionally, there is no agreement regarding the question of selective versus routine use of mesh. Some authors recommend the routine use of prosthetic mesh in order to prevent tension on the hiatal crura and therefore decrease hiatal hernia recurrence. Other authors use mesh selectively—for example, in patients in whom a sufficient tension-free hiatal closure cannot be achieved with simple sutures. For some authors, the indication for

reinforcement of the hiatal crura with prosthetic material depends on the size of the hiatal defect.

Another point of controversy focuses on the shape and material of the prosthetic mesh. Some authors routinely use polypropylene meshes for hiatal closure, believing that polypropylene rapidly incorporates and that the developing scar tissue strengthens the muscular fibers of the hiatal crura. Other authors discourage the use of polypropylene due to the development of visceral adhesions and the risk of intestinal fistula [47]. On the other hand, polytetrafluoroethylene (PTFE) has been recommended for hiatal closure because of its low adhesive potential.

### Technique and results of prosthetic hiatal closure

Several techniques have been described for prosthetic closure of the hiatal crura. Basically, two different approaches have to be differentiated: mesh repair without primary sutured crura (“tension free”) or mesh repair with primary cruroplasty (Table 1).

Kuster and Gilroy [35] preferred tension-free anterior repair of the hiatal defect. In six patients with large paraesophageal hernia, the hiatal crura could not be sutured anterior to the esophagus without significant tension. Therefore, a nonabsorbable polyester fiber mesh (Mersilene, Ethicon, Somerville, NJ, USA) was placed on the hiatus as an anterior onlay patch, overlapping the hiatal crura approximately 2 cm in all directions. The mesh was secured to the crural edges with staples. No intraoperative or postoperative mesh-related complications occurred during a follow-up period of 8–22 months. Postoperative gastrointestinal series showed no evidence of postoperative hernia recurrence; however, two patients had slippage of a small part of the posterior segment of the fundus. None of these patients developed postoperative mesh-related dysphagia or GERD symptoms during the follow-up period.

A similar technique has been used by Paul et al. [44] in three elderly patients. A 5 × 10 cm PTFE mesh (Gore-Tex, W. L. Gore, Flagstaff, AZ, USA) was cut to cover the hiatal defect and then was placed as an anterior onlay patch. The mesh was secured at the lower mesh edges and then sutured in a running fashion up to the top of the mesh. In this small series, there were no complications, and for a mean follow-up period of 10 months there were no hernia recurrences.

An interesting technique to achieve a tension-free hiatal closure has been described by Huntington [31]. If a tension-free crural closure with simple sutures was not possible, then a relaxing incision on the diaphragm was performed to gain crural mobility for a simple sutured hiatoplasty. The diaphragmatic defect of the relaxing incision was then closed with a polypropylene patch. This technique was used successfully in eight patients with paraesophageal hernia; there was no recurrence during a follow-up period of 8 months.

Casaccia et al. [11] published their experience with an innovative physiological composite “A”-shaped mesh. The authors first performed a physical and geometrical analysis of the esophageal hiatus with a theoretical

**Table 1.** Results of laparoscopic hiatal hernia repair with mesh prosthesis

| Reference                   | Year | Patients ( <i>n</i> ) |         | Mesh material                            | Repair               | Follow-up (months) | Recurrence rate |           |
|-----------------------------|------|-----------------------|---------|--|----------------------|--------------------|-----------------|-----------|
|                             |      | Mesh                  | Nonmesh |  |                      |                    | Mesh            | Nonmesh   |
| Kuster and Gilroy [35]      | 1993 | 6                     | —       | Polyester                                | LPEHR                | 8–22               | 0               | —         |
| Pitcher et al. [46]         | 1995 | 2                     | 10      | PTFE                                     | LPEHR (4), LAR×S (8) | —                  | 0               | 0         |
| Odsdotir et al. [42]        | 1995 | 10                    | —       | n.a.                                     | LARS                 | 8.9                | 0               | —         |
| Edelman [16]                | 1995 | 5                     | —       | Polypropylene                            | LARS                 | —                  | 0               | —         |
| Behrns and Schlinkert [6]   | 1996 | 2                     | 10      | n.a.                                     | LPEHR(5), LARS (7)   | 6                  | 0               | 0         |
| Trus et al. [52]            | 1997 | 1                     | 75      | n.a.                                     | LPEHR(5), LARS(71)   | ≤ 16               | 5 (7%)          | —         |
| Huntington [31]             | 1997 | 8                     | —       | Polypropylene                            | —                    | 8                  | 0               | —         |
| Paul et al. [44]            | 1997 | 3                     | —       | PTFE                                     | LPEHR (2), LARS (1)  | 10                 | 0               | —         |
| Willekes et al. [57]        | 1997 | 30                    | —       | PTFE                                     | LARS                 | —                  | 0               | —         |
| Frantzides and Carlson [17] | 1997 | 3                     | —       | PTFE                                     | LARS                 | ≤ 11               | 0               | —         |
| Medina et al. [39]          | 1998 | 2                     | 18      | Polypropylene                            | LPEHR (6), LARS (14) | 6–48               | 0               | 0         |
| Hawasli and Zonca [26]      | 1998 | 27                    | —       | Polypropylene                            | LARS                 | 1–56               | 0               | —         |
| Carlson et al. [7]          | 1998 | 44                    | —       | Polypropylene                            | PEHR                 | 52                 | 0               | —         |
| Simpson et al. [50]         | 1998 | 38                    | —       | Polyester                                | LARS                 | 15                 | 0               | —         |
| Schulz [49]                 | 1998 | 161                   | 157     | Polypropylene                            | LARS                 | —                  | 2 (1.2%)        | 12 (7.1%) |
| Horgan et al. [28]          | 1999 | 5                     | 36      | n.a.                                     | LARS                 | —                  | 0               | —         |
| Wu et al. [58](48)          | 1999 | 6                     | —       | Polypropylene                            | LARS                 | —                  | —               | —         |
| Carlson et al. [9]          | 1999 | 15                    | 16      | PTFE                                     | LARS                 | 12–36              | 0               | 3 (18.8%) |
| Frantzides et al. [20]      | 1999 | 17                    | 18      | PTFE                                     | LARS                 | 36                 | 0               | 3 (16.6%) |
| Basso et al. [5]            | 2000 | 67                    | 65      | Polypropylene                            | LARS                 | 22.5–48.3          | 0               | 9 (13.8%) |
| Hui et al. [29]             | 2001 | 12                    | 12      | Polypropylene                            | LARS                 | 24–48              | 0               | 0         |
| Lambert and Huddart [36]    | 2001 | 7                     | —       | Polypropylene                            | LARS                 | 12                 | 0               | —         |
| Livingston et al. [38]      | 2001 | 10                    | 22      | PTFE                                     | LARS                 | 1–72               | 0               | 3 (13.6%) |
| Athanasakis et al. [3]      | 2001 | 3                     | 7       | PTFE                                     | LARS                 | 12                 | 0               | 0         |
| Frantzides et al. [19]      | 2002 | 36                    | 36      | PTFE                                     | LARS                 | 6–72               | 0               | 8 (22%)   |
| Meyer et al. [40]           | 2002 | 10                    | —       | PTFE (5), polypropylene (5)              | LARS                 | 8–40               | 0               | —         |
| Kamolz et al. [32]          | 2002 | 100                   | 100     | Polypropylene                            | LARS                 | 12                 | 1 (1%)          | 9 (9%)    |
| Casaccia et al. [11]        | 2002 | 8                     | —       | PTFE                                     | —                    | 8                  | 0               | —         |
| Granderath et al. [23]      | 2002 | 170                   | 361     | Polypropylene                            | LARS                 | 12                 | 1 (0.6%)        | 22 (6.1%) |
| Morales et al. [41]         | 2002 | 9                     | 55      | PTFE                                     | LARS                 | —                  | 1 (1.1%)        | 3 (5.4%)  |
| Champion and Rock [12]      | 2003 | 52                    | —       | Polypropylene                            | LPEHR                | 7–60               | 1 (1.9%)        | —         |
| Leeder et al. [37] (56)     | 2003 | 14                    | 39      | Polypropylene                            | LARS                 | 6–89               | 2 (14%)         | 3 (7.6%)  |
| Diaz et al. [15] (57)       | 2003 | 9                     | 107     | Polypropylene, small intestine submucosa | LARS                 | 30 ± 25            | 2 (33%)         | 19 (21%)  |
| Oelschlager et al. [43]     | 2003 | 9                     | —       | Small intestine submucosa                | LARS                 | 3–16               | 1               | —         |
| Granderath et al. [21]      | 2003 | 24                    | —       | Polypropylene                            | RELARS               | 12                 | 0               | —         |
| Ponsky et al. [48] (58)     | 2003 | 1                     | —       | n.a.                                     | —                    | 21                 | 0               | —         |
| Keidar and Szold [33]       | 2003 | 10                    | 23      | Polypropylene                            | LARS                 | 46–76              | 1 (10%)         | 4 (18%)   |
| Granderath et al. [24]      | 2005 | 50                    | 50      | Polypropylene                            | LARS                 | 12                 | 4 (8%)          | 13 (26%)  |

LARS, laparoscopic antireflux surgery; LPEHR, laparoscopic paraesophageal hernia repair; n.a., not available; PTFE, polytetrafluoroethylene; RELARS, revisional laparoscopic antireflux surgery; PEHR, paraesophageal hernia repair

model. Based on their findings regarding the physiological strengths of the hiatal crura with or without direct sutures, they performed an anatomical study on 20 cadavers to verify the anatomical findings of their theoretical model. As a result, they developed a special A-shaped polypropylene–PTFE mesh (BARD Composix mesh, C. R. Bard, Murray Hill, NJ, USA) that, when positioned over the hiatal defect, was intended to effect closure similar to the physiological condition. In eight patients with large type II and type III hiatal hernia, laparoscopic repair was performed with this composite A-shaped mesh. Intraoperatively, the authors found that the mesh fit well in the hiatal region, with good handling and easy placement on the diaphragm. Post-operative dysphagia occurred in two patients for up to 3 months after surgery, but no recurrence was observed during an average follow-up of 8 months.

Based on the possibility of mesh-related complications such as esophageal stricture, mesh migration, or visceral erosion, Oelschlager et al. [43] advocated the use

of a new type of mesh made from porcine small intestine submucosa (SIS) for laparoscopic repair of paraesophageal hernias. The authors closed the hiatal crura with interrupted 2–0 silk sutures and then positioned a U-shaped 7 × 10 cm four-ply bioabsorbable mesh (Surgis, Cook Biotech, West Lafayette, IN, USA) posteriorly so that the mesh covered the crural repair. The mesh was secured with interrupted silk sutures to the diaphragm. This technique was used in nine patients with large paraesophageal hernias that could not be closed without tension. In eight patients who were available for follow-up, only one had a small (2 cm) recurrent hiatal hernia on barium esophagram; this recurrence was asymptomatic. Another patient had to undergo pneumatic dilatation for persistent mild dysphagia but without signs of anatomic failure on endoscopy or barium swallow. There were no other complications in this series.

Another approach to crural closure with biomaterial has been described by Varga et al. [54]. In this study, the hiatoplasty was performed with the ligamentum teres in

addition to simple sutures. After closing the hiatal crura with nonabsorbable interrupted sutures, the mobilized ligamentum teres was pulled between the closed crura and posterior esophagus and then sutured to the crura. This created a U-shaped hiatal onlay reinforcement. This technique was performed in four patients with type III hiatal hernia. There were no perioperative complications related to this kind of hiatoplasty. One patient had minor episodic epigastric pain postoperatively; otherwise, all patients were relieved of symptoms. No recurrent hiatal hernia occurred during follow-up of 3–11 months.

### Basso's experience

Basso et al. adopted three different approaches to the hiatoplasty. In the first period, the hiatoplasty was performed by means of two or three nonabsorbable stitches. In the second period, they adopted a tension-free hiatoplasty using a 3 × 4 cm polypropylene mesh. Recently, they have been adopting a hiatoplasty either with mesh or with suture and mesh. They have come to this solution because they had a high incidence of recurrence or slipping. When reexamining the videos of the first operation, they determined that the problem was disruption of the right pillar. Apart from surgical technique, the size of the hernia and the structure of the pillars are important anatomical elements for the genesis of failures.

In a published series of 65 patients who underwent laparoscopic Nissen fundoplication with simple sutured hiatal closure [5], the authors experienced a hiatal hernia recurrence rate of 13.8% during a mean follow-up of 48.3 months. After reviewing the videotapes of these patients, it became clear that the crural sutures were under tension, and that hiatal disruption led to postoperative intrathoracic migration of the fundic wrap. Due to these findings, the authors began using a 3 × 4 cm polypropylene mesh for posterior hiatal reinforcement. The mesh was secured with staples on the upper side and on the lateral sides of both crura as a tension-free hiatoplasty. This technique was used in a subsequent group of 67 patients who underwent laparoscopic Nissen fundoplication for GERD. During a mean follow-up of 22.5 months, there were no complications related to the prosthetic mesh nor hiatal hernia recurrence.

### Champion's experience

Champion et al. [12] preferred prosthetic reinforcement of primarily sutured crura. Similar to Basso et al., in one study these authors used a 3 × 5 cm polypropylene mesh for posterior hiatal closure. After placing interrupted permanent sutures posteriorly to the esophagus, the polypropylene mesh was placed as an onlay prosthesis and then fixed with a hernia stapler along the crural edges. The mesh was further secured with a centrally placed permanent mattress suture; this ensured that the upper edge of the mesh was positioned at least 1 cm

below the upper edge of the crural repair. This technique was performed in 52 consecutive patients with symptomatic GERD and a large hiatal/paraesophageal hernia. During a mean postoperative follow-up of 25 months, only one patient developed a postoperative intrathoracic wrap migration; this was caused by violent retching in the recovery room after surgery. Later, this patient underwent revisional surgery due to recurrent GERD symptoms. Importantly, no mesh migrations or visceral erosion occurred in this series of patients. In 1995, after observing and reoperating on a number of recurrences after laparoscopic antireflux surgery, it became apparent that a hiatal hernia was foremost a hernia of the diaphragm and surgeons should apply the same techniques and approaches for closure as they would for defects in other locations, such as the groin and anterior abdominal wall. Simple closure of the crural muscle did not suffice with large defects and prosthetic reinforcement appeared to be beneficial from initial reports in the literature, but the indications were not well-defined. The debate concerned not only whether to use prosthetics but also when to employ them. Between 1995 and 1997, Champion prospectively measured the hiatal diameter in 476 primary laparoscopic antireflux procedures with simple posterior suture closure of the hiatus and demonstrated a recurrence rate of 0.9% if the initial crural diameter was  $\leq 4.5$  cm and a 10.6% recurrence risk if the diameter was  $\geq 5.0$  cm. This difference was highly significant ( $p < 0.000001$ ); therefore, initial hiatal diameter in the anterior–posterior plane as a selective indication for crural reinforcement with a prosthetic material was utilized.

The choice of prosthetic material was a dilemma because Champion had reservations initially about employing mesh near the esophagus and chose to utilize bovine pericardium as a biologic patch. Four different shapes in the form of a “U” shape, a keyhole collar shape, an onlay buttress, and a tension-free repair were tried (Figs. 1–4). A significant postop dysphagia rate was encountered with the U, collar, and tension-free repairs because they all rested against the esophagus posteriorly and left a ridge or “shelf” that was visible on esophagogastrosocopy. At approximately this same time, information became available that bovine pericardium can undergo significant contracture over time, so there was a risk of stenosis of the hiatus due to scarring of the prosthetic material.

Cost of the prosthesis material is another consideration, and bovine pericardium was approximately \$400 and PTFE was \$1,000 at our facility. In addition, these materials are opaque, which obscures visualization and makes accurate fixation more difficult. The authors ultimately settled on polypropylene mesh because it is inexpensive, malleable, and easiest to work with, but it must not be placed in contact with the esophagus. The mesh is positioned and fixed posteriorly at least 1 cm below the crural repair, and the mesh is covered with the 360° posterior fundoplication (Fig. 5). Although Champion et al. have not experienced an erosion of prosthetic material in their series, they acknowledge it is possible, and resection of a portion of the fundus is technically preferable to an esophageal repair.

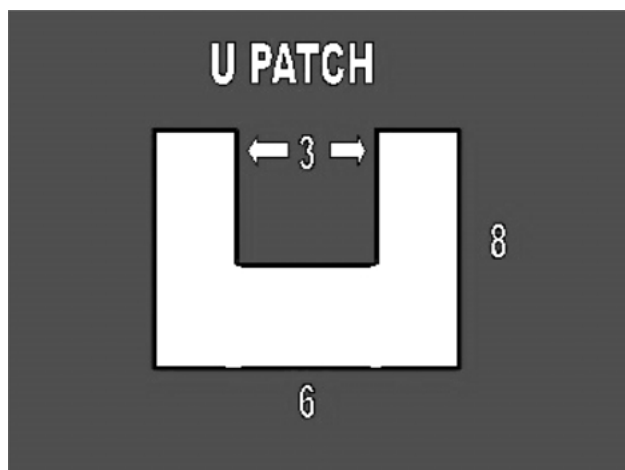


Fig. 1. "U"-shaped mesh.

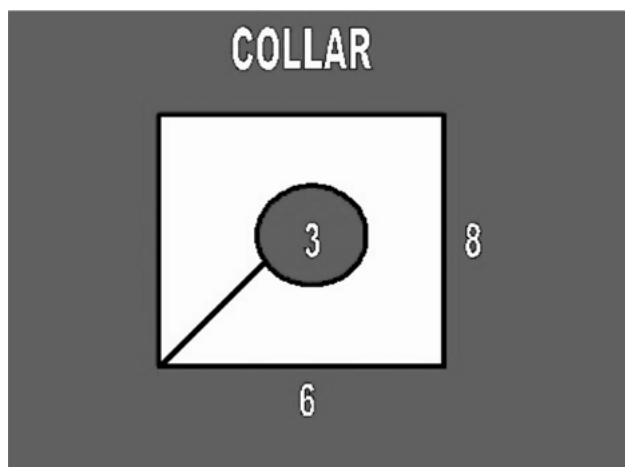


Fig. 2. Keyhole collar shape mesh.

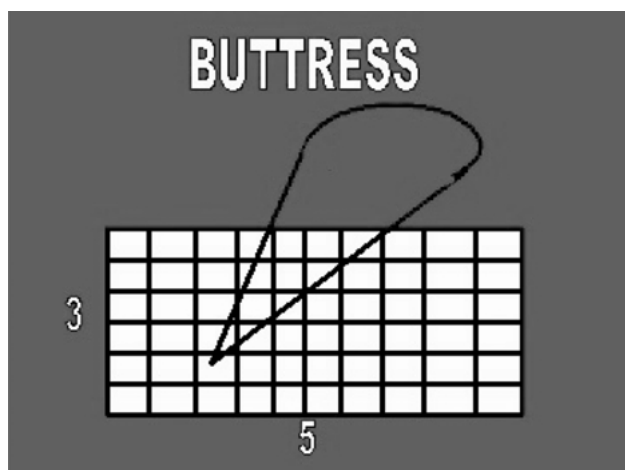


Fig. 3. Onlay buttress.

A 9-year follow-up of 65 patients with polypropylene mesh cruroplasty is available and only one recurrence (1.5%) has been observed. Recently, they have



Fig. 4. Tension-free repair.

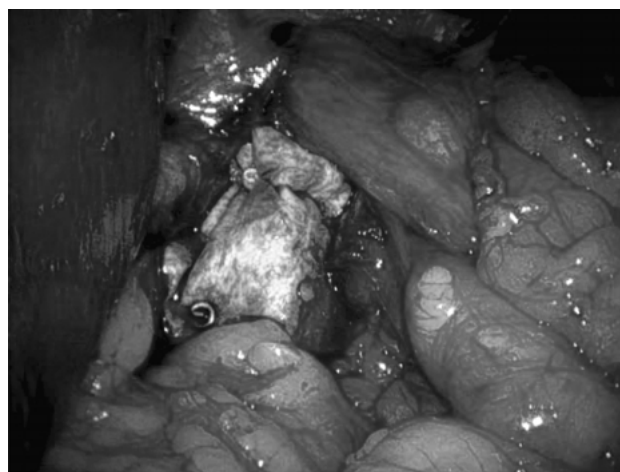


Fig. 5. Surgisis mesh cruroplasty.

begun to explore the use of porcine SIS biologic material while repairing large paraesophageal hernias during laparoscopic Roux-en-Y gastric bypass for morbid obesity and have experienced no recurrences in a small series with short follow-up. A biologic material is preferable in this technique due to the contaminated nature of the gastric bypass, with spillage of bacteria in 22% of procedures, and its risk of infection of a permanent prosthesis.

Champion et al. caution that all recurrences after paraesophageal hernia repair are not due to crural breakdown, and esophageal shortening can contribute to a significant number of recurrences. Therefore, they have employed a "Wedge Collis" gastroplasty in 36% of repairs and believe this contributes to less tension and a lower recurrence rate.

#### Szold's experience

Keidar and Szold [33] used a circular mesh with a similar shape as that used by Frantzides and Carlson [17]. Out of a sample of 33 patients, 10 patients with large para-

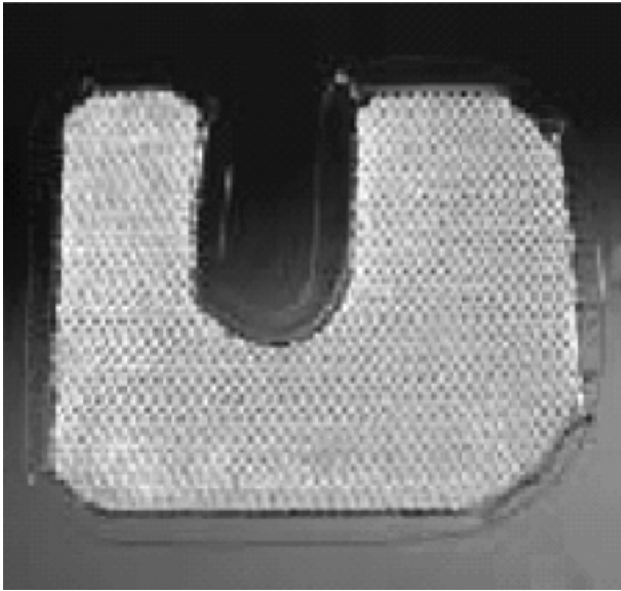


Fig. 6. Composite mesh.



Fig. 7. Anchored mesh cruroplasty.

esophageal hernias underwent laparoscopic prosthetic hiatal repair. The simple cruroplasty was then reinforced with polypropylene mesh [Gore-Tex and Prolene (Ethicon, Somerville, NJ, USA)]. The mesh was precut to an oval sheet, placed around the esophagus, and fixed to the diaphragm using a hernia stapler. During a follow-up of 46–76 months, the satisfaction score was good to excellent for the majority of patients. Only one of the mesh-repaired patients developed a hiatal hernia recurrence compared to four patients who underwent repair without mesh. No complications related to the use of the mesh were seen in this study. These authors began using prosthetic meshes for repairs of large diaphragmatic hernias in 1996. In the first 4 years, they used polypropylene mesh with no mesh-related complications. To increase the theoretical safety of the procedure, they began using a preformed composite mesh with polyester on one side and a hydrophilic collagen material on the other side (Parietex, Sofradim, France) (Fig. 6). Data were collected prospectively. They studied the safety and



Fig. 8. Mesh *in situ* with fundoplication.

efficacy of using a mesh for the reinforcement of diaphragmatic hernia repair.

A preformed prosthetic mesh was used routinely for the repair of any diaphragmatic hernia measuring 4 cm or larger and all recurrent diaphragmatic hernias. The mesh was fashioned in an asymmetrical U shape to cover the lateral and posterior aspects of the defect. In most cases, a loose primary repair was performed and reinforced with the precut mesh. The mesh was anchored with hernia tacks at two or three points (Fig. 7). A fundoplication was added to the procedure in all cases (Fig. 8). The patient charts were reviewed for intraoperative, postoperative, and follow-up complications and results.

During a period of 7 years, a total of 238 patients had a diaphragmatic hernia repair. Of these, a mesh was used in 55 patients (23%); 20 patients were operated on for a recurrent diaphragmatic hernia, and in 33 a mesh was used for repair of a defect larger than 4 cm. Recently, a preformed composite mesh has been used that is easy to place over the defect, and the average time to place and fix it is 4 min. There were no intraoperative or postoperative complications related to the mesh.

During a follow-up of 58 months, there were two symptomatic hernias (3.6%) that necessitated a second repair. In addition, in four patients a small sliding hernia was diagnosed that did not necessitate any intervention. There were no long-term complications that could be related to the use of mesh. These results, together with those of published reports in the past 2 years, suggest that the long-term results of mesh repair are good and there are only few complications related to the mesh. The results are also interesting because they include the use of several types of mesh, including PTFE, polypropylene, coated polyester, and biological mesh (porcine SIS), so that it seems that the potential complications are not inherent to the use of mesh but rather the result of the surgical technique. Another interesting implication of these data relates to the possible routine use of mesh in the surgical treatment of GERD. It is well-known that the most common failure of antireflux surgery, necessitating revisional surgery in up to 5% of patients, is wrap herniation due to failure of the

diaphragmatic repair [21]. It seems that since the use of mesh in this setting is safe, one may speculate that routine use of mesh reinforcement of the diaphragmatic repair may eliminate this failure and the need for re-intervention.

### Frantzides and Carlson's experience

Frantzides and Carlson state that, to their knowledge, Dr. Robert Condon at the Medical College of Wisconsin (Milwaukee, WI, USA) was the first to address the problem of an unacceptably high recurrence rate after (open) sutured hiatal herniorrhaphy by using a mesh-reinforced cruroplasty. Beginning in the late 1970s, Condon instituted a policy of polypropylene onlay to the diaphragm for patients with large hiatal hernia with intrathoracic stomach [7]. His technique consisted of a sutured posterior cruroplasty onto which a sheet of monofilament polypropylene (Marlex) was placed, followed by a gastrostomy. In order to accommodate passage of the esophagus, a "keyhole" was cut in the center of the mesh. During a 15-year period, 44 patients with intrathoracic stomach were treated in such a manner. After a mean follow-up of 52 months (range, 2 months to 15 years), the clinical recurrence rate was zero [7]. At the time of its publication in 1998, this study represented one of the largest series of prosthesis-reinforced diaphragmatic hernia repairs, either open or laparoscopic.

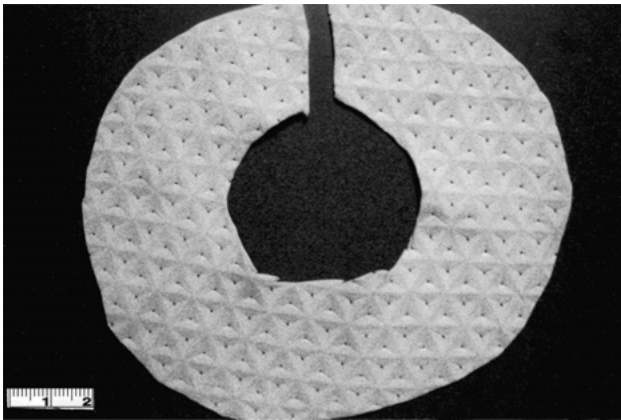
Encouraged by the results of open mesh repair of diaphragmatic hernia, Frantzides and Carlson elected to perform the repair with a minimally invasive approach. They did have a concern regarding the use of a stiff prosthetic mesh (e.g., Marlex) at the hiatus because this mesh did erode into the esophagus in one patient from the open series [7]. Polypropylene mesh erosion into the exposed bowel has been a frequent problem in mesh repair of anterior abdominal wall defects, especially in the presence of acute inflammation [55]. They believed that the use of PTFE at the hiatus might lessen the risk for erosive complications since only a handful of cases have been reported documenting PTFE as the cause or suspected cause of a bowel fistula (at the time we were contemplating such repairs, no reports of erosive complications from PTFE could be found). Another theoretical concern they had was whether the use of mesh would be of benefit in the repair of diaphragmatic hernia. Their retrospective series suggested that utilization of mesh decreased the hernia recurrence rate, but they did not have any controlled data that confirmed this. Therefore, after a small number of cases to demonstrate the feasibility of minimally invasive hiatal herniorrhaphy with PTFE onlay reinforcement [17], they performed a randomized controlled trial to test whether mesh placement reduced the recurrence rate after laparoscopic diaphragmatic hernia repair.

They hypothesized that a benefit from mesh placement most likely would be seen in patients with a large hiatal defect (which we defined as  $\geq 8$  cm). Seventy-two patients with GERD and large defect hiatal hernia were

enrolled into this trial [19]. The study population consisted of a subset of all patients ( $> 600$ ) undergoing primary minimally invasive antireflux surgery under the care of Frantzides. The decision whether to enroll a patient into the study was made after intraoperative measurement of the hiatal defect. If the defect diameter was  $\geq 8$  cm, then the subject was randomized, and a simple posterior cruroplasty with or without PTFE onlay reinforcement followed by a floppy Nissen fundoplication was performed. After a mean follow-up of 3.3 years, the recurrence rate in the cruroplasty-only group was 22% (8/36), and the rate in the cruroplasty plus PTFE group was zero. There were no mesh-related complications. The authors concluded that PTFE reinforcement of posterior cruroplasty was indicated for hiatal defects  $\geq 8$  cm.

Their technique of minimally invasive hiatal hernia repair has been described in detail elsewhere [18]. The patient is placed in a modified lithotomy position with 15–20° of reverse Trendelenburg tilt, and the surgeon stands between the patient's legs. Five 10-mm ports are employed; this gives maximum flexibility in instrument choice, including atraumatic 10-mm tissue graspers (atraugrip grasper, Pilling & Weck Surgical, Ft. Washington, PA, USA). The liver is retracted with an inflatable nontraumatic balloon retractor (Soft Wand atraumatic balloon, Circon, Southborough, MA, USA). The contents of the hiatal hernia (stomach, omentum, transverse colon, etc.) are reduced using the atraumatic grasper. The lesser omentum is then entered at the avascular area above the caudate lobe, and the incision is extended to the anterior arch of the crura. The hernia sac is reduced and excised. Dissection of the sac should be done meticulously so that pneumothorax is avoided. Routine excision of the hernia sac is advocated; without such excision, the subsequent dissection can be difficult and confusing. The esophagus should be mobilized such that the distal 5 cm lies within the abdomen without tension. The authors prefer to employ a lighted esophageal bougie during this part of the procedure; this can aid in the identification of the esophagus, which can be a difficult task. After the esophagus is fully mobilized, a posterior cruroplasty is performed with nonpledgeted, interrupted sutures of braided polyester. If an anterior hiatal defect is present at this point, then a one- or two-stitch anterior cruroplasty is employed. A PTFE patch is then cut from a larger sheet of mesh; a keyhole (3.5 cm circular defect) is cut into the center of the mesh to accommodate the esophagus (Fig. 9). The patch is introduced into the abdomen through a trocar (avoiding contact with the skin) and then applied as an onlay to the diaphragmatic repair, ensuring that the macroporous (rough) surface of the mesh faces the diaphragm. The prosthetic is anchored in place with a rigid laparoscopic hernia stapler (Fig. 10). This 10 mm instrument fires titanium staples; the authors have found its performance optimal for securing PTFE to the diaphragm. The procedure is completed with a floppy three-stitch, 2 cm-long Nissen fundoplication performed over a 50- to 60-Fr bougie.

There are issues regarding the technique of mesh fixation to the diaphragm; specifically, whether to apply



**Fig. 9.** PTFE onlay patch is constructed to have an oval shape with a horizontal diameter of 12 cm and anterior–posterior dimension of 10 cm. A 3.5 cm “keyhole” is made in the center of the mesh to accommodate passage of the esophagus.

the mesh as an onlay or to perform a tension-free repair. Frantzides and Carlson have preferred the former—that is, to complete a primary cruroplasty first and then cover the cruroplasty with an onlay patch. In this situation, the mesh acts as a buttress for the sutured cruroplasty, relieving the tissue repair from the forces of intraabdominal pressure, respiratory excursion, and so on. In the tension-free repair, the crura are not approximated; the mesh bridges the native defect. Currently, there is no evidence from the field of mesh hiatal herniorrhaphy to support the use of onlay repair over tension-free repair (or vice versa). Their preference for the onlay repair has been their practice pattern, and they have had and continue to have salutary results from this practice. Practically speaking, it is easier to staple the mesh in place around the esophagus when it is surrounded by the sutured crura. In a small number of cases, it will be impossible to suture the crura together secondary to excessive tension, poor tissue, or for other reasons. In these situations, a tension-free application of the prosthetic should be employed. Finally, it is likely the presence of the mesh (and not whether it is applied as an onlay or a bridge) that prevents hernia recurrence.

In order for the mesh to have an optimal effect (i.e., produce the lowest possible recurrence rate), it should cover the repair with a large “overlap.” That is, the mesh should extend beyond the crural margins by as much as the local anatomy will allow (Fig. 10). Practically speaking, extension of the mesh in this location is limited to the right by the inferior vena cava, anteriorly by the left lobe of the liver, posteriorly by retroperitoneal structures, and to the left by the spleen. Thus, caution should be taken to avoid injury to any of these structures. The importance of several centimeters of mesh extension beyond the entire circumference of a hernial defect has been borne out by a large amount of retrospective data from underlay repair of ventral herniorrhaphy, both open and laparoscopic [27, 56]. If a surgeon is faced with a 4 cm round-shaped ventral hernia, then the diameter of the mesh used in an underlay repair typically should be 8–10 cm, which



**Fig. 10.** Completed mesh repair of a hiatal hernia. The crura first were closed with simple sutures of 2–0 braided polyester, and then a patch as shown in Fig. 9 was applied to the cruroplasty (i.e., as an onlay) and stapled circumferentially in place. Note the extensive overlap of the repair by the mesh.

permits a 2 or 3 cm extension of the mesh beyond the entire circumference of the defect. Although it is difficult to satisfy these criteria for mesh coverage of a hiatal defect, the precept of mesh overlap of the hernial defect should be kept in mind when applying this technique to a hiatal hernia.

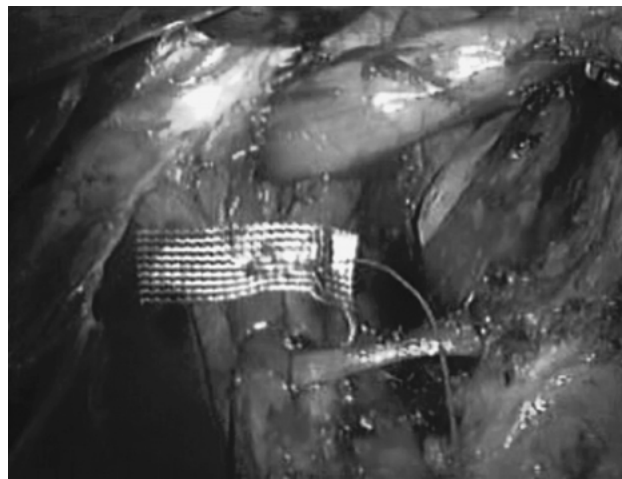
The actual firing of the stapler can be a tricky maneuver because accidental stapler deployment can injure the heart, which can result in a fatal outcome [34]. The precise technical details of stapling PTFE to the diaphragm with proximity of the heart are difficult to convey in written form. The surgeon must use enough pressure on the stapler to ensure that the staple penetrates the prosthesis and secures an adequate tissue bite but not so much pressure that the staple penetrates the diaphragm and breaches the pericardium. The attainment of this skill is facilitated with training, anatomic knowledge, and experience.

Since the conclusion of their randomized trial [19] they have routinely employed PTFE mesh reinforcement during minimally invasive repair of large hiatal hernia. They have decreased their threshold for mesh usage to hiatal defects whose diameter is 5 or 6 cm. Their original indication for the utilization of PTFE reinforcement during hiatal herniorrhaphy was a defect size  $\geq 8$  cm; this cutoff size is relatively large. Since they had an impressive difference in outcome between the control and mesh groups in their randomized trial [19], they felt justified in broadening the indication for mesh usage. Since 2000, they have performed 63 minimally invasive hiatal hernia repairs; PTFE was employed in 28 (44%) of these herniorrhaphies. Since 1992, 64 patients have undergone laparoscopic large hiatal hernia repairs with placement of PTFE prosthesis. They have yet to document a recurrence after mesh reinforcement of minimally invasive hiatal hernia repair with their technique. In addition, no patient has been documented to have mesh infection, erosion, or contraction (“mesh shrinkage”





**Fig. 11.** Simple cruroplasty.



**Fig. 12.** Simple cruroplasty + posterior 1 × 3 cm polypropylene mesh repair.

[1]). In the literature, a few cases have been reported regarding PTFE erosion into a gastrointestinal lumen, but this has not dissuaded us from using PTFE only reinforcement of sutured cruroplasty for the repair of the large hiatal defect.

#### Primary authors' experience

The high rate of postoperative intrathoracic wrap migration after laparoscopic antireflux surgery prompted us to use prosthetic meshes for crural closure in December 1998. In all patients who underwent laparoscopic antireflux surgery at our surgical unit, hiatal hernia recurrence with intrathoracic wrap migration was the most common cause of anatomic failure after primary laparoscopic antireflux surgery. In more than 70% of patients who underwent laparoscopic refundoplication after primary failed antireflux surgery, intrathoracic wrap migration was found as the reason for failure.

In a prospective nonrandomized trial [23], we compared 361 patients with GERD who underwent laparoscopic Nissen or Toupet fundoplication with simple crural closure to 170 GERD patients who underwent laparoscopic antireflux surgery with simple hiatal closure reinforced with polypropylene mesh. In the group of patients who underwent primary cruroplasty, the number of sutures depended on the size of hiatal hernia; in these patients, the crura were approximated with two to four interrupted nonabsorbable polyfilament sutures (Fig. 11).

In the mesh-cruroplasty group, the crura were approximated with simple interrupted sutures as described previously. Additionally, a 1 × 3 cm section of polypropylene mesh (cut from a 10 × 15 Prolene mesh for groin hernia repair) was placed on the sutured crura as a posterior onlay and sutured with one stitch on the lateral sides of both the right and the left crus (Fig. 12).

Follow-up examinations were performed 6 weeks, 3 months, and 1 year after surgery. After 1 year of follow-up, a significant difference in the postoperative occur-

rence of intrathoracic wrap migration was found. In the initial group with nonmesh hiatoplasty, postoperative intrathoracic wrap migration occurred in 6.1% of patients compared to 0.6% of patients who underwent crural closure with polypropylene mesh onlay. There was also a significant difference in the incidence of postoperative dysphagia. Patients with mesh-cruroplasty had a dysphagia rate of 35.3% compared to 19.8% in the nonmesh group 3 months after surgery; however, the dysphagia rate decreased at the 1 year visit and was not significantly different between the two groups (4.9 vs 4.4%).

These findings were reevaluated in another nonrandomized trial [32], in which 100 GERD patients with simple crural closure were compared to 100 GERD patients with simple closure reinforced with the 1 × 3 cm polypropylene mesh hiatoplasty. The postoperative dysphagia rate and its impact on quality of life were evaluated for a period of 12 months after surgery. The postoperative dysphagia rate was significantly higher in the mesh group at 3 month follow-up (32.3 vs 16.7%) but decreased to comparable values at 1 year follow-up (4.8 vs 5.4%). In addition to these results, quality of life significantly improved after surgery in both groups. This improvement remained stable up to 1 year postoperatively, was comparable between the two groups, and was similar to that of a healthy control group.

To verify these findings, a prospective randomized study was performed on 100 GERD patients scheduled for laparoscopic Nissen fundoplication [24]. Fifty patients were prospectively randomized to laparoscopic 360° floppy Nissen fundoplication with simple sutured posterior hiatoplasty, and 50 were randomized to laparoscopic 360° floppy Nissen fundoplication with posterior 1 × 3 cm polypropylene mesh onlay. Follow-up of 12 months was obtained in all patients. Three months after surgery, a significant difference in postoperative intrathoracic wrap migrations was observed. Five patients (10%) in the nonmesh group had a recurrence compared to one patient (2%) in the mesh-group. Twelve months after surgery, the recurrence rate

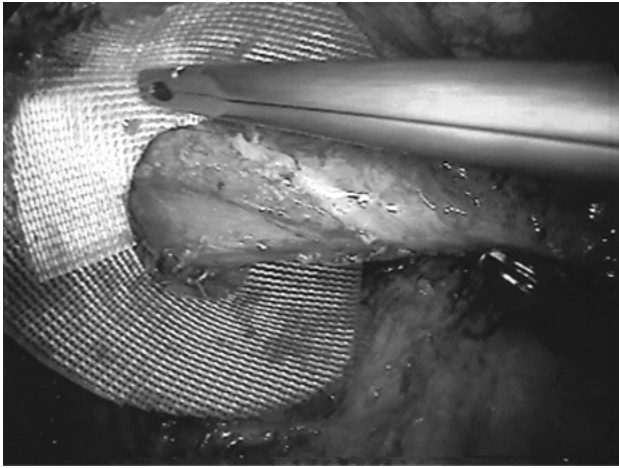


Fig. 13. Simple cruroplasty + circular polypropylene mesh repair.

increased to four patients (8%) in the mesh group and 13 patients (26%) in the nonmesh group. In addition, patients with prosthetic hiatal closure had a higher dysphagia rate at 3 month follow-up (16 vs 4%), as previously observed. However, 1 year after surgery, the dysphagia rate was the same for both groups (4%).

A different type of prosthetic mesh was used in 24 patients who underwent laparoscopic refundoplication in our surgical unit for failed primary antireflux surgery. The cause of failure in all these patients was a symptomatic intrathoracic wrap migration [21]. The failed hiatal repair was primarily approximated with interrupted nonabsorbable sutures and then reinforced with a circular precut polypropylene mesh. The mesh was cut out with a 3 or 4 cm keyhole as described by Frantzides and Carlson [18]. The mesh was placed around the esophagus and secured to the diaphragm and crura with a hernia stapler (Fig. 13). All patients were followed for 12 months after surgery, and none had a hiatal hernia recurrence. There has been no evidence of any mesh-related complications, such as erosion, migration, or visceral perforation, in our patients.

We also are working on other alternatives for hiatal closure. The higher dysphagia rate in patients with hiatal mesh prosthesis has led us to use a special V-shaped mesh with porous PTFE on one side and expanded PTFE on the other side (Crurasoft Composix mesh, C. R. Bard) for large hiatal hernia repair. After dissection of the hiatal crura, the mesh is brought into the abdomen and positioned on to the crura as a tension-free posterior onlay. The mesh is fixed with interrupted sutures on the edges of the mesh and secured with staples on the lateral side of the mesh (Fig. 14). In addition, we are participating in a multicenter study on the use of Parietex, a newer mesh that, similar to the Composix mesh, combines two different materials. Parietex composite mesh has a three-dimensional weave of polyester on one side with a hydrophilic collagen material on the other. The resorbable collagen side has been designed for the prevention of intraabdominal adhesions to the mesh in the early postoperative period. The polyester side ensures rapid tissue ingrowth with



Fig. 14. Tension-free posterior Crurasoft mesh repair.

permanent reinforcement. In conjunction with participating colleagues and the manufacturer, we have designed a special V shape of this mesh specifically for laparoscopic closure of the hiatal crura. The mesh is used both for tension-free hiatal closure (Fig. 15) and as an additional reinforcement of primary sutured hiatal crura. Positioned as a posterior onlay prosthesis, the mesh is secured to the diaphragm with a hernia stapler.

#### Complications of prosthetic crural closure

The use of prosthetic materials in surgery for GERD and/or large hiatal hernia repair is accompanied by a low incidence of foreign body complications (Table 2). For instance, the use of Teflon pledgets in fundoplication has been associated with visceral erosion, foreign body migration, or gastroesophageal fistula after surgery [2, 4, 14].

In particular, a risk for complications related to the use of prosthetic materials for closure of the hiatal crura has been predicted by some authors. The focus is on the possibility of erosion or migration of the mesh into the esophagus or stomach, as well as complications due to severe mesh adhesions, infection, or the development of fibrotic strictures in the hiatal area. In a study by Carlson et al. [7], one patient (2.3%) out of 44 who underwent open prosthetic hiatal closure for large hiatal hernia repair developed a mesh erosion into the esophagus 29 months after surgery. Edelman [16] reported one patient out of five who had to undergo revisional surgery after primary laparoscopic paraesophageal hernia repair with mesh. This patient had severe dysphagia due to esophageal stenosis secondary to mesh-induced fibrosis. Likewise, Trus et al. [52] also reported one patient who had undergone primary laparoscopic mesh repair for paraesophageal hernia who then suffered from refractory postoperative dysphagia. During re-laparotomy, the authors found a circular scar at the distal esophagus caused by the hiatal mesh. The mesh had to be excised, a myotomy was performed, and then the

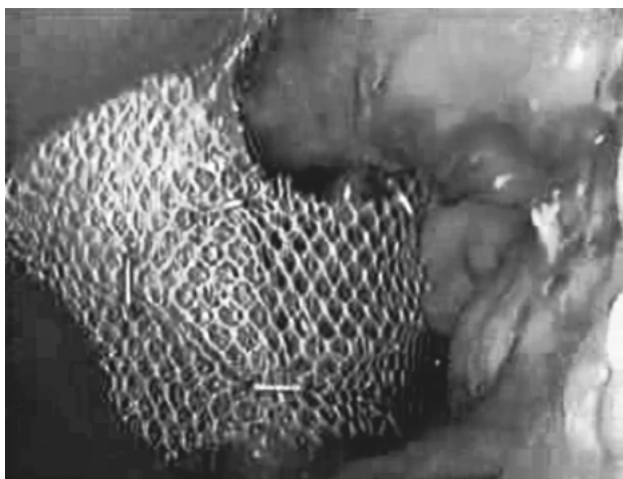


Fig. 15. Parietex mesh repair.

crura were approximated. Persistent postoperative dysphagia refractory to dilatations was reported by Van der Peet et al. [53]. One patient who underwent laparoscopic hiatal hernia repair with Dacron mesh reinforcement had a significant fibrotic reaction to the mesh; this had to be removed during a reoperation. Another two patients with mesh-related complications were reported by Casabella et al. [10]. One patient developed fibrotic damage at the hiatus postoperatively; the other patient had a mesh erosion into the esophagus. Both of these patients underwent redo-surgery and required distal resection of the esophagus because of the mesh intrusion into the lumen. Coluccio et al. [13] also reported one patient who required resection of the distal esophagus due to a mesh-related complication. This patient underwent large hiatal hernia repair with the use of a PTFE prosthesis, which subsequently migrated into the cardiac lumen. During reoperation, the mesh had to be removed, and the patient required a distal esophageal resection. A fatal complication was described by Kempainen et al. [34]. This patient had a large paraesophageal hernia with acute thoracic herniation and incarceration of the stomach. The patient underwent laparoscopic hiatal hernia repair with tension-free hiatoplasty using PTFE. Fixation of the mesh was performed using a hernia stapler. After surgery, this patient developed a cardiac tamponade caused by a stapler laceration of a coronary vein.

Although there have been few complications related to prosthetic mesh after laparoscopic antireflux surgery or large hiatal hernia repair, some authors recommend the use of biomaterials or autologous tissue to avoid any risk of complication secondary to prosthetic mesh. Varga et al. [54] advocated the use of ligamentum teres for reinforcement of the hiatal crura in four patients with a hiatal hernia  $\geq 6$  cm. Similarly, the successful use of biomaterial has been described by Oelschlager et al. [43]. Nine patients underwent laparoscopic paraesophageal hernia repair with the use of a porcine SIS mesh for crural closure to avoid mesh-related esophageal or gastric injury.

Table 2. Complications of prosthetic crural closure

| Reference                    | Year | No. of patients (%) | Type of prosthesis | Complications   | Reoperation  |
|------------------------------|------|---------------------|--------------------|---|--|
| Edelman [16]                 | 1995 | 1 (20%)             | Polypropylene      | Esophageal stenosis due to mesh-induced fibrosis              | Laparoscopic revision  |
| Trus et al. [52]             | 1997 | 1 (1.3%)            | n.a.               | Mesh-induced esophageal scarification                         | Re-laparotomy with esophageal myotomy                                    |
| Carlson et al. [7]           | 1998 | 1 (2.3%)            | Polypropylene      | Esophageal mesh erosion (asymptomatic)                        | Transhiatal esophagectomy for Barrett's adenocarcinoma 41 months postop. |
| Kempainen and Kiviluoto [34] | 2000 | 1                   | PTFE               | Cardiac tamponade secondary to mesh fixation by tacks (death) | Re-laparotomy with mesh removal  |
| Van der Peet et al. [53]     | 2000 | 1 (4.5%)            | Polyester          | Hiatal fibrosis   | Re-laparotomy with distal esophagectomy                                  |
| Casabella et al. [10]        | 1996 | 2 (13%)             | n.a.               | Fibrotic hiatal damage/esophageal mesh erosion                | Re-laparotomy with distal esophagectomy                                  |
| Coluccio et al. [13]         | 2000 | 1                   | PTFE               | Penetration of the cardiac lumen                              | Re-laparotomy with distal esophagectomy                                  |

n.a., not available; PTFE, polytetrafluoroethylene

## Conclusion and future perspectives

In general, hiatal reinforcement with the use of prosthetic meshes has proven to be a safe and effective procedure to prevent postoperative hiatal hernia recurrence both in laparoscopic surgery for hiatal or paraesophageal hernia repair and in laparoscopic antireflux surgery. A few comparative studies and trials of laparoscopic hiatal closure with simple sutures versus mesh hiatoplasty have shown that patients with a prosthetic hiatal closure have a lower rate of postoperative hiatal hernia recurrence in comparison to patients with simple hiatal repair. However, some patients with prosthetic hiatal closure suffer from prolonged postoperative symptoms such as dysphagia or chest pain. Fortunately, this resolves in most of patients without further treatment. When the procedure is performed properly, a true complication related to the use of prosthetic material for hiatal closure is a rare condition.

A consensus regarding a standard indication for the use of prosthetic mesh for hiatal closure does not exist. Some authors advocate the use of prosthetic meshes empirically only in patients in whom a tension-free crural closure with simple sutures seems impossible. However, other authors employ prosthetic hiatoplasty in a more liberal matter. All these authors agree that the primary indication for prosthetic hiatal closure should be the size of the hiatal defect.

Regarding the characteristics of the mesh, most authors agree that the ideal mesh has to be easy to handle during laparoscopy, able to adhere to the diaphragmatic surface on the one side, and be benign to the visceral surface on the other side.

The shape of the mesh is still a matter of controversy. Most authors recommend a posterior onlay repair; others have advocated the use of circular prostheses with good results. This topic will be a matter of future research, especially when long-term results of published series are available.

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