Use of absorbable meshes in laparoscopic paraesophageal hernia repair

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Abstract

Paraesophageal hernia (PEH) repair is one of the most challenging upper gastrointestinal operations. Its high rate of recurrence is due mostly to the low quality of the crura and size of the hiatal defect. In an attempt to diminish the recurrence rates, some clinical investigators have begun performing mesh-reinforced cruroplasty with nonabsorbable meshes like polypropylene or polytetrafluoroethylene. The main problem with these materials is the occurrence, in some patients, of serious mesh-related morbidities, such as erosions into the stomach and the esophagus, some of which necessitate subsequent esophagectomy or gastrectomy. Absorbable meshes can be synthetic or biological and were introduced in recent years for PEH repair with the intent of diminishing the recurrence rates observed after primary repair alone but, theoretically, without the risks of morbidities presented by the nonabsorbable meshes. The current role of absorbable meshes in PEH repair is still under debate, since there are few data regarding their long-term efficacy, particularly in terms of recurrence rates, morbidity, need for revision, and quality of life. In this opinion review, we analyze all the presently available evidence of reinforced cruroplasty for PEH repair using nonabsorbable meshes (synthetic or biological), focusing particularly on recurrence rates, mesh-related morbidity, and long-term quality of life.

Key words: Paraesophageal hernia; Laparoscopy; Mesh; Absorbable; Biological

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with significant morbidity (i.e., erosions). In this paper, we discuss the use of absorbable meshes (synthetic and biologic) in paraesophageal hernia repair.

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INTRODUCTION

There are four types of hiatal hernias (HHs). Type I (sliding HH) are the most common, and their surgical indication is usually for gastroesophageal reflux disease (GERD). Types II [true paraesophageal hernia (PEH); fundus herniation with an abdominal esophagogastric junction], III (fundus and esophagogastric herniation) and IV (fundus, esophagogastric junction as well as another abdominal organ, such as colon) are usually referred as PEHs. The PEHs are uncommon, accounting for only 5%-10% of HHs, but with more than 90% of them being type III.

The proper management of PEH is controversial and even their surgical indication is now under debate. Historically, all PEHs were operated because of a higher complication rate observed after conservative treatment. Today, their management has shifted to a case-by-case decision, since the risk of the repair can be high in elderly patients with multiple comorbidities and the risk of complications (according to observation) seems to be lower than in the historical reports[1].

One of the main problems of laparoscopic PEH repair is a high recurrence rate - being 12%-42% in some large series[2], while other series have shown up to 60%. To improve these results, some clinical investigators began to use prosthetic materials to reinforce the crural closure. The first mesh-reinforced cruroplasties used nonabsorbable materials like polypropylene or polytetrafluoroethylene (PTFE)[3]. The occurrence of serious morbidity, in some patients, after the nonabsorbable mesh placement (i.e., erosions into the stomach or the esophagus, some of which required esophagectomy or gastrectomy) has kept the use of these materials from becoming standard[4-7].

The ideal mesh material should be able to help reduce tension of the crural closure, without causing erosion or dysphagia, and with provision of long-term duration. This ideal material has not yet been found.

Absorbable meshes were introduced to maintain the theoretical benefit of reducing the recurrence rate without the associated morbidity of the nonabsorbable materials. They can be synthetic, such as Vicryl® (Ethicon, Somerville, NJ, United States) or Bio-A® (Gore Medical, Newark, DE, United States), or biological, such as Surgisis® (Cook Medical, Bloomington, IN, United States), AlloDerm® (Allergan PLC, Dublin, Ireland), or Strattice™ (Allergan PLC) (Table 1). Although they seem to be safe, with very low short- and long-term morbidity rates, the main questions regarding their applicability are long-term efficacy and, in some cases (biological), their high costs.

A recent survey, conducted by the Society of American Gastrointestinal Endoscopic Surgeons (known as SAGES) and answered by more than 2500 members, revealed that among surgeons using mesh for HH repair, 67% preferred absorbable material. Among the high-volume surgeons (> 20 cases of PEH repair per year), 23% reported using mesh reinforcement in the majority of their cases, while the remaining 77% of surgeons reported using it in approximately half of their cases[8]. PEH repairs continue to be so controversial that a clinical guideline for the management of HH concluded that there is not sufficient evidence to support or to speak against the use of mesh to reinforce crural closure[9].

We conducted a thorough search of the Medline and PubMed databases that would allow us to discuss the various results published by different groups worldwide, using all kinds of absorbable meshes for laparoscopic PEH repair.

EXPERIENCES WITH ABSORBABLE SYNTHETIC MESHES

One of the first publications of crural reinforcement with an absorbable mesh (Bio-A®) described work by Massullo et al[10]. This initial experience consisted of only 11 patients with GERD or PEH. All patients received a reinforced laparoscopic
Table 1 Different types of absorbable meshes

| Type of material | Composition                        | Commercial name   |
|------------------|------------------------------------|-------------------|
| Synthetic        | Polyglactin 910                    | Vycril®           |
| Synthetic        | Polyglycolic acid (67%)            | Bio-A®            |
|                  | Trimethylene carbonate (33%)       |                   |
| Biological       | Porcine small intestine submucosa  | Surgisis®         |
| Biological       | Acellular human dermis             | AlloDerm®         |
| Biological       | Bovine pericardium collagen matrix | Veritas®          |
| Biological       | Porcine acellular dermal collagen  | Permacol®         |
| Biological       | Porcine-derived acellular dermal   | StratticeTM       |

1Medtronic, Minneapolis, MN, United States.

cruroplasty with Bio-A® mesh, after which they underwent either Nissen or Toupet fundoplication. Mean follow-up was 13 mo, with 1 case of recurrence (9%) and no mesh-related complications (MRCs). The clinical value of this initial experience was limited, however, because of the small number of patients and the short follow-up.

A later prospective series of 70 patients, consisting of 48 PEH and 22 large type I HH, was published in 2013 by Powell and coworkers[11]. The crural reinforcement was also performed with Bio-A® mesh but without the classical U-shape. Instead, the investigators cut the mesh only to cover the crural closure, in an attempt to make no contact with the dissected esophagus. On short-term follow-up, there were no MRCs.

Iossa et al[12] recently published a retrospective series reporting their mid-term results on 120 patients with Bio-A® mesh-reinforced cruroplasty. Mean follow-up was 42 mo, and recurrence rates were 5.4% in the obese group and 7.1% in the nonobese population. No MRCs were recorded. The value of this paper is limited, however, since most of the patients were obese and having undergone concomitant bariatric surgery (sleeve gastrectomy) and the rest of the patients having been operated because of GERD, with only 6 cases representing PEH. Nevertheless, the study showed that mesh placement was safe, with no MRCs, and recurrence rate was low.

Asti et al[13] published a retrospective experience of 100 cases of reinforced cruroplasty with Bio-A® mesh, after which all patients received a Toupet fundoplication. The indications for mesh placement were weak or frail crura and large HH (90% of the cases were PEH). No MRCs were observed and the recurrence rate was 9%, with a mean follow-up of 30 mo, and mostly in patients with type III PEH. Although this is a retrospective series, it has the value of showing the safety of Bio-A® mesh placement with a low recurrence rate in the mid-term. Other small retrospective series have yielded similar results[14,15].

Zehetner and coworkers[16] published their experience with reinforced cruroplasty using polyglactin mesh (Vycril®) secured with a biological glue (BioGlue® surgical adhesive; CryoLife Inc, Kennesaw, GA, United States). This material has a degradation time between 6 wk and 8 wk. Of the 35 patients with an intrathoracic stomach (defined as > 50% of the stomach inside the thoracic cavity), 21 completed a 1-year follow-up, at which point they were evaluated by esophagogram, pH monitoring, and upper endoscopy. The recurrence rate was 9.5% (2 cases; 1 having GERD symptoms and 1 being asymptomatic). No MRCs were observed. These different experiences are summarized in Table 2.

EXPERIENCES WITH ABSORBABLE BIOLOGIC MESHES

Oelschlager et al[17] published, in 2006, a multicenter prospective and randomized trial, comparing suture alone vs reinforced cruroplasty with Surgisis® for the treatment of PEH. A total of 108 patients with symptomatic large PEH were enrolled, 51 in the Surgisis arm and 57 in the suture-alone arm. All demographic and PEH type distributions were similar among both groups. At 6-mo follow-up, there was a significant improvement in all the symptoms that had been described in the preoperative period. The majority of patients (90%) underwent an upper gastrointestinal contrast study, the data from which showed a statistically significant difference in recurrence rate in favor of the Surgisis group (24% vs 9% respectively). On multivariate analysis, the only factor associated with a lower risk of recurrence was the placement of Surgisis®.

The long-term follow-up of this experience[17] was published in 2011. Of the original
108 patients, the investigators were able to contact 72, now with a median follow-up of 58 mo. No differences were observed between the two groups in terms of frequency or severity of upper gastrointestinal symptoms. Recurrence rates were 59% in the suture-alone group and 54% in the Surgisis group. The conclusion of the study is that the initial advantage for the use of biologic reinforcement of the cruroplasty was erased in long-term follow-up (5 years). However, the high recurrence rate observed in this experience might be biased by the fact that the diagnosis was made only by experienced radiologists and any herniation into the hiatal space was considered as a recurrence. The responses on quality of life (QOL) questionnaires remained satisfactory.

Lee et al[19] from the Nebraska University retrospectively reviewed their experience with reinforced cruroplasty with AlloDerm® mesh. This material is biologic and is supposed to be fully incorporated in the recipient tissue at 9 mo postapplication. The study evaluated 52 patients, with a median follow-up of 16 mo. No MRCs were observed, and the recurrence rate was 3.8%.

A more recent experience from the same group consisted of a retrospective review of their experience with 35 patients who submitted to reinforced cruroplasty with Strattice™ mesh. All patients had PEH at least of 5 cm on upper endoscopy, with a mean hernia size of 10 cm. At a short follow-up of 12 mo, 5 recurrences were observed (14%). The investigators concluded that the use of this mesh was safe, producing short-term results similar to those of other comparable materials[20].

In a study designed to identify factors associated with PEH recurrence after reinforced cruroplasty with biologic material, Lidor and coworkers[21] from Johns Hopkins University found that the risk of recurrence was higher in patients with intrathoracic stomach. The material used in this study was the Veritas mesh (Baxter International, Deerfield, IL, United States) and the recurrence rate was 27% at 1-year follow-up, with most of the patients reporting a better QOL despite recurrence. No MRCs were reported. At 36 mo, most patients reported overall satisfaction but symptoms such as heartburn, early satiety and nausea remained as in the preoperative period. The investigators’ conclusion was that, despite a high recurrence rate, most of the patients remained asymptomatic and reported “good” on QOL questionnaires. These different experiences using biological meshes are summarized in Table 3.

### EXPERIENCES COMPARING MULTIPLE MATERIALS

Tam et al[22] retrospectively reviewed 795 patients, of which 106 received crural mesh reinforcement, with 84% of the cases receiving a biological mesh. The recurrence rate was similar between both groups. This might be explained by the fact that most patients requiring mesh placement were older and had bigger hernias with poor quality crura, with some even having a completely intrathoracic stomach. Three patients (2.8%) had MRCs. Two patients suffered from a severe fibrosis around a biological mesh causing dysphagia, with one requiring several endoscopic dilatations and the other esophagectomy. One patient suffered a cardiac tamponade that required sternotomy and right coronary artery hemostasis, due to a tacker injury. The investigators recommend selective use of mesh cruroplasty.

Parsak et al[23] published an interesting prospective and randomized trial comparing crural reinforcement with polypropylene vs polyglactin mesh in patients operated for GERD. A total of 150 patients were included in the study (75 receiving polypropylene and 75 receiving polyglactin). Postoperative morbidity was similar for both groups, with no MRCs. At a mean follow-up period of approximately 36 mo, the recurrence rate was 7.5%, similar between both arms of the study. No erosion was reported in any group.
Table 3  Experiences with biological mesh

| Author          | Study design                  | n               | Type of Mesh | Recurrence | MRC  | Median FU in mo |
|-----------------|-------------------------------|-----------------|--------------|------------|------|-----------------|
| Oelschlager et al[17] | RCT                           | 108 (51 with mesh) | Surgisis®    | 9%         | No   | 6               |
| Oelschlager et al[18] | RCT                           | 72 (33 with mesh)  | Surgisis®    | 54%        | No   | 58              |
| Lee et al[19]    | Retrospective                 | 52              | AlloDerm®    | 3.8%       | No   | 16              |
| Lomelin et al[20]| Retrospective                 | 35              | Strattice™   | 14%        | No   | 12              |
| Lidor et al[21]  | Prospective non-randomized    | 111             | Veritas®     | 27%        | No   | 36              |

FU: Follow-up; MRC: Mesh-related complication; RCT: Randomized-controlled trial.

Zehetner et al[24] published in 2011 a retrospective evaluation comparing open vs laparoscopic PEH repair. In this experience, they used multiple mesh materials (Surgisis®, Vycril®, and Bio-A®) and the recurrence rate was 18%, similar between the open and laparoscopic approach groups, with the latter being superior in terms of shorter hospital stay and reduced morbidity.

An interesting prospective and randomized trial was conducted by Watson et al[25]. They compared suture cruroplasty (43 cases) vs reinforced cruroplasty with absorbable mesh (41 cases receiving Surgisis®) and nonabsorbable mesh (42 cases receiving TiMESH (PFM Medical Titanium gmbh, Nürnberg, Germany) in patients with large PEH. No differences were observed in term of recurrence between the three arms of the study and - as seen in most of the other studies previously cited in this review - most were asymptomatic. A limitation of this study is its short follow-up of only 12 mo, since this duration might not allow for detection of late recurrences and late complications of nonabsorbable meshes (i.e., erosion)[25]. A later evaluation of QOL performed on these patients at 24-mo follow-up showed no differences between the groups.

Jones et al[27] published, in 2015, one of the few papers reporting on long-term follow-up of reinforced cruroplasty with the use of an absorbable mesh. Most large hernias in this study were operated using biological material (AlloDerm® and Strattice™), whereas synthetic material (Bio-A®) was used mostly for the smaller ones. No MRC was observed. At 5 years after surgery, radiologic recurrence was 39%, but most of the preoperative symptoms were significantly better in the postoperative period.

Finally, a recent meta-analysis by Huddy et al[28], evaluating results of suture-alone cruroplasty vs absorbable mesh-reinforced cruroplasty vs nonabsorbable mesh-reinforced cruroplasty found that the addition of the mesh significantly reduces recurrence rate, with more benefits being obtained with the nonabsorbable material. The rate of surgical revisions was also significantly reduced with the addition of a mesh. There were no reports of erosions in the study, probably because of a short-term follow-up. These different experiences using multiple materials are summarized in Table 4.

**CONCLUSION**

Laparoscopic crural reinforcement with absorbable material (synthetic or biological) is becoming accepted by the surgical community, as has been revealed by a large survey conducted by SAGES. This event is probably related more to their safety profiles (few MRCs reported) instead of their long-term recurrence rates. More studies with longer follow-up periods are needed to clarify this. The actual evidence shows, however, that despite high recurrence rates, most patients remain asymptomatic, with good QOL, and very few require surgical revisions.
**Table 4 Experiences with multiple mesh materials**

| Author         | Study design   | n  | Type of mesh                              | Recurrence | MRC | Median FU in mo |
|----------------|----------------|----|-------------------------------------------|------------|-----|-----------------|
| Tam et al(22)  | Retrospective  | 106| Mostly biological                         | 22%        | 28% | NS              |
| Parsak et al(23)| RCT           | 150| 75 Polypropylene/75 Polyglactin           | 7.5%       | No  | 36              |
| Watson et al(23)| RCT         | 126| 43 Suture alone                           | Similar, about 20% | No | 12              |

FU: Follow-up; NS: Not stated; RCT: Randomized-controlled trial.

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