Impact of Crural Relaxing Incisions, Collis Gastroplasty, and Non—Cross-linked Human Dermal Mesh Crural Reinforcement on Early Hiatal Hernia Recurrence Rates

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BACKGROUND: Hernia recurrence is the leading form of failure after antireflux surgery and may be secondary to unrecognized tension on the crural repair or from a foreshortened esophagus. Mesh reinforcement has proven beneficial for repair of hernias at other sites, but the use of mesh at the hiatus remains controversial. The aim of this study was to evaluate the outcomes of hiatal hernia repair with human dermal mesh reinforcement of the crural closure in combination with tension reduction techniques when necessary.

STUDY DESIGN: We retrospectively reviewed the records of all patients who had hiatal hernia repair using AlloMax Surgical Graft (Davol), a human dermal biologic mesh. Objective follow-up was with videoesophagram and/or upper endoscopy at 3 months postoperatively and annually.

RESULTS: There were 82 patients with a median age of 63 years. The majority of operations (85%) were laparoscopic primary repairs of a paraesophageal hernia with a fundoplication. The crura were closed primarily in all patients and reinforced with an AlloMax Surgical Graft. A crural relaxing incision was used in 12% and a Collis gastroplasty in 28% of patients. There was no mesh-related morbidity and no mortality. Median objective follow-up was 5 months, but 15 patients had follow-up at 1 or more years. A recurrent hernia was found in 3 patients (4%).

CONCLUSIONS: Tension-reducing techniques in combination with human biologic mesh crural reinforcement provide excellent early results with no mesh-related complications. Long-term follow-up will define the role of these techniques and this biologic mesh for hiatal hernia repair. (J Am Coll Surg 2014;219:988—992. © 2014 by the American College of Surgeons. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license [http://creativecommons.org/licenses/by-nc-nd/3.0/].)

Hiatal hernias are common and increase with age. The sliding type of hiatal hernia contributes to the pathophysiology of gastroesophageal reflux disease (GERD); a paraesophageal hernia (PEH) is associated with potentially catastrophic complications including bleeding, incarceration, and perforation. Reduction of a hiatal hernia and crural closure are integral parts of an antireflux operation or PEH repair. In the past, most of these procedures were done open, either via a transabdominal or a transthoracic approach, and failure was most commonly in the form of a slipped or disrupted fundoplication. However, since the 1990s, a shift has occurred and the majority of procedures both for reflux and PEH repair are being done laparoscopically. Now, the most common form of failure is a recurrent hiatal hernia.

In particular, hernia recurrence is the Achilles' heel of PEH repair, for which objective rates in excess of 50% at 5 years have been reported.[1,2] Mesh reinforcement of the crural closure has been advocated in an effort to reduce hernia recurrence. Although synthetic mesh has been shown to be beneficial, the risk of mesh erosion into the esophagus has kept many esophageal surgeons from adopting synthetic mesh for routine use at the hiatus. Absorbable or biologic mesh at the hiatus would be less likely to erode, but long-term follow-up of a

randomized multicenter trial of PEH repair using Surgisis mesh (Surgisis, Cook Biotech Inc) found no reduction in hernia recurrence compared with primary crural closure without mesh.[2] Following the results of this trial we abandoned Surgisis and used a new biologic mesh (AlloMax Surgical Graft, Davol Inc) for crural reinforcement during antireflux surgery or PEH repair. AlloMax graft is a sterile, non—cross-linked human collagen matrix that supports cellular ingrowth and revascularization.

We also were concerned that hernia recurrence may be related to underappreciated tension on the crural closure or a foreshortened esophagus. Therefore we adopted adjunct techniques including crural relaxing incisions and the wedge-fundectomy Collis gastroplasty to address tension when encountered intraoperatively. The aim of this study was to evaluate our results with the use of AlloMax graft reinforcement of the primary crural closure along with adjunct techniques to reduce tension when necessary in patients undergoing antireflux surgery or PEH repair.

METHODS

Patients

A retrospective chart review was performed to identify all patients who had an AlloMax graft placed at the hiatus during repair of a sliding or paraesophageal hiatal hernia. The first use of this mesh at our center was in January 2011, and we included all patients who had their operation before January 22, 2013 in this study. Preoperative evaluation included upper endoscopy, videoesophagram, high resolution esophageal motility, and, when indicated, esophageal pH monitoring. Paraesophageal hernias were defined as the presence of at least 50% of the stomach in the chest, with the gastric fundus located above the gastroesophageal junction.

Postoperative follow-up was scheduled at 3 months and annually in all patients and included physical examination and videoesophagram. Upper endoscopy was performed selectively to evaluate patients with symptoms or an abnormal videoesophagram, after Collis gastroplasty to rule out esophagitis related to acid production by the gastric tube above the fundoplication, and for surveillance in patients with Barrett's esophagus. Recurrence was defined as any size hernia seen on videoesophagram or on upper endoscopy. This study was approved by the IRB of the University of Southern California.

Surgical technique

The surgical technique was similar in all patients and has been previously described.[3] The pleura were opened routinely for PEH repairs and occasionally for large sliding hernias. This prevented a mediastinal seroma from forming
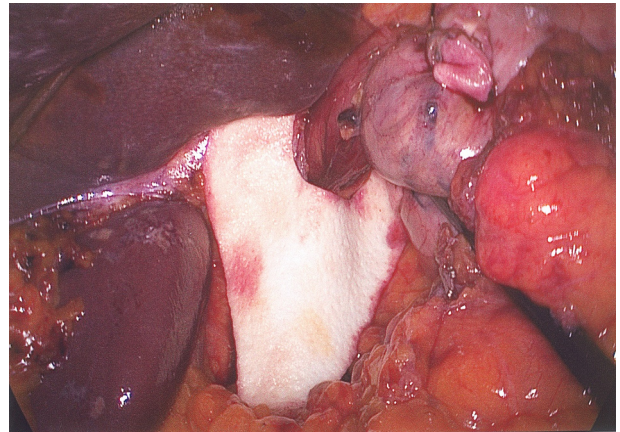
Figure 1. The completed repair showing the AlloMax Surgical Graft patch cut into a heart-shaped pattern and placed posterior to the esophagus after crural closure. The mesh is typically secured with 2-0 silk sutures and glue.

and allowed fluid to drain into the pleural space. It also enhanced lung re-expansion by collapsing the mediastinal space. All patients had a fundoplication tailored to the patient's esophageal manometry; it was either a complete 360-degree Nissen or a Toupet partial fundoplication. Crural tension was evaluated by visual assessment and haptic feedback. If attempts to bring the crural pillars together with graspers were difficult or impossible, a relaxing incision was performed in the right, left, or both hemidiaphragms, as previously described.[4,5] When less than 3 cm of intra-abdominal esophagus was present after mediastinal mobilization a wedge-fundectomy, Collis gastroplasty was performed as previously described.[6,7]

In all patients, the crura were closed primarily using pledgeted 0-Ethibond (Ethicon) horizontal mattress sutures. The pledgets were cut from the sides of the 7 × 10 cm unhydrated AlloMax graft before its use for crural reinforcement. After crural closure, the AlloMax patch was cut into a heart-shaped pattern and placed posterior to the esophagus (Fig. 1). The graft was secured with absorbable tacks (AbsorbaTack, Covidien) or more commonly, 2-0 silk sutures and Tisseel glue (Tisseel Fibrin Sealant, Baxter International Inc).

Statistics

Comparisons between groups were performed using the chi-square test. A p value less than 0.05 was considered statistically significant.

RESULTS

There were 82 patients (26 men and 56 women), with a median age of 63 years, who had hiatal hernia repair with an AlloMax graft reinforcement of the primary crural

Table 1. Operative Details

Operative detail	Sliding		PEH		
	n	%	n	%	p Value
n	35		47		
Operation					
Primary	34	97	42	89	0.232
Re-do procedure	1	3	5	11	
Fundoplication					
Nissen	31	89	34	72	0.100
Toupet	4	11	13	28	
Tension-reducing techniques					
Collis gastroplasty	2	6	21	45	0.0001
Crural relaxing incision	0		10	21	0.004

PEH, paraesophageal hernia.

closure. The majority of operations (85%) were primary repairs done laparoscopically (Table 1). There was no difference in the type of fundoplication performed in patients with a PEH vs those with a sliding hiatal hernia, but patients undergoing repair of a PEH were significantly more likely to have a Collis gastroplasty or crural relaxing incision. Crural relaxing incisions (8 right sided, 1 left sided, 1 bilateral) were necessary to achieve tension-free primary crural closure in 21% of patients with a PEH. There were 5 patients who had both a Collis gastroplasty and a relaxing incision performed. Of these, 4 were patients undergoing primary repair and 1 was a reoperation. There were 6 re-do operations for recurrent hiatal hernia and failed fundoplication. Adjunct techniques in these patients included Collis gastroplasty in 3 patients and a relaxing incision in 1 patient.

Perioperative morbidity was uncommon and typically minor (Table 2). One patient underwent laparoscopic re-exploration for a falling hematocrit. A blood clot along the greater curvature of the stomach was evacuated but no source of bleeding was identified, and the patient subsequently recovered without incident. One patient had a stent placed for a leak from the Collis staple line. Six patients developed pleural effusions and 5 patients underwent thoracentesis or tube drainage. There were no mesh-related complications and no operative mortality.

Objective follow-up was available in 69 patients at a median of 5 months postoperatively, and in 15 patients

Table 2. Perioperative Morbidity

Laparoscopic re-exploration for postoperative bleed
Pulmonary embolus (2 patients)
Pleural effusion (6 patients; 5 treated with thoracentesis or drain placement with resolution)
Esophageal leak (successfully treated with stent placement)
Port site hernia
Removal of suture granuloma (chronic sinus tract)

at 1 or more years. The follow-up was by videoesophagram in 79%, upper endoscopy in 52%, and both in 48% of patients. Two patients underwent conversion from a Nissen to a Toupet for protracted dysphagia. A small recurrent hernia was found in 3 patients (4%) by upper endoscopy, but no patient has required reoperation. All recurrences developed after primary laparoscopic repair of a PEH (n = 2) or sliding hiatal hernia (n = 1). One recurrence was in a patient who had a Collis gastroplasty and a right relaxing incision; no adjunct procedures were performed in the other 2 patients.

DISCUSSION

A recurrent hiatal hernia is the most common form of anatomic failure after laparoscopic hiatal hernia repair and fundoplication.[1] Hernia recurrence is particularly common after laparoscopic PEH repair; the rate exceeds 50% at 5 years when objective studies such as barium swallow or upper endoscopy are done to evaluate the repair.[1,2] These recurrence rates are higher than those in historic reports with open repairs.[1,8] The explanation for the higher recurrence rate with laparoscopic repair is unclear, but theories include the lack of deep bites during crural closure with the use of laparoscopic suturing devices and reduced adhesions associated with a laparoscopic compared with an open procedure. However, an alternative explanation is that during laparoscopic repairs there may be an underappreciation of tension on the repair. This tension can come from 2 directions: axial tension related to esophageal shortening and lateral tension related to widely splayed crura that must be reapproximated as part of the repair. The consequences of tension on hernia recurrence are well documented at other sites including inguinal and ventral hernias.[9]

In an effort to reduce tension and improve outcomes with laparoscopic hiatal hernia repair, we adopted adjunct techniques to reduce tension when encountered. These techniques included a diaphragm relaxing incision or a wedge-fundectomy Collis gastroplasty. In this series, a crural relaxing incision was performed in 12% and a Collis gastroplasty in 28% of patients. These numbers increased to 21% and 45%, respectively, in those undergoing PEH repair. In part, these high numbers are related to the addition of patients undergoing reoperations when tension was likely a contributing factor to the initial failure, but also to the complexity of patients who are sent to a tertiary referral center.

When a relaxing incision was deemed necessary, it was most commonly performed on the right side. This is the easiest of the diaphragmatic relaxing incisions. If the right side relaxing incision was inadequate, or if the right crus

was too thin to allow a relaxing incision, then a left-sided diaphragmatic relaxing incision was used. To avoid phrenic nerve injury this incision was not placed radially; instead, it followed the inferior margin of the rib out laterally.[3,5] Large openings between the abdomen and thorax are well tolerated during laparoscopic surgery, and in the absence of an injury to lung parenchyma no chest tube or pleural drainage catheter was placed at the conclusion of the surgery. Symptomatic postoperative pleural effusions were managed with an ultrasound or CT-guided pigtail drain.

The most commonly encountered form of tension was related to a short esophagus. The existence and importance of esophageal shortening continues to be debated, but if present and unaddressed, it can place the repair under tension. Our practice was to add a Collis gastroplasty when there was less than 3 cm of intra-abdominal esophagus after mediastinal esophageal mobilization. We have found the wedge-fundectomy technique to be simple to perform and associated with few complications.[7] In this series, there was 1 patient with an esophageal leak related to the Collis staple line. This patient had chronic leukemia and poor healing, and the leak was treated with endoscopic stent placement. After a Collis gastroplasty, we routinely performed upper endoscopy at 3 months, and if esophagitis related to the gastroplasty was found, the patient was placed on acid suppression medication. We have not found the addition of a Collis gastroplasty to be associated with significant dysphagia.[7]

All patients had primary crural closure despite, in some cases, a massive hiatal opening. The crural closure was reinforced with an AlloMax biologic mesh graft placed posterior to the esophagus. Rarely, if sutures were placed anterior to the esophagus to prevent a "speed bump" deformity, the Allomax graft was placed completely around the esophagus. It has been our practice to routinely use mesh to reinforce the primary crural closure in patients with a large ($\geq$5 cm) sliding or paraesophageal hernia, those with thin or atrophic crural pillars, and in all patients undergoing a reoperation for recurrent hiatal hernia. Our rationale is that the crura lack fascia and are often thin in patients with a sizeable hiatal hernia. In addition, the diaphragm moves 15,000 to 20,000 times a day with respiration and contracts vigorously with coughing, sneezing, or vomiting. Finally, there is a natural pressure gradient between the chest and abdomen that encourages migration of intra-abdominal organs into the chest should a separation develop in the crural reapproximation.

The use of mesh at the hiatus remains controversial. Permanent synthetic mesh has been reported to reduce the frequency of hernia recurrence, but at the risk of mesh infection or erosion.[10] A variety of techniques have been reported for placement of the mesh. Some have placed it posterior to the esophagus; others create a "key-hole" for the esophagus within the mesh and reinforce the entire hiatus. There are also advocates for a "tension-free" crural repair similar to that described for inguinal hernia repairs.[10] This technique bridges the crura with mesh rather than attempting primary crural closure. An important fact about all synthetic mesh types is that they shrink or contract over time. When placed around the esophagus using the "key-hole" technique, this contraction can lead to significant dysphagia and mesh erosion. Bridging the crura with synthetic mesh has been associated with the highest risk for mesh erosion given the "sawing" motion of the esophagus over the mesh with each swallow.[11,12] Erosion of synthetic mesh into the esophagus is a devastating problem, often necessitating an esophagectomy. In the absence of erosion, the use of synthetic mesh has been associated with a significantly increased risk for some type of resection rather than a redo fundoplication during reoperative surgery.

An alternative to synthetic mesh is an absorbable or biologic mesh. These types of mesh may reduce the risk of erosion and cause less difficulty if a reoperation is necessary. There are several different types of absorbable mesh, but there are few data on the efficacy of these meshes. A report on the use of Vicryl (Ethicon) mesh and BioGlue (CryoLife) showed a 9.5% recurrence rate at a median follow-up of 14 months.[13] Another nonpermanent type of mesh is a biologic mesh. Biologic meshes come from human, bovine, or porcine sources, but all are acellular collagen matrices that support host fibroblast ingrowth and gradually incorporate into the native tissue. One of the early biologic meshes used at the hiatus was Surgisis, made from porcine intestinal submucosa. However, this mesh has fallen out of favor after a multi-institutional randomized trial using this mesh to reinforce the primary crural repair in patients with a PEH showed a hernia recurrence rate of more than 50% in both the Surgisis group and the nonmesh control group at 5 years.[2]

After the results of this trial, we abandoned Surgisis and began trying other mesh types, including the AlloMax Surgical Graft, for crural reinforcement during antireflux surgery or PEH repair. AlloMax is a non–cross-linked human dermal collagen matrix that supports cellular ingrowth and revascularization. It is sterile and virally inactivated and is much thinner than the porcine dermal grafts. In addition to using Allomax to reinforce the crural closure, we used Allomax pledgets for the primary crural closure. The pledgets were cut from the edges of the

7×10 cm piece of Allomax graft. Further, the Nissen stitch was an Allomax-pledgeted 2-0 Prolene (Ethicon) horizontal mattress suture. Consequently, there was no permanent pledget material or mesh in contact with the stomach or esophagus and we have had no erosions with the Allomax mesh.

Our study is limited in that it was retrospective and not all patients adhered to the prescribed follow-up. This could lead to an under-appreciation of the hernia recurrence rate, although there was nothing to indicate that patients who did not return were any different from those who completed follow-up. In addition, the median follow-up of 5 months in most patients is short, and with longer follow-up, more recurrent hernias may develop because there is known to be a steady increase in recurrence with length of follow-up, particularly after PEH repair.[14] In addition, in this study there was no comparison group in which we didn't use mesh reinforcement or adjunct techniques to reduce tension because we strongly believe that all of these are critical components to long-term successful repair of a hiatal hernia. Lastly, there was no comparison to other types of mesh in this series.

CONCLUSIONS

Mesh has been useful to reduce hernia recurrence rates at most sites in the body, and logically, it should be useful at the hiatus as well. However, the hiatus is unique in that there are 2 forms of tension that are applied against a hiatal hernia repair, and failure to address tension likely contributes to the documented high objective hernia recurrence rate, particularly after PEH repair. In this study we used crural relaxing incisions and a Collis gastroplasty when necessary to reduce tension, and AlloMax graft reinforcement of the primary crural closure in all patients. Our early results confirm the efficacy of this approach, with no erosions, few complications, and objective evidence of an intact repair in 96% of patients. Further follow-up will define the role of these techniques and of AlloMax graft for reinforcement of the primary crural closure during antireflux surgery or PEH repair.

Author Contributions

Study conception and design: DeMeester
Acquisition of data: Alicuben, Worrell

Analysis and interpretation of data: Alicuben, Worrell, DeMeester
Drafting of manuscript: Alicuben, Worrell, DeMeester
Critical revision: Alicuben, Worrell, DeMeester

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