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Hiatal hernia repair with mesh: a survey of SAGES members

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Abstract
Background Primary repair of large hiatal hernia is associated with a high recurrence rate. The use of mesh may reduce this recurrence rate. The indication for mesh use, the type of mesh to use, and the placement technique are controversial. A survey of surgeon practice was undertaken to obtain a better understanding of the controversies surrounding this clinical problem.
Methods A questionnaire on the technique and results of mesh hiatal herniorrhaphy was sent to 1,192 members of the Society of Gastrointestinal and Endoscopic Surgeons (SAGES).
Results There were 275 responses; 261 of these were analyzed. A total of 5,486 hiatal hernia repairs with mesh were reported; 77% and 23% were performed laparoscopically vs open, respectively. The most common indication for mesh usage was an increased size hiatal defect (46% of respondents). The most common mesh types were biomaterial (28%), polytetrafluoroethylene (25%), and polypropylene (21%). Suture anchorage was the most common fixation technique (56% of respondents). The findings showed a failure rate of 3%, a stricture rate of 0.2%, and an erosion rate of 0.3%. Biomaterial tended to be associated with failure, whereas nonabsorbable mesh tended to be associated with stricture and erosion.
Conclusions The use of mesh during hiatal hernia repair resulted in a reported recurrence rate which appeared to be lower than that obtained historically without mesh. No one mesh type was clearly superior in terms of avoiding failure and complication.

Keywords Hiatal hernia repair · Hiatal herniorrhaphy · Mesh · Recurrence · Gastroesophageal reflux disease · Paraesophageal hernia · Stricture · Erosion · Prosthetic · Biomaterial

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Repair of a hiatal defect with primary cruroplasty has been associated with a recurrence rate in the range of 10% to 20% or higher depending on the series and the definition of recurrence [1–11]. On the other hand, a growing body of literature consisting of both controlled [12–14] and retrospective [1, 15–25] data now supports the use of prosthetic material in the repair of large hiatal hernias, primarily because mesh use results in a lower recurrence rate. The evolution of hiatal hernia treatment thus appears to be following a course similar to that observed for the

treatment of ventral and inguinal hernias. Although the efficacy and durability of hiatal hernia repair generally have improved with prosthetic use, a number of issues have been raised regarding mesh repairs, such as the precise indication for mesh use, the type of mesh to use, and the optimal technique of mesh placement [13, 22]. In addition, despite growing concern about the incidence of mesh-associated complications at the hiatus [11, 26–30], the incidence of these complications is unknown. This report describes a survey of surgeon experience culled from an organization of gastrointestinal surgeons taken to estimate the complication rate associated with mesh use at the esophageal hiatus, and to obtain an appreciation of surgeon practice habits and attitudes toward such mesh usage.

Materials and methods

In 2006, a total of 1,192 questionnaires were ground-mailed to members of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES). The mailing list was a portion of the total SAGES membership (about 5,096 at that time) which allowed their address to be viewable in the members section of the SAGES Web site (www.sages.org). The questionnaire is shown in Fig. 1. Completed questionnaires were mailed back to the authors. The survey was anonymous unless the respondent elected to provide contact information on the questionnaire sheet. The survey responses were tabulated using Microsoft Excel (www.microsoft.com). Statistical testing was done with

Fig. 1 Questionnaire on hiatal hernia repair with mesh

1. How many hiatal hernias have you repaired with mesh reinforcement?
   Laparoscopic _____ Open _____

2. What is the hiatal hernia size threshold at which you decide to use mesh for the repair?
   Any _____ >3 cm _____ >5 cm _____ >8 cm _____ Other: _____

3. What mesh material do you utilize? Please specify the prosthesis trade name.
   Polypropylene (i.e., Prolene, Marlex) _____ How many _____
   Polytetrafluoroethylene (i.e., PTFE) _____ How many _____
   Biomaterial (i.e., Alloderm, Surgisis) _____ How many _____
   Other _____ How many _____

4. How do you routinely place the mesh?
   Inlay _____ How many _____
   Onlay _____ How many _____
   Anterior _____ How many _____
   Posterior _____ How many _____
   360° around esophagus _____ How many _____
   Partially around esophagus _____ How many _____
   Other _____ How many _____

5. What is used for anchorage? How are these anchorage devices placed?
   Staples _____ Technique of placement (i.e., multiple rows, spacing)
   Spiral Tacs _____ _____
   Sutures _____
   Other (specify) _____

6. What kind and how many complications have you seen?
   Strictures _____ Kind of mesh _____
   Erosion into… _____ Kind of mesh _____
   Failed repair _____ Kind of mesh _____ Technique _____
   Other _____ Kind of mesh _____

7. How many mesh infections have you seen?
   Primary infection _____
   Secondary infection due to _____
   Other _____

8. Have you seen complications from other surgeons? And if so, what kind and how many?
   Strictures _____ Kind of mesh _____
   Erosion into… _____ Kind of mesh _____
   Failed repair _____ Kind of mesh _____ Technique _____
   Other _____ Kind of mesh _____

9. If you are willing to discuss any of these complications via phone, please provide a phone number.

SAS, version 9.1.3 (www.sas.com). A p value less than 0.05 was considered significant.

Results

The 1,192 questionnaires mailed generated 275 responses (response rate, 23.1%). Of these 275 responses, 264 contained sufficient data for use in this report. The total number of mesh hiatal hernia repairs reported by this group of 264 surgeons was 5,486, which included 4,242 laparoscopic (77.3%) and 1,244 open (22.7%) repairs. The mean number of laparoscopic repairs per surgeon was 16 ± sd 51 (median, 3; range, 0–530), and the mean number of open repairs per surgeon was 5 ± sd 40 (median, 0; range, 0–500). The distribution of laparoscopic compared with open repairs among the surgeons is shown in Fig. 2. Not surprisingly, this distribution is skewed toward zero. Notably, approximately 75% of the surgeons did not perform any open repairs at all. The fraction of surgeons performing no laparoscopic repairs was approximately 33%. The fraction of surgeons performing >15 laparoscopic or open repairs was 24% and 3%, respectively. Viewed another way, 33 surgeons (12% of all) performed 75% of the laparoscopic repairs, while three surgeons (1% of all) performed 75% of the open repairs.

The indications reported for mesh utilization in hiatal hernia repair are given in Table 1. The most common indication (reported by about half of the respondents) was the size of the hiatal defect, with 5 cm being the most common threshold. About 10% of the respondents used mesh in all hiatal hernia repairs (i.e., routinely). The types of mesh used in all 5,486 repairs are shown in Fig. 3. The three most common mesh substances were biomaterial, polytetrafluoroethylene (PTFE), and polypropylene, each accounting for about one-fourth of the total.

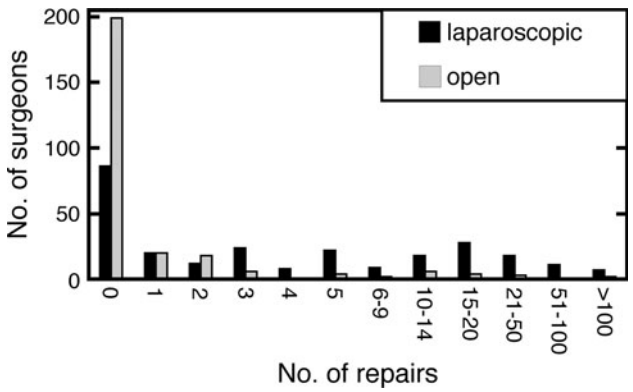

Fig. 2 Number of surgeons versus number of hiatal hernia repairs with mesh (open or laparoscopic approach)

Table 1 Indications for mesh usage in hiatal hernia repair

Mesh indication	Questionnaires[a] (%)
Size of defect	45.8
Defect > 3 cm	8.7
Defect > 5 cm	24.2
Defect > 8 cm	12.9
Tension on the crura	10.2
Routine (i.e., all repairs)	8.0
Paraesophageal hernia	5.7
Recurrent hernia	4.9
Poor crural tissue	4.6
Obesity	0.8
COPD	0.4
Elderly patient	0.4
No details	0.8
No indication given	37.5

COPD chronic obstructive pulmonary disease

[a] Values given as a percent of the 264 analyzed questionnaires. Percentages do not add up to 100 because respondents could enter more than one indication

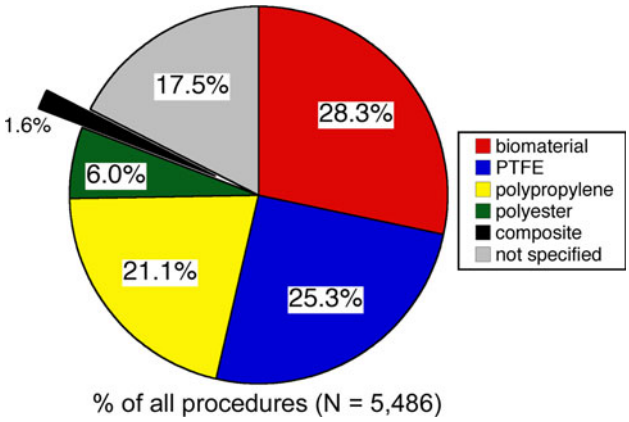

Fig. 3 Type of mesh used with respect to all procedures

The techniques of mesh placement for all procedures are summarized in Table 2. There are a variety of descriptors which overlap, such as onlay vs inlay, anterior vs posterior, and so forth. A common technique that emerged from Table 2 was on onlay (typically meaning application of the mesh onto the hiatal region after performance of a primary sutured cruroplasty), with the mesh positioned posterior to the esophagus but not completely surrounding it (i.e., noncircumferential). In approximately 10% of the cases, the mesh was positioned in a 360° (i.e., circumferential) configuration around the esophagus. The most common configuration used in cases with a noncircumferential mesh placement was a 270° mesh wrap (used by 43.8% of this subgroup). The techniques of mesh anchorage in hiatal

Table 2 Technique of mesh placement used in all hiatal hernia repairs ($n = 5,486$)

Placement technique	Procedures[a] (%)
Inlay	7.36
Onlay	39.1
Anterior	13.6
Posterior	34.2
U-shape	3.74
Circumferential mesh	9.86
Noncircumferential mesh	34.1

[a] Percentages do not add up to 100 because respondents could enter more than one placement technique

Table 3 Technique of mesh anchorage used, by surgeon ($n = 264$)

Anchorage technique	Surgeons[a] (%)
Sutures	56.4
Tacks	23.9
Staples	12.9
Fibrin glue adjunct	1.1
Not specified	30.3

[a] Percentages do not add up to 100 because respondents could enter more than one anchorage technique

hernia repair with respect to respondents are given in Table 3. Sutures were the most common choice, used by more than half of the respondents, followed by tacks.

The number of failures among the hiatal hernia repairs with mesh reported by all the respondents was 174, which yielded a failure rate of 3.17%. The number of failures with respect to the type of mesh used is shown in Fig. 4A. Biomaterial was the most common material associated with failure, found in 44% of the failed cases. Unfortunately, the mesh type was not specified by the respondents for 30% of the failures. The mesh-specific failure rates are shown in Fig. 4B. The highest rate was for biomaterial (5%), with the other failure rates at half the biomaterial rate or less. The mesh-specific failure rates shown in Fig. 4B were significantly different ($p < 0.001$, chi-square test). Although the questionnaire (Fig. 1) did not contain a specific query concerning the mechanism of repair failure, enough of the correspondents (about two-thirds) provided sufficient information on failure mechanisms to permit a description, which is shown in Fig. 5. The mechanisms of failure shown in Fig. 5 are those described by the respondents. The most common mechanism (23% of all failures) was loose hiatoplasty, followed closely by failure of mesh anchorage.

The respondents were asked to provide information on three specific complications of mesh hiatal hernia repair: infection, stricture, and erosion [22]. The overall incidence

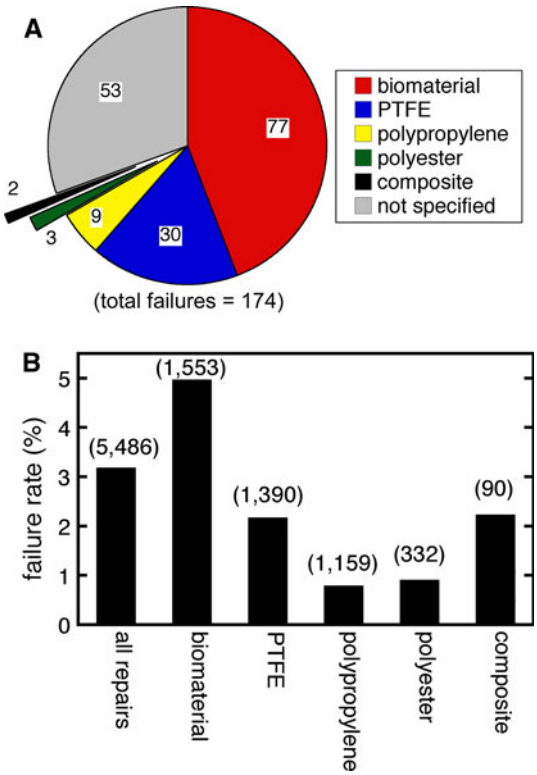

Fig. 4 **A** Failures of hiatal hernia repair with respect to type of mesh used. **B** Mesh-specific failure rates. The values in parentheses are the number of procedures performed with each mesh type

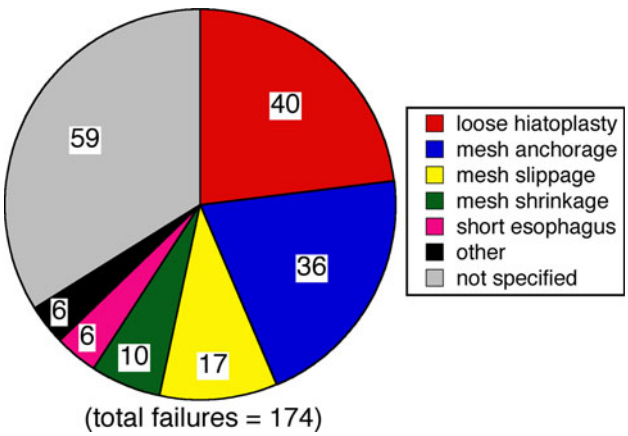

Fig. 5 Mechanism of failure after hiatal hernia repair with mesh

of mesh infection was 0.42% (i.e., 23 of 5,486 cases). The incidence of primary mesh infection (no identifiable cause present) was 0.26%, and the incidence of secondary mesh infection (identifiable cause present, such as perforation) was 0.16%. The mesh-specific rates of infection did not differ (data not shown). For strictures and erosions, the case totals were respectively 11 (0.20% incidence) and 15 (0.27% incidence), which yielded a combined incidence rate of 0.47%. The mesh-specific rates for stricture and

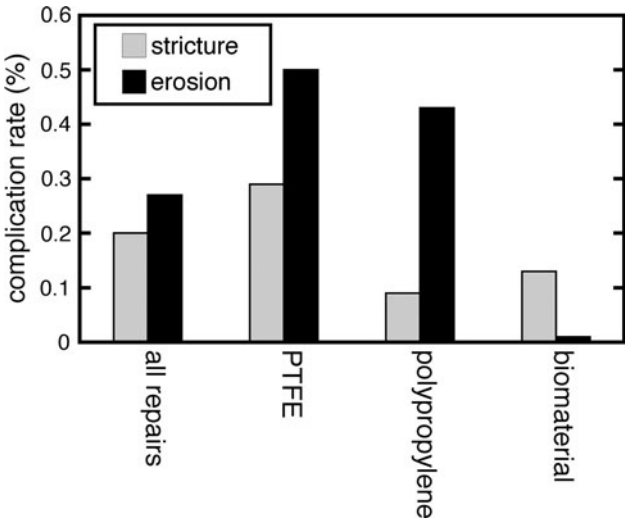

Fig. 6 Rate of stricture and erosion after hiatal hernia repair with mesh with respect to the type of mesh used

erosion are shown in Fig. 6. Although the bars might appear different, there was no significant difference among the stricture rate for repairs done with PTFE vs polypropylene vs biomaterial ($p = 0.65$, Fisher's exact test). The difference among the mesh-specific erosion rates, however, did reach statistical significance ($p = 0.0067$, Fisher's exact test), with PTFE having have the highest erosion rate (7 in 1,390 cases, 0.5%) and biomaterial having an erosion rate of zero.

The questionnaire also collected information on cases of complicated or failed mesh hiatal hernia repair referred to the respondents by other surgeons. The numbers of strictures, erosion, and failure of repair with respect to the type of mesh material used in these referred cases are shown in Table 4. Denominator information was not available for this referral data, so the rates for the events in Table 4 could not be calculated. In any event, the failures in Table 4 appeared to be reasonably distributed among the three specified mesh materials (biomaterial, polypropylene, and PTFE). Biomaterial was not found in any referred cases of erosion.

Table 4 Complications and failures referred to the questionnaire respondents by other surgeons

Mesh	Failures (*n*)	Strictures (*n*)	Erosion (*n*)
Biomaterial	18	6	0
Polypropylene	10	7	15
PTFE	12	1	6
Not specified	29	1	3
Totals	69	15	24

PTFE polytetrafluoroethylene

Discussion

Although the rationale for using prosthetic mesh to repair large defects of the esophageal hiatus is strengthening, a number of controversies are associated with such use, including the indication for mesh placement, the type of mesh to use, the configuration of the mesh with respect to the hiatus and esophagus, and how the mesh is anchored in place [11]. The described survey sought information on how these controversies were handled by surgeons who use mesh for hiatal hernia repair. Similar to other survey-based studies, a number of caveats to this study should be acknowledged. The retrospective data obtained from this survey all were self-reported by the respondents. No attempt was made to acquire independent verification of the numbers each surgeon gave. Therefore, the accuracy of the survey data is unknown. The definition of each term used in the survey (e.g., hiatal hernia, infection, failure) was left to the discretion of each respondent. This could have introduced imprecision into the results secondary to differing definitions. For instance, a complication reported as an erosion actually may have been an iatrogenic perforation interpreted as an erosion. In addition, the survey was not designed to discriminate among the multiple proprietary meshes typically present in each mesh category (e.g., Ultrapro™ [Ethicon, Inc., Somerville, NJ] vs Prolene™ [Ethicon, Inc., Somerville, NJ] vs Marlex™ [Bard Davol, Warwick, RI] in the polypropylene group), which would have eliminated the ability to differentiate among mesh subtypes. This survey also was not designed to question the relative need for mesh in hiatal hernia repair because the questionnaire did not seek comparative information on nonmesh repairs. The conclusions drawn from the survey data may be affected by the aforementioned caveats.

Despite these reservations, however, some trends in the survey data did emerge. Regarding the indication for mesh placement, the size of the hiatal defect (especially a 5 cm defect) won a plurality of opinion as the most common indication for mesh use, followed by tension on the sutured cruroplasty. But what exactly is meant by defect size, and how is it measured? Some authors have described an intraoperative area measurement of the hiatal defect, and then utilize a closure method which is based on this measurement [31]. Others have used the radial distance from the esophagus to a crural column [32], some have used preoperative hiatal area measurement using barium radiography [33], and yet others (including us) simply use the transverse dimension to describe defect size [12]. The survey was not designed to collect data on how the surgeons measured defect size.

One of the more controversial areas in mesh hiatal hernia repair is the type of mesh that should be used. For a perspective on this issue, the recurrence rate for inguinal

and ventral hernia repair generally has been lower with the use of prosthetic coverage (results not reviewed here); mesh now is commonly employed in the repair of inguinal and ventral defects in many developed countries. Unfortunately, mesh-related complications (e.g., infection, erosion, seroma, pain) have been a trade-off in this paradigm shift of abdominal wall hernia repair [34–38]. Mesh-related complications also afflict prosthesis-reinforced repair of the hiatal defect [27–30, 39]. Not surprisingly, and despite the data demonstrating reduced hernia recurrence, there is ongoing debate on whether mesh ever should be placed at the esophageal hiatus [26, 40], primarily because mesh-associated complications, although rare, can be devastating when they occur.

What then is the incidence of serious complications (i.e., infection, erosion, and stricture) associated with mesh use at the hiatus? To date, this topic primarily has been the concern of case reports and small series [20, 27–30], which have lacked a denominator through which an incidence could be calculated. In the present report, however, we have data that can, perhaps, approximate an incidence for the complications of infection, erosion, and stricture associated with the use of mesh in hiatal hernia repair. For all the mesh types grouped together, this rate was 2 to 4 patients per 1,000 for each complication. Calculation of mesh-specific complication rates, however, showed that no cases of erosion were associated with biomaterial. The incidence of stricture also appeared to be lower with biomaterial use, although this latter difference was not significant. Moreover, it appears that the use of PTFE was associated with a small but defined incidence of erosion and stricture at the esophageal hiatus. Until recently, PTFE (i.e., expanded PTFE [ePTFE]) was assumed to have benign behavior when apposed to hollow viscera [27, 29, 30, 37, 38].

Given these data on the association of stricture and erosion with the use of nonbiologic mesh at the esophageal hiatus, it might be concluded that the use nonbiologic mesh (e.g., polypropylene, ePTFE, polyester) at the esophageal hiatus should be abandoned in favor of biomaterial usage (e.g., cadaveric human skin, porcine intestinal submucosa, crosslinked collagen). Such a conclusion would be clouded by several issues. First, the survey data of this report cannot be verified, so this data can only approximate real-world results. Second, the publications of others [11, 27–30] describing an association of nonbiologic mesh with serious complications are mostly anecdotal, without denominator information. Third, the data of this report do not discriminate complications associated with the use of older-generation heavyweight permanent mesh from those associated with newer-generation lightweight coated permanent mesh. The latter likely is as efficacious in preventing hernia recurrence as the former, but with a more benign profile [41–43]. This is an emergent area of surgical technology. Finally, there is the issue of recurrence with biomaterial usage. Long-term animal studies have shown that biomaterials, for the most part, are resorbed after several months in situ [44, 45]. To date, good-quality long-term studies on biomaterial efficacy in abdominal wall surgery are not available; there has been a concern that hernia recurrence will be higher compared to rates obtained with permanent mesh [46, 47].

Our survey data indicated that biomaterial was associated with a 5% "failure" rate, which is statistically higher than the rates associated with permanent mesh, which ranged from 1% to 2%. For comparison, a 2006 trial of paraesophageal hernia repair with or without biomaterial (porcine intestinal submucosa) documented recurrence rates of 9% and 24%, respectively, after a follow-up period limited to 6 months [13]. The recurrence rate in the mesh arm of a similar trial that used PTFE was zero [12]. So at this point in the evolution of hiatal hernia surgery, there may be a trade-off in the choice of prosthetic mesh for the repair: choose permanent mesh, and there is the risk of erosion; choose biologic mesh, and there is the risk of recurrence. Good scientific data to support a specific choice of mesh for the repair currently are lacking. In the authors' practice, a mesh hiatal hernia repair is performed with circumferential placement of a lightweight coated nonbiologic mesh (e.g., Parietex™ [Covidien Autosuture, Mansfield, MA], Ultrapro™) anchored to the diaphragm and crural bundles [48]. Great care is taken to keep the mesh closely apposed to the crural bundles and off of the esophagus. We have not seen any cases of stricture or erosion in our practice with this technique. We suggest that at least some of the strictures and erosions associated with nonbiologic mesh have resulted from placement of the mesh too close to the esophagus. Of course, we cannot draw a valid conclusion about the relative safety of our technique because we do not have the requisite number of patients, which would be several thousand.

For anchorage of the mesh to the crural bundles and diaphragm, suturing was the most common technique, followed by tacking and stapling. A rare but potentially fatal complication with mesh-reinforced hiatal hernia repair that has arisen cardiac injury and tamponade [49–51]. The cause of this complication typically is ascribed to placement of an anchoring device (suture, tack, or staple) through the diaphragm and into the heart. A search through the Food and Drug Administration's MAUDE Web site (Manufacturer and User Facility Device Experience, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM) in June 2009 revealed five cases of tamponade associated with use of the helical tacker during mesh repair of the hiatus (search details not shown). Although

the helical tacker has been implicated in this complication [52], it seems reasonable to avoid deploying any anchoring device into the diaphragm in the region of the cardiac impulse during mesh-reinforced hiatal hernia repair.

It is usually at this point in the Discussion section of a paper on retrospective clinical data that the authors will make a plea for a randomized controlled trial to answer the questions that their manuscript has raised. Not surprisingly, this sequence of events also applies to this article. A well-designed trial could address a number of questions that this and other reports have raised regarding hiatal hernia repair with mesh, such as what type of mesh to use, how it should be configured around the esophagus, how it should be anchored, and so forth. Unfortunately, the reality of the situation is that an adequately-powered clinical trial involving a surgical procedure is difficult and expensive. Thus, such trials rarely are accomplished. Therefore, as surgeons, we are left to generate recommendations and guidelines based mostly on retrospective experience and not on prospective data.

At this stage, no firm recommendations on the use of mesh at the esophageal hiatus can be made. There are a number of suggestions and/or opinions that we would deliver, though. The message with the strongest support is that the recurrence rate for hiatal herniorrhaphy with a "large" defect is lower with mesh use than with suture repair. Both biologic and nonbiologic mesh are efficacious in this regard, though there may be subtleties within differing rates of recurrence, stricture, or erosion. The majority of surgeons who use mesh prefer a noncircumferential placement with suture anchorage, but others have had excellent results with different placement techniques. This area of surgery is undergoing evolution, including the development of safer and more efficacious mesh material. Solid recommendations about mesh hiatal herniorrhaphy will need to await such developments and the accumulation of more data.

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