



Mesh placement for hiatal hernia repair: can we solve the controversy?

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Abstract: Hiatal hernia is a common disorder characterized by the protrusion of abdominal structures other than esophagus in thoracic cavity. Large hiatal hernias, also called paraesophageal hernia (PEH), contain a large part of the stomach, including other organs, into the mediastinum. The Guidelines of Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) recommends that patients' age and comorbidities must be considered before to decide the routine elective repair of asymptomatic PEH. Nevertheless, truly asymptomatic PEH are rare and post-prandial chest fullness or shortness of breath are often the symptoms present instead of heartburn and reflux. The complete reduction of the mediastinal sac with a wide esophageal mobilization and a tension-free hiatal closure are necessary for a correct PEH repair. However, a tension-free cruroplasty is not easy, with a recurrence rate of up to 42%. The introduction of synthetic mesh (SM) reinforcement, could ameliorate the results and several studies have reported lower recurrence rates with its use. However, also severe complications have been reported and biological meshes (BMs) have been proposed as an alternative although with conflicting results regarding efficacy. On the other hand, several studies describe better clinical results on long term follow-up than expected even with a high radiological recurrence rate.

Keywords: Hiatal hernia; biological mesh (BM); nonabsorbable mesh; polytetrafluoroethylene (PTFE); polypropylene (PP)

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Introduction

Guidelines for the Management of Hiatal Hernia published by the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) (1) describe hiatal hernia as a common disorder characterized by the protrusion of abdominal structures other than esophagus into the thoracic cavity. Anatomic criteria permit categorization into four subtypes. Around 95% of all hiatal hernias are type I. Although only type II is pure paraesophageal hernia (PEH), types III and IV are also referred to as PEH and are becoming increasingly more common with the aging of

the population. Over 90% of large hiatal hernias are type III hernias, with a large part of the stomach herniating into the mediastinum (2). The S.A.G.E.S guidelines recommend that patients' age and comorbidities be considered before routine elective repair of asymptomatic PEH is decided. Nevertheless, patients with truly asymptomatic PEH are rare. Heartburn and reflux are common in less severe stages while post-prandial chest fullness or shortness of breath are frequent in patients with larger hernias (2).

Correct PEH repair involves complete reduction of the mediastinal sac with a wide esophageal mobilization and a tension-free hiatal closure (3). However, a tension-free

cruroplasty is not easy, and recurrence has been reported in up to 42% of cases (4). In an effort to lower recurrence rates, Kuster and Gilroy introduced synthetic mesh (SM) reinforcement in 1993 (5) and several studies have since reported a decrease in recurrence rates with its use (6,7). Nevertheless, severe complications have also been reported (8-10) and biological mesh (BM) has been proposed as an alternative. Results regarding the efficacy of mesh, however, are conflicting (11). While long-term clinical results are good, several studies (12-14) have reported a high radiological recurrence rate.

Recurrence of PEH and influencing factors

The immediate clinical outcome of laparoscopic PEH repair is highly satisfactory (15). However, when compared with the open approach the recurrence rate is higher than expected at midterm follow-up (4,15). In 2000, Hashemi *et al.* (4) reported an objective recurrence rate (determined by videoesophagram) of 42% after laparoscopic repair of PEH compared with 15% after open repair. One decade later, with the introduction of absorbable mesh reinforcement in 84% of patients and Collis gastroplasty in 40% of patients, they reported a reduction in the hernia recurrence rate similar to that seen with the open approach (16). Several authors have analysed the possible factors influencing the hernia recurrence rate after laparoscopic PEH repair. One reason for failure of the hiatal repair is tension in the lateral portions of the diaphragm near the crura after approaching the pillars of a particularly wide hiatus (15). However, the size of the hernia is not the only factor. The structure of the pillars is also an important anatomical element for the genesis of failure (17). The use of mesh may therefore provide better results because it reinforces hernia repair.

Another aspect influencing the failure of hiatal repair is the length of the esophagus. Laparoscopic pneumoperitoneum elevates the diaphragm and can give surgeons the impression of more intra-abdominal esophagus than there really will be once the diaphragm returns to its normal position with deflation of the pneumoperitoneum (16). In addition, it can be complex to precisely determine the gastroesophageal junction in chronic herniation of proximal stomach (16). In 1957, Collis described the technique for lengthening the esophagus. Currently, the most popular adapted technique creates the gastroplasty tube by excising a wedge of the fundus (18).

The role of the short esophagus in hernia recurrence has been evaluated by several authors, such as Morino *et al.* (19). In a series of 65 patients submitted to elective laparoscopic repair of large hiatal hernia they found 14 patients had primary closure, 37 received a mesh, and 14 underwent a Collis-Nissen gastroplasty. The recurrence rate was 35% in the mesh group, considerably lower than the 77% in the primary closure group. No recurrences were observed in the Collis-Nissen group, even though a case of distal esophagus perforation requiring esophagectomy and posterior esophagocoloplasty was described in this group. The authors recommend intraoperative evaluation once the hernia dissection has been performed because the correct preoperative diagnosis of a short esophagus is extremely difficult. They also recommend an intraoperative endoscopic evaluation of the esophagogastric junction to decide whether or not Collis-Nissen gastroplasty is required (19).

When should a mesh be placed?

The management of paraesophageal hernias continues to spark controversy. In the last decade, at least 24 systematic reviews and meta-analysis on PEH repair have been published but only four randomized clinical trials (RCTs) have compared PEH repair with and without mesh (see *Table 1*). One of these RCTs is the trial of Frantzides *et al.* (6), where the authors compared the laparoscopic repair of hiatal hernia >8 cm with and without polytetrafluoroethylene (PTFE) mesh reinforcement. They reported a recurrence rate of 0/36 *vs.* 8/36 (22%), respectively, at a median follow-up of 2.5 years. The meta-analysis of Antoniou *et al.* (23), that included RCTs of Frantzides (6), Granderath (20) and Oelschlager (24), also found a lower incidence of recurrence with the use of mesh. These results appeared to provide a high level of evidence for the use of mesh in hiatal hernia repair. Nevertheless, the follow-up of these studies did not allow conclusions to be drawn regarding the long-term effect. In addition, after a follow-up of more than 4 years, the randomized study of Oelschlager (21) observed no differences in recurrence rates between patients receiving primary repair and those receiving mesh reinforcement. However, we must take into account that while Oelschlager (21,24) used BM, Frantzides (6) and Granderath (20) used SM, and no long-term results have yet been published. A fourth randomized study by Watson *et al.* (22,25) compared the use of absorbable mesh, nonabsorbable mesh, and primary suture in 126 patients. After a follow-up of only

Table 1 Randomized clinical trials comparing PEH repair with and without mesh

Author/year	Mesh group (N)	Suture group (N)	Mesh type	Mean follow-up (months)	Recurrence rate		Reoperation rate	
					Mesh	Suture	Mesh	Suture
Frantziades/2002, (6)	36	36	SM	40	0	22%	0	13.8%
Granderath/2005, (20)	50	50	SM	12	8%	26%	8%	NR
Oelschlager/2011, (21)	57	51	BM	58	46%	41%	0	3.5%
Watson/2019, (22)	39 (SM)/35(BM)	33	SM/BM	60	42.9% (SM)/56.7% (BM)	39.3%	13% (SM)/ 11% (BM)	15%

PEH, paraesophageal hernia; SM, synthetic mesh; BM, biological mesh; NR, not reported.

Table 2 Systematic reviews and meta-analysis comparing mesh *vs.* suture

Author/year	Studies included	Type of studies	Number patients		Follow-up (months)	Recurrence		Mesh related complications
			Mesh	No mesh		Mesh	No mesh	
Antoniou/2012, (23)	3	3 RCT	131	136	6/12	5.8%	24.3%	–
Furnée/2013, (28)	26	3 RCT, 16 ChS, 7 C-C	924	340	25	14.6%	26.3%	–
Müller-Stich/2015, (29)	12	3 RCT, 9 OCS	328	310	34	12.1%	20.5%	1.9%
Antoniou/2015, (30)	5	2 RCT, 1 P, 2 R	161	156	6/12	3.7%	16.7%	–
Hudy/2016, (27)	9	4 RCT, 2 P, 3 R	366	310	–	14.5%	24.5%	–
Tam/2016, (14)	13	3 RCT, 4 P, 4 R, 2 O	673	521	–	13%	24%	–
Memon/2016, (31)	4	4 RCT	226	180	ND	16.3%	27.5%	–
Zhang/2017, (32)	11	4 RCT, 4 P, 3 R	719	755	ND	9.4%	2.6%	–
Sathasivam/2019, (11)	9	4 RCT, 5 O	517	425	ND	OR: 0.48 P<0.05 favoring mesh group		–

OR, odds ratio; NOS, Ottawa Newcastle score; OCS, observational clinical studies; RCT, randomized clinical trial; P, prospective; R, retrospective; O, observational; ChS, cohort study; C-C, case-control; ND, not determined.

12 months, they observed that overall outcomes after sutured repair and mesh repair were similar. In another study of note, Zaninotto *et al.* (26) performed a follow up of 64 months, evaluating patients who underwent mesh surgery by endoscopy every 2 years. They observed that all recurrences occurred within the first eight postoperative months.

In a meta-analysis in 2016, Huddy *et al.* (27) evaluated the results obtained in patients following suture repair (SR), BM or SM repair. They also carried out a survey of surgeons to establish a perspective of current practice. They concluded that both BM and SM reduce the rate of recurrence compared to suture, but they found insufficient

evidence regarding the optimum technique if risks and benefits were considered. Other meta-analyses offer similar conclusions regarding the recurrence rate comparing mesh repair *vs.* suture (see *Table 2*).

Due to the lack of convincing RCTs, expert opinion (33,34) was requested to answer questions concerning the use of mesh in PEH repair. Using a Delphi consensus process, Bonrath and Grantcharov (33) attempted to generate information on current practices and highlight key topics of disagreement based on the opinions from a panel of European experts from high-volume centers regarding foregut surgery. Eighteen of the 27 initially identified experts participated throughout the entire consensus

process. Consensus was a majority of at least two-thirds of the participants. However, no consensus was reached regarding the importance of mesh use for PEH repair. Only 7 panellists considered the role of mesh reinforcement of the hiatus “important” or “very important”. Nevertheless, the majority (n: 12) felt that mesh use was relevant under specific circumstances. The size of the hiatal defect and the quality of the crura were the factors influencing the decision for mesh use for most individuals who used mesh (10/14). In the same year, Furnée *et al.* (35) published the results of a web-based questionnaire completed by 165 European upper gastrointestinal (GI) surgeons identified through the European Association for Endoscopic Surgery. The majority of respondents (77.6%, 128 respondents) used mesh selectively, depending on the size of the hiatus, the tension on the sutured cruroplasty, or both.

Which type of mesh should I use?

The characteristics of the mesh used should be taken into consideration. Many different materials and configurations of mesh are available, but consensus regarding the best option is lacking. The Delphi process of Bonrath and Grantcharov (33) did not reach a consensus regarding the type of mesh. Of the 165 surgeons who completed the questionnaire of Furnée *et al.* (35), 154 reported that they used some type of mesh in hiatal hernia repair (routinely or selectively). The most frequently used types were polypropylene (PP) by 52.6%, followed by expanded PTFE (ePTFE) by 32% and biomesh by 27.9%. The option for the majority was thus an SM. This result is quite different from the results of the survey among SAGES members (36). American surgeons preferred the absorbable type of mesh (67%).

When analyzing the results of RCTs according to the type of mesh favoured, Oelschlager (21) did not observe significantly lower recurrence rates after a long-term follow-up with the use of BM reinforcement. In their review of the literature, Panait *et al.* (37) reached the conclusion that definitive evidence is still lacking to support the use of biologic or bioabsorbable materials to reinforce hiatal closure in the cure of PEH.

Frantzides (6) and Granderath (20) used SM but their long-term results have not yet been published. Granderath (38), however, published their long-term experience with circular PP mesh reinforcement in a series of 33 patients who underwent laparoscopic refundoplication, and after a follow-up of 60 months, the

radiological study revealed a recurrence rate of 6%.

Watson *et al.*'s randomized study (25) comparing absorbable mesh, nonabsorbable mesh, and primary suture did not identify significant differences in the recurrence rate between groups (23.1% after SR, 30.8% after absorbable mesh, and 12.8% after nonabsorbable mesh). There is no consensus regarding the configuration of the mesh employed (39) but the options seem to have narrowed down somewhat. Furnée *et al.* (35) stated that at present, the most frequently used configuration is the rectangular or “U” shape, positioned posteriorly to the esophagus.

What about complications with mesh implants?

In 2009, Stadlhuber *et al.* (40) published a series of 28 patients with mesh-related complications after hiatal hernia repair. Most patients (23 cases) required mesh removal due to intraluminal erosion in 17 cases. Esophagectomy was required in six patients, while another three patients had a partial or total gastrectomy.

For the time being, we cannot establish the exact rate of mesh-associated complications. Müller-Stich *et al.* (29) analysed their incidence through a systematic review including 124 studies (19 case reports) with a total of 5,499 patients submitted to laparoscopic PEH repair with mesh cruroplasty. They reported 91 (1.9%) mesh-associated complications. The main causes were erosions of the esophagus, the stomach, or the aorta, followed by stenoses and cardiac tamponades. Four fatal complications occurred, all originating from cardiac tamponades due to the staples used for the fixation of the mesh to the hiatus. PP and PTFE were the most frequently used materials (71.5% of patients), followed by BM. Complication rates were 0.8% for PP mesh, 2.5% for PTFE mesh and 1.3% for BM. These results are similar to those observed in two other consecutive patient series where the complication rates published were about 1% (41,42). This incidence may seem low, but the implications are serious. We should take into account that we do not know the real incidence of secondary complications due to migration and erosion because most studies do not include long-term results. However, data available to date seems that around 90% of mesh-related complications occur within two years after surgery (29,39,43).

Müller-Stich *et al.* (29) described a similar incidence of mesh-related complications for BM and SM, but they did not specify the type of complications due to each type of mesh (BM *vs.* SM). Serious complications are more

Table 3 Follow-up results: Rx recurrence vs. reoperation

Author/year	N	Follow-up (months)	Rx recurrence	Symptoms	Reoperation of recurrence
Oelschlager <i>et al.</i> (47)	72	58	57%	–	3%
Aly <i>et al.</i> (48)	100	nr	23%	NR	4%
Jobe <i>et al.</i> (49)	52	39	32%	19%	4%
Luketich <i>et al.</i> (50)	662	30	15.7%	11%	3%
Dallemagne <i>et al.</i> (13)	85	118	66%	15.7%	2%
Zaninotto <i>et al.</i> (26)	54	71	20%	22%	9%
Targarona <i>et al.</i> (12)	77	108	46%	22%	3.9%

NR, not reported; Rx, radiological.

commonly associated with synthetic materials and BM is suggested as an alternative. A survey among SAGES members published by Frantzides *et al.* (44)—and including a total of 5486 PEH repairs—observed that biomaterial tended to be associated with failure while SM tended to be associated with stricture and erosion. PP mesh has the propensity to erode the surrounding tissue over an uncertain period ranging from days to years. It is also known to induce a significant fibrotic reaction, possibly reducing recurrence rates but carrying the risk of complications related to fibrosis of the lower esophagus. PTFE, on the other hand, may lead to high dysphagia rates (33,45). The shape of the mesh must also be considered. Five years ago, the key-hole shape was still used by around 25% of European surgeons (35) compared to 10% of US surgeons according to a report by Frantzides *et al.* in 2010 (44). The risk of mesh contracting and causing stricture at the gastroesophageal junction is a strong argument against circular positioning (31). Chen *et al.* (46) initially used a keyhole-shaped mesh, but within 16 months of the operation, three of nine patients required reoperation because the mesh migrated into the esophagus. They thus switched to a “U”-shaped composite mesh and reported no complications after a follow-up of more than 5 years.

Impact on quality of life (QOL)

Even if the recurrence rate is high, the incidence of patients requiring surgery is low (see *Table 3*). Zehetner *et al.* (16) observed that no patients with a recurrent hernia had a serious or catastrophic complication related to the recurrence, suggesting that the natural history of a small recurrent hernia is different from that of the original intrathoracic stomach. Findings from another author

support this concept. In their study with a mean follow-up of 11 years, White *et al.* (51) found 10 hernia recurrences in 31 patients, but only 20% of them were true PEH recurrences and reoperation was necessary only for two patients. Dallemagne (13), with a median follow-up of 118 months, reported a 2% reoperation rate despite an objective recurrence rate of 66%. Their findings are comparable data to those of Targarona *et al.* (12) who reported a recurrence rate of 46.5% and a reoperation rate of 3.9%.

All authors seem to agree that no surgery is required in cases of recurrence if the patient is asymptomatic. In the European expert consensus published by Bonrath *et al.* (33) symptomatic recurrence was the only diagnostic factor that achieved agreement for revision surgery. Armijo *et al.* (52) analyzed a series of 322 patients submitted to PEH repair in order to identify factors that can predict hiatal hernia recurrence. Hernia recurrence was defined as a maximal vertical height of a hernia ≥ 2 cm above the diaphragm detected by an upper GI contrast study. With a mean follow-up of 20 months, 15.5% of patients had an objective hiatal hernia recurrence, but only 6% of them had a large hiatal hernia (≥ 5 cm) and required a redo hiatal hernia repair. The overall rate of reoperation was 1%.

Interest also focuses on QOL. In their long-term follow-up series, Targarona *et al.* (12) reported a mean gastrointestinal quality of life index (GIQLI) of 111 (range, 59–137) for patients with hiatal recurrence, comparable to that obtained for non-recurrence groups. The results were comparable to those reported by Dallemagne (13). Oelschlager *et al.* (21,47) analyzed long-term clinical data from the group of patients enrolled in a previously published RCT comparing laparoscopic PEH repair with or without using BM reinforcement. They observed that although radiologic recurrences were frequent, they did not

appear to impact on QOL or cause clinical symptoms. They appeared to remain well-controlled, with the exception of hiatal hernias ≥ 40 mm producing a modest increase in heartburn. Patient satisfaction was high, and the need for reoperation was low. PEH repair with or without BM did not seem to influence QOL. Koetje *et al.* (53) also analyzed QOL outcomes from their previous published RCT (25), comparing sutures versus repair with BM versus SM. With a follow-up of two years in 72.2% of patients, they observed a significant improvement in QOL, measured by SF-36, with no significant differences between groups.

Conclusions

Since the first data comparing primary suture *vs.* mesh reinforcement in laparoscopic PEH repair were published around 20 years ago, we continue to ask the same questions: whether to perform hiatoplasty with simple interrupted sutures or with prosthetic material, and if we use a mesh, what material and what shape are the most appropriate.

The heterogeneity of data hinders the interpretation of results. In a systematic review including 26 studies, Furnée *et al.* (28) observed that only 50% of studies reported the definition of large hiatal herniation and only the 19% of studies used the same definition. The wide variety of materials and shape of the mesh used adds even more heterogeneity.

In conclusion, consensus about the type of mesh continues to be elusive and we clearly need a higher level of evidence to address the controversy. In the meantime, it seems that mesh reinforcement can effectively reduce the hernia recurrence rate. Mesh-associated complications are few, but because they are serious most experts recommend mesh use only in specific circumstances, particularly those in relation to the size of the hiatal defect and the quality of the crura.

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