Expert Commentary: Mesh Reinforcement of Hiatal Closure

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Introduction

Laparoscopic paraesophageal hernia (PEH) repair has posed a challenge to surgeons ever since Cuschieri reported the first case in 1992 [1]. To this day, it remains a technically demanding procedure that requires advanced training and expertise [2].

The principles of PEH repair, whether laparoscopic or open, involve primary closure of the hiatus around the esophagus after complete reduction of the hernia sac. However, this repair is associated with a high failure rate, which has led surgeons to use prosthetic graft materials to reinforce the hiatal closure. This approach was extrapolated from success with tension-free mesh repairs of other types of hernias, such as abdominal wall defects. Multiple variations to the traditional PEH repair have been tried, with a view to refine the technique and reduce the risk of recurrence.

Attempts at crural reinforcement date back almost 100 years. Hedblom et al. first used autologous fascia lata in 1925 to buttress the crural closure [3, 4]. Later, prosthetic materials such as tantalum [5], polyvinyl formaldehyde sponge [6], and polytetrafluoroethylene (PTFE) [7] were introduced as reinforcement materials for use at the hiatus. Currently, several different types of prosthetics, in a wide range of materials and sizes, are available for this purpose. Regardless of approach, however, the recurrence rate remains between 20–59% at 5 years [8–12]. For the purpose of this report, we will use the term "mesh" to describe these materials used to support

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the hiatal closure, although some of these products are solid sheets of material with various surfaces designed to promote or discourage ingrowth, while others are truly mesh with various weights and pore sizes.

Despite the high recurrence rate, most recurrences are asymptomatic and infrequently require a repeat operation [13–15]. Moreover, reported sequelae of the use of synthetic materials near the esophagus are not inconsequential and include erosion, perforation, obstruction, and increased risk of major complications at revisional surgery. Bioabsorbable and bioprosthetic meshes seem to be safer than synthetic meshes at the hiatus, but are considerably more costly and may be associated with a higher risk for delayed recurrences.

In this chapter, we will review the literature comparing outcomes of hiatal mesh reinforcement to simple closure during laparoscopic paraesophageal hernia repair.

Synthetic (Nonabsorbable) Mesh

Types

Polypropylene, polytetrafluoroethylene (PTFE), and polypropylene with covalently bonded titanized surface (Timesh ®) are types of synthetic mesh that are commonly used for this purpose.

Impact on Recurrence

Synthetic mesh reinforcement seems to reduce at least short-term recurrences of PEH compared to primary closure alone.

During the 1990s, multiple small series were published regarding the use of synthetic mesh reinforcement during paraesophageal hernia repair [16–19]. These reports were quite heterogeneous, with each group reporting a different technique for reinforcing the hiatus with mesh and each using different materials. These were small case series (n = 1–5), and follow-up was limited to 3–6 months. There were no mesh-related complications reported, possibly due to the small number of patients and short follow-up.

Carlson MA et al. [20] reported the very first randomized controlled trial (RCT) of laparoscopic paraesophageal hernia repair with prosthetic reinforcement [20]. These authors randomized 31 patients to posterior cruroplasty vs cruroplasty with mesh reinforcement using polytetrafluoroethylene (PTFE). The mesh was used as onlay reinforcement in a keyhole fashion to accommodate the esophagus. All patients underwent an esophagogastroduodenoscopy (EGD) and esophagogram at 3 months after surgery and every 6 months thereafter, with a median follow-up ranging between 12 and 36 months. No recurrences were reported in the mesh group; three recurrences (18.8%) were reported in the cruroplasty-alone group. Of these, two underwent repeat operative repair for symptoms. Unfortunately, perioperative

symptoms and quality of life were not reported in either group, and the definition of "recurrence" was not described.

Since this study, there have been multiple RCTs comparing laparoscopic hiatal hernia repair with mesh to simple closure of the hiatus (Table 24.1). Many of these reported reduced recurrence rates with synthetic mesh and an increased need for reoperation for symptomatic recurrence in patients repaired without mesh [18, 21]. The follow-up intervals in these studies ranges from 6 to 36 months.

Cost

While very few trials report cost of repair with synthetic mesh versus primary closure, use of mesh is logically more costly than primary closure alone. The mesh itself has an inherent cost, and the additional operating room time needed to place the mesh after primary crural closure must be factored in as well. In one study, an additional cost of $1050 USD was estimated with the use of PTFE when compared to primary closure [20]. Another report found use of PTFE for hiatal reinforcement increased case costs by $960+/−70 USD [22]. The additional cost for the mesh techniques needs to be balanced against the substantial cost of reoperation for a symptomatic recurrence. These data are not available.

Synthetic Nonabsorbable Mesh-Related Complications

Several types of complications have been described following crural reinforcement with synthetic mesh during paraesophageal hernia repair. Bleeding, stricture, and erosion of mesh into the stomach or esophagus (Figs. 24.1 and 24.2) are the most commonly reported [21, 23, 24].

Esophageal stenosis causing dysphagia is an oft-described sequela of using synthetic nonabsorbable mesh at the hiatus. These cases frequently require either operative or endoscopic intervention to treat the dysphagia. If the mesh can be removed endoscopically, the resulting stricture may be dilated, potentially avoiding operative intervention. If reoperation is necessary, however, the risk of partial esophagectomy or gastrectomy is high [16, 25–31]. One publication reported 20 cases of mesh-related complications after laparoscopic paraesophageal hernia repair, 8 involving polypropylene and 12 involving PTFE. The complications included mesh erosion in 12 patients and dense fibrosis around the esophagus in the remaining 8, all causing significant dysphagia. Only two of these patients were managed non-operatively [32]. The remaining patients required operations ranging from laparoscopic retrieval of mesh to esophagectomy.

All available RCTs comparing permanent synthetic hiatal mesh to absorbable mesh or no mesh have had short follow-up durations (12–36 months), which may explain the low rate of reported mesh-related complications in these trials. In a recent survey of European surgeons using synthetic mesh for hiatal reinforcement, 523 respondents reported encountering mesh complications at least once in their

Table 24.1 Randomized controlled trials, systematic reviews, and meta-analyses comparing paraesophageal hernia repair with mesh to simple closure of the hiatus

Authors	Year	Type	Inclusion criteria	Exclusion criteria	Mesh used	N	Follow-up	QoL/need for reoperation	Recurrence detection method	Outcomes
Carlson et al.	1999	RCT	Defects >8 cm. Lap PEH with mesh vs no mesh	Defects <8 cm	PTFE	31	12–36 m	NR.	EGD. Esophagogram.	Decreased recurrence with mesh. No mesh-related complication.
Frantzides et al.	2002	RCT	Lap PEH with mesh vs no mesh		PTFE	72	12 m	QoL = NR. Reoperation: 5/8 patients (no mesh group).	EGD. Esophagogram.	Decreased recurrence with mesh. No mesh-related complications.
Graderath et al.	2005	RCT	Lap PEH with mesh vs no mesh	Poor esophageal motility	Polypropylene	100	12 m	QoL = NR. Reoperation: 4/4 (no mesh group).	EGD. Barium swallow.	Decreased recurrence with mesh. More dysphagia with mesh at 1 week,6 weeks, and 3 months.
Oelschlager et al.	2006	RCT	Lap PEH repair with biologic mesh vs no mesh	Recurrence, previous gastric surgery, emergency surgery	Surgisis	108	6 m	QoL = both significantly improved (mesh>none mesh). Reoperation:NA.	UGI series.	Decreased short-term recurrence with mesh. No mesh-related complications.
Oelschlager et al.	2011	RCT-FU	5 years F/u on RCT from 2006		Surgisis	72	5 ys	QoL = no difference. Reoperation: 2/20 no mesh group & 0/14 mesh group.	UGI series.	No difference. No difference in complications.
Antoniou et al.	2012	MA	RCT mesh vs no mesh	None	Variety	267(3 RCTs)	6–12 m	NR.	EGD. Barium swallow.	Decreased recurrence with mesh. Possible more dysphagia with mesh repair.

Furnee et al.	2013	SR	Lap PEH repair with mesh	Studies with <10 pt., emergency surgery	Biomesh and polypropylene	924 (26 study)	25 m	NR.	N/a.	Decreased in short term. Similar long-term recurrence. 0.2% esophageal erosion and 0.5% extensive mesh-related fibrosis.
Watson et al.	2014	RCT	Cruroplasty vs absorbable vs nonabsorbable mesh		Surgisis and Timesh	126	12 m	QoL = NR. Reopration = 0/5.	EGD. Barium swallow.	No difference in recurrence. No difference in complications.
Antoniou et al.	2015	MA	Biologic mesh vs cruroplasty	If no specific f/u modality	Biologic	295(5 studies)	12–36 m	NR.	EGD. Barium swallow.	Decreased short-term recurrence with mesh. No difference in long-term recurrence. Complications not reported.
Koetji et al.	2015	RCT	Cruroplasty vs absorbable vs nonabsorbable		Surgisis and Timesh	126	24 m	QoL = no difference. Reoperation: NR.	EGD. Barium swallow.	No difference in QoL or recurrence. Complications not reported.
Memon et al.	2016	MA	RCTs only, LAP PEH repair with mesh and no mesh	Non randomized reports and emergency cases	Variety	406(4 studies)	6 m	QoL = NR. Reoperation: (OR 3.73) in favor of mesh group	EGD. Barium swallow.	No difference in short-term complications.
Tam et al.	2016	MA	Large PEH repair with mesh vs no mesh	Studies not reporting recurrence	Variety	13 study	6 m–5y	QoL = no difference. Reoperation = no difference.		Available evidence is weak. Cannot routinely recommend mesh.

RCT randomized controlled trials, *SR* systematic review, *MA* meta-analysis

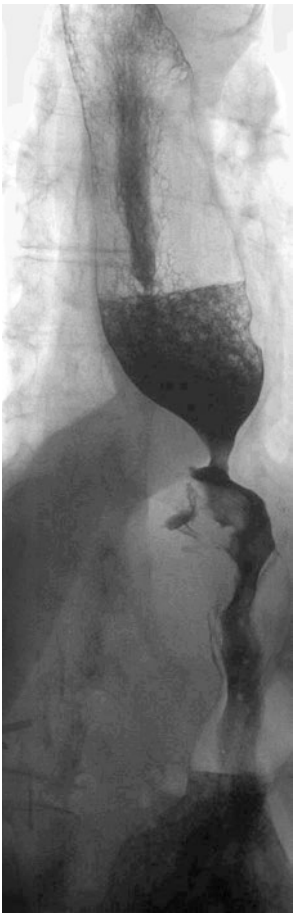

Fig. 24.1 Upper GI study showing severe esophageal stricture caused by synthetic (permanent) mesh used to reinforce the hiatus during HH repair and sleeve gastrectomy

careers. These complications included mesh erosion (21%), esophageal stenosis (25%), mesh infection (7%), and cardiac tamponade (7%) [33]. The respondents to this survey highlight the very real, and often delayed, risk of serious complications of synthetic mesh for paraesophageal hernia repair.

The use of Teflon pledgets has also been associated with complications. In one retrospective review of 1175 cases of laparoscopic paraesophageal hernia repair, 11 patients developed symptoms from Teflon pledgets erosion that occurred more than 2 months after surgery [34]. These patients presented with dysphagia, recurrent symptoms of reflux, and melena.

Absorbable Mesh

Types

Surgisis®, Strattice ™, Alloderm®, and Gore's BioA® are the more commonly reported absorbable products used for hiatal hernia repair.

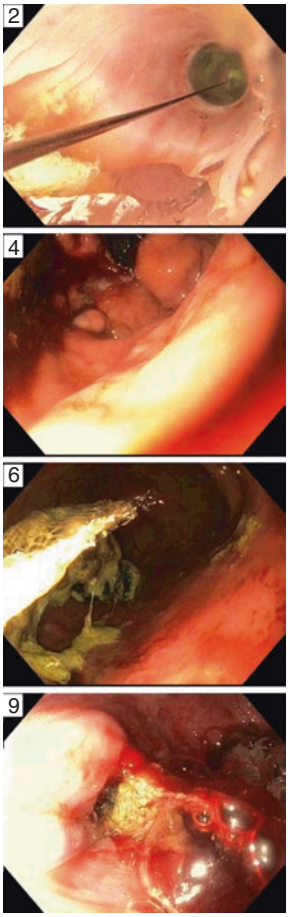

Fig. 24.2 Gastroscopy showing synthetic mesh erosion into the esophagus causing significant stricture. The patient presented with severe dysphagia several years after PEH repair. Multiple endoscopic dilatations were required. The mesh was retrieved endoscopically

Impact on Recurrence

Similarly to synthetic nonabsorbable mesh, multiple RCTs and systematic reviews have been conducted comparing absorbable or biologic mesh to simple closure of the hiatus. The well-known RCT by Oelschlager et al., in 2006 [35], compared Surgisis® to simple closure of the diaphragmatic pillars. In the Surgisis® group, a piece of Surgisis® was prepared and cut in a U configuration. The mesh was then placed with the base of the U overlying the posterior hiatal closure and sutured in place with interrupted sutures. A total of 108 patients were randomized and followed for 6 months. Recurrence was defined as a hiatal hernia >2 cm diagnosed on upper gastrointestinal imaging or the need for reoperation secondary due to wrap disruption, migration, or herniation at any time during the study period. Initial results showed a significantly lower recurrence rate in the mesh group versus the simple closure group (9 vs 24%, $p = 0.04$). Based on these early results, the authors concluded that hiatal reinforcement with Surgisis® resulted in fewer recurrences

when compared to simple closure of the hiatus [35]. This trial stimulated enthusiasm for the use of biologic material to supplement crural closure. However, a follow-up study of these same patients examining recurrence rates at 5 years showed no difference between groups [10].

Two RCTs compared synthetic mesh, biologic mesh, and simple closure after PEH repair. These studies found no difference in recurrence rates among all three groups at 12 months [36] and 24 months [11], with recurrence rates ranging from 12% to 30%.

No reports could be found specifically examining the efficacy of bioprosthetic absorbable mesh for crural reinforcement. A retrospective review of a single institution database found no significant difference in hernia recurrence rates or complications with BioA® and biologic meshes [37]. Another retrospective series of 114 patients undergoing both sliding and PEH repair with BioA® mesh reported a recurrence rate of 0.9% with a median follow-up of 1 year. While this low recurrence rate is highly encouraging, this study has several significant limitations, including its retrospective nature, lack of long-term follow-up, and inclusion of small (sliding) hiatal hernias [38]. No mesh-related complications were reported in either series. As prospective data are lacking, no meaningful conclusions can be drawn regarding the efficacy of bioprosthetic mesh for prevention of hiatal hernia recurrence.

Cost

No trials have directly compared cost differences between various mesh repairs versus primary closure alone. However, use of these meshes is clearly more costly than simple primary closure. While costs of materials vary somewhat by region, biologic meshes have been reported to cost up to $1202 USD per case and other materials up to $483 USD [39].

Absorbable Mesh-Related Complications

Mesh-related complications are in general far less common or devastating for absorbable meshes compared to permanent synthetic crural reinforcements. Fibrosis and dysphagia seem to be the most common sequelae of absorbable mesh placed next to the esophagus. One series described four patients who developed dysphagia and pain after paraesophageal hernia repair with absorbable mesh reinforcement. Of these, one required reoperation to remove the mesh as it was determined to be the cause of his dysphagia, and another required multiple endoscopic dilatations [34]. Another series described 6 patients who developed dysphagia due to extensive fibrosis around the gastroesophageal junction after absorbable mesh use [32].

As with randomized controlled trials of permanent mesh for hiatal reinforcement, most RCTs examining outcomes with absorbable mesh report only short-term outcomes. In the Oelschlager 5-year follow-up study of 108 patients randomized to

no mesh versus Surgisis reinforcement, no significant mesh-related complications were reported [10]. In general, it seems complications of absorbable mesh occur less frequently, and are less devastating, than those encountered when permanent mesh is used at the hiatus.

Meta-analyses of Randomized Controlled Trials

Since the results of individual RCTs regarding the value of mesh reinforcement at the hiatus have been conflicting, numerous systematic reviews and meta-analyses (SR&MAs) have been conducted [2, 9, 40–43]. Most of these grouped synthetic and biologic meshes together in their analysis of outcomes, and the majority have concluded there is insufficient evidence to support routine mesh reinforcement of any type at the hiatus.

In 2016 alone, there were two such systematic reviews and meta-analyses published [2, 9]. Memon et al. reviewed four randomized controlled trials (406 patients) comparing mesh repair to simple closure during laparoscopic hernia repair [9]. The median follow-up was 6 months. They concluded that all included RCTs suffered from poor methodological quality and that there is presently no evidence to support the routine use of mesh. The report by Tam et al. (2016) analyzed 26 studies comparing mesh repair to simple closure in laparoscopic paraesophageal hernia repair with recurrence as the primary outcome [2]. They found the odds of hernia recurrence in the mesh repair group were 49% less (OR 0.51, 95% CI 0.30 to 0.87; $p = 0.014$) relative to the baseline group of simple repair. However, there was no significant difference in the need for reoperation between mesh and non-mesh groups (odds ratio 0.42, 95% CI 0.13 to 1.37; $p = 0.149$). Furthermore, the included studies were highly variable with respect to type of mesh used, definition of recurrence, and time to objective follow-up, which ranged between 6 and 117 months, such that a favorable conclusion toward mesh repair could not be made. Of the studies included in the same meta-analysis, three studies reported six mesh-related complications including five mesh erosion into the esophagus and one unspecified complication requiring mesh removal [2].

Significance of Hiatal Hernia Recurrence After Paraesophageal Hernia Repair

Recurrence has classically been used as a metric of quality after paraesophageal hernia repair. As such, the goal of paraesophageal hernia repair historically has been to avoid recurrences of any size, even small type I hernias. As described above, the majority of RCTs and other studies examining mesh reinforcement after hiatal closure report follow-up of only ~6–24 months; few of these report on pre- vs postoperative quality of life or symptoms (Table 24.1). The one trial which did report on these outcomes at 5 years in patients receiving biologic vs no mesh found no

differences in symptoms, quality of life, or need for reoperation between groups, regardless of hernia recurrence [10].

In the absence of direct data, need for reoperation may be used as a surrogate for poor quality of life or intolerable symptoms. In large series reporting on 5–10 years of follow-up, the rate of reoperation appears to be quite low (0–4.8%) [8, 10]. Furthermore, in studies that have reported long-term quality of life and symptoms scores, these appear to improve and remain stable over time irrespective of hernia recurrence [8, 44–46]. In light of these results, it seems that anatomical recurrence alone is not a sufficient indicator of operative "failure" after PEH repair.

Summary

Despite numerous RCTs and other clinical reports, the available data do not presently support the routine use of mesh for crural reinforcement over primary cruroplasty alone. While synthetic nonabsorbable mesh use has been shown to result in lower anatomic recurrence rates, most recurrences are of little clinical significance and do not warrant the risk of catastrophic complications from permanent mesh placed at the hiatus. Absorbable materials might lessen the risk of serious complications but result in similar long-term recurrence rates to primary closure with considerable additional cost.

As such, it is our opinion, based on the available evidence at this time, that routine mesh reinforcement after primary hiatal hernia repair is of little clinical value and associated with elevated risk of complications and cost. We recommend against the use of permanent mesh entirely and suggest that bioabsorbable meshes be used only selectively.

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