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# A systematic review and meta-analysis of mesh versus suture cruroplasty in laparoscopic large hiatal hernia repair

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## Structured Abstract

**Background—**Equipoise exists regarding whether mesh cruroplasty during laparoscopic large hiatal hernia repair improves symptomatic outcomes compared to suture repair.

**Data Source—**Systematic literature review (MEDLINE and EMBASE) identified 13 studies (1194 patients; 521 suture and 673 mesh) comparing mesh versus suture cruroplasty during laparoscopic repair of large hiatal hernia. We abstracted data regarding symptom assessment, objective recurrence, and reoperation and performed meta-analysis.

**Conclusions—**The majority of studies reported significant symptom improvement. Data were insufficient to evaluate symptomatic versus asymptomatic recurrence. Time to evaluation was skewed toward longer follow-up after suture cruroplasty. Odds of recurrence (OR 0.51, 95% CI 0.30–0.87; overall p=0.014) but not need for reoperation (OR 0.42, 95% CI 0.13–1.37; overall p=0.149) were less after mesh cruroplasty. Quality of evidence supporting routine use of mesh cruroplasty is low. Mesh should be used at surgeon discretion until additional studies evaluating symptomatic outcomes, quality of life and long-term recurrence are available.

### Keywords

Hernia; Hiatal; Surgical Mesh; Treatment Failure; Fundoplication; Recurrence; Symptom Assessment

## Introduction

Laparoscopic repair of large hiatal hernia is a technically demanding procedure requiring significant experience in advanced foregut surgery. The tenets of repair shared by most high-volume surgeons include complete mediastinal sac reduction, mobilization of at least 2–3 cm of tension-free intraabdominal esophagus, and tension-free hiatal closure.(1) Difficulty

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achieving tension-free closure and unacceptably high recurrence rates with a laparoscopic approach prompted exploration of mesh reinforcement to improve hiatal closure durability. Several early studies, including three randomized controlled trials, reported reduced objective recurrence rates with mesh cruroplasty.(2–4) More recent reports, however, suggest that long-term durability comparing mesh with suture cruroplasty does not differ significantly.(5) In addition, though rare, major complications and deaths from mesh cruroplasty have been reported.(6, 7)

Thus, equipoise exists regarding routine use of mesh for crural reinforcement during laparoscopic repair of large hiatal hernia. Additionally, a critical and unanswered question is whether objective recurrences (i.e. identified on routine barium esophagram) influence symptomatic relief and need for re-intervention, which are the outcomes of interest when examined from the patient perspective. Therefore, our study aim was to determine whether mesh cruroplasty was associated with differential outcome compared to suture cruroplasty in the operative management of large hiatal hernia using systematic literature review and meta-analysis. The study population consisted of patients with large hiatal hernia who underwent laparoscopic repair. Outcomes included symptoms, rates of recurrence and reoperation, and symptoms associated with objective recurrence.

## Methods

Systematic literature review was performed using MEDLINE and EMBASE to identify studies addressing the repair of large hiatal hernias with synthetic reinforcement. Reference lists of eligible studies were reviewed for additional studies meeting inclusion criteria. The final query date was October 12, 2013. Data were independently abstracted by two reviewers. Operative details, including the number and location of sutures for suture cruroplasty, and the type and shape of mesh used for reinforcement were extracted. Surgical quality metrics were assessed, including documentation of sac reduction, esophageal mobilization and tension-free crural closure. Symptom assessment methods, such as scheduled time to evaluation, use of standardized scales, symptom outcomes and reporting of long-term adverse outcomes were recorded. Primary outcomes for meta-analysis were rates of objective recurrence and need for reoperation for recurrent hernia or symptoms. The Grading of Recommendations Assessment, Development and Evaluation (GRADE) system was used to assess study quality;(8–10) systematic review and meta-analysis was performed according to PRISMA statement guidelines.(11)

## Statistical analysis

Statistical analysis consisted of meta-analysis applied to rates of hiatal hernia recurrence and rates of reoperation from all included studies. These rates were calculated by technique (mesh versus suture cruroplasty) and summarized as an odds ratio. Due to concerns about variations between study characteristics such as hernia definition and approach to repair, a random effects meta-analysis model was selected to adjust the meta-analytic weights for possible effect size heterogeneity. $I^2$ heterogeneity statistic was computed for each meta-analysis, with pre-defined determinations of low, moderate, and high heterogeneity at $I^2$ = 25%, 50%, and 75%, respectively.(12) $P < 0.05$ was set for statistical significance,

corresponding to 95% confidence intervals for the summarized meta-analysis odds ratio estimate. All analysis was performed in Stata 13.1, with the assistance of the user-written "metan" command for meta-analysis.(13, 14)

## Results

Identification, screening, eligibility and inclusion details are shown in Figure 1. Articles were included if 1) they focused on large hiatal hernia repair in adults and/or provided data for the subsets of adult patients with large hiatal hernia; 2) compared mesh to non-mesh repair; and 3) examined differences in hernia recurrence. If two manuscripts reported on the same cohort of patients, the manuscript with the longest clinical follow-up time was included. Review of references for additional manuscripts was performed. Thirteen publications meeting inclusion criteria were identified: 3 randomized controlled trials(2, 3, 5) and 10 observational studies (4 prospective;(15–18) 4 retrospective;(19–22) and 2 with design not specified.(23, 24) Study quality using the GRADE Working Group approach was performed (Table 1). Objective definition of large hiatal hernia varied between studies and was not specified in three; six studies defined a minimum defect size ranging from 5 to 8 cm or greater. Three studies used percent of gastric herniation (range 30% to 50% or greater). One study used a hiatal surface area of >10 $cm^2$. (Table 2)

### Approach to laparoscopic large hiatal hernia repair

Twelve of 13 studies specifically described hernia sac reduction and nine studies described extensive esophageal mobilization. The described length of necessary intra-abdominal esophagus ranged from 2.5 to 5cm. Gouvas described esophageal mobilization carried to the inferior pulmonary veins without a specified length of intraabdominal esophagus.(23) Oelschlager reported use of Collis gastroplasty at the discretion of the surgeon,(5) while Goers elected to exclude these patients.(16) Nine studies reported posterior placement of cruroplasty sutures, and 63% (5 of 8) reported use of 2–3 sutures (range 2 to 8). (Table 2) Three studies placed an additional anterior suture if the crura remained splayed after posterior cruroplasty.(5, 18, 23) The types of mesh and mesh shape varied widely within and across studies. (Table 2)

### Symptom assessment after laparoscopic repair of large hiatal hernia

Symptom assessment, outcomes and assessment metrics from individual studies were reviewed (Table 3). Symptom assessment prior to and following laparoscopic repair was reported in only 1 of 3 randomized controlled trials. Among the observational studies, only 5 (50%) reported pre- and postoperative symptoms stratified by repair type. In the Oelschlager randomized trial,(5) a standardized symptom questionnaire was used pre- and post-operatively to assess changes in symptoms, and quality of life was assessed using the 36-item Health Survey (SF-36).(25, 26) They found similar symptom severity at nearly 5-years of follow-up between the mesh and suture groups, with significant improvement in symptom frequency and severity compared to preoperative values. Only dysphagia in the suture group was unchanged from baseline measures.

Of the 10 observational studies, eight reported significant improvement in the majority of preoperative symptoms, including heartburn, regurgitation, dysphagia, chest discomfort, chest pain, and other respiratory or cardiac symptoms.(5, 15, 17, 19, 21–23) Two studies reported that significantly more patients who received mesh complained of dysphagia in early follow-up compared to patients with suture repair.(16, 23) Stable dysphagia in the overall group was reported by Braghetto.(15)Six studies assessed pre- and post-operative symptoms by cruroplasty types,(5, 16, 17, 19, 21, 23) including varying combinations of heartburn, regurgitation, chest pain, dysphagia, abdominal pain, bloating, nausea, vomiting, early satiety, dyspnea, arrhythmias, anemia, and hoarseness. Eight studies performed symptom assessment based on presence/absence, severity, and/or frequency without validated symptom measures. For example, Dallemagne and colleagues found significant improvement in rates (present/absent) of heartburn, chest pain, regurgitation, respiratory, anemia (<p<0.001) and dysphagia (p<0.05) for all patients. In their study, mean satisfaction scores were similar (90 versus 100 comparing mesh to suture; p=0.522).(19) In comparison, Ringley and colleagues examined the symptom frequency (never, once a month, once a week, once a day, and several times a day) and found that pre- and postoperative mean symptom frequency scores (heartburn, regurgitation, dysphagia, chest pain, and hoarseness) were improved in both mesh and suture groups. Mean scores were less than 1 (less than once a month or never) for all symptoms assessed in both groups postoperatively, but were not compared between the two groups. Postoperative dysphagia requiring dilation was a complaint for 1 patient in each group.(17) Zaninotto and colleagues did not stratify symptoms by repair type and reported rates of postoperative symptoms without comparison to preoperative symptoms. They found that 22% of patients reported dysphagia, retrosternal discomfort, and regurgitation. One patient with severe dysphagia immediately postoperatively required reoperation and was found to have malpositioned mesh. In their study, dysphagia and/or chest/upper abdominal pain were considered surgical failures.(18)

A paired analysis comparing pre- and post-operative symptoms was performed in only 1 study.(23) Heartburn, regurgitation, dysphagia, chest pain, epigastric or chest discomfort, and abdominal bloating were graded using a combined severity/frequency scale: grade 0 (absent); grade I (mild and less than 2 episodes per week); grade II (moderate severity 2 – 7 times a week); grade III (constant); and grade IV (persistent, severe, and incapacitating). Respiratory and cardiovascular symptoms were assessed separately. The proportion of patients reporting any symptom and in the symptom grade for all of symptoms at 3, 6, 12 months, and 3 years postoperatively improved significantly, but the proportion with new or unchanged symptoms was not reported.

In contrast to the studies above, 3 studies used validated symptom scales, including the Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) scale,(27, 28) and the Gastrointestinal quality of life index and satisfaction scale.(29) Using the GERD-HRQL scale (defined in Table 3), Soricelli and colleagues reported significant improvement compared to baseline scores. Stratified by repair type, they found that overall GERD-HRQL score was statistically lower after suture plus on-lay mesh compared to suture cruroplasty (2.6 ± 7.0 versus 4.0 ± 6.6; p=0.04). They also found that suture plus on-lay mesh had a lower score compared to mesh alone (2.6 ± 7.0 versus 4.2 ± 8.2; p=0.03) while suture versus mesh alone was not statistically different. Morino and colleagues used the

GERD-HRQL scale and the Visick classification to rank the outcome of surgery (defined in Table 3); at a median follow-up of 58 months, 65% of patients reported no symptoms, 11% reported minimal symptoms without lifestyle changes or need to see a physician, 15% reported significant symptoms requiring physician input and lifestyle changes and 9% reported symptoms as bad or worse than preoperatively. The paper did not stratify by treatment type or provide the results of the GERD-HRQL scale that was reportedly used for symptom monitoring. Ten patients had dysphagia with recurrence and underwent reoperation; there were equal numbers of reoperation in each group. Five patients had persistent heartburn but treatment was not described. Thirteen patients with recurrence were asymptomatic.

In addition to substantial variability in approach to symptom assessment, the time-frame for follow-up was skewed toward much longer symptom and objective follow-up in the suture group, likely due to the shift in practice from primarily suture to primarily mesh over time. (Tables 3 and 4) Only 4 of 13 studies reported time to symptom assessment stratified by repair type,(16, 17, 19, 21) while the remaining provided a range, median, mean, or did not report. Of those that reported this metric, median time to symptom assessment varied greatly (6.5 months to 151 months).(3, 5, 15–24)

Only 6 of 13 studies reported the presence or absence of long-term adverse outcomes. Two studies specifically reported the absence of any mesh-related erosions, although the study by Oelschlager mentioned this only in the discussion and not in the results, while Grubnik and colleagues stated that there were no cases of esophageal stricture with either repair type.(3, 5, 24) Three studies reported 6 mesh-related complications including 1 mesh erosion requiring esophagectomy,(18) 1 unspecified complication requiring mesh removal,(22) 3 patients with esophageal stenosis due to mesh-induced fibrosis with a 4th case of esophageal stricture and erosion requiring esophageal resection and reanastomosis.(23) In the studies reporting mesh-related complications, Goretex™,(18) and polypropylene mesh(22, 23) were used. Synthetic mesh was also used in the studies by Frantzides(3) and Grubnik,(24) who reported no mesh related complications or esophageal strictures, respectively, while Oelschlager and colleagues utilized biosynthetic mesh material.(5) (Table 2)

## Hernia recurrence and reoperation rates

Five of 13 studies provided a definition of hernia recurrence. Morino and colleagues described any general evidence of gastric herniation above the level of the diaphragm,(20) while Oelschlager defined a maximum vertical height greater than 2 cm from the level of the diaphragm adjacent to the fundoplication to the top of the wrap.(5) All but one study used contrast esophagram to assess recurrence outcomes. Six studies used a combination of esophagram, esophagogastroduodenoscopy (EGD), manometry, and pH testing to monitor for anatomic recurrence. Time to objective follow-up stratified by cruroplasty type was available in only 4 studies. (Table 4)

Overall, 49 recurrences and 13 reoperations were reported after mesh cruroplasty. Of 673 patients having mesh repair, follow-up evaluation was reported for 354 (53%); Carlson and Soricelli reported reoperations and recurrences, but not the number of patients undergoing followup evaluation for either mesh or suture cruroplasty.(2, 22) (Table 4) The overall

recurrence rate after mesh cruroplasty, therefore, is 13% (46/354), with a reoperation rate of 3.7%. In comparison, 103 recurrences and 31 reoperations were reported after repair with suture cruroplasty. Of 521 patients having suture repair, follow-up evaluation was reported for 382 (73%). The overall recurrence rate after suture cruroplasty was 24% (91/382) and the reoperation rate was 6% (23/382). The proportion of patients available for evaluation in followup was significantly greater following suture cruroplasty compared to mesh cruroplasty (73% vs 53%; p=0.0001). Frantzides, Zaninotto and Grubnik reported significantly lower rates of recurrence with mesh cruroplasty, ranging from 7 to 33% absolute difference compared to suture cruroplasty ($p<0.05$).(3, 18, 24) In contrast, Braghetto, Dallemagne, and Oelschlager did not find a statistically significant difference in rates of recurrence.(5, 15, 19) The remaining studies did not publish a comparison of recurrence rates. In the Morino study, 16 (of 23) recurrences were identified at the 3 month follow-up.(20) Two studies found a statistically significant decrease in reoperation rates with mesh cruroplasty. (22, 24)

Meta-analysis for odds of hernia recurrence with mesh cruroplasty compared to suture cruroplasty was performed, including 11 of 13 studies.(3, 5, 15, 17–21, 23, 24) Odds of hiatal hernia recurrence were 49% less after mesh cruroplasty, relative to the baseline group of suture cruroplasty (Figure 2. OR 0.51, 95% CI 0.30–0.87; p=0.014). Combining 8 studies that reported rates of reoperation,(3, 5, 19–24) odds of reoperation following hernia repair were 58% less after mesh cruroplasty, relative to the baseline group of suture cruroplasty, but did not reach statistical significance (Figure 3. OR 0.42, 95% CI 0.13–1.37; p=0.149).

### Assessment for symptoms associated with recurrence

Of 11 studies that compared pre- and post-operative symptoms, 8 studies reported excellent symptomatic results after both mesh and suture repairs despite high rates of reported hernia recurrence.(5, 15, 17–19, 21–23) For example, despite recurrence rates of 54% and 59% in mesh and suture repairs, respectively, Oelschlager found no difference in symptom complaints or quality of life.(5) Similarly, Dallemagne found that there were no differences in Gastrointestinal Quality of Life scores between the groups with and without recurrence (116 vs. 115, respectively, p=0.36).(19) Only 5 studies provided rates of symptomatic recurrence; 100% (8/8) of recurrences were symptomatic as reported by Frantzides,(3) while 67% (2/3) were symptomatic in the Carlson study,(2) 57% in both the Gouvas (4 of 7) (23) and Muller-Stich (4 of 7) (21) studies, and 73% (11/15) in the study by Zaninotto and colleagues.(18) Only Grubnik and colleagues reported symptomatic recurrences stratified by repair type, however; 92% (11/12) of recurrences in the suture group and 88% (7/8) in the mesh group were symptomatic.(24) Recurrence-associated symptoms included chest pain, early satiety, lower physical functioning by SF-36, and dysphagia.(5, 20) Overall, given the lack of direct comparisons in the published studies, there was insufficient data to draw conclusions regarding whether objective recurrence was significantly associated with worse symptom outcomes.

## Discussion

Using systematic review and meta-analysis, we have shown that data available to address the question of whether routine mesh cruroplasty is indicated in repair of large hiatal hernia is heterogeneous, with tremendous variability in several areas, including the definition of both large hiatal hernia and hernia recurrence, the approach to symptom assessment and objective evaluation of recurrence, and reporting of re-intervention. Patient-centered outcomes, including comparison of pre- and postoperative symptoms and determination of symptomatic recurrences, were rarely assessed and mesh-related complications were rarely reported. Objective follow-up was substantially shorter after mesh compared to suture cruroplasty, with only half of the mesh patients available for followup, compared to nearly 75% of suture patients. Taking these limitations into account, meta-analysis for recurrence favored mesh cruroplasty during laparoscopic large hiatal hernia repair to reduce short-term and reoperation rates, while neither approach was favored when considering need for reoperation.

### Symptom assessment after laparoscopic repair of large hiatal hernia

When we evaluated studies for their approach to symptom assessment and symptom outcomes, we found that data regarding comparisons of symptom relief were inadequate or unavailable in the majority of studies, while only 1(23) used paired analysis, making it difficult to aggregate symptom data from different studies and to determine whether symptom complaints were new, unchanged, or resolved. The failure of all but one study to use paired analysis in comparing pre- and post-operative symptoms is particularly important given the loss of patients to follow-up, which can be very high in the observational studies and even in randomized controlled trials. When unpaired analysis is used, the proportions of patients within each group are compared, but the preoperative symptoms may not be from the same group of patients as the postoperative symptom assessments. In addition, the changes in symptoms within a patient are not assessed. For example, if patient ‘A’ reports preoperative heartburn but is not available for postoperative symptom assessment while patient ‘B’ did not have preoperative symptom assessment, but denies heartburn postoperatively, heartburn control is 100%, but symptom resolution for patient ‘A’ is, in fact, unknown. This limitation is overcome with paired analysis; by including only patients with preoperative and postoperative symptom assessment and accounting for repeated measures within a patient, one is able to discern whether an individual patient has symptom resolution, persistent symptoms or new symptoms. From the perspective of the patient, the likelihood of symptom resolution and new symptoms is much more relevant and important than a simple observation of the change in proportions within a group of patients compared to preoperative symptoms. Equally important, paired analysis provides a true measure of the proportion of patients with symptom resolution and new symptoms following large hiatal hernia repair.

### Recurrence and reoperation after laparoscopic repair of large hiatal hernia

Our findings are similar to previously published meta-analyses with regard to differences in recurrence, but extended the systematic review to include a critical assessment of the adequacy of patient-reported outcomes measures as described above. A meta-analysis of 3 randomized trials by Antoniou and colleagues found a 4-fold increased risk of recurrence in

primary suture closure, with weighted mean recurrence rates of 24.3% after suture repair and 5.8% following mesh-reinforced repair.(30) The initial meta-analysis used 6 month outcomes data from the Oelschlager study. When the 5-year Oelschlager data were used instead, odds of hernia recurrence dropped by nearly 50%, from 4.2 times higher in the suture group down to only 2.3 times higher(4, 5) (OR 4.2; 95% CI 1.8–9.5 vs. OR 2.3; 95% CI 1.2–5.1, respectively), which is very similar to the 49% reduction in odds of recurrence with mesh cruroplasty compared to suture in our meta-analysis. Interestingly, in the Oelschlager trial, patient-reported outcomes remained good to excellent, and reoperations were low (0 in mesh group and 2 in non-mesh). These findings suggest that the durability of repair with bioprosthetic mesh and suture cruroplasty decays over time and that objective recurrence may not be as important a quality metric as has been assumed for the past decade. Importantly, the 5-year follow-up in their study is nearly twice as long as the time to follow-up for the majority of the mesh cruroplasty patients included in the current meta-analysis, suggesting that much longer follow-up is needed to determine true differences in recurrence rates.

Furnee and colleagues also published a meta-analysis of 1264 patients in 26 studies, including the three randomized trials in the present study, with 924 mesh and 340 suture cruroplasty patients.(31). They also found significant differences in recurrence between groups (26.3% after suture and 14.6% after mesh cruroplasty). Their study included 16 cohort studies, however, which only reported patients repaired with mesh cruroplasty. Representing 67% of the overall mesh group, these patients did not have suture controls. Given our finding of significant heterogeneity in approach to repair, hernia and recurrence definitions, and symptom assessment, observed differences between groups could reflect true differences in repair durability or, alternatively, differences in these other variables.

Our meta-analysis did not favor mesh cruroplasty over suture cruroplasty with regard to the odds of reoperation. The available data for analysis were limited, with only 8 studies reporting re-intervention. In the 2 studies that found a statistically significant difference between groups in their reoperation rates, there were a total of 4 reoperations in the mesh group and 11 in the suture group. Importantly, 4 reoperations were required specifically for mesh-related complications such as erosion, and mesh-induced fibrosis.(18, 22, 23) Interestingly, all 3 studies with reported long-term adverse outcomes used synthetic mesh. This may reflect the a true low risk of erosion and infection with biological mesh, but the lack of reporting on this outcome did not allow further exploration of this in the current studies. As such, the true rate of mesh-related complications after prosthetic reinforcement of hiatal closures cannot be determined from the current review, but has been reported to range from 1.3% to 20%.(32) A 28-case series of mesh complications after prosthetic reinforcement of hiatal closure was published by Stadlhuber and colleagues.(32) Mesh-related complications presented at an average of 17.3 months (range 1 to 120 months) after operation, with associated dysphagia, heartburn, chest pain, fever, epigastric pain, and weight loss. Twenty-three required reoperation for mesh removal; the intraoperative findings included 17 cases of mesh erosion, 6 cases of hiatal stenosis and 5 cases of dense fibrosis. Esophagectomy (n=7), partial gastrectomy (n=2), and total gastrectomy (n=1) were required. These types of complications, though rare, have a substantial impact on patient quality of life and can result in need for major interventions, such as esophagectomy, or death.

### Assessment for symptoms associated with recurrence

With the limitations of available symptom assessment in mind, the next issue is whether objective recurrence, as seen on barium esophagram, is associated with worse symptom outcomes. Unfortunately, the studies included in this systematic review did not address this question adequately. Oelschlager evaluated symptomatic recurrences for the entire cohort and found that symptom relief was similar whether objective recurrence was noted or not, but did not stratify the data by type of repair or perform paired symptom analysis. As such, assessment of new or recurrent symptoms associated with objective recurrence was not possible.(5) Of all the reviewed studies, only Grubnik and colleagues provided rates of symptomatic recurrence stratified by type of repair; in contrast to the long-term outcomes from the Oelschlager trial, they found that the majority of recurrences were symptomatic. (24) Overall, this systematic review provide insufficient data to compare the results of durable symptom relief and new or persistent symptoms.

### Conclusions regarding the evidence for routine use of mesh cruroplasty

In summary, available evidence supporting mesh cruroplasty during laparoscopic repair of large hiatal hernia is of low quality and potentially biased by a lack of hernia recurrence definition and differences in time to objective follow-up between mesh and suture cruroplasty groups. The significant variability between studies posed a challenge to compare and merge patient characteristics and outcomes. This limits the quality of the meta-analysis and ability to provide generalizable conclusions and recommendations. Future studies should focus on patient-related outcomes, using validated measures of symptoms assessment and quality of life and paired analysis strategies. Additional outcomes of interest for future studies should include reoperation rates for symptomatic hernia recurrence and/or symptoms as well as other postoperative interventions such as need for anti-reflux medications and endoscopic procedures. Until such studies are available, the evidence to support routine use of mesh cruroplasty in laparoscopic repair of large hiatal hernias is weak and cannot be recommended. Use of mesh for reinforcement of the cruroplasty should be performed at the discretion of the surgeon.

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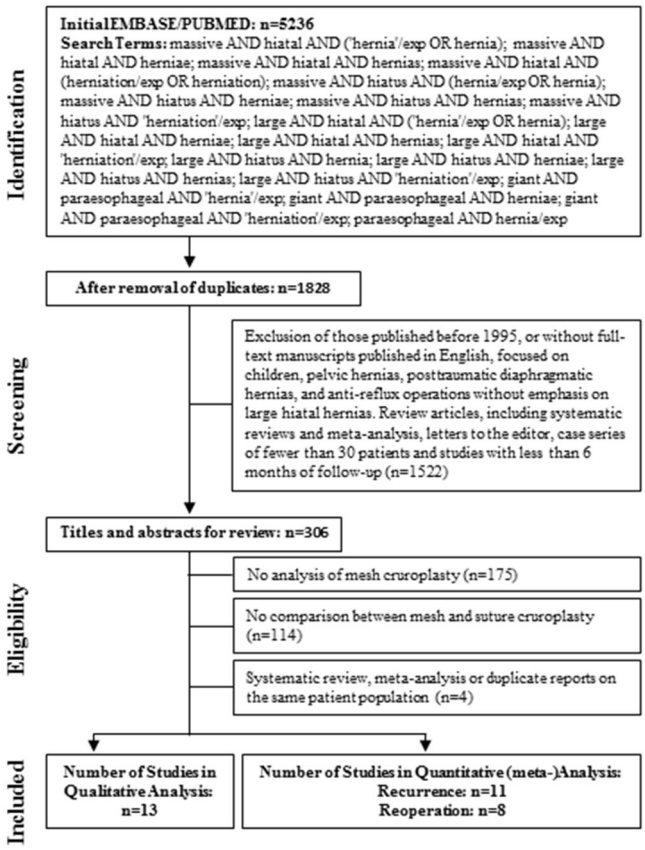


**Figure 1.**
PRISMA flow diagram outlining the literature review process

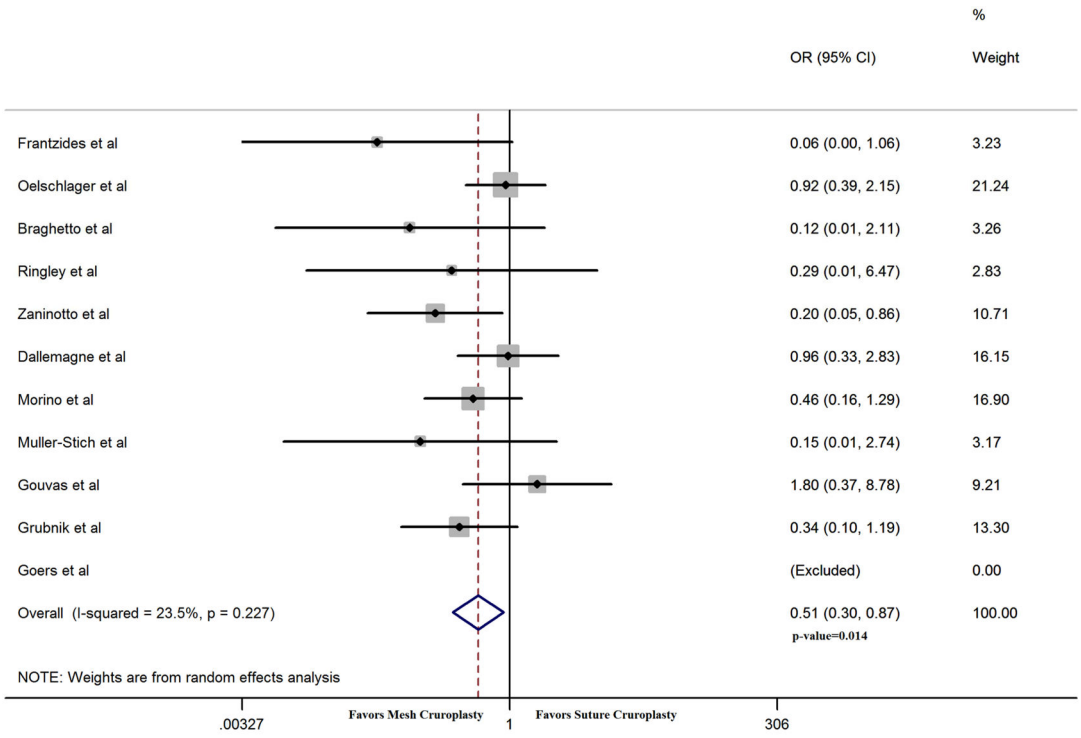


**Figure 2.**
Meta-analysis of recurrence after laparoscopic large hiatal hernia repair

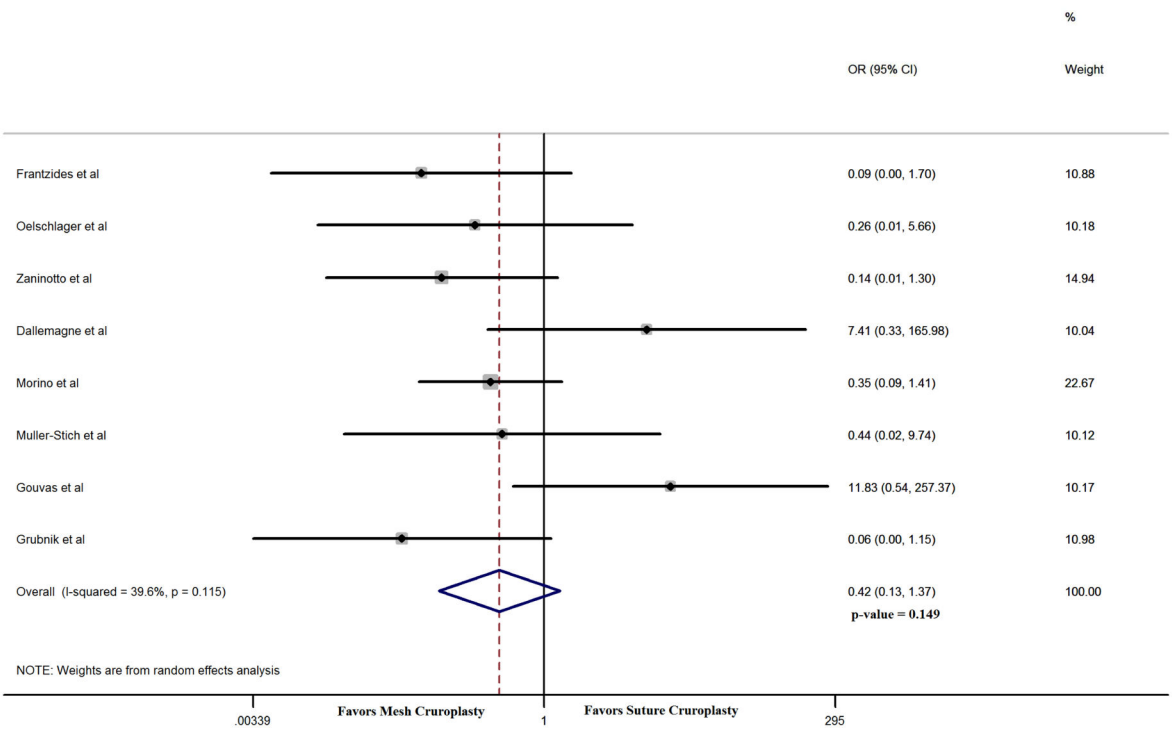


**Figure 3.**
Meta-analysis of need for reoperation after laparoscopic large hiatal hernia repair

**Table 1**

Grade Evidence Profile on Impact of Mesh Cruroplasty in Laparoscopic Repair of Large Hiatal Hernias based on GRADE Working Group

| Outcome | Number of Studies | Number of Patients | Quality | Consistency | Directness | Effect Size | GRADE score[a] |
|---|---|---|---|---|---|---|---|
| **Recurrence rate** | 13 | 1094 | Serious limitations (−3) | Inconsistent results (−1) | Indirect (−1) | N/A | Very low |
| **Reoperation rate** | 8 | 826 | Mild limitations (−1) | No important inconsistency | Direct | N/A | Moderate |
| **Symptom improvement** | 11 | 991 | Serious limitations (−3) | No important inconsistency | Direct | N/A | Very low |
| **Symptomatic recurrence** | 5 | 277 | Mild limitations (−1) | No important inconsistency | Indirect (−1) | N/A | Low |

A Quality of evidence and definitions: HIGH QUALITY – Further research is very unlikely to change our confidence in the estimate of the effect; MODERATE QUALITY – Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate; LOW QUALITY – Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate; VERY LOW QUALITY – Any estimate of effect is very uncertain(10)

**Table 2**

Systematic review of study design and details of mesh and suture cruroplasty

| Author | Number of Patients by Repair Type | Study Design | Definition of Hernia | Suture location | # of Sutures | Mesh Type | Mesh Shape |
|---|---|---|---|---|---|---|---|
| Carlson et al 1999(2) | **Mesh**: n=16 **Suture**: n=15 | RCT | Crural splaying 8 cm or greater | Posterior | NR | Fenestrated PTFE | Keyhole |
| Frantzides et al 2002(3) | **Mesh**: n=36 **Suture**: n=36 | RCT | Crural splaying 8 cm or greater | NR | NR | Fenestrated PTFE | Keyhole |
| Oelschlager et al 2011(5) | **Mesh**: n=57 **Suture**: n=51 | RCT | Greater than 5 cm upper gastrointestinal barium study | Posterior | NR | SIS | U-shaped |
| Braghetto et al 2010(15) | **Mesh**: n=23 **Suture**: n=58 | Prospective | Crural splaying 5 cm or greater received mesh and <5 cm crural splaying suture only | NR | 3–4 | Vicryl poliglecaprone-25:polypropylene composite SIS | NR |
| Goers et al 2011(16) | **Mesh**: n=56 **Suture**: n=33 | Prospective | 30% or more gastric herniation | Posterior pledgeted | NR | Biomesh NOS | Posterior onlay |
| Ringley et al 2006(17) | **Mesh**: n=22 **Suture**: n=22 | Prospective | Crural splaying greater than 5 cm | Posterior | 2–4 | Acellular dermal matrix | Posterior onlay |
| Zaninotto et al 2007(18) | **Mesh**: n=35 **Suture**: n=19 | Prospective | 1/3rd or more gastric herniation | Posterior | 2–3 | Goretex™: polypropylene Composite | Keyhole onlay |
| Dallemagne et al 2011(19) | **Mesh**: n=25 **Suture**: n=60 | Retrospective | 50% or more gastric herniation | Posterior or pledgets | NR | Polyester:collagen composite SIS | NR |
| Morino et al 2006(20) | **Mesh**: n=37 **Suture**: n=14 | Retrospective | 6 cm or greater length from top of gastric folds to crural pinch by endoscopy; 50% or more herniation; or 5 cm hiatal defect intraoperatively | Posterior pledgeted (PTFE) | 5 (3–8) | PTFE Polypropylene PTFE:polypropylene composite | U-shaped ‘tension-free’ bridge |
| Muller-Stich et al 2006(21) | **Mesh**: n=16 **Suture**: n=36 | Retrospective | NR | Posterior | 3–4 | Polypropylene Vicryl: polypropylene | Butterfly- shaped |
| Soricelli et al 2009(22) | **Mesh**: n=138 **Suture**: n=37 | Retrospective | NR | NR | 2–3 | Polypropylene | Posterior onlay |

| Author | Number of Patients by Repair Type | Study Design | Definition of Hernia | Suture location | # of Sutures | Mesh Type | Mesh Shape |
|---|---|---|---|---|---|---|---|
| Gouvas et al 2011(23) | **Mesh**: n=20 **Suture**: n=48 | Observational - NOS | Type II, III, or IV PEH | Posterior | 2–3 | Polypropylene Duo-mesh | Keyhole or U- shaped onlay |
| Grubnik et al 2013(24) | **Mesh**: n=192 **Suture**: n=92 | Observational - NOS | HSA >10 $cm^2$ | Posterior | 2–3 | Poliglecaprone- 25:polypropylene composite | “Sandwich” technique |

RCT = Randomized Controlled Trial. NR = Not Recorded. PTFE = Polytetrafluoroethylene. SIS = Small Intestine Submucosa. NOS = Not Otherwise Specified. PEH = Paraesophageal Hernia. HSA = Hiatal Surface Area.

**TABLE 3**

Symptom Assessment, Outcomes and Assessment Metrics

| Author | Time to Symptom Assessment | Standardized Assessment | Symptom Assessment Type | Paired Analysis | Analysis of Outcomes |
|---|---|---|---|---|---|
| Carlson et al 1999(2) | NR | No | NR | No | NR |
| Frantzides et al 2002(3) | Median 2.5 yrs (6 mo-6 yrs) | No | NR | No | NR |
| Oelschlager et al 2011(5) | Median 59 mo (40–78mo); Only n=33 SIS n=39 suture | Yes - pre- and post-operatively | Severity | No | Significant improvement in proportion of both groups in reported symptoms compared to baseline; no differences between groups at follow-up |
| Braghetto et al 2010(15) | 3 to 5 yrs | Yes | Present or absent | No | Not stratified by cruroplasty type; proportion with heartburn significantly improved compared to baseline, with stable dysphagia rate |
| Goers et al 2011(16) | **Mesh:** 6.5 mo (n=40) **Suture:** 9.5 mo (n=32) | Yes | Frequency and/or severity (0 to 4 scale) | No | Proportion of patients with heartburn, chest pain, abdominal pain and inability to belch significantly greater in non-mesh patients; no comparison to baseline measures |
| Ringley et al 2006(17) | **Mesh:** 6.7 (3–12) mo (n=15/22) **Suture:** 12.2 (8–28) mo (n=22/22) | Yes | Frequency | No | Mean frequency scores significantly improved within both groups comparing pre- to postoperative symptom assessment |
| Zaninotto et al 2007(18) | Median 71 mo (IQR 39–97) | No | Present or absent | No | Not stratified by cruroplasty type; overall proportion with postoperative symptoms = 22%(dysphagia, retrosternal discomfort, regurgitation); no comparison to baseline |
| Dallemagne et al 2011(19) | **Mesh**:151 mo (21–186) **Suture**: 65 mo (17–143) | Yes - postoperative only | Pre-op: present or absent<br>Post-op: GIQLI[a], 5-pt Likert scale | No | Significant improvement in proportion of patients with symptoms compared to preoperative in all patients<br>No difference in postoperative GIQLI or satisfaction scale between groups |
| Morino et al 2006(20) | Median 58 mo (12–124) | Yes | GERD-HRQL[b], Visick Classification[c] | No | Not stratified by cruroplasty type; outcomes reported as proportions of patients using Visick Classification[c] without stratifying by type or comparison to preoperative symptoms. The majority (65% had no symptoms while 9% had symptoms as bad or worse than preoperatively) |
| Muller-Stich et al 2006(21) | **Mesh**: 20 mo (10–60) **Suture**: 67 mo (9–117) | Yes - postoperative only | Present or absent | No | Proportion of patients who are symptom-free or only mild gas bloating not significantly different between groups; Outcome ‘Good’ or ‘Very good’ in ~95% in both groups with no difference in rate of patients reporting willingness to undergo operation again |
| Soricelli et al 2009(22) | **Mesh**: Mean 117.6 mo and 69.3 months (two techniques) | Yes | GERD-HRQL[b] | No | Not stratified by cruroplasty type; significant improvement in mean GERD-HRQL scores for all patients compared to preoperative symptoms; |

| Author | Time to Symptom Assessment | Standardized Assessment | Symptom Assessment Type | Paired Analysis | Analysis of Outcomes |
|---|---|---|---|---|---|
| | **Suture**: Mean 95.1 mo (87%) | | | | Mesh only had significantly lower GERD-HRQL than suture only (4 vs 2.6; p=0.03) |
| Gouvas et al 2011(23) | 3 years (45 pts) | Yes | Frequency and severity | Yes | Significant reduction in the proportion of patients with all symptoms at follow-up; dysphagia, chest discomfort, cardiac and respiratory symptoms significantly more likely in mesh patients at 12 months |
| Grubnik et al 2013(24) | Mean 28.6 mo (10–48 mo) | No | Present or absent | No | No difference in proportion of patients with postoperative reflux symptom recurrence or persisting dysphagia |

[a]GIQLI = GastrointestinalQuality of Life Index: Patients assess GI quality of life using five subscales, including GI symptoms, emotion, physical function, social function, and medical treatment. Scores on the subscales range form 0–4, with total scores ramging from 0–144. Higher scores represent better HRQL.

[b]GERD-HRQL: The Gastroesophageal Reflux Disease-Health Related Quality of Life instrument. Patients rate heartburn severity overall, while lying down, while standing up, after meals, impact of heartburn on diet and sleep, dysphagia, pain with swallowing, gas bloat, and the impact of medications on daily life on the following scale: No symptoms = 0; Symptoms noticeable, but not bothersome = 1; Symptoms noticeable and bothersome, but not every day = 2; Symptoms bothersome every day = 3; Symptoms affect daily activities = 4; Symptoms are incapacitating, unable to do daily activities = 5

[c]Visick classification: grade 1, no symptoms; grade 2, minimal symptoms, no lifestyle changes, no need to see a physician; grade 3, significant symptoms that require lifestyle changes with a physician's help; grade 4, symptoms as bad or worse than preoperatively

**TABLE 4**

Objective Recurrence and Reoperation Rates and Assessment Metrics

| Author | Time to Evaluation for Objective Recurrence | Assessment Type | | Recurrence (n, %) | Reoperation (n, %) | Adverse Outcomes |
|---|---|---|---|---|---|---|
| Carlson et al 1999(2) | 12 to 36 mo | Esophagram | **Mesh**:<br>**Suture**: | 0[#]<br>3[#] | 0[#]<br>2[#] | NR |
| Frantzides et al 2002(3) | Median 2.5 yrs (6 mo-6 yrs) | Esophagram | **Mesh**:<br>**Suture**: | 0/36 (0)*<br>8/36 (22) | 0/36 (0)<br>5/36 (14) | No mesh-related strictures, erosions or infections |
| Oelschlager et al 2011(5) | **Mesh:** Mean 5.0 yrs (3.7 – 6.2 yrs; n=26)<br>**Suture:** Mean 4.9 yrs (3.6 – 6.5 yrs; n=34) | Esophagram | **Mesh**:<br>**Suture**: | 14/26 (54)<br>20/34 (59) | 0/26 (0)<br>2/34 (5.9) | Use of mesh was not associated with any adverse side effects (noted in discussion but not reported in results section) |
| Braghetto et al 2010(15) | 3 to 5 years | Esophagram | **Mesh**:<br>**Suture**: | 0/23 (0)<br>10/58 (17) | NR | NR |
| Goers et al 2011(16) | **Mesh:** 6.5 mo (n=40)<br>**Suture:** 9.5 mo (n=32) | Esophagram, manometry and pH testing | **Mesh**:<br>**Suture**: | 0/40 (0)<br>0/32 (0) | NR | NR |
| Ringley et al 2006(17) | **Mesh:** mean 6.7 mo (n=15/22)<br>**Suture:** mean 9.5 mo (n=22/22) | Esophagram | **Mesh**:<br>**Suture**: | 0/15 (0)<br>2/22 (9) | NR | NR |
| Zaninotto et al 2007(18) | **Mesh:** Median 33 mo<br>**Suture:** Median 64 mo | Esophagram and endoscopy | **Mesh**:<br>**Suture**: | 3/35 (8.6)*<br>8/19 (42) | 1/35 (2.9)<br>4/19 (21) | Early reoperation for mesh malposition (Day 3) with subsequent esophagectomy for erosion |
| Dallemagne et al 2011(19) | 99 mo (17–186); (n=35/85) | Esophagram | **Mesh**:<br>**Suture**: | 9/14 (64)<br>14/21 (67) | 2/14 (14)<br>0/21 (0) | NR |
| Morino et al 2006(20) | 3 months in 16 patients; not reported in remaining 7 patients; not reported by group | Esophagram, EGD, pH and manometry | **Mesh**:<br>**Suture**: | 13/37 (35)<br>10/13 (77) | 5/37 (14)<br>5/13 (38) | NR |
| Muller-Stich et al 2006(21) | **Mesh:** 20 mo (10–60)<br>**Suture:** 67 mo (9–117) | Esophagram | **Mesh**:<br>**Suture**: | 0/16 (0)<br>7/36 (19) | 0/16 (0)<br>2/36 (5.6) | NR |
| Soricelli et al 2009(22) | **Mesh:** 89 ± 29.8 mo<br>**Suture:** 95 ± 45 mo | EGD (3 and 12 months) then symptom driven | **Mesh**:<br>**Suture**: | 3[#]<br>9[#] | 3[#]<br>6[#] | 1 of 204 with polypropylene required laparoscopic removal |
| Gouvas et al 2011(23) | 1 year | Esophagram, pH and manometry | **Mesh**:<br>**Suture**: | 3/20 (15)<br>4/48 (8) | 2/20 (10)<br>0/48 (0) | 3 mesh-induced fibrosis; 1 mesh-induced fibrosis with erosion requiring resection |
| Grubnik et al 2013(24) | Mean 28.6 mo (10–48 mo) | Esophagram, EGD and pH testing | **Mesh**:<br>**Suture**: | 4/92 (4.4)<br>8/63 (12.7) | 0/92 (0)<br>5/63 (7.9) | No cases of esophageal stricture in either repair type |

NR = Not recorded; EGD = Esophagogastroduodenoscopy;

[#]Denominator for number of patients available for long-term assessment for recurrence and reoperation not provided in the manuscript