Laparoscopic Repair of Very Large Hiatus Hernia With Sutures Versus Absorbable Mesh Versus Nonabsorbable Mesh

A Randomized Controlled Trial

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Objective: Determine whether absorbable or nonabsorbable mesh in repair of large hiatus hernias reduces the risk of recurrence, compared with suture repair.

Background: Repair of large hiatus hernia is associated with radiological recurrence rates of up to 30%, and to improve outcomes mesh repair has been recommended. Previous trials have shown less short-term recurrence with mesh, but adverse outcomes limit mesh use.

Methods: Multicentre prospective double blind randomized controlled trial of 3 methods of repair: sutures versus absorbable mesh versus nonabsorbable mesh. Primary outcome—hernia recurrence assessed by barium meal radiology and endoscopy at 6 months. Secondary outcomes—clinical symptom scores at 1, 3, 6, and 12 months.

Results: A total of 126 patients enrolled: 43 sutures, 41 absorbable mesh, and 42 nonabsorbable mesh. Among them, 96.0% were followed up to 12 months, with objective follow-up data in 92.9%. A recurrent hernia (any size) was identified in 23.1% after suture repair, 30.8% after absorbable mesh, and 12.8% after nonabsorbable mesh ($P = 0.161$). Clinical outcomes were similar, except less heartburn at 3 and 6 months and less bloating at 12 months with nonabsorbable mesh; more heartburn at 3 months, odynophagia at 1 month, nausea at 3 and 12 months, wheezing at 6 months; and inability to belch at 12 months after absorbable mesh. The magnitudes of the clinical differences were small.

Conclusions: No significant differences were seen for recurrent hiatus hernia, and the clinical differences were unlikely to be clinically significant. Overall outcomes after sutured repair were similar to mesh repair.

Keywords: hiatus hernia, laparoscopy, mesh repair, randomized controlled trial

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Laparoscopic surgery for the treatment of patients with a very large hiatus hernia is now standard clinical practice. This problem occurs most commonly in elderly patients, and in the early days of laparoscopic antireflux surgery it represented less than 10% of the antireflux surgery and hiatus hernia repair workload.[1] However, as laparoscopic techniques for repair have become more reliable, surgeons have been referred more patients with very large hiatus hernias, and in recent years the number of patients with this problem has increased greatly, now comprising approximately 50% of the laparoscopic antireflux surgery workload in our practices.[1] In the 1990s, the standard approach to laparoscopic repair of very large hiatus hernias entailed complete dissection of the hernia sac from the mediastinum, hiatal repair with sutures, and a fundoplication.[2,3] Although good clinical outcomes were reported after laparoscopic repair, and clinical success rates of approximately 90% have been described,[2,3] later studies, which utilized barium meal radiology follow-up, demonstrated that suture repair alone is associated with radiological recurrence rates of approximately 25% to 30%, although only 5% of these patients actually develop symptoms from the recurrent hernia.[4] Nevertheless, concern remains that patients with an asymptomatic recurrence could develop problems later.

Mesh repair has been suggested as a strategy to prevent hernia recurrence, as it applies the principles of groin hernia repair, that is, tension-free repair with prosthetic reinforcement, and it is technically straightforward to perform laparoscopically. Although good results have been reported from case series of mesh repair, some surgeons are concerned that the potential advantages of mesh repair might be offset by the risk of the mesh eroding into the esophageal lumen, and other complications.[5] Difficulties also occur when assessing the outcomes of mesh repair, as there is great variability between mesh types and configurations, and little standardization of surgical techniques.

Three randomized trial have examined the impact of mesh repair of the esophageal hiatus, 2 in the context of very large hiatus hernia.[6–9] In 1 study, Frantzides et al[6] enrolled 72 patients to undergo repair with sutures versus a piece of polytetrafluoroethylene mesh and the results at median 2.5 years follow-up showed a reduction in hernia recurrence from 22% to 0%. In another study, Oelschlager et al[7] reported 6-month outcomes from a multicenter trial of 108 patients who underwent repair with sutures versus an absorbable mesh, and hernia recurrence was reduced from 24% to 9% at short-term follow-up. Later follow-up, however, revealed no outcome differences.[8]

Currently, there remains uncertainty about the preferred technique for repair of very large hiatus hernia, with surgeons disagreeing about whether or not to use mesh, and if mesh is used, what type of mesh and what configuration is optimal. To inform this debate, we conducted a multicenter prospective double-blinded randomized trial designed to determine the effectiveness of mesh repair for very large hiatus hernia. In this study, we compared a sutured repair technique with 2 different mesh types—absorbable versus nonabsorbable, with posterior placement of mesh for hiatal repair.

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METHODS

In this multicentre prospective double-blind randomized controlled trial, 3 laparoscopic methods for repair of very large hiatus hernia were compared; repair using sutures alone versus sutures and absorbable mesh versus sutures and nonabsorbable mesh. The study tested the hypothesis that the incidence of postoperative hiatus hernia would be reduced by the addition of mesh reinforcement to a standardized suture repair technique, with the primary outcome determined by the integrity of the hiatal repair assessed by barium meal radiology and upper gastrointestinal endoscopy.

Trial Design

The trial was undertaken at 4 centers in Adelaide and Melbourne, Australia. All surgery was performed by or directly supervised by 1 of 9 upper gastrointestinal surgeons and undertaken within a university teaching hospital or an associated private hospital. All individuals undergoing elective laparoscopic repair of a very large hiatus hernia, irrespective of age, were considered for entry. A very large hiatus hernia was defined as containing at least 50% of the stomach. Patients were excluded if they had undergone previous surgery involving the stomach or the esophagogastric junction, or if they required any additional procedure in addition to hiatus hernia repair.

Patients were consented before surgery and randomized 1:1:1 in the operating room after commencing the operation to 1 of 3 groups:

1. Repair using sutures alone
2. Repair using sutures reinforced by absorbable mesh (4 ply Surgisis ES, Cook Biotech, Indiana)
3. Repair using sutures reinforced by nonabsorbable mesh (TiMesh, PFM Medical, Köln, Germany).

Randomization was undertaken by opening a sealed envelope. The envelopes were prepared before commencing the trial and shuffled independently by 2 research nurses. More envelopes were prepared than needed to ensure that the randomization could not be anticipated by the operating surgeon. Patients were not told which operation variant was performed, and clinical follow-up was undertaken by a research nurse who was blinded to the surgical procedure. Objective follow-up investigations were also performed in a blinded fashion.

Preoperative workup included endoscopy and barium meal radiology. Esophageal manometry and pH monitoring was used selectively in patients with significant reflux symptoms, but often omitted in patients in whom the indication for surgery was mechanical symptoms resulting from the very large hernia in whom an anterior partial fundoplication was planned as a gastropexy.

Operating Technique

Before commencing the trial, surgical techniques were standardized across sites after a consensus meeting between the participating surgeons, and exchange of videos of the standard operating techniques. Laparoscopic repair was commenced in a similar fashion. The initial steps entailed full dissection of the hiatus hernia sac from the mediastinum, and complete reduction of the sac's contents into the abdomen.[10] An esophageal lengthening procedure was never added. The hiatal defect was narrowed to a diameter of approximately 2.5 cm using posterior hiatal sutures, supplemented by additional anterior hiatal sutures if needed to achieve an adequate closure. In patients randomized to 1 of the 2 mesh repair groups, a rectangular piece of mesh (Surgisis or TiMesh) measuring 2- to 3-cm high × 4- to 5-cm wide was cut and placed over the posterior hiatal repair sutures and the hiatal pillars, but not around the esophagus. The mesh overlapped the left and right hiatal pillars behind the esophagus and did not encircle the esophagus. It was anchored in place using either sutures or a mechanical "tacker" (ProTack, Covidien, New Haven, CT). The mesh repair aimed to reinforce the sutured hiatal repair, and it applied a similar technique to that reported by Granderath et al,[9] but using a larger piece of mesh. A fundoplication was then constructed in all patients, with the choice of the fundoplication type at the operating surgeon's discretion. If any laparoscopic procedure was converted to an open procedure, the randomization schedule was still followed, and if any procedure varied from the trial allocation, the patient remained in the trial and their allocated group for subsequent (intention to treat) analysis.

Postoperative Care

After surgery, patients were allowed oral fluids on the day of surgery, and soft food the next day. Barium meal radiology was performed routinely before discharge, to detect any early problems amenable to early laparoscopic reintervention, and to confirm integrity of hiatal repair at the time of discharge. If the appearances were unsatisfactory, the operation site was reinspected laparoscopically and action taken on the basis of the findings.

Follow-up Assessment

The primary outcome for the trial was recurrence of hiatus hernia. Hernia recurrence was determined 6 months after surgery using 2 objective investigations—barium meal radiology and upper gastrointestinal endoscopy. A recurrent hiatus hernia was defined as any evidence of stomach above the level of the diaphragm, irrespective of size. A subgroup of patients with a recurrent hernia, which was of 2 cm or greater vertical height was also identified. The results of barium meal radiology were reported by radiologists blinded to the details of the hiatal repair technique, and reporting was checked by experienced upper gastrointestinal surgeons. Endoscopy was also undertaken in a blinded fashion by upper gastrointestinal surgeons who were experienced in assessing esophagogastric anatomy after antireflux surgery.

Secondary outcomes were clinical symptom scores, and clinical recurrence of the hernia leading to reintervention. Symptoms were assessed 1, 3, 6, and 12 months after surgery, and analysis and data collection aimed to identify postoperative reflux symptoms, postoperative side effects, and overall satisfaction with the outcome after surgery. To evaluate these outcomes, all patients were interviewed before surgery and at 1, 3, 6, and 12 months after surgery and using a structured questionnaire. Longer-term follow-up is continuing, and outcomes will be reported when available. The structured questionnaire was similar to a questionnaire used in other studies reported by our group.[11] Follow-up data were collected by telephone interview by research nurses based in Adelaide. The presence or absence of the following symptoms was sought: heartburn, chest pain, epigastric pain, regurgitation, dysphagia for lumpy solids, soft solids and liquids, odynophagia, early satiety, epigastric bloating, anorexia, nausea, vomiting, nocturnal coughing and wheezing, and diarrhea. The ability to relieve bloating and whether a normal diet was being consumed was also determined.

Zero to 10 analog scales (0 = no symptoms, 10 = severe symptoms) were used to assess heartburn, dysphagia for liquids, and dysphagia for solids. A validated dysphagia score (0 = no dysphagia, 45 = severe dysphagia), which combines information about difficulty swallowing 9 types of liquids and solids, was also applied.[12] Overall outcome was determined using 3 previously described scores.[11] Patients ranked the outcome of surgery using a modified Visick grading (score 1 to 5, 1 = no symptoms, 5 = worse after surgery), an outcome score (excellent, good, fair, or poor), and an analog satisfaction score (0 = dissatisfied, 10 = satisfied). A quality-of-life assessment was

also performed using the SF-36 questionnaire, but these data will be analyzed and reported elsewhere.

Statistics and Sample size

Before commencing the trial, a power calculation determined that 126 patients (42 per group) would be required to demonstrate a 25% difference (30% vs 5%) between groups for radiological recurrence of hiatus hernia, at a significance level of $P < 0.05$ and power of 80%. The proposed magnitude of difference was based on reported outcome differences from the randomized trial reported by Frantzides et al,[6] and objective outcome studies reported by us[4] and others.[13] The sample size was also determined to be sufficient to demonstrate a 13% difference (18% vs 5%) for a 2-way comparison of mesh versus suture repair. All data were entered into a computerized database (Filemaker Pro, version 12, Filemaker, Inc., Santa Clara, CA). Data were analyzed within the database or exported to GraphPad Prism Version 6.0 (GraphPad Software, Inc., San Diego, CA) for statistical testing. Analyses were undertaken on an intention-to-treat basis with patients classified according to randomization. The 3 groups were compared separately. The χ^2 test was used to evaluate 3×2 contingency tables. Comparison of continuous data sets was undertaken using 1-way analysis of variance.

The protocol for this trial was approved by the Southern Adelaide Clinical Human Research Ethics Committee and the Clinical Research Ethics Committees for all other participating hospitals.

RESULTS

From February 2006 to September 2012, 126 patients were enrolled in the trial. Forty-three were randomized to undergo repair using sutures alone, 41 repair with absorbable mesh (Surgisis) and 42 nonabsorbable mesh (TiMesh). Of the 126 patients entered, 117 (92.9%) were interviewed 1 month after surgery, 118 (93.7%) at 3 months, 122 (96.8%) at 6 months, and 121 (96.0%) at 12 months. Objective follow-up data were available for 117 (92.9%) at 6 months follow-up. Follow-up is summarized in Figure 1. No patient withdrew from the study. Missing data were the result of an inability to contact patients at specific follow-up intervals. One patient in the suture repair group died 7 days after surgery (see later).

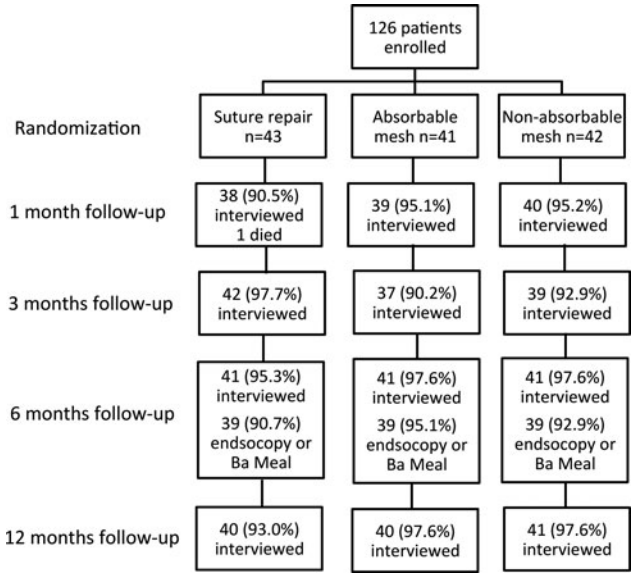

FIGURE 1. CONSORT diagram summarizing recruitment and follow-up compliance.

Preoperative Assessment

The preoperative demographic details for the 3 groups of patients were similar, and are summarized in Table 1. Preoperative symptom scores are summarized in Tables 2 to 6. Less patients in the TiMesh group reported heartburn or chest pain symptoms before surgery. The mean chest pain score was also lower in this group (Table 3), and more patients in the TiMesh group reported a Visick score of 1 or 2 before surgery (Table 6). All other preoperative symptoms were similar for the 3 groups.

Surgery

As randomization occurred in the operating room, all patients underwent surgery. One patient randomized to repair with TiMesh underwent a sutured repair only and the nonabsorbable mesh was not placed. The operating surgeon for that patient encountered a very wide hiatus, with the aorta encompassing the area where the left hiatal pillar is usually found, and was not able to suture a piece of mesh in place. All other patients underwent surgery according to the randomization schedule. Operating time and the number of sutures used for hiatal repair were similar for all 3 groups (Table 7). A fundoplication was added in all patients, and in all but 2 a partial fundoplication was constructed.

Two (1.6%) patients were thought to have a shortened esophagus at surgery—1 in the suture repair group and 1 in the TiMesh group. An esophageal lengthening procedure was not performed in any patient enrolled in the trial. Two procedures were converted to open surgery, both in the suture repair group, because of a bleeding short gastric blood vessel and intra-abdominal obesity respectively. Intra-operative complications are listed in Table 8. One patient in the Surgisis group experienced an esophageal perforation during placement of an esophageal bougie. This was initially sutured but then managed with a temporary esophageal stent inserted on the 10th day after surgery.

Early Hospital Outcomes

The mean length of stay after surgery was similar for the 3 groups (Sutures—4.2 days, Surgisis—4.3, TiMesh—4.3). Postoperative complications occurred in a similar proportion of patients in all groups and are summarized in Table 8. Four patients underwent early laparoscopic reoperation in the suture repair group, and 1 patient died suddenly 7 days after surgery following a presumed pulmonary embolus or myocardial infarct. In the Surgisis group, 1 patient experienced an esophageal perforation, which was initially repaired with sutures but eventually required placement of a temporary esophageal stent 10 days later. In the TiMesh group, 3 patients underwent early reoperation, with 1 of these converted to an open procedure to excise part of the gastric fundus, which was perforated at the site of the fundoplication sutures. Both of the patients thought to have a shortened esophagus developed an acute hiatus hernia and underwent early revision surgery with rerepair of the hiatus. Both subsequently had an excellent clinical outcome and did not have a hernia when assessed objectively at 6 months. Two (1.6%) late revision procedures were performed, 1 for a recurrent hiatus hernia after suture repair and 1 for dysphagia after repair with TiMesh.

Objective Postoperative Investigations

The outcomes for the objective assessment with barium meal radiology and endoscopy are summarized in Table 9. There were no statistically significant differences in the rate of recurrent hiatus hernia between the 3 groups for any comparisons. Of patients, 100 (79.4%) underwent barium meal radiology at 6 months, 100 (79.4%) underwent endoscopy, and 117 (92.9%) underwent at least 1 of these 2 investigations. Using barium meal radiology, a recurrent hiatus hernia

TABLE 1. Preoperative Parameters

	Randomization			
Variable	**Suture Repair**	**Surgisis**	**TiMesh**	***P***
Age (yrs)	67.8 (64.7–70.9)	68.0 (65.1–70.9)	68.1 (64.7–71.5)	0.991
Sex (M:F)	14:29	10:31	16:26	0.403
Height (cm)	1.65 (1.63–1.70)	1.64 (1.61–1.68)	1.66 (1.63–1.70)	0.556
Weight (kg)	82.5 (77.3–87.7)	78.7 (74.0–83.4)	79.4 (73.7–85.0)	0.516
BMI (kg/m^2)	29.6 (28.0–31.2)	29.4 (27.8–31.0)	28.5 (26.6–30.5)	0.663
Duration of symptoms (yrs)	9.7 (6.2–13.1)	10.2 (5.9–14.2)	7.3 (4.6–10.0)	0.496

All data are expressed as mean (95% confidence intervals) or n (%). Analysis of variance used to compare continuous data sets, χ^2 test used to assess categorical variables.

TABLE 2. Assessment of Heartburn Using 0 to 10 Visual Analog Scale

	Sutures	**Surgisis**	**TiMesh**	***P***
Preoperative	2.24 (1.29–3.20)	2.05 (1.18–2.92)	1.65 (0.86–2.44)	0.614
Postoperative (mo)				
1	0.58 (0.092–1.07)	0.69 (0.027–1.36)	0.73(0.098–1.35)	0.936
3	0.45 (0.062–0.84)	1.57 (0.60–2.54)	0.38 (−0.19 to 0.96)	0.022
6	1.49 (0.58–2.40)	1.44 (0.48–2.40)	0.17 (−0.092 to 0.44)	0.024
12	1.10 (0.45–1.76)	1.28 (0.37–2.20)	0.55 (0.059–1.04)	0.303

All data are expressed as mean (95% confidence intervals).

TABLE 3. Assessment of Chest Pain Using 0 to 10 Visual Analog Scale

	Sutures	**Surgisis**	**TiMesh**	***P***
Preoperative	2.88 (1.74–4.02)	4.35 (3.13–5.57)	1.45 (0.57–2.31)	0.0013
Postoperative (mo)				
1	1.34 (0.52–2.22)	1.36 (0.52–2.20)	1.13 (0.29–1.97)	0.903
3	1.19 (0.39–1.99)	1.60 (0.67–2.52)	0.74 (0.03–1.46)	0.343
6	0.83 (0.26–1.40)	1.20 (0.46–1.94)	0.54 (−0.05 to 1.12)	0.329
12	0.82 (0.14–1.51)	1.10 (0.37–1.83)	0.38 (−1.04 to 0.85)	0.261

All data are expressed as mean (95% confidence intervals).

of any size was identified in 22 (22.0%), and a hernia measuring 2 or more cm in length was identified in only 3 (3.0%). Using endoscopy, a recurrent hiatus hernia of any size was identified in 32 (32.0%), and a hernia measuring 2 or more cm in length was identified in 8 (8.0%). The objective outcome data for both tests was combined for a reanalysis, which prioritized the barium meal outcome assessment and supplemented the endoscopy outcome assessment in the patients who had not undergone a barium meal radiology. With this analysis, a recurrent hiatus hernia of any size was identified in 26 (22.2%), and a hernia measuring 2 or more cm in length was identified in 5 (4.3%) patients. When this definition of hernia recurrence was used to compare Mesh repair (both mesh types) versus repair with only sutures, the rate of hernia recurrence was 17/78 (21.8%) versus 9/39 (23.1%; $P = 1.00$, Fisher's exact test), and 2/78 (2.6%) versus 3/39 (7.7%; $P = 0.329$) for hernias measuring 2 cm or more in length.

One- to 12-Month Postoperative Clinical Outcome

The clinical follow-up outcomes at 1, 3, 6, and 12 months are summarized in Tables 2 to 6. Heartburn analog symptom scores were significantly lower in the TiMesh group at 3 and 6 months, with higher scores in the Surgisis group (Table 2). Chest pain and dysphagia scores were similar at all follow-up points (Tables 3 and 5). A range of other symptom scores were significantly worse in the Surgisis group—odynophagia at 1 month, nausea at 3 and 12 months, wheezing at 6 months, and inability to belch at 12 months (Table 4). In addition, the patients in the TiMesh group were less likely to report bloating at 12 months. Scores of overall satisfaction were similar for all 3 groups (Table 6). None of the 5 patients with a postoperative hernia of 2 cm or more in length identified primarily by barium meal (supplemented by endoscopy assessment in those who did not undergo barium meal) underwent revision surgery within the follow-up period. Four of the 5 reported an excellent clinical outcome at 12 months, with satisfaction scores of 8, 9, 9, and 10, and no significant symptoms. One of the 5 patients (Surgisis group) reported bloating and chest pain, and a satisfaction score of 5. At 12 months follow-up, this patient was being considered for possible revision surgery.

DISCUSSION

The reports of good early outcomes for hiatal repair with mesh in randomized trials of mesh versus sutured repair of large hiatus hernias has encouraged the wider use of mesh for repair for very large hiatus hernias, despite concerns about the risk of mesh erosion and added difficulties if subsequent surgical revision is required. At follow-up of up to 12 months, our trial identified no major differences for mesh versus sutured repair of very large hiatus hernias. In particular, no significant differences were seen between the 3 repair types for the primary study outcome of hernia recurrence measured by barium meal radiology and endoscopy. The secondary outcomes that were

TABLE 4. Preoperative and Postoperative Symptoms Assessed Using Yes Versus No Questions

	Preoperative			1 mo			3 mo			6 mo			12 mo		
Symptom	**Sutures**	**Surgisis**	**TiMesh**	**Sutures**	**Surgisis**	**TiMesh**	**Sutures**	**Surgisis**	**TiMesh**	**Sutures**	**Surgisis**	**TiMesh**	**Sutures**	**Surgisis**	**TiMesh**
Heartburn	**66.7%**	**63.4%**	**40.5%***	15.8%	10.3%	15.0%	14.3%	24.3%	5.1%	31.7%	20.0%	12.2%	25.0%	27.5%	14.6%
Chest pain	**45.2%**	**61.0%**	31.0%†	26.3%	25.6%	17.5%	19.0%	21.6%	12.8%	14.6%	22.5%	9.8%	15.0%	15.0%	4.9%
Epigastric pain	50.0%	53.7%	54.8%	21.1%	35.9%	35.0%	21.4%	37.8%	20.5%	31.7%	25.0%	29.3%	25.0%	27.5%	12.2%
Regurgitation	66.7%	51.2%	61.9%	2.6%	12.8%	12.5%	9.5%	21.6%	10.3%	26.8%	17.5%	12.2%	15.0%	25.0%	17.1%
Odynophagia	14.3%	9.8%	4.8%	**0%**	**7.7%**	0%‡	2.4%	5.4%	2.6%	4.9%	5.0%	2.4%	2.5%	2.5%	0%
Early Satiety	54.8%	54.8%	50.0%	52.6%	56.4%	60.0%	57.1%	37.8%	41.0%	46.3%	47.5%	39.0%	45.0%	50.0%	29.3%
Epigastric bloat	64.3%	70.7%	47.6%	39.5%	30.8%	32.5%	35.7%	40.5%	17.9%	39.0%	37.5%	19.5%	**42.5%**	**42.5%**	19.5%‖
Anorexia	33.3%	24.4%	23.8%	31.6%	35.9%	30.0%	21.4%	18.9%	20.5%	12.2%	17.5%	14.6%	12.5%	20.0%	4.9%
Nausea	35.7%	24.4%	50.0%	26.3%	15.4%	15.0%	**4.8%**	**27.0%**	10.3%§	12.2%	22.5%	17.1%	**15.0%**	**27.5%**	4.9%**
Vomiting	21.4%	31.7%	31.0%	2.6%	7.7%	5.0%	2.4%	5.4%	0%	9.8%	12.5%	4.9%	7.5%	15.0%	2.4%
Coughing	38.1%	41.5%	26.2%	8.3%	7.7%	7.5%	11.9%	5.4%	10.3%	14.6%	17.5%	17.1%	12.5%	17.5%	9.8%
Wheezing	28.6%	22.0%	11.9%	2.6%	5.1%	5.0%	7.1%	5.4%	7.7%	**0%**	**15.0%**	7.3%¶	7.5%	17.5%	9.8%
Can relieve bloat	69.0%	47.5%	55.0%	73.7%	66.7%	60.0%	71.4%	54.1%	74.4%	73.2%	67.5%	75.6%	**92.5%**	**72.5%**	97.5%††
Eats normal diet	59.5%	50.0%	65.0%	42.1%	30.8%	25.0%	83.3%	70.3%	82.1%	75.6%	77.5%	87.8%	92.5%	85.0%	95.0%
Diarrhea	NA	NA		28.9%	15.4%	27.5%	16.7%	13.5%	7.7%	19.5%	27.5%	12.2%	25.0%	17.5%	19.5%
Increased flatus	NA	NA		57.9%	64.1%	55.0%	66.7%	62.2%	56.4%	58.5%	62.5%	48.8%	57.5%	47.5%	41.5%

All data indicate percentage of patients interviewed at each time point. No statistically significant differences were demonstrated between the 3 groups ($P \geq 0.05$ at all follow-up intervals) except where indicated. All P's < 0.05 are highlighted in bold.

*$P = 0.031$, †$P = 0.023$, ‡$P = 0.046$, §$P = 0.0119$, ¶$P = 0.0328$, ||$P = 0.0424$, **$P = 0.0197$, ††$P = 0.0017$.

TABLE 5. Dysphagia Assessment

	Preoperative			1 mo			3 mo			6 mo			12 mo		
	Sutures	**Surgisis**	**TiMesh**	**Sutures**	**Surgisis**	**TiMesh**	**Sutures**	**Surgisis**	**TiMesh**	**Sutures**	**Surgisis**	**TiMesh**	**Sutures**	**Surgisis**	**TiMesh**
Dysphagia															
Lumpy solids	42.9%	41.5%	31.0%	18.4%	30.8%	12.5%	23.8%	24.3%	15.4%	19.5%	15.0%	9.8%	15.0%	17.5%	19.5%
Soft solids	14.3%	19.5%	11.9%	5.3%	7.7%	5.0%	7.1%	5.4%	5.1%	0%	5.0%	4.9%	2.5%	5.0%	2.4%
Liquids	11.9%	19.5%	14.3%	7.9%	7.7%	7.5%	7.1%	0%	2.6%	0%	10.0%	0%	2.5%	5.0%	0%
Visual analog scale															
Solids	2.7 (1.6–3.8)	3.2 (2.1–4.4)	2.2 (1.1–3.3)	1.4 (0.5–2.2)	2.3 (1.2–3.5)	1.3 (0.4–2.2)	1.8 (0.9–2.6)	1.6 (0.7–2.5)	1.4 (0.3–2.4)	1.3 (0.15–2.2)	1.2 (0.5–1.9)	1.1 (0.3–1.8)	1.1 (0.4–1.9)	1.5 (0.7–2.2)	1.1 (0.3–1.8)
Liquids	0.9 (0.1–1.6)	1.4 (0.6–2.2)	1.0 (0.2–1.8)	0.3 (−0.2 to 0.8)	0.7 (0.2–1.3)	0.4 (−0.1 to 0.9)	0.3 (−0.1 to 0.7)	0.5 (−0.1 to 1.2)	0.3 (−0.1 to 0.7)	0.2 (−0.04 to 0.5)	0.5 (0.04–0.9)	0.07 (−0.1 to 0.2)	0.3 (−0.1 to 0.7)	0.5 (0.1–0.9)	0.0 (0.0–0.0)
Dysphagia score (0–45)															
Overall score	6.9 (3.9–10.0)	8.8 (5.3–12.4)	8.7 (4.5–13.0)	11.7 (7.8–15.6)	18.7 (14.9–22.5)	17.6 (14.2–20.9)	5.1 (2.7–7.5)	7.2 (3.5–11.0)	4.2 (1.3–7.1)	4.8 (2.3–7.4)	4.9 (1.9–7.8)	4.2 (1.5–6.9)	2.9 (1.0–4.8)	4.8 (1.9–7.8)	2.4 (0.8–4.0)
Scored 0 only	52.4%	47.5%	62.5%	44.7%	20.5%	20.0%	54.8%	56.8%	74.4%	61.0%	67.5%	70.7%	75.0%	62.5%	75.0%

All data indicate percentages or mean (95% confidence intervals).

No statistically significant differences were demonstrated between groups ($P \geq 0.05$ at all follow-up intervals).

TABLE 6. Outcome Scores, Satisfaction Score and Visick Grading

	Preoperative			1 mo			3 mo			6 mo			12 mo		
	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh
Outcome															
Excellent or Good	N/A	N/A	N/A	86.8%	79.5%	77.5%	95.2%	86.5%	89.7%	85.4%	87.5%	92.7%	90.0%	79.5%	95.0%
Fair or Poor	N/A	N/A	N/A	13.2%	20.5%	22.5%	4.8%	13.5%	10.3%	14.6%	12.5%	7.3%	10.0%	20.5%	5.0%
Modified Visick grade															
1&2	28.6%	15.0%	50.0%*	78.9%	79.5%	77.5%	92.9%	75.7%	87.2%	82.9%	85.0%	90.2%	87.5%	79.5%	95.0%
3, 4 & 5	71.4%	85.0%	50.0%*	21.1%	20.5%	22.5%	7.1%	24.3%	12.8%	17.1%	15.0%	9.8%	12.5%	20.5%	5.0%
Satisfaction score															
Mean score	N/A	N/A	N/A	8.6	8.3	8.5	9.4	8.6	9.2	8.3	8.4	9.5	8.8	8.2	9.4
95% confidence interval	N/A	N/A	N/A	(8.0–9.3)	(7.5–9.1)	(7.7–9.2)	(9.1–9.7)	(7.7–9.5)	(8.6–9.8)	(7.5–9.1)	(7.6–9.2)	(9.1–9.9)	(8.3–9.4)	(7.3–9.2)	(9.0–9.8)
Correct decision to have operation	N/A	N/A	N/A	97.4%	97.3%	97.5%	97.6%	94.6%	100%	92.7%	97.5%	97.6%	97.5%	90.0%	97.5%

All data given as percentages or mean (95% confidence intervals). No statistically significant differences were demonstrated between groups ($P \geq 0.05$ at all follow-up intervals), except $^{*}P = 0.0030$.
N/A indicates not applicable.

measured by the clinical questionnaire also revealed no major differences in overall outcome, although there were some statistically significant differences between heartburn scores, and the incidences of nausea and bloating, with the outcomes pointing toward a somewhat poorer clinical outcome after repair with Surgisis, and a better outcome for TiMesh due to less bloating issues. However, most clinical outcomes were similar for all 3 repair types, and the differences were probably insufficient to support any claim that one particular technique was better then the others.

The outcomes from our study differ from those reported in the 3 other published randomized trials of mesh versus sutured repair, which all reported a reduced incidence of hiatus hernia after mesh repair. In the study reported by Frantzides et al,[6] the incidence of hernia recurrence at median 2.5 years follow-up was reduced from 22% to 0%. Oelschlager et al[7] reported a reduction from 24% to 9% at 6 months follow-up, and Granderath et al[9] reported a reduction from 26% to 8% at 12 months. In Frantzides et al's trial, patients underwent repair using a piece of polytetrafluoroethylene mesh that encircled the esophagus. The 0% recurrence rate after mesh repair in this study was not replicated in the other trials, perhaps reflecting the encirclement of the esophagus by the mesh prosthesis. However, many surgeons remain reluctant to place mesh fully around the esophagus because of the perceived risks of mesh erosion and hiatal fibrosis at longer term follow-up.[5] Unfortunately, because late follow-up from this study has not been reported, Frantzides et al's results have not addressed this issue.

Oelschlager et al[7] used Surgisis to reinforce the hiatus posteriorly and around the sides of the esophagus. In their trial, the early results at 6 months follow-up appeared promising.[7] However, a subsequent report of 5 years follow-up revealed very high recurrence rates of 59% versus 54% in the 2 groups and provided little support for repair with absorbable mesh.[8] In this trial, Oelschlager et al defined a hiatus hernia to be present if it exceeded 2 cm in vertical length. This was different to our study, in which as we included all hernias, irrespective of their size. When a similar definition of hernia size 2 cm or more was applied in our trial, the "hernia" recurrence rate was substantially lower (Table 9), and only 5 patients were identified by barium meal radiology (supplemented by endoscopy) to have a hernia larger than 2 cm.

Granderath et al's randomized trial included patients undergoing laparoscopic Nissen fundoplication for gastroesophageal reflux with or without a hiatus hernia and enrolled a different set of patients to those included in the other 2 trials and our current trial.[9] Hence, it did not directly address the issue of how best to repair a large hiatus hernia. Their technique did, however, entail a posterior hiatal repair with sutures, which was reinforced by an on-lay of a 3 cm × 1 cm piece of polypropylene mesh, a similar approach to that used in our trial, although we used a larger piece of mesh. Their main outcome measure was the incidence of fundoplication migration into the mediastinum, and in their control group this occurred in 26% of patients. In a report from an earlier randomized trial conducted in our Departments, we identified a much lower 6% incidence of fundoplication migration using barium meal radiology 6 months after surgery in patients who underwent a sutured hiatal repair with no mesh.[11]

Three patients in the suture repair group in the current trial underwent early laparoscopic reoperation for an acute hiatus hernia, and one required revision for a hiatus hernia at 7 months, compared to 1 early recurrence in the nonabsorbable mesh group and none in the absorbable mesh group. This was offset, however, by a higher number of patients in the absorbable mesh groups found to have a hiatus hernia at 6 months, and a more revision procedures for a tight hiatal repair in the nonabsorbable mesh group. When all of these outcomes are considered together, the risk of adverse outcomes seemed to be

TABLE 7. Perioperative Outcomes

	Randomization			
	Suture Repair	**Surgisis**	**TiMesh**	***P***
Operating time (min)	111.8 (91.0–132.7)	110.3 (96.7–123.9)	111.8 (102.2–132.1)	0.831
No. sutures used for hiatal repair	4.93 (4.37–5.49)	4.75 (4.41–5.36)	4.71 (4.06–5.36)	0.817
Fundoplication type	1—Nissen 5—Posterior partial 37—Anterior partial	0—Nissen 4—Posterior partial 37—Anterior partial	1—Nissen 8—Posterior partial 33—Anterior partial	

Data are expressed as mean (95% confidence intervals).

TABLE 8. Complications and Reoperations

	Randomization		
	Suture Repair	**Surgisis**	**TiMesh**
Intraoperative complications	2—Pneumothorax 1—Bleed from short gastric	1—Pneumothorax 1—Esophageal perforation	1—Minor splenic injury
Major complications and revision operations (30 d)	1—Tight hiatal repair (early reoperation) 3—Acute hiatus hernia (laparoscopic reoperation) 1—Death-day 7	1—Esophageal perforation (stent on day 10)	2—Tight hiatal repair (early reoperation) 1—Acute hiatus hernia and gastric perforation (open reoperation)
Revision operations after 30 d	1—Recurrent hiatus hernia (reoperation at 7 mo)	Nil	1—Dysphagia (reoperation at 8 mo)

TABLE 9. Radiology and Endoscopy Outcomes at 6 Months Follow-up

	Sutures	**Surgisis**	**TiMesh**	***P***
Barium meal radiology				
Studied	31 (72.1%)	34 (82.9%)	35 (83.3%)	
Hiatus hernia—any size	7 (22.6%)	11 (32.4%)	4 (11.4%)	0.110
Hiatus hernia—2 cm+	1 (3.2%)	2 (5.9%)	0 (0.0%)	0.357
Endoscopy				
Studied	31 (72.1%)	34 (82.9%)	35 (83.3%)	
Hiatus hernia—any size	11 (35.5%)	13 (37.1%)	8 (22.9%)	0.346
Hiatus hernia—2 cm+	2 (6.5%)	3 (8.8%)	2 (5.6%)	0.858
Barium meal radiology and endoscopy				
Underwent barium meal radiology or Endoscopy	39 (90.7%)	39 (95.1%)	39 (92.9%)	
Hiatus hernia—any size (barium meal radiology outcome prioritized)	9 (23.1%)	12 (30.8%)	5 (12.8%)	0.161
Hiatus hernia—2 cm+ (barium meal radiology outcome prioritized)	3 (7.9%)	2 (5.9%)	0 (0.0%)	0.223

All data are expressed as n (%) unless otherwise indicated.

similar for all repair types. Furthermore, we have always applied a low threshold for early laparoscopic reexploration of the operative site within the first few days, and our experience has confirmed that correction of potential problems identified by contrast radiology in the first few days, has a minimal impact on recovery, and minimizes the risk of later more difficult revision surgery.[14]

There are several factors that might impact on recurrence rate after laparoscopic repair of a very large hiatus hernia, including surgeon experience and technique. Our trial was commenced in 2006, and the surgeons contributing patients all had substantial prior experience with the techniques used in the trial. In addition, care was taken to preserve the fascial coverings over the edges of the hiatus as these provide support for hiatal repair sutures.[2] If not protected, the hiatal muscle can be exposed and the hiatal defect can be enlarged by the process of hiatal dissection until it cannot be closed without mesh. In our trial, the hiatus was closed adequately by sutures in all patients.

Strengths of our trial include a very high rate of clinical and objective follow-up, blinding of the patients and the follow-up process, and few exclusions. The trial was run across multiple sites in the public and private sectors in Australia and the results should be generalizable, at least in the Australian context where repair of very large hiatus hernias is usually undertaken by experienced upper gastrointestinal surgeons. Limiting the generalizability of the results, however, is the testing of only 1 mesh configuration. However, the configuration was similar to that used in 2 of the 3 previous randomized trials. When establishing the protocol for the trial, there was no enthusiasm in Australia for encircling the esophagus with mesh as some surgeons had encountered problems with mesh erosion and hiatal fibrosis in patients in whom the technique described by Frantzides et al[6] had been used. For this reason, posteriorly placed mesh reinforcement of a sutured hiatal repair was the most acceptable approach for the participating surgeons. However, care should be taken before trying to extrapolate the results of our trial to mesh repair using different mesh shapes and different mesh placement techniques.

The follow-up in our trial is currently limited to 12 months, and the outcomes from Oelschlager et al's trial do suggest that results can

change with more extended follow-up,[8] so longer term follow-up to confirm our initial findings is also needed. This is underway. Further barium meal radiology and endoscopy examinations are scheduled for 3 to 4 years after surgery, and the outcomes will be reported when they become available. Another potential weakness is that a large number of clinical outcomes were evaluated, and there is a risk of false-positive *P* values with multiple data analyses. However, the trend data and positive *P* values consistently pointed to a somewhat poorer clinical outcome in the group of patients who underwent repair with Surgisis, although the magnitude of these differences are unlikely to be clinically significant. With a larger trial, however, the trend toward a higher hernia recurrence rate after Surgisis repair might have become statistically significant.

The outcomes of our trial have shown no significant differences for the assessed primary outcome—recurrent hiatus hernia at radiology or endoscopy, and in general, the clinical outcome differences between the 3 techniques were small and unlikely to be clinically significant. The rate of recurrent hiatus hernia measuring 2 cm or greater in size was low across all groups. The results of this randomized trial do not add support for the routine use of mesh repair of very large hiatus hernias.

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