

Five Year Follow-up of a Randomized Controlled Trial of Laparoscopic Repair of Very Large Hiatus Hernia With Sutures Versus Absorbable Versus Nonabsorbable Mesh

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Objective: To determine whether absorbable or nonabsorbable mesh repair of large hiatus hernias is followed by less recurrences at late follow-up compared to sutured repair.

Summary of Background Data: Radiological recurrences have been reported in up to 30% of patients after repair of large hiatus hernias, and mesh repair has been proposed as a solution. Earlier trials have revealed mixed outcomes and early outcomes from a trial reported previously revealed no short-term advantages for mesh repair.

Methods: Multicentre prospective double-blind randomized controlled trial of 3 methods of hiatus hernia repair; sutures versus absorbable mesh versus nonabsorbable mesh. Primary outcome – hernia recurrence assessed by barium meal X-ray and endoscopy at 3–4 years. Secondary outcomes – clinical symptom scores at 2, 3, and 5 years.

Results: 126 patients were enrolled – 43 sutures, 41 absorbable mesh, and 42 nonabsorbable mesh. Clinical outcomes were obtained at 5 years in 89.9%, and objective follow-up was obtained in 72.3%. A recurrent hernia (any size) was identified in 39.3% after suture repair, 56.7% – absorbable mesh, and 42.9% – nonabsorbable mesh ($P = 0.371$). Clinical outcomes were similar at 5 years, except chest pain, diarrhea, and bloat symptoms which were more common after repair with absorbable mesh.

Conclusions: No advantages were demonstrated for mesh repair at up to 5 years follow-up, and symptom outcomes were worse after repair with absorbable mesh. The longer-term results from this trial do not support mesh repair for large hiatus hernias.

Keywords: hiatus hernia, laparoscopy, mesh repair, randomized controlled trial (*Ann Surg* 2020;272:241–247)

Laparoscopic approaches to repair of large hiatus hernias are now standard but can be followed by recurrence. Studies reported in the 2000's identified high rates of radiological recurrence after

sutured repair when assessed by Barium meal radiology,^{1–3} although most radiological recurrences seem to be asymptomatic.⁴ Mesh repair techniques were developed in response to the reported radiological recurrence risk, with the aim of reducing the risk of hernia recurrence. Short term outcomes from early randomized trials suggested that mesh repair did significantly reduce the risk of recurrence.^{5–7} However, subsequent trials, and longer follow-up from one of the early trials have failed to support the earlier reports.^{8–10} Five randomized trials addressing whether mesh repair achieves a more durable repair for large hiatus hernia, compared with repair using sutures alone, have now been published.^{5–10}

The 3 earliest trials from Frantzides et al, Granderath et al, and Oeschlager et al all reported reductions in hernia recurrence rates at short term follow-up.^{5–7} However, later follow-up from Oeschlager et al's trial demonstrated similar outcomes at 5 years follow-up after repair with Surgisis (absorbable mesh) versus sutures alone,¹⁰ highlighting the need for longer-term follow-up in all trials. We subsequently reported outcomes at 12 months from a 3-armed trial which enrolled 126 patients to repair with sutures versus posteriorly placed absorbable (Surgisis) or nonabsorbable mesh.⁸ No significant differences in hernia recurrence rates were seen for mesh versus sutured repair, and the symptom outcomes were generally similar, but with some poorer symptom outcomes after repair with Surgisis. We concluded that at short term follow-up sutured repair was equally effective, and the results from this trial failed to support the routine use of mesh. A subsequent trial from the Netherlands reported similar outcomes, with no differences at 12 months follow-up in a 2-armed trial of sutured repair versus repair with posteriorly placed nonabsorbable mesh.⁹

As the results of the reported trials have been mixed, and longer-term outcomes have only been reported from one trial, longer-term outcomes from more trials are needed to inform the debate about whether or not mesh should be used to reduce the risk of recurrence after repair of very large hiatus hernias. When we established our randomized trial of sutured versus absorbable versus nonabsorbable mesh repair, the protocol included both early and late objective assessment with endoscopy and barium meal radiology. In this paper we report the longer-term outcomes from this trial, including objective assessment at 3–4 years, and clinical follow-up to 5 years.

METHODS

The trial protocol has been described previously.⁸ In brief, this multicentre prospective double-blind randomized controlled trial compared 3 laparoscopic methods for repair of very large hiatus hernia; repair using sutures versus absorbable mesh versus nonabsorbable mesh. The study tested the hypothesis that the incidence of

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postoperative hiatus hernia determined at barium meal X-ray and upper gastrointestinal endoscopy would be reduced by adding posterior mesh reinforcement to a standardized suture repair technique.

The trial was undertaken in university teaching hospitals and private hospitals in 4 centers in Adelaide and Melbourne, Australia, and surgery was undertaken by experienced upper gastrointestinal surgeons. Patients were eligible for inclusion if they had a very large hiatus hernia, defined as containing at least 50% of the stomach. Exclusions included previous gastric surgery, or a requirement for an additional procedure in addition to hiatus hernia repair.

Patients were randomized 1:1:1 after commencing surgery to 1 of 3 procedures;

- (a) Repair using sutures alone.
- (b) Repair using sutures reinforced by absorbable mesh (4 ply Surgisis ES; Cook Biotech, IN).
- (c) Repair using sutures reinforced by a lightweight monofilament woven nonabsorbable mesh (TiMesh, PFM Medical, Köln, Germany).

Laparoscopic repair included dissection of the hernia sac and reduction of its contents into the abdomen.¹¹ The hiatal defect was narrowed to approximately 2.5 cm diameter using posterior hiatal sutures, supplemented by anterior sutures if required. If randomized to mesh repair, a piece of Surgisis or TiMesh measuring 2–3 cm high $\times$ 4–5 cm wide was placed over the posterior hiatal repair sutures and the hiatal pillars and secured to reinforce the sutured repair. A fundoplication was then added, with the type at each surgeon's discretion.

Patients were blinded to the method of hiatal repair, and clinical follow-up was undertaken by a “blinded” research nurse. Objective follow-up was also blinded. For this paper, the primary outcome was recurrence of hiatus hernia at late follow-up, determined 3–4 years after surgery using Barium meal X-ray and upper gastrointestinal endoscopy. A recurrent hiatus hernia was considered to be any stomach above the level of the diaphragm, irrespective of size. The vertical height of any hernia was measured. Radiologists were blinded when reporting Barium meal X-rays. Endoscopy was undertaken in a blinded fashion by experienced upper gastrointestinal surgeons who were unaware of the repair technique.

Secondary outcomes were clinical symptom scores, further surgery for a recurrent hiatus hernia, and surgical revision for any indication. Symptoms assessed at 1, 3, 6, and 12 months after surgery have been reported previously.⁸ Symptom assessment using a structured questionnaire continued yearly to determine symptoms of gastro-esophageal reflux, postoperative side effects, and overall satisfaction with the outcome after surgery. For this paper clinical outcomes at 2, 3, and 5 years are reported. Clinical follow-up data was collected at a telephone interview by a research nurse. The presence or absence of the after symptoms was sought using yes/no responses; heartburn, chest pain, epigastric pain, regurgitation, dysphagia for lumpy solids, soft solids and liquids, early satiety, epigastric bloating, ability to relieve bloating anorexia, nausea, vomiting, nocturnal coughing and wheezing, diarrhea, and whether a normal diet was being consumed.

Previously described 0–10 analog scales (0 = no symptoms, 10 = severe symptoms) assessed heartburn, dysphagia for liquids, and dysphagia for solids.¹² A dysphagia score (0 = no dysphagia, 45 = severe dysphagia) which combined information about difficulty swallowing 9 types of liquids and solids was also applied.¹³ Overall outcome was determined using a previously described modified Visick grading (score 1–5, 1 = no symptoms, 5 = worse after surgery), an outcome score (excellent, good, fair, or poor), and an analog satisfaction score (0 = dissatisfied, 10 = satisfied).¹²

Statistics and Sample Size

As described previously, a power calculation determined that 126 patients (42 per group) would be required to demonstrate a 25% difference (30% vs 5%) between groups for the primary outcome of hiatus hernia recurrence, at a significance level of $P < 0.05$, and power of 80%.⁸ The postulated difference was determined after considering outcome data from studies published at the time the protocol was established. These included reports of hernia recurrence rates of 30%–42% after sutured repair,^{2,14} and early data from randomized trials suggesting that mesh might reduce the risk of early recurrence by more than 20%.⁵

Analyses were undertaken on an intention to treat basis. Data was analyzed using GraphPad Prism Version 6.0 (GraphPad Software Inc., San Diego, California). The Chi-squared test was used to evaluate 3×2 contingency tables, and comparisons of continuous data sets were undertaken using 1-way analysis of variance. The protocol for this trial was approved by the Clinical Research Ethics Committees at each participating hospital.

RESULTS

Demographic details and early follow-up to 12 months have been reported previously.⁸ To facilitate benchmarking of the outcomes in this paper the baseline data reported in our earlier paper is again reported in the tables in this paper. One hundred twenty-six patients were enrolled from February 2006 to September 2012 and randomized to undergo repair using sutures alone ($n = 43$), absorbable mesh (Surgisis; $n = 41$), or nonabsorbable mesh (TiMesh; $n = 42$).

Follow-up is summarized in Figure 1. No patient withdrew from the trial. One hundred fifteen (91.3%) of the 126 patients were interviewed at 2 years after surgery, 109 (86.5%) at 3 years, and 107 (84.9%) at 5 years. Across the 5 years follow-up 5 patients died, and 2 patients were not able to be assessed after admission to nursing homes. Twelve (9.5%) were lost to follow-up or withdrew. Objective follow-up data was available for 86 (72.3%) of the 119 patients who were available for follow-up at 3 to 4 years.

Preoperative demographic details and symptom scores for the 3 groups were shown to be similar in our earlier report, and full details of the surgery are also described elsewhere.⁸ The 3 groups were well matched. Demographic details have been reported before and are summarized in Supplementary Table 1, <http://links.lww.com/SLA/B854>.⁸ All but 1 patient underwent surgery according to the randomization schedule, with 1 patient randomized to repair with TiMesh undergoing a sutured repair only. A partial fundoplication was added in 124 patients, and a Nissen in 2. A full breakdown of fundoplication types is summarized in Supplementary Table 2, <http://links.lww.com/SLA/B854>. There were no significant differences between groups for fundoplication type. Esophageal lengthening procedures were not performed. Perioperative complications have been described previously and were similar for the 3 groups.⁸

Objective Investigations at 3–4 Years

The outcomes for objective assessment with barium meal radiology and endoscopy are summarized in Table 1. There were no statistically significant differences in the rate of recurrent hiatus hernia between the 3 groups for any comparisons. Of the 119 patients who were alive and potentially available for follow-up, 62 (52.1%) underwent barium meal radiology at 3–4 years, and 73 (61.3%) underwent endoscopy. Eighty-six (72.3%) underwent at least 1 of these 2 investigations. Using barium meal radiology, a recurrent hiatus hernia of any size was identified in 27 (43.5%) of 62 patients who underwent this test, and a hernia measuring 2 or more cm in length was identified in only 9 (14.5%) of these patients. Using

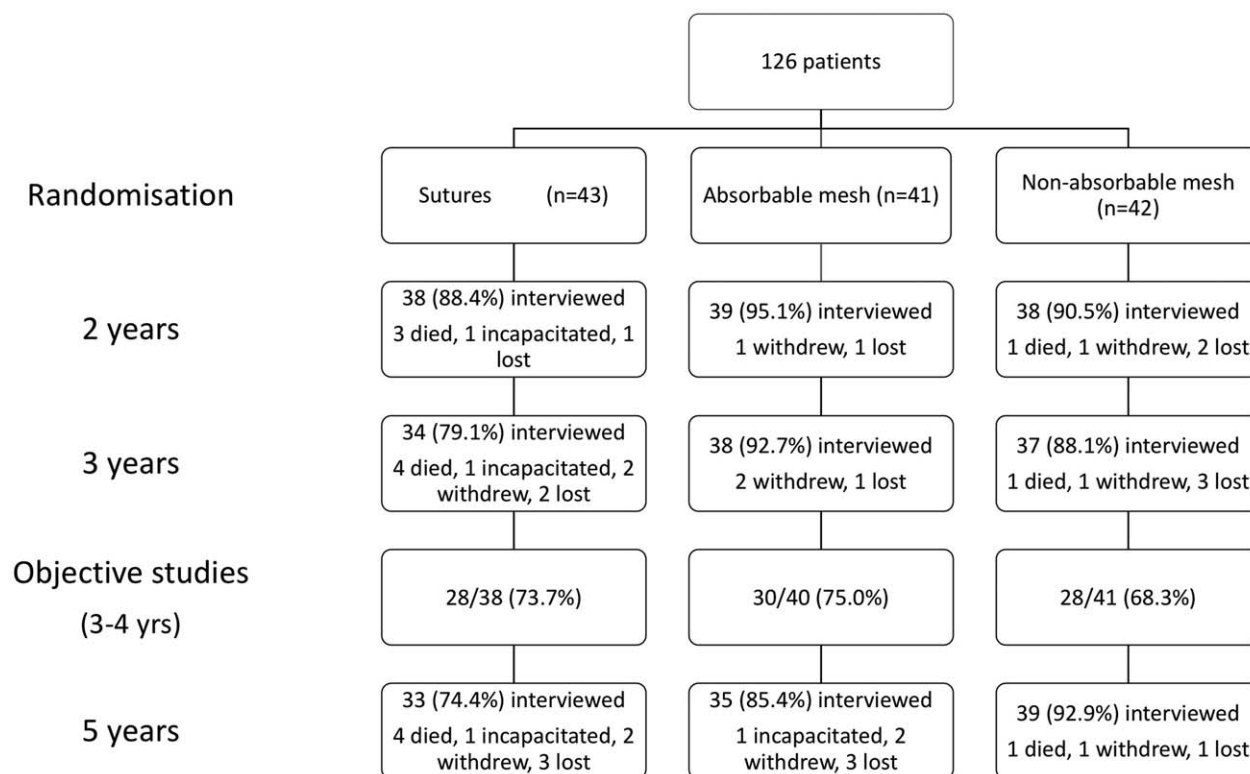


FIGURE 1. CONSORT diagram summarizing follow-up compliance.

endoscopy, a recurrent hiatus hernia of any size was identified in 38 (52.1%) of 73 patients who underwent endoscopy, and a hernia measuring 2 or more cm in length was identified in 11 (15.1%). When the objective outcome data for both tests were combined for an analysis which prioritized the barium meal outcome and supplemented the endoscopy outcome in the patients who had not undergone a barium meal, a recurrent hiatus hernia of any size was identified in 40 (46.5%) of 86 patients who underwent at least 1 test. In this analysis a hernia measuring 2 or more cm in length was identified in 9 (10.5%). When using this definition of hernia recurrence to compare mesh repair (both mesh types) versus repair with only sutures, the rate of hernia recurrence was 29/58 (50.0%) versus 11/28 (39.3%; $P = 0.368$, Fisher exact test; difference between

proportions = 0.095, 95% confidence intervals -0.104 to 0.2932), and 8/58 (13.8%) versus 1/28 (3.6%; $P = 0.261$) for hernias measuring 2 or more cm in length. A 2-way comparison of hernia recurrence of any size for the suture repair group versus absorbable mesh revealed no differences between those 2 groups [11/28 vs 17/30, $P = 0.202$; difference between proportions = 0.1738 (-0.08361 to 0.4312)]. Similarly, no difference was seen for a 2-way comparison of suture repair versus nonabsorbable mesh [11/28 vs 12/28, $P = 1.00$; difference between proportions = 0.03689 (-0.2294 to 0.3031)].

We also tested the potential impact of missing data from the 33 individuals who were potentially alive and available for investigation at later follow-up. For this analysis we assumed that the patients who

TABLE 1. Radiology and Endoscopy Outcomes at 3–4 yr Follow-up

	Sutures	Surgisis	TiMesh	P-value
Barium Meal Radiology				
Studied	n = 19 (50.0%)	n = 23 (57.5%)	n = 20 (48.8%)	
Hiatus hernia – any size	7 (36.8%)	12 (65.2%)	8 (40.0%)	0.564
Hiatus hernia – 2 cm+	1 (3.2%)	4 (17.4%)	0 (0.0%)	0.377
Endoscopy				
Studied	n = 20 (52.6%)	n = 26 (65.0%)	n = 27 (65.9%)	
Hiatus hernia – any size	8 (40.0%)	15 (57.7%)	15 (55.6%)	0.443
Hiatus hernia – 2 cm+	1 (2.5%)	6 (23.1%)	4 (14.8%)	0.236
Barium Meal and Endoscopy				
Underwent Barium meal or endoscopy	n = 28 (73.7%)	n = 30 (75.0%)	n = 28 (68.3%)	
Hiatus hernia – any size (Barium meal outcome prioritized)	11 (39.3%)	17 (56.7%)	12 (42.9%)	0.371
Hiatus hernia – 2 cm+ (Barium meal outcome prioritized)	1 (3.6%)	4 (13.3%)	4 (14.3%)	0.347

All data expressed as n (%).

TABLE 2. Preoperative and Postoperative Symptoms at 2–5 yr Assessed Using Yes Versus No Questions

Symptom	Preop			2 yr			3 yr			5 yr		
	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh
Heartburn	66.7%	63.4%	40.5%*	15.8%	20.5%	31.6%	23.5%	21.1%	27.0%	24.2%	22.9%	25.6%
Chest pain	45.2%	61.0%	31.0%†	10.5%	25.6%	10.5%	6.6%	28.9%	10.8%	3.0%	22.9%	5.1%#
Epigastric pain	50.0%	53.7%	54.8%	15.8%	41.0%	21.1%‡	14.7%	28.9%	27.0%	24.2%	28.6%	30.8%
Regurgitation	66.7%	51.2%	61.9%	7.9%	33.3%	28.9%§	17.6%	18.4%	18.9%	21.2%	17.1%	17.9%
Early Satiety	54.8%	54.8%	50.0%	34.2%	33.3%	26.3%	29.4%	34.2%	27.0%	18.2%	31.4%	30.8%
Epigastric bloating	64.3%	70.7%	47.6%	28.9%	46.2%	26.3%	23.5%	31.6%	21.6%	15.2%	42.9%	25.6%*
Anorexia	33.3%	24.4%	23.8%	10.5%	23.1%	7.9%	14.7%	15.8%	16.2%	6.1%	8.6%	12.8%
Nausea	35.7%	24.4%	50.0%	10.5%	20.5%	10.5%	17.6%	21.1%	16.2%	12.1%	20.0%	17.9%
Vomiting	21.4%	31.7%	31.0%	0%	7.7%	10.5%	5.9%	10.5%	5.4%	3.0%	11.4%	12.8%
Coughing	38.1%	41.5%	26.2%	15.8%	20.5%	7.9%	17.6%	10.5%	8.1%	21.2%	14.3%	17.9%
Wheezing	28.8%	22.0%	11.9%	10.5%	12.8%	5.3%	5.9%	7.9%	2.7%	12.1%	11.4%	12.8%
Can relieve bloating	69.0%	47.5%	55.0%	70.3%	79.5%	68.4%	79.4%	65.8%	73.0%	71.9%	62.9%	76.3%
Eats normal diet	59.5%	50.0%	65.0%	86.5%	94.7%	92.1%	91.2%	65.8%	83.8%*	84.4%	80.0%	82.1%
Diarrhea	NA	NA		16.3%	30.8%	13.2%	14.7%	21.1%	0% 	15.2%	34.3%	12.8%††
Increased flatus	NA	NA		34.2%	43.6%	36.8%	35.3%	39.5%	18.9%	30.0%	45.7%	35.9%

All data is % patients interviewed at each time point.

No statistically significant differences were demonstrated between the 3 groups ($P = >0.05$ at all follow up intervals) except where indicated.

* $P = 0.031$, † $P = 0.023$, ‡ $P = 0.014$, § $P = 0.020$, || $P = 0.016$, ¶ $P = 0.021$, * $P = 0.0197$, ** $P = 0.036$, †† $P = 0.048$.

underwent a sutured repair but no investigations all had an undiagnosed recurrent hernia, and that all patients who underwent a mesh repair with Surgisis or TiMesh but no investigations did not have a recurrent hernia. Analysis of this adjusted data set did not reveal a significant difference between the groups for hernia recurrence (sutures – 21/38 vs Surgisis – 17/40 vs TiMesh – 12/41; $P = 0.647$)

Late Clinical Outcomes

Clinical follow-up at 2, 3, and 5 years are summarized in Tables 2–6. Overall, the clinical outcomes were good in all 3 groups. In general, any differences between the 3 groups was associated with a poorer symptom outcome for patients undergoing repair with absorbable mesh (Surgisis). No advantages were seen for repair with nonabsorbable mesh (TiMesh) over sutured repair. At 2 years follow-up patients who underwent repair with absorbable mesh reported a higher prevalence of epigastric pain, regurgitation, and dysphagia for liquids, and this group was less likely to report a good or excellent

outcome after surgery. At 3 years the absorbable mesh group reported higher dysphagia and chest pain scores, a greater frequency of diarrhea, and they were more likely to report dietary restrictions. At 5 years the absorbable mesh groups were more likely to report bloating and diarrhea, and their chest pain scores were significantly higher.

Across 5 years follow-up 14 (11.1%) patients underwent a revision operation. Nine (7.1%) revisions were for hiatus hernia, 3 (2.4%) acutely within the first 3 days after surgery, and 6 (4.8%) at a later stage between 7 and 102 months after the first operation. The reasons for further surgery in each trial group are summarized in Table 7. The rate of revision surgery was similar in all 3 groups.

DISCUSSION

The use of mesh for repair of very large hiatus hernias remains a source of disagreement, with conflicting outcomes reported from

TABLE 3. Assessment of Heartburn Using 0–10 Visual Analog Scale

	Sutures	Surgisis	TiMesh	P-value
Preoperative	2.24 (1.29–3.20)	2.05 (1.18–2.92)	1.65 (0.86–2.44)	0.614
Postoperative				
2 years	0.82 (0.177–1.454)	1.49 (0.515–2.459)	1.16 (0.380–1.935)	0.733
3 years	0.85 (0.221–0.329)	1.00 (0.329–1.671)	0.70 (0.245–1.160)	0.128
5 years	1.48 (0.519–2.449)	1.23 (0.442–2.015)	1.95 (0.952–2.940)	0.836

All data are expressed as mean (95% CI's).

TABLE 4. Assessment of Chest Pain Using 0–10 Visual Analog Scale

	Sutures	Surgisis	TiMesh	P-value
Preoperative	2.88 (1.74–4.02)	4.35 (3.13–5.57)	1.45 (0.57–2.31)	0.0013
Postoperative				
2 years	0.51 (–0.040–1.067)	1.33 (0.462–2.205)	0.42 (–0.035–0.877)	0.110
3 years	0.44 (–0.031–0.913)	1.76 (0.757–1.152)	0.54 (–0.071–1.152)	0.029
5 years	0.19 (–0.037–0.421)	1.54 (0.459–2.618)	0.23 (–0.244–0.711)	0.011

All data are expressed as mean (95% CI's).

TABLE 5. Dysphagia Assessment

	Preop			2 yr			3 yr			5 yr		
	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh
Dysphagia												
Lumpy solids	42.9%	41.5%	31.0%	23.7%	12.8%	10.5%	17.6%	18.4%	10.8%	18.2%	8.6%	10.3%
Soft solids	14.3%	19.5%	11.9%	2.6%	10.3%	0%	2.9%	13.2%	0%†	3.0%	0%	2.6%
Liquids	11.9%	19.5%	14.3%	0%	7.7%	0%*	0%	7.9%	0%	3.0%	0%	2.6%
Visual analog scale												
Solids	2.7 (1.6–3.8)	3.2 (2.1–4.4)	2.2 (1.1–3.3)	1.53 (0.73–2.33)	1.00 (0.36–1.64)	0.89 (0.36–1.64)	1.56 (0.55–2.57)	1.61 (0.63–2.59)	0.97 (0.17–1.78)	2.41 (1.22–3.60)	1.69 (0.70–2.67)	1.40 (0.47–2.32)
Liquids	0.9 (0.1–1.6)	1.4 (0.6–2.2)	1.0 (0.2–1.8)	0.47 (0.050–0.90)	0.44 (–0.009–0.88)	0.13 (–0.14–0.40)	0 (0–0)	0.63 (0.89–1.17)	0† (0–0)	0.56 (–0.17–1.30)	0.80 (0.094–1.51)	0.58 (–0.026–1.18)
Dysphagia score (0–45)												
Overall score	6.9 (3.9–10.0)	8.8 (5.3–12.4)	8.7 (4.5–13.0)	3.90 (1.56–6.23)	4.13 (1.22–7.04)	2.47 (0.90–4.05)	4.62 (1.59–7.65)	5.71 (2.42–9.00)	2.51 (0.75–4.27)	5.53 (1.99–9.08)	5.24 (2.15–8.32)	4.18 (1.41–6.96)
Scored 0 only	52.4%	47.5%	62.5%	63.2%	76.9%	73.7%	67.6%	71.1%	78.4%	53.1%	64.7%	70.7%

All data given as percentages or mean (95% CIs).

No statistically significant differences were demonstrated between groups ($P = >0.05$ at all follow up intervals) except where indicated.* $P = 0.050$, † $P = 0.023$, ‡ $P = 0.008$.

TABLE 6. Outcome scores, Satisfaction Score and Visick Grading

	Preop			2 yr			3 yr			5 yr		
	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh	Sutures	Surgisis	TiMesh
Outcome												
Excellent or Good	n/a	n/a	n/a	92.1%	76.9%	94.7%†	91.2%	84.2%	91.9%	90.6%	80.0%	84.2%
Fair or Poor	n/a	n/a	n/a	7.9%	23.1%	5.3%†	8.8%	15.8%	8.1%	9.4%	20.0%	15.8%
Modified Visick grade												
1&2	28.6%	15.0%	50.0%*	86.8%	73.6%	92.1%	88.2%	86.5%	94.6%	84.4%	80.0%	86.8%
3, 4 & 5	71.4%	85.0%	50.0%*	13.2%	26.4%	7.9%	11.2%	13.5%	5.4%	15.6%	20.0%	13.2%
Satisfaction score												
Mean score	n/a	n/a	n/a	8.97 (8.30–9.65)	8.63 (7.90–9.37)	9.16 (8.48–9.84)	9.00 (8.38–9.63)	8.45 (7.71–9.18)	8.87 (8.04–9.69)	8.78 (8.05–9.51)	8.34 (7.66–9.03)	8.95 (8.42–9.48)
95% CI	n/a	n/a	n/a									
Correct decision to have operation	n/a	n/a	n/a	97.4%	94.9%	100%	88.2%	97.4%	97.3%	96.9%	91.4%	94.7%

All data given as percentages or mean (95% CIs).

No statistically significant differences were demonstrated between groups ($P = >0.05$ at all follow up intervals), except * $P = 0.0030$, † $P = 0.035$.

n/a indicates not applicable.

TABLE 7. Reoperations

	Randomization		
	Suture Repair = 5	Surgisis = 4	TiMesh = 5
Early revision operations (30 d)	1 - Tight hiatal repair 2 - Acute hiatus hernia	1 - Endoscopic stent for esophageal perforation	2 - Tight hiatal repair 1 - Acute hiatus hernia and gastric perforation
Revision operations after 30 d	2 - Recurrent hiatus hernia (reoperation at 7 mo and 4.5 yr)	3 - Recurrent hiatus hernia (reoperation at 15 mo, 2 yr and 2 yr)	1 - Dysphagia (reop at 8 mo) 1 - Recurrent hiatus hernia (reoperation at 13 mo)

case series and randomized trials.^{1–10} Previously reported results at follow-up to 12 months from the randomized trial reported in the current paper found no differences for hernia recurrence rates after mesh versus sutured repair, and no major differences for most clinical outcomes, except for more heartburn, nausea, and bloating after repair with Surgisis, and less bloating symptoms after repair with TiMesh.⁸ As the overall clinical outcomes were similar at 12 months after all 3 types of repair, we concluded that the earlier outcomes from this trial did not support the routine use of mesh for repair for very large hiatus hernias.

However, the early outcomes from our trial differed from the early outcomes reported in randomized trials reported by Frantzides et al, Granderath et al, and Oelschlager et al.^{5–7} In those trials the incidence of hernia recurrence at short term follow-up was reduced from 22% to 0%, 26% to 8%, and 24% to 9%, respectively after mesh repair. This contrasts with the early outcomes from a more recent report from Oor et al which revealed similar findings to the current study, with no difference for nonabsorbable mesh (TiMesh) versus sutured repair at 12 months follow-up.⁹ Considered together, the short-term follow-up outcomes from the 5 published randomized trials have been mixed, and clear support for mesh repair has not emerged.

To date, only Oelschlager et al have reported longer-term outcomes from a randomized trial of mesh versus sutured repair for large hiatus hernia.¹⁰ In their trial, which used Surgisis to reinforce the hiatus posteriorly and around the sides of the esophagus, 5-year follow-up revealed radiological recurrence rates of 59% versus 54%. These rates were significantly higher than those seen at early follow-up, but were not significantly different between the 2 groups, and the longer-term results did not support repair with absorbable mesh. The difference between short- and long-term outcome data in Oelschlager et al's trial also highlighted the need to be cautious when interpreting early outcomes, and the importance of obtaining longer-term follow-up in all trials of mesh versus sutured repair.

The longer-term outcome data from our trial are consistent with the Oelschlager et al's earlier report, and also fail to support the routine use of mesh for repair of very large hiatus hernias. The incidence of hernia recurrence at 3–4 years, assessed by barium meal radiology and/or endoscopy was not significantly different for all 3 repair techniques. Furthermore, there was no trend towards a higher recurrence rate after sutured repair, with the highest recurrence rate seen following repair with Surgisis, and the lowest incidence of hernias measuring more than 2 cm in length seen following sutured repair. The number of reoperations for recurrent hiatus hernia were also similar in all 3 groups. Considered together, the longer-term outcomes from our trial and Oelschlager et al's do not support the use of mesh, and in the absence of conflicting longer-term data from other trials, it is difficult to make a case for mesh repair to reduce the risk of late hiatus hernia recurrence.

Consistent with the previously reported early clinical outcomes from our trial,⁸ the analysis of secondary outcomes suggested a poorer symptom outcome in the group who underwent repair using

Surgisis, with chest pain, diarrhea and bloat symptoms more common following repair with Surgisis. Other trend data pointed towards a poorer outcome in this group. Considered in context, it is reasonable to conclude that the clinical outcomes following repair with sutures alone were not inferior to repair with mesh.

The overall rate of late hernia recurrence identified in our trial varied from 39.3% following repair with sutures, to 42.9% following repair with TiMesh and 56.7% with Surgisis. Whilst these rates might seem high, they are consistent with the late recurrence rates of 54% and 59% reported by Oelschlager et al,¹⁰ and rates of 21% to 42% in case series for sutured repair reported in the early 2000's.^{1–3} In a previous study, we evaluated the significance of small recurrent hiatus hernias after laparoscopic repair of very large hiatus hernias by following a cohort of 115 patients with a radiologically identified but clinically asymptomatic hernia for a mean 74 months.⁴ Ninety-five percent of those patients remained asymptomatic. Only 2 patients required surgical intervention to repair a recurrent hiatus hernia across the 74 months mean follow-up. These findings were consistent with the findings of our current trial which identified larger hernias in a smaller subset of 3.6%–14.3% of the overall cohort, and only 6 (4.8%) patients underwent revision surgery beyond the first postoperative week, suggesting that the extent of the clinical problem of recurrent hiatus hernia in earlier studies has been overestimated by the use of surrogate measures such as barium radiology. The majority of small recurrent hiatus hernias identified by barium meal radiology at late follow-up are probably not clinically significant, suggesting that surgeons should reconsider their views about what outcomes are important after hiatus hernia repair, and prioritize adverse symptom outcomes and reoperation/reintervention rates over small anatomical defects that are probably not important.

Strengths of the trial reported in our current paper include a high rate of clinical and objective follow-up at up to 5 years, and the double-blind randomized methodology which continued across the follow-up period. The trial was run in several Australian public and private hospitals and reflects the Australian health care context in which repair of large hiatus hernias is generally undertaken by specialist upper gastrointestinal surgeons. A potential limitation of our trial; however, is that it tested only 1 of several possible mesh configurations. Nevertheless, the configuration used in the trial was similar to that used in the majority of reported randomized trials, and posterior placement of mesh is perhaps the most common configuration currently used, with fewer surgeons choosing to fully encircle the esophageal hiatus with mesh due to concerns about potential mesh erosion and hiatal fibrosis.^{15,16}

A further possible limitation is the choice of mesh types. When finalizing the protocol for the current study we sought consensus about acceptable mesh types. At that time Surgisis was considered to be the best absorbable mesh choice. However, alternative absorbable meshes have since been marketed. For example, Bio-A tissue reinforcement (W.L. Gore & Associates, Flagstaff, AZ) has been advocated as an alternative absorbable mesh that is absorbed more slowly than Surgisis.¹⁷ Whilst it would be interesting to

evaluate Bio-A and other mesh types in another randomized trial, it seems likely we have already tested the range of mesh types with Bio-A likely to fall somewhere between Surgisis and TiMesh based on its absorption profile, and therefore unlikely to achieve a better outcome than TiMesh or sutured repair. For now, it seems unlikely that an alternative posteriorly placed absorbable mesh will achieve a different outcome to that seen in this trial, and therefore lead to different conclusions than those being drawn.

The longer-term objective and clinical outcomes from the current randomized trial of sutured versus absorbable versus nonabsorbable mesh have not shown any advantages for the use of mesh for repair of very large hiatus hernias. The incidence of small recurrent hernias was high across all 3 groups, but consistent with previous objective outcome studies. Mesh repair did not reduce the incidence of these hernias, and in most individuals recurrent hernias were small and asymptomatic. The results of this randomized trial do support for the routine use of mesh repair of very large hiatus hernias.

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