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ORIGINAL SCIENTIFIC REPORT

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Quality of life following repair of large hiatal hernia is not influenced by the use of mesh—Longer-term follow-up from a randomized trial

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Abstract

Introduction: The use of prosthetic mesh in laparoscopic repair of large hiatus hernias remains controversial. Clinical and quality of life outcomes from a randomized controlled trial of mesh versus suture repair previously showed few differences at early follow-up. This study evaluated longer-term quality of life outcomes from that trial.

Methods: A prospective, multicentre, double blind randomized controlled trial assessed three methods of repair for large hiatus hernias: sutures-only versus absorbable mesh versus non-absorbable mesh. Quality of life was assessed using the Short-Form 36 (SF-36) questionnaire which was completed preoperatively and then at 3, 6, 12 months following surgery and annually thereafter. SF-36 outcomes were compared across the three repair techniques at longer-term follow-up (3–6 years), and to earlier baseline and 12-month outcomes.

Results: 126 patients were randomized; 43—suture-only, 41—absorbable mesh and 42—non-absorbable mesh. Questionnaires were completed by 118 patients preoperatively, 115 at 12 months and 98 at longer-term follow-up (median 5 years). There were no significant differences between the repair techniques for the subscale and composite scores at longer-term follow-up. The mental component score improved significantly after surgery and was sustained across follow-up for all techniques. The physical component score also improved significantly but was lower at longer-term follow-up compared to the 12-month follow up in both mesh groups.

Conclusion: Surgical repair of large hiatus hernias provides sustained long-term improvement in quality of life. The addition of mesh does not improve quality of life.

Trial Registration: This trial is registered with the Australia and New Zealand Clinical Trials Registry ACTRN12605000725662.

KEYWORDS

esophagus

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1 | INTRODUCTION

Large hiatal hernia is often considered to be present when more than 30%–50% of the stomach herniates into the mediastinum.[1] They represent 5%–10% of all hiatus hernias and are more prevalent in individuals over the age of 70 years.[1,2] In addition to an association with gastroesophageal reflux, large hiatus hernias often present with early satiety and post-prandial pain. Patients can also experience dyspnea, iron-deficiency anemia secondary to Cameron's ulcers and some may present with life threatening complications such as gastric volvulus, strangulation and perforation.[3,4] In Australia, the aging population has been associated with an increase from 10% to 30% of large hiatus hernias making up the surgical caseload of specialized units.[5]

Laparoscopic repair of large hiatus hernia delivers an excellent clinical outcome for most patients.[6] The principles of surgery involve complete hiatal sac dissection, reduction of the stomach and the distal 2–3 cm of esophagus back into the abdomen, tension-free closure of the widened hiatus, and a fundoplication of some sort. However, recurrent hiatus hernias of any size after surgery are common and have been reported in between 15% and 66% at late follow-up.[7,8]

The use of prosthetic mesh reinforcement remains controversial. It was hoped that mesh would reduce hiatal hernia recurrence in a similar way to mesh repair of abdominal wall hernias. However, reported mesh erosion into the esophagus or stomach has led some surgeons to be wary of non-absorbable mesh with a subsequent preference for absorbable mesh instead.[9,10] Preliminary favorable randomized studies demonstrated an early reduction in recurrence with mesh repair.[11–13] However, at longer-term follow-up, initial differences disappeared.[14] Our own randomized controlled trial demonstrated no differences in recurrence at short or long-term follow-up for suture versus absorbable versus non-absorbable mesh repair.[15,16] This is consistent with a recent meta-analysis of the seven reported randomized control trials, which also demonstrated no significant difference in recurrence following mesh repair using either absorbable or non-absorbable mesh.[17]

However, hiatus hernia recurrence is only one measurable outcome, and it does not necessarily indicate failure from the patients' perspective. As, Wang et al. demonstrated, while patients with recurrent hiatus hernias rarely report obstructive symptoms, overall clinical outcomes remain excellent, with most individuals still expressing high levels of satisfaction, and experiencing low surgical revision rates following hernia recurrence, even though the use anti-reflux medication is increased.[18] Quality of life outcomes are an indicator of the outcome from the patients' perspective. The Short-Form 36 (SF-36) is a well-validated and widely used quality of life questionnaire which evaluates overall general, mental and physical well-being.[19] We have used this in our randomized controlled trial, and have previously reported short-term quality of life follow-up which showed a significant improvement in overall quality of life outcomes following surgery, but no significant differences between the three repair techniques.[20] In the current study, we evaluated longer-term quality of life outcomes to see if the earlier findings were sustained at longer follow-up.

2 | METHODS

A prospective, double-blind randomized controlled trial was performed. Full details of the trial protocol have been published previously.[15] The trial compared different laparoscopic techniques for repair of very large hiatus hernias; suture only repair, suture repair with absorbable mesh (Surgisis) and suture repair with non-absorbable mesh (Timesh). The results of follow-up investigations and clinical symptom outcomes at 12 months and 5 years have been reported previously.[15,16] Quality of life outcomes using the SF-36 have been reported at 1–2 years.[20] The current study extends the quality of life outcomes to 5-year follow-up.

2.1 | Summary of original trial protocol

This study was performed in four centers in Adelaide and Melbourne, Australia and nine surgeons performed the operations. Patients undergoing elective repair for a very large hiatus hernia (defined as >50% of intrathoracic stomach) were included in the study, and randomized 1:1:1 to suture-only repair versus suture repair reinforced by absorbable mesh (4 ply Surgisis® ES, Cook Biotech) versus suture repair reinforced by non-absorbable mesh (Timesh®, PFM, Medical). All patients were blinded to the procedure performed. Clinical follow-up was undertaken by a research nurse who was also blinded.

A standardized surgical approach was performed. The hernia sac was completely dissected from the mediastinum and contents were reduced into the abdomen. The hiatus was re-approximated with posteriorly placed interrupted non-absorbable sutures. Supplemental anterior sutures were added if needed for adequate closure. Participants in the mesh groups had a rectangular piece of mesh (Surgisis or Timesh) measuring 2–3 cm high *x* 4–5 cm wide placed in a retro-esophageal fashion over the posterior hiatal stitches and anchored to the diaphragm using either sutures or a mechanical “tacker”. This was followed by a fundoplication, with the type being at each surgeon's discretion.

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2.2 | Follow-up assessment

Patients underwent barium meal X-ray and gastroscopy at 6 months and 3–4 years follow-up, and also completed a structured symptom questionnaire which included quality of life assessment at 3, 6, 12 months, and annually thereafter. The analysis of the objective and symptom outcomes have been published elsewhere.[15,16]

2.3 | Quality of life assessment

Patient reported quality of life outcomes were assessed at the same time as the symptom questionnaires, and were measured using the 36-item Short Form Survey (SF-36), a standardized, validated instrument consisting of 36 questions or items.[19] Thirty-five of the 36 items contribute to scoring 8 health subscales, which include: physical functioning, role physical, bodily pain, general health, vitality, social functioning, role emotional and mental health. The final item asks patients to compare their health to that of a year previously to measure reported health transition. The eight subscales and the reported health transition items are each converted into a 0–100 score. The higher the score, the better the quality of life on that scale. The subscales also contribute to the calculation of two overarching component scales: the physical component scale or mental component scale.[21]

A z-score (statistical measurement in relation to the mean value) for each scale was calculated by subtracting the general Australian population mean from each of the SF-36 scores and dividing the difference by the corresponding scale standard deviation from the general population. Each SF-36 z-score is multiplied by its respective physical or mental coefficient factor and then summed across the eight products. Norm based scoring is achieved by multiplying each aggregate component scale by 10 and adding the result to 50. The Australian population figures and deviations were derived from the Australian Bureau of Statistics.[22]

For data analysis, we compared the physical and mental component scales and the eight individual subscales pre-operatively, at 1 year post-operative and at longer-term follow-up. We also compared quality of life outcomes between the different repair techniques at each time point. The follow-up time point used for longer-term follow-up was 5 years. To maximize completeness of follow-up, if 5 years data was missing, then 6 years outcome data was used. If this was also missing then 4 years data was used, then 3 years data if no other data was available. If no follow-up data at 3–6 years was available, the patient was considered to be lost to follow-up.

2.4 | Data analysis and ethics

Analysis was performed using IBM's Statistical Package for Social Sciences (SPSS; version 19 for Apple Macintosh). Parametric data was analyzed using independent sample *t* tests, and one-way ANOVA tests. A *p*-value of less than 0.05 was considered to be statistically significant. The protocol for this study was approved by the Human Research Ethics Committee at each participating hospital.

3 | RESULTS

From July 2006 to September 2012, 126 patients were enrolled and randomized to the following groups: 43 to suture-only repair, 41 to repair with absorbable mesh (Surgisis), and 42 to repair with nonabsorbable mesh (TiMesh). Baseline demographics were similar between the three groups and are reported in the original study report.[15]

SF-36 questionnaires were completed by 118 patients (93.7%) preoperatively, 115 at 12 months, and 98 at longer-term follow-up. Four patients died by 12 months follow-up and a further five died between 12 months and 5 years, yielding quality of life follow-up rates for potentially alive patients of 94.3% at 12 months and 83.8% at longer-term follow-up. Missing data points were due to inability to contact some participants at specific follow-up intervals, or where patients chose not to return a completed questionnaire. Follow-up completeness is summarized in Figure 1. For longer-term follow-up, SF-36 results from 5 years follow-up were available for 64 patients. Six years follow-up data was available and used for a further seven patients, 4 years follow-up was used for 21, and 3 years follow-up was used for six patients. Mean follow-up was 4.7 years (median 5). At longer term follow-up the mean age of the patients was 72.04 years (SD = 9.52), 95% CI (70.14, 73.94) for the full cohort, and 71.00 years (SD = 8.74), 95% CI (67.47, 74.53) in the suture-only repair group, 72.14 years (SD = 8.42), 95% CI (69.33, 74.95) in the absorbable mesh group and 72.69 years (SD = 11.19), 95% CI (69.16, 76.22) in the nonabsorbable mesh group. There were no statistically significant age differences at long-term follow-up between the three groups ($p = 0.238$, ANOVA).

3.1 | SF-36 subscale results

The outcomes for each of the eight subscale components are detailed in Figure 2A–H with full data provided in Tables S1 and S2. There were no significant differences preoperatively between the three groups for

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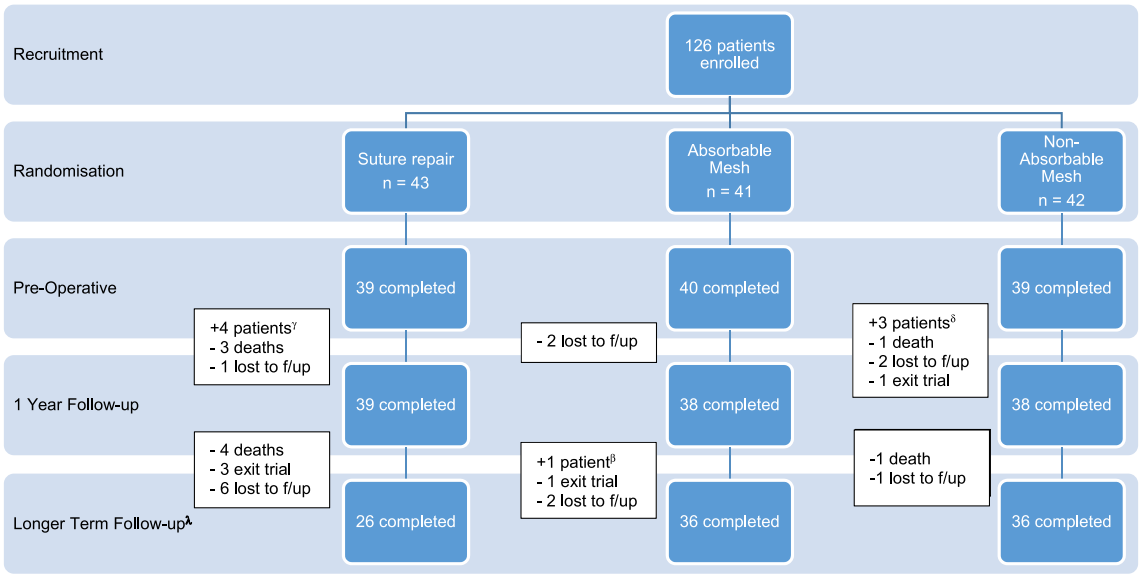

FIGURE 1 Follow-up completeness within the randomized trial. γ–4 patients completed 1 year follow-up questionnaire but did not provide pre-operative data, β—1 patient completed pre-operative and 5 years follow-up, but not 1 year follow-up. δ—3 patients completed 1 year follow-up but not pre-operative questionnaire. λ—Long term follow-up was 5 years data where available. When not available 6 years, 4 years or 3 years follow-up substituted. [Colour figure can be viewed at wileyonlinelibrary.com]

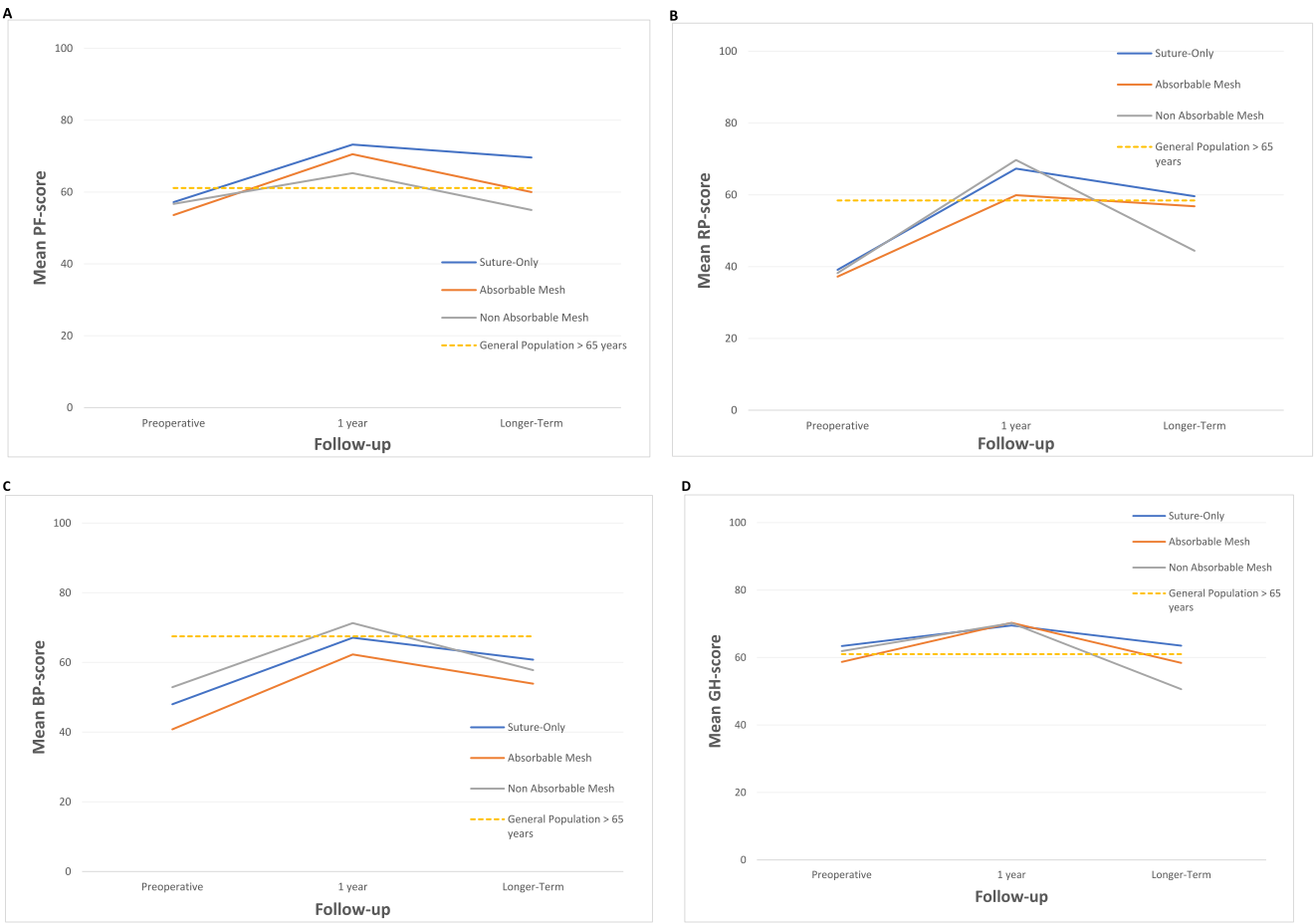

FIGURE 2 Short-Form 36 subscales for different repair groups benchmarked against population norms (full data analysis in Table S1). (A), Physical Function (PF) score. (B), Role Physical (RP) score. (C) Bodily Pain (BP) score. (D), General Health (GH) score. (E), Vitality (VT) score. (F), Social Functioning (SF) score. (G), Role Emotional (RE) score. (H), Mental Health (MH) score. [Colour figure can be viewed at wileyonlinelibrary.com]

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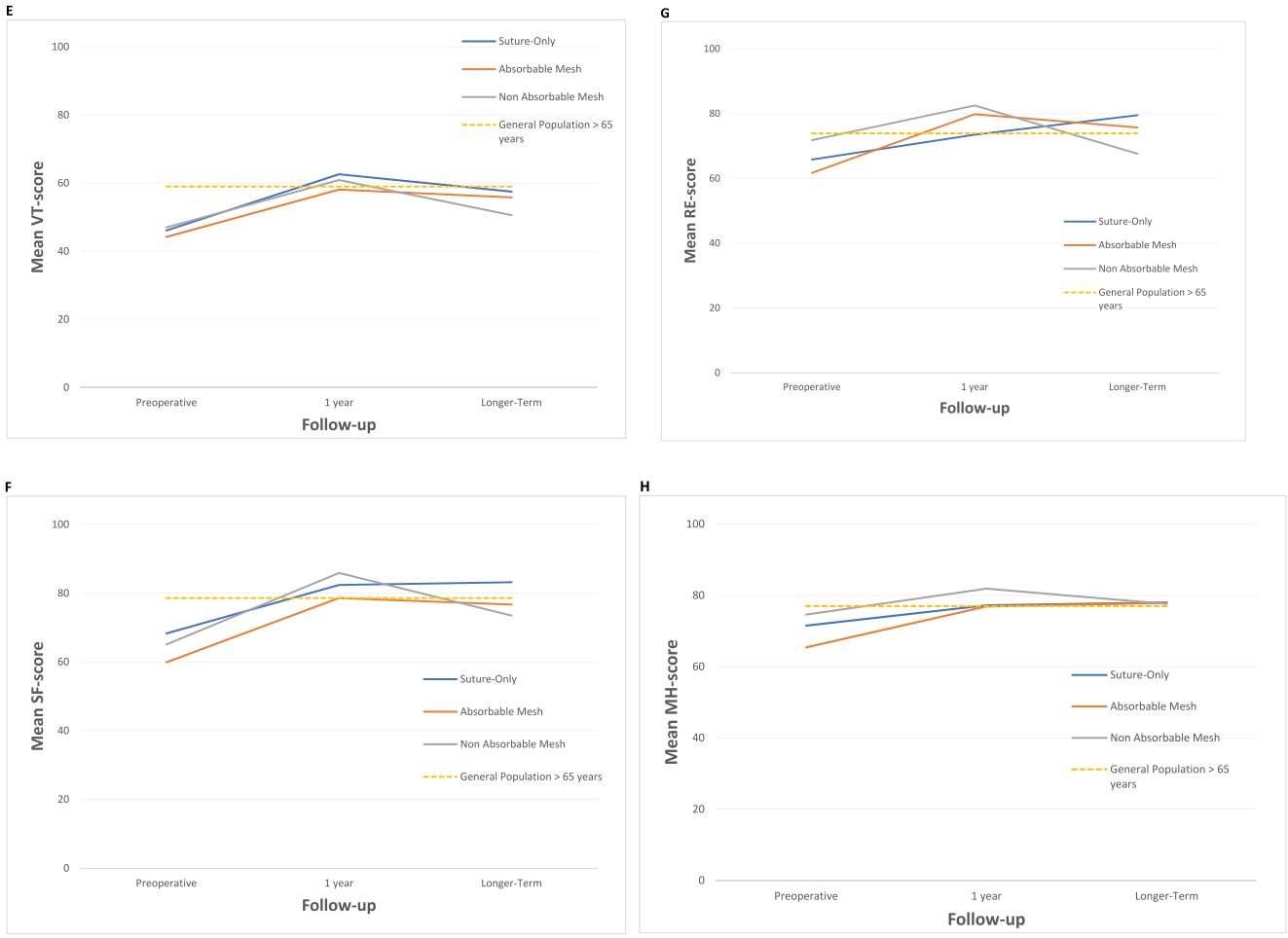

FIGURE 2 (Continued)

each of the 8 subscale scores. There were also no significant differences for scores for any subscale between the different repair technique groups at either 1 year or longer-term follow-up. Improvements were seen from pre-operative to 1 year post-operative subscale scores and from pre-operative to longer-term post-operative scores (see Figure 2A–H, and Table S2). When the three trial groups were combined into a single larger cohort, significant improvements were seen in all eight subscales at 12 months post-operatively compared to preoperatively, and also for longer term follow-up outcomes versus preoperative (Table 1).

3.2 | Physical and mental component score outcomes

The Mental component score (MCS) outcomes for the three groups are summarized in Figure 3 (full data in Table S2). Scores were not significantly different between the three groups at each follow-up point. Scores improved from preoperative to 1 year and longer-term follow-up, and this improvement reached statistical significance for all improvements except preoperative versus 1 year for the suture repair group, and preoperative versus longer-term for the non-absorbable mesh group. When the three repair groups were compared with each other at each time point, there were no significant differences noted for the Mental Component Scores at any follow-up point; preoperative (46.7 vs. 43.9 vs. 47.9, $p = 0.300$), 1 year (49.5 vs. 49.9 vs. 52.5, $p = 0.300$) or longer-term follow-up (50.7 vs. 50.6 vs. 49.2, $p = 0.824$).

The Physical component score (PCS) outcomes for the 3 groups are summarized in Figure 4 (full data in Table S2). Scores were not significantly different between the three groups at each follow-up point. Scores improved from preoperative to 1 year. At longer-term follow-up, the PCS had declined for all groups and was only significantly higher for the suture-only repair group (46.9 vs. 50.4, $p = 0.050$). When the three repair groups were compared with each other at each time point, there were no significant differences at any time point;

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TABLE 1 Preoperative versus follow-up short-form 36 scores for the entire cohort (all groups combined).

	Pre-operative versus 1 year follow-up scores	*p*-value	Pre- operative versus longer-term follow-up scores	*p*-value
SF-36 subscales				
Physical functioning	55.8 versus 69.7	<0.001	55.8 versus 60.7	0.104
Role physical	38.2 versus 65.6	<0.001	38.2 versus 53.0	0.006
Bodily pain	47.2 versus 66.9	<0.001	47.2 versus 57.8	0.002
General health	61.3 versus 70.0	0.002	61.3 versus 59.6	0.300
Vitality	45.7 versus 60.6	<0.001	45.7 versus 54.3	0.007
Social functioning	64.4 versus 82.3	<0.001	64.4 versus 77.3	<0.001
Role emotional	66.4 versus 78.6	0.010	66.4 versus 73.2	0.182
Mental health	70.5 versus 78.7	0.001	70.5 versus 77.8	0.003
Component scores				
Physical component score (PCS)	46.3 versus 52.4	<0.001	46.3 versus 47.9	0.105
Mental component score (MCS)	45.8 versus 50.4	<0.001	45.8 versus 49.8	0.005

Note: Data is mean scores for each group.
p values determined using Independent *t*-test.

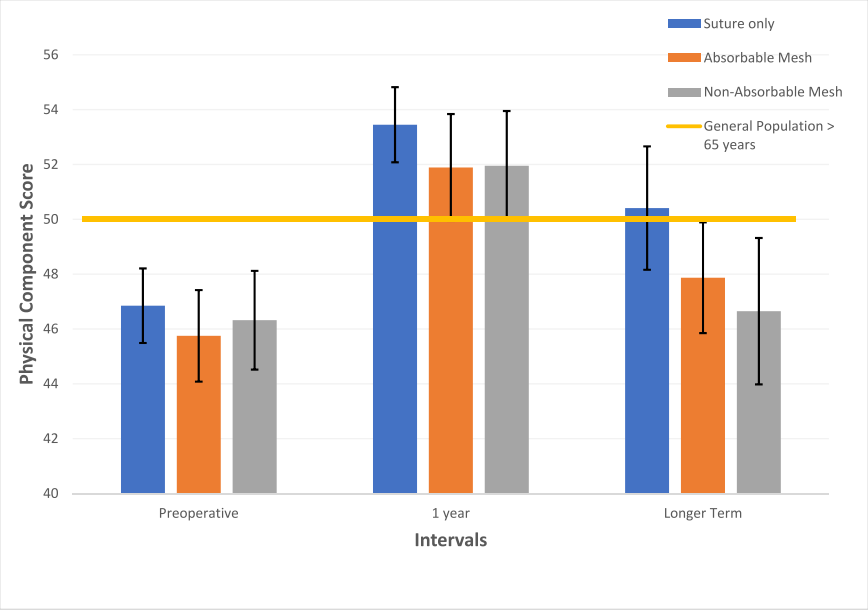

FIGURE 3 Physical component score for different repair groups benchmarked against population norms. [Colour figure can be viewed at wileyonlinelibrary.com]

preoperative (46.9 vs. 45.8 vs. 46.3, $p = 0.851$), 1 year (53.5 vs. 51.6 vs. 51.9, $p = 0.659$) and longer-term follow-up (50.4 vs. 47.6 vs. 46.7, $p = 0.375$).

When all three trial groups were combined into a single larger cohort, there was a significant improvement in physical component scores at 1 year follow-up (46.3 vs. 52.4, $p < 0.001$) but not for preoperative versus longer term follow-up (46.3 vs. 47.9, $p = 0.109$). For the whole cohort, Mental component scores significantly improved from preoperative to 1 year follow-up (45.8 vs. 50.4, $p < 0.001$) and this improvement was sustained at longer-term follow-up (45.8 vs. 50.7, $p = 0.045$).

4 | DISCUSSION

Laparoscopic repair is the standard surgical approach for large hiatus hernias and is associated with good clinical outcomes in most patients. However, small

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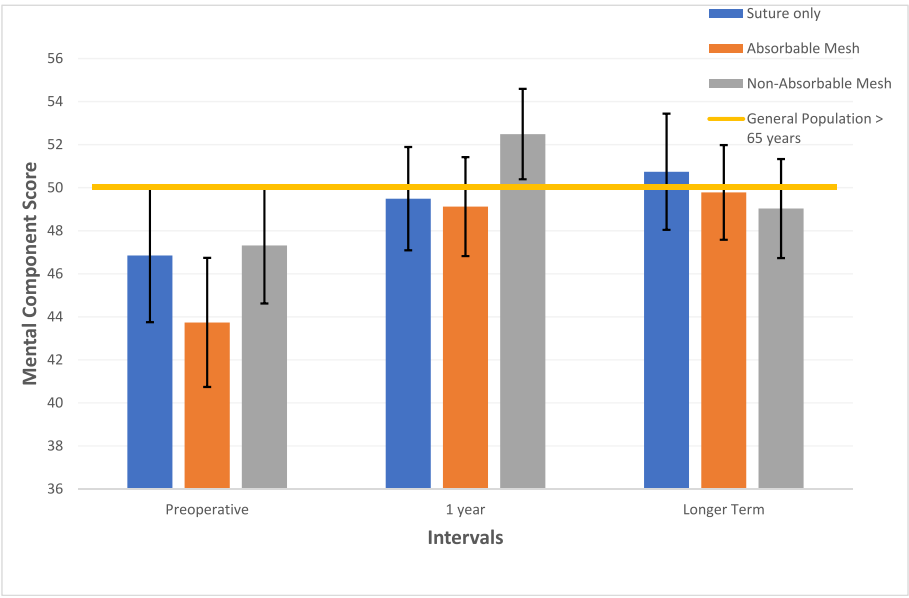

FIGURE 4 Mental component score for different repair groups benchmarked against population norms. [Colour figure can be viewed at wileyonlinelibrary.com]

hernia recurrences are common and the role of mesh reinforcement is controversial. In our randomized trial, we compared three different approaches to repair; suture-only repair, versus sutures plus absorbable mesh, and sutures plus nonabsorbable mesh. We have previously reported that this trial identified no significant differences between the approaches for hernia recurrence rate or clinical symptom outcomes at short or longer-term follow-up.[15,16]

Large hiatus hernias can negatively impact quality of life. Quality of life outcomes provide an alternative and holistic measure of the patient's overall health, well-being and functional status. There is a paucity of this type of data following hiatus hernia repair, especially at longer-term follow-up. Our previous short-term quality of life outcomes showed this improved significantly after surgery, but with no significant differences between repair techniques.[20] Our current study expanded the length of follow-up to determine if the improvements in quality of life are sustained across the longer term, and to determine any differences in outcome between the surgical techniques.

Quality of life outcomes measured before surgery in patients with large hiatus hernias were significantly worse than an equivalent general population of >65 years age. After surgery at both short and longer-term follow-up, physical and mental component scores as well as all SF-36 subscale scores returned to that of the general population, demonstrating a significant quality of life benefit following laparoscopic repair of large hiatus hernia, irrespective of the specific repair technique.

Our study did demonstrate some decline in the physical component scores at longer-term follow-up, following a significant improvement in scores at 1 year follow-up, compared to baseline. However, physical component scores did not return to preoperative levels. Furthermore, this decline likely represents an age-related physical decline in study population followed across 5 years, with the mean age for the study population increasing from 68 years at baseline to 73 years at longer-term follow-up. Of interest, when this decline was evaluated within each study group, the suture repair group still maintained improved physical component scores at longer-term follow-up compared to baseline, confirming no trend toward a poorer outcome in this group, compared to the 2 mesh repair groups.

An alternative explanation for the later decline in the physical component scores is the development of recurrent hiatus hernias. In our previous report of clinical and objective long term follow-up from the current trial we did identify small asymptomatic recurrent hernias in approximately 40% of the overall cohort.[16] It is possible that this contributed to the decline in the physical component scores at late follow-up, however, these hernias were usually less than 2 cm in length, and we have previously shown that small recurrent hernias are asymptomatic in most patients.[18]

Mental component scores also improved significantly and did not decline, with sustained improvement still seen at longer-term follow-up. When comparing the outcomes between different groups, we found no differences between repair techniques for the physical and mental component scores at any time-point.

In another mesh repair trial which randomized 145 patients with a hiatus hernia of any size to suture-only or non-absorbable mesh repair, Analatos et al found similar results.[23] They found both physical and mental

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component scores improved at 1 and 3 years after surgery, with no significant differences between the 2 cohorts, and at 13 years follow-up there were still no differences between the two groups. As with our trial, Analatos et al identified sustained improvement in both the physical and mental component scores in the suture only group, whereas only the MCS improved in the mesh group. Why the addition of mesh to a standard suture repair did not achieve sustained improvement in the physical component scores in either of these trials is not clear.

We found no significant differences in any quality-of-life outcomes when comparing suture-only versus mesh techniques. This is consistent with a recent systematic review by Date et al. which included six studies which compared quality of life outcomes for mesh versus non-mesh techniques. Five out of these six studies reported no statistically significant differences between the two groups.[24] An important finding in our study was that prior to repair patients with large hiatus hernias had significantly worse quality of life outcomes than the general population of that age group (>65 years), and after surgery the physical and mental component scores and subscales scores returned to levels similar to the general population, confirming the significant benefit of laparoscopic repair of large hiatus hernia.

A potential weakness of our current study is the lack of consensus about which quality of life and symptom assessment tools should be used to measure outcomes following surgery for large hiatus hernias. A systematic literature review of 220 studies, found 46 different quality of life and symptom severity tools have been used and 89 different symptoms are reported.[25] The gastroesophageal reflux disease health-related quality of life is the most commonly used assessment tool in patients with paraesophageal hernias.[25] It uses a 0—5 Likert scale and focuses on the impact of heartburn and regurgitation. However, it does not capture other "mechanical" symptoms caused by a large hiatus hernias, and it also lacks their impact on mental well-being. The Gastrointestinal Quality of Life Index (GIQLI) covers a broader range of gastrointestinal symptoms, but also does not ask about non-GI symptoms caused by large hiatus hernias such as dyspnea, wheeze and anemia. We used the SF-36 as it is well validated and captures the patients' overall GH, physical and mental well-being. In our original trial, we used it in conjunction with a symptom questionnaire to capture disease specific presentations. More recently, a specific paraesophageal hernia symptoms tool (POST) has been developed by an expert consensus process, although this tool remains unvalidated.[26] It is hoped this will provide a future universal measurement tool to better assess outcomes for patients undergoing surgery for large hiatal hernias.

A further limitation of our current study is that a lower number of patients completed longer-term follow-up. However, 82.4% of alive patients did complete the SF-36 questionnaire at longer-term follow-up, and this is a higher rate than seen in many other longer-term follow-up studies. A methodological strength of our data was data collection at regular annual intervals within a randomized control trial.

In conclusion, the longer-term quality of life outcomes from this randomized trial of sutured versus mesh repair for very large hiatus hernia showed no quality of life advantages following the use of mesh. Further, there were no trends toward better outcomes following mesh repair. In the absence of demonstrable advantages following mesh repair we conclude that adding mesh is not required, and a sutured repair is sufficient for the repair of a very large hiatus hernia.

AUTHOR CONTRIBUTIONS

Mathew A. Amprayil: Data curation; formal analysis; methodology; writing – original draft. **Tanya Irvine**: Data curation; formal analysis; project administration; supervision; writing – review & editing. **Sarah K. Thompson**: Funding acquisition; methodology; project administration; supervision; writing – review & editing. **Tim Bright**: Methodology; project administration; supervision; writing – review & editing. **Ahmad Aly**: Conceptualization; funding acquisition; methodology; project administration; writing – review & editing. **Peter G. Devitt**: Conceptualization; funding acquisition; methodology; project administration; supervision; writing – review & editing. **Glyn G. Jamieson**: Conceptualization; funding acquisition; methodology; project administration; resources; supervision; writing – review & editing. **David I. Watson**: Conceptualization; data curation; formal analysis; funding acquisition; methodology; project administration; resources; supervision; writing – review & editing.

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CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author.

ETHICS STATEMENT

The protocol for this study was approved by the Human Research Ethics Committee at each participating hospital.

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