QUALITY OF LIFE FOLLOWING REPAIR OF LARGE HIATAL HERNIA IS IMPROVED BUT NOT INFLUENCED BY USE OF MESH: RESULTS FROM A RANDOMIZED CONTROLLED TRIAL

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Hiatus hernia, Mesh repair, Laparoscopy, Randomized controlled trial, Quality of life.

Trial registration – This trial is registered with the Australia and New Zealand Clinical Trials Registry ACTRN12605000725662

ABSTRACT

Introduction

Laparoscopic surgery is the treatment of choice for repair of large hiatus hernia, but can be followed by recurrence. Repair with prosthetic mesh has been recommended to prevent recurrence, although complications following mesh repair have generated disagreement about whether or not mesh should be used. The early objective and clinical results of a randomized trial of repair with mesh vs. sutures have been reported, and revealed few differences. In the current study we evaluated quality of life outcomes within this trial at follow-up to 2 years.

Methods

In a multicenter prospective double-blind randomized trial three methods for repair of large hiatus hernia were compared: sutures vs. repair with absorbable mesh (Surgisis) vs. non-absorbable (Timesh). Quality of life assessment using the Short-Form 36 (SF-36) questionnaire was undertaken at 3, 6, 12 and 24 months after surgery. SF-36 outcomes (8 individual scales and 2 composite scales) were determined for each group, and compared between groups, and across different follow-up points.

Results

126 patients were enrolled - 43 sutures, 41 absorbable mesh and 42 non-absorbable mesh. 115 (91.3%) completed a preoperative questionnaire, and 113 (89.7%) completed the post-operative questionnaire at 3 months, 116 (92.1%) at 6 months, 114 (90.5%) at 12 months, and 91 (72.2%) at 24 months. The SF-36 Physical and Mental Component scores (PCS & MCS) improved significantly following surgery, and this improvement was sustained across 24 months follow-up ($p<0.001$ for PCS and MCS at each follow-up point). There were no significant differences between the groups for the component scores or the eight SF-36 subscale scores at each follow-up time. 29 individuals had a recurrence at 6 months follow-up, of which 9 were symptomatic. The PCS were higher in patients with recurrence vs. without ($p<0.01$), and in patients with a symptomatic recurrence vs. asymptomatic recurrence vs. no recurrence ($p=0.001$).

Conclusion

SF-36 measured quality of life improved significantly after repair of large hiatal hernia at up to 2 years follow-up, and there were no differences in outcome for the different repair

techniques. The use of mesh vs. no mesh in repair of large hiatal hernia did not influence quality of life.

INTRODUCTION

Laparoscopic approaches are standard for the surgical treatment of gastro-esophageal reflux disease and hiatus hernia, and achieve good clinical outcomes in most patients[1,2]. A subgroup undergoing surgery present with a very large hiatus hernia and when more than 50% of the stomach herniates, the stomach can rotate and lead to mechanical symptoms including chest pain, early satiety, dysphagia, vomiting, and gastric volvulus.

A standard approach to laparoscopic repair of very large hiatus hernias entails complete dissection of the hernia sac from the mediastinum, hiatal repair with posteriorly placed sutures, followed by construction of a fundoplication[3]. Initial clinical outcomes following this approach are good, but objective follow-up using barium meal X-ray has demonstrated radiological recurrence rates of 25-45% at late follow-up, although less than 5% of patients actually develop symptoms from a recurrent hernia[4-6]. However, there are concerns that radiological hernia recurrences could become symptomatic or progress to complications at later follow-up[4-6], and for this reason "tension-free" repair techniques using prosthetic mesh have been proposed[7]. Whilst uncontrolled studies suggest mesh reinforcement might be followed by lower recurrence rates[7-9], the use of mesh can also be followed by significant complications such as erosion of mesh into the esophageal or gastric lumen, and surgery to deal with this can lead to esophagectomy[10,11]. Absorbable biomeshes are advocated by some surgeons for hiatal hernia repair to avoid mesh erosion [12].

To date, only a few randomized controlled trials have compared mesh vs. sutures for repair of large hiatal hernias. Frantzides et al and Oeschlager et al both reported reductions in hernia recurrence at short term follow-up [12,13], although at later follow-up Oeschlager et al identified no differences[14]. We recently reported the outcomes for a trial which randomized 126 patients to repair with sutures vs. absorbable vs. non-absorbable mesh, and showed no differences in hernia recurrence rates at 12 months follow-up for patients undergoing sutured vs. mesh repair[15]. All previous papers reporting outcomes from randomized trials have focused on objective investigations and hernia recurrence rates.

There can, however, be differences between objectively assessed surgical outcomes and patient reported outcomes. It is also known that quality of life is impaired in patients suffering gastro-esophageal reflux[16-18], and improves following laparoscopic antireflux surgery[19,20]. In our

randomized trial of large hiatus hernia repair with sutures vs. absorbable mesh vs. non-absorbable mesh, we also measured quality of life using the Short-Form 36 (SF-36) questionnaire, a widely used and well-validated questionnaire which evaluates general well-being and functional status[21,22]. In this paper we evaluated the impact of three different methods of repair of large hiatal hernia on changes in SF-36 measured quality of life within the setting of a randomized controlled trial.

Methods

In a prospective double-blind randomized controlled trial we compared three laparoscopic methods of repair of very large hiatus hernias: repair using sutures vs. Biomesh vs. non-absorbable mesh. The full details of the trial protocol and the objective and clinical symptom outcomes to 12 months follow-up have been reported elsewhere[15]. In the current study we determined the impact of the 3 different methods on SF-36 measured quality of life at follow-up of up to two years.

Summary of trial protocol

The trial was undertaken in 4 centers in Adelaide and Melbourne, Australia, with surgery performed or supervised by one of 9 surgeons. Individuals undergoing elective laparoscopic repair of a very large hiatus hernia were enrolled, with a very large hiatus hernia defined as containing at least 50% of the stomach. Patients were randomized 1:1:1 to repair using sutures vs. repair using sutures reinforced by absorbable mesh (4 ply Surgisis® ES, Cook Biotech, Indiana, USA) vs. repair using sutures reinforced by non-absorbable mesh (Timesh®, PFM Medical, Köln, Germany). Patients were blinded to the operation variant and clinical follow-up was undertaken by a research nurse who was also blinded to the procedure type.

Surgical techniques were standardized, and included full dissection of the hernia sac from the mediastinum, and complete reduction of the sac's contents into the abdomen[1,3]. Esophageal lengthening procedures were not added. The hiatal defect was narrowed using posterior hiatal sutures, supplemented by anterior hiatal sutures if needed. When randomized to mesh repair, a rectangular piece of mesh (Surgisis or Timesh) measuring 2-3cm high x 4-5cm wide was placed over the posterior hiatal repair sutures and the hiatal pillars (but not encircling the esophagus), and anchored in place using either sutures or a mechanical "tacker". A fundoplication was then added. If any procedure varied from the trial allocation, the patient remained in the allocated group for intention to treat analysis.

Follow-up and quality of life assessment

Follow-up using Barium meal X-ray, upper gastrointestinal endoscopy and clinical symptom scores has been reported elsewhere[15]. Symptom scores were obtained with a Visual Analog Scale (VAS) of 0-10, by a 'blinded' research nurse using a structured questionnaire 3, 6, 12

and 24 months after surgery. In addition, patients completed SF-36 Quality of Life (QoL) questionnaires before surgery and at the same follow-up time points.

The SF-36 questionnaire is a widely used and well validated questionnaire (23,24), consisting of 36 items. The questionnaire is summarised in Table 1. Thirty five questions contribute to eight subscales, and the other question stands alone and assesses "Reported Health Transition" (RHT). The scores of the eight subscales and the RHT question are each converted into a 0-100 score. A higher score indicates a better QoL on that subscale. The subscales can also be converted into two summarizing component scales: a "Physical Component Scale" (PCS) and a "Mental Component Scale" (MCS). The PCS and the MCS have been validated by Ware et al[22]. The component scales provide summary overviews of the SF-36 outcomes.

For calculation of the PCS and MCS, the 8 subscales are standardized using a z-score transformation: population means are subtracted from the subscale scores, and this difference is divided by the standard deviations of the norm population. The computed z-scores are then aggregated into the physical and mental component scales. Each SF-36 subscale z-score is multiplied by its respective physical factor score coefficient and the eight products are summed. Similarly, this is done for the mental component scale by using the mental factor score coefficients. The last step is transforming each component score to norm-based scoring. This is accomplished by multiplying each aggregate component scale score by 10 and adding the resulting product to 50. To provide a comparable study population for our study, population norm scores were derived from the Australian population aged 65-74 years, with equal numbers of males and females collected by the Australian Bureau of Statistics in 1995.

For data analysis, pre- and postoperative PCS and MCS scores as well as the individual sub-scales were compared for the overall population to assess changes in quality of life before vs. after hiatal hernia repair, and also for the three trial groups separately to determine differences in quality of life between the different repair techniques at each follow-up point.

Recurrence of hiatal hernia

As part of the trial protocol, patients underwent objective assessment using upper gastrointestinal endoscopy and barium meal radiology 6 months after surgery. The presence or absence of a recurrent hiatus hernia was determined, and patients with a recurrence were classified as symptomatic or asymptomatic based on symptom scores. Barium meal radiology

was reported by radiologists blinded to the hiatal repair technique, and endoscopy was undertaken in a blinded fashion by upper gastrointestinal surgeons experienced in assessing anatomy after fundoplication. A recurrent hiatus hernia was defined as any evidence of the stomach sitting above the level of the diaphragm, irrespective of size. A symptomatic recurrent hiatus hernia was defined as 1) objective evidence of a recurrent hernia, and 2) heartburn symptoms scored as 3 or greater using a 0-10 analogue scale (details published elsewhere[15]). PCS and MCS scores determined six months after surgery in patients with a recurrence were compared to scores in patients without recurrence. PCS and MCS scores in patients with a symptomatic recurrence were compared to scores in patients with asymptomatic recurrence, and also to those without recurrence.

Statistics and Ethics

All analyses were performed on an intention-to-treat basis, with all patients remaining in their initial allocated trial group for data analysis. Parametrically distributed data were analysed using Paired Samples T-tests, One-way ANOVA tests and Student T-tests. Non-parametric data were analysed using Kruskal-Wallis tests and Mann-Whitney U-tests. Statistical analyses were performed using IBM's Statistical Package for Social Sciences (SPSS), version 19 for Apple Macintosh OS (IBM corp., Armonk, New York, USA). 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. The study was conducted in accordance with the World Medical Association declaration of Helsinki (revised 1989), and the National Health and Medical Research Council of Australia's guidelines on human experimentation.

Results

From July 2006 to September 2012, 126 patients were enrolled in the randomized trial. Forty three were randomized to undergo hiatal repair with sutures ('Sutures only' cohort), 41 to repair with Surgisis ('Biomesh' cohort), and 42 to repair with Timesh ('Timesh' cohort). As reported elsewhere[15] baseline characteristics were comparable for the three study groups.

115 (91.3%) completed a preoperative SF-36 questionnaire, 113 (89.7%) a questionnaire at 3 months, 116 (92.1%) at 6 months, 114 (90.5%) at 12 months, and 91 (72.2%) at 24 months. Data analysis was undertaken using a paired analysis comparing baseline preoperative scores vs. postoperative scores. Hence, data was only analysed for patients who completed both the preoperative questionnaire and at least one of the postoperative questionnaires. This yielded 105 (83.3%) patients who completed preoperative and 3 months postoperative questionnaires, 106 (84.1%) preoperative and 6 months postoperative questionnaires, 104 (82.5%) preoperative and 12 months postoperative questionnaires, and 83 (65.9%) who completed both the preoperative and the 24 months postoperative SF-36 questionnaire. Completion rates were comparable for the three groups. Missing data were due to inability to contact patients at specific time points or because patients chose not to complete and return the questionnaire.

Physical and Mental Component Score outcomes

Figures 1 and 2 summarise the outcomes for the PCS and MCS scores. For the entire trial cohort the post-operative PCS and MCS scores were significantly higher than the pre-operative scores at all follow-up points (Paired t-tests; $p<0.001$ for PCS and MCS at each follow-up point). When the trial groups were compared separately, the PCS scores for all three groups improved significantly at 3, 6, 12 and 24 months postoperatively compared to the pre-operative scores ($P<0.001$-0.044). The follow-up MCS scores were not significantly different ($P>0.05$) to the pre-operative scores at all time points in the 'Sutures only' group. In the 'Biomesh' group, the MCS score was significantly higher at 12 months ($p=0.012$, posthoc alpha=0.013) but not at other time points, whereas in the 'Timesh' group the MCS scores were significantly higher at 12 and 24 months, but not at 3 and 6 months ($P=0.028$ $P=0.168$, $P<0.001$, $P<0.001$ respectively).

When the 3 trial groups were compared at each time point, there were no significant differences between the three groups for either the PCS or the MCS scores (One-Way

ANOVA comparing the three cohorts pre-operative vs. postoperative scores (3, 6, 12 & 24 months)).

SF-36 subscale outcomes

The SF-36 subscale outcomes are summarised in figures 3-11. There were no significant differences between the three groups with respect to the pre-operative scores for each of the eight subscales of the SF-36, with the exception of the 'sutures only' vs. the 'Biomesh' group for the "Reported Health Transition" scale ($p=0.003$, Mann Whitney-U, post-hoc correction alpha=0.017). All eight subscales of the SF-36 improved significantly at 3, 6, and 12 months following surgery, compared to the respective pre-operative scores. Seven subscales also improved significantly at 24 months, but not the "Role Functioning-Emotional" scale. There were no significant differences between the three trial groups for scores at any postoperative follow-up time point.

Recurrence

Twenty patients were found to a recurrent hiatus hernia (any size) six months after surgery. Nine (31%) of these were symptomatic. Patients with a recurrent hernia had significantly lower PCS scores, compared to patients without recurrence (46.9 versus 51.2; $p<0.01$). For the MCS scores, however, there was no significant difference for recurrence vs. no-recurrence (48.8 versus 50.7; $p=0.213$). For the 3-way comparison of symptomatic vs. asymptomatic recurrence vs. no recurrence, patients with symptomatic recurrences had significantly lower PCS scores ($p=0.001$), whereas for the MCS scores there was no difference ($p=0.453$).

Discussion

Laparoscopic approaches are now the standard surgical approach to repair of very large hiatus hernias. However, the choice of laparoscopic repair techniques can vary between different groups, and consensus is yet to be reached about the role of mesh vs. sutured repair, synthetic vs. biological meshes, and mesh configurations - encircling vs. placed posteriorly. In our randomized trial we compared 3 different approaches to repair, including sutures vs. synthetic vs. biological mesh. We recently reported no significant differences for hernia recurrence or clinical outcomes for the 3 repair methods in the trial[15], and these results were similar to the late follow-up outcomes reported previously by Oelschlager et al[14]. In both our trial and Oelschlager's trial the mesh configuration reinforced the hiatal repair posteriorly, a different technique to that used by Frantzides et al who fully encircled the esophagus with mesh[13]. Our decision to use a posterior mesh reinforcement technique was based on encouraging early trial outcomes from both Oelschlager et al[14] and Granderath et al[23], as well as concern that encircling the esophagus with mesh might increase the risk of mesh erosion[11].

Previous reports from randomized trials[13,14,15,23], and other studies[4,6,10] have all focussed on clinical and objective outcome parameters. However, quality of life is an alternative patient reported outcome, which reflects the general well-being and the functional status of patients. It also provides complementary information which informs surgical outcomes, and provides a perspective that might be more relevant to the individual patient[24]. In our randomized trial we used the Short-Form 36 (SF-36) questionnaire to assess general quality of life across various follow-up points. The SF-36 questionnaire is a general quality of life, rather than a disease specific quality of life questionnaire, and it has been widely validated in a range of different countries and language groups[25,26]. It has been used elsewhere to evaluate quality of life following laparoscopic surgery, including laparoscopic anti-reflux surgery[20,22].

Our current study revealed a general improvement in quality of life following laparoscopic repair of large hiatus hernias, and this manifested at all follow-up time points from three months to 2 years. Apart from the "Role Functioning-Emotional" subscale at 24 months follow-up, there was a significant improvement in all subscales of the SF-36 questionnaire, the two composite scales and the Reported Health Transition at three, six, 12, and 24 months postoperatively, when compared to the pre-operative scores. This confirms the effectiveness

of laparoscopic repair of large hiatal hernias, and supports other studies that have shown good clinical and objective outcomes following this surgery[14,15].

When comparing quality of life improvements across the different trial cohorts, however, no significant differences were seen between the three groups at each follow-up point, although following surgery, the SF-36 scores did improve in a similar fashion in each group. This suggested that each surgical technique (Sutures vs. Surgisis vs. Timesh) yielded a similar improvement in quality of life, and these results are consistent with the lack of significant clinical and objective outcome differences that we have reported elsewhere[15].

Recurrence of hiatus hernia was the primary outcome of this trial, and this outcome has been reported in detail elsewhere[15]. Analysis of this outcome vs. quality of life revealed significantly lower quality of life scores in patients with a recurrence compared to those without. However, this was seen solely for the physical component score, not for the mental component score. In the same manner, patients with a symptomatic recurrence had a poorer quality of life outcome compared to those with an asymptomatic recurrence, again only for the physical component score.

After considering the lack of differences seen for quality of life, clinical outcomes and objective outcomes for mesh vs. sutured repair of very large hiatus hernia in our randomized trial, and the lack of significant differences for mesh vs. sutured repair in the 5 year outcomes reported by Oelschlager[14], we now find it difficult to use mesh for the repair of very large hiatus hernias. It could be argued that the alternative technique of completely encircling the esophagus with mesh might yield a different outcome. However, the data supporting this approach is only from the trial reported by Frantzides et al in 2002 which enrolled 72 patients and then followed them for a median 2.5 years[13]. Good results at late follow-up, or other trials have not been reported, and are needed to confirm the safety of encircling the esophagus with polytetrafluoroethylene mesh. Others have reported significant problems with mesh erosion which we would prefer to avoid[11].

Overall quality of life was significantly better at up to two years follow-up after laparoscopic repair of very large hiatal hernias, with or without posteriorly placed mesh. Whilst the use of mesh did not improve the quality of life, the overall data from this trial has revealed a sustained improvement in quality of life following laparoscopic repair of very large hiatus

hernia, and this supports the liberal use of surgical repair of large hiatus hernia in this cohort of patients. However, recurrence of hiatus hernia did impact on physically related aspects of quality of life. Longer follow-up will be required to confirm the durability of these outcomes.

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TABLES

TABLE 1

Parameters measured by SF36

Concept	**Summary**
Physical Functioning	Extent to which health limits physical activities
Role Functioning-Physical	Extent to which physical healthy interferes with work or other daily activities
Bodily Pain	Intensity of pain and effect of pain on normal work
General Health	Personal evaluation of health
Vitality	Feeling energetic
Social functioning	Extent to which physical health or emotions interfere with social activities
Role Functioning-Emotional	Extent to which emotional problems interfere with work or daily activities
Mental Health	General mental health
Reported Health Transition	Evaluation of current health compared to one year ago

FIGURE LEGENDS

FIGURE 1

"Physical Component Scale" (PCS) vs. follow-up

FIGURE 2

"Mental Component Scale" (MCS) vs. follow-up

FIGURE 3

SF-36 "physical functioning" (PF) scores

FIGURE 4

SF-36 "role functioning - physical" (RP) scores

FIGURE 5

SF-36 "bodily pain" (BP) scores

FIGURE 6

SF-36 "general health" (GH) scores

FIGURE 7

SF-36 "vitality" (V) scores

FIGURE 8

SF-36 "social functioning" (SF) scores

FIGURE 9

SF-36 "role functioning - emotional" (RE) scores

FIGURE 10

SF-36 “mental health*”* (MH) scores

FIGURE 11

SF -36 “reported health transition” (RHT) scores

FIGURE 1

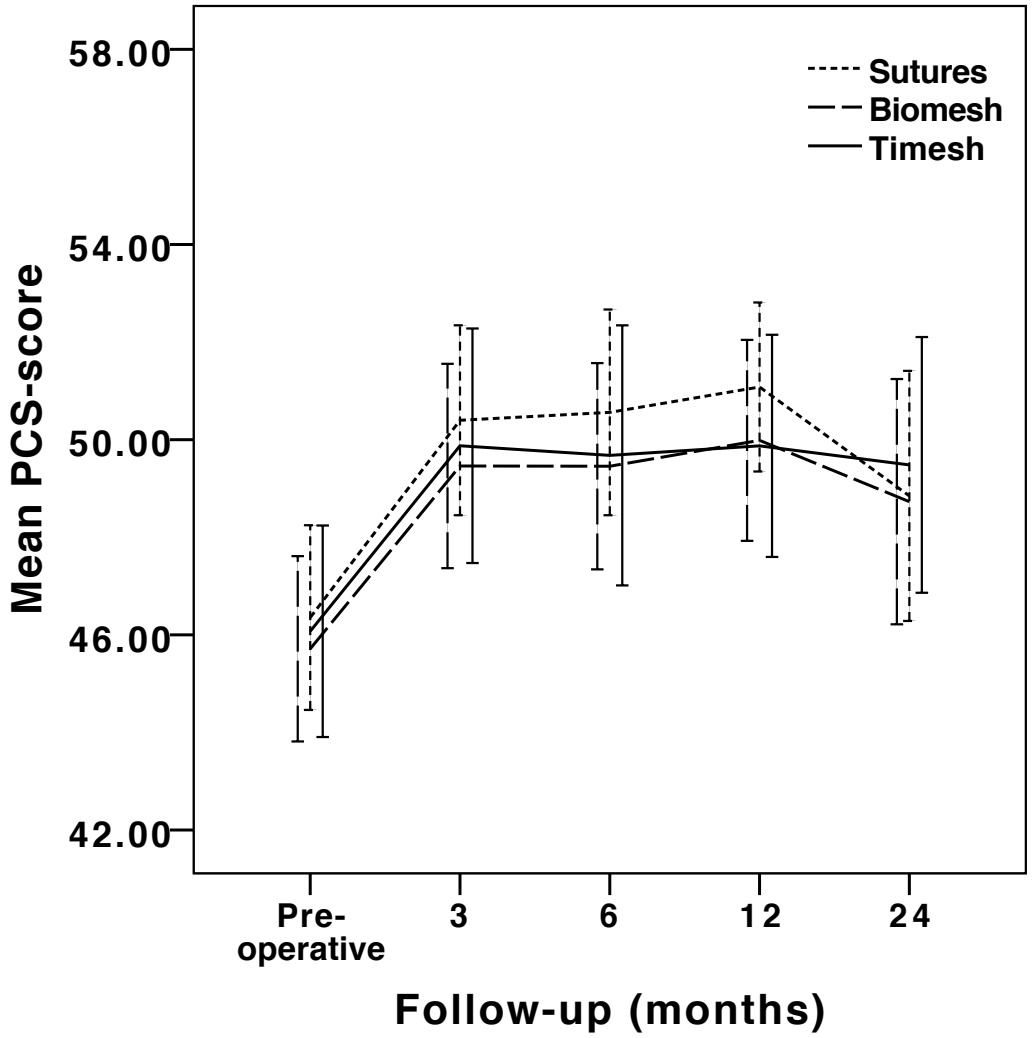

58.00
54.00
50.00
46.00
42.00
Mean PCS-score
Sutures
Biomesh
Timesh
Pre-
operative
3
6
12
24
Follow-up (months)

FIGURE 2

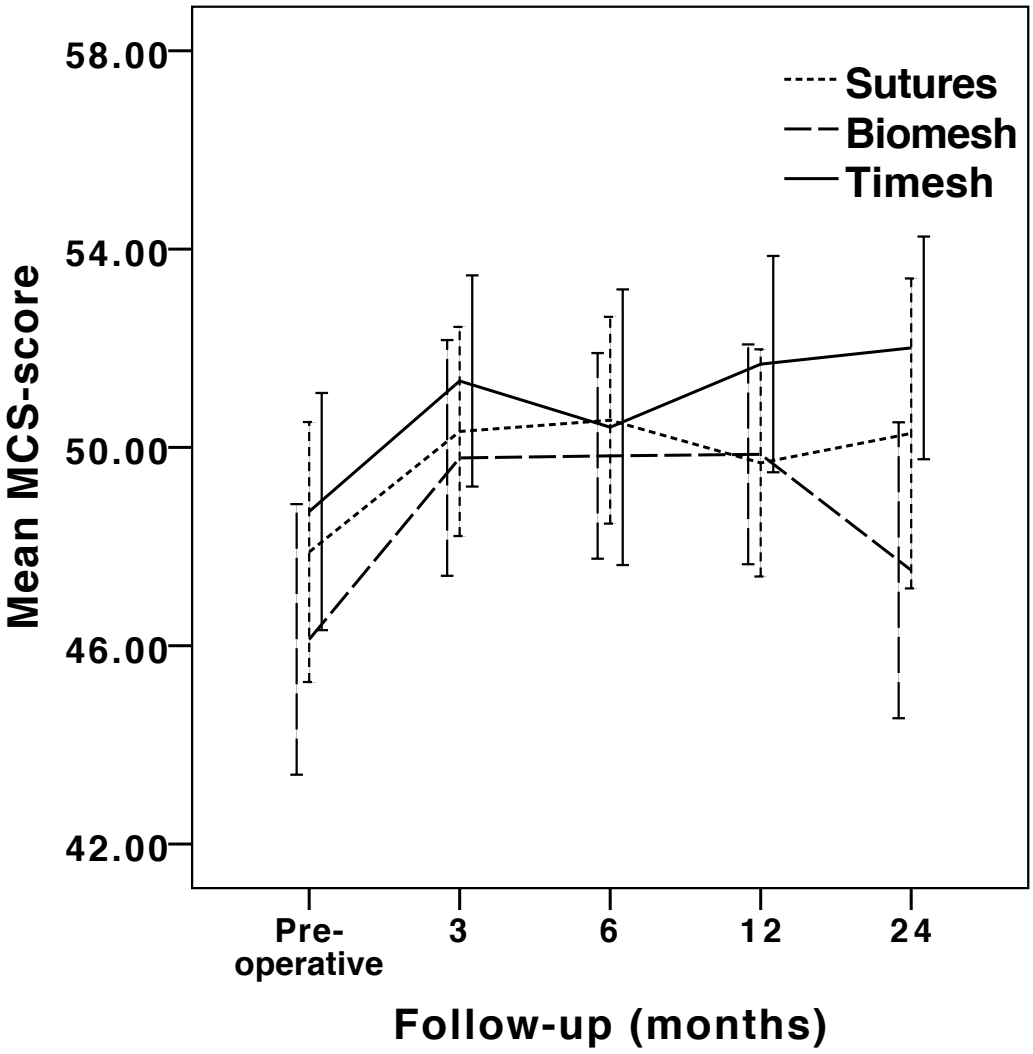

58.00
54.00
50.00
46.00
42.00
Mean MCS-score
Sutures
Biomesh
Timesh
Pre-
operative
3
6
12
24
Follow-up (months)

FIGURE 3

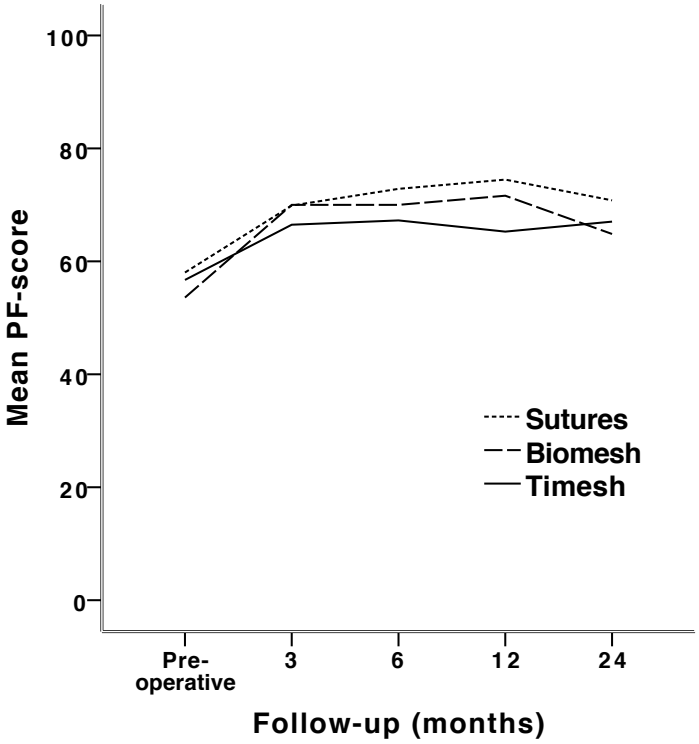

100
80
60
40
20
0
Mean PF-score
Sutures
Biomesh
Timesh
Pre-
operative
3
6
12
24
Follow-up (months)

FIGURE 4

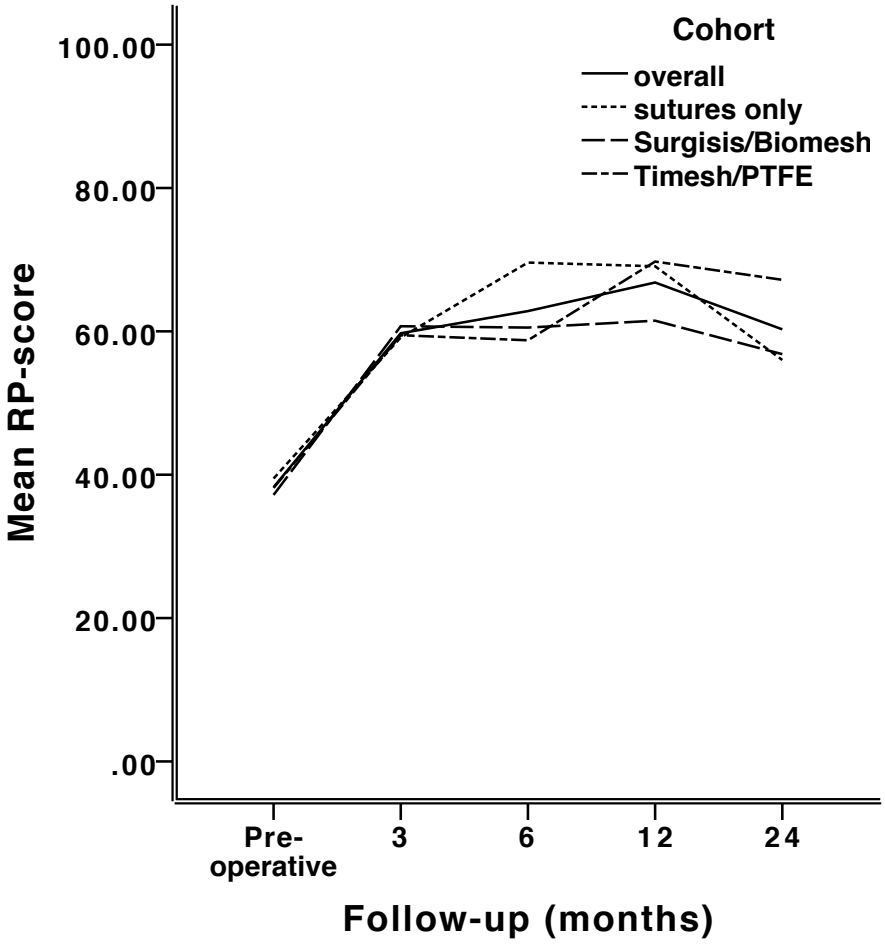

Cohort
overall
sutures only
Surgisis/Biomesh
Timesh/PTFE
100.00
80.00
60.00
40.00
20.00
.00
Mean RP-score
Pre-operative
3
6
12
24
Follow-up (months)

FIGURE 5

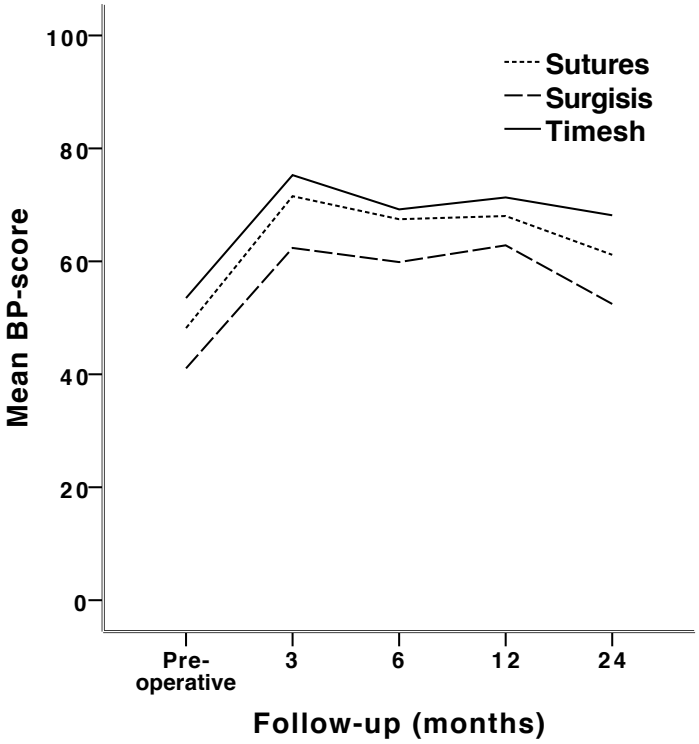

Sutures
Surgisis
Timesh
Mean BP-score
100
80
60
40
20
0
Pre-
operative
3
6
12
24
Follow-up (months)

FIGURE 6

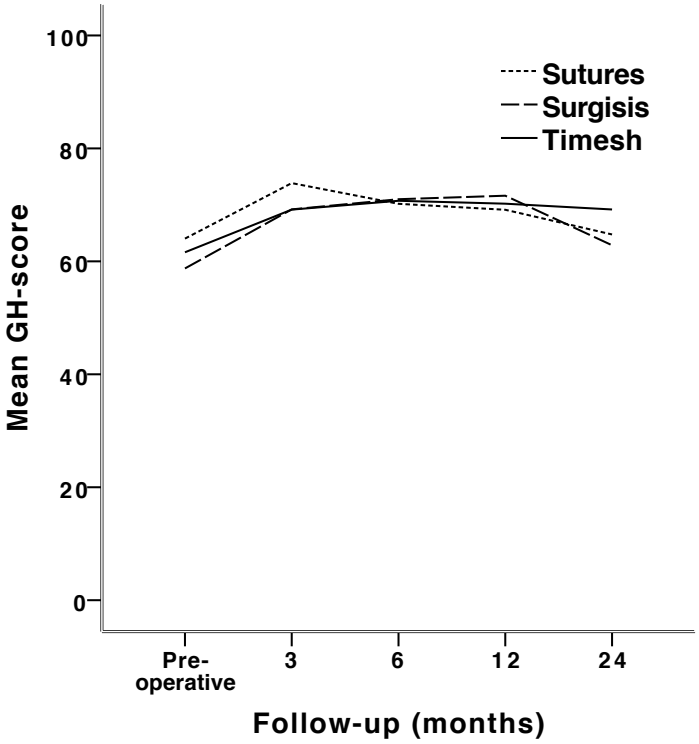

100
80
60
40
20
0
Mean GH-score
Sutures
Surgisis
Timesh
Pre-
operative
3
6
12
24
Follow-up (months)

FIGURE 7

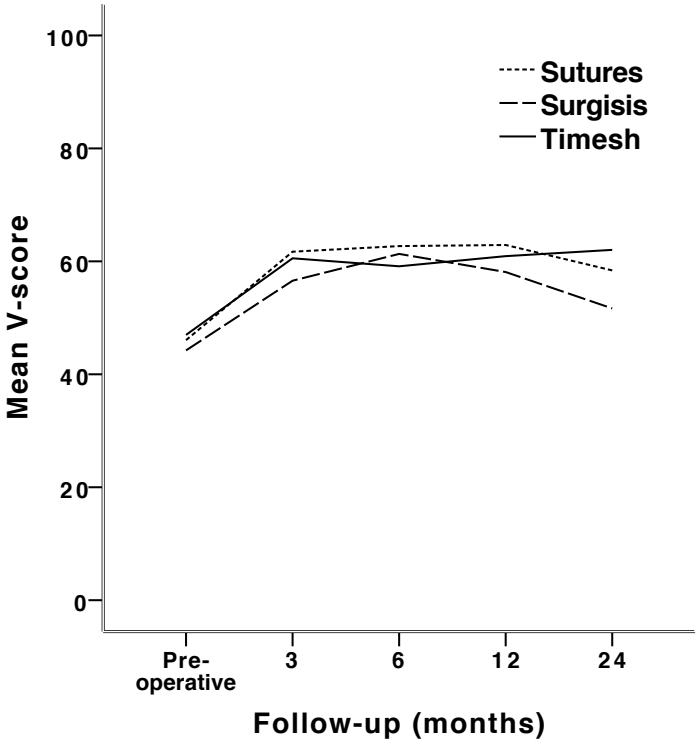

100
80
60
40
20
0
Mean V-score
Sutures
Surgisis
Timesh
Pre-
operative
3
6
12
24
Follow-up (months)

FIGURE 8

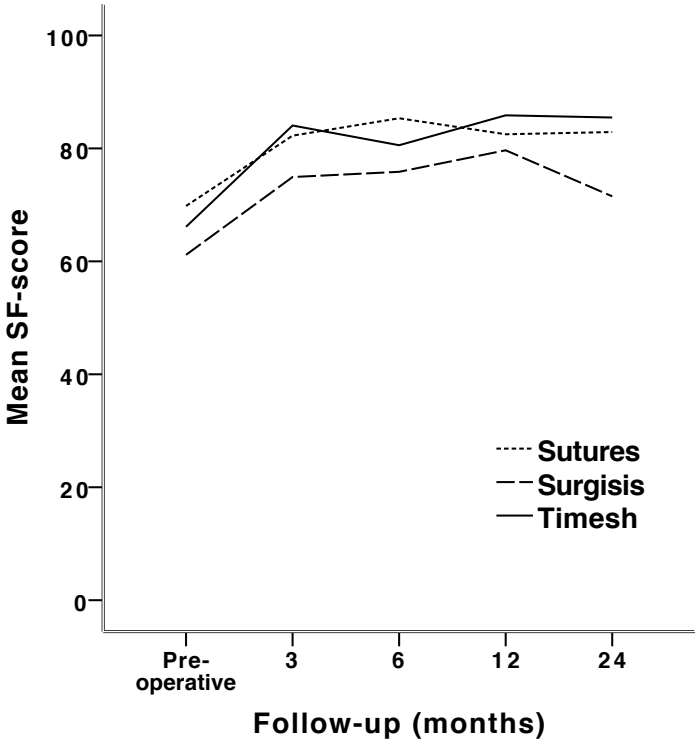

100
80
60
40
20
0
Mean SF-score
Sutures
Surgisis
Timesh
Pre-
operative
3
6
12
24
Follow-up (months)

FIGURE 9

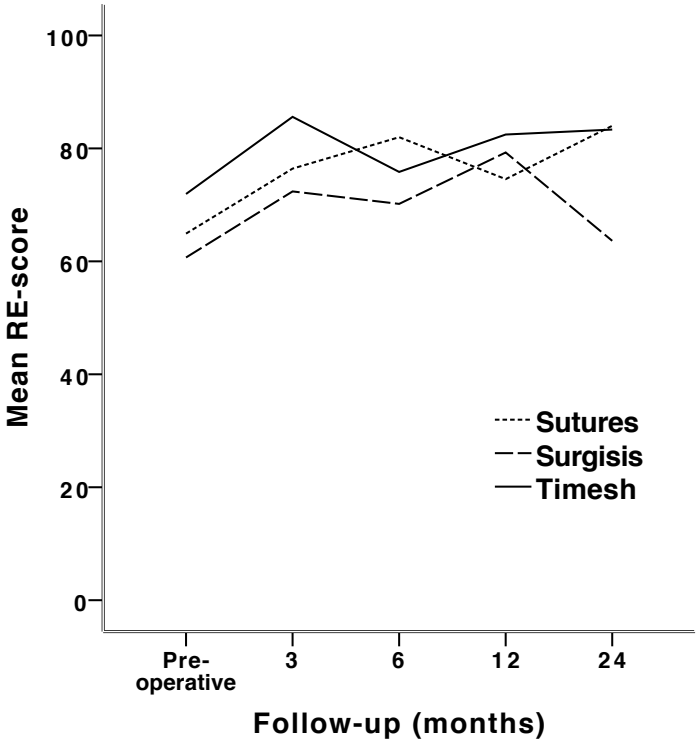

100
80
60
40
20
0
Mean RE-score
Sutures
Surgisis
Timesh
Pre-
operative
3
6
12
24
Follow-up (months)

FIGURE 10

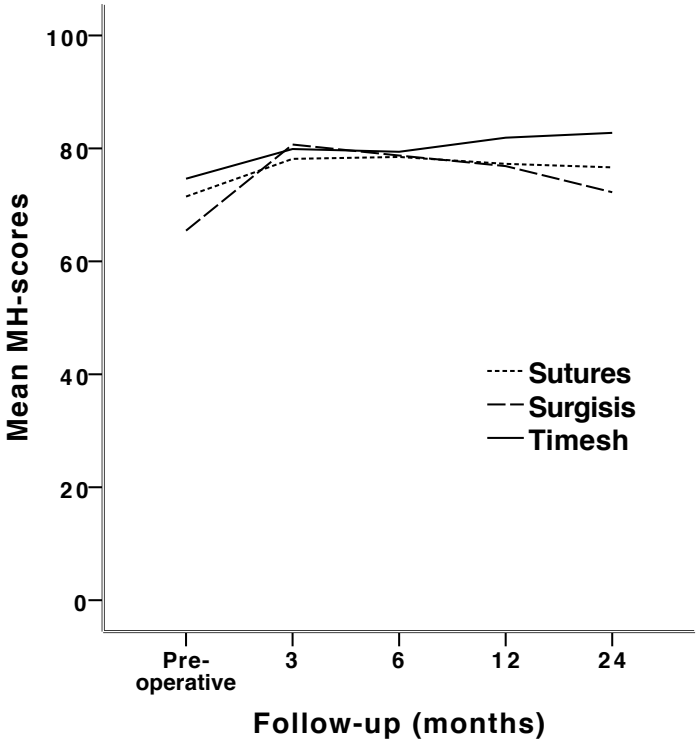
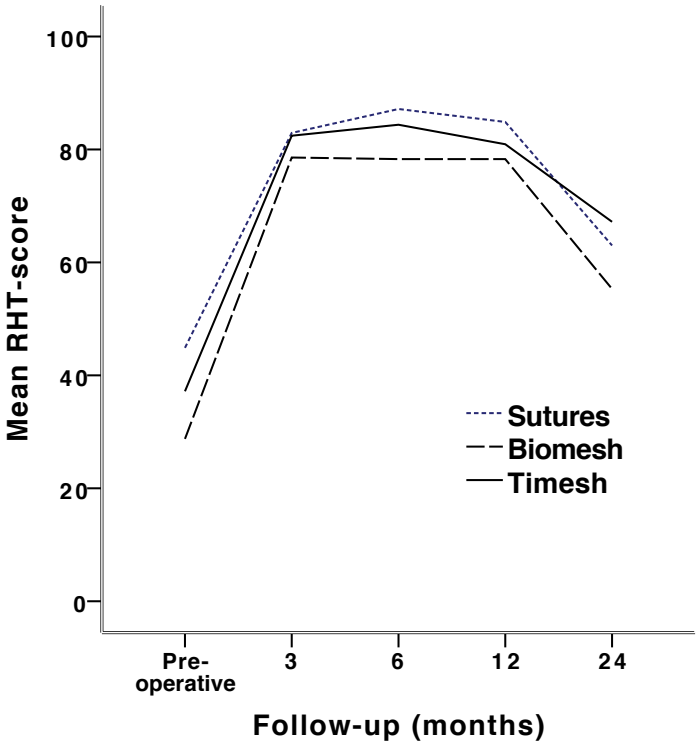

100
80
60
40
20
0
Mean MH-scores
Sutures
Surgisis
Timesh
Pre-
operative
3
6
12
24
Follow-up (months)

FIGURE 11


100
80
60
40
20
0
Mean RHT-score
Sutures
Biomesh
Timesh
Pre-
operative
3
6
12
24
Follow-up (months)