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A multi-center, prospective clinical trial of a hepatic derived porcine surgical mesh for the laparoscopic repair of symptomatic paraesophageal hernias

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ABSTRACT

Introduction: We report the results of a multicenter trial evaluating a unique, biological mesh (MIROMESH) derived from decellularized porcine liver for hiatal cruralplasty during laparoscopic PEHR.
Methods: 41 subjects underwent a laparoscopic PEHR which included primary crural closure, and MIROMESH onlay. Subjects were assessed at 2-weeks and 6, 12, 18 and 24 months using the SF-36, GERD-HRQL questionnaire, and VAS GERD related symptoms, and UGI.
Results: Mean procedure time was 143.0 (±45.2) minutes, 93% had a Type III hiatal hernia and median LOS was 3 days. Of 27 patients available for 2 years follow up, no patients required surgical reintervention for symptomatic hernia recurrence or adverse events. Radiographic follow up revealed a 10% hiatal hernia recurrence rate. GERD HRQL scores were significantly improved from baseline to two years follow up. All the GERD symptoms measured showed significant and sustained improvement at all postoperative time periods.
Conclusion: The utilization of MIROMESH for crural reinforcement during laparoscopic PEHR resulted in excellent symptomatic improvement in our multicenter trial with a 10% 2 year radiographic recurrence rate.

Introduction

Laparoscopic paraesophageal hernia repair has a relatively high rate of hernia recurrence with primary suture repair of the crural defect.[1–4] Several investigators have evaluated multiple methods to reduce that recurrence rate through various synthetic, biologic, and absorbable synthetic materials utilized to buttress the hiatal closure. Many of these evaluations are from single institutions, retrospective in nature, without objective radiologic follow up, significantly limiting a fair comparison and complete evaluations of the outcomes of each of these approaches. To date, the highest-level evidence in this field comes from a multicenter prospective randomized trial completed by Oelschlager et al., that randomized 108 patients to either primary suture or biologic mesh (Small Intestinal Submucosa (SIS)) repair.[4] These authors initially reported favorable outcomes in the short term with the biologic graft, but during long term follow up; the mesh only seemed to delay inevitable recurrence of the hiatal hernia.[5] They concluded that biologic mesh seems to add some early benefit to the hiatal hernia repair, but further refinements in the properties and performance of the biologic graft are necessary to provide long term durability to laparoscopic paraesophageal hernia repairs.[5] However, the lack of understanding as to the potential mechanisms for biologic graft failure at the hiatus, should limit an overly simplistic viewpoint of categorizing all biologic grafts as one entity. A thorough evaluation of the effect of source material, harvesting, and processing

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techniques should all be considered in future analysis of the merit of a biologic graft to reduce hiatal hernia recurrence rates.

In an attempt to improve upon biologic graft performance, a novel hepatic porcine derived graft (MIROMESH, Miromatrix, Eden Prairie, MN) was developed. This graft is processed using an innovative perfusion decellularization technique that theoretically allows for preservation of native tissue and the potential for early cellular population and revascularization, and an optimal environment for tissue ingrowth.[6] In animal models, this graft has been shown to promote improved cellular infiltration compared to non-crosslinked porcine dermis.[6] However, correlation of the histologic findings of this biologic mesh to long term graft performance in a clinically relevant setting is necessary. To evaluate this hepatic derived porcine graft, a multi-center prospective study was conducted to determine the long-term outcomes of MIROMESH when used during laparoscopic paraesophageal hernia repairs to prevent symptomatic and radiographic recurrence.

Methods

From August 2015 to May 2016, 6 centers (Cleveland Clinic, University of Kentucky, Carolinas Medical Center, Monmouth Medical Center, Virginia Heartburn and Hernia Institute, and Medical College of Wisconsin) enrolled 41 patients in a multicenter prospective single arm study evaluating the outcomes of a novel hepatic derived porcine biologic mesh for repair of symptomatic paraesophageal hernias. Inclusion and exclusion criteria are displayed in Table 1. The study was approved by the Cleveland Clinic Institutional Review Board, as well as each of the participating institutions IRB's, and compliance with all standards were met. Patients who agreed to participate provided written informed consent and all data was managed in compliance with HIPAA guidelines. The trial was registered on ClinicalTrials.gov NCT02436681.

Surgical technique

Antibiotics and DVT prophylaxis were delivered according to SCIP guidelines and patients were placed in the supine or split leg table position according to each surgeon's preference. Laparoscopic ports were placed based on each center's routine which typically consisted of 5 ports. The hernia sac was completely dissected free from the mediastinum, but was not required to be resected from the esophageal attachments in the abdomen. The gastro-esophageal junction was returned in a tension free infra-diaphragmatic position with intra-abdominal length measuring at least 2 cm. If insufficient length was achieved, a Collis gastroplasty was permitted at the surgeon's discretion. The crural pillars were measured with an intra-abdominal ruler and maximal width and height was recorded. The hiatus was closed with interrupted permanent sutures. The closure was typically posterior, but anterior closure sutures were permitted if necessary.

An appropriately sized piece of MIROMESH was prepared in a U configuration and secured to the primary crural closure posterior and laterally using interrupted permanent sutures in at least 3 points of fixation. A small space, of at least 0.5 cm away from the edge of the crus was left to avoid excessive contact with the esophagus. The use of a Bougie, fundoplication and anterior gastropexy was left to the discretion of the surgeon and recorded.

Table 1
Patient eligibility criteria.

Inclusion Criteria
Consenting adult from 18 to 80 years old
Candidate for elective laparoscopic paraesophageal hernia repair
Greater than 5 cm hiatal hernia in axial/vertical dimension
Evidence of Type II or III paraesophageal hernia
Free of cognitive or speech impairment
Commit to non-smoking for at least 4 weeks prior to procedure
Exclusion Criteria
Prior esophageal or gastric surgery
Sensitivity to Porcine material
Pregnant or plan for pregnancy in next 2 years
Immunocompromised (HIV, organ transplant, on chemotherapy)
Required emergent surgery for acute gastric volvulous or strangulation
ASA $\geq$ 4
BMI $\geq$40
Life expectancy less than 2 years
Have an associated GI disease that requires extensive medical or surgical intervention (eg Crohn's Disease) that might interfere with quality of life assessment

Study outcome measures

The primary endpoint of this study was hernia recurrence requiring surgical re-intervention at two years postoperatively due to symptoms or adverse events. The secondary endpoints include radiologic recurrence, symptomatic improvement, quality of life, adverse events and perioperative outcomes described below.

Hernia recurrence assessment

Upper Gastrointestinal (UGI) series were performed preoperatively, postoperative day #1, 1 year, and 2 years postoperatively. Images were read by local radiologists and reports were confirmed by study team. Local radiologists were given specific instructions on definitions of recurrence and measurement requirements. Hiatal hernia recurrence on radiologic imaging included any of the following findings: at least 2 cm of stomach, wrap, fundus, or any organ above the diaphragm as previously described by Oelschlager et al.[4] For patients with a recurrent hernia, the distance from the apex of the hiatus to the posterior decussation of the left and right crus was recorded in centimeters. Hernia recurrences were further classified into <2 cm recurrence, 2–4 cm recurrence, or >4 cm recurrence. For the purposes of analysis, any recurrence less than 2 cm was not considered a radiographic recurrence.

Symptom questionnaire

A standardized symptom questionnaire was administered preoperatively, 2 weeks, 2 months, 6 months, 1 year, 18 months, and 2 years postoperatively. The GERD Health Related Quality of Life (GERD-HRQL) survey was used to assess symptomatic improvements from the surgery.[7] The survey provides a quantitative method of measuring GERD symptoms severity. The GERD-HRQL has been shown to be reliable, valid and practical for assessment of symptom severity in GERD.[7] The instrument contains a total of 10 scaled items (Likert 0–5, with higher score indicating worse symptoms), and a patient-reported global satisfaction assessment (satisfied, neutral, or dissatisfied).

In addition at each time point, the patients completed a Visual Analog Scale (VAS) to assess the following hernia related symptoms: regurgitation, chest pain, abdominal pain, nausea, vomiting, postprandial pain, cardiovascular, and pulmonary symptoms. This scale recorded symptoms over the prior 7 days by drawing a line on a 10-cm scale with 0 representing “no effect on life” and 10 representing “extreme effect on life”.

Quality of life

The SF-36v2^{tm}, 36 item Health Survey was administered preoperatively, 2 weeks, 2 months, 6 months, 1 year, 18 months, and 2

years postoperatively. The SF-36 is a validated questionnaire measuring eight domains; four of these are related to physical health and four are related to mental health.[8] These eight domains include physical functioning, role-physical, role emotional, bodily pain, vitality, mental health, social functioning, and general health. The SF-36 scores are standardized on a 100-point scale, with the lowest quality of life 0, and the best quality of life 100.

Operative details

Pertinent operative details included operative time measured from first skin incision to skin closure. The management of the mediastinal hernia sac was recorded as fully or partially dissected from the mediastinum (a protocol deviation), fully, partially, or not dissected from the esophagus, and/or excised. The hiatal hernia defect was measured intra-operatively with an intracorporeal ruler. Measurements included the maximal height (anterior-posterior distance from apex of hiatus to posterior decussation of the left and right crus). The hernia width was measured in centimeters as the maximal distance between the left and right crus. The type of crural closure and whether a lateral relaxing incision was performed were documented. The shape of the mesh was documented as well and a U shape configuration was recommended. The performance and type of fundoplication was also noted. Other pertinent technical details included suture type for mesh fixation to the diaphragm, gastropexy sutures, gastrostomy tube, or Collis gastroplasty performed. The intra-operative length of intra-abdominal esophagus was documented by the surgeon after closure of the crus, without tension on the esophagus and an insufflation pressure of 15 mmHg.

Patient Co-Morbidities

Pertinent patient medical history included BMI (kg/m^2), gender, ethnicity, race, American Society of Anesthesia Score (ASA), smoking history (current, ex-smoker, never smoker), and general review of systems. Length of hospital stay was measured from time of surgery to time of hospital discharge based on meeting individual surgeon criteria.

Statistical considerations

This prospective trial was designed to gather long term information on performance with no pre-specified hypothesis. Continuous data were summarized using means, standard deviations, medians, and ranges. In addition, where assessments are made over time, the differences from baseline were statistically tested to see if different from zero using paired Student's t-test. An alpha of 0.05 was considered statistically significant and no adjustments for multiple testing were made. Categorical data were presented as counts and percentages. Radiologic hernia recurrence rates and 95% confidence intervals were calculated using Kaplan Meier survival analysis, and a stepwise logistic model with alpha of 0.15 was run to check for possible predictors of recurrence.

Results

Fifty patients were consented in the trial and 9 were subsequently excluded (Ineligible per inclusion criteria (3), withdrew consent (2), mesh not implanted because a lateral relaxing incision was performed and that area was bridged with synthetic mesh(1), or procedure canceled (3)). The trial group consists of 41 patients. A total of 27 (70%) patients completed the 24 months follow up. Fourteen patients did not complete follow up due to death (2), withdrew consent (2), and lost to follow up (10).

Patient demographics

Baseline patient characteristics included 81% females, mean age 63.3 years ± 12.5 (range 26–79), BMI 30.7 ± 4.0 (range 22–39), 71% never smoked, and ASA class was 1 (n = 1, 2.4%), 2 (n = 23, 56.1%), and 3 (n = 17, 42%). Concomitant medical conditions are displayed in Table 2. Preoperative work up and diagnostic modalities performed are reported in Table 3.

Operative details

All patients had a laparoscopic transabdominal approach and no patients required conversion to an open procedure. The hernia sac was removed from the mediastinum in all patients and in 63.4% (n = 26) it was fully excised from its esophageal insertion. The mean intra-operative hiatal hernia height was 6.0 cm ± 1.3 (range 3.0–9.0 cm) and the mean hernia width was 4.1 cm ± 1.2 (range 2.0–6.0 cm). At the completion of the crural repair a mean of 3.7 cm ± 1.1 (range 2.0–6.0 cm) of intra-abdominal esophagus was achieved and no Collis gastroplasties were performed. The crus was repaired primarily in all cases with interrupted permanent sutures and no lateral relaxing incisions were necessary. The mesh was U shaped in 39/41 cases (95%) and in two other cases it was C shaped. Mesh sizes included 6 × 8 cm (n = 19, 46%), 8 × 8 cm (n = 21, 51%), and 10 × 10 cm (n = 1, 2.4%). Non absorbable sutures were utilized to fixate the mesh to the diaphragm in 100% of cases and additional absorbable tacks and sealants were utilized in one patient each. A fundoplication was performed in 32 cases (78%), and the configuration was a Dor (n = 1, 3.1%), Nissen (n = 20, 62.5%), and Toupet (n = 11, 34.4%). Sutured anterior gastropexy was performed in 21 patients (51.2%), and a gastrostomy tube was utilized in 4 cases (9.8%). The mean operative time was 142.6 min ±45.7 (range 62–228 min), and the mean length of stay was 3 days ±1.5 (range 2–8 days).

Peri-operative complications

There were no major intraoperative complications reported. Eighteen postoperative adverse events were recorded. Four were considered serious and none were felt to be device related. The four serious adverse events included cardiopulmonary arrest (n = 1), readmission (n = 2), and severe postoperative nausea and vomiting (n = 1). The 14 other non serious adverse events are detailed in Table 4. There was one perioperative mortality in this series, in the patient that arrested on postoperative day one due to cardiogenic shock.

Table 2
Medical comorbidities in 41 patients.

Characteristic	Overall %
Diabetes	12.2%
Preoperative Anemia	24.4%
Barrett's Esophagus	4.9%
Dysphagia	7.3%
GERD	90.2%
Back Pain	34.1%
Chronic Obstructive Pulmonary Disease	4.9%
Cardiovascular Disease	2.4%
Congestive Heart Failure	0%
Hypertension	61%
Renal Disease	2.4%
History of Cancer	14.6%

Table 3
Preoperative esophageal evaluation of patients.

Diagnostic Modality	Rate
Plain Chest X Ray	17.1%
CT scan	29%
EGD	71%
Esophageal Manometry	19.5%
pH testing	4.9%
Hernia Type based on imaging	
Type II	5%
Type III	92.5%
Type IV	2.5%
Mean Estimated Hernia Height Above Diaphragm	7.5 cm ± 2.5 (range 3.0–15 cm)

Table 4
Non serious adverse events.

Adverse Event	Event Rate
Abdominal Pain	N = 1 (2.4%)
Diarrhea	N = 1 (2.4%)
Dysphagia	N = 1 (2.4%)
Edema at GE Junction	N = 2 (4.9%)
Food Bolus Obstruction	N = 1 (2.4%)
Acute Gastric Distension	N = 1 (2.4%)
Anterior Gastropexy Pain	N = 1 (2.4%)
Mild Hypoxia	N = 1 (2.4%)
Nausea and Vomiting	N = 2 (4.9%)
Pleural Effusion requiring drainage	N = 1 (2.4%)
Soreness	N = 1 (2.4%)
Urinary Tract Infection	N = 1 (2.4%)

Hernia recurrence

Clinical and radiologic follow up was available in 38 patients at 2 weeks, 30 at 12 months, and 27 at two years. Radiologic evaluation demonstrated hiatal hernia recurrences in 3 patients. All of the anatomic recurrences were documented as 2–3 cm. None of these patients required surgical reintervention for these small recurrences detected on imaging follow up. Based on the Kaplan Meier analysis depicted in Fig. 1 there was a 10% (95% CI 3–29%) rate of anatomic recurrence.

Symptomatic outcomes

The GERD-HRQL symptoms measured showed significant and sustained improvement at all post-operative time points. GERD HRQL scores were significantly improved from baseline to two years follow up 19.3 to 3.8 ($p < 0.0001$) respectively (Fig. 2). Preoperatively 17.9% of patients reported satisfaction with their condition while at 2 years 89% of patients reported satisfaction. Three patients were neutral and one patient was dissatisfied with their outcome at 24 months. GERD VAS symptom results are displayed in Fig. 3. These showed a significant and sustained improvement throughout the 24 month study period for regurgitation, chest pain, abdominal pain, nausea, vomiting, post prandial chest pain, cardiovascular and pulmonary symptoms.

Quality of life assessment

Quality of life, as assessed by the SF 36 questionnaire, was significantly improved at all time points. Overall quality of life improvement from baseline to 24 months is displayed in Table 5. There were improvements in all areas measured in the SF 36 from baseline to 24 months follow up, including statistically significant improvements in physical function, social function, and physical component summary score.

Multivariate analysis of recurrent hernia

A stepwise logistic regression analysis was performed to identify any factors that might correlate with hernia recurrence. Patient age, hernia width, BMI, presence of an anterior gastropexy (suture or gastrostomy tube), fundoplication, and intra-abdominal esophageal length were assessed. Given the low rate of hernia recurrence and relatively small sample size, there was no one feature that strongly correlated with hernia recurrence.

Symptomatic effect of recurrent hernia

To determine the effect of a radiologic recurrence on patient reported outcomes, we performed a subgroup analysis evaluating those patients with anatomic radiographic recurrence and those without recurrences. Fig. 4 demonstrates a comparison between those patients with a recurrence and those without based on the GERD HRQL scores. There were no major differences between the groups except at twelve and twenty four months patients with a recurrence had a higher GERD HRQL score. However, when evaluating the global satisfaction scores, 2 of the three patients with a recurrence reported being satisfied with the procedure, and one was neutral. Only one patient in the study reported being dissatisfied with the procedure at 24 months and that patient did not have a recurrence. Symptomatic assessment revealed no significant difference in outcomes between those patients with our without a recurrence for all 8 measured symptoms. (Data not shown) SF 36 results showed no significant differences from baseline to 24 months between those patients with a recurrence and those without in all 8 domains and physical and mental component summary score. (Data not shown).

Discussion

This prospective multicenter study found that this porcine derived hepatic biologic graft resulted in excellent long term symptomatic outcomes after laparoscopic paraesophageal hernia repair and is safe for use. We observed no graft related complications such as esophageal erosions or strictures during long term follow up. The radiologic recurrence rate was 10%, and importantly these recurrences were small, minimally symptomatic, and none required surgical re-intervention or were correlated with patient dissatisfaction with the procedure. Given these encouraging findings, in cases in which a biologic graft is felt to be necessary during laparoscopic paraesophageal hernia repair, MIROMESH is an effective surgical option.

One of the ongoing controversies in paraesophageal hernia surgery is the need for a buttress material for the crural closure and

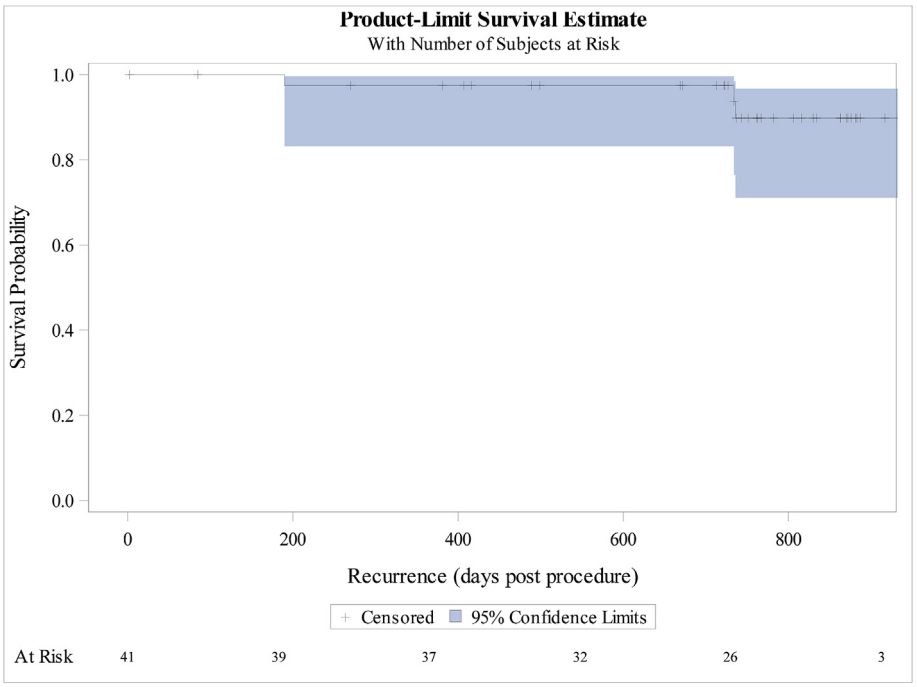

Fig. 1. Kaplan-Meier Analysis of long term anatomic hiatal hernia recurrence rates.

the ideal construct of that material. The most recent meta-analysis on this topic ultimately concluded that the data to support routine use of mesh at the hiatus is low, and its use should be based on surgical discretion at the time of surgery.[9] Schlottmann et al. reported a 39% rate of mesh utilization during hiatal hernia repair in almost 10,000 cases in the ACS-NSQIP.[10] Still, in cases where the surgeon does feel a mesh material is warranted, the choice between synthetic and biologic grafts can be daunting. Synthetic mesh has been extensively studied as a cost effective and durable method of reinforcing the crural closure. Several randomized controlled trials have reported excellent long term results with low rates of dysphagia, complications, erosions and hernia recurrences.[3,11] However, others have reported devastating complications related to synthetic mesh placed at the esophageal hiatus.[12–15] Despite the favorable results in the literature with synthetic mesh at the hiatus, a 2010 survey of SAGES members reported that the most common mesh utilized in hiatal hernia repair was a biologic material.[16] Given the explosion of new biologic grafts for complex abdominal wall reconstruction, there is a plethora biologic grafts available for paraesophageal hernia repairs as well. There is a paucity of data

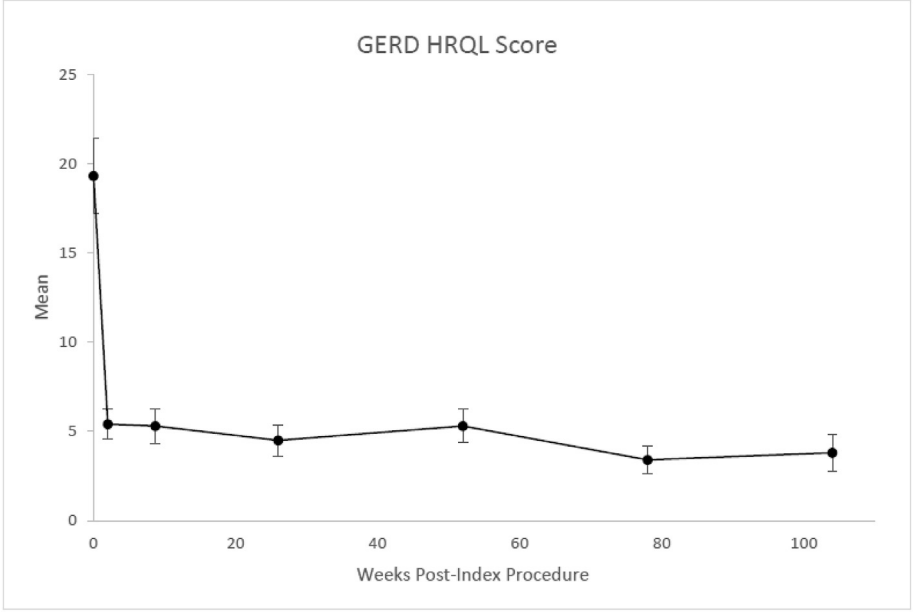

Fig. 2. Mean composite GERD-HRQL score as a function of weeks post-index procedure. Time zero indicates pre-operative baseline. All post-index procedure time points are significantly different from the pre-operative baseline ($p < 0.0001$).

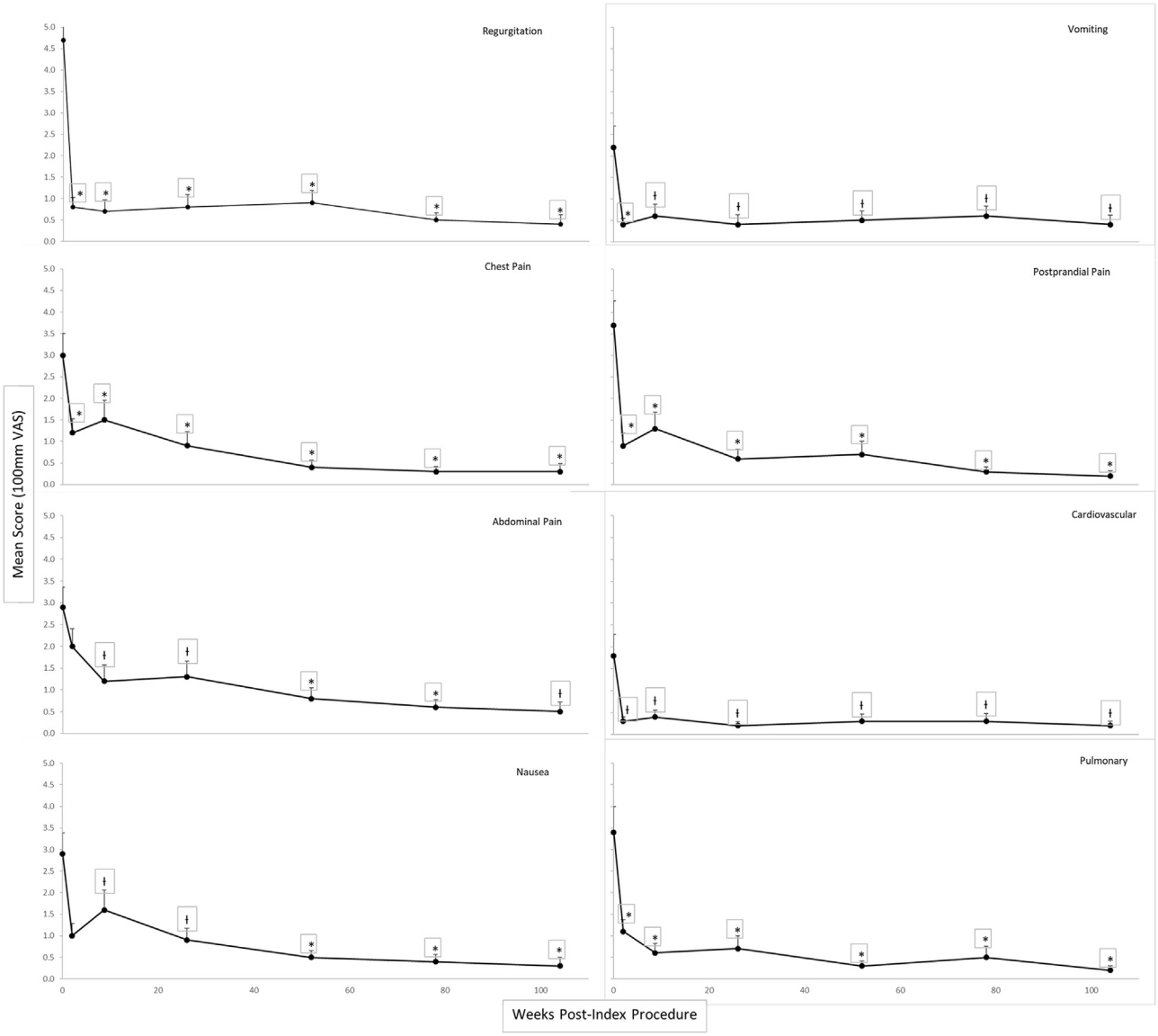

Fig. 3. Mean scores for all GERD VAS symptom scales as a function of weeks post-index procedure. Time zero indicates pre-operative baseline. Significance from baseline is indicated by ǂ $p < 0.05$ and * $P < 0.001$.

evaluating the performance of one biologic graft versus another in any clinical setting. While many products claim specific processing and source material advantages, clinical data substantiating these claims is extremely limited.

The search for the ideal biologic prosthesis has been ongoing and likely will continue. Features of the "right" biologic graft likely depend on the specific situation in which it is being utilized. It is important to realize that a biologic graft should perform well from a histological perspective with early cellular infiltration and eventual graft remodeling and collagen deposition. However, it also must perform in the long term to reduce hernia recurrence and stabilize the surrounding tissue. Many biologic grafts utilized today have extensive rodent and small animal histological analysis, but little is understood as to how these grafts perform in a clinically relevant situation. Even more critical, when utilized at the hiatus, given the close proximity to the esophagus, it should not cause excessive scaring and potential erosions or strictures. This study provides the first evidence that this graft did not result in any long term issues related to the peri-esophageal fibrosis and provided a durable repair material.

While many biologic grafts of different source material and processing techniques are available, the specific method in graft processing may significantly affect performance. Most biologic scaffolds are generated by immersion decellularization.[17–20] This

Table 5
SF 36 scores from baseline to 24 months. Data presented as Mean ± SD.

SF 36	Baseline	24 Months	P value
Physical Functioning	**38.9 ± 9.5**	**45.6 ± 10.6**	**0.0138**
Physical Role	40.2 ± 10.8	48.8 ± 9.5	0.0524
Bodily Pain	42.5 ± 8.9	48.4 ± 9.8	0.0713
General Health Perceptions	50.0 ± 9.8	53.0 ± 8.9	0.5418
Vitality	45.5 ± 10.9	52.7 ± 9.9	0.0979
Social Functioning	**42.5 ± 10.7**	**49.5 ± 8.8**	**0.0178**
Emotional Role	42.2 ± 11.4	50.6 ± 9.3	0.0587
Mental Health	47.0 ± 10.8	53.2 ± 7.5	0.0994
Physical Component Summary Score	**41.5 ± 9.9**	**47.2 ± 9.3**	**0.0468**
Mental Component Summary Score	46.6 ± 12.0	53.6 ± 8.0	0.0990

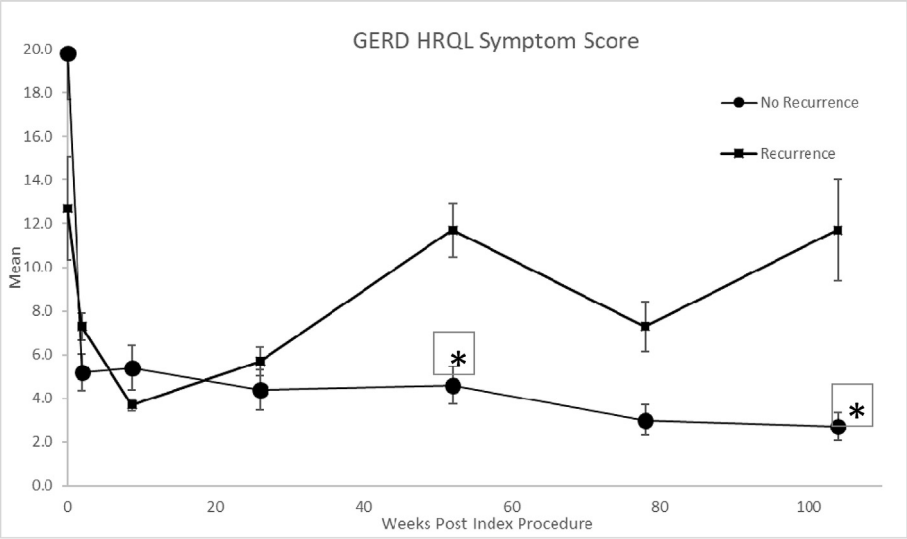

Fig. 4. Mean composite GERD-HRQL score for subjects with and without a recurrent hiatal hernia as a function of weeks post-index procedure. Time zero indicates pre-operative baseline. Asterisks indicate a significant difference between the cohorts ($p < 0.05$).

technique is limited to relatively thin and dense tissues to maintain adequate mechanical properties necessary of a mesh material. These grafts processed in this manner include dermis, pericardium, small intestine submucosa, and urinary bladder matrix.[21,22] These can result in a relatively dense collagen matrix which has been shown to impede early cellular infiltration.[21,22] Recently, a novel collagen matrix processing technique was developed and is termed perfusion decellularization.[23] In this approach, the native lumen (vessel or ducts) are utilized to perfuse a decellularization solution to the entire organ or tissue. This technique allows the decellularization of larger, less dense tissues while maintaining the native architecture which purportedly results in improved recellularization.[24] Using this technology, a novel biologic prosthetic derived from a whole porcine liver (MIROMESH; Miromatrix, Eden Prairie, MN) with intact remnant portal triads was developed. In a small rodent model, the utilization of this graft resulted in superior cellular infiltration when compared to a non cross linked porcine dermal graft.[6] The current study further validates that when this material is utilized at the hiatus during paraesophageal hernia repair, it performed in a reasonable manner to prevent recurrence and improve patient's symptoms.

The lack of a control group in this study limits our ability to conclude the superiority of MIROMESH to reduce paraesophageal hernia recurrence rates over sutures alone or other biologic grafts. However, the design and objective follow up of our prospective multicenter trial does lend itself to comparisons of other multicenter prospective randomized controlled trials. Specifically, Oelschlager et al. initially reporting on 108 patients randomized to suture repair or biologic graft reinforcement (SIS).[4] Their inclusion and exclusion criteria are very similar to our series and the hernia width appears to be comparable. In their study, they initially reported excellent results but at 5 years the recurrence rates were equivalent and over 50%. Our series only has 2 years follow up, but it is encouraging that our symptomatic recurrence rate remains zero, and all of the radiographic recurrences were small and did not negatively affect patients satisfaction or objective quality of life assessments. Another more recent randomized controlled trial by Watson et al., reported the outcomes of 126 patients randomized to suture repair alone, biologic mesh (SIS), or non absorbable synthetic mesh.[25] Although they did not find a statistically significant difference in their study, it was likely under powered and the actual differences of radiographic recurrence at only one year follow up was suture repair 23%, biologic repair 31%, and non absorbable mesh 13% ($p = 0.161$). Given that the biologic mesh (SIS) used in this study had an over 3 x's higher recurrence rate than our biologic graft at half the follow up, it is possible that the utilization of a different biologic graft might have resulted in more favorable outcomes. Our study has similar strengths to these previous trials in that the follow up was not only symptomatically evaluated but also radiographically, with objective definitions of hernia recurrence. In the future design of randomized controlled trials in this field, we would suggest that this porcine derived hepatic graft should serve as the biologic arm when compared to suture or synthetic mesh repairs.

Clear definitions of a successful outcome in paraesophageal hernia repair remains controversial. While the gold standard remains objective radiographic assessment, as performed in our series, the clinical and practical relevance for patients of those findings remains debatable. Our series is notable for a relatively low rate of anatomic recurrence of 10% at 2 years follow up. Even more important is that the majority of these patients remained satisfied with their outcomes, the recurrences were small and they did not require surgical reintervention. It is possible that without mesh these recurrences might have been larger and perhaps would have gone on to require a reintervention, but our study does not permit that assessment. It is also noteworthy that no one major factor allowed us to predict anatomic recurrence in this population; however, this should be interpreted with caution as the overall sample size is relatively small and the statistical power is low to detect differences.

One of the strengths of our prospective study and analysis is that all patients had preoperative symptomatic assessment which allows for a more clear symptomatic assessment in the postoperative period, further reinforced with repeated measures over several time points. This allows us to determine if an individual patient has symptom resolution, persistent symptoms, or new symptoms. Since many other studies of biologic and absorbable synthetic material placed at the hiatus are retrospective in nature, these types of analysis are not possible. The nearly 90% patient reported satisfaction rate at 2 years in our series suggests that the addition of this material to the hiatal hernia repair is also effective.

Conclusion

In conclusion, this study shows that MIROMESH, a porcine hepatic derived biologic graft, is safe and effective to use for crural reinforcement during laparoscopic paraesophageal hernia repair and results in excellent long term symptomatic improvement, with no reinterventions, and a 10% 2 year radiographic recurrence rate.

Disclosures

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