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Retrospective Review and Prospective Follow-up of 85 Consecutive Patients Treated With a Novel Hepatic-derived Surgical Mesh for Hiatal Hernia Repair: Outcomes, Surgical Complications, and Revisions

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Abstract: This study examined outcomes, surgical complications, and revisions in patients treated with laparoscopic Nissen fundoplication for hiatal hernia and substantial gastroesophageal reflux disease. In total, 85 consecutive patients who underwent hernia repair with MIROMESH Biologic Matrix, a novel hepatic-derived surgical mesh served as subjects. Subjects were contacted by phone, consented, and participated in an Institutional Review Board-approved structured phone interview. Responses were acquired from 73 of the 85 patients. The gastroesophageal reflux disease health–related quality of life showed significant improvement postoperatively. Subjects reported high satisfaction with the procedure. The use of proton pump inhibitors was significantly reduced. Three minor complications were reported; these were quickly resolved without further sequelae. There were no mesh-related complications. No subjects reported further surgery. Placement of the surgical mesh, during surgery, to reinforce the hiatal repair was easy and safe. Excellent outcomes and no revisions a mean of 1.3 years after surgery suggest that a durable repair had been achieved.

Key Words: paraesophageal hernia, gastroesophageal reflux disease, laparoscopic hiatal hernia repair, fundoplication, hepatic-derived surgical mesh

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The surgical community has made significant progress since Soresi[1] suggested that hiatal hernias could be responsible for numerous maladies and published his technique for hiatal hernia repair in 1919. Few today would dispute that assumption, but neither would they claim that the technique has been perfected. The goals of symptom control, safety, and durability for this repair have generated numerous technical revisions and strong opinions.

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Laparoscopic Nissen fundoplication has reached an acceptable level of standardization and is typically used to control the symptoms of gastroesophageal reflux disease (GERD), medically refractory reflux, and obstructive symptoms. When done without complication or recurrence in well-selected patients, the procedure accomplishes the goal of controlling the symptoms of reflux while allowing patients to eat without dysphagia.[2–4]

Long-term surgical data has confirmed that most patients are satisfied with the surgical outcome, and laparoscopic fundoplication failure is infrequent.[5–8] Not every case, however, results in long-term success[9] despite advancements in technology and techniques.[10] Failures, that is hernia recurrences, are mostly associated with (often early) herniation of the gastroesophageal junction through the hiatus,[11] a herniation through the diaphragm,[12] or the disruption of the cruroplasty and herniation of the stomach into the chest.[13] Postoperative failure of the hiatal closure has been referred to as the "Achilles heel" of the operation.[12,14] This suggests that avoiding technical failures will reduce the number of failed laparoscopic Nissen fundoplication procedures.

Reinforcing the hiatal closure with a prosthetic may reduce the failure rate. Surveys suggest that this surgical technique is gaining popularity in the United States[15] where polypropylene, polytetrafluroethylene, and biomaterials each accounted for about 25% of the mesh being used, and Europe where polypropylene accounts for 53% of repairs.[16] The synthetic, nonresorbable mesh is of concern because of severe complications, which may be more common than currently reported.[17] The use of biological mesh has shown promise in terms of outcomes, need for revision, and complications.[18,19] The current study examines the outcomes, revision rates, and complications of a novel hepatic-derived surgical mesh [(HD-SM) MIRODERM Biologic Matrix; Miromatrix, Eden Prairie, MN].

MATERIALS AND METHODS

Study Design

This study is a retrospectively identified, observational, single-arm study of 85 consecutive patients who underwent laparoscopic Nissen with hiatal hernia repair. Consecutive patients who underwent a laparoscopic hiatal hernia repair with a novel HD-SM and were at least 6-month postsurgery were identified through a chart review and invited to participate in the study.

A review of the anesthesiologist report, operative report, hospital chart, and office chart were used to collect demographics, pathology information, and surgical parameters and to identify any operative or perioperative complications. Routinely, a preoperative DeMeester score, 24-hour pH test,

proton pump inhibitor use, and a gastroesophageal reflux disease health–related quality of life (GERD-HRQL) score were obtained and available in the patient files. All patients were evaluated with high-resolution impedance manometry to ensure no preexisting esophageal motility disorders were present before fundoplication.

Patients were contacted by phone and asked to participate in a short, scripted, telephone interview that asked them questions regarding their current condition with respect to their hernia repair. If the patients agreed to participate, they were given a verbal informed consent, were told that information from their medical records would be used, that no protected health information would be used except to determine their age, surgery date, and time from surgery. If they chose to continue participation, a copy of the verbal consent was mailed to them. The verbal "Research Subject Information Sheet" (ie, verbal consent form), protocol, and the scripted follow-up phone interview were approved by the Western Institutional Review Board (Olympia, WA; Study Number 1176785).

During the phone interview, subjects were presented with each of the 10 GERD-HRQL questions and asked to rate their symptoms from "0" to "5" on the basis of each individual question of the GERD-HRQL. They were also asked, "How satisfied are you with your present condition" with the 3 possible answers being "Satisfied," "Neutral," or "Dissatisfied." They were asked, on a scale of "0" to "10," how likely they were to recommend this procedure to a friend or loved one with the same condition. Finally, they were asked if they used any proton pump inhibitors in the preceding 3 months and whether they had any surgical revisions since the index procedure. Responses were recorded on a patient-specific datasheet and entered into an electronic data file.

Surgical Biological Mesh

A novel HD-SM, MIROMESH (Miromatrix) was used in all cases. The mesh is made by perfusion decellularization of a porcine liver leaving the intact, acellular, collagen, liver matrix. The matrix is then compressed and cut to size leaving a durable, highly permeable, surgical mesh intended to be implanted to reinforce soft tissue. Perfusion decellularization makes use of the liver's native vascular tree to remove all cellular material while preserving the native vascular channels when the process is complete. This simultaneously yields a strong tissue scaffold while maintaining the native vascular channels throughout the graft to promote ingrowth. The result of this proprietary process is an architecturally intact, biochemically active scaffold. Likely because of this, the HD-SM has shown superior cellular infiltration at 90 days when compared with a denser non–cross-linked porcine dermal-based prosthetic in a rat model.[20] We theorize that these unique characteristics of the HD-SM may lead to improved incorporation into crura and improved durability of the hiatal hernia repair.

Surgical Technique

All patients underwent a standardized repair by the same surgeon (G.K.G.) and assistant (D.B.). Five trocars were used to gain access to the hernia. The hiatus was closed with 0-Ethibond sutures (Johnson and Johnson, Somerville, NJ) utilizing an extracorporeal knot pusher with the sutures being placed ~1 cm apart. Typically, 3 (39.3%) or 4 (34.5%) sutures were needed to perform the simple hiatal closure (range, 2 to 7). Short gastric vessels were always transected, and the fundus and cardia were fully mobilized. The distal esophagus was dissected circumferentially to identify and protect the vagus nerves. The esophagus was further mobilized in the mediastinum so that 2 to 3 cm of esophagus lay without tension below the diaphragm in an intrabdominal position. The hiatal closure was then typically reinforced with a custom made onlay, a 5×5 cm horseshoe-shaped HD-SM graft (Fig. 1). The HD-SM is produced as a flat sheet, in the surgical suite, it is easily custom cut for each case immediately before use. The HD-SM was typically secured with 3 or 4 (73.8%) 0-Ethibond sutures placed after the crura had been closed but before the fundoplication. The first suture was placed in the midline of the mesh directly over the hiatal closure sutures and incorporated the crura. The second and third sutures were placed on the edges of the mesh incorporating the right and left crura, respectively, at ~11 o'clock and 1 o'clock positions. A fourth stitch, if utilized was placed similarly and 1 cm below the first between the mesh anchored to the crural closure. Care was taken to ensure that the mesh was not impinging the esophagus in any way and typically was kept 0.5 to 1 cm away from the back wall of the esophagus to avoid a "clothesline" effect. The fundoplication was created in a loose manner without a bougie. The fundoplication was secured with three 0-Ethibond sutures placed 1 cm apart. The sutures ran from fundus to fundus, fundus to esophagus to fundus, and finally from fundus to gastroesophageal junction to fundus. With the paraesophageal hernia repairs, the hernia sac was fully dissected and reduced from the mediastinum but not excised or removed from the abdomen. A sutured gastropexy utilizing a single 0-Ethibond suture was used to anchor the antrum to the anterior abdominal wall after paraesophageal hernia repair (see Video, Supplemental Digital Content 1, http://links.lww.com/SLE/A217, showing onlay placement procedure). All patients were discharged home the day after surgery once they had shown that they were physiologically stable and tolerating a liquid or soft diet.

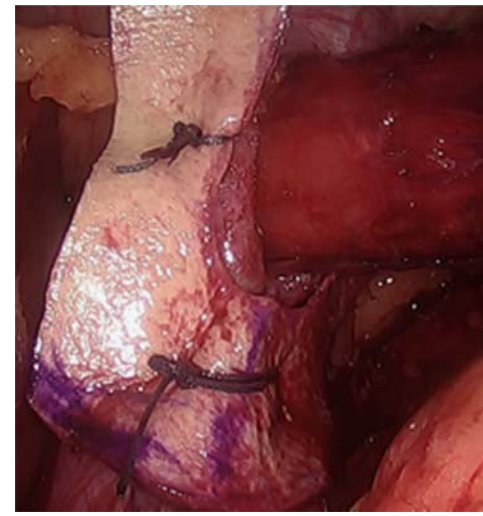

FIGURE 1. Hepatic-derived surgical mesh horseshoe–shaped onlay.

Statistical Analysis

The mean and SD or the median and range were calculated for continuous variables. Nominal variables are summarized in frequency histograms or percentages. Situations where the sample size listed is <73 indicates that some of the data could not be recovered. Preoperative and postoperative values were compared using a Student paired

TABLE 1. Subject Demographics and Preoperative Characteristics

Characteristic	Value [n (%)]	N
Sex		85
Female	55 (64.7)	
Male	30 (35.3)	
Age (mean ± SD) (y)	56.0 ± 12.7	85
Weight (mean ± SD) (lb)	181.7 ± 35.0	65
BMI (mean ± SD) (kg/m^2)	28.7 ± 4.8	66
DeMeester score (mean ± SD)	18.9 ± 14.9	50
24-hour pH (mean ± SD) (%)	5.23 ± 4.1	50
No. patients (N = 85)		85
GERD	59 (69.4)	
Hiatal hernia	62 (72.9)	
Paraesophageal hernia	24 (28.2)	
Hernia type		85
I	42 (49.4)	
II	13 (15.3)	
III	13 (15.3)	
IV	4 (4.7)	
Not specified	13 (15.3)	

BMI indicates body mass index; GERD, gastroesophageal reflux disease.

TABLE 2. Details of Surgical Procedure

Characteristic	Value [n (%)]	N
Procedure length (mean ± SD)	69 ± 20	85
Mesh shape		85
Horseshoe	67 (78.8)	
C-shaped	17 (20.0)	
U-shaped	1 (1.2)	
Mesh size (cut) (cm)		85
1×3	1 (1.2)	
3×3	1 (1.2)	
4×4	1 (1.2)	
4×5	3 (3.5)	
5×5	63 (74.1)	
5×6	14 (16.5)	
6×6	2 (2.4)	
Sutures to secure HD-SM		85
2	6 (7.1)	
3	33 (39.3)	
4	29 (34.5)	
5	13 (15.5)	
6	2 (2.4)	
7	1 (1.2)	

HD-SM indicates hepatic-derived surgical mesh.

t test or other inferential statistics as appropriate. Statistical significance was assumed when $P \leq 0.05$.

RESULTS

In total, 85 patients were identified as having the index surgery between November 3, 2015 and March 1, 2017. At the time of follow-up interview, subjects were a mean of 1.3-year postsurgery (range, 0.5 to 1.8 y; 58 were at least 1-y postsurgery). Of the 85 patients identified, 74 were located and 11 could not be located. Of the 74 patients located all but 1 agreed to participate. This left a cohort of 73 for final outcome assessment.

The majority of subjects were female individuals (64.7%) and the mean age was 55.9 at the time of surgery. Mean weight and mean body mass index were 181.7 lbs and 28.7 kg/m^2, respectively. Both the 24-hour pH score and the DeMeester score were indicative of a population with GERD, and a majority of subjects were codiagnosed with GERD and hiatal hernia. Details of subject characteristics may be found in Table 1. A total of 76 subjects and all 73 of the subjects who provided follow-up had a preoperative GERD-HRQL scores available for comparison. Similarly, a chart review for the entire cohort was completed and proton pump inhibitors use could be positively confirmed in 73 subjects. The hiatal hernia repair was a revision for 1 subject, whereas for 2 other subjects this was their third revision.

The HD-SM used for the onlay was typically cut from a 6×8 cm graft into a horseshoe shape (78.8%) and when customized it measured 5×5 cm (74.1%). Dependent on the exact anatomy, C-shaped and U-shaped HD-SM may have been used. Likewise, the range of (cut) HD-SMs were 1×3 cm to 6×6 cm. The HD-SM was most often secured with 3 or 4 sutures (range, 2 to 7). Mean skin to skin surgical time was 69 minutes (range, 18 to 173). Details of the surgical placement may be found in Table 2.

There were 3 noted operative or perioperative complications, all of which resolved without treatment and were not related to the HD-SM. Complications consisted of a 1-cm tear of the right liver lobe, operative atrial flutter, and minor bleeding from short gastric vessels. No complication required treatment, extended hospitalization, or surgical time nor did the complication produce any further sequelae except for the atrial flutter. In the case of atrial flutter, the subject remained hospitalized overnight for observation and released the next morning.

Follow-up was obtained from 73 of the 85 (85.9%) consecutive subjects identified for participation. The mean time from the index procedure to follow-up was 1.3 years (range, 0.5 to 1.8). Of the 73 subjects who agreed to participate, none reported an additional laparoscopic procedure or revision. The vast majority of subjects reported that they were satisfied with the procedure (Fig. 2). The 95% confidence interval for 86.3% of subjects who reported "satisfied" is 76.2% to 93.2%. Mirroring the high satisfaction rate, 87.7% of the subjects reported that their likelihood to recommend this procedure to a friend or loved one with a similar condition was 8, 9, or 10. Although only 12.3% reported their likelihood to recommend was 7 or less. Before surgery, 85.9% of the subjects reported proton pump inhibitor use. In contrast, in the 3 months previous to their follow-up interview, the percent of subjects who reported proton pump inhibitor use was

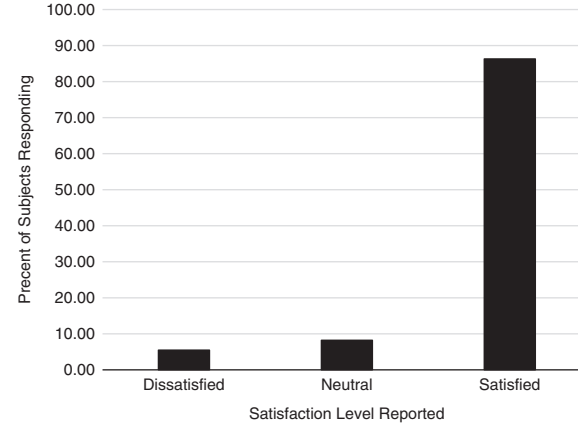

FIGURE 2. Percent of subjects responding as a function of their satisfaction level with the procedure (n = 73).

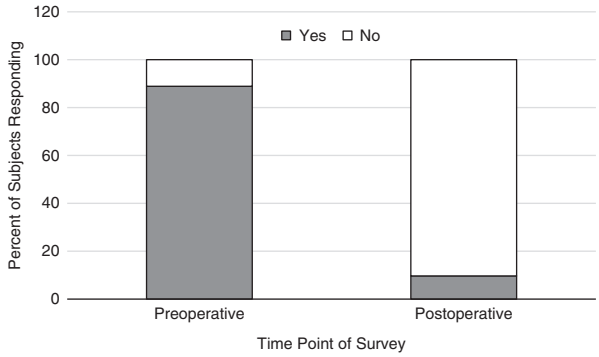

FIGURE 3. Percent of subjects reporting proton pump inhibitor use before hernia repair and in the 3 months immediately before their follow-up interview. The percent of subjects using proton pump inhibitors was significantly reduced postsurgery ($P < 0.0001$).

significantly reduced to 9.7%. Figure 3 presents proton pump inhibitor use both before surgery and in the 3 months preceding the follow-up interview.

Mean preoperative and postoperative scores for the GERD-HRQL are presented in Figure 4. Mean scores are shown for both the entire cohort (all, n = 73) and for only those respondents that completed the survey greater than 12-month postindex procedure (12 mo, n = 58). Preoperative scores were 27.7 and 27.5 for the entire cohort and the 12-month cohort, respectively. These values were significantly reduced ($P < 0.001$) postoperatively for both the cohorts (7.1 and 8.0, respectively). An item analysis of question 10 "if you take medications, does this affect your daily life?" revealed that the mean preoperative score was 3.12 and was significantly reduced to 0.33 postoperatively ($P < 0.001$).

DISCUSSION

Laparoscopic Nissen fundoplication has proven benefits for patients with GERD, symptomatic hiatal hernias when performed by well-trained laparoscopic surgeons.[8,21] The present study confirms the utility and safety of a laparoscopic Nissen fundoplication in the cohort observed. GERD symptoms were greatly improved, subjects were very much satisfied with the surgical outcome, and medication use was significantly reduced. Further, there were no revisions reported during the short-term to mid-term follow-up.

The procedure was well tolerated with only 3 complications identified. These were unremarkable, resolved without treatment or further sequelae, and related to the surgical procedure and not the mesh or its fixation. This is typical of laparoscopic procedures of this type regardless of what mesh is used.[22,23] There were no HD-SM-related complications reported. The lack of infection or mechanical complications is in line with other reports of biologicals and absorbable mesh and superior compared with synthetic mesh.[17,18,24] The laparoscopic Nissen fundoplication also yielded excellent symptom reduction over the short-term to mid-term follow-up. There was significant improvement in the GERD-HRQL scores both for the entire cohort and the minimum 1-year cohort. Over 85% of the subjects reported being satisfied with the procedure and were highly likely to recommend the procedure for others with the same condition. This adds further data to the growing body of evidence showing that when laparoscopic Nissen fundoplication is used to treat hiatal hernias and to control symptoms of GERD it is typically a safe and effective procedure.[19,25]

Most subjects reported that they were no longer using proton pump inhibitors. This is consistent with reports of improvement in heartburn and the general reduction of symptoms. Importantly, this is also internally consistent with the line-item analysis showing that the subjects reported fewer issues with medication and effects on daily life. Wang et al[26] showed that subjects with small recurrent hernias were more likely to report heartburn and proton pump inhibitor use than those without recurrences. The convergent drug data presented here suggest that the cohort studied here are less likely to have small recurrent herniations during the time frame reviewed.

Recurrence rates vary widely; however, it is clear that the use of permanent mesh will yield a reduction in hernia recurrence.[2,27,28] Despite this, recurrence rates as high as 8% have been reported within 1 year of the index procedure when a permanent prosthetic was used to buttress the hiatal repair.[29] Although less data are available for bioresorbable or biological mesh, it seems that reinforcement leads to fewer recurrences in the short term, differences in the long term, however, were not confirmed.[30,31] Although the current study did not complete imaging to identify the asymptomatic anatomic recurrence rate, it is consistent with previous efforts in that symptoms were well controlled and there were no reports of subsequent endoscopic procedures or hernia repairs. Further, during an unrelated procedure we had the opportunity to examine an HD-SM that had been placed 50 days prior. It demonstrated a secure attachment, good incorporation, and the beginning of vascularization. This is consistent with our expectation that this mesh may contribute to increased strength of the hiatal closure and a more durable repair over time.

In this study, we retrospectively identified 85 patients for whom we reinforced the hiatal closure with an HD-SM onlay. As such it suffers from the typical weaknesses of a retrospective review including potential selection bias, information bias, and the potential that those subjects who could not or would not participate may have had a disproportionally negative impact on the data set. To strengthen the design, we selected a consecutive cohort, used a consistent, Institutional Review Board-approved survey, and were able to obtain an 86% response rate.

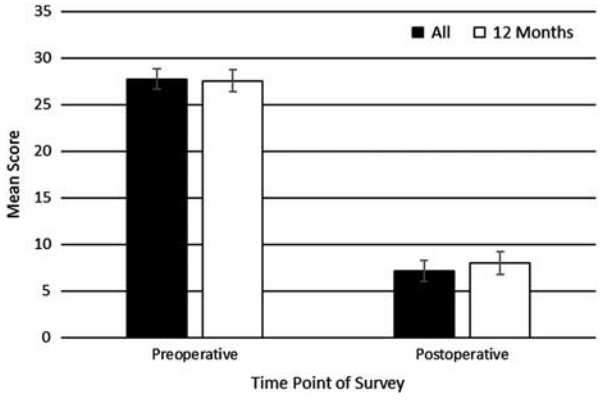

FIGURE 4. Mean gastroesophageal reflux disease health–related quality of life score (±1 SEM) as a function of timepoint of the survey. Solid bars include all respondents (n = 73) and open bars include only respondents who completed the survey greater than 12 months after the procedure (n = 58). For both cohorts, differences between preoperative and postoperative scores were statistically significant ($P < 0.0001$).

In conclusion, the data presented here show that laparoscopic Nissen fundoplication with a novel HD-SM is a safe procedure with no mesh-related complications over this short to medium follow-up. Symptom reduction was significant and lasting, and subjects were very satisfied with the procedure and the results obtained. There were no serious complications identified and no revisions completed. This data are consistent with a growing body of evidence that suggests that relative to some experiences with permanent prostheses, this biological mesh safely yields good clinical outcomes and reduces revisions. The definition of success and failure with respect to hiatal hernia repair is not well defined. Patients can remain clinically asymptomatic despite the interval development of recurrent hiatal hernias in the postoperative period. Now that we have a cohort of patients that are moving into a 2 to 4-year follow-up after hiatal hernia repair, we have the opportunity to make stronger statements about the durability of a repair utilizing this novel biological mesh. To this end we will combine objective (esophagogastroduodenoscopy and upper gastrointestinal series x-ray) data with subjective data to further clarify the idea of success and failure in these patients in a follow-up study.

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