



Does Treatment of the Hiatus Influence the Outcomes of Magnetic Sphincter Augmentation for Chronic GERD?

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Abstract

Background Hiatal dissection, restoration of esophageal intra-abdominal length, and crural closure are key components of successful antireflux surgery. The necessity of addressing these components prior to magnetic sphincter augmentation (MSA) has been questioned. We aimed to compare outcomes of MSA between groups with differing hiatal dissection and closure.

Methods We retrospectively reviewed 259 patients who underwent MSA from 2009 to 2017. Patients were categorized based on hiatal treatment: minimal dissection (MD), crural closure (CC), formal crural repair (FC), and extensive dissection without closure (ED). The primary outcome was normalization of postoperative DeMeester score (≤ 14.72). Univariable and multivariable logistic regression was used to assess which preoperative predictors achieved normalization.

Results Of the 197 patients, MD was used in 81 (41%); FC in 42 (22%); CC in 40 (20%); and ED in 34 (17%). Normalization occurred in 104 (53%) patients, with MD achieving normalization in 45/81 (56%); FC in 25/42 (60%); CC in 21/40 (53%); and ED 13/34 (38%). After regression, FC was most likely to normalize acid exposure. The presence of a hiatal hernia, defective LES, and higher preoperative DeMeester score were less likely to achieve normalization.

Conclusions Hiatal dissection with restoration of esophageal length and crural closure during MSA increases the likelihood of normalizing acid exposure.

Keywords Magnetic sphincter · GERD · Hiatal hernia · Surgical outcomes · Antireflux surgery · Diaphragm

A functioning reflux barrier is composed of 4 components: the lower esophageal sphincter (LES) especially its overall and intra-abdominal length; the flap valve enforced by the angle of His; the crural diaphragm or hiatal canal; and the phrenoesophageal ligament.¹ In patients with chronic gastroesophageal reflux disease (GERD), one or more of these components are defective leading to the retrograde flow of gastric

juice into the esophagus. During surgical reconstruction or repair of a defective reflux barrier, the principles of antireflux surgery recommend restoring the distal esophagus (LES) to the intra-abdominal position, crural closure, and augmentation of the LES by recreating the angle of His and preventing early effacement or opening of the LES with a fundoplication.²

Magnetic sphincter augmentation (MSA) with the LINX Reflux Management System® (Torax Medical/Ethicon, Minneapolis, MN) is an alternative to traditional fundoplication used to restore the reflux barrier. The initial implantation technique called for a simple, standardized technique with minimal alteration of the anatomy of the cardia to leave as much of the native structure of the reflux barrier intact allowing the device to “augment” the native sphincter by limiting LES effacement.³ However, several analyses on the outcomes of MSA demonstrated that the presence of a structurally defective sphincter, the presence of a hiatal hernia, and a Hill grade 2 valve could negatively influence the degree of reflux control.⁴ Missing from these analyses was data on if and how the hiatus was addressed during MSA implantation.

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The aim of this study was to assess the objective outcomes of MSA based upon how the esophageal hiatus was managed during implantation. We hypothesized that formal dissection of the hiatus, restoration of intra-abdominal length, and crural closure followed by MSA implantation are superior to minimal dissection of the anatomy first proposed for MSA implantation.

Methods

A retrospective review of prospectively collected data was completed for patients undergoing laparoscopic MSA from January 2009 until January 2017. De-identified data was pooled from one previously published source, the multi-institutional, prospective, single-arm Pivotal Trial,⁵ and two prospectively maintained databases at Swedish Medical Center and the Oregon Clinic. The Institutional Review Boards at Swedish Medical Center and Providence Portland Medical Center approved the study. Informed consent was provided for magnetic sphincter implantation; however, individual patient consent for this study was waived because of the study's retrospective nature.

Patients were included in this analysis whose age was greater than 18 and less than 85 years and who had a documented history of GERD with increased esophageal acid exposure on pH testing. Hiatal hernias up to 5 cm were included in this analysis. Patients were excluded if there was a history of prior gastric or esophageal surgery, the presence of endoscopically visible Barrett's > 2 cm or esophageal stricture. Patients with a known allergy to titanium, stainless steel, nickel, or iron were also excluded. Patients who underwent removal of the device before the 12-month pH test were also excluded.

Data abstracted from the databases included patient demographic information including age, gender, and body mass index (BMI). The use of and response to proton pump inhibitor (PPI) therapy was categorized as complete (if the patient had no symptoms), partial (improvement in the symptoms), or absent (no change in symptoms). Clinical symptom severity was measured with the Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) scale.⁶

We classified the GEJ anatomy using the Hill classification, assessed the absence or presence and grade of esophagitis according to the Los Angeles (LA) classification, and documented the absence or presence and size of hiatal hernia, measured from the top of the rugal folds to the diaphragmatic impressions.

All patients in the study were required to have pre- and post-MSA pH testing with either a 48-h wireless probe or a 24-h impedance pH catheter at the 12-month follow-up mark. The highest score during a 48-h period evaluation used for the

DeMeester score and percentage of total, upright, and supine time pH was less than 4.

The LES was categorized using the preoperative manometry by taking the LES resting and residual pressure, and overall and abdominal length, and defining three nominal categories: structurally normal or containing 1, or 2 + structural defects, defined by the following characteristics: resting pressure < 6 mmHg, total LES length < 2 cm, or intra-abdominal LES length < 1 cm.^{4, 7, 8}

The operative management of the esophageal hiatus was assessed in the Pivotal Trial participants by reviewing the submitted operative videos. The review was conducted by a single surgeon (Dr. Tom DeMeester) independent of this study. In this review, three approaches were identified: minimal dissection (MD): minimal or no dissection of the hiatus; formal crural repair (FC): hiatal dissection, return of esophageal length, and crural closure; and extensive dissection without closure (ED): dissection of the hiatus, return of esophageal length but without crural closure. The operative records and available video were also reviewed at the two sites by two other investigators (MMI and CD) with one additional approach being identified that was defined as crural closure (CC): posterior dissection alone with single or double suture closure.

Statistical analyses were performed using SAS. The primary outcome was normalization of the postoperative DeMeester (DMS) score (≤ 14.72). Categorical data is presented as counts and percentage, and continuous variables are summarized using means with standard deviation or median (interquartile range) as appropriate. Key predictors of outcome were identified from prior studies as preoperative Hill grade, preoperative hiatal hernia, and preoperative defective sphincter defined as at least 1 of resting pressure < 6 mmHg, total LES length < 2 cm, or intra-abdominal LES length < 1 cm.⁹ Univariate logistic regression models were fit to determine which, if any, factors were predictive of the outcome. Variables that were significant in the univariate models were considered for inclusion in the multivariable model along with the key predictors of outcome from the literature. A p value ≤ 0.05 was considered statistically significant.

Results

There were 259 patients who underwent MSA during the study period with 43 patients excluded who had not attained a minimal follow-up of 12 months and a further 19 patients excluded whose preoperative DeMeester score was missing or ≤ 14.72 or the postoperative DeMeester score was not available; thus, leaving 197 patients for analysis.

The most common treatment of the hiatus was MD in 81 (41.1%) patients followed by FC in 42 (21.3%), CC in 40 (20.3%), and ED in 34 (17.2%). The patient's preoperative

characteristics divided by hiatal treatment are detailed in Table 1. The most frequently device size implanted was a 14-bead (42.1%) followed by 13-bead (26.4%), 15-bead (20.8%), 12-bead (6.1%),¹ and 16-bead (4.6%).

There were no intraoperative adverse events, and 3 major postoperative complications were recorded: one patient had an asthma exacerbation and required ICU admission and 2 more patients required return to the OR on postoperative day 1. One patient experienced an obstruction at the gastroesophageal junction during FC and required removal of one of the hiatal stitches with complete resolution of symptoms, and the other one had an acute gastric herniation after FC that required reduction of the stomach and closure of the hiatus with one more stitch.

The overall median postoperative DeMeester score was 14.2 with 104 (52.8%) patients normalizing the postoperative DeMeester score with FC achieving normalization in 25/42 (60%), MD in 45/81 (56%), CC in 21/40 (53%), and ED 13/34 (38%). Only 21/174 (12.1%) patients reported using any PPIs post-MSA implantation. In patients reporting PPI use, it was most common in patients who underwent MD or CC and lowest in the FC and ED groups ($p < 0.001$) (Table 2).

There was improvement from preoperative to 1-year postoperative GERD-HRQL scores in all four groups (Table 3). However, there were no statistical differences between groups at 1 year after surgery. The CC group had the lowest preoperative scores and the highest postoperative scores, thus the smallest improvement ($p = 0.003$). Furthermore, when comparing GERD-HRQL scores only in patients who remained with abnormal pH values at 1 year after surgery, there were no differences between the groups (Table 3).

Graphical analysis comparing treatment of the hiatus by hiatal hernia size demonstrates FC was most likely to achieve normalization when no hernia and hernias < 2 cm were encountered compared to other treatments. However, all four types of closure experienced less normalization with increasing hernia size (Fig. 1). Comparatively, when a normal lower esophageal sphincter is encountered, the MD approach is most likely to achieve normalization of the DMS and is similar to FC when a defective sphincter is encountered (Fig. 2). The ability to achieve normalization when analyzed by Hill grade is widely varied with FC having the greatest likelihood in Hill grade 2, and similar likelihood to CC with Hill grade 1 and MD and ED with Hill grade 3. In Hill grade 4, MD has the greatest likelihood of normalization (Fig. 3).

During univariable logistic regression analyses, female gender, a hiatal hernia up to 2 cm and greater than 2 cm, defective LES, and preoperative DeMeester score were identified as significant predictors of normalization of the DeMeester score. Neither treatment group (FC, MD, CC or

ED) nor Hill grade was statistically significant predictors (Table 4).

During multivariable logistic regression analysis using treatment group, gender, hiatal hernia, defective LES, and preoperative DeMeester score identified that FC was more likely to normalize DMS than MD (OR = 3.07, 95%CI = 1.15–8.19, $p = 0.0247$) or ED (OR = 4.89, 95%CI = 1.55–15.43, $p = 0.0068$). In patients where no hiatal hernia was identified, it was more likely to achieve a normal DMS than when a hernia up to 2 cm (OR = 0.31, 95%CI = 0.13–0.71, $p = 0.005$) or a hernia > 2 cm (OR = 0.16, 95%CI = 0.07–0.38, $p < 0.0001$) was present in the patient. When comparisons of no hernia to the presence of any size hernia were made, the results remained significant (OR = 0.32, 95%CI = 0.18–0.59, $p = 0.0002$). Furthermore, the presence of a preoperative defective LES (OR = 0.37, 95%CI = 0.15–0.91, $p = 0.03$) was less likely to achieve a normalized DMS. A higher preoperative DeMeester score (OR = 0.99, 95%CI = 0.97–1, $p = 0.0598$) seemed to influence the ability to achieve a normalized DMS, but this result was not significantly positive (Table 5).

Discussion

The primary finding in this study of hiatal treatment and magnetic sphincter augmentation is that formal closure defined as hiatal dissection, restoration of intra-abdominal LES length, and crural closure is most likely to normalize the DeMeester score when combined with implantation of a magnetic sphincter device. However, each of the crural closure techniques led to normalization of esophageal acid exposure in a certain percentage of patients suggesting that other factors likely provide some contribution to the restoration of the reflux barrier. Lastly, normalization of esophageal acid exposure is not necessarily required for patients to experience an improvement in quality of life as evidenced by the postoperative GERD-HRQL scores.

The finding that FC had the greatest likelihood of achieving a normal post-MSA DeMeester score was not surprising. In addition to following long-standing surgical principles such as restoring intra-abdominal length, the technique restores the crural barrier. Several papers have provided support for crural closure as an important component of the reflux barrier. Firstly, during reconstruction of the reflux barrier with Nissen fundoplication, an intraoperative manometric study demonstrated that barrier function (especially LES pressure) was mostly related to the crural closure.² Secondly, when manometric changes on the LES in patients who underwent MSA were examined, it was discovered that patients with hiatal closure were more likely to restore an abnormal, preoperative LES to a normal, postoperative LES compared to those without hiatal closure.⁹ Lastly, an older study by Kahrilas et al.

¹ The 12-bead device is no longer available.

Table 1 Preoperative characteristics divided by treatment modality

Variable	Category	Minimal dissection (MD)	Crural closure (CC)	Formal crural repair (FC)	Extensive dissection w/o closure (ED)
<i>N</i>		81	40	42	34
Age	Median	53.0 (43.0–60.7)	50.5 (37.5–61.9)	53.2 (43.1–60.8)	49.7 (35.6–56.7)
Gender	Male	41 (50.6%)	22 (55.0%)	21 (50.0%)	21 (61.8%)
	Female	40 (49.4%)	18 (45.0%)	21 (50.0%)	13 (38.2%)
BMI	Median	26.1 (24.4–28.9)	27.5 (24.0–29.5)	27.0 (25.0–29.9)	27.9 (25.7–29.6)
Esophagitis	None	52 (64.2%)	22 (55.0%)	18 (42.9%)	24 (70.6%)
	A	18 (22.2%)	14 (35.0%)	13 (31.0%)	7 (20.6%)
	B+	11 (13.6%)	4 (10%)	11 (26.2%)	3 (8.8%)
Hill grade	1	15 (18.5%)	5 (12.5%)	5 (11.9%)	11 (32.4%)
	2	20 (24.7%)	7 (17.5%)	11 (26.2%)	4 (11.8%)
	3	23 (28.4%)	15 (37.5%)	10 (23.8%)	5 (14.7%)
	4	11 (13.6%)	10 (25.0%)	10 (23.8%)	6 (17.6%)
	Missing	12 (14.8%)	3 (7.5%)	6 (14.3%)	8 (23.5%)
Hiatal hernia size	None	45 (55.6%)	11 (27.5%)	7 (16.7%)	15 (44.1%)
	Up to 2 cm	21 (25.9%)	14 (35.0%)	9 (21.4%)	8 (23.5%)
	2–3 cm	12 (14.8%)	11 (27.5%)	13 (31.0%)	6 (17.6%)
	> 3 cm	3 (3.7%)	4 (10.0%)	13 (31.0%)	5 (14.7%)
DeMeester Score	Median	33.3 (24.2–48.7)	45.1 (33.2–61.4)	32.3 (26.9–54.9)	39.4 (30.0–50.3)
%time pH < 4	Median	9.3 (6.8–15.0)	13.9 (9.6–19.7)	10.3 (7.4–15.2)	11.4 (8.6–13.7)
%time pH < 4 > 4.5	Yes	76 (93.8%)	38 (95.0%)	39 (92.9%)	34 (100%)
Defective sphincter	No	17 (21.0%)	6 (15.0%)	4 (9.5%)	9 (26.5%)
	Yes	55 (67.9%)	32 (80.0%)	37 (88.1%)	22 (64.7%)
	Missing	9 (11.1%)	2 (5.0%)	1 (2.4%)	3 (8.8%)
LES length	Median	2.5 (2.0–3.6)	2.2 (1.7–3.0)	2.9 (1.9–3.8)	3.7 (3.0–5.0)
LES intra-abdominal length	Median	1.3 (0.5–1.9)	0.0 (0.0–1.2)	1.3 (0.0–2.5)	1.7 (0.6–2.5)
LES basal pressure	Median	18.9 (10.6–24.7)	18.7 (13.0–28.0)	16.0 (8.1–22.7)	15.2 (9.0–20.9)
LES residual pressure	Median	4.7 (1.6–7.6)	5.8 (3.8–7.9)	3.5 (1.3–6.1)	4.9 (1.2–7.5)
Distal wave amplitude	Median	74.4 (61.3–105.8)	64.2 (48.2–92.7)	65.8 (52.0–79.0)	70.0 (57.6–80.0)
% peristalsis	Median	92.0 (85.0–100)	100 (90.0–100)	100 (80.0–100)	100 (100–100)
GERD-HRQL	Median	24.5 (18.0–31.0)	20.0 (14.0–27.0)	28.0 (22.0–33.0)	27.0 (24.0–32.0)

also demonstrated that pressure at the GEJ was determined by the hiatal canal.¹⁰

Two recent papers also looked at the role of crural closure with MSA. The first compared patients with no hiatal hernia (MSA only, presumed MD) with patients who had hiatal hernia repair with MSA (FC) and hiatal hernia without repair plus MSA (MD).¹¹ Although they concluded there was a trend to improved outcomes with hernia repair, the outcomes including pH normalization were similar across groups. These results are similar to our study in that different hiatal repairs were able to normalize acid exposure and highlight the fact that crural repair is not the only factor contributing to reflux control. Comparatively, a second study concluded that formal closure of the hiatus during MSA implantation resulted in less

recurrent GERD compared to patients undergoing minimal dissection. They defined recurrent GERD based on resumption of PPIs after successful initial postoperative wean (1.5% vs 15%).¹² These results are similar to our series where 5.4% (2/37) of FC patients and 19.7% (14/71) of MD patients in the current series resumed PPIs. However, only 60% (25/42) of these FC patients and 56% (45/81) of MD patients demonstrated normal esophageal acid exposure by pH testing. Moreover, both groups in self-reported quality of life reported median GERD-HRQL scores of 2. Unfortunately, the resumption of PPIs and GERD-HRQL scores, while important metrics, do not necessarily indicate that patients have control of their GERD. From the patient perspective, these are excellent outcomes, but objective evidence of GERD control by pH

Table 2 PPI use at 1 year after surgery

PPI use	Minimal dissection (MD)	Crural closure (CC)	Formal crural repair (FC)	Extensive dissection w/o closure (ED)	Total
<i>N</i>					
missing	10	8	5	0	
No	57 (80.3%)	27 (84.4%)	35 (94.6%)	34 (100%)	153
Yes	14 (19.7%)	5 (15.6%)	2 (5.4%)	0 (0%)	21
Total	71	32	37	34	174

Table 3 Preoperative and 1-year postoperative HRQL grouped by hiatal treatment overall, and in patients with abnormal pH at 1 year postoperative (defined as DMS > 14.72 or %time pH < 4 > 4.5)

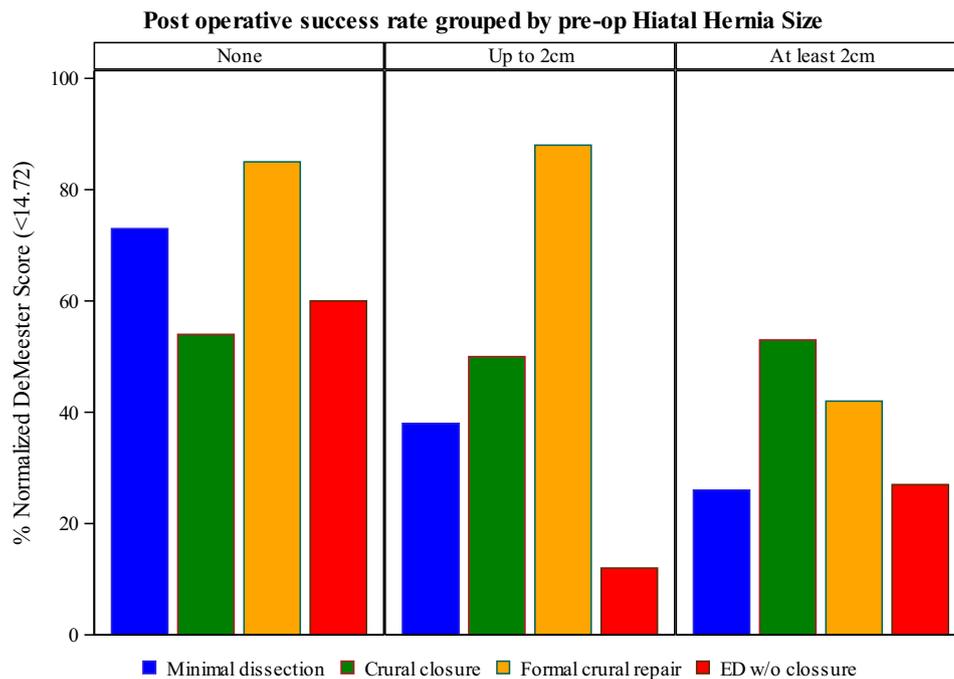
	Minimal dissection (MD)	Crural closure (CC)	Formal crural repair (FC)	Extensive dissection w/o closure (ED)
<i>N</i>	81	40	42	34
Preoperative HRQL	25 (18–31)	20 (14–27)	28 (22–33)	27 (24–32)
<i>N</i> missing	3	3	3	0
HRQL at 1 year	2 (0–4)	5 (3–11)	3 (1–6)	3 (1–8)
<i>N</i> missing	43	11	6	3
Patients with preoperative and 1-year HRQL				
<i>N</i>	38	27	33	31
Preoperative HRQL	26 (20–31)	19 (11–25)	28 (23–33)	28 (24–33)
1-year HRQL	2 (0–4)	4 (2–11)	2 (1–5)	3 (1–8)
Change in HRQL	23 (17–30)	11 (6–19)	26 (21–30)	23 (16–28)
Patients with abnormal pH at 1 year				
<i>N</i>	37	19	17	21
Preoperative HRQL	26 (12–31)	19 (9–25)	30 (19–34)	27 (24–34)
<i>N</i> missing	2	2	2	0
HRQL–1 year	2 (0–3)	3 (1–12)	2 (2–6)	4 (0–11)
<i>N</i> missing	27	8	1	2

HRQL health-related quality of life score

testing is arguably a more important outcome if our goals are to prevent the development Barrett’s and prevent progression of disease.

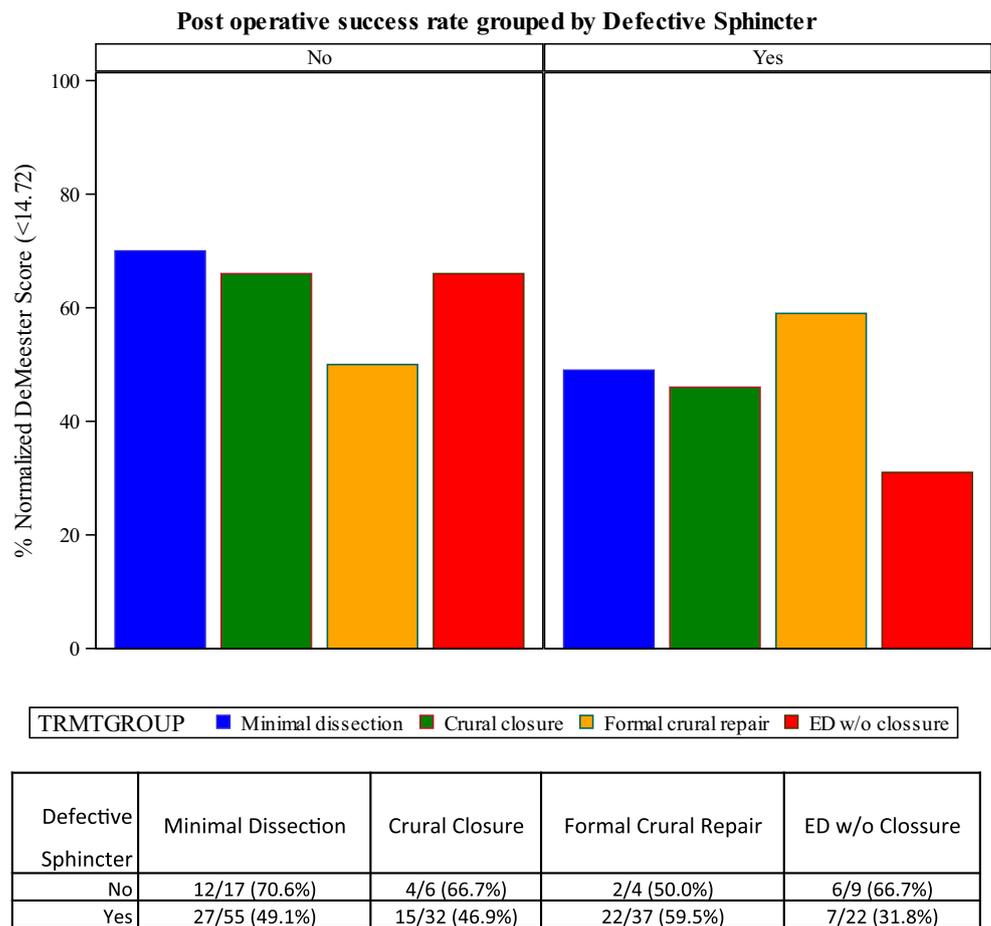
The rates of normalization of the DeMeester score in this study are similar to the original MSA study⁵ which reported 58% normalization but are lower than reported by Bonavina

Fig. 1 Normalization of acid exposure by hiatal treatment and hernia size



Hiatal Hernia	Minimal Dissection	Crural Closure	Formal Crural Repair	ED w/o Closure
None	33/45 (73.3%)	6/11 (54.5%)	6/7 (85.7%)	9/15 (60.0%)
Up to 2cm	8/21 (38.1%)	7/14 (50.0%)	8/9 (88.9%)	1/8 (12.5%)
At least 2cm	4/15 (26.7%)	8/15 (53.3%)	11/26 (42.3%)	3/11 (27.3%)

Fig. 2 Normalization of acid exposure by treatment group and presence of a defective LES



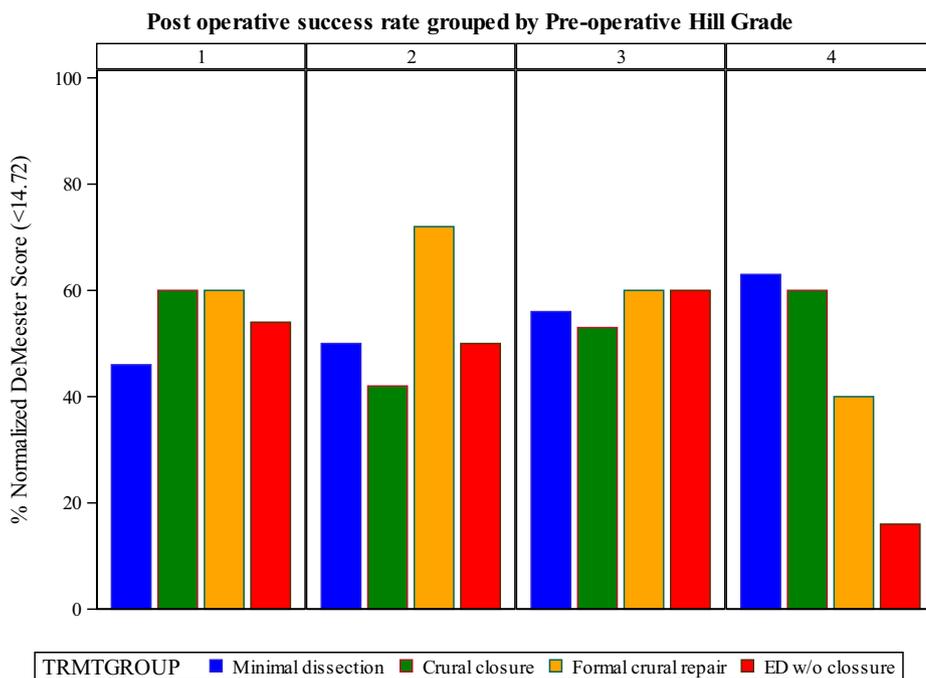
et al.¹³ at 67% and much lower than the 72% reported from Post Approval Study.¹⁴ These results highlight several issues with MSA implantation. Firstly, the original implantation technique has evolved quickly but that does not mean that FC is the silver bullet and data are required to look at reflux control as well as new onset dysphagia, which can result from over tightening of the crura. Secondly, it is unclear how normalization or failure to achieve normalization fits in with patient-reported symptoms scores that are normal. Last, as the indications for implantation broaden (larger hernias, etc.), it is unknown whether the device will be able to achieve normalization.

It appears that several other factors also influence the ability to achieve a normalized score including hiatal hernia size, a higher preoperative DMS, and a defective LES. It is likely that these factors are related and several explanations can be made. Firstly, there is a relationship between increasing hiatal hernia size and the presence of a defective LES, thus making it more difficult to restore the LES characteristics to normal.¹⁵ The presence of a defective sphincter or more likely the ability to restore a defective LES to a normalized LES seems to be a key factor in acid control with MSA implantation.^{4, 9} Secondly, even a 3 to 5-cm hiatal hernia produces some element of a “tubularized” cardia that may be easily mistaken as the

esophagus if not carefully assessed. If the GEJ is incorrectly identified during implantation, then, it is possible the device may lay below the true EG junction resulting in less effective reflux control. Upper endoscopy at the time of MSA implantation is recommended to ensure the most accurate placement of the device. Lastly, the presence of higher preoperative DMS, though not statistically significant, suggests that more advanced stages of GERD have a negative impact on achieving reflux control. When encountered in a patient with a larger hernia and defective LES, that patient should be counseled about the potential lower success rate at controlling GERD but may have a good symptomatic outcome with MSA.

Going forward, it would seem that the simple conclusion and recommendation for surgeons performing MSA is that every patient should undergo formal closure of the hiatus after esophageal mobilization and restoring length. However, patient variables such as hernia size or a defective LES seem to influence normalization of acid exposure that challenge this simple conclusion. In most high-volume MSA centers, this implantation technique has been adopted based on the surgeon’s clinical experience alone. For patients, they can be reassured that formal closure with MSA will provide a high rate of freedom from PPIs and improvement in clinical symptoms. But,

Fig. 3 Normalization of acid exposure by treatment group and preoperative Hill grade



Pre operative Hill Grade	Minimal Dissection	Crural Closure	Formal Crural Repair	ED w/o Closure
1	7/15 (46.7%)	3/5 (60.0%)	3/5 (60.0%)	6/11 (54.5%)
2	10/20 (50.0%)	3/7 (42.9%)	8/11 (72.7%)	2/4 (50.0%)
3	13/23 (56.5%)	8/15 (53.3%)	6/10 (60.0%)	3/5 (60.0%)
4	7/11 (63.6%)	6/10 (60.0%)	4/10 (40.0%)	1/6 (16.7%)

Table 4 Univariable logistic regression analysis

Predictor	Category	Not normalized (n = 93)	Normalized (n = 104)	Logistic regression			
				OR	Lower CL	Upper CL	p value
Treatment group	MD	36 (38.7%)	45 (43.3%)	Reference group			
	CC	19 (20.4%)	21 (20.2%)	0.88	0.41	1.89	0.75
	FC	17 (18.3%)	25 (24.0%)	1.18	0.55	2.51	0.67
	ED	21 (22.6%)	13 (12.5%)	0.49	0.22	1.12	0.09
Age	Mean	51.6 (14.8)	49.2 (12.7)	0.99	0.97	1.01	0.22
Gender	Male	60 (64.5%)	45 (43.3%)	Reference group			
	Female	33 (35.5%)	59 (56.7%)	2.38	1.34	4.24	0.003
Hill grade	1	17 (18.3%)	19 (18.3%)	Reference group			
	2	19 (20.4%)	23 (22.1%)	1.08	0.44	2.64	0.86
	3	23 (24.7%)	30 (28.8%)	1.17	0.50	2.73	0.72
	4	19 (20.4%)	18 (17.3%)	0.85	0.34	2.12	0.72
Hiatal hernia size	None	24 (25.8%)	54 (51.9%)	Reference group			
	Up to 2 cm	28 (30.1%)	24 (23.1%)	0.38	0.184	0.79	0.009
	> 2 cm	41 (44.1%)	26 (25.0%)	0.28	0.14	0.56	0.0003
Defective sphincter	No	12 (12.9%)	24 (23.1%)	Reference group			
	Yes	75 (80.6%)	71 (68.3%)	0.47	0.22	1.02	0.06
DeMeester score	Mean	47.8 (20.4)	38.2 (30.2)	0.98	0.97	0.97	0.01

MD minimal dissection, CC crural closure, FC formal crural repair, ED extensive dissection without crural closure, OR odds ratio, CL confidence limit

Table 5 Multivariable logistic regression analysis

Odds ratio estimates				
Effect	Point estimate	95% Wald confidence limits		<i>p</i> value
Treatment group				
CC compared to MD	1.73	0.67	4.44	0.25
FC compared to MD	3.07	1.15	8.19	0.02
ED compared to MD	0.63	0.24	1.64	0.34
Extra pairwise tests				
CC vs FC	0.56	0.20	1.58	0.28
CC vs ED	2.75	0.89	8.55	0.08
FC vs ED	4.89	1.55	15.43	0.007
Gender				
Female vs Male	2.60	1.33	5.07	
Hiatal Hernia*				
< 2 cm vs no hernia	0.31	0.13	0.70	0.005
> 2 cm vs no hernia	0.16	0.06	0.38	< 0.0001
Extra pairwise tests				
< 2 cm vs > 2 cm	1.95	0.80	4.71	0.14
Defective sphincter	0.38	0.15	0.91	0.03
Preoperative DeMeester score	0.99	0.97	1.00	0.06

*2–3 cm and > 3 cm groups were combined due to small cell sizes

MD minimal dissection, CC crural closure, FC formal crural repair, ED extensive dissection without crural closure

the minimal dissection technique relied on native structures to achieve augmentation and also left the phrenoesophageal membrane intact in hopes of preventing transmediastinal herniation of the device. With formal closure, surgeons potentially could worsen a normal LES as shown in Fig. 2 where the normalization rate is less than MD. In a prior study, a normal LES was worsened 18% of the time.⁹ Additionally, FC now relies on the cicatrix surrounding the esophagus and hiatus to maintain its position.¹⁶ At present, it appears that the rate of transmediastinal herniation is less than 4% but long-term follow-up is required.^{16, 17}

Several observations can be made when outcomes are broken down by hernia size, defective sphincter, and Hill grade when only MD and FC are considered. First, outcomes using MD progressive worsen with increasing hernia size and, although FC yields better outcomes at all sizes of hernia, there is a drop in normalization with larger hernias. Second, outcomes by Hill grade have a wide variation in normalization across all hiatal treatment options. This may be due to how the Hill grading system is used and applied by endoscopists rather than MSA performance and outcomes. Third, when a Hill grade 2 valve is encountered, it likely has more of a hiatal hernia component than can be estimated a laparoscopy which is why FC leads to the greatest likelihood of achieving normalization with Hill grade 2 patients.

There are several limitations to our paper. Firstly, it is a retrospective review and analysis of prospectively

collected data. Nonetheless, it is subject to the limitation of a retrospective analysis. Secondly, although there appears to be a reasonable number of patients, the number of patients in each type of repair and in each clinical factor subcategory such as Hill grade 4 is small. Thirdly, the measurement of hernia size is imprecise and the number of patients with hernias larger than 3 cm is small and interpretations and inferences on the utility of MSA in patients with larger hernias cannot be made with this dataset. Fourthly, even though Hill grade has well-described characteristics, it is partly subjective and we did not review or reclassify the patients and accepted the treating surgeon’s description. Lastly, the one key strength of our study is that all patients had a preoperative and postoperative pH testing allowing for comparison between the groups.

Conclusions

During implantation of a magnetic sphincter augmentation device, hiatal dissection, esophageal mobilization, and crural closure are most likely to normalize the postoperative DeMeester score. It appears that more advanced GERD disease as evidenced by the presence of a hiatal hernia, a defective LES, and higher DeMeester score might negatively impact the ability to normalize esophageal acid exposure during magnetic sphincter augmentation.

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