

# Efficacy of magnetic sphincter augmentation in patients with large hiatal hernias

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## Abstract

**Background** Magnetic sphincter augmentation (MSA) has demonstrated long-term safety and efficacy in the treatment of patients with gastroesophageal reflux (GERD), but its efficacy in patients with large hiatal hernias has yet to be proven. The aim of our study was to assess outcomes of MSA in patients with hiatal hernias  $\geq 3$  cm.

**Methods** We retrospectively reviewed all patients who underwent MSA at our institutions over a 6-year period. Information obtained consisted of patient demographics, symptoms of GERD, preoperative GERD Health-Related Quality-of-Life (HRQL) scores, perioperative details, and implantation of the MSA device. Primary endpoints included postoperative GERD-HRQL scores, proton-pump inhibitor (PPI) use, symptom change, and procedure-related complications. A large hiatal hernia was defined as a hernia measuring  $\geq 3$  cm by intraoperative measurement.

**Results** A total of 192 patients were reviewed. Median follow-up was 20 months (3–75 months). Mean GERD-HRQL scores in the overall population before and after MSA were 18.9 and 5.0, respectively ( $p < 0.001$ ). In the majority of patients symptoms improved or resolved ( $N = 177$ ,  $p < 0.001$ ). Fifty-two patients (27.0 %) had a hiatal hernia  $\geq 3$  cm (range 3–7 cm). Their mean GERD-HRQL score decreased from 20.5 to 3.6 ( $p < 0.001$ )

following MSA. When compared to patients with smaller hernias, patients with large hiatal hernias had decreased postoperative PPI requirement (9.6 vs. 26.6 %,  $p = 0.011$ ) and lower mean postoperative GERD-HRQL scores (3.6 vs. 5.6,  $p = 0.027$ ). The percent of patients requiring postoperative intervention for dysphagia was similar (13.5 vs. 17.9 %,  $p = 0.522$ ), as was the incidence of symptom resolution or improvement (98.1 vs. 91.3 %,  $p = 0.118$ ).

**Conclusion** MSA in patients with large hiatal hernias demonstrates decreased postoperative PPI requirement and mean GERD-HRQL scores compared to patients with smaller hernias. The incidence of symptom resolution or improvement and the percentage of patients requiring intervention for dysphagia are similar. Short-term outcomes of MSA are encouraging in patients with gastroesophageal reflux disease and large hiatal hernias.

**Keywords** GERD · LINX · MSA · Magnetic sphincter augmentation · Hiatal hernia

Acid suppression with proton-pump inhibitors (PPIs) is the first-line therapy for patients with gastroesophageal reflux disease (GERD) [1–8]. Interestingly, up to 40 % of patients remain symptomatic despite medical treatment [9–11]. Furthermore, the fundamental physiologic abnormality, an incompetent lower esophageal sphincter (LES), remains unaddressed allowing for persistent reflux of gastric contents into the distal esophagus [12, 13]. Laparoscopic nissen fundoplication is the gold-standard surgical antireflux procedure that restores LES competence by plicating it with the gastric fundus, and it is offered to patients with an inadequate response to PPIs or severe reflux disease [14–17]. The Nissen fundoplication is a technically complex procedure that permanently alters gastric anatomy and

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has the potential for side effects such as gas bloat, inability to belch or vomit, and dysphagia [18]. As a consequence, less than 1 % of patients with severe GERD undergo this procedure to avoid unwanted side effects leaving a significant proportion of patients inadequately treated [19, 20]. The emergence of the magnetic sphincter augmentation (MSA) device referred to as the LINX<sup>®</sup> Reflux Management System (Torax Medical; Shoreview, MN USA) has provided a potential solution for this population of inadequately treated patients. It has shown to be a safe and efficacious alternative to LNF, with an improved side effect profile [15, 18, 21, 22]. MSA utilizes a ring of dynamic interconnected magnetic beads that augments LES pressure to minimize pathologic reflux, while preserving normal gastric anatomy. It simulates normal LES function by allowing actuation of the beads and thus expansion of the distal esophageal lumen, facilitating bolus transport. A recent multicenter institutional study has validated the long-term efficacy and safety of MSA with the LINX device at 5 years post-implantation in patients with mild to moderate reflux disease [13]. The utility of the device has yet to be evaluated in patients with more advanced disease including those with hiatal hernias measuring 3 cm or larger. The aim of our study is to evaluate short-term outcomes of MSA in patients with large hiatal hernias.

## Methods

### Study population

We performed a retrospective analysis of all patients who underwent MSA with LINX at the Keck Hospital of the University of Southern California (Los Angeles, CA USA) and our affiliate institution, Hoag Memorial Presbyterian (Newport Beach, CA USA), between May 2009 and December 2015. Approval was obtained from the institutional review board prior to the commencement of the study. Inclusion criteria were symptomatic GERD patients 18 years or older who were suitable surgical candidates, confirmed evidence of GERD by increased esophageal acid exposure on 24-h pH monitoring, and persistent reflux symptoms despite maximal PPI therapy. Patients with a history of esophageal or gastric surgery, esophageal/gastric cancer, esophageal stricture (or other gross anatomic abnormalities of the esophagus), esophageal dysmotility, or a known allergy to titanium were excluded from the study. Of note, the presence of Barrett's metaplasia was not an exclusion criterion although patients with evidence of dysplasia did not undergo MSA.

### Symptomatic and preoperative assessment

All patients underwent evaluation with 48-h esophageal pH monitoring and upper gastrointestinal endoscopy prior to operative intervention. DeMeester scores were calculated while patients were off PPIs, and a score >14.72 was indicative of GERD [23]. A preoperative videoesophagram (VEG) or esophageal manometry was used to assess the patient's esophageal motility and identify those with a motility abnormality. Baseline GERD-HRQL scores were obtained prior to surgical therapy. The GERD-HRQL questionnaire quantifies GERD symptoms with ten questions regarding heartburn, dysphagia, and gas bloat; each scored 0–5 from least to most severe. Evidence of preoperative extraesophageal symptoms (i.e., cough, voice change, or hoarseness) or difficulty swallowing was based on patient reporting.

### Postoperative assessment

Surgical outcomes were evaluated at 6 months and yearly thereafter and consisted of GERD-HRQL score, appraisal of PPI requirement, dysphagia requiring dilation, change in symptoms, and procedure-related complications. Symptom improvement or resolution was based on patient response to verbal inquiry.

### Surgical procedure

LINX implantation was performed by two surgeons (JL and NB) at our two facilities using a standard protocol as previously described [19]. The size of the hiatal hernia was measured intraoperatively in a uniform fashion. Once the abdomen was insufflated, a laparoscopic grasper was used to measure the axial distance from the crura to the apex of the hernia sac. Dissection of the hernia was begun by first identifying the right crus and developing a plane between the crus and the hernia sac. Dissection in this plane allows complete reduction of the hernia sac from the mediastinum. This provided visualization of the esophagus and allowed its mobilization from the gastroesophageal junction up to the mid-hilum. Care was taken to assure there was 2–3 cm of intra-abdominal esophageal length when the esophagus was not under tension. A primary posterior cruroplasty was then performed using figure-of-eight 0-Ethibond sutures. When the hiatal repair was complete, the external circumference of the esophagus was measured at the gastroesophageal junction using a sizing tool and the appropriate LINX device was implanted using the previously published technique [19]. There were no dietary restrictions postoperatively. Following MSA implantation, PPIs were weaned off over the first postoperative month as tolerated.

## Statistical analysis

Demographic, preoperative, and postoperative data were entered into a centralized database with accessibility limited to members of the research team. Continuous variables were analyzed using descriptive statistics (e.g., mean and median). Categorical variables were summarized using frequency distributions. Post-implantation outcomes were evaluated using a two-tailed paired Student's *t* test, with patients serving as their own control. Patients were stratified into two groups based on hiatal hernia size  $\geq 3$  cm or  $< 3$  cm by intraoperative measurement. A Fischer's exact test was used to evaluate differences in categorical variables between patients with large hiatal hernias ( $\geq 3$  cm) and those with smaller or no hiatal hernia. Continuous variables were compared between groups using an independent samples *t* test. All statistical analyses were performed using SPSS Statistics V. 22 (IBM). Statistical significance was indicated by a *p* value  $\leq 0.05$ .

## Results

The study population consisted of 192 patients with a median age of 56 years (range 18–81 years). There were 103 males (53.6 %) and 89 females. Median follow-up time was 20 months (3–75 months). Median preoperative GERD-HRQL score was 19.0 (range 1–44), and mean BMI was 25.9. Laryngopharyngeal reflux symptoms were present in 38.0 % of patients, and 25.0 % of patients complained of preoperative dysphagia. Barrett's metaplasia was present in 45 patients, none of whom had evidence of dysplasia. Fifty-two patients (27.1 %) had an intraoperative measured hiatal hernia of 3 cm or larger (range 3–7 cm). Median follow-up time for patients with large hiatal hernias was 12 months (range 3–24 months). Patients were divided into two groups; those with hiatal hernias measuring 3 cm or larger and those with hiatal hernias less than 3 cm in size or no hernia. Demographics and GERD characteristics were compared between groups (Table 1). Patients in the large hiatal hernia group were older, had a longer duration of GERD symptoms, a higher preoperative DeMeester score, and a higher incidence of esophagitis.

The overall population showed a significant reduction in the mean GERD-HRQL score following MSA (18.9 vs. 5.0,  $p < 0.001$ ) and 92.2 % had resolution or improvement of their symptoms. Mean GERD-HRQL score decreased from 20.5 to 3.6 ( $p < 0.001$ ) in patients with large hiatal hernias following MSA. Patients with large hiatal hernias had a lower PPI requirement ( $p = 0.011$ ) compared to those with smaller hernias, although the rate of symptom improvement ( $p = 0.118$ ) and dysphagia requiring intervention ( $p = 0.522$ ) were similar (Fig. 1).

Patients with large hiatal hernias had a significant decrease in postoperative GERD-HRQL score (3.6 vs. 5.6,  $p = 0.027$ ) compared to those with smaller or no hernia (Fig. 2). Major intraoperative or postoperative complications did not occur in either group. Three patients had the device explanted, none of whom were in the large hiatal hernia group. The reason for removal was the development of a subsequent gastric cancer in one patient and persistent GERD symptoms in two patients. In the latter, the removed device was exchanged for a smaller size in one and replaced with a Nissen fundoplication in the other. Both patients reported improved symptom control with the remedial procedure.

## Discussion

Magnetic sphincter augmentation with LINX augments the LES preventing pathologic reflux while preserving gastroesophageal anatomy. Long-term safety and efficacy trials have demonstrated a significant reduction in post-MSA quality-of-life scores, an 87 % elimination in PPI use at 3 years, and a favorable side effect profile [15]. MSA implantation in patients with uncomplicated reflux has demonstrated equivalent efficacy in symptomatic reflux control with less gas bloat symptoms when compared to patients who underwent fundoplication in a propensity matched-pair analysis of 100 patients [19]. The aforementioned studies excluded patients with hiatal hernias larger than 3 cm.

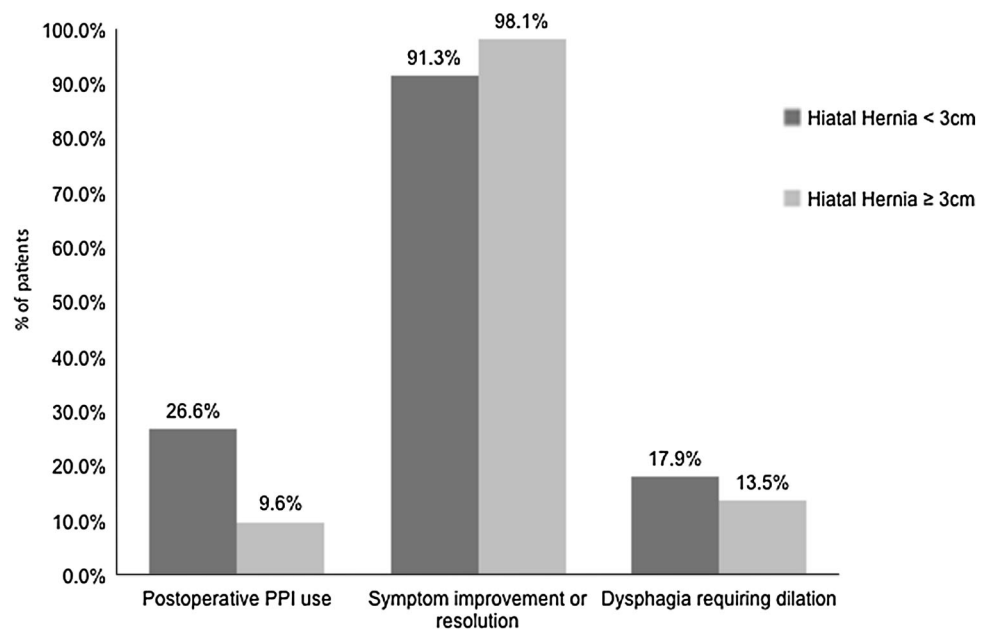
Although previous studies have confirmed the efficacy of MSA in uncomplicated reflux, the current study is the first to evaluate the utility of LINX MSA in patients with characteristics of severe GERD, specifically large hiatal hernias. Of particular interest is that patients who had large hiatal hernias also had a longer duration of GERD, higher preoperative 24-h pH scores, and a greater incidence of esophagitis. Despite having more advanced disease, there was a higher PPI elimination rate and a lower mean postoperative GERD-HRQL score in patients with large hiatal hernias. Symptom improvement or resolution was similar between the two groups (98.1 vs. 91.3 %,  $p = 0.118$ ), and there was no significant difference in the incidence of dysphagia requiring intervention (13.5 vs. 17.9 %,  $p = 0.522$ ).

The improved outcomes in patients with large hiatal hernias may reflect the integral role of the crura, in addition to LES augmentation, in lower esophageal barrier function. In a study by Woodward et al., hiatal herniorrhaphy was compared to Nissen fundoplication in patients with concomitant hiatal hernias and reflux esophagitis [24]. In this study, 127 patients underwent crural repair alone, while 103 matched patients underwent fundoplication alone

**Table 1** Comparison of demographics and preoperative GERD characteristics

Preoperative characteristics	Hiatal hernia <3 cm (N = 140)	Large hiatal hernia ≥3 cm (N = 52)	p value
Age, years	49.8	64.3	<0.001
Sex, % of patients			0.871
Male	54.3 %	51.9 %	
Female	45.7 %	48.1 %	
BMI, kg/m <sup>2</sup>	25.6	26.7	0.148
Preoperative GERD-HRQL score	18.6	20.5	0.264
GERD duration, years	10.6	15.8	0.002
Preoperative Dysphagia, % of patients	26.4 %	18.4 %	0.398
DeMeester score	39.3	52.4	0.047
Esophagitis, % of patients			0.012
None	70.7 %	47.4 %	
Class A	25.0 %	34.2 %	
Class B	2.9 %	13.2 %	
Class C	0.7 %	5.2 %	
Class D	0.7 %	0.0 %	
LPR, % of patients	36.8 %	42.1 %	0.574
Barrett's metaplasia, % of patients	20.0 %	33.3 %	0.082

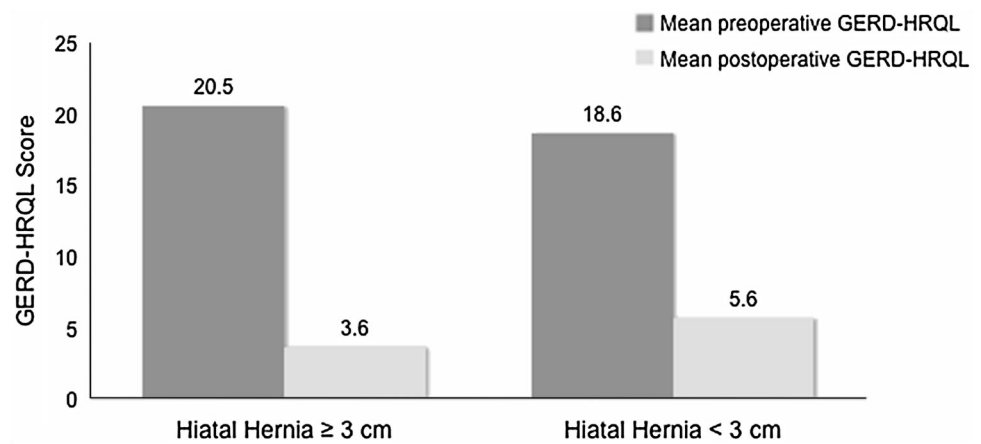
BMI body mass index, GERD gastroesophageal reflux disease, GERD-HRQL GERD health-related quality-of-life score, LPR laryngopharyngeal reflux

**Fig. 1** Comparison of postoperative GERD outcomes between groups. PPI proton-pump inhibitor

without crural repair. Esophageal reflux confirmed by pH measurement occurred in 54 % of patients in the crural repair only group and 49 % of the Nissen group, suggesting that crural repair may be as important as LES reinforcement in reflux control. A separate study evaluated the individual contributions of crural closure and Nissen fundoplication to LES pressure and length using intraoperative

high-resolution manometry [25]. They found that crural closure had a greater contribution to increasing LES pressure, while Nissen fundoplication contributed more to intra-abdominal LES length. A more recent study by Pandolfino et al. [26] suggested that the radial separation of the crura may be even more important than the LES or axial displacement of the hiatal hernia in barrier function.

**Fig. 2** Comparison of preoperative and postoperative GERD-HRQL scores. *GERD-HRQL* GERD health-related quality-of-life score



The principle emerging from these reports and our experience is that maintaining a 2–3 cm intra-abdominal length, deterring the effacement of the LES without altering the anatomy of the gastroesophageal junction, and obtaining a proper and sustained closure of the hiatus are the essential components of the GERD barrier function [24, 25].

Hiatal herniorrhaphy clearly appears to be imperative in patients with LES incompetence and large hiatal hernias, but what defines a large hiatal hernia and how we measure this is unclear. In one study, hiatal hernias 3 cm or larger were correlated with an LES of shorter length and lower pressure suggesting that a hernia begins to effect esophageal function when it is 3 cm or larger [27]. Another study demonstrated a higher incidence of hiatal hernias measuring 2 cm or larger on endoscopy in patients with Barrett’s metaplasia when compared to controls with or without esophagitis [28]. Thus, the exact size at which a hiatal hernia may alter LES function is unknown. Furthermore, there are no preoperative or intraoperative modalities of hiatal hernia measurement that are consistently accurate and uniformly utilized across studies. In the present study, we used an intraoperative axial measurement from the crura to the apex of the hernia sac to approximate hiatal hernia size. Koch et al. [29] demonstrated that preoperative evaluation of hernia size with barium did not correlate with the presence or size of an intraoperative hiatal defect in patients undergoing paraesophageal hernia repair.

Intraoperative detection of hiatal hernias can also be problematic. It is not uncommon for a surgeon to be misled by what appears to be normal-appearing hiatal anatomy on initial intraoperative inspection and a “hidden” hiatal hernia be missed. During the course of the hiatal dissection, a hernia can then be uncovered that is “telescoping” up thru what appeared to be normal crura. Because of this potential for missing “hidden” hiatal hernias, it is our practice to perform a complete hiatal dissection and crural repair when any of the preoperative testing or

intraoperative modalities suggests the presence of a hernia of any size.

The Achilles heel of hiatal hernia repair is recurrence. When it occurs, it commonly leads to the return of reflux and esophagitis. In the current study, the repair consisted of dissecting out and reducing the hernia, performing a posterior closure of the crura using figure-of-8, 0 permanent sutures, maintaining 2–3 cm of esophagus in the abdomen, and implanting the LINX MSA device to deter the effacement of the LES. With this repair, there have been no symptomatic recurrences at a median follow-up time of 12 months. We recognize this is short follow-up as long-term studies of laparoscopic paraesophageal hiatal hernia repair demonstrate recurrence rates exceeding 50 % irrespective of the use of mesh [30]. Furthermore, patients in our study did not undergo routine postoperative VEG or endoscopy unless indicated by persistent postoperative symptoms. Consequently, asymptomatic recurrences may have been missed. Our findings, however, are encouraging in regard to a new surgical approach to GERD patients with large hiatal hernias. We hypothesize that recurrent hernia rates with LINX are likely to be few due to the fibrous encapsulation of the device. The fibrotic reaction around the hiatus is likely to create its own “circumferential biologic mesh” which inherently reinforces the crural repair. The potential role of additional mesh in the prevention of hiatal hernia recurrence is controversial as it may restrict the dynamic nature of the device.

There are several limitations to our study. Data were gathered retrospectively and is potentially subject to both selection and information biases as this review spanned over a 6-year period. After successful introduction of the LINX device into our clinical practice, our understanding of its potential for patients with large hiatal hernias evolved and we began expanding our patient selection to those with hiatal hernias  $\geq$ 3 cm over the last 2 years of our study. Thus, patients in our large hiatal hernia group had a shorter

follow-up time compared to those in our control group. Consequently, the improved postoperative outcomes with respect to PPI requirement and GERD-HRQL scores seen in our large hiatal hernia group may be secondary to a relatively shorter follow-up period. Long-term follow-up with objective postoperative measures of reflux and screening for hiatal hernia recurrence are required to confirm the durability of MSA in this patient population. Although our results are encouraging and may broaden the application of MSA, prospective trials comparing MSA and Nissen fundoplication will be needed to reveal the optimal surgical therapy in patients with gastroesophageal reflux and large hiatal hernias.

## Conclusion

Magnetic sphincter augmentation in patients with large hiatal hernias demonstrates improved outcomes with respect to postoperative PPI requirement and mean GERD-HRQL scores. The incidence of symptom resolution or improvement and dysphagia requiring intervention are similar to patients with smaller or no hiatal hernia. Short-term outcomes of MSA are encouraging in patients with gastroesophageal reflux disease and large hiatal hernias.

## Compliance with ethical standards

**Disclosures** Dr. Lipham is a consultant for Torax<sup>®</sup> Medical, manufacturer of the LINX<sup>®</sup> reflux management system. Drs. Rona, Reynolds, Schwameis, Oh, Vong, Zehetner, Sandhu, Samakar, Katkhouda, and Bildzukewicz have no conflicts of interest or financial ties to disclose.

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