



# The current status of magnetic sphincter augmentation in the management of gastroesophageal reflux disease

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**Abstract:** Magnetic sphincter augmentation (MSA) using the LINX<sup>®</sup> Reflux Management System is a surgical option for the management of gastroesophageal reflux disease (GERD). This technique involves the laparoscopic placement of a band of magnetic beads around the distal esophagus. The beads augment the function of lower esophageal sphincter (LES) by preventing the proximal reflux of gastric contents at rest, while expanding during swallowing to allow the unimpeded passage of food boluses. Despite the lack of randomized controlled trials evaluating the efficacy of MSA, recent long-term retrospective studies support the procedure's safety and efficacy in controlling reflux symptoms and improving quality of life. When compared to laparoscopic fundoplication for the management of reflux, MSA has shown comparable symptoms control and acceptable side effect/complication profile. Complications including dysphagia and erosion have been described. The device can be removed laparoscopically if intolerance or complications develop. Careful patient selection is paramount in order to select the appropriate patients for this technique.

**Keywords:** LINX, magnetic sphincter augmentation (MSA); gastroesophageal reflux disease (GERD); GORD

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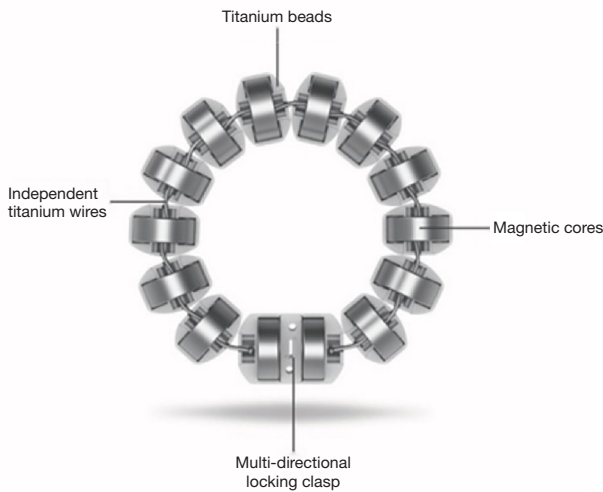
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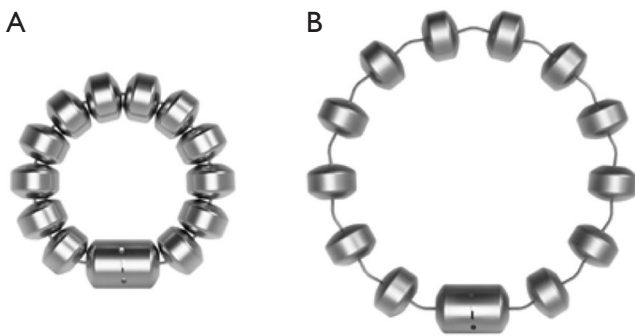
## Introduction

Gastroesophageal reflux disease (GERD) is among the most common gastrointestinal diseases with a prevalence of 10–20% (1). GERD significantly impairs patient quality of life, often due to symptoms of heartburn and regurgitation. Reflux disease can also cause complications including erosive esophagitis, peptic stricture and Barrett's esophagus, a precursor of esophageal adenocarcinoma. The first line of treatment of GERD consists of lifestyle modifications and gastric acid suppression. However, these measures do not address the underlying physiologic cause of reflux in many patients, namely ineffective lower esophageal sphincter (LES) function, and breakthrough acid reflux symptoms occur in 17–44% of patients while taking proton pump inhibitors (PPI) (2).

Following its initial description in 1956 and its subsequent refinement, Nissen fundoplication has been the gold-standard surgical treatment for GERD (3). Surgical fundoplication creates a supraphysiologic antireflux valve that is highly effective in controlling acid reflux and eliminating GERD symptoms, but is also associated with significant postoperative side-effects including dysphagia, bloating, and the inability to vomit or belch. Also, the outcomes of laparoscopic fundoplication may vary significantly due to a center's case volume and surgeon's expertise. Currently, it is estimated that only 1% of patients with GERD receive a fundoplication procedure (4). In response to the need for highly efficacious minimally invasive treatment options, several laparoscopic and endoscopic procedures have been developed including



**Figure 1** Structure of the LINX® Reflux Management System.



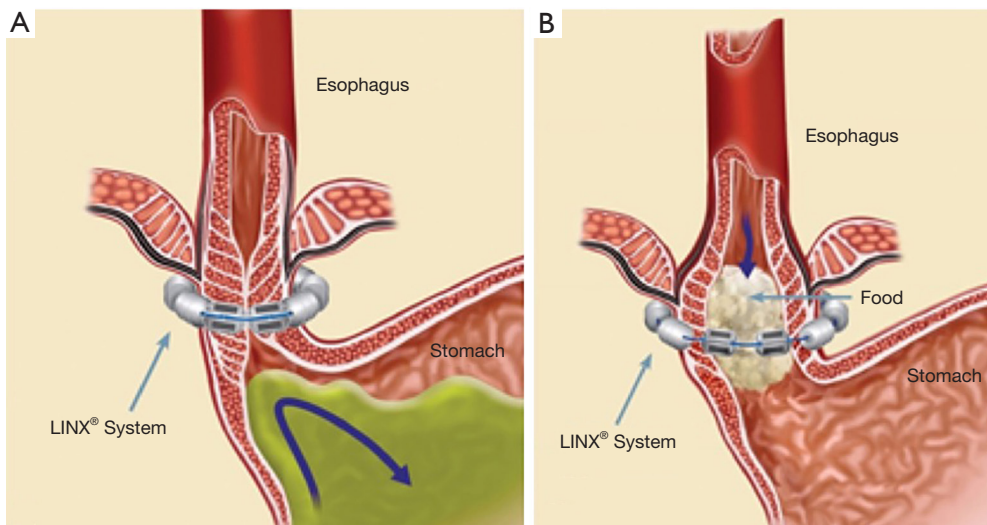
**Figure 2** Closed (A) and open (B) configurations of the LINX® Reflux Management System.

laparoscopic magnetic sphincter augmentation (MSA) using the LINX® Reflux Management System (Torax Medical, St Paul, MN, USA). The purpose of this article is to review the technique, outcomes and complications of MSA.

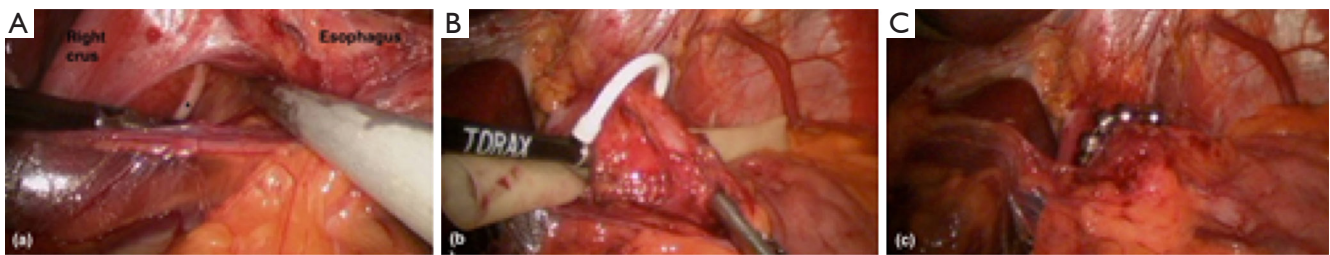
**The device**

The LINX® Reflux Management System is a band of magnetic beads that forms a ring around the lower esophagus (Figure 1). Each bead has a magnetic core that is covered by a titanium casing. The beads are interconnected by titanium wires that allow each bead to move independently. This structure maintains the ring in the contracted form at rest and allows it to expand during the passage of a food bolus (Figure 2). At rest, the short distance between the magnetic beads results in a higher attraction force. This force augments the barrier function of the LES and prevents the gastric juice from refluxing proximally. When a food bolus passes through the LES the ring expands and the attraction force decreases allowing unimpeded passage of the bolus (Figure 3). The same happens when intragastric pressure increases during belching or vomiting. The device is available in multiple sizes which are determined by the number of beads in the ring (13 to 17 beads). The appropriate device is selected using a sizing instrument that is passed around the esophagus and correlates the esophageal size with the appropriately sized device.

The placement of a prosthetic ring around the GE



**Figure 3** Depiction of the LINX® Reflux Management System during rest (A) and passage of fluid bolus (B).



**Figure 4** Laparoscopic LINX<sup>®</sup> Reflux Management System placement. (A) A tunnel is created between the posterior vagus nerve (asterisk) and the esophagus; (B) the sizing instrument is used to determine the size of the device used; (C) the final position of the device.



**Figure 5** Laparoscopic placement of the LINX<sup>®</sup> Reflux Management System (7).

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junction is not a novel idea. The Angelchik device, introduced in 1979, was a silicone ring that was surgically placed around the GE junction in patients with GERD and secured in place with Dacron tape. This device fell out of favor after poor long-term outcomes were shown including dysphagia rates of up to 45% and high reoperation, removal and complication rates (5). In contrast to the Angelchik device, MSA using the LINX<sup>®</sup> Reflux Management System allows the dynamic changes of the diameter of the magnetic ring with the closed configuration preventing reflux and the open configuration allowing passage of food boluses. Patients who underwent esophageal manometry before and after MSA were noted to have improvement (increase) in LES resting pressure, LES residual pressure and distal esophageal contraction amplitude (6).

### Surgical technique

MSA is performed using a 4-port laparoscopic technique similar to that utilized for laparoscopic Nissen fundoplication

(LNF). After obtaining laparoscopic access, the pars flaccida of the gastrohepatic ligament is opened to expose the right crus of the diaphragm. Any sliding hiatal hernia is reduced and a circumferential esophageal dissection is completed at the level of the hiatus. If necessary, a posterior cruroplasty is performed using interrupted non-absorbable sutures. When this is complete, the posterior vagus nerve is dissected free from the posterior wall of the distal esophagus. The appropriate position of the MSA device is two centimeters proximal to the gastroesophageal (GE) junction as determined laparoscopically by the gastric fat pad. A Penrose drain is placed around the esophagus excluding the posterior vagus nerve. The sizing instrument is then used to determine the appropriate size of the device, and the device is introduced and passed around the esophagus. The magnetized ends are mated and the device is locked in place around the lower esophagus (Figures 4,5).

### Patient selection

The preoperative evaluation for MSA device placement is the same as that for laparoscopic fundoplication. Objective documentation of GERD is needed in the form of ambulatory pH testing. Barium esophagogram and upper endoscopy are helpful in evaluating the anatomy including the identification of large hiatal hernias, severe esophagitis or Barrett's esophagus. Esophageal manometry is essential to ensure that the distal esophageal peristalsis is sufficient to overcome the 20–25 mmHg device opening pressure. There are no specific manometric parameters that determine the appropriate use of MSA. MSA has not been evaluated when distal esophageal peristaltic amplitude is less than 35 mmHg on wet swallows or when less than 70% of swallows demonstrate peristaltic contractions. Furthermore, MSA should be avoided in the presence a known motility disorder such as achalasia, nutcracker esophagus, diffuse esophageal

spasm or hypertensive LES.

The ideal patient for MSA is a patient with:

- (I) Partially PIP responsive typical GERD symptoms;
- (II) Positive ambulatory pH testing;
- (III) Absent or small (<3 cm) hiatal hernia.

Exclusion criteria for MSA include:

- (I) Large hiatal hernia (>3 cm);
- (II) Severe esophagitis;
- (III) Long-segment Barrett's esophagus;
- (IV) Significant abnormality in esophageal manometry;
- (V) Allergy to stainless steel, titanium, nickel or iron.

The manufacturer reports the device to be MRI scanning compatible up to 0.7 or 1.5 Tesla depending on the version of the device used (8).

## Outcomes

The initial feasibility studies of MSA showed its safety and feasibility in porcine models (9). These were shortly followed by human feasibility studies from Italy showing that the device can be placed laparoscopically with minimal dissection and a short learning curve compared to LNF (10). Receiving the approval from the US Food and Drug Administration (FDA) in 2012 has facilitated the use of the device in the USA (11).

The feasibility trial evaluated 44 patients who underwent MSA at four centers in Italy, USA and Netherlands between 2007 and 2008. This single arm trial, where patients serve as their own controls, compared the outcomes following MSA implantation to patient's baseline characteristics. The outcomes were reported at 1 to 2 years, 3 to 4 years and more than 5 years postoperatively. GERD health-related quality of life (HRQL) scores improved from 25.7 at baseline to 3.8 at 1 year, 2.4 at 2 years, 3.3 at 4 years and 2.9 at more than 5 years. All patients were taking PPIs at baseline. The rate of PPI cessation was 90% at 1 year, 85% at 2 years, 80% at 3 to 4 years and 88% at more than 5 years. The percentage of time the pH was less than 4 was 11.9% at baseline and this improved to 3.1% at 1 year, 2.4% at 2 years, 3.8% at 3 years and 4.6% at more than 5 years. More than 86% of patients reported satisfaction with their current condition while off-PPIs at 1, 2, 4 and more than 5 years compared to 0% at baseline (12-14).

These sustained outcomes were replicated in the pivotal trial. This multi-center prospective trial evaluated 100 patients who underwent laparoscopic MSA at 14 centers (13 in USA and one in the Netherlands). The median time to implant the device was 36 minutes (range, 7-125 minutes).

All patients were discharged within 1 day after surgery. Postoperative outcomes were evaluated at 3 and 5 years. GERD HRQL scores improved from 11 on-PPI and 27 off-PPI to 2 at 3 years and 4 at 5 years postoperatively. More than 50% improvement in GERD HRQL scores was achieved in 92% of patients at 3 years. More than 50% improvement in PPI use was achieved in 93% of patients at 3 years and PPI use decreased from 100% preoperatively to 15% at 5 years. Normalization of ambulatory pH testing or more than 50% improvement in pH testing was achieved in 64% of patients at 3 years. No device erosions, migrations of malfunctions were reported at 5 years. *Table 1* summarizes the studies evaluating MSA outcomes.

## Comparison to other surgical GERD treatments

To date, there have been no randomized controlled trials comparing laparoscopic MSA to laparoscopic antireflux surgery. However, several retrospective studies have compared the outcomes of laparoscopic MSA to laparoscopic fundoplication. Warren *et al.* performed a retrospective review of 201 patient who underwent MSA and 214 patients who underwent LNF for a total of 415 patients. The procedures were performed at three high-volume esophageal centers in the USA. Propensity score matching was performed and 114 patients were analyzed in each arm. The mean follow up was 11 months for MSA and 16 months for LNF ( $P<0.001$ ). There was no statistically significant difference in preoperative GERD HRQL (21 *vs.* 19;  $P=0.56$ ) or postoperative GERD HRQL (6 *vs.* 5;  $P=0.54$ ). MSA patients had greater ability to belch (97% *vs.* 66%;  $P<0.001$ ) and vomit (88% *vs.* 40%;  $P<0.001$ ). The MSA group reported gas-bloat symptoms less frequently than LNF group (41% *vs.* 59%;  $P=0.008$ ). Mild dysphagia was more common with MSA (44% *vs.* 32%;  $P=0.04$ ). Moderate and severe dysphagia rates were similar in both groups. The MSA group was more likely to require postoperative PPI (24% *vs.* 12%;  $P=0.02$ ). Patient satisfaction was similar in both groups (88% *vs.* 89%;  $P=0.61$ ) (21). *Table 2* summarizes the studies comparing laparoscopic MSA and fundoplication procedures (18,21-26).

Skubleny *et al.* conducted a systematic review of studies comparing MSA to LNF and included three studies in the meta-analysis. These included a total of 688 patients of which 415 underwent MSA and 273 underwent LNF. Operative time was shorter for MSA compared to LNF (63.7 *vs.* 76.8 minutes). MSA was found to be superior to LNF in maintaining the patient's ability to belch (95.2%

**Table 1** Studies evaluating short and long-term outcomes of magnetic sphincter augmentation

Source	N	Follow-up	Description
Bonavina, 2010 (12)*	44	1 and 2 years	Multi-institutional prospective study. Participating institutions from Italy, USA and the Netherlands
Lipham, 2012 (13)*	44	3–4 years	Multi-institutional prospective study. Participating institutions from Italy, USA and the Netherlands
Bonavina, 2013 (15)	100	Median of 3 years	Single center prospective study of consecutive cases from Italy
Ganz, 2013 (16)**	100	3 years	Multi-institutional prospective study. 14 participating institutions from USA and the Netherlands
Reynolds, 2014 (17)	67	Median of 5 months	Prospective study from two institutions
Riegler, 2015 (18)	202	1 year	Multicenter prospective study (22 institutions) from four countries (Austria, Germany, Italy and the UK). Also included 47 patients who underwent laparoscopic Nissen fundoplication
Saino, 2015 (14)*	44	33 patients followed $\geq 5$ years	Multi-institutional prospective study. Participating institutions from Italy, USA and the Netherlands
Czosnyka, 2016 (19)	102	Mean 7.6 months	Two community-based health systems in USA
Ganz, 2016 (20)**	100	85 patients followed $\geq 5$ years	Multi-institutional prospective study. 14 participating institutions from USA and the Netherlands

\*, feasibility trial reporting short-term, mid-term & 4-year outcomes; \*\*, pirated trial reporting 3- & 5-year outcomes.

**Table 2** Studies comparing magnetic sphincter augmentation and laparoscopic fundoplication procedures

Source (year)	Total number	MSA (n)	LNF (n)	Follow-up	Description
Louie, 2014 (22)	66	34	32	$\geq 6$ months	Retrospective case-controlled study of consecutive patients, included patients with hiatal hernia <3 cm
Reynolds, 2015 (23)	179	62	117	1 year	Retrospective, patients matched using propensity scoring
Sheu, 2015 (24)	24	12	12	7 months	Retrospective, single-center, case-controlled study; matched patients for age, gender and hiatal hernia
Riegler, 2015 (18)	249	202	47	1 year	LNF patients were older, more likely to have Barrett's esophagus and had larger hiatal hernias
Warren, 2016 (21)	415	201	214	354 patients (MSA 169, LNF 185) were followed for 1 year	Multi-institutional retrospective study (three high-volume centers in USA). Included a propensity matched comparison
Reynolds, 2016 (25)	119	52	67	1 year	Retrospective
Asti, 2016 (26)	238	135	103	>1 year	Propensity matched cohort

MSA, magnetic sphincter augmentation; LNF, laparoscopic Nissen fundoplication.



**Figure 6** Laparoscopic removal of the LINX<sup>®</sup> Reflux Management System (36). Available online: <http://www.asvide.com/articles/1721>

*vs.* 65.9%;  $P < 0.01$ ) and vomit (93.5% *vs.* 49.5%;  $P < 0.01$ ). Bloating was more common with LNF compared to MSA but this did not reach statistical significance (53.4% *vs.* 26.7%;  $P = 0.06$ ). Postoperative dysphagia and PPI elimination rates were similar.

Seeing as reflux is a chronic disease, and long-term outcomes are of paramount importance, studies are needed to compare the long-term efficacy, complications, and need for repeat intervention (endoscopic dilations and reoperations) between MSA and laparoscopic fundoplication procedures. No studies have compared MSA to PPI therapy. The CALIBER study is an ongoing randomized controlled trial designed to compare MSA to double-dose PPIs for the management of GERD symptoms.

### Special situations

As experience with MSA procedure accumulates, the indications for this procedure may expand to include patients with larger hiatal hernias (>3 cm) and patients with GERD following bariatric procedures. These situations have been evaluated in small cohort studies.

### Hiatal hernia

The presence of a large hiatal hernia was initially thought of as an exclusion criterion for MSA device placement. However, some early data are showing encouraging results of MSA in this patient population. Rona *et al.* retrospectively reviewed 192 patients who underwent MSA placement in their institution. Fifty-two patients (27%) had a hiatal hernia  $\geq 3$  cm (range, 3–7 cm). In these patients their mean GERD-HRQL score decreased from 20.5 preoperatively to

3.6 postoperatively ( $P < 0.01$ ). When compared to patients with smaller hernias, patients with large hiatal hernias had lower postoperative PPI requirement (9.6% *vs.* 26.6%;  $P = 0.01$ ) and lower mean postoperative GERD HRQL scores (3.6 *vs.* 5.6;  $P = 0.03$ ). The rates of severe dysphagia and symptom resolution were similar to patients with smaller hiatal hernias (27).

### GERD following bariatric procedures

The management of GERD following sleeve gastrectomy is complicated. The altered gastric anatomy makes traditional treatments such as fundoplication impossible. While this issue is controversial, many believe that sleeve gastrectomy can worsen pre-existing reflux disease or create “de novo” GERD (28). Off-label use of MSA to manage GERD in patients with a prior sleeve gastrectomy has been described in a case series (29). Other case reports have also describes the use of MSA to treat GERD following Roux-en-Y gastric bypass (30–32). More studies are needed to further explore the role of MSA procedure in this growing subset of patients. The RELIEF study is an ongoing prospective, multicenter study evaluating the safety and efficacy of MSA in sleeve gastrectomy patients with GERD.

### Complications

The most common complication of MSA is dysphagia. Some degree of postoperative dysphagia can be observed in 34% to 79% of patients. Dysphagia is most noticeable shortly after MSA device placement but it tends to resolve over time with conservative management. Significant improvement is usually noticed 8 weeks postoperatively. The reported rates of dysphagia beyond 3 years postoperatively are 4% to 6% compared to 5% rate of dysphagia at baseline (prior to MSA device placement) (10,16,17,20,21,23,33,34).

In a small proportion of patients (6.7%) recurrent reflux symptoms or severe dysphagia can lead to MSA device removal (35). In some patients the device was removed due to the need to obtain an MRI for an unrelated problem. This issue was more common with the first generation devices which were only compatible up to 0.7 Tesla. The device removal can be achieved laparoscopically in the majority of patients (*Figure 6*). This requires locating the device and incising the fibrous capsule that envelops each of the beads. Once a few beads are freed the connecting wire is divided to facilitate removal. We recommend obtaining a preoperative x-ray as well as consulting the previous

operative implant record to allow a count of the beads in order to ensure complete device removal. Laparoscopic fundoplication performed as a concomitant procedure with device removal has been described. Asti et al described the removal of 11 devices out of 164 implants with a 48 month median follow up. A partial or total fundoplication procedure was performed concurrently in all patients. Recurrent heartburn or regurgitation was the most common indication for removal (46%) followed by dysphagia (37%). There were no morbidities associated with the procedure. Follow duration ranged from 12 to 58 months at which time all patients reported satisfaction with their condition and GERD HRQL scores were within normal limits (37).

Device erosion into the esophagus has been described. The exact incidence of this complication is unknown. Eleven cases of device erosion was reported to the FDA Manufacturer's and User's Device Experiences (MAUDE) database in 2016 (38). This seemingly uncommon complication mandates removal of the device. The technique for endoscopic removal has been described and follows similar concepts to the endoscopic removal of eroded gastric bands (39). The chronic erosion process allows scarring on the extraluminal portion of the device that prevents a full thickness defect of the esophageal wall when the device is retrieved. Other potential complications include migration and device malfunction (40).

## Conclusions

MSA is a novel surgical option for the management of GERD. Short- and long-term data demonstrate excellent control of reflux symptoms, objective GERD control, and improvement in patient quality of life with an acceptable side-effect profile. MSA compares favorably to LNF in retrospective trials, but randomized controlled trials comparing MSA to best medical management and LNF are needed to confirm the findings of the currently available retrospective studies.

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## Footnote

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at <http://dx.doi.org/10.21037/ales.2017.06.13>).

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*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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