

Review

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Comparative outcomes of laparoscopic fundoplication and magnetic sphincter augmentation: is there a difference?

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Abstract

The prevalence of gastrointestinal reflux disease and reflux-related complications continue to rise, and treatment options are limited. Medical management alone is often ineffective and chronic use carries inherent risk. Magnetic sphincter augmentation represents a reasonable and viable treatment option for appropriately selected patients. Compared to surgical wraps, magnetic sphincter augmentation (MSA) may provide similar rates of patient satisfaction, anti-acid medication cessation, and decreased esophageal acid exposure. Additionally, MSA may lower postoperative gas bloat symptoms and better preserve the ability to belch or vomit, versus surgical wraps. Magnetic sphincter augmentation, however, is still relatively new, and further study is needed to evaluate and compare outcomes more appropriately to that of surgical wraps.

Keywords: LINX[®], magnetic sphincter augmentation, fundoplication, anti-reflux surgery, gastroesophageal reflux disease (GERD), reflux, minimally invasive surgery, foregut surgery

INTRODUCTION

Gastroesophageal reflux disease (GERD) is highly prevalent and increasing worldwide. Reported rates approach 30% in North America, 26% in Europe, 33% in the Middle East, and 8% in East Asia^[1,2]. Incidence



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rates are also growing in younger populations and are concerning with the concomitant increase of reflux-related complications, including erosive esophagitis, peptic strictures, related respiratory illnesses, Barrett's esophagus (BE), and esophageal adenocarcinoma^[3-5].

Proton-pump inhibitor (PPI) use, however, is significant in all age groups, and treatment failure occurs in 40% of patients and is not without risk. Chronic PPI use has been linked retrospectively to increased risk of enteric infections (i.e., *Clostridium Difficile* colitis), pneumonia, osteoporosis, nutritional deficiencies, and interference of anti-platelet medications metabolism elevating cardiac risk^[3,6]. Even maximally dosed PPIs may be inadequate to prevent clinically significant reflux in the presence of a mechanically defective lower esophageal sphincter^[2,5].

Despite this, rates of anti-reflux surgery have been in decline. This is at least in part due to apprehension of variable outcomes associated with laparoscopic fundoplication (LF). Generally, LF is associated with excellent long-term heartburn relief with > 90% patient satisfaction more than 20 years after surgery^[7]. However, the surgical technique is not standardized and outcomes, including adverse effects, often vary^[2,4].

The LINX® Reflux Management System uses magnetic sphincter augmentation (MSA) and has been proposed as a solution for those that fall into this “treatment gap”^[5,8]. Proponents of MSA state that implantation will decrease surgical technique variation, avoid significant hiatal and gastric dissection, and expands to allow normal physiologic passage of gas or gastric content when needed. These characteristics address the general concerns of laparoscopic fundoplication and provide patients with a reasonable and viable intermediary treatment option^[5,9].

The LINX® device was approved by the U.S. Food and Drug Administration (FDA) in 2012 for uncomplicated cases of GERD. Several single-arm safety and efficacy studies followed, and subsequently, comparative studies between MSA and LF. Results thus far have been encouraging and recent studies are looking to extend indications for MSA use. Feasibility studies for MSA in severe or complicated reflux are now emerging, specifically in the setting of large hiatal hernias, severe esophagitis, and in bariatric patients^[10,11].

INDICATIONS AND TECHNIQUE

LINX® reflux management system

The LINX® device was approved in 2012 for the treatment of reflux in patients aged 21-75 with abnormal pH testing who continued to have symptoms despite maximal medical therapy^[12].

At that time, it had not been evaluated for those with hiatal hernia larger than 3 cm, BE, Los Angeles grade C or D esophagitis, esophageal stricture, esophageal or gastric varices, body mass index over 35 kg/m², major motility disorders [i.e., known achalasia, nutcracker esophagus, diffuse esophageal spasm, hypertensive lower esophageal sphincter (LES), or distal esophageal motility less than 35 mm Hg in peristaltic amplitude on wet swallows or less than 70% peristaltic sequences], scleroderma, malignancy, or in the setting of prior anti-reflux surgery.

The MSA device consists of biocompatible titanium beads with magnetic cords linked with titanium wires to form an expandable ring. The device is placed around the LES and augments the intraluminal pressure. The ring will expand when challenged by a food bolus or physiologic passage of gas or gastric contents (i.e., belching or vomiting)^[4,13]. In 2015, the FDA approved the next generation of the device, which is compatible and safe with 1.5 Tesla magnetic resonance imaging (MRI), whereas previously, it was limited to 0.7 Tesla.

The device is implanted laparoscopically under general anesthesia. In contrast to laparoscopic fundoplication, the gastric fundus and short gastric arteries are not mobilized or transected. Hiatal dissection is minimized, and the phreno-esophageal ligament and hepatic branch of the vagus nerve are preserved, if possible^[5,14]. The gastrohepatic ligament remains largely intact, and the posterior and greater curvature of the stomach is not extensively mobilized. The plane between the vagal nerves and the esophagus is entered, and the esophagus is circumferentially dissected, then measured. The appropriately sized MSA device is then introduced in this location and the opposing ends are clasped. Postoperatively, a chest film is performed to check the correct placement of the device. Patients are instructed to start a soft diet immediately after and patients are typically discharged within 24 h^[5,15].

Laparoscopic fundoplication

Laparoscopic Nissen Fundoplication has been the gold standard for anti-reflux surgery. First described by Dr. Rudolph Nissen in 1955, the procedure has undergone several modifications over time, and technique may vary between surgeon and institution today. The aim is to augment the pressure of the LES by mobilizing the gastric fundus and creating a short and floppy 360-degree wrap around the gastroesophageal junction (GEJ). Typically, this is done over a bougie to prevent narrowing. The mediastinal esophagus is mobilized to ensure at least 2-3 cm of the tension-free intra-abdominal esophagus and the hiatus is repaired. Although the 360-degree Nissen fundoplication has been the gold standard, partial wraps are becoming increasingly popular, with recent data supporting lower rates of postoperative dysphagia, gas bloat symptoms, and equivalent long-term patient satisfaction and reflux control^[7].

OUTCOMES

MSA safety and efficacy

In the treatment of uncomplicated reflux disease, MSA is safe and significantly more effective than maximal medical treatment alone^[16]. The CALIBER study is a randomized control trial, which demonstrated the superiority of MSA over twice daily PPI use at 12 months in terms of patient satisfaction, regurgitation symptoms, bloating, flatulence, and dysphagia^[17].

Current data on MSA outcomes are encouraging, however, limited to five years. Patients have reliably reported significant improvement in satisfaction scores, PPI cessation, and maintained the ability to belch and vomit if needed. Mild dysphagia may occur immediately postoperatively but is usually self-limiting. Severe dysphagia requiring endoscopic dilation or reoperation is rare and does not occur more frequently than after surgical wraps. There have been sporadic reports of device erosion. Most recently, an erosion rate of 0.3% was reported at a 5-year follow-up. Thus far, all eroded devices were able to be removed safely via laparoscopic or endoscopic approaches with unremarkable postoperative courses^[18,19].

Comparative studies

Initial short-term comparative studies of MSA and LF excluded patients with complicated GERD from the MSA arm - that is, the prevalence of patients with a hiatal hernia > 3 cm, grade C or D esophagitis, BE, or BMI above 35 kg/m² were higher in LF groups. However, 6 months after implantation, significant and similar improvements were seen in both MSA and LF patients for GERD-health-related quality of life (GERD-HRQL) scores and DeMeester scores. MSA patients report fewer gas bloat symptoms and felt they were capable of belching more than the LF group^[13,20,21].

After one year, Riegler *et al.* compared 202 MSA and 47 LF patients and reported similar improvement in GERD-HQRL scores between groups^[22]. Despite patients in the LF cohort having larger hiatal hernias and a higher prevalence of BE, both groups reported similar improvements in regurgitation and PPI cessation. However, MSA patients had less gas bloat (10% vs. 31.9%; $P < 0.001$) symptoms, and preserved ability to

belch (98.4% vs. 88.9%; $P = 0.007$) or vomit (91.3% vs. 44.4%; $P < 0.001$) compared to LF patients.

One year propensity-matched studies continued to support this trend. Warren *et al.* compared 114 MSA and 114 LF patients which also showed similar improvement in GERD-HRQL scores - and MSA patients continued to report preserved ability to belch (96% vs. 69%) and vomit (95% vs. 43%), with less gas bloat (47% vs. 59%) when compared to their LF counterparts^[23]. Mild dysphagia and resumption of PPIs (24 vs. 12; $P = 0.02$) were higher in the MSA group. These findings were supported by a similar study by Reynolds *et al.* involving 50 MSA and 50 LF patients. However, severe dysphagia was reported at higher rates after LF (10.6% vs. 0%; $P = 0.022$)^[14]. When compared to propensity-matched patients who underwent laparoscopic Toupet (versus Nissen) fundoplication, there were no differences in GERD-HRQL scores, PPI cessation, gas bloat, and dysphagia at one year^[9].

Bonavina *et al.* conducted a large, multicenter registry study comparing 465 MSA to 166 LF over three years^[4]. Both groups again improved similarly in total GERD-HRQL score and satisfaction. PPI rates declined from 97.8% to 24.2% and 95.8% to 19.5% in the MSA and LF groups, respectively. Both groups were able to belch, although the MSA group reported a better ability to vomit (91.2% MSA vs. 68.0%) successfully when needed.

These outcomes are sustained when analyzed for a median 5-year follow-up of 25 MSA and 45 LNF patients. Total GERD-HRQL scores, reported rates of dysphagia, and bloating were similar between groups^[24].

A recent study by Wu *et al.* attempted to better characterize the quantitative difference between MSA and LF^[25]. Using impedance planimetry (EndoFlip™), measurements were taken at the gastroesophageal junction after cruroplasty and either MSA implantation or fundoplication. This revealed a significantly lower distensibility index (DI) for MSA patients ($1.9 \pm 0.8 \text{ mm}^2/\text{mmHg}$; $N = 24$) versus that of either laparoscopic Toupet ($3.5 \pm 1.3 \text{ mm}^2/\text{mmHg}$; $N = 59$) or Nissen ($3.5 \pm 1.4 \text{ mm}^2/\text{mmHg}$; $N = 24$) fundoplication. Although dysphagia rates were similar between all three groups, Toupet fundoplication GERD-HRQL scores were significantly greater than in the MSA or Nissen group. It is not clear why the lower DI in patients receiving MSA compared to that of the two surgical wraps does not translate into clinically significant dysphagia and indicates more study is needed into the quantitative changes imposed at the GEJ by MSA versus surgical wraps [Table 1].

Meta-analysis, reviews

When pooled, early data comparing MSA and LF are similar to the directly comparative studies. Six-to-twelve-month follow-up of 7 observational cohort studies with combined cohorts of 585 MSA and 525 LF patients, favored MSA in terms of gas bloat (OR: 0.39; 95%CI: 0.25-0.61; $P < 0.001$), ability to belch (OR: 5.53; 95%CI: 3.73-8.19; $P < 0.001$) and vomit (OR: 10.10; 95%CI: 5.33-19.15; $P < 0.001$). GERD-HQRL, PPI cessation, dysphagia requiring endoscopic dilation, and reoperation rates were similar between groups. Moreover, the authors point out that heterogeneity of GERD-HRQL was low in this pooled analysis indicating a high level of agreement between studies for patient satisfaction findings^[2,26].

When comparative study data was combined with single cohort data, again, no significant deviations were seen in GERD-HRQOL score, PPI cessation, dysphagia, and reoperation. Gas bloat and ability to belch continued to favor those who had received MSA. In this pooled analysis of 632 MSA and 467 LF patients, the rate of MSA erosion and reoperation was 0.3% and 3.3%, respectively^[19]. Most recently, a meta-analysis inclusive of 1138 MSA patients reported rates of postoperative dysphagia and endoscopic dilation of 29%

Table 1. Summary of comparative studies

References	Year	Study design	MSA/LF	Follow-up (months)	GERD-HRQL	PPI cessation	Regurgitation	DeMeester	Dysphagia	Belching	Vomiting	Gas bloat	Total cost
Louie et al. ^[20]	2014	Retrospective case-control	34/32	6-10	ND	-	-	ND	ND	67% MSA 0% LF P = 0.0001	-	ND	-
Reynolds et al. ^[14]	2015	Retrospective propensity-matched	50/50	12	ND	ND	-	-	ND	91.5% MSA 74.5% LF P = 0.028	95.7% MSA 78.7% LF P = 0.004	0% MSA 10.6% LF P = 0.022	-
Sheu et al. ^[21]	2015	Retrospective case-control	12/12	7	-	-	-	-	50% MSA 0% LF P = 0.01	-	-	-	-
Riegler et al. ^[22]	2015	Prospective multicenter cohort	202/47	12	ND	81.8% MSA 63.0% LF P = 0.03	58.2% to 3.1% MSA 60.0% to 13.0% LF P = 0.014	-	-	91.3% MSA 44.4% LF P = 0.001	-	10.0% MSA 31.9% LF P = 0.001	-
Warren et al. ^[23]	2016	Retrospective multicenter propensity-matched	114/114	12	ND	75% MSA 88% LF P = 0.02	-	-	44% MSA 32% LF P = 0.02	97% MSA 66% LF P = 0.001	88% MSA 40% LF P = 0.001	41% MSA 59% LF P = 0.008	-
Asti et al. ^[9]	2016	Retrospective propensity-matched	135/103*	12-80	ND	ND	-	-	ND	-	-	ND	-
Reynolds et al. ^[8]	2016	Retrospective cohort	52/67	12	ND	ND	-	-	-	90% MSA 64% LF P = 0.01	96% MSA 81% LF P = 0.01	23% MSA 53% LF P = 0.01	ND
Bonavina et al. ^[4]	2021	Prospective multicenter cohort	465/166	36	ND	ND	-	-	ND	ND	ND	-	-
O' Neill et al. ^[24]	2022	Retrospective cohort	25/45	62-69	ND	ND	-	-	ND	-	-	ND	-

*MSA was compared to laparoscopic Toupet fundoplication for this study (versus Nissen Fundoplication). P-values are listed when reported for significant differences in reported symptoms. MSA: Magnetic sphincter augmentation; LF: laparoscopic fundoplication; GERD-HRQL: gastroesophageal reflux disease-health-related quality of life; ND: no difference.

and 7.4%, respectively^[27] [Table 2].

Table 2. Summary of systemic reviews and meta-analyses comparing MSA vs. LF

References	Year	Included studies	MSA/LF	Follow-up (months)	GERD-HRQL	PPI cessation	Dysphagia	Endoscopic dilation	Belching	Vomiting	Gas bloat	Reoperation	MSA erosion	MSA removal
Chen <i>et al.</i> ^[26]	2017	4	299/325	6-12	-	ND	ND	ND	ND	ND	RR: 0.71 95%CI: 0.54-0.94 P = 0.02	ND	-	-
Skubleny <i>et al.</i> ^[29]	2017	3	415/273	7-16	-	ND	ND	ND	95.2 MSA 65.9% LF P < 0.00001	93.5% vs. 49.5% P < 0.0001	ND	-	-	-
Aiolfi <i>et al.</i> ^[2]	2018	7	686/525	6-12	ND	ND	-	ND	OR: 5.53 95%CI: 3.73- 8.19 P < 0.001	OR: 10.10 95%CI: 5.33- 19.15 P < 0.001	OR: 0.39 95%CI: 0.25-0.61 P < 0.001	ND	-	-
Guidozzi <i>et al.</i> ^[19]	2019	19*	632/467	6-44	ND	ND	ND	-	OR: 12.34 95%CI: 6.43- 23.7	-	OR: 0.34 95CI: 0.16- 0.71	ND	0.30%	3.30%

*This study pooled data from 6 comparative studies and 13 single-cohort studies. *P*-values are listed when reported for significant differences in reported symptoms. LF: Laparoscopic fundoplication; GERD-HRQL: gastroesophageal reflux disease-health-related quality of life; PPI: proton-pump inhibitor; MSA: magnetic sphincter augmentation; ND: no difference; OR: odd's ratio; RR: relative risk.

Dysphagia, device explantation, and erosion

There is data to support the safety and efficacy of MSA with acceptable risk. Intraoperative complications are 0.1%, explantation of 1.1 to 6.7%, and erosion of 0.1 to 1.2%. There are no reported deaths^[18].

The most common adverse effect is dysphagia in the immediate postoperative period, which is 43% to 83%. Persistent dysphagia may occur in up to 19% of patients, but the majority will resolve within three months, while few will require endoscopic dilation^[28,29].

Endoscopic dilation is effective in 67% to 76.9% of patients with persistent dysphagia^[18]. This may be due to non-standardization of whether the crural repair is performed, which may vary between reported studies. One would expect, with newer studies incorporating larger hiatal hernias and complicated reflux cases, rates of postoperative dysphagia may rise^[20,30]. When reoperation was necessary, a crural closure was noted to be the culprit in one case and symptoms resolved when the crural repair was redone^[23]. Richards and McRae laparoscopically explored two patients and found the MSA device was encapsulated in scar tissue, preventing expansion^[13]. Capsulotomy was performed and the dysphagia subsequently resolved.

Device explantation has been reported rarely in patients with persistent GERD or dysphagia. In those instances, device removal has been uncomplicated and completed in a single stage. Conversion to fundoplication is done successfully and authors feel relatively easy given the limited dissection needed for MSA^[13,23].

Re-operative rates between MSA versus LF are similar over time^[22,24].

Erosion of the MSA device also appears to be rare. In the literature, erosion rates are as high as 1.2% but may have been influenced by early variation in surgical technique when the device first came to market. A recent study with 5-year data reports a 0.3% erosion rate. All eroded devices in the literature have been successfully explanted using a combination of laparoscopic and endoscopic techniques^[23]. Currently, data is limited to short and mid-term outcomes (i.e., 5-year follow-up), and long-term adverse event rates remain to be seen.

Cost

In 2016, Reynolds *et al.* performed an indirect preliminary comparative cost analysis involving 52 MSA and 67 LF patients^[8]. Total billable supply costs were higher in MSA patients (LINX® device approximate cost: \$5000); however, this was offset by shorter operative time (66 vs. 82 minutes for MSA vs. LF, respectively), length of stay (MSA patients were discharged from the recovery room), and lower need for pharmaceuticals, labs/tests/imaging, and room and board. Mean charges were \$48,491 for MSA and \$50,111 for LF. At one year follow-up, both groups improved similarly in GERD-HRQL and PPI cessation, and MSA patients performed better in terms of gas bloat symptoms and ability to belch or vomit^[31].

LIMITATIONS

There are several limitations to this review. Approval of MSA is relatively recent, and the volume and quality of direct comparative studies are low. Moreover, the majority of reported outcomes are qualitative and based on patient-reported surveys (i.e., GERD-HQRL responses) and subject to recall bias. As mentioned previously, long-term data remains to be seen. Further study is needed with standardized surgical approaches and long-term follow-up to better evaluate the relationship between the MSA and surgical wraps.

CONCLUSION

Gastrointestinal reflux disease rates and its sequelae are rising worldwide and increasingly involve younger populations. While PPI therapy is first-line and its use seems ubiquitous, it is not without drawbacks. Patients who partially or poorly respond to medical management alone are at increased risk for reflux disease progression. Magnetic sphincter augmentation of the LES represents a reasonable and viable treatment option. There is evidence supporting the safety and efficacy of MSA for uncomplicated reflux cases, and the superiority of MSA compared to PPIs alone for reflux-related outcomes. Compared to surgical wraps, MSA demonstrates similar short and mid-term improvement in terms of patient satisfaction, PPI cessation, and DeMeester score. MSA may also achieve better postoperative gas bloat symptoms and preserve the ability to belch or vomit compared to surgical wraps. However, interpretation of the available data is made with caution, as no comparative randomized control trials exist between MSA and surgical wraps. Additionally, follow-up in all published studies to date is no longer than five years. At present, for appropriately selected patients, MSA is at least non-inferior to surgical wraps, and represents a reasonable and viable intermediary treatment option. However, further study is needed to compare both the benefits and adverse effects of MSA more appropriately versus surgical wraps.

DECLARATIONS

Authors' contributions

Made substantial contributions to the literature review, writing, and editing: Kitamura RK

Made substantial contributions to the design, review, and writing of the manuscript: Kenric MM

Availability of data and materials

All data and studies referenced for this review article is available in the reference section of this manuscript.

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Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

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