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# Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease

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**Abstract**
*Background* Magnetic sphincter augmentation (MSA) has emerged as an alternative surgical treatment of gastroesophageal reflux disease (GERD). The safety and efficacy of MSA has been previously demonstrated, although adequate comparison to Nissen fundoplication (NF) is lacking, and required to validate the role of MSA in GERD management.
*Methods* A multi-institutional retrospective cohort study of patients with GERD undergoing either MSA or NF. Comparisons were made at 1 year for the overall group and for a propensity-matched group.
*Results* A total of 415 patients (201 MSA and 214 NF) underwent surgery. The groups were similar in age, gender, and GERD-HRQL scores but significantly different in preoperative obesity (32 vs. 40 %), dysphagia (27 vs. 39 %), DeMeester scores (34 vs. 39), presence of microscopic Barrett's (18 vs. 31 %) and hiatal hernia (55 vs. 69 %). At a minimum of 1-year follow-up, 354 patients (169 MSA and 185 NF) had significant improvement in GERD-HRQL scores (pre to post: 21–3 and 19–4). MSA patients had greater ability to belch (96 vs. 69 %) and vomit (95 vs. 43 %) with less gas bloat (47 vs. 59 %). Propensity-matched cases showed similar GERD-HRQL scores and the differences in ability to belch or vomit, and gas bloat persisted in favor of MSA. Mild dysphagia was higher for MSA (44 vs. 32 %). Resumption of daily PPIs was higher for MSA (24 vs. 12, $p = 0.02$) with similar patient-reported satisfaction rates.
*Conclusions* MSA for uncomplicated GERD achieves similar improvements in quality of life and symptomatic relief, with fewer side effects, but lower PPI elimination rates when compared to propensity-matched NF cases. In appropriate candidates, MSA is a valid alternative surgical treatment for GERD management.

**Keywords** Gastroesophageal reflux disease · Anti-reflux surgery · Multi-institutional · Nissen fundoplication · Outcomes

Chronic gastroesophageal reflux disease (GERD) is a common disease affecting up to 25 % of the US population [1]. Despite a wide clinical and physiologic spectrum ranging from mild reflux symptoms to severe regurgitation and aspiration, Barrett's esophagus and adenocarcinoma [1–6], therapeutic options have been predominately limited to: proton pump inhibitors (PPIs) and anti-reflux surgery, predominately Nissen fundoplication (NF) [7–9]. While PPIs have been shown to effectively control GERD symptoms in most patients, up to 40 % of patients are not completely controlled by maximal medical therapy and continue to experience breakthrough symptoms [2]. Despite this significant percentage of patients experiencing inadequate control of their reflux symptoms, less than 1 % will opt for surgery to treat their symptoms of GERD. Consequently, there is significant therapy gap between

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those completely satisfied with their medical management and those seeking surgical treatment for GERD [10–15].

This therapy gap persists even though NF has been shown to be more effective than PPIs at controlling reflux disease, particularly when performed at specialized centers [7, 16–19]. Underutilization and delayed employment of anti-reflux surgery is likely due, in part, to patient and referring provider concerns about long-term durability, potential for intraoperative complications, and postoperative NF side effects including dysphagia, the inability to belch or vomit, and resulting hyperflatulence and bloating [16, 20–29]. More recently less invasive anti-reflux surgery options have emerged to address this treatment gap and target patients earlier in the GERD disease process.

In March 2012, the United States Food and Drug Administration approved the use of magnetic sphincter augmentation (MSA), as an alternative surgical intervention in the management of GERD based on two single-arm studies involving 144 patients [16, 30]. Several additional studies have confirmed the safety and efficacy of MSA in the treatment of chronic GERD [16, 24, 30–34]. However, there is a lack of comparative data evaluating MSA against NF and comparisons that have been completed have been predominately limited to single-center retrospective reviews with limited sample sizes [25, 35–37]. Larger, multi-center comparative data are necessary in order to validate MSA as an alternative surgical treatment in the management of chronic GERD.

The aim of the present study was to validate MSA as an anti-reflux procedure through comparison of perioperative and clinical outcomes following MSA to NF in clinical practice, in a standardized fashion, for a larger number of patients than previously published.

## Materials and methods

From April 6, 2007, to December 12, 2014, three high-volume esophageal centers participated in a retrospective case–control review of prospectively collected data on patients who underwent either MSA or NF for the treatment of chronic GERD. The institutional review board at each center approved the study. Since the magnetic sphincters were placed as part of clinical care, the need to implant the devices under a research protocol was waived. Standard informed consent was provided for surgical intervention; however, individual patient consent for this study was waived because of the study's retrospective nature.

Patients were identified in each center's database and included if they met the inclusion and exclusion criteria and the patient was eligible for either MSA or NF during the study time period. Patients included in the NF group were often eligible for MSA implantation, but excluded from MSA because of insurance denial, MRI requirements, patient preference, or known allergy to titanium, stainless steel, nickel. Patients were included if they were greater than 18 years and less than 85 years, had a documented history of GERD at least partially responsive to PPI treatment, and positive pH testing. Patients were excluded if they had prior gastric or esophageal surgery, a hiatal hernia greater than 3 cm in size, esophageal dysmotility (as defined by manometry findings demonstrating effective swallows <70 % and/or, distal esophageal amplitude of <35 mm Hg), and the presence of endoscopically visible Barrett's or esophageal stricture.

A total of 455 patients (222 MSA and 233 NF) were identified as having undergone surgical intervention for GERD. From this, 21 MSA and 19 NF patients were excluded from analysis as a result of inadequate follow-up data. Ultimately, 415 patients (201 MSA and 214 NF) were selected for comparative analysis, and a subgroup of 354 patients (169 MSA and 185 NF) with a minimum of 1-year follow-up were used to validate clinical outcomes. When the preliminary analysis demonstrated differences between the groups, a propensity analysis was completed matching patients based upon preoperative esophagitis, presence of microscopic Barrett's, hiatal hernia size, Hill grade and BMI (Fig. 1).

Data collected from the medical record included: patient demographic information including age, gender, and body mass index (BMI). Results from the preoperative evaluation included: barium swallow; endoscopic findings including Hill classification, the absence or presence and grade of esophagitis according to the Los Angeles (LA) classification, the absence or presence and size of hiatal hernia, measured from the top of the rugal folds to the diaphragmatic impressions; pH analysis with a 48-h wireless probe or 24-h impedance pH catheter, with the highest score during a 48-h period evaluation used for the DeMeester score and percentage of time that pH was less than 4; high-resolution manometry; and clinical symptom severity as measured with the Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD HRQL) scale. Surgical outcomes included operative time and hiatal closure. Postsurgical data included length of stay, 30 day major and minor complications and need for explant, revision or postoperative dilation. The evaluation of treatment effect was done by comparing postsurgical to presurgical GERD-HRQL scores, postoperative ability to belch or vomit, PPI use, and patient satisfaction, when available.

## Procedure

MSA implantation and NF was completed laparoscopically for all patients. MSA implantation was completed using the LINX Reflux Management System (Torax Medical,

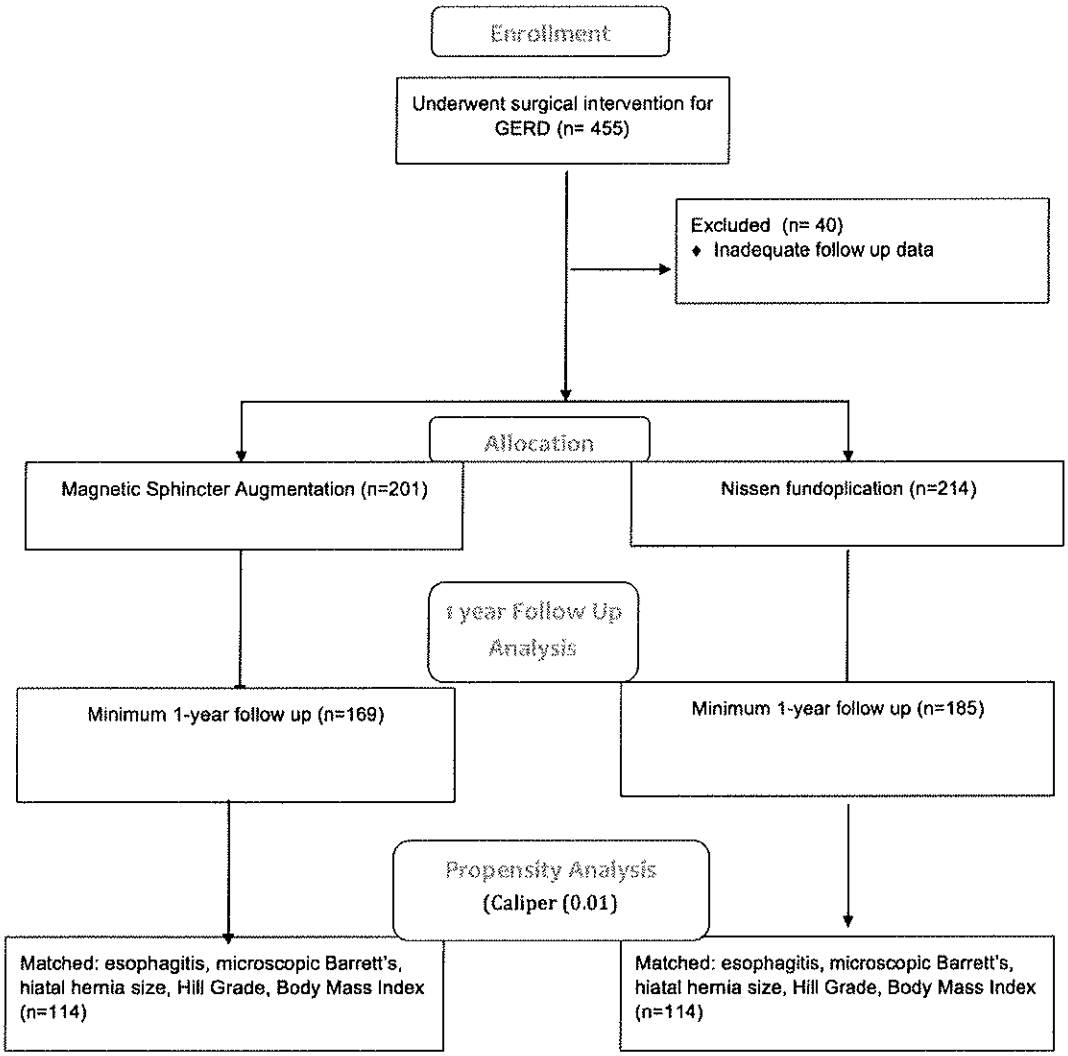


**Fig. 1** Patient enrollment distribution

Shoreview Minnesota). The magnetic sphincter is composed of a series of magnets set in a titanium casing and connected by titanium wires, which augments the lower esophageal sphincter and controls reflux by limiting lower esophageal shortening and relaxation during gastric distention [35]. Implantation is completed using 5 ports in a similar configuration traditionally used for NF, with minimal hiatal dissection, posterior closure of the crura with 1–2 sutures if indicated, and preservation of the gastroesophageal junction, specifically the phrenoesophageal ligament, and gastric anatomy. The complete procedure has been previously described and published in detail [32, 35]. The surgical approach for NF was left to the discretion of the individual surgeon; however, all surgeries included the basic tenets of an anti-reflux repair including hiatal dissection and closure if indicated, reestablishment of at least 2 cm of intra-abdominal esophageal length, fundus mobilization with division of the short gastric vessels, and creation of a symmetrical wrap over an appropriately sized Bougie (58–60 Fr.) at the gastroesophageal junction.

Data between groups were compared with the Student's $t$ test for continuous variables and the Pearson $X/2]$ test for categorical variables. Differences were considered significant at the $p \leq 0.05$ level. Propensity matching was completed using a caliper of 0.01. Statistical analysis was performed using the SPSS 19 statistical software package.

## Results

A total of 415 patients (201 MSA and 214 NF) underwent comparative analysis (Table 1). The groups were similar with respect to age, gender, and GERD-HRQL scores. Patients undergoing MSA had a significantly smaller body

mass index than those undergoing NF and were less likely to report preoperative dysphagia.

During preoperative evaluation (Table 1), MSA patients were found to have lower DeMeester scores, a lower incidence of microscopically identified Barrett's esophagus, but similar rates of esophagitis and percent time pH less than 4. MSA patients were also less likely to have a hiatal hernia, and when present it was likely to be smaller than patients who underwent NF. When the hiatus was assessed by Hill classification, more grade I and 3 valves were present in patients who underwent MSA, while a significantly greater percentage of patients who underwent NF had preoperative Hill grade 4 valves.

The operating time and length of stay were significantly shorter in patients undergoing MSA versus NF (60 vs. 76 min; and 13 vs. 32 h respectively; $p < 0.001$). Statistically significantly more patients had a hiatal closure with NF (19 % MSA vs. 83 % NF, $p < 0.001$).

There were no mortalities, and overall there were no significant differences in 30-day postoperative minor and major morbidities. There was one major complication in a MSA patient, which involved GEJ obstruction and required a return to the operating room for removal of a crural stitch. Three major complications were noted in the NF group including one GEJ obstruction requiring a return to the operating room for fundoplication wrap revision, and two retroesophageal abscesses, associated with biologic mesh placement and bioglue, necessitating surgical drainage (Table 2).

Two patients had removal of their magnetic sphincter, and two patients had revision of their NF. The two fundoplication revisions were for recurrence of hiatal hernia with symptomatic GERD. With respect to the MSA explants, one patient was converted from MSA to NF at 13 months postoperatively for failure to control reflux, as evidenced by positive pH testing and persistent clinical symptoms; and one patient had a device erosion. This patient presented with dysphagia 20 months after implantation. An initial esophagogastroduodenoscopy (EGD) showed no evidence of erosion or other abnormality. A second EGD, performed 30 days later for persistent dysphagia, demonstrated a portion of the magnetic sphincter within the esophageal lumen. This was removed by cutting the exposed magnetic beads with an endoscopic Endoloop Cutter (Olympus Medical Systems, Center Valley, PA, USA). Serial endoscopies demonstrated complete healing of the erosion without any further complication. The patient elected to have the remainder of the device removed laparoscopically 90 days later and has since had a full recovery with no significant complications.

A total of 354 patients (169 MSA and 185 NF) had a minimum of 1-year follow-up, with a 12-month median

**Table 1** Patient demographics and preoperative characteristics[a]

| | MSA ($n = 201$) | NF ($n = 214$) | $P$ value |
|---|---|---|---|
| Age (years) | 54 (42–64) | 52 (43–64) | 0.76 |
| Gender | 52 %M, 48 %F | 43 %M, 57 %F | 0.06 |
| BMI > 30 (%) | 32 | 40 | 0.05 |
| GERD-HRQL | 21 (15–25) | 19 (15–25) | 0.56 |
| Preoperative dysphagia (%) | 27 | 39 | 0.008 |
| % time pH < 4 | 10 (6–15) | 11 (7–16) | 0.20 |
| DeMeester Score | 34 (21–51) | 39 (27–56) | 0.03 |
| Esophagitis LA class (%) | | | |
| None | 63 | 59 | 0.48 |
| A | 18 | 15 | 0.42 |
| B | 13 | 14 | 0.72 |
| C | 4 | 8 | 0.14 |
| D | 2 | 4 | 0.3 |
| Barrett's esophagus (%) | 18 | 31 | 0.001 |
| Hiatal Hernia present (%) | 55 | 69 | 0.002 |
| Hiatal Hernia size (cm) | 1 (0–2) | 2 (0–2) | <0.001 |
| Preoperative hill grade (%) | | | |
| I | 7 | 1 | 0.001 |
| II | 19 | 19 | 0.09 |
| III | 42 | 29 | 0.02 |
| IV | 32 | 51 | <0.001 |

[a] All data, unless otherwise specified, expressed as median values with (interquartile range)

**Table 2** Adverse events

| | MSA (%) ($n = 201$) | NF (%) ($n = 214$) | $P$ value |
|---|---|---|---|
| Major complications (30 days) | 0.5 | 1.4 | 0.34 |
| Minor complications (30 days) | 7 | 9 | 0.49 |
| Explant/revision | 1 | 0.9 | 0.66 |

duration of follow-up for both MSA and NF. Both groups reported significant improvement in GERD-HRQL scores with no significant difference in the postoperative GERD-HRQL scores between the MSA and NF patients (3 MSA vs. 4 NF, $p = 0.17$)(Fig. 2).

Patients who underwent MSA were significantly more likely, than those undergoing NF, to retain the ability for eructation and emesis. Additionally, the patients who underwent MSA were less likely to experience gas bloat. The incidence of moderate or severe dysphagia was similar between the 2 groups, while MSA patients had significantly higher incidence of mild dysphagia ($p = 0.02$)(Table 3).

An equal distribution of MSA and NF patients resumed daily PPI use, reported satisfaction with the procedure (85 % MSA vs. 91 % NF, $p = 0.09$) and likelihood of undergoing the procedure again (90 % MSA vs. 89 % NF, $p = 0.75$).

Propensity analysis (Table 4) identified 114 matched pairs with similar preoperative esophagitis, presence of microscopic Barrett's, hiatal hernia size, Hill grade and BMI. The mean follow-up was 11 months for MSA and 16 months for NF ($p < 0.001$). There was no significant difference between the matched pairs with respect to postoperative GERD-HRQL scores, but postoperative daily PPI use was higher in the MSA group. Patients who underwent MSA were more likely to have mild postoperative dysphagia, less likely to experience gas bloat, and had greater retention of the ability for postoperative vomiting and eructation. Although patient-reported satisfactions with the procedures were similar, patients undergoing MSA were more likely to report they would undergo the same procedure again.

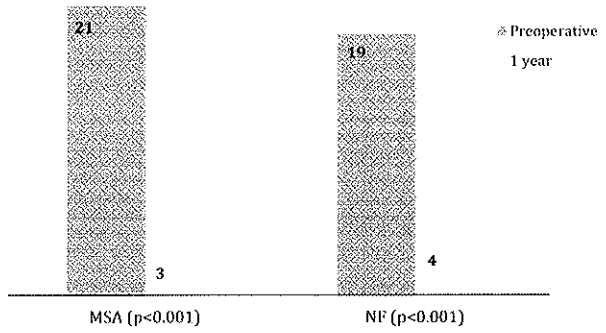


**Fig. 2** Preoperative and postoperative 1-year HRQL scores in patients who underwent magnetic sphincter augmentation (MSA) and Nissen fundoplication (NF)

## Discussion

The primary finding in this large multi-institutional study is that MSA achieves excellent symptom resolution as measured by the GERD-HRQL questionnaire. When compared to patients undergoing NF, the GERD-HRQL is similar in patients who have achieved at least 1-year follow-up and in propensity-matched patients. MSA also appears to maintain normal physiologic function of the LES as evidenced by the ability to belch and vomit with less gas/bloat symptoms. The incidence of dysphagia is also similar between the two groups. These results add to an increasing knowledge base and experience with MSA, while the comparative data against NF provide validation of MSA as an addition to the surgical management of GERD. Lastly, these results also provide insight into the role MSA will play in the management of GERD.

The results of MSA in this study are similar to those from previously published studies [16, 24, 25, 30–34]. Under strict inclusion criteria, a median GERD-HRQL score of 2 was achieved after MSA in the initial report on outcomes [31]. The minor differences in GERD-HRQL scores in the current series, when compared to previous studies, are likely due to the slightly relaxed inclusion criteria (e.g., patients included with grade C + esophagitis) as more centers are implanting the device and more experienced LINX surgeons are becoming comfortable with the outcomes of the device. Despite this expansion, there has been very consistent symptom relief measured with MSA.

The comparative data illustrate the significant differences in side effect profiles of these two procedures. The inability to belch and vomit is often raised by patients as a concern when contemplating NF [7, 8]. MSA appears to retain that ability as well as having less gassy or bloating sensations which is theoretically due to the dynamic nature of the device allowing gastric venting by way of transient relaxations. Some degree of dysphagia is expected with a NF and is anticipated with post MSA about 2 weeks into the healing process. We were surprised to see that at 1 year, MSA patients appeared to experience a slightly higher rate of "mild" dysphagia compared to propensity-

**Table 3** Quality of life at 1 year

| | MSA (%) ($n = 169$) | NF (%) ($n = 185$) | $P$ value |
|---|---|---|---|
| Ability for eructation | 96 | 69 | <0.001 |
| Ability for emesis | 95 | 43 | <0.001 |
| Gas bloat | | | |
| None | 53 | 41 | 0.03 |
| Mild | 27 | 40 | 0.02 |
| Moderate | 14 | 16 | 0.65 |
| Severe | 5 | 3 | 0.24 |
| Dysphagia | | | |
| None | 42 | 53 | 0.04 |
| Mild | 44 | 32 | 0.03 |
| Moderate | 13 | 11 | 0.57 |
| Severe | 1 | 5 | 0.24 |
| Postoperative PPI | 19 | 14 | 0.18 |

**Table 4** Quality of life: propensity-matched analysis

| | MSA (%) ($n = 114$) | NF (%) ($n = 114$) | $P$ value |
|---|---|---|---|
| GERD-HRQL | 6 | 5 | 0.54 |
| Postoperative PPI | 24 | 12 | 0.02 |
| Ability for eructation | 97 | 66 | <0.001 |
| Dysphagia | | | |
| None | 42 | 53 | 0.31 |
| Mild | 44 | 32 | 0.04 |
| Moderate | 13 | 11 | 0.15 |
| Severe | 1 | 5 | 0.55 |
| Gas bloat | | | |
| None | 59 | 41 | 0.008 |
| Mild | 30 | 42 | 0.08 |
| Moderate | 9 | 16 | 0.09 |
| Severe | 2 | 1 | 0.58 |
| Ability for emesis | 88 | 40 | <0.001 |
| Ability for eructation | 97 | 66 | <0.001 |
| Satisfaction | 88 | 89 | 0.61 |
| Would undergo procedure again | 93 | 83 | 0.01 |

matched NFs. Our experience suggests this difference is related to several postoperative differences. Patients undergoing NF learn to eat over time with a graduated diet and learn to slow down ingestion early on to adjust to new anatomy, whereas MSA patients eat regular food immediately after surgery and have yet to modify ingestion but when instructed to slow down their eating pattern immediately obtain relief of this mild dysphagia.

The PPI elimination rate of 76 % is slightly lower than reported by previous studies which has shown PPI elimination rates of 81–85 % in multiple studies some of which have long-term follow-up out to 5 years or more [16, 24, 25, 31, 32, 37]. Comparatively, studies with longer-term follow-up with NF show a steady resumption of PPIs beginning at 1 year [38]. What is interesting is that despite a higher need for PPIs postoperatively, patients who underwent MSA were equally satisfied with their outcome but more likely to report that they would undergo the procedure again. Presumably, in this group of uncomplicated GERD patients, MSA has struck a reasonable balance between symptom control and the need for PPIs while lessening the troublesome side effects related to NF that patients and referring MDs are concerned about. The result of this balance is that it likely will increase the number of patients undergoing anti-reflux surgery since 40 % of patients on PPIs still have troublesome symptoms but because of the side effects of NF were waiting on the sidelines until something "better" came along.

Even though entry into this trial was restricted so that patients were required to be eligible for both procedures, it

is apparent there are subtle preoperative differences in these two populations with more Barrett's, as well as more and larger hiatal hernias in patients undergoing NF. This suggests that there may have been a subtle selection bias in which MSA is being applied versus in whom NF is being offered. For most surgeons, the patients with symptomatic GERD without a hernia or esophagitis represents a departure from the typical patient referred to most practices for NF who usually have Barrett's, a moderate to large hiatal hernia, are overweight and a defective LES with bipositional reflux. Along the spectrum of GERD, the patients with complicated GERD, a larger hiatal hernia, erosive esophagitis, esophageal strictures, endoscopically visible Barrett's esophagus, or motility disorders may be better served by NF [4, 9, 25]. In these patients with advanced disease, the LES is likely to be severely defective or absent and may require reconstruction rather than augmentation. The addition of MSA increases the treatment options for GERD by targeting patients with uncomplicated disease earlier in the disease spectrum that are inadequately managed with medical therapy, but not so severe they are willing to accept the side effects of NF.

This study has several limitations. First, its retrospective nature is subject to inherent biases. Second, it should be noted that all of the centers were high-volume esophageal centers, and high-volume surgeons with extended proficiency in dissection of the diaphragmatic hiatus, performing laparoscopic fundoplication, and early adopters of MSA technology. This may limit the applicability of the results outside of high-volume esophageal centers. Lastly, the lack of an objective postoperative GERD control measure such as postoperative pH is acknowledged. However, prior series including a small comparative trial have documented the ability of MSA to normalize pH and with the consistent results seen across trials would be expected to be similar in the current study [31, 35].

In conclusion, MSA in patients with uncomplicated GERD results in equivalent symptom control, improved quality of life but lower PPI elimination rates when compared to propensity-matched NF cases. MSA had significantly less side effects and patients retained their ability to belch and vomit. MSA offers patients an effective procedure with a better side effect profile and is an alternative surgical treatment option for patients with GERD that is not adequately controlled by PPI's and has not progressed to the point of needing a Nissen fundoplication.

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**Compliance with ethical standards**

**Disclosures** Drs. Lipham, Taiganides and Louie have received consulting fees from Torax Medical. Drs. Warren, Reynolds, Zehetner, Bildzukewicz, Aye, and Farivar, and Ms. Mickley have no conflicts of interest or financial ties to disclose.

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