



Review paper

Magnetic surgery for lower esophageal sphincter augmentation: two decades of research and innovation

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ARTICLE INFO

Keywords:

Gastroesophageal reflux disease
Hiatal hernia
Proton-pump inhibitors
Barrett's esophagus
Lower esophageal sphincter
Magnetic sphincter augmentation

ABSTRACT

Gastroesophageal reflux disease (GERD) exhibits a significant prevalence within the Western countries, wherein approximately 30 % of individuals report symptoms associated with reflux. Magnetic sphincter augmentation (MSA) is a standardized laparoscopic intervention initially designed for patients who are not satisfied with pharmacologic management and for those diagnosed with early-stage GERD who may not qualify as optimal candidates for fundoplication surgery. The MSA device is designed to encircle the esophagogastric junction and enhance the natural antireflux barrier through the application of magnetic force without causing mechanical compression. MSA, particularly when performed in conjunction with crural reinforcement, has demonstrated significant efficacy in alleviating symptoms of GERD, reducing dependence from proton-pump inhibitors, diminishing esophageal acid exposure, and enhancing patients' overall quality of life. Safety concerns like erosion and migration occur infrequently and are not linked to mortality. This surgical intervention is reversible, allowing for laparoscopic removal of the device if deemed necessary. A potential limitation of the MSA procedure lies in its contraindication for patients undergoing imaging in high-field strength Tesla magnetic resonance systems. Understanding the physiology of the MSA implant and selecting patients based on the GERD phenotype are critical for improving the long-term outcomes of the procedure. Individualizing the choice of the operative technique in GERD patients can increase acceptance of the surgical procedure and reduce the burden of the disease.

1. Introduction

Current therapy for gastroesophageal reflux disease (GERD) is frequently reported as being unsatisfactory by patients, gastroenterologists, and surgeons. Approximately 40 % of patients exhibit resistance or only partially respond to proton-pump inhibitor (PPI) therapy [1,2], and even dose escalation may prove insufficient in alleviating volume regurgitation. Also, in spite of continuous PPI therapy, persistent non-acid reflux and nocturnal acid breakthrough may represent significant risk factors for progression to Barrett's metaplasia and esophageal adenocarcinoma [3,4]. In addition, there are growing concerns over the long-term consequences of PPI-induced acid suppression, mainly the risk of *Clostridium difficile* infection, community-acquired pneumonia, bone fractures, reduced absorption of vitamin B12 and magnesium, hypergastrinemia, and multiple drug interactions [5,6].

Surgical intervention holds the promise of a definitive cure for GERD by augmenting both components of the antireflux barrier,

namely the lower esophageal sphincter (LES) and the crural diaphragm [7]. However, due to inconclusive evidence due to the lack of robust, high-quality randomized trials, contemporary guidelines [8–10] advocate that the selection of an antireflux procedure should be entrusted to the discretion of the individual surgeon and tailored to the unique needs of each patient. The laparoscopic Nissen fundoplication still represents the benchmark gold standard, demonstrating safety, efficacy, and durability when performed in a standardized manner within specialized centers [11]. However, several studies [12–14] suggest that partial Toupet and Dor funduplications may offer comparable outcomes in terms of reflux control while exhibiting a reduced incidence of side effects.

Despite the remarkably low incidence of morbidity and mortality rates [15], fundoplication is often underutilized due to prevailing perceptions of its failure rates and associated side effects. Furthermore, the variability of clinical outcomes, influenced by inter-individual practice and surgical expertise [16], has constrained the widespread adoption of this procedure, particularly in patients with early-stage GERD. Patients

Peer review under responsibility of Xi'an Jiaotong University.

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<https://doi.org/10.1016/j.magmed.2025.100025>

Received 22 January 2025; Received in revised form 17 May 2025; Accepted 23 May 2025

Available online 26 May 2025

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undergoing Nissen fundoplication are particularly susceptible to potential complications such as bloating, the inability to belch and vomit, and the occurrence of persistent dysphagia that may necessitate revisional surgery [17]. These factors contribute to the general tendency to refer only patients with long-standing, severe disease and large hiatal hernias for fundoplication. In the United States, a decline in the utilization of surgical fundoplication has been observed over the past decade [18–20]. Paradoxically, the underutilization of antireflux procedures stands in sharp contrast to the growing acknowledgment of GERD as a progressive condition capable of leading to carditis, cardiac metaplasia, intestinal metaplasia, and ultimately, to adenocarcinoma of the distal esophagus [21–23]. The constraints inherent in both medical and surgical treatment modalities have compelled a significant number of patients to either resign themselves to lifelong reliance on pharmacotherapy, or to incur in the potential risks associated with surgical intervention such as alterations in anatomy and physiology, adverse effects, and the possible long-term deterioration in outcomes. The Magnetic sphincter augmentation (MSA) device was introduced in 2007 to obviate the technical issues and the potential adverse events associated with fundoplication [24]. The aim was also to standardize and make antireflux surgery more reproducible, and to fill the existing gap between medical and surgical therapy [24] (Fig. 1).

2. Technology and biomechanics of MSA

The MSA, which is named as LINX™ Reflux Management System, is a minimally invasive procedure aimed to control GERD-related symptoms which was first implanted in 2007 [24]. It is a nonbulky device (1.2 g) composed of a series of beads designed to be noncompressive by its roman-arch configuration (Fig. 2). The LINX procedure is currently used to prevent progression of early-stage GERD or to treat more advanced disease associated to hiatus hernia [25]. The LINX device represents a pioneering advancement in the management of GERD, functioning as a mechanical augmentation to the physiological barrier against reflux through the application of magnetic force. This innovative implant has gained approval for magnetic resonance imaging (MRI) scans up to 1.5 T underscoring its safety profile in modern diagnostic imaging. It is formed by individual neodymium-iron-boron magnets encapsulated within hermetically sealed titanium casings, and is available in different sizes (13 to 17 beads) to accommodate individual patients' anatomy. The beads are interconnected via independent titanium wires, forming a flexible and expandable ring that is positioned circumferentially around the LES. In a state of rest, each bead maintains contact with its adjacent counterparts, and the magnetic force inherent in each bead perpetually enhances the LES's resistance to opening under increased intragastric pressure. This mechanism ensures that the device remains responsive to physiological

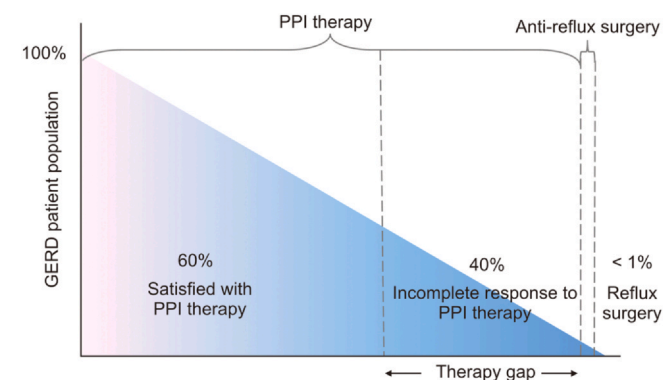


Fig. 1. Diagram of therapy gap between PPI therapy and reflux surgery. PPI, proton-pump inhibitor; GERD, gastroesophageal reflux disease.



Fig. 2. Diagram of the magnetic device. The device was first implanted in human 2007 in Italy. It is a nonbulky device (1.2 g) composed of a series of titanium-encased, rare-earth magnetic beads interconnected via biocompatible titanium alloy wires. It is designed to be noncompressive by its roman-arch configuration. This device is laparoscopically implanted at the gastroesophageal junction (GEJ), where it exerts adaptive magnetic augmentation of the lower esophageal sphincter (LES).

demands while simultaneously reinforcing the LES's natural barrier function. A key feature of the LINX device is its dynamic nature; the beads can move independently, allowing for unimpeded esophageal motion during swallowing, belching, and vomiting. This design eliminates the risk of esophageal compression and preserves the normal range of motion, thereby minimizing side effects commonly associated with traditional antireflux procedures. By limiting the distension of the esophagogastric junction and preventing LES shortening and effacement in response to increased intragastric and intra-abdominal pressures, the LINX device effectively curtails gastroesophageal reflux, offering patients a viable alternative to lifelong medication dependence or the risks associated with more invasive surgical interventions [26–28]. The magnetic bond between the beads is disconnected by the force of a swallowed bolus, allowing the beads to separate and a bolus to freely pass. The attraction force between magnets exponentially reduces with the separation distance and is independent of the number of beads. The device, while augmenting the LES, allows to accommodate a swallowed bolus or the escape of elevated intragastric pressure allowing belching or vomiting (Fig. 3) [29]. During the healing process after implantation, the device is usually covered by a thin sheath of fibrous tissue, yet it does not integrate into the esophageal wall. However, a thick fibrous capsule as a result of a foreign body reaction may exert an additional force on the LES [30,31].

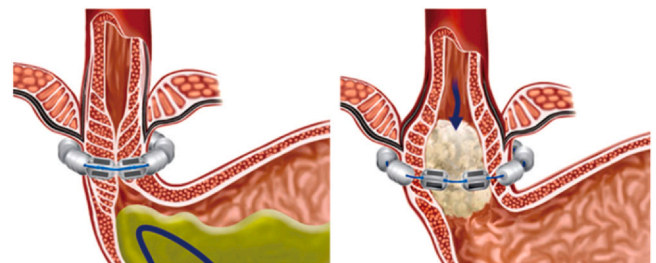


Fig. 3. Closed and open configurations of LINX™ device. This flexible device forms a ring that rests around the LES in a circular fashion. Some of the beads separate from each other to allow transport of the swallowed bolus. Reproduced with permission from [29].

3. Patient selection

Laparoscopic antireflux surgery is a reasonable therapeutic option for young and otherwise healthy individuals, especially men, who seem to have the lowest rate of postoperative GERD recurrence and may otherwise require daily PPI therapy for decades [32]. The SAGES guidelines [33] have recommended LINX, for appropriately selected patients who meet indications for antireflux surgery, as part of the armamentarium in the treatment of GERD. The most recent American College of Gastroenterology guidelines for GERD recommend the LINX procedure as an alternative to laparoscopic fundoplication for patients with regurgitation who fail medical management (strong recommendation, moderate level of evidence) [34]. The preoperative evaluation of individuals considered for a LINX procedure is analogous to that for any other antireflux intervention. Standard diagnostic procedures encompass a barium swallow examination, upper gastrointestinal endoscopy with biopsy sampling, high-resolution esophageal manometry, and esophageal pH or pH-impedance monitoring. In cases where patients exhibit atypical symptoms or present borderline objective criteria for the diagnosis of pathological reflux, or evidence of esophageal motility disorders, further investigation for assessment of autonomic nerve dysfunction, autoimmunity, psychological profile, gastroparesis, rumination, cannabis use, small intestinal bacterial overgrowth, and irritable bowel syndrome may be necessary before planning antireflux surgical therapy. Individuals with established allergies to titanium or nickel, those afflicted by autoimmune conditions, and those in need of ongoing MRI surveillance should be excluded as candidates for the LINX procedure [35,36].

4. Surgical technique

The LINX procedure in patients without intraoperative evidence of hiatal hernia may require minimal dissection with preservation of the phrenoesophageal ligament [24]. The choice to perform a formal crural repair is contingent upon the preoperative assessment of GERD severity and the intraoperative confirmation of a hiatal hernia. Division of the phrenoesophageal ligament and complete mediastinal dissection are typically advised to achieve an adequate, tension-free length of the intra-abdominal esophagus.

The operation is performed under general anesthesia employing a conventional laparoscopic technique. There is a lack of consistent evidence to advocate for the utilization of single-port access, three-dimensional cameras, or robotic assistance. Surgical dissection starts by dividing the peritoneum on the anterior aspect of the gastroesophageal junction beneath the insertion point of the inferior leaf of the phrenoesophageal ligament and above the junction of the hepatic branch with the anterior vagus nerve. The lateral surface of the left crus is dissected away from the posterior fundic wall without dividing the short gastric vessels. The gastro-hepatic ligament is opened both above and below the hepatic branch of the anterior vagus nerve to facilitate the preparation of the retro-esophageal window. Gentle dissection is performed from the right side towards the left crus, just above the crural decussation, to identify the posterior vagus nerve. The esophagus is suspended using a Penrose drain, and a tunnel is created between the vagus nerve and the esophageal wall (Fig. 4A). A sizing tool featuring a soft, white magnetic tip, activated via a handset, is employed to ascertain the appropriate size of the LINX device for implantation. The handset incorporates a numerical indicator that corresponds to the size range of the device (Fig. 4B). The sizing tool is introduced through the tunnel created between the esophageal wall and the posterior vagus nerve bundle (Fig. 4C). Once the esophagus is encircled, a non-compressive device size can be selected by rotating the shaft of the instrument, ensuring that the white loop can move freely up and down along the esophageal wall, and sizing up by 1 bead if there is no movement (Fig. 4D). As a confirmatory step, the sizer can be incrementally closed until the magnetic tip disengages, and then sizing up

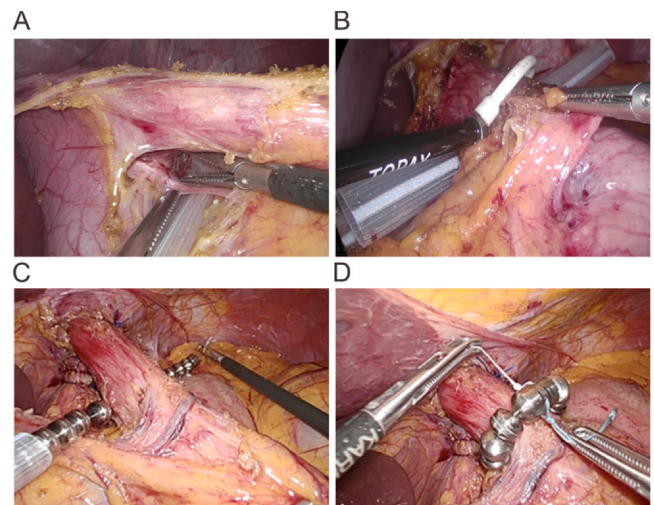


Fig. 4. The key surgical steps of the LINX procedure. (A) A tunnel is created between the posterior vagus nerve and the esophageal wall; the esophagus is then suspended using a 16 Fr silicone Penrose drain. (B) A magnetic sizing tool is used to ascertain the appropriate size of the device to be selected for implantation. (C) The device is introduced through the tunnel. (D) The two clasps are joined on the anterior surface of the esophagus.

by 2 or 3 beads [37]. The LINX device is subsequently introduced through the tunnel, and its opposing ends are maneuvered to the anterior surface of the esophagus, where they are joined by engaging the two clasps.

Patients are typically discharged either on the same day as their surgery or on the first postoperative day, contingent upon obtaining a chest film to verify the proper positioning of the device. Over the subsequent three weeks, PPI therapy is gradually tapered off. Patients are instructed to chew their food thoroughly and consume five smaller meals throughout the day to stimulate esophageal peristalsis and facilitate the expansion of the LINX device. This dietary approach contrasts with the post-fundoplication instructions, where the early return to a normal diet aims to deter the development of a restrictive fibrous capsule around the implant during the initial postoperative weeks. Dysphagia is deemed a normal occurrence within the first three months post-surgery, with its peak incidence typically observed between the third and sixth postoperative weeks. In response to dysphagia, patients are advised to temporarily switch to a semiliquid diet. Should dysphagia persist beyond three months, a brief course of steroids and/or an endoscopic pneumatic dilation may be warranted [38–40].

5. Early and intermediate-term outcomes

The feasibility investigation of MSA encompassed 44 patients who underwent implantation between February 2007 and October 2008 [24,29,41,42]. Patients acted as their own controls to evaluate the impact of treatment on symptoms, PPI use, and esophageal acid exposure. The primary inclusion criteria for the feasibility trial were an age range of > 18 to < 85 years, the presence of typical reflux symptoms at least partially responsive to PPI therapy, abnormal esophageal acid exposure, and normal contractile amplitude and waveform in the esophageal body. The primary exclusion criteria included a history of dysphagia, prior upper abdominal surgery, previous endoluminal anti-reflux interventions, a sliding hiatal hernia exceeding 3 cm, esophagitis graded above grade A, and/or the existence of histologically confirmed Barrett's esophagus. Patients exhibiting abnormal manometric results (distal esophageal contraction amplitude of < 35 mmHg during wet swallows or < 70% propulsive peristaltic sequences) were also excluded. All MSA devices were successfully implanted using a laparoscopic technique, with a median operative duration of 40 min. Patients were advised to resume a regular diet following a chest X-ray and

radiological assessment of esophageal transit. Forty-three percent of patients reported mild postoperative dysphagia, which resolved without treatment by 90 days. Thirty-three patients (75%) were followed up for a period of up to 5 years. The mean total GERD-Health Related Quality of Life (GERD-HRQL) score off PPI decreased significantly from 25.7 at baseline to 2.9%, and 94% of patients experienced a reduction of more than 50% in the total score. Complete cessation of PPI or a reduction of 50% or more in the daily dosage was achieved by 88% and 94% of patients, respectively, and 91% of patients expressed satisfaction with their outcomes. Esophageal pH testing was conducted in 20 patients at 5 years: 85% of patients achieved either normal esophageal acid exposure or a reduction of at least 50% from baseline, and 70% of patients achieved normalization of the pH profile. Three patients underwent device explantation: one due to persistent dysphagia, one due to the necessity of undergoing magnetic resonance imaging, and the last one opted for a Nissen fundoplication due to ongoing GERD symptoms. All removals were safely performed via laparoscopy.

Identical rigorous inclusion criteria and both subjective and objective peri-operative evaluations were employed in a large multi-institutional investigation encompassing 100 patients across 13 centers [43]. Notable improvements were observed in the quality of life associated with GERD, regurgitation episodes, and esophageal acid exposure levels. The utilization of PPIs declined to 13% at 3 years, and patient satisfaction with reflux management escalated to 94% following implantation. Despite 14% of patients experiencing bloating post-implantation, none of them regarded this symptom as severe. Patients maintained their capacity to belch and vomit. A certain degree of dysphagia was evident in 68% of patients but diminished to 4% by the 3-year follow-up. 5% of patients assessed the dysphagia as severe, and the device was removed in three of these patients, resulting in complete symptom alleviation.

Subsequent single-center investigations further corroborated the effectiveness of the LINX procedure. In Milan, Italy, a cohort of 100 consecutive patients underwent LINX implantation from 2007 to 2012, with a median implantation duration of 3 years. A notable decrease in acid exposure time and improvement in GERD-HRQL scores was observed: 85% of patients achieved freedom from daily PPI dependency [44]. Supplementary published data confirmed comparable favorable outcomes [45–51]. Significantly, a one-year randomized clinical trial [52] comparing the LINX procedure with PPI demonstrated the superiority of the LINX procedure in managing moderate to severe regurgitation and reducing esophageal acid exposure. In another study [53], Body Mass Index (BMI) exceeding 35 kg/m², Hill grade 2 or poorer valve competence, and manometrically dysfunctional LES were inversely associated with positive outcomes. A retrospective single-center review of 553 patients [54] identified factors linked to favorable LINX procedure outcomes as age < 45 years, male gender, GERD-HRQL > 15, and an abnormal DeMeester score. Several studies [55,56] examining the efficacy of MSA in patients with laryngopharyngeal reflux and/or weakly acidic reflux indicated the procedure's effectiveness in carefully chosen candidates. Patients with the highest preoperative Reflux Symptom Index questionnaire scores exhibited the most favorable responses to antireflux surgery [57].

5.1. Comparison of MSA and fundoplication

Observational research revealed comparable management of reflux symptoms following surgical fundoplication or LINX implantation. Nevertheless, the Nissen fundoplication cohort exhibited a greater proportion of patients experiencing an inability to belch and vomit, accompanied by more pronounced gas-bloat symptoms. Conversely, quality of life metrics were analogous between patients treated with LINX or Toupet fundoplication [58–65]. Magnetic sphincter augmentation demonstrated efficacy in patients with severe GERD [66–68]. Three meta-analyses [69–71] comparing LINX and fundoplication

indicated that the former was linked to fewer gas-bloat symptoms and better capacity for eructation and vomiting, while PPI discontinuation rates, dysphagia necessitating endoscopic dilation, and GERD-HRQL scores were comparable between the two patient cohorts.

5.2. Effect of combining MSA and full crural repair

The short- to intermediate-term outcomes of the LINX procedure when performed in conjunction with systematic crural repair appear more advantageous than those of LINX alone, irrespective of hiatal hernia size [72–77]. A multivariable logistic regression analysis [78] showed that full mediastinal dissection, accompanied by restoration of intra-abdominal esophageal length and formal crural repair, was most likely to normalize esophageal acid exposure (point estimate 1.73; 95% CI 1.15–8.19; $p = 0.02$).

5.3. Effect of MSA on Barrett's esophagus

Regression of Barrett's esophagus was noted in 72% of patients one year following LINX implantation. Notably, patients with short-segment intestinal metaplasia who experienced normalization of esophageal acid exposure were more likely to achieve regression [79,80].

6. Long-term outcomes

Although the majority of data collected since the clinical introduction of the LINX device have primarily concentrated on short- and intermediate-term outcomes, the reported results at 5 years or beyond post-implantation indicate that the initially promising short- and mid-term efficacy and safety profiles of the procedure maintain relative stability over the long-term. Notably, the incidence of dysphagia is significantly reduced at 5-year. Presently, all available long-term outcome data originate from patient cohorts who were selected for LINX implantation under early, restricted indications and obsolete treatment protocols, thereby underscoring the necessity for additional investigations with extended follow-up periods [81]. Ferrari et al. [82] presented longitudinal outcome data spanning 6 to 12 years from 124 patients who underwent LINX device implantation at a single institution, with a median follow-up duration of 9 years. The mean GERD-HRQL score notably declined from 19.9 to 4.01 at the most recent clinical assessment. Furthermore, the prevalence of grade 2–4 regurgitation significantly decreased from 59.6% to 9.6%, and 79% of patients discontinued their use of PPIs. The mean percentage of time with esophageal pH < 4 decreased from 9.7% to 4.2% ($p < 0.001$), indicating a substantial reduction in acid exposure. Among the cohort, four patients who had previously undergone radiofrequency ablation for Barrett's esophagus without dysplasia prior to LINX implantation, and whose esophageal acid exposure normalized post-surgery, were monitored for up to 8 years without recurrence of intestinal metaplasia. Predictive factors for a favorable outcome included an age at intervention of < 40 years and a total GERD-HRQL score > 15. In a propensity-matched cohort study [83] including 354 patients with a minimum 5-year follow-up, quality-of-life outcomes of MSA demonstrated durable improvements compared to Nissen fundoplication, especially when a complete mediastinal dissection and hiatal repair were performed during MSA implantation.

7. MSA and refractory GERD after sleeve gastrectomy

Laparoscopic sleeve gastrectomy (LSG) performed in obese patients is linked to the potential for exacerbation of pre-existing GERD or the onset of new-onset GERD. The prevalence of Barrett's esophagus appears to be at least six-fold greater compared to the general population. This observation is indeed concerning and warrants serious consideration until the physiologic impact of this operation and the strategies to prevent GERD-related complications is better understood. In

individuals with the body mass index (BMI) 30 to 35 and PPI-refractory GERD after sleeve gastrectomy, primary antireflux surgery remains a valid alternative to Roux-en-Y gastric bypass in expert hands. A recent systematic review analyzed 14 studies including 109 patients with a median follow-up of 18.9 months. Both the GERD-HRQL score (38 ± 13 vs 10 ± 11 ; $p = 0.0078$) and daily PPI use (97.4% vs 25.3% ; $p < 0.0001$) were significantly improved [84]. In a prospective multicenter study [85], 30 patients who underwent MSA implantation were monitored for 12 months post-procedure. Two severe adverse events (dysphagia and pain, 6.7% incidence) were reported, both of which resolved without residual complications. Notably, GERD-HRQL scores exhibited substantial improvement, accompanied by a reduction in daily PPI usage. Additionally, 44% of patients demonstrated normalization or a $\geq 50\%$ decrease in total distal acid exposure time, from 16.2% to 11%. A more recent study [86] demonstrated that, among post-sleeve gastrectomy patients with a BMI < 35 , normal sleeve morphology, low intragastric pressure, and LES pressures < 18 mmHg, the MSA device emerged as an effective and enduring therapeutic option, offering sustained long-term advantages. Notably, at follow-up periods exceeding 3 years, merely 25% of sleeve gastrectomy patients continued to require daily PPI therapy.

8. Safety profile

Safety concerns, including MSA device migration, erosion, and penetration into the gastrointestinal lumen, have been infrequent and have not been linked to mortality. An examination of the safety profile of 1000 initial implants across 82 hospitals [87] revealed a 1.3% hospital readmission rate, a 5.6% requirement for postoperative endoscopic dilations, and a 3.4% reoperation rate. All reoperations were conducted electively for the purpose of device removal. The most prevalent symptoms were dysphagia and the recurrence of reflux symptoms. In the US multicenter single-arm trial [88], 7% of enrolled patients had their devices removed due to persistent dysphagia in 4 cases, vomiting in 1 case, chest pain in 1 case, and reflux in 1 case.

Transient dysphagia is a common event during the first 3 months after the implant and generally requires dietary adjustments. If necessary, a short course of steroids combined with endoscopic dilatation using a 15 mm through-the-scope balloon is feasible and safe. In a multicenter retrospective review including 144 patients [40], success after initial dilation occurred in 49.3%, patients, overall success rate with dilation was 83.3%, and the risk of device explant was 12%. Another investigation utilizing data from the MAUDE database [89], encompassing 3283 patients who underwent surgery between 2012 and 2016, reported a 2.7% removal rate; notably, 88% of these removals took place within 2 years following implantation. In a retrospective series involving 268 patients who received MSA implantation and were followed up for 23 months, 2% of patients required reoperation, with the most common reason being recurrent hiatal hernia. Additionally, 1% of patients needed endoscopic dilation, and the use of a LINX device size < 13 was identified as the sole factor associated with postoperative dysphagia [90]. The outcomes of reoperations for laparoscopic LINX removal were documented in a series of 164 consecutive patients [91]. The reoperation rate was 6.7%. The primary symptoms necessitating device removal were as follows: recurrence of heartburn or regurgitation in 46% of cases, dysphagia in 37%, and chest pain in 18%. In two patients (1.2%), full-thickness erosion of the esophageal wall with partial endoluminal penetration of the device. The median duration of implant was 20 months, and 82% of the patients underwent device removal between 12 and 24 months after the initial operation. The operative time ranged from 25 to 150 min, and the postoperative course was generally uneventful. At the most recent follow-up, the GERD-HRQL score was normalized in all patients.

The development of exuberant scar tissue forming a constrictive capsule around the device [92] and variations in the positioning and sizing of MSA device may contribute to persistent dysphagia [93]. A

subsequent analysis of the manufacturer's database revealed that the majority of erosions were associated with size 12, which is no longer available [94–96]. This finding underscores the importance of careful device sizing and positioning to minimize the risk of complications and optimize patient outcomes. Advancements in the techniques employed during the MSA procedure, encompassing comprehensive mediastinal dissection, reinforcement of the posterior crural region, utilization of an oversized or larger-sized device, have led to enhanced clinical results and a decline in the rates of device removal over time. Laparoscopic explantation of the MSA device carried out by expert surgeons in a tertiary care facility appears safe and effective. The device is completely mobilized and removed by opening the outer layer of the scar capsule. A partial or total endoscopic approach may be indicated and feasible in case of erosion [91]. A study [97] including 40 patients undergoing device removal, 77.5% for dysphagia and 22.5% for GERD, showed that removal for dysphagia was associated with satisfactory outcomes. Removal for GERD without antireflux surgery had worse outcomes on all measures.

9. Pathophysiological changes after MSA implantation

The precise mechanism underlying the action of MSA and its prolonged physiological impact on esophageal motility and wall compliance remain incompletely elucidated. In a retrospective cohort study conducted [98], a group of 45 patients who had undergone MSA implantation underwent repeated high-resolution manometry (HRM) examinations at an average follow-up duration of 12 months. There was a notable rise in LES length, integrated relaxation pressure (IRP), intrabolus pressure (iBP), and esophagogastric junction contractile integral (EGJ-CI). Furthermore, all parameters related to esophageal contractility, including distal esophageal amplitude (DEA), mean distal contractile integral (DCI), and the percentage of normal swallows, showed a significant increase following the surgical procedure. Interestingly, ineffective esophageal motility (IEM) reverted to a normal motility pattern in 36% of the cases. None of these manometric characteristics were linked to postoperative dysphagia, which was solely associated with the presence of dysphagia at the baseline assessment. The impact of MSA on the EGJ profile was also explored [99] in a retrospective study encompassing 100 patients with an average follow-up period of 14.9 months. They observed a statistically significant increase in both the overall and intra-abdominal length of the LES, as well as an elevation in the mean resting LES pressure, IRP, and iBP. The higher postoperative IRP values were associated with the normalization of distal esophageal acid exposure and a substantial reduction in the DeMeester score, indicating that the increased outflow resistance at the EGJ effectively prevents reflux. Esophageal peristalsis and bolus clearance remained unaltered.

In another study [100], patients who experienced relief from reflux and dysphagia following MSA underwent assessment at a median follow-up duration of 13 months. Notably, both the upper limit of IRP and the upper limit of iBP exceeded the reference values specified in the Chicago Classification version 3.0. These values were even more elevated when a formal crural repair was performed in conjunction with MSA implantation. Comparable findings were reported in another study [101], who identified an upper limit of iBP value of 30 mmHg after MSA in a cohort of asymptomatic patients. Despite these individuals were typically diagnosed with postoperative EGJ outflow obstruction based on these elevated pressure values, they exhibited favorable clinical outcomes. This suggests that the conventional diagnostic criteria for EGJ outflow obstruction may not fully capture the complex physiological changes induced by MSA and associated procedures, and that the clinical relevance of these pressure alterations requires further investigation.

The overall clinical implication of these studies is that it is crucial for patients undergoing MSA to exhibit an adequate esophageal contractility or a sufficient peristaltic reserve to counteract the resistance

created by the MSA device and the fibrous capsule that forms around it. While pneumatic dilation can be an effective treatment option for patients who continue to experience postoperative dysphagia, in some cases, removal of the MSA device may be necessary [40]. Preoperatively identifying manometric abnormalities appears to be a valuable strategy for categorizing patients who are at a higher risk of developing persistent dysphagia. A robust peristaltic reserve, as indicated by the DCI after multiple rapid swallows, seems to be associated with a lower likelihood of dysphagia following MSA implantation [102]. In the multicenter study by Baisson et al. [103] involving 210 patients (105 with ineffective esophageal motility-IEM and 105 without), several independent risk factors were identified for the need of endoscopic dilation or MSA device removal. These factors included age over 45 years, preoperative dysphagia, MSA device size smaller than 15 beads, and less than 40% intact swallows on preoperative manometry. Importantly, all patients who required device removal had a DCI of less than 200 mmHg and less than 20% intact swallows. In another study by Ayazi et al. [104] encompassing 475 patients, independent risk factors for dysphagia were found to be a DCI of less than 750 mmHg, distal wave amplitude less than 42 mmHg, and less than 80% peristalsis. Additionally, patients who received size 13–14 MSA devices had significantly higher IRP, higher distal contraction amplitude, and higher DCI compared to those who received size 15–17 devices. These findings underscore the need for further prospective studies with high-quality pre- and postoperative HRM data. Such studies are essential to better understand the thresholds of baseline physiological impairment that can still be effectively treated with MSA. Indeed, the innovative design of the MSA poses unique challenges to the ability of the patient to adapt to the implant. *Ex vivo* studies have shown that the efficacy of the MSA depends on its ability to prevent effacement and to open the LES when challenged by gastric distention [30]. The physical properties of the magnets, which are subjected to the Coulomb law, are different from that of native tissues made of collagen and elastin. Therefore, resistance to reflux is maximal at rest and decreases exponentially when the food bolus opens the MSA, the distance between beads increases, and the device is capable of nearly doubling its diameter. While the magnetic beads maintain their ability to open within the fibrous capsule that surrounds the MSA device, the capsule itself may exert an additional LES augmenting force [105].

Impedance planimetry assessed via the functional lumen imaging probe (FLIP) constitutes a contemporary technique for real-time assessment of esophagogastric junction (EGJ) and esophageal wall distensibility. Although the role of FLIP technology in the preoperative assessment of patients being considered for antireflux surgery has yet to be ascertained [106], intraoperative FLIP is efficiently employed to evaluate the tightness of an antireflux repair by quantifying EGJ compliance and identifying optimal distensibility ranges. Intraoperative FLIP measurements have revealed that crural repair is a pivotal factor leading to a reduction in EGJ compliance [107]. Multiple investigations have documented the association between diverse fundoplication modalities and intraoperative FLIP distensibility parameters, as well as the link between the esophagogastric junction distensibility index (EGJ-DI) and patient-reported outcomes, particularly postoperative dysphagia [108,109]. The standardization of intraoperative FLIP procedures is of utmost importance to enhance the interpretation and generalizability of data, potentially leading to improved clinical outcomes [110]. Wu et al. [111] carried out a retrospective study that compared the outcomes of patients who underwent MSA or fundoplication and were followed up for 1–2 years. The esophageal cross-sectional area, minimum diameter, and EGJ-DI were found to be lower following MSA in comparison to Nissen and Toupet fundoplication. However, the postoperative GERD-HRQL, Reflux Symptom Index (RSI), and dysphagia scores were comparable. A recent meta-analysis [112] of EndoFLIP measurements in healthy and asymptomatic individuals suggested the use of an EGJ-DI cut-off value of $> 2 \text{ mm}^2/\text{mmHg}$ for clinical practice. This recommendation aligns with the findings of Su et al.

[113], who reported that a $\text{DI} < 2.0 \text{ mm}^2/\text{mmHg}$ was associated with an elevated risk of postoperative gas-bloat and dysphagia following fundoplication. Despite the lower DI observed with MSA, the quality of life at 1–2 years post-procedure was not significantly different from that of fundoplication [114]. The implementation of standardized intraoperative protocols and the utilization of normative FLIP values may aid in comprehending MSA biomechanics, calibrating the surgical technique, and optimizing patient outcomes [115].

10. Conclusions

The MSA procedure was devised to fulfill the needs of patients with inadequate response to medical management and those in the early stages of GERD who are generally not regarded as suitable candidates for fundoplication. This procedure has demonstrated significant efficacy in reducing symptoms and esophageal acid exposure, particularly when performed alongside systematic crural reinforcement. New data from HRM and FLIP measurements appear to enhance our understanding of physiology, refine patient selection criteria, and optimize procedural outcomes. Eventually, upcoming randomized trials may determine the disease severity threshold at which MSA is comparable to or outperforms fundoplication. Such data may contribute to better define the concept of personalized antireflux surgery.

CRedit authorship contribution statement

Quan Wang: Writing – review & editing, Visualization, Methodology, Data curation. **Luigi Bonavina:** Writing – review & editing, Writing – original draft, Visualization, Validation, Software, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization.

Declaration of competing interest

As associate editor, Luigi Bonavina recused himself from all review process related to this article to ensure the fairness and objectivity of the review. The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

Quan Wang is supported in part by the China Scholarship Council (CSC) program_Visit Scholarship (CSC_NO. 202408610128), and is official visit scholar in the Department of Biomedical Sciences for Health, University of Milan.

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