Review

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Real-world evidence with magnetic sphincter augmentation for gastroesophageal reflux disease: a scoping review

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Summary
Background The burden of gastroesophageal reflux disease (GERD) is high, with up to 30% of the Western population reporting reflux-related symptoms with or without hiatal hernia. Magnetic sphincter augmentation (MSA) is a standardized laparoscopic procedure for patients who are dissatisfied with medical therapy and for those with early-stage disease who would not usually be considered ideal candidates for fundoplication. The MSA device is manufactured in different sizes and is designed to augment the physiologic barrier to reflux by magnetic force.
Methods An extensive scoping review was performed to provide a map of current evidence with respect to MSA, to identify gaps in knowledge, and to make recommendations for future research. All the authors contributed to the literature search in PubMed and Web of Science and contributed to summarizing the evidence.
Results Magnetic sphincter augmentation, especially in combination with crural repair, is effective in reducing GERD symptoms, proton pump inhibitor use, and esophageal acid exposure, and in improving patients' quality of life. Safety issues such as device erosion or migration have been rare and not associated with mortality. The MSA device can be removed laparoscopically if necessary, thereby preserving the option of fundoplication or other therapies in the future. Contraindication to scanning in high-power Tesla magnetic resonance systems remains a potential limitation of the MSA procedure. High-resolution manometry and functional lumen imaging probes appear to be promising tools to predict procedural outcomes by improving reflux control and reducing the incidence of dysphagia.
Conclusion A consensus on acquisition and interpretation of high-resolution manometry and impedance planimetry data is needed to gain better understanding of physiology, to improve patient selection, and to pave the way for a personalized surgical approach in antireflux surgery.

Keywords Lower esophageal sphincter augmentation · Hiatus hernia repair · High-resolution manometry · Functional lumen imaging probe · Barrett's esophagus

Main novel aspects

- Indications and standard practices of magnetic sphincter augmentation have evolved over time, but there is still limited evidence regarding predictors of success and long-term outcomes.
- Knowledge of esophageal physiology and an appropriate management pathway in a multidisciplinary context are important for satisfactory outcomes.
- Individualized approach is an emerging concept that may change the future scenario of antireflux surgery.

Introduction

Current therapy for gastroesophageal reflux disease (GERD) is frequently reported to be less than satisfactory by patients, gastroenterologists, and surgeons. About 40% of patients are resistant or only partially respond to proton pump inhibitor (PPI) therapy [1, 2], and even doubling the dose may be inadequate to relieve regurgitation and improve quality of life. Therapy with PPI does not have any direct pharmaco-

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logic impact on the dynamics of the antireflux barrier. Persistent nonacid reflux and nocturnal acid breakthrough can still occur despite maximal PPI therapy, and may lead to volume regurgitation with pulmonary aspiration and Barrett's metaplasia, the major risk factor for esophageal adenocarcinoma [3, 4]. In addition, there are growing concerns over the long-term consequences of chronic acid suppression (reduced vitamin B12 and magnesium absorption, interaction with clopidogrel, risk of *Clostridium difficile* infection, hypergastrinemia, enterochromaffin-like cell hyperplasia, parietal cell hypertrophy leading to rebound acid hypersecretion, and even the risk of gastric cancer) [5–7].

Surgical therapy has the potential to cure GERD by reinforcing both components of the antireflux barrier, i.e., the lower esophageal sphincter (LES) and the crural diaphragm (CD). Because of equivocal evidence and the lack of robust and high-quality randomized trials, current guidelines suggest that the choice of an antireflux procedure should be left to the discretion of the individual surgeon and be best suited to the individual patient [8–10]. Laparoscopic Nissen fundoplication remains the current reference gold standard and has been shown to be safe, effective, and durable when performed in specialized centers [11]. Systematic reviews and meta-analyses [12], randomized clinical trials [13], and recent recommendations [14] suggest that the Toupet fundoplication provides equivalent results in terms of reflux control and a lower rate of side effects compared to Nissen fundoplication.

Despite the remarkably low morbidity and mortality rates [15], fundoplication is underused due to the perception of failure and side effects associated with this operation. Also, variability in clinical outcomes related to interindividual practice and surgical expertise [16] has limited the adoption of this procedure, especially in patients with early-stage GERD. Patients undergoing Nissen fundoplication are especially at risk for potential side effects of the procedure such as bloating, an inability to belch and vomit, and the occurrence of persistent dysphagia that may require revisional surgery [17]. These are the main reasons why gastroenterologists tend to refer for fundoplication only patients with long-lasting severe disease and large hiatal hernias. A decline in the use of surgical fundoplication has been noted in the US over the past decade [18–20]. Further, early recognition and treatment of GERD in young patients is critical to prevent long-term complications, even in patients under continuous acid-suppressive medication [21]. Paradoxically, underuse of antireflux procedures is in contrast to the increasing recognition of GERD as a progressive disease leading to carditis, cardiac metaplasia, intestinal metaplasia, and eventually adenocarcinoma of the distal esophagus [22, 23]. However, the limitations of both PPI therapy and fundoplication have led many patients to either tolerate life-time drug dependence and incomplete symptomatic relief, or to undertake the risk of a surgical procedure that alters gastric anatomy, may have side effects, and may deteriorate over time.

Concept and clinical application of the MSA procedure

Magnetic sphincter augmentation (MSA-Linx™ Reflux Management System; Johnson & Johnson, New Brunswick, NJ, USA) is a minimally invasive procedure designed to provide a permanent solution to GERD. The Linx procedure can be used with the intent to prevent progression of early-stage GERD or to treat more advanced disease associated with hiatus hernia [24]. The Linx is a mechanical device designed to augment the physiologic barrier to reflux by magnetic force. The device consists of individual neodymium iron boron magnets hermetically sealed within titanium casings and is currently manufactured in different sizes, from 13–17 beads. The beads are interlinked with independent titanium wires to form a flexible and expandable ring. At rest, each bead is in contact with adjacent beads in a Roman arch configuration. The beads can move independently of the adjacent beads, creating a dynamic implant that does not compress the esophagus and does not limit its range of motion upon swallowing, belching, or vomiting. Rather, the Linx device prevents reflux by limiting distension of the esophagogastric junction and preventing LES shortening and effacement in response to challenges of intra-gastric and intra-abdominal pressure [25–28]. Separation of the beads occurs when intragastric pressure overcomes the magnetic attraction force and is independent of the number of beads. The Linx, while augmenting the LES, allows for expansion to accommodate a swallowed bolus or the escape of elevated intra-gastric pressure associated with belching or vomiting. During the healing process after implantation, the device is encapsulated in fibrous tissue but is not incorporated into the esophageal wall [29], which makes it possible to remove the device without damaging the esophagus. The fibrous capsule exerts an additional LES-augmenting force. The Linx has recently received magnetic resonance imaging (MRI) approval for scanning in systems up 1.5 T.

The preoperative assessment of patients who are candidates for a Linx procedure is essentially similar to any other antireflux intervention. Routine testing includes a barium swallow study, upper gastrointestinal endoscopy with biopsies, esophageal manometry, and esophageal pH or pH-impedance monitoring [30]. In patients with atypical symptoms and/or borderline objective criteria for diagnosis, further assessment for gastric emptying disorders, rumination, cannabis use, irritable bowel syndrome, and small intestinal bacterial overgrowth may be necessary to exclude a functional etiology; also, psychological profile evaluation is recommended in selected individuals. Patients with known allergies to titanium or nickel, those with au-

toimmune disorders, and those who require surveillance MRI should not be considered for the Linx procedure.

Compared to fundoplication, the Linx procedure in patients without hiatus hernia requires minimal dissection and potential preservation of the phrenoesophageal ligament [25]. The procedure is performed under general anesthesia using a standard laparoscopic approach. There are no available data supporting the use of single-port access, three-dimensional camera, or robotics for performance of the Linx procedure. Surgical dissection begins by dividing the peritoneum on the anterior surface of the gastroesophageal junction below the insertion of the inferior leaf of the phrenoesophageal ligament and above the junction of the hepatic branch to the anterior vagus nerve. The lateral surface of the left crus is dissected from the posterior fundic wall without dividing the short gastric vessels. The gastrohepatic ligament is opened above and below the hepatic branch of the anterior vagus nerve to facilitate preparation of the retroesophageal window. Gentle dissection from the right side is made towards the left crus just above the crural decussation to identify the posterior vagus nerve. The esophagus is suspended with a Penrose drain, and a tunnel is created between the vagus and the esophageal wall (Fig. 1). A sizing tool consisting of a soft white magnetic tip actuated through a handset is used to determine the appropriate size of the Linx device to be implanted. The handset contains a numerical indicator that corresponds to the size range of the device. The sizing tool is placed through the tunnel dissected between the esophageal wall and the posterior vagus nerve bundle. 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 is free to move up and down along the esophageal wall, and sizing up 1 bead if there is no movement (Fig. 2). As confirmation, the sizer can be incrementally closed until the magnetic tip pops off, followed by sizing up by 2 or 3 beads [31]. The Linx device of appropriate size is introduced through the tunnel and the opposing ends are brought to the anterior surface of the esophagus and simply connected together by engaging the two clasps (Fig. 3). The decision to proceed with formal crural repair depends on the severity of GERD as assessed preoperatively and the presence of a hiatal hernia as confirmed intraoperatively. If in doubt, division of the phrenoesophageal ligament and full mediastinal dissection is recommended to obtain an adequate and tension-free length of intraabdominal esophagus (Fig. 4).

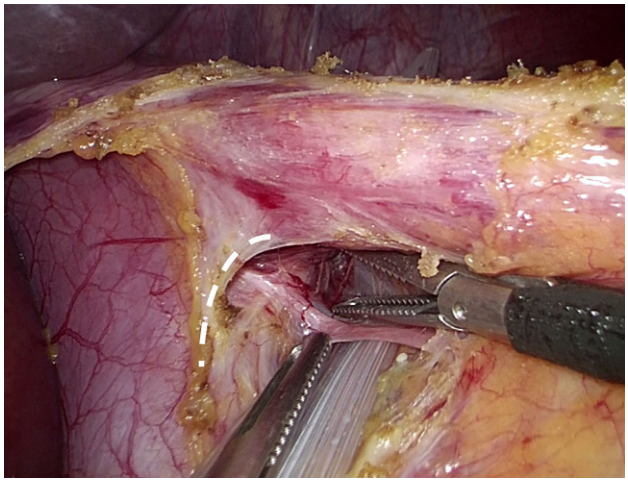

Fig. 1 Laparoscopic view of the retroesophageal window after limited dissection. A tunnel is made between the posterior vagus nerve and the esophageal wall

Patients are usually discharged the same day of surgery or on the first postoperative day after obtaining a chest film to check the position of the Linx device (Fig. 5). Patients are counselled to chew well, eat five small-volume meals during the day, and to gradually discontinue PPI therapy. Dysphagia is considered normal during the first 3 months after surgery, with a peak generally occurring between the third and the sixth postoperative week. In such circumstances, a temporary switch to a semiliquid diet is recommended. Persistent dysphagia may occasionally require a short course of steroids and/or endoscopic pneumatic dilation [32–35].

Methods

An extensive scoping review was conducted up to November 1, 2022, to provide a map of the current evidence with respect to MSA and to identify gaps in knowledge. All the authors contributed to the literature search in PubMed and Web of Science and contributed to summarizing the evidence. Both observational and randomized studies were considered eligible for inclusion.

Results

A total of 77 original articles were retrieved. Only one was a randomized trial comparing MSA and PPI use. Assessment of clinical outcomes was based on subjective (symptom scores, quality of life metrics, change in PPI use) and objective criteria (radiological, endoscopic, manometric, pH or pH-impedance parameters). Adverse events requiring reoperation or endoscopic dilation were noted.

Early and intermediate-term outcomes

The MSA feasibility study included 44 patients implanted between February 2007 and October 2008; the short-term, mid-term, 4-year, and final results of this study have been published previously [25, 36–38]. Patients served as their own control to assess the effect of treatment on symptoms, PPI use, and esophageal acid exposure. The primary criteria

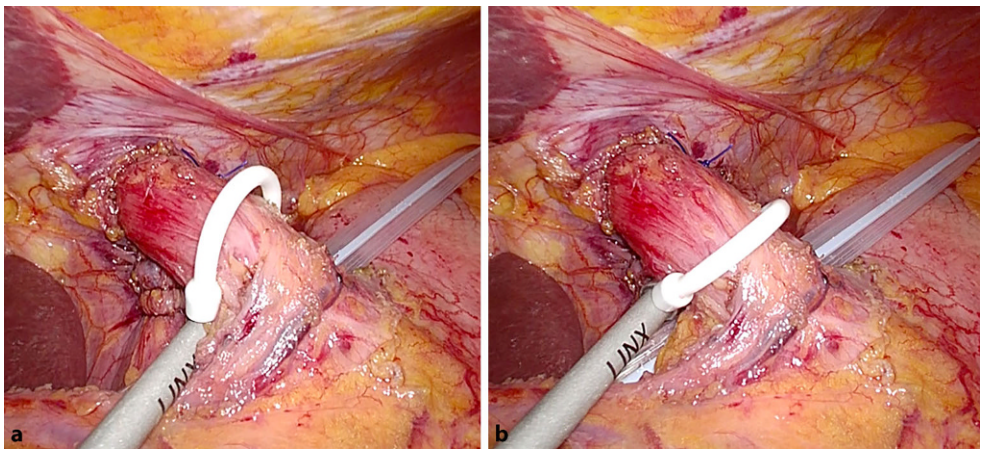

Fig. 2 The loop of the sizer is closed non-compressively around the esophagus (**a**), gently tilted (**b**), and then opened until the magnetic tip pops off to decide the most appropriate number of device beads

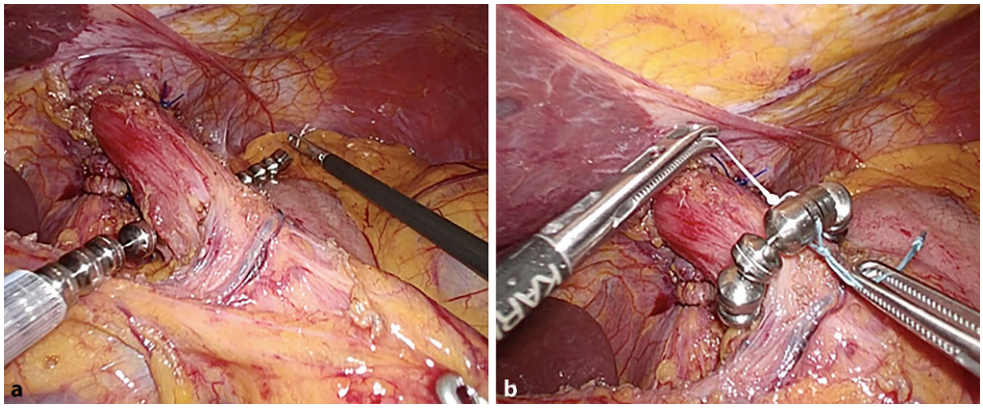

Fig. 3 The Linx device (Johnson & Johnson) is introduced through the tunnel around the esophagus and the clasps are engaged on the anterior surface of the esophagus

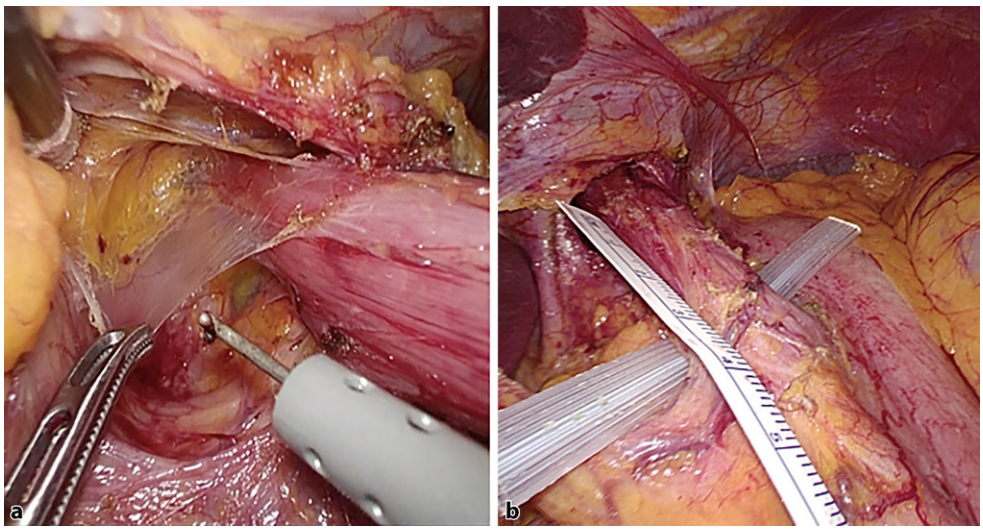

Fig. 4 Full mediastinal dissection is required in most patients to obtain an adequate and tension-free length of intraabdominal esophagus

for inclusion in the feasibility trial were age >18 and <85 years, typical reflux symptoms at least partially responsive to PPI therapy, abnormal esophageal acid exposure, and normal contractile amplitude and wave form in the esophageal body. The primary criteria for exclusion were history of dysphagia, previous upper abdominal surgery, previous endoluminal antireflux procedures, sliding hiatal hernia >3 cm, esophagitis >grade A, and/or the presence of histologically documented Barrett's esophagus. Patients with abnormal manometric findings (distal esophageal contraction amplitude of less than 35 mm Hg on wet swallows or <70% propulsive peristaltic sequences) were also excluded. All Linx devices were successfully implanted via a laparoscopic approach, and the median operative time was 40 min. Patients were instructed to resume a regular diet after a chest film and radiological assessment of the esophageal transit had been

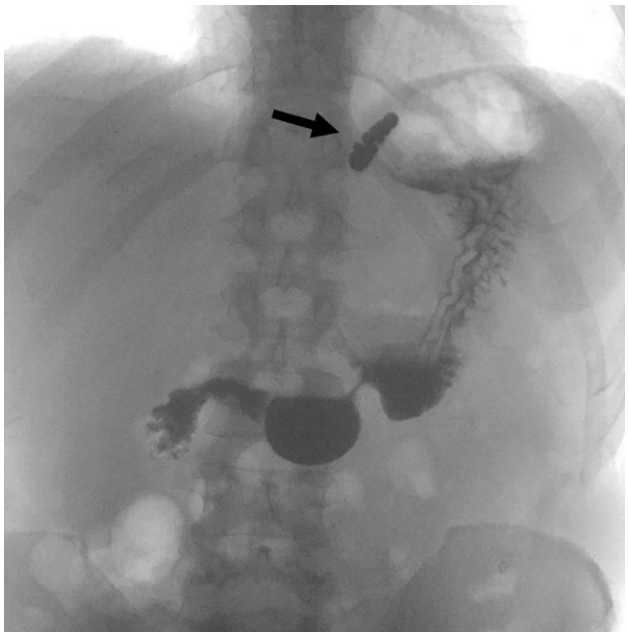

Fig. 5 Typical radiological appearance of the Linx device (Johnson & Johnson) on the first postoperative day

performed. Of all patients, 43% complained of mild postoperative dysphagia that resolved by 90 days without treatment. In the study, 33 patients (75%) were followed up to 5 years. The mean total GERD-HRQL score off PPI significantly decreased from 25.7 at baseline to 2.9, and 94% of patients had a greater than 50% reduction in the total score compared to baseline. Complete cessation of PPI or a reduction of 50% or more of the daily dose was achieved by 88% and 94% of patients, respectively, and 91% of patients declared to be satisfied with their outcomes. Esophageal pH testing was completed in 20 patients at 5 years: 85% of patients achieved either normal esophageal acid exposure or had at least a 50% reduction from baseline, and 70% of patients achieved normalization of the pH profile. Three patients were explanted: one because of persistent dysphagia, one because of the need to undergo MRI, and the last one elected to have a Nissen fundoplication for persisting GERD symptoms. All removals were safely performed via laparoscopy.

Similar rigorous inclusion criteria and perioperative subjective and objective assessment were used for a larger multi-institutional study involving 100 patients at 13 centers [39]. Significant improvements were seen in GERD-related quality of life, regurgitation, and esophageal acid exposure. Use of PPI dropped to 13% at 3 years and patient satisfaction with reflux control increased to 94% after implantation. Importantly, these positive results were stable, showing no degradation over the study time period. Although 14% of patients reported bloating after implantation, no patients rated this symptom as severe. Patients retained their ability to belch and vomit. Dysphagia was present to some extent in 68% of patients but decreased to 4% by 3 years. Dysphagia was rated as severe by 5% of patients and the device was removed in 3 of them with complete symptom resolution.

Subsequent single-center studies further validated the efficacy of the Linx procedure. In Milan, Italy, 100 consecutive patients underwent Linx implantation between 2007 and 2012. Median implant duration was 3 years. There was a significant reduction in acid exposure time and improvement of GERD-HRQL score; freedom from daily dependence on PPI was achieved in 85% of the patients [40]. Additional published data [41–46] confirmed similar satisfactory results. Importantly, a 1-year randomized clinical trial comparing the Linx procedure with PPI showed the superiority of Linx in controlling moderate to severe regurgitation and reducing esophageal acid exposure [47]. However, in another study, body mass index $>35\,kg/m^2$, presence of Hill 2 or worse valve competency, and a manometrically defective LES had a negative association with good outcome [48]. A few studies investigating the efficacy of MSA in patients with laryngopharyngeal reflux and/or weakly acidic reflux found that this procedure is effective in carefully selected individuals [49, 50]. Patients with the highest preoperative scores of the Reflux Symptom Index questionnaire had the best response to antireflux surgery [51].

Observational studies found comparable control of reflux symptoms after surgical fundoplication or Linx implant. However, in the Nissen fundoplication group there was a higher rate of patients with inability to belch and vomit, along with more severe gas-bloat symptoms, whereas quality of life scores were similar in patients treated either by Linx or Toupet fundoplication [52–59]. Magnetic sphincter augmentation also proved effective in patients with severe GERD [60–62]. Two meta-analyses comparing Linx and fundoplication reported that the former was associated with less gas-bloat symptoms and an increased ability to vomit and belch, while PPI suspension rate, dysphagia requiring endoscopic dilatation, and GERD-HRQL were similar in the two patient groups [63, 64].

The short- and intermediate-term results of the Linx procedure combined with systematic crural repair appear more favorable compared to Linx alone regardless of the size of hiatus hernia [65–70]. A multivariable logistic regression analysis confirmed that full mediastinal dissection with restoration of intraabdominal esophageal length and formal crural repair was most likely to normalize esophageal acid exposure (point estimate 1.73; 95% confidence interval 1.15–8.19; $p=0.02$) [71]. Last but not least, regression of Barrett's esophagus was observed in 72% of patients at 1 year after Linx implant; interestingly, patients with short-segment intestinal metaplasia in whom esophageal acid exposure reversed to normal were more likely to achieve regression [72, 73].

Long-term outcomes

A retrospective single-center review of 553 patients [74] showed that the factors associated with a favorable outcome of the Linx procedure are age younger than 45 years, male sex, GERD-HRQL > 15, and an abnormal DeMeester score. Ferrari et al. [75] provided 6–12-year outcome data in 124 patients implanted with Linx at a single institution and followed for a median of 9 years. The mean GERD-HRQL score decreased from 19.9 to 4.01 at the latest office visit, the prevalence of grade 2–4 regurgitation decreased from 59.6 to 9.6%, and 79% of patients discontinued PPI use. The mean percent time pH < 4 decreased from 9.7 to 4.2% ($p < 0.001$). Four patients who had received radiofrequency ablation treatment for Barrett's esophagus without dysplasia before the Linx implant and had esophageal acid exposure normalized after surgery were followed for up to 8 years without recurrence of intestinal metaplasia. Predictors of a favorable outcome were age at intervention < 40 years and total GERD-HRQL score > 15.

Safety profile of the MSA procedure

Safety issues with MSA have been rare and not associated with mortality. An analysis of the safety profile of the first 1000 implants worldwide in 82 hospitals showed a 1.3% hospital readmission rate, 5.6% need of postoperative endoscopic dilation, and a 3.4% reoperation rate [76]. All reoperations were performed electively for device removal. The most common symptoms were dysphagia and recurrence of reflux symptoms. In addition, 7% of patients enrolled in the US multicenter single-arm trial had the device removed due to persistent dysphagia in four, vomiting in one, chest pain in one, and reflux in one [77]. Another study from the MAUDE database, including 3283 patients operated between 2012 and 2016, reported a 2.7% removal rate; 88% of the removals occurred within 2 years after implantation [78]. In a retrospective series of 268 patients who received MSA implantation and were followed for 23 months, 2% of patients required reoperation commonly due to recurrent hiatal hernia; 1% of patients required endoscopic dilation, and the Linx device size ≤ 13 was the only factor associated with postoperative dysphagia [79]. Asti et al. reported the results of reoperations for laparoscopic Linx removal in a series of 164 consecutive patients [80]. The reoperation rate was 6.7%. The main presenting symptoms requiring device removal were recurrence of heartburn or regurgitation in 46%, 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 occurred. The median implant duration was 20 months and 82% of the patients were explanted between 12 and 24 months after the index operation. Operative time ranged from 25 to 150 min and postoperative course was uneventful. At the latest follow-up (12–58 months), the GERD-HRQL score was normalized in all patients. Exuberant scar tissue that forms a constrictive capsule around the device [81] and variations in positioning and sizing of the MSA may account for persistent dysphagia ([82]; Fig. 6). It should be noted that at the time of introduction of MSA in clinical practice, there was a size 12 Linx device. Subsequent analysis of the manufacture's database found that the majority of erosions were associated with size 12, which is no longer available [83, 84].

High-resolution manometry and impedance planimetry findings

The mechanism of action and the long-term physiologic effects of MSA on esophageal motility and wall compliance are not completely understood due

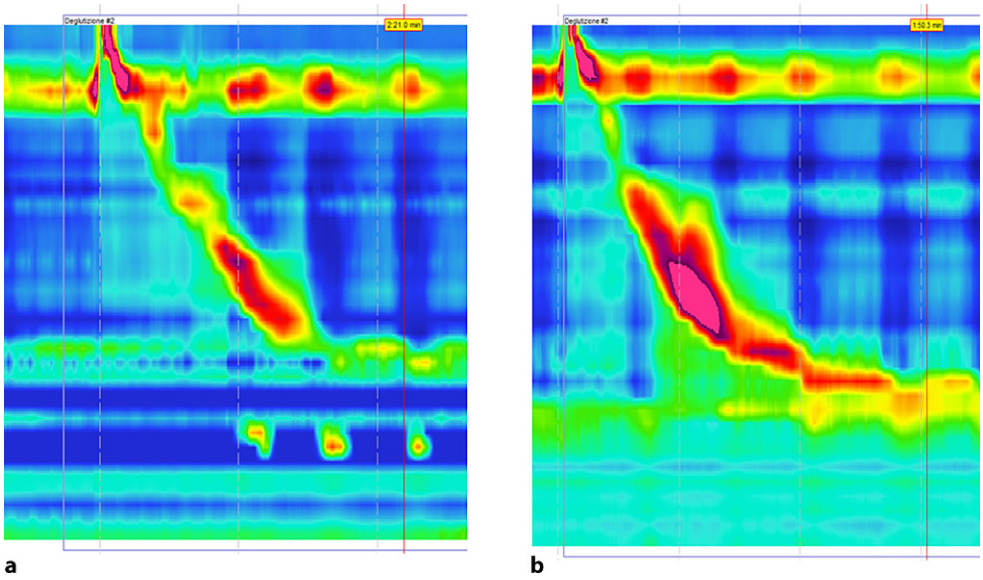

Fig. 6 High-resolution manometry findings before (**a**) and 1 year after (**b**) Linx implant showing restoration of intraabdominal lower esophageal sphincter length and increase of distal contractile integral (DCI)

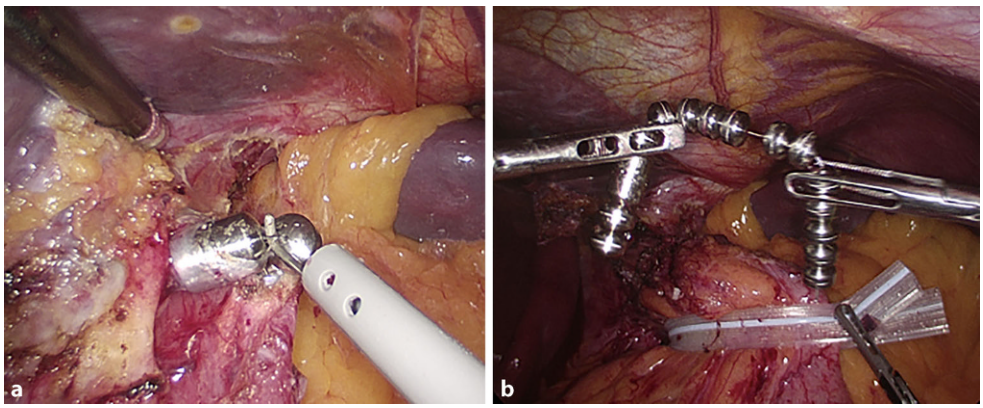

Fig. 7 Laparoscopic removal of the Linx device: **a** the titanium wire between two adjacent beads is divided using electrocautery or harmonic scalpel after incision of the fibrous capsule; **b** the device is completely removed

to the relative paucity of objective high-resolution manometry (HRM) and functional luminal imaging probe (FLIP) data available in the literature. In a retrospective cohort study by Riva et al. [85], 45 patients implanted with MSA underwent HRM at a mean follow-up of 12 months. There was a significant increase of LES length, integrated relaxation pressure (IRP), intrabolus pressure (iBP), and esophagogastric contractile integral (EGJ-CI). Also, all parameters of esophageal contractility such as distal esophageal amplitude (DEA), mean distal contractile integral (DCI), and percentage of normal swallows significantly increased after MSA. Interestingly, ineffective esophageal motility (IEM) reversed to normal motility in 36% of cases. None of these manometric features were associated with postoperative dysphagia, which correlated only with the presence of dysphagia at baseline (Fig. 7). The effect of MSA on the esophagogastric junction (EGJ) profile was also investigated by Ayazi et al. [86] in a retrospective study including 100 patients with a mean follow-up of 14.9 months. They found an increase of the overall and intraabdominal length of LES ($p<0.001$), and also an increase of mean resting LES pressure ($p<0.001$), IRP ($p<0.001$), and iBP ($p<0.001$). The higher postoperative IRP values correlated with normalization of distal esophageal acid exposure and with a significant decrease of the DeMeester score, suggesting that the increased outflow resistance at the EGJ prevents reflux. Esophageal peristalsis and bolus clearance remained unchanged after MSA.

Siboni et al. [87] conducted a retrospective study in patients who were free of reflux and dysphagia after MSA. These patients were assessed at a median follow-up of 13 months. Interestingly, both the upper limit of IRP and the upper limit of iBP were above the reference values of the Chicago Classification v. 3.0. The values were found to be even higher when a formal crural repair was associated with MSA implantation. Similar results were reported by Ayazi et al. [88], who found a 30 mm Hg upper limit of the iBP value after MSA in a cohort of asymptomatic patients. These individuals, who would usually be diagnosed with postoperative EGJ outflow obstruction, had good clinical outcomes.

The clinical implication of these studies is that patients should have sufficient contractility or peristaltic body reserve to overcome the resistance imposed by the MSA and its surrounding fibrous capsule. Although pneumatic dilation is effective in 67% of patients with persistent postoperative dysphagia, some of these may require removal of the MSA device [32]. Preoperative identification of manometric abnormalities would be useful to stratify patients with an increased risk of persistent dysphagia. Dominguez-Profeta et al. [89] found that adequate peristaltic reserve using the DCI after multiple rapid swallows correlated with a decreased incidence of dysphagia following MSA implantation. In a multicenter study including 210 patients, 105 with IEM and 105 without IEM, Baison et al. [90] found that age >45 years, preoperative dysphagia, MSA size <15 beads, and <40% intact swallows on preoperative manometry were independent risk factors for the need of endoscopic dilation or device removal. All patients requiring removal had a DCI<200 mm Hg and <20% intact swallows. Ayazi et al. [91], in a study including 475 patients, reported that DCI<750 mm Hg (odds ratio [OR] 4.81, $p=0.007$), distal wave amplitude ≤42 mm Hg (OR 4.28, $p=0.030$), and <80% peristalsis (OR 2.54, $p=0.030$) were independent risk factors for dysphagia. Interestingly, patients receiving size 13 or 14 devices had a significantly higher IRP and higher distal contraction amplitude and DCI compared to individuals who received sizes 15, 16, and 17. Further prospective studies with high-quality pre- and postoperative HRM data are definitely needed to understand the thresholds of baseline physiologic impairment that can still be effectively treated with MSA and to define more robust normal cutoff values after MSA implantation.

Impedance planimetry measured by functional lumen imaging probe (FLIP) is a modern technology for real-time evaluation of EGJ and esophageal wall distensibility (Fig. 8 and 9). While the role of FLIP in the preoperative work-up of patients who are candidates for antireflux surgery remains to be determined [92], intraoperative FLIP is effectively used to assess

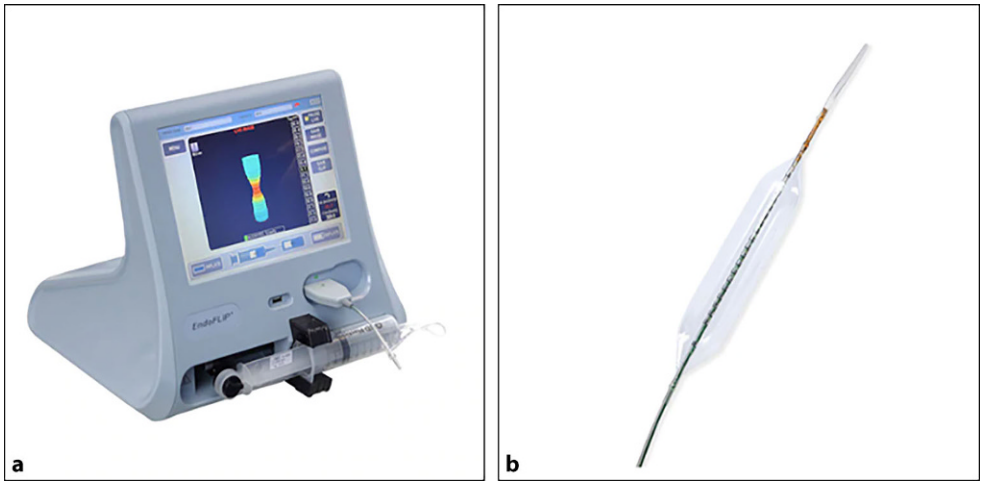

Fig. 8 Functional lumen imaging probe system (EndoFLIP™ 1.0 Impedance Planimetry System; Medtronic) (**a**) and measurement catheter (**b**). The software allows for a color-coded topographic display of the esophageal lumen

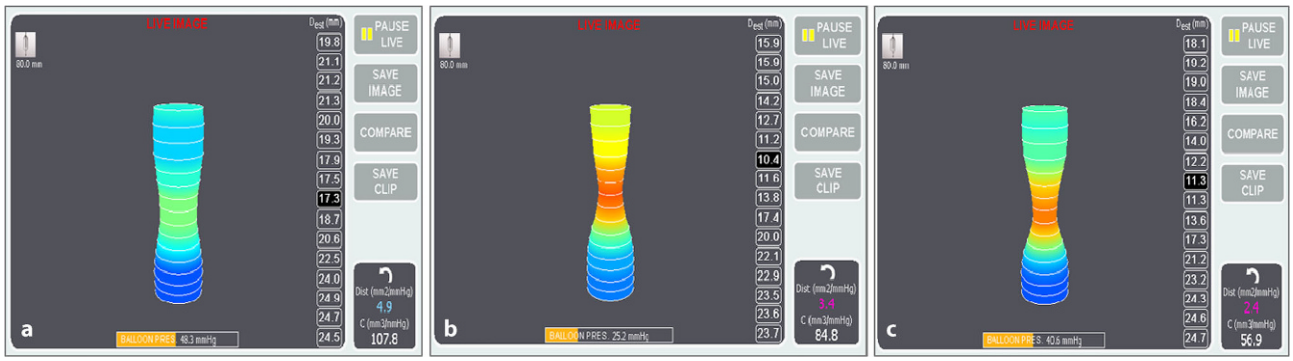

Fig. 9 Typical intraoperative EndoFLIP (EndoFLIP™ 1.0 Impedance Planimetry System; Medtronic) pattern of a patient with gastroesophageal reflux disease at baseline (**a**), after crural repair (**b**), and after magnetic sphincter augmentation implant (**c**)

the tightness of an antireflux repair by measuring EGJ compliance and ideal distensibility ranges. Intraoperative FLIP measurements showed that crural closure is the most important determinant of decreased EGJ compliance [93]. Several studies have reported the correlation between different types of fundoplication and intraoperative FLIP distensibility metrics, and the correlation between EGJ distensibility index (EGJ-DI) and patient-reported outcomes, especially postoperative dysphagia [94, 95]. Intraoperative standardization of FLIP is critical to improve the interpretation and generalizability of data and may result in better clinical outcomes [96]. Wu et al. [97] conducted a retrospective study comparing the outcomes of patients undergoing MSA or fundoplication who were followed for 1–2 years. The esophageal

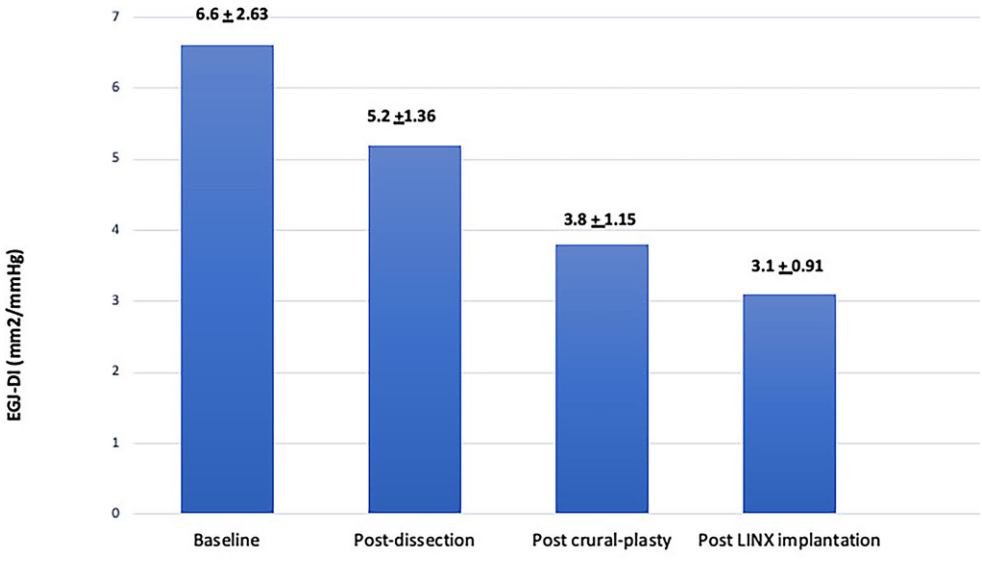

Fig. 10 Change of esophagogastric junction distensibility index at various intraoperative timepoints in 6 patients. Values are expressed as mean ± SD. *Linx* MSA-Linx™ Reflux Management System (Johnson & Johnson). (Data from the authors' experience)

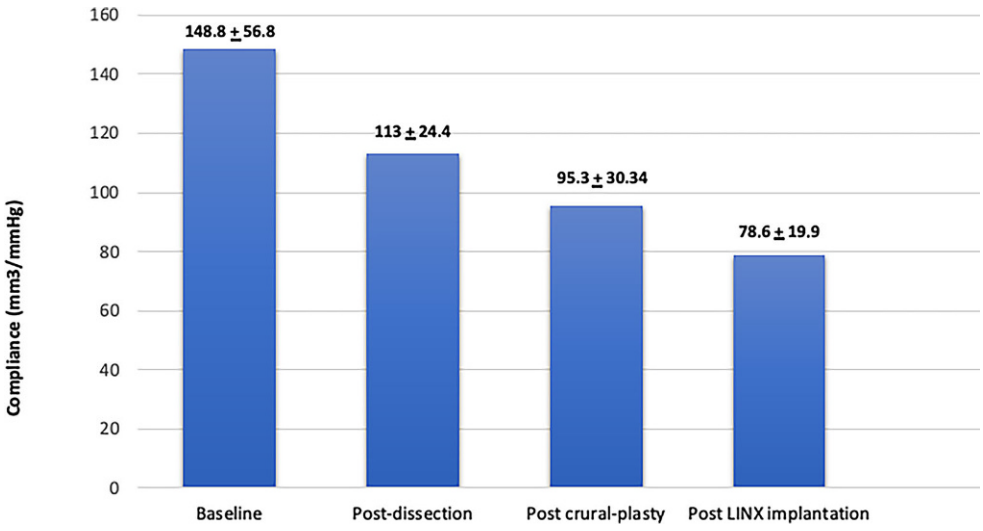

Fig. 11 Change of compliance at various intraoperative timepoints in 6 patients. Values are expressed as mean ± SD. *Linx* MSA-Linx™ Reflux Management System (Johnson & Johnson). (Data from the authors' experience)

cross-sectional area, the minimum diameter, and the EGJ-DI were lower after MSA compared with Nissen and Toupet fundoplication, but postoperative GERD-HRQL, RSI, and dysphagia score were comparable among the groups. A recent meta-analysis of EndoFLIP (EndoFLIP™ 1.0 Impedance Planimetry System; Medtronic, Dublin, Ireland) measurements in healthy and asymptomatic subjects recommended using an EGJ-DI cut-off ≥ 2 mm^2/mm Hg for clinical practice [98]. This is consistent with the findings of Su et al. [99], who reported that a DI < 2.0 mm^2/mm Hg was associated with an increased risk of postoperative gas-bloat and dysphagia after fundoplication. Despite lower DI, quality of life with MSA at 1–2 years was not different from fundoplication [100]. The use of standardized intraoperative protocols and of normative FLIP values may help to understand MSA biomechanics, calibrate the surgical procedure, and optimize outcomes. Whether intraoperative use of EndoFLIP can help in choosing the appropriate MSA device size remains to be investigated (Fig. 10 and 11).

Conclusion

The MSA procedure was developed to address the unmet needs of patients with an unsatisfactory response to medical therapy and those with early-stage GERD who would not usually be considered ideal candidates for fundoplication. This procedure has proven highly effective in decreasing symptoms and esophageal acid exposure, especially if combined with systematic crural repair. More HRM and FLIP data are needed to improve the understanding of physiology, patient selection, and procedural outcomes. Also, randomized trials are awaited to establish at which stage of disease severity MSA may be equivalent or superior to fundoplication. This will pave the way for a more personalized and tailored antireflux surgery.

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Declarations

Conflict of interest C. Froiio, A. Tareq, V. Riggio, S. Siboni, and L. Bonavina declare that they have no competing interests.

Ethical standards All procedures performed in studies involving human participants or on human tissue were in accordance with the ethical standards of the institutional and/or national research committee (Internal review board approval: HSD 2022-173) and with the 1975 Helsinki declaration and its later amendments or comparable ethical standards. Informed consent was obtained from all individual participants included in the study.

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