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·特邀述评·

Novel technology for lower esophageal sphincter augmentation: indications and limits in current surgical practice

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Abstract Gastroesophageal reflux disease (GERD) is primarily driven by dysfunction of the lower esophageal sphincter (LES), allowing gastric contents to reflux into the esophagus and leading to symptoms, mucosal injury, and impaired quality of life. Traditional antireflux procedures such as Nissen, Toupet, and Dor fundoplication aim to reinforce the LES and restore the physiological and mechanical components of the antireflux barrier. Yet concerns regarding postoperative dysphagia, gas-bloat, durability, and long-term recurrence have limited their broader adoption. As advances in minimally invasive surgery have progressed, prosthetic LES augmentation devices-including the magnetic LINX™ system and the RefluxStop™ silicone implant-have emerged as reversible, anatomy-preserving alternatives designed to directly enhance sphincter competence while minimizing common complications. This review summarizes the functional anatomy of the esophagogastric junction, core principles of antireflux surgery, and the mechanisms underlying fundoplication failure. Evidence from short- and long-term studies demonstrates that both Magnetic Sphincter Augmentation (MSA) and the RefluxStop procedure effectively reduce acid exposure, improve GERD-related quality of life, and provide durable reflux control, even in patients with impaired esophageal motility or prior failed surgery. These techniques complement traditional fundoplication and offer expanding therapeutic opportunities for personalized GERD management. Continued refinement of patient selection, procedural technique, and long-term evaluation will help define the optimal role of LES augmentation within contemporary antireflux surgery.

Key words Gastroesophageal Reflux; Lower Esophageal Sphincter; LES Augmentation; Hiatal Hernia; Fundoplication; LINX Procedure; RefluxStop Procedure

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食管下括约肌增强的新型技术：当代外科实践中的适应证与局限性

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摘　要　胃食管反流病（GERD）主要由食管下括约肌（LES）功能障碍所致，使胃内容物反流入食管，从而引发反流症状、黏膜损伤并降低生活质量。传统的抗反流手术方式，如 Nissen、Toupet 及 Dor 胃底折叠术，旨在增强 LES 功能并重建抗反流屏障的生理与机械组成部分，但术后吞咽困难、胀气综合征、持久性不足及远期复发等问题，限制了其更广泛的应用。随着微创外科技术的不断发展，假体型 LES 增强装置——包括磁性 LINX™ 系统和 RefluxStop™ 硅胶植入物——作为可逆、保留解剖结构的新型替代方案应运而生，其设计目标是在直接增强括约肌功能的同时，尽可能减少常见并发症的发生。本文综述了食管胃结合部的功能解剖、抗反流手术的基本原理以及胃底折叠术失败的机制。来自短期及长期随访研究的证据表明，磁性括约肌增强术及 RefluxStop 手术均可有效降低食管酸暴露，改善 GERD 相关生活质量，并在食管动力障碍或既往抗反流手术失败的患者中仍能获得持久的抗反流效果。这些技术是对传统胃底折叠术的重要补充，为 GERD 的个体化治疗提供了更加丰富的选择。未来，通过进一步优化患者筛选、手术技巧及长期疗效评估，将有助于明确 LES 增强技术在现代抗反流外科中的最佳定位。

关键词　胃食管反流；食管下括约肌；括约肌增强；食管裂孔疝；胃底折叠术；LINX 手术；RefluxStop 手术

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Over the past decades, laparoscopic fundoplication has dominated the scenario of antireflux surgery and is still considered the gold-standard treatment for gastroesophageal reflux disease (GERD). Although the Nissen fundoplication (360° fundic wrap) is the most common procedure, both the Toupet (180°/270° posterior fundic wrap) and the Dor (90°/180° anterior fundic wrap) partial fundoplications have more recently emerged as suitable alternative options to augment the lower esophageal sphincter (LES). Clinical studies have shown that the outcomes of partial fundoplications compare favorably with those of the Nissen and that the risk of side-effects (dysphagia, gas-bloat syndrome, inability to belch and vomit) is minimal[1–2]. However, the long-term durability of fundoplication remains uncertain. This trend has contributed to a decline in laparoscopic antireflux surgery and has limited its widespread adoption among surgeons and gastroenterologists. As a result, it is often considered a last-resort option for patients with severe reflux symptoms or for those who partially respond or relapse after maximal proton-pump inhibitor (PPI) therapy[3-4]. The lack of surgical centralization, the limited availability of high-quality randomized trials, variable quality of patient-accessible online information, and concerns about postoperative adverse events have all contributed to fundoplication's limited reputation. In recent years, technological innovations have paved the way for novel laparoscopic procedures and prosthetic materials aimed at reinforcing the compromised antireflux barrier.

1　Functional anatomy of the esophagogastric junction (EGJ)

The American Foregut Society has recently revisited classical concepts regarding the anatomy and physiology of the antireflux barrier[5–6] and has proposed a novel endoscopic grading system to evaluate the competency of

the EGJ, primarily based on the axial length of hiatal hernia, the diameter of the hiatal opening, and the presence or absence of the gastroesophageal flap valve[7]. Evidence indicates that reflux symptoms and complications in patients with GERD are associated with anatomic and functional abnormalities involving not only the LES but also the crural diaphragm and the gastroesophageal flap valve. A defective antireflux barrier may be associated with a hypotonic or short LES, an altered geometry of the gastroesophageal flap valve/angle of His, and/or a hiatal hernia which may aggravate GERD by delaying clearance of the bolus and the refluxate from the herniated stomach. Based on these concepts, it is reasonable to consider that the fundoplication augments the LES, i.e. the physiological antireflux barrier, while the length of intra-abdominal esophagus, the gastroesophageal flap valve, and the crural diaphragm augment the mechanical antireflux barrier. Failure of the LES alone may potentially be repaired by fundoplication, whereas in patients with more severe and multiple defects all the physiological and mechanical components need to be fully restored to achieve adequate reflux control[8].

2 Physiological principles of fundoplication

The modern antireflux surgery was established after the serendipitous efforts of Rudolf Nissen and his key observation that plicating the gastric fundus around the esophagogastric anastomosis in an effort to prevent leakage was highly effective also in preventing esophagitis of the esophageal remnant. Almost simultaneously, Code and co-workers established the presence of the LES, a high-pressure zone in the distal esophagus that was identified as the major opponent of gastroesophageal reflux. GERD was then accepted as a disease entity independent of hiatal hernia, and the Nissen procedure was quickly adopted worldwide as the surgical procedure of choice. It has been speculated that fundoplication prevents gastroesophageal reflux by restoring the length and pressure of the LES and by reducing the distensibility of the distal esophagus and the number of transient sphincter relaxations [9-10]. A multicenter European trial comparing medical therapy with PPI and fundoplication performed in selected centers by expert surgeons showed that 92% of medical patients and 85% of surgical patients were in remission at 5 years of follow-up[11]. However, despite its remarkably low morbidity and mortality, fundoplication remains underutilized due to its perceived anatomical complexity[12] and risk of long-term side effects and/or recurrent reflux. Also, the variability of reported clinical outcomes have restricted the adoption of this procedure to patients with long-lasting refractory esophagitis or large hiatal hernias. In an effort to reduce the potential side-effects of the Nissen operation, the Toupet fundoplication has then emerged as a primary antireflux procedure in several institutions worldwide. Systematic reviews and Meta-analyses have shown that a partial fundoplication provides similar reflux control compared to Nissen fundoplication and can decrease the incidence of dysphagia, gas-bloating, and reoperations[13-14]. Use of the anterior Dor fundoplication may further minimize the risk of dysphagia since the intra-abdominal esophagus is not pushed forward or angulated by the fundic wrap[15]. No significant differences regarding side effects, reflux symptoms, and overall satisfaction at 10 years were found when comparing the outcomes of a 180° anterior fundoplication with the Nissen fundoplication. The reoperation rate was also lower with the Dor owing to a lower incidence of dysphagia and hiatal hernia. Supporting data for the anterior 90° or 120° partial fundoplication is less robust, with recurrent reflux being more common at 5-year follow-up[16-17].

3 Etiology of failed fundoplication

Antireflux surgery may fail for a variety of reasons, including inadequate preoperative assessment, suboptimal planning of a tailored surgical strategy, and technical errors that result in a malfunctioning fundoplication or insufficient crural repair. Early failures, particularly in cases of partial or large hiatal hernia, can also occur due to precipitating events such as postoperative coughing or retching, heavy lifting, abdominal straining, or trauma, all of which cause sudden increases in intra-abdominal pressure and disruption of the diaphragm or the fundoplication. Persistent dysphagia that may require revisional surgery can result from a wrap that is too tight or too long, lateral torsion caused by tension from intact short gastric vessels or a small fundus, a wrap constructed

with the gastric body rather than the fundus, or recurrent hiatal hernia. Long-term studies on antireflux surgery failures indicate that deterioration of the fundoplication and re-herniation rates increase over time due to weakness of the central tendon of the diaphragm and the left-lateral portion of the crura[18–19]. In addition, revisional antireflux surgery is ultimately required in up to 17% of patients[20]. Laparoscopic revision can be technically challenging and carries an increased risk of operative complications and recurrence, particularly in patients with previous failed repairs, the presence of non-absorbable mesh, or morbid obesity.

4 Prosthetic LES augmentation: rationale and clinical utility

Novel surgical procedures based on the use of prosthetic materials to augment the LES have emerged as an alternative to both the total and partial fundoplications in an attempt to achieve a better trade-off between reflux control and the risk of troublesome side-effects, and to increase the durability of the repair over time.

4.1 Technique and results of the LINX procedure

The Magnetic Sphincter Augmentation (MSA) procedure (LINX™) was originally designed to limit the technical variability of fundoplication in young patients with early progressive GERD[21]. The procedure is performed laparoscopically and consists of implanting a ring consisting of a variable number of magnetic beads to encircle the distal esophagus (Figure 1). When no hiatal hernia is present, only a limited surgical dissection with preservation of the phrenoesophageal ligament and the short gastric vessels is feasible. A randomized clinical trial comparing the LINX procedure with PPI showed the superiority of surgery in controlling moderate to severe volume regurgitation and in reducing esophageal acid exposure [22]. Further, real-world studies have shown that the LINX procedure performed in combination with crural repair is more effective in reducing GERD symptoms, PPI use, and esophageal acid exposure[23–24]. Contraindications to undergo scanning in high-power Tesla (>1.5 T) magnetic resonance (MR) systems remain a potential limitation of this procedure. Overall, safety issues have been rare and not associated with mortality. Explant of the MSA device and concomitant fundoplication may be necessary for persistent symptoms, device erosion, or for the need of MR imaging[25]. Twelve-year outcome data in patients implanted at a single institution and followed for a median of 9 years showed that the mean GERD-HRQL score decreased from 19.9 to 4.0 at the latest office visit, the prevalence of grade 2−4 regurgitation decreased from 59.6% to 9.6%, and 79% of patients discontinued use of PPI. The mean time pH<4 decreased from 9.7% to 4.2%. 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 a total GERD-HRQL score >15 [26]. Patients should have adequate esophageal contractility to overcome the resistance imposed by the LINX™ device and its surrounding fibrous capsule. Although pneumatic dilation is effective in about two-thirds of patients with persistent postoperative dysphagia, some of these individuals who develop excess scarring may require removal of the device. Preoperative identification of motility abnormalities at high-resolution manometry would be useful to stratify patients at increased risk of persistent dysphagia. Adequate peristaltic reserve after multiple rapid swallows correlated with decreased incidence of dysphagia following the LINX procedure[27]. In a multicenter study including 210 patients - half of them with ineffective esophageal motility diagnosed with high-resolution manometry - age >45 years, preoperative dysphagia, device size <15 beads, and <40% intact swallows on preoperative manometry were independent risk factors for postoperative endoscopic dilation or device removal. All patients requiring LINX removal had a distal contractile integral of <200 mmHg (1 mmHg= 0.133 kPa) and <20% intact swallows [28].

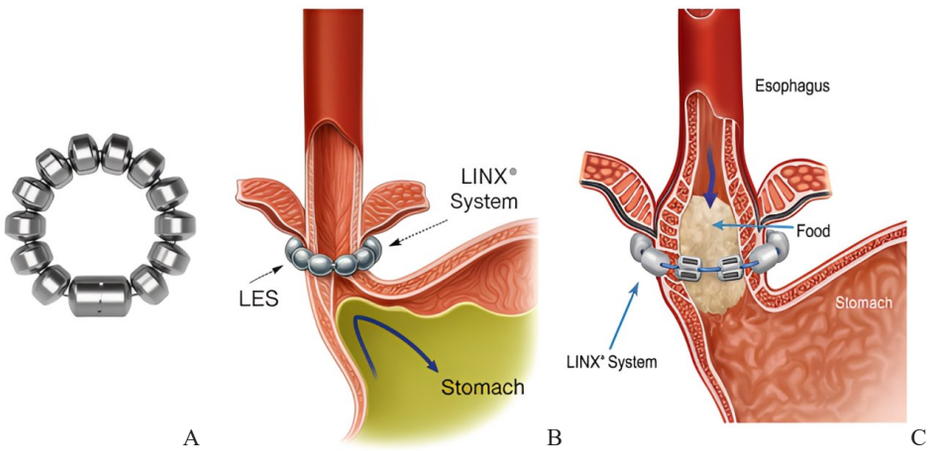

Figure 1 The LINX™ device and the rationale of the LINX procedure A: The Magnetic Sphincter Augmentation (MSA) device consists of a series of titanium-encased magnetic beads connected by independent titanium wires, forming a flexible ring; B: Schematic illustration of the LINX™ system positioned around the LES, showing how the prosthetic magnetic bead ring reinforces the LES while preserving physiological swallowing dynamics by allowing transient separation of the beads during bolus transit and subsequent reapproximation to prevent reflux; C: Functional depiction of the LINX™ system during bolus transit, showing that as food passes through the EGJ the magnetic beads momentarily separate to accommodate the bolus before reapproximating to restore the antireflux barrier, with labels indicating the esophagus, stomach, and direction of bolus movement

4.2 Technique and results of the RefluxStop procedure

The RefluxStop procedure is designed to stabilize the EGJ in the abdomen using a small silicon device implanted laparoscopically in the anterior wall of the gastric fundus above the level of the LES. The implant of the device is routinely preceded by the following steps: extensive esophageal dissection and cruroplasty, accentuation of the angle of His with restoration of the gastroesophageal flap valve, and creation of an anterior 90° fundoplication. Division of the short gastric vessels and complete mobilization of the posterior aspect of the fundus are mandatory to perform an adequate fundoplication and to enable invagination of the prosthetic device into a gastric fundic pocket. Rather than encircling the distal esophagus as the LINX, the RefluxStop™ device keeps the LES below the diaphragm, prevents unfolding or herniation of the fundoplication in the chest, and restores the gastroesophageal flap valve and the angle of His (Figure 2).

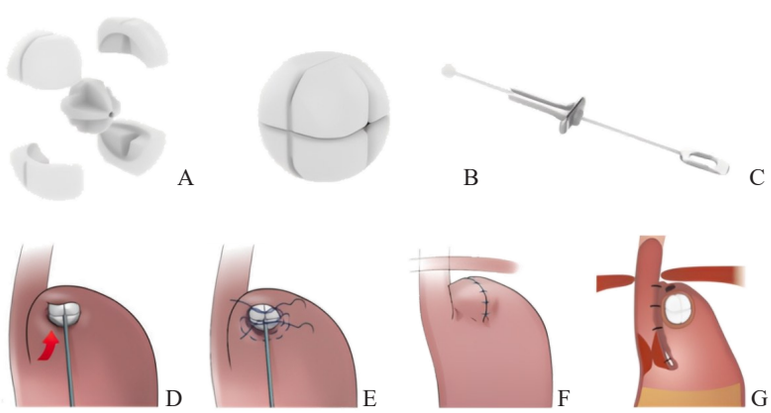

Figure 2 The RefluxStop™ device, dedicated tool and placement process A–B: The sphere shaped device is made of medical grade silicone, Consists of 5 parts for optimal flexibility and is 24.5 mm in diameter, slightly larger than a Euro coin; C: The tool for implanting the device; D–G: The stepwise process of the RefluxStop procedure, which restores and maintains the position of the components of the antireflux barrier, allowing it to function normally

Current clinical results with the RefluxStop procedure show that restoration of distal esophageal length and the gastroesophageal flap valve, combined with anterior fundoplication and a silicon prosthesis to stabilize the EGJ below the diaphragm, can provide durable reflux control with minimal side-effects. Notably, the RefluxStop procedure can safely be offered to patients with ineffective esophageal motility[29–30]. The reported 5-year results with this procedure in 50 patients showed no serious adverse events related to the device. The average GERD-HRQL score decreased by 93.1% from baseline. No clinically significant dysphagia was observed, and daily regurgitation improved by 97.9%. The mean percentage of total time with pH <4 fell from 16.3% to 0.8%. Notably, the RefluxStop procedure has also proven feasible, safe, and effective in patients with large hiatal hernias or in those with prior failed antireflux surgery [31–32]. This technique offers a favorable balance between reflux control and adverse effects and is expected to undergo evaluation in randomized clinical trials in the near future.

5 Conclusions

Laparoscopic antireflux surgery continues to evolve, and the emergence of implant-based LES augmentation devices represents an important step toward more physiologic and durable reflux control. As shown across available evidence, both MSA and the RefluxStop implants can effectively reduce acid exposure, improve GERD-related quality of life, and offer an alternative to the traditional fundoplication. These innovations underscore the need for surgeons to adhere to fundamental operative principles, receive structured training, and develop proficiency with device-specific techniques to optimize outcomes and minimize complications. Refining patient selection via preoperative physiologic testing and enhance long-term durability, while minimizing side-effects such as dysphagia, remain a priority of antireflux surgery. Rigorous clinical trials and long-term surveillance of emerging implantable devices are essential to define their comparative effectiveness and safety. Ultimately, the trend toward personalized, anatomy-preserving, and reversible antireflux interventions is expected to broaden therapeutic options and bring us closer to tailored, durable, and patient-centered GERD management[33–34].

Conflict of interest: *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.*

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