Magnetic Sphincter Augmentation for the Treatment of Gastroesophageal Reflux Disease

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Introduction

The surgical treatment of gastroesophageal reflux disease can be distilled into basic components: achieving appropriate length of intra-abdominal esophagus, diaphragmatic crura re-approximation, and lower esophageal sphincter (LES) augmentation. LES augmentation traditionally has been achieved with partial or full fundoplication wraps. As an alternative to fundoplication, a magnetic lower esophageal sphincter augmentation device (LINX® Reflux Management System, Torax Medical, Ethicon US, USA) has been FDA approved for fundus-sparing treatment of GERD.

Proposed benefits of magnetic sphincter augmentation (MSA) include reduced operative time, no specialized postoperative diet, reversibility, and consistent improvement in symptom scores with less risk of dysphagia and gas bloat symptoms. These results have been shown in various cohort studies [1–4].

Indications for Surgery

The indications for surgery mirror that for traditional anti-reflux surgery, with some exclusions [5–7]. Good candidates for surgery include patients with normal esophageal motility and medically refractory reflux verified by impedance pH testing

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[1–4]. Hiatal hernia greater than 3 cm was not included in the FDA trial for indications in LINX placement; however, recent literature shows that the device can successfully be placed on moderate hiatal hernias, described as "expanded indications" [8–11]. One relative contraindication for use includes large paraesophageal hernias, as it is believed the fundoplication may help reduce the rate of recurrence due to bulking effect at the hiatus. Another contraindication is esophageal dysmotility, as the risk of dysphagia postoperatively is increased [7, 12, 13].

The key to this procedure is successful dissection of a plane between the posterior wall of the esophagus and the posterior vagus nerve, allowing a path for the magnetic beads to encircle the esophagus. The device is sized with the provided sizing tool in order to place the appropriate number of beads (augmentation of LES without constriction). Some, including the authors of this text, advocate for more extensive dissection of the hiatus in all patients (see Section "Minimal Dissection Versus Obligate Dissection" below).

Patient Positioning

The patient is positioned on a beanbag in supine position on the operating table. After induction of anesthesia, the patient is positioned with the arms out and legs split; each leg is secured to the table individually using circumferential padded straps. The arms are secured to each arm board, after which the beanbag is set in place while forming a saddle between the patient's legs and allowing room for strong arm retractor placement on the right side.

Surgical Technique

The operation is started by performing upper GI endoscopy to evaluate for LES location, hiatal hernia, and any unexpected esophageal or gastric lesions. Abdominal access is then obtained in the left upper quadrant, and port placement is shown in Fig. 15.1. The strong arm/Nathanson retractor is placed in the subxiphoid position for liver retraction.

Starting at the left crus, the phreno-esophageal ligament is divided and left-sided hiatal dissection performed. The pars flaccida is then divided near the right crus (above the hepatic branch of the vagus nerve) and the right hiatal dissection completed. Any hiatal hernia is reduced and the esophagus mobilized to obtain 2 cm of intra-abdominal esophagus. The crura is then closed from posterior to anterior with a zero self-retaining nonabsorbable suture (Fig. 15.2). Care is taken to allow for adequate hiatal opening for the esophagus and to not allow any "ramping" of the esophagus off of the posterior closure. The posterior vagus is then identified, and a window is created bluntly between the vagus and the posterior esophagus (Fig. 15.3a). Once the window is created, the band sizer is placed through from the left-hand port (Fig. 15.3b). After careful measuring, the appropriately sized LINX device is placed around the esophagus. The device is locked in place with the

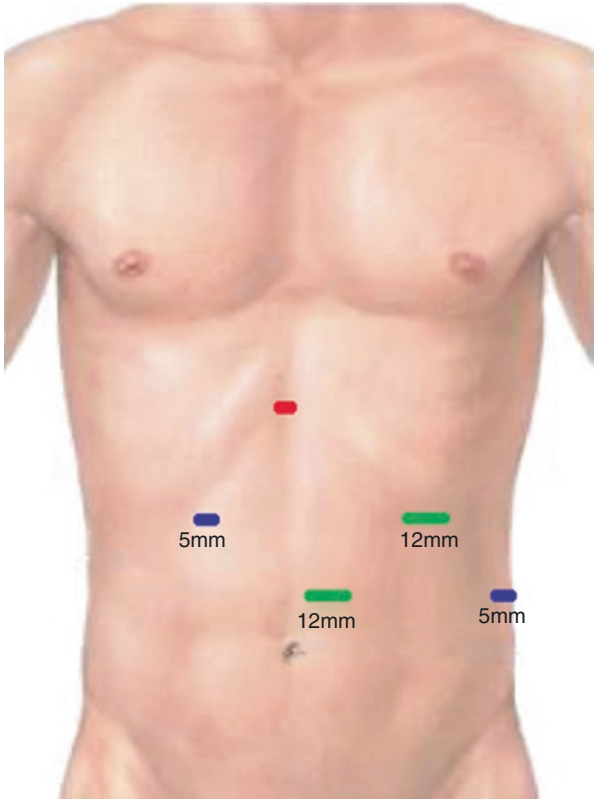

Fig. 15.1 Port placement

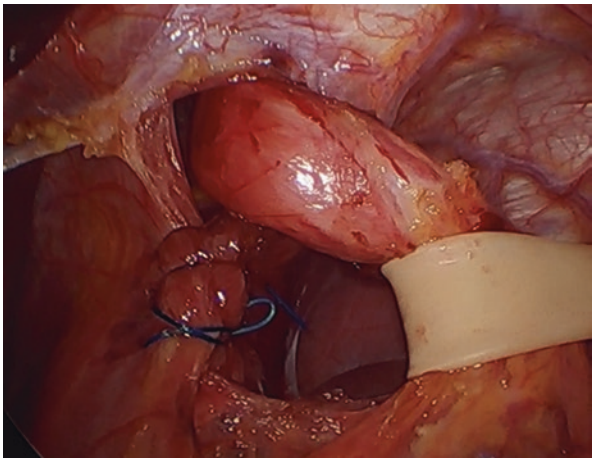

Fig. 15.2 Full hiatal dissection and cruroplasty. Adequate length of intra-abdominal esophagus

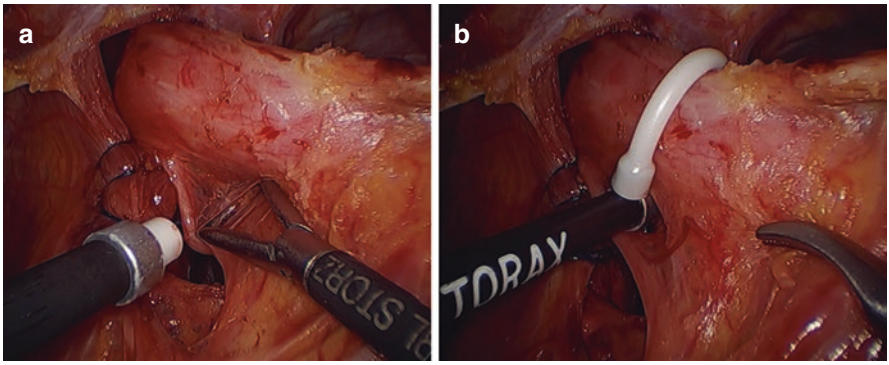

Fig. 15.3 (**a**) Dissection of window between posterior vagus nerve and the esophagus at the LES. (**b**) MSA sizer placement (number of magnetic beads indicated on device handle)

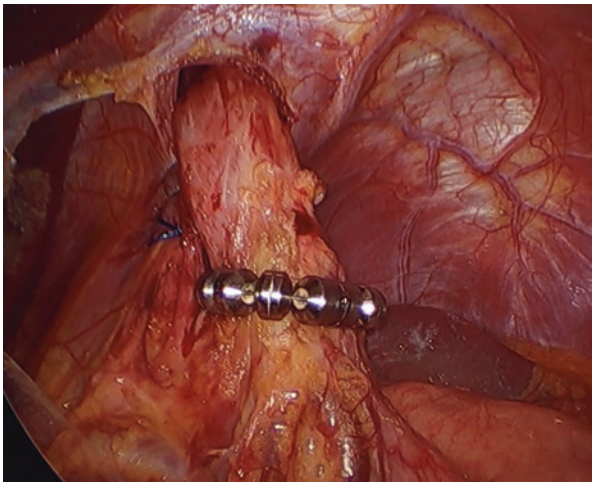

Fig. 15.4 Final LINX position at lower esophageal sphincter

automatic locking mechanism (Fig. 15.4). The LINX is positioned below the diaphragm, on top of the hepatic branch of the vagus. Completion upper GI endoscopy is performed to verify appropriate position at the lower esophageal sphincter with good opening of the GE junction on insufflation; bead indentation can be seen on retroflexion (Fig. 15.5).

Postoperative Care

The patient is extubated in the operating room and transferred to the ward for overnight observation. A major difference in dietary management after magnetic LES augmentation is the immediate implementation of a regular diet. While liquid diet is common after fundoplication to help prevent early dysphagia and gas bloat, the

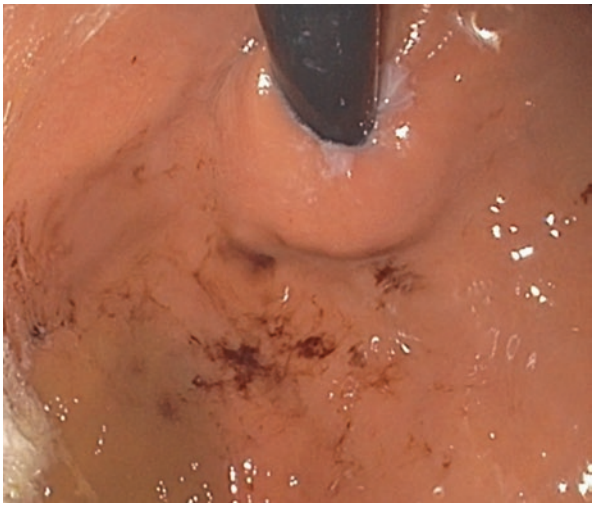

Fig. 15.5 Completion endoscopy showing augmented sphincter. GE junction traversed easily with no resistance and maintained patency

regular diet after LINX allows the patient to "exercise" the beads. It is believed that with a liquid diet after LINX, the beads do not actuate as intended and a scar capsule can form causing dysphagia; this may ultimately require endoscopic pneumatic dilation to break the scar tissue. On the other hand, regular food boluses passing through the beads allow for actuation and more normal function. Patients are discharged often on POD#1 after tolerating regular food; select patients may be amenable for discharge from the recovery unit on POD#0 (outpatient procedure).

Outcomes

Most patients undergoing MSA have favorable results with decrease in reflux symptoms and improvement of pH testing. The device decreases esophageal acid exposure, improves reflux symptoms, and allows cessation of PPI in most patients [1–4]. Studies at 3- and 5-year follow-up have shown relief of GERD symptoms, minimal long-term side effects, and ability for device removal [2–4, 7, 14, 15]. Other advantages include decreased operative time, less technical dissection (in minimal dissection cohorts), and allowing for potential reversibility or conversion to fundoplication in the future [6].

Observational cohort studies show that MSA compares well with posterior fundoplication; however, large randomized controlled trials comparing LINX with posterior fundoplication are needed to verify indications and outcomes compared to traditional anti-reflux surgery [6, 14, 16].

Expanded indications (use in large hiatal hernia, Barrett's esophagus, post-bariatric surgery) are currently being studied and need to be tested long term to further compare to traditional anti-reflux surgery [6]. However, early results are positive for use in large hiatal hernia [8–11]. Additionally, positive results have been seen in small cohorts for patients receiving LINX post bariatric surgery [17].

Currently, the LINX device is not FDA approved for treatment in Barrett's esophagus, although some consider its use as an off-label indication. Further studies regarding the use of LINX in Barrett's esophagus are also needed.

Minimal Versus Obligate Hiatal Dissection

Traditional MSA placement consisted of minimal hiatal dissection with preservation of the phreno-esophageal ligament in patients without a hiatal hernia. Recent data has shown that full dissection of the hiatus with re-approximation of crura has had improved results including less recurrence of reflux and hiatal hernia, likely due to undiagnosed hiatal hernia or underlying pathology of the diaphragmatic crura in reflux disease [18].

Complications

Significant complications after MSA include dysphagia and esophageal perforation/erosion of the device. Dysphagia occurs in up to 15.5% of patients. Dilation is required in 5.6% with response to dilation around 70%, occurring usually <90 days after implantation [7, 12, 13]. Predictors of post-op dysphagia are pre-op dysphagia and esophageal dysmotility, indicating that LINX should be placed only in patients with normal esophageal motility.

Erosion overall incidence is 0.1% (29 of 9453 devices placed as of July 2017). Highest rate of erosion in undersized devices (12 beads highest rate). Erosion rates are lower than those seen in lap band placement, thought due to small size, dynamic nature of device, and no significant tissue compression [6, 19]. Devices with 12 beads have been pulled from the market. As technique and device sizes change over time, erosion rates are expected to plateau or decrease.

Removal

LINX removal, though rare, has been indicated for slippage, erosion, or conversion to another anti-reflux surgery (e.g., fundoplication). The device can be removed if necessary, and the majority of removals have been non-emergent and without long-term consequences. Device removal for any reason has been performed in 3.4% of patients (dysphagia 2.2%, GERD symptoms 0.7%, erosion 0.1%) [7]. Removal is effectively achieved in most cases with minimally invasive techniques [20].

Conclusion

Magnetic lower esophageal sphincter augmentation shows good results with respect to symptom scores and objective pH testing (reduced overall acid exposure and DeMeester scores). Magnetic LES augmentation should be another tool in the armamentarium against reflux disease for the foregut surgeon. Close follow-up with the surgeon and access to upper GI endoscopy for treating early or refractory dysphagia are necessary.

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