Review Article

Post-operative gastroesophageal reflux disease after magnetic sphincter augmentation and transoral incisionless fundoplication

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Abstract: First-line treatment for gastroesophageal reflux disease (GERD) consists of lifestyle modifications and anti-reflux medication with proton pump inhibitors (PPI) being the most common. Approximately 30% of patients continue to suffer despite these medications. New surgical and endoscopic techniques have been developed to treat medically refractory GERD. Nontraditional surgical therapies include magnetic sphincter augmentation (MSA) and transoral incisionless fundoplication (TIF). Initial studies with each of these approaches have demonstrated promising results and their roles in treating reflux are still evolving. Studies for both procedures have demonstrated promising long-term results in regards to reduced PPI usage, symptom relief, and improvement in quality of life. In addition, these procedures have been shown to be safe with a low incidence of adverse events. Although initial studies with each of these approaches have demonstrated promising results, their roles in treating reflux are still evolving. As their roles in anti-reflux surgery continue to expand, this also opens up the potential for complications including dysphagia and persistent reflux disease. The purpose of this review article is to discuss the mechanism of action and outcomes for both MSA and TIF. In addition, we will discuss the evaluation and management of patients who require re-operation for complications following each procedure.

Keywords: Magnetic sphincter augmentation (MSA); transoral incisionless fundoplication (TIF); anti-reflux surgery

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Introduction

Gastroesophageal reflux disease (GERD) is the most common foregut disorder and the prevalence continues to rise (1). First-line treatment consists of lifestyle modifications and anti-reflux medication with proton pump inhibitors (PPI) being the most common. Despite these measures, approximately 30% of patients suffer refractory GERD (2,3). Newer therapies were developed to close the gap between medications and traditional surgical procedures (fundoplication), such as magnetic sphincter augmentation (MSA) and transoral incisionless fundoplication (TIF). MSA is performed utilizing LINX® (Torax Medical, Inc., Shoreview, MN, USA; part of the Johnson & Johnson family of companies), a magnetic ring that mechanically restores

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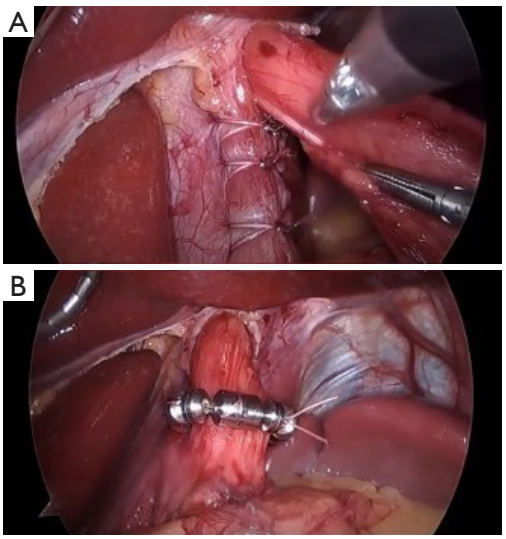

Figure 1 (A) Repair of a small hiatal hernia with (B) LINX® placement.

competency to the reflux barrier without altering the hiatal or gastric anatomy (4). TIF (EndoGastric Solutions, Inc., Redmond, WA, USA) is an endoscopic anti-reflux procedure that rotates the fundus of the stomach around the distal esophagus by applying polypropylene fasteners to recreate a continent lower esophageal sphincter (5). This aims to mimic traditional fundoplication surgery utilizing an endoscope.

Initial studies with each of these approaches have demonstrated promising results. As with any anti-reflux procedure, it still has the potential for complications, such as dysphagia or persistent reflux. The purpose of this review article is to understand the causes of failure for both MSA and TIF as well as discuss the evaluation and management of patients who develop post-operative complications.

MSA

The MSA device is made up of a series of magnetic beads that are interconnected by a titanium wire and allow for expansion dependent on the applied pressure. The device is laparoscopically placed around the esophagogastric junction and uses magnetic force to enhance the anti-reflux barrier function (6). When the beads are closed, this magnetic force is approximately 40 grams; however, when fully distanced they apply much less force, approximately 7 grams. As a result, the device allows the bolus during swallowing to pass through the esophagus. In addition, it is dynamic and can allow the release of elevated gastric pressure when a patient needs to belch or vomit. Consequently, the MSA augments the lower esophageal sphincter at rest and prevents inappropriate transient relaxation that would lead to reflux symptoms (7).

There have been multiple short-term prospective studies that have reported clinical improvements in GERD following MSA. Louie *et al.* reported that at one-year following MSA placement 87.4% of patients had completely discontinued PPI use, while in separate studies, 75.3% and 85% of patients reported a cessation of PPIs. In addition, post-operative esophageal acid normalization was achieved in 74% and 75% of patients. Subjective improvement was also seen in 84% of patients reported via the Gastroesophageal Reflux Disease-Health Related Quality of Life questionnaire (GERD-HRQL) (8,9). These results have remained consistent in studies with long-term follow up (8,10). There have been recent reviews comparing MSA with traditional surgical approaches, such as Nissen fundoplication. In a review by Chen *et al.*, they found that MSA had shorter operative times and length of stay when compared to Nissen fundoplication, while producing similar outcomes in regards to PPI usage (11).

An important practice that has been changed in recent years to improve outcomes after MSA placement is related to how the hiatus is managed. During its early use, patients with small or no hiatal hernia did not routinely undergo a full mediastinal dissection. It was thought that MSA was independent of the status of the hiatus and was unnecessary in patients with no hiatal hernia. It appears that this approach underestimated the importance of the crura to the competence of the anti-reflux mechanism. Further studies have demonstrated that dissection of the hiatus with crural closure resulted in less hiatal hernia recurrence and reflux symptoms compared to the previous minimal hiatal dissection (12). Therefore, hiatal dissection and/or repair of a concomitant hiatal hernia during MSA is necessary (*Figure 1*).

Another potential area where MSA has become uniquely effective for treating GERD is in post-bariatric surgery patients. As the number of bariatric surgeries continues to rise, specifically sleeve gastrectomy, medically refractory GERD has limited options due to the altered anatomy. Historically, the surgical treatment for medically refractory GERD following sleeve gastrectomy is conversion to Roux en-Y gastric bypass. However, MSA has been shown to be a safe and effective rescue therapy for symptomatic reflux following bariatric surgery, and can be considered as an alternative treatment (13,14).

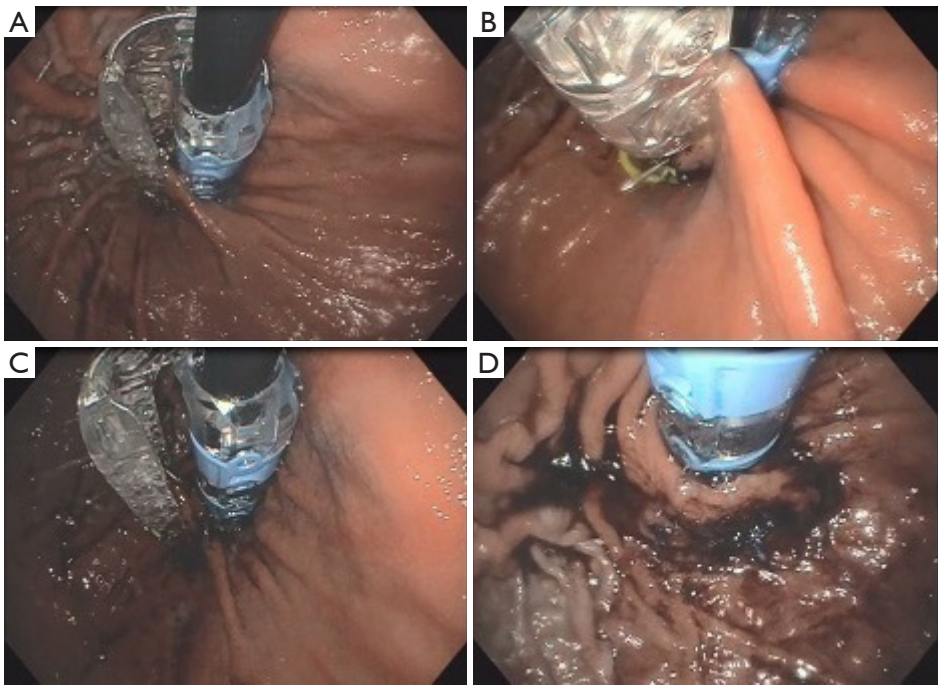

Figure 2 Endoscopic findings of a TIF. (A,C) The length of the valve being constructed with traction of tissue into the device. (B) The tissue mold is closed and fasteners are deployed to create full-thickness serosa-to-serosa plications. (D) After the TIF, endoscopy shows a reconstructed valve. TIF, transoral incisionless fundoplication.

It is important to note the contraindications to MSA. Currently, the device is not recommended for patients with evidence of impaired esophageal motility (<70% effective swallows, mean wave amplitude <35), Los Angeles (LA) grade esophagitis > grade A, Barrett's esophagus, scleroderma, or large hiatal hernias >3 cm (15).

TIF

TIF is an endoscopic anti-reflux procedure that rotates the fundus of the stomach around the distal esophagus, mimicking a traditional fundoplication surgery. TIF is performed using a disposable, single-use, EsophyX® device (EndoGastric Solutions). The EsophyX® device is designed to create full-thickness serosa-to-serosa plication and reconstruct valves approximately 3 cm in length, and 200° to 300° in circumference (*Figure 2*). This results in tightening and reinforcing of the sling fibers in the proximal stomach, accentuating the cardiac notch, steepening the angle of His, and reestablishing the flap valve mechanism (16).

TIF has often been compared to PPI therapy in several randomized trials (17,18). According to Trad *et al.*, 63 patients with GERD refractory to PPI received TIF versus maximum standard dose PPI therapy (19). At 6 months, both regurgitation and extraesophageal symptoms were eliminated in more TIF than PPI patients, and 90% of TIF patients were off PPIs. After 6 months, all patients in the PPI group crossed over to the TIF group. At three years, 90% and 88% of patients reported elimination of troublesome regurgitation and atypical symptoms, respectively (20). At five years, troublesome regurgitation was eliminated in 80% of patients, 34% were on PPI therapy with mean improvement in GERD-HRQL scores from 22.2 to 6.8 (21).

Although results compared to PPI therapy have been promising, the durability of TIF is less certain. In a meta-analysis of 5 randomized trials and 13 prospective studies, PPI use after TIF increased over time and the average satisfaction rate was 69% at 6 months. While the majority of patients who underwent TIF resumed PPIs, they did so at reduced doses (22). Alternatively, in another recent review on TIF, patient satisfaction was 75% with a reduction in PPI use by 84% at 1 year (23). The inconsistency reported in the literature could be due to the fact that there have been two generations of the TIF device, TIF1 and TIF2. In a recent systematic review and meta-analysis by Chandan

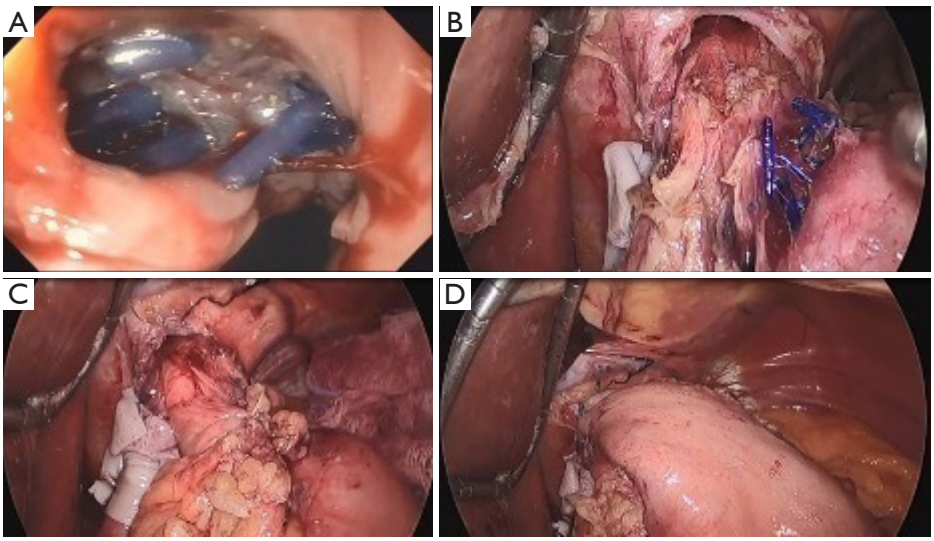

Figure 3 Iatrogenic esophageal perforation during TIF. (A) Endoscopic findings of esophageal perforation. (B,C) Removed and repaired with sutures and (D) partial fundoplication performed. TIF, transoral incisionless fundoplication.

et al., the authors evaluated outcomes for solely using the TIF2 device. They reported similar efficacy compared to MSA based on post-operative GERD-HRQL scores. Despite these results, MSA seemed to outperform TIF2 in regards to long-term PPI use. Overall, 91.3% of patients were able to stop PPI therapy after MSA, while only 63.8% of patients were able to stop PPIs after TIF2 (24). In another systematic review and meta-analysis by Bell *et al.*, the authors reported that TIF2 provided durable relief of GERD symptoms at up to 9 years with 70% of patients free of daily PPI use (25). While the long-term efficacy and durability of TIF has been debated among providers due to the heterogenicity of the current data available, recent studies analyzing the TIF2 device have demonstrated promising results.

A concomitant surgical hiatal hernia repair with TIF is now being increasingly performed with initial studies suggesting that it is safe and effective. A small case series by Gergen *et al.* demonstrated that patients who underwent surgical hiatal hernia repair with TIF had improvement in symptoms with a low rate of adverse events (26). Another multicenter study conducted by Jaruvongvanich *et al.* demonstrated that surgical repair with TIF is feasible and associated with a lower rate of adverse events when compared to laparoscopic Nissen fundoplication (27). It is important to note that TIF is only indicated for patients with a hiatal hernia less than 2 cm as there are concerns with feasibility and efficacy with larger hiatal hernias (28). While these initial studies have shown promising results, the utility of a concurrent surgical hiatal hernia repair with a TIF remains uncertain. Further studies are necessary to validate its use, including prospective and comparative studies to surgical hiatal hernia repair and fundoplication.

The incidence of severe adverse events following TIF is reported at 2.4%. The most reported patient-related adverse events are perforation and laceration (*Figure 3*). Other reported adverse events included bleeding, pleural effusion, part of device breaking within patient, conversion to an open procedure, and abscess formation (22,29).

There have been studies comparing TIF to traditional surgical procedures, such as Nissen fundoplication. In a recent review that included 7 trials comprising 1,128 patients, Richter *et al.* found that TIF produced the largest increase in health-related quality of life. Despite this, they found that Nissen fundoplication had the greater ability to improve the physiologic parameters of GERD, including increased lower esophageal sphincter pressure and decreased percent time pH <4 (30).

The contraindications to TIF procedure are similar to MSA. Currently, the procedure is not recommended for patients with advance erosive esophagitis, Barrett's esophagus, scleroderma, major esophageal motility disorders, gross esophageal abnormalities, or hiatal hernias >2 cm (31). If a hiatal hernia is greater than 2cm, a TIF may be performed in conjunction with a laparoscopic hiatal hernia repair. This is referred to as a cTIF, which is a TIF

with a concomitant hiatal hernia repair and initial studies are encouraging.

Evaluation and management following failed MSA or TIF

Regardless of the technique used, a concern following anti-reflux procedures is re-intervention due to persistent symptoms and/or other complications. This can occur after any anti-reflux procedure and it presents a difficult problem for the surgeon/endoscopist. The evaluation and management of a patient who presents with recurrent GERD symptoms after prior anti-reflux procedures is complex. It is important to decide whether the patient is a good candidate for surgical reintervention as it is critical to identify whether they possess any high-risk factors that may have led to their presentation. Certain patients presenting as surgical failures were potentially at high risk for low satisfaction following their primary anti-reflux surgery and, therefore, remain at high risk for dissatisfaction after a redo operation. Risk factors for this include poor response to medical acid suppression, atypical symptoms, or a normal preoperative pH study (32,33). The presence of these risk factors may help counsel the patient, aid in decision making, and help guide preoperative diagnostic testing.

The evaluation of a patient referred for a possible breakdown of an anti-reflux surgery needs to be completed with the most common etiologies in mind. Specifically, prior to considering a revisional surgery, a careful review of the patient's work up preceding the index operation needs to be conducted. A comprehensive review of imaging and investigations prior to the index surgery may provide clues as to the cause of the presenting symptoms. A close examination of the previous operative notes should also be done for proper operative planning.

The most common complaint following MSA placement is dysphagia, and it is most prevalent in the early post-operative period occurring at a rate of 12% to 20% (34). This typically resolves within 3 months as inflammation subsides and the device is encapsulated. Patients are encouraged to eat solid food at frequent intervals for the first 4 weeks following MSA placement to prevent further scarring at the esophagogastric junction (34). Dysphagia can be treated with endoscopic balloon dilatations along with a course of oral steroids. Despite, this persistent post-operative dysphagia beyond 3 months can occur at rates of 7% to 15% (9,34-36). Device erosion can occur, but is rare. Estimated rates of erosion using global data are 0.05% at 1 year and 0.3% at 4 years after surgery (37). Persistent dysphagia despite medical or endoscopic intervention may require explantation. Rates of MSA explantation vary from 1 % to 7%. When explantation is required, former MSA patients are at risk for developing recurrent GERD symptoms (8,9,12,38). Recurrent GERD in the absence of dysphagia is most often related to a hiatal hernia recurrence with migration of the device (12).

In regard to TIF, a review of 15 published studies reported failure rates of approximately 7% to 8% (39). However, this review included results using both TIF1 and TIF2 devices. In the review by Chandan *et al.*, outcomes were analyzed for solely the TIF2 device. In their review, technical failure rate was much lower and was reported as 1.5% (24). Patients with failures after TIF will usually have a technical or anatomic explanation for their presentation. In redo anti-reflux operations for TIF, disrupted fasteners are most often reported as the primary mechanism of technical failure (40). This could be due to the loosening of the anterior and posterior fastener sets over time causing a worsening of the anti-reflux mechanism. In addition, mobilization of the stomach cannot be achieved to reduce tension on the gastric fundus. This could apply a continuous downward tension onto the fundoplication and cause the fasteners to pull through, leading to failure (41). Another possible mechanism of TIF technical failure could be due to how the valve is constructed during TIF. In one TIF technique, the construction of the valve starts centrally at the greater curvature side and moves anteriorly and posteriorly. A concern with this method is that the resulting valve is not as adherent on the endoscope and too low on the cardia, thus leading to an incompetent fundoplication. A technical change has been suggested, in which the deployment of fasteners starts on the anterior and posterior corners of the gastric wall closer to the lesser curvature, and then moves centrally. With this technique, a more tightened and adherent valve to the endoscope can be constructed (42).

In general, upper endoscopy and esophagram are performed in all patients to help delineate anatomy and evaluate for a hiatal hernia. Endoscopy also allows for the evaluation of the esophageal mucosa, including assessment for various types of esophagitis and changes concerning for Barrett's or malignancy. An esophagram allows for further characterization of the anatomy and emptying of the esophagus. Objective pH testing can also be performed to confirm pathologic acid exposure. Evaluation with high-resolution esophageal manometry (HRM) can be performed

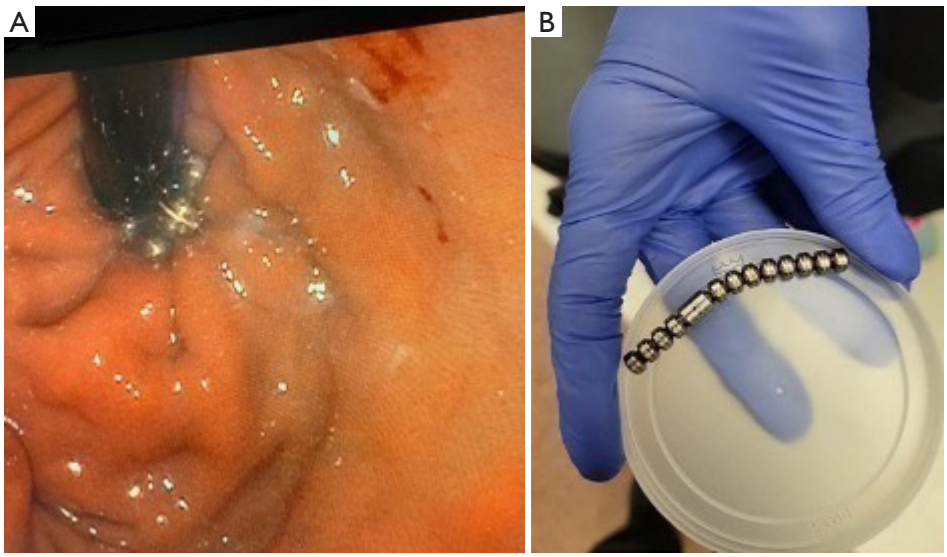

Figure 4 Eroded LINX® prior to (A) and after endoscopic removal (B).

to assess for the strength and coordination of the esophageal contractions in all patients being considered for revisional surgery.

Re-operative management

Re-operative surgery following TIF is most often required due to recurrent GERD symptoms refractory to anti-reflux medications. This is often caused by disrupted fasteners, which results in a failed or slipped wrap. The recommended revisional surgery for a failed TIF is a redo partial or total fundoplication (40). This is typically performed laparoscopically under general anesthesia. After TIF, the remaining wrap can be freed by cutting the polypropylene fasteners so that a fundoplication can be performed. Some fasteners can erode into the gastric lumen and taking them out endoscopically prior to a laparoscopic procedure is helpful. When approaching a redo TIF operation laparoscopically, it is often difficult to find all the fasteners that need to be removed as they can cause firm adhesions between the stomach, esophagus, and diaphragm. Mobilization and dissection of the stomach from the esophagus and diaphragm should be done with caution as there is increased risk of injury to the gastric wall (43). Due to the inherent difficulty of removing all possible fasteners, we most often convert these patients to a partial fundoplication instead of a total in order to prevent over-rotating or causing any odd twists of the wrap to prevent possible post-operative dysphagia.

For those patients undergoing reoperation following MSA, treatment options include MSA device replacement or fundoplication (Dor or Toupet) with optional crural repair as indicated. This is typically performed laparoscopically under general anesthesia. In cases of erosion, the MSA device can be removed endoscopically by cutting the titanium wires and removing the device (*Figure 4*). Adhesions between the stomach, the left lobe of the liver, and the diaphragm are lysed. The scar tissue at the gastroesophageal junction corresponding to the site of the LINX® implant is identified. The scar tissue is divided to expose a pair of the anterior titanium beads. The independent titanium wire connecting the beads is cut with scissors, and one bead is grasped and retracted upward. This allows step-by-step cutting of the thin fibrous capsule overlying each bead and pulling out of the device (*Figure 5*). The total bead count in the explanted device is confirmed, and the device removed through a 10–12 mm port. Intraoperative endoscopic assistance can be used as an adjunct intraoperatively to evaluate the integrity of the esophageal mucosa during and after the laparoscopic removal.

To our knowledge, only four small case series have been published assessing outcomes of revisional fundoplication following a failed TIF. In these studies, three reported no incidences of esophageal or gastric perforation (40,44,45), while another gastric perforation in two patients (43). Overall, the studies reported that these procedures were associated with a low rate of

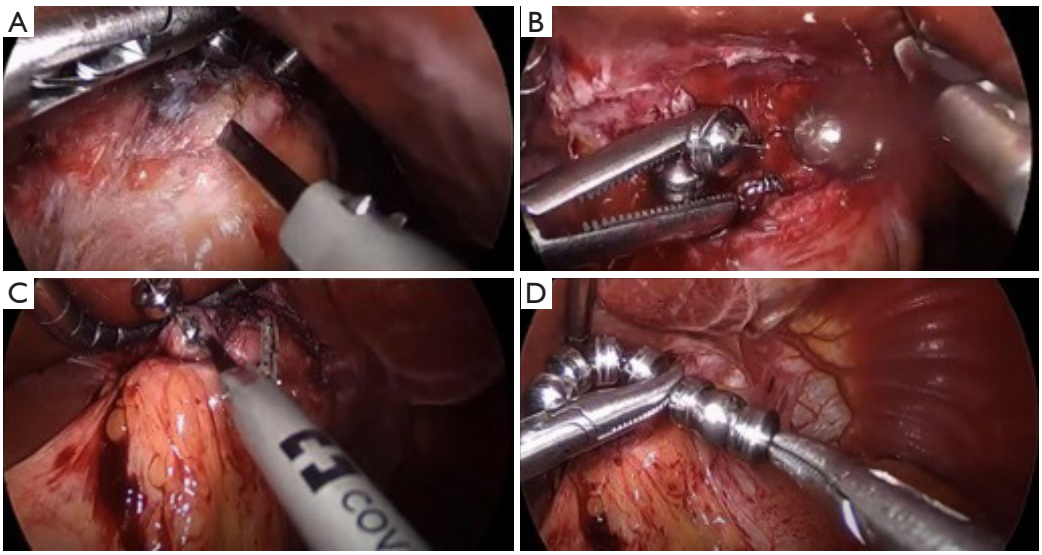

Figure 5 Laparoscopic removal of the LINX® device. (A) The scar tissue at the gastroesophageal junction corresponding to the site of the LINX® implant is identified and divided to expose a pair of the anterior titanium beads. (B) The independent titanium wire connecting the beads is cut with scissors. (C) One bead is grasped and retracted upward, and this allows step-by-step cutting of the thin fibrous capsule overlying each bead. (D) The device is pulled out and the total bead count in the explanted device is confirmed.

adverse events postoperatively. One study reported significant improvements in esophagitis and PPI usage following revisional surgery for a failed TIF. However, they also observed a relatively high rate of post-operative dysphagia with 27% of patients requiring endoscopic dilation (44). In regards to MSA removal, there have been studies evaluating patients who underwent explantation. The most common reasons for removal reported are recurrent GERD symptoms and dysphagia. It has been suggested that supine esophageal acid exposure before initial LINX® placement, higher preoperative GERD-HRQL scores, and higher post-operative GERD-HRQL scores are predictive factors for explantation (46,47). Overall, it appears that outcomes following LINX® removal are good. According to a study by Tatum *et al.*, symptoms prompting removal of the MSA device resolved in 52% of patients and improved in an additional 35% at last contact (48). No major post-operative complications were observed following LINX® removal in similar recent studies, indicating that it can be done safely if necessary (46,48).

Conclusions

MSA and TIF are two novel techniques that have been introduced in recent years for the treatment of refractory GERD. Both procedures have shown promise in initial studies. MSA has shown durable outcomes in the long-term. Although the initial studies on TIF are promising, further studies are required to delineate its long-term durability and efficacy. Re-operation following either TIF or MSA for recurrent symptoms can be performed safely; however, both carry an increased risk of complications compared to the index operation.

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Footnote

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Conflicts of Interest: Both authors have completed the ICMJE uniform disclosure form (available at https://dmr.amegroups.com/article/view/10.21037/dmr-23-15/coif). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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