



# Acute Achalasia Following Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease: A Case Report

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## Abstract

**Background:** Magnetic Sphincter Augmentation (MSA) is an effective surgical option for treatment of refractory gastroesophageal reflux. Post-operative dysphagia, pain, nausea, and device erosion are reported, requiring device explantation. A recently reported erosion rate is 0.3% requiring explantation. Dysphagia is a common indication for removal at a rate of 1.6% while previous case reports describe rare instances of acute achalasia secondary to Nissen fundoplication; there are no reports of this phenomenon with MSA. We describe a case of acute achalasia post MSA placement with complete resolution following surgical extraction.

**Case Report:** A 72-year-old female with chronic gastroesophageal reflux underwent laparoscopic MSA. Her pre-operative evaluation was normal with respect to upper endoscopy, manometry, and esophagram. She developed acute dysphagia and oral intolerance within 10 days of MSA. Barium swallows showed food particles and retained barium with no evidence of magnetic bead ring distention at the GE junction, indicating malfunctioning of the device. Prompt evaluation by endoscopy showed stricture at the gastroesophageal junction. Despite two endoscopies with balloon and Maloney dilatations, she had persistent severe oral intolerance. High-resolution manometry demonstrated an absence of esophageal motility with 75% LES relaxation. Removal of the device led to complete symptom resolution. Follow-up manometry 2 weeks post-removal showed normal esophageal motility and LES function, while barium swallow demonstrated scant reflux.

**Conclusion:** This is the first case of acute achalasia secondary to MSA device implantation. Complete resolution occurred after device explant with clinical and manometric resolution. MSA remains an effective, safe surgical intervention for gastroesophageal reflux with rare complications requiring reoperation for device removal.

**Keywords:** Foregut; GERD; Achalasia; Magnetic sphincter augmentation; Laparoscopic

## Abbreviations

EGD: Esophagogastroduodenoscopy; GE Junction: Gastroesophageal Junction; GERD: Gastroesophageal Reflux; LES: Lower Esophageal Sphincter; MSA: Magnetic Sphincter Augmentation

## Introduction

Gastroesophageal Reflux (GERD) is a common ailment, affecting 18.1% to 27.8% of the population in North America [1-6]. With GERD, the Lower Esophageal Sphincter (LES) fails to prevent the gastric contents from bathing the esophagus with acidic fluid. Acutely, this is associated with significant symptoms of pain and burning.

Longstanding exposure can lead to Barrett's esophagus or intestinal metaplasia, which is a risk factor for developing esophageal adenocarcinoma [6]. The LINX<sup>®</sup> Reflux Management System (Torax Medical, Inc., Shoreview, MN, USA) was developed for the treatment of refractory GERD via Magnetic Sphincter Augmentation (MSA). The device consists of a series of titanium beads with magnetic cores hermetically sealed inside. The beads are interlinked by titanium wires and form a flexible ring that encloses the LES without permanent disruption of gastric anatomy. This recreates the functional capacity of a normal LES. Clinical studies have shown MSA to be an effective long-term treatment for GERD as it decreases esophageal acidity exposure, reduces the need for long

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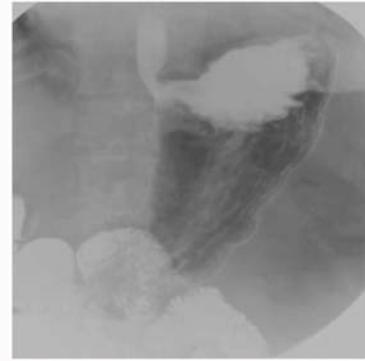
term proton pump inhibitor dependence, and improves quality of life [7,8]. Similar efficacy between MSA and Nissen fundoplication has been demonstrated, providing a surgical option for reflux disease without the potential effects of gas-bloat and inability to belch or vomit [1]. In January 2012, the Food and Drug Administration (FDA) approved the use of the LINX device for the treatment of GERD. A recent study has found the overall device removal rate for the first 1000 cases performed worldwide to be 3.4% [3]. Despite promising clinical results and overall device success, the nuances of potential post-operative complications are still evolving. We present a case of a patient that developed acute dysphagia and studies consistent with secondary achalasia requiring MSA device explanation within 1 month of placement.

## Case Presentation

A 72-year-old female presented with a 30-year history of gastroesophageal reflux symptoms, including regurgitation and burning chest pain partially controlled by proton pump inhibitor. Past medical history included well-controlled hypertension and hypothyroidism. Routine work-up included pre-operative endoscopy, Bravo pH testing, esophageal manometry, and contrast esophagram. Esophagogastroduodenoscopy (EGD) showed normal mucosa and an anatomically normally located GE junction. Bravo pH study confirmed mild to moderate regurgitation with elevated acid scores both days of the 48-h study. Manometry demonstrated normal esophageal peristalsis as well as normal Lower Esophageal Sphincter (LES) pressure with appropriate relaxation to swallows. The esophagram confirmed mild esophageal reflux, normal passage of contrast into stomach, and no visible hernia (Figure 1). She was deemed a good candidate for MSA and hiatal hernia repair.

Standard laparoscopic device implantation was performed with concomitant hiatal hernia repair. Following mobilization of the GE junction and distal esophagus with complete reduction of hernia with intraabdominal esophagus restored, the Torax<sup>®</sup> sizing device was used for appropriate sizing and a 13-bead MSA device was employed at the level of the GEJ. The crura was repaired performed using a single posterior #0 silk stitch. There were no immediate perioperative concerns. The patient was discharged Post-Operative Day (POD) 0 on a full diet.

On POD 10 she was seen in clinic with complaints of dysphagia with solids. A contrast esophagram was performed demonstrating a non-functioning device with retained esophageal barium column and minimal passage through the GEJ. The device was in an appropriate location and orientation. EGD demonstrated a tight but traversable stricture below the Gastroesophageal (GE) junction where the magnet ring was visible on the gastric cardia. The point of narrowing was balloon dilated to 20 mmHg. Symptoms of dysphagia and oral intolerance improved, but quickly returned within 5 days of the procedure. A second endoscopy allowed easy passage into the stomach but retained esophageal food was noted. Therapeutic dilation with a 52F Maloney dilator was performed without sustainable result. Repeat contrast esophagram revealed mild esophageal dilatation with delayed emptying across the point of MSA (Figure 2). Esophageal manometry at this point demonstrated only 75% relaxation at the lower esophageal sphincter, with 8.3 mmHg residual pressure for 2.2 sec. The distal esophageal amplitude was 44 mmHg. 9% peristalsis was antegrade, 73% simultaneous and 18% retrograde at 30 cm/s velocity. Following careful review and collaborative team discussion, consent was given for surgical explant.



**Figure 1:** Esophagram demonstrating minimal amount of esophageal reflux without visible hiatal hernia, and normal flow of barium contrast into the stomach and duodenum.



**Figure 2:** Esophagram showing no evidence of distension of MSA device located at the GE junction with administration of thin barium. Multiple food particles are noted within the esophagus suggestive of a nonfunctioning MSA device. There is minimal passage of thin barium into the stomach.

On POD 21, laparoscopic removal was performed requiring extraction in 3 separate pieces due to significant adhesions at the level of the gastroesophageal junction. The device was dissected off of the esophagus in a right to left and circumferential fashion. The fundus was adherent to the crura and required mobilization by dividing the upper-most short gastric vessels. All 13 beads of the device were accounted for following explantation. EGD confirmed stricture resolution and no evidence of intraluminal trauma. There were no intraoperative concerns.

Within 24 h of the removal of the MSA, the patient had improvement in her symptoms of dysphagia and pain. Her post-operative course was complicated by an ileus that responded to nasogastric decompression from POD 4-7. Within 8 days of device removal, she was symptom free and was discharged home tolerating a clear liquid diet for 4 days, followed by full liquids, with progression to a full diet over 4 weeks. A 2-week post-explant manometry demonstrated normal esophageal motility with 91% antegrade peristalsis and normal LES function. An EGD was also performed which was unremarkable. Repeat endoscopy at 5 years postoperatively showed no evidence of esophagitis or Barrett's esophagus. Clinical follow up at 8 years post device removal depicts well controlled GERD symptoms with esomeprazole 40 mg daily. The patient was happy with clinical status and no further surgical intervention was warranted.

## Discussion

Magnetic sphincter augmentation is a safe and effective

alternative for the surgical treatment of GERD [9,10]. Designed as an anatomy preserving surgical intervention, promising outcomes have been described at both at 1 and 5 years [9,10]. Of the first 100 patients who received the MSA device in the FDA trial, only 6% had any bothersome dysphagia at 5 years and no device erosions, migrations or malfunctions were reported [11]. Safety analysis of the first 1000 implants showed a 3.4% rate of reoperation for device removal. The majority of these cases were dictated by dysphagia at a rate of 2.2% [3]. The median time to removal was 94 days. This patient's severe acute symptoms of dysphagia prompted a full evaluation with repeat endoscopy, upper GI, and manometry. Despite a normal pre-LINX device manometry, the MSA device resulted in severe symptoms and manometric findings that normalized after surgical explant. Although rarely reported, this sequence has been seen following laparoscopic fundoplication with several case reports describing development of secondary achalasia. Wrap take-down resulted in prompt improvement in symptoms and normalization of manometric studies [12-14]. In addition, reversible pseudoachalasia after laparoscopic gastric banding has been reported in a bariatric surgery [15]. Similarly, in this case of secondary achalasia following MSA, there was complete resolution of GEJ outflow obstruction following device removal. Although the exact mechanism of these rare events remain unclear, several hypothesis exist including, an accentuated inflammatory process with subsequent scar formation, the unveiling of subclinical esophageal dysmotility, and technical error.

## Conclusion

This is the first case report of acute achalasia secondary to Magnetic Sphincter Augmentation. Although acute achalasia in this setting is rare, symptomatic disturbances of esophageal motility may occur post-magnetic sphincter augmentation. This case highlights the importance of diligent pre- and post-operative evaluation with prompt surgical management and device removal, as indicated, to reverse the effect.

## Lessons Learned

Magnetic sphincter augmentation device placement has been shown to be a safe and effective surgical treatment for GERD in select patients. However the procedure is not entirely without risk; this case highlights the development of acute achalasia after MSA placement. Any acute onset of dysphagia after MSA placement should be worked up appropriately, and device removal performed when appropriate.

## Disclosures

Dr. Horgan has stock options with TORAX™ Medical Inc. Dr. Jacobsen has two grants with TORAX™ Medical Inc, the first for *The CALIBER Study: Randomized Controlled Trial of LINX versus Double-Dose Proton Pump Inhibitor Therapy for Reflux Disease*, and the second for *A Post-Approval Study of the LINX® Reflux management system*.

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