Six to Twelve Year Outcomes of Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease

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Overview[1]

This single-center, retrospective, single-arm study demonstrates the long-term safety and effectiveness of magnetic sphincter augmentation (MSA) in a cohort of patients implanted greater than 6 years and up to 12 years (median 9 years). Of the 335 subjects implanted with MSA between March 2007 and March 30, 2020, 124 subjects were followed long term, and their results are presented here. All adverse events were assessed from the time of implant through the last visit. To assess efficacy, gastroesophageal reflux disease health-related quality of life (GERD-HRQL) scores, proton-pump inhibitor (PPI) usage, and esophageal acid exposure were compared to baseline. Favorable outcomes were defined as a ≥50% reduction in GERD-HRQL score and PPI cessation. Predictors of long-term clinical success were also identified. It is notable that during the study period, the surgical procedure evolved from minimal to full crural dissection. This is the first report of a cohort of patients who have completed 6 to 12 years of follow-up after MSA.

Results[1]

Long-term outcomes in 124 patients with 6 to 12 years follow-up, median follow-up of 9 years (IQR2)

Long-term Safety

- There were no erosions or migrations
- 3 patients required device removal, for a rate of 2.4%

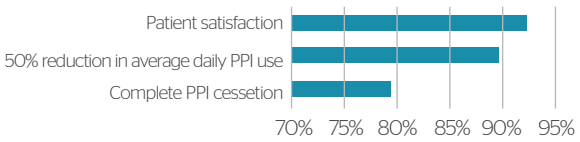
Long-term Efficacy

- 89% of patients met the criteria for favorable outcomes
- 89% patients who completed pH monitoring at 6-12 years follow up achieved either normal esophageal acid exposure or had at least a 50% reduction from baseline

Primary reasons for MSA device removal by length of follow-up

	6-12 years (n=124)
Erosions	0
Regurgitation	0
Heartburn	1
Dysphagia	1
Need for MRI	1

Long-term (6-12) Efficacy Outcomes



	Baseline n=124	6-12 yrs n=91	*P* value
Mean total percent time with pH<4 (Esophageal pH off PPI)	9.70	4.20	<0.001
DeMeester score	40.70	16.30	<0.001
Grade 2-4 regurgitation	59.60%	9.60%	<0.01
Total median GERD-HRQL score	19.90	4.01	<0.001

Predictors[1]

Utilizing a multivariate analysis, independent predictive variables of successful outcome were confirmed to be age <40 years and a baseline GERD-HRQL score of >15.

Complete cohort safety results (n=335)[1]

9.2% (n=31; 28 in the 1-5 years; 3 in the 6-12 years follow up) device removal rate, majority within 6 years of follow-up

1.8% (n=6; 6 in the 1-5 years; 0 in the 6-12 years follow up) erosion rate

No device migrations

2.4% (n=8) required a single pneumatic dilation due to persistent dysphagia at 11, 13, 21, 23, 28, 53, 60, 65 months respectively

Most complications requiring MSA removal occurred in those patients with 12*- and 13-bead devices.

Conclusion[1]

In the longest published clinical experience on MSA to date, the authors concluded that the incidence of adverse events was low during the study time frame, providing reasonable assurance that the risk of MSA complications does not increase with longer implant duration. Efficacy outcomes were observed to be sustained up to 12 years post-implantation.

Note: Two different sizer tools were used over the course of this study. Please consult the Instructions For Use for the appropriate use of the current sizer tool

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*12 bead implants no longer available in the market commercially

LINX® Reflux Management System Important Safety Information

The LINX® Reflux Management System is a laparoscopic, fundic-sparing anti-reflux procedure indicated for patients diagnosed with Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing, and who are seeking an alternative to continuous acid suppression therapy (i.e. proton pump inhibitors or equivalent) in the management of their GERD.

Rx Only

Contraindications: Do not implant the LINX Reflux Management System in patients with suspected or known allergies to titanium, stainless steel, nickel, or ferrous materials.

Warnings: The LINX device is considered MR Conditional in a magnetic resonance imaging (MRI) system up to either 0.7 Tesla (0.7T) or 1.5 Tesla (1.5T), depending on the LINX model implanted. Scanning under different conditions may result in serious injury to you and/or interfere with the magnetic strength and the function of the device. In the event alternative diagnostic procedures cannot be used and MRI is required, the LINX device can be safely removed utilizing a laparoscopic technique that does not compromise the option for traditional anti-reflux procedures. It is recommended that patients receiving the LINX device register their implant with the MedicAlert Foundation (www.medicalert.org) or equivalent organization.

Failure to secure the LINX device properly may result in its subsequent displacement and necessitate a second operation.

Laparoscopic placement of the LINX device is major surgery and death can occur.

General Precautions: The LINX device is a long-term implant. Explant (removal) and replacement surgery may be indicated at any time. Management of adverse reactions may include explantation and/or replacement.

The use of the LINX device in patients with a hiatal hernia larger than 3 cm should include hiatal hernia repair to reduce the hernia to less than 3 cm. The LINX device has not been evaluated in patients with an unrepaired hiatal hernia greater than 3 cm.

The safety and effectiveness of the LINX device has not been evaluated in patients with Barrett's esophagus or Grade C or D (LA classification) esophagitis.

The safety and effectiveness of the LINX device has not been evaluated in patients with electrical implants such as pacemakers and defibrillators, or other metallic, abdominal implants.

The safety and effectiveness of the LINX Reflux Management System has not been established for the following conditions:

- Scleroderma
- Suspected or confirmed esophageal or gastric cancer
- Prior esophageal or gastric surgery or endoscopic intervention
- Distal esophageal motility less than 35 mmHg peristaltic amplitude on wet swallows or <70% (propulsive) peristaltic sequences or High Resolution Manometry equivalent, and/or a known motility disorder such as Achalasia, Nutcracker Esophagus, and Diffuse Esophageal Spasm or Hypertensive LES
- Symptoms of dysphagia more than once per week within the last 3 months
- Esophageal stricture or gross esophageal anatomic abnormalities (Schatzki's ring, obstructive lesions, etc.)
- Esophageal or gastric varices
- Lactating, pregnant or plan to become pregnant
- Morbid obesity (BMI >35)
- Age < 21

Potential Side Effects: Potential adverse events associated with laparoscopic surgery and anesthesia include adverse reaction to anesthesia (headache, muscle pain, nausea), anaphylaxis (severe allergic reaction), cardiac arrest, death, diarrhea, fever, hypotension (low blood pressure), hypoxemia (low oxygen levels in the blood), infection, myocardial infarction, perforation, pneumonia, pulmonary embolism (blood clot in the lung), respiratory distress, and thrombophlebitis (blood clot). Other risks reported after anti-reflux surgery procedures include bloating, nausea, dysphagia (difficulty swallowing), odynophagia (painful swallowing), retching, and vomiting.

Potential risks associated specifically with the LINX Reflux Management System include achalasia (lower part of esophagus does not relax), bleeding, cough, death, decreased appetite, device erosion, device explant/re-operation, device failure, device migration (device does not appear to be at implant site), diarrhea, dyspepsia (indigestion), dysphagia (difficulty swallowing), early satiety (feeling full after eating a small amount of food), esophageal spasms, esophageal stricture, flatulence, food impaction, globus sensation (sensation of a lump in the throat), hiccups, inability to belch or vomit, increased belching, infection, impaired gastric motility, injury to the esophagus, spleen, or stomach, nausea, odynophagia (painful swallowing), organ damage caused by device migration, pain, peritonitis (inflammation of the peritoneum), pneumothorax (collapsed lung), regurgitation, saliva/mucus build-up, stomach bloating, ulcer, vomiting, weight loss, and worsening of preoperative symptoms (including but not limited to dysphagia or heartburn).

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Reference: 1. Ferrari D, Asti E, Lazzari V, Siboni S, Bernardi D, Bonavina L. Six to 12-year outcomes of magnetic sphincter augmentation for gastroesophageal reflux disease. *Sci Rep.* 2020;10(1):13753. doi:10.1038/s41598-020-70742-3.

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