Introduction of Mechanical Sphincter Augmentation for Gastroesophageal Reflux Disease into Practice: Early Clinical Outcomes and Keys to Successful Adoption

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BACKGROUND: A new device for mechanical sphincter augmentation (MSA) of the lower esophageal sphincter was approved by the FDA on March 22, 2012. We report early experience with MSA, specifically addressing postoperative management.

STUDY DESIGN: Between October 1, 2011 and June 1, 2013, 150 patients were evaluated for MSA. Of these, 66 patients underwent device implantation; the first implant was April 10, 2012. All patients had objectively confirmed gastroesophageal reflux disease (GERD) with pH testing, acceptable esophageal motility, and no significant hiatal hernia (>3 cm). All patients experienced clinical improvement on antisecretory medication, but incomplete symptom control or medication intolerance.

RESULTS: All patients were successfully implanted without intra- or perioperative complications. Average length of hospital stay was 0.7 days. At an average follow-up of 5.8 months (range 1 to 18.6 months), 92% of patients are satisfied or neutral with their GERD condition, and 83% are proton pump inhibitor free. The GERD-Health-Related Quality of Life (HRQL) scores are similar to those of patients without GERD. There were no device ulcers or erosions and no devices explanted. Thirteen patients underwent additional testing for dysphagia or persistent symptoms. Calls with questions and nursing involvement in the first 6 months postoperatively were 3 times what is typical for fundoplication patients. Dysphagia and regurgitation were the most common concerns. All these symptoms were improving over time.

CONCLUSIONS: Single-center early results are promising and parallel those from a multicenter trial. There is significant interest in MSA, with referrals and direct patient appointments specifically for MSA. Outcomes improve over time after implantation. The surgeon learning curve is different than with the Nissen, both in operative technique and postoperative management. This is a promising new offering for patients with GERD, and surgeons will need to learn how to integrate this into their practices. (J Am Coll Surg 2014;218:776–782. © 2014 by the American College of Surgeons)

Throughout the career of most physicians in practice today, the mainstay of therapy for gastroesophageal reflux disease (GERD) has been antacids or antisecretories (histamine blockers or proton pump inhibitors [PPI]). Except for a brief period in the late 1990s when laparoscopic antireflux surgery was gaining popularity, surgery is typically offered only for patients with complicated GERD, for example, persistent esophagitis unresponsive to medication or those with a large hiatal hernia. The promise that the introduction of laparoscopy to antireflux surgery would revolutionize our care of reflux was never realized, in large part because of the inability of surgeons across a large spectrum of practices and experiences to bring about consistent, high-quality outcomes with laparoscopic antireflux surgery. The most commonly performed antireflux operation, the 360-degree esophagogastric fundoplication (Nissen fundoplication), first described in 1956,[1] has changed little over the past 48 years. Put simply, we have had very little

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Abbreviations and Acronyms

EGD = esophagogastroduodenoscopy
GERD = gastroesophageal reflux disease
HRQL = Health-Related Quality of Life
LES = lower esophageal sphincter
MSA = mechanical sphincter augmentation
PPI = proton pump inhibitor

substantial innovation or change in our armamentarium with which to treat patients suffering with GERD beyond medication to suppress acid production or a fundoplication to augment the lower esophageal sphincter (LES) and return the LES/esophageal hiatus relationship. These limited and incomplete solutions for GERD leave millions of patients continuing to suffer with poor or incomplete control of their reflux.[2]

The Linx Anti-reflux Management System (Torax Medical, Inc), developed over the last 10 years after extensive testing through a pre-market approval (PMA) process and approved by the Food and Drug Administration in March 2012,[3] is composed of a magnetic "bracelet" that is laparoscopically placed around the gastroesophageal junction to augment the LES. The results of a prospective study of 100 patients undergoing Linx implantation at 14 different US centers, a mix of academic and community hospitals, revealed remarkably consistent results, with the majority of patients experiencing normalization of their esophageal pH after implantation (68% experienced a statistically significant reduction in esophageal acid exposure time, 58% normalized their pH), and nearly 90% of patients remained free of any PPI use at 3 years after implantation.[4] No patients experienced intra- or perioperative complications from the procedure. These results suggest that introduction of this device to the care of patients with GERD may provide an additional, significant intervention for GERD, with a wide variety of surgeons able to consistently achieve success in mechanically improving or arresting pathologic GERD.

The aim of the study described here was to review the early experience of a single experienced foregut surgeon with integrating Linx into a busy and mature foregut practice, specifically assessing the early clinical outcomes and perioperative management of this new offering for GERD. An emphasis was placed on cataloging patient selection and perioperative management, seeking to optimize successful introduction into practice.

METHODS

Between October 1, 2011 and September 26, 2013, 150 patients were evaluated for MSA (a waiting list was generated before FDA approval). Of these, 66 patients underwent device implantation by a single surgeon, with the first implant on April 10, 2012 (Fig. 1). All patients were evaluated by a medical and/or surgical team focused on esophageal disease, with a senior gastroenterologist and surgeon, each with more than 20 years of experience in managing GERD patients, collaborating on the introduction of Linx to the practice and management of patients.

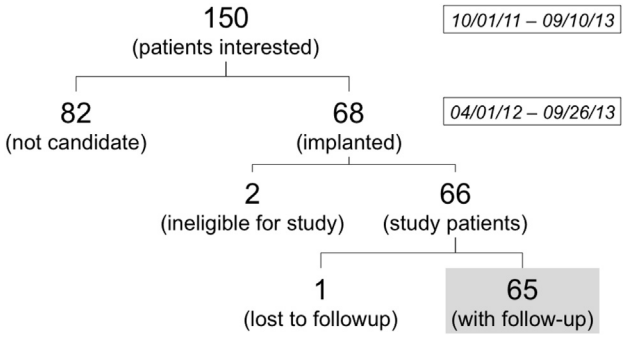

Figure 1. Study population.

All patients considered for implantation underwent a structured work-up to include esophagogastroduodenoscopy (EGD) and contrast swallow. Those not disqualified for consideration based on a large hiatal hernia, Barrett's esophagus, or active grade B esophagitis or higher also underwent esophageal pH testing and esophageal motility. All implanted patients had objectively confirmed GERD based on pH testing, acceptable esophageal motility, and no evidence of significant hiatal hernia (>3 cm) or advanced GERD. Nine patients had normal pH tests while on maximal medication, but abnormal impedance pH documenting nonacid reflux. All patients also experienced clinical improvement on antisecretory medication, with incomplete symptom control, medication intolerance, or side effects. The demographics of the study population are detailed in Table 1.

The technique for Linx implantation has been previously described.[5] A minimal dissection technique to create the space for Linx encirclement of the gastroesophageal junction was adhered to, and a posterior crural stitch was used if the esophageal hiatus appeared patulous or if a sliding type herniation persisted after placement of the Linx.

The implanting surgeon managed patients postoperatively, along with an esophageal-focused gastroenterologist and a nursing team with extensive experience in managing both pre- and postoperative antireflux surgery patients. A standardized protocol is used for postoperative management of all patients after foregut surgery. Due to concern about the impact of nausea and retching after a fundoplication, all fundoplication patients remained in

Table 1. Demographics and Preoperative Data

Demographic	Data
Patients, n	66
Age, mean, y (range)	53.7 (18–86)
Age > 65, n (%)	19 (29)
Male:female	28:38
BMI, mean (weight/height^2), kg/m^2	26.0 (17.6–34.1)
BMI > 30 kg/m^2, n (%)	16 (24)
Clinical history	
Hiatal hernia, n	44
Barrett's, n	3
pH	
% time < 4.0*, mean (range)	9.7 (0.4–31.6)
DeMeester Score, mean (range)	32.3 (1.4–67)

*Nine patients with normal pH while on proton pump inhibitors, and documented nonacid reflux.
BMI, body mass index.

Table 2. Operative Data

Variable	Data
Patients with successful implantation, n	66
Complications, n	0
Patients having cruroplasty, n (%)	37 (56)
First half of series	26/33 (79)
Second half of series	12/33 (36)
No. of crural sutures, median per case, n (range)	1.0 (1–4)
First half of series	1.0 (1–3)
Second half of series	2.0 (1–4)
Hospital length of stay, mean, d	0.75
Same day discharge, no. patients (%)	17 (25)

the hospital for the first postoperative night. Also, fundoplication patients were maintained on a liquid and soft diet for at least 4 weeks postoperatively. In contrast, Linx patients were allowed discharge from the hospital on the day of surgery if adequately recovered from anesthesia. Additionally, because the process of swallowing a bolus of food facilitates opening of the device, Linx patients were specifically instructed to eat a regular diet immediately postoperatively, thereby assuring that during healing, the tissue is pliable with the function of the device. If patients experienced distressing dysphagia they were allowed to eat a soft diet for 2 weeks. They were specifically instructed to not regress to a liquid-only diet.

The number and types of calls and clinic visits were documented, including the types of patient questions and concerns. The volume and nature of these calls were compared with those commonly seen with patients after fundoplication. A research nurse contacted patients at intervals postoperatively to assess quality of life (GERD-Health-Related Quality of Life [HRQL]),[6,7] use of PPIs or other GERD medications, satisfaction, and to catalog any additional GERD- or surgery-related physician visits or interventions.

RESULTS

All patients taken to the operating room with the intent of Linx implantation were successfully implanted (Table 2). No procedures were converted to a fundoplication. No patients experienced an intra- or perioperative complication. Cruroplasty was used in 37 (56%) patients and was performed more commonly early in the patient series (in the first half of the series, 26 of 33; 79%) due to a more extensive dissection used to identify vagal anatomy and to assure proper device placement. As the technique became more standardized, a more minimal dissection could be used and the use of cruroplasty decreased (in the second half of the series, 12 of 33; 36%). More sutures were needed for cruroplasty later in the series, indicating closure of legitimate hiatal defects rather than iatrogenic defects (Table 2). Average hospital length of stay was 0.75 days. For administrative reasons, an overnight stay was mandated for patients numbers 16 to 57. For the 25 patients who had the option of day-of-surgery discharge, 15 (60%) could be discharged on the day of surgery. Those who stayed overnight typically had their operations later in the day or were slower to completely recover from anesthesia by the end of the regular scheduled surgical day.

At a median follow-up of 5.8 months (range 1 to 18.6 months), the majority of patients were satisfied or neutral with their condition after Linx implantation (Table 3). Overall, 83% of patients are no longer using any PPIs. Median GERD-HRQL score postoperatively is 6 compared with a median score of 26 preoperatively (Table 4).

Over time, the clinical response to Linx evolved and improved (Table 3). Increasing numbers of patients became satisfied or neutral with their outcomes over time.

Additional foregut diagnostics or interventions were undertaken in 13 patients overall (20%, Table 4). No patients have undergone explant of the device and there have been no ulcers or erosions. Interventions are largely diagnostic (12 patients underwent contrast swallow, 9 patients underwent EGD, 4 patients underwent dilation, 5 had pH testing, and 1 underwent a motility test). All testing was normal. Dilations were done for persistent dysphagia despite normal contrast swallow. The pH testing was for persistent "heartburn" and motility for dysphagia despite dilation. These interventions were more likely early in the series than later, with 10 of 13 patients in the first half of the series undergoing testing

Table 3. Clinical Outcomes

Outcomes	Overall	< 6 mo	> 6 mo
Follow-up in 65 patients,* mean, mo	5.8 (range 1−18.6)	39 (60%)	26 (40%)
Off PPI, n (%)	54/65 (83)	36/46 (78)	21/26 (81)
PPI dose (none, PRN, QD, BID), n	54, 1, 7, 3	38, 2, 3, 3	21, 0, 5, 0
GERD-HRQL score	6	8	2
Satisfaction (satisfied or neutral), n (%)	60/65 (92)	37/42 (88)	23/25 (92)

*1 patient lost to follow-up.
BID, twice daily; GERD-HRQL, gastroesophageal reflux disease-health-related quality of life; PPI, proton pump inhibitor; PRN, as needed; QD, once daily.

or dilation within 2 to 6 months after implant. This compared with only 3 patients from late in the series undergoing any interventions.

The volume and nature of calls to nurses from patients with questions or concerns followed 2 distinct patterns. The first was calls about difficulty swallowing 2 to 6 weeks after implantation. The second was calls about the return of GERD symptoms and regurgitation of saliva or liquids 3 to 6 months after implantation. Although a minority of patients called with questions or concerns, the frequency and pattern of calls were distinctly different when compared with those of postfundoplication patients. During the same postoperative periods of time, the most common reason for a call from a fundoplication patient would be chest pain in the first 2 to 6 weeks, and abdominal bloating and excess flatulence from 4 to 6 weeks after fundoplication. The frequency of calls after MSA was 3 times that for the postfundoplication patients. Later in the series, patients were educated specifically about dysphagia and regurgitation and how to manage these occurrences during their preoperative teaching. In the latter half of the MSA series, the number of calls significantly decreased.

Table 4. Additional Testing/Interventions

Testing/intervention	Patients, n
Total	13
Contrast swallow	12
EGD	9
Dilation	4
pH test	5
Motility test	1
Specific intervention	
7 dilations in 4 patients	
3 dilations, n	1
2 dilations, n	1
1 dilation, n	2
17 contrast swallows in 12 patients	
2 contrast swallows, n	3
3 contrast swallows, n	1
1 contrast swallow each, n	8
12 EGDs in 9 patients	
3 EGDs	1
2 EGDs	1
1 EGD	7

EGD, esophagogastroduodenoscopy.

DISCUSSION

Lower esophageal sphincter augmentation using the Linx Reflux Management System is a promising new addition to the tools available to a surgeon for management of GERD.[4,5,8-13] Our clinical outcomes with use of this device in 66 patients parallels published results from a 100-patient multicenter study that formed the basis for FDA approval,[3] and a 100-patient series from surgeons in Italy.[5] In these, as in this series, 80% to 90% of patients are PPI free at latest follow-up and overall, are satisfied or neutral with their GERD condition after Linx implantation. Scores of GERD-HRQL drop to near normal levels and, while not detailed here, pH normalizes in the majority of patients. We only have postoperative pH in 5 patients with 4 of 5 having normalized their pH.

The focus of this study was to better understand the adoption and integration of Linx into practice. The experience reported here reveals several important features of the use of Linx. First, proper patient selection is critical, but is fairly straightforward. As was the case in the pivotal trial,[4] adhering to rather strict work-up and selection criteria for Linx placement should ensure good outcomes similar to those seen here and in other published reports. In any foregut practice there will be patients who meet criteria for surgery but who have enough confounding gastrointestinal symptomatology to make one pause before offering surgery. Similar reservations apply to the use of Linx. Although we cannot objectively study this, it is our impression that a few of the patients who remained less satisfied with their Linx outcome, in retrospect, would have similarly been questionable fundoplication patients despite documented abnormal pH, normal esophageal motility, and no significant hiatal hernia. In addition to pH confirmed pathologic GERD, typical GERD symptoms that respond favorably to PPIs and

limited other gastrointestinal symptomatology should predict optimal outcomes.

Probably the most important observation in this experience is the tendency to approach these patients as one would fundoplication patients, both intraoperatively and in postoperative management. Early in the series we were more likely to surgically approach the gastroesophageal junction as we would with a laparoscopic fundoplication, and with this, disrupt the phrenoesophageal membrane and effect a more complete hiatal dissection. This more extensive dissection made identification of the vagal anatomy more comfortable, but often led to the need to reconstruct the esophageal hiatus because of a near circumferential hiatal dissection. Put simply, we needed to repair an iatrogenic hiatal defect. With increasing experience and a focus on minimal dissection to preserve the phrenoesophageal ligament, the need to place a crural stitch decreased. In the first half of this series, crural stitches were used in 79% of patients compared with only 36% later in the series. Although this series did not find a relationship between outcomes and the need to perform a cruroplasty, the pivotal trial did show a tendency toward normalization of esophageal pH when no crural sutures were needed. Today, a crural stitch is only used if, after the dissection is complete and the phrenoesophageal ligament has been preserved, there remains a "dimple" at the esophageal hiatus or the Linx device appears to be readily drawn into the mediastinum after implantation. The other situation in which crural stitches are used is when a more extensive dissection is needed to reduce a significant hernia unsuspected on preoperative imaging. The need for this should be infrequent if careful patient screening for hiatal hernia is followed and MSA is not used when a hiatal hernia greater than 3 cm is suspected.

Postoperative management also needs to be highlighted and differentiated from that after a fundoplication. This is most obvious when considering the incidence of dysphagia and its management. With a fundoplication, we specifically mitigate the occurrence of dysphagia by prescribing a liquid and soft food diet for 1 month or more postoperatively. With this, patients anticipate the difficulty swallowing inherent with any operation at the gastroesophageal junction and religiously avoid foods that might cause difficulty swallowing. In contrast, because of the desire to have the Linx device opening and closing during healing, Linx patients are explicitly instructed to assume a regular diet. This induces difficulty swallowing, and in the pivotal trial, slightly more than 60% of patients reported dysphagia 1 month after surgery. This is far more than we see with fundoplication patients, but not surprising considering the different postoperative management strategy. Another observation regarding this dysphagia is its time course. After fundoplication, dysphagia appears to progressively improve starting from the first postoperative day. In contrast, Linx patients often tolerate a regular breakfast the first morning after surgery, and 5 to 7 days later cannot tolerate that same meal without dysphagia. Again, the pivotal trial found that dysphagia resolved over time, with approximately 60% experiencing dysphagia at 1 month, 30% at 3 months, 15% at 6 months, and then fewer than 5% with significant dysphagia at 12 months. The findings in this series support the improved outcomes realized over time after implantation.

Another feature of the post-Linx patient is the feeling of GERD, and regurgitation of saliva and liquids that appears weeks to months after implantation. Early in our experience, we studied these patients with contrast swallow and EGD. Dilations were also performed in some patients. Through all of these tests and interventions, no anatomic explanation was found for these symptoms other than some pooling of a slight amount of contrast after bolus transit. Assuming that this complex of symptoms was likely esophageal stasis and incomplete esophageal clearance, especially of liquid, management for these symptoms became the use of crackers or other foods that might absorb retained esophageal fluid and result in a dense bolus that could then be propelled through the augmented gastroesophageal junction. This strategy has had remarkable effects in resolving these symptoms.

This constellation of postoperative findings suggests that the edema and healing post-Linx implantation follows a different time course than after a fundoplication, and the esophagus slowly regains adequate function to effectively propel a bolus through the augmented LES and to clear the esophagus of retained fluid. In every patient with these symptoms, time and advice about diet management resulted in resolution. Dilations brought about only transient improvement and no patients have had their device explanted for persistent problems with esophageal clearance or recurrent GERD.

CONCLUSIONS

In summary, mechanical LES augmentation using the Linx Reflux Management System is a promising new treatment for GERD. Select patients do very well and the results appear to be reproducible across a spectrum of surgeon practices. Differentiating the use and management of MSA from that of fundoplication will be important to help patients achieve good outcomes. Surgeons who want to use MSA in their practice should learn the intraoperative technique of minimal dissection, be sure to have a team that can provide the necessary postoperative support for patients, and clearly and explicitly differentiate the management of these patients from that of fundoplication patients.

Author Contributions

Study conception and design: Smith, Devault
Acquisition of data: Buchanan
Analysis and interpretation of data: Smith
Drafting of manuscript: Smith
Critical revision: Smith, Devault

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Discussion

DR DAVID ADAMS (Charleston, SC): How can we improve the quality of surgical treatment of gastroesophageal reflux disease (GERD)? Practically every week, I see in referral examples of why we need to improve the surgical treatment of GERD. It's the laparoscopic Nissen patient who can't swallow because of a gastrogastric wrap or an early recurrent hernia or a wrap too tight for someone with ineffective esophageal motility.

This seminal report, which has many clinical and practical pearls, describes a new device that has been a magnet for patients who want to avoid the laparoscopic Nissen complications they've read about on the Internet: gas bloat, dysphagia, and post-Nissen diarrhea are some of the side effects that no one wants. The big question is, does a Linx Anti-reflex Management System (LINX) procedure avoid these complications?

Dr Smith, you've emphasized the delayed dysphagia issue with the LINX procedure and the increased patient calls. Is the long-term outcome in your practice and experience sufficiently better than a laparoscopic Nissen, which is a good operation when properly done, so that you will expand the indications for the LINX procedure?

How big a hiatal hernia is too big? What about long-segment Barrett's? What about nonacid reflux? What is the maximum body mass index? What motility criteria are you using? How many ineffective swallows are too many? In the value equation of the LINX, what about the cost? Does the $2,000 cost of the device subtract from the hospital contribution margin sufficiently so that the hospital limits its use? Is a CPT code on the horizon?

Last, for the skeptics in the crowd, will you tell them why this bracelet won't erode like the Angelchik prosthesis did?

DR MARY T HAWN (Birmingham, AL): Dr Smith presents one of the largest single-surgeon experiences with the LINX sphincter augmentation device. The short-term follow-up yields good control of reflux symptoms, with 20% of patients reporting dysphagia or persistent symptoms requiring additional testing. He offers sage advice on the technical aspects of the operation and important tips on postoperative education and management.

My main question for you is, where do you think this device fits in the spectrum of GERD management? How many patients were satisfied vs neutral? Are you satisfied with neutral? Do you think that this device will lower the indication for surgery for reflux, and can we expect similar results in those patients? And how do you estimate in consultation on the need for future a MRI examination, a current contraindication to a LINX implantation?

I echo Dr Adams' concerns about what makes this device different; why won't it erode into the esophagus? And, finally, as our patients always ask us, what would you advise your brother or your daughter if they were considering having surgery for reflux?

DR DANIEL SMITH: Better than a Nissen? I think it's equivalent to a Nissen and has a better side-effect profile. That's how I would sum this up. It looks like it's controlling reflux. This goes beyond just the data I've shown you today. The Pivotal Trial, in 100 patients who have been followed now for almost 4 years, the reflux control and the ability to avoid long-term proton pump inhibitor use is at least as good as with a Nissen. And it's got a much more favorable side-effect profile; in particular, the bloating, the gas bloat, and the excess flatulence that keep many patients away from the Nissen are minimal after mechanical sphincter augmentation.

This procedure is fairly reproducible across a large spectrum of surgeons' practices. The Pivotal Trial included 14 centers, half of