GERD: A Growing and Misunderstood Dilemma
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General, Minimally Invasive GI and Bariatric Surgery

Goals and Objectives
• Define GERD and hiatal hernia
• Workup for GERD
• Why consider anti-reflux surgery
• Surgical treatment options

4. www.ASGE.org
**Common**
- Heartburn
- Chest pain
- Regurgitation
- Dysphagia

**Less common**
- Chronic cough
- Hoarseness
- Dental problems
- Recurrent pneumonias
- Worsening asthma
- Abdominal bloating
- Chronic sore throat
- Sleep disturbance
- Nausea
- Globus
- Bad breath

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**ESOPHAGITIS**
- Inflammation of the esophagus
- Erosion of the lining of the esophagus

**STRICTURE**
- Scarring of the esophagus
- Leads to dysphagia
• Change in the lining of the esophagus
• Secondary to chronic reflux or exposure to stomach contents
• Will occur in 10–15% of individuals with GERD
• More common in males

Precancerous lesion
• Probably bile related, not acid

Three types of severity
• No dysplasia
• 0.5–1% risk per year of developing adenocarcinoma
• Low-grade dysplasia
• High-grade dysplasia

6th most common cause of cancer deaths worldwide

Estimated that there will be approximately 20,000 new cases this year in the U.S. alone
Hiatal hernia

• Occurs when part of the upper stomach bulges or herniates into the chest cavity.
• Often present in patients with GERD.

Comprehensive evaluation

• Initial visit with GI
• Discuss symptom history, success/failure, medical and surgical history
• Discuss evaluation and treatment options
• Arrange for procedures
  – EGD, Bravo pH, high-resolution manometry, barium esophagram
  – +/- nuclear gastric scintigraphy

Symptom management

Diet modification

• Caffeine
• Chocolate
• Alcohol
• Carbonated Beverages
• Fatty Foods
• Tomato-based Foods
• Spicy foods
• Fruits
Antacids
• Neutralizes the stomach acid
• Provides fast relief, usually short term

Histamine Blockers (H2 blockers)
• Reduces acid production by blocking the histamine receptor

Proton Pump Inhibitors (PPIs)
• Reduces acid production by blocking proton pump receptor
• Usually more effective than H2 blockers

Benefits
• Reduces the amount of acid in the stomach
• May reduce inflammation of esophageal lining
• Provides symptom relief, but relief can be temporary

Limitations
• DOES NOT affect the lower esophageal sphincter
• DOES NOT prevent reflux
• May require life-long use and dose increases
Why might medication not be effective?

• Taking meds incorrectly
• Disease is progressing – sphincter is getting worse and medication is no longer enough
• Patients may have symptoms that do not respond well to medication in: regurgitation, chronic cough, hoarseness or asthma
• Reflux is not the primary cause of their symptoms – need to see Reflux Specialist for testing

Percentage of patients experiencing breakthrough symptoms while on a PPI (among all patients)

- 62% Breakthrough Symptoms
- 38% Breakthrough Symptoms

FDA: Possible Fracture Risk with High-Dose, Long-Term Use of Proton Pump Inhibitors
May 25, 2010

Labeling changes will reflect this safety information. The FDA, Food and Drug Administration, is advising consumers and health care providers to be aware that long-term use of high doses of proton pump inhibitors (PPIs) may increase the risk of fractures of the hip, wrist, and spine. There is also an increased risk of fractures of the jaw with higher doses of certain PPIs. The labeling of the PPIs will be changed to reflect these risks.

FDA Drug Safety Communication: Low magnesium levels can be associated with long-term use of Proton Pump Inhibitor drugs (PPIs)
March 2, 2011

The U.S. Food and Drug Administration (FDA) is informing the public that prescription proton pump inhibitor (PPI) drugs, used to reduce stomach acid production, may cause low serum magnesium levels (hypomagnesemia) if used for a prolonged period of time (usually greater than one year). The labeling of the PPIs will be changed to reflect this risk.

FDA Drug Safety Communication: Clostridium difficile-associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs)
February 8, 2012

The U.S. Food and Drug Administration (FDA) is informing the public that Clostridium difficile-associated diarrhea can be associated with stomach acid drugs known as proton pump inhibitors (PPIs).

Proton Pump Inhibitor Usage and the Risk of Myocardial Infarction in the General Population (PLOS ONE, Published: June 10, 2015)

Proton Pump Inhibitors and Risk of Incident CKD and Progression to ESRD (JASN, Accepted for publication February 23, 2016)

Association of Proton Pump Inhibitors With Risk of Dementia: A Pharmacoepidemiological Claims Data Analysis (JAMA, April, 2016)
Why Surgery?
• Failure of medications to resolve or improve symptoms
• Cost of daily medications
• Avoid lifetime medications
• Long term side-effects of GERD medication
• Barrett’s esophagus condition
• Concerns for esophageal cancer risk
• Disease progression

Traditional Reflux Surgery has Limitations
Nissen Fundoplication
• Key steps:
  – Short gastric vessels are divided
  – Crural dissection
  – Closure of the hiatus/hiatal hernia repair
  – Upper portion of stomach wrapped around the LES and sutured in place

• Limitations:
  – Inconsistent outcomes (highly surgeon-dependent)
  – Permanent anatomical alteration
  – Side effects (limited ability to belch/vomit); gas bloat
  – Questions about durability

LINX: A Revolutionary Solution for GERD

Nissen Fundoplication

• Key steps:

Nissen Fundoplication

• Key steps:

Nissen Fundoplication

• Key steps:

Nissen Fundoplication

• Key steps:
Design allows augmentation without compression of esophagus.

Interlinked Titanium Beads allow dynamic opening.

Magnetic Cores provide augmentation (15-25 mmHg)*


* Data on File

LINX Design and Function
- Non-compressive
- Magnet strength precisely calibrated to restore LES function while preserving physiologic function
- Exact sizing
- MRI compatible up to 1.5T
LINX Allows Physiologic Function
Closed to Reflux
Opens to Swallows, Belching, Vomiting

LINX® Esophagus stomach
Acid
Esophagus stomach
LINX® Food

LINX System 15-25 mm Hg
Normal Peristaltic Pressures 35-80 mm Hg
Gastric Pressures 5-10 mm Hg

Data on file
LINX FDA Approval and IFU:
March 22, 2012 (Updated 2015)

…”Torax Medical has provided valid scientific data that supports the reasonable assurance of Safety and Effectiveness of the LINX device when used in accordance with the indications for use”

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.

LINX is Redefining Reflux Surgery
▪ Creates a New “Sphincter”
▪ One Way Valve
▪ Disrupts Native Anatomy
▪ Supra-physiologic
▪ “Irreversible” procedure

Nissen
▪ Creates a New “Sphincter”
▪ One Way Valve
▪ Disrupts Native Anatomy
▪ Supra-physiologic
▪ “Irreversible” procedure

 Ling"°
▪ Augment the Weak LES
▪ Increases LES Yield Pressure
▪ Preserves Native Anatomy
▪ Physiologic
▪ Removable

* Data on file
LINX: A Highly Reproducible Reflux Procedure


*As reported by LINX providers

20+ Peer Reviewed Publications

Two FDA 5-year studies completed

Long term efficacy and safety validated (9 years)

>6 comparative studies show preferable outcomes to Nissen fundoplication

Real-world commercial outcomes exceed pre-approval trial results

LINX is 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 equivalents) in the management of their GERD.
Patient Benefits Sustained to Five Years


LINX Addresses the Side Effects of GERD


Benefits of LINX Consistently Demonstrated

Across Studies
Benefits of LINX Consistently Demonstrated Across Studies

**Safety Experience – >12,000 Patients**

<table>
<thead>
<tr>
<th>Occurrence Rate</th>
<th>2.7%</th>
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</thead>
<tbody>
<tr>
<td>Device Removal</td>
<td>2.7%</td>
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<tr>
<td>Postoperative Complications</td>
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<tr>
<td>Device Erosion</td>
<td>0.15%</td>
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<tr>
<td>Device Migration</td>
<td>0.0%</td>
</tr>
<tr>
<td>Device Malfunction</td>
<td>0.0%</td>
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LINX Offers Unique and Important Benefits to Patients and Physicians

• Clinically proven durability, safety and efficacy
• Preserves physiologic function (belch and vomit)
• Reproducible, minimally invasive procedure
• Allows for restoration of the reflux barrier
• Requires no permanent anatomic alteration
• Removable and preserves future treatment options


Preliminary Data Presented at DDW 2017

Randomized Control Trial comparing Magnetic Sphincter Augmentation (LINX) to double-dose PPI (Omeprazole 20mg bid) in patients with troublesome regurgitation symptoms.

LINX Targets the LES = Reflux control

PPIs Target gastric acid = Acid control
Study Overview

Design

- Prospective, Multicenter Randomized Study (22 sites).
- Patients with moderate to severe regurgitation despite once-daily PPI therapy and having abnormal pH test off acid-suppressive medication.
- Primary Endpoint: % of patients reporting elimination of moderate or severe regurgitation at 6 months (FSQ measure).

Percent of Patients Achieving Primary Endpoint

- 92.6% LINX • BID PPI
- 8.6% p<.001

Percent of patients achieving >50% Reduction in GERD-HRQL Score at 6M Compared to Baseline

- 88.9% LINX • BID PPI
- 8.8% p<.001
Reflux Episodes and DeMeester Score

Patients with reflux episodes and DeMeester <14.92

Adverse Events

<table>
<thead>
<tr>
<th>Arm</th>
<th>Event</th>
<th>Sex/Age</th>
<th>Onset from Implant (days)</th>
<th>Treatment</th>
<th>Outcome</th>
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</thead>
<tbody>
<tr>
<td>LINX</td>
<td>Esophageal spasms</td>
<td>Male/66</td>
<td>0</td>
<td>Hospitalization</td>
<td>Resolved</td>
</tr>
</tbody>
</table>

Interim Number of SAEs Reported: 1 LINX and 0 PPI

First treatment center of its kind in Wisconsin dedicated to providing individualized care

- Comprehensive, state-of-the-art testing
- Thorough education
- Treatment alternatives
- Works in association with Prevea HTC in Sheboygan (Dr. Wolfert)
What About GERD and Morbid Obesity???

- 2-4 hours
- 1-2 day hospital stay
- Rapid weight loss
- Most weight loss in first 6-12 months, up to 18 months
- Restrictive and malabsorptive
  - Vitamin/mineral deficiencies

Laparoscopic Gastric Bypass (Roux-en-Y gastric bypass)

JUST ONE MORE THING…
- Outpatient, endoscopically placed and removed
- Provides significant resistance
- 6 months in, then remove
- 12 months counseling
- Out-of-pocket, but financing options available
- BMI 30-40
  - Bridging the weight gap
- >40% excess weight loss at 1 year
  - Average 30 lbs
- 1 pt thus far, lost 30 lbs in 1 month

ReShape Dual Balloon

Questions?