Novel Antireflux Procedures

Matthew G. Hartwig, M.D.
Assistant Professor of Surgery
Duke University Medical Center
Complete Management of GERD

- Medical management of GERD
- Endoscopic anti-reflux procedures
  - Enteryx®
  - Gatekeeper®
  - Stretta®
  - EsophagyX®
  - EndoCinch®
  - NDO Plicator®
- Surgical anti-reflux procedures
  - Fundoplication, Angelchik®, Linx®
Gastroesophageal Reflux Disease

• Significant public health concern
• Most common upper GI disease
• Accounts for 5 million office visits per year
• PPI’s are the most effective management of GERD
• 100 million PPI prescriptions and 14 billion dollars in sales in 2010 alone.
Treatment for GERD: Medical management

PPI is the most effective management for GERD.

Symptomatic relief in

27% placebo, 60% H2RA, 83% PPI.

Esophagitis healed in

24% placebo, 50% H2RA, 78% PPI.

Some patients have relief from H2RAs.

Higher and more frequent dosing of H2RA is still inferior to PPI.

Treatment for GERD: Medical management

In an era of PPI’s, why do we need invasive therapies?

- Up to 20% of patients with breakthrough symptoms
- Economic expense of chronic medical use
- Newer evidence suggesting complications to long-term PPI use (i.e. malabsorption, CAP, bone fractures, etc.)
- Non-acid reflux material may be detrimental (i.e. laryngopharyngeal reflux)
Endoscopic Anti-reflux Procedures
Treatment for GERD: ENTERYX®

- Biopolymer injectate purchased by Boston Scientific.
- Approved by FDA in 2003
  - Improvements in GERD-QOL, PPI use and pH exposure.
- Takes 45-60 minutes
- Recalled by Boston Scientific in 2005
  - Esophageal perforation
  - Aortic injection

Duke Surgery
Treatment for GERD: Gatekeeper Reflux Repair System (GRRS)®

- Injectable polyacrylonitrile hydrogel prosthesis.
- Prospective trials suggested efficacy

- Gatekeeper Trial
  - Planned interim analysis demonstrated no efficacy
  - Medtronic stopped trial early
Treatment for GERD: STRETTA

• Pioneered by Dr. David Utley, approved by FDA in 2000.
  – Curon Medical bankrupt in 2006
  – Mederi Therapeutics re-introduces in 2010
• RFA (low power, 5 watts)
• LES and gastric cardia remodel and transient LES relaxations decrease
• Performed under conscious sedation
• Takes 45-60 minutes
• Covers 2-3 cm in length

Duke Surgery
Treatment for GERD: STRETTA
Treatment for GERD: STRETTA

- **Multiple prospective case series**
    - 111 GERD patients followed to 12 months
    - Improvements in QOL and symptoms, decrease in PPI use (88% to 30%) and decreased, but still abnormal, acid exposure (10.2% to 6.4%).
    - Lost 20% of patients to f/u, no control, authors all with equity stake in company.
    - 109 drug-refractory GERD patients on 2x daily PPI Rx.
    - Total GERD score from 28 to 7, satisfaction score from 1.4 to 3.8. 75% off or PRN antacid only
    - 13 (12%) asked for 2nd procedure (fundoplication or Stretta)
Treatment for GERD: STRETTA

- Randomized, sham-controlled trials
  - Corley et al. Improvement in GERD symptoms after RFA energy, a randomized, sham-controlled trial. Gastroenterology 2003;125:668
    - 64 GERD patients followed to 12 months. Sham group crossed over at 6 months.
    - Improvements in heartburn and SF 36 QOL and decreased GERD symptoms at 6 months (60% vs. 30%).
    - Equal improvements in PPI use for treated and sham patients and no change in pH exposure for either
    - May not provide a decrease in refluxate
    - 36 patients randomized in 12/12/12 fashion
    - 12 month follow-up, 56 lesions per session
    - Primary outcome off PPI GERD-HRQL scores showed improvements of 18%, 51%, and 65%, respectively
    - 50% of patients off all antacid medications in treatment arms, 0% in the sham group.
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    - 12 month follow-up, 56 lesions per session
    - Primary outcome off PPI GERD-HRQL scores showed improvements of 18%, 51%, and 65%, respectively
    - 50% of patients off all antacid medications in double-dose treatment arm, 0% in the sham group.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Sham therapy</th>
<th>Single Stretta Treatment</th>
<th>Double Stretta treatment (performed 10/12 patients)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean HRQL score off medications (range)</td>
<td>Before Sham Stretta (n = 12)</td>
<td>24.8 ± 4.6 (24–36)</td>
<td>14.4 ± 4.8 (9–33)</td>
</tr>
<tr>
<td>No. of patients with HRQL ≤ 11 at the end of follow-up</td>
<td>21 (7.0%)</td>
<td>2 (7.0%)</td>
<td>2 (7.0%)</td>
</tr>
<tr>
<td>Mean 24-h total time pH&lt;4.2 (range)</td>
<td>9.9 ± 2.6 (5.8–13.7)</td>
<td>9.4 ± 1.4 (4.7–12.3)</td>
<td>8.8 ± 2.8 (4.2–13.4)</td>
</tr>
<tr>
<td>No. of patients with mean 24-h total time pH&lt;4.2 (normalized)</td>
<td>0 (2.5)</td>
<td>5 (2.5)</td>
<td>7 (2.5)</td>
</tr>
<tr>
<td>Esophagitis grade (normal/A/B)</td>
<td>0/9/3</td>
<td>4/8/0</td>
<td>4/4/0</td>
</tr>
<tr>
<td>Mean LES pressure (mmHg, range)</td>
<td>14.1 ± 3.6 (9.8–19.3)</td>
<td>16.9 ± 3.7 (9–19.5)</td>
<td>16.2 ± 3.3 (9.5–18.6)</td>
</tr>
<tr>
<td>Patients post-Stretta off GERD medications</td>
<td>0 (0%)</td>
<td>2 (0%)</td>
<td>6 (0%)</td>
</tr>
</tbody>
</table>
Treatment for GERD: STRETTA

- Randomized, sham-controlled trials
    - Double-blind, randomized, sham-controlled cross-over study.
    - 3 and 6 month follow-up at single center.
    - Primary outcome barostat distensibility before and after sildenafil.
    - Sham showed no change in GEJ compliance, but Stretta showed > 50% reduction.
    - Compliance normalized with sildenafil suggesting fibrosis is not cause.
    - pH measurements did not change for either group?
Treatment for GERD: STRETTA

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Treatment for GERD: STRETTA

- Recent Meta-analysis
    - 18 studies over 10 years including 1441 patients.
    - Up to 2 years mean follow-up.
    - Stretta decreased heartburn scores (3.55 to 1.19 pooled)
    - Stretta improved GERD-HRQL
    - pH exposure decreased (DeMeester 44.4 to 28.5) but didn’t normalize.

### Results Summary of Meta-Analysis

<table>
<thead>
<tr>
<th>Outcome Variable</th>
<th>Studies (n)</th>
<th>Patients (n)</th>
<th>Mean Follow-up (mo)</th>
<th>Pre-STRETTA</th>
<th>Post-STRETTA</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Subjective Measurements</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GERD-HRQL</td>
<td>9</td>
<td>433</td>
<td>19.8</td>
<td>26.11</td>
<td>9.25</td>
<td>0.0001</td>
</tr>
<tr>
<td>QOLRAD</td>
<td>4</td>
<td>250</td>
<td>25.2</td>
<td>3.30</td>
<td>9.25</td>
<td>0.0010</td>
</tr>
<tr>
<td>SF-36 Physical</td>
<td>6</td>
<td>299</td>
<td>9.5</td>
<td>36.45</td>
<td>46.12</td>
<td>0.0001</td>
</tr>
<tr>
<td>SF-36 Mental</td>
<td>5</td>
<td>264</td>
<td>10.0</td>
<td>46.79</td>
<td>55.16</td>
<td>0.0015</td>
</tr>
<tr>
<td>Heartburn Score</td>
<td>9</td>
<td>525</td>
<td>24.1</td>
<td>3.55</td>
<td>1.19</td>
<td>0.0001</td>
</tr>
<tr>
<td>Satisfaction Score</td>
<td>5</td>
<td>366</td>
<td>21.9</td>
<td>1.43</td>
<td>4.07</td>
<td>0.0006</td>
</tr>
<tr>
<td><strong>Objective Measurements</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Esophageal Acid Exposure (%Ph&lt;4)</td>
<td>11</td>
<td>364</td>
<td>11.9</td>
<td>10.29</td>
<td>6.51</td>
<td>0.0003</td>
</tr>
<tr>
<td>DeMeester score</td>
<td>7</td>
<td>267</td>
<td>13.1</td>
<td>44.37</td>
<td>28.53</td>
<td>0.0074</td>
</tr>
<tr>
<td>LES pressure</td>
<td>7</td>
<td>263</td>
<td>8.7</td>
<td>16.54</td>
<td>20.24</td>
<td>0.0302</td>
</tr>
</tbody>
</table>
Treatment for GERD: STRETTA

- **Stretta versus fundoplication**
    - 140 patients offered Stretta or Lap Fundo. LES lower, more hiatal hernia’s, and preoperative pH exposure higher in lap fundo group.
    - Equal improvement in QOL at 6 mos.
    - 58% of Stretta patients and 97% of lap fundo off PPI’s at 1 year.
    - 86% of Stretta and 96% of lap fundo patients satisfied.
Treatment for GERD: STRETTA®

• Can Stretta® improve gastroparesis?
  – Noar et al. Gastroparesis associated with GERD and corresponding reflux symptoms may be corrected with RFA of the cardia and esophagogastric junction. Surg Endosc 2008; 22(1):2440-4
    • 31 GERD patients with concomitant delayed gastric emptying on nuclear study.
    • 27 improved emptying, with 23 (74%) normalized.
  • Why?
    – Decrease in TLESR’s?
    – Alteration of pacemaker function?
    – Removal of symptoms or meds?
Treatment for GERD: STRETTA®

• Stretta Summary
  – Most extensively studied
    • 30 peer reviewed, including 4 randomized, controlled study and meta-analysis
    • Only minor adverse events reported.
    • Appropriate for patients with GERD symptoms > 6 months who decline or are ineligible for laparoscopic fundoplication.
    • Avoid if hiatal hernia > 2cm, severe esophagitis, long segment Barrett’s, dysphagia
    • One concern may be continued abnormal acid exposure despite improvements in symptoms (ie. LPR, Barrett’s, esophagitis, other complications of GERD)
    • Overall, quality of evidence according to the GRADE system is HIGH (++++) and strength of recommendation is STRONG.
Treatment for GERD: EndoCinch®

- First endoscopic sewing device with FDA approval in 2000

- Provided full thickness plication. Multiple variations in techniques, including number of plications and location.
Treatment for GERD: EndoCinch®

- Appears safe with few complications reported including pharyngitis, nausea, bleeding, hypoxia, and dysphagia. Comparable to surgery.
  - 60 patients randomized, sham controlled, single center
  - 12 mo. Improvement in symptoms and PPI use compared to sham, but no difference in acid exposure.
- Durability questioned.
  - Reported only 17% of plications fully intact after 18 months and 26% no sutures could be found. 80% treatment failure rate by symptoms.
- Compared to laparoscopic fundoplication
  - At 1 year surgery provided better symptoms improvement and decrease in acid exposure, but with a higher rate of dysphagia. Equal improvements in PPI use.
Treatment for GERD: NDO Plicator®

- FDA approval in 2003
- Provided full thickness, serosa-to-serosa plication.
  - 80 patients randomized, sham controlled
  - 3 mo. Improvement in symptoms and acid exposure, 50% still required PPI’s
- Questions of safety including perforation and death and poor sales
- Not currently available in U.S.
**Treatment for GERD: EsophyX®**

- EndoGastric Solutions Inc.
- FDA approval in 2007
- Currently available
- Provided full thickness, serosa-to-serosa plication via multiple H-fasteners (6-15)
- More analogous to surgical fundoplication.
- Requires general anesthesia and up to 2 hours to complete
- 200-300 degree plication
- Has been referred to as
  - Endoluminal Fundoplication (ELF)
  - Transoral Incisionless Fundoplication (TIF)
Treatment for GERD: EsophyX®

- Restores angle of His
- Large overtube advanced over video gastroscope
- “Corkscrew” grasper pulls fundus tissue down into retroflexed t-fastener device.
- H-fasteners plicate fundus to create a neo-GEJ
Treatment for GERD: EsophyX®

- Prospective studies suggest benefit for TIF 1.
    - Describes evolution of EsophyX from bench to phase 2 clinical trials
    - Phase 2 trial enrolled 27 patients looking at ELF, LARS, and EPS. pH normalized 67%, 96%, and 30%.
    - 84 patients with 12 month follow-up. 49 with hiatal hernia < 2cm
    - All hernias reduced. LES tone improved. 80% discontinued PPI’s. 40% normalized pH.
Treatment for GERD: EsophyX®

• Prospective studies suggest benefit for TIF 2.
    • 42 patients with up to 2 year follow-up. No complications.
    • 60% off PPI’s at 6 months, 42% off PPI’s at 2 years. 4 (10%) went on to LNF.
    • 100 consecutive patients with 6 month follow-up. No complications.
    • GERD HR-QOL normalized in 73%. 80% off of PPI’s completely (92% on before).
Treatment for GERD: EsophyX®

- Transoral Incisionless Fundoplication versus Lap Fundoplication.

    - Randomized trial of ELF, LNF, and Plication. (Plication device was taken off market during study)
    - 52 patients enrolled (16, 18, and 18, respectively). 12 month follow-up.
    - No statistically significant differences in efficacy.
    - Big problems include 2 types of endoscopic therapy. Underpowered. Strange results such as average length of stays for TIF of 3 days and for LNF 6.4 days.

  - Frazzoni et al. Reflux parameters as modified by EsophyX or laparoscopic fundoplication in refractory GERD. *Aliment Pharmacol Ther*. 2011;34:67-75.
    - Non-randomized, open-label.
    - 20 patients with severe GERD despite high-dose PPI’s
    - 10 patients chose TIF, 10 chose LNF
    - pH 3 months after procedure normalized in 50% of TIF and 100% of LNF
    - GERD associated symptoms present in 60% of TIF and 0% of LNF
Treatment for GERD: EsophyX®

• Complications of Transoral Incisionless Fundoplication
  – Esophageal perforation
  – Hemorrhage requiring transfusion
  – Pneumothorax
  – Mediastinal abscess
Treatment for GERD: EsophyX®

• Conclusions
  – May provide reasonable alternative to LNF for patients who have failed medical management of GERD
    • With hiatal hernia no greater than 2 cm
    • Without severe esophagitis or extended Barrett’s
  – Significant learning curve
  – No long term data available past 2 years
  – Lack of randomized, sham-controlled studies
  – Overall quality of evidence LOW (++) , GRADE recommendation WEAK.
Surgical Anti-reflux Procedures
Treatment for GERD: Surgical Fundoplication

- Rudolph Nissen first performed “gastroplication” in 1955.
- Large body of literature with over 500 peer reviewed publications since that time.
- Multiple variations including partial and complete wraps available.
- Techniques include open, laparoscopic, and robotic
Treatment for GERD: Surgical Fundoplication

• Medical versus Surgical Treatment
  – At least 7 randomized, controlled trials with follow-up from 1-10.6 years
  – 6 of 7 showed objective evidence of decreased acid exposure and increased LES pressure
    • Only the Spechler JAMA article did not, which was underpowered
  – Multiple studies showed comparable to improved QOL with surgery and high patient satisfaction rates
    • Only 1 randomized study did not…the Spechler JAMA article…
  – Majority of literature suggests 10-20% PPI use up to 8 years after surgery
    • One randomized study reported PPI use at 62% at 10 years…the Spechler JAMA article…
Treatment for GERD: Surgical Fundoplication

- Medical versus Surgical Treatment
Treatment for GERD: Surgical Fundoplication

- Medical versus Surgical Treatment Cost Analysis
  - One randomized trial looked at cost-effectiveness
    - Total Rx costs less at 5 years in 3 countries, more in 1 (Finland)
    - Open, instead of laparoscopic nature of the procedure
    - European cost analysis may not be applicable
  - Cost-utility modeling suggests breakpoint in favor of surgery at 10 years.
Treatment for GERD: Surgical Fundoplication

- **LOTUS Trial**
  - Randomized, open trial in Europe between 2001-2009 with 5 year follow-up.
  - 554 patients randomized to esomeprazole (allowing for dose escalation) or surgery (standardized of technique).
  - Only PPI responders randomized for the study.
  - At 5 years, K-M estimates of treatment failure were 85% in the surgical group, compared to 92% in the PPI cohort.
Treatment for GERD: Surgical Fundoplication

- **LOTUS Trial**
  - Serious adverse events were similar at 5 years between groups.

<table>
<thead>
<tr>
<th>Table 2. Safety Assessments</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td></td>
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<tr>
<td>Serious adverse events&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>No. of patients with a serious adverse event</td>
</tr>
<tr>
<td>No. of patients with a fatal serious adverse event</td>
</tr>
<tr>
<td>Blood variables, mean</td>
</tr>
<tr>
<td>Hemoglobin, g/L</td>
</tr>
<tr>
<td>Vitamin B&lt;sub&gt;12&lt;/sub&gt;, pmol/L</td>
</tr>
<tr>
<td>Serum gastrin, pg/mL</td>
</tr>
<tr>
<td>Chromogranin A, ng/mL</td>
</tr>
<tr>
<td>Alkaline phosphatase, u/L</td>
</tr>
<tr>
<td>Calcium, mmol/L</td>
</tr>
<tr>
<td>Vitamin D, nmol/L</td>
</tr>
<tr>
<td>Homocysteine, μmol/mL</td>
</tr>
</tbody>
</table>

Abbreviations: LARS, laparoscopic antireflux surgery; NA, not applicable.  
<sup>a</sup>See also eTable 2. Total at 5 years is cumulative.  
<sup>b</sup>One patient in each group died after the end of the study, but the serious adverse event started during the study.
Treatment for GERD: Surgical Fundoplication

• Predictors of success
  – Pre-operative patient compliance with meds predicts improvement in QOL and decreased dysphagia
  – Major depression before surgery associated with more GI symptoms and lower QOL after surgery.
    • Ameliorated with cognitive behavioral therapy.
  – Atypical symptoms respond less well
  – Response to PPI
    • No response to PPI associated with lower satisfaction postop, but overall good success rates achievable
  – Esophageal dysfunction by manometry associated with increased postop GI complaints
Treatment for GERD: Surgical Fundoplication

• Summary
  – Surgery is an equally as effective alternative to medical therapy for GERD.
  – Surgical therapy directly addresses mechanical issues of GERD and allows for reduction of hiatal hernias and minimization of reflux material.
  – For surgery to be effective it needs to be associated with minimal morbidity and cost…this has in turn been linked to high volume surgeons and centers.
  – Has been performed in small numbers following failed endoscopic therapies with similar success as reoperative surgery after prior fundoplication.
Treatment for GERD: Angelchik®

• Anti-reflux prosthesis approved by FDA in 1979
  – Collar-shaped silicone device
  – Placed around GEJ, secured with Teflon straps
  – Over 25,000 placed world-wide
  – Multiple problems including:
    • Migration
    • Erosion
    • Dysphagia (nearly 25% requiring removal)
    • Displacement
  – Not currently used
Treatment for GERD: Linx Reflux Management System®

• Anti-reflux prosthesis approved by FDA in 2012
  – Torax Medical Inc.
  – Laparoscopically placed around GEJ.
  – Miniature string of inter-linked titanium beads with magnetic cores
  – Beads can temporarily separate to allow swallowed bolus, allow belching, etc.
  – Procedure takes less 30-60 minutes
  – Outpatient surgery
Treatment for GERD: Linx Reflux Management System®
Treatment for GERD: Linx Reflux Management System®

- Normal Peristaltic Pressures: 35-80 mm Hg
- Linx® System: 20-25 mm Hg
- Gastric Pressures: 5-10 mm Hg

CLOSED to Reflux

OPEN to Swallowing
Treatment for GERD: Linx Reflux Management System®
Treatment for GERD: Clinical Evidence for Linx Reflux Management System®

**ORIGINAL ARTICLE**

**Esophageal Sphincter Device for Gastroesophageal Reflux Disease**

Robert A. Ganz, M.D., Jeffrey H. Peters, M.D., Santiago Horgan, M.D., Willem A. Bemelman, M.D., Ph.D., Christy M. Dunst, M.D., Steven A. Edmundowicz, M.D., John C. Lipham, M.D., James D. Luketich, M.D., W. Scott Melvin, M.D., Brant K. Oelschlager, M.D., Steven C. Schlack-Harer, M.D., C. Daniel Smith, M.D., Christopher C. Smith, M.D., Dan Dunn, M.D., and Paul A. Taiganides, M.D.

Treatment for GERD: Clinical Evidence for Linx Reflux Management System®

Table 1. Components of Esophageal pH Measurements.*

<table>
<thead>
<tr>
<th>Variable</th>
<th>Baseline</th>
<th>1 Year</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>No. of Patients</td>
<td>Median Value</td>
<td>No. of Patients</td>
</tr>
<tr>
<td>pH &lt;4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total percentage of time</td>
<td>100</td>
<td>10.9</td>
<td>96</td>
</tr>
<tr>
<td>Percentage of time upright†</td>
<td>100</td>
<td>12.7</td>
<td>96</td>
</tr>
<tr>
<td>Percentage of time supine‡</td>
<td>98</td>
<td>6.0</td>
<td>96</td>
</tr>
<tr>
<td>Total no. of reflux episodes</td>
<td>100</td>
<td>161.0</td>
<td>96</td>
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<tr>
<td>No. of reflux episodes lasting &gt;5 min</td>
<td>99</td>
<td>12.0</td>
<td>96</td>
</tr>
<tr>
<td>Longest reflux episode (min)</td>
<td>99</td>
<td>29.0</td>
<td>96</td>
</tr>
<tr>
<td>DeMeester score§</td>
<td>97</td>
<td>36.6</td>
<td>96</td>
</tr>
</tbody>
</table>

* All testing was performed with the use of the Bravo pH monitoring system (Given Imaging) at baseline and at 1 year.
† Time upright was defined as the time during which the patient was not recumbent.
‡ Time supine was defined as the time during which the patient was recumbent.
§ The DeMeester score is a composite score of factors quantified during a 24-to-48-hour pH study, with a score of 14.7 or more indicating abnormal reflux. Factors include the percentage of time that the pH was less than 4 during the total period of assessment, during the time in an upright position, and during the time in a supine position; the total number of reflux episodes; the number of episodes lasting more than 5 minutes; and the duration of the longest episode (in minutes).

Treatment for GERD: Clinical Evidence for Linx Reflux Management System®

Treatment for GERD: Clinical Evidence for Linx Reflux Management System®

Treatment for GERD: Clinical Evidence for Linx Reflux Managmenent System®

### Table 2. Adverse Events and Device Removal.

<table>
<thead>
<tr>
<th>Event</th>
<th>Patients (N = 100)</th>
<th>Maximum Level of Intensity*</th>
<th>Device Removal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Mild</td>
<td>Moderate</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>68</td>
<td>47</td>
<td>16</td>
</tr>
<tr>
<td>Bloating</td>
<td>14</td>
<td>12</td>
<td>2</td>
</tr>
<tr>
<td>Pain</td>
<td>25</td>
<td>7</td>
<td>13</td>
</tr>
<tr>
<td>Odynophagia</td>
<td>8</td>
<td>4</td>
<td>3</td>
</tr>
<tr>
<td>Hiccups</td>
<td>8</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Nausea</td>
<td>7</td>
<td>3</td>
<td>2</td>
</tr>
<tr>
<td>Inability to belch or vomit</td>
<td>6</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>4</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Flatulence</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Belching</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Weight loss</td>
<td>2</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Food impaction</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Globus sensation†</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Irritable bowel syndrome or dyspepsia</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Regurgitation of sticky mucus</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Uncomfortable feeling in chest</td>
<td>1</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Vomiting</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Persistent GERD symptoms‡</td>
<td>1</td>
<td>0</td>
<td>1</td>
</tr>
</tbody>
</table>

Treatment for GERD: Clinical Evidence for Linx Reflux Management System®

Laparoscopic Magnetic Sphincter Augmentation vs Laparoscopic Nissen Fundoplication: A Matched-Pair Analysis of 100 Patients

Jessica L Reynolds, MD, Joerg Zehetner, MD, FACS, Phil Wu, BS, Shawn Shah, BS, Nikolai Bildzukewicz, MD, FACS, John C Lipham, MD, FACS
Treatment for GERD: Clinical Evidence for Linx Reflux Management System®

Table 3. Preoperative Demographics and GERD Characteristics

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>MSA (n = 50)</th>
<th>LNF (n = 50)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>53.0</td>
<td>54.0</td>
<td>0.748</td>
</tr>
<tr>
<td>Sex, n</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>30</td>
<td>27</td>
<td>0.686</td>
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<tr>
<td>Female</td>
<td>20</td>
<td>23</td>
<td></td>
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<tr>
<td>BMI, kg/m²</td>
<td>26.4</td>
<td>26.7</td>
<td>0.741</td>
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<tr>
<td>GERD duration, mo</td>
<td>146.9</td>
<td>144.5</td>
<td>0.932</td>
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<tr>
<td>GERD-HRQL score</td>
<td>19.7</td>
<td>18.8</td>
<td>0.596</td>
</tr>
<tr>
<td>Esophagitis, n</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>None</td>
<td>35</td>
<td>36</td>
<td>0.711</td>
</tr>
<tr>
<td>A</td>
<td>9</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>B</td>
<td>5</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>C</td>
<td>1</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>D</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Hiatal hernia size, cm</td>
<td>1.5</td>
<td>1.6</td>
<td>0.735</td>
</tr>
</tbody>
</table>
Treatment for GERD: Clinical Evidence for Linx Reflux Management System®

• Results for Linx vs LNF
  – Similar reported rates of complete resolution of symptoms at 1-year.
    • Linx 24 of 47 (51.1%)
    • LNF 23 of 47 (48.9%)
    • p = 0.978
  – Similar GERD-HRQL scores at 1-year
    • Linx 4.2
    • LNF 4.3
    • p = 0.879
  – Similar rates of stopping PPI at 1-year
    • Linx 39 of 47 (83%)
    • LNF 43 of 47 (91.5%)
    • p = 0.355
Results for Linx vs LNF

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  - Linx: 39 of 47 (83%)
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  - $p = 0.355$
Treatment for GERD: Clinical Evidence for Linx Reflux Management System®

• Results for Linx vs LNF
  – Similar reported rates of mod-severe dysphagia at 1-year.
    • Linx 5 of 47 (10.6%)
    • LNF 6 of 47 (12.8%)
    • p = 0.766
  – Less severe gas-bloat at 1 year for Linx.
    • Linx 0 of 47 (0%)
    • LNF 5 of 47 (10.6%)
    • p = 0.022
  – Belching and emesis at 1-year
    • Linx 4 of 47 (8.5%) unable to belch and 2 of 47 (4.3%) unable to vomit
    • LNF 12 of 47 (25.5%) unable to belch and 10 of 47 (21.3%) unable to vomit
    • p = 0.004
Treatment for GERD: Summary

- PPI’s remain the mainstay of therapy for GERD; however, a significant number of patients will have persistent symptoms or other indication for mechanical methods of reducing GERD.

- Surgical fundoplication is well-studied with good efficacy and safety profiles for patients requiring intervention. Remains the gold-standard for interventions.
Treatment for GERD: Summary

• Current endoscopic therapies commercially available include:
  – Endocinch®
  – EsophyX®
  – Stretta®

• A dynamic and pliable augmentation to the LES may provide the most efficacious GERD treatment with fewer side effects of other endoscopic or surgical options (i.e. Linx®)
Operative Treatments for GERD: the composition of an elegy?

Thank You