Endoscopic vs Surgical Therapies for GERD: Is it Time to Put down the Scalpel…?

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An effective treatment of GERD is expected to:

- Relieve symptoms
- Heal esophagitis (if present), and
- Prevent chronic complications. \(^1\)\(^-\)\(^3\)

Depending on the stage of the disease, treatment consists of PPIs or antireflux surgery (or procedures). \(^2\)

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Endoscopic vs Surgical Therapies for GERD

Normal Anatomy
Fully Functional Valve Prevents Reflux

Dysfunctional Valve
Reflex

Gray's Anatomy, 1997

Lower Esophageal Sphincter (LES)

Gastroesophageal Flap Valve (GEV)
Endoscopic vs Surgical Therapies for GERD

Options

• **Endo**
  - Transoral incisionless fundoplication (TIF)
  - Stretta™
  - MUSE™

• **Surgical**
  - Lower esophageal magnetic augmentation (Linx®)
  - Fundoplication
Endoscopic vs Surgical Therapies for GERD

History of Endoluminal Treatment Options

- Suture: EndoCinch, NDO Plicator
- RF Energy: Stretta
- Injection: EnteryX, Gatekeeper
Transoral Incisionless Fundoplication

- 40 - 60 minute procedure
- 12 SerosaFuse fasteners
  (3.0 propylene sutures)
- General anesthesia
- Outpatient
- Exclude Barrett’s, Class C/D esophagitis, HH > 2 cm
Endoscopic vs Surgical Therapies for GERD

**TIF Outcomes**

- Most prospective case series comparing pre-TIF to post-TIF
- Average follow-up ranges from 6 – 12 months
- Patients range from 8 - 124
- TEMPO Trial
  - RCT TIF vs PPI
- RESPECT Trial
  - RCT TIF vs Sham + PPI
Endoscopic vs Surgical Therapies for GERD

TEMPO

- US-based, multicenter (N=7), prospective, open label, randomized comparative study
- TIF (39) vs double dose PPI (21)
- TIF improved ambulatory pH metrics, but was not better than maximal dose PPI
- Normalization of esophageal acid exposure was not achieved following TIF in all patients
Endoscopic vs Surgical Therapies for GERD

RESPECT Trial

- US-based, Multicenter (N=8), prospective TIF (87) vs sham (42) randomized trial with 6 month f/u
- Excluded BMI > 35, HH > 2 cm, Class C/D esophagitis

- TIF effective in eliminating GERD symptoms, especially regurgitation, with a low failure rate and good safety profile at 6 months.
Endoscopic vs Surgical Therapies for GERD

TIF Summary

• Similar anti-reflux mechanism to Nissen fundoplication
• Generally tolerated well by patients
• Appears to have less short and long term side effects than Nissen (less gas / bloating)
• Long term durability studies are lacking
• RCTs are ongoing
• Does not preclude performing Lap Nissen
Endoscopic vs Surgical Therapies for GERD

HOW STRETTA WORKS

- Multi-level RF remodels LES and cardia
  - Increased Wall thickness
  - Decreased Tissue Compliance
  - Increased LES Pressure
  - Decreased TLESRs

- 45 minute procedure
- Outpatient
- Rapid recovery
  - Most are back to work/activities the following day
- < 2cm HH


# STRETTA Efficacy

META-Analysis - 18 Studies – 1,441 Patients

<table>
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<th>Outcome Variable</th>
<th>Studies (n)</th>
<th>Patients (n)</th>
<th>Mean Follow-up (mo)</th>
<th>Pre-Stretta</th>
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</table>

Endoscopic vs Surgical Therapies for GERD

**STRETTA Efficacy**

Sustained improvement in symptoms of GERD & antisecretory drug use:
4-year follow-up of the Stretta® procedure.

- **96 PATIENTS - 48 MONTHS**
- **75% OFF ALL MEDICATION**
- **NO SERIOUS COMPLICATIONS**


- **83 PATIENTS - 48 MONTHS**
- **86.4% OFF DAILY MEDICATIONS**
- **NO SERIOUS COMPLICATIONS**

Reymunde A, Santiago N. *Gastrointest Endosc*. 2007 Mar;65(3):361-6

Long-term results of RF energy delivery for treatment of GERD. Results of a 48 month prospective study.

- **56 PATIENTS - 48 MONTHS**
- **72% OFF ALL MEDICATION**
- **1 TRANSIENT COMPLICATION**

Dughera et al, *Diagnostic and Therapeutic Endoscopy*, August 2011
Endoscopic vs Surgical Therapies for GERD

10 Year Stretta Efficacy Study

- Prospective, 217 patients followed for > 4 years
- 99 patients analyzed at 10 years
- Complications:
  - 2 patients--minor gastric bleeding (self limited)
- 10 year Results:
  - 72% had normalization of GERD-HRQL
  - 64% had reduction in PPI dose
  - 41% had elimination of PPI
- Limitations: 50 Lost to follow up

- Conclusion—After Stretta GERD-HRQL scores, satisfaction, and PPI use significantly improved and results were immediate and durable at 10 years

Noar et al. Surgical Endoscopy 2014 28: 2323-33
Endoscopic vs Surgical Therapies for GERD

Linx®

- Standard Laparoscopic Approach
- Generally Completed in Less Than 1 Hour
- No Alteration to Gastric Anatomy
- Reversible
- No Post-Operative Adjustments

- Small HH
- Normal motility
- No routine MRI
- No metal allergies
- ??
- Larger HH, Barrett’s, prior anti-reflux procedure, sleeve
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-Haerer, M.D., C. Daniel Smith, M.D., Christopher C. Smith, M.D., Dan Dunn, M.D., and Paul A. Taiganides, M.D.
Esophageal Acid Exposure

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Elimination of Daily PPIs

Patients Reporting Daily PPI Use (%)

- Feasibility
- Pivotal

Baseline: N=100
12 month: N=97
24 month: N=90
36 month: N=32
48 month: N=25

Discover ▪ Teach ▪ Heal
Patient Satisfaction

- Feasibility
- Pivotal

N=100 Baseline
N=44
N=95 12 month
N=90
N=39
N=35
N=31 24 month
N=23 48 month

Patients Satisfied (%)
Reduced Gas Bloat

Severity of Gas Bloat

- FREQUENTLY
- CONTINUOUSLY

Percent of Patients Reporting

Baseline | 12 Month Post LINC | 24 Month Post LINC

Discover ▪ Teach ▪ Heal
What to Expect After Surgery
• Return to a normal diet as soon as tolerated
• Follow steps to manage dysphagia, if encountered
• Return to normal physical activity within a week
• Patients generally maintain ability to belch and vomit
• LINX Implant Card provided to all patients

SIDE EFFECTS
• Ability to Belch
  • 99% of patients retained ability to belch
• Inability to Vomit
  • 0% at 12 months
  • 1% at 24 months
Endoscopic vs Surgical Therapies for GERD

Nissen Fundoplication
The Best Fundoplication?

- 360°
- 270° posterior
- 180° posterior
- 180° anterior
- 120° anterior
Endoscopic vs Surgical Therapies for GERD

Outcomes of GERD/PEH Repair

- 90% improvement in reflux symptoms
- 87% absence of objective reflux
- 50% improvement from preoperative motility disorders
- Excellent or good patient satisfaction in 92%
- 77% (Nissen) durability at 11 years in approp pts

Morgenthal CB et al. Surg Endosc 2007
Endoscopic vs Surgical Therapies for GERD

Lap Nissen Fundoplication

- 1,000 cases
- Average hospital stay 1.2 days
- Resolution of symptoms at 1 year: 94%
- Major complications: 2%
- Long term complications: 2-62%
  - Gas and bloating
  - Dysphagia

Endoscopic vs Surgical Therapies for GERD

Nissen vs Meds

• VA cooperative study/RCT
• Maximal meds vs surgery in medically refractory patients
• Results
  – 2/3 resolved in surgical group at 12 months
  – Less than 1/3 resolved in medical group
• Conclusion:
  – For PPI-refractory GERD, surgery is superior to meds

Endoscopic vs Surgical Therapies for GERD

**Fundoplication**

- ~75% durable at 10 years
- HH recurrence may sabotage fundo
- In experienced hands, gas/bloat uncommon
- Highly safe and effective

Pre-procedure

Post-procedure
Endoscopic vs Surgical Therapies for GERD

Meds

Endolumenal Surgery

Esophageal Magnetic Augmentation

Mild GERD

Early disease, no anatomic correction required

Severe GERD

Anatomic correction warranted