

# Endoscopic vs Surgical Therapies for GERD:

Is it Time to Put down the Scalpel...?

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General Surgery Residency Program Director  
UC Irvine Medical Center

Chief of Surgery  
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# Endoscopic vs Surgical Therapies for GERD

## GERD Treatments

- An effective treatment of GERD is expected to:
  - Relieve symptoms
  - Heal esophagitis (if present), and
  - Prevent chronic complications. <sup>1-3</sup>
- Depending on the stage of the disease, treatment consists of PPIs or antireflux surgery (or procedures). <sup>2</sup>

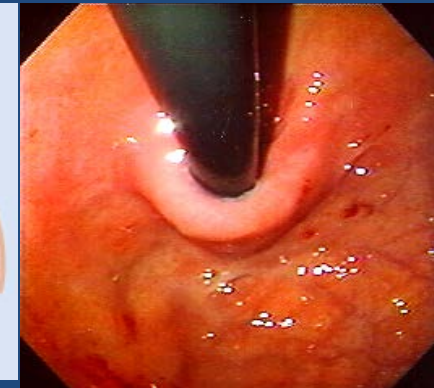
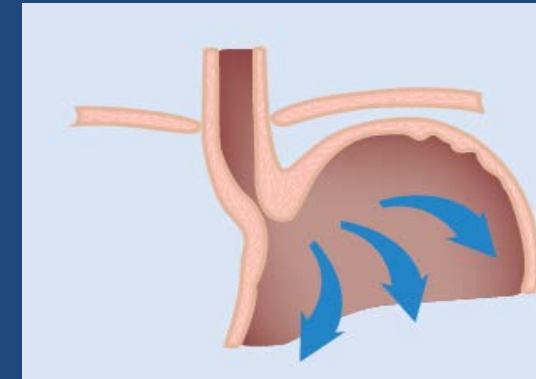
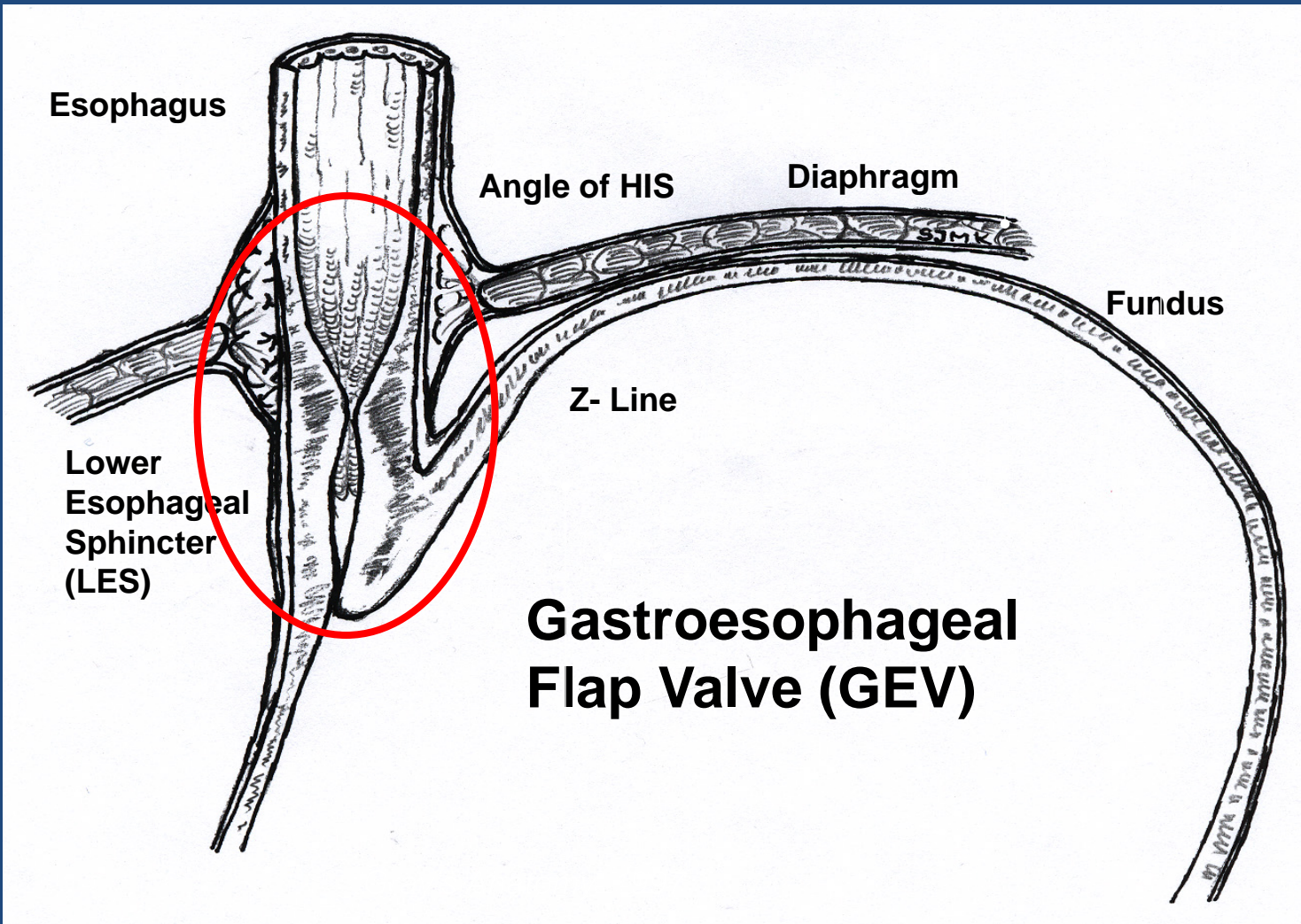
1 Spicak. *Dig Dis* 2007;25:183-187.

2 Tytgat et al. *Aliment Pharmacol Ther* 2008;27:249-256.

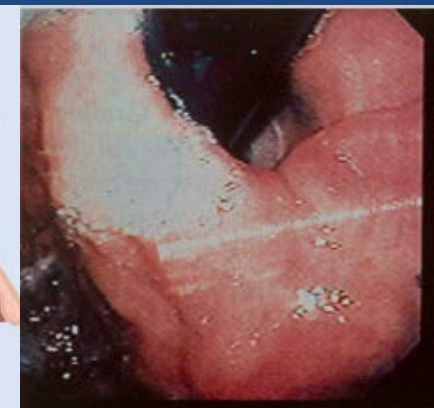
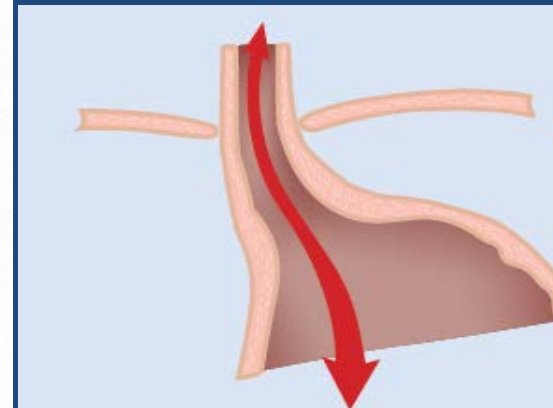
3 Wolfe, Lowe. *J Clin Gastroenterol* 2007;41:S209-S216.



# Endoscopic vs Surgical Therapies for GERD



**Normal Anatomy**  
Fully Functional Valve Prevents Reflux



**Dysfunctional Valve**  
Reflux

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# Endoscopic vs Surgical Therapies for GERD

## Options

- **Endo**

- Transoral incisionless fundoplication (TIF)
- Stretta™
- MUSE™

- **Surgical**

- Lower esophageal magnetic augmentation (Linx®)
- Fundoplication

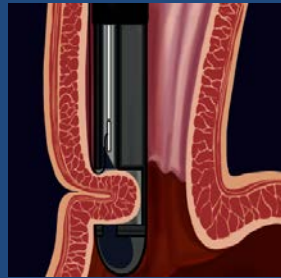




# Endoscopic vs Surgical Therapies for GERD

## History of Endoluminal Treatment Options

Suture



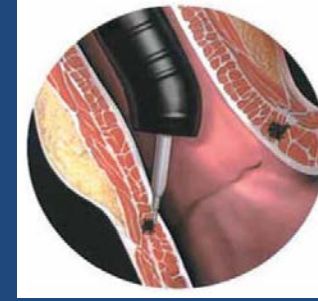
EndoCinch

RF Energy



Stretta

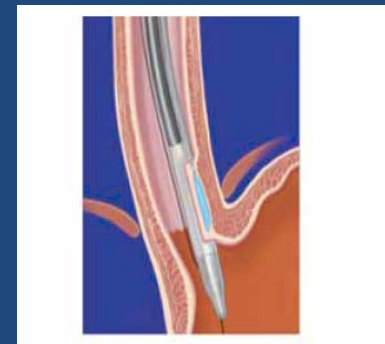
Injection



EnteryX



NDO Plicator



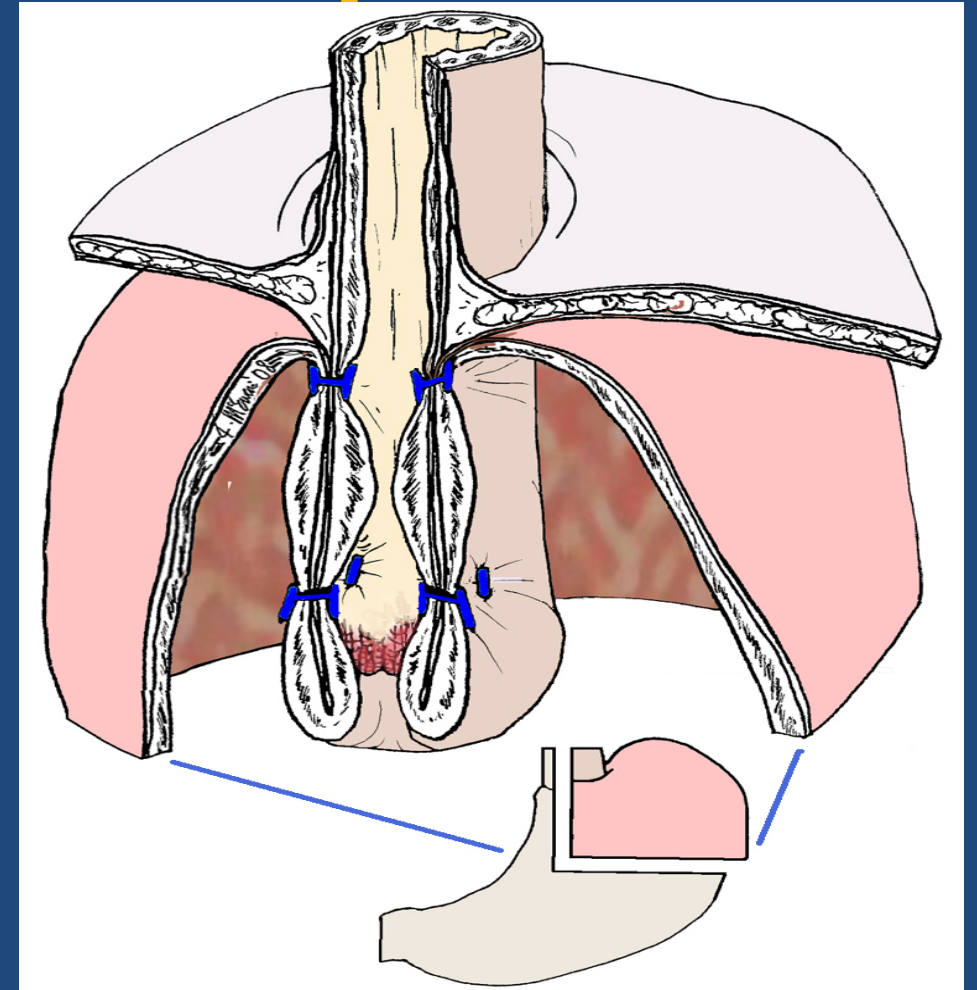
Gatekeeper



# Endoscopic vs Surgical Therapies for GERD

## 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



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# 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

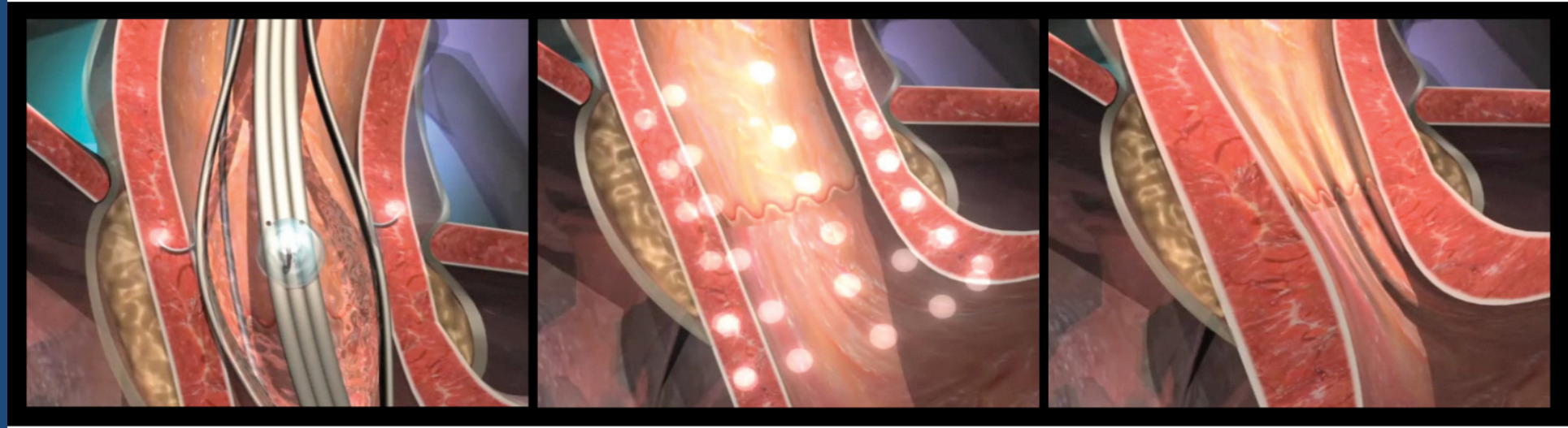
## TIF Summary

- 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

Outcome Variable	Studies (n)	Patients (n)	Mean Follow-up (mo)	Pre-Stretta	Post-Stretta	P-value
<b>SUBJECTIVE MEASUREMENTS</b>						
GERD-HRQL	9	433	19.8	26.11	9.25	0.0001
QOLRAD	4	250	25.2	3.30	9.25	0.0010
SF-36 Physical	6	299	9.5	36.45	46.12	0.0001
SF-36 Mental	5	264	10.0	46.79	55.16	0.0015
Heartburn Score	9	525	24.1	3.55	1.19	0.0001
Satisfaction Score	5	366	21.9	1.43	4.07	0.0006
<b>OBJECTIVE MEASUREMENTS</b>						
Esophageal Acid Exposure (%Ph<4)	11	364	11.9	10.29	6.51	0.0003
DeMeester score	7	267	13.1	44.37	28.53	0.0074
LES pressure	7	263	8.7	16.54	20.24	0.0302

Perry et al. *Surg Laparosc Endosc Percutan Tech* 2012;22:283–288



# 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

Noar MD, Lotfi-Emran S. *Gastrointest Endosc.* 2007 Mar; 65(3): 367-72.

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**Long-term results of RF energy delivery for treatment of GERD: sustained improvements in symptoms, quality of life, & drug use at 4-year follow-up.**

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

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

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**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

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# 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



*The* NEW ENGLAND  
JOURNAL *of* MEDICINE

n engl j med 368;8 nejm.org, february 21, 2013 719

original article

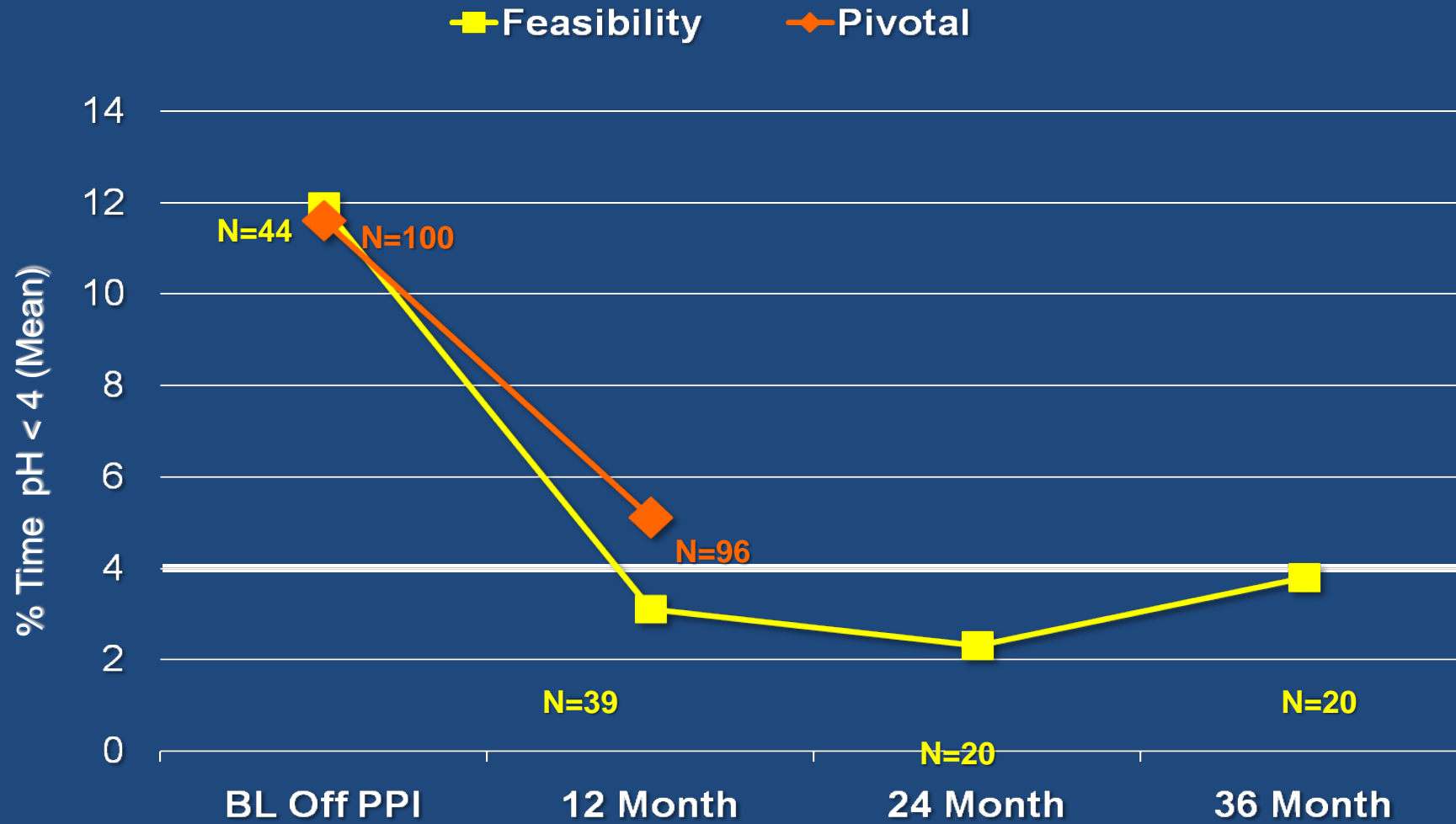
# Esophageal Sphincter Device for Gastroesophageal Reflux Disease

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-Haerer, M.D., C. Daniel Smith, M.D., Christopher C. Smith, M.D.,  
Dan Dunn, M.D., and Paul A. Taiganides, M.D.

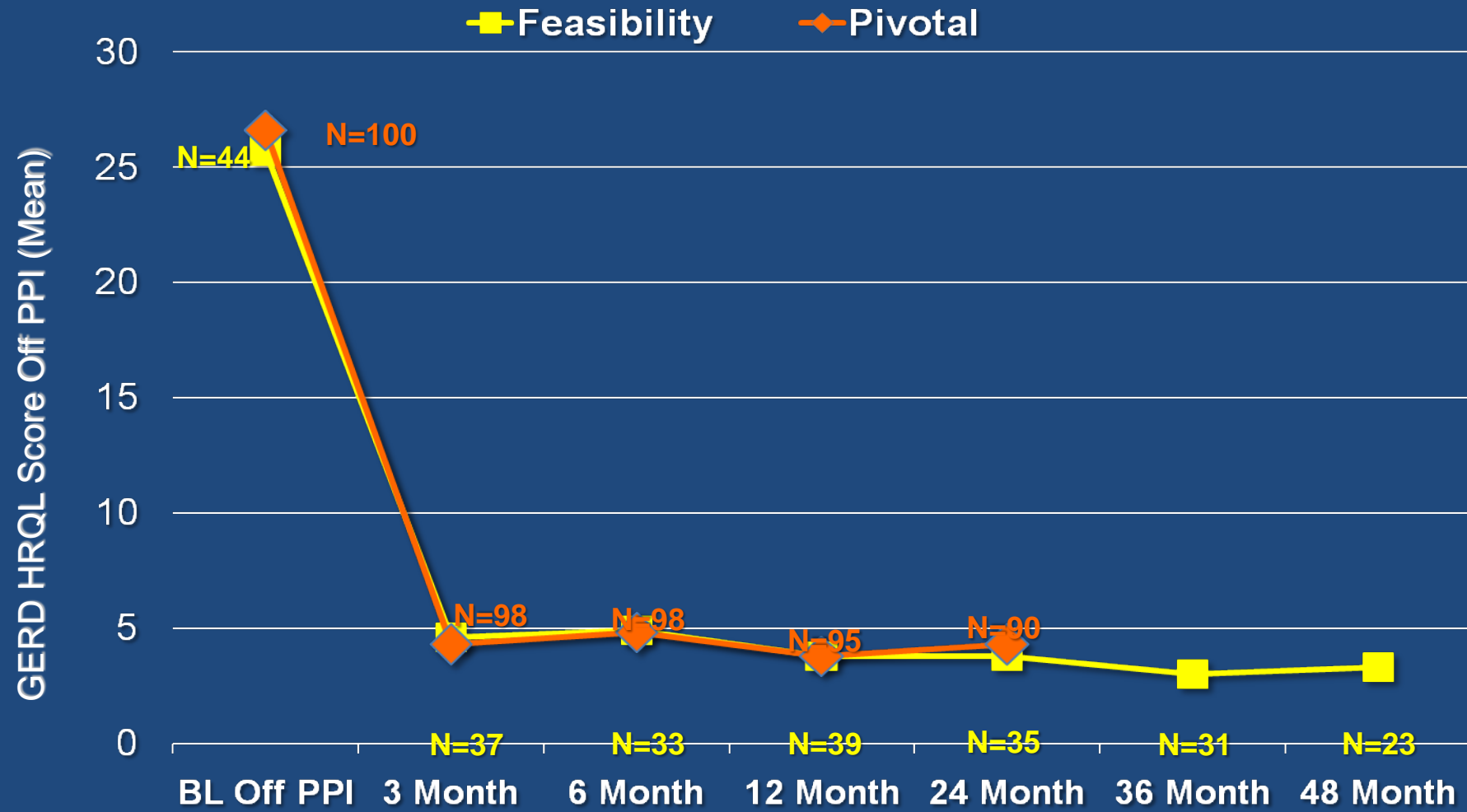




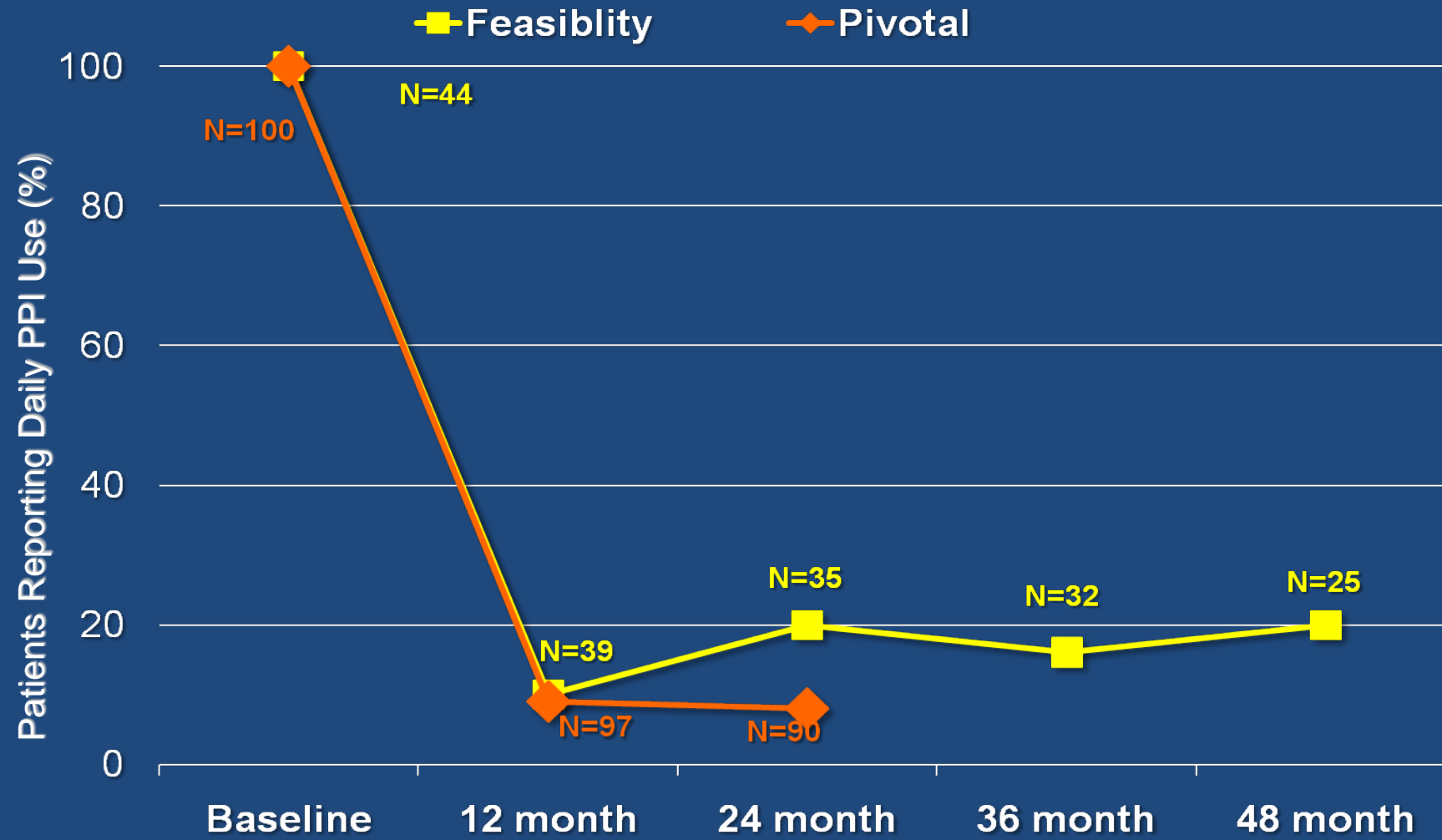
# Esophageal Acid Exposure



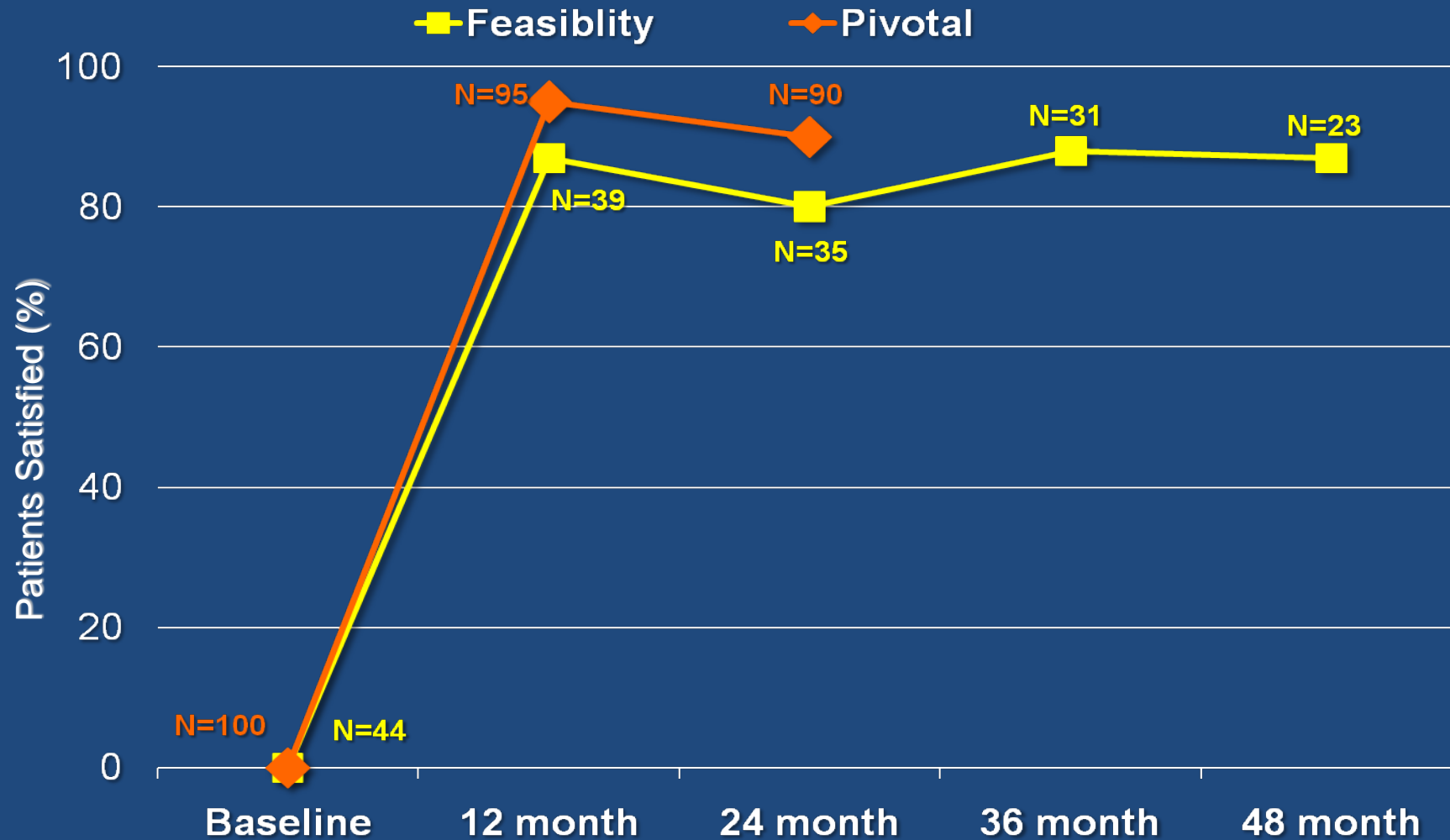
# Patient Quality of Life: GERD-HRQL Off PPI's



# Elimination of Daily PPIs



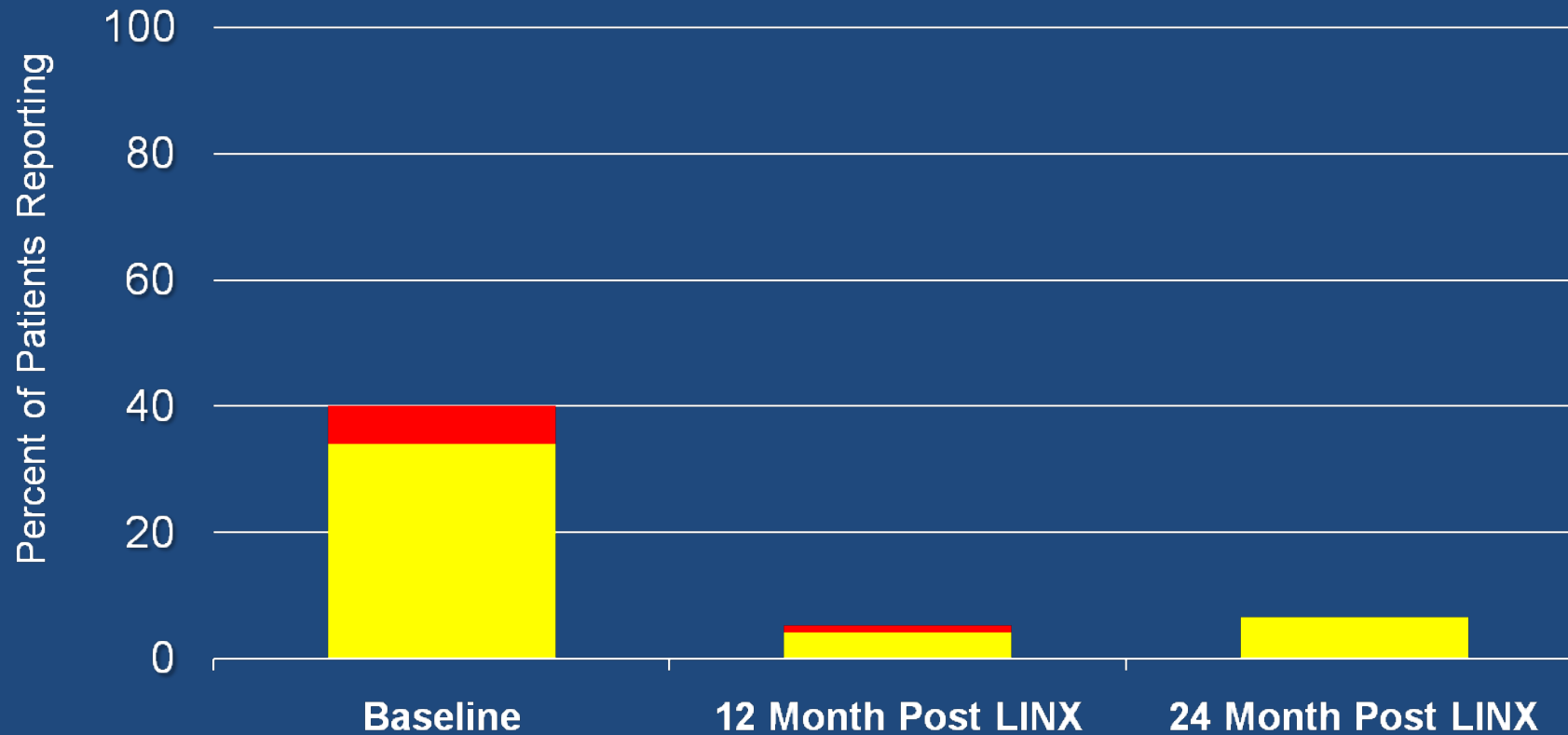
# Patient Satisfaction



# Reduced Gas Bloat

## Severity of Gas Bloat

■ FREQUENTLY ■ CONTINUOUSLY



# Endoscopic vs Surgical Therapies for GERD

## Linx Summary

### 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

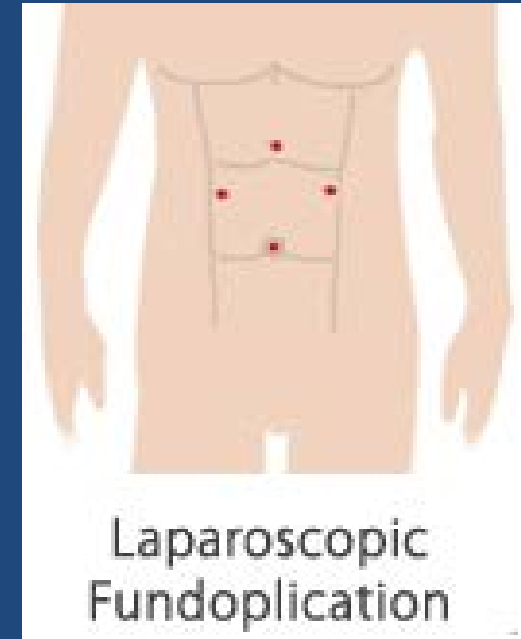
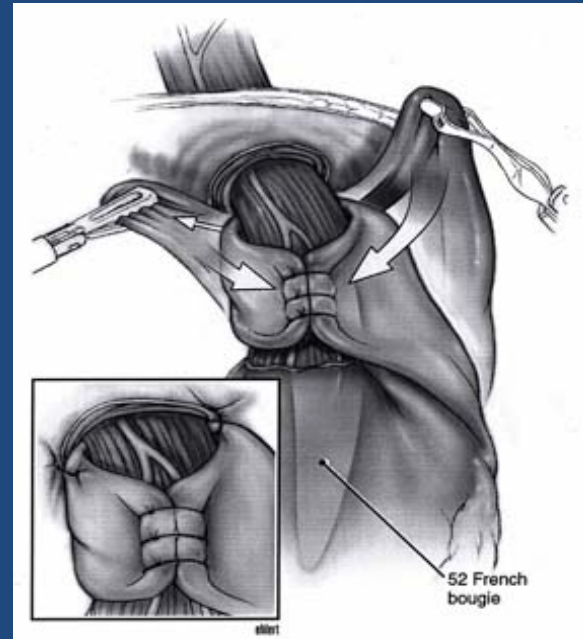
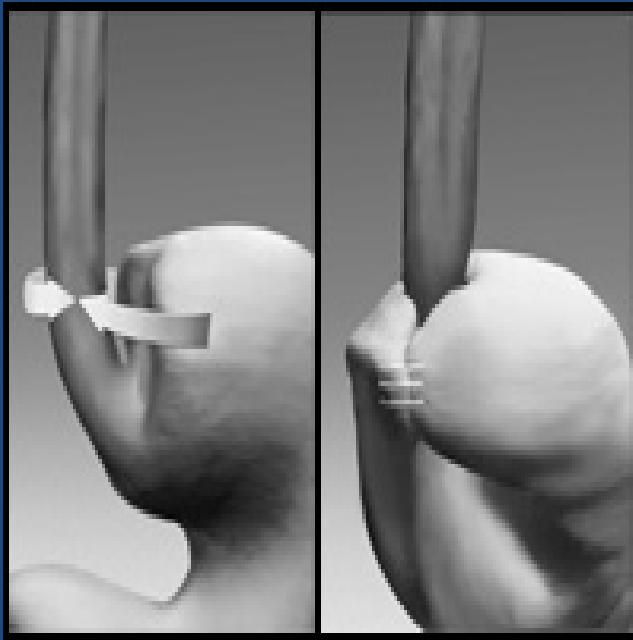
### SIDE EFFECTS

- **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

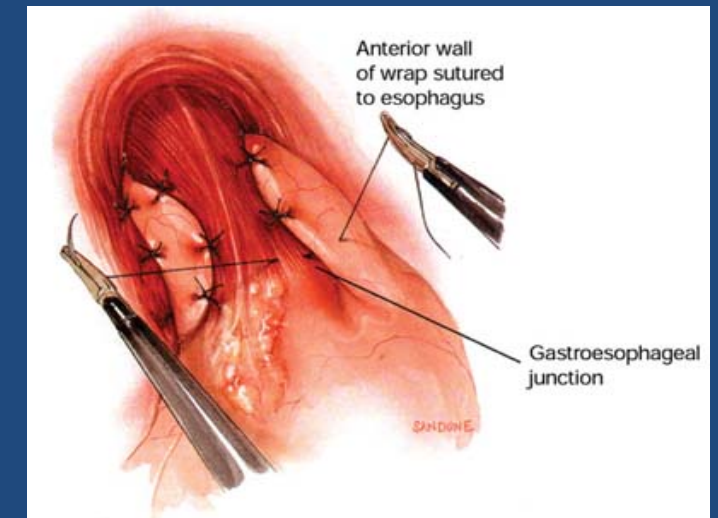
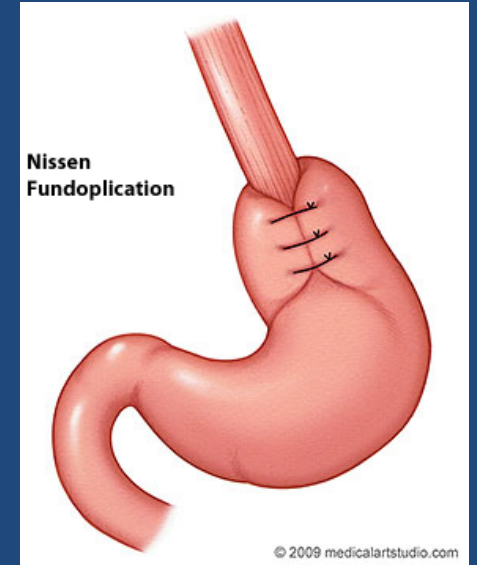
## Nissen Fundoplication



# Endoscopic vs Surgical Therapies for GERD

## The Best Fundoplication?

- 360°
- 270° posterior
- 180° posterior
- 180° anterior
- 120° anterior



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# 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

Swanstrom LL, et al. Am J Surg 1999; 177:359-63

- Excellent or good patient satisfaction in 92%

Pierre AF, et al. Ann Thorac Surg 2002; 74:1909-16

- 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

Hunter JG, et al. Surgical Endoscopy 2001



# 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

Spechler S, et al. In Press 2018



# Endoscopic vs Surgical Therapies for GERD

## Fundoplication

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



Pre-procedure



Post-procedure



# Endoscopic vs Surgical Therapies for GERD

