Personalized Approaches to GERD

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Objectives

- Identify appropriate patients to consider surgical consultation for GERD
- Define the evaluation of patients considering reflux surgery.
- Discuss the currently available options for anti-reflux surgery

GERD: Epidemiology and Cost

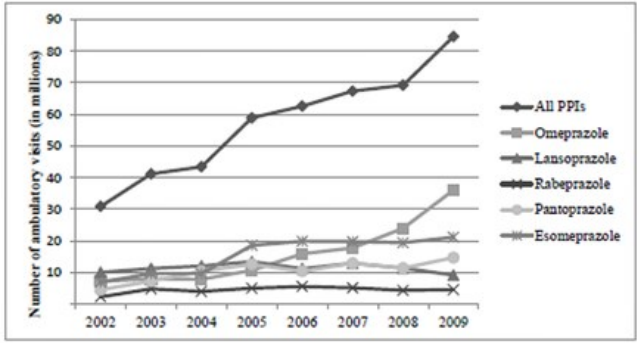
- In the U.S., more than 60 million adults experience GERD-like symptoms at least monthly
  - Most common outpatient diagnosis for patients with a GI complaint

- $12 billion spent on GERD trx in 2004
  - 2/3 attributed to PPIs
  - % of patients prescribed a PPI during outpatient visit doubled between 2002 and 2009

Why do we need new treatment approaches for GERD?

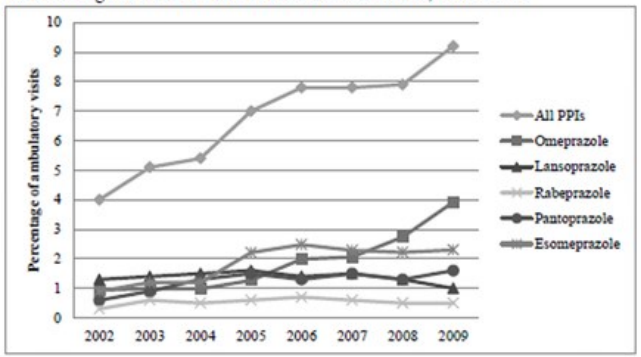
- Proton Pump Inhibitors
  - Most commonly used medications for GERD
  - Requires continuous therapy, and 30% have breakthrough sx
  - Concern about cost and risk of complications
- Laparoscopic Fundoplication
  - GI side effects
    - Dysphagia, flatulence and Bloating

a. Number of visits in which PPI use was documented, 2002 – 2009[a]



a Weighted national estimates based on the sample that was surveyed

b. Percentage of visits in which PPI use was documented, 2002 – 2009[a,b]



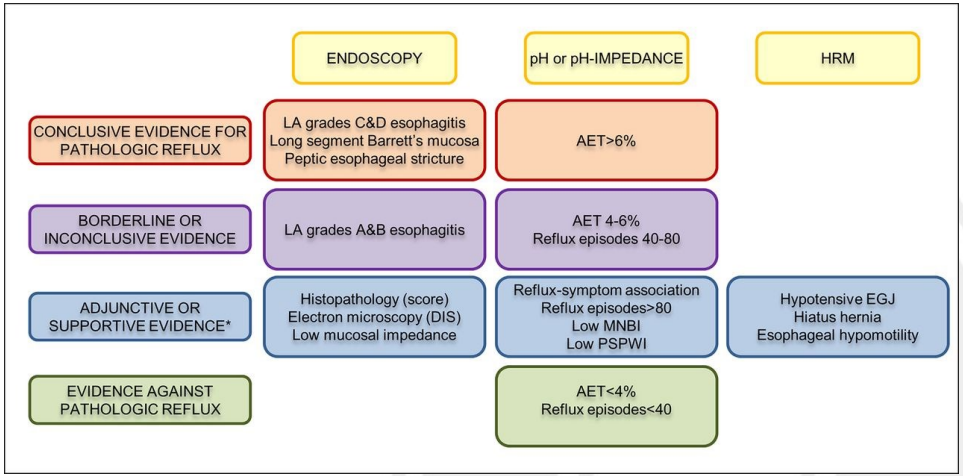
a Weighted percentages based on the sample that was surveyed
b $p<0.001$ for trend across years in all PPI use, omeprazole use, pantoprazole use, esomeprazole use, and pantoprazole after controlling for changes in patient characteristics

ERSITY

GERD Definition

GERD is a condition which develops when the reflux of gastric content causes troublesome symptoms or complications

- Esophageal Syndromes
  - Symptomatic Syndromes
    - 1.Typical Reflux Syndrome
    - 2.Reflux Chest Pain Syndrome
  - Syndromes with Esophageal injury
    - 1. Reflux Esophagitis
    - 2. Reflux Stricture
    - 3. Barrett's Esophagus
    - 4.Esophageal Adenocarcinoma
- Extraesophageal Syndromes
  - Established Associations
    - 1. Reflux Cough Syndrome
    - 2. Reflux Laryngitis Syndrome
    - 3. Reflux Asthma Syndrome
    - 4. Reflux Dental Erosion Syndrome
  - Proposed Associations
    - 1. Pharyngitis
    - 2. Sinusitis
    - 3. Idiopathic Pulmonary Fibrosis
    - 4. Recurrent Otitis Media



The Montreal Definition and Classification of Gastroesophageal Reflux Disease: A Global Evidence-Based Consensus. Nimish Vakil, Sander V van Zanten, Peter Kahrilas, John Dent and Roger Jones the Global Consensus Group

So When Should We Consider Surgery?

1. Acid control - management or prevention of complications
    - Esophagitis
    - Stricture
    - Barrett's esophagus
2. Symptom control - patient QoL
3. Concerns about long-term PPI use

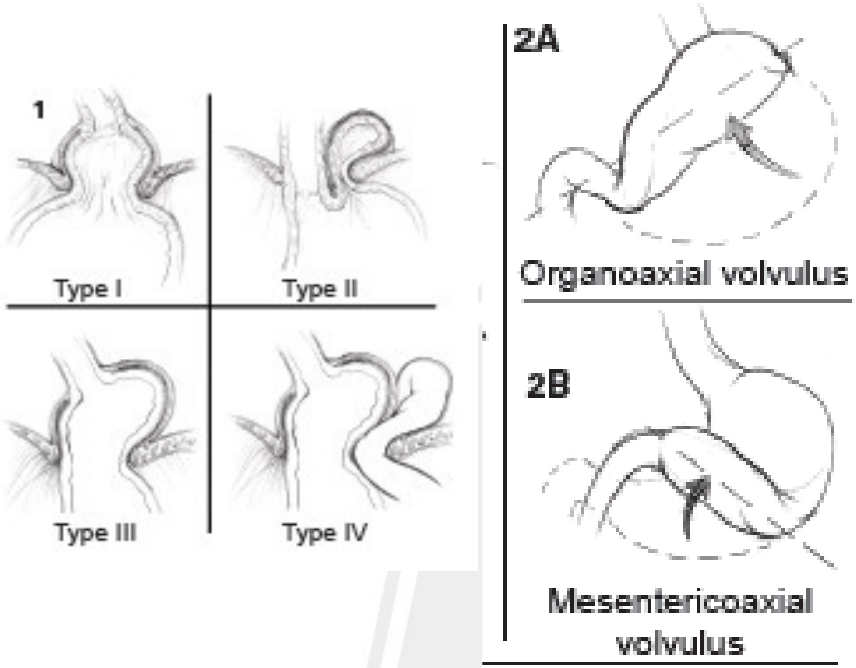
Must Consider Risks, Benefits and Side Effects of Available Treatment Approaches

- Proton Pump Inhibitors
  - Most commonly used medications for GERD
  - Requires continuous therapy, and 30% have breakthrough sx
  - Concern about cost and risk of complications
- Laparoscopic Fundoplication
  - GI side effects
    - Dysphagia, flatulence and Bloating

Symptom	LNF (180)	PPI (192)	P-value
Heartburn	8%	16%	0.140
Regurgitation	2%	**13%**	<0.001
Dysphagia	**11%**	5%	<0.001
Bloating	**40%**	28%	<0.001
Flatulence	**57%**	40%	<0.001

Where Does Hiatal Hernia Fit In?

- Classify patients based on whether symptoms are indicative of GERD or Hiatal Hernia.
- Management is mostly dictated by symptoms, NOT the presence or absence of a hernia.

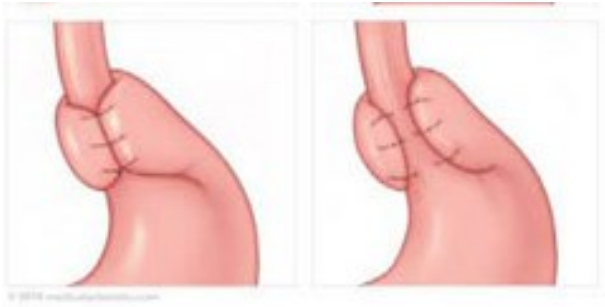


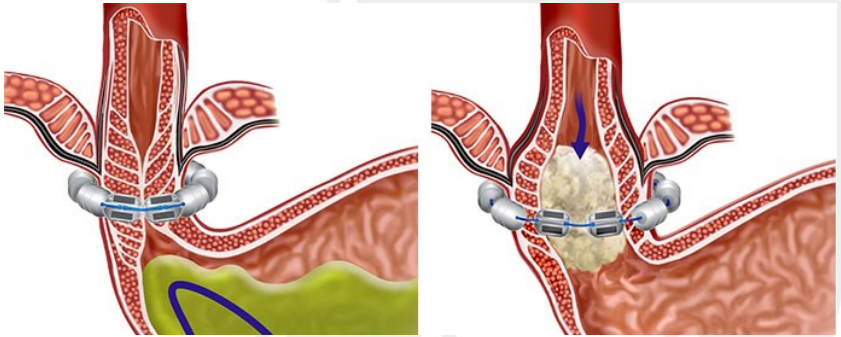
Preoperative Evaluation

- 1. EGD
  - All patients must have an EGD prior to surgery
- 2. pH study
  - Need to establish the diagnosis of GERD (r/o functional HB)
- 3. Manometry
  - Assess adequate motility for full fundoplication/Linx
  - Need to rule out achalasia, scleroderma esophagus
- 4. UGI
  - Mostly useful for patients with PEH, or to r/o small HH

Currently Available Procedural Treatment Options

- Laparoscopic Fundoplciation
  - Nissen fundoplication (360°)
  - Toupet fundoplication (270°)
- Linx (magnetic GEJ reinforcement)
- Transoral Incisionless fundoplication (Esophyx)





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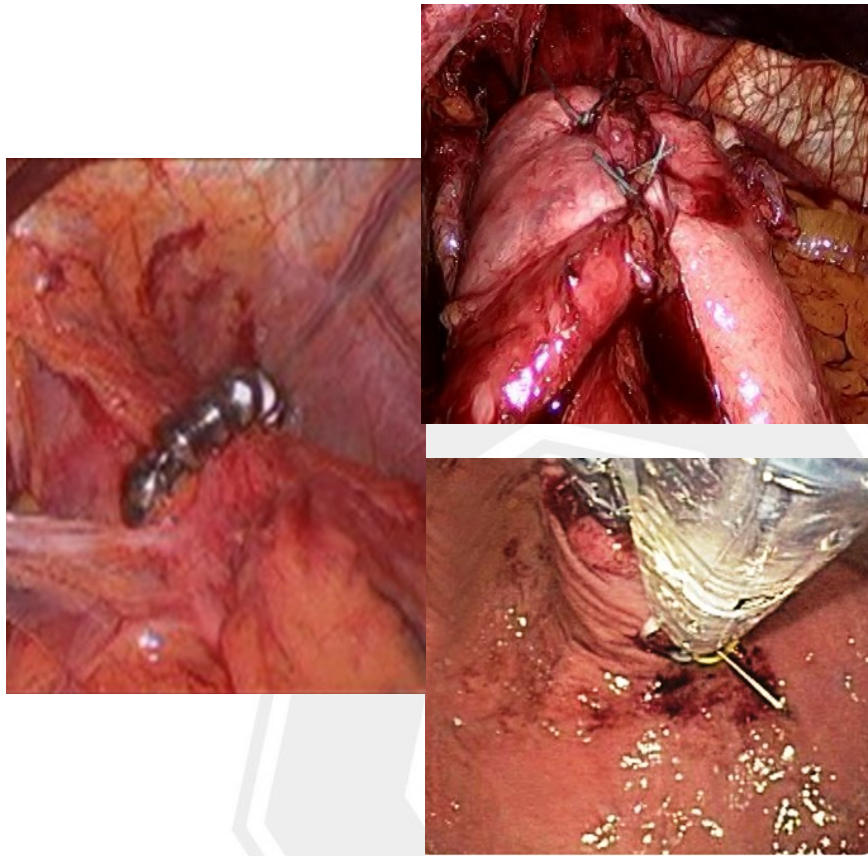


Transoral Incisionless Fundoplication (TIF)

- Over-the-scope device inserted by mouth
- Allows treatment *without abdominal incisions*
  - 30 - 60 minute procedure
  - General anesthesia
  - 14-20 fasteners
  - Post-op discomfort minimal
  - Rapid recovery

RESPECT Trial

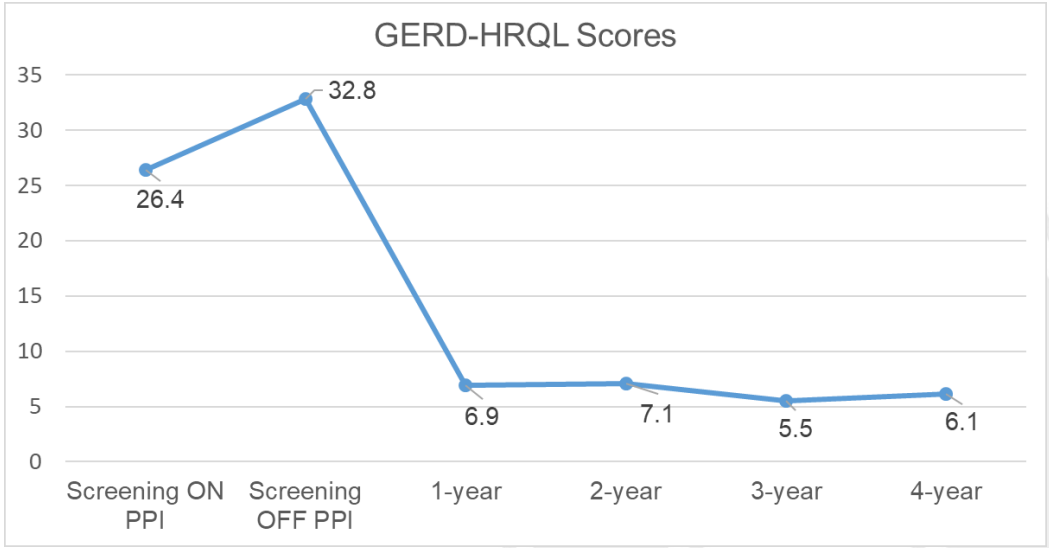
- RCT of TIF v Sham procedure
  - Troublesome regurgitation, + pH
  - TIF kept on placebo medication
  - Failures at 3 months unblinded and crossed over
- 81 TF vs 38 Sham/PPI (per protocol analysis)
  - 15 (39%) early failures in sham group
  - 10 (12.3%) in TF group

- **Resolution of troublesome regurgitation in 67% of TF patients compared to 45% of Sham/PPI patients.**

Hunter et al. Gastroenterology. 2015

TEMPO Trial

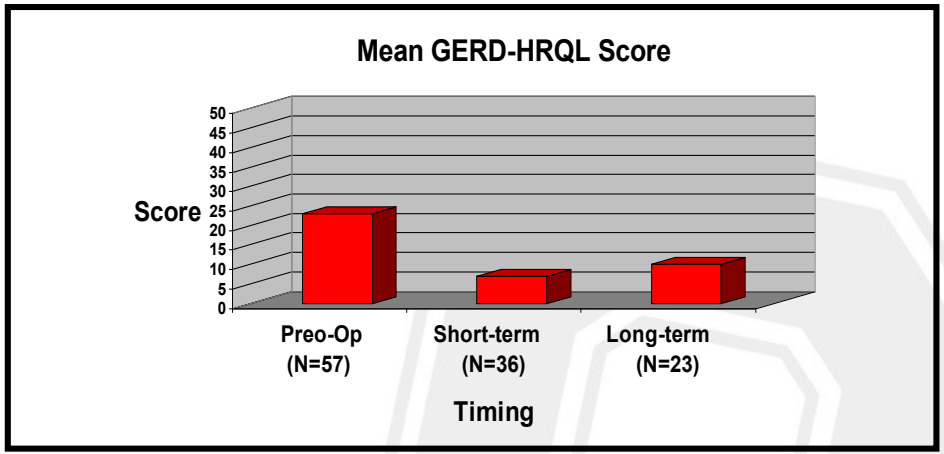
- 63 patients
  - randomized to TIF (n=40) or PPI (n=23)
- 36 months follow-up
  - 91% of patients reported elimination of troublesome regurgitation
  - **58% were able free of daily PPI therapy after 4 years**



Trad et al. Surg Endosc. 2017

OSU Long-Term Follow-up Study

- 57 OSUMC patients undergoing TIF between 2007-2014
  - Median FU 98 months (8.2 years)
- Results:
  - 12 had reflux surgery
  - *74% PPI use*
  - **78% patients satisfied or neutral**
  - Mean GERD-HRQL score 10 ($p<0.01$)



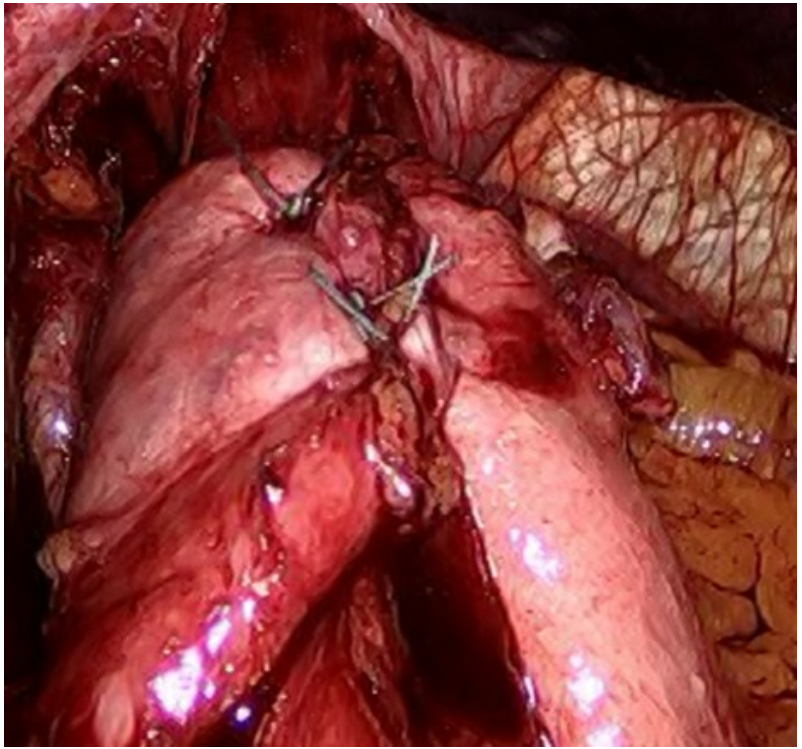
Chimukangara et al. Surg Endosc, 2019

TIF Conclusions

- Effectively reduces GERD symptoms in select patients
- *Low incidence of side effects*, but does not consistently normalize esophageal pH
- Long-term data suggest high rates of PPI dependence

- **EXPENSIVE**

LNF vs Linx®: Mechanisms of Action



Linx®: Patient Selection

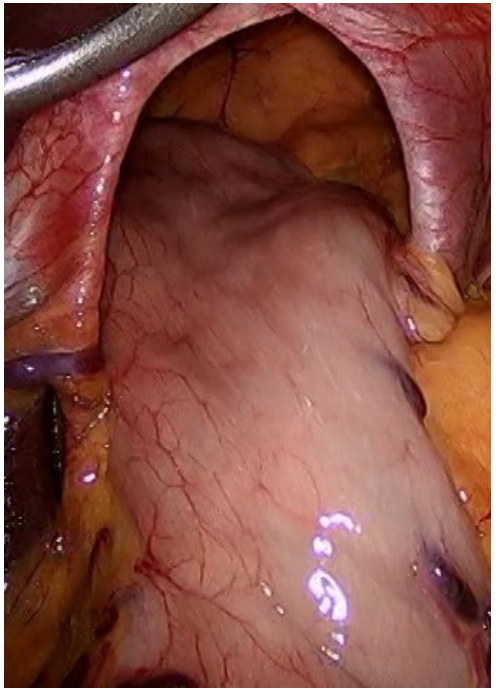
- Patient with mild/moderate GERD symptoms +/- hiatal hernia with concerns about costs and side effects of long-term PPI use
  - *Positive pH test*
  - **Normal esophageal motility**
  - No severe esophagitis or long-segment BE

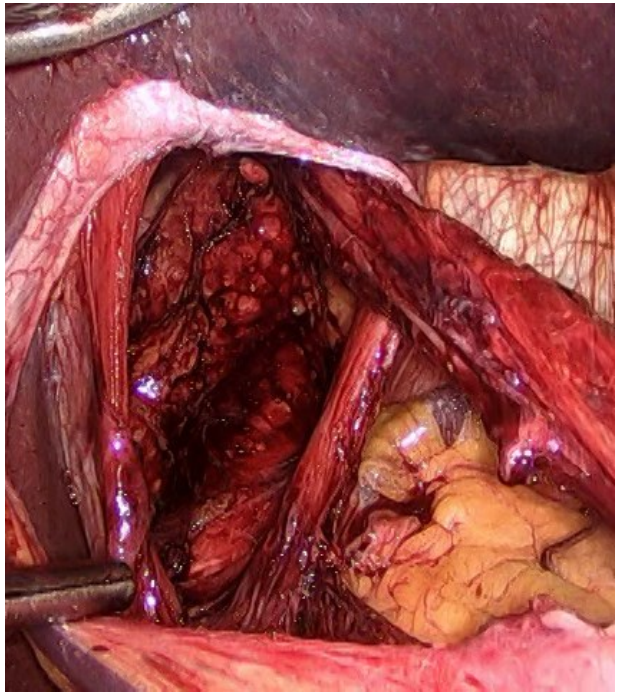
LNF vs Linx®: Technique and Recovery

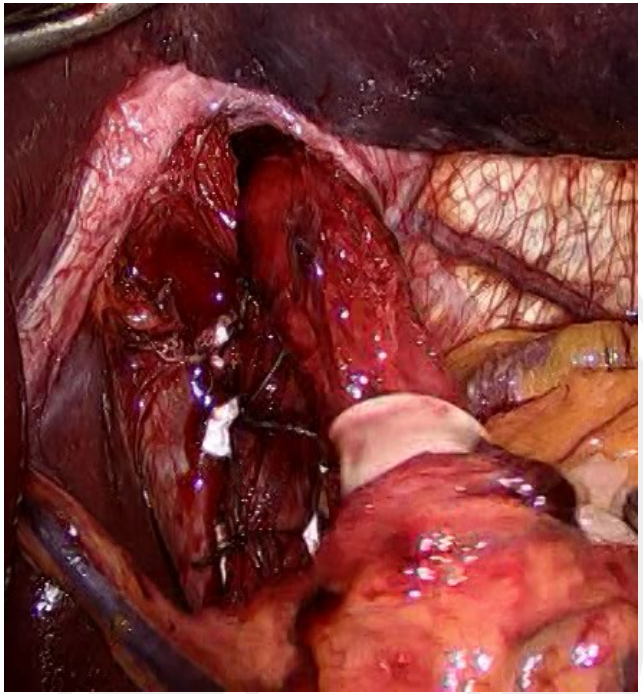
- LNF
- 4 port Laparoscopy
- Complete dissection of hiatus and gastric fundus
- **Overnight hospital stay**
- Modified diet for 4-6 weeks
- Discontinuation of PPI

- Linx®
- 4 port laparoscopy
- *Minimal gastric dissection* (↓ OR time)
- Outpatient procedure
- Resume normal diet early
- Discontinue PPI therapy

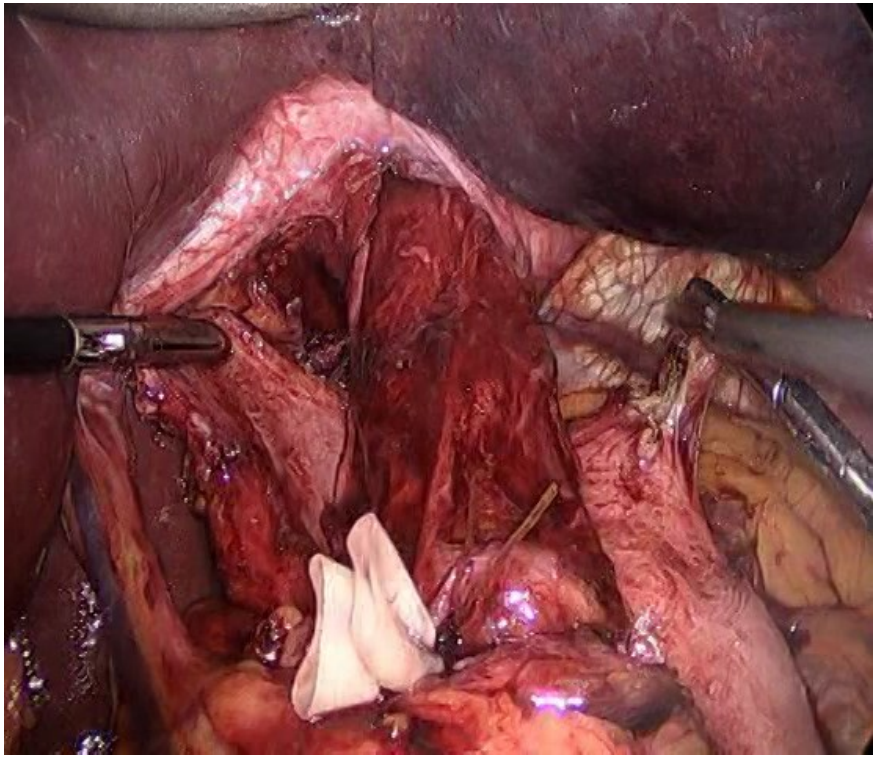
Technique: LNF

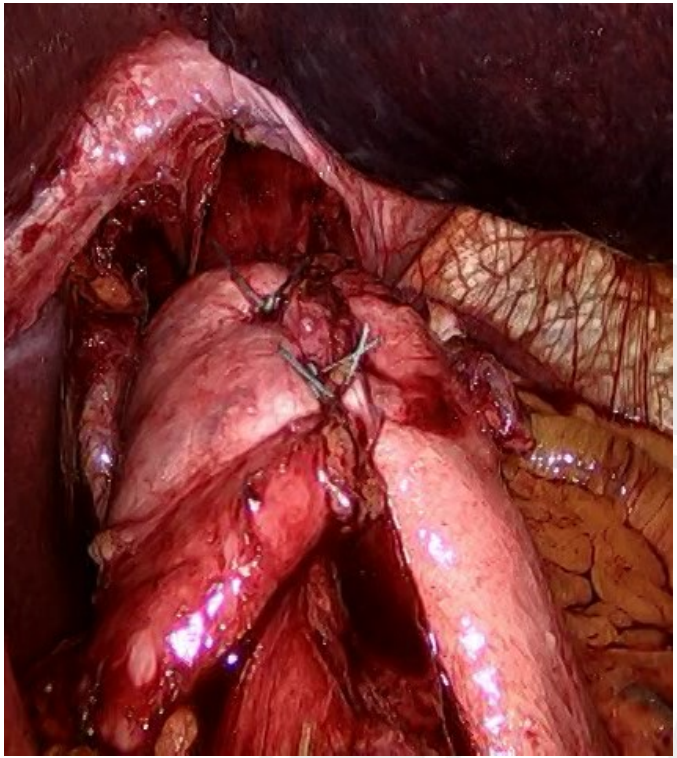




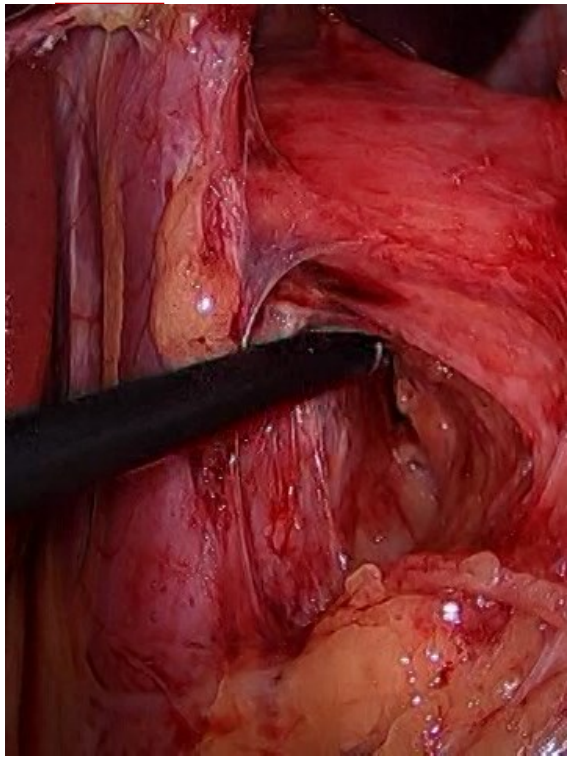


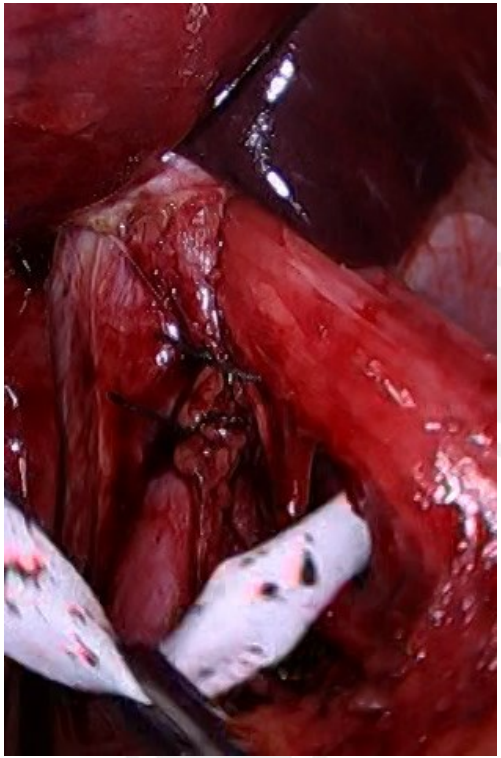
Technique: LNF





Technique: Linx®





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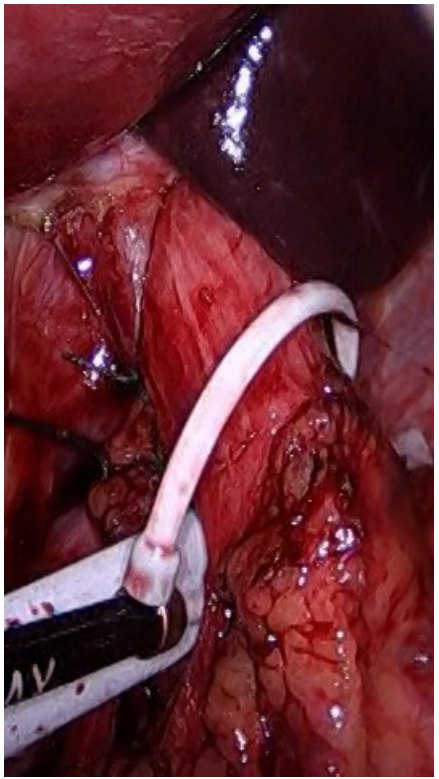
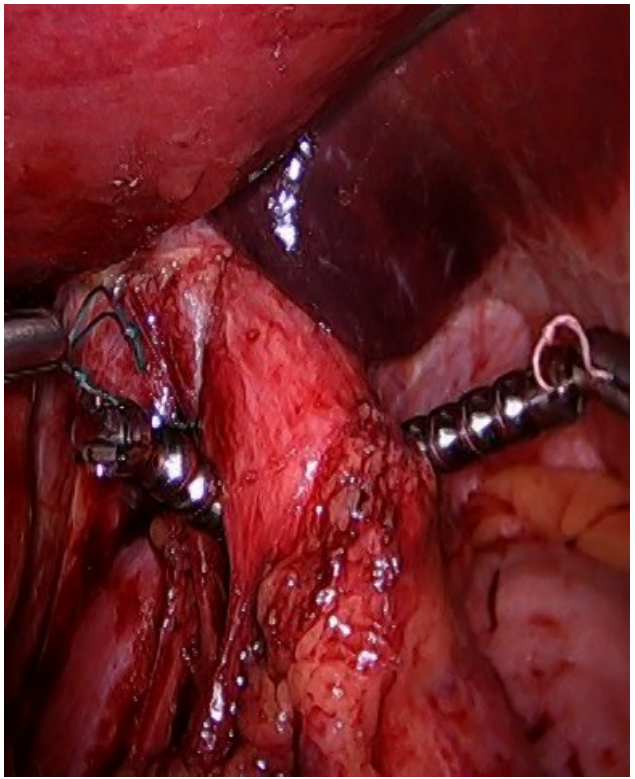




LNF vs Linx®: Efficacy

- LNF
- Excellent relief of HB and regurgitation
- Normalizes pH in up to 93% of cases
- >90% PPI cessation after 1 year
- High rates of patient satisfaction

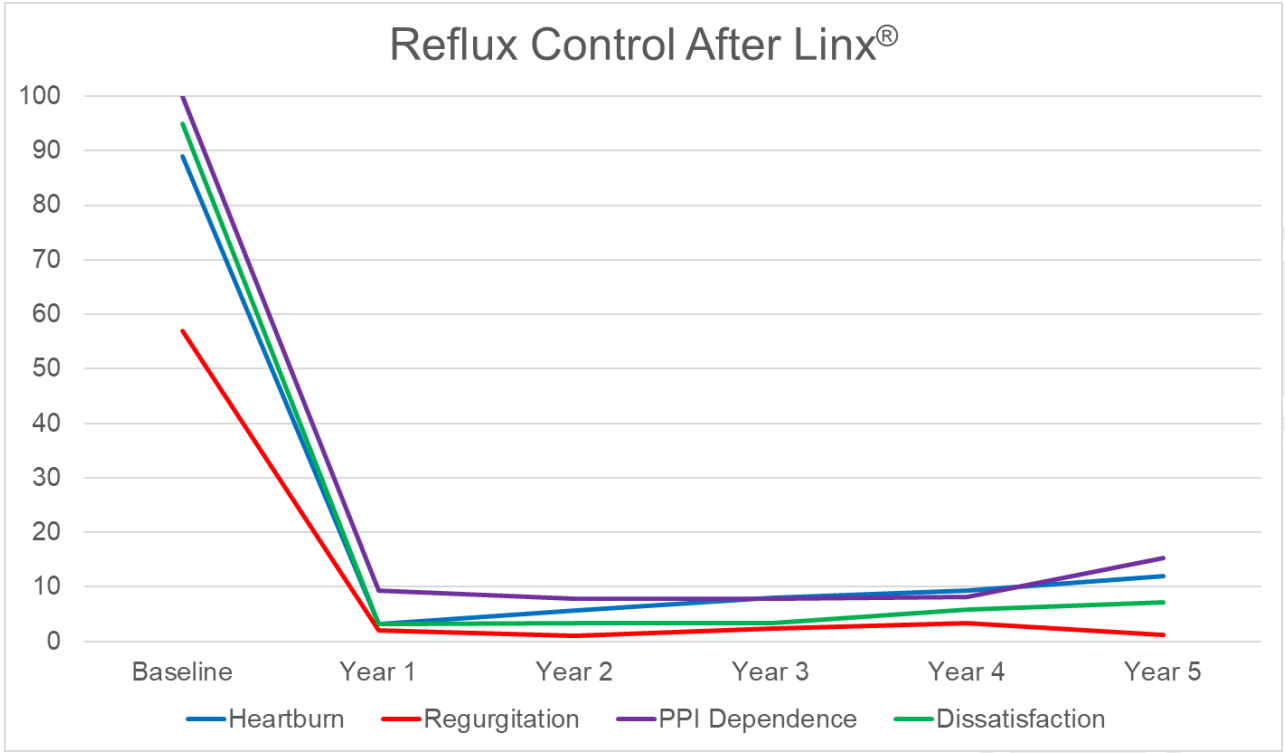
- Linx®
- Similar reductions in GERD symptom scores to LNF
- pH normalization in 58%
- >90% PPI cessation after 1 year
- High rates of patient satisfaction

LNF vs Linx®: Durability

Series	FU (yrs)	HB relief (%)	Revisions (%)	Off meds (%)
Morganthal (USA)	11.0	89	10.8	70
Dallemange (BEL)	10.3	96	1.4	92
Bammer (USA)	6.4	94	1.0	86
Lafullarde (AUS)	6.0	87	14.2	88
Anvari (CAN)	5.0	--	3.6	89
Booth (GBR)	4.0	90	6.3	86

Morganthal et al. J Gastrointest Surg, 2007

LNF vs Linx®: Durability



Ganz et al. Clin Gastroenterol Hepatol, 2015

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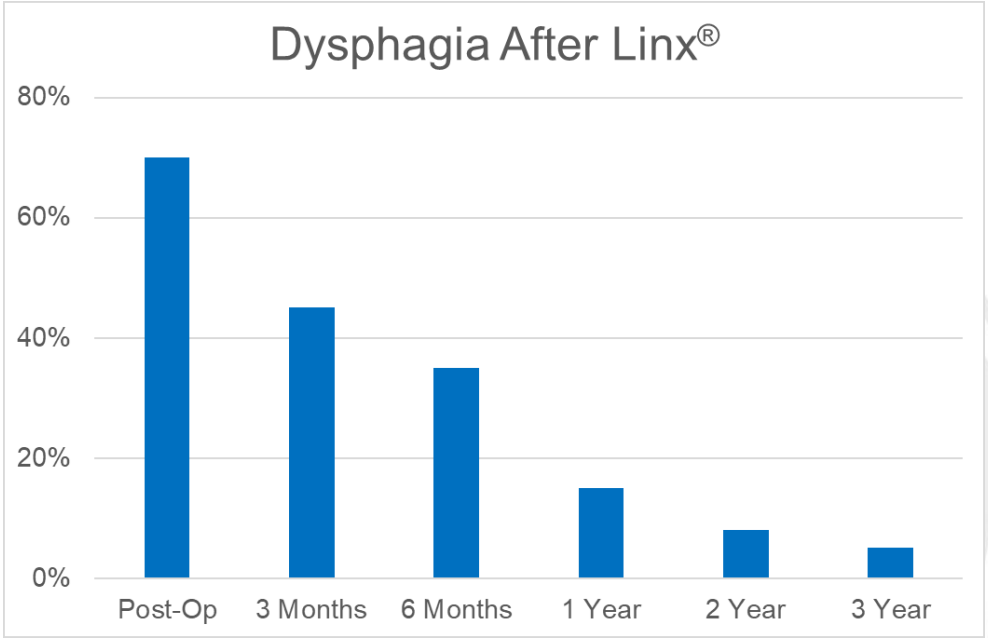
LNF vs Linx®: Side Effects

Adverse Events Following Linx®				
Event	Overall Incidence	Maximun Level of Intensity		
		Mild	Moderate	Severe
Dysphagia	68%	47%	16%	5%
Bloating	14%	12%	2%	0%
Pain	25%	7%	13%	5%



Ganz et al. N Engl J Med, 2013

LNF vs Linx®: Conclusions

- LNF
  - Excellent control of both symptoms and acid control
  - Remains operator dependent
  - Discussion of benefit vs side effects is paramount to achieve high rates of patient satisfaction
  - Very good long-term outcomes
- Linx®
  - Easier to standardize technique
  - Is also associated with side effects (dysphagia) that must be discussed preoperatively
  - Patient selection remains extremely important
  - Potential for long-term efficacy, but data lacking at this time

Overall Conclusions

- Who should be considered for surgery?
  - Patients with breakthrough symptoms on medical therapy
  - Those with contraindications to PPI therapy
  - Those thought to be at high risk for long-term PPI therapy
  - Patients with complicated GERD

- ***There is no single best treatment choice for GERD patients and therapy must be tailored to a patient's specific condition and treatment goals***


THANK YOU
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