

A Vicious Spiral...

Dynamic Failure of the LES

Esophageal exposure to excessive gastric juices

Mucosal injury (by acid and bile)

Inflammatory deterioration of LES components

Permanent failure of the LES = GERD

Classification of gastroesophageal reflux disease symptoms

Typical symptoms

Heartburn and regurgitation

Atypical symptoms

Chronic cough, asthma, hoarseness, chronic laryngitis, throat-clearing, chest pain, dyspepsia, nausea

Alarm symptoms

Dysphagia, odynophagia, bleeding, weight loss, anemia, chest pain

Why is GERD a problem?

Symptoms of GERD greatly affect quality of life!

Eating/drinking problems	81%
Food intolerance	61%
Inability to eat what one likes	55%
Eat less than usual	45%
Difficulty getting good night sleep	49%
Trouble getting to sleep	39%
Feeling unwell	55%
Irritable	55%
Interferes with daily activities	20%

Talley N, Gastroenterolo 2001

Why is GERD a problem?

H+ direct ion Injury occurs at pH <2

Bile acids can also cause mucosal injury in alkaline environments



GERD by the Numbers

25-35%

Americans suffer from Heartburn

7-10%

have symptoms

EVERY DAY

The Impact of GERD

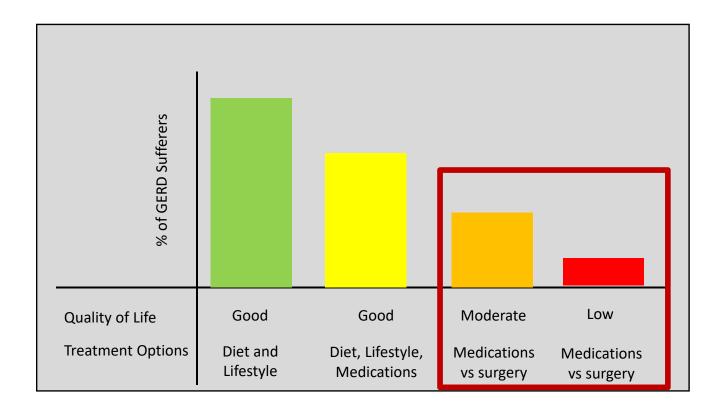
4.7 Million people in the US were hospitalized in 2010 for GERD-related symptoms, complications and treatment (National Institutes of Health)

Up to **20%** of primary care visits address GERD in some way

GERD symptoms result in almost \$2 BILLION in lost productivity each week of the year (American college of Gastroenterology)

Nearly **65 MILLION**prescriptions are written
annually for GERD in the US
(National Institutes of
Health).

So what should we DO about GERD?



Back to the Basics

The "ideal" treatment for a disease process successfully restores key pathophysiologic mechanisms as close to normal as possible

Why is GERD a problem?

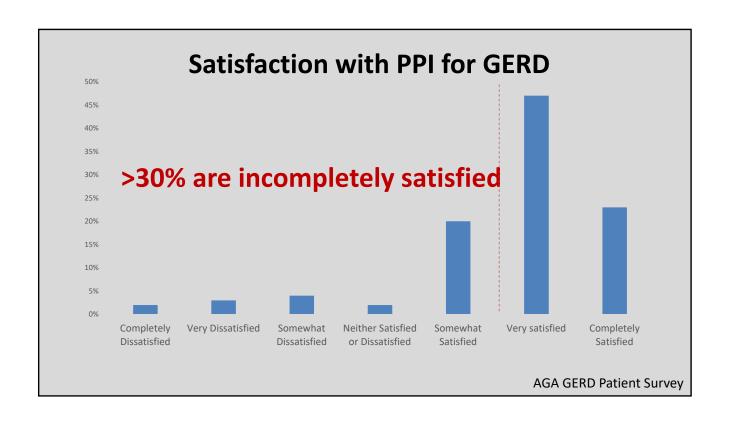
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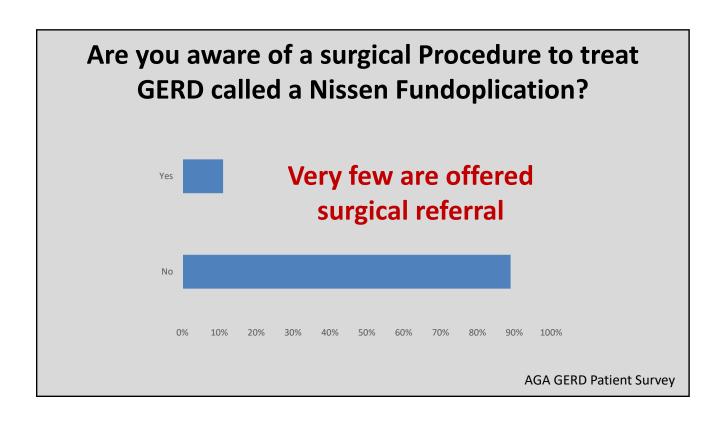
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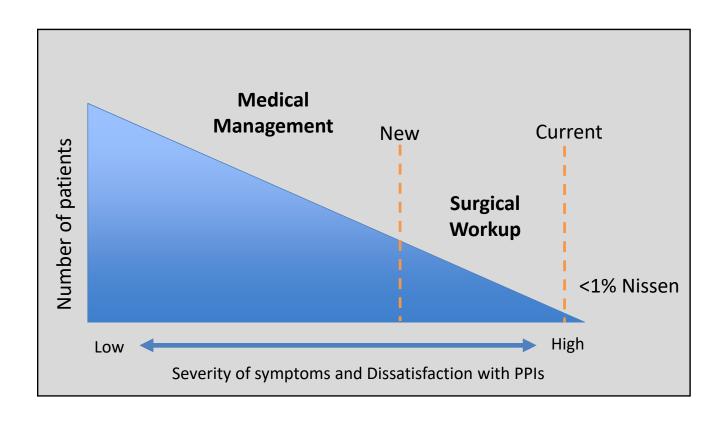


Proton Pump Inhibitors (PPIs) Risks vs Rewards...

Long term use increases risk of osteopenia, renal disease, dementia,





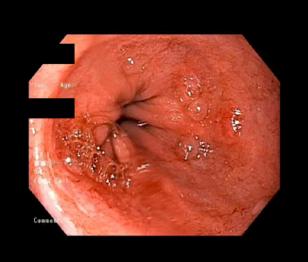


How do you PROVE someone has GERD?

Objective Testing

The big 4: Upper Endoscopy, pH Probe, Esophagram and Manometry

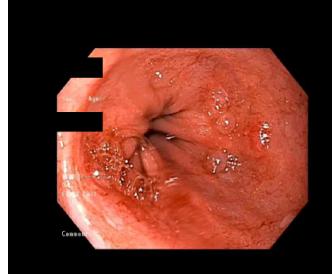
PSA: Many surgeons prefer to do some or all of this pre-operative workup on their own (particularly EGD and manometry) so feel free to discuss it with them prior to ordering the testing.



Upper Endoscopy

Must rule out complications of GERD

Good for evaluating hernia anatomy



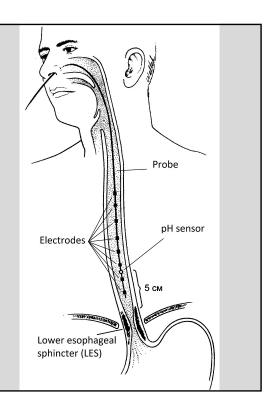
Who needs it?

>60yo with dyspepsia

<60yo with refractory symptoms, alarm symptoms, or chronic symptoms</p>

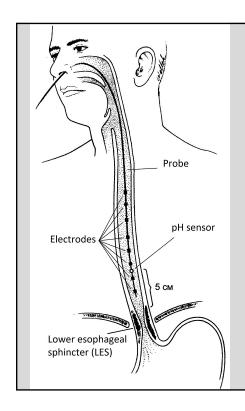
pH Testing

Sensors within the esophagus measure quantity of acid reflux



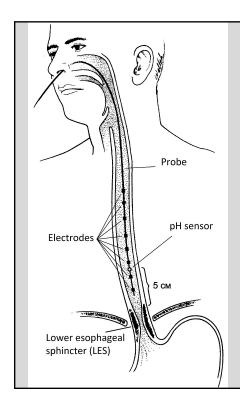
Test ON PPIs: can tell you if the PPIs are adequately suppressing Acid but will not confirm the diagnosis of GERD

Test OFF PPIs: True test for GERD MUST HOLD FOR 7 DAYS



24 Hour pH monitoring

- Intranasal catheter that remains in place for 24h
- 2 probes 10cm apart (proximal and distal)
- Monitors for pH <4 (normal esophagus ~7)
- Records frequency and duration of episodes
- Symptom monitor attached



24 Hour pH monitoring

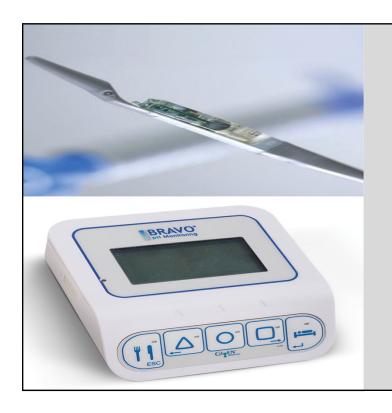
PROS:

- Inexpensive
- Measures fluid reflux too (not just acid)
- Office Procedure

CONS:

- Need manometry info in order to place correctly
- Uncomfortable
- Short recording span





Bravo Probe

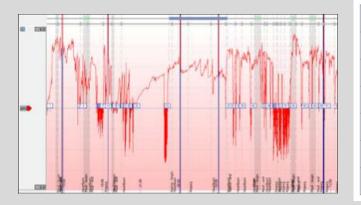
PROS:

- Higher sensitivity
- Less bothersome
- Longer recording (up to 72 hours)

CONS:

- More expensive
- Requires endoscopy

DeMeester Score



Components of 24-h Esophageal pH Monitoring

Percent total time pH<4

Percent Upright time pH<4

Percent Supine time pH<4

Number of reflux episodes

Number of reflux episodes ≥ 5 min

Longest reflux episode (minutes)

DMS >14.72 indicates GERD

How bout measuring Symptoms???

Symptom Correlation Score: How often were perceived symptoms associated with a reflux event within 5 minutes.

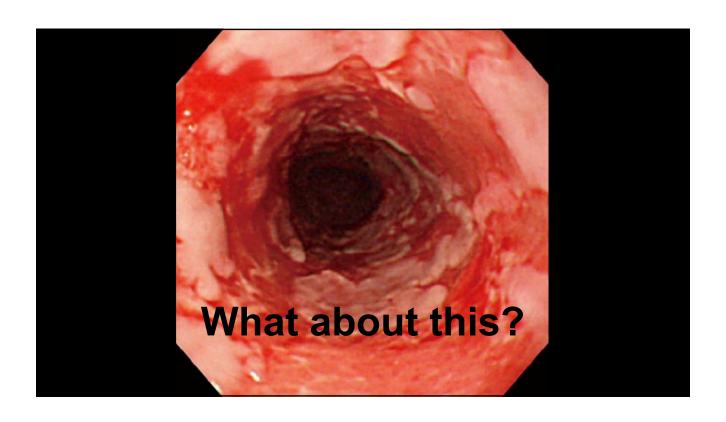
- Positive if 50% of episodes related
- Easy to get false positives by chance

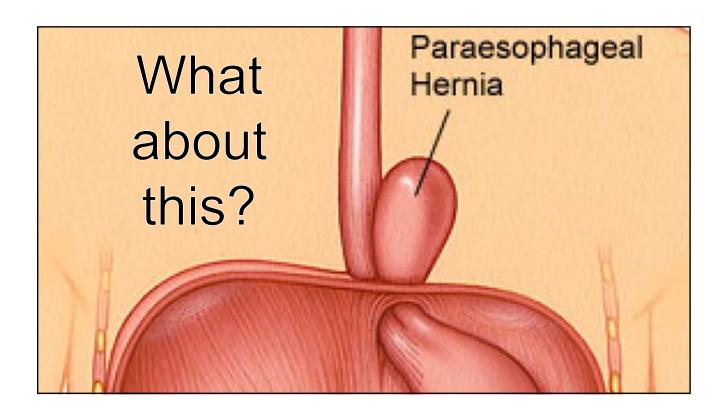
Symptom Severity Index: What percent of reflux episodes are associated with symptoms.

- Perhaps more valuable?

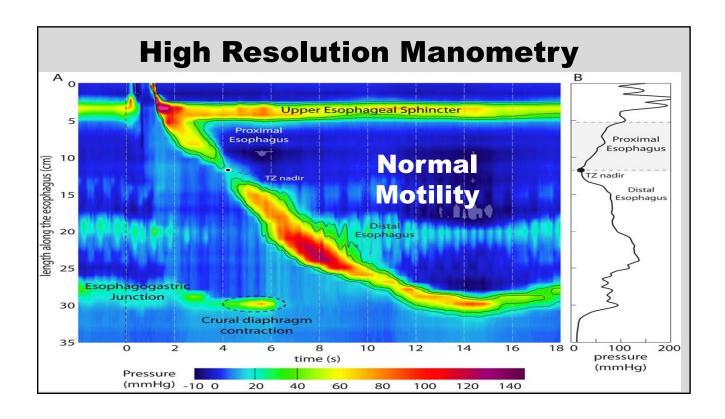
Symptom Association Probability: Fancy stats combining the above two parameters.

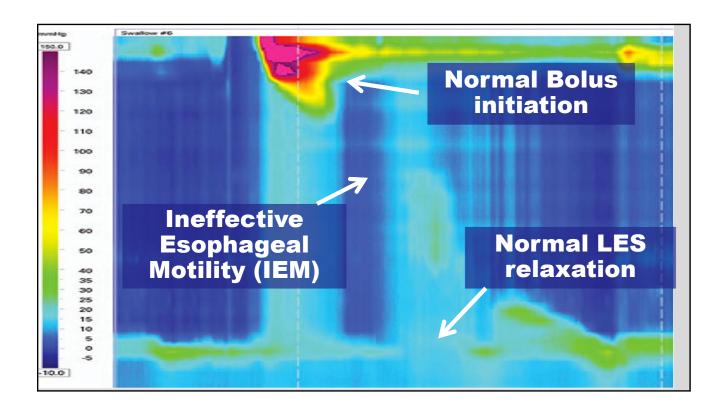
- Probably the best
- Need >95% to be a true positive

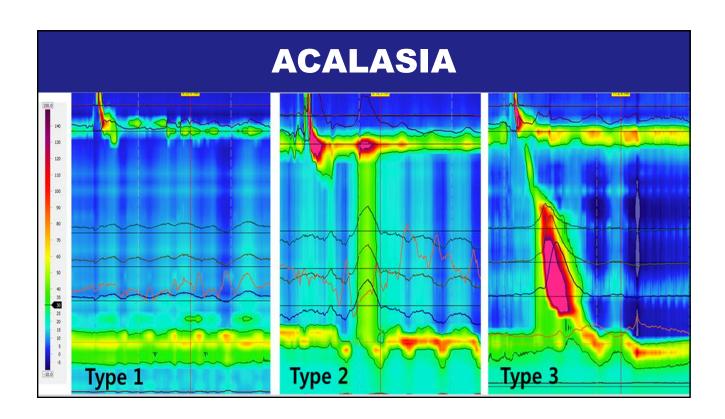












Upper GI: Anatomic Information



Good for: Hernia Evaluation Anatomy

Not so good for: Reflux? Dysmotility?

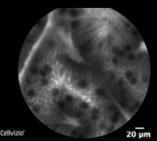
Advanced Diagnostic Techniques

Endoflip



Live motility measurements taken endoscopically

Cellvizio



Live pathology with confocal microscopy done during EGD

Who will be a good surgical candidate?

Best Predictors of GOOD response to Surgery are:

Positive pH test (DMS)
Typical Symptoms
GOOD response to PPI
First time surgery

Be thoughtful when discussing surgery but do inform patients that it is an option.

Even if a patient has reflux, surgery may not be the best option for them depending on their workup.

Summary

GERD is a prevalent disease that results from the anatomic failure of the lower esophageal sphincter.

Lifestyle, medications and surgery all play a role in the therapy of patients with increasingly severe GERD

4 key tests to workup GERD: EGD, pH, Manometry, UGI

Careful patient workup and selection can identify patients likely to do well with antireflux surgery.



Surgical Management of Gastroesophageal Reflux Disease and Hiatal Hernia

Kyle A. Perry, MD, FACS

Professor of Surgery
Division of General and Gastrointestinal Surgery
Director, Comprehensive Esophageal Health Center
The Ohio State University Wexner Medical Center



MedNet21
Center for Continuing Medical Education

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 symptoms
 - Concern about cost and risk of complications
- Laparoscopic Fundoplication
 - Gold Standard surgical treatment
 - GI side effects
 - Dysphagia, flatulence and <u>Bloating</u>

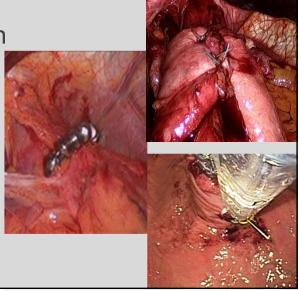
So When Should We Consider Surgery?

- 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



Currently Available Procedural Treatment Options

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



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







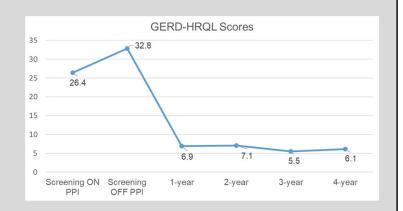
RESPECT Trial

- 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

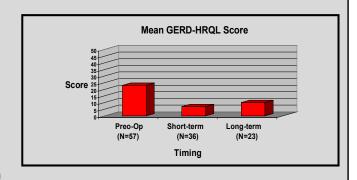
- 63 patients
 - randomized to TIF (n=40) or PPI (n=23)
- 36 months follow-up
 - 91% of patients reported elimination of troublesome regurgitation
 - 58% were able free of daily PPI therapy after 4 years



Trad et al. Surg Endosc. 2017

OSU Long-Term Follow-up Study

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

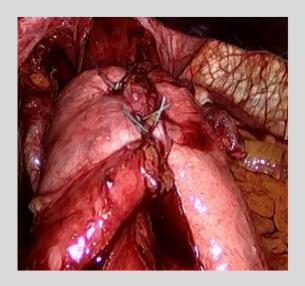


Chimukangara et al. Surg Endosc, 2019

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

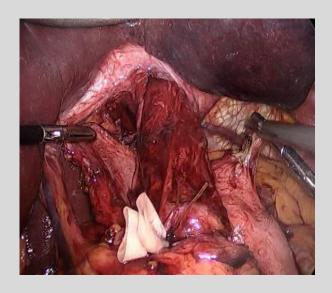
Technique: LNF

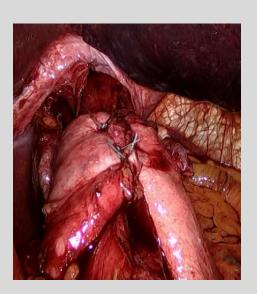


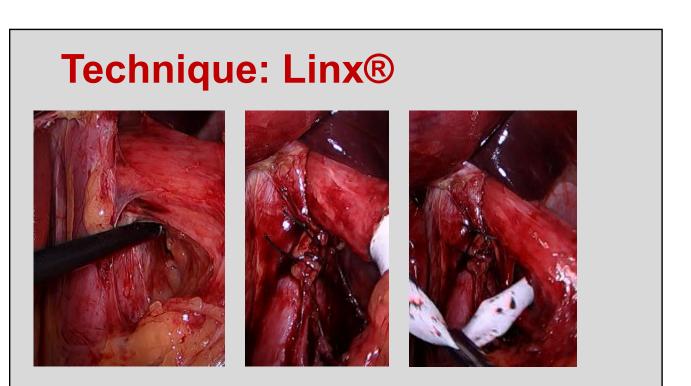


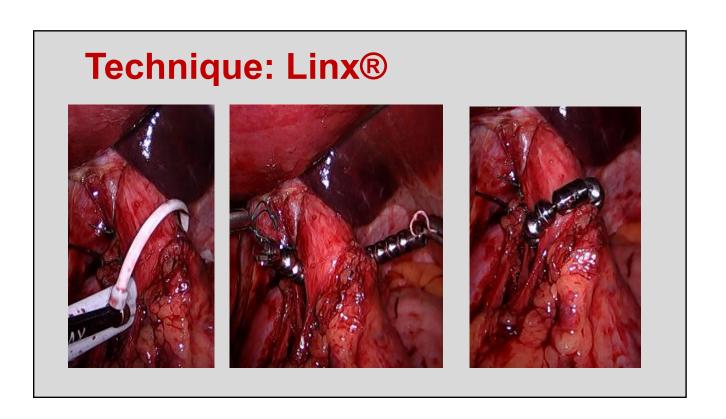


Technique: LNF









LNF vs Linx®: Efficacy

LNF

- Excellent relief of HB and regurgitation
- Normalizes pH in up to 93% of cases
- >90% PPI cessation after1 year
- High rates of patient satisfaction

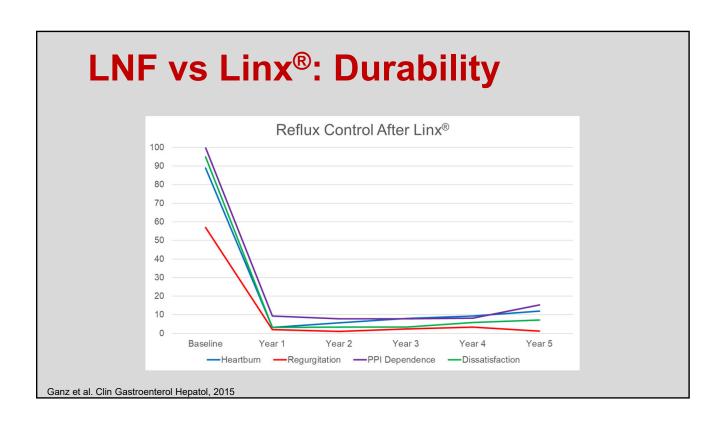
Linx®

- Similar reductions in GERD symptom scores to LNF
- pH normalization in 58%
- >90% PPI cessation after1 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

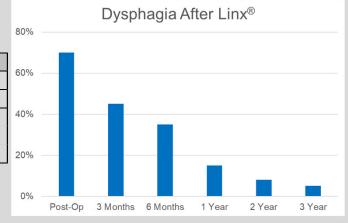


LNF vs Linx®: Side Effects

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

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 longterm 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

