



Improving People's Lives Through Innovations in Personalized Health Care

Modern Management of GERD and Barrett's Esophagus

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Disclosures

- None



Objectives

- Discuss the currently available strategies for endoscopic and laparoscopic GERD management
- Discuss the current approach to the management of Barrett's esophagus



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 treat GERD?

1. Symptom control - patient QoL
2. Acid control - management or prevention of complications
 - Esophagitis
 - Stricture
 - Barrett's esophagus



Complications of PPI Therapy

- Increased risk of osteoporosis
 - Calcium non-absorption and bone fractures
- Increased enteric infections
 - C. diff
- Cost?
 - Name brand PPI → \$\$\$
 - Six month cost can range from \$204 to \$4200
 - BID Nexium → \$2,800 (235/mo)
- Drug-drug interaction issues
 - Plavix with PPI and increased risk of heart disease
- Dementia
- Renal Insufficiency



LNF

- Excellent control of both symptoms and acid control
- Operator dependent
- Associated with side effects
 - Bloating, dysphagia
- Fundoplication is best applied to the individual with severe symptomatic reflux disease, and/or mild to moderate esophageal damage.



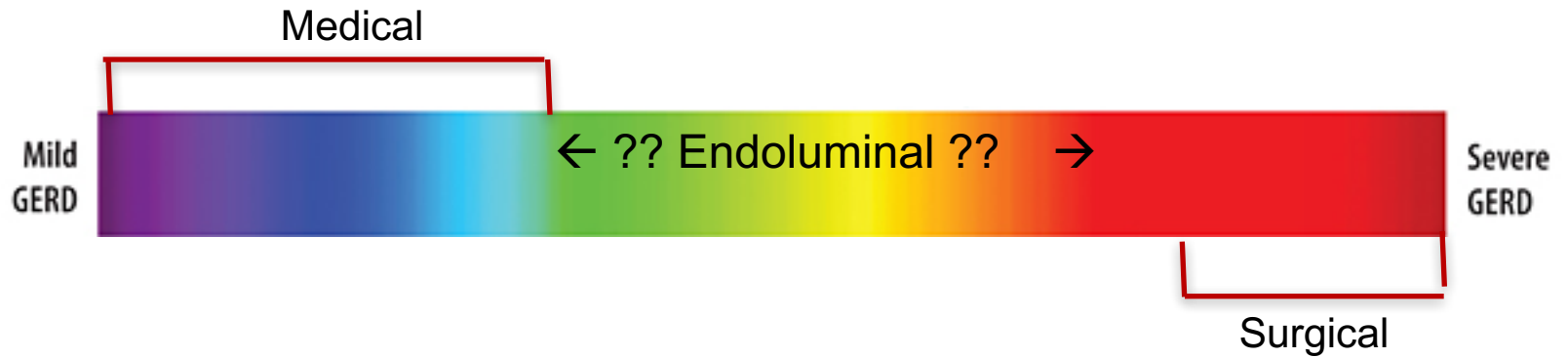
Typical GERD Patient in Surgery Clinic

- 2009:
 - Severe GERD with very poor symptom control
 - Large hiatal hernia

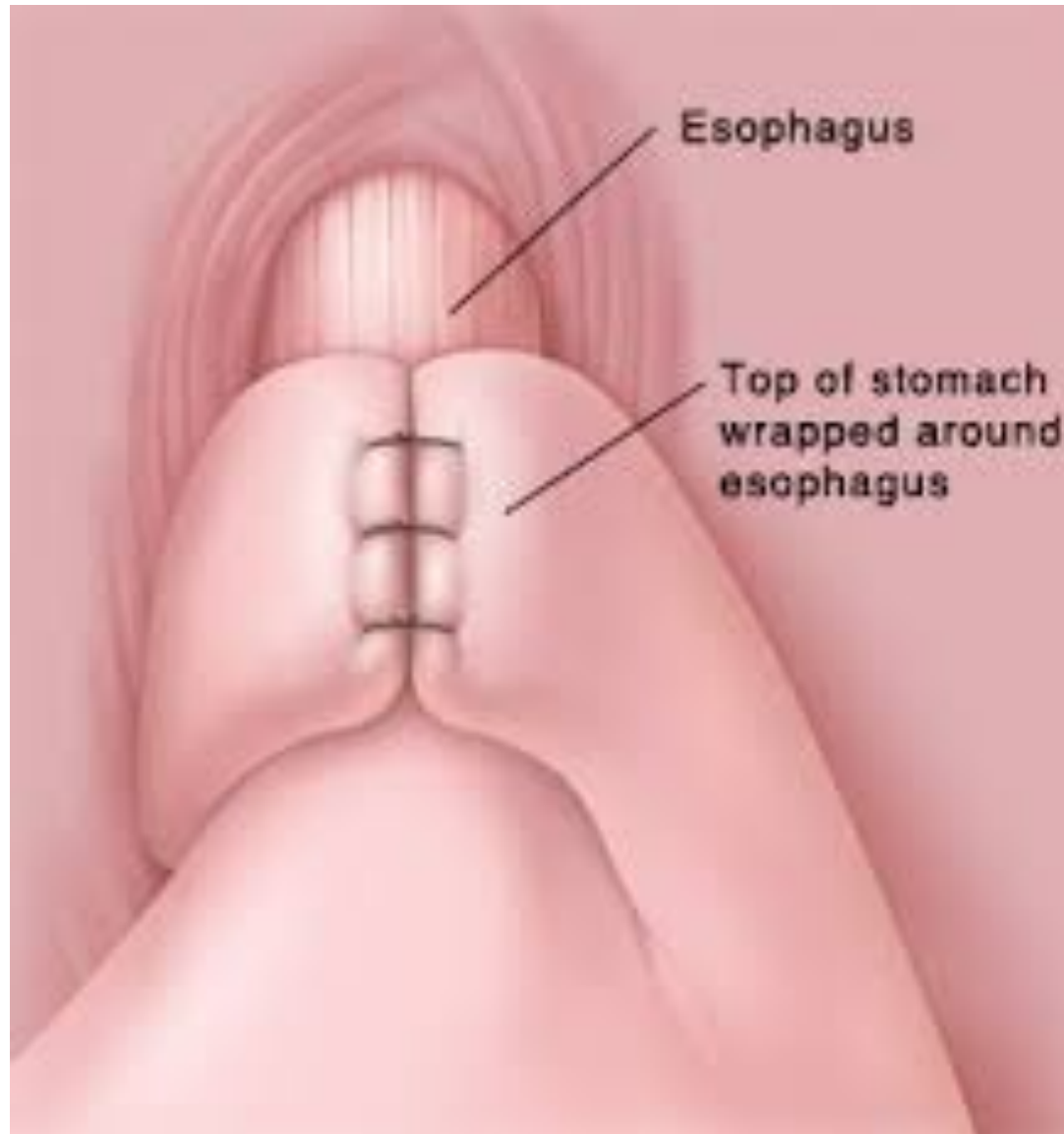
- 2014
 - Patient with mild/moderate GERD symptoms +/- hiatal hernia with concerns about costs and side effects of long-term PPI use



GERD Disease Spectrum



How does LNF Work?



Laparoscopic Nissen Fundoplication

- Overnight stay required
- Modified diet for 4-6 weeks
- Normalizes pH in up to 93% of cases
- Excellent Long Term Results (11 yrs):
 - 85% patients off PPI
 - Improved Quality of life
 - High rates of patient satisfaction

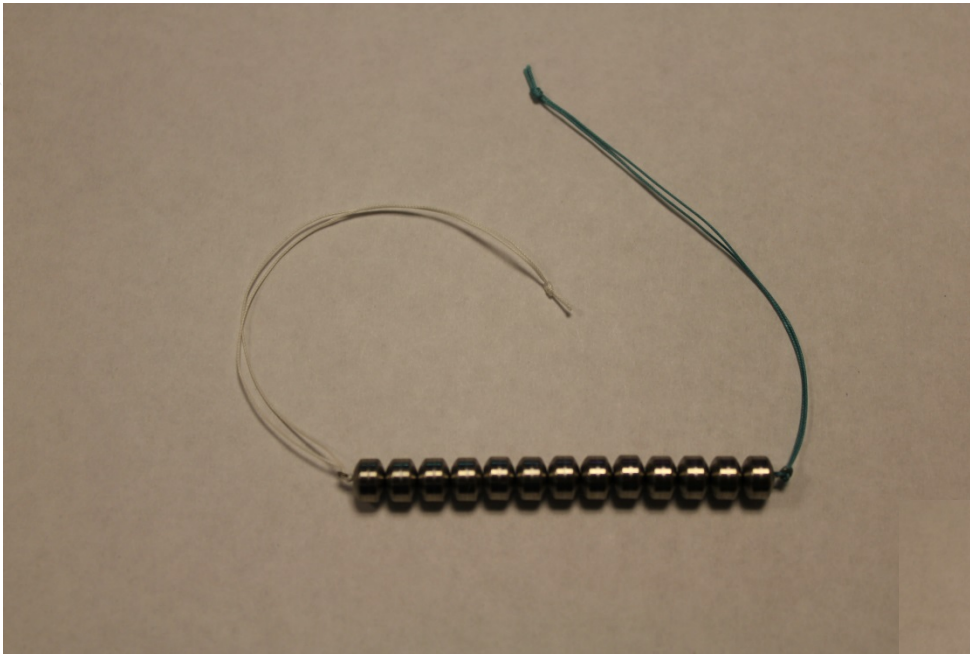


Head to Head: Surgery versus PPI's

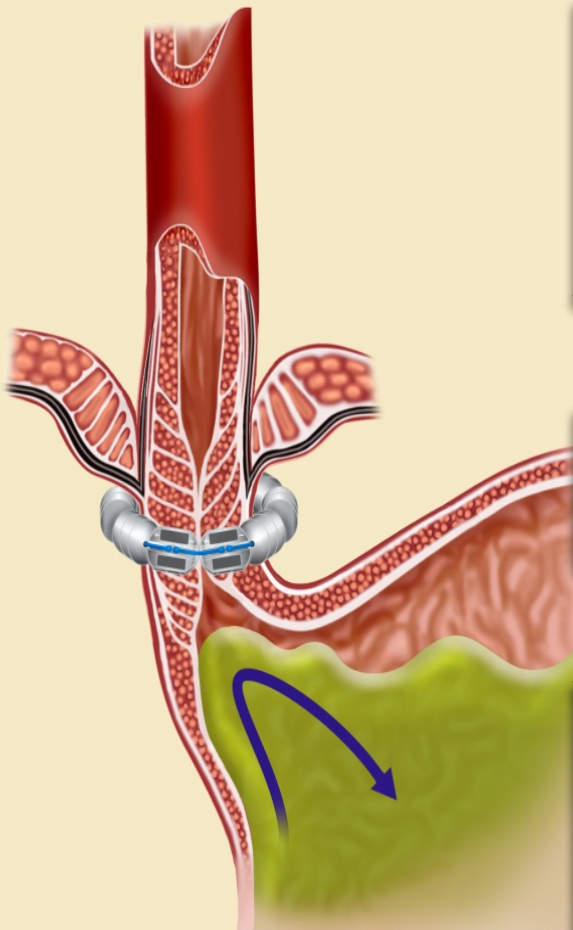
Symptom	LNF (180)	PPI (192)	P-value
Heartburn	8%	16%	0.140
Regurgitation	2%	13%	<0.001
Dysphagia	11%	5%	<0.001
Bloating	40%	28%	<0.001
Flatulence	57%	40%	<0.001



Linx: Device



Linx: Procedure

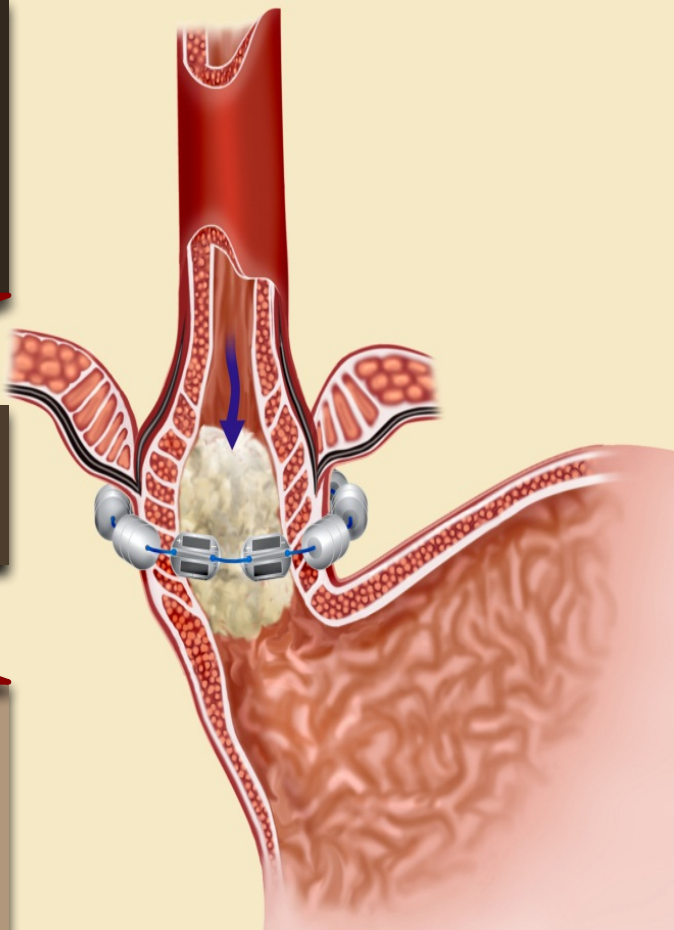


CLOSED to Reflux

Normal Peristaltic Pressures
35-80 mm Hg

LINX® System
20-25 mm Hg

Gastric Pressures
5-10 mm Hg

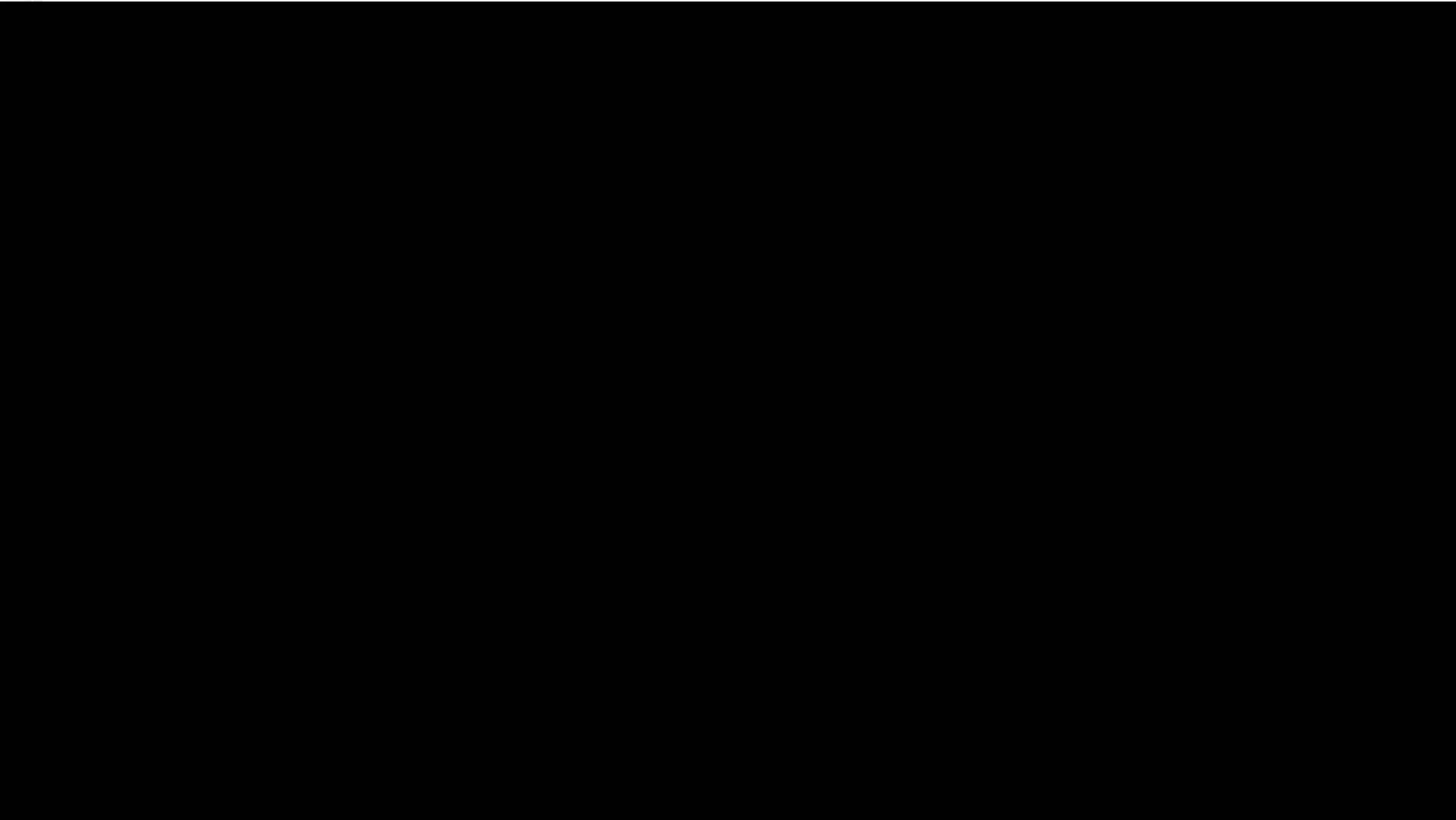


OPEN to Swallowing

Linx: Technique

- 4 port laparoscopy – Similar to LNF
- Minimal dissection at the hiatus
- Device placed between the esophageal wall and posterior vagus nerve

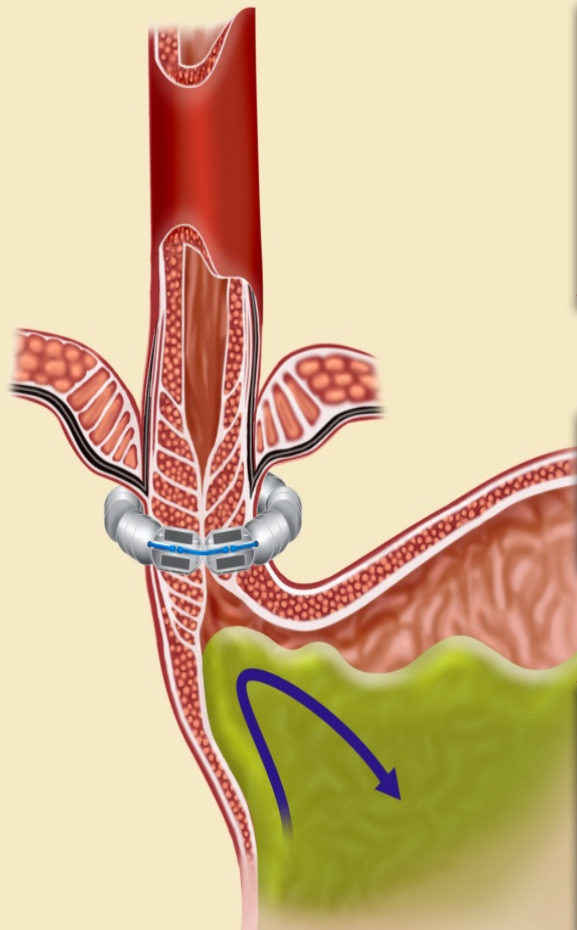




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How Does Linx Work?

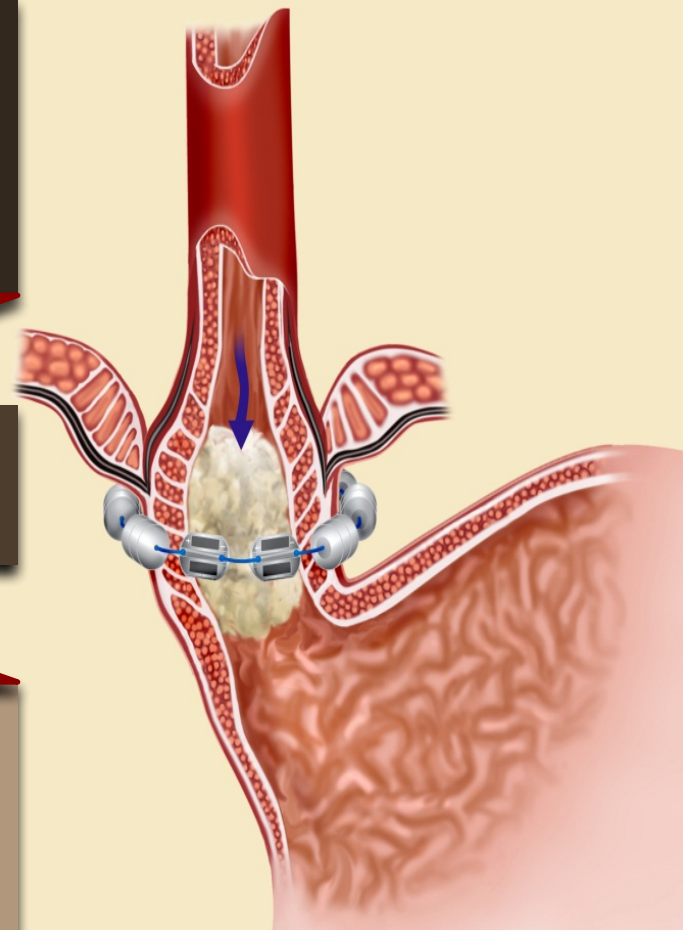


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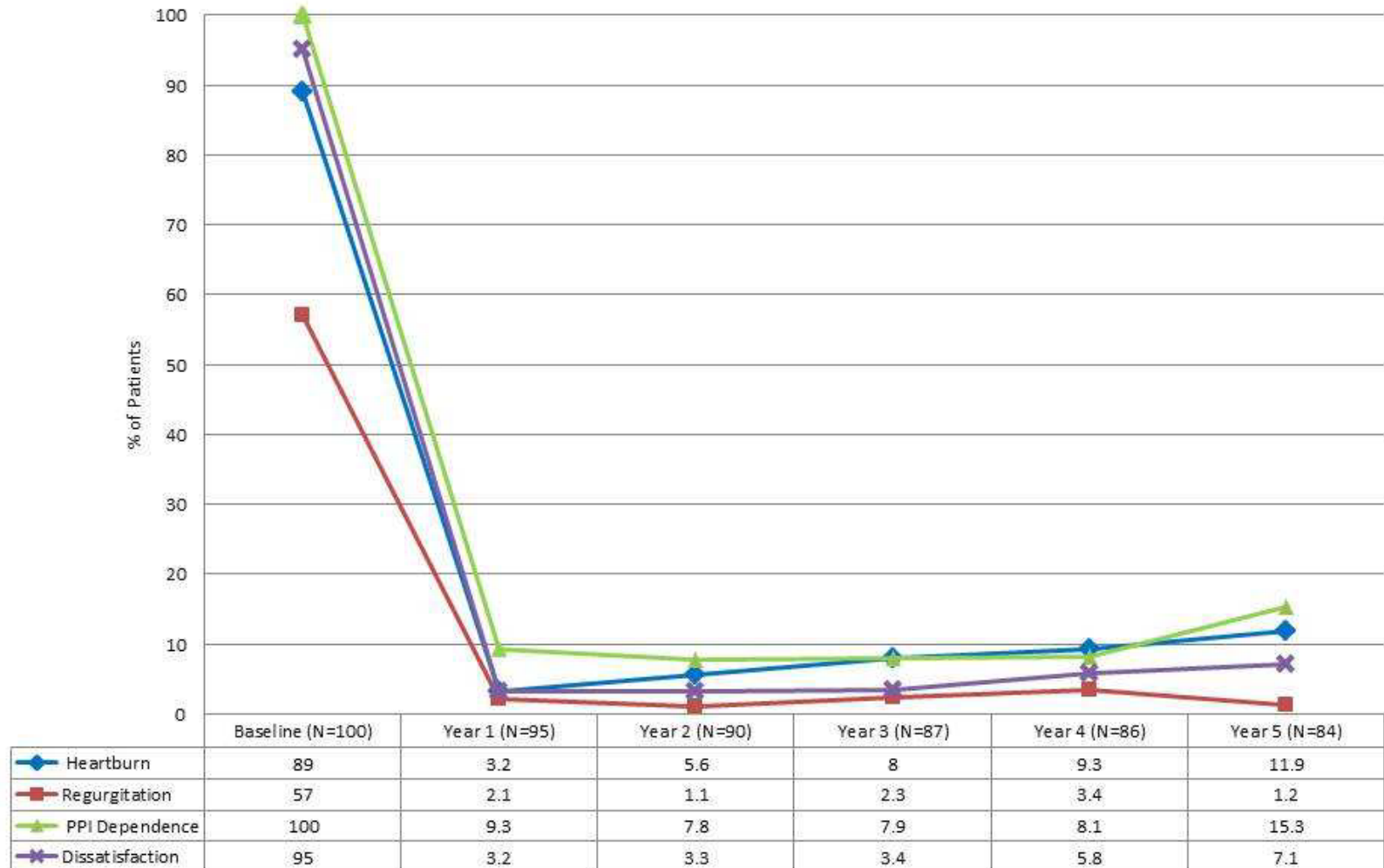


OPEN to Swallowing



Linx: 5 Year Results

Figure 3. Reflux Control after Magnetic Sphincter Augmentation



P<0.001 for comparison between baseline and all follow-ups

Linx: Complications/Side Effects

- Dysphagia in 68%
 - Moderate to severe in 21%
 - 3% required device removal
- Bloating – 14% (almost all mild)
- 6 devices removed
 - 3 for dysphagia
 - 1 each for pain, emesis, and persistent symptoms



Linx: Potential Advantages & Questions

- Advantages:
 - Easy to standardize procedure
 - Potential for durable GERD relief
- Questions:
 - Durability
 - Erosion?
 - Cost-benefit analysis

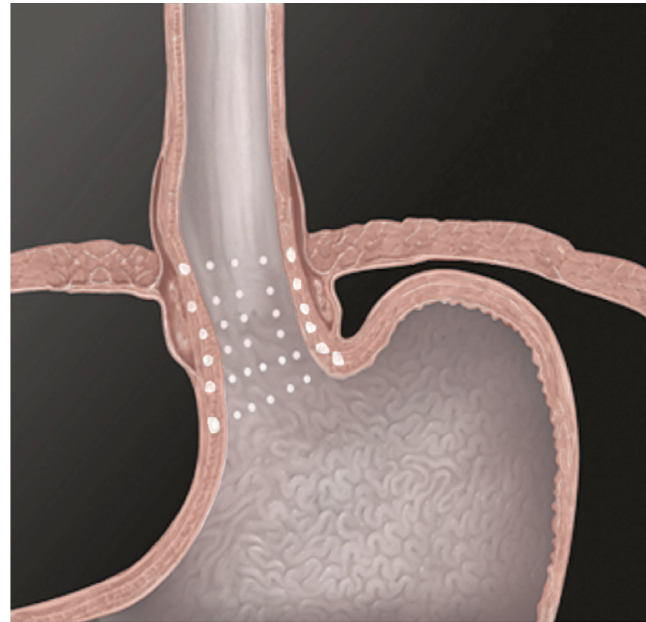
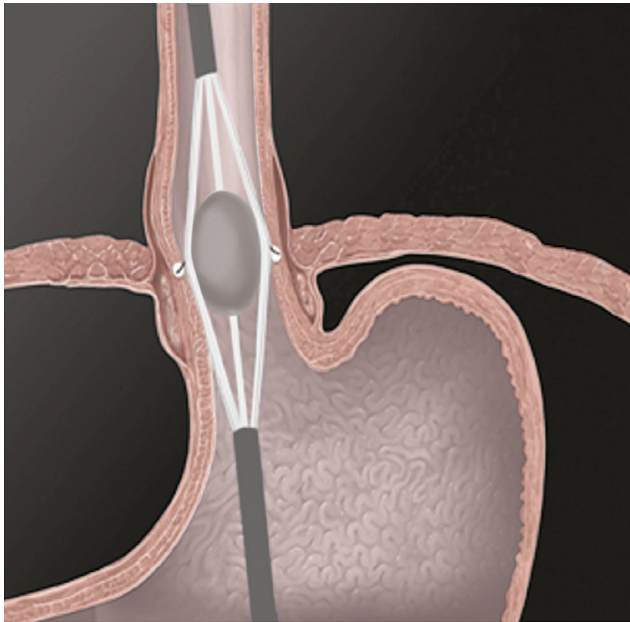


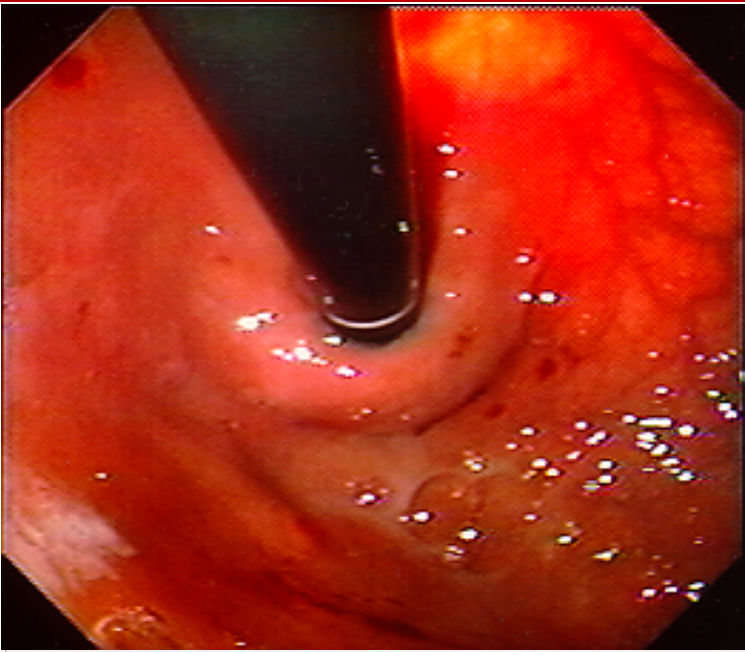
Stretta Procedure

- EGD with identification of GE junction
- Placement of catheter above GEJ
 - Rf Application, 45 degree rotation
 - 8 applications, 2 below, 4 above GE jxn
- Total time about 30 minutes
 - Outpatient
 - Under sedation in the GI suite

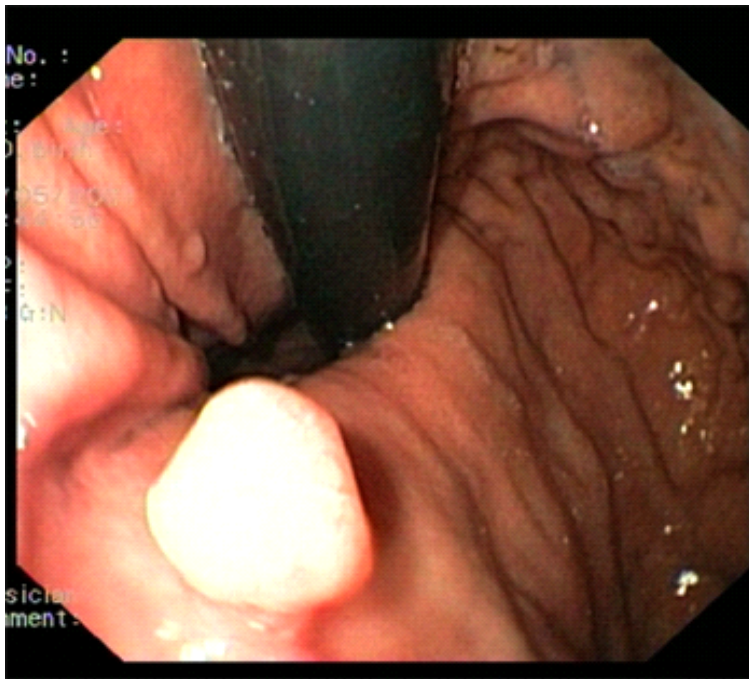
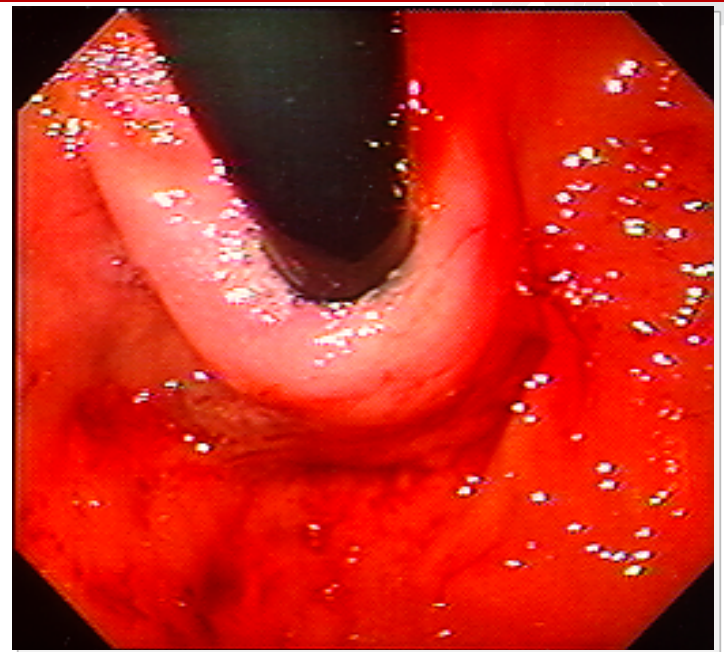


STRETTA: Device

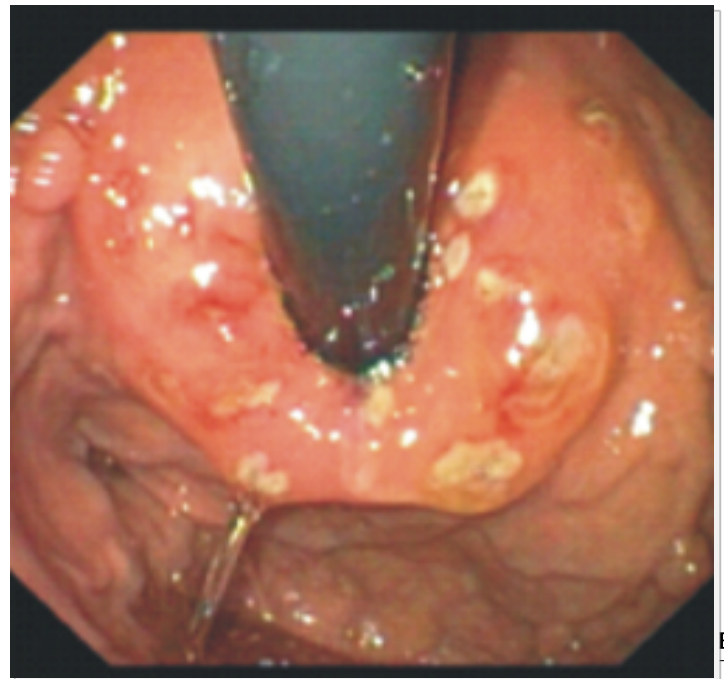




NISSEN



STRETTA



Stretta Registry

- 558 patients, 33 centers
- Follow-up 1-33 months
- 15% out beyond year follow-up
- Median drug requirement:
PPI bid (baseline) → prn antacids (follow-up)
- 90% would recommend to friend
- Patients > 1 year after treatment had better results as compared to patients < 1 yr



Long-Term Follow-up

10 year (Noar 2014)

217 patients

99 1w/ complete 10 year data

72% normalized GERD HRQL

41% off PPIs

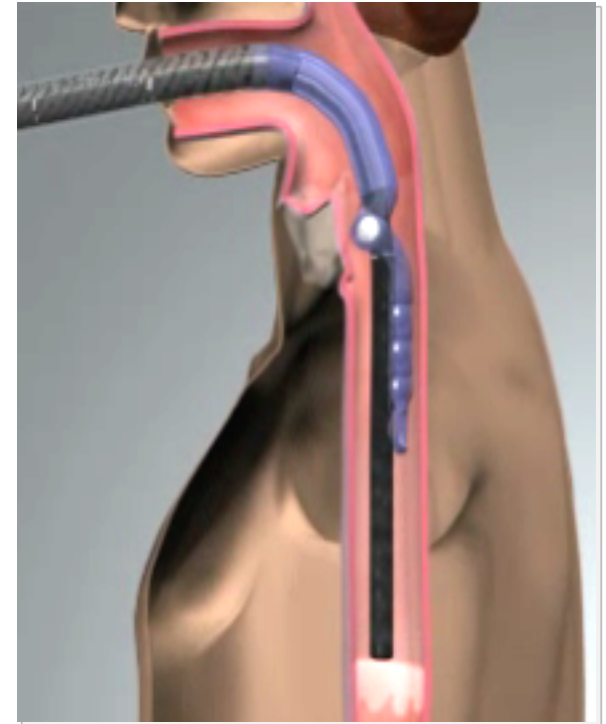
8 year (Dughera 2014)

26 patients w/ 8 year follow-up

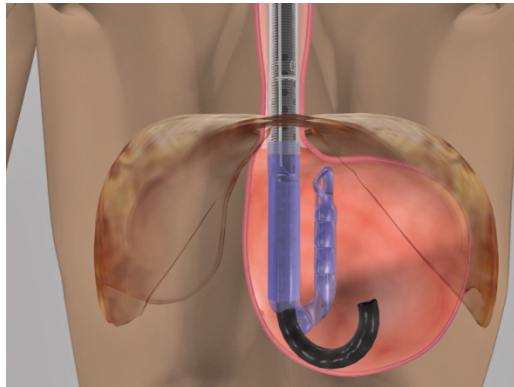
76% free of daily acid reducing meds

Endoluminal Fundoplication (Esophyxy)

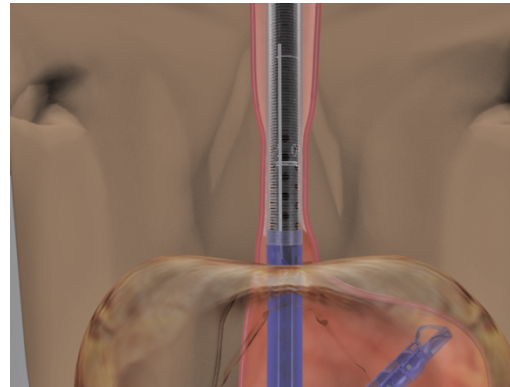
- The device is inserted by mouth along with an endoscope
- Allows treatment without abdominal incisions in patients with moderate GERD



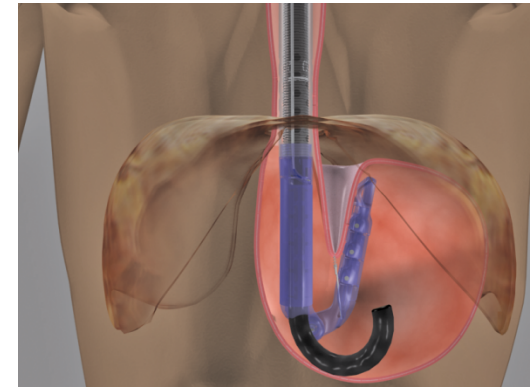
Transoral Fundoplication



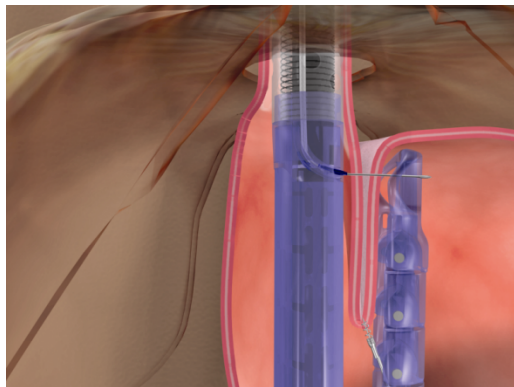
Close tissue mold and rotate device to midpoint of neo-valve.



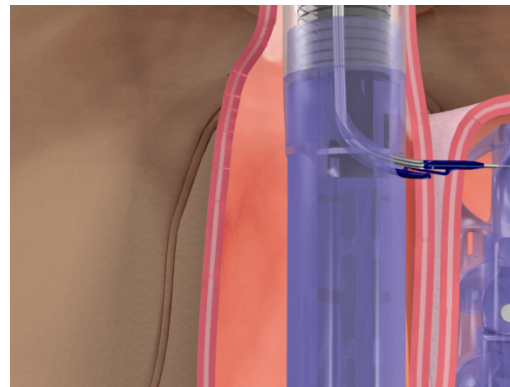
Apply vacuum and reduce hiatal hernia (if applicable). Advance endoscope into stomach, position in a retroflex view.



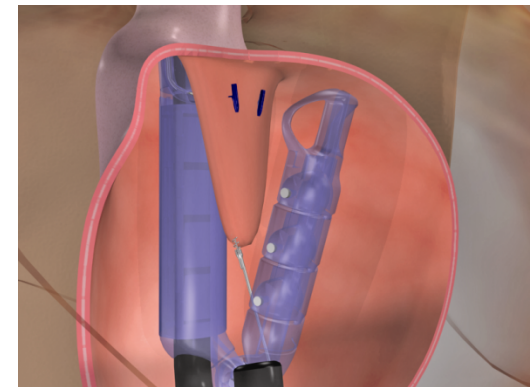
Deflate stomach, retract and massage 5 cm of tissue within the tissue mold. Subsequent tissue retractions may yield < 5 cm.



Inflate stomach. Deploy stylet under direct visualization.



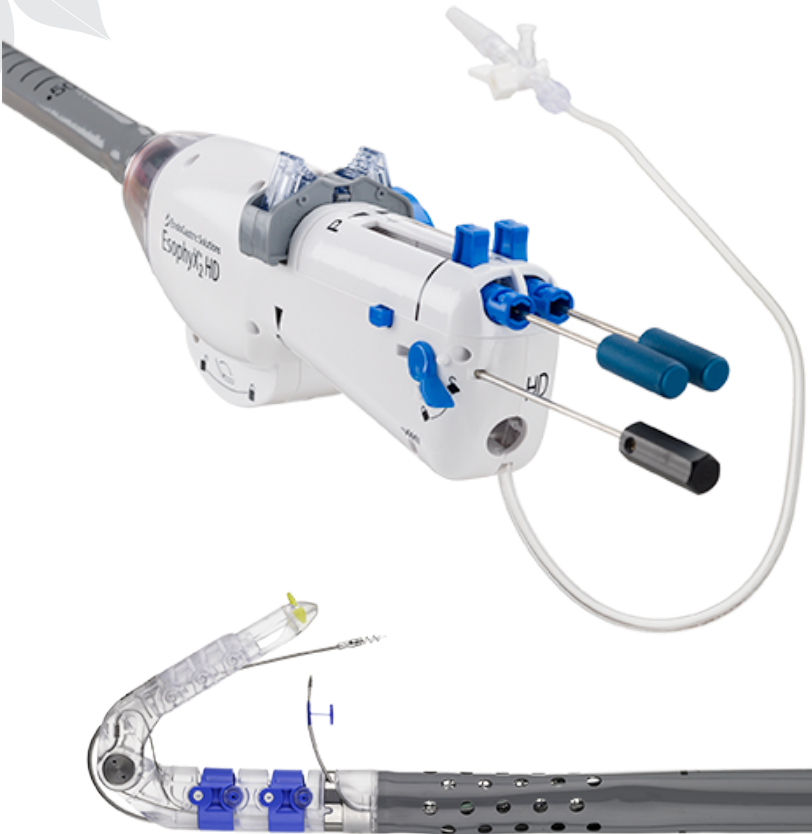
Deploy fastener. Maintain pressure on fastener pusher while retracting stylet.



Disengage helical retractor by rotating retractor control counter-clockwise. Return helix to home position.



EsophyX Device Evolution



EsophyX HD

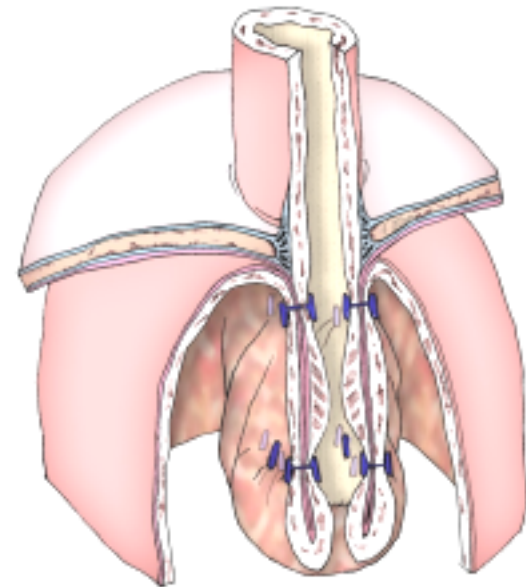


EsophyX Z



TF Procedure

- 45 - 60 minute procedure
- General anesthesia
- 14-20 fasteners
- Overnight stay
- Post-op discomfort minimal
- Rapid recovery



RESPECT Trial

- RCT of TIF v Sham procedure
 - Troublesome regurgitation, + pH
 - TIF kept on placebo medication
 - Sham underwent 45minute anesthesia with manipulation of scope and bougie; then on 40mg PPI
 - Failures at 3 months unblinded and crossed over



RESPECT Trial

- 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.



TEMPO Trial

- 63 patients
 - randomized to TIF (n=40) or PPI (n=23)
 - all patients in PPI control group crossed over and received TIF after 6 months
- 36 months follow-up
 - 91% of patients reported elimination of troublesome regurgitation
 - 70% were able free of daily PPI therapy



US TIF Registry

- Multicenter prospective study of TIF procedure.
- 158 patients, 24 month follow-up.
- At 2 years, 70% of patients reported > 50% improvement in regurgitation.
- Daily PPI use from 91% to 29%

- *No new onset dysphagia or bloating, 2% excess flatulence.*



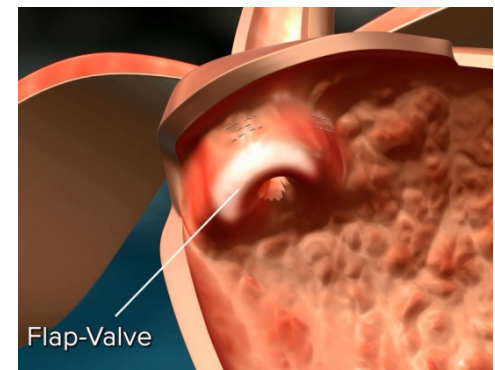
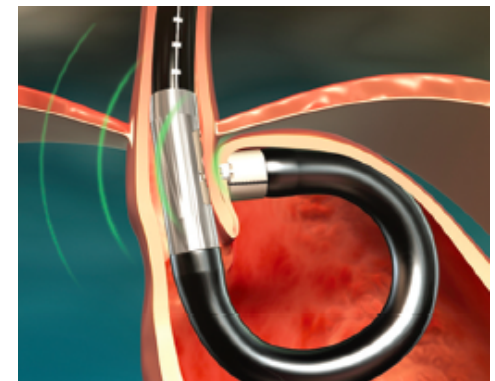
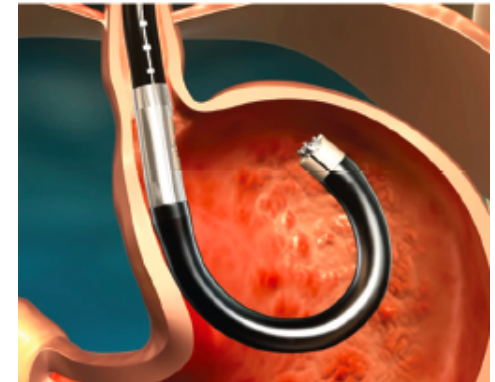
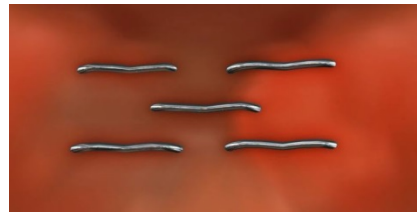
TIF Conclusions

- Effectively reduces GERD symptoms in select patients
- Low incidence of side effects, but does not consistently normalize esophageal pH
- RCT data emerging to solidify efficacy of this procedure
- Device improvements have simplified procedure
- **EXPENSIVE**



Medigus

1. Advance into stomach and retroflex
2. Retract the MUSE system to 3cm proximal to GE Junction, clamp tissue and staple fundus to esophagus
3. Remove MUSE to change stapling cartridge and repeat in 2-4 locations to create flap valve (150–180° anterior wrap)



MUSE Multicenter Study

- 66 patients underwent MUSE
 - 6 month follow-up
- 50% reduction in GERD-HRQL achieved in 48 (73%) patients
- PPI cessation achieved in 65%
 - At least 50% dose reduction in 85%

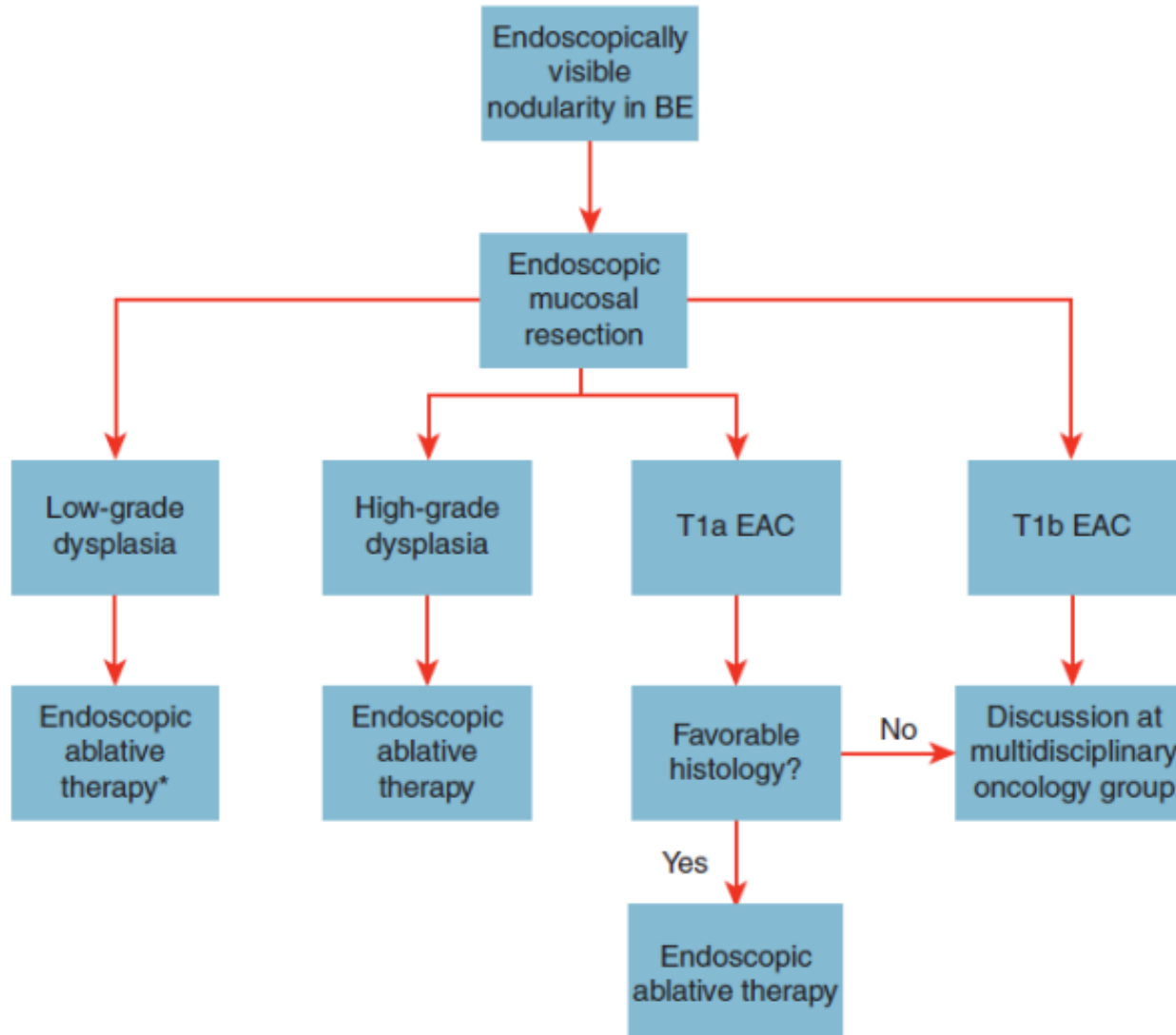


Endolumenal Therapy Conclusions

- Generally less efficacious, but with more favorable side effect profile compared to LNF
- May find a role for management of patients with symptoms well controlled with daily PPI and minimal or no hiatal hernia
- Need to achieve adequate efficacy at a relatively low cost to gain wider acceptance

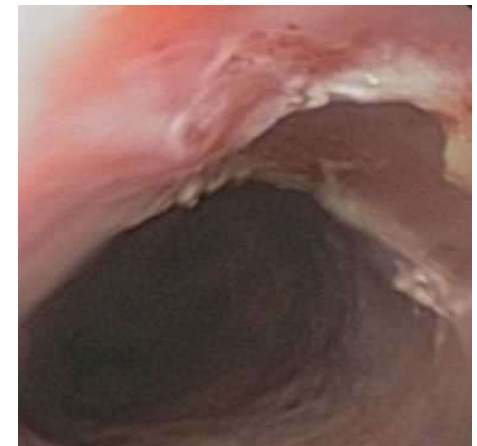


BE Therapy: Endoscopic Eradication Therapy

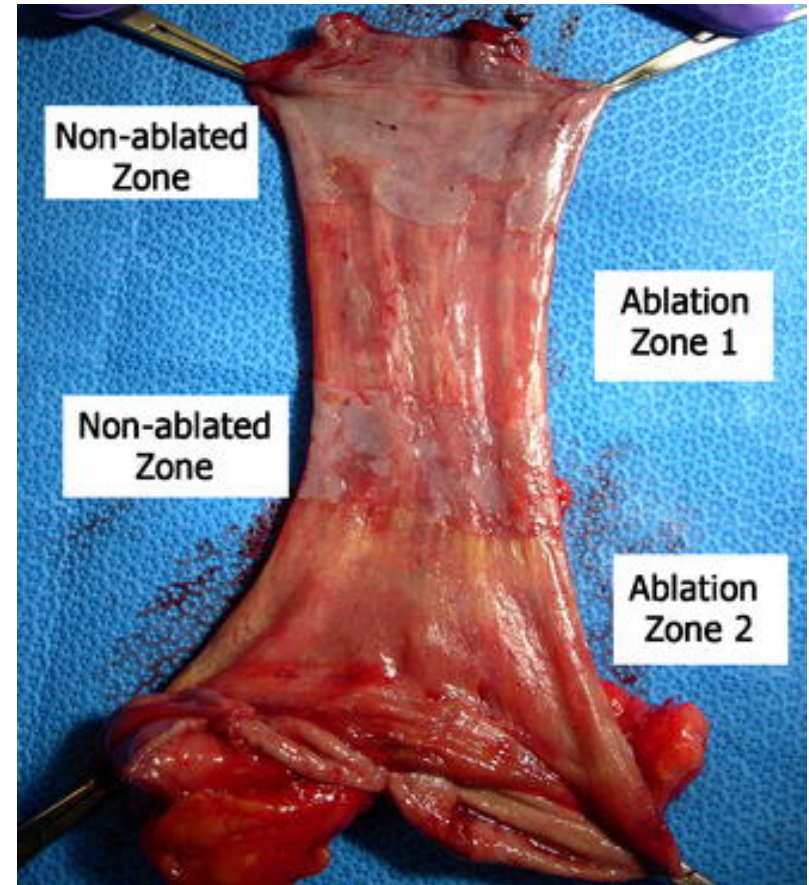
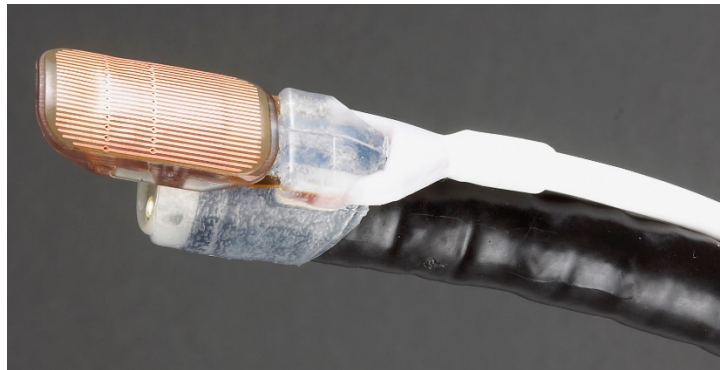
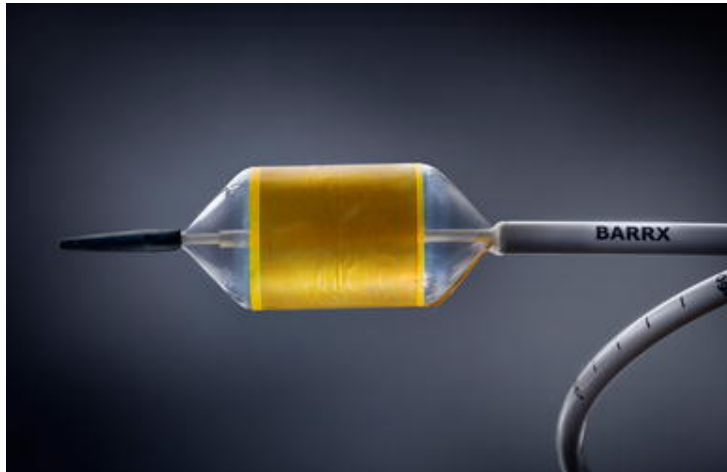


BE Therapy: Endoscopic Mucosal Resection

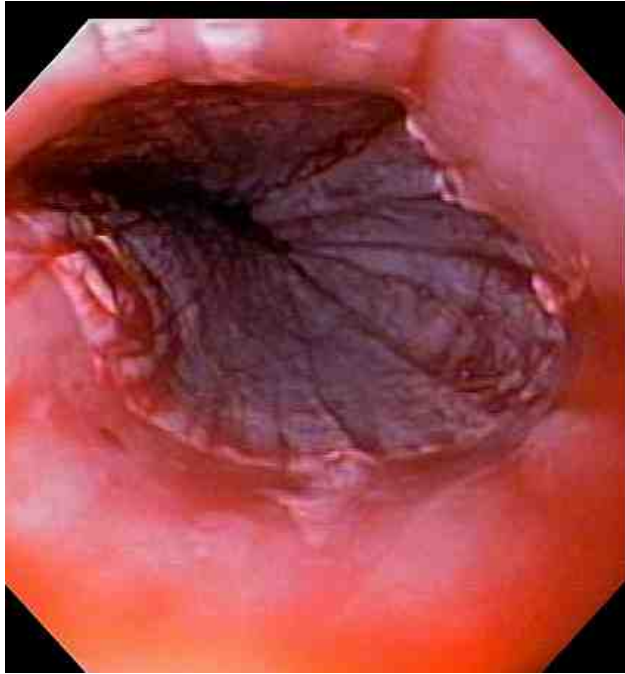
- Cap based Endoscopic Mucosal Resection + ablation
 - Can achieve complete resection of nodular BE and early stage tumors
 - Low morbidity 1-8% (perforation, bleeding stricture)



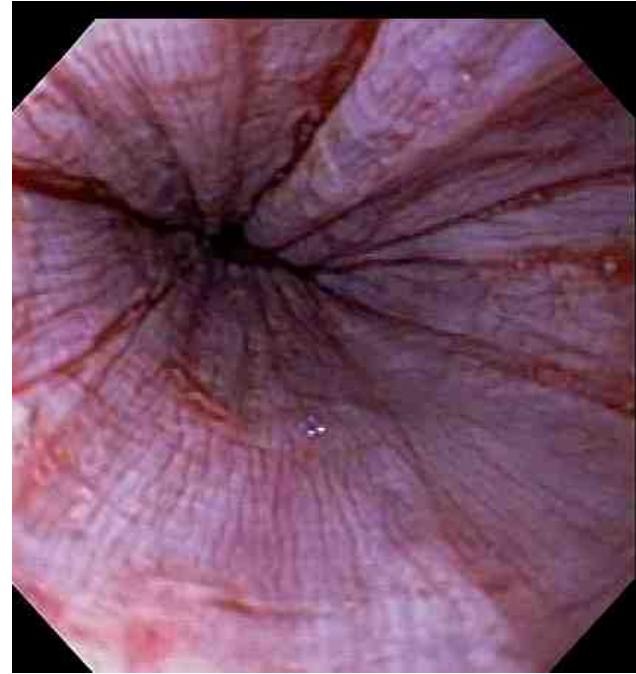
BE Therapy: Radiofrequency Ablation



BE Therapy: Radiofrequency Ablation



Margin of Treatment



View in Treatment Area

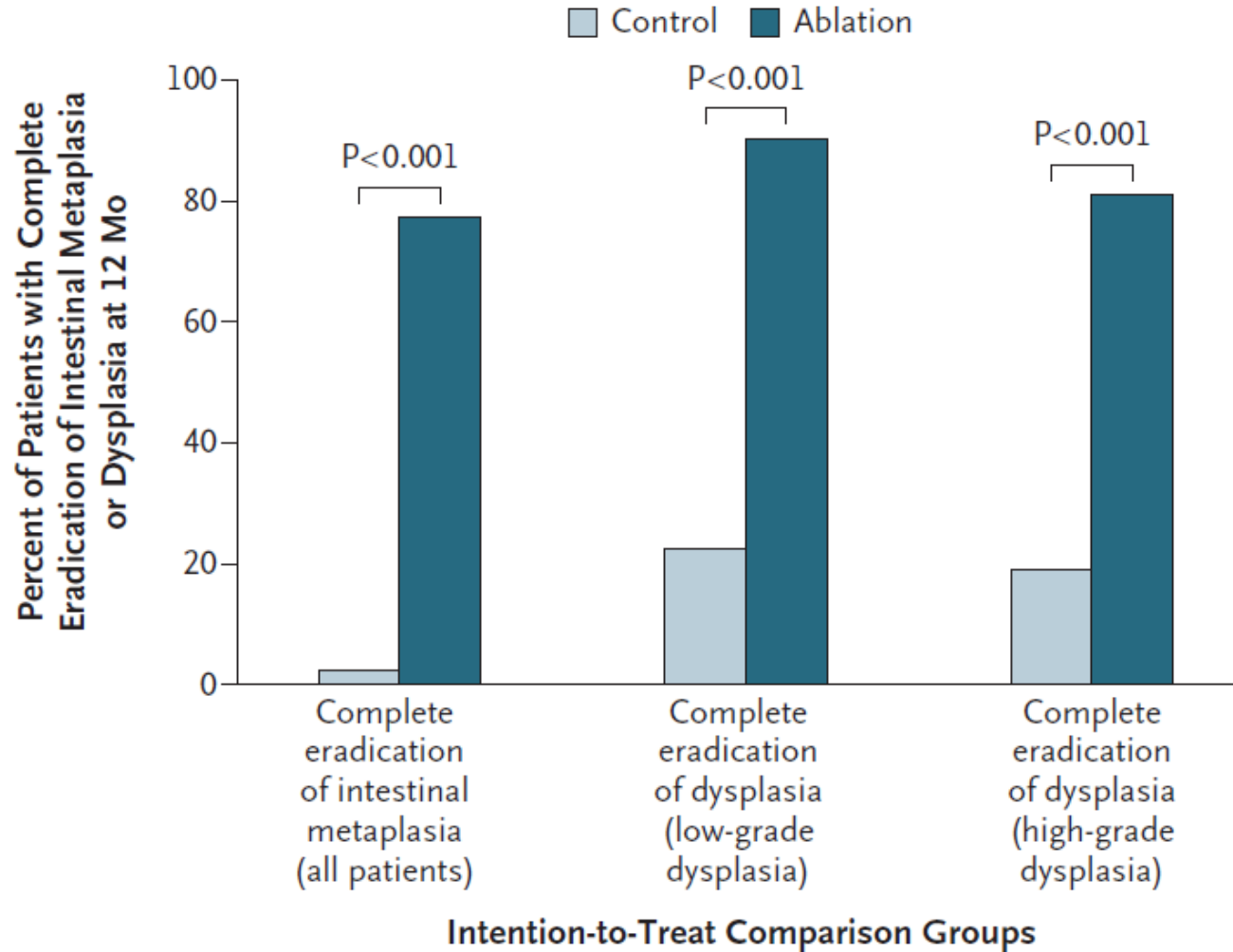
Both images are After one Application of energy



BE Therapy: Radiofrequency Ablation



BE Therapy: RFA



BE Therapy: Endoscopic Eradication Therapy

- EET should not be used for patients with NDBE due to the low risk of progression to esophageal cancer
- Dysplastic BE should be managed with EET
 - Nodular disease should be assessed with EMR
 - If dysplastic BE or T1a EAC is identified, the remaining mucosa should be ablated
 - Patients with positive margins of resection or submucosal invasion should be referred for surgical evaluation
- For patients with non-nodular dysplastic BE, RFA is the preferred method of mucosal ablation



BE Therapy: Esophagectomy

- Survival of patients operated on for HGD with no cancer or T1N0 disease is equivalent to control population without cancer.
- BUT...
 - Perioperative complications in 58%
 - Perioperative mortality is 4%
 - Ave length of hospital stay 13.7 days
 - 31% of patients require post hospital care

BE Therapy: Esophagectomy

- Consider Esophagectomy for:
 - Failed EET
 - T1a Tumor with high risk features
 - Poorly differentiated tumor
 - Lymphovascular invasion
 - Patient is unwilling to comply with endoscopic follow-up
 - Young patients with multifocal disease in the setting of long-segment Barrett's esophagus



Thank You

