Magnetic Sphincter Augmentation

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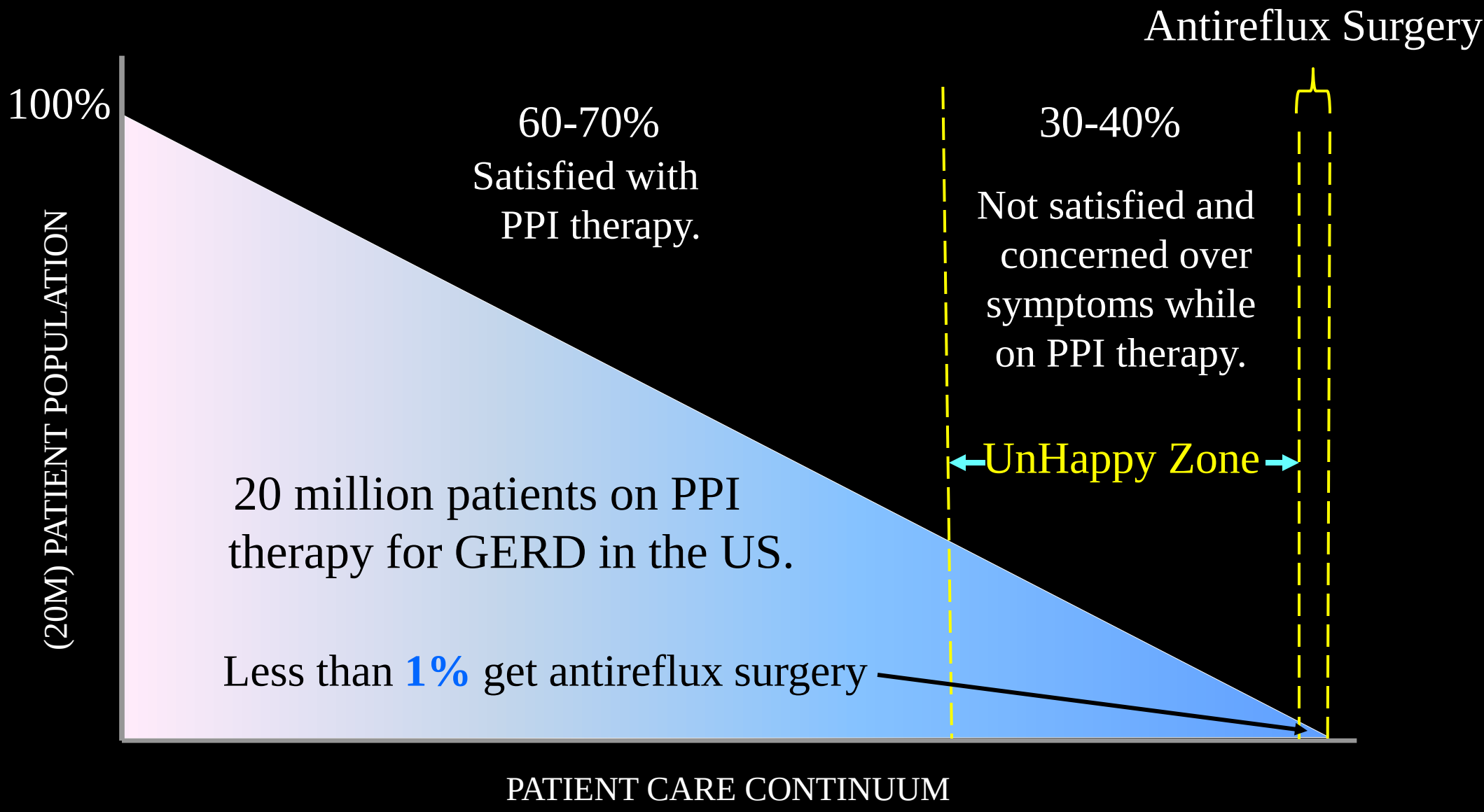
Disclosures

- Consultant for Torax Medical
- Consultant for Medtronic / Covidien

GERD Therapy in 2014

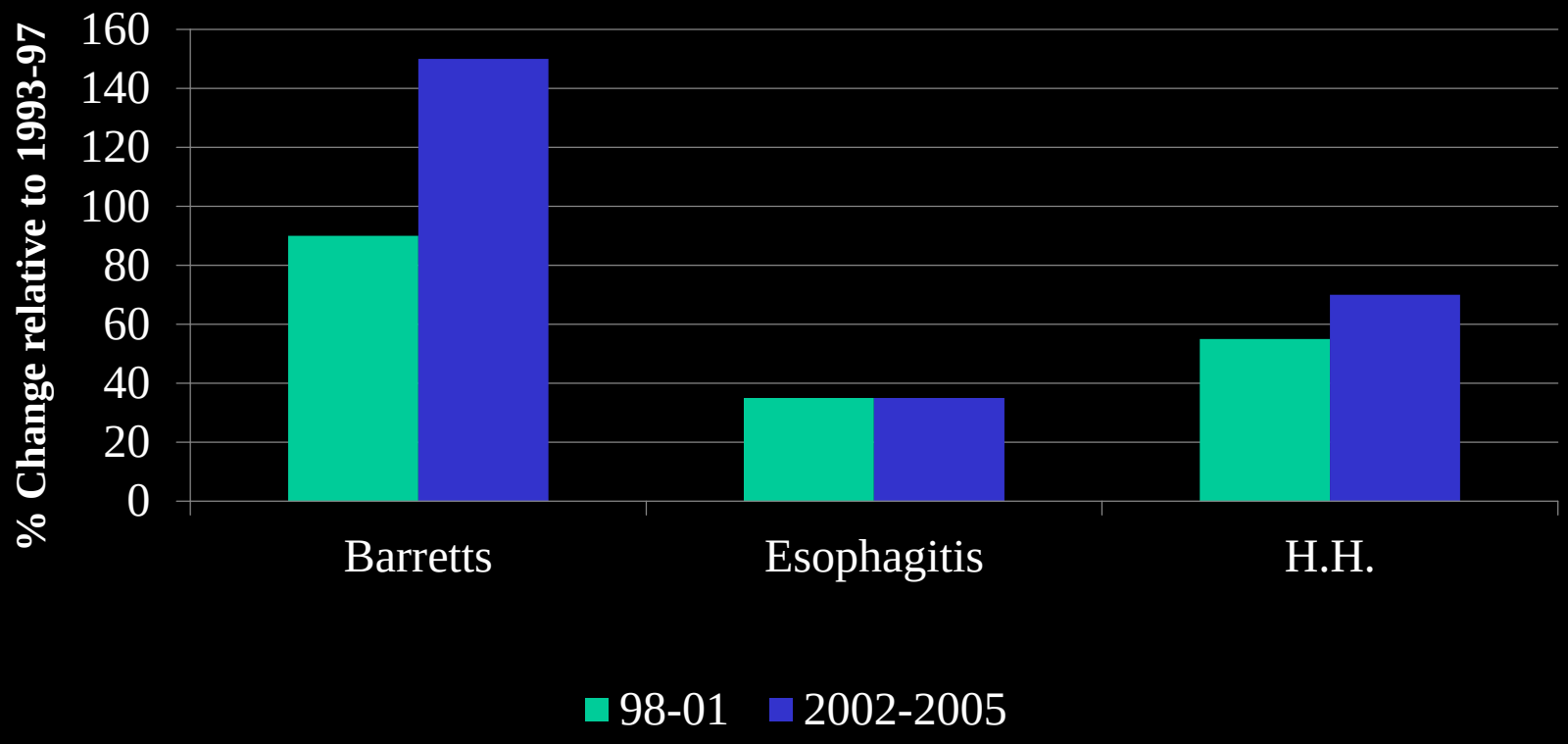


Eur J Epidemiol (2011) 26:739–745
DOI 10.1007/s10654-011-9596-z

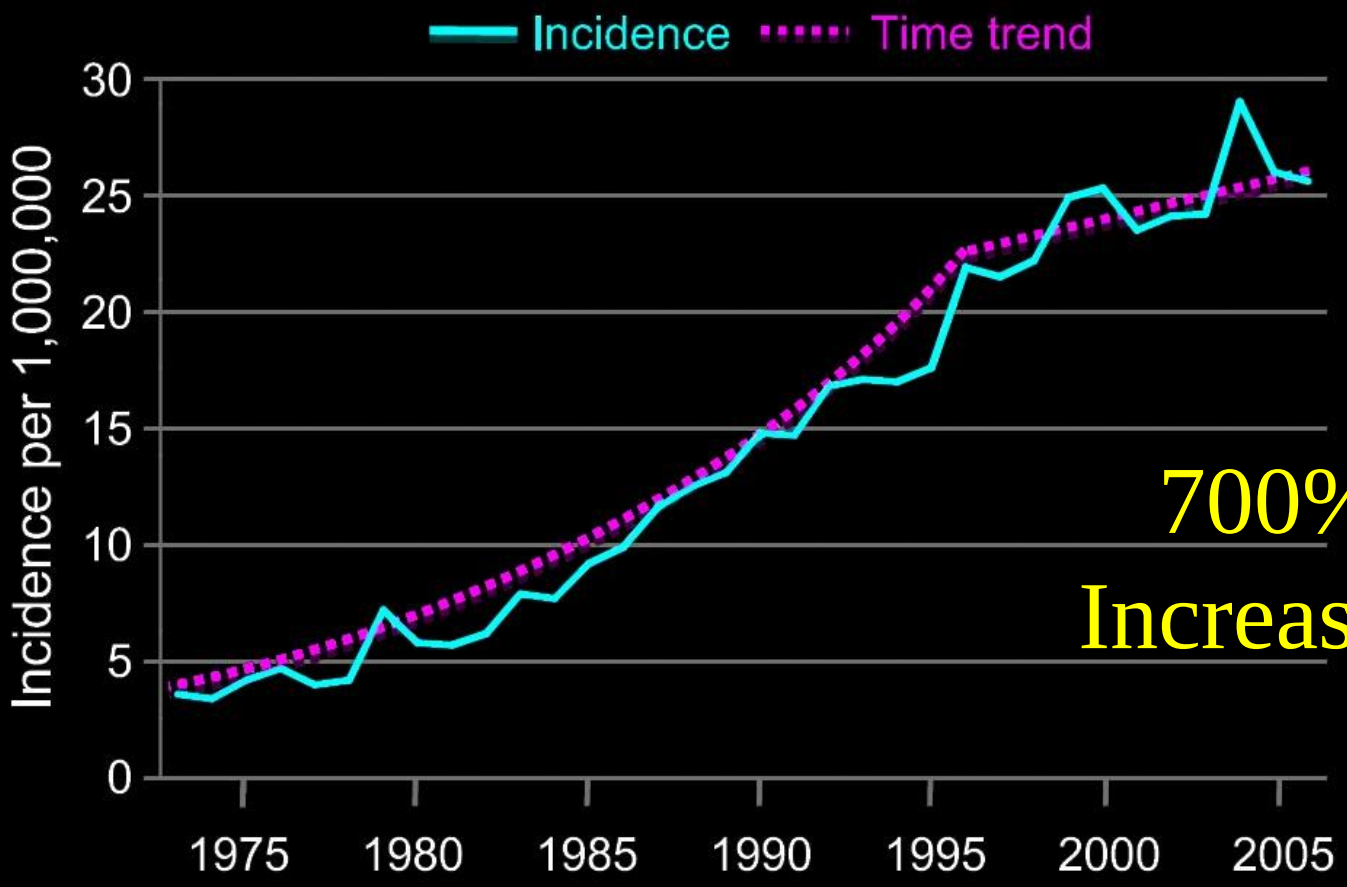
GASTRO-INTESTINAL EPIDEMIOLOGY

Increasing incidence of Barrett's oesophagus: a population-based study

Helen G. Coleman · Shivaram Bhat · Liam J. Murray · Damian McManus · Anna T. Gavin · Brian T. Johnston



Overall Incidence Trend in Esophageal Adenocarcinioma (1973-2006)



Pohl, H., et al., *Cancer Epidemiol Biomarkers Prev*; 19 (6); 1468-70

Tough Choices for Patients

NEED A GERD TREATMENT OPTION THAT…

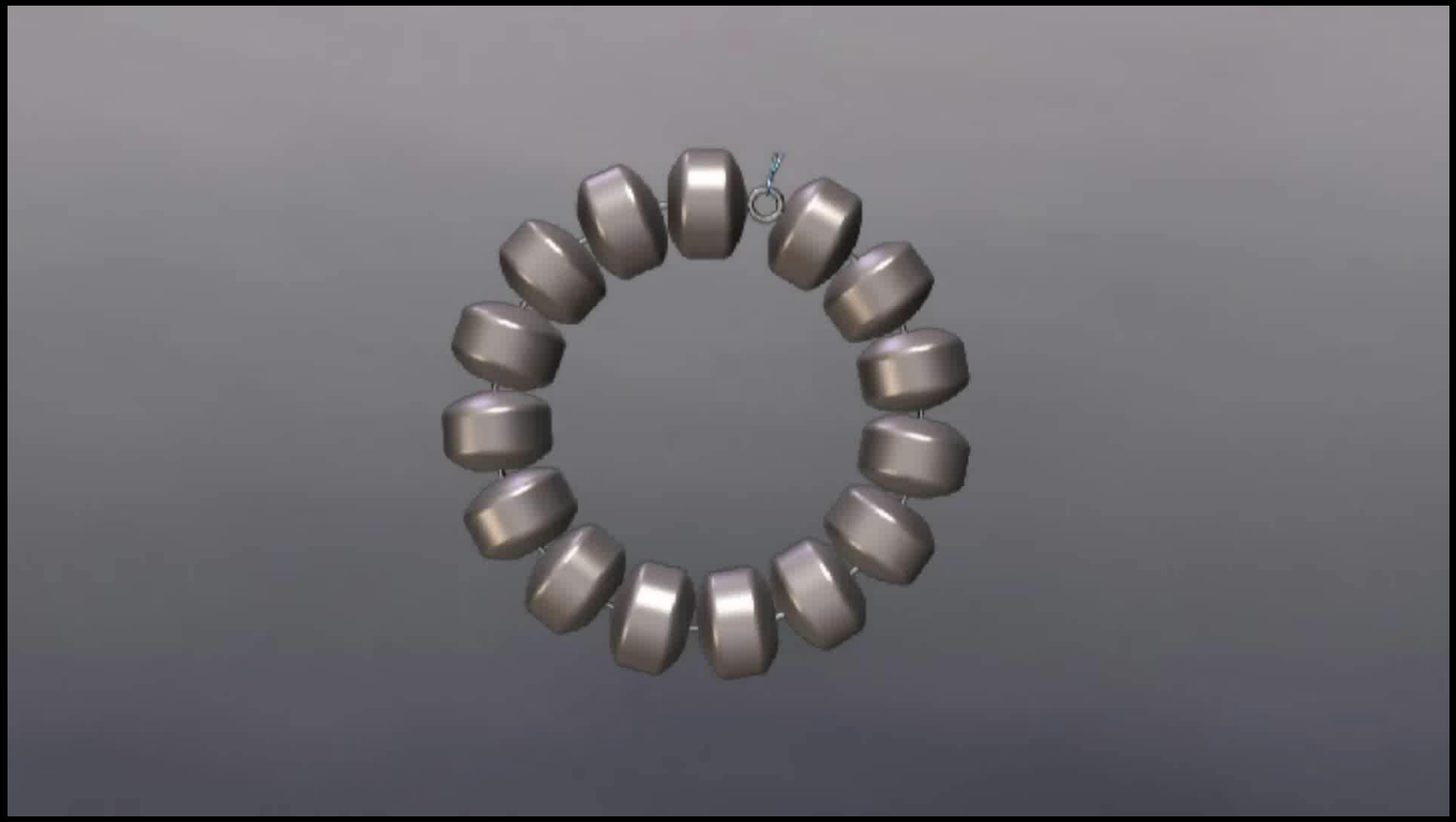
Targets reflux and the anti-reflux barrier
Preserves normal anatomy
Maintains normal functions of LES (belch, vomit)
Highly reproducible
Safe and Reversible

What About…….

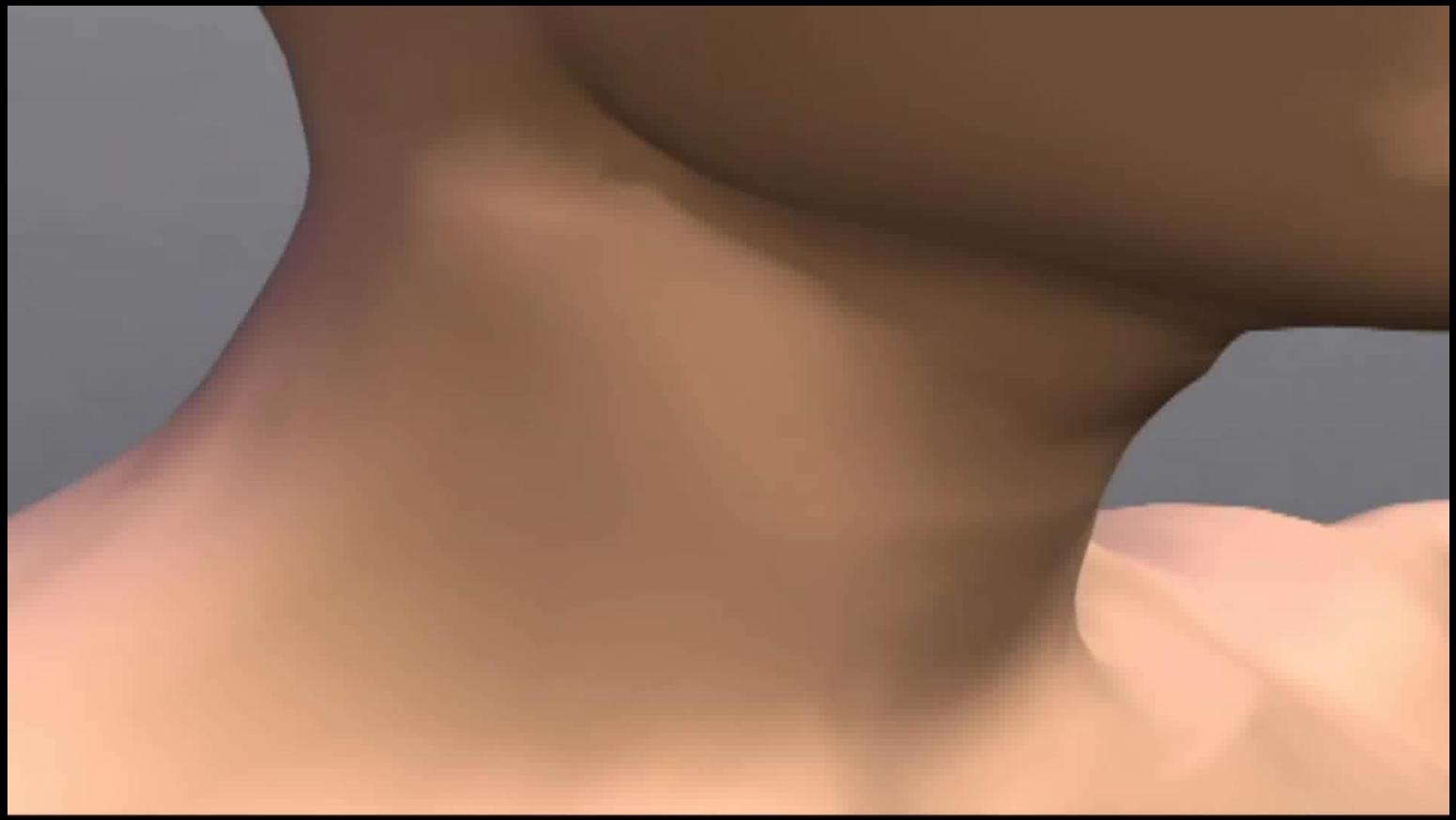
“Magnetic Sphincter Augmentation to Address this Therapy Gap???”

What About……

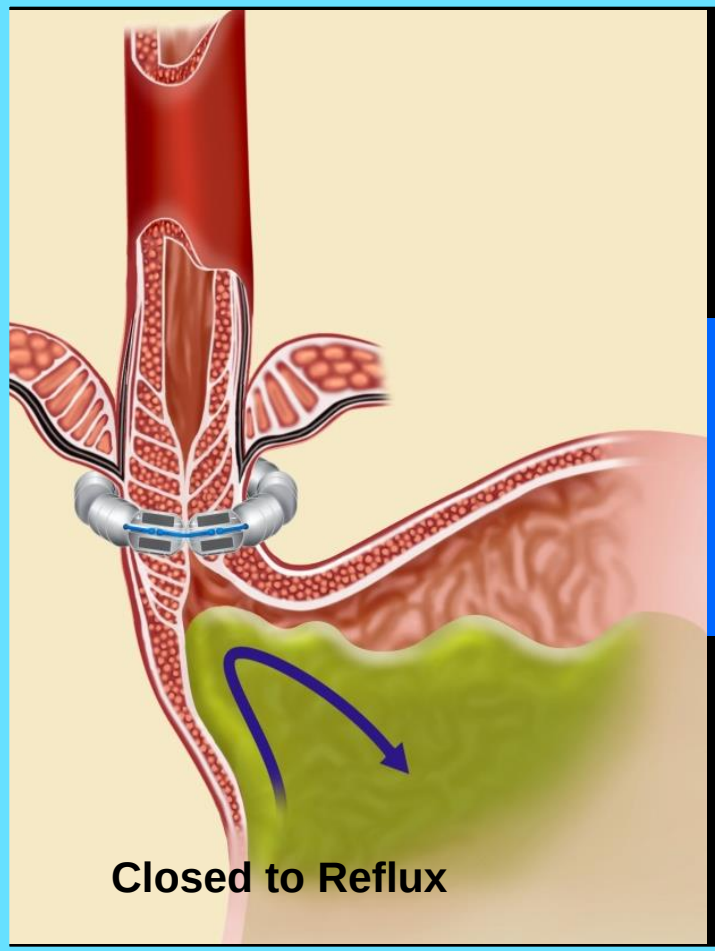
Why Magnets?



Magnetic Sphincter Augmentation



LINX System Allows Physiologic Function

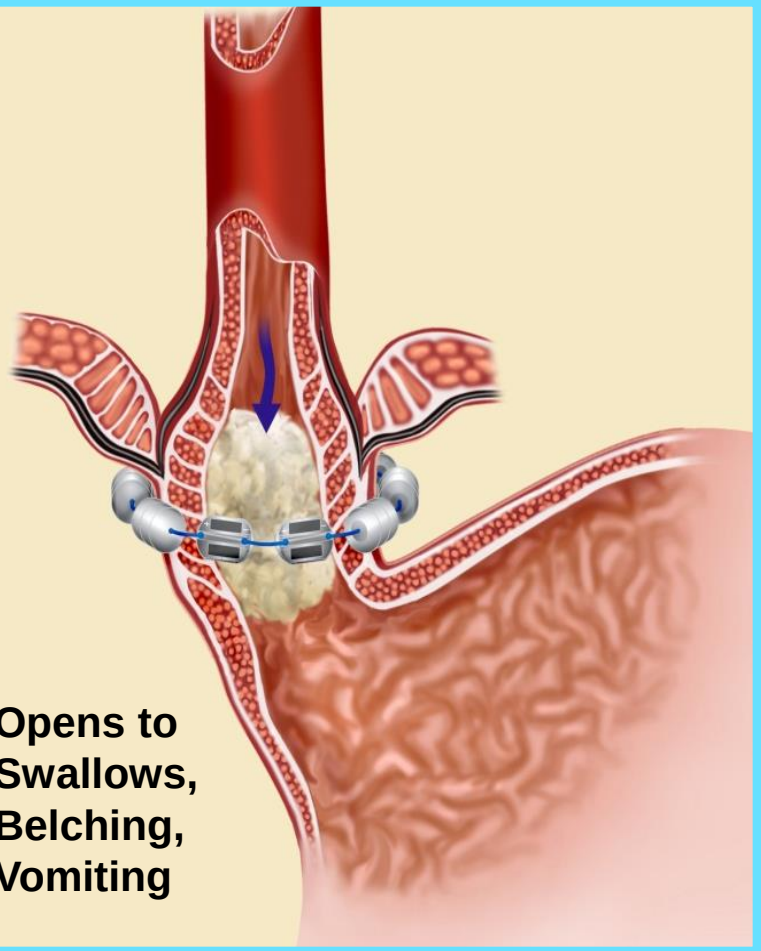


Closed to Reflux

Normal Peristaltic Pressures **35-80 mmHg**

LINX System **Dynamic Barrier of ~20 mmHg**

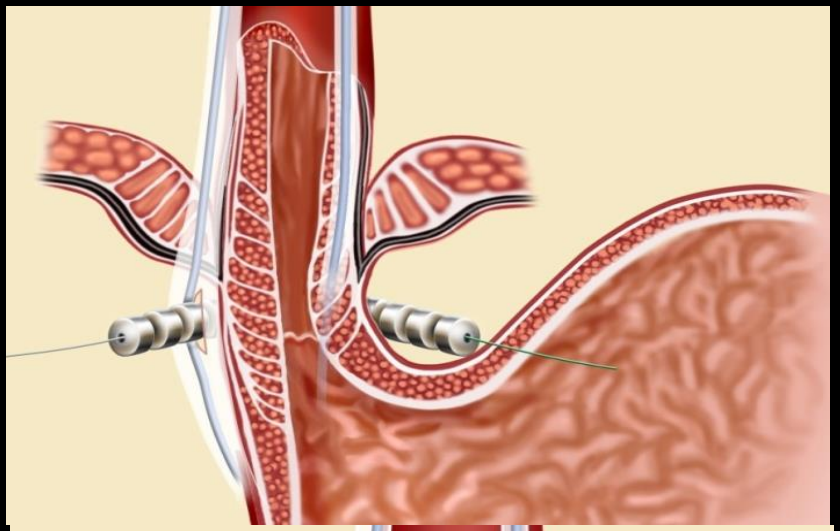
Intragastric pressure **5-10 mmHg**

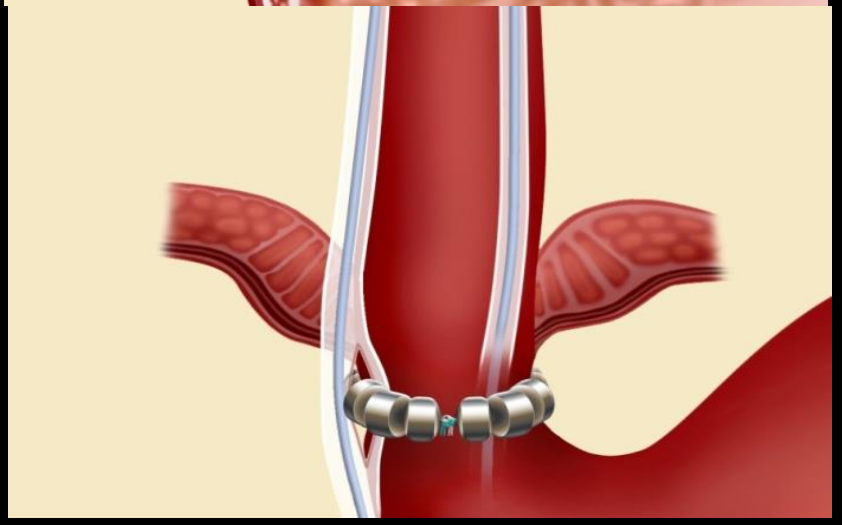


Opens to Swallows, Belching, Vomiting

LINX Sphincter Augmentation

- Laparoscopic Placement
- 20-30 min Procedure
- Limited Dissection
- No Alteration in the Normal Anatomy
- Outpatient



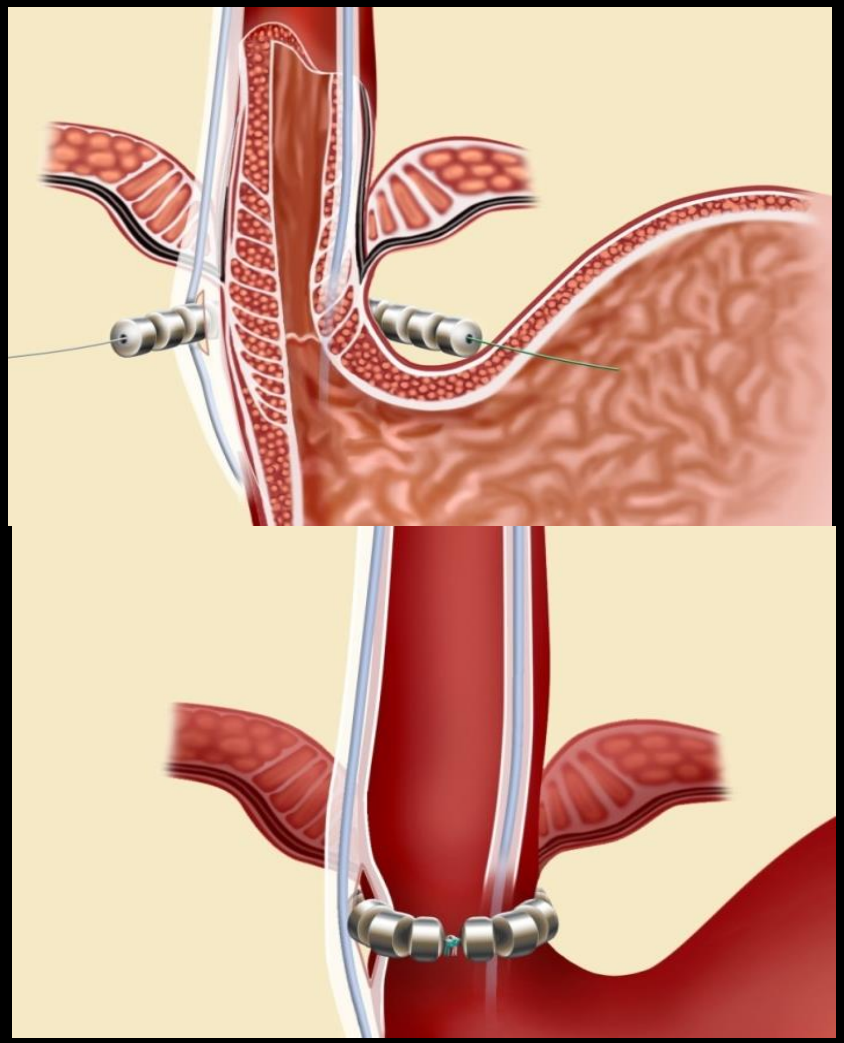


LINX Sphincter Augmentation

Laparoscopic
Placement
of the LINX Device

LINX Sphincter Augmentation

- Regular diet immediately post-op
- Allow patients to **belch**
- Allow patients to **vomit**
- Eliminate/decrease **gas & bloating** Associated with the Nissen

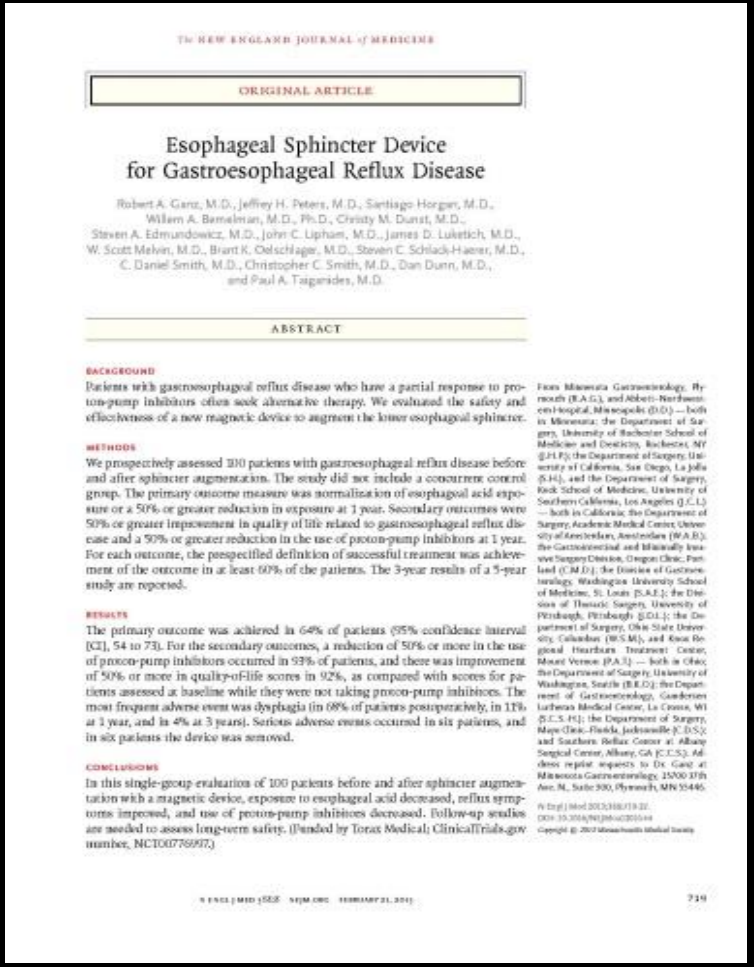


Torax Medical – The Pathway

- **The LINX® Reflux Management System**
  - Two FDA PMA/IDE trials
    - Feasibility Trial 44 pts
    - Pivotal Trial 100 pts
  - 1st implant (IDE Trial) Feb. 2007
  - Five years later:
    - Unanimous FDA Panel recommendation and subsequent FDA Approval (PMA)

Pivotal Trial

- 100 Patients
- 16 Centers
- First Implant Jan 2009
- 3 year results published



The NEW ENGLAND JOURNAL of MEDICINE

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.

ABSTRACT

BACKGROUND

Patients with gastroesophageal reflux disease who have a partial response to proton-pump inhibitors often seek alternative therapy. We evaluated the safety and effectiveness of a new magnetic device to augment the lower esophageal sphincter.

METHODS

We prospectively assessed 100 patients with gastroesophageal reflux disease before and after sphincter augmentation. The study did not include a concurrent control group. The primary outcome measure was normalization of esophageal acid exposure or a 50% or greater reduction in exposure at 1 year. Secondary outcomes were 50% or greater improvement in quality of life related to gastroesophageal reflux disease and a 50% or greater reduction in the use of proton-pump inhibitors at 1 year. For each outcome, the prespecified definition of successful treatment was achievement of the outcome in at least 60% of the patients. The 3-year results of a 5-year study are reported.

RESULTS

The primary outcome was achieved in 64% of patients (95% confidence interval [CI], 54 to 73). For the secondary outcomes, a reduction of 50% or more in the use of proton-pump inhibitors occurred in 93% of patients, and there was improvement of 50% or more in quality-of-life scores in 92%, as compared with scores for patients assessed at baseline while they were not taking proton-pump inhibitors. The most frequent adverse event was dysphagia (in 68% of patients postoperatively, in 11% at 1 year, and in 4% at 3 years). Serious adverse events occurred in six patients, and in six patients the device was removed.

CONCLUSIONS

In this single-group evaluation of 100 patients before and after sphincter augmentation with a magnetic device, exposure to esophageal acid decreased, reflux symptoms improved, and use of proton-pump inhibitors decreased. Follow-up studies are needed to assess long-term safety. (Funded by Torax Medical; ClinicalTrials.gov number, NCT00776997.)

From Minnesota Gastroenterology, Plymouth (R.A.G.), and Abbott–Northwestern Hospital, Minneapolis (D.D.) — both in Minnesota; the Department of Surgery, University of Rochester School of Medicine and Dentistry, Rochester, NY (J.H.P.); the Department of Surgery, University of California, San Diego, La Jolla (S.H.), and the Department of Surgery, Keck School of Medicine, University of Southern California, Los Angeles (J.C.L.) — both in California; the Department of Surgery, Academic Medical Center, University of Amsterdam, Amsterdam (W.A.B.); the Gastrointestinal and Minimally Invasive Surgery Division, Oregon Clinic, Portland (C.M.D.); the Division of Gastroenterology, Washington University School of Medicine, St. Louis (S.A.E.); the Division of Thoracic Surgery, University of Pittsburgh, Pittsburgh (J.D.L.); the Department of Surgery, Ohio State University, Columbus (W.S.M.), and Knox Regional Heartburn Treatment Center, Mount Vernon (P.A.S.) — both in Ohio; the Department of Surgery, University of Washington, Seattle (B.K.O.); the Department of Gastroenterology, Gundersen Lutheran Medical Center, La Crosse, WI (S.C.S.-H.); the Department of Surgery, Mayo Clinic, Florida, Jacksonville (C.D.S.); and Southern Reflux Center at Albany Surgical Center, Albany, GA (C.C.S.). Address reprint requests to Dr. Ganz at Minnesota Gastroenterology, 15700 37th Ave. N., Suite 300, Plymouth, MN 55446.

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February 21, 2013

Trial Design

Inclusion

- Age 18-75 years
- Typical GERD symptoms >6 months
- Pathologic GERD – (esophageal pH<4 for >4.5% of time)
- Daily PPI use
- Symptomatic improvement on PPIs

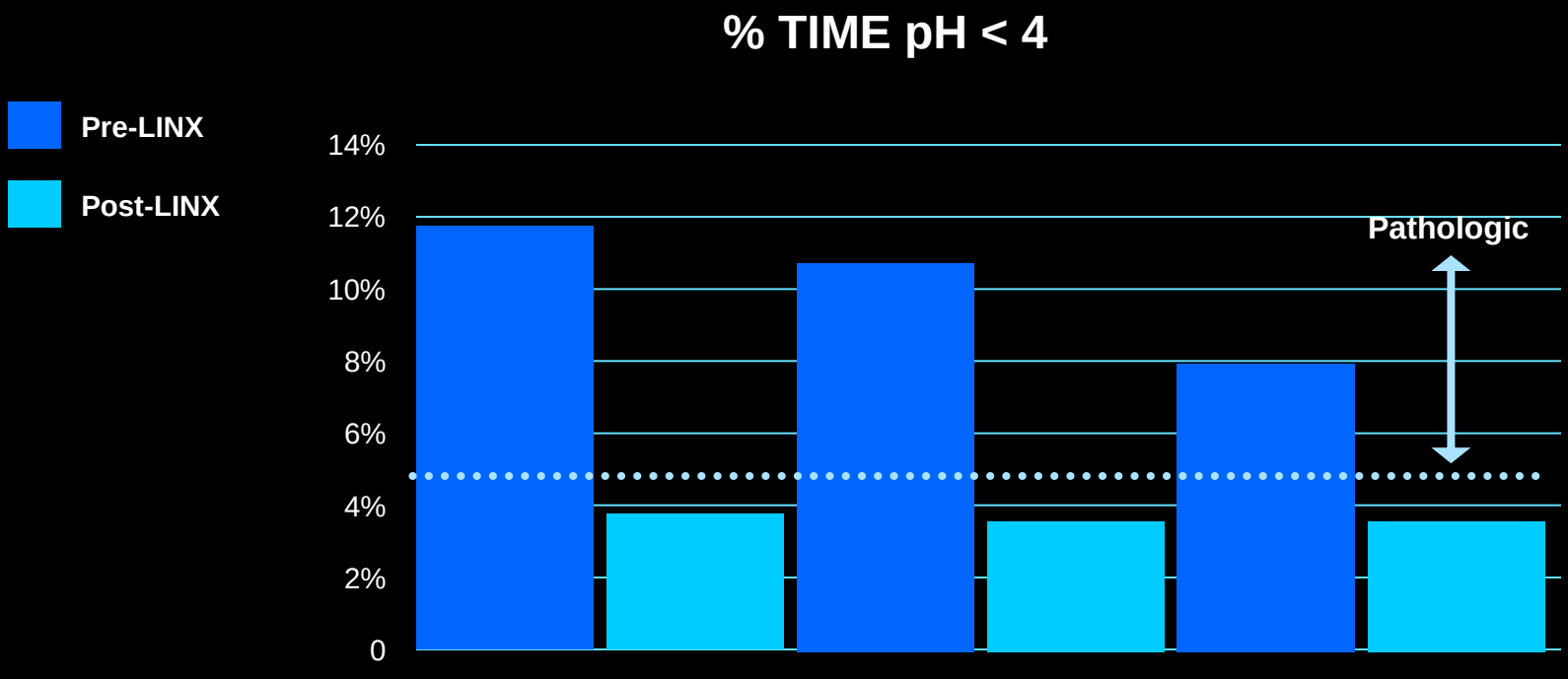
Exclusion

- Hiatal hernia (>3cm)
- Esophagitis Grade C or D (LA classification)
- Barrett's esophagus
- Esophageal motility disorder

- Endpoints
  - Primary: Acid Exposure
  - Secondary: GERD HRQL and PPI Use

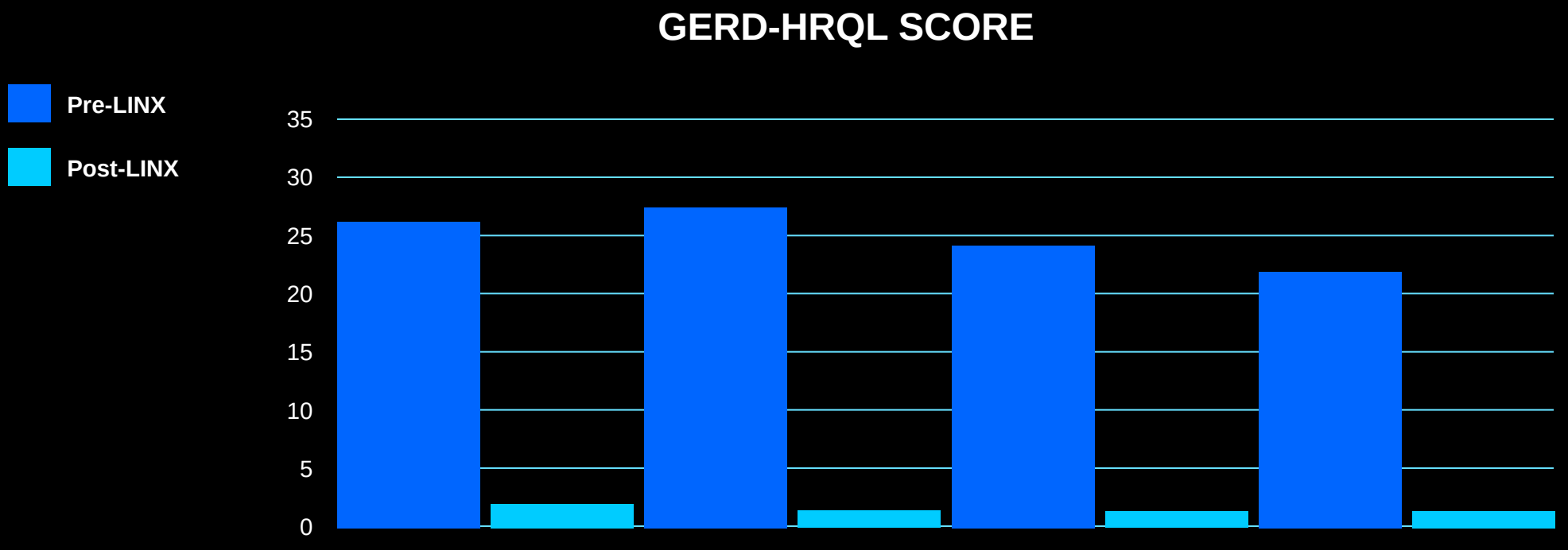
Efficacy

Reduction in Esophageal Acid Exposure



STUDY	FDA PILOT	FDA PIVOTAL	MILAN EXPERIENCE
Centers/Patients:	4/44	14/100	1/100
F/U Range:	4 Years	1-3 Years	1-6 Years
Published Studies:	Surgical Endoscopy	New England Journal Of Medicine	Journal American College Of Surgery

Control of Heartburn Symptoms



STUDY	FDA PILOT	FDA PIVOTAL	MILAN EXPERIENCE	EU REGISTRY
Centers/Patients:	4/44	14/100	1/100	19/249
F/U Range:	4 Years	1-3 Years	1-6 Years	1 Year
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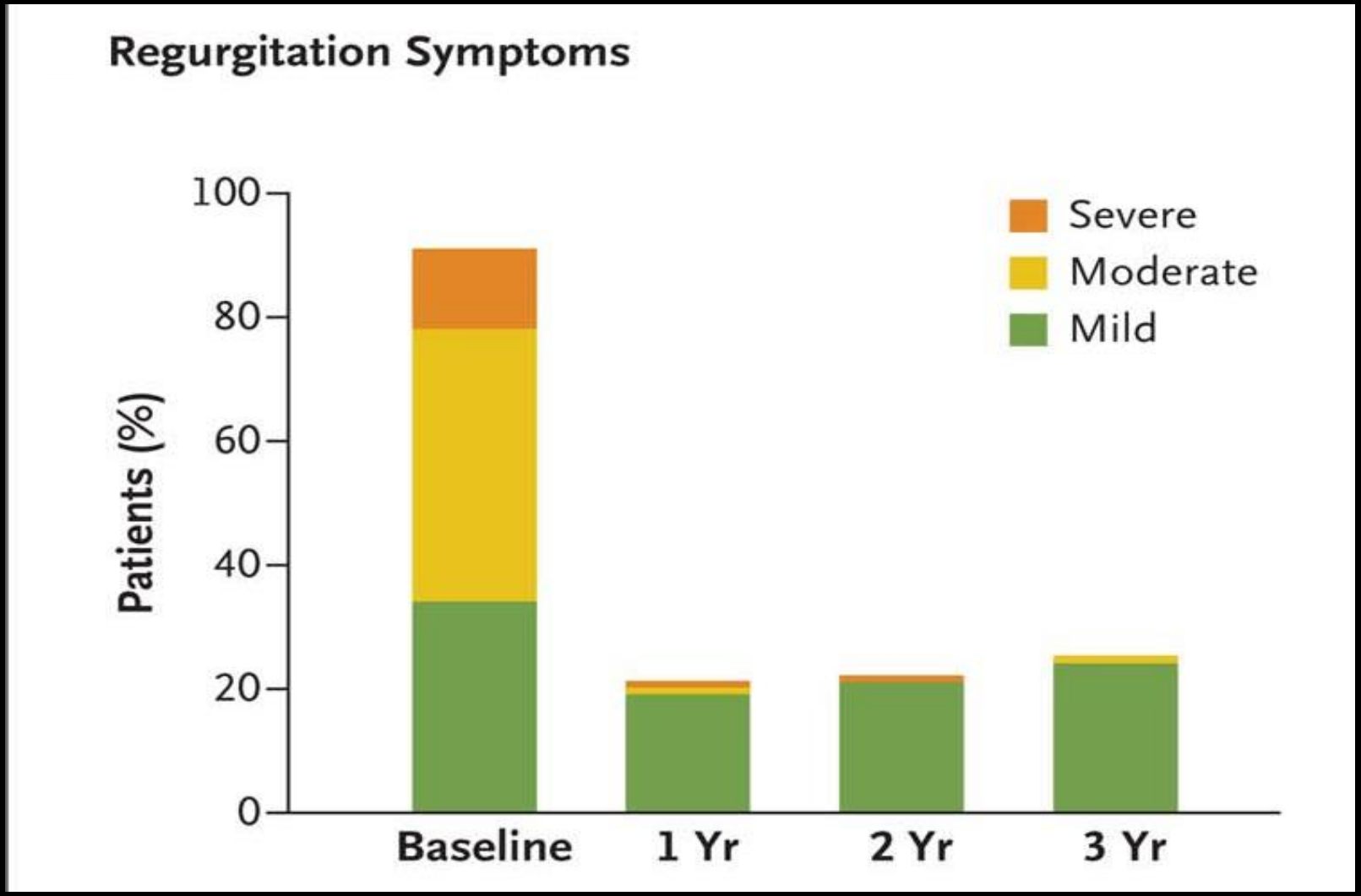
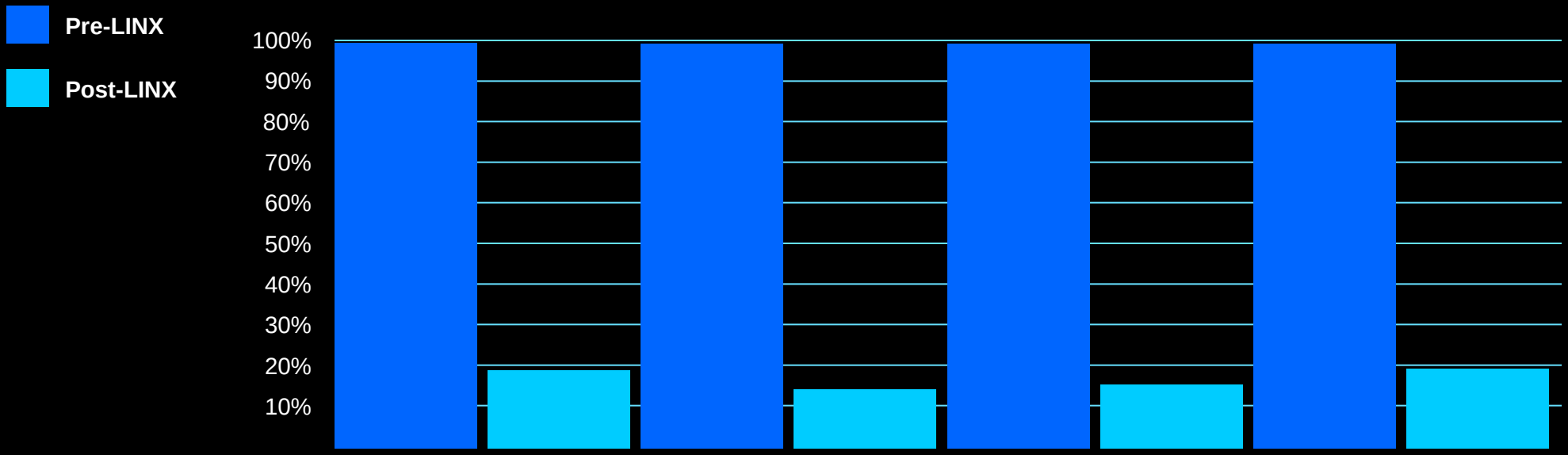
Improvement in Regurgitation



Ganz RA et al. N Engl J Med 2013;368:719-727

Freedom of PPI Dependence

PERCENT OF PATIENTS TAKING ANY PPIs



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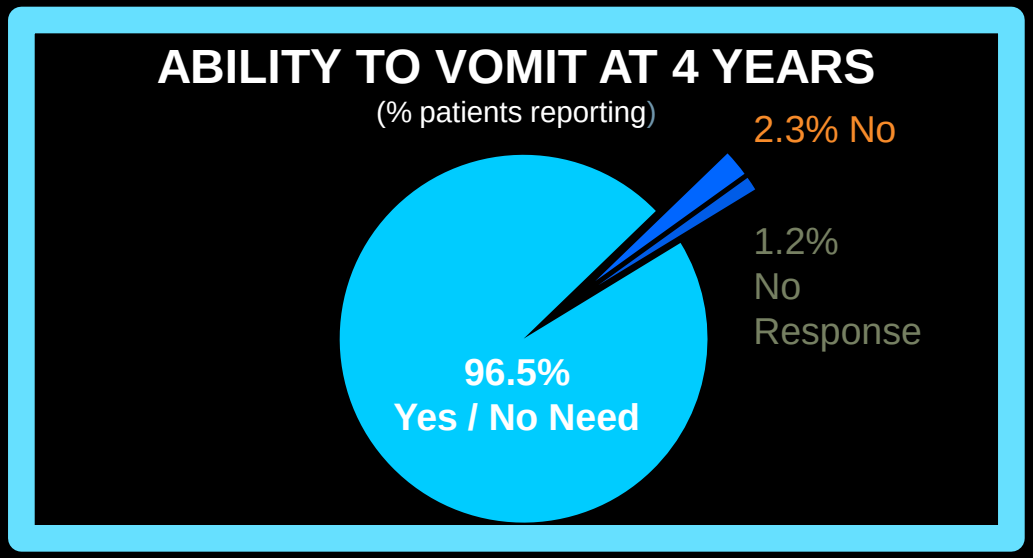
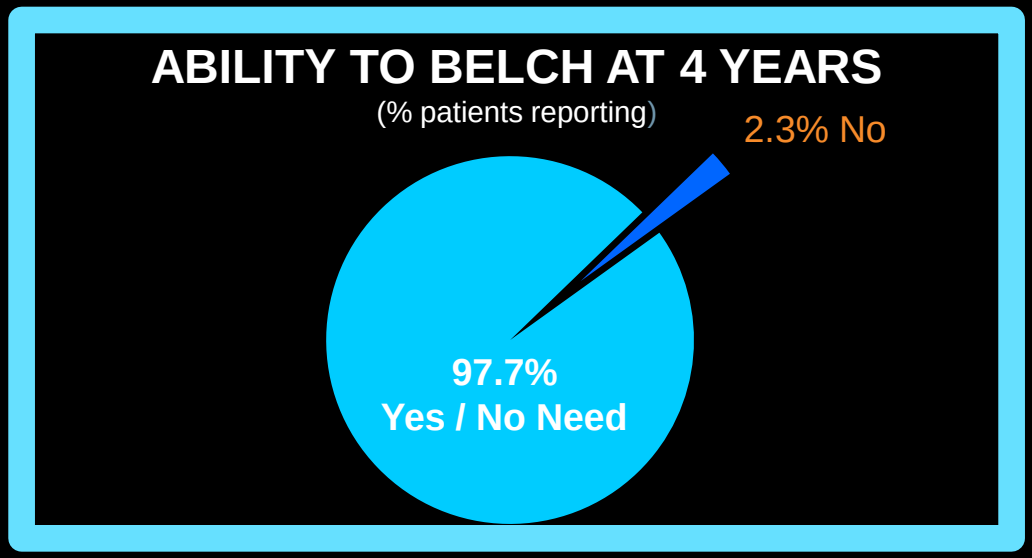
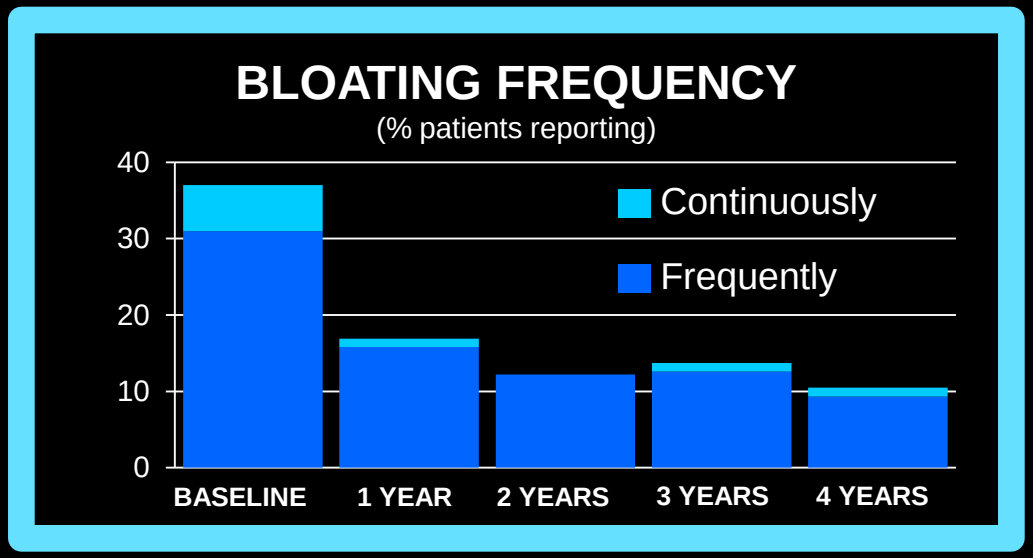
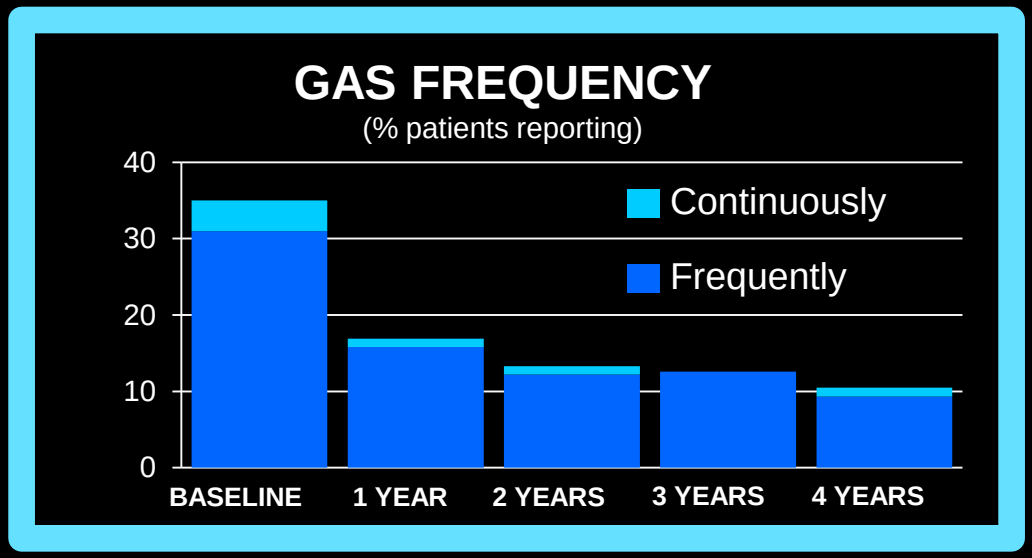
Ability to Belch & Vomit



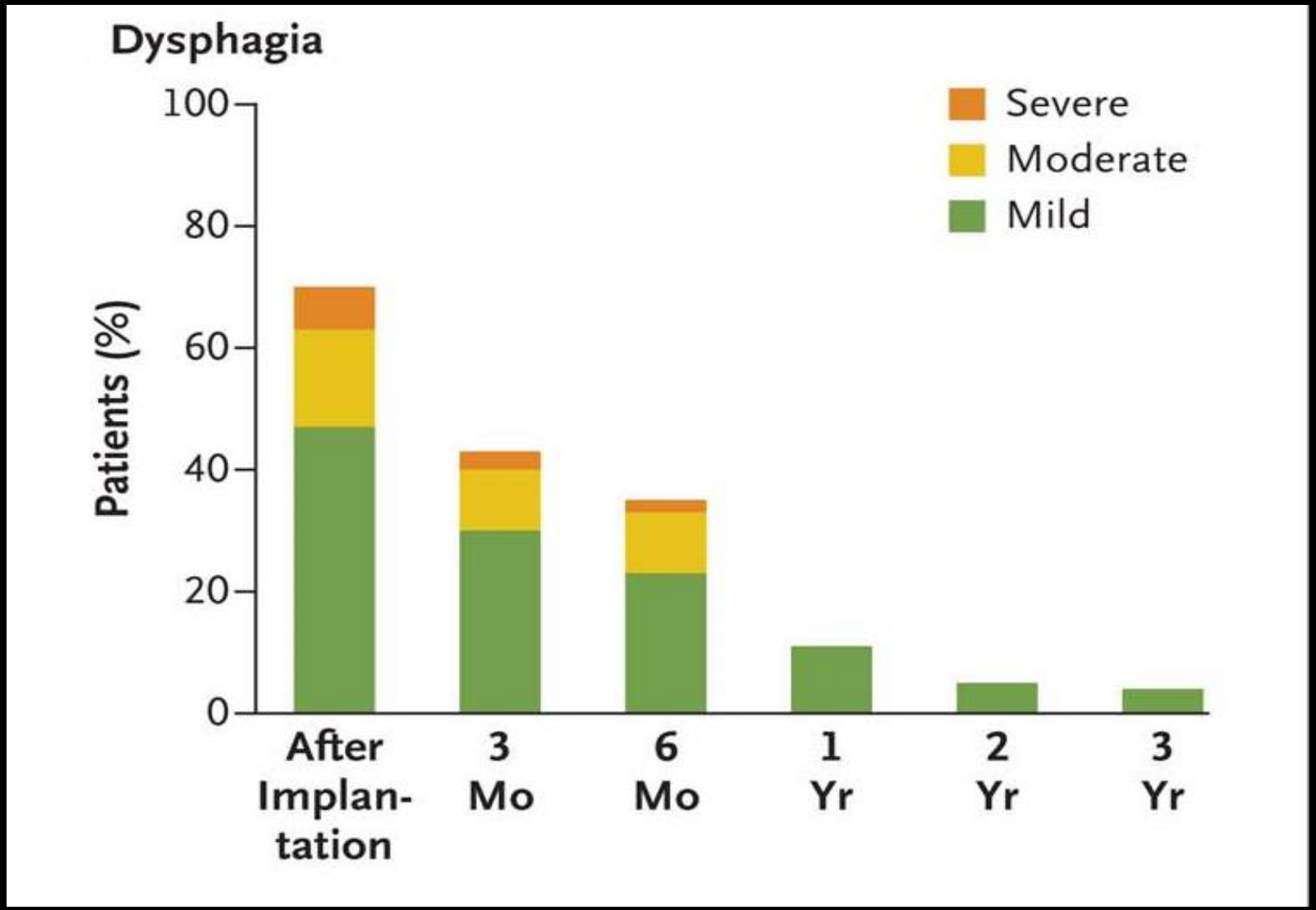






Side Effects

Dysphagia



Ganz RA et al. N Engl J Med 2013;368:719-727

Summary of LINX Safety

N=1048

	Pre-Approval Occurrence Rate	Post- Approval Occurrence Rate	Overall Occurrence Rate
Esophageal Dilation	13.9%	4.3%	5.6%
Device Removal	6.2%	3.0%	3.4%
Readmission Rate	2.1%	1.2%	1.3%
Perioperative Complication	0.0%	0.1%	0.1%
Device Erosion/Migration	0.0%	0.1%	0.1%
Device Malfunction	0.0%	0.0%	0.0%

Lipham et al, Safety Analysis of the First 1000 Patients Treated with Magnetic Sphincter Augmentation for GERD. *Diseases of the Esophagus* Apr 2014

LINX Device Can Be Removed

– Laparoscopic procedure

– No complications related to removal

– Anatomy not significantly altered

– Nissen fundoplication an option after removal

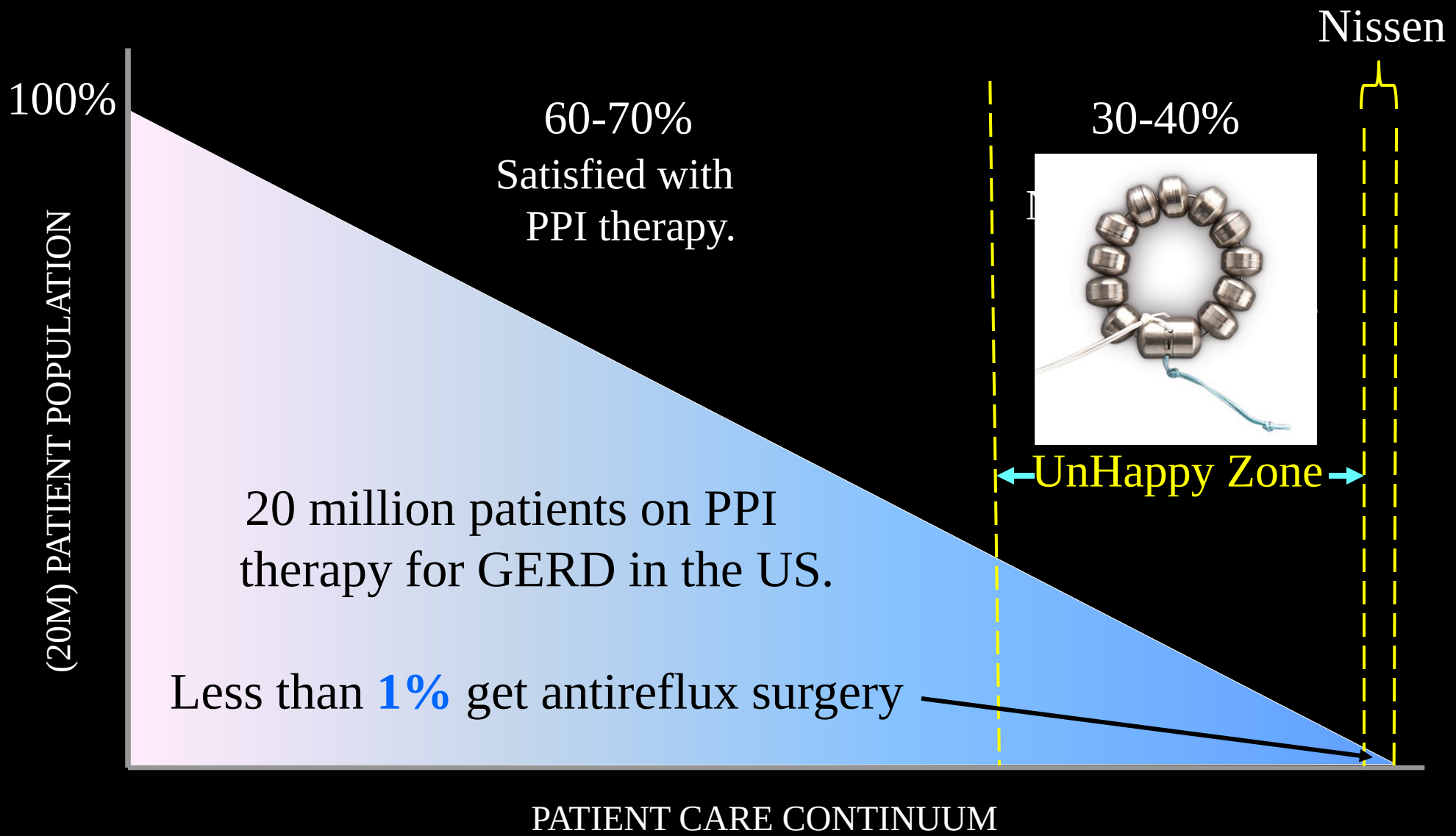
World Wide Experience

- Total implants >2,000
- Follow-up >7 years
- No procedural complications
- Procedure Reversal Rate ~2-3%
  - ½ Persistent Dysphagia
  - ½ Continued GERD
- Safety:
  - No Migrations
  - 3 Erosion (0.2%)

Who is the LINX Patient??

- Younger Patients
- Internet Savvy
  - Know more about the Linx than I do
  - Know more about Me than my Wife does
- Mild to Moderate GERD Patient
  - Smaller H.H
  - NERD or Mild Esophagitis (LA Grade A or B)
  - Normal Motility
  - Moderately Well Controlled on PPI’s

Who is the LINX Patient??



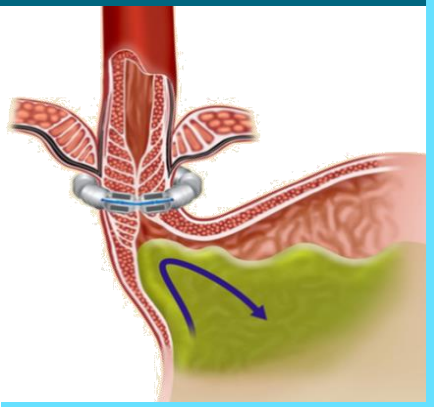
A Better GERD Treatment Continuum

PPI Responders
- Intermittent HB
- Food intolerance

Medical Therapy: Transient Sphincter Failure

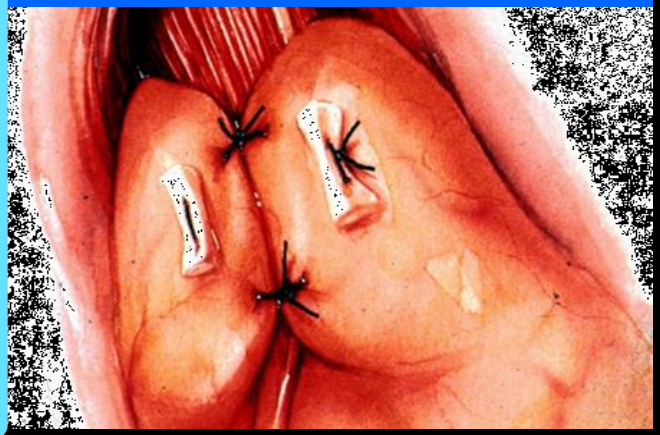
Progressing Disease
- Escalating dosage
- Uncontrolled regurgitation
- New or worsening extra-esophageal symptoms
- Persistent esophagitis

LINX System: Partial Sphincter Failure



End Stage Disease
- Barrett's esophagus
- Large hiatal hernia
- Esophageal dysmotility

Fundoplication: Advanced Sphincter Failure



Conclusions

- LINX provides an option for patients not fully responsive PPIs and not pursuing Nissen fundoplication
- Valid scientific data that supports safety and effectiveness:
  - Reduced acid exposure (Normalization 80%)
  - Improved symptoms (>90% Satisfied)
  - Elimination of PPI Use (85%)
- Benefits outweigh risks
- Stop the Progression of GERD