Options for Gastroesophageal Reflux: Endoluminal

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The patient with GERD

Prescribe the power of

NEW ADMINISTRATION FORM

PREVACID®

LANSOPRAZOLE

PROVEN PROTON PUMP INHIBITOR

Power to relieve the pain of erosive esophagitis

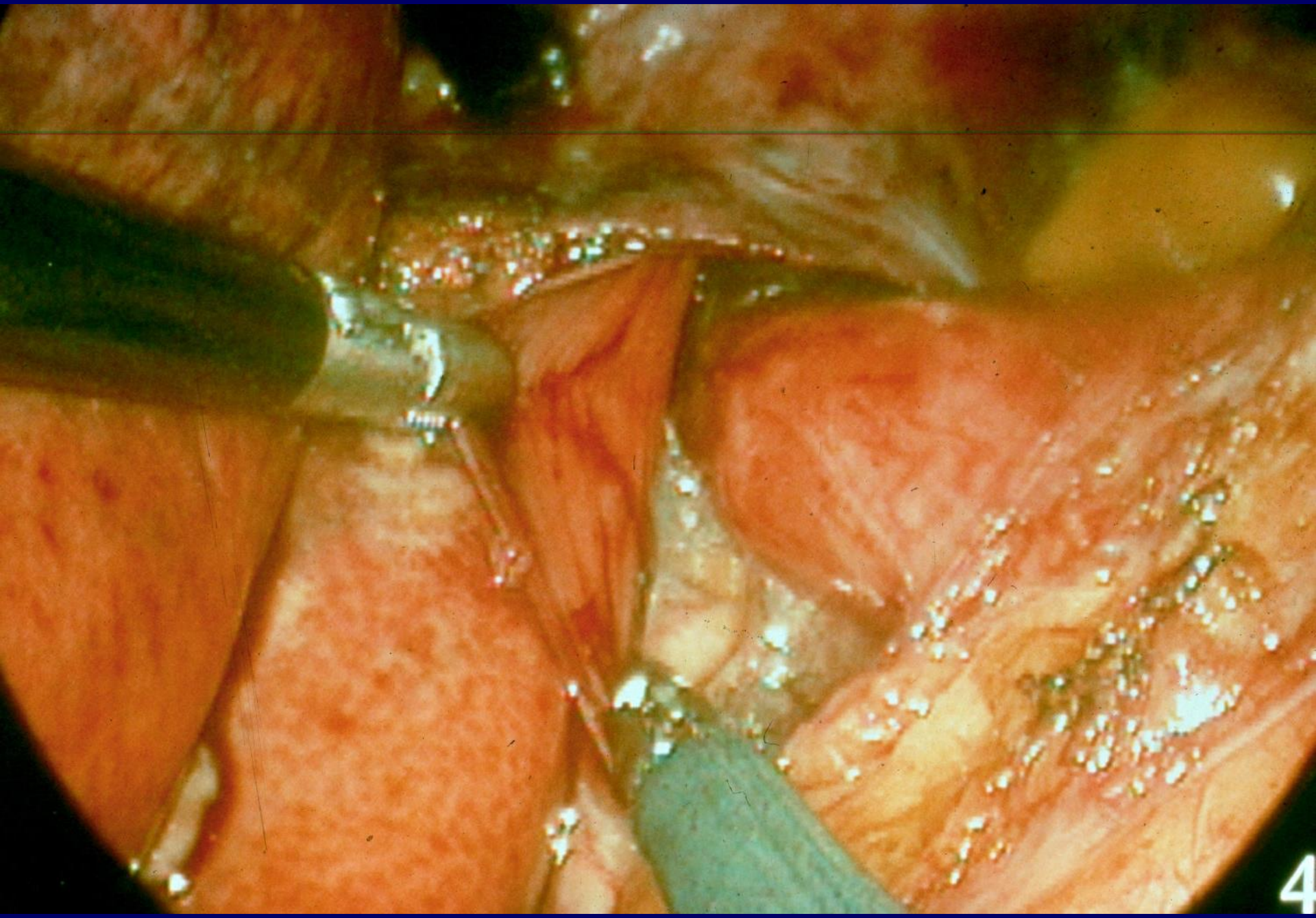
Median percentage of nights patients were free from heartburn:

Power to heal erosive esophagitis effectively

PREVACID 30 mg once a day healed 95% of patients with erosive esophagitis in 8 weeks.

Now PREVACID can be sprinkled!

Patients who have difficulty swallowing capsules can open the capsule, sprinkle the granules on a tablespoon of applesauce, and swallow it immediately. The granules should not be chewed or crushed.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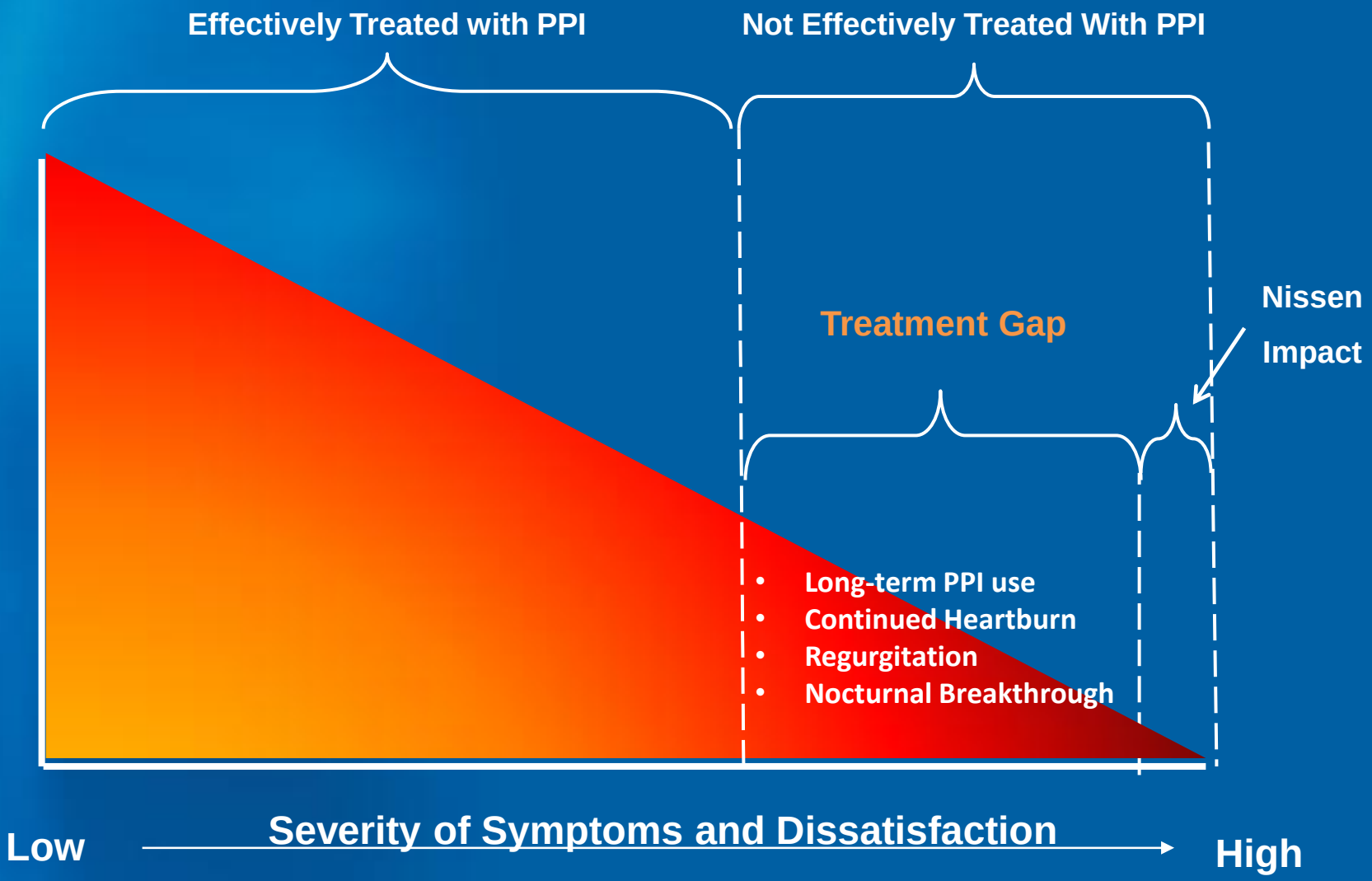
The Therapy Gap



New Options for Gastroesophageal Reflux

- Old Options (lifestyle, diet and medical Rx)
- Radio Frequency Energy Application to the Gastroesophageal Junction (Stretta)
- Transoral Endoscopic Plication
  - Endocinch, NDO
- Transoral Incisionless Fundoplication:
- Mechanical Barriers
- Injection of Biomaterials (Enteryx)
- Laparoscopic Magnetic Augmentation
- Nissen Fundoplication

stretta™

A new, minimally invasive treatment for GERD

www.curonmedical.com

Stretta: Procedure

- Outpatient Endoscopy Procedure
- Placement of catheter at GE junction
- Rfe Application, 45 degree rotation
- 8 applications, 2cm below, 6 above GE jxn
- repeat endoscopy
- Total time about one hour
- Few complications reported

Long Term data

- 50 pts referred for surgery, Stretta
- 32 pts with long term f/u (53 months)
- 19 of 32 underwent ARF surgery for sxs
- 13 responders had improved GERD QoL and Symptom score

  – Dundon JM, Melvin WS, Surg innov, 2009.

Long Term data

- 108pts 4 year f/u
- 96 pts at 48 months
- Heartburn Scores 3.6 to 1.8*
- GERD QoL 27.8 to 7.1*
- Medication usage 100% to 75%

Noar, et al. GIE, March , 2007

- 83 pts at 48 months follow up
- GERD symptom score 24 to 4.3*
- GERD QoL 2.7 to 0.6*
- Medication 100% to 13.6%*

– Reymunde A., et al. GIE, March, 2007.

Stretta New Data

- 48 month followup, multi center, Europe
- 56 pts evaluated (69 pts treated)
- GERD and HRQL improved significantly
- 41 of 56 were off PPIx
- Apppears that Stretta is effective and durable

  - Dughera, etal., 2011

Stretta: Meta Analysis

Outcome Variable	Studies (n)	Patients (n)	Mean Follow-up (mo)	Pre-Stretta	Post-Stretta	P-value
GERD-HRQL score	9	433	19.8	26.11	9.25	0.0001
QOLRAD score	4	250	25.2	3.30	4.97	0.0010
Heartburn score	9	525	24.1	3.55	1.19	0.0001
Satisfaction score	5	366	21.9	1.43	4.07	0.0006
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

Table 1: Comparison of Pre-Operative and Latest Post-Operative Observations of the Study Parameters

Banarjee, Perry, Melvin, Surg Lap Endo Perc Tech, 2012

No Evidence for Efficacy of Radiofrequency Ablation for Treatment of Gastroesophageal Reflux Disease: A Systematic Review and Meta-Analysis.

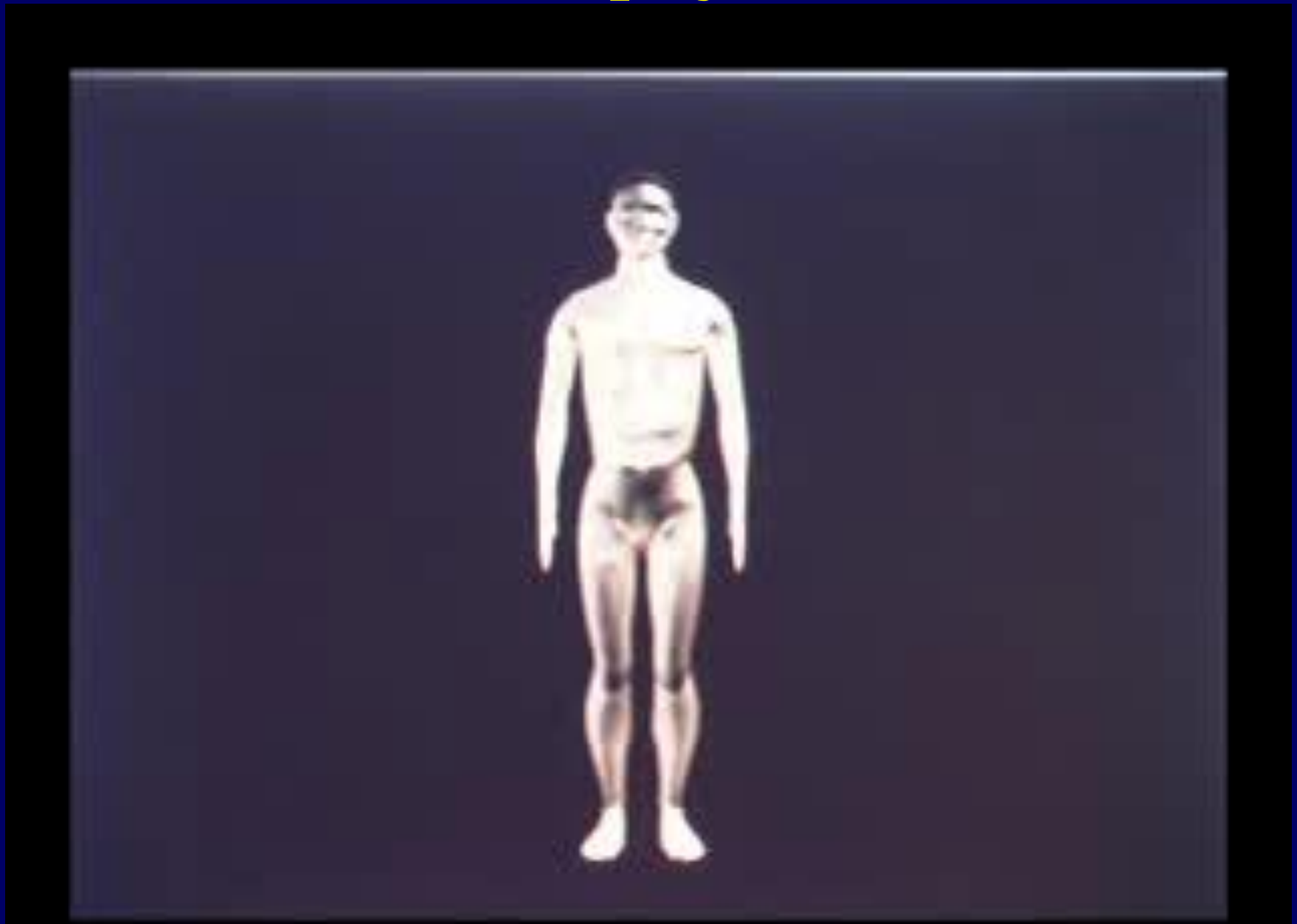
- Evaluated 4 trials and evaluated 153 pts
- No improvement compared to sham or ppi
- No change in pH or HRQL

- Clin Gastro Hepatol, 2014
- Lipka S, Kumar A, Richter J.

Economics

- Approved by the FDA in 2000
- CPT code assigned in 2004 (43257)
- Curon bankrupt in December 2006
- Technology Acquired
- Currently Available, Mederi Therapeutics
- Available worldwide for clinical use

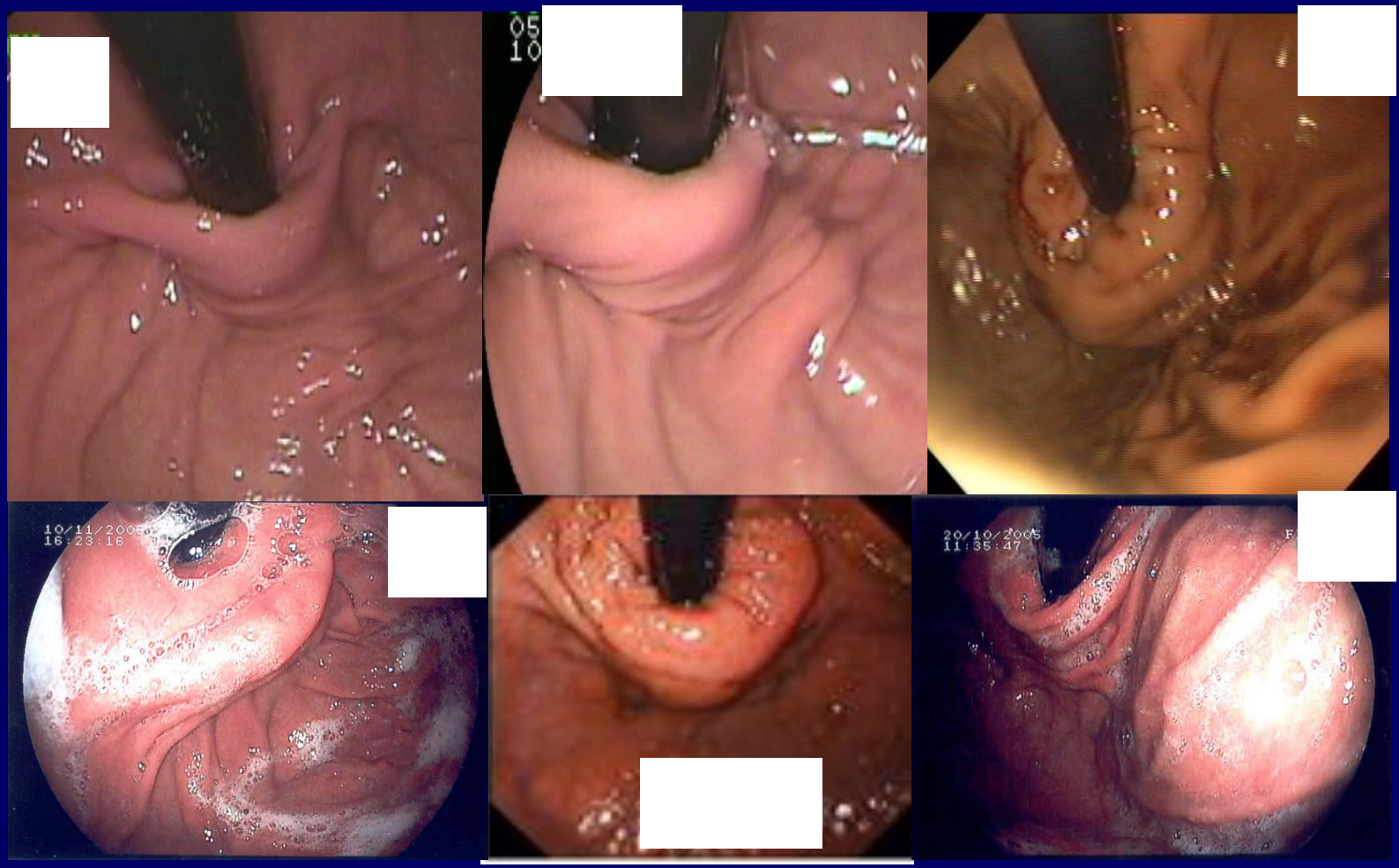
Esophyx



Esophyx:
Transoral Incisionless Fundoplication

- Approved for US in Sept 2007
- Over the scope fundoplication device
- Under direct vision
- Full thickness anchoring devices
- Reduce small Hiatal Hernias
- General anesthesia, short stay
- Gaining long term experience

EsophyX™ vs. Nissen



Esophyx at Ohio State

- Single institution prospective study all pts undergoing EsophyX Sept 07 - March 09
- Demographics, procedure related complications
- Outcomes:
  - safety
  - symptomatic improvement: symptom scores (Anvari) and HRQL (Velanovich) and PPI use

Results: Symptoms

	Preop	**Postop**	**p**
HRQL (Velanovich)	22 (13)	8 (7)	0.002
Symptom Score (Anvari)	34 (14)	16 (15)	0.004
Medication use	100%	65% 41% preop 24% half dose	

Esophyx Data

- 37 consecutive pts with GERD
- 68% respiratory symptoms
- All uncerwent TIF, endsocopically
- 2 complications
- 6month follow up:
  - 82% no drugs, 54% no symptoms, 21% better
  - 5 (13.5%) had LS nissen for failure

Bell R, Freeman KD. Surg endo, 2010

Esophyx : Long Term

- 38 pts with three year follow up (56% pts had hiatal hernia)
- One peri op bleeding
- 14 pts (36%) underwent ARF surgery
- Remaining pts QOL scores improved
- 76% off meds
- In subset results were satisfactory
    - Witteman BP, etal, Surg Endosc, 2012

Esophyx: Multicenter Registry

- Prospective data collection: 100 patients
- No procedural complications.
- 6month f/u:
- GERD HRQL normalized 73%
- Reflux Symptom Score Median 24 to 7
- pH normalized in 54% (15 out of 28)
- Safe, good symptom control
  - Bell RW, et al, JACS 2012

Meta Analysis

Measurement	No Studies	Total Patients	Average Decrease	Mean Follow-up (Months)	P-value
GERD-HRQL score	9	325	20.6	8.2	0.0001*
RSI Score	2	133	23.3	6.8	0.1026
Continued PPI use	9	320	25.0%	9.2	0.0001*
Hiatal hernia incidence	3	63	36.0%	7.5	0.2423
Mean LES pressure	3	103	-5.0 mmHg	10.1	0.0762
Esophageal Acid Exposure Time (% time ph <4)	3	99	2.8%	10.0	0.2027
DeMeester Score	3	107	7.7	10.0	0.2008
Number of acid refluxes	4	61	22.1	6.7	0.3066

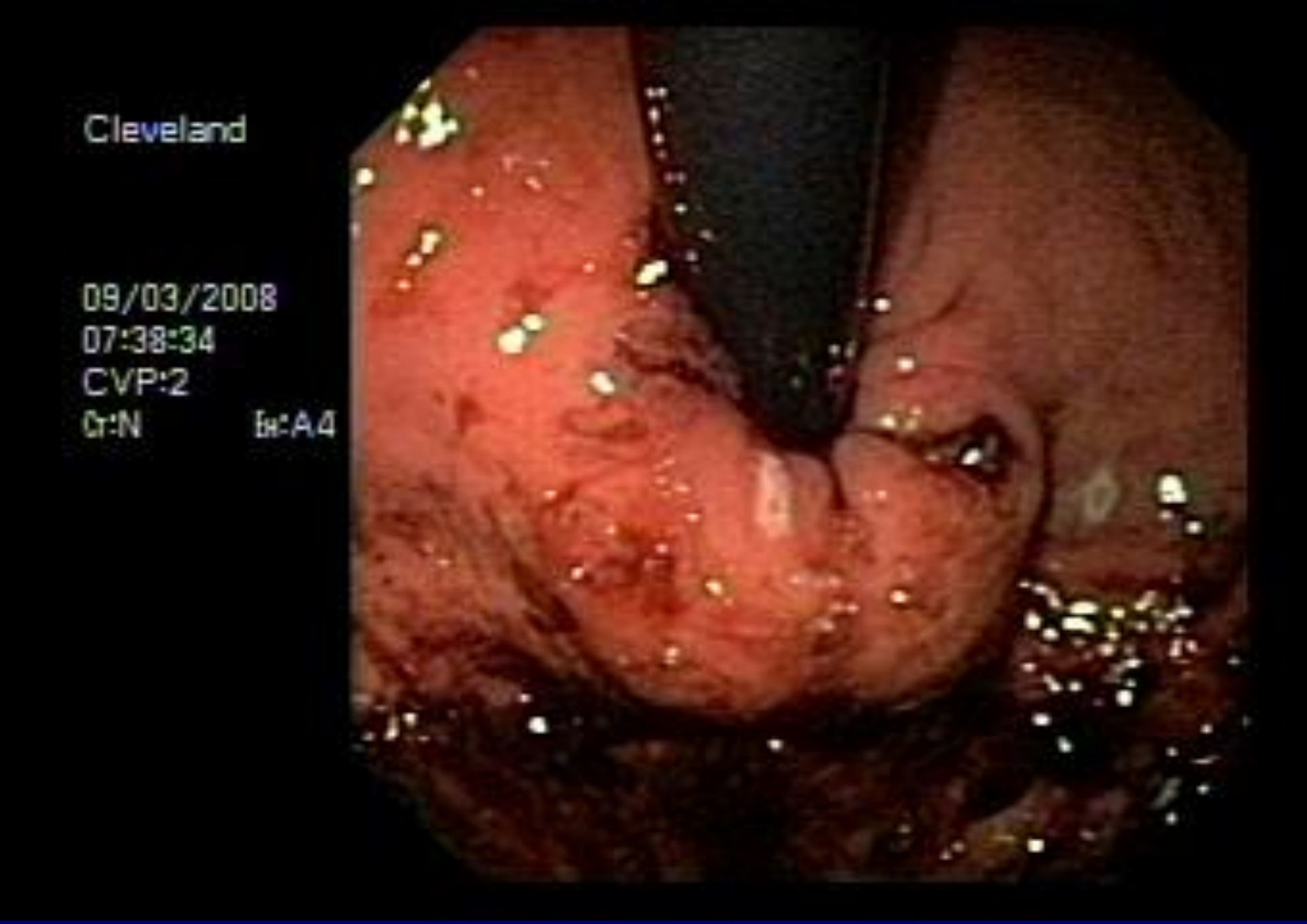
TIF for Regurgitation

- Multicenter trial, randomized blinded sham controlled vs, BID Prilosec
- Symptoms scores, pH studies and evaluations at 2, 12 and 26 weeks
- Rreduced regurgitation(67 vs 45% p=.023)
- pH improved with TF more than sham
- GERD symptoms were reduced in both

- Hunter JG, Melvin WS, et al, Gastroenterology, 2015

New Data Collection

- AGA sponsored STAR Registry
- Comparing TIF to Nissen in patietns with troublesome GERD
- Case control data registry
- First pt enrolled in 2014, three year plan


Cleveland
09/03/2008
07:38:34
CVP:2
Gr:N
En:A4

Medigus

Medigus/ MUSE

- 11SRS vs 16 Lap Nissen
- Safe efficient use
- Shorter OR time
- No diff in PPI
- No difference in HRQL

  – Danalioglu , A, et al. Dig Endosc, 2013

SRS/MUSE , Multicenter

- 69 pts, 6 sites, 6 month follow up
- GERD HRQL, > 50% Improvement in 73%
- Off PPIs: 42% none
- Total time pH<4.0, mean decreased (p.001)
  - pH upright, supine, and total epsisode #, n.s.
- 1 post op bleed, 1 perf (Chest tube)

  - Zucherl , J. et al. Surg Endosc, 2014.

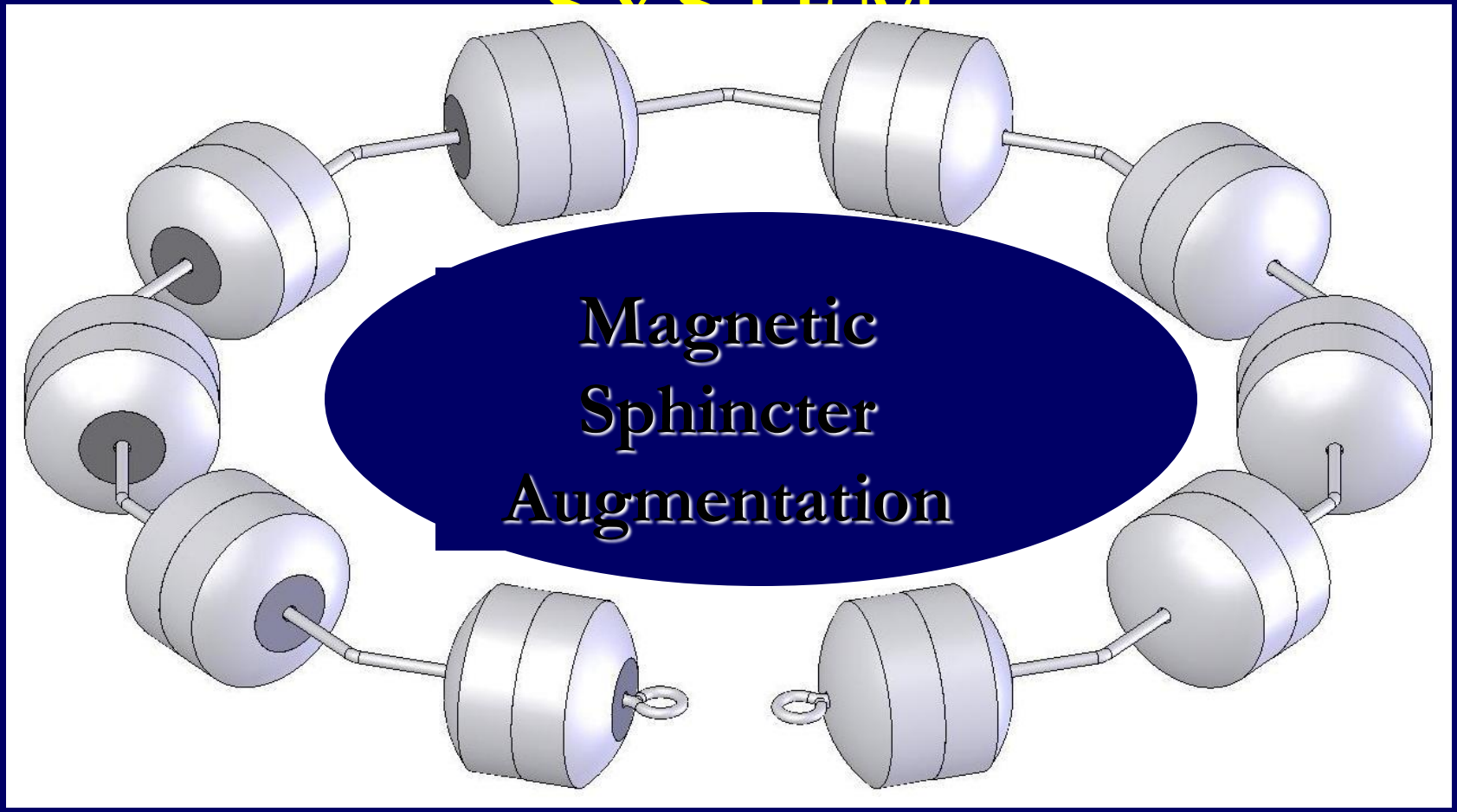
SRS/MUSE Medigus

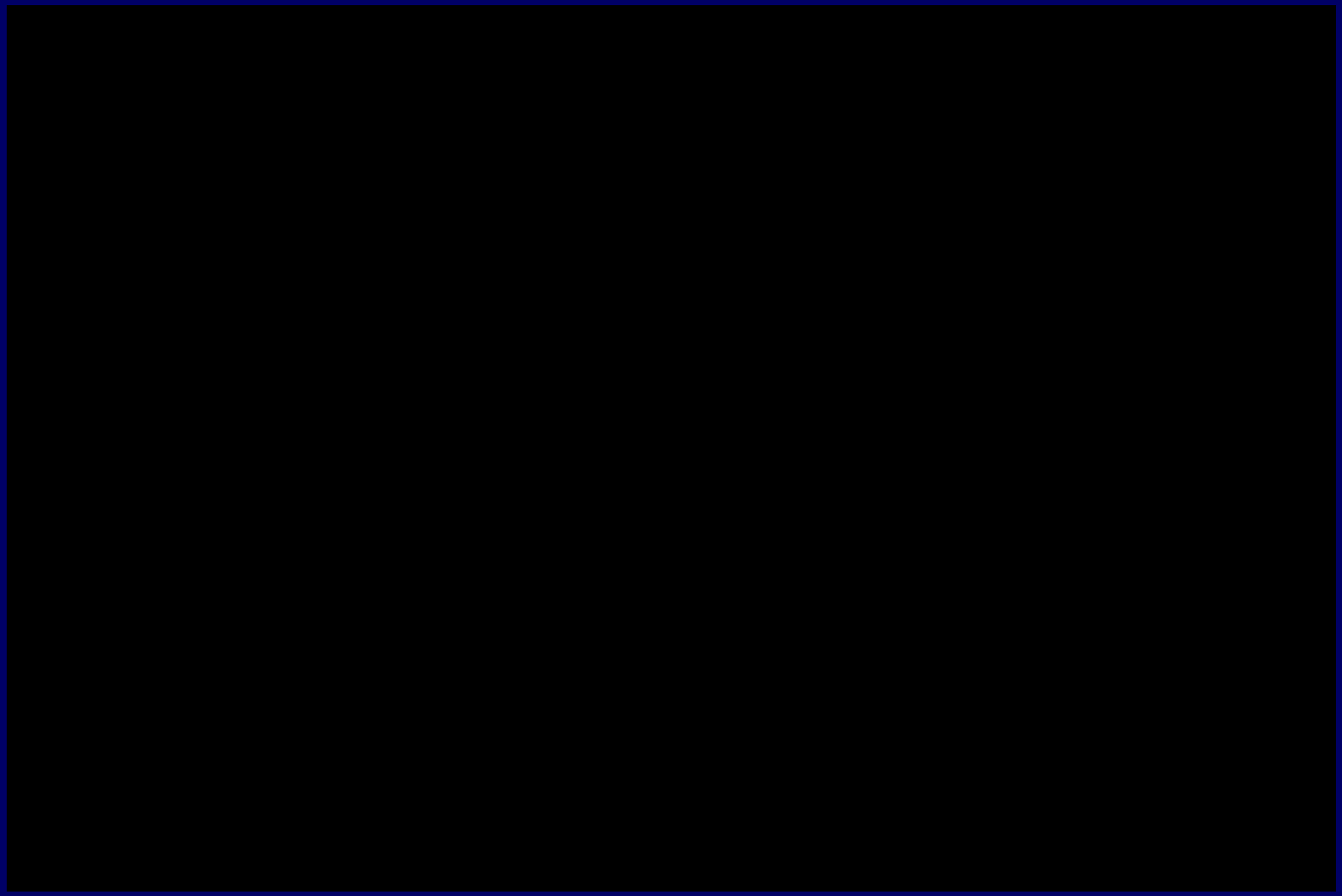
- FDA approved, Q1 2014
- International registry underway
- Available in select centers currently
- Data will accumulate
- Reimbursement and finances are important

Endoluminal Fundoplication

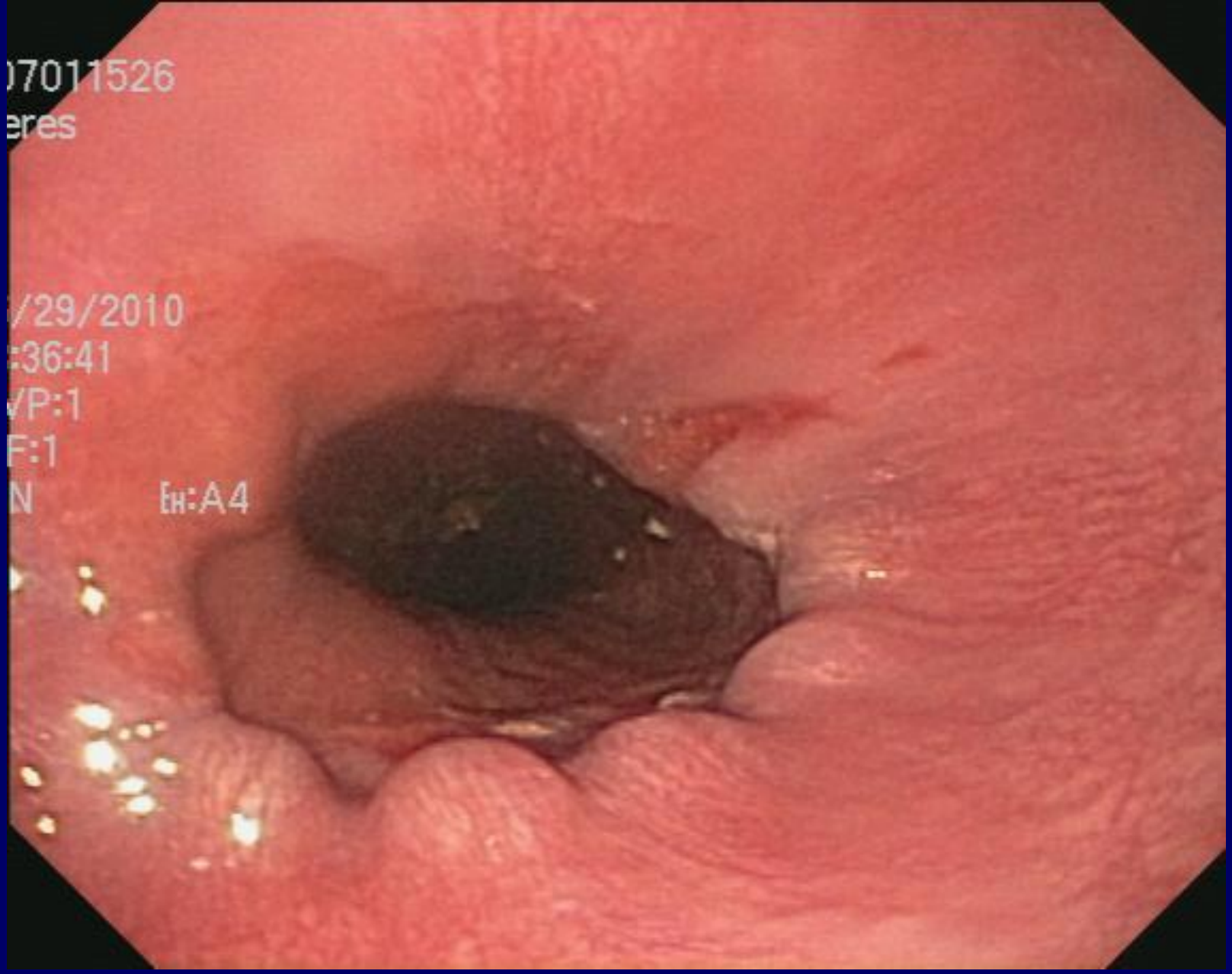
- Finances are important
- 2014: Not widely funded, considered “experimental”
- February 2015 CPT assigned
- RUC evaluation is ongoing
- Will become active January 2016

LINX™ ANTI-REFLUX SYSTEM





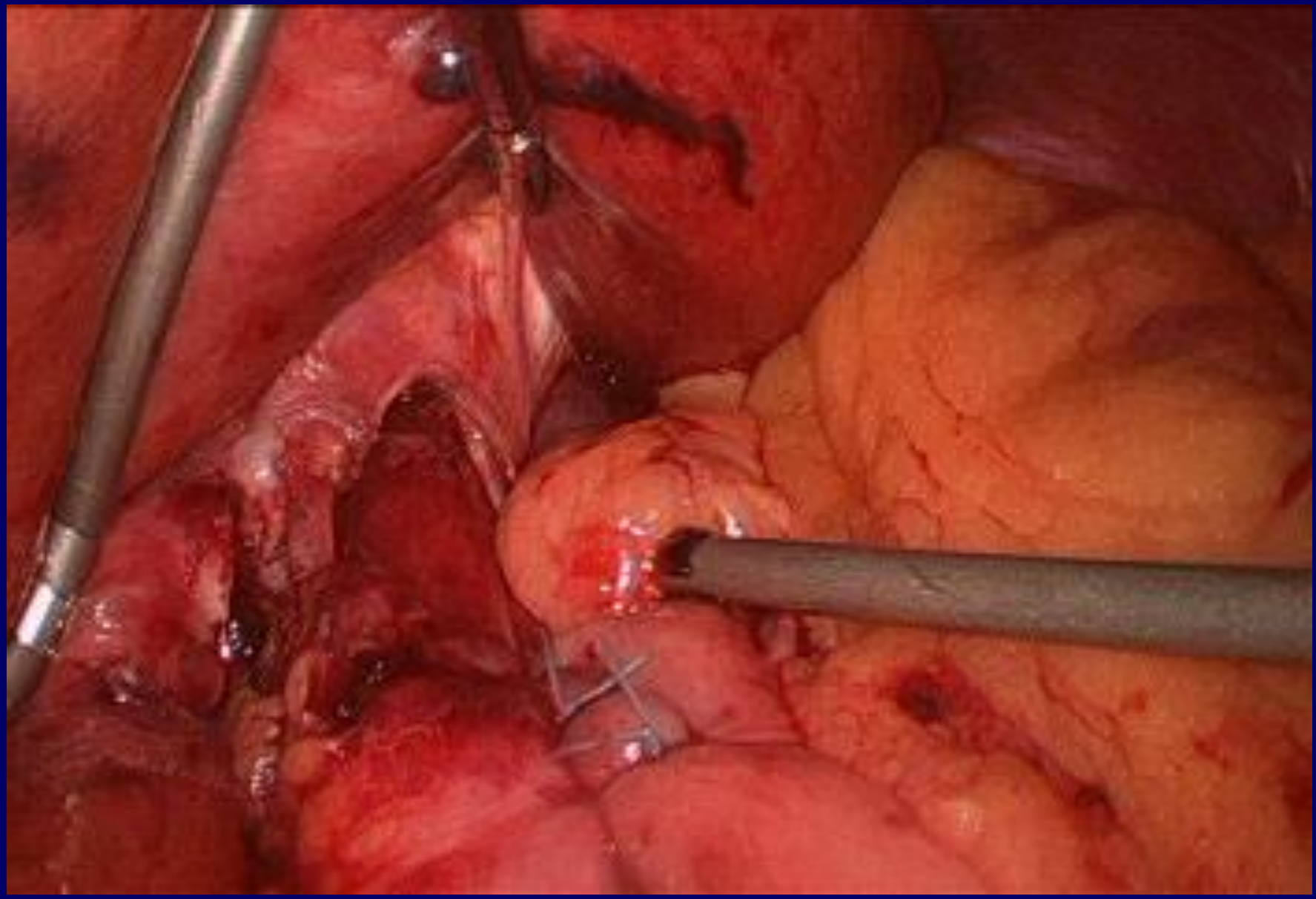
Torax: Operative Placement



One Year Follow up EGD

Lynx Economics

- About 7000 sold and installed
- A few explantations, no late erosions
- Appears Safe
- CPT 2015 is a Category 3
- Not widely reinbursed
- Difficult to use clinically right now



Clinical Spotlight Review : Endoluminal GERD

2/2013

by the Society of American Gastrointestinal and Endoscopic Surgeons

- **EsophyX**
- Long term data is not yet available for EsophyX. In short term follow-up, from 6 months to 2 years, EsophyX may be effective in patients with typical and atypical GERD. Further studies are required to define optimal techniques and most appropriate patient selection criteria…
- Quality of Evidence: (++). GRADE Recommendation: Weak
- **Stretta**
- Stretta is considered appropriate therapy for patients being treated for GERD who are 18 years of age or older, who have had symptoms of heartburn, regurgitation, or both for 6 months or more, who have been partially or completely responsive to anti-secretory pharmacologic therapy, and who have declined laparoscopic fundoplication.
- Quality of Evidence: (++++). GRADE Recommendation: Strong

American College of Gastroenterology Guidelines for the diagnosis and management of gastroesophageal reflux disease

- Surgical therapy is a treatment option for long-term therapy in GERD patients. **(Strong recommendation, high level of evidence)**
- Surgical therapy is generally not recommended in patients who do not respond to PPI therapy. **(Strong recommendation, high level of evidence)**
- Preoperative ambulatory pH monitoring is mandatory in patients without evidence of erosive esophagitis. All patients should undergo preoperative manometry to rule out achalasia or scleroderma-like esophagus. **(Strong recommendation, moderate level of evidence)**
- Surgical therapy is as effective as medical therapy for carefully selected patients with chronic GERD when performed by an experienced surgeon. **(Strong recommendation, high level of evidence)**
- Obese patients contemplating surgical therapy for GERD should be considered for bariatric surgery. Gastric bypass would be the preferred operation in these patients. **(Conditional recommendation, moderate level of evidence)**
- The usage of current endoscopic therapy or transoral incisionless fundoplication cannot be recommended as an alternative to medical or traditional surgical therapy. **(Conditional recommendation, moderate level of evidence)**

Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. Am J Gastroenterol. 2013 Mar;108(3):3

GERD Treatment: The Bottom Line

- PPI's for most pts
- Mechanical reconstruction of the GE jxn offers the best acid and bile reflux control
- Transoral fundoplication is promising and emerging as option for pts with normal anatomy
- Stretta is now available and data suggests good symptom control in many patients
- Magnetic Augmentation provides excellent early results
- LS Nissen is very good with ~90% good success, 80-90% off meds.
- Barretts ablation and reflux control may decreasing the risk of esophageal cancer.
- Evaluation of objective data including costs is important

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