LINX® Reflux Management System

Gastroenterology and Urology Medical Devices Panel Meeting,

January 11, 2012

Gaithersburg, MD

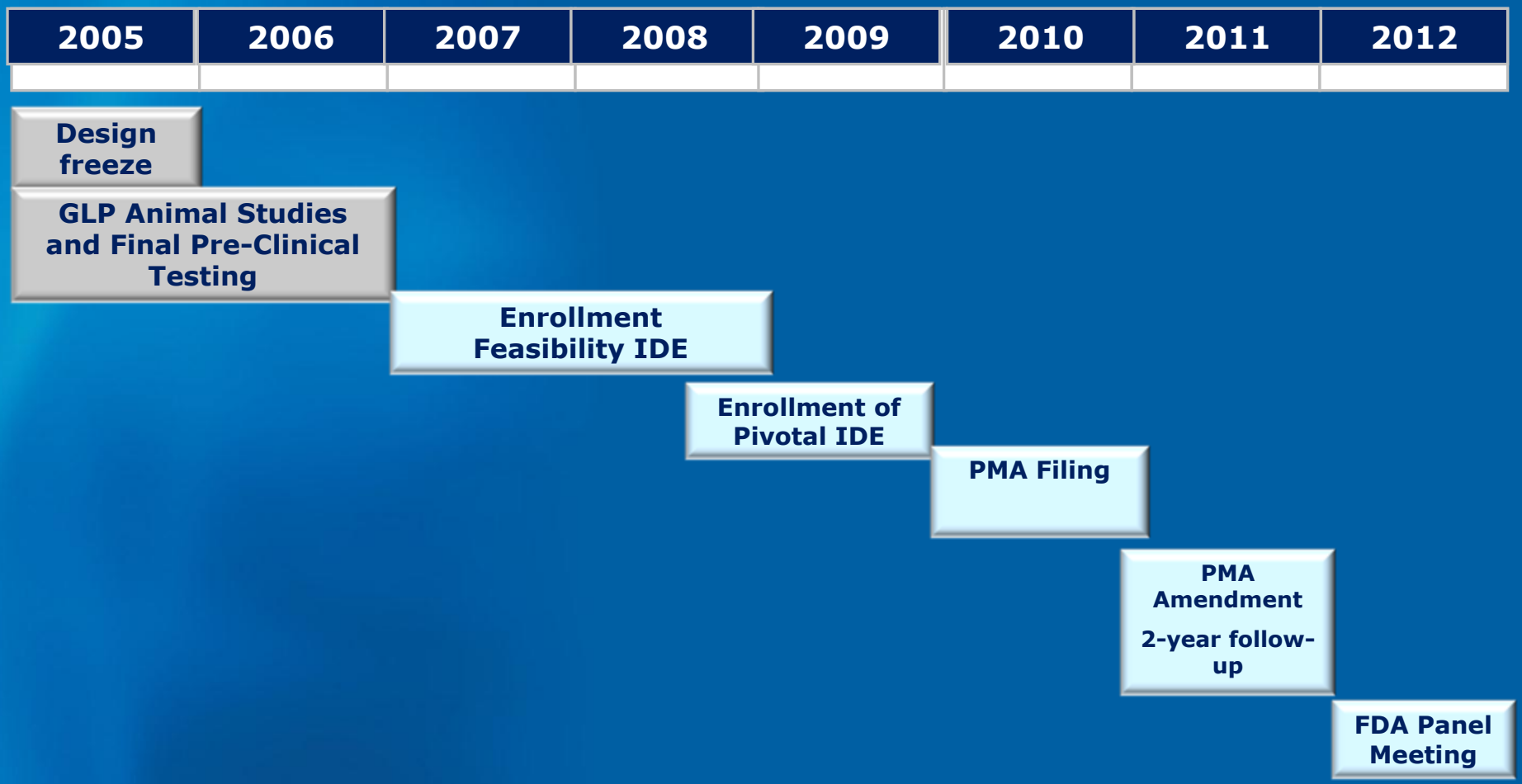
AGENDA

Introduction	**Todd Berg** *CEO* *Torax Medical*
Pathophysiology of GERD	**Tom DeMeester, MD** *Professor of Surgery, Chair Emeritus* *Department of Surgery -- USC*
Device Overview and Pre-Clinical Activities	**Todd Berg** *CEO* *Torax Medical*
LINX Feasibility and Pivotal IDE Clinical Trials	**Daniel Smith, MD** *Chair Department of Surgery – Mayo Jacksonville*
Post Market Studies and Closing Comments	**Todd Berg** *CEO* *Torax Medical*

Torax Medical, Inc.

Founded:	November 2002 Minneapolis – St. Paul, MN
Objective:	To develop a device to improve the barrier function of the esophageal sphincter
Company Approach:	Engineering and Physician collaboration

Regulatory Timeline – LINX Reflux Management System



Clinical Experience Overview

LINX Experience

- Feasibility and Pivotal IDE Clinical Trials
- Commercially available in Europe

Published Papers

- Gastrointestinal Endoscopy – Feb 2008
- Journal of Gastrointestinal Surgery – Dec 2008
- Annals of Surgery – Nov 2010

Investigator Engagement

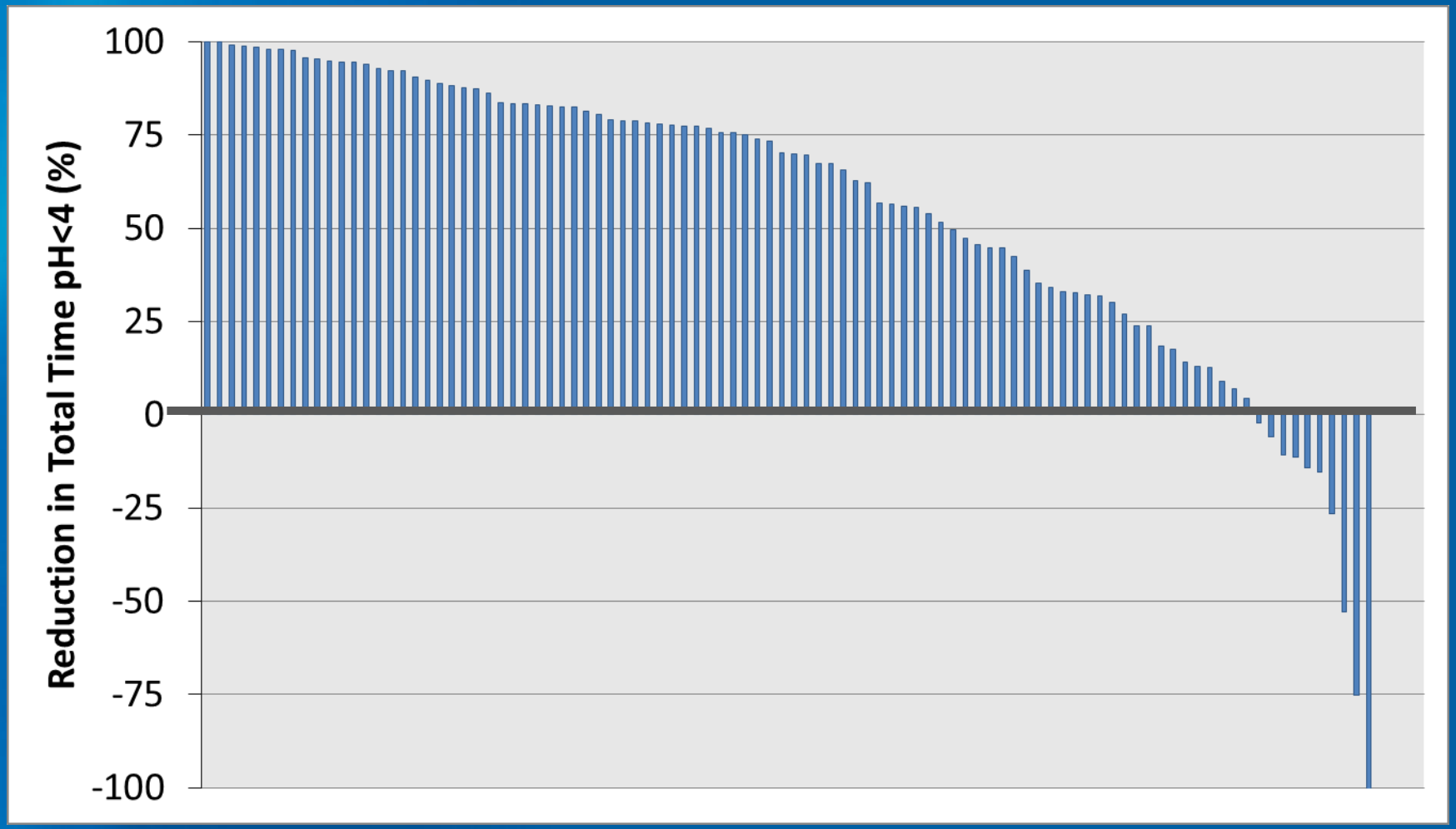
- All investigators remain actively engaged with a continued collaboration of data and experiences

Today's Focus

Device	LINX Reflux Management System
Patient Profile	Chronic GERD symptoms despite long-term acid suppression therapy
Therapeutic Benefit	Reduction in esophageal acid exposure, control of heartburn, and elimination of PPI use

Evidence of Reduced Acid Exposure

90% (86/96) Achieved Reduced Esophageal Acid Exposure



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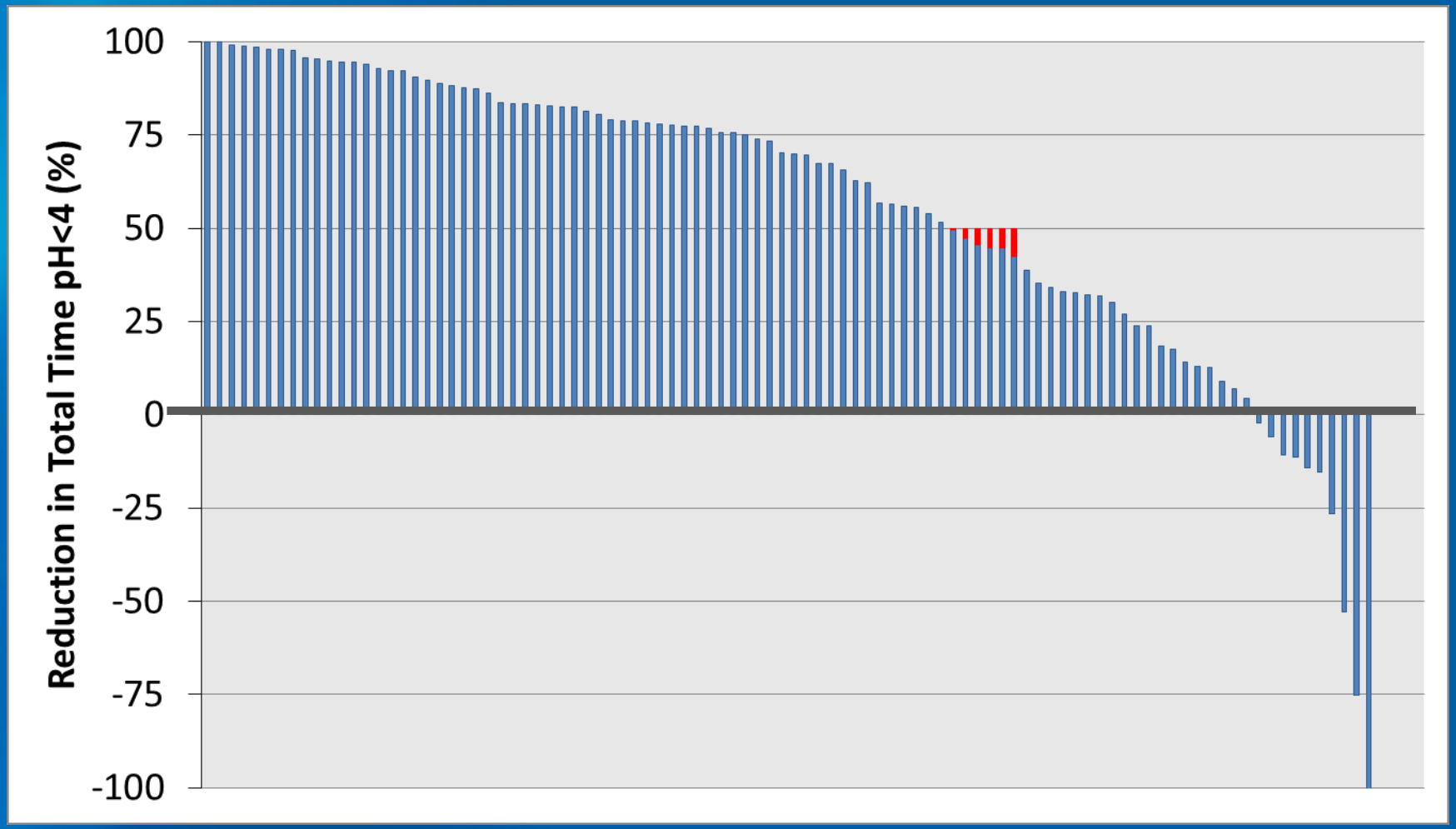
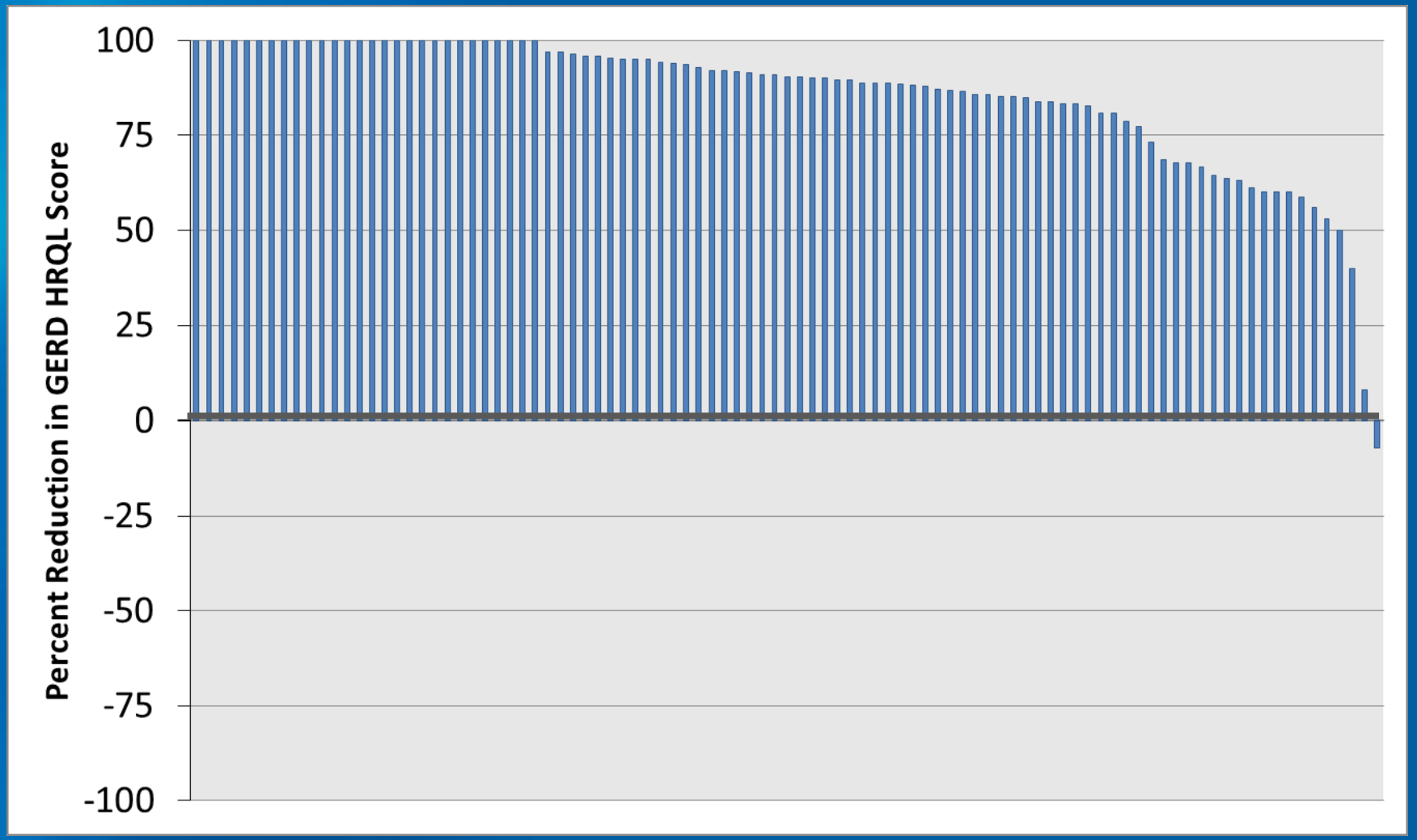


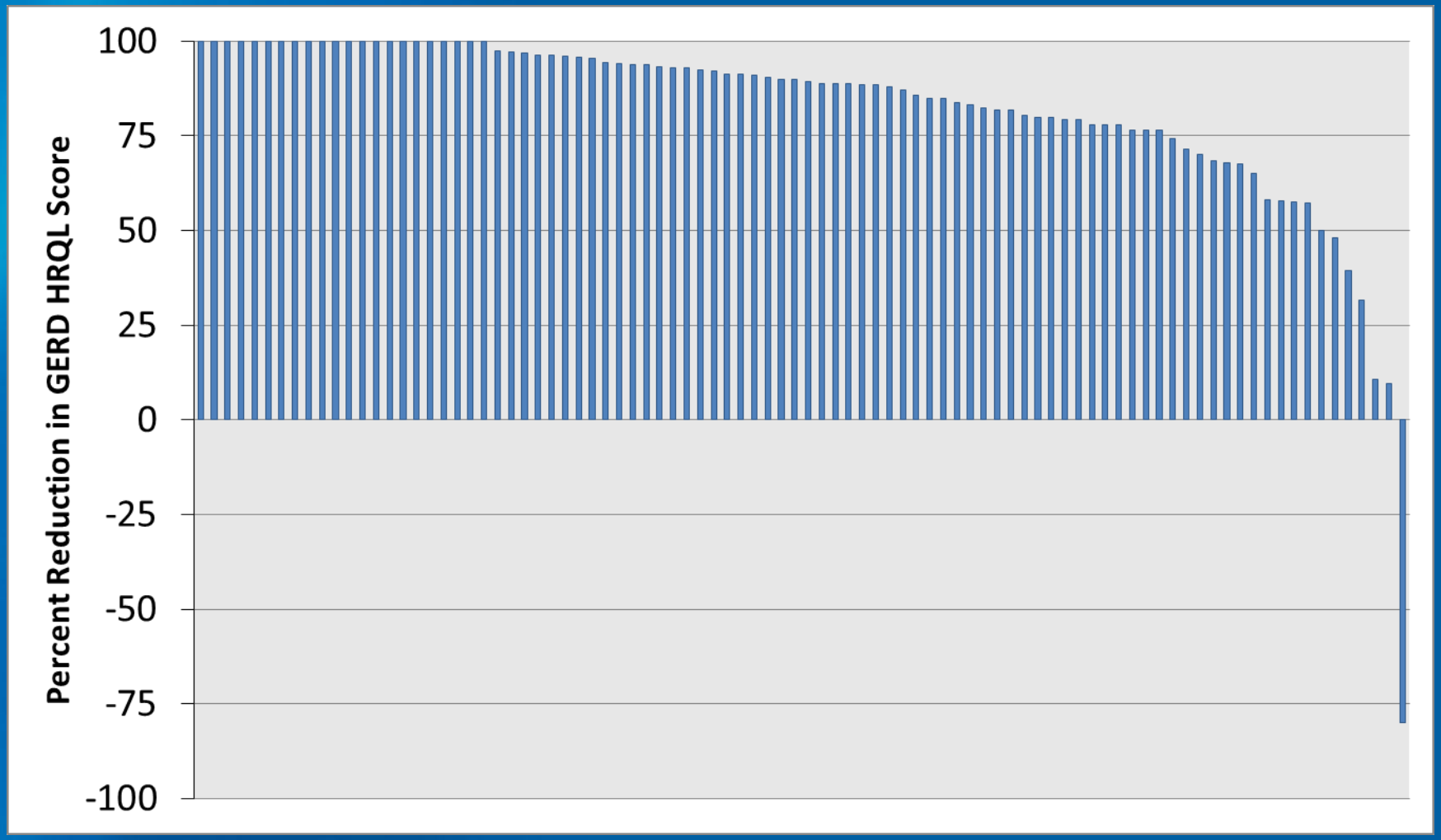
GERD HRQL Score Reduction at 1 Year

99% (94/95) Achieved Reduction in HRQL Scores

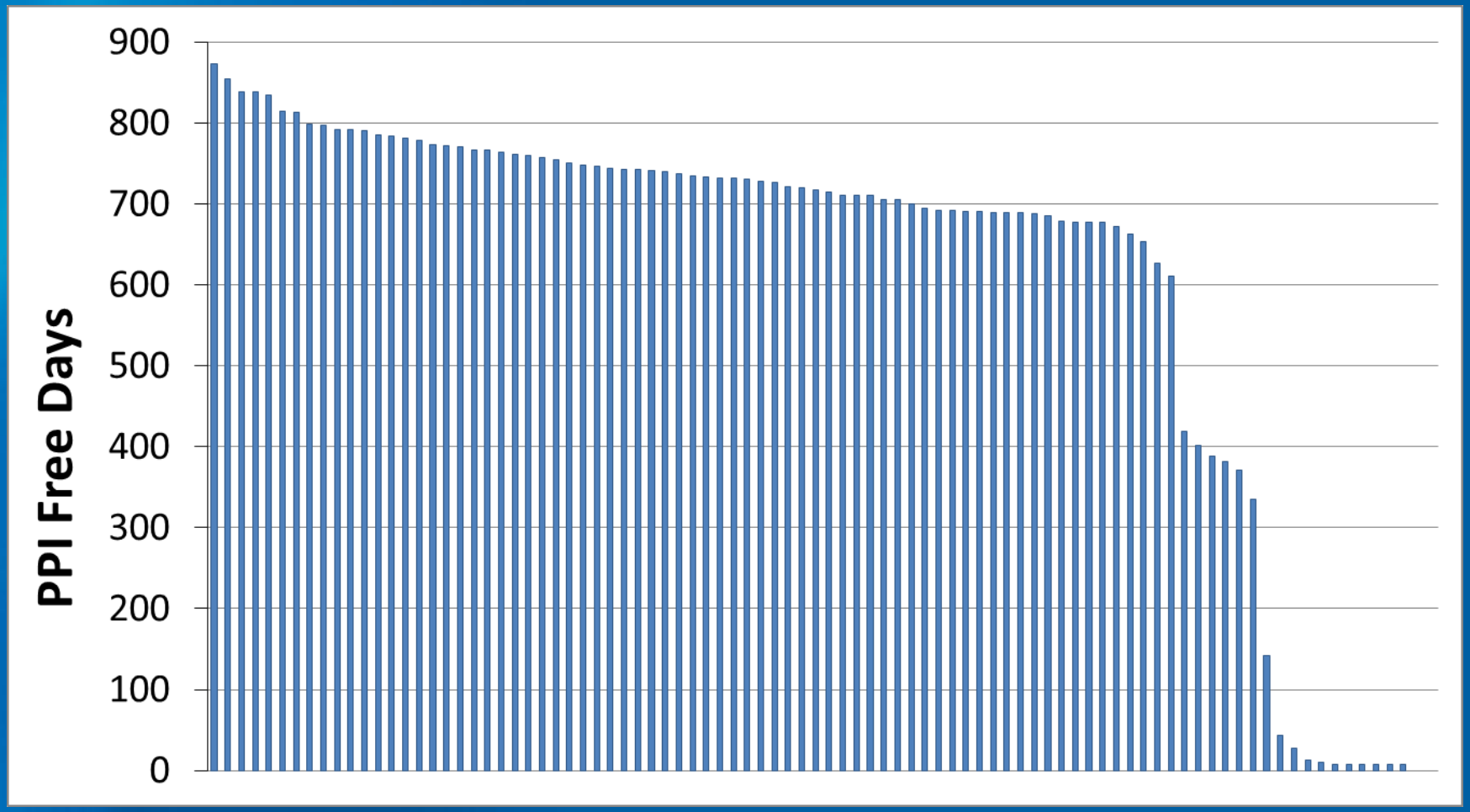


GERD HRQL Score Reduction at 2 Years

99% (89/90) Achieved Reduction in HRQL Scores



PPI Free Days
As of Last Follow-Up



Principal Observations
LINX Pivotal Trial

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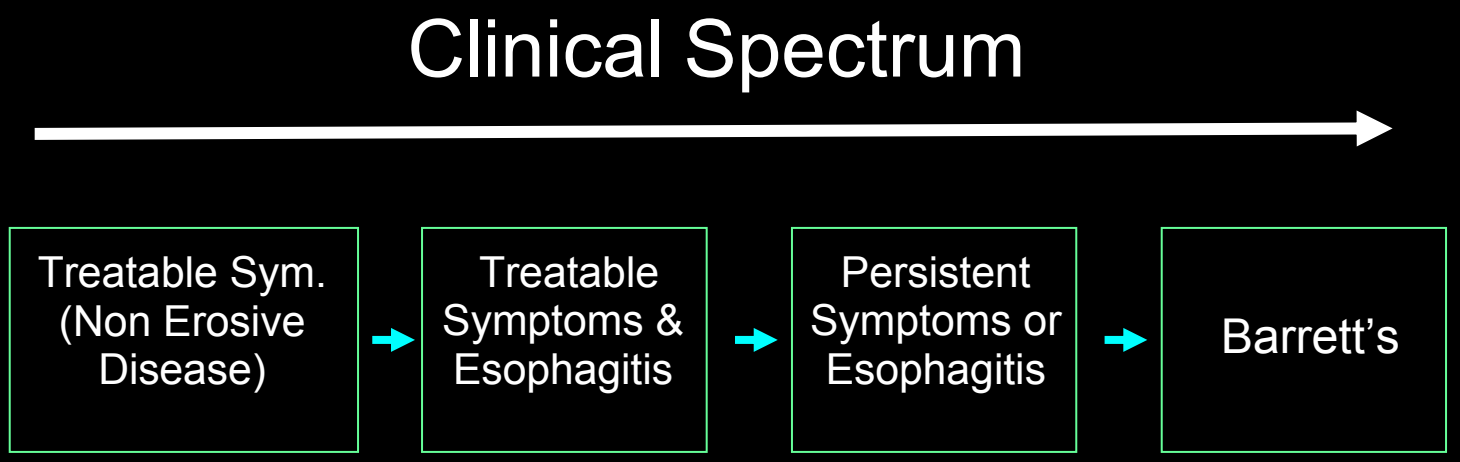
Pathophysiology of GERD

Tom DeMeester, MD

Professor of Surgery, Chair Emeritus,
Department of Surgery, USC

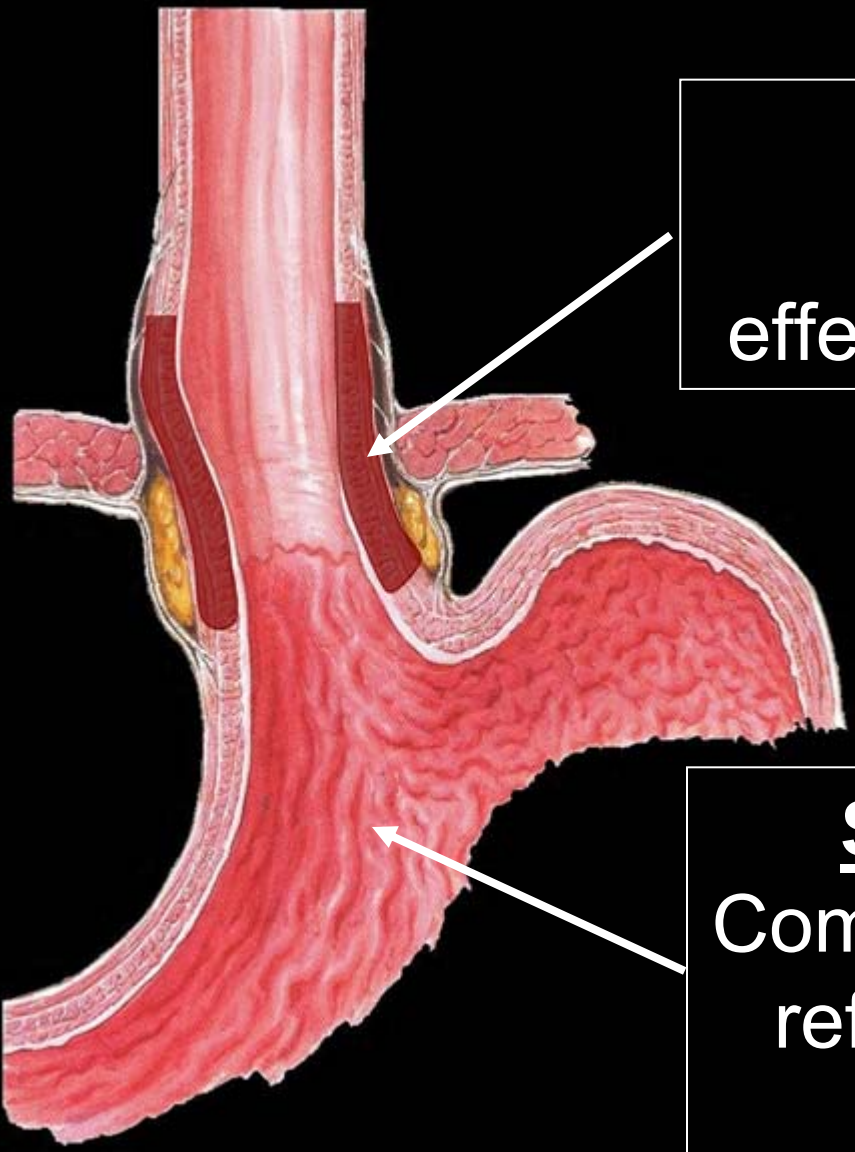
GERD is a chronic progressive disease that affects 10-20% of adults in the western world.

Dent J. Gut 2005;54:710-717



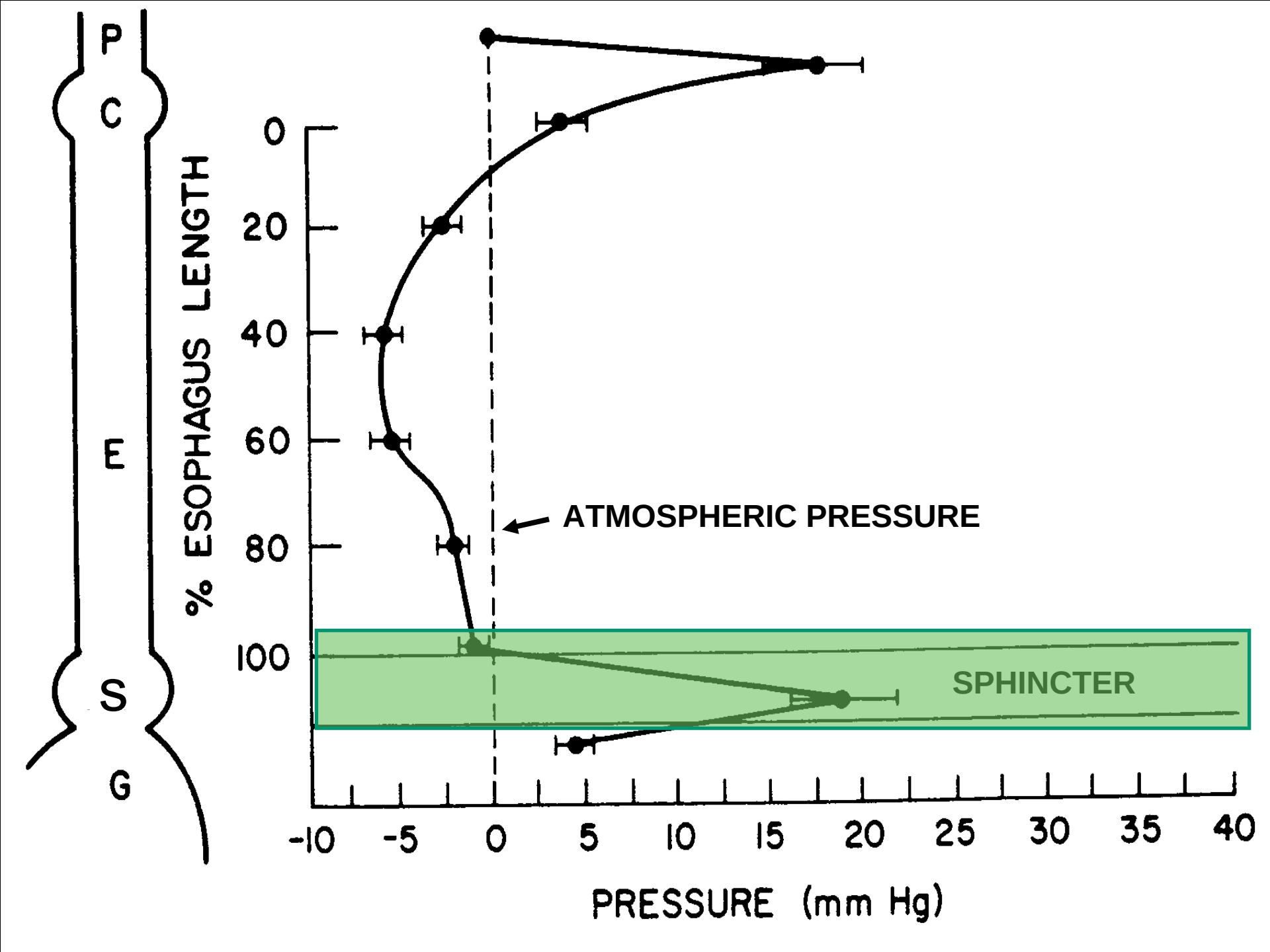
Lord et al. J Gastrointest Surg 2009;13:602-610

Fundamental Abnormality of GERD

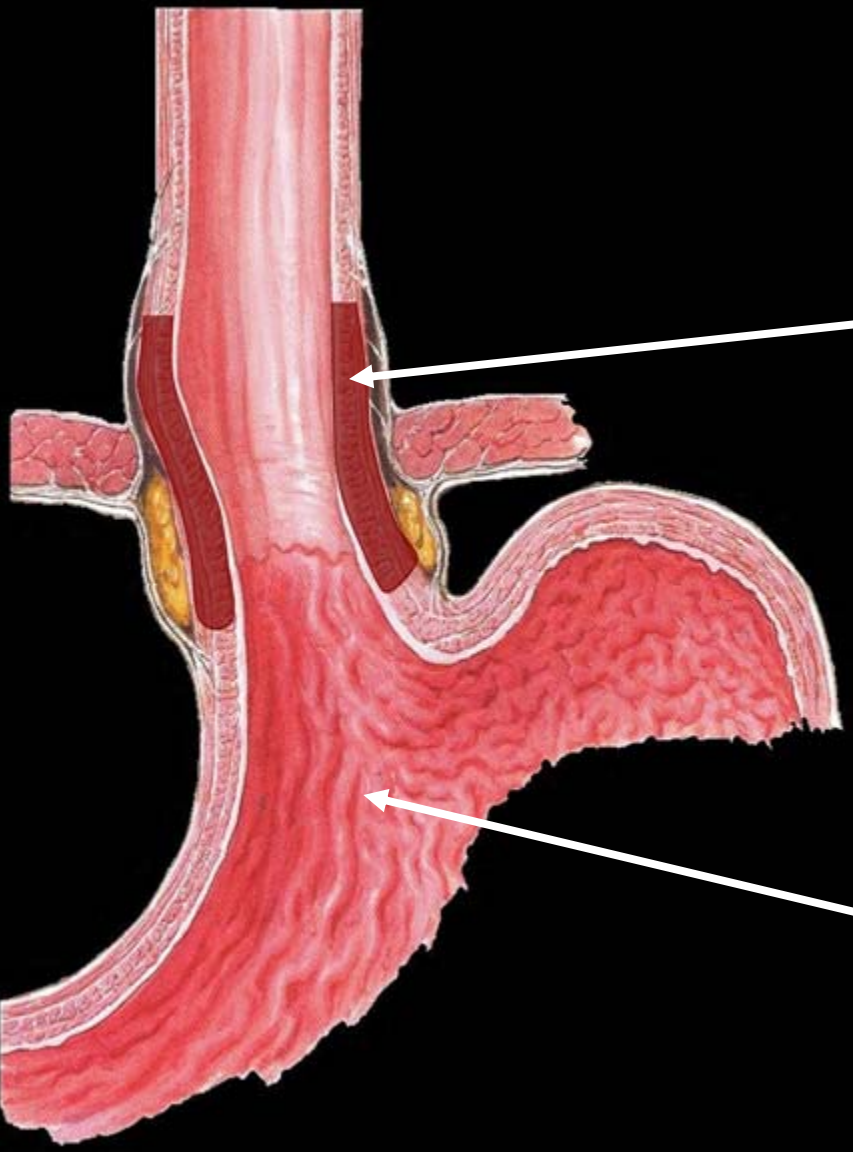


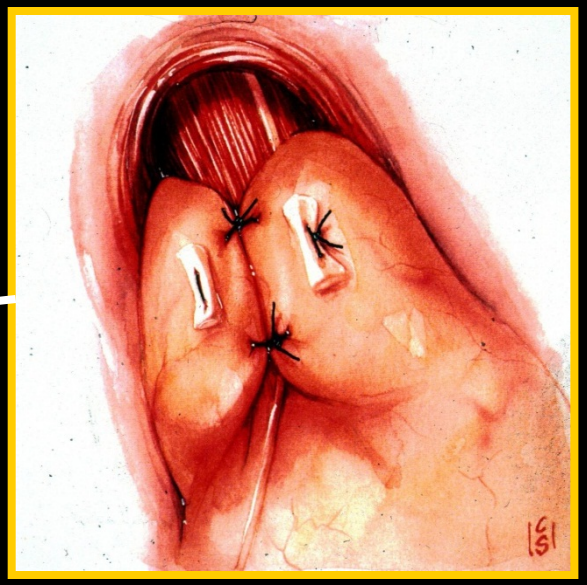
Primary
Loss of an effective sphincter

Secondary
Composition of the refluxed gastric juice

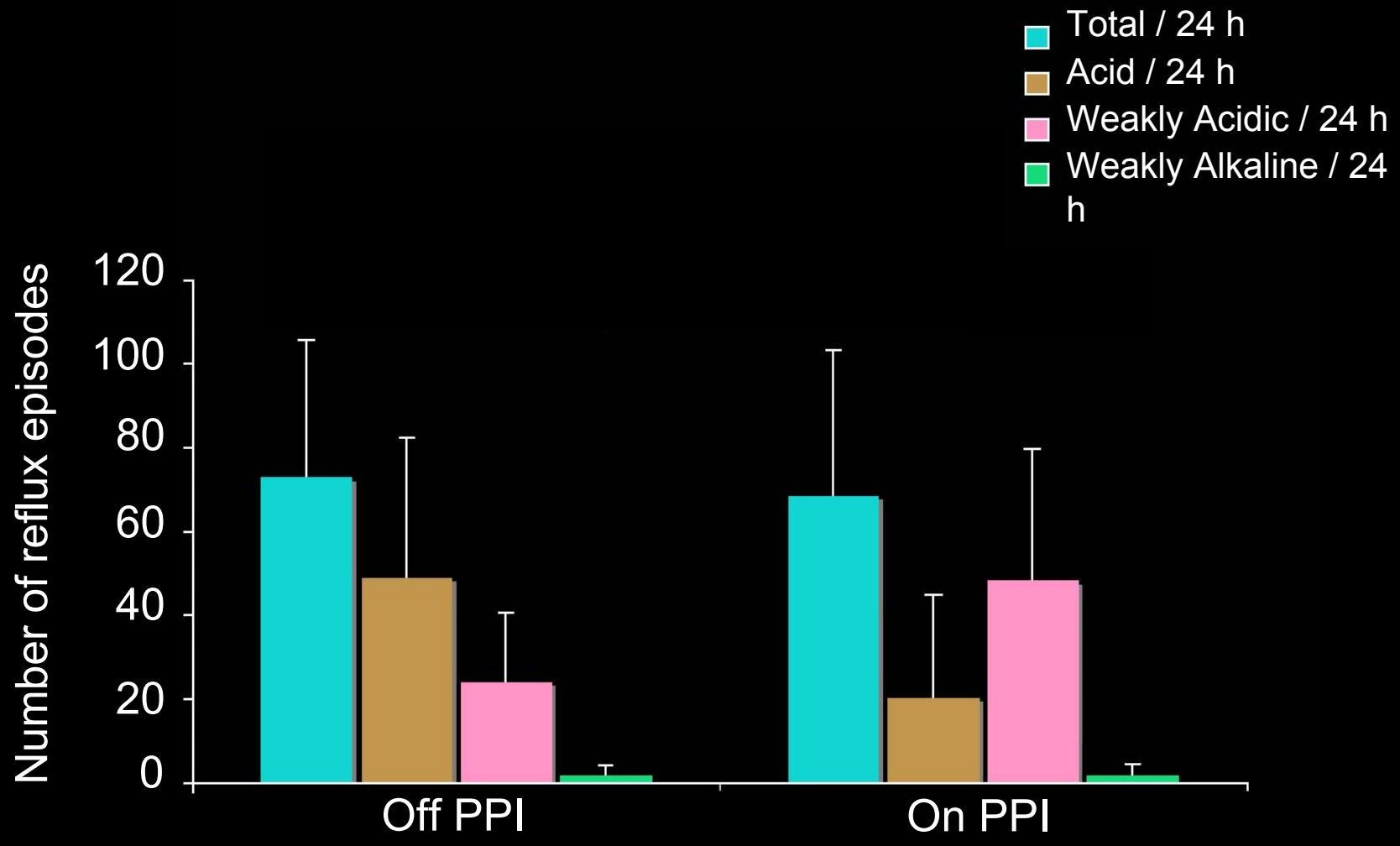

P
C
E
S
G
% ESOPHAGUS LENGTH
0
20
40
60
80
100
ATMOSPHERIC PRESSURE
SPHINCTER
-10
-5
0
5
10
15
20
25
30
35
40
PRESSURE (mm Hg)

Current Therapy of GERD





Number and Type of Reflux Episodes: On and Off PPI



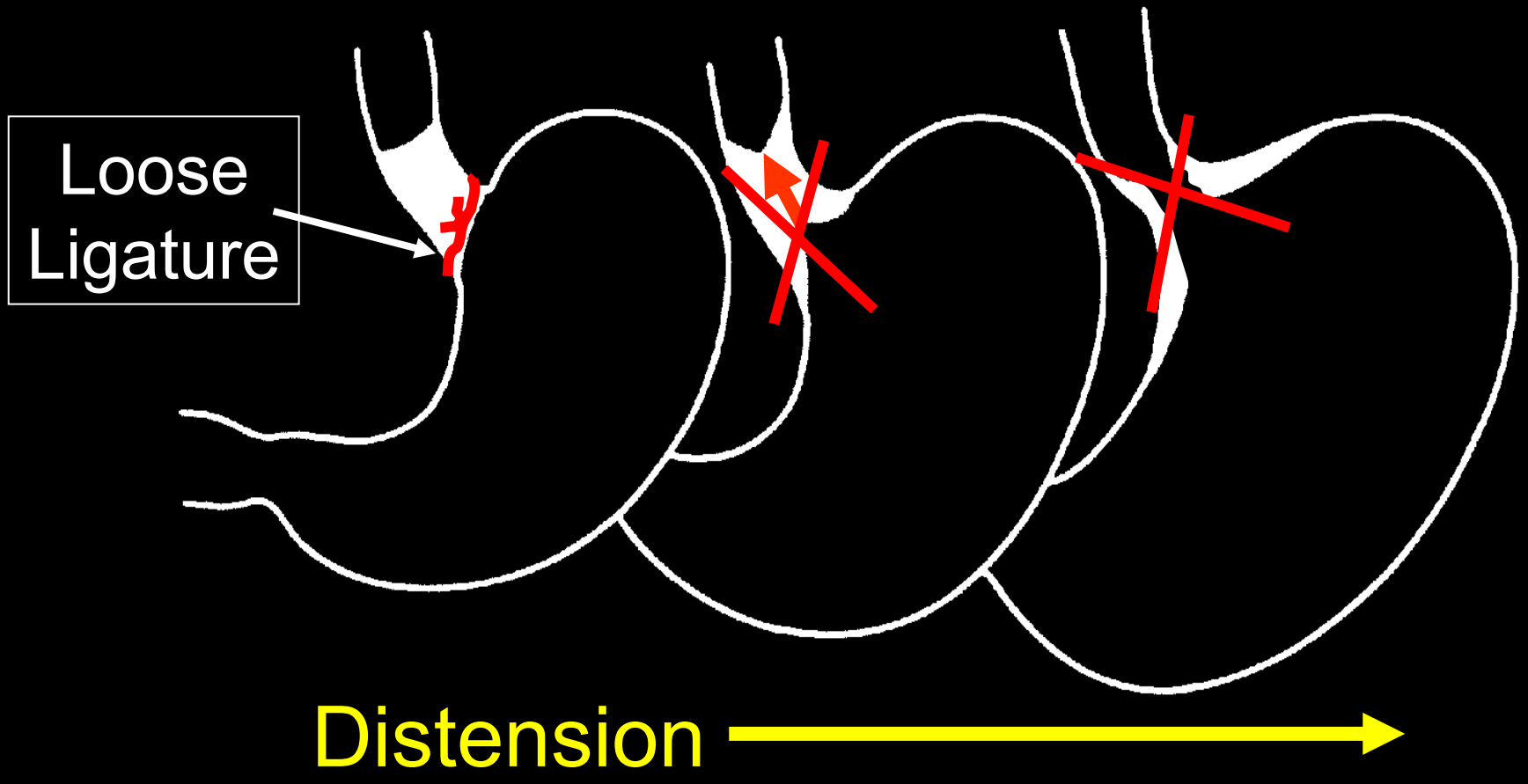
Hemmink GJM et al., *Am J Gastroenterol* 2008;103:2446-53

Patient's Anxiety: 2012

- Persistent symptoms despite PPI therapy
- Life long medication dependency
- Outcome, side effects and finality of a Nissen fundoplication.
- What does this mean for me in the long term?

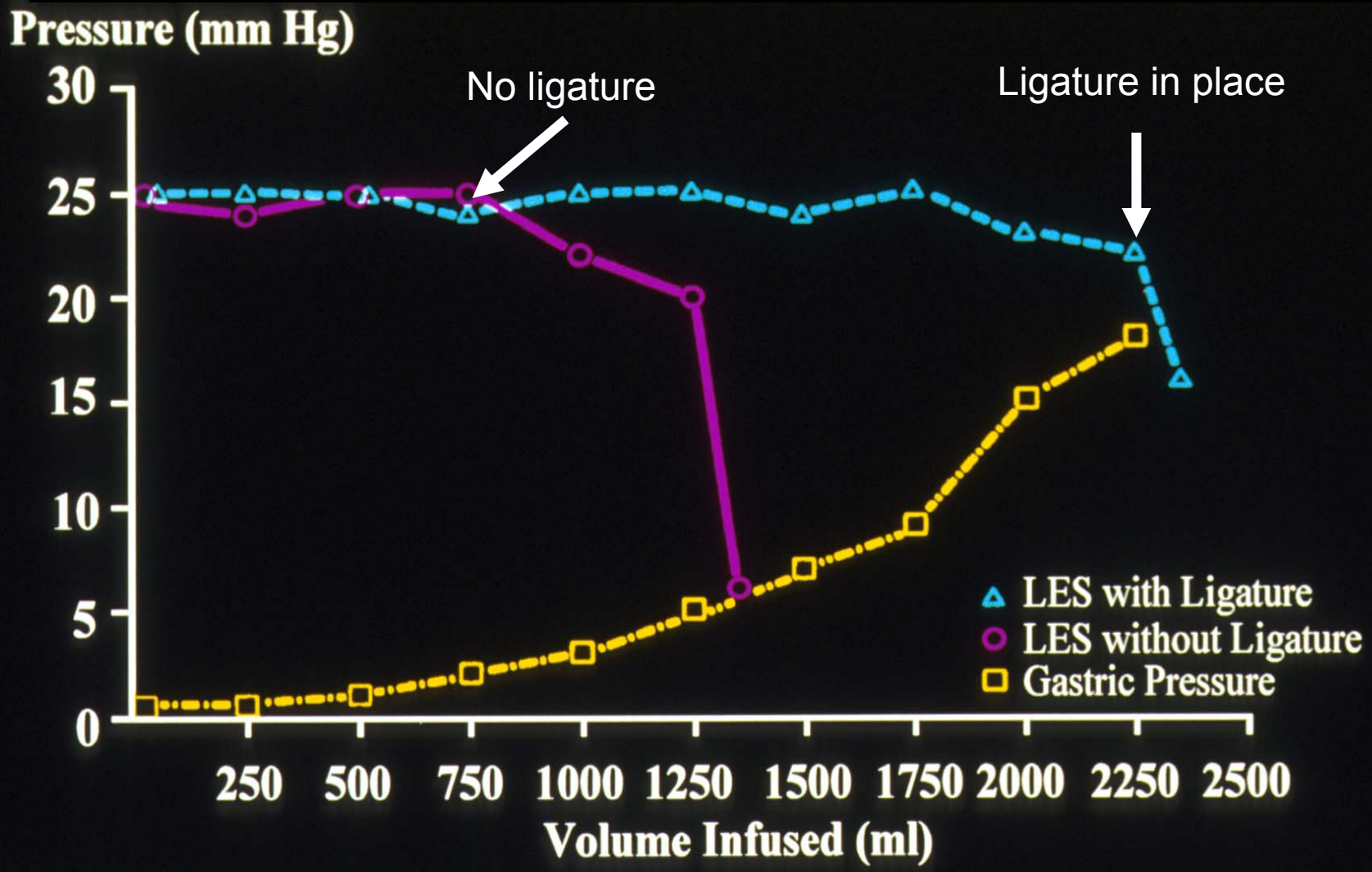
Where do we go?

Samelson's Observation



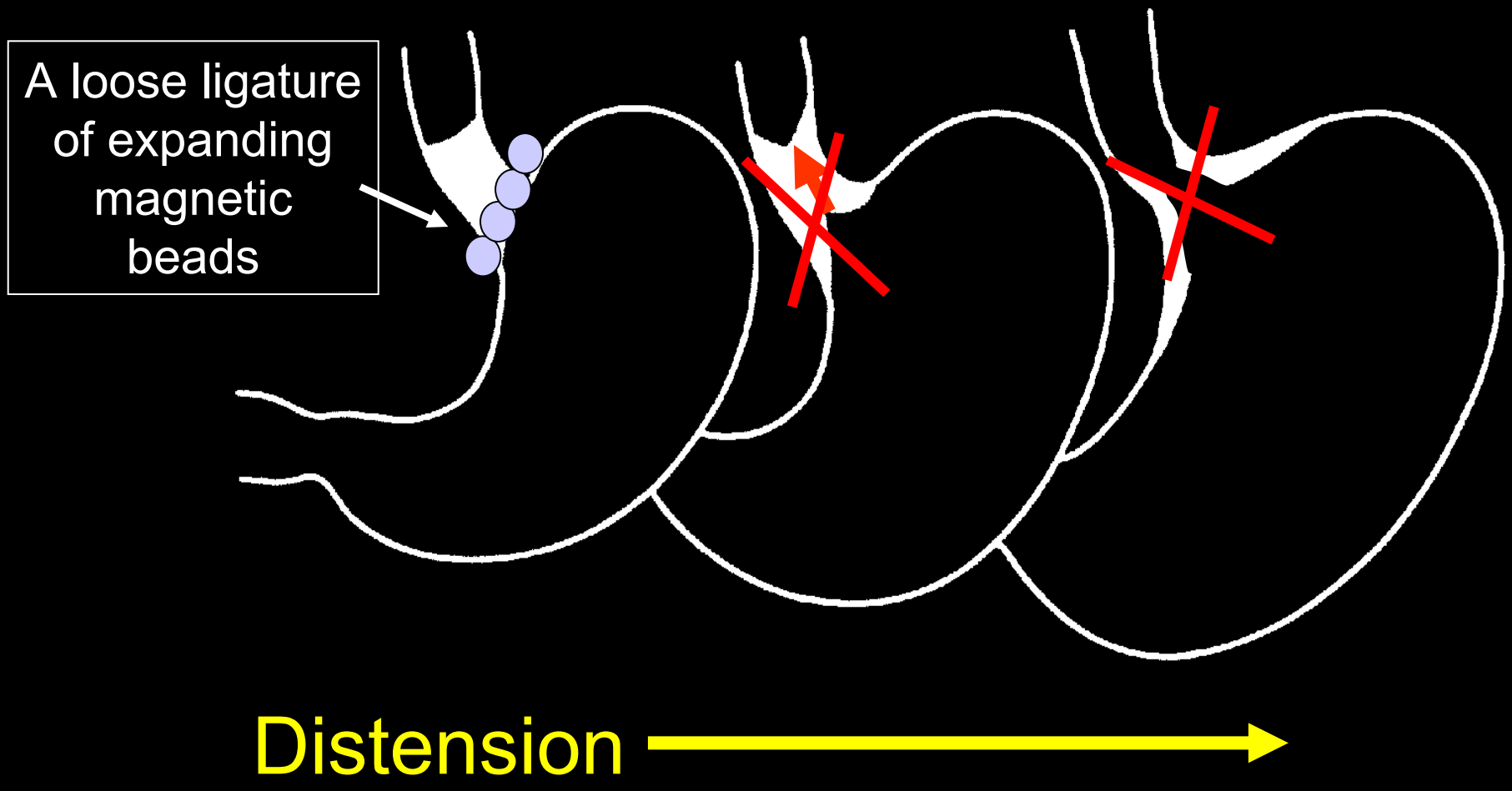
SL Samelson, HF Weiser, CT Bombeck, JR Siewert, FE Ludtke, AH Hoelscher, SF Abuabara, LM Nyhus, Ann Surg,1983;197:254-259

Sphincter Augmentation with a Loose Ligature



SL Samelson, HF Weiser, CT Bombeck, JR Siewert, FE Ludtke, AH Hoelscher, SF Abuabara, LM Nyhus, Ann Surg,1983;197:254-259

The LINX Sphincter Augmentation Device

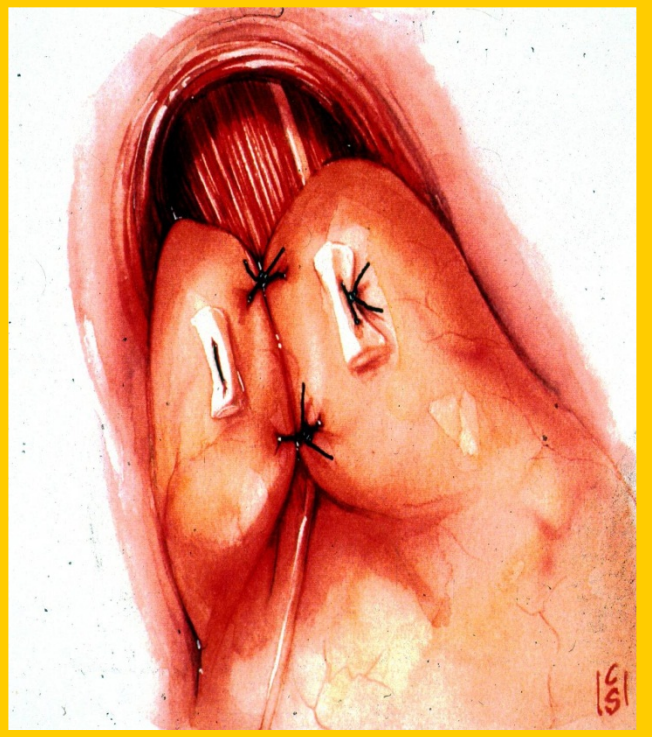


GERD Treatment Options

Medication

Augmentation

Reconstruction



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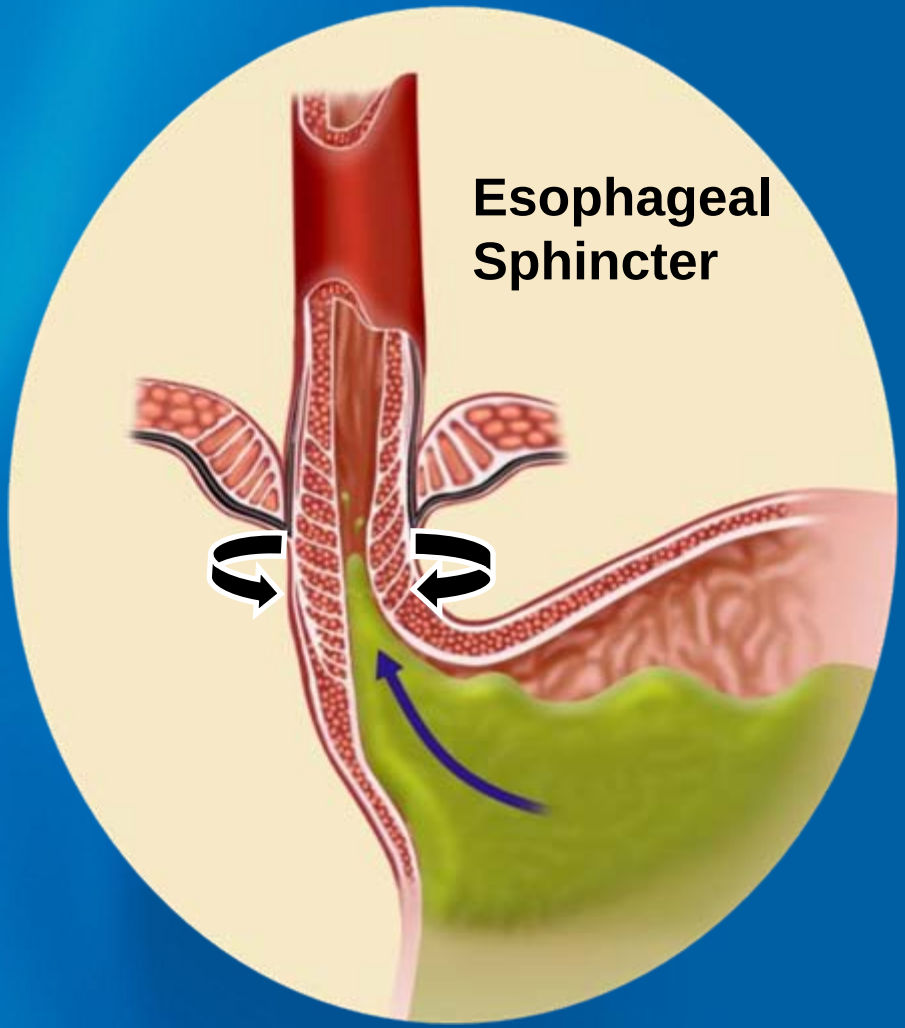
LINX Device Overview

Todd Berg

CEO, Torax Medical

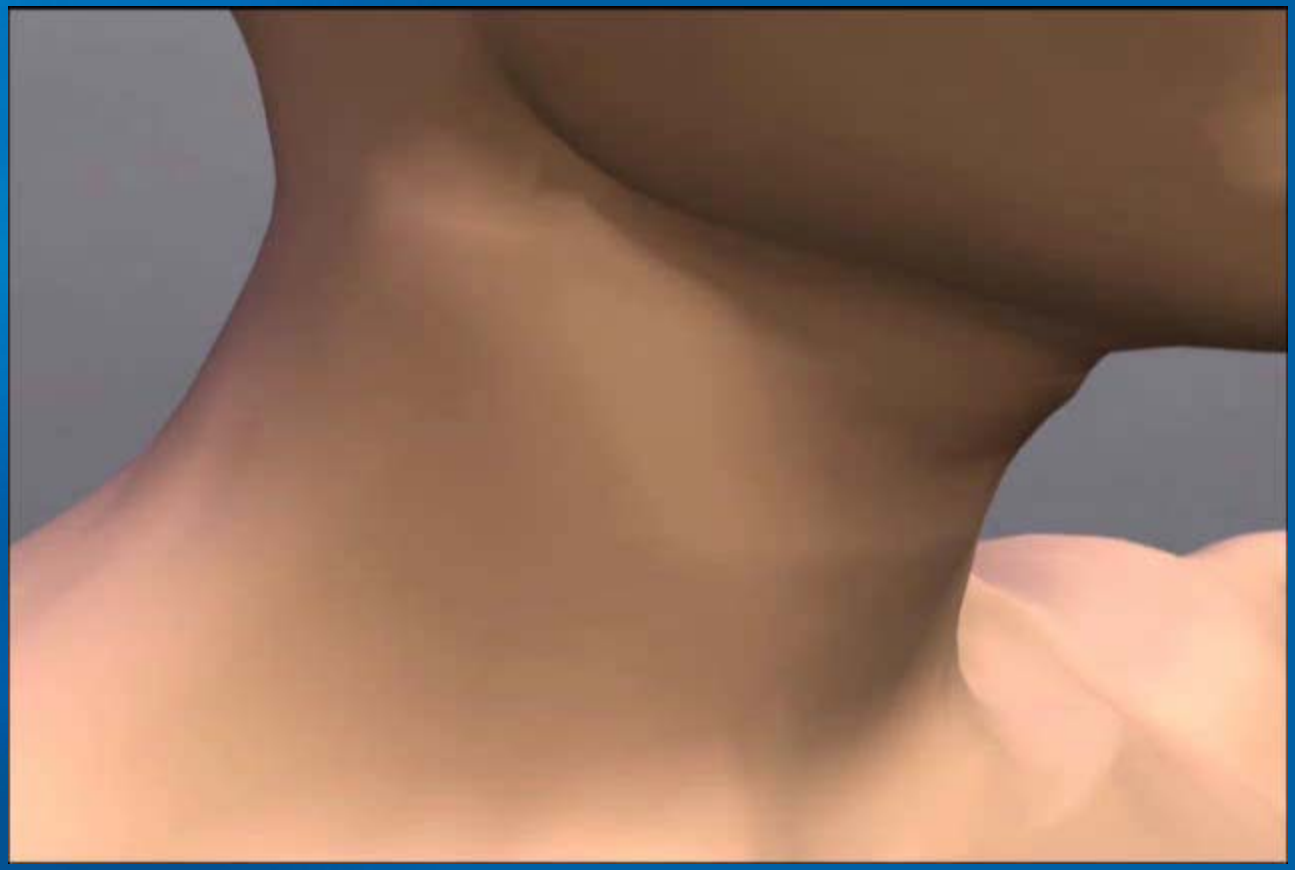
The Esophageal Sphincter



Reflux occurs due to abnormal sphincter opening

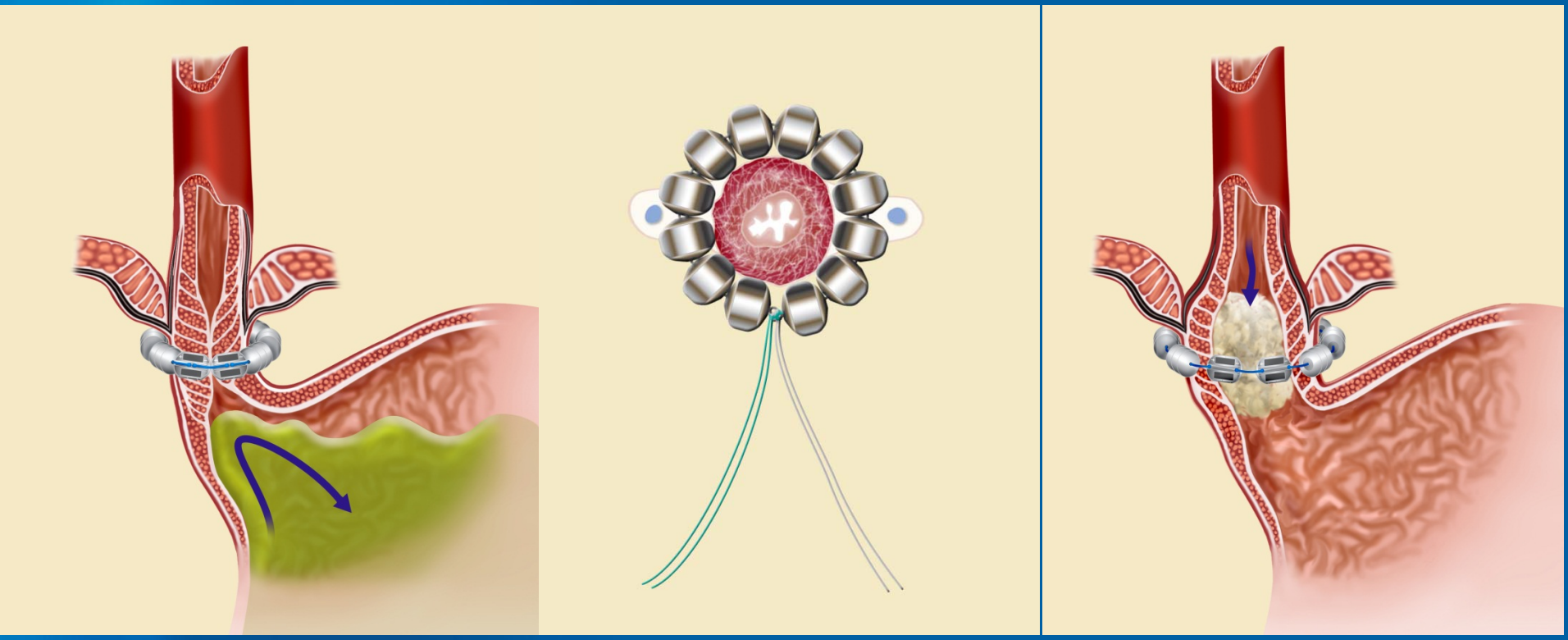
Development goal -minimize abnormal opening without changing normal sphincter functions

LINX Animation



The LINX Design

LINX In-Vivo



Resistance

Non Compressive

Expansion

LINX Barium Swallow

LINX Procedure

The LINX Procedure

- Laparoscopic approach
- Standard instruments and techniques
- Minimal dissection

LINX Pre-Clinical Activities

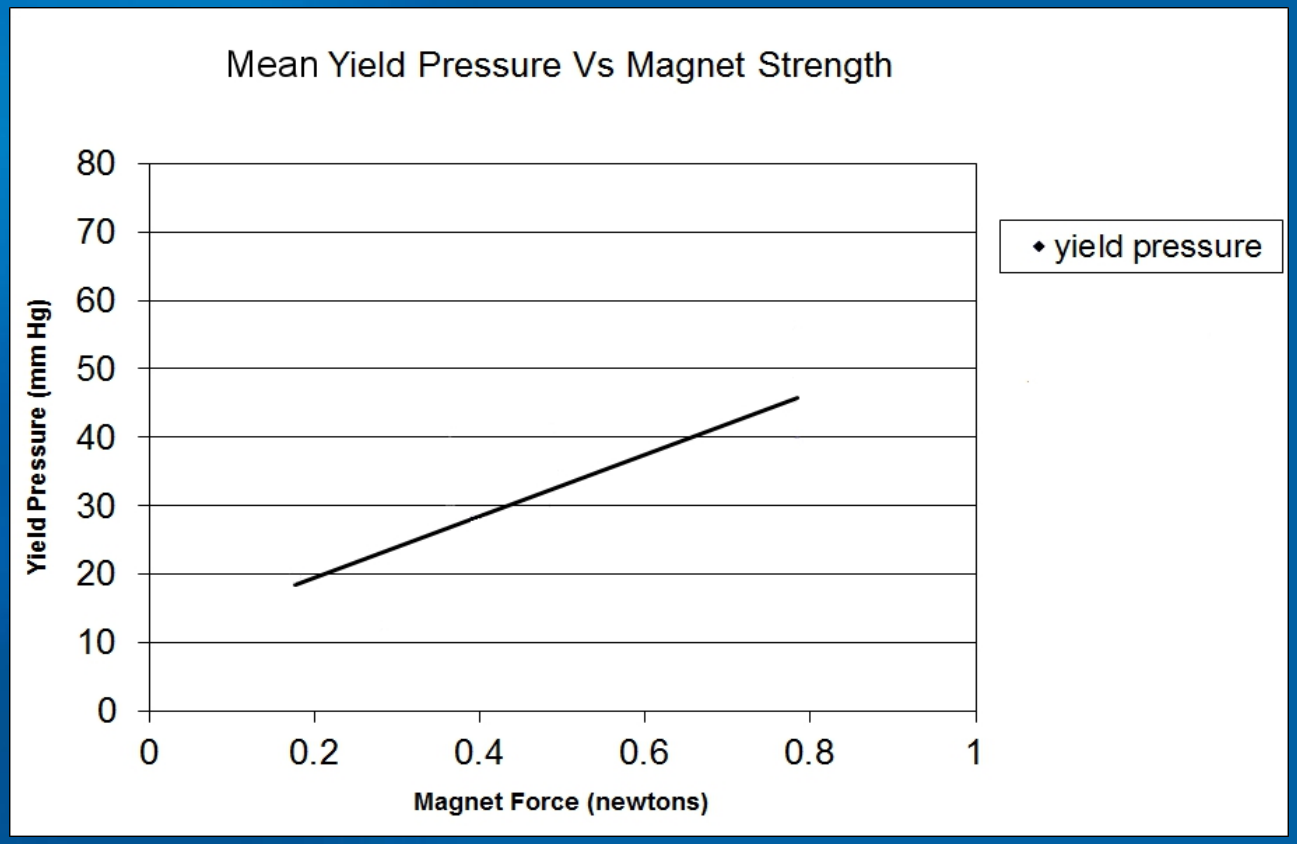
Pre-Clinical Objectives

The LINX Reflux Management System has undergone extensive pre-clinical testing to assess the following properties:

- Physiologically compatible forces
- Biocompatibility and bio-stability
- Long term durability

Physiologically Based Magnetic Forces

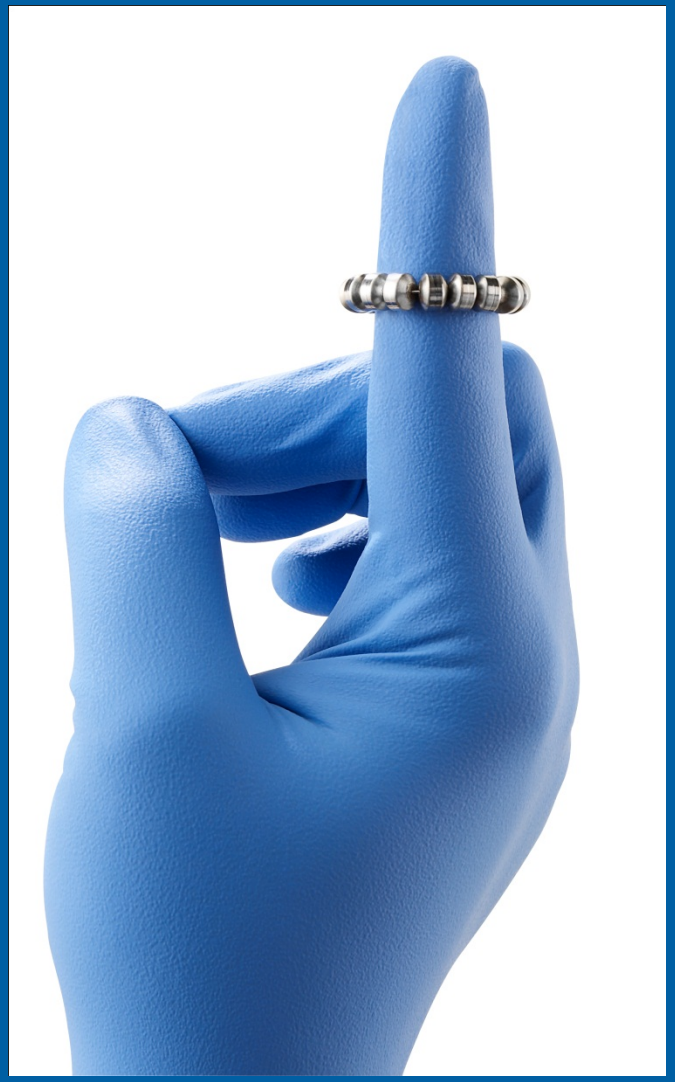
Yield pressure studies showed that gastric yield pressure directly correlated with increasing magnet forces



Ganz, R, Gostout, C, Grudem, J, et al. Use of a magnetic sphincter for the treatment of GERD; a feasibility study. GIE 2008;16: 287-294

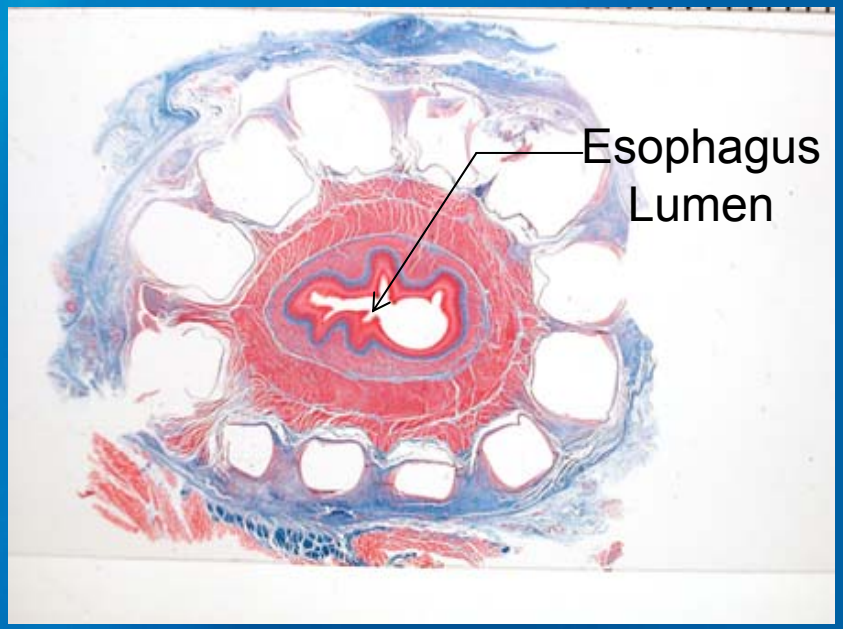
Physiologic Design of LINX

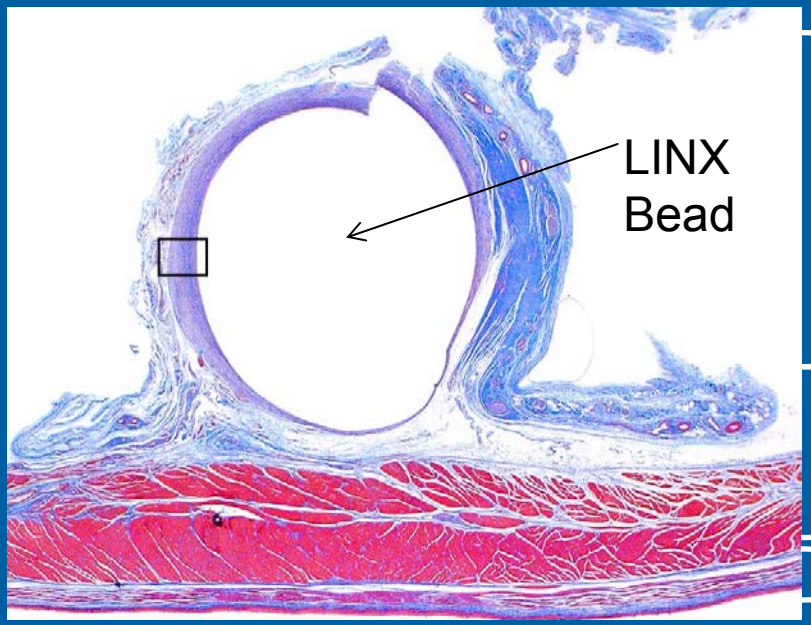
- Very small volume; <2cc
- No chronic forces at rest
- Compatible with esophageal movements



Stable Healing Response

Histologic examinations did not present any significant safety concerns and were consistent with a typical foreign body response





Pre-Clinical Conclusions

- The LINX device remains compliant after healing
- Mechanically durable
- No signs of erosion or migration
- Magnetic forces compatible with sphincter functions

LINX Study Design

Pivotal Study Design Considerations

Randomized Control

Nissen

- Enrollment and Standardization concerns

PPI

- Insufficient for treatment group
- Documented history of use
- Standardizing drug regimens difficult

Placebo Considerations

- Objective measures
- Long-term follow-up

Pivotal Study Design Rationale

Single-arm, self-controlled trial is appropriate:

- Patient specific disease history
- Apply multiple measures of effectiveness
- Provide long-term follow-up
- Include objective measures

Pivotal Trial Endpoints

EFFICACY	≥60% of subjects will achieve success[1]
Primary Reduced Esophageal Acid Exposure	Normalize or reduce by ≥50% the total % time
Secondary Heartburn Reduction-GERD HRQL	Reduce by ≥50% total GERD-HRQL score
Secondary Reduced PPI dependence	Reduce by ≥50% average daily PPI usage

SAFETY OBJECTIVE	Estimate rate of related Serious Adverse Events

1-Based on a lower bound 97.5% CI

LINX Indication

Proposed LINX Indication

The Torax LINX Reflux Management System is indicated for those individuals diagnosed with pathologic Gastroesophageal Reflux Disease (GERD) as defined by abnormal pH testing and who continue to have chronic GERD symptoms despite anti-reflux drug therapy.

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LINX Safety and Effectiveness: Feasibility and Pivotal Clinical Trials

C. Daniel Smith, MD

Professor & Chair

Department of Surgery

Mayo Clinic Florida

Feasibility and Pivotal IDE Trials

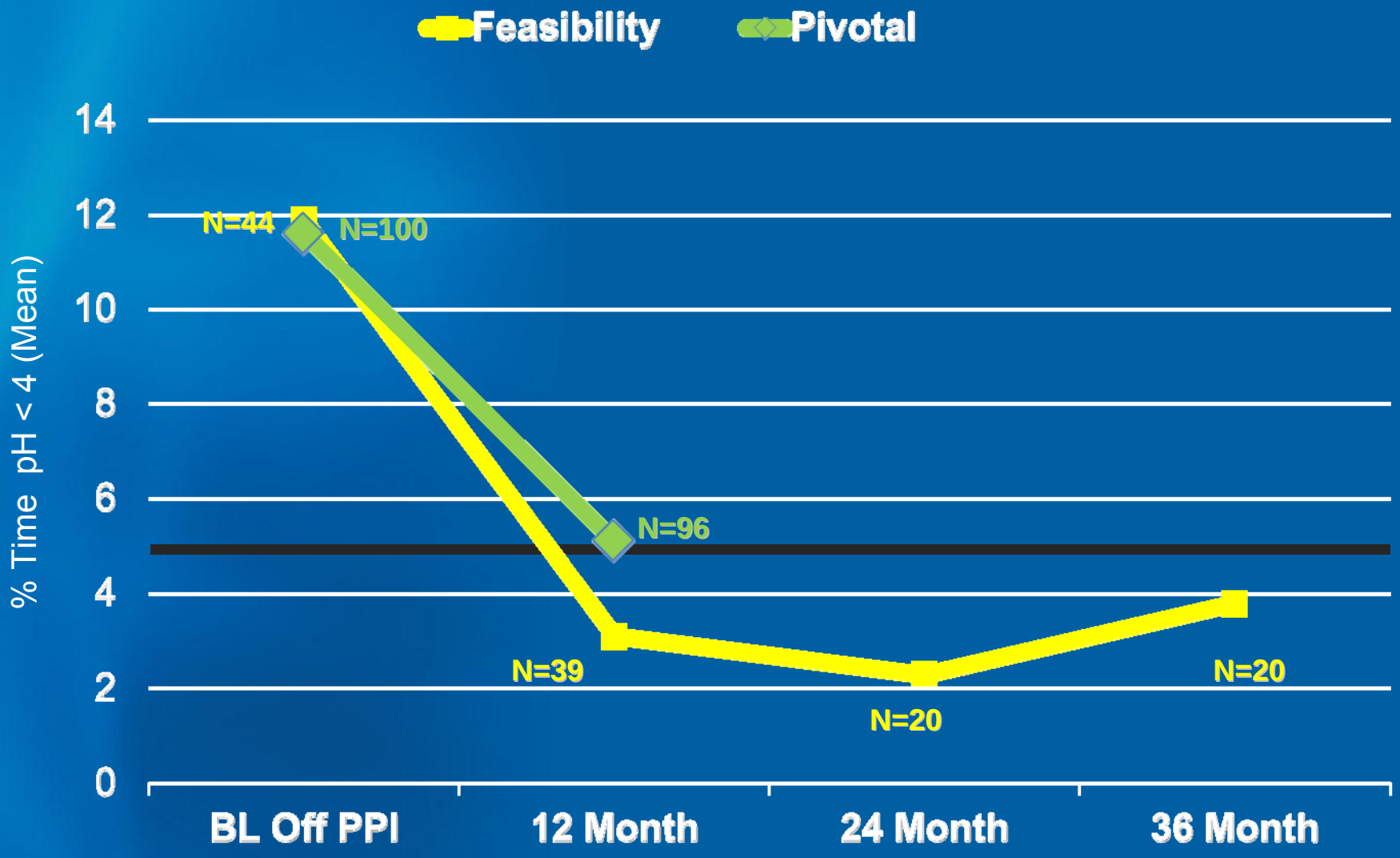
	Feasibility	Pivotal
Number of subjects	44	100
Number of centers	4	16
Design	Prospective, patient own control group	Prospective, patient own control group
Patient enrollment	• Pathologic reflux • Chronic symptoms despite medical therapy	• Pathologic reflux • Chronic symptoms despite medical therapy
First Implant	Feb 2007	Jan 2009
Follow-up	• Completed 2 and 3 year • Planned to 5 year	• Completed 2 year • Planned to 5 year

Measures of Effectiveness and Safety

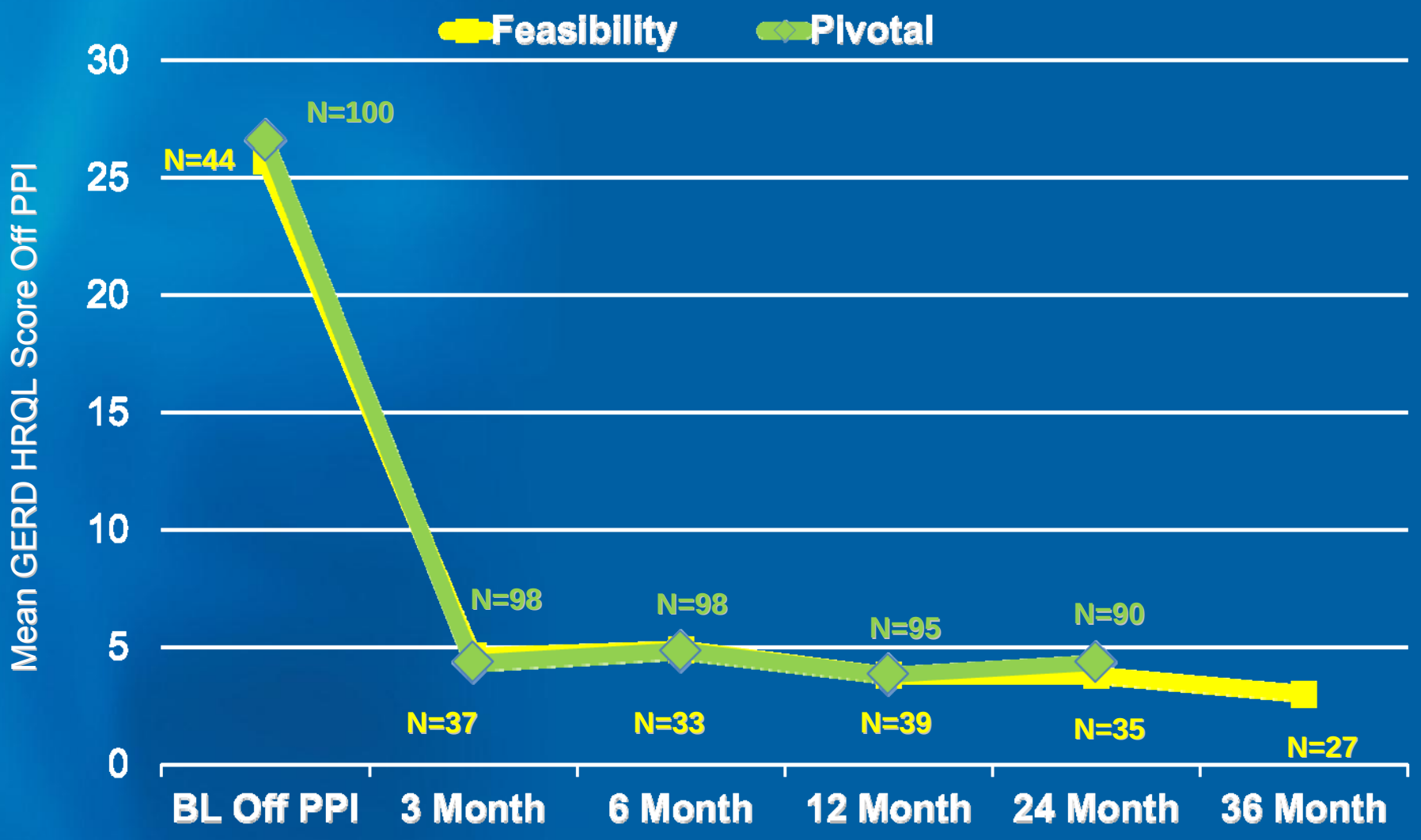
- Effectiveness
  - Reduction in esophageal acid exposure
  - Reduction in GERD-HRQL Score
  - Reduction in PPI Use
- Safety
  - Serious Adverse Event Rate (SAE)

Feasibility and Pivotal Trials: Overview of Clinical Results

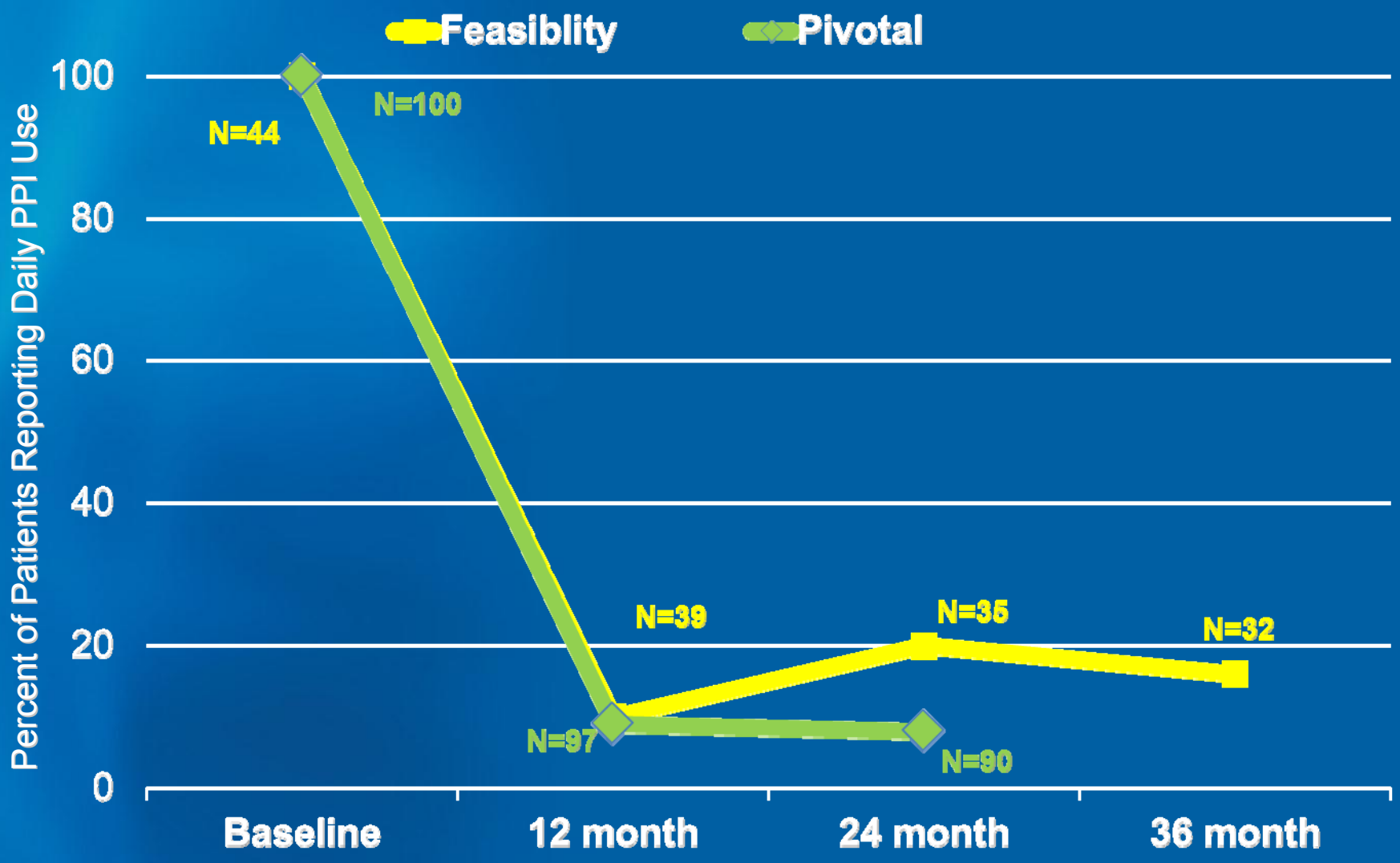
Esophageal Acid Exposure



GERD-HRQL Score off PPI



Daily PPI Dependence



Acceptable Safety Profile Established

- 144 subjects with implant 2 to 4 years
- No intra-operative complications
- No reports of device migration, erosion or device failures
- SAEs

  4% Feasibility

  6% Pivotal

Pivotal Trial

Pivotal Trial Overview

Purpose	To evaluate safety and effectiveness
Design	Prospective, Multi-center, Single-arm
Control	Subject as own control
Subjects	257 screened 100 implanted
Endpoint Analyses	12 months Treatment Group (all implanted subjects)
Follow-up	Discharge, 1wk, 3M, 6M, 12M – 60M (annually)
-Completed	24 months
-Subject Completion	12 months – 98% 24 months – 90%

Centers and Investigators

Abbott/ MNGI	MN	R. Ganz, D. Dunn
Albert Einstein Med Ctr	PA	P. Katz
American Med Ctr, Amsterdam, NL		P. Fockens, W. Bemelman, A. Smout
Gundersen Lutheran	WI	S. Schlack-Haerer, S. Kothari
Knox Community	OH	P. Taiganides
Legacy Medical Center	OR	C. Dunst, L. Swanstrom
Mayo Jacksonville	FL	C.D. Smith, K. DeVault
Nashville Med Research	TN	R. Pruitt
Ohio State Univ	OH	S. Melvin
Phoebe Putney	GA	C. Smith
Univ of Pittsburgh	PA	J. Luketich
Univ of Rochester	NY	J. Peters
Univ of Washington	WA	C. Pellingrini, B. Oelschlager
Univ of CA – San Diego	CA	S. Horgan
Univ of Southern California	CA	J. Lipham
Washington University	MO	S. Edmundowicz, B. Matthews

Key Pivotal IDE Eligibility Criteria

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

Pivotal Trial Endpoints

EFFICACY	≥60% of subjects will achieve success[1]
Primary Reduced Esophageal Acid Exposure	Normalize or reduce by ≥50% the total % time
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SAFETY OBJECTIVE	Estimate rate of related Serious Adverse Events

1-Based on a lower bound 97.5% CI

Additional Pre-Specified Assessments

Efficacy
pH testing
GERD-HRQL
PPI use
Regurgitation – frequency & severity
Esophagitis
Patient Satisfaction
Heartburn – frequency and severity
Extra-esophageal symptoms

Side Effects
Ability to belch
Ability to vomit
Diet Tolerance
Gas bloat – frequency & severity

Safety
Dysphagia
Pain
Motility
Endoscopy
Barium swallow
X-ray
Weight loss

All assessments were actively surveyed through study period.

Pivotal Trial

Demographics and Surgical Procedure

Baseline Characteristics

Parameter	Measurement	Results (N = 100)
Age (years)	Mean ±SD	50±12.4
BMI	Mean ±SD	28±3.4
Gender % (n/N)	Male Female	52% 48%
Total % pH Time <4	Mean ±SD	12±4.7
Esophagitis	(%) Grade A or B	40%
GERD-HRQL Total Score	Mean ±SD On PPI Off PPI	 12.0±6.8 26.6±6.6

GERD History - Baseline

	RESULTS (N = 100)
GERD Mean	13 years
Duration of PPI Use Mean	6 years
Heartburn – Moderate or Severe Primary reason for visit and/or interfering with daily activities	89%
Regurgitation – Moderate or Severe With position change and/or constant presence of aspirations	57%

Uncomplicated Surgical Procedure

Measurement	Result
Surgical Procedure Time Mean ±SD (*Last port in to first port removed)*	39±22.8 minutes
Procedure Failure	0%
Operative Complication Rate	0%
Discharge SAE Rate	0%
Length of Stay ▪ Same day discharge ▪ Next day discharge	 50% 50%

Note: No roll-in or training implants. All implants included in analysis.

Pivotal Trial

Efficacy Outcomes

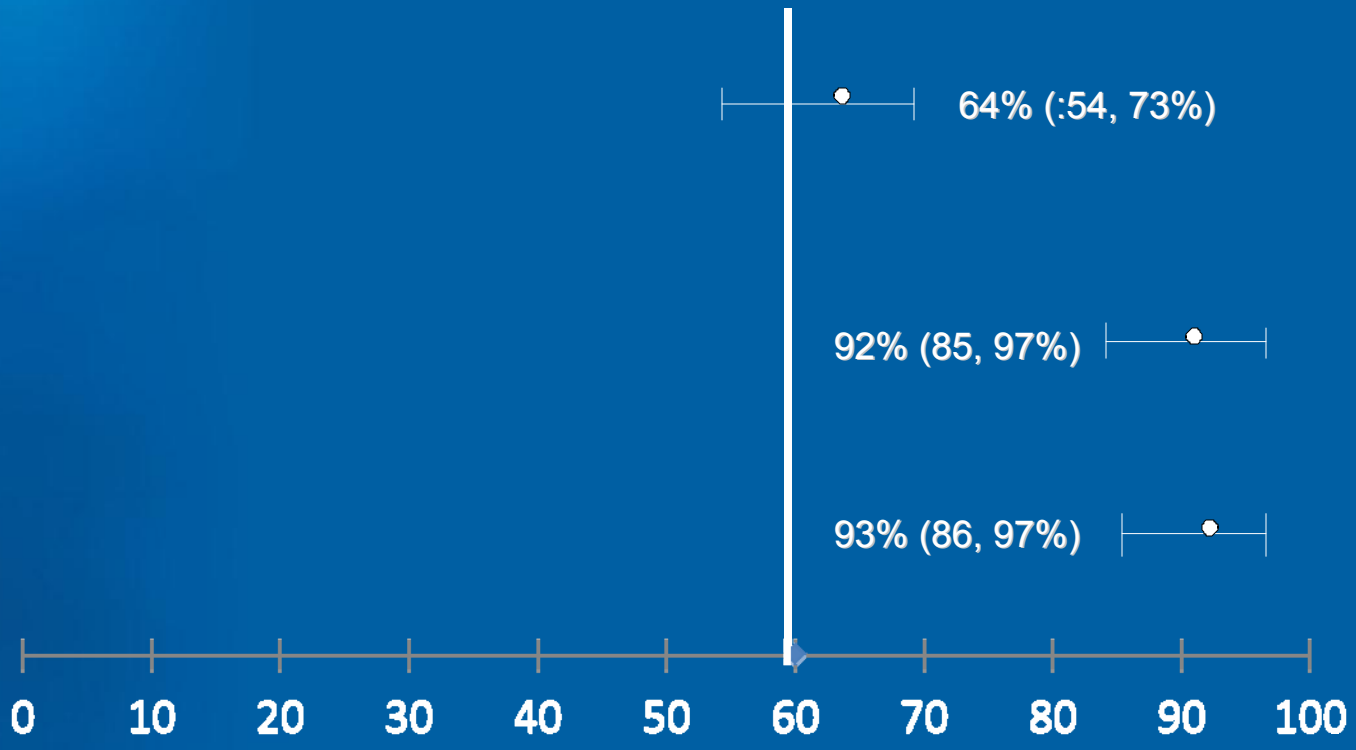
Summary of Efficacy Endpoints

Percent Successful (95% Binomial Exact Confidence Limits)

Primary: pH
Normalization or ≥ 50% reduction

Secondary: GERD
≥ 50% reduction in GERD-HRQL

Secondary: PPI
≥ 50% reduction in daily PPI use



Patients Not Achieving the pH Endpoint

Clinical Success Achieved and Maintained

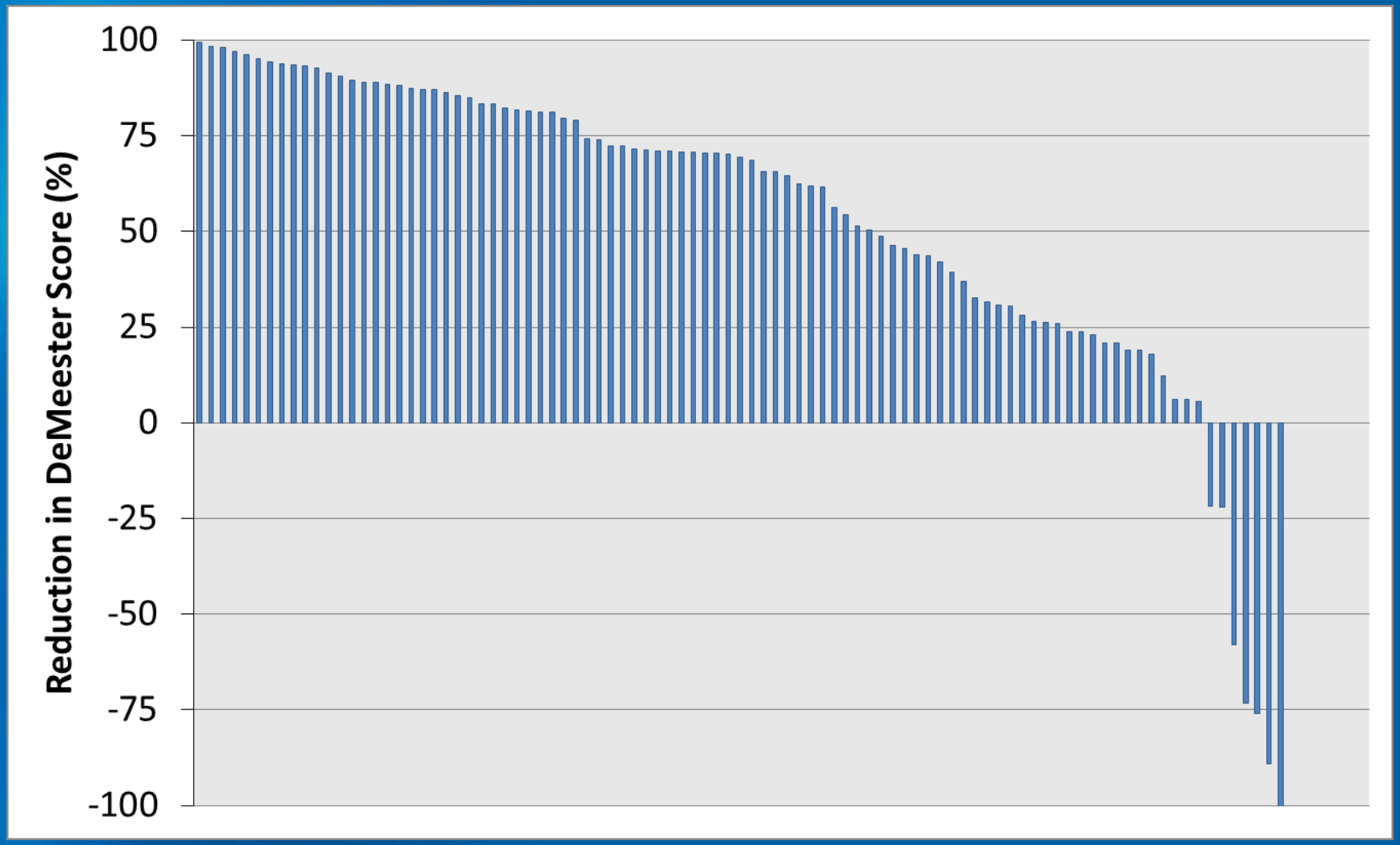
Measurement	Baseline	12 months	24 months
Mean Total GERD-HRQL Score Off PPI	28.4	**5.9**	**5.5**
Daily PPI Use	100%	**21%**	**17%**
Regurgitation – Severe or Moderate	72%	**6%**	**4%**
Esophagitis	44%	**21%**	**17%**

Pivotal Mean DeMeester Score Components

PARAMETER*	N	BASE-LINE	N	12 Month	P VALUE
Total time pH<4 (%)	100	**11.6**	96	**5.1**	<.0001
Total upright time pH<4 (%)	100	**14.0**	96	**6.5**	<.0001
Total supine time pH<4 (%)	98	**7.8**	95	**2.9**	<.0001
Total number of reflux episodes	100	**175**	96	**82.8**	<.0001
Number of reflux episodes >5min	99	**12.4**	96	**6.1**	<.0001
Longest reflux episode (min)	99	**37.4**	96	**19.7**	<.0001
DeMeester Score	97	**41.0**	95	**18.7**	<.0001

*All pH testing completed with Bravo capsule endoscopically placed

Evidence of Reduced DeMeester Score 92% (86/93)



Pivotal Trial
GERD-HRQL Results

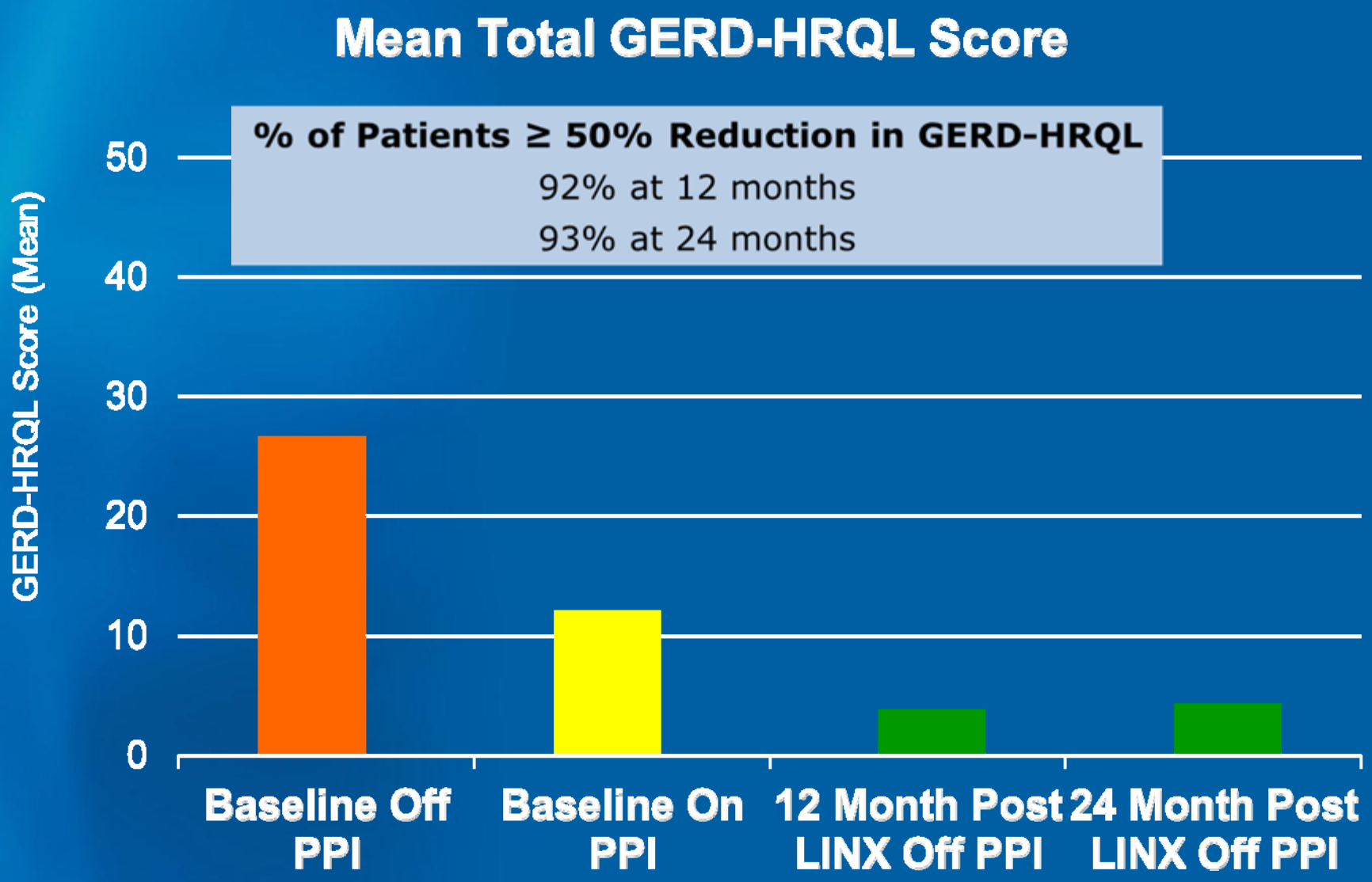
GERD-HRQL Questionnaire[1]

- Validated questionnaire, specific to GERD
- 10 Questions Scored
    - 6 heartburn related
    - 2 swallowing related
    - 1 gassy/bloating
    - 1 medication

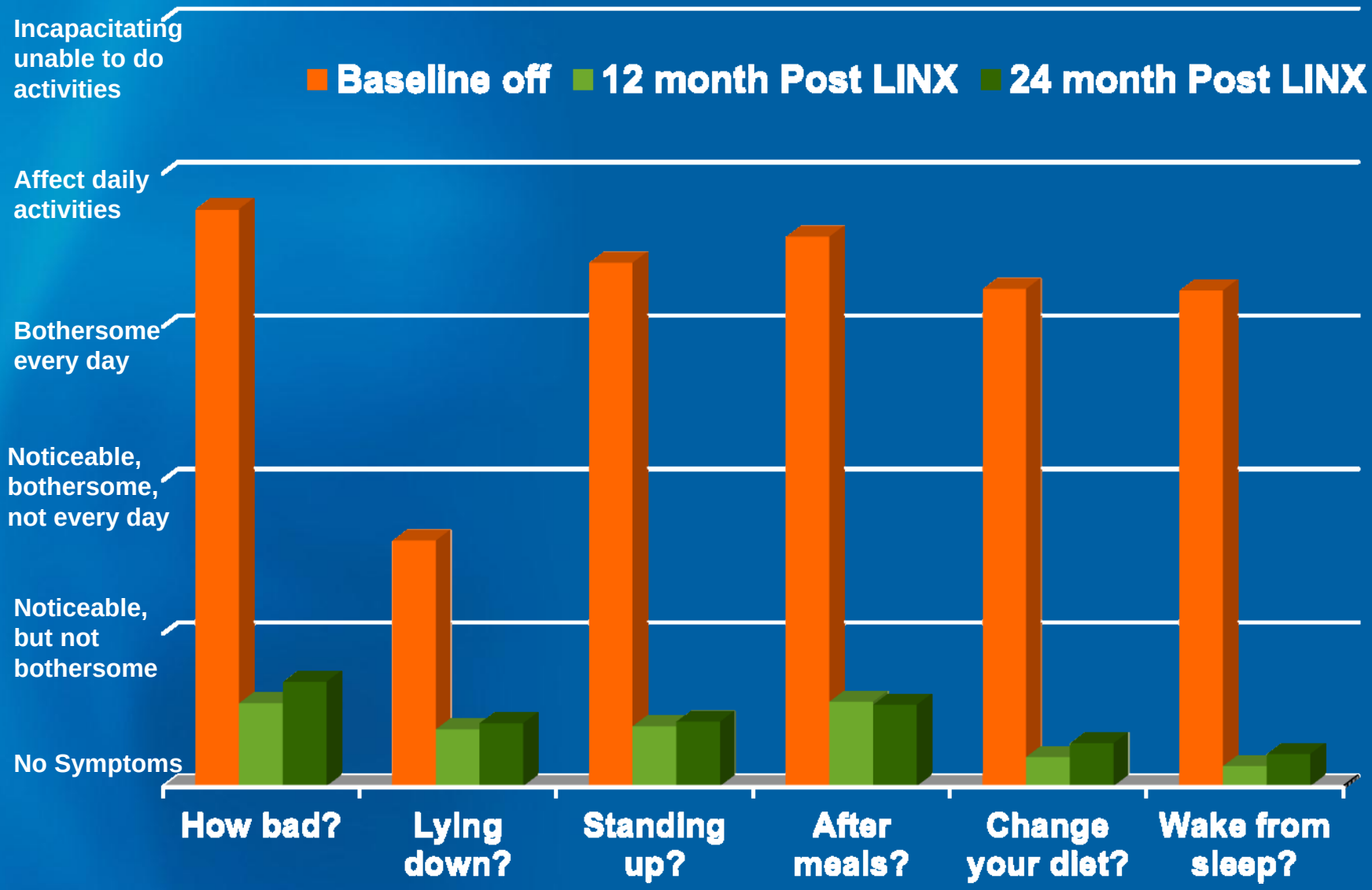
- Scoring Scale 0 – 5
    - 0 = No symptoms
    - 1 = Symptoms noticeable but not bothersome
    - 2 = Symptoms noticeable and bothersome
    - 3 = Symptoms bothersome every day
    - 4 = Symptoms affect daily activities
    - 5 = Symptoms are incapacitating – unable to do activities

(1) Velanovich – Diseases of the Esophagus (2007) 20, 130-134

Sustained Control of GERD Symptoms



Heartburn Questions: Mean Score



Pivotal Trial
PPI Use

Elimination of Daily PPI Dependence

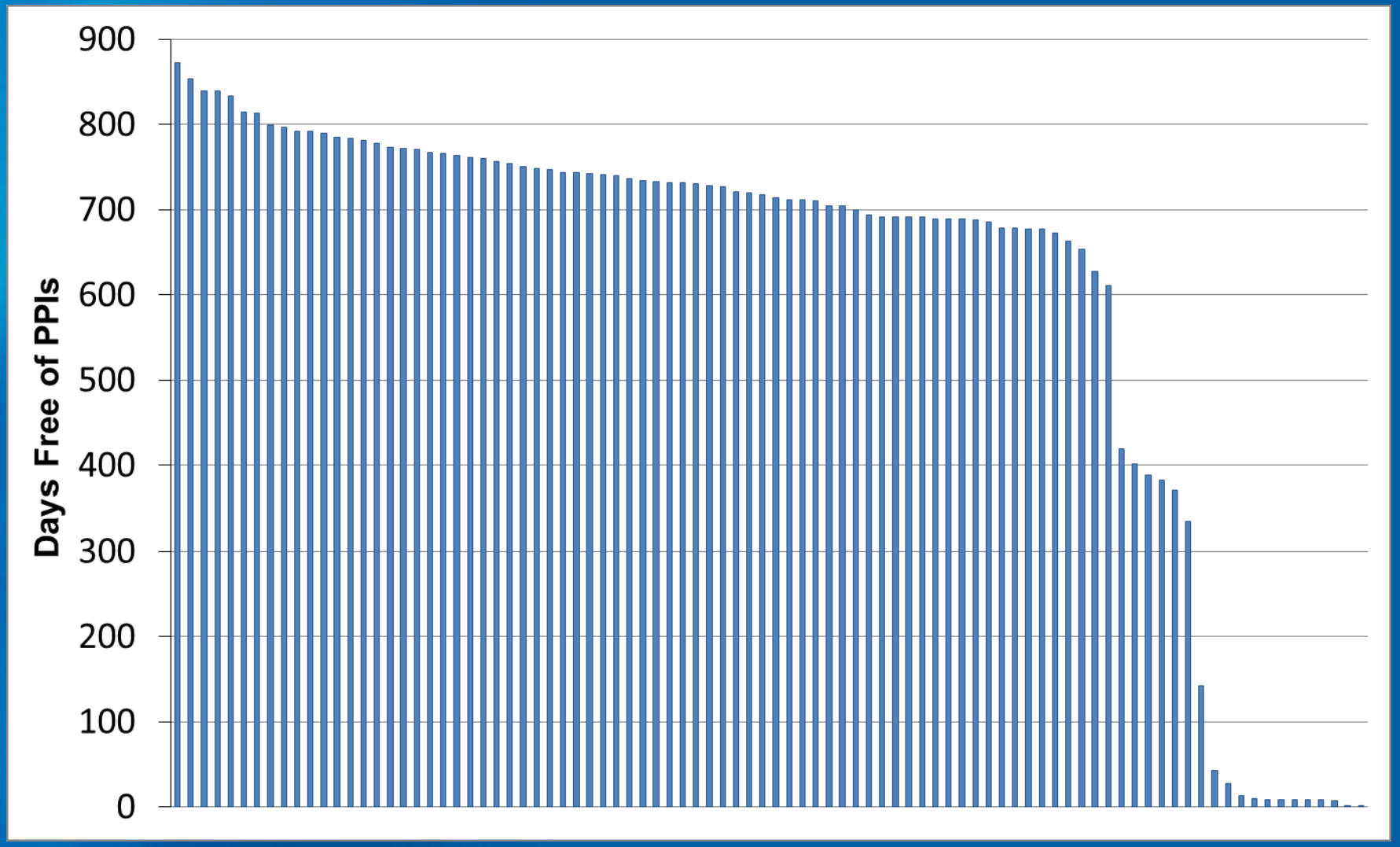
Free of Daily PPI Dependence

Baseline	12 Months Post-LINX	24 Months Post-LINX
0%	91%	92%

PPI Frequency of Use

Frequency	Baseline	12 Months Post-LINX	24 Months Post-LINX
QD	64%	7%	7%
BID	35%	2%	1%
TID	1%	0%	0%

PPI Free Days
As of Last Follow-Up



Pivotal Trial
Univariate Analysis: Predictors of Primary Efficacy Endpoint

Univariate Predictors of Primary Endpoint

Univariate Predictor	Subgroup	% Successful (Number of Subjects/Total)	p-value
Age	< 53 years	62.0% (31 / 50)	0.71
	≥ 53 years	66.0% (33 / 50)	
Gender	Male	51.9% (27 / 52)	0.009
	Female	77.1% (37 / 48)	
BMI	Normal (<25)	73.7% (14 / 19)	0.80
	Overweight (25-30)	58.2% (32 / 55)	
	Obese (≥ 30)	69.2% (18 / 26)	
Site Group	Site 001	58.3% (7/12)	0.70
	Site 008	57.1% (12/21)	
	Site 011	80.0% (8/10)	
	Site 013	75.0% (9/12)	
	Site 018	60.0% (6/10)	
	Sites 003, 004, 006, 007, 012, 016	52.9% (9/17)	
	Sites 005, 009, 017	72.2% (13/18)	
Hiatal hernia	None	77.3% (34 / 44)	0.005
	Yes – repaired	66.7% (20 / 30)	
	Yes – not repaired	38.5% (10 / 26)	

Univariate Predictors of Primary Endpoint cont.

Univariate Predictor	Subgroup	% Successful (Number of Subjects/Total)	p-value
Esophagitis	None	66.7% (40 / 60)	0.69
	Grade A	63.6% (14 / 22)	
	Grade B	55.6% (10 / 18)	
LES Resting Tone Hypotensive	< 10.0	59.4% (19 / 32)	0.66
	≥ 10.0	65.7% (44/ 67)	
Procedure Time	< 36 min	64.0% (32 / 50)	0.95
	≥ 36 min	64.0% (32 / 50)	
Device Size	12 Beads	60.0% (3 / 5)	0.44
	13 Beads	63.6% (14 / 22)	
	14 Beads	65.2% (30 / 46)	
	15 Beads	68.0% (17 / 25)	
	16 Beads	0.0% (0 / 2)	
Time with GERD	< 10 years	69.0% (29 / 42)	0.62
	≥ 10 years	60.3% (35 / 58)	
Time on PPIs	< 5 years	66.0% (33 / 50)	0.93
	≥ 5 years	62.0% (31 / 50)	

Efficacy Endpoints by Baseline Hernia Assessment (≤3 cm)

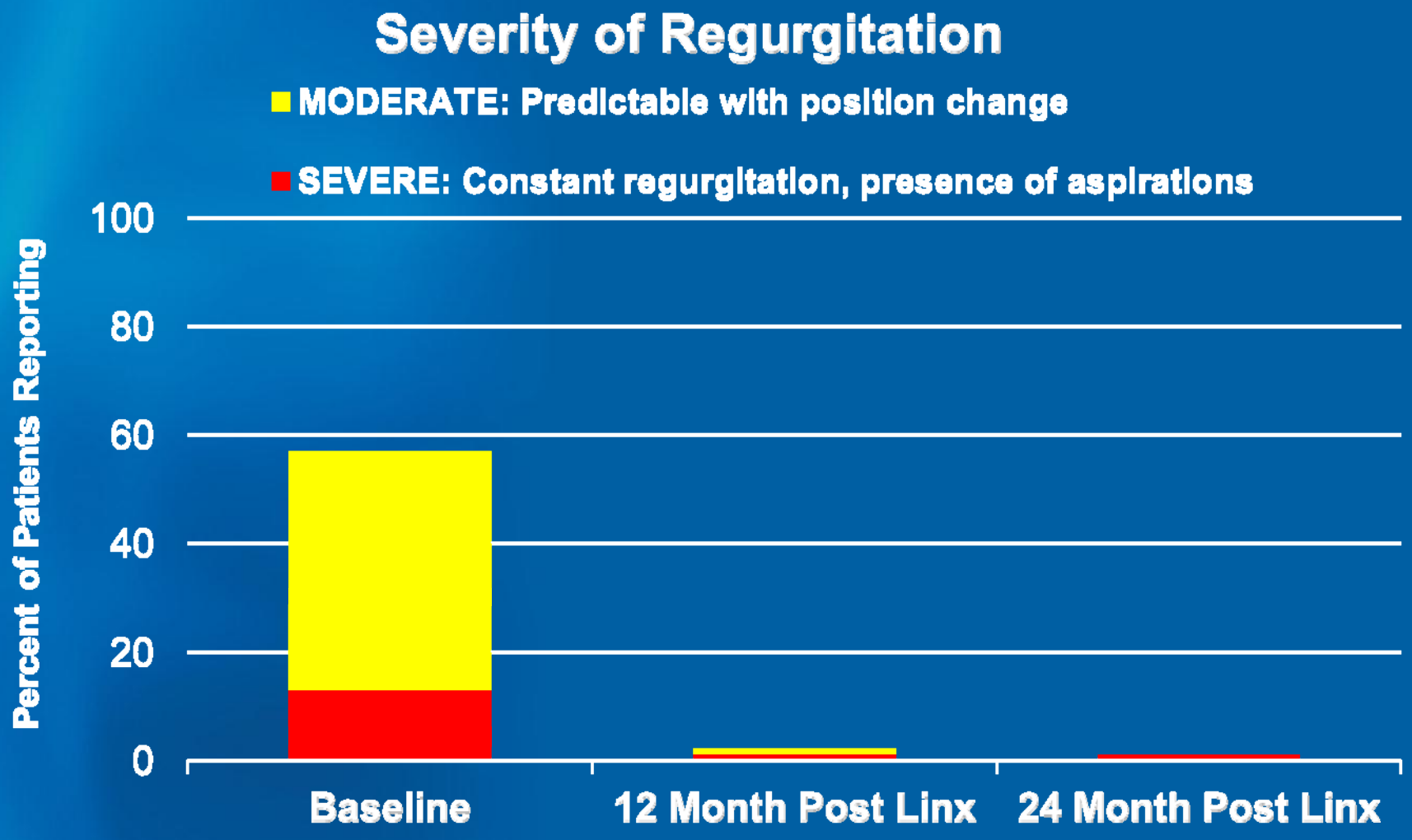
Hernia at Baseline	N	pH Endpoint Success	GERD-HRQL Endpoint Success	PPI Use Endpoint Success
None	44	77%	89%	91%
Yes – repaired	30	67%	100%	97%
Yes – not repaired	26	39%	89%	92%

	pH Endpoint Success	95% CI
No hernia or hernia repaired	73.0% (54 / 74)	61.4, 82.7%

Pivotal Trial

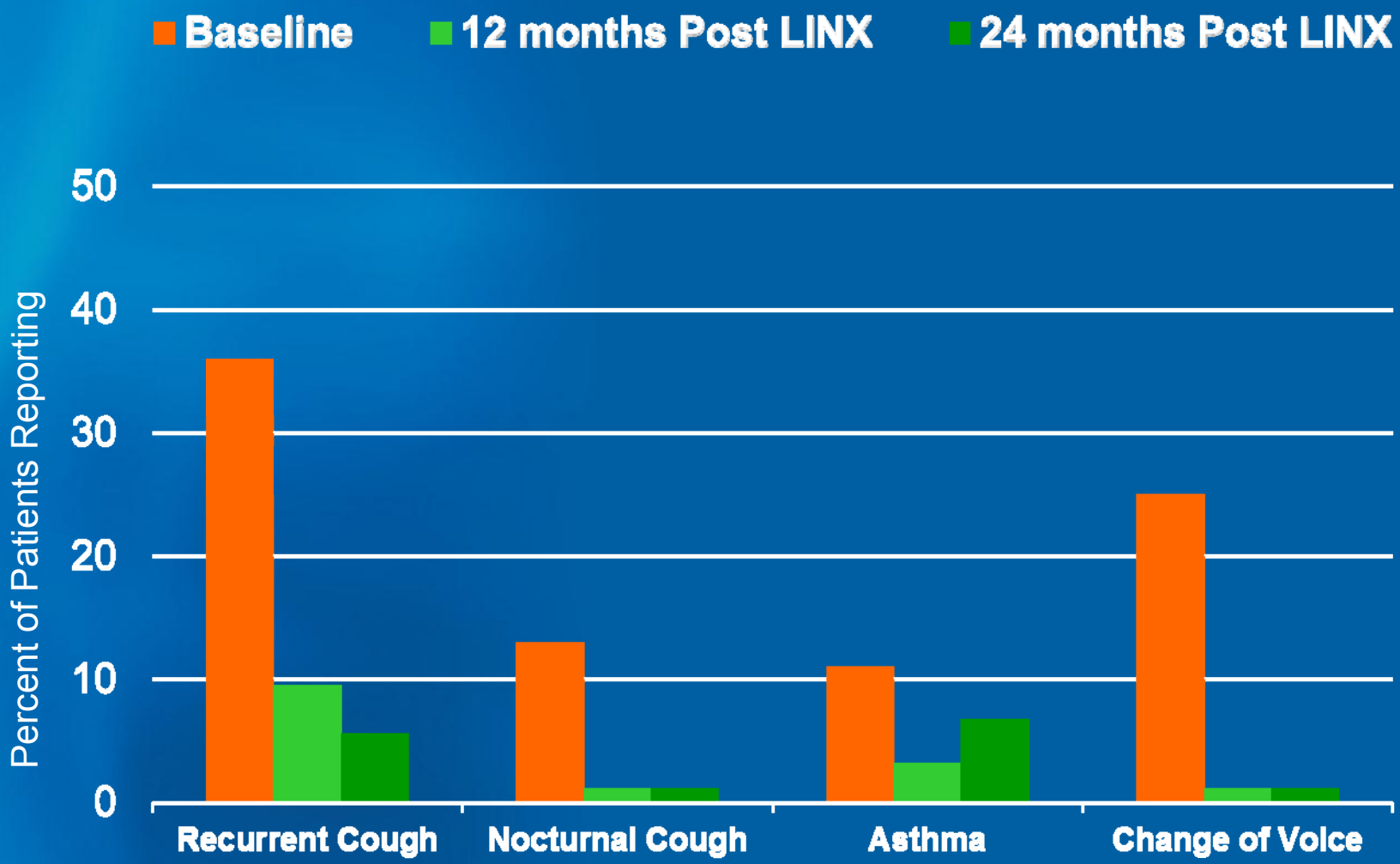
Additional Efficacy Measures

Sustained Control of Regurgitation



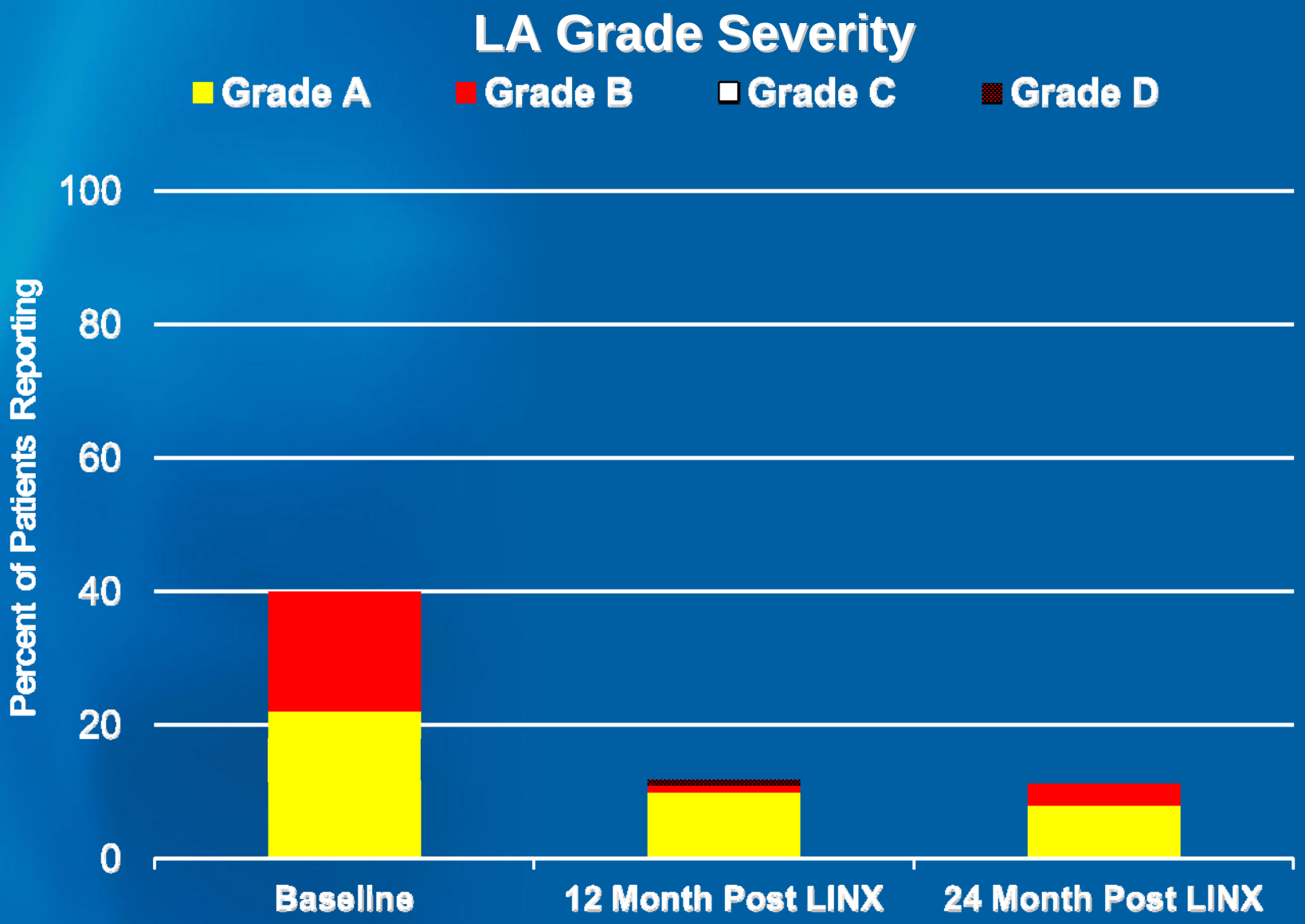
Note: As actively queried by Foregut Questionnaire

Control of Extra Esophageal Symptoms



Note: As actively queried by Foregut Questionnaire

Control of Esophagitis



Pivotal Trial

Potential Side Effects

Minimal Side Effects

Ability to Belch

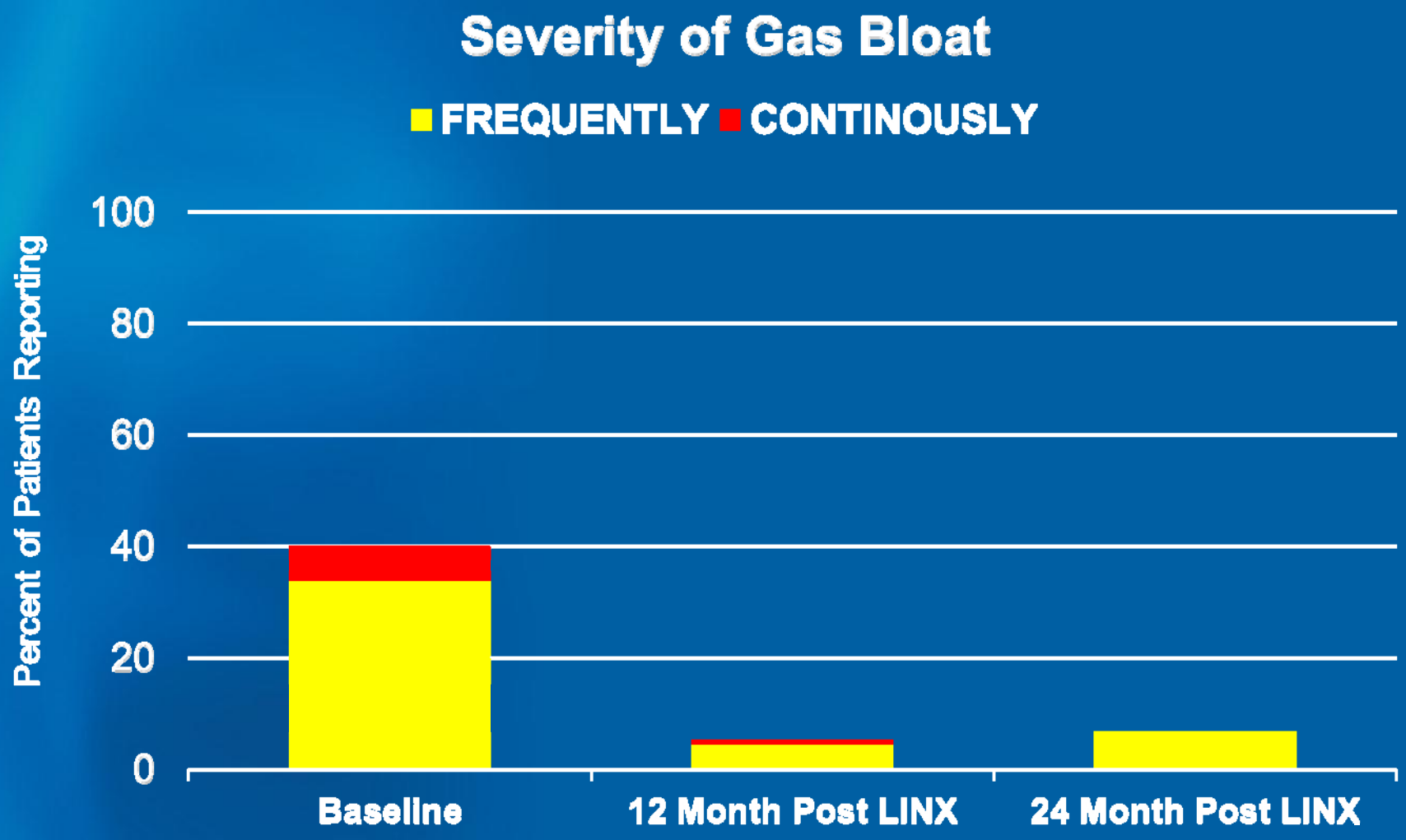
- 99% of patients throughout study period

Inability to Vomit

- 0% at 12 months
- 1% at 24 months

Note: As actively queried by Foregut Questionnaire

Reduced Gas Bloat



Note: As actively queried by Foregut Questionnaire

High Level of Patient Satisfaction

How satisfied are you with your present condition?

GERD-HRQL Satisfaction	Baseline Off PPI	12 Months Post-LINX Off PPI	24 Months Post-LINX Off PPI
Satisfied	0%	95%	90%
Neutral	5%	2%	7%
Dissatisfied	95%	3%	3%

Pivotal Trial

Safety and Adverse Events

Demonstrated Safety

Serious Adverse Event

Endpoint	% Subjects (95% CI)
Serious Adverse Events	6% (2.2 – 12.6%)

Acceptable Safety Profile Established

Serious Adverse Events – Related or Unknown

Subject ID	Event	Description	Status
03-005-004	Dysphagia Nausea	Explanted 31 days after implant	Resolved
03-004-004	Dysphagia Odynophagia	Explanted 93 days after implant	Resolved
03-008-021	Dysphagia	Explanted 21 days after implant	Resolved
03-008-018	Pain Vomiting	Hospitalized for pain; Explanted 357 days after implant for vomiting	Resolved (pain) Ongoing, no follow-up deemed necessary (vomiting)
03-008-020	Vomiting	Hospitalized 2 days after implant for <2 days	Resolved
03-018-002	Nausea	Hospitalized 2 days after implant for <2 days	Resolved

LINX Device Can Be Removed

- Laparoscopic procedure
- No complications related to removal
- Anatomy not significantly altered
- Nissen fundoplication an option after removal

Summary of Related Adverse Events

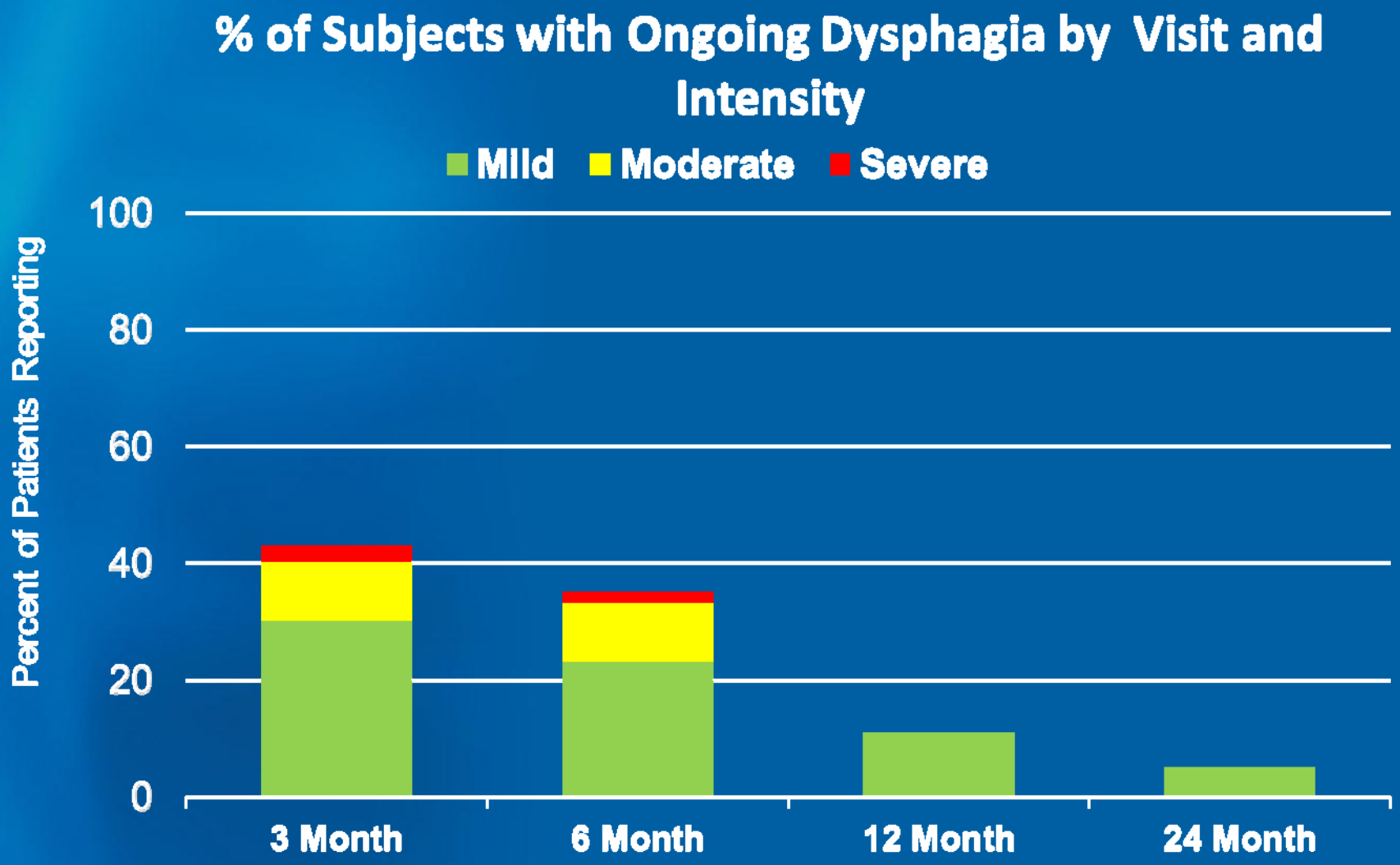
Adverse Event[1]	% Subjects
Dysphagia	68%
Pain	24%
Stomach Bloating	14%
Nausea	7%
Odynophagia	8%
Hiccups	8%
Inability to belch or vomit	6%

[1] AEs with Frequency ≥5%

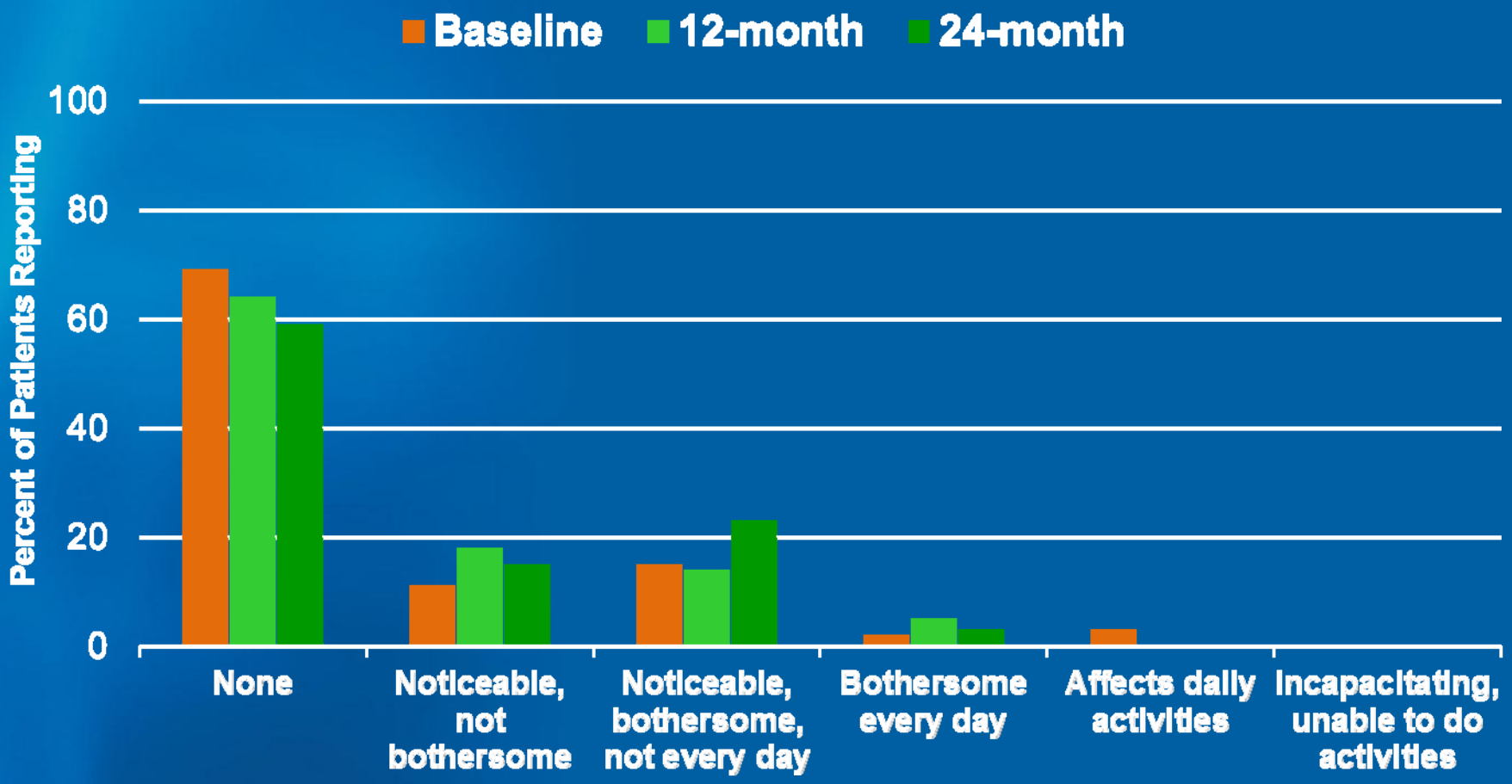
Dysphagia Observations

- Any complaint reported per protocol
- Post-op diet was NOT restricted
- Characterization of dysphagia
  - Mild and well tolerated in large majority of cases
  - Not a daily occurrence in >90% subjects
  - High levels of satisfaction (GERD-HRQL)
- Effective management
  - Dilations are a safe and effective option

Dysphagia Observations



GERD-HRQL Difficulty Swallowing



Foregut Questionnaire	BL	3M	6M	12M	24M
Events/wk	1.4	2.1	1.9	1.8	1.2

Pain - Intensity and Frequency

Intensity	Baseline % (n/N)	Month 12 % (n/N)	Month 24 % (n/N)
None	22.0% (22/100)	80.0% (76/95)	75.6% (68/90)
Minimal	21.0% (21/100)	12.6% (12/95)	12.2% (11/90)
Moderate	40.0% (40/100)	6.3% (6/95)	10.0% (9/90)
Severe	17.0% (17/100)	1.1% (1/95)	1.1% (1/90)
No response	0.0% (0/100)	0.0% (0/95)	1.1% (1/90)
Change from BL		**Month 12**	**Month 24**
Improved		72.6% (69/95)	67.8% (61/90)
Same		22.1% (21/95)	25.6% (23/90)
Worsened		5.3% (5/95)	5.6% (5/90)
No response		0.0% (0/95)	1.1% (1/90)
Frequency/Week	**Baseline N=99**	**Month 12 N=95**	**Month 24 N=89**
Mean±SD (Median)	30.4±82.1 (7.0)	1.8±8.9 (0.0)	0.7±2.5 (0.0)
Range	0.0, 700.0	0.0, 70.0	0.0, 21.0

Note: As actively queried by Foregut Questionnaire

Chest Pain – Severity and Frequency

Severity	Baseline % (n/N)	Month 12 % (n/N)	Month 24 % (n/N)
None	31.0% (31/100)	80.0% (76/95)	84.4% (76/90)
Minimal – Occasional episodes	36.0% (36/100)	16.8% (16/95)	11.1% (10/90)
Moderate – Predictable with position change, straining or lying down	21.0% (21/100)	3.2% (3/95)	4.4% (4/90)
Severe – Interfering with activities of daily life	12.0% (12/100)	0.0% (0/95)	0.0% (0/90)
Change from BL		**Month 12**	**Month 24**
Improved		61.1% (58/95)	63.3% (57/90)
Same		34.7% (33/95)	30.0% (27/90)
Worsened		4.2% (4/95)	6.7% (6/90)
Frequency/Week	**Baseline**	**Month 12**	**Month 24**
N	99	95	90
Mean±SD (Median)	23.9±81.2 (2.0)	1.1±6.0 (0.0)	0.2±0.6 (0.0)
Range	0.0, 700.0	0.0, 56.0	0.0, 4.0

Note: As actively queried by Foregut Questionnaire

Overall Acceptable Safety Risk

- 144 patients implanted between 2-4 years
- No deaths
- No intra-operative complications
- No device failures
- No device erosions or migrations

Serious Adverse Events

- 6% (8/144)
- No late onset (>1 year)

Conclusion / Observations

- Device closely reproduces native LES function - dynamic
- Improvement over current surgical options
  - Very few can perform a good fundoplication – tricky operation
  - Greatly ameliorates the side effects
  - Low complications and favorable pattern of failure
- Addresses a significant unmet need
- Positively transforms patients' lives
- LINX would be a tremendous positive addition to current options for GERD

AGENDA

Introduction	**Todd Berg** *CEO* *Torax Medical*
Pathophysiology of GERD	**Tom DeMeester, MD** *Professor of Surgery, Chair Emeritus* *Department of Surgery -- USC*
Device Overview and Pre-Clinical Activities	**Todd Berg** *CEO* *Torax Medical*
LINX Feasibility and Pivotal IDE Clinical Trials	**Daniel Smith, MD** *Chair Department of Surgery – Mayo Jacksonville*
Post Market Studies and Closing Comments	**Todd Berg** *CEO* *Torax Medical*

Post Market Programs

Extended Follow Up -Pivotal Trial

Screen	Implant	3m	6m	12m	24m	36mo	48mo	60mo	Type of follow-up
X				X					**Health History**
X		X	X	X	X	X	X	X	**GERD-HRQL Questionnaire**
X		X	X	X	X	X	X	X	**Foregut Symptom Questionnaire**
X		X	X	X	X	X	X	X	**PPI, H2, Antacid and other Medication Use**
X				X					**Esophageal pH**
X				X					**Manometry/Motility**
X				X	X			X	**EGD Endoscopy**
X				X					**Barium Esophagram (Fluoroscopy)**
	X			X	X			X	**Abdominal/Chest X-ray**
	X	X	X	X	X	X	X	X	**Adverse Events**

Proposed Post Approval Study

Primary Objectives

- Confirm long-term safety and efficacy benefits

Design

- Prospective, multi-center, single-arm study
- 25 sites and 200 patients

Endpoints

- Serious device related adverse events
- Maintain control of symptoms (≥ 50% reduction in the total GERD-HRQL score)

Summary of Benefit and Risk

Todd Berg

CEO, Torax Medical

The Successful LINX Patient

Baseline % of Pts	Characteristic	Post-LINX % of Pts 2 Years
100%	Daily PPI dependence	8%
70%	Reflux affecting their sleep on a daily basis	2%
76%	Reflux affecting their food tolerances on a daily basis	2%
57%	Moderate or severe regurgitation including aspirations	1%
55%	Severe heartburn affecting their daily life	1%
51%	Experiencing extra esophageal symptoms in addition to heartburn and/or regurgitation	12%
40%	Esophagitis	11%

Rationale for Approval