Minimally Invasive and Novel Therapeutics (M.I.N.T.)
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LINX After Bariatric Surgery

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HARVARD MEDICAL SCHOOL

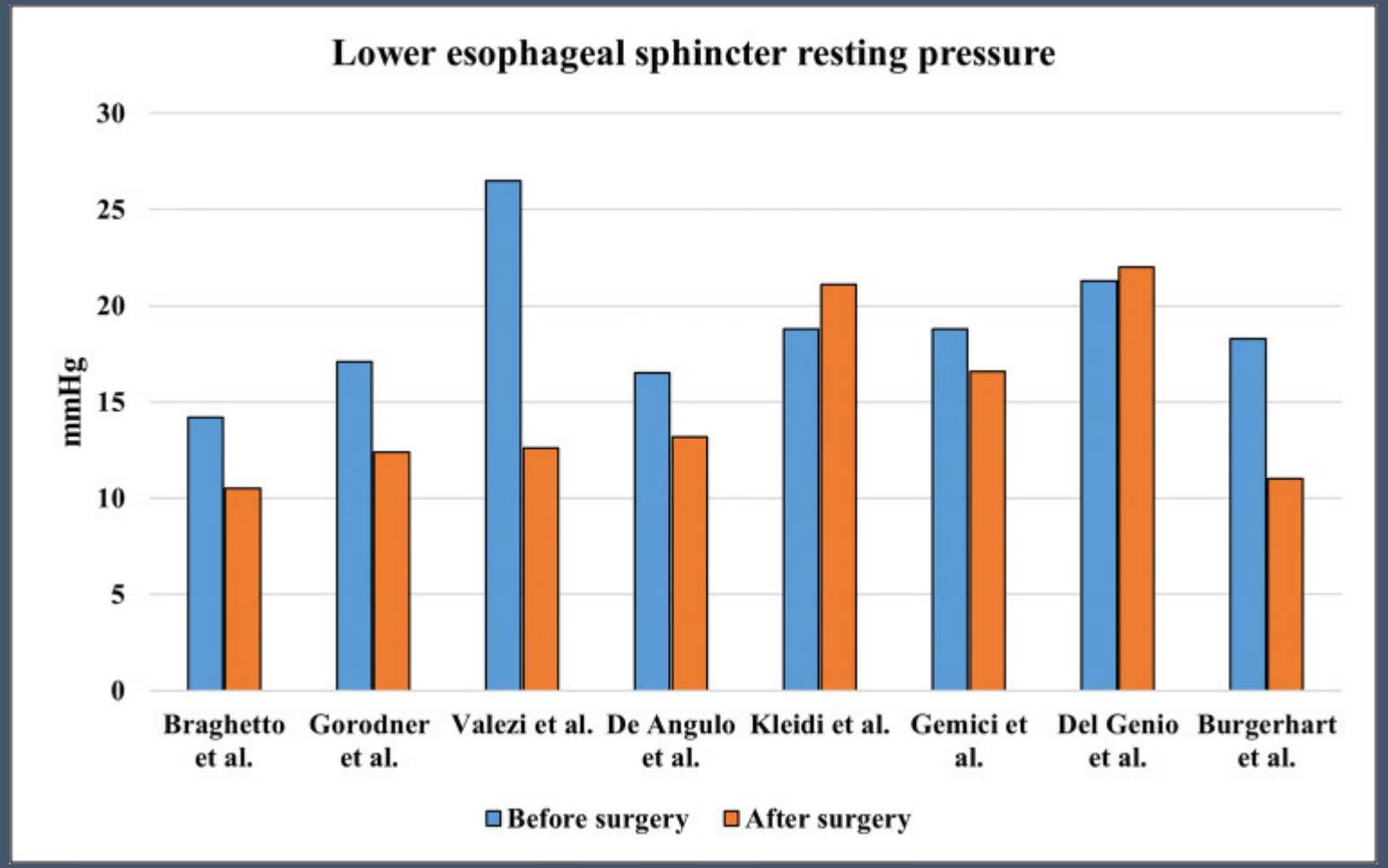
GERD after Sleeve Gastrectomy

- 20-30%% of patients after LSG will develop de novo symptoms of GERD
- Significant heterogeneity on esophagitis after LSG (6%-63%)
- PPIs remain a mainstay of management of GERD after LSG, but significant subset of patients are non-responders
- Surgical options include
  - Laparoscopic hiatal hernia repair after LSG (if hiatal hernia)
  - Conversion to Roux-en-Y gastric bypass
  - LINX ???

HARVARD MEDICAL SCHOOL

DuPree CE et al. *JAMA Surg. 2014*
Oor JE et al. *Am J Surg.* 2016

GERD after Sleeve Gastrectomy



6 out of 8 studies suggest lower LES resting pressure after sleeve gastrectomy

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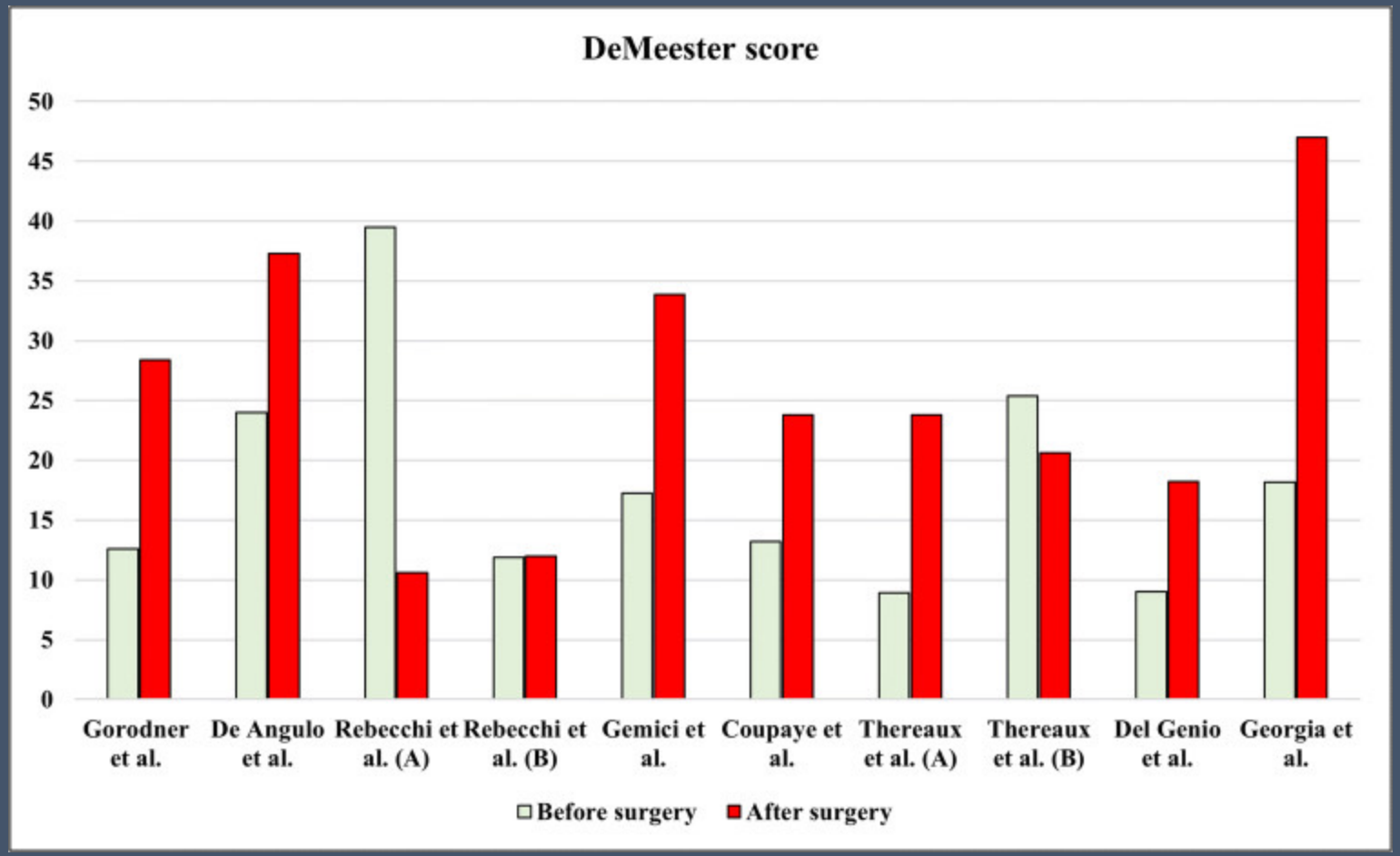
Balla A et al. Langenbecks Arch Surg. 2021

GERD after Sleeve Gastrectomy



8 out of 10 studies suggest increased DeMeester score after sleeve gastrectomy

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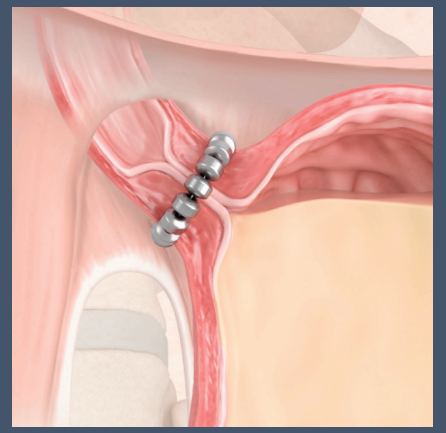
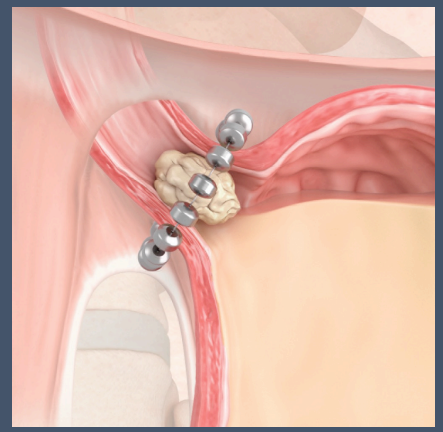
Balla A et al. Langenbecks Arch Surg. 2021

LINX

- LINX Reflux Management System (magnetic sphincter augmentation) is designed to augment the lower esophageal sphincter as a treatment for GERD
- LINX augments resting pressure of the LES
  - Gastric pressures 5-10 mm Hg
  - LINX System 15-25 mm Hg
  - Normal peristaltic pressures 35-80 mm Hg
- Recommended in the 2022 ACG GERD Guideline





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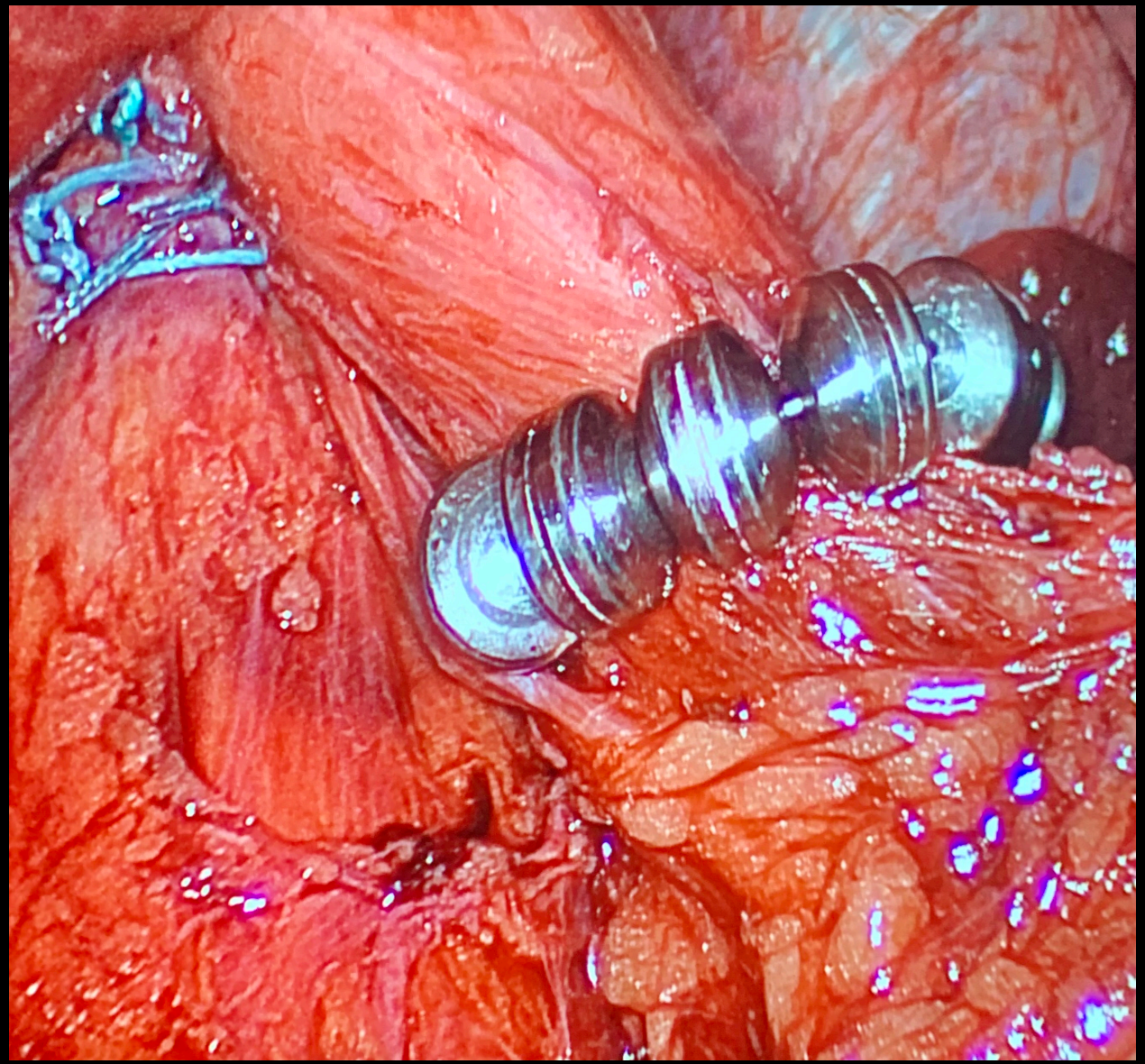
Katz PO et al. *Amer J Gastroenterol.* 2022

Hiatal hernia repair and cruroplasty if indicated

Placement of LINX device between posterior vagus nerve and esophagus



Establishing 3-5 cm of intra-abdominal esophagus

Appropriate sizing of LINX with sizer device (“pop plus three”)

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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.

- 3-year results of a prospective (industry-funded) multicenter trial (14 centers)
- Inclusion:
  - 6 month h/o GERD, partial response to PPI, and abnormal pH
- Exclusion: Barrett's, Grade C or D esophagitis, BMI > 35, dysmotility, large hiatal hernia
- 100 patients, no control group

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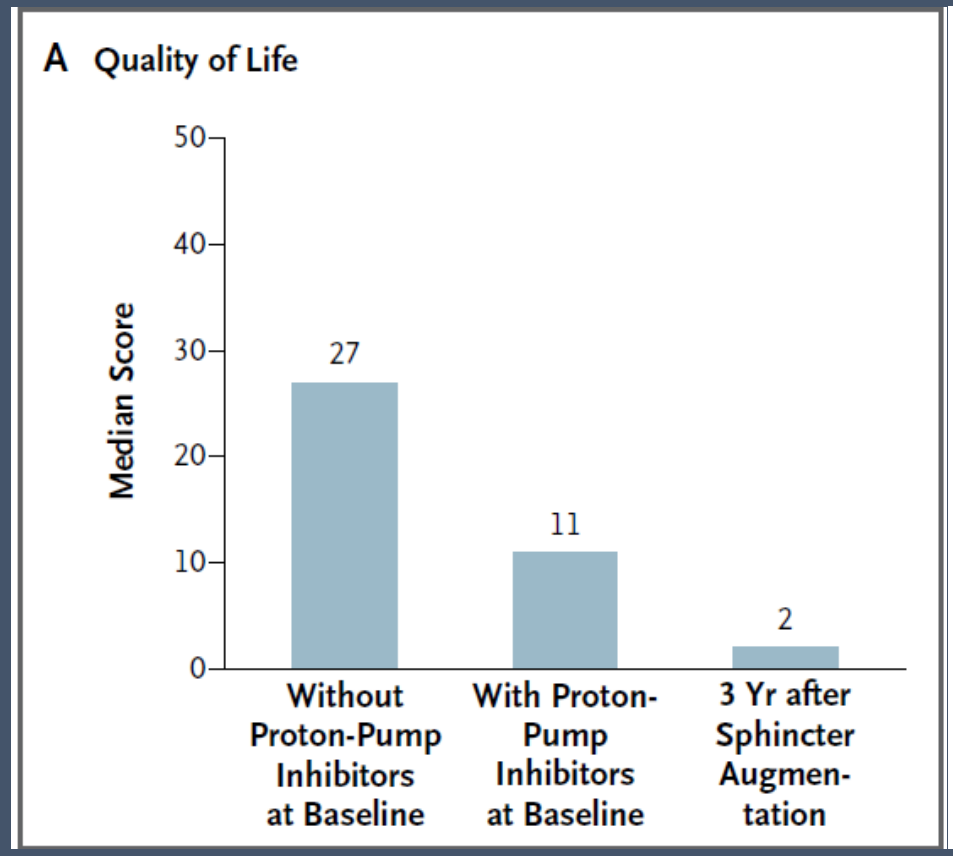
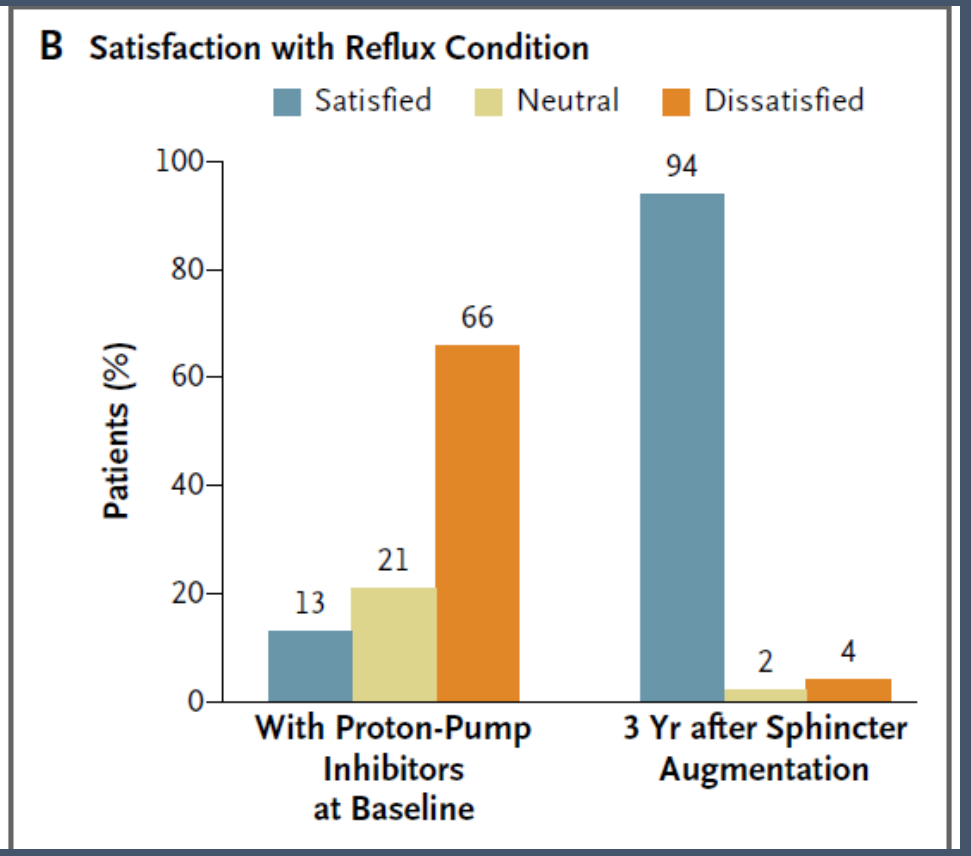
Ganz RA et al, *NEJM*, 2013

LINX Can Improve Quality of Life

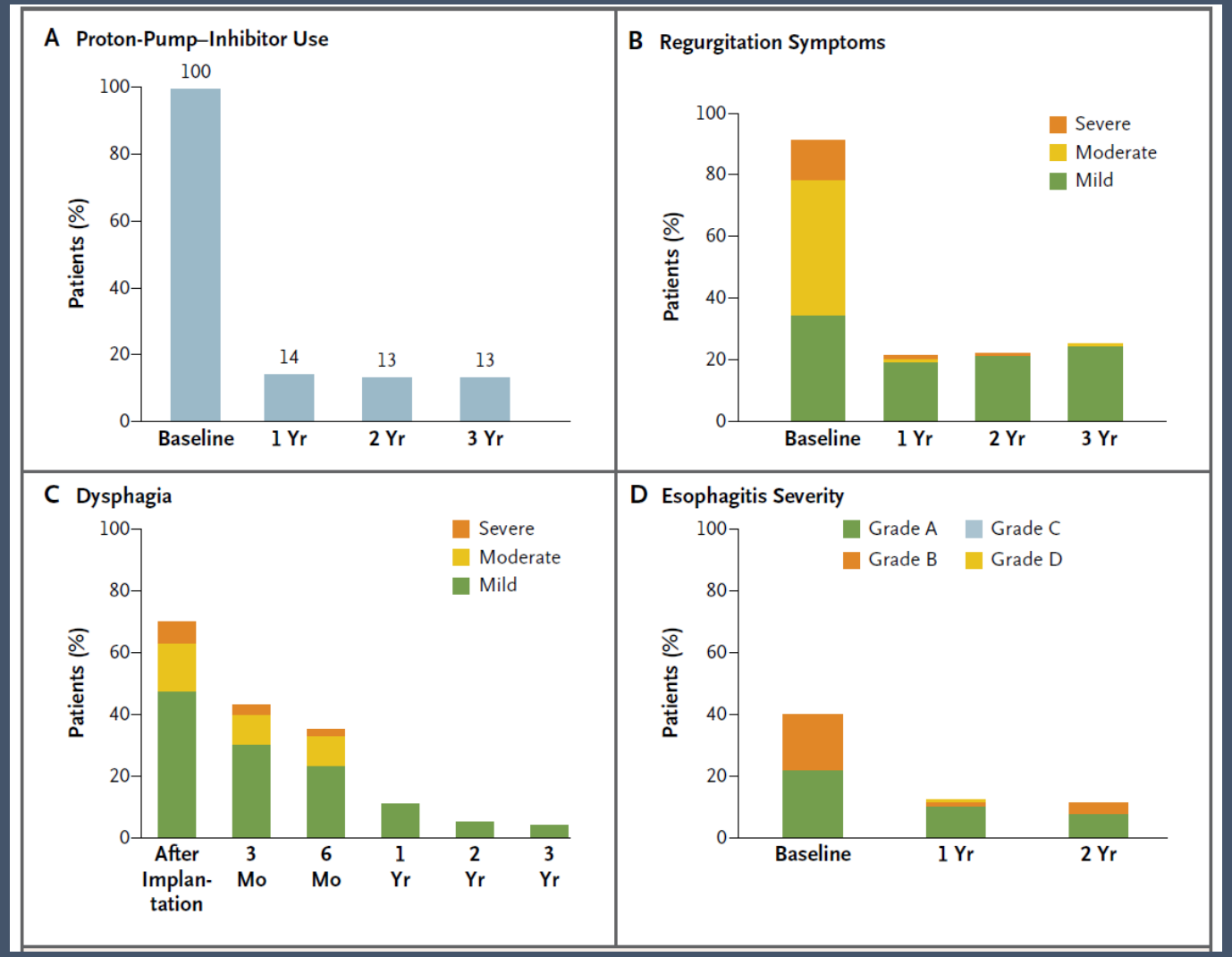




HARVARD MEDICAL SCHOOL

Ganz RA et al, *NEJM*, 2013

LINX Can Improve Symptoms



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A et al, *NEJM*, 2013

LINX Can Objectively Improve pH

Table 1. Components of Esophageal pH Measurements.*

Variable	Baseline		1 Year		P Value
	No. of Patients	Median Value	No. of Patients	Median Value	
pH <4					
Total percentage of time	100	10.9	96	3.3	<0.001
Percentage of time upright†	100	12.7	96	4.3	<0.001
Percentage of time supine‡	98	6.0	96	0.4	<0.001
Total no. of reflux episodes	100	161.0	96	67.0	<0.001
No. of reflux episodes lasting >5 min	99	12.0	96	4.0	<0.001
Longest reflux episode (min)	99	29.0	96	13.0	<0.001
DeMeester score§	97	36.6	96	13.5	<0.001

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A et al, *NEJM*, 2013

MSA Compared to Fundoplication

1-Year Outcomes	Magnetic Sphincter Augmentation (n=114)	Nissen Fundoplication (n=114)
GERD-HRQL (score)	6	5
Postoperative PPI (%)*	24%	12%
Ability for eructation (%)*	97%	66%
Dysphagia (%,Moderate to Severe)	14%	16%
Satisfaction (%)	88%	89%
Would undergo procedure again (%)*	93%	83%

* $P < 0.05$

Warren et al, *Surg Endoscopy*, 2016

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RELIEF Trial

- RELIEF Trial
  - Single arm Investigational Device Exemption (IDE Study) to evaluate safety of MSA in patients who previously underwent LSG
  - N=30
  - Indications
    - Prior LSG with greater than 6 months of GERD symptoms requiring PPI use
    - Exclusions matched pivotal study: BMI>35, scleroderma, varices, Barrett's esophagus, esophageal dysmotility, Grace C/D esophagitis, stricture, or allergy to Ti, Ni, steel
  - Primary outcomes
    - Esophageal acid exposure time
    - ≥50% reduction in GERD-HRQL
    - ≥50% reduction in average daily PPI dosage

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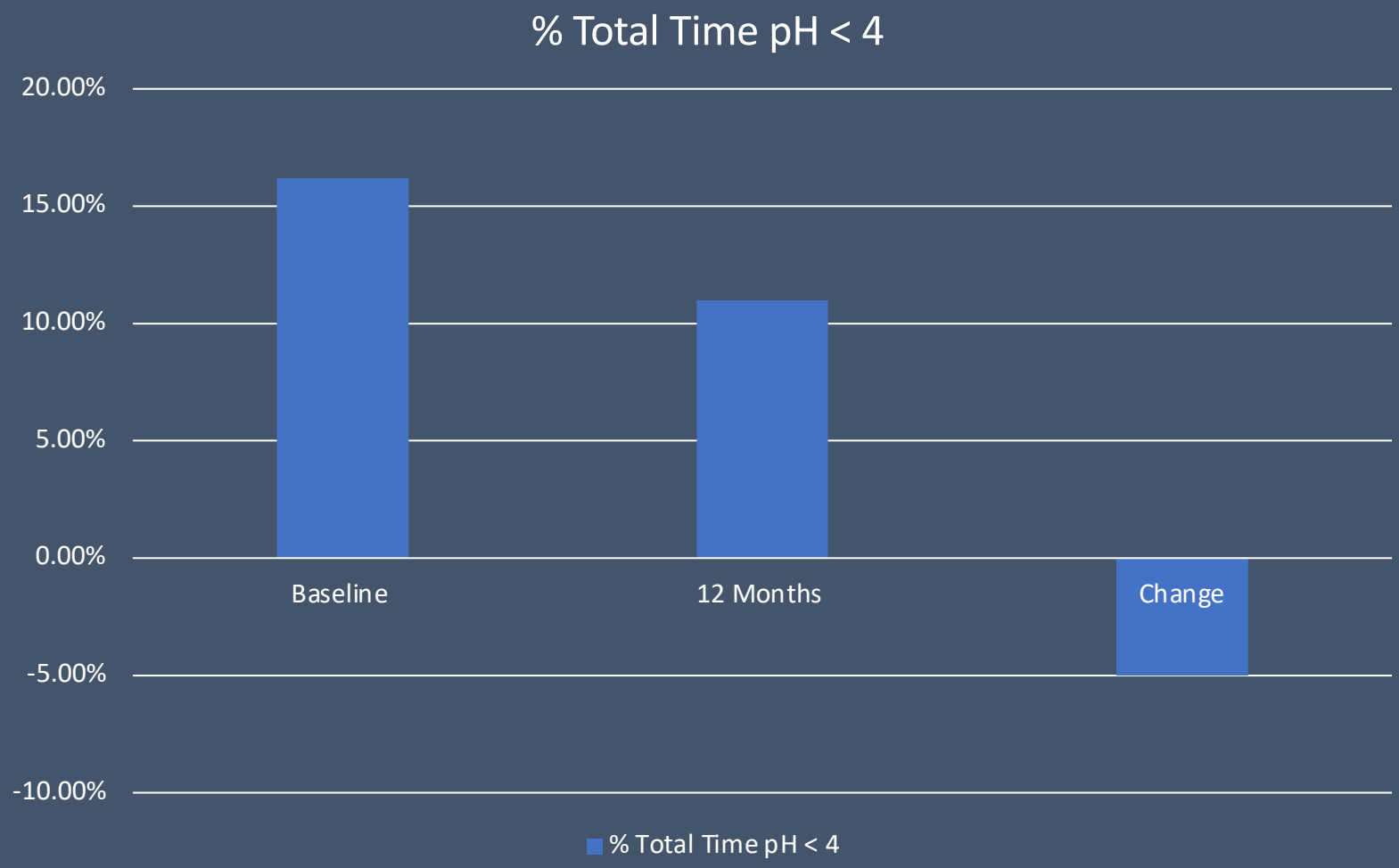
RELIEF Trial



* P=0.038

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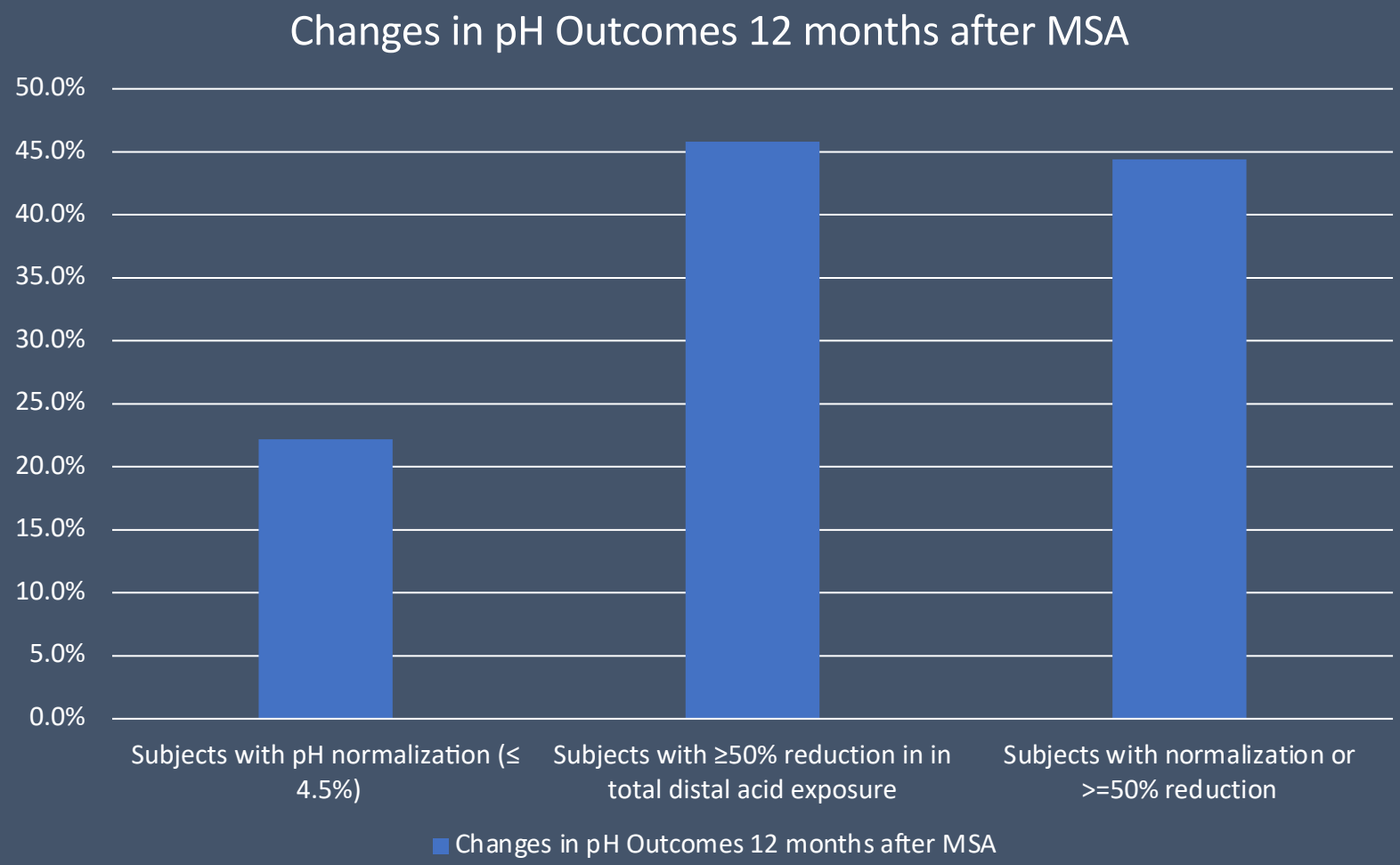
RELIEF Trial



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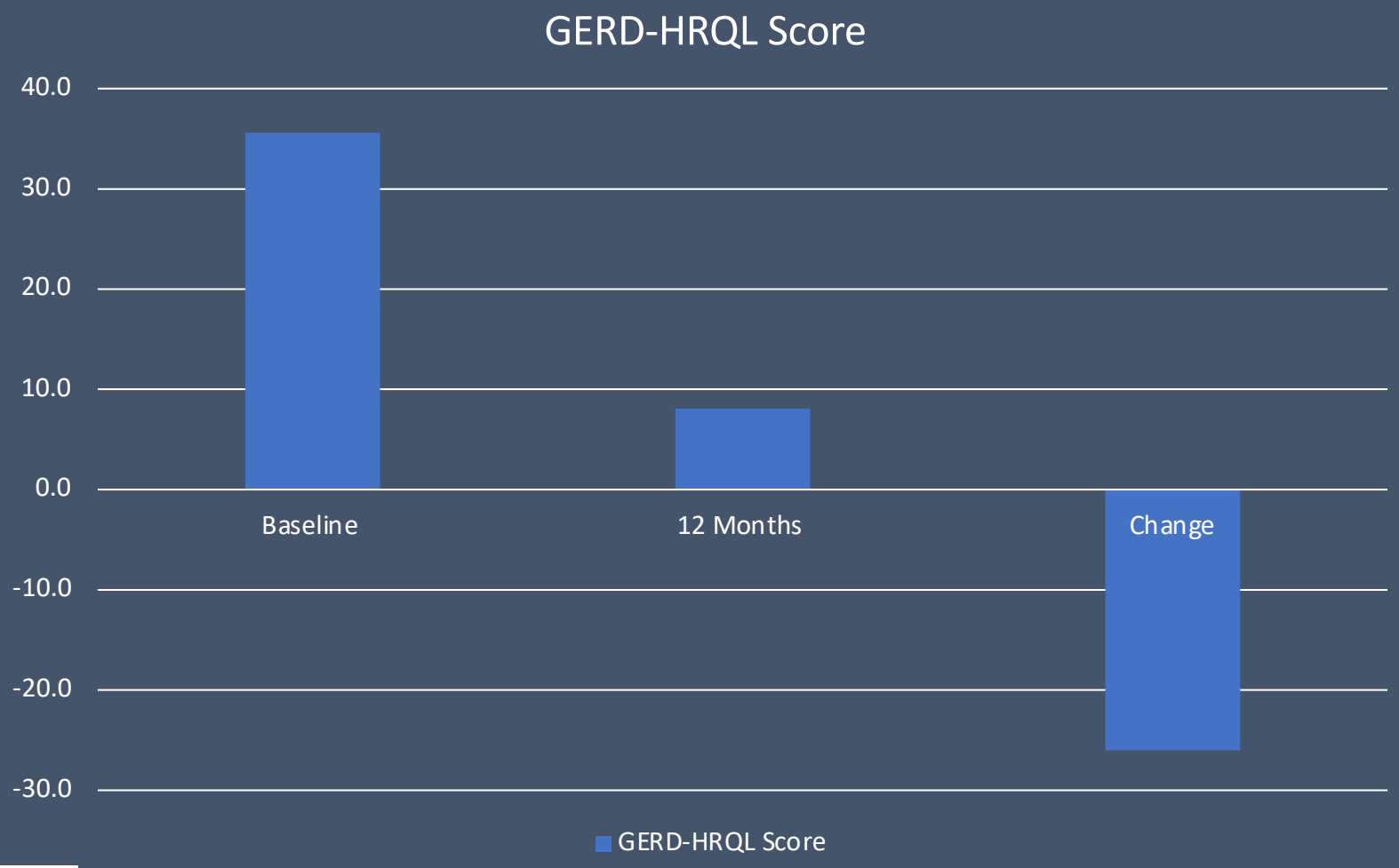
RELIEF Trial



80.8% had at least a 50% reduction in GERD-HRQL

* P < 0.001

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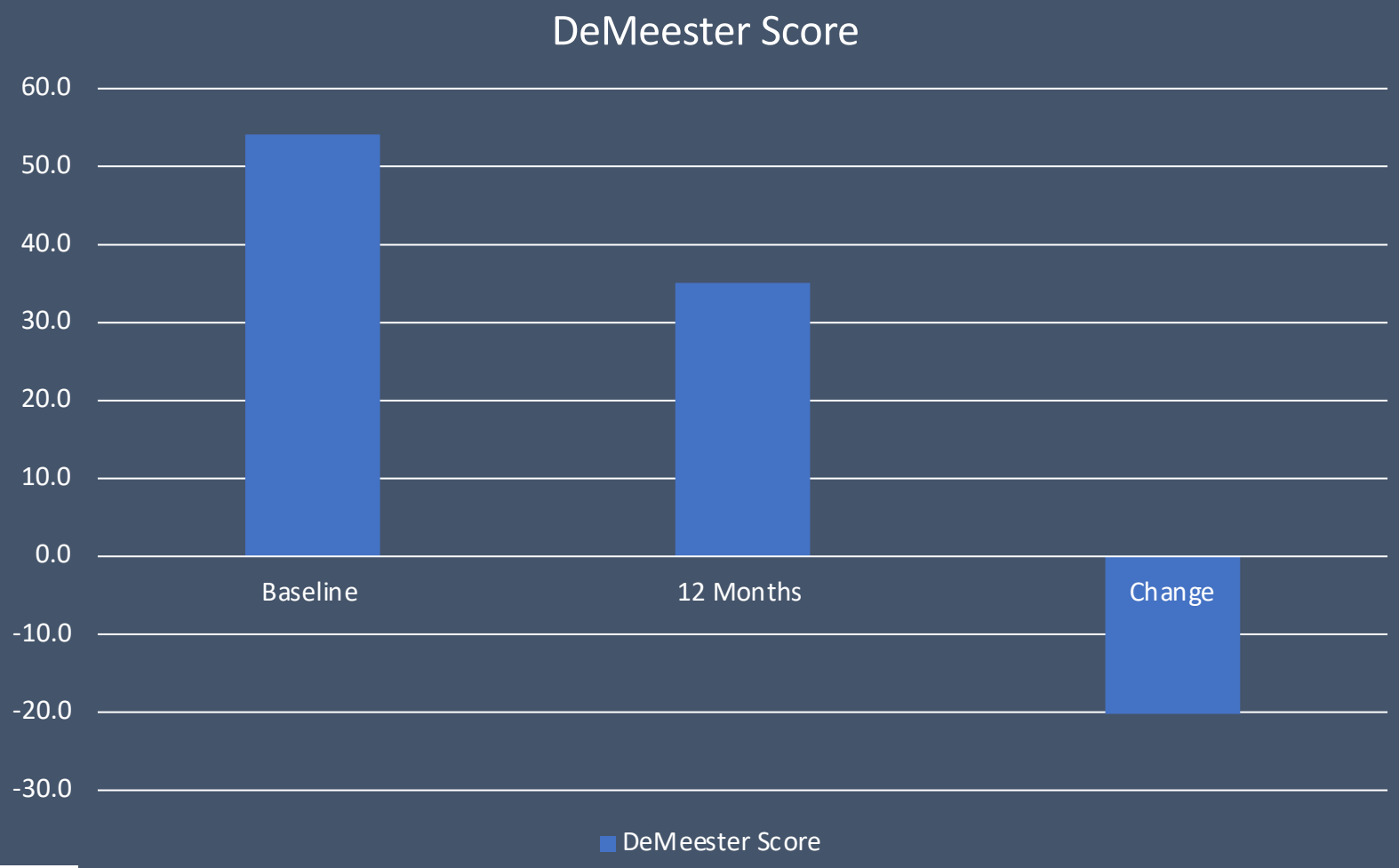
RELIEF Trial



16.7% had normal DeMeester 12 months (83.3% with improved but abnormal DeMeester)

* P=0.005

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Conclusions

- FDA IFU now allows for MSA in patients who have undergone LSG
- Patient selection remains critical
  - LINX does not overcome sleeve morphology contributing to GERD
    - Need to address underlying issue (hiatal hernia, sleeve stenosis, proximal dilation)
- No free lunch
  - RELIEF Trial
    - Dysphagia: 16.7%
    - Explantation: 6.7% (n=2, dysphagia and conversion to RYGBP)
- Is it the hiatal hernia repair or the LINX the critical component to reducing GERD after LSG?
- LINX can be considered as part of the surgical treatment of GERD after LSG in select patients

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DuPree CE et al. *JAMA Surg. 2014*
Oor JE et al. *Am J Surg.* 2016