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y Metabólica

# Magnetic Spinchter augmentation for Sleeve: Latest results . But erosion?

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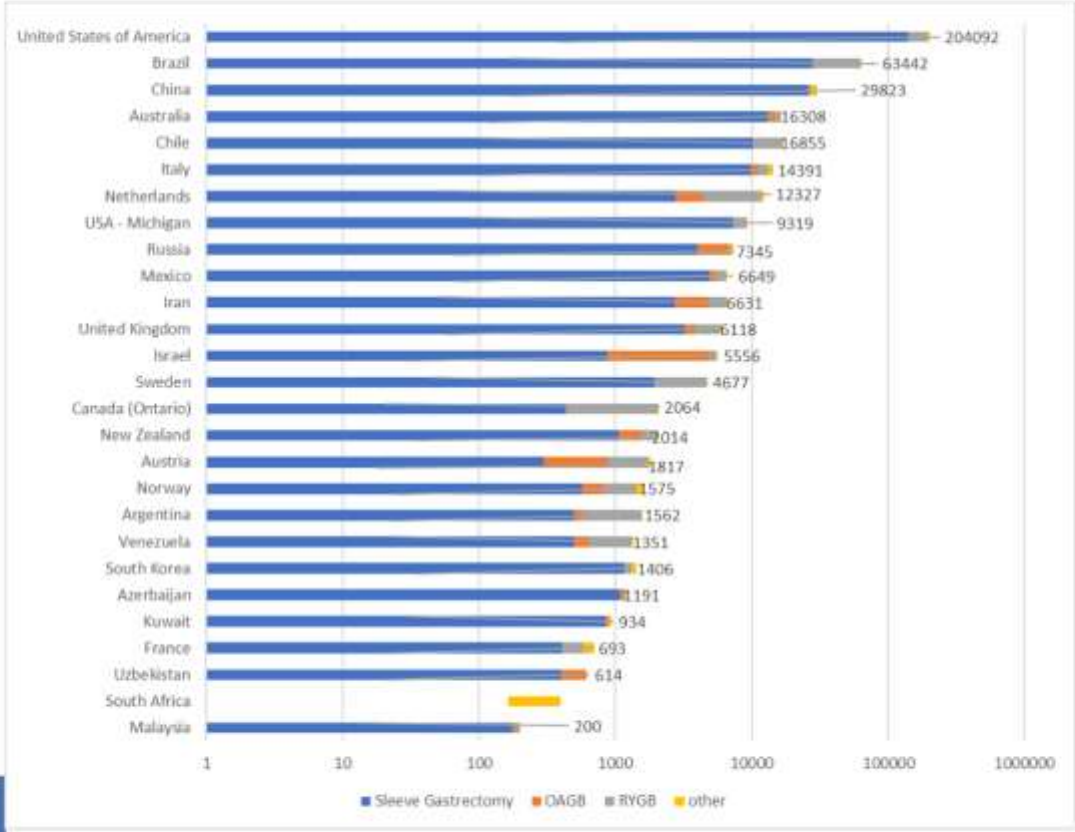
# Case Volume 2022 Worldwide




**450.000 cases**

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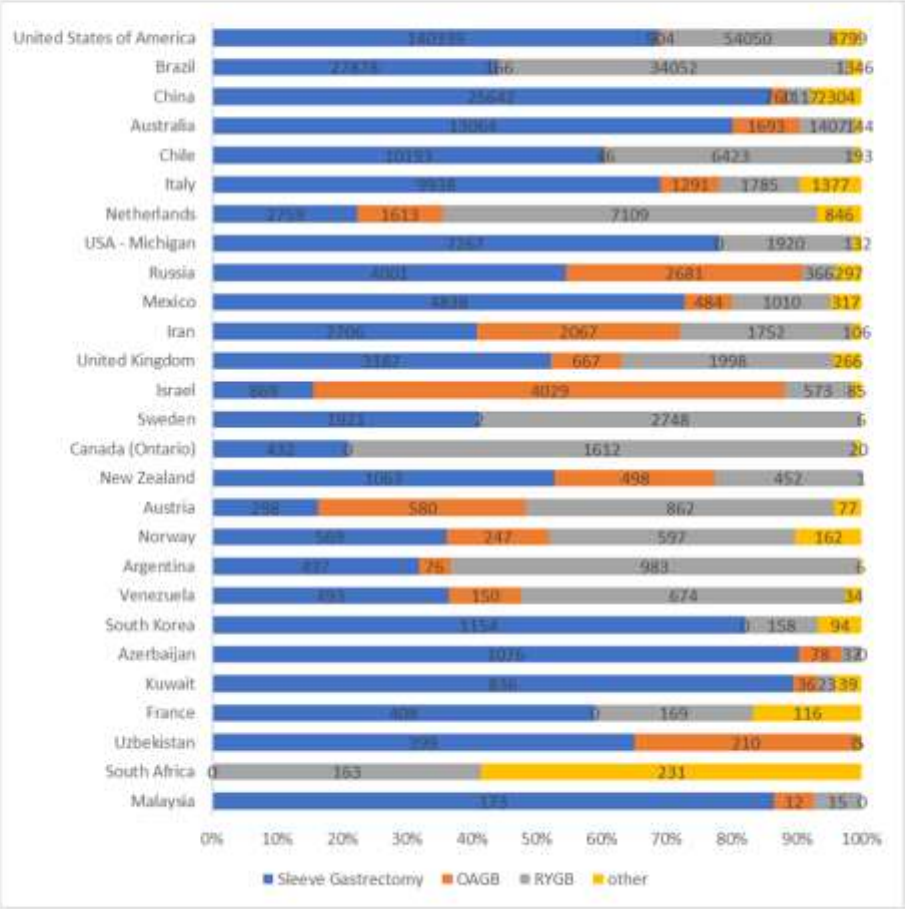
# Case Volume 2022 Worldwide




**270.000 Sleeves a year**

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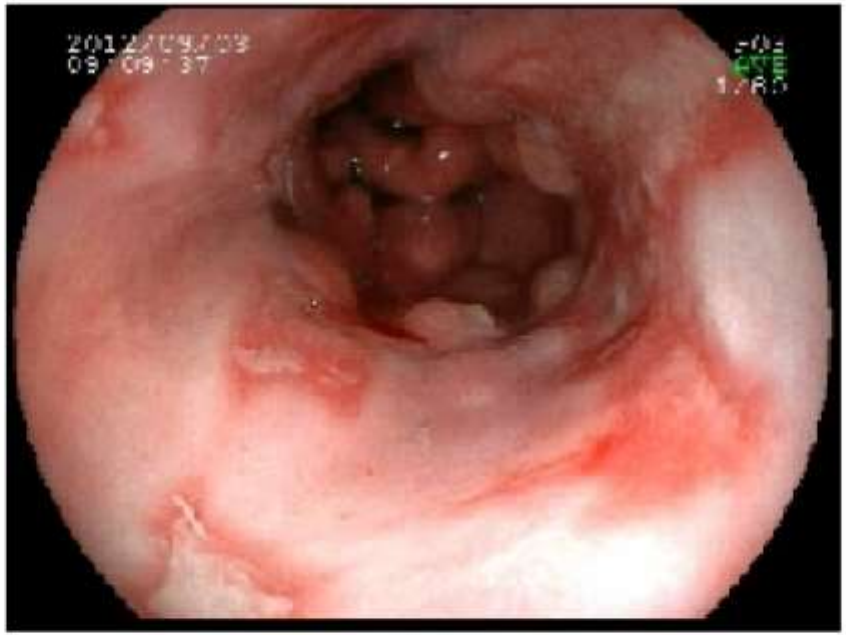
# Case



Original article

# Gastroesophageal reflux disease and Barrett's esophagus after laparoscopic sleeve gastrectomy: a possible, underestimated long-term complication

Alfredo Genco, M.D.[a], Emanuele Soricelli, M.D.[a,*], Giovanni Casella, M.D., Ph.D.[a], Roberta Maselli, M.D.[a], Lidia Castagneto-Gissey, M.D.[a], Nicola Di Lorenzo, M.D.[b], Nicola Basso, M.D.[a]

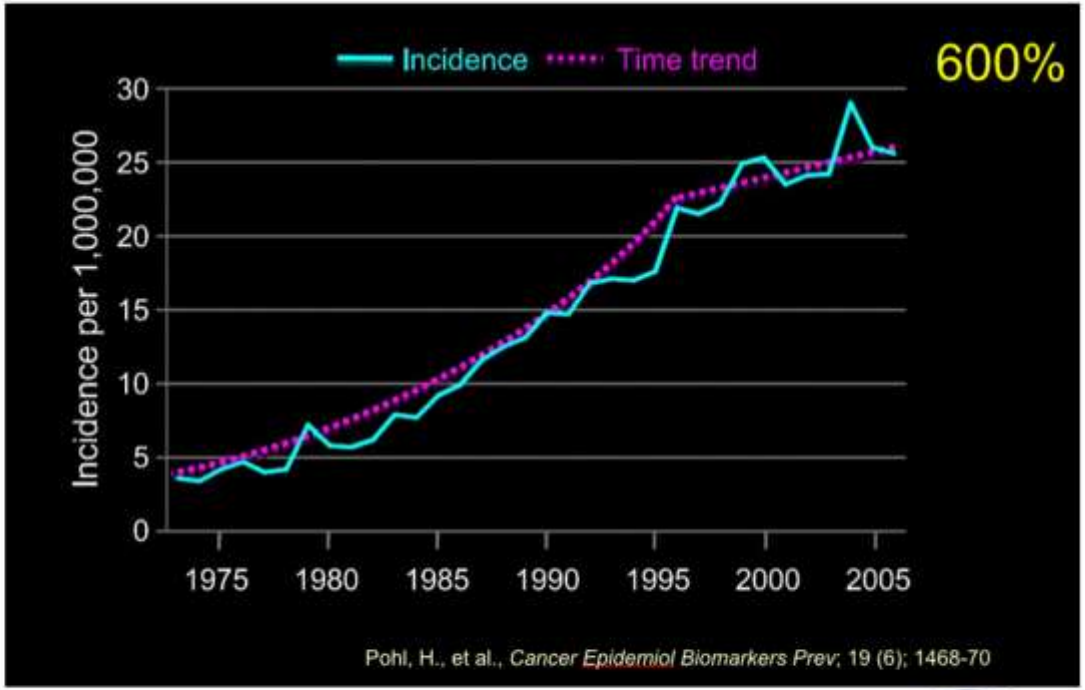
Table 1

Preoperative versus postoperative GERD symptoms, PPI intake, and endoscopic findings

| 110 patients | Preoperative | Follow-up | *P* |
|---|---|---|---|
| GERD symptoms | 33.6% (37 pts) | 68.1% (75 pts) | <.0001 |
| VAS score | 1.8 | 3 | .018 |
| Daily PPI intake | 19.1% (21 pts) | 57.2% (63 pts) | <.0001 |
| Class A esophagitis | 12.7% (14 pts) | 46.3% (51 pts) | <.0001 |
| Class B esophagitis | 8.1% (9 pts) | 32.7% (36 pts) | <.0001 |
| Class C esophagitis | 3.6% (4 pts) | 11.8% (13 pts) | .04 |
| Class D esophagitis | 0 | 9.1% (10 pts) | .0016 |
| Barrett's esophagus | 0 | 17.2% (19 pts) | <.0001 |

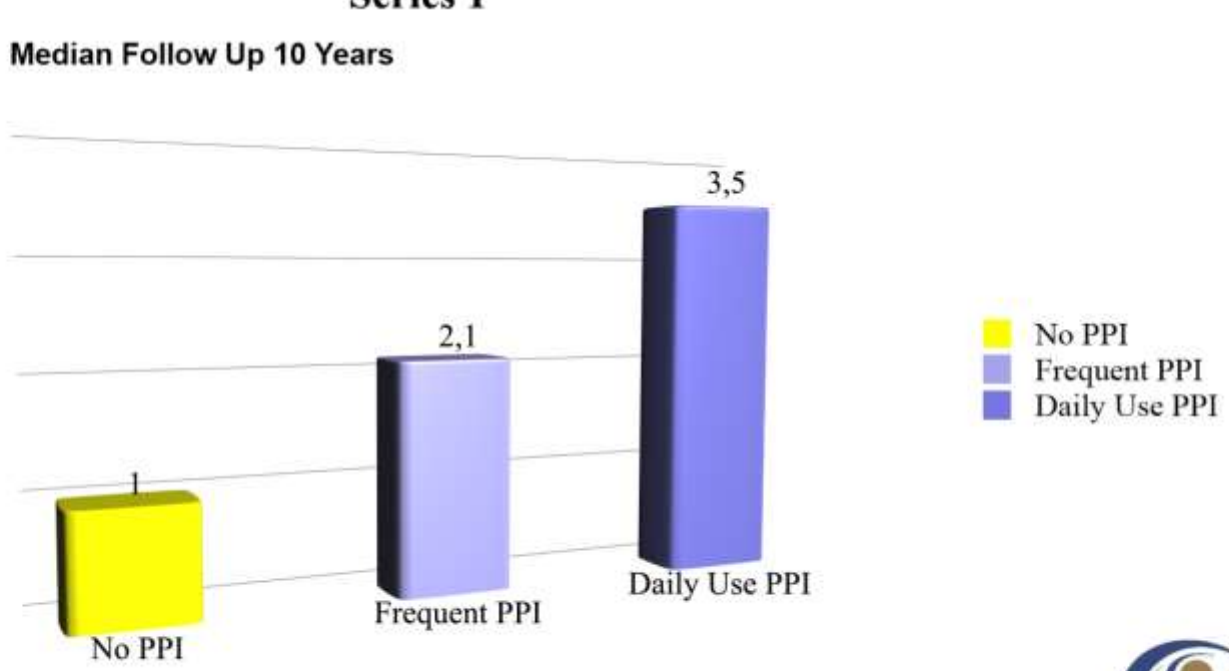
# Esophageal Cancer incidence

- "90-95% Success @ 1yr"
- 98% Success @ 3 mos (n=247)
- 139 pts median f/u 10.2 yrs
- 27.1% Failure @ 10 years
  - Primarily due to HH



# Progression to Adenocarcinoma While On PPI Therapy

***A nationwide study of 9883 newly diagnosed pts with Barrett's esophagus***




F. Hvid-Jensen et al. Aliment Pharmacol Ther 2014; 39: 984-991 Denmark

# LINX (Magnetic sphincter augmentation )


**Fig. 1** Timeline of procedure and device development

Tokarski A. Evolution of a novel technology for gastroesophageal reflux disease: a safety perspective of magnetic sphincter augmentation. Dis Esophagus. 2021 Nov 11;34(11):doab036. doi: 10.1093/dote/doab036. PMID: 34117494; PMCID: PMC8597906.

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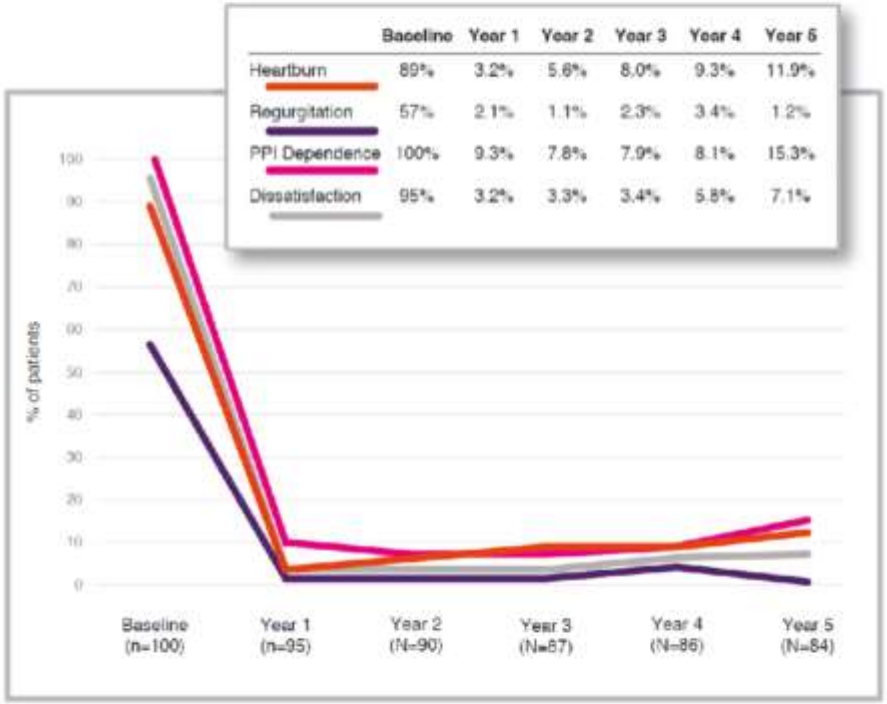
# LINX (Magnetic sphincter augmentation )


* Augment the Weak LES
* Increases LES Yield Pressure
* Preserves the Anatomy
* More Physiologic Design
* Allows for Belching
* Allows for Vomiting
* Reversible




Ganz et al. Clin Gastroenerol Hepatol: 2015 Jun 1.

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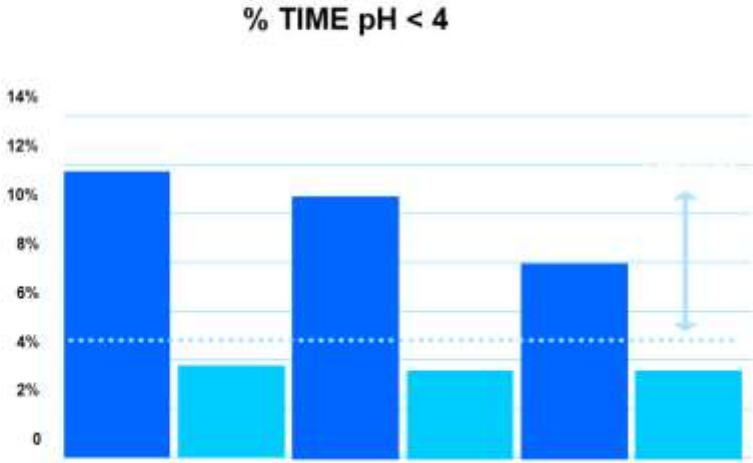
# Reduction in Esophageal Acid Exposure




| 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 |

Pilot: Lipham, et al. Surg Endosc DOI 10.1007/s00464-012-2289-1

Piv: Ganz et al. N Engl Med 2013 368;8

Milan: Bonavina, et al. J Am Coll Surg 2013;217:577-585

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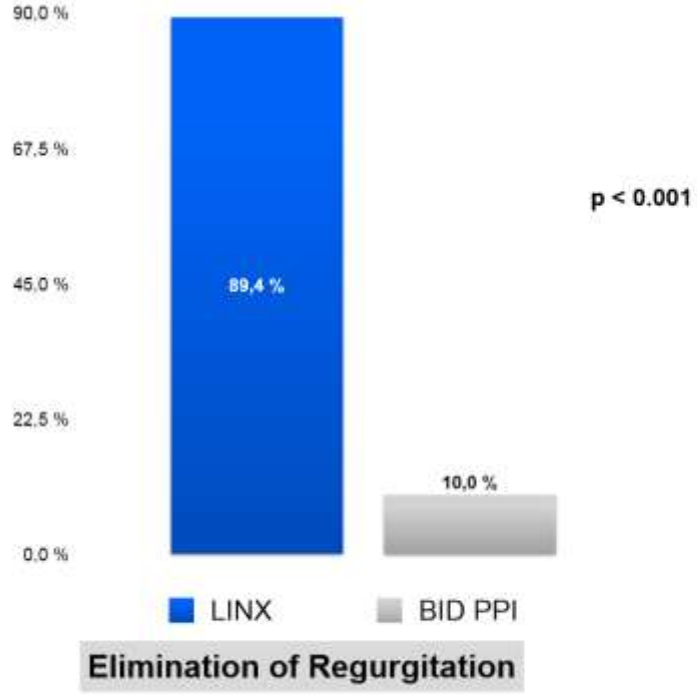
# RCT – Interim Results

## LINX vs PPI Regurgitation


- Study Design
  - 50 LINX
  - 100 BID PPI
  - Follow up at 6 mos
    - Symptoms, Impedance pH
- Reflux Normalization
  - Impedance pH
  - **91%** LINX vs
  - 58% BID PPI p<0.001
- GERD HRQL (>50% Improvement)
  - BID PPI 8% vs
  - LINX 81% p < 0.001
    - 92% PPI Elimination Rate



*Diseases of the Esophagus* (2021) 1–7
DOI: 10.1093/dote/doab036

DISEASES OF THE ESOPHAGUS

ISDE The International Society for Diseases of the Esophagus

**Original Article**

# Evolution of a novel technology for gastroesophageal reflux disease: a safety perspective of magnetic sphincter augmentation

Janet DeMarchi,[1] Michael Schwiers,[2] Mark Soberman,[3] Allison Tokarski[4]

**Table 1** Summary of clinical experience

| | |
|---|---|
| Number of patients | |
| USA | 24,070 |
| OUS | 3,709 |
| Number of implanting centers | |
| USA | ~350 |
| OUS | ~90 |
| Median (Q1, Q3) implant duration (months) | 19.6 (9.2, 33.3) |
| Number of patients by implant duration | |
| <1 year | 8,836 (31.8%) |
| 1–3 years | 12,961 (46.7%) |
| >3–5 years | 4,060 (14.6%) |
| >5 years | 1,922 (6.9%) |

Tokarski A. Evolution of a novel technology for gastroesophageal reflux disease: a safety perspective of magnetic sphincter augmentation. Dis Esophagus. 2021 Nov 11;34(11):doab036. doi: 10.1093/dote/doab036. PMID: 34117494; PMCID: PMC8597906.

# Evolution of a novel technology for gastroesophageal reflux disease: a safety perspective of magnetic sphincter augmentation

Janet DeMarchi,[1] Michael Schwiers,[2] Mark Soberman,[3] Allison Tokarski[4]

**Table 2** Reason for device removal and mean time to removal

| Reason for removal | Number of removals | Percentage of total removals | Mean time to removal, months (±SD) |
|---|---|---|---|
| Dysphagia | 292 | 47.9 | 10.9 (11.9) |
| Persistent GERD | 125 | 20.5 | 20.5 (13.0) |
| Erosion | 27 | 4.4 | 25.0 (12.9) |
| Abdominal pain/pain | 46 | 7.6 | 15.8 (14.3) |
| Discontinuous device† | 17 | 2.8 | 33.7 (6.0) |
| Need for MRI | 11 | 1.8 | 28.6 (13.2) |
| Vomiting | 16 | 2.6 | 7.4 (8.2) |
| Gastroparesis | 4 | 0.7 | 20.7 (18.5) |
| Device migration | 3 | 0.5 | 12.6 (17.7) |
| Other/unknown | 68 | 11.2 | 6.8 (6.4) |
| **Total removals** | **609** | **100.0** | **14.6 (13.4)** |

†Discontinuous devices were the result of a manufacturing issue that resulted in a voluntary recall in 2018.

Tokarski A. Evolution of a novel technology for gastroesophageal reflux disease: a safety perspective of magnetic sphincter augmentation. Dis Esophagus. 2021 Nov 11;34(11):doab036. doi: 10.1093/dote/doab036. PMID: 34117494; PMCID: PMC8597906.

# Standard vs Expanded Indications for Esophageal Magnetic Sphincter Augmentation for Reflux Disease

## Standard Indications

- Patients with GERD
- Normal motility
- Body mass index < 35
- No prior foregut surgery
- No or small (<3 cm) hiatal defect

## Expanded Indications

- Prior sleeve gastrectomies
- Prior fundoplications
- Prior gastric bypass
- Hiatal hernias larger than 3 cm
- BMI > 35

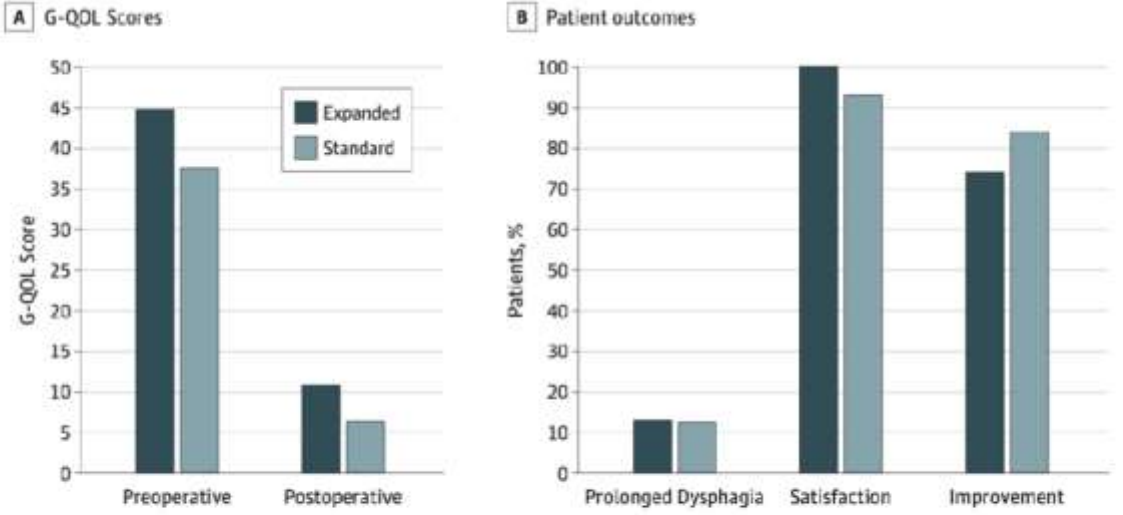
Kuckelman JP, Phillips CJ, Hardin MO, Martin MJ. Standard vs Expanded Indications for Esophageal Magnetic Sphincter Augmentation for Reflux Disease. JAMA Surg. 2017 Sep 1;152(9):890-891. doi: 10.1001/jamasurg.2017.1606. PMID: 28593252; PMCID: PMC5831443.

JAMA Surgery
American Medical Association

# Standard vs Expanded Indications for Esophageal Magnetic Sphincter Augmentation for Reflux Disease

John P. Kuckelman, DO, Cody J. Phillips, DO, [...], and Matthew J. Martin, MD

## Figure. Postoperative Outcomes Shown for Both Expanded and Standard Indications




Preoperative and postoperative gastroesophageal reflux disease quality of life (G-QOL) scores (A) and patient outcomes (B) shown for both expanded and standard indications. There were no significant differences seen between the 2 groups.

Kuckelman JP, Phillips CJ, Hardin MO, Martin MJ. Standard vs Expanded Indications for Esophageal Magnetic Sphincter Augmentation for Reflux Disease. JAMA Surg. 2017 Sep 1;152(9):890-891. doi: 10.1001/jamasurg.2017.1606. PMID: 28593252; PMCID: PMC5831443.

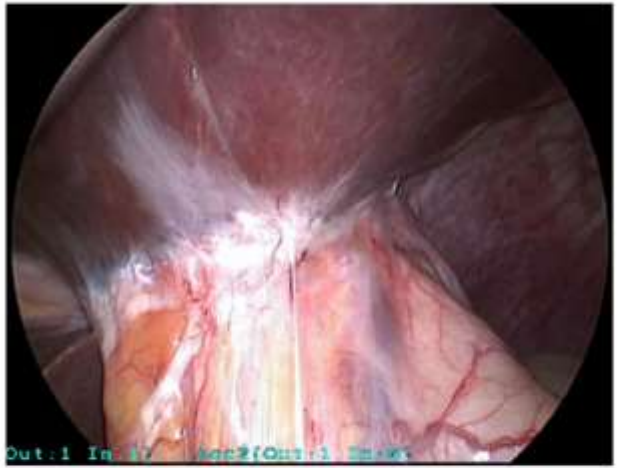
Surgical Endoscopy
https://doi.org/10.1007/s00464-018-6059-6

es?

# Hiatal hernia recurrence following magnetic sphincter augmentation and posterior cruroplasty: intermediate-term outcomes

Kais A. Rona[1] · James M. Tatum[1] · Joerg Zehetner[3] · Katrin Schwameis[1] · Carol Chow[2] · Kamran Samakar[1] · Adrian Dobrowolsky[1] · Caitlin C. Houghton[1,2] · Nikolai Bildzukewicz[1,2] · John C. Lipham[2,4]

- 47 of 52 pts >1yr post op
- Follow up Yearly
  - VEG and/or EGD
- Median Follow up 19 mos (12-39)
  - GERD HRQL 20.3 to 3.1
  - PPI Elimination Rate 89%
- Recurrence Rate (2/47) 4.3%
- Preliminary Recurrence Rate Appears to be Lower than Standard Repair

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# Magnetic sphincter augmentation: a viable rescue therapy for symptomatic reflux following bariatric surgery

Ryan C. Broderick[1] · C. Daniel Smith[2] · Joslin N. Cheverie[1] · Pablo Omelanczuk[3] · Arielle M. Lee[1] · Rebeca Dominguez-Profeta[1] · Robert Cubas[1] · Garth R. Jacobsen[1] · Bryan J. Sandler[1] · Karl-Hermann Fuchs[1] · Santiago Horgan[1]

13 identified patients underwent LINX placement after bariatric surgery

8 LSG, 4 LRYGB, and 1 duodenal switch.

77% female

average BMI 30.1

Pre-operative DeMeester score was 24.8

5 patients were on daily PPI, 6 on BID PPI, and 1 on PPI + H2 blocker.

## Results

- Decreased medication usage post-operatively, with 4 patients taking daily PPI, and 9 off medication completely.
- A GERD-HRQL score was obtained pre- and post-operatively in 6 patients with average reduction from 25 to 8.5 ($p$ value 0.002).
- Two patients experienced complications requiring endoscopic dilation after LINX placement. 100% of patients reported overall satisfaction post procedure

Broderick RC, Smith CD, Cheverie JN, Omelanczuk P, Lee AM, Dominguez-Profeta R, Cubas R, Jacobsen GR, Sandler BJ, Fuchs KH, Horgan S. Magnetic sphincter augmentation: a viable rescue therapy for symptomatic reflux following bariatric surgery. Surg Endosc 2020 Jul;34(7):3211-3215. doi: 10.1007/s00464-019-07096-z. Epub 2019 Sep 4. PMID: 31485930.

# Feasibility and Efficacy of Magnetic Sphincter Augmentation for the Management of Gastroesophageal Reflux Disease Post-Sleeve Gastrectomy for Obesity

Leena Khaitan[1] · Michael Hill[2] · Michael Michel[3] · Patrick Chiasson[4] · Philip Woodworth[5] · Reginald Bell[5] · Ragui Sadek[6] · Aaron Hoffman[7] · Kari Loing[8] · Paula Veldhuis[8] · William Petraiuolo[8] · Carlos Anciano[9]

- 31 Linx Implants after Sleeve gastrectomy
- 2 Removals
- At 12 months post-LINX implant, 80.8% of subjects reported at least a 50% reduction in total GERD-HRQL scores when compared with baseline
- Percentage of subjects who reported being dissatisfied with their GERD symptoms went from 96.7% (29/30) at baseline to 23.1% (6/26) at 12 months.
- DeMeester score at baseline was 54.1 and at 12 months decreased to 35.1 ($P = 0.005$).

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# Linx post Bariatric Surgery in Chile

**Camilo Boza MD FACS FASMBS**
**Clínica Meds , Santiago , Chile**

# My cases

22 year old

66 year old

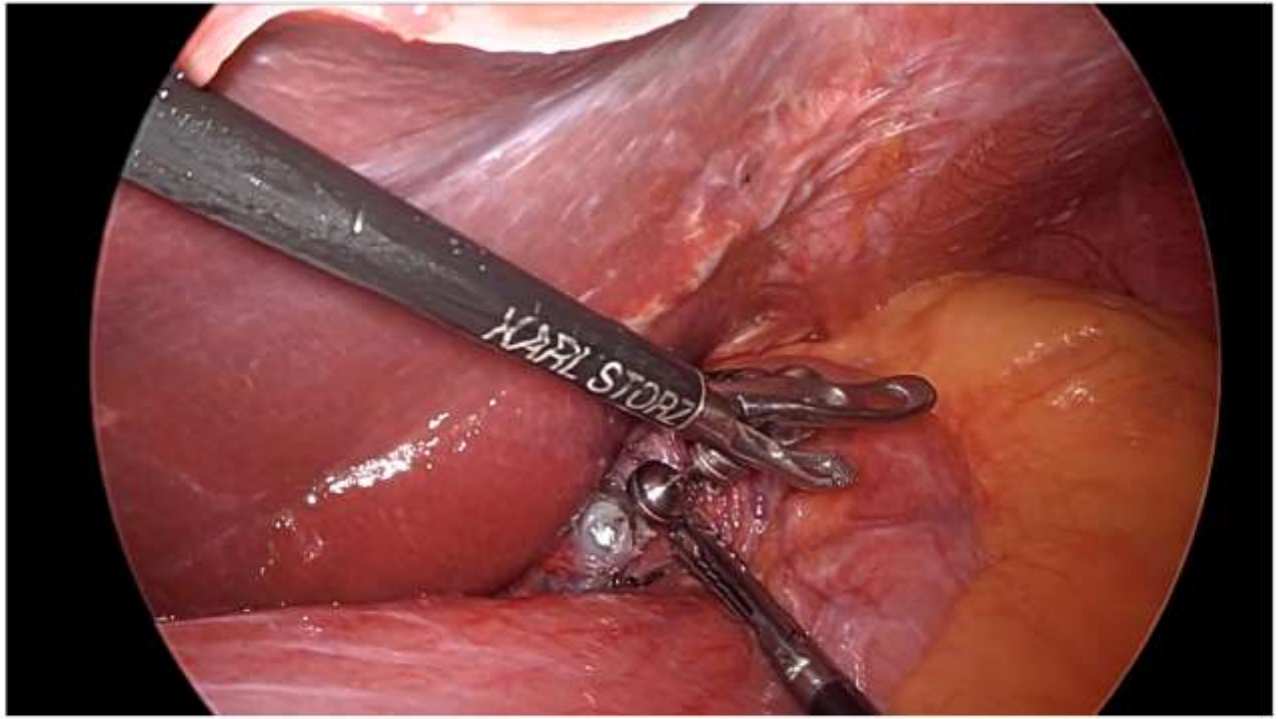

15/03/2018
01:31:38 PM
1/60
3

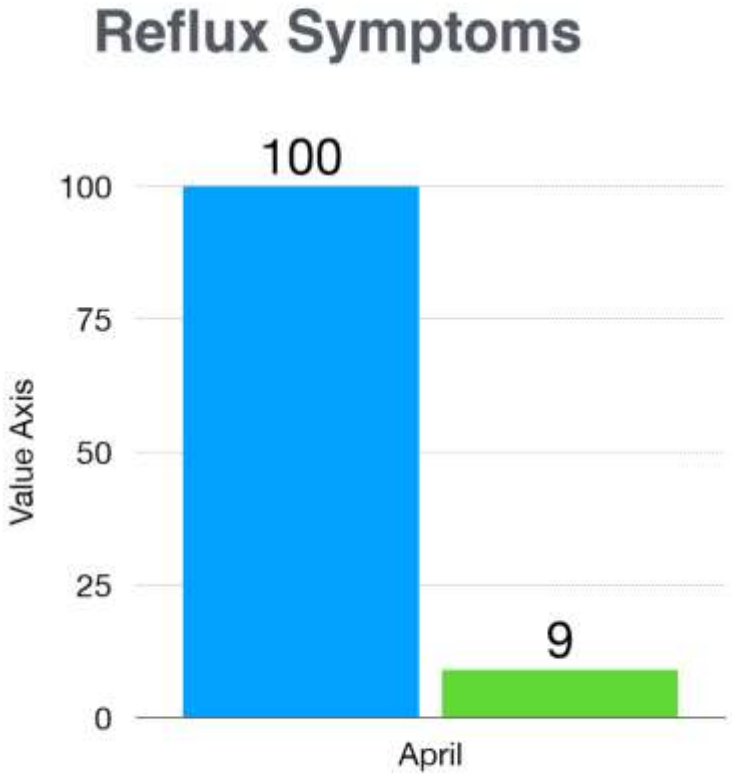
# Linx post Bariatric

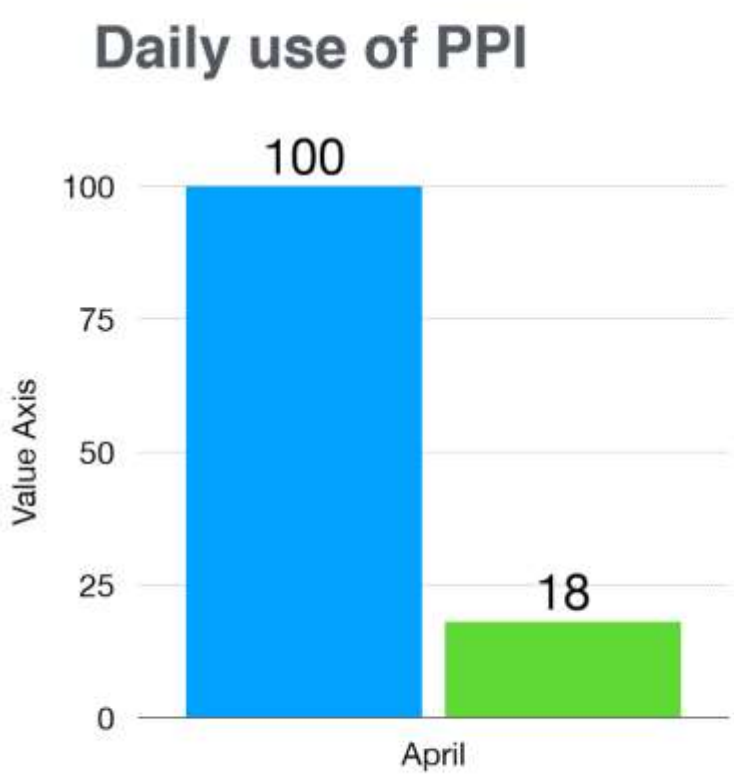
- 26 cases
- 24 after Sleeve - 2 after Bypass
- Daily use of PPI
- Regurgitation
- Bad quality of life

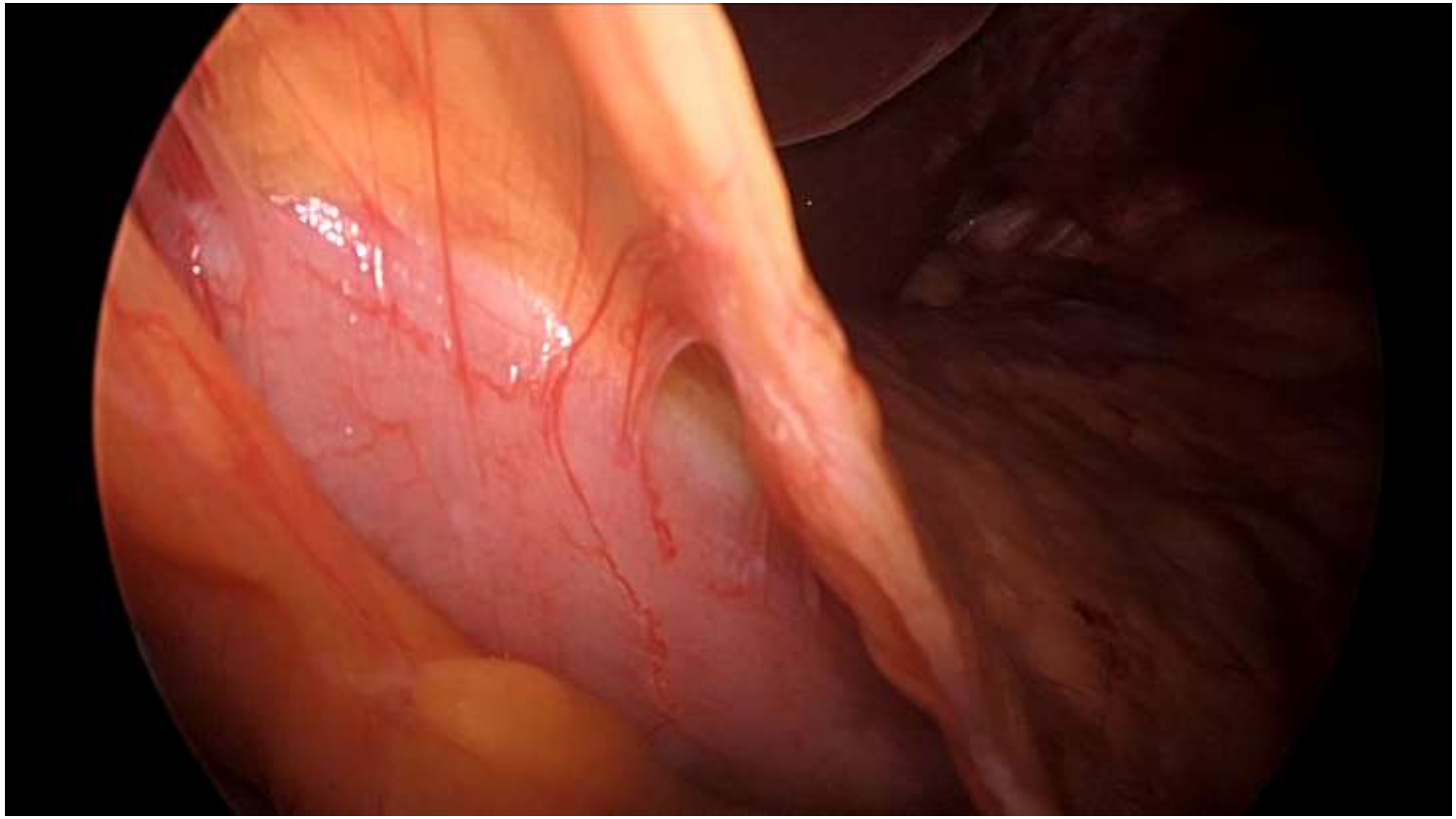
- Surgical complications : 0%
- Late removal 4/26 15%
- Satisfied 72%

# Linx post Bariatric




Reflux Symptoms
100
100
75
50
25
0
Value Axis
9
April


Daily use of PPI
100
100
75
50
25
0
Value Axis
18
April



# Discusion

- Linx is a reasonable option for Reflux after sleeve
- Always resolve hiatal hernia
- The holy grail will be how to lower sleeve migration

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