

Session: "SURGICAL ECONOMICS"
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"The Raise and Fall of Beloved Medical Devices – Lessons Learned"

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**Weight Loss Center
of Chattanooga**

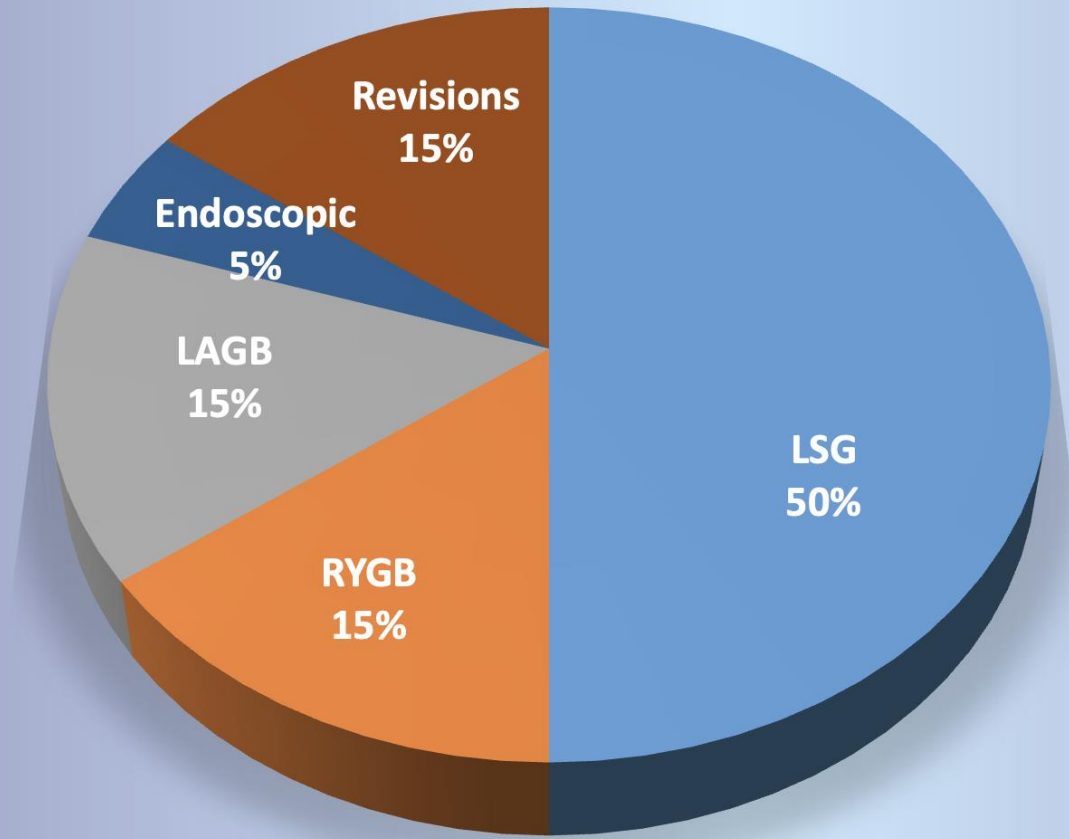
Medical and Surgical Weight Loss Specialists

Conflict of Interest Disclosures

- Gore: speaker
- ReShape Lifesciences: consultant
- Olympus: speaker
- Allurion: consultant
- Medtronic: consultant, speaker
- Applied Medical: consultant
- Ethicon: speaker
- Intuitive: speaker
- GT Metabolic: consultant, speaker

Case Mix Disclosure Slide

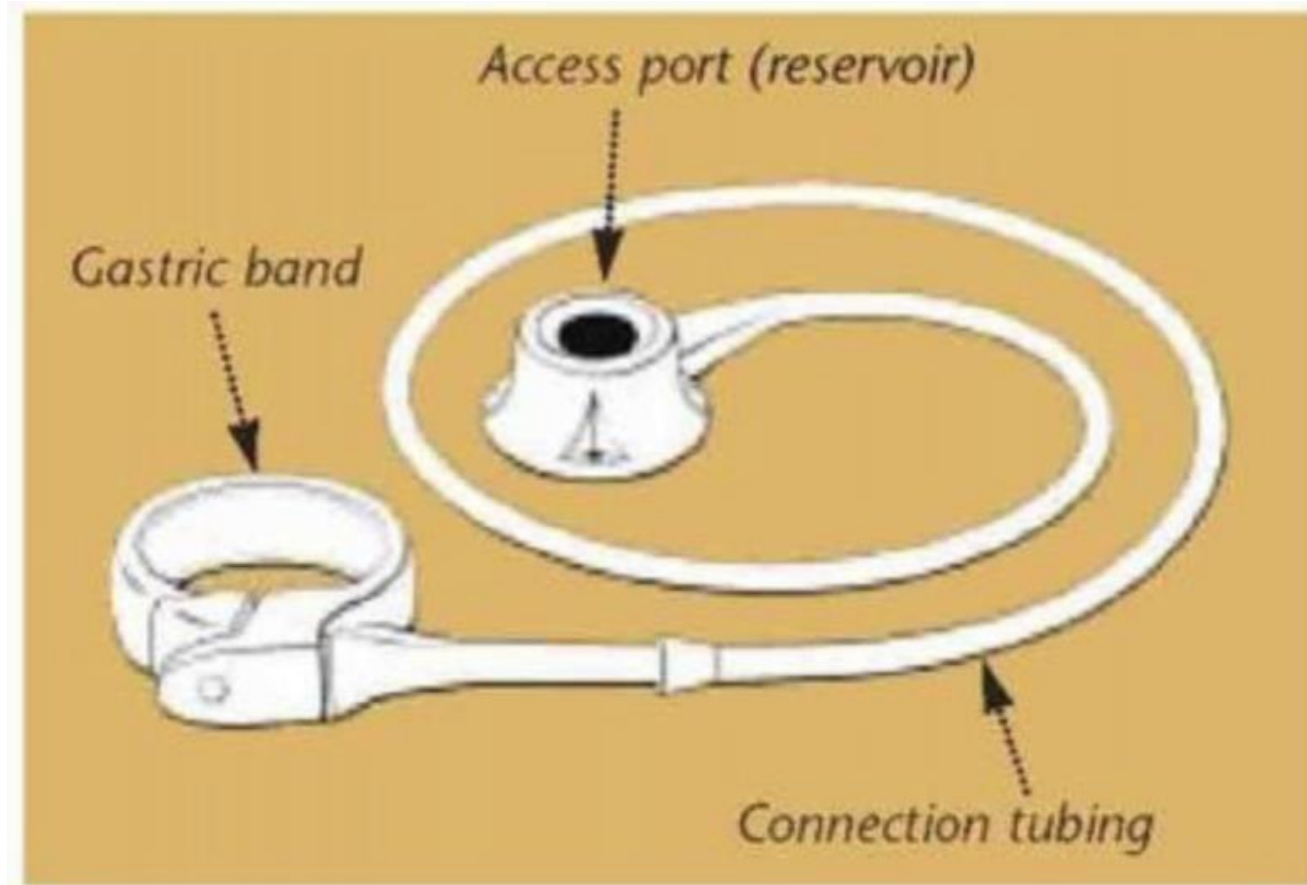
Whole career procedures



- LSG
- RYGB
- LAGB
- BPD/DS
- OAGB
- LoopDS
- Endoscopic
- Revisions

Raise and Fall of a Medical Device: A Case Study on the Lap-Band

Lap-Band FDA approved in 2001



FDA clinical trial A

36% EWL at 3 yrs

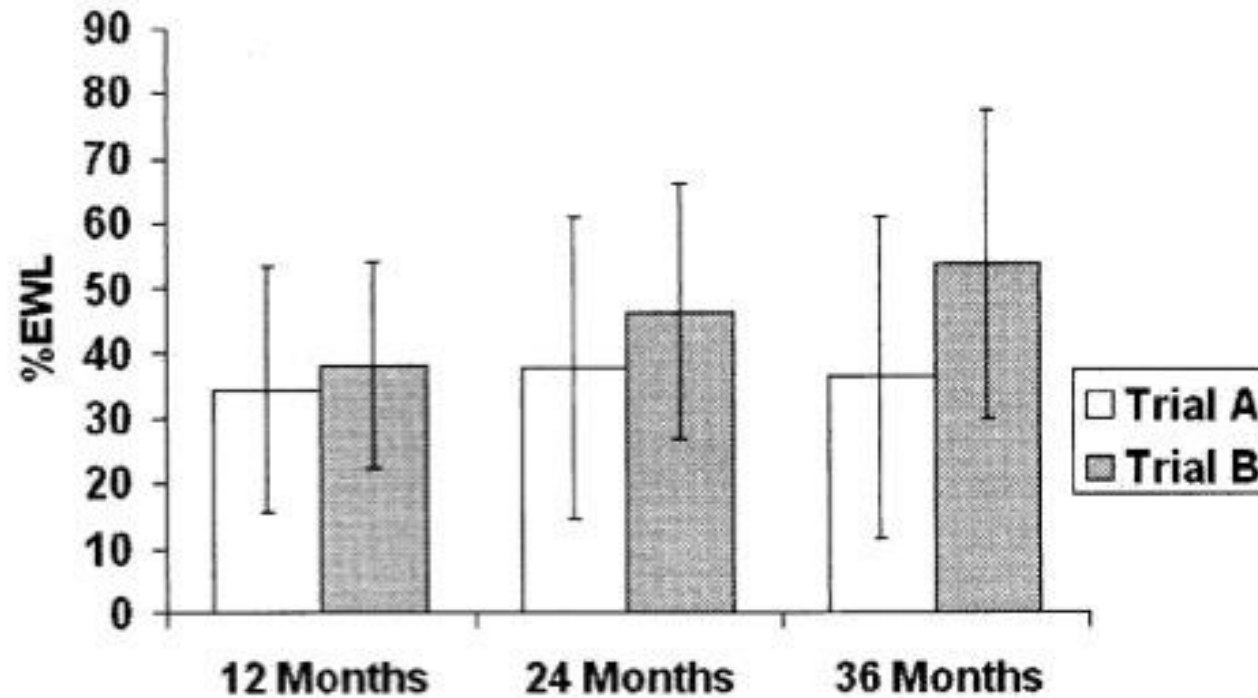
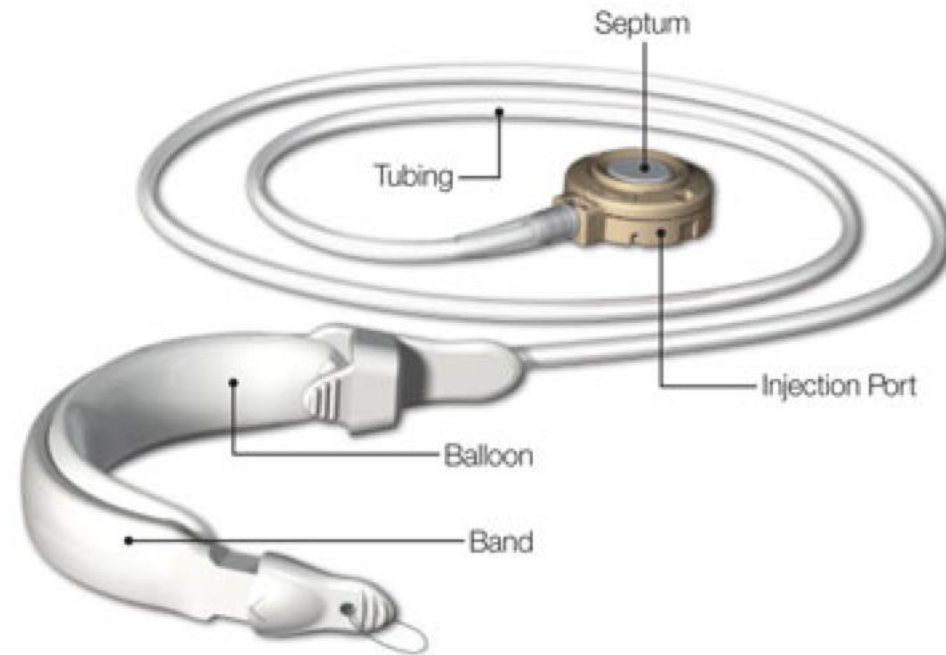
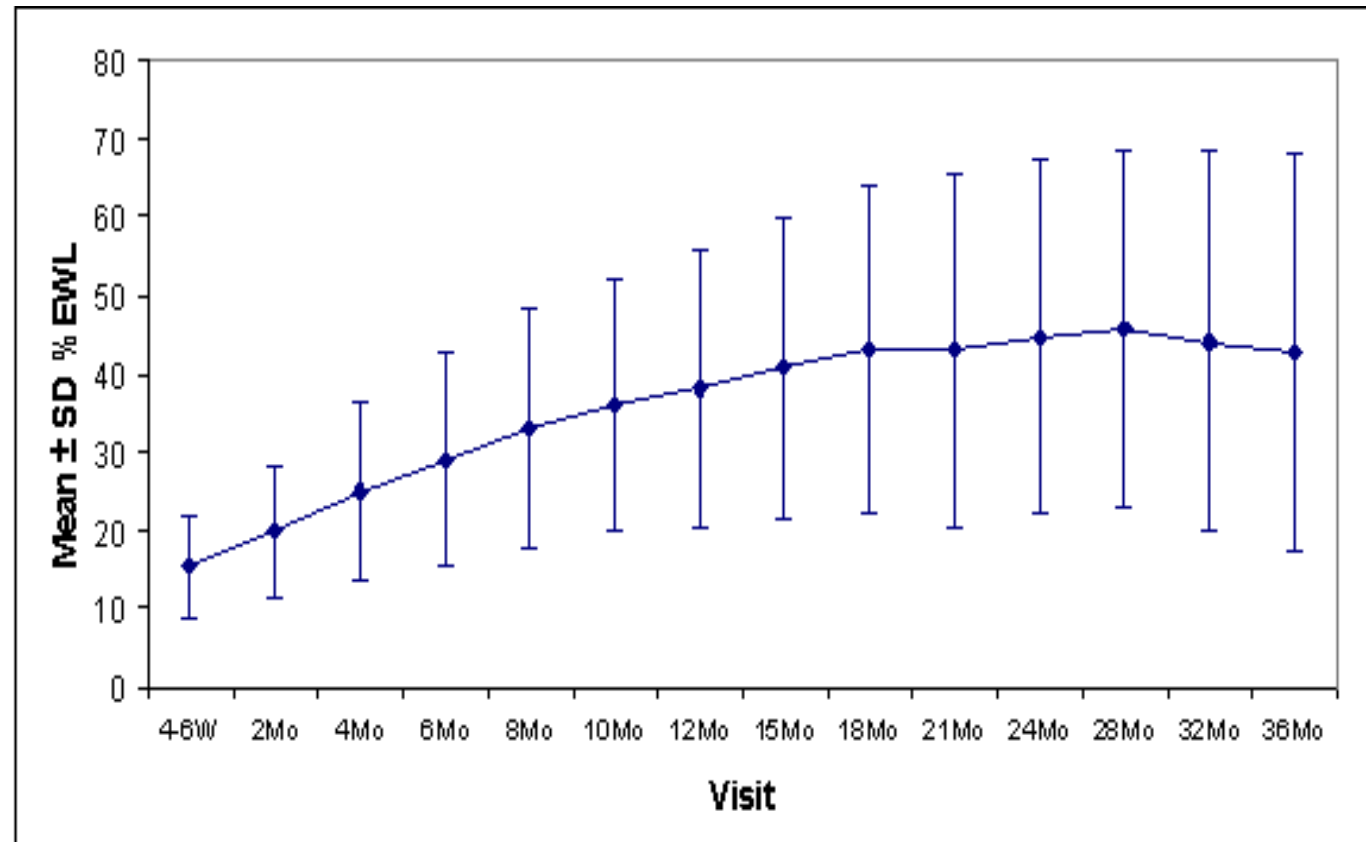


Fig. 1. Mean percent excess weight loss (%EWL) by follow-up visit is shown for Food and Drug Administration (FDA) Trial A [11] and for 63 patients in FDA Trial B [12] of the LAP-BAND device.

Realize band FDA approved in 2007



U.S. Swedish Band Trial Observed %EWL by Visit (2006)



41%EWL


What has happened since 2001?

The Promise of the Lap-Band

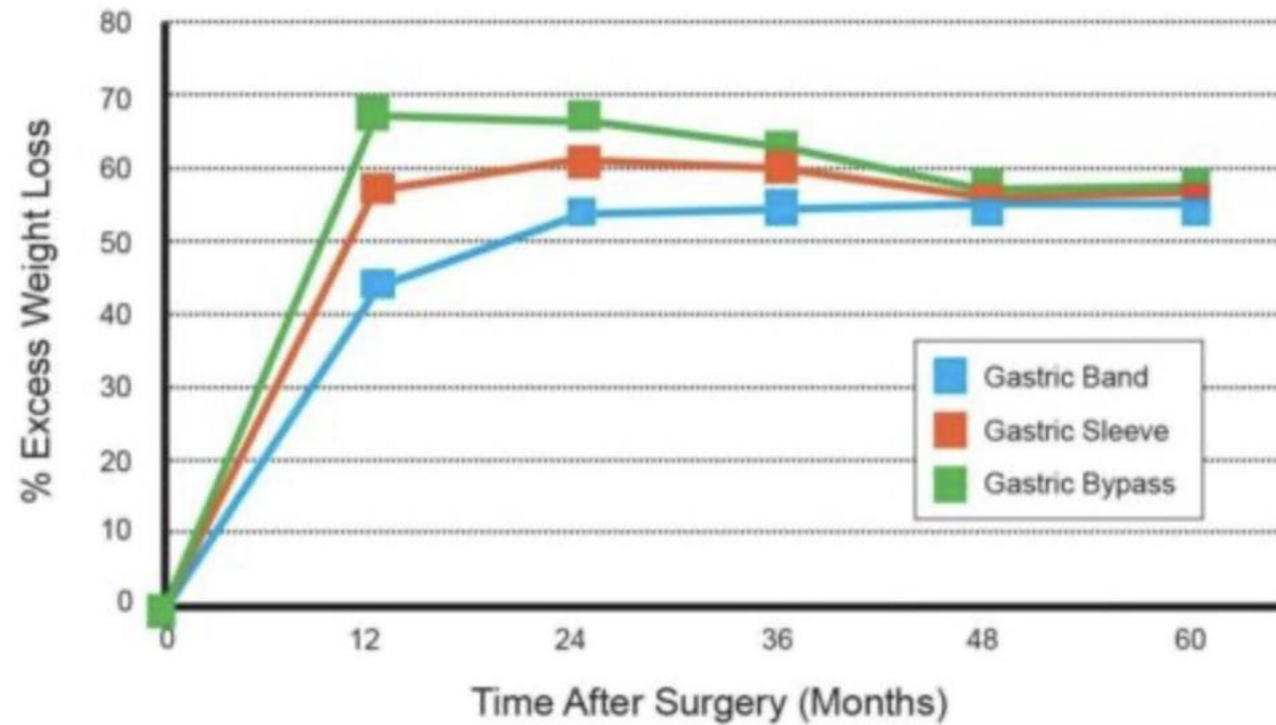
- Marketed as:
 - ✓ Minimally invasive
 - ✓ Reversible and adjustable
 - ✓ Low complication profile (initially)

Rapid **adoption by surgeons and patients**

First major mistake:

 **Overstating Lap-Band results and comparing it to gastric bypass** in terms of weight loss and outcomes — despite lack of equivalent data (“**overselling the outcomes**”)

Became **synonymous with bariatric innovation** in the early 2000s



O'Brien et al. Obesity is a Surgical Disease: Overview of Obesity and Bariatric Surgery, ANZ J Surg, **2004**; 74: 200-204.

Peak Success – Commercial & Clinical Boom

10-fold increase in cases between 2001–2006

Aggressive **direct-to-consumer marketing**

Centers built **entire business models** around it

Appealed to **low-risk patients** and self-pay models

- Industry partners invested heavily in **training & infrastructure**

Change your outside



Alex Jones
lost 85 lbs.
Results may vary

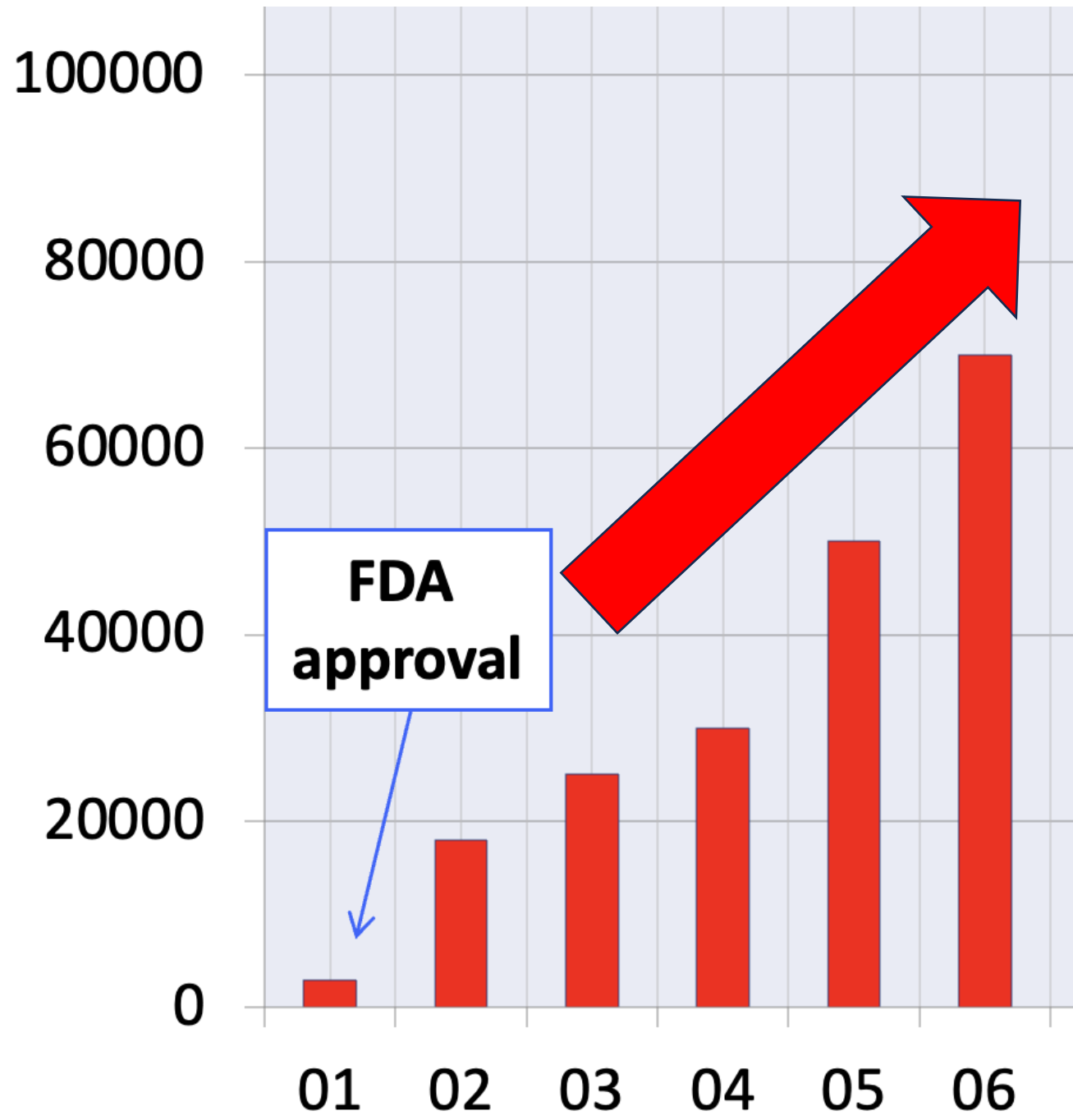


Keep your insides



Keep the Weight Off & the Stomach In



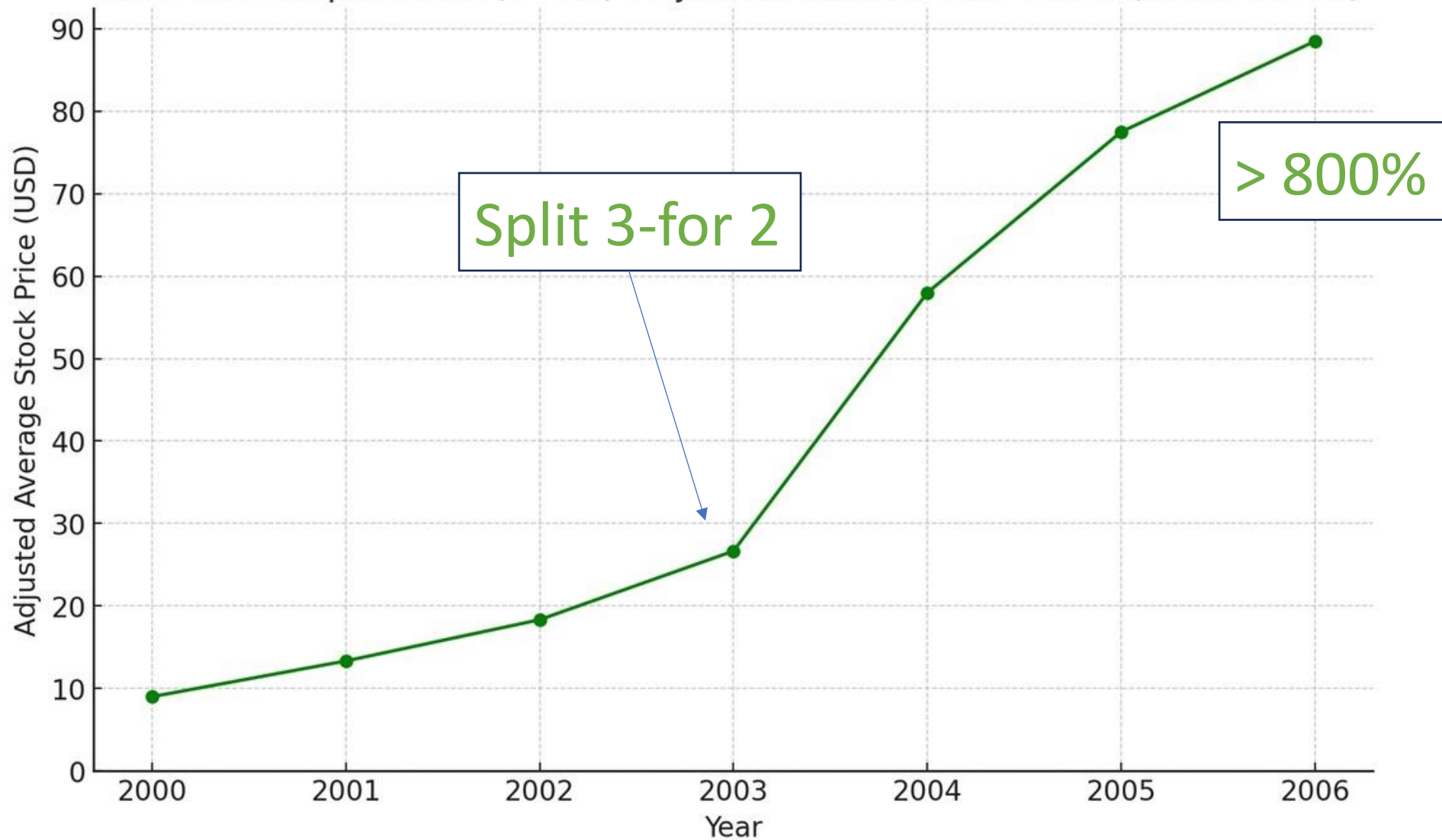




Industry - major lost of an opportunity

- Ethicon (J&J) decided NOT to purchase the Lap-Band in 2001 and bought the Swedish Band in 2002 for \$112 million (with NO FDA approval and a competitive FDA approved product)
 - Started FDA trial: 2003 -> FDA approval: 2007
- INAMED was selling in 5 years close to \$400 million
- INAMED was acquired by Allergan for \$3.2 Billion in 2006

INAMED Corporation (IMDC) Adjusted Stock Price Trend (2000-2006)





Real-world outcomes failed to match
initial promise

Great variability between band patients and
centers

Weight Loss distribution

Bessler et al SOARD 4(2008):468-91

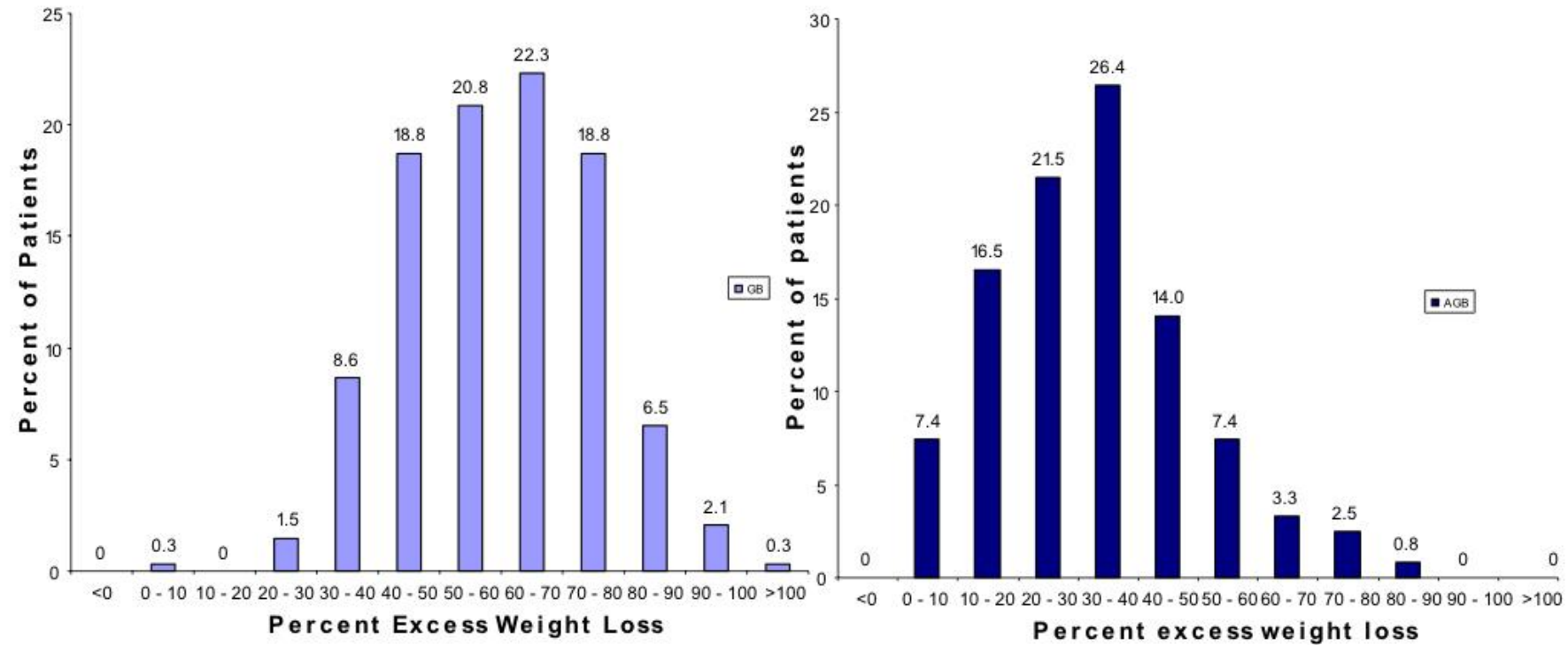


Fig. 1. %EWL at 1 year postoperatively.

Weight Loss distribution

Bessler et al SOARD 4(2008):468-91

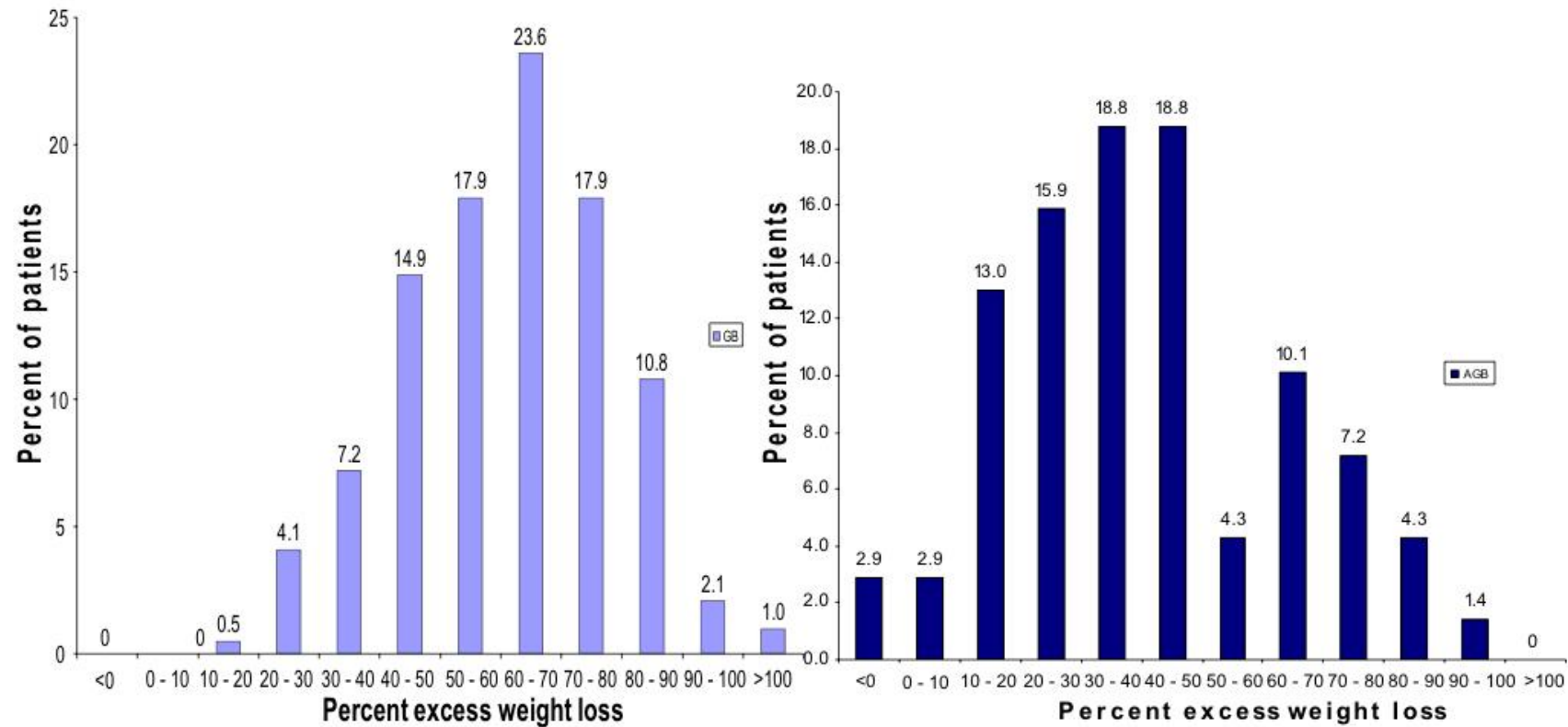


Fig. 2. %EWL at 2 years postoperatively.

Weight Loss distribution

Bessler et al SOARD 4(2008):468-91

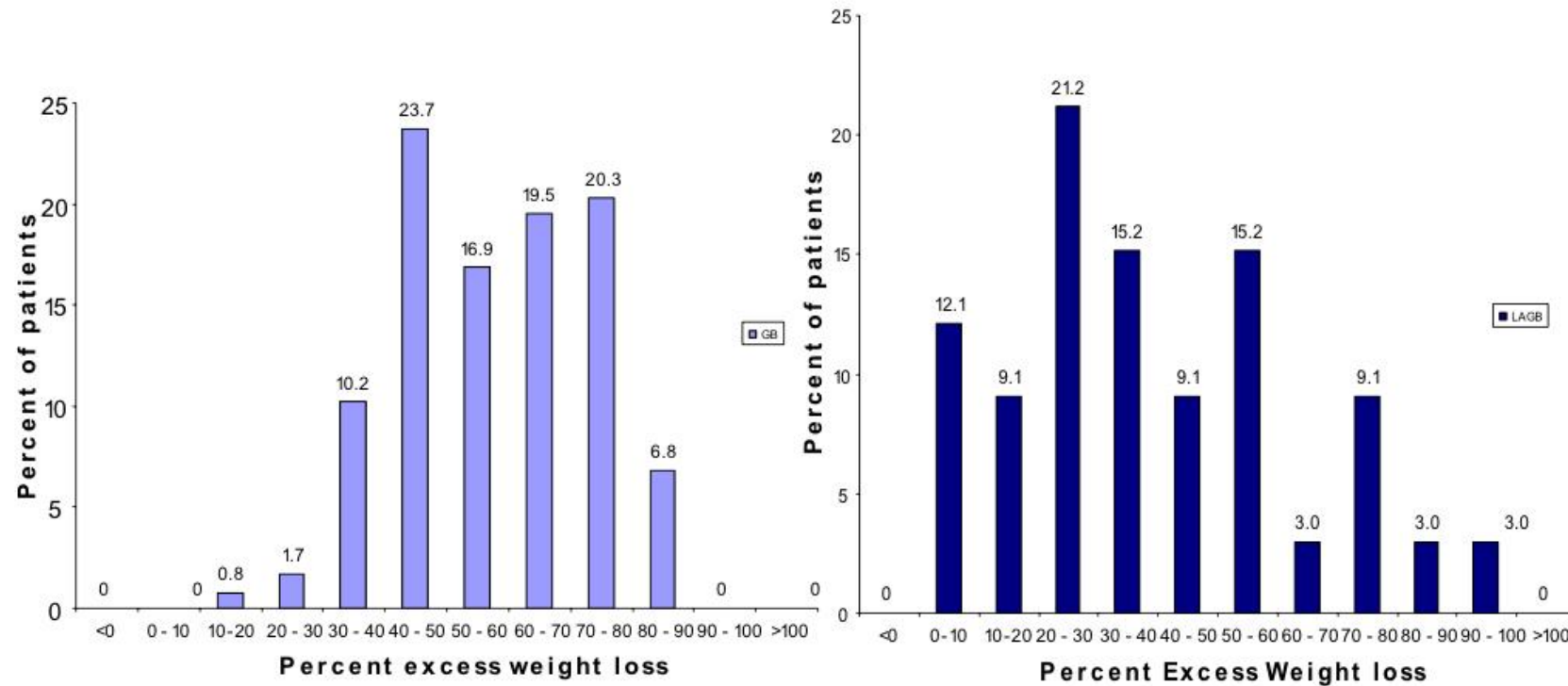
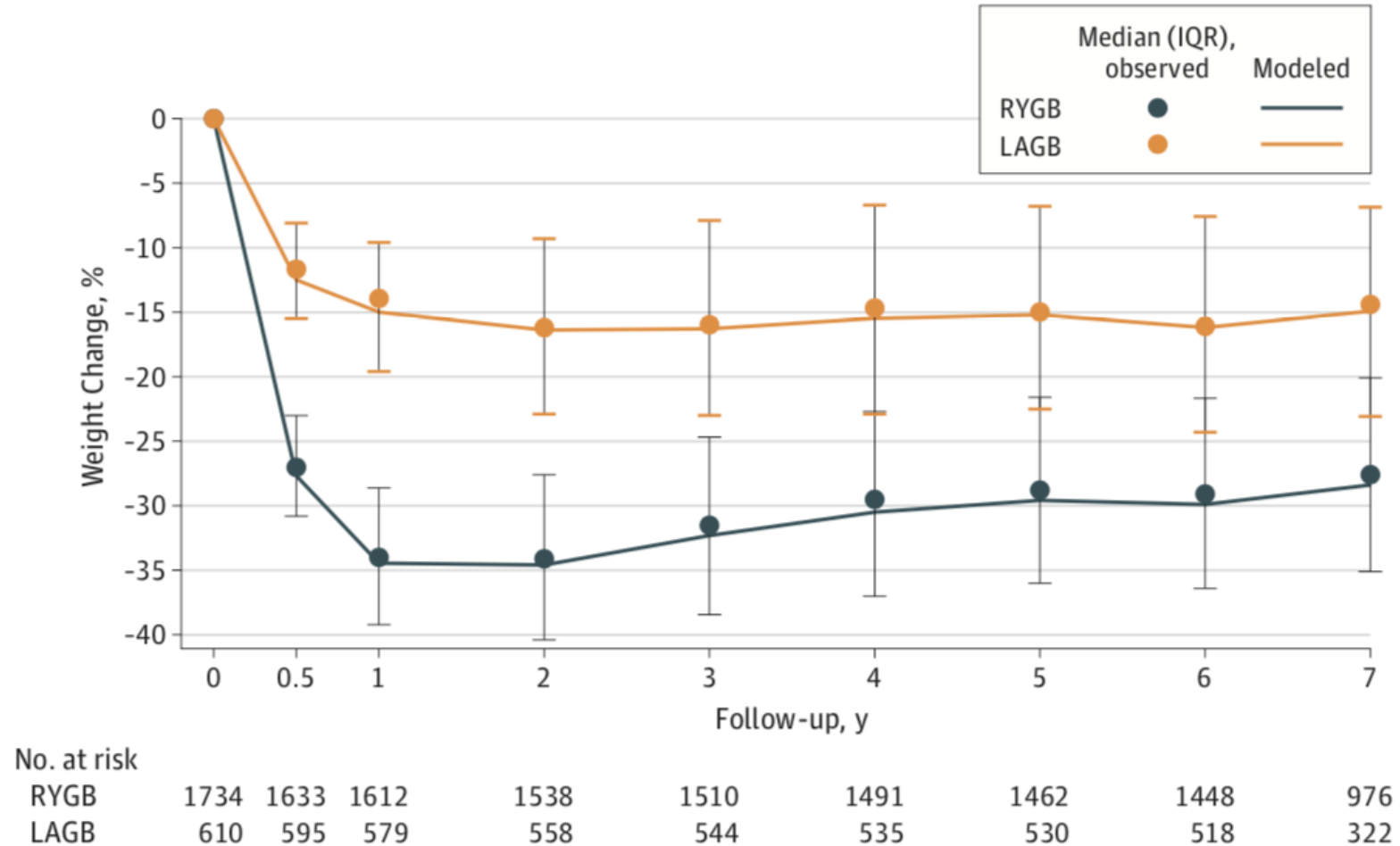


Fig. 3. %EWL at 3 years postoperatively.

LABS data RNY vs Band

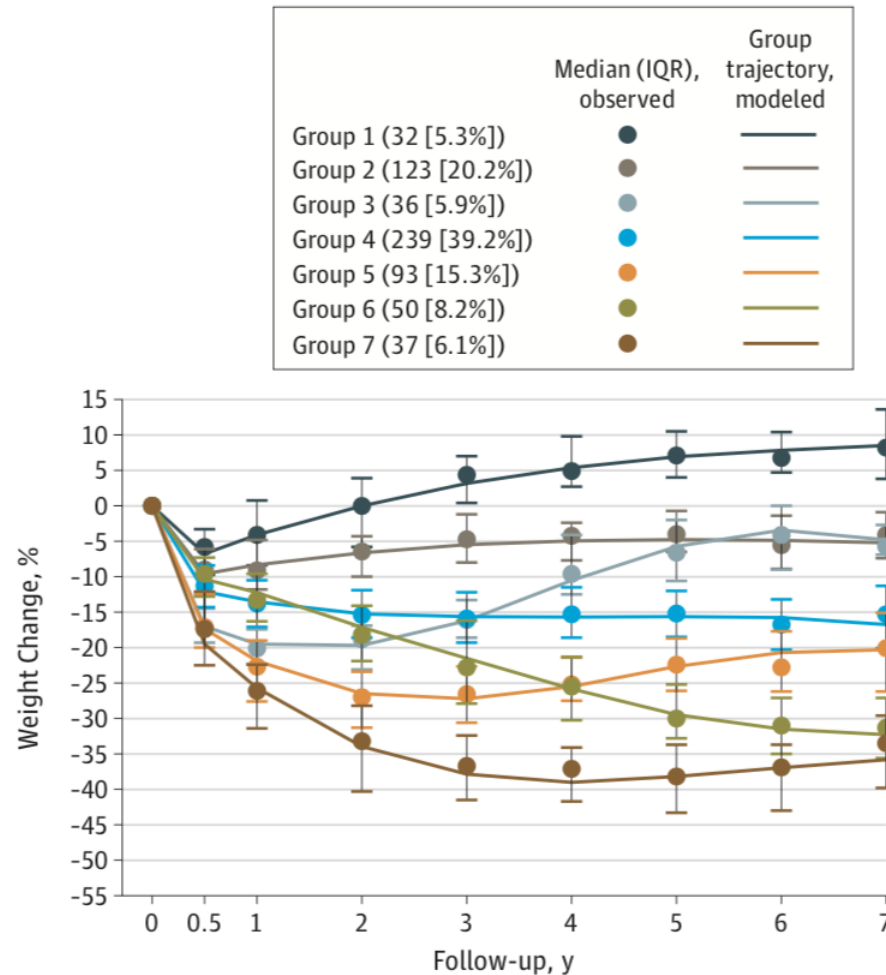
JAMA Surgery Dec 2017



LABS data: LAGB

JAMA Surgery Dec 2017

B Laparoscopic adjustable gastric band

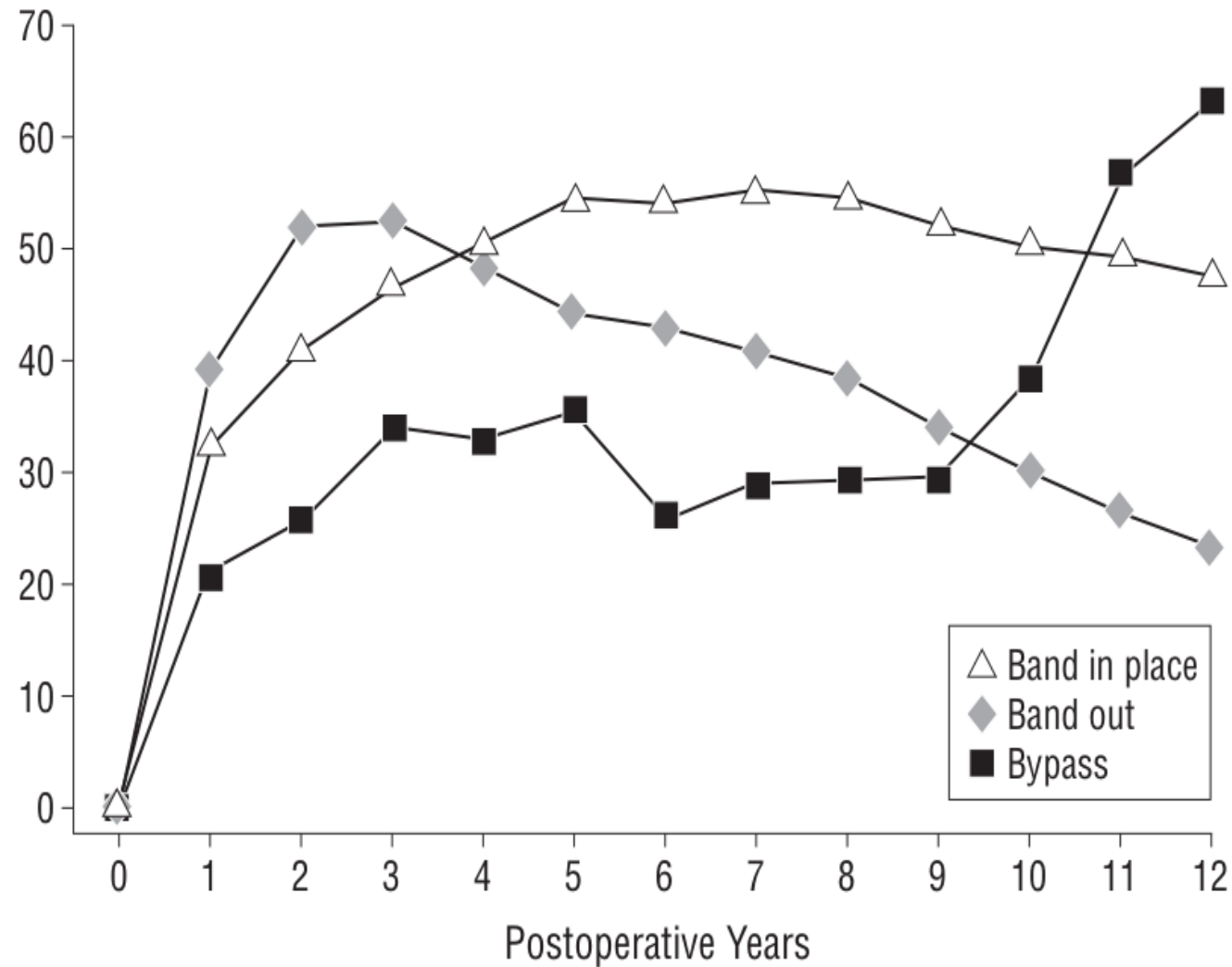


Long-term data showing high rate of band failures

Explant rates overtook implant rates by mid-2010s
Declining surgeon interest – **seen as “legacy”
technology**

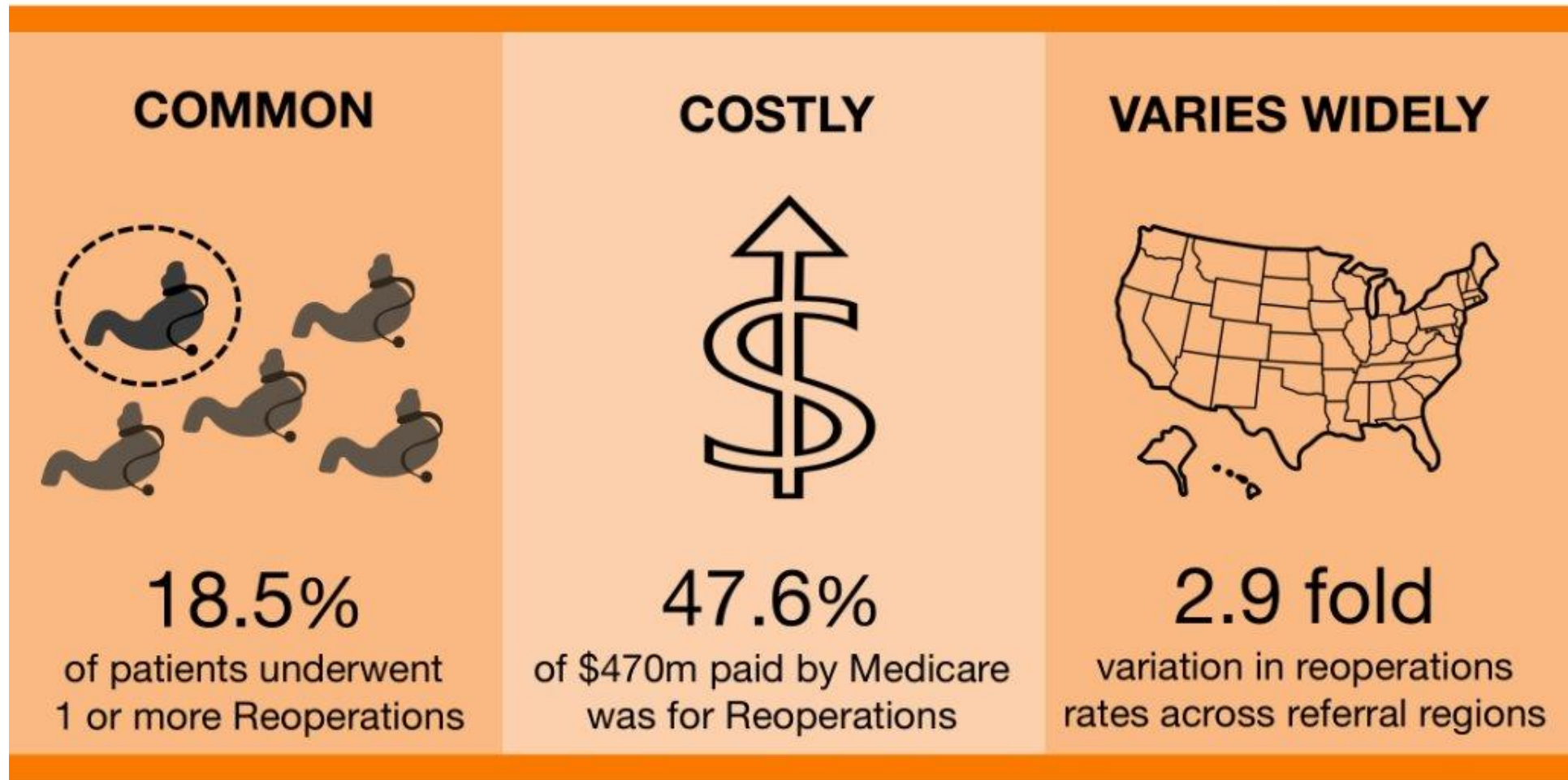
Long-term Outcomes of Laparoscopic Adjustable Gastric Banding

Jacques Himpens, MD; Guy-Bernard Cadière, MD, PhD; Michel Bazi, MD;
Michael Vouche, MD; Benjamin Cadière, MD; Giovanni Dapri, MD Arch Surg
2011



**Band complications and
conversions - expensive**

Medicare Claims 2006-2013: Device Reoperation after Laparoscopic Gastric Band Surgery



Ibrahim et al. *JAMA Surg* May 2017.

JAMA Surgery

Negative Media Stories

Lap-Band sales **plummeted globally**

Device no longer core to modern bariatric programs

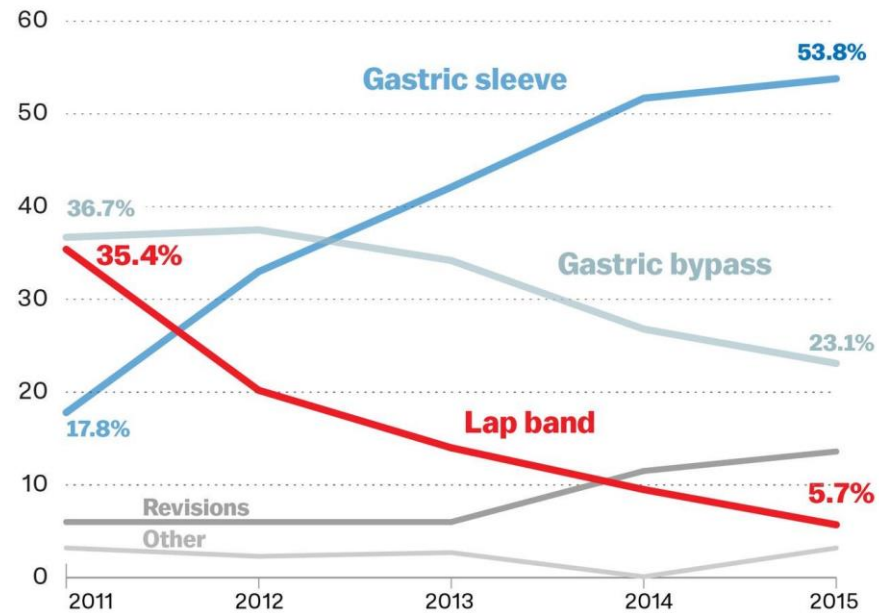
The lap band for weight loss is a tale of medicine gone wrong

It doesn't lead to weight loss and often requires more surgery. "I wouldn't wish it on my worst enemy."

Updated by Julia Belluz | @juliaoftoronto | julia.belluz@voxmedia.com | May 25, 2017, 2:20pm EDT

The lap band has become less popular — but still accounts for 6 percent of weight-loss surgeries

Estimate of bariatric surgery numbers 2011 to 2015

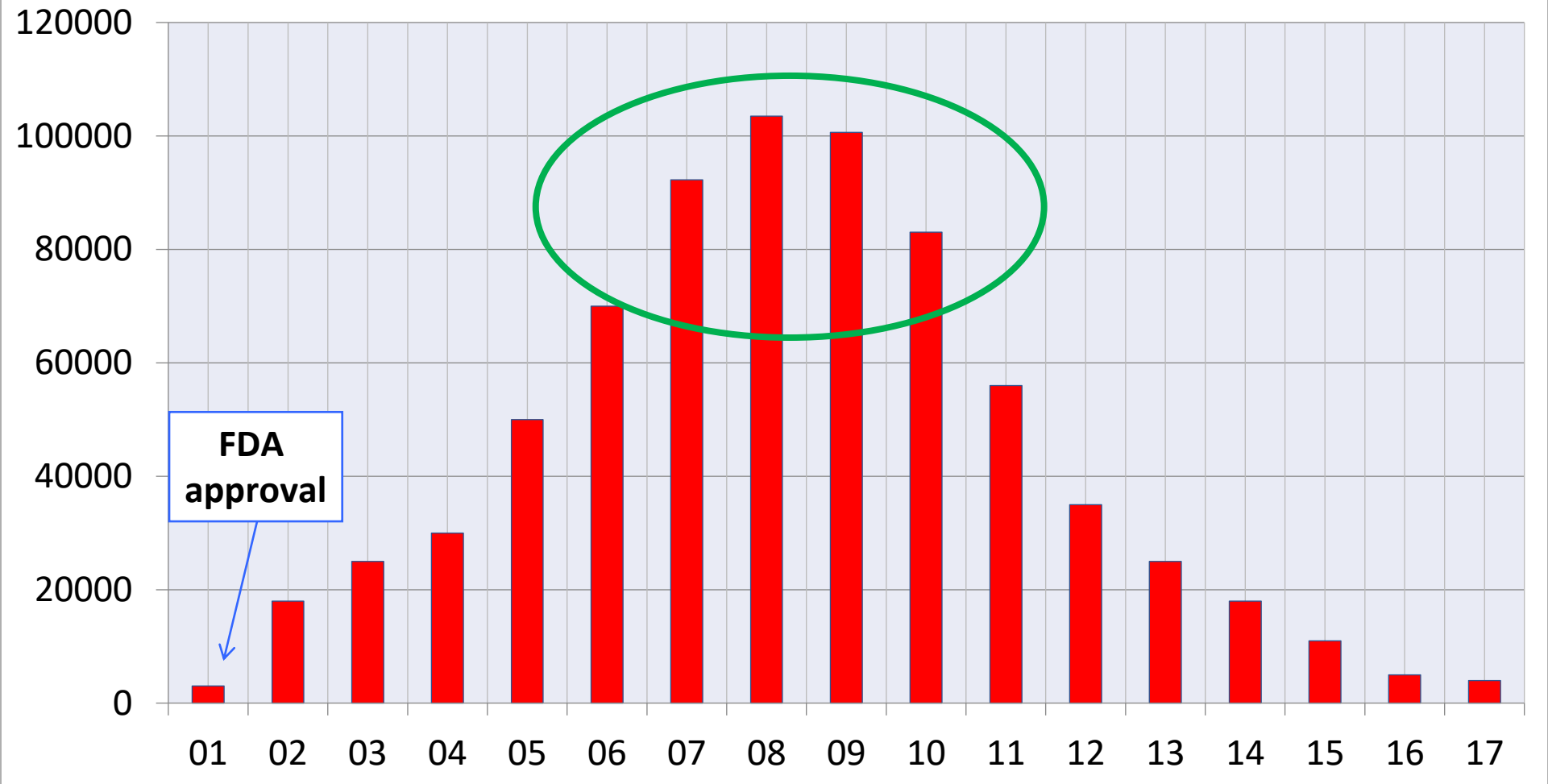


Source: ASMBS American Society for Metabolic and Bariatric Surgery



Band numbers

Gastric Banding Cases in the United States



Year (2001-2017)

Key Lessons – From Innovation to Obsolescence


Short-term data ≠ long-term outcomes (mismatch)

Aggressive marketing without clinical maturity can backfire

Real-world registry data is critical

- **Devices are not one-size-fits-all**

Final Thoughts

- We must **learn from past cycles** – innovation needs **clinical humility**
“The Lap-Band wasn’t a failure of intention.
It was a failure of long-term vision and system-level checks.”
- We owe it to patients to **balance innovation with accountability**
-  **Recognize this as a shared failure:**
“The fall of the Lap-Band was not just a device issue — it was a failure of both industry and clinicians to safeguard patient interests.”



May 3rd-7th

“NO ONE LEFT BEHIND”

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Thank You!

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