Brigham and Women's Hospital
Founding Member, Mass General Brigham
Center *for* Weight Management and Wellness

HARVARD MEDICAL SCHOOL

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Endoscopic Suturing Devices:

Are we ready for primetime?

The new devices will replace the old ones

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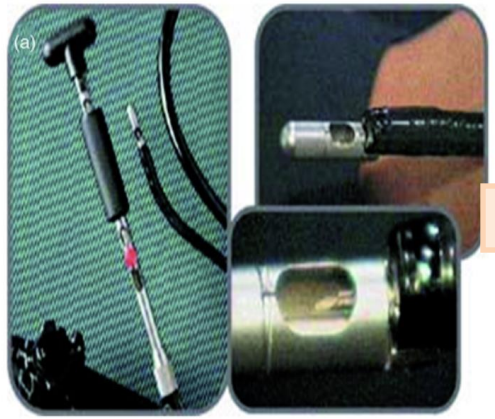
Disclosures

- **Boston Scientific** – consultant, research support
- **Cook Medical** – consultant, research support
- **EndoSim** – royalty
- **ERBE** – consultant
- **Fractyl** – consultant, research support, advisory board
- **FujiFilm** – consultant, research support
- **Madrigal** – consultant
- **Merit Medical** – consultant, advisory board
- **Morphic Medical** – consultant, research support
- **Olympus** – consultant, advisory board
- **Spatz Medical** – consultant
- **USGI Medical** – consultant, research support

Evolution of Endoscopic Suturing

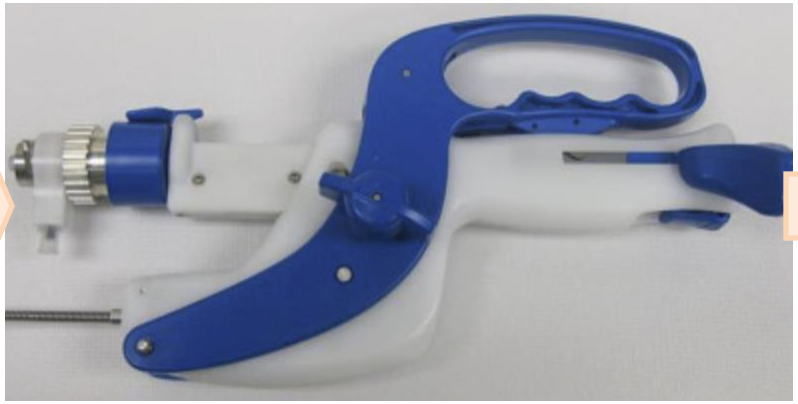


EndoCinch

- Proof-of-concept
- Superficial suturing
- FDA-cleared in 2000 for GERD

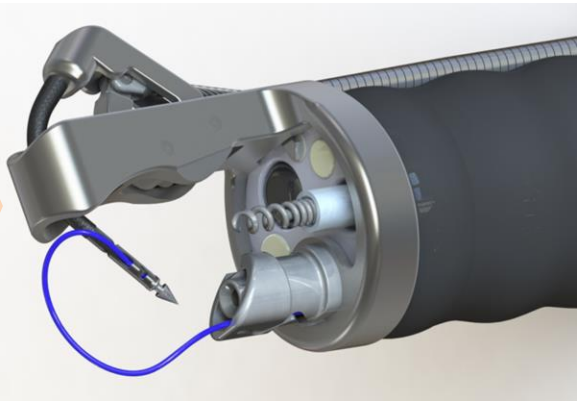
Eagle Claw

- First full-thickness suturing device
- Prototype of the Overstitch
- Animal studies published ~2005-2006



Overstitch Gen I

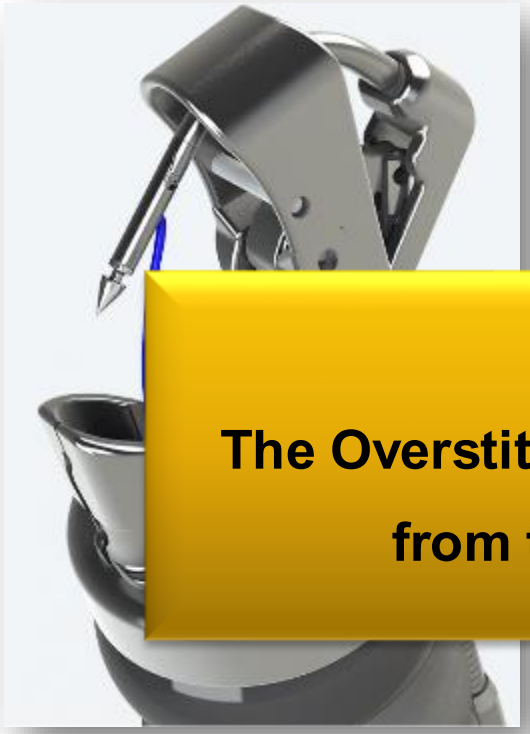
- First commercial full-thickness suturing device
- Bulky and complex to operate
- Launched ~2008-2011



Overstitch Gen II

- Current mature full-thickness suturing device
- Launched ~2011

Current Endoscopic Suturing Device



- ❑ Mounted on a dual channel endoscope
- ❑ One channel is for needle pickup
- ❑ One channel is for helix

is strapped onto the scope

In 2022

The Overstitch suturing device received de novo marketing authorization from the FDA for the treatment of obesity and weight regain

OverStitch Gen II

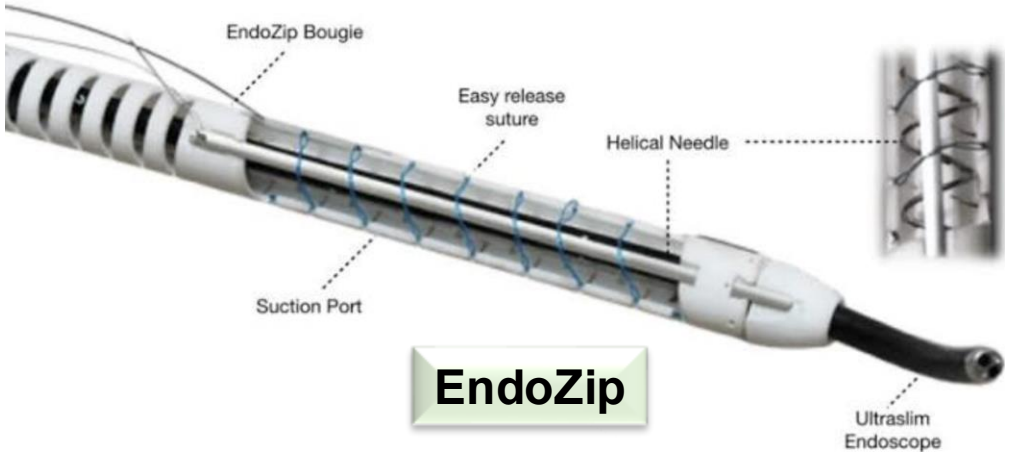
OverStitch NXT

Other Endoscopic Suturing/Plication Devices

IOP

Endomina

Envision



EndoZip

Myth 1

Myth #1: Endoscopic suturing is already ready for prime time

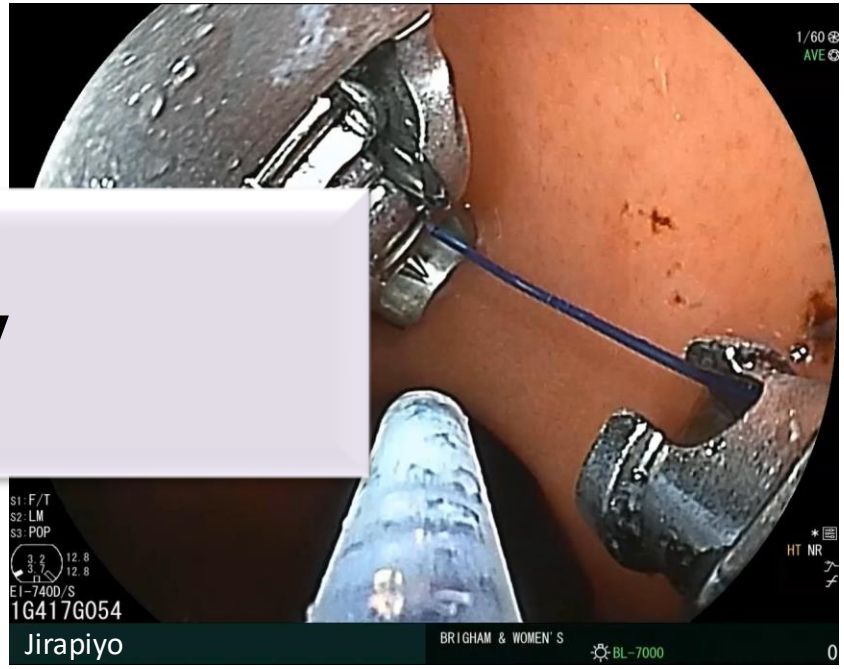
Fact #1: The procedures are. The technology still has limitations

Endoscopic Sleeve Gastroplasty

American Society for Gastrointestinal Endoscopy–European Society of Gastrointestinal Endoscopy guideline on primary endoscopic bariatric and metabolic therapies for adults with obesity

Pichamol Jirapinyo, MD, MPH,[1,*]
Árpád V. Patai, MD, PhD,[5] Rahul
Marc Barthet, MD, PhD,[7] Carolin
Christopher G. Chapman, MD,[10]
Vivek Kumbhari, MBChB, PhD,[13]
Aurora D. Pryor, MD, MBA,[17] Rol
Francois Pattou, MD,[20] Shira Zell
Konstantinos Triantafyllou, MD,
Shelby Sullivan, MD[15,†]

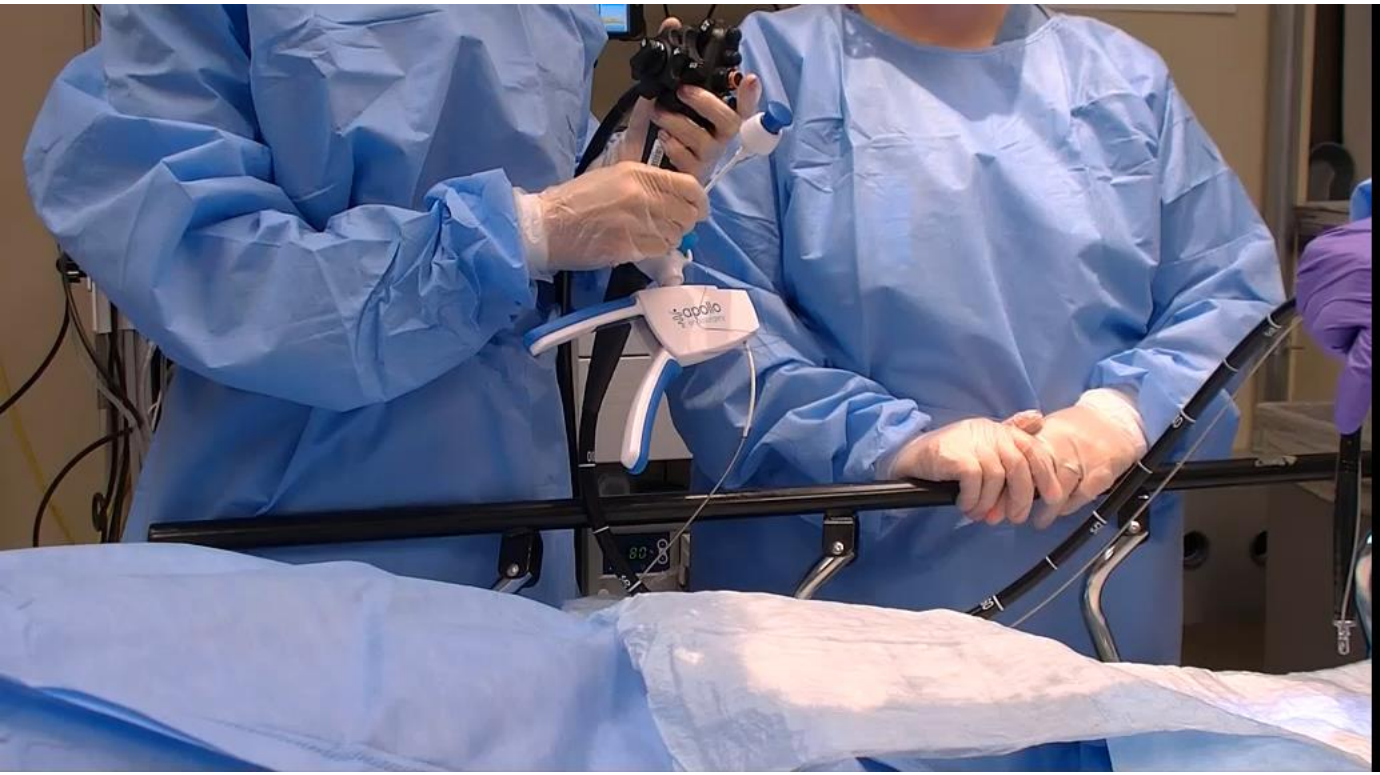
The procedure is ready

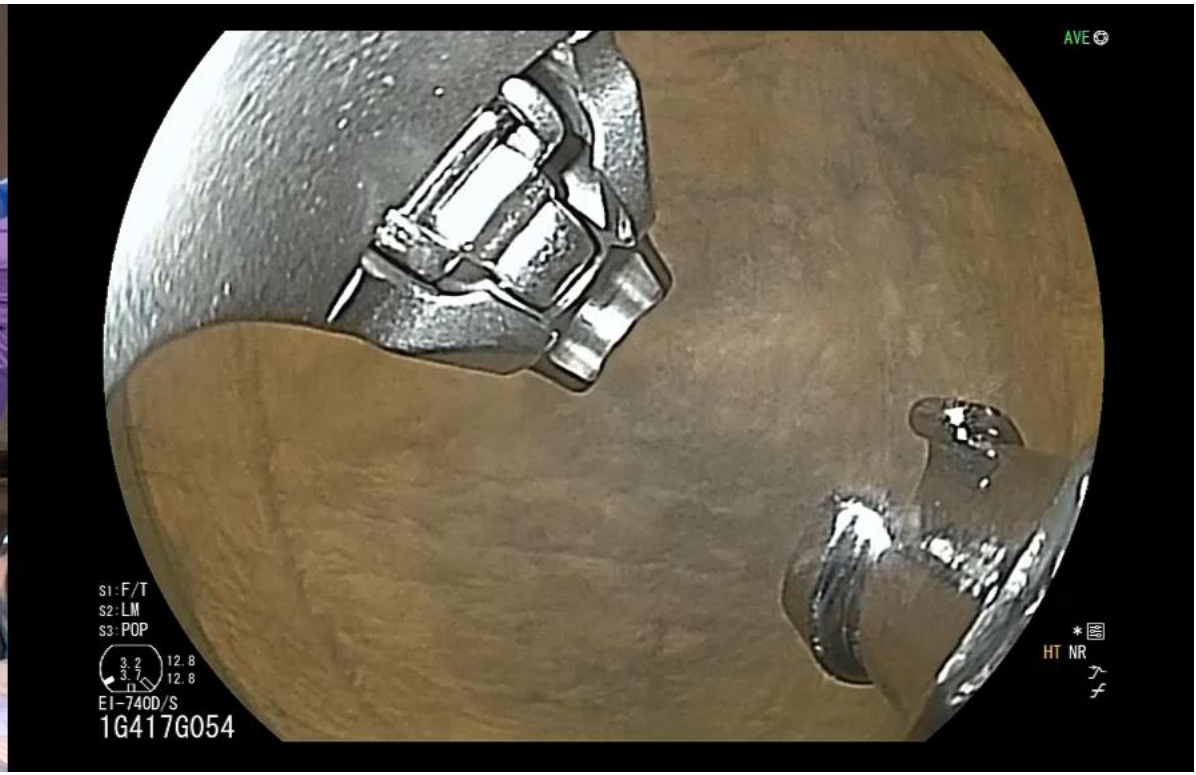


IFSO Bariatric Endoscopy Committee Evidence-Based Review and Position Statement on Endoscopic Sleeve Gastroplasty for Obesity Management

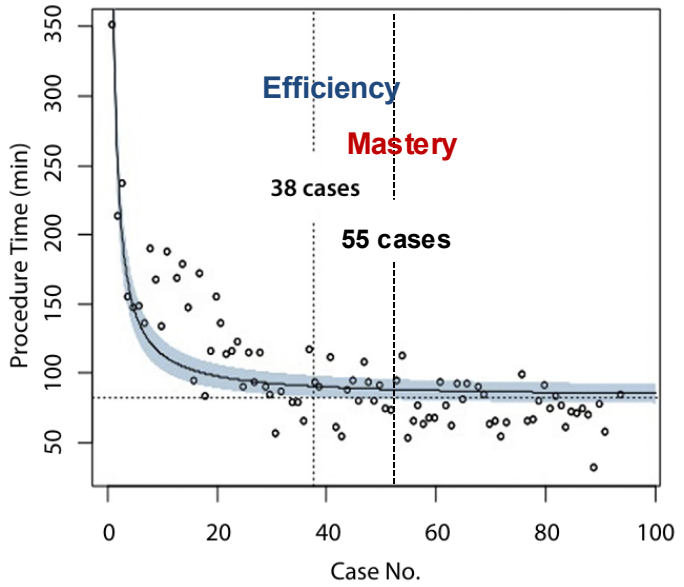
Barham K. Abu Dayyeh[1,10] · Christine Stier[2] · Aayed Alqahtani[3] · Reem Sharaiha[4] · Mohit Bandhari[5] · Silvana Perretta[6] · Sigh Pichamol Jirapinyo[7] · Gerhard Prager[8] · Ricardo V. Cohen[9]

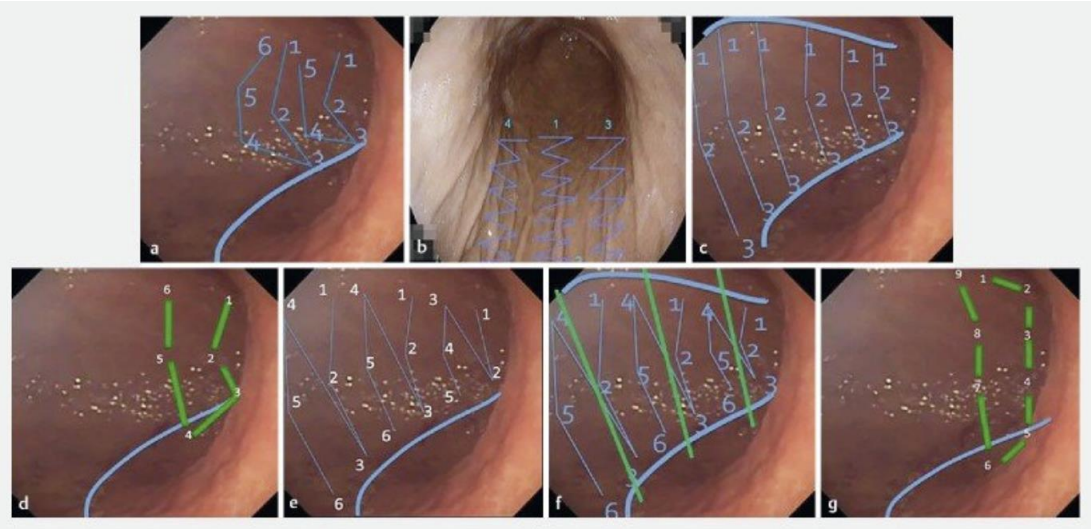
Steps of Endoscopic Suturing





Limitations of the Current Endoscopic Suturing System





- **Technical complexity**
- **Procedure time**
- **Learning curve**
- **Reproducibility/scalability**

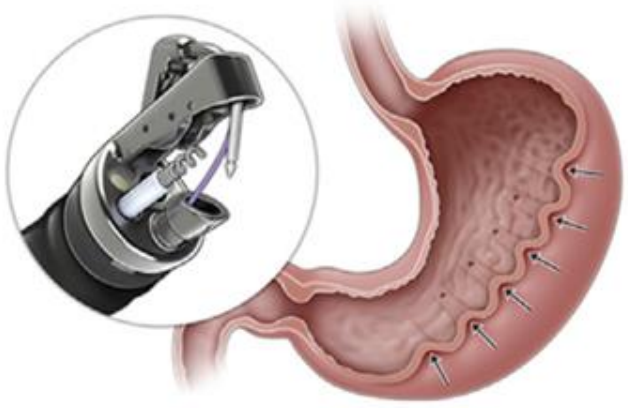
Saumoy M, et al. GIE. 2018;87:442-7.

Myth 2

Myth #2: New suturing devices are just another way of doing the same thing

Fact #2: They are trying to solve different limitations

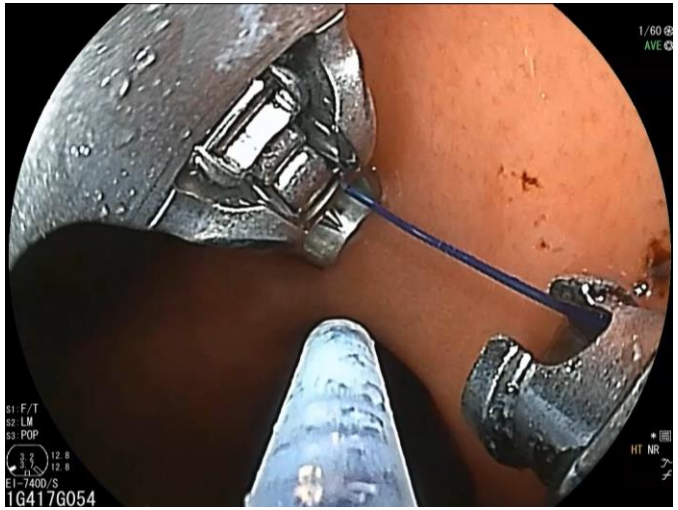
Endoscopic Gastric Remodeling

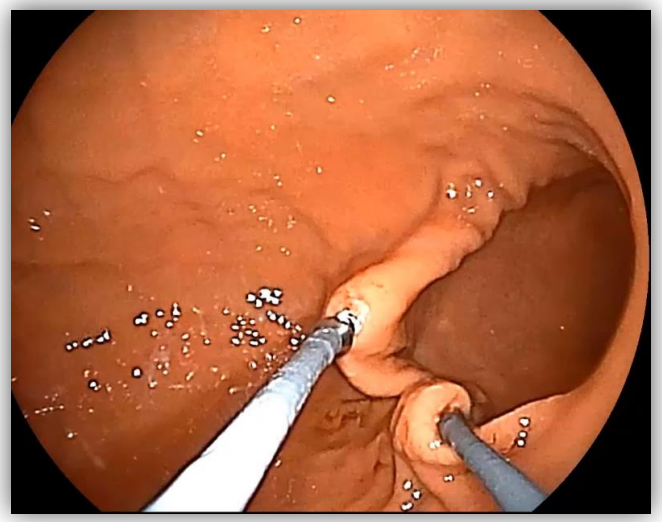


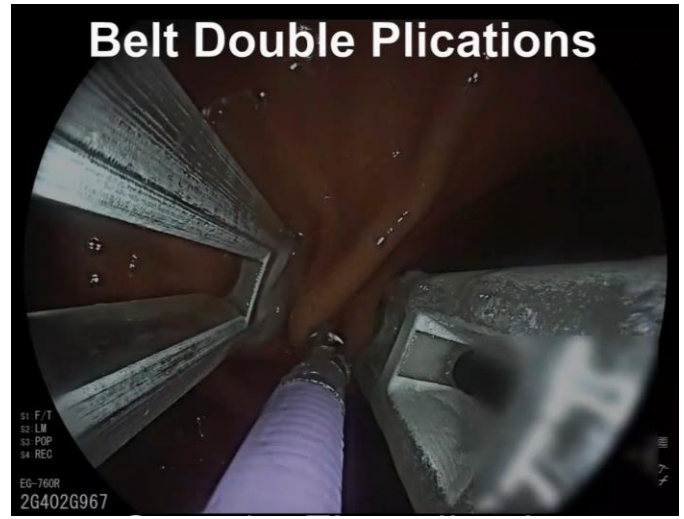
Endoscopic gastric remodeling
(ESG)

Endoscopic gastric remodeling
(POSE)

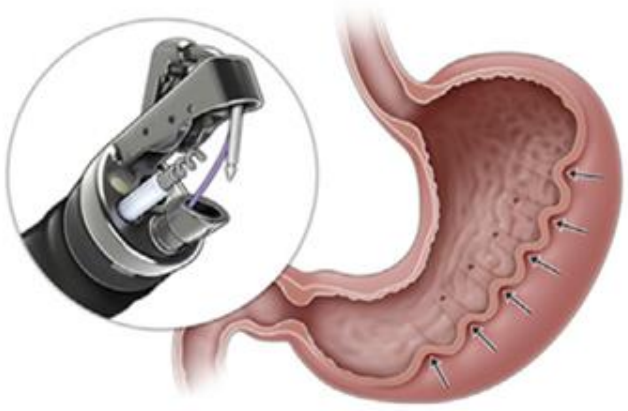
Endoscopic gastric remodeling
(Endomina)







Endoscopic Gastric Remodeling



Endoscopic gastric remodeling
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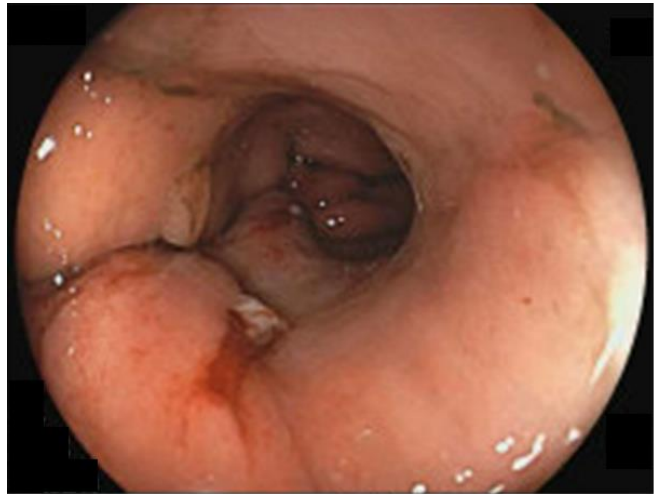
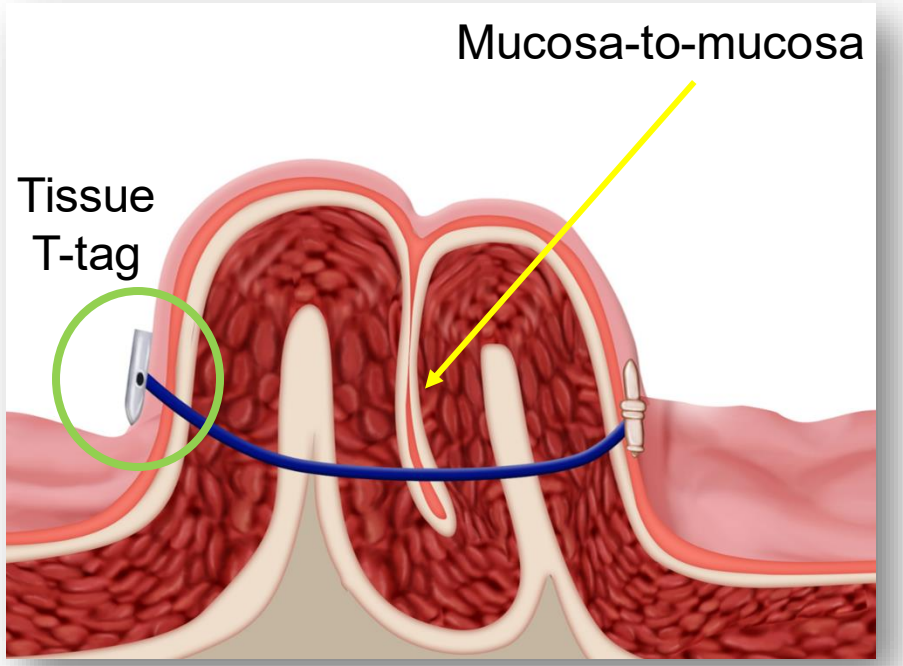
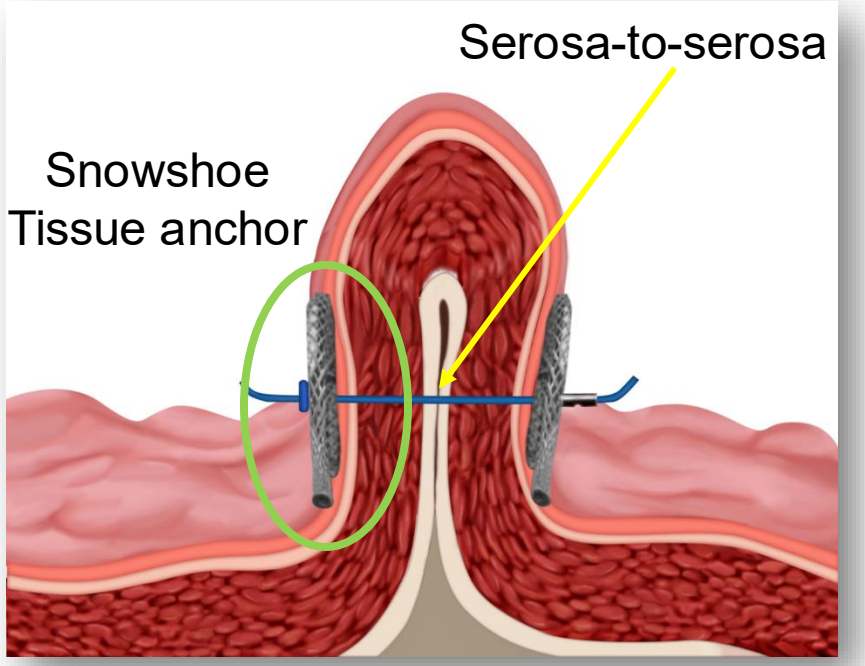


Suturing versus Plication



Endoscopic Suturing (ESG)

Tissue is approximated in a mucosa-to-mucosa fashion



Endoscopic Plication (POSE/Endomina)

Tissue is approximated in a serosa-to-serosa fashion

Jirapinyo P, Thompson CC. GIE. 2022;96:479-86.

Incisionless Operating Platform (IOP)

Incisionless Operating Platform (IOP)

Cleared by the FDA for tissue approximation in 2006

Transport
54F handle with 4 channels

G-Lix
Tissue grasper

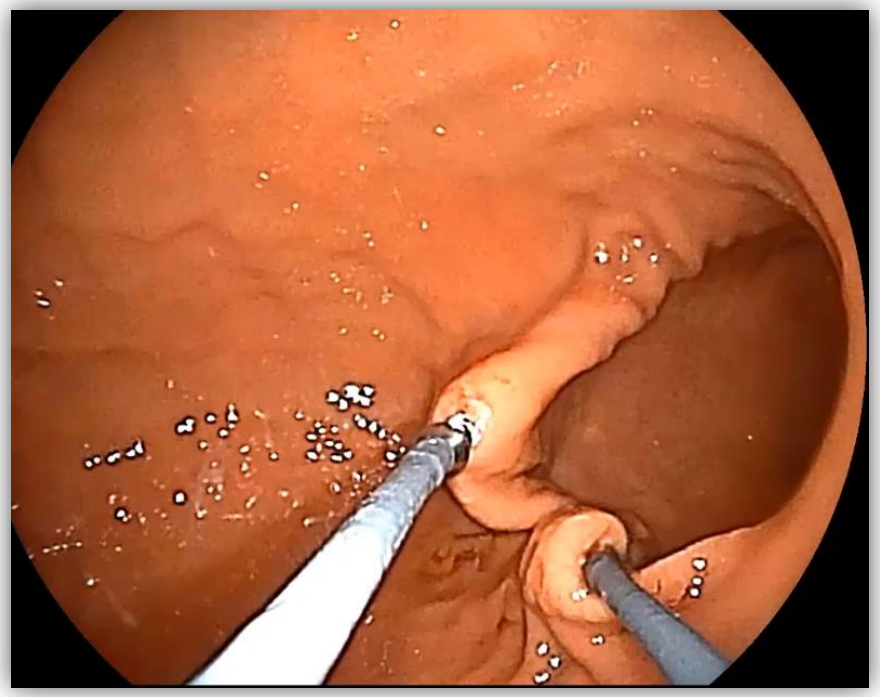
G-Cath
Tissue anchor delivery system

G-Prox
Tissue anchors

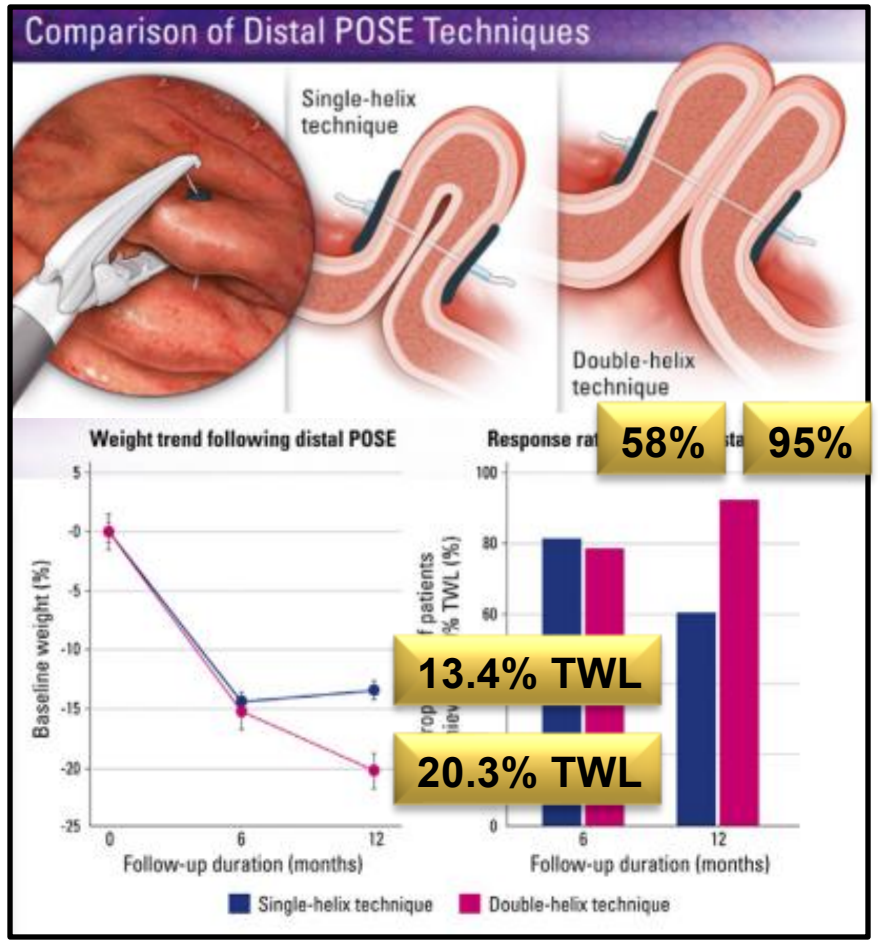
Comparison of distal primary obesity surgery endolumenal techniques for the treatment of obesity (with videos)

Pichamol Jirapinyo, MD, MPH,[1,2] Christopher C. Thompson, MD, MSc[1,2]

GIE Gastrointestinal Endoscopy



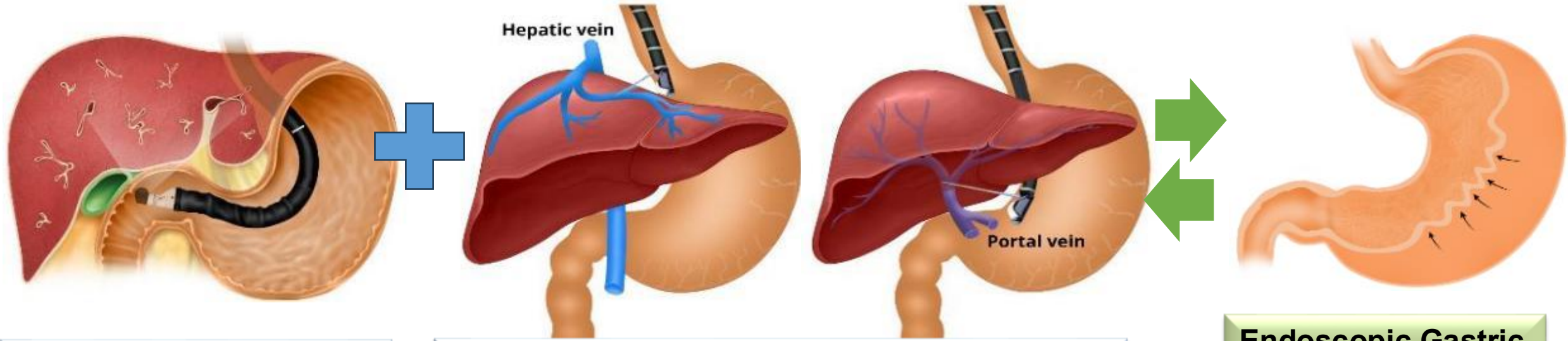
- 110 patients (baseline BMI 38.2 ± 6.1 kg/m^2)
- Efficacy: **15.8 ± 8.9 % TWL at 1 year**
- Safety: SAE rate 0.9% (gastric perforation)



Jirapinyo P, Thompson CC. GIE. 2022;96(3):479-486.

Effect of POSE on Histologic MASH

- A single-center, 12-month, prospective observational study (n = 20 subjects)
- Inclusion criteria: BMI ≥30 kg/m^2 & biopsy-proven MASH with ≥F1 fibrosis
- Exclusion criteria: Decompensated cirrhosis



EUS-guided Liver Biopsy (EUS-LBx)

Months 0 and 12

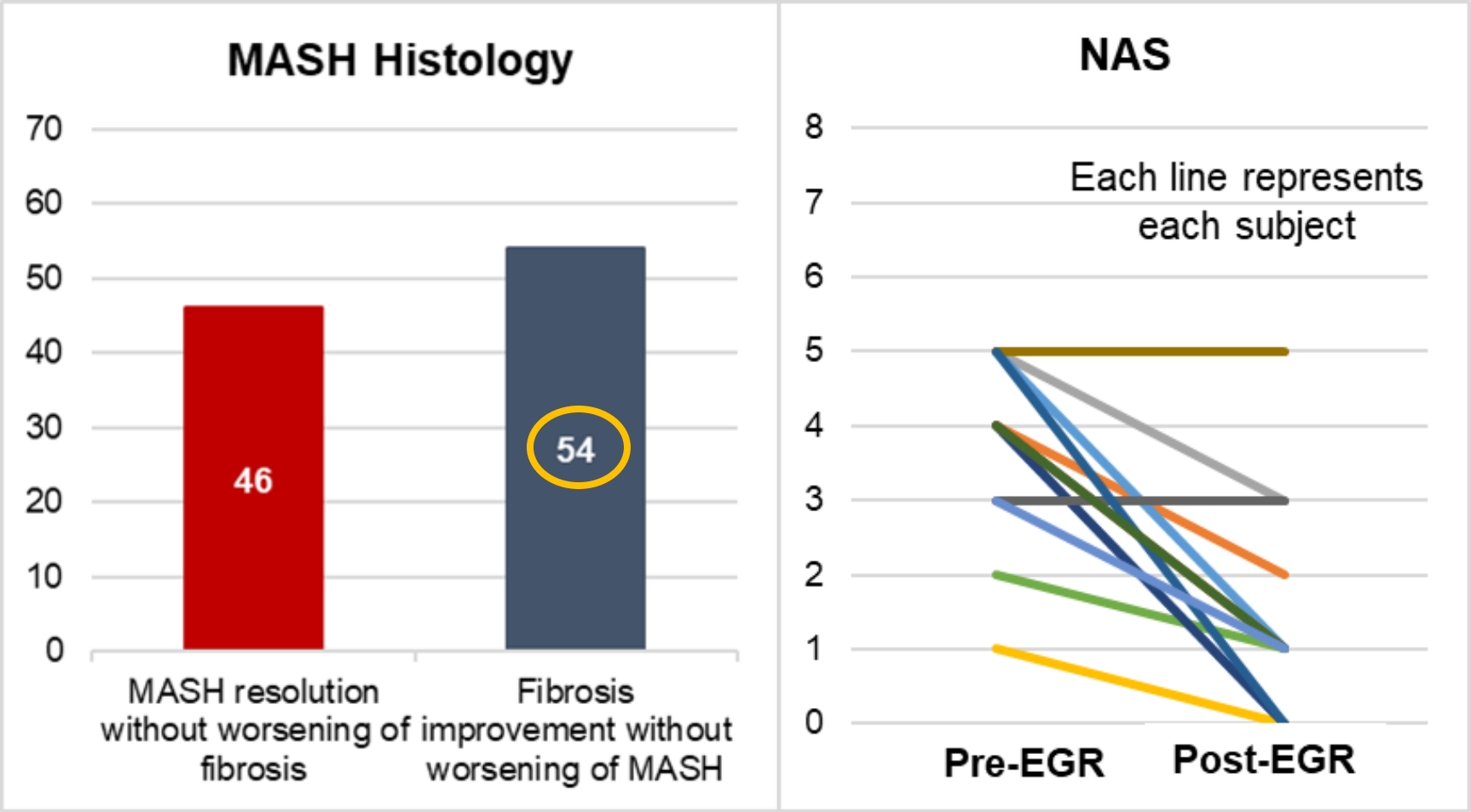
EUS-guided Portosystemic Pressure Gradient (EUS-PPG)

Months 0 and 12

Endoscopic Gastric Remodeling (EGR)

Jirapinyo P, Papke DJ, Garcia-Tsao G, et al. Gastrointest Endosc. 2026 Mar 3. Online ahead of print.

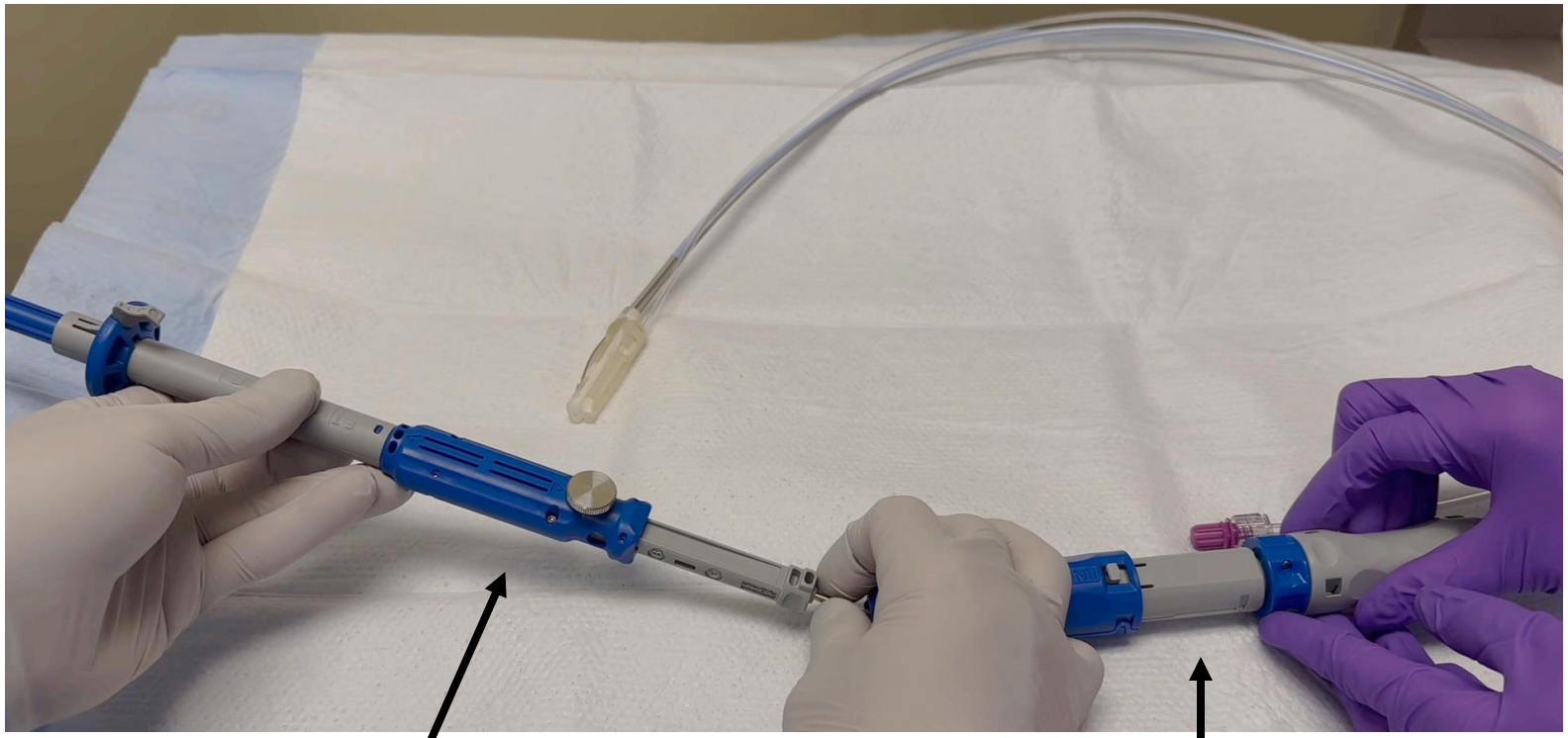
Effect of POSE on Histologic MASH



Jirapinyo P, Papke DJ, Garcia-Tsao G, et al. Gastrointest Endosc. 2026 Mar 3. Online ahead of print.

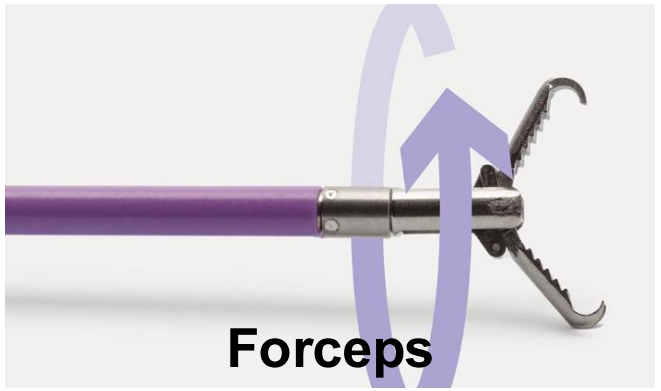
Endomina

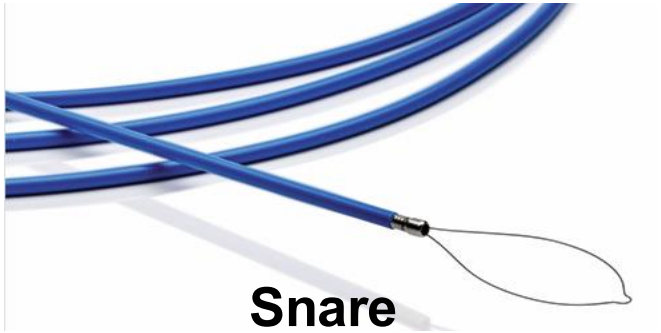
Potentially less $$



TAPES

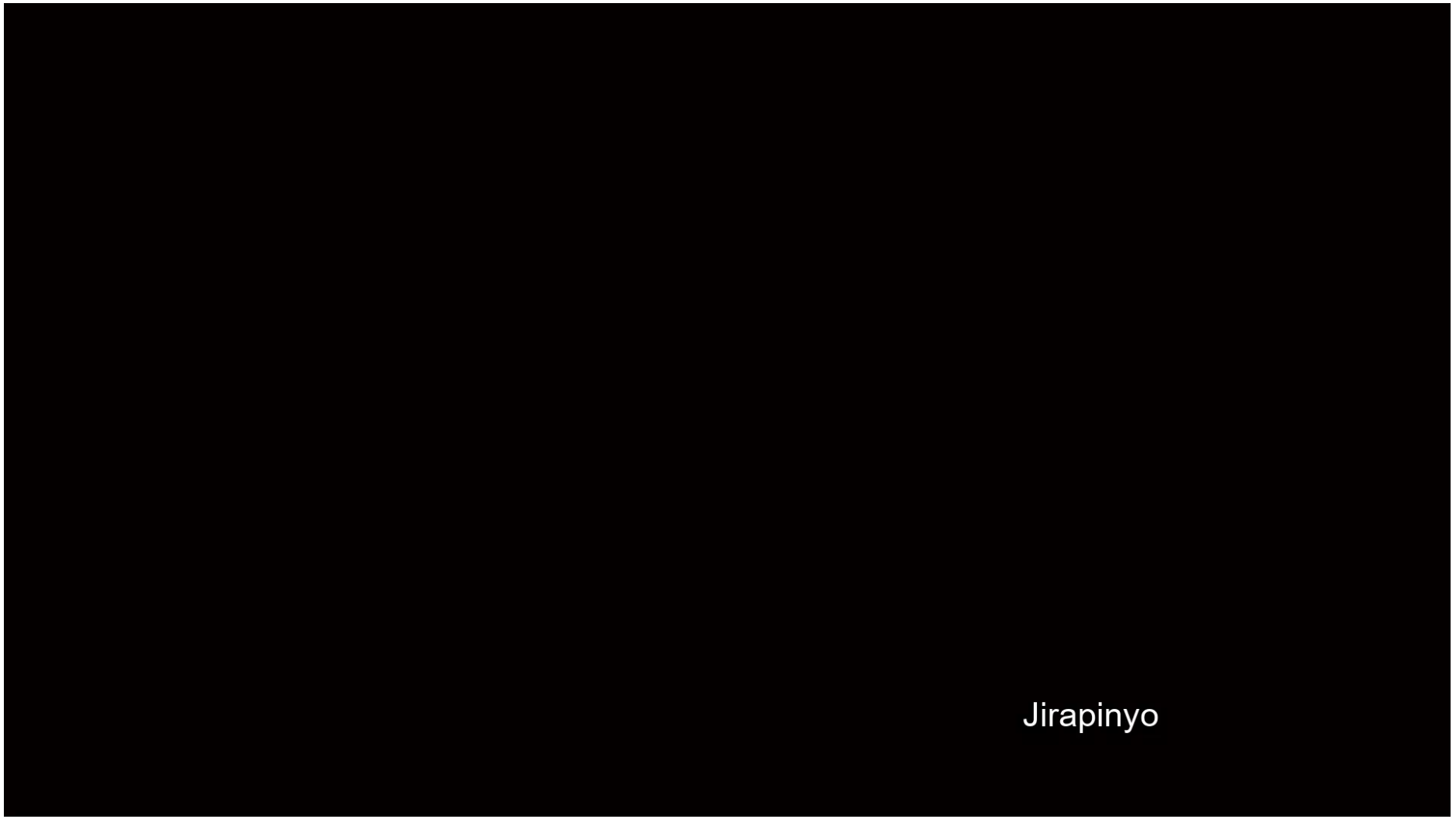
Endomina
Triangular Platform





Received FDA clearance in 2021

Endominal Endoscopic Gastric Remodeling

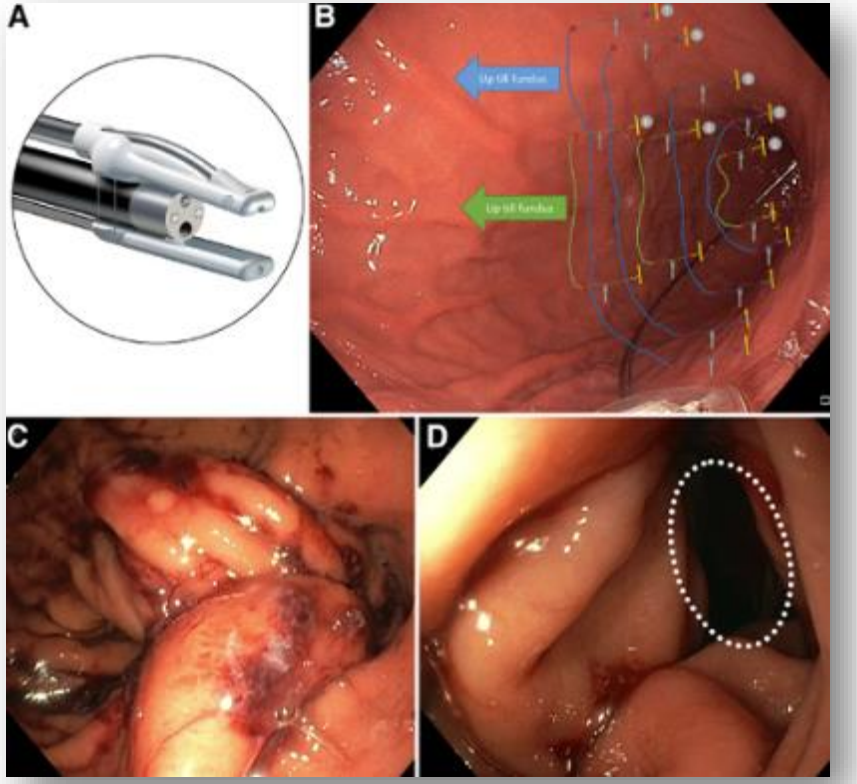


Endoscopic sutured gastroplasty in addition to lifestyle modification: short-term efficacy in a controlled randomised trial

Vincent Huberty [1], Ivo Boskoski [2], Vincenzo Bove,[2] Pauline Van Ouytsel,[1] Guido Costamagna,[2] Marc A Barthet [3], Jacques Devière[1]

Gut

- A 2:1 randomized controlled trial of patients with obesity (n=71)
  - Endomina EGR
  - Lifestyle modification
- At 6 months, the control group was crossovered to EGR
- At 6 months, the EGR group experienced **11% TWL**
  the control group: 2.7% TWL
- At 12 months, the combined EGR group experienced **11.9% TWL**
- There were no SAEs



Huberty V, Boskoski I, Bove V, et al. Gut. 2021;70:1479-1485.

Emerging Suturing Devices

Simple Stitch

Received FDA clearance in 2025

- Simple steps
- Potentially less costs
- No human data yet

Endozip

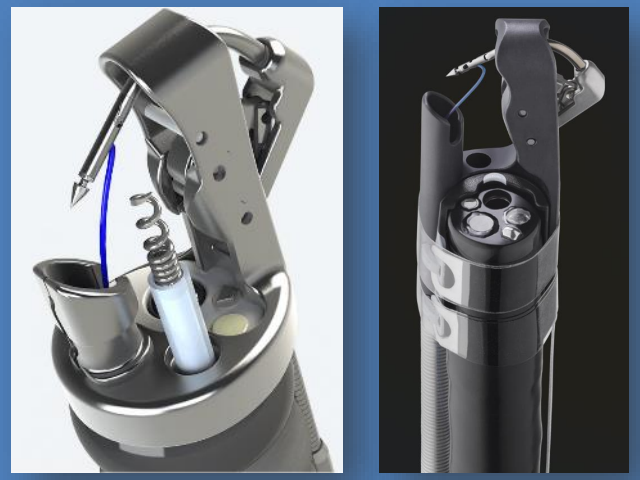
U.S. Pivotal trial ongoing (Endozip vs Overstitch)

- Automated
- Potentially more reproducible/scalable
- OUS data: 13.2% TWL at 12 months

Myth 3

Myth #3: If it's easier and faster, it will replace OverStitch

Fact #3: Not so fast

Characteristics		
Versatility	+++	+
Evidence	+++	+/++
Automation/Simplicity	+	+++
Standardization	++	**+++ potential**
Learning curve	Longer	**Potentially shorter**
Procedure time	Longer	**Potentially shorter**
Long-term durability	+++	?
Cost-effectiveness	?	?

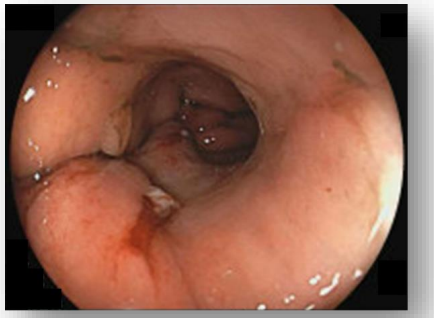
Myth 4

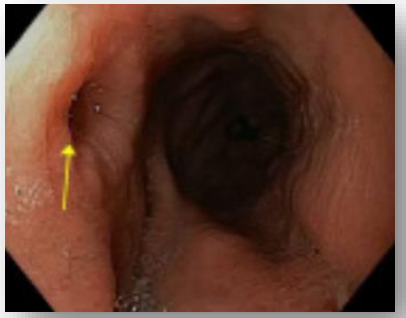
Myth #4: One suturing platform will win

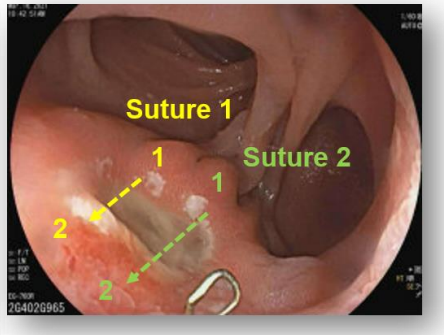
Fact #4: The future is probably procedure-specific

The right device for the right procedure

Procedure	Likely direction
Primary ESG/EGR	Dedicated/automated system; Full-thickness
TORe/Revision of MBS	Flexible suturing; Allows full-circumferential pursestring; Full-thickness
Defect closure	General purpose suturing
Stent fixation	General purpose suturing







Conclusion

- Endoscopic suturing procedures are ready for prime time
  - ESG and TORe are evidence-based, established therapies
- Conventional suturing remains the benchmark for versatility and evidence
- New devices may make standardized procedures, particularly primary gastroplasty, faster, easier and more reproducible
- The future is likely not one winner. It is the right device for the right procedure

Thank you

Contact: pjirapinyo@bwh.harvard.edu
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