From Duodenaljejunal Bypass Liner to Duodenal Resurfacing to Endoscopic Bypass procedures…

Evolution of endoscopic small bowel interventions

Manoel Galvao Neto MD MsC IFSO IFASMBS FASGE

IFSO NAPOLI 2023

Disclosures

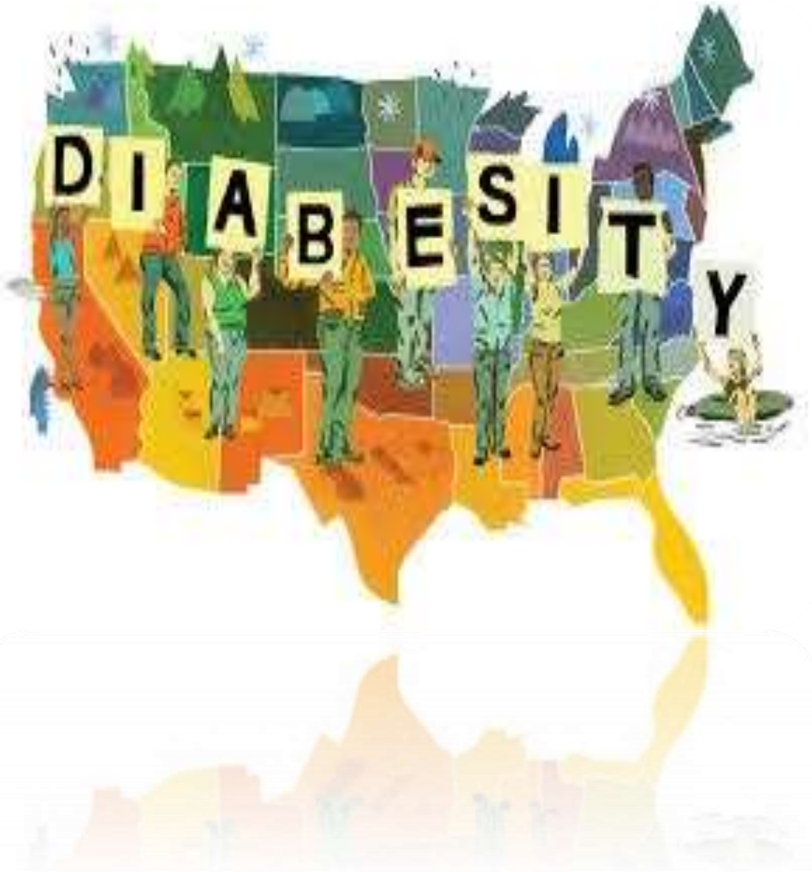
Manoel Galvao Neto

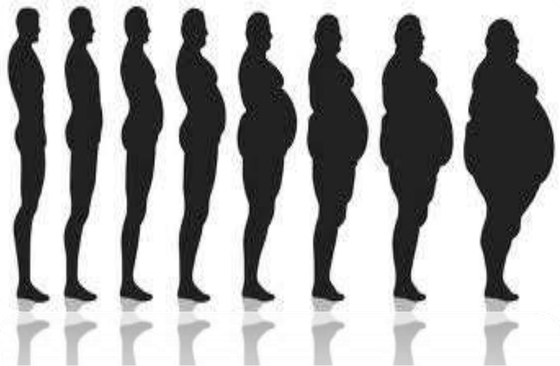
- ✓ *Gi Dynamics*
- ✓ *Apollo EndoSurgery*
- ✓ *USGI*
- ✓ *ERBE*
- ✓ *Keyron*

- ✓ International consultant
- ✓ Scientific Advisory Board

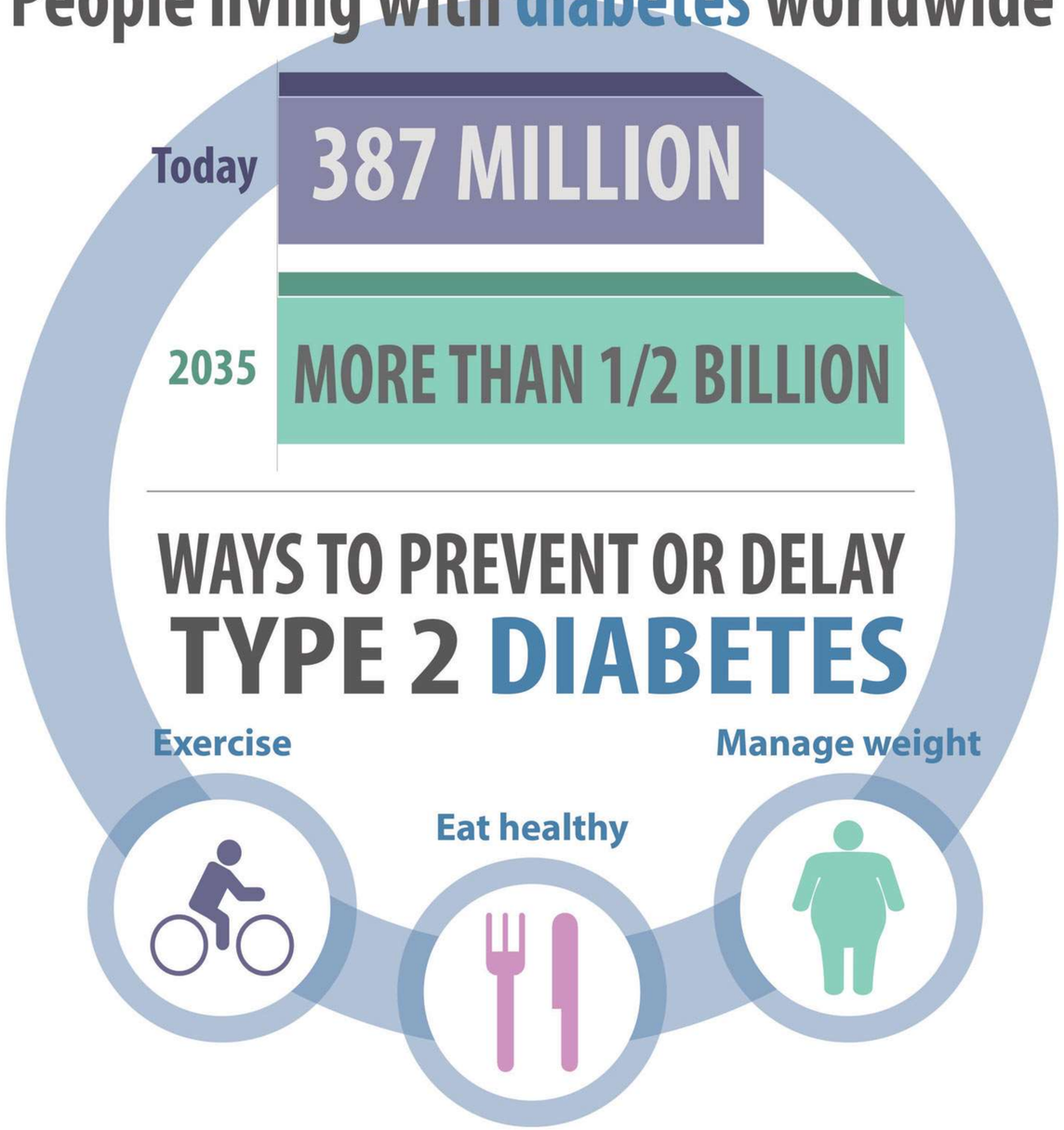
Bariatric Endoscopy

Globesity evolving to Diabesity…





People living with diabetes worldwide

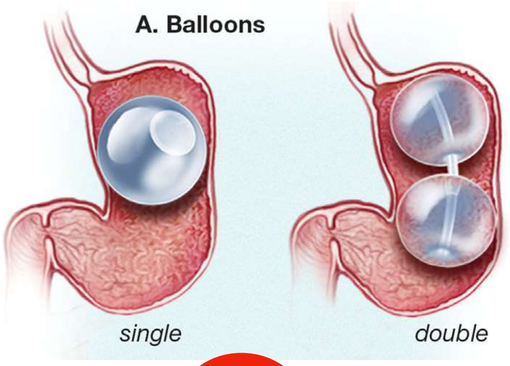


WAYS TO PREVENT OR DELAY TYPE 2 DIABETES

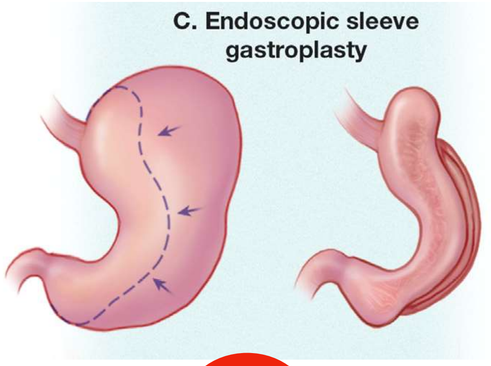
Learn more at www.cdc.gov/diabetes

Data courtesy of the International Diabetes Federation (www.idf.org)

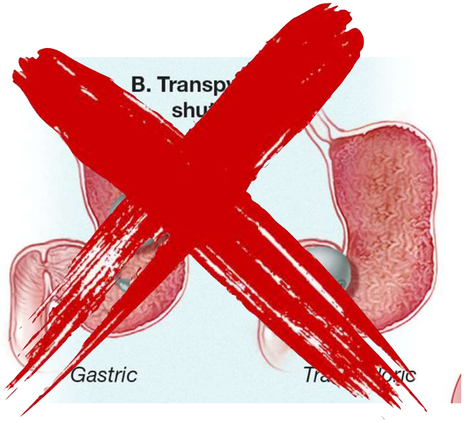
Interventions on the Stomach



FDA



FDA



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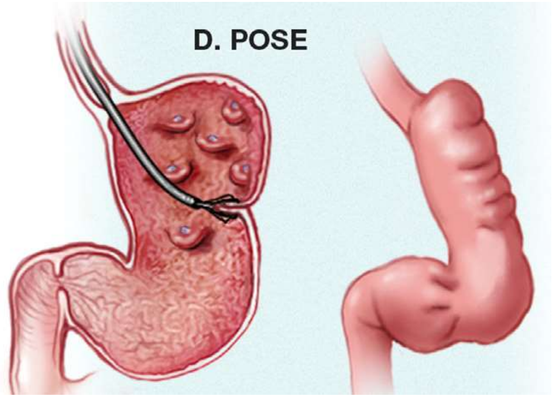
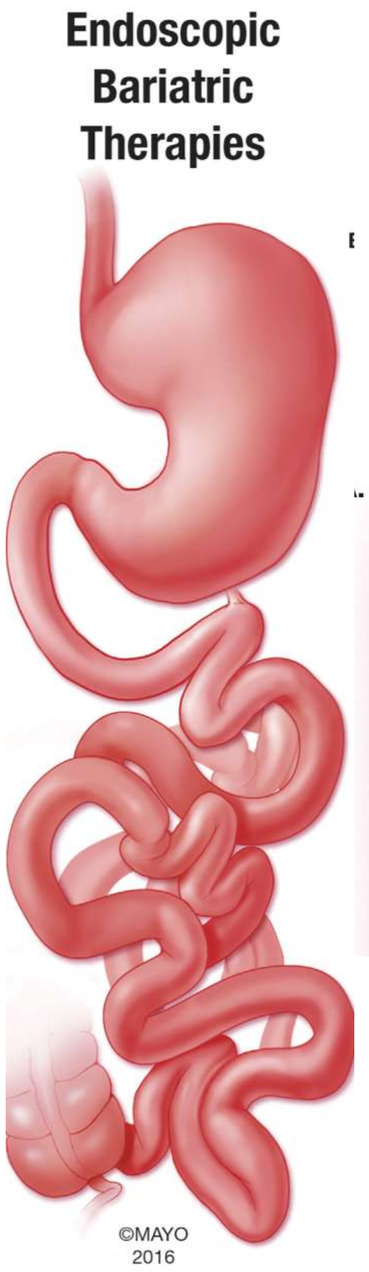
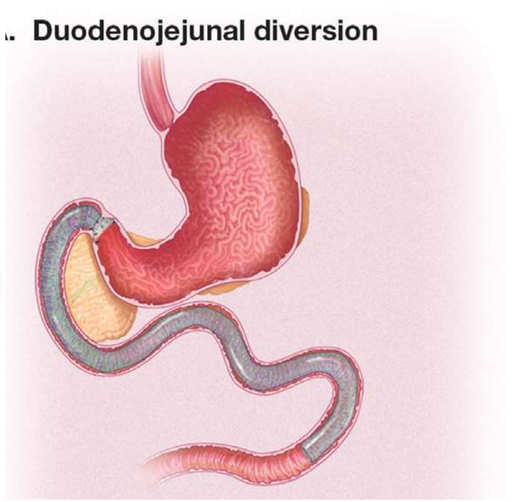


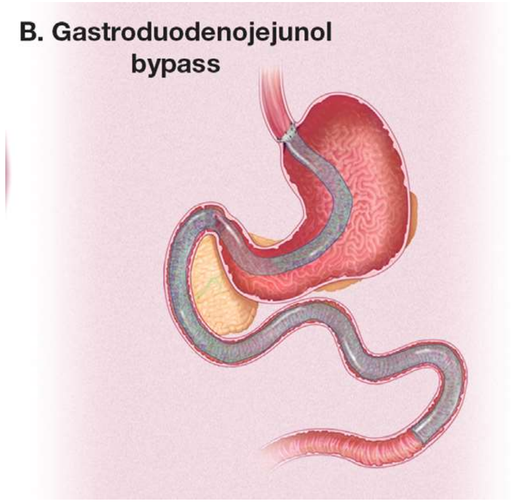
FDA

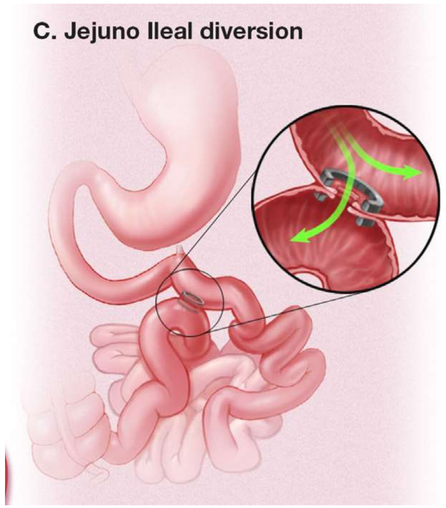
FDA

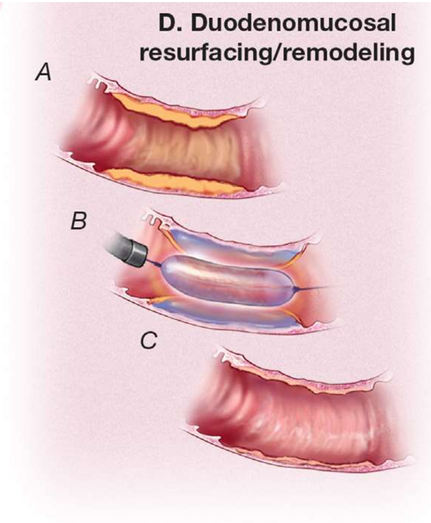
Interventions on the Bowel





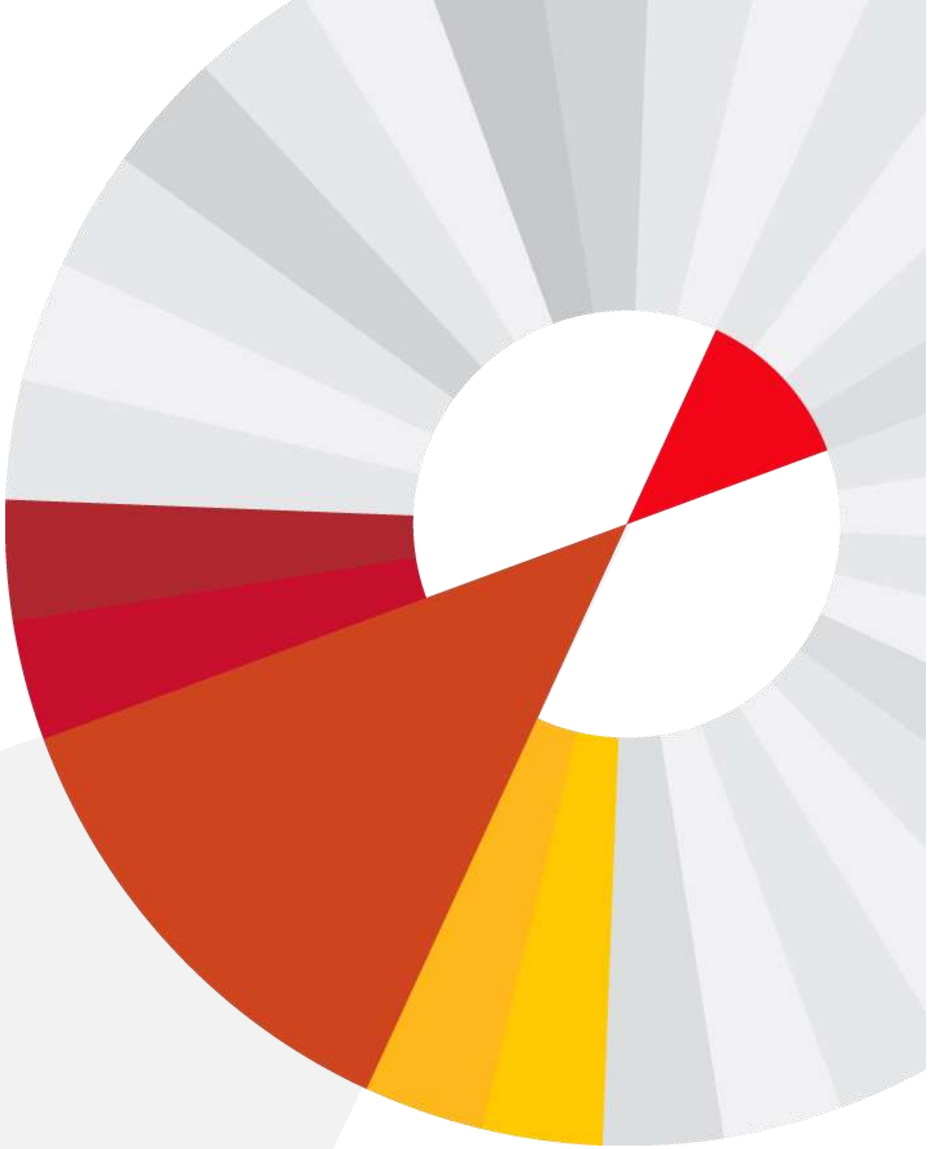




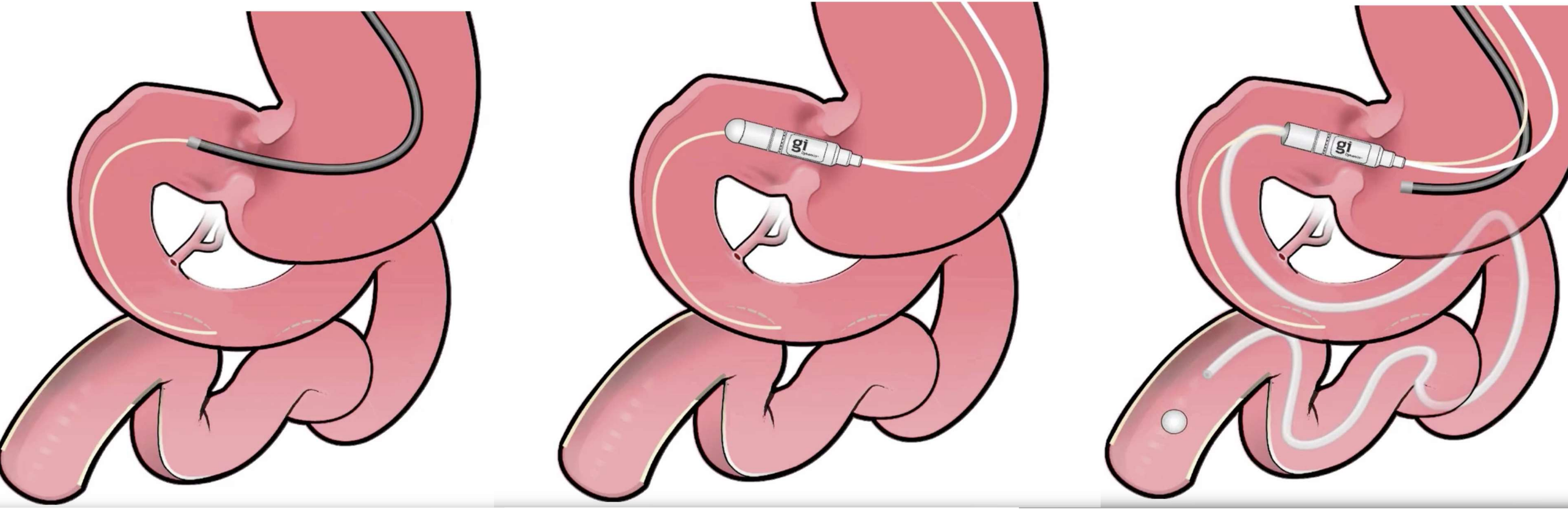


EXP

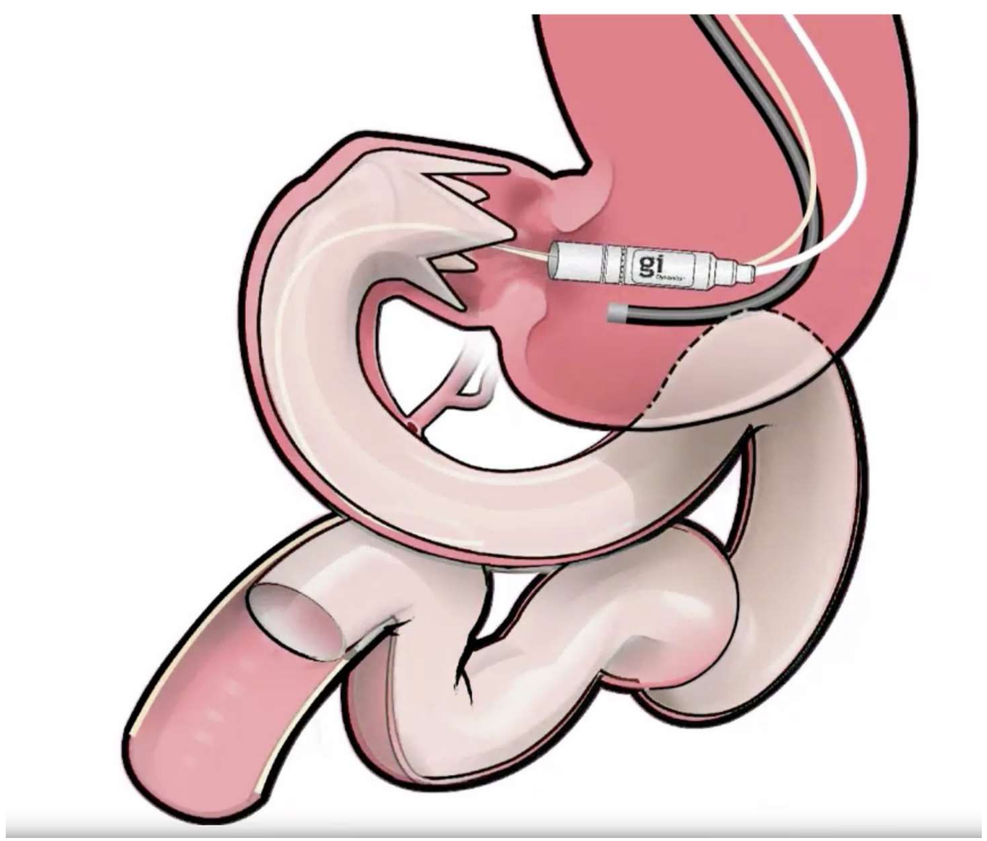
ENDOSCOPIC DUODENOJEJUNAL BYPASS WITH GI SLEEVE



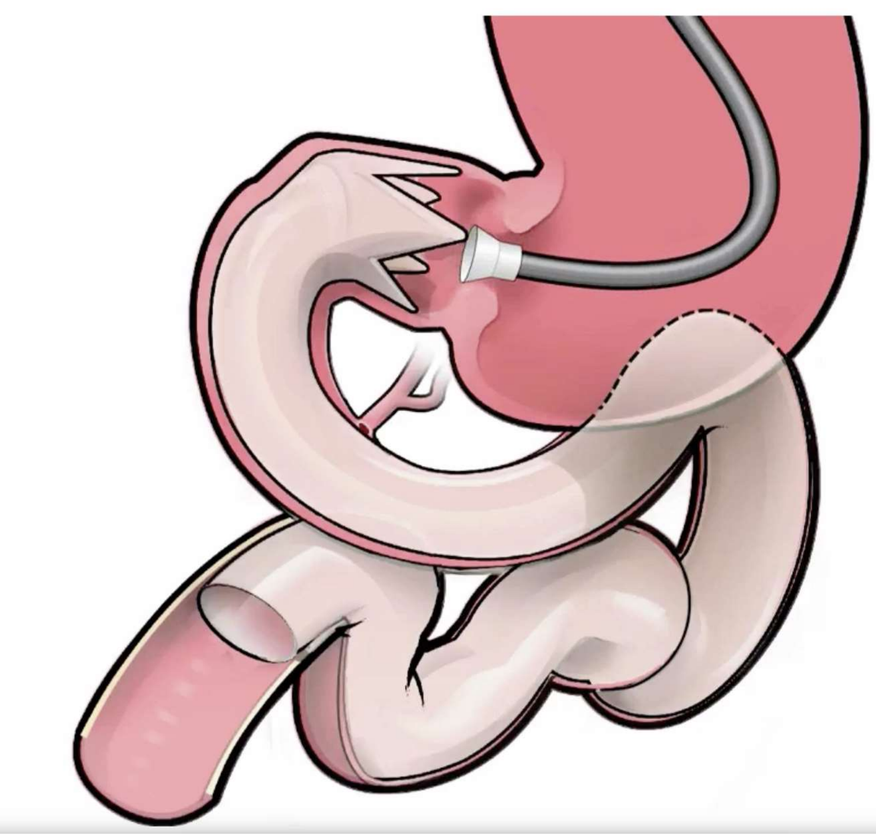
Procedure - Implant

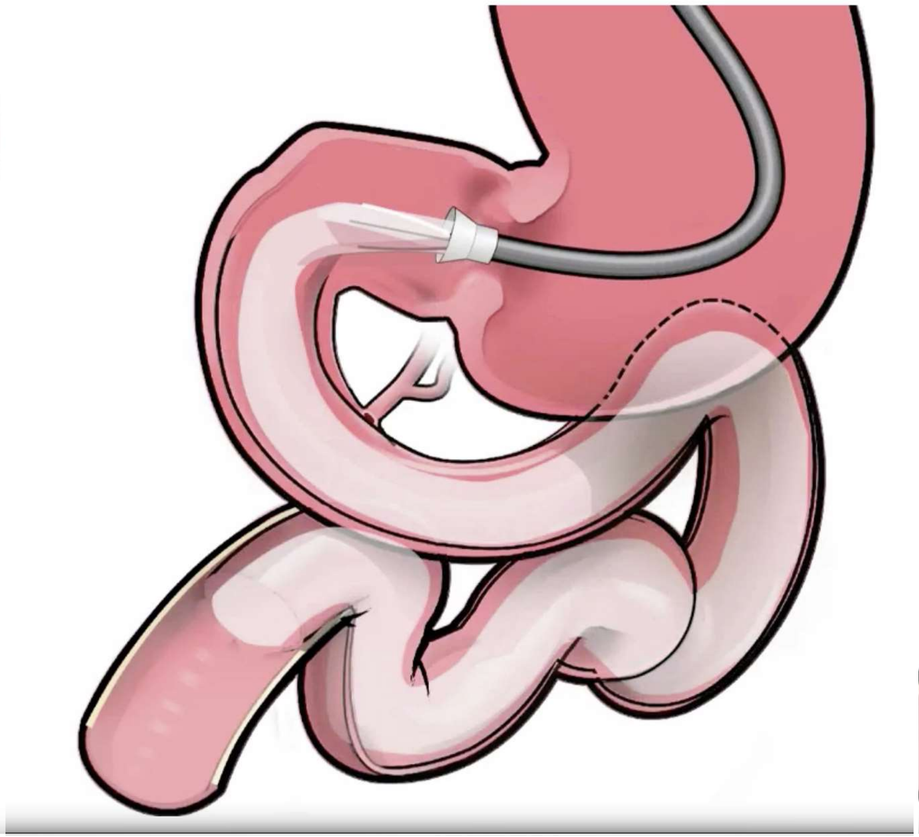


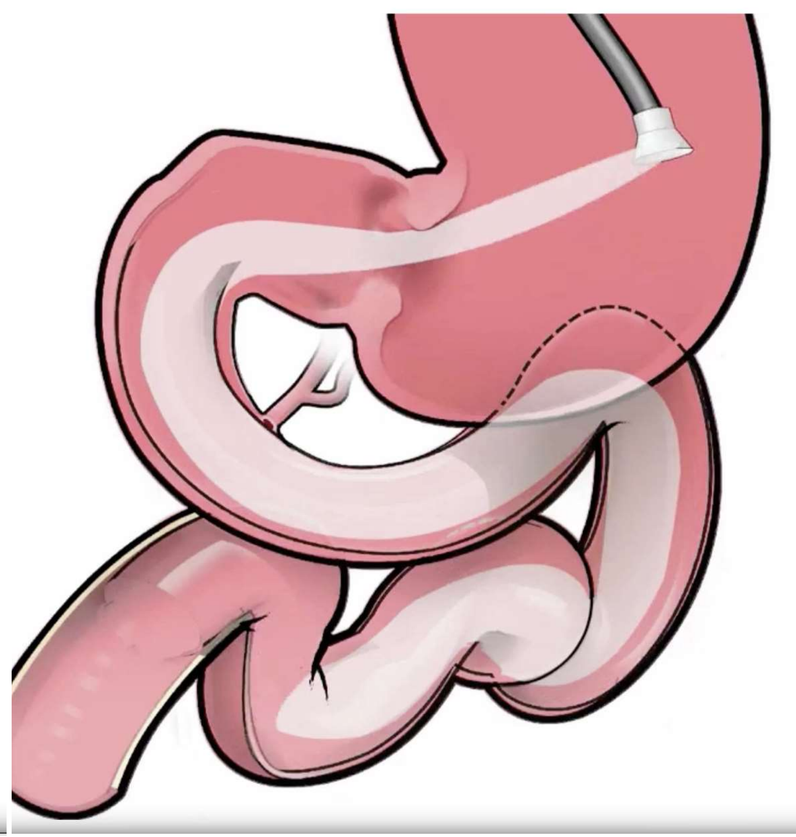
Procedure - mechanistic



Procedure - Explant







ELSEVIER

Video Available Online

Surgery for Obesity and Related Diseases 4 (2008) 55–59

SURGERY FOR OBESITY AND RELATED DISEASES

Original article with video

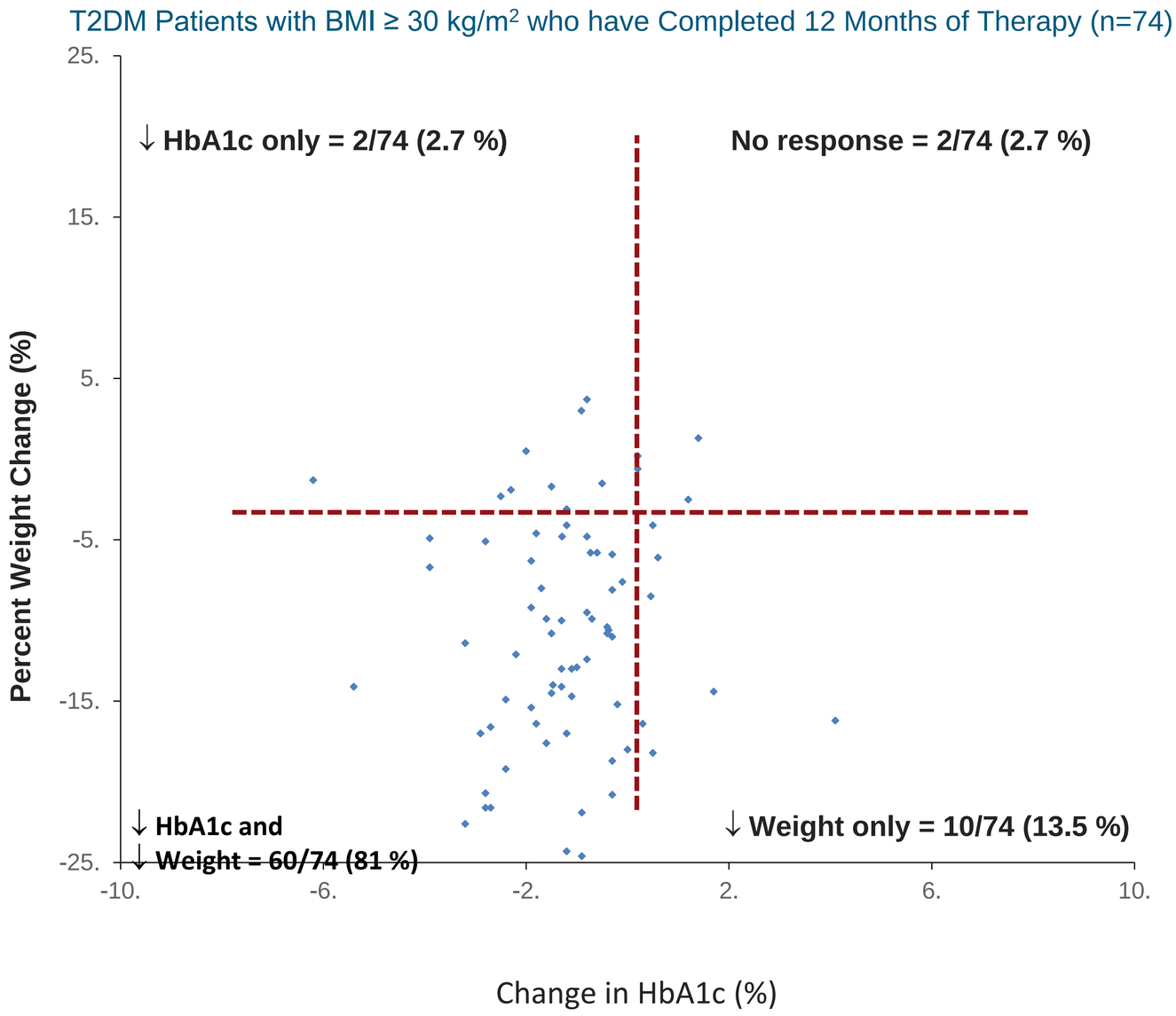
First human experience with endoscopically delivered and retrieved duodenal-jejunal bypass sleeve

Leonardo Rodriguez-Grunert, M.D.[a], Manoel Passos Galvao Neto, M.D.[b], Munir Alamo, M.D.[a], Almino Cardoso Ramos, M.D.[b], Percy Brante Baez, M.D.[a], Michael Tarnoff, M.D., F.A.C.S.[c,*]

[a]*Centro de Cirugía de la Obesidad, Hospital DIPRECA, Las Condes, Santiago de Chile*
[b]*Gastro Obeso Center, São Pãulo, Brazil*
[c]*Department of Surgery, Tufts-New England Medical Center, Boston, Massachusetts*

Received May 11, 2007; revised June 26, 2007; accepted July 6, 2007

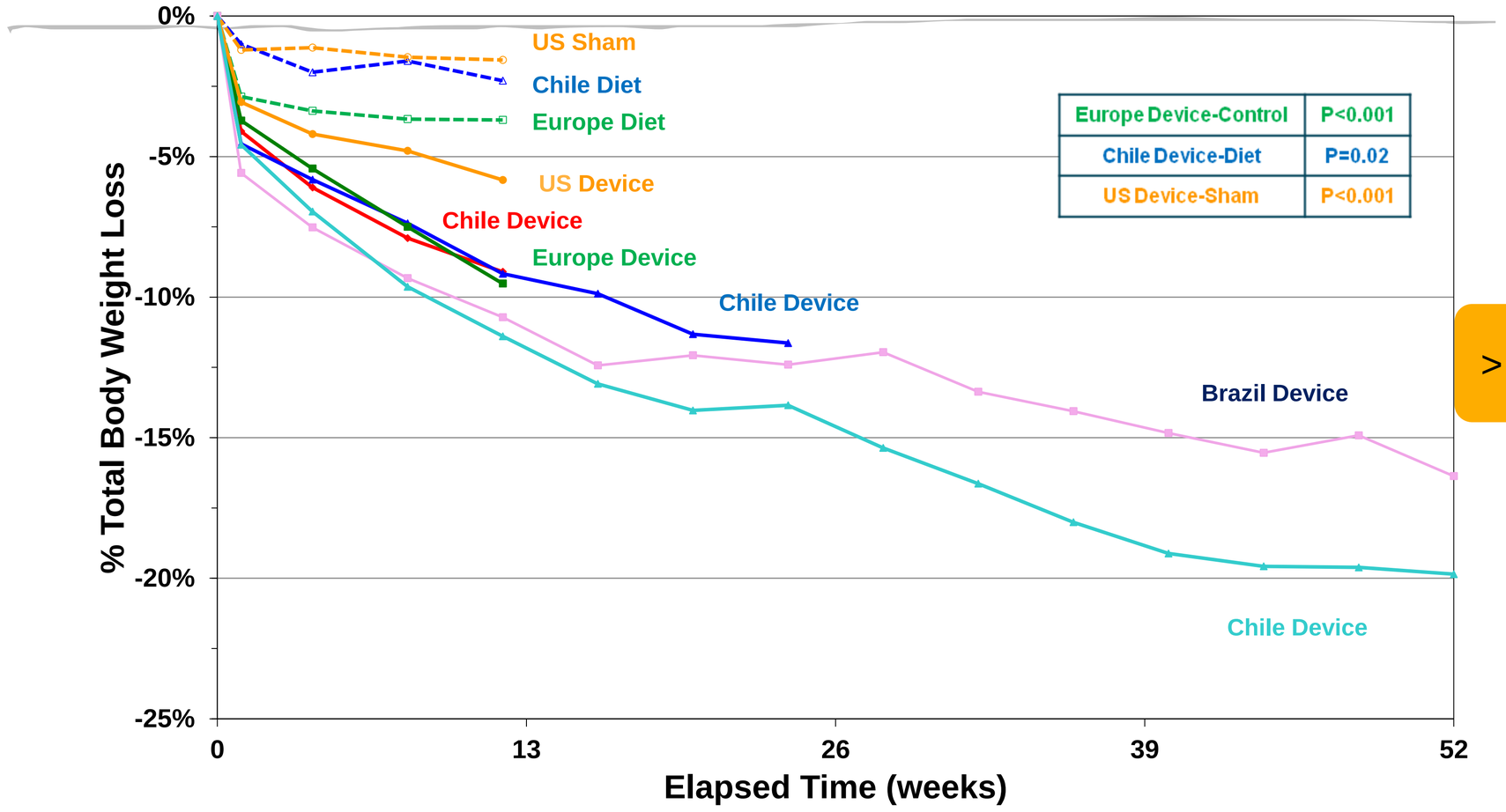
DJ Bypass positively affects weight loss and glycemic control for the majority of patients



- 1-1.5% H1AC

DJ Bypass

Significant weight loss



> 10% TWL @1Y

Results from prospective comparative trials data...

ASGE TECHNOLOGY COMMITTEE SYSTEMATIC REVIEW AND META-ANALYSIS

ASGE Bariatric Endoscopy Task Force systematic review and meta-analysis assessing the ASGE PIVI thresholds for adopting endoscopic bariatric therapies

Prepared by: ASGE BARIATRIC ENDOSCOPY TASK FORCE AND ASGE TECHNOLOGY COMMITTEE

Barham K. Abu Dayyeh, MD, MPH, Nitin Kumar, MD, Steven A. Edmundowicz, MD, FASGE, Co-Chair, Bariatric Endoscopy Task Force, Sreenivasa Jonnalagadda, MD, FASGE, Michael Larsen, MD, Shelby Sullivan, MD, Christopher C. Thompson, MD, MSc, FASGE, Co-Chair, Bariatric Endoscopy Task Force, Subhas Banerjee, MD, FASGE, Chair, Technology Committee

This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.

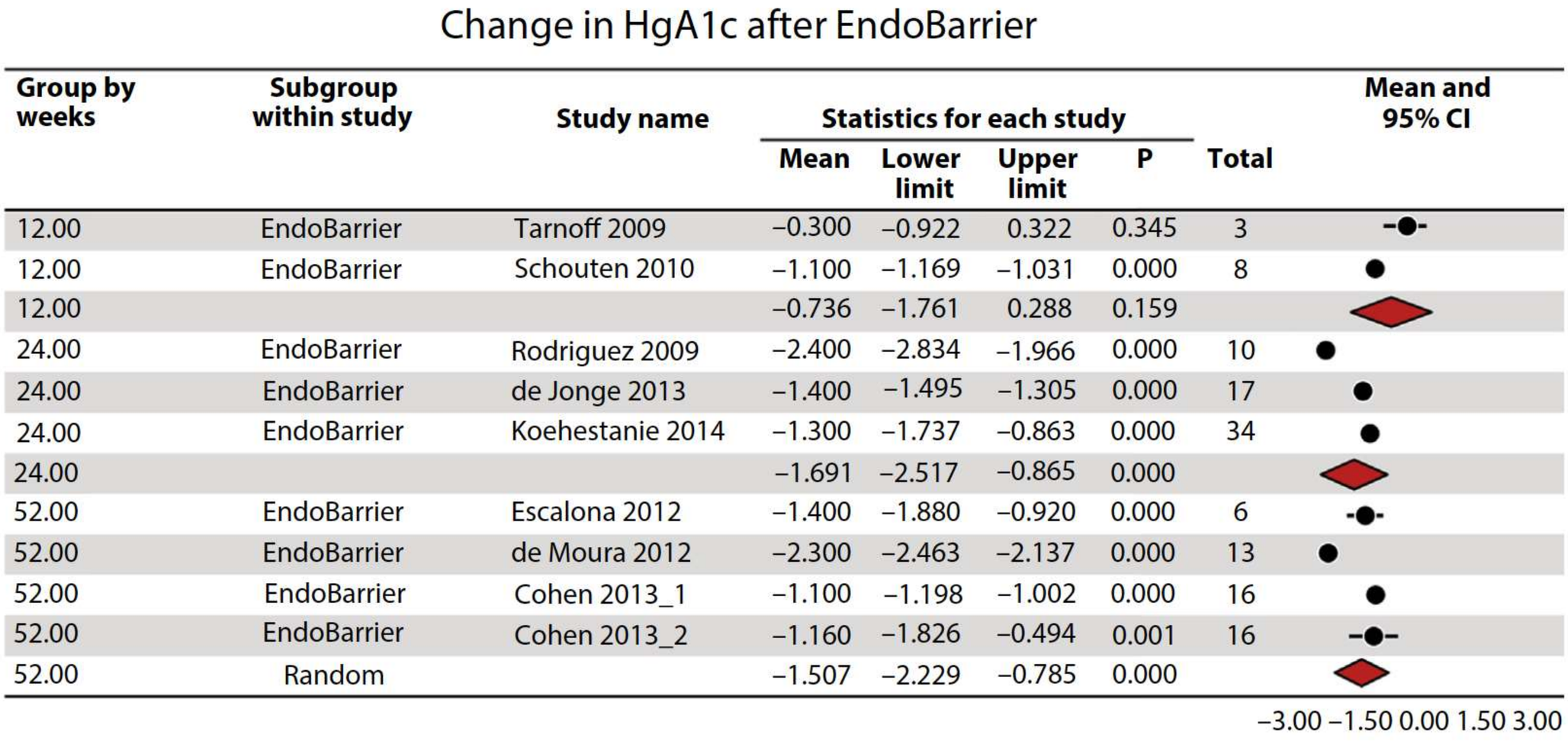


Figure 7. Forest plot depicting changes in glycosylated hemoglobin (HgA_{1c}) after 12, 24, and 52 weeks of EndoBarrier implantation.

Mean difference in HgA1c between EndoBarrier and control groups in RCTs

Study name	Subgroup within study	Statistics for each study				Sample size		Difference in means and 95% CI
		Difference in Mean	Lower limit	Upper limit	P	EndoBarrier	Control	
Rodriguez 2009	EndoBarrier	−1.700	−2.440	−0.960	0.000	10	4	
Schouten 2010	EndoBarrier	−0.700	−1.059	−0.341	0.000	8	2	
Koehestanie 2014	EndoBarrier	−0.900	−1.780	−0.020	0.045	34	35	
	Random	−1.052	−1.677	−0.426	0.001			

−3.00 −1.50 0.00 1.50 3.00

Favors EndoBarrier Favors Control

Endotrial (FDA trial) enrollment suspended

- **March 5th , 2015:**
  - **Hepatic abscess rate higher than expected…**

ENDO Trial Primary Endpoint: HbA1c

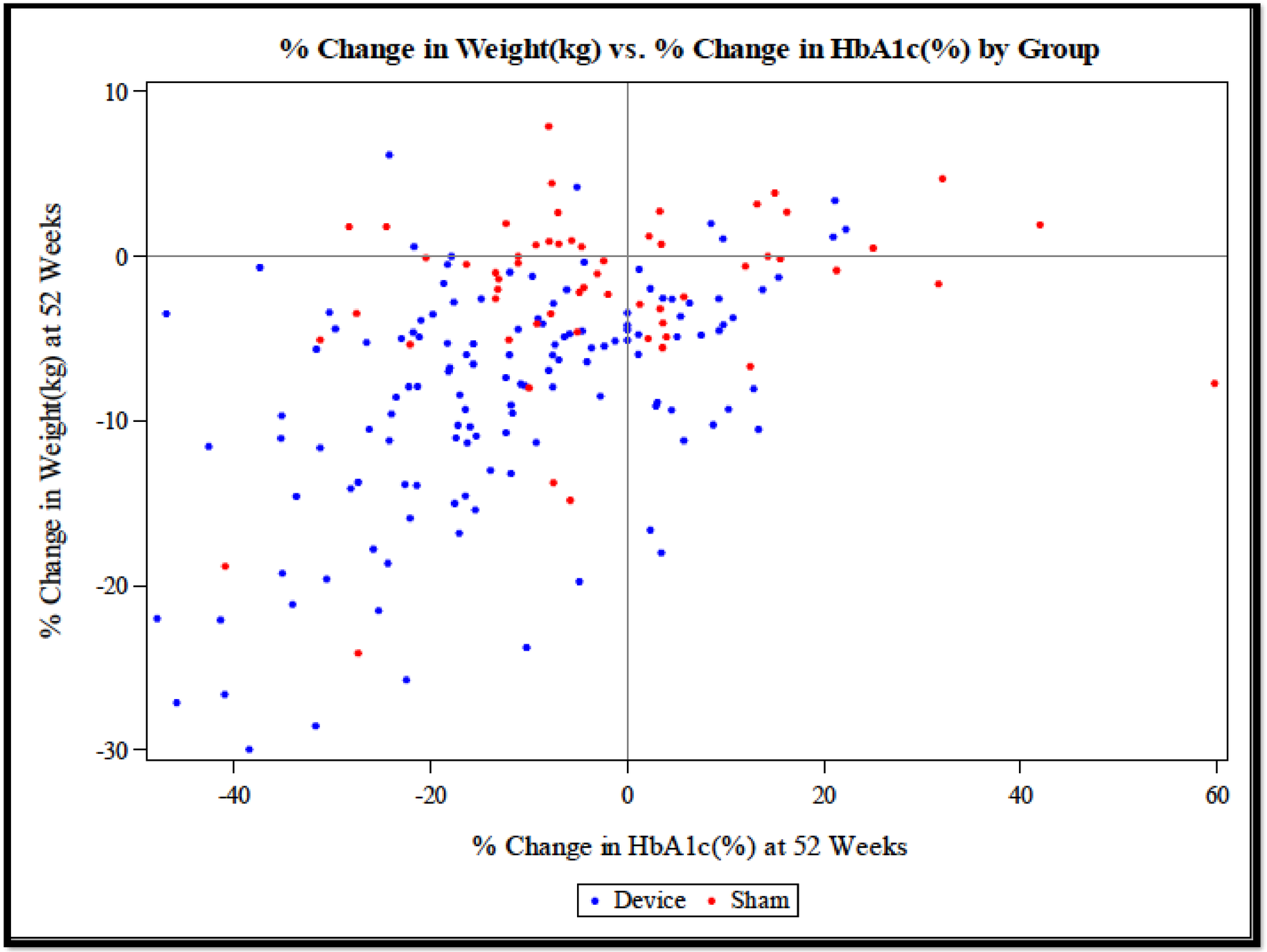
Supportive preliminary analysis of data

- At the time of primary endpoint efficacy analysis, HbA1c data was available for **141 patients at 12 months**
- Treatment effect (delta) on HbA1c at 12 months: **1.11 units** in favor of EndoBarrier versus control and statistically significant: p-value 0.008

Time post-enrollment	EndoBarrier	Sham	p-value*
12 months	-1.25 ± 0.15	-0.14 ± 0.22	0.008

**p-values test superiority against predefined success criterion of a 0.4-unit treatment effect. Both time points show a statistically significant effect in a simple test of superiority.*

Liver abscess rate 7/201 = 3.48%


% Change in Weight(kg) vs. % Change in HbA1c(%) by Group
10
0
-10
-20
-30
% Change in Weight(kg) at 52 Weeks
-40
-20
0
20
40
60
% Change in HbA1c(%) at 52 Weeks
Device
Sham

Endotrial (FDA trial) enrollment suspended

- **September , 2018:**
- **FDA approves a new trial to 9m use…**

Review | Published: 12 December 2022

The Effectiveness and Safety of the Duodenal-Jejunal Bypass Liner (DJBL) for the Management of Obesity and Glycaemic Control: a Systematic Review and Meta-Analysis of Randomized Controlled Trials

Erika Yuki Yvamoto , Diogo Turiani Hourneaux de Moura, Igor Mendonça Proença, Epifanio Silvino do Monte Junior, Igor Braga Ribeiro ✉, Pedro Henrique Boraschi Vieira Ribas, Matheus Cândido Hemerly, Victor Lira de Oliveira, Sergio A. Sánchez-Luna, Wanderley Marques Bernardo & Eduardo Guimarães Hourneaux de Moura

Obesity Surgery **33**, 585–599 (2023) | Cite this article

The effectiveness and safety of the duodenal-jejunal bypass liner (DJBL) for the management of obesity and glycaemic control: A systematic review and meta-analysis of randomized controlled trials

METHODS

Systematic review and meta-analysis.

Randomized Controlled Trials:

- Intervention group:
- Control group:

DJBL

Sham or lifestyle modification

10 Randomized Controlled Trials
Total of **681** obese patients:
391 in DJBL vs. **290** in control group

RESULTS

- The DJBL showed:

a **higher** weight loss;
+ 11.4% [+ 7.75 to + 15.03%

a higher decrease in HbA1c;
− 2.73 ± 0.5 vs. − 1.73 ± 0.4

compared to the control group.

- Adverse events of DJBL:

Severe AEs: **19.7%**.

Most AEs were treated with explantation.

CONCLUSIONS

- The DJBL **did not reach** the ASGE/ASMBS thresholds and FDA requirements for the treatment of **obesity.**

- The high rate of SAEs should be analyzed with caution, as many of these patients had **greater benefit than harm**.

- DJBL is one important tool for the management of **obesity and T2DM.**

IFSO

OBESITY SURGERY
The Journal of Metabolic Surgery and Allied Care

1,022 patients from 33 centers in 10 countries

Endoscopic Duodenal-Jejunal Bypass Liner Treatment for Type 2 Diabetes and Obesity: Glycemic and Cardiovascular Disease Risk Factor Improvements in 1,022 Patients Treated Worldwide

Diabetes Care 2023;46:e89–e91 | https://doi.org/10.2337/dc22-1952

Robert E.J. Ryder,[1] Katharina Laubner,[2] Marek Benes,[3] Martin Haluzik,[3] Lynne Munro,[4] Harry Frydenberg,[4] Julian P. Teare,[5] Aruchuna Ruban,[5] Sigal Fishman,[6] Erwin Santo,[6] Rainer Stengel,[7] Charlotte De Jonge,[8,9,10] Jan W. Greve,[11,12] Ricardo V. Cohen,[13] Cristina M. Aboud,[13] Gerald J. Holtmann,[14] Graeme Rich,[15] Jess J. McMaster,[14] Tadej Battelino,[16,17] Primoz Kotnik,[17] James P. Byrne,[18] John C. Mason,[19] Justin Bessell,[20] Jeanine Bascomb,[21] Lillian Kow,[21] Janes Collins,[22] Jacob Chisholm,[22] Peter N. Pferschy,[23] Harald Sourij,[23] Melissa L. Cull,[1] Melanie C. Wyres,[1] Russell Drummond,[24] Barbara McGowan,[25] Stephanie A. Amiel,[26] Mahi Yadagiri,[1] Piya Sen Gupta,[1,25] Jens Aberle,[27] and Jochen Seufert[2]

Diabetes Care

American Diabetes Association®

1,022 patients from 33 centers in 10 countries

Impact of EndoBarrier treatment on HbA_{1c} ranges (%)

All	646	8.3 ± 1.8	7.1 ± 1.3	−1.3 ± 1.5	<0.001
HbA_{1c} 7.0–7.9	141	7.5 ± 0.3	6.8 ± 0.8	−0.7 ± 0.8	<0.001
HbA_{1c} 8.0–8.9	158	8.4 ± 0.3	7.3 ± 1.0	−1.1 ± 1.0	<0.001
HbA_{1c} 9.0–9.9	96	9.4 ± 0.3	7.8 ± 1.1	−1.6 ± 1.1	<0.001
HbA_{1c} ≥10	111	11.2 ± 1.2	8.0 ± 1.5	−3.2 ± 1.7	<0.001

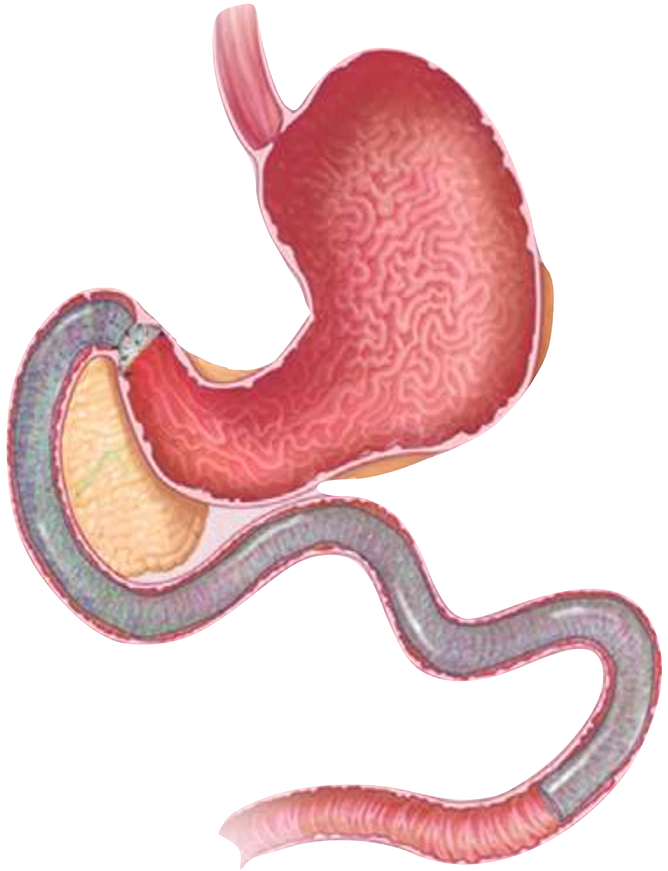
Impact of EndoBarrier treatment on BMI ranges (kg/m^2)

All	808	41.2 ± 10.0	36.6 ± 8.8	−4.6 ± 3.6	<0.001

Impact of EndoBarrier treatment on weight, systolic BP, and cholesterol

Weight (kg)	811	120.2 ± 25.3	106.9 ± 23.8	−13.3 ± 9.7	<0.001
BMI (kg/m^2)	808	41.2 ± 10.0	36.6 ± 8.8	−4.6 ± 3.6	<0.001
Systolic BP (mmHg)	448	135.7 ± 18.0	129.5 ± 17.0	−6.3 ± 19.2	<0.001
Cholesterol (mmol/L)	467	4.8 ± 1.2	4.2 ± 1.0	−0.6 ± 1.03	<0.001

MOHAK
BARIATRICS & ROBOTICS
WEIGHT LOSS & DIABETES SURGERY CENTRE



New trial - 2023

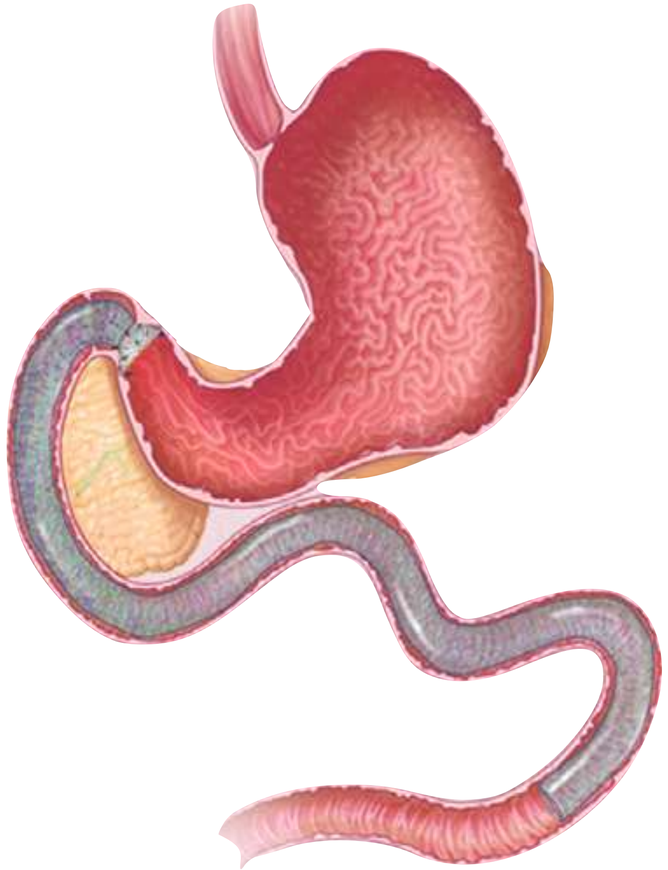
10 years

Up to 15 %TWL

Drop of 1.5 - 2.0 HgA1C

Safe?

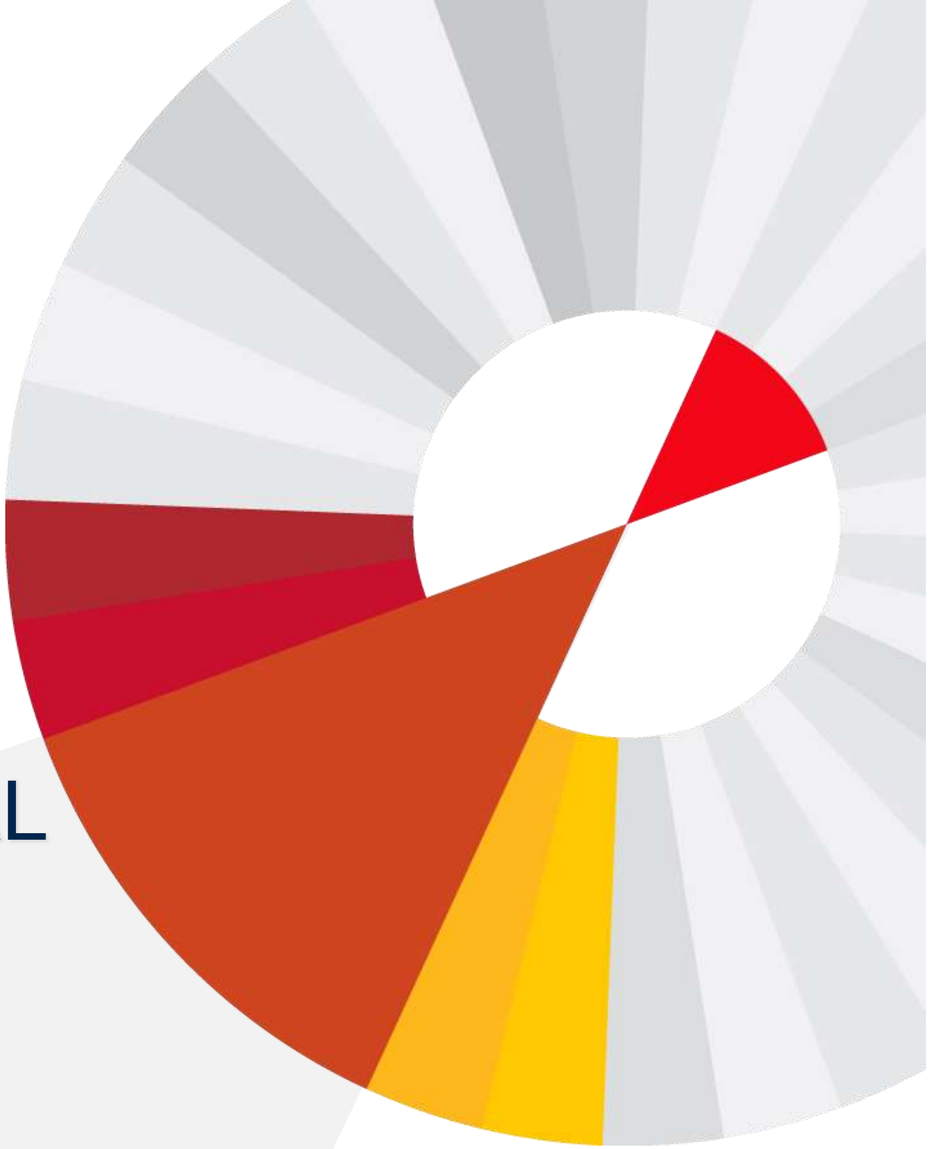
Experimental

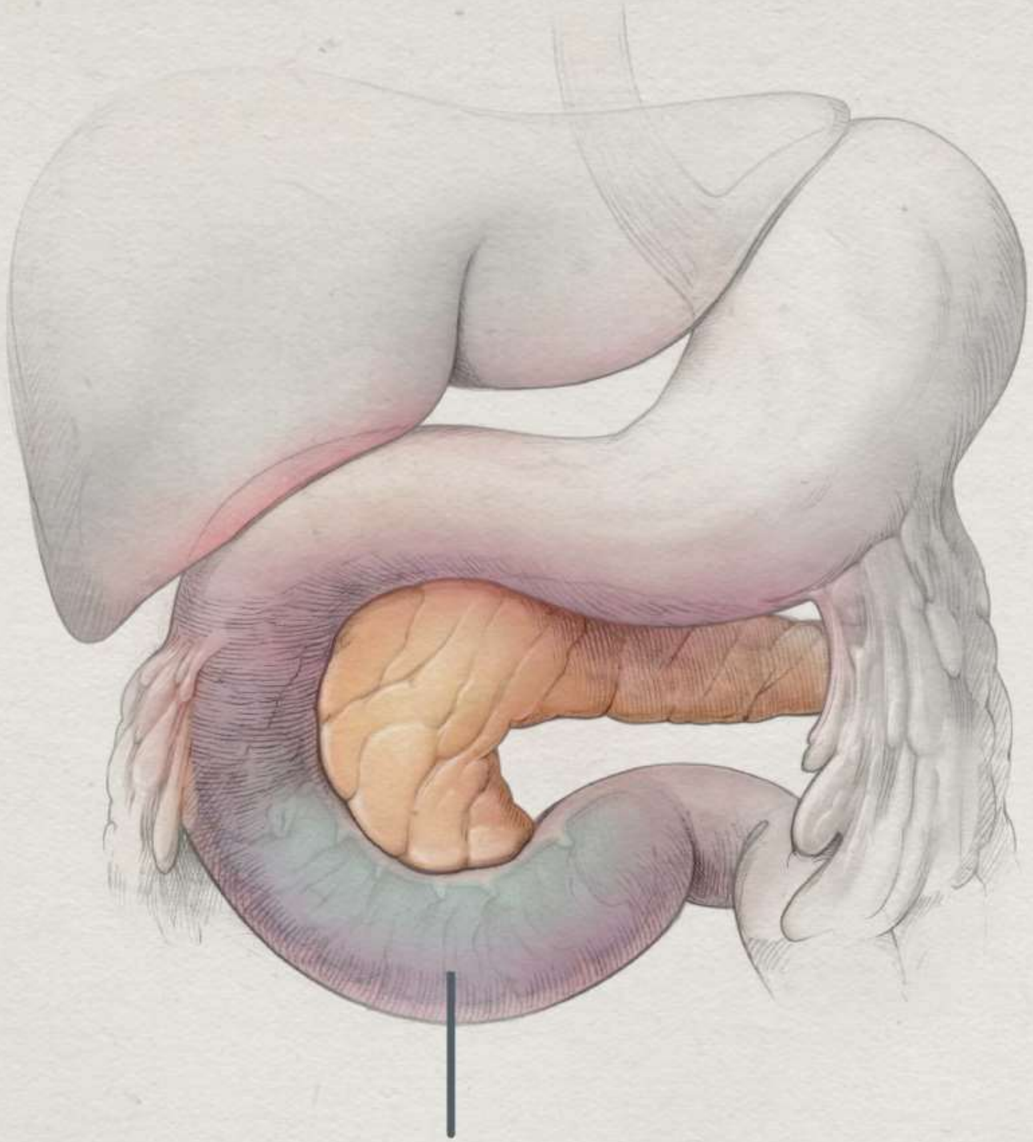


FDA Study

ENDOSCOPIC

THERMAL DUODENAL MUCOSAL RESURFACING




Duodenal mucosa

Video GIE
An official video journal of the American Society for Gastrointestinal Endoscopy

September 2016 Volume 1, Issue 1, Pages 10–11

Hydrothermal duodenal mucosal resurfacing: a novel procedural therapy for metabolic disease

Manoel Galvao Neto, MD
Gastro Obeso Center, São Paulo, Brazil
Department of Surgery, Florida International University, Florida, USA
Leonardo Rodriguez, MD, Pablo Becerra, MD
CCO Clinical Center for Diabetes, Obesity and Reflux, Santiago, Chile
Shweta Mani, MS
Fractyl Laboratories, Inc., Waltham, Massachusetts, USA
Richard Rothstein, MD
Department of Medicine, Geisel School of Medicine at Dartmouth, Hanover, New Hampshire, USA

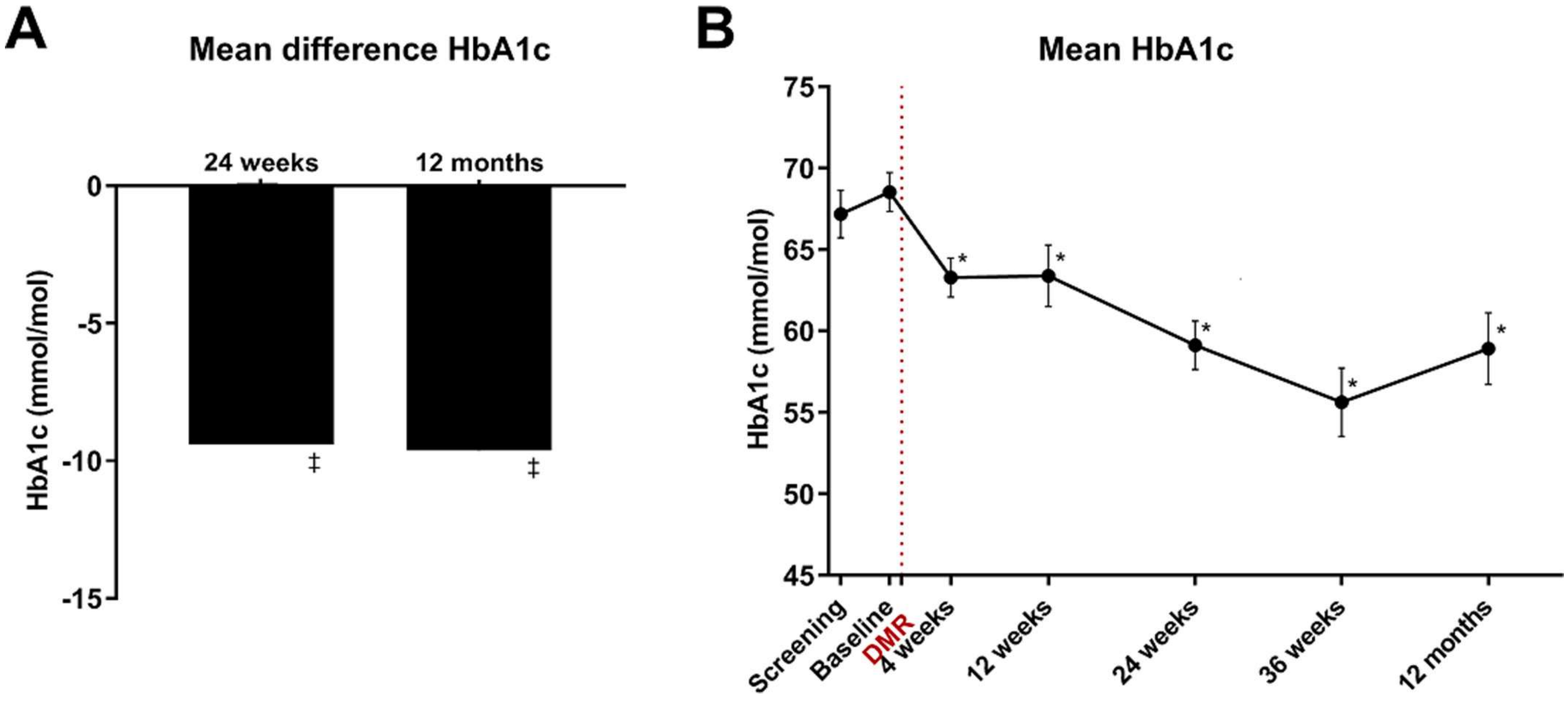
Open Access | Altmetric 0

DOI: http://dx.doi.org/10.1016/j.vgie.2016.07.011

Endoscopic Duodenal Mucosal Resurfacing for the Treatment of Type 2 Diabetes: 6-Month Interim Analysis From the First-in-Human Proof-of-Concept Study

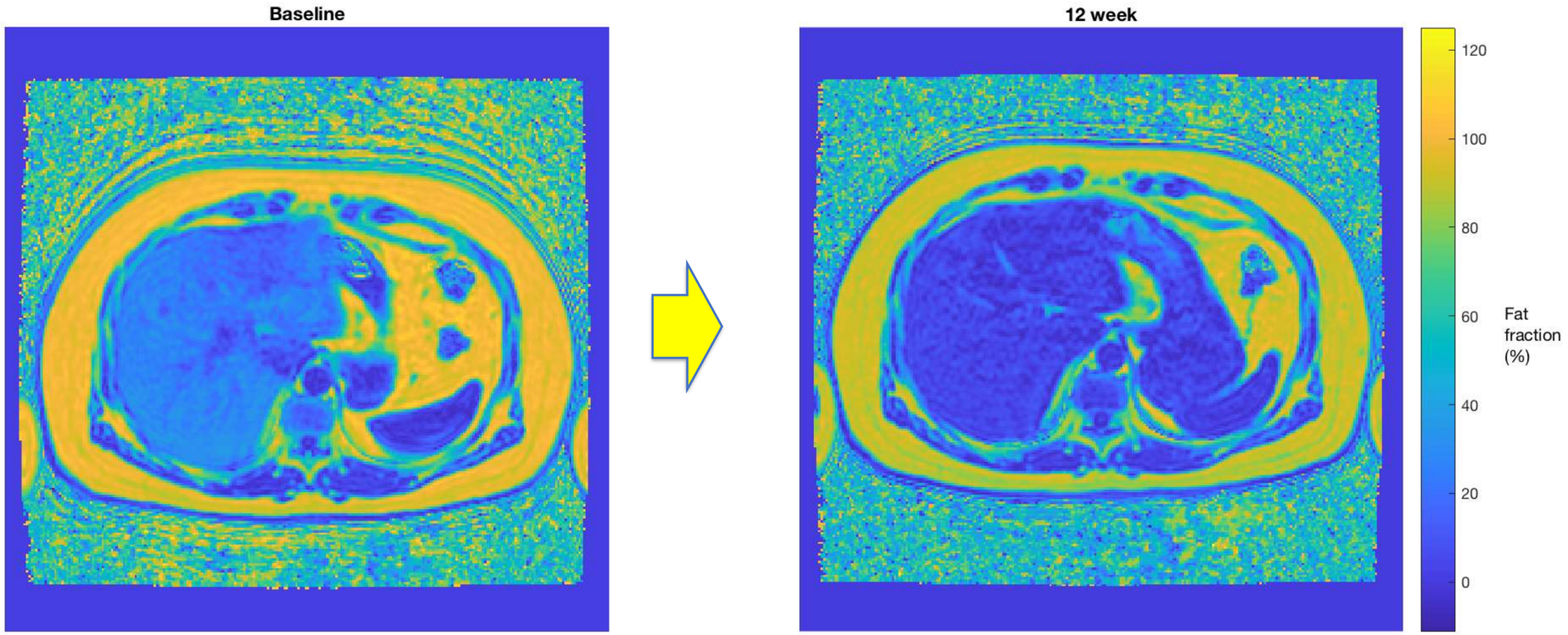
Harith Rajagopalan,[1] Alan D. Cherrington,[2] Christopher C. Thompson,[3] Lee M. Kaplan,[4] Francesco Rubino,[5] Geltrude Mingrone,[6] Pablo Becerra,[7] Patricia Rodriguez,[7] Paulina Vignolo,[7] Jay Caplan,[1] Leonardo Rodriguez,[7] and Manoel P. Galvao Neto[8,9]

Diabetes Care 2016;39:1–8 | DOI: 10.2337/dc16-0383


A
Mean difference HbA1c
24 weeks
12 months
0
-5
-10
-15
HbA1c (mmol/mol)
‡
‡
B
Mean HbA1c
75
70
65
60
55
50
45
HbA1c (mmol/mol)
*
*
*
*
*
Screening
Baseline
DMR
4 weeks
12 weeks
24 weeks
36 weeks
12 months

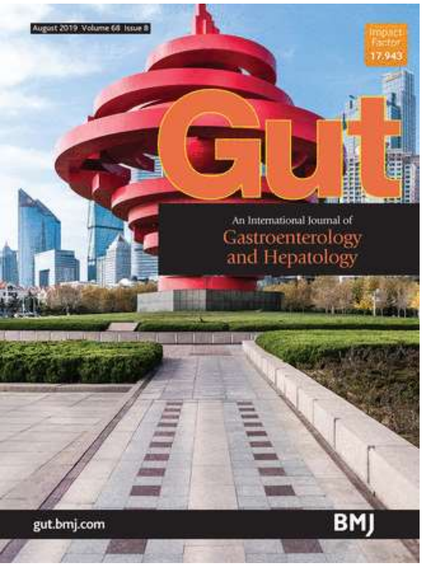
MRI hepatic fat fraction (PDFF)

Single case illustration



On MRI-PDFF images, a darker hue is indicative of a reduction in Hepatic fat content

Maggs, et al. Poster presented at: AASLD 2018 The Liver Meeting; November 9-12; Publication Number 0742



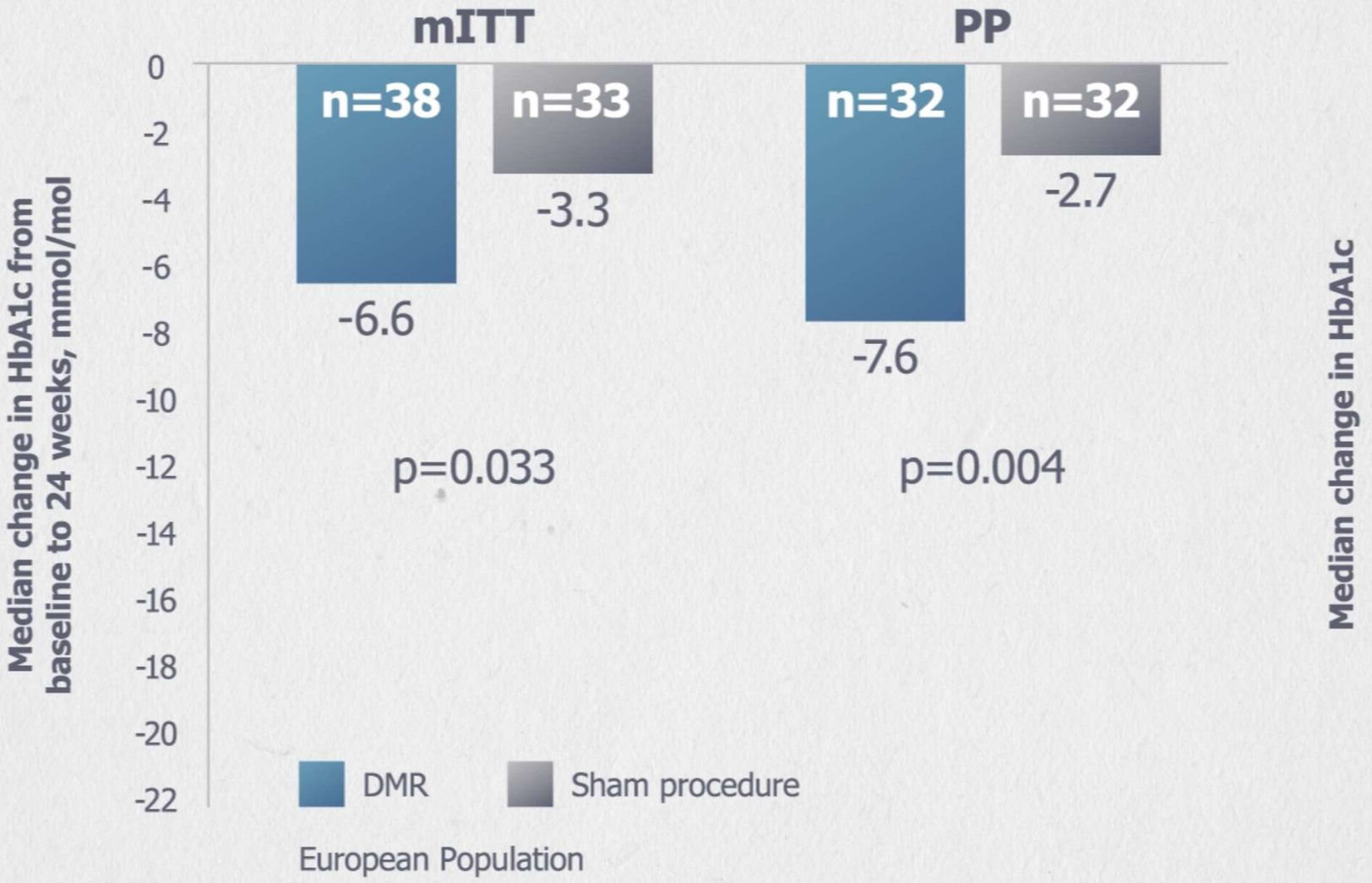
Original research

Safety and efficacy of hydrothermal duodenal mucosal resurfacing in patients with type 2 diabetes: the randomised, double-blind, sham-controlled, multicentre REVITA-2 feasibility trial

2021

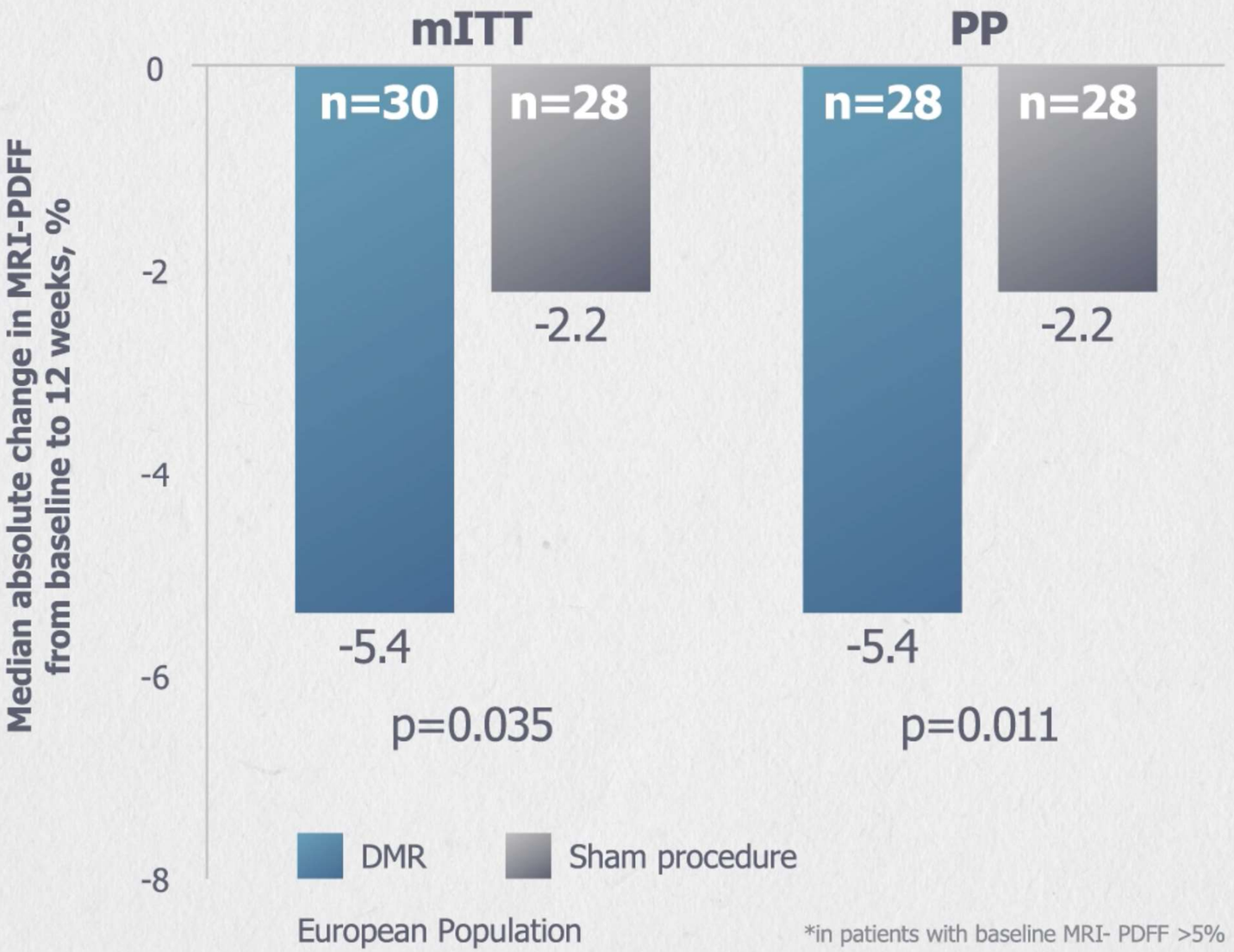
Geltrude Mingrone ,[1,2] Annieke CG van Baar,[3] Jacques Devière,[4] David Hopkins,[5] Eduardo Moura,[6] Cintia Cercato,[7] Harith Rajagopalan,[8] Juan Carlos Lopez-Talavera,[8] Kelly White,[8] Vijeta Bhambhani,[8] Guido Costamagna,[9] Rehan Haidry,[10] Eduardo Grecco,[11] Manoel Galvao Neto,[11] Guruprasad Aithal ,[12] Alessandro Repici,[13,14] Bu'Hussain Hayee ,[10] Amyn Haji ,[15] A John Morris,[16] Raf Bisschops ,[17] Manil D Chouhan,[18] Naomi S Sakai,[18] Deepak L Bhatt,[19] Arun J Sanyal,[20] J J G H M Bergman ,[3] Investigators of the REVITA-2 Study

HbA1c



European Population

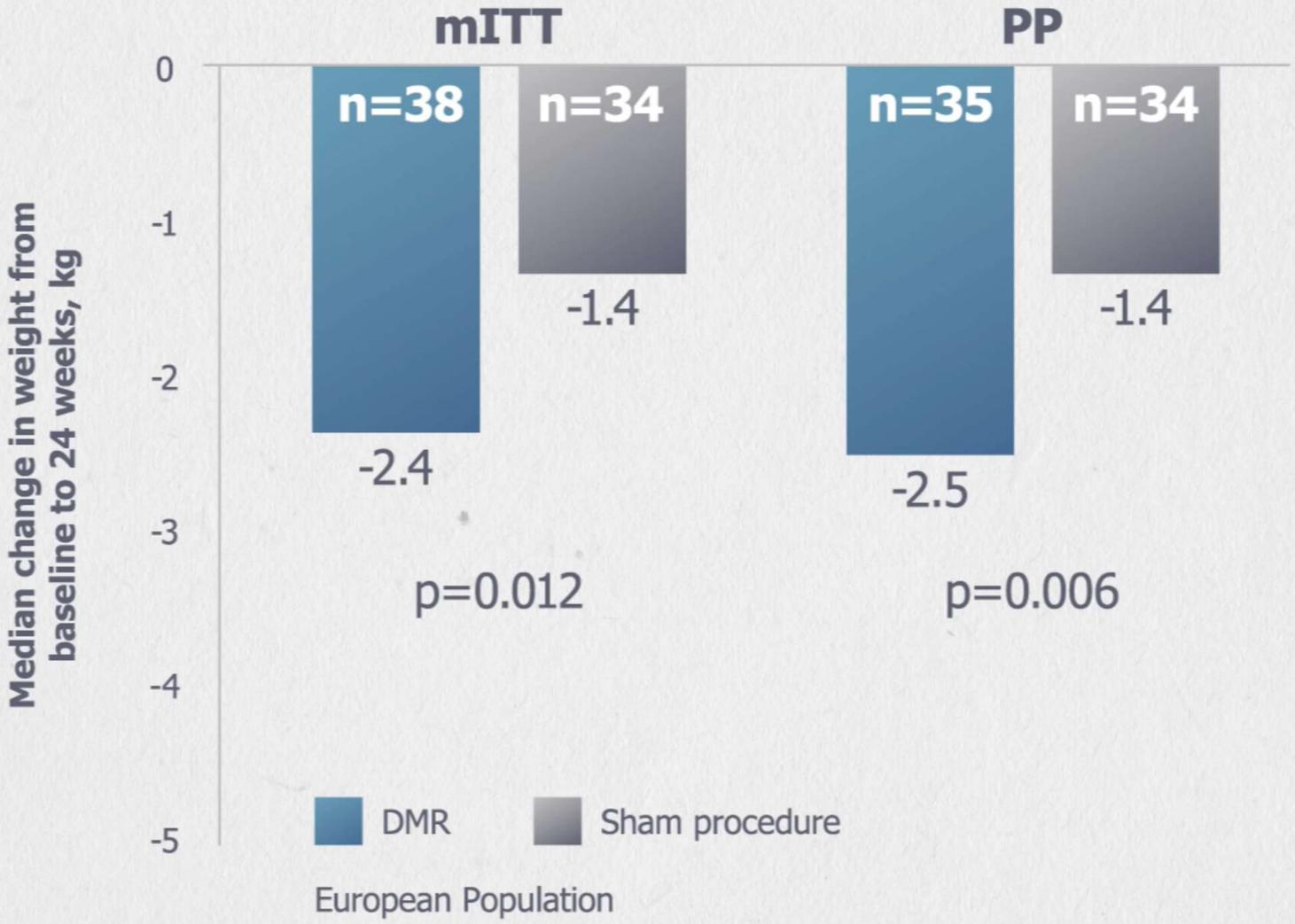
Liver MRI-PDFF*



European Population

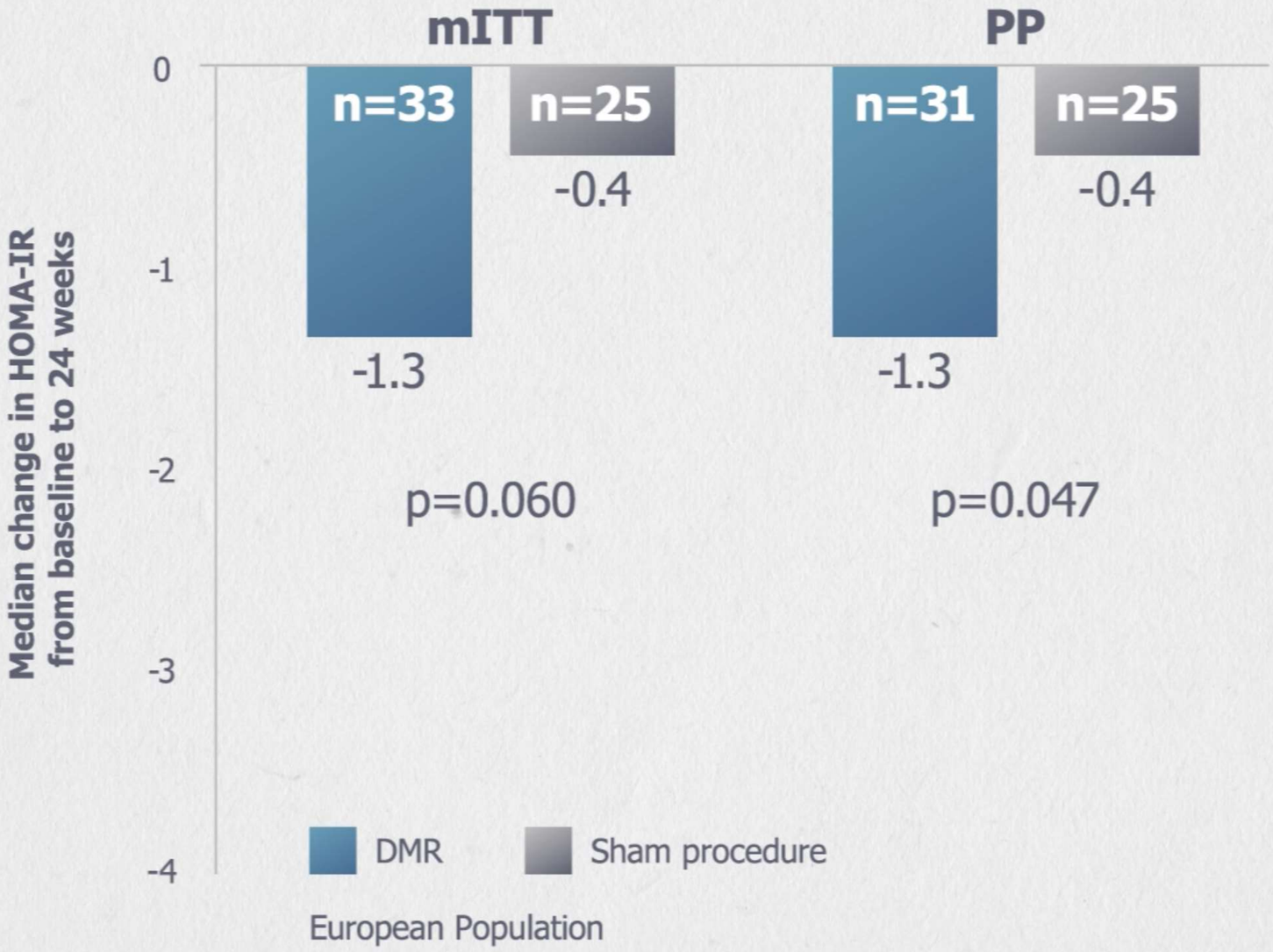
*in patients with baseline MRI- PDFF >5%

Weight



European Population

HOMA-IR


mITT
PP
0
-1
-2
-3
-4
n=33
n=25
n=31
n=25
-0.4
-0.4
-1.3
-1.3
p=0.060
p=0.047
Median change in HOMA-IR from baseline to 24 weeks
DMR
Sham procedure
European Population

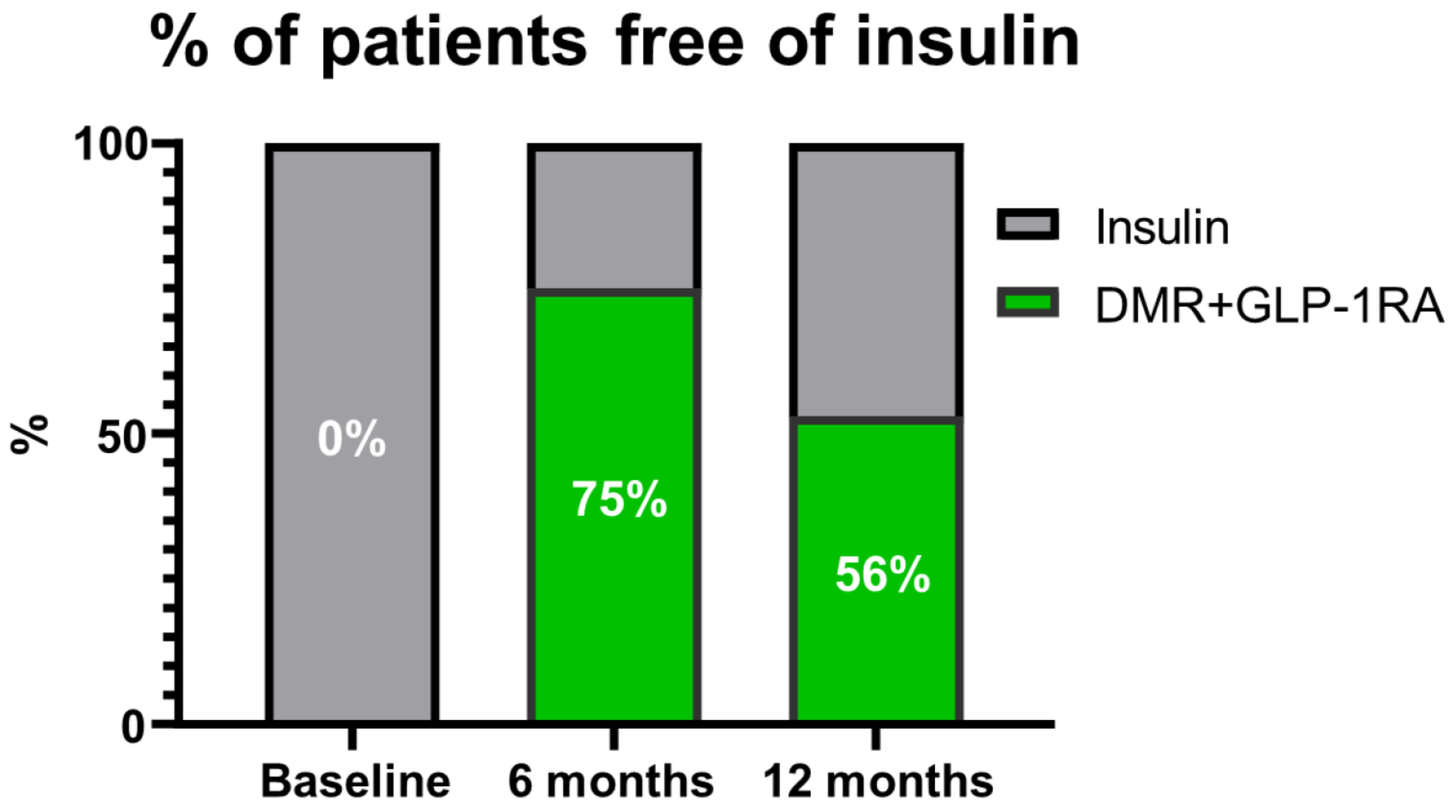
Duodenal mucosal resurfacing combined with GLP-1RA may eliminate insulin treatment in type 2 diabetes while improving glycaemic control and metabolic health

S. Meiring[1], A.C.G. van Baar[1], P. Smeele[1], T. Vriend[2], F. Holleman[3], M.R. Soeters[3], J.G.P. Tijssen[4], M. Nieuwdorp[5], J.J.G.H.M. Bergman[1]

[1]Gastroenterology and Hepatology, Amsterdam University Medical Centers, location AMC, Amsterdam, the Netherlands;
[2]Dietetics, Amsterdam University Medical Centers, location AMC, Amsterdam, the Netherlands;
[3]Internal Medicine, Amsterdam University Medical Centers, location AMC, Amsterdam, the Netherlands;
[4]Cardiology; Amsterdam University Medical Centers, location AMC, Amsterdam, the Netherlands;
[5]Internal and Vascular Medicine, Amsterdam University Medical Centers, location AMC, Amsterdam, the Netherlands.

Primary endpoint;

Responders : HbA1c < 59 mmol/mol



Endocrinetoday

By Regina Schaffer

Perspective from Ali Aminian, MD

+ Source/Disclosures

May 05, 2021 | 2 min read

SAVE

Duodenal mucosal resurfacing gains FDA breakthrough device designation for type 2 diabetes

ADD TOPIC TO EMAIL ALERTS

The FDA granted breakthrough device designation for a first-in-class duodenal mucosal resurfacing intervention for adults with insulin-treated type 2 diabetes, according to an industry press release.

"Adults with insulin-treated type 2 diabetes"

FDA TRIAL PILOT

- 2019:
  - FDA trial will begin…

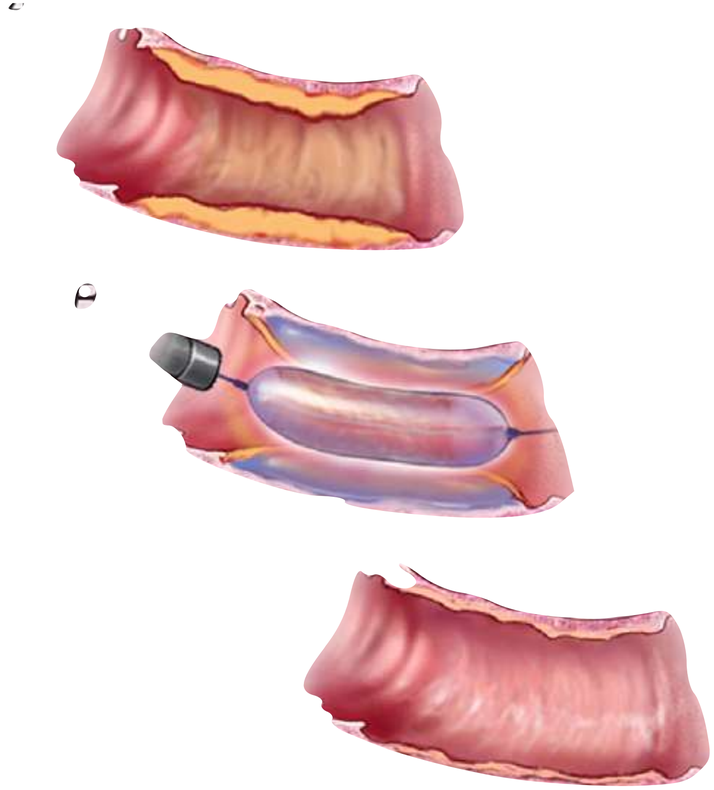
5 years

Not for weight loss

Drop of 1.2 - 1.4 HgA1C

Safe

Experimental but with a Breakthrough FDA ap

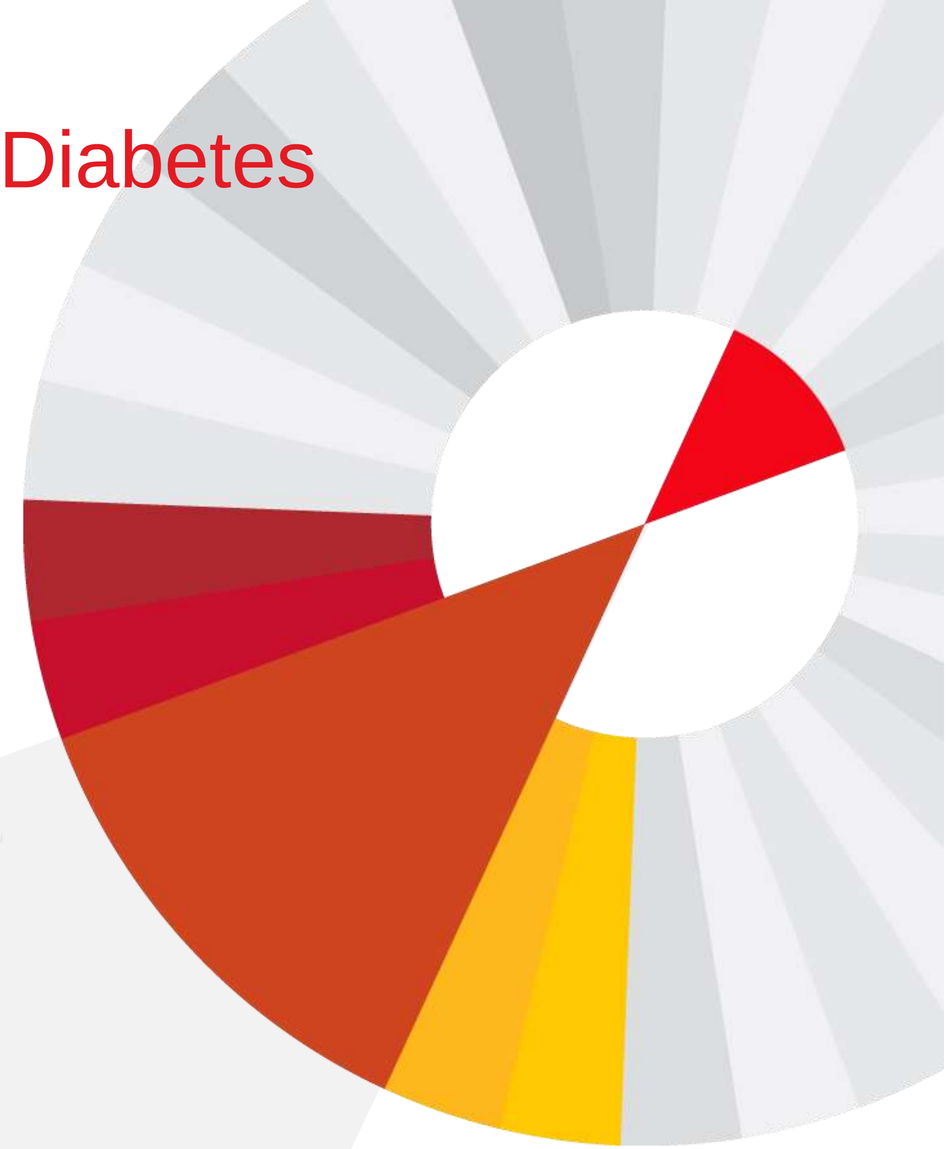


FDA Study

Endoscopic treatment of Diabetes

ENDOSCOPIC

LASER DUODENAL MUCOSAL RESURFACING

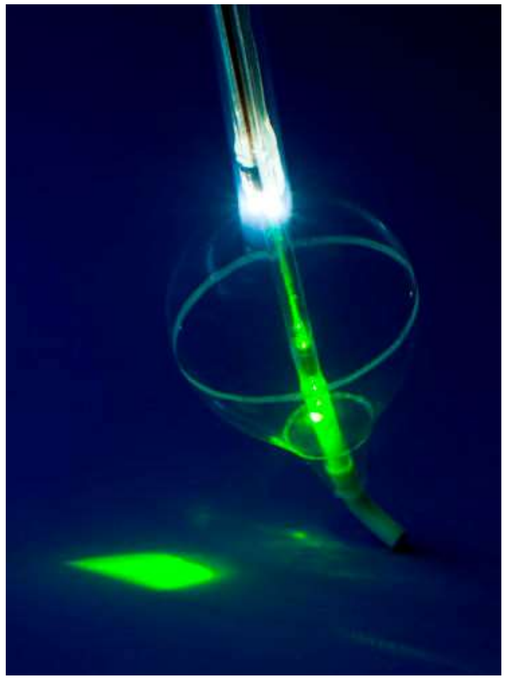


IN PARTNERSHIP WITH

American Diabetes Association.

APRIL 8-10, 2019, NEW YORK CITY

LASER ABLATION FOR THE TREATMENT OF TYPE 2 DIABETES – PRELIMINARY FIRST IN HUMAN STUDY RESULTS



M. Benes , Marcovitch , E. Goldin , M. Milos , A. Herschkovitz , M. Haluzik
Digma Medical Ltd., Givat Shmuel, Israel.

IN PARTNERSHIP WITH American Diabetes Association.

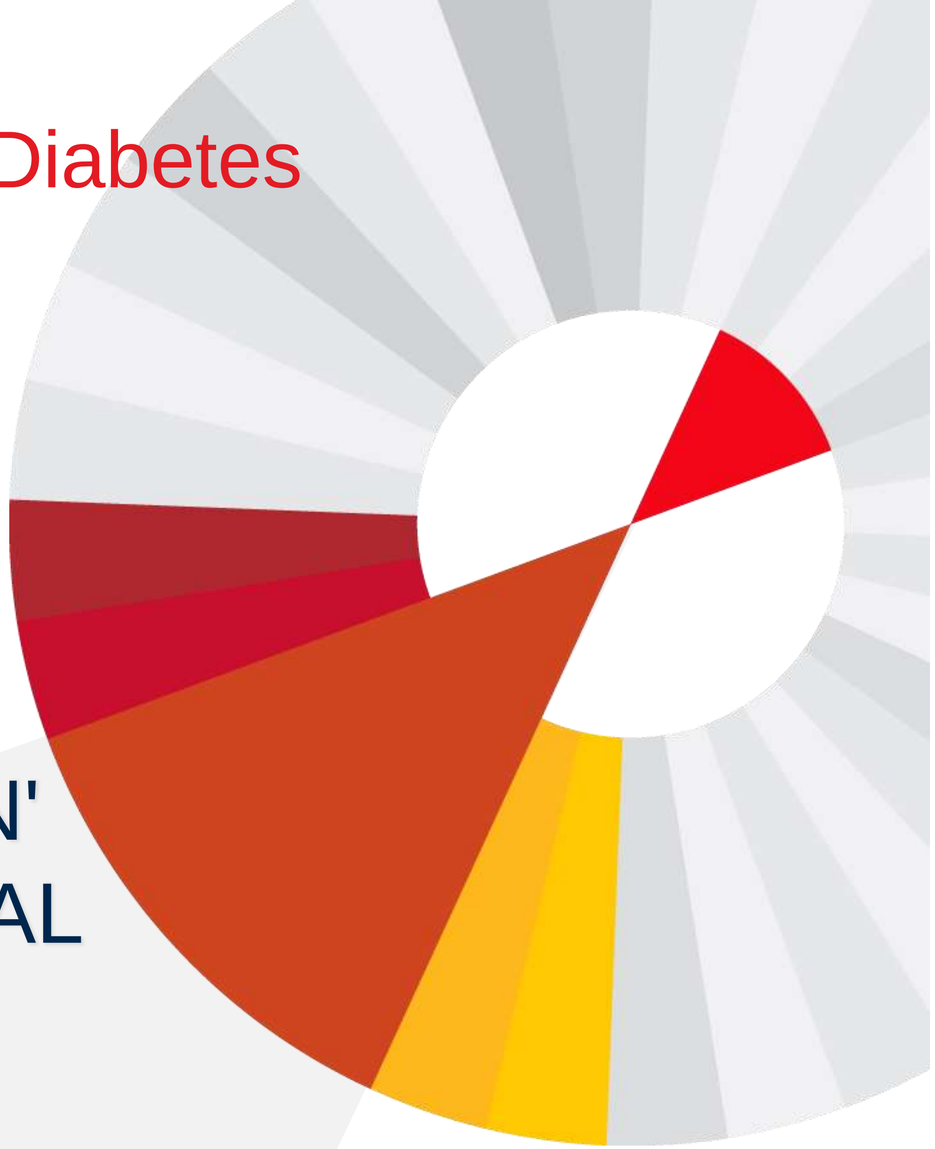
APRIL 8-10, 2019, NEW YORK CITY

LASER ABLATION FOR THE TREATMENT OF TYPE 2 DIABETES – PRELIMINARY FIRST IN HUMAN STUDY RESULTS

- N= 6 / FU = 6m
  - HbA1c from 9.4 to 8.4
  - All procedures completed successfully.
  - Median procedure time was 78 minutes.
  - No Adverse events device related.
  - No change in GI symptoms or behavior

M. Benes , Marcovitch , E. Goldin , M. Milos , A. Herschkovitz , M. Haluzik
Digma Medical Ltd., Givat Shmuel, Israel.

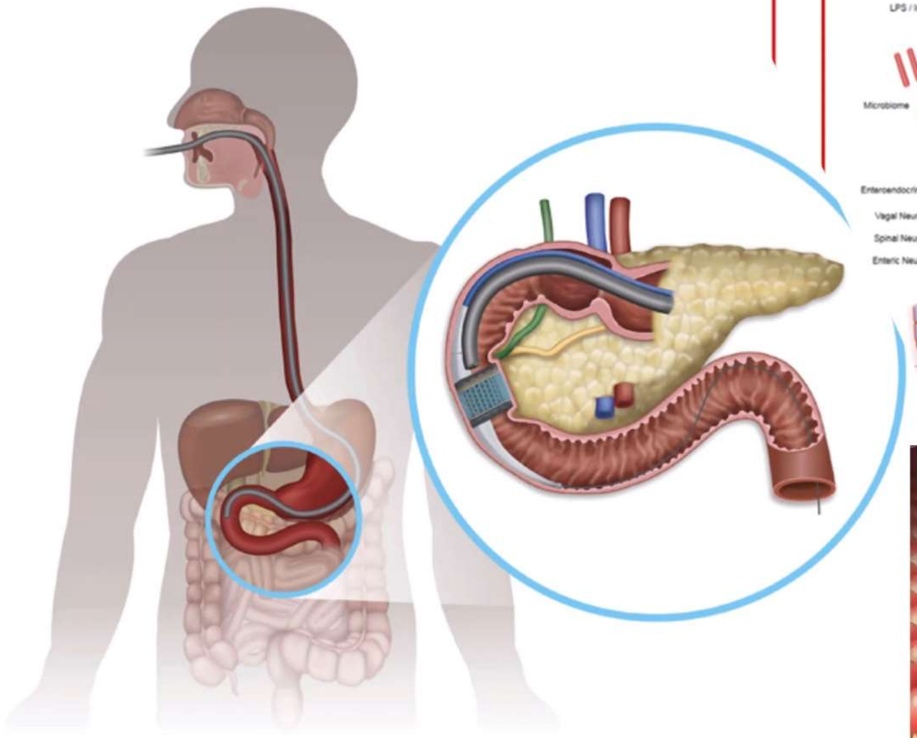
Endoscopic treatment of Diabetes

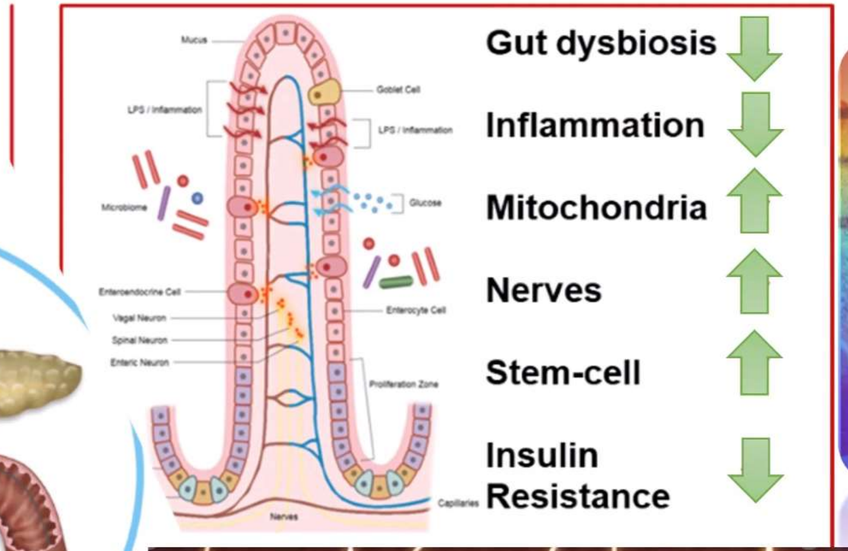


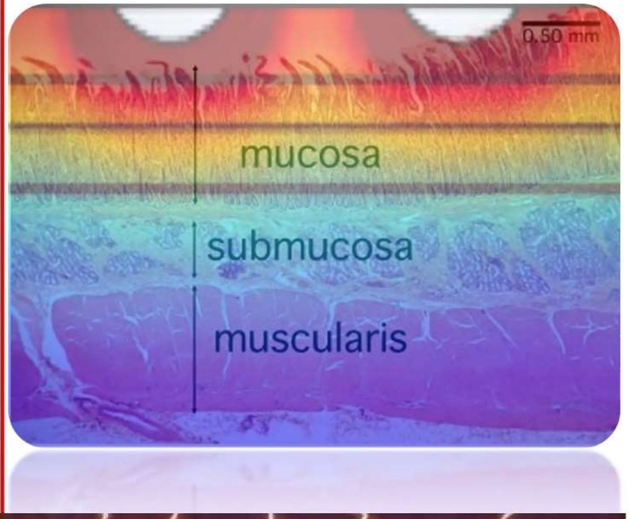
ENDOSCOPIC

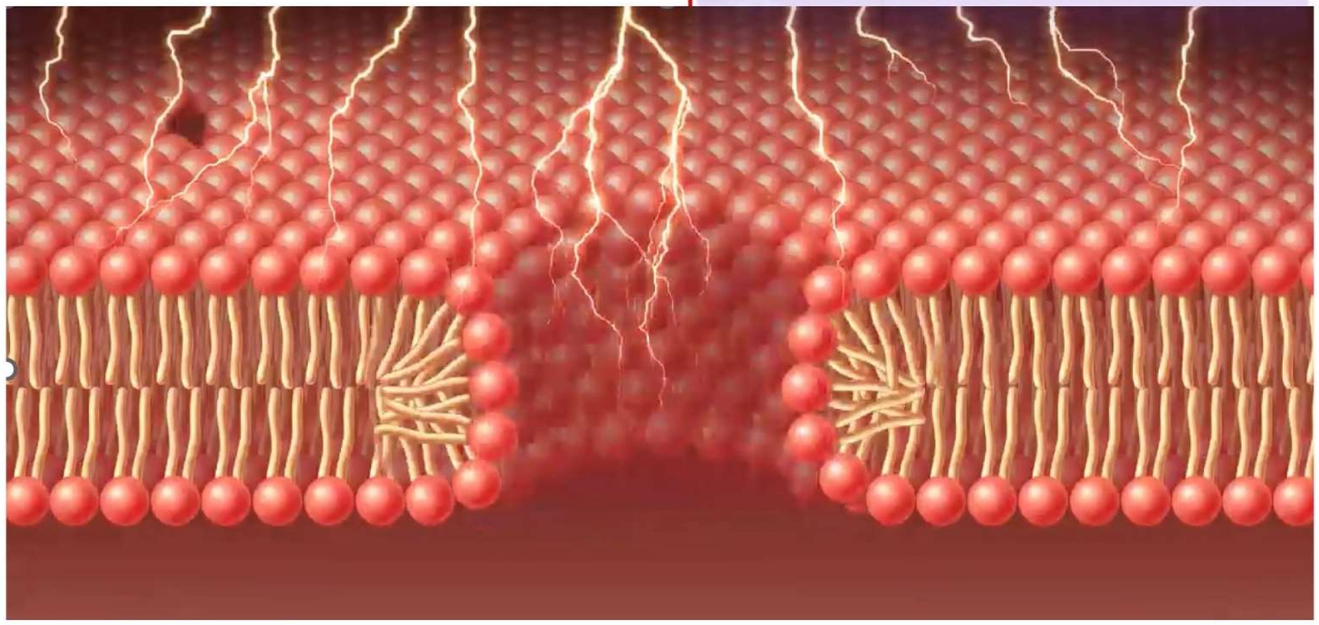
'ELECTROPORATION'
DUODENAL MUCOSAL
RESURFACING

Regenerative Medicine Paradigm for Type II Diabetes + Novel Non-thermal Energy in the GI Tract (Pulsed Electric Field)









Endogenex

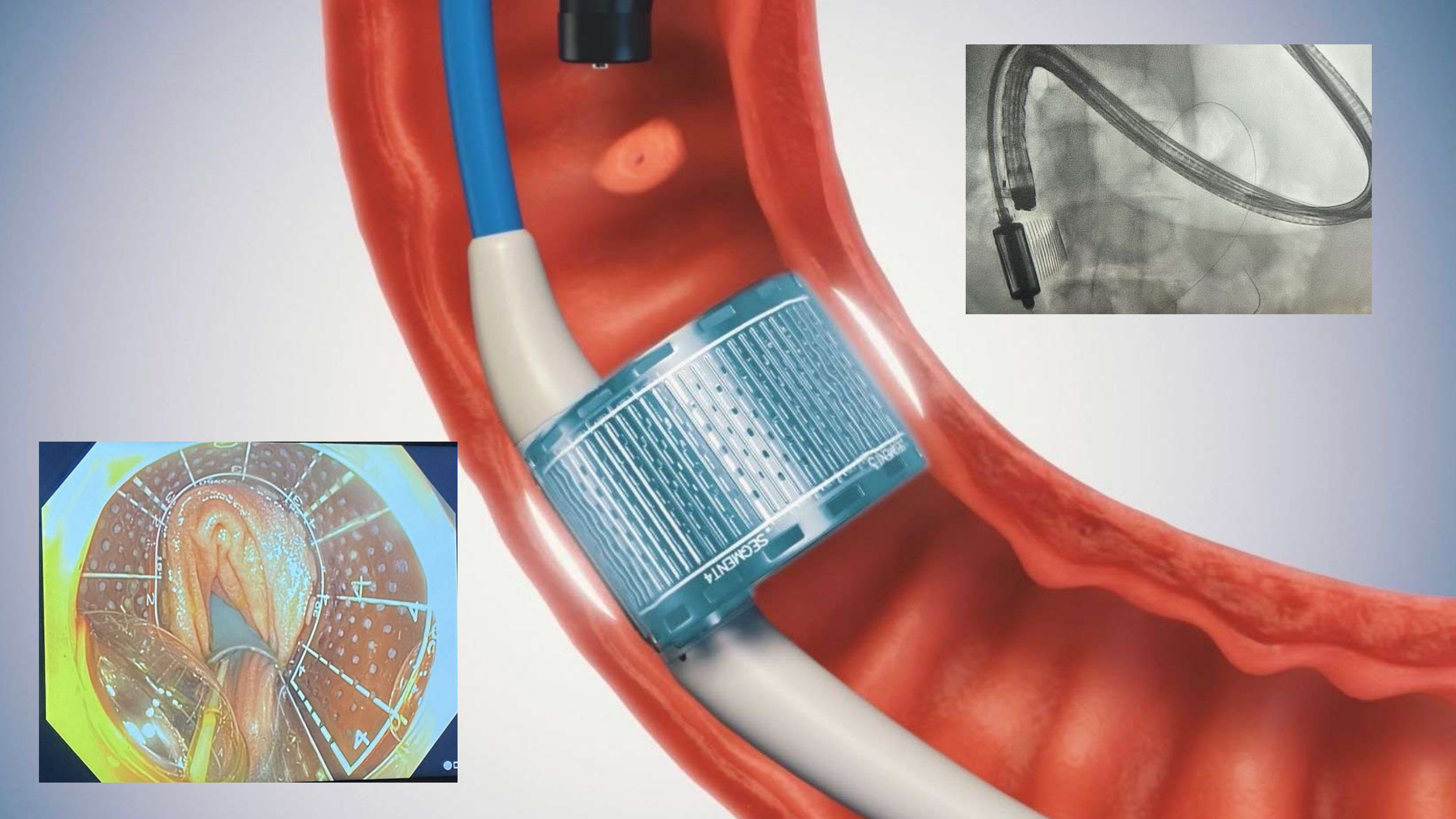
Bringing New Energy to the Treatment of Type 2 Diabetes

Electroporation

Meaning…

Electroporation, or electropermeabilization, is a microbiology technique in which an electrical field is applied to cells in order to increase the permeability of the cell membrane, allowing chemicals, drugs, or DNA to be introduced into the cell.

Wikipedia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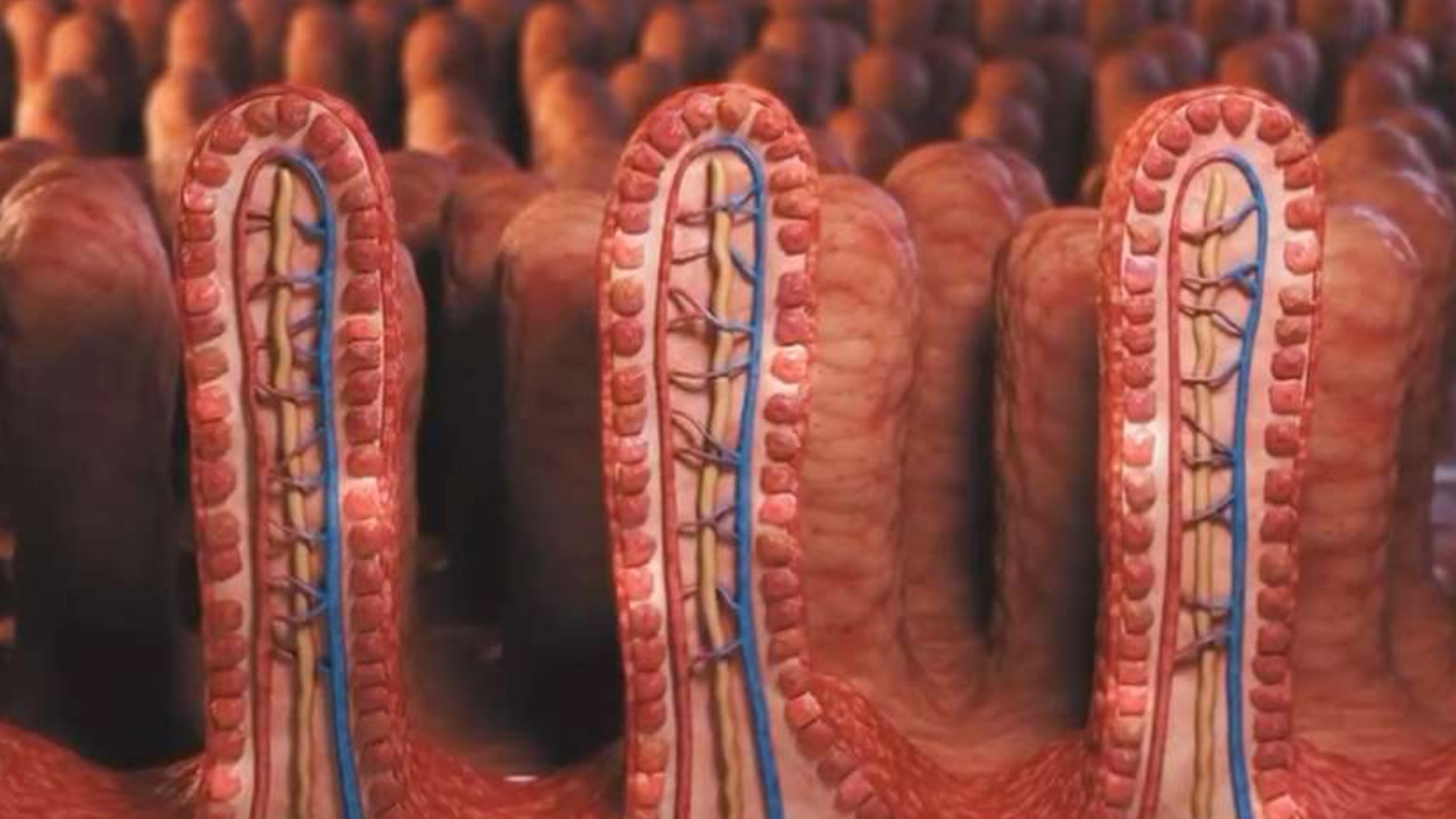

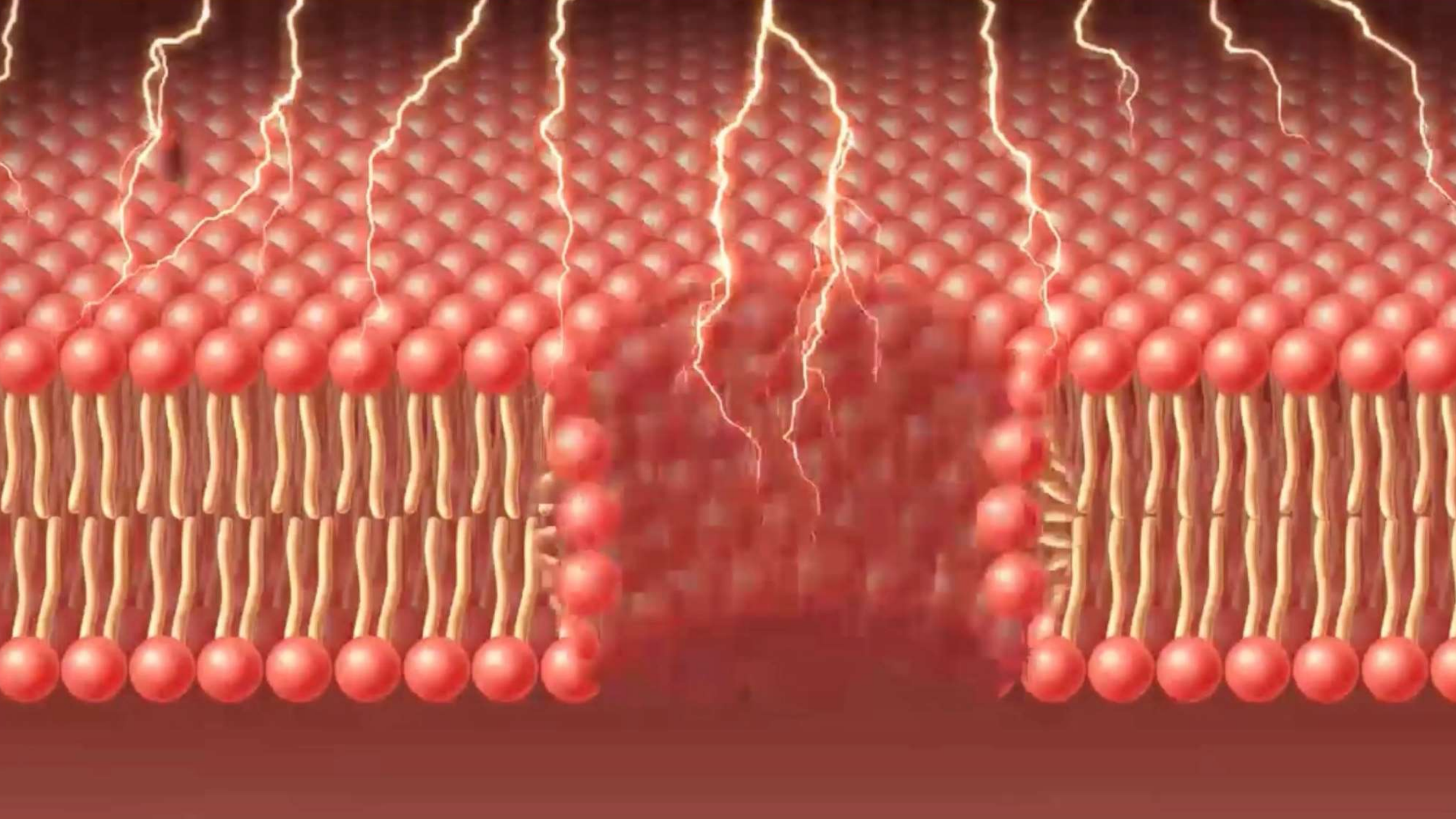

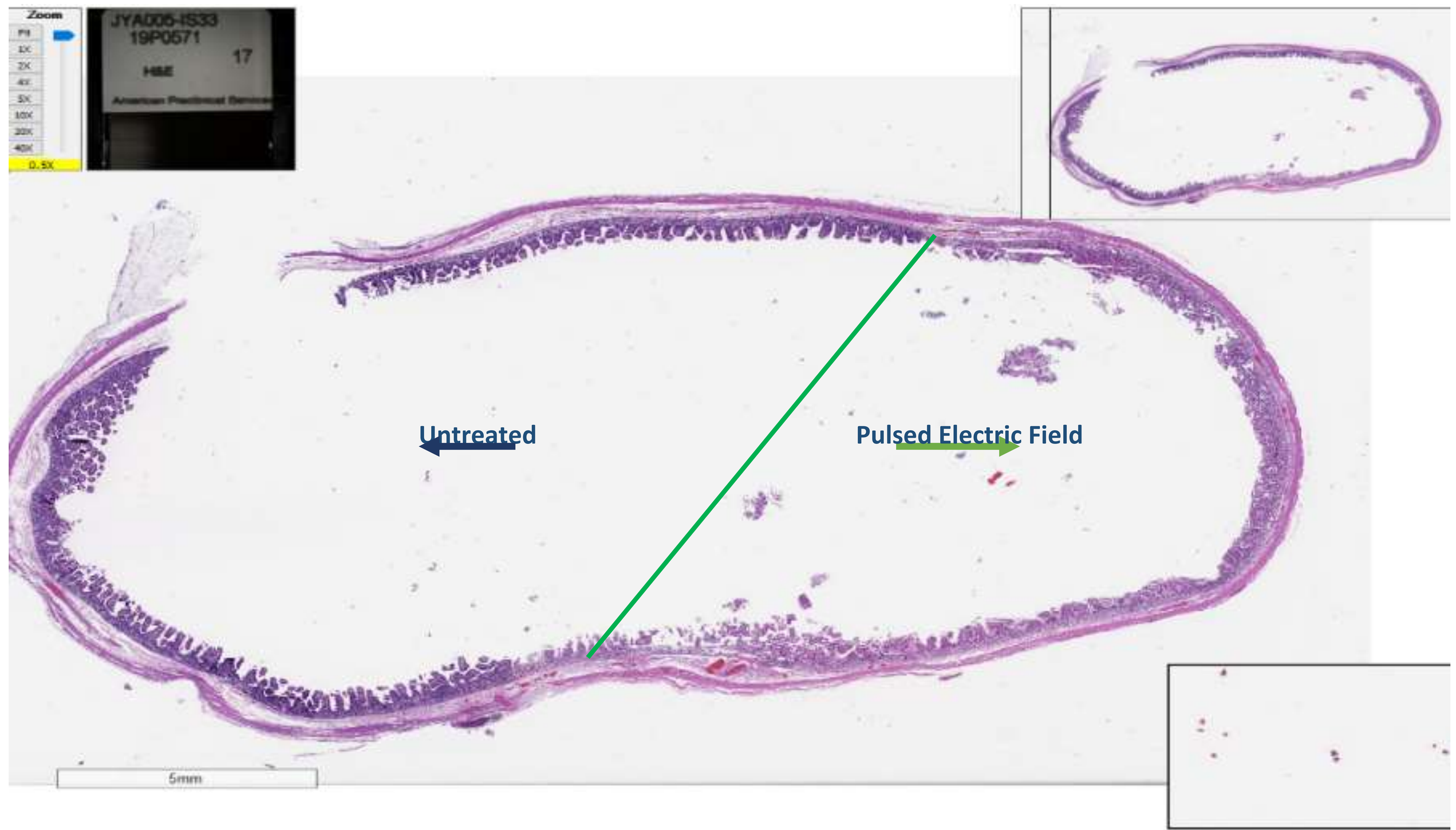
Zoom
Fit
1X
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JYA006-IS33
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17
H&E
American Preclinical Services
Untreated
Pulsed Electric Field
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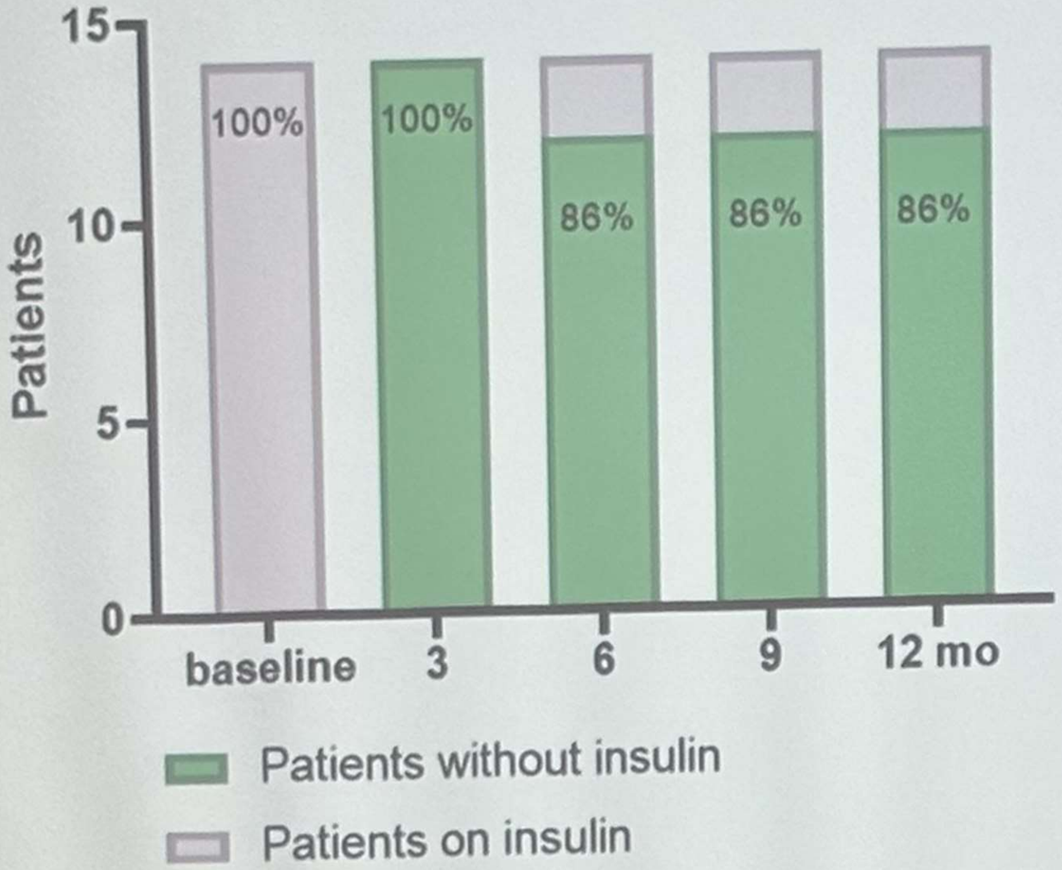


Improved glycemic control

- Improved HbA1c and time with adequate blood glucose levels

Improved metabolic health

- >50% reduction of liver fat

@DDW2023 Abstracts #46, 1108, 1272

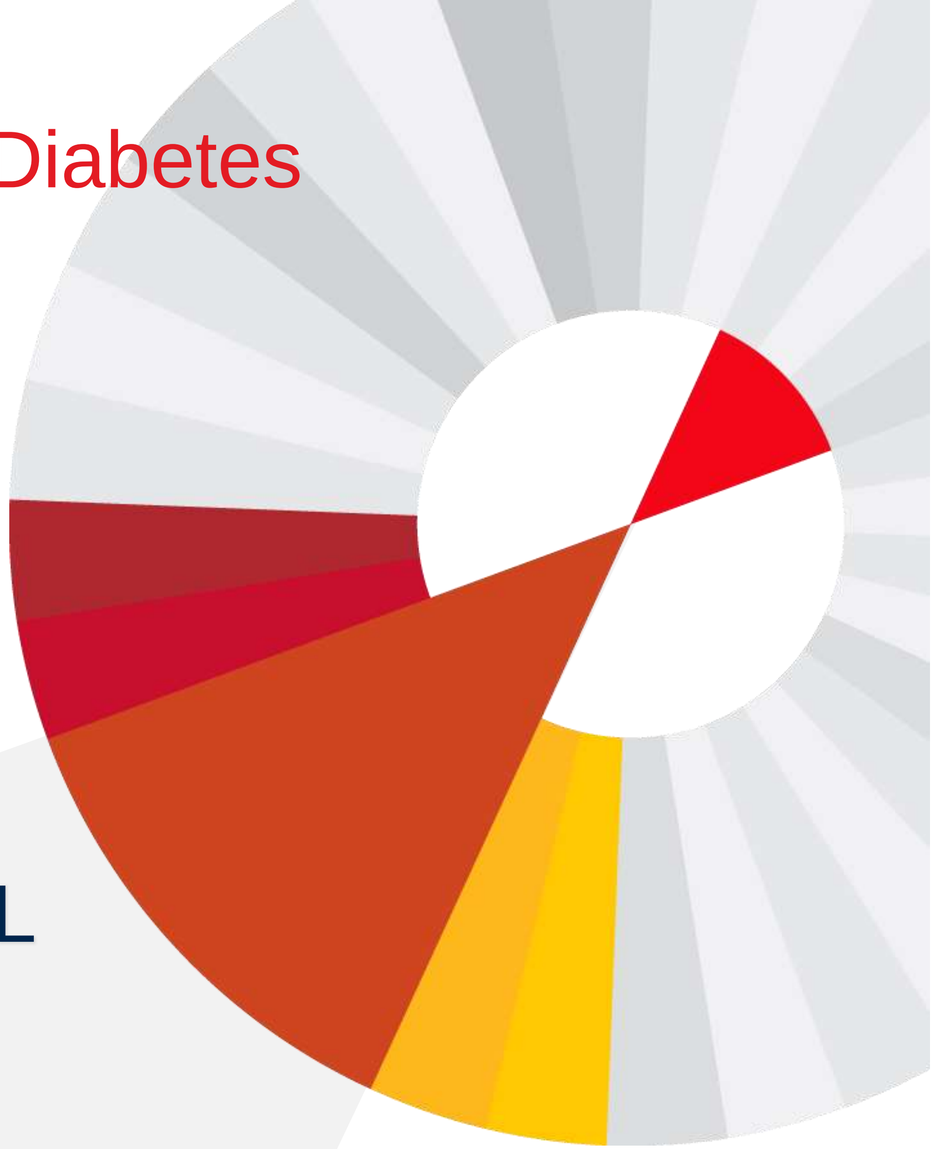
00:00

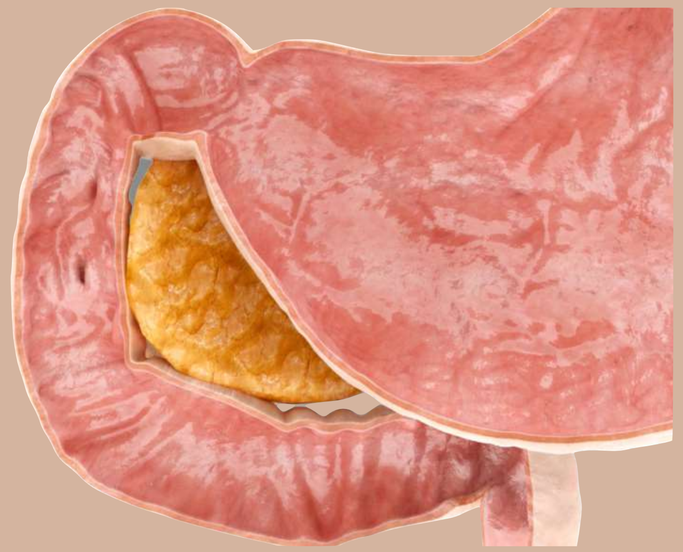
Endoscopic treatment of Diabetes

ENDOSCOPIC

'VAPOR'

DUODENAL MUCOSAL RESURFACING



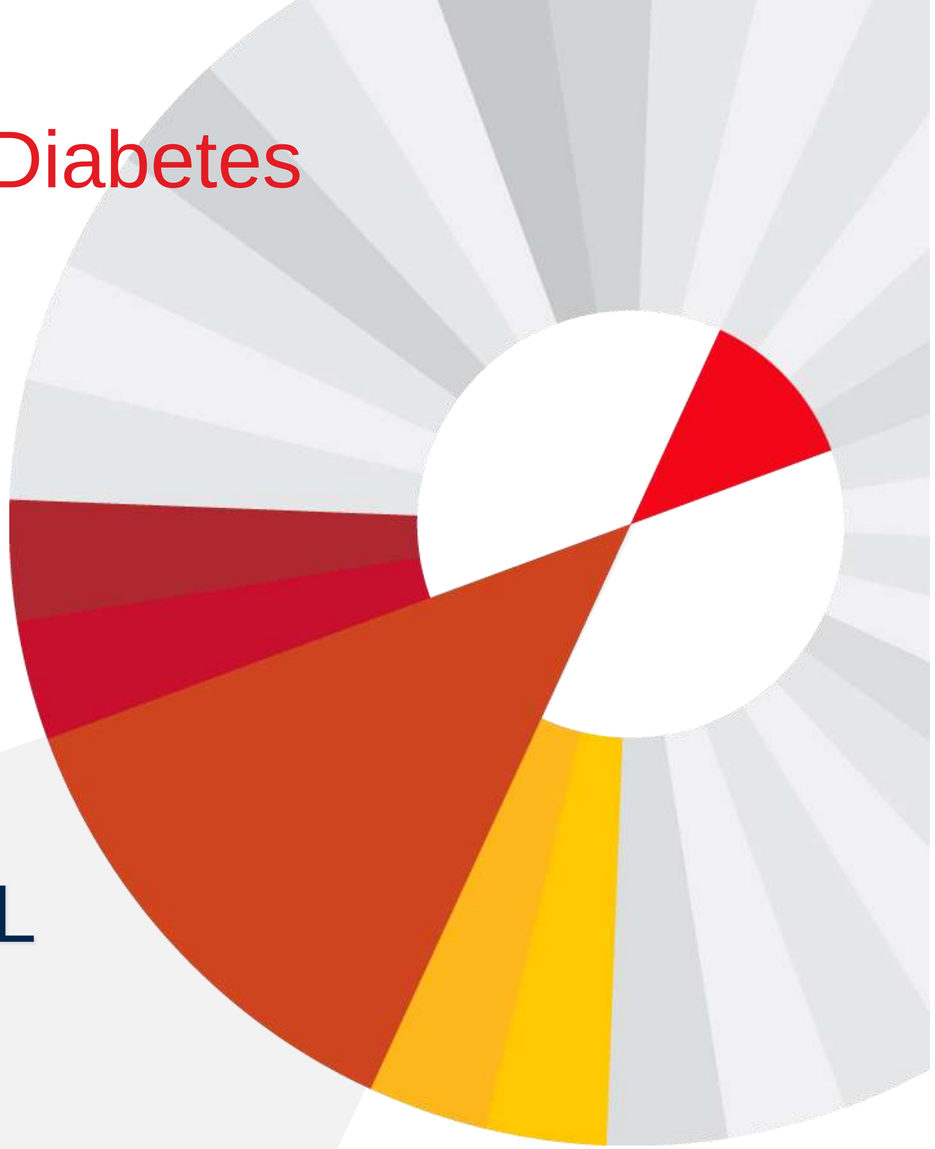


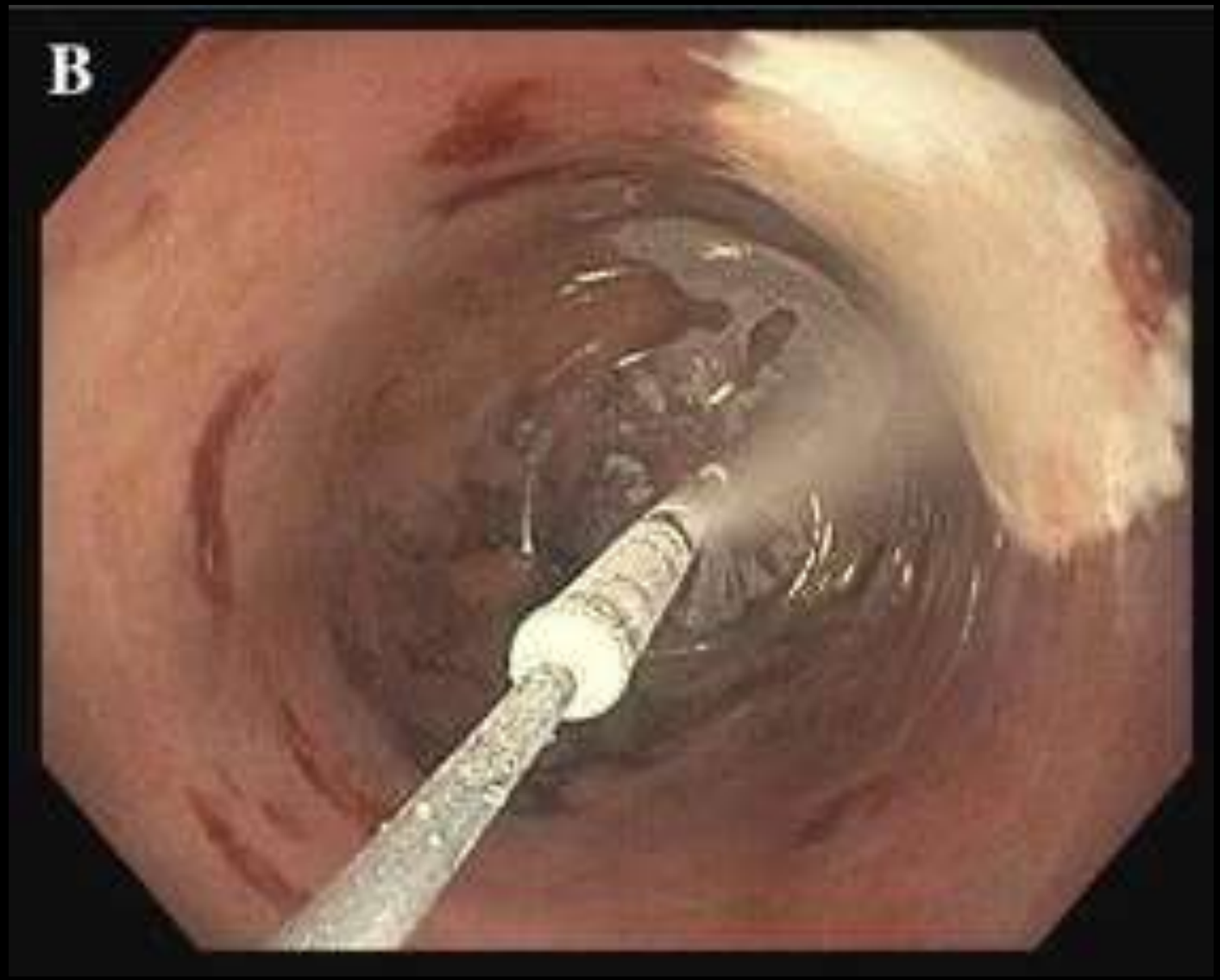
Endoscopic treatment of Diabetes

ENDOSCOPIC

‘CRYO'

DUODENAL MUCOSAL RESURFACING

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Endoscopic treatment of Diabetes

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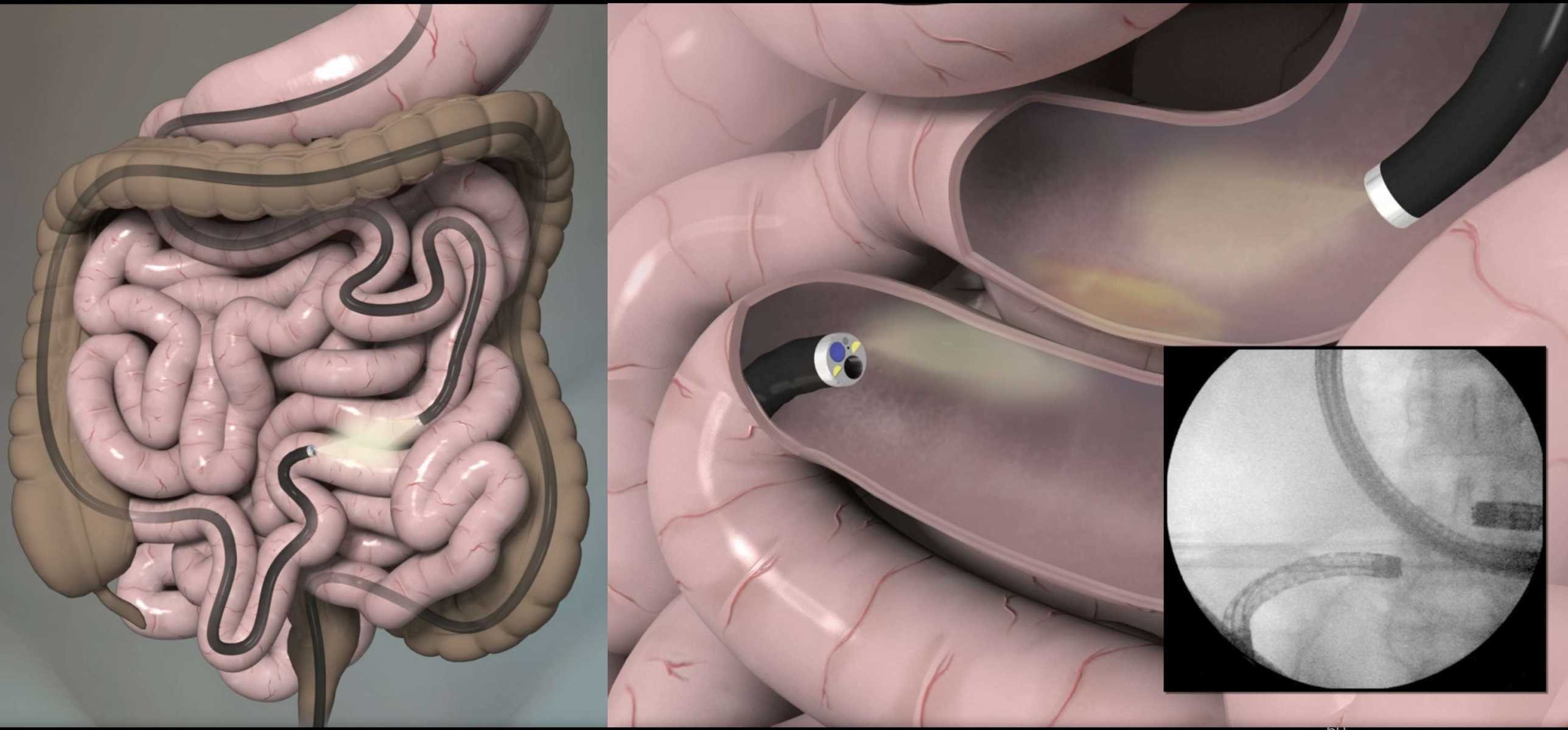
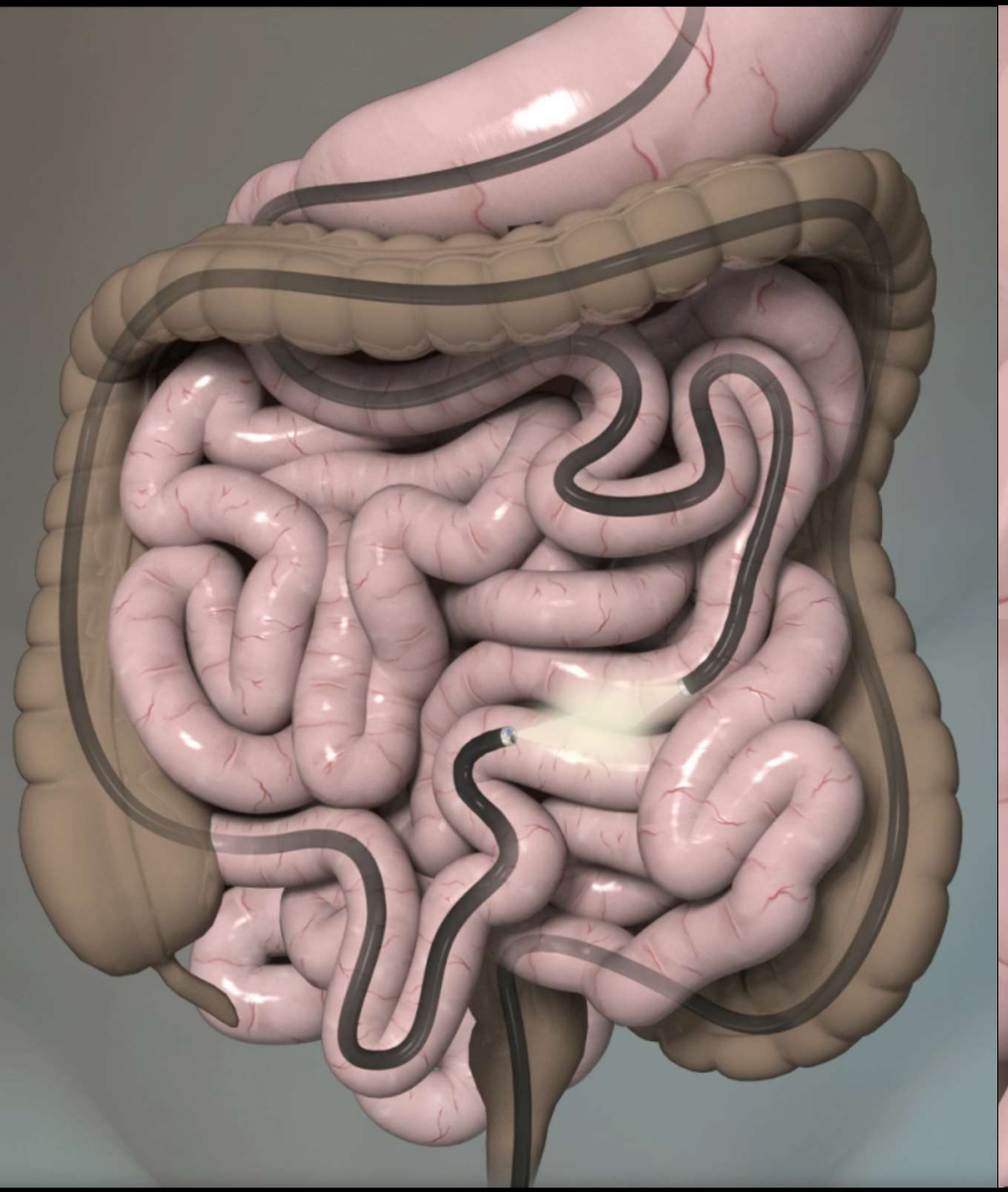
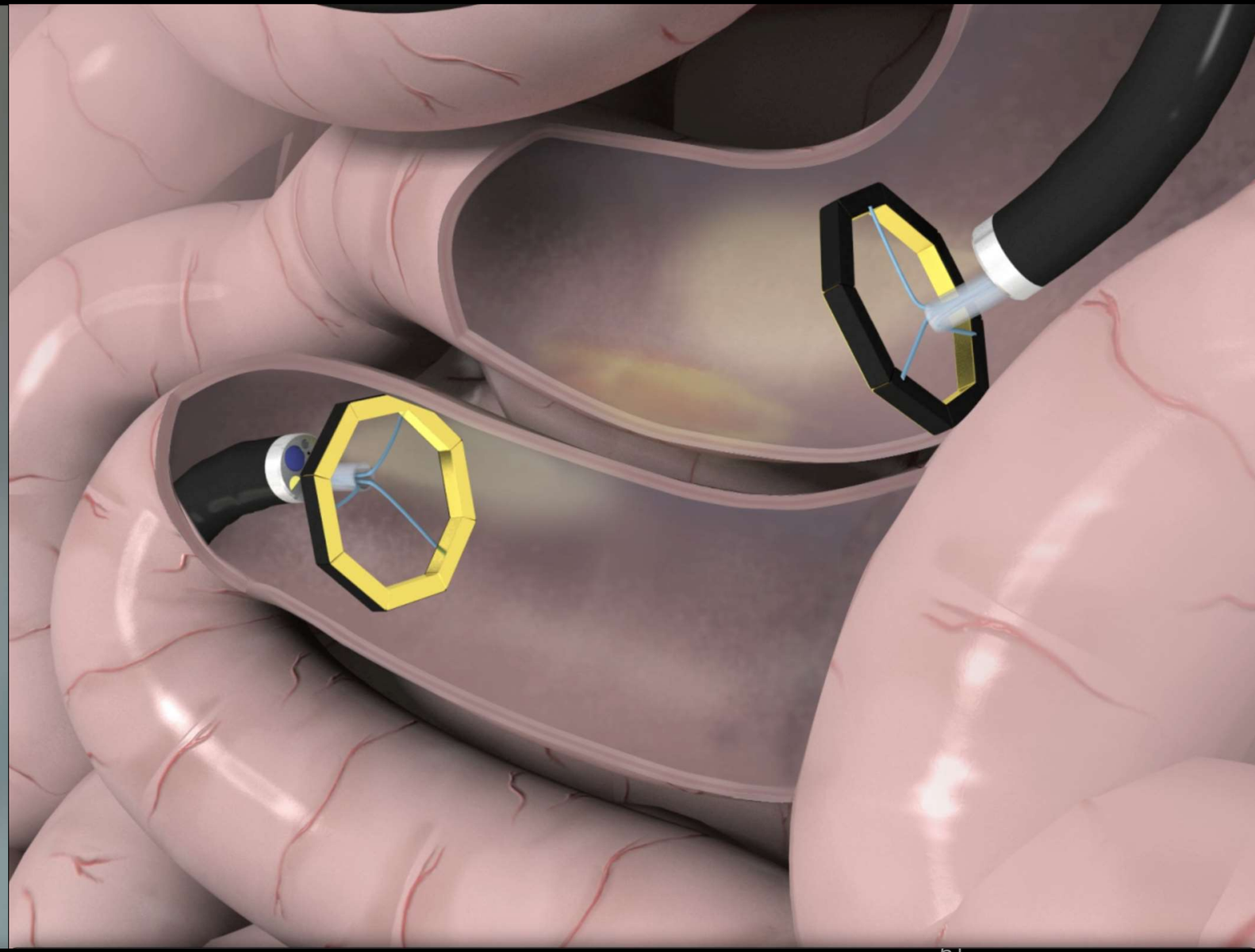
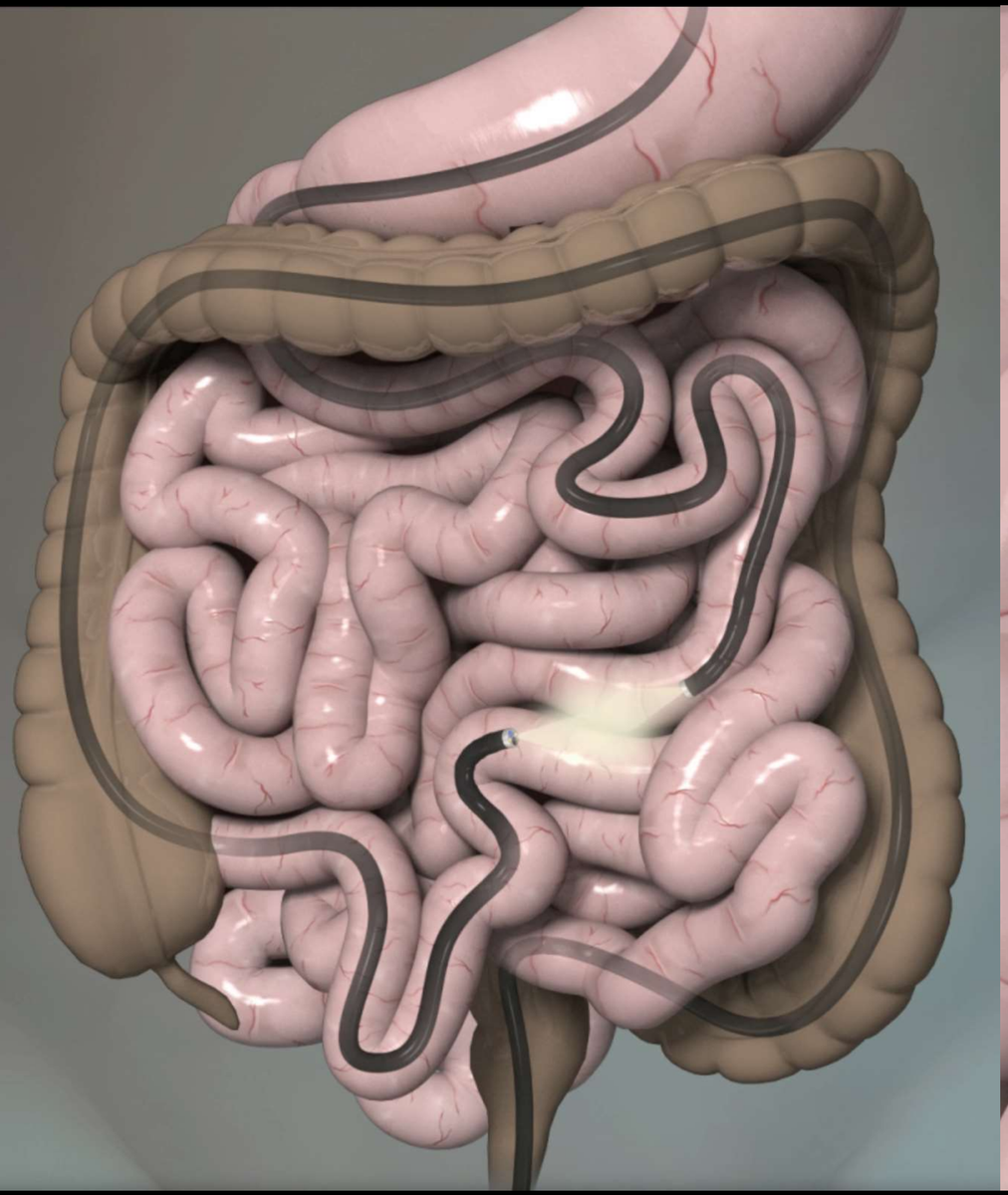
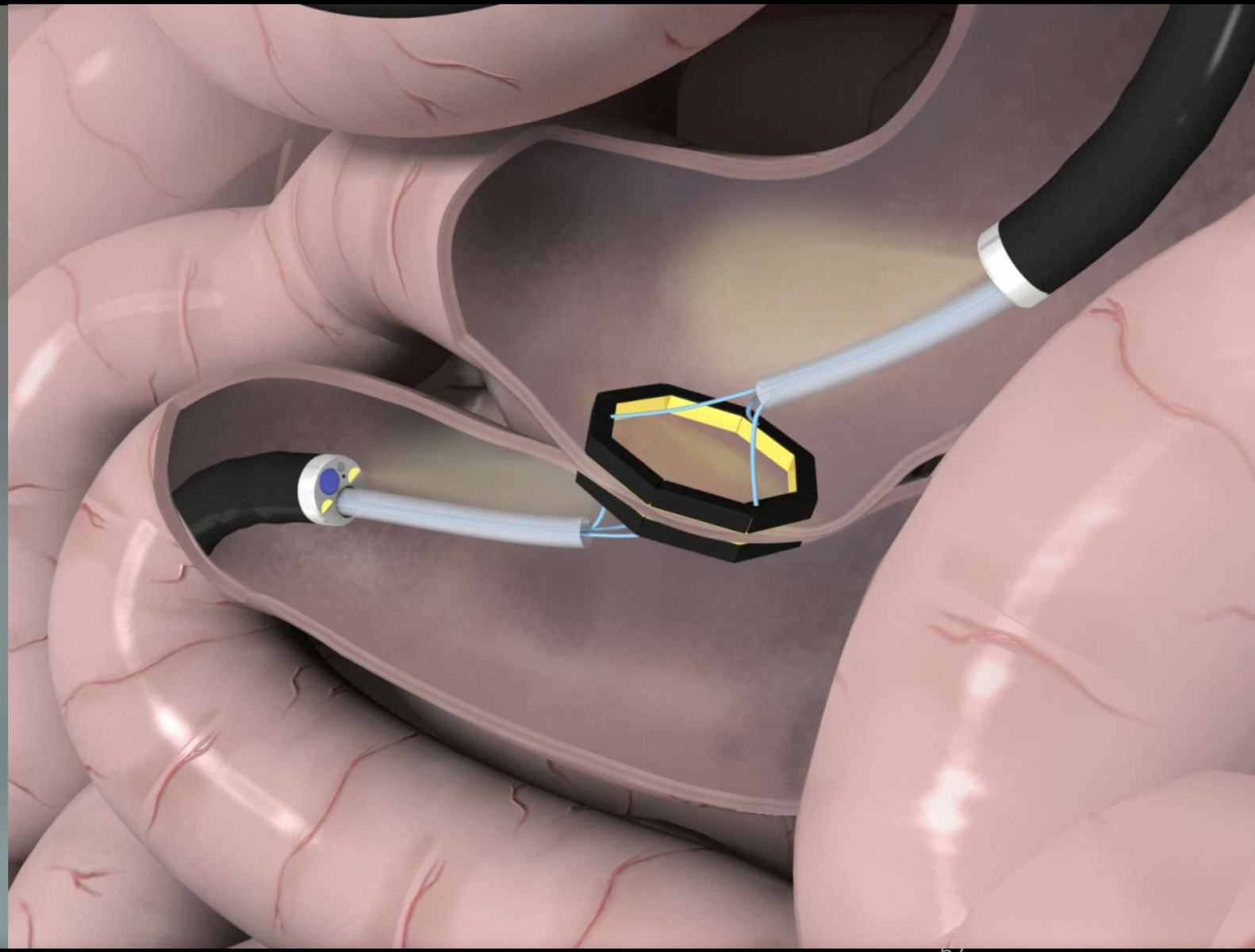
JEJUNO – ILEAL BYPASS

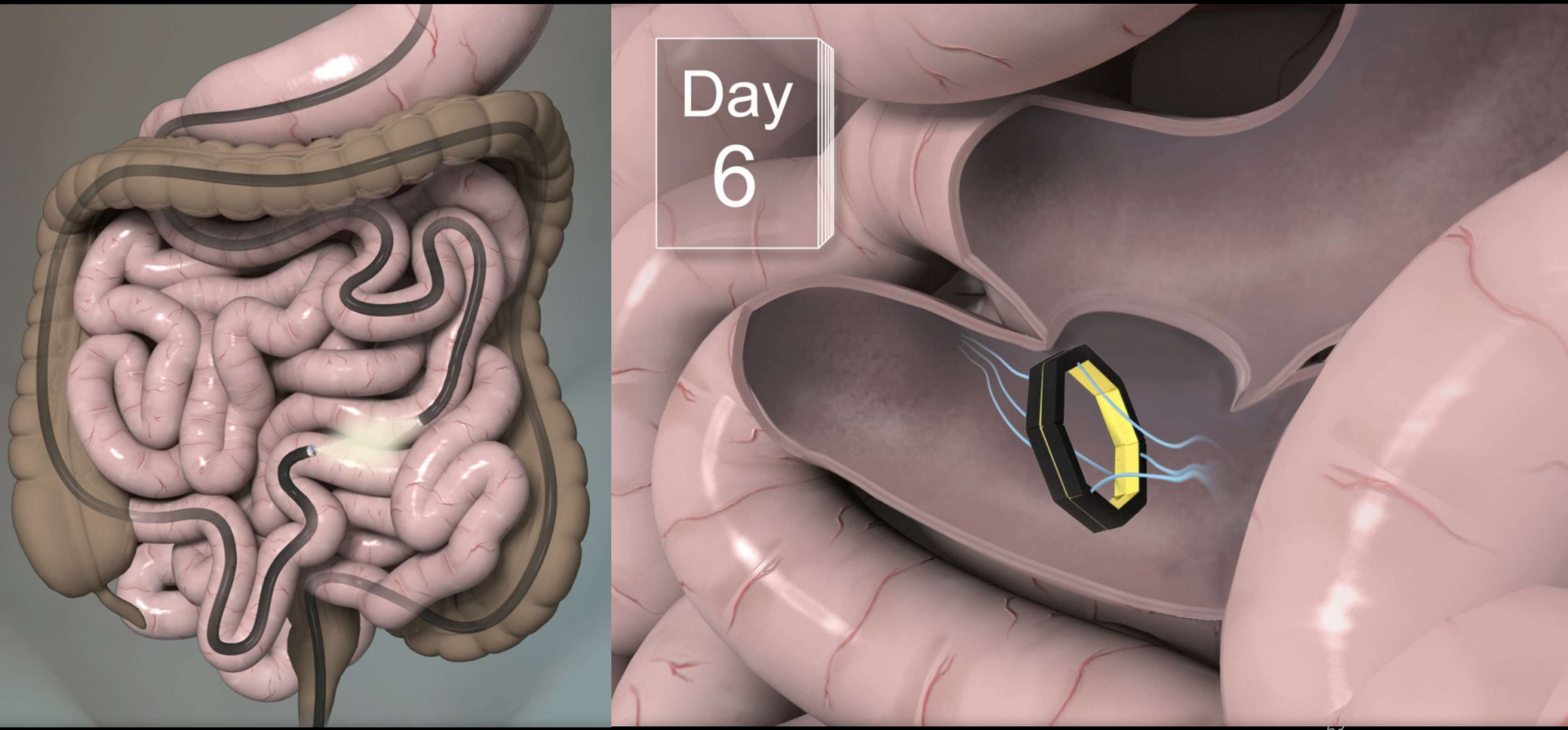








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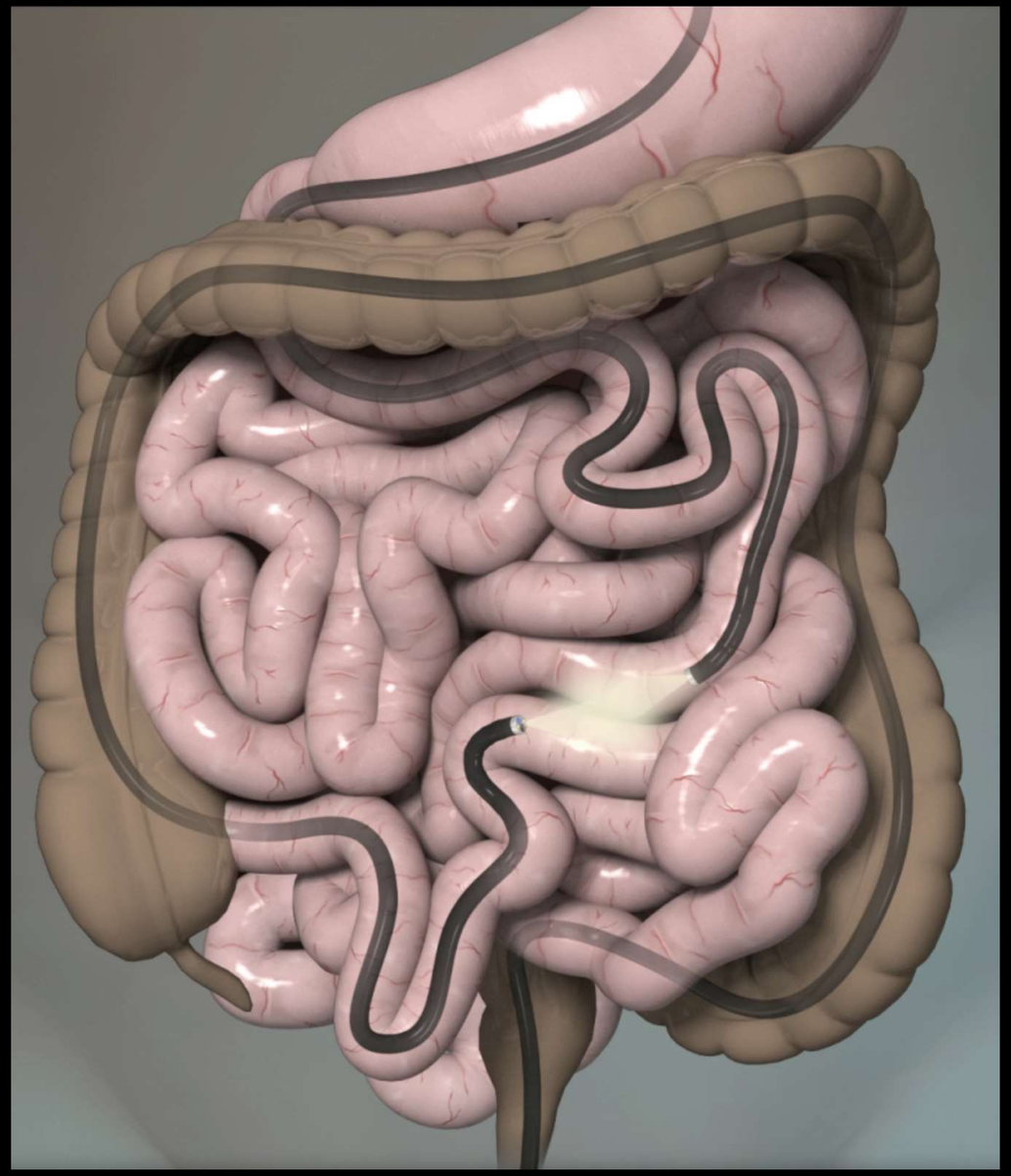
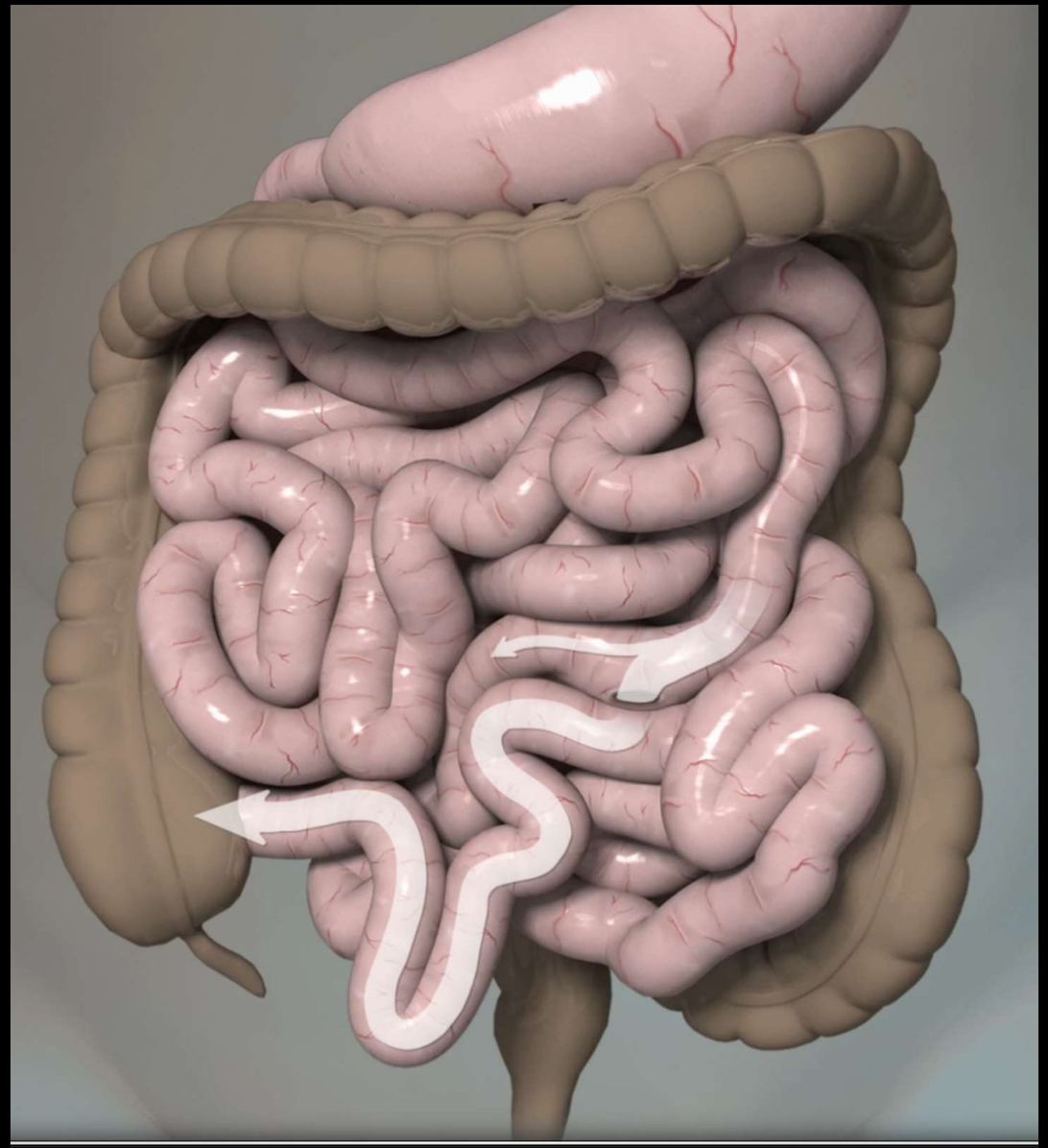




NEW METHODS: Clinical Endoscopy

Partial jejunal diversion using an incisionless magnetic anastomosis system: 1-year interim results in patients with obesity and diabetes

Evžen Machytka, MD, PhD,[1] Marek Bužga, MSc, PhD,[2] Pavel Zonca, MD, PhD,[1] David B. Lautz, MD,[3,4] Marvin Ryou, MD,[5] Donald C. Simonson, MD, MPH, ScD,[6] Christopher C. Thompson, MD, MSc[5]

Ostrava, Czech Republic; Concord, Boston, Massachusetts, USA

Trial record **1 of 59** for: gi windows

Previous Study | Return to List | Next Study

Endoscopic Procedure for Jejunal to Ileal Diversion to Treat Type 2 Diabetes

ClinicalTrials.gov Identifier: NCT03130244

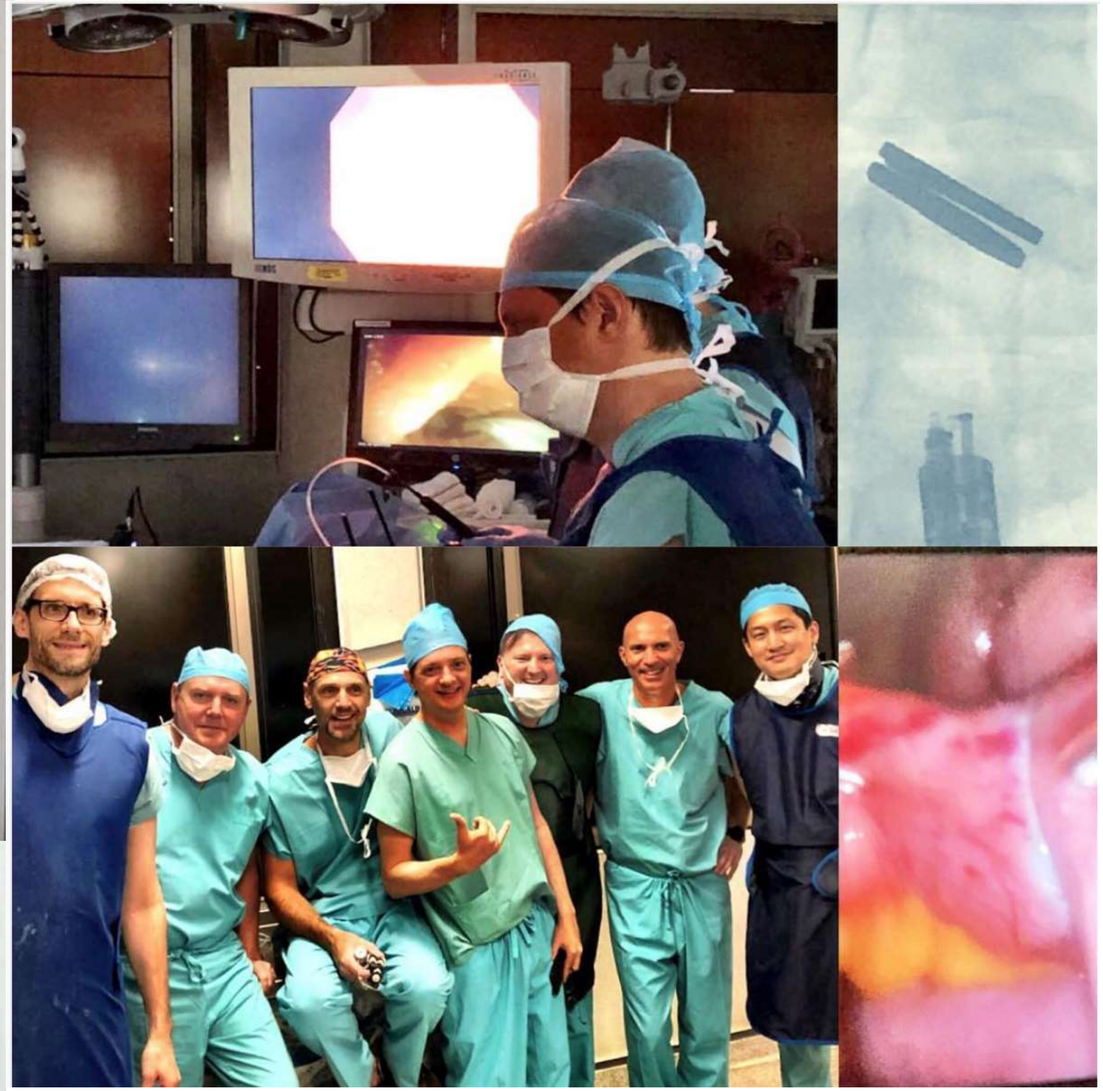
Recruitment Status : Recruiting
First Posted : April 26, 2017
Last Update Posted : August 1, 2017

See **Contacts and Locations**

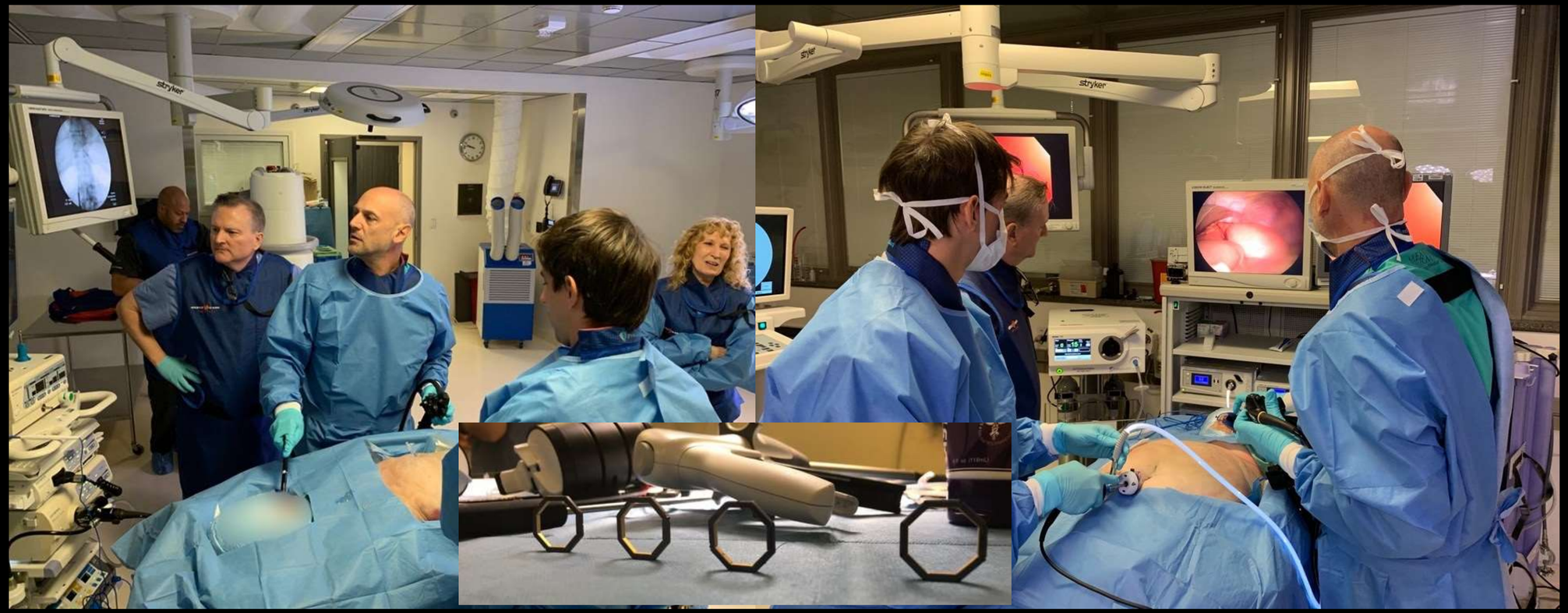
Sponsor:
GI Windows, Inc.

Information provided by (Responsible Party):
GI Windows, Inc.


Brazil ABC Medical School
M. Galvão Neto
USA Harvard School
C. Thompson
ArgentinaAlemán Hospital
Baron B. Rudolf
HA Hospital Alemán
Deutsches Hospital



GI Windows - New developments



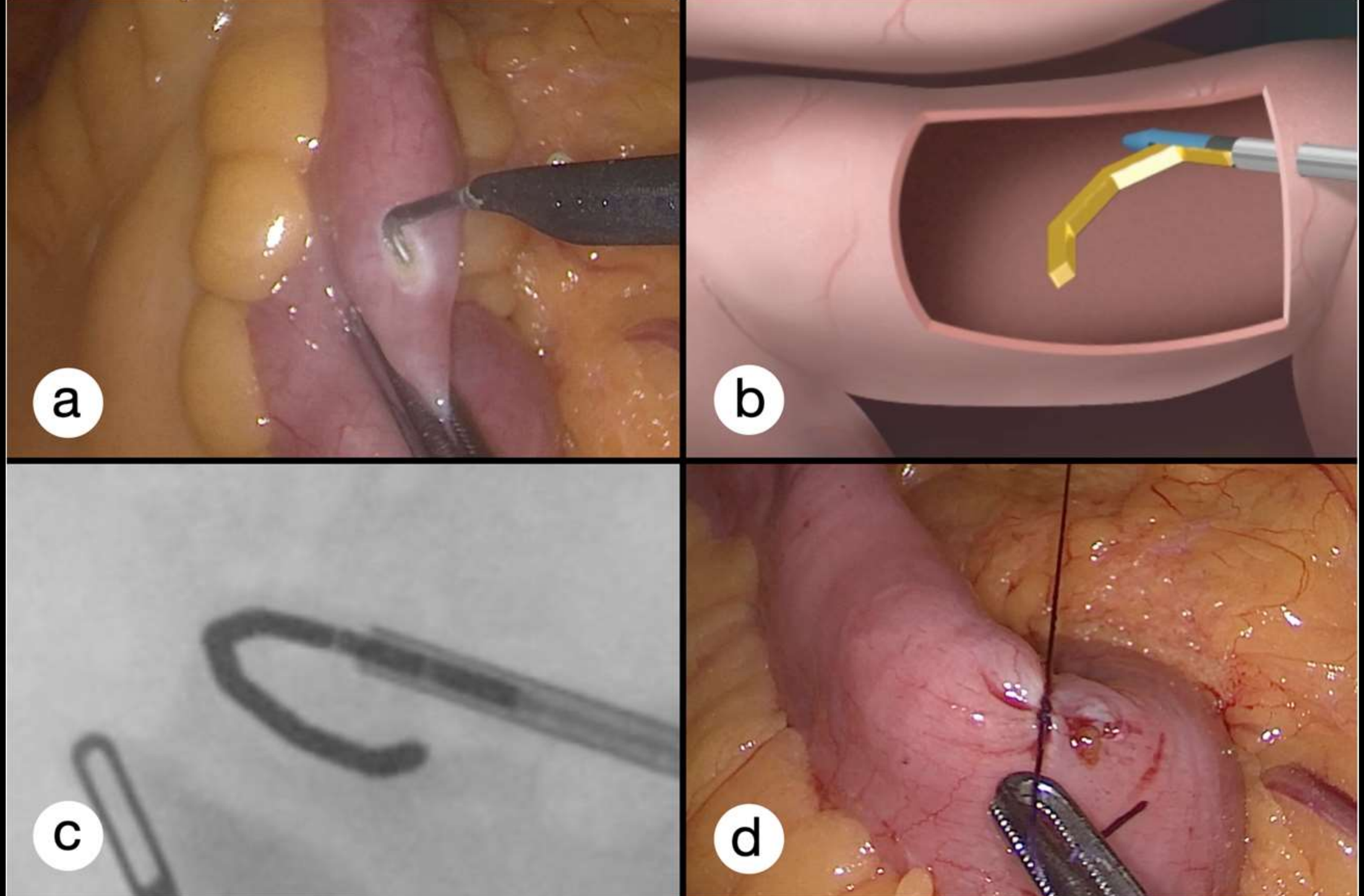
Obesity Surgery
https://doi.org/10.1007/s11695-021-05554-z

NEW CONCEPT

Sutureless Duodeno-Ileal Anastomosis with Self-Assembling Magnets: Safety and Feasibility of a Novel Metabolic Procedure

Francisco Schlottmann[1] · Marvin Ryou[2] · David Lautz[3] · Christopher C. Thompson[2] · Rudolf Buxhoeveden[1]

Received: 2 April 2021 / Revised: 9 June 2021 / Accepted: 16 June 2021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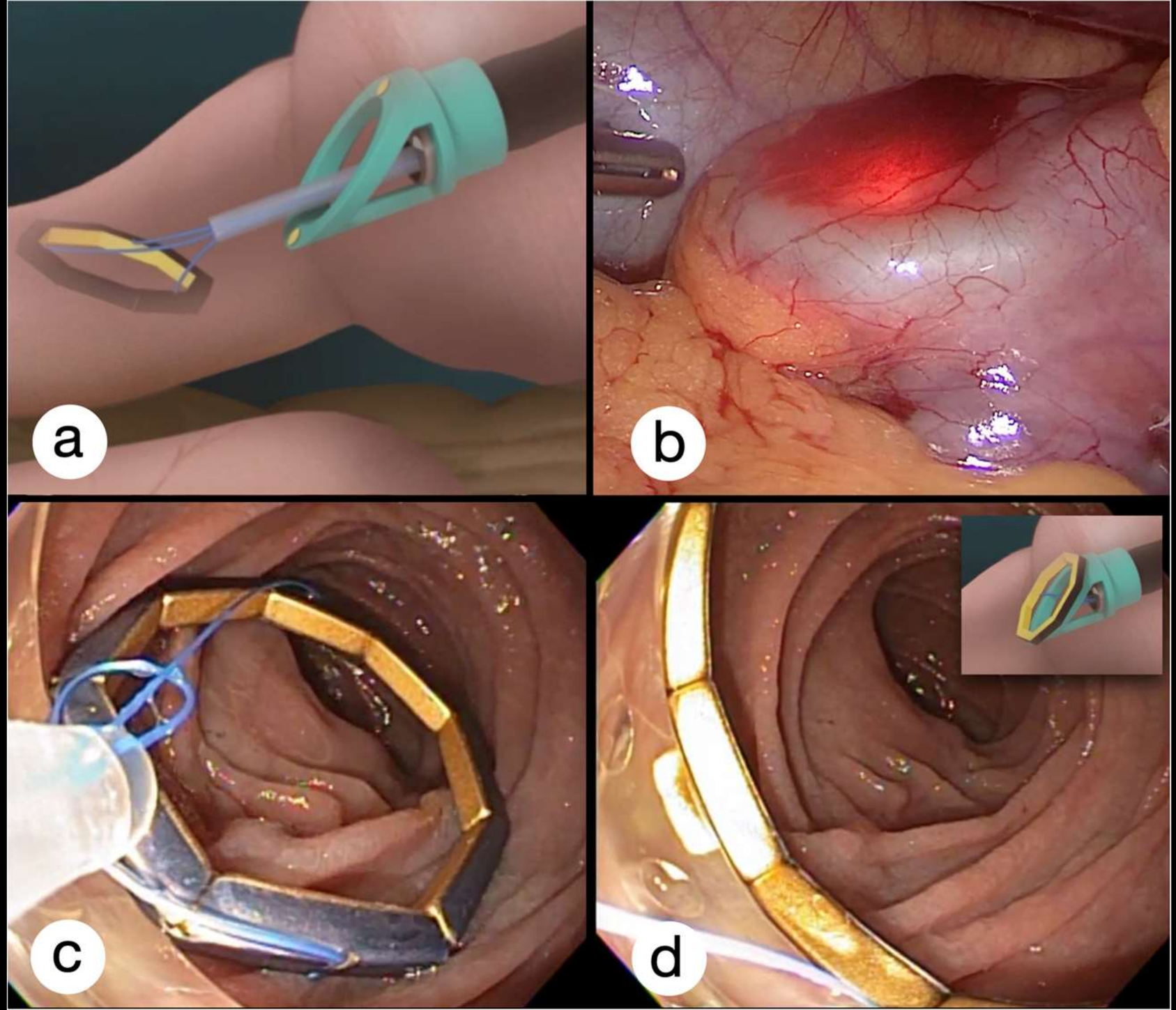
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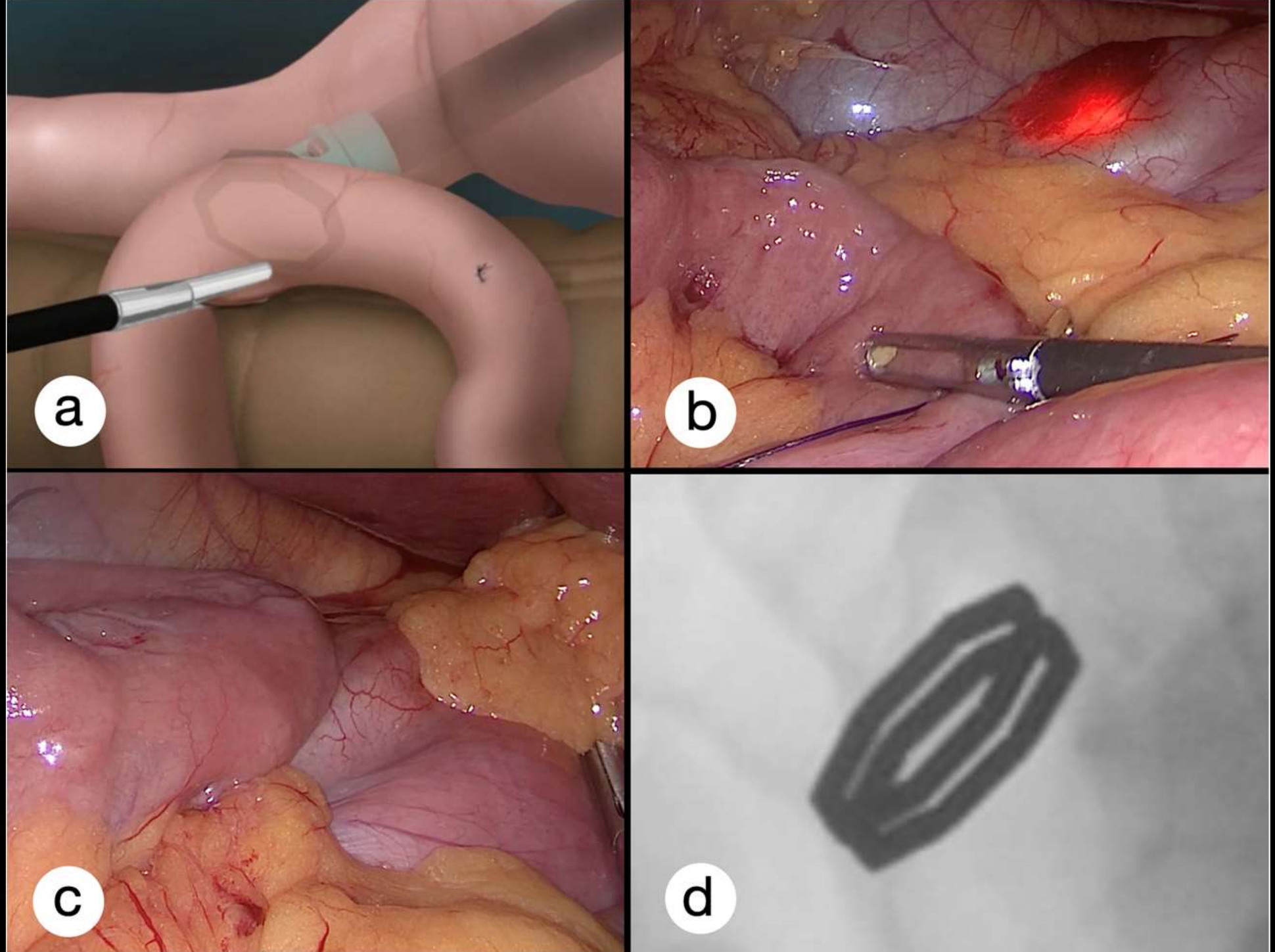
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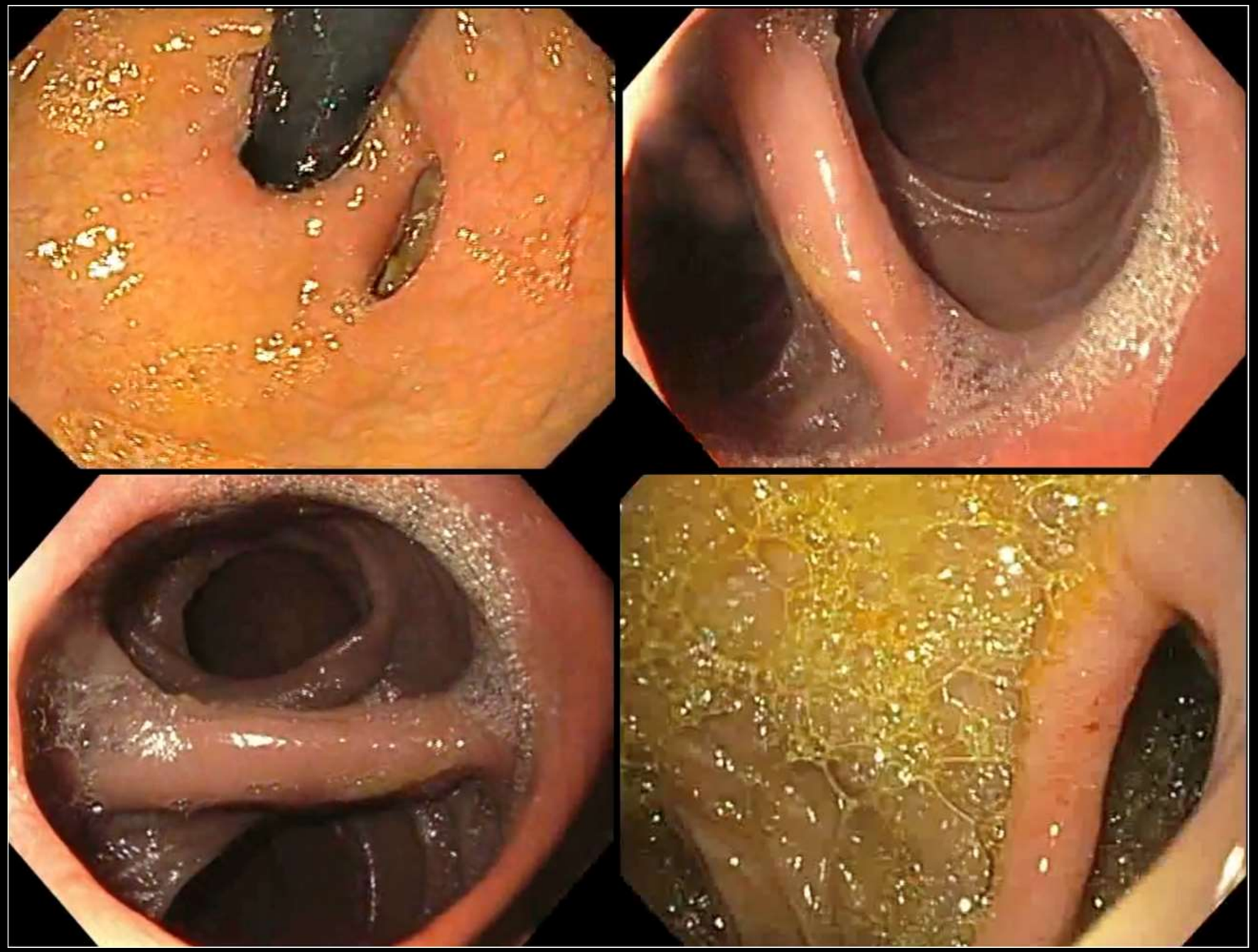

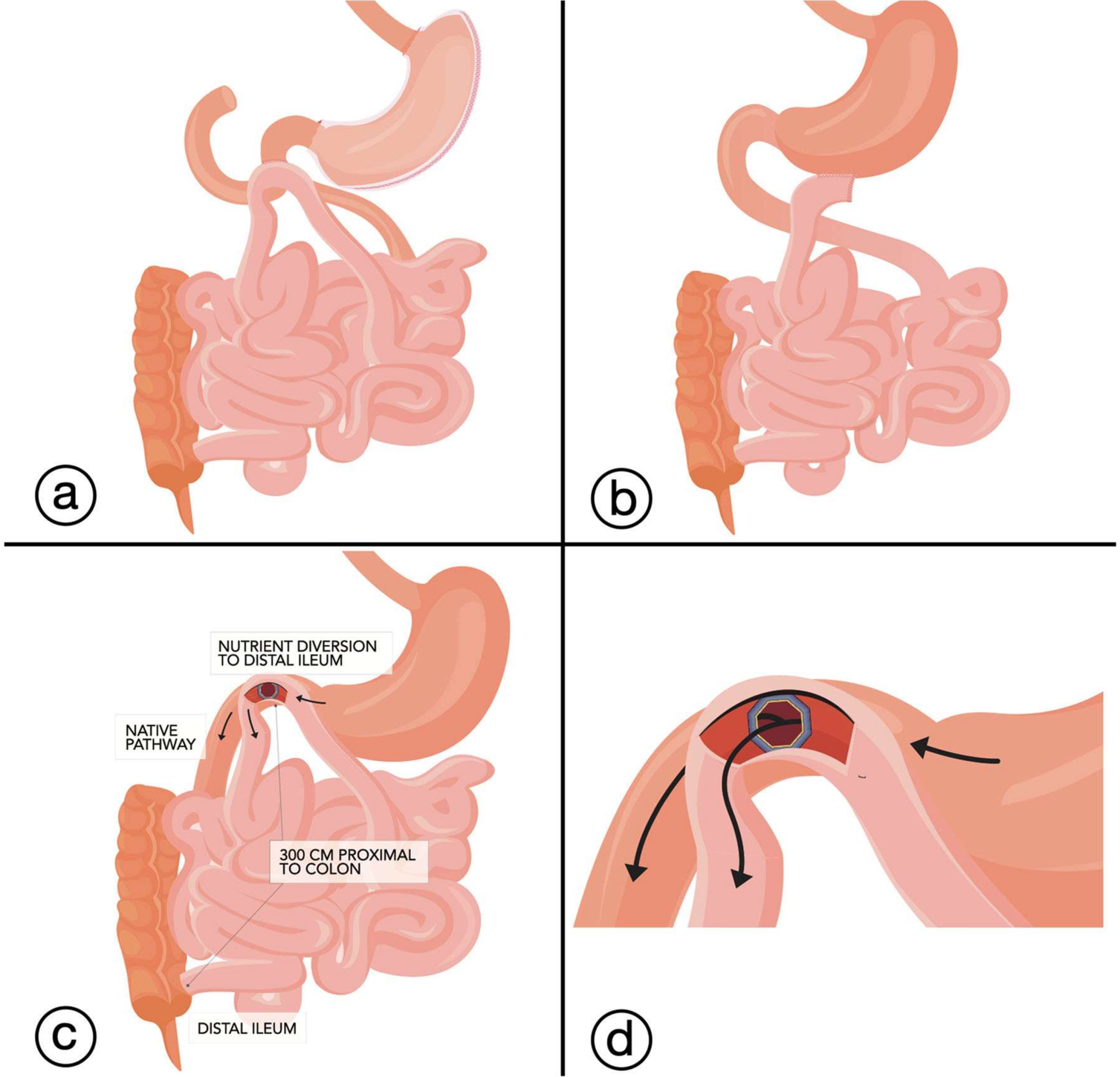
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b
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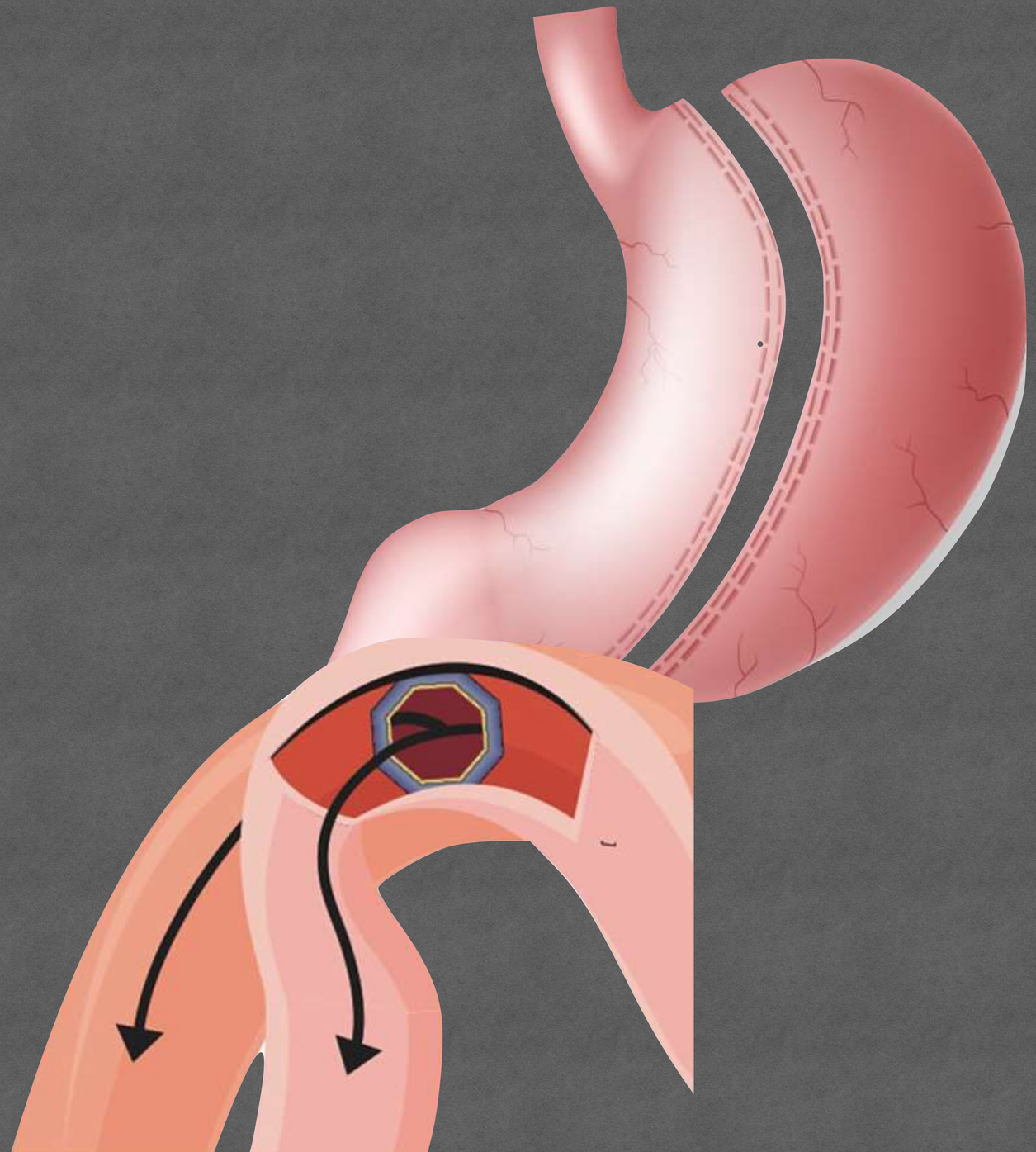
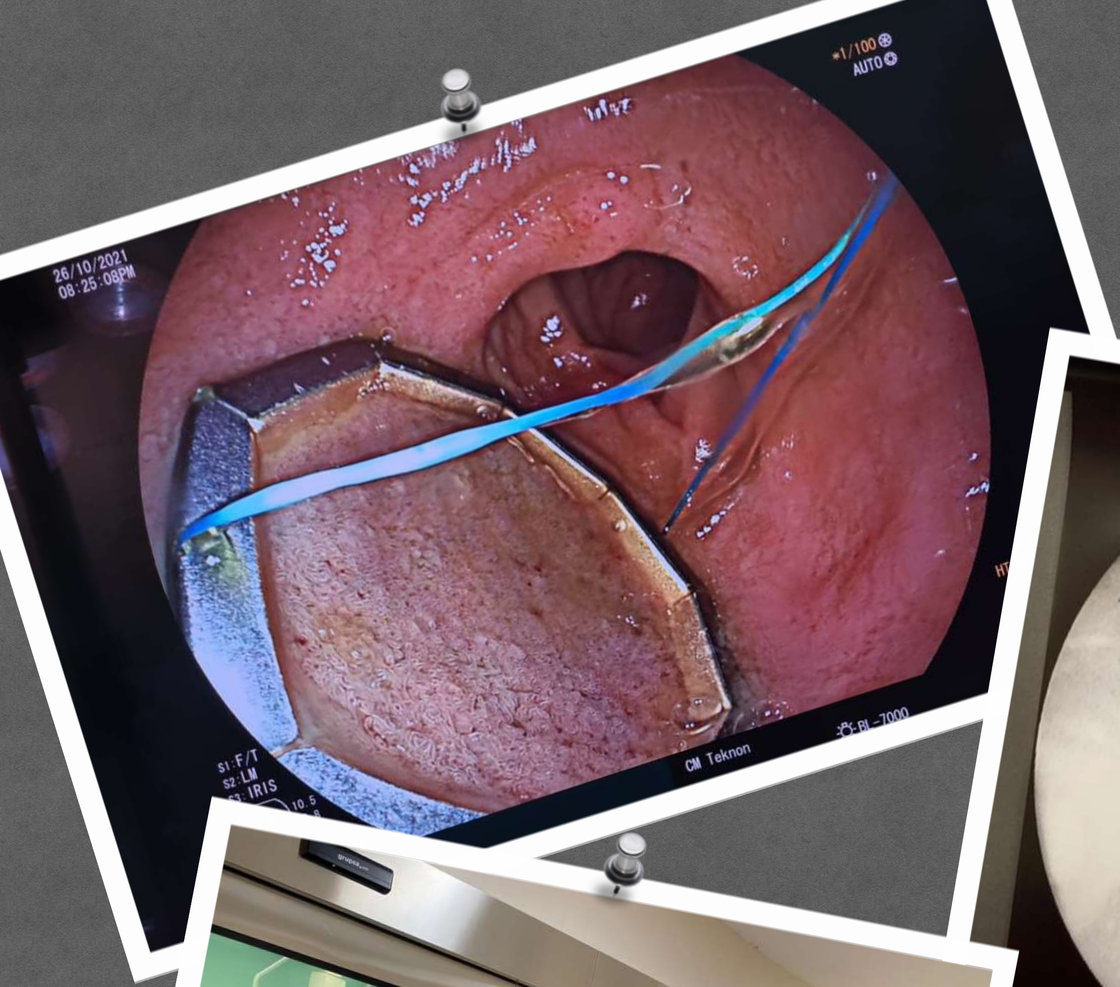
300 CM PROXIMAL
TO COLON
DISTAL ILEUM
c
d

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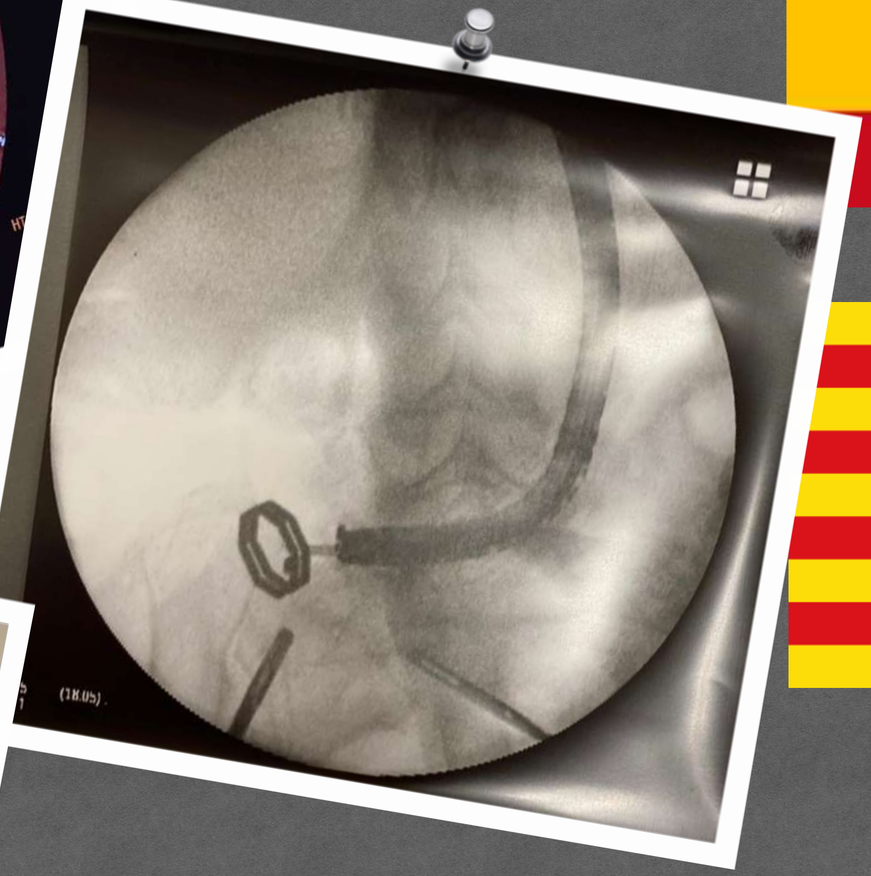
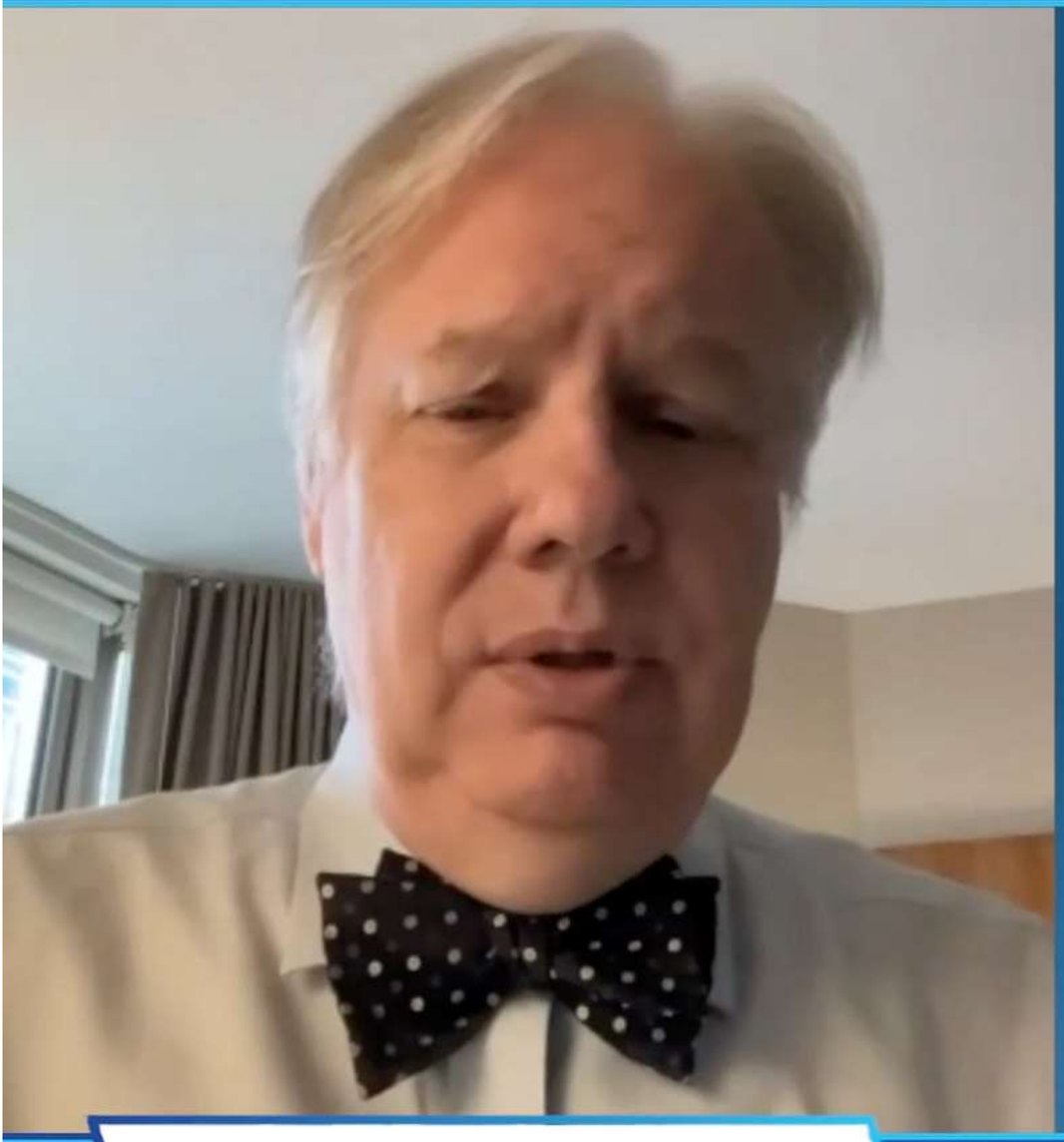




New Anti-diabetes operation "Duodenal Bipartition"

Gagner *Ann Surg Innov Res (2015) 9:6*
DOI 10.1186/s13022-015-0015-0

ASIR ANNALS OF SURGICAL INNOVATION AND RESEARCH

RESEARCH ARTICLE Open Access

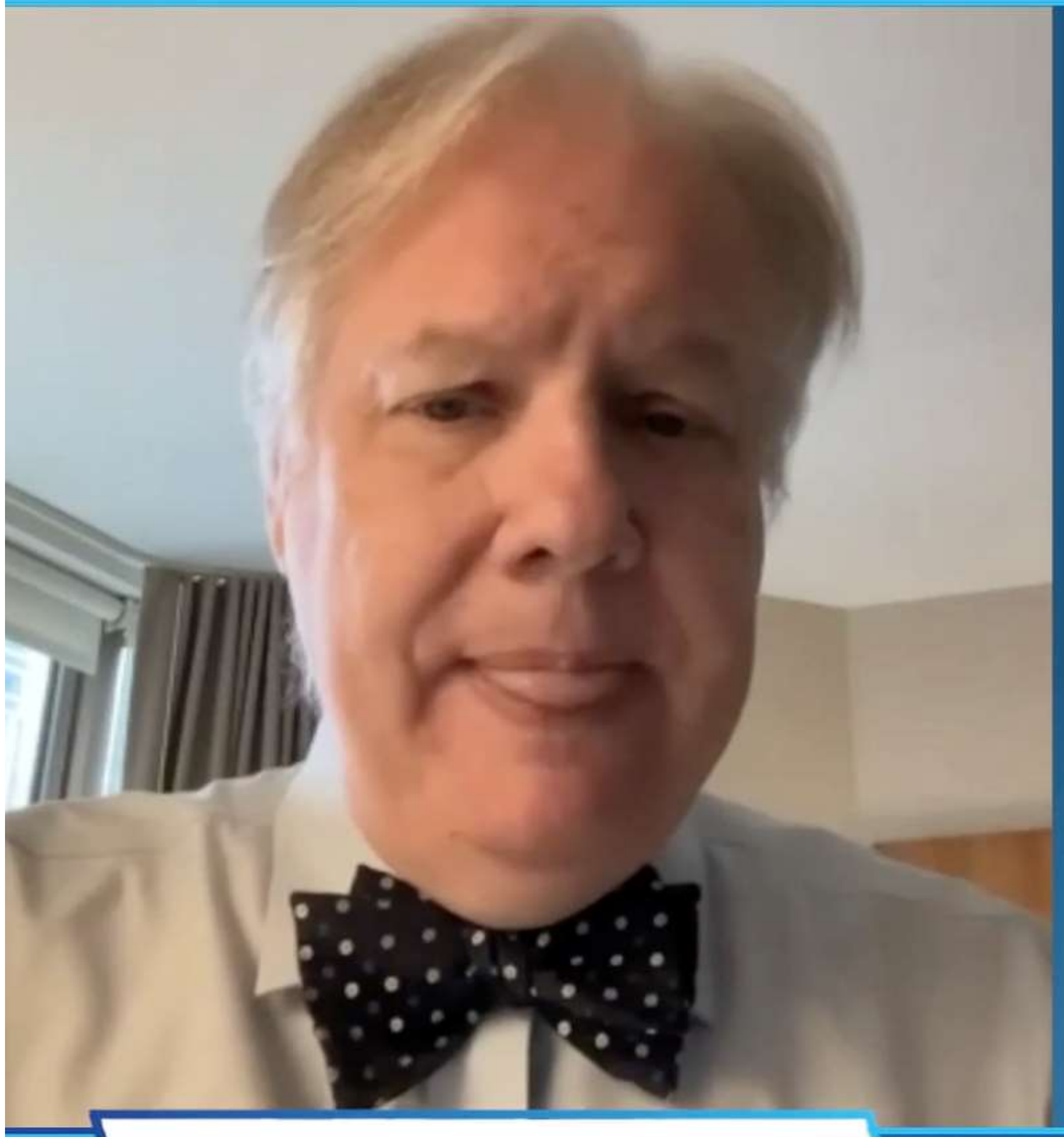
Safety and efficacy of a side-to-side duodeno-ileal anastomosis for weight loss and type-2 diabetes: duodenal bipartition, a novel metabolic surgery procedure

Michel Gagner*

Gagner M. Safety and efficacy of a side-to-side duodeno-ileal anastomosis for weight loss and type-2 diabetes: duodenal bipartition, a novel metabolic surgery procedure. Ann Surg Innov Res. 2015 Oct 14;9:6.

Dr. Michel GAGNER
MD, FRCSC, FACS, FASMBS, FSSO

MAGDI
MAGNETIC DUODENO-ILEOSTOMY



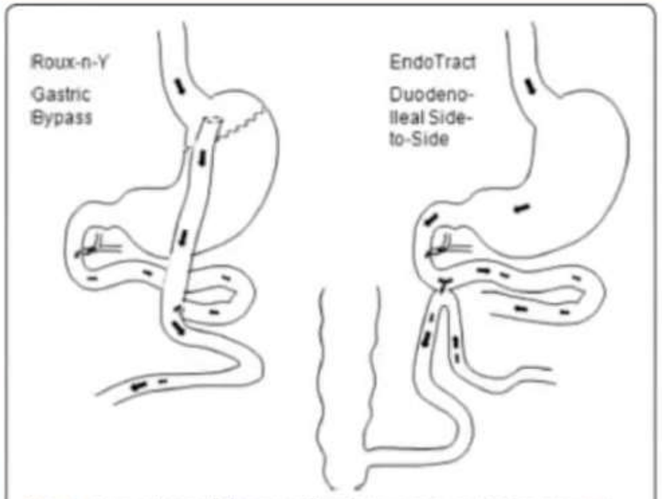


Fig. 4 Comparison of digestive flow between a gastric bypass and a side-to-side duodeno-ileal anastomosis. Alimentary flow and biliopancreatic secretions are mixing in a Y channel (100–150 cm in mid jejunum) in a gastric bypass, while in a side-to-side duodeno-ileal anastomosis, the alimentary flow is divided between a regular jejuno-ileal channel and a distal ileal channel, and biliopancreatic secretions are mixing in the proximal duodenum

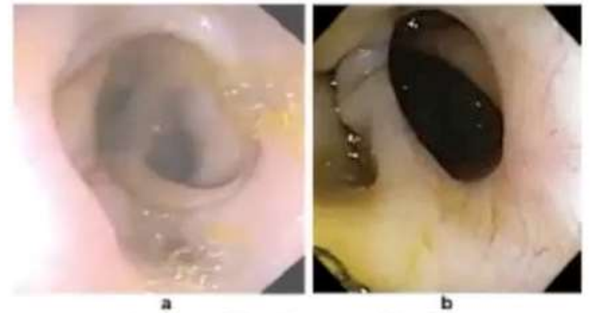


Fig. 5 **a** Duodenoscopy of the 3rd portion of the duodenum, showing a healed side-to-side duodeno-ileal anastomosis, with proximal ileum on the *right* and distal ileum on the *left* of the figure. **b** Duodenoscopy of the 3rd portion of the duodenum from a different animal, showing a healed side-to-side duodeno-ileal anastomosis, with distal duodenum on the far *right* of the figure

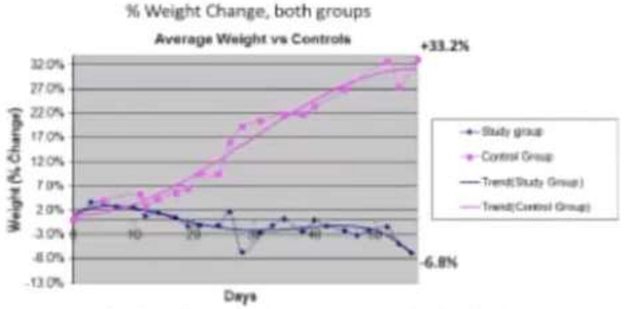


Fig. 6 Graph of % of weight change in animals that had a side-to-side duodeno-ileal anastomosis (study group) versus sham controls, over time in days. At 56 days, control animals had gained 33.2 % of weight, while study animals had lost 6.8 % of weight

GT Metabolic

AIS CHANNEL

MAGDI

MAGNETIC DUODENO-ILEOSTOMY

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MD, FRCSC, FACS, FASMBS, FSSO

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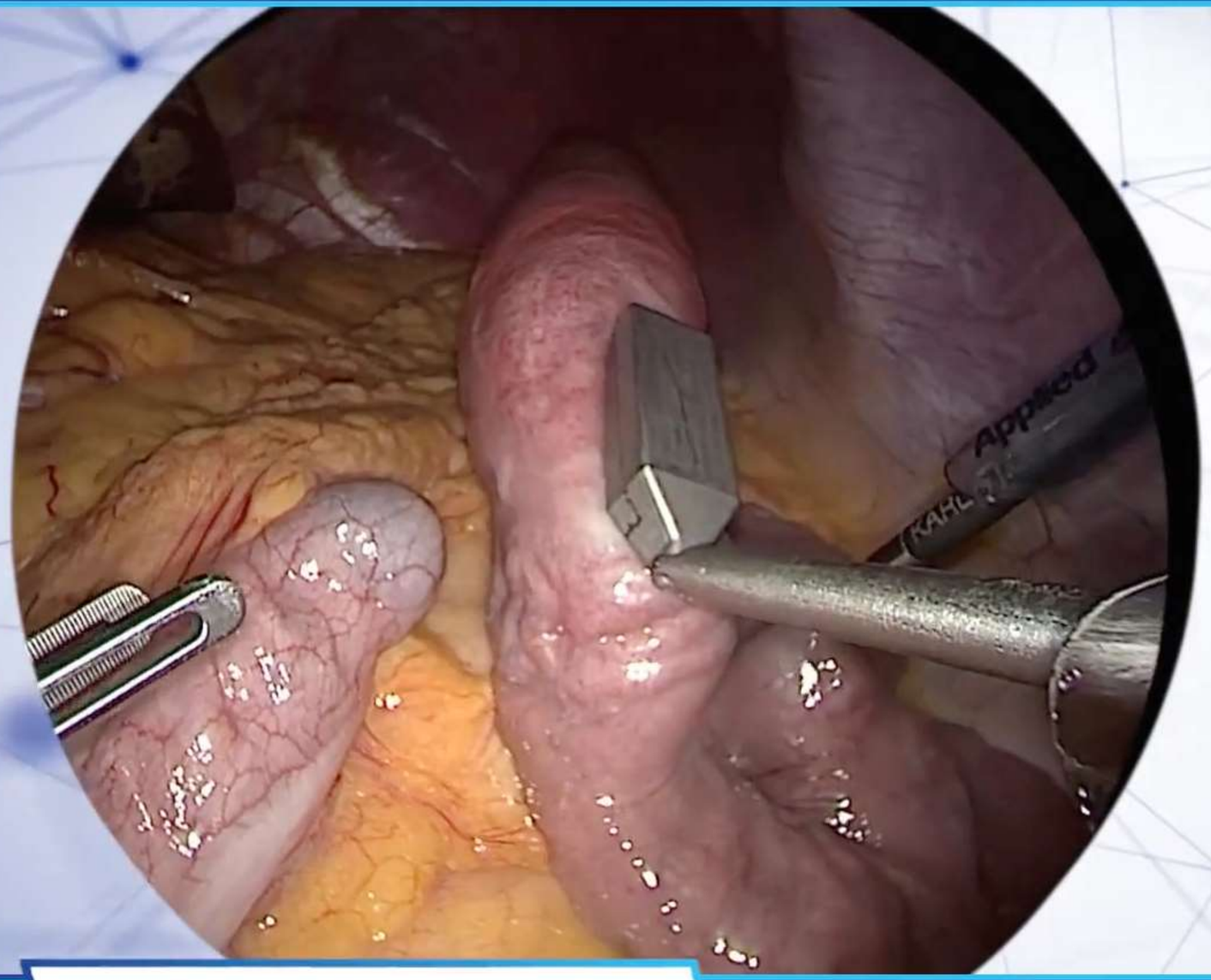
MAGNETIC DUODENO-ILEOSTOMY



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AIS CHANNEL

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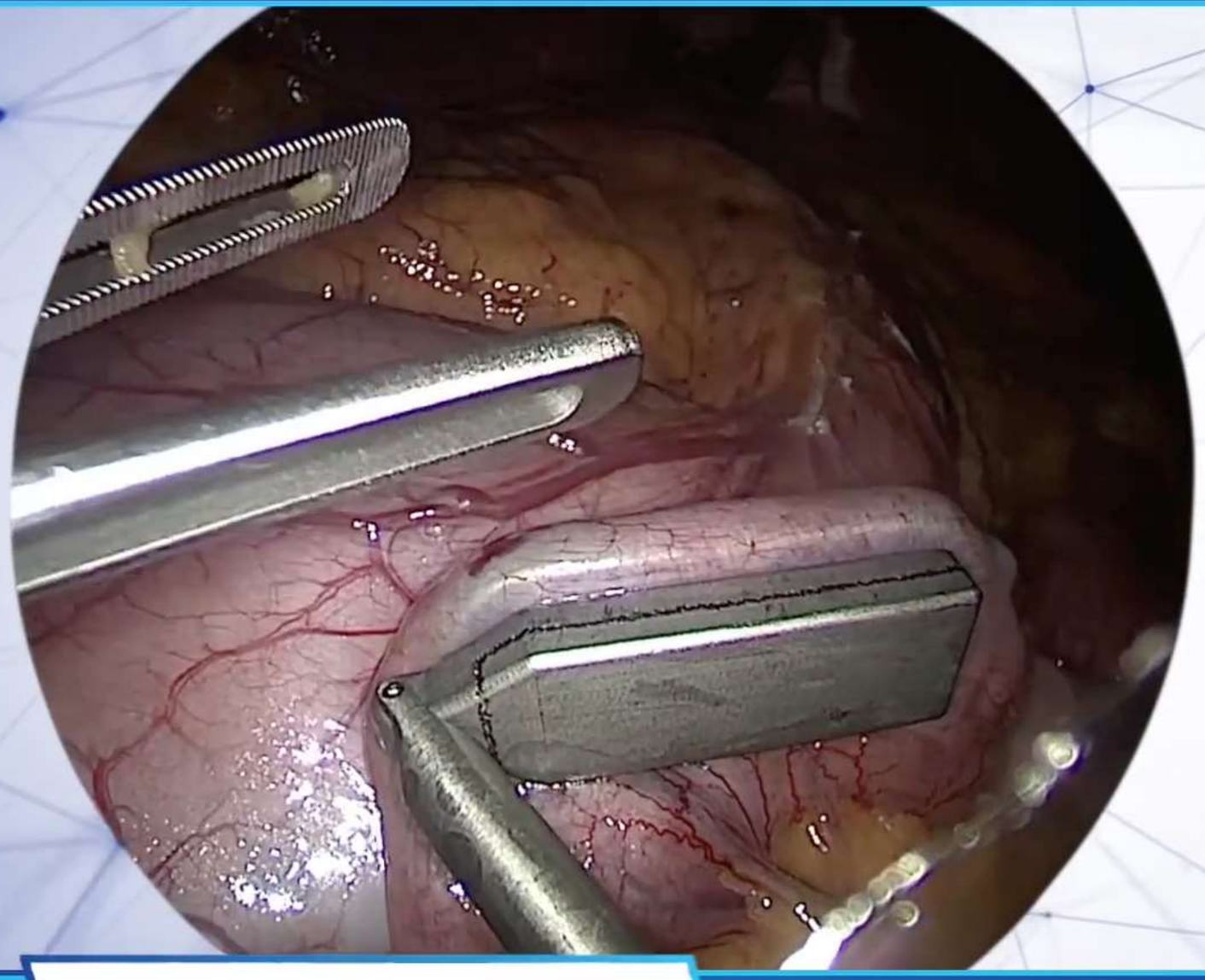
MAGNETIC DUODENO-ILEOSTOMY



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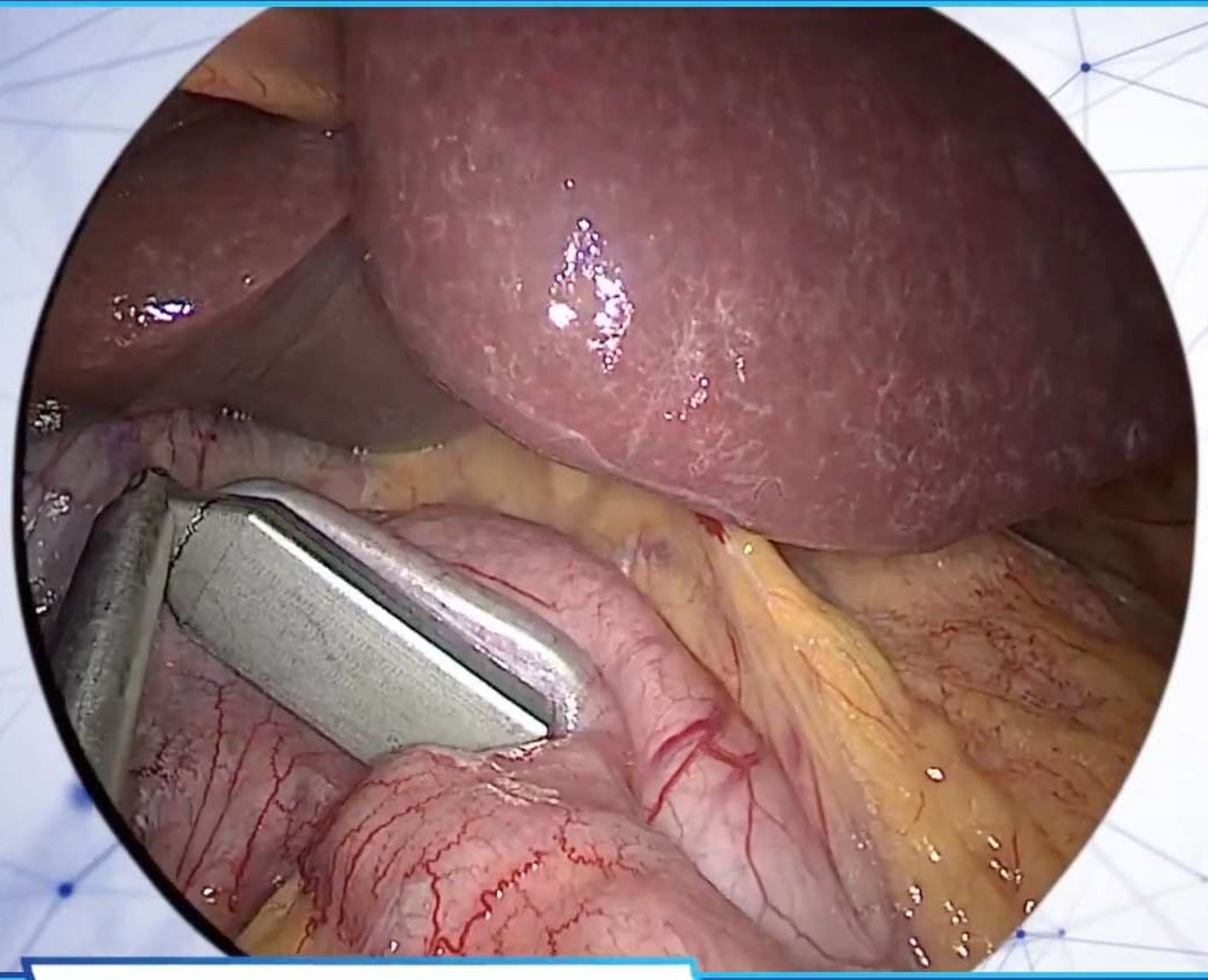

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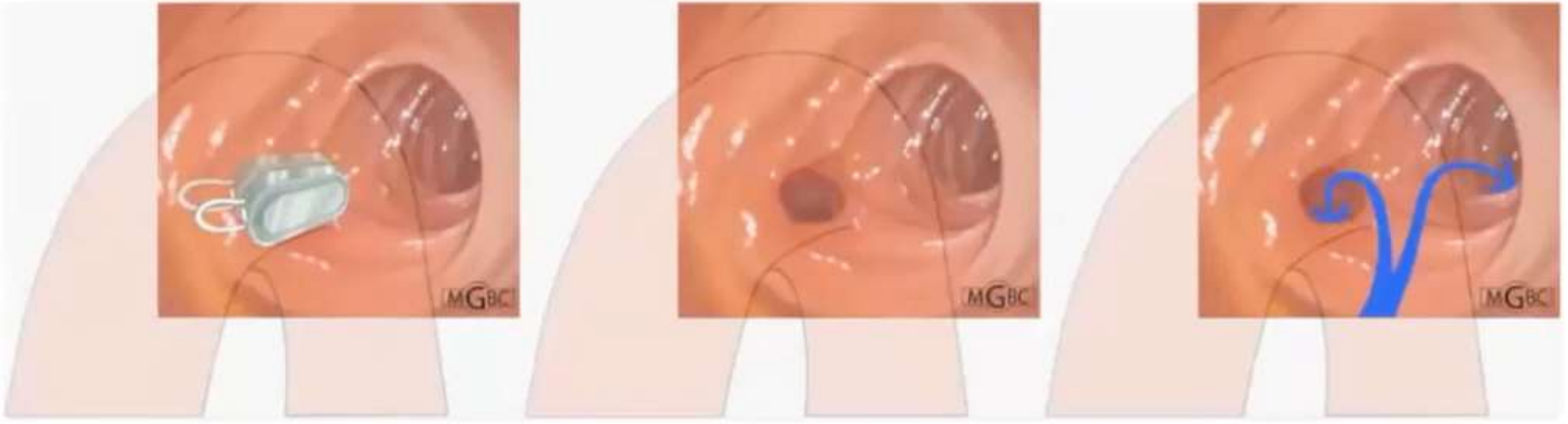
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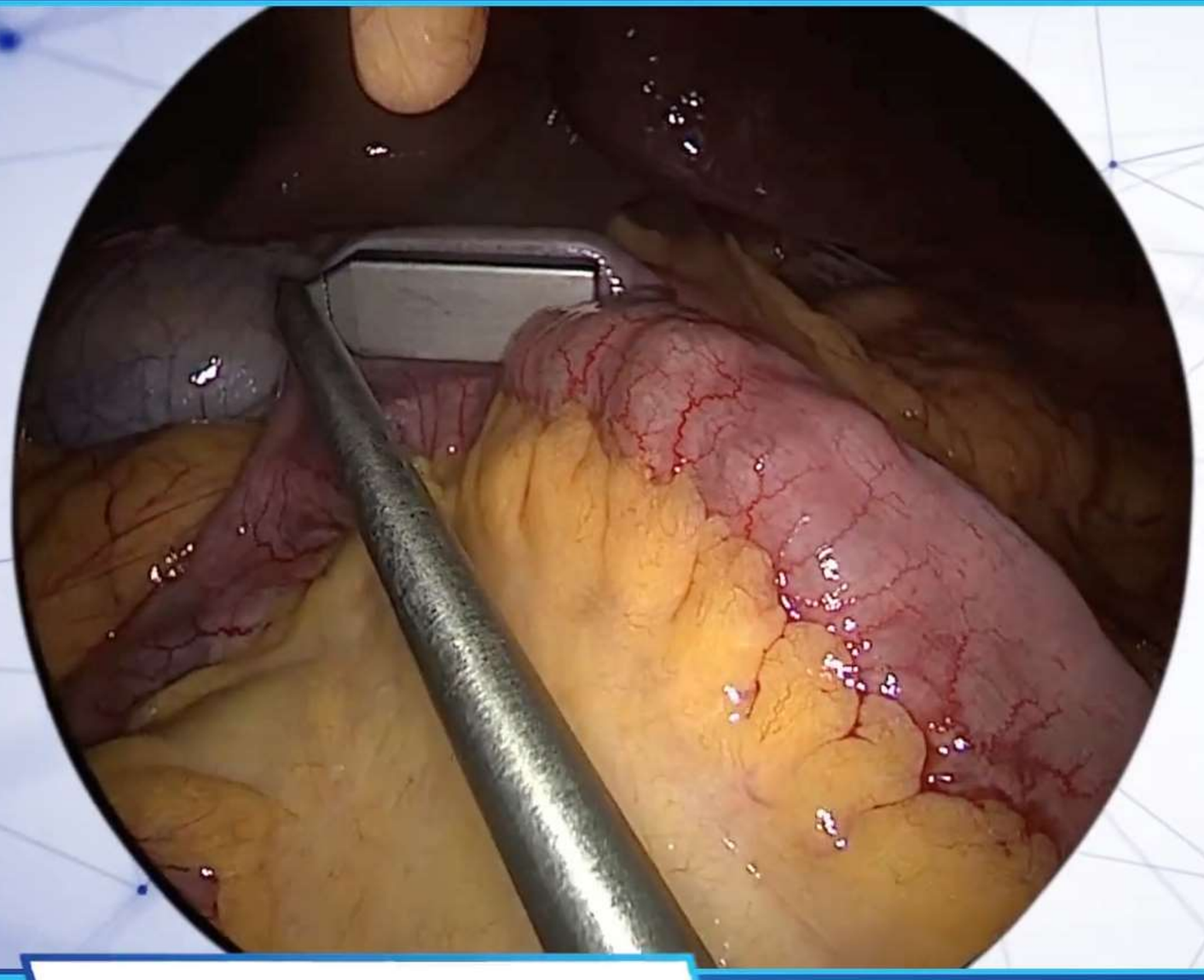
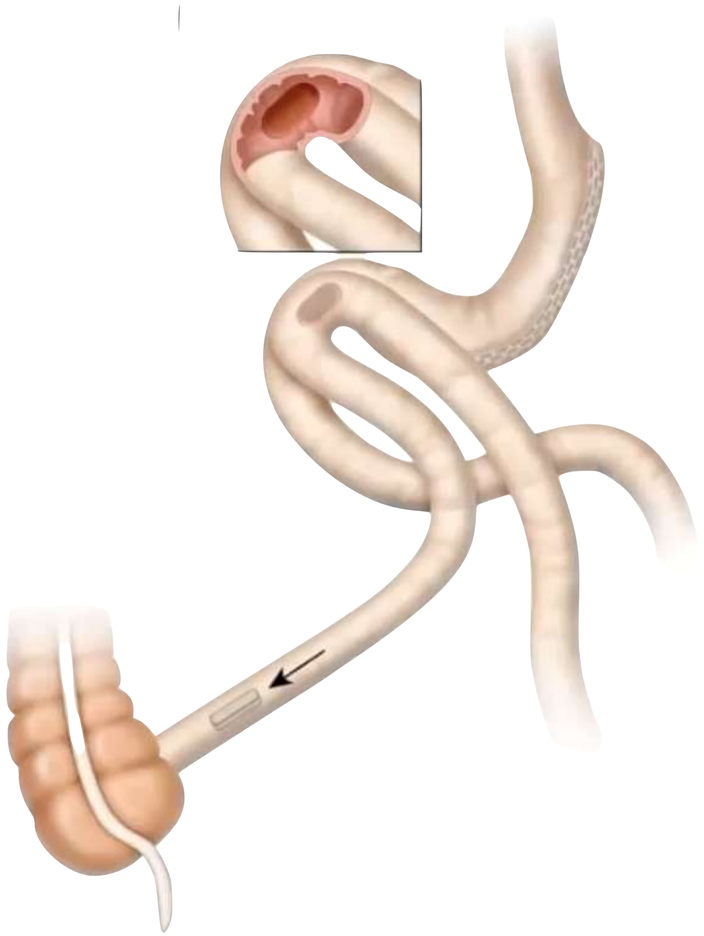
MAGDI
MAGNETIC DUODENO-ILEOSTOMY



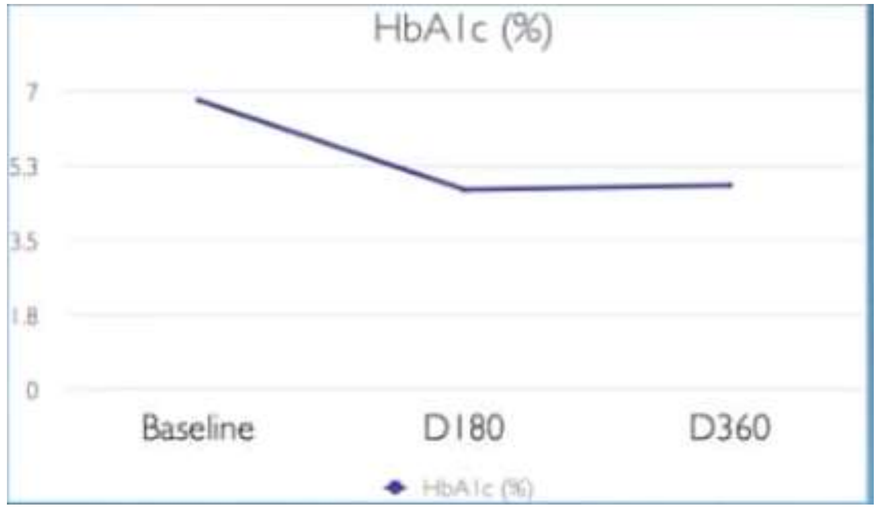
GT Metabolic

AIS CHANNEL

24pt
28%TWL @6m
34%TWL @12m



Obesity Indicator	D180 n=24	D360 n=5
Proportion of Subjects >5% TWL	100% (24/24)	100% (5/5)
% TWL Mean (SEM)	28 (0)	34.0 (1.4)
% EWL Mean (SEM)	66 (3)	80.2 (6.6)



03 years

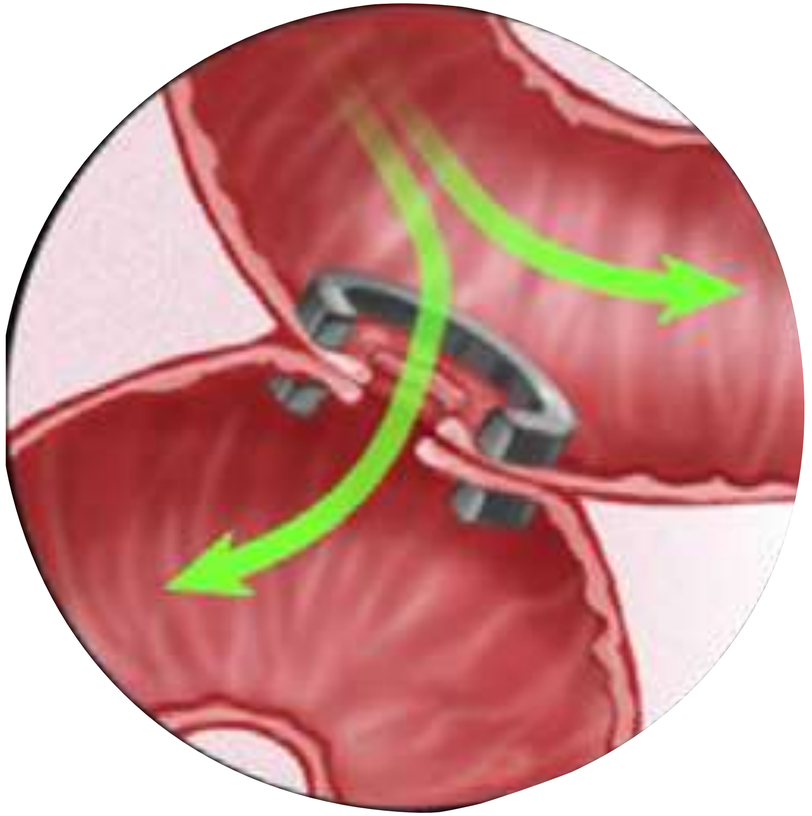
Up to 18%TWL

Drop of 1.5 - 2.0 HgA1C

Safe

Experimental

On its infancy…



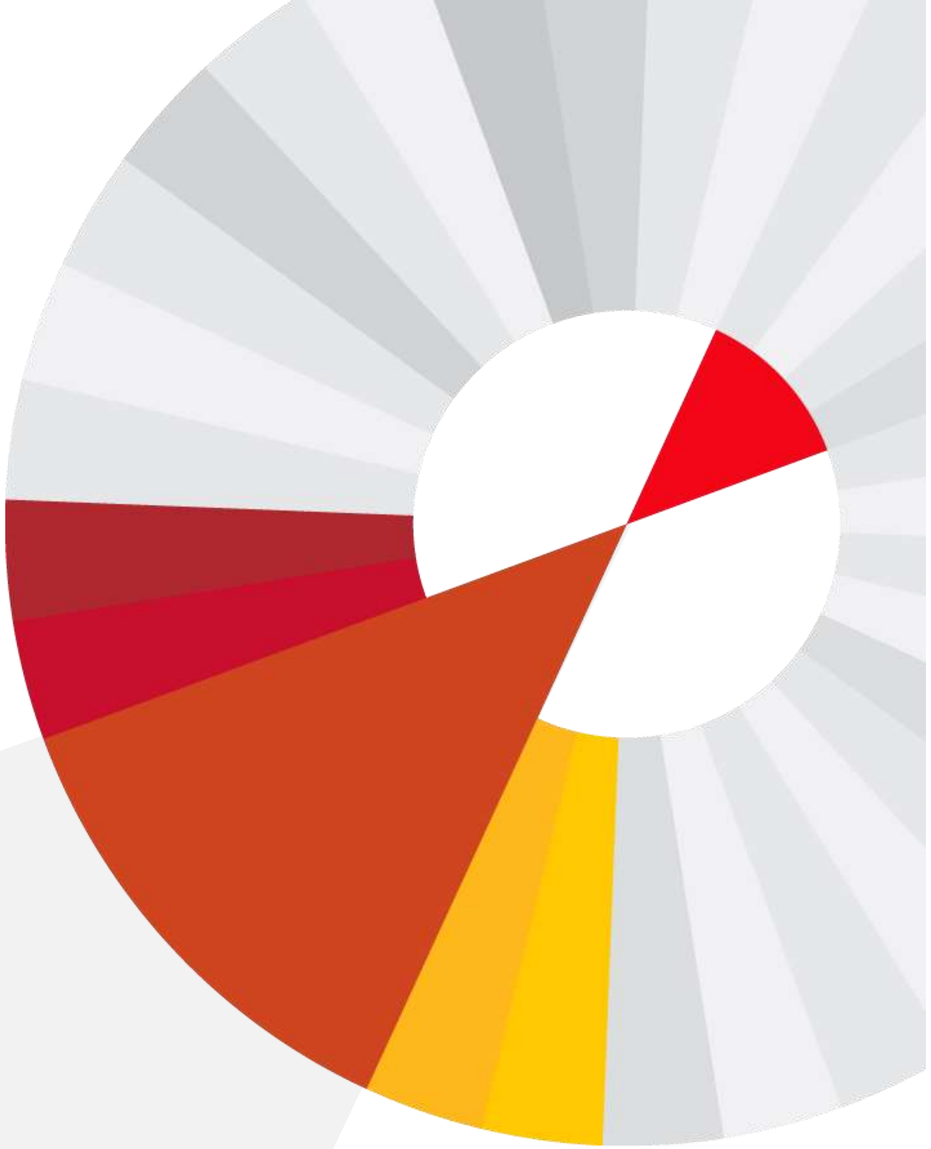
METABOLIC ENDOSCOPY
HARD ENDPOINTS

- 1 point drop on H1AC
  - All
- + 10%TWL
  - Duodenal-Jejunal bypass (DJB) ; Magnetic bowel anastomosis
- Taking patients out of insulin
  - DMR
- Add effect to GLP1 analogues
  - DJB
- Clinical use
- None (DJB; DMR about to be)

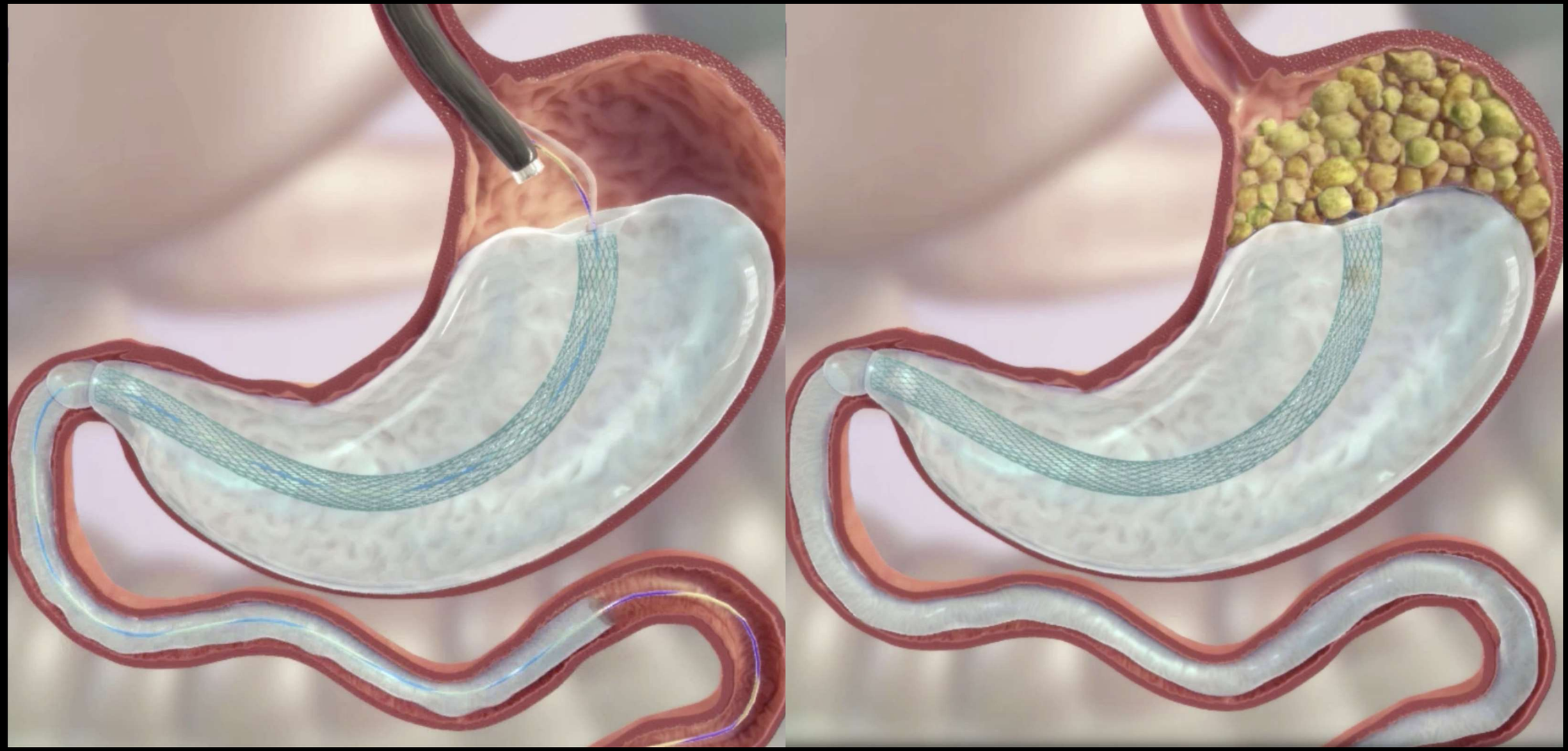
ENDOSCOPIC

GASTRO-DUODENO - JEJUNAL BYPASS

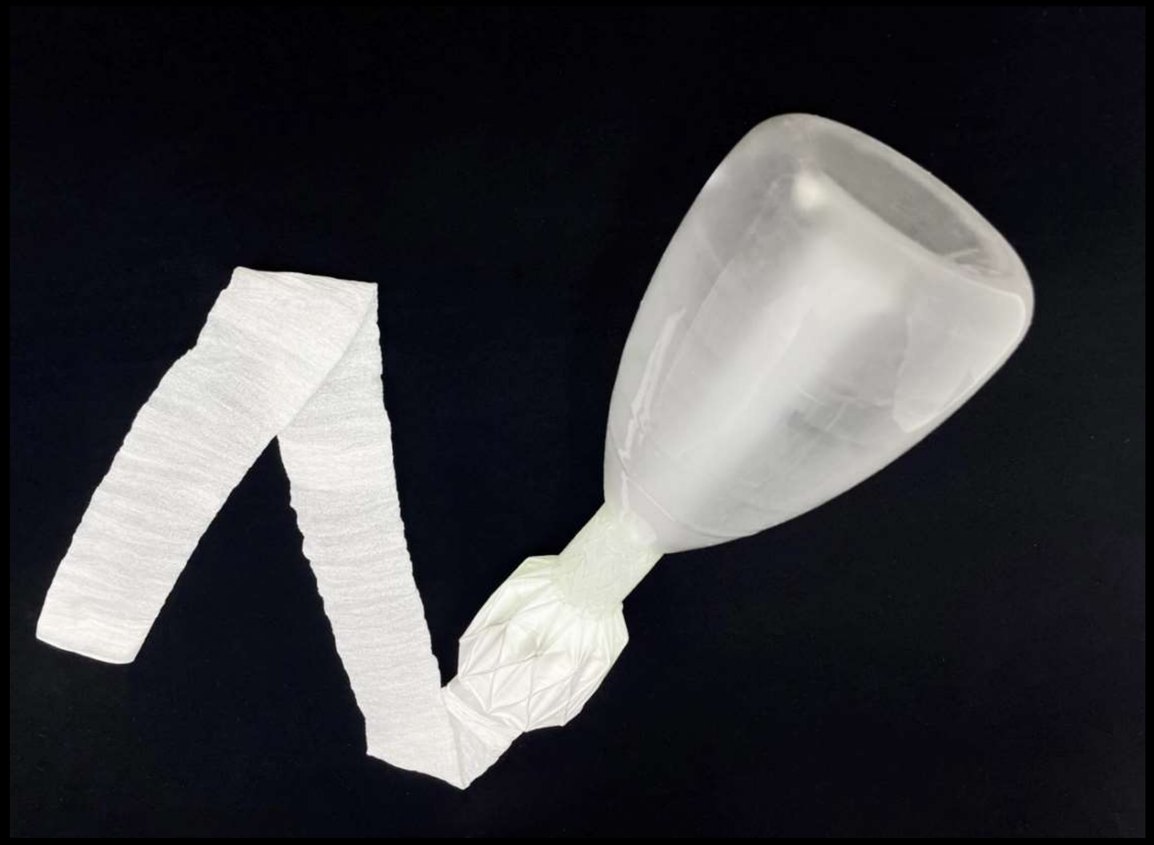
“FOREPASS

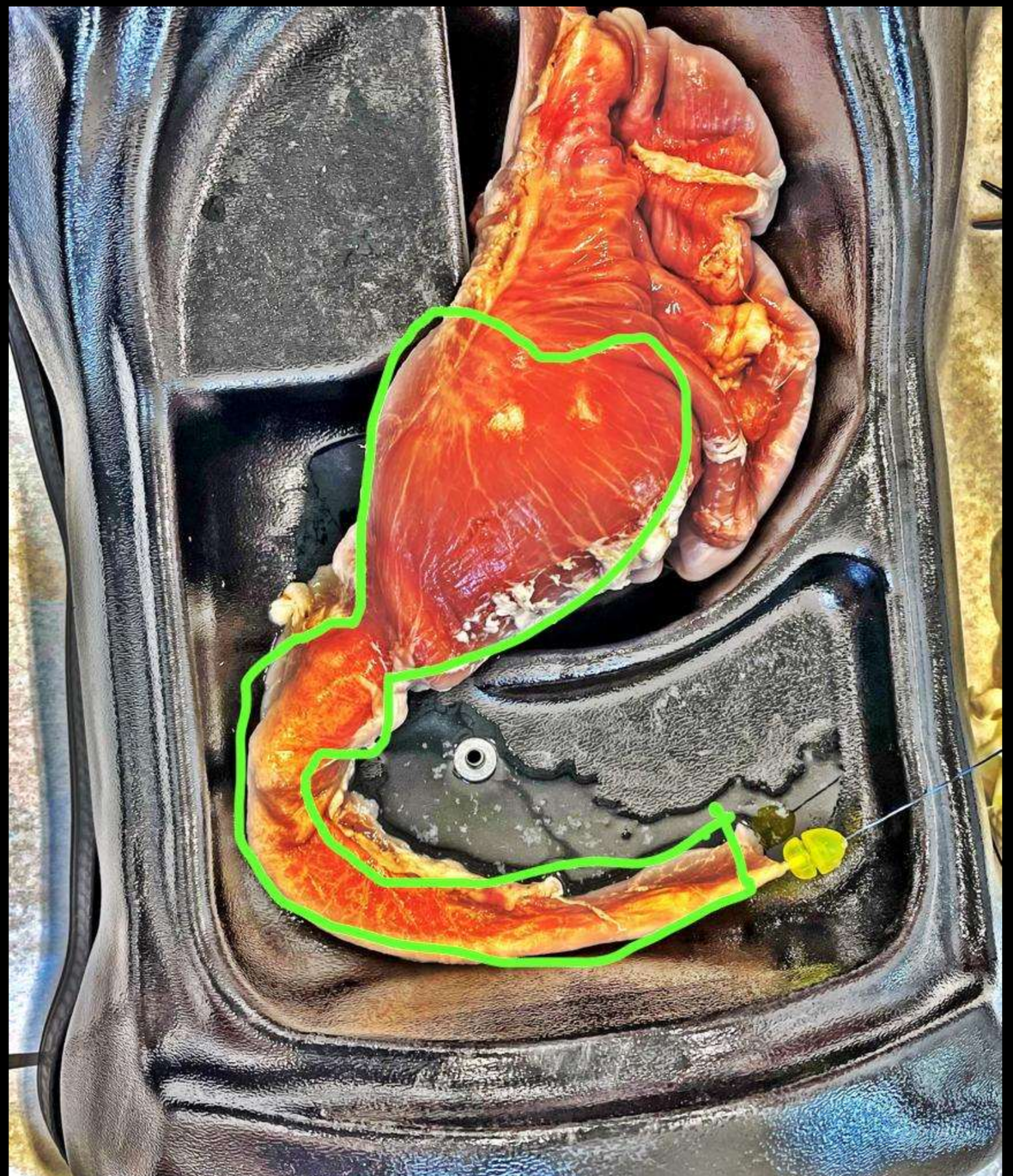


SleeveBallon



SleeveBallon





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Gemeli Hospital animal lab, Rome, Italy

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Research paper

Simulation of gastric bypass effects on glucose metabolism and non-alcoholic fatty liver disease with the Sleeveballoon device

James Casella-Mariolo [a,1], Lidia Castagneto-Gissey [b,1], Giulia Angelini [c], Andrea Zoli [c], Pierluigi Marini [a], Stefan R. Bornstein [d,e], Dimitri J. Pournaras [f], Francesco Rubino [e], Carel W. le Roux [g,h], Geltrude Mingrone [c,e,i,*], Giovanni Casella [b,**]

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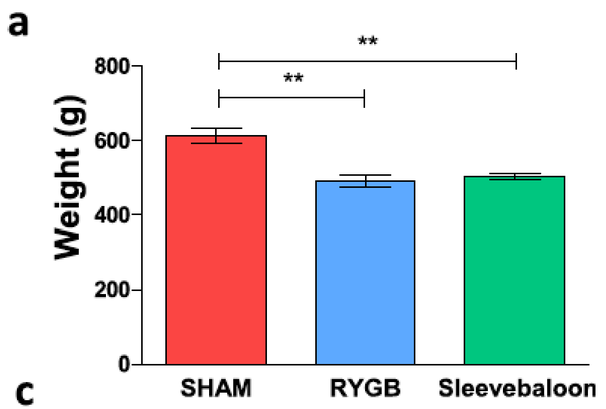
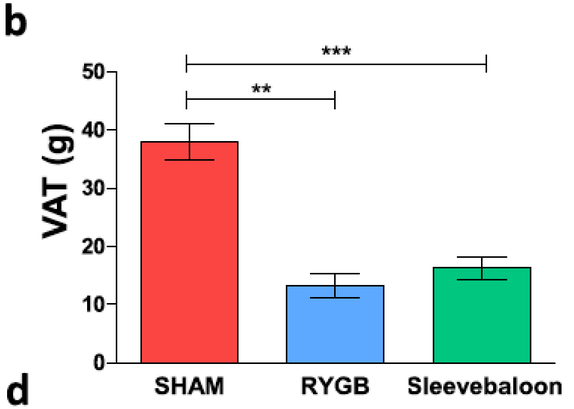
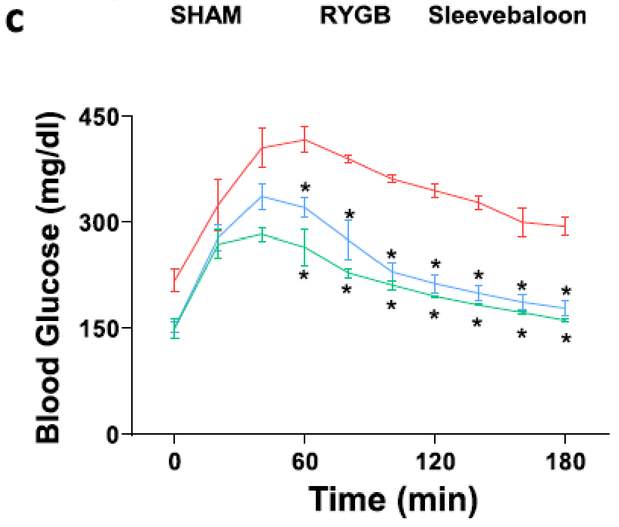
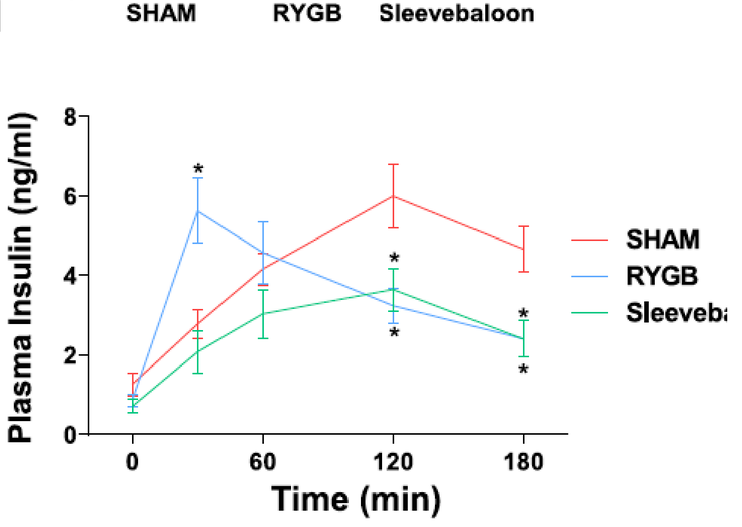
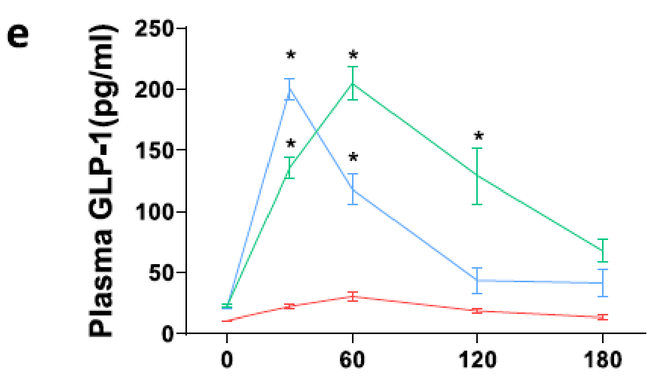


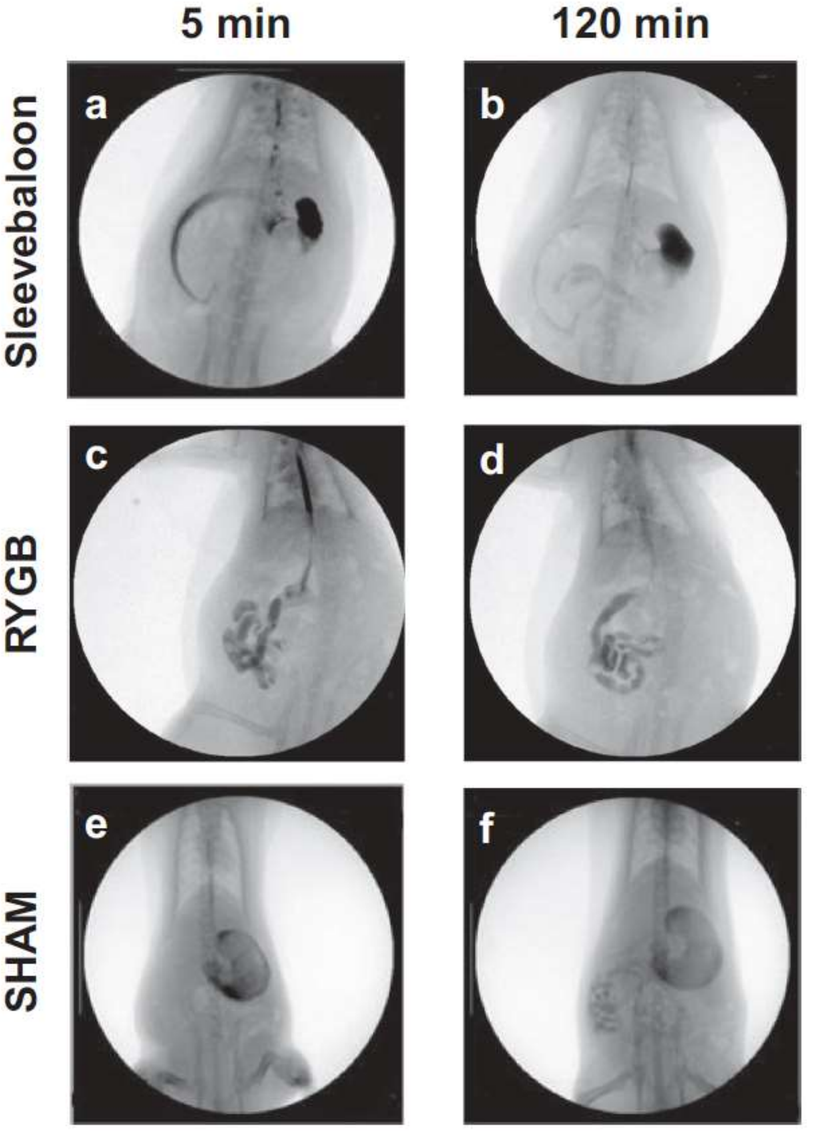


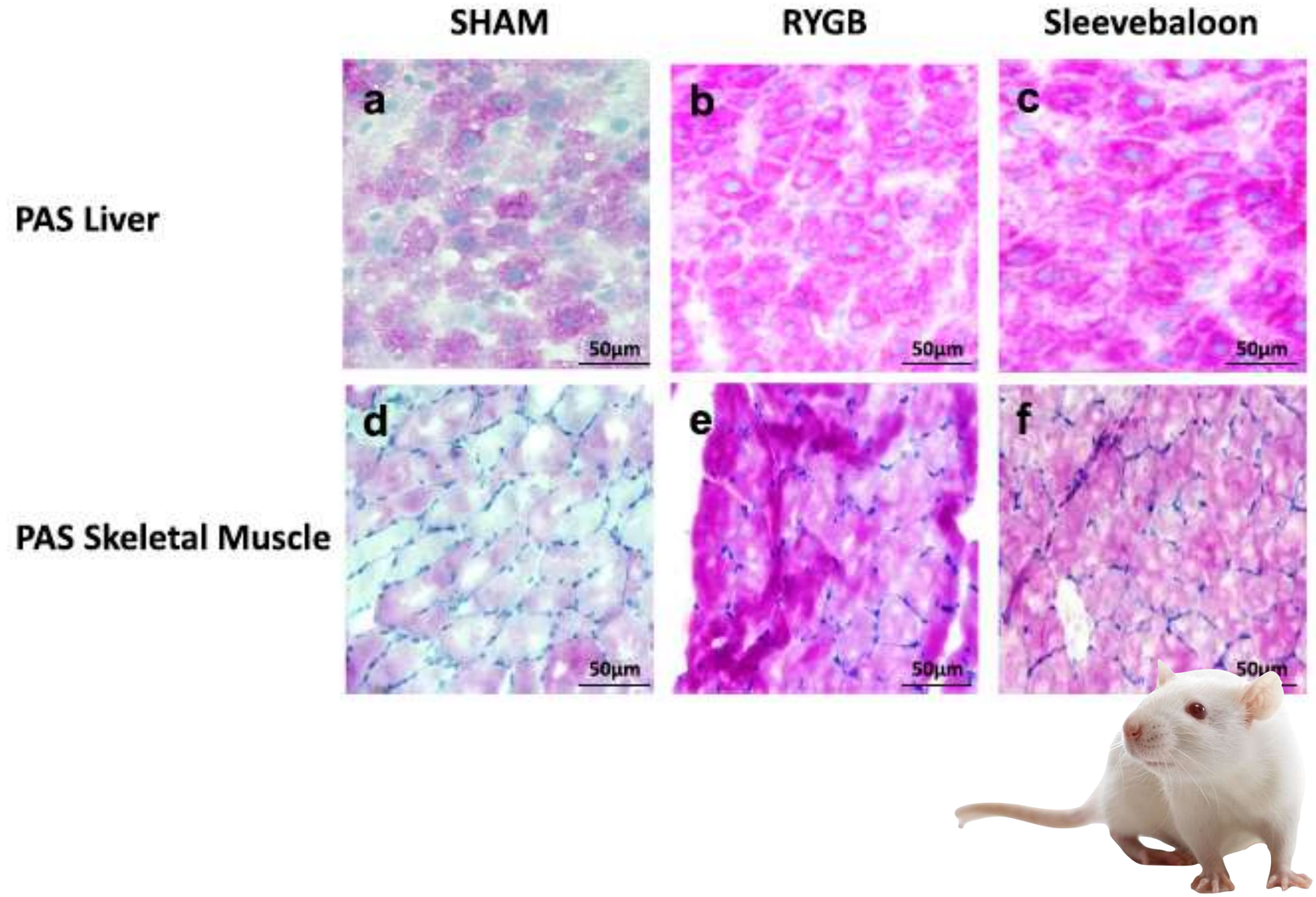


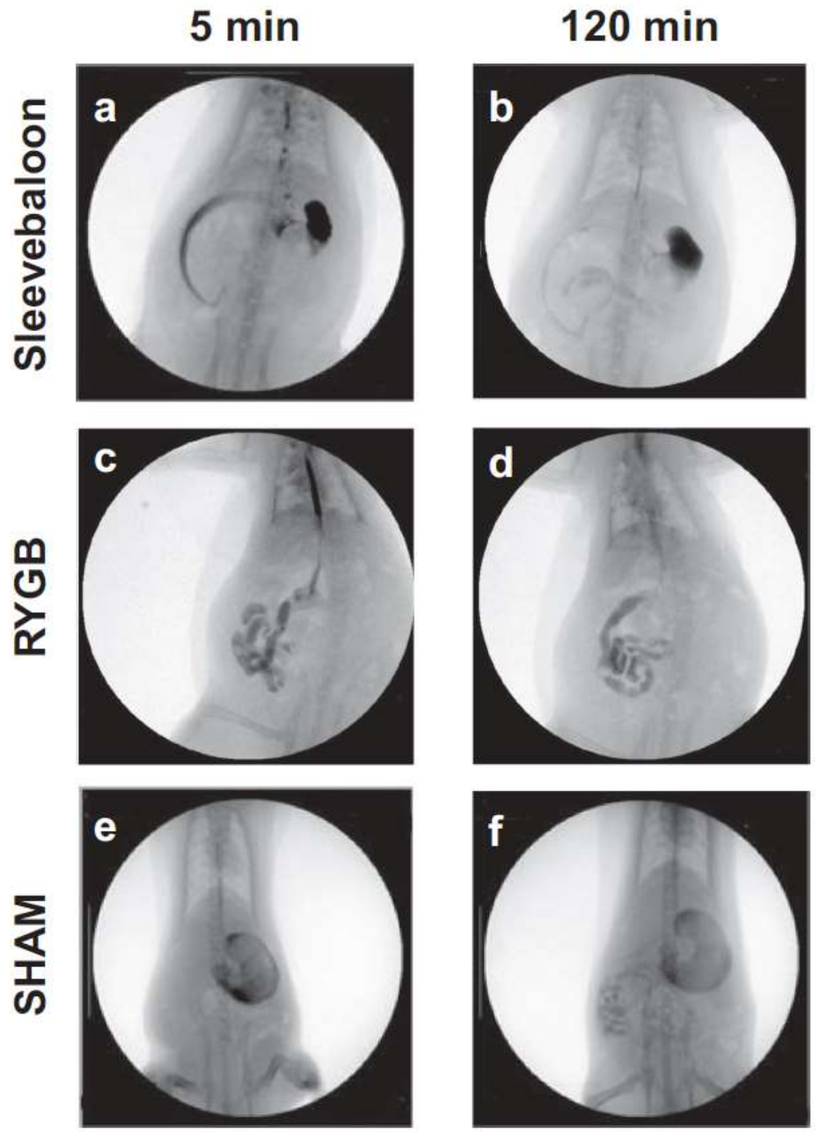




J. Casella-Mariolo et al. / EBioMedicine xxx (2019) xxx




SHAM
RYGB
Sleevebaloon
PAS Liver
PAS Skeletal Muscle
a
b
c
d
e
f
50µm


5 min
120 min
Sleevebaloon
RYGB
SHAM
a
b
c
d
e
f

From Duodenaljejunal Bypass Liner to Duodenal Resurfacing to Endoscopic Bypass procedures…

Evolution of endoscopic small bowel interventions

Manoel Galvao Neto MD MsC IFSO IFASMBS FASGE

IFSO NAPOLI 2023