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ENDOSCOPIC TREATMENT OF PRIMARY AND SECONDARY OBESITY

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Presenter Disclosure Slide

Manoel Galvao Neto, MD

Ethicon Endosurgery

International consultant / Professional education

GI Dynamics

International consultant / Scientific Advisory Board

Apollo Endosurgery

International consultant / Scientific Advisory Board

Alacer biomedics

International consultant / Scientific Advisory Board

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GASTRO OBESO CENTER

December of 1999 – December of 2010

Procedures actually done

Adjustable Gastric Band		1331p
Gastric Bypass		6711p
Lap Gastric Bypass banded	1897p	
Lap gastric Bypass non banded	3771p	
Open Gastric Bypass (72banded)	972p	
BPD - D.S.		110p
Vertical Gastrectomy - “Sleeve”		714p
Intragastric Balloon		439p
Metabolic surgery (DJB + metabolic bypass)		279p
Sub-total 1		9584p

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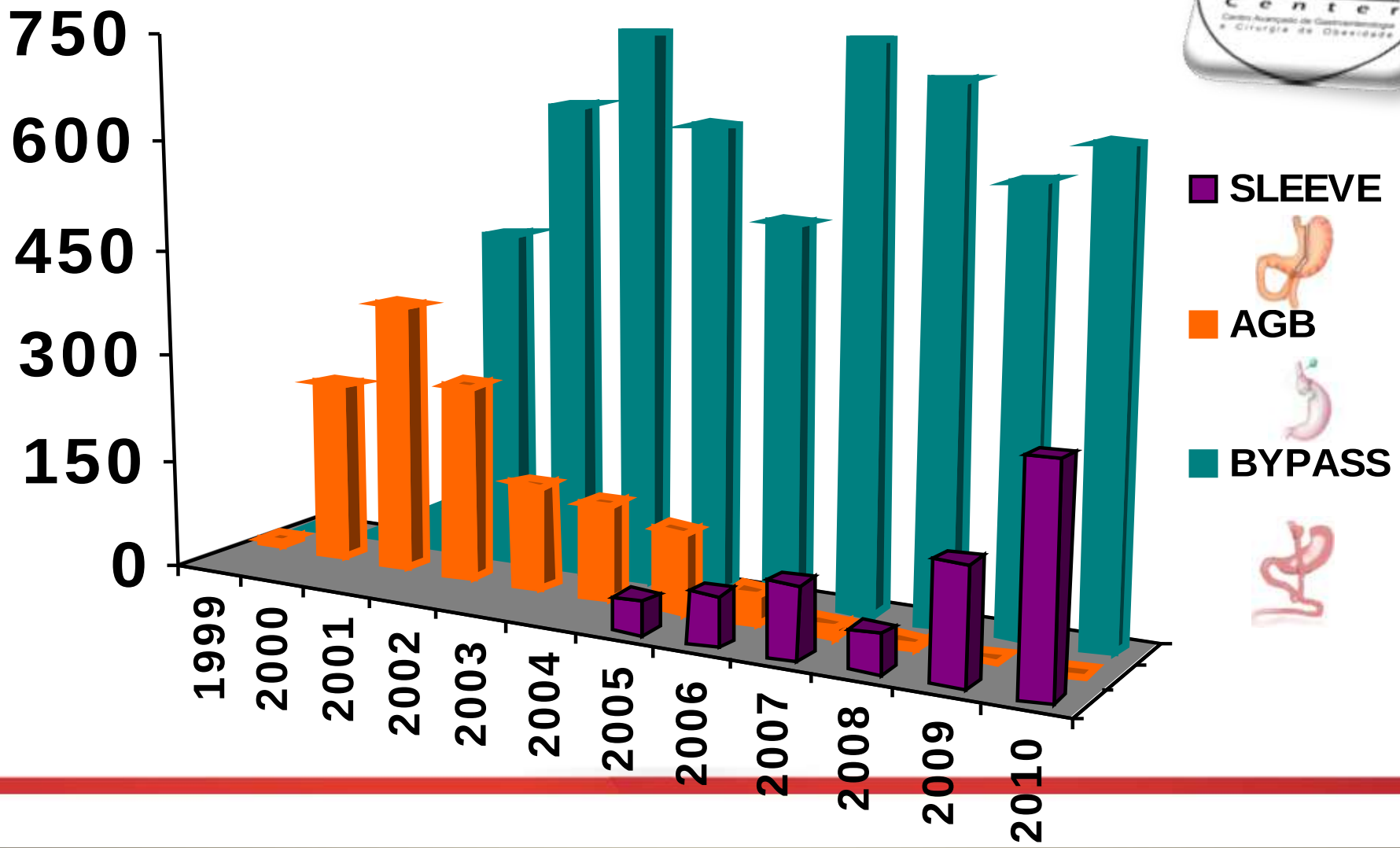
GASTRO OBESO CENTER

December of 1999 – December of 2010



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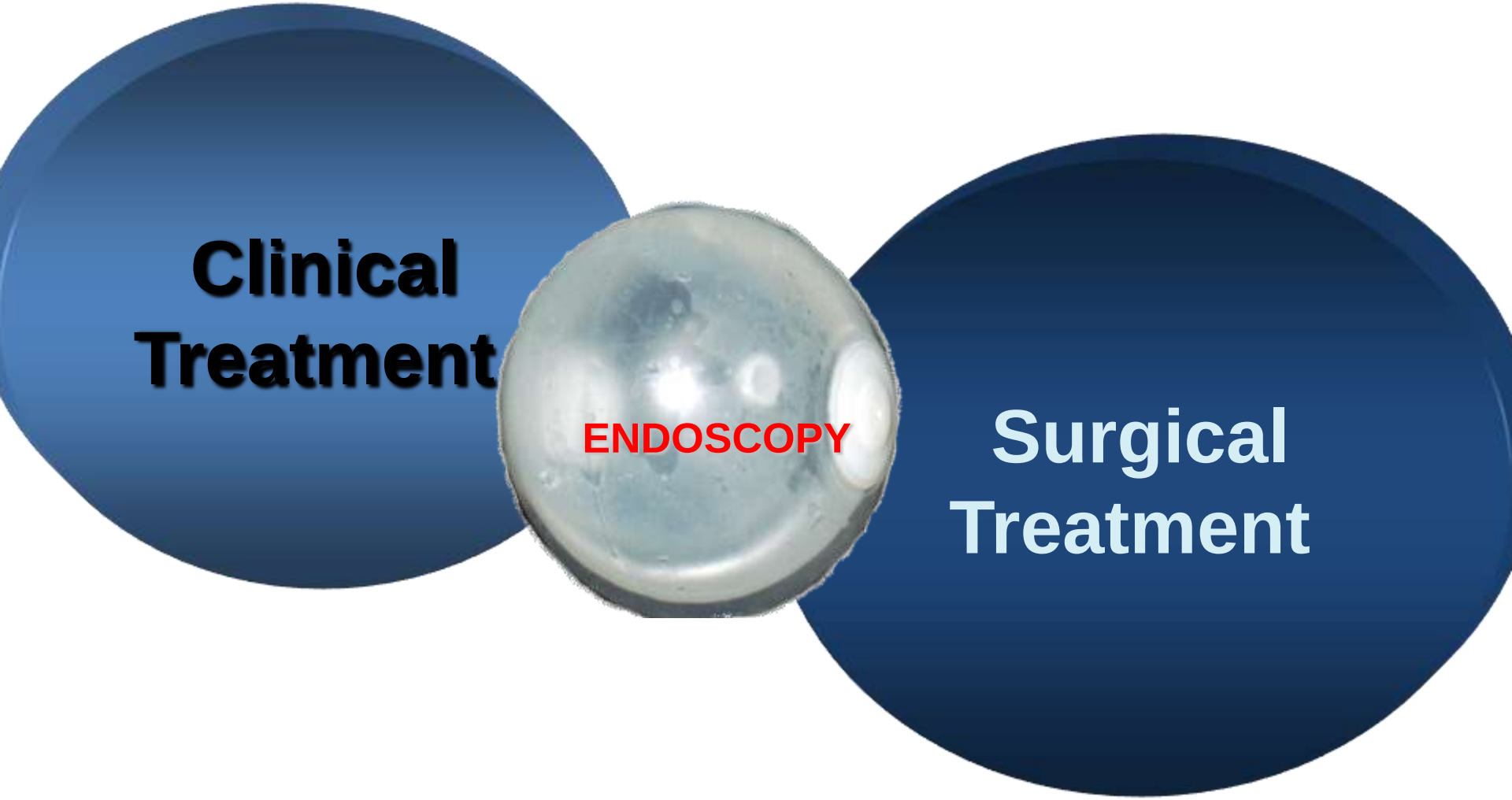
Obesity endoscopic treatment



Obesity endoscopic treatment

Comparison with bariatric surgery

- Surgery outcomes
  - Long term efficacy
  - Higher probability of complications and mortality
  - Needs for a multidisciplinary team support
- Endolumenal outcomes
  - Short term efficacy
    - Possibility of weight regain after removal
  - Lesser probability of complications and mortality
  - Needs for a multidisciplinary team support

Comparison with bariatric surgery

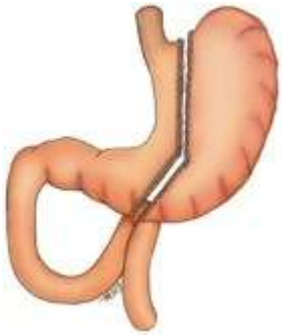
- Comparison with Sleeve gastrectomy

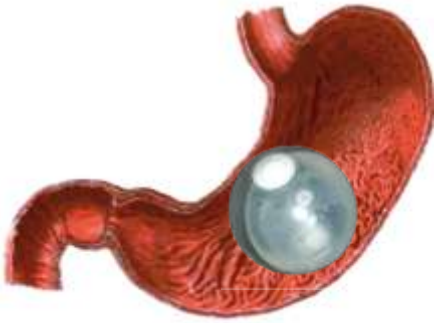
Obesity Surgery, **15**, 612-617

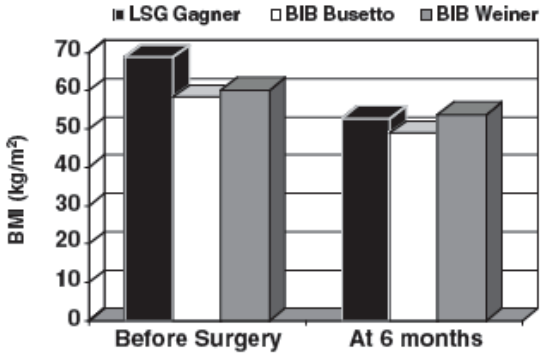
Laparoscopic Sleeve Gastrectomy is Superior to Endoscopic Intragastric Balloon as a First Stage Procedure for Super-Obese Patients (BMI ≥50)

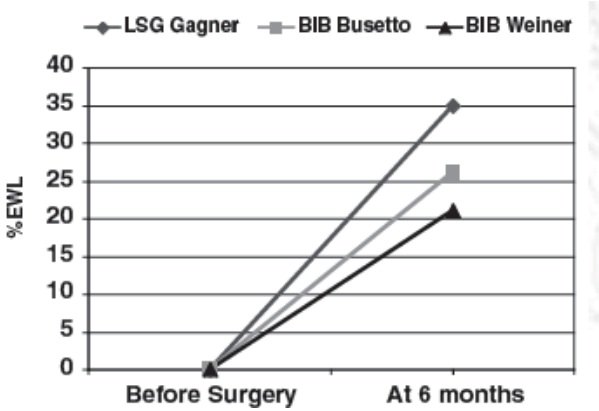
Luca Milone, MD; Vivian Strong, MD; Michel Gagner, MD, FRCSC, FACS

New York Presbyterian Hospital, Weill College of Medicine of Cornell University, Department of Surgery, New York, NY, USA









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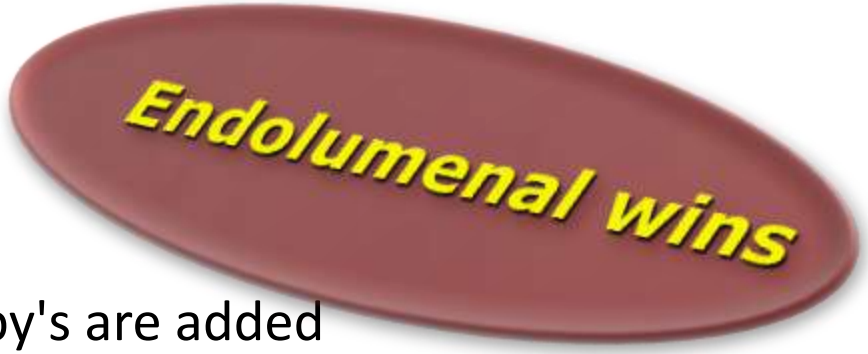
Obesity endoscopic treatment

Comparison with bariatric surgery

- Mortality
  - Endoscopic treatment
    - Close to zero
      - Very low risk
  - Surgery
    - Mortality depends upon
      - Patient clinical conditions
      - Medical care environment
      - Surgical team expertise

Obesity endoscopic treatment

Comparison with clinical treatment



- Clinical treatment
  - Short term efficacy
    - Lesser than the balloon
  - Improve results when more therapy's are added
    - Diet + Weight loss meds + Exercise
  - ↑ levels of patients quitting before the end of treatment
- Balloon
  - Short term therapy
  - Works solo
  - ↓ levels of patients quitting before the end of treatment

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Endoscopic treatment of obesity

Current technologies

PRIMARY
OBESITY TREATMENT

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Endoscopic treatment of obesity

New technologies

SPACE OCCUPYING DEVICES

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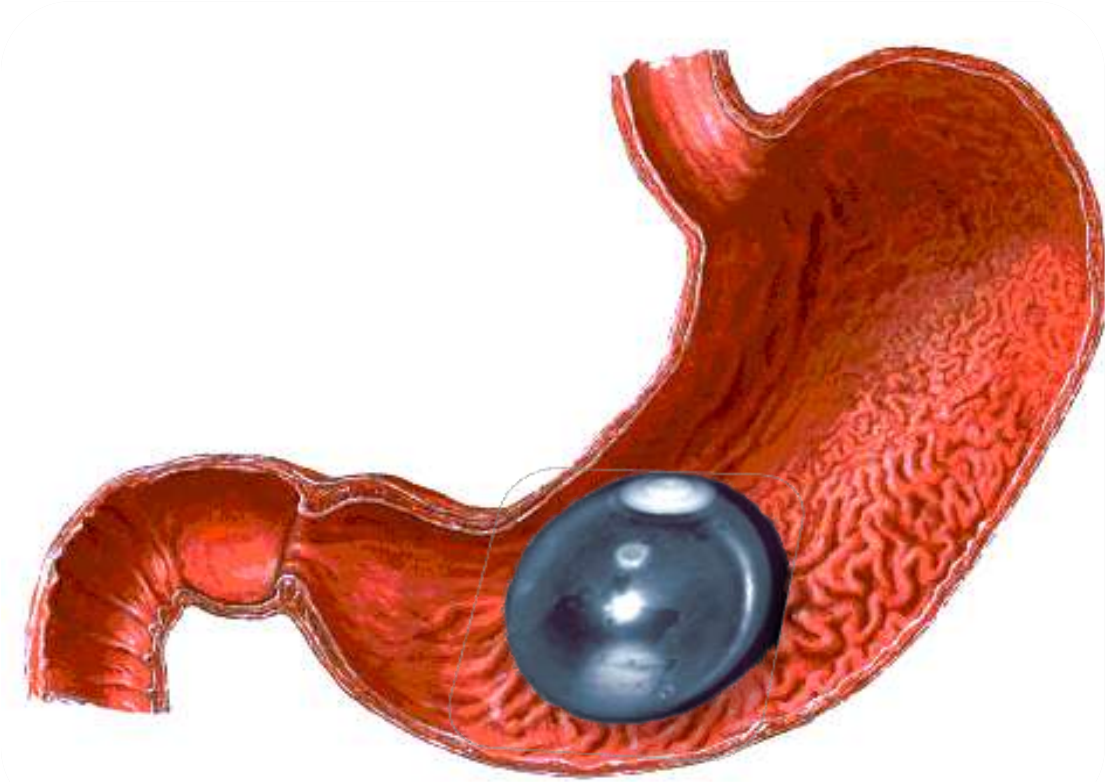
Intragastric balloon

Allergan® - BIB®



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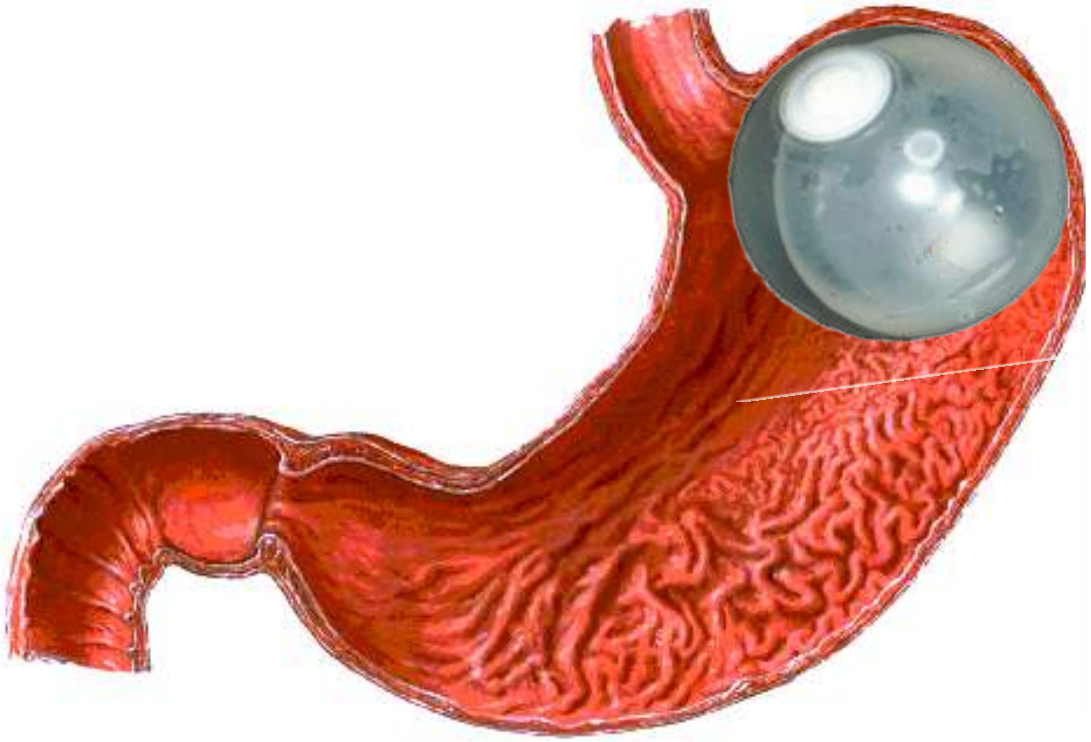
Intragastric balloon

Helioscopie® - Heliosphere®



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Intragastric balloon

Adjustable - Spatz Balloon®

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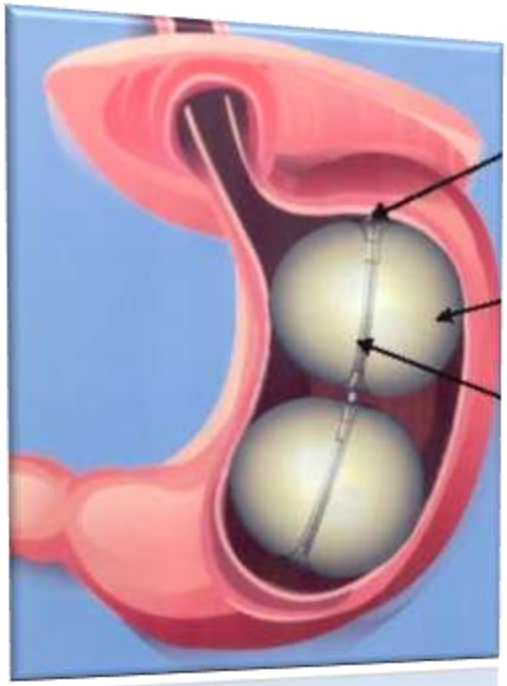
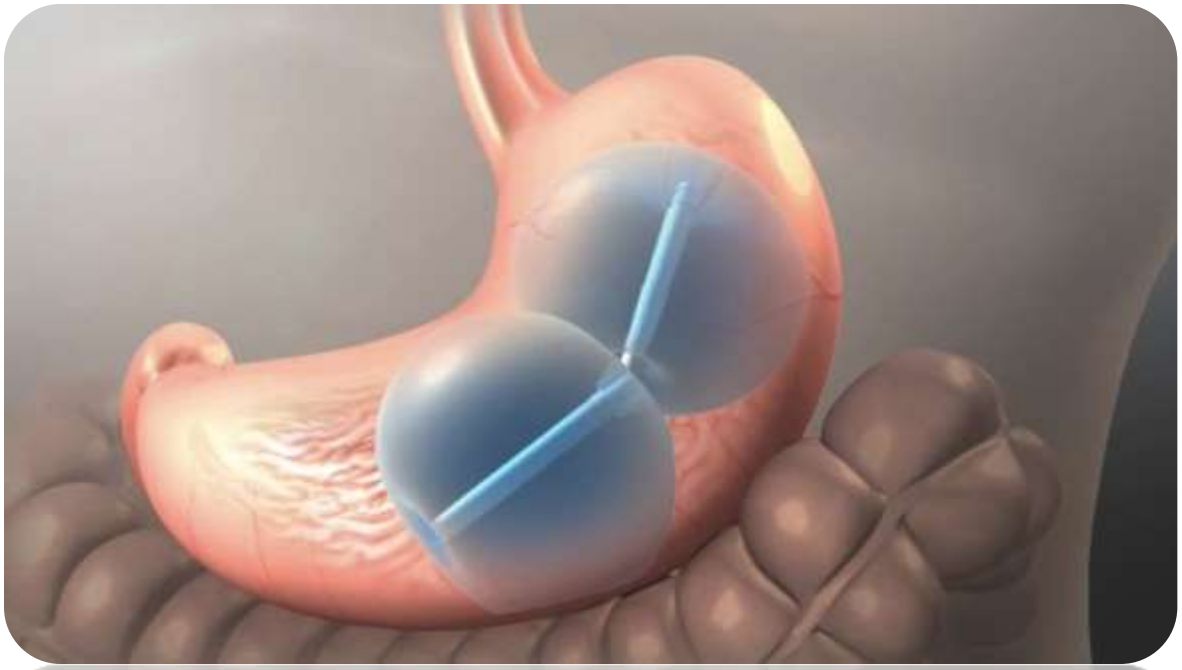
Intragastric balloon

Duo - ReShape®





Courtesy of Dr. Jaime Ponce - USA

Balão intragastrico Allergan® - BIB®

280p*

- Casuística Gastro Obeso Center
- Média de perda do excesso de peso a 6m(%EWL)
  - IMC 35-40 Kg/M2 ↓ 38,1%
  - IMC 40-50 Kg/M2 ↓ 42,5%
  - IMC > 50 Kg/M2 ↓ 45,3%
- Efeitos colaterais
  - Náuseas e vômitos 65%
  - Dor abdominal 30%
  - Desidratação 09%

*Efetivamente seguidos

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Brazilian Society of Digestive Endoscopy - SOBED

National BIB training program 2011

- Training
  - SOBED – training centers
  - Attendees implants under proctorship supervision
    - SOBED - Specialists
      - Under Regional Consul of Medicine scrutiny
- First training workshop - SP –2011
  - 16 implanted patients
  - All under multidisciplinary team follow-up
  - *No complications at implant and explants*

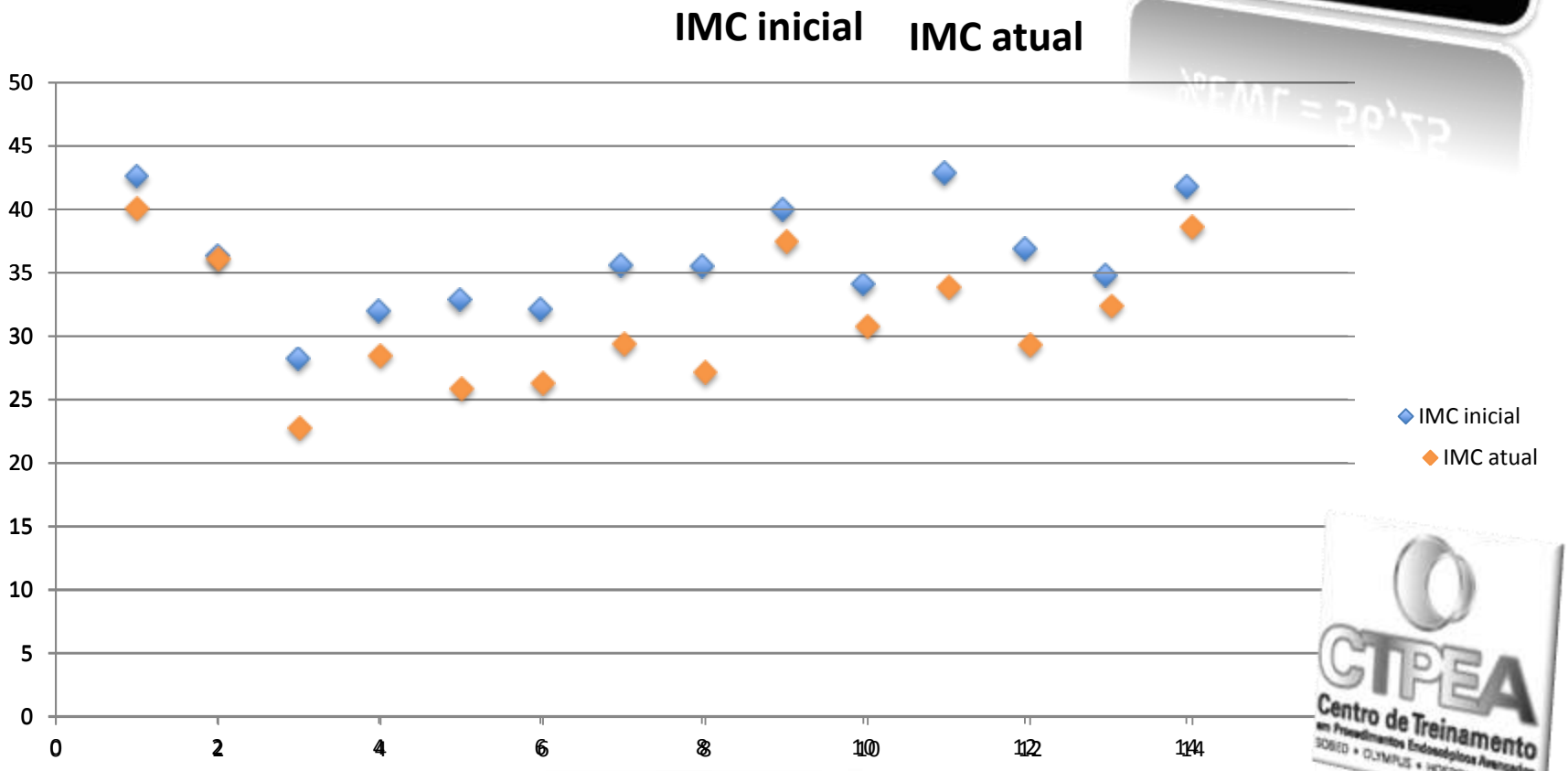
Brazilian Society of Digestive Endoscopy - SOBED

National BIB training program 2011

Initial BMI= 36,12

Final BMI= 31,34

%EWL = 56,25



Intragastric balloon Helioscopie® - Heliosphere®

- Casuistic Multi-center – Brazil

Center	N	F/ M	Pre-op weight	Pre-op BMI	Total Weight loss	% EWL
Sao Rafael Hospital – BA *Cristina Martins, MD*	82	53F / 29M	117kg (81 – 156)	37Kg/M^2 (34-52)	18Kg (7-46)	38%
Obesity and Surgery Treatment Nucleus – BA *Marcelo Falcao, MD Erivaldo Alves, MD*	38	29F / 9M	107Kg (78 – 132)	35,7Kg/M^2 (32-44)	13Kg (5,8-27,3)	52%
Gastro Obeso Center – SP *Manoel Galvao Neto, MD Almino Ramos, MD*	63	48F / 15M	98Kg (75-122)	31,5Kg/M^2 (27-48)	14,7Kg (10 – 37,8)	34,5%
Federal University of Pernambuco – PE *Josemberg Campos, MD*	27	20F / 7M	115Kg (72-141)	35,3Kg/M^2 (29-41)	13,6Kg (10 – 37,8)	35,8%

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Endoscopic treatment of obesity

New technologies

RESTRICTIVE PROCEDURES

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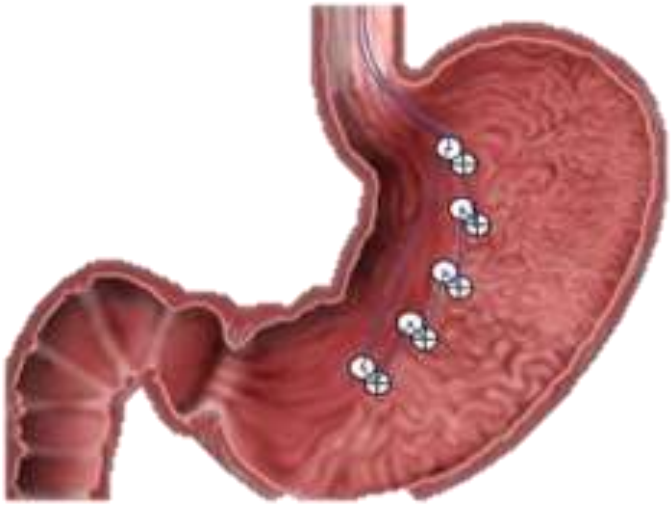
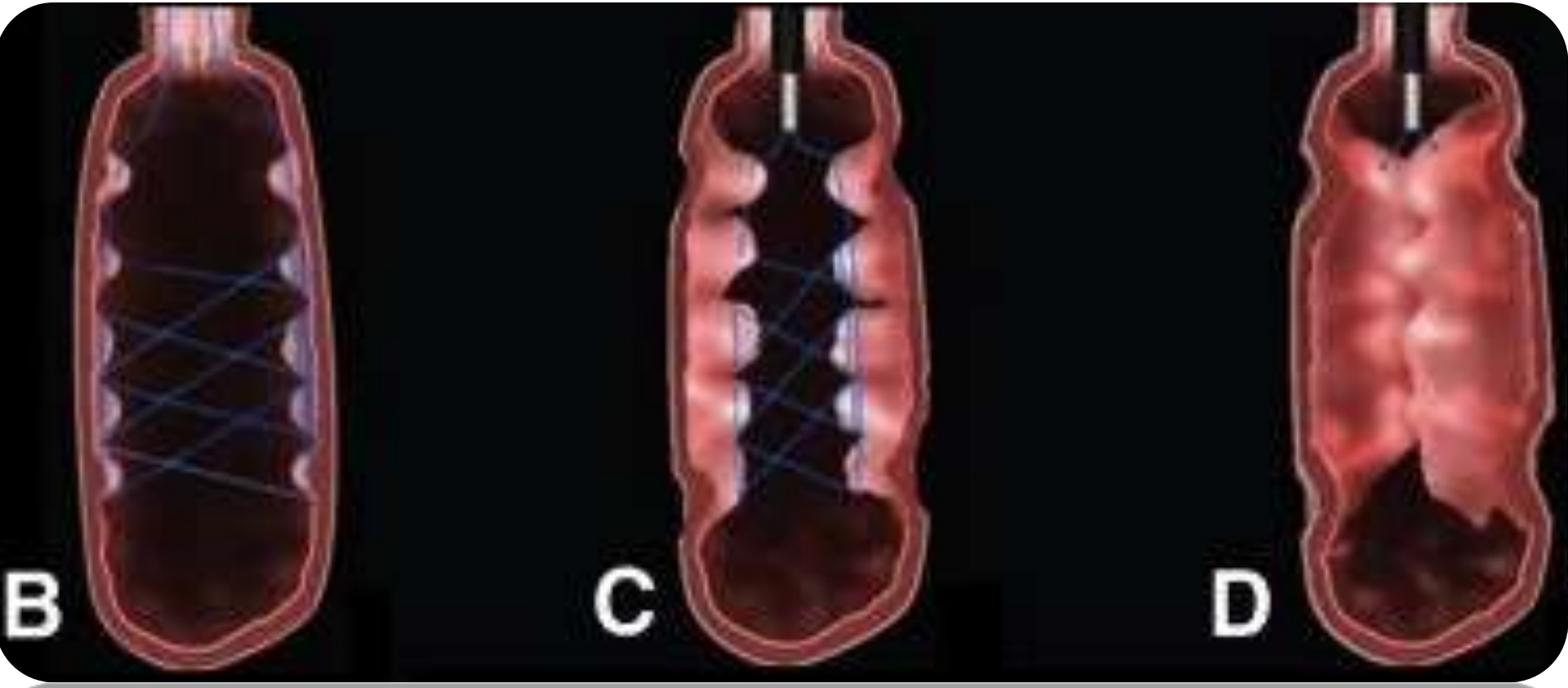
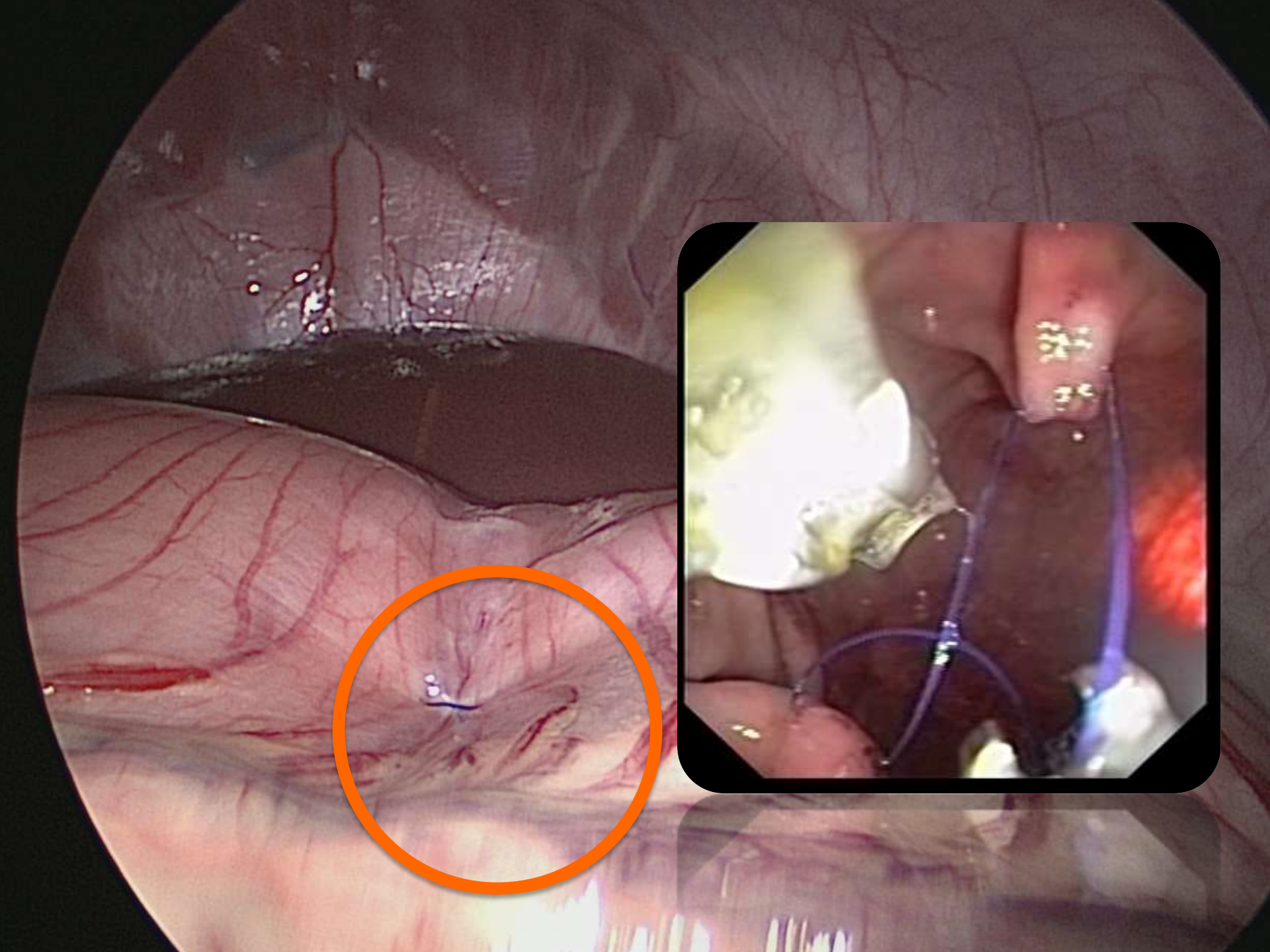
Endoscopic treatment of obesity

New technologies

RESTRICTIVE PROCEDURES CONCEPTS




B
C
D



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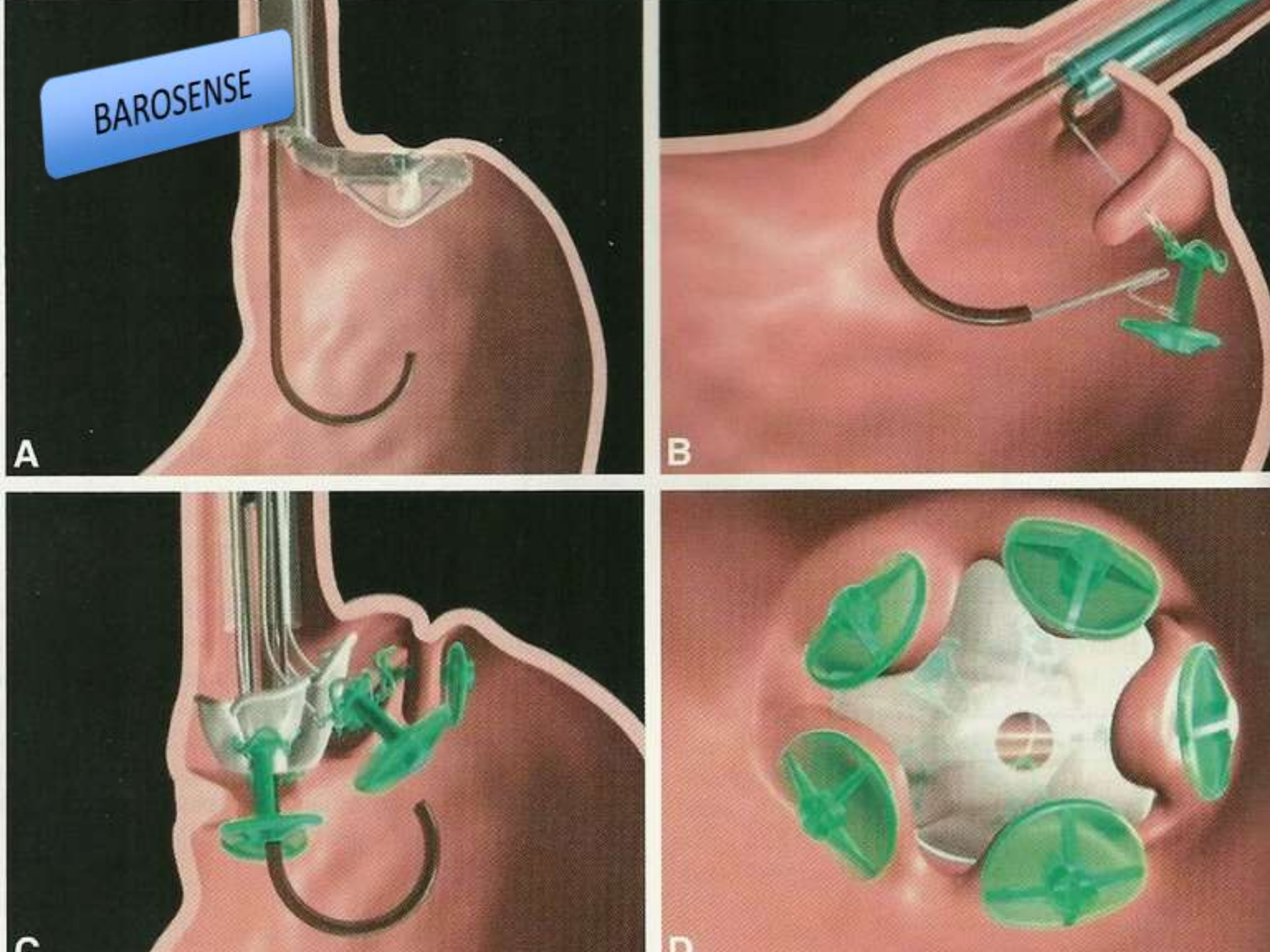
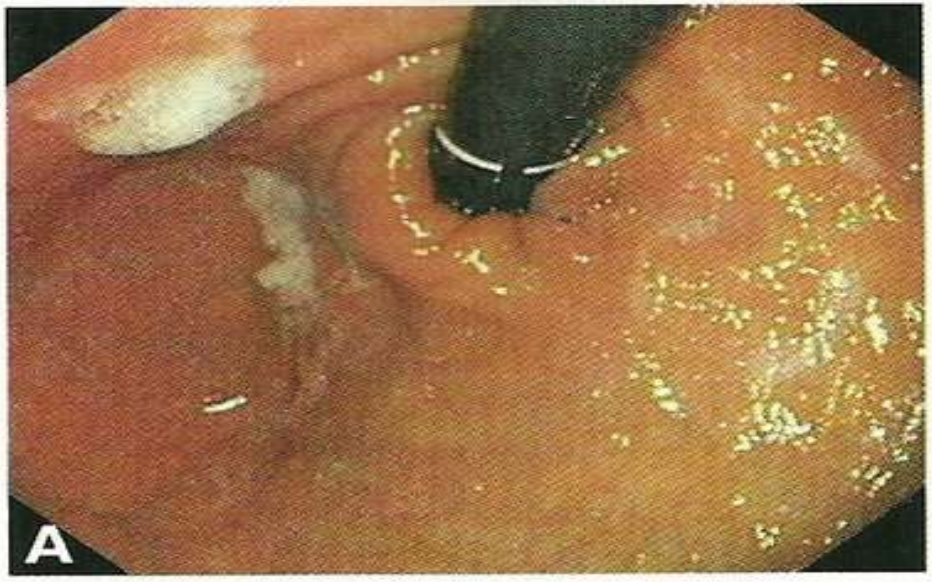
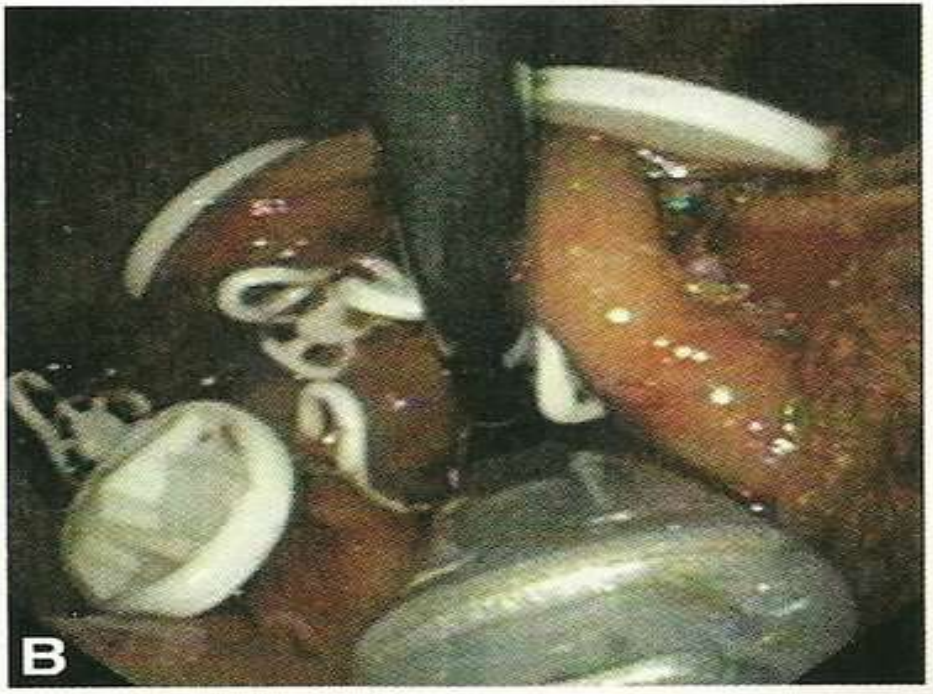
Endoscopic treatment of obesity

New technologies

ENDOSCOPIC
"BAND LIKE" GASTROPLASTY


BAROSENSE
A
B
C
D





13 PT

- 40-50BMI

28%EWL

- 3M

Comp

- 1 perf
- 2 pneumo-p

Koen de Jong,MD, et al.
Gastroint Endosc. 72,3 2010. 497-502

Multi-Center Feasibility Study of Trans-oral Endoscopic Restrictive Implant System (TERIS) for Treatment of Obesity

This study has been completed.

First Received on June 27, 2008. Last Updated on February 7, 2012 History of Changes

Sponsor:	BaroSense Inc.
Information provided by (Responsible Party):	BaroSense Inc.
ClinicalTrials.gov Identifier:	NCT00707720

Purpose

The Barosense Trans-oral Endoscopic Restrictive Implant System (TERIS) is an investigational system being evaluated for safety The system uses endoscopic guidance to trans-orally implant a restrictive reservoir for food entering the stomach in obese and morbidly obese subjects to induce early and prolonged satiety. The Intended Use of the system is for the treatment of obesity.

Condition	Intervention	Phase
Obesity	Device: TERIS procedure	Phase I

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

- **Prospective, observational study**
  - **Tertiary-care referral hospital in The Netherlands**
- **Results at 3m**
  - **%EWL 28%.**
  - **BMI comes from 42.1 to 37.9 kg/m2.**
- **Complications**
  - **1 perforation / 2 pneumo-peritoneum**

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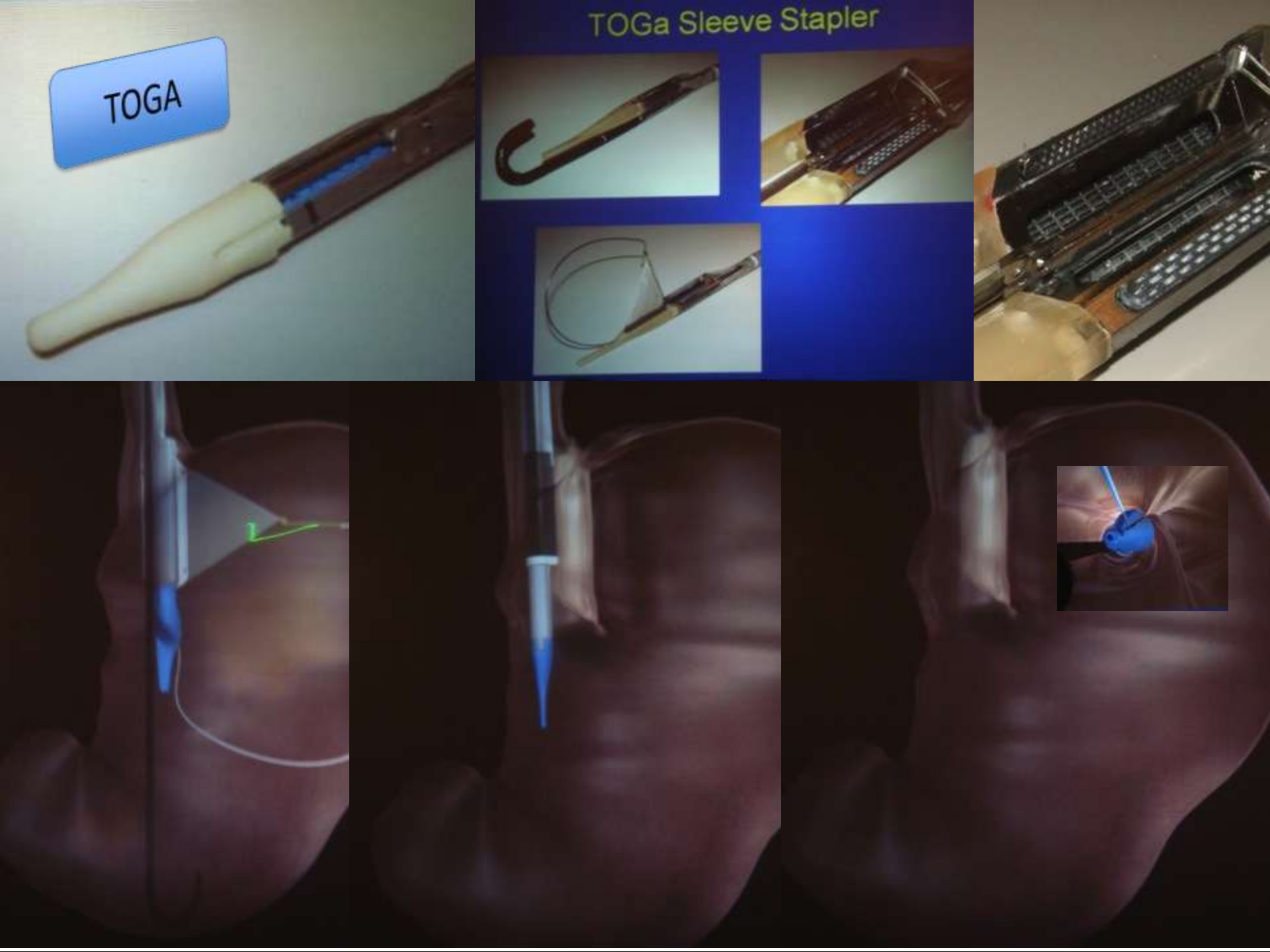
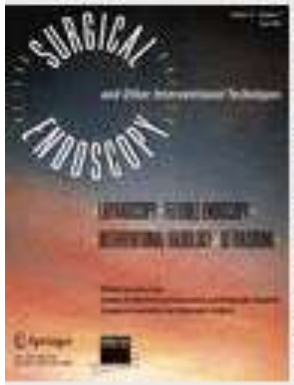
Endoscopic treatment of obesity

New technologies

ENDOSCOPIC
"MASON LIKE" GASTROPLASTY


TOGA
TOGa Sleeve Stapler



Safety, feasibility and weight loss after transoral gastroplasty: First human multicenter study

Journal	Surgical Endoscopy
Publisher	Springer New York
ISSN	0930-2794 (Print) 1432-2218 (Online)
Issue	Volume 22, Number 3 / March, 2008
DOI	10.1007/s00464-007-9662-5
Pages	589-598
Subject Collection	Medicine
SpringerLink Date	Thursday, November 01, 2007

PDF (476.8 KB) HTML

J. Devière[1], G. Ojeda Valdes[2], L. Cuevas Herrera[2], J. Closset[1], O. Le Moine[1], P. Eisendrath[1], C. Moreno[1], S. Dugardeyn[1], M. Barea[1], R. la de Torre[3], S. Edmundowicz[4] and S. Scott[3]

Original article

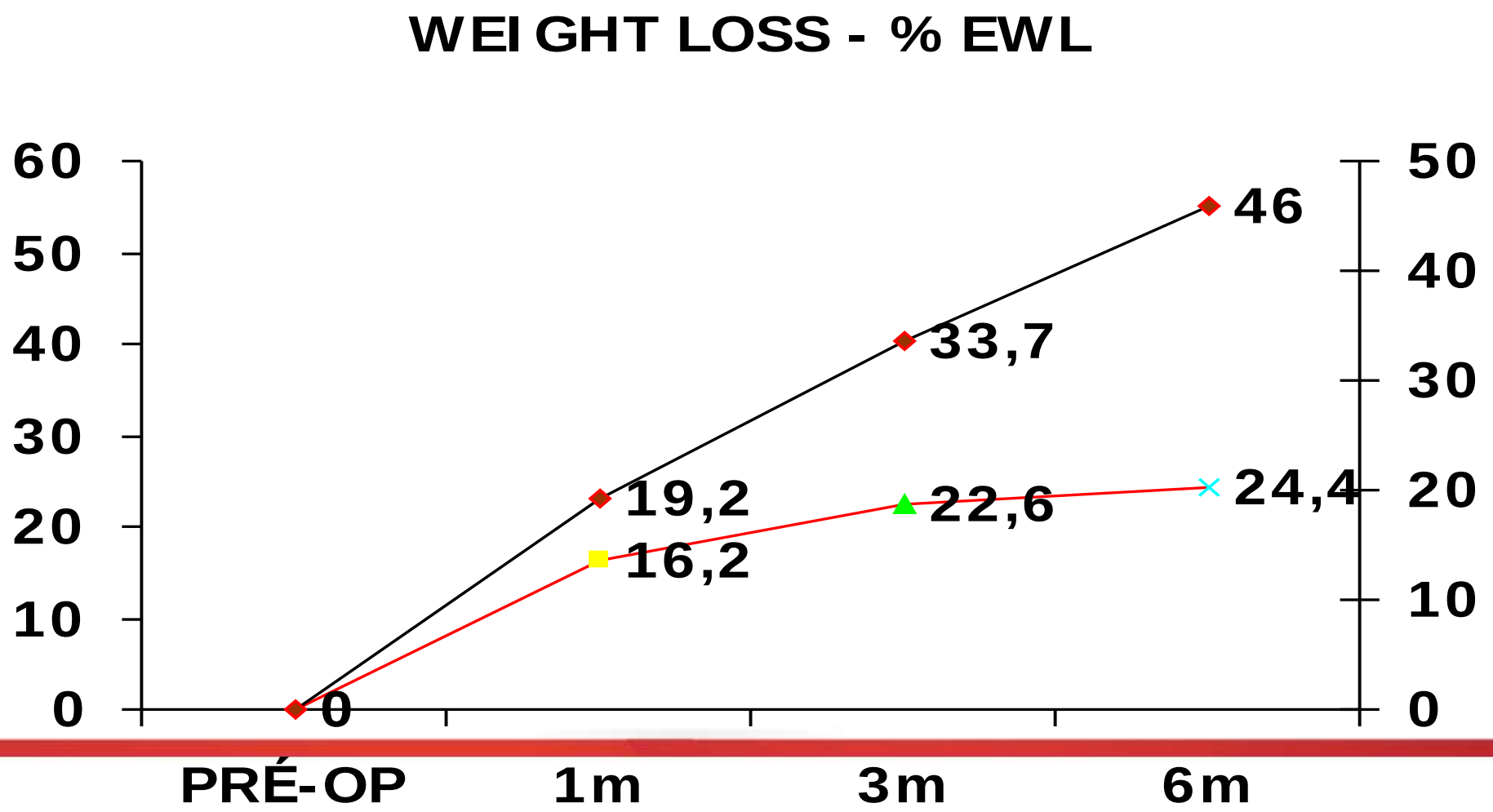
Endoscopy 2008; 40: 406-413
DOI: 10.1055/s-2007-995748

Transoral gastroplasty is safe, feasible, and induces significant weight loss in morbidly obese patients: results of the second human pilot study

C. Moreno[1], J. Closset[1], S. Dugardeyn[1], M. Baréa[1], A. Mehdi[1], L. Collignon[1], M. Zalcman[3], M. Baurain[2], O. Le Moine[1], J. Devière[1]

TOGA SLEEVE GASTROPLASTY

First X Second study



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ENDOLUMENAL
"VERTICAL GASTRECTOMY LIKE"
GASTROPLASTY

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Endoluminal Vertical gastropasty

BARD®

Fogel R. et al. Clinical experience of transoral suturing for an endoluminal vertical gastroplasty: 1-year follow-up in 64 patients: Gastrointest Endosc 68(1);51-8, 2008

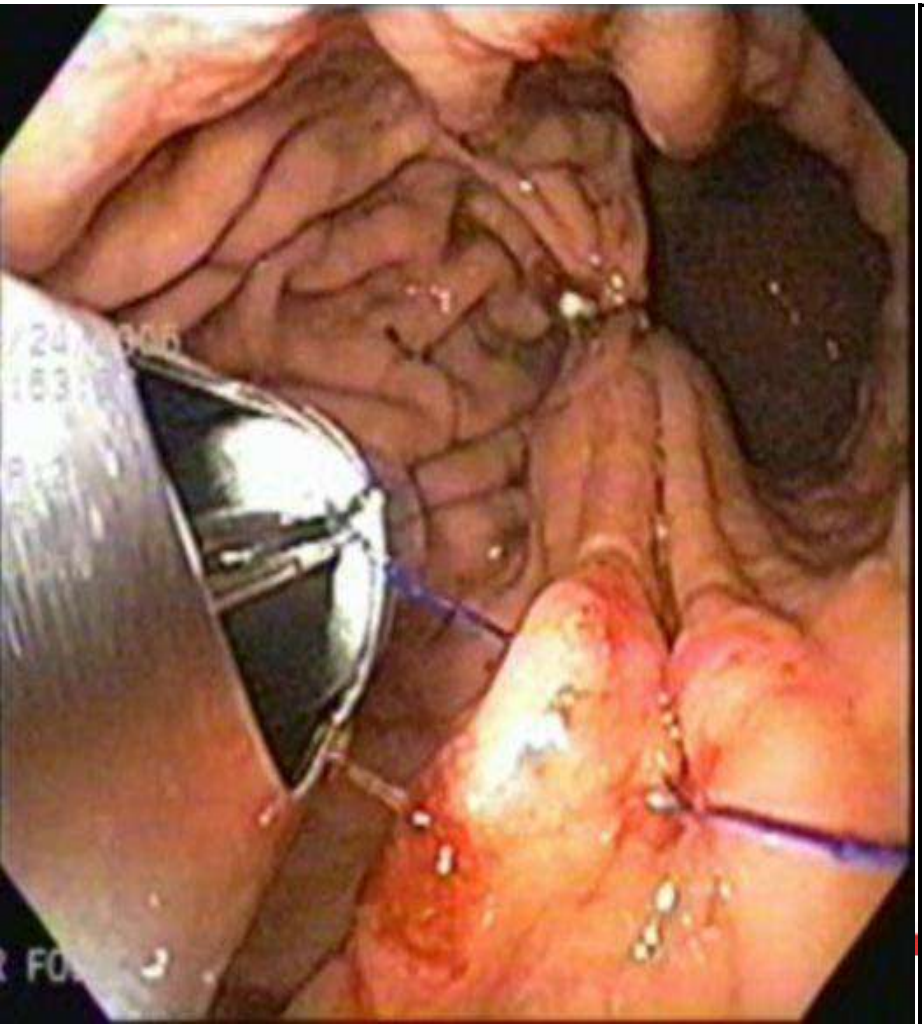
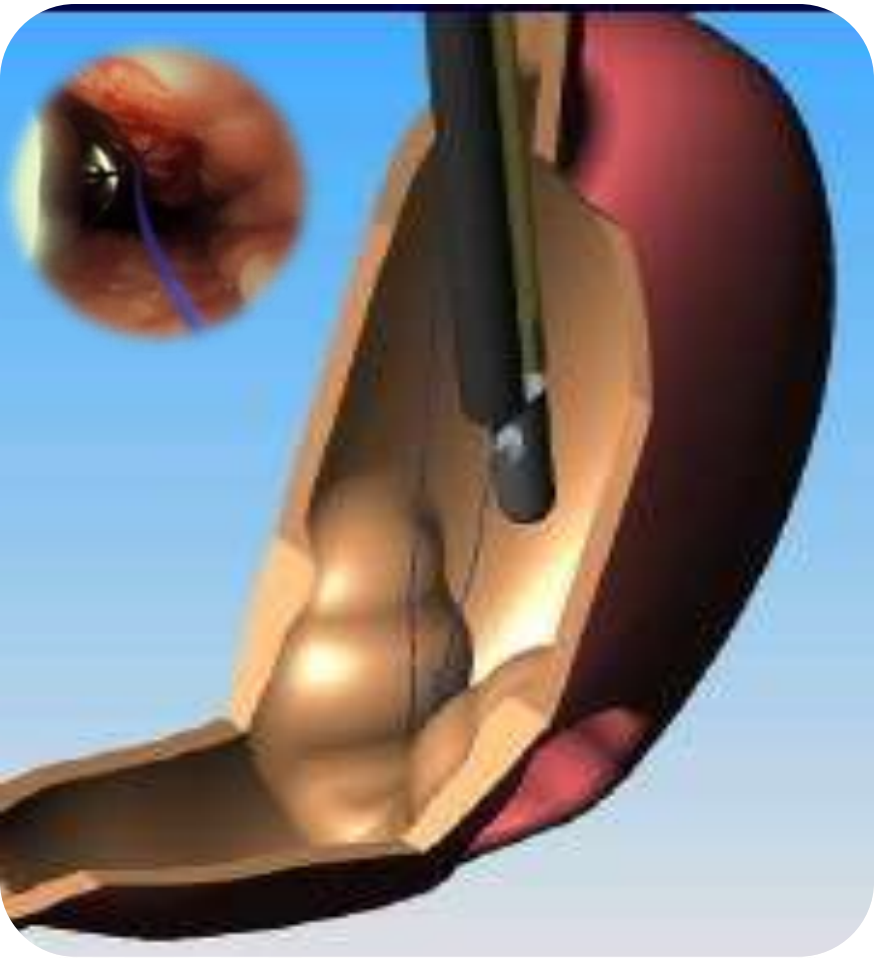


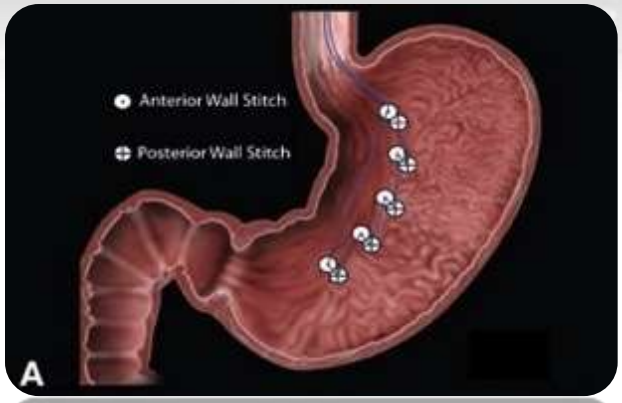
Table 1. Baseline Patient Characteristics

	Baseline Value
Total Population	n = 103
Gender, n (%)	
Men	42 (40.8)
Women	61 (59.2)
Mean age, y ± SD [Range]	39.2 ± 11.5 [17 - 69]
BMI kg/m² ± SD [Range]	38.5 ± 6.6 [27.0 - 60.0]
Sub-Population: < 35 BMI	n = 31
Gender, n (%)	
Men	6 (19.4)
Women	25 (80.6)
Mean age, y ± SD [Range]	40.2 ± 13.0 [18 - 69]
BMI kg/m² ± SD [Range]	31.3 ± 2.2 [27.0 - 34.0]
Sub-Population: 35-40 BMI	n = 27
Gender, n (%)	
Men	7 (25.9)
Women	20 (74.1)
Mean age, y ± SD [Range]	36.4 ± 12.0 [17 - 59]
BMI kg/m² ± SD [Range]	37.0 ± 1.3 [35.0 - 39.0]
Sub-Population: > 40 BMI	n = 45
Gender, n (%)	
Men	29 (64.4)
Women	16 (35.6)
Mean age, y ± SD [Range]	40.2 ± 10.0 [21 - 61]
BMI kg/m² ± SD [Range]	44.4 ± 4.9 [40.0 - 60.0]

Endoluminal Vertical gastropasty

BARD®





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New technologies

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GASTROPLASTY

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Endoscopic Endolumenal Greater Curvature Plication – EGCP

A case series

Endoscopic Endolumenal Greater Curvature Plication (EGCP) – a case series

- Authors
  - *Manoel Galvão Neto, MD* — *Gastro Obeso Center, Sao Paulo, Brazil*
  - *Natan Zundel, MD* — *Florida International University, Miami, USA*
  - *Josemberg Campos, MD* — *Federal University of Pernambuco, Recife, Brazil*
  - *Alonso Alvarado, MD* — *San Fernando Clinic Hospital, Panama, Panama*
  - *Lyz Bezerra Silva, MD* — *Federal University of Pernambuco, Recife, Brazil*
  - *Jorge Orillac, MD* — *San Fernando Clinic Hospital, Panama, Panama*
  - *Sohail Shaikh, MD* — University of Maryland St. Joseph Medical Center, USA
  - *Eddie Gomez, MD* — Jackson Health System, Miami, USA
  - *Erik Wilson, MD* — University of Texas Medical School, Houston, USA
  - *Christopher Thompson, MD* — Brigham and Women's Hospital Harvard , Boston, USA

Endoscopic Endolumenal Greater Curvature Plication (EGCP) – a case series

- Background
  - Endoscopic endolumenal treatment of Grade I (BMI 30-35) obesity with EGCP using the Overstitch™ device (Apollo Endosurgery, Inc., Austin, Texas) to reduce stomach size through tissue approximation
- Study design
  - Cases series under IRB control
- Aim
  - Safety, technical feasibility, durability and short-term efficacy

Endoscopic Endolumenal Greater Curvature Plication (EGCP) – a case series

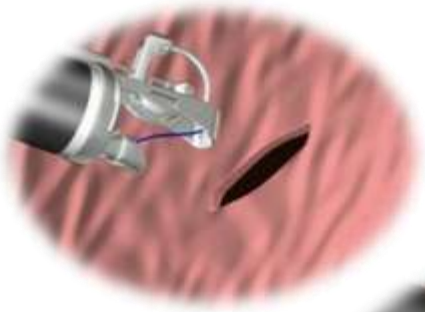
- Methods
  - 4 female subjects underwent EGCP at the Clínica Hospital San Fernando, Panamá, in june 2012.
- Casuistic
  - BMI of 30-35 Kg/m^2 (mean 32.85)
  - Age between 18 and 60 years (mean 25.6y)
  - Failure of clinical treatment for obesity
  - Main exclusion criteria were significant gastrointestinal diseases and previous digestive surgery

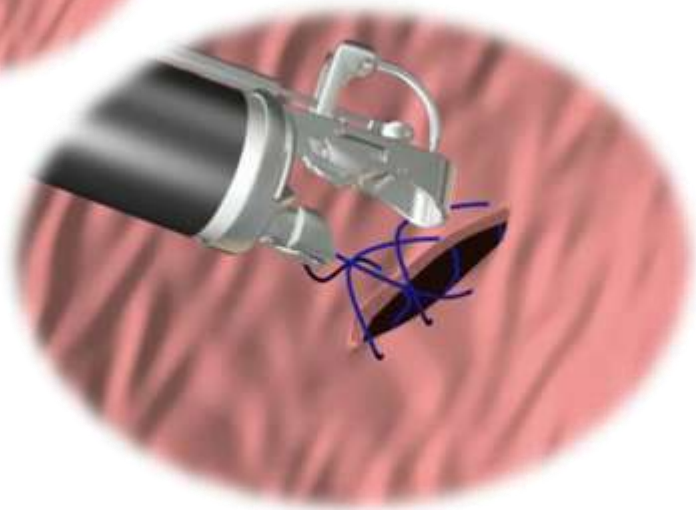
Endoscopic Endolumenal Greater Curvature Plication (EGCP) – a case series

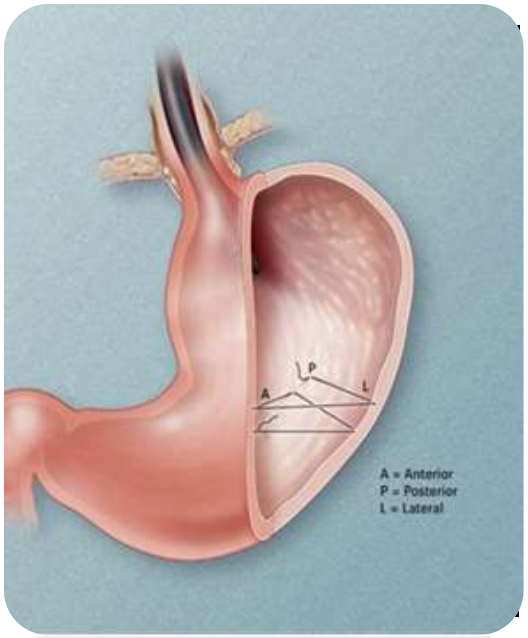
- Procedure
  - Inpatient basis, under general anesthesia.
  - The procedure is done after endoscopic evaluation of the upper digestive tract and insertion of the overtube (Guardus, US Endoscopy™).
  - Interrupted prolene 2-0 sutures are placed in a way to “infold” the greater curvature creating a tube-like path, reducing gastric volume.
  - Mean operative time was 96 min (50-190 min),
    - The longest procedure was in a patient with a J-shaped stomach, making plication more difficult.

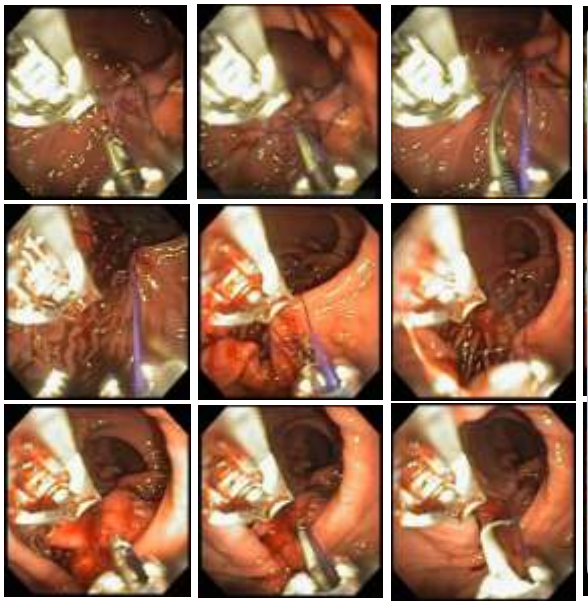
Endoscopic Endolumenal Greater Curvature Plication (EGCP) – a case series

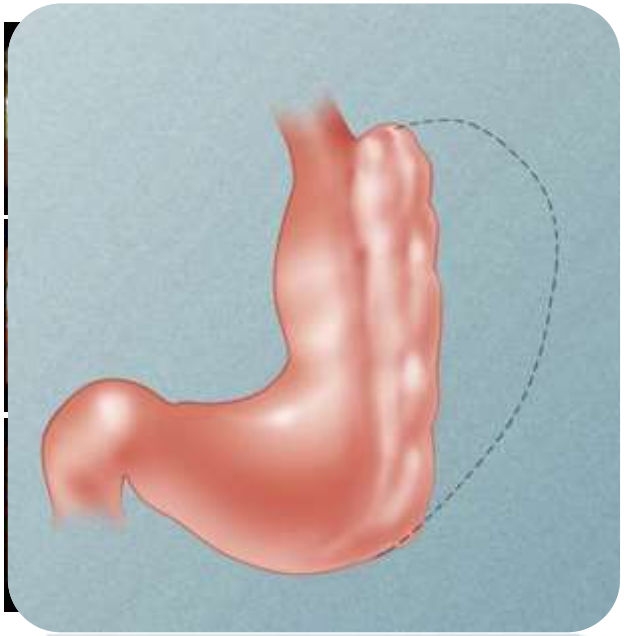
- Procedure

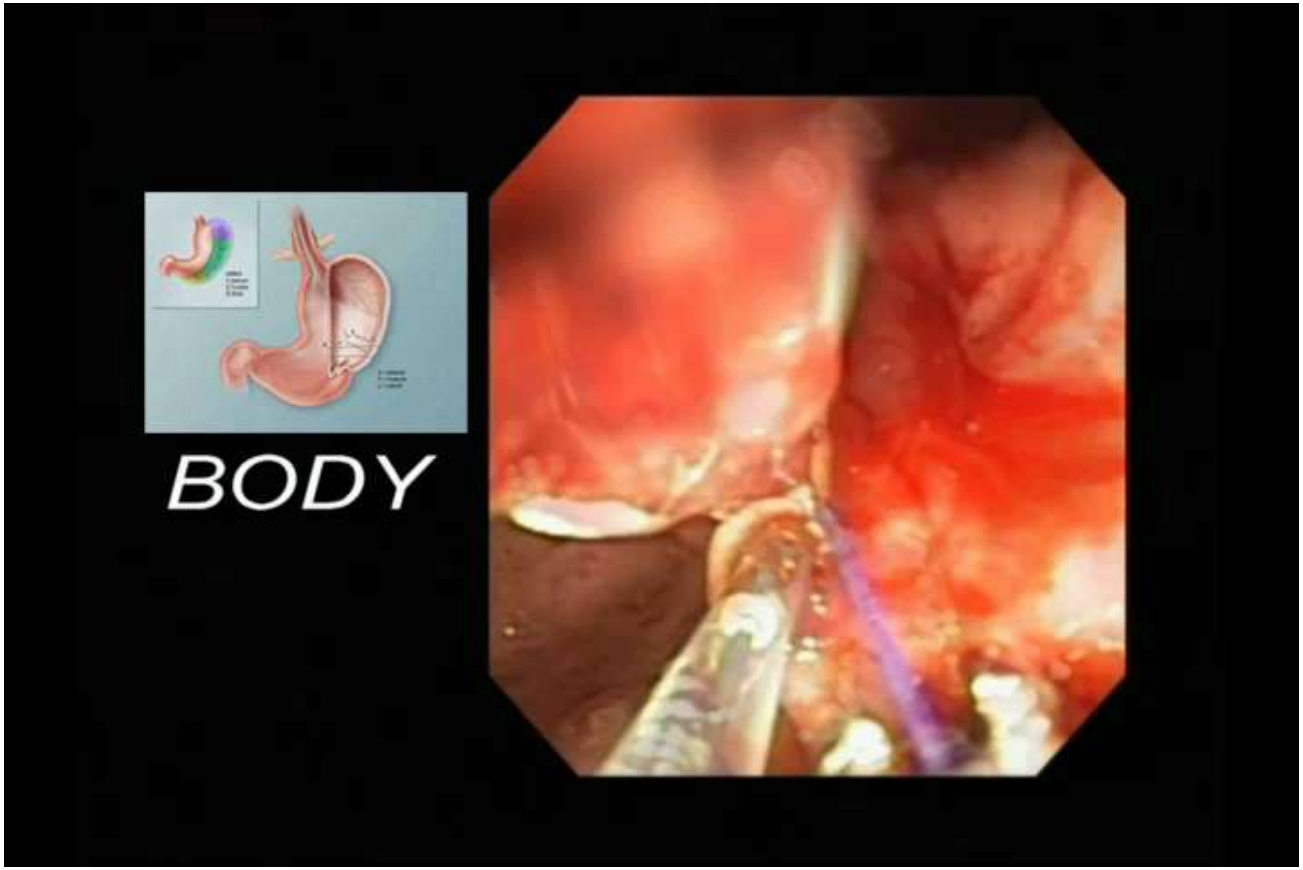





A
P
L
A = Anterior
P = Posterior
L = Lateral



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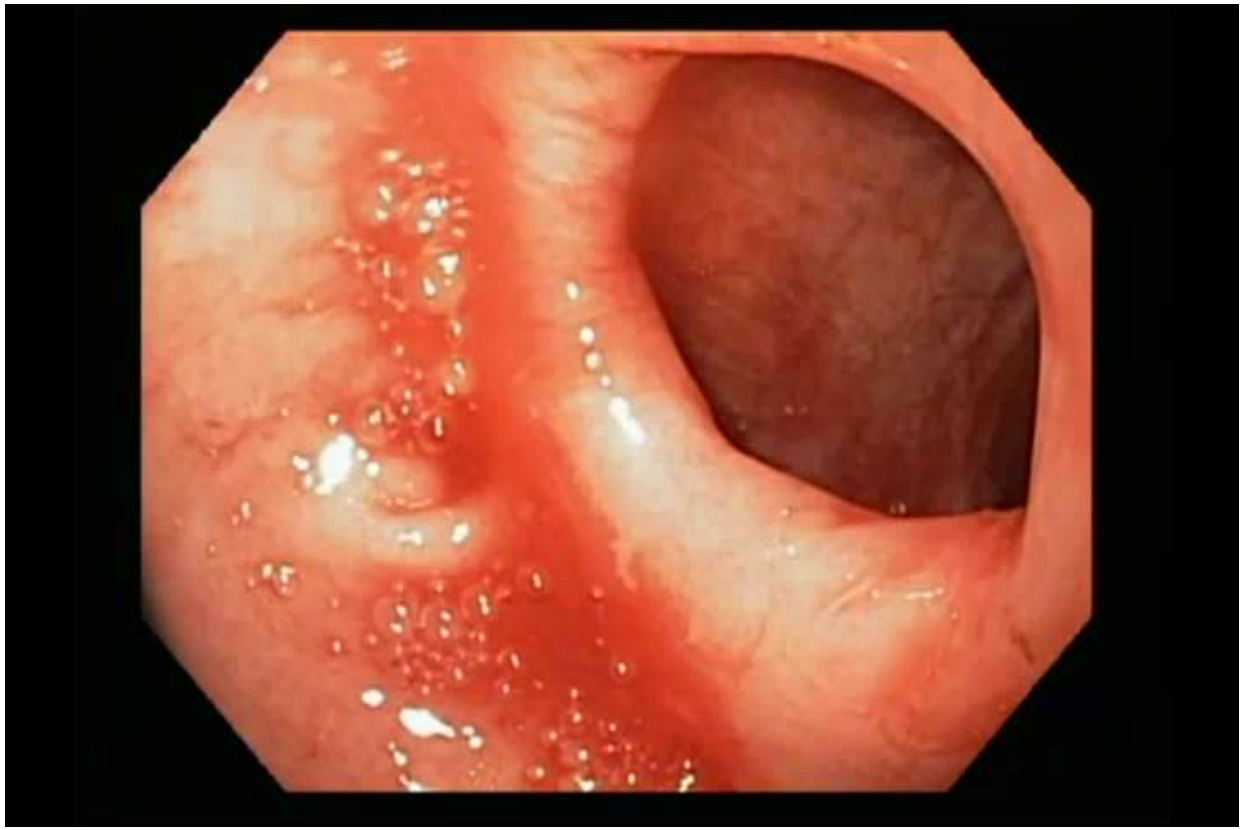

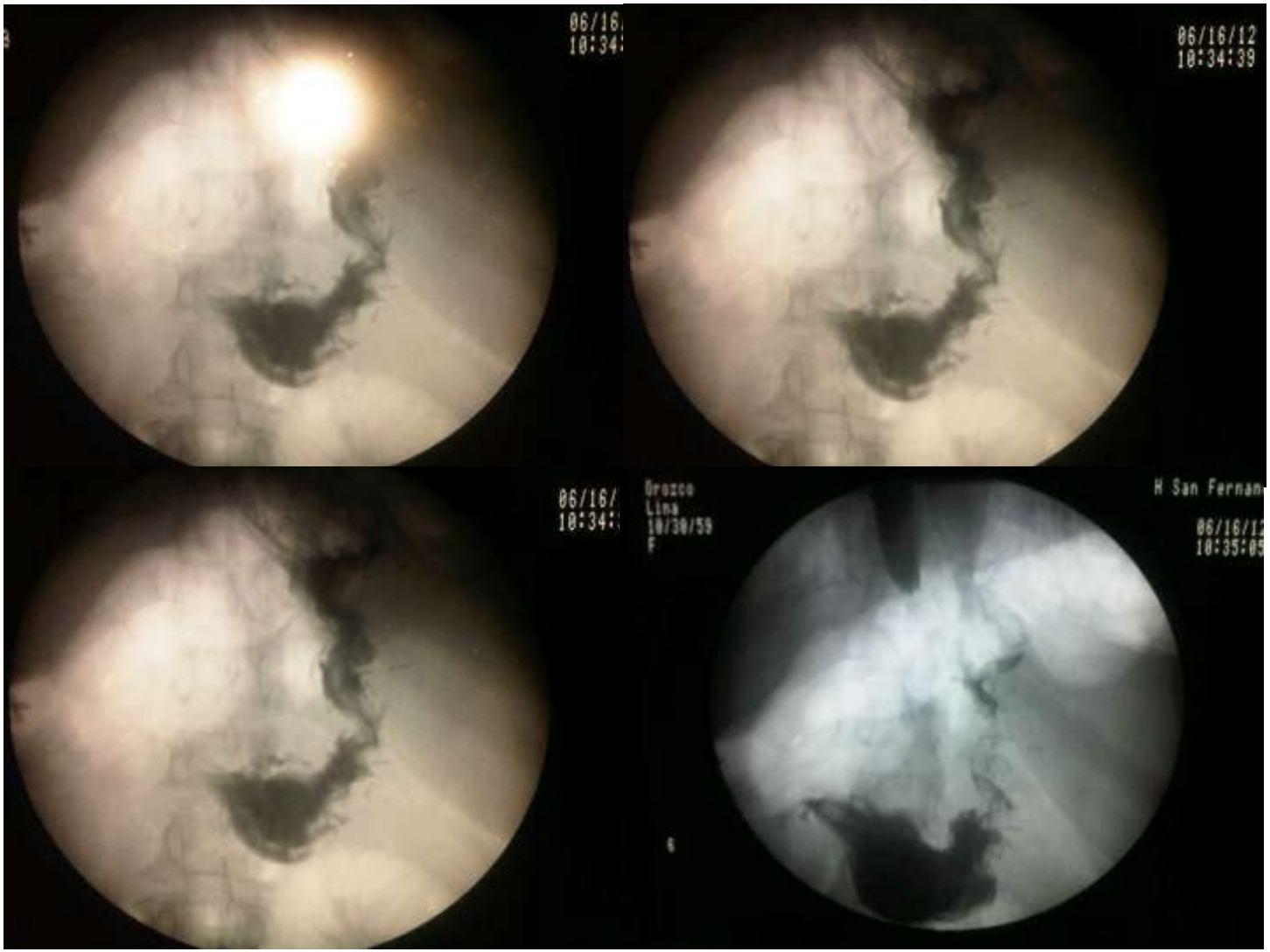
06/16/12
10:34:39
Orozco
Lima
10/30/59
F
H San Fernan

Endoscopic Endolumenal Greater Curvature Plication (EGCP) – a case series

- AE and complications
  - No intraoperative complications were recorded
  - All subjects had pneumoperitoneum and light abdominal pain, treated with NSAIDs and were discharged on the following morning
    - Patient 2 presented nausea and vomiting, staying a full day in the hospital.
  - A barium swallow was done to assess gastric anatomy

Endoscopic Endolumenal Greater Curvature Plication (EGCP) – a case series

- Results @ 6m

Patient	Initial weight (Kg)	Initial BMI (Kg/m^2)	Final weight (Kg)	Weight loss (Kg)	Final BMI (Kg/m^2)
1 -K.Z	89.1	32.0	69.5	19.6	24.7
2- V.T	89.0	32.0	75.0	14.0	26.9
3- J.S	86.9	32.4	69.1	17.8	26.0
4- L.C	95.0	35.0	85.0	10.0	32.4
Mean	90.0 Kg	32.85 Kg/m^2	74.65 Kg	15.35 Kg	27.5 Kg/m^2

Endoscopic Endolumenal Greater Curvature Plication (EGCP) – a case series

- Results @ 6m
  - In a contrasted radiography, gastric lumen seems to remain reduced,
  - All patients still refer early satiety,
    - One still refers mild nausea after ingestion of large amounts of food
  - No complications were reported

Endoscopic Endolumenal Greater Curvature Plication (EGCP) – a case series

- Conclusions @ 6m
  - EGCP as presented is feasible with a good safety profile and promising early results

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Endoscopic treatment of obesity

New technologies

Partial resriction
Or not restriction at all…


POSE

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Endoscopic treatment of obesity

New technologies

ENDOLUMENAL
"GASTRIC VOLUME REDUCTION

Courtesy of doctor Santiago Horgan, UCSD, USA

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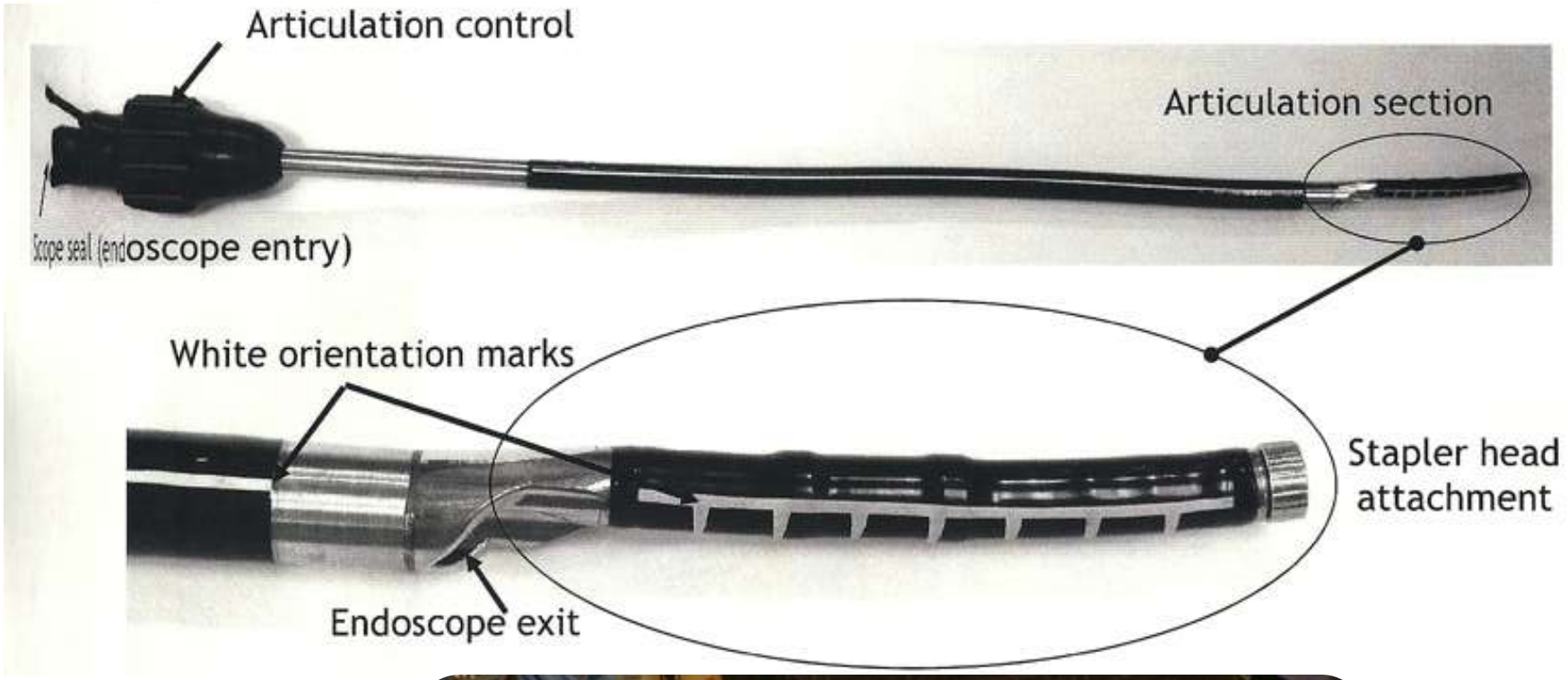
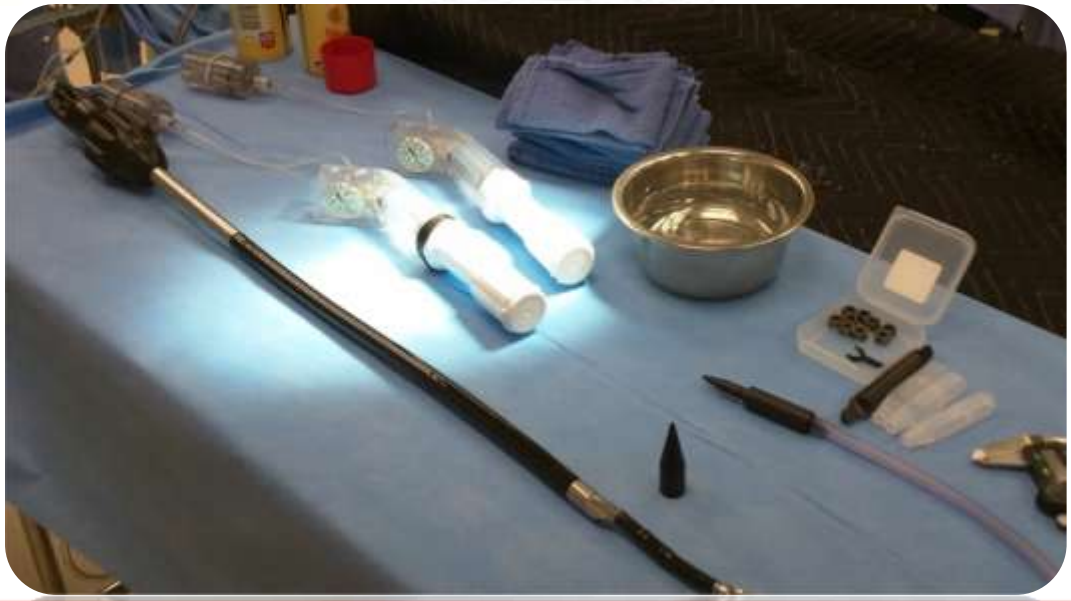
A rticulated
C ircular
E ndoscopic
Stapler

Santiago Horgan et al


Articulation control
Articulation section
Scope seal (endoscope entry)
White orientation marks
Stapler head attachment
Endoscope exit



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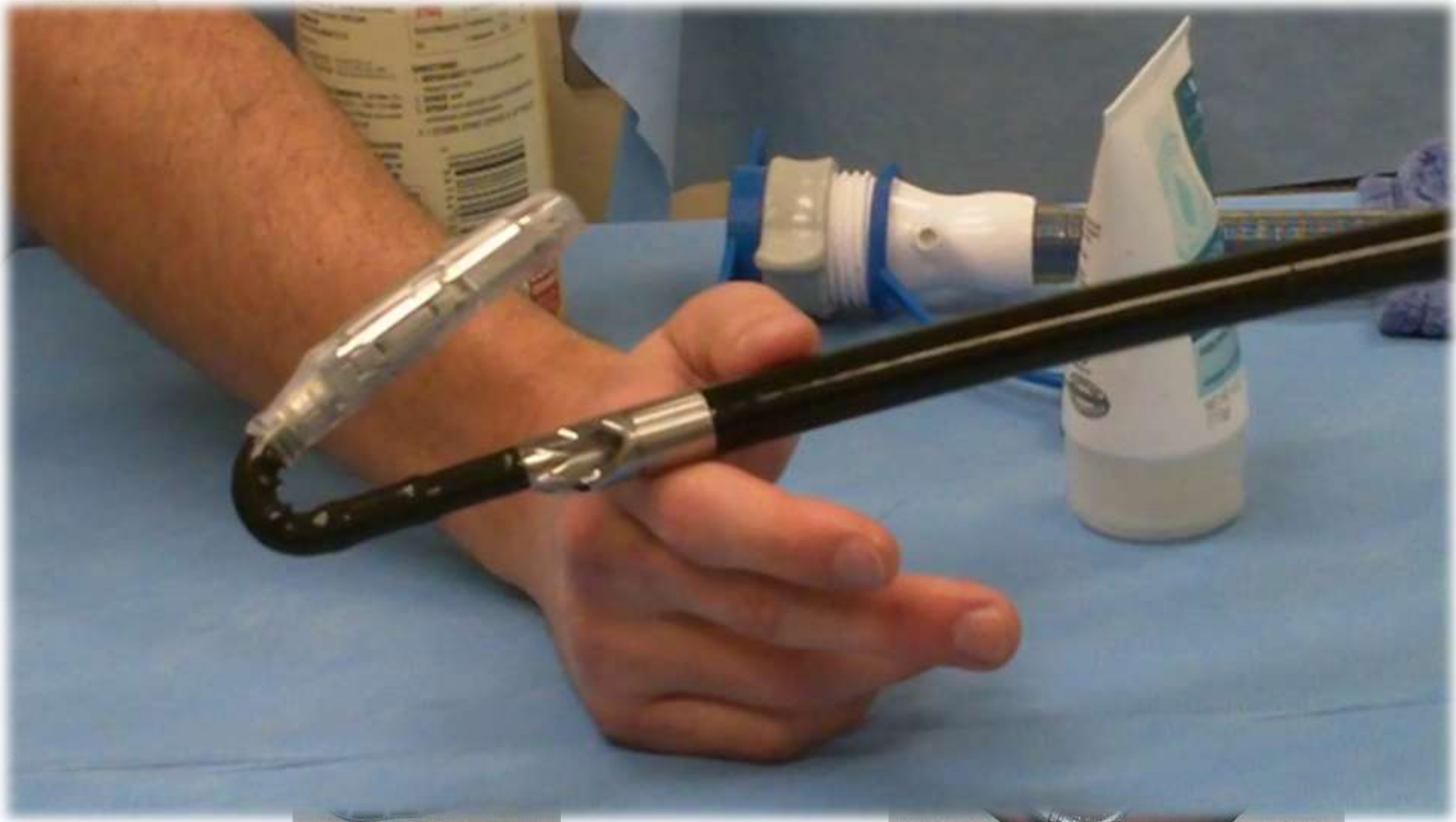
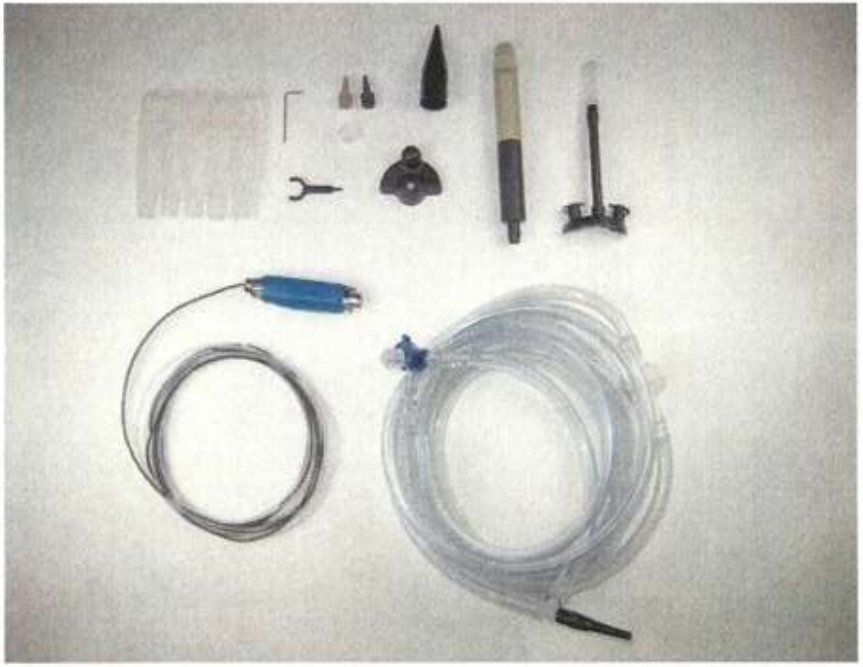
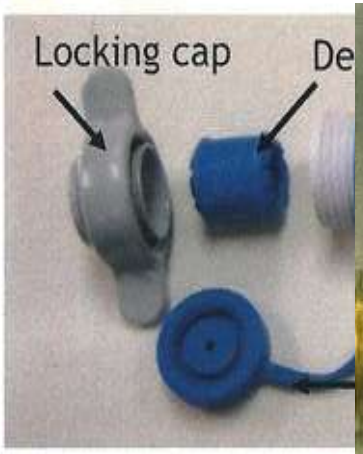
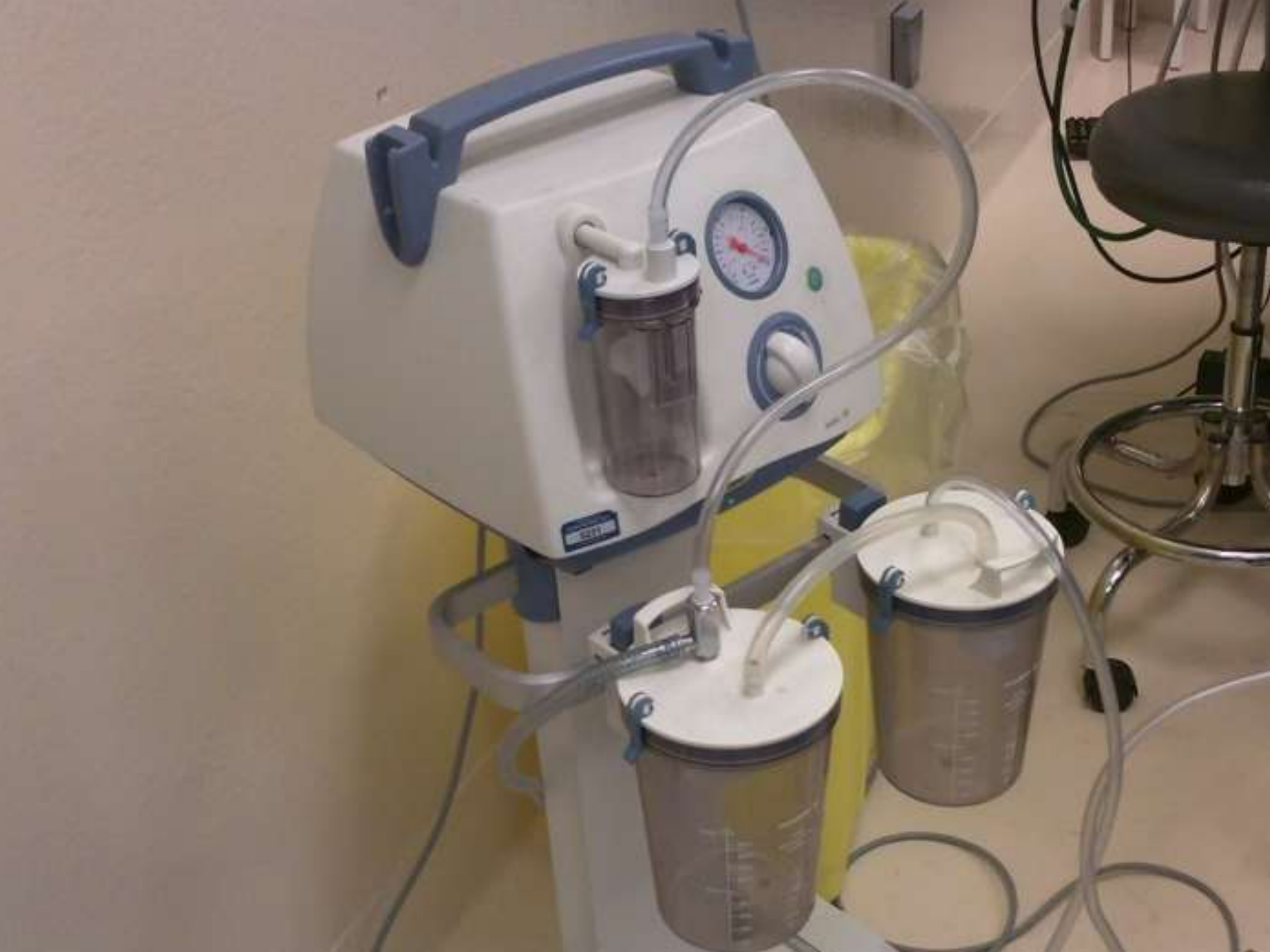


- ACE Stapler
  - Stapler handle (reusable)
  - Stapler head and accessories (single patient use)
  - draulic amplifiers and
    on syringes (single
    se)



- 60F Endogastric Tube (EGT) and Introducer Bougie





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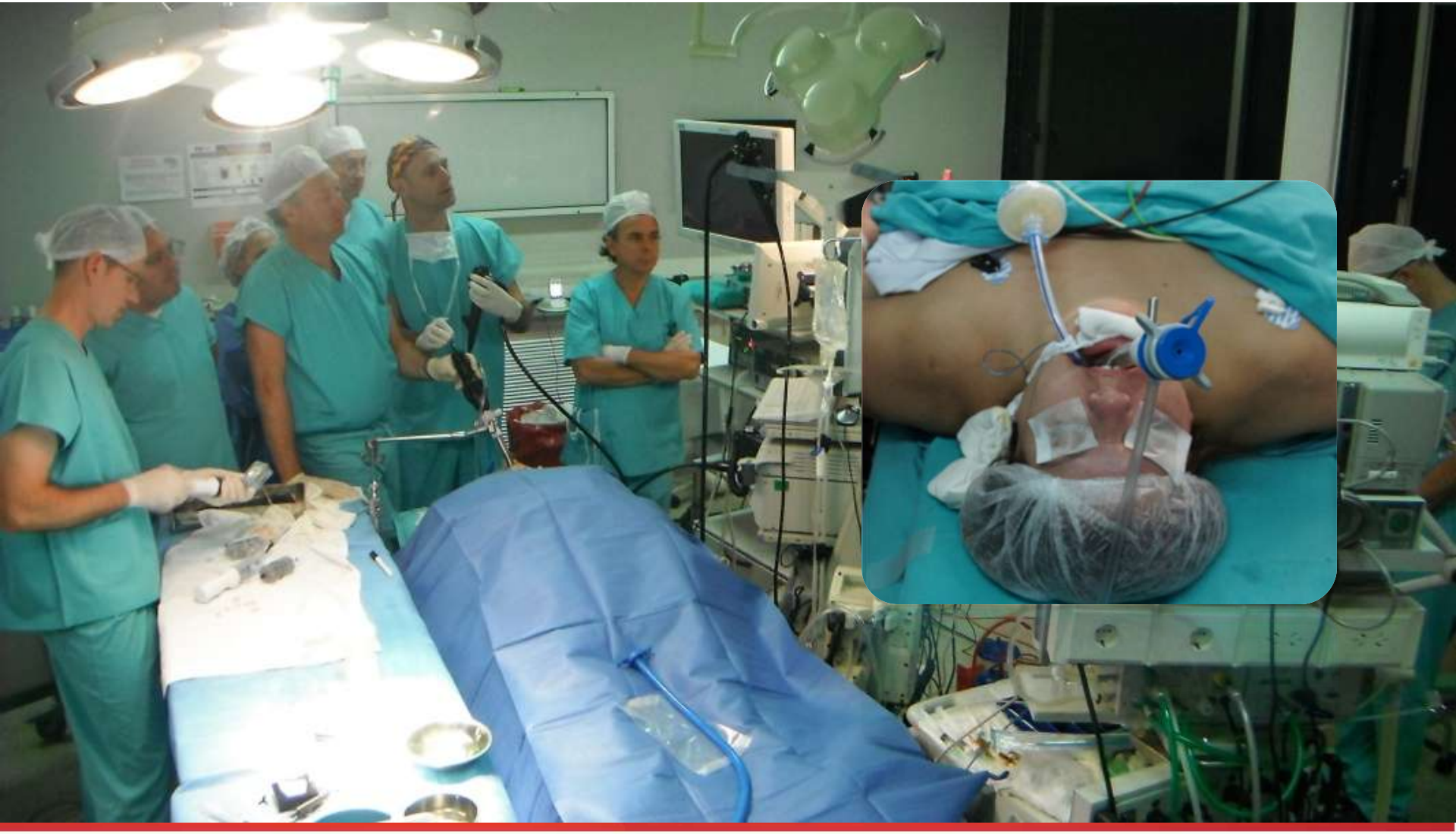

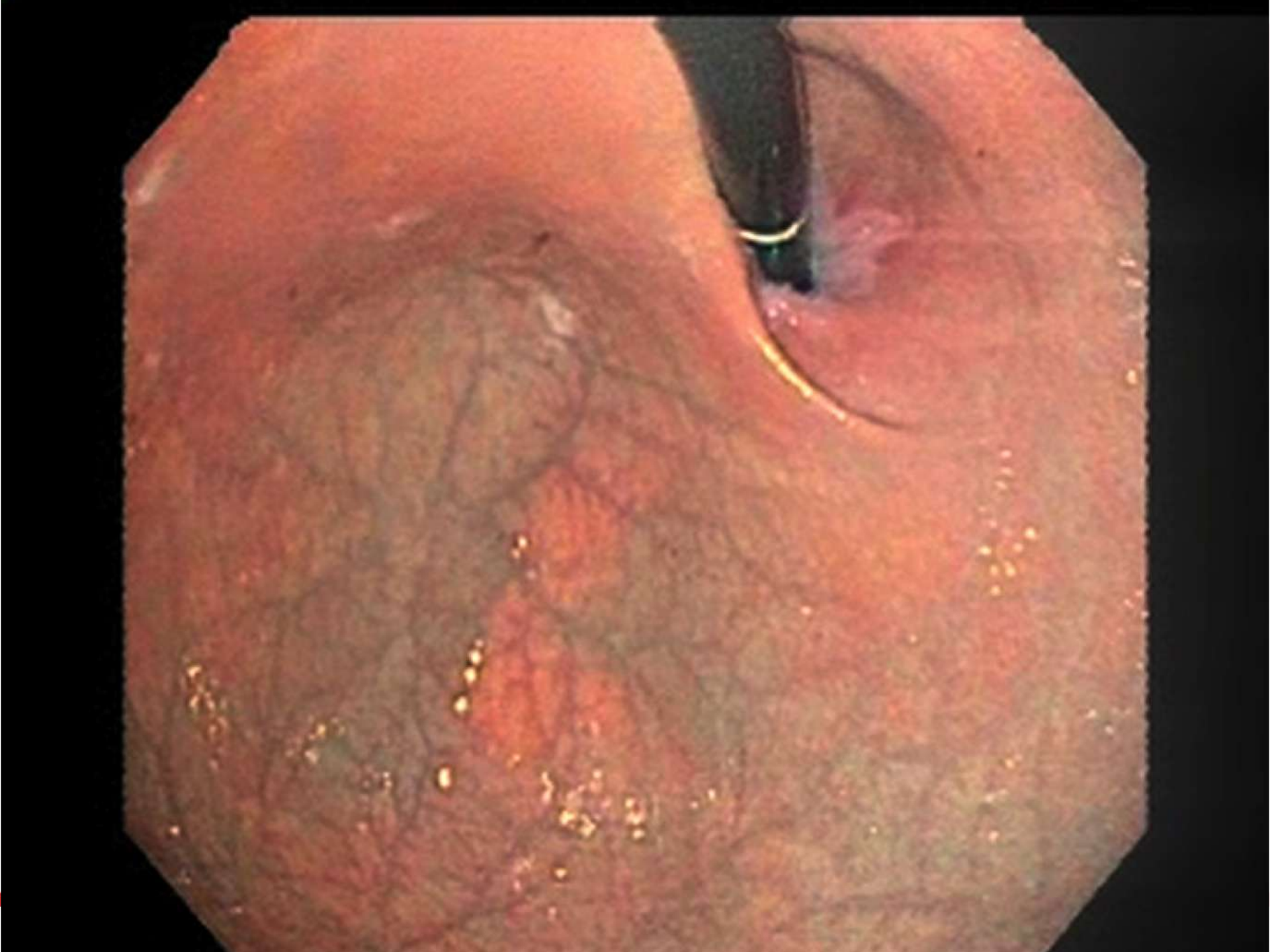

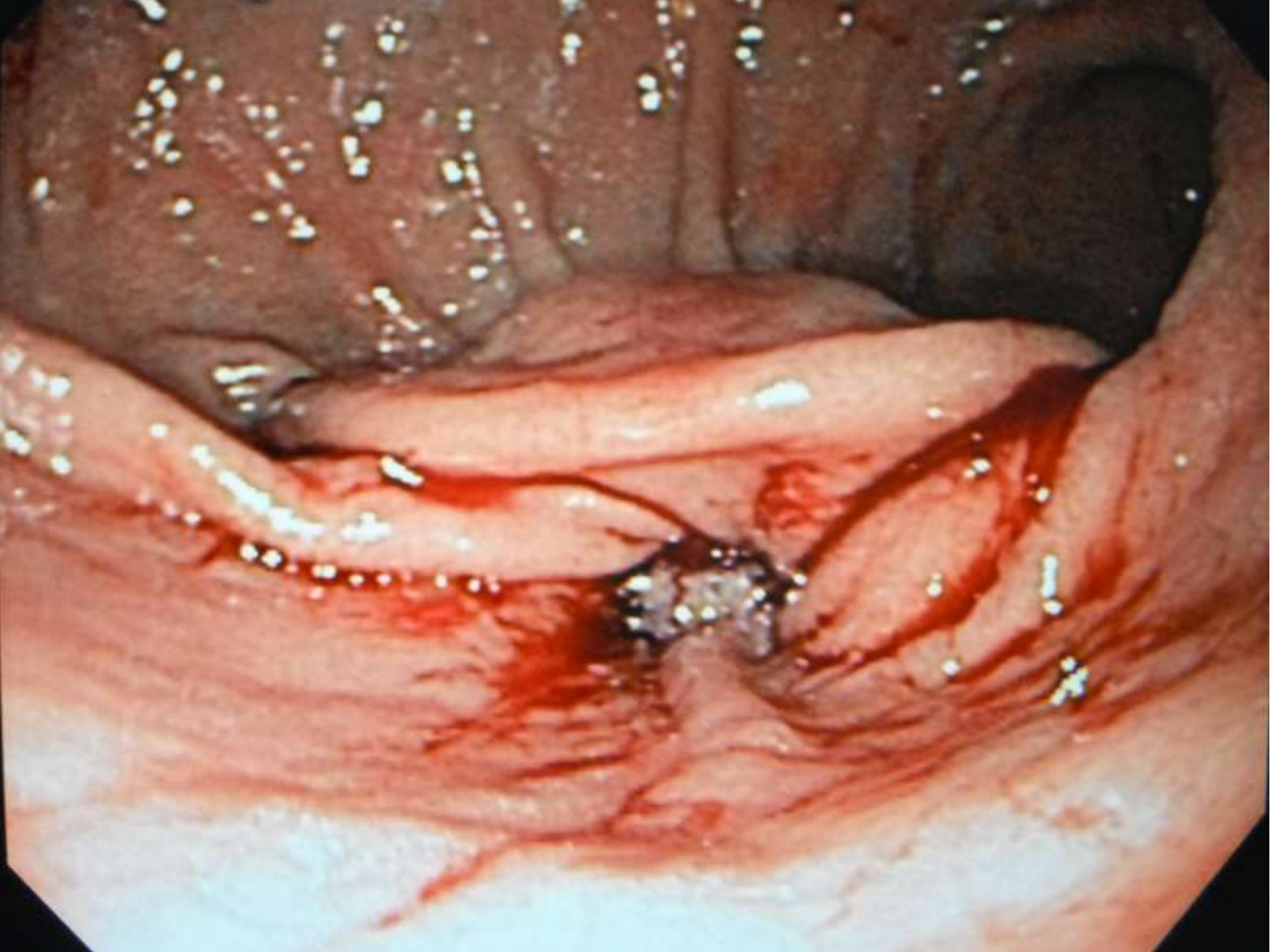

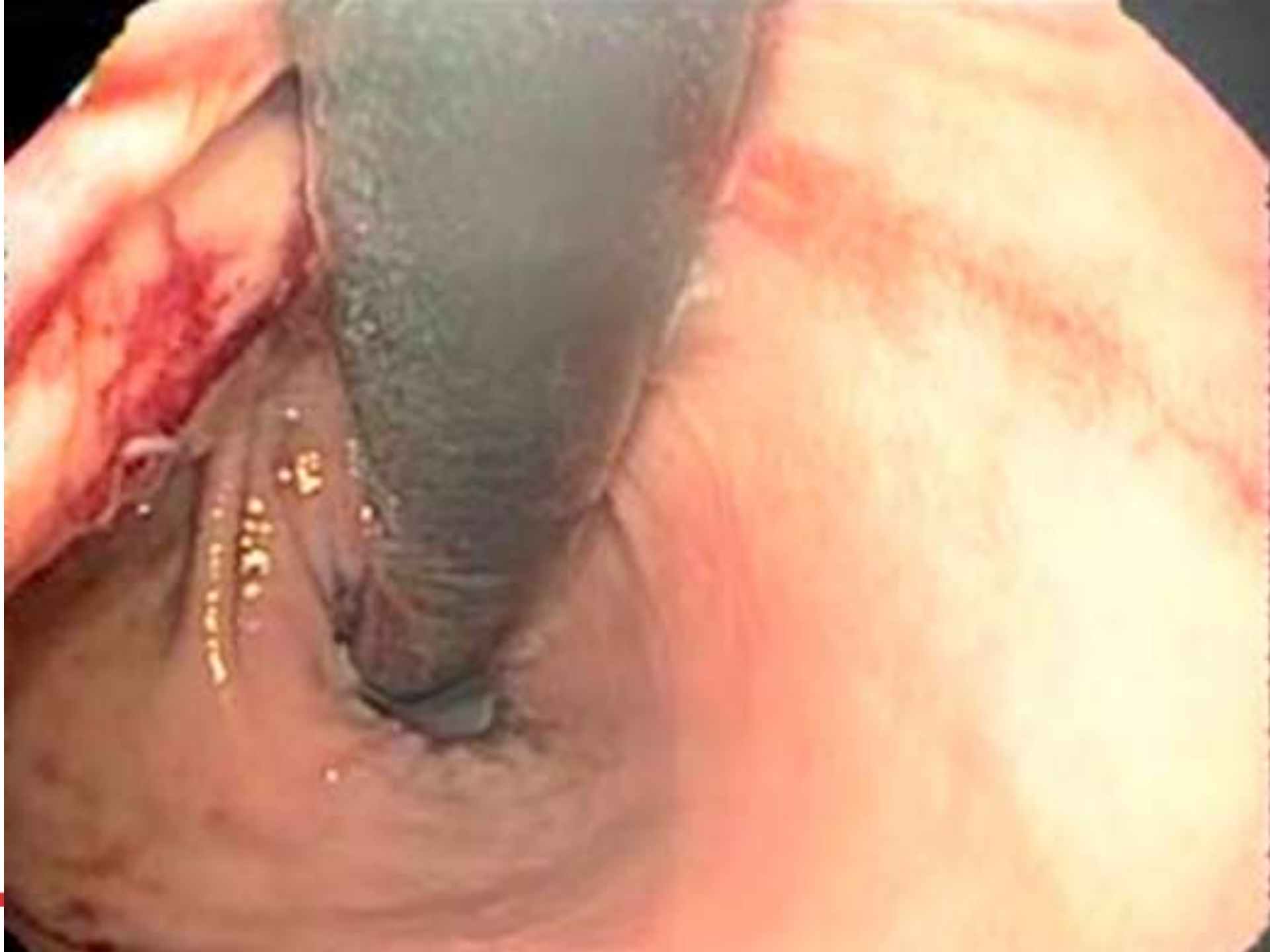

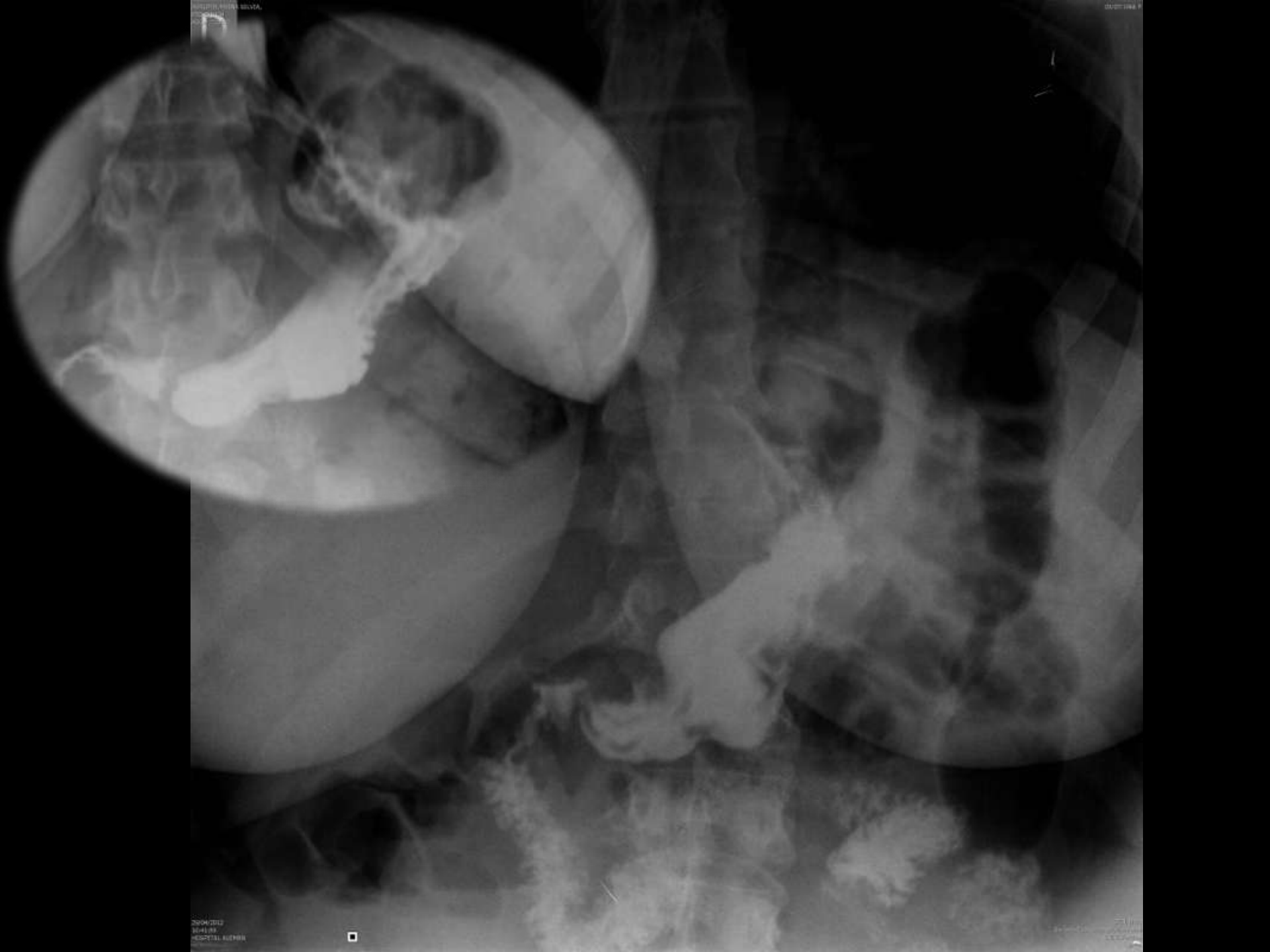

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Endoscopic treatment of obesity

New technologies

"SLEEVED" BYPASS PROCEDURES

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Endoscopic treatment of obesity

New technologies

ENDOSCOPIC ENDOLUMINAL GASTRO-DUODENAL-JEJUNAL BYPASS

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- Santiago Horgan, M.D.
- Professor of Surgery
- Director Minimally Invasive and Robotic Surgery

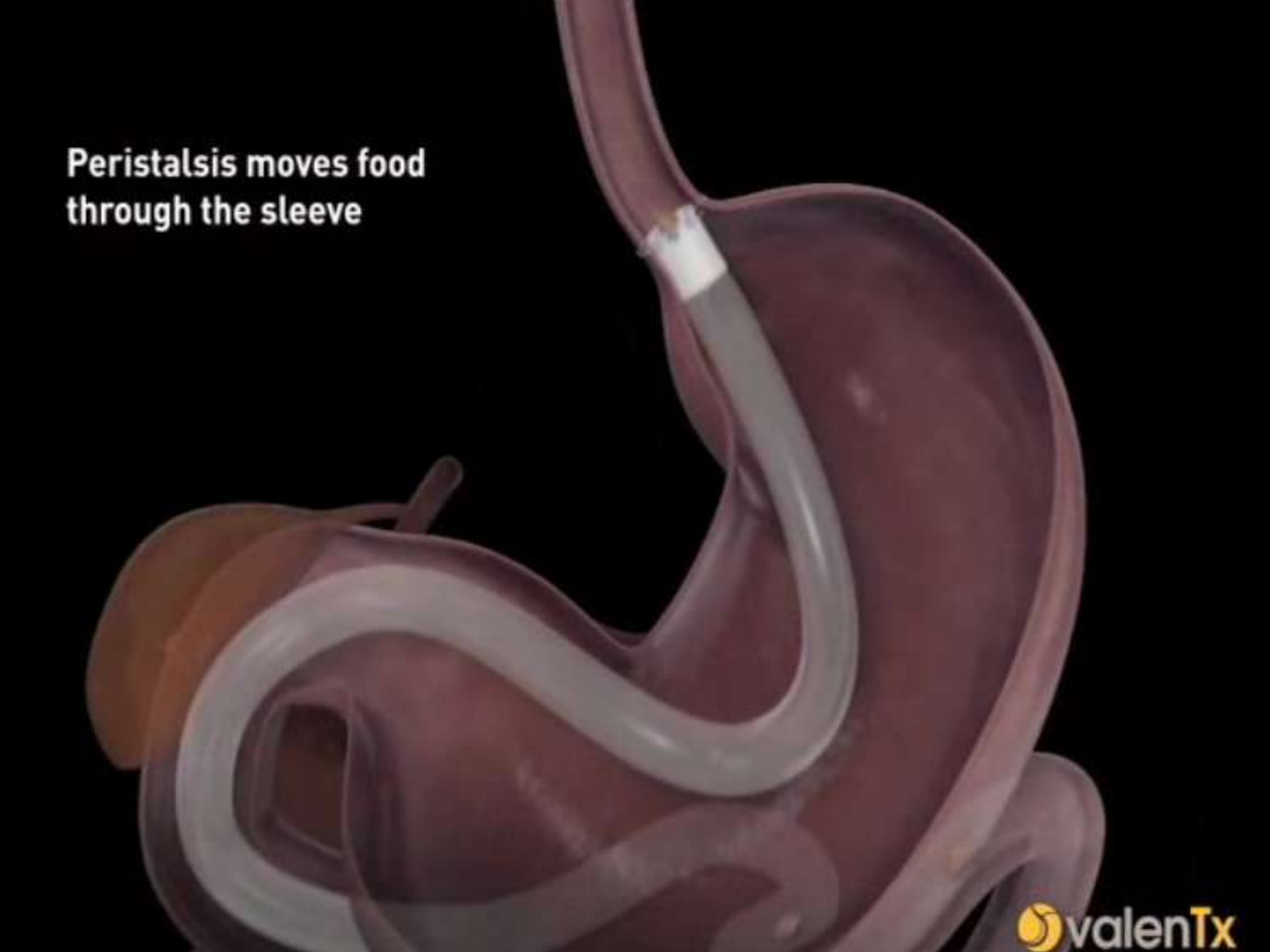
- Director Center for the Future of Surgery
- Depa

UNIVERSITY of CALIFORNIA, SAN DIEGO
SCHOOL OF MEDICINE


Oxlen Tx


Proximal sleeve is
pulled up to the GEJ
valenTx


Transmural anchors are placed
valenTx


Peristalsis moves food
through the sleeve
valenTx

ClinicalTrials.gov
A service of the U.S. National Institutes of Health

Home Search Study Topics Glossary

Search

Full Text View | Tabular View | No Study Results Posted | Related Studies

Feasibility Trial of ValenTx Endo Bypass System

This study has been completed.

First Received on September 21, 2010. No Changes Posted

Sponsor:	ValenTx, Inc.
Information provided by:	ValenTx, Inc.
ClinicalTrials.gov Identifier:	NCT01207804

Purpose

The purpose of the study is to provide initial clinical data to support the feasibility of use of the ValenTx Endo Bypass system in enhancing weight loss and co-morbidity resolution in morbidly obese patients.

Condition	Intervention
Obesity	Device: ValenTx Endo Bypass System

Study Type: Interventional
Study Design: Allocation: Non-Randomized
Endpoint Classification: Safety/Efficacy Study
Intervention Model: Single Group Assignment
Masking: Open Label
Primary Purpose: Treatment

Official Title: A Single Center Feasibility Trial of the Safety and Efficacy of the ValenTx Endo Bypass System in Obese Patients

- Collaborative study lead by
  - UCS Medical Center
  - Imperial College of London
    - Conducted at the Hospital San Jose de Monterrey, Mexico,
      - 12 patients
      - 12-week trial.
      - Patients completing the study achieved an average %EWL 39.5%.

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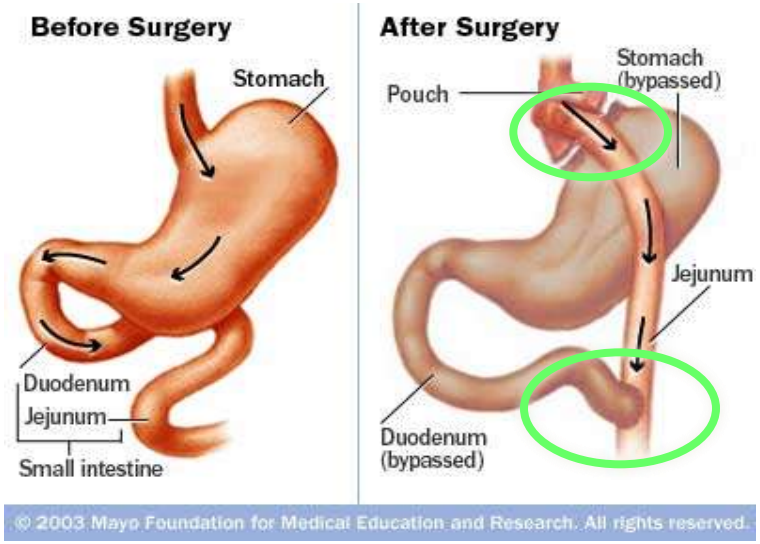

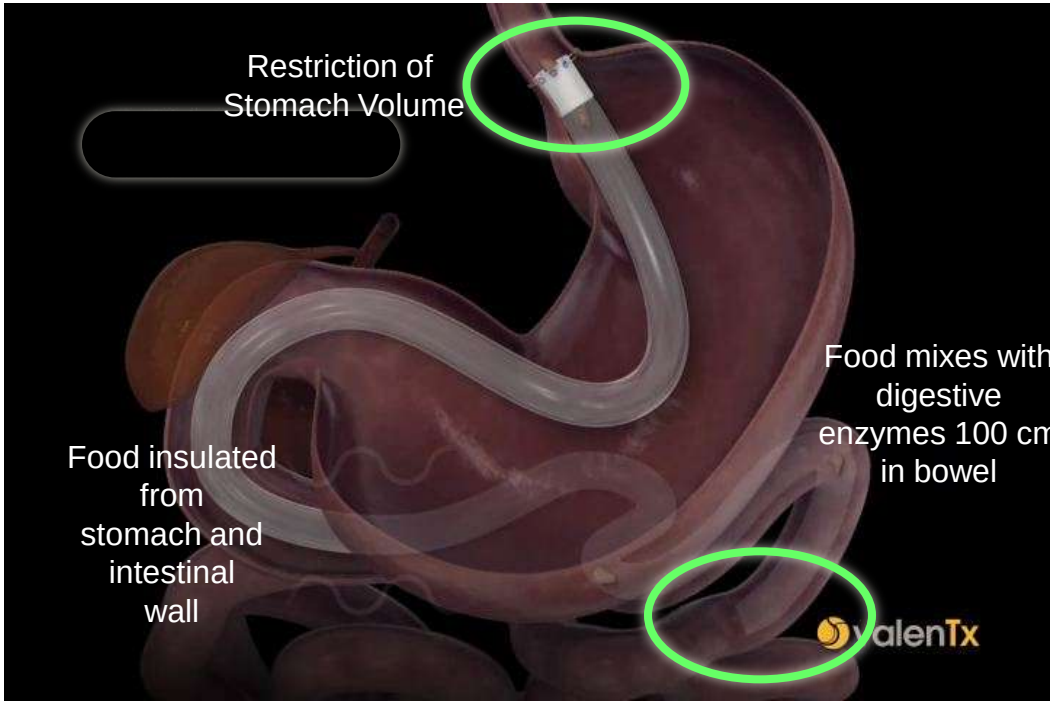

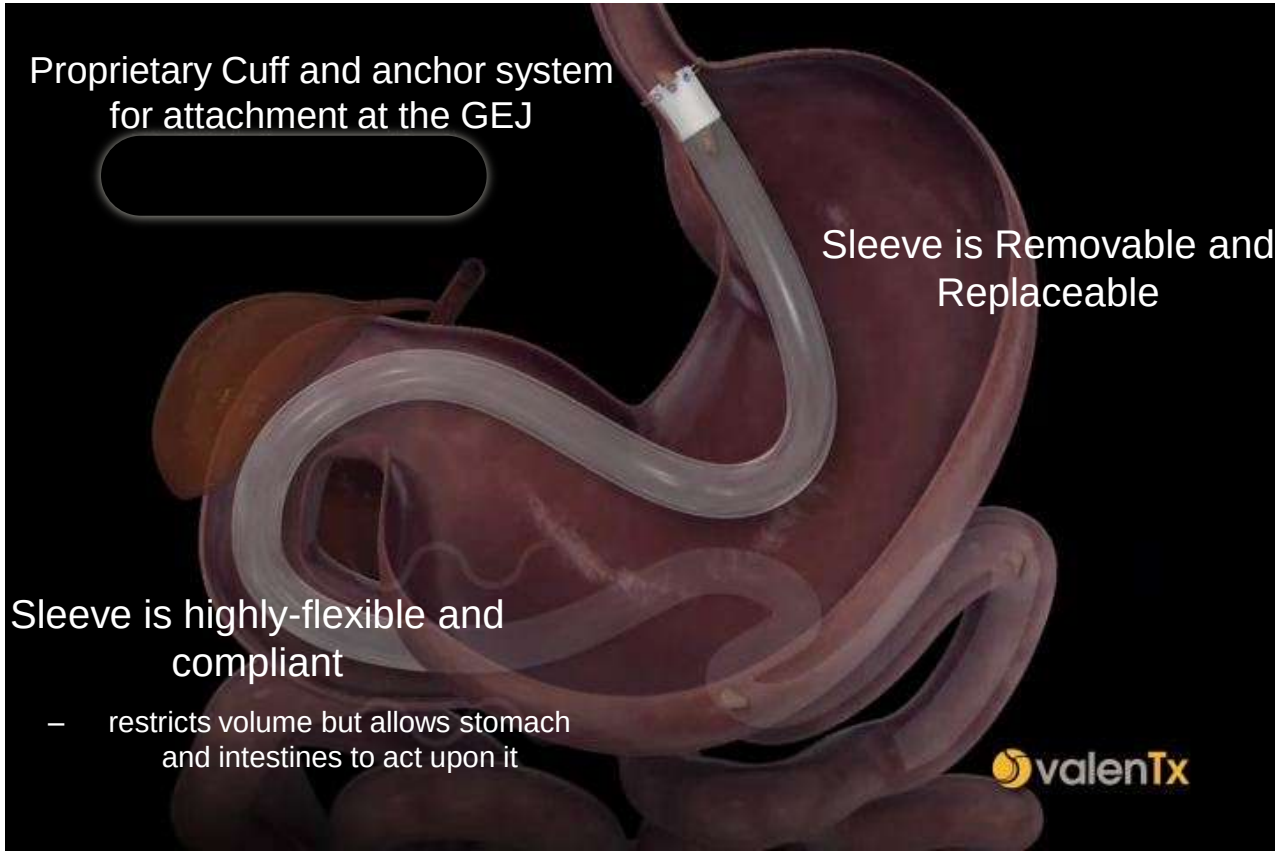
Proprietary Cuff and anchor system for attachment at the GEJ
Sleeve is Removable and Replaceable
Sleeve is highly-flexible and compliant
– restricts volume but allows stomach and intestines to act upon it
valenTx

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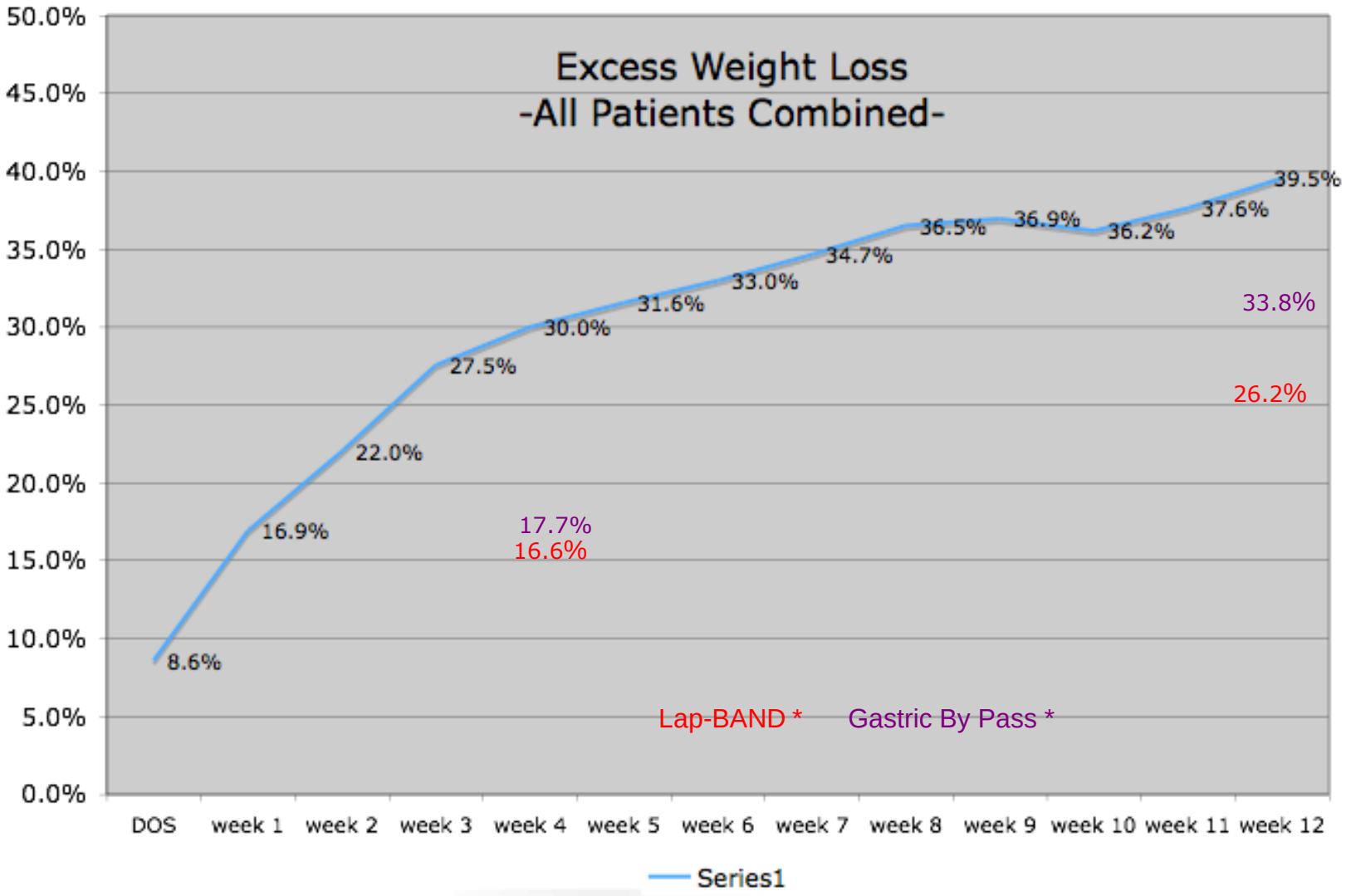
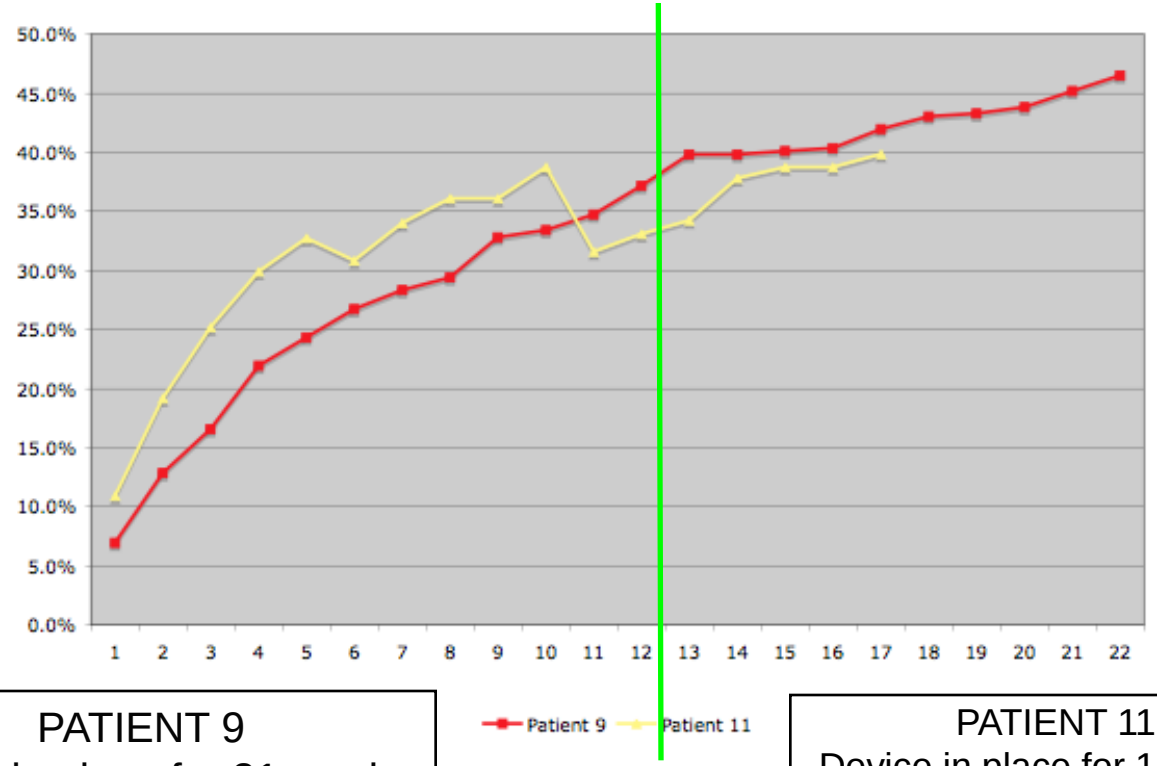
Excess Weight Loss





PATIENT 9
Device in place for 21 weeks
Total pounds lost: 76.6
Starting BMI: 52
Current BMI: 37
Excess WL: 47%

PATIENT 11
Device in place for 16 weeks
Total pounds lost: 47
Starting BMI: 46.3
Current BMI: 37
Excess WL: 40%
Off diabetic meds immediately

12-week Excess Weight Loss	• High: 64% • Low: 25% • Mean: 40%
Comorbidities	• Diabetics (n=4) - resolved • Hypertensive (n=2) - resolved • Decreased joint pain • Ability to exercise • Improved quality of life scores • High satisfaction with therapy

Infection	None
Bleeding	None
Nausea/vomiting	None
Bowel Injury	None
Mucosal Injury	None
Nutritional Deficiency	None
Dumping Syndrome	None

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ENDOSCOPIC DUODENOJEJUNAL BYPASS WITH GI SLEEVE

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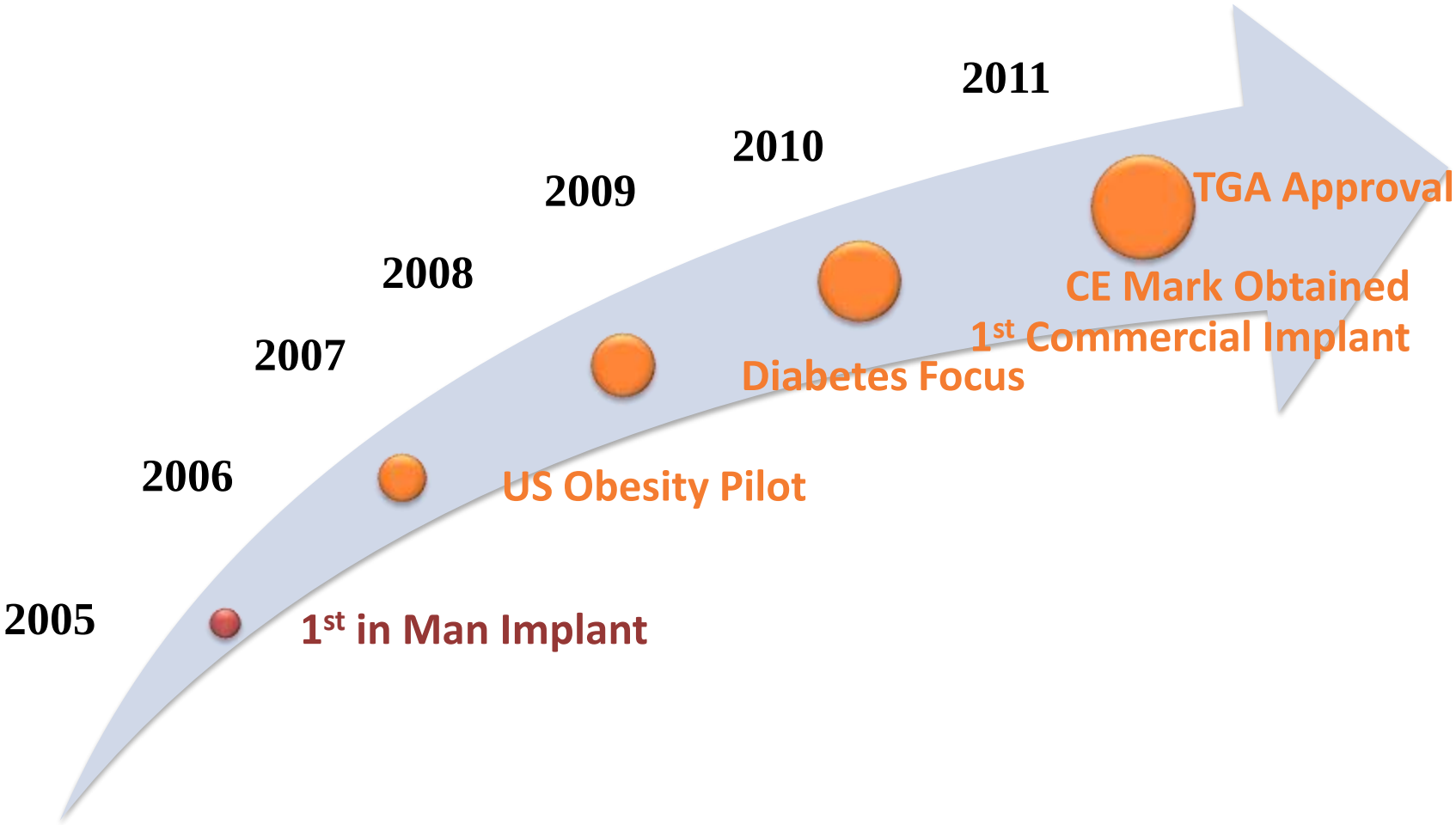


Over 500 EndoBarrier Implants to date

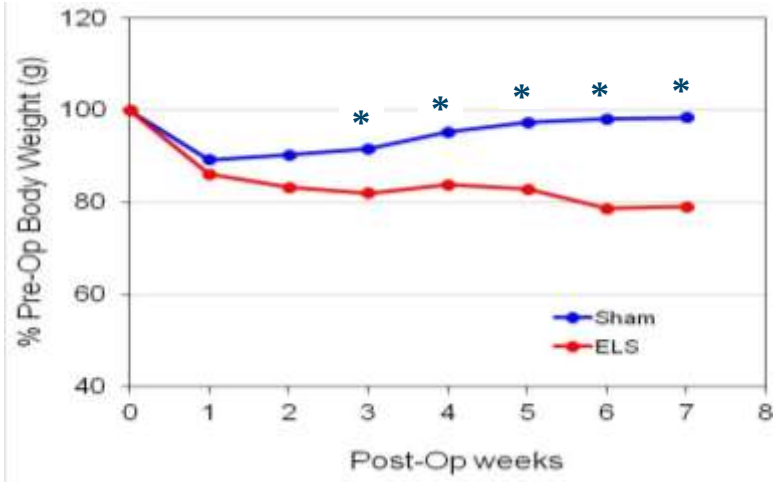
Mechanism of Action Studies

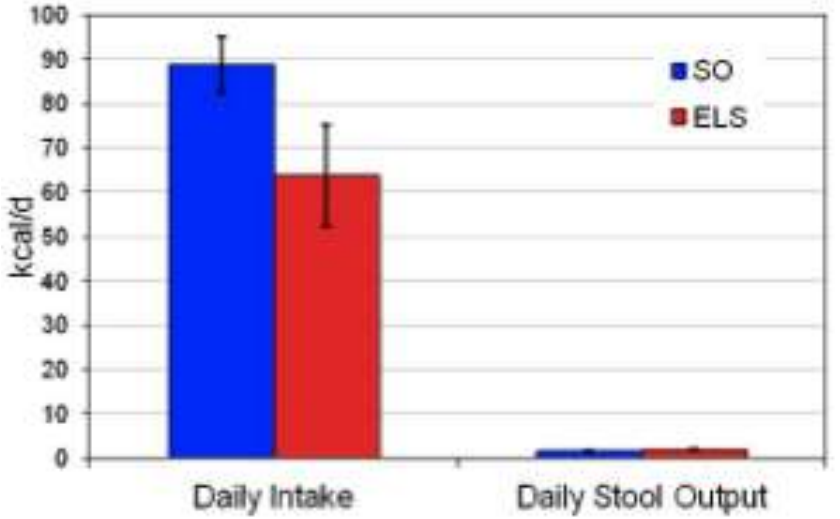
- Pre-clinical studies (rats)
  - Sprague-Dawley rats on high-fat diet
    - obese and pre-diabetic
  - Surgically implanted with scale model of EndoBarrier
- Human mechanistic study
  - 17 subjects (sub-study of 07-1)
  - GI peptide profiles at different time points
- Results reveal common mechanisms with Roux-en-Y gastric bypass

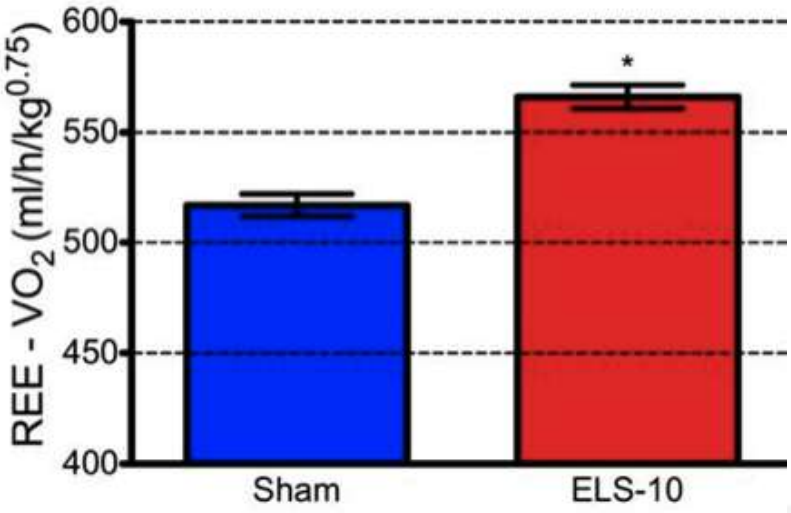
Rat endoluminal sleeve (ELS)

EndoBarrier for human use

Energy Balance Studies – Rodent Studies







Conclusions

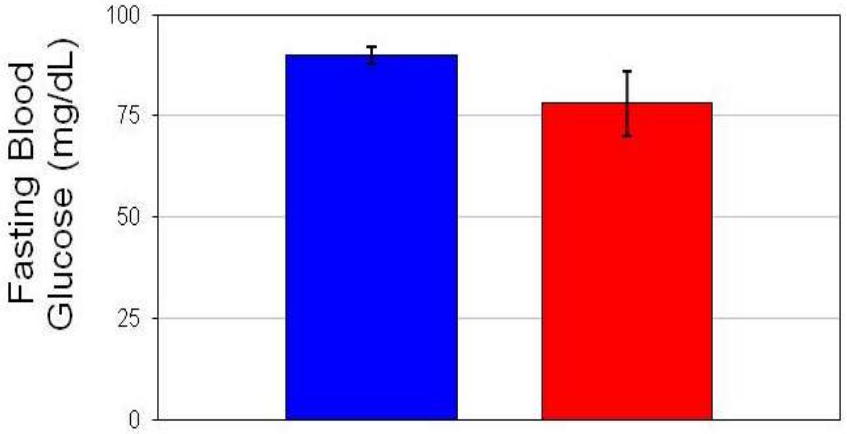
- **ELS implantation induces weight loss**
- **Weight loss results from decreased food intake and increased resting energy expenditure**
- **NO evidence of significant calorie malabsorption**

REE = resting energy expenditure

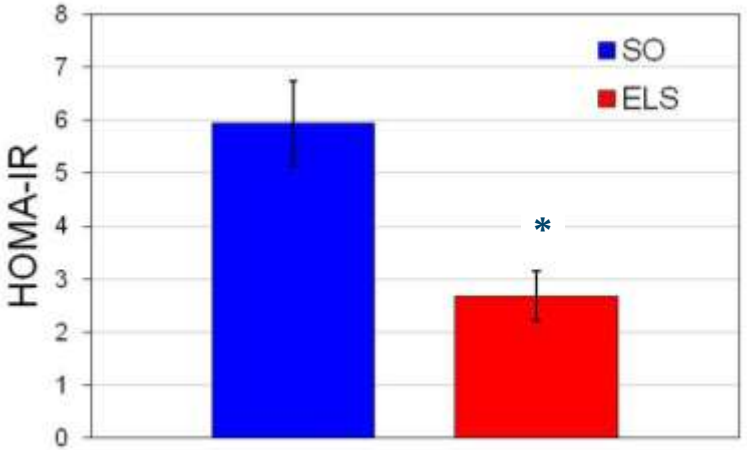
***p <0.05**

Glucose Homeostasis – Rodent Studies

Fasting Glucose

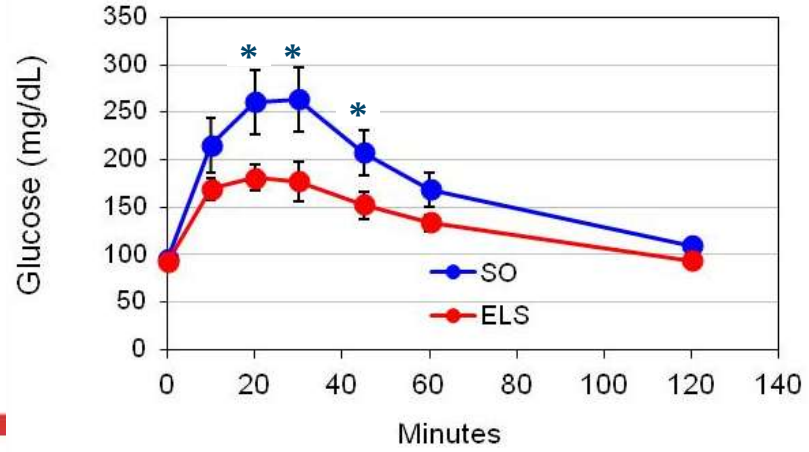


Insulin Resistance



HOMA-IR = fasting glucose x fasting insulin

Oral Glucose Tolerance Test



Conclusions

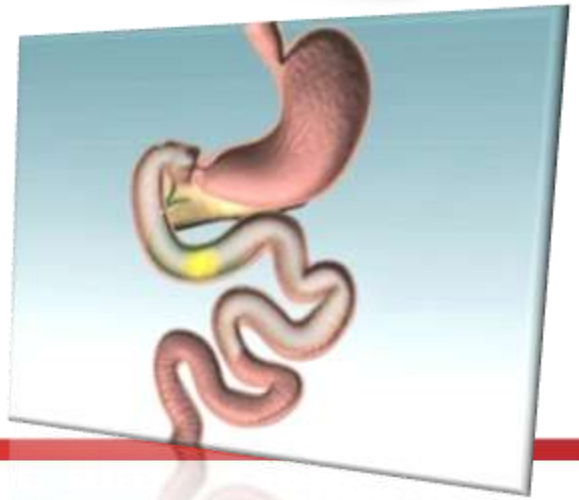
- **ELS implantation induces decreased fasting glucose and enhanced insulin sensitivity**
- **ELS results in normalization of oral and parenteral glucose tolerance**

***p <0.05**

The EndoBarrier

Gastrointestinal Liner

- Impermeable liner
- Anchored in the duodenum, 60 cm long
- Endoscopically placed and removed
- Provides a duodenal-jejunal exclusion
- T2DM and weight loss studied
- Over 1000 patients since 2005



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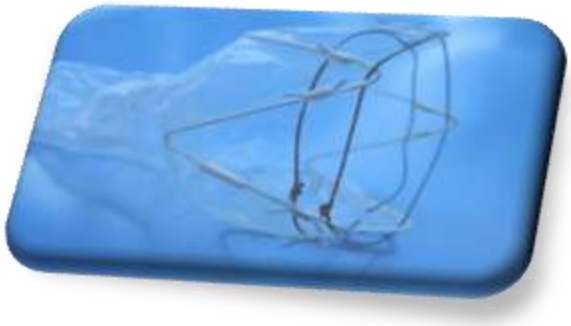
The EndoBarrier

Gastrointestinal Liner



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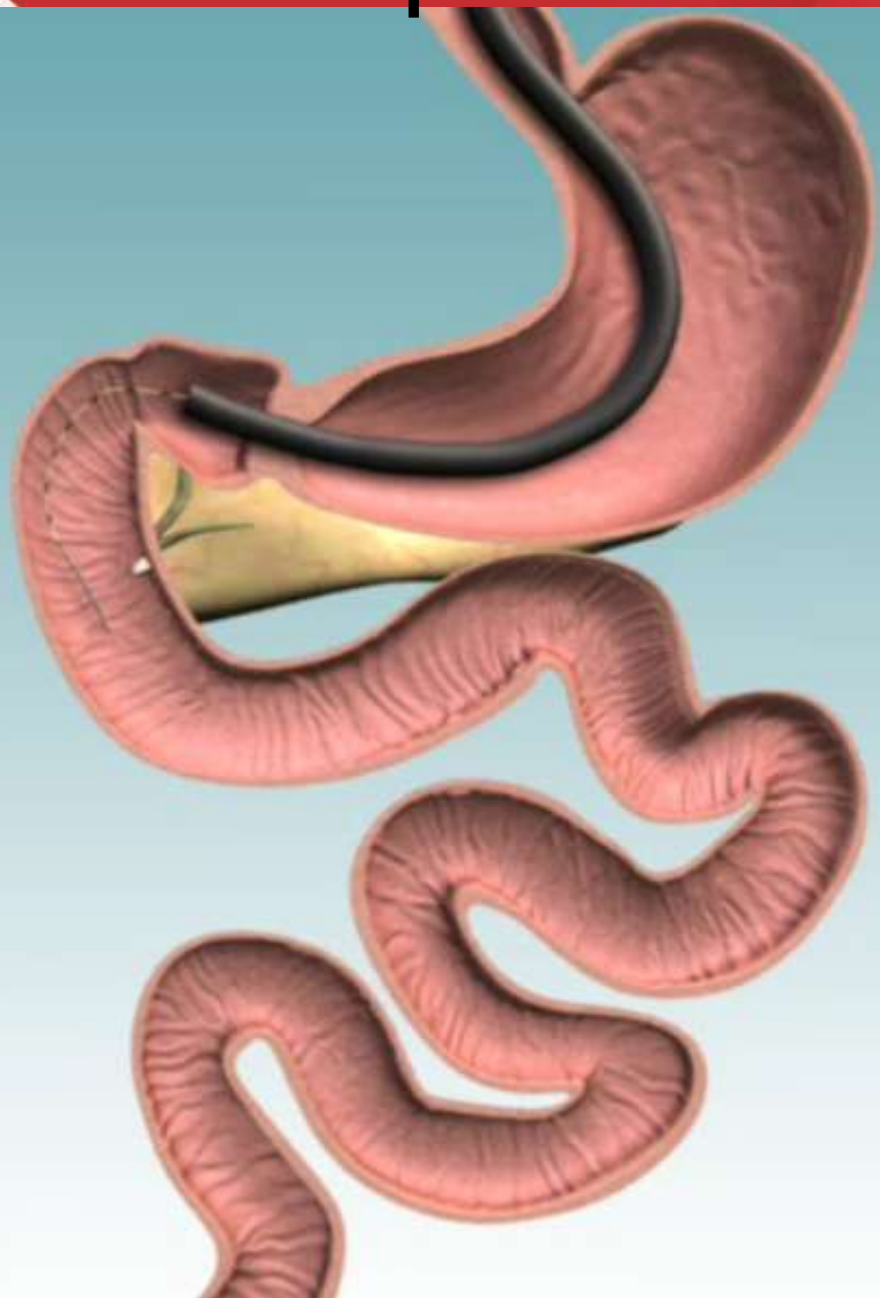
Implant



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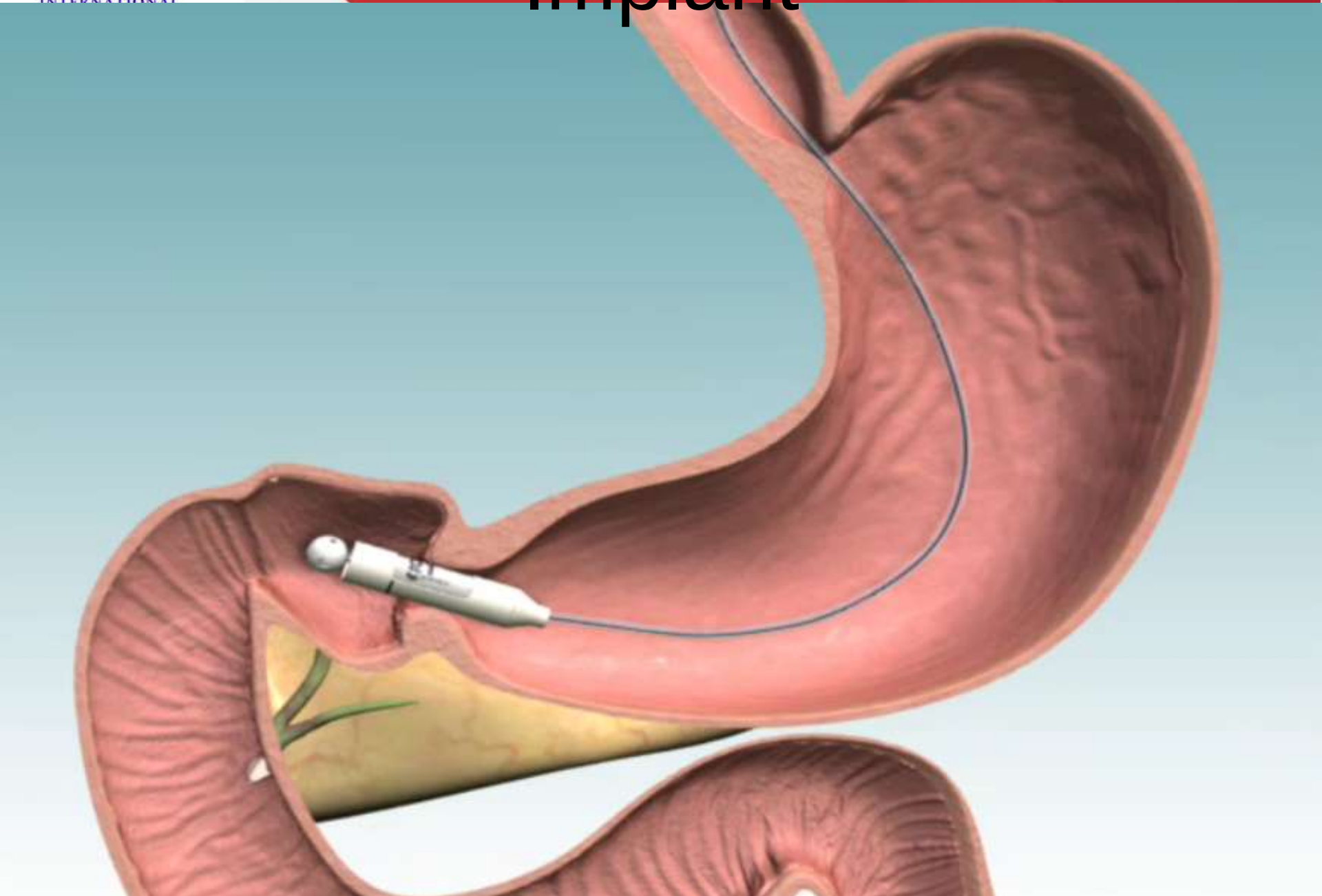

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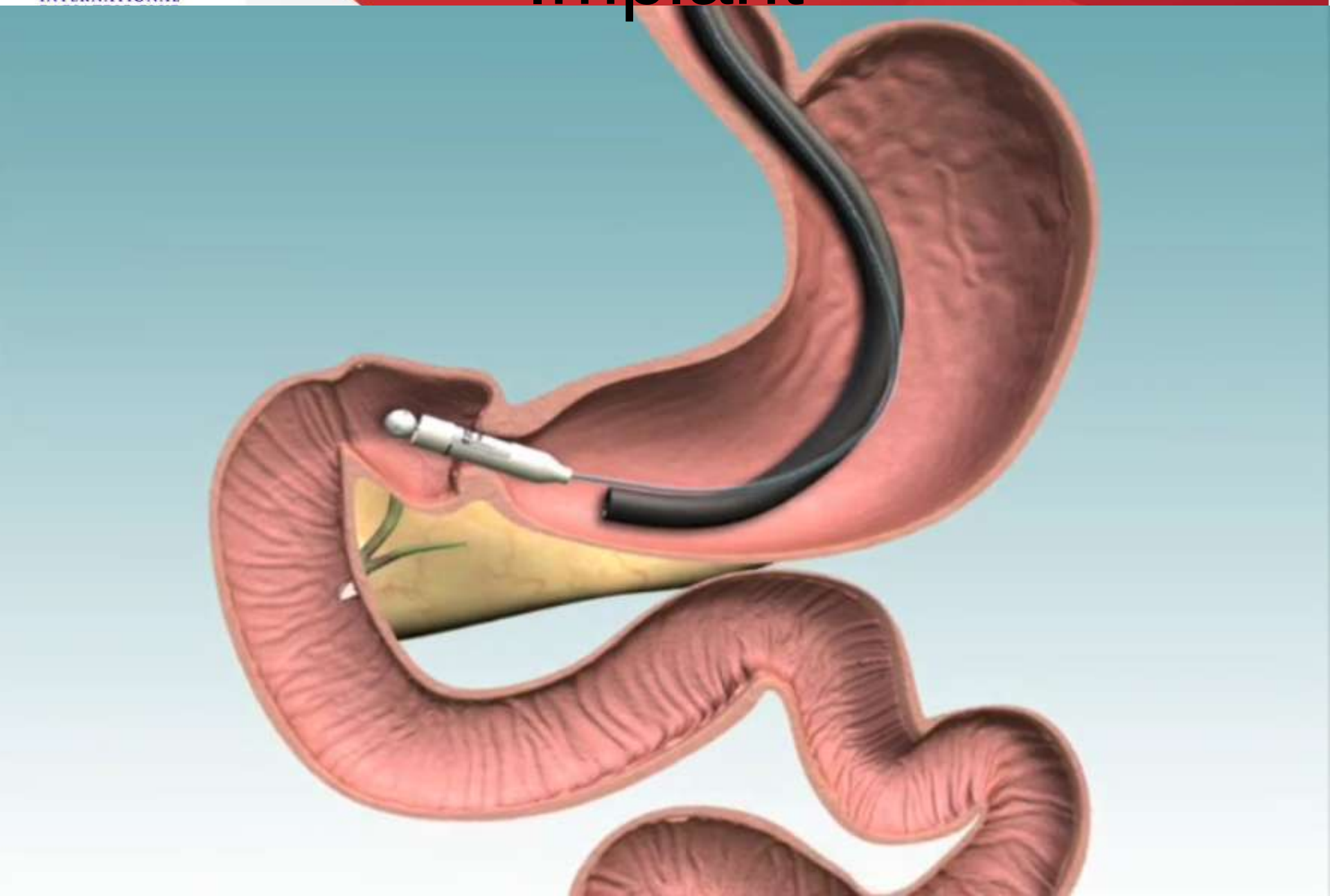
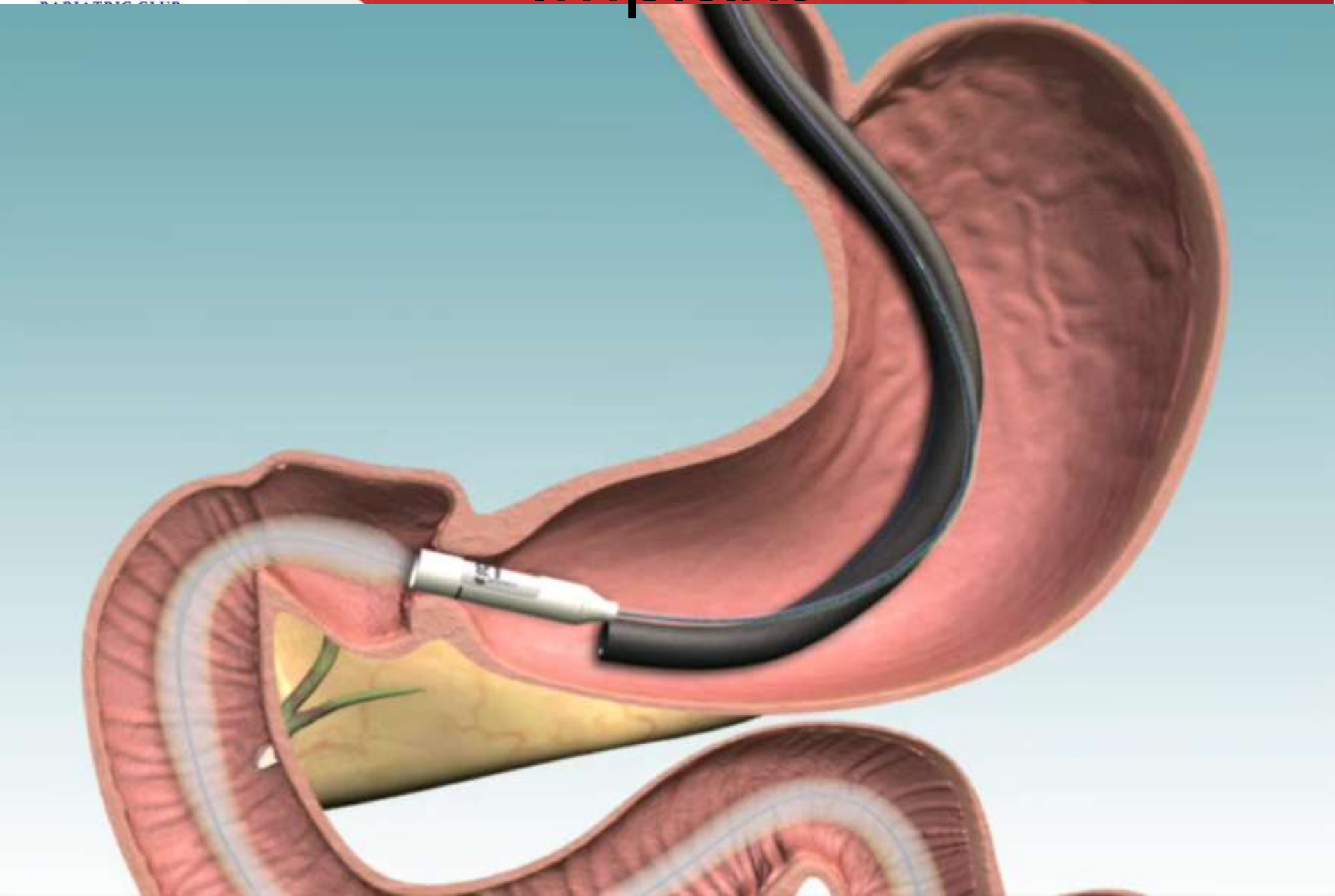


Implant

Implant



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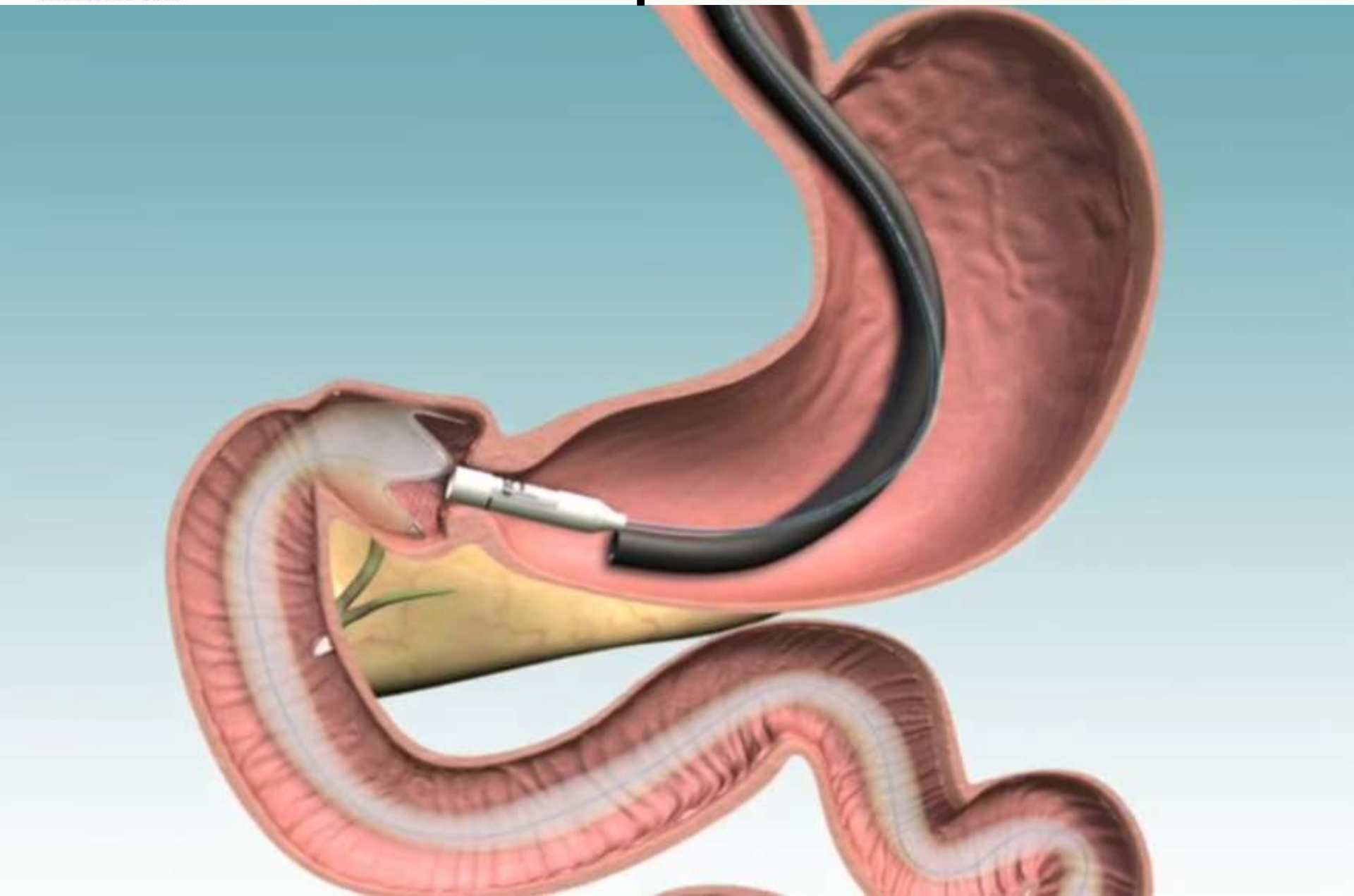

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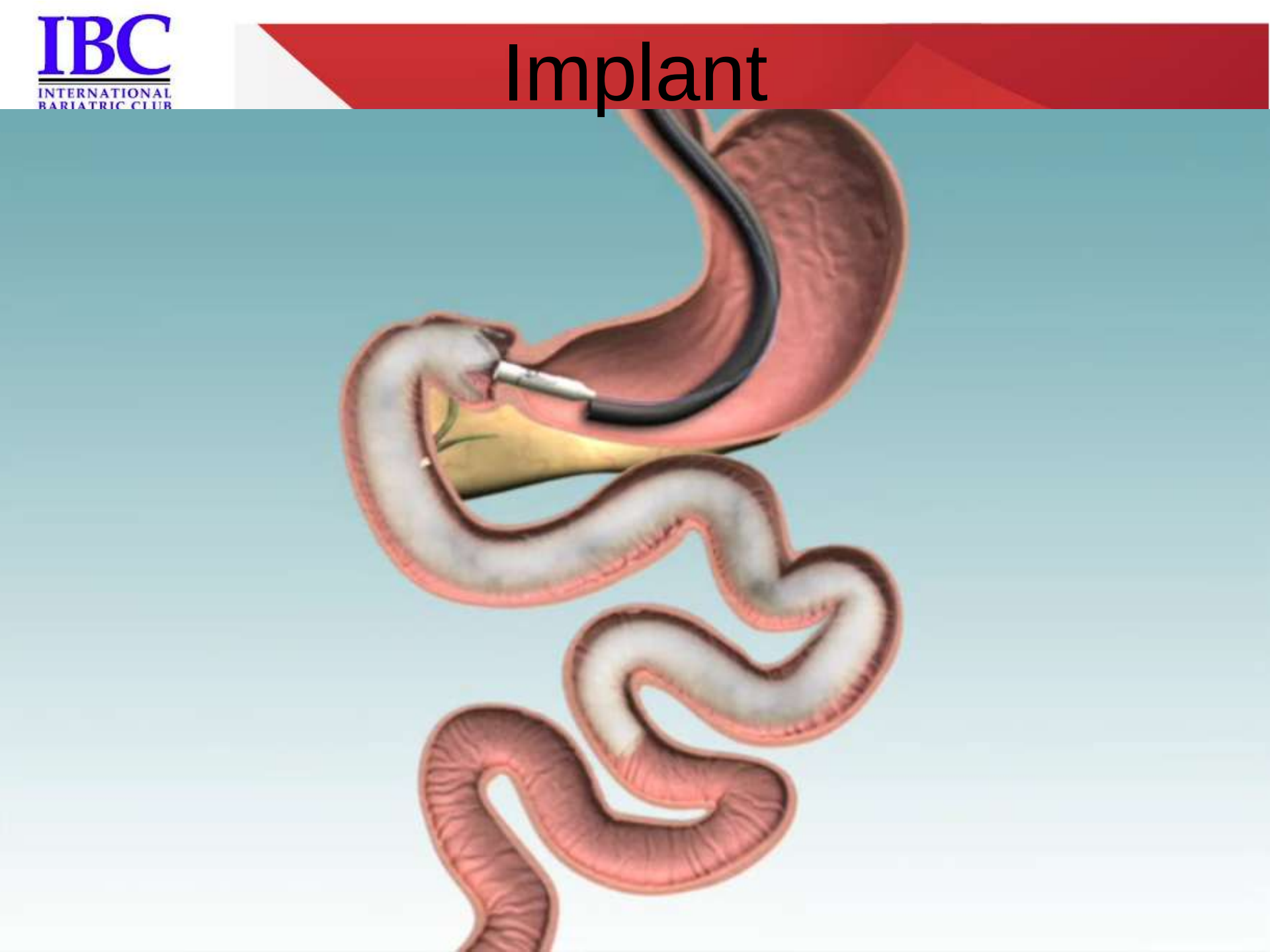

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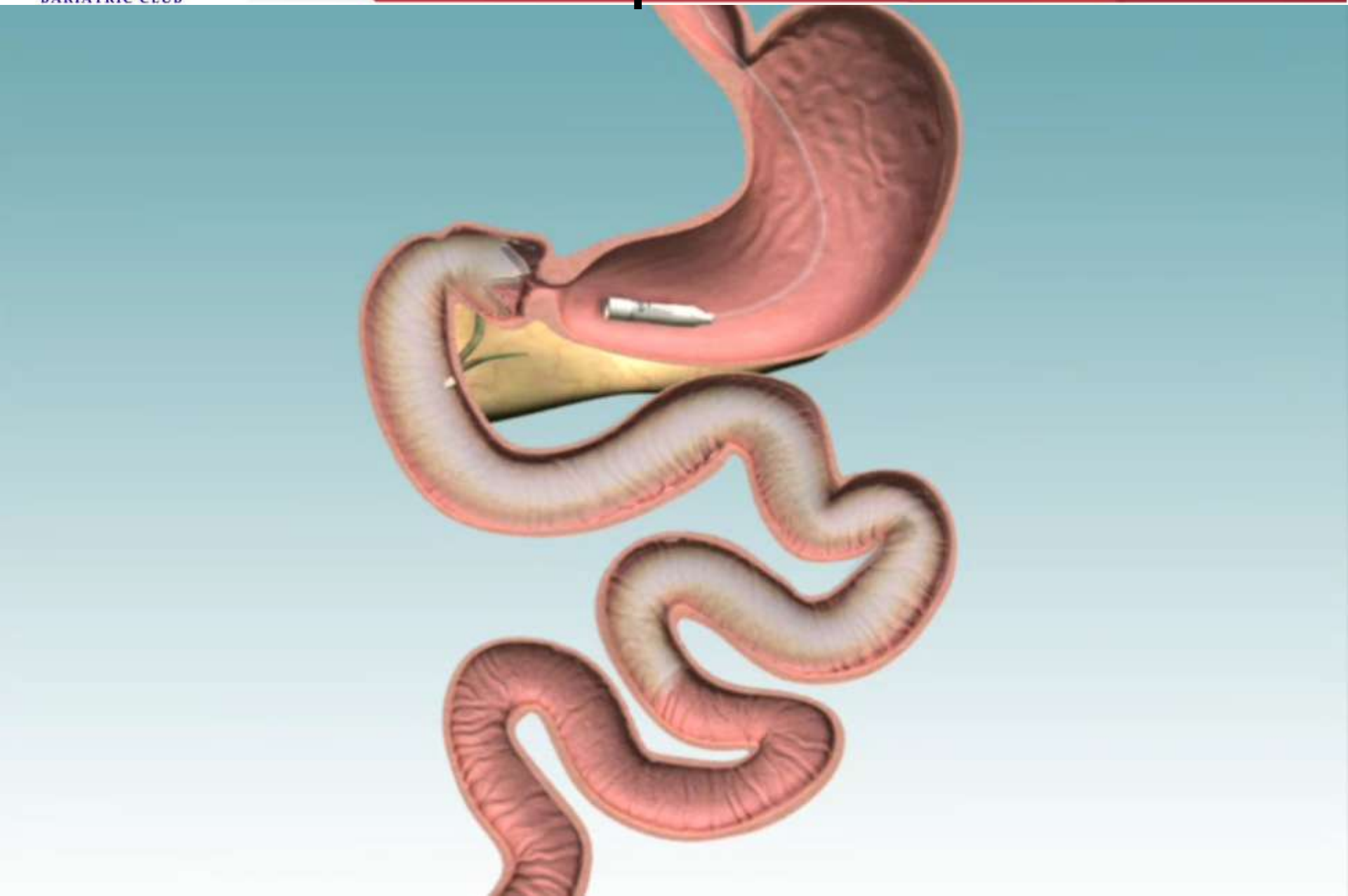
Implant



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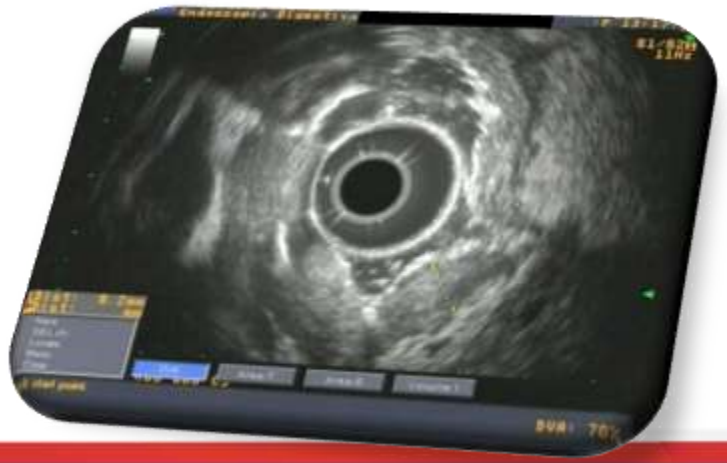
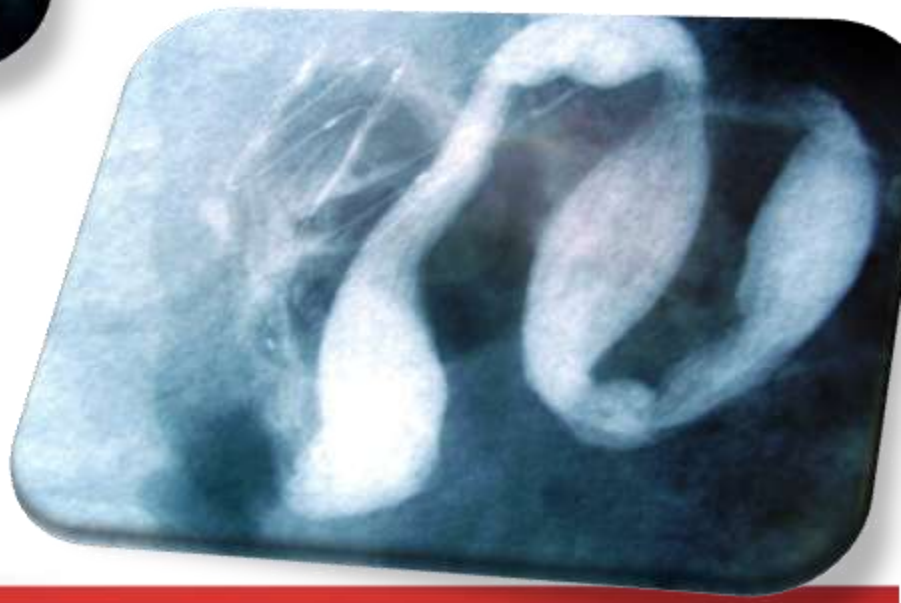
Device – Concept





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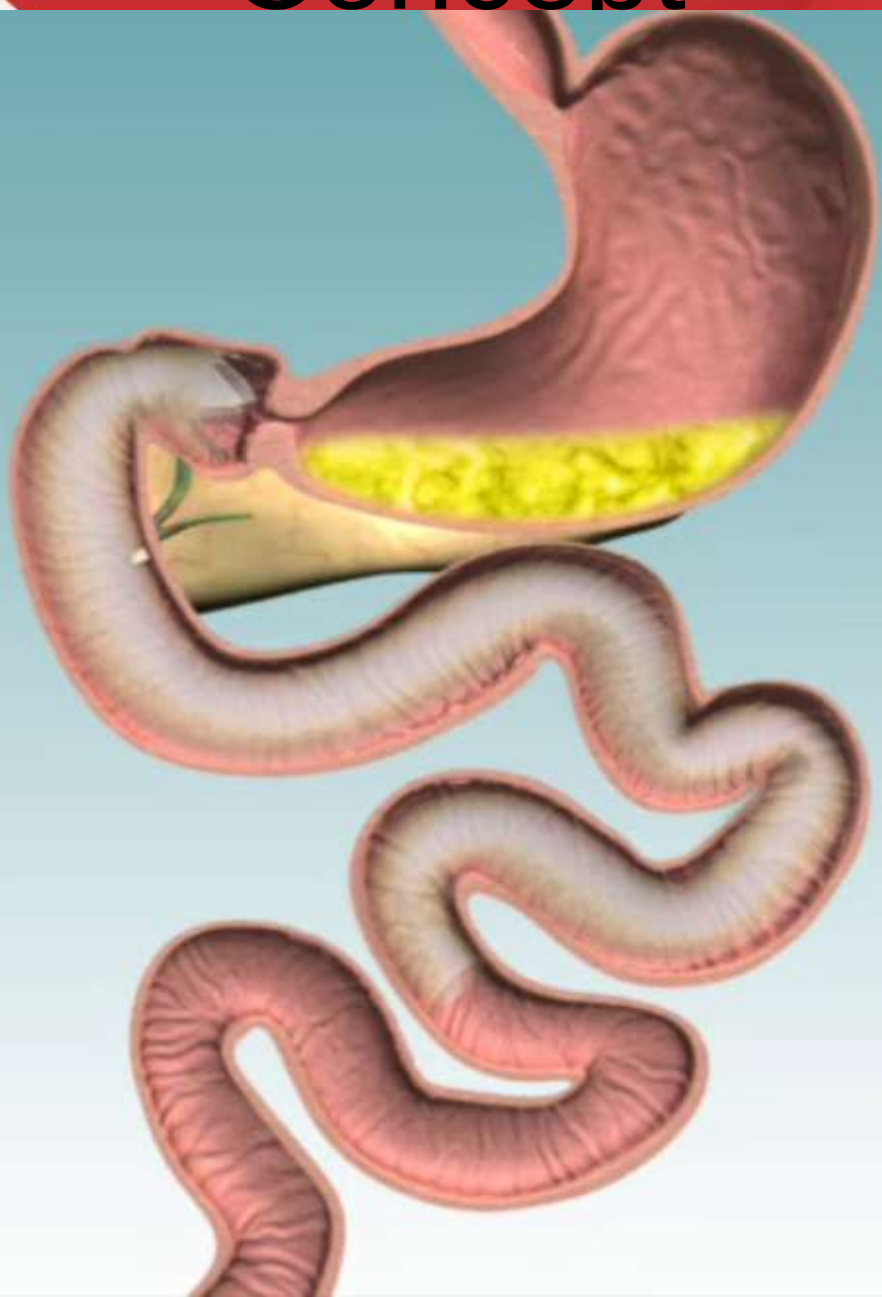
Concept



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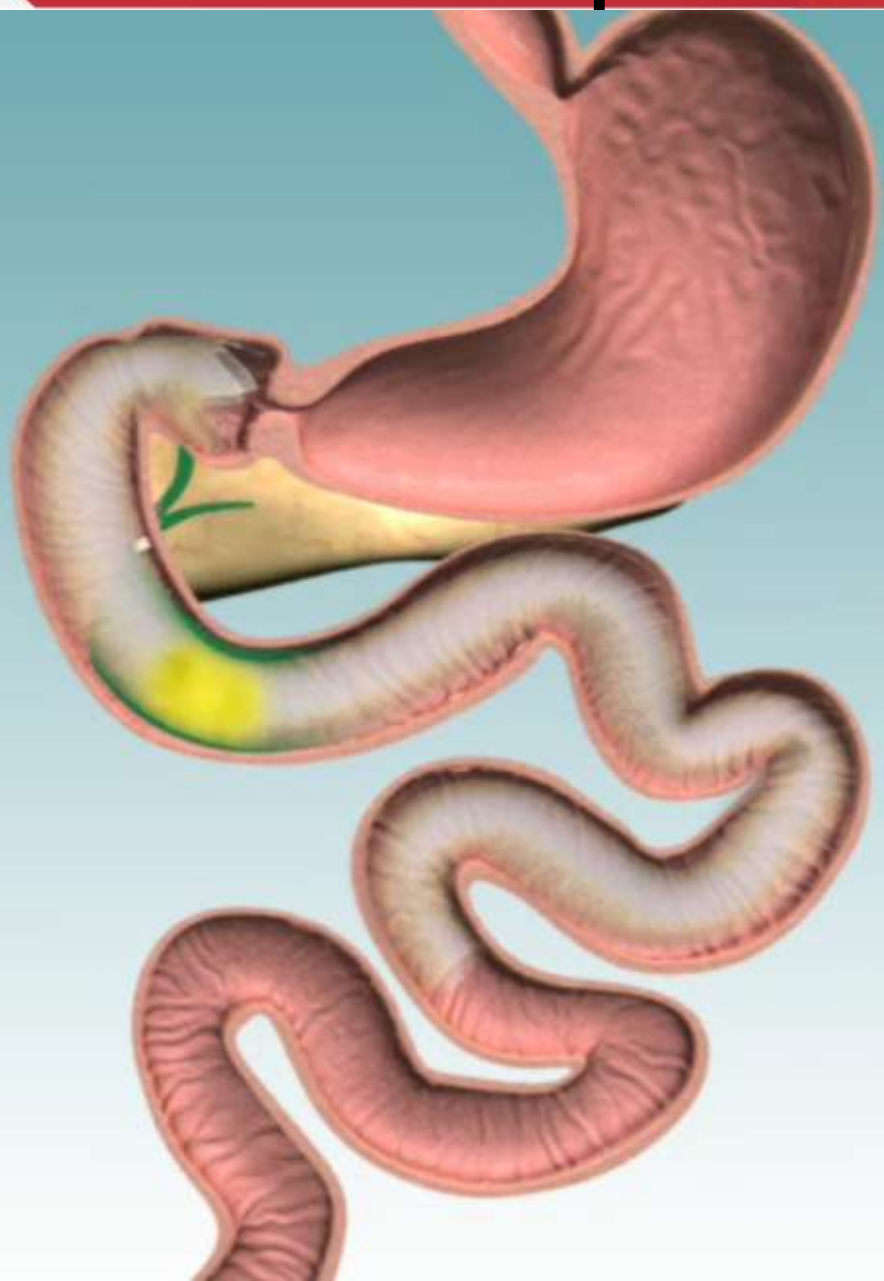
Concept



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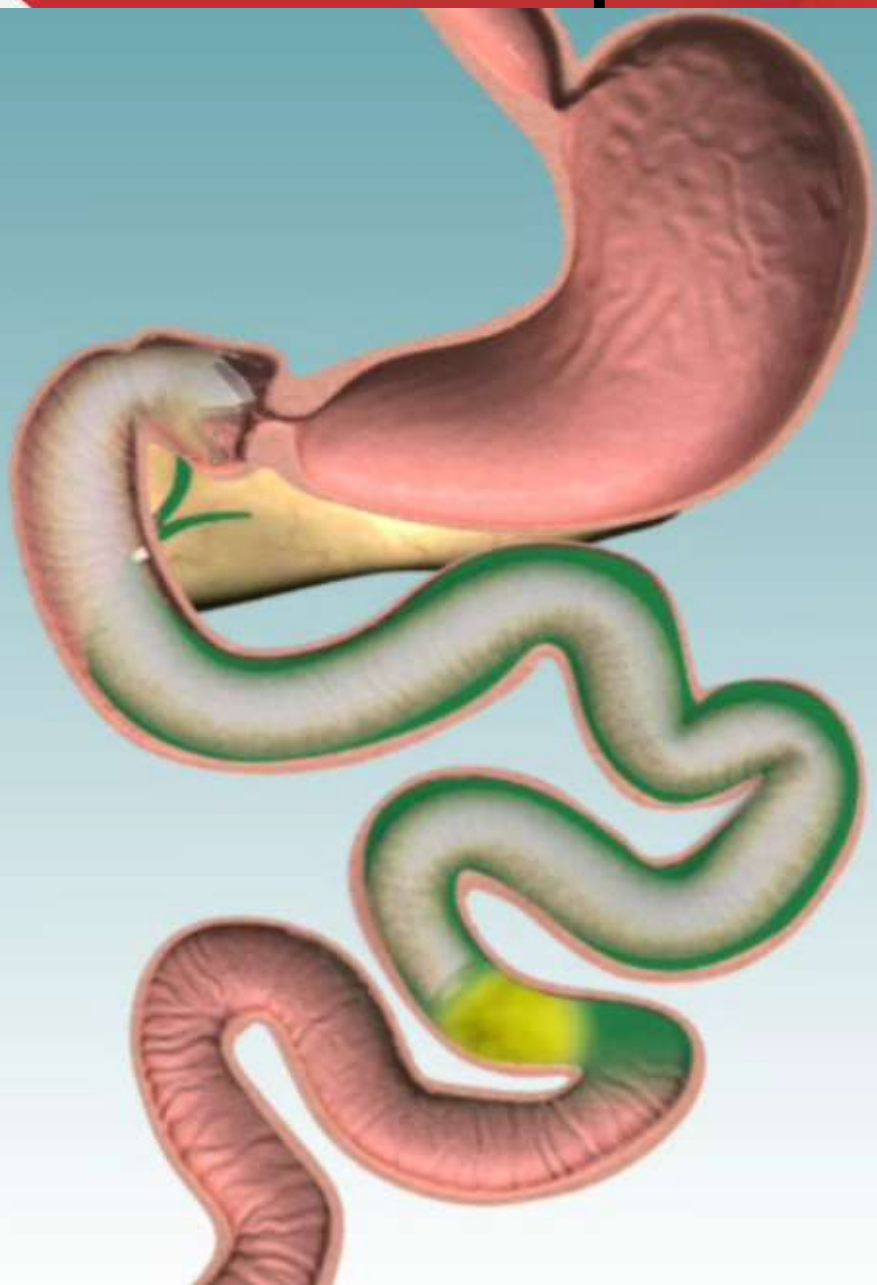
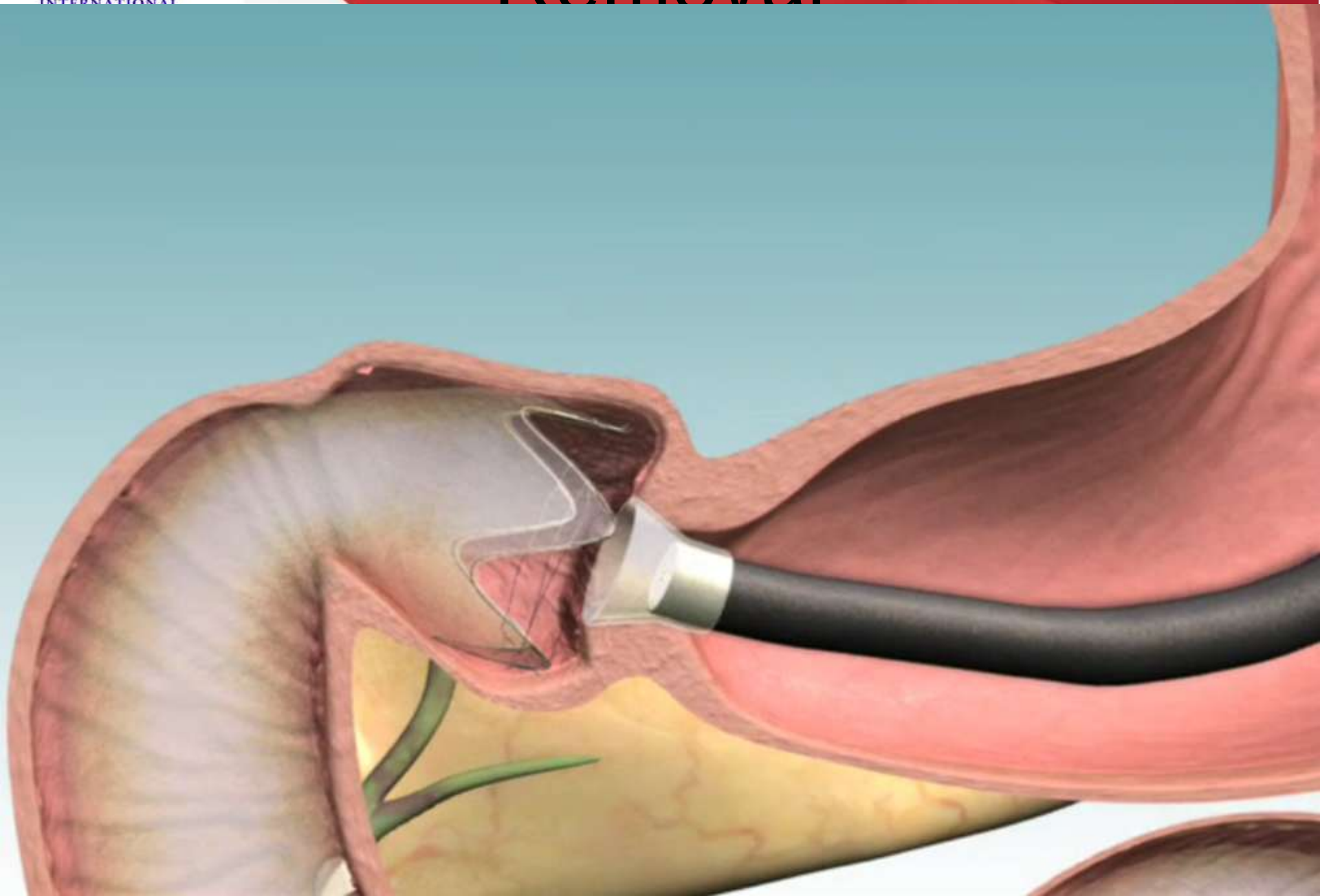
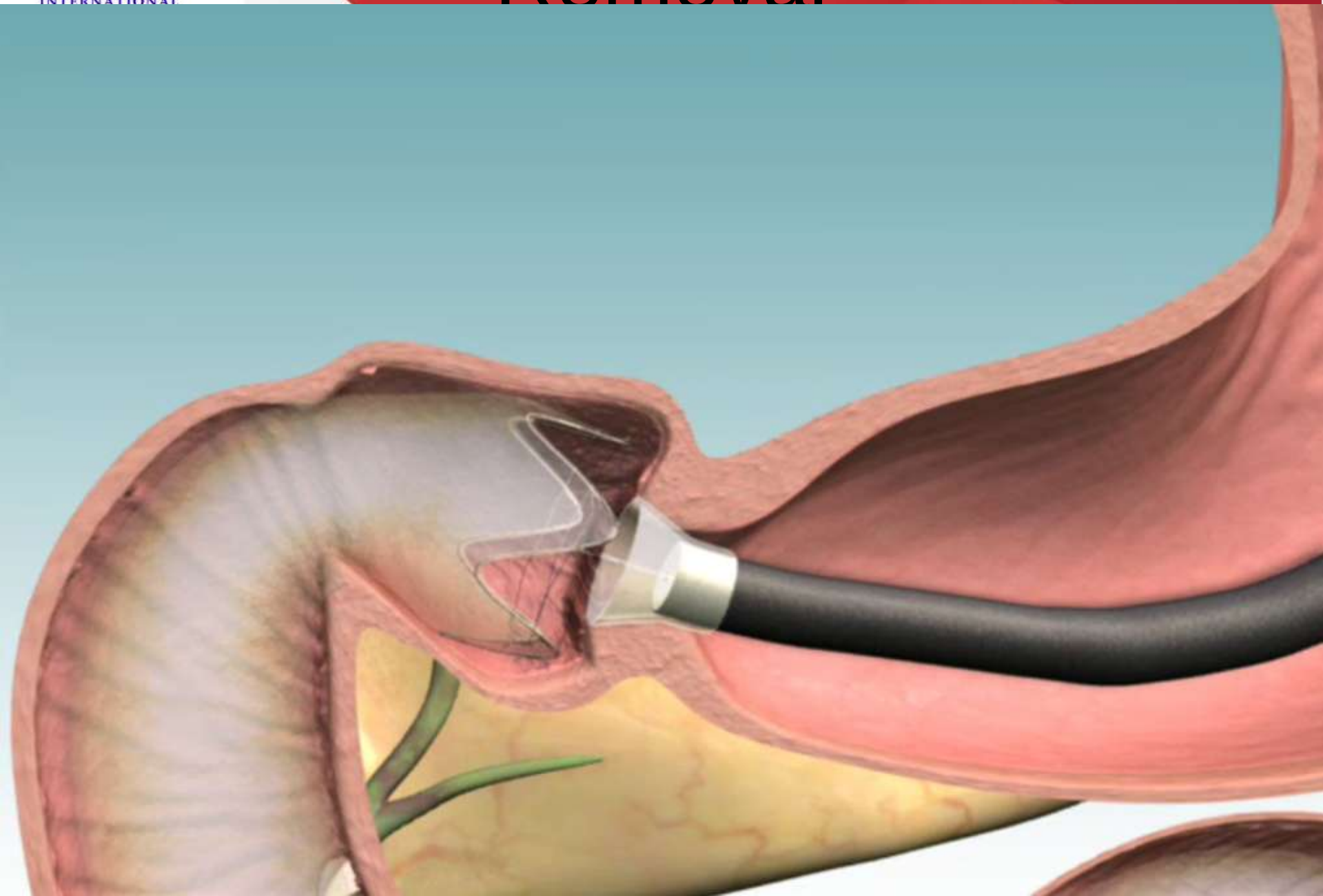
Concept



Removal



Removal



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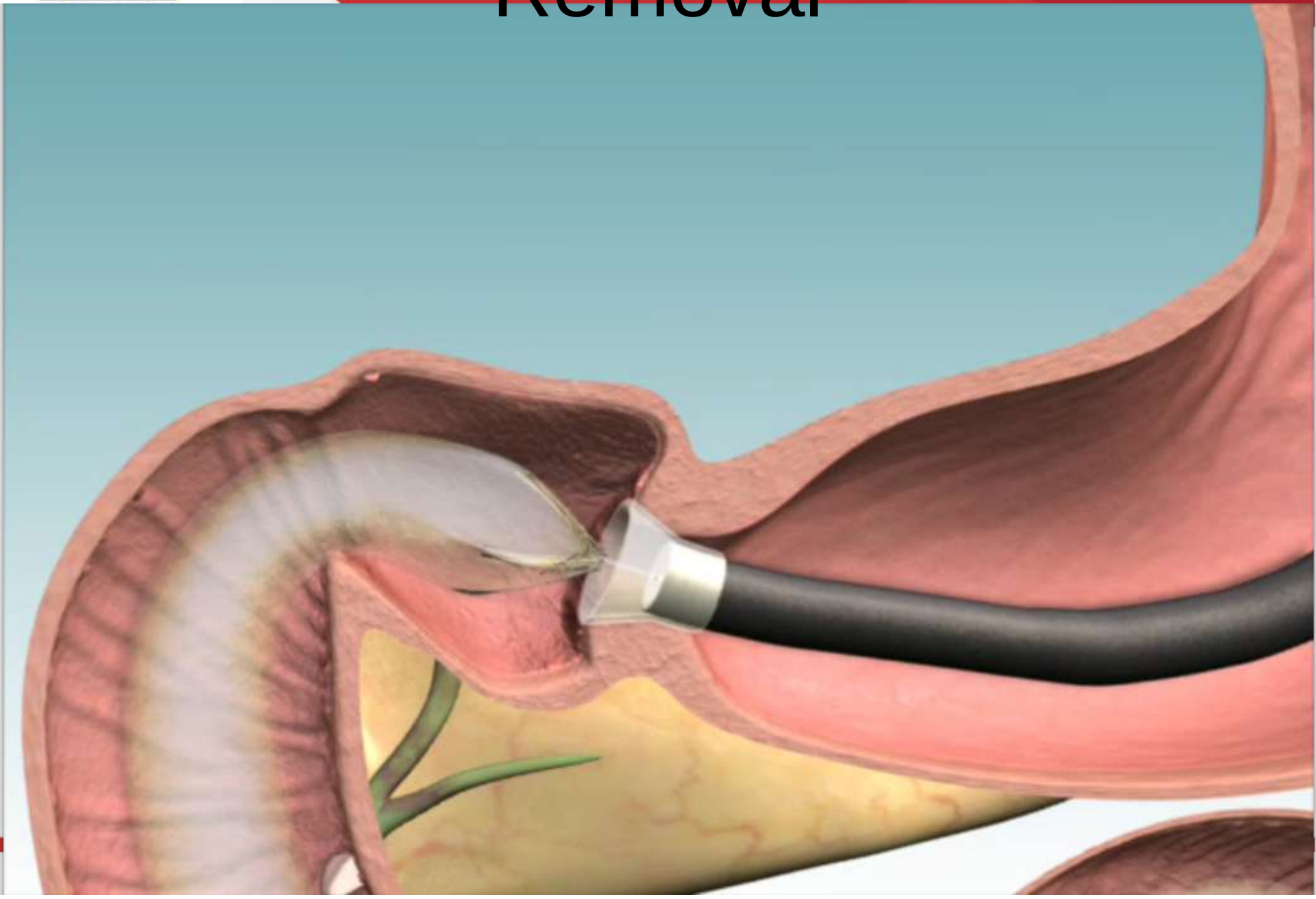
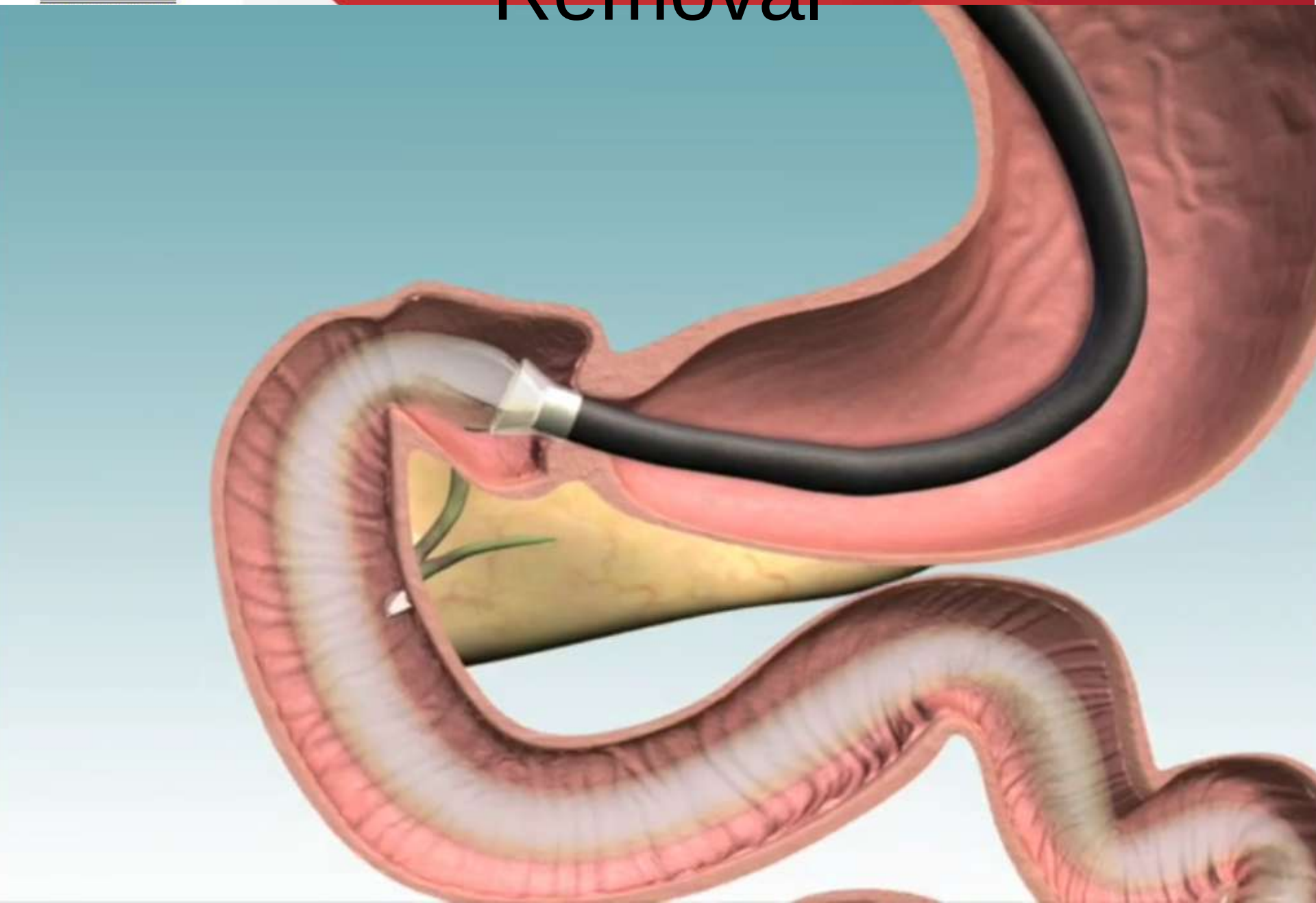


IBC

Removal



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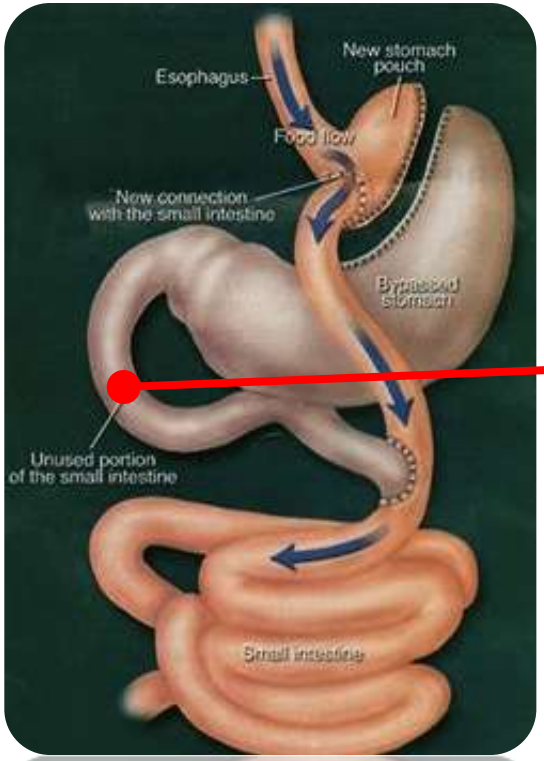
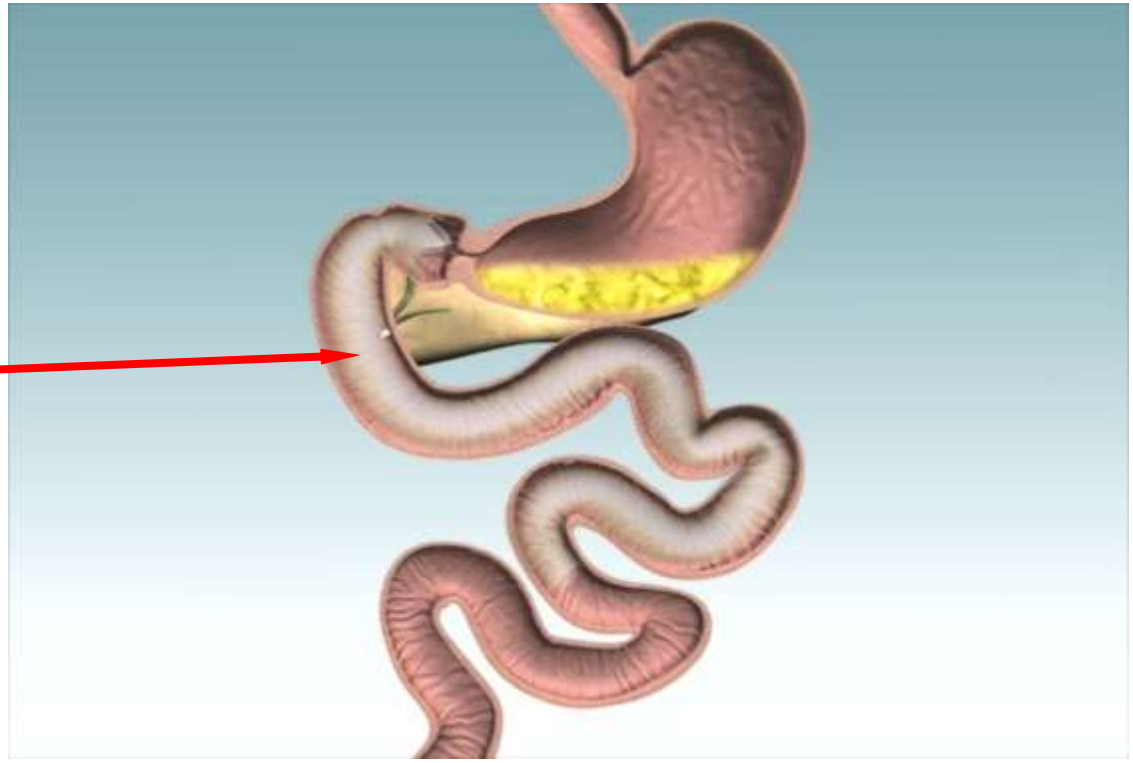
Procedural Comparison







ENDOSCOPIC DUODENOJEJUNAL BYPASS WITH GI SLEEVE

OBESITY – SAFETY - EFICACY
CLINICAL TRIALS

ELSEVIER

Surgery for Obesity and Related Diseases xx (2007) xxx–xxx

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

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 Pāulo, Brazil*
[c]*Department of Surgery, Tufts-New England Medical Center, Boston, Massachusetts*

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

First Reports of Cases

Surgical Innovation
Volume 14 Number 4
December 2007 275-278

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http://online.sagepub.com

Duodenal–Jejunal Bypass Sleeve: A Totally Endoscopic Device for the Treatment of Morbid Obesity

Keith S. Gersin, MD, Jennifer E. Keller, MD, Dimitrios Stefanidis, MD, Connie S. Simms, RN, Delois D. Abraham, RN, Stephen E. Deal, MD, Timothy S. Kuwada, MD, and B. Todd Heniford, MD

Surg Endosc
DOI 10.1007/s00464-008-0125-4

Open label, prospective, randomized controlled trial of an endoscopic duodenal-jejunal bypass sleeve versus low calorie diet for pre-operative weight loss in bariatric surgery

M. Tarnoff · L. Rodriguez · A. Escalona · A. Ramos · M. Neto · M. Alamo · E. Reyes · F. Pimentel · L. Ibanez

Received: 2 May 2008 / Accepted: 24 July 2008

RANDOMIZED CONTROLLED TRIAL

A Multicenter, Randomized Efficacy Study of the EndoBarrier Gastrointestinal Liner for Presurgical Weight Loss Prior to Bariatric Surgery

Ruben Schouten, MD, Carianne S. Rijs, MD,† Nicole D. Bouvy, MD, PhD,‡ Wim Hameeteman, MD, PhD,§ Ger H. Koek, MD, PhD,§ Ignace M. C. Janssen, MD,† and Jan-Willem M. Greve, MD, PhD**

ORIGINAL ARTICLE

Open-label, sham-controlled trial of an endoscopic duodenojejunal bypass liner for preoperative weight loss in bariatric surgery candidates

Keith S. Gersin, MD, Richard I. Rothstein, MD, Raul J. Rosenthal, MD, Dimitrios Stefanidis, MD, PhD, Stephen E. Deal, MD, Timothy S. Kuwada, MD, William Laycock, MD, Gina Adrales, MD, Melina Vassiliou, MD, Samuel Szomstein, MD, Stephen Heller, MD, Anne Marie Joyce, MD, Frederick Heiss, MD, Dmitry Nepomnayshy, MD

Charlotte, North Carolina; Hanover, New Hampshire; Weston, Florida; Burlington, Massachusetts, USA

(Clinical trial registration number: NPT00469391.)

ELSEVIER

Surgery for Obesity and Related Diseases 5 (2009) 371–374

SURGERY FOR OBESITY AND RELATED DISEASES

Surgeon at work

Radiographic appearance of endoscopic duodenal-jejunal bypass liner for treatment of obesity and type 2 diabetes

Andy Levine[a,*], Almino Ramos, M.D.[b], Alex Escalona, M.D.[c], Leonardo Rodriguez, M.D.[d], Jan Willem Greve, M.D.[e], Ignace Janssen, M.D.[f], Richard Rothstein, M.D.[g], Dmitry Nepomnayshy, M.D.[h], Keith S. Gersin, M.D.[i], David Melanson[a], Ronald Lamport[a], Ezra Fishman[a], Kenneth Malomo[a], Lee M. Kaplan, M.D.[j], Manoel Galvao Neto, M.D.[b]

[a]*GI Dynamics, Incorporated, Lexington, Massachusetts*
[b]*Gastro Obeso Center, São Paulo, São Paulo, Brazil*
[c]*Hospital Universidad Catolica, Pontificia Universidad Catolica de Chile, Santiago, Chile*
[d]*Centro de Cirugía de la Obesidad, Hospital DIPRECA, Santiago, Chile*
[e]*University Hospital, Maastricht, The Netherlands*
[f]*Ziekenhuis Rijnstate, Arnhem, The Netherlands*
[g]*Dartmouth Hitchcock Medical Center, Lebanon, New Hampshire*
[h]*Lahey Clinic Medical Center, Burlington, Massachusetts*
[i]*Carolinas Medical Center, Charlotte, North Carolina*
[j]*Massachusetts General Hospital, Boston, Massachusetts*

Received September 15, 2008; revised December 15, 2008; accepted February 13, 2009

ELSEVIER

Surgery for Obesity and Related Diseases 6 (2010) 126–131

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

Initial human experience with restrictive duodenal-jejunal bypass liner for treatment of morbid obesity

Alex Escalona, M.D.[a], Ricardo Yáñez, M.D.[a], Fernando Pimentel, M.D.[a], Manoel Galvao, M.D.[b], Almino Cardoso Ramos, M.D.[b], Dannae Turiel, M.D.[a], Camilo Boza, M.D.[a], Diego Awruch, M.D.[a], Keith Gersin, M.D.[c,*], Luis Ibáñez, M.D.[a]

[a]*Department of Digestive Surgery, Pontificia Universidad Católica de Chile Faculty of Medicine, Santiago, Chile*

[b]*Gastro-Obeso Center, São Paulo, São Paulo, Brazil*

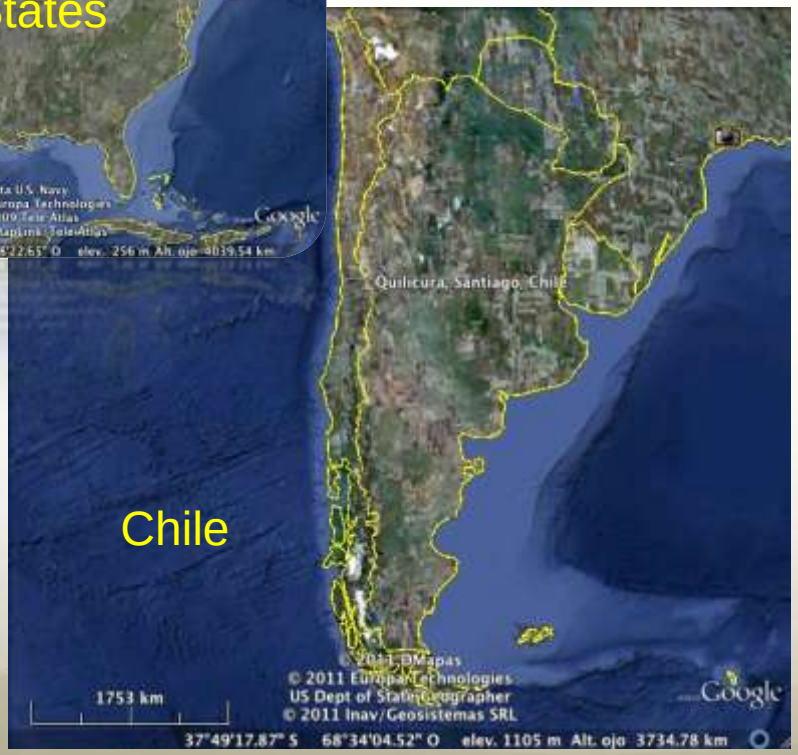
[c]*Department of Surgery, Carolinas Medical Center, Charlotte, North Carolina*

Received May 17, 2009; revised December 10, 2009; accepted December 28, 2009

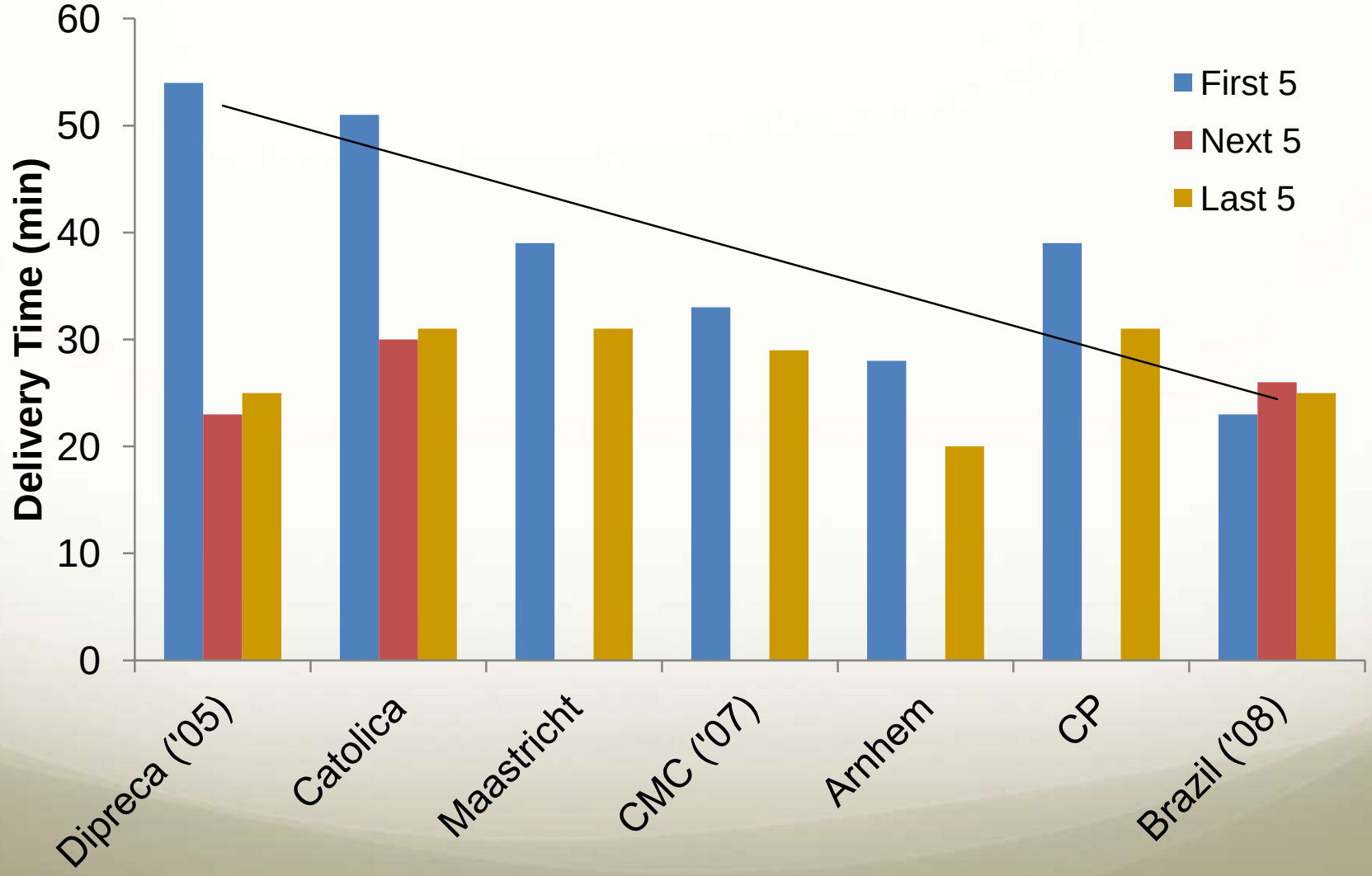
ENDOSCOPIC DUODENOJEJUNAL BYPASS WITH GI SLEEVE

WEIGHT LOSS RESULTS

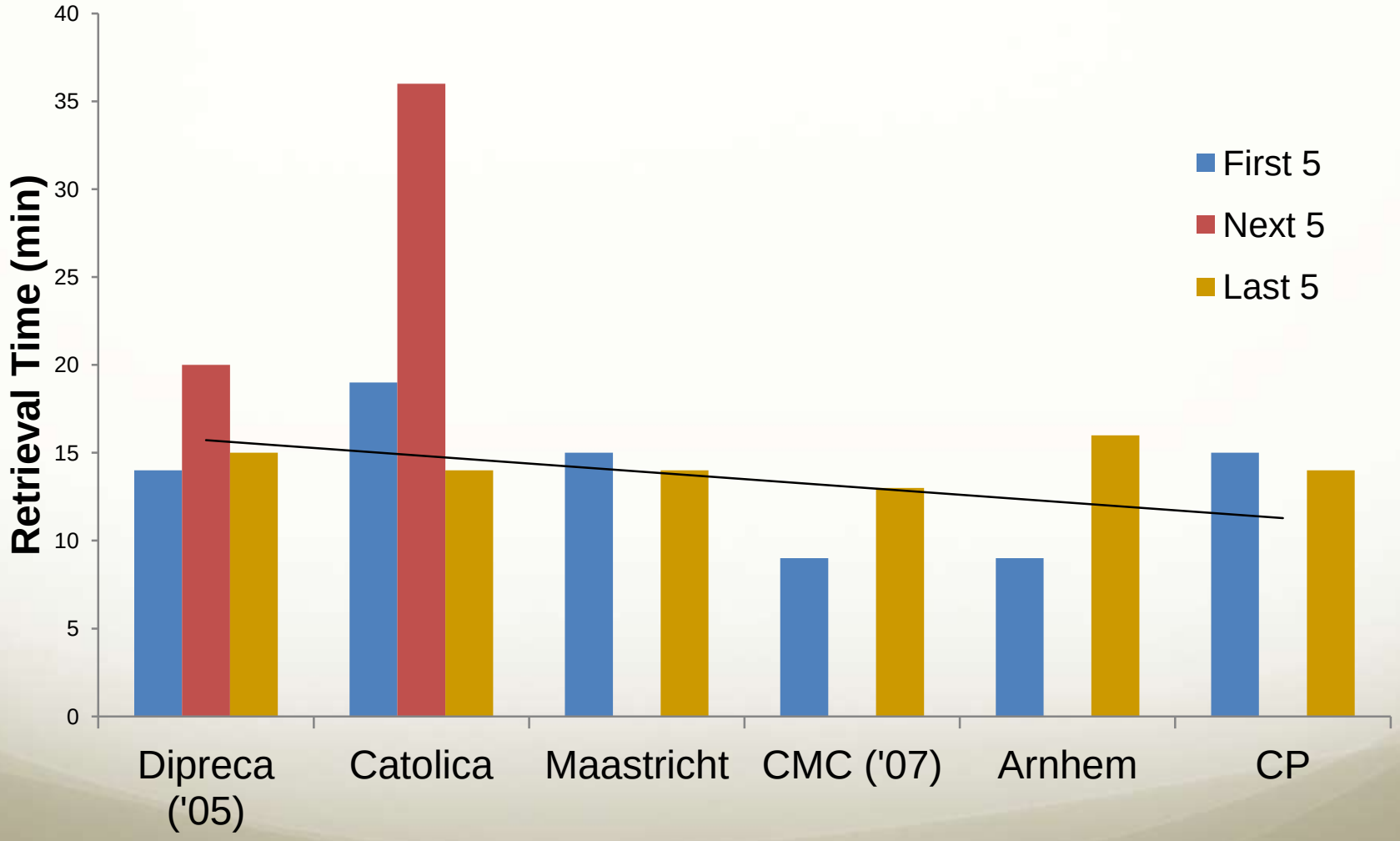
World Experience
434pt



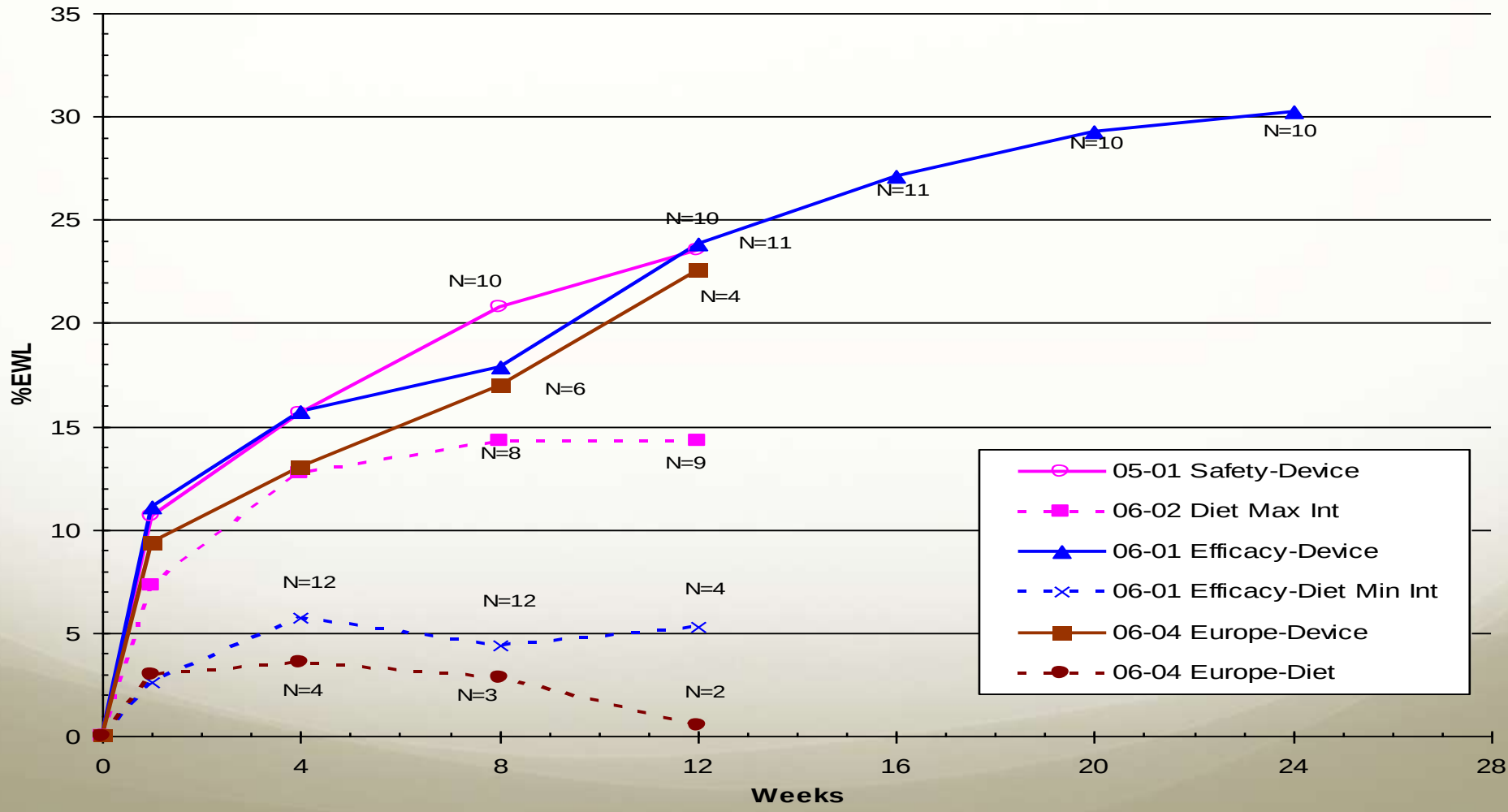
Delivery Learning Curve



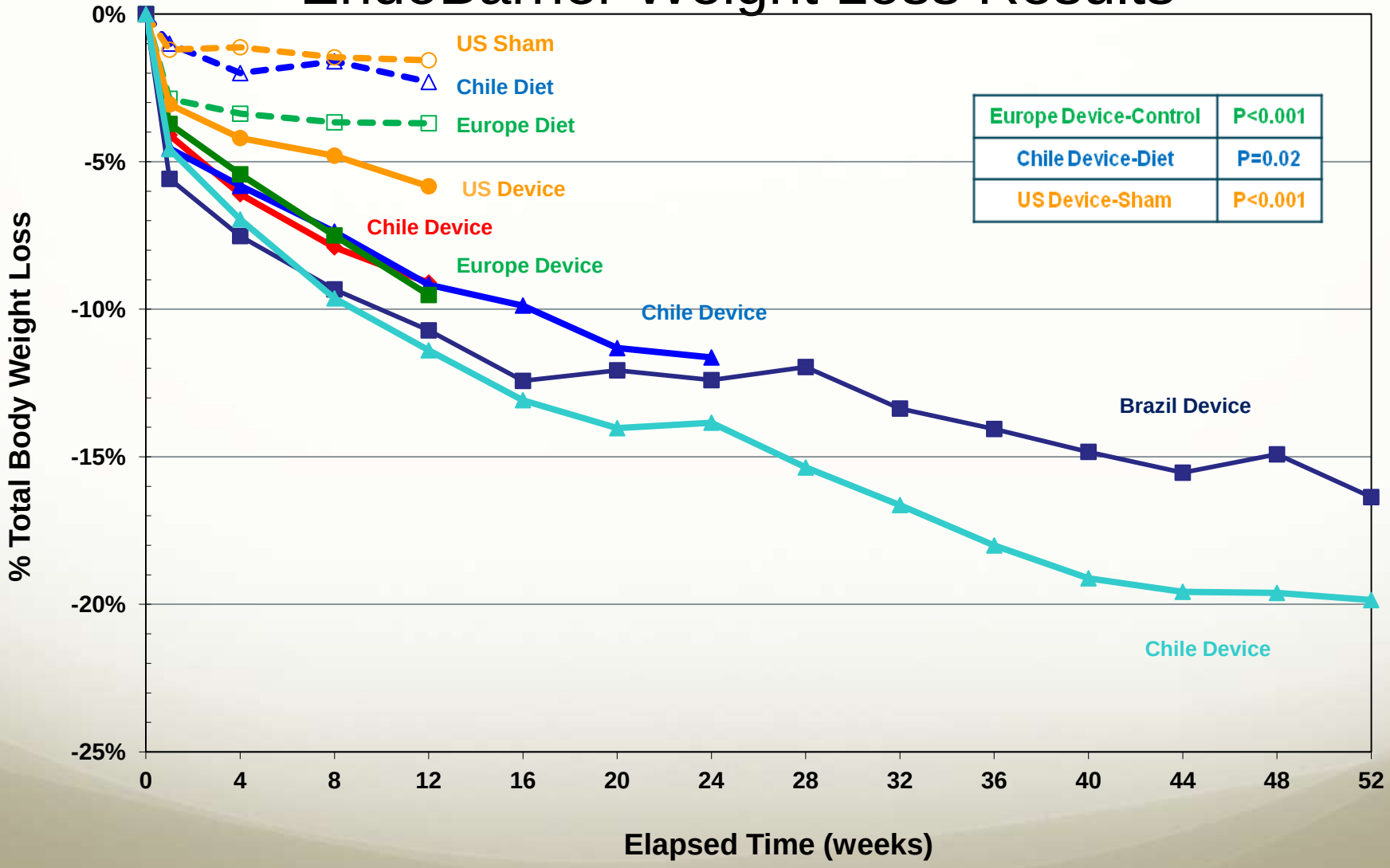
Retrieval Learning Curve



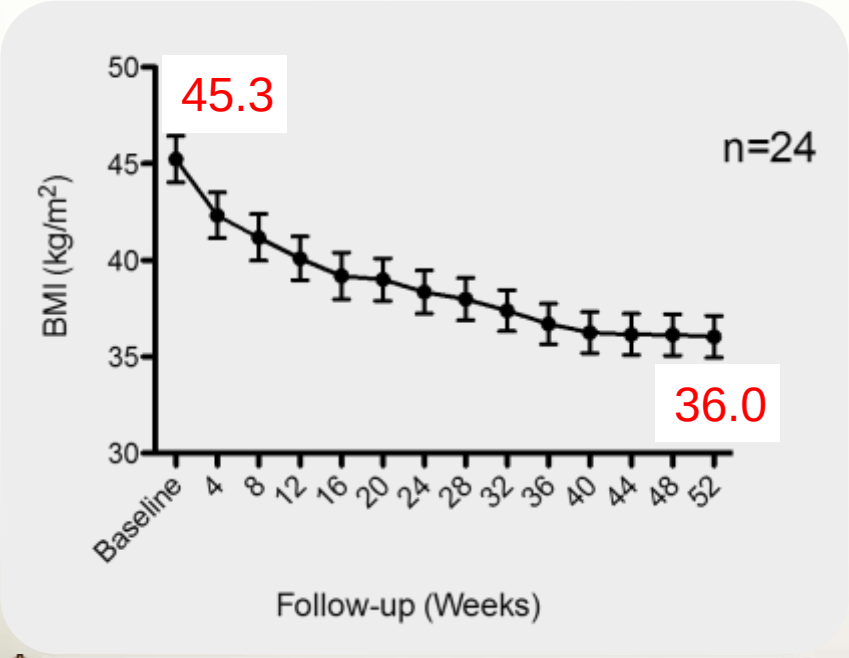
EndoBarrier™ Liner Weight Loss

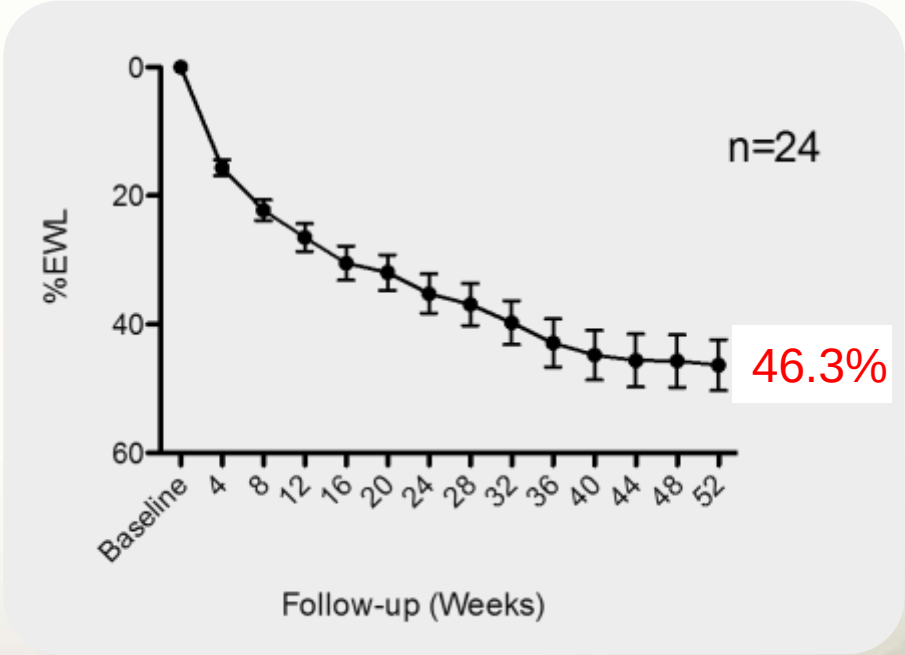


EndoBarrier Weight Loss Results

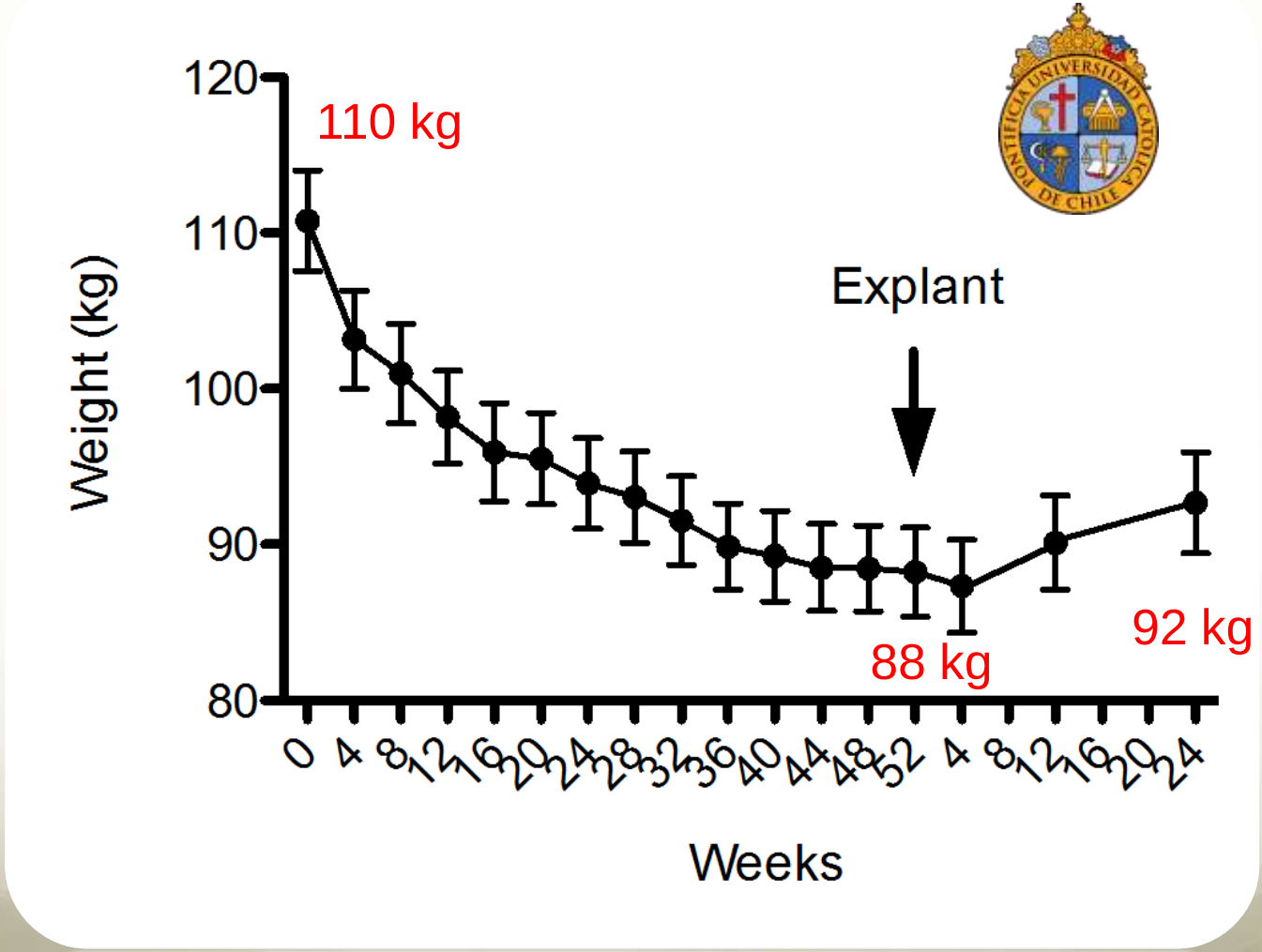


Weigh loss – 1y





Post-explant weight pattern



ENDOSCOPIC DUODENOJEJUNAL BYPASS WITH GI SLEEVE

DIABETES TREATMENT RESULTS

EndoBarrier™ Liner T2DM treatment

First study

Dipreca Hospital

Dr Leonardo Rodrigez, Phd

American Diabetes Association.

Cure • Care • Commitment®

EndoBarrier Linner

DIA-2009-0063-Rodriguez_
Type: original-artic

DIABETES TECHNOLOGY & THERAPEUTICS
Volume 11, Number 11, 2009

DOI: 10.1089/dia.2009.0063

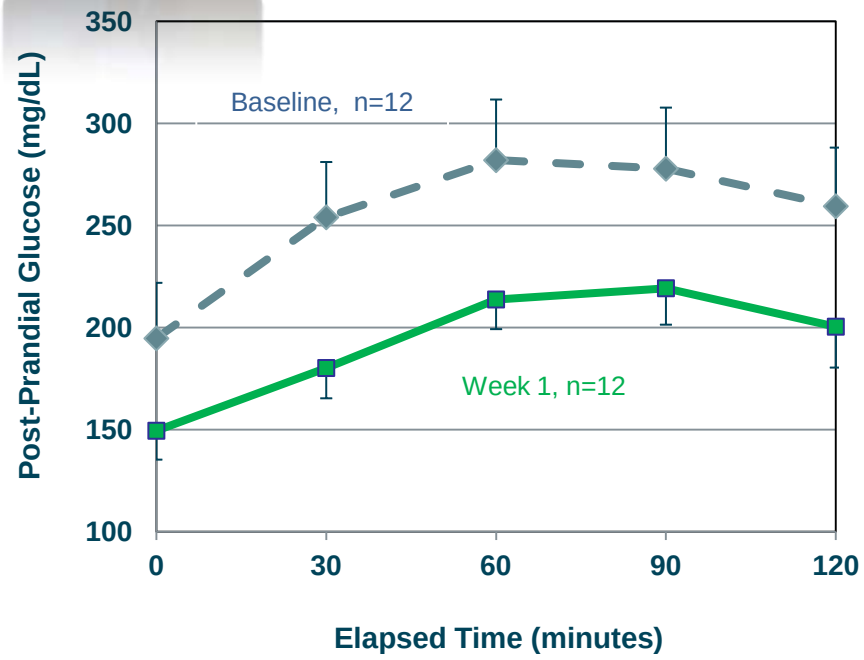
Pilot Clinical Study of an Endoscopic, Removable Duodenal-Jejunal Bypass Liner for the Treatment of Type 2 Diabetes

Leonardo Rodriguez, M.D., M.B.S.,[1] Eliana Reyes, M.D.,[1] Pilar Fagalde, M.D.,[1] Maria Soledad Oltra, M.D.,[1] Jorge Saba, M.D.,[1] Carmen Gloria Aylwin, M.D.,[1] Carolina Prieto, M.D.,[1] Almino Ramos, M.D., M.B.S.,[2] Manoel Galvao, M.D., M.B.S.,[2] Keith S. Gersin, M.D.,[3] and Christopher Sorli, M.D.[4]

Rodriguez MD....Ramos A , Galvao Neto M et al.

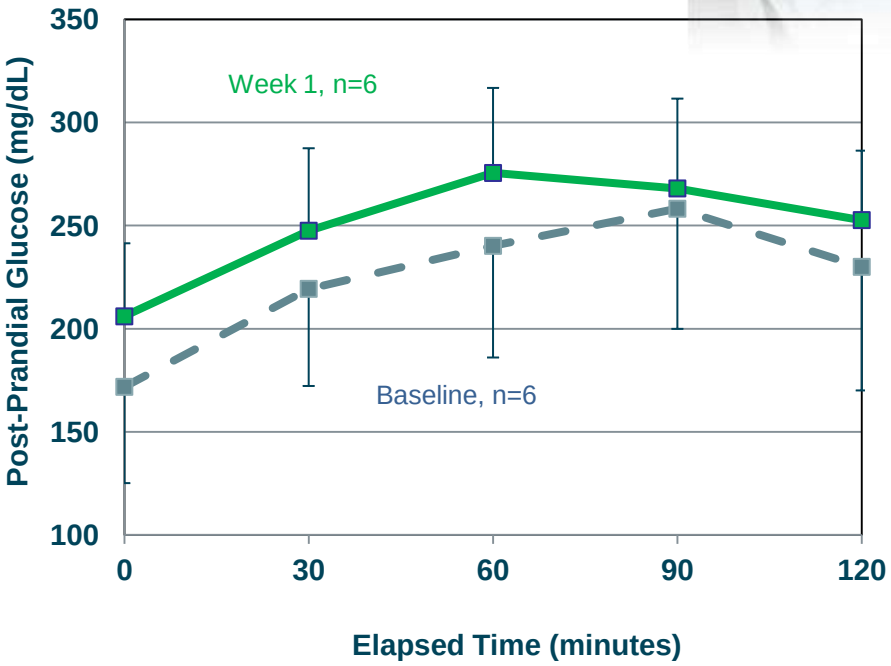
EndoBarrier Liner

EndoBarrier Subjects



AUC *decreased* by 19.1% at Week 1

Sham Subjects



AUC *increased* by 10.8% at Week 1

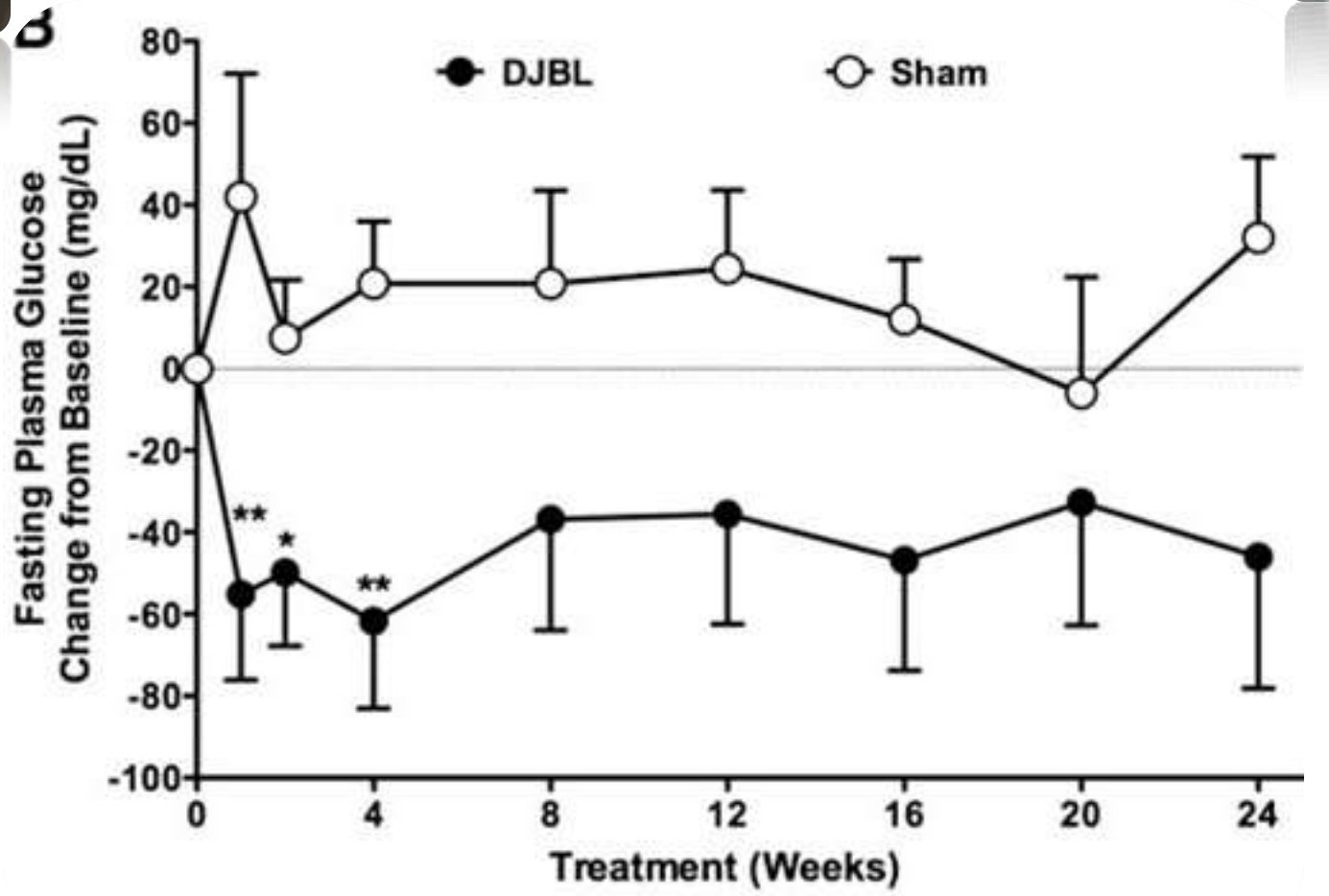
p=0.014

Data Presented at ADA Annual Meeting, June 2008

Rodriguez MD... Ramos A , Galvao Neto M et al.

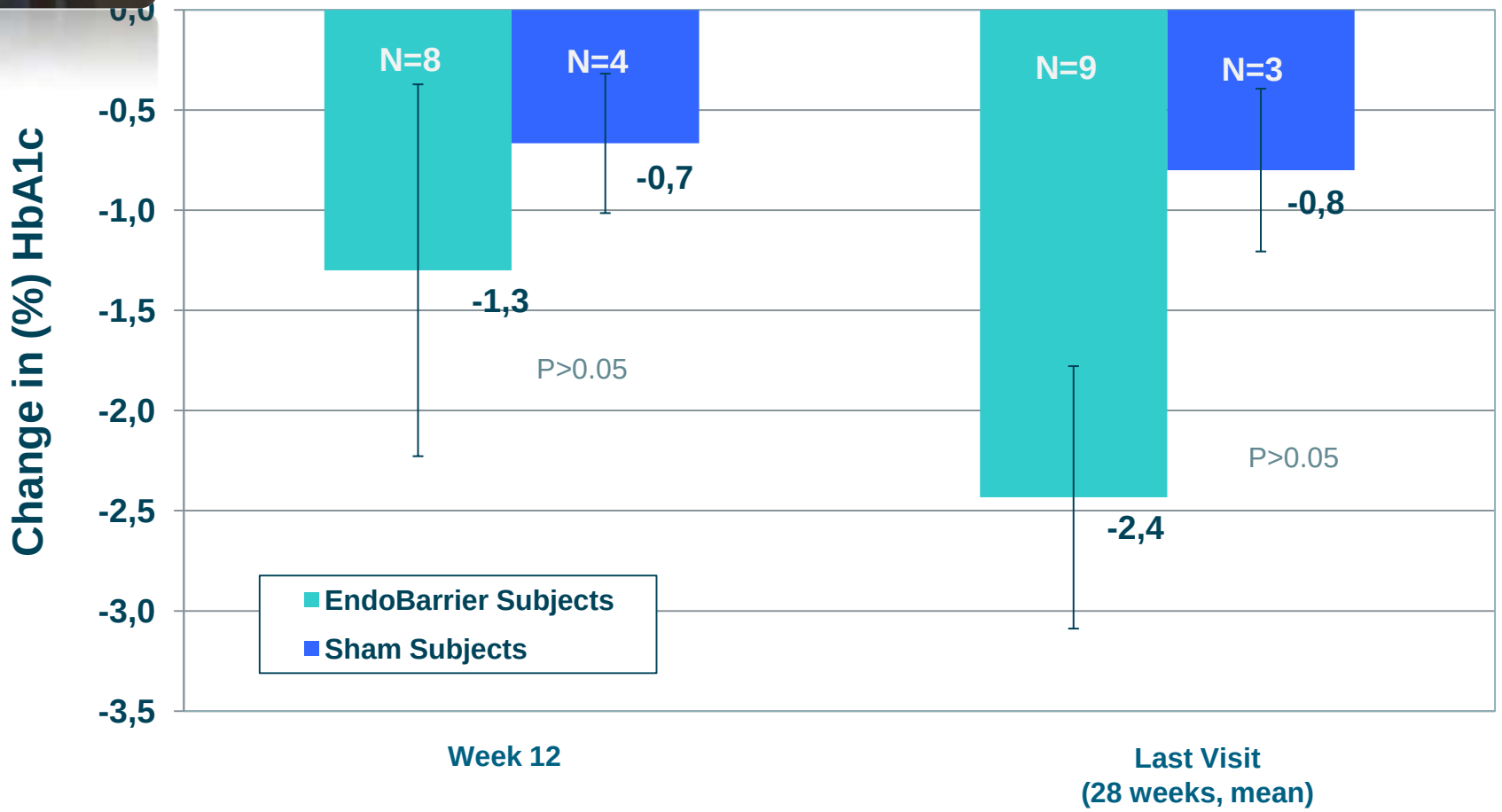
Fasting Glucose Glucose

Glucose Results



EndoBarrier Gastrointestinal Liner

Baseline %HbA1c= 9.2 for EndoBarrier and 9.0 for Sham



Data Presented at ADA Annual Meeting, June 2008

Rodriguez MD, Ramos A , Galvao Neto M et al.

EndoBarrier™ Liner T2DM treatment

Second study

São Paulo University

Dr Eduardo Moura, Phd

Chicago, IL, USA, 2011

The EndoBarrier Gastrointestinal Liner

OBES SURG
DOI 10.1007/s11695-011-0387-0

CLINICAL RESEARCH

Improvement of Insulin Resistance and Reduction of Cardiovascular Risk Among Obese Patients with Type 2 Diabetes with the Duodenojejunal Bypass Liner

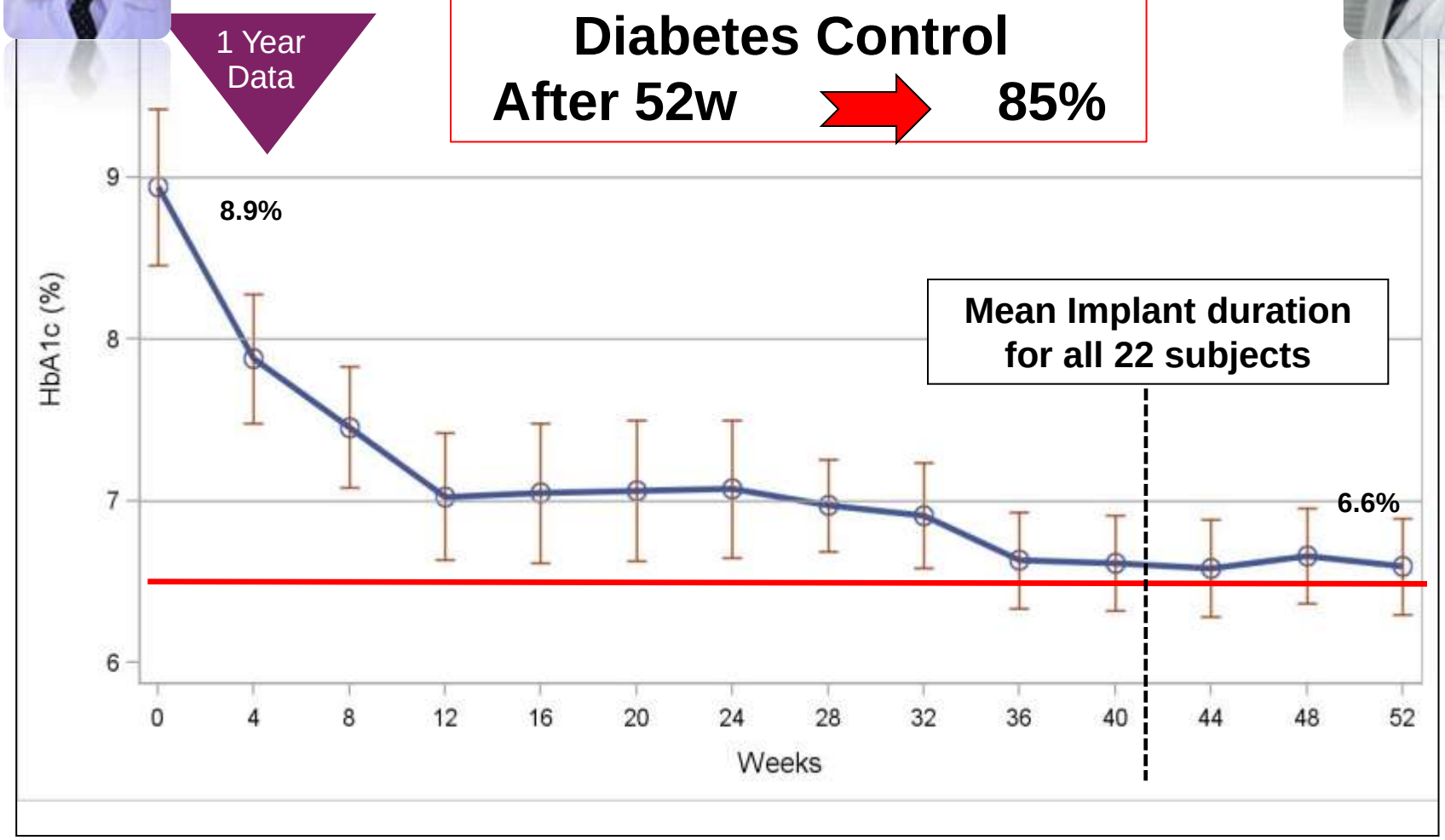
Eduardo Guimarães Hourneaux de Moura · Ivan Roberto Bonotto Orso · Bruno da Costa Martins · Guilherme Sauniti Lopes · Suzana Lopes de Oliveira Manoel dos Passos Galvão-Neto · Marcio Correa Mancini · Marco Aurélio Sant Paulo Sakai · Almino Cardoso Ramos · Arthur Belarmino Garrido-Júnior · Alfredo Halpern · Ivan Cecconello

Moura EGH PhD... Ramos A , Galvao Neto M et al.

Studied T2DM pts BMI 35 to 70

1 Year Data

Diabetes Control
After 52w → 85%



Moura EGH PhD....Ramos A , Galvao Neto M et al.

	Baseline	52 weeks	p value
Weight (kg)	125.4 ± 28.3	105.0 ± 20.5	**<.0001**
BMI (kg/m^2)	45.9 ± 9.2	38.5 ± 6.7	**<.0001**
Waist circumference (cm)	134.9 ± 18.0	124.8 ± 15.4	**<.0001**
Blood pressure (mmHg) Systolic Diastolic	 130.9 ± 10.4 80.0 ± 6.3	 129.6 ± 18.1 78.0 ± 10.6	 **0.83** **0.60**
Total cholesterol (mg/dl) HDL LDL Triglycerides	206.5 ± 36.5 40.4 ± 7.6 124.5 ± 27.8 228.1 ± 98.3	179.5 ± 32.0 38.2 ± 7.8 110.1 ± 19.2 157.3 ± 47.9	**0.001** **0.38** **0.01** **<.001**
Glucose (mg/dl)	175.6 ± 49.5	126.7 ± 40.5	**<.0001**
Insulin (mg/dl)	23.6 ± 18.3	10.9 ± 5.2	**0.016**
HOMA IR	9.6 ± 7.1	4.6 ± 8.6	**<.0001**
HbA1c (%)	8.8 ± 1.7	6.4 ± 1.0	**0.001**

EndoBarrier™ Liner T2DM treatment

Third study

Osvaldo Cruz Hospital

Dr Ricardo Cohen, Phd

ASBMS / IFSO award
international best oral presentation

JCEM ONLINE

Brief Report—Endocrine Care

A Pilot Study of the Duodenal-Jejunal Bypass Liner in Low Body Mass Index Type 2 Diabetes

Ricardo Vitor Cohen, Manoel Galvão Neto, Jose Luis Correa, Paulo Sakai, Bruno Martins, Carlos Aurélio Schiavon, Tarissa Petry, Joao Eduardo Salles, Cristina Mamedio, and Christopher Sorli

The Center of Excellence of Metabolic and Bariatric Surgery (R.V.C., J.L.C., C.A.S., T.P., J.E.S.), Biomedical Research Unit (C.M.), Department of Endoscopy (B.M., P.S.), Hospital Oswaldo Cruz, São Paulo, SP 01323-903, Brasil; Gastro Obeso Center (M.G.N.), São Paulo, SP 01308-000, Brasil; and Diabetes Clinic (C.S.), Billings Hospital, Billings, Montana 59101

EndoBarrier™ Liner T2DM treatment

- Low BMI - T2DM
- Non-randomized, single arm
- Single Center
  - Oswaldo Cruz (Sao Paulo, Brazil)

- Planned duration - 52 weeks with a 1 year follow-up period
- BMI: 26-50
- 1 week liquid diet followed by institution's Bariatric standard of care diet

Ricardo Cohen, MD, Galvao Neto, MD

Subject Disposition

- 23 enrolled
- 20 implanted
- Mean implant duration 45 weeks
- 16 completed 1 year with implant
- 4 early removals
  - 1 Non-device related
    - Month 3, non-compliance with study visits
  - 3 Device related
    - 2 @ months 6 and 10, device migration
    - 1 @ month 7, GI Distress (abdominal pain)

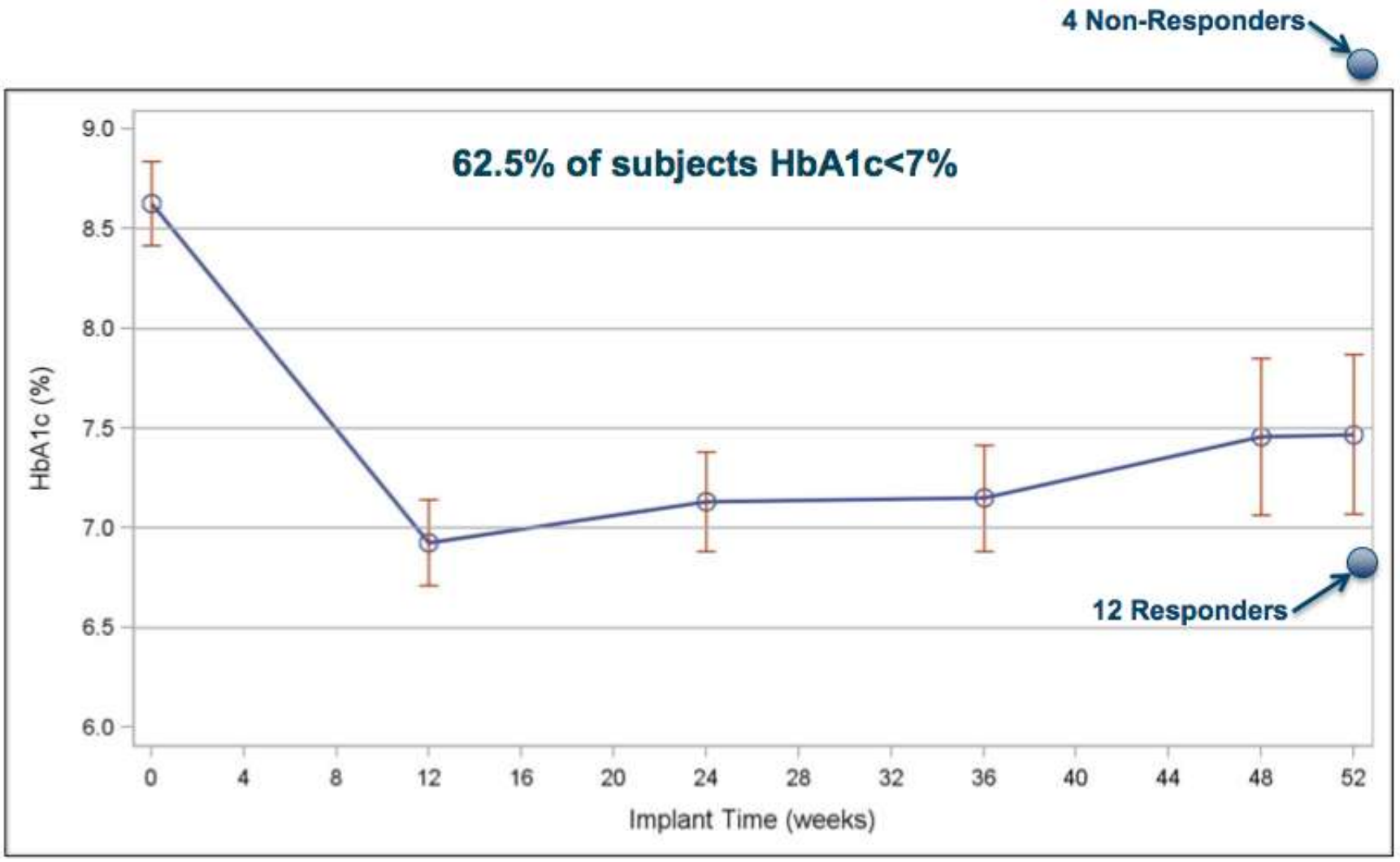
Ricardo Cohen, MD, Galvao Neto, MD

Baseline Demographics

	(N=20)
Age (years)	
Mean (Min, Max)	49.8 (35.3, 62.1)
Gender, n (%)	
Male	13 (65.0)
Female	7 (35.0)
BMI (kg/m^2)	
Mean (Min, Max)	30.0 (22.8, 35.7)
HbA1c (%)	
Mean (Min, Max)	8.7 (7.4, 10.2)
Glucose Lowering Meds, n (%)	
Mono therapy	4 (20.0)
Combination oral therapy	16 (80.0)
Duration of Diabetes (yrs)	
Mean (Min, Max)	6.6 (2.0, 10.0)

Glycemic Control

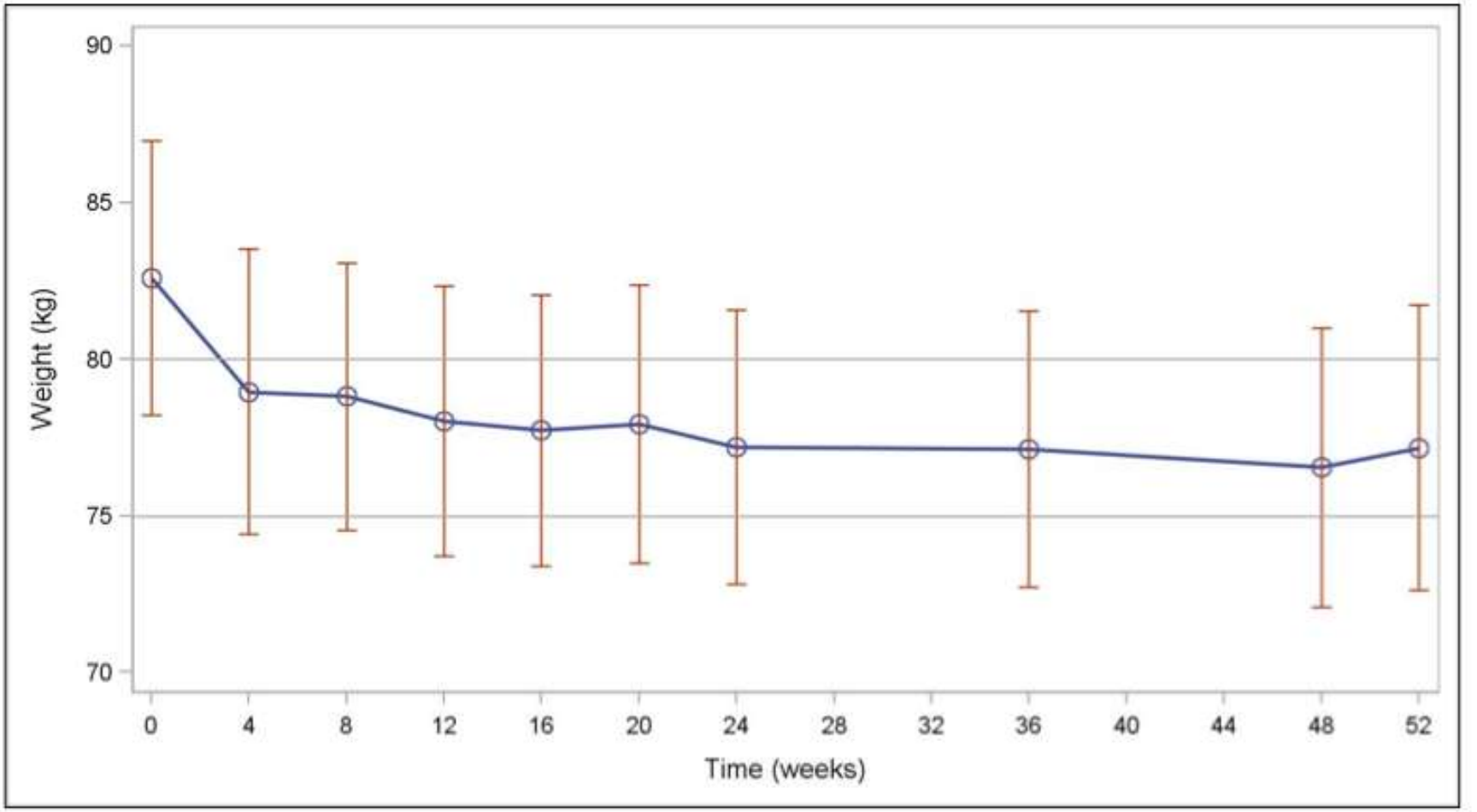
Completers



Ricardo Cohen, MD, Galvao Neto, MD

Weight Loss

Completers



Ricardo Cohen, MD, Galvao Neto, MD

Cardio-Metabolic Risk Factors

n=15 completers*

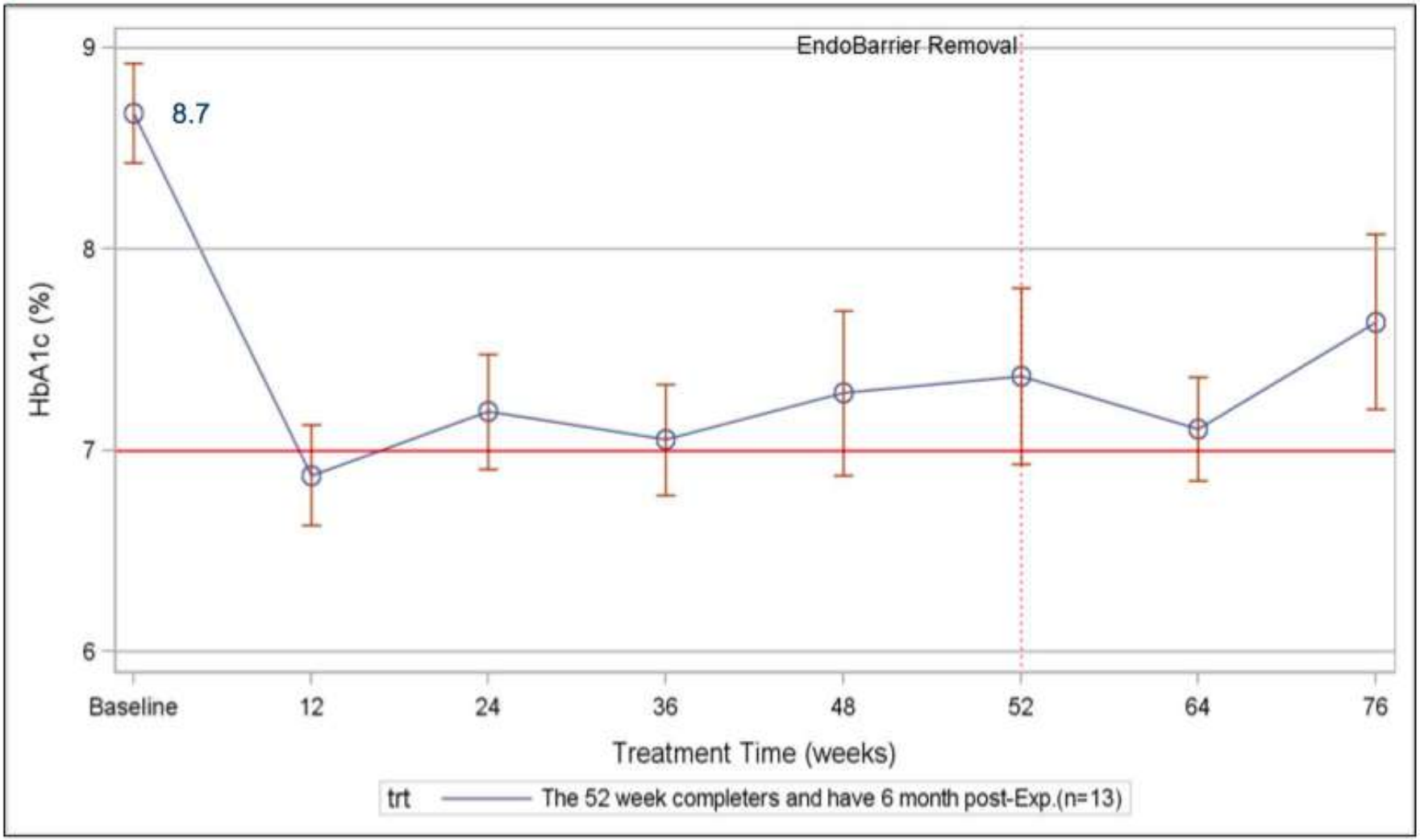
	Baseline	1 Year
Weight (kg)	83.6 ± 4.6	77.2 ± 4.6
Total cholesterol (mg/dl)	218.0 ± 12.7	189.3 ± 8.4
LDL (mg/dl) **	134.7 ± 11.5	111.1 ± 7.5
Triglycerides (mg/dl)	223.6 ± 31.2	195.9 ± 34.1
Glucose (mg/dl)	198.7 ± 15.6	148.5 ± 12.1
HbA1c (%)	8.6± 0.2	7.3 ± 0.4

* Data not available for 1 completer at 1 year

**LDL data only available for n=13 at baseline

Ricardo Cohen, MD, Galvao Neto, MD

# Post-Explant Glycemic Control
n=13



Ricardo Cohen, MD, Galvao Neto, MD

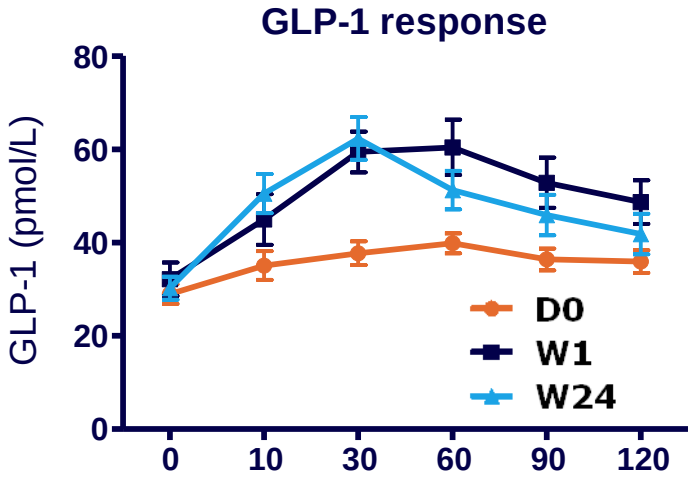
EndoBarrier™ Liner T2DM treatment

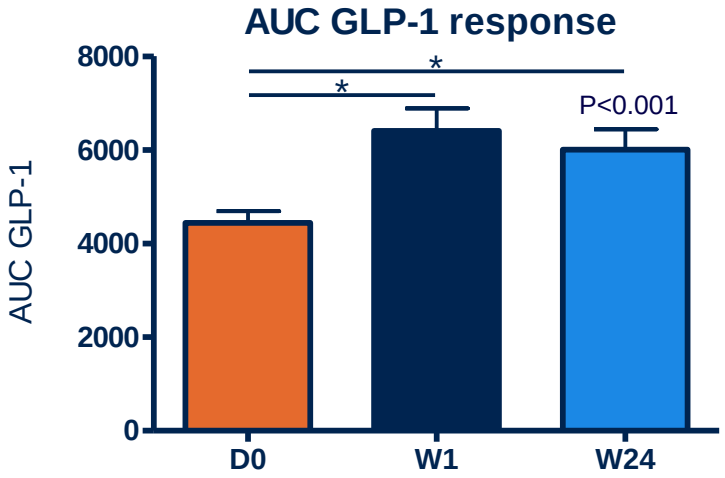
Fourth study

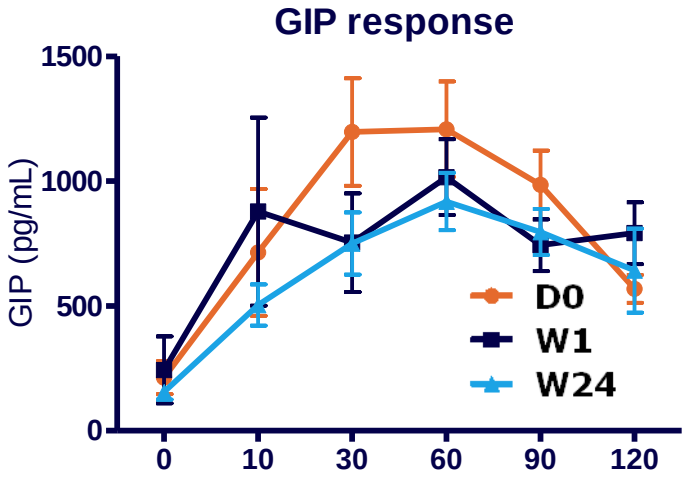
Netherlands

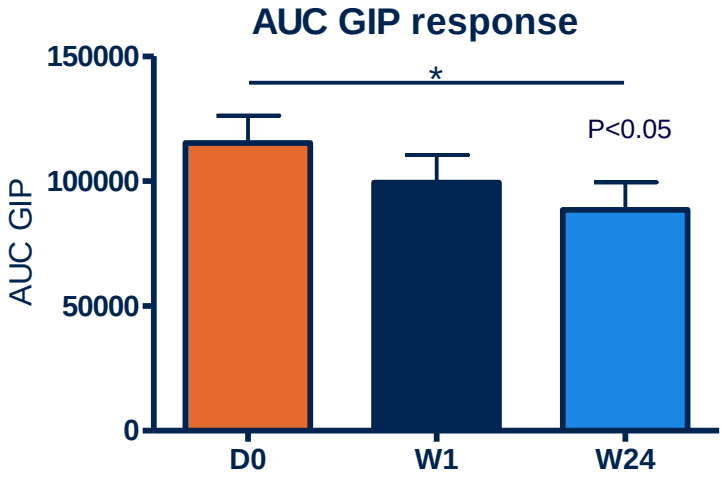
Dr Verban F. J, MD

EndoBarrier™ Liner T2DM treatment



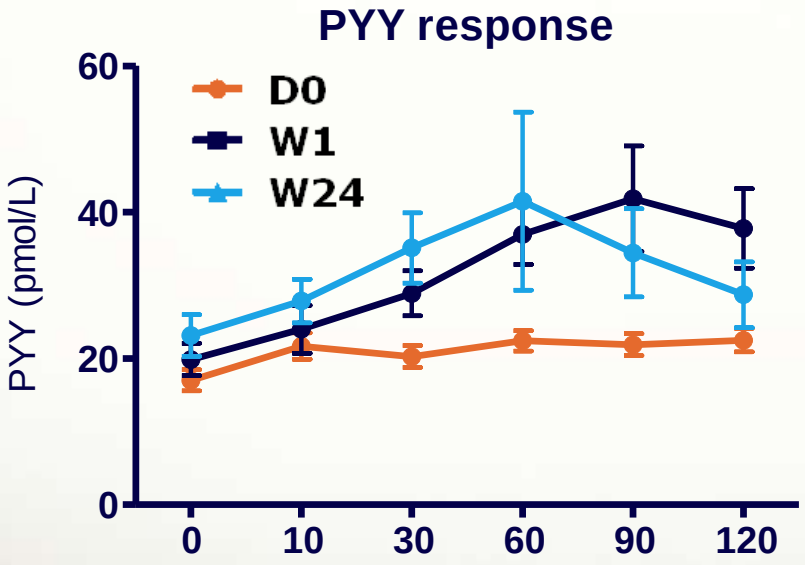


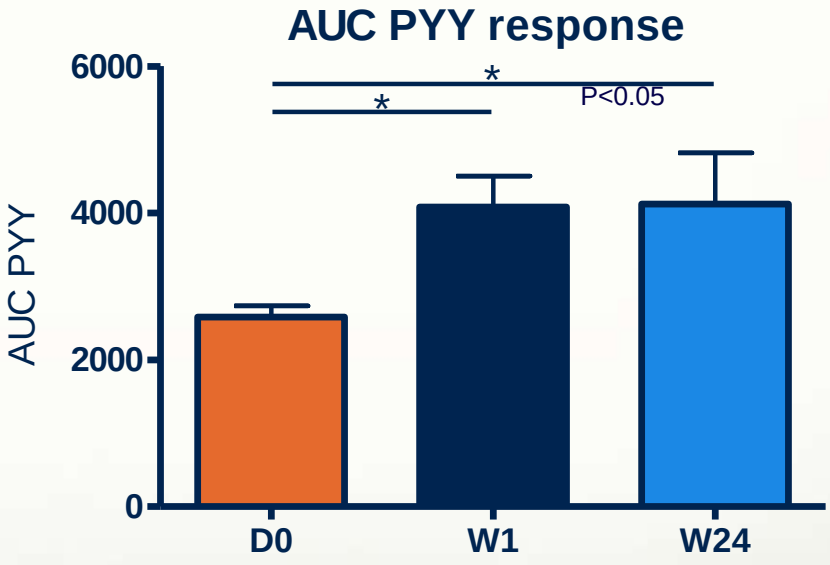




Verban F. J, MD, Greeve J., PhD

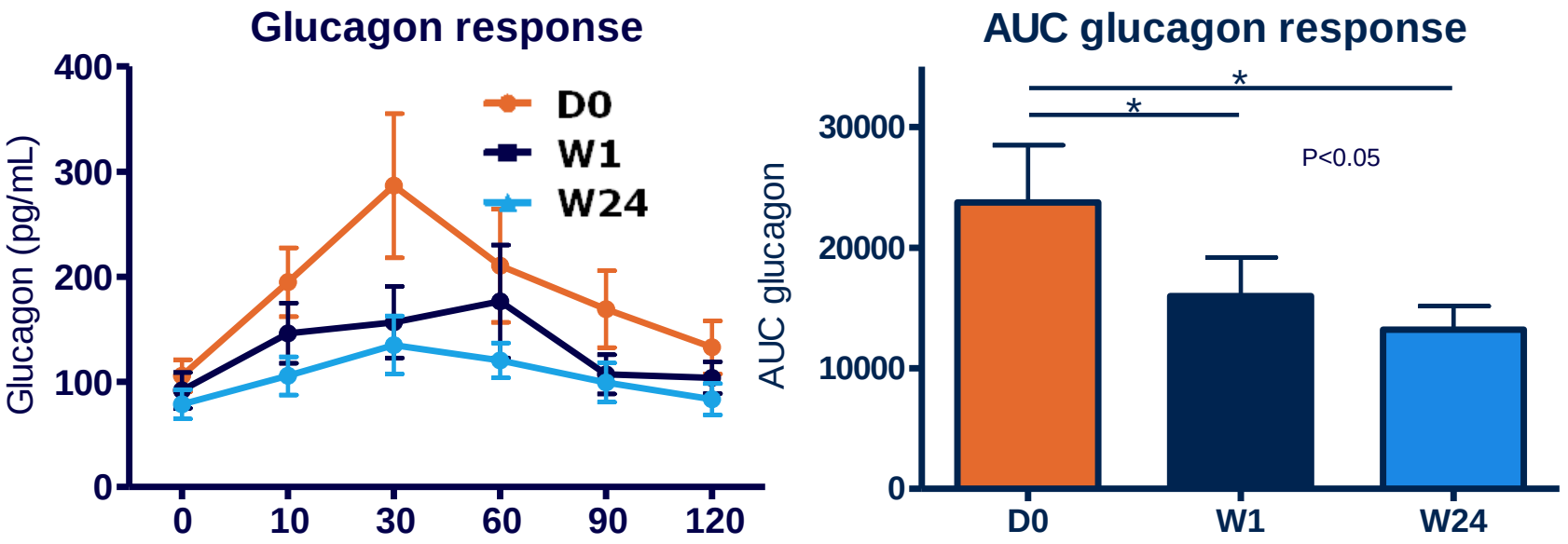
PYY Response





D0=pre-implantation

Glucagon Response



D0= pre-implantation

EndoBarrier up to 2y…

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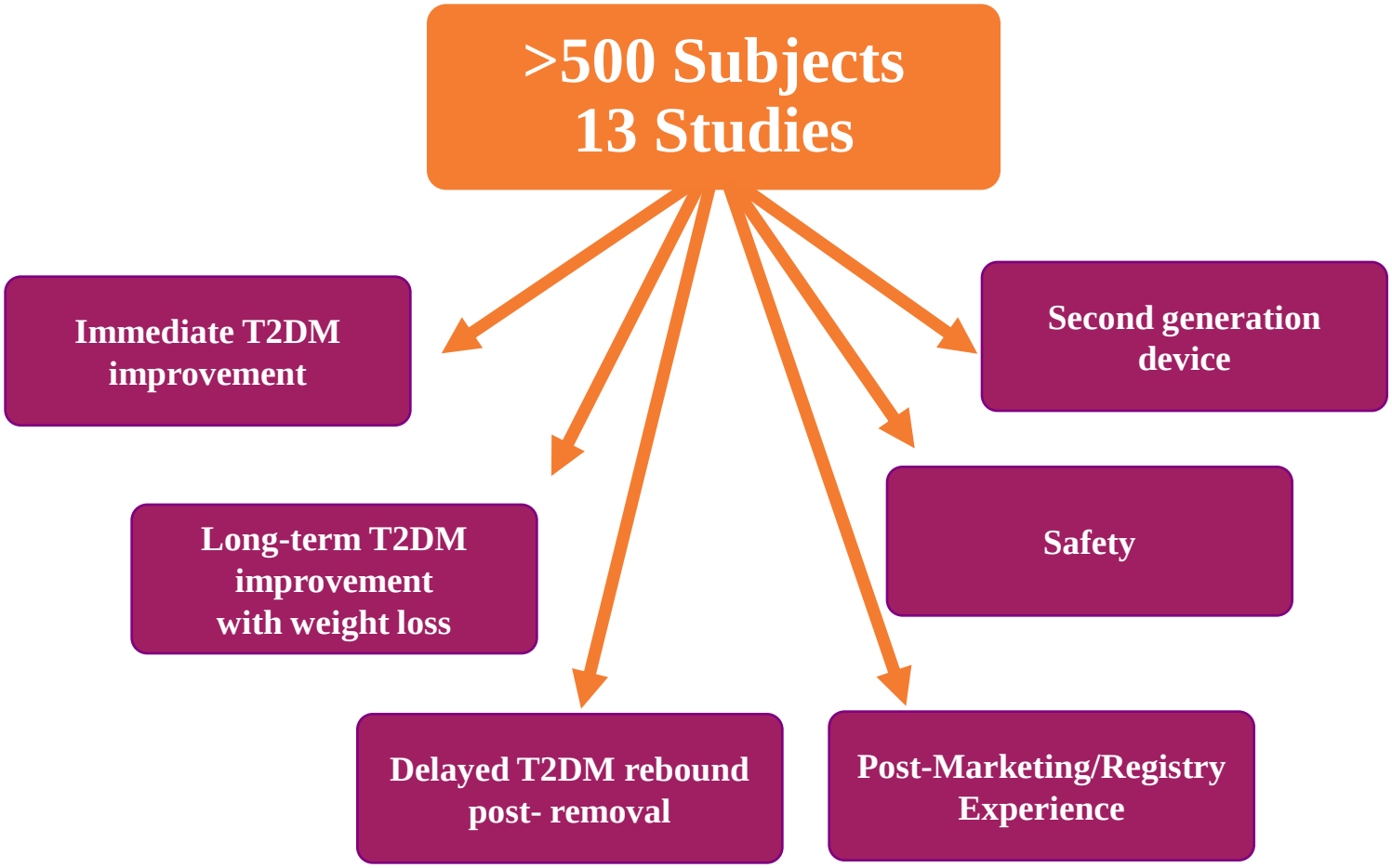
Adverse Events

- All devices removed endoscopically
- 2 major complications
- No mortality
- Common Events
  - Nausea, vomiting, abdominal pain
- Rare Adverse Events
  - GI hemorrhage, dehydration, constipation, diarrhea, hypoglycemia, vitamin or mineral deficiencies, liner obstruction

EndoBarrier Experience



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Endoscopic treatment of obesity

New technologies

"NEVER FULL"

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WHAT FIRST COMES TO MIND

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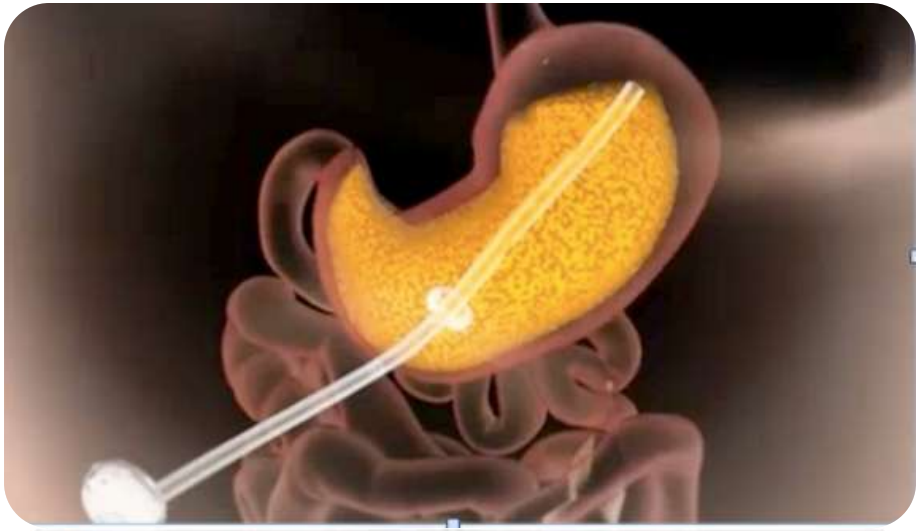

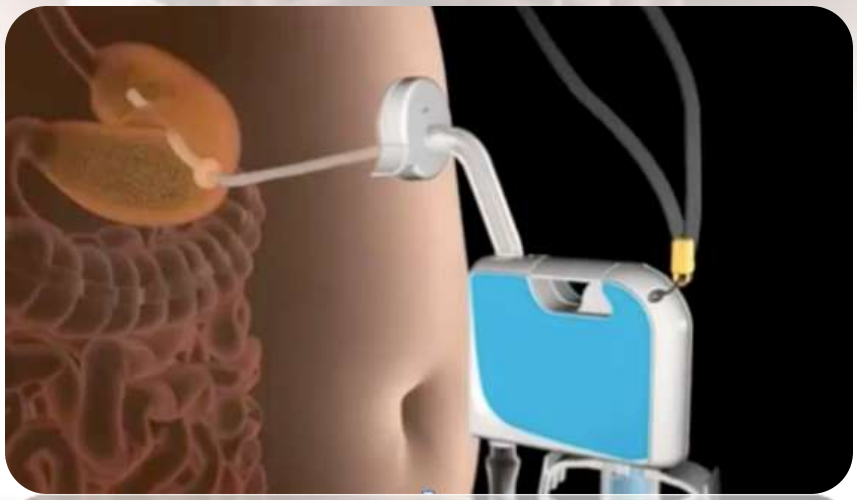

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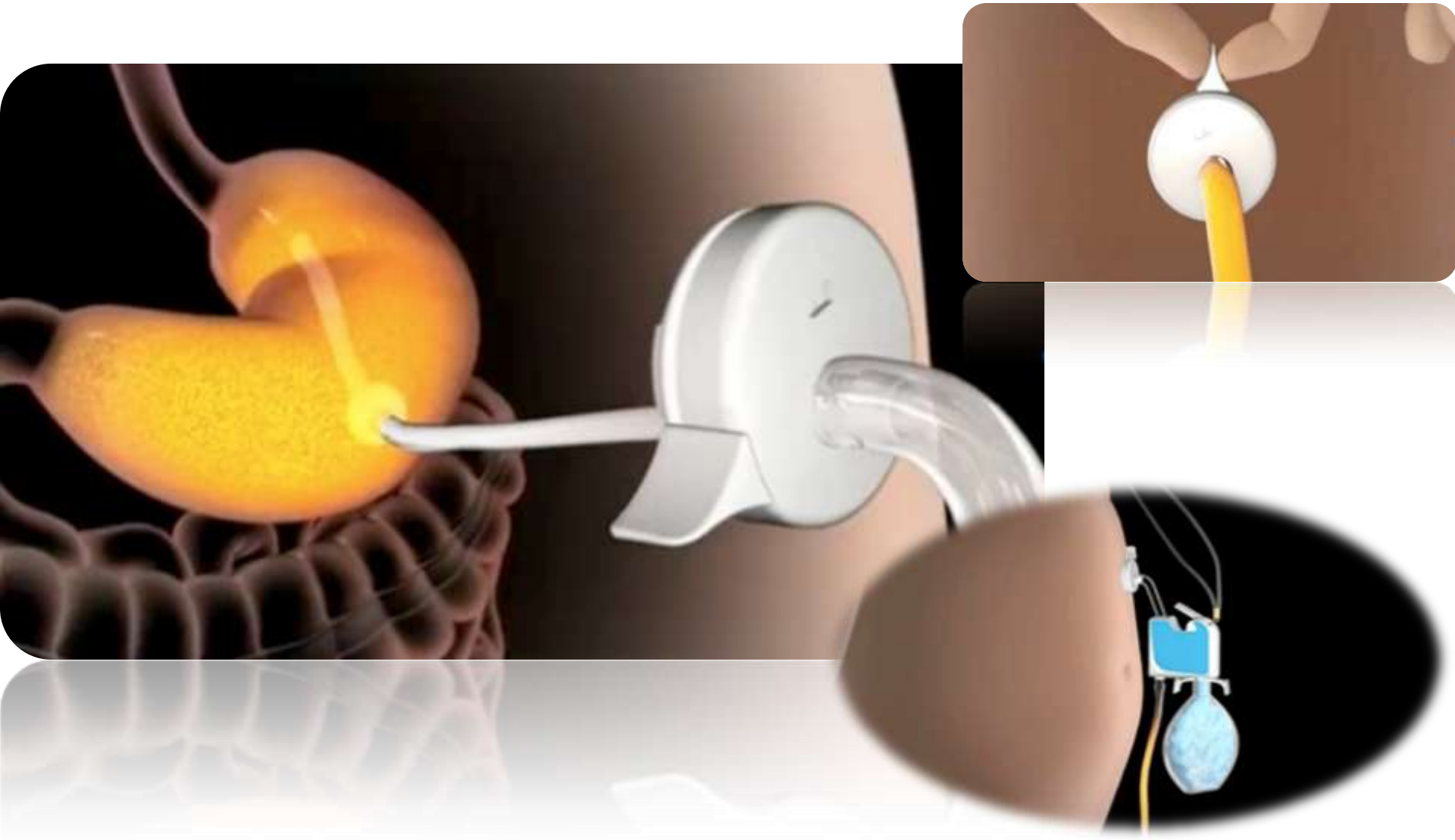

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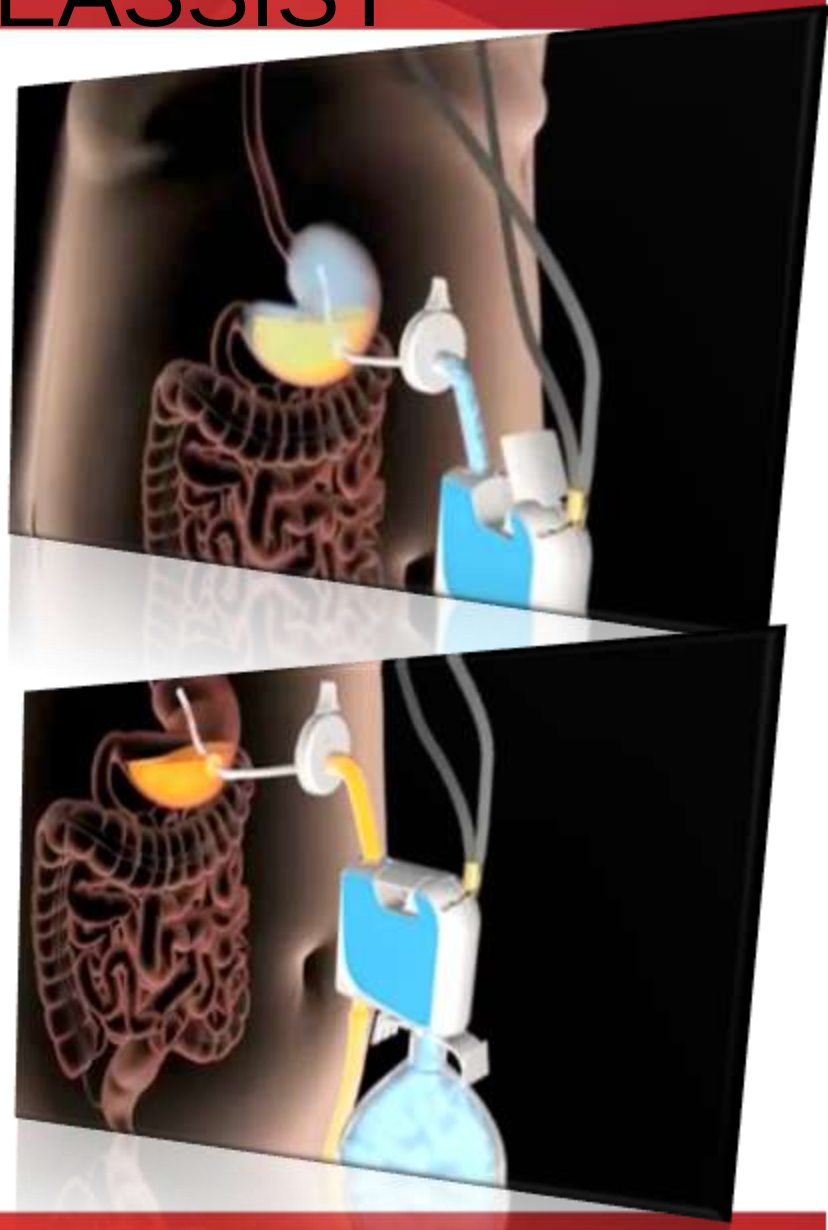

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Washington University School of Medicine

Aspiration Therapy For Treating Obesity: A Randomized Controlled Trial of a Novel Endoscopic Therapy

[1,2]Shelby Sullivan, [1]Steven Edmundowicz, [2]Richard Stein, [1]Sreenivasa Jonnalagadda, [1]Daniel Mullady, and [2]Samuel Klein *
[1]Division of Gastroenterology, [2]Center for Human Nutrition, Washington University School of Medicine, St. Louis, Missouri USA

Abstract

Background: Successful weight loss is difficult to achieve with lifestyle intervention. Bariatric surgery is the most effective therapy but can cause serious complications. We evaluated the use of a novel endoscopic therapy as a treatment for obesity.

Methods: Eighteen subjects were randomized in a 2:1 ratio to 52 weeks of Aspiration Therapy plus lifestyle intervention (AT) (BMI=42.0±4.7 kg/m²) or lifestyle intervention alone (LIA) (BMI=43.4±5.3 kg/m²). AT involves endoscopic placement of a novel gastrostomy tube (A-Tube™) and siphon assembly (Aspire Bariatrics, King of Prussia, PA), which are used to aspirate gastric contents 20 min after meal consumption. This procedure takes 5-10 min and removes ~40% of ingested calories. Lifestyle intervention was provided as a 15-session diet and behavioral education program to both groups.

Results: Ten of 11 AT and 4 of 7 LIA subjects completed the 52-wk study. Among completers, AT and LIA subjects lost 20.6 ± 7.6% (49.0±24.4 percent excess weight loss [%EWL]) and 5.9±10.0% (14.9±24.6 %EWL) body weight, respectively (p<0.04). An intention-to-treat analysis did not change the statistical significance of the findings. No serious adverse events occurred. Adverse events reported included abdominal discomfort, constipation/diarrhea, and decreased serum Fe/anemia, which resolved with treatment. A battery of psychological and eating assessments did not detect adverse effects of AT on mood, eating behavior, attitudes towards eating, or perceived hunger/satiety, and there was no evidence of compensation for aspirated calories by increasing food intake.

Conclusions: The results from this pilot study demonstrate the potential of AT as a safe and effective approach for treating obesity.

Background

Successful weight loss is difficult to achieve in obese people. Bariatric surgery is the most effective available therapy, but can cause serious medical complications and is expensive.

Percutaneous Endoscopic Gastrostomy has been used safely for more than 30 years to feed patients who cannot eat. Therefore, this technology provides an opportunity to facilitate weight loss by accessing the stomach and removing gastric contents after eating before digestion and absorption occurs.

Aim

The purpose of this pilot study was to conduct a randomized controlled trial to test the hypothesis that decreasing calorie intake by aspirating gastric contents after meals through a modified gastrostomy tube (A-tube), in conjunction with lifestyle therapy, will result in greater weight loss than lifestyle therapy alone.

Figure 1. A-Tube Schematic

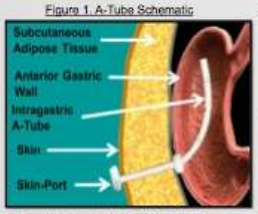
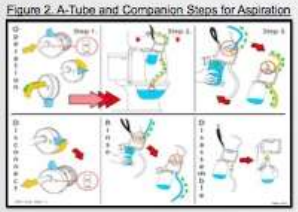


Figure 2. A-Tube and Companion Steps for Aspiration



*Dr. Sam Klein is a shareholder of Aspire Bariatrics.

Methods

- Subjects were randomized 2:1 (Aspiration Therapy n = 11:Lifestyle Intervention alone n = 7)
- The A-Tube was successfully placed endoscopically in all 11 subjects. Tube conversion to the skin port and instruction on use of the siphon assembly was done 12-14 days after A-Tube placement. Aspiration Therapy subjects were also treated with a proton pump inhibitor and potassium supplement to prevent hypokalemia.
- All subjects participated in a 12-month Lifestyle Intervention program, which included low calorie diet counseling and 15 individual behavioral education sessions covering topics on self monitoring, goal setting, stimulus control, physical activity, stress management and relapse prevention.
- Excess weight is defined as total body weight minus weight at BMI 25.0 kg/m² .
- Successful weight loss was defined as achieving 25% excess weight loss.

Results

Ten of 11 subjects in the Aspiration Therapy group and 4 of 7 subjects in the Lifestyle Intervention group completed the 12-month study and were included in the analyses.

Table 1. Subject Demographic and Clinical Characteristics

	Lifestyle Intervention	Aspiration Therapy
Number (M/F)	4 (1/3)	10 (0/10)
Age (years)	45.3 ± 5.7	38.7 ± 7.1
Weight (kg)	105.3 ± 5.0	112.2 ± 14.5
BMI (kg/m²)	39.3 ± 2.2	42.0 ± 4.4

Figure 3. A-Tube skin port

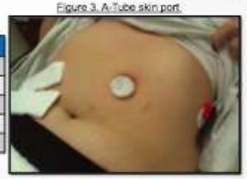


Figure 4. Percent Excess Weight Loss at 52 weeks

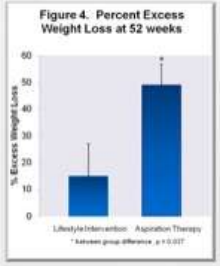


Figure 5. Percent Absolute Weight Loss at 52 weeks

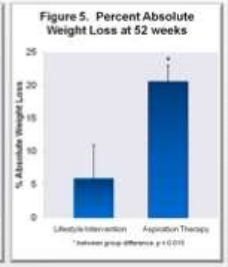
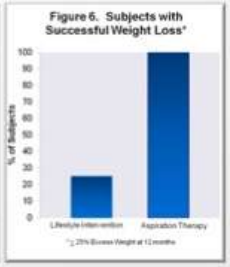


Figure 6. Subjects with Successful Weight Loss*



Results

Figure 7. Percent Excess Weight Loss at 6 and 12 months

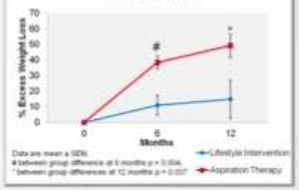


Table 2. Adverse Events in Subjects Randomized to Aspiration Therapy*

Adverse Event	Subjects Affected
Pain <4 wks after placement	11
Pain > 4 wks after placement	10
Peristomal irritation	6
Constipation	8
Peristomal bleeding	5
Peristomal infection	2
Anemia	4
Insomnia	1

* All adverse events resolved with observation or conservative treatment.

Eating Disorder Examination

•The Eating Disorder Examination (EDE) is a semi-structured interview that was used to assess the main diagnostic, behavioral, and cognitive features of eating disorders.

•Aspiration therapy did not induce binge eating or purging behaviors or avoidance of eating in any participant.

•Body weight and shape did not become more important after treatment in either group, whereas discomfort seeing one's body improved (p = 0.012), and discomfort exposing body shape to others improved (p = 0.004) in the Aspiration Therapy group.

Table 3. Eating Disorder Examination at baseline and change with the Intervention

	Baseline		Change	
	Lifestyle Intervention	Aspiration Therapy	Lifestyle Intervention	Aspiration Therapy
Avoidance of Eating	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
Avoidance of Exposure	2.0 ± 1.4	2.4 ± 1.7	0.2 ± 2.2	-2.0 ± 1.7*
Desired Weight	145.2 ± 7.3	156.6 ± 11.3	-0.9 ± 10.4	-4.3 ± 11.5
Dietary Rules	0.0 ± 0.0	0.6 ± 1.9	0.7 ± 1.5	0.6 ± 1.9
Discomfort Seeing Body	2.7 ± 0.8	1.8 ± 1.8	-1.2 ± 2.0	-1.8 ± 1.8 #
Eating in Secret	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
Empty Stomach	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
Guilt About Eating	0.7 ± 0.9	0.3 ± 0.5	-0.7 ± 0.9	-0.3 ± 0.9
Importance of Shape	2.5 ± 0.5	2.7 ± 1.7	-0.2 ± 2.4	-0.5 ± 1.8
Importance of Weight	2.2 ± 0.5	2.6 ± 1.7	0.2 ± 1.7	-0.6 ± 1.6
Preoccupation with food	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0
Reaction to weighing	0.0 ± 0.0	0.0 ± 0.0	0.7 ± 1.5	0.4 ± 0.7
Social eating	0.2 ± 0.8	0.2 ± 0.4	0.0 ± 0.8	-0.2 ± 0.4

Conclusions

The results from this pilot study demonstrate the potential of Aspiration Therapy in conjunction with lifestyle intervention as a safe and effective approach for treating obesity.

These results suggest that psychosocial factors are important drivers of food intake in obese people, rather than a physiological signal for more calories or true "hunger" to meet a specific set point. Removing food contents after eating allowed our subjects to satisfy their drive to eat without the consequence of excessive energy absorption.

This study was funded by Aspire Bariatrics

poster presentation of this study from The Obesity Society (October 3, 2011)*

http://www.aspirebariatrics.com

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Samuel Klein, MD

Board Member

Dr. Sam Klein, co-founder of Aspire, is the William H. Danforth Professor of Medicine, Director of the Center for Human Nutrition, Director of the Center for Applied Research Sciences, Chief of the Division of Geriatrics and Nutritional Sciences, and Medical Director of the Weight Management Program at Washington University School of Medicine in St. Louis, Missouri. Dr. Klein received an MD degree from Temple University Medical School in 1979 and an MS degree in Nutritional Biochemistry and Metabolism from the Massachusetts Institute of Technology in 1984. He completed residency training in Internal Medicine and a Clinical Nutrition fellowship at University Hospital in Boston, a National Institutes of Health Nutrition and Metabolism Research fellowship at Harvard Medical School, and a Gastroenterology fellowship at The Mt. Sinai Hospital in New York. He is board certified in Internal Medicine, Gastroenterology, and Nutrition.

Dr. Klein is past-president of the North American Association for the Study of Obesity and the American Society for Clinical Nutrition, and initial chair of the Integrative Physiology of Obesity and Diabetes NIH study section. He was elected to the American Society for Clinical Investigation in 1996 and to the American Association of Physicians in 2008. Dr. Klein has had consistent R01 funding from the National Institutes of Health since 1990, and has published more than 300 papers in nutrition, metabolism, and obesity. He has received several awards for his research, including the American Gastroenterological Association (AGA) Miles and Shirley Fiterman Foundation Award in Nutrition, the AGA Masters Award for Outstanding Achievement in Basic or Clinical Research in Digestive Sciences, The Obesity Society TOPS Research Achievement Award and the Daniel P. Schuster Distinguished Investigator Award in Clinical and Translational Science from Washington University School of Medicine.

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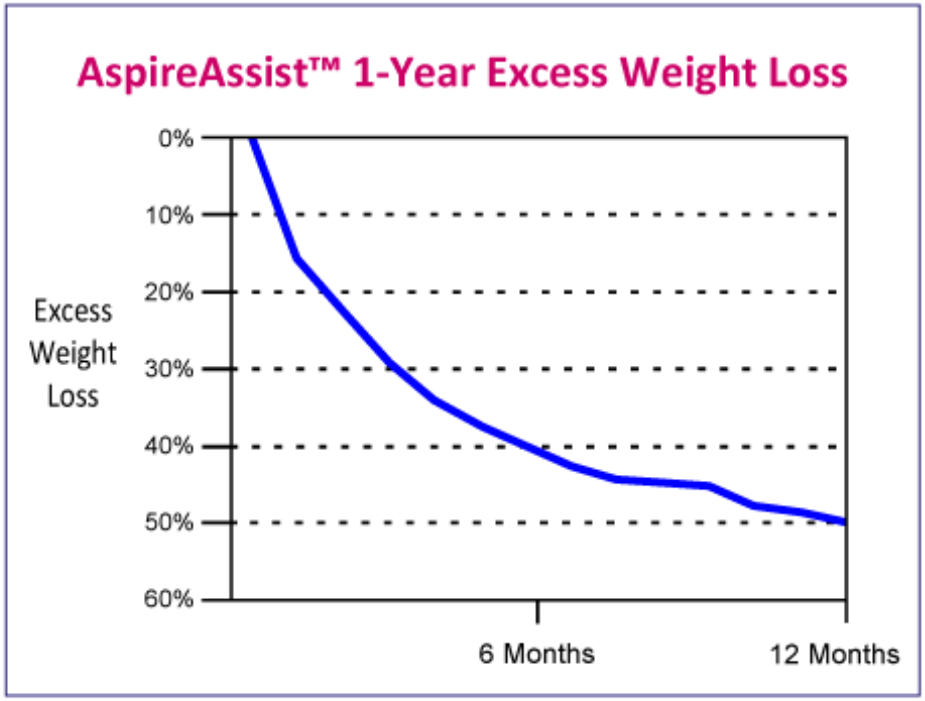

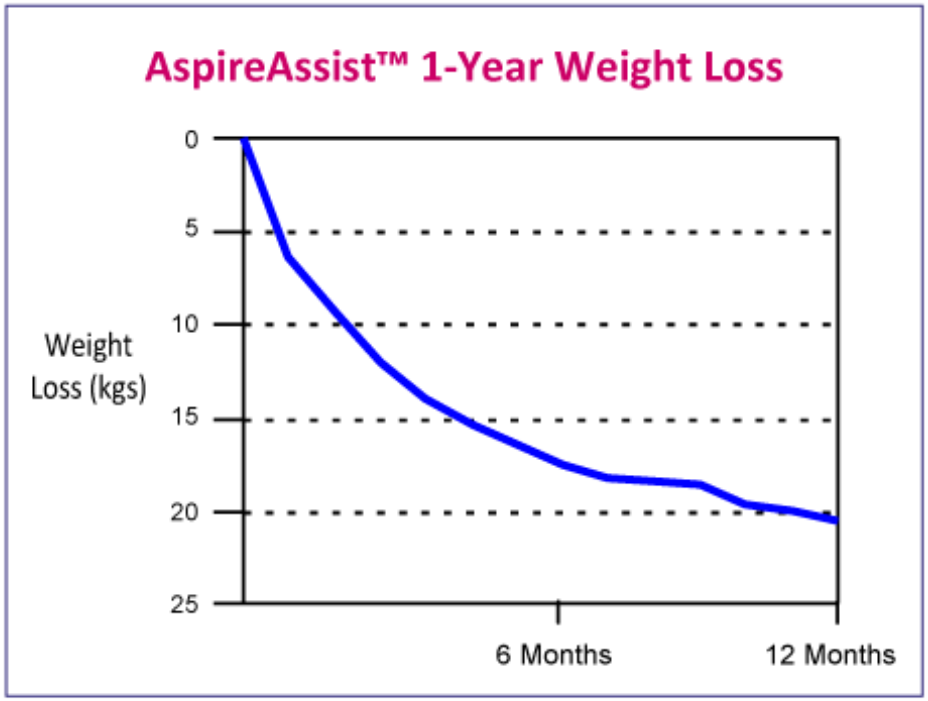

poster presentation of this study from The Obesity Society (October 3, 2011)*

http://www.aspirebariatrics.com

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	AspireAssist™	Adjustable Gastric Banding	Gastric Bypass	Sleeve Gastrectomy
Safety and Efficacy				
Excess Weight Loss (first year)	**49%[1] (n=10)**	**48%[2]**	**62%[2]**	**55%[3]***
Serious Complications	**4%[1] (Buried Bumper) (n=24)**	17%[4,**] (Includes slippage/dilation, erosion, obstruction, death)	14%[4,**] (Includes staple line failure, leaking, bleeding, obstruction, marginal ulcer, death)	0-24%[3,**] (Includes staple line failure, bleeding, postoperative strictures, death)
Procedure				
Average Procedure Time	**20 min**	78 min[5]	165 min[5]	100 min[5]
Anatomical changes	**Minor: stoma to stomach**	Moderate	Major	Major
Procedure Type (most commonly)	**Percutaneous (1-cm incision)**	Laparoscopic (~5 small incisions)	Laparoscopic (~5 small incisions)	Laparoscopic (~5 small incisions)
Reversible	**Yes**	Yes	No	No
Anesthesia	**Conscious Sedation**	General Anesthesia	General Anesthesia	General Anesthesia
Length time in hospital/clinic (avg)	**2 hours**	1.7 days[5]	4.2 days[5]	4.4 days[5]
Life After Procedure				
Vomiting or dumping syndrome	**No**	Regurgitation/ vomiting is common initially[8]	Sugary food can cause dumping	No
Food/Drink Recommendations	**Gradually learn healthy behaviors**	Very small meals (~200ml or <1 cup)[6]; no drinking with meals	Very small meals (~200ml or <1 cup)[7]	Very small meals (~200ml or <1 cup)

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Aspire Bariatrics raises $16 million

December 20, 2011 2:13 pm by Stephanie Baum | 0 Comments

Aspire Bariatrics, a King of Prussia-based medical device company focused on weight loss, has raised $16.2 million of a $20 million target through a combination of equity, warrants and options, according to a filing with the U.S. Securities and Exchange Commission.

The development stage company commercializing its Aspire Assist device for obesity is nearing completion of its U.S. pilot trials and expects to launch the product outside the United States in early 2012 and within the U.S. in early 2014, according to a biography of CEO Katherine Crothall on the University City Science Center's website. Crothall was scheduled to speak at the science center Oct. 10.

About 39 have invested in the current offering as of Dec. 15, according to the filing.

Crothall has also served as a principal at Liberty Venture Partners, a Philadelphia venture capital firm focused on medical technology and IT companies. She also founded and served as CEO of Animas Corp., a manufacturer of insulin infusion pumps located in West Chester, Pennsylvania, until it was acquired by Johnson and Johnson (NYSE:JNJ) in February 2006.

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Endoscopic treatment of ***secondary obesity***

New technologies

ENDOSCOPIC SUTURING REVISION OF ROUX-AND-Y GASTRIC BYPASS

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ENDOSCOPIC TREATMENT OF PRIMARY AND SECONDARY OBESITY

Galvão Neto, MD
Almino Ramos, MD
Josemberg Campos, MD

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JOSEMBERG M. CAMPOS, PHD

Cirurgia Obesidade Endoscopia Gastroenterologia Videolaparoscopia
NeoGastro

Recife, PE, Brazil

ALMINO C. RAMOS, MD

Gastro Obeso Center
10 AMOS

Sao Paulo, SP, Brazil

MANOEL GALVAO NETO, MD

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Cirurgia Obesidade Endoscopia Gastroenterologia Videolaparoscopia
NeoGastro

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Gastro Obeso Center

Centro Avançado de Gastroentereologia e Cirurgia da Obesidade

ALMINO CARDOSO RAMOS

MANOELA GALVÃO

MANOEL GALVÃO NETO

ANDREY CARLO

THALES DELMONDES

www.gastroobesocenter.com.br

SECONDARY OBESITY TREATMENT

Weight regain

- RNY gastric bypass patients
  - Weight regain
    - Gastroplasty dilation
    - Gastrojejunostomy dilation
    - Loss of “ring” (banded gastroplasty)
    - Gastro-gastric fistulas

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SECONDARY OBESITY TREATMENT

Weight regain

- Weight regain in-between 5 to 10 years
  - 10% - 20% (estimated)
- Gastric bypass revision
  - Up to 12%
- Literature
  - 17 papers (838p)
    - 118p (14%) major complications
    - Mortality 11p (1.3%)
  - Lap revision 64p
    - 6p (9%) major complications
      - Operative time (mean) of 4.5h

Gagner M. Lap Reop Bariatric Surgery : 27 consecutive patients. Obes Surg, (12) 254-260, 2002.
Jones KB. Revisional bariatric Surgery-potentially safe and effective. SOARDS 1 (2005) 599-603

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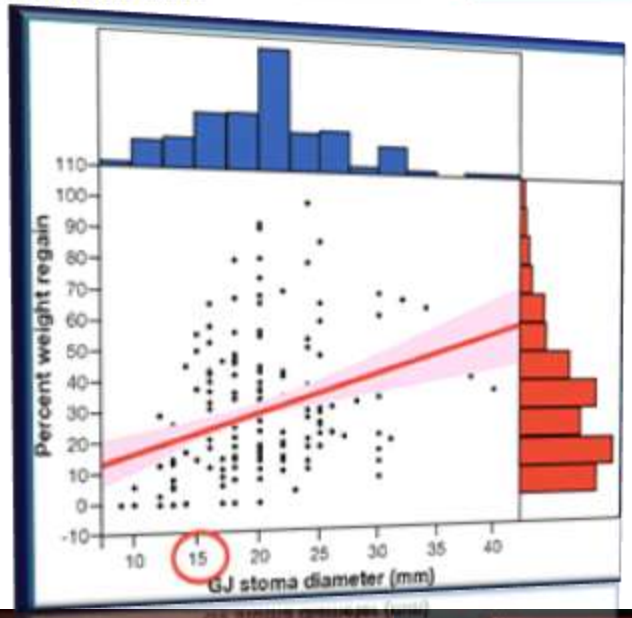
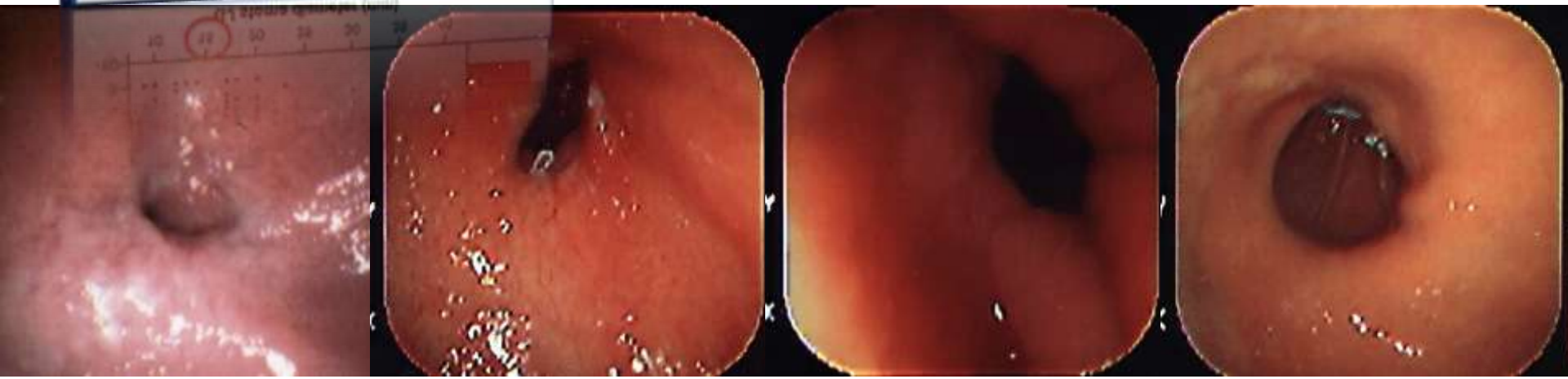
GJ dilation = Wt regain



AbuDayyehBK,LautzDB, ThompsonCC. ClinGastroenterolHepatol 2011;9(3):228-33



< 10mm **10-12mm** **12-16mm** **> 16mm**

GJ – Diameter - Therapeutic window = 10-16mm

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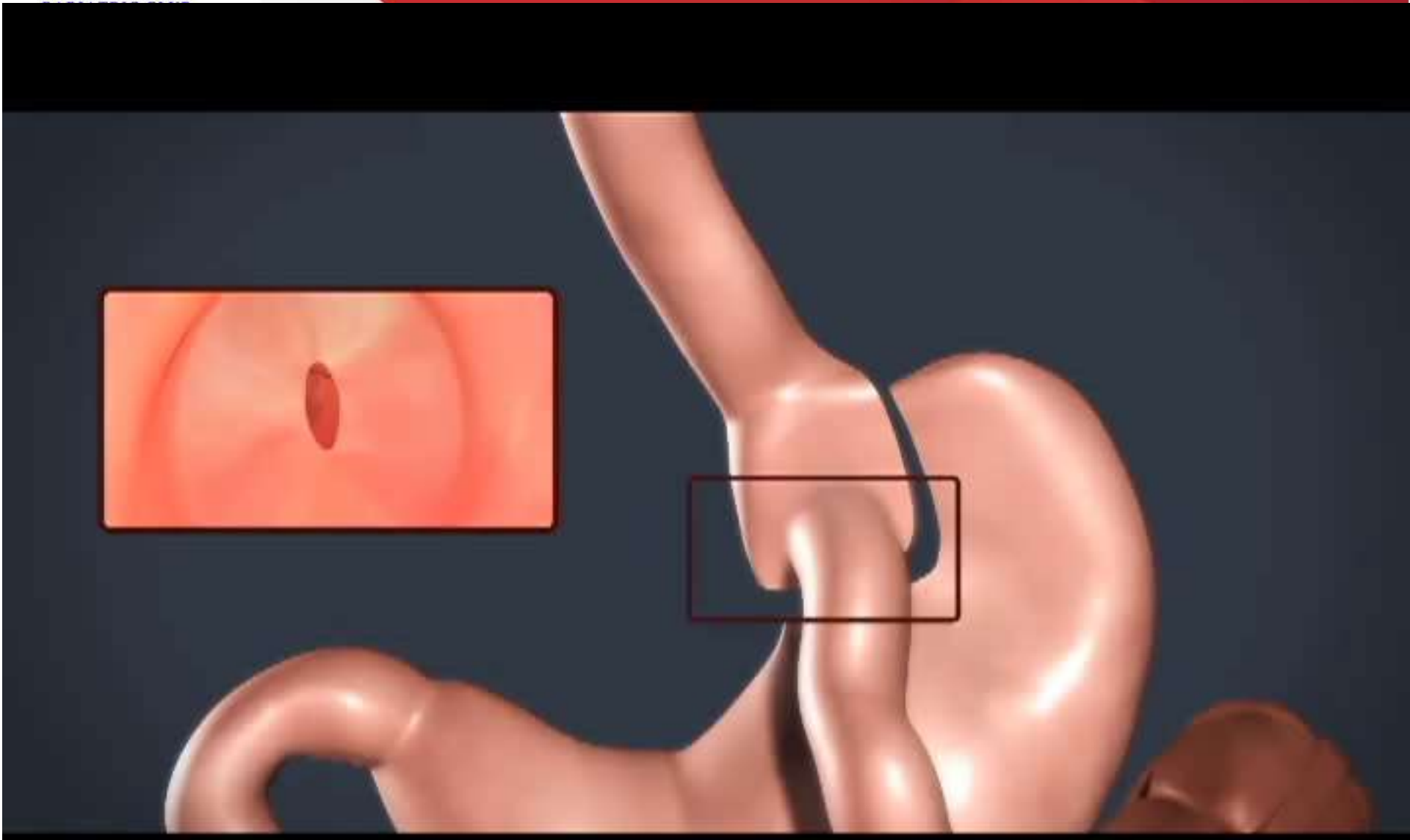
SECONDARY OBESITY TREATMENT



A Peer-Reviewed Publication

BARIATRIC TIMES

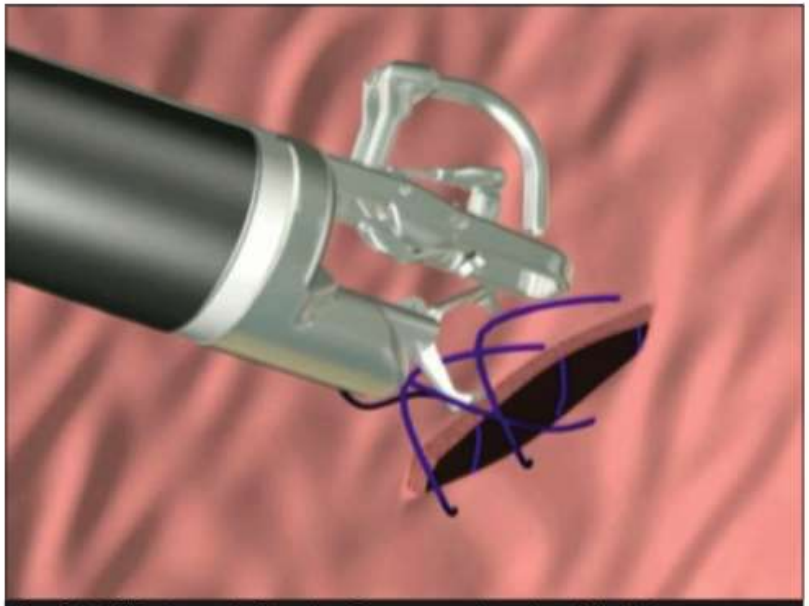
Clinical Developments and Metabolic Insights in Total Bariatric Patient Care

Volume 8, Number 6 June 2011

Endoscopic Revision of Roux-en-Y Gastric Bypass Stomal Dilation with a Suturing Device: Preliminary Results of a First Out-of-United States Series

by MANOEL GALVÃO NETO, MD; LEONARDO RODRIGUEZ, MD; NATAN ZUNDEL, MD; JUAN CARLOS AYALA, MD; JOSEMBERG CAMPOS, PHD; and ALMINO RAMOS, MD

Bariatric Times. 2011;8(6):32–34



OverStitch™ Endoscopic Suturing System used to place full thickness endoluminal sutures. Photo courtesy of Apollo Endosurgery, Inc.

FIGURE 1. A tissue anchor acts like a needle. Photo courtesy of Apollo Endosurgery, Inc.

FIGURE 2. Open handle mounted on the scope. Photo courtesy of Apollo Endosurgery, Inc.

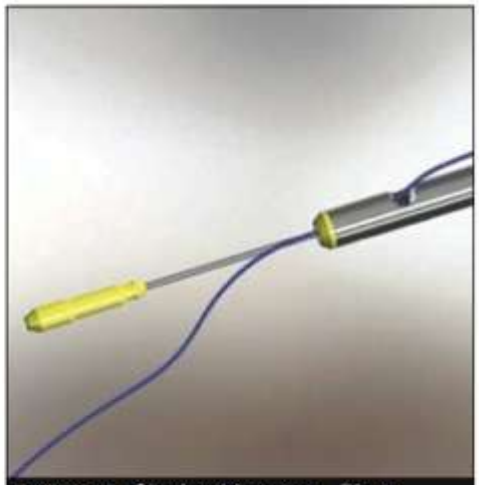


FIGURE 3. Cinch with suture. Photo courtesy of Apollo Endosurgery, Inc.

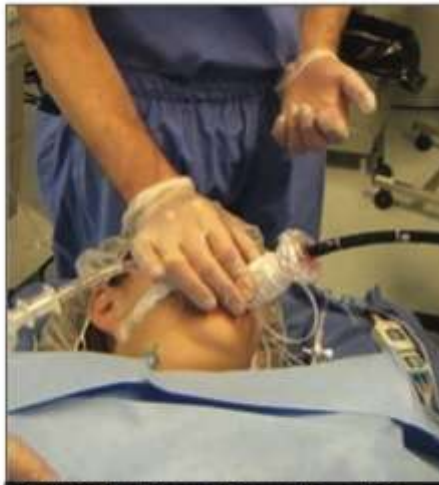


FIGURE 4. External view of overtube

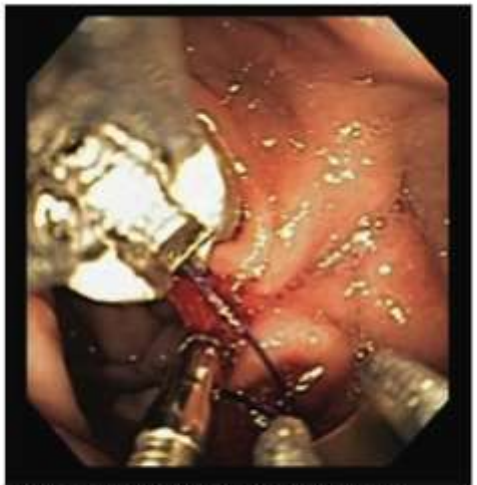


FIGURE 5. Internal image of suture

FIGURE 6. External image of handle while suturing

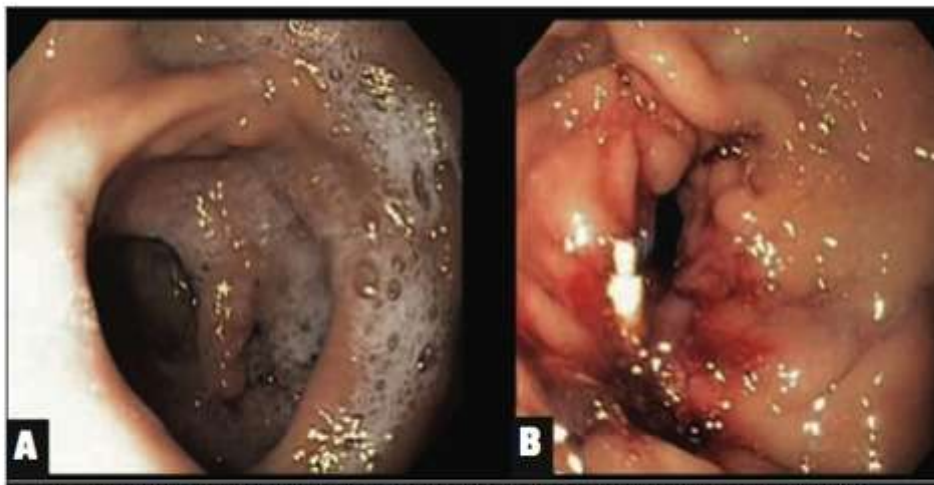


FIGURE 7. Gastro-Jejunostomy prior to (A) and immediately following (B) the procedure

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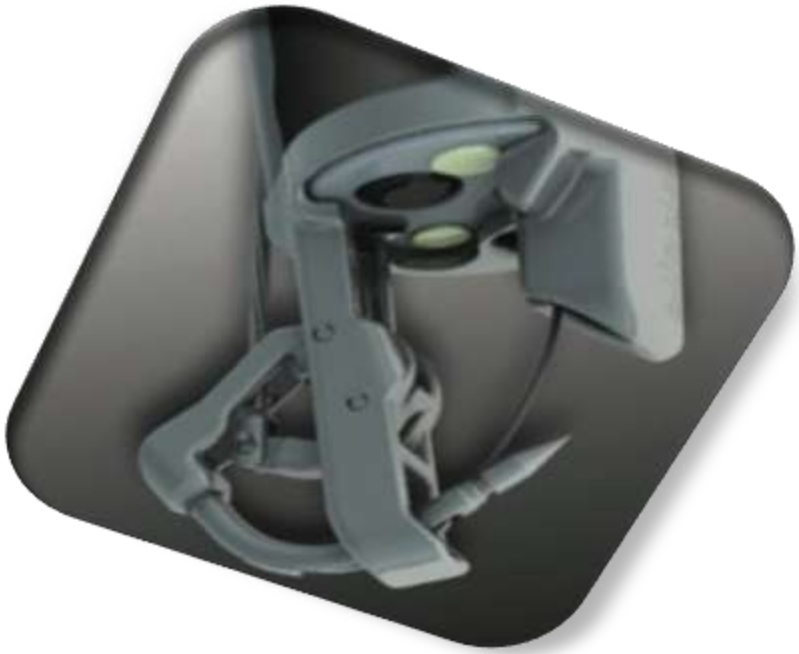
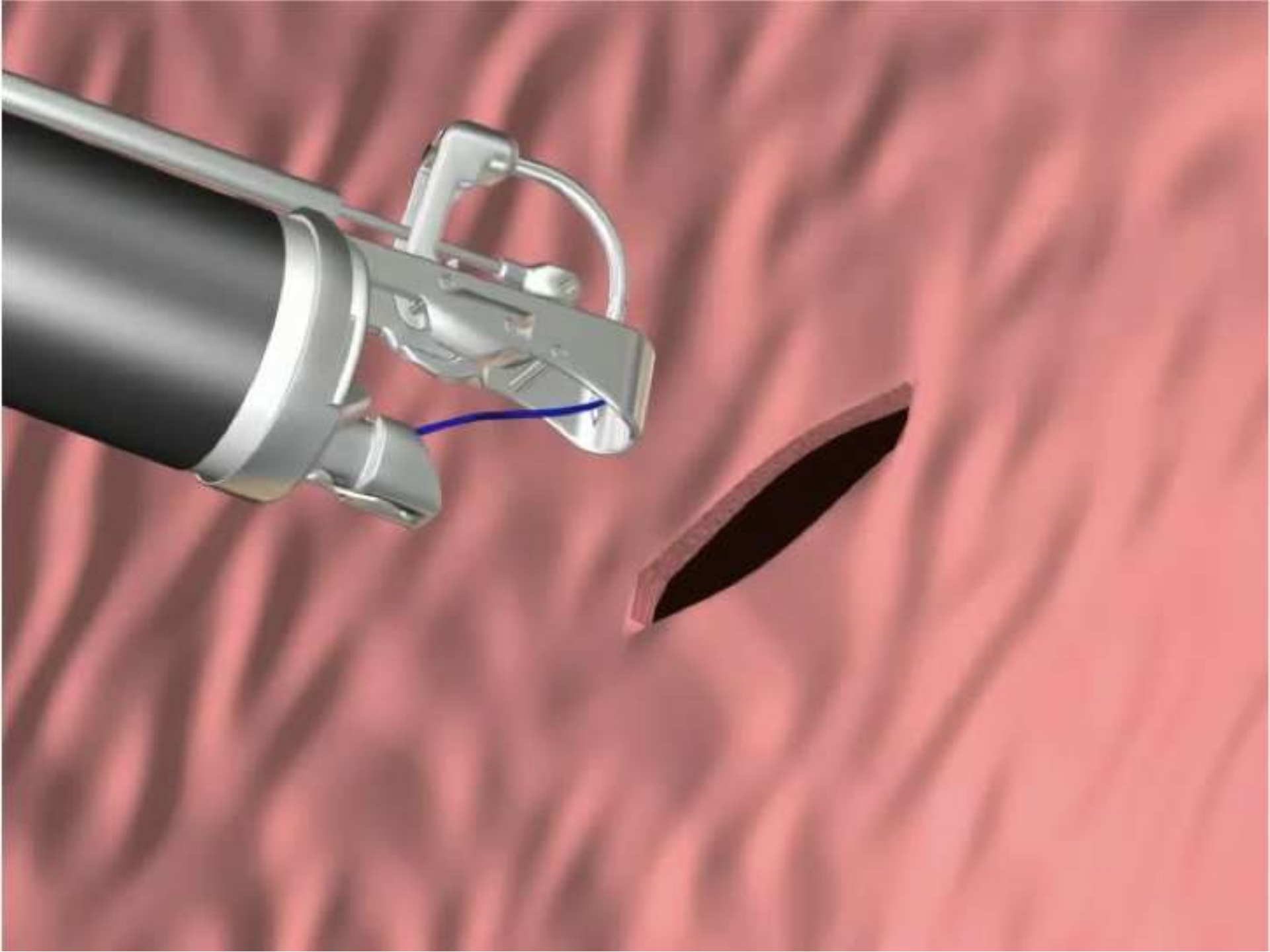
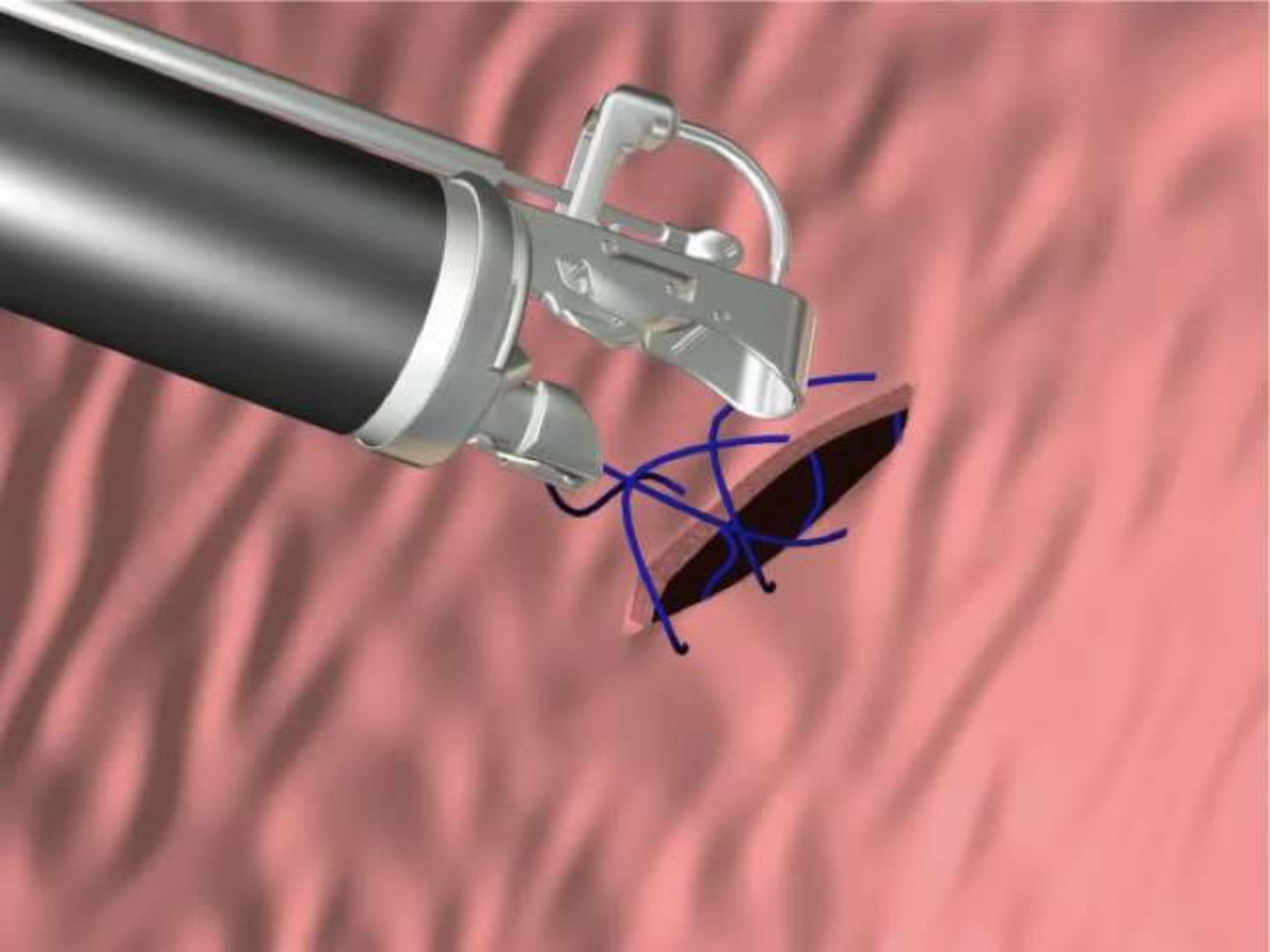
Endoluminal Vertical gastropasty

Apollo®







SECONDARY OBESITY TREATMENT

Weight regain

- First O.U.S series (Safety targeting)
  - Clinica Indisa and Gastro Obeso Center – Santiago Chile
    - Galvao Neto, M.MD
    - Rodrigez L, MD
    - Ayala JC, MD
    - Ramos A,MD
  - N = 15 of 15pt
    - Early outcomes 1m follow-up
      - All losing weight (6 – 8Kg)
      - No severe AE

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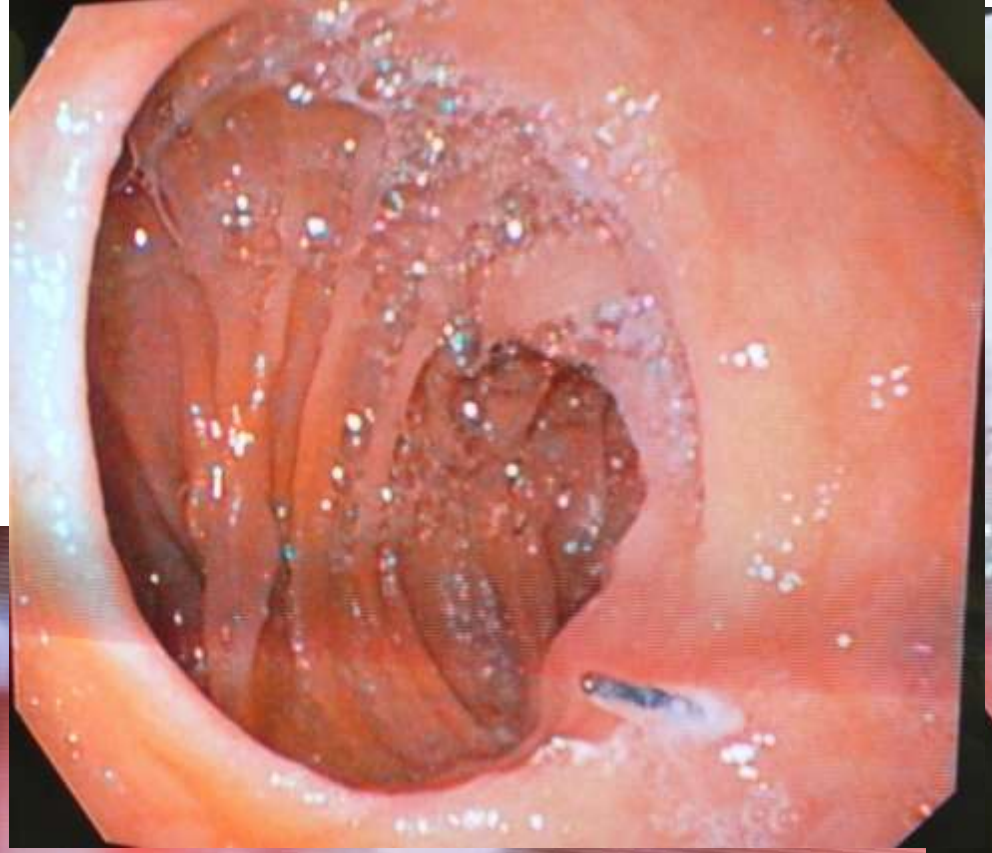
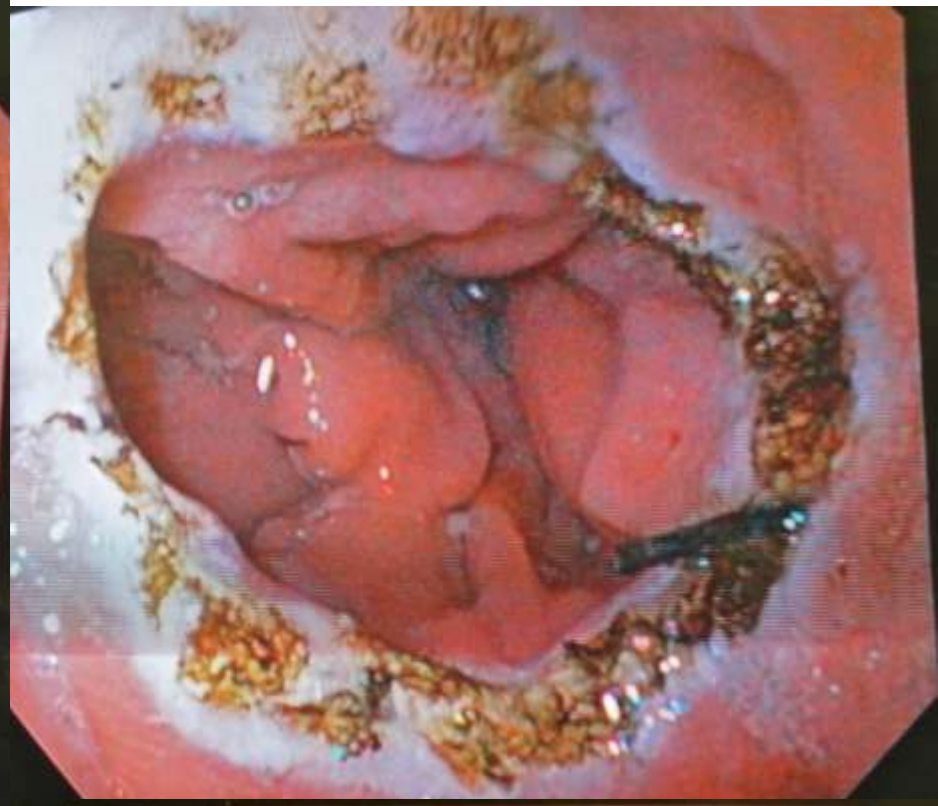
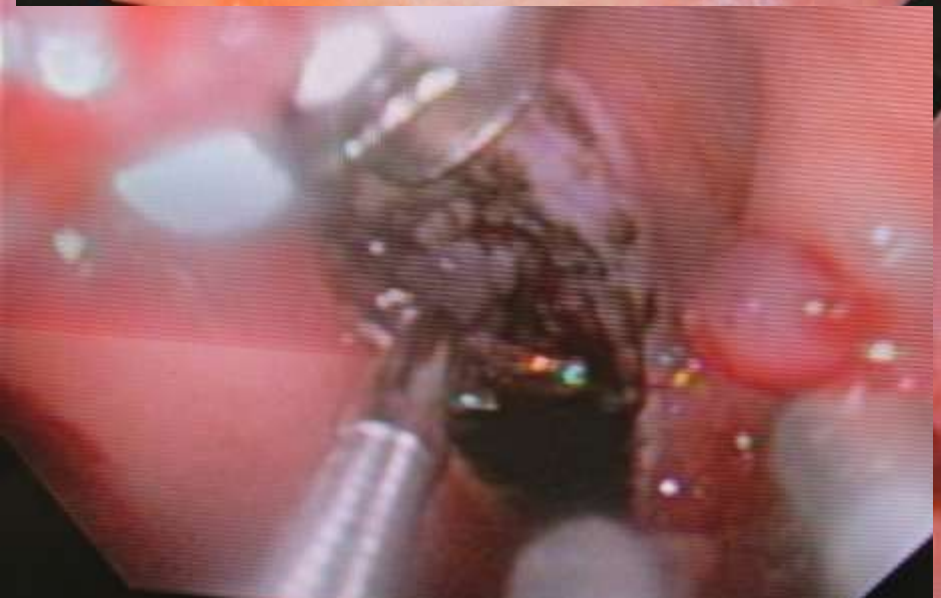
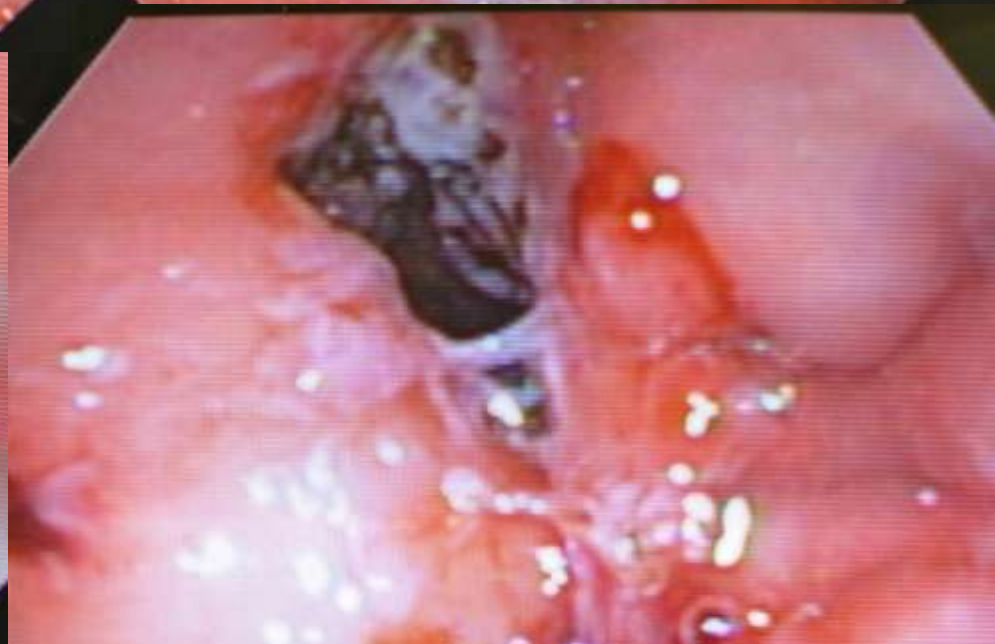
SECONDARY OBESITY TREATMENT

Weight regain

- First O.U.S series (Safety targeting)
  - FIU and Gastro Obeso Center – Miami, Florida
    - Galvao Neto, M.MD
    - Natan Zundel, MD
    - Ramos A, MD
  - N = 5 of 15pt

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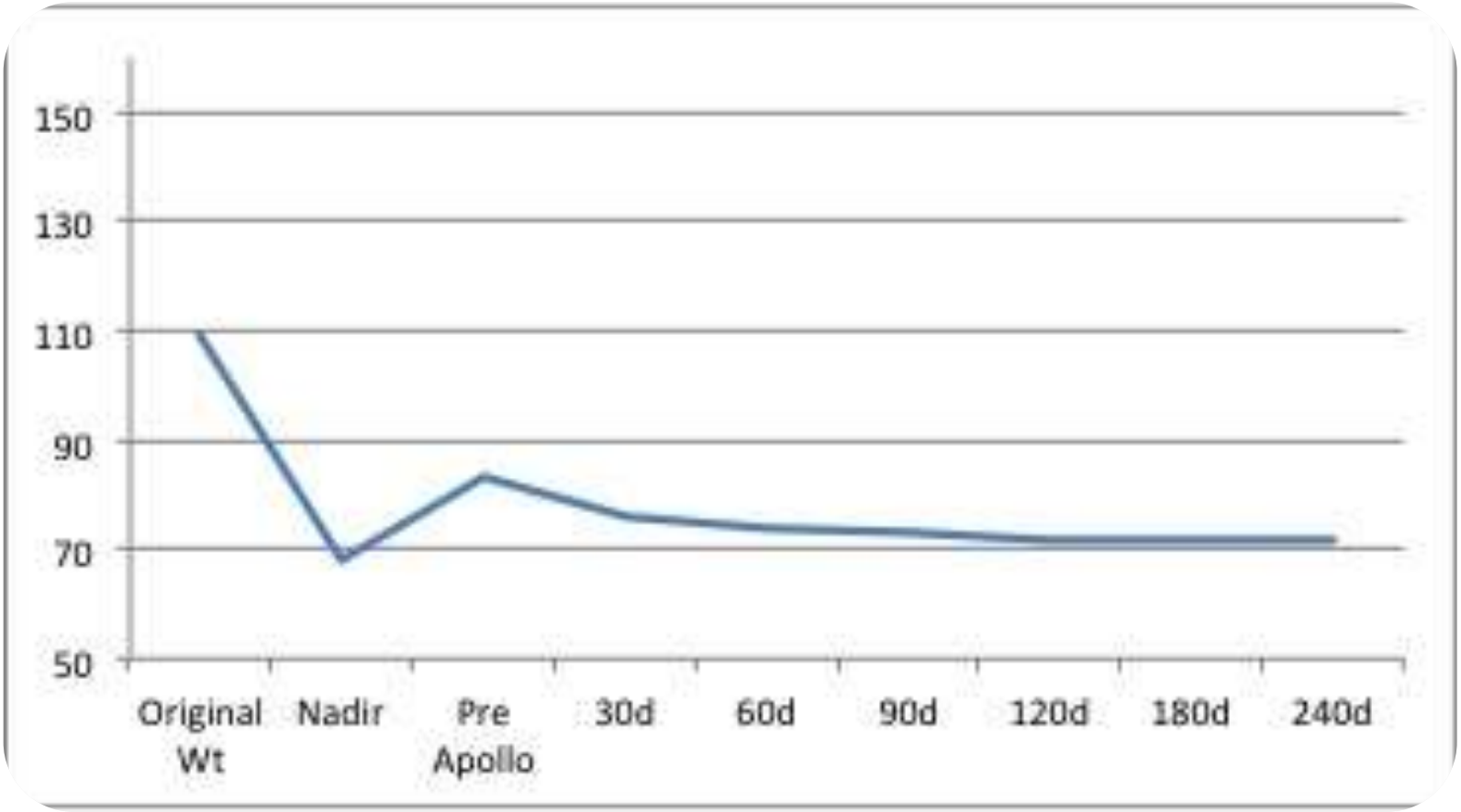
SECONDARY OBESITY TREATMENT

Weight regain – EXTENDED DATA



BRIGHAM AND WOMEN'S HOSPITAL
HARVARD MEDICAL SCHOOL

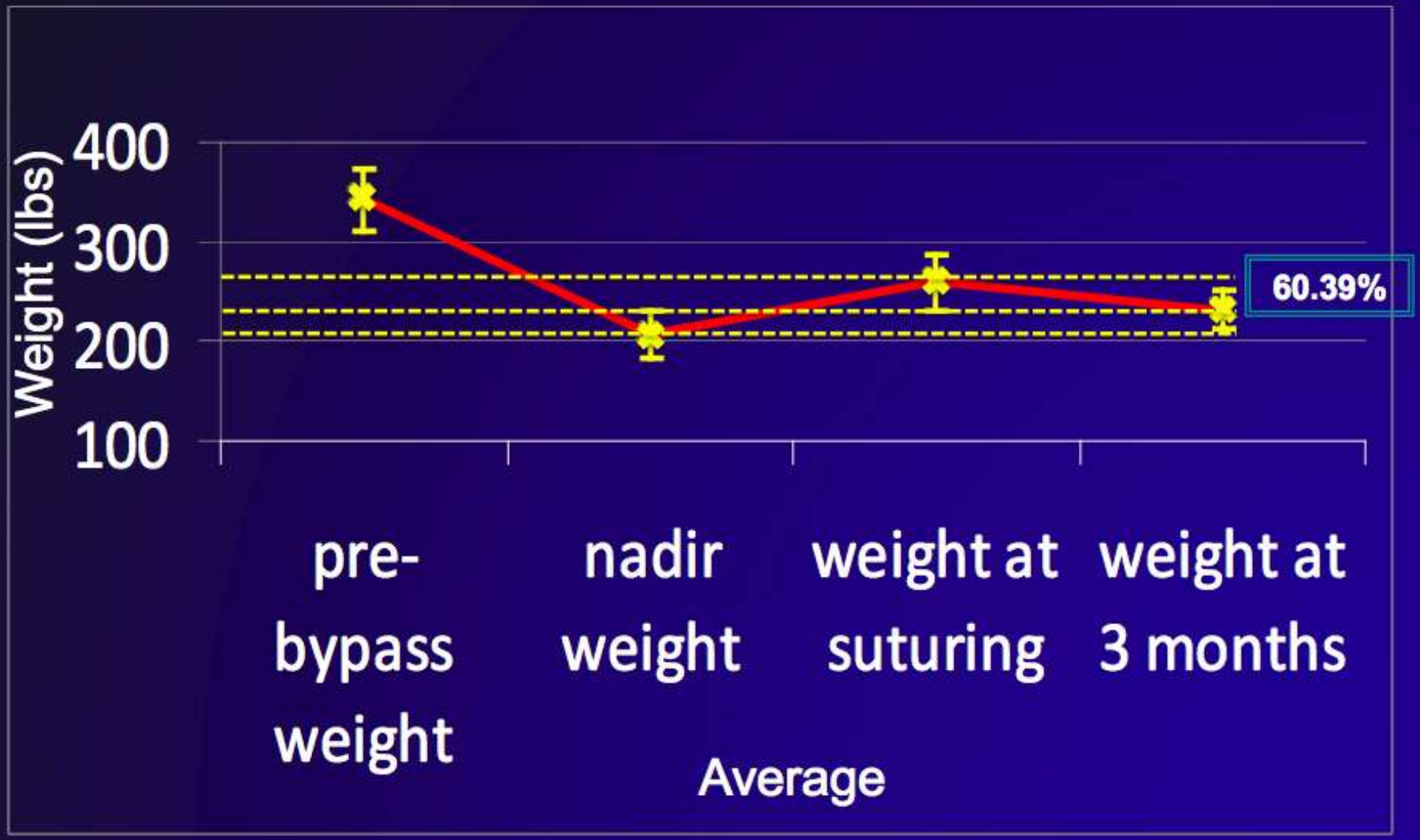
Endoscopic Repair of Dilated Gastrojejunal Anastomoses Using a Novel Endoscopic Suturing Device

Pichamol Jirapinyo, Barham K. Abu Dayyeh, James Slattery, Michele B. Ryan, Rabindra R. Watson, David B. Lautz, Christopher C. Thompson

Pilot Study

- Aim:
  - To demonstrate technical feasibility, safety and short term efficacy
- Study design:
  - Prospective interventional case series
  - 22 consecutive RYGB patients with weight regain and a dilated stoma

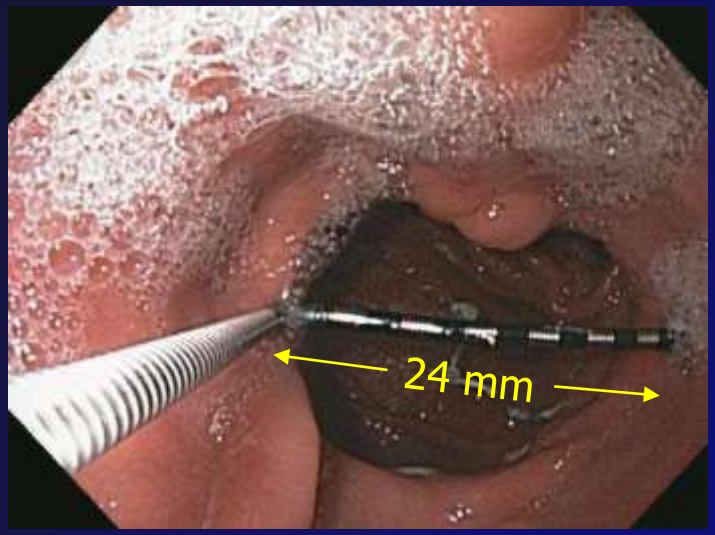
Results

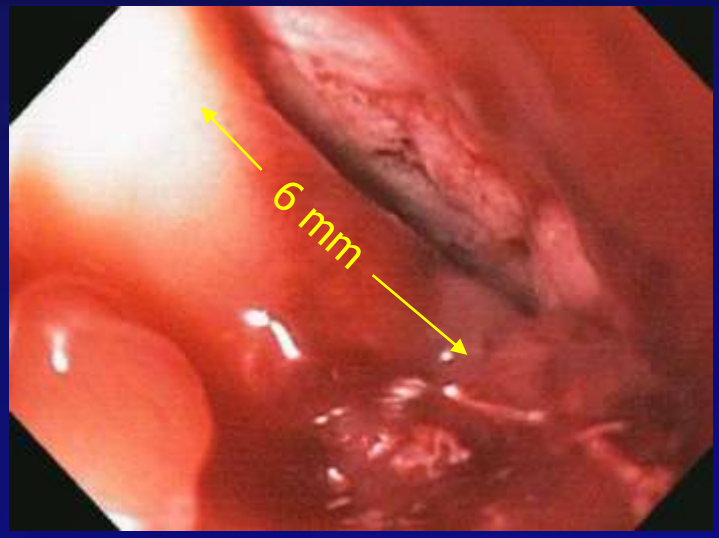

Weight (lbs)
400
300
200
100
60.39%
pre-bypass weight
nadir weight
weight at suturing
weight at 3 months
Average

Follow-up Endoscopy

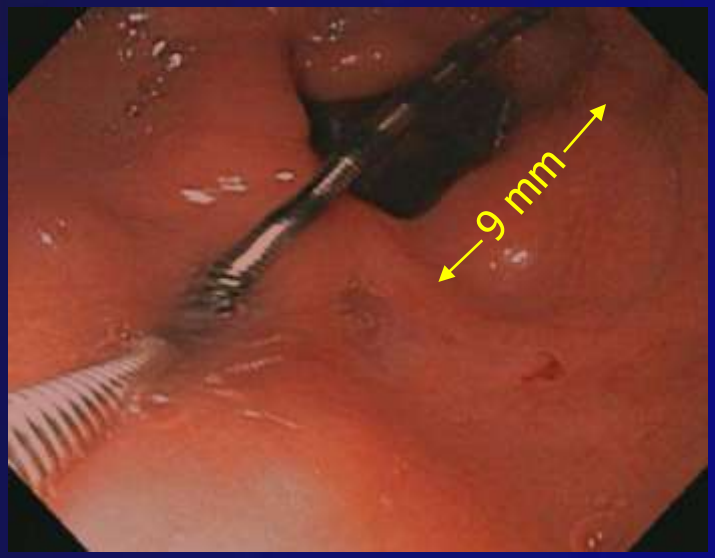
Patient 14:
-31 lbs

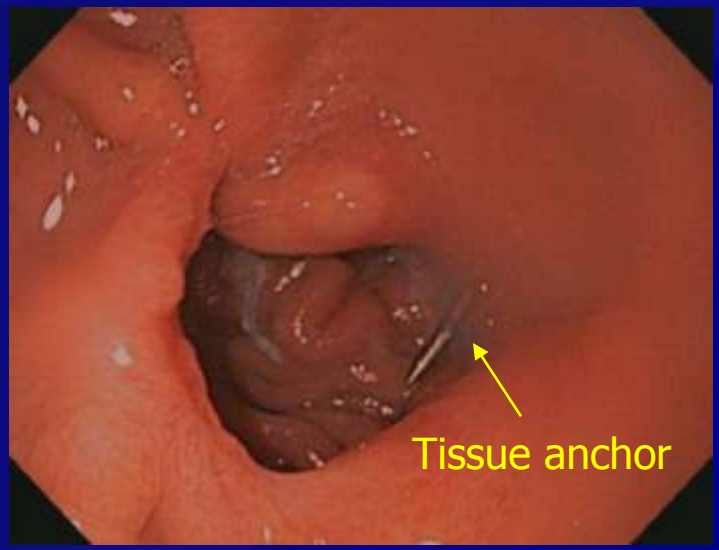
Initial procedure





3 months





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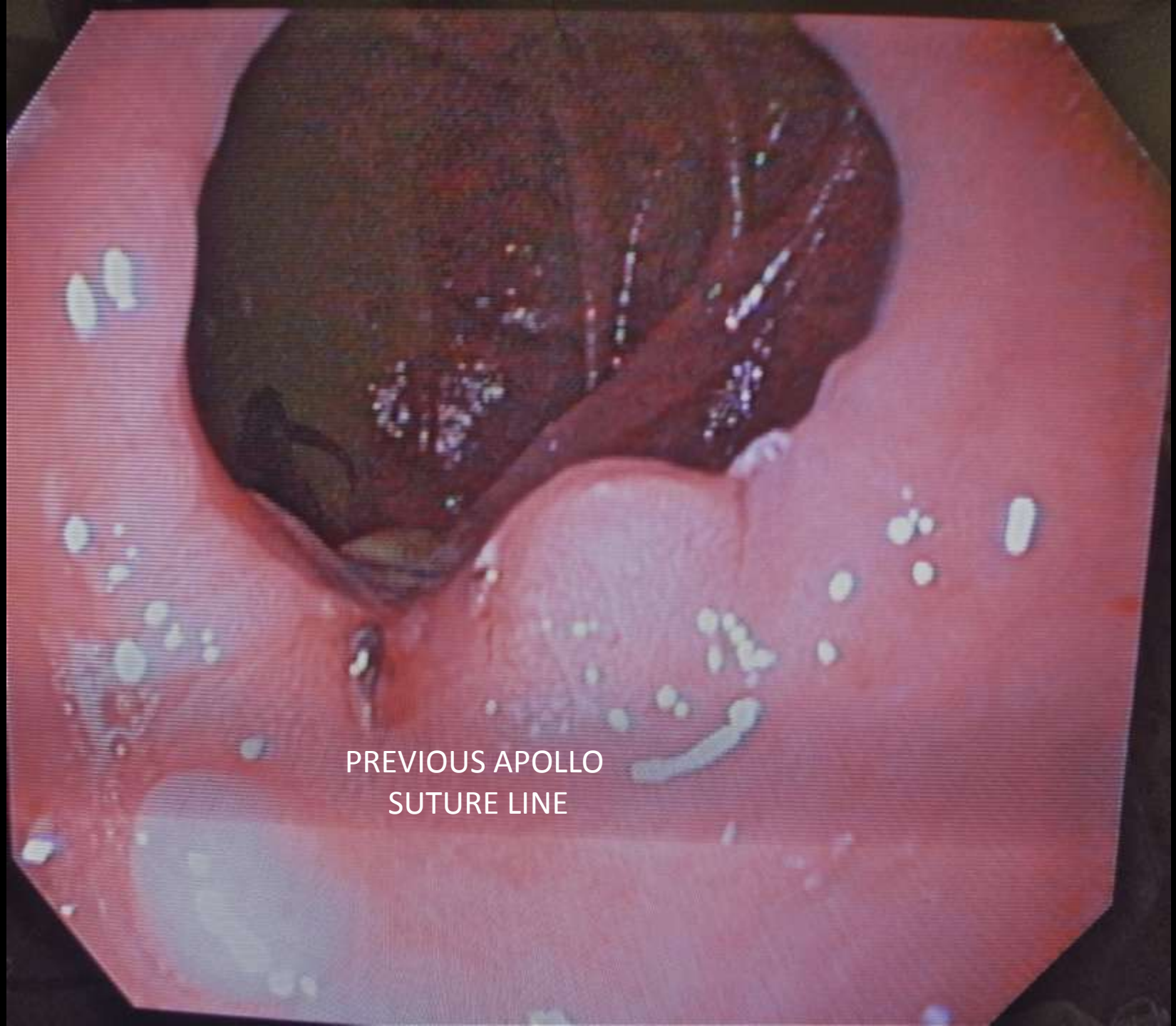
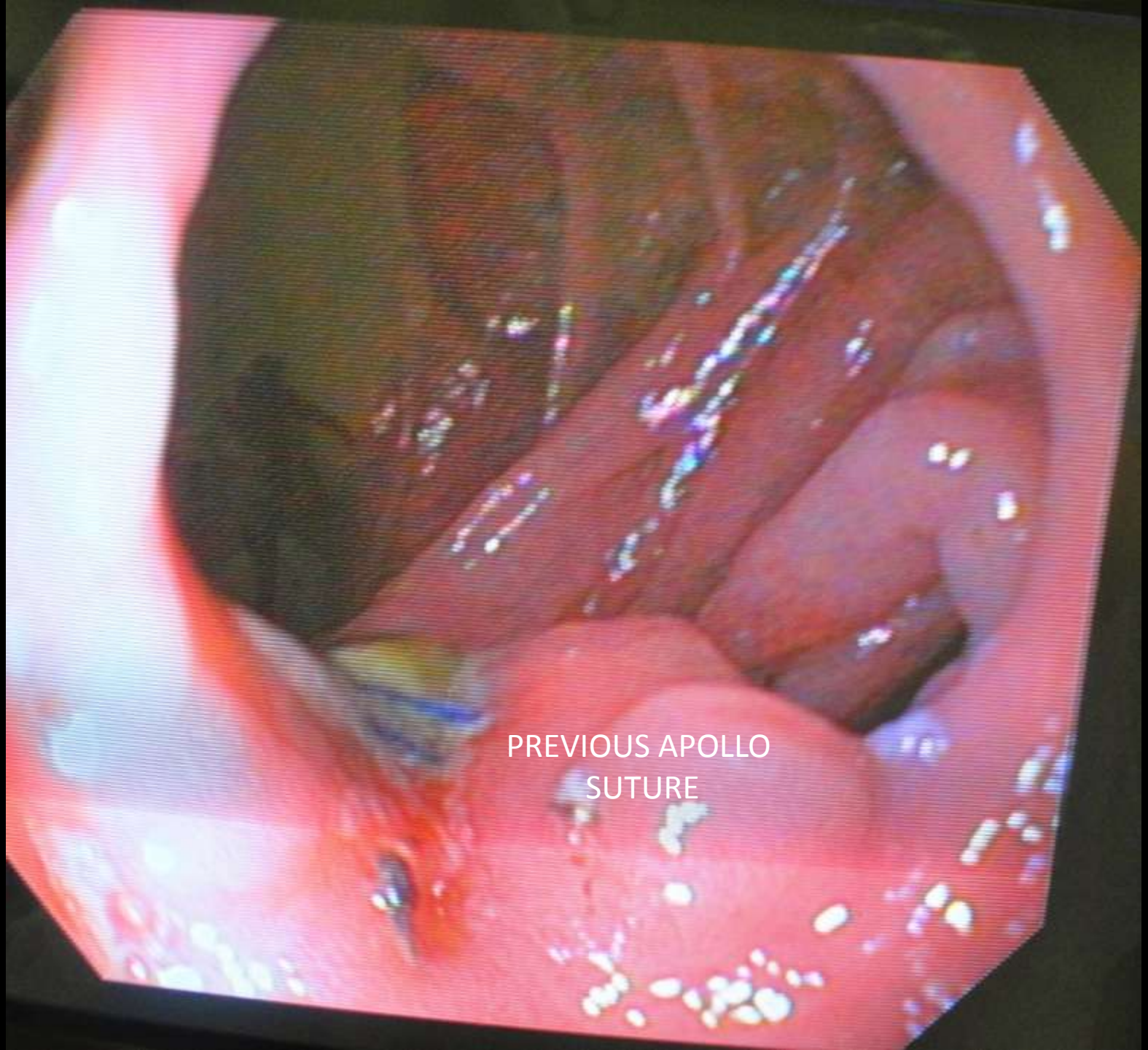
APOLLO RNY REVISIONS

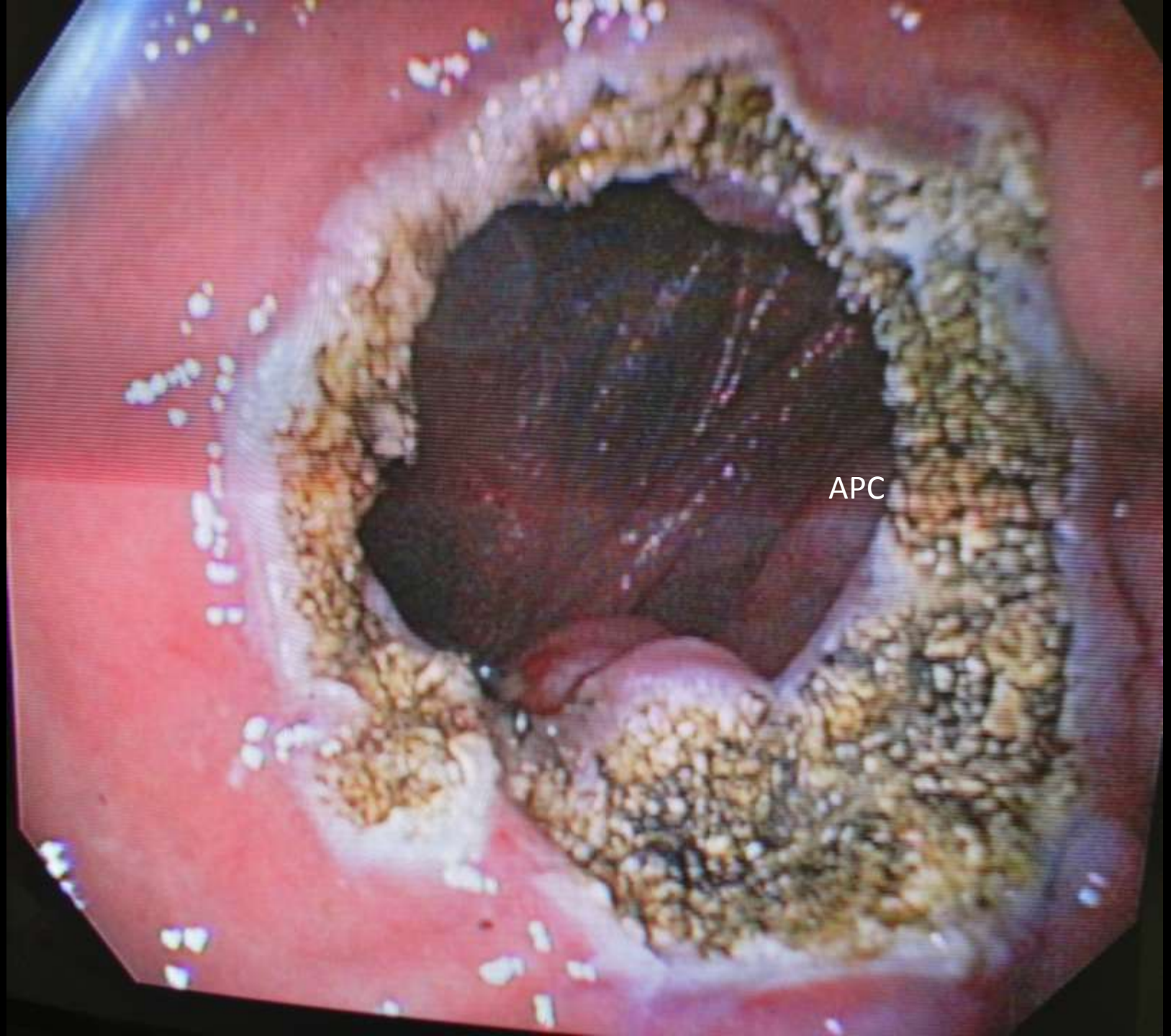
Case 1

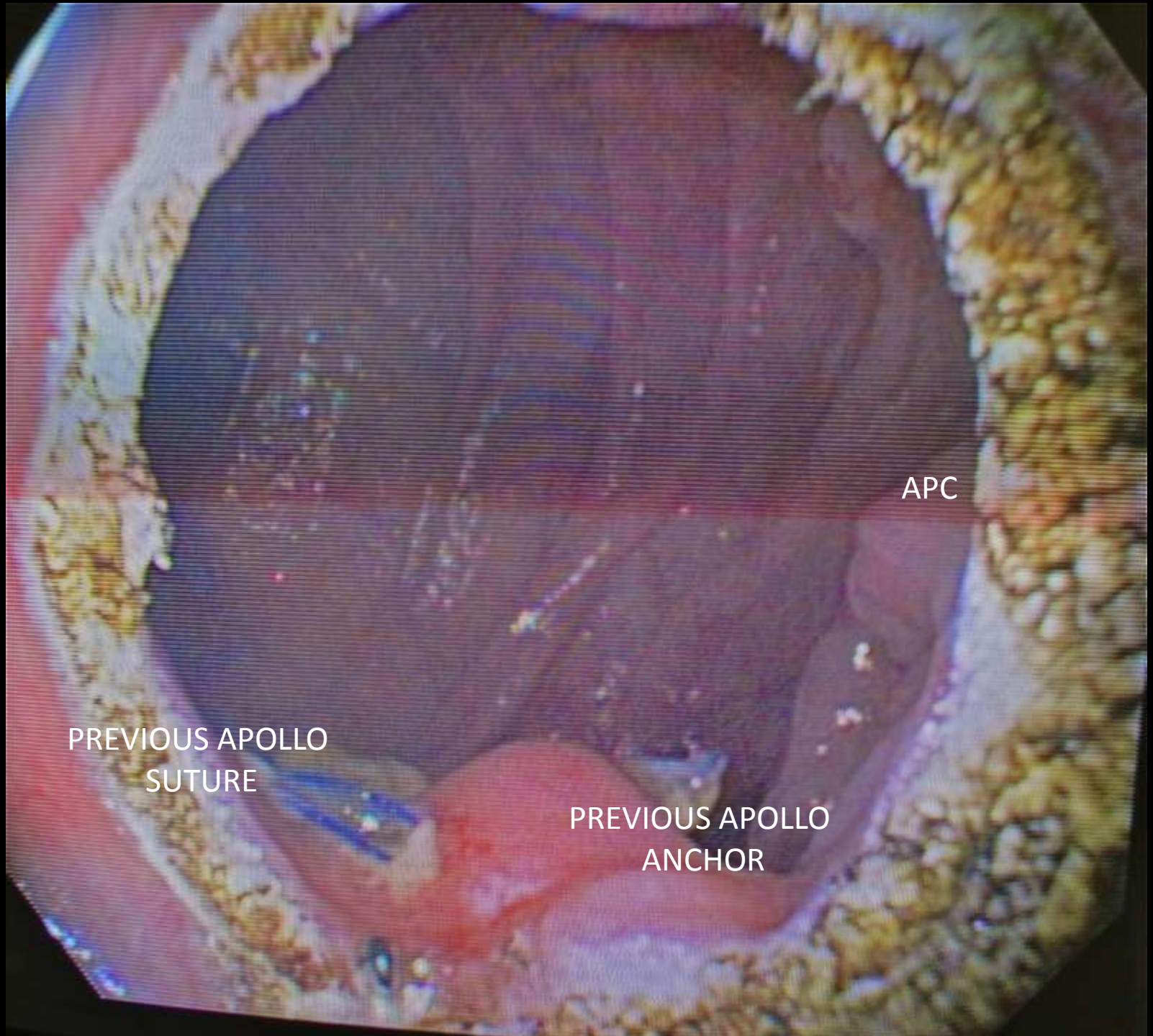
“Revision Of Revision”

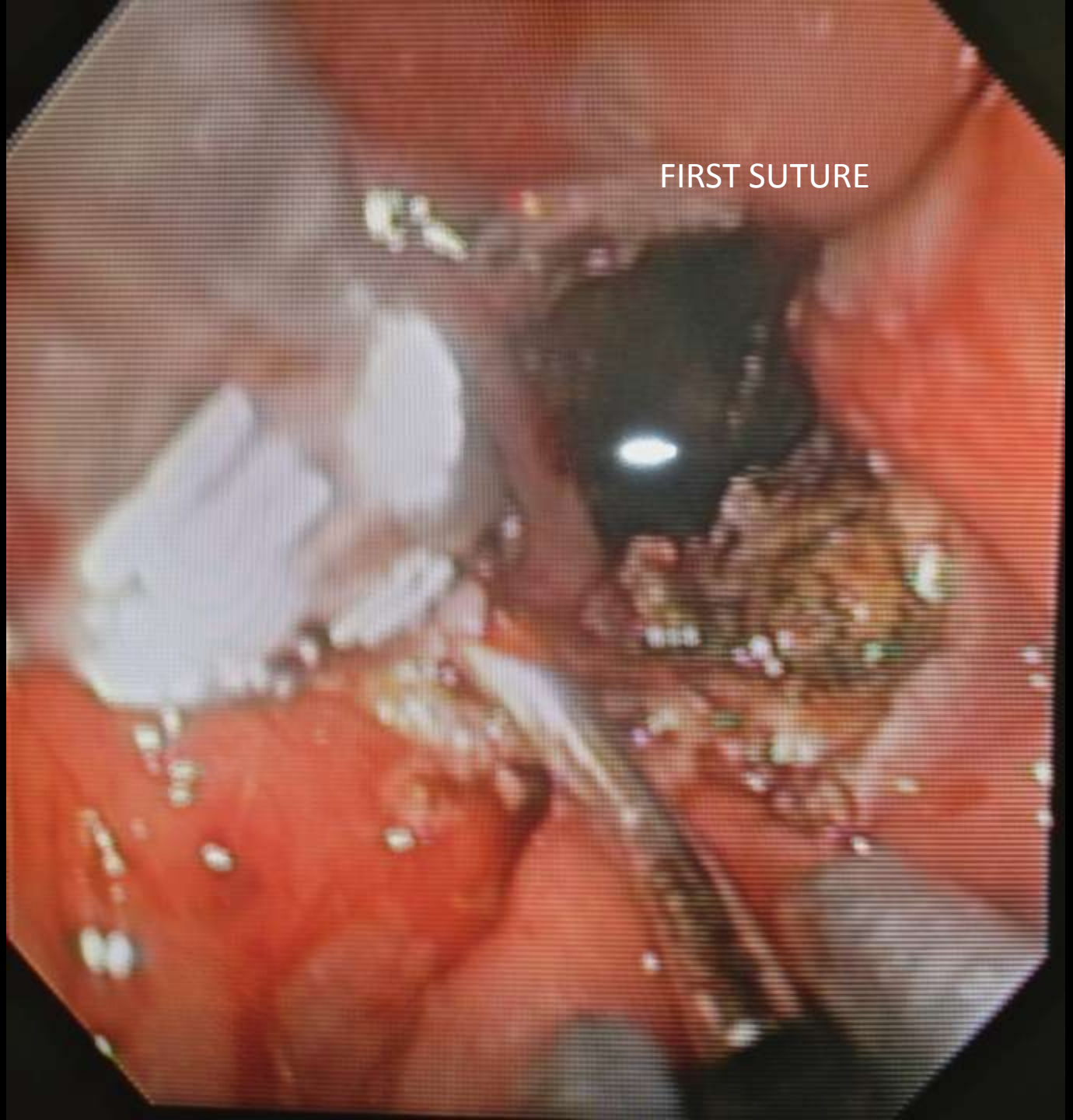
8 Month Durability

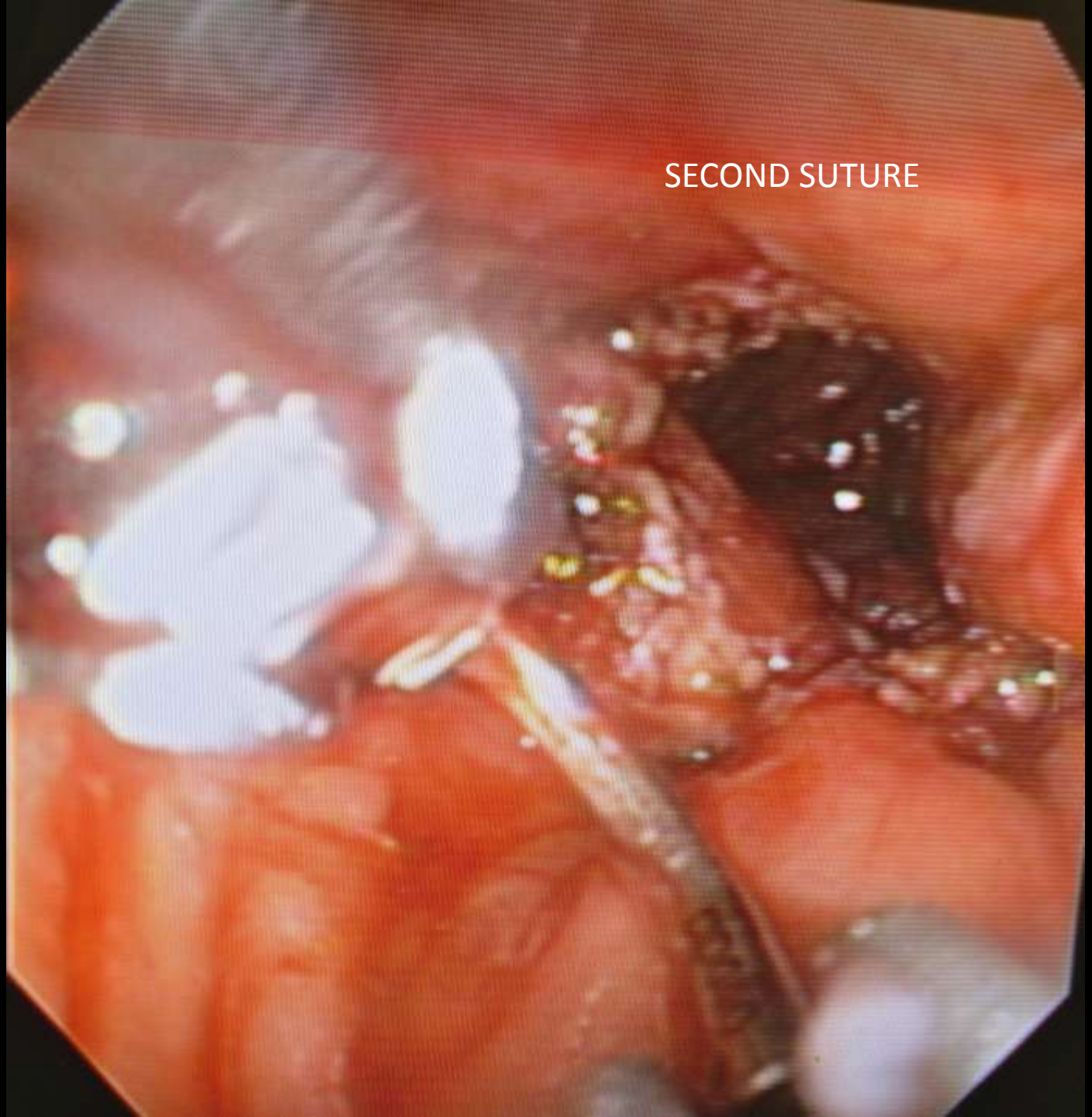

PREVIOUS APOLLO
SUTURE LINE

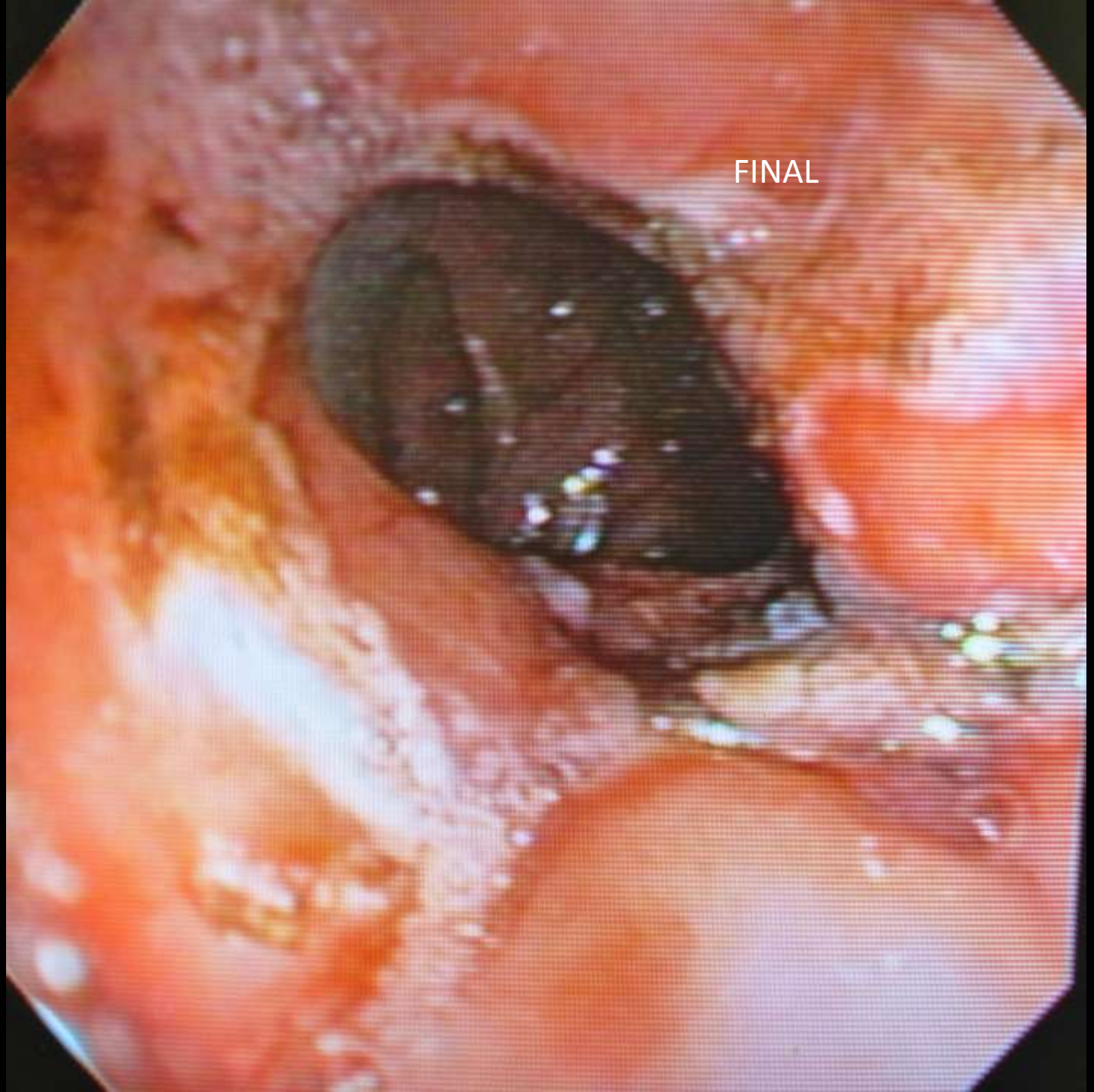

PREVIOUS APOLLO
SUTURE

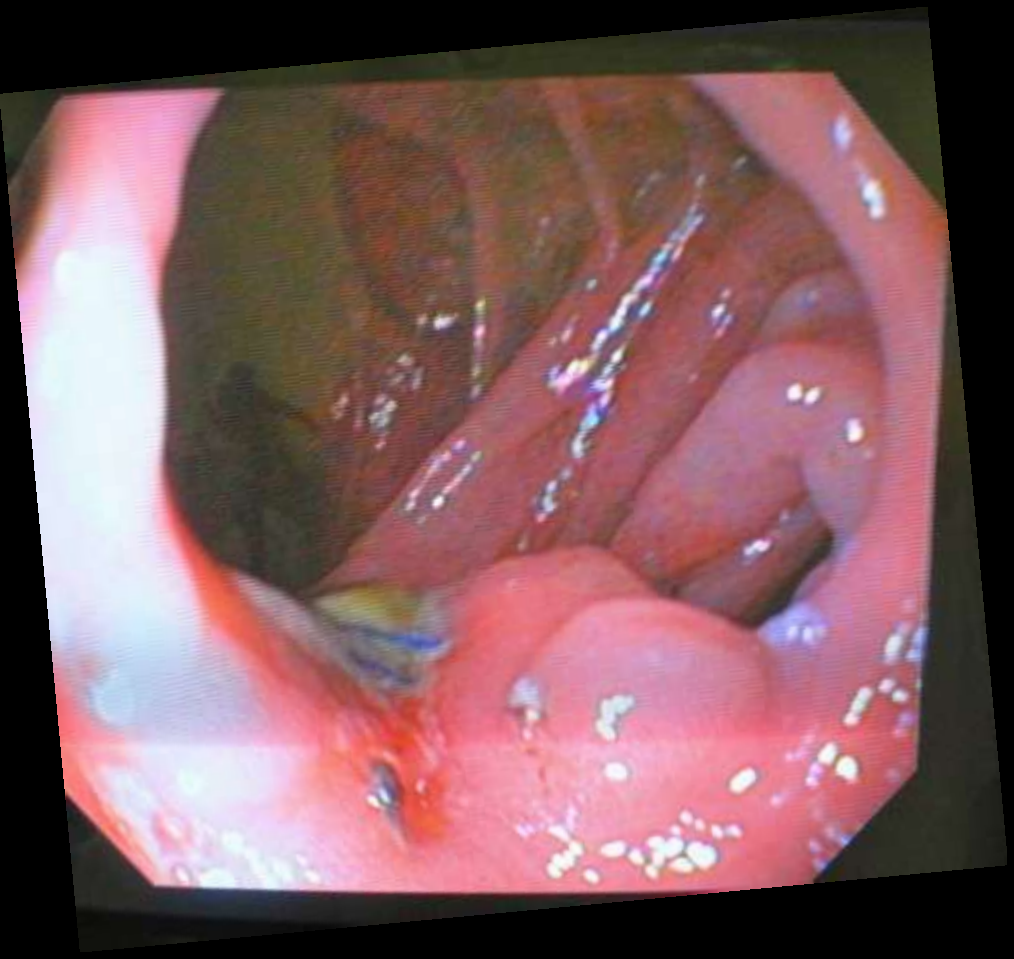

APC


APC
PREVIOUS APOLLO SUTURE
PREVIOUS APOLLO ANCHOR

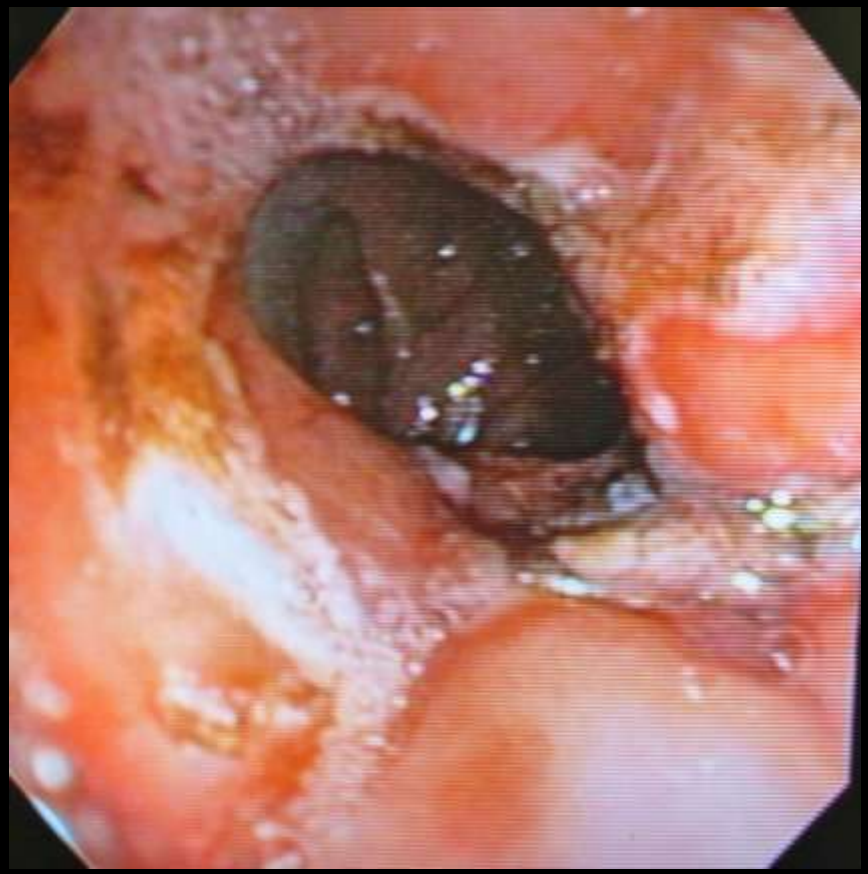

FIRST SUTURE


SECOND SUTURE


FINAL



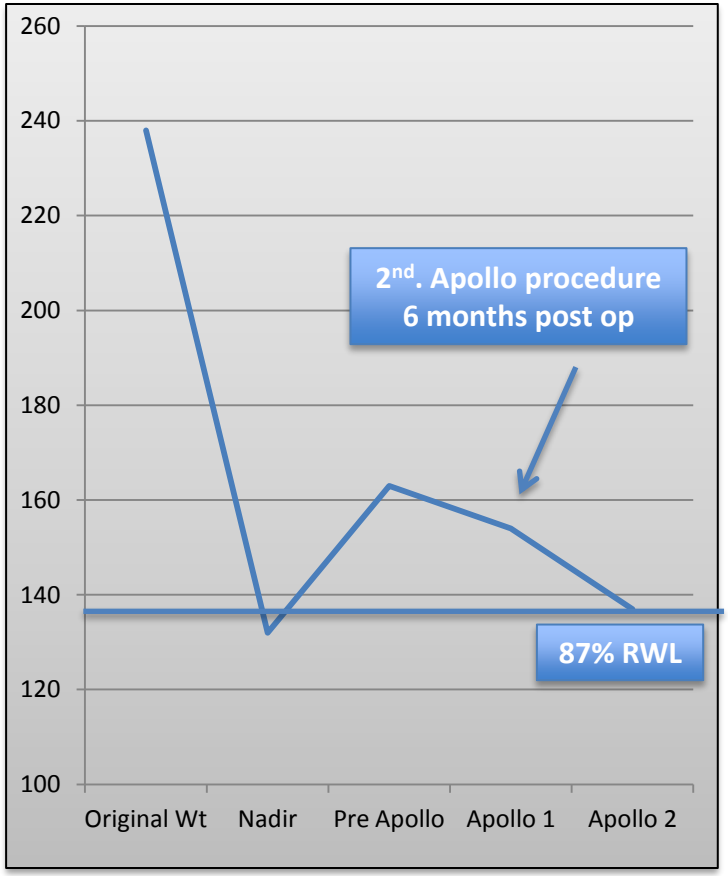
BEFORE



AFTER

Redo Procedure

- Redo of one patient from original first 4 procedures.
  - Patient started at 238lbs and reached a Nadir wt of 132lbs and since regained weight to 163lbs
  - First Apollo procedure (outlet > 10mm) resulted in 30%RWL (9lbs)
  - Second Apollo procedure (2 additional stitches) resulted in additional 17lbs wt. loss and a new %RWL of 86.
  - Patient currently weighs 137lbs (5 lbs above Nadir wt.)



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THANKS!

galvaon@gmail.com