MAGNETIC SURGERY will have a significant place for Revision for Weight Gain after Metabolic/Bariatric Surgery

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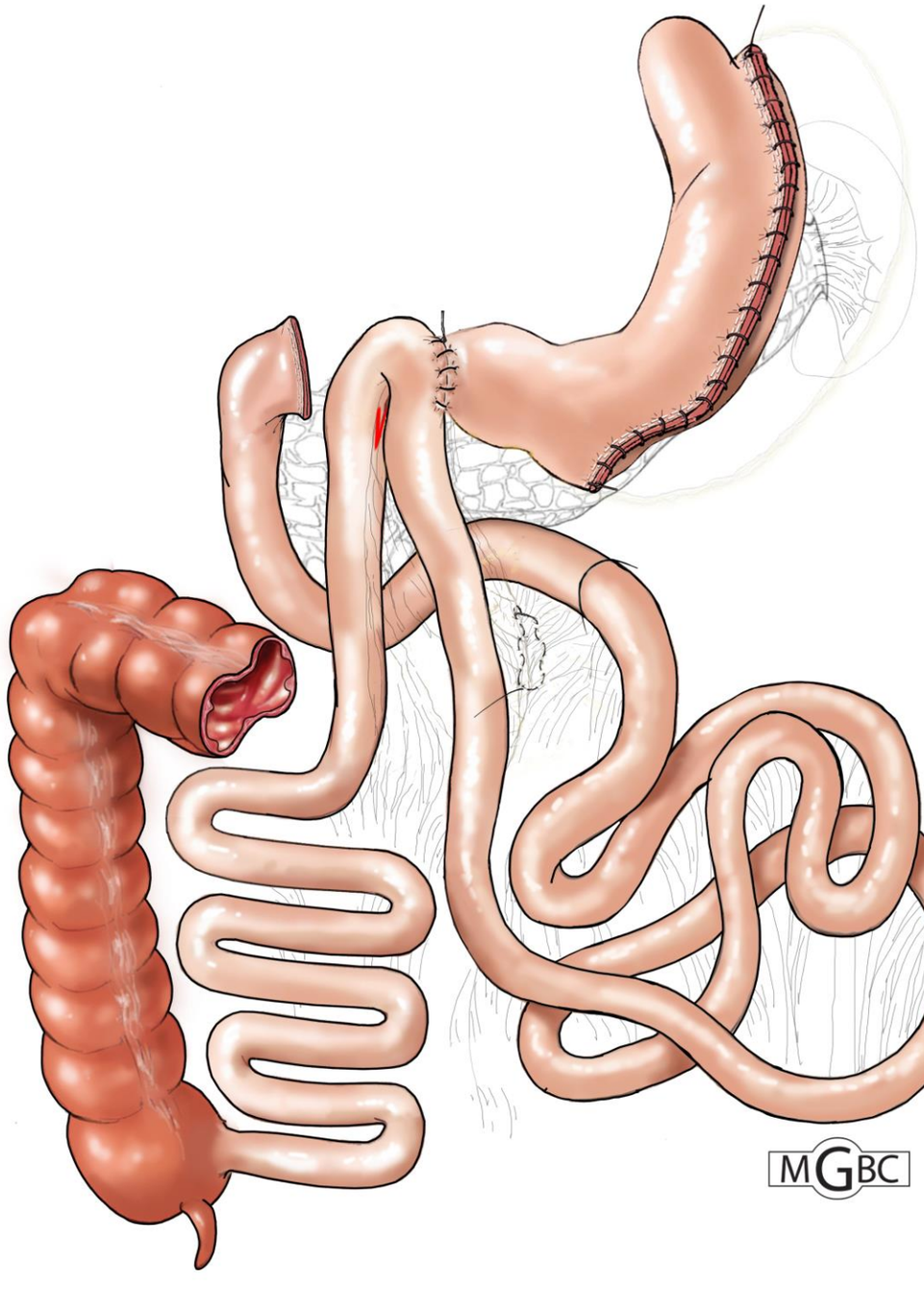
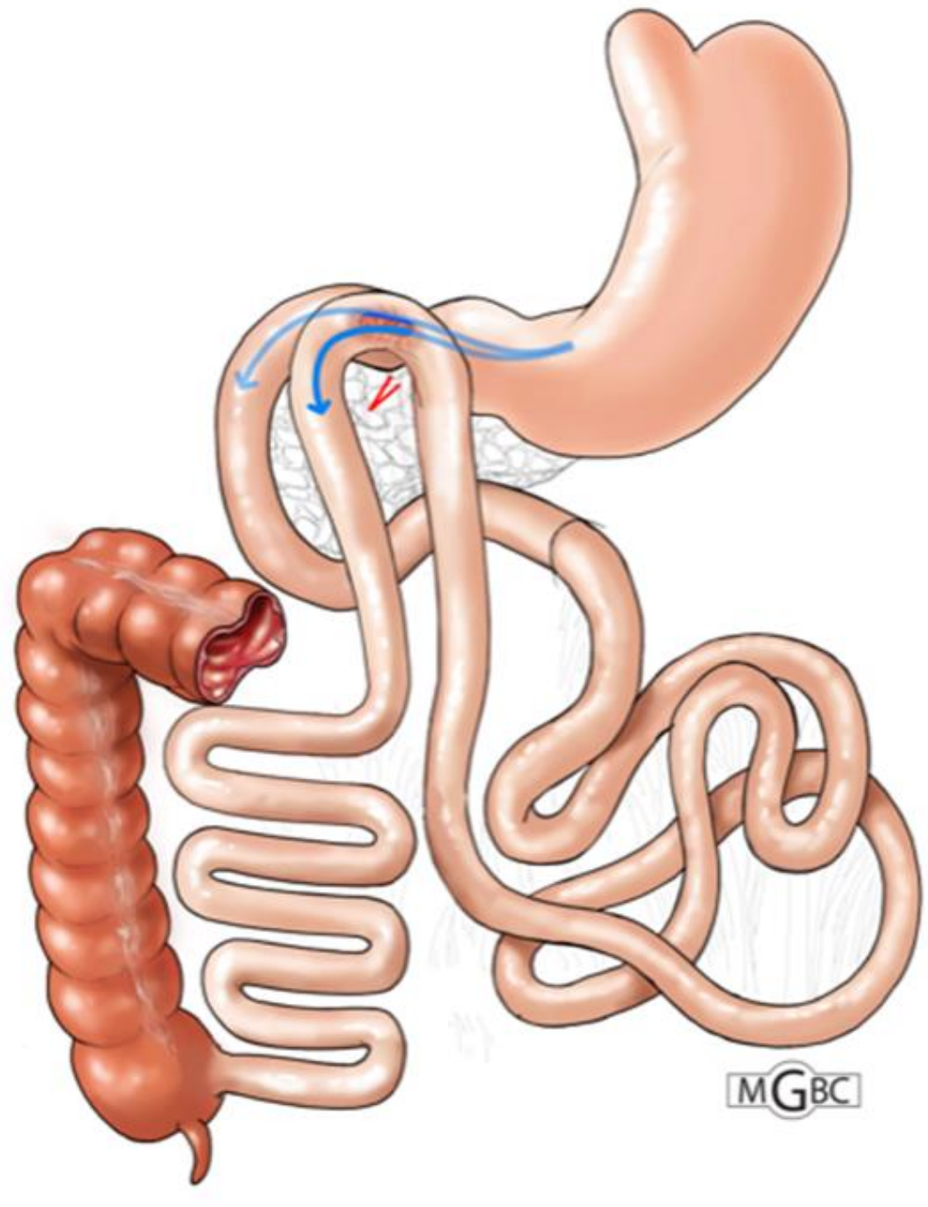
Financial Disclosures

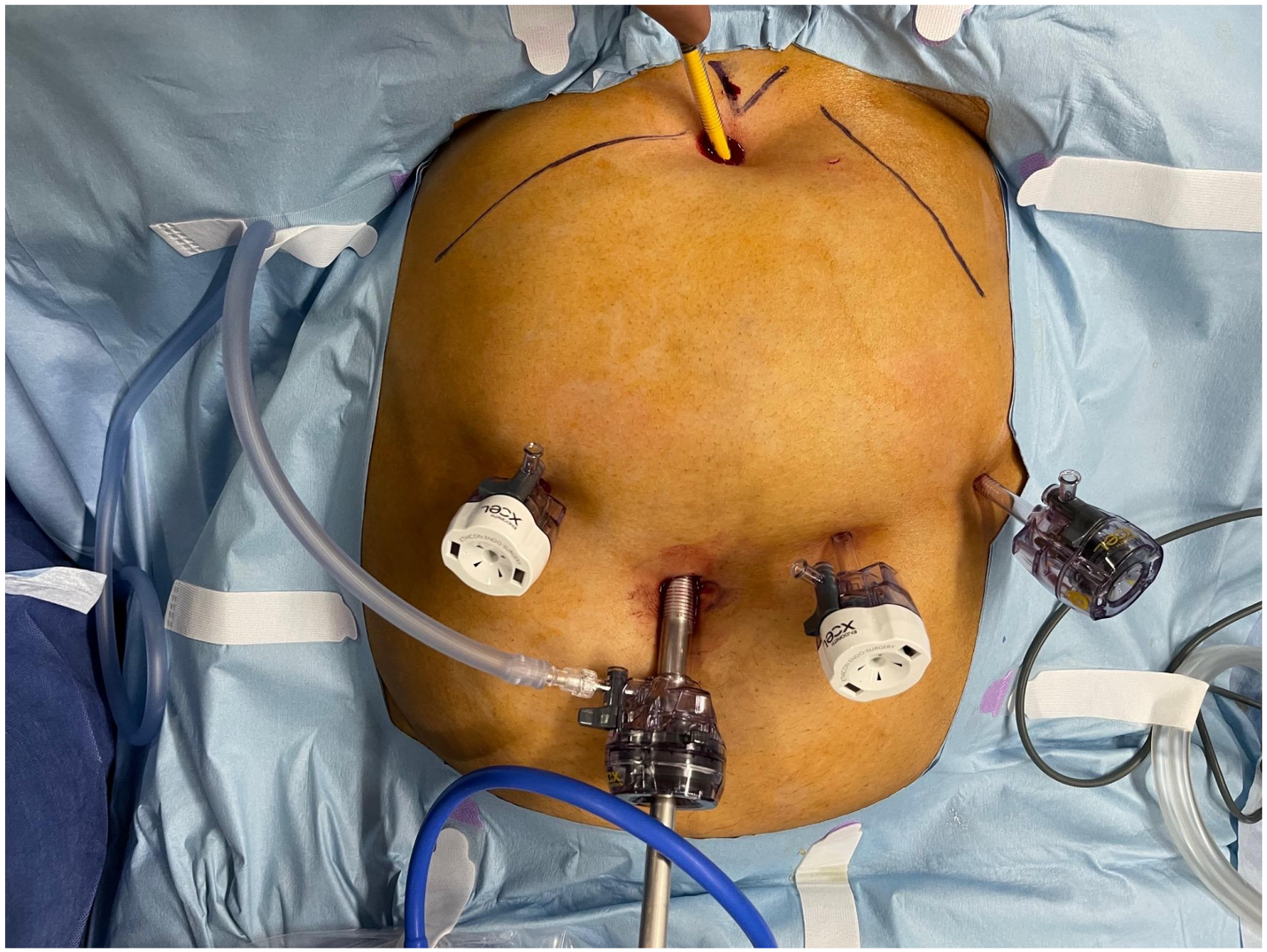
Lexington Medical	Stock Ownership/consultant
GT Metabolic Solutions Inc	Stock Ownership/consultant/Board

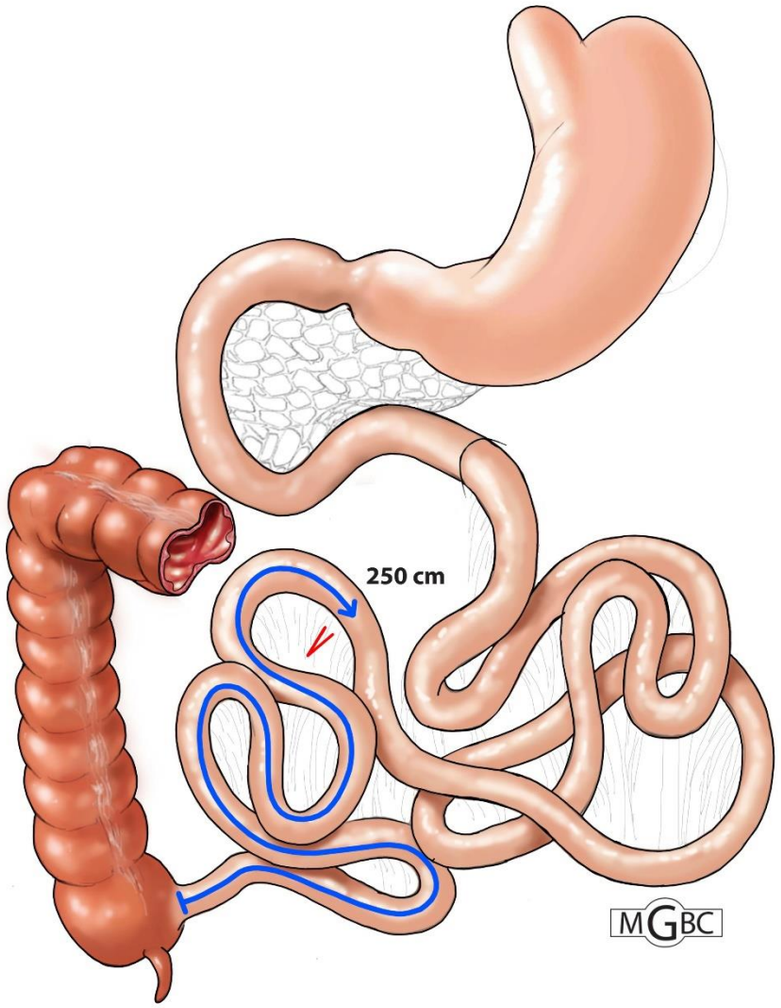
SADI vs MAGDI

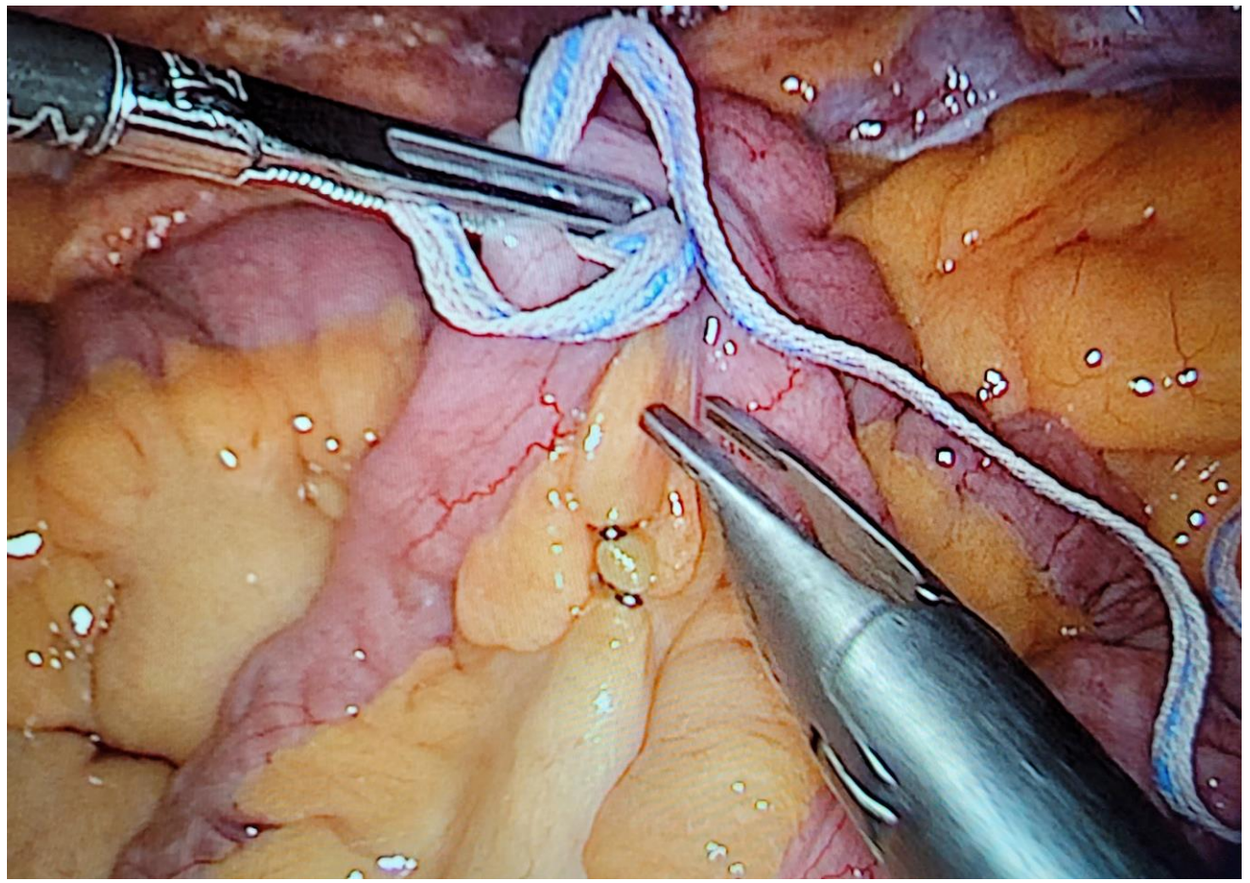




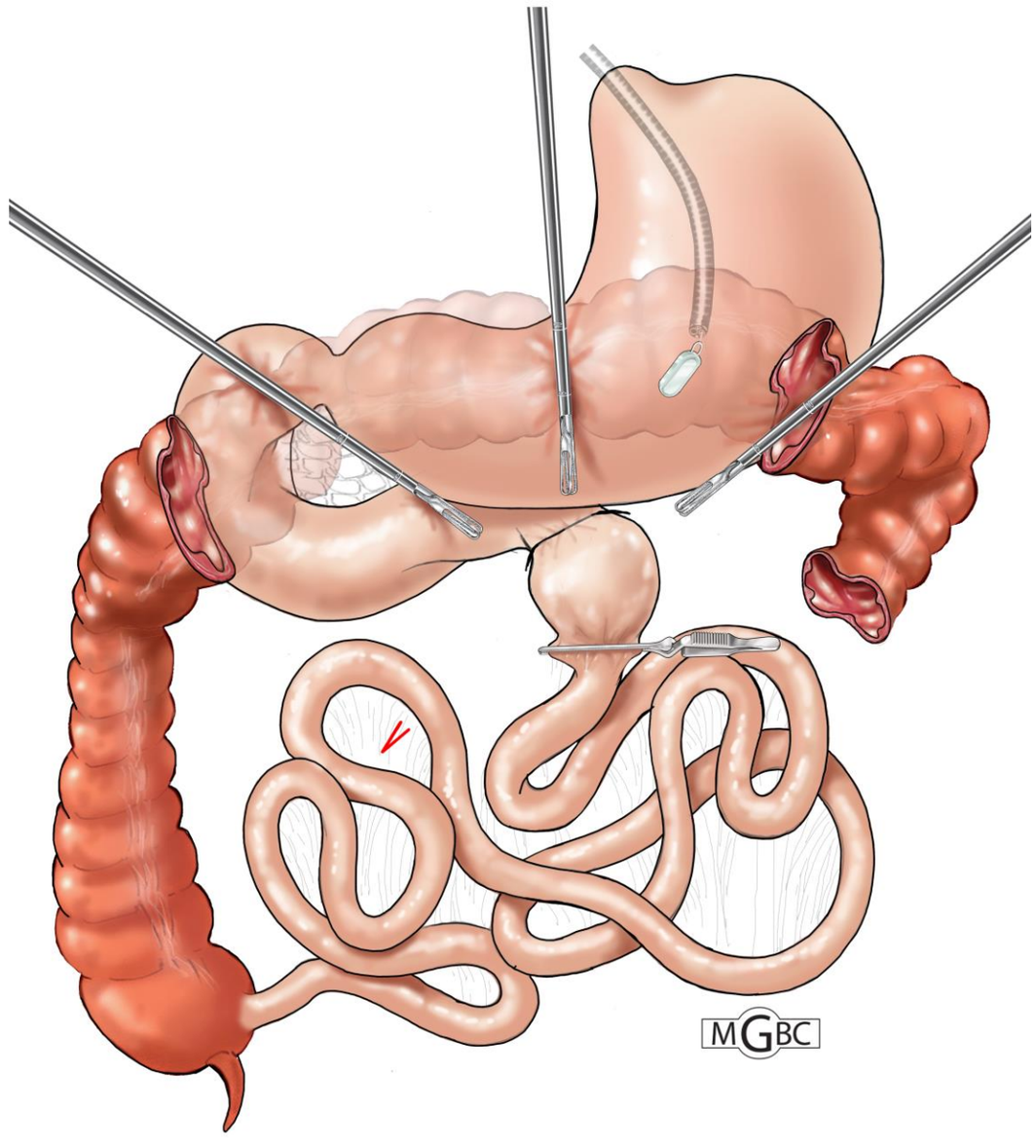
Laparoscopic assisted procedure

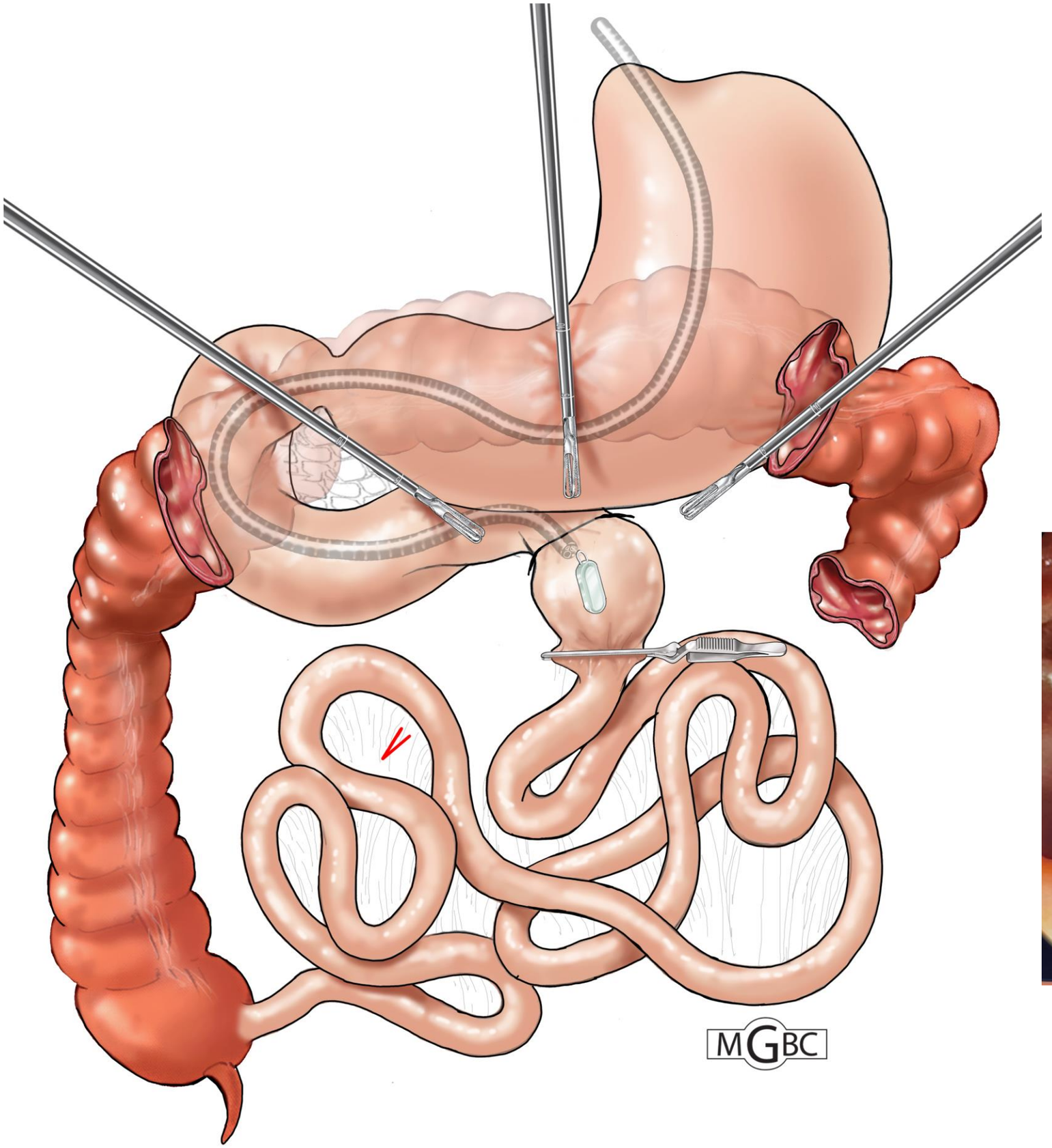



250 cm
MGBC



The MAGNET System
Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy

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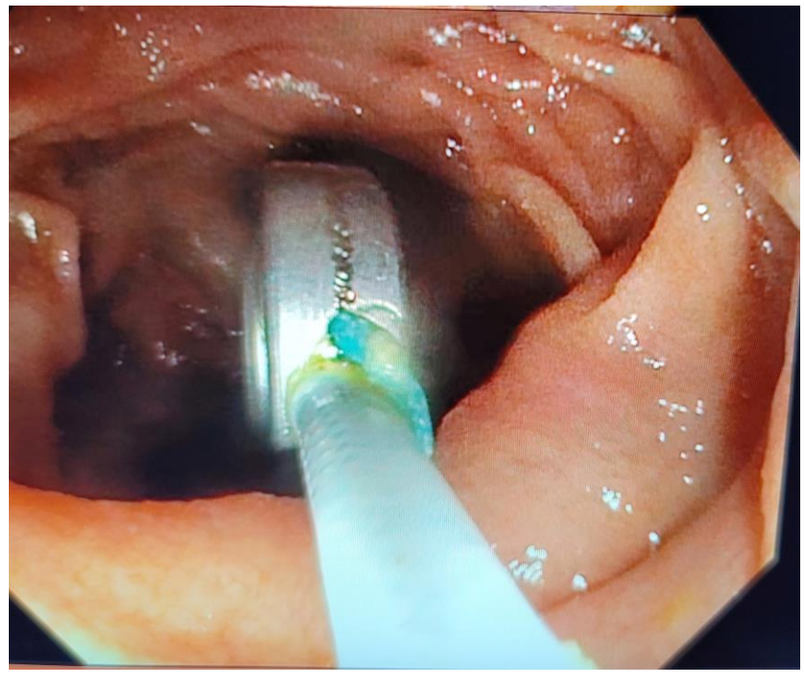

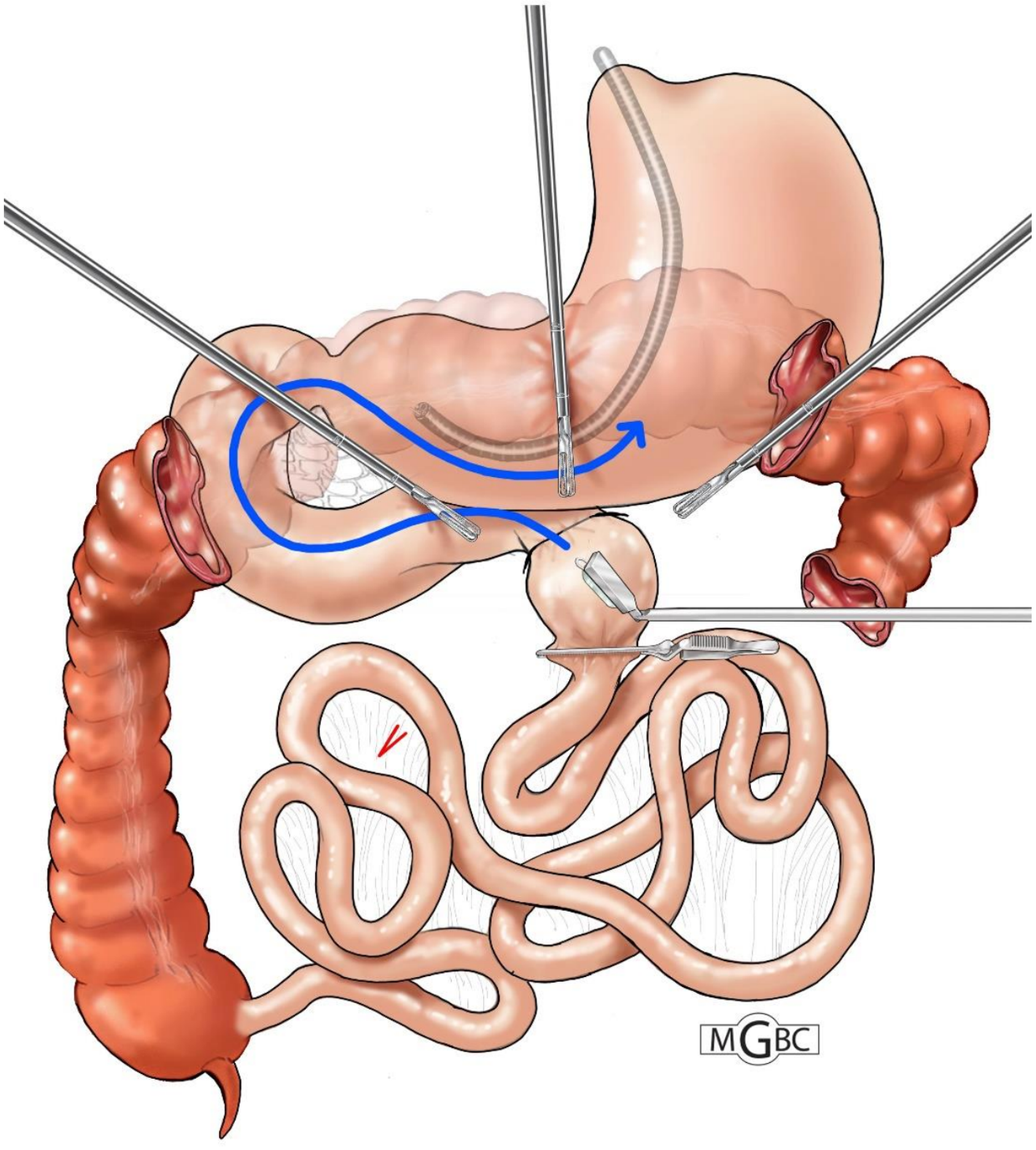
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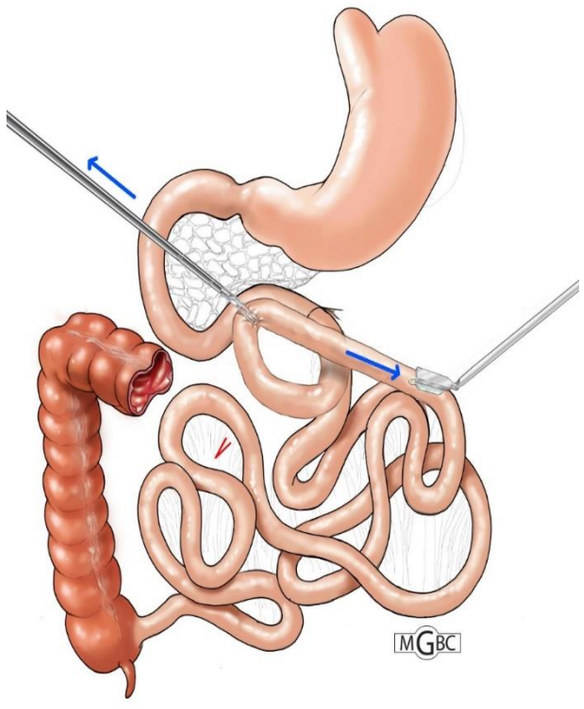

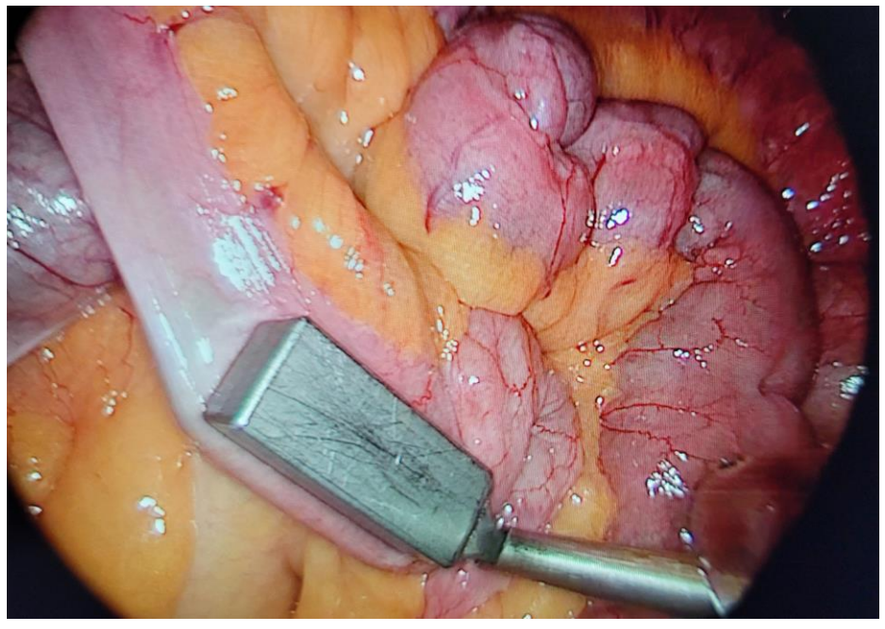

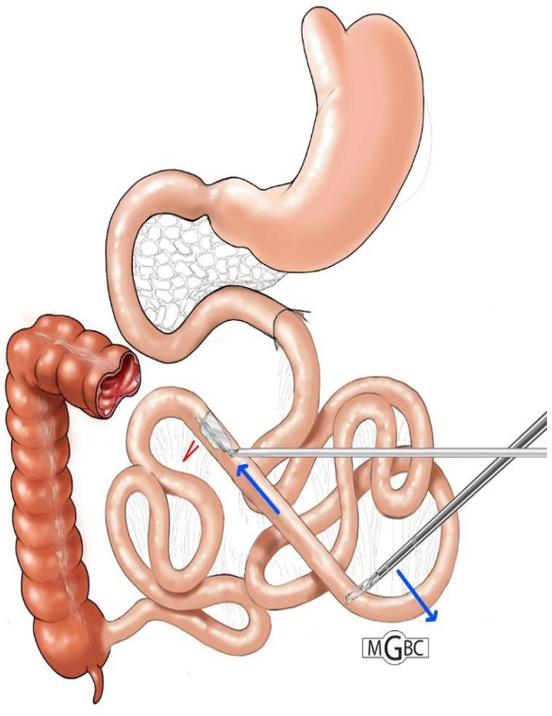

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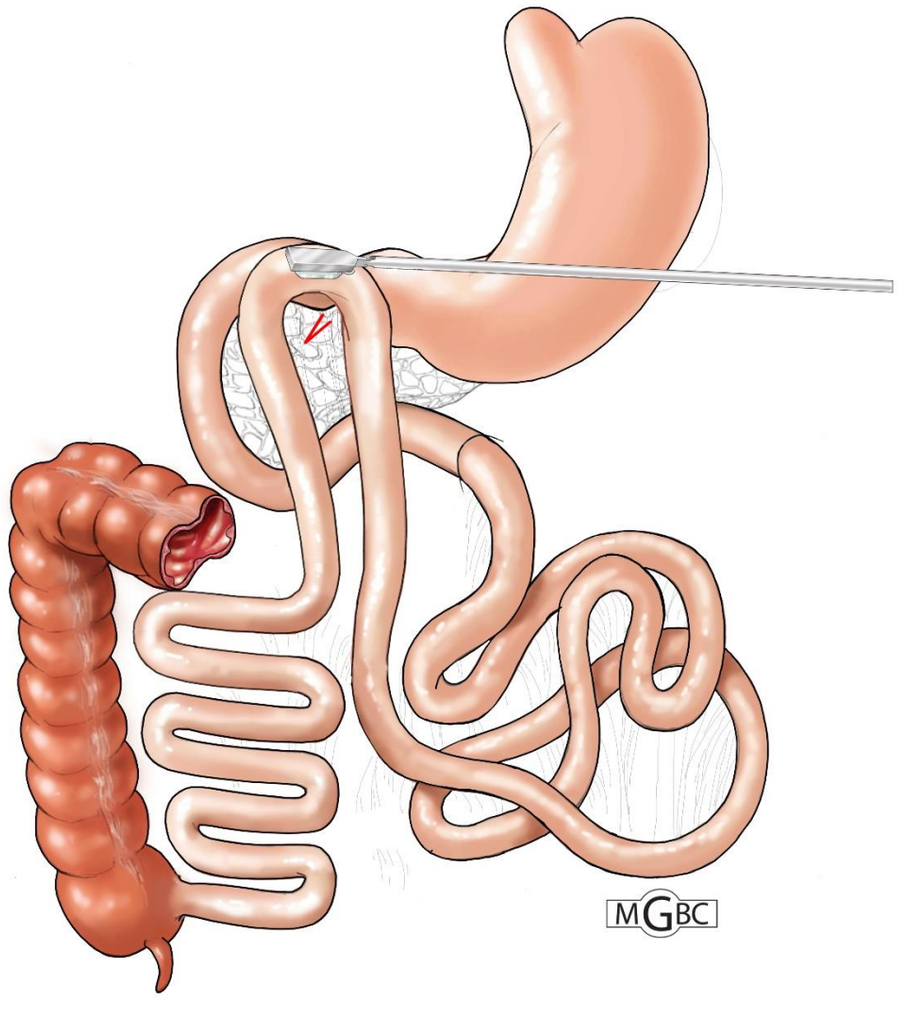

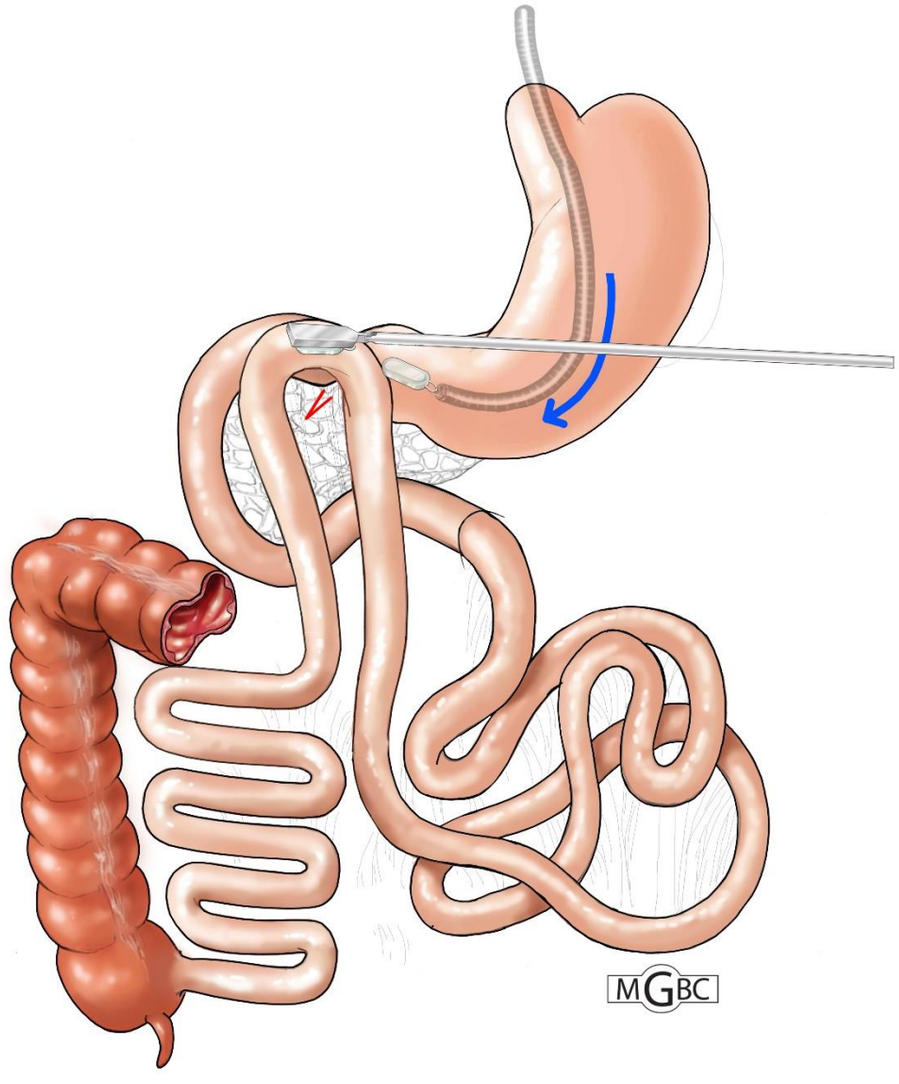

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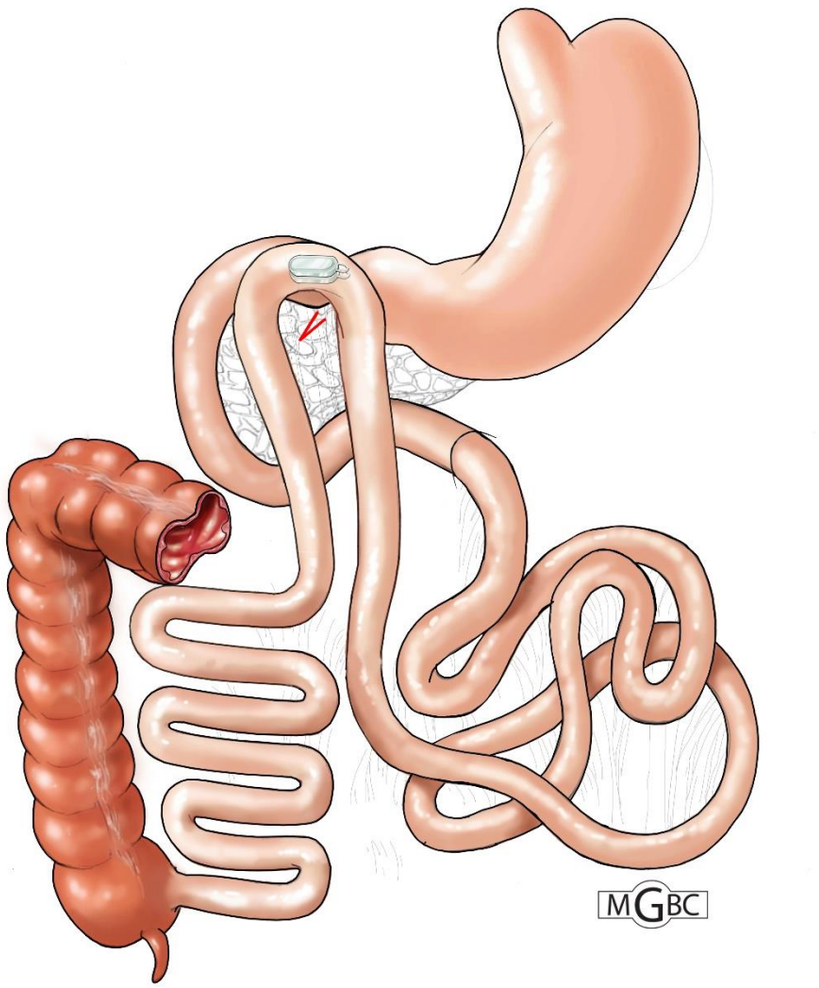
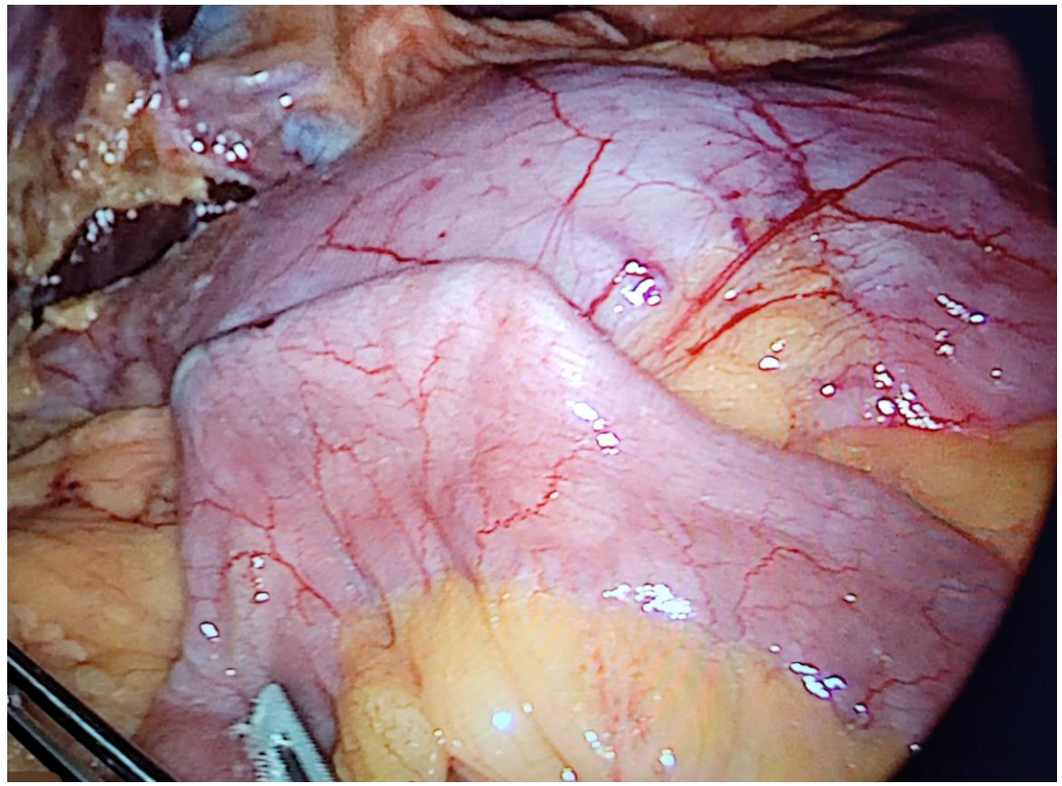
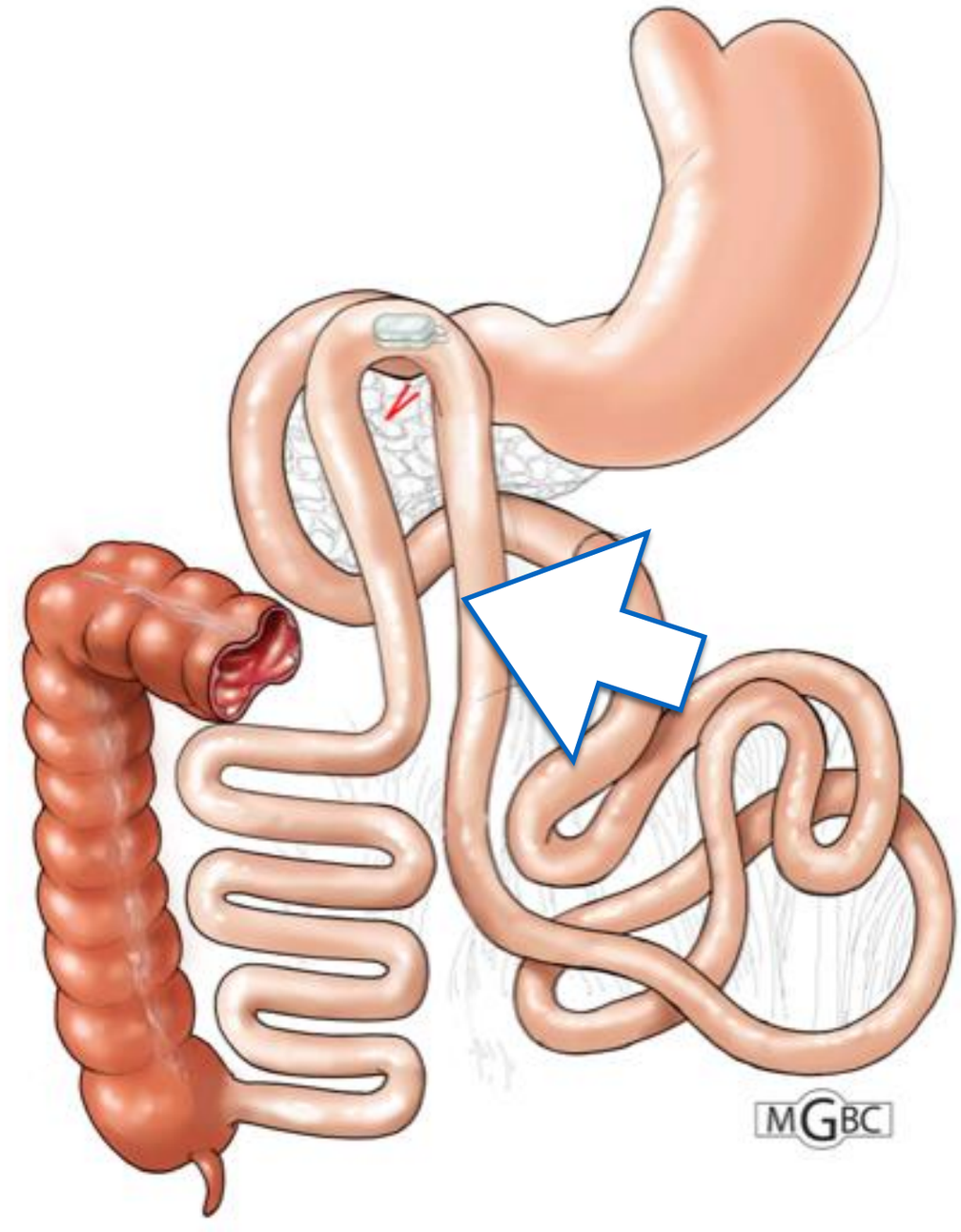
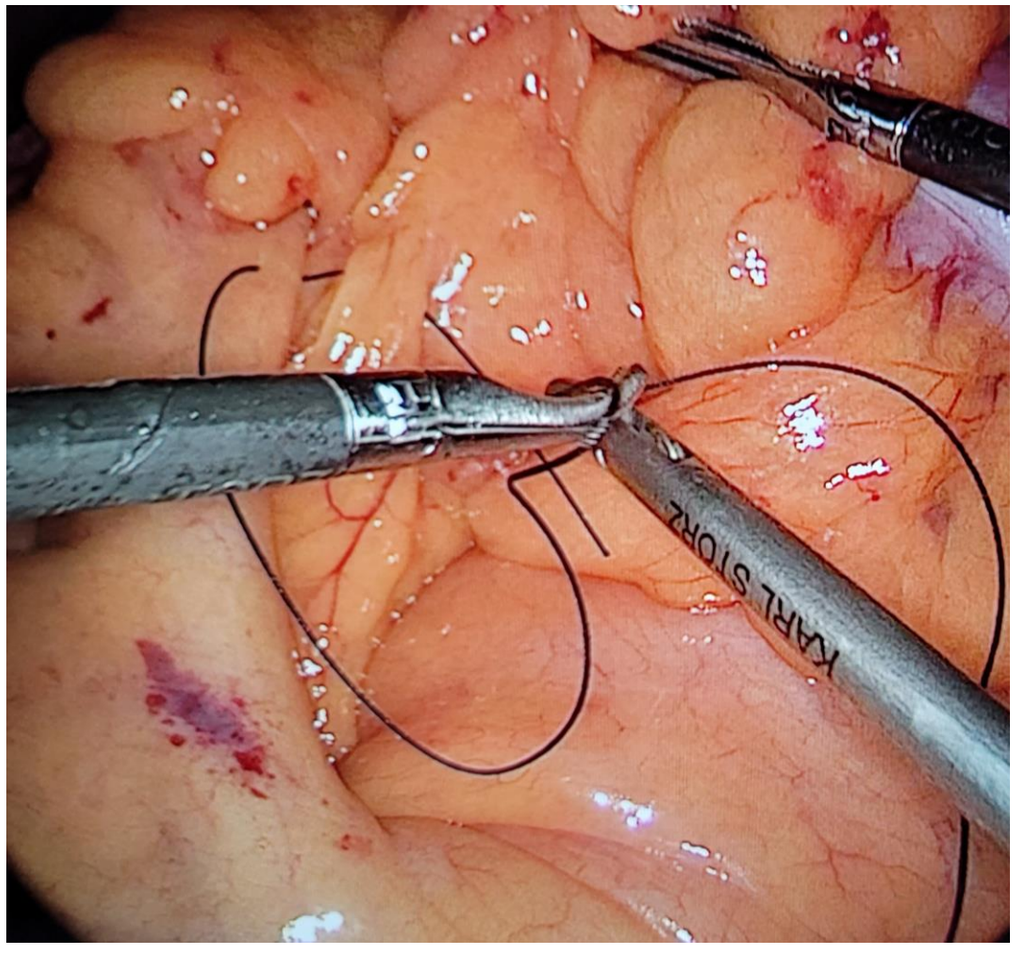


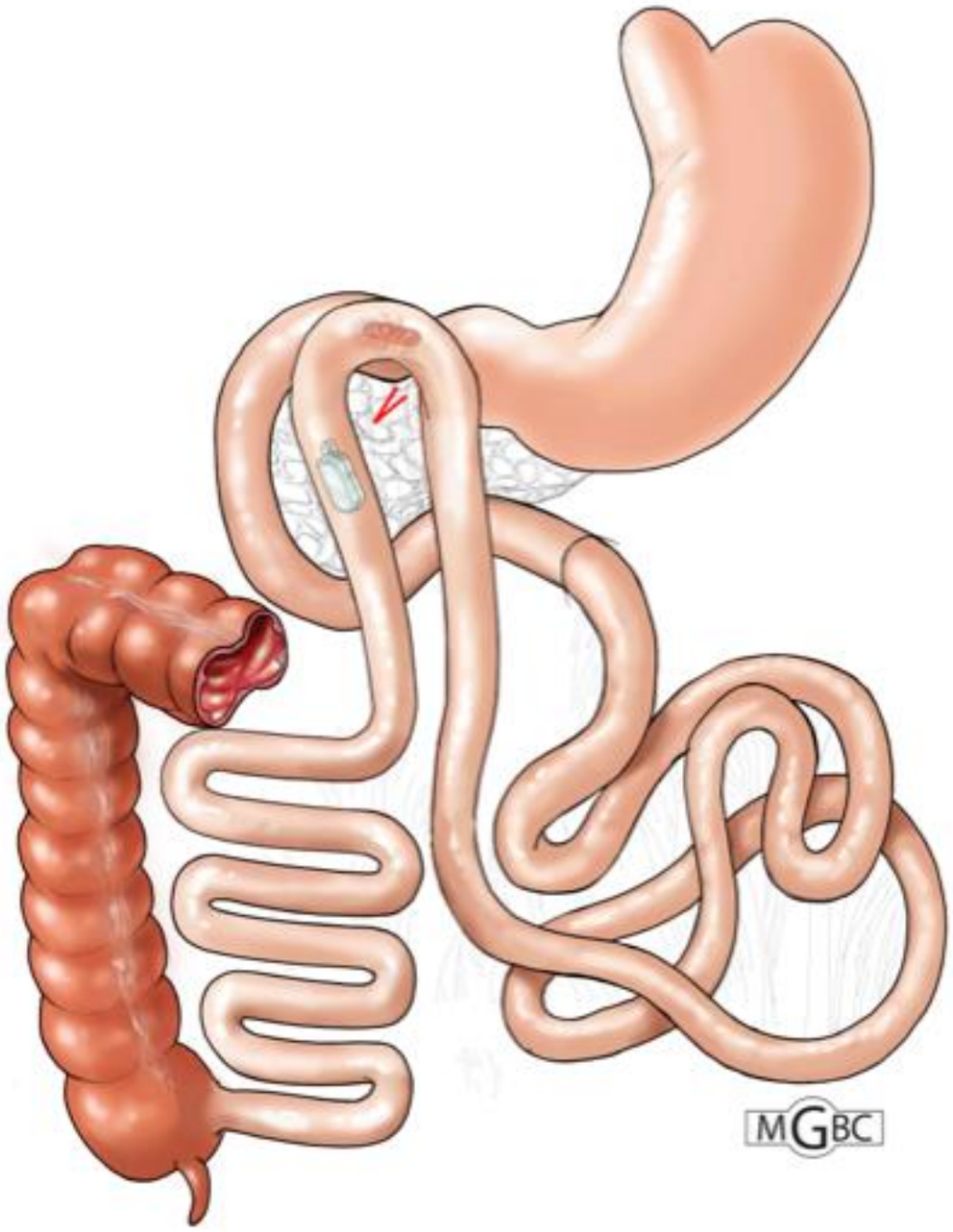


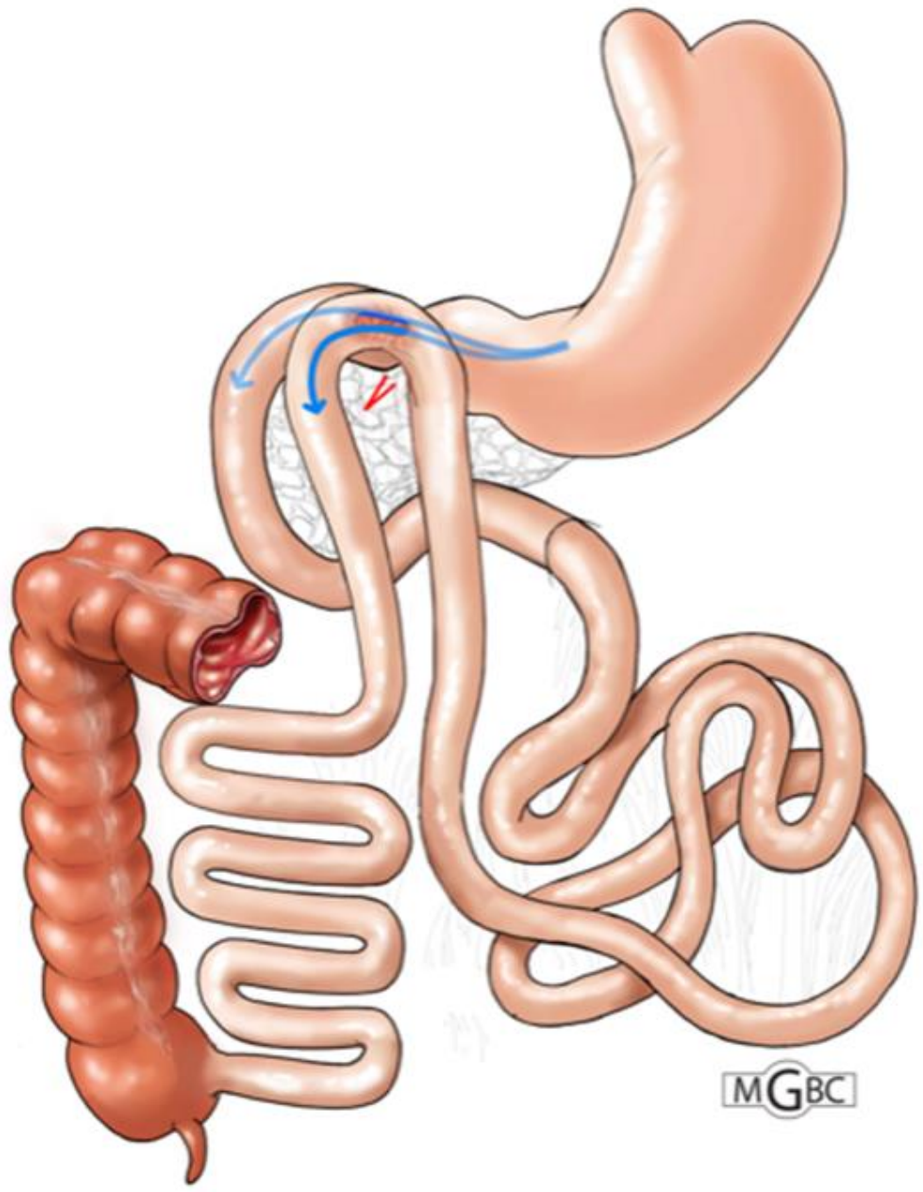
Mesenteric defect





Duodenal Bipartition





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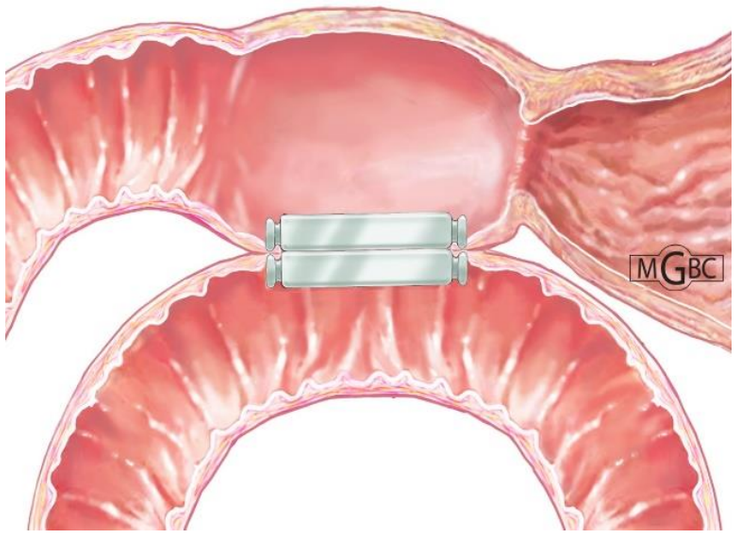

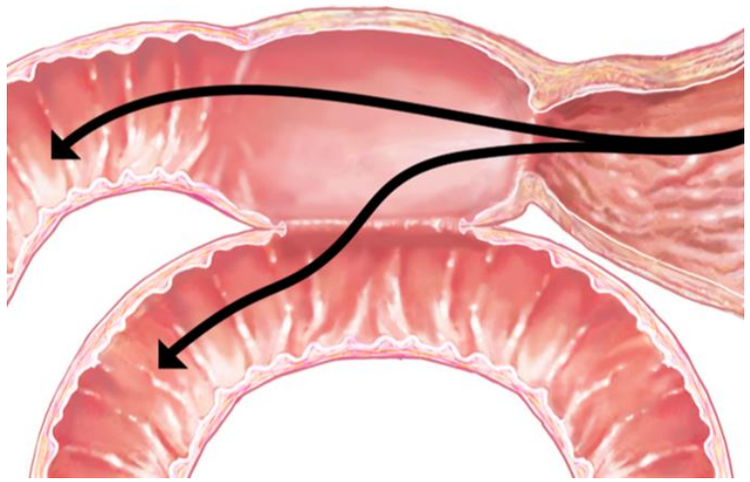

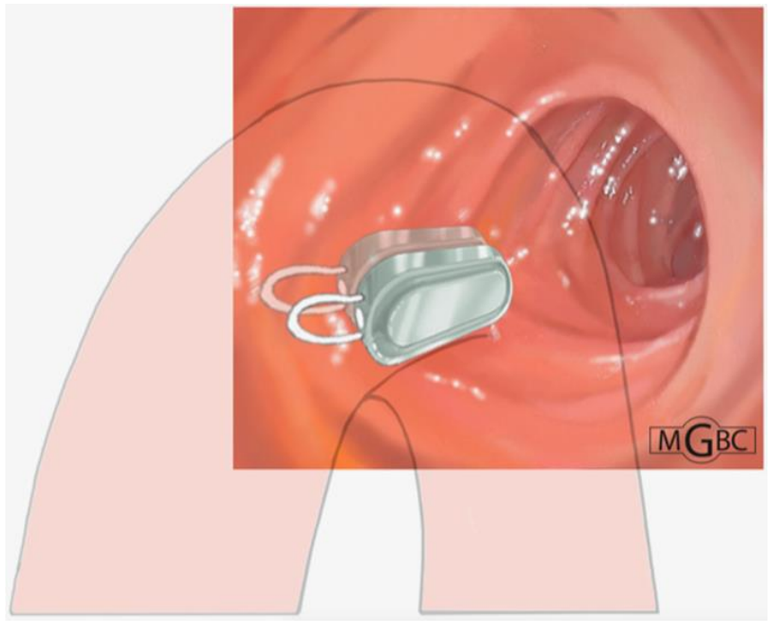

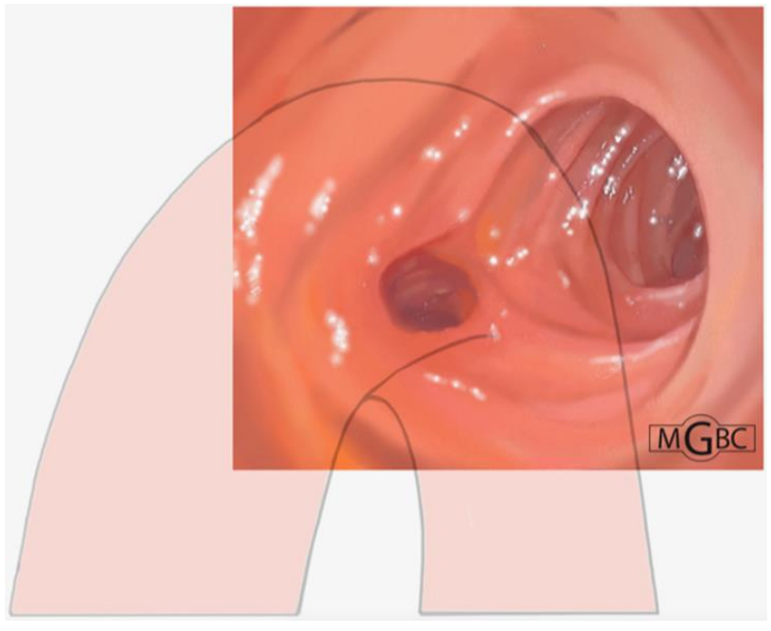

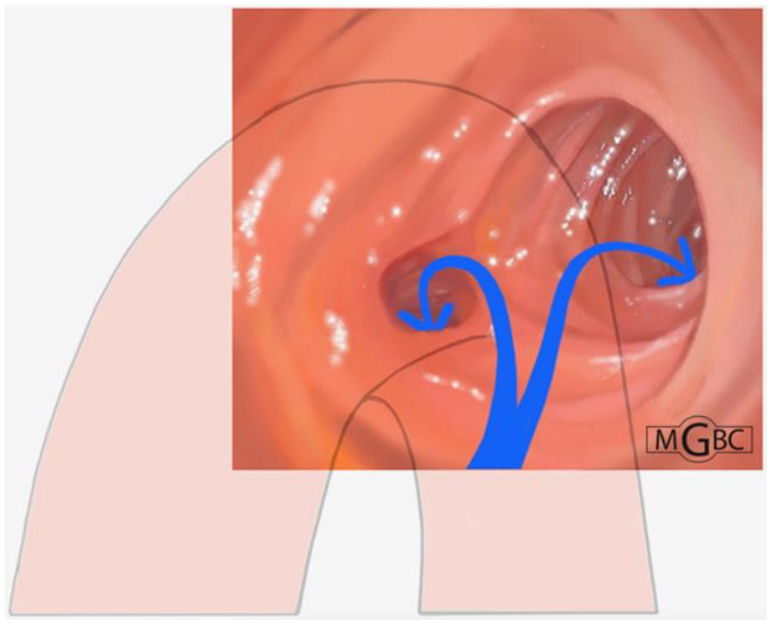

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SURGERY FOR OBESITY AND RELATED DISEASES

Original article

Side-to-side magnetic duodeno-ileostomy in adults with severe obesity with or without type 2 diabetes: early outcomes with prior or concurrent sleeve gastrectomy

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Table 1. Patient characteristics and perioperative outcomes

Characteristics	**Side-to-side MagDI-*after*-SG (revision)** n=19	**Side-to-side MagDI+SG (concurrent; primary)** n=24	**P-value**
Preoperative			
Age, yrs, mean±SEM (range)	43.7±2.0 (28.0-57.0)	43.7±1.8 (28.0-59.0)	0.981
Females, n (%)	18 (94.7)	20 (83.3)	0.363
Ethnicity			
Caucasian, n (%)	18 (94.7)	18 (75.0)	0.112
Not offered, n (%)	1 (5.3)	6 (25.0)	
Height, cm, mean±SEM (range)	161.5±2.8 (125.0-184.0)	165.5±1.6 (154.0-185.0)	0.204

Table 1. Patient characteristics and perioperative outcomes

Characteristics	**Side-to-side MagDI-*after*-SG (revision)** n=19	**Side-to-side MagDI+SG (concurrent; primary)**	**P-value**
Weight, kg, mean±SEM (range)	107.3±5.2 (69.6-156.5)	121.9±3.3 (97.0-155.0)	< 0.05
BMI, kg/m^2, mean±SEM (range)	41.0±1.4 (30.2-52.3)	44.4±0.8 (36.8-50.9)	< 0.05
Waist circumference (cm), mean±SEM (range)	124.1±3.6 (97.0-150.0)	128.1±2.7 (109.0-163.0)	0.459
Ideal weight kg, mean±SEM (range)	65.5±2.2 (39.1-84.6)	68.6±1.4 (59.3-85.6)	0.223
Excess weight, kg, mean±SEM (range)	41.8±4.0 (13.1-81.7)	53.4±2.4 (32.2-71.1)	< 0.05

Table 1. Patient characteristics and perioperative outcomes

Characteristics	**Side-to-side MagDI-*after*-SG (revision)** n=19	**Side-to-side MagDI+SG (concurrent; primary)** n=24	**P-value**
Type 2 diabetes, n (%)	1 (5.3)	9 (37.5)	< 0.05
$HbA1_C$, %, mean±SEM	7.1 (–)	6.2±0.3 (5.0-10.0)	NA
Glucose, %, mean±SEM	119.6 (–)	112.7±5.8 (82.0-178.8)	NA

Table 1. Patient characteristics and perioperative outcomes

Characteristics	**Side-to-side MagDI-*after*-SG (revision)** n=19	**Side-to-side MagDI+SG (concurrent; primary)** n=24	**P-value**
Perioperative			
Operative time, min, mean±SEM (range)	67.0±4.7 (33.0-120.0)	175.1±8.6 (99.0-250.0)	< 0.001
Hospital stay, days, mean±SEM (range)	1.1±0.1 (1.0-2.0)	6.0±1.7 (2.0-40.0)*	< 0.01
Expulsion of magnets, days, mean±SEM (median)	39.0±4.6 (35.0)	48.2±4.7 (48.5)	< 0.05

mary Outcome: 100% Magnet System Feasibility and Performan

Feasibility / Performance Criteria (D90)	n (%)
Placement of the device with >90% alignment of Magnets	24 (100%)
Passage of the device without invasive re-intervention	24 (100%)
Creation of a patent anastomosis confirmed radiologically	24 (100%)

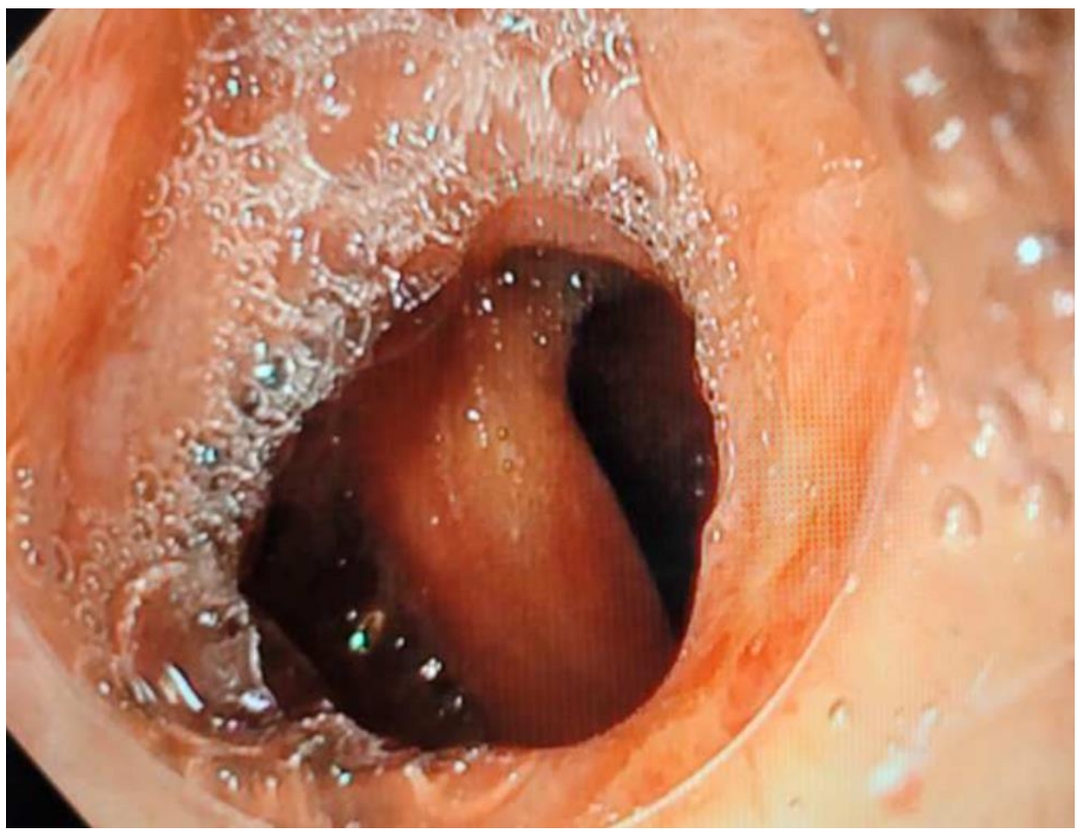
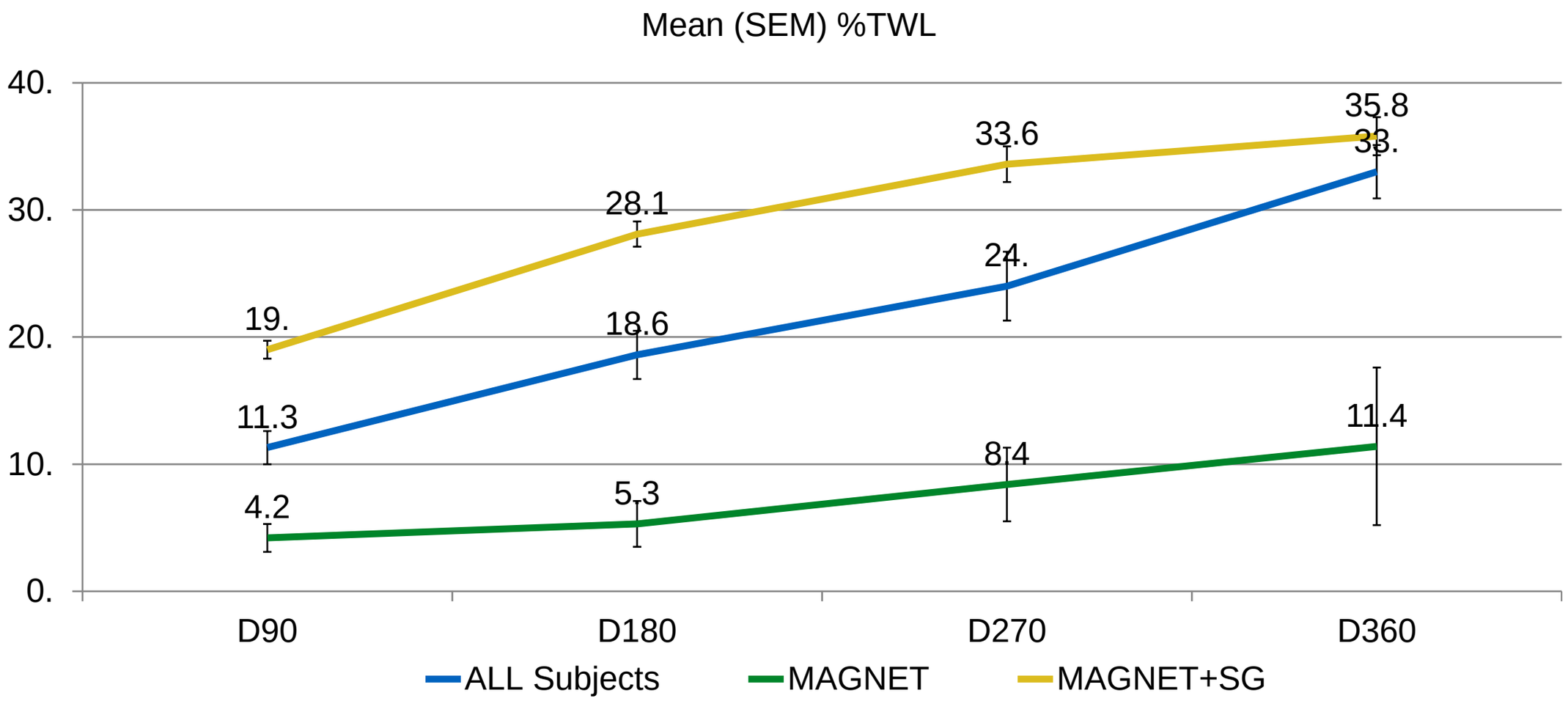


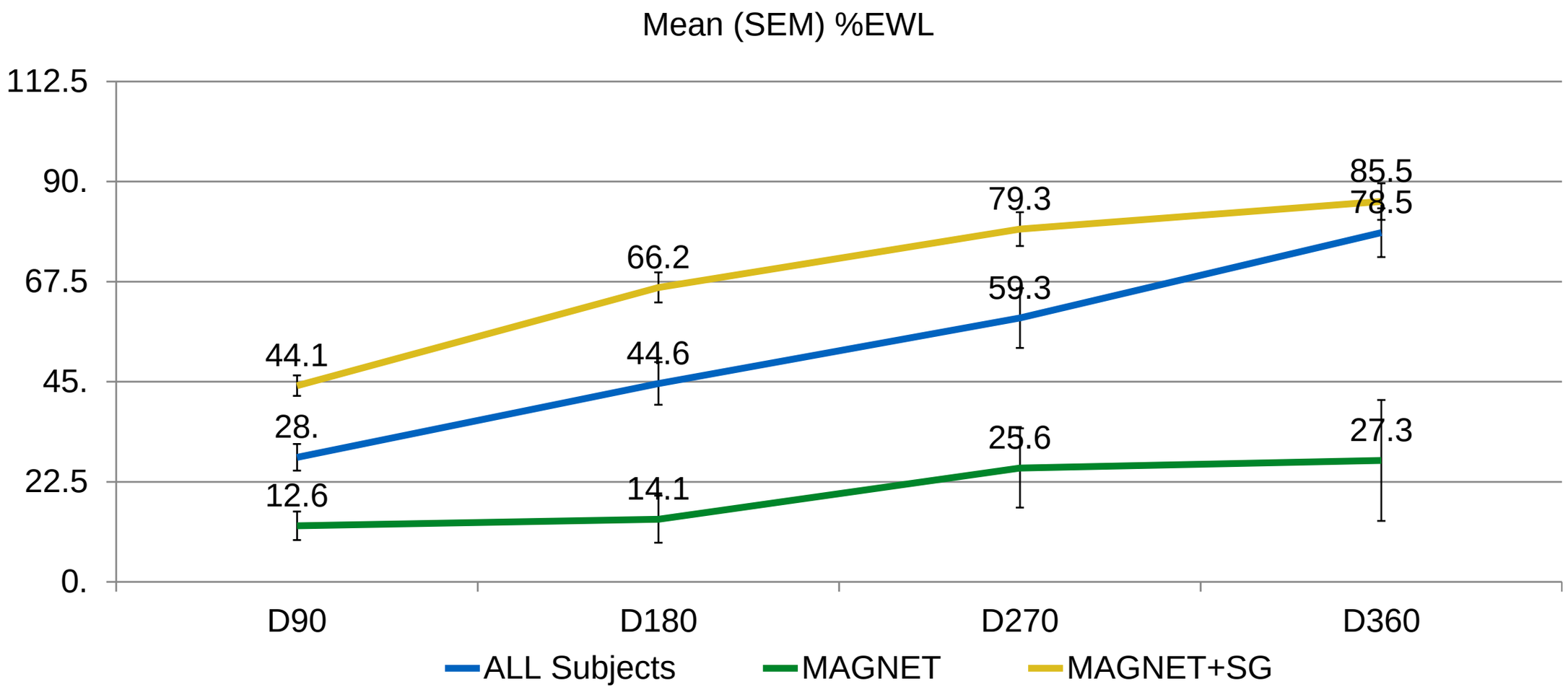
Table 3. Evolution of weight following side-to-side Magnet Anastomosis System duodeno-ileostomy after prior sleeve gastrectomy (MagDI-*after*-SG) or MagDI+SG (concurrent) from baseline through 12 months

Treatment group	**Weight parameter**	**Baseline** Mean ±SEM	**3-month follow-up** Mean ±SEM	Mean change ±SEM (95%CI)	Within-group P-value†	**6-month follow-up** Mean ±SEM	Mean change ±SEM (95%CI)	Within-group P-value†	**12-month follow-up** Mean ±SEM	Mean change ±SEM (95%CI)	Within-group P-value†
MagDI-*after*-SG	Absolute weight, kg	107.3±5.2 (n=19)	102.3±5.5 (n=18)	5.1±1.6 (1.7, 8.5)	<0.05	101.6±6.5 (n=13)	8.0±2.5 (2.6, 13.5)	<0.01	95.0* —	12.3* —	<0.01* —
MagDI+SG		121.9.±3.3 (n=24)	99.8±3.0 (n=23)	23.2±0.9 (21.2, 25.2)	<0.001	87.8±2.8 (n=24)	34.2±1.6 (30.9, 37.4)	<0.001	77.6±4.7 (n=5)	40.0±3.1 (31.4, 48.6)	<0.001 —
Between-group P-value§	—	<0.05	0.677	—	—	<0.05	—	—	<0.05*	—	—
MagDI-*after*-SG	BMI, kg/m^2	41.0±1.4 (n=19)	39.2±1.5 (n=18)	1.9±0.6 (0.7, 3.3)	<0.05	37.6±1.6 (n=13)	3.0±0.9 (1.0, 5.0)	<0.01	34.0* —	7.0* —	<0.01* —
MagDI+SG		44.4±0.8 (n=24)	36.3±0.8 (n=23)	8.5±0.3 (7.8,9.1)	<0.001	32.0±0.8 (n=24)	12.4±0.4 (11.5, 13.3)	<0.001	29.3±1.5 (n=5)	15.1±1.0 (12.2, 18.0)	<0.001 —
Between-group P-value§	—	<0.05	0.066	—	—	<0.01	—	—	<0.05*	—	—
Treatment group			Proportion > 5.0% TWL	Mean %TWL ±SEM	Mean %EWL ±SEM	Proportion > 5.0% TWL	Mean %TWL ±SEM	Mean %EWL ±SEM	Proportion > 5.0% TWL	Mean %TWL ±SEM	Mean %EWL ±SEM
MagDI-*after*-SG	—	—	44.4 (8/18)	4.7±1.5 (n=18)	12.6±3.9 (n=18)	69.2 (9/13)	7.0±2.1 (n=13)	17.4±5.9 (n=13)	>69.2 —	11.0* —	28.0* —
MagDI+SG	—	—	100.0 (23/23)	19.0±0.7 (n=23)	44.1±2.3 (n=23)	100.0 (24/24)	28.1±1.0 (n=24)	66.2±3.4 (n=24)	100.0 (n=5)	34.0±1.4 (n=5)	80.2±6.6 (n=5)
Between-group P-value§	—	—	<0.001¶	<0.001	<0.001	<0.001¶	<0.001	<0.001	<0.001¶*	<0.001*	<0.001*

Percent Total Weight Loss (%TWL) over one year



Percent Excess Weight Loss (%EWL) over one year



Early Data Demonstrates Safety of the Magnet System

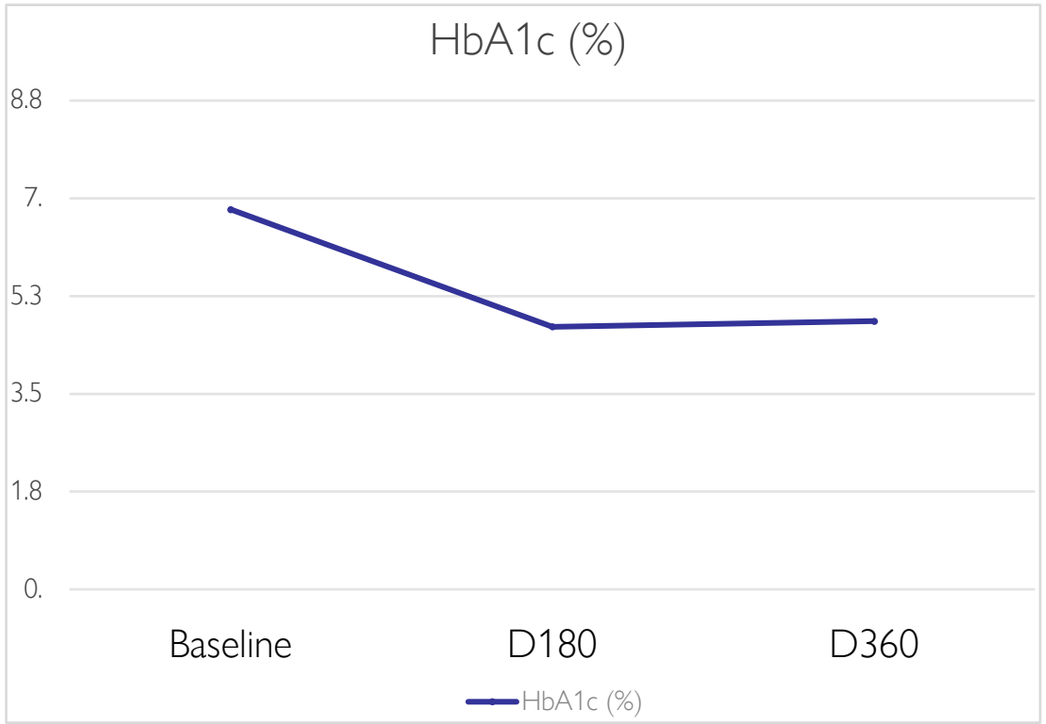
Clavien-Dindo Classification (n total AEs)	Procedure – D30 (n=57)	>D30 – D180 (n=57)	TOTAL (n=57)
Grade I	17 (30%)	8 (14%)	25 (44%)
Grade II Requiring pharmacological treatment	9 (16%)	13 (23%)	22 (39%)
Grade III Requiring surgical, endoscopic, or radiological intervention	6 (10%)	4 (7%)	10 (17%)
Grade IV Life-threatening	0 (0%)	0 (0%)	0 (0%)
Grade V Death of a patient	0 (0%)	0 (0%)	0 (0%)
TOTAL Adverse Events	32 (56%)	25 (44%)	57 (100%)

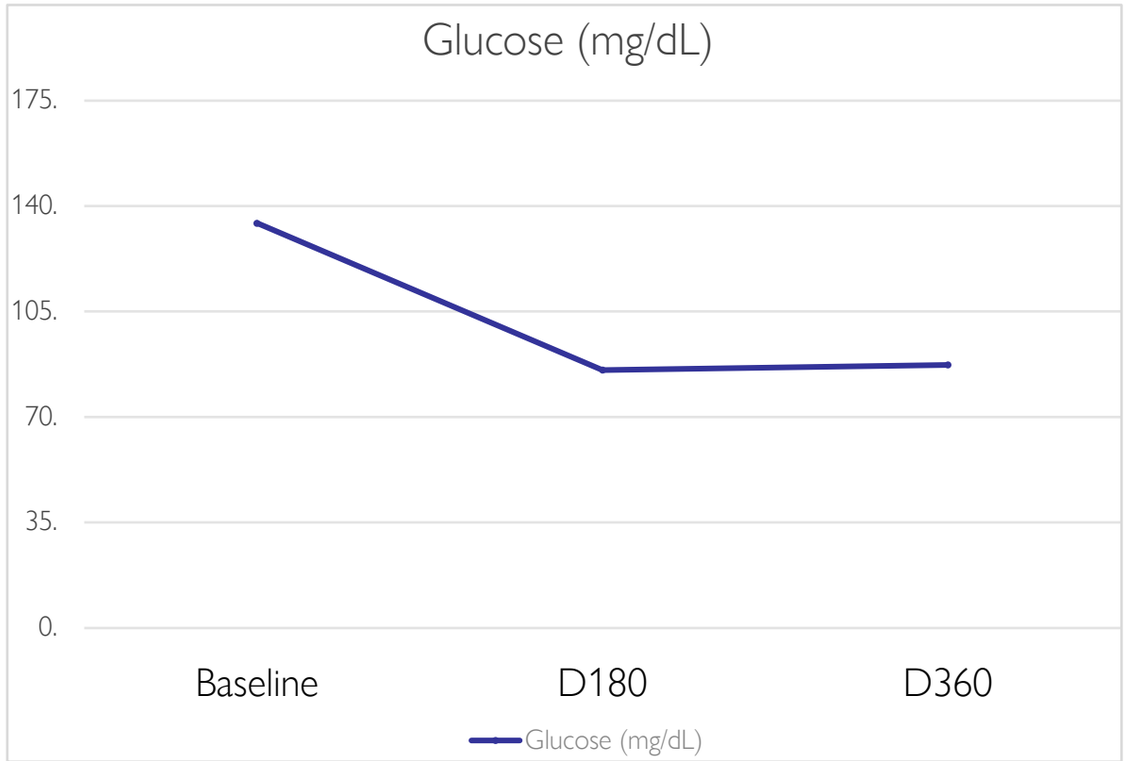
Table 2. Clavien-Dindo Classification grade II and III severe adverse events (SAEs) following side-to-side magnetic duodeno-ileostomy with sleeve gastrectomy (MagDI+SG) and side-to-side MagDI-*after*-SG through 6 months

Side-to-side magnetic duodeno-ileostomy *plus* sleeve gastrectomy (concomitant; primary)				
Event	**CDC Grade**	**MagDI+SG procedure related?**	**Magnet System related?**	**Description**
Urinary tract infection	II Mild	Yes	No	Patient presented with fever on day 1 after MagDI+SG study procedure, prolonging hospitalization. Urinary analysis confirmed infection; treated with 1 dose Fosfomycin; resolved with no sequelae.
Dehydration	II Moderate	No	No	Post MagDI+SG, patient hospitalized for dehydration and hypokalemia outside country 67 days (holiday); hospitalized again for nausea, vomiting, abdominal pain with suspicion of gastritis; hypokalemia was supplemented, event resolved.
Post-SG ano-rexia+diarrhea, nausea, vomiting	II Moderate	No	No	Patient presented with diarrhea 54 days post MagDI+SG procedure: stools watery, not bloody, ≥7 episodes/. 2 days later, vomiting began with dehydration, anorexia, dizziness. Abdominal CT showed no features or perforation. Hospitalized 24 hrs for monitoring with rehydration, IV antiemetics. Symptoms resolved without sequelae.
JI obstruction on flange	III Mild	Yes	No	At MagDI+SG procedure, mesenteric defect closed per protocol. Patient presented 115 days later with occlusion of small intestine by internal hernia in mesentery. Laparoscopic repair performed; discharged 2nd day without sequelae.
Major pneumoperi-toneum on gastric fistula	III Severe	No	No	On postoperative MagDI+SG day 2, patient developed fever (38.5° C) and antibiotics we restarted. Abdominal CT revealed major pneumoperitoneum. No objectified leakage found on exploratory laparoscopy. Patient developed sepsis; was started on amukin. Thoraco-abdominal CT (injection+barium) showed no leakage or infiltration, but with bi-basal pneumonia; treated with antibiotics. CT scan with gastrografin revealed fistula on left edge of SG + localized abscess. Stents placed and removed. Esophageal prostheses placed in lower esophagus and at EGJ. Naso-jejunal tube placed, and replaced with central line + parenteral nutrition; all later removed. Persistent para-esophageal fistula with leak. Esophageal stents removed; two stents placed in fistula. Abdominal CT with no major findings; patient discharged. SAE determined to be post-SG gastric fistula with favorable evolution after 3 months of multiple hospitalizations and treatments.

Pelvic fluid collection	III Severe	Yes	No	On day 2 post MagDI+SG, patient developed fever with inflammatory syndrome, tachycardia, and desaturation (7-18-22). CT showed free liquid in pelvis; antibiotics started. Patient feeling slightly better, but with persistent inflammatory syndrome; 2nd CT showed pelvic collection which was drained in surgery transvaginally under general anesthesia. Procedure complicated by bleeding 2 days after; gynecology team put stiches at vaginal incision. After 2nd fever spike, antibiotics changed. After good evolution, antibiotics stopped, and patient discharged (8-11-22) in good general condition. Patient presented to Emergency Room 10-24-22 with fever, reporting purulent vaginal bleeding that stopped 48 hours before, coinciding with start of fever. She was admitted to hospital and seen by the gynecology department. CT showed pelvic collection, which was drained transvaginally. She was discharged 10-1-22 in good general condition. The source of pelvic collection was not ascertained.
Cholecysto-lithiasis + choledocho-lithiasis	III Severe	No	No	Patient presented July 2022 with abdominal pain in upper right quadrant approx. 2 months after MagDI+SG procedure. Investigations showed choledocholithiasis with gallstones in gallbladder. Patient underwent ERCP+sphincterotomy in July and was scheduled for cholecystectomy in October. In August, another episode of choledocholithiasis; 2nd ERCP performed in September with cholecystectomy the following day.
Abdominal pain+nausea and vomiting	III Severe	No	No	Post MagDI+SG procedure 4 mo., patient presented with complaints of abdominal pain on right side predominantly increasing for 2 days. Unable to eat/drink for 2 days, with this difficulty since surgery. Hospitalized for treatment; gastroscopy performed. Pain determined unrelated to study device or procedure.

Secondary Outcomes Collected for Early Signals





8 of 9 diabetics are off from anti-diabetics drugs

Summary

All 43 subjects received a side-to-side DI compression anastomosis with the Magnet System (study procedure)

All cases (100%) resulted in successful alignment of the two Magnets with passage of the device naturally without migration or separation and none (0%) required invasive re-intervention

All anastomoses were confirmed patent radiologically and remained patent through 6-12 months of follow up.

Summary

All adverse events were of grade III or lower on the Clavien-Dindo Class grading system. None were determined related to the Magnet device.

There were no reports of anastomotic bleeds, leaks, obstruction, or infection and no deaths, known risks with conventional techniques (sutures or staples)

The secondary outcomes of weight loss and functional improvement in metabolic indicators
are promising in this cohort at 6-12 months.

The MAGGI (MAGnetic Gastro-Ileostomy) Study

Canada

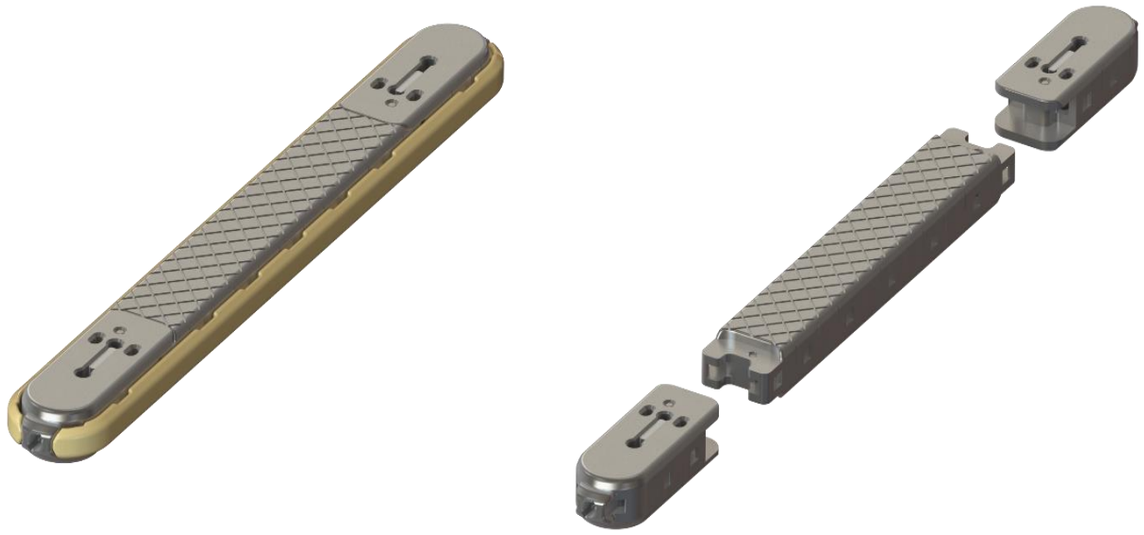
01JUL2024 Interim Data

Dr. Michel Gagner

Investigational Use ONLY.

GT Metabolic Solutions products are under development and not available for sale within any geography.

GI/GJ Biofragmentable Magnet

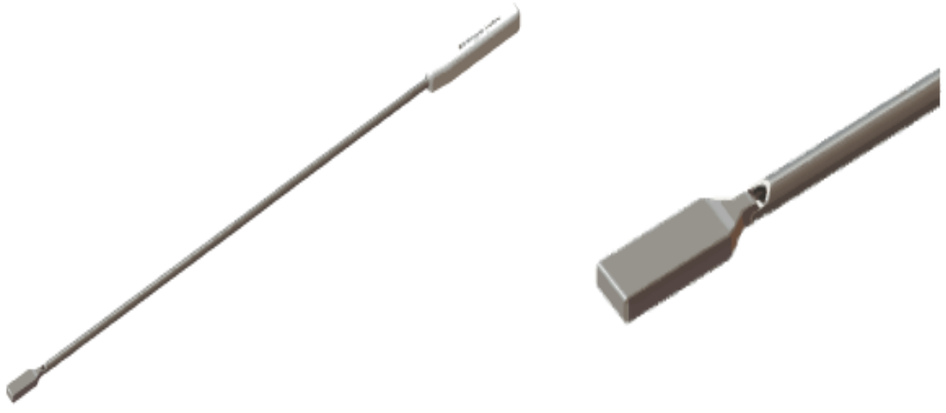


Assembly (left),

Post PGLA fragmentation (right)

Magnetic Anastomosis Delivery System

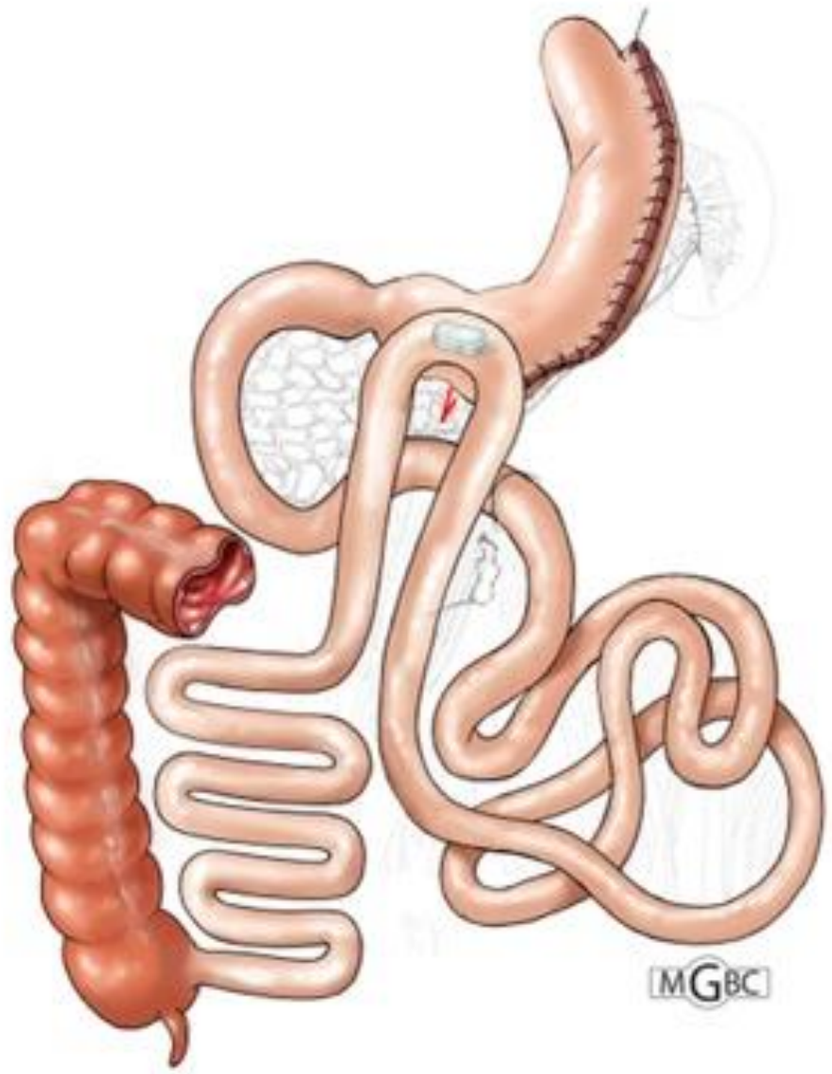
Laparoscopic Positioning Devices



- Site: Westmount Square Surgical Center, Montreal, Quebec Canada
- n=7 enrolled for gastro-ileal anastomosis between Nov 6, 2023, and May 27, 2024
- All subjects have passed day 30 follow up and five followed to six months.

Baseline Characteristics	All subjects (n=7)
Clinical	
Prior Sleeve Gastrectomy ≥12 months: n (%)	7 (100%)
Type 2 Diabetes: n (%)	0 (0%)
Body Mass Index (BMI): Mean (SEM)	38.8 (0.9) kg/m^2
Age	
Mean (SEM)	44.3 (2.4) years
Min, Max	37, 54 years
Gender	
Female: n (%)	5 (71%)
Male: n (%)	2 (29%)

*n=23


MGBC

- The MAGGI System was successfully placed in all n=7 subjects
  - Some challenges to navigate the 80mm device through the pylorus in two cases, left Magnet in stomach and placed second distal Magnet via enterotomy in the ileum
- All subjects have passed a paired set of docked Magnets naturally without migration or separation and none (0%) required invasive re-intervention.

Feasibility / Performance Criteria	n=6 (%)
Placement of the device with ≥90% alignment of Magnets	6 (100%)
Passage of the device without invasive re-intervention	6 (100%)
Creation of a patent anastomosis confirmed radiologically	6 (100%)

- Median expulsion time (n=6): 24.3 days

  (Mean (SEM): 32.8 (7.3) days) (Range 14 – 59 days)

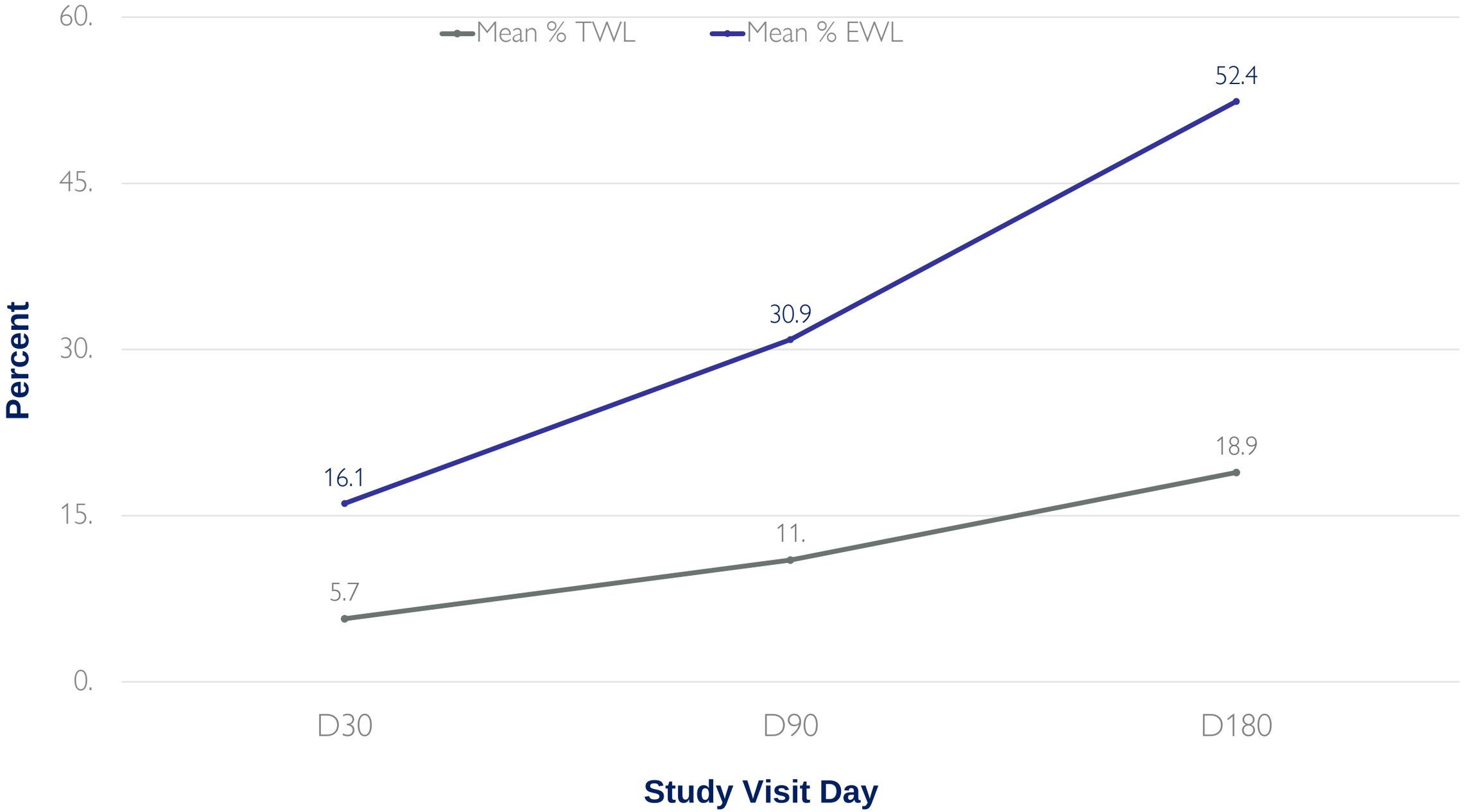
Event	Serious AE?	Clavien-Dindo Grade by Sponsor	Severity	Relationship to Device	Relationship to Procedure	Days Since Procedure
Anemia	No	II	Mild	Not Related	Possibly Related	91
Constipation	No	I	Mild	Not Related	Not Related	11
Diarrhea	No	I	Mild	Not Related	Not Related	31
Diarrhea	No	I	Mild	Not Related	Possibly Related	14
Diarrhea	No	II	Mild	Not Related	Not Related	127
GERD	No	II	Mild	Not Related	Possibly Related	20
Hematochezia (blood in stool)	No	I	Mild	Not Related	Not Related	62
Hemorrhoids	No	II	Mild	Not Related	Not Related	42
Hordeolum (stye in L eye)	No	I	Mild	Not Related	Not Related	4
Hypoalbuminemia	No	II	Mild	Not Related	Possibly Related	168
Hypoproteinemia	No	II	Mild	Not Related	Possibly Related	168
Nausea	No	I	Mild	Not Related	Not Related	93
Nausea	No	I	Mild	Not Related	Possibly Related	12
Nausea	No	I	Mild	Not Related	Not Related	18
Otitis	No	I	Mild	Not Related	Not Related	30
Vomiting	No	I	Mild	Not Related	Not Related	114
Vomiting	No	I	Mild	Not Related	Not Related	14
Vomiting	No	I	Mild	Possibly Related	Possibly Related	10
Anal fissures and internal hemorrhoids	**Yes**	**III**	**Moderate**	**Not Related**	**Not Related**	**79**
Anemia	**Yes**	**II**	**Mild**	**Not Related**	**Not Related**	**85**

- Two SAEs determined not related to Magnet or procedure.

- Early Obesity Indicators:

Indicator	**D30** N=7/7	**D90** n=5/7	**D180** n=5/7
Proportion of Subjects ≥5% TWL	43% (3/7)	100% (5/5)	100% (5/5)
% TWL Mean (SEM)	5.5% (1.1)	11.0% (2.2)	18.9% (3.9)
% EWL Mean (SEM)	16.0% (3.2)	31.0% (6.8)	52.4% (11.0)

- Early Metabolic Indicators: none of the subjects had Type 2 Diabetes


60.
45.
30.
15.
0.
Percent
Mean % TWL
Mean % EWL
52.4
30.9
16.1
18.9
11.
5.7
D30
D90
D180
Study Visit Day

- The MAGGI System was placed successfully for gastro-ileostomy in the n=5 Stage 1 FIH cases and the independent DSMB reviewed safety information and approved study continuation.
- A total of n=7 have now been enrolled using 80mm device.
- While the sample size is small, early obesity indicators show 52% EWL and 19% TWL at 180 days in subjects (n=5) with prior Sleeve Gastrectomy and subsequent weight gain.
- More patients and longer follow-up are needed, with nutritional profiles.