MAGDI: Side-to-Side Linear Magnetic Duodeno-Ileostomy for Obesity with or without Type-2 Diabetes Mellitus: A Multi-Institutional Study.

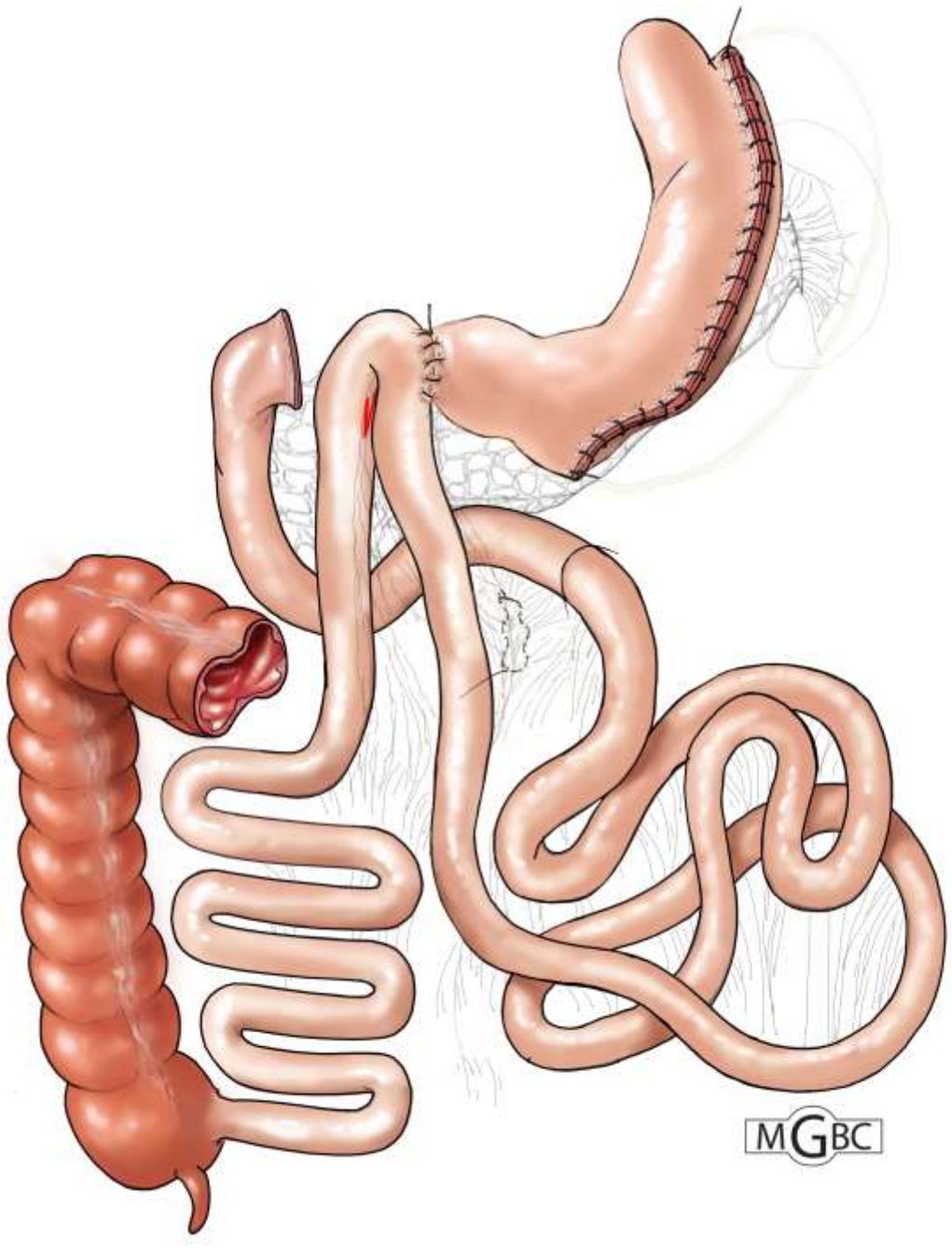
Michel Gagner, MD, FRCSC, FACS[1]; Antonio J Torres, MD[3], FACS(Hon), Guy-Bernard Cadiere, MD[2]; Lamees Almutlaq, MD, FRSCSC[1;] Andres Sanchez-Pernaute,MD[3]; Levan Koiava, MD[4]
David Abuladze, MD[4]

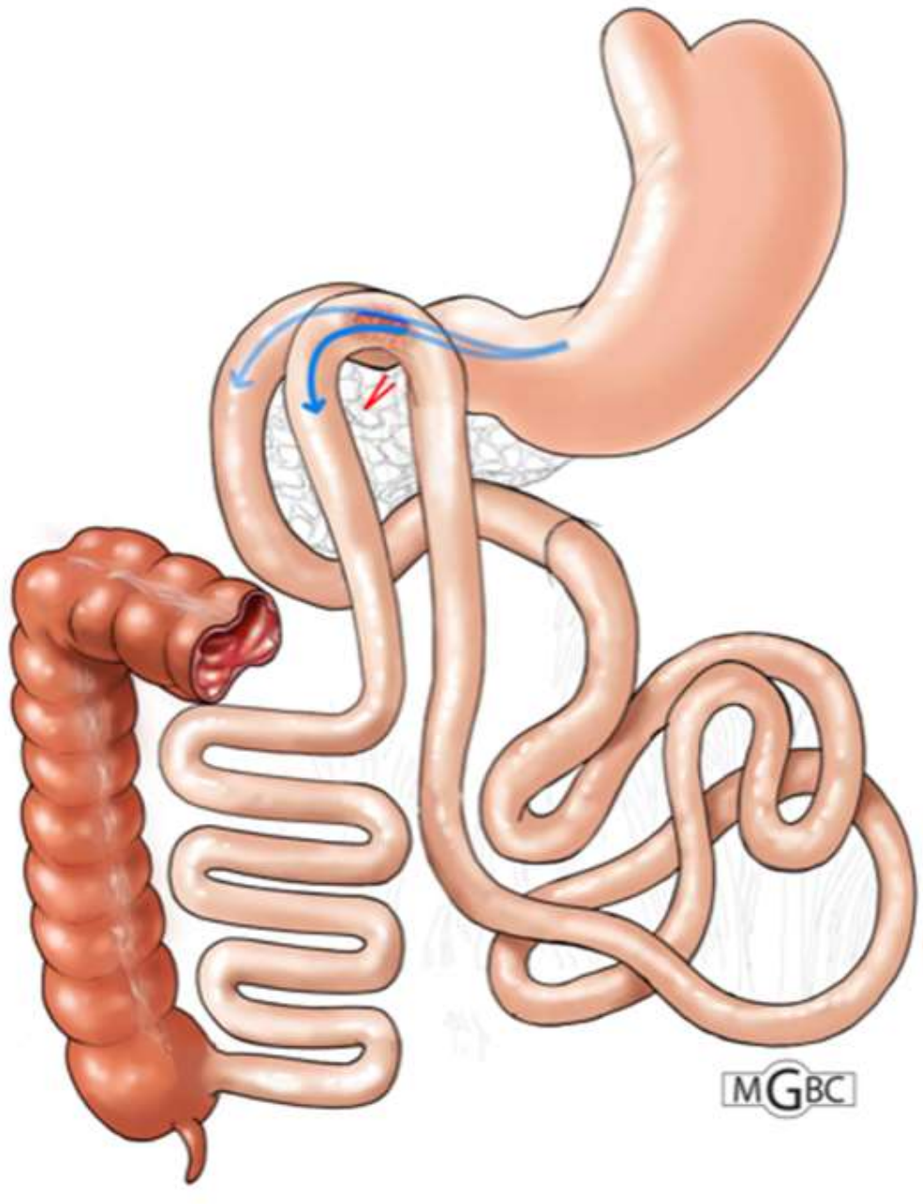
1 Westmount Square Surgical Center, Westmount, Quebec, Canada;
2 CHU St-Pierre, Brussels, Belgium;
3 Hospital Clinico San Carlos, Madrid, Spain;
4 Innova Medical Center, Tbilisi, Georgia

Financial Disclosures

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

SADI vs MAGDI





Surgical Endoscopy
https://doi.org/10.1007/s00464-023-10105-x

Side-to-side duodeno-ileal magnetic compression anastomosis: design and feasibility of a novel device in a porcine model

Michel Gagner[1] · Todd Krinke[2] · Maxime Lapointe-Gagner[1] · J. N. Buchwald[3]

Received: 28 February 2023 / Accepted: 23 April 2023

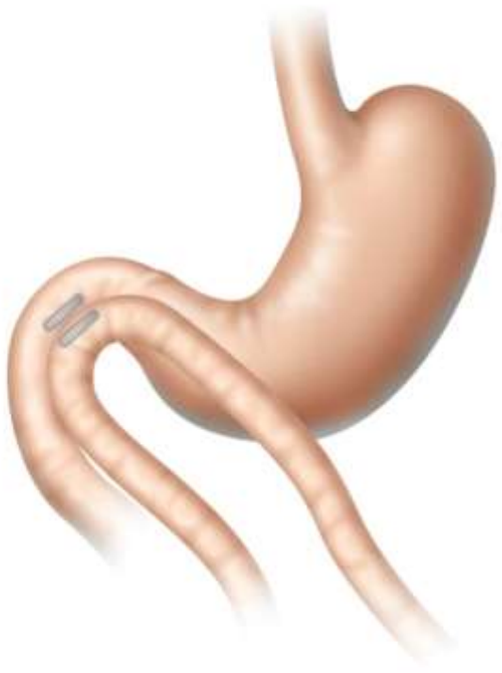


Fig. 1 Duodeno-ileal compression anastomosis by pairing of two linear magnets. The proximal magnet is positioned in the duodenum by gastroscopy and the distal magnet in the ileum by laparoscopy. After inter-magnet tissue compression and necrosis, the united magnets are expelled naturally

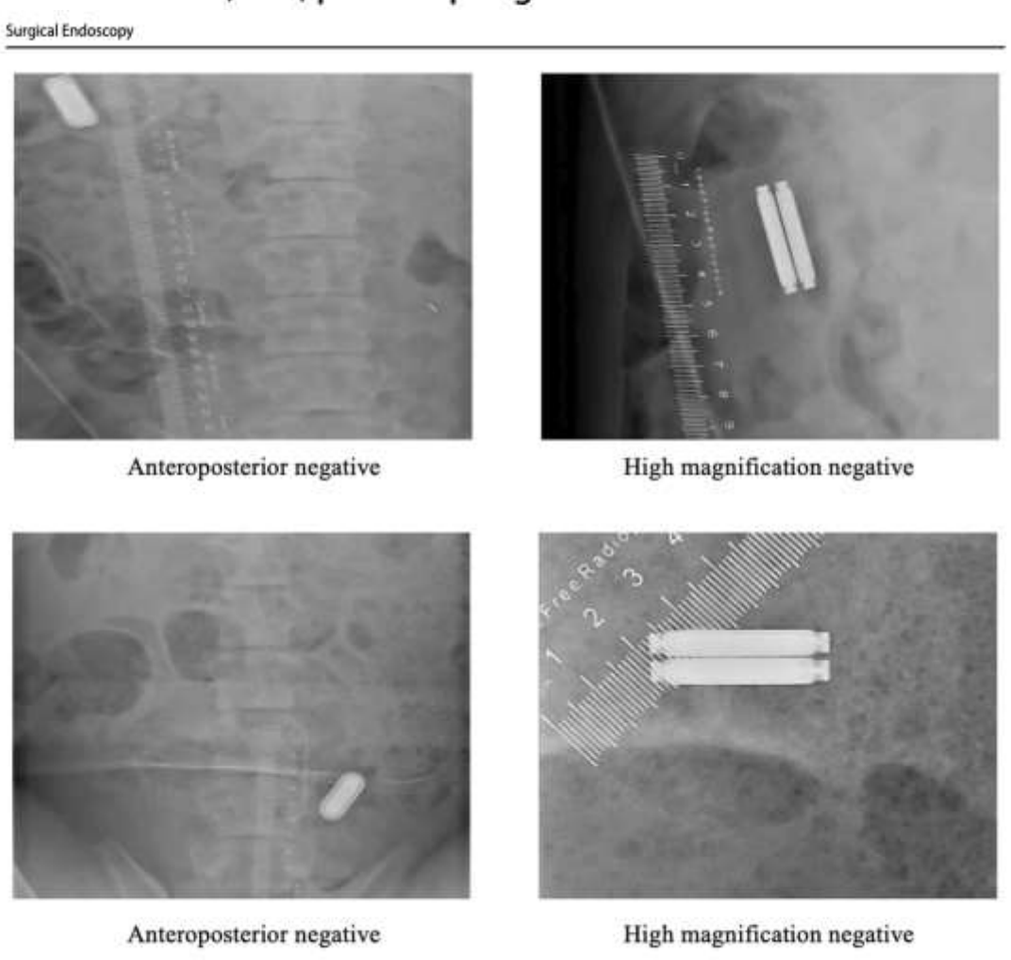
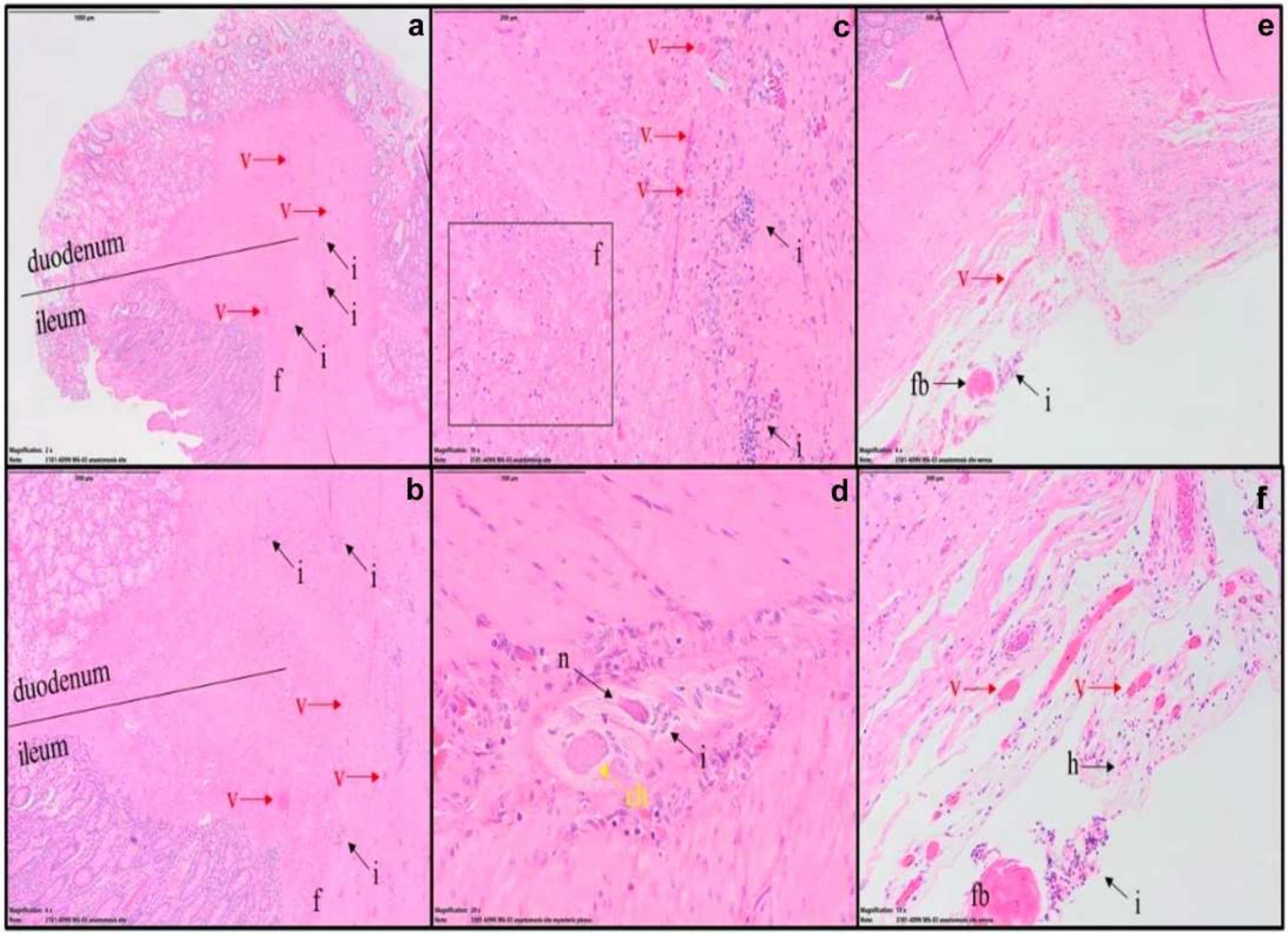


Fig. 3 Radiograph of magnetic compression anastomosis site in 4 animals, day of procedure

Fig. 4 A patent porcine duodeno-ileostomy at 6 weeks, on the right the double lumen afferent and efferent ileal loop, and on the left the native duodenum. In duodenoscopy of the pig, the endoscope must rotate 360° in the stomach, inversing the image

Fig. 5 Representative gross necropsy images of side-to-side duodeno-ileal (DI) magnetic compression anastomosis (MCA) and jejunal enterotomy (JE) sites. **a** Low magnification image of the serosal aspect of the side-to-side DI MCA site (white solid rectangle); **b** Low magnification image of the serosal aspect of the JE site (white dashed rectangle); **c** Higher magnification of the serosal aspect of the side-to-side DI MCA (white rectangle); **d** Higher magnification view of the serosal aspect of the JE site (dashed, white rectangle)


a
duodenum
ileum
v
v
v
i
i
i
f
b
duodenum
ileum
v
v
v
i
i
f
c
v
v
v
f
i
i
d
n
i
e
v
fb
i
f
v
v
h
fb
i

Primary endpoints:

Feasibility/performance: The side-to-side anastomosis duodeno-ileostomy will be considered feasible and performs as intended if ≥80% meet success defined as:

Placement of the Magnet System (>90% alignment of Magnets)

Passage of Magnets without surgical re-intervention; and

Creation of a patent anastomosis, confirmed radiologically

Safety: incidence of treatment emergent adverse events (AEs)

Secondary endpoints:

Body weight reduction (%TWL, %EWL, proportion of subjects with ≥5% TWL, BMI)

Functional improvement of metabolic indicators (HbA1c, blood glucose)

Inclusion Criteria

1. 18-65 years of age, inclusive, at the time of informed consent
2. BMI 30-50, inclusive with either:
    - Previous-sleeve gastrectomy ($\geq$ 12 months) with either T2DM (defined as HbA1c $\geq$ 6.5%) or weight regain; or
    - T2DM without previous gastrectomy; or
    - Undergoing Laparoscopic Single Anastomosis Duodenal-Ileal bypass with Sleeve (SADI-S) where duodeno-ileostomy is performed side-to-side with the Magnet System and BMI > 40
3. Agrees to refrain from any type of additional bariatric or reconstructive surgery that would affect body weight for 1 year
4. If a child-bearing female, subject must commit to not becoming pregnant and agree to use contraception for 1 year
5. Willing and able to comply with protocol requirements

Of 54 patients

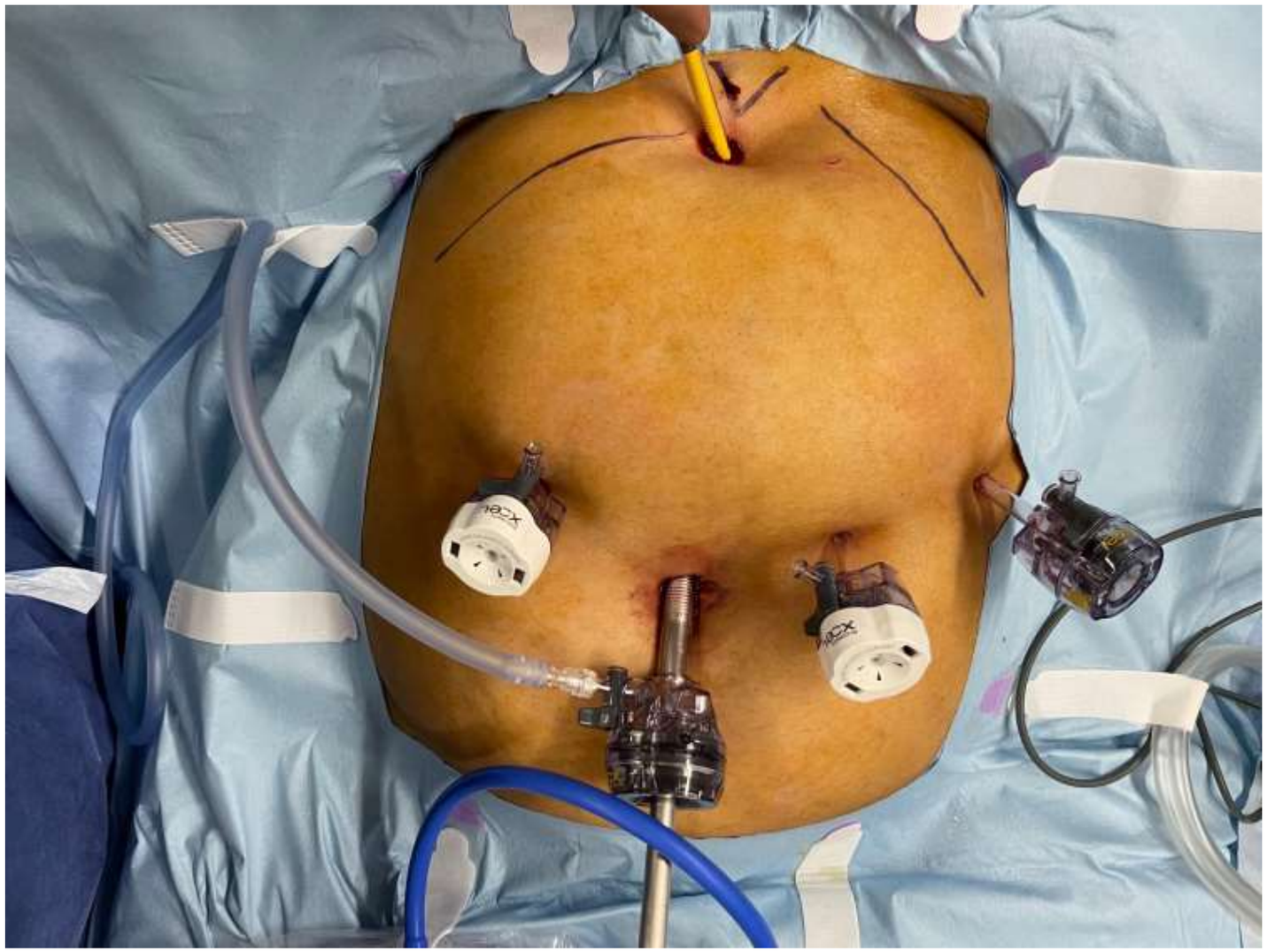
Clinical Sites: Canada, Belgium, Republic of Georgia, Spain

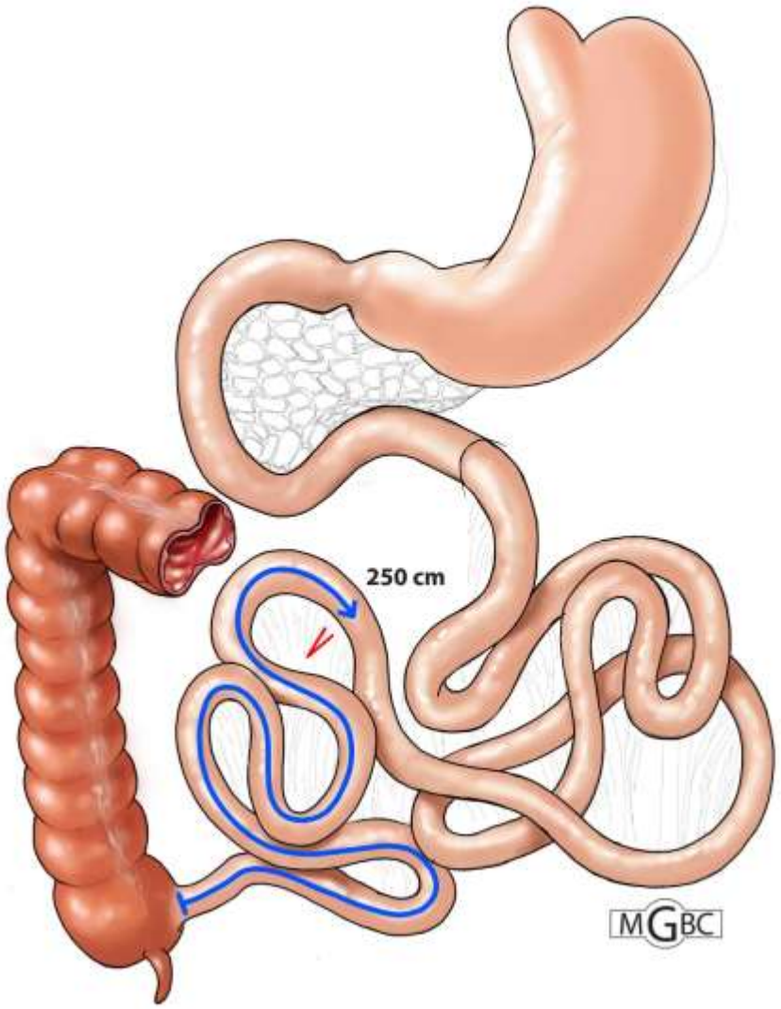
n=43 subjects enrolled between 22 Nov 2021 and 30 May 2023

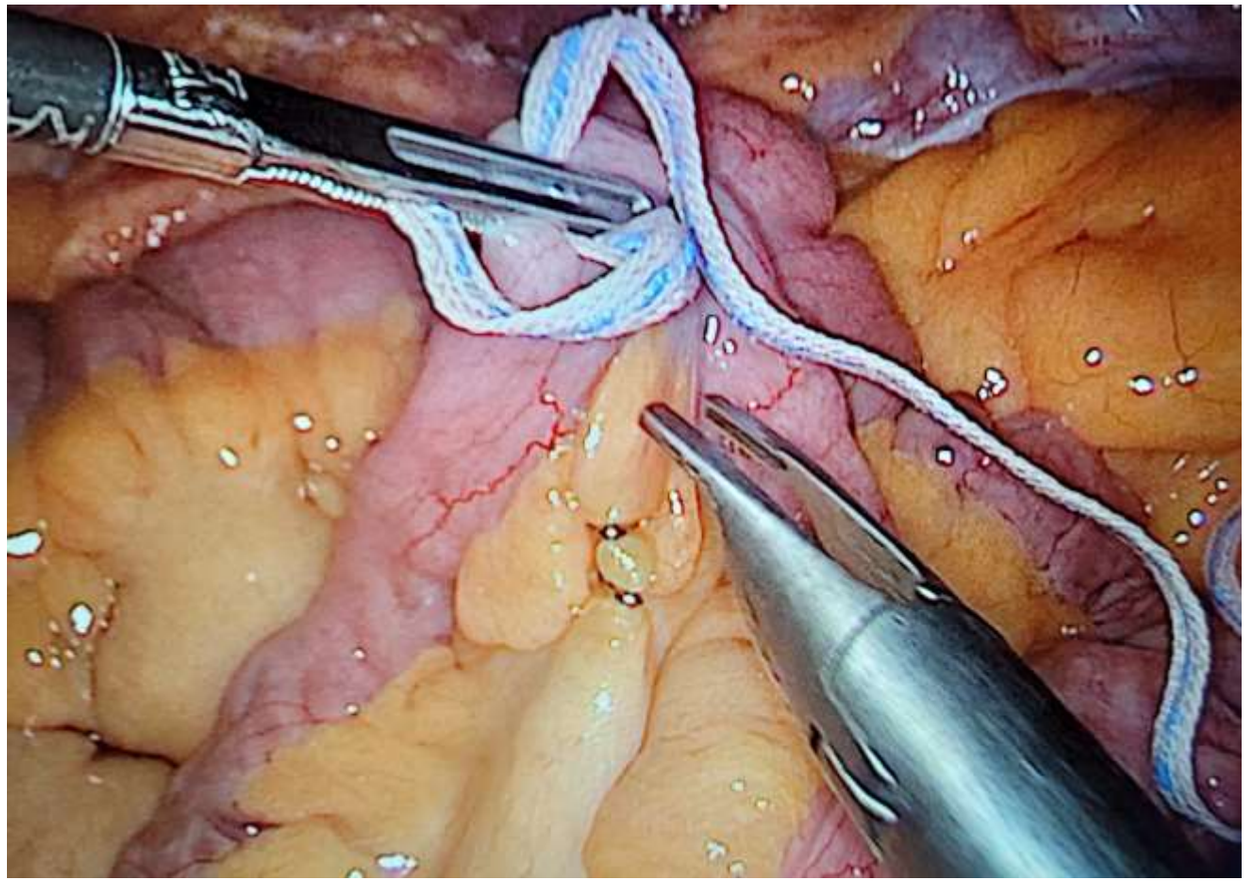
All subjects completed six months of follow up

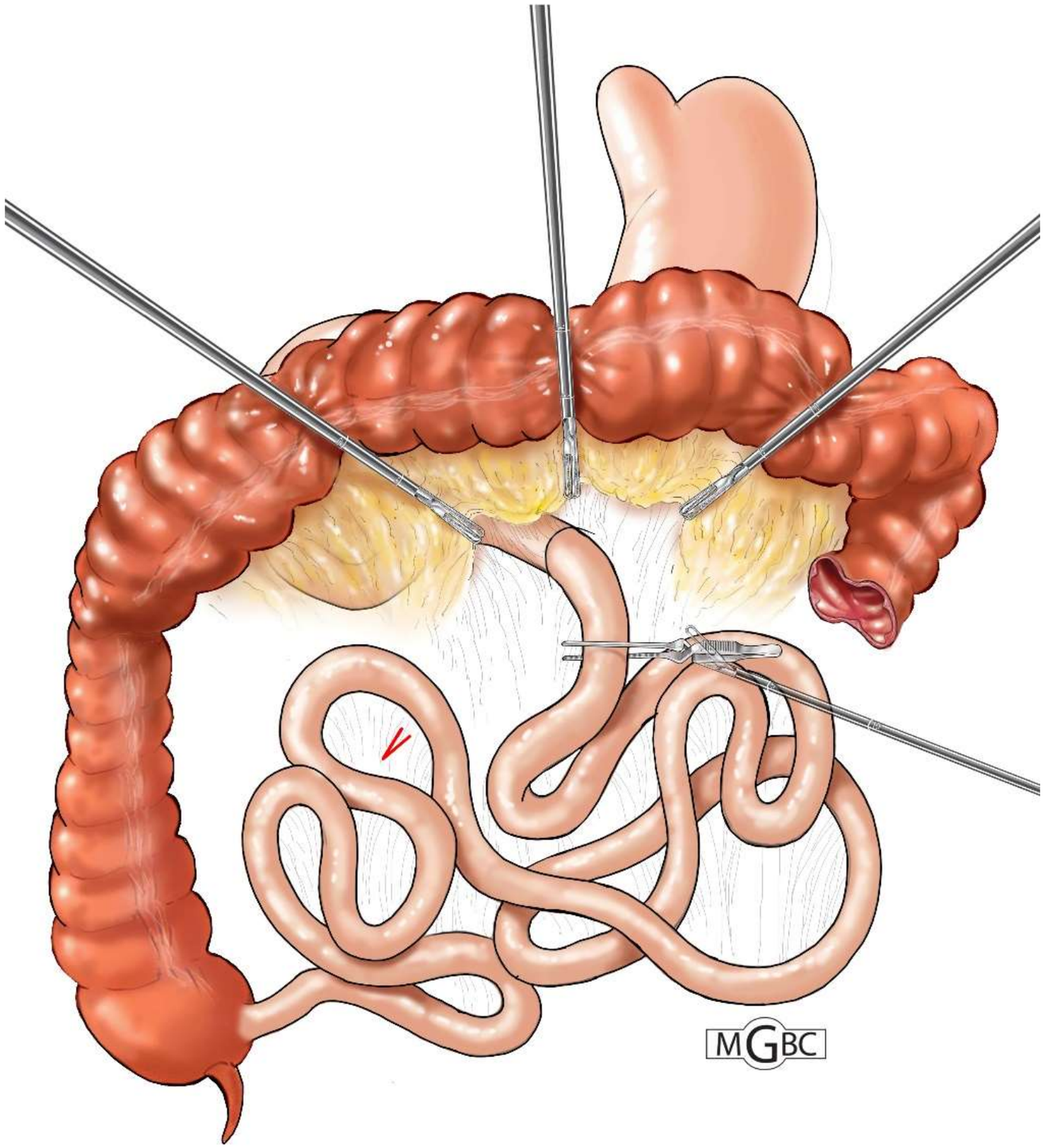
A subset (n=5) completed one year follow up (last D360 visit 06 Dec 2022)

Laparoscopic assisted procedure

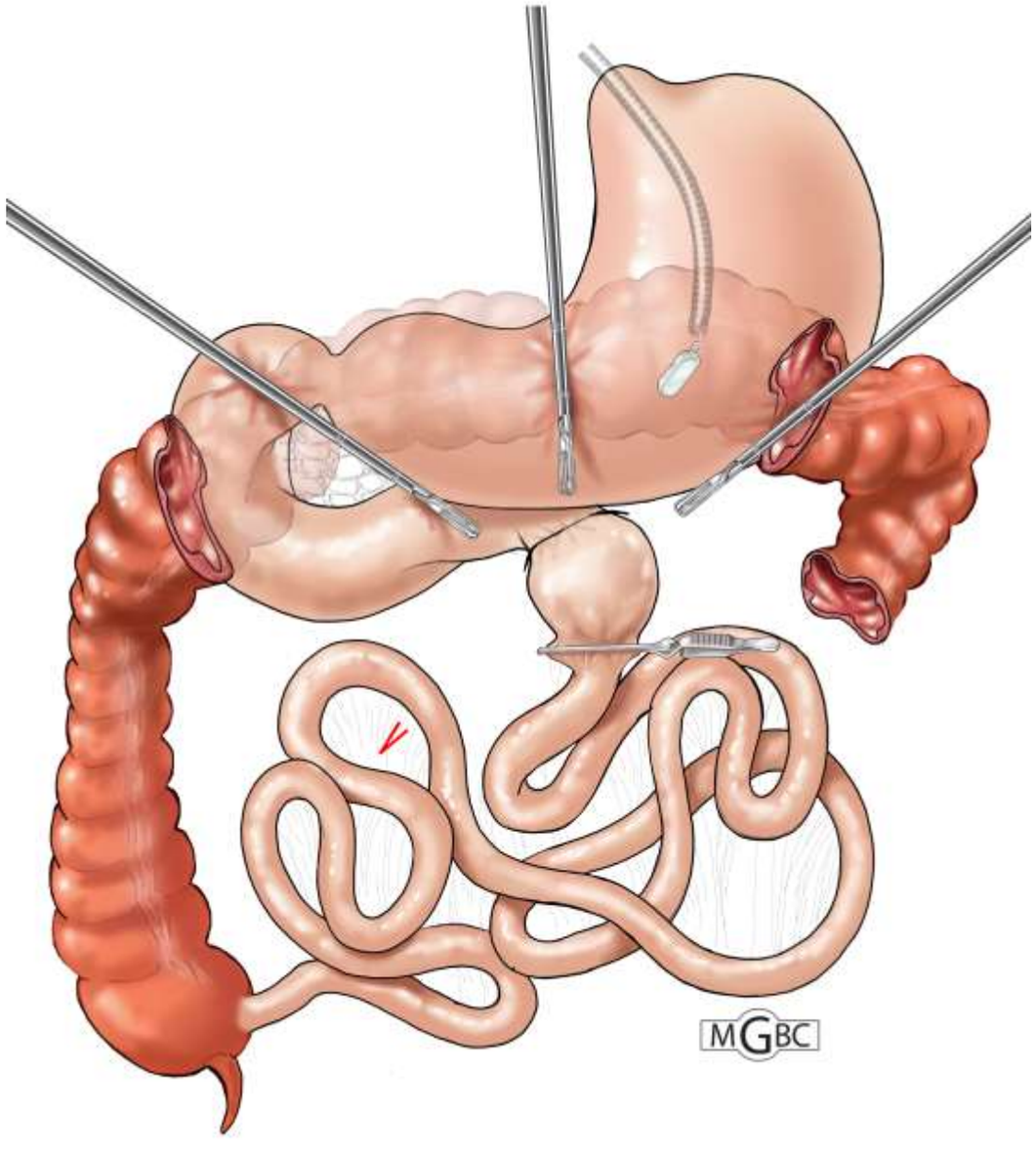


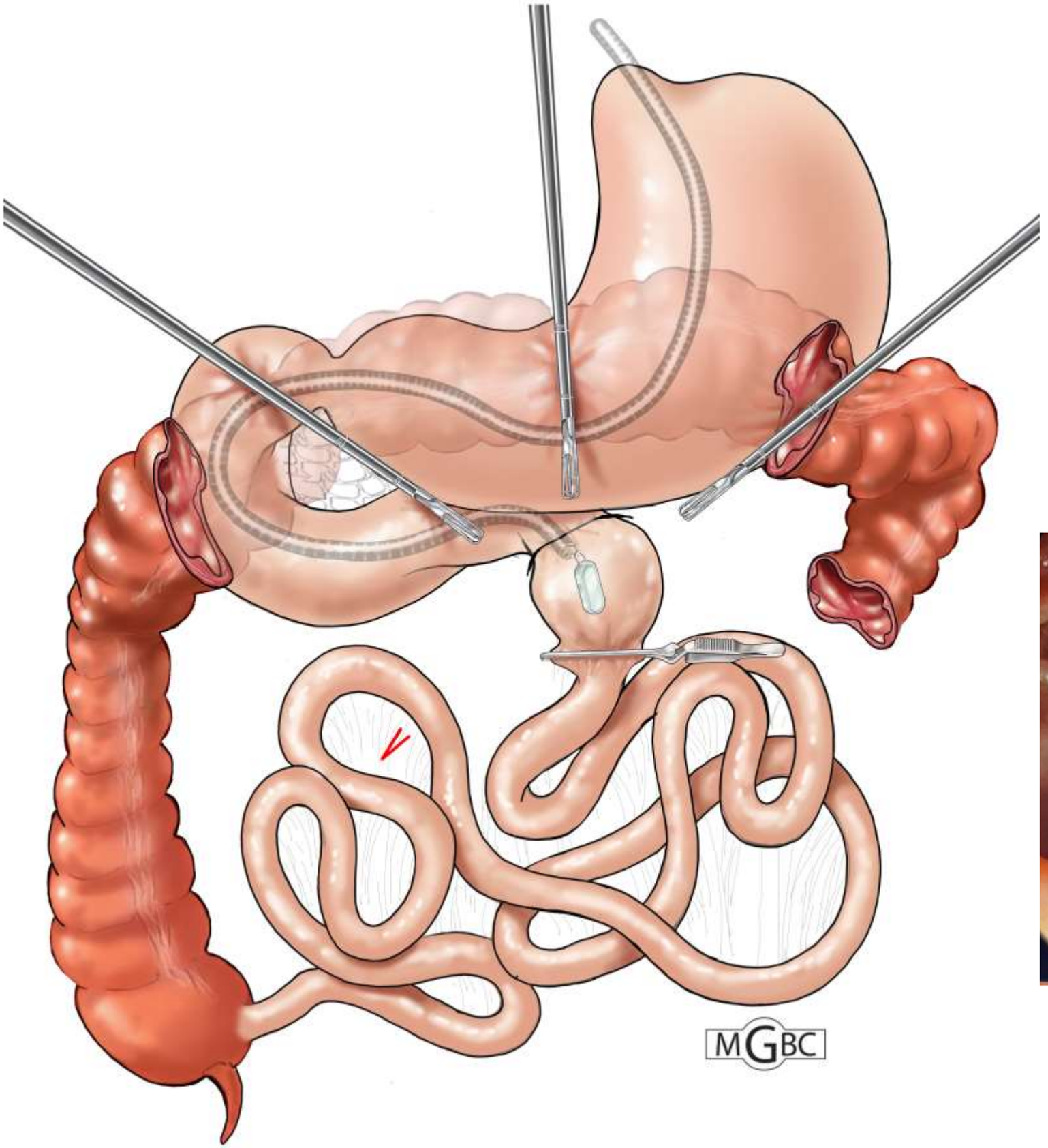

250 cm
MGBC

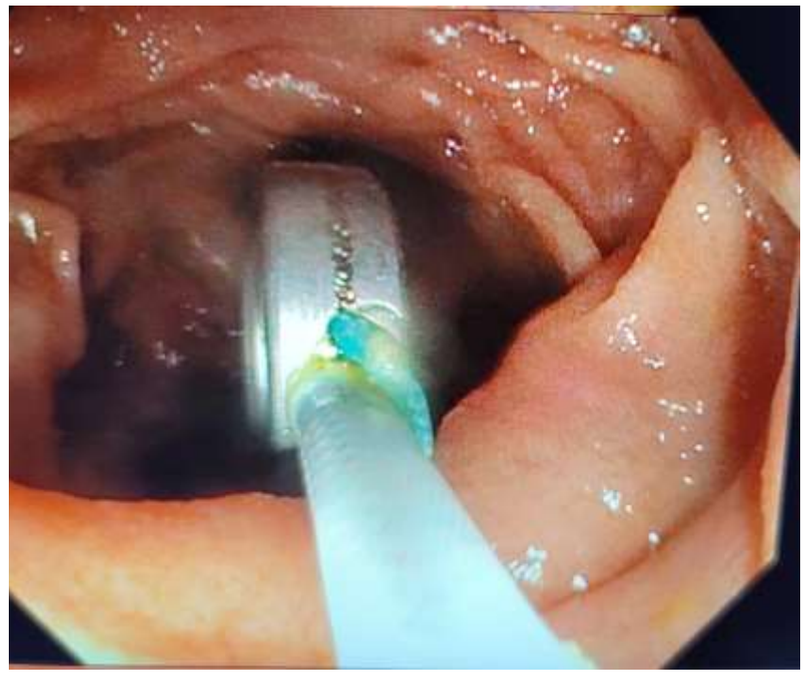


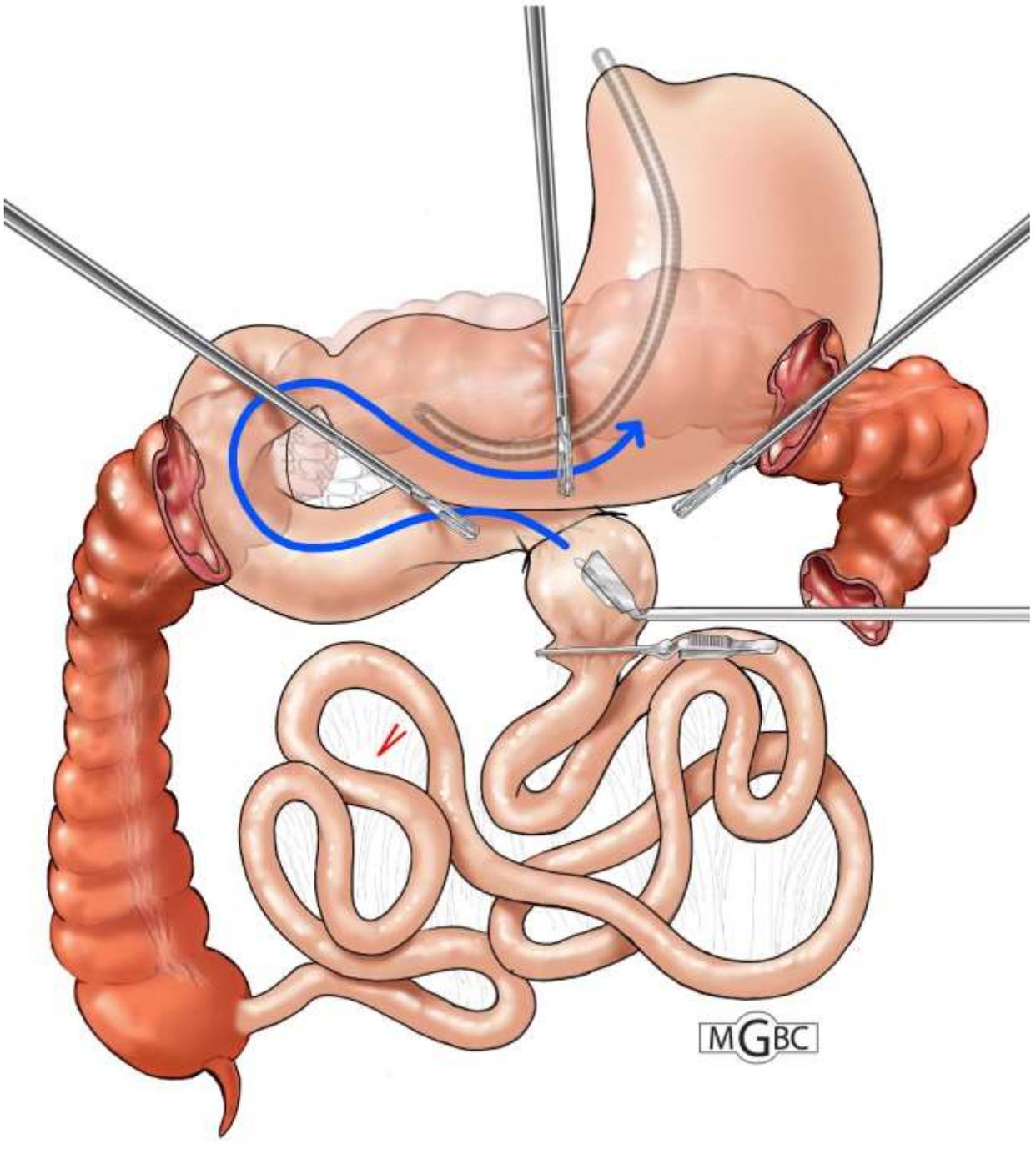

MGBC

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

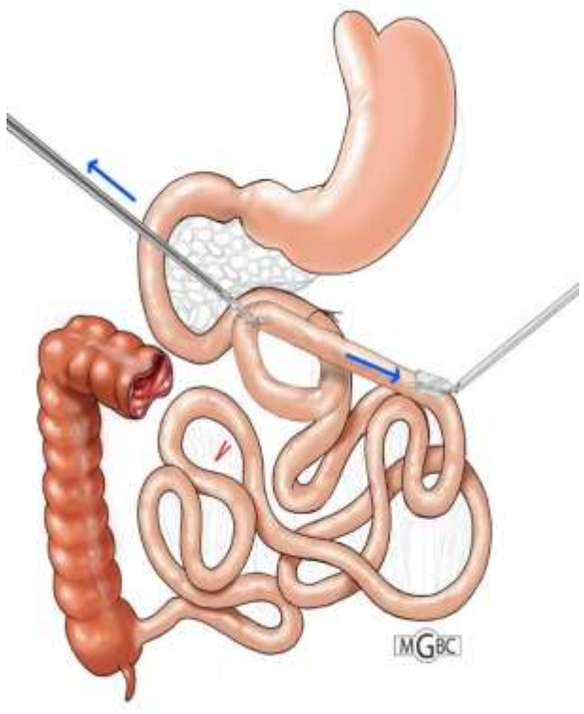


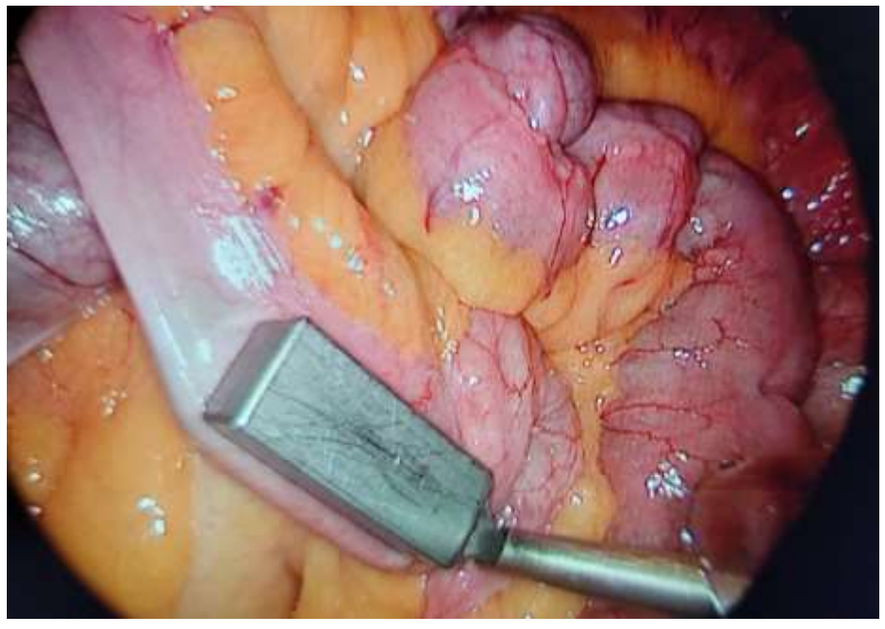

MGBC

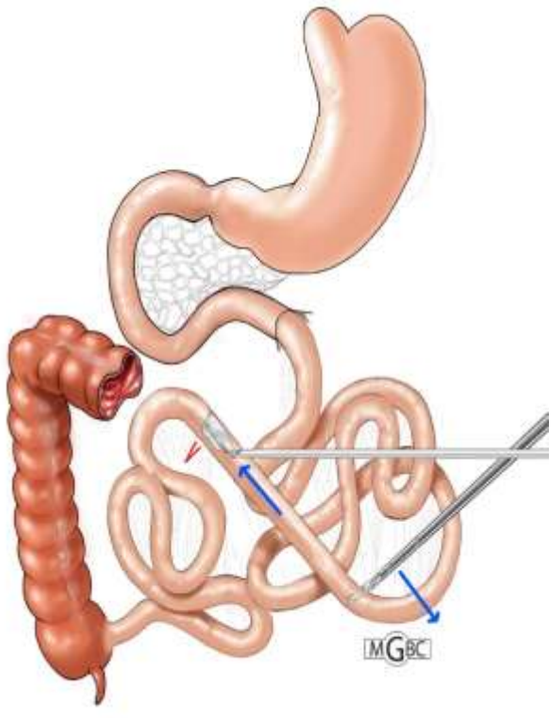



MGBC

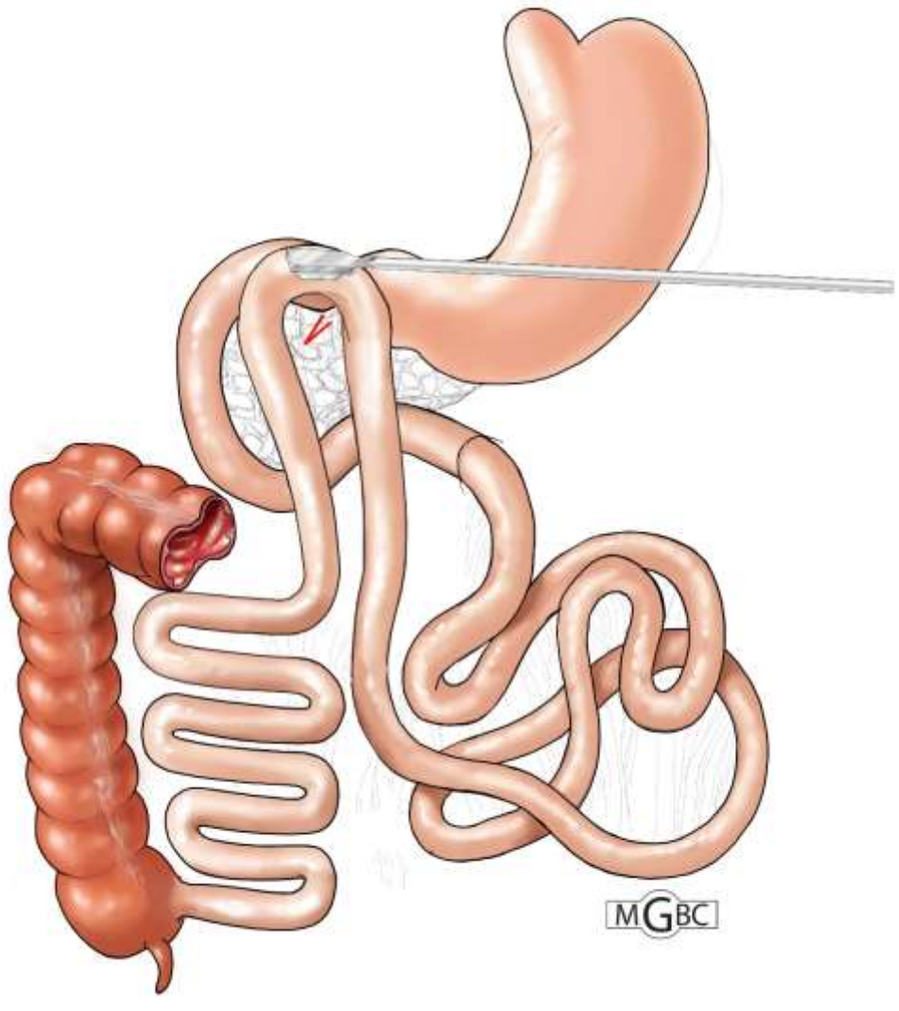
The MAGNET System
Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy

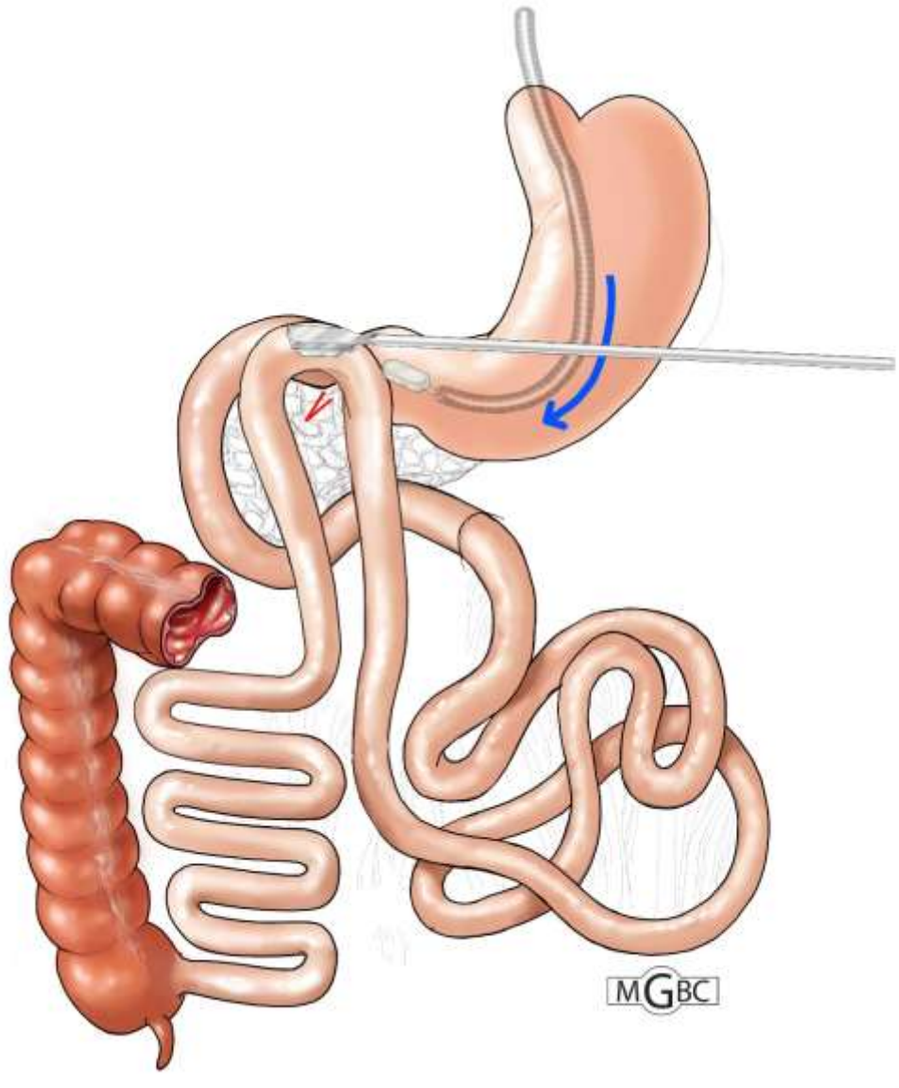




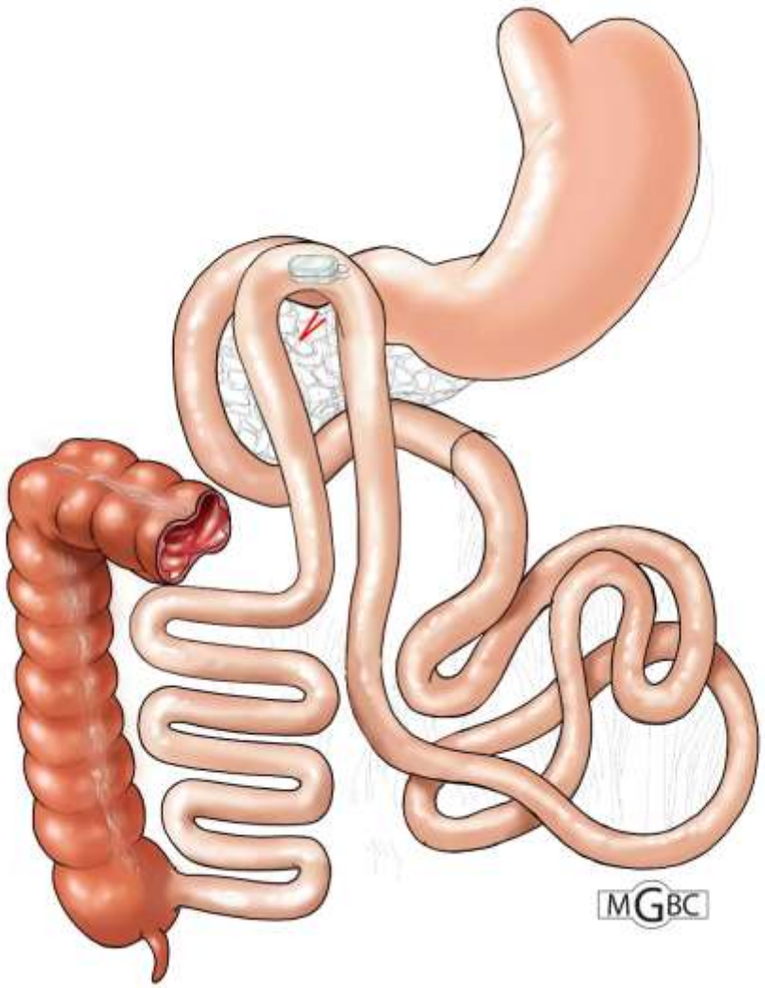


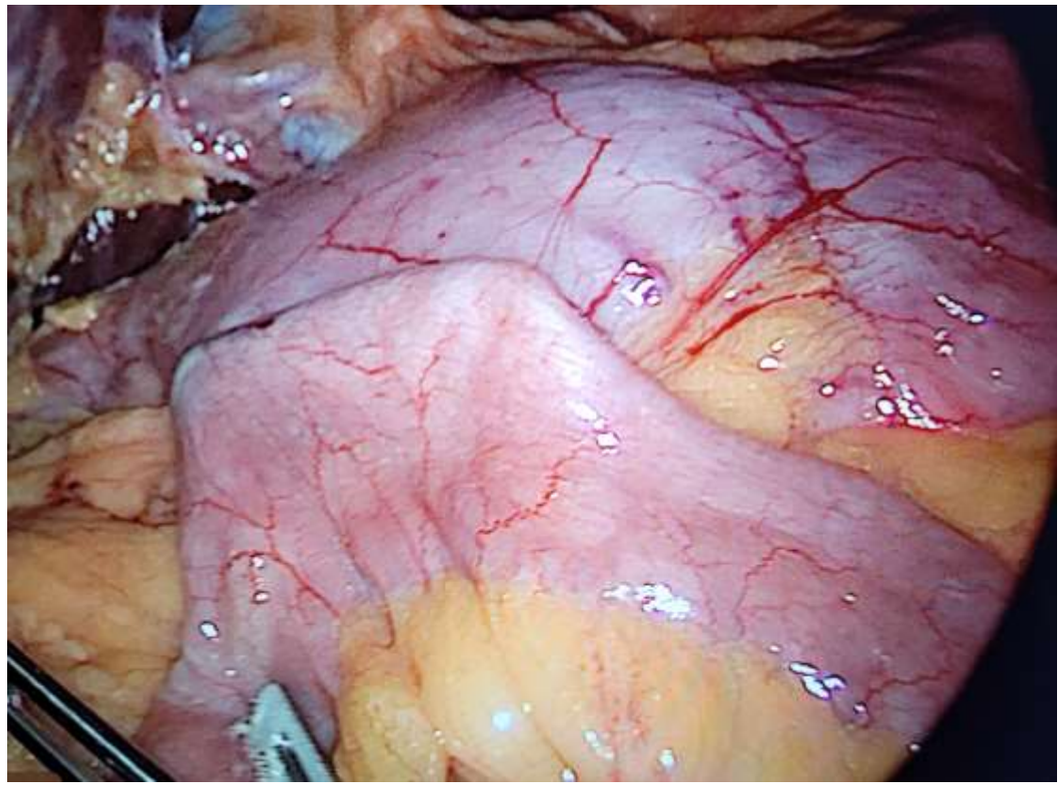
The MAGNET System
Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy



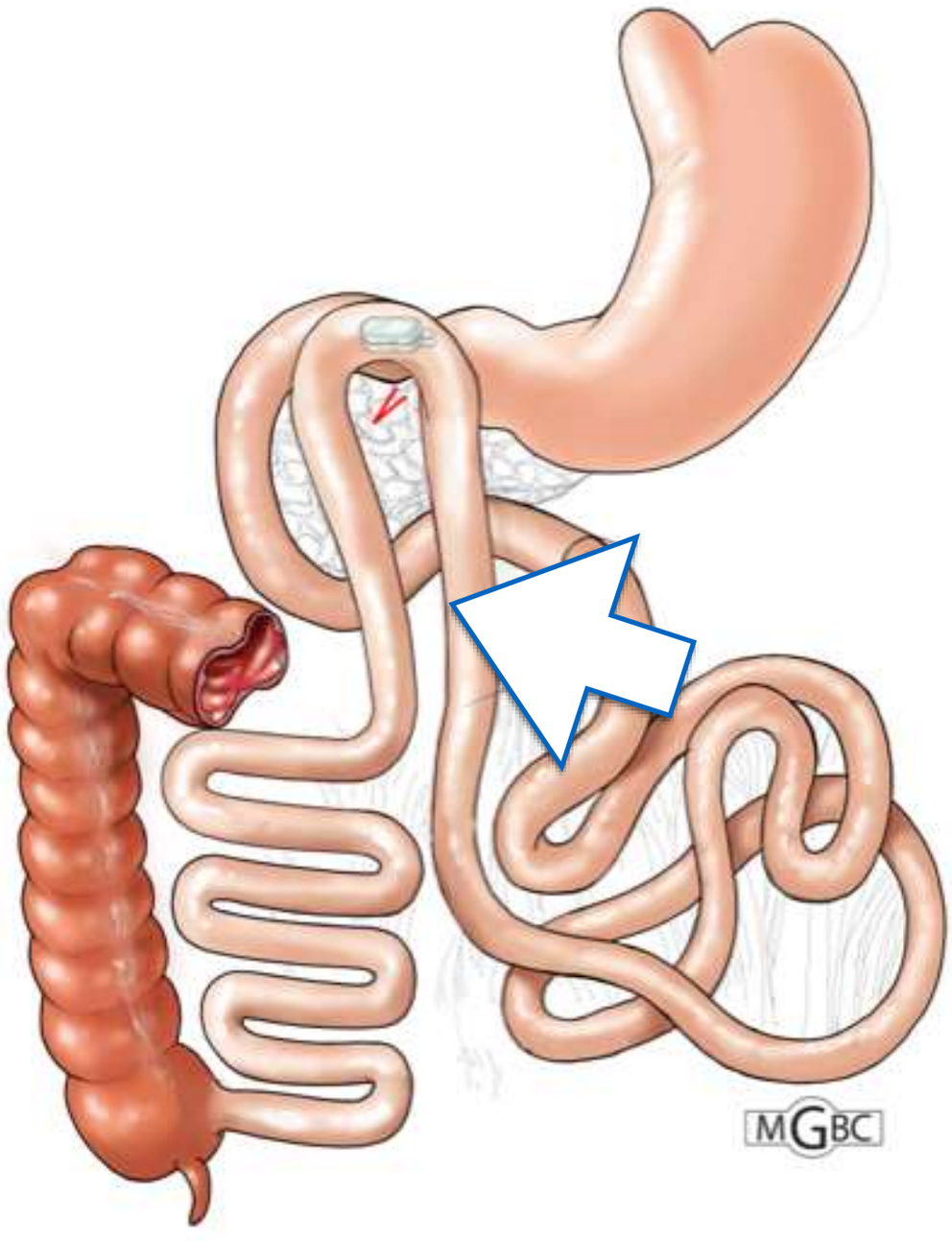


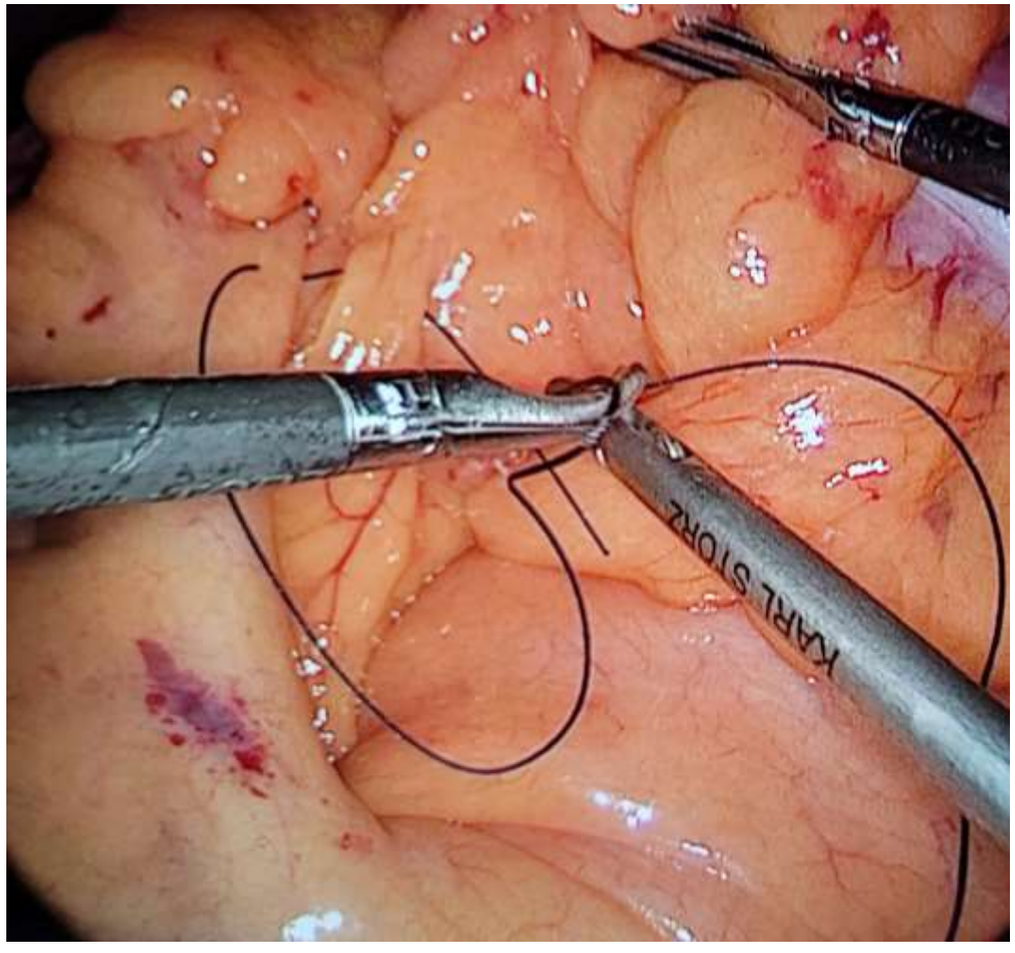
The MAGNET System
Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy



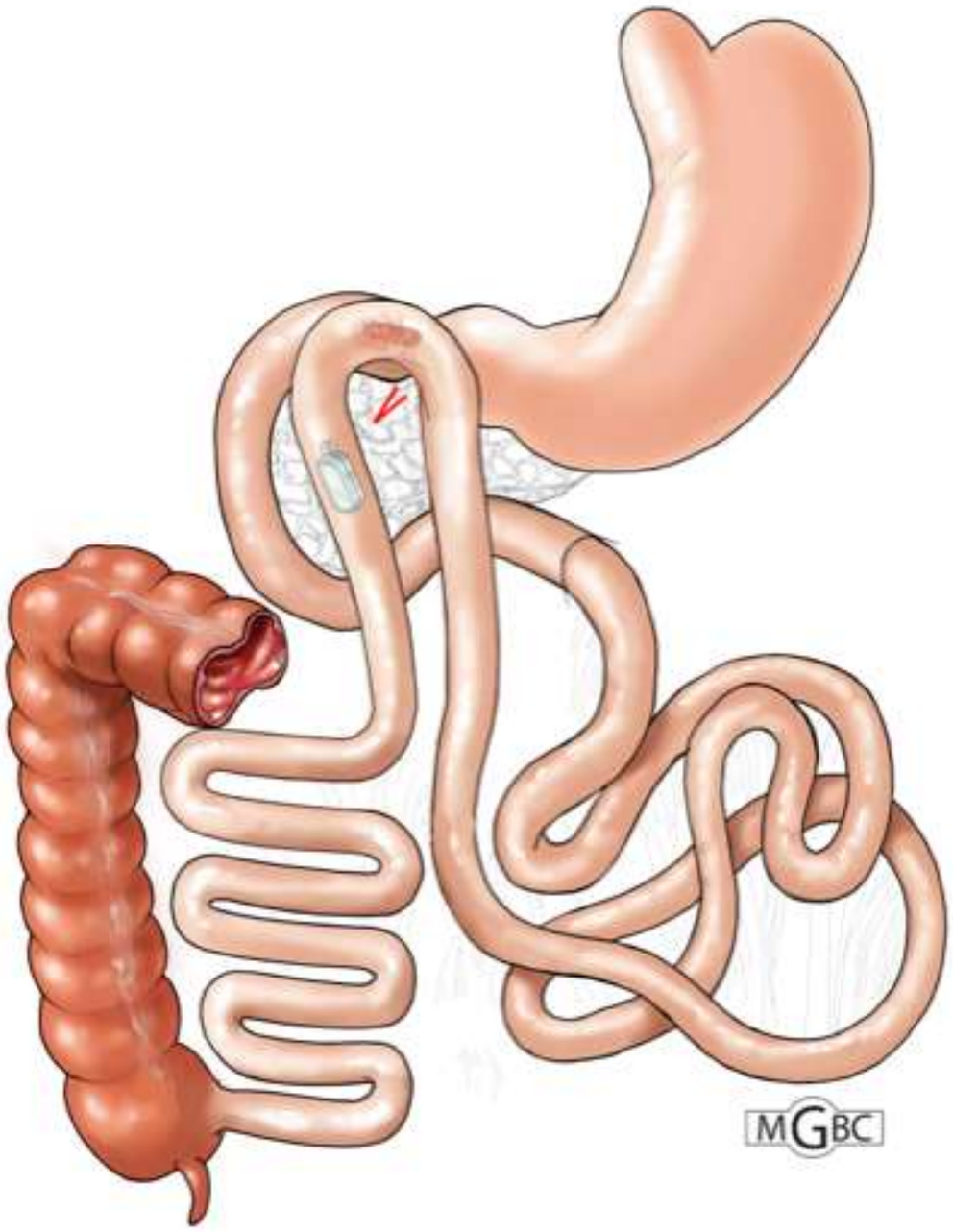


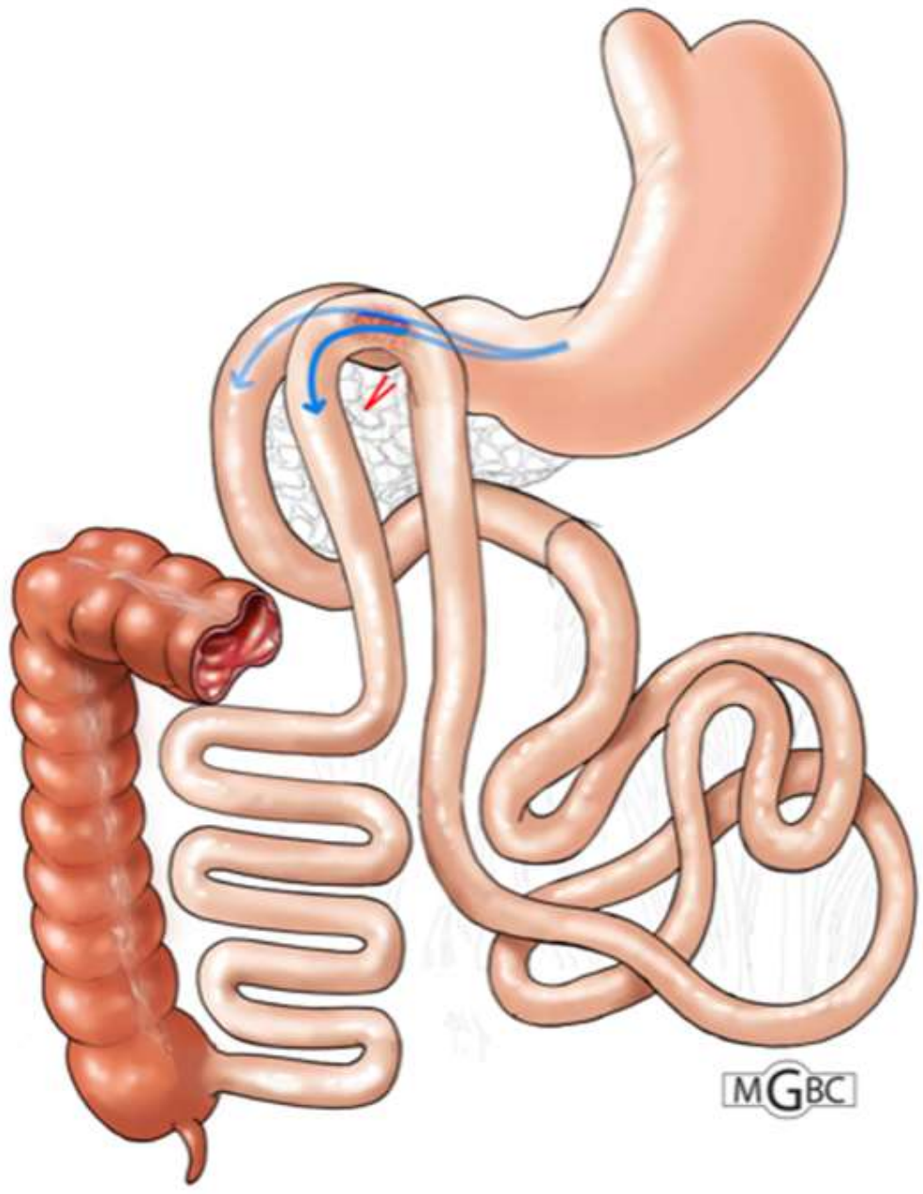
Mesenteric defect



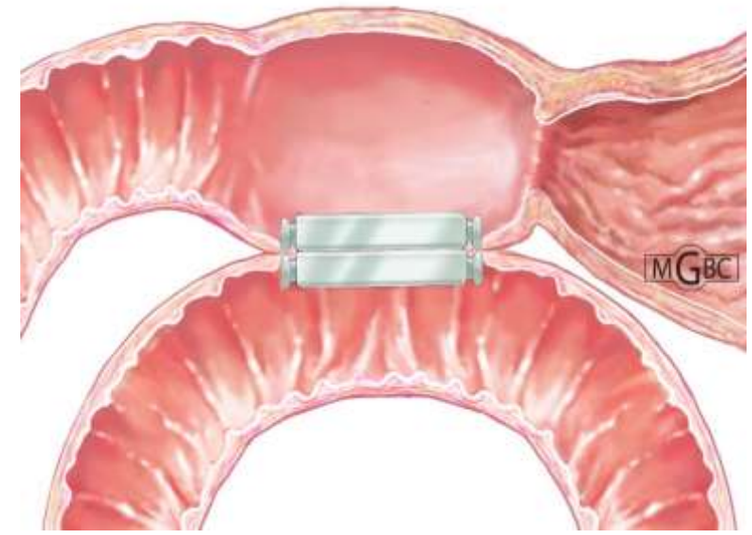


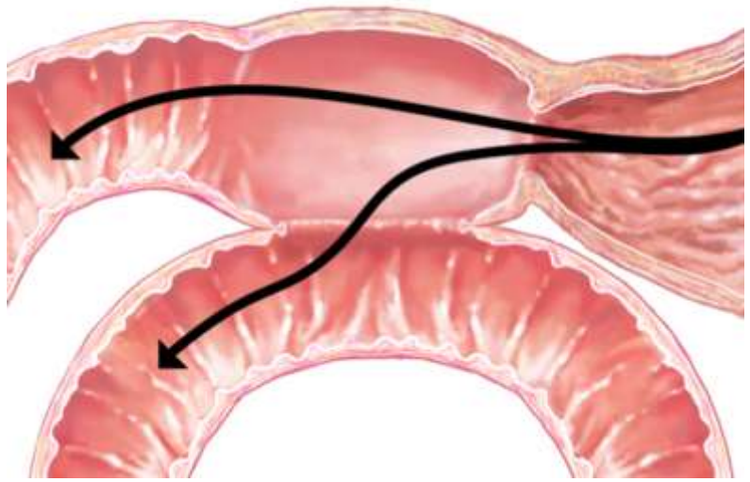
Duodenal Bipartition

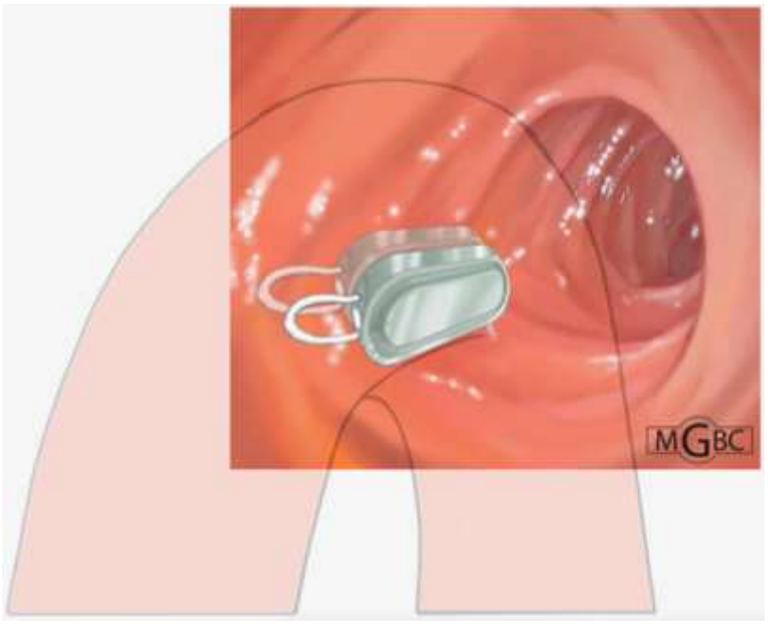


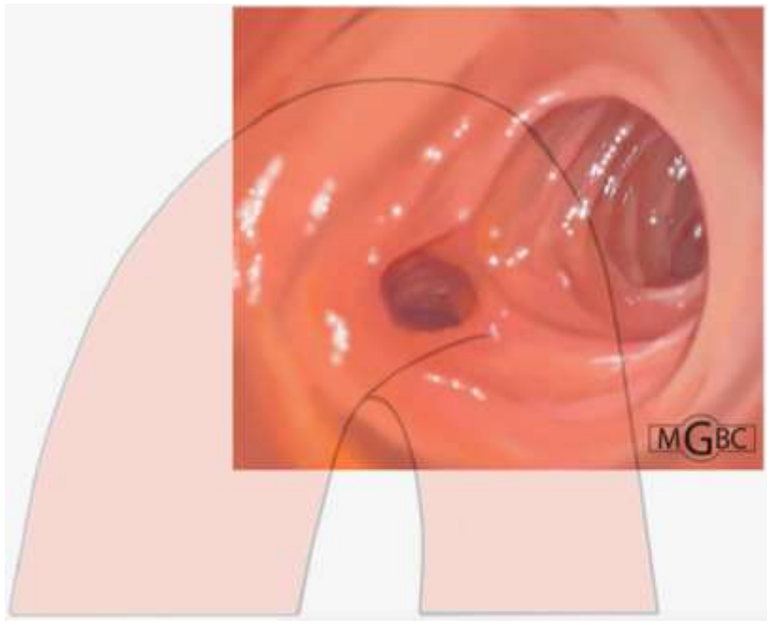


Duodenal Bipartition









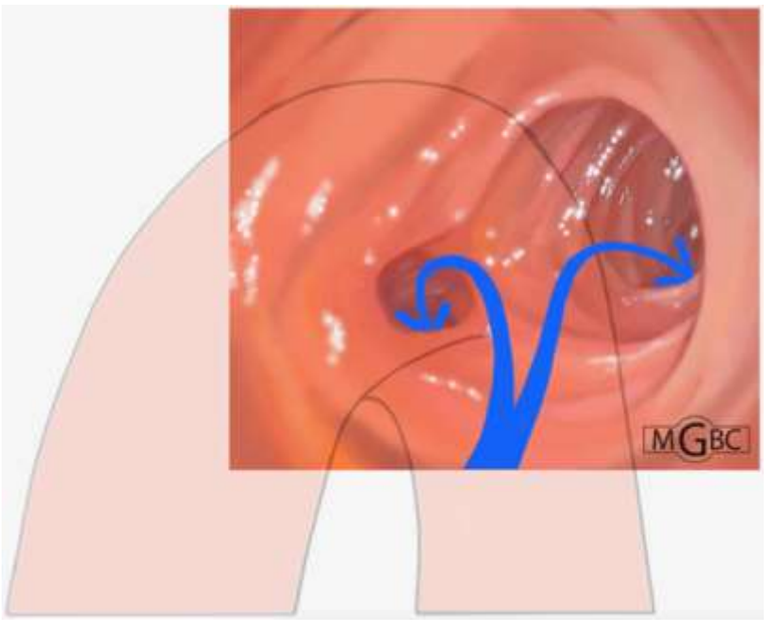


Table 1. Patient characteristics and perioperative outcomes

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%)

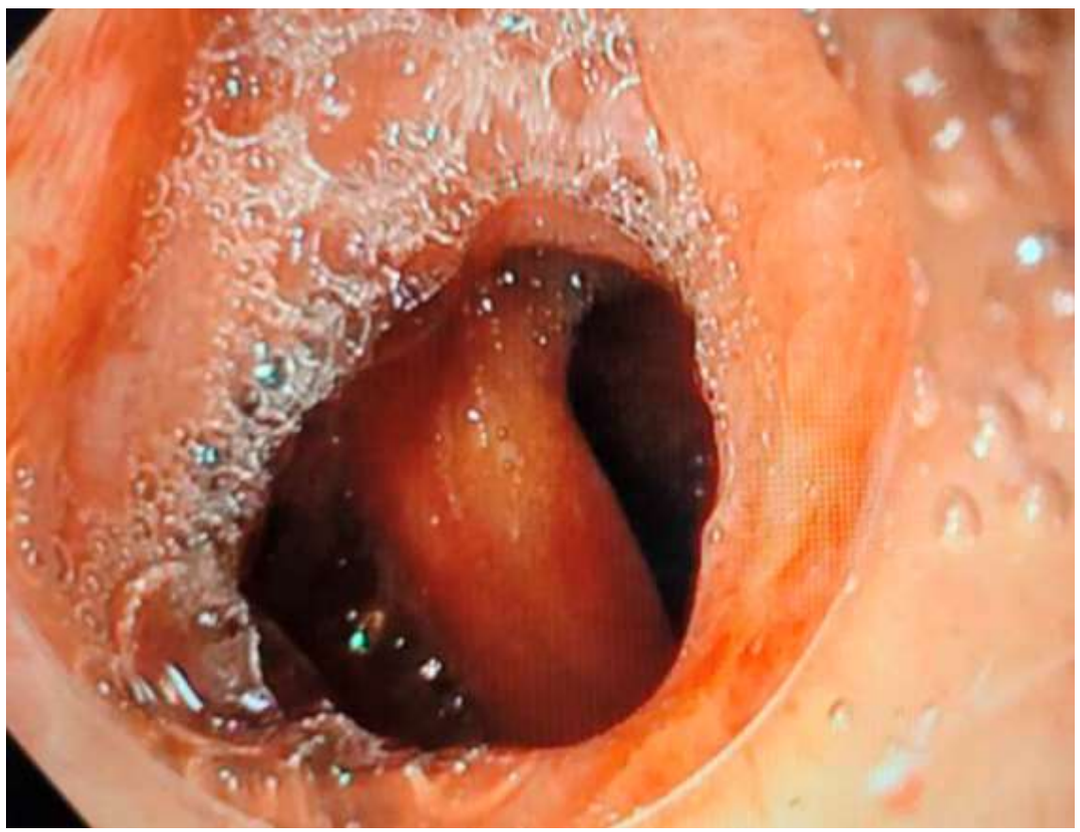
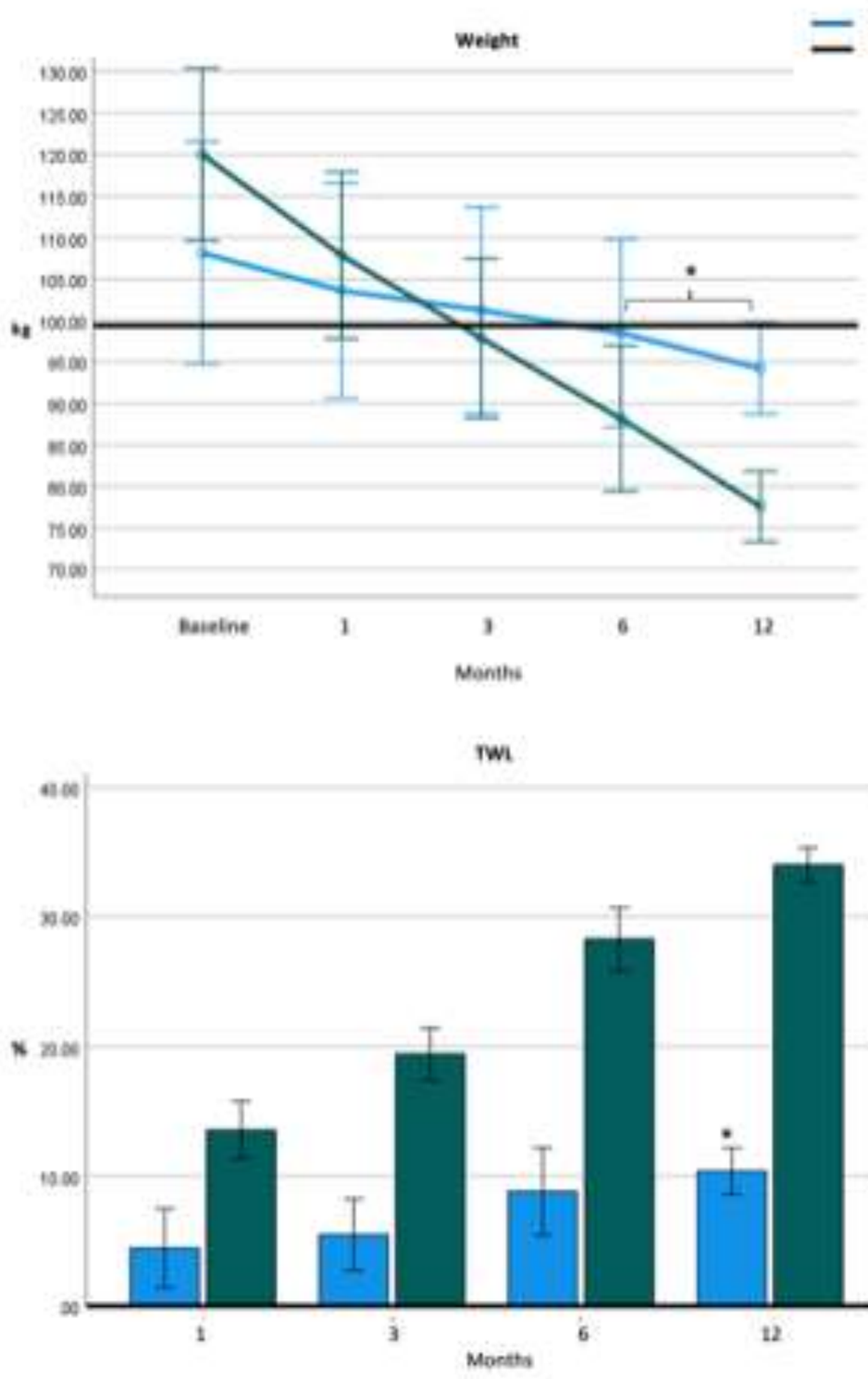
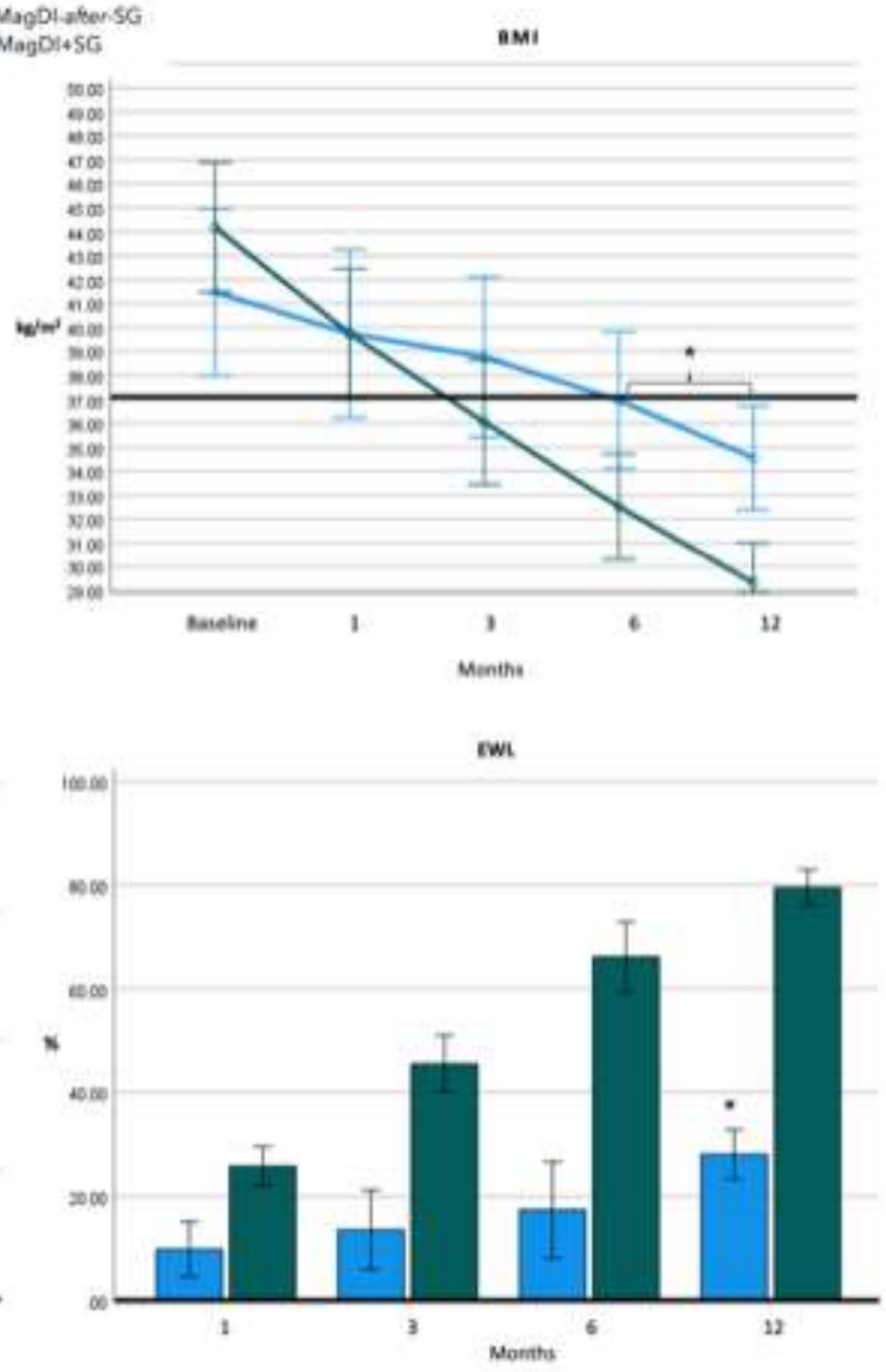


Table 3. Evolution of weight following side-to-side Magnet Anastomosis System duodeno-ileostomy after prior sleeve gastrectomy (MagDI-*after*-SG) or MagDI+SG (concurrent) from baseline through 12 months

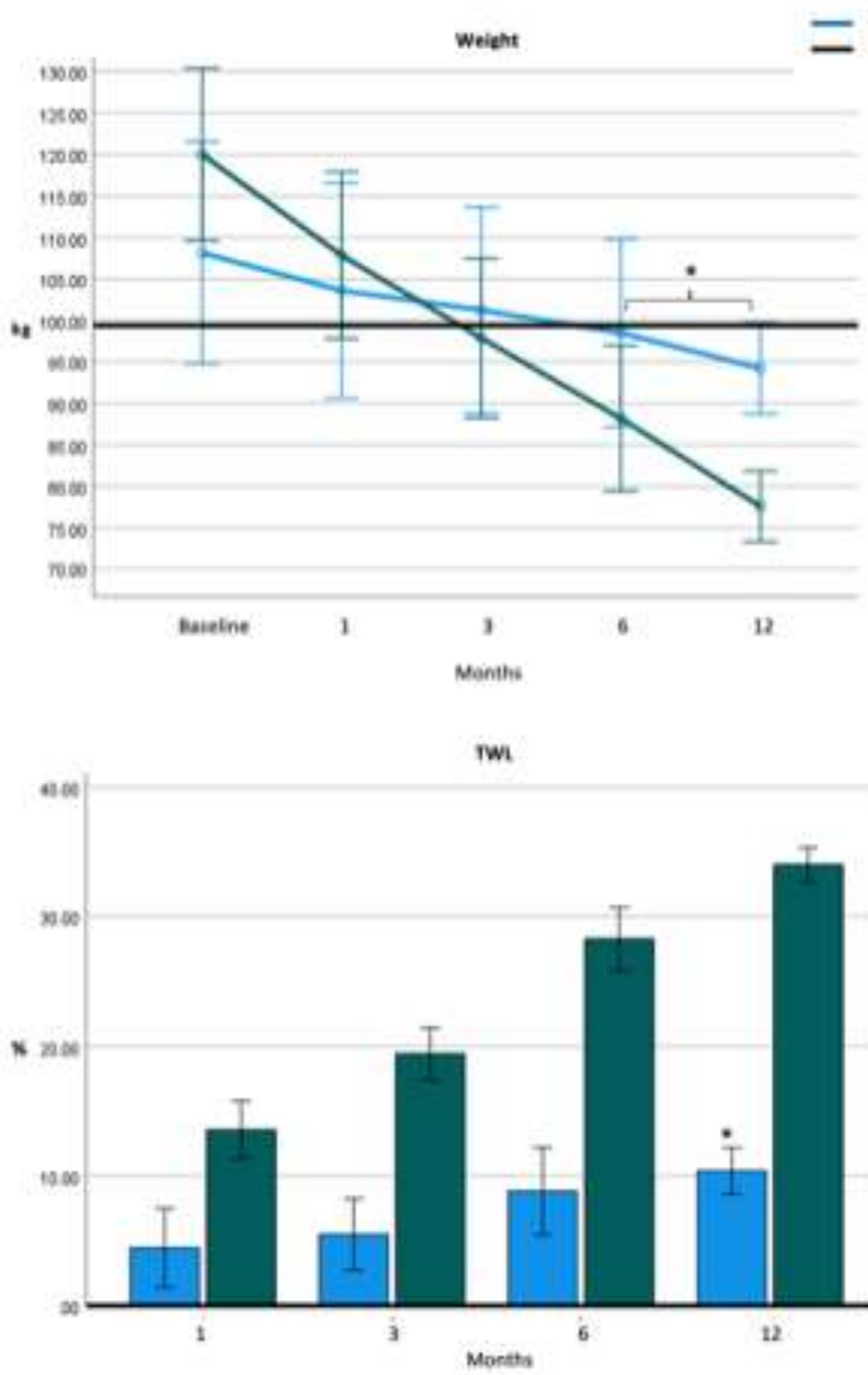
Treatment group	**Weight parameter**	**Baseline** Mean ±SEM	**3-month follow-up** Mean ±SEM	Mean change ±SEM (95%CI)	Within-group P-value†	**6-month follow-up** Mean ±SEM	Mean change ±SEM (95%CI)	Within-group P-value†	**12-month follow-up** Mean ±SEM	Mean change ±SEM (95%CI)	Within-group P-value†
MagDI-*after*-SG	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*

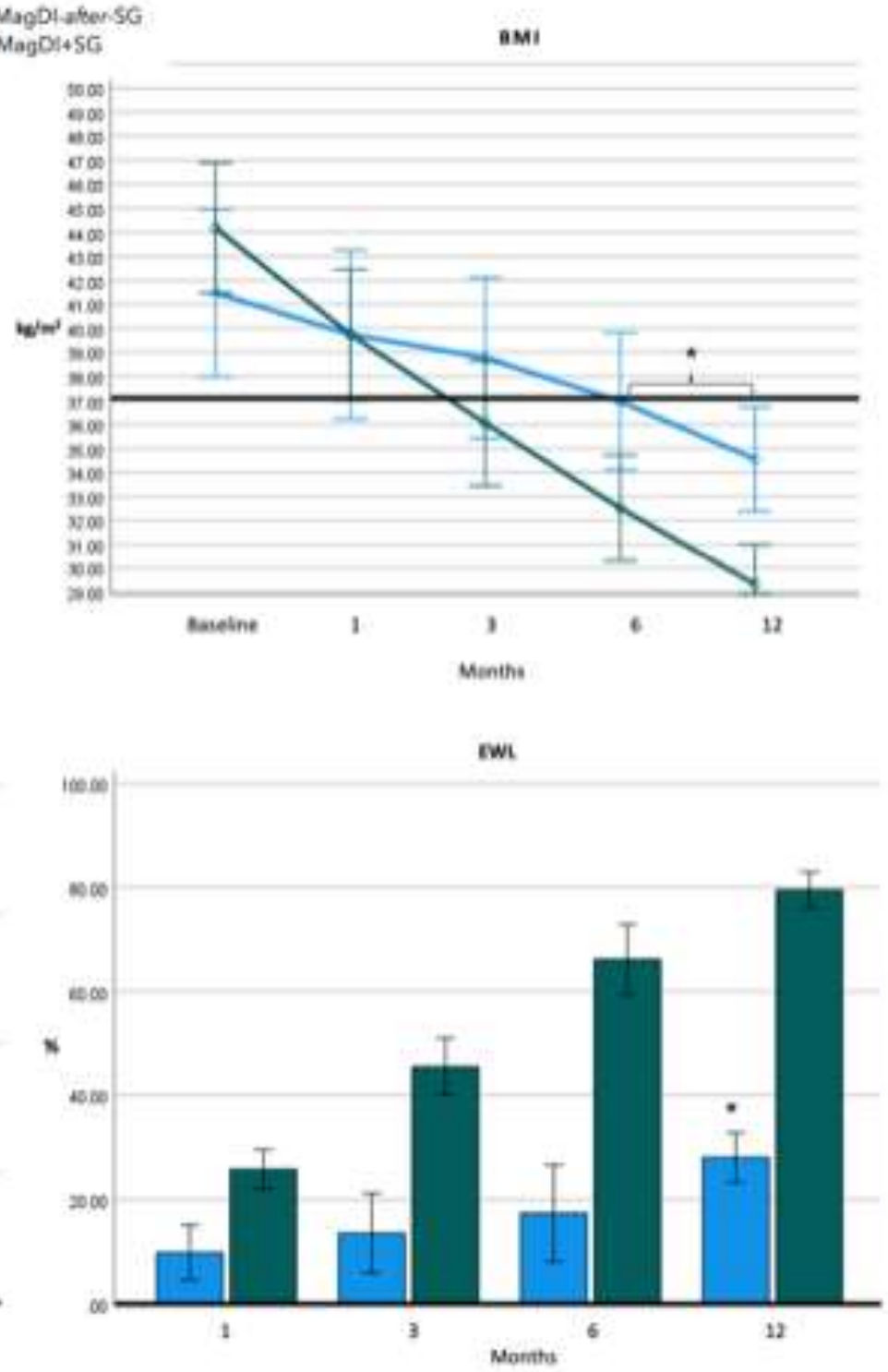

Weight
MagDI-after-SG
MagDI+SG
kg
130.00
125.00
120.00
115.00
110.00
105.00
100.00
95.00
90.00
85.00
80.00
75.00
70.00
*
Baseline
1
3
6
12
Months


BMI
kg/m²
50.00
49.00
48.00
47.00
46.00
45.00
44.00
43.00
42.00
41.00
40.00
39.00
38.00
37.00
36.00
35.00
34.00
33.00
32.00
31.00
30.00
29.00
*
Baseline
1
3
6
12
Months

TWL
%
40.00
30.00
20.00
10.00
00
*
1
3
6
12
Months

EWL
%
100.00
80.00
60.00
40.00
20.00
00
*
1
3
6
12
Months


Weight
MagDI-after-SG
MagDI+SG
kg
130.00
125.00
120.00
115.00
110.00
105.00
100.00
95.00
90.00
85.00
80.00
75.00
70.00
*
Baseline
1
3
6
12
Months


BMI
kg/m²
50.00
49.00
48.00
47.00
46.00
45.00
44.00
43.00
42.00
41.00
40.00
39.00
38.00
37.00
36.00
35.00
34.00
33.00
32.00
31.00
30.00
29.00
*
Baseline
1
3
6
12
Months

TWL
%
40.00
30.00
20.00
10.00
00
*
1
3
6
12
Months

EWL
%
100.00
80.00
60.00
40.00
20.00
00
*
1
3
6
12
Months

80%

28%

Side-to-side magnetic duodeno-ileostomy *after* sleeve gastrectomy (second-step; revision)				
Event	**CDC Grade**	**MagDI-*after*-SG procedure related?**	**Magnet related?**	**Description**
Anemia	II Severe	No	No	Patient presented 85 days post MagDI-*after*-SG study procedure with complaints of heavy menstruation and reported losing a lot of blood. Patient newly reported receiving a hormonal intrauterine device (IUD) though had not previously reported gynecological issues. Blood test results showed anemia and she was advised to go to the emergency room for treatment. She will continue to be followed for her pre-existing gynecological issues.
Cholecystitis	III Moderate	No	No	Patient went to the emergency room with back and abdomen pain 113 days post MagDI-*after*-SG study procedure. Patient was diagnosed with acute cholecystitis and underwent a laparoscopic cholecystectomy. The study investigator presumed gallstones had been present before the study procedure.
Kidney stones	III Moderate	No	No	Patient presented to the hospital and was diagnosed with kidney stones 108 days post MagDI-*after*-SG study procedure. Intramuscular anti-inflammatory medication was given for pain control. The patient subsequently had surgery to remove four kidney stones and recovered without sequelae.

Early Data Demonstrates Safety of the Magnet System

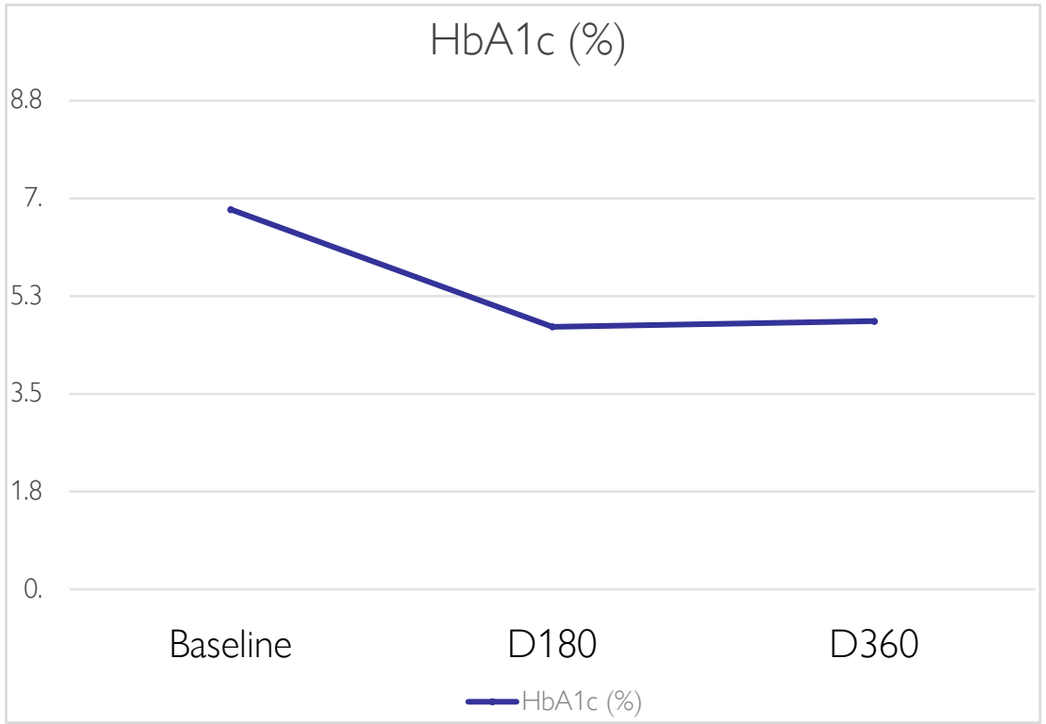
Clavien-Dindo Classification (n total AEs)	Procedure – D30 (n=57)	>D30 – D180 (n=57)	TOTAL (n=57)
Grade I	17 (30%)	8 (14%)	25 (44%)
Grade II Requiring pharmacological treatment	9 (16%)	13 (23%)	22 (39%)
Grade III Requiring surgical, endoscopic, or radiological intervention	6 (10%)	4 (7%)	10 (17%)
Grade 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%)

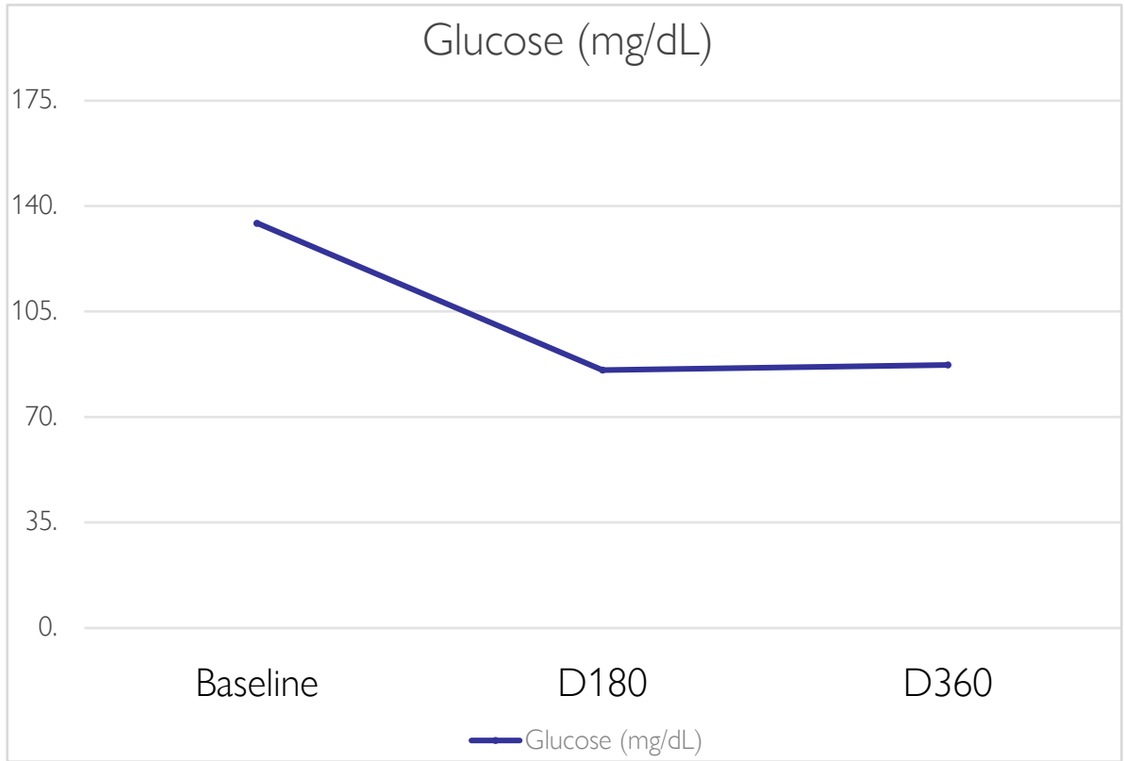
Table 2. Clavien-Dindo Classification grade II and III severe adverse events (SAEs) following side-to-side magnetic duodeno-ileostomy with sleeve gastrectomy (MagDI+SG) and side-to-side MagDI-*after*-SG through 6 months

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.