Side-to-side Magnetic Duodeno-ileostomy (MAGDI) without gastrectomy for type-2 diabetes. Early data from a prospective cohort.

Michel Gagner MD, FRCSC, FACS

Chief of Surgery, Westmount Square Surgical Center
Senior Consultant, Department of Surgery
Westmount-Montreal, Quebec, Canada

- Dr David Abuladze, Dr Lavan Koiava, Magda Abuladze

- Department of Surgery

- Innova Medical Center, Tbilisi, Georgia

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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]

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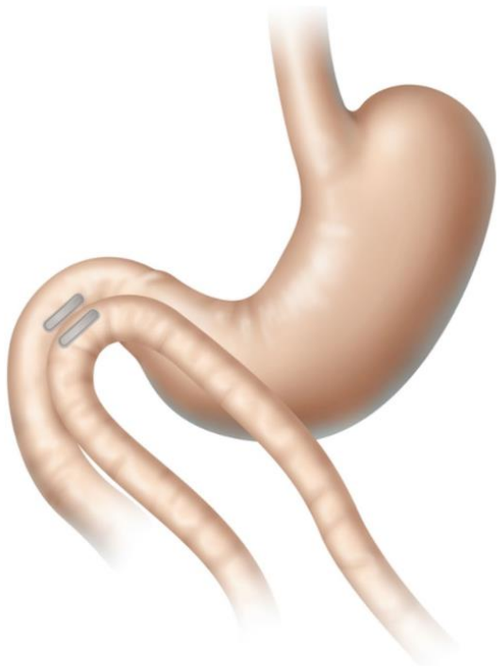


Fig. 1 Duodeno-ileal compression anastomosis by pairing of two linear magnets. The proximal magnet is positioned in the duodenum by gastroscopy and the distal magnet in the ileum by laparoscopy. After inter-magnet tissue compression and necrosis, the united magnets are expelled naturally

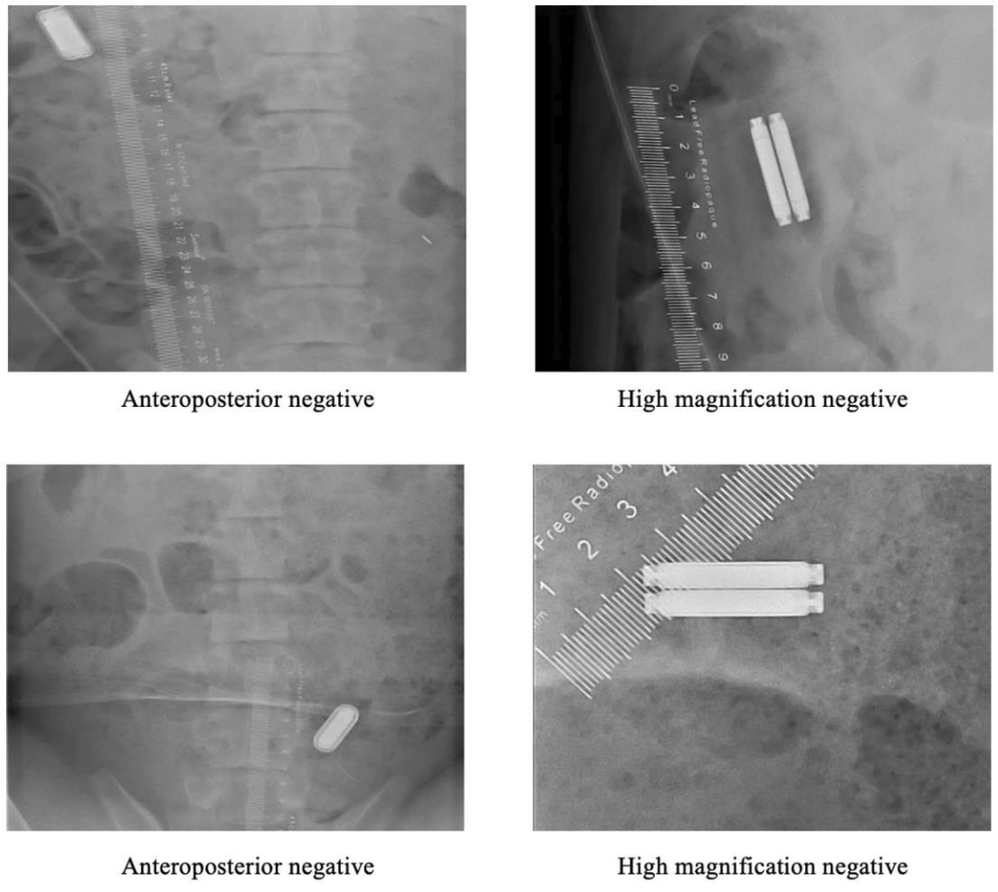


Fig. 3 Radiograph of magnetic compression anastomosis site in 4 animals, day of procedure

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

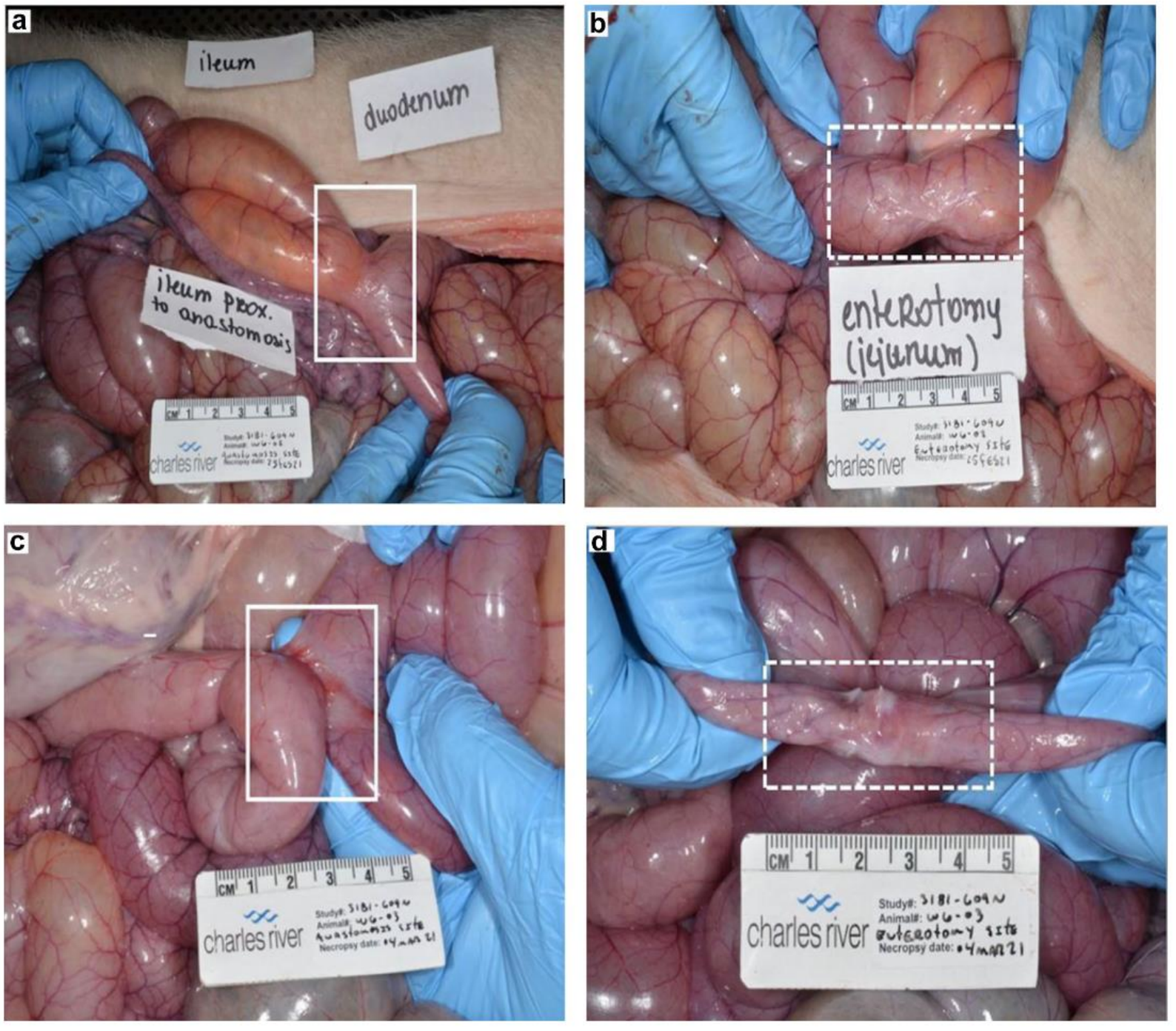
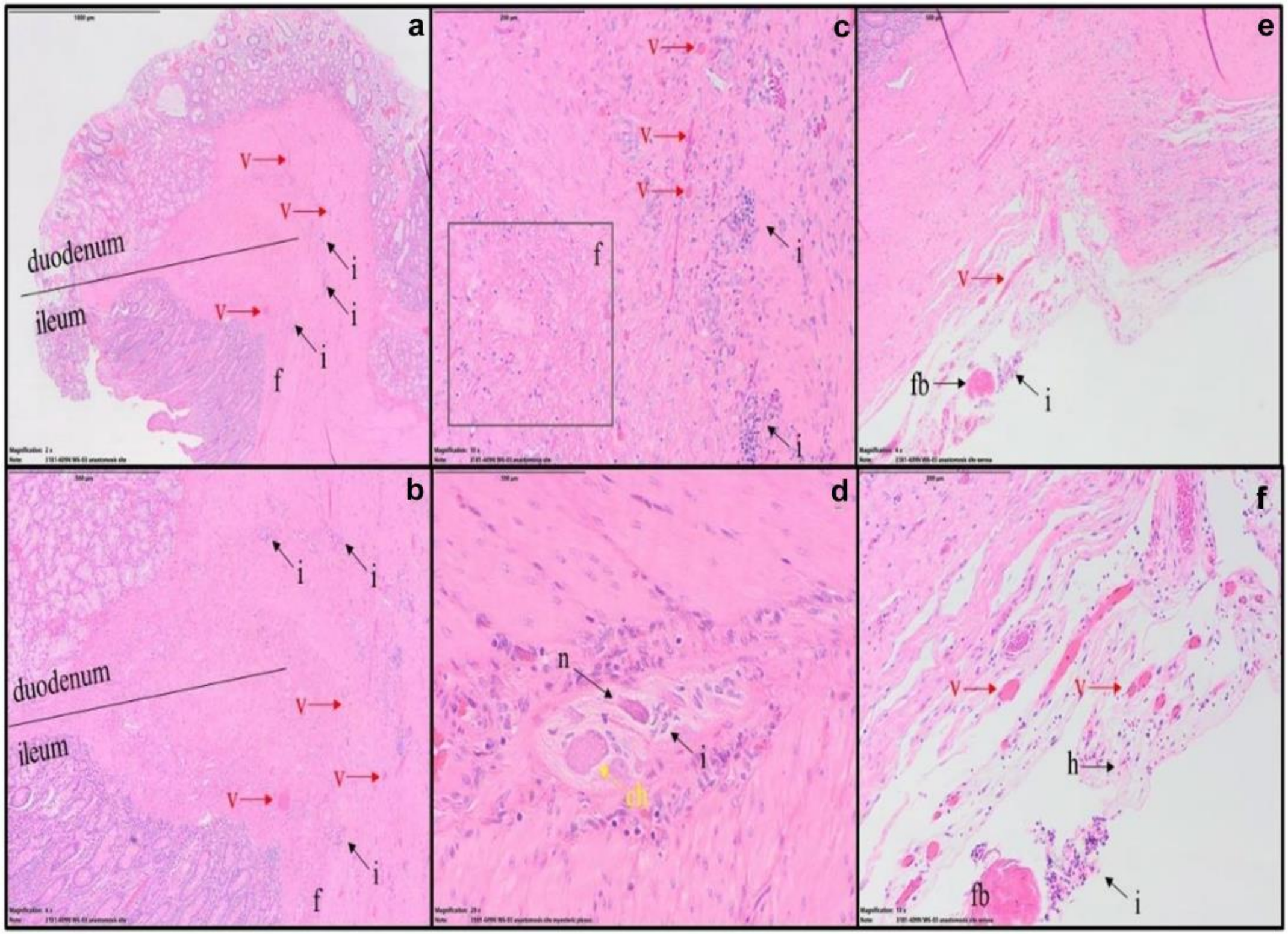


Fig. 5 Representative gross necropsy images of side-to-side duodeno-ileal (DI) magnetic compression anastomosis (MCA) and jejunal enterotomy (JE) sites. **a** Low magnification image of the serosal aspect of the side-to-side DI MCA site (white solid rectangle); **b** Low magnification image of the serosal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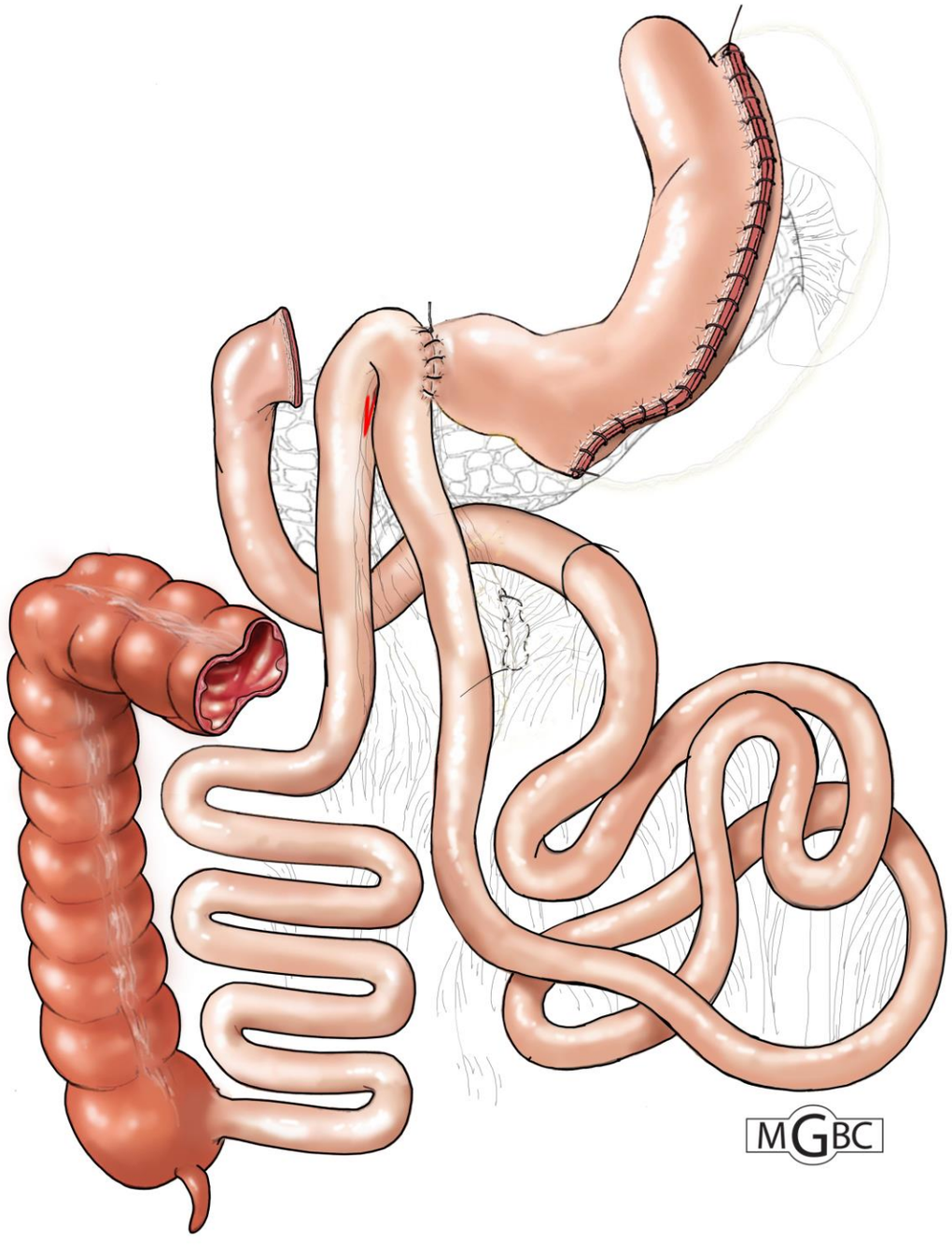
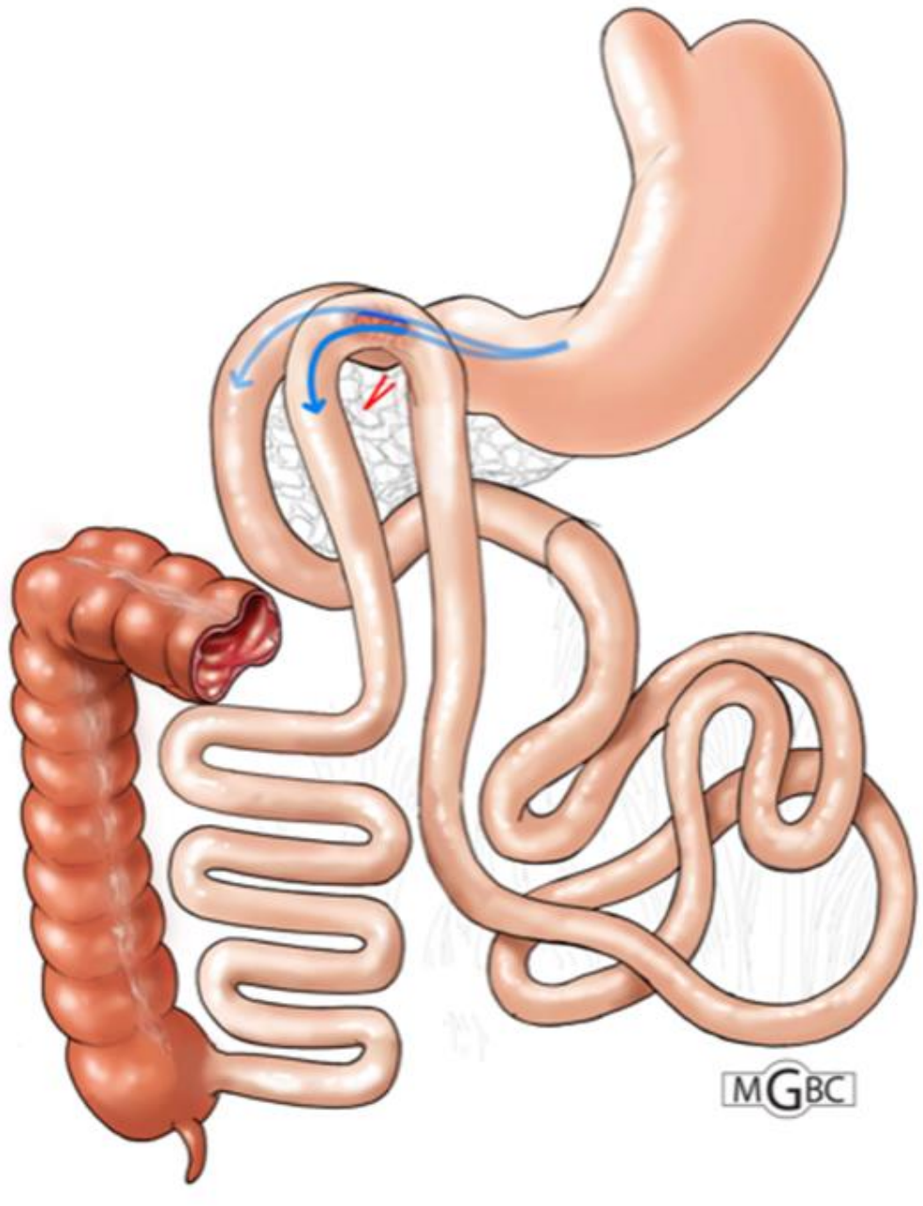
SADI vs MAGDI





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

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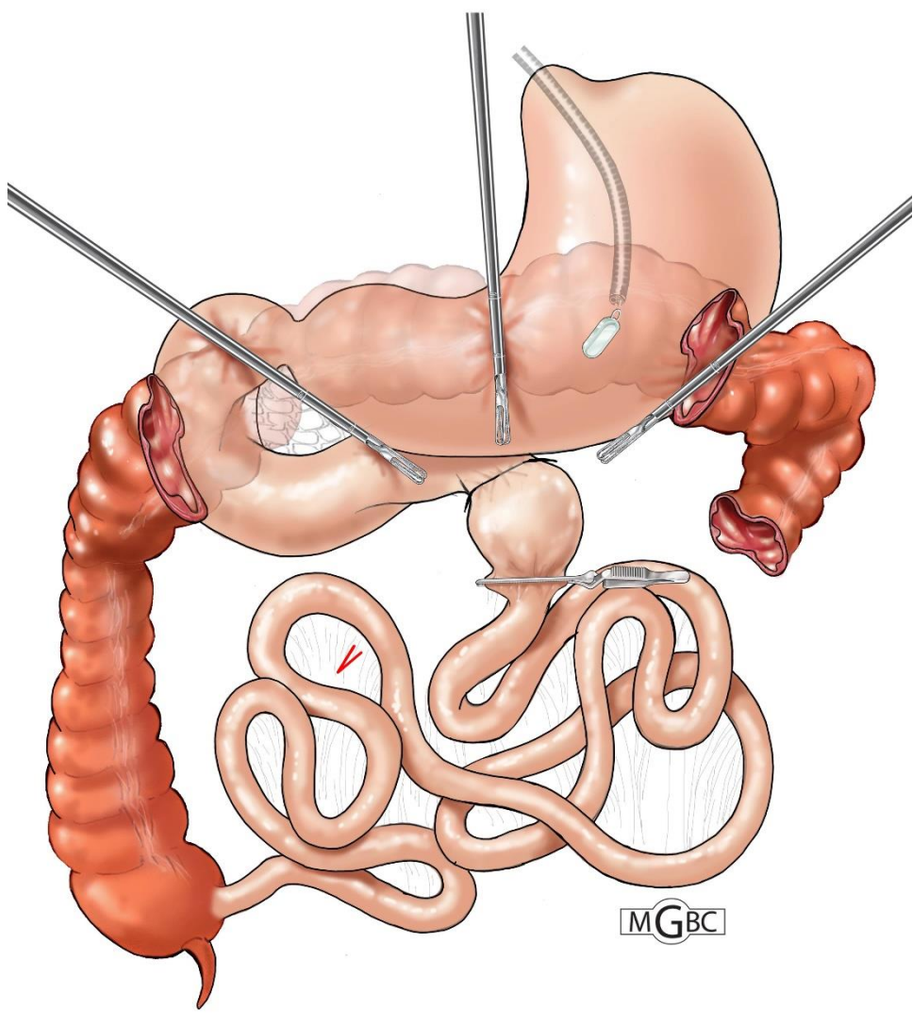

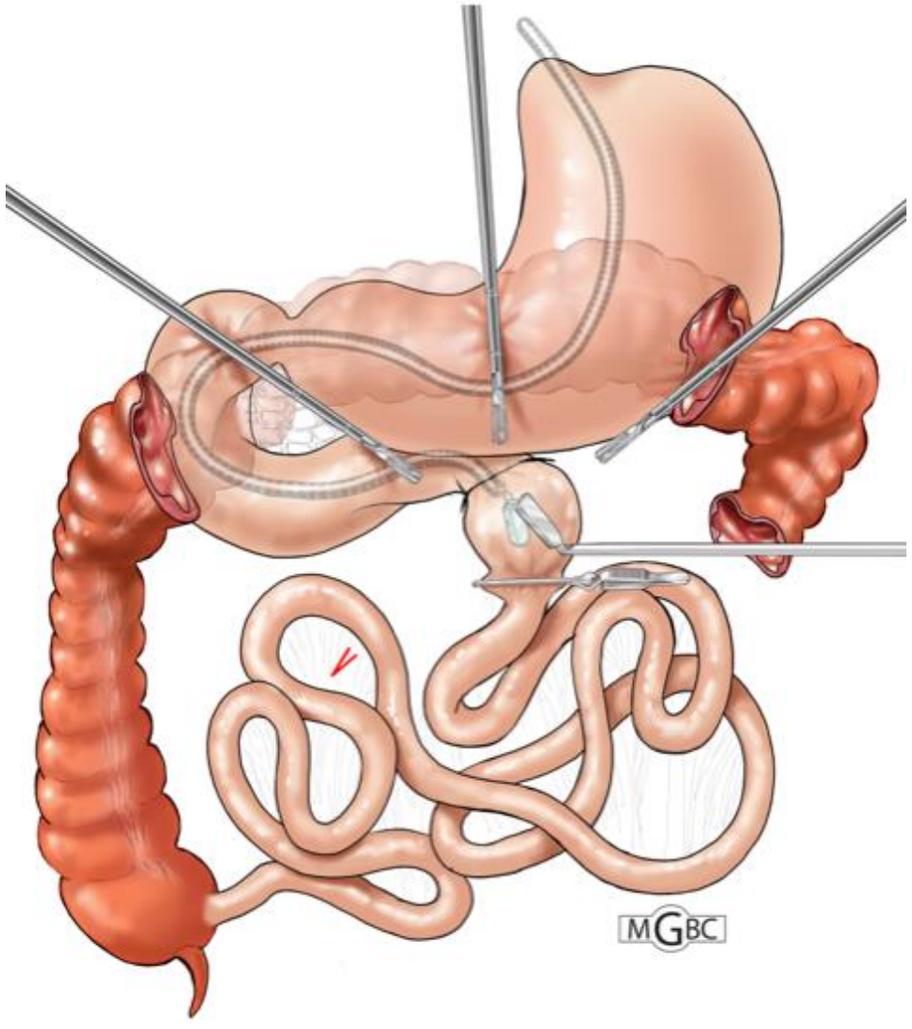

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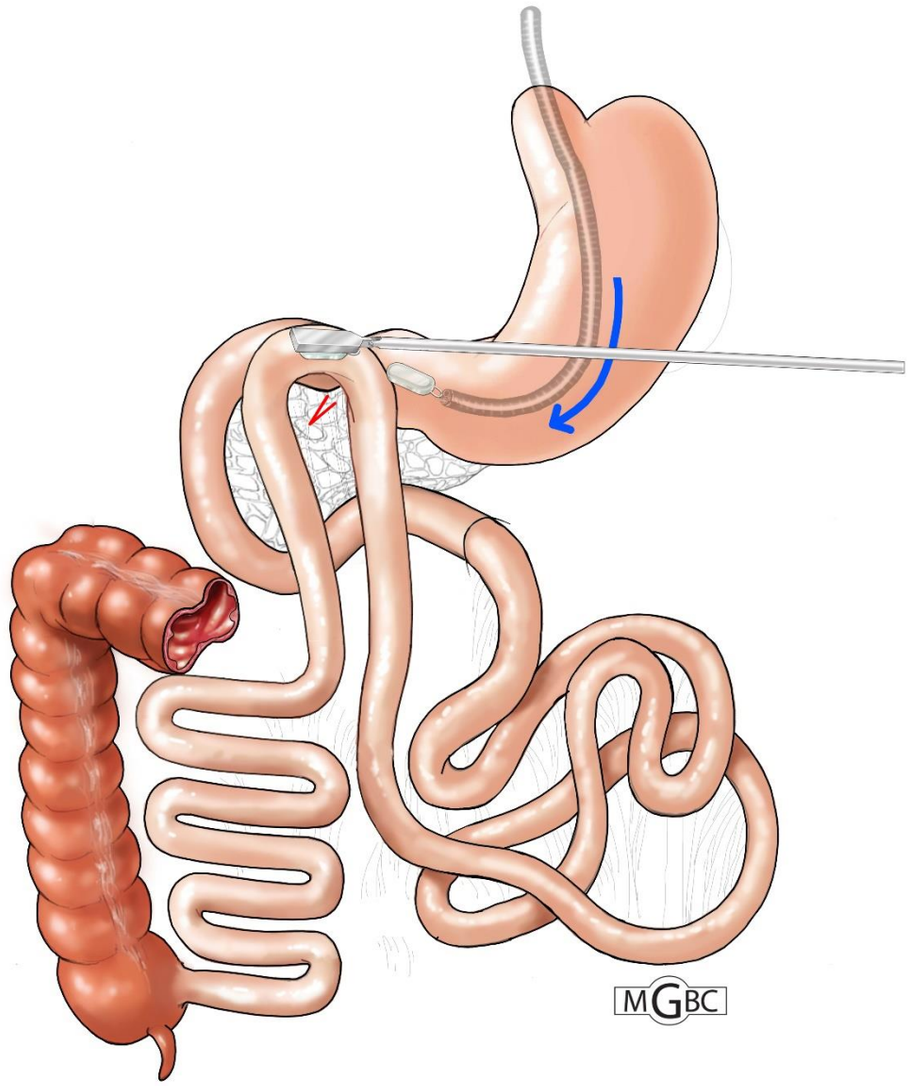

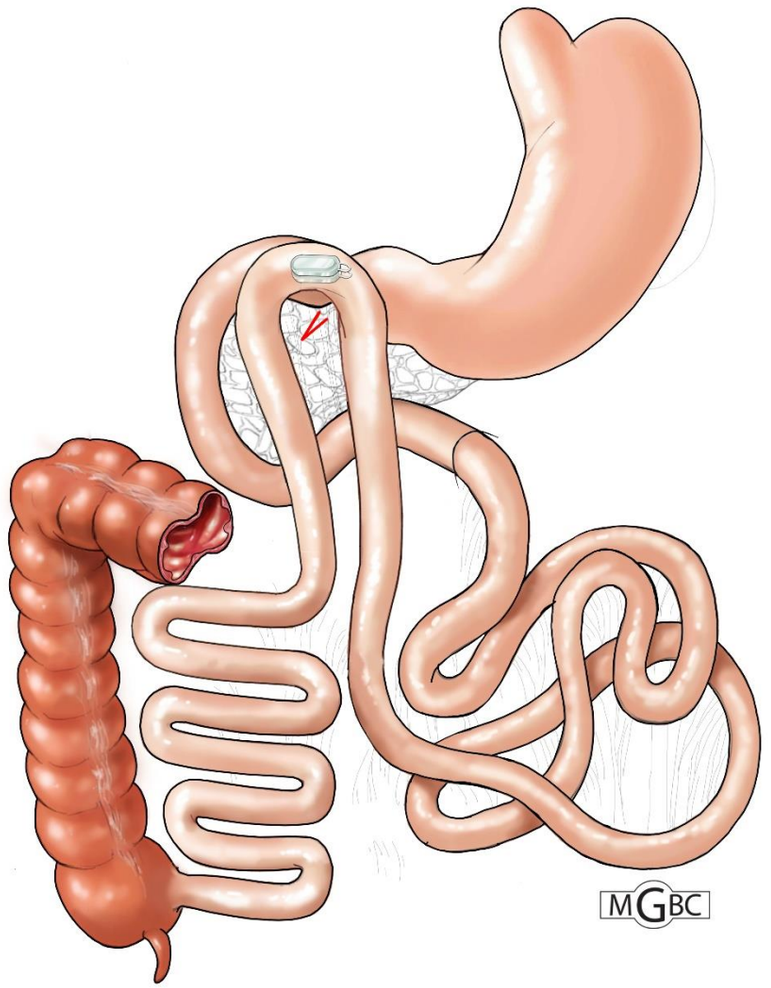

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ORIGINAL CONTRIBUTIONS

First-in-Human Side-to-Side Magnetic Compression Duodeno-ileostomy with the Magnet Anastomosis System

Michel Gagner[1] · David Abuladze[2] · Levan Koiava[2] · J. N. Buchwald[3] · Nathalie Van Sante[4] · Todd Krinke[5]

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Abstract

Purposes Classical gastrointestinal anastomoses are formed with sutures and/or metal staples, resulting in significant bleeding and leak rates. This study evaluated the feasibility and safety of the novel magnet anastomosis system (MS) to create a side-to-side duodeno-ileal (DI) diversion for weight loss and type 2 diabetes (T2D) resolution.

Materials and Methods Patients with severe obesity (body mass index (BMI) ≥ 35 kg/m^2 with/without T2D ($HbA1_C \geq 6.5\%$)) underwent the study procedure, a side-to-side MS DI diversion, with a standard sleeve gastrectomy (SG). A linear magnet was delivered by flexible endoscopy to a point 250 cm proximal to the ileocecal valve; a second magnet was positioned in the first part of the duodenum; the bowel segments containing magnets were apposed, initiating gradual anastomosis formation. Laparoscopic assistance was used to obtain bowel measurements, obviate tissue interposition, and close mesenteric defects.

Results Between November 22 and 26, 2021, 5 female patients (mean weight 117.6 ± 7.1 kg, BMI (kg/m^2) 44.4 ± 2.2) underwent side-to-side MS DI + SG. All magnets were successfully placed, expelled without re-intervention, and formed patent durable anastomoses. Total weight loss at 12 months was 34.0 ± 1.4% (SEM); excess weight loss, 80.2 ± 6.6%; and BMI reduction, 15.1. Mean $HbA1_C$ (%) dropped from 6.8 ± 0.8 to 4.8 ± 0.2; and glucose (mg/dL), from 134.3 ± 17.9 to 87.3 ± 6.3 (mean reduction, 47.0 mg/dL). There was no anastomotic bleeding, leakage, obstruction, or infection and no mortality.

Conclusions Creation of a side-to-side magnetic compression anastomosis to achieve duodeno-ileostomy diversion in adults with severe obesity was feasible and safe, achieved excellent weight loss, and resolved type 2 diabetes at 1-year follow-up.

Trial Registration Clinicaltrials.gov Identifier: NCT05322122.

i

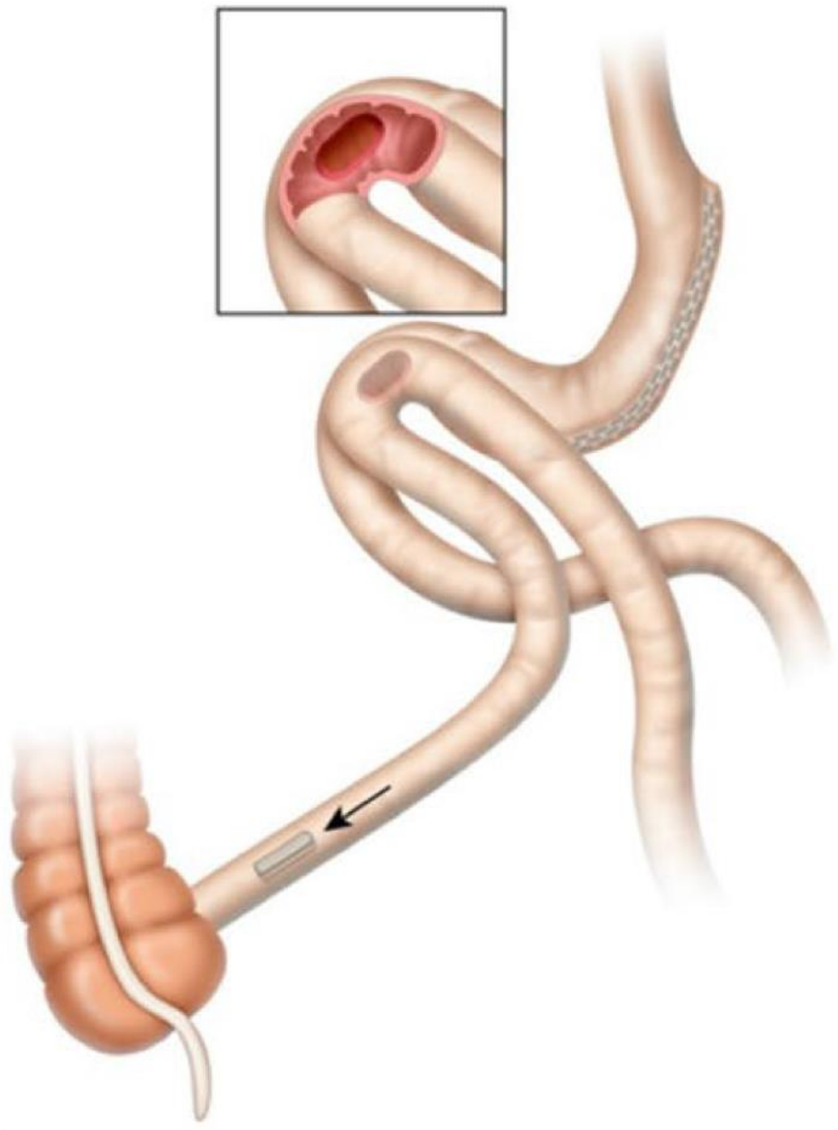
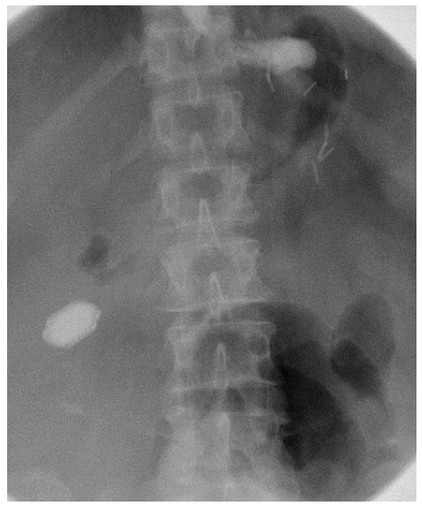
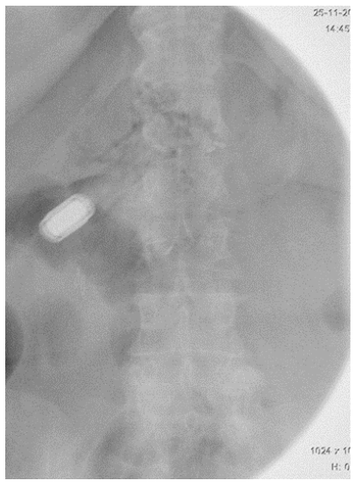
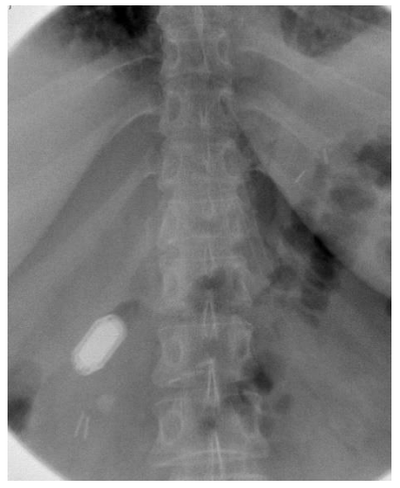


Table 1 Baseline patient demographic and clinical characteristics

Characteristics	$N=5$
Age, yrs, mean ± SEM (range)	44.2 ± 3.5 (34–55)
Females, *n* (%)	5 (100.0)
Ethnicity, Caucasian	5 (100.0)
Weight, kg, mean ± SEM	117.6 ± 7.1
Body mass index, kg/m^2, mean ± SEM	44.4 ± 2.2
Associated medical conditions, *n* (%)	
Type 2 diabetes mellitus	4 (80.0)
Non-alcoholic steatosis disease	2 (40.0)
Dyslipidemia	2 (40.0)
Hepatic steatosis	1 (20.0)
$HbA1_C$, %, mean ± SEM	6.8 ± 0.8
Glucose, mg/dL, mean ± SEM	134.3 ± 17.9
Prior sleeve gastrectomy ≥ 12 months, *n* (%)	0 (0.0)
Indicated for SADI-S, where duodeno-ileostomy is side to side, *n* (%)	5 (100.0)
Smoking status, *n* (%)	1 (20.0)
Menopause, *n* (%)	3 (60.0)

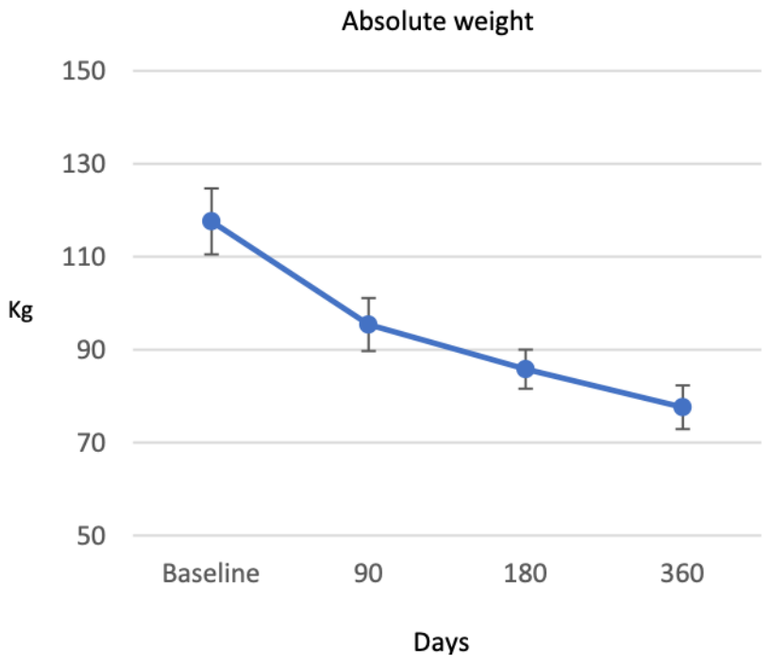
The MAGNET System - Stage 1- Primary endpoint Device Delivery Success-Safety Population



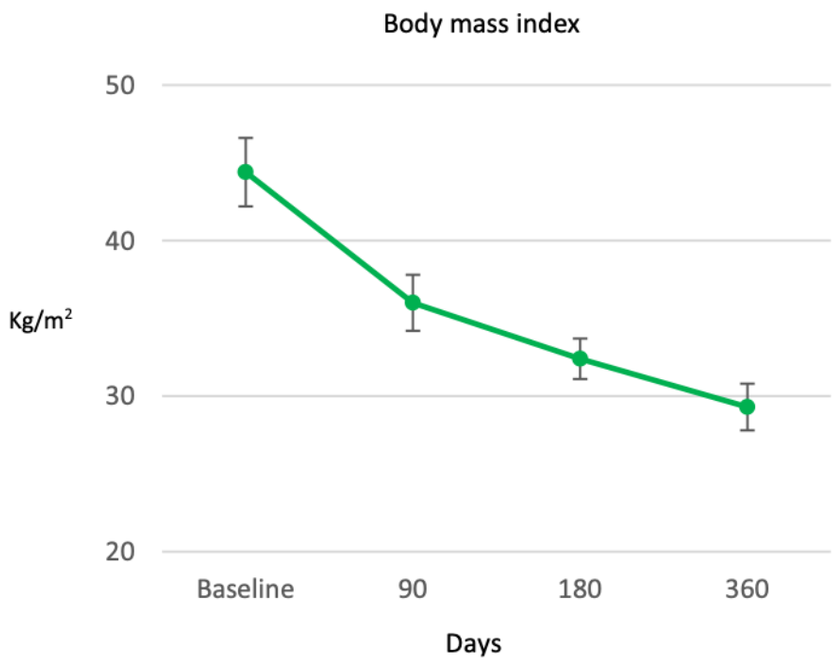
Procedure date	Duration of procedure mean in min (SD)	Placement of the magnet
22, 24, 25 and 26 November 2021	154 (24.48)	100%

(a)



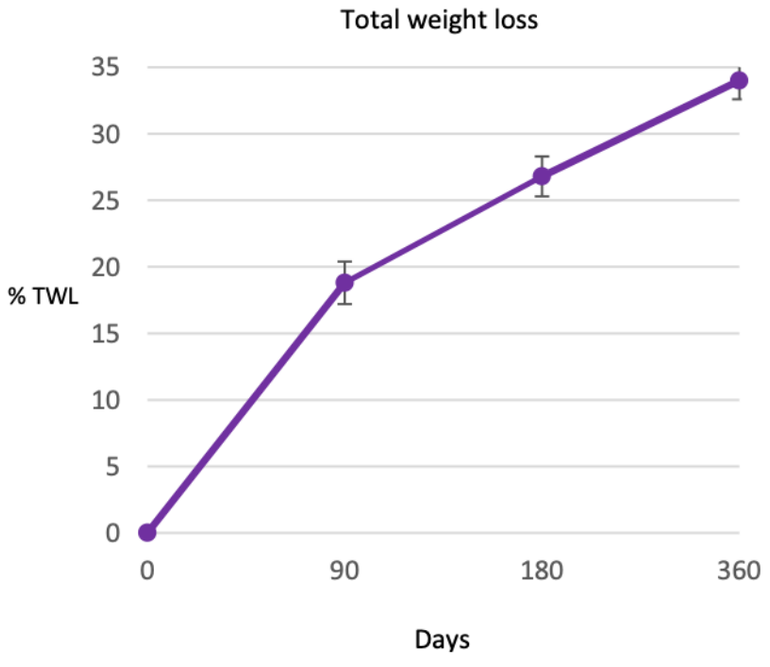
Mean±SEM			
117.6±7.1	95.4±5.7	85.8±4.2	77.6±4.7

(b)



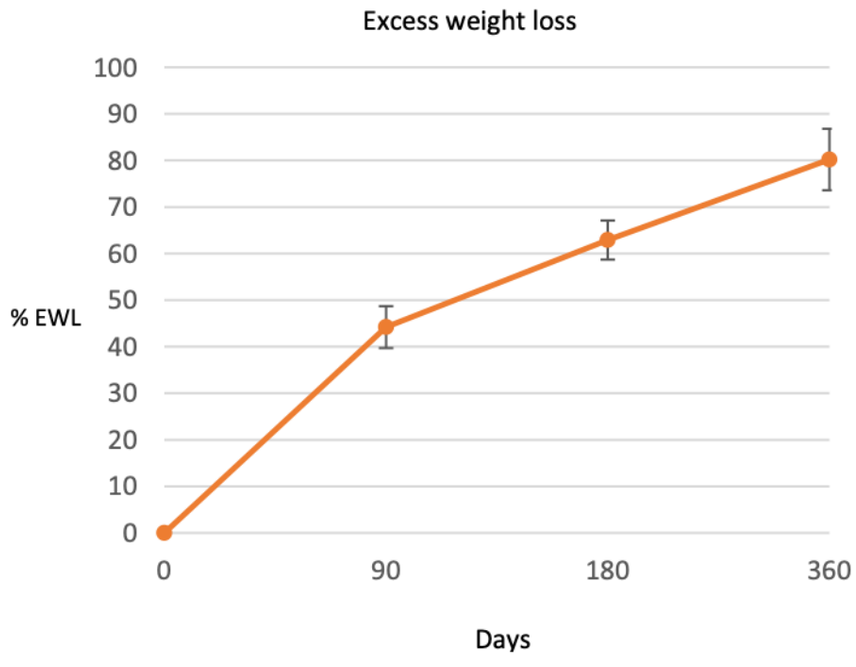
Mean±SEM			
44.4±2.2	36.0±1.8	32.4±1.3	29.3±1.5

(c)



Mean±SEM			
0.0	18.8±1.6	26.8±1.5	34.4±1.4

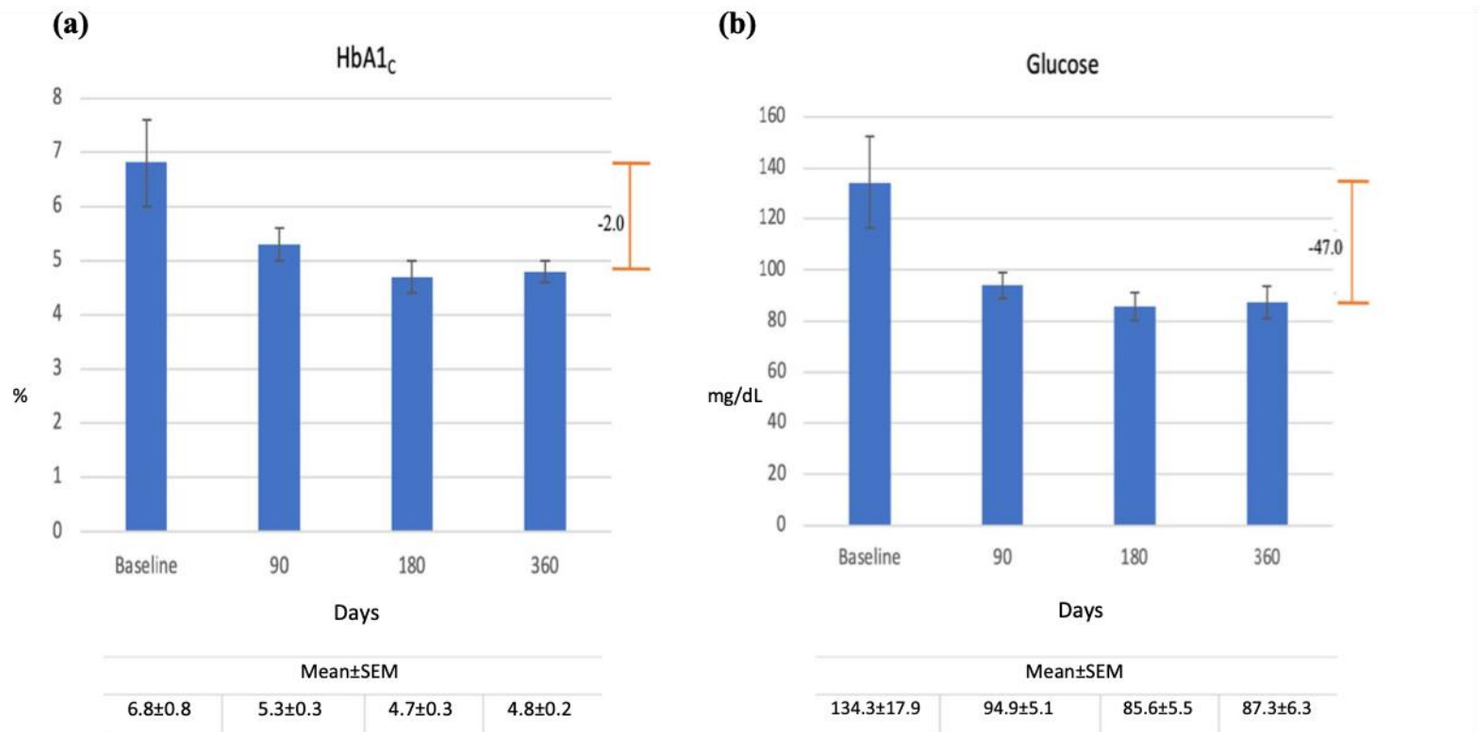
(d)



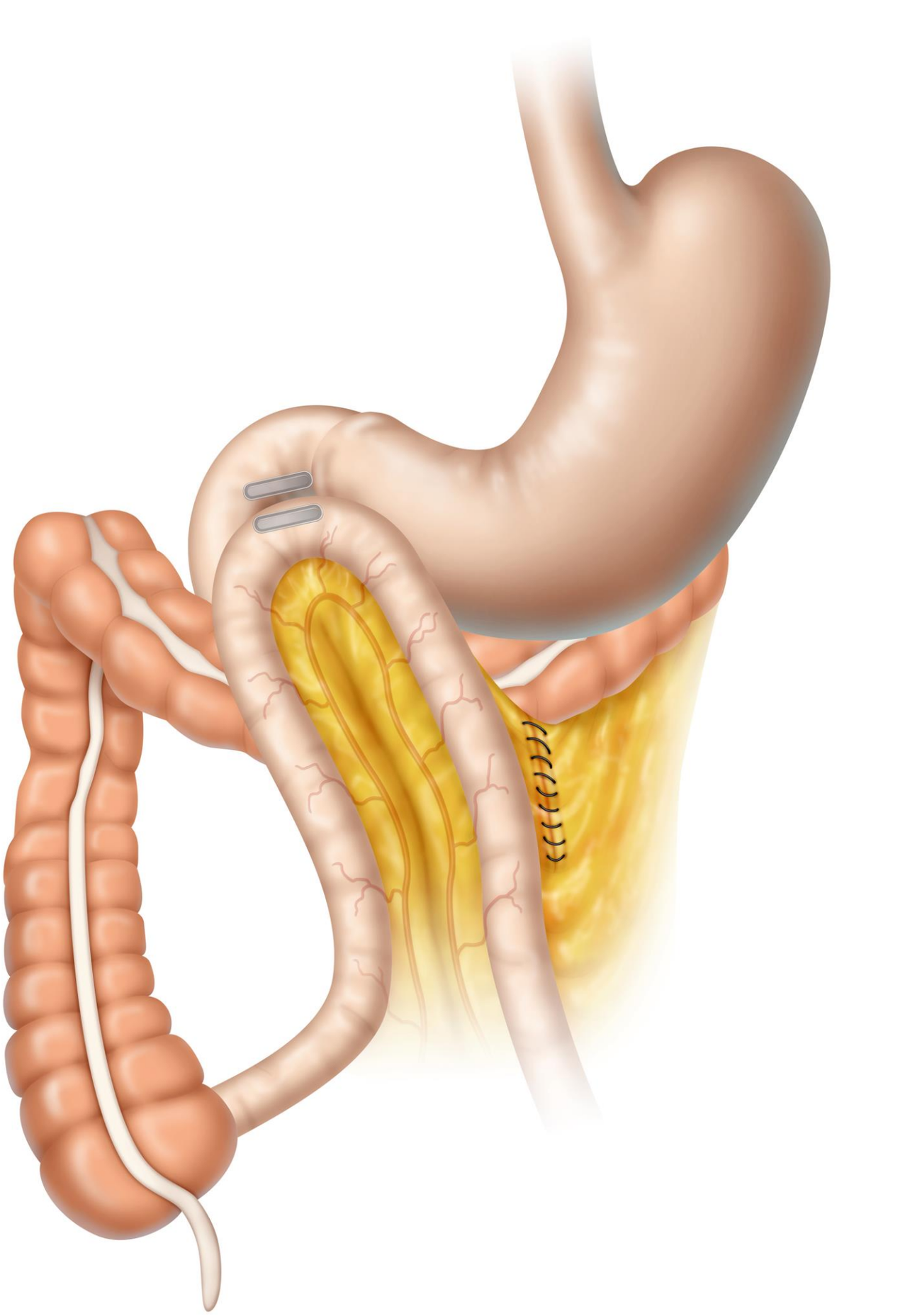
Mean±SEM			
0.0	44.2±4.5	62.9±4.2	80.2±6.6

Table 2 Adverse events by number and severity post side-to-side magnet system duodeno-ileostomy with sleeve gastrectomy through day 360 by Clavien-Dindo Classification

	All patients ($N=5$) *n* (%)					
Adverse event	Grade I	Grade II	Grade III	Grade IV	Grade V	Total
Mucosal tear of upper esophagus due to overtube insertion	1	0	0	0	0	1 (6.3)
Serosal tear of ileum (5 mm) due to laparoscopic forceps	0	0	1	0	0	1 (6.3)
Mild abdominal pain from procedure wounds	3	0	0	0	0	3 (18.8)
Intra-abdominal hematoma at sleeve staple line, upper left quadrant	0	1	0	0	0	1 (6.3)
Vitamin B_{12} deficiency	3	2	0	0	0	5 (31.3)
Vitamin D deficiency	0	1	0	0	0	1 (6.3)
COVID-19 positive	3	0	0	0	0	3 (18.8)
Constipation	0	1	0	0	0	1 (6.3)
Number of adverse events	10 (62.6)	5 (31.2)	1 (6.2)	0 (0)	0 (0)	16 (100)



Easy to Swallow, version 2.0



- Use of the Magnet System to achieve duodeno-ileostomy without gastrectomy in fifteen (15) patients with diabetes.
- This is a first-in-human study with the second-generation Magnet that replaces a metal edging with biofragmentable flange; the device is swallowable.
- **Site:** Innova Medical Centre, Tbilisi, Georgia
- Key **Inclusion Criteria**:
  - Age: 18 – 65 years
  - BMI: 30-35 kg/m^2
  - Type 2 Diabetes Mellitus
- Key **Exclusion Criteria**:
  - No prior sleeve gastrectomy procedure

- Study initiated December 20, 2022, with n=15 subjects enrolled
- All 9 subjects have reached one-month and one-third of the subjects are out one year post procedure (33.3%, 5/15)

Baseline Characteristics	All subjects (n=15)
Clinical	
Type 2 Diabetes: n (%)	15 (100 %)
Weight (kg): Mean (SEM)	97.6 (2.9)
Body Mass Index (BMI): Mean (SEM)	33.0 (0.4) kg/m^2
Age	
Mean (SEM)	53.6 (1.5) years
Min, Max	42 , 61 years
Gender	
Female: n (%)	8 (53.3%)
Male: n (%)	7 (46.7%)

*n=23

- The MagDI System was successfully placed in all (15/15, 100%) subjects
- The first Magnet was easily swallowed with no issues, thereby eliminating one endoscopy for the patients.
- All passed the paired set of docked Magnets naturally without migration or separation and none (0%) required invasive re-intervention.

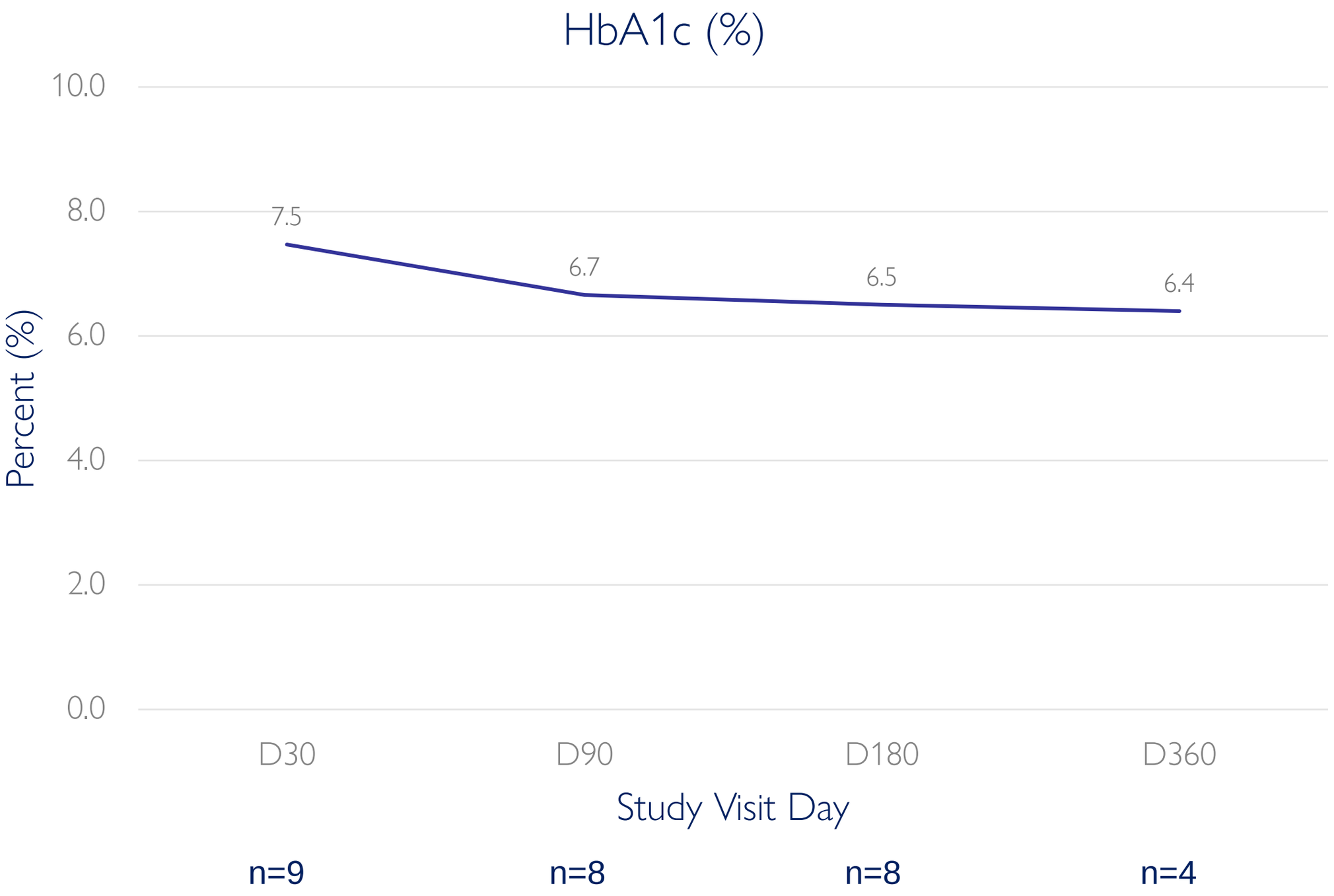
Feasibility / Performance Criteria	n=15 (%)
Placement of the device with ≥90% alignment of Magnets	15 (100%)
Passage of the device without invasive re-intervention	15 (100%)
Creation of a patent anastomosis confirmed radiologically	15 (100%)

- Median expulsion time: 24 days (Mean 23.8 days; Range 15 – 29 days)
- Three (3) subjects were not aware that Magnets passed.

Clavien-Dindo Classification	All Subjects (n=15)
Grade I: (n (% of Cohort AEs)) Deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions. Antiemetics, antipyretics, analgesics, diuretics and electrolytes, and physiotherapy allowed.	14 (50%)
Grade II: (n (% of Cohort AEs)) Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition included.	12 (43%)
Grade III: (n (% of Cohort AEs)) Requiring surgical, endoscopic, or radiological intervention.	2 (7%)
Grade IV: (n (% of Cohort AEs)) Life-threatening complication (including certain CNS complications) requiring Intermediate Care/Intensive Care Unit-management.	0 (0%)
Grade V: (n (% of Cohort AEs)) Death of a patient.	0 (0%)
TOTAL Adverse Events	28 (100%)

- The majority of adverse events (93%, 26/28) were Clavien-Dindo Grade I or II.
- One grade III event, a case of duodenitis, was assessed as related to the device. The patient was empirically treated with antibiotics, no infection determined, and no bleeding or leakage.


Percent Weight Loss
% TWL
% EWL
60.
45.
30.
15.
0.
Percent
20.3
36.8
43.9
54.
4.7
8.2
9.7
11.4
D30
D90
D180
D360
n=15
n=8
n=8
n=4
Study Visit Day


HbA1c (%)
10.0
8.0
6.0
4.0
2.0
0.0
Percent (%)
7.5
6.7
6.5
6.4
D30
D90
D180
D360
Study Visit Day
n=9
n=8
n=8
n=4

Subject#		Concominant medications before procedure	Concominant medications now	
04-05-01	Finished Study	Metformin 2000mg daily, Vildagliptini 100 mg daily	Vilda Denk 25mg, daily	
04-05-02	Finished Study	Vildagliptini 100 mg daily, Siofor 1000mg, 2x daily	Siofor 1000mg, twice daily	
04-05-03	Finished Study	Metformin 1000mg daily, Victoza 1.2mg, daily	Vilda Denk 50mg, twice daily Siofor 1000mg, twice daily	
04-05-05	Finished Study	Diabeton MR 60mg, daily Glucophage 1000mg, twice daily Forxiga 10mg daily	Diabeton MR 60mg, daily Glucophage 500mg, twice daily Forxiga 10mg daily	
04-05-06	Finished Study	Glucophage 1000mg, twice daily Forxiga 10mg daily Janumet 50mg, twice daily	Metformin twice daily 1000 mg	
04-05-08	About to have day 270	Galvus Met 50/1000mg, twice daily	Glucophage XR 500mg, daily	
04-05-09	About to have day 270	Janumet 50mg, twice daily, Forxiga 10mg daily	Janumet 50mg, twice daily	
04-05-10	About to have day 270	Forxiga 10mg daily, Galvus Met 50/1000mg, twice daily	Forxiga 10mg daily Galusmet 50mg twice daily Siofor 500mg, daily	
04-05-11	About to have day 270	Siofor 1000mg, 2x daily, Amaryl 4mg, daily, Galusmet 50mg twice daily	Doesn't take any medication for diabetes type 2	
04-05-13	Just had day 90 visit	Sinjardy 0.1mg, daily	Sinjardy 0.1mg, daily	
04-05-15	Just had day 90 visit	Amaryl 2mg, daily Aglinox 10mg, daily Siofor 750mg, daily Galvus Met 50/1000mg	Amaryl 2mg, twice daily	
04-05-16	Just had day 90 visit	Amaryl 4mg, daily	Doesn't take any medication for diabetes type 2	
04-05-17	Just had day 90 visit	Metformin 1000mg twice daily Forxiga 10mg, daily	Metformin 1000mg twice daily Forxiga 10mg, daily Amaryl 3mg, daily Galvus Met 50/1000mg, twice daily	
04-05-18	Just had day 90 visit	Glucophage 1000mg, twice daily	Glucophage 1000mg, twice daily	
04-05-19	Just had day 90 visit	Glucophage 1000mg, twice daily, Forxiga 10mg daily	Glucophage 1000mg, daily	

- After Magnetic Duodeno-ileostomy (MAGDI) using 40mm linear magnets, early results demonstrated:

- Patent anastomosis, with passage of magnets at 24 days (mean).

- >50% EWL at 1 year

- Promising resolution or improvements of Type-2 Diabetes on all patients

- More than half of patients reached an HbA1c of <6.5%.

Thank You