Duodenal Bipartition: Concept and Clinical Options at the present time.

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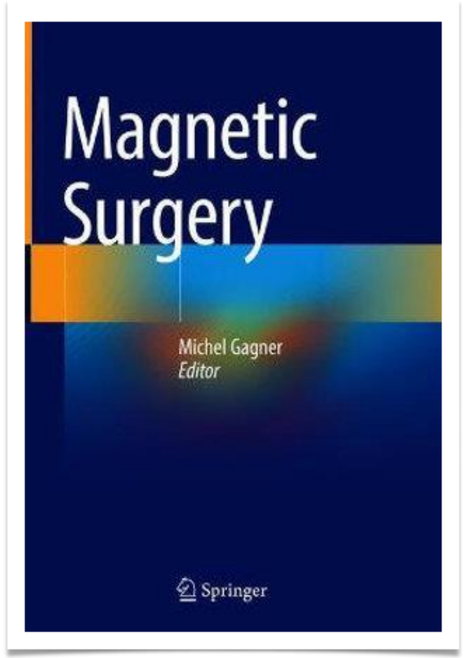
Financial Disclosures

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



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INNOVATION AND RESEARCH

RESEARCH ARTICLE Open Access

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

Michel Gagner*

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

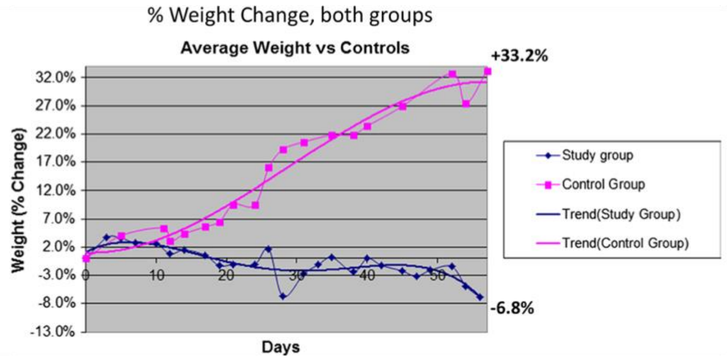

Fig. 6 Graph of % of weight change in animals that had a side-to-side duodeno-ileal anastomosis (study group) versus sham controls, over time in days. At 56 days, control animals had gained 33.2 % of weight, while study animals had lost 6.8 % of weight

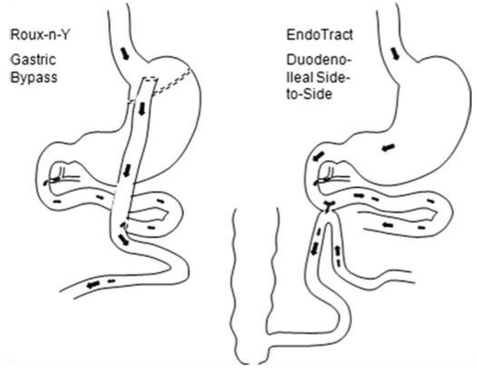

Fig. 4 Comparison of digestive flow between a gastric bypass and a side-to-side duodeno-ileal anastomosis. Alimentary flow and bili-opancreatic secretions are mixing in a Y channel (100–150 cm in mid jejunum) in a gastric bypass, while in a side-to-side duodeno-ileal anastomosis, the alimentary flow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

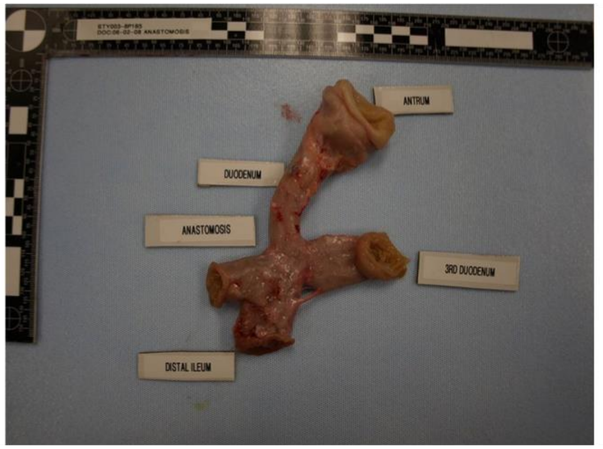

Fig. 7 Macroscopic external view of a side-to-side duodeno-ileal anastomosis at 56 days

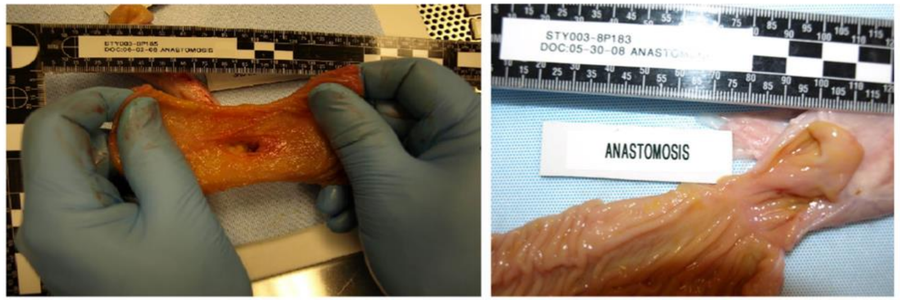

Fig. 8 **a** Macroscopic luminal view (from the ileum side) of a side-to-side duodeno-ileal anastomosis at 56 days. **b** Macroscopic luminal view of a longitudinal opening of a side-to-side duodeno-ileal anastomosis at 56 days

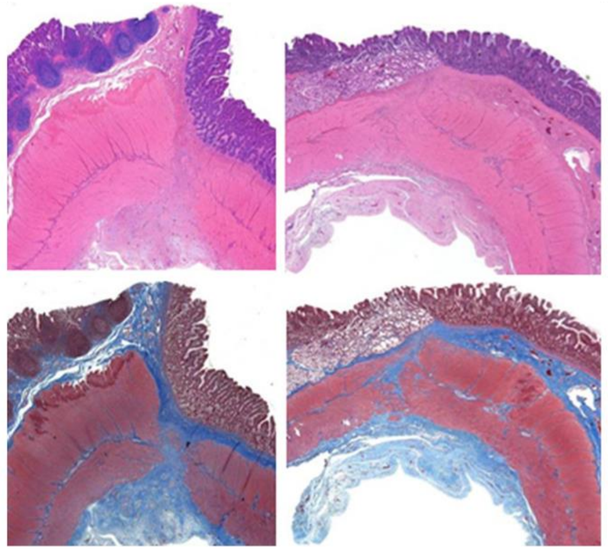

Fig. 10 **a**–**d** Longitudinal sections through the well healed duodenal-ileal anastomotic site. It appears that all layers of the intestine are apposed (muscular layers not closely apposed) although only a small portion of the ileal mucosa is present in the first second (**a**, **b**) and the mucosa overlying the anastomotic site is absent in the second section (**c**, **d**). Abundant fibrous connective tissue (*blue* in trichrome stain) separates the muscle layers of the two portions of the intestine. The serosa appears slightly edematous and serosal vessels appear prominent with perivascular edema. There is no evidence of infection, inflammation or dehiscence at the anastomotic site. All images—×20 magnification. **a**, **c** H & E stain; **b**, **d** Masson's trichrome stain

Table 2 Mean values of serum biochemical profiles at baseline, day 3 and 56

	Time after duodenum-ileal anastomosis		
	Baseline	**Day 3**	**Day 56**
Glucose	75.75	101.25	88.50
AST	35.25	29.00	39.25
Total protein	6.53	6.40	5.05
Albumin	3.45	3.30	2.58
Urea N	5.00	8.75	15.00
Creatinine	1.38	1.30	1.15
Phosphorous	7.20	7.00	6.00
Calcium	10.23	9.60	9.10
Sodium	141.75	140.25	136.25
Potassium	3.65	3.80	4.25
Chloride	102.00	98.00	103.25
Bicarbonate	27.75	29.00	26.75
Gamma-GT	26.75	24.25	21.25

AST alamine serum trasnferase, *N* nitrogen, *GT* glutamine transferase

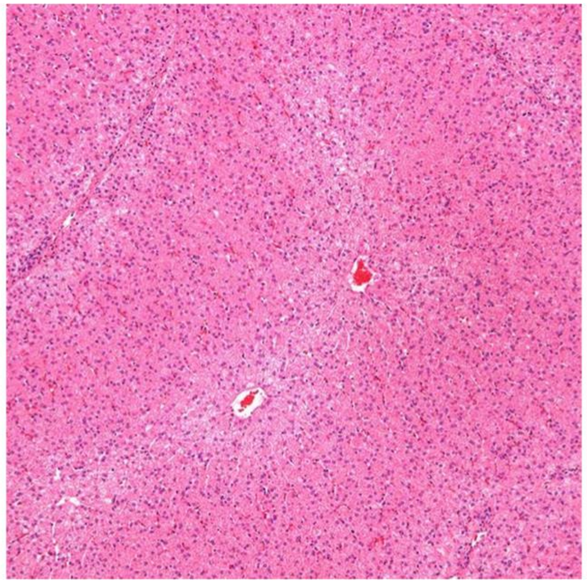

Fig. 11 Liver histology at 56 days. Subtle centrilobular hepatocellular swelling and granularity (consistent with glycogen deposition) is noted in this animal. H & E stain, ×100 magnification

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The Director of the United States Patent and Trademark Office

Has received an application for a patent for a new and useful invention. The title and description of the invention are enclosed. The requirements of law have been complied with, and it has been determined that a patent on the invention shall be granted under the law.

Therefore, this

United States Patent

Grants to the person(s) having title to this patent the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States of America or importing the invention into the United States of America, and if the invention is a process, of the right to exclude others from using, offering for sale or selling throughout the United States of America, or importing into the United States of America, products made by that process, for the term set forth in 35 U.S.C. 154(a)(2) or (c)(1), subject to the payment of maintenance fees as provided by 35 U.S.C. 41(b). See the Maintenance Fee Notice on the inside of the cover.

Joseph Matal

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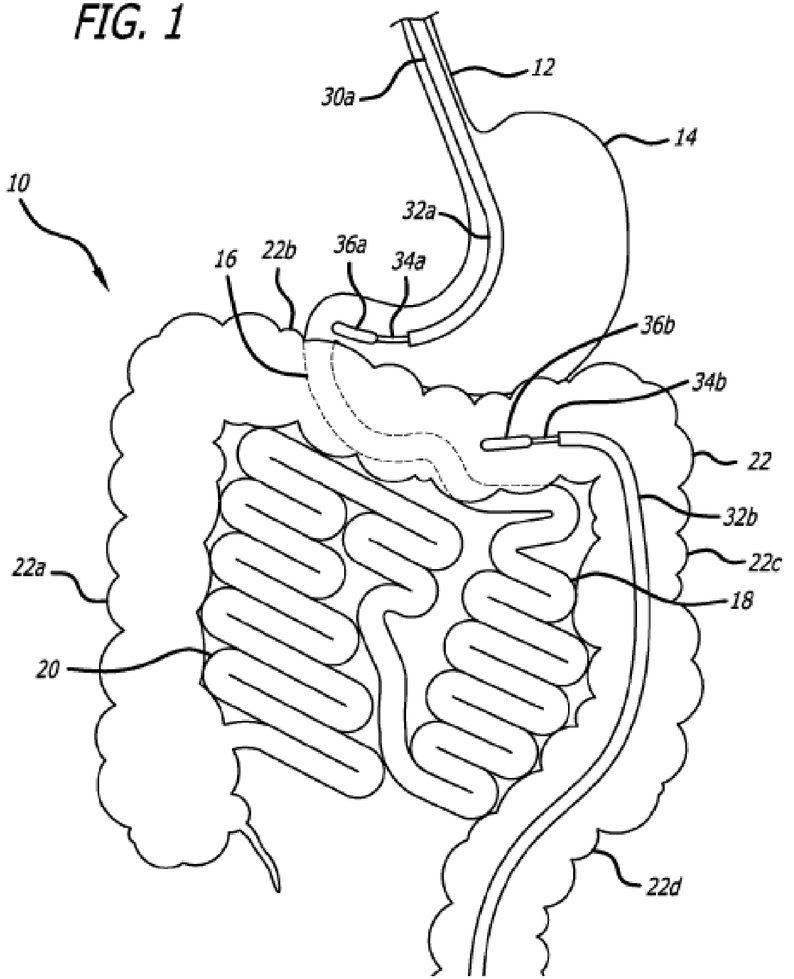
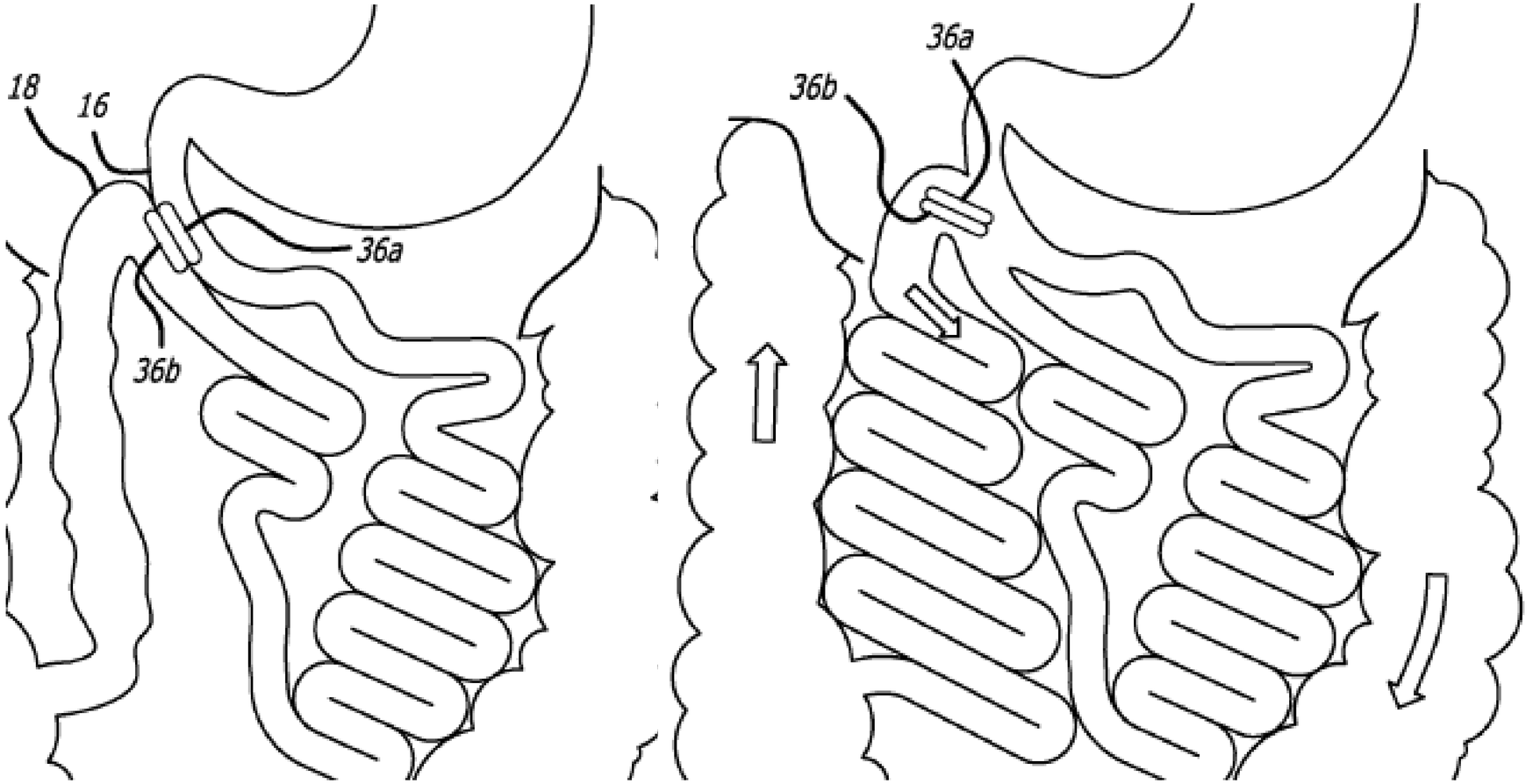
FIG. 1



(12) **United States Patent**

(10) **Patent No.: US 9,801,635 B2**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LETTER TO THE EDITOR

Duodeno-Ileal Anastomosis with Self-Assembling Magnets: Initial Concepts and Basis of This Operation

Michel Gagner[1,2]

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Linear

Surgical Endoscopy
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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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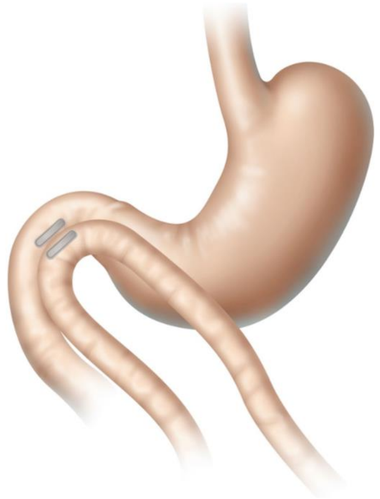


Fig. 1 Duodeno-ileal compression anastomosis by pairing of two linear magnets. The proximal magnet is positioned in the duodenum by gastroscopy and the distal magnet in the ileum by laparoscopy. After inter-magnet tissue compression and necrosis, the united magnets are expelled naturally

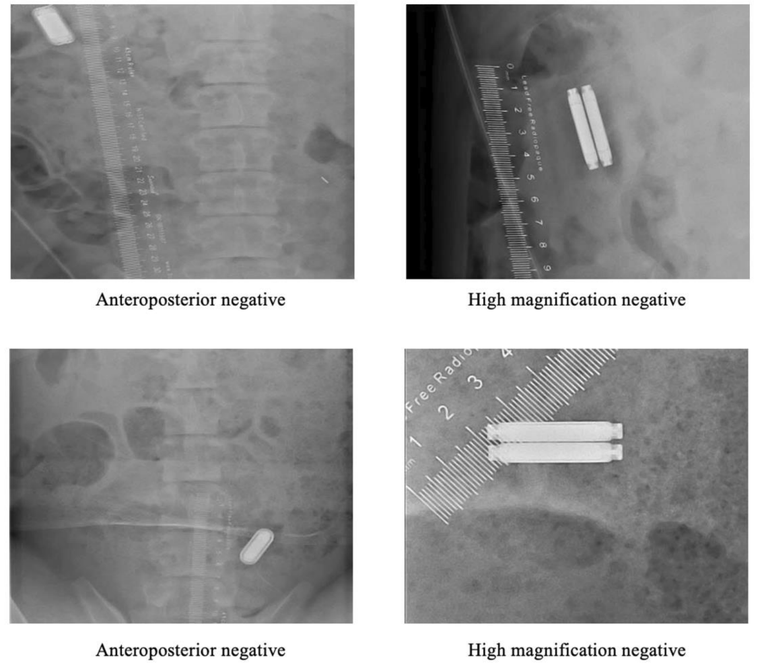


Fig. 3 Radiograph of magnetic compression anastomosis site in 4 animals, day of procedure

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

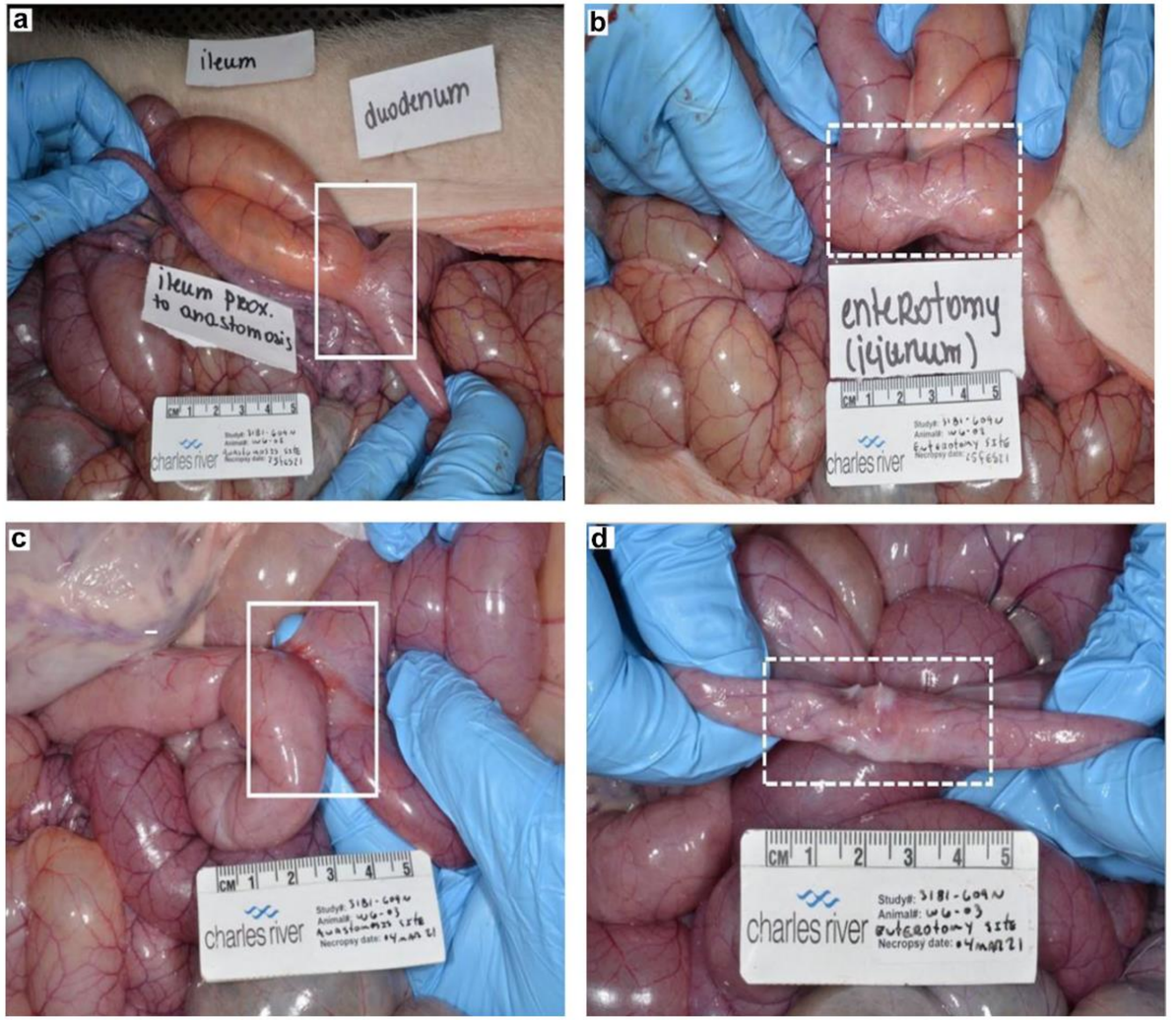
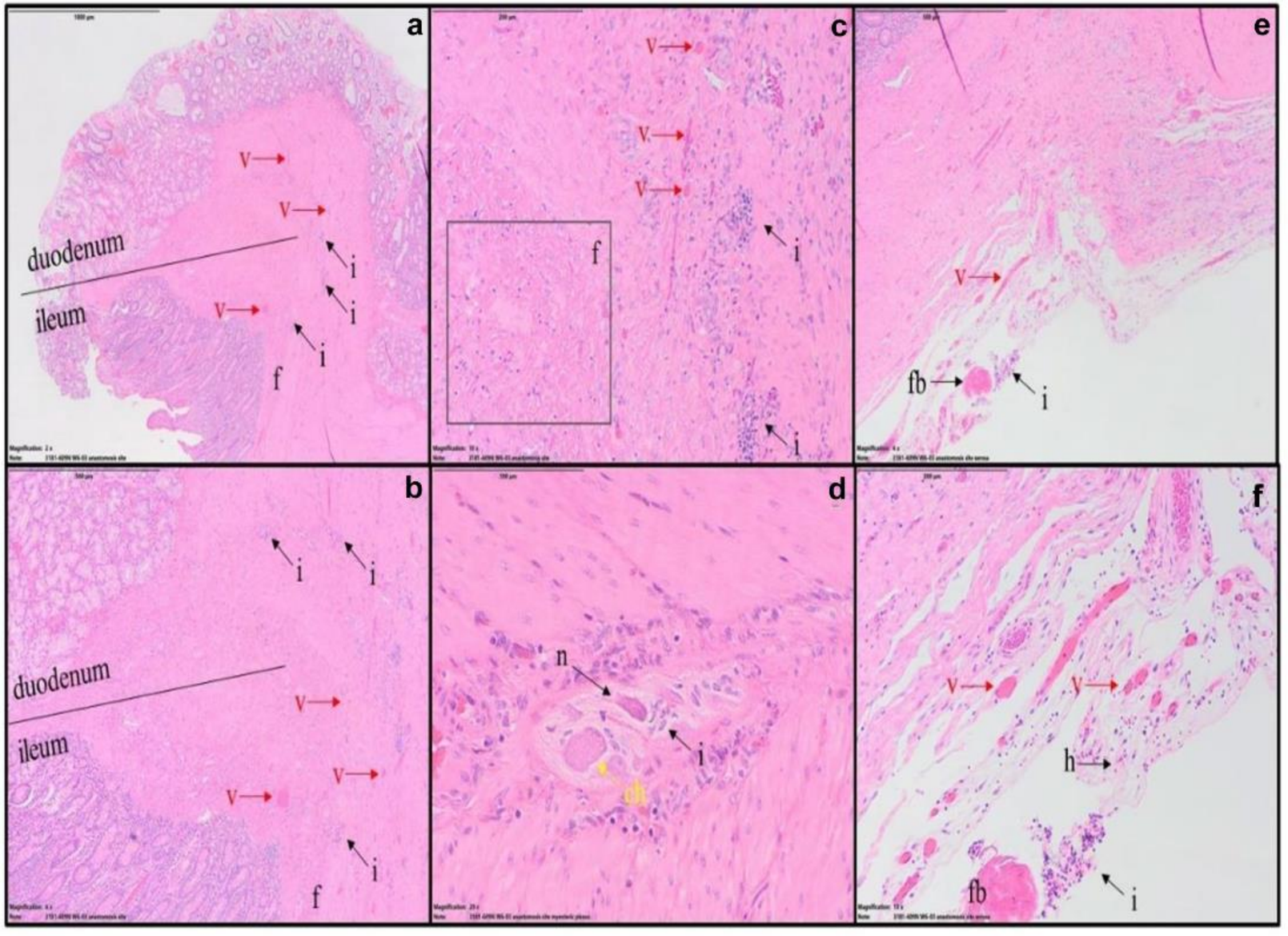


Fig. 5 Representative gross necropsy images of side-to-side duodeno-ileal (DI) magnetic compression anastomosis (MCA) and jejunal enterotomy (JE) sites. **a** Low magnification image of the serosal aspect of the side-to-side DI MCA site (white solid rectangle); **b** Low magnification image of the serosal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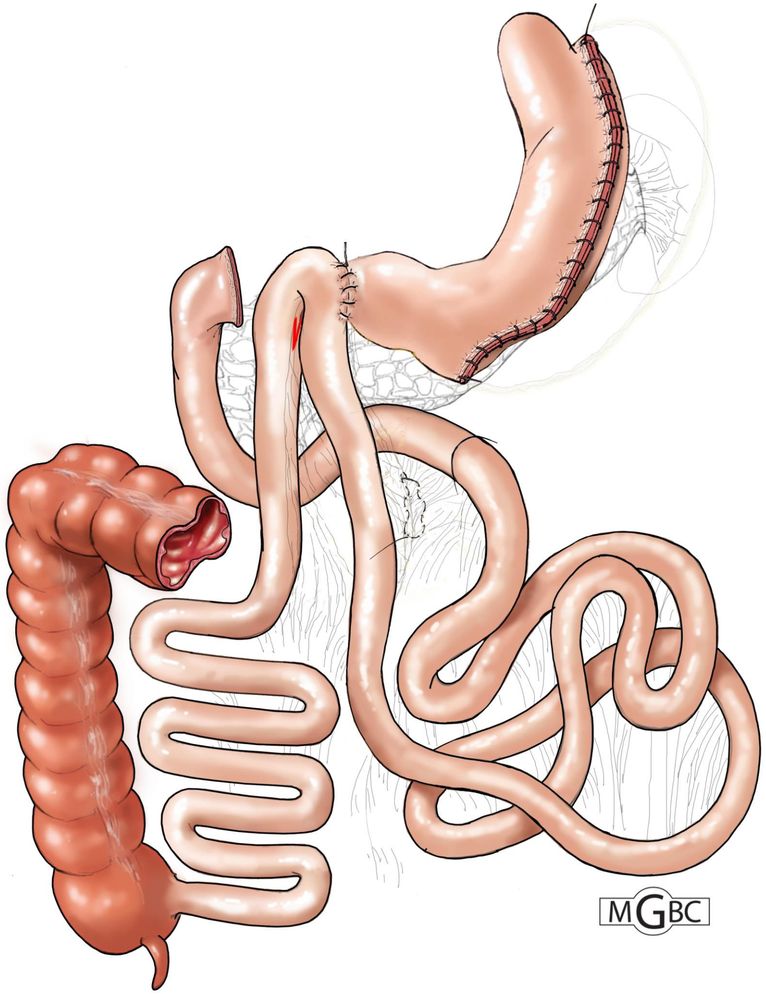
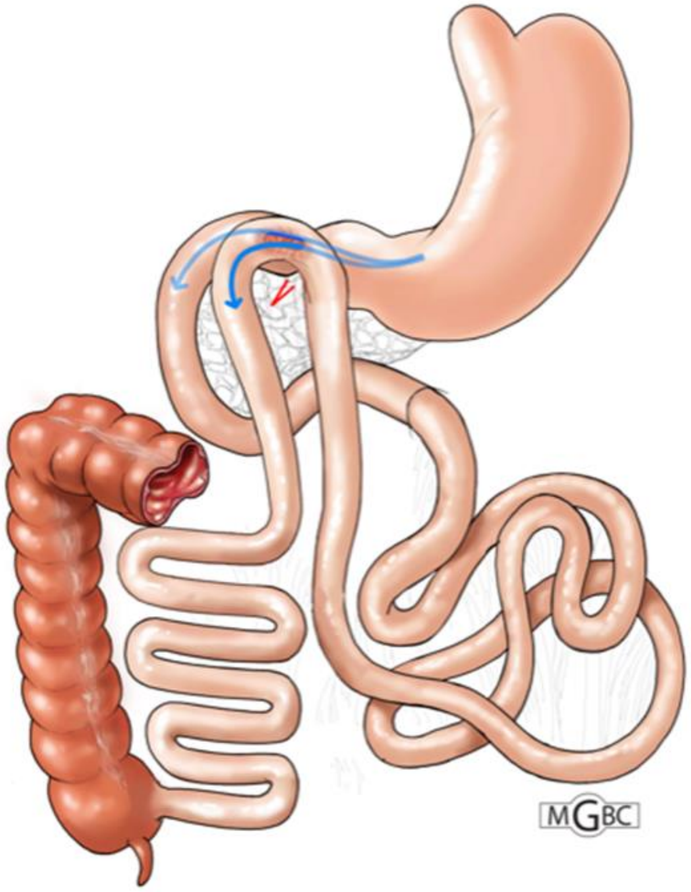
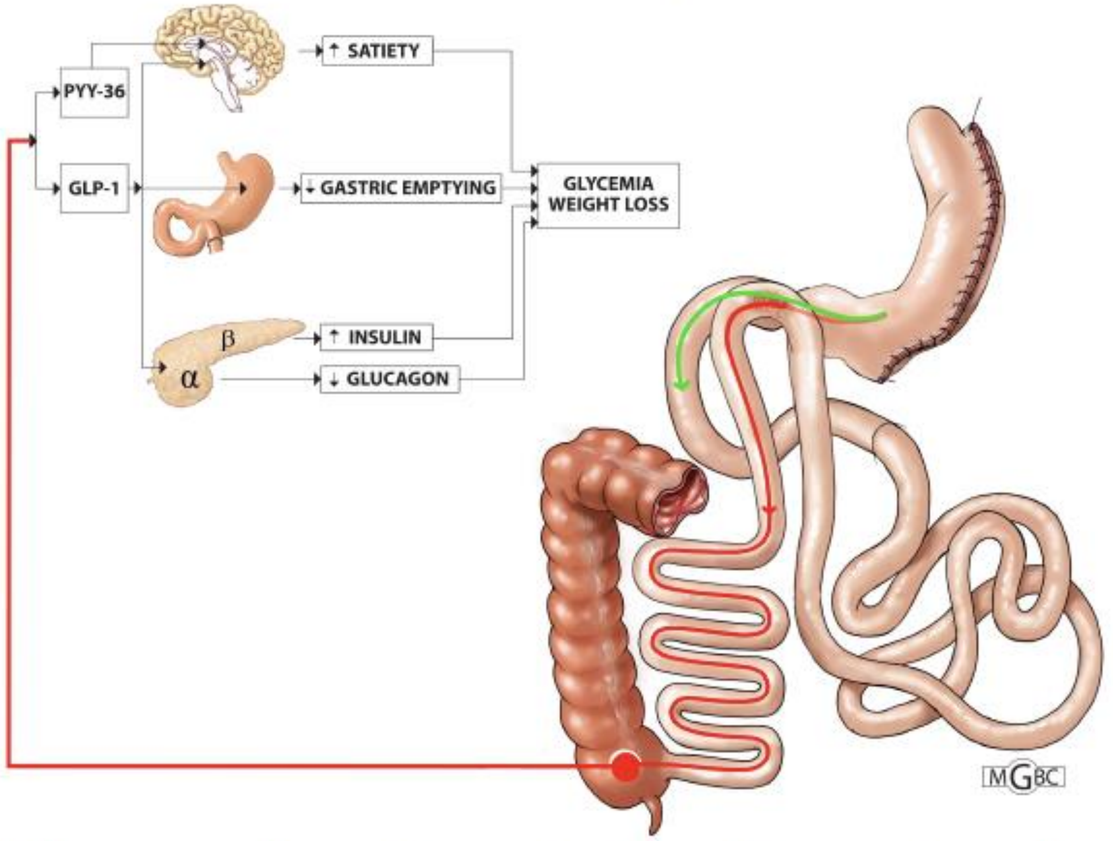
SADI vs MAGDI



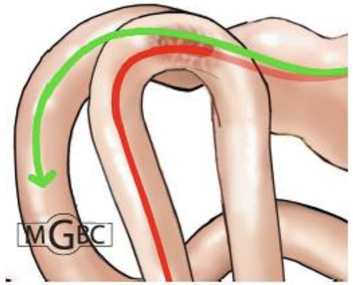


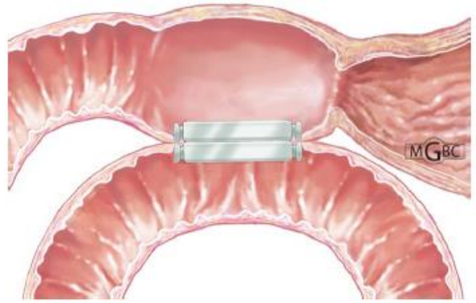
side to side duodeno ileal bipartition anastomosis

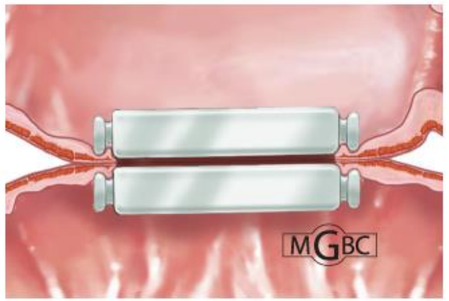


- The goal of the procedure is to maintain the neuroendocrine effects of the SADI while minimizing the deleterious effects of malabsorption.

Side to side DI bipartition
using magnetic compression anastomosis (MAGDI)







Obesity Surgery (2023) 33:2282–2292
https://doi.org/10.1007/s11695-023-06708-x

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.

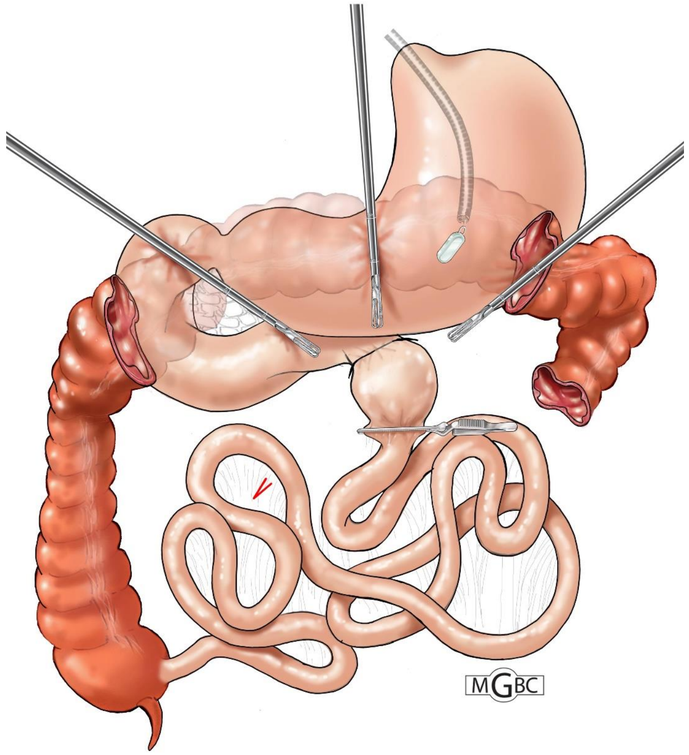
Materials and Methods Patients with severe obesity (body mass index (BMI) ≥ 35 kg/m^2 with/without T2D ($HbA1_C \geq 6.5\%$)) underwent the study procedure, a side-to-side MS DI diversion, with a standard sleeve gastrectomy (SG). A linear magnet was delivered by flexible endoscopy to a point 250 cm proximal 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.

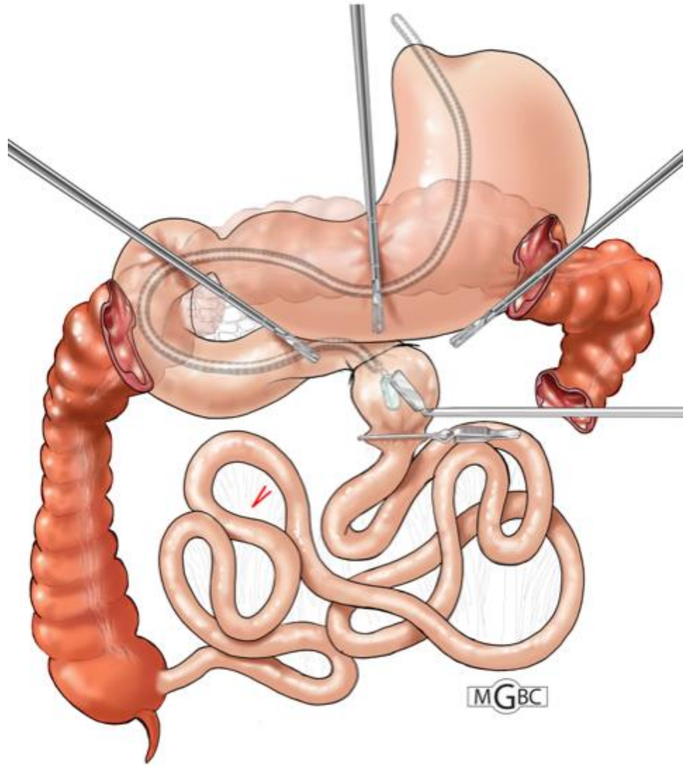
Results Between November 22 and 26, 2021, 5 female patients (mean weight 117.6 ± 7.1 kg, BMI (kg/m^2) 44.4 ± 2.2) underwent side-to-side MS DI + SG. All magnets were successfully placed, expelled without re-intervention, and formed patent durable anastomoses. Total weight loss at 12 months was 34.0 ± 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.

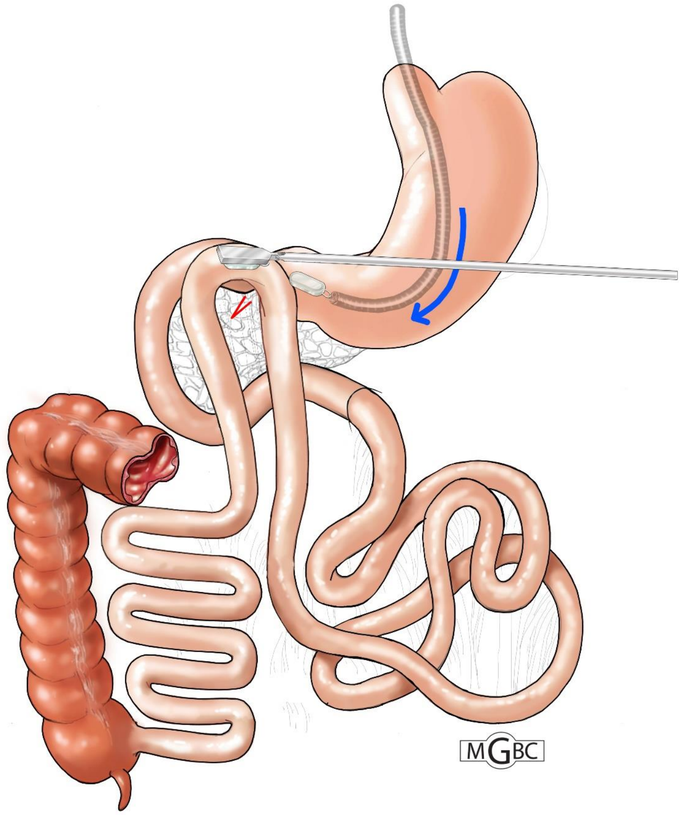
Trial Registration Clinicaltrials.gov Identifier: NCT05322122.

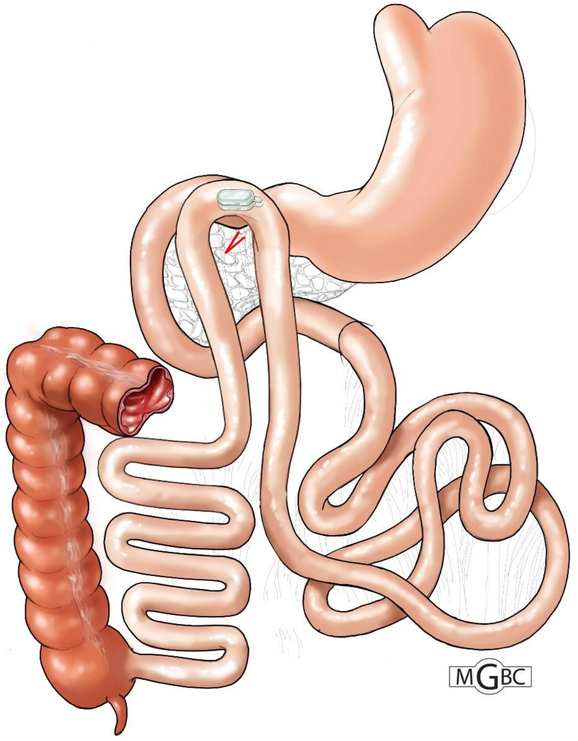
The MAGNET System
Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy





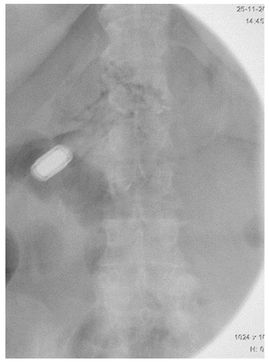
The MAGNET System
Creation of Side-to-Side Compression Anastomosis Duodeno-Ileostomy





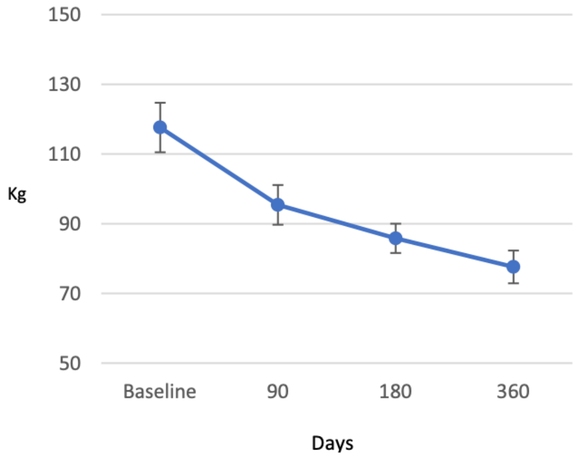
The MAGNET System - Stage 1- Primary endpoint Device Delivery Success- Safety Population





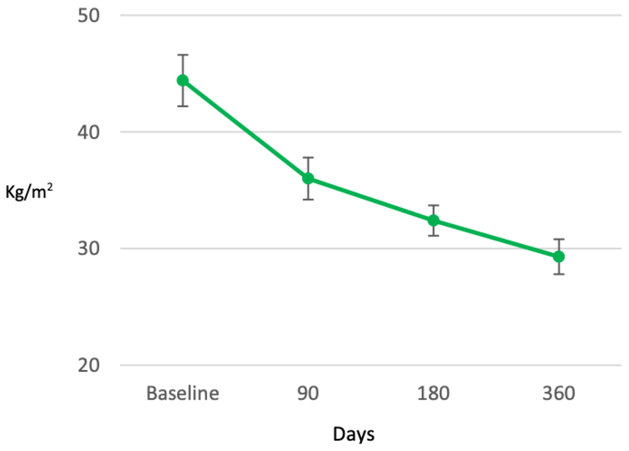
Procedure date	Duration of procedure mean in min (SD)	Placement of the magnet
22, 24, 25 and 26 November 2021	154 (24.48)	100%

(a)



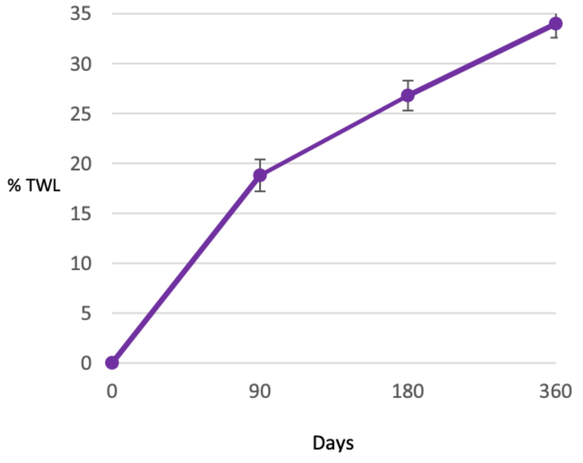
Mean±SEM			
117.6±7.1	95.4±5.7	85.8±4.2	77.6±4.7

(b)



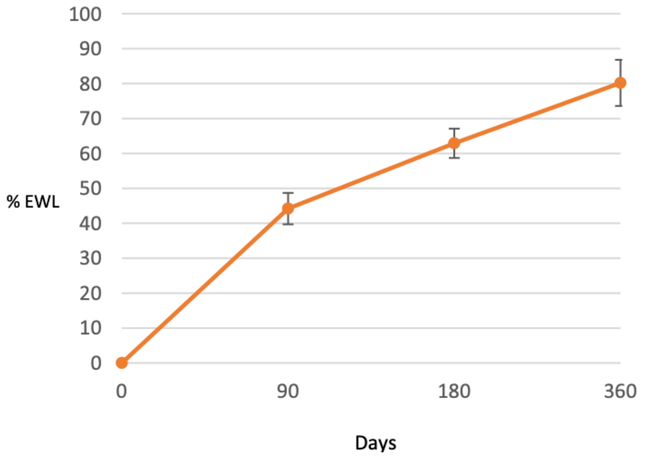
Mean±SEM			
44.4±2.2	36.0±1.8	32.4±1.3	29.3±1.5

(c)



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

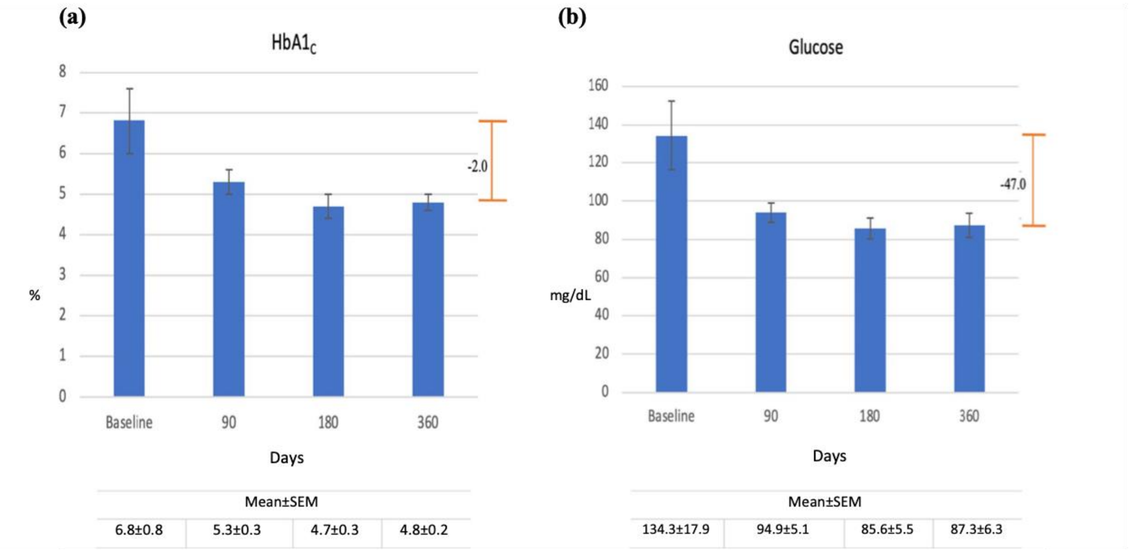
(d)



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)



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2023 SAGES ORAL

Side-to-side magnet anastomosis system duodeno-ileostomy with sleeve gastrectomy: early multi-center results

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Abstract

Introduction Gastrointestinal anastomoses with classical sutures and/or metal staples have resulted in significant bleeding and leak rates. This multi-site study evaluated the feasibility, safety, and preliminary effectiveness of a novel linear magnetic compression anastomosis device, the Magnet System (MS), to form a side-to-side duodeno-ileostomy (DI) diversion for weight loss and type 2 diabetes (T2D) resolution.

Methods In patients with class II and III obesity (body mass index [BMI, kg/m^2] ≥ 35.0–≤ 50.0 with/without T2D [HbA1C > 6.5%]), two linear MS magnets were delivered endoscopically to the duodenum and ileum with laparoscopic assistance and aligned, initiating DI; sleeve gastrectomy (SG) was added. There were no bowel incisions or retained sutures/staples. Fused magnets were expelled naturally. Adverse events (AEs) were graded by Clavien-Dindo Classification (CDC).

Results Between November 22, 2021 and July 18, 2022, 24 patients (83.3% female, mean ± SEM weight 121.9 ± 3.3 kg, BMI 44.4 ± 0.8) in three centers underwent magnetic DI. Magnets were expelled at a median 48.5 days. Respective mean BMI, total weight loss, and excess weight loss at 6 months (n = 24): 32.0 ± 0.8, 28.1 ± 1.0%, and 66.2 ± 3.4%; at 12 months (n = 5), 29.3 ± 1.5, 34.0 ± 1.4%, and 80.2 ± 6.6%. Group mean respective mean $HbA1_C$ and glucose levels dropped to 1.1 ± 0.4% and 24.8 ± 6.6 mg/dL (6 months); 2.0 ± 1.1% and 53.8 ± 6.3 mg/dL (12 months). There were 0 device-related AEs, 3 procedure-related serious AEs. No anastomotic bleeding, leakage, stricture, or mortality.

Conclusion In a multi-center study, side-to-side Magnet System duodeno-ileostomy with SG in adults with class III obesity appeared feasible, safe, and effective for weight loss and T2D resolution in the short term.

ELSEVIER

Surgery for Obesity and Related Diseases 20 (2024) 341–353

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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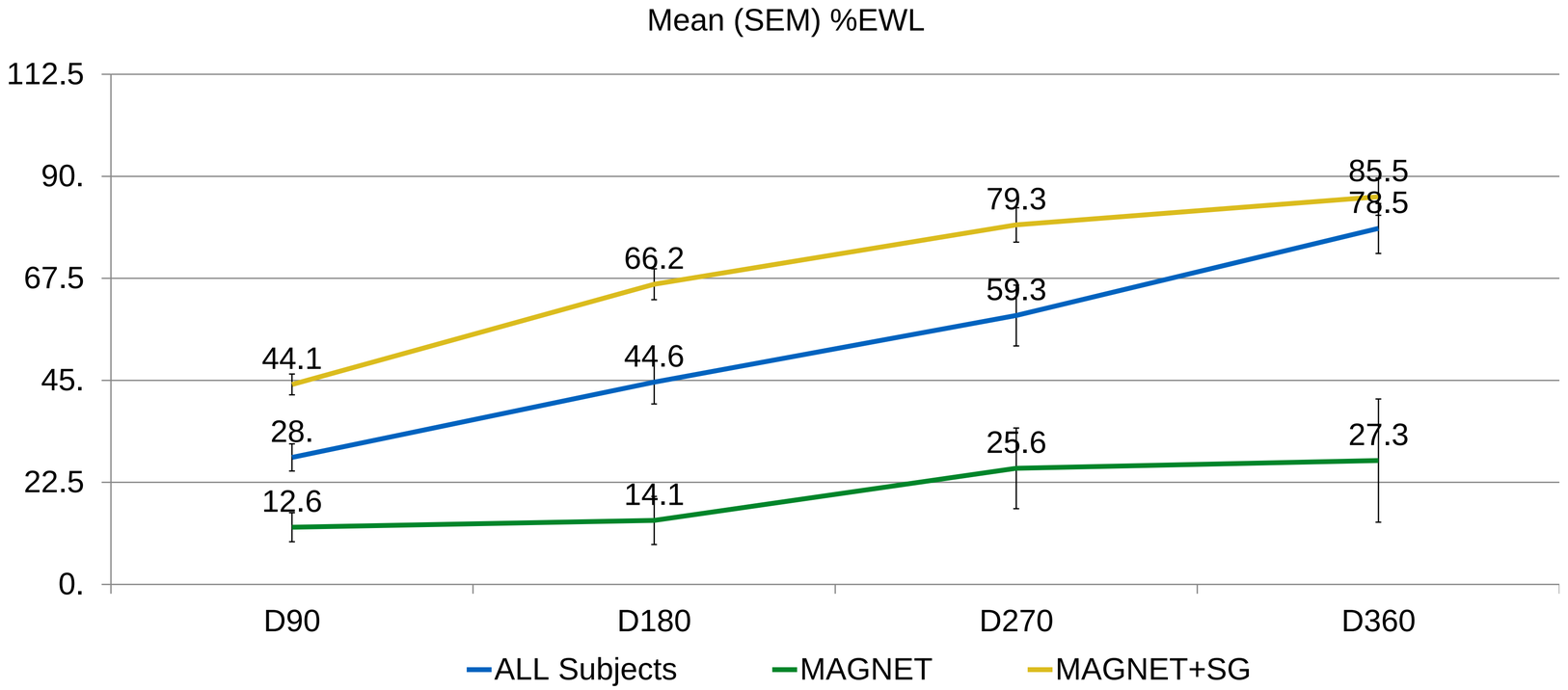
Percent Excess Weight Loss (%EWL) over one year



Obesity Surgery (2024) 34:3569–3575
https://doi.org/10.1007/s11695-024-07432-w

NEW CONCEPT

Spanish Experience with Latero-Lateral Duodeno-Ileostomy + Sleeve Gastrectomy with Magnet Anastomosis System

Jana Dziakova[1,2,3] · Antonio Torres[1,2,3] · Maja Odovic[1] · José Miguel Esteban[4] · Manuel Vázquez-Romero[4] · Andrea Castillo[1] · Andrés Sánchez-Pernaute[1,2,3] · Michel Gagner[5,6]

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Abstract

Background The partial diversion of intestinal contents facilitates achieving and maintaining weight loss and improving glycemic control in patients with obesity and with or without T2DM. The purpose of this study is to report our experience and 1-year follow-up with novel modification of SADI-S.

World Journal of Surgery

ORIGINAL SCIENTIFIC REPORT

Magnetic single-anastomosis side-to-side duodeno-ileostomy for revision of sleeve gastrectomy in adults with severe obesity: 1-year outcomes

Michel Gagner ✉, Lamees Almutlaq, Gismonde Gnanhoue, J. N. Buchwald

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https://doi.org/10.1002/wjs.12304

The study was presented in part at the American College of Surgeons Annual Clinical Congress in the Scientific Forum, October 2023.

Journal of Gastrointestinal Surgery 28 (2024) 640–650

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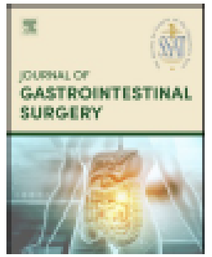

Original Article

Sleeve gastrectomy with duodenoileal bipartition using linear magnets: feasibility and safety at 1-year follow-up

Guy-Bernard Cadière [a], Mathilde Poras [a,*], Marie-Thérèse Maréchal [a], Luca Pau [a], Raoul Muteganya [a], Marc van Gossum [a], Benjamin Cadière [a], Nathalie Van Sante [b], Michel Gagner [c]

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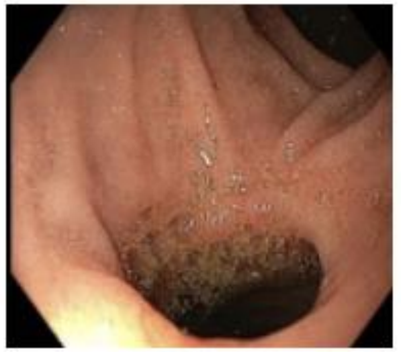
Gastroscopy

Patient 1

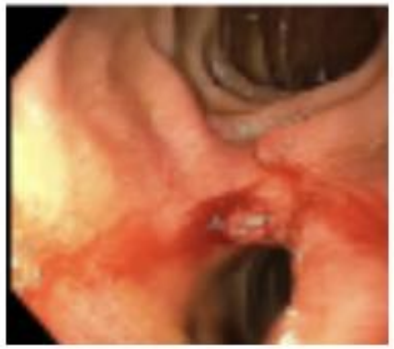
Patient 2

Patient 3



Patient 4

Patient 5



Patient 6

Patient 7

Patient 8

Patient 9

Patient 10

Gastroscopy

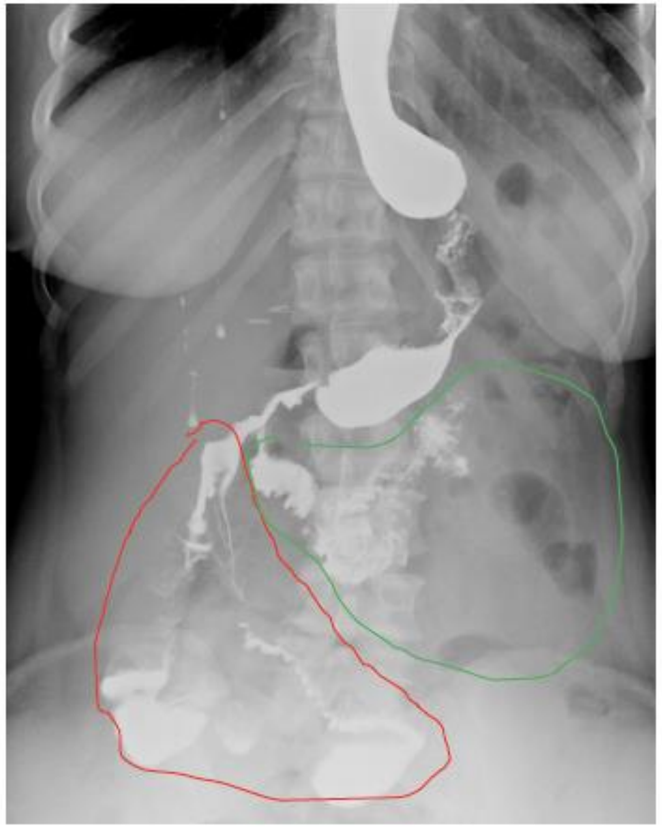
4 Months

1 Year

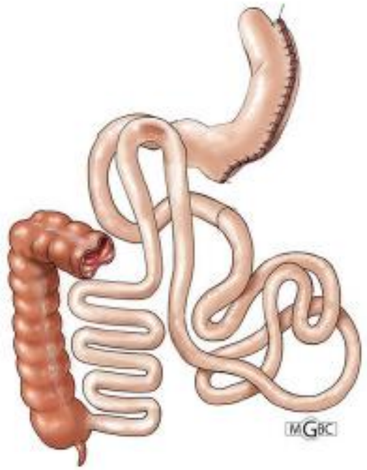
2 Years

5/10 patients
5/5 allow introduction of gastroscope 9.5

Barium swallow



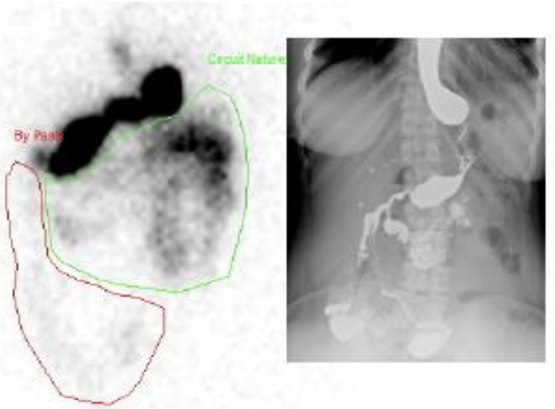
Ileal loop

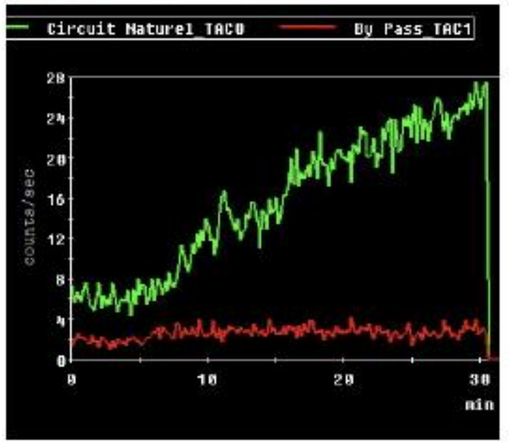


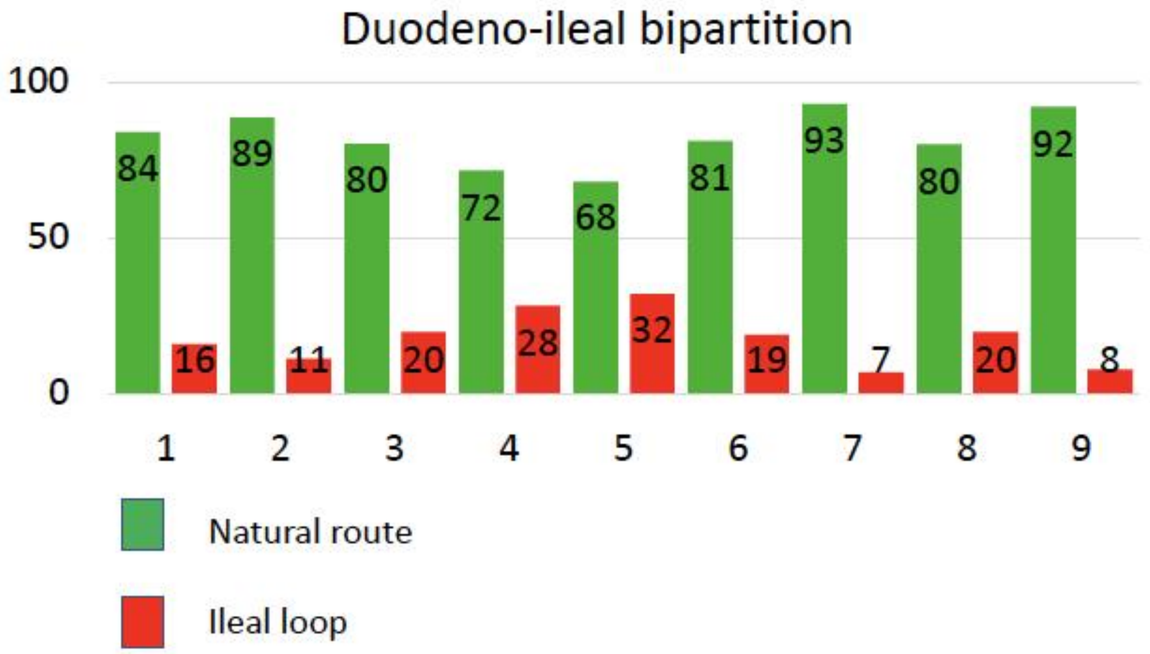
Natural pathway

isotopic study

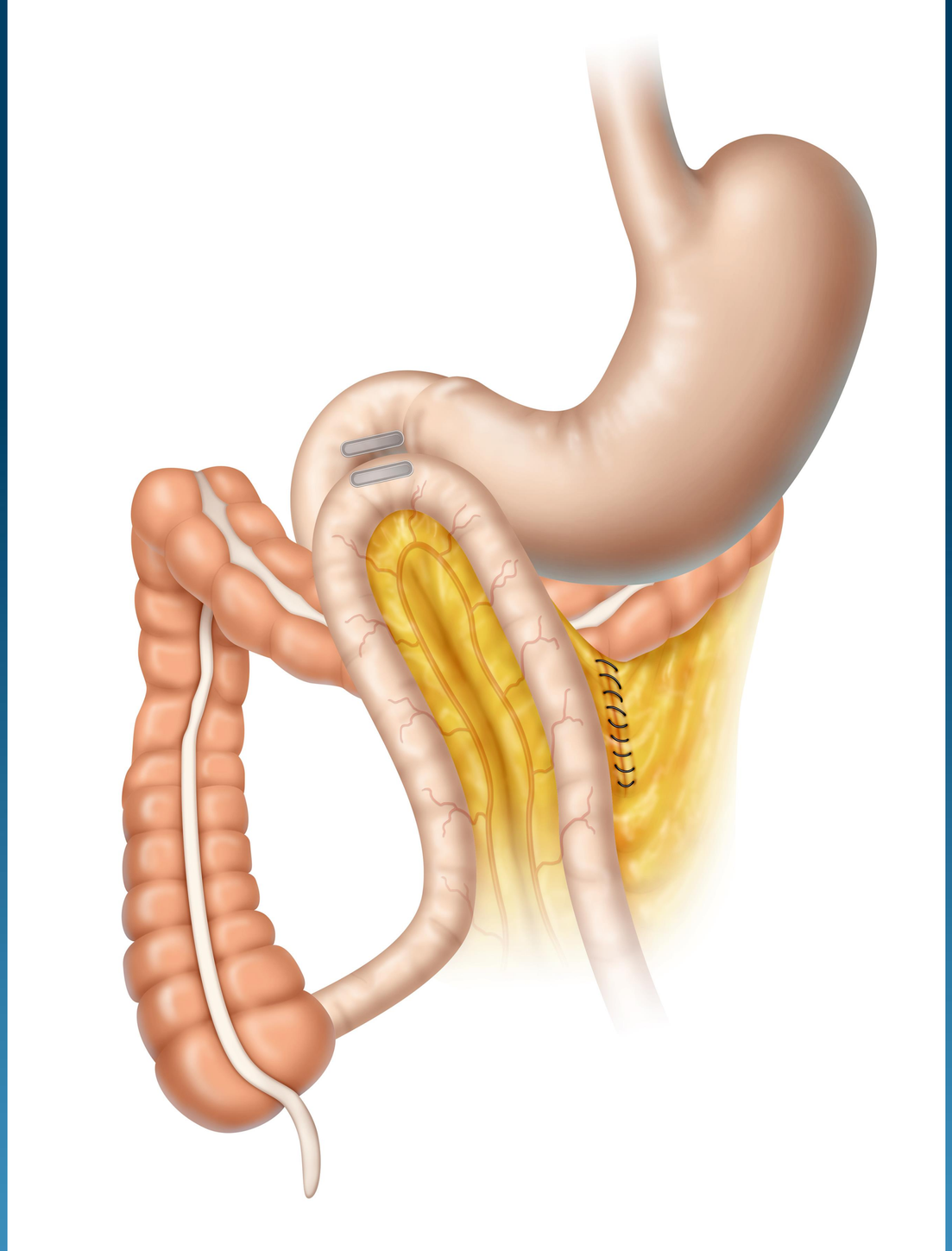
- 9/10
- Median 19 % of radioactive activity (marked yoghurt) in the ileal loop







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%)

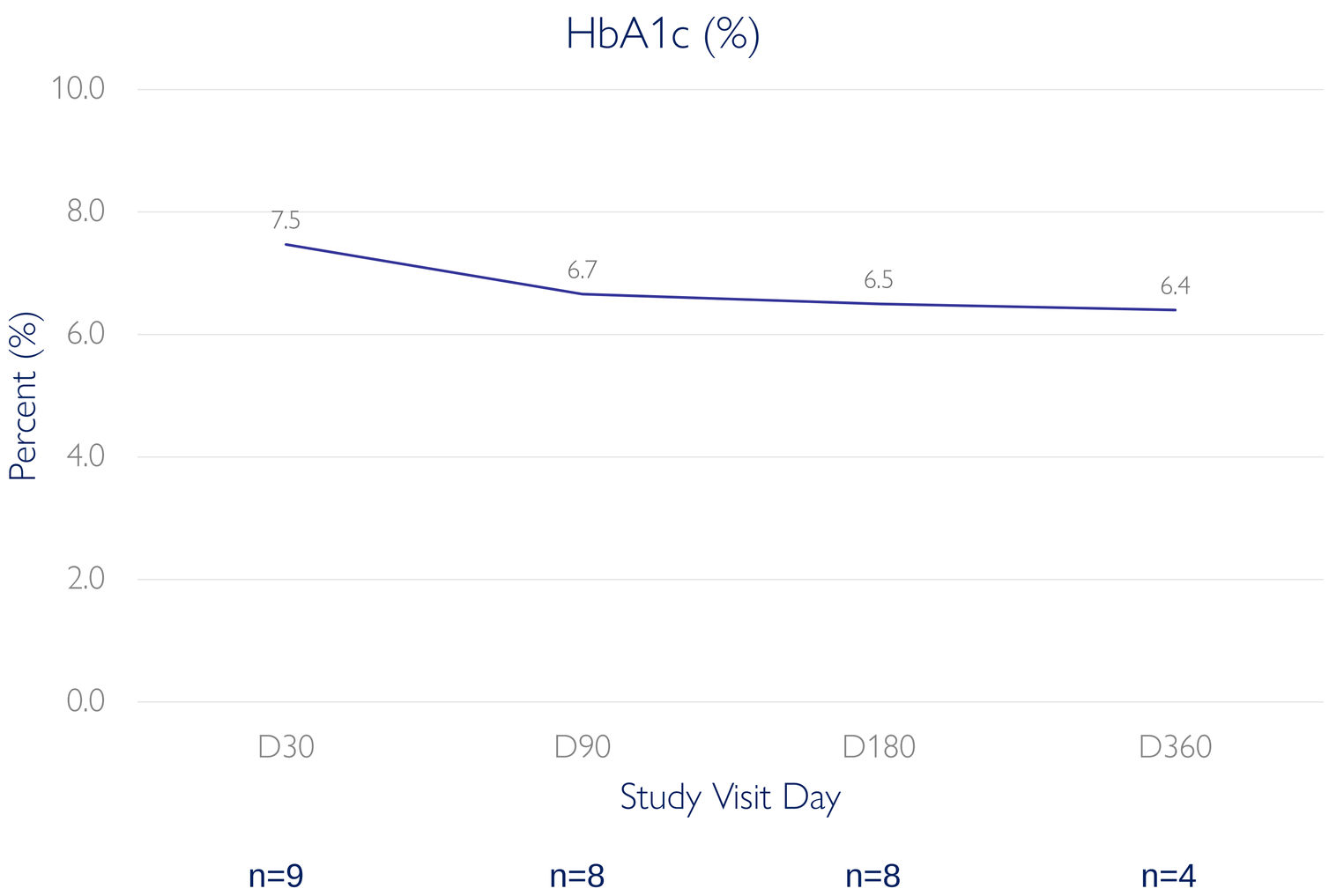
*n=23

- 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.


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

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.

- 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%.