Magnetic Surgery is the next revolution in Bariatric Surgery

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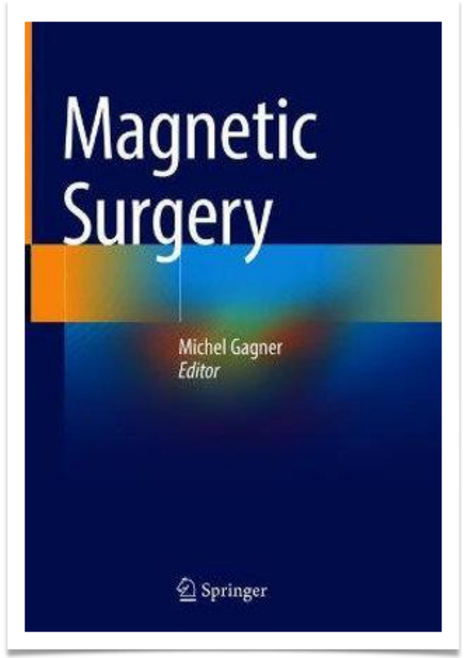
Financial Disclosures

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



Magnes Lapis
Magnettes

Magnets

Mathieu Jaboulay (1860-1913) and His Innovations in Vascular and General Surgery

Surgical Innovation
2020, Vol. 27(1) 120–123

DOI: 10.1177/1553350619875926
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Konstantinos Laios, MD, PhD[1], Vangelis Bontinis, MD[2], Alkis Bontinis, MD[2], Evangelos Mavrommatis, MD[1], Pavlos Lytsikas-Sarlis, MD[2], Gregory Tsoucalas, MD, PhD[3], and George Androutsos, MD, PhD[4]

Figure 1. Mathieu Jaboulay (1860-1913).

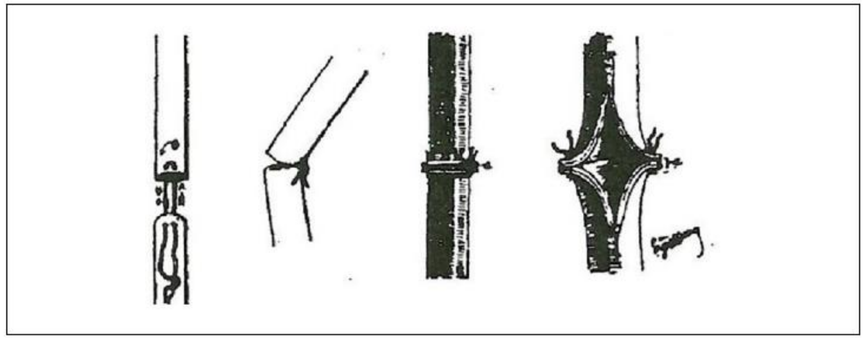


Figure 2. Jaboulay method.

Jaboulay M, Briau E. Recherches expérimentales sur la suture et la greffe artérielle. *Lyon Méd*. 1896;81:97-99.

Auguste and Louis Lumière

Travailleurs de l'usine des freres Lumiere a Lyon

245.032

BUREAU DES BREVETS D'INVENTION
FRANÇAIS & ÉTRANGERS
Créé en 1820

LÉPINETTE & RABILLOUD
INGÉNIEURS
LYON — 66, Avenue de Saxe (Cours Morand) — LYON

Brevet d'Invention de 15 ans

pour: "Appareil servant à l'obtention et à la vision des épreuves chrono-photographiques"

Demande formée par :

MM. Auguste Lumière
et Louis Lumière

MÉMOIRE DESCRIPTIF

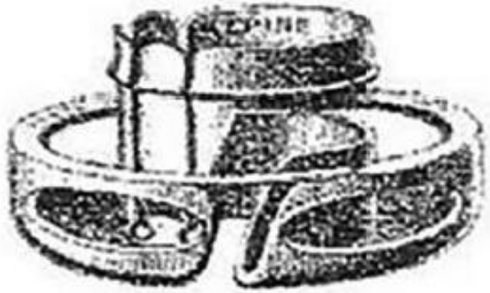
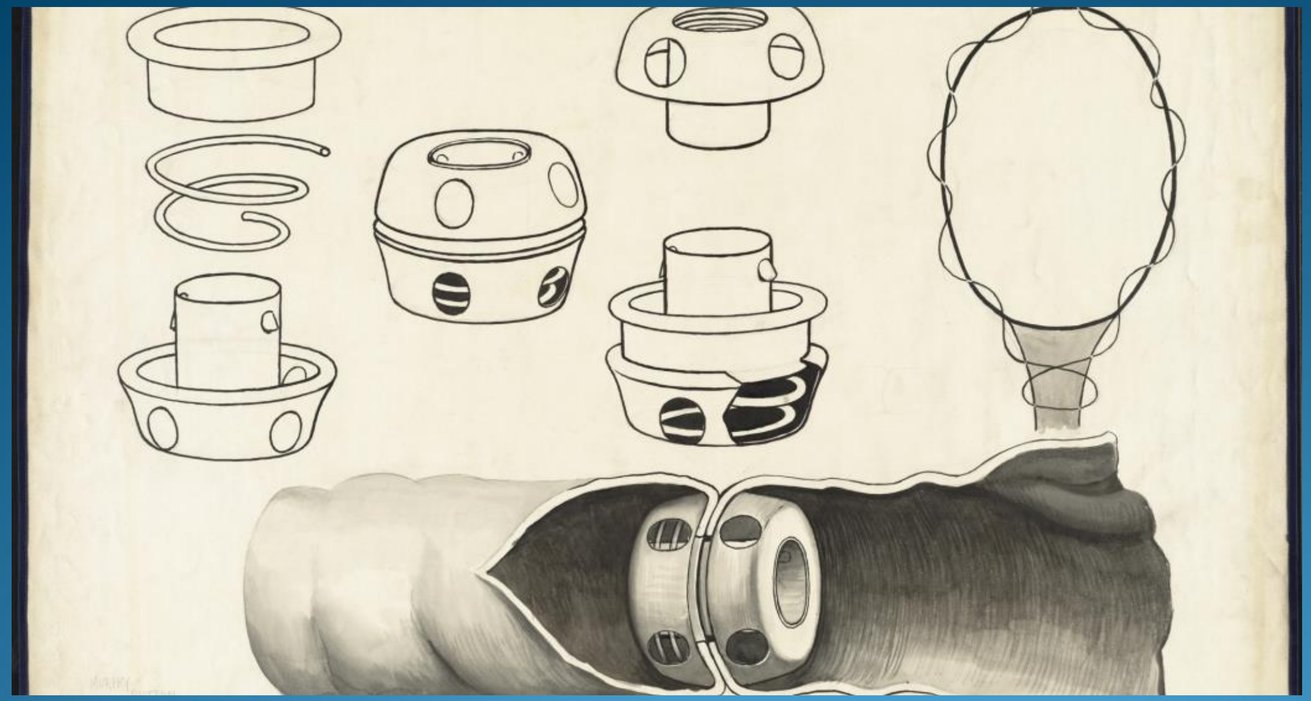


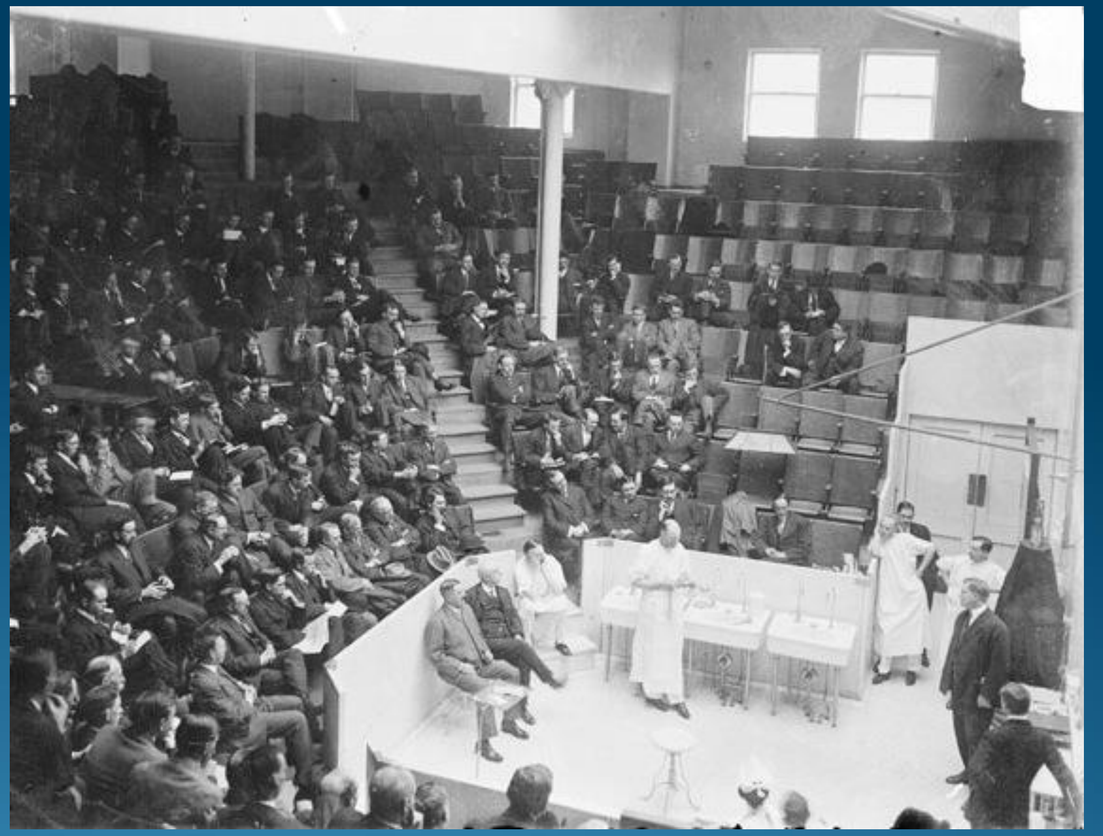
Figure 3. Jaboulay button.

Compression Anastomoses
Murphy Button, 1892

Murphy Button

The Murphy button, introduced by Dr. Murphy in 1892, was a major breakthrough in intestinal surgery. It allowed operations to be performed quickly and efficiently, reducing the risk of patient shock. The cap of each mushroom-shaped half was stitched to an intestinal opening and the stems were joined. As the sections of intestine healed together, the area directly attached to the metal button decayed, releasing it to be passed.

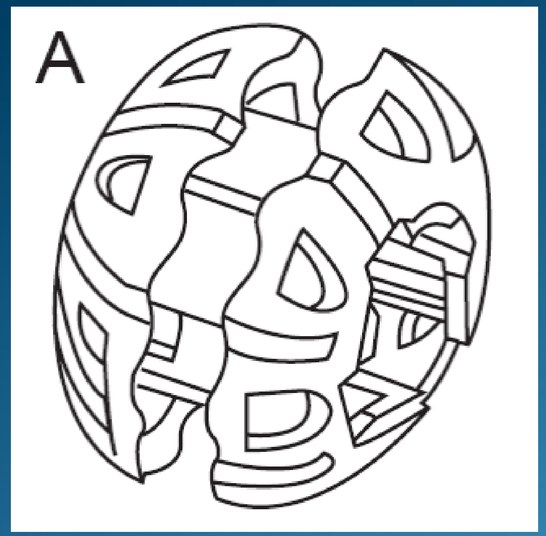


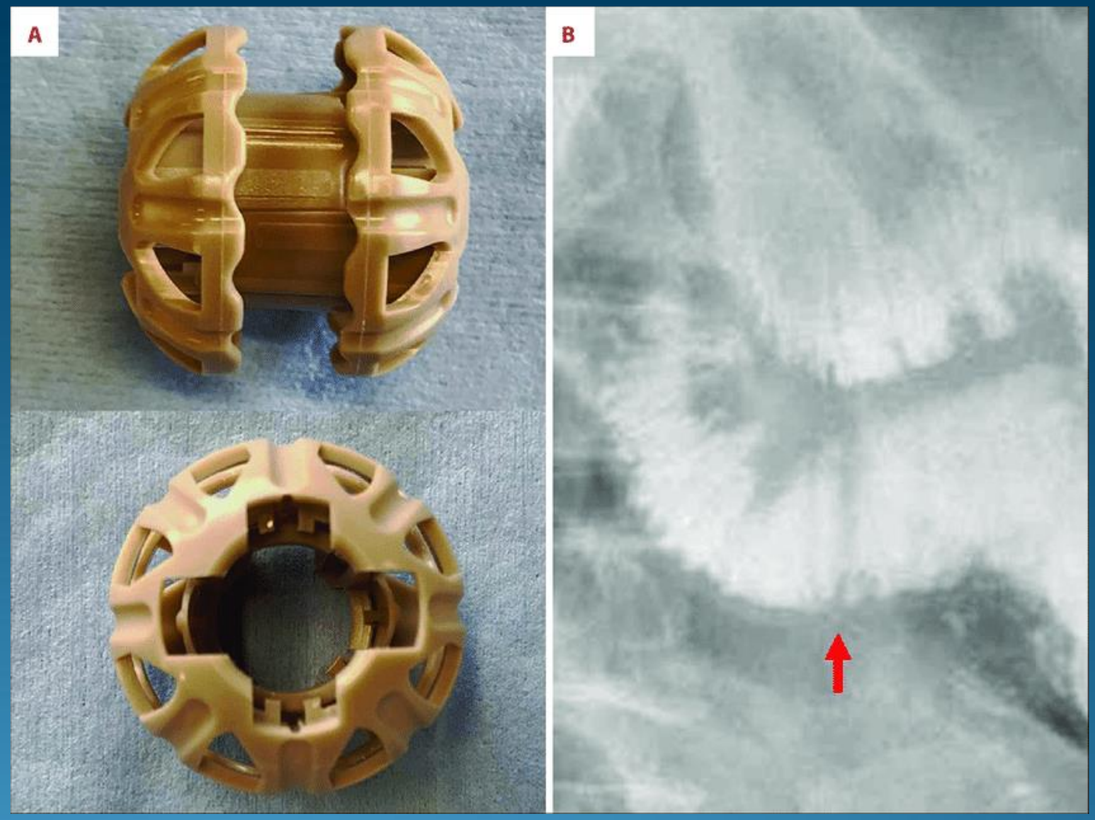


Murphy JB. Cholecysto-intestinal, gastro-intestinal, entero-intestinal anastomosis, and approximation without sutures. Med Rec (NY) 1892; 42: 665-676.

Valtrac 1984

BAR (Biofragmentable Anastomotic Ring) Valtrac® system





Obesity Surgery, 8, 267–282

Biliopancreatic Diversion with a Duodenal Switch

Douglas S. Hess MD, FACS; Douglas W. Hess MD

Wood County Hospital, Bowling Green, OH, USA

Background: This paper evaluates biliopancreatic diversion combined with the duodenal switch, forming a hybrid procedure which is a combination of restriction and malabsorption.

Methods: The evaluation is of the first 440 patients undergoing this procedure who had had no previous bariatric surgery. The mean starting weight was 183 kg, with 41% of our patients considered super morbidly obese (BMI > 50).

Results: There was an average maximum weight loss of 80% excess weight by 24 months post-

BPD without some of the associated problems. This operation is now used by us for all our bariatric patients, both in primary surgical procedures and reoperations.

The difficulty of establishing an operation that has both long- and short-term success is well known. Bariatric surgery is either restrictive or malabsorptive in nature, each with its own advantages, disadvantages and complications. While

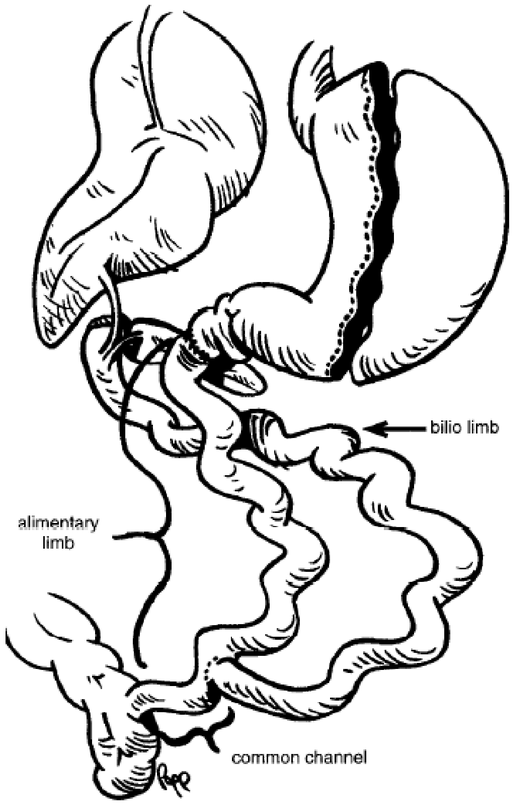


Figure 2. Biliopancreatic diversion with duodenal switch procedure.

<u>This is a secret</u>: Double small bowel compression anastomoses have been performed with the most difficult bariatric intervention

In thousands of cases with little anastomotic morbidity since the ‘80s

and is anastomosed to this duodenum with a Valtrac anastomosing ring end-to-end using a 1.5 mm gap and a 25 mm diameter Valtrac. The mesentery is sutured to the posterior peritoneal wall to prevent internal hernias. The proximal ileum is taken distally to the previously marked area on the distal ileum and an end-to-side anastomosis is performed with a Valtrac anastomosing ring (1.5 mm gap and 25 mm diameter) and the mesentery is closed with a running suture.

DAT: Delayed Anastomosis Technology

Slow compression, avoiding leaks and bleeding

Gagner *Ann Surg Innov Res (2015) 9:6*
DOI 10.1186/s13022-015-0015-0

ASIR
ANNALS OF SURGICAL
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

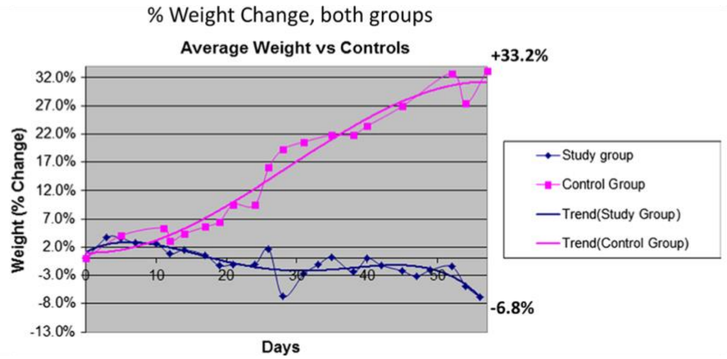


Fig. 6 Graph of % of weight change in animals that had a side-to-side duodeno-ileal anastomosis (study group) versus sham controls, over time in days. At 56 days, control animals had gained 33.2 % of weight, while study animals had lost 6.8 % of weight

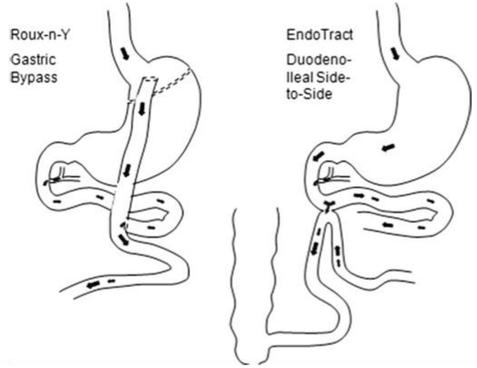


Fig. 4 Comparison of digestive flow between a gastric bypass and a side-to-side duodeno-ileal anastomosis. Alimentary flow and bili-opancreatic secretions are mixing in a Y channel (100–150 cm in mid jejunum) in a gastric bypass, while in a side-to-side duodeno-ileal anastomosis, the alimentary flow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

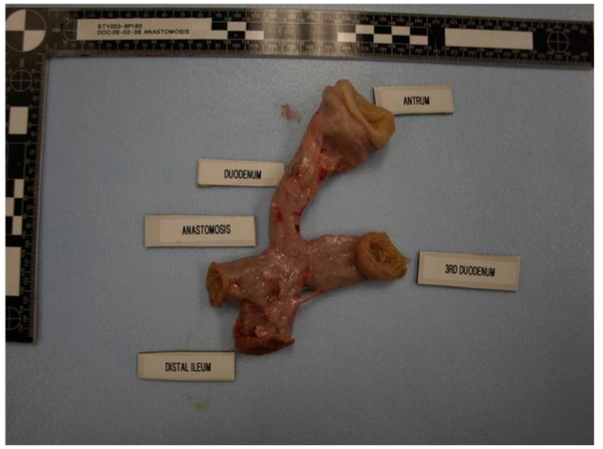


Fig. 7 Macroscopic external view of a side-to-side duodeno-ileal anastomosis at 56 days

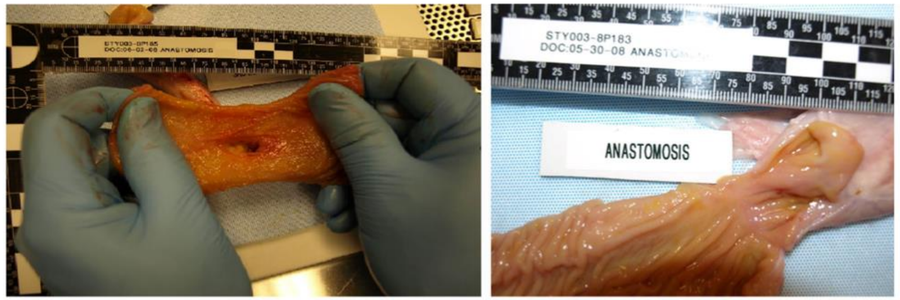


Fig. 8 **a** Macroscopic luminal view (from the ileum side) of a side-to-side duodeno-ileal anastomosis at 56 days. **b** Macroscopic luminal view of a longitudinal opening of a side-to-side duodeno-ileal anastomosis at 56 days

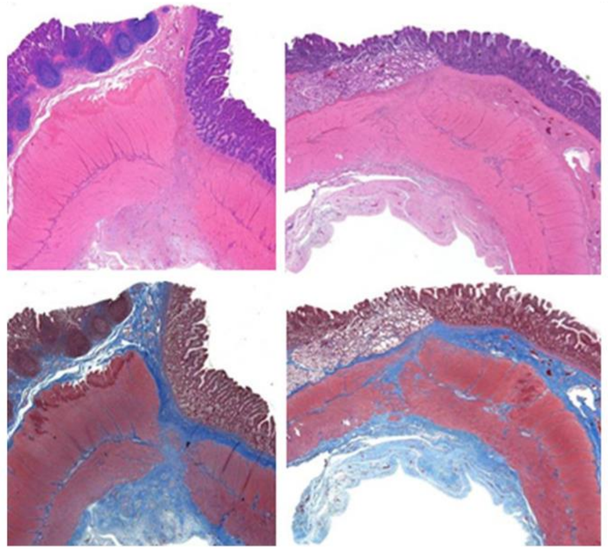


Fig. 10 **a**–**d** Longitudinal sections through the well healed duodenal-ileal anastomotic site. It appears that all layers of the intestine are apposed (muscular layers not closely apposed) although only a small portion of the ileal mucosa is present in the first second (**a**, **b**) and the mucosa 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

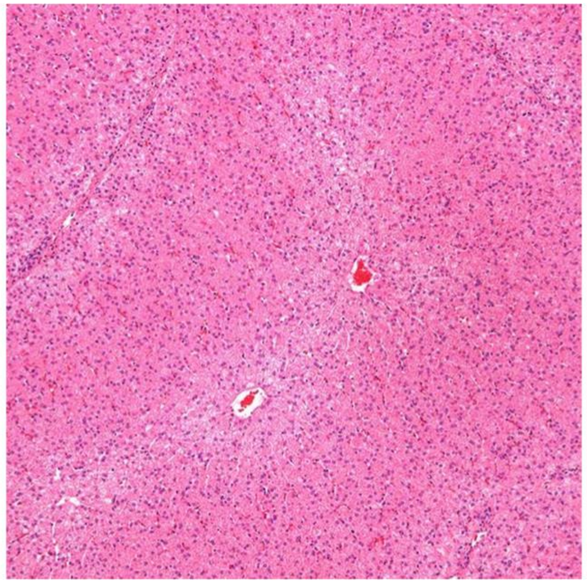
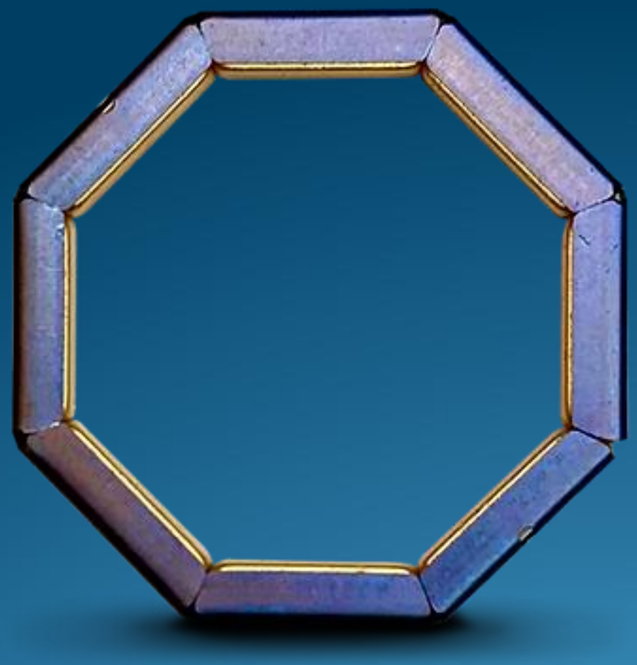


Fig. 11 Liver histology at 56 days. Subtle centrilobular hepatocellular swelling and granularity (consistent with glycogen deposition) is noted in this animal. H & E stain, ×100 magnification

Linear



Octogonal

Circular

Obesity Surgery (2022) 32:932–933
https://doi.org/10.1007/s11695-021-05771-6

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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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

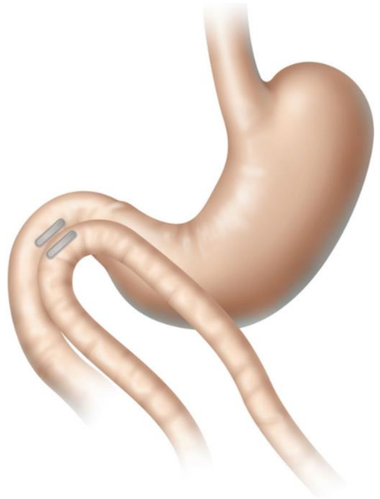


Fig. 1 Duodeno-ileal compression anastomosis by pairing of two linear magnets. The proximal magnet is positioned in the duodenum by gastroscopy and the distal magnet in the ileum by laparoscopy. After inter-magnet tissue compression and necrosis, the united magnets are expelled naturally

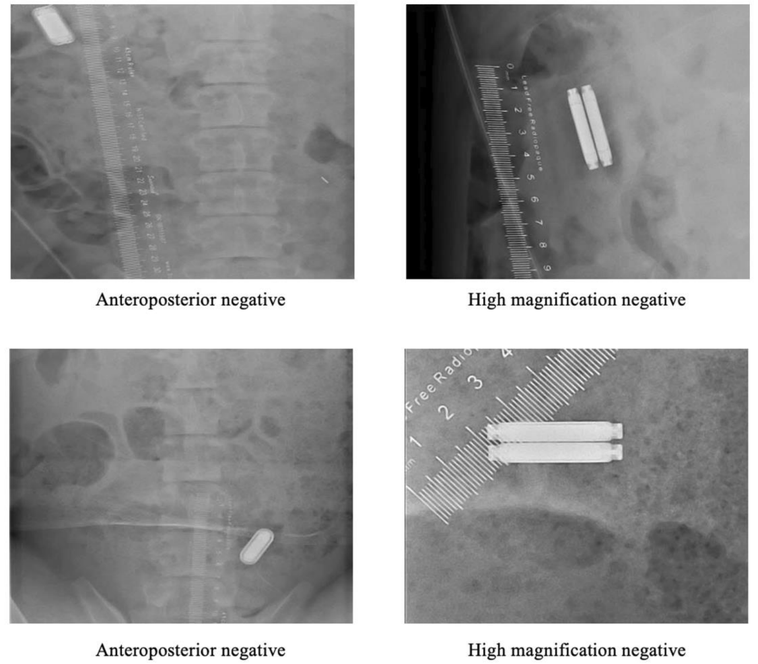


Fig. 3 Radiograph of magnetic compression anastomosis site in 4 animals, day of procedure

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

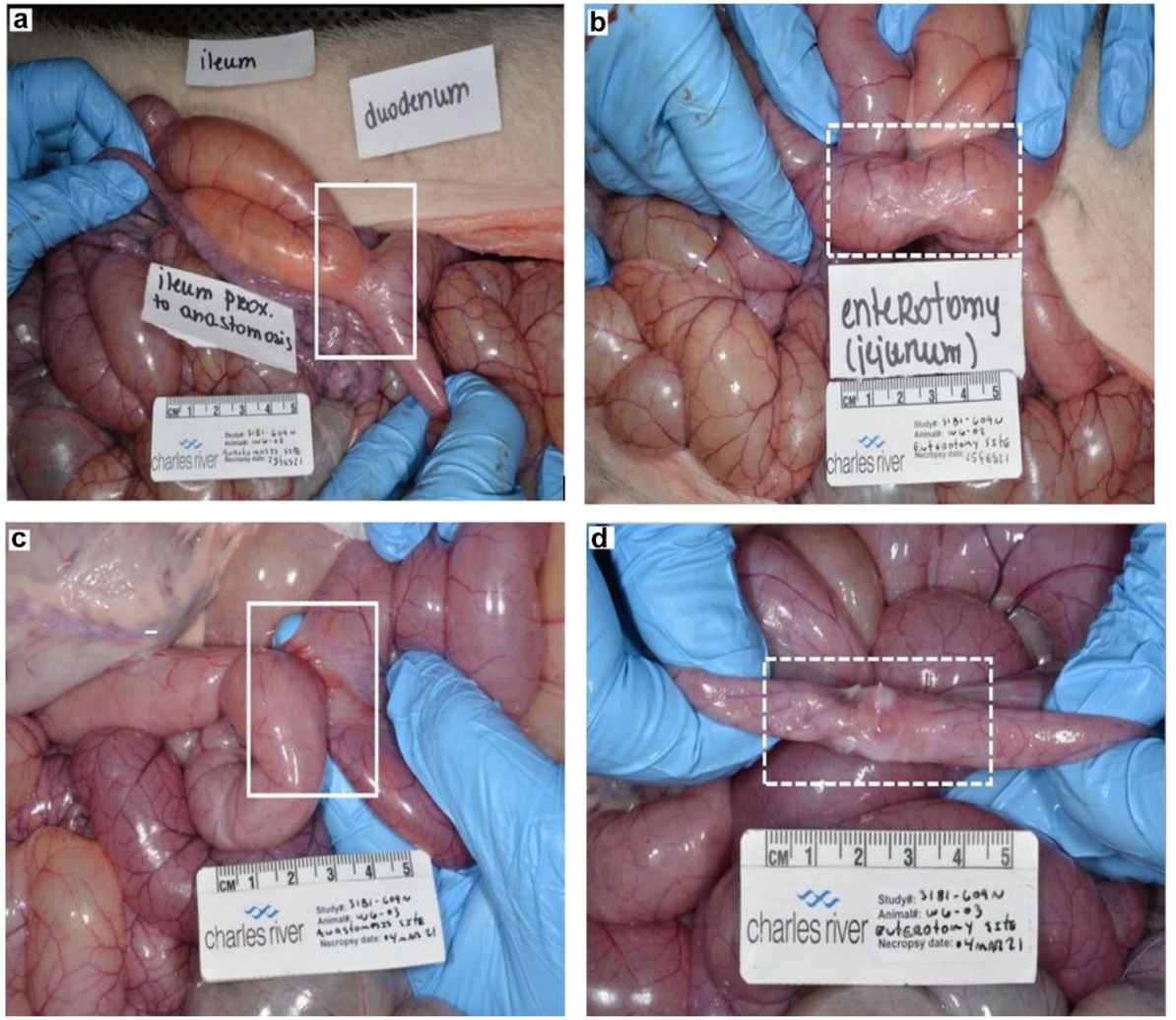
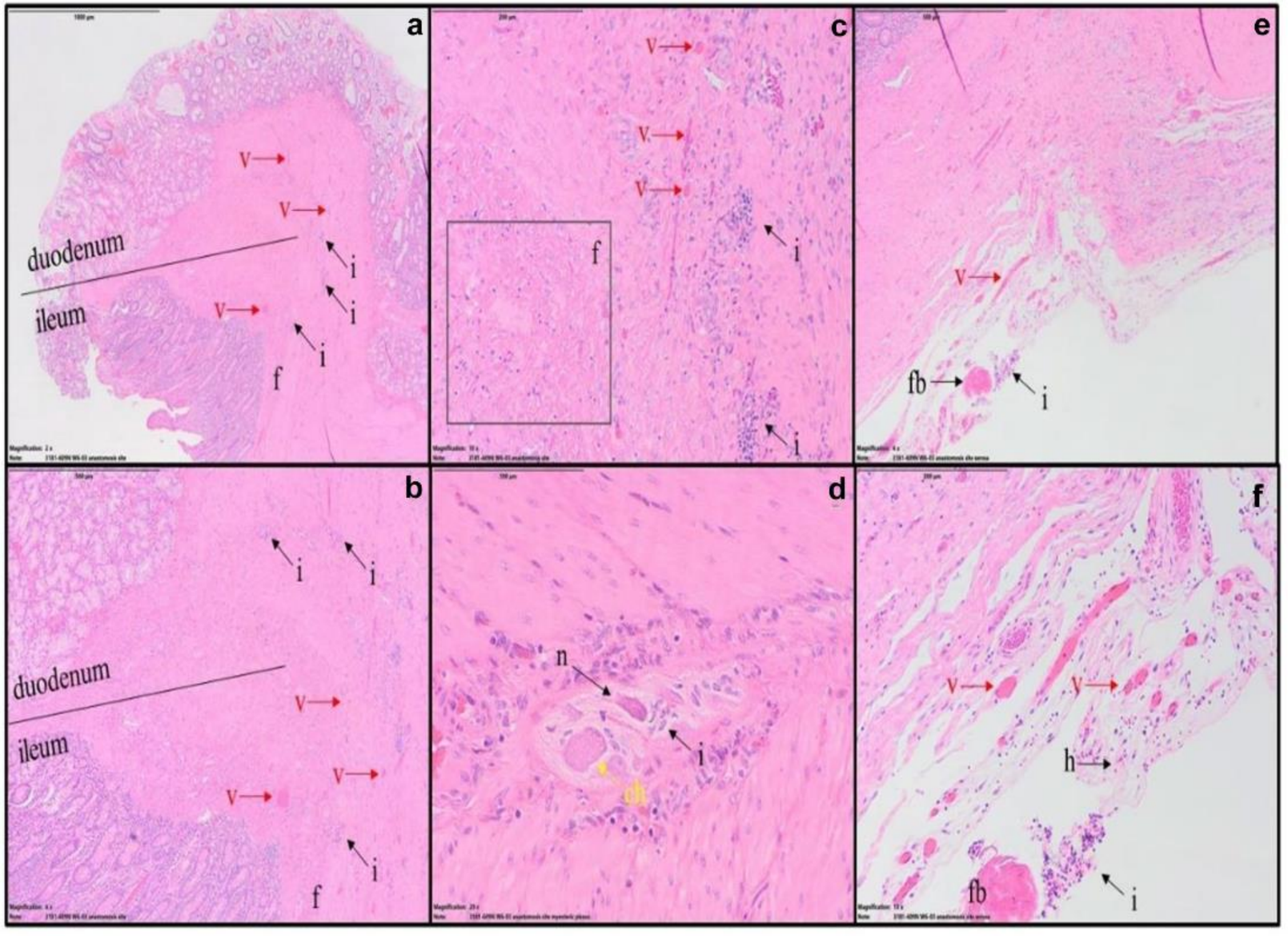


Fig. 5 Representative gross necropsy images of side-to-side duodeno-ileal (DI) magnetic compression anastomosis (MCA) and jejunal enterotomy (JE) sites. **a** Low magnification image of the serosal aspect of the side-to-side DI MCA site (white solid rectangle); **b** Low magnification image of the serosal 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
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Magnamosis II: Magnetic Compression Anastomosis for Minimally Invasive Gastrojejunostomy and Jejunojejunostomy

Kullada O Pichakron, MD, FACS, Eric B Jelin, MD, Shinjiro Hirose, MD, FACS, Patrick F Curran, MS, Ramin Jamshidi, MD, Jacob T Stephenson, MD, Richard Fechter, Michael Strange, MS, Michael R Harrison, MD, FACS

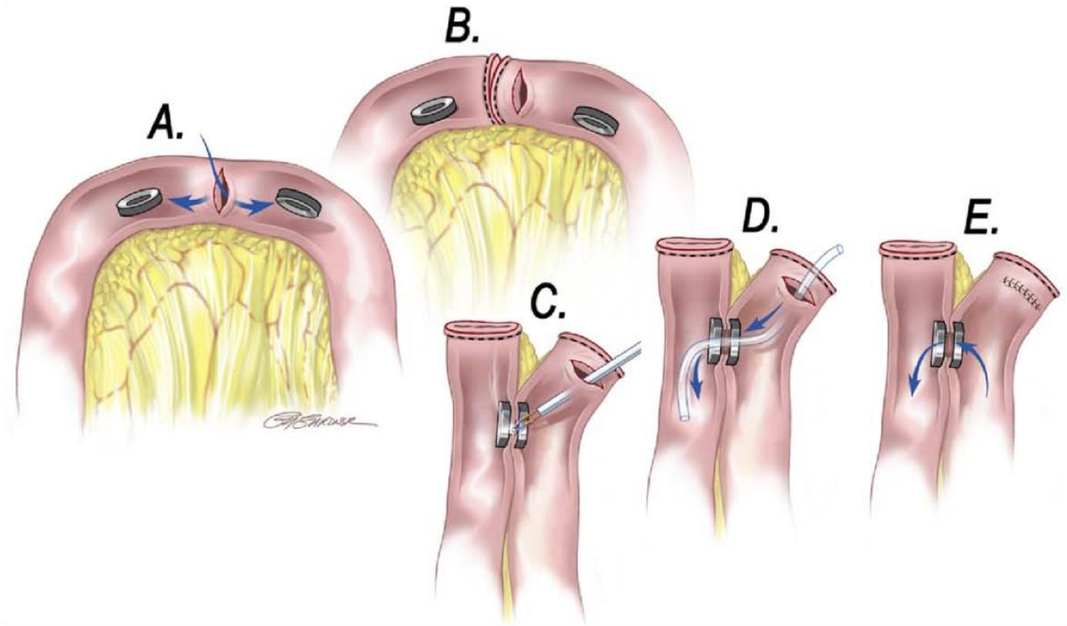


Figure 2. Magnamosis technique: laparoscopic jejunojejunostomy. Courtesy of Gil Gardner.

Burst Pressure is higher

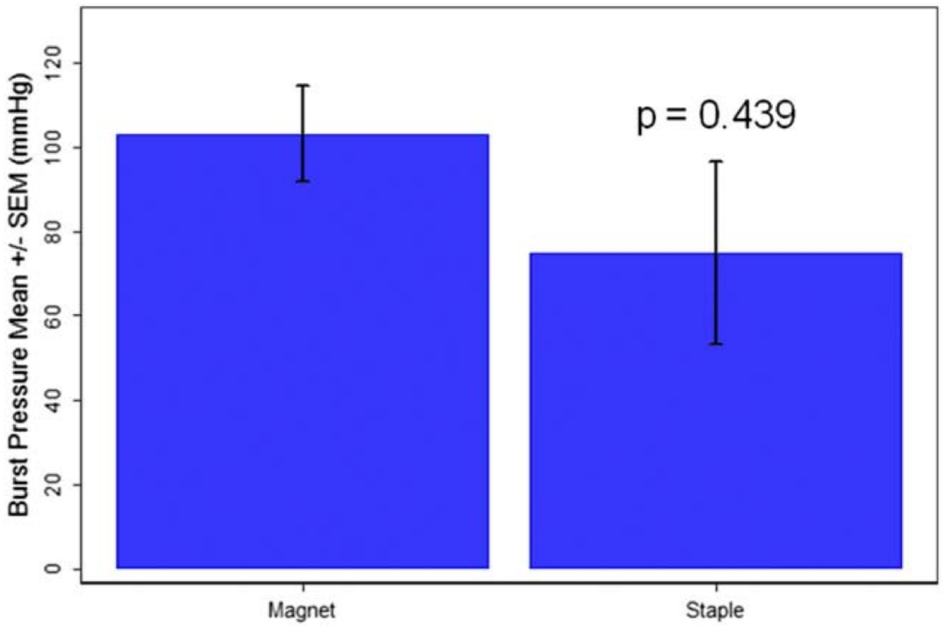


Figure 4. Mechanical burst pressure testing: jejunojejunostomy.

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]

Received: 20 February 2023 / Revised: 23 June 2023 / Accepted: 26 June 2023 / Published online: 2 July 2023

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.

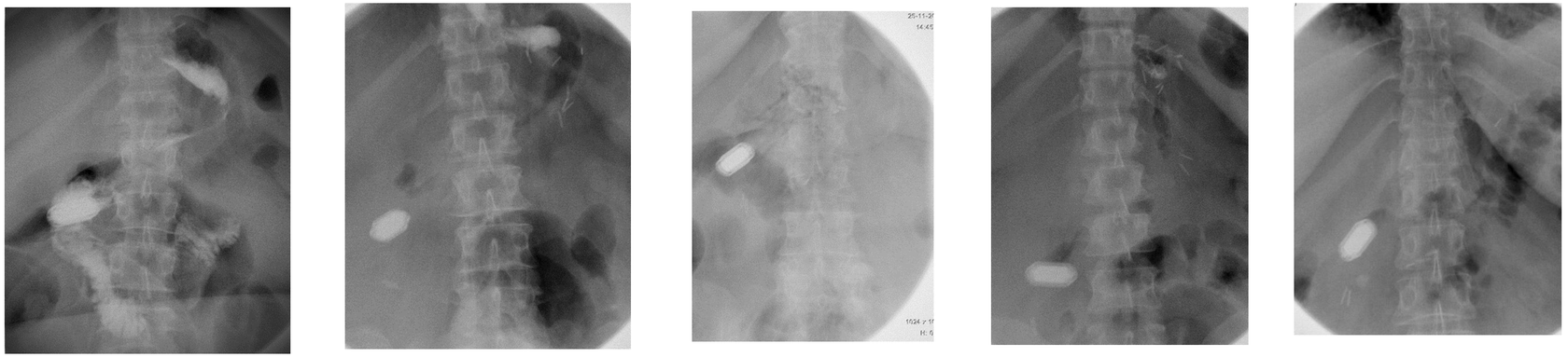
Materials and Methods Patients with severe obesity (body mass index (BMI) ≥ 35 kg/m^2 with/without T2D ($HbA1_C \geq 6.5\%$)) underwent the study procedure, a side-to-side MS DI diversion, with a standard sleeve gastrectomy (SG). A linear magnet was delivered by flexible endoscopy to a point 250 cm proximal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

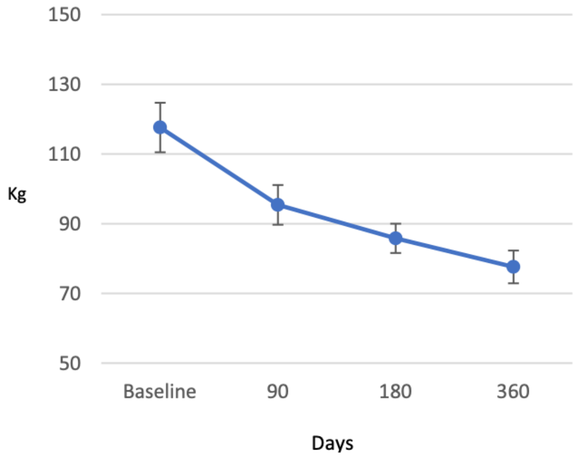
Trial Registration Clinicaltrials.gov Identifier: NCT05322122.

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



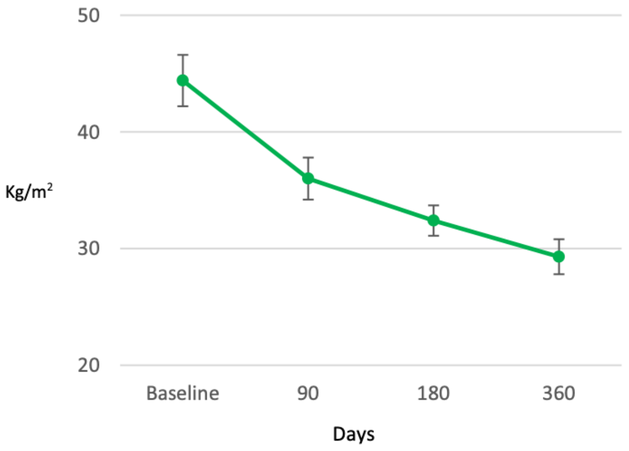
Procedure date	Duration of procedure mean in min (SD)	Placement of the magnet
22, 24, 25 and 26 November 2021	154 (24.48)	100%

(a)



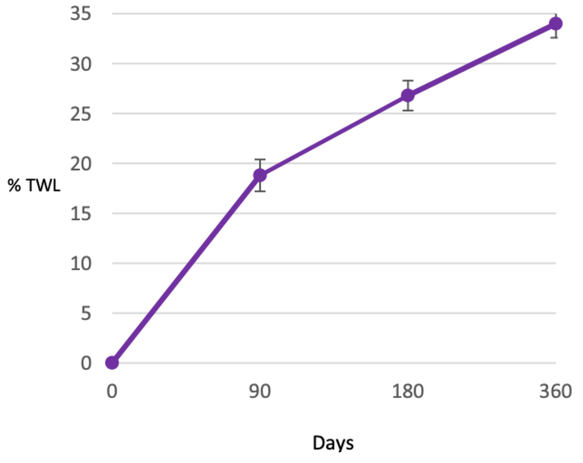
Mean±SEM			
117.6±7.1	95.4±5.7	85.8±4.2	77.6±4.7

(b)



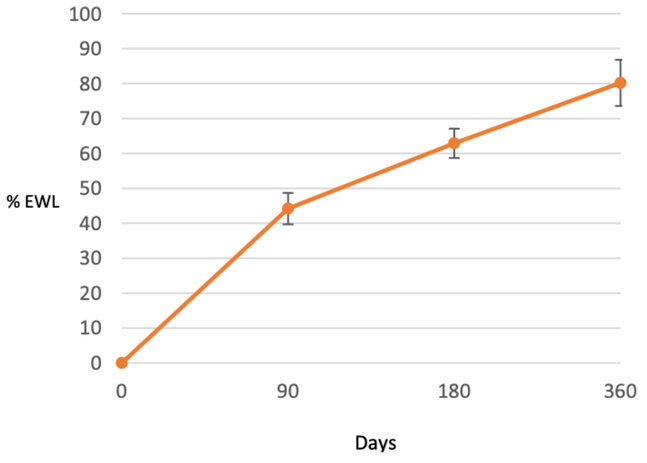
Mean±SEM			
44.4±2.2	36.0±1.8	32.4±1.3	29.3±1.5

(c)



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

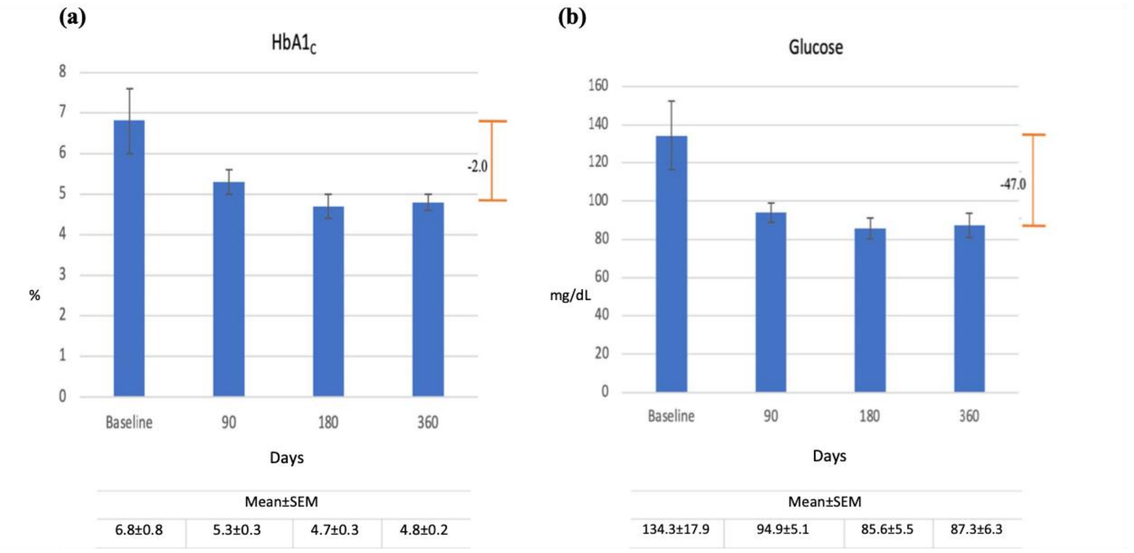
(d)



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)



Surgical Endoscopy (2023) 37:6452–6463
https://doi.org/10.1007/s00464-023-10134-6

2023 SAGES ORAL

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

Michel Gagner[1,8] · Guy-Bernard Cadiere[2] · Andres Sanchez-Pernaute[3] · David Abuladze[4] · Todd Krinke[5] · J. N. Buchwald[6] · Nathalie Van Sante[7] · Marc Van Gossum[2] · Jana Dziakova[3] · Levan Koiava[4] · Maja Odovic[3] · Mathilde Poras[2] · Lamees Almutlaq[1] · Antonio J. Torres[3]

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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.

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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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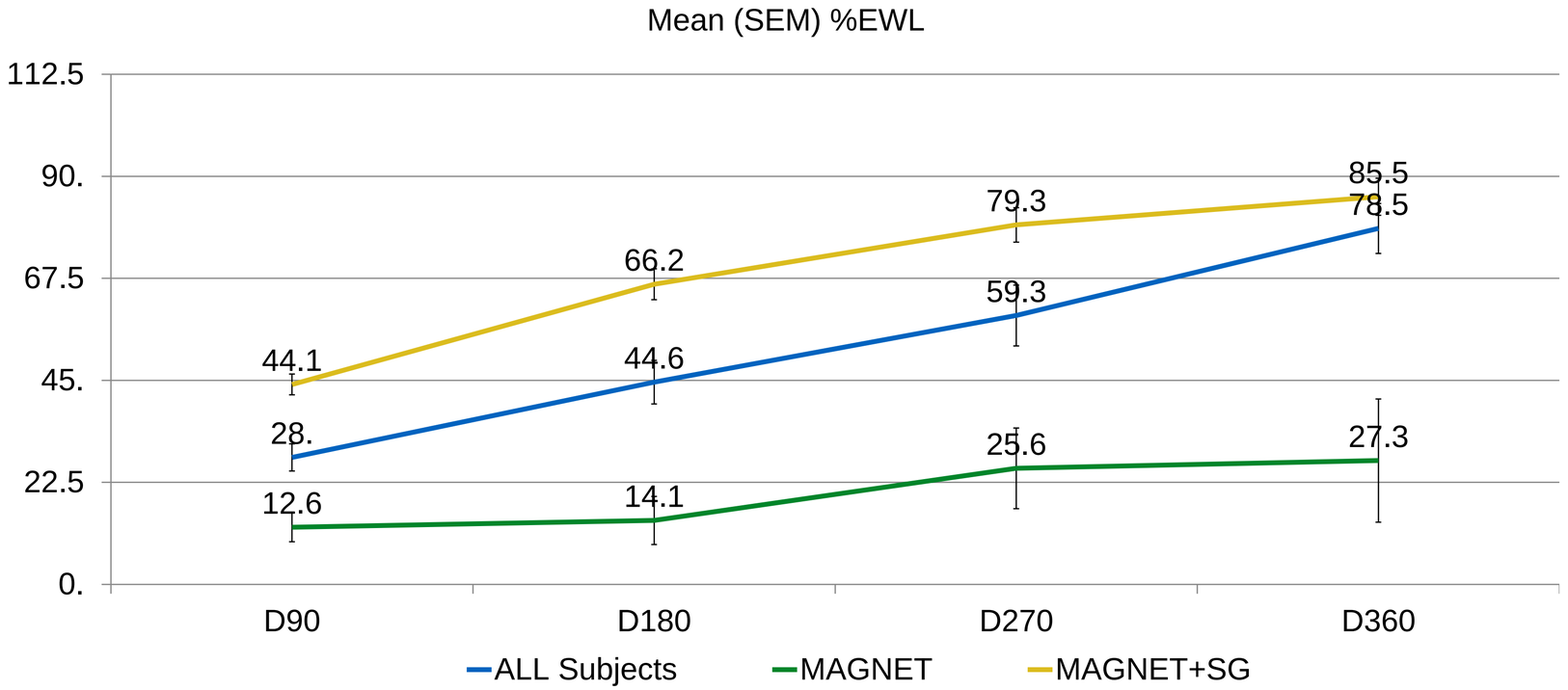
Percent Excess Weight Loss (%EWL) over one year



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]

Received: 17 February 2024 / Revised: 22 July 2024 / Accepted: 23 July 2024 / Published online: 2 August 2024

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.

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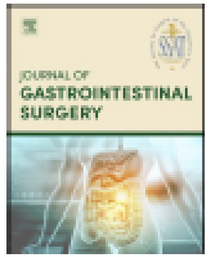

Original Article

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

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Surgery for Obesity and Related Diseases ■ (2024) 1–10

SURGERY FOR OBESITY AND RELATED DISEASES

Original article

Magnetic compression anastomosis gastrojejunostomy: feasibility and efficacy of a novel device in a swine model

Michel Gagner, M.D.[a,*], Todd Krinke, B.Sc.[b], Maxime Lapointe-Gagner, M.Sc.[a], Jane N. Buchwald, B.A.[c]

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Received 24 January 2024; accepted 26 April 2024

GT Metabolic Wins De Novo Nod for Magnet Compression Anastomosis Tech

The company's first-generation MagDI system is used for side-to-side duodeno-ileal anastomosis.

Michel Gagner, MD, pioneer in magnetic compression anastomosis surgery. Photo: GT Metabolic Solutions.

Decision date: July 2nd, 2024

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Device Classification Under Section 513(f)(2)(De Novo)

510(k)[7] | DeNovo[8] | Registration & Listing[9] | Adverse Events[10] | Recalls[11] | PMA[12] | HDE[13] | Classification[14] | Standards[15]

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Device Classification Name	Magnetic Compression Anastomosis System[22]
De Novo Number	DEN240013
Device Name	MagDI System
Requester	Gt Metabolic Solutions, Inc. 3050 Three Springs Court San Jose, CA 95140
Contact	Lisa Griffin Vincent
Regulation Number	878.4816[23]
Classification Product Code	SAH[24]
Date Received	03/26/2024
Decision Date	07/02/2024
Decision	Granted (DENG)
Classification Advisory Committee	General & Plastic Surgery
Review Advisory Committee	General & Plastic Surgery
Reclassification Order	Reclassification Order[25]
Type	Post-NSE

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