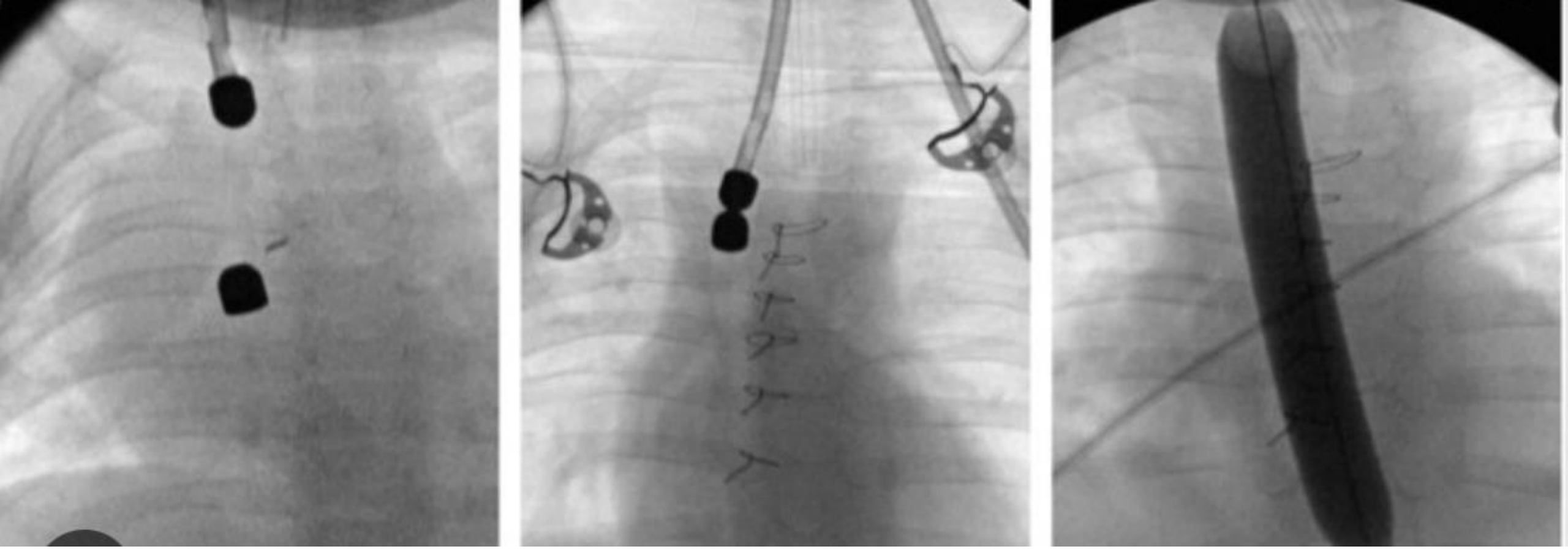
What’s happening in magnetic surgery ?

Mark Magdy

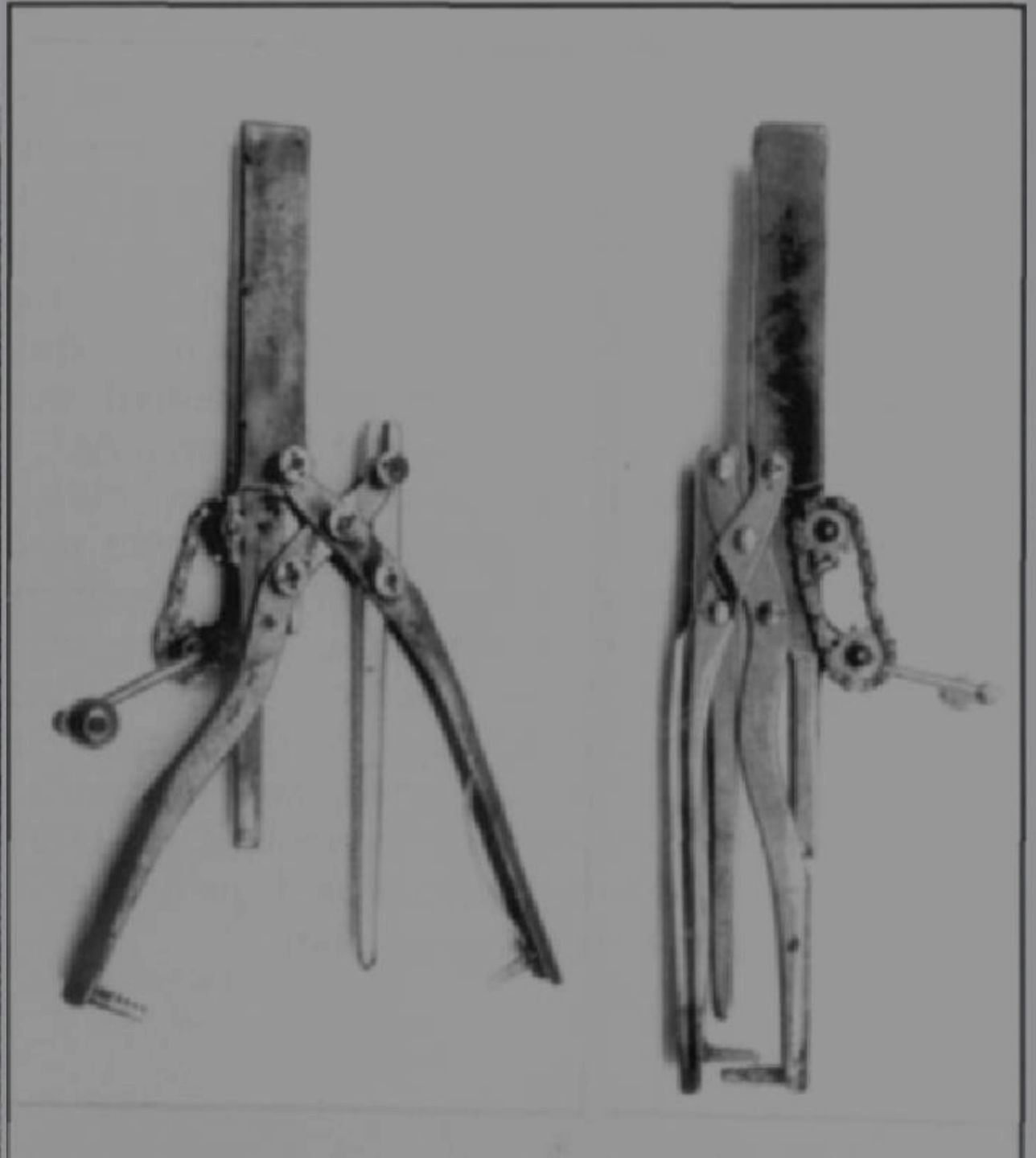
Disclosures

PI Investigator for GT Metabolics Magnetic Duodenal Ileostomy Australian Study.

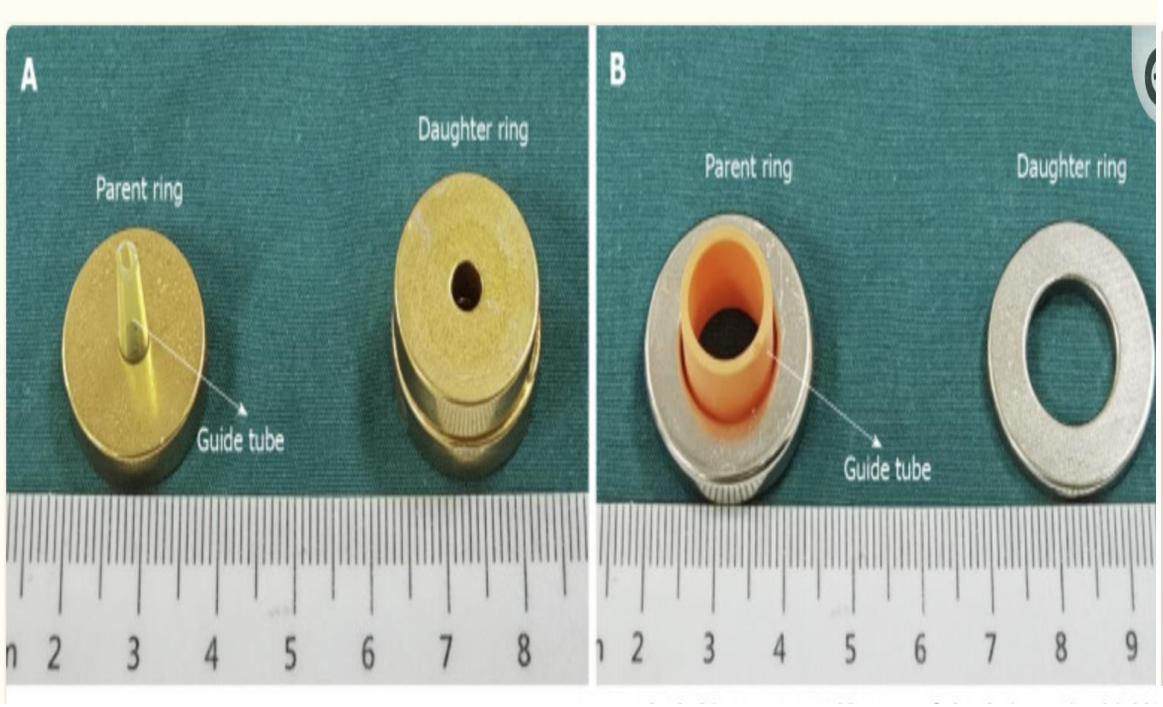


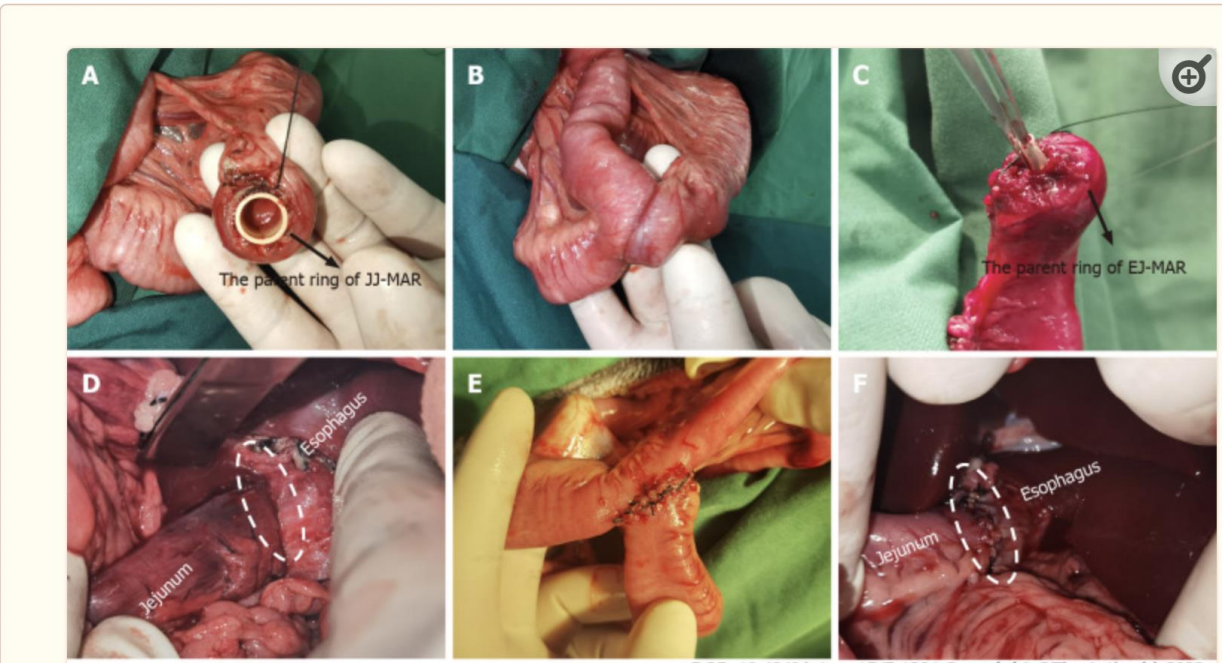
History

- The use of magnets for the treatment of long gap Oesophageal atresia (LGEA) was first described in 1975 by Hendren and Hale [1]. Recently, a renewed interest in magnetic compression for Oesophageal anastomosis or “magnamosis” has resurfaced.



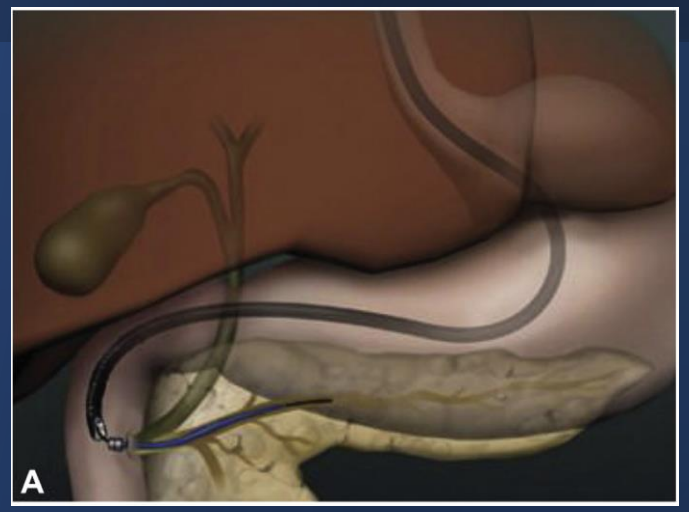
Post Oesphagectomy

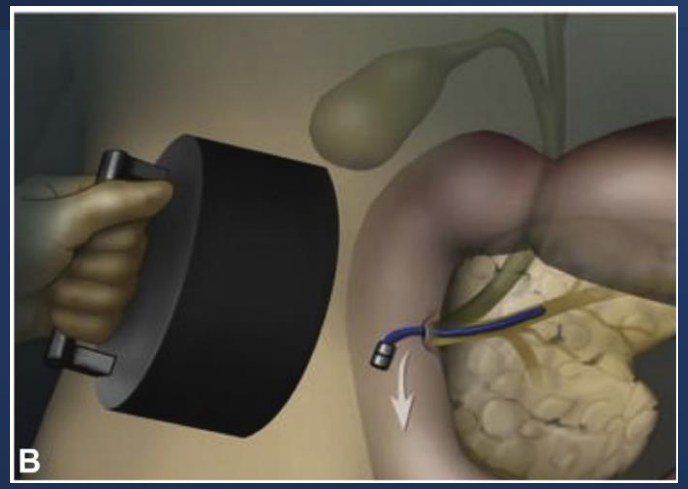


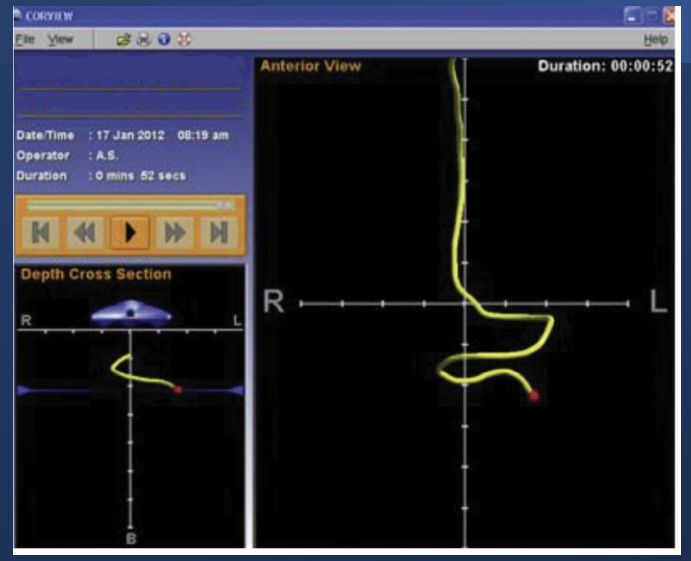


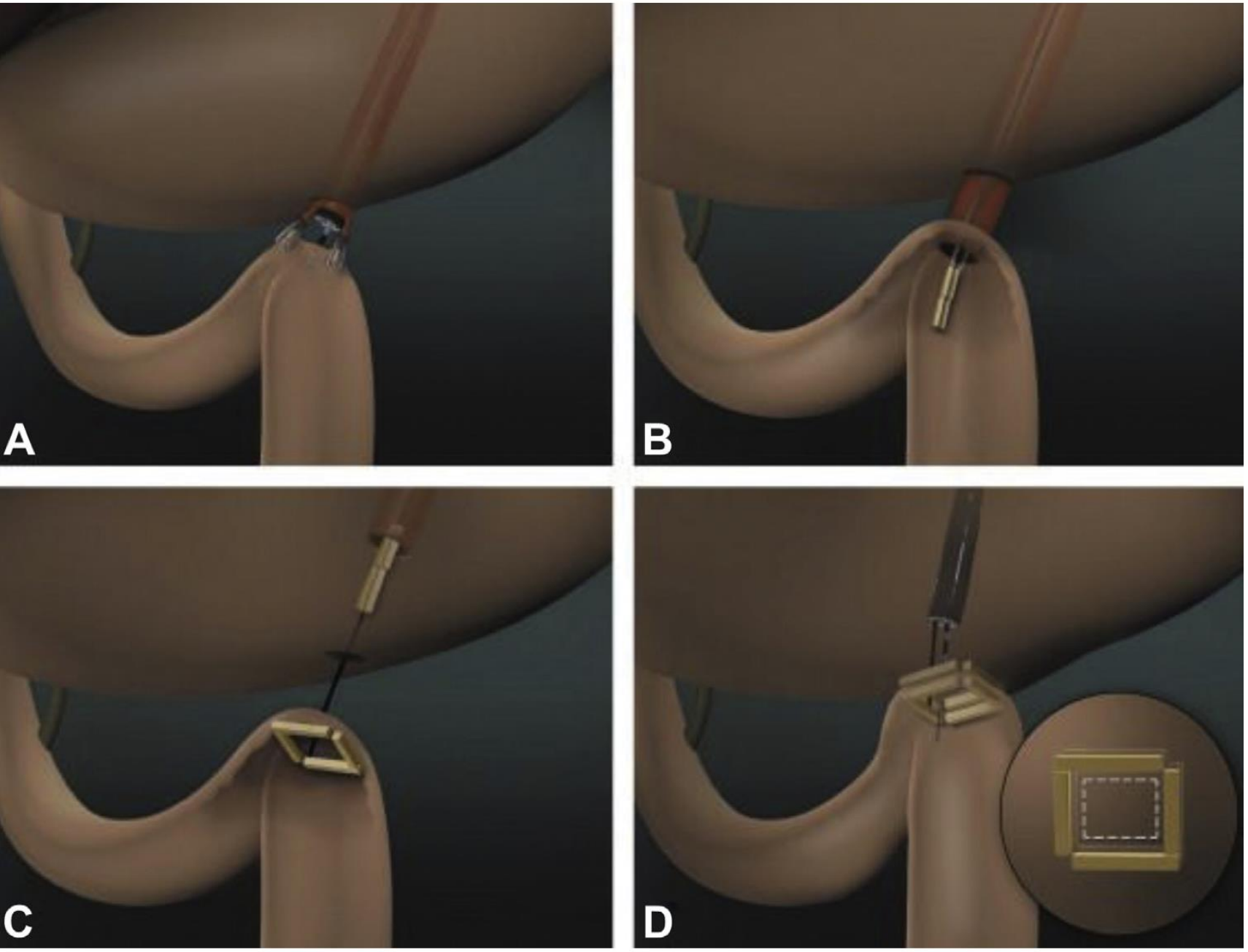
		Connecting two enteric segments (e.g., stomach, small intestine, and colon)	Magnamosis Magnetic Compression Anastomosis Device (Myka Labs, UCSF Surgical Innovations, San Francisco, CA, USA)	Cope 1995 [34], Chopita 2005 [35], Jamshidi 2009 [36], Myers 2010 [37], Pichakron 2011 [38], Gonzales 2012 [39], Wall 2013 [40], Russell 2014 [41], and Graves 2017 [42]
	Magnetic compression anastomosis between two paired intraluminal magnets (spherical, discoid, ring, and cylindrical)	Connecting the proximal intestine to the distal intestine to create a bypass channel (i.e., bariatric surgery)	Self-Forming Magnetic Anastomosis Device (GI Windows Surgical, West Bridgewater, MA, USA)	Ryou 2016 [43], Machytka 2017 [44], Schlottman 2021 [45], Gumustop 2022 [46], and Ore 2022 [47,48]
NC		Connecting the proximal and distal esophageal pouches in esophageal atresia (congenital disorder)	Magnamosis Connect-EA (Myka Labs, UCSF Surgical Innovations, San Francisco, CA, USA); Flourish Pediatric Esophageal Atresia Device (Cook Medical, Bloomington, IN, USA)	Zaritzky 2009 [49], Zaritzky 2014 [50], Dorman 2016 [51], Slater 2019 [52], Muensterer 2020 [53], Wolfe 2020 [54], Muensterer 2021 [55], and Evans 2022 [56]
		Connecting the bile duct to the stomach or small intestine to bypass bile duct stricture		Mimuro 2003 [57], Muraoka 2005 [58], Matsuno 2009 [59], and Jang 2020 [60]
		Resecting a strictured esophagus, small intestine, bile duct, or colon		Takamizawa 2007 [61], Woo 2017 [62], Kamada 2020 [63], Isozaki 2020 [64], Liu 2020 [65], Kılıç

Endoscopic Magnetic Explosion









- Endoscopic tools have revolutionized procedures performed.
- EUS guided gastro-enterostomy.
- EUS guided Axios stent drainage procedures

Laboratory based testing

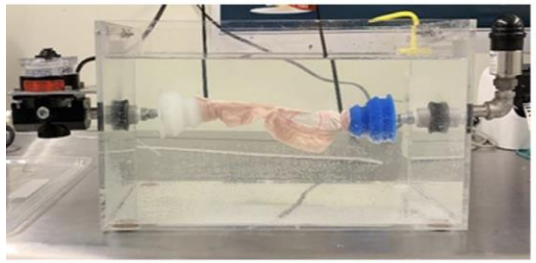


Figure 4. Burst pressure testing fixture.

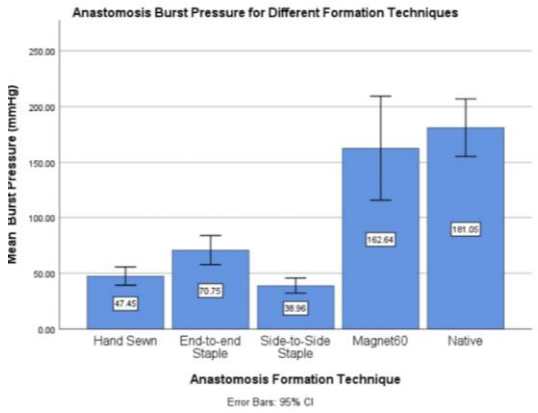
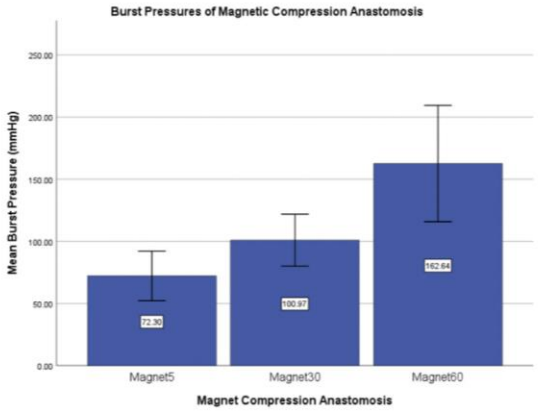
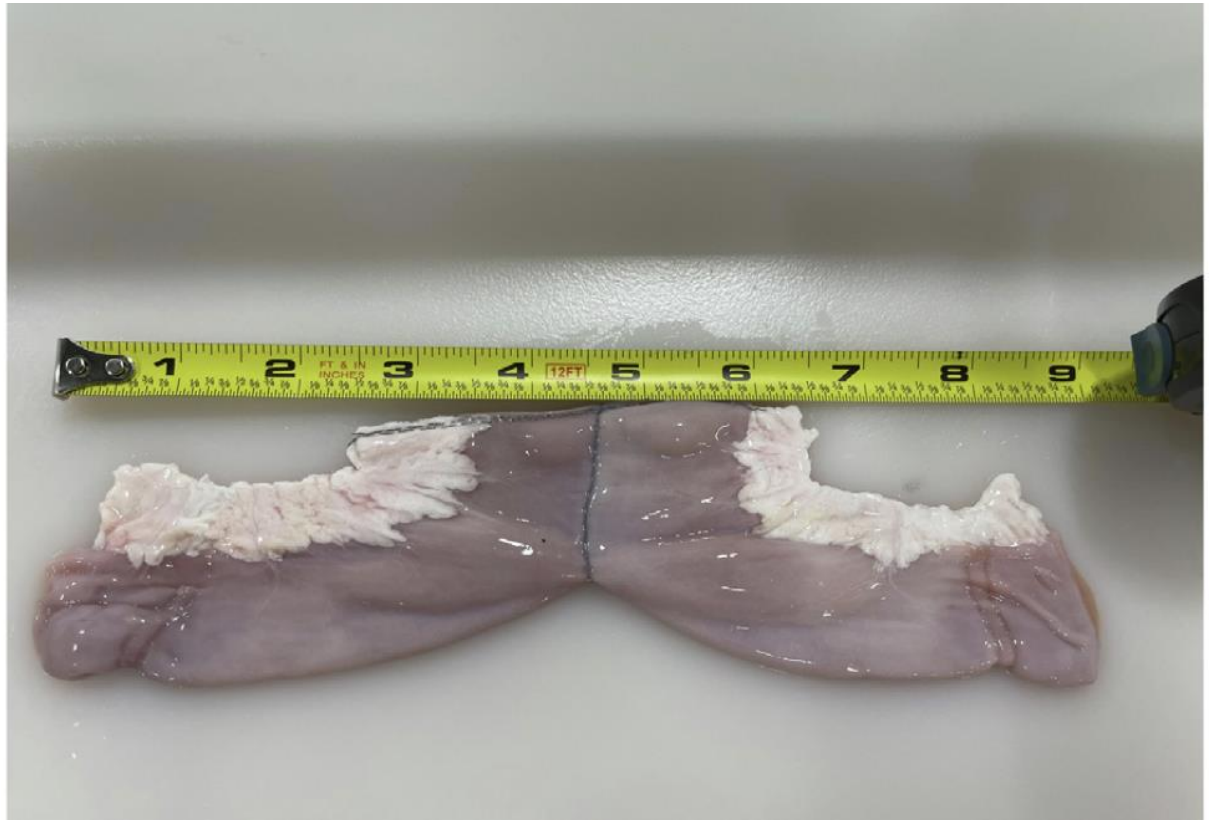


TABLE 1. Average anastomotic bursting pressures

Groups	Bursting pressure, mm Hg (mean ± SD)
Hand sutured	47.45 ± 9.77[a]
End-to-end stapled	70.75 ± 18.30[b]
Side-to-side stapled	38.96 ± 6.41[a]
Magnetic 5	72.30 ± 16.06[b,c]
Magnetic 30	100.97± 13.14[c]
Magnetic 60	162.64± 29.38[d]
Native tissue	181.05± 36.02[d]

Statistical difference between groups with different superscript letters: $P < .05$.





GI Windows

- GT Metabolics

Surgical Endoscopy
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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.

Keywords Metabolic/bariatric surgery · Magnetic compression anastomosis · Magnet system · Duodeno-ileostomy · Sleeve gastrectomy · Obesity · Type 2 diabetes

Metabolic/bariatric surgery (MBS) is substantially more effective and durable in achieving weight loss and type 2 diabetes control than conventional lifestyle change and medication [1–3]. MBS is also highly cost effective in managing patients with T2D with/without obesity, saving insurers > $76.5 million in T2D medication costs in the first post-MBS year in one state alone [4]. MBS is safe, with approximately the same short-term morbidity of common procedures such as cholecystectomy and appendectomy [5, 6]. Since the introduction of laparoscopic technique in Roux-en-Y gastric bypass (RYGB) by Wittgrove and Clark (1993) [7, 8], minimally invasive surgery (MIS) has continued to reduce operative and long-term MBS risk [9, 10] and encompass novel modes of access (e.g., endoscopic, natural orifice transluminal endoscopic surgery [NOTES], robotic),

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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 ($HbA1_C$ ≥ 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.

Keywords Metabolic/bariatric surgery, Magnetic compression anastomosis · Duodeno-ileostomy · Sleeve gastrectomy · Obesity · Type 2 diabetes

Key Points
- First-in-human compression anastomosis with the magnet system was feasible and safe.
- Magnetic s-i-s duodeno-ileostomy + SG achieved excellent weight loss and T2D resolution.
- Magnet system formed incisionless, sutureless anastomoses with no retained materials.
- Gradual anastomosis creation: no bleeds, leaks, obstruction, or infection at 1 year.

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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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ABSTRACT

Background: Single-anastomosis metabolic/bariatric surgery procedures may lessen the incidence of anastomotic complications. This study aimed to evaluate the feasibility and safety of performing side-to-side duodenoileal (DI) bipartition using magnetic compression anastomosis (MCA). In addition, preliminary efficacy, quality of life (QoL), and distribution of food through the DI bipartition were evaluated.

Methods: Patients with a body mass index (BMI) of ≥35.0 to 50.0 kg/m^2 underwent side-to-side DI bipartition with the magnet anastomosis system (MS) with sleeve gastrectomy (SG). By endoscopic positioning, a distal magnet (250 cm proximal to the ileocecal valve) and a proximal magnet (first part of the duodenum) were aligned with laparoscopic assistance to inaugurate MCA. An isotopic study assessed transit through the bipartition.

Results: Between March 14, 2022 to June 1, 2022, 10 patients (BMI of 44.2 ± 1.3 kg/m^2) underwent side-to-side MS DI. In 9 of 10 patients, an SG was performed concurrently. The median operative time was 161.0 minutes (IQR, 108.0-236.0), and the median hospital stay was 3 days (IQR, 2-40). Paired magnets were expelled at a median of 43 days (IQR, 21-87). There was no device-related serious advanced event within 1 year. All anastomoses were patent with satisfactory diameters after magnet expulsion and at 1 year. Respective BMI, BMI reduction, and total weight loss were 28.9 ± 1.8 kg/m^2, 15.2 ± 1.8 kg/m^2, and 34.2% ± 4.1%, respectively. Of note, 70.0% of patients reported that they were very satisfied. The isotopic study found a median of 19.0% of the meal transited through the ileal loop.

Conclusion: Side-to-side MCA DI bipartition with SG in adults with class II to III obesity was feasible, safe, and efficient with good QoL at 1-year follow-up. Moreover, 19% of ingested food passed directly into the ileum.

Introduction

Surgery is the only treatment for class III obesity that has proven effective over the long term [1,2]. The American Society for Metabolic and Bariatric Surgery and the International Federation for the Surgery of Obesity and Metabolic Disorders (IFSO) have endorsed the safety and efficacy of 7 metabolic/bariatric surgery (MBS) procedures, including Roux-en-Y gastric bypass (RYGB), sleeve gastrectomy (SG), and duodenal switch (DS); moreover, there is no consensus that 1 intervention is best for every patient.

Procedural complexity, complications, and insufficient weight loss or weight regain require ongoing technical improvements and inspire the development of new interventions to avert these challenges. One such minimally invasive surgery strategy is the reduction of the number of gastrointestinal (GI) anastomoses, as applied in single-anastomosis duodenoileal (DI) bypass with SG (SADI-S) and single-anastomosis sleeve ileal bypass (SASI) [3,4]. Each procedure involves the creation of an SG, an end-to-side bipartition between

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SURGERY FOR OBESITY AND RELATED DISEASES

Original article

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

Michel Gagner, M.D.[a,*], Lamees Almutlaq, M.D.[a], Guy-Bernard Cadiere, M.D., Ph.D.[b], Antonio J. Torres, M.D., Ph.D.[c], Andres Sanchez-Pernaute, M.D., Ph.D.[c], Jane N. Buchwald, B.A.[d], David Abuladze, M.D.[e]

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Abstract

Background: Conventional metabolic/bariatric surgical anastomoses with sutures/staples may cause severe adverse events (AEs).

Objectives: The study aim was to evaluate the feasibility, safety, and effectiveness of primary and revisional side-to-side duodeno-ileostomy (DI) bipartition using a novel magnetic compression anastomosis device (Magnet Anastomosis System [MS]).

Setting: Multicenter: private practices and university hospitals.

Methods: In patients with body mass index ([BMI, kg/m^2] ≥ 35.0 to ≤ 50.0 with/without type 2 diabetes [T2D] glycosylated hemoglobin [HbA1C > 6.5 %]), two linear MS magnets were delivered endoscopically to the duodenum and ileum with laparoscopic assistance and aligned, initiating magnet fusion and gradual DI (MagDI). The MagDI-*after*-SG group had undergone prior sleeve gastrectomy (SG); the MagDI + SG group underwent concurrent SG. AEs were graded by Clavien-Dindo Classification (CDC).

Results: Between November 22, 2021 and May 30, 2023, 43 patients (88.0% female, mean age 43.7 ± 1.3 years) underwent the study procedures. The MS met feasibility criteria of magnet device placement, creation of patent anastomoses confirmed radiologically, and magnet passage in 100.0% of patients. There were 64 AEs, most were CDC grade I and II, significantly fewer in the MagDI-after-SG group ($P < .001$). No device-related AEs including anastomotic leakage, bleeding, obstruction, infection, or death. The MagDI-after-SG group experienced 6-month mean weight loss of 8.0 ± 2.5 kg ($P < .01$), 17.4 ± 5.0% excess weight loss (EWL). The MagDI + SG group had significantly greater weight loss (34.2 ± 1.6 kg, $P < .001$), 66.2 ± 3.4% EWL. All patients with T2D improved.

Clinicaltrials.gov Identifier: NCT05322122.

Financial disclosure: This study was supported by a research grant from GT Metabolic Solutions, Inc. (San Jose, CA), a company invested in magnetic surgery.

Ethical approval statement: The study was conducted in compliance with the registered Clinicaltrials.gov protocol (#NCT05322122) in accord with the

Written informed consent was obtained with adequate understanding and consent of all participating patients.

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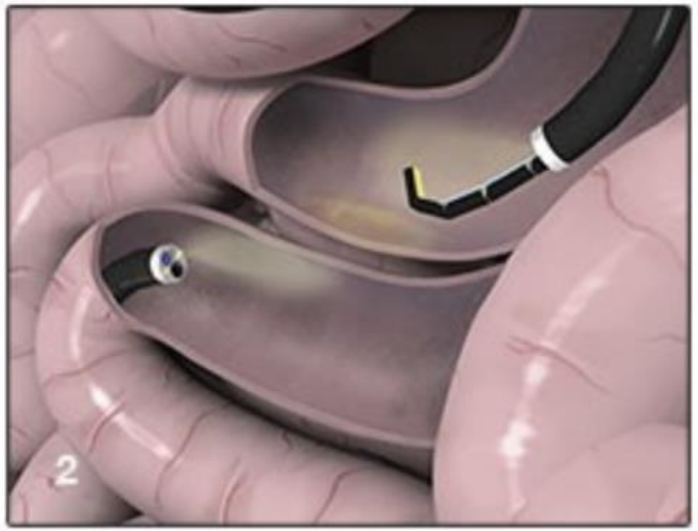
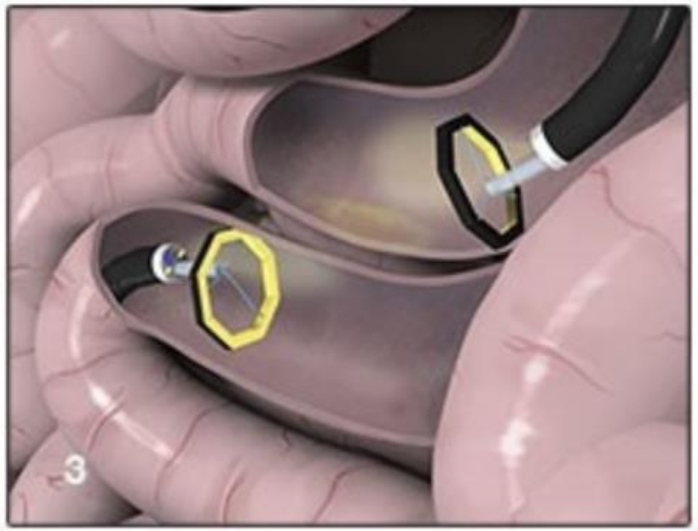
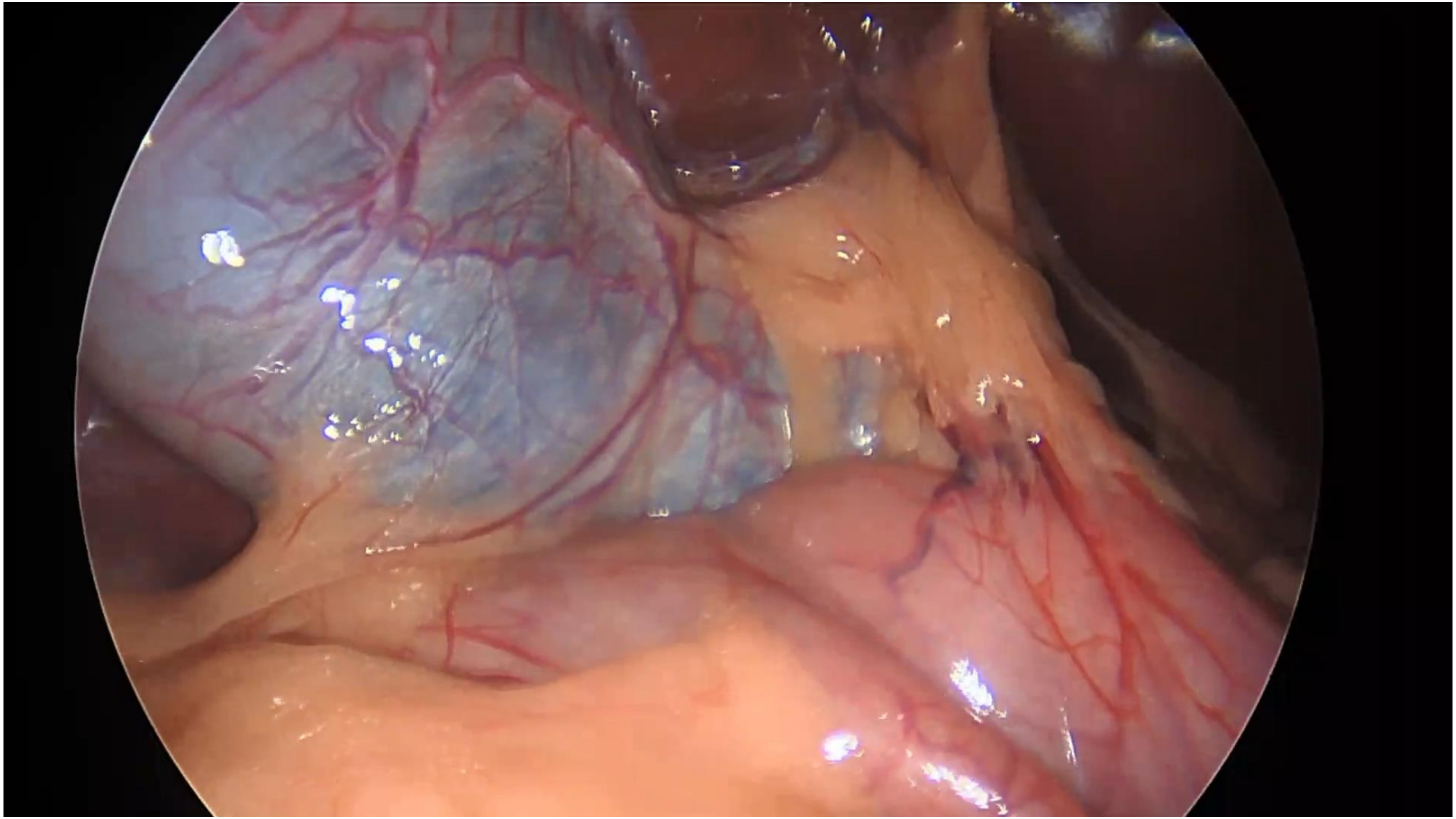
- Technique

Two standard endoscopes are used to access the small bowel





Self-forming magnets are deployed from the working channel of each endoscope



Magnetic Future

NEW TECHNOLOGY ON THE HORIZON.

MULTIPLE MAGNETS WITH SUSPECTED VARIABLE UPTAKE

ESSENTIALLY ADDED TOOL TO THE BOX