

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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## 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<sup>2</sup>] ≥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.

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**Ethical approval statement:** The study was conducted in compliance with the registered [Clinicaltrials.gov](https://doi.org/10.1016/j.soard.2023.10.018) protocol (#NCT05322122) in accord with the ethical standards of the institutional research committee, and with the 1964 Helsinki declaration and its recent amendments, as well as with ISO14155 regulations, 21 CFR Parts 11, 50, 54, 56, and 812 Good Clinical Practices.

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

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**Conclusions:** In early results of a multicenter study, the incisionless, sutureless Magnet System formed patent, complication-free anastomoses in side-to-side DI with prior or concurrent SG. (Surg Obes Relat Dis 2024;20:341–353.) © 2024 American Society for Metabolic and Bariatric Surgery. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

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

Metabolic/bariatric surgery (MBS) is underutilized [1,2] although it is markedly more effective than standard medical care in achieving durable weight reduction and type 2 diabetes (T2D) resolution in patients with obesity [3–5]. However, in separate large analyses of the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP) in patients with a postoperative leak, the risk of death was 31–35 times higher [6]; leak and bleeding were the greatest overall contributors to intensive care admission, reoperation, and end-organ dysfunction [7]. Construction of healthy, patent, durable anastomoses is crucial to preventing leak and other major complications in MBS. In particular, retention of foreign materials (i.e., staples, sutures, clips, glue, stents) in conventionally formed anastomoses may instigate chronic inflammation that contributes to leak, bleeding, infection, and stricture development [8].

Compression anastomosis (CA) devices (e.g., bio-fragmentable anastomotic ring, nickel-titanium ring/clip) [9–11] have been found as effective as stapled/sutured anastomosis formation [12,13], yet they also require intraoperative placement of permanent hardware to ensure gastrointestinal (GI) attachment [14]. In contrast, a novel *magnetic* CA (MCA) device, the Magnet Anastomosis System (MS), intraoperatively initiates a process of incisionless, suture-/staple-free anastomosis creation that is completed postoperatively over several weeks. Employing this delayed anastomosis technology (DAT) [15,16] with the MS eliminates the risks incurred by retained foreign materials.

A progression of study designs to evaluate the MS was undertaken, each based on a magnetic side-to-side duodeno-ileostomy (DI) anastomosis (MagDI) formed with two linear MS magnets that were paired, fused gradually, and expelled naturally (Fig. 1); a sleeve gastrectomy (SG) was performed concurrently. Technical feasibility, safety, and preliminary efficacy of the MS in MagDI were shown in (1) an initial preclinical study using a porcine model [17]; (2) a first-in-human (FIH) single-site investigation [18]; and (3) an international multicenter study [19]. The current expanded multi-center study compared early outcomes of patients who underwent MagDI independently, as a revisional second step after prior SG, and patients who received concomitant MagDI + SG.

## Patients and methods

### Study design

A prospective, open-label, clinical study (the Magnet Study; [clinicaltrials.gov](https://clinicaltrials.gov) NCT#05322122) of the MS (GT Metabolic Solutions, San Jose, CA) in the construction of side-to-side DI with concurrent SG for patients with class III obesity (body mass index [BMI, kg/m<sup>2</sup>]  $\geq 40.0$  to  $\leq 50.0$ ) was conducted in two stages with a 1-year follow-up period: Stage 1 assessed the magnet design, procedure feasibility, safety, and preliminary efficacy of FIH side-to-side MagDI + SG outcomes at one site (Republic of Georgia). Stage 2 assessed the same endpoints in three centers (Georgia, Belgium, Spain). The current study extended Stage 2 to incorporate a fourth center (Canada) in an evaluation of side-to-side MagDI + SG compared with solo side-to-side MagDI-*after*-SG (a revision of primary SG  $\geq 12$  months prior).

### Ethical conduct

Ethics Committees and institutional review boards of the centers approved the investigational device protocol and an independent safety monitoring board followed the progress of the study for adverse events (AEs) and severe AEs (SAEs). The Helsinki Declaration and ISO14155 regulations and international 21 CFR Good Clinical Practices for patient protection were observed throughout the study.

### Inclusion and exclusion

Requirements for inclusion required patients to be 18–65 year old with a BMI of  $\geq 30.0$  to  $\leq 50.0$  kg/m<sup>2</sup> and T2D (HbA<sub>1c</sub>  $\geq 6.5\%$ ) with no prior MBS *or* with weight regain or residual T2D following previous SG  $\geq 12$  months; *or* with a BMI  $\geq 40$  kg/m<sup>2</sup> who were candidates for laparoscopic single-anastomosis DI with SG (SADI-S). Patients agreed not to undergo additional MBS or reconstructive surgery for 1 year; females agreed not to become pregnant and to use contraception for 1 year.

Study exclusions included: type 1 diabetes; uncontrolled T2D, dyslipidemia, hypertension, and sleep apnea; injectable insulin use; prior non-MBS intestinal, colonic, or duodenal surgery; prior trauma, implant of prostheses, disease, scarring, abnormal anatomy, or genetic preconditions that prevented or contraindicated the study procedure;

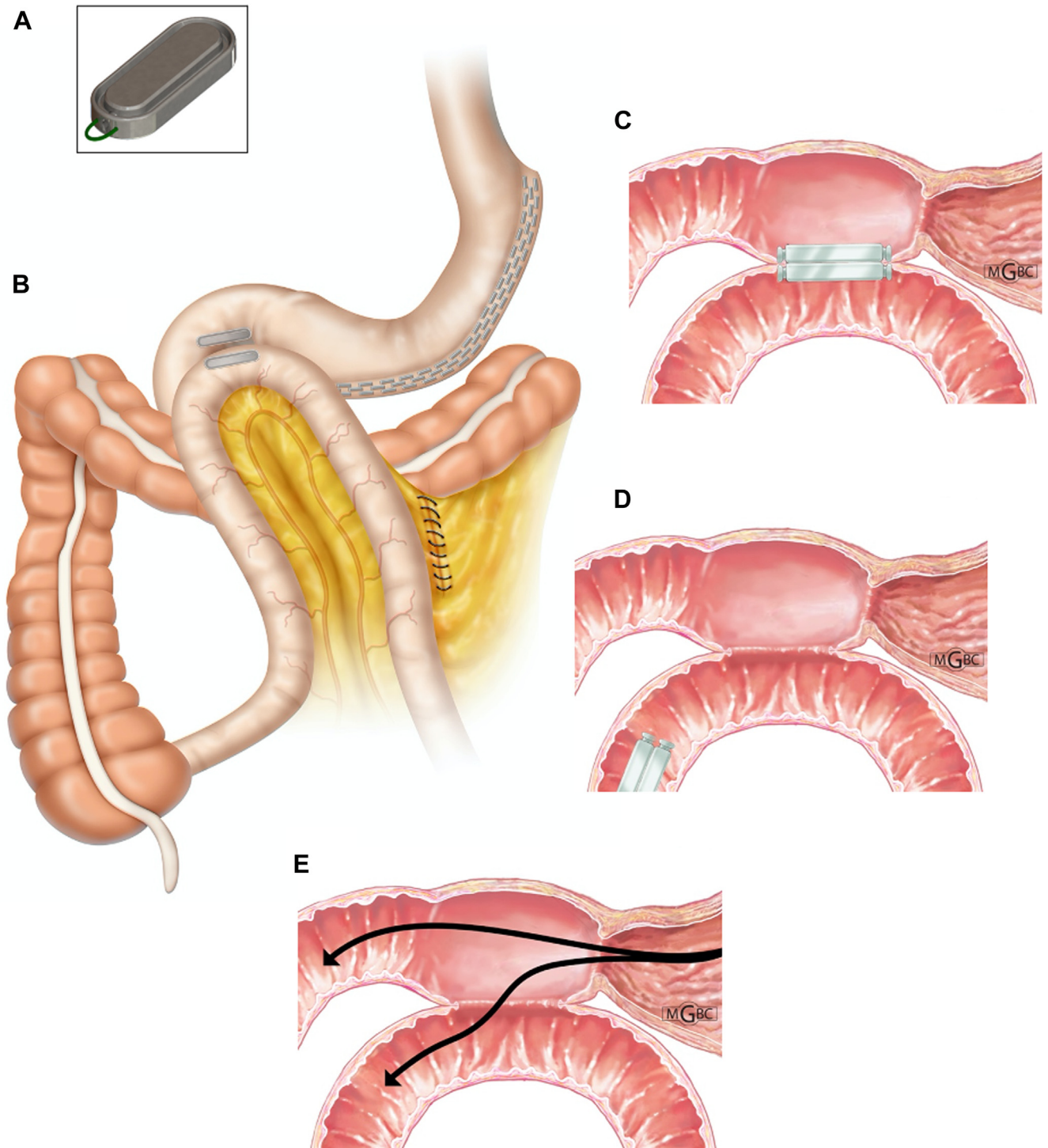


Fig. 1. (A) Magnet Anastomosis System (MS) magnet. (B) After the distal MS magnet is endoscopically positioned at the ligament of Treitz and directed through the jejunal lumen to the ileum by laparoscopic magnetic positioning device assistance, it is raised anterior and latero-lateral to the postpyloric duodenum to align with the endoscopically delivered proximal MS magnet and the mesenteric space is closed. (C) In approximately 2–4 weeks, magnets fuse and the patent duodeno-ileal (DI) anastomosis is formed. (D) The magnet pair detaches and is expelled naturally. (E) Alimentary contents pass through the DI bipartition into duodenum and ileum.

refractory gastroesophageal reflux disease (GERD), helicobacter pylori positive and/or active ulcer disease, Barrett’s esophagus; large hiatal hernia; inflammatory bowel disease

or colonic diverticulitis; an anomaly or condition precluding access by gastroscopy or laparoscopy; implantable pacemaker or defibrillator; untreated or poorly controlled

psychiatric illness; substance abuse history; pregnancy, breastfeeding, or unwillingness to use a proven contraception method; an associated medical condition (AMC)/comorbidity presenting a safety concern; an interventional procedure 30 days before/after the procedure; stroke/TIA within 6 months of study consent; chronic anticoagulation therapy (except aspirin); active infection requiring antibiotics; inability to comply with the follow-up schedule; participation in a separate clinical investigation; known allergies to device components or contrast media; limited life expectancy due to terminal disease; positive Covid-19 test before the procedure; and conditions investigators believe may prevent 360-day follow-up.

### Endpoints

The primary endpoint for both groups was feasibility/performance assessed by (1) correct technical MS magnet positioning in 90.0% of magnets, (2) magnet passage without surgical reintervention, and (3) creation of patent DI anastomoses verified endoscopically at 3 and 12 months. If the MS performed as above in  $\geq 80\%$  of treated patients, the primary endpoint was considered met. The primary safety endpoint, incidence, and severity of AEs/SAEs was characterized by Clavien-Dindo Classification (CDC) [20].

Secondary endpoints were early measures of MBS efficacy in terms of weight loss (kg) including the proportion of patients with  $>5.0\%$  total weight loss (TWL) and, if T2D present, T2D improvement (reduction of T2D medications; lowered levels of HbA<sub>1c</sub> and blood glucose). TWL was calculated by:  $([\text{initial weight} - \text{follow-up weight}] / [\text{initial weight}] \times 100)$ ; excess weight loss (%EWL) by:  $([\text{initial weight} - \text{follow-up weight}] / [\text{initial weight} - \text{ideal body weight}] \times 100)$ ; and BMI loss by:  $(\text{initial BMI} - \text{post-intervention BMI})$ .

### Surgical procedure

The MS was designed for the purpose of creating the side-to-side bipartition of a duodeno-ileal (DI) anastomosis. The MS is composed of a pair of linear BC42 neodymium magnets (.75" length  $\times$  .25" width  $\times$  .125" thickness) with a 2.3-mm-offset flange and titanium casing (Ti-6Al-4V ELI grade-23; KJ Magnetics, Pipersville, PA). The full endoscopic technique with laparoscopic support to develop side-to-side MS DI has been previously described [18,19]. Briefly, after marker placement in the ileum 250 cm from the cecum, the distal MS magnet is transported orogastrically to the ligament of Treitz, directed through the jejunum by a magnetized positioning tool to the marked ileal position; the distal ileal magnet is elevated over the transverse colon anterior and latero-lateral to the postpyloric duodenum where the proximal MS magnet has been positioned endoscopically; the two magnets are aligned and the mesenteric defect closed. In several weeks, magnets are fused, detach from the patent DI anastomosis, and are expelled

naturally, facilitating transit of the alimentary content through both duodenum and ileum (Fig. 2).

### Postoperative care

The dietitian or nutritionist discussed the postoperative diet and the follow-up visits (day 30, 60, 90, 180, and beyond) with each patient. A regimen similar to that for SADI-S patients was administered following surgery including multivitamins, Vitamin B<sub>12</sub>, Calcium, Iron, and Vitamin D.

### Statistical analysis

Descriptive statistics were calculated and analyses were performed using the SPSS statistical package (version 20.0; IBM, Chicago, IL). Qualitative variables were reported using frequencies and percentages and evaluated using the chi-square test or Fisher's exact test. Quantitative variables were reported using means and standard error of the mean (SEM), medians and ranges, and/or 95% CIs. Quantitative measures of change from baseline were analyzed using the paired-samples t-test; between-group comparisons along continuous variables were carried out using the independent-samples t-test. All statistical tests were two-tailed and alpha was set at  $P < .05$ .

## Results

### Patient characteristics

Between November 22, 2021 and May 30, 2023, 43 patients (88.0% female; 84.0% Caucasian) with a mean age of  $43.7 \pm 1.3$  years (range 28.0–59.0) underwent side-to-side MagDI-after-SG or side-to-side MagDI + SG. The MagDI-after-SG group ( $n = 19$ ) mean baseline absolute weight was  $107.3 \pm 5.2$  kg (range: 69.6–156.5) with a BMI of  $41.0 \pm 1.4$  (30.2–52.3). MagDI + SG group ( $n = 24$ ) baseline weight was  $121.9 \pm 3.3$  kg (97.0–155.0) with a BMI of  $44.4 \pm .8$  (36.8–50.9) (Table 1). One MagDI-after-SG patient (5.0%) and nine MagDI + SG patients (37.5%) were diagnosed with T2D, most on medications at study enrollment.

### Feasibility

The MS successfully met feasibility criteria: placement of the device with alignment of magnets, creation of a patent anastomosis confirmed radiologically and/or endoscopically (Fig. 3) and passage of the paired magnets without AEs requiring re-intervention was achieved in all 43 (100.0%) patients. Median hospital stay was 2 days (mean  $\pm$  SEM:  $3.8 \pm 1.0$  days) for the full cohort. Hospital stay was significantly shorter for the MagDI-after-SG patient group ( $n = 19$ ) with a median time of 1 day ( $1.1 \pm .1$ ) compared to the MagDI + SG group ( $n = 24$ ) median stay of 3.5 days ( $6.0 \pm 1.7$ ) ( $P < .01$ ). The time to device expulsion (self-

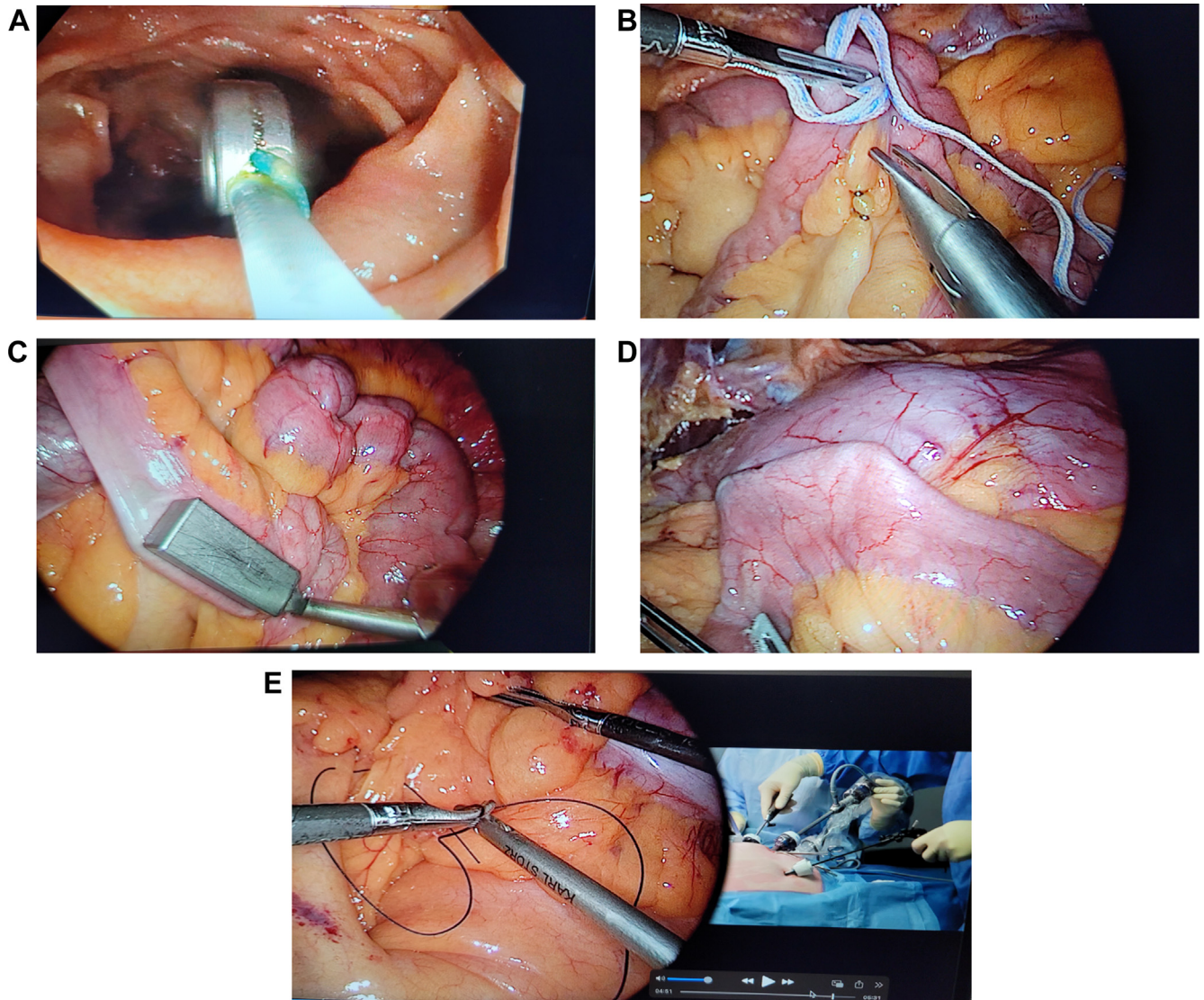


Fig. 2. Intraoperative imaging of endoscopic technique with laparoscopic support in formation of side-to-side linear Magnet Anastomosis System duodeno-ileostomy: (A) The distal magnet is transported from the duodenum to the proximal jejunum attached to a catheter within the flexible endoscope; (B) titanium clips are positioned on the ileal mesentery 250 cm from the ileocecal valve; (C) a laparoscopic positioning device transports the endoluminal magnet from the proximal jejunum to the ileum where marking clips have been positioned; (D) after a proximal magnet is placed in the duodenum, the two magnets are unified by bringing the ileum ante-colic and anterior to the first part of the duodenum (micro-positioning enables placement of the magnet pairing approximately 2 cm distal to the pylorus); (E) Petersen's mesenteric defect is closed with nonabsorbable running suture on the left side, uniting the mesentery of the transverse colon with the mesentery of the ileum. Reprinted with permission: Gagner M, Almutlaq L. MagDI: Laparoscopic/endoscopic magnetic side-to-side duodeno-ileostomy. ASMBS Annual Congress: Top Videos Session. 2023 June 27.

report) ranged from 14 to 92 days. The MagDI-after-SG group experienced device expulsion at a median 35 days ( $39.0 \pm 4.6$ ) and the MagDI + SG group at a median 48.5 days ( $48.2 \pm 4.7$ ) ( $P < .01$ ) (Table 1). Expulsion was confirmed through imaging.

### Complications

Among 64 AEs reported in the study, complications were significantly fewer in the MagDI-after-SG group (10.9%, 7/64) than in the MagDI + SG cohort (89.1%, 57/64) ( $P <$

.001). There were 25 CDC grade I (39.1%, 25/64), 24 grade II (37.5%, 24/64), 15 grade III (23.4%, 15/64), and 0 grade IV or V (.0%, 0/64) events. Twenty-eight (43.8%, 28/64) of these were associated with the surgical procedure. No (.0%, 0/64) adverse events were related to the MS device itself. There were no anastomotic bleeds, leaks, obstruction, or infection and no deaths.

Among AES, there were 7 serosal tissue tears (CDC grade III) prior to closing the study procedure; none reached the designation of SAE. These events were related to the use of laparoscopic bowel forceps to manipulate the intestines

Table 1  
Patient characteristics and perioperative outcomes

Characteristics	Side-to-side MagDI- <i>after</i> -SG (revision) n = 19	Side-to-side MagDI + SG (concurrent; primary) n = 24	P value
<b>Preoperative</b>			
Age, yrs, mean $\pm$ SEM (range)	43.7 $\pm$ 2.0 (28.0–57.0)	43.7 $\pm$ 1.8 (28.0–59.0)	.981
Females, n (%)	18 (94.7)	20 (83.3)	.363
Ethnicity			
Caucasian, n (%)	18 (94.7)	18 (75.0)	.112
Not offered, n (%)	1 (5.3)	6 (25.0)	
Height, cm, mean $\pm$ SEM (range)	161.5 $\pm$ 2.8 (125.0–184.0)	165.5 $\pm$ 1.6 (154.0–185.0)	.204
Weight, kg, mean $\pm$ SEM (range)	107.3 $\pm$ 5.2 (69.6–156.5)	121.9 $\pm$ 3.3 (97.0–155.0)	<.05
BMI, kg/m <sup>2</sup> , mean $\pm$ SEM (range)	41.0 $\pm$ 1.4 (30.2–52.3)	44.4 $\pm$ .8 (36.8–50.9)	<.05
Waist circumference (cm), mean $\pm$ SEM (range)	124.1 $\pm$ 3.6 (97.0–150.0)	128.1 $\pm$ 2.7 (109.0–163.0)	.459
Ideal weight kg, mean $\pm$ SEM (range)	65.5 $\pm$ 2.2 (39.1–84.6)	68.6 $\pm$ 1.4 (59.3–85.6)	.223
Excess weight, kg, mean $\pm$ SEM (range)	41.8 $\pm$ 4.0 (13.1–81.7)	53.4 $\pm$ 2.4 (32.2–71.1)	<.05
Type 2 diabetes, n (%)	1 (5.3)	9 (37.5)	<.05
HbA <sub>1c</sub> , %, mean $\pm$ SEM	7.1 (–)	6.2 $\pm$ .3 (5.0–10.0)	NA
Glucose, %, mean $\pm$ SEM	119.6 (–)	112.7 $\pm$ 5.8 (82.0–178.8)	NA
<b>Perioperative</b>			
Operative time, min, mean $\pm$ SEM (range)	67.0 $\pm$ 4.7 (33.0–120.0)	175.1 $\pm$ 8.6 (99.0–250.0)	<.001
Hospital stay, days, mean $\pm$ SEM (range)	1.1 $\pm$ .1 (1.0–2.0)	6.0 $\pm$ 1.7 (2.0–40.0)*	<.01
Expulsion of magnets, days, mean $\pm$ SEM (median)	39.0 $\pm$ 4.6 (35.0)	48.2 $\pm$ 4.7 (48.5)	<.05

BMI = body mass index; HbA<sub>1c</sub> = glycosylated hemoglobin; SEM = standard error of the mean; NA = not applicable (insufficient sample size for comparison).

\* Outliers: (severe adverse events = 24 d, pelvic collection (first episode); 40 d, pneumoperitoneum + pneumonia).

during the grasp-and-pull maneuver to move the intraluminal distal MS magnet to the target ileal position; all tears were repaired during the procedure without sequelae. Eight additional CDC grade III events included a case of abdominal pain with nausea and vomiting, acute cholecystitis, cholecystolithiasis with choledocholithiasis, substenosis at the mid-section of the new gastric sleeve, a jejunal intestinal

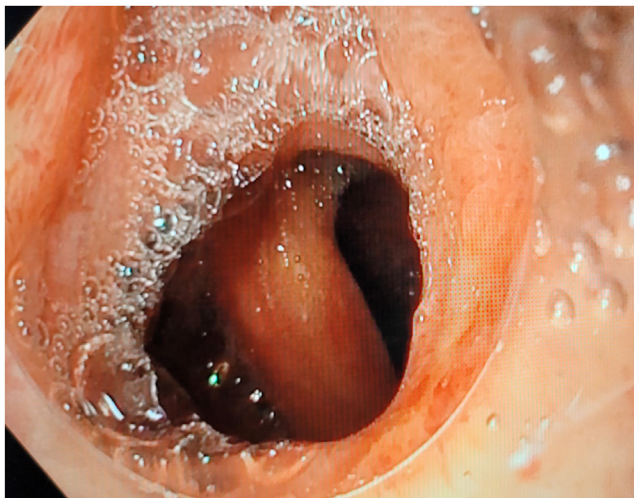


Fig. 3. Endoscopic view of a patent side-to-side duodeno-ileal anastomosis formed with the Magnet Anastomosis System from the pylorus looking distally toward the first part of the duodenum.

obstruction (at the mesenteric defect post closure), kidney stones, a major pneumoperitoneum, and a pelvic collection.

By protocol definition, 11 CDC grade II and III events met criteria as SAEs (not device related); 3 in the MagDI-*after*-SG group and 8 in the MagDI + SG group. SAEs are presented in Table 2 by CDC grade, relatedness to the procedure, and severity assessment. Three of the SAEs (4.7%, 3/64), all in the MagDI + SG group, were determined to be related to the surgical procedure (not device). The first of these was a urinary tract infection with persistent fever presenting on post-operative day 1 that prolonged hospitalization, was treated with fosfomycin, and resolved. The second event was a case of pelvic fluid collection accompanied by fever with inflammatory syndrome, tachycardia, and desaturation on post-operative day 2. The patient was found to have free liquid in the pelvis, which was treated by the gynecology team over a few months. The patient recovered following two transvaginal drainage procedures, although no definitive cause of the collection was identified. The third AE was a jejunal obstruction by an internal hernia at the mesentery despite mesenteric defect closure during the procedure by the investigator. Laparoscopic repair was performed, and the patient was discharged on the second day without sequelae.

#### Secondary efficacy endpoints

##### Weight

Weight outcomes at 3- and 6-month follow-up timepoints for the two treatment groups are presented in Table 3 and

Table 2  
Clavien-Dindo classification grade II and III 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 day 1 after MagDI + SG study, prolonging hospitalization. Urinary analysis confirmed infection; treated with 1 dose Fosfomycin; resolved without sequelae.
Dehydration	II Moderate	No	No	Post MagDI + SG, patient hospitalized for dehydration and hypokalemia outside country 67 d (holiday); hospitalized again for nausea, vomiting, abdominal pain with suspicion of gastritis; hypokalemia was supplemented, event resolved.
Post-SG anorexia + diarrhea, nausea, vomiting	II Moderate	No	No	Patient presented with diarrhea 54 d post MagDI + SG procedure: stools watery, not bloody, $\geq 7$ episodes/. 2 d later, vomiting began with dehydration, anorexia, dizziness. Abdominal CT showed no features or perforation. Hospitalized for monitoring with rehydration, IV antiemetics; symptoms resolved.
II obstruction on flange	III Mild	Yes	No	At MagDI + SG procedure, mesenteric defect closed per protocol. Patient presented 115 d 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	Post MagDI + SG day 2, fever; antibiotics restarted. CT revealed major pneumoperitoneum. No leakage on laparoscopy. Sepsis developed; started amukin. Thoraco-abdominal CT showed no leakage or infiltration, but bi-basal pneumonia; treated with antibiotics. CT revealed fistula on left SG edge + localized abscess. Stents placed and removed. Lower esophageal prostheses placed at EGJ. Persistent paraesophageal fistula with leak. Stents removed; two stents placed in fistula. On CT no findings; patient discharged.
Pelvic fluid collection	III Severe	Yes	No	Day 2 post MagDI + SG, patient developed fever + inflammatory syndrome, tachycardia, desaturation (7-18-22). CT showed free liquid in pelvis; antibiotics started. Persistent inflammatory syndrome; 2nd CT pelvic collection drained transvaginally. Bleeding 2 d after; stiches placed at vaginal incision. After 2nd fever, antibiotics changed. Good evolution, discharged (8-11-22). Patient to ER 10-24-22 with fever, purulent vaginal bleeding. Pelvic collection on CT drained transvaginally. Discharged 10-1-22.
Cholecysto-lithiasis + choledocho-lithiasis	III Severe	No	No	Patient presented July 2022 with abdominal pain upper right quadrant 2 mo after MagDI + SG. Choledocholithiasis with gallstones in gallbladder. Patient underwent ERCP + sphincterotomy in July; scheduled for cholecystectomy in Oct. In August, 2nd episode of choledocholithiasis; 2nd ERCP in Sept., cholecystectomy.
Abdominal pain + nausea and vomiting	III Severe	No	No	Post MagDI + SG procedure 4 mo, patient complaints of abdominal pain on right side increasing for 2 d. Unable to eat/drink for 2 d since surgery. Hospitalized; gastroscopy performed. Pain determined unrelated to study device or procedure.

(continued on next page)

Table 2 (continued)

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 d post MagDI-after-SG with heavy menstruation. Newly reported receiving a hormonal intrauterine device (IUD) though had not previously reported gynecological issues. Blood test results showed anemia, she was advised to go to ER. She will be followed for her pre-existing gynecological issues.
Cholecystitis	III Moderate	No	No	Patient went to ER with back and abdomen pain 113 d post MagDI-after-SG. Diagnosed acute cholecystitis, underwent cholecystectomy. The study P.I. presumed gallstones had been present before the study procedure.
Kidney stones	III Moderate	No	No	Patient presented and was diagnosed with kidney stones 108 d post MagDI-after-SG. I.M. anti-inflammatory medication given for pain control. The patient subsequently had surgery to remove four kidney stones and recovered without sequelae.

MS = Magnet System; DI = duodeno-ileostomy; SG = sleeve gastrectomy; JI = jejunioleal; D = day; EGJ = esophagogastric junction; ERCP = endoscopic retrograde cholangiopancreatography.

Clavien-Dindo Classification of surgical complications [21]: Grade I: 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. Grade II: Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions and total parenteral nutrition included. Grade III: Requiring surgical, endoscopic, or radiological intervention. Grade IV: Life-threatening complication (including certain central nervous system complications) requiring Intermediate Care/Intensive Care Unit-management. Grade V: Death of a patient.

**Fig. 4.** MagDI-after-SG group (n = 19) mean body weight was significantly reduced from 107.3 ± 5.2 kg at baseline to 102.3 ± 5.5 kg at 3-month follow-up (n = 18) ( $P < .05$ ). At 6 months, 13 MagDI-after-SG patients (follow-up rate: 68.4%) experienced an overall mean weight reduction from baseline of 8.0 ± 2.5 kg ( $P < .01$ ). The mean BMI reduction from baseline at 6-month follow-up in the MagDI-after-SG group was 3.0 ± .9 kg/m<sup>2</sup> ( $P < .01$ ). These changes equate to an overall mean EWL of 17.4 ± 5.9% and TWL of 7.0 ± 2.1% at 6 months. Also, at 6-month postprocedure, 69.2% (9/13) of patients in the MagDI-after-SG group achieved greater than 5.0% TWL with a maximum TWL of 21.5%.

Comparatively, the MagDI + SG group experienced significantly greater weight loss with a mean weight reduction from baseline of 34.2 ± 1.6 kg ( $P < .001$ ) at 6 months (100.0% follow-up): (Table 3). Mean BMI reduction at 6-month follow-up was 12.4 ± .4 kg/m<sup>2</sup> ( $P < .001$ ); respective mean EWL and TWL were 66.2 ± 3.4% and 28.1 ± 1.0%. Further, 100.0% (24/24) of patients in the MagDI + SG group surpassed the efficacy criterion of 5.0% TWL with values ranging from 20.5% to 37.6%. Weight trends for each treatment group are depicted in Fig. 4A–D.

Twelve-month weight follow-up is also presented in Table 3 and Fig. 4A–D for available MagDI + SG patients (n = 5), and data for MagDI-after-SG patients was tentatively projected out to 12 months using the existing 6-month data curve. By extrapolation, MagDI-after-SG mean weight may drop from 107.3 to 95.0 kg at 12 months, representing a BMI loss of 7.0 kg/m<sup>2</sup> with a corresponding TWL of 11.0% and EWL of 28.0%. In comparison, the MagDI + SG group demonstrated 12-month BMI loss of 15.1 kg/m<sup>2</sup> with a corresponding TWL of 34.0% and EWL of 80.2%.

#### Type 2 diabetes

Seventy-eight percent (7/9) of patients in the MagDI + SG group diagnosed with T2D were under treatment with anti-diabetic medications at enrollment. All seven (100.0%) were taking fewer T2D medications 6 months post procedure; 85.0% (6/7) had ceased all medications. Also, within the same time frame, MagDI + SG group mean HbA1C fell from 6.2 ± .3% to 5.1 ± .2% ( $P < .05$ ) and mean glucose fell from 112.7 ± 5.8 mg/dL to 86.5 ± 3.5 mg/dL ( $P < .001$ ). The one patient in the MagDI-after-SG group with confirmed T2D continued with anti-diabetic medications; however, patient HbA1c level fell

**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	3-mo follow-up			6-mo follow-up			12-mo follow-up		
		Mean ±SEM	Mean ±SEM	Mean change ±SEM (95%CI)	Within-group P-value <sup>†</sup>	Mean ±SEM	Mean change ±SEM (95%CI)	Within-group P-value <sup>†</sup>	Mean ±SEM	Mean change ±SEM (95%CI)	Within-group P-value <sup>†</sup>
MagDI- <i>after</i> -SG	Absolute weight, kg	107.3 ± 5.2 (n = 19)	102.3 ± 5.5 (n = 18)	5.1 ± 1.6 (1.7, 8.5)	<.05	101.6 ± 6.5 (n = 13)	8.0 ± 2.5 (2.6, 13.5)	<.01	95.0*	12.3*	<.01*
MagDI + SG		121.9 ± 3.3 (n = 24)	99.8 ± 3.0 (n = 23)	23.2 ± .9 (21.2, 25.2)	<.001	87.8 ± 2.8 (n = 24)	34.2 ± 1.6 (30.9, 37.4)	<.001	77.6 ± 4.7 (n = 5)	40.0 ± 3.1 (31.4, 48.6)	<.001
Between-group P-value <sup>‡</sup>	—	<.05	.677	—	—	<.05	—	—	<.05*	—	—
MagDI- <i>after</i> -SG	BMI, kg/m <sup>2</sup>	41.0 ± 1.4 (n = 19)	39.2 ± 1.5 (n = 18)	1.9 ± .6 (.7, 3.3)	<.05	37.6 ± 1.6 (n = 13)	3.0 ± .9 (1.0, 5.0)	<.01	34.0*	7.0*	<.01*
MagDI + SG		44.4 ± .8 (n = 24)	36.3 ± .8 (n = 23)	8.5 ± .3 (7.8, 9.1)	<.001	32.0 ± .8 (n = 24)	12.4 ± .4 (11.5, 13.3)	<.001	29.3 ± 1.5 (n = 5)	15.1 ± 1.0 (12.2, 18.0)	<.001
Between-group P value <sup>‡</sup>	—	<.05	.066	—	—	<.01	—	—	<.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- <i>after</i> -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 ± .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 <sup>‡</sup>	—	<.001 <sup>§</sup>	<.001	<.001	<.001 <sup>§</sup>	<.001	<.001	<.001 <sup>§*</sup>	<.001*	<.001*	

BMI = body mass index; TWL = total weight loss; EWL = excess weight loss; SEM = standard error of the mean.

\* 12-mo follow-up for MagDI-*after*-SG is projected only (extrapolated trend from existing data).

<sup>†</sup> Paired-samples *t* test (change from baseline).

<sup>‡</sup> Independent-samples *t* test.

<sup>§</sup> Chi-square test.

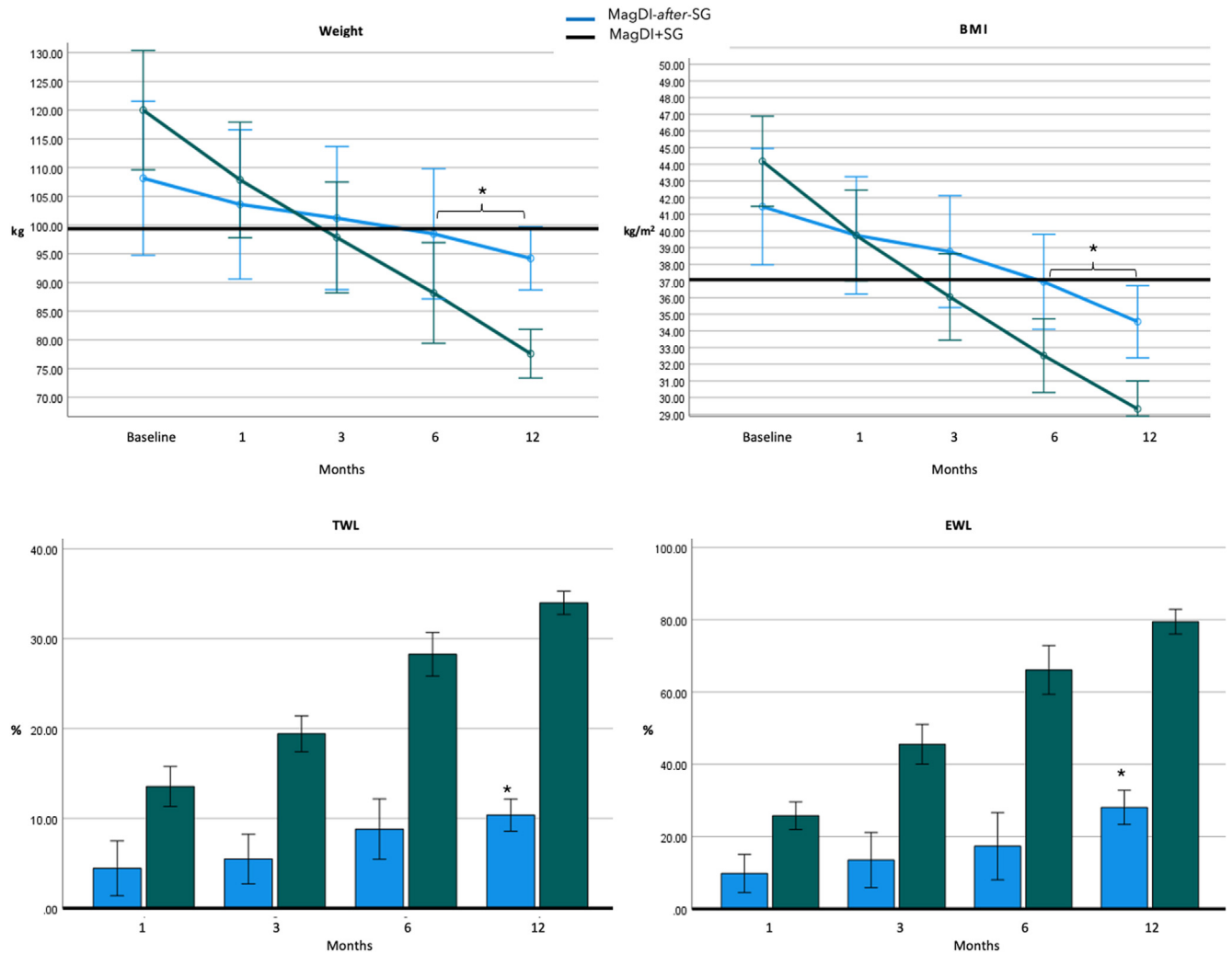


Fig. 4. Weight trends for side-to-side Magnet Anastomosis System duodeno-ileostomy with sleeve gastrectomy groups (MagDI-after-SG and MagDI + SG) in terms of absolute weight; body mass index (BMI, kg/m<sup>2</sup>); total weight loss (%TWL); and excess weight loss (%EWL). Blue line or bar denotes MagDI-after-SG; green line or bar denotes MagDI + SG. Asterisk (\*) indicates extrapolated results.

from 7.1% at baseline to 5.4% at 6-month follow-up and glucose fell from 119.6 mg/dL to 73.4 mg/dL.

## Discussion

The linear Magnet Anastomosis System was designed to reduce surgical complications associated with conventional anastomosis formation. Its use in creating a DI is technically simpler than that of other single-anastomosis procedures such as SADI-S and single-anastomosis sleeve ileal bypass (SASI) [22,23]. Investigators at the four centers found the MS feasible to use in constructing the DI bipartition. Incisionless, sutureless placement of the MS was well tolerated, magnets were expelled naturally without migration, erosion, or pair separation. Anastomoses were durably patent through 6 months and required no surgical reintervention in 100.0% of the 43 patients. No

anastomotic leaks, bleeding, obstruction, infection, or death occurred in either treatment group. The 3 CDC grade II and III SAEs in the MagDI-after-SG group and 8 in the MagDI + SG group were not related to the MS device. While preliminary at 3–6 months, a small significant weight reduction was observed in the MagDI-after-SG cohort that was additive to pre-existing weight loss from the initial SG.

Clinical magnetic DI bipartition was performed by one other team in a study of 8 patients with no prior SG (median BMI 38.8 kg/m<sup>2</sup>) [24]. An octagonally shaped proximal magnet was delivered to the duodenum endoscopically and a distal magnet to the ileum laparoscopically using a 5-mm ileotomy; magnets were joined and effected patent anastomoses. However, closure using absorbable suture introduces the possibility of leak near, or at the DI site. In the current study, magnetic DI was performed without

enterotomy using laparoscopic assistance only to position and align the linear MS magnets in the small bowel segments; the intestinal barrier was not crossed.

As expected, MagDI + SG operative duration was significantly longer than that of solo MagDI-after-SG. MagDI + SG hospital stay was similar to that of SADI-S (2 days) and SASI (3.2 days) [21]. An unexpected benefit of MagDI-after-SG was the significantly more rapid expulsion of fused magnets (median 35 days) than that observed with primary MagDI + SG (median 48.5 days).

Ongoing innovation in MIS technique to secure the long-term patency of the anastomosis is a vital focus for MBS. In a recent meta-analysis of 16 studies, 10 DI anastomotic leaks were reported [25]. In the current study, MagDI was associated with several nonanastomotic AEs that required postoperative care. However, no AEs frequently associated with stapled/sutured enterotomies were present, nor were reoperations required. AEs and SAEs were primarily related to the SG, a finding reinforced by the much-reduced incidence of AEs demonstrated in the context of independent MagDI-after-SG. The markedly lower morbidity in this group illuminates the protective contribution of magnetically performed DI.

Weight loss with MagDI-after-SG was not expected to be comparable to primary MagDI + SG at 3–6 months, yet patients experienced a small significant absolute weight loss and BMI reduction and corresponding increases in TWL and EWL. While weight loss was less, and slower to occur in MagDI-after-SG, the modest improvement in weight parameters was additive to that of the index SG. As is typical of MBS procedures, weight loss is likely to continue through 1 year, and perhaps, as observed after second-step SADI-S and SASI, through 2 years [26–29]. In the extrapolation of the MagDI-after-SG 6-month data curve out to 1 year, a total mean BMI loss from baseline of 7.0 kg/m<sup>2</sup> was posited, representing an overall EWL of 28.0%. Primary 12-month MagDI + SG EWL of 80.2% exceeded that of other single-anastomosis procedures at 12 months (e.g., SADI-S and SASI EWL: 74.1% and 77.4% at 12 months, respectively, by a systematic review and a separate meta-analysis) [21,25].

Very good T2D resolution was also seen in MagDI + SG patients (85.0%). The lack of patients with T2D for analysis in the MagDI-after-SG group was due to its resolution in the majority of patients following their index SG.

### Limitations

Limitations of this study include the small size of the two groups and lack of a randomized design; thus, reporting of preliminary trends was appropriate. Future studies would benefit from collection of nutritional data to elucidate patients' altered chemistry profile following side-to-side MS

DI bipartition to compare with that of other SG-based single-anastomosis procedures.

### Conclusions

In a multicenter study with a small sample size, the incisionless, sutureless Magnet Anastomosis System in concurrent DI + SG appeared to offer a safe, effective option for the indication of obesity with T2D. At short-term follow-up, independent side-to-side MagDI seemed to provide an effective, low-risk second step after inadequate SG. In both groups, the Magnet System formed patent, complication-free anastomoses.

### Disclosures

*Michel Gagner has numerous patents related to magnetic technology, is a cofounder of GT with stock options, and is a consultant for Medtronic, Inc. and Lexington Medical, Inc. with stock options in Lexington Medical, Inc. Lamees Almutlaq holds stock options in GT Metabolic Solutions. Guy-Bernard Cadière is a consultant for GT Metabolic Solutions and member of its scientific advisory board without remuneration. Antonio Torres is a GT consultant and has received a grant from GT Metabolic Solutions. Andres Sanchez-Pernaute is a GT consultant and has received fees from Novo Nordisk, Medtronic, Johnson & Johnson, and Gore Medical. Jane Buchwald is a GT consultant with stock options; she received recent grants from Ethicon, Inc., M.I.D., Society of Bariatric and Metabolic Surgeons of Kazakhstan, Holy Family Hospital, Israel, and Clinique de la Sauvegarde. David Abuladze is a GT consultant without remuneration.*

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### Editorial comment

## Comment on: 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

Although bariatric surgery is generally considered very safe, there remains a real risk of adverse events related to anastomotic leaks. Recent systematic reviews and meta-analyses have demonstrated that leak rates after gastric bypass range from approximately .7%–1.0% [1,2]. Studies suggest that leaks are more common in patients with multiple comorbidities and after open or revisional surgery [1,2], and other studies suggest that technique-specific factors and device-specific factors do not contribute to the development of leaks [3]. Ongoing work is dedicated to mitigating the risk of this complication through the creation of novel anastomotic techniques, focusing on incisionless, suture-less,

and staple-less methods [4]. Thus, the question persists: what is the best technique for anastomoses in bariatric surgery?

In this issue of *Surgery for Obesity and Related Diseases*, Gagner et al. performed a multicenter prospective clinical study evaluating a novel magnetic compression device for the creation of primary and revisional magnetic side-to-side duodeno-ileostomy anastomoses (MagDI). MagDI was performed without enterotomy using laparoscopic assistance to endoscopically position and align the magnets in the small bowel. The difficulty in this technique, though emphasized by the authors to be easier than a traditional