

GI MAGNETS

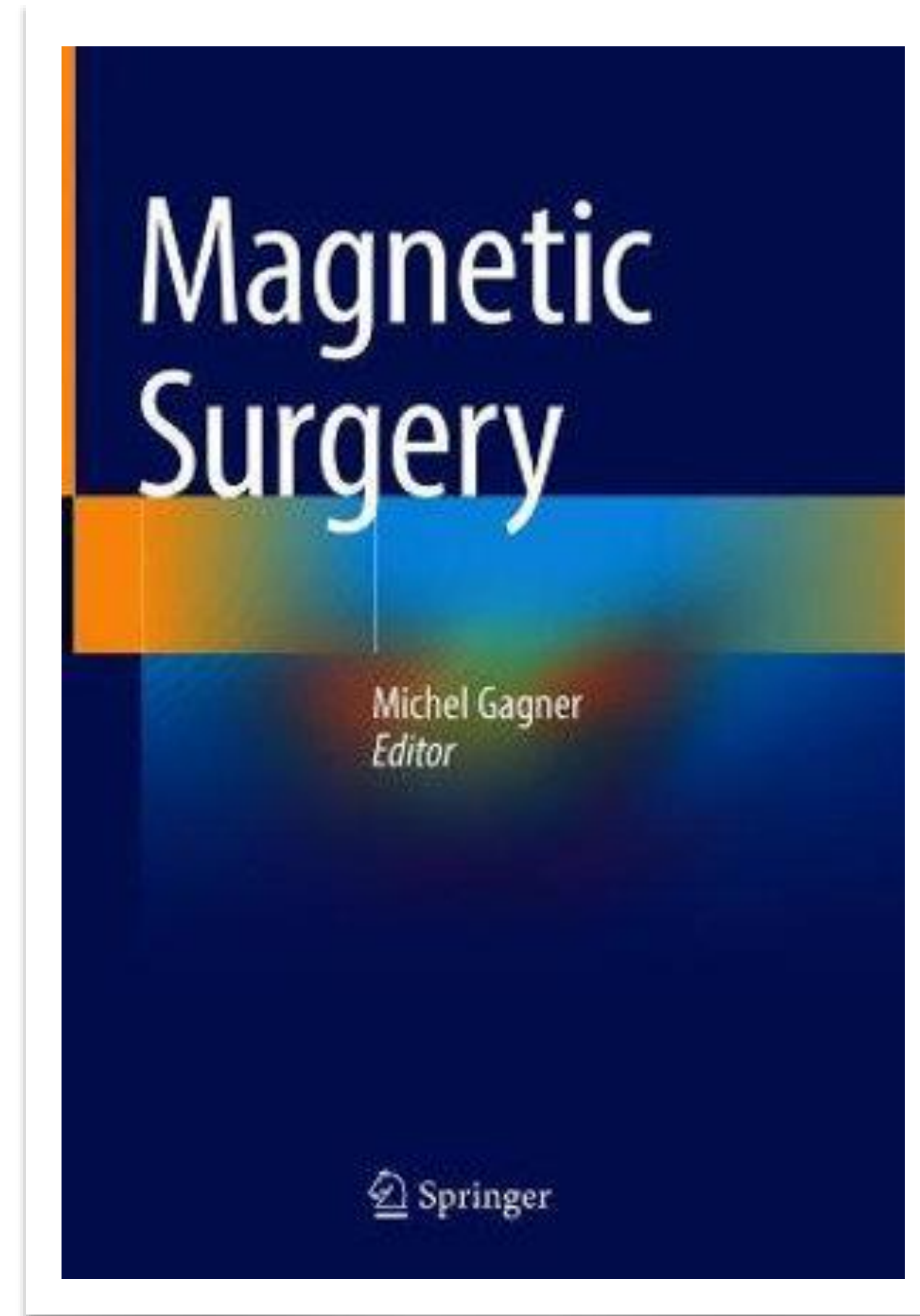
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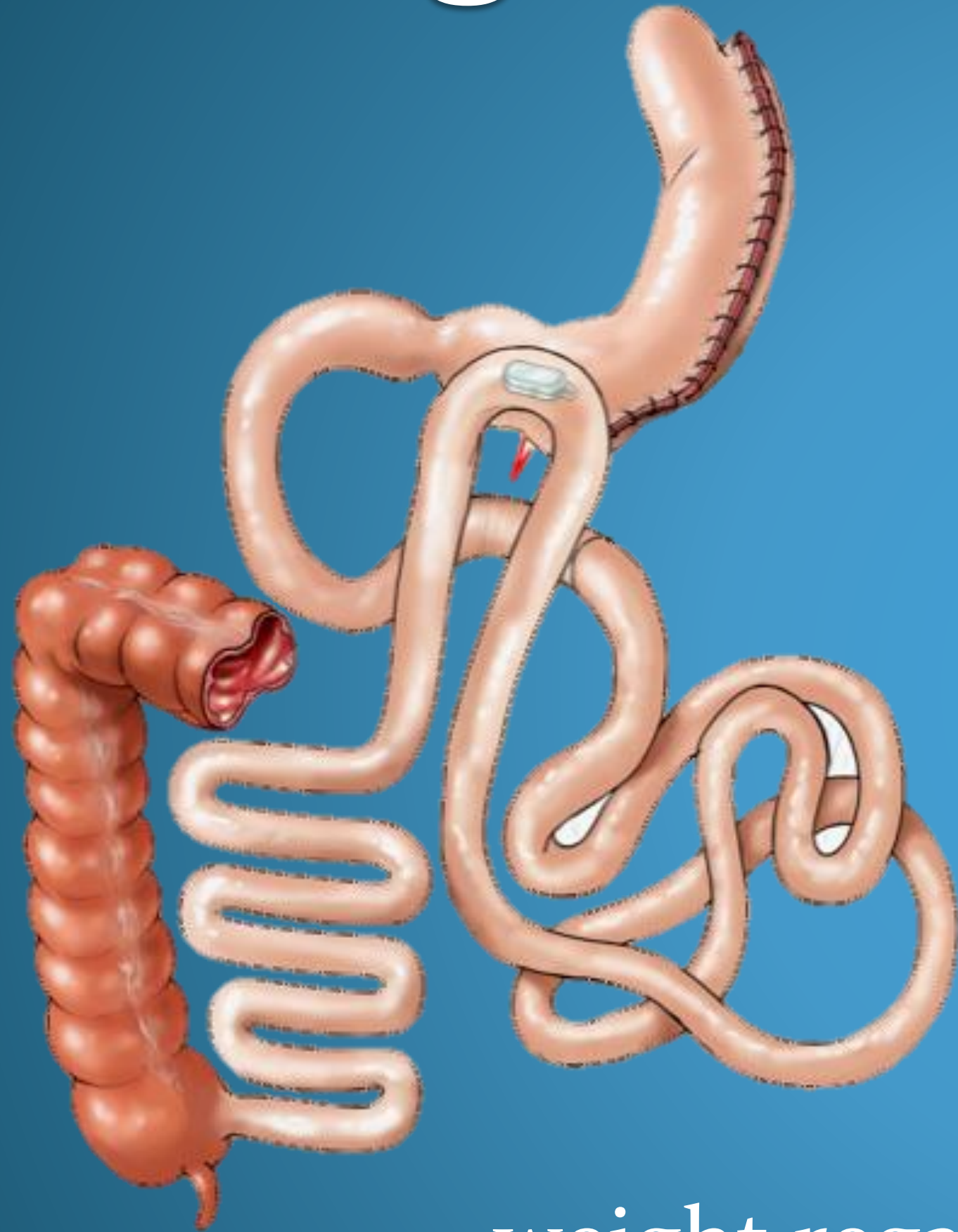
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Disclosures

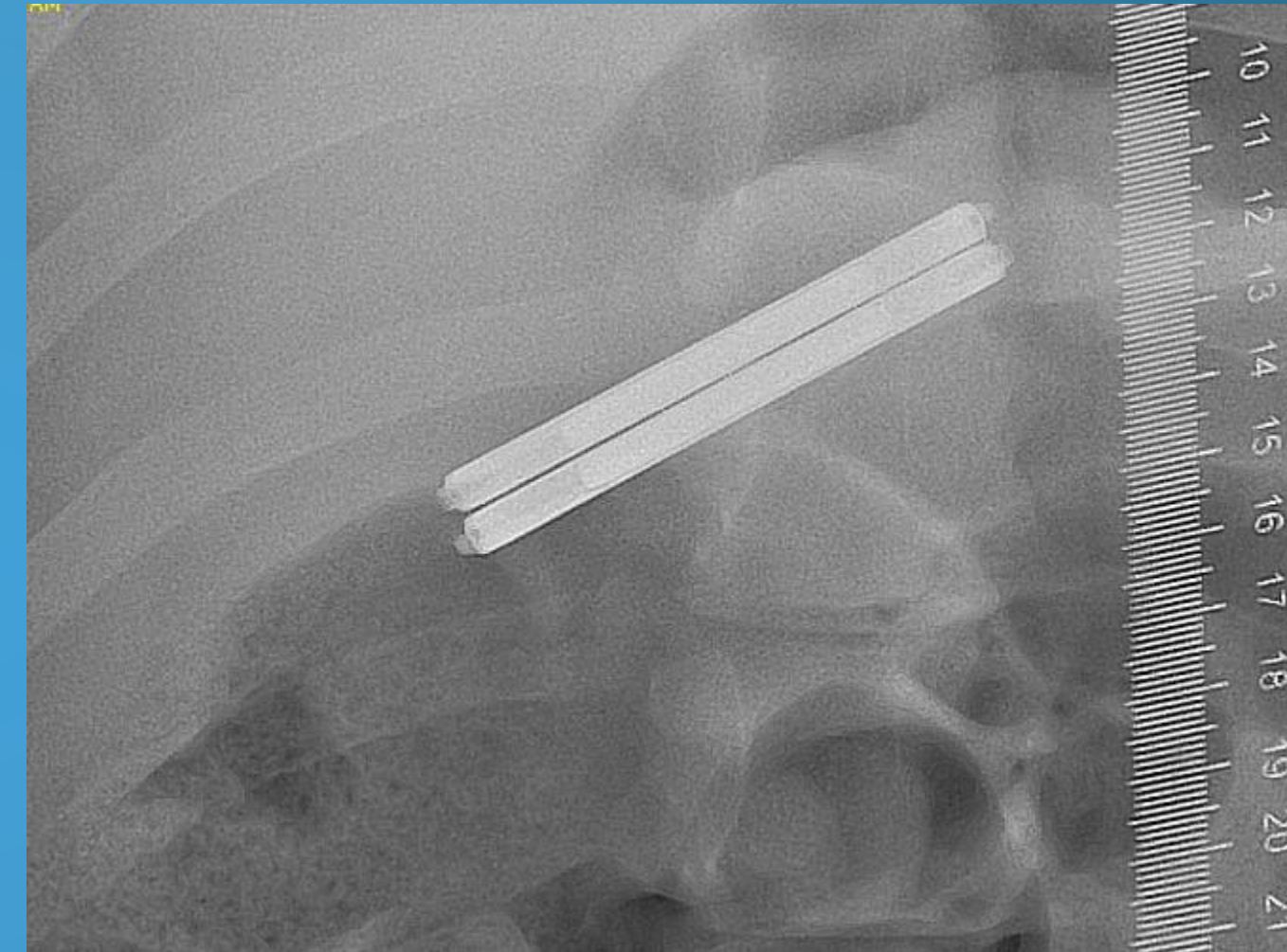
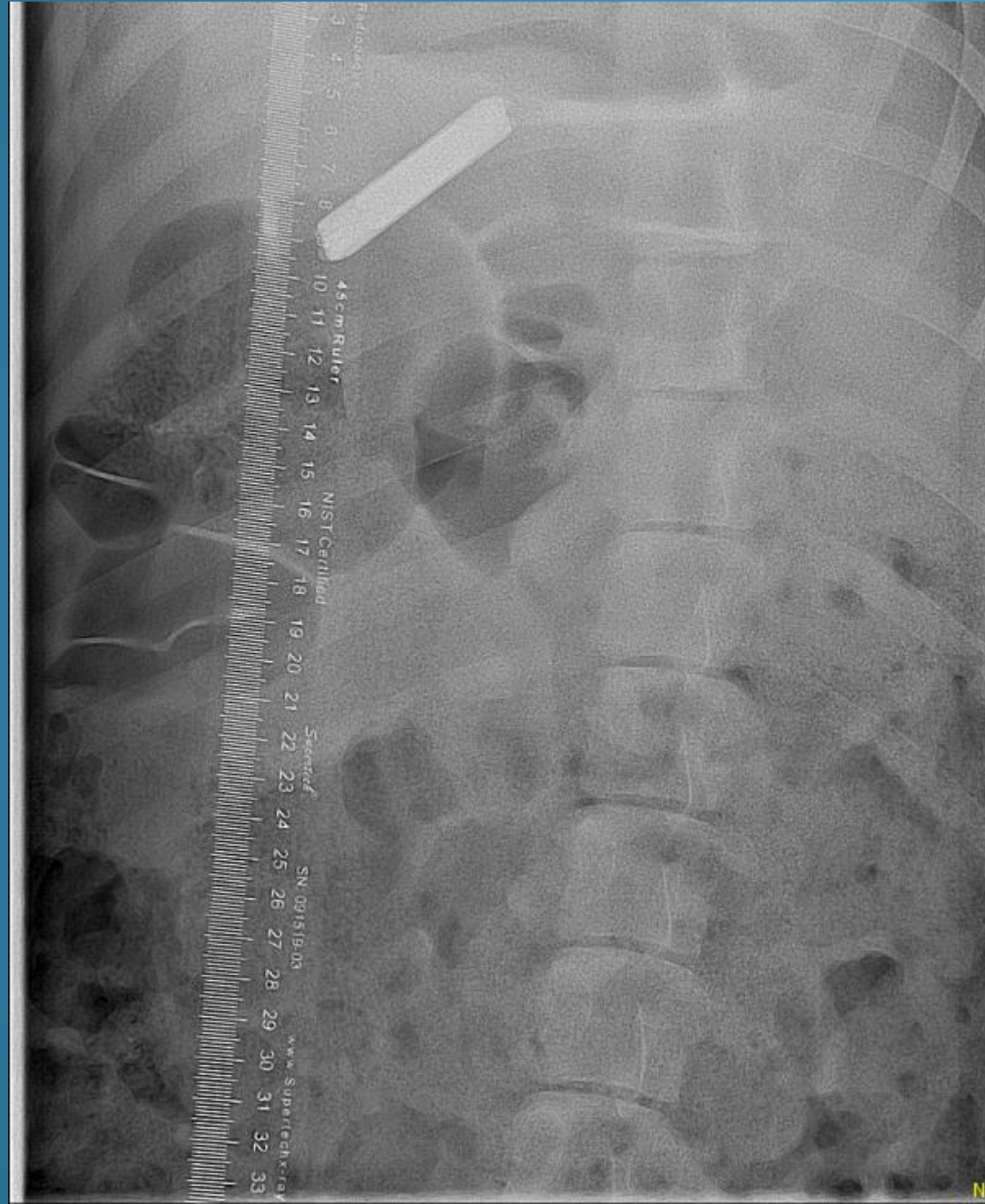
- Stock ownership:
- Lexington medical
- GT Metabolic



Magnetic Gastro-Ileostomy (MAGGI)



In patients post Sleeve Gastrectomy
weight regain or failure to lose adequate weight
Lower antrum and ileum at 250-350 cm (SASI)

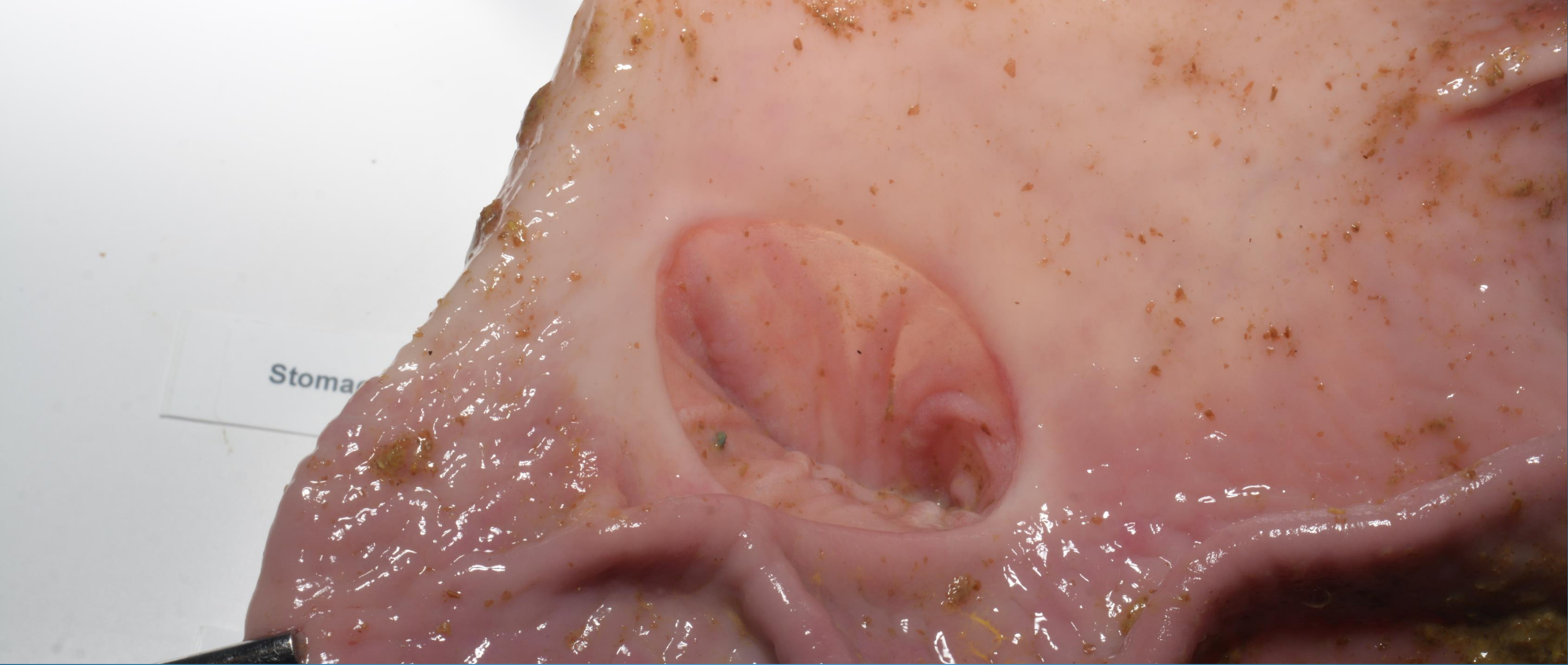


POD #06











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SURGERY FOR OBESITY
AND RELATED DISEASES

Original article

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

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Abstract

Background: Means of addressing technical challenges in forming gastrojejunostomy (GJ) anastomoses and maintaining their patency are sought.

Objectives: Evaluation of preclinical feasibility and healing efficacy of a novel linear magnetic compression anastomosis (MCA) device to form a patent GJ versus sutured jejunal enterotomy (JE) sites in swine.

Setting: Single-center veterinary testing facility.

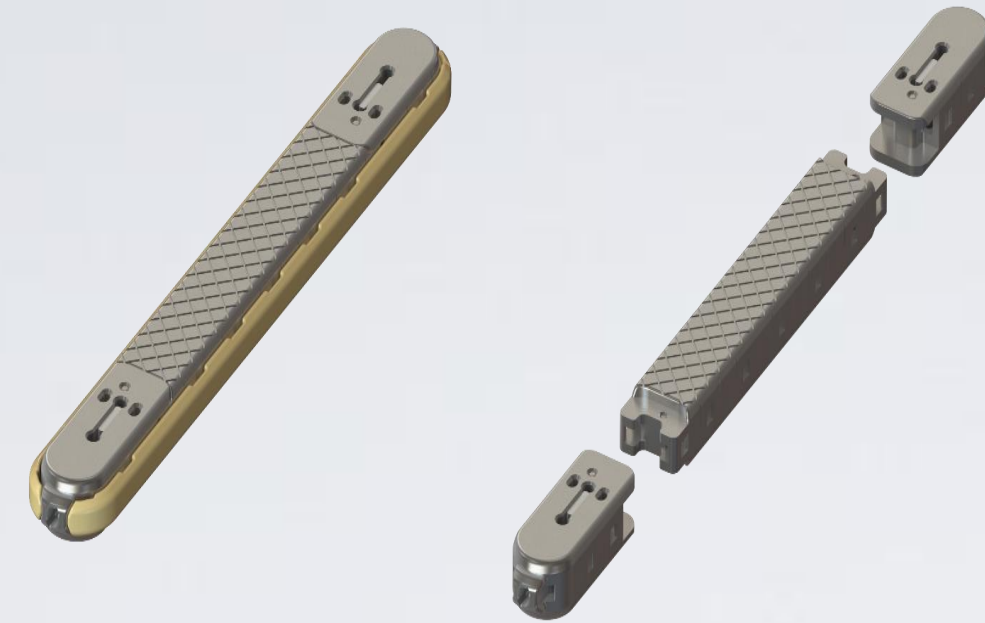
Methods: Feasibility of 3 prototype sizes (4, 6, and 8 cm) of a metal MCA device (MCAD) to form a patent GJ was evaluated over 6 weeks. A distal magnet was laparoscopically inserted in the jejunum, a proximal magnet was placed gastroscopically in the stomach; magnets were aligned to gradually form an anastomosis, self-detached, and be expelled. At necropsy, MCAs were assessed for patency and compared with JE tissues to evaluate wound healing.

Results: MCADs aligned at the GJ location without complications. In 5/6 MCAD pairs, dislodgement occurred between 7 and 26 days; expulsion 13–31 days; 1 MCAD pair was retained in the stomach. At necropsy, all pigs were healthy, gaining a mean 15.0 kg. Anastomoses were not adequately patent in 2/4 pigs receiving the 4-cm or 6-cm MCADs because their linear length was too small. But, anastomoses of both pigs receiving the 8-cm MCADs maintained full patency. Minimal inflammation and fibrosis were seen in MCA specimens versus sutured enterotomies.

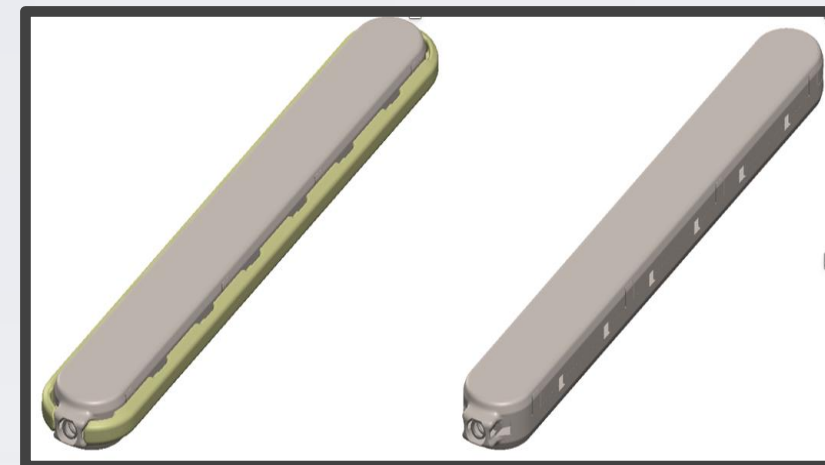
Conclusions: A novel linear MCA device was feasible and effectively created a patent GJ anastomosis in swine with minimal inflammation and fibrosis. The MCAD may be appropriate for

Biofragmentable Magnet

80mm
Magnet

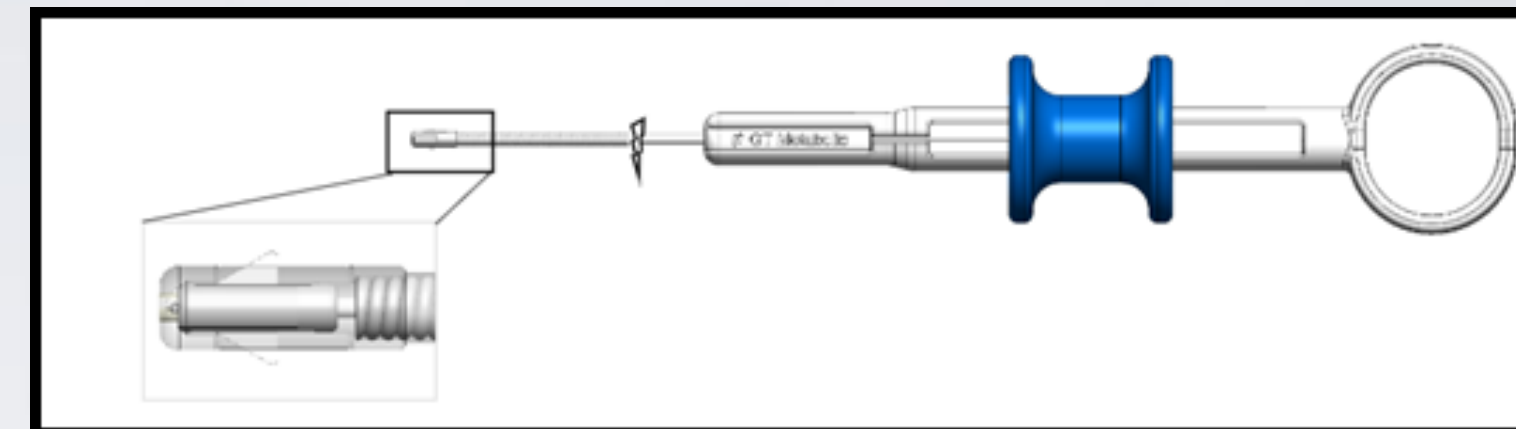


60mm and
70mm
Magnets
(same design)



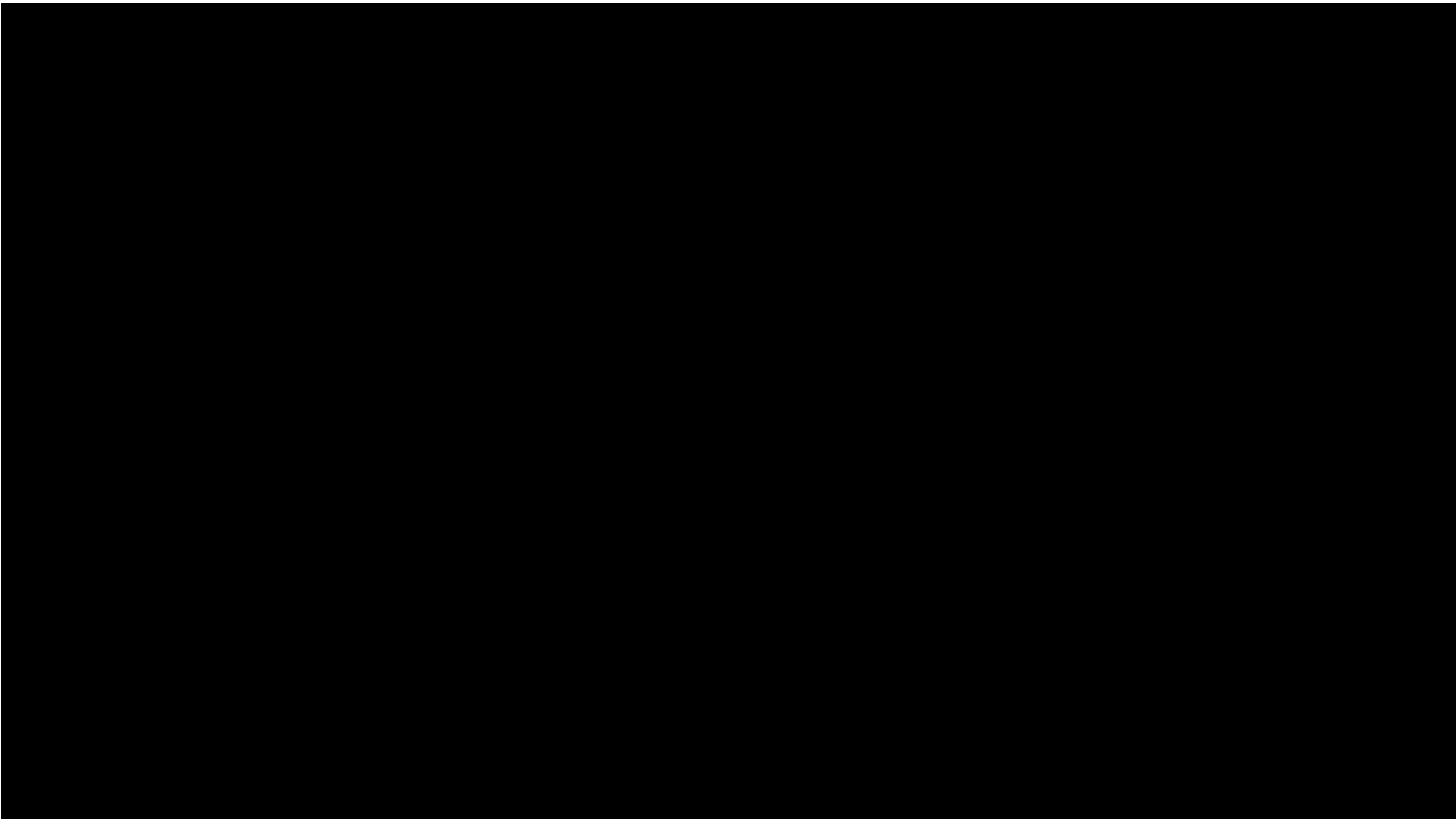
Assembly (left),
Post PGLA fragmentation (right)

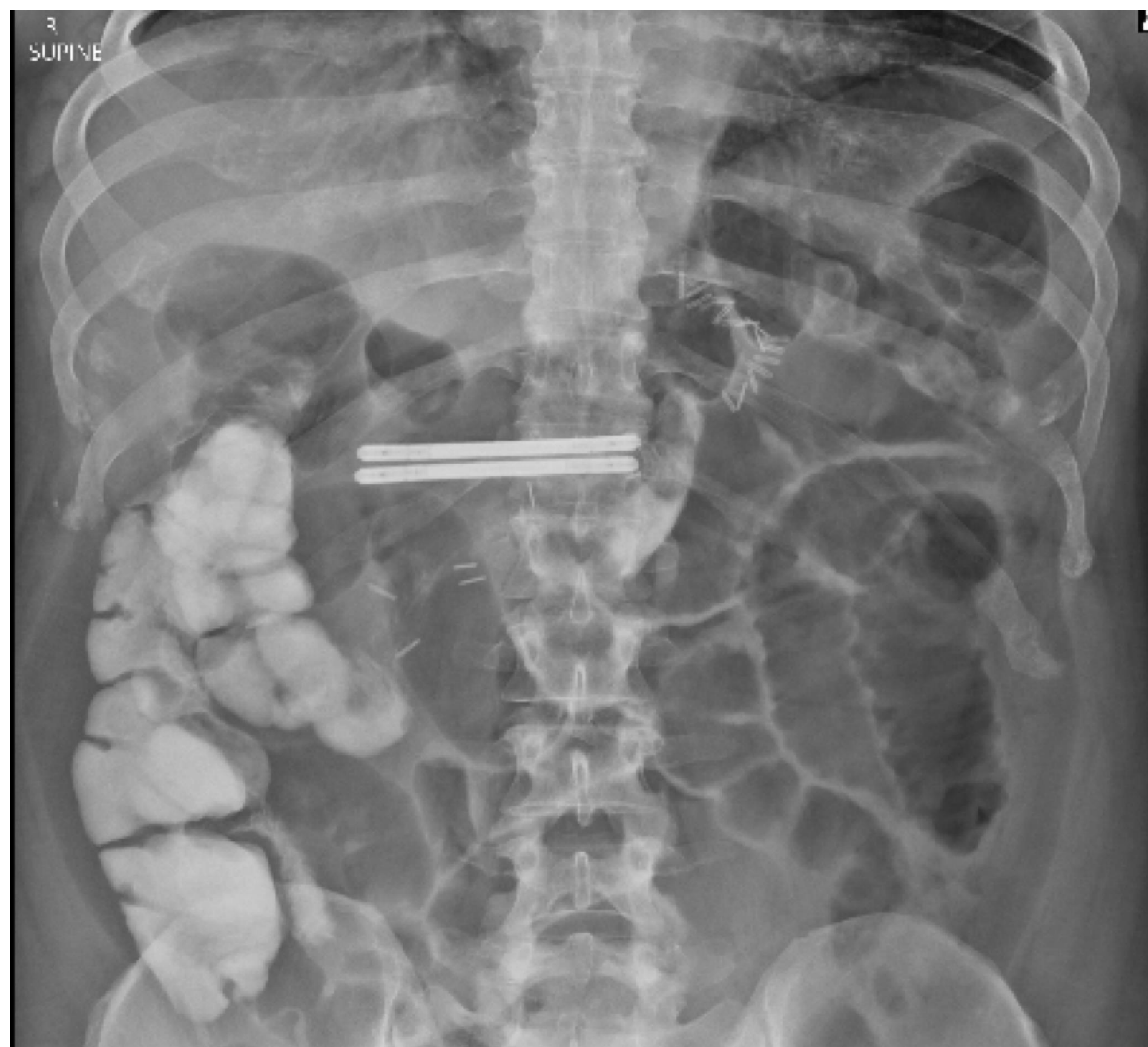
Magnetic Anastomosis Delivery System

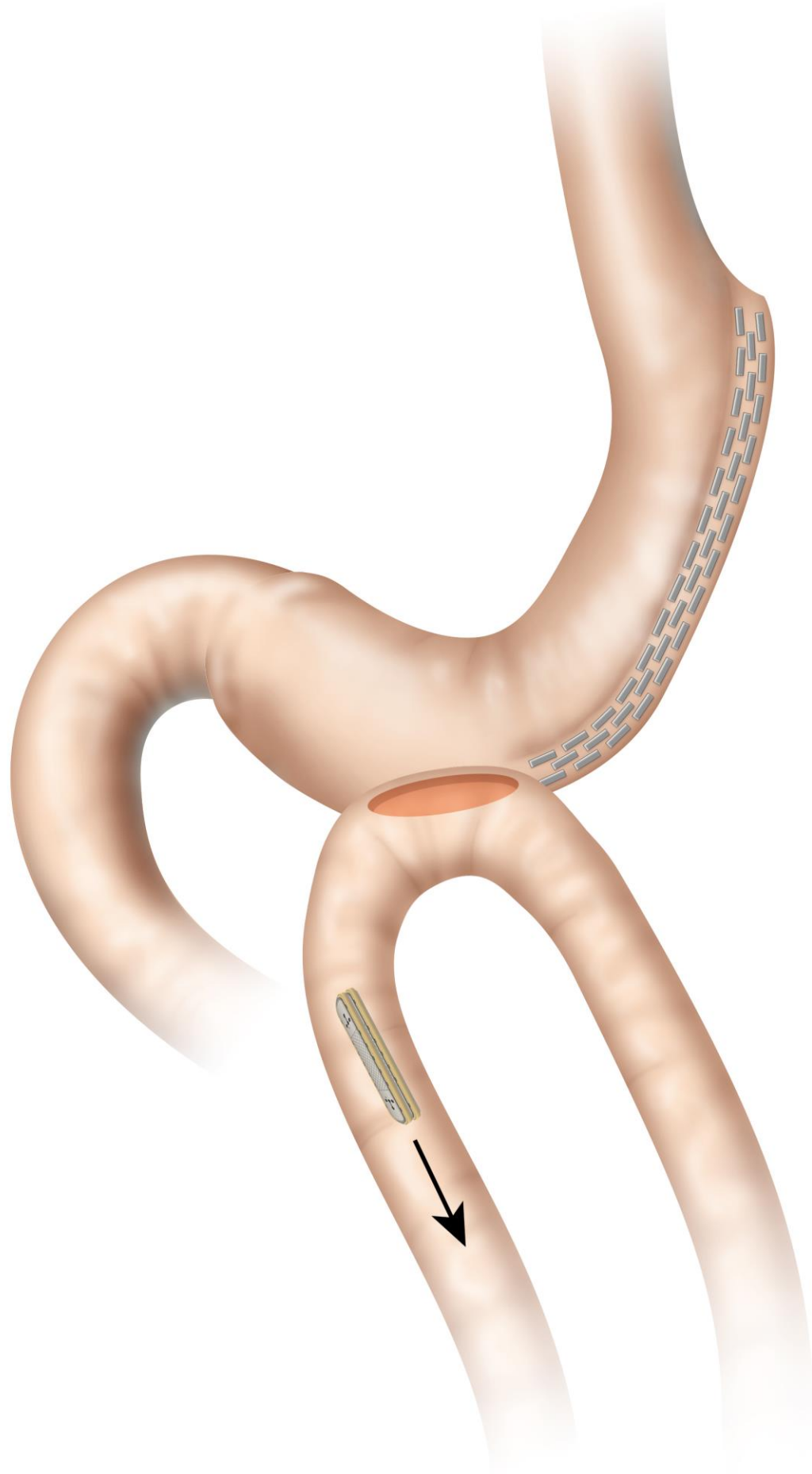


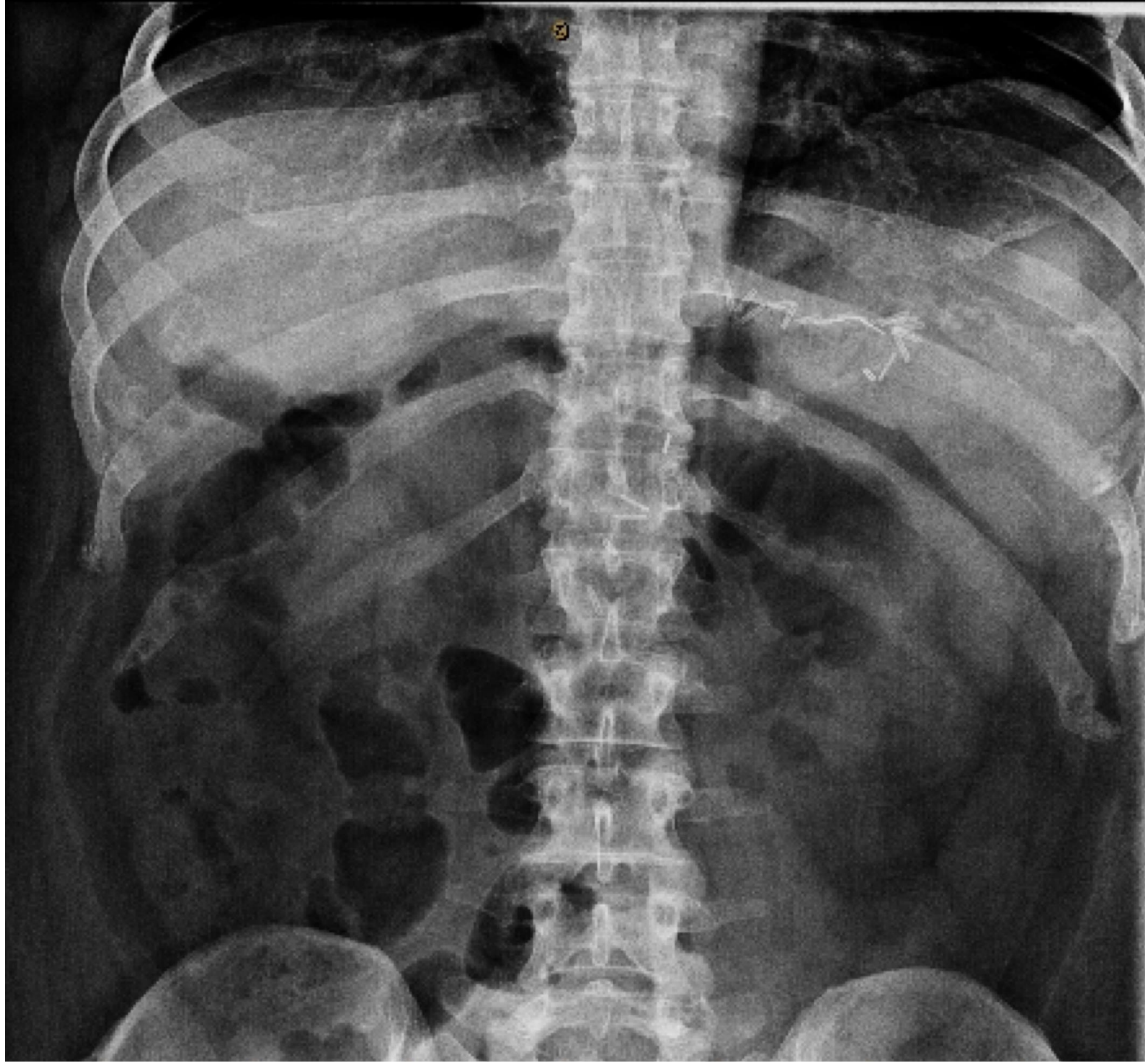
Laparoscopic Positioning Devices

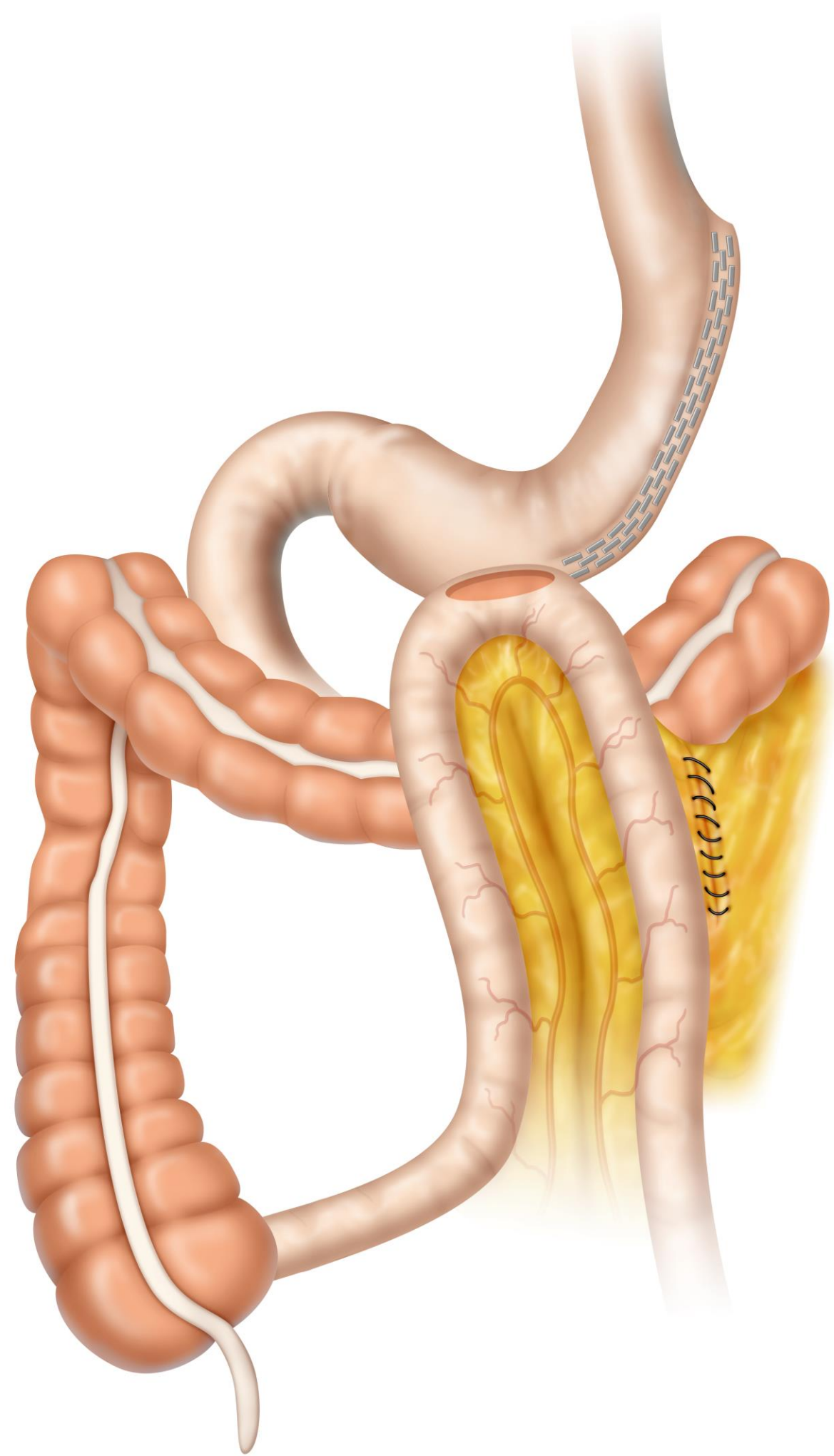












The MAGGI Study – Enrollment

- Sites with enrollment to date:
 - Westmount Square Surgical Center, Montreal, Quebec Canada (Dr. Michel Gagner)
 - Hospital Luisíadas Amadora, Lisbon, Portugal (Dr. Rui Ribeiro)
 - Cleveland Clinic Abu Dhabi, UAE (Dr. John Rodriguez)
- n=20 treated between November 6, 2023, and July 10, 2025
- Follow-up by Site:

| Study Visit | Canada (80mm or 70mm Magnet) N (% cohort) | Portugal (70mm or 60mm Magnet) N (% cohort) | UAE (70mm Magnet) N (% cohort) | MAGGI TOTAL N (% Total) |
|--------------------|--|--|---|--|
| Treated | 8 (100%) ^a | 10 (100%) ^b | 2 (100%) | 20 (100%) |
| Day 30 | 8 (100%) ^c | 10 (100%) | 2 (100%) | 20 (100%) |
| Day 90 | 7 (87.5%) | 10 (100%) | 0 | 17 (85%) |
| Day 180 | 7 (87.5%) | 10 (100%) | 0 | 17 (85%) |
| Day 360 | 7 (87.5 %) | 0 (0%) | 0 | 7 (35%) |

^an=1 70mm + n=7 80mm

^bn=1 60mm + n=9 70mm

^cone subject (70mm) missed D30, but was seen at D60

The MAGGI Study – Baseline Characteristics

| Baseline Characteristics | All subjects (N=20) |
|--|------------------------------|
| Clinical | |
| Prior Sleeve Gastrectomy \geq 12 months: n (%) | 20 (100%) |
| Body Weight: Mean (SEM) | 101.0 (3.0) kg |
| Body Mass Index (BMI): Mean (SEM) | 37.1 (0.8) kg/m ² |
| Type 2 Diabetes: n (%) | 1 (5.0%) |
| HbA1c (%): Mean (SEM) | 5.3 (0.1) % |
| Glucose (mg/dL): Mean (SEM) | 88.5 (1.7) mg/dL |
| Age | |
| Mean (SEM) | 46.5 (1.7) years |
| Min, Max | 37, 60 years |
| Gender | |
| Female: n (%) | 14 (82.4%) |
| Male: n (%) | 3 (17.6%) |
| Self-Reported Ethnicity | |
| White or Caucasian | 17 (85.0%%) |

Adverse Event Summary by Magnet Size

| Adverse Event Characteristics | 80mm Magnet | 70+60mm Magnet | Total ALL MAGGI |
|--|-------------|----------------|-----------------|
| Number Subjects Treated in Cohort (% All MAGGI) | 7 (35%) | 13 (65%) | 20 (100%) |
| Unique Subjects with AEs: N (% Cohort) | 7 (100%) | 10 (76.9%) | 17 (85%) |
| Total AEs by Cohort: N (% Total AEs) | 34 (57.6%) | 25 (42.4%) | 59 |
| Total Serious Adverse Events (SAEs): | | | |
| N (% Total SAEs) | 6 (50%) | 6 (50%) | 12 (100%) |
| N (% Cohort AEs) | 6 (17.6%) | 6 (24%) | 12 (20.3%) |
| N Unique Subjects (% Cohort Subjects) | 7 (100%) | 10 (76.9%) | 9 (45%) |
| N Related to Magnet Device (% Cohort AEs) | 0 (0%) | 0 (0%) | 0 (0%) |

- Some trend with 80mm having higher number of AEs (40% of ALL subjects and 60% of ALL AEs)
- No significant difference between the 80mm and 70+60mm datasets (small numbers)

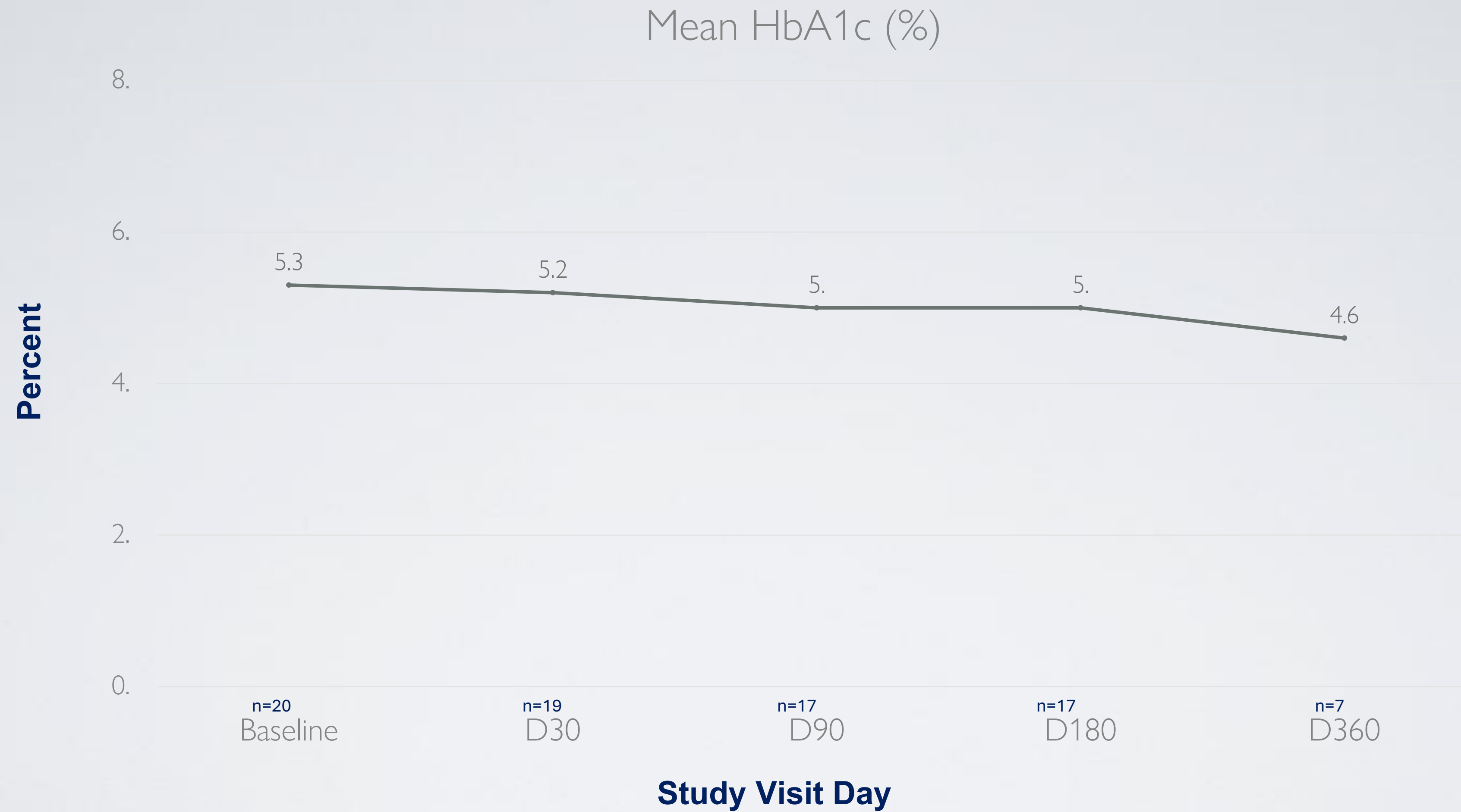
| 80 (%) | 70+60 (%) | | | | | |
|--------|-----------|---------|-------------|---|--|--|
| 35 | 65 | | | | | |
| 100 | 76.9 | | | | | |
| 57.6 | 42.4 | | | | | |
| 50 | 50 | | | | | |
| 17.6 | 24 | | | | | |
| 100 | 76.9 | | | | | |
| 0 | 0 | | | | | |
| | | p-value | 0.423256076 | one-sided t-test, assume equal variance | | |

Secondary Endpoints: % Total and Excess Weight Loss (MAGGI)



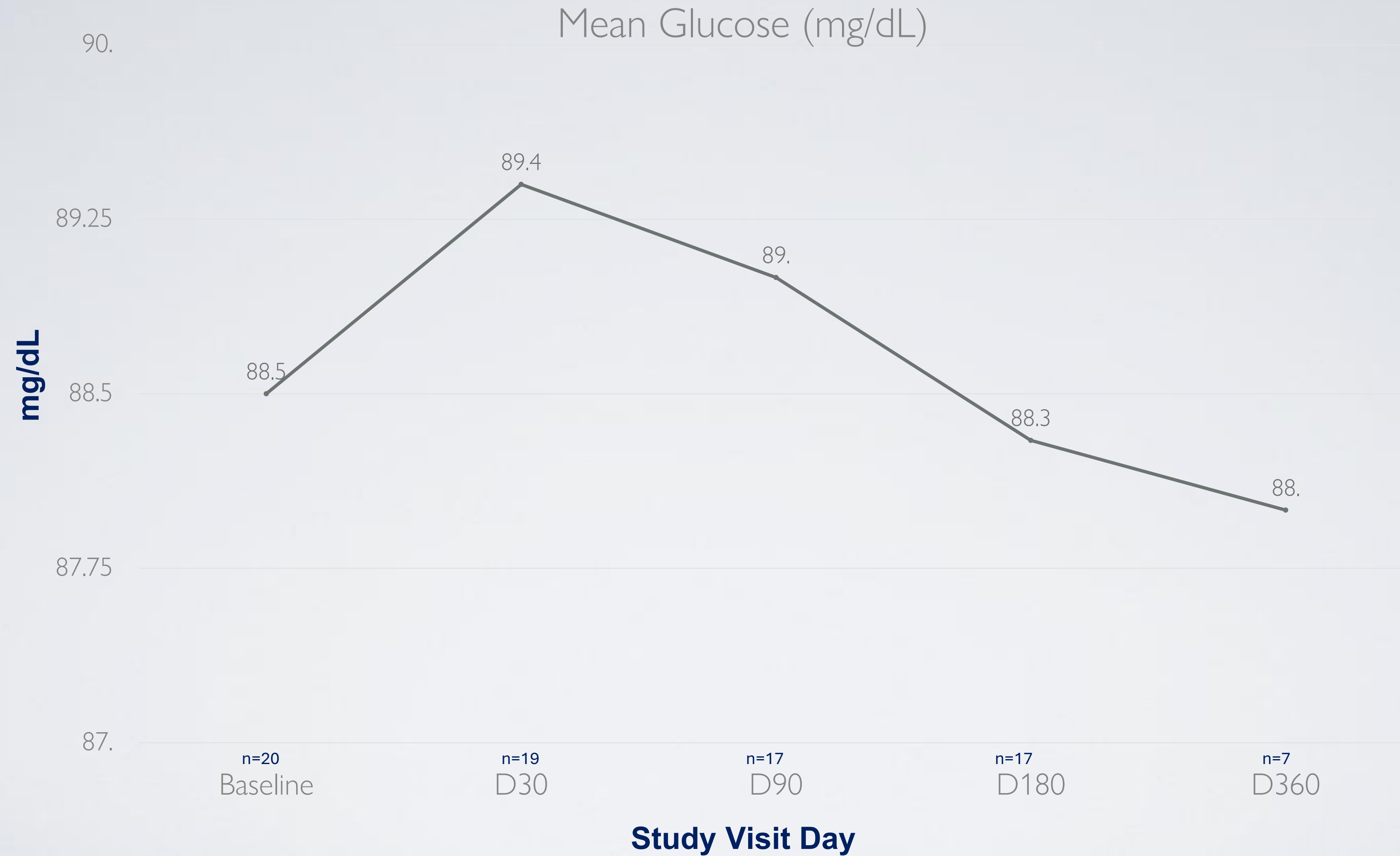
Early Metabolic Indicators (MAGGI)

Note: only one patient with T2D



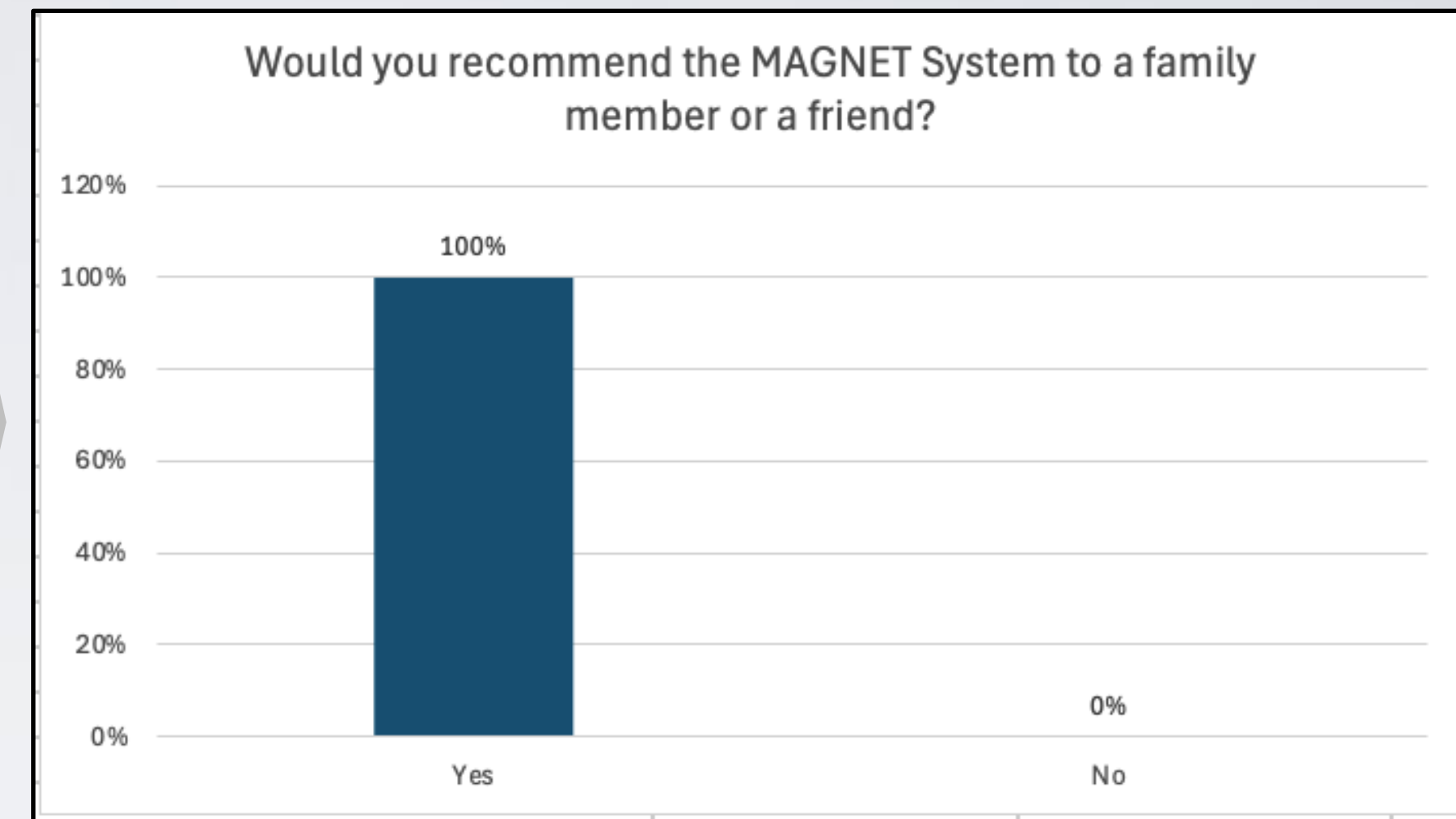
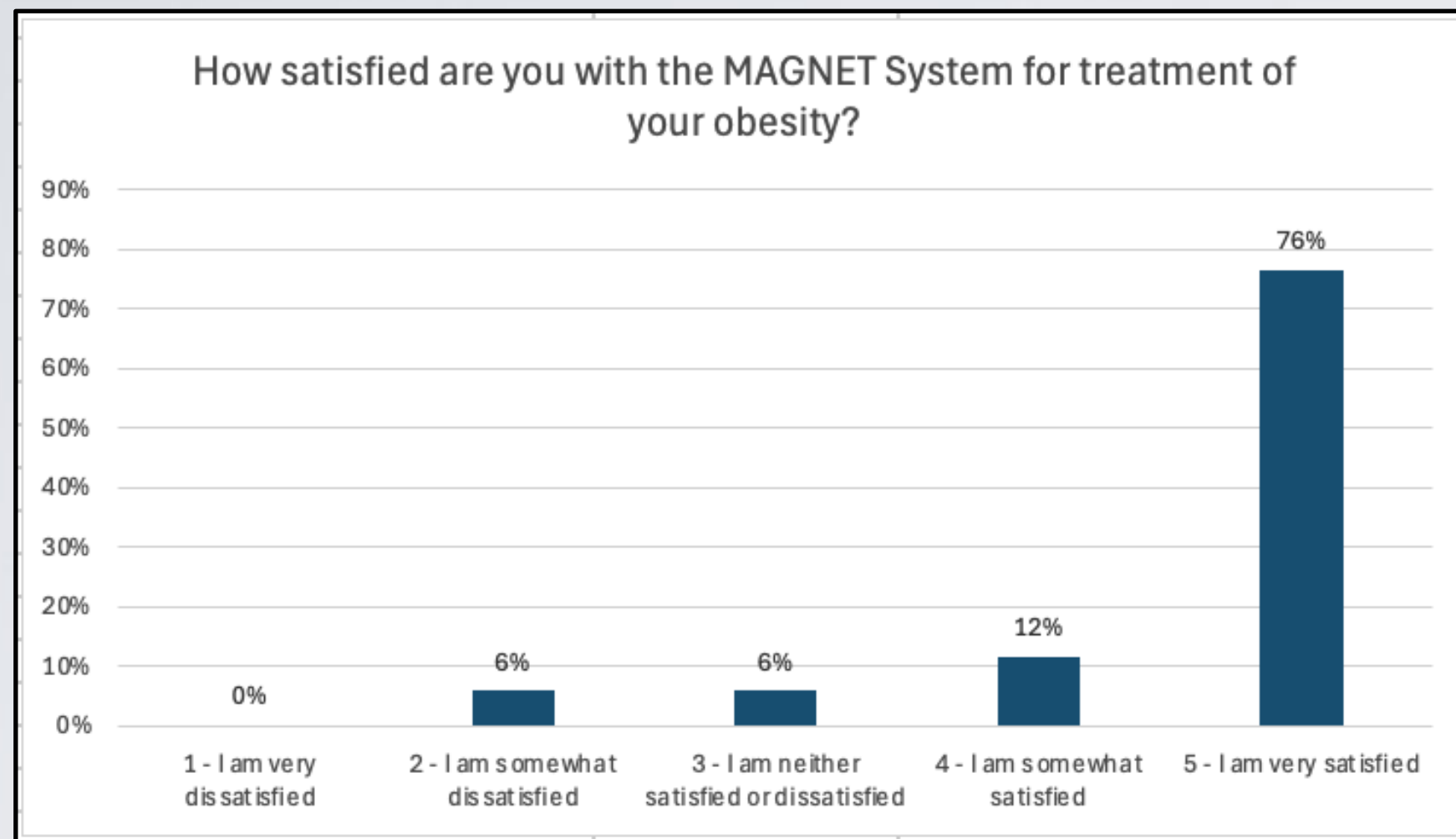
Early Metabolic Indicators (MAGGI)

Note: only one patient with T2D



Most subjects were satisfied at 6-months post MAGGI

N=17 followed through D180



MAGGI Conclusions

- The MAGGI system was placed successfully in all 20 cases and met performance success with 19 subjects reaching primary endpoint:
 - In one (1) case the Magnets (70mm) created a patent anastomosis, but devices did not drop. The devices were retrieved endoscopically.
 - One (1) subject continues to be followed for device expulsion.
- MAGGI was completely reversed in one (1) participant unable to tolerate the underlying diversion symptoms; procedure was straight forward and performed with no issues.
- Safety profile is promising with most (80%, 28/35) events at Clavien-Dindo I-II.
 - Two perforations (one bowel, one at anastomosis) were iatrogenic and repaired without additional sequelae.
- Secondary endpoints related to obesity indicators show 66% EWL and 23.4% TWL at one year in subjects undergoing gastro-ileostomy with MAGGI following previous failed sleeve gastrectomy.
- With 17 subjects followed to 6-months, 88% were satisfied with MAGGI used in a procedure for weight loss and all (100%) would recommend to family/friends.