Endoscopic intestinal bypass creation by using self-assembling magnets in a porcine model

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Background and Aims: A purely endoluminal method of GI bypass would be desirable for the treatment of obstruction, obesity, or metabolic syndrome. We have developed a technology based on miniature self-assembling magnets that create large-caliber anastomoses (Incisionless Anastomosis System [IAS]). The aim of this study was to evaluate procedural characteristics of IAS deployment and long-term anastomotic integrity and patency.

Methods: We performed a 3-month survival study of Yorkshire pigs (5 interventions, 3 controls). Intervention pigs underwent simultaneous enteroscopy/colonoscopy performed with the animals under intravenous sedation. The IAS magnets were deployed and coupled with reciprocal magnets under fluoroscopy. Every 3 to 6 days pigs underwent endoscopy until jejunocolonic anastomosis (dual-path bypass) creation and magnet expulsion. Necropsies and histological evaluation were performed. The primary endpoints were technical success; secondary endpoints of anastomosis integrity, patency, and histological characteristics were weight trends.

Results: Under intravenous sedation, endoscopic bypass creation by using IAS magnets was successfully performed in 5 of 5 pigs (100%). Given porcine anatomy, the easiest dual-path bypass to create was between the proximal jejunum and colon. The mean procedure time was 14.7 minutes. Patent, leak-free anastomoses formed by day 4. All IAS magnets were expelled by day 12. All anastomoses were fully patent at 3 months with a mean diameter of 3.5 cm. The mean 3-month weight was 45 kg in bypass pigs and 78 kg in controls ($P = .01$). At necropsy, adhesions were absent. Histology showed full re-epithelialization across the anastomosis without fibrosis or inflammation.

Conclusion: Large-caliber, leak-free, foreign body–free endoscopic intestinal bypass by using IAS magnets can be safely and rapidly performed in the porcine by model using only intravenous sedation.

A purely endoluminal method for the creation of a durable intestinal bypass may be desirable for the treatment of obesity, type 2 diabetes, and malignant obstructions.[1-4] Our group devised a purely endoscopic device and method for intestinal bypass creation (Incisionless Anastomosis System [IAS]) by using compressive force delivered by self-assembling magnets. These "smart" magnets are endoscopically delivered and self-assemble into a predetermined macro configuration capable of creating large-caliber anastomoses. When identical macro magnets occupy adjacent lumens, they couple to form a portal for bypass. Over several days, these magnets fuse, slough off, and are naturally expelled, leaving behind a large side-to-side anastomosis (ie, dual-pathway anastomosis).

The IAS evolved from technology previously called self-assembling magnets for endoscopy, which our group used for successful gastrojejunostomy creation in an acute porcine model.[5] The overarching aim of this particular study was to evaluate IAS in a long-term survival model. The specific aims of this study were to evaluate (1) the procedural characteristics of the refined IAS design, (2) the time required for a bypass to form, (3) acute and longer-term safety, (4) 3-month patency, (5) histological characteristics of the anastomosis, and (6) overall 3-month weight trends.

Abbreviation: IAS, Incisionless Anastomosis System.

DISCLOSURE: *Dr Ryou disclosed that he is a founder of and consultant to, receives royalties from, and has equity in GI Windows and is a consultant to and received honoraria from Covidien and Medtronic. Dr Thompson is a founder of and consultant to, receives royalties from, and has equity in GI Windows; receives research support from and is a consultant to Olympus and Bard; is a consultant to Boston Scientific; is a consultant to, receives royalties from, and has stock in Beacon Endoscopic/Covidien. Dr Agoston disclosed no financial relationships relevant to this publication.*

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METHODS AND MATERIALS

This preclinical study focused on defining the procedural characteristics of IAS delivery and the characteristics

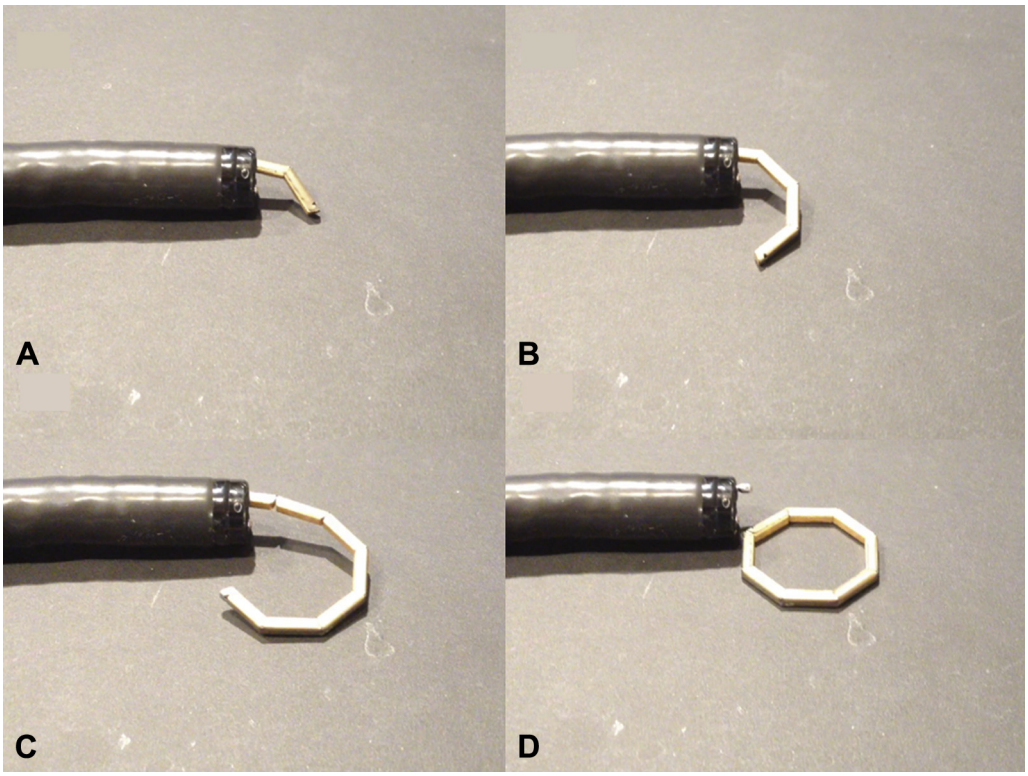

Figure 1. Sequential deployment of Incisionless Anastomosis System magnet through instrument channel of pediatric colonoscope (**A-D**).

of the resulting intestinal bypass. It is important to note that although our previously published study used a natural orifice surgery strategy, the IAS required only endoluminal delivery, without breach of the intestinal tract.

Incisionless Anastomosis System

The IAS includes a pair of a self-assembling magnetic octagons. IAS components were constructed by using neodymium-iron-boron magnets coated in a proprietary bio-safe material. The IAS was designed for delivery through a pediatric colonoscope (Fig. 1).

Survival animal studies

This study was conducted with approval by the Institutional Animal Use and Care Committee. Survival studies were performed in a total of 8 juvenile Yorkshire pigs (30-40 kg), with interventions performed in 5 pigs, and 3 litter-matched controls.

Pigs were given nothing by mouth for 24 hours preprocedure and were sedated by using intramuscular injection of tiletamine and zolazepam, xylazine, and atropine. General anesthesia was not used.

Enteroscopy and colonoscopy were simultaneously performed. Pairs of IAS magnets were deployed under both fluoroscopic and endoscopic guidance. After deployment and self-assembly, the IAS magnets were manipulated using magnet-tipped catheters (Fig. 2). Capture and proper mating of reciprocal magnets were gauged by fluoroscopic appearance and also marked the end of the procedure. Procedure times were recorded. Video logs were maintained throughout.

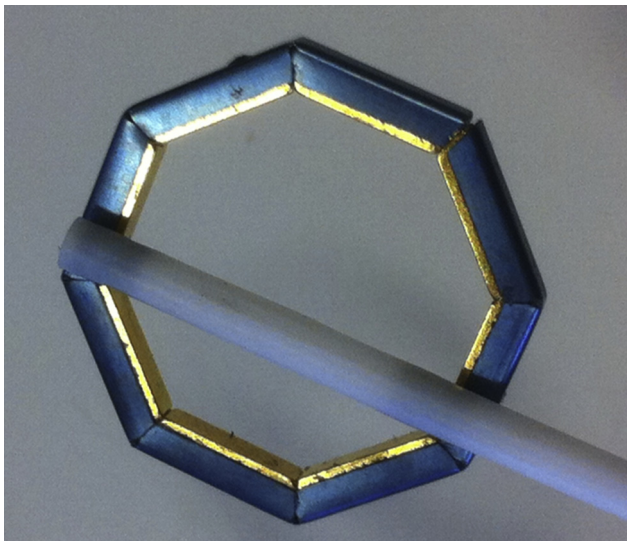

Figure 2. Fully formed Incisionless Anastomosis System magnet manipulated by magnet-tipped catheter.

All animals were recovered and underwent daily inspection to assess food intake and general appearance. All animals, including controls, were fed a standard diet