

Original article

Initial human experience with restrictive duodenal-jejunal bypass liner for treatment of morbid obesity

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Abstract

Background: The duodenal-jejunal bypass liner is an endoscopically placed and removable intestinal liner that creates a duodenal-jejunal bypass, leading to diabetes improvement and weight loss. The aim of the present study was to evaluate the clinical effects and safety of the duodenal-jejunal bypass liner combined with a restrictor orifice (flow restrictor).

Methods: The device was endoscopically implanted in 10 patients (body mass index 40.8 ± 4.0 kg/m²) and removed after 12 weeks. Dilation of the restrictor orifice was performed as clinically indicated with a 6-, 8-, or 10-mm diameter through-the-scope balloon. The measured outcomes included the percentage of excess weight loss, total weight loss, adverse events, and gastric emptying (GE) at baseline, weeks 4 and 12 of implantation, and 3–5 months after device removal. GE was measured by scintigraphy at 1, 2, and 4 hours after implantation.

Results: The percentage of excess weight loss and total weight loss at explantation was $40\% \pm 3\%$ (range 21–64%) and 16.7 ± 1.4 kg (range 12.0–26.0), respectively. The 4-hour GE was $98\% \pm 1\%$ at baseline, $72\% \pm 6\%$ at 4 weeks ($P = 0.001$ versus baseline), and $84\% \pm 5\%$ at 12 weeks ($P < .05$ versus baseline). After explantation, the rate of GE returned to normal in 7 of 8 subjects, but remained slightly delayed in 1 subject (84% at 4 hours). Episodes of nausea, vomiting, and abdominal pain required endoscopic dilation of the restrictor orifice with a 6-mm through-the-scope balloon in 7 patients and a 10-mm balloon in 1, with no clinically significant adverse events.

Conclusion: Endoscopic implantation of a combination flow restrictor and duodenal-jejunal bypass liner induced substantial weight loss. The implanted patients exhibited delayed GE that was reversed after device removal. (Surg Obes Relat Dis 2010;6:126–131.) © 2010 American Society for Metabolic and Bariatric Surgery. All rights reserved.

Keywords:

Bariatric surgery; Obesity treatment; EndoBarrier gastrointestinal liner; Gastric emptying

In 2004, 66% of U.S. adults were overweight or obese, with 5% classified as morbidly obese (body mass index [BMI] ≥ 40 kg/m²) [1]. Overweight and obesity are risk factors for increased morbidity, mortality, and type 2 diabetes mellitus (T2DM) [2–4]. A meta-analysis examining the correlation between the baseline

BMI and subsequent mortality in 57 prospective studies found that each 5-kg/m² increase in BMI > 25 kg/m² was associated with an ~30% greater overall mortality [3]. In contrast, a 12-year mortality analysis of overweight patients with T2DM found that intentional body weight loss was associated with a 25% reduction in total mortality and a 28% reduction in cardiovascular disease and diabetes mortality [5]. Additionally, a weight reduction of 9.1–13.2 kg was associated with a 33% reduction in mortality [5].

Bariatric surgery has emerged as an effective method of producing durable weight loss in morbidly obese patients [6,7]. Bariatric surgery has also shown notable effectiveness in re-

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versing T2DM and other co-morbidities. Amelioration of medical conditions and the prevention of future medical problems have been reported as the primary reasons most patients pursue bariatric surgery [8]. Current options for weight loss surgery include Roux-en-Y gastric bypass (RYGB), biliopancreatic diversion, sleeve gastrectomy, and adjustable gastric banding. Concerns regarding the morbidity and mortality associated with these procedures have prevented their wide-scale adoption [8]. However, despite its inherent risks, bariatric surgery is associated with a lower rate of mortality than untreated obesity during the long term [6].

Roux-en-Y and biliopancreatic diversion reroute chyme such that the duodenum and proximal jejunum are completely bypassed, effectively promoting the delivery of chyme directly to the jejunum [6]. In an effort to treat obese patients less invasively, several nonoperative, endoluminal procedures have been tried with varying success [9,10]. Many of these procedures share in common their ability to reduce the gastric volume, thereby restricting the passage of food through the stomach into the duodenum. One possible alternative to bariatric surgery is the duodenal-jejunal bypass liner (DJBL; EndoBarrier Gastrointestinal Liner, GI Dynamics, Lexington, MA), an endoscopically placed and removable intestinal liner. As shown in Fig. 1, the DJBL is a 60-cm, impermeable, fluoropolymer liner anchored in the proximal duodenum that prevents chyme from contacting the proximal intestine, similar to the RYGB but without the gastric restriction. Bile and pancreatic secretions pass along the outer wall of the impermeable liner and mix with the chyme distal to the liner in the jejunum.

The DJBL has undergone clinical studies to demonstrate its effect on weight reduction in morbidly obese subjects [11–13]. In the case report by Gersin et al. [11], a 119.5-kg woman had lost 4.6 kg within 1 month after DJBL implantation and 9.1 kg at 3 months, with no device-related adverse events. Additional clinical experience with the DJBL was reported by Rodriguez-Grunert et al. [12]. In a 12-week, open-label study of obese subjects, the DJBL was associated with a mean weight reduction of 10.2 kg in the 10 subjects completing the entire treatment period, corresponding to a mean excess weight loss (EWL) of 24%. Additionally, 3 of the 4 subjects with T2DM at baseline had normalization of the blood glucose concentration within 24 hours of DJBL implantation. Clinical experience with the DJBL was extended by a 12-week study of obese subjects randomized to either DJBL with a low-calorie diet ($n = 25$) or diet alone ($n = 14$) [13]. At 12 weeks, the mean EWL was 22% (10.3 kg) in the DJBL arm and 5% (2.6 kg) in the control arm. Of the 3 patients with T2DM in the DJBL arm, all had improved glycemic control at 1 week after device implantation. Thus, this novel device has been shown capable of promoting weight loss by an endoscopic, reversible duodenal-jejunal bypass.

A modified DJBL implant was created that included a 4-mm restrictor orifice distal to the anchor to slow gastric emptying (GE), in addition to the effects demonstrated by the DJBL-mediated duodenal bypass. Evaluations of the flow-restrictor DJBL in a growing porcine model have indicated that reduced weight gain

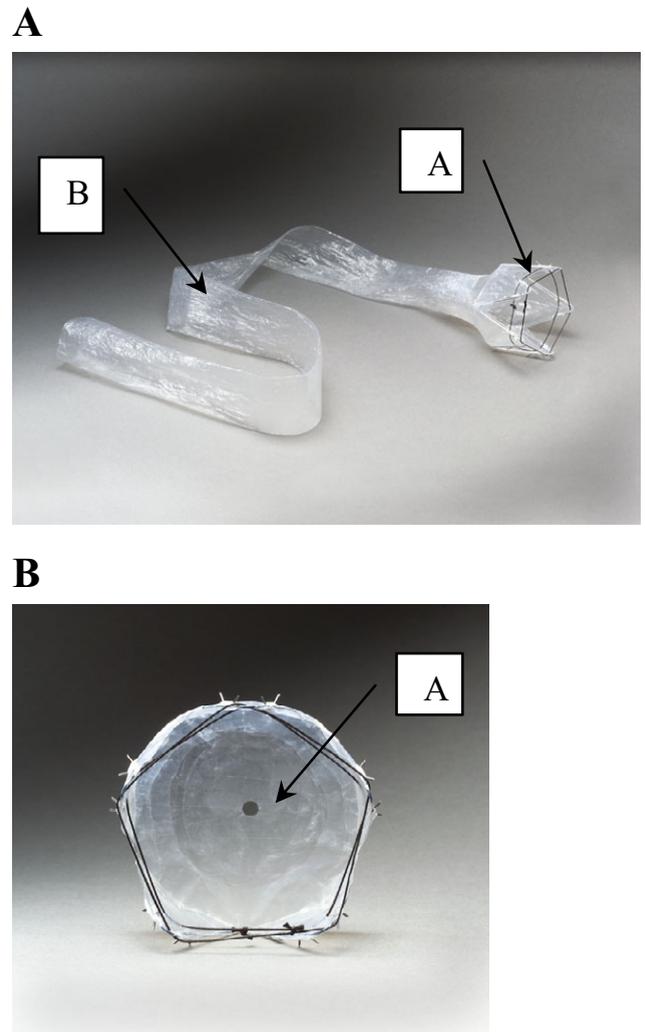


Fig. 1. (A) Unmodified duodenal-jejunal bypass liner (DJBL) showing anchor at arrow A and liner at arrow B. (B) End view of modified DJBL 4-mm orifice.

was safely achieved with orifices >3 and <6 mm [14]. With orifices <3 mm, the pigs had difficulty maintaining their weight. With orifices >5 mm, the effect weight was minimal. The clinical trial we have reported was performed to evaluate the effect of the flow-restrictor DJBL on weight loss and GE in obese humans.

Methods

Study design and population

The present open-label, single-center, 12-week pilot trial investigated the use of the DJBL modified with a 4-mm restrictor orifice distal to the anchor (Fig. 1). The trial was conducted according to the principles of Good Clinical Practice, in compliance with the Medical Device Regulations for Chile, and included ethics committee approval and subject informed consent.

The patients were ≥ 18 and ≤ 55 years old, with a history of failure with nonoperative weight loss methods. Their baseline BMI was ≥ 40 kg/m² and ≤ 60 kg/m² or ≥ 35 kg/m² with significant co-morbidities. All subjects were candidates for RYGB. The

women were postmenopausal, surgically sterile, or taking oral contraceptives. The subjects were excluded if they were using weight loss medications or appetite suppressants or had a history of gastrointestinal tract abnormalities, including gastrointestinal bleeding conditions or anemia/iron deficiency, previous gastrointestinal surgery, current infection, or congenital or acquired anomalies of the gastrointestinal tract. All patients were required to discontinue nonsteroidal anti-inflammatory drugs, corticosteroids, and drugs known to affect gastrointestinal motility.

Endpoints and clinical assessments

The primary endpoints were the 12-week safety and the efficacy (weight change). All patients underwent assessments of GE kinetics and a baseline examination. The long-term follow-up after explantation varied for each subject and was ≤ 5 months. After device implantation, fasting blood tests, a satiety questionnaire, and safety assessments were performed weekly for the first month and then at monthly intervals through week 12. Scintigraphy was repeated at weeks 4 and 12 and at 3–5 months after explantation. Upper endoscopy was repeated at week 4 after implantation and 2 weeks after explantation. The patients were counseled by a dietician at their initial visit and instructed to consume a 1-week liquid diet after implantation, followed by a pureed diet for the second week. They were then advanced to a solid diet.

For scintigraphy [15], the patients fasted for 8 hours and then consumed a meal within 10 minutes that included 2 large eggs (120 g) radiolabeled with technetium-99m. Imaging was performed in the anterior and posterior projections at 0, 1, 2, and 4 hours after the meal. Subject preparation, meal preparation and ingestion, and image acquisition were kept constant for all subjects at all visits.

Device implantation and explantation

The DJBL has been previously described in detail [11–13]. The flow-restrictor DJBL consists of the DJBL and a fluoropolymer plate at its proximal end with a 4-mm orifice (Fig. 1). The small orifice in the plate serves to increase the resistance to stomach emptying. The orifice can be dilated ≤ 10 mm using commercially available through-the-scope balloon catheters in 2-mm increments. The patients underwent general anesthesia for the delivery and removal of the device. All subjects had received a proton pump inhibitor the evening before implantation and were advised to continue taking it through the 2-week postexplant visit. Implantation and explantation was performed as previously described [11–13].

Statistical analysis

The continuous variables are summarized using descriptive statistics. Categorical variables are summarized using frequency statistics. Analyses were performed using Statistical Analysis Systems software, version 9.2 or later (SAS Institute, Cary, NC). The “intent-to-treat” population was defined as all treated subjects. Excess weight was calculated according to the ideal body weights listed in the 1983 Metropolitan Life tables.

Results

Study population

A total of 13 subjects were screened, 11 were enrolled, and 10 met the study criteria and were successfully implanted with the flow-restrictor DJBL (intent-to-treat population). The included subjects were a mean age \pm standard deviation of 39 ± 12 years old (range 18–54 years), 80% women, and 90% white and 10% other. The baseline body weight was 108.4 ± 16.9 kg, corresponding to a baseline BMI of 40.8 ± 4.0 kg/m² (range 35.9–47.8 kg/m²). Of the 10 subjects, 6 had hypertension, 4 had hyperlipidemia, 9 had hepatic steatosis, and 1 had T2DM. Also, 4 subjects were taking metformin, 1 for T2DM, 1 for polycystic ovary disease, and 2 for insulin resistance. The subjects were administered the proton pump inhibitor, omeprazole, 20 mg daily, the evening before implantation and continuing through 2 weeks after explantation.

The mean \pm standard error device implantation time was 29 ± 2 minutes (range 18–43 minutes), with a fluoroscopy duration of 10 ± 1 minutes (range 5–15 minutes). Of the 10 subjects, 7 had orifice dilation of 4–6 mm at 31 ± 6 days (range 16–60 days) after implantation. Of the 10 subjects, 1 underwent an additional orifice dilation from 6 mm to 10 mm at 31 days after implantation; 3 underwent orifice dilation between baseline and week 4; and 4 underwent orifice dilation between weeks 4 and 12.

The device was removed endoscopically at 12 weeks after implantation. The explantation time was 47 ± 17 minutes (range 10–155 minutes), with a fluoroscopy duration of 5 ± 2 minutes (range 1–18). Subject duration on study was 88 ± 2 days (median 92).

Weight loss

The patients' body weight progressively decreased during the entire treatment period (Fig. 2A,B). By week 4, the subjects had had an EWL of $25\% \pm 2\%$ (range 13–38%). By week 12, the subjects had had an EWL of $40\% \pm 3\%$ (range 22–64%), corresponding to a total weight loss of 16.7 ± 1.4 kg (range 12.0–26.0). The mean BMI progressively decreased during the observation period from 40.8 kg/m² at baseline to 36.7 kg/m² at week 4 (-4.1 ± 0.4 -kg/m² change from baseline) and 34.5 kg/m² at week 12 (-6.34 ± 0.5 -kg/m² change from baseline).

GE and satiety

Gastric emptying at baseline was clinically normal at $>90\%$ within 4 hours in all 10 subjects (Fig. 2C–E). During the treatment period, the GE rate was reduced in all subjects. The 4-hour GE rate was significantly reduced at 4 weeks ($72\% \pm 6\%$, range 39–99%; $P = .001$) and 12 weeks ($84\% \pm 5\%$, range 52–96%; $P < .05$). GE, as measured by the time to achieve 50% emptying, was $1.4 \pm .2$ hours at baseline and had increased to $3.2 \pm .4$ hours at 4 weeks ($P = .002$) and $3.0 \pm .4$ hours at 12 weeks ($P = .009$). GE data were not available at week 12 for 2 subjects who were unavailable for testing.

GE was slower in the subjects with the greatest amount

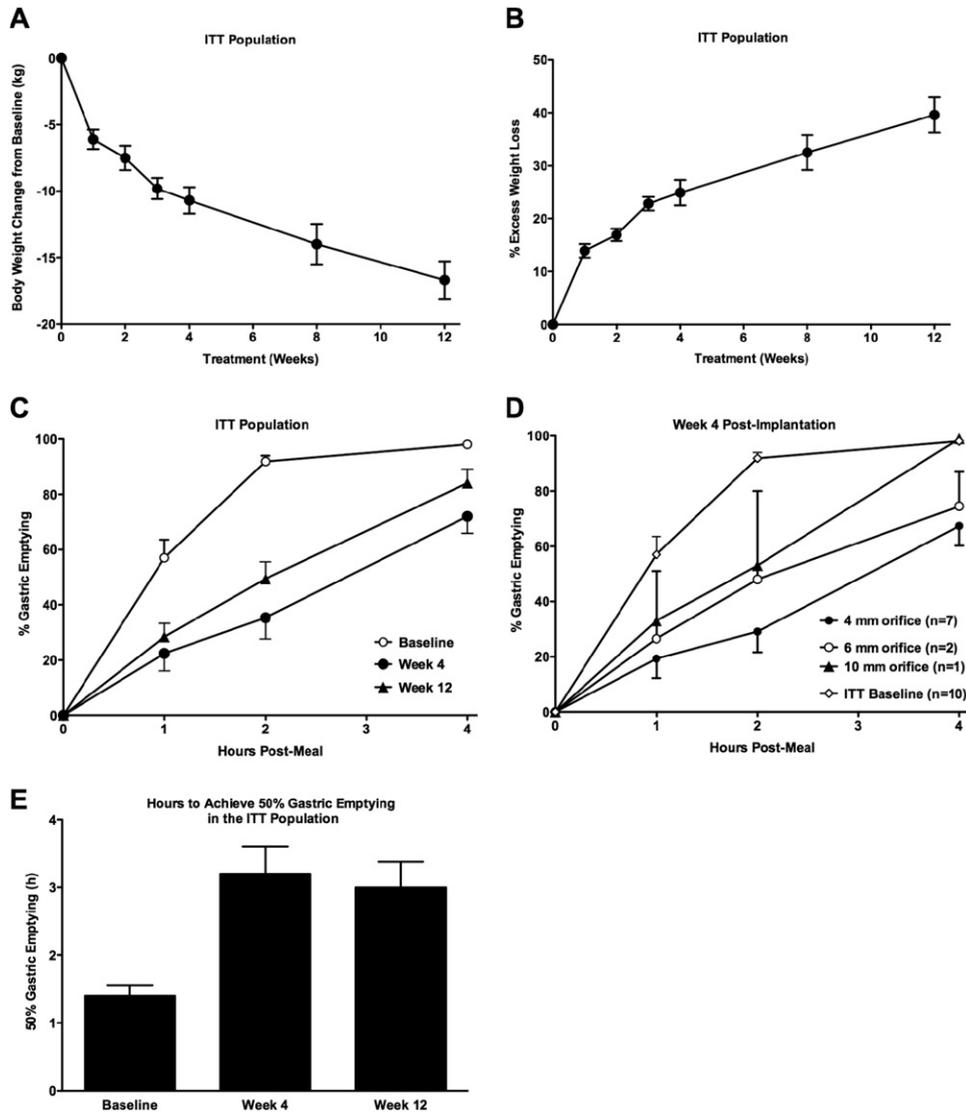


Fig. 2. Body weight reductions and gastric emptying (GE) kinetics in subjects implanted with modified duodenal-jejunal bypass liner (DJBL) with a restrictor orifice distal to the anchor. (A) Absolute body weight loss. (B) Percentage of excess body weight loss. (C,D) Percentage of stomach emptied during 4-hour observation period for entire intent-to-treat population and stratified by orifice diameter at week 4. (E) Time to achieve 50% GE. Three subjects underwent orifice dilation between baseline and week 4; 4 underwent orifice dilation between weeks 4 and 12. Intent-to-treat population was 10 at baseline and week 4 and 8 at week 12. Data presented as mean \pm standard error.

of restriction. At 4 weeks, the GE at 4 hours of the 1 subject with a 10-mm orifice was normal at 99%. GE at 4 hours of the subjects with a 4-mm orifice was $67\% \pm 7\%$, and for those with a 6-mm orifice was $75\% \pm 13\%$.

After explantation, the rate of GE returned to normal in 7 of 8 subjects; however, it remained slightly delayed in 1 subject (84% at 4 hours). No subjects experienced symptoms of gastroparesis.

At all visits during implantation, all subjects reported feeling greater satiety than before the study began.

Safety and tolerability

Safety was evaluated in the randomized population ($n = 11$). Of the 11 subjects, 9 reported ≥ 1 device-related adverse event, including upper abdominal pain in 64% ($n = 7$), vomiting in 46% ($n = 5$), nausea in 18% ($n = 2$),

procedural vomiting in 27% ($n = 3$), and procedural nausea in 36% ($n = 4$). All these events were mild or moderate.

Periodic episodes of nausea, vomiting, or abdominal pain led to endoscopic dilation of the restrictor orifice with a 6-mm balloon between weeks 2 and 8 in 7 subjects. One subject required a second dilation with a 10-mm balloon. All 10 subjects were successfully implanted and endoscopically explanted at 12 weeks.

Discussion

The present exploratory clinical trial evaluated the safety of a flow restrictor-DJBL and its effect on body weight and GE. The goal of adding the restrictor to the DJBL was to increase resistance to stomach emptying, thereby increasing

the duration of satiety and decreasing food intake. Of particular significance in the present study was the additive effect of the restrictor, allowing subjects to achieve an average EWL of 40% after 12 weeks combined with increased satiety. This compared favorably to previously published data with the unmodified DJBL of 22% EWL at 12 weeks [13]. To address variable subject tolerance, the orifice could be dilated endoscopically with commercially available gastrointestinal through-the-scope balloon catheters. Combining the DJBL and restrictor into a single device had an additive effect on weight loss. This implies the possibility of 2 distinct mechanisms of action through which these devices might act. Hypothetically, the DJBL might cause appetite changes as a result of foregut and/or hindgut hormonal triggers whose pathways are not yet fully understood [16,17].

The flow-restrictor DJBL successfully slowed GE, with the greatest changes occurring in those with the smallest orifice diameter. The rate of GE returned to normal after the device was removed, and no subjects experienced symptoms of gastroparesis. The flow-restrictor DJBL has been engineered such that the orifice can be dilated, allowing for customization of the orifice size to accommodate patients' variable tolerance to gastric outlet restriction. An initial restrictor plate orifice size of 4 mm was chosen from an engineering analysis indicating the pressure decrease across the orifice, which is the antral pressure required to push chyme through the orifice, should increase sharply as the orifice diameter decreased to <4 mm [14]. Key assumptions in the present analysis were the reported duodenal and antral pressures of 50–70 cm H₂O [18]. Thus, the most probable orifice size predicted to create an appropriate physiologic elevation of antral pressure was 3–5 mm, with orifice diameters >6–7 mm predicted to have little effect on GE kinetics. Furthermore, the pylorus is thought to restrict the size of particles exiting the stomach to ≤2 mm [18]. Of the 10 subjects in our study, 70% required dilation of the 4-mm orifice and 1 required a second dilation because of periodic nausea, vomiting, or abdominal pain. This suggests that the initial calculation of a 4-mm restrictor might have been too small and suggests a larger orifice should be selected initially. The present trial also demonstrated that the flow-restrictor DJBL can be implanted and removed endoscopically, with a favorable safety profile. The most common adverse symptoms in the present trial were periodic nausea, vomiting, and abdominal pain that resolved with dilation of the orifice.

Conclusion

The presented data support an important role for the flow-restrictor DJBL as a treatment option of obesity. The additive effects of the combination of a duodenal bypass and gastric outlet restriction have been presumed to result from the combined effects of delayed GE and neurohormonal changes as a result of the bypassed intestine. Additional research is warranted to delineate the complimentary effects of these proposed mechanisms of action.

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Disclosures

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Editorial comment

Comment on: Initial human experience with restrictive duodenal-jejunal bypass liner for treatment of morbid obesity

Escalona et al. have presented their initial experience with an innovative modification of the duodenal-jejunal bypass liner (DJBL). In this report, the authors present their results with 10 patients who had a flow restrictor placed at the proximal end of the DJBL. Importantly, they also evaluated the physiologic effects of this modification using gastric emptying studies. This small pilot study was well planned and executed and builds on the previous investigations of this type of device.

In this study, the excess weight loss at 12 weeks after implantation was 40%, impressive for an endoscopic therapy and greater than the 22% excess weight loss reported in a previous study using the DJBL without a flow restrictor [1]. Gastric emptying of a solid meal was measured throughout the study and clearly demonstrated an effect with the placement of the flow restrictor. This study and the preclinical work the authors report suggest that the diameter range in which the desired effect on gastric emptying can be achieved is narrow. Small increases in outlet diameter normalized gastric emptying and a flow restrictor that was too narrow caused intolerable symptoms. This narrow therapeutic window that produces the intended effect on gastric emptying is intriguing and requires additional study. The authors did not measure the diameter of the flow restrictors at explantation to correlate this with their intended diameter using endoscopic dilation. If feasible, these data would have been helpful to correlate the clinical effects seen with the ultimate diameter of the restrictor.

From the initial work with the DJBL with and without the flow restrictor, it appears that the effects of duodenal exclusion and delayed gastric emptying are additive. However, a high percentage of patients reported mild to moderate abdominal pain (64%) and vomiting (46%) after DJBL implantation. These symptoms prompted dilation of the restrictor, but in previous randomized studies of the DJBL without the flow restrictor, mild to moderate abdominal pain occurred in >80% of patients and vomiting in >33% [1,2]. These results suggest that the anchoring device, rather than the flow restrictor, might be the primary source of these symptoms, at least early after implantation. Other than achieving excellent short-term clinical results, this device provides the basis for additional mechanistic studies to

evaluate the relationship between gut hormones and diabetes and specific manipulations of the gastrointestinal tract.

One question this study does not answer is how much weight gain occurs after the device has been removed. Presumably, because gastric emptying returns to normal and the proximal gastrointestinal tract is again exposed to nutrient flow, patients would regain the weight with time. Durability is one of the primary concerns when bariatric surgeons are questioned about primary endoluminal therapy for obesity [3]. Thus, the question remains whether a role exists for a bariatric endoscopic device or procedure that is not permanent. Many skeptics of these evolving endoluminal therapies are quick to compare them to surgical procedures and expect the same degree of efficacy and durability. The significantly lower risk associated with endoluminal therapies, however, should put them on a different playing field than surgery. Ideally, this new field will attract more patients and generate many more referrals because these procedures are safer than surgery. Even with modest weight loss and the need for periodic revisions or device replacement, these primary endoscopic therapies are likely to appeal to patients and referring physicians. Additionally, they might play a role in staging patients for surgery or selecting the appropriate surgical procedure. If these types of procedures are ultimately adopted and performed within a comprehensive bariatric program, they have the potential to fill the large gap between medical therapy and surgery for the treatment of obesity.

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