Surgical Endoscopy (2018) 32:4436–4442
https://doi.org/10.1007/s00464-018-6186-0

Totally endoscopic implant to effect a gastric bypass: 12-month safety and efficacy outcomes

Bryan J. Sandler[1] · Laurent Biertho[2] · Mehran Anvari[3] · Roberto Rumbaut[4] · Luis Alonso Morales-Garza[5] · Gustavo Torres-Barrera[4] · Simon Marceau[2] · Dennis Hong[3] · C. Daniel Smith[6] · Santiago Horgan[1]

Received: 7 December 2017 / Accepted: 6 April 2018 / Published online: 20 April 2018

Abstract

Background Only a small percentage of candidates for bariatric surgery ever undergo a procedure for weight loss. Devices duplicating key effects of bariatric surgeries with removable, fully trans-oral implants could extend their benefits to patients unwilling to undergo anatomy-altering abdominal surgeries.

Methods Thirty-two obese subjects (mean BMI: 42.3) were enrolled in a prospective, multicenter, single-arm, feasibility trial of the first fully trans-oral endoscopic gastrointestinal bypass device. The device is a cuff attached to the distal esophagus by transmural anchors and connected to a 120-cm sleeve diverting undigested nutrients to the jejunum. Bodyweight, vital signs, adverse events, medications, HbA1c, fasting glucose, and lipids were collected at baseline and follow-up visits. Device status was endoscopically assessed every 6 months.

Results The fully trans-oral procedure was successful in all subjects without intraoperative adverse events or postoperative infections. Twenty-eight of 32 subjects (88%) remained implanted with continuing follow-up beyond their 12-month visit. At 12 months, the 32 subjects had lost an average of 44.8% of excess body weight, 17.6% of total body weight, 20.8 kg, and 7.5 BMI points. Weight loss depended on capture of ingesta by the esophageal cuff, with 18 of 32 subjects without visible gaps around their cuffs at the 6 month endoscopy having significantly greater EWL (53.6 vs. 33.4% in the remaining subjects, $p < 0.002$). Mean HbA1c and fasting glucose declined by 1.1% points and 29 mg/dL in type 2 diabetic subjects, 80% of whom had remission of their diabetes at 12 months.

Conclusion This study demonstrates the feasibility, safety, and efficacy of a fully trans-oral gastrointestinal bypass implant. This purely endoscopic device may provide a valuable addition to the armamentarium of treatment available for the management of morbid obesity.

Keywords Endoluminal bariatric surgery · Obesity · Surgical endoscopy · Gastric bypass · Bariatric surgery · And endoscopic surgery

✉ Bryan J. Sandler
bsandler@ucsd.edu

[1] Division of Minimally Invasive Surgery, Department of Surgery, UC San Diego, San Diego, CA, USA

[2] Département de Chirurgie, Université Laval, Quebec, QC, Canada

[3] Department of Surgery, McMaster University, Hamilton, ON, Canada

[4] Hospital de Tec de Monterrey, Monterrey, Nuevo León, Mexico

[5] Tecnologico de Monterrey, Escuela de Medicina y Ciencias de la Salud, Monterrey, Mexico

[6] Esophageal Institute of Atlanta, Atlanta, GA, USA

Weight loss surgery is recognized as an effective treatment for severe obesity, producing greater and more durable weight loss and more significant improvement in obesity-related comorbidities, than can be achieved with medical or diet interventions alone [1–3]. Despite this, only a small percentage of candidates for weight loss surgery undergo this treatment. For example, in the US < 1% of those who meet the NIH criteria [4] undergo a weight loss operation, and the number of procedures performed is outpaced fourfold by the growing population of candidates [5–7].

One of the main reasons for this underutilization of weight loss surgery is patient concern over the risk of an invasive procedure and the permanent alteration to gastrointestinal anatomy that is a part of all currently available

weight loss operations [8, 9]. Due to these concerns, there are currently multiple efforts underway to develop an endoscopic procedure that would duplicate the effects of currently effective weight loss operations using implants that require no abdominal incisions or permanent anatomical alterations.

One such implant consists of a cuff anchored to the distal esophagus and connected to a 120-cm polymer sleeve extending through the stomach and duodenum into the jejunum. The device is intended to mimic the effects of a Roux-en-Y gastric bypass surgery by mechanically restricting meal size and bypassing the digestive stomach and duodenum thereby delivering undigested nutrients more distally into the small intestine where mixing with biliopancreatic secretions can then occur. We previously reported experience with this endoluminal gastrointestinal bypass device in 34 patients [10, 11] where esophageal attachment was achieved through a combination of an endoscopic and laparoscopic approach to safely and reliably secure the device to the distal esophagus. This experience established proof of the concept of an intraluminal device that could be anchored in the distal esophagus for an extended period (mean duration 7.5-month device implant; range 0.5–12 months) and removed without serious complications or permanent damage to the esophagus.

With this proof of concept, the implant delivery technique was refined to allow totally endoscopic placement of the implant. Herein we report 12-month treatment outcomes from this totally endoscopic implant including safety and efficacy outcomes.

Methods

Study design

This study is a prospective, multicenter, single-arm, feasibility trial conducted at a private bariatric practice and community hospital in Mexico and two university-affiliated medical centers in Canada. Primary outcomes specified in the trial protocol are safety as indicated by the frequency of serious device- or procedure-related adverse events, and percent excess weight loss (%EWL) and percent total bodyweight loss (%TBL) at 12-month post-implant. The appropriate Mexican and Canadian federal agencies as well as local institutional ethics committees at the study sites approved the protocol and the informed consent form. The trial is registered on ClinicalTrials.gov under the trial identifier NCT02954003, and all subjects read and signed the informed consent prior to implant.

Inclusion and exclusion criteria

Trial subjects were required to be between the ages of 18 and 55, to meet the 1991 NIH criteria [6] for bariatric surgery (BMI $\geq$ 40 or BMI $\geq$ 35 with comorbidity), to have a BMI $\leq$ 50 at screening, to be able to provide informed consent and comply with study procedures, and to have failed in prior attempts at weight loss using non-surgical methods. Subjects were excluded if they had previous gastric or esophageal surgery, a history of GI bleeding, diabetes mellitus type 1, were pregnant or at risk of pregnancy and unwilling to use contraception, had abnormal findings in the screening esophagram or esophagogastroduodenoscopy (e.g., ulcers, polyps, hiatal hernia, strictures), were receiving steroid treatment or had an immunosuppressive disease, or had any health condition that would contraindicate an elective endoscopic procedure.

Gastrointestinal bypass device

Implanted components of the endoluminal gastrointestinal bypass device are shown in Fig. 1. The components include a polyester and silicone cuff (Fig. 1B) which is anchored in the distal esophagus with full-thickness placement of collapsible nitinol crown anchors (Fig. 1C) tied to a polyether ether ketone (PEEK) button by a polypropylene suture, and a 120-cm fluoropolymer sleeve (Fig. 1A) with a radiopaque stripe and a flange at its proximal end for attachment to the esophageal cuff implant. The cuff's leading edge is scalloped, incorporating eight eyeleted tabs through which the esophageal anchors are placed. The scalloped leading edge was adopted to facilitate fully trans-oral, endoscopic anchoring and to allow the cuff to more readily collapse and expand with the esophageal lumen. A silicone-coated bell at the bottom of the cuff is used to secure the sleeve flange to the cuff.

Implant procedure

The fully endoscopic implant procedure is performed under general anesthesia in either an operating room or surgical endoscopy suite. Steps include tissue marking 2 cm proximal to the squamocolumnar junction (SCJ) for localization of esophageal anchor placement (Fig. 2A), placement and anchoring of cuff in the distal esophagus (Fig. 2B), and sleeve deployment through the pylorus and into the proximal jejunum with final attachment of the proximal sleeve to the cuff sleeve flange (Fig. 2C). Full deployment of the device is then confirmed fluoroscopically (Fig. 2D).

During anchor placement, an anchor placement device (APD) effects full-thickness anchor placement in the distal esophagus. Vacuum is applied to the side port, drawing the

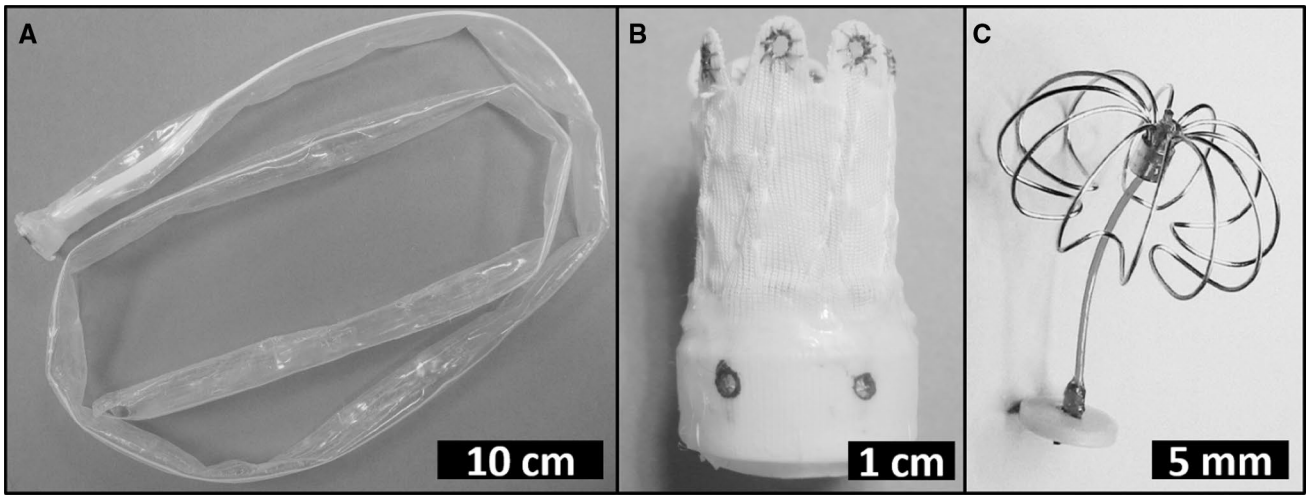


Fig. 1 Implanted components of the gastrointestinal bypass device. **A** 120-cm fluoropolymer sleeve; **B** polyester esophageal cuff; **C** esophageal cuff anchor

esophageal wall into the port above the needle tip, and the needle is extended through each tab eyelet and then through the esophageal wall, placing the self-expanding nitinol crown on the exterior of the esophagus. After needle withdrawal, vacuum is released the APD rotated and the process is repeated until all eight cuff tabs are anchored. With this, the orad end of the completed cuff implant is anchored in the distal esophagus (Fig. 2B) and the cuff body extends through the gastroesophageal junction, such that the silicone-coated bell is in the gastric lumen (Fig. 2C). The implant process is completed by securing the flared, proximal end of the sleeve (Fig. 2C) to the silicone-coated polyester cuff bell.

The sleeve can be removed or replaced without affecting the cuff implant. This feature also allows two-stage implantation, with the sleeve being implanted during a separate endoscopy sometime after cuff implant. Delaying sleeve placement could increase implant durability by allowing fibrotic encapsulation of the nitinol crown anchors to stabilize them prior to the load of the sleeve. To explore this hypothesis, 9 of 32 implants were performed in two stages, with the 120-cm bypass sleeve being implanted a month or more after the cuff. In the two-stage procedure, a 15-cm sleeve stump is placed during the cuff implant to prevent acid reflux through the cuff into the esophagus.

After implant, subjects were recovered from anesthesia and observed in the hospital overnight. All subjects completed a liquid contrast esophagram (Fig. 2D) prior to discharge on the first postoperative day to confirm device positioning and the absence of any evidence of esophageal leaks. At discharge, subjects were instructed to maintain a liquid diet for 2 weeks, to progressively add soft and pureed foods over the subsequent 2 weeks, and to transition to a regular diet thereafter. Apart from these instructions, no further dietary guidance was provided under the study protocol.

Follow-up visit data collection

Clinic visits were scheduled at 1, 2 weeks and 1 month after implant and monthly thereafter through 12-month post-implant. After device explant, subjects are followed for an additional year, with visits at 1-, 6-, and 12-month post-explant. Bodyweight, vital signs, waist measurements, and concomitant medications were recorded at the preoperative baseline visit and all follow-up visits. Subjects were queried about adverse health events at every visit and all reported events were recorded. Subjects completed an obesity-specific quality of life instrument (the IWQOL-Lite [12]) preoperatively and at 6 and 12 months.

To provide data on implant durability, regular endoscopic inspection of the cuff implant was performed at 6-month intervals. Subjects were explanted if a follow-up endoscopy found three unanchored cuff tabs, or two unanchored tabs with at least two other tab tops migrated below the SCJ. While this report is limited to the first 12 months of follow-up, implanted subjects continue to be followed until their devices meet the explant criteria, or they reach 36-month post-implant.

Outcome measures

The primary weight loss measure reported here is mean %EWL from the preoperative baseline visit. Percent EWL for each subject at each follow-up point is calculated as

$$\%\mathrm{EWL} = 100 \times \left(\mathrm{Weight}_{\mathrm{Baseline}} - \mathrm{Weight}_{\mathrm{Follow\text{-}up}}\right) / \left(\mathrm{Weight}_{\mathrm{Baseline}} - \mathrm{Ideal\ Weight}\right),$$

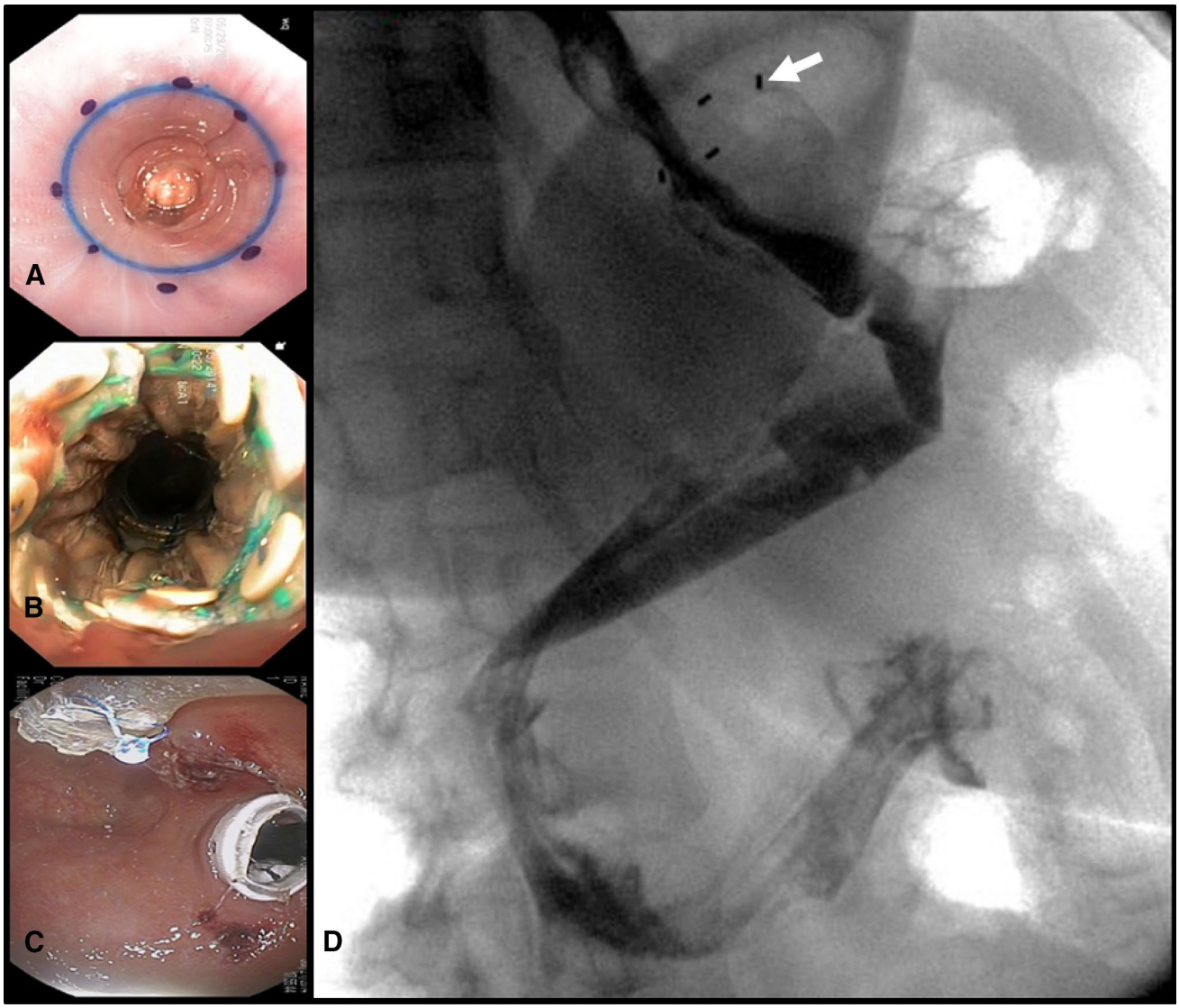


Fig. 2 Endoscopic and radiographic views of the gastrointestinal bypass implant. **A** Mucosal tissue marks in the distal esophagus used to guide cuff and anchor positioning; **B** orad end of the completed cuff implant in the distal esophagus; **C** retroflex view of the proximal sleeve flange in the gastric lumen with the aborad end of the implanted cuff just below the gastroesophageal junction; **D** contrast flowing from the esophagus into the cuff and through the sleeve in a 1-day post-implant esophagram, with a white arrow indicating a radiopaque marker in the implanted cuff

where weight values are expressed in kilograms and Ideal Weight = 25 × (Height in meters)^2. Mean percent total bodyweight loss (%TBL), mean absolute weight loss in kilograms, and mean reductions in BMI from the preoperative baseline visit through each follow-up are also reported.

Adverse events were tabulated by type, frequency, timing, duration, and number of subjects affected. Physician investigators at each study site classified each event's relatedness to the device or procedure as unrelated, unlikely, possible, probable, or definite. Physician investigators also categorized the event severity as mild, moderate or severe according to standard criteria [13].

Data Analyses

Data were analyzed according to the intent-to-treat (ITT) principle, including all subjects who underwent an implant procedure, regardless of outcome. Missing data were imputed using the last observation carried forward (LOCF) method, or, for cases where the subject was observed before and after the missing visit, linear interpolation between observed values. Model-based *t* tests and standard errors from mixed model repeated measures (MMRM) regressions were used for statistical inference and 95% confidence interval estimation. Rates of anchor dislodgement were compared

across single-procedure cuff and sleeve implants and cases where sleeve implants were delayed by a month or more using negative binomial regression. All analyses were completed using SAS Version 9.3 (SAS Institute, Cary, North Carolina).

Results

Subject baseline characteristics

Between December of 2013 and October of 2014, a total of 32 subjects were enrolled and underwent the fully trans-oral gastrointestinal bypass device implant procedure at the three study sites. Subjects (Table 1) were typical of patients seeking weight loss surgery, being predominantly middle-aged females with class III obesity.

Implant procedures

All 32 subjects were successfully implanted with the gastrointestinal bypass device, with 28 of 32 (87.5%) devices remaining in place through the 12-month post-implant visit. Implant procedures were performed by five different surgeons at the three study sites. For the 23 implants in which the cuff and sleeve were implanted as a single procedure, mean operative time from first endoscope insertion to last removal was 150 min. At the two study sites performing > 10 implants, operative times declined with experience, such that mean times for the last five implants at each site were 125 and 111 min. No patient experienced an intraoperative adverse event. In the 256 anchors placed in these 32 patients, there was no evidence of esophageal leakage in contrast swallows completed the day after surgery, and no anchor site infections or other anchor-related complications.

Device durability

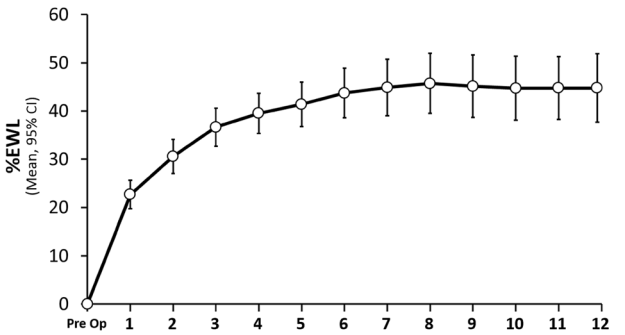
At 6 months, 25 of 256 anchors (10%) had dislodged from the esophageal wall in 9 of 32 subjects (28%). In one subject, all 8 anchors became dislodged during the course of repeated vomiting episodes at 4.5 months resulting in acute release of the device into the downstream bowel, necessitating surgical removal of the detached device from the small bowel. Three subjects met the protocol explant criteria based on their 6-month follow-up endoscopy and were explanted between 6 and 9 months. At the 12-month endoscopic follow-up, 17 of 224 anchors (7%) were dislodged in 12 of 28 subjects (43%) still implanted. Cuff tabs were placed approximately 2 cm above the SCJ at implant, but with gradual distal migration 22 and 24% of tab tops were below the SCJ at the 6- and 12-month endoscopies. Supporting the hypothesis that delaying full-length sleeve implantation by a month or more would improve durability, the rate of anchor dislodgements was significantly lower in the 9 subjects with delayed sleeve implants as compared to the 23 subjects receiving cuff and sleeve implants as a single procedure. During the first 12-month post-implant, there were 0.4 anchor dislodgments per implanted subject year in the delayed sleeve cases as compared to 2.4 anchor dislodgements per implanted subject year in the single-procedure cases ($p < 0.02$).

Weight loss

Figure 3 shows mean %EWL by months from implant with 95% confidence interval bounds, as well as monthly means for %TBL, weight loss (WL) in kg, and reductions in BMI. From the preoperative baseline visit through 12-month

Table 1 Subject baseline characteristics

Location (*N*, %)	
Canada	18 (56%)
Mexico	14 (44%)
Age (mean, range)	37.5 (20–50)
Females (*N*, %)	24 (75%)
Weight (mean kg, range)	118.1 (94–149)
BMI (mean kg/m^2, range)	42.3 (36–49)
Obesity class (*N*, %)	
Class II (35 ≤ BMI < 40)	11 (34%)
Class III (BMI ≥ 40)	21 (66%)
Comorbidity (*N*, %)	
Type II diabetes	5 (16%)
Hypertension	13 (41%)
Hyperlipidemia	11 (35%)
Metabolic syndrome	18 (56%)



	Pre Op	1	2	3	4	5	6	7	8	9	10	11	12
%EWL	0.0	22.7	30.6	36.6	39.5	41.4	43.7	44.9	45.7	45.1	44.7	44.8	44.8
%TBL	0.0	8.9	12.0	14.5	15.6	16.4	17.3	17.8	18.0	17.8	17.6	17.7	17.6
WL (kg)	0.0	10.6	14.2	17.1	18.5	19.4	20.5	21.0	21.3	21.0	20.7	20.8	20.8
−ΔBMI	0.0	3.8	5.1	6.1	6.6	7.0	7.4	7.5	7.6	7.5	7.4	7.5	7.5

Fig. 3 Mean ITT weight loss from baseline by months from implant ($N = 32$ subjects)

post-implant, subjects lost an average of 44.8% of excess body weight, 17.6% of total body weight, 20.8 kg, and 7.5 BMI points. At 12 months, all subjects had lost weight; 91% had lost at least 20% of their baseline excess weight, and 75% had lost more than a third of their baseline excess weight. Twelve-month %TBL exceeded 10% in 88% of subjects, and exceeded 15% in 75% of subjects. Weight loss was similar across study sites, with mean 12-month %EWL being 44.3% in Canadian and 45.4% in Mexican subjects. As in our studies of the earlier gastrointestinal bypass devices that required laparoscopically assisted implant [10, 11], weight loss was strongly associated with the degree of capture of oral ingested content by the cuff. Anchor dislodgement and/or distal migration creates gaps between the cuff and the esophageal mucosa allowing ingested content to flow more readily around the device into the stomach. Mean weight loss at 12 months was significantly greater in the 18 of 32 subjects without anchor dislodgements or visible gaps around their cuffs at the 6-month endoscopy (53.6% EWL vs. 33.4% EWL in the remaining 14 subjects, $p < 0.002$). The proportion of missing data in the study is small, with 28 of 32 subjects (88%) being observed at 12-month post-implant, and 31 of 32 (97%) being observed at or after 12-month post-implant.

Quality of life

There were substantial and statistically significant improvements ($p < 0.0001$) in IWQoL-Lite [12] scores from baseline to 12-month post-implant, including a 38% improvement in the mean total score and improvements in mean physical function, self-esteem, public distress, sexual life, and work subscale scores ranging from 31 to 44%.

Adverse events

A total of 166 non-serious adverse events with at least probable relatedness to the device or implant procedure were reported through 12 months. Most events (71%) occurred within 60 days of implant when subjects were acclimating to the device and progressing from liquids to a normal diet. The 6 most frequent events, accounting for 70% of the total, were epigastric pain, heartburn or acid reflux, regurgitation, vomiting, dysphagia, and nausea. All 32 subjects reported at least one event and all but one of the 166 non-serious events were classified as mild (112 events) or moderate (54 events) in severity. All 166 events were resolved without sequelae, median duration from onset to resolution was 7 days, and 95% of events were resolved with either no treatment (90 events) or medication alone (68 events). The single non-serious event assigned a severity of "severe" was a 12-h episode of epigastric pain and esophageal spasm that resolved without treatment.

Through 12 months, there were 6 events affecting 6 of 32 subjects (19%) meeting the ISO 14155:2011 [14] criteria for serious adverse device effects (SADEs). Three occurred within 14 days of implant in subjects hospitalized due to an inability to retain liquids. In two cases, the subjects were treated with medication and discharged when able to retain fluids. The third subject was discharged after endoscopic replacement of the sleeve with a 15-cm sleeve stump; the sleeve was kinked in the stomach causing a relative obstruction. A full-length sleeve was re-implanted at a later date with no further events. The fourth SADE was food impaction of the distal esophagus and cuff at 89-day post-implant. Pieces of steak were removed endoscopically leaving the sleeve in place, allowing the impaction to fully resolve. The final two SADEs both followed knotting of the sleeve, believed to have occurred when the sleeve was returned to the stomach by retrograde intestinal contractions during vomiting. In one case, the subject had repeated episodes of epigastric pain relieved by vomiting starting 2 months after implant. The sleeve knot, which was likely both a result of and contributor to the vomiting, was not recognized until the device became completely dislodged at 4.5 months and was removed from the small bowel by laparotomy. In the other case, vomiting and abdominal pain at 11.5 months after implant were investigated with an abdominal CT scan which revealed a concentration of the radiopaque sleeve stripe in a distended proximal duodenum. The subject's symptoms resolved after the knotted sleeve was removed endoscopically.

Conclusions

While implanting and maintaining an endoluminal device in the gastrointestinal tract is challenging, this study demonstrates considerable progress toward a viable gastrointestinal bypass device for the treatment of obesity. For the first time, such a device was implanted in the distal esophagus using a fully trans-oral endoscopic technique with no need for concurrent abdominal laparoscopy. The 12-month device-specific survival of 87.5% in this location is significant as is the lack of any significant procedure-related complications. This experience establishes that such an endoscopic implant can achieve weight loss comparable to the currently accepted, albeit significantly invasive and permanent procedure of laparoscopic sleeve gastrectomy.

There remain opportunities to improve upon this experience. While a 12-month implant survival of 87.5% is significant, when considering weight loss interventions, 12-months may be considered medium-term rather than long-term durability. However, it should be pointed out, in those patients who retained the implant longer than 12-months, weight loss was maintained suggesting that the effectiveness of

the device at inducing and maintaining weight loss remains as long as the device remains in place. Nine of 32 patients (28%) retained their implant for > 24 months with the longest duration of implant being 36 months, the maximum allowed under the study protocol. This suggests that even longer-term durability is possible. Ensuring full-thickness anchor placement, minimizing drag on the device to limit migration, and techniques to effect some tissue in-growth into the anchoring cuff promise even greater durability beyond 12 months. Additionally, our experience with an earlier generation of this device demonstrated maintained weight loss at 14-month post-explantation, at 30% EWL, for patients who completed 12 months of therapy with the device [11].

While adverse events were largely mild and managed conservatively with dietary modification, medications or time, premature device release did result in one patient requiring laparotomy to remove a device from the small bowel. It remains unclear whether the device might have passed on its own without surgical intervention, but to test this hypothesis was not believed reasonable. In all other patients, careful monitoring allowed early recognition of implant dislodgement and elective, endoscopic removal.

Limitations of this study are a few. First, this is a non-randomized, multicentered trial, so the lack of randomization of the investigation arm versus standard medical treatment or surgical treatment can be an area of future investigation. Additionally, the numbers of patients included in this early device trial are relatively small, limiting the power of the statistical analysis, again an area for future study. Lastly, data on the metabolic effects of the device, its effect on comorbid conditions, including diabetes, hypertension, and other weigh-related medical problems are forthcoming.

In summary, a totally endoscopic and removable implant to mimic the effects of RYGBP resulted in a mean 12-month intent-to-treat EWL of 44.8%, with 87.5% of implants still in place at 12 months after implant. This technique proved to be safe, with no intraoperative adverse events, postoperative infections, or evidence of esophageal leaks observed in 256 endoscopic esophageal anchor placements. Such results are significant for this type of device and placement, and provide great promise for a future totally endoscopic procedure to effect a magnitude of weight loss only achievable through invasive surgery.

This study demonstrates the safety, efficacy, and promise of a fully trans-oral, endoscopically delivered device to effect weight loss in the challenging morbidly obese patient population. The device is safe, well tolerated in the majority of patients whom it is placed, and utilizes a relatively simple procedure that can be completed within 2 h. With an average 44% EWL at 12 months, the results produced with this device mirror the results seen in patients undergoing sleeve gastrectomy, a thoroughly more invasive procedure. The on-going device development and procedural refinement will continue to improve the durability, delivery, and impact of this novel treatment for the difficult disease that is morbid obesity in the twenty-first century.

Compliance with ethical standards

Disclosures Drs. Sandler, Rumbaut, Morales-Garza, Smith, and Horgan are consultants of ValenTx, Inc. Dr. Biertho received grant funding from ValenTx, Inc. during the conduct of this study. Dr. Torres-Barrera received consulting fee from the Instituto Technologico de Monterrey during the conduct of this study. Drs. Anvari, Marceau, and Hong have no conflicts of interest or financial ties to disclose.

References

1. O'Brien PE, Dixon JB, Laurie C, Skinner S, Proietto J, McNeil J, Strauss B, Marks S, Schachter L, Chapman L, Anderson M (2006) Treatment of mild to moderate obesity with laparoscopic adjustable gastric banding or an intensive medical program: a randomized trial. Ann Intern Med 144:625–633
2. Schauer PR, Bhatt DL, Kirwan JP, Wolski K, Brethauer SA, Navaneethan SD, Aminian A, Pothier CE, Kim ES, Nissen SE, Kashyap SR, Investigators S (2014) Bariatric surgery versus intensive medical therapy for diabetes—3-year outcomes. N Engl J Med 370:2002–2013
3. Sjostrom L, Lindroos AK, Peltonen M, Torgerson J, Bouchard C, Carlsson B, Dahlgren S, Larsson B, Narbro K, Sjostrom CD, Sullivan M, Wedel H (2004) Lifestyle, diabetes, and cardiovascular risk factors 10 years after bariatric surgery. N Engl J Med 351:2683–2693
4. American Society for Bariatric and Metabolic Surgery (2014) New procedure estimates for bariatric surgery: what the numbers reveal. ASMBS Connect, May 2014
5. Nguyen NT, Vu S, Kim E, Bodunova N, Phelan MJ (2015) Trends in utilization of bariatric surgery, 2009–2012. Surg Endosc 30:1–5
6. National Institute of Diabetes and Digestive and Kidney Diseases (1991) Gastrointestinal surgery for severe obesity. NIH Consens Statement 9:1–20
7. US Centers for Disease Control and Prevention (2014) Behavioral risk factor surveillance system 2004–2013. CDC, Atlanta
8. Sarwer DB, Ritter S, Wadden TA, Spitzer JC, Vetter ML, Moore RH (2013) Attitudes about the safety and efficacy of bariatric surgery among patients with type 2 diabetes and a body mass index of 30–40 kg/m^2. Surg Obes Relat Dis 9:630–635
9. Stanford FC, Kyle TK, Claridy MD, Nadglowski JF, Apovian CM (2015) The influence of an individual's weight perception on the acceptance of bariatric surgery. Obesity 23:277–281
10. Sandler BJ, Rumbaut R, Swain CP, Torres G, Morales L, Gonzales L, Schultz S, Talamini M, Horgan S (2011) Human experience with an endoluminal, endoscopic, gastrojejunal bypass sleeve. Surg Endosc 25:3028–3033
11. Sandler BJ, Rumbaut R, Swain CP, Torres G, Morales L, Gonzales L, Schultz S, Talamini MA, Jacobsen GR, Horgan S (2015) One-year human experience with a novel endoluminal, endoscopic gastric bypass sleeve for morbid obesity. Surg Endosc 29:3298–3303
12. Kolotkin RL, Crosby RD (2002) Psychometric evaluation of the impact of weight on quality of life-lite questionnaire (IWQOL-lite) in a community sample. Qual Life Res 11:157–171
13. US Department of Health and Human Services (2009) Common terminology criteria for adverse events (CTCAE) version 4.0. US DHHS, Washington, DC
14. International Standards Organization (2011) ISO 14155:2011(EN) Clinical investigation of medical devices for human subjects—good clinical practice. ISO, Geneva