

AACE/TOS/ASMBS Guidelines

# Endoluminal revision of gastric bypass for weight regain—a systematic review

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## Abstract

**Background:** Weight recidivism after Roux-en-Y gastric bypass (RYGB) is a challenging problem for patients and bariatric surgeons alike. Traditional operative strategies to combat weight regain are technically challenging and associated with a high morbidity rate. Endoluminal interventions are thus an attractive alternative that may offer a good combination of results coupled with lower periprocedure risk that might one day provide a solution to this increasingly prevalent problem. The purpose of this article is to systematically review the available literature on endoluminal procedures used to address weight regain after RYGB, with specific attention to the safety profile, efficacy, cost, and current availability. This review focuses only on endoluminal procedures that are performed for weight regain after RYGB, as opposed to primary endoluminal obesity procedures.

**Methods:** This study was a retrospective review.

**Results:** Several methods of endoluminal intervention for weight regain are reviewed, ranging from injection of inert substances to suturing and clipping devices. The literature review shows the procedures on the whole to be well tolerated with limited efficacy. The majority of the literature is limited to small case series. Most of the reviewed devices are no longer commercially available.

**Conclusions:** Endoluminal therapy represents an intriguing strategy for weight regain after RYGB. However, the current and future technologies must be rigorously studied and improved such that they offer durable, repeatable, cost-effective solutions. (Surg Obes Relat Dis 2013;9:335–343.) © 2013 American Society for Metabolic and Bariatric Surgery. All rights reserved.

## Keywords:

Weight regain; Recidivism; RYGB; Endoluminal therapy

The field of bariatric surgery has grown dramatically over the past 15 years as a result of the epidemic of obesity coupled with improved surgical techniques and outcomes. The number of bariatric procedures performed in the United States is estimated at 113,000 per year [1]. Although the

success of a variety of bariatric procedures has been well documented, an ongoing concern is long-term weight regain after surgery. It is estimated that up to 20% of patients will fail to achieve satisfactory weight loss (>50% excess weight loss [EWL]) or will experience significant weight regain (>15% from nadir [2–5]). Given the ever-increasing volume of patients choosing to undergo surgery, the numbers of patients with recidivism will also increase, presenting a significant challenge for management to the surgical community.

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The exact mechanism of weight regain after Roux-en-Y gastric bypass (RYGB) surgery is unknown. This is an inadequately studied patient population, but it is likely that a combination of genetic, physiologic, behavioral, and anatomic factors contributes to their weight regain. Determining which of these factors is driving weight regain in a specific patient is a formidable scientific challenge, and long-term prospective studies are needed in this area. In fact, the evidence that pouch and/or stoma size after weight loss surgery influences weight regain is limited to observational studies. Surgeons have long speculated that loss of restriction because of either pouch or stoma dilation is a significant contributor [6–8]; however, this has yet to be proved in large controlled trials. In 1 study of 228 patients followed for > 10 years, significant weight regain occurred continuously after patients reached their nadir weight [5]. The overall success rate of 79.6% was attributed to a small pouch size, although often in the setting of “wide open” anastomoses. The authors did not show an increase in pouch size over the 5-year period using upper gastrointestinal x-ray. Although upper gastrointestinal x-ray may not be an accurate test of pouch size (the pouch may not distend with a liquid ingestion and the liquid medium is not necessarily a reflection of solid food intake), this study does underscore the fact that control of satiety is likely complex and it is clear that weight gain can occur in cooperative, well-motivated patients.

One study looked at 165 patients after RYGB who were referred for upper endoscopy [9]. These patients underwent endoscopy for a variety of indications (abdominal pain, nausea, vomiting, and evaluation for gastrogastric fistula) and as a matter of standard practice had the gastrojejunal stoma diameter measured. Significant weight regain (defined as  $\geq 20\%$  of maximum weight lost) occurred in 59% of the patients examined. Gastrojejunal stoma diameter was associated significantly with weight regain in univariate analysis, leading the authors to conclude that stoma diameter is a risk factor for weight regain. The limitations of this study are numerous, including its retrospective nature, lack of information on nutritional habits, lack of information on surgical technique and immediate postoperative stoma diameter, and perhaps most important, lack of a reference group of patients without weight regain who happened to present for endoscopy.

Perhaps the most compelling evidence of the influence of pouch and stoma size on weight loss after RYGB comes from a report of 380 patients who underwent upper endoscopy at a mean of 5.9 years after RYGB [10]. These patients were divided into 2 groups: (1) those who had maintained successful weight loss (EWL > 50% or a body mass index [BMI] < 30 kg/m<sup>2</sup>) referred for gastrointestinal symptoms and (2) those who hadn't who were referred for weight regain. All patients had pouch and stoma measurements taken; stomas > 2 cm in diameter were considered

enlarged, and pouches > 6 cm in length or > 5 cm in width were considered enlarged. In the 175 patients with successful weight loss, a majority (63.4%) had normal pouch and stoma size. By contrast, in the 205 patients referred for weight regain, only 28.8% had normal pouch and stoma size ( $P < .001$ ). Pouch length, volume, and stoma diameter correlated inversely with excess weight loss. Multivariate analysis found stoma diameter to be independently associated with weight regain. The strength of this study is its inclusion of a comparison group of patients with successful weight loss, demonstrating a majority with normal anatomy. The fact that patients with weight regain had anatomic abnormalities almost twice as often as patients who had acceptable weight loss lends credence to the concept that pouch and stoma size do influence weight loss (and weight regain) after gastric bypass.

Given that dietary and behavioral modification are unlikely to be effective in this group of patients, many surgeons have undertaken revisional surgery to improve restriction. Traditional revisional bariatric surgery for weight gain is technically challenging and associated with a high rate of morbidity [11–13]. Endoluminal techniques for reducing pouch and stoma size have the potential to improve restriction with lower morbidity.

Numerous endoluminal strategies have been used as revisional therapy for weight regain after gastric bypass, including injection of sclerosing agents and endoscopic suturing. This article reviews the available evidence on techniques published in human trials. To provide as current a review as possible for these innovative and emerging techniques, we have included references to abstracts presented at national meetings as well as articles published in non-peer-reviewed journals.

### Sclerotherapy

Sclerotherapy attempts to increase restriction by injecting a sclerosant in perianastomotic (or pouch) tissue. Using an endoscopic injection needle, the sclerosing agent (usually sodium morrhuate) is injected at various points around a dilated anastomosis. This technique was first reported in 2003 by Spaulding [14], who treated 20 patients by injecting an average of 6 cc of sodium morrhuate. In this study, 75% of patients lost 9% total weight at 6-month follow-up. In a retrospective review, Spaulding et al. published results with 1-year follow-up of sclerotherapy [15]. This study identified 32 of 147 patients who had undergone sclerotherapy for dilated anastomosis after gastric bypass with at least 1-year follow-up data. Of the 32 patients, 90% either lost weight (at a rate of .39 kg/mo) or had weight stabilization. The remaining 10% continued to gain weight. No procedure-related complications were reported.

Loewen and Barba reported on 71 patients who underwent sclerotherapy after an average weight regain of

18 pounds from nadir [16]. An average of 13 cc of sodium morrhuate was injected circumferentially, and 49% of patients underwent repeat injection. A total of 30% of patients lost weight in this series, while 42% had no change and 28% continued to gain weight. Of the patients who lost weight, the average weight loss was  $19 \pm 9$  lb, whereas those patients who gained weight gained  $23 \pm 17$  lb. Catalano et al. reported on 28 patients undergoing sclerotherapy with an average injection volume of 14.5 cc [17]. Injection was successful in only 64% of patients, and 1 patient developed symptoms of stomal stenosis requiring dilation. Mean weight loss in the 28 patients was 22.3 kg at 18-month follow-up. A 2010 report by Madan et al. [18] describes 6 patients treated with sclerotherapy, 50% of whom lost  $\geq 5$  kg.

The most recent study on sclerotherapy retrospectively reviews 231 patients undergoing 575 sclerotherapy procedures [19]. In this cohort, patients had regained an average of 36% of their lost weight from nadir. Patients underwent either single or multiple injections of sodium morrhuate under sedation with a low incidence of minor complications. The average weight loss after injection was 4.5 kg at 6 months (18% of weight regained after RYGB). Patients who underwent  $>1$  sclerotherapy procedure or who had experienced greater weight regain had greater weight loss. The authors note that weight regain at 6 and 12 months from the last sclerotherapy procedure had stabilized in 92% and 78% of the cohort, respectively, at least suggesting the possibility that the effect of sclerotherapy may be transient in nature.

Sclerotherapy is generally a straightforward procedure with few complications. The procedure can be repeated, which may be of significant benefit to patients. Because of its simplicity, it could be performed at numerous centers without the need for specialized equipment. Sclerosing agents are commercially available for use. However, its effectiveness is limited, with relatively modest weight loss at short-term follow-up. To date, the literature regarding this technique is limited to retrospective reviews of small case series with very short follow-up.

### **Bard EndoCinch suturing system**

The EndoCinch suturing system (C.R. Bard, Inc., Murray Hill, NJ) was developed by Dr. Paul Swain and consists of a hollow capsule that is fit onto the end of an endoscope and uses suction to pull tissue into the capsule. A hollow needle is used to pass the suture through the tissue in the capsule, and the suture is then tied with a knot-pusher. Several sutures can be placed at the dilated gastrojejunostomy to reduce its size, or sutures can be placed at the site of a gastrogastic fistula.

Schweitzer first reported on the use of EndoCinch to treat dilated anastomoses [20] in 4 patients. This descriptive report describes reducing the stoma size from  $>20$  mm

preoperatively to  $<15$  mm postoperatively. Two of these patients also had their gastric pouches plicated near the stoma. The patients were noted to report feeling full earlier with a decrease in caloric consumption and subsequent weight loss (however, no details on the amount of weight loss or time period are specified).

In 2006, Thompson et al. published a pilot study of 8 patients who experienced an average of 24 kg weight gain from nadir after RYGB undergoing the EndoCinch procedure [21]. All of the procedures were carried out under general anesthesia. The mean anastomotic diameter at endoscopy was 25 mm. An average of 2 stitches were placed at the anastomoses with a procedure time of 98 minutes. Several of the later procedures were modified to include a mucosal ablation at the site of suture placement. At a mean follow-up of 4 months, 6 of 8 patients lost an average of 10 kg. Four patients reported durable improvement in satiety, while 3 reported only transient improvement. Those 3 patients underwent repeat plication with subsequent increased weight loss. All of the procedures (8 primary and 3 subsequent) were performed without significant complication.

Results of a multicenter, randomized, double-blind, sham-controlled trial (RESTORe trial) were presented in 2010 [22]. Seventy-seven patients with inadequate weight loss or weight regain and a dilated stoma after RYGB were randomly assigned to undergo EndoCinch reduction versus a sham procedure. Follow-up was out to 6 months and was assessed by physicians blinded to treatment status. All procedures were performed under general anesthesia and included a mucosal ablation with electrocautery. Adverse events were reported equally between groups and included nausea, vomiting, constipation, and throat pain. A mean of 4 stitches were placed, with technical success (reduction in stoma size to  $<10$  mm) achieved in 89% of procedures. At 6 months, the EndoCinch group achieved 4.7% weight loss, compared with 1.9% for those in the sham group ( $P = .041$ ). Ninety-six percent of patients in the EndoCinch group achieved weight loss or weight stabilization, compared with 78% in the sham group ( $P < .001$ ).

The EndoCinch has also been used to revise other complications of gastric bypass. In 2010, Fernández-Esparach et al. reported on a group of 6 patients with intractable dumping syndrome and dilated anastomoses [23]. Using a combination of argon ablation, fibrin glue, and at least 2 interrupted EndoCinch stitches, anastomotic size was reduced from 23 mm to 8 mm. One patient had hematemesis postprocedurally, which was treated endoscopically. All 6 patients had complete and persistent resolution of their dumping symptoms, with a median follow-up of almost 2 years. The same authors reported on the use of EndoCinch to close gastrogastic fistulas, a historically common cause of weight gain after RYGB [24], particularly in the era of nondivided gastric bypass. Although repair of the fistulas was technically feasible, long-term durability was not

demonstrated, with only 30% of small (<10 mm) fistulas remaining closed, and none of those fistulas with an initial size of >20 mm remained closed.

The original EndoCinch device was technically complicated and required multiple steps to create tissue approximation. The newest version of the device (which has been used in a trial for primary treatment of obesity) is considerably less bulky, requiring fewer exchanges to “cinch” and plicate the tissue. Of primary concern is the superficial nature of the tissue bites (mainly mucosal and submucosal) and thus the durability of plications. The device is not currently commercially available.

### StomaphyX

StomaphyX (Endogastric Solutions, Inc., Redmond, WA) is a tissue approximation device that uses H-fasteners and can create full-thickness, serosa-to-serosa, endoluminal plications. This device is used over an ordinary endoscope. The initial pilot experience with StomaphyX was published in 2010 on 39 patients who underwent pouch reduction [25]. The procedures were performed under general anesthesia, with 37 of 39 being done on an outpatient basis. The average number of H-fasteners placed was 17, with an average procedure time of 35 minutes. Eighty-seven percent of patients experienced sore throat lasting <2 days, and 77% of patients had epigastric pain that lasted a few days. Weight loss at 1 month in 34 patients was 5.4 kg (10.6% EWL), and in 6 patients followed out to 1 year, weight loss was 10.0 kg (19.5% EWL).

Another group reported on the use of StomaphyX in 64 patients who had either inadequate weight loss, dumping syndrome, or gastroesophageal reflux disease after RYGB [26]. In this series, serial plications were used starting just above the gastrojejunostomy and proceeding within the gastric pouch up to just below the gastroesophageal junction, requiring an average of 23 H-fasteners per case (mean operating time 50 minutes). All but 2 of the patients were discharged on the day of the procedure, and 1 patient was observed for bleeding, which did not require transfusion. Stoma diameter was reduced from 22 mm to 9 mm, and the length of the gastric pouch was reduced 33%. For the 42 patients who underwent the procedure for dumping syndrome, symptoms were improved in all patients and completely resolved in 30 (71%). In 80% of patients with gastroesophageal reflux disease, symptoms improved, and in 20%, there was complete symptom resolution. Weight loss in this cohort averaged 7.3 kg (range 0–31 kg), and 79% of patients did not regain weight during the very short follow-up period (minimum 3 months; range 3–12 months).

StomaphyX has been used to revise pouches after failed vertical banded gastroplasty [27]. In 2011, Manouchehri reported on 14 patients who had significant weight gain after vertical banded gastroplasty. These patients underwent StomaphyX plication with an average operating time of

55 minutes and median follow-up of just over 4 months. Patients lost an average of 10 kg (or 3.6 kg/m<sup>2</sup> in BMI) over the follow-up period, which was statistically significant. There was no difference between groups regardless of what type of preprocedure pouch or staple-line status.

A significant limitation of the design of the StomaphyX device is that it allowed access to only the pouch, rather than the gastrojejunostomy itself. Therefore all plications were limited to the pouch and had no influence on true stoma diameter. Gastric pouches with significant fundus posed a challenge because the device with endoscope had a difficult time reaching that tissue secondary to the rigidity of the overall apparatus. In addition, investigators report that because of the large size of the device, obtaining tissue plication at different levels within the pouch was difficult to achieve. Finally, although the device is capable of creating full-thickness (serosa-to-serosa) plications, this is often not the case, because of limitations of the chamber that holds tissue into the device while the H-fastener is deployed. Although a relative wealth of studies have been published on StomaphyX showing some success, the device is no longer commercially available.

### Incisionless Operating Platform

The Incisionless Operating Platform includes the Transport Multi-lumen Platform, the g-Prox Grasping/Tissue Approximation Device, g-Cath tissue Anchor Delivery Catheters, and a variety of endosurgical tissue graspers (USGI Medical, Inc., San Clemente, CA). This multilumen system has 1 channel for an endoscope and 3 operating channels and has been used extensively for stoma reduction after RYGB in a procedure called ROSE (restorative obesity surgery endoscopic). The tissue-grasping device enables large, full-thickness tissue bites.

Early results of the ROSE procedure were first published in 2009. A pilot study of 5 patients reported technical feasibility and safety (no adverse events) with weight loss of 7.8 kg at 3 months [28]. This same group went on to publish a series of 20 patients later that year [29] who had gained an average of 13 kg after their nadir weight with dilated gastrojejunostomies. Patients underwent tissue approximation at both the gastrojejunostomy and within the gastric pouch (average number of tissue plications per patient was 5). The gastrojejunostomy diameter was reduced an average of 16 mm, a 65% reduction from the preprocedure diameter. The average procedure time was 103 minutes, and anchors were successfully placed in 17 of 20 patients. There were no significant complications, although most patients experienced bloating and mild throat pain. The average weight loss was 5.8 kg at 1 month and 8.8 kg at 3 months.

Results of a multicenter registry of patients undergoing the ROSE procedure were published in 2010 [30]. Patients were enrolled at 9 different institutions and underwent the

procedure from February to August 2008. Of the procedures, 88% were performed in the operating room and 12% were performed in the endoscopy suite. Eighty-five percent of all patients were discharged on the day of the procedure. There were 3 mild esophageal tears; all were asymptomatic, and 1 required an endoscopic clip as a precaution. The most common discharge observations were pharyngitis (41%), nausea/vomiting (12%), and abdominal pain (11%), all of which resolved during the follow-up period. At least 1 anchor was successfully placed in 97% of cases, with an average time of 87 minutes. The stoma and pouch diameter and length were reduced by 50% and 44%, respectively. At 6 months after the procedure ( $n = 97$ ), patients had lost 18% of excess weight (average 6.5 kg), representing 32% of the weight regained since the nadir after gastric bypass.

A follow-up to this study was published [6] with longer-term weight loss results. At 12 months after the procedure ( $n = 73$ ), mean weight loss and percentage of EWL was 5.9 kg and 14.5%, respectively. Anchor presence was confirmed endoscopically in 61 of 66 patients (92%) at 1 year.

The outcomes of the ROSE procedure are believed to be modest. Although stoma size has been influenced in reports, in practice the tissue anchors are more easily placed in the gastric pouch rather than at the anastomosis. This may in part explain its limited effectiveness. Currently the device is not commercially available in the United States, and company efforts are focusing on use of the device as a primary endoluminal treatment of obesity, rather than in revision for weight regain.

### OTSC-clip

The OTSC-clip (Ovesco AG, Tübingen, Germany) is made of Nitinol and is mounted on a transparent applicator cap placed on the tip of an endoscope (over-the-scope; OTSC). Tissue to be approximated is grasped with 2 endoscopic forceps passed down a scope with 2 working channels and pulled within the applicator cap. A string is pulled to release the clip, clamping the tissue in place. Several versions of the clip exist, including blunt-toothed, sharp-toothed, and long-toothed.

In 2011 Heylen et al. reported the results of the OTSC-clip used in 94 patients with dilated gastrojejunostomy and 10% weight gain after RYGB [31]. All procedures were performed under general anesthesia (average time 35 minutes) with 1 or sometimes 2 clips placed. The mean preprocedure stoma diameter was 35 mm and was reduced to an average of 8 mm after placement of clips (average reduction of 80%). No major complications were reported. In 5 patients with postprocedure dysphagia, an endoscopy was performed. Endoscopic dilation was required in two of these patients in whom symptoms did not resolve. At approximately 3 months postprocedure the mean BMI dropped from 45.8 kg/m<sup>2</sup> to 29.7 kg/m<sup>2</sup>. At 1 year postprocedure, mean BMI was 27.4 kg/m<sup>2</sup>. At 3 months postprocedure, at least 29% of the clips were still attached

to the pouch outlet (the authors assume that there may be even more clips present because of their low radio-opacity).

Given the functionality of the device within the gastric pouch and around the gastrojejunostomy, success in influencing weight regain may be limited. To date, data are extremely sparse to support its use for this function. This commercially available device may be more applicable in management of complications such as leaks or fistulas.

### OverStitch Endoscopic Suturing System

The OverStitch Endoscopic Suture System (Apollo Endosurgery, Inc., Austin, TX) was developed from its predecessor the Eagle Claw suturing device. The OverStitch is a cap-based suturing system that mounts onto a double-channel endoscope. A curved needle deploys both interrupted and running, full-thickness sutures under direct visualization, which are secured with a Cinch device. The OverStitch has been used clinically to close gastrointestinal fistulas [32] and gastrogastic fistula after RYGB [33], but to date, there are no peer-reviewed publications on its use as a revisional strategy for weight gain.

A small U.S. series was presented in 2011 at the Digestive Disease Week conference in Chicago by Jirapinyo, et al. [34]. They reviewed 9 patients with dilated gastrojejunostomy after RYGB (defined as stomal diameter >18 mm) who underwent plication of their stomas with the OverStitch device. Average preprocedure stoma size was 26.2 mm. All 9 procedures were technically satisfactory, resulting in a postprocedure stoma size <10 mm, with an average time of 36 minutes. A median of 3 interrupted stitches were placed. At 1-month follow-up, the authors reported 6.9% weight loss (4.5–9.5 kg). Several complications were reported, including persistent emesis and self-limited bleeding in 1 patient and intolerance to liquids in 1 patient who required balloon dilation 4 days after the initial procedure.

Another series of 8 patients treated in Chile and Colombia was recently described in a Bariatric Times article [35]. Preprocedure stoma size averaged 25 mm, and all 8 patients had successful stomal reduction with OverStitch under general anesthesia (average 38 minutes). Three stitches were placed, reducing stoma size to 10 mm in all but 1 patient. Postoperative weight loss at 90 days in 4 patients varied from 6–8 kg, and no complications were reported. In an abstract presented at the American Society for Metabolic and Bariatric Surgery 29th Annual meeting in San Diego, Manoel et al. reported on 9 patients in Latin America who underwent stomal revision with the OverStitch device [36]. There were no complications in this group, and patients were able to lose an average of 61% of their regained weight.

The use of OverStitch to perform gastrojejunostomy repairs is technically feasible and appears to be well tolerated. Larger and deeper depth of tissue approximation is technically attainable, which may offer an advantage over

other devices. In addition, this system has shown promise in endoscopic treatment of other bariatric complications, including leaks, fistulas, and oversewing of marginal ulcers. It is the only commercially available endoluminal suturing device on the market. The device has undergone changes to allow for ease of use and fewer exchanges and appears to allow greater depth of penetration than other suturing devices.

**Summary**

As the obesity epidemic continues to increase, so will the number of surgical procedures to combat it. However, given the lack of standardization in surgical technique and the body’s attempt to resist surgical weight loss in the long term, we will continue to see patients who have weight regain or suboptimal weight loss. Endoluminal therapies to address weight regain offer the potential of meaningful impact with low morbidity. This review of the data in this emerging field highlights that outcome measurements and benchmarks for “success” after a revisional endoluminal procedures are not clearly established. Future studies should focus on methods to standardize the definitions of failure and the way in which a response to endoluminal intervention is measured and reported. As with most of the bariatric literature, there are inconsistencies across different publications in outcome reporting that makes interpreting the body of data difficult. Given that endoluminal revisions are a relatively new area within bariatric surgery, this is a great opportunity to establish expectations for study design, standard methods of outcome reporting, and benchmarks for success among those who are moving this field forward.

In assessing any new technology, it is important to consider the goals of said therapy in conjunction with potential morbidity. It may not be reasonable to expect outcomes of an endoluminal intervention to approach outcomes seen in conventional surgical procedures. In a recent survey of ASMBS members on endoluminal procedures, respondents believed that the level of success (i.e., percent excess weight loss) should be proportionate to risk of the intervention. That is, an endoluminal intervention that effects 10%–20% EWL should carry no more risk than a therapeutic endoscopy, and an intervention that effects 30%–40% EWL should have equivalent risk to that of standard laparoscopic adjustable gastric banding [37]. It is also evident from this survey that weight loss expectations after revisional procedures are less among bariatric surgeons than weight loss after primary bariatric operations. A paper jointly published by the ASGE and ASMBS recommends that endoscopic bariatric therapies be evaluated on multiple endpoints, including weight loss, safety profile, efficacy, durability, and impact on anatomy [38].

The exact mechanism of weight recidivism remains elusive; however, several studies have correlated weight regain with anatomic variations, most notably in the gastric pouch and the proximal anastomosis. Although several small studies have reported weight stabilization and further modest weight loss with the incorporation of the aforementioned techniques, the results of endoluminal therapies have been largely disappointing thus far (Table. 1), leading to abandonment of much of the technology. However, the timing of intervention as well as the ability to repeat the therapy may play an even larger role when one considers that treatment of obesity is lifelong, as is the disease. Any endoluminal therapy

Table 1  
Weight loss

Therapy	Weight loss <sup>a</sup>	Safety <sup>b</sup>	Technical feasibility <sup>c</sup>	Repeatability <sup>d</sup>	Efficacy <sup>e</sup>	Durability <sup>f</sup>	Availability <sup>g</sup>	Cost <sup>h</sup>
Sclerotherapy	-	+++	+++	+++	-	-	+	+++
EndoCinch	-	++	+	++	-	-	-	+
StomaphyX	-	++	+	++	-	-	-	+
IOP	-	++	+	++	-	-	-	+
OTSC Clip	-	+++	++	++	-	-	+	++
Overstitch	-	++	++	++	-	-	+	++

<sup>a</sup>This grading system for weight loss is based on percent excess weight loss (%EWL) and total weight loss (%TWL) attainable by the intervention. - Insufficient data. + Equivalent to medical therapy, minimal 5% TWL change. ++ Minimum 20% EWL. +++ Equivalent to gastric banding, minimum 25% EWL.

<sup>b</sup>This grading system compares the intervention with other endoscopic procedures (e.g., those with minimal risk such as colonoscopy with polypectomy or those with potential for significant risk such as ERCP with sphincterotomy). + Moderate risk. ++ Modest risk. +++ Minimal risk.

<sup>c</sup> +++ Simple procedure with no special equipment. ++ Moderately complex. + Significantly complex.

<sup>d</sup> + Not repeatable. ++ Repeatable a limited number of times. +++ Can repeat treatment on an ongoing basis.

<sup>e</sup> - Insufficient data. + Achieves relative risk reduction by affording mild to moderate weight loss. ++ Modest effect on weight loss or metabolic disease, without necessary substantial weight loss. +++ Profound effect on weight loss and metabolic illnesses.

<sup>f</sup> - Insufficient data. + Rapid effect of therapy (weight loss or metabolic improvement) with short-term duration (6 mo). ++ Minimal effect of 1 year of therapy is repeatable. +++ Sustained effect of therapy for 5 years.

<sup>g</sup> - Not commercially available. + Commercially available.

<sup>h</sup>This grading system compares the therapies on a relative scale with a standard endoscopic (colonoscopy with polypectomy or endoscopic retrograde cholangiopancreatography with sphincterotomy) or surgical (adjustable gastric band) interventions. +++ Equivalent to colonoscopy. ++ Equivalent to ERCP with sphincterotomy. + Equivalent to adjustable gastric band.

for weight regain (or inadequate weight loss) should be rigorously investigated, with primary endpoints focusing not only on weight loss or stabilization but also on obesity comorbidity control. All endoluminal therapies are not equal and will continue to evolve and improve to make them technically more feasible with the potential for increased durability and repeatability and improved cost-effectiveness. Only after studies with appropriate control groups are completed for these technologies will we be able to accurately assess the risk/benefit ratio for these interventions as well as the general applicability of the techniques.

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## Editorial comment

# Comment on: “Endoluminal Revision of Gastric Bypass for Weight Regain – A Systematic Review”

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In this issue of *Surgery for Obesity and Related Diseases*, the ASMBS Emerging Technology Committee has published an updated review of endoluminal technologies that have been utilized in the bariatric surgery patient population. The Executive Council endorses this review and commends the committee for its hard work in providing a comprehensive update of this field.

In 2009, the ASMBS published a position statement on Emerging Endosurgical Intervention for Treatment of Obesity that outlined the expectations for responsible use of endoluminal procedures for primary or revisional bariatric procedures, the role of industry in clinical device trials, the importance of adequate training and skill acquisition, and the performance of these procedures as part of a multidisciplinary bariatric program.

The existing position statement has been reviewed with the current Emerging Technology review in mind and, given the relatively low number of devices that have remained in the marketplace and the low number of publications regarding their use, there is insufficient data to support updating the Society’s position statement on this topic at this time. In addition, the principles of safe and responsible use of any emerging technology outlined in the original statement have not changed. The ASMBS Executive Council encourages continued innovation in this and other areas of bariatric surgery. The responsible development and use of new or less invasive interventions in accordance with the following guidelines has great potential to benefit our patients and our field. A synopsis of the existing position statement is provided here, and the full statement is available on the ASMBS website at [www.asmb.org](http://www.asmb.org).

Emerging technologies present an opportunity for us to improve patient outcomes and are essential to the

evolution of the practice of medicine. Current ethical standards indicate that innovation requires appropriate oversight to assess the relative merits and potential adverse consequences. There are currently a number of endoluminal innovations and novel devices and technologies in various stages of development or application to the elective treatment of obesity, including revisional interventions. Theoretical goals of these therapies include decreasing the invasiveness, risk, and barriers to acceptance of effective treatment for obesity, but these outcomes cannot be assumed and must be proven.

Therefore, use of novel technologies should be limited to clinical trials done in accordance with ethical guidelines of the ASMBS and designed to evaluate the risk and efficacy of the intervention. Results of appropriate trials should include generation of data for risk/benefit analysis, assessments of disability, durability, and the resource utilization associated with the intervention.

To avoid inappropriate influence by for-profit medical device companies on clinical trial results, it is essential to ensure the integrity of clinical trials by recommending for-profit companies that sponsor biomedical research studies should not be solely or primarily involved in collecting and monitoring of data, in conducting the data analysis, or in preparing the manuscript reporting study results. These responsibilities should primarily or solely be performed by academic investigators who are not employed by the company sponsoring the research. Furthermore the society supports the registration of all clinical research trials and mandatory reporting of outcomes whether favorable or not.

If evidence supports use of a new intervention, several other factors need to be considered before clinical application outside the controlled environment of a clinical trial. Clinical use of a new intervention should be practiced in the setting of a multidisciplinary