Endoluminal Gastric Pouch Revision

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Brian Hodgens, Simon Che, and Dean J. Mikami

Chapter Objectives

1. Describe the incidence of weight regain after bariatric surgery and the current management.
2. Describe endoluminal therapies for revision of gastric pouch after weight regain.
3. Describe future approaches in the management of weight recidivism.

Introduction

Bariatric surgery has become the primary treatment against obesity. Obesity is a national as well as global health epidemic. In 2015, the prevalence of obesity in the United States was 38.8% in adults and 18.5% among children [1]. These individuals suffer from preventable deaths due to heart disease, stroke, and diabetes. Bariatric surgery has increased in popularity with 228,000 procedures being performed in 2017 compared to 158,000 done in 2011 [2].

The success of bariatric surgery is limited by its availability, failure to lose weight, and weight regain. In particular weight regain, or weight recidivism, has resulted in patients taking the risk to undergo additional bariatric revision surgery. Of the 228,000 bariatric surgeries performed in the United States in 2017, 14% of these were revision surgeries, a number that has steadily grown over the last 4 years [3]. While the Roux-en-Y gastric bypass (RYGB) has now been surpassed by the sleeve gastrectomy as the most commonly performed operation, the RYGB still accounted for 17% (nearly 39,000 operations) of surgeries last year. Gastric pouch dilation and gastrojejunostomy (GJ) dilation have been associated with weight recidivism, so finding safe and effective techniques to revise the gastric pouch remains an important discussion point.

Minimal weight gain between 18 and 24 months postoperatively can occur; however as many as 33% of bariatric patients, especially the super obese, can experience continued weight gain more than 2 years after surgery [4]. Not only can this negate the positive metabolic effects of the original surgery, it also takes a psychological toll on the patient that can easily lead them to stray from the long-term multidisciplinary treatment plan. While optimizing medical and psychological support is mandatory to help these patients, revisional procedures can also help correct anatomic causes that allow weight regain.

The most common anatomic reasons for weight gain are gastric pouch enlargement, anastomotic dilation, and gastrogastric fistula. Pouch size directly correlates with weight loss in laparoscopic RYGB patients, as smaller pouches enable more weight loss [5]. Along those same lines, a larger GJ anastomosis diminishes the restrictive effect of surgery and allows more food consumption leading to weight gain. Surgical revision of these postoperative changes is feasible and effective; however they can be high risk and are associated with higher rates of adverse events [6].

Surgical revision of RYGB includes revision of the GJ anastomosis, adjustable banding of the gastric pouch, lengthening of the biliopancreatic or roux limbs to increase malabsorption, and converting to a duodenal switch. Indications for proceeding with surgical revision include failure to lose weight, weight regain, and return of metabolic comorbidities (particularly diabetes mellitus). Review of studies following re-operative revisions shows complication rates between 20% and 33% with leak rates >10% [7]. Since weight regain is difficult to define and may also be treated with medical management, detailed discussion of risks and benefits should be undertaken prior to any operative procedures. For these reasons, a shift toward endoscopic management of these problems is underway as creative and advanced techniques are being developed which produce acceptable results, are safe, and well tolerated by patients.

B. Hodgens · S. Che · D. J. Mikami (✉)
Department of Surgery, University of Hawaii John A. Burns School of Medicine, Honolulu, HI, USA
e-mail: dmikami2@hawaii.edu

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Endoscopic Treatment

There remains a large gap between surgical and medical management of obesity and bariatric surgery-related complications. Weight regain has a nebulous definition and its true impact on overall health and metabolic conditions is difficult to study. Exploring endoscopic treatments for gastric pouch revision has gathered momentum in the last 10 years as it avoids the increased morbidity of re-operative surgery and has demonstrated potential for sustained weight loss. Critics will point toward meager overall weight loss numbers and questionable long-term durability of these devices; however they deserve consideration as a tool for gastric pouch revision.

Historically, endoluminal bariatric treatments were developed for primary treatment of obese patients, focusing on early intervention in class 1 obese patients (BMI 30–35) to prevent metabolic comorbidities. The ESSENTIAL trial in 2017 compared the POSE procedure (Primary Obesity Surgery, Endoluminal) (Figs. 35.1 and 35.2) to sham surgery and demonstrated a statistically significant difference in weight loss with treatment group experiencing an average of 4.5% total body weight loss at 12 months after intervention. The groups were intentionally not enrolled in intensive lifestyle programs which help highlight the efficacy of the procedure in absence of any other therapy. Fifty-six percent of the treatment group also benefited from improvement or resolution of diabetes at 12 months, further demonstrating the therapeutic effect of endoluminal therapy on weight loss and hormonal changes [8].

While the endoluminal devices do not stand up to bariatric surgery in terms of durability and total amount of weight loss, long-term data is available that supports their use for revision of gastric pouches as opposed to operative revision of the pouch. There is a well-described correlation between a small gastrojejunal stoma (<1 cm) and superior % EBW loss [9, 10]. Overeating leads to gastric pouch distension and dilation of the GJ anastomosis which accommodates increasing amounts of food leading to potentially rapid weight regain. The goal of many endoscopic pouch revision therapies is to halt weight regain and attempt to restore initial pouch dimensions (pouch length 3 cm, stoma size 1 cm) to induce further weight loss. Techniques to accomplish this range from partial-thickness plication of gastric folds, argon plasma coagulation of the GJ anastomosis, to injection of sclerosing substances to induce stomal narrowing. Most data gathered on these studies are small retrospective series; however overall experience has been increasing and long-term follow-up data is becoming more available.

Restorative Obesity Surgery Endoscopic (ROSE) approach is a safe and effective endoscopic technique that plicates elongated gastric pouch tissue to re-create a smaller gastric pouch and narrowed GJ anastomosis. The technique utilizes the Incisionless Operating Platform (USGI Medical), a flexible multi-lumen device that allows multiple working instruments to be intraluminal under endoscopic visualization. Excess tissue is grasped with a grasper, and expandable tissue fasteners are deployed through the tissue to plicate the gastric pouch, narrow a widened anastomosis, and close gastro-gastric fistulae. In a small series by Raman et al., ROSE was shown to halt weight regain in 90% of patients

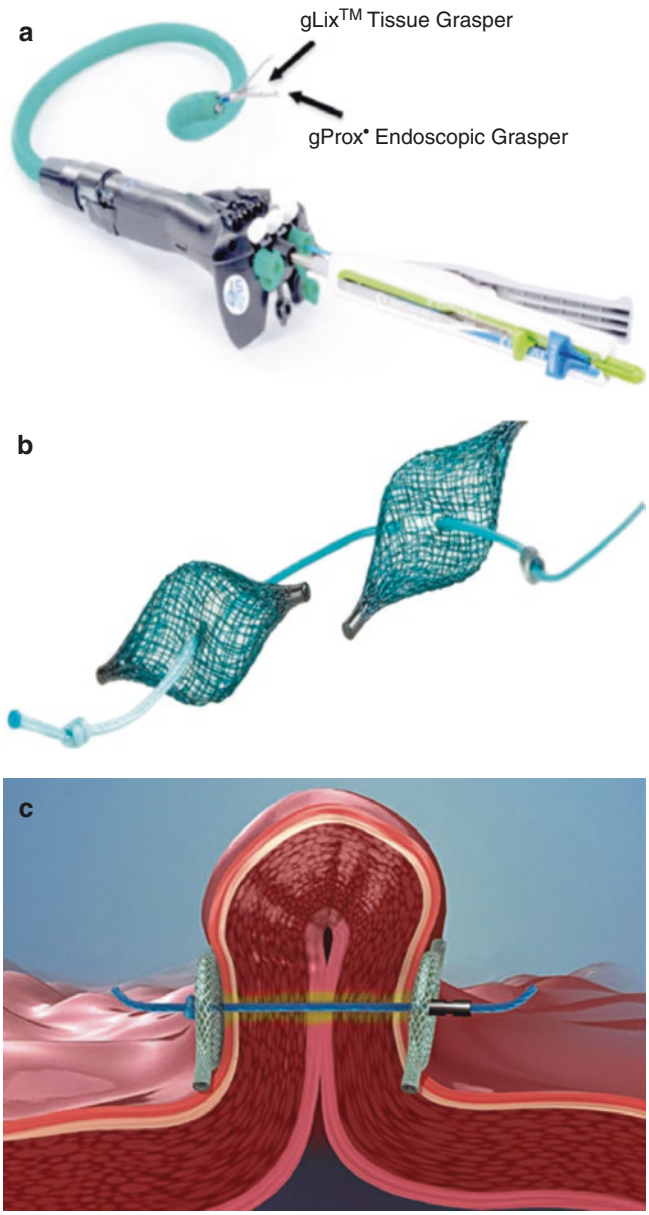

Fig. 35.1 (**a**) Incisionless Operating Platform™ with TransPort® Endoscopic Access Device; (**b**) g-Cath EZ™ Suture Anchors; (**c**) schematic of anchors holding plicated tissue permitting serosal approximation. (From: Espinós et al. [28]. Reprinted with permission from Springer Nature)

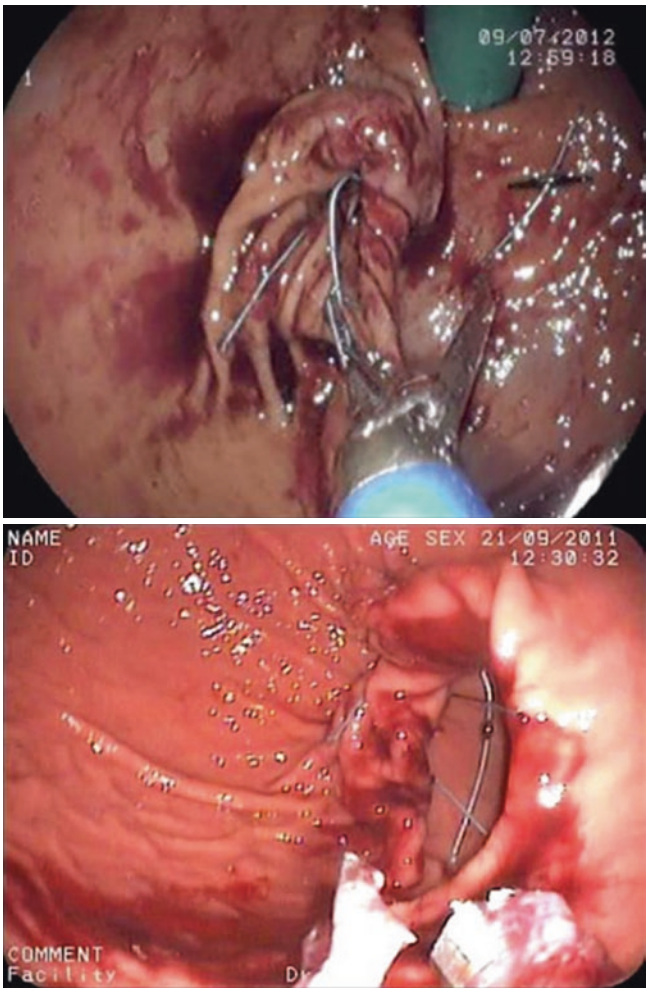

Fig. 35.2 Endoscopic view of fundal and distal body plications immediately post-POSE. (From: Espinós et al. [28]. Reprinted with permission from Springer Nature)

and produce 25% of EBW loss at 5 months after intervention [11]. Long-term results with this platform are questionable, with several studies demonstrating a return to pre-procedure pouch size and stoma diameter, as well as weight regain [12].

StomaphyX (EndoGastric Solutions) is a device that performs endoscopic full-thickness gastric plication in a similar fashion to the ROSE technique (Figs. 35.3, 35.4, and 35.5). Data shows that the procedure is safe and effective at halting weight regain, and some studies show acceptable amounts of weight loss (mean weight loss 7.3 kg) up to 12 months later [13]. Results are variable, however, and several other studies show no change in long-term weight loss and demonstrate high rates of pouch re-expansion due to failure of the sutures and their fasteners [14]. In a retrospective review of 59 patients undergoing StomaphyX, Goyal et al. noted that 12 patients undergoing endoscopy at 18 months demonstrated no sustained reduction in pouch or stoma size [15]. This device is no longer on the market.

Trans-oral reduction (TORe) is an endoscopic suturing technique that is a safe and effective way to reduce the size of a dilated GJ anastomosis with the Overstitch Endoscopic Suturing System from Apollo Endosurgery (Fig. 35.6). In comparison to a sham procedure in 2013, Thompson et al. demonstrated weight loss or stabilization in 96% of patients undergoing the procedure, and successful GJ reduction and associated weight loss have been reported with few adverse events [16–18]. The device slides over the endoscope and uses multiple ports to introduce a tissue grasping corkscrew and a needle passing device. The tissue is grasped on one side of the stoma and pulled into the scope while deploying the needle across the tissue. This is repeated on the other side of the stoma, and the suture is cinched down, and anchors deploy to fix the suture in place. Prior to suturing, it is recommended to use argon plasma coagulation to ablate the stoma as this promotes scarring and more reliable stomal stenosis. Full-thickness suturing has demonstrated superior weight loss results compared to superficial thickness and full-thickness sutures in addition to APC demonstrate better weight loss at long-term follow-up [19–21]. The newer platforms allow purse-string sutures to be placed which have proven to be more durable and associated with greater weight loss at 12 months than interrupted sutures. Current studies report a total weight loss of around 10 kg at 12 months corresponding to 40% or regained weight lost [22].

Sclerotherapy has emerged as a successful endoscopic therapy for treating weight regain in those with dilated gastrojejunostomy. It was first used as a treatment of bleeding esophageal varices causing scarring and collapsing of injected veins. Treatment was associated with a 10% risk of esophageal stricture due to injection of sclerosing agent into the muscular layer of the esophagus. In 2003, Spaulding first described the use of sclerotherapy in bariatrics to decrease the size of dilated anastomosis [23]. This technique was performed endoscopically by injecting a sclerosant, often sodium morrhuate, at the gastrojejunostomy site resulting in decreased size and compliance of the stoma. There have been multiple publications documenting the safety and feasibility of sclerotherapy in the treatment of weight regain after Roux-en-Y gastric bypass.

The initial series by Spaulding reported a 3% incidence of dilated gastrojejunostomy. Twenty patients underwent intramuscular injection of 5% sodium morrhuate circumferentially around the gastrojejunostomy site. Sclerotherapy treatment resulted in a gastrojejunostomy of 9–10 mm in all 20 patients with an average of 1.3 treatments with six 1 cc injections per treatment. Seventy-five percent of patients experienced an average weight loss of 5.8 kg at 2 months post-procedure. Spaulding showed that sclerotherapy was a safe treatment to restore gastric bypass anatomy but also reinforced the need for active exercise and diet to treat weight

Fig. 35.3 StomaphyX™ device main body. (From Mikami et al. [13]. Reprinted with permission from Springer Nature)

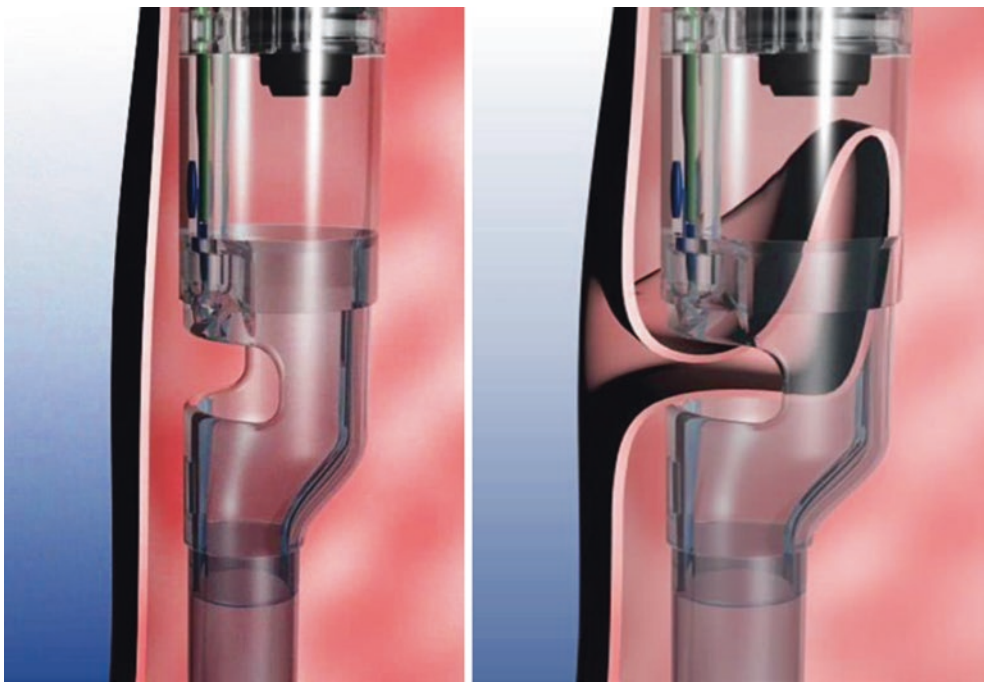

Fig. 35.4 StomaphyX™ mechanism of tissue approximation. (From Mikami et al. [13]. Reprinted with permission from Springer Nature)

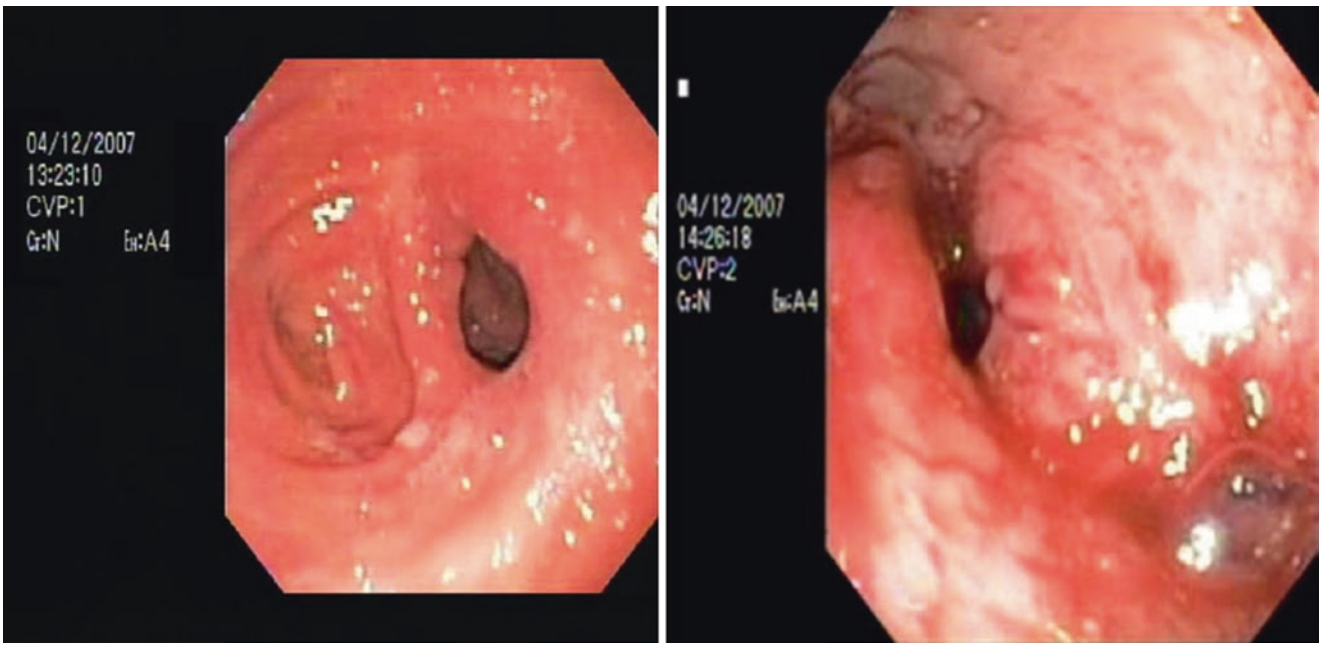

Fig. 35.5 (*left*) Pre StomaphyX™ anastomotic diameter; (*right*) Post StomaphyX™ anastomotic diameter. (From Mikami et al. [13]. Reprinted with permission from Springer Nature)

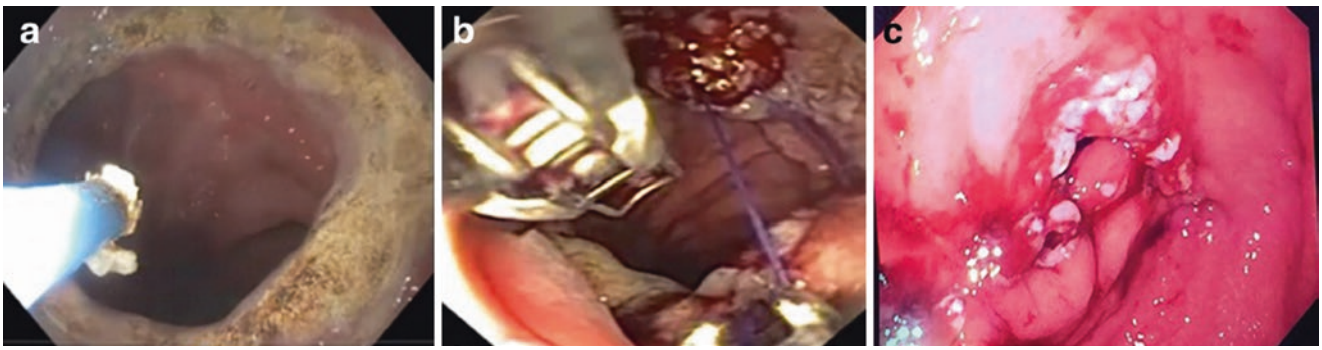

Fig. 35.6 Application of Overstitch Endoscopic Suturing System, Apollo Endosurgery. (**a**) Ablation of anastomosis with argon plasma coagulator. (**b**) Intraoperative suturing with OverStitch device. (**c**) Results of surgery: Distinct constriction of anastomosis. (From: Stier and Chiappetta [29]. Reprinted with permission from Springer Nature)

recidivism. The main complications of this procedure were postoperative pain and occasional vomiting that resolved within 2 weeks [23]. In 2007, Spaulding et al. published a long-term series of patients who underwent sclerotherapy. Of 147 patients who underwent sclerotherapy from 1999 to 2006, 32 patients were available for follow-up after 1 year with 56.3% of patients losing weight, 34.4% stabilizing their weight, and 9.4% gaining weight [24].

Since this original series, there have been larger studies documenting the efficacy and safety of sclerotherapy in the treatment of weight regain. The largest study was completed by Dayyeh et al. and included 231 consecutive patients undergoing 575 sclerotherapy sessions. The median weight regain from nadir weight loss was 36%, and the average gastrojejunostomy stoma was 19 mm. Seventy-six percent of patients undergoing sclerotherapy had stabilized their weight at 12 months. This review also showed that those who underwent two or more sclerotherapy sessions were more likely to stabilize their weight regain compared to those who only underwent one procedure, 90% vs 58% [25]. Data from Giurgius et al. provided long-term results with a mean follow-up at 22 ± 14 months with the longest follow-up at 60 months. Forty percent of their 48 patients followed up for 2 years or longer. This study provided more modest results with 58% noted to have weight stabilization at 2 years [26]. Of recent series, the most aggressive sclerotherapy was performed by Catalano et al. His group injected sclerosant until the tissue became deep purple. In 28 patients, 64% lost at

least 75% of their regained weight. This study also noted that large pre-stoma diameter was a risk for treatment failure [27]. Sclerotherapy seems to be an effective, minimally invasive method for treating weight regain after bariatric surgery.

Sclerotherapy also seems to be a relatively safe procedure when compared to gastrojejunostomy revision. The most common complication is postoperative pain with studies showing up to 75% post-inject pain for 12–23 h. Catalano et al. showed that 10 of 28 patients had shallow ulcerations which all healed with 8 weeks of PPI [27]. Dayyeh et al. further went on to show that only 1% of patients had ulceration on repeat endoscopy [25]. Overall, sclerotherapy is a safer option when compared to operative revision.

Conclusion

Endoluminal gastric pouch revision may offer a safe option for patients with weight recidivism, but long-term studies need to be done to evaluate the durability of these procedures. The key principles to treat weight regain still include the psychological and behavior aspects of obesity, and a thorough workup needs to be completed before undergoing any type of procedure. Mechanical causes of weight regain include gastric pouch enlargement, GJ anastomotic dilation, and gastric-gastric fistula which may be amenable to endoscopic interventions. Future directions in this exciting field will rely on the advancement of endoluminal platforms to make endoluminal surgery easier, safer, and more durable.

Question Section

1. What is the goal pouch size (length) and stoma diameter following endoluminal pouch revision therapy?
   A. 6 cm long, 2 cm stoma
   B. 3 cm long, 1 cm stoma
   C. 5 cm long, 1 cm stoma
   D. 1 cm long, 1 cm stoma
   E. 3 cm long, 2 cm stoma
2. With regard to trans-oral reduction of the gastric pouch, which of the following techniques have demonstrated best long-term weight loss results?
   A. Partial-thickness purse-string suturing
   B. Interrupted full-thickness suturing
   C. Argon plasma coagulation
   D. Argon plasma coagulation + full-thickness purse-string suturing
   E. Argon plasma coagulation + full-thickness interrupted suturing
3. Sclerotherapy is an endoluminal therapy associated with which of the following:
   A. Frequent ulceration
   B. Perforation at injection sites
   C. Weight stabilization due to narrowing a dilated GJ anastomosis
   D. No lasting weight loss in patients with weight regain after gastric bypass
   E. Weight stabilization only with a normal GJ diameter
4. Endoluminal gastric pouch revision is preferred to revisional surgery for which of the following reasons:
   A. Superior long-term weight loss
   B. Lower morbidity
   C. Fewer interventions required
   D. Longer procedural times

References

1. Hales CM, Carroll MD, Fryar CD, Ogden CL. Prevalence of obesity among adults and youth: United States, 2015–2016. National center for health statistics (NCHS). Data Brief. 2017;288:1–8.
2. ASMBS. Estimate of Bariatric Surgery Numbers, 2011–2017. 2018 [cited 2018; Available from: https://asmbs.org/resources/estimate-of-bariatric-surgery-numbers].
3. ASMBS Clinical Issues Committee. Bariatric surgery in class I obesity (body mass index 30-35 kg/m(2)). Surg Obes Relat Dis. 2013;9(1):e1–10.
4. Magro DO, Geloneze B, Delfini R, Pareja BC, Callejas F, Pareja JC. Long-term weight regain after gastric bypass: a 5-year prospective study. Obes Surg. 2008;18(6):648–51.
5. Roberts K, Duffy A, Kaufman J, Burrell M, Dziura J, Bell R. Size matters: gastric pouch size correlates with weight loss after laparoscopic Roux-en-Y gastric bypass. Surg Endosc. 2007;21(8):1397–402.
6. Inabnet WB 3rd, Belle SH, Bessler M, Courcoulas A, et al. Comparison of 30-day outcomes after non-LapBand primary and revisional bariatric surgical procedures from the longitudinal assessment of bariatric surgery study. Surg Obes Relat Dis. 2010;6(1):22–30.
7. Hallowell PT, Stellato TA, Yao DA, Robinson A, Schuster MM, Graf KN. Should bariatric revisional surgery be avoided secondary to increased morbidity and mortality? Am J Surg. 2009;197(3):391–6.
8. Sullivan S, Swain JM, Woodman G, Antonetti M, et al. Randomized sham-controlled trial evaluating efficacy and safety of endoscopic gastric plication for primary obesity: the ESSENTIAL trial. Obesity (Silver Spring). 2017;25(2):294–301.
9. Horgan S, Jacobsen G, Weiss GD, Oldham JS Jr, et al. Incisionless revision of post-Roux-en-Y bypass stomal and pouch dilation: multicenter registry results. Surg Obes Relat Dis. 2010l;6(3):290–5.
10. Thompson CC, Jacobsen GR, Schroder GL, Horgan S. Stoma size critical to 12-month outcomes in endoscopic suturing for gastric bypass repair. Surg Obes Relat Dis. 2012;8(3):282–7.
11. Raman SR, Holover S, Garber S. Endolumenal revision obesity surgery results in weight loss and closure of gastric-gastric fistula. Surg Obes Relat Dis. 2011;7(3):304–8.
12. Gallo AS, DuCoin CG, Berducci MA, Nino DF, et al. Endoscopic revision of gastric bypass: holy grail or epic fail? Surg Endosc. 2016;30(9):3922–7.

13. Mikami D, Needleman B, Narula V, Durant J, Melvin WS. Natural orifice surgery: initial US experience utilizing the StomaphyX device to reduce gastric pouches after Roux-en-Y gastric bypass. Surg Endosc. 2010;24(1):223–8.
14. Ong'uti SK, Ortega G, Onwugbufor MT, Ivey GD, Fullum TM, Tran DD. Effective weight loss management with endoscopic gastric plication using StomaphyX device: is it achievable? Surg Obes Relat Dis. 2013;9(1):113–7.
15. Yimcharoen P, Heneghan HM, Singh M, Brethauer S, Schauer P, Rogula T, Kroh M, Chand B. Endoscopic findings and outcomes of revisional procedures for patients with weight recidivism after gastric bypass. Surg Endosc. 2011;25(10):3345–52.
16. Thompson CC, Chand B, Chen YK, DeMarco DC, et al. Endoscopic suturing for transoral outlet reduction increases weight loss after roux-en-Y gastric bypass surgery. Gastroenterology. 2013;145(1):129–137 e3.
17. Jirapinyo P, Dayyeh BK, Thompson CC. Gastrojejunal anastomotic reduction for weight regain in roux-en-y gastric bypass patients: physiological, behavioral, and anatomical effects of endoscopic suturing and sclerotherapy. Surg Obes Relat Dis. 2016;12(10):1810–6.
18. Jirapinyo P, Kroner PT, Thompson CC. Purse-string transoral outlet reduction (TORe) is effective at inducing weight loss and improvement in metabolic comorbidities after roux-en-Y gastric bypass. Endoscopy. 2018;50(4):371–7.
19. Kumar N, Thompson CC. Comparison of a superficial suturing device with a full-thickness suturing device for transoral outlet reduction (with videos). Gastrointest Endosc. 2014;79(6):984–9.
20. Kumar N. Weight loss endoscopy: development, applications, and current status. World J Gastroenterol. 2016;22(31):7069–79.
21. Brunaldi VO, Jirapinyo P, de Moura DTH, Okazaki O, et al. Endoscopic treatment of weight regain following roux-en-y gastric bypass: a systematic review and meta-analysis. Obes Surg. 2018;28(1):266–76.
22. Schulman AR, Kumar N, Thompson CC. Transoral outlet reduction: a comparison of purse-string with interrupted stitch technique. Gastrointest Endosc. 2018;87(5):1222–8.
23. Spaulding L. Treatment of dilated gastrojejunostomy with sclerotherapy. Obes Surg. 2003;13(2):254–7.
24. Spaulding L, Osler T, Patlak J. Long-term results of sclerotherapy for dilated gastrojejunostomy after gastric bypass. Surg Obes Relat Dis. 2007;3(6):623–6.
25. Abu Dayyeh BK, Jirapinyo P, Weitzner Z, Barker C, Flicker MS, Lautz DB, Thompson CC. Endoscopic sclerotherapy for the treatment of weight regain after Roux-en-Y gastric bypass: outcomes, complications, and predictors of response in 575 procedures. Gastrointest Endosc. 2012;76(2):275–82.
26. Giurgius M, Fearing N, Weir A, Micheas L, Ramaswamy A. Long-term follow-up evaluation of endoscopic sclerotherapy for dilated gastrojejunostomy after gastric bypass. Surg Endosc. 2014;28(5):1454–9.
27. Catalano MF, Rudic G, Anderson AJ, Chua TY. Weight gain after bariatric surgery as a result of a large gastric stoma: Endotherapy with sodium morrhuate may prevent the need for surgical revision. Gastrointest Endosc. 2007;66(2):240–5.
28. Espinós JC, et al. Early experience with the incisionless operating platform™ (IOP) for the treatment of obesity: the primary obesity surgery endolumenal (POSE) procedure. Obes Surg. 2013;23(9):1375–83.
29. Stier C, Chiappetta S. Endoluminal revision (OverStitch (TM), Apollo Endosurgery) of the dilated gastroenterostomy in patients with late dumping syndrome after proximal Roux-en-Y gastric bypass. Obes Surg. 2016;26(8):1978–84.