CASE REPORT JSLS

Using the StomaphyX™ Endoplicator to Treat a Gastric Bypass Complication

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ABSTRACT

Background and Objectives: As the number of bariatric operations performed increases, the number of patients requiring reoperation for failed weight loss is expected to proportionately increase. Natural orifice surgery is an alternative approach to revisional gastric bypass surgery when postoperative complications, such as dilatation of the gastrojejunostomy, gastrogastric fistula, and gastric pouch, dilation occur.

Methods: The present article reports on the safe and successful use of an endoscopic tissue plicating device in a patient found to have a dilated gastric pouch and a gastrogastric fistula 12 years after an open, nondivided RYGB.

Results: The procedure was performed without complications and resulted in a reduced pouch size to approximately 30cc to 50cc and redirection of the flow of gastric contents through her gastrojejunostomy. The patient's early satiety returned and, 1 year postoperatively, she had incurred a 45-pound weight loss.

Discussion: The morbidity and mortality of revision gastric bypass was avoided while the patient's goal of moderate weight loss was achieved. Tissue plicating devices offer an alternative for repair of some postbariatric complications. With the rapid advances in endoluminal technology and increasing experience with natural orifice surgery, the ability to successfully address surgical problems through less invasive means will continue to improve.

Key Words: Bariatric surgery, Complications, Fistula, Endoscopy.

INTRODUCTION

Obesity is becoming an increasingly widespread epidemic in the United States. According to a study performed between 1999 and 2004,[1] the incidence of overweight children and adolescents has increased from 13.9% in 1999 to 2000 to 17.1% in 2003 to 2004. Similarly, obesity in adults has increased from 30.5% to 32.2% during the same time period. As a result, the number of weight loss surgeries being performed in the United States has predictably increased from 13 365 in 1998 to more than 100 000 in 2003. This upward trend in bariatric surgery is likely to continue until the obesity epidemic is controlled. With this, bariatric surgeons are now encountering the challenge of more and more patients who require revisional procedures secondary to failed weight loss or complications.

Single institution case series[2] indicate that revisions are performed in 5% to 60% of patients who have undergone primary restrictive or restrictive-malabsorptive procedures. Approximately 10% to 40% of patients fail to achieve long-term weight loss after Roux-en-Y gastric bypass (RYBG), usually secondary to dilation of the gastric pouch, and less commonly to gastrogastric (GG) fistula.[3] Both open and laparoscopic surgical revision procedures have been used for repair. However, surgical intervention can be challenging and fraught with serious morbidities, even in the most experienced hands. Secondary to factors like extensive intraabdominal adhesions, ulcers, inflammation, bowel obstructions, and metabolic disturbances leading to poor nutrition, revisional surgery can lead to undesirable outcomes. These include leak, obstruction, perforation, staple-line disruption, blind loop syndrome, bleeding, stricture, sepsis, wound dehiscence, pulmonary embolism, and death.[4] Natural orifice surgery using the StomaphyX endoplicator is an alternative approach to revisional gastric bypass surgery when postoperative complications occur. Its minimally invasive nature makes it a safe and promising approach that may be associated with fewer intraoperative and postoperative complications. The following case highlights the use of StomaphyX to restore weight loss in a patient after nondivided RYGB.

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CASE REPORT

A 45-year-old white female presented 12 years after an open, nondivided RYGB. Over the preceding 6 months, she no longer experienced early satiety and gained 40 pounds. An upper GI (UGI) revealed a dilated gastric pouch and a GG fistula, which was confirmed on endoscopy. The pouch was estimated to be 150cc to 200cc with a 2-cm GG fistula. The gastrojejunal (GJ) stoma was also dilated.

The patient elected to proceed with natural orifice surgery using the StomaphyX device. The device did not allow placement of plications directly at the fistula site, but did allow placement of full-thickness fasteners in a concentric fashion from the GJ to the gastroesophageal junction. Pouch size was reduced to approximately 30cc to 50cc. Although postoperative UGI showed persistent GG fistula, it also showed delayed flow through the GJ and a marked decrease in pouch size, which ultimately enabled the patient to achieve her desired outcome of weight loss.

At 2 months after surgery, the patient had regained early satiety and lost 25 pounds. Now, nearly 1 year after her gastric pouch endoplication, she continues to experience early satiety and has lost 45 pounds. We will continue to follow this patient and record her progress, as more long-term data are necessary to evaluate the true efficacy of this procedure (**Figure 1).**

DISCUSSION

Although bariatric surgery can result in durable and significant weight loss, throughout its approximate 50-year history, it has also been laden with failed operations and serious postoperative complications that require revision. Because of the significantly higher perioperative complication rate, the risk of revisional surgery must be balanced against its potential benefit. The risk of developing perioperative complications after revisional bariatric surgery is 2 to 3 times greater, and the leak rate may be 5 to 10 times higher. This is likely related to factors such as impaired tissue quality and markedly decreased blood supply in reoperative areas.[5] Despite this, some authors advocate operative revision for failed weight loss, because of eventual improvement in comorbidities associated with obesity.[6]

One study reviewed a prospective database of patients undergoing both primary and open revisional bariatric procedures between 1998 and 2007. Of note, in this study inadequate weight loss alone was not viewed as an indication for revision. A 9-fold increase in leaks, a 2- to 5-fold increase in ICU utilization, and a 1.5-fold increase in length of stay in patients undergoing revisional compared with primary bariatric surgery was found. Despite this, researchers had a 0% 30-day postoperative mortality rate for revisions. They concluded that, in experienced hands and via the open approach, revisional bariatric surgery can be safe.[2] Another case series reported on the outcomes of 215 consecutive revisional bariatric operations performed by 1 surgeon over the past 22 years. All but 3 of these procedures were performed open. Weight loss failure was the indication for 151 of these, and complications from the primary procedure were the indication for the other 64. Researchers found major perioperative com-

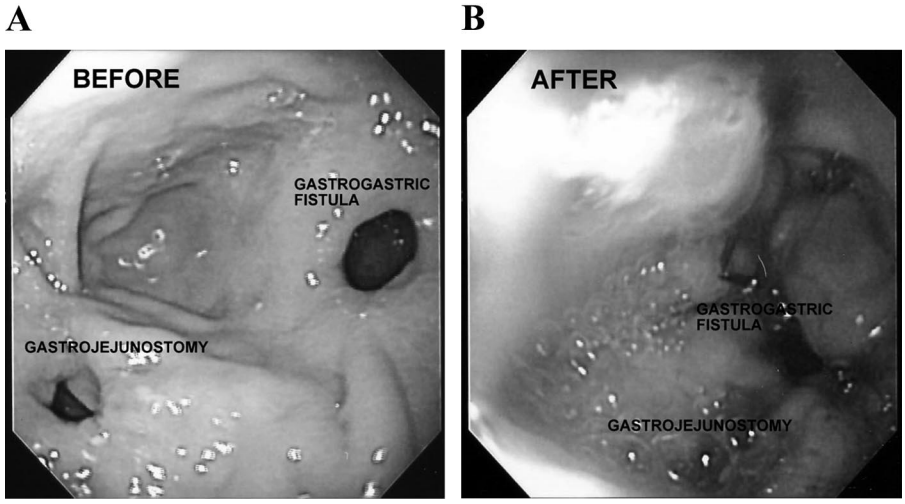

Figure 1. Endoscopy before **(a)** and after **(b)** plication using the StomaphyX.

plications in 45 patients (21%): 15 leaks, 11 wound infections, 3 pulmonary embolisms, and 16 miscellaneous, including 3 deaths (1.4%). Complications were more frequent, occurring 36.9% of the time in patients who had had primary procedures performed by other surgeons, versus 10.3% of patients on whom the surgeon had performed the initial procedure. This led him to suggest that surgeons should perform their initial revisions on their own patients, rather than patients being referred from other surgeons.[5]

Because the number of operations performed for treating morbid obesity has increased almost 10-fold during the past decade, the number of patients requiring bariatric revision for failed weight loss or complication has proportionately increased also. While most of these are performed open, some laparoscopic revisions performed on primary laparoscopic operations, show fewer wound complications, less blood loss, and lower mortality.[6]

With the advent of natural orifice surgery, the armamentarium of possibilities to treat patients with failed primary bariatric procedures has further broadened. Those most likely to benefit from these procedures, in addition to the morbidly obese, include the critically ill and those at high risk for surgery because of significant comorbidities.[7] A case series of 3 patients with chronic gastric leaks after RYGB showed successful leak closure using a variety of endoscopic methods. These included argon plasma coagulation, hemoclips, fibrin glue, Polyflex stent placement, and distal GJ stenosis dilation. In all patients, leak closure was achieved and symptoms resolved completely. The only complication was stent migration in one patient, and it was retrieved endoscopically.[4] In addition, a retrospective analysis[8] looked at treating 19 patients after various bariatric procedures (11 with leaks, 2 with chronic fistulas, and 6 with strictures) with endoscopic stent placement. Oral feeding was started immediately in 79% of patients. At mean follow-up of 3.6 months, 90% had symptomatic improvement and 84% had resolution of leak or stricture. Healing occurred at a mean of 33 days for leak, 46 days for fistula, and 7 days for stricture. Stent migration occurred in 58% of stents placed, with 3 requiring surgical removal. Another case series[9] of 8 patients with significant weight regain and dilated GJ anastomosis after RYGB demonstrated the effectiveness of endoscopically placed sutures at the rim of the GJ anastomosis. When tightened, these sutures created tissue plications that reduced the anastomotic size. At 4 months, 6 of the 8 patients had lost weight (average of 10kg), and their BMIs went from an average of 40.5 to 37.7. All endoscopic pouch reductions were done without significant complication.

Most recently, a review[10]of the initial US experience using the StomaphyX device to decrease gastric pouch size in patients undergoing RYBG concluded that endoluminal revision using the StomaphyX may offer a safe and effective alternative to revisional bariatric surgery. The authors used the StomaphyX to perform endoluminal reduction of gastric pouches in 39 patients, over 90% of whom were female with an average age of 47.8 years and an average body mass index (BMI) of 39.8 kg/m^2. At 2 weeks postprocedure, patients had lost an average of 3.8kg (7.4% excess body weight loss, EBWL). At 6 months, the remaining patients being followed (n=14) had lost 8.7kg (17% EBWL), and at 1 year, the 6 patients still being followed had lost 10kg (19.5% of EWBL). As with our patient, symptoms improved, and no major complications occurred.

The above studies suggest that some postbariatric complications can be successfully addressed using endoscopic methods. Although several endoscopic examinations were required, surgery and its associated complications were avoided. The procedures were tolerated well with minimal complications.[4]

Our case report demonstrates that the StomaphyX is another device that warrants consideration in patients failing to achieve satisfactory weight loss after RYGB. With further study, and more long-term data, the efficacy of this procedure will be better elucidated. We have had difficulty recruiting patients for StomaphyX endoluminal revision at our institution, because the procedure is not covered by insurance, and the majority of our patients are Medicare or Medicaid insured. Despite this, we suggest that all postbariatric surgery patients with nonlife-threatening complications, such as dilated gastric pouch, dilated GJ anastomosis, and GG fistula be considered for endoluminal repair using StomaphyX. Exclusion criteria for endoluminal revision should include the presence of peritoneal signs or a free perforation and leak into the peritoneal space, both of which require emergent operative repair.

The StomaphyX is a transoral device that places full-thickness polypropylene SerosaFuse fasteners, creating gastric plications. These fasteners are nonabsorbable and have strength equivalent to a 3-0 suture. Through tension-free tissue approximation, they can be used to shrink stoma and gastric pouch sizes. There have been several case studies in which the device was successfully used for pouch and anastomosis volume reduction. A case report of 2 patients has also shown StomaphyX to be effective in treating gastric leaks after RYGB.[3] We attempted to ad-

dress our patient's gastrogastric fistula using the device (**Figure 2).**

One potential drawback of the device is that its overall structure and tip length somewhat limit the operator's ability to manipulate it. As a result, we were unable to place fasteners in the location necessary to completely close the gastrogastric fistula. However, the dilated gastric pouch and GJ stoma were successfully reduced. As a result, the restrictive portion of the patient's initial procedure was recreated. Her early satiety returned and she began, and continues, to lose weight. In addition, the procedure was fast (lasting approximately one hour), well tolerated, and without complication. The patient went home the following morning after tolerating a clear liquid diet, which was advanced to a regular diet within the next couple of days. The morbidity and mortality of revision gastric bypass was avoided while the patient's goal of moderate weight loss was achieved (**Figure 3).**

CONCLUSION

The StomaphyX is an alternative for repair of some post-bariatric complications. In this case, although the gastrogastric fistula remained patent, both the pouch size and GJ stoma were reduced, allowing the patient to again experience early satiety. She, therefore, continues to lose weight by restrictive means. With the rapid advances of endoluminal technology and increasing experience with

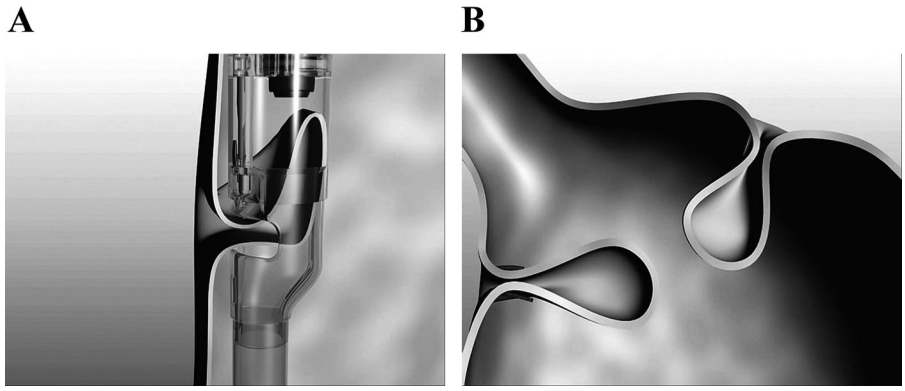

Figure 2. (a) Tissue is drawn into the chamber, and **(b)** plications are created when the fasteners are deployed.

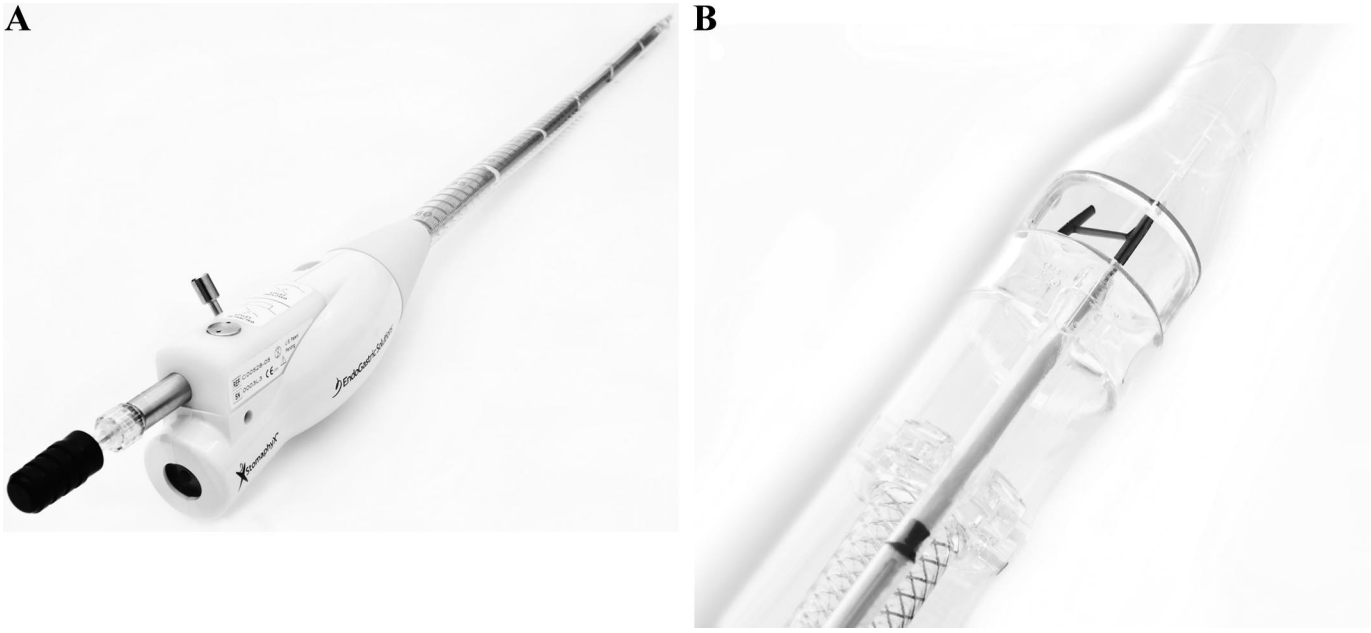

Figure 3. StomaphyX (a) Device and **(b)** tip.

natural orifice surgery, the ability to successfully address surgical problems through less-invasive means will continue to improve.[11] Future research must focus not only on the technological development of these devices, but also on their long-term safety, efficacy, and durability, compared with surgical alternatives, as they are applied in the clinical setting.

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