Natural Orifice Surgery (NOS) Using StomaphyX™
for Repair of Gastric Leaks after Bariatric Revisions

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Abstract Gastric leaks represent serious complications of
bariatric surgery. With the increasing popularity and perfor-
mance of bariatric procedures, the incidence of leaks and
associated complications are expected to increase. Minimally
invasive natural orifice surgery represents a novel and
promising approach to gastric leak management, especially for
morbidly obese patients who are at much higher risk from open
or laparoscopic surgical procedures. The present article reports
two cases of the safe and successful use of the EndoGastric
Solutions StomaphyX™ device to alter the flow of gastric
contents and repair gastric leaks resulting from bariatric revision
surgery. Both patients were at a high risk and could not undergo
another open or laparoscopic surgery to correct the leaks that
were not healing. The StomaphyX procedures lasted approxi-
mately 30 min, were performed without any complications, and
resulted in the resolution of the gastric leaks in both patients.

Keywords RYGB · Revision · Complications · Bariatric ·
Volume reduction

Introduction

The Roux-en-Y gastric bypass (RYGB) is the most commonly
performed bariatric procedure in the USA to treat morbid
obesity [1]. Numerous studies have documented the effec-
tiveness of RYGB in promoting excess body weight loss
typically in the 65–80% range after 1.5 to 2 years [1].
Despite the favorable short-term outcomes of this bariatric
surgical procedure, approximately 10–40% of patients do not
achieve successful long-term weight loss [2]. The weight
regain occurs typically within 2 to 7 years after RYGB
surgery and is associated with dilation of the pouch or stoma
[3, 4]. Several open and laparoscopic bariatric revision
procedures have been used in an attempt to correct these
dilations, but they all have been associated with serious
complications, such as perforations, obstruction, staple-line
disruption, blind loop syndrome, stomal ulcer, and incisional
hernias [2, 5, 6]. The most feared complication of gastric
surgery for morbid obesity, however, is a postoperative
gastric leak with the development of peritonitis [2, 5]. After
RYGB, leaks have been reported at the gastrojejunostomy,
the distal stomach, or the jejunojenuostomy in up to 5% of
all revision procedures with a significant morbidity and
mortality rate that may exceed 50% [7, 8].

StomaphyX™ (EndoGastric Solutions, Inc., Redmond,
WA, USA) is an incisionless transoral fastening device that
creates plications using polypropylene SerosaFuse™ fasten-
ers (Fig. 1). StomaphyX has been cleared by the US Food and
Drug Administration for tissue approximation and ligation
in the gastrointestinal (GI) tract. The device has been
successfully used for pouch and anastomosis volume reduc-
tion [9, 10]. The present study reports the results of two
patients who were treated with StomaphyX for management
of gastric leaks that developed after revisions of RYGB.

Case 1

A 58-year-old woman underwent a RYGB procedure at
another institution in 2003. The procedure was successful
and resulted in the creation of a 40-cc gastric pouch. The
patient completed counseling for eating disorders before
and after her original surgery. Unexpected events in her life,
however, brought on depression, and she subsequently returned to overeating, which resulted in dilation of the gastric pouch to 600 cc and commensurate weight regain.

Once the patient regained control of her personal life and her eating habits, she complained of a lack of satiety. An open pouch reduction surgery was undertaken after extensive discussions with the patient, counselors, and her family members. The patient initially did well after the surgery, but by day 12, she complained of increasing abdominal pain and experienced fever of 38.9°C. Computer tomography revealed a leak from the gastric pouch. The patient was taken to the operating room and underwent debridement of the staple line from the area of the initial surgery, dehiscence on the gastric pouch (approximately 2 cm in length), primary closure with drainage, and placement of a feeding jejunostomy in the biliopancreatic limb. Despite an initially successful procedure, a leak had redeveloped on day 5 and required another sump drain to be placed. The jejunostomy feeding tube was utilized, but there was ongoing minute reflux of tube feeds, bile, and gastric contents from the pouch recovered by the drains. The output of the drains was more than 50 cc per hour when the patient was on tube feeds and 20 cc per hour when total parenteral nutrition (TPN) was used; therefore, TPN was used to maintain the patient’s nutritional status. A positive nitrogen balance was attained by an adequate caloric intake and confirmed by a pre-albumin level greater than 14. The drains were slowly backed out but resulted in no improvement in the patient’s gastric leak. The patient remained medically stable and afebrile.

An upper endoscopy was performed, and the leak was found to be in a dependent position relative to the gastrojejunostomy (Fig. 2), assuring that gastric contents flowed preferentially through and placed pressure on the leak. Removal of residual sutures was performed endoscopically, and the leak was estimated to be approximately 24F bougie in size (7.6 mm). The patient received conservative therapy with maximal nutritional support, but there was no progression in the healing of the leak for 4 months. Because of the patient’s condition, another open revision surgery was considered to be of high risk.

As an alternative to an open or laparoscopic procedure, the patient elected to undergo natural orifice surgery (NOS) using the StomaphyX device. The patient was taken to the operating room and placed under general anesthesia. An upper endoscopy was performed to identify the anatomical landmarks of the pouch and to locate the leak. The endoscope was then inserted through the shaft of the StomaphyX device (Fig. 1), and the device was introduced through the patient’s mouth into the pouch under continuous visualization. Once inside the pouch, vacuum was employed to draw a large fold of tissue proximal to the leak into the shaft of the device. The stylet of the device, which is maintained entirely within the shaft at all times, was advanced, and the first polypropylene fastener was deployed across the base of the tissue fold creating a stable full-thickness plication. Without removing the device from the patient, another five plications were created circumferentially at 1 cm from the leak. The plications on opposing sides of the leak were then pulled together and fastened to each other using the StomaphyX device in the same manner that was used to create the first plications. Additional three fasteners were deployed to create a bridge of tissue to shield the leak. The device was removed, and a second upper

![Fig. 1](image1.png)

**Fig. 1** A general view (a) and the shaft part (b) of the StomaphyX device

![Fig. 2](image2.png)

**Fig. 2** Upper GI radiography showing leak inferior to the jejunum in patient 1
gastrointestinal endoscopy was performed to evaluate the results (Fig. 3). The duration of the procedure from insertion of the devices to its withdrawal was 30 min. There were no perioperative or postoperative complications. The endoscopy revealed that the leak was reduced by at least 70%. The side of the pouch was also shortened to eliminate the dependency of the leak relative to the gastrojejunostomy. By pleating the pouch and including the leak, the revised anatomy of the pouch formed a ridge of tissue that changed the flow of gastric contents. This was documented by a change in irrigation flow before and after the StomaphyX procedure. At this time, the outflow from the drains essentially stopped. The leak rapidly closed within a few days, and all drains were removed. The patient was released 4 days after the procedure and was instructed to remain on a liquid diet, avoid strenuous physical activities for the first 1 to 2 weeks, and advance progressively to a regular diet and normal lifestyle activities over the following 5 to 6 weeks. An endoscopy examination at 6 months revealed the absence of a leak or fistula.

Case 2

A 42-year-old man desired a revision for weight regain after an RYGB performed in 1997. Five years after the original RYGB, a perforated stomach ulcer was diagnosed and treated at another institution by closing the ulcer and reconfiguring the small bowel. Ten years after the original RYGB, the patient underwent additional revisional surgery. A vertical sleeve and duodenal switch was performed. A leak of about 1 cm in diameter developed immediately along the staple line of the vertical sleeve within 5 cm from the gastroesophageal junction (Fig. 4) and was accompanied by symptomatology typical for a leak. The leak did not close despite NPO and conservative therapy with maximal nutritional support by tube feeds. The nutritional support provided an adequate caloric intake and a positive nitrogen balance, which was confirmed by a pre-albumin level greater than 14. The patient remained stable, but there was no improvement in the leak after 6 weeks despite the drains being slowly backed out.

The patient underwent the NOS StomaphyX procedure under general anesthesia following the protocol used for patient 1. The procedure lasted 30 min and resulted in the creation of six plications and a tissue shield over the leak. A computer tomography scan performed the next day confirmed that the leak had been completely eliminated (Fig. 5). No perioperative complications or postoperative symptoms were reported. The patient was released 4 days after the procedure and followed the same dietary and...
Discussion

The two cases presented in this article demonstrated a successful repair of gastric pouch leaks using the StomaphyX device. In the first case, the StomaphyX procedure resulted in reducing the leak by 70% and promoted its healing by diverting the gastric content flow in such a way that the leak was no longer dependent to the gastrojejunostomy. In the second case, the leak was not dependent upon the gastrojejunostomy, and the StomaphyX device was used to close the leak and create a shield of tissue that allowed the leak to heal. The StomaphyX procedures were fast and safe, as they lasted only 30 min and did not result in any complications. Both patients were released in 4 days after the procedure and were able to return to their normal diet and lifestyle within 60 days.

The StomaphyX device made possible the repair of gastric leaks in two patients who were not candidates for the standard higher risk open or laparoscopic procedures. The transoral StomaphyX device proved invaluable to these patients. Transoral incisionless surgery using StomaphyX eliminates the risk of incisional infection and incisional herniation and reduces the risk of nosocomial infections. It is expected that, with future modifications, StomaphyX will allow handling of post-gastric bypass leaks, fistulas, perforated ulcers, and, possibly, other post-bariatric complications, which are expected to increase with the increasing popularity and performance of bariatric procedures.

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References

1. Thompson CC, Slattery J, Bundga ME, Lautz DB. Peroral endoscopic reduction of dilated gastrojejunal anastomosis after Roux-en-Y gastric bypass: a possible new option for patients with weight regain. Surg Endosc. 2006;20:1744–8.
2. Elder KA, Wolfe BM. Bariatric surgery: a review of procedures and outcomes. Gastroenterology. 2007;132:2253–71.
3. Fernandez AZ, Jr., DeMaria EJ, Tichansky DS, Kellum JM, Wolfe LG, Meador J, et al. Experience with over 3,000 open and laparoscopic bariatric procedures: multivariate analysis of factors related to leak and resultant mortality. Surg Endosc. 2004;18:193–7.
4. Higa KD, Boone KB, Ho T. Complications of the laparoscopic Roux-en-Y gastric bypass: 1,040 patients—what have we learned? Obes Surg. 2000;10:509–13.
5. Sugerman HJ. Bariatric surgery for severe obesity. J Assoc Acad Minor Phys. 2001;12:129–36.
6. Gould JC, Garren MJ, Starling JR. Lessons learned from the first 100 cases in a new minimally invasive bariatric surgery program. Obes Surg. 2004;14:618–25.
7. Madan AK, Lanier B, Tichansky DS. Laparoscopic repair of gastrointestinal leaks after laparoscopic gastric bypass. Am Surg. 2006;72:586–90; discussion 590–591.
8. Schwartz RW, Strodel WE, Simpson WS, Griffen WO, Jr. Gastric bypass revision: lessons learned from 920 cases. Surgery. 1988; 104:806–12.
9. Higa KD, Boone K, Nimeri A, Tercero F, Jackson A, Khan A. Gastric bypass: increased restriction for poor weight loss. Surg Endosc. 2007;21:1922–3.
10. Nguyen NT. Reoperations and revisions in bariatric surgery. Surg Endosc. 2007;21:1907–8.