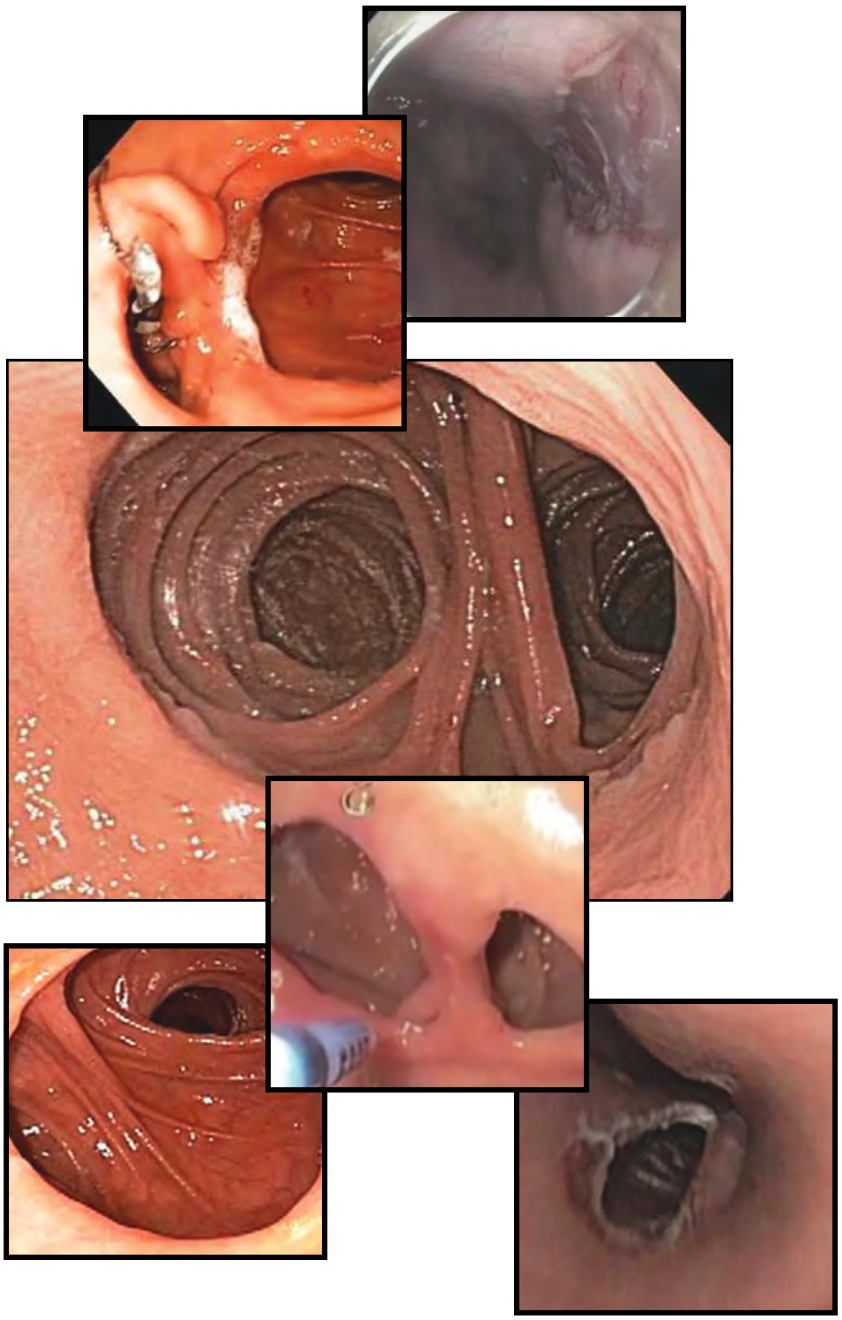
Endoscopic Suturing

A Compendium of Current Clinical Experience

Inside



Vol. 10, No. 11 • November 2013 • Supplement B

Bariatric Times

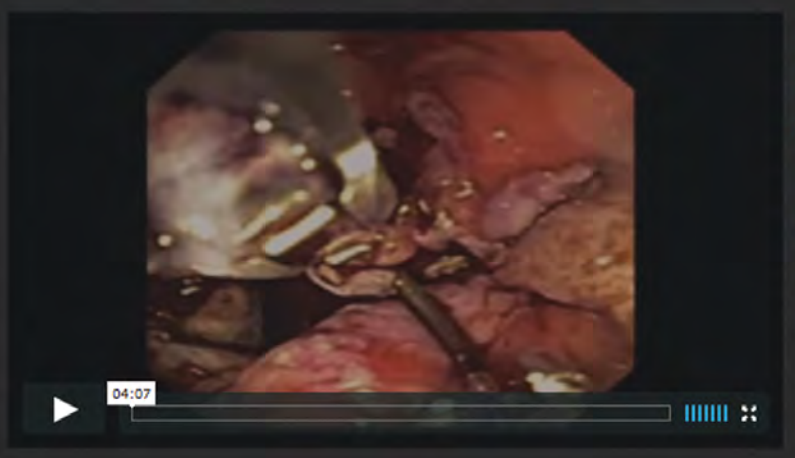
Clinical Developments and Metabolic Insights in Total Bariatric Patient Care

Scan this QR code for the digital edition.

Sponsored by:

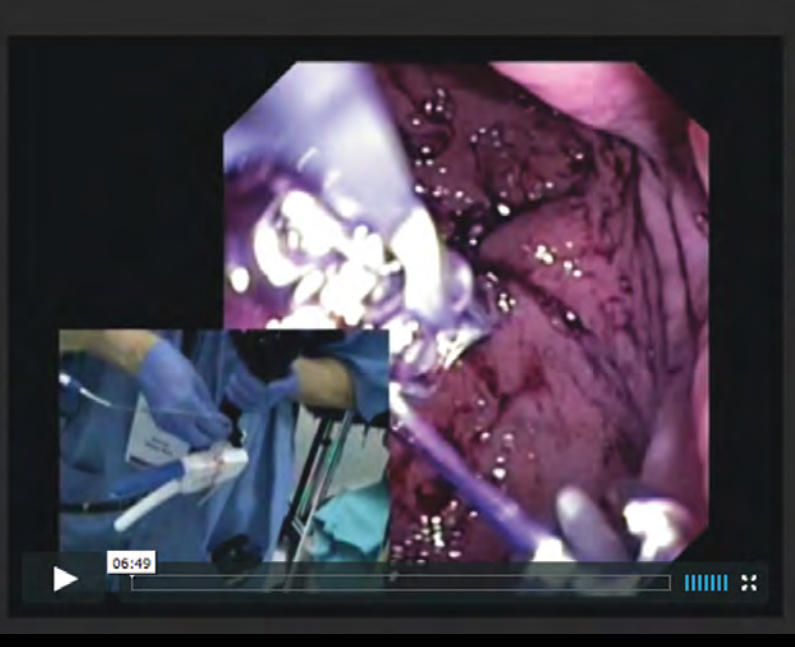
apollo endosurgery

Endoscopic Suturing: A Compendium of Current Clinical Experience



Utilization of Endoscopic Suturing for Management of Weight Regain: Transoral Outlet Reduction

United States Experience
Video by Christopher C. Thompson, MD, and Nitin Kumar, MD



Utilization of Endoscopic Suturing for Management of Weight Regain: Transoral Outlet Reduction

Outside the United States Experience
Video by Manoel Galvao Neto, MD

PLUS

- **Endoluminal Plication of a Dilated Gastric Sleeve to Re-initiate Weight Loss**
  by George M. Eid, MD, FACS, FASMBS
- **Closure of a POEM Mucosotomy**
  by Stavros N. Stavropoulos, MD
- **OverStitch™ Endoscopic Suturing System by Apollo Endosurgery**

To view more videos of endoscopic suturing using the OverStitch™ system, visit
www.apolloendo.com/video/

OverStitch™ Endoscopic Suturing System

Full thickness surgical suturing delivered through a flexible endoscope

To learn more about our broad range of applications, scan the code or visit apolloendo.com.

Defining the Future of Endoscopic Surgery™

apollo endosurgery

October 2013 MKT-00145-00 R01

CLINICAL EDITORS

Natan Zundel, MD, FACS
Clinical Professor of Surgery, Florida International University College of Medicine, Miami, Florida

Christopher C. Thompson MD
Brigham and Women's Hospital, Boston, Massachusetts

Suturing is the most basic skill learned by surgeons all around the world. The use of suture in the GI tract to perform procedures and manage complications has well been tested and proven over years of clinical practice. The skill of suturing has taken us from ligating vessels to complex bowel anastomosis and everything in between. As laparoscopy was introduced, we longed for the ability to use this basic skill to further less invasive procedures. The laparoscopic cholecystectomy was our entry into this new world but it wasn't until the advent of laparoscopic needle drivers and dedicated laparoscopic suturing devices that our procedures were able to advance to the point they are now.

Today, we're on the verge of the next step in improving patient care by fully leveraging flexible endoscopy to further reduce the invasiveness of surgery. Just as in laparoscopy, there has always been a need for the basic skill of suturing to be used in a new application. Flexible endoscopic suturing is here, and in this compendium the authors describe their experiences and the benefit to patients, institutions and the healthcare system.

We begin this collection by looking further into the need for suturing and the proper metrics to train and evaluate competencies in the inevitable move to true surgical endoscopy. Following this foundation article, we take a look at the use of endoscopic suturing and its role in the management of post Roux-en-Y procedure weight regain; both in the US and outside the US. This section concludes with a discussion on a similar approach to weight regain in post-gastric sleeve patients.

Section II explores endoscopic gastroplasty as a primary metabolic and bariatric procedure. We take a look at experiences of experienced gastroenterologists and surgeons both in the US and outside the US. While these results are preliminary, there is certainly positive evidence this approach could be part of a multidisciplinary program.

Section III takes a closer look at the associated costs for obesity, weight loss and the overall cost-effectiveness of endoscopic bariatric therapy, specifically under accountable- care payment models. This link between improving quality while reducing costs is critical in our evolving healthcare system.

Sections IV and V discuss the benefits and possibilities of endoscopic suturing. First, we address the use of endoscopic suturing in the management of adverse outcomes in patients who have undergone bariatric and/or metabolic procedures. Following that article, we take a look at the endless possibilities the use of endoscopic suturing can bring to patients by increasing effectiveness while decreasing invasiveness.

We hope you enjoy this compendium on endoscopic suturing. Additionally, we encourage you to visit our digital edition and view the accompanying videos and animation.

Sincerely,
Natan Zundel, MD, FACS

Table of Contents

Bariatric Times (ISSN 1551-3572) is published by Matrix Medical Communications, 1595 Paoli Pike, Ste. 103, West Chester, PA 19380. Telephone: (866) 325-9907 or (484) 266-0702, Fax: (484) 266-0726. Printed in USA.

Matrix Medical Communications
1595 Paoli Pike, Suite 103
West Chester, PA 19380

"A stitch in time saves nine…." The Critical Nature of Suturing for Flexible Endoscopic Surgery

by Lee L. Swanstrom, MD

Bariatric Times. 2013;10(11 Suppl B):B4.

AUTHOR AFFILIATION: Dr. Swanstrom is from the Division of GI/MIS Surgery, The Oregon Clinic, Portland Oregon; and is Innovations Director, Institut Hospitalo Universitaire, Strasbourg, France.
ADDRESS FOR CORRESPONDENCE: Lee L. Swanstrom, MD, 4805 NE Glisan, Suite 6N50, Portland, OR 97213; Phone: (503) 281-0561; Fax: (503)-281-0575; E-mail lswanstrom@orclinic.com
FUNDING AND DISCLOSURES: No funding was provided. Dr. Swanstrom is on the scientific advisory board for Apollo Endosurgery, Inc. and has received education and research grants from Olympus and Boston Scientific.

The fields of surgery and interventional endoscopy come closer and closer to an inevitable overlap, if not merger: surgery, due to its increasing reliance on videoscopic perception and its patient-driven move toward less access trauma; and endoscopy, due to its increasing ability to replicate or replace surgical procedures. The obvious and unavoidable overlap will require evolution on the part of practitioners as well metrics to measure competence and expertise in both disciplines. In surgery, the ability to place a stitch and tie a secure knot has been the hallmark physical attribute of the skilled surgeon for many millenniums. The inaugural ritual for medical students and residents today is suturing on a pig's foot or throwing knots around the bedpost of a call room. This is despite the fact that most surgeries no longer require suturing in the face of clips, glues, and staples. The same is true for laparoscopic surgery. Program directors insist that residents and fellows practice suturing (not cutting or retraction or tissue handling) on a pelvic trainer. The Fundamentals of Laparoscopic Surgery (FLS) exam, which is a high-stakes cognitive and manual skills test required for board certification, has, as its most discriminating task, the laparoscopic placement of a stitch and tying of a knot. This is included in the FLS despite the fact that, once again, most common laparoscopic procedures (e.g., gallbladders, hernias, colectomy, appendectomy) do not involve suturing and, even for those that do, there are multiple devices that render the manual placement of a stitch unnecessary. I believe there are three reasons for this. First, tradition certainly still carries weight and many surgeons will suture where they could have clipped or stapled for the pure aesthetic pleasure it carries. Suturing also demands bimanual dexterity and good eye/hand coordination and as such offers a measurable metric for surgical skill. Finally, no matter how good staplers, suturing machines, or glues are, they are not universally applicable and, in a tight situation, it will be a surgeon skilled with needle and thread who salvages a procedure or corrects a complication.

It is, therefore, perhaps the most salient sign that endoscopy has moved into the realm of surgery that we have today, the ability to suture endoscopically. One of the highest priorities of the international natural orifice transluminal endoscopic surgery (NOTES) movement was achieving robust and secure enterotomy closure, and suturing naturally came to the forefront.[1] Industry responded with enthusiasm, sensing suturing might represent a disruptive paradigm shift in endoscopy. Multiple devices were trialed including the following: Tissue Apposition System (TAS [Ethicon, Inc., Blue Ash, Ohio, United States]), flexible Endo Stitch™ (Covidien, Norwalk, Connecticut, United States), and advanced bimanual operating platforms that could suture with standard surgical suture, such as the DDES (Boston Scientific, Natick, Massachusetts, United States) and Endo Samurai (Olympus, Tokyo, Japan).[2] Unfortunately, none of these devices reached commercialization due to the global economy, an unclear marketing pathway, and sabotage by the FDA.

Despite these contrary forces, and serving as an indication of the need for endoscopic suturing, two companies have commercially available suturing devices on the market, Apollo Endosurgery (Austin, Texas, United States) and USGI Medical (San Clemente, California, United States). The USGI device is currently marketed only as a bariatric procedure device. The Apollo OverStitch™ Endoscopic Suturing System is approved and marketed as a general suturing device.

Currently, the OverStitch™ Endoscopic Suturing System (Apollo Endosurgey, Inc.) is the only device on the market that permits general endoscopic surgery. This is sufficient to have enabled a variety of creative uses: suturing stents in place, closure of fistulas and leaks, full thickness resections, and others. It is the start of a new future for interventional endoscopy.

REFERENCES

1. Rattner D, Hawes R, Swanstrom LL, and the ASGE/ SAGES working group on NOTES. ASGE/SAGES Working Group on Natural Orifice Translumenal Endoscopic Surgery; White Paper October 2005. *Gastrointest Endosc*. 2006;63(2):199–203.
2. Sclabas G, Swanstrom LL. Secure closure methods in NOTES. *Surg Innovation*. 2006;13(1):2–330.

Utilization of Endoscopic Suturing for Management of Weight Regain: Transoral Outlet Reduction

United States Experience

by Nitin Kumar, MD; Erik B. Wilson, MD; and Christopher C. Thompson, MD

Bariatric Times. 2013;10(11 Suppl B):B5–B6.

AUTHOR AFFILIATIONS: Drs. Kumar and Thompson are from Brigham and Women's Hospital, Boston, Massachusetts. Dr. Thompson is also from Harvard Medical School, Boston, Massachusetts. Dr. Wilson is from The University of Texas Medical School at Houston, UT Specialty Surgery Clinic, Bellaire, Texas.
ADDRESS FOR CORRESPONDENCE: Dr. Christopher C. Thompson, 75 Francis St., Thorn 1404, Boston, MA 82115; Phone: (617)-525-8266; Fax: (617) 264-6342; E-mail: cthompson@hms.harvard.edu
FUNDING AND DISCLOSURES: No funding was provided. Dr. Kumar reports no conflicts of interest. Dr. Wilson is a consultant for Apollo Endosurgery, Inc. Dr. Thompson is a consultant for and/or has received research support from Apollo Endosurgery, Inc., USGI Medical, Oluympus, and Boston Scientific. He has ownership interest in GI Windows.

Roux-en-Y gastric bypass (RYGB) has resulted in dramatic weight loss and resolution of comorbidities in millions of patients to date. However, postoperative weight regain occurs in a significant number of patients, and jeopardizes these benefits.[1] Many RYGB patients reach a weight plateau within two years, after which 30 percent begin to regain weight. Nearly two-thirds of patients experience significant weight regain within four years.[2–5]

One independent predictor of weight regain is larger GJA aperture (Figure 1).[6,7] Surgical revision to address dilated GJA is associated with higher complication rates than the primary surgery.[8–10] Possible reasons include older patient age, complex anatomy, and postoperative scarring.

Transoral outlet reduction (TORe) offers a less invasive method for revision. First described in 2004, TORe is currently supported by level 1 evidence.[11,12] RESTORe, a randomized, sham-controlled, double-blinded trial using a suction-based, superficial-thickness suturing device, was recently published.[13] That study included 77 patients with GJA diameter >20mm. TORe was effective, with 96 percent of the TORe group having weight loss or stabilization during the six-month follow-up period. Mean weight loss was 3.8 percent versus 0.3 percent in the sham group (p=0.02) in the intent-to-treat analysis. The adverse event rate for TORe was similar to sham. One notable finding was that only 76 percent of plications remained at six-month endoscopy, likely due to the superficial nature of stitch placement.

The OverStitch™ Endoscopic Suturing System (Apollo Endosurgery, Inc., Austin, Texas) is a full-thickness suturing device that has recently been studied for TORe in 25 patients.[14] The average preprocedure GJA aperture was 26.4mm, and average postprocedure GJA aperture was 6mm (Figure 2). No significant adverse events occurred. Patients lost 69.5 percent of weight regained after RYGB at six months. Average weight loss was 11.7kg after six months and 10.8kg after one year.

Superficial-thickness TORe and full-thickness TORe were directly compared in a matched cohort study of 118 patients matched by pre-TORe GJA aperture, BMI, and age.[15] Weight loss after six months was 4.4±0.8kg in the superficial-thickness group versus 10.6±1.8kg in the full-thickness group (p<0.01). Weight loss at one year was 2.9±1.0kg in the superficial-thickness group versus 8.6±2.5kg in the full-thickness group (p<0.01). These results were presented at Digestive Diseases Week (DDW) 2013 and have been submitted for publication. A historic comparison was performed, comparing weight loss in each arm of the cohort with the TORe and sham groups in the RESTORe trial (Figure 3). The interrupted stitch suturing method used in these studies has since been modified to a pursestring technique (Figure 4), with superior early results, which have been submitted for publication and will be presented at Obesity Week 2013 (see video at http://endoscopicsuturing.metabolicsurgery.tv).

TORe has proven safe and effective for weight regain after RYGB. TORe provides patients with a minimally invasive option to address this challenging problem, and should be provided in the context of a multidisciplinary approach addressing diet and lifestyle modification.

REFERENCES

1. Christou NV, Look D, MacLean LD. Weight gain after short- and long-limb gastric bypass in patients followed for longer

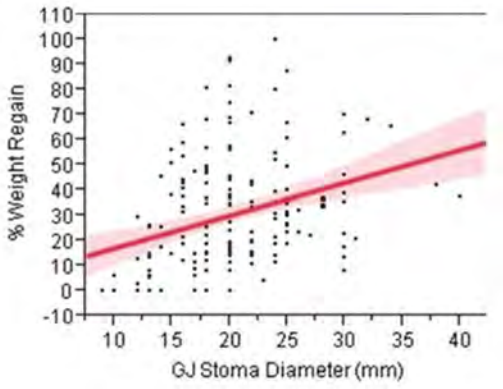


FIGURE 1. Larger GJA aperture is a signficant independent predictor of weight regain

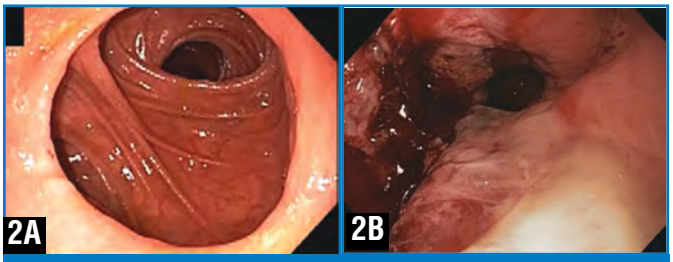


FIGURE 2. GJA prior to (A) and after (B) TORe

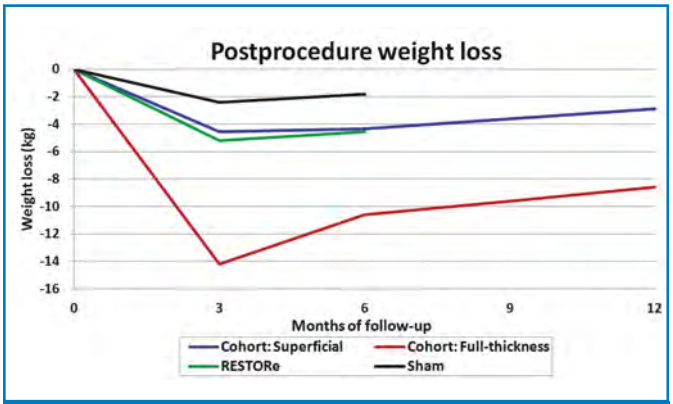


FIGURE 3. Post-TORe weight loss after superficial TORe, full-thickness TORe, and randomized RESTORe trial (TORe and sham)

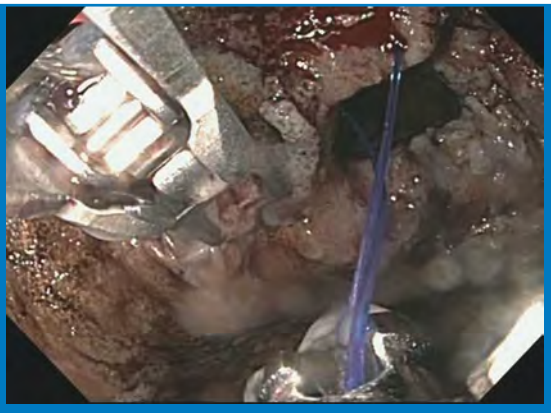


FIGURE 4. The pursestring technique for TORe

than 10 years. *Ann Surg*. 2006;244(5):734–740.
2. Mitchell JE, Lancaster KL, Burgard MA, et al. Long-term follow-up of patients' status after gastric bypass. *Obes Surg*. 2001;11:464–8.
3. Brolin RE. Bariatric surgery and long-term control of morbid obesity. *JAMA*. 2002;288:2793-2796.
4. Hsu LK, Benotti PN, Dwyer J, et al. Nonsurgical factors that influence the outcome of bariatric surgery: a review. *Psychosom Med*. 1998;60:338–46.
5. Magro DO, Gelonese B, Delfini R, et al. Long-term weight regain after gastric bypass: a 5-year prospective study. *Obes Surg*. 2008; 18(6):648–665.
6. Dayyeh BK, Lautz DB, Thompson CC. Gastrojejunal stoma diameter predicts weight regain after Roux-en-Y gastric bypass. *Clin Gastroenterol Hepatol*. 2011;9(3):228–233.
7. Muller MK, Wildi S, Scholz T, et al. Laparoscopic pouch resizing and redo of gastro-jejunal anastomosis for pouch dilatation following gastric bypass. *Obes Surg*. 2005;15:1089–1095.
8. Coakley BA, Deveney CW, Spight DH, et al. Revisional bariatric surgery for failed restrictive procedures. *Surg Obes Relat Dis*. 2008;4:581–586.
9. Dapri G, Cadiere GB, Himpens J. Laparoscopic conversion of adjustable gastric banding and vertical banded gastroplasty to duodenal switch. *Surg Obes Relat Dis*. 2009;5:678–683.
10. Ryou M, Ryan MB, Thompson CC. Current status of endoluminal bariatric procedures for primary and revision indications. *Gastrointest Endosc Clin N Am*. 2011;21(2):315–333.
11. Thompson, CC, Carr-Locke, DL, Saltzman, J, et al. Peroral endoscopic repair of staple-line dehiscence in Roux-en-Y gastric bypass: a less invasive approach [abstract]. *Gastroenterology*. 2004; 126 (Suppl 2):A.
12. 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;20:1744–1748.
13. Thompson CC, Chand B, Chen YK, et al. Endoscopic suturing for transoral outlet reduction increases weight loss after Roux-en-Y gastric bypass surgery. *Gastroenterology*. 2013;145(1):129–137.
14. Jirapinyo P, Slattery J, Ryan MB, et al. Evaluation of an endoscopic suturing device for transoral outlet reduction in patients with weight regain following Roux-en-Y gastric bypass. *Endoscopy*. 2013;45(7):532–536.
15. Kumar N, Lautz DB, Thompson CC. Comparison of a suction-based superficial suturing device with a full-thickness suturing device for transoral outlet reduction: a matched cohort study [abstract]. *Gastrointest Endosc*. 2013;77(5):AB203–AB204.

Utilization of Endoscopic Suturing for Management of Weight Regain: Transoral Outlet Reduction

Outside the United States Experience

by Manoel Galvao Neto, MD

Bariatric Times. 2013;10(11 Suppl B):B7–B8.

AUTHOR AFFILIATIONS: Dr. Galvao Neto is scientific coordinator of Gastro Obeso Center, Sao Paulo, Brazil, and Esophageal Motility Lab Coordinator at Mario Covas Hospital, Santo Andre, Brazil.
ADDRESS FOR CORRESPONDENCE: Manoel Galvao Neto, MD, scientific coordinator of Gastro Obeso Center, Sao Paulo, Brazil, Esophageal Motility lab coordinator at Mario Covas Hospital, Santo Andre, Brazil, Barata Ribeiro Street, 273. Offices 101. Sao Paulo, Brazil 01308-000
FUNDING AND DISCLOSURES: No funding was provided. Dr. Galvao Neto is an international consultant for Apollo Endosurgery, Inc. (Austin, Texas, United States)

Bariatric surgery has been proven to be the most valuable treatment for patients with morbid obesity by effectively lowering excess weight while controlling surrounding comorbidities and lowering mortality. The Roux-en-Y gastric bypass (RYGB) is among the most performed bariatric procedures but, despite its initial weight loss results, it has a failure rate of 20.4 percent for patients with morbid obesity and 34.9 percent for patients with super obesity within 10 years of the initial procedure.[1] There are many potential causes for this failure; however, enlargement of the gastrojejunostomy (GJ) stoma and/or gastric pouch are commonly noted.[6]

Postsurgical failure in weight loss can be defined in many different ways. Perhaps the most common measure of success or failure is the achievement of 50-percent excess weight loss (EWL) from the pre-procedure weight. If this is not achieved, a surgical revision is often suggested. Surgical revisions are, by nature, complex and associated with significant morbidity, and even questionable efficacy. Returning these patients to surgery, and to the potential associated risks, has given rise to the use of endolumenal therapies to address the needs of patients requiring revisional bariatric surgery.

The development of endolumenal therapies and devices can fulfill the window for a less invasive approach that keeps the principles of surgical outlet revision while avoiding intra-abdominal surgery. This brief article will describe the initial outside the United States series of RYGB endoscopic GJ stomal and pouch revision by means of an endoscopic suturing device. This is an update from the article published in the June 2011 issue of *Bariatric Times*.[7]

At that time, the authors had published a retrospective series analysis with institutional review board (IRB)-approved chart review and with patients under informed consent. The article focused on evaluating safety and short-term efficacy of the OverStitch™ Endoscopic Suturing System (Apollo Endosurgery, Inc., Austin, Texas) in patients with significant weight regain after RYGB. All patients were at least two years post-RYGB and multidisciplinary follow-up. Patients meeting these criteria were then screened with endoscopy and X-rays to determine if they had a gastrojejunostomy over 2cm in diameter. Exclusion criteria included those patients who were unable to undergo general anesthesia or an upper endoscopy procedure. This study of eight patients was done with the first generation OverStitch (Apollo Endosurgery, Inc.) device.

The study included seven women and one man between 28 and 58 years old (M=40.5y). The patients' pre-RYGB BMI ranged from 38 to 44kg/m^2 (M=40.4kg/m^2) and pre-RYGB weight from 97 to 138kg (M=1,11kg) with a weight loss nadir (minimum weight loss) from 87 to 60kg (M=67.8kg) and weight regain of 9 to 33kg (M=22kg). Pre-procedure pouch size varied from 2 to 6cm (M=3cm) and pre-procedure stoma size varied from 20 to 40mm (M=25mm).

All patients were put under general anesthesia and an esophageal overtube was placed. Procedure time was recorded from 20 to 60 minutes (M=38min). All but one patient had three stitches applied from the lesser to the greater curvature of GJ, reducing the stoma size up to 10mm in diameter. In the one exception case, the stoma size was reduced to less than 15mm. No intra- or postoperative complications or mortality was noted.

On this initial series, all patients were followed for one year, achieving a mean of 63-percent regained weight loss (RWL) (35–95%RWL). One patient with initial poor weight loss had a follow-up endoscopic revision at eight months.

Clinical findings at the time of the second revision showed a 2 to 3cm diameter GJ from the previous 4 to 5cm. This was subsequently revised to less than 1cm with three more stitches, achieving 87 percent RWL at the one year follow-up.

Following this initial series, a second-generation device was introduced and more cases were performed under proctorship keeping the same good safety profile and generating similar one-year results. With this second series, an additional step was added using argon plasma on the GJ (2L/m on 60–70w) previous to the application of sutures. The usage of argon plasma has been noted to assist with healing. Ensuring a full-thickness bite was also made simpler by the addition of the Helix™ Device (Apollo Endosurgery, Inc.), which enables suturing all parts of the pouch. The procedure is now performed clinically in Chile, Colombia, Panama, and the Dominican Republic. From those countries, 42 additional cases were performed and data from those cases have been collated with data from the first- and second-series information (Table 1).

European regulatory approval was granted in early 2013 and an additional 32 cases were performed; 20 in Spain, eight in Italy, one in Greece, and three in France. To date, no complications or mortality have been reported from these OUS series. While data are limited from these series currently, we expect it to be forthcoming in the near future.

TABLE 1. Updated casuistic since initial Chilean series (Latin and Central America)

	N	M/F	COMPLICATION	MORTALITY	FOLLOW-UP
CHILE *Rodriguez L, Escalona A, Galvao Neto M*	31	5/26	Zero	Zero	Up to 2y
COLOMBIA *Zundel N*	3	1/2	Zero	Zero	Up to 1y
PANAMA *Alvarado A*	3	1/3	Zero	Zero	Up to 1y
DOMINICAN REPUBLIC *Sahdala N, Betances L*	4	0/4	Zero	Zero	Up to 6m

FIGURE 1. Dilated gastrojejunal outlet post Roux-en-Y

FIGURE 2. Argon plasma (APC) on GJ

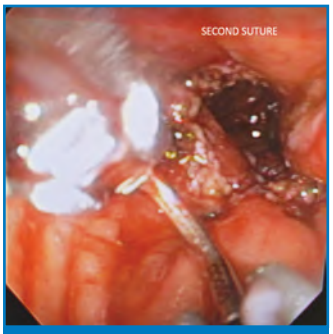


FIGURE 3. GJ reduced to less than 1cm after endoscopic repair

FIGURE 4. Suturing repair with OverStitch™ Endoscopic Suturing System

CONCLUSION

This initial OUS experience has proven that the use of endoscopic suturing for the treatment of post-RYGB weight regain is safe and provides good preliminary results.

Video Feature

View a video of utilization of endoscopic suturing for management of weight regain

REFERENCES

1. Christou N, Look D, MacLean L. Weight gain after short- and long-limb gastric bypass in patients followed for longer than 10 years. *Ann Surg*. 2006;244:734–740.
2. Nesset EM, Kendrick ML, Houghton SG, et al. A two-decade spectrum of revisional bariatric surgery at a tertiary referral center. *Surg Obes Relat Dis*. 2007;3(1):25–30.
3. Magro DO, Gelonese B, Delfini R, et al. Long-term weight regain after gastric bypass: a 5-year prospective study. *Obes Surg*. 2008; 18(6):648–651.
4. Schwartz R, Strodel W, Simpson W, Griffen W. Gastric bypass revision: lessons learned from 920 cases. *Surgery*. 1988;104:806–12
5. Gagner M, Gentileschi P, De Csepel J, et al. Laparoscopic reoperative bariatric surgery: Experience from 27 consecutive patients. *Obes Surg*. 2002;12:254–260.
6. Abu Dayyeh BK, Lautz DB, Thompson CC. Gastrojejunal stoma diameter predicts weight regain after Roux-en-Y gastric bypass. *Clin Gastroenterol Hepatol*. 2011;9(3):228–233.
7. Galvao Neto M, Rodriguez L, Zundel N, Ayala JC, Campos J, Ramos A. Endoscopic revision of Roux-en-Y gastric bypass stomal dilation with a suturing device: Preliminary results of a first out-of-United-States series. *Bariatric Times*, 2011;8(6):32–34.
8. Thompson CC, Roslin MS, Chand B, et al. M1359 RESTORE: Randomized evaluation of endoscopic suturing transorally for anastomotic outlet reduction: A double-blind, sham-controlled multi-center study for treatment of inadequate weight loss or weight regain following Roux-en-Y gastric bypass. *Gastroenterology*. 2010;138(5)Supplement 1: S–388.

Endoscopic Plication of the Sleeve

by George M. Eid, MD, FACS, FASMBS

Bariatric Times. 2013;10(11 Suppl B):B9–B10.

AUTHOR AFFILIATIONS: Dr. Eid is Associate Professor of Surgery, University of Pittsburgh, Pittsburgh, Pennsylvania.
ADDRESS FOR CORRESPONDENCE: George Eid, MD, 3380 Blvd. of the Allies, Pittsburgh, PA 15213; Phone: (412) 512-2134; E-mail: georgemeid@hotmail.com
FUNDING AND DISCLOSURES: No funding was provided. Dr. Eid reports no conflicts of interest relevant to the content of this article.

INTRODUCTION

Laparoscopic sleeve gastrectomy (LSG) is emerging as a safe and effective primary treatment modality for morbid obesity. Despite the effectiveness of LSG surgery, treatment failures are encountered with insufficient long-term weight loss or renewed weight gain. Many revisional surgical options have been described, including, but not limited to, LSG conversion to Roux-en-Y gastric bypass (RYGB), duodenal switch (DS), as well as re-sleeve and gastric plication of the gastric sleeve. Due to the high rate of morbidity associated with laparoscopic and open revisional surgery, ranging from 5 to 20 percent complication rates, less invasive endoscopic procedures may offer an attractive alternative.[1,2] Hereby, I describe an endoscopic approach to create endoluminal plications with an endoscopic suturing device in dilated gastric sleeves to re-initiate weight loss.

PATIENT WORK-UP

It is well known that weight regain following bariatric procedures is multifactorial including technical failures, poor diet and exercise adherence, and psychological factors, which should not be underestimated. While it is difficult to delineate with certainty the exact causes of weight re-gain in LSG patients, it is imperative that all patients presenting to my practice for weight re-gain should undergo a detailed preoperative work-up. It includes an upper gastrointestinal (UGI) series to assess the sleeve anatomy and to rule out the presence of a retained fundus as opposed to an enlarged gastric sleeve. In addition, patients are evaluated by our bariatric dietitian to identify dietary causes of weight re-gain, ranging from poor dietary adherence (e.g., grazing and frequent snacking) and/or the ability to ingest large meals. An obvious presence of a significant psychological disturbance should warrant a psychiatric evaluation referral prior to any surgical interventions.

Following successful behavioral and dietary modifications and interventions, and if an enlarged sleeve gastrectomy is determined to be contributing to the patient's weight re-gain, an endoscopic plication of the sleeve is offered.

PROCEDURE DEVELOPMENT

Animal porcine studies were initially conducted prior to offering the procedure to eligible patients. The endoscopic suturing device, the OverStitch™ Endoscopic Suturing System (Apollo Endosurgery, Inc., Austin, Texas) was evaluated using combined endoscopic/laparoscopic views of the pig stomach. Sutures were placed to approximate the opposite walls of the stomach resulting in a full thickness apposition (See video at http://www.endoscopicsuturing.metabolicsurgery.tv). Following the euthanasia of the pig, the stomach was extracted and the sutures were evaluated confirming the full-thickness and secure nature of the sutures placed.

TECHNIQUE

Under general anesthesia, and with the patient in a supine position, an endoscopy is performed using a single channel endoscope with an overtube placed at the proximal end of the device. This step is performed to delineate the anatomy of the sleeve and identify the distal aspect of the gastric sleeve. Subsequently, the gastric mucosa corresponding to the gastric wall where the sutures are to be placed is superficially cauterized using an argon coagulator. This step is performed with the goal of delineating the sleeve anatomy and potentially decreasing the amount of mucosal bleeding during the suture placement. With

the overtube left in place, the OverStitch™(Apollo Endosurgery, Inc.), mounted on a double-channel endoscope, is passed into the esophagus. The device is used to create multiple, figure of eight, full-thickness plications within the gastric sleeve starting distally, at the level of the incisura and moving proximally, just below the gastroesophageal junction. The number of sutures placed varies among patients, but would include at least 6 to 8 sutures. It is worth noting that having the ability to switch between single- and double-channel endoscopy using a dual tower system, can be beneficial in reassessing the sleeve anatomy and clearing the stomach from bleeding mucosa, which are better performed using the single-channel endoscope.

POSTOPERATIVE MANAGEMENT

Initially, patients were admitted overnight for observation with UGI performed the following day prior to starting a liquid diet. Common complaints included sore throat, epigastric pain, nausea, and bloating. Only minimal pain medications were needed. The procedures were performed in conjunction with lifestyle modification. Patients were advanced to a regular diet over a four-week period. Monthly postoperative visits were recommended to our patients.

RESULTS

A total of five patients have undergone the endoscopic plication of the sleeve. More detailed results are being tabulated for a peer-reviewed publication, but preliminary results are showing resumption of weight loss ranging 30 to 40Lbs at around six months postoperatively. Besides the complaints stated earlier, there were no adverse events and zero mortality.

CONCLUSION

Gastric sleeve volume reduction using endoluminal plications is showing some early promising results to address weight regain following LSG. Long-term results are still needed to validate this approach. Based on personal observations, an endoluminal approach for revisional bariatric surgery may be a more viable option if offered in the early phases of weight re-gain and prior to patients reaching a BMI of 40kg/m^2 or more.

REFERENCES

1. Gautier T, Sarcher T, Contival N, Le Roux Y, Alves A. Indications and mid-term results of conversion from sleeve gastrectomy to Roux-en-Y gastric bypass. *Obes Surg*. 2013;23(2):212–215.
2. Rebibo L, Fuks D, Verhaeghe P, et al. Repeat sleeve gastrectomy compared with primary sleeve gastrectomy: a single-center, matched case study. *Obes Surg*. 2012;22(12):1909–1915.

FIGURE 1. UGI obtained on a LSG patient as part of the work-up performed prior to the endoluminal plication of the sleeve

FIGURE 2. UGI obtained on the same patient on Postoperative Day 1 following the endoluminal plication of the sleeve showing significant narrowing of the dilated stomach as compared the preoperative 1 UGI

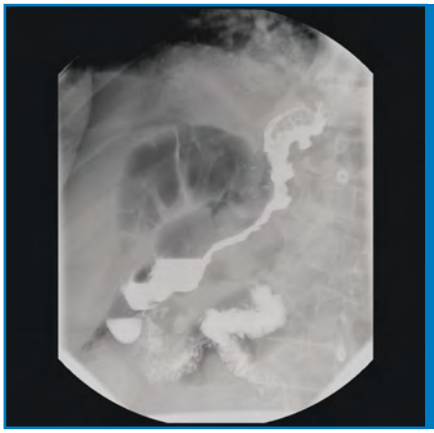


FIGURE 3. Another postoperative UGI showing the reduced intra-luminal volume of the gastric sleeve

www.endoscopicsuturing.metabolicsurgery.tv

Video Feature

View a video of endoluminal plication of a dilated gastric sleeve to re-initiate weight loss

Scan here for the exclusive video

Endoscopic Gastroplasty as a Primary Metabolic and Bariatric Procedure: United States Experience

by Barham K. Abu Dayyeh, MD, MPH, and Christopher Gostout, MD

Bariatric Times. 2013;10(11 Suppl B):B11–B12

AUTHOR AFFILIATIONS: Drs. Abu Dayyeh and Gostout are from Mayo Clinic, Rochester, Minnesota.
ADDRESS FOR CORRESPONDENCE: Christopher Gostout, MD, 200 First St. SW, Rochester, MN 55905; E:mail: gostout.christopher@mayo.edu
FUNDING AND DISCLOSURES: This study was partially funded by a grant from Apollo Endosurgery, Inc. and career development award by the Mayo Department of Medicine to Barham K. Abu Dayyeh, MD, MPH. Dr. Abu Dayyeh reports no conflicts of interest relevant to the content of this article.

INTRODUCTION

Obesity is a global problem crossing age, ethnicity, and socioeconomic boundaries. According to the World Health Organization's 2010 Global Burden of Disease Study, obesity and its associated conditions are now among the highest contributors to the global burden of disease and have replaced communicable diseases in children as major contributors to this burden.[1] Despite our increased knowledge of the complex neural, hormonal, metabolic, and inflammatory mechanisms regulating energy intake and expenditure, it is a paradox that the only current treatment for obesity that is effective in the long term is bariatric/metabolic surgery.[2] Lifestyle modification and available pharmacological approaches have poorly sustained effects, relatively weak efficacy, or side effects. The effects of bariatric surgery, however, are fundamentally different from those of restrictive diets, as distinct alterations of the gastrointestinal tract produce a multitude of physiological adaptations in body weight, promoting a more durable and better weight loss over that which has been seen with restrictive diets alone.[3] This is powerfully demonstrated by the observation that sleeve gastrectomy, a surgical procedure that reduces gastric volume by 75 to 80 percent compared with traditional Roux-en-Y gastric bypass (RYGB) that involves multiple surgical alterations to the stomach and small intestines, results in similar postprandial increases in gut neurohormones and seems to be an equally efficacious alternative to RYGB.[2,4]

Advances in flexible endolumenal endoscopy include reliable endoscopic suturing tools for transoral endoscopic gastric volume reduction in a fashion similar to sleeve gastrectomy for the primary endoscopic treatment of obesity and metabolic disease.[5–7] We reported the feasibility of this approach to weight loss and refer to the procedure as endoscopic sleeve gastroplasty.[8] In an ongoing institutional review board (IRB) protocol, we have performed the procedure in six subjects with obesity thus far (age 37 [SD 9.5], five women, all Caucasian, BMI 36kg/m^2 [SD 2.2]) and one man. The sleeve gastroplasty was created using the Overstitch™ Endoscopic Suturing System (Apollo Endosurgery, Inc., Austin, Texas) to place free-hand, full-thickness, closely spaced interrupted sutures through the gastric wall from the prepyloric antrum to the gastroesophageal (GE) junction (Figure 1) in an outpatient setting. Repeat three-month endoscopy performed in all subjects revealed thick fibrous bridges in the body and fundus of the stomach greatly limiting gastric accommodation. These findings correlated with significant improvement in weight and eating behaviors as measured by a standardized validated questionnaire administered during the study. Ongoing follow-up continues. Primary gastric reduction has also subsequently been performed by a second group of therapeutic endoscopists on four patients using a different suturing technique relying on sets of running stitches (Figure 2), which expedites the procedure. The starting BMI in this group was 33kg/m^2 and 28kg/m^2 after six months, with an average weight loss of slightly more than 15kg. Our hope is that our endoscopic technique can provide a cost-effective and minimally invasive alternative to traditional bariatric surgery to allow its application to a wider segment of the population with obesity.

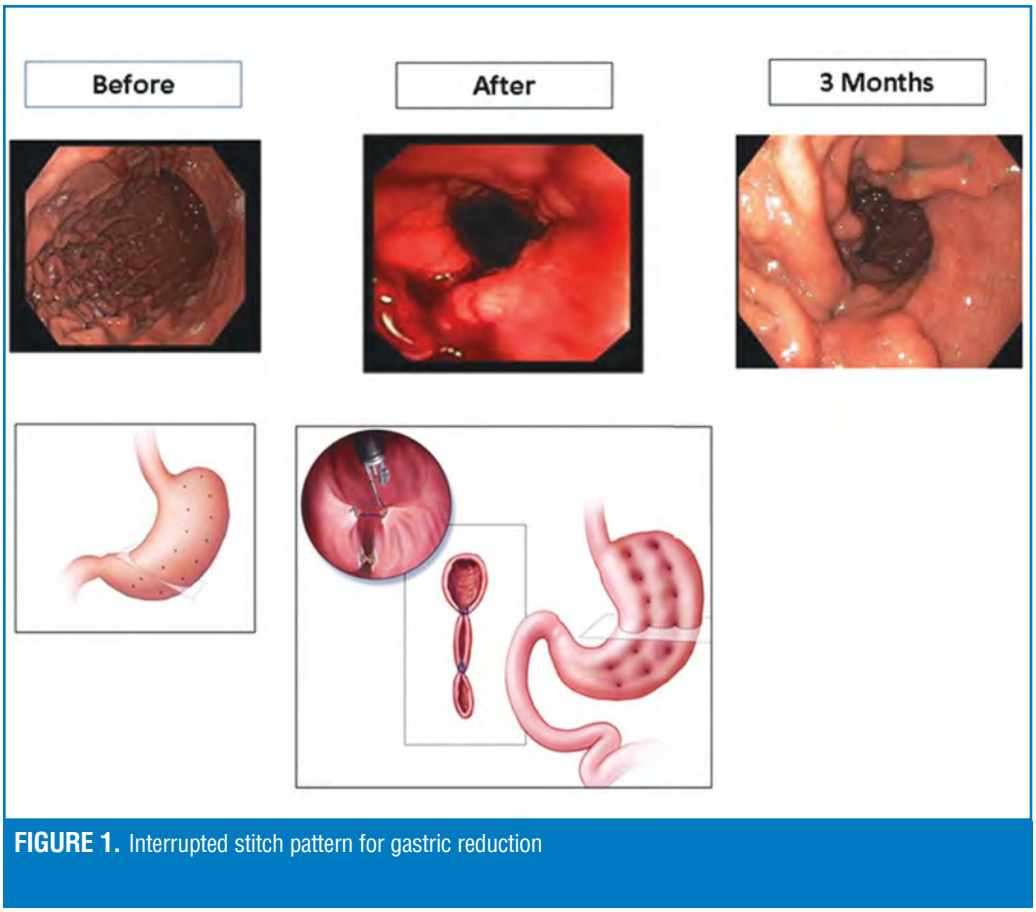


FIGURE 1. Interrupted stitch pattern for gastric reduction

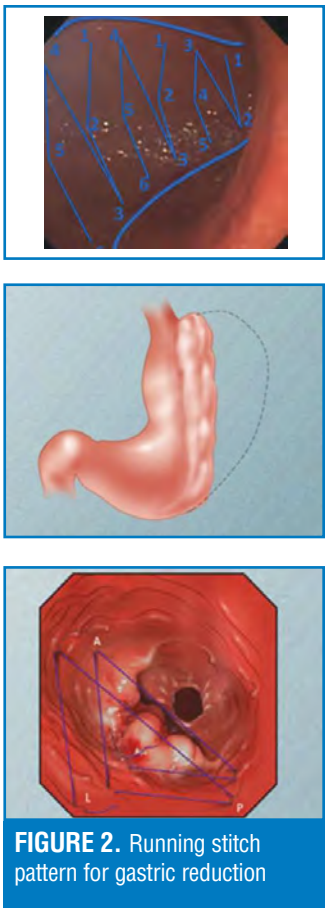


FIGURE 2. Running stitch pattern for gastric reduction

REFERENCES

1. Lim SS, Vos T, Flaxman AD, et al. A comparative risk assessment of burden of disease and injury attributable to 67 risk factors and risk factor clusters in 21 regions, 1990-2010: a systematic analysis for the Global Burden of Disease Study 2010. *Lancet*. 2012;380:2224–2260.
2. Schauer PR, Kashyap SR, Wolski K, et al. Bariatric surgery versus intensive medical therapy in obese patients with diabetes. *N Engl J Med*. 2012;366:1567–1576
3. Sumithran P, Prendergast LA, Delbridge E, et al. Long-term persistence of hormonal adaptations to weight loss. *N Engl J Med*. 2011;365:1597–1604.
4. Peterli R, Wolnerhanssen B, Peters T, et al. Improvement in glucose metabolism after bariatric surgery: comparison of laparoscopic Roux-en-Y gastric bypass and laparoscopic sleeve gastrectomy: a prospective randomized trial. *Ann Surg*. 2009;250:234–241.
5. Brethauer SA, Chand B, Schauer PR, Thompson CC. Transoral gastric volume reduction as intervention for weight management: 12-month follow-up of TRIM trial. *Surg Obes Relat Dis*. 2012;8(3):296–303.
6. Fogel R, De Fogel J, Bonilla Y, De La Fuente R. Clinical experience of transoral suturing for an endoluminal vertical gastroplasty: 1-year follow-up in 64 patients. *Gastrointest Endosc*. 2008;68(1):51–58.
7. Galvao Neto M, Zundel N, Campos JM, et al. Endoluminal greater curvature Plication—a case series. Presented at: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) 2013 Annual Meeting. April 17–20, 2013; Baltimore, Maryland.
8. Abu Dayyeh BK, Rajan E, Gostout CJ. Endoscopic sleeve gastroplasty: a potential endoscopic alternative to surgical sleeve gastrectomy for treatment of obesity. *Gastrointest Endosc*. 2013;78:530–535.

Endoscopic Gastroplasty as a Primary Metabolic and Bariatric Procedure: Outside the United States Experience

by Nicole Peña Sahdala, MD; Alonso Alvarado, MD; Erik B. Wilson, MD; and Natan Zundel, MD, FACS, FASMBS

Bariatric Times. 2013;10(11 Suppl B):B13–B15.

AUTHOR AFFILIATIONS: Dr. Peña Sahdalá is Clinical Professor of Medicine, Universidad Pedro Henriquez Urena (UNPHU), Santo Domingo, Dominican Republic. Dr. Alvarado is a surgeon and Associate Professor, Panama University San Fernando Hospital, Panama City, Panama. Dr. Wilson is from The University of Texas Medical School at Houston, UT Specialty Surgery Clinic, Bellaire, Texas. Dr. Zundel is Clinical Professor of Surgery and Vice-chairman, Department of Surgery, Florida International University Herbert Wertheim College of Medicine, University Park, Florida; and Director, Baritric Institute, Jackson, North Miami, Florida.
ADDRESS FOR CORRESPONDENCE: Natan Zundel, MD, FACS, Clinical Professor of Surgery, Vice-Chairman, Department of Surgery, Herbert Wertheim College of Medicine, 11200 S.W. 8th St., Modesto A, Maidique, Miami, FL 33199; Phone: (305)-308-3035;
Fax: (305)-466-4970; E-mail: drnazuma99@yahoo.com
FUNDING AND DISCLOSURES: No funding was provided. Dr. Peña Sahdalá is a proctor for Apollo Endosurgery, Inc. Dr. Alvarez reports no conflicts of interest. Dr. Wilson is a consultant for Apollo Endosurgery, Inc. Dr. Zundel is a consultant for Apollo Endosurgery, Inc., Ethicon, Inc., Olympus, and Applied Medical.

INTRODUCTION

The increase in prevalence of obesity in Latin America follows global patterns that have rendered 1.5 billion adults worldwide as overweight or obese. The numbers of adults and children with weight issues have increased dramatically in the past 20 years. Once considered only a problem in high-income countries like the United States, where nearly 70 percent of the adult population is overweight, obesity is now growing fastest in developing nations, such as Africa and Latin America, according to the World Health Organization (WHO). There is also evidence that Mexico and other countries in Central and South America are already seeing the burden of obesity shift from the wealthy to the poor.

These changes are likely due to dietary modifications that occur as countries improve their socioeconomic status. As societies gain wealth, more calories are derived from western foods, and this results in dietary increases of total fat and sugars. This altered diet heavy in processed foods and drinks, combined with an increasingly sedentary lifestyle, has led to dramatic rises in the rate of overweight and obese populations in countries previously unaffected by the western obesity epidemic. Due to these changes in diet and lifestyle, comorbidities of obesity, such as insulin resistance, type 2 diabetes, cardiovascular disease, and cancer have also shown an increased prevalence.

According to WHO, currently at least 35 percent of adults aged 20 and over are overweight, with the worldwide prevalence of obesity nearly doubling between 1980 and 2008. The prevalence of obesity is highest in the WHO regions of the Americas, where 62 percent of the population is overweight, and 26 percent of people are obese. The data available on obesity trends in Central and South America shows a rapid increase in BMI over the last 30 years, and current obesity rates that mimic those in the United States and Canada.[1] Work done by Finucane et al estimates that more than 30 percent of women and 20 percent of men in Latin America have obesity.[1] Recently, similar results have been reported from a study conducted in Mexico that showed nearly 70 percent of people are overweight, and 30 percent of adults are obese.[2]

The implications of such dramatic increases in obesity are far reaching. In a recent report, the Pan American Health and Education Foundation (PAHEF) stated, "Obesity does not only affect individuals, it attacks entire societies. Public health, social security, economic viability, and social stability are all put at risk by obesity's implications, especially in the poorest sectors of society." Public health officials estimate the cost of treating obesity in Mexico alone will balloon to nearly $12 billion by 2017.

Treating obesity in Latin America is simply challenging. As government officials in these countries struggle to prevent obesity, lobbyists from food and drink industries thwart efforts to restrict the sale of processed foods in schools and the physicians' efforts to educate their patients on the risks of obesity are often fruitless. Patients who do qualify and are open to surgical intervention often find limited availability to bariatric surgeons. The number of well-trained individuals is lower than in other parts of the world, and the high cost of these procedures coupled with the requirements of BMI over 35kg/m^2 restrict the number to whom a surgical solution can be offered. Less invasive techniques have been studied in populations with obesity, including restrictive procedures, such as intragastric balloons, endoscopic gastroplications, and others, such as the endoluminal duodenojejunal bypass sleeve.

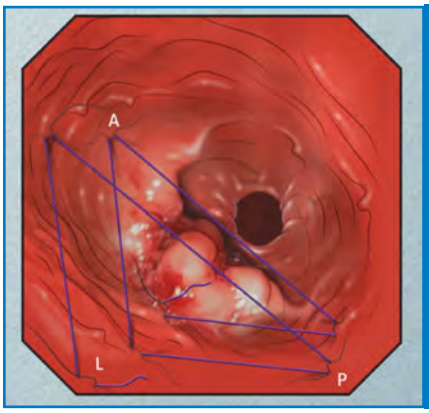


FIGURE 1. Endoscopic view of suture pattern

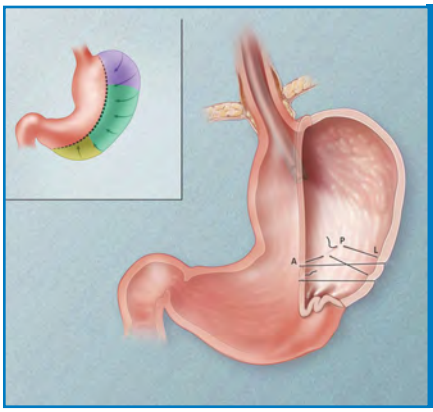


FIGURE 2. Endoscopic gastroplication pattern

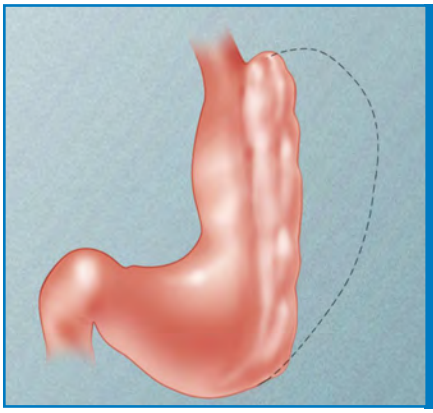


FIGURE 3. Plicated stomach

After a trial in porcine models documented evidence of full-thickness suturing achieved endoscopically, the OverStitch™ Endoscopic Suturing System (Apollo Endosurgery, Inc., Austin, Texas) was approved by the United States Food and Drug Administration (FDA) for mucosal approximation and endoscopic suturing. This endoscopic suturing device was used to create endoscopic gastroplications. This has allowed us to decrease the size of the gastric cavity by suturing closed opposing walls in the stomach, virtually mimicking a laparoscopic gastroplication, using only endoscopic techniques to suture along the greater curvature and form a sutured endoscopic sleeve.

The patients selected presented with BMIs ranging from 27 to 46kg/m^2, and did not qualify for conventional bariatric surgical procedures, and/or did not wish to undergo surgery. Rigorous exclusion criterion were followed and all participating centers obtained institutional review board (IRB) approval for this particular study.

For the endoscopic gastroplication, patients receive general anesthesia and intubation for airway protection. Patients are then positioned in left lateral decubitus and an upper endoscopy is performed. An overtube is placed to protect the proximal esophagus and oropharynx. Using an argon plasma coagulator or cautery we proceed to mark the anterior and posterior walls of the stomach, creating a guideline for the endoscopic sutures sites. The change and distortion of the gastric luminal anatomy following placement of intraluminal sutures dictate the need for guidelines in the stomach to maintain orientation.

After completing the markings, a dual-channel therapeutic endoscope mounted with the OverStitch device (Apollo Endosurgery, Inc.) is inserted through the overtube to the distal gastric body. The suture pattern is started at the incisura and continues proximally towards the fundus. The suture pattern has evolved, but the goal is still to utilize sutures to approximate the anterior, lateral, and posterior gastric walls in a triangular fashion (Figures 1–3). Each triangular pattern consists of approximately six bites of tissue before the suture is "tied" off using the OverStitch Suture Cinch device (Apollo Endosurgery, Inc.); this is repeated approximately six to eight times.

After the entire greater curvature has been sutured and collapsed along with the fundus, a second line of sutures is placed medially to reinforce the initial line of stitches. This second inner row of sutures helps to further reduce the size of the stomach. This technique used by the authors has been presented elsewhere.[3]

During the procedure, the full-thickness bites can cause some bleeding of the gastric mucosa and the amount of blood, while not dramatic, varies in each procedure. Thus, to help achieve optimal visualization, switching to a standard endoscope to wash the area and clear debris is sometimes warranted.

At the end of the procedure, the gastric cavity resembles a tubular lumen along the lesser curvature and the greater curvature is now a line of cinched, plicated gastric mucosa. The pattern of the sutures not only reduces the stomach diameter, but also shortens it substantially with an accordion effect.

To date in our Latin American cases, no severe adverse events have been noted, although all patients have postoperative pneumoperitoneum. This is mostly asymptomatic because carbon dioxide insufflation is used routinely during this procedure and is felt to be important in the prevention of postoperative pain. Patients complained of some epigastric discomfort and nausea, which were treated with liquid oral medications and daily proton pump inhibitors (PPIs). To date there have been zero events of mortality and zero significant morbidity reported. These patients have experienced slight nausea, colicy pain from the intraluminal CO_2, and discomfort, but this is to be expected. No infections, abscesses, or bleeding events have been documented.

After the procedure, the patient is sent home and kept nil per os (NPO) until the next morning when a contrast swallow is performed to detail the anatomy. These patients are followed closely by a nutritionist, and a liquid diet is started a week prior to the procedure and is continued for at least one week after the procedure. The patient is then advanced slowly to normal small meals over 4 to 6 weeks very similarly to a post surgical bariatric diet. An exercise plan that avoids workouts that increase intra-abdominal pressure is recommended during the first month. Initially, walking is optimal and then progressively patients may increase the intensity. This plan is meant to educate the patients to have better eating and exercise habits.

To date, the total number of primary endoscopic gastroplications in Latin America and Europe is 23.

Procedure times varied between 95 to 240 minutes. It is worthy to note that the time has decreased with the experience of the physician performing the endoscopic gastroplication, similar to results published by Abu Dayyeh et al.[4]

Of the 23 patients, 19 were women and four were men, with ages between 22 to 52 years old. The initial BMI was between 27 to 46 kg/m^2 (M: 34kg/m^2), the pre-procedure weights ranged from 158 to 262Lbs (M: 204Lbs). Six patients underwent the procedure over six months from the time this article was published. The average recorded weight loss at six months was 32Lbs. The remaining patients have follow up between 1 to 3 months, with an average weight loss of 16.6Lbs. at 30 days (Table 1).

TABLE 1. Patient data.

PATIENT	GENDER	AGE	INITIAL WEIGHT (Lbs.)	INITIAL BMI (kg/m^2)	WEIGHT LOSS (Lbs.) AT 30 DAYS	WEIGHT LOSS AT 6 MONTHS
1	F	52	209	38	19	22
2	F	22	196	32	20	30
3	F	36	191	32	28	39
4	F	32	196	32	20	43
5	F	33	158	30	15	15
6	F	43	226	35	21	42
7	F	46	176	27	23	N/A
8	F	45	230	39	21	N/A
9	F	51	187	30	10	N/A
10	F	32	218	37	20	N/A
11	F	32	224	44	20	N/A
12	F	32	201	40	18	N/A
13	F	24	163	28	8	N/A
14	M	50	226	34	23	N/A
15	F	34	249	46	15	N/A
16	F	41	183	30	15	N/A
17	F	24	159	28	18	N/A
18	M	41	262	39	26	N/A
19	F	45	194	33	11	N/A
20	M	51	231	38	5	N/A
21	M	36	260	37	13	N/A
22	F	35	176	27	18	N/A
23	F	30	192	30	16	N/A

N/A: Data not yet available. Panama: Drs. Alvarado, Galvao, Gomez, Orillac, Peña Sahdala, Thompson, Wilson, Zundel; Dominican Republic: Drs. Betances, Gomez, Peña Sahdala, Shaikh, Thompson, Zundel; Spain: Drs. Galvao, Lopez-Nava

Primary endoscopic gastric plication procedures are performed in Latin American countries and Spain with the success of endoscopic gastroplication having been well received by both patients and physicians and embraced by surgeons and gastroenterologists alike.

The evolution of endoluminal therapies and novel devices can fulfill the need to aide the increasing number of overweight patients who do not qualify for surgical procedures, and those obese patients who do not wish to undergo a surgical bariatric procedure. Since this is a minimally invasive option, we may be able to offer these services to a wider population.

REFERENCES

1. Finucane MM, Stevens GA, Cowan MJ, et al. National, regional, and global trends in body-mass index since 1980: systematic analysis of health examination surveys and epidemiological studies with 960 country-years and 9.1 million participants. *Lancet*. 2011;377:557–567.
2. Barquera S, Campos-Nonato I, Hernandez-Barrera L, et al. Obesity and central adiposity in Mexican adults: results from the Mexican National Health and Nutrition Survey 2006. *Salud publica de Mexico*. 2009;51 Suppl 4:S595–603.
3. Galvao Neto M, Zundel N, Campos J, et al. Endoluminal greater curvature plication—A case series. Presented at: Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Annual Meeting; April 17–20, 2013.
4. Abu Dayyeh BK, Rajan E, Gostout CJ. Endoscopic sleeve gastroplasty: a potential endoscopic alternative to surgical sleeve gastrectomy for treatment of obesity. *Gastrointest Endosc*. 2013;78(3):530–535.

Endoscopic Bariatric Surgery under Accountable Care Payment Models

by Bipan Chand, MD, FACS, FASMBS, FASGE

Bariatric Times. 2013;10(11 Suppl B):B16–B17.

AUTHOR AFFILIATIONS: Bipan Chand, MD, FACS, FASMBS, FASGE, is Associate Professor of Surgery, Loyola University, Stritch School of Medicine, Maywood, Illinois.
ADDRESS FOR CORRESPONDENCE: Bipan Chand, MD, FACS, FASMBS, FASGE, 2160 S. First Ave., Maywood, IL 60153; Phone: (708) 327-2820; Fax: (708) 216-4415; E-mail: bchand@lumc.edu
FUNDING AND DISCLOSURES: No funding was provided. Dr. Chand reports no conflicts of interest relevant to the content of this article.

PREVALENCE OF OBESITY

Over the last three decades, the prevalence of obesity has continued to rise (Figure 1). Among Americans 20 years of age and older, 78.4 million have obesity (BMI≥30kg/m^2)—36.8 million men and 41.6 million women.[1] The current annual cost related to adults with overweight and obesity is estimated to be $254 billion ($208 billion in lost productivity secondary to premature morbidity and mortality and $46 billion in direct medical costs). If current trends in the growth of obesity continue, total healthcare costs attributable to obesity could reach $861 to $957 billion by 2030, which would account for 16 to 18 percent of United States health expenditures (Figure 2). Under Accountable Care, healthcare providers will strive to reduce these costs. In endoscopy, new approaches to bariatric care management that improve outcomes while reducing costs are of great interest to therapeutic endoscopists, general surgeons, facility administrators, payers, and employers.

Current treatment modalities for obesity and associated metabolic comorbidities include lifestyle modification, diet, and pharmacologic agents. However, these have been shown to have limited effectiveness and durability, with high rates of attrition.[1] Surgical intervention is the most effective treatment to date, resulting in sustainable and significant weight loss along with resolution of metabolic comorbidities in up to 80 percent of patients.[2,3] Furthermore, bariatric surgery results in a significant decrease in overall mortality among patients with obesity compared to individuals with obesity who are untreated or managed nonoperatively.[4]

Currently, the standard of care for surgical intervention requires an open or laparoscopic approach. Less invasive endoscopic approaches in bariatric surgery are needed.

THE COST EFFECTIVENESS OF ENDOSCOPIC BARIATRIC THERAPY

Given that all current surgical procedures require general anesthesia and have procedure-specific complications (mortality=0–4.1%, morbidity=0.1–70%),[5] there is still a need for less invasive weight loss interventions. Endoluminal interventions may be able to fill the gap between conventional medical weight and surgical intervention. The potential of these therapies includes reduced morbidity and improved access. A range of endoscopic modalities may fit this profile. Endoscopic bariatric therapy (EBT) may have various roles, including primary therapy, early intervention, bridge therapy, and metabolic therapy. Any new surgical, endoscopic or nonsurgical weight loss intervention should include defined threshold of efficacy, balanced with risks of the intervention. EBT, performed entirely through the gastrointestinal (GI) tract using flexible endoscopes, offers the potential for ambulatory weight loss procedures with a superior safety and cost profile compared to open or laparoscopic bariatric surgery. Such benefits increase the appeal and acceptance of this therapy to patients.[5] Early adopters are reporting feasibility, safety, and effectiveness. I believe endoscopic therapy will be an appropriate intervention for individuals with lower classes of obesity (i.e., Class 1).

The current literature for EBTs is promising. Long-term results are needed to establish durability and societal benefit, especially as it relates to employee productivity and reduced consumption of chronic care services. The durability and repeatability of EBTs will complement the incentives that therapeutic endoscopists are facing with Accountable Care Organizations (ACOs). EBTs offer new approaches that are clinically less invasive for the patient, while financially shifting to a lower site of service than open and laparoscopic surgery.

As healthcare financing reform alters healthcare delivery models, EBTs are in the right place at the right time. This link between improving quality while reducing costs will hasten the adoption of EBTs for appropriately selected patients in ACOs.

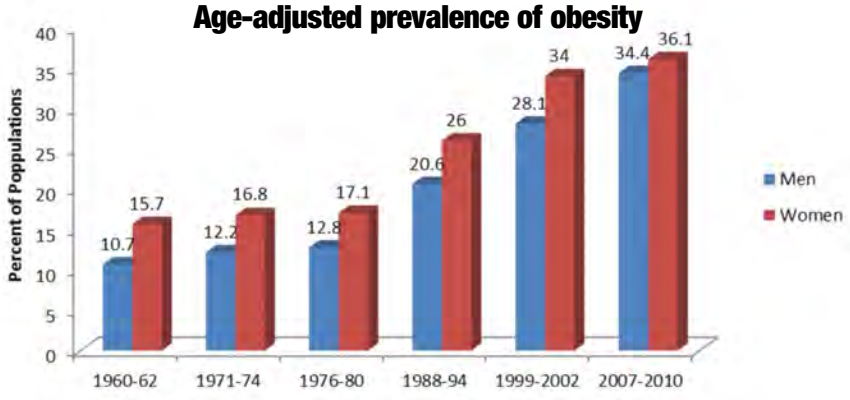


FIGURE 1. Age-adjusted prevalence of obesity in adults 20 to 74 years of age

Source: National Health Examination Survey: 1960-1962; National Health and Nutrition Examination Survey: 1971–1974,1979–1980, 1988–1994, 1999–2002, and 2007–2010; Data derived from Health, United States, 2011 (National Center for Health Statistics)[1]

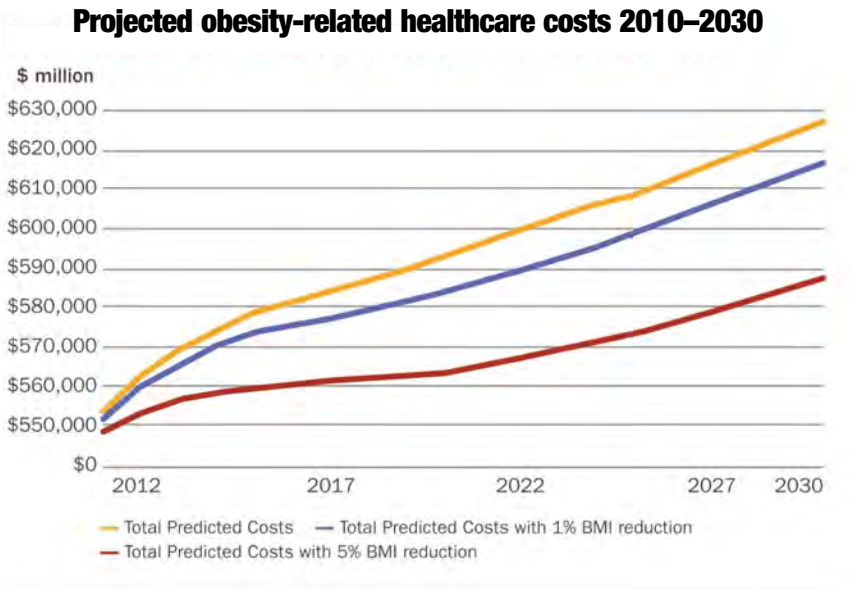


FIGURE 2. Graph showing the correlation between obesity and healthcare spending in the United States. Three scenarios are shown—Total predicted costs of obesity-related healthcare if: 1) obesity rate trends continue; 2) the population reduces BMI rates by one percent, and 3) the population reduces BMI rates by five percent.

Source: F as in Fat: How Obesity Threatens America's Future 2012 and 2013. A report from the Trust for America's Health (TFAH) and the Robert Wood Johnson Foundation (RWJF).

REFERENCES

1. Padwal R, Li, SK, Lau DC. Long-term pharmacotherapy for obesity and overweight. *Cochrane Database Syst Rev*. 2004(3):CD004094.
2. Buchwald H, Avidor Y, Braunwald E, et al. Bariatric surgery: a systematic review and meta-analysis. *JAMA*. 2004;292:1724–1737.
3. Buchwald H, Estok R, Fahrbach K, et al. Weight and type 2 diabetes after bariatric surgery: systematic review and meta-analysis. *Am J Med*. 2009;122:248–256 e5.
4. Sjostrom L, Narbro K, Sjostrom CD, et al Effects of bariatric surgery on mortality in Swedish obese patients. *N Engl J Med*. 2007;357:741–752.
5. Cote GA, Edmundowicz SA. Emerging technology: endoluminal treatment of obesity. *Gastrointest Endosc*. 2009;70:991–999.
6. Clinical Issues Committee of the American Society for Metabolic and Bariatric Surgery. Updated Position Statement on Sleeve Gastrectomy as a Bariatric Procedure. *Surg Obes Relat Dis*. 2010;6(1):1–5.

Endoscopic Suturing for the Treatment of Complications Arising in Metabolic and Bariatric Patients

by Sergey V. Kantsevoy, MD, PhD

Bariatric Times. 2013;10(11 Suppl B):B18–B19.

AUTHOR AFFILIATIONS: Dr. Kantsevoy is Clinical Professor of Medicine, University of Maryland School of Medicine; Director of Therapeutic Endoscopy, Mercy Medical Center, Baltimore, Maryland
ADDRESS FOR CORRESPONDENCE: Sergey V. Kantsevoy, MD, PhD, 4 Melisa Court, Owings Mills, MD, 21117; Phone: (410) 332-9040; Fax: (410) 659-1162
FUNDING AND DISCLOSURES: No funding was provided. Dr. Kantsevoy is a shareholder in Apollo Endosurgery, Inc.

INTRODUCTION

The prevalence of obesity in adults and children around the world has increased dramatically over the last several decades.[1–3] One result of this prevalence is the increase in bariatric surgery for correction of obesity and obesity-related comorbidities.[4] Although very effective in weight reduction, bariatric surgery carries a risk of serious postoperative adverse outcomes.[5] Endoscopic suturing is a consistent method of addressing these outcomes, and one device that enables this type of surgery, the OverStitch™ Endoscopic Suturing System (Apollo Endosurgery, Inc., Austin, Texas), has been commercially available in United States since 2011. Fistulas, including gastro-peritoneal, gastroenteric, gastrocutaneous, and gastro-gastric, can develop after gastric bypass and sleeve gastrectomy procedures. Thirty-four patients have thus far been treated with flexible endoscopic suture closure in the Mercy Medical Center, Baltimore, Maryland, United States. Two highly illustrative cases are presented here, which provide an overview of the complete approach to these difficult management problems.

ENDOSCOPIC SUTURING FOR CORRECTION OF EARLY ADVERSE OUTCOMES POST-BARIATRIC SURGERY

Closure of gastroperitoneal fistula. The patient was a 41-year-old man with esophago-peritoneal fistula after Roux-en-Y gastric bypass (RYGB). Endoscopic examination revealed an 8mm fistula, large enough to allow visibility of an intra-peritoneal drain through the fistula (Figure 1). Multiple attempts were made to close the fistula with the application of endoscopic clips and fibrin glue, but all were unsuccessful. After these failures, the fistula was closed endoscopically with three separate stitches using the OverStitch™ system (Apollo Endosurgery, Inc.). In addition, a fully covered esophageal stent (Polyflex™, Boston Scientific, Natick, Massachusetts, United States) was deployed and sutured to the esophageal wall to protect the suture line and to divert the food away from the fistula (Figure 2). After several weeks and complete healing of the fistula, the sutures were cut off and the stent was removed.

Closure of a gastro-gastric fistula after previous Roux-en-Y gastric bypass. A 52-year-old woman presented with a large fistula between gastric pouch and gastric remnant (Figure 3). On the first endoscopy, ablation of gastric mucosa around the fistula with argon plasma coagulator was performed and then the fistula was closed with three endoscopically placed sets of sutures. However, the fistula opened up again. During the second endoscopy, an endoscopic mucosal resection was performed around the fistula.The fistula was then closed with three separate stitches directed at opposing the mucosal resection sites (Figure 4), which eliminated interposition of any mucosa and allowed complete healing of the fistula.

FIGURE 1. Large esophago-peritoneal fistula with clearly seen drain inside the peritoneal cavity.

FIGURE 2. The fistula closed with endoscopic sutures and then a fully covered esophageal stent deployed and sutured onto the esophageal wall with endoscopic suturing device

FIGURE 3. Large fistula between the gastric pouch and gastric remnant in a patient with prior Roux-en-Y gastric bypass

FIGURE 4. The fistula completely closed with endoscopically placed sutures

CONCLUSION

The development of fistulas after bariatric surgery presents a frustrating and costly problem both for the patient and the physician. The ability to close fistulas with accurately placed full-thickness sutures, made from within the gut lumen, is a major and long-awaited breakthrough in flexible endoscopic therapy. This newly available technology will be beneficial not only for treatment fistulas, but also for other complicated problems.

In conclusion, endoscopic suturing with the OverStitch™ Endoscopic Suturing System (Apollo Endosurgery, Inc.) can be successfully used for correction of early and late adverse outcomes after bariatric surgery and can even eliminate persistent entero-peritoneal and gastro-gastric fistulas after previous bariatric surgery.

REFERENCES

1. Strauss RS, Pollack HA. Epidemic increase in childhood overweight, 1986–1998. *JAMA*. 2001;286: 2845–2848.
2. Hedley AA, Ogden CL, Johnson CL, et sl. Prevalence of overweight and obesity among US children, adolescents, and adults, 1999–2002. *JAMA*. 2004; 291:2847–2850.
3. Ogden CL, Carroll MD, Flegal KM. Epidemiologic trends in overweight and obesity. *Endocrinol Metab Clin North Am*. 2003; 32:741–760, vii.
4. Nguyen NT, Masoomi H, Magno CP, et al. Trends in use of bariatric surgery, 2003-2008. *J Am Coll Surg*.; 2011;213(2):261–266.
5. Lim RB, Blackburn GL, Jones DB. Benchmarking best practices in weight loss surgery. *Curr Probl Surg*. 2010;47(2):79–174.

Endoscopic Suturing for Secure Closure of Full-Thickness Defects in the GI Tract

by Stavros N. Stavropoulos, MD; Rani J. Modayil, MD; Kumkum S. Patel, MD, MPH; David Friedel, MD; and James H. Grendell, MD

Bariatric Times. 2013;10(11 Suppl B):B20–B23.

AUTHOR AFFILIATIONS: Drs. Stavropoulos, Modayil, Patel, Friedel, and Grendell are all from the Division of Gastroenterology, Hepatology and Nutrition, Winthrop University Hospital, Mineola, New York, United States.
ADDRESS FOR CORRESPONDENCE: Stavros N. Stavropoulos, MD, 222 Station Plaza North, Suite 428, Mineola, NY 11501; Phone: (516) 663-4623; Fax: (516) 663-4617; E-mail: sstavropoulos@winthrop.org
FUNDING AND DISCLOSURES: No funding was provided. Dr. Stavropoulos has received honoraria from Boston Scientific and ERBE. Drs. Modayil, Patel, Friedel, and Grendell report no conflicts of interest relevant to the content of this article.

INTRODUCTION

Endoscopists have yearned for the ability to close full-thickness defects in the GI tract—whether intentional, such as those in full-thickness resections, or accidental, such as perforations—in the same secure fashion that surgeons are accustomed to with hand-sewn or stapled closures. Until recently, endoclips and larger over-the-scope (OTSC) clips were the predominant devices available to endoscopists for tissue approximation. These endoscopic clips have a fixed maximal aperture that is no larger than 12 to 15mm and require larger defects to be reduced to this size before the clip can be deployed across the defect in order to approximate its edges. Furthermore, these clips, particularly endoclips, lack the strength to enclose large amounts of tissue. Therefore, attempts to close defects that have thick edges often result in tissue tearing or misdeployed clips and failed closure. Additionally, the depth of tissue captured by endoscopic clips is unpredictable and often only involves mucosa. This results in superficial closure and risk of clip dislodgement and leakage of luminal contents.

Endoscopic suturing allows secure closure of defects of arbitrary size and depth as well as defects with everted or thick edges that are challenging to close with endoclips. Tissue defects can be approximated with running or interrupted sutures to achieve closure in a manner that was previously only possible with surgical devices. The OverStitch™ Endoscopic Suturing System (Apollo Endosurgery, Inc., Austin, Texas) represents a commercially available, United States Food and Drug Administration (FDA)-approved device that allows endoscopic suturing and has revolutionized the ability to close large full-thickness defects of the GI tract. Gastroenterologists no longer need to constrain their endoscopic resections to the mucosal and submucosal layers. Large full-thickness defects breeching the GI tract wall, those that would have previously been deemed perforations requiring emergent surgical repair, can now be managed endoscopically with endoscopic suturing. This type of secure sutured closure is essential to minimizing the risk of leakage of luminal contents into the peritoneal cavity.

A sutured closure that involves full-thickness or near full-thickness tissue "bites" can provide the level of security against leakage of luminal contents that is required to opt for conservative management of perforations rather than emergency surgery. This is crucial in high-risk organs, such as the colon, where delayed or unappreciated leakage after inadequate closure may result in severe morbidity, as has been described with clip closure.[1]

Here, we discuss and illustrate use of endoscopic suturing to close full-thickness defects in the GI tract created during "near luminal," "short range" NOTES procedures, such as POEM (Per Oral Endoscopic Myotomy), STER (Submucosal Tunnel Endoscopic Resection), and EFTR (Endoscopic Full-Thickness Resection).

POEM

POEM, a NOTES approach to Heller myotomy, consists of an intentional breech of the muscularis propria from the luminal side of the esophagus. Therefore, without a method that ensures secure closure of the defect, POEM would have an unacceptably high risk of leakage of luminal contents and resultant mediastinal sepsis. At the time of initial development of POEM approximately five years ago,[2] endoscopic suturing was not available. What made secure closure possible with the use of endoclips was the submucosal tunnel technique. A mucosotomy is created and only after tunneling in the submucosa for some distance is the muscularis incision made.[2] Thus, the perforations in the mucosa and the muscularis propria are "offset" by several centimeters of submucosal tunnel that creates a mucosal flap valve that minimizes the risk of leakage and only requires closure of the mucosotomy site with endoclips. The issues with endoclip closure described previously also apply to the closure of the POEM mucosotomy. Endoscopic suturing may offer advantages over clips.

Advantage 1. If the muscularis propria is inadvertently perforated during creation of the mucosotomy, the tunneled approach offers no protection against leakage and a secure full-thickness closure of this perforation of the wall of the esophagus is required. Successful use of the OverStitch™ device (Apollo Endosurgery, Inc.) for such an indication has been described in the literature.[3]

Advantage 2. Endoscopic suturing may allow earlier discharge and even same day discharge after POEM. Endoclips only approximate the mucosal edges of the mucosotomy site and thus are prone to dislodgement at much lower mechanical forces compared to sutures that securely tie together mucosa, submucosa, and often, muscularis propria as well. Ren et al[4] described a case of early clip dislodgement and mucosotomy dehiscence with food contamination of the tunnel and food impaction resulting in morbidity. If POEM is to become a same-day ambulatory procedure, as envisioned by many expert POEM operators, secure tunnel closure is of paramount importance. Discharge of POEM patients is often delayed when there are concerns about the adequacy of endoclip closure or concerns about the patient's adherence to post-POEM liquid diet since solid food boluses may be more likely to cause premature endoclip dislodgment, as described in the case by Ren et al.[4] Endoscopic suturing may minimize such concerns and allow routine same-day discharge of most POEM patients.

Advantage 3. Closure of the mucosotomy site with endoclips can be particularly challenging in patients with advanced and long-standing achalasia. In these patients, due to prolonged food stasis, there is marked thickening and friability of the mucosa and thickening of the submucosa, resulting in very thick edges that are hard to capture and approximate with currently available endoclips. The large amount of tissue within the clip arms creates excessive tension during clip closure, which results in tissue tearing or early clip deployment prior to complete closure of the arms of the clip. Again, endoscopic suturing in these patients is invaluable in achieving secure closure.

At our center, we have utilized endoscopic suturing for closure in the most recent 21 POEMs out of a series of 90 POEM procedures. Endoscopic suturing allowed earlier discharge of these patients compared to the prior 69 cases for which endoclips were used for closure (see video at http://www.endoscopicsuturing.metabolicsurgery.tv/). No other data exist in the POEM literature to date.

ENDOSCOPIC FULL-THICKNESS RESECTION TECHNIQUES

Recently, pioneering endoscopists have reported endoscopic interventions that intentionally breech the GI tract wall as part of the procedure but do not involve venturing with the endoscope into the abdomen or mediastinum to perform distant interventions as described in traditional NOTES. These "near luminal" NOTES procedures include POEM (discussed previously), the prototypical such procedure, and the more recently reported full-thickness endoscopic resection techniques to remove muscularis and serosa-based deep-seated subepithelial tumors.[2,5] These techniques are variations of endoscopic submucosal dissection (ESD) utilizing the same knives and methodology but applied to levels deeper than the submucosa. They achieve endoscopic R0 en bloc full-thickness resection of deep-seated subepithelial tumors. They include Submucosal Tunnel Endoscopic Resection (STER),[2] an offshoot of POEM utilizing the submucosal tunnel method to ensure secure closure of the full-thickness defect in the wall of the GI tract, and endoscopic full-thickness resection (EFTR),[5] direct full-thickness resection with closure of the resultant perforation with endoclips. These techniques are particularly useful for resection of tumors located in areas, such as the esophagus, GE junction, pylorus, lesser curvature, and gastric cardia, where limited, organ-preserving surgical resection is often challenging or impossible. Furthermore, unlike laparoscopic techniques or hybrid laparoscopic plus endoscopic techniques, pure endoscopic resection offers a less invasive approach for complete resection of tumors, particularly small GI stromal tumors. While most of these tumors in the 2 to 5cm size range are low risk lesions, most current guidelines recommend

resection.[6] It is thought that such endoscopic full-thickness resection techniques can be extended beyond resection of stromal tumors to include resection of early mucosal neoplasms such as large or advanced colorectal adenomas (Figures 1–3).

Studies have demonstrated substantial rates of wound dehiscence and leakage with clip-based closure of full-thickness GI tract wall defects in animals[7] and humans.[8] The deep and reliable closure created by endoscopic suturing appears ideally suited for closure of such defects. Reliable closure is essential to minimize risk of dehiscence, leakage, and peritonitis with attendant severe morbidity. Furthermore, it is the sine qua non for wide adoption of these techniques, particularly in countries with high medicolegal liability.

CASE PRESENTATIONS

Recently, a group reported on the depth of full-thickness endoscopic sutures placed in normal areas of the colon of patients scheduled to undergo colectomy.[9] Examination of the resected specimen revealed subserosal depth of the sutures and adequate suture hold and tissue plication. At this moment, endoscopic suturing data using for closure of defects post-EFTR are nonexistent. At our center, we had used endoscopic suturing with the OverStitch™ device (Apollo Endosurgery, Inc.) to close full-thickness defects in patients undergoing endoscopic full thickness resection of tumors of the UGI tract and colon. Early in our series, we have used endoscopic clip-based methods. On more recent patients, we have used the OverStitch™ device (Apollo Endosurgery, Inc.). These data have been submitted for publication. Here, we present three illustrative cases.

Figure 1 illustrates OverStitch™ (Apollo Endosurgery, Inc.) endoscopic sutured closure of full-thickness defect in the antrum after EFTR of a hypoechoic tumor that was shown on pathology to represent a schwanomma.

Figure 2 illustrates OverStitch™ (Apollo Endosurgery, Inc.) endoscopic sutured closure of full-thickness defect in the rectum after EFTR of a lesion that was shown on pathology to represent a T1 well differentiated carcinoma with deep submucosal invasion.

Figure 3 illustrates OverStitch (Apollo Endosurgery, Inc.) endoscopic sutured closure of full-thickness defect in the sigmoid colon after EFTR of a tumor that was shown on pathology to represent a leiomyoma with high risk histologic features.

In an accompanying video, which can be viewed at http://www.endoscopicsuturing.metabolicsurgery.tv, we demonstrate use of the OverStitch device (Apollo Endosurgery, Inc.) to close the mucosotomy at the origin of a POEM submucosal tunnel. We demonstrate, for comparison purposes, clip closure of the mucosotomy at the origin of a POEM submucosal tunnel.

CONCLUSION

The advent of the OverStitch™ (Apollo Endosurgery, Inc.) device, a relatively inexpensive device with a reasonably short learning curve, is enabling rapid development of full-thickness resection techniques by providing a potentially easier and more reliable closure method compared to endoscopic clips. Data on the use of OverStitch™ (Apollo Endosurgery, Inc.) for closure of full-thickness GI tract defects are limited so far, but enthusiastic adoption of the device in the United States should result in rapid accumulation of data and ensuing publications. This is already occurring for bariatric indications,[10] and we expect that studies on defect closure are not too far behind.

REFERENCES

1. Rodriguez Lopez M, Blanco JI, Martinez R, et al. Clipping for endoscopic perforations: initial success but late complication requiring surgery. *Surg Endosc*. 2013 May 10. [Epub ahead of print].
2. Inoue H, Ikeda H, Hosoya T, et al. Submucosal endoscopic tumor resection for subepithelial tumors in the esophagus and cardia. *Endoscopy*. 2012;44(3):225–230.
3. Kurian AA, Bhayani NH, Reavis K, Dunst C, Swanström L. Endoscopic suture repair of full-thickness esophagotomy during per-oral esophageal myotomy for achalasia. *Surg Endosc*. 2013 May 25. [Epub ahead of print].
4. Ren Z, Zhong Y, Zhou P, Xu M, Cai M, et al. Perioperative management and treatment for complications during and after peroral endoscopic myotomy (POEM) for esophageal achalasia (EA) (data from 119 cases). *Surg Endosc*. 2012; 26 (11):3267–3272.
5. Zhou PH, Yao LQ, Qin XY, et al. Endoscopic full-thickness resection without laparoscopic assistance for gastric submucosal tumors originated from the muscularis propria. *Surg Endosc*. 2011;25(9):2926–2931.
6. Demetri GD, von Mehren M, Antonescu CR, et. al. NCCN Task Force Report: Update on the Management of Patients with Gastrointestinal Stromal Tumors. *J Natl Compr Canc Netw*. 2010;8:S1–S41.
7. von Renteln D, Schmidt A, Vassiliou MC, Rudolph HU, Caca K. Endoscopic full-thickness resection and defect closure in the colon. *Gastrointest Endosc*. 2010;71(7):1267–1273.
8. Wang L, Ren W, Fan CQ, Li YH, Zhang X, Yu J, et al. Full-thickness endoscopic resection of nonintracavitary gastric stromal tumors: a novel approach. *Surg Endosc*. 2011;25(2):641–647.

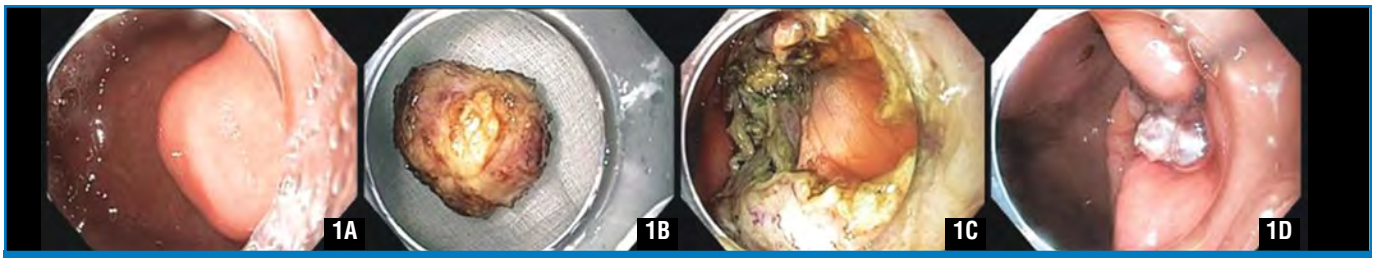


FIGURE 1. Endoscopic image of gastric muscularis propria based subepithelial tumor (A); 25mm schwannoma (B); Resection crater revealing serosa with peritoneal fat seen through the serosa (C); Endoscopic sutured closure of defect (D)

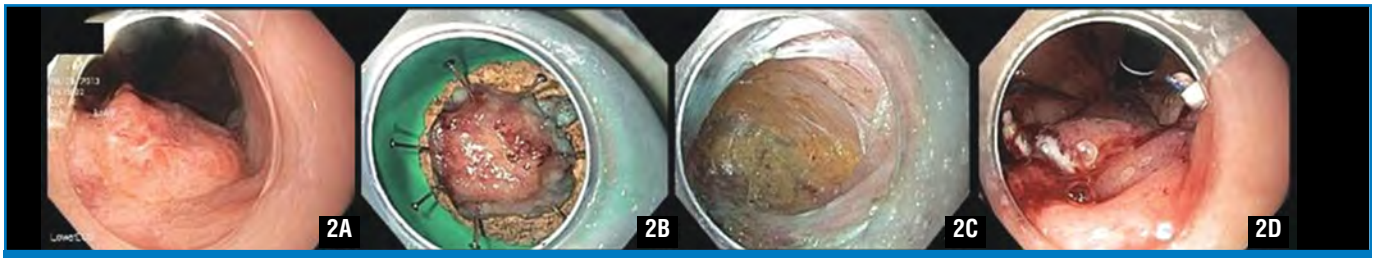


FIGURE 2. Endoscopic image of rectal carcinoma invading deeply into the submucosa (A); 18mm rectal low-grade adenocarcinoma (B); Resection defect demonstrating perirectal fat, and pelvic wall (C); Endoscopic sutured closure of defect (D)

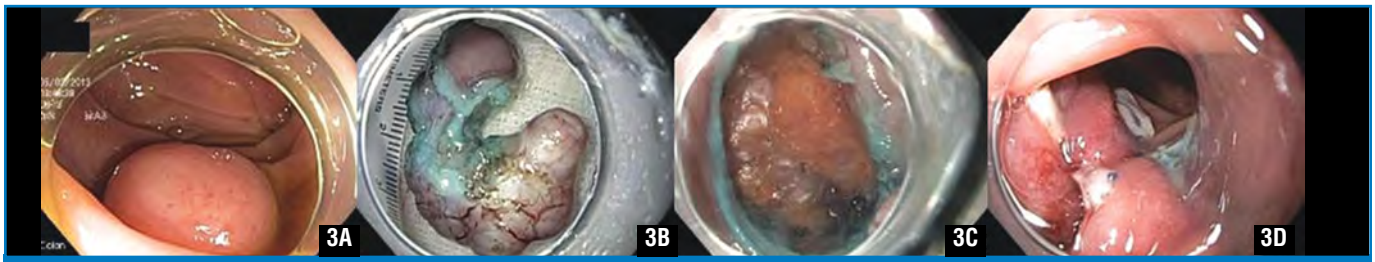
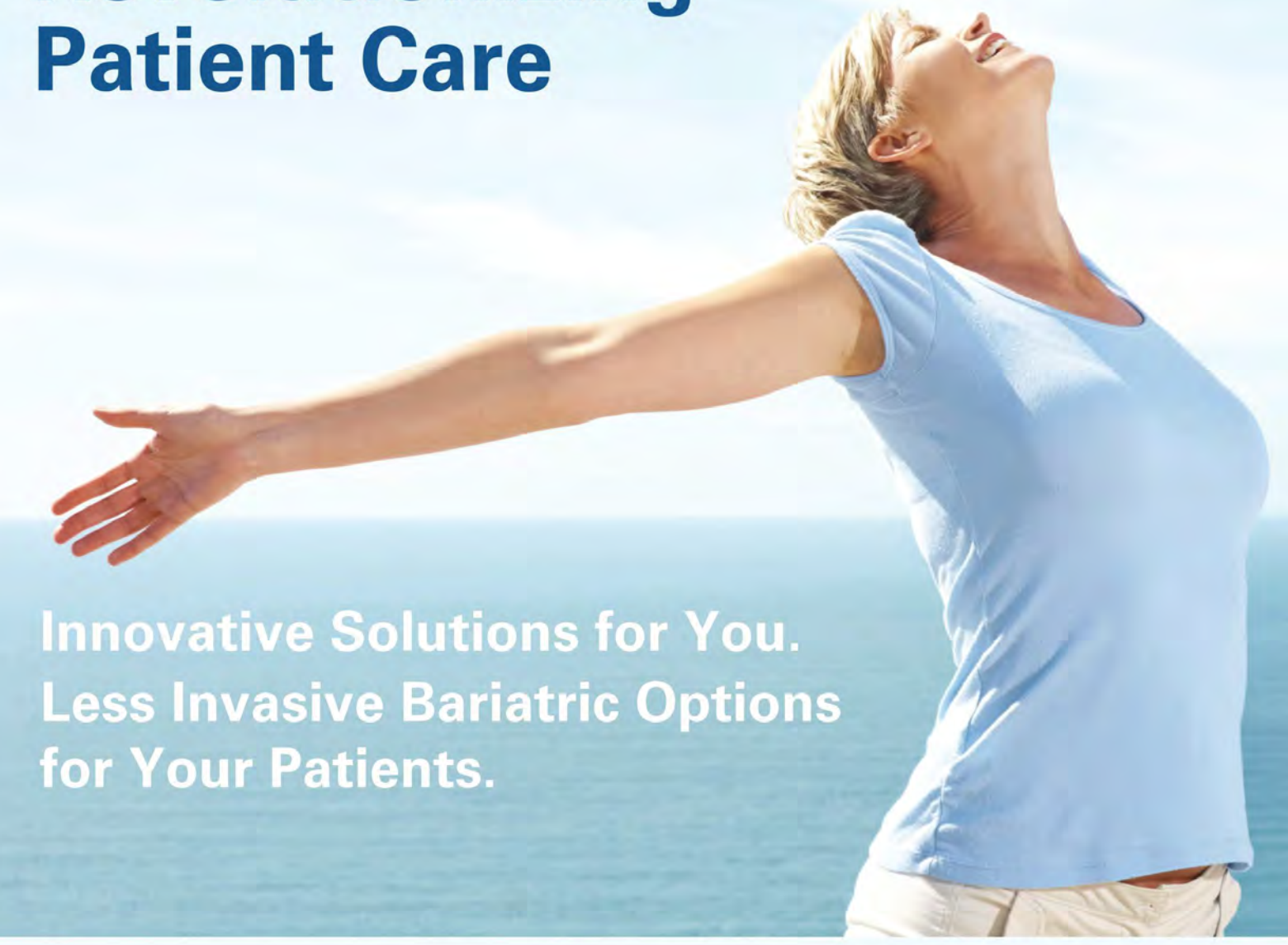


FIGURE 3. Endoscopic image of endoluminal portion of larger sigmoid muscularis propria based subepithelial tumor (A); 30mm leiomyoma with high risk histology (B); Resection crater demonstrating serosa with peritoneal fat seen through the serosa (C); Endoscopic sutured closure of defect (D)

9. Pauli EM, Delaney CP, Champagne B, Stein S, Marks JM. Safety and effectiveness of an endoscopic suturing device in a human colonic treat-and-resect model. *Surg Innov*. 2013 Feb 26. [Epub ahead of print].
10. Neto MG, Rodriguez L, Zundel N, et. al. Endoscopic Revision of Roux-en-Y gastric bypass stomal dilation with a suturing device: Preliminary results of a first out-of-United States series. *Bariatric Times*. 2011;8(6):32–34.

Revolutionizing Patient Care



Innovative Solutions for You. Less Invasive Bariatric Options for Your Patients.

To find out more, contact your Apollo Endosurgery representative at 877-ENDO-130 or visit www.apolloendo.com.

Defining the Future of Endoscopic Surgery™

apollo endosurgery

October 2013 MKT-00144-00 R01