**ORIGINAL ARTICLE** 



# Per-Oral Plication of (Neo)Esophagus: Technical Feasibility and Early Outcomes

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# Abstract

**Background** Endoscopic sleeve gastroplasty is an example of endoscopic sutured plications being used to remodel a gastrointestinal organ. With per-oral plication of the esophagus (POPE), similar plications are used to remodel the dilated and redundant megaesophagus of end-stage achalasia. Redundancies and dilations can also develop in the neoesophagus of a patient with prior esophagectomy. Megaesophagus and a redundant neoesophagus can both lead to debilitating dysphagia, regurgitation, and recurrent aspiration pneumonia. Traditionally, this anatomic problem requires complex revisional or excisional surgery, to which POPE offers an incisionless alternative.

**Methods** This is a dynamic manuscript with video demonstration of POPE, as well as review of five cases performed in 1 year. Data were collected in a prospectively maintained database, and the institutional review board approved retrospective review for this publication. The procedure is performed using a dual-channel upper endoscope fixed with an endoscopic suturing device, with the patient supine under general anesthesia.

**Results** POPE was technically completed in all cases with no serious complications, and patients either went home the same day or spent one night for observation. Most patients reported immediate and substantial symptomatic improvement. Objective pre- and post-measures include esophagram and nuclear gastric emptying studies.

**Conclusion** This article discusses early experience at one institution with POPE, with detailed description of the procedure and technical considerations. An accompanying video reviews two cases, one with megaesophagus and one with a gastric conduit. While this novel procedure has limited and rare indications, it offers a low-morbidity solution to a challenging anatomic problem that traditionally requires invasive surgery.

 $\label{eq:constraint} \begin{array}{l} \mbox{Keywords} \ \mbox{Plication of esophagus} \cdot \mbox{Endoscopic suturing} \cdot \mbox{Endoluminal suturing} \cdot \mbox{Achalasia} \cdot \mbox{Esophagectomy} \cdot \mbox{Delayed emptying} \\ \end{array}$ 

# Introduction

Endoscopic suturing is a relatively new tool that can be used to remodel gastrointestinal organs. Two clinical scenarios that can benefit from endoscopic remodeling are a dilated "end-stage" esophagus of achalasia and a dilated gastric conduit after esophagectomy. Both these conditions can result in chest discomfort, frequent regurgitation and aspiration,

H. Mason Hedberg hhedberg@northshore.org and typically are considered to need surgical revision for symptom improvement.

Achalasia is a primary motor disorder of the esophagus characterized by esophageal body aperistalsis and lack of lower esophageal sphincter relaxation. While there is no cure, symptoms may be palliated by pneumatic dilation, botulinum toxin injection, and surgical myotomy. Despite the success of these treatment options, some patients suffer from progressive deterioration of esophageal function, and some patients fail to present for timely treatment. Endstage achalasia results in megaesophagus, where the organ is dilated and tortuous or "sigmoid" in shape. This can result in "sump" formation—areas where food and oral secretions can pool (Fig. 1). Patients may experience frequent regurgitation, aspiration pneumonia, chest discomfort, and esophageal erosion/ulceration.1

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Fig. 1 End-stage achalasia depicted by a tortuous 'sigmoid' esophagus with sump formation (arrow)

The standard treatment for end-stage achalasia with a dilated and poorly functional esophagus is surgical resection and replacement with a gastric, colonic, or small bowel neoesophageal conduit. Even when performed in high-volume centers, esophagectomy for end-stage achalasia retains one of the highest risks of morbidity and mortality in the realm of gastrointestinal surgery. As an alternative, esophageal mucosectomy from a cervico-abdominal approach has been described. This technique invaginates and resects redundant esophageal mucosa in order to narrow and straighten the organ. While this approach is able to improve symptoms while preserving the esophagus, it is not without its own technical challenges and morbidity and is not commonly performed.3

A progression similar to the development of megaesophagus may occur with the neoesophagus after esophagectomy. Delayed gastric conduit emptying (DGCE) after esophagectomy is a fairly common problem affecting 15–39% of patients.4–6 To empty, the gastric conduit must overcome the pressure gradient from the thorax to the abdomen, and division of the vagus nerves during esophagectomy impairs pyloric relaxation and peristalsis. Technical factors such as torsion, narrow hiatus, or redundant conduit may contribute to DGCE. In the early postoperative period, DGCE increases risk of aspiration, pneumonia, and anastomotic leak. Longterm, it can lead to malnutrition and poor quality of life.7 Medical and endoscopic interventions are preferred for initial management to improve emptying. However, delayed emptying due to dilation and sump formation will not be addressed by medications or emptying procedures. These cases ultimately require surgical revision or resection and replacement of the conduit.8–10

Endoscopic suturing is a relatively recent technological advancement used to address gastrointestinal (GI) tract defects such as fistulas and perforations, to prevent endoscopic stent migration, and to revise or remodel portions of the GI tract. For example, endoscopic sleeve gastroplasty (ESG) utilizes endoscopic suturing to functionally achieve the same anatomical result as sleeve gastrectomy without resection or removal of tissue.11 Our aim was to apply the principles of gastric remodeling for weight loss to remodeling a megaesophagus or redundant neoesophagus in order to achieve the functional result of esophageal mucosectomy. Plication of the (neo)esophageal mucosa and submucosa should similarly narrow the organ, as shown in a simplified cartoon (Fig. 2). Rather than weight loss, the goal of these plications is to improve emptying and alleviate pain, regurgitation, and aspiration. In this case series, we present the technical feasibility and outcomes from our early experience with per-oral plication of the (neo)esophagus (POPE).

#### Methods

The institutional review board approved a retrospective review of patients who had undergone POPE from November 2019 through September 2020. All procedures were elective, and patients either stayed overnight for observation or went home the same day. For a procedure like POPE with a rare indication, patients present with a long and complex medical/surgical history. Therefore, preoperative workup is not standardized; it is tailored to the patient. It may include high-resolution manometry, barium esophagram, endoscopy, and nuclear gastric emptying study in order to rule out other causes of poor esophageal or gastric emptying. Likewise, we do not have standardized objective testing after POPE; tests are ordered if indicated for persistent symptoms. Data collection consisted of chart review beginning with the patient's initial consultation, including previous or new preoperative workup, outcome and tolerance of the procedure itself, and any subsequent objective testing, complications, admissions, or procedures up to the date of data collection. Patients described their most bothersome symptoms at their **Fig. 2** Simplified image demonstrating a sump in a dilated gastric conduit (**a**). Right panel demonstrating a straightened conduit after plications have been applied to the redundant portion (**b**)



initial consultation and % improvement at their postoperative follow-up visit.

#### Device

The endoscopic suturing device, OverStitch<sup>TM</sup> (Apollo Endosurgery Inc. Austin, TX), uses a detachable head placed at the end of the endoscope and a handle placed close to the proximal opening of the accessory channels. The Over-Stitch<sup>TM</sup> requires a double-channel endoscope (Olympus GIF-2TH180). A lever on the handle drives the needle driver on the detachable head. Suture is introduced through the larger accessory channel using a needle passing catheter. The OverStitch<sup>TM</sup> Tissue Helix (Apollo Endosurgery Inc. Austin, TX) is used through the smaller, second accessory channel to screw into and pull tissue up to the needle driving head. The components of the system are shown in Fig. 3. We place an OverTube<sup>TM</sup> (Apollo Endosurgery Inc. Austin, TX), to protect the oropharynx and upper esophagus from excessive abrasive trauma by the OverStitch<sup>TM</sup>.

# Procedure

We perform POPE under general anesthesia in the supine position. Anesthesia should be made aware of aspiration

risk in these cases—due to anatomic emptying problems, the (neo)esophagus likely contains undigested food and fluid despite patients remaining *nil per os* for 12 h or more. After confirming the patient and procedure in a standard time-out, the esophagus or neoesophagus is closely inspected with a high-resolution single-channel endoscope (Olympus GIF HQ190) for unexpected pathology. If appropriate, impedance planimetry to interrogate the esophagogastric junction (EGJ) or pylorus (EndoFLIP<sup>TM</sup>, Medtronic Inc., Warsaw, IN) is performed to ensure the adequacy of prior myotomies. If indicated, per-oral endoscopic myotomy (POEM) or peroral pyloromyotomy (POP) could be repeated at the time of POPE. We have previously published on expected planimetry values after complete myotomies of the EGJ and pylorus, which help guide intraoperative decision-making.12–14

An OverTube<sup>TM</sup> is placed, and the dual-channel endoscope is fitted with the OverStitch<sup>TM</sup>. A 2–0 polypropylene non-absorbable surgical suture is loaded and the device tested outside the body. The scope is introduced and advanced to the most distal area of redundancy. Bites of tissue are taken from anterior to posterior along the surface of the redundancy, being sure to leave adequate lumen behind to avoid stricture. When the suture line is complete, the suture is cinched, anchored, and cut using the OverStitch<sup>TM</sup> Suture Cinch. The scope is withdrawn, and the next plication **Fig. 3** Apollo Overstitch<sup>™</sup> device. Left panel (**a**) showing the endcap with needle driving apparatus and Tissue Helix. Right panel (**b**) showing the control devices—lever for driving the needle and needle passing catheter in the accessory channel. Images used with permission of Apollo Endosurgery



proceeds as the prior. Plications are placed in a distal to proximal manner until the sump has been eliminated. The number of plications and the number of bites per plication is dependent upon the individual's anatomy. When plication is complete, the high-resolution scope is re-introduced to inspect for hemostasis and inadvertent injuries.

# Results

A summary of patient characteristics and technical parameters are in Table 1. There were five patients and six procedures evaluated on chart review. Each POPE procedure was technically completed successfully with no intraoperative complications. In general patients complained of a few days of mild chest and/or back discomfort managed with over the counter pain medications. There were no 30-day adverse events related to the procedure. Three patients spent the night in the hospital for observation, and two were discharged home the same day.

Four patients had a primary diagnosis of achalasia and one of esophageal cancer. Two patients had previously undergone esophagectomy with gastric pull-up. These two patients had known DGCE and were status-post POP with persistent symptoms. The remaining three achalasia patients had a history of surgical myotomy, two laparoscopic Heller's and one by an open thoracic approach. Adequacy of the prior myotomies, whether of the pylorus or LES was

| Table 1 | Demographics and basic | course for the five patients included in | the series. Proc time $=$ procedure time | (minutes); LOS = length of stay |
|---------|------------------------|--|--|---------------------------------|
|---------|------------------------|--|--|---------------------------------|

|         |     |     |  |                           |           |                     |     | _                |                           |
|---------|-----|-----|--|---------------------------|-----------|---------------------|-----|------------------|---------------------------|
| Patient | Age | Sex | History  | Symptoms                  | Proc time | Number<br>plication | LOS | Complaints       | Symp-<br>toms<br>improved |
| 1       | 38  | М   | Achalasia s/p Heller, megae-<br>sophagus         | Regurgitation             | 60        | 4                   | 0   | Chest pain       | 100%                      |
| 2       | 52  | F   | Achalasia s/p Heller, esophagec-<br>tomy         | Regurgitation, pneumonias | 92        | 4                   | 1   | Chest/ back pain | 50%                       |
| 3       | 84  | М   | Achalasia s/p Heller, megae-<br>sophagus         | Food impaction            | 35        | 2                   | 1   | None             | 100%                      |
| 4       | 66  | М   | Esophageal cancer s/p<br>esophagectomy           | Regurgitation, pneumonias | 175       | 3                   | 1   | None             | 0%                        |
| 5       | 47  | F   | Achalasia s/p thoracic myotomy,<br>megaesophagus | Regurgitation, heartburn  | 36        | 3                   | 0   | Chest/ back pain | 50%                       |

assessed intraoperatively by impedance planimetry, and no re-do myotomies were deemed necessary.

One achalasia patient's main complaint was recurrent food impaction; the other four complained primarily of regurgitation. Two had recurrent hospitalizations for aspiration pneumonia. These two patients have not had hospital admissions for aspiration pneumonia since intervention—a total of 15 months between the two patients. Patient 1 no longer experiences esophageal food impaction, and patient 1, who prior to POPE was purging before bed to prevent nocturnal regurgitation, no longer needs to do so. Four of the five patients noted substantial or complete improvement of their most bothersome symptoms. These improvements have persisted to the writing of this manuscript—a total of 25 months among the four patients. The pre- and postintervention esophagrams of patient 3 are shown in Fig. 4, demonstrating resolution of the mid-esophageal sump.

Although there are no consensus guidelines for diagnostic standards, we find nuclear GES to be a useful modality to assess for objective evidence of improved emptying after a procedure. For example, Fig. 5 shows a timeline of patient 2's clinical course. After doing well for several years after esophagectomy, she developed regurgitation and recurrent aspiration pneumonia. GES showed severely delayed emptying. POP was performed with some improvement in symptoms and GES.



Fig. 5 Timeline of patient 2's clinical course, from minimally invasive esophagectomy (MIE), to per-oral pyloromyotomy (POP), to per-oral plication of esophagus (POPE). Tables below show progression nuclear gastric emptying results



Fig. 4 Patient 3's pre- (a) and post- (b) esophagrams. Patient 1 experienced food impaction and regurgitation prior to POPE due to the large sump in the mid/upper esophagus indicated by the arrow in panel a. After POPE, the esophagus is straightened and the sump is no longer apparent However, she was readmitted with pneumonia, prompting POPE. GES and symptoms further improved, and she has remained out of the hospital since.

Patient 4 is the one patient with no improvement after initial POPE. Minimally invasive three-hole esophagectomy had been performed for early-stage esophageal adenocarcinoma 2 years prior, and the patient quickly began struggling with symptoms of delayed gastric emptying. He underwent POP 3 months later with minimal improvement, and a redo POP in another 3 months, but continued to have symptoms of poor emptying. Further elective treatment was delayed due to COVID-19. He managed at home on a mostly liquid diet, until he presented to the emergency room with dyspnea and regurgitation. Cuts from a CT scan that admission are shown in Fig. 6. It appears that a distal twisting of his gastric conduit as it exits the chest resulted in a gastric outlet obstruction. He recovered quickly from this acute episode with nasogastric decompression and subsequently tolerated a liquid diet. He was taken to the OR for POPE to straighten the conduit and alleviate the distal kink. Similar to ESG, the lateral edge of the conduit was plicated to remove redundancy and tubularize the organ. However, he experienced no improvement in symptoms. He was brought back to the OR for a fully covered endoscopic stent placed across the pylorus and duodenum to promote straightening of the now chronically kinked segment. Additionally, some redundancy along the lesser curve was plicated to help straighten the kink distally. Since this intervention, the patient has experienced 100% improvement in his dysphagia and regurgitation. The stent is scheduled to be removed 2 months after it was placed.

The accompanying video summarizes the indications and technical execution of POPE and elaborates on the clinical courses of patients 1 and 2.

#### Discussion

#### **Patient Selection**

The two clear candidate populations for POPE are those with longstanding achalasia and those with a neoesophageal conduit. The clinical approach is different for the two groups. Patients with end-stage megaesophagus either managed to live a long time without treatment or received treatment in the past and are presenting with recurrent or persistent symptoms of dysphagia and regurgitation. Patients with sigmoid esophagus who have not been treated previously should undergo myotomy initially to assess improvement prior to considering POPE. For patients with prior treatment, symptoms may be due to an inadequately treated lower esophageal sphincter (LES), an overtreated and scarred EGJ, sump formation, or a combination of these. High-resolution manometry will likely resemble a pattern of achalasia: aperistalsis and absent LES relaxation. Manometry findings alone are not helpful determining if a redo myotomy is indicated, since a previously treated LES may not relax and basal pressures may vary. Barium swallow is helpful to determine if contrast is being "hung up" at the EGJ and/or in a sump. The dynamic flow of contrast should clearly demonstrate an anatomic reason for the patient's symptoms in order to offer POPE. Ultimately endoscopy and impedance planimetry are the best to evaluate these complex cases. Pseudoachalasia can be ruled out, the LES can be objectively evaluated to assess a prior myotomy, and anatomic evidence of sump formation can be directly visualized.

Cases determined to have an EGJ outlet obstruction, by barium swallow and/or impedance planimetry, either previously had an incomplete myotomy/balloon disruption, or have developed EGJ scarring. EGJ scarring may develop due to prior procedures and/or post-myotomy reflux. If scarring is suspected, dilation can be attempted first. If incomplete

**Fig. 6** CT from a hospital admission of patient 4 prior to POPE. While there may be an element of sump formation in the massively dilated conduit (**a**), there is also a function outlet obstruction caused by angulation of the duodenum entering the abdomen through the hiatus (**b**, arrow). This patient ultimately experienced symptom improvement after second POPE and duodenal stent



myotomy is suspected and anatomy is amenable to POEM, this can be attempted prior to or after dilation. If POEM does not improve symptoms, laparoscopic exploration of the hiatus should be performed with Heller myotomy. In cases where extensive scarring prevents safe surgical myotomy, esophagectomy is indicated. Barium swallow should be performed at each step in this treatment algorithm since persistent symptoms may be due to sump formation not addressed by successful resolution of EGJ outlet obstruction via myotomy.

DGCE is a well-known complication following esophagectomy. The patients in this series had their esophagectomies at our center by minimally invasive threehole (McKeown) approach, where we create a 4-5-cm gastric tube prior to pull-up with anastomosis in the neck. Both patients did well for 3-5 years prior to developing emptying issues. We consider endoscopic pyloromyotomy to be the first-line treatment for DGCE. We again rely on impedance planimetry to assess the pylorus prior to intervention and to confirm a complete myotomy. Planimetry is also useful to assess the appropriateness of redo myotomy for patients with persistent or recurrent symptoms. DGCE in the context of an open and distensible pylorus may be due to sump formation or other anatomic outlet obstruction, as seen in patient 4 in our series. Barium swallow will help determine whether a sump is present that would benefit from a targeted plication. As demonstrated in the accompanying video, a row of plications running along the surface of a sump can straighten the organ and improve emptying. Like with patient 4, more complex anatomic problems will require individually tailored remodeling solutions, and POPE alone may not be sufficient to improve emptying. In addition to preoperative GES and barium esophagram, more complex anatomy may be evaluated using 3D reconstructions of computed tomography images. This may provide a better visualization of the problematic anatomy and assist in preoperative planning.

# **Technical Considerations**

It is critical to maintain orientation while performing POPE and other endoscopic surgical procedures. Major landmarks identifiable during upper endoscopy with normal anatomy include the cricopharyngeus, aortic arch, left bronchus, left atrium, and EGJ. These are helpful to determine position along the length of the esophagus. The aortic arch/left bronchus and left atrium are generally in the upper left field of view during endoscopy of a supine patient and can be used to help maintain anterior–posterior orientation. Anatomic landmarks may not be reliable in a megaesophagus or neoesophageal conduit. A useful maneuver is to drip some saline or water from the end of an injection needle—drips will fall down with gravity indicating the posterior direction for a supine patient. Once oriented, the position of vital structures surrounding the esophagus/conduit should be kept in mind as the procedure is carried out. Additionally, special consideration should be made to avoid suturing the greater curve of the gastric conduit during revision as to protect its blood supply from the gastroepiploic artery.

The OverStitch<sup>TM</sup> is capable of taking full-thickness bites of the GI tract. During ESG, full-thickness plications are desirable, theoretically improving durability of the revision. However, there are case reports of injury to surrounding structures during ESG such as gallbladder perforation.15 Presumably the Tissue Helix can be driven beyond the gastric serosa and pull other tissues into the needle's path during a plication. While this is a rare event during ESG, injuries such as these in the mediastinum could be life threatening. As demonstrated in the attached video, care is taken to avoid drilling too deeply with the Tissue Helix during POPE-the intent is to capture the submucosa and not drill deeper. Additionally, the endoscope remains a few centimeters from the mucosa, forcing the tissue to be pulled away from surrounding structures into the needle's path. The tissue should pull away from the mediastinum easily, with clear tenting of the tissue before taking a bite.

#### Durability

ESG is a relatively new procedure lacking long-term data. A recent meta-analysis shows some weight loss parameters to be equivalent to laparoscopic sleeve gastrectomy at 12 months, and some series show persistent weight loss beyond 24 months.16 This implies the plications are intact, continuing to promote weight loss at 1 year. It is unknown how long a plicated stomach will maintain its remodeled shape. Durability for POPE may be inferior to ESG, since the esophagus lacks a serosa and aggressive, full thickness bites are unadvised. Durability will likely depend upon a variety of factors individual to each patient, such as extent of redundancy, number of plications, and number of bites per plication.

Case reports of re-do ESG for inadequate weight loss already exist.17 These cases were completed without complication and patients had improved weight loss. It is reasonable to assume POPE could also be repeated if symptoms recur. For some patients, it may be possible to completely avoid a highly morbid esophagectomy or conduit revision using endoscopic remodeling as needed. It is possible that repeat plication would increase the technical difficulty and morbidity of a definitive surgical intervention, and it may be wise to turn to surgery early if symptoms cannot be controlled after a few endoscopic attempts.

#### Limitations

This is a very limited case series, intended as a descriptive study of the POPE procedure and its indications. We can draw no conclusions regarding superiority of this approach to end-stage achalasia/neoesophageal anatomic issues over traditional esophagectomy or surgical conduit revision. While we do present some objective data demonstrating improvement of emptying after POPE, there was no standardized pre- and post-procedure evaluation for these five patients. Given the subjective nature of symptomatic assessment and the execution of the procedure itself, it standardized pre- and post-operative assessment by timed barium esophagram would be valuable in further exploration of this technique.

### Declarations

**Conflict of Interest** Dr. Ujiki reports consulting fees from Boston Scientific, Olympus, and Cook Medical and speaker fees from Gore, Medtronic, and Erbe, ass outside the submitted work. Drs. Hedberg, Attar, and McCormack have nothing to disclose.

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