



Endoscopic tissue approximation in clinical practice and the OverStitch device: a narrative review

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Objective: The current article describes modern endoscopic technologies that allow for advanced endoscopic tissue approximation and suturing. These technologies include such devices as through the scope and over the scope clips, endoscopic suturing OverStitch device and through the scope suturing X-Tack device.

Background: Since the original introduction of the diagnostic endoscopy, progress in the field has been astonishing. Over the past several decades endoscopy has made numerous advancements allowing for a minimally invasive mechanism to treat life threatening conditions such as gastrointestinal (GI) bleeding, full thickness injuries, as well as chronic medical conditions such as morbid obesity and achalasia.

Methods: A narrative review of all relevant and available literature on endoscopic tissue approximation devices over the last 15 years ago was conducted.

Conclusions: Multiple new devices, including endoscopic clips and endoscopic suturing devices, have been developed for endoscopic tissue approximation that allow advanced endoscopic management of a wide variety of GI tract conditions. It is critical for practicing surgeons to actively participate in the development and use of these new technologies and devices in order to maintain leadership in the field, hone expertise, and to drive innovation. Further research in minimally invasive applications for these devices is needed as they continue to be refined. This article provides a general overview of the devices available and their clinical applications.

Keywords: Endoscopic tissue approximation; endoscopic clips; endoscopic suturing; OverStitch device; X-Tack device

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Introduction

Endoscopic clips and suturing devices have evolved over the past 15 years to have a wide range of applications including closure of perforations, leaks, fistulas, mucosal defects after resections, anti-reflux and weight loss procedures and others. These advancements in endoscopic technologies and devices have allowed for innovations in the management of a wide variety of esophageal and foregut conditions.

We present the following article in accordance with the Narrative Review reporting checklist (available at <https://aoe.amegroups.com/article/view/10.21037/aoe-21-50/rc>).

Overview of currently available devices

Through the scope clips

Various through the scope endoscopic clips have allowed



Figure 1 Resolution 360 clip as an example of through the scope clip. Used with permission from Boston Scientific Corporation, Inc.



Video 1 Video of clinical applications of endoscopic tissue approximation.

for control of gastrointestinal bleeding, and approximation of mucosal injuries and full thickness defects (*Figure 1*, *Video 1*: 0:09, 1:22). The use of endoscopic clips was initially described over 30 years ago (1). Since then, the variety and functionality of modern-day clips has progressed exponentially. Most of the modern through the scope clips can be used in an endoscope with a 2.8-mm working channel, which is the majority of the diagnostic endoscopes on the market. These clips can be used as an effective monotherapy for hemostasis, when compared to injections or thermal coagulation (1,2). Overall, through the scope clips allow for excellent field exposure and visualization due to their compact size, and can be used in most commercially available endoscopes. Of the multitude of the products available, in our practice we prefer Resolution 360™ (Boston Scientific, Marlborough, MA, USA) clip. In authors opinion this particular device has superior performance due to precise 1:1 control of the rotational position of the distal tip (3). The Resolution 360 clip has been demonstrated to have 100% reliability when fired on a 10-mm gel, simulating



Figure 2 Ovesco Clip—over the scope clip system. Used with permission from Ovesco Endoscopy AG. OTSC® is a registered trademark of Ovesco Endoscopy AG, a company based in Tübingen, Germany.

firing across dense fibrinous tissue such as an ulcer.

Over the scope clip system (Ovesco Clip)

The Ovesco Clip (Ovesco Endoscopy AG, Tübingen, Germany) is an over-the-scope nitinol clip, widely known as a “bear claw” or “bear trap” for its characteristic appearance (*Figure 2*). Nitinol is a biocompatible metal alloy, with unique properties, particularly shape memory upon heating. The clip was FDA approved for use in the US in 2010. The system is composed of an applicator cap that the clip is mounted on, a thread and thread retriever, and a hand wheel that releases the clip. Once the target lesion is identified, it is suctioned into the cap. The thread is tightened with the hand wheel, which closes the clip system and helps anchor the tissue. Once it is determined that all the target tissue is pulled into the cap, the clip can be deployed. There are three types of clip tooth shapes—traumatic (used to close fistulas, perforations), atraumatic (used for controlling bleeding), gastrostomy closure, and caps of different depths that allow for grasping tissue during the approximation (3,4).

OverStitch Endoscopic Suturing System

The OverStitch Endoscopic Suturing System (Apollo Endosurgery, Austin, TX, USA) was initially developed in

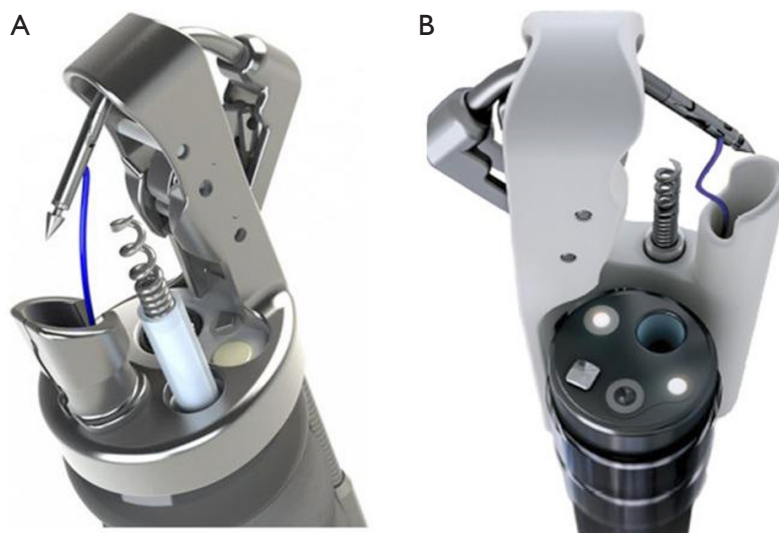


Figure 3 OverStitch device. Over the scope suturing device. (A) Original first-generation device for use with double lumen therapeutic endoscope. (B) OverStitch SX device, available for use with any diagnostic endoscope. Used with permission from Apollo Endosurgery, Inc.

2009, and FDA approved in 2010 (*Figure 3*). An updated version of the device was released in 2011, fitting only double channel Olympus therapeutic endoscope. In 2018 the new generation OverStitch SX was launched, featuring the ability to use the device with a single-channel endoscope, allowing compatibility with all four commercially available platforms (Olympus, Pentax, Fuji and Storz). While more expensive and more time consuming compared to through or over the scope clips, the OverStitch device provides classical surgical suturing, potentially offering better approximation of larger defects, or defects with irregular edges (5,6).

The components of the device include an end cap, that is mounted on the end of the scope, a needle driver handle, an anchor exchange catheter and a tissue retraction helix device that assists in approximating the tissue. The original OverStitch device is mounted on the distal end of a double-channel therapeutic endoscope, while the OverStitch SX works with a single-channel endoscopes, essentially transitioning the working channel to externally attached components (5).

The suture is mounted on the exchange catheter, and passed down through the operating channel, where it is transferred to the needle driver. The helix device is then anchored in and used to retract the target tissue back into the device. The needle driver handle is then closed, passing the anchor and suture through the grasped tissue. The anchor exchange catheter is advanced over the anchor,

and locked into place. The anchor exchange catheter is retracted, pulling the anchor exchange catheter away from the needle body, and then the tissue is released from the device by releasing the helix device. The needle driver handle is then released, leaving a full thickness suture placement. These steps can be repeated for further closure of defects with interrupted or continuous stitches. The suture is closed by releasing the anchor exchange catheter, which disengages the anchor from the device. The cinch catheter is then advanced, and tension pulled on the suture, closing the defect. Next, the cinch is deployed, and the suture locked in place and cut. The design of the device allows for multiple reloads without having to remove the endoscope (6) (*Video 1: 2:36, 4:10, 5:19*).

X-Tack

The X-Tack (Apollo Endosurgery, Austin, TX) is a newly developed through-the-scope suturing tool that allows for closure of tissue defects with nearly surgical suturing via the endoscope channel (*Figure 4*). The novel device uses helical coil tissue tacks that are pre-strung on a suture, and can be placed along the edge of the resected tissue, then cinched together to achieve tissue re-approximation. The main benefits of this device are that it allows for closure of defects in areas difficult to reach with larger devices, and it allows for immediate use without extraction of the endoscope for installation of the suturing device (7).

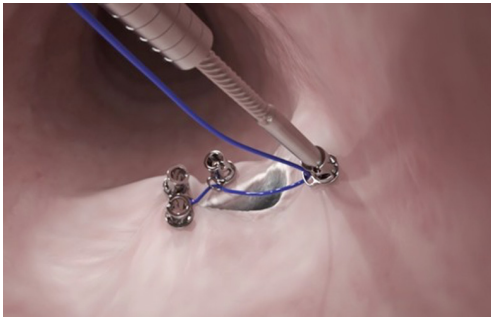


Figure 4 X-Tack System. Through the scope suturing device. Used with permission from Apollo Endosurgery, Inc.

Applications of the tissue approximation and suturing devices

Full thickness gastrointestinal defects

Full thickness gastrointestinal defects can be categorized as either acute or non-acute. Acute defects can occur iatrogenically, such as perforations during endoscopic procedures, spontaneously, in cases of malignancies, ulcers, or Boerhaave syndrome or traumatically, from foreign bodies, blunt and penetrating trauma (4). Non-acute defects can occur from leaks - due to anastomotic breakdown, infections or inflammation. Over time leaks can develop epithelialized tracts, resulting in fistulas. Leaks are a known and feared complication following esophagectomies, that can result in a prolonged hospital stay, require a return to the operating room and increase mortality (4,8). Management of these complications is complex, including the need for long-term antibiotics, nutrition optimization and further temporizing measures. Surgical resections are often challenging, due to infected and friable tissue from long-term inflammation. The high morbidity of these open repairs is the driving force behind the numerous endoscopic interventions that have been recently developed.

Management of acute defects

Endoscopic repair of acute full thickness defects has been well established in the literature. The use of over the scope clips was analyzed in a review study of 24 publications and 466 acute injuries initially managed by endoscopic closure (9). In 419 (90%) cases successful closure of the defect was achieved. A single adverse event was reported with an additional full thickness injury during the endoscopic intervention. This analysis has demonstrated

over-the-scope clipping as a safe alternative to surgery in patients with acute full thickness gastrointestinal tract defects. Previous studies have also demonstrated the efficacy of through the scope clipping in management of smaller perforations <10 mm, with a 100% success rate across several case reports (10-12) (*Video 1: 0:09*).

Management of non-acute defects

Endoscopic suturing techniques have allowed for further minimally invasive management of leaks and fistulas, providing surgical suture closure of the defects, mimicking that of the open procedures via endoscopic approach (13,14) (*Video 1: 1:22*). Chon *et al.* studied the management of upper gastrointestinal (UGI) leaks with endoscopic suturing with the OverStitch device (15). The authors reviewed 13 patients with postoperative leaks, five of whom had previous failed attempts at leak closure with endoscopic clipping, stenting or vacuum therapy. They demonstrated 100% success in leak management in patients who had not had prior attempts at leak management (61.5%). In patients who had previously undergone endoscopic treatments, the procedure was unsuccessful, requiring further intervention for correction of the leaks (38.5%) (15). Mukewar *et al.* reviewed 56 patients who underwent fistula closure with the OverStitch device, and presented initial technical success in 100% of cases, with 17 (30%) patients requiring delayed repeat endoscopic intervention. These repeat interventions included additional endoscopic suturing procedures and six patients required surgery (16). In another study of 97 patients with either fistulas or leaks, Morrell *et al.* achieved 66% successful closure at 6 months, with only 15% of patients requiring surgical intervention (13).

Stent anchoring

Covered self-expanding esophageal stents are used in the palliation of malignant strictures, and in the treatment of esophageal perforations, leaks and fistulas. A common complication of this procedure is stent migration, occurring in up to 40% of cases (17). Whereas placement of clips and snares has been reported for stent fixation, it is technically challenging and has a high rate of complications. Endoscopic suturing has emerged as the preferred method of stent fixation (*Video 1: 2:36*). Kantsevov *et al.* reviewed 7 patients in whom the OverStitch device was used for correcting migrated stents, or prophylactically during initial stent placement. In both groups there was no

stent migration after suture fixation (18). A comparison study in patients with locally advanced esophageal cancer demonstrated over three times lower migration rates in the group with suture fixation (8% vs. 27%) (19). Similarly, Ngamruengphong *et al.* in the analysis of 125 patients with benign UGI diseases, such as strictures, leaks, fistulas and perforations, showed decrease in the migration rate to 16% from 33% with the use of suture fixation (20). A meta-analysis by Law *et al.* identified 14 studies with 212 patients who had placement of self-expandable metal stents with endoscopic suture fixation. They described a 17% migration rate after placement of endoscopic sutures. Migration after placement was identified endoscopically and radiographically. In addition to the significantly lower rates of migration seen in the endoscopic suture fixation group, those patients had a longer time to stent migration resulting in better clinical outcomes, and overall required fewer procedures (21).

Endoscopic suturing in the management of gastroesophageal reflux disease (GERD)

Rising incidence of GERD propelled this problem into the forefront of the healthcare focus. Whereas medical therapy remains a gold standard for initial intervention, in patients who fail medical treatment, anti-reflux surgery is the next step. Increasing focus on minimally invasive approaches lead to the development of several endoscopic procedures for the management of GERD. There is little data available on the utility of the OverStitch device in the surgical management of GERD. However, several publications allude to the utility of endoscopic suturing in post-esophagectomy reflux. Reflux after radical esophagectomy, called gastric tube-esophageal reflux (GTER) is a well-known condition that significantly affects quality of life and leads to various complications (22). A small animal study demonstrated the feasibility of using the OverStitch device in a post-esophagectomy pig model to create an anti-reflux valve. The device was used to create a funnel using a posterior plication method in a series of four animals. Effectiveness of the funnel was evaluated using water soluble contrast to determine a reflux angle, which was higher after funnel creation in all cases, and a pH monitoring, which showed a stable pH compared to significant reflux seen before the procedure. The authors reported a median operating time of 43 minutes, and saw no post-operative adverse events (23). Nagase *et al.* replicated the procedure in a 69-year-old male esophageal cancer survivor who was 10 years from his initial

resection and suffering from severe GTER. They reported improvements in postoperative pH control, and the patient reported significant improvements in his quality of life (22).

Applications in peroral endoscopic myotomy

Achalasia is the most common esophageal motility disorder. The etiology is believed to be a neurodegenerative process of the vagus nerve and myenteric plexus, resulting in failure of lower esophageal sphincter relaxation and loss of esophageal peristalsis. High-resolution manometry (HRM) is a gold standard diagnostic test, allowing further subdivision of the condition into three subtypes (24-26).

Pneumatic balloon dilation and surgical cardiomyotomy are gold standard interventions for management of achalasia (27,28). In the last decade, perioral endoscopic myotomy (POEM) has emerged as a safe, minimally invasive technique used in the treatment of these patients. The procedure involves four distinct steps—mucosotomy, submucosal tunneling, myotomy proper and closure of the mucosotomy. Adequate closure of the mucosotomy at the conclusion of the procedure is crucial for preventing spilling of luminal content into the mediastinum. The mucosotomy at the entry site can be closed with endoscopic clips or the OverStitch device (6,29) (*Video 1*: 0:09, 4:10).

Pescarus *et al.* performed a case-controlled study looking at endoclips versus endoscopic suturing in mucosotomy closure during POEMs. The authors found that closure time was significantly shorter with clipping (16±12 vs. 33±11 minutes), and a higher overall cost was associated with suturing (1,502±849 vs. 2,521±575 USD). However, in a case of inadvertent full thickness defect during initial mucosotomy, successful closure was achieved with the OverStitch device. The authors highlight that while the OverStitch device was slower than clipping, it was very useful in cases where the defect was so large that closure with endoscopic clips would have been difficult secondary to the small jaw span of the clips (30). The authors of this article preferentially utilize OverStitch device for the purpose of mucosotomy closure after submucosal procedures due to the watertight nature of the closure. Clips usually utilized as a rescue technique in cases where due to difficult angles adequate exposure and application of suture is challenging or impossible.

Applications in bariatric procedures

Obesity is a serious public health concern affecting 39%

of the world's population, or nearly two billion people worldwide (31). In the US, obesity is the second leading cause of preventable death, and is a major risk factor for heart disease, stroke, diabetes, and several cancers. Whereas bariatric surgery has been shown to be an effective treatment for obesity, complications after bariatric surgery include leaks, perforations and fistulas, reaching 3–20% morbidity and 0.1–0.5% mortality rate (32).

Endoscopic therapies for bariatric weight loss have been shown to be safe and effective in treatment of obesity, as a bridge to surgical treatment, and are becoming a popular treatment choice for patients who do not qualify for bariatric surgery. Endoscopic sleeve gastrectomy (ESG) was developed in 2008 and is similar to a laparoscopic sleeve gastrectomy (LSG) in that it acts to create a restrictive pattern of weight loss (33). During the procedure, the OverStitch system is used to place full thickness stitches along the greater curvature of the stomach from the prepyloric antrum to the gastroesophageal junction, creating a restrictive, sleeve-like configuration (33).

Several studies have looked at the efficacy of the OverStitch in ESG. Neto *et al.* analyzed 233 patients, with a mean baseline body mass index (BMI) of 34.7 who underwent an ESG. Weight loss was 17.1% at 6 months, and 19.7% at 12 months, with only one bleeding complication (33). A study of 91 patients by Sharaiha *et al.* showed a 14.4% total body weight loss at 6 months, 17.6% at 12 months, and 20.9% at 24 months in a population with a mean pre-procedure BMI of 40.7 ± 7.0 kg/m². Significant reduction in hemoglobin A1c, systolic blood pressure, alanine aminotransferase and serum triglycerides were also seen, and complications included a perigastric leak that occurred in one patient (34). In the largest study to date, Alqahtani *et al.* reviewed 1,000 patients with a mean baseline BMI of $33.3 (\pm 4.5)$ kg/m² who underwent ESG and were followed for 18 months post-procedurally. Mean total weight loss was $13.7\% \pm 16.8\%$ at 6 months, $15\% \pm 7.7\%$ at 12 months, and $14.8\% \pm 8.5\%$ at 18 months. Complications included readmission in 24 (2.4%), severe abdominal pain in 8 (0.8%) and bleeding in 7 (0.7%) patients, with only 2 (0.2%) of them requiring blood transfusion. Five (0.5%) patients required re-do ESG and 8 (0.8%) patients were revised to a sleeve gastrectomy. As in other publications, significant improvement in hypertension, diabetes and dyslipidemia were seen (35).

Novikov *et al.* compared ESG, LSG and laparoscopic adjustable gastric banding (LAGB). The authors analyzed 278 patients with a mean baseline BMI of $43.82 (\pm 0.5)$ kg/m².

Of these, 91 patients underwent ESG, 120 LSG, and 67 had a LAGB. At 6 months weight loss in the LSG group was 23.48% *vs.* 14.37% in the ESG group and 12.68% in the LAGB group. Weight loss was similar at 12 months, with the greatest in the LSG, followed by ESG and LAGB (29.28% *vs.* 17.57% *vs.* 13.30%). When stratified by BMI <40 kg/m², and adjusting for age, gender and American Society of Anesthesiologists (ASA), there was no significant difference in percent total body weight lost at 12 months across all three different procedures. The complication rate in the LSG group was 9.17% and included peri-gastric leaks, wound dehiscence with herniation, postoperative ileus and wound infection requiring antibiotics. The ESG demonstrated lower overall complication rate at 2.20% and included a peri-gastric leak, while the rate in LAGB complications was 8.96% and included band removal due to obstruction, abdominal pain, and a wound infection (36).

Conclusions

Significant progress in the spectrum of diseases successfully managed with endoscopic interventions is predicated upon refinement of endoscopic technologies and instrumentation. More advanced procedures, like resection of the neoplasms, closure of fistulas and perforation, and even anatomical interventions, such as anti-reflux valves or gastrectomy are dependent on the advanced techniques of tissue approximation. Available through the scope or over the scope clipping and suturing instruments have facilitated astonishing growth in the field. Future developments and refinements of the technology are likely to result in many currently common surgical procedures becoming obsolete and being replaced by endoscopic interventions. Surgeons, especially foregut specialists, need to stay abreast of the developments to retain expertise and leadership roles in this rapidly evolving field.

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