

Douglas G. Adler MD, FACG, AGAF, FASGE, Series Editor

## Current Developments in Endoscopic Suturing



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Endoscopic suturing is an advanced endoscopic technique utilizing a minimally-invasive approach for the correction of gastrointestinal wall defects. Currently, the Overstitch™ endoscopic suturing system (Apollo Endosurgery Inc., Austin, Texas) is the only endoscopic suturing system approved in the United States by the FDA. Though its applications remain experimental, there is a burgeoning body of literature demonstrating a variety of therapeutic interventions utilizing endoscopic suturing. From closure of mucosal/submucosal defects, gastrointestinal perforations and fistulae, to closure of natural orifice transluminal endoscopic surgery (NOTES) sites and even applications in endoscopic bariatrics, a number of innovative techniques are being developed to make use of this technique. In this review, we provide an overview of the latest developments in endoscopic suturing, with specific focus on the Overstitch™ endoscopic suturing system.

### INTRODUCTION

Prior to the development of endoscopic suturing, surgical intervention was frequently utilized in the correction of transmural defects of the gastrointestinal tract. However, in recent years, advances in endoscopic technique and new technology have led to exciting improvements in the ability to close such defects endoscopically utilizing a minimally invasive approach. In addition to the closure of gastrointestinal fistulae and perforations, a wider proliferation of natural orifice transluminal endoscopic surgery (NOTES) has

renewed interest in the ability to endoscopically close defects.<sup>1</sup>

Endoscopic suturing is among such techniques under development. Currently, in the United States, there is only one FDA-approved endoscopic suturing system on the market, the Overstitch™ endoscopic suturing system (Apollo Endosurgery, Austin, Texas).<sup>1</sup> At present, the majority of techniques that have used this system remain at the experimental phase. However, numerous published case reports, case series and a small number of studies have described a variety of indications for which endoscopic suturing has been utilized.

In this review, we describe the technique for using the Overstitch™ endoscopic suturing system, as well as the applications of the Overstitch™ system.

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## TECHNIQUE

The Overstitch™ endoscopic suturing system is a disposable, single-use device designed to mount onto a double-channel endoscope, the Olympus GIF-2T160 or GIF-2T180 (Olympus America, Center Valley, Pennsylvania),<sup>2</sup> allowing for the creation of either interrupted or running sutures. It was initially approved by the FDA in 2008, with an additional revision of the device in 2011.<sup>1</sup>

The current device is much simplified in comparison to its earlier predecessor. It consists of an end cap which mounts over the scope tip, with a hooked suture arm which is controlled via a hand lever attached near the hand controls of the endoscope (Figure 1).<sup>3</sup> Suture material is passed from a cassette at the operator end of the endoscope through one of the operating channels, to a tissue anchor at the distal tip of the endoscope. Either absorbable (2-0 and 3-0 polydioxanone) or non-absorbable (2-0 and 3-0 polypropylene) suture material is available.<sup>3</sup> In use, the tissue anchor is driven into the target tissue via the hooking motion of the suture arm. Repeated motion of the arm then allows for running sutures if desired. Once complete, a cinching device is used to secure the sutures. These techniques are illustrated in Figure 2.

To facilitate placement of full-thickness sutures, a helix device included in the kit may be passed through the second channel of the endoscope to screw into the target tissue. Retraction of the device then brings the target tissue into the path of the suturing arm, allowing for full-thickness suturing.<sup>2,3</sup>

## APPLICATIONS

### Closure of Defects

There has been a great deal of interest in developing endoscopic techniques by which transmural defects can be closed. Endoscopic suturing shows great promise in the ability to accomplish this, though these techniques have only been applied in a small number of case reports, case series and animal models.

There are a variety of clinical scenarios in which the Overstitch™ system has been used to close defects. The Overstitch™ system has been applied to help close chronic gastrocutaneous fistulae following removal of percutaneous endoscopic gastrostomy (PEG) tubes.<sup>4,5</sup> This technique was used successfully following failure of prior attempts at closure by other means, such as endoclips, glue, and over-the-scope clips. Similarly,



**Figure 1.** The OverStitch™ endoscopic suturing system mounted on an endoscope  
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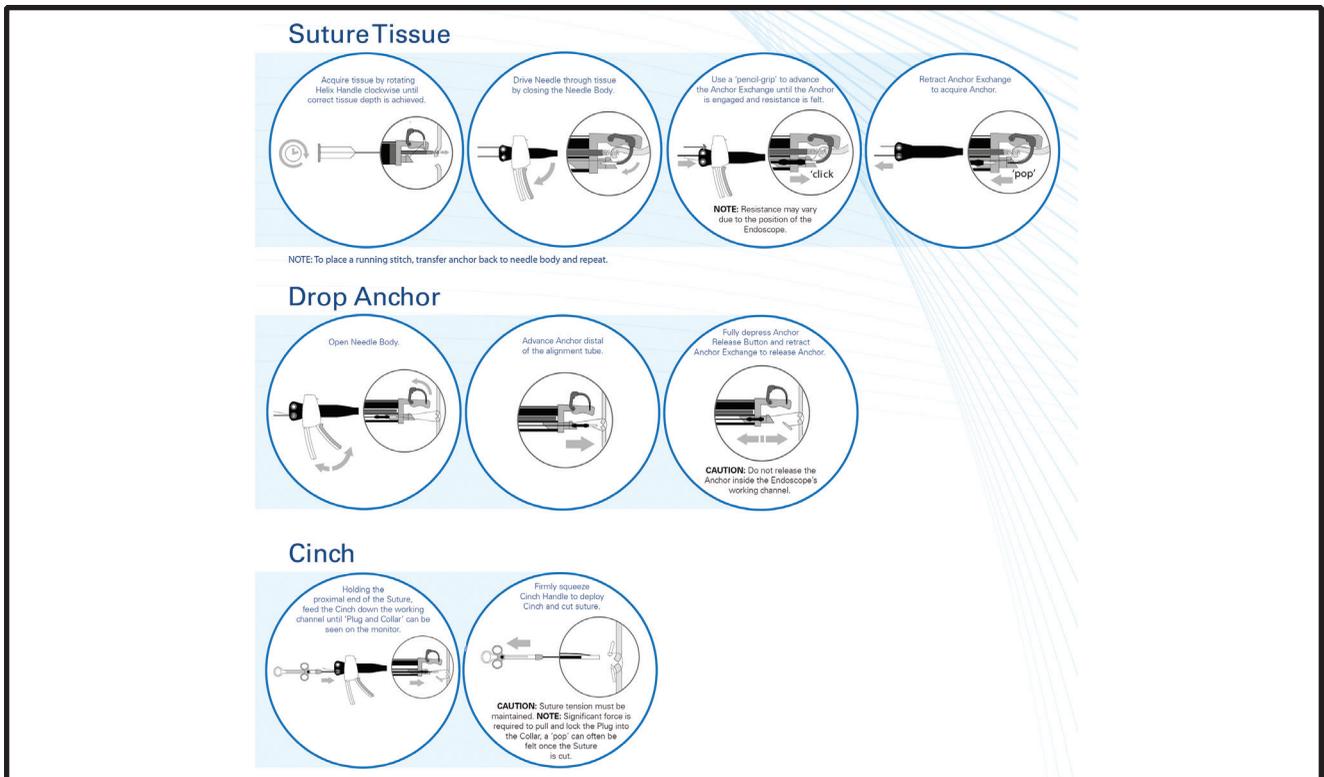
another case report demonstrated successful reduction of an enlarged PEG stoma using the Overstitch™ device.<sup>6</sup>

This Overstitch system has also been used to close a chronic esophago-pleural fistula that developed after a Boerhave syndrome.<sup>7</sup> In this case, the fistula was refractory to prior therapy attempts using endoclips and esophageal stent placement. A follow-up esophagram 4 weeks after the initial suturing demonstrated a persistent small defect, which was effectively closed with repeat endoscopic suturing, argon plasma coagulation and fibrin glue.

Over the years, increasing interest in endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), natural orifice transluminal endoscopic surgery (NOTES), and peroral endoscopic myotomy (POEM) has led to the use of endoscopic suturing in the closure of partial and full thickness defects created during such procedures.

Kantsevov et al.<sup>8</sup> described a series of twelve consecutive patients who underwent ESD with subsequent closure using the Overstitch™ device. The mean size of the defects closed was  $42.5 \pm 14.8$  mm, and there were no immediate or delayed adverse events.

Endoscopic suturing in NOTES procedures remains limited at present to animal models. Chiu et al.<sup>9</sup> performed full-thickness gastric resections on a porcine model followed by effective and complete closure using the Overstitch™ device.



**Figure 2.** Technique of endoscopic suturing with the Overstitch™ device Copyright Apollo Endosurgery, Inc., used with permission

Several reports have also described successful closure of defects, intentional or otherwise, created during the course of performing POEM.<sup>10-12</sup> Interestingly, a retrospective analysis comparing endoscopic suturing to clips in post-POEM closure found no significant difference in cost or length of closure time, length of stay, or complications.<sup>3</sup>

### Stent Fixation

Fully covered self-expanding metal stents are often used to either relieve obstructive lesions within the gastrointestinal lumen, such as strictures or mass lesions, or to bridge over defects, such as perforations or fistulae. While the silicon covering of gastrointestinal luminal stents prevents leakage of luminal material from the sides of the stent and allows for easy stent removal in the future if necessary; the covered feature can also predispose these stents to migration. Previous attempts to anchor these stents in place using clips have shown inconsistent results.

At present, there have been only a few small studies that have examined the technique of using endoscopic suturing to anchor gastrointestinal luminal stents. Rieder et al.<sup>13</sup> found within a porcine model that there was a significant increase in the force needed to displace

a stent secured with sutures (n=12; mean force 20.4 N; 95% confidence interval [CI]: 15.4-25.4; P<0.01) versus clips (n=8; mean 6.1 N; 95%CI 4.7-7.6). A subsequent proof-of-concept study in five patients demonstrated initial successful stent fixation to the esophageal wall by suturing, although there was one instance of stent migration attributed to a superficially placed suture.<sup>13</sup> Fujii et al.<sup>14</sup> reported a case series of eighteen patients who underwent esophageal stent fixation to the gastrointestinal luminal wall for a multitude of indications including esophageal perforations/fistulas/strictures, gastric fistulas and enteric fistulas. Complete clinical success was achieved in 56% of patients. However, the authors reported a stent migration rate of 33% even with suturing of the stent. More recently, Sharaiha et al.<sup>15</sup> compared stent migration in patients who had placement of esophageal stents with and without endoscopic suture anchoring to the wall. They demonstrated that there was only an 11% stent migration in patients with suturing, compared to a 55% stent migration in the control group without sutures. A large multicenter retrospective analysis by Sharaiha et al.<sup>16</sup> demonstrated even better rates of clinical success, 91.4% at 68 day follow up.

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Overall, the currently available data seem to suggest improved stent migration rates when endoscopic suturing is used, with little adverse events directly attributable to the suturing technique.

### **Endoscopic Bariatric Therapy**

There has been a great deal of interest recently in incorporating endoscopic suturing techniques into the fast-growing field of endoscopic bariatric therapy. Currently, these exploratory studies largely fall into one of three categories: endoscopic sleeve gastropasty, repair of defects created during bariatric surgery, and post-bariatric surgery revision.

Endoscopic sleeve gastropasty is an innovative application of endoscopic suturing involving the placement of sutures along the gastric wall to achieve gastric volume reduction in order to approximate the effect of a surgical sleeve gastrectomy. Abu Dayyeh et al.<sup>17</sup> described this technique in a pilot feasibility study of 4 patients, which involved the placement of full-thickness, interrupted sutures using the Overstitch™ system to bring together the anterior wall and posterior wall of the stomach and therefore form a sleeve reminiscent of that created during a surgical sleeve gastrectomy. This technique has the advantage of being incisionless, minimally invasive, and potentially providing an alternative option for patients who would not make ideal surgical candidates or for whom surgical bariatric surgery would be overtreatment.<sup>3</sup>

A 2008 study by Fogel et al.<sup>18</sup> using an older version of the suturing system (Endocinch™) reported an impressive 58% excess weight loss at 12 month follow up after endoscopic sleeve gastropasty. However, subsequent studies have been unable to replicate such dramatic weight loss. More recently, utilizing the RESTORE suturing system, the latest iteration of the Endocinch device, Brethauer et al.<sup>19</sup> reported a mean excess weight loss of 27.7% at 12 month follow up.

Two small studies have further evaluated the use of endoscopic sleeve gastropasty using the Overstitch™ device for weight reduction. In a study of 20 patients, Lopez-Nava et al.<sup>20</sup> reported a mean weight loss of 19.3 kg (17.8% of initial weight) at 6 months after the procedure. Similarly, Sharaiha et al.<sup>21</sup> reported a mean weight loss of 33.0 kg at 6 months (30% of initial weight) in a study of 10 patients.

The results of these studies seem to indicate that endoscopic sleeve gastropasty could potentially be

a viable therapeutic option for specific subsets of the bariatric population, demonstrating modest weight reduction with minimal adverse effects. However, long-term data for sustained weight loss is unavailable, and at least one study<sup>19</sup> using the RESTORE device seemed to demonstrate at least partial release of some of these sutures at 12 month follow up.

Endoscopic suturing has also been used in cases of post-bariatric therapy complications, such as marginal ulcerations, fistulae, and leaks. Jirapinyo et al.<sup>22</sup> have described the use of endoscopic suturing in 3 patients who had developed marginal ulcerations after Roux-en-Y gastric bypass (RYGB) surgery that was refractory to medical therapy. In all three cases, endoscopic suturing was used successfully to close up the ulcer bed, leading to durable healing of the ulcer.

Finally, endoscopic suturing has been used for post-bariatric revision to tighten up dilated gastrojejunal stoma. It has been reported that increased stoma diameter is associated with weight gain following RYGB.<sup>23</sup> Options for patients under these circumstances usually involved surgical revision.<sup>3</sup> However, endoscopic suturing has the potential of being able to fix such enlarged stoma with less morbidity than surgery but still with efficacious outcomes.

Thus far, two studies have examined the effects of stoma reduction using endoscopic suturing, often referred to as transoral outlet reduction (TORe). Jirapinyo et al.<sup>24</sup> performed TORe on a total of 25 patients with weight gain after RYGB and dilated gastrojejunal stoma. There was a 100% technical success rate, with a mean 77.3% reduction in stoma diameter from an average of 26.4 mm prior to the endoscopic procedure to an average of 6 mm (range 3-10 mm) after the procedure. The mean weight loss at 3, 6, and 12 month follow up was 11.5 kg, 11.7 kg, and 10.8 kg, respectively.

A multicenter, randomized study by Thompson et al.<sup>25</sup> produced similarly positive findings. In this study, patients with weight gain or inadequate weight loss after RYGB and stoma larger than 2 cm were randomized to either a TORe intervention group or a sham procedure group. Compared to the control group, those that underwent TORe had significantly greater mean percentage weight loss (3.5% in the intervention group vs. 0.4% in the control group,  $P=0.021$ ).

Further studies are still needed to refine this technique of stomal revision. For example, a recent study<sup>26</sup> demonstrated even greater weight loss when

full-thickness sutures were used for stoma reduction compared to superficial sutures, despite achieving similar stoma size reductions. Likewise, the ideal degree of stoma reduction still needs to be determined. Thompson et al.<sup>27</sup> found an inverse relationship between the stoma size and weight loss.

## CONCLUSION

Endoscopic suturing is an emerging technique in the field of therapeutic endoscopy that is rapidly broadening its potential indications for use. In this review, we summarize the variety of indications for which endoscopic suturing has been used, as described under current literature. Endoscopic suturing has been used to close a variety of transmural defects, as well as to anchor covered metallic endoluminal stents to the gastrointestinal wall and hence prevent their migration. There is also an expanding role for endoscopic suturing in bariatric therapy, including revision of dilated gastrojejunal stomas, fixing marginal ulcerations and other defects, and in primary use as endoscopic sleeve gastropasty. While the currently available body of literature is small, there is active interest in exploring new areas of development for this technique, as well as further refining existing protocols. The coming years are sure to see even more advances in this burgeoning field. ■

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