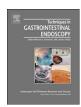
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# Endoscopic suturing for closure of transmural defects



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### ABSTRACT

For many years reliable endoscopic closure of transmural defects of the gastrointestinal (GI) tract has remained a challenging task. These defects can be caused by unintentional complications of diagnostic and therapeutic endoscopy (perforation) or they can be a result of full-thickness resection of GI tract lesions. Perforation during flexible endoscopy still remains the most worrisome complication, which usually requires urgent surgical (or laparoscopic) intervention for closure of the perforation or resection of affected segment of GI tract. Over the last 20 years various instruments and accessories have been used for closure of transmural GI tract defects. Although closure of the accidental small defects could be achieved with through-the-scope hemostatic clips, these devices are not suitable for tissue opposition of defects with large diastasis between the tissue edges. To eliminate shortcomings of clips closure, various types of endoscopic suturing device (suction based, working overtubes with preloaded stitches, T-bars, over-the-scope clips, etc.) have been tried for closure of transmural defects. However, these devices have numerous inherent problems and many are no longer commercially available. The most recent version of Overstitch endoscopic suturing device in the United States is versatile, user-friendly and allows reliable, full-thickness, "surgical quality" airtight closure of transmural GI tract defects. Overstitch endoscopic suturing device is an important tool for closure of transmural GI tract defects and should be considered in endoscopy centers performing high-risk, advanced diagnostic and therapeutic endoscopic procedures.

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For many years, reliable endoscopic closure of transmural defects of the gastrointestinal (GI) tract has remained a challenging task. These defects can be caused by unintentional complications of diagnostic and therapeutic endoscopy (perforation) or they can be a result of full-thickness resection of GI tract lesions. Perforation during flexible endoscopy still remains the most worrisome complication, which usually requires urgent surgical (or laparoscopic) intervention for closure of the perforation or resection of affected segment of GI tract. Over the last 20 years, various instruments and accessories have been used for closure of transmural GI tract defects.

For closure of the small defects, through-the-scope endoscopic clips have been previously used [1]. These clips are advanced through the biopsy channel of flexible endoscope and several

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types of endoscopic clips are currently commercially available (QuickClip2 and QuickClip Pro [Olympus Optical Ltd, Tokyo, Japan], Resolution [Boston Scientific, Natick, MA) and Instinct [Cook Medical, Bloomington, IN]). The latest generation of endoscopic clips (Resolution, Instinct, and QuickClip Pro) can be opened and closed several times until adequate position of the clip is achieved. However, the through-the-scope endoscopic clips have common weakness: these accessories were created for endoscopic hemostasis and not for tissue approximation. Attempts to close defects with large diastasis between the edges or efforts to grab and approximate large bulk of tissue are usually unsuccessful due to buckling of the clip's prongs or tearing the tissue.

To correct this intrinsic limitation of endoscopic clips, a combination of clips and endoscopic loop (PolyLoop, Olympus Optical Ltd, Tokyo, Japan) has been suggested [2,3]. Use of PolyLoop-clips techniques requires a double-channel endoscope. Through a channel of the endoscope a loop is advanced and positioned around the edges of the full-thickness defect [2,3]. Later, through the second channel of the endoscope, endoscopic clips are applied to attach the loop to the edges of full-thickness defect. The loop is then tightened to approximate mucosal edges. After tightening of the first PolyLoop a second application of

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PolyLoop-clips sequence could be needed (if the resulting defect is still large) or, in case of a small diastasis, several additional clips can be applied to achieve complete closure of the full-thickness defect.

Although several case reports demonstrated successful closure of transmural defects with PolyLoop-clips combination, this technique accomplishes only an approximation of mucosal edges and does not reliably achieve "surgical suturing quality" full-thickness closure of GI tract defects.

To eliminate the use of a double-channel endoscope, Yahagi et al have recently reported use of clips and slip knot combination, which allows closure similar to those by PolyLoop-clips combination through a single-channel endoscope [4]. However, this technique was used for closure of mucosal defects after endoscopic submucosal dissection only in animals and it is unclear whether it works in case of full-thickness GI tract defects in humans.

Over-the-scope clips have been developed for full-thickness closure of GI tract defects (OTSC [Ovesco Endoscopy, Tübingen, Germany] and Padlock Clip [Aponos, Kingston, NH]). The distal end of the flexible endoscope is preloaded with the over-the-scope clip and then advanced into GI tract. Both edges of the GI tract wall defect are pulled into the clip and then the clip is deployed to close the defect [18-20]. They are robust devices allowing even a full-thickness closure [21]. However, the size of the closing defect is limited by the space inside the over-the-scope clip. In addition, these clips are very difficult to remove in case of suboptimal placement and cannot be repositioned after initial deployment [6].

Several devices for endoscopic suturing have been developed over the last 20 years [5,6]. The following sections discuss the various classes of suturing devices.

## 1. Suction-based endoscopic suturing devices

A variety of endoscopic suturing devices are based on suctioning tissue into a suction chamber through which a needle with suture was passed (EndoCinch [Bard, Murray Hill, NJ], LSI Solution [Victor, NY], and Spiderman [Ethicon Endo Surgery, Cincinnati, OH]) [7]. After placing the needle through both tissue edges the suture was completed with extracorporeal knot tying or

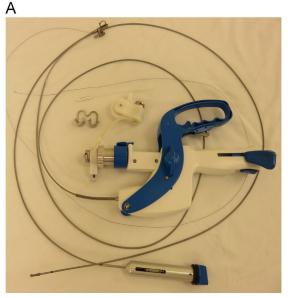
intracorporeal cinching. The devices required removal from GI tract for reloading of a new needle. The major limitation with the suction-based suturing devices was unpredictable depth of the suture delivery [8]. In addition most sutures were located only in the mucosal and submucosal layers and could not provide adequate tissue approximation.

## 2. Overtube-based endoscopic suturing devices

Another class of endoscopic suturing devices uses an overtube with preloaded stitches (NDO plicator [NDO Surgical, Mansfield, MA] and EsophyX [EndoGastric Solutions, Redmond, WA]) [7,9]. The overtube has an internal lumen for a small-diameter endoscope, which is used only for observation and to guide the suture placement. These devices were specifically designed for endoscopic treatment of gastroesophageal reflux disease. However, currently only the EsophyX system is still commercially available for clinical use [9].

#### 3. Tissue anchor devices

Various tissue-anchoring devices have been developed for closure of GI tract defects (TAS system [Ethicon Endo Surgery, Cincinnati, OH], T-bars [Cook Endoscopy, Winston-Salem, NC], and T-bars [Olympus Optical LTD, Tokyo, Japan]). These devices use hollow needles deploying T-bars into the opposite edges of an incision [10-12]. The T-bars are then pulled together and intracorporeally cinched with a specially designed locking mechanism. The inherent problem of these suturing devices was the blind puncture of the GI tract wall, which could potentially cause damage to adjacent intraperitoneal organs and blood vessels [13]. In addition, closure of full-thickness defects with T-bars inverts the edges, does not achieve layer-to-layer opposition, and results in histologically inferior tissue healing [12]. Only one of these devices (TAS system) received Food and Drug Administration clearance for clinical use in USA. Despite successful use of the TAS system for closure of transmural GI tract defects in animal experiments and a few human cases, the TAS system is no longer commercially available for clinical use in humans.



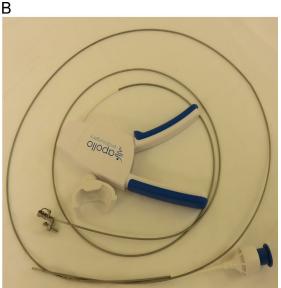


Fig. 1. Overstitch endoscopic suturing device. (A) First generation of the Overstitch endoscopic suturing device. (B) Second (current) generation of the Overstitch endoscopic suturing device. (Color version of figure is available online.)

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