Step-by-step instruction: using an endoscopic tack and suture device for gastrointestinal defect closure

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BACKGROUND AND AIMS

Closure of mucosal and full-thickness defects in flexible endoscopy has become a major concern in interventional endoscopy.[1] Multiple closure devices and techniques have been developed in the past years.[2-6] However, the closure of large (>30 mm) tissue defects remains challenging, and over-the-scope clips and endoscopic suturing require removal of the endoscope for preparation of the device, which is not optimal, particularly for right-sided colon lesions.

The X-Tack Endoscopic HeliX Tacking System (Apollo Endosurgery, Inc, Austin, Tex, USA) is a new through-the-scope suture-based device specifically designed for closure and healing of large and irregularly shaped GI tract tissue defects. The device has recently been approved by the Food and Drug Administration for the approximation of soft tissue in minimally invasive endoscopic procedures (eg, closure of endoscopic submucosal dissection or mucosal resection sites, fistulas, perforations, or leaks). The device is not approved for acutely bleeding ulcers. Alternative, not-yet-studied uses may include tissue traction for resection procedures and tissue marking.

This novel endoscopic tool is a suture-based device consisting of four 5-mm surgical steel helix tacks strung on a 3-0 polypropylene suture. It is available in 2 different lengths to accommodate either a gastroscope or a colonoscope and is deployed entirely through the working channel (2.8 mm or larger) without endoscope withdrawal from the patient. The suture runs through an eyelet on all 4 tacks, and each tack is advanced 1-by-1 along the suture string and deployed into the target tissue. After placing all of the tacks into healthy tissue adjacent to a defect and tightening the suture, a suture cinch analogous to the previously available OverStitch cinch, but made longer to accommodate the colonoscope, is used to secure the construct.

In a survival preclinical study leading to the approval of the device for clinical use, no adverse events related to the novel suturing device were encountered. Potential adverse events could include delayed perforation or bleeding if the system is not properly placed. In addition, use of the device should be avoided in patients with allergic reactions to surgical steel or polypropylene.

The aim of this video (Video 1, available online at www.giejournal.org) is to demonstrate the use of this novel endoscopic device.

ASSEMBLY, SET UP, AND USE OF THE NOVEL ENDOSCOPIC HELIX TACKING SYSTEM

The different components of the device are shown in Figure 1 and include:

1. A push catheter used to thread the tacks and suture. The catheter comes with the first tack preloaded.
2. A channel liner that covers the push catheter.
3. A handle drive at the end of the push catheter that functions in a Persian-drill style to drill the tacks into the tissue. A blue button with a sliding function allows deployment of the tack from the push catheter into target tissue.
4. A mounting platform to be attached to the endoscope that is used to house the loading card.
5. A loading card that contains the additional 3 tacks.
6. A suture cinch, sold separately, that is used to secure the suture and tacks construct to yield durable closure of the resection site.

STEP-BY-STEP ASSEMBLY AND USE OF THE X-TACK DEVICE

1. Firmly attach the mounting platform to the endoscope's handle.
2. After lifting of the cap of the biopsy port cover, the push catheter and channel liner with the first tack preloaded are fed through a 2.8-mm or larger working channel until they exit the distal end of the endoscope and the proximal funnel-shaped end of the channel liner contacts the biopsy port cover.
3. Next, the loading card containing the 3 additional tacks is secured on the mounting platform.
4. The push catheter is released by removing the red rubber tab at the proximal end of the channel liner.
5. The first tack is advanced firmly into healthy tissue 5 to 10 mm from the edge of a mucosal defect, drilled into the target tissue by activating the Persian-drill style handle drive, and deployed from the push catheter by

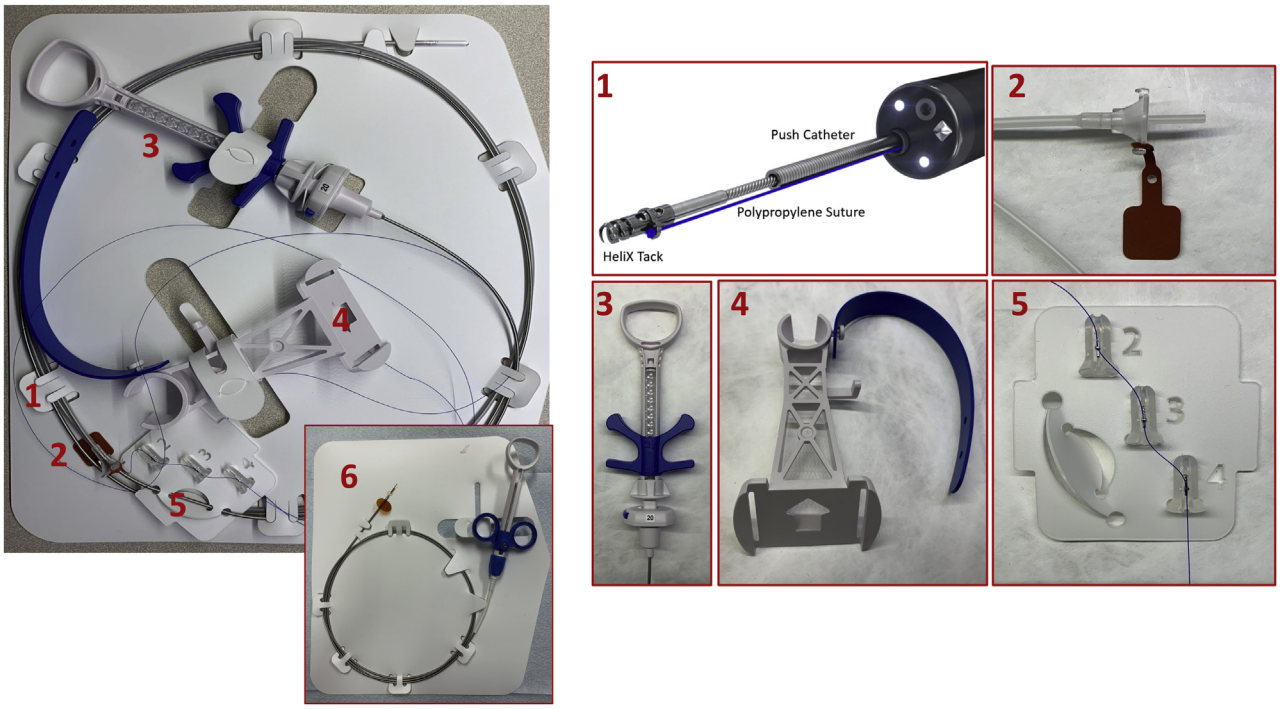

Figure 1. Endoscopic HeliX Tacking System: device components. 1, Push catheter, tacks, and suture. 2, Channel liner and red rubber tab at the proximal end of the push catheter. 3, Handle drive. 4, Mounting platform. 5, Loading card containing the tacks. 6, Suture cinch.

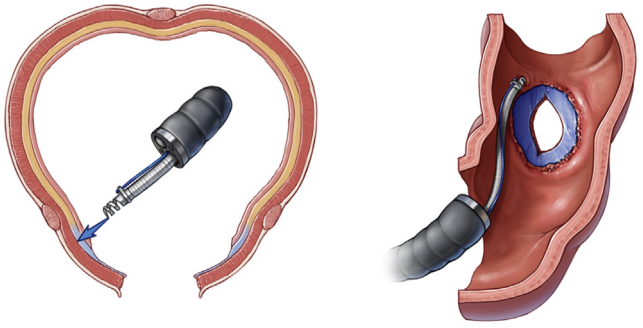

Figure 2. Precise placement of the first tack, which is drilled into the healthy tissue adjacent to the GI tract defect.

pushing the blue button and sliding it away from the handle (Fig. 2). If the tack is inadequately placed before deployment from the push catheter, the drill function of the catheter's handle drive can be reversed, removing the tack from the tissue. After the first tack is placed, the push catheter is removed from the endoscope alongside the suture and is then reloaded with the subsequent tack from the loading card. This tack is then deployed in a similar manner (Fig. 3).

6. After deployment of the second tack, tension is placed on the suture to remove slack between the tacks before deployment of the tack from the push catheter. A third and fourth tack are then deployed using the same technique, taking care to place tension on the suture before releasing it from the push catheter. If a tack is released prematurely, it can be left on the suture and the next tack loaded on the catheter to continue with the intended suture sequence. If needed, an additional device construct may be used to achieve the necessary closure. Potential suture patterns include a running (zig-zag) pattern, a figure 8 or "X" pattern, and a purse-string (Fig. 4), although the ideal pattern has not been studied.

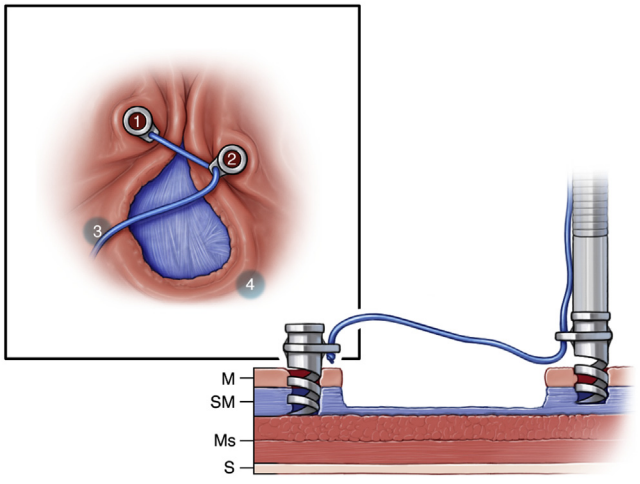

Figure 3. Sequential deployment of tacks around the lesion. *M*, Mucosa; *SM*, submucosa; *Ms*, muscularis mucosa; *S*, serosa.

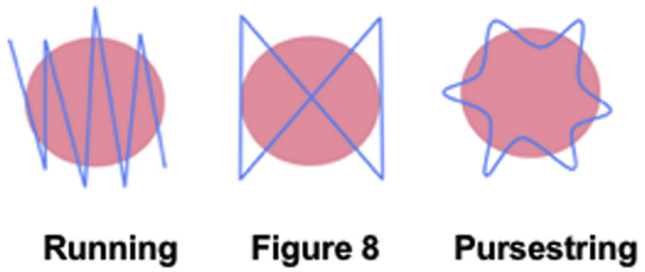

Figure 4. Potential suture patterns.

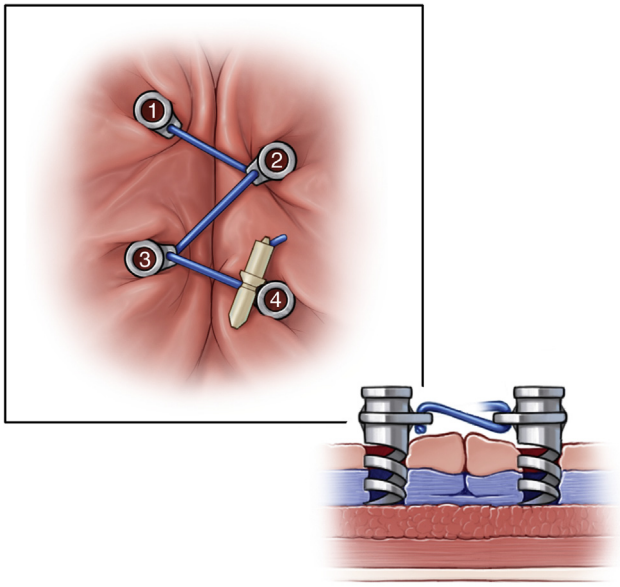

Figure 5. Closure of the defect after cinching the tack and suture construct.

7. After all tacks have been placed, final tension is applied to the suture, and the push catheter and channel liner are removed from the endoscope to prepare the suture cinch that will maintain tension on the tissue tacks and suture (Fig. 5).
8. The distal end of the suture is threaded through the loading loop of the cinch, and the cinch is advanced over the suture. It is important that only moderate tension be carefully applied to the suture to avoid breaking it. Once the desired final tension is reached, the cinch handle is opened to release the safety mechanism. To deploy the cinch, the handle is squeezed with 1 hand followed by continuous squeezing of the handle with 2 hands until the suture cutter is activated to release the cinch. Finally, both the cinch and suture tail are removed from the endoscope.

CONCLUSIONS

In conclusion, the X-Tack is a device newly approved by the Food and Drug Administration for closure of GI mucosal and full-thickness wall defects. It is placed entirely through a standard diagnostic endoscope or colonoscope working channel without removing the endoscope from the patient. This device may be particularly helpful for the closure of larger defects or perforations, particularly in the proximal colon where access by other endoscopic closure devices can be challenging. Clinical use validation and cost-benefit studies are anticipated.

DISCLOSURE

Dr Rajan discloses intellectual property with Medtronic. Dr Storm is a consultant for GI Dynamics, ERBE, Enterasense, and Apollo Endosurgery and receives research support from Enterasense, Boston Scientific, and Apollo Endosurgery. All other authors disclosed no financial relationships.

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