



Follow-up outcomes of mucosal defect closures after endoscopic resection using a helix tacking system and endoclips

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Background and Aims: The X-Tack endoscopic HeliX tacking system (Apollo Endosurgery, Austin, Tex, USA) has recently been approved by the Food and Drug Administration and is slowly gaining popularity for the closure of large tissue defects. Despite its increasing use, outcome data of using the X-Tack system for mucosal defect closure after endoscopic resection (ER) are limited. Here, we report the follow-up outcomes of a series of cases that underwent ER and mucosal closure aided by the HeliX tacking system.

Methods: We identified a total of 5 cases in which the X-Tack system and endoclips were used for mucosal defect closure after ER. The cases involved ER of large and/or flat polyps in the duodenum and colon. The patients were followed up at 4, 6, and 9 months after ER.

Results: In all cases, X-Tacks with endoclips achieved complete closure of the large mucosal defects. None of the patients experienced any adverse events, such as abdominal pain or bleeding. At follow-up, the X-Tacks either fell off or were seen grouped or situated as a single piece (tack) in the mucosa where initially placed. None of the endoclips were found during the follow-up endoscopic examinations.

Conclusions: The X-Tack system together with endoclips facilitated complete closure of large mucosal defects, especially for lesions located in difficult locations. At follow-up, several retained X-Tacks were found either in groups or as a single piece. The X-Tacks seen in groups will likely fall off with repetitive pulling forces with food or feces. However, the single tacks that were secured in the wall may stay indefinitely. The novel HeliX tacking system seems to be a promising aid for the effective closure of large mucosal defects; however, further studies are needed to assess the long-term outcome of this novel system. (VideoGIE 2022;7:268-72.)

The X-Tack Endoscopic HeliX Tacking System (Apollo Endosurgery, Austin, Tex, USA) is a new through-the-scope (TTS), suture-based device, specifically designed for approximation of the edges of large and irregular shaped defects in minimally invasive endoscopic procedures (eg, closure of EMR, endoscopic submucosal dissection [ESD], and the closing of fistulas, perforations, or leaks). This innovative endoscopic tool consists of four 5-mm surgical steel helix tacks strung on a 3-0 polypropylene suture.¹ To achieve appropriate tissue apposition, the suture-tethered X-Tacks are independently placed into the healthy tissue adjacent to a tissue defect and then cinched to secure the suture in place. One of the advantages of using X-Tack is its ability to approximate large defects when TTS clips are inadequate, eliminating the need for scope withdrawal for the use of another device. X-Tack is conditionally magnetic resonance imaging safe.

In a porcine model, the X-Tack system was shown to be effective in tissue closure of 2- to 5-cm mucosal defects, even in some areas when TTS clips failed.² Recently, a few case reports have successfully demonstrated the usefulness of X-Tack in accomplishing large mucosal

defect closure.^{3,4} However, the durability and follow-up outcome after using the X-Tack system are not well known. Therefore, we aimed to report follow-up outcomes of a series of patients who underwent endoscopic resection (ER) and closure of the mucosal defect aided by the X-Tack system. In all cases, additional endoclips were used to achieve a high-quality closure (no exposed submucosal tissue) of mucosal defects. Institutional review board approval was obtained for this study.

CASE 1

A 74-year-old man was referred for ER of a 30-mm sessile polyp in the third portion of the duodenum occupying one-half circumference of the duodenal lumen (Fig. 1). The polyp was removed by EMR in a piecemeal fashion aided by the avulsion technique. At the end of the procedure, 2 sets of X-Tacks followed by 4 endoclips were successfully placed to achieve defect closure. The stepwise application of the X-Tack device is demonstrated in Video 1 (available online at

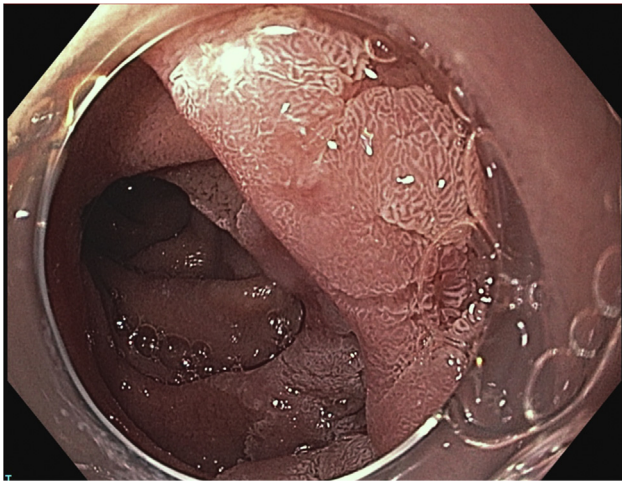


Figure 1. A 30-mm sessile polyp in the third portion of the duodenum occupying one-half of the circumference of the duodenal lumen.

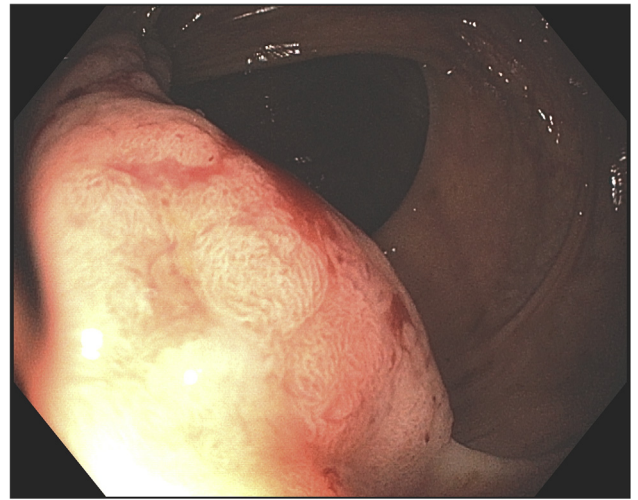


Figure 3. A 45-mm sessile polyp in the proximal ascending colon on the fold distal to the ileocecal valve.

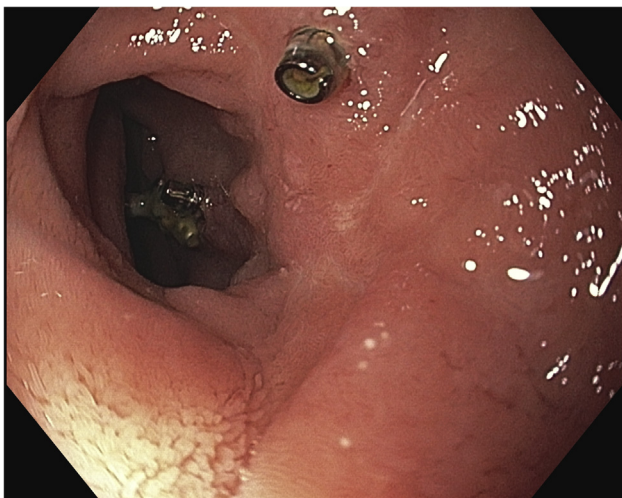


Figure 2. Follow-up endoscopy performed at 4 months showed a residual set of X-Tacks near the postpolypectomy scar, and 2 single tacks were found buried in the duodenal mucosa.



Figure 4. No residual X-Tack was found at the scar site at 4-month follow-up.

www.giejournal.org). Follow-up endoscopy performed after 4 months showed 1 set of residual X-Tacks near the postpolypectomy scar. Two single tacks were found separately situated within the duodenal mucosa (Fig. 2). An attempt to remove the single tack by grasping with a rat tooth forceps met significant resistance; thus, it was left in situ. The scar otherwise appeared healthy with no evidence of residual polyp or recurrence.

CASE 2

A 70-year-old man underwent ESD of a 45-mm sessile polyp in the proximal ascending colon on the fold distal to the ileocecal valve (Fig. 3). The polyp was successfully removed in en bloc fashion, and defect closure was

achieved by using 1 set of X-Tack and 9 endoclips. Follow-up colonoscopy after 4 months showed a healthy-appearing scar with no residual clips or X-Tacks near the scar site (Fig. 4).

CASE 3

A 53-year-old woman underwent a rectal ESD of a 15-mm flat polyp surrounded by scars from a previous polypectomy attempt with a previously placed tattoo proximally and distally (Fig. 5). Two sets of X-Tacks and 3 endoclips were placed at the end of the resection, resulting in complete closure of the mucosal defect. Colonoscopy performed after 6 months showed a clean-based scar with no evidence of residual tissue or

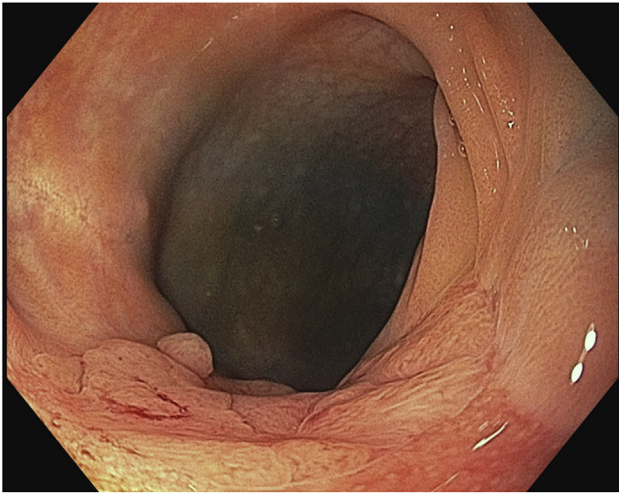


Figure 5. A 15-mm flat polyp surrounded by scars from a previous polypectomy attempt with a previously placed tattoo proximally and distally.

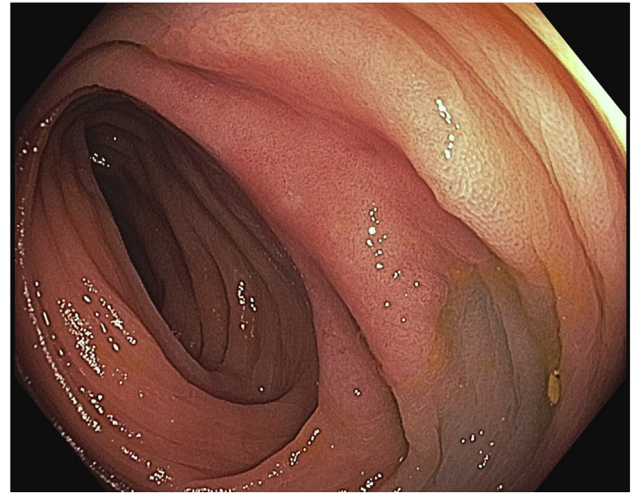


Figure 7. A 30-mm nongranular lateral spreading lesion at the hepatic flexure.



Figure 6. Follow-up after 6 months showed residual X-Tacks situated at the periphery of the scar, and no hemostatic clips were seen.

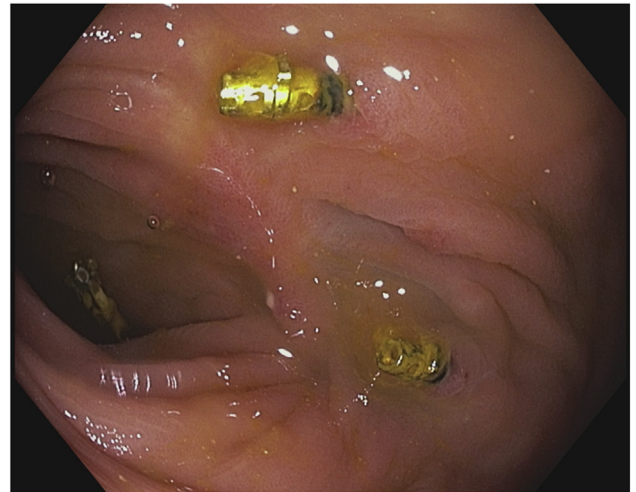


Figure 8. At 6-month follow-up, 1 set of the X-Tacks were seen in a group and 2 single tacks were found deeply situated in the mucosa adjacent to the scar.

recurrence. Two sets of residual X-Tacks were seen situated at the periphery of the scar, but no endoclips were seen. We found the X-Tacks to be grouped (Fig. 6), and attempts to remove them with a standard biopsy forceps were unsuccessful.

CASE 4

A 36-year-old woman underwent hybrid ESD for removal of a 30-mm nongranular lateral spreading lesion at the hepatic flexure (Fig. 7). After the resultant piecemeal ER, 2 X-Tack devices and 6 endoclips were placed, resulting in complete closure of the mucosal defect. At 6-month follow-up, a 10-mm residual tissue was seen at the scar site. This was removed by underwater

EMR. At follow-up, 1 set of the X-Tack was seen in a group, and 2 single tacks were found situated inside the mucosa adjacent to the scar (Fig. 8). None of the endoclips were found during the follow-up procedure.

CASE 5

A 70-year-old woman underwent piecemeal EMR of a 50-mm sessile polyp located in the third portion of the duodenum occupying 60% of the circumference of the duodenal lumen (Fig. 9). Two X-Tack systems and 6 endoclips were successfully placed, with complete closure of the defect after mucosal resection. Follow-up endoscopy was performed after 9 months. This revealed 1 residual X-Tack that was grouped and a single tack

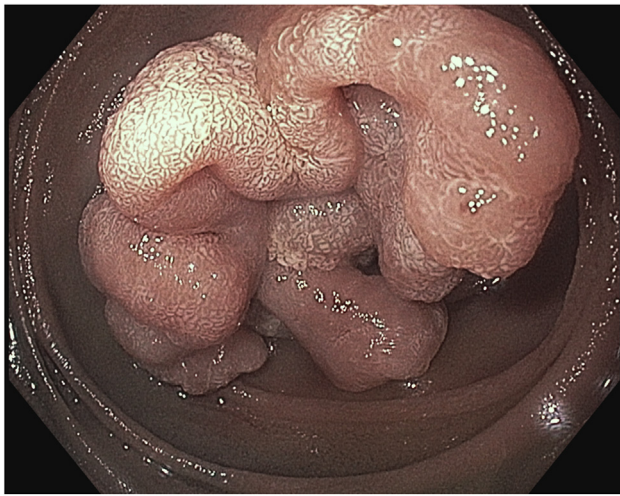


Figure 9. A 50-mm sessile polyp located in the third portion of the duodenum occupying 60% of the circumference of the duodenal lumen.

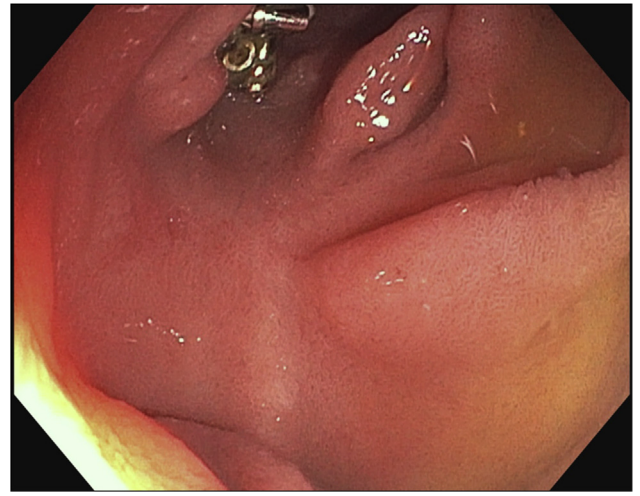


Figure 10. Follow-up endoscopy after 9 months revealed 1 residual X-Tack that was grouped near the postmucosectomy scar.

TABLE 1. Follow-up findings of the included cases

Serial number	Age (y)	Sex	Lesion size (mm)	Location	Type of endoscopic procedure	No. of X-Tack systems used for defect closure	No. of endoclips used for complete closure	Follow-up period (mo)	Follow-up findings
1	74	M	30	Duodenum (third portion)	EMR	2	4	4	One X-Tack system was seen in group. Two single X-Tacks found separately deep in the duodenal mucosa. Clips were not found.
2	70	M	45	Ascending colon	ESD	1	9	4	No X-Tacks or clips were found.
3	53	F	15	Rectum	ESD	2	3	6	Two sets of X-Tacks found in groups. No clips were noted.
4	36	F	30	Hepatic flexure	Hybrid ESD	2	6	6	One set of X-Tack was seen in group. Two single X-Tacks were seen near the scar. No clips were seen.
5	70	F	50	Duodenum (third portion)	EMR	2	6	9	One X-Tack was seen grouped and another single tack was near the scar site. Other X-Tack system and clips were not found.

near the postmucosectomy scar (Fig. 10). The other X-Tack system and the endoclips were not found. Several attempts to remove the X-Tacks using biopsy forceps were made but were unsuccessful. A 3-mm residual tissue noted near the scar site was removed with hot biopsy forceps.

All patients described had no abdominal pain or bleeding after the ER and defect closure. This case series demonstrates the outcomes of defect closure using the X-Tack system with endoclips at 4, 6, and 9 months after ER (Table 1). The X-Tack system with endoclips facilitated the closure of large mucosal defects, especially in lesions in difficult locations. In some cases, a large number of endoclips were used to achieve a high-quality closure (no exposed submucosal tissue) to reduce the risk of delayed bleeding. During the follow-up period, we

observed that the X-Tacks either fell off or were grouped or situated as a single piece in the mucosa where initially placed. None of the endoclips were seen at the follow-up. We attempted to remove the remaining X-Tacks with standard biopsy forceps and rat-tooth forceps, but both devices were unsuccessful in removing the retained tacks without unscrewing them counterclockwise. We believe that the X-Tacks seen in the group will eventually fall off with the repetitive pulling forces of food or feces. An intact suture grouping the X-Tacks is likely the important factor in them falling off by themselves. However, the single tacks that were buried inside the mucosa will likely stay indefinitely. This may be because the X-Tacks were either screwed deeply in the subepithelial layer or deeper during the index procedure or there was early disconnection before all tacks were dislodged from the tissue as a group.

In conclusion, although the novel X-Tack system is a promising device to aid the effective closure of large mucosal defects, further studies are needed to assess the long-term outcomes of this novel system.

DISCLOSURE

Dr Fukami is a consultant for Boston Scientific, Olympus America, and Creo Medical. All other authors disclosed no financial relationships.

Abbreviations: ER, endoscopic resection; ESD, endoscopic submucosal dissection; TTS, through-the-scope.

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<https://doi.org/10.1016/j.vgie.2022.03.002>

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