CHARACTERISTICS, RECOMMENDED TECHNIQUES AND PITFALLS OF A NOVEL ENDOSCOPIC 4 TACK SUTURE WOUND CLOSURE SYSTEM

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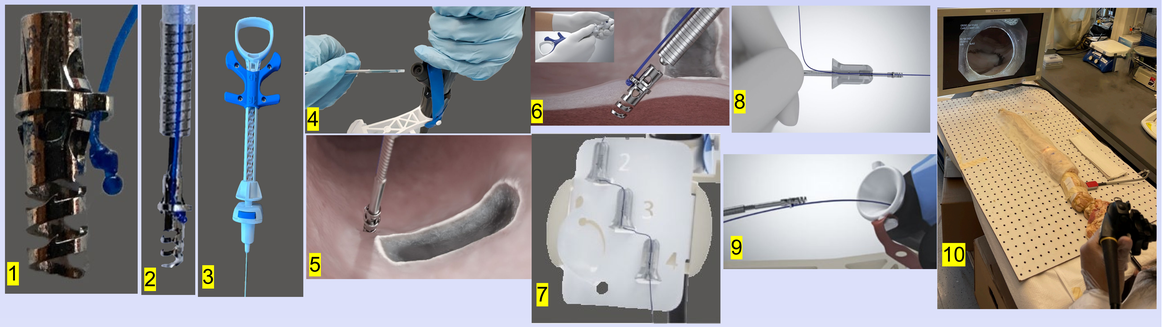
Background/Aim

Endoscopic mucosal resection (EMR) and endoscopic submucosal dissection (ESD) removal of large sessile colorectal polyps creates sizable mucosal wounds[1]. Closure of the defect, if possible, is preferred and may decrease the rate of delayed hemorrhage and perforation[2]. Closing large mucosal wounds with standard endoscopic clips is a challenge and, in many cases, not possible. Also, at best, clip closure joins the mucosal layers only. Another option are Over The Scope (OTS) clips; however, they cannot bridge large defects. Some endoscopic suturing platforms permit full thickness closure but require a therapeutic double channel upper endoscope and tip attachments; also, these are difficult technique to master. Clearly, there is a need for more versatile wound closure methods that can be used with standard colonoscopes. Our method closes wounds with 4 threaded metal tacks that are individually "drilled" into the mucosal edges and are joined by a suture which pulls the tacks together and is secured by a plastic plug. This system can be used with any length colonoscope with a single instrument channel. This ex vivo porcine large bowel study was done to assess: 1) present insertion techniques and device failures 2) Z and X tack patters 3) 1 and 2 card closures (4 vs 8 tacks).

Methods

Insertion method: The tacks one at a time, are mounted on an insertion device that is introduced into the colon via the working channel though a catheter sleeve and then pushed firmly into the mucosa 0.5-1.0 cm from the wound edge at the desired location. Closing the "Persian Drill" handle of the insertion tool rotates the threaded tack clockwise driving the tack into the bowel wall. After confirming good placement, the tack is released by pressing the blue button on the handle and sliding it forward. The insertion tool is withdrawn, and the next tack loaded onto it from the tack card mounted on the scope's handle. While the assistant holds the external end of the suture and prevents it from being pulled into the scope, the loaded tool is then reinserted beyond the scope tip, pushed firmly into the mucosal surface at the chosen spot, and then fired. This process is repeated until all 4 tacks have been placed. The catheter sleeve and the insertion device are then removed. Next the end of the suture is threaded through a loop at the end of the cinch closure device and pulled through a channel in the tip. While securing the suture's end outside the cinch is inserted into the colon and positioned over the wound after which the suture is pulled tightly which draws the tacks together and unites the wound edges. After confirming that the tacks are tightly grouped and while maintaining tension on the suture, the cinch handle is closed which pulls the suture through the plastic cinch, secures the closure, and then cuts the suture.

Study Protocol: A total of 35 wound closures in ex vivo bovine large bowel were carried out using the device. Prepped and frozen ex vivo colon (+ anus) was used; after thawing 4 mucosal defects, 2-4 cm in diameter, created through a colotomy that was subsequently closed, were located 20-35 cm from the anus. Four (1 tack card) and 8 tack closures (2 cards) were made. The closures were performed in X or Z suture pattern. The closures were video recorded and after placement each colon was opened. and the closures inspected. Device function, integrity of tack placement and the wound closures were assessed.



Figures

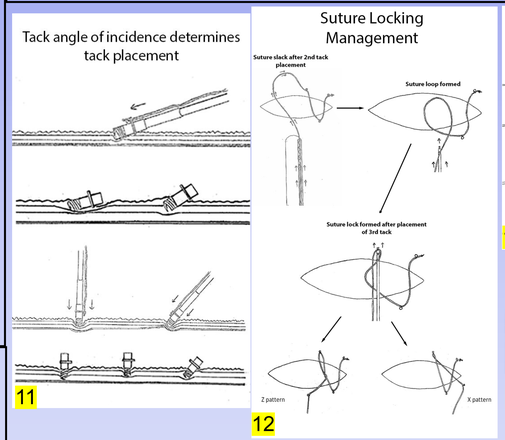
Left:
1) Tack Device
2) Delivery tip of Persian Drill
3) Persian Drill Handle
4) Loading device into scope
5) Placing 1st tack into submucosa
6) Tack release mechanism
7) Tack Card Holder
8) Reloading Delivery device
9) Loading Tack
10) Ex vivo animal model for endoscopy training

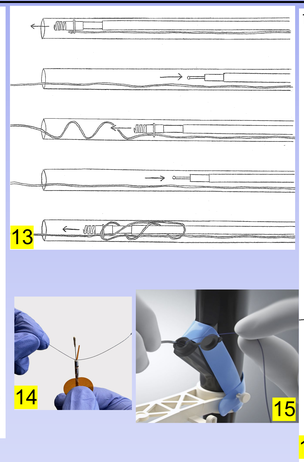
Right:
11) Tack angle mechanics
12) Suture Locking management
13) Knot formation schematic
14) Loading cinch device
15) Suture management
16) Tack Cinch Mechanism
17) Sagittal view of cinch
18/19) Card Closure types
20) Closure Patterns

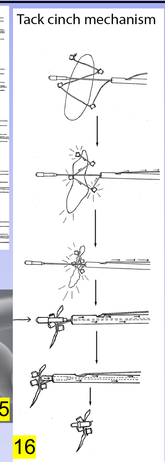
Results

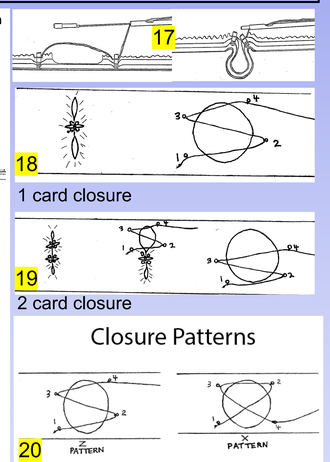
The opposite sides of the mucosal edges of the ex vivo bovine colon wounds were successfully opposed in 29 of 35 closures (82%). A single tack card (4 tacks) and unifying suture was used for closure in 15 (43%) of cases whereas 2 tack cards and sutures were used for 18 (57%) of the closures. Half of the closures used X pattern (30) and the rest were Y pattern (29). No difference in results was noted between the X and Z suture pattern. Two card closures resulted in less exposed submucosa vs 1 card. Longitudinal closure resulted in non-critical luminal narrowing. Closures included the deep bowel wall in 52% (18 wounds); tack penetration depth was: submucosa, 33.8% ; muscularis propria, 42.5%; transmural, 21.5%; and mucosa only, 1.8%. The distance from the wound edge to the tacks were: 0-2 mm, 32.6% of tacks; 2.1-4 mm, 37.4%; 4.1-6 mm, 22.5 %; ≥6.1 mm, 7.5%. Issues associated with unsuccessful closure included: suture breakage, mid suture knot, tack dislodgement, and very loose closure. Choice of X and Z suture pattern did not impact results.

Limitations: Reasons for failure in this technique included tack dislodgement post placement, suture breakage prior to cinch placement, knot formation along the suture mid procedure, loose closure, and locking the suture. Management of the long suture during tack and cinch placement is critical. There is a tendency for suture to be pulled into the scope/colon when inserting the tacks that may result in loops and knots that, if unresolved, lead to failure. Careful attention to the suture and placement of traction on the outer end prevents knots formation. It is important to verify that the tack is adequately embedded in the bowel wall prior to releasing it from the delivery device. If poorly inserted, the tack can be further screwed into or out of the wall manually by twisting the delivery tool shaft to the right or the left. Very superficial tacks may dislodge; if a tack comes loose after release from the delivery tool there is little that can be done. Finally, when the 3rd tack is placed it is possible to lock the suture if there is excess suture in the bowel that creates a loop that the delivery device is passed through prior to implantation.









Conclusion

It was possible to successfully approximate the edges of 2-4 cm diameter wounds with this 4 tack suture system. This tack system successfully opposed the edges of 82% of wounds in this model. 64% of tacks extended into muscularis propria or serosa; 52% of closures included deep wall. Transverse closures are recommended. X and Z suture patterns were equivalent, and 2 card closures left fewer submucosal gaps. The tack distance from edge goal should be ≥5 mm. There is a definite learning curve associated with this system and it is recommended that ex vivo animal models be used for initial training. Familiarity with the device and an understanding of the potential pitfalls and critical aspects of the implantation & cinching procedure is needed for the safe use of this system. More study is needed.

References

1 - McCarty, T. R., & Aihara, H. (2020). Current state of education and training for endoscopic submucosal dissection: Translating strategy and success to the USA. Digestive Endoscopy, 32(6), 851-860.
2 - Omori, J., Goto, O., Habu, T. *et al.* Prophylactic clip closure for mucosal defects is associated with reduced adverse events after colorectal endoscopic submucosal dissection: a propensity-score matching analysis. *BMC Gastroenterol* **22**, 139 (2022). https://doi.org/10.1186/s12876-022-02202-3