Preliminary Results of an Ex Vivo Porcine Large Bowel Mucosal Wound Closure Study Assessing the Indications for and Utility of an Endoscopic Clip Capable of Transiently Grasping One Mucosal Edge to the Opposite Wound Edge

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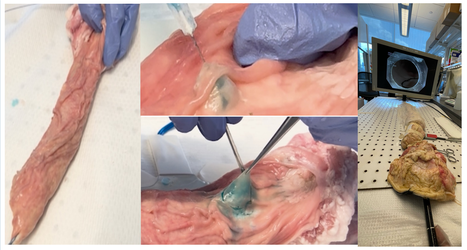
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Introduction

Endoscopic submucosal dissection (ESD) and Endoscopic mucosal resection (EMR) create large mucosal wounds during endoscopic minimally invasive surgery (MIS). If possible, mucosal closure is carried out, to help reduce the chance of any potential perforation, bleeding, or possible infection [1]. There are a variety of closure techniques, but endoscopic clips remain the main method of closure [2]. Even with clips being the mainstay, some endoscopic wounds can be challenging to close with standard clips, therefore the need for alternatives must be explored. An endoscopic clip (Mantis, (M)), recently released, can be partly closed to grasp 1 mucosal edge that is then pulled/pushed to the opposite wound edge and then reopened, the free leg positioned and then fired to join the wound edges [3]. This advanced clip costs more than standard clips and is best used when closure is not otherwise possible. This ex vivo porcine colon wound study was undertaken to determine how often M clips are needed for wounds between 1.7 and 2.5 cm in diameter. The preliminary results are explored in the study.

Methods

Frozen porcine large bowel (with intact anus, sphincter, rectum and 1-2 feet of distal colon) specimens were obtained from a commercial vendor (Animal Technologies; Tyler, Texas) thawed and prepared for this study. A total of 5-6 mucosal wounds were made in each colon via a longitudinal colotomy that was subsequently closed. The proximal colon ends was occluded and a colonoscope inserted via the anus. Leakage from the sphincter was prevented via rubber bands attached to A PEG board (Fig A). An attempt was made to close each wounds with Resolution clips (Boston Scientific, Boston, MA); if that failed then an M clip was used (Fig B). The number of clips needed per wound and the type of closure obtained was noted (mucosa to mucosa; mucosa to submucosa; or submucosa x 2). The diameter and surface area of each wound was also noted.



A. Creating lesions and utilization of ex vivo porcine colon model



Fig B. Resolution vs. Mantis

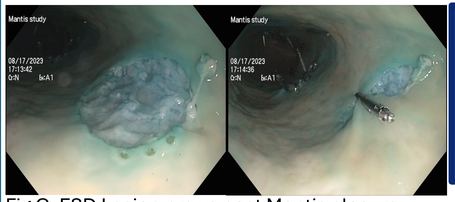


Fig C. ESD Lesion pre vs post Mantis closure

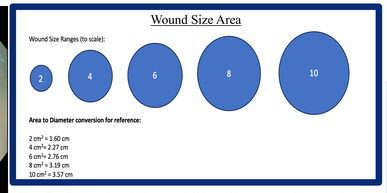


Fig D. Relative Wound Size Created in ex vivo Porcine Model

Wound Diameter (cm)	Surface Area (cm^2)	Closure with R Clips Only (n, %)	Closure with M Clips Required (n, %)	1 M Clip Used (n, %)	2 M Clips Used (n, %)	3 M Clips Used (n, %)
1.7 - 3.5	2.27 - 9.62	10 (33.3%)	20 (66.6%)	15 (75%)	4 (20%)	1 (5%)

Table 1: Wound Closure Data

Wound Diameter Category	Total Wounds (n)	Wounds Requiring M Clips (n, %)
> 2.26cm	13	11 (85%)
<= 2.26cm	17	9 (53%)

Table 2: Wound Size vs. Need for M Clips

Closure Type	Percentage
Mucosa to Mucosa	82%
Hybrid	12.50%
Purely Submucosal	5.50%

Table 3: Closure Type Data

Malfunction Type	Occurrences (n)
Broken Arm	6
Clip Fell Off During Closure	2
Clip Fell Off Prior to Placement	1

Table 4: Clip Malfunction Data

Results

A total of 30 wounds, in 6 colons, were closed; a total of 86 Resolution (R) type and 26 Mantis (M) clips were used (mean, 3.5 clips/wound). Wound diameters ranged from 1.7 - 3.5 cm (area, 2.27-9.62 cm^2). In 10/30 (33.3%) wounds, closure was possible with R clips alone; in the other 20 wounds (66.6%) M clip(s) were required (1 M, 15 wounds [75%]; 2 M, 4 [20%]; 3 M, 1 [5%]) after which R clips completed the closure. A direct relationship was noted between wound size and need for M clips; M clips were needed in 85% (11/13) of wounds with diameter > 2.26cm (surface area > 4cm^2) vs 53% of smaller wounds (area 2.27- 4 cm^2). Mucosa to mucosa closures were obtained in 82% vs. hybrid closures in 12.5% and purely submucosal placement in 5.5%. Clips malfunctioned 10% of the time (broken arm (6), clip fell off delivery tool during closure (2) and prior to placement (1)) (Tables 1-4).

Conclusion

This ex vivo study demonstrates the utility of the novel Mantis clip in the closure of medium to large endoscopic mucosal wounds (Fig C). In wounds ranging from 1.7 to 2.5 cm in diameter, the Mantis clip was necessary in 56.9% of the cases where standard Resolution clips were inadequate. Particularly for wounds larger than 2.26 cm in diameter, Mantis clips were more often required for adequate closure, indicating a correlation between wound size and the necessity for this advanced closure device. The majority of closures achieved mucosa-to-mucosa approximation, with a lower incidence of hybrid and submucosal closures. The study also highlighted a 7.1% malfunction rate of the clips, with a total of 112 R and M clips utilized, the Mantis clip showing potential as a reliable alternative when traditional methods fail. However, given the higher cost of Mantis clips, their use should be reserved for situations where standard clips are ineffective. Further studies would be beneficial to establish the clinical relevance of these findings.

References

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