



Benchtop study demonstrates potential for both procedural efficiencies and reduced clips closing simulated tissue defects using Anchor, Mobilize, Close with the MANTIS™ Clip.

Background & Objective:

Traditionally a 'zipper' technique is used to close large defects from the ends of the defect because conventional clips are limited by their jaw opening width^{1,2}. (Figure 1, bottom panel)

Figure 1



The MANTIS Clip (abbreviated MANTIS), with TruGrip™ anchor prongs, enables physicians to "Anchor-Mobilize-Close" (AMC) defects starting from the middle of the defect (Figure 1, upper panel). With the AMC approach, it is possible to span defects larger than the opening width of the device³. Because the AMC approach is independent of the opening jaw width, it **may have the potential to**^{3,4}:

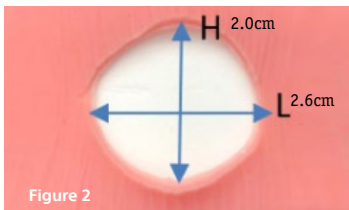
- **Require fewer devices to achieve large defect closure**
- **Result in improved efficiency**
- **Reduce procedural time for closure**

This, benchtop study compared the closure of a large (<3cm) standardized, synthetic tissue model defect using AMC approach with the MANTIS, compared to zipper technique with standard Through-The-Scope (TTS) clips. Sixteen physicians participated in the study.³

Methods:

Sixteen MD health care professionals (HCPs) experienced with interventional endoscopic gastroenterology each closed 2 simulated defects (n.b. sample size n=32). Each physician completed closure of a standardized synthetic tissue model (Tactility Mimetic Bowel, Chamberlain Group) defect using zipper or AMC approaches, in a randomized order. Overall, the synthetic tissue model defects were on average 2.6cm length x 2.0cm height (Figure 2).

For the AMC approach, the MANTIS device was used. For zipper technique a variety of clips were used; the samples of TTS clips were selected to represent various hemostatic clips on the market. Clips included in the zipper arm were Boston Scientific Resolution™ 360 Clip and two additional competitive clips on the market. The time and number of clips were compared using descriptive statistics.



Results:

When comparing the Anchor Mobilize Close (AMC) approach using MANTIS, to zipper technique using conventional TTS clips, physicians were able to complete the procedure, on average, in less time and using fewer clips³ (Table 1).

- **AMC approach using MANTIS:** 3.5 devices (range 2-4 devices) in 176 seconds (2.93 minutes)
- **Zipper technique with conventional clips:** 7.8 devices (range 4-9 clips) in 461 seconds (7.68 minutes)
- **The AMC approach decreased:**
 - › The number of clips needed to close defect **4.3 clips, 55% reduction**³
 - › Time of closure by **285 seconds (4 minutes 45 seconds), 62% improvement**³

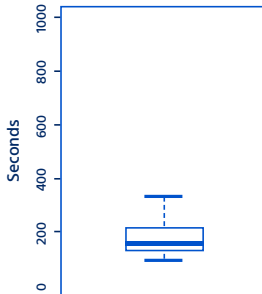
Above results are based on averages.

Estimated Economic Benefits:

Time within the endoscopy suite has economic value; prior studies have estimated the average value of time per minute in the suite at \$42.02.⁴ Using this estimate, the 4.75 minutes potentially saved with AMC approach may be valued at upwards of nearly \$200 per simulated defect (\$42.04/minute x 4.75 minutes = \$199.69). To estimate the potential total economic value, the savings from different numbers of hemostatic devices between AMC and zipper (4.3 fewer clips with AMC) approaches needs to be considered. However, hemostatic device cost can vary. Thus, to estimate potential total economic value, systems and physicians considering the AMC approach using MANTIS need to consider their specific costs and pricing of both MANTIS and predicate zipper TTS clips alongside these estimated economic value of potential time savings*.

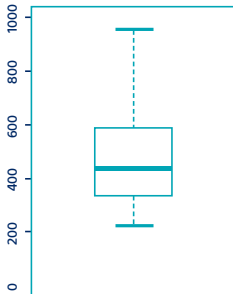
* Bench testing may not necessarily be indicative of clinical performance.

Table 1: Time and Quantity of Clips required comparing Anchor-Mobilize-Close Approach and Zipper Technique on Simulated Tissue Defect						
Time to close defect				Quantity of clips used per defect		
	MANTIS: AMC (seconds)	Other Clips: Zipper (seconds)	Average Difference	MANTIS: AMC (Clips)	Other Clips: Zipper (Clips)	Average Difference
Average	176	461	4 min 24 seconds AMC= 62% less time*	3.5	7.8	4.3 Clips
Standard Deviation	62	183		.8	2.5	AMC= 55% fewer clips*
Range	101-338	225-950		2-4	4-9	

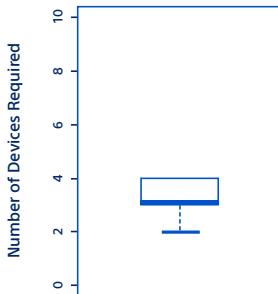


Seconds

AMC Approach

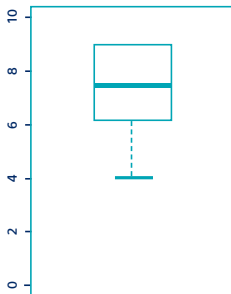


ZIPPER Technique



Number of Devices Required

AMC Approach



ZIPPER Technique

Conclusion:

In a benchtop study, AMC approach using MANTIS required 4.3 fewer clips and reduced task time by 4.75 minutes compared to zipper technique using other commercialized TTS clips. These results suggest potential efficiencies and economic value with the AMC approach using MANTIS; further studies in clinical settings are needed to validate this data.

* Bench testing may not necessarily be indicative of clinical performance.

1. Liaquat, H., Rohn, E., & Rex, D. K. Prophylactic clip closure reduced the risk of delayed postpolypectomy hemorrhage: Experience in 277 clipped large sessile or flat colorectal lesions and 247 control lesions. *Gastrointestinal Endoscopy*, 2013, 77(3): 401-407. <https://doi.org/10.1016/j.gie.2012.10.024>
2. Staudenmann D., Choi K., Kaffes A., Saxena P. Current endoscopic closure techniques for the management of gastrointestinal perforations. *Ther Adv Gastrointest Endosc*, 2022;15: 1-12
3. Boston Scientific conducted a bench study to gather feedback from 16 paid physicians on the use of commercially representative MANTIS™ Clips on excised porcine stomach model and synthetic tissue model. Data on file. The objective of the study was to evaluate MANTIS Clip's tissue apposition and mobilization design features as compared against Boston Scientific Resolution™ 360 Clips, and other competitive clips. The bench study was performed with minimal training via some preparation in the ex-vivo model. Bench testing results may not necessarily be indicative of clinical performance. Each physician conducted one closure per product brand. The data showed that the average time and clip quantity to close the defects when using the MANTIS Clip was less than the combined average time (reduced by 4 mins 45 seconds) and clip quantity (reduced by 4) for the Resolution 360 and other competitive devices. Bench testing results may not necessarily be indicative of clinical performance.
4. Smith, T., Evans, J., Moriel, K., Tihista, M., Bacak, C., Dunn, J., Rajani, R., & Childs, B. The Cost of OR Time is \$46.04 per Minute. *Journal of Orthopaedic Business*, 2022, 2(4), 10-13. <https://doi.org/10.55576/job.v2i4.23>

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

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