INTERVENTIONAL ENDOSCOPY

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Randomized Controlled Trial Comparing the Efficacy and Cost of 2 Novel Through the Scope Tissue Approximation Devices

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Introduction: Closure techniques for large endoscopic resection defects (ERD) continue to evolve. Focus has shifted from 1 step tissue apposition to tissue approximation first, which allows healthy mucosal tissue to be brought in close proximity to each other, followed by complete closure. In this study we compare the clinical efficacy and cost of 2 novel through the scope (TTS) tissue approximation devices in the management of large ERD.

Methods: In a single-center RCT study conducted from Aug 2022 to May 2023, we compared the effectiveness of the dual-action tissue clip (DAT) and the TTS tack/suture device (TSD) for closure of ERD measuring >20mm (width) and >30mm (length). Closure method was randomly assigned. The primary outcome was tissue approximation and approximation cost. Tissue approximation was defined as having ≤15mm of visible resection bed, using only the assigned device. Complete closure, without any visible resection bed remaining, was achieved using standard TTS instruments. Both outcomes were verified by a trained third-party observer.

Results: 56 patients were included (Table 1). Tissue approximation (88% vs 83.9%, *P* =0.92) and complete closure rates (92% vs 93.5%, *P*=0.83) were similar for both TSD and DAT groups, respectively. 60% (n=3) of DAT failures (Figure 1) underwent successful tissue approximation using TSD. 33% (n=1) of TSD failures, underwent successful tissue approximation using the DAT clip. Multivariable analysis demonstrated a circular ERD shape was 21.1 times more likely to be associated with approximation failure (*P*=0.004) in both groups. TSD was able to approximate all 4 duodenal ERD, while DAT was unable to approximate any duodenal ERD. Approximation cost ($973.6 vs $673.1, *P*=0.002) and closure cost/mm2 ($1.6/mm2 vs $1.0/mm2, *P*=0.002) were lower in the DAT arm. Tissue approximation time (12.2 minutes vs 4 minutes, *P*< 0.0001) and closure clinical speed (72.7 mm2/min vs 153.5mm2/min, *P*= 0.003) was faster in the DAT group. Mild device related adverse events occurred once in the TSD group vs twice in the DAT group. Clinically significant delayed bleeding occurred once in both groups, while patients resumed anticoagulation.

Conclusion: In this RCT, both TTS approximation devices equally facilitate approximation and closure of large ERD. Tissue approximation with the DAT clip was faster and more cost-effective than TSD for most resection bed shapes and sizes. However, TSD may be more effective for approximation of duodenal ERD.

	DAT clip failure #1	DAT clip failure #2	DAT clip failure #3
Location	Duodenum	Duodenum	Stomach
Polyp size, mm	50mm X 40mm	30mm X 30mm	40mm X 30mm
Resection bed size, mm2	2000 mm2	900 mm2	1200 mm2
Resection bed shape	50% circumference	Circle	Circle
Why it failed?	Could not grasp both edges	Tissue was tearing upon grasping	Tissue was tearing upon grasping
Crossover to other arm	Yes	Yes	Yes
Tissue Approximation	2 sets of X-tack	2 sets of X-tack	2 sets of X-tack
Complete Closure	Yes	Yes	Yes
	DAT clip failure #4	DAT clip failure #5	
Location	Rectum	Transverse Colon	
Polyp size, mm	40mm X 35mm	80mm X 30mm	
Resection bed size, mm2	1400 mm2	3600 mm2	
Resection bed shape	Circle	50% circumference	
Why it failed?	Slippage of clips, resection bed was too large	Resection bed was too large	
Crossover to other arm	No	No	
Tissue Approximation	No	Yes- One DAT, TTS clips	
Complete Closure	No	No	
	TSD failure #1	TSD failure #2	TSD failure #3
Location	Cecum	Ascending Colon	Sigmoid Colon
Polyp size, mm	35mm X 30mm	60 X 20	35mm X 20mm
Resection bed size, mm2	1050 mm2	1200	700 mm2
Resection bed shape	Circle	Ellipse	50% circumference
Why it failed?	Difficulty in advancing sheath through endoscope	Device malfunctioned	Suture broke
Crossover to other arm	Yes	No	No
Tissue Approximation	Yes	No	No
Complete Closure	Yes	No	No

[1210] **Figure 1.** Outcomes of device failures in DAT and TSD groups.

Table 1. Clinical Outcomes for Subjects Undergoing Tissue Approximation and Defect Closure After Endoscopic Resection

	TSD (n=25)	DAT (n=31)	*P* value
Mean Age, *years +/- SD*	66.3 +/- 4.7	64.5 +/ 3.5	0.52
Female, *n (%)*	12 (48)	19 (61.3)	0.32
Anticoagulation, *n (%)*	2 (8)	1 (3.2)	
Location of polyp, *n (%)*			
Ileocecal valve	0	1 (3.2)	
Cecum	3 (12)	7 (22.6)	
Ascending colon	9 (36)	7 (22.6)	
Transverse colon	4 (16)	5 (16.1)	
Descending colon	2 (8)	2 (6.5)	
Sigmoid colon	2 (8)	3 (9.7)	

Table 1. (*continued*)

	TSD (n=25)	DAT (n=31)	*P* value
Rectum	2 (4)	2 (6.5)	
Stomach	0	2 (6.5)	
Duodenum	4 (16)	2 (6.5)	
Resection via ESD, *n (%)*	16 (64)	20 (64.5)	0.5
Resection via Hybrid- ESD, *n (%)*	6 (24)	6 (19.4)	0.6
Resection via EMR, *n (%)*	3 (12)	5 (16.1)	0.48
En bloc resection, n (%)	18 (81.8)	25 (96.2)	0.1
Average resection bed size, *mm^2 +/- SD*	1127 +/- 264	1207 +/- 222	0.63
Tissue approximation complete, *n (%)*	22 (88)	26 (83.9)	0.92
Complete resection bed closure, *n (%)*	23 (92)	29 (93.5)	0.83
# of instruments needed for approximation, *median*	1	2	
# of additional instruments needed for complete closure, *mean +/- SD*	3.1 +/- 0.7	2.6 +/- 0.5	0.62
Average cost of approximation, $ +/- SD	973.6 +/- 166	673.1 +/-105	**0.002**
Average cost of complete closure, $ +/- SD	1578 +/- 252	1111.9 +/- 164	**0.003**
Average closure cost/mm^2, $/$mm^2$ +/- SD	1.6 +/- 0.9	1.0 +/- 0.8	**0.002**
Average approximation time, min +/- SD	12.2 +/- 2.6	4+/- 1.5	< **0.001**
Average closure speed, mm^2/min +/- SD	72.7 +/- 17.4	153.5 +/- 36.3	**0.003**
Total procedure time, min +/- SD	103.1 +/- 16.9	97.7 +/-13.2	0.6
Adverse events			
Device related, n (%)*	1 (4)	2 (6.5)	0.2
Post electrocautery syndrome, n (%)**	3 (12)	2 (6.5)	0.73
Delayed bleeding n (%)***	2 (8%)	2 (6.5)	0.61

*All related to intraprocedural bleeding occurring from device trauma. All self-limited except 1 DAT patient who required coagulation grasper to treat ** All patients treated with antibiotics at home and did not require admission *** One patient in both groups had self-limited bleeding, resolving without admission or intervention. One patient in X-tack group required PRBC, hospital admission and endoscopic treatment, X-tack was in place. One patient in the DAT group required intervention with evidence that the DAT clip had dislodged. Both patients were on anticoagulation.

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Similar Efficacy of a Novel Bipolar Radiofrequency Ablation Knife to Monopolar Current Knife in Endoscopic Submucosal Dissection of Colonic Lesions: A Non-Inferiority Randomized Trial

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Introduction: Monopolar current knives (MC) are commonly used for Endoscopic Submucosal Dissection (ESD) but variations in tissue composition and consistency can limit their effectiveness. To overcome these challenges, a novel bipolar radiofrequency ablation (RFA) cutting knife (BC), was developed. This randomized controlled trial aims to evaluate the efficacy of the BC vs MC during colonic ESD.
Methods: We conducted a non-inferiority trial at a single US referral center to evaluate a new bipolar ESD knife for colonic ESD. Inclusion criteria were G-LST ≥ 30 mm or non-GLST lesions ≥ 20mm, while ICV, appendix lesions, and pedunculated polyps were excluded. Randomization was done using computer software. The primary outcome was successful completion of dissection with the intended knife and technical success (en bloc/R0 resection rates). Secondary endpoints included dissection speed and post-procedure pain scores.
Results: In this study, 70 patients with a total of 72 polyps were included. The Bipolar Current (BC) group had 37 patients, while the Monopolar Current (MC) group had 33 patients (Table 1). Most patients (87.1% in BC and 100% in MC) were treated with a single knife (P=0.7). Five patients required knife change due to limited rotation of the bipolar knife and intraprocedural bleeding. In the MC group, all patients required an additional instrument for injection, unlike the BC group where only 14.7% needed it (P=0.05). The use of traction or stabilization devices did not significantly differ between the groups (P=0.52 vs. 0.15). Similar findings were observed when crossover cases were excluded. Both groups demonstrated comparable en bloc resection rates (97%, P=1) and R0 resection rates (90.1% vs. 97%, P=0.85). Dissection speed was similar between the groups, and there were no significant differences in pain scores at 1 hour and 24 hours post-procedure (24-hour pain scores: 1.8 ± 2.5 in BC vs 0.8 ± 2.3 in MC, P=0.14).
Conclusion: The bipolar ESD knife showed comparable technical success, en bloc resection, R0 resection, dissection speed, and post-procedural pain scores compared to the monopolar knife, the bipolar knife has the advantage of performing submucosal injection, dissection, and coagulation without requiring instrument or catheter switching. However, it has limitations in challenging locations or vascular lesions. Additional studies are required to assess if the bipolar knife enhances resource allocation compared to the monopolar knife.

Table 1. **Demographic characteristics and procedural outcomes of the study groups**

	Bipolar group (N=37 patients, 39 lesions)	Monopolar group (N=33)	Value
Age (mean ± SD)	64.3 ± 12.3	63.2 ± 14.2	0.6
Gender (male)	19 (51.3%)	14 (43.7%)	0.4
Technique			1
ESD	35 (89.7%)	30 (90.9%)	
Hybrid ESD	4 (10.2%)	3 (9%)	
Endoscopic size (mm)	34.1± 11.2	34.7 ± 10.3	0.6
Paris classification			0.1
IIa	2 (5.1%)	6 (18.1%)	
IIa-c	11 (28.2%)	4 (12.1%)	
Is	22 (54.1%)	23 (69.9%)	
IIc	4 (10.2%)	0 (0%)	