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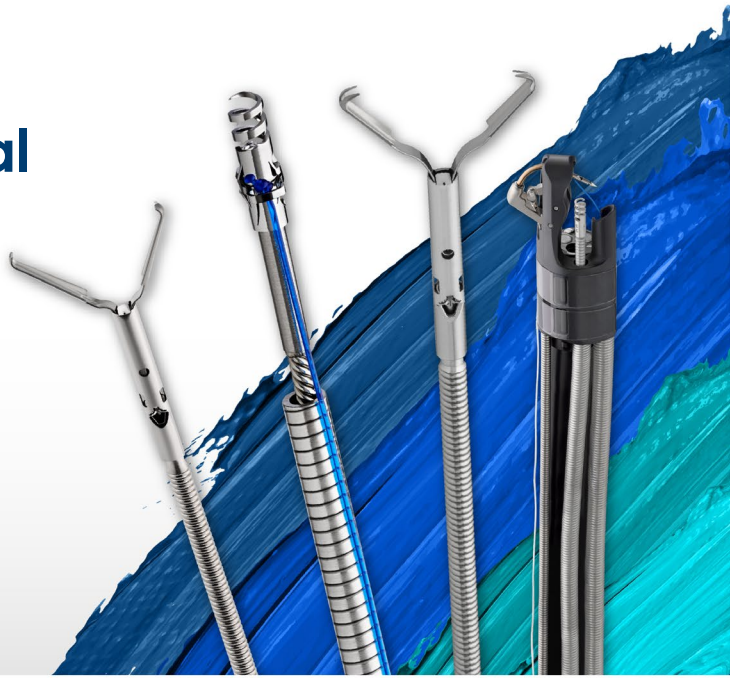
Defect Closure Clinical Literature Summary



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Resolution™ Clip Family

X-Tack™ Endoscopic HeliX Tacking System

MANTIS™ Clip

OverStitch™ Family

Resolution™ Clip Family

Hemoclipping of chronic canine ulcers: a randomized, prospective study of initial deployment success, clip retention rates, and ulcer healing

Abstract

Background: Several different hemoclips are marketed for endoscopic hemostasis of nonvariceal upper GI (UGI) bleeding. No previous reports have compared success rates of clip deployment onto bases of chronic gastric ulcers (GUs), clip retention rates, or their influence on ulcer healing.

Objectives: For the treatment of chronic GUs, to compare three different hemoclips with multipolar electrocoagulation (MPEC) and control.

Design: Randomized, controlled study.

Subjects: Seven adult dogs with prehepatic portal hypertension had GUs created by rubber band ligation. Animals received oral proton pump inhibitors daily and underwent weekly endoscopies to quantitate clip retention and ulcer healing.

Interventions: One week after banding, 10 chronic ulcers were randomized in pairs to control (no endoscopic treatment), MPEC, or different hemoclips (QuickClip2 [QC], TriClip [TC], or Resolution Clip [RC]).

Main outcome measurements: Times and success of hemoclip deployment, clip retention rates, and ulcer healing rates on weekly endoscopies.

Results: Success rates of clip deployment were 100% for the RC, 93.1% for the TC, and 83.3% for the QC. Clip retention rates were significantly higher with the RC than the QC or TC at 1 to 3 weeks. Retained clips did not delay GU healing compared with MPEC or control.

Conclusions: Hemoclipping time was similar with all three clips; the RC was retained significantly longer than the QC or TC, hemoclips did not delay ulcer healing compared with control or MPEC, and all three hemoclips were safe and no complications such as bleeding and weight loss were noted.

Discover the study

Jensen DM. *et al.*, Hemoclipping of chronic canine ulcers: a randomized, prospective study of initial deployment success, clip retention rates, and ulcer healing. Gastrointestinal Endoscopy, 2009 Nov;70(5):969-75 Jul 28.

Resolution™ Clip Family

Choosing the right through-the-scope clip: a rigorous comparison of rotatability, whip, open/close precision, and closure strength (with videos)

Abstract

Background and aims: Many new through-the-scope clips are available, and physicians often select clips based on physical characteristics and/or cost. However, functional profiles may be equally important and have not been methodically assessed. We evaluated 5 commercially available clips: Resolution 360, Instinct, Quick Clip Pro, Dura Clip, and SureClip.

Methods: We rigorously compared clips on multiple characteristics, including rotatability, overshoot, open/close precision, and tensile/closure strength. Clips were tested in 4 different endoscope configurations:

1. Straight
2. Duodenal sweep
3. Full retroflexion
4. Across the duodenoscope elevator

Results: For rotatability, the Resolution 360 was the fastest due to its unique functionality in allowing primary MD control in rotation ($p < .05$). The Resolution 360, SureClip, and Dura Clip were able to rotate through the prescribed sequence across all scope configurations.

For overshoot, the SureClip and Resolution 360 had the least overshoot for the straight configuration at 0%. All clips had > 75% overshoot at more strained configurations. For open/close precision, the SureClip and Dura Clip showed precise opening/closing with the ability to stop at any point. The remaining clips exhibited abrupt opening with more controlled closure. For tensile strength, the Quick Clip Pro generated the highest peak force as would be required in lateral tissue manipulation (4.8 lb, $p < .005$). For closure strength, the Instinct overall showed the most gel compression, and along with the Resolution 360, showed 100% deployment success for all gel tissue thicknesses (up to 10 mm).

Conclusions: Each clip has a unique physical and functional profile, which may be a factor in selection depending on the clinical circumstance.

Discover the study

Wang TJ. *et al.*, Choosing the right through-the-scope clip: a rigorous comparison of rotatability, whip, open/close precision, and closure strength (with videos). Gastrointest Endosc. 2019 Jan;89(1):77-86.e1

Resolution™ Clip Family

Clip Closure Prevents Bleeding After Endoscopic Resection of Large Colon Polyps in a Randomized Trial

Abstract

Background & aims: Bleeding is the most common severe complication after endoscopic mucosal resection of large colon polyps and is associated with significant morbidity and cost. We examined whether prophylactic closure of the mucosal defect with hemoclips after polyp resection reduces the risk of bleeding.

Methods: We performed a multicenter, randomized trial of patients with a large nonpedunculated colon polyps (≥20mm) at 18 medical centers in North America and Spain from April 2013 through October 2017.

Patients were randomly assigned to groups that underwent endoscopic closure with a clip (clip group) or no closure (control group) and followed. The primary outcome, postprocedure bleeding, was defined as a severe bleeding event that required hospitalization, a blood transfusion, colonoscopy, surgery, or another invasive intervention within 30 days after completion of the colonoscopy. Subgroup analyses included postprocedure bleeding with polyp location, polyp size, or use of periprocedural antithrombotic medications. We also examined the risk of any serious adverse event.

Results: A total of 919 patients were randomly assigned to groups and completed follow-up. Postprocedure bleeding occurred in 3.5% of patients in the clip group and 7.1% in the control group (absolute risk difference [ARD] 3.6%; 95% confidence interval [CI] 0.7%-6.5%). Among 615 patients (66.9%) with a proximal large polyp, the risk of bleeding in the clip group was 3.3% and in the control group was 9.6% (ARD 6.3%; 95% CI 2.5%-10.1%); among patients with a distal large polyp, the risks were 4.0% in the clip group and 1.4% in the control group (ARD -2.6%; 95% CI -6.3% to -1.1%). The effect of clip closure was independent of antithrombotic medications or polyp size. Serious adverse events occurred in 4.8% of patients in the clip group and 9.5% of patients in the control group (ARD 4.6%; 95% CI 1.3%-8.0%).

Conclusions: In a randomized trial, we found that endoscopic clip closure of the mucosal defect following resection of large colon polyps reduces risk of postprocedure bleeding. The protective effect appeared to be restricted to large polyps located in the proximal colon.

Discover the study

Pohl H. *et al.*, Clip Closure Prevents Bleeding After Endoscopic Resection of Large Colon Polyps in a Randomized Trial. Gastroenterology. 2019 Oct;157(4):977-984.e3.

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MANTIS™

A new through-the-scope clip with anchor prongs is safe and successful for a variety of endoscopic uses

Abstract

Background & aims: Endoscopic through-the-scope clips (TTSC) are used for hemostasis and closure. We documented the performance of a new TTSC with anchor prongs.

Patients and methods: We conducted a prospective case series of the new TTSC in 50 patients with an indication for endoscopic clipping at three hospitals in the United States and Canada. Patients were followed for 30 days after the index procedure. Outcomes included defect closure and rate of serious adverse events (SAEs) related to the device or procedure.

Results: Fifty patients had 56 clipping procedures. Thirty-four procedures were clipping after endoscopic mucosal resection (EMR) in the colon (33) or stomach (1), 16 after polypectomy, two for hemostasis of active bleeding, and one each for fistula closure, per-oral endoscopic myotomy mucosal closure, or anchoring a feeding tube. Complete defect closure was achieved in 32 of 33 colon EMR defects and 21 of 22 other defects. All clips were placed per labeled directions for use.

In 41 patients (82.0%), prophylaxis of delayed bleeding was reported as an indication for endoscopic clipping. There were three instances of delayed bleeding. There were no device-related SAEs. The only technical difficulty was one instance of premature clip deployment.

Conclusions: A novel TTSC with anchor prongs showed success in a range of defect closures, an acceptable safety profile, and low incidence of technical difficulties.

Discover the study

Guardiola, John J. *et al.,* A new through-the-scope clip with anchor prongs is safe and successful for a variety of endoscopic uses. Endosc Int Open. 2024 Jun 21;12(6):E812-E817.

MANTIS™

Use of anchor pronged clips to close complex polyp resection defects

Closure of defects following complex polyp resection decreases risk of postprocedural bleeding.[1-7] The MANTIS clip (Boston Scientific, Marlborough, Mass, USA) is a variation of through-the-scope clips designed to help close larger resection defects (Fig. 1).[8] The clip uses anchor prongs to maintain a secure grasp on wound edges (Video 1, available online at www.videogie.org).

In the clip drag technique, the anchor pronged clip is opened and closed (but not deployed) on the normal edge of the defect. The clip is then gently brought to the other edge of the defect, at which point the clip is opened, closed on the other edge, and then deployed.

Alternatively, in the open clip technique, the opened clip is used to anchor the tissue on one edge of the wound. The scope is maneuvered with the open clip dragging the edge of the wound and closing the clip over an opposing edge of the wound. This technique may be particularly suitable when closing a wound in a distal to proximal fashion to avoid excessive narrowing of the lumen that could result if a lateral-to-lateral edge closure approach was used...

Discover the study

Wei MT. *et al.*, Use of anchor pronged clips to close complex polyp resection defects, VideoGIE. 2023 Apr 4;8(6):245-246.

X-Tack™

Novel through-the-scope suture closure of colonic EMR defects (with video)

Abstract

Background: Large colon polyps removed by EMR can be complicated by delayed bleeding. Prophylactic defect clip closure can reduce post-EMR bleeding. Larger defects can be challenging to close using through-the-scope clips (TTSCs), and proximal defects are difficult to reach using over-the-scope techniques. A novel, through-the-scope suturing (TTSS) device allows direct closure of mucosal defects without scope withdrawal. The goal of this study was to evaluate the rate of delayed bleeding after the closure of large colon polyp EMR sites with TTSS.

Methods: A multicenter retrospective cohort study was performed involving 13 centers. All defect closure by TTSS after EMR of colon polyps ≥ 2 cm from January 2021 to February 2022 were included. The primary outcome was rate of delayed bleeding.

Results: A total of 94 patients (52% female; mean age, 65 years) underwent EMR of predominantly right-sided (n = 62 [66%]) colon polyps (median size, 35mm; interquartile range, 30-40 mm) followed by defect closure with TTSS during the study period. All defects were successfully closed with TTSS alone (n = 62 [66%]) or with TTSS and TTSCs (n = 32 [34%]), using a median of 1 (interquartile range, 1-1) TTSS system. Delayed bleeding occurred in 3 patients (3.2%), with 2 requiring repeated endoscopic evaluation/treatment (moderate).

Conclusions: TTSS alone or with TTSCs was effective in achieving complete closure of all post-EMR defects, despite a large lesion size. After TTSS closure with or without adjunctive devices, delayed bleeding was seen in 3.2% of cases. Further prospective studies are needed to validate these findings before wider adoption of TTSS for large polypectomy closure.

Discover the study

Bi D. *et al.*, Novel through-the-scope suture closure of colonic EMR defects (with video). Gastrointest Endosc. 2023 Jul;98(1):122-129.

OverStitch™

Safety and efficacy of a novel suturing device for closure of large defects after endoscopic submucosal dissection (with video)

Abstract

Background: Endoscopic suturing enables full closure of large defects after endoscopic submucosal dissection (ESD). However, its use is limited by the need for a double-channel endoscope. A novel closure system, the OverStitch Sx (Apollo Endosurgery, Austin, Tex, USA), compatible with any single-channel endoscope, was introduced to address these shortcomings. The aim of this study was to assess the safety and feasibility of OverStitch Sx for the closure of large defects after ESD.

Methods: This is a prospective single-center feasibility study of patients who underwent closure of large defects after ESD using the OverStitch Sx system. Main outcomes of the study are technical and clinical success, same-day discharge rate, and adverse event rate.

Results: Thirty-three patients were enrolled. The mean diameter of included lesions was 5.38 ± 2.52 cm. The defect occupied ≥ 50% of the lumen circumference in 70% of the cases. En-bloc resection, R0 resection, and curative resection were achieved in 97%, 87.5%, and 78.8% of patients, respectively. Technical success and clinical success were seen in 93.9% and 90.9% of the cases, respectively. Same-day hospital discharge was achieved in 77.4% of patients. Total adverse event rate was 35.7%, including delayed bleeding in 1 patient after rectal ESD that was managed conservatively, self-resolving rectal pain in 7 patients, rectal stricture requiring dilation in 1 patient, and temporary dysphagia in 1 patient. No immediate or delayed perforation was reported.

Conclusions: OverStitch Sx enabled safe and effective closure of large defects after ESD. Future trials are needed to determine its superiority over OverStitch for the closure of defects in challenging locations.

Discover the study

Keihanian T. *et al.,* Safety and efficacy of a novel suturing device for closure of large defects after endoscopic submucosal dissection (with video). Gastrointest Endosc. 2023 Sep;98(3):381-391.

OverStitch™

Endoscopic clips versus overstitch suturing system device for mucosotomy closure after peroral endoscopic pyloromyotomy (G-POEM): a prospective single-center study

Abstract

Background: G-POEM is an emerging method for treatment of severe gastroparesis. Safe mucosal closure is necessary to avoid adverse events. The aim of this study was to compare the efficacy of two closure methods: clips and endoscopic suturing (ES) after G-POEM.

Methods: We performed a single center, prospective study. The closure method was assigned at the discretion of an endoscopist prior to the procedure. The main outcome was the proportion of subjects with successful closure. Unsuccessful closure was defined as a need for a rescue method, or a need for an additional intervention or incomplete closure-related adverse events. Secondary outcomes were the easiness of closure (VAS score 1 = very difficult, 10 = easy), closure time, and cost.

Results: A total of 40 patients [21 female; mean age, range 47.5; (20-74)] were included; 20 received ES and 20 clips [mean number of clips 6; range (4-19)]. All 20 patients with ES (100%, 95% CI 84-100%) and 18 patients with clips (89%, 95% CI 70-97%) had successful closure ($p = 0.49$). One patient needed a rescue method (KING closure) and the other patient an additional clipping on POD1. Closure with clips was quicker [mean time 9.8 (range 4-20) min vs. 14.1 (5-21) min; $p = 0.007$] and cheaper [mean cost 807 USD (± 402) vs. 2353 USD (± 145); $p < 0.001$]. Endoscopist assessed the easiness of ES and clips as comparable [mean VAS, range 7.5 (3-10) (ES) vs. 6.9 (3-10) (clips); $p = 0.3$].

Conclusions: Both ES and clips are effective methods for mucosal closure in patients undergoing G-POEM. However, centres using clips should have a rescue closure method available as clips may fail in some patients. Closure with ES is more costly than with clips.

Discover the study

Hustak R. *et al.*, Endoscopic clips versus overstitch suturing system device for mucosotomy closure after peroral endoscopic pyloromyotomy (G-POEM): a prospective single-center study. Surg Endosc. 2022 Dec;36(12):9254-9261.

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