Improving the Success of Endoscopic Mucosal Closure: Case Reports Using QuickClip Pro™

Case Reports by Peter V. Draganov, MD and Sergey Kantsevoy, MD

Introduction

Hemostasis clips are now well-established in standard gastroenterological practice for common indications, such as bleeding ulcers, and are increasingly being used for less common indications (eg, securing stents, closing fistulas). Advanced age and use of antithrombotic therapy are major risk factors for gastrointestinal bleeding. It is expected that use of hemostasis clips will continue to grow given the aging population and widespread use of antiplatelet and anticoagulant medications in the elderly. This white paper focuses on the use of clips for POEM and ESD closure due to the difficult nature of closing these large defects and the number of clips typically required to do so.

The Olympus QuickClip Pro, a hemostasis clip, combines the ability to open, close, and re-open with 360-degree rotation for bleed control and defect closure. (See Figures 1A and 1B.) It is designed to be used in conjunction with an Olympus endoscope for endoscopic clip placement within the gastrointestinal (GI) tract for the following purposes: endoscopic marking, as a supplementary closure method for GI tract luminal perforation <20 mm that can be treated conservatively, and hemostasis for (1) mucosal/sub-mucosal defects <3 cm, (2) bleeding ulcers, (3) arteries <2 mm, (4) polyps <1.5 cm diameter, and (5) diverticula in the colon. In Food and Drug Administration (FDA)-reviewed simulated testing, QuickClip Pro demonstrated the ability to remain in place at least 14 days.4

QuickClip Pro is magnetic resonance imaging (MRI) conditional; patients may have an MRI within specified parameters post-clip placement. QuickClip Pro is made of Elgiloy®, an alloy that is 2.7 times stronger than stainless steel, to resist bending of the clip arms. The clip has an 11 mm adjustable opening to provide a firm and adequate grasp on tissues (See Figure 1C.) and the ability to pivot at the sheath connection. The unique sheath design prevents damage to the working channel of the scope and allows for smooth insertion and precise handling in a number of scope positions. (See Figure 2.) The handle of QuickClip Pro produces an audible click when the clip is deployed, helping to minimize accidental clip deployment.4
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The main competitors of QuickClip Pro are the Boston Scientific Resolution® Clip, Cook Medical Instinct™ Endoscopic Hemoclip, and Olympus QuickClip2™.4

The Resolution clip is comprised of stainless steel and its intended use is the same as that of QuickClip Pro with the addition of prophylactic clipping to reduce the risk of delayed bleeding post-lesion resection and anchoring to affix jejunal tubes to the wall of the small bowel.5 Similar to QuickClip Pro, the Resolution clip can open, close, and re-open (up to 5 times), has an 11 mm wide opening, and is MRI conditional; however, it lacks predictable rotational ability and the ability to deploy through a retroflexed endoscope.6,7

Instinct has the ability to open, close, re-open, and rotate (360 degrees bidirectional rotation).4,8 Similar to Resolution, Instinct can open and close up to 5 times prior to deployment.8 It is MRI conditional and has the same intended use as QuickClip Pro with 2 exceptions; Instinct is not intended for the repair of GI tract luminal perforations or hemostasis for diverticula in the colon.9 Compared with QuickClip Pro and Resolution, Instinct has a larger jaw opening at 16 mm,8,9 which can hinder its positioning in locations with limited space. Numerous malfunctions (mostly deployment issues) with Instinct have been reported to the US FDA, which have caused it to be on and off the market.10-13 Further, Instinct does not have an audible deployment click, making timing of deployment difficult to discern.4

QuickClip2 is an Olympus product with a long successful history. It is made of stainless steel and has the same intended use as QuickClip Pro.14 QuickClip2 can rotate, has a jaw opening of 9 mm, and is also available with longer arms (QuickClip2 Long™) that open to 11 mm.15 QuickClip Pro provides some additional device features compared with QuickClip2 including MRI compatibility, and most importantly, the ability to re-open, and a greater gripping strength.4,16

Herein, we present 2 interesting and difficult cases in which the unique features of QuickClip Pro enabled successful mucosal closure.
Case Report 1

A 65-year-old patient with long-standing achalasia, and who had previously failed Botox injection and pneumatic dilation, presented for evaluation and discussion of therapeutic options. The patient had dysphagia to solids and liquids and, because of an inability to maintain adequate oral intake and nutrition, body weight loss was evident (10 lbs). A barium swallow test was performed, which showed a dilated esophagus and delayed esophageal emptying.

High-resolution esophageal manometry was diagnostic of type II achalasia, based on the Chicago classification. During per-oral endoscopic myotomy (POEM), an initial mucosal incision of 10 mm was made, which permitted entry to the submucosa without difficulty. However, during the procedure, pressure from the endoscope caused enlargement of the mucosal incision.

Closure of the mucosectomy entry site was anticipated to be difficult because of the widely gaping, enlarged incision; therefore, QuickClip Pro was chosen. Closure was easily accomplished with 7 QuickClip Pro clips. (See Figure 3.) Successful closure was facilitated by the controlled rotation of QuickClip Pro, which allowed for precise alignment of the clip and easy approximation of the edges. An esophagram after the procedure confirmed complete closure with no extravasation of contrast. Placement of all clips was successful; none had to be removed due to misplacement.

The patient was treated with POEM for achalasia. Mucosectomy closure was anticipated to be difficult because of the patient’s dilated esophageal lumen and enlarged mucosal incision site. Successful closure was achieved using QuickClip Pro (3A) with no misplacement of clips (3B). QuickClip Pro made the closure technically easy.

POEM=per-oral endoscopic myotomy.
Case Report 2
A 51-year-old woman with a history of gastroesophageal reflux disease and a hypothyroid state (total thyroidectomy in 2009) was referred for endoscopic removal of a large (20 mm) and very flat pre-cancerous polyp (sessile serrated adenoma, non-granular, 0-IIa by Paris classification) that was found in the cecum during a previous screening colonoscopy. The procedures and outcome of this case are depicted in Figure 4. The polyp, which was too flat to remove with an endoscopic snare, was lifted via submucosal injection using an Olympus 25 gauge InjectorForceMax needle. Endoscopic submucosal dissection (ESD) was then performed with a dual knife, and the polyp was removed en bloc with 5 mm margins of healthy tissue.

This resulted in a large mucosal defect over 30 mm in diameter, which was completely closed using 4 QuickClip Pro clips. The patient reported no pain or complaints and was discharged home after the procedure. No complications were detected on follow-up.

The patient had a flat pre-cancerous polyp (sessile serrated adenoma) in the cecum (A). ESD was performed to remove the polyp (B, C), and QuickClip Pro was used to completely close the resultant mucosal defect (D, E). The polyp was large, measuring 20 mm in diameter (F).

ESD=endoscopic submucosal dissection.
Discussion

The design and features of QuickClip Pro, as described earlier, allow for precise handling and predictable performance with MRI conditionality. The 360-degree rotational ability of QuickClip Pro is particularly important because it shortens procedure time, allows precise positioning of the clip, and improves treatment efficacy and cost-effectiveness by decreasing the number of misfired and wasted clips.4,6 These features, taken together, contribute to the uniqueness of QuickClip Pro and its versatility, responsiveness, and effectiveness. The 2 cases presented here demonstrate that successful mucosal closure can be achieved using QuickClip Pro even under difficult conditions.

Case Report 1 presented with a history of achalasia. Although relatively rare, the incidence of achalasia appears to be rising with a doubling from about 0.8/100,000 per year in the 1980s to 1.6/100,000 per year in the 2000s.18 The cause of achalasia is unknown, but may be the result of an autoimmune response, infectious agent, and/or genetic predisposition.18 Case Report 1 had previously failed Botox injection and pneumatic dilation, both of which are known to be associated with high rates of recurrence.19 POEM was chosen as the best therapeutic option for Case Report 1. Use of POEM as a successful alternate treatment for achalasia was first described in 2010 by Inoue and colleagues.20 Recent analyses suggest that POEM and laparoscopic Heller’s myotomy provide similar efficacy outcomes in patients with achalasia (eg, Eckhart’s score, lower esophageal sphincter pressure, post-operative pain, need for analgesics, length of hospital stay, and symptomatic gastroesophageal reflux/reflux esophagitis) while POEM significantly reduces operative time.21 However, the procedure can be challenging with multiple adjacent endoclips being required for adequate closure. Routine closures usually require between 5 to 10 endoclips.22,23 Mucosectomy closure was anticipated to be difficult in Case Report 1 because of the patient’s dilated esophageal lumen and enlarged mucosal incision site. Despite the increased complexity, secure closure was achieved with only 7 endoclips.

Case Report 2 described a pre-cancerous polyp that was large (20 mm), very flat, and located in the cecum, all of which contribute to a challenging removal.24 The polyp was successfully removed using ESD, which is particularly useful for large lesions because it allows for en bloc removal.25 In contrast, lesions of this size are generally only amenable to piecemeal resection when endoscopic mucosal resection is used.25 En bloc resection has the advantage of permitting adequate histological evaluation of resected tissue margins and being associated with lower rates of recurrence compared with piecemeal resection.25,26 If ESD was not possible, the patient would have needed major surgery (laparoscopic right hemicolectomy). The size of the mucosal defect post-ESD was large. Patients with such a large defect are usually admitted to the hospital for several days of in-patient observation due to risk of delayed post-procedural complications (bleeding, perforation). Instead, 4 QuickClip Pro clips were used to completely close the defect and allow the patient to be discharged home the same day. The rotation of QuickClip Pro allowed for precise positioning of the clips to adequately approximate and close the edges of the mucosal defect post ESD. Moreover, the strong arms of the clips easily approximated the large diastasis between the defect’s edges. Closure of post-ESD defects reduces the risk of delayed bleeding and perforation, potential complications of the procedure.27 Consistent with these findings, Case Report 2 had no immediate or delayed complications.
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