New Devices and Techniques for Handling Adverse Events: Claw, Suture, or Cover?

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KEYWORDS

• Endoscopic closure • Endoscopic suturing • Over-the-scope-clip
• Cardiac septal defect occluder • Perforation • Fistula • Anastomotic leak

KEY POINTS

- Two devices are currently approved by the US Food and Drug Administration for endoscopic closure of gastrointestinal defects, including perforations, anastomotic leaks, and fistulas: the over-the-scope clip and the endoscopic suturing system.
- A third device, the cardiac septal defect occluder, has been adapted for use in the gastrointestinal tract.
- Devices are under development to facilitate closure by improving access to defects and simplifying closure.

INTRODUCTION

With the development of natural orifice translumenal endoscopic surgery (NOTES) and as therapeutic endoscopic procedures become more sophisticated, closure for iatrogenic mural defects of the gastrointestinal (GI) tract has become an evolving area in advanced interventional endoscopy.[1] Endoscopic clips were among the first endoscopic devices used for closure of perforations but are less effective for closure of larger defects, because of limited opening distance between jaws, low closure force, and inability to accomplish deep tissue capture.[2] Devices and techniques are under development to facilitate closure of GI wall defects. The ideal closure device should be inexpensive, safe, readily available (on demand), and easy to use and should provide rapid, reliable, and durable closure.[3]

INDICATIONS/CONTRAINDICATIONS

Endoscopic closure may be indicated in cases of inflammatory or neoplastic fistulas, dehiscence of surgical anastomoses, and iatrogenic or spontaneous perforations of

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the GI tract.[3] Advanced endoscopic procedures, including large polypectomies, endoscopic mucosal resection (EMR), endoscopic submucosal dissection (ESD), and peroral endoscopic myotomy (POEM), have become more commonplace, and the mural defects caused by the procedures themselves are amenable to endoscopic closure. Complications from bariatric surgery and colorectal surgery, including chronic anastomotic leaks and marginal ulcers, may also benefit from endoscopic alternatives.[4] An important contraindication to isolated endoscopic closure involves the clinical setting of delayed perforation with peritonitis and septic fluid collections.[5] **Table 1** lists indications and contraindications for endoscopic closure.

DEVICES

In the mid 1990s, endoscopic closure of gastric and colonic perforations with hemostatic clips was reported.[2,6] Since then, a variety of techniques have been used to close mucosal defects caused by polypectomy, EMR, ESD, POEM, and electrocautery.[4] The need for endoscopic solutions for closure of intentional transmural defects has continued to increase, particularly with current NOTES driven efforts at full-thickness resection.[7,8] The techniques used in human subjects include an over-the-scope clip (OTSC) (OVESCO, Tübingen, Germany; Padlock, Aponos Medical, Kingston, NH), the endoscopic suturing system (OverStitch, Apollo Endosurgery, TX), and cardiac septal defect occluders.[3]

Over-the-Scope Clip

The OTSC system is an endoscopic hemostatic clip that was first intended for the treatment of nonvariceal GI bleeding.[9] These clips, also referred to as the "bear claw", are made of elastic biocompatible nitinol capable of full-thickness closure through tissue approximation.[9,10] The device was approved by the US Food and Drug Administration (FDA) in 2010.[3]

Compared with standard through-the-scope (TTS) clips, OTSCs can provide single application closure for defects up to 2 cm.[5] The OTSC is believed to produce more durable closure than standard TTS clips, because of its ability to apply a greater compressive force, and when used in conjunction with specially designed tissue graspers provides single-layer full-thickness closure of open defects.[10–12] The OTSC has also been used for resection of submucosal tumors, treatment of bleeding lesions, and esophageal stent fixation.[10]

Endoscopic Suturing System

The endoscopic suturing system is a disposable, single-use suturing device that allows placement of running or interrupted full-thickness sutures using either permanent (polypropylene) or absorbable suture material.[13] In contrast to hemostatic endoscopic clips, the device was specifically designed to simulate hand sewing for any type of

Table 1
Endoscopic closure: indications and contraindications

Indications	Contraindications
Fistulas (inflammatory or neoplastic)	Uncontained perforations
Dehiscence of surgical anastomosis	Peritonitis
Perforations (iatrogenic or spontaneous)	
Mural defects from large polypectomies, EMR, ESD, POEM	
Anastomotic leaks	
Marginal ulcers	