

Endoscopic closure devices

The ASGE Technology Committee provides reviews of new or emerging endoscopic technologies that have the potential to affect the practice of GI endoscopy. Evidence-based methodology is used, with a MEDLINE literature search to identify pertinent preclinical and clinical studies on the topic and a MAUDE (U.S. Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the “related articles” feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases, data from randomized, controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. For this review, the MEDLINE database was searched through October 2011 using the keywords “enterotomy,” “gastrotomy,” “colostomy,” “perforation,” “fistula,” “natural orifice transluminal endoscopic surgery,” “closure,” “endoscopic suturing,” “endoscopic clipping,” and “placating.”

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BACKGROUND

Nonsurgical closure of the GI wall may be desired in the setting of inflammatory or neoplastic fistulae, dehiscence of surgical anastomoses, and spontaneous or iatrogenic perforations. Closure is also necessary after natural orifice transluminal endoscopic surgery (NOTES®). Several devices and techniques are being developed to allow

endoscopic closure of these GI wall defects. The ideal closure device should be inexpensive, safe, and easy to use. It should provide rapid, reliable closure, which is both robust and durable, and should also be effective in the closure of larger defects.

Among the first endoscopic devices used for the closure of small perforations were endoscopic clips.¹ Clips were discussed in a previous technology committee document.² Although endoscopic clips may provide an adequate closure solution for small defects, they are less useful for larger defects because of the restricted opening distance between their jaws, low closure force, and inability to accomplish deep-tissue capture. These deficiencies are particularly troublesome when trying to use endoscopic clips in the setting of the inflamed, indurated, and fibrotic tissue associated with chronic fistulae. Case reports and small case series also describe successful closure of perforations, fistulae, and anastomotic leaks by using tissue glues and covered self-expandable metal stents.³⁻⁵ However, these too provide an inadequate and unreliable solution. An unmet need has therefore persisted for a reliable and robust endoscopic solution for the closure of mural defects, both spontaneous and iatrogenic. With the development of NOTES as a new and potentially viable surgical platform, there has been an increasing interest and immediacy in the need to develop dedicated devices and techniques that allow closure of enterotomies. Although many endoscopic closure devices have undergone testing and evaluation in bench and animal models, only a few have been used in human subjects and only 2 are being actively marketed in the United States at this time.

EMERGING TECHNOLOGY

Over-the-scope clip

An over-the-scope clip (OTSC) (Ovesco, Tübingen, Germany) has been developed for the closure of small mural defects and bleeding ulcers.⁶ In animal models, reliable full-thickness closure of defects of as large as 27 mm was achieved with this device.⁷ The OTSC produces more durable closure than standard endoclips⁸ because of its ability to grasp more tissue, include the entire thickness of the visceral wall, and apply a greater compressive force. The OTSC received Conformite Europeene certification in Europe in 2009 and 510(k) clearance by the U.S. Food and Drug Administration (FDA) in 2010.

Description of the device. The device includes an applicator cap, a nitinol clip, and a hand wheel (Fig. 1).

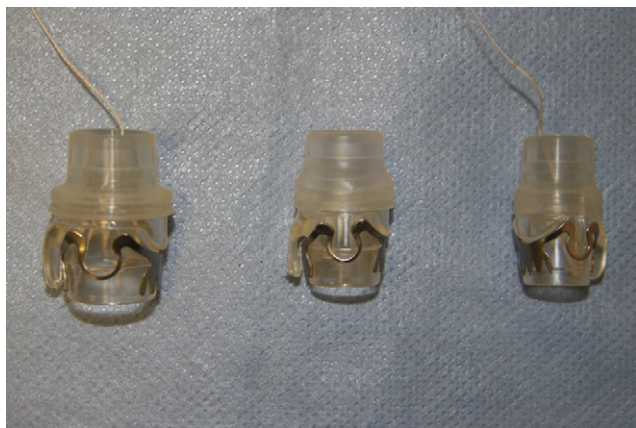


Figure 1. Over-the-scope clips: applicator caps; 3 sizes.



Figure 2. Over-the-scope clips: type a (rounded) (left), type t (pointed) (middle), and type gc (longer pointed) (right).

The applicator cap, with a mounted nitinol clip, is affixed to the tip of the endoscope in a manner similar to that of a variceal band-ligation cap. The clip fits onto the cylindrical cap in the open position. Caps are available in 3 diameters to accommodate various endoscope diameters: 11 mm (designed for endoscope diameters 9.5–11 mm), 12 mm (for endoscope diameters 10.5–12 mm), and 14 mm (for endoscope diameters 11.5–14 mm). With the applicator cap attached to the endoscope, the corresponding outer diameter of the instrument is 16.5, 17.5, or 21 mm. Caps are also available in 2 depths (3 and 6 mm) to allow variation in the amount of tissue grasped during approximation. Clips come in 3 different sizes to match the cap sizes and also with 3 different shapes of teeth (Fig. 2): type a (rounded), type t (pointed), and type gc (longer pointed). Clips with rounded teeth are used where the goal is tissue compression for hemostasis, particularly in the thinner walled esophagus and colon. Pointed teeth improve tissue capture and decrease the risk of the clip slipping in indurated or fibrotic tissue and are used for perforation and fistula closure. Clip type gc with longer

pointed teeth was designed for use in the thicker walled stomach.

The applicator cap incorporates a clip release thread, which is pulled retrogradely through the working channel of the endoscope and fixed onto a hand wheel mounted on the working-channel access port of the endoscope. The clip is released by turning the hand wheel, in a manner similar to deploying a variceal ligation band. On deployment, the clip returns to its baseline closed shape, capturing and compressing the tissue that was suctioned into the applicator cap. The deployed clips deliver enough compression force to allow firm apposition. Smaller defects can be closed by merely suctioning the defect and surrounding tissue into the cap, followed by clip deployment. Larger defects require one of the assist devices described in the following.

Assist devices. Three additional instruments are available separately that facilitate use of the OTSC.

Reloader. This device assists in mounting additional clips onto the applicator cap after deployment of the initial clip. Use of this device is only necessary if more than 1 clip is placed in the same treatment session.

Twin grasper. This device, which enables the user to grasp opposite edges of the defect sequentially and pull them together, facilitates apposition of the tissue before clip deployment. It is particularly useful for larger defects and for chronic defects associated with indurated tissue where suction alone may be inadequate to approximate tissue. It is available in flexible catheter lengths of 165 and 220 cm for use with gastroscopes and colonoscopes, respectively. An endoscope working channel of at least 3.2 mm is required to use this device, which is advanced along side the clip release thread. The device has 2 lateral, independently controlled, hinged, mobile jaws that can be apposed against an immobile, common central jaw, thereby allowing tissue approximation. The approximated tissue is then pulled into the applicator cap, additional suction applied if necessary, and the clip is then deployed by turning the hand wheel.

Anchor. This device is used to retract fibrotic tissue (eg, chronic fistulae and ulcers) into the cap when simple suction or the twin grasper may not be effective.⁹ This accessory consists of a 165-cm long flexible catheter with 3 retractable needle pins. When released, the 3 pins pierce tissue along a curved path, thereby anchoring it. The tissue can then be pulled into the applicator cap, suction applied if necessary, and the clip deployed. The anchor is then retracted and removed. An endoscope working channel of at least 3.2 mm is required to use this device with the OTSC system.

Overstitch endoscopic suturing system

The Overstitch endoscopic suturing system (Apollo Endosurgery, Austin, Tex) is a disposable, single-use suturing device that is mounted onto a double-channel therapeutic endoscope and allows placement of either running or



Figure 3. Overstitch: end cap attached to endoscope.

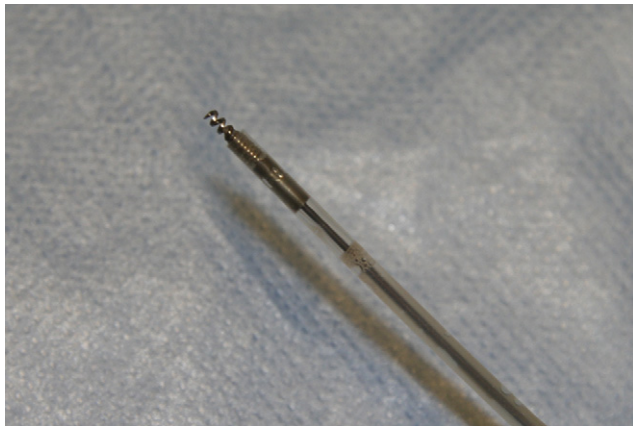


Figure 4. Overstitch: helix device.

interrupted full-thickness sutures (Figs. 3 and 4). The device represents an evolution of the previously described Eagle Claw device.^{10,11} A drawback is that it is only compatible with a single endoscope, the Olympus 2T160. The device obtained FDA 510(k) clearance in 2008. The initially marketed Overstitch device had multiple parts and was therefore relatively more complex to put together and use. The new version, released in October 2011, has been significantly simplified.

Description of device and technique. The device comprises 3 main parts: the end cap, the needle driver handle, and an anchor exchange catheter. Additional necessary assist components include a suture cassette, a cinching device, a helix device, and an overtube. The end cap, attached to the distal tip of the endoscope, houses a hinged, curved, hollow needle body that opens and closes in an arc. The needle driver handle opens and closes the suture arm. The suture cassette contains a suture that is attached to a tissue anchor, which serves as a T tag. Both absorbable (2-0 and 3-0 polydioxanone) and nonabsorbable (2-0 and 3-0 polypropylene) sutures are available. The tissue anchor attaches to the suture arm and acts as the tip of the suturing needle. Once a suture has been

positioned through tissue, the anchor exchange catheter allows the tip of the needle to be retracted so that additional tissue can be pierced.

Devices adapted for use in the GI tract

Cardiac septal defect occluders. The Amplatzer Septal Occluder (AGA Medical Group, Plymouth, Minn) is a device developed for occlusion of cardiac septal defects. However, the device has been used off-label for the closure of GI fistulae.¹²⁻¹⁵ This dumbbell-shaped device consists of 2 self-expandable disks composed of nitinol mesh with polyester fabric connected by a short waist. It is constrained within a 70-cm delivery catheter and deployed over an endoscopically placed guidewire similar to a self-expandable metal stent. The delivery catheter is too short to be passed through an endoscope, but the device can be deployed under direct visualization by passing the endoscope alongside it. After implantation, the device apposes the wall on each side of the defect, mechanically occluding it and potentially creating a platform for subsequent tissue ingrowth. The devices are available in a variety of waist diameters and waist lengths to allow closure of a range of defects. Selection of an appropriately sized device can be aided by sizing the mural defect by inflation of balloons of known diameter.

Closure devices tested only in bench and animal studies

These devices are detailed in Tables 1 through 3.

CLINICAL RESULTS

OTSC

Several case series have demonstrated successful use of the OTSC in the closure of acute GI perforations, anastomotic leaks, and chronic GI fistulae.^{6,9,50-55} Kirschniak et al⁶ initially described the use of this device in the successful closure of 2 small (4 and 8 mm) iatrogenic colonic perforations and 2 deep mucosal resection sites (also 4 and 8 mm in size) in colonic and gastric walls. A further case report from the same group described closure of a gastric perforation related to necrotizing pancreatitis with the placement of 2 adjacent OTSCs.⁵⁶ This group recently reported their accumulated experience in the use of the OTSC in the closure of 11 GI perforations (4 retroperitoneal) and 8 chronic GI fistulae.⁵⁴ All GI perforations were successfully closed with the OTSC. However, 2 of 5 gastric and all 3 colonic fistulae were noted to recur between 5 and 11 days after initial transient closure with the OTSC.

A more detailed case series from another group describes the performance of the OTSC in 12 patients with anastomotic leaks, perforations, or fistulae.⁵⁷ Primary closure was achieved in 9 of these 12 patients, giving an immediate success rate of 75%, with long-term success maintained in 8 patients (66%). The 4 treatment failures

TABLE 1. Endoscopic closure techniques

Technique	Description	Assist devices	Animal studies
Trial of no closure of defect	Gastric puncture dilated with balloon. Because there is dilation only, the muscularis approximates edges and closes defect.	None	Porcine, ¹⁶ canine ¹⁷ survival
Self-approximating tunnel/flap	Submucosal tunnel with exit site distant from mucosal entry site; mucosa closed with clips.	Endoscopic hemostatic clips	Porcine gastric, ^{18,19} and esophageal ²⁰ closure
Gastropexy method	Gastrotomy is pulled up to anterior abdominal wall and sutured in place with transmural T tags or other sutures.	Endoscopic grasping forceps, T tags	Porcine survival ²¹
Omentoplasty method	Omental patch is pulled into gastric defect to plug hole, and is fixed in place with clips.	Endoscopic hemostatic clips and forceps	Porcine survival ²²

included a patient in whom clip placement was not successful because of the inability to approximate tissue, a patient with a chronic gastrocutaneous fistula in whom the clip detached within 1 day of placement, and 2 patients with chronic enterocutaneous fistulae for which the OTSC deployed, but only incomplete closure was achieved. Successful closure was invariably achieved (100%) if the defects were closed within a week of diagnosis, compared with a 57% closure rate when defects were closed more than 4 weeks after diagnosis. Another European group described their experience closing perforations and anastomotic leaks with the OTSC.⁵⁵ Successful closure was achieved and surgery avoided in 4 of 7 patients. In a further case series of patients with perforations, fistulae, and anastomotic leaks, successful closure was achieved in 8 of 10 patients.⁵² Although the OTSC is cleared by the FDA for closure of defects as large as 20 mm, closure of larger gastric defects by using 2 clips deployed adjacent to each other has been reported.^{56,57}

The induration and fibrosis associated with chronic fistulae may result in failure of adequate tissue apposition and a consequent inability to deploy the OTSC satisfactorily.⁹ This may result in challenging, protracted procedures. In a recent small case series, OTSC placement was successful in only 2 of 4 patients, despite procedure times ranging from 24 to 93 minutes.⁹ Cauterization of the margins of chronic fistulae has been advocated to facilitate subsequent closure with the OTSC.⁵¹

Initial results of an ongoing prospective multicenter European study evaluating the performance of the OTSC in iatrogenic perforations have been published in abstract form.⁵⁸ OTSC placement was attempted in 14 patients with iatrogenic GI tract perforation in a variety of locations. The procedure was abandoned in 1 patient because of a device-related esophageal mucosal laceration. The OTSC

was successfully deployed in 13 patients. Closure was successful and achieved rapidly, with a median closure time of 4 minutes, 30 seconds. Contrast studies performed within 24 hours indicated no contrast extravasation in any patient. Twelve patients did well and resumed an oral diet at a median of 1 day post-procedure. One patient deteriorated because of incomplete closure and died despite subsequent surgery.

Overall, the initial data suggest that OTSCs are effective in closing acute perforations and to a lesser extent in the closure of chronic fistulae.

Overstitch

Only a single case report has currently been published documenting use of the Overstitch device for the closure of a refractory gastrocutaneous fistula.⁵⁹ A small case series (6 patients) published only in abstract form describes initial closure of rectovaginal and gastromediastinal fistulae as well as gastrogastic fistulae after Roux-en-Y gastric bypass; no long-term follow-up is available.⁶⁰

Cardiac septal defect occluders

Case reports describe the use of cardiac septal defect occluders in the successful initial closure of tracheoesophageal, tracheogastric, and gastrocolonic fistulae.¹²⁻¹⁵

SAFETY

A single perforation was reported after placement of the OTSC for a bleeding duodenal ulcer.⁵⁷ Mucosal lacerations have been reported after advancement of the OTSC through the upper esophageal sphincter and esophagus.^{55,58} Device malfunction resulting in partial release with the clip stuck to the applicator cap has been reported.⁹ This report describes premature complete release during a training session in an animal laboratory, resulting

TABLE 2. Endoscopic closure devices: animal studies

Device	Company	Description	Assist devices	Animal studies
Adaption of older devices designed for other use				
Bioabsorbable plugs	W.L. Gore & Associates, Flagstaff, Ariz	Gore bioabsorbable hernia plug, a plug made from biodegradable polymer	Placed surgically in a proof-of-concept study	Canine survival ²³
Cardiac septal occluder	AGA Medical, Plymouth, Minn	Nitinol, dumbbell-shaped plug with polyethylene terephthalate sewn-in patch	None	Porcine survival ²⁴
Mucosal clips	Olympus, Center Valley, Pa; Boston Scientific, Natick, Mass	Endoscopic hemostatic clips used to approximate tissue for closure	None or endoscopic grasping forceps	Porcine survival ^{25,26}
Endoloops	Olympus	Defect gathered up and sealed with endoloops alone or in combination with clips or endoscopic hernia tacks	Endoscopic grasping forceps, clips, hernia tacks	Porcine survival ²⁷⁻³⁰
Tissue anchors	Cook Endoscopy, Winston-Salem, NC; Ethicon Endosurgery, Cincinnati, Ohio; other noncommercial groups	T bars and other types of anchors placed transmurally and cinched or sutured in place to effect closure	Endoscopic graspers, needles	Porcine gastric explants and porcine survival studies ³¹⁻³⁵
New dedicated experimental devices				
Looped (connected) T anchors	Cook Endoscopy	T tags have a small metal loop on the cross piece. Multiple tags can be loaded on 1 suture, and when tension is applied, a purse-string closure is obtained	Friction-fit collar or other cinching device	Porcine survival ^{36,37}
OTSCs	Aponos, Kingston, NH	OTSC nitinol clip shaped like 6-point star. Internal prongs gather defect together and keep it closed	Endoscopic grasping forceps, delivery pod, T tags as needed	Porcine survival ³⁸
Flexible linear stapler	Power Medical, (now owned by Covidien, New Haven, Conn)	Defect closed by gathering it into jaws of flexible surgical stapler and firing to close tissue	Endoscopic grasping forceps	Porcine nonsurvival ³⁹ and survival ⁴⁰
Circular stapler	Power Medical	Absorbable mesh with interwoven endoloop is stapled into gastrotomy with cutting circular stapler. Defect closed by cinching endoloop.	Laparoscopic assistance needed	Porcine gastric explant, canine survival ⁴¹

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TABLE 2. (Continued)

Device	Company	Description	Assist devices	Animal studies
Suturing devices	LSI Solutions, Victor, NY	Prototype device creating purse-string suture	None	Porcine gastric explant ⁴²
		Eagle Claw flexible suturing device	None	Porcine gastrotomy closure, survival ⁴³
Endoscopic rivets	N/A (prototype)	Bioabsorbable polymer rivet with absorbable magnesium alloy needle tip	None mentioned	Explanted stomachs ⁴⁴

OTSC, Over-the-scope clip; N/A, not available.

TABLE 3. Devices tested in humans (not currently marketed for endoscopic closure)

Device	Company	Brief description	Assist devices	Human studies	Comments
T anchors	Ethicon Endo Surgery, Cincinnati, Ohio	T anchors cinched together in pairs	Endoscopic grasping forceps as needed	Has been used for closure of gastrogastic fistulae after Roux-en-Y gastric bypass ⁴⁵	Case reports only, no long-term data available
NDO plicator	NDO Surgical, Mansfield, Mass	Single-use, pledgeted, suture implants	Tissue grasper, various guidewires	Designed as an endoscopic therapy for GERD ⁴⁶	Case reports only, no long-term data available
G Prox	USGI Medical, San Clemente, Calif	Flexible tissue grasper that can deliver expandable tissue anchors	Transport (shape-locking overtube)	Gastric closure during transgastric cholecystectomy ^{47,48}	Appears effective for gastrotomy closure in NOTES
Endocinch	Bard, Murray Hill, NJ	Endoscopic suturing device intended for creating plications at GE junction to act as an antireflux procedure	Endoscopic suturing device	Has been used for closure of gastrogastic fistulae after Roux-en-Y gastric bypass ⁴⁹	Case reports only, no long-term data available

NOTES, Natural orifice transluminal endoscopic surgery; GE, gastroesophageal.

in the OTSC inadvertently attaching a twin grasper device to the GI wall, tethering the endoscope. Clips that are partially dislodged over the cap before deployment should therefore be removed and replaced; care should also be taken to avoid inadvertent deployment of the clip over the twin grasper.

Significant postprocedural pain was reported in a single patient after application of the OTSC.⁵⁵ Clip detachment within a day of successful placement was reported,⁵⁷ and this possibility should be considered in patients who deteriorate clinically after initial successful clip deployment. Poorly placed or partially detached clips may also po-

tentially compromise relatively narrow lumens such as the esophagus. Although the OTSC often detaches with healing of the underlying lesion, follow-up endoscopic procedures have indicated sustained clip attachment for as long as 123 days in some patients.⁵⁵ In patients in whom the clip detaches, it appears to pass spontaneously. To date, there have been no reports of obstruction after clip placement. Clips have also been removed endoscopically 3 months after application for management of perforation.⁶

Safety data are not available for GI applications of the Overstitch device and cardiac septal occluders.

RESEARCH AGENDA

Although initial case series using these devices are encouraging, further large prospective studies should be performed to evaluate the safety, efficacy, ease of use, and relative cost benefits of these devices in the closure of acute and chronic GI wall defects.

A major issue in the closure of GI wall defects is maintaining sufficient air insufflation of the lumen to allow adequate visualization for repair. Methods to improve air insufflation and visualization should be studied in conjunction with these closure devices, including abdominal venting and the use of carbon dioxide for insufflation.

SUMMARY

Several new devices offer the prospect of robust and durable endoscopic closure of acute and chronic GI wall defects, including spontaneous and iatrogenic perforations, anastomotic leaks, and chronic fistulae. They may also allow satisfactory closure of enterotomies created for NOTES procedures. The OTSC and Overstitch systems are currently being marketed in the United States. Case series have demonstrated the effectiveness of the OTSC in the closure of acute defects. Its efficacy in chronic fistulae may be partially impaired by the difficulties in approximating indurated, fibrotic tissue for closure. The Overstitch device is more complex to use and is not suited for smaller lumens. However, it offers the potential advantages of being able to close larger or more chronic defects. Further prospective studies are needed to define the role of these devices in the closure of GI wall defects.

DISCLOSURE

All authors disclosed no financial relationships relevant to this publication.

Abbreviations: ASGE, American Society for Gastrointestinal Endoscopy; FDA, U.S. Food and Drug Administration; OTSC, over-the-scope clip.

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