Efficacy of full-thickness GI perforation closure with a novel over-the-scope clip application device: an animal study

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Background: A novel, over-the-scope clip (OTSC) system may be suitable for closure of various GI perforations. The strength and maximum diameter of closure for a single OTSC, however, are unknown.

Objective: To determine the maximum closure capacity (diameter) and pressure threshold for a single OTSC.

Design: Prospective ex-vivo study.

Setting: Academic medical center.

Method: Full-thickness, standardized defects of 5 mm, 10 mm, 15 mm, 20 mm, and 25 mm were created in porcine stomachs. Similarly, full-thickness defects of 10 mm, 20 mm, 25 mm, 30 mm, and 35 mm were created in porcine colons. A single OTSC was endoscopically deployed 5 times for each full-thickness defect size in an ex-vivo endoscopic simulator.

Main Outcome Measurements: Each closure site was tested under water with compressed air for burst pressure.

Results: We achieved successful closure in all stomach defects ranging from 5 to 20 mm by using 12-mm OTSCs with short teeth and colon defects ranging from 10 to 30 mm with 14-mm OTSCs with short teeth. Mean (± standard deviation [SD]) burst pressures for the gastric closure sites were 74.9 ± 17.5 mm Hg for 15-mm defects, 49.3 ± 21.6 mm Hg for 20-mm defects, and 15.2 ± 4.1 mm Hg for 25-mm defects. Mean (± SD) burst pressures for the colon closure sites were 117.9 ± 40.1 mm Hg for 20-mm defects, 57.4 ± 4.2 mm Hg for 30-mm defects, and 10.9 ± 7.6 mm Hg for 35-mm defects.

Limitations: Ex-vivo study, does not reflect difficult locations.

Conclusion: Full-thickness tissue defects ranging from 5 to 20 mm in the stomach and from 10 to 30 mm in the colon can be closed adequately with a single OTSC in an ex-vivo experimental setting. Tissue defects larger than 20 mm in the stomach and 30 mm in the colon may require more than one OTSC or supplemental endoclips to achieve adequate closure. Endoscopic inspection of the closure site does not assure adequate closure of larger perforations. (Gastrointest Endosc 2011;74:1369-75.)

Abbreviations: NOTES, natural orifice translumenal endoscopic surgery; OTSC, over-the-scope clip; ESD, endoscopic submucosal dissection; EMR, endoscopic mucosal resection; EUS, endoscopic ultrasound; FNA, fine needle aspiration; ERCP, endoscopic retrogrado cholangiopancreatography; IACUC, institutional animal care and use committee.

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The invasiveness and complexity of endoscopic procedures are increasing, based on the development of new therapeutic techniques and devices. With more advanced therapeutic endoscopic procedures, endoscopists may be confronted more often with perforations, fistulas, and anastomotic leaks, for which nonsurgical closure may spare patients from open or laparoscopic surgical interventions. Most cases of iatrogenic perforations occur during therapeutic procedures, such as endoscopic submucosal dissection (ESD), EMR, EUS-guided FNA, and ERCP sphincterotomy.[1-4] Perforations occurring during diagnostic and therapeutic endoscopy may be large in diameter.[5] Furthermore, natural orifice translumenal endoscopic surgery (NOTES) is advancing, and effective and reliable endoscopic closure methods will be required before NOTES can be safely implemented in humans on a large-scale basis.

Endoscopic perforations treated with endoclips have been described in the literature since 1997.[6] However, full-thickness defects closed with endoclips have limitations. For example, their closure is confined to the mucosal layer, there is a relatively low closure force, and the opening span between the jaws is restricted. Therefore, multiple clips are commonly applied for perforations.[7-9] A new over-the-scope clip (OTSC) system (Ovesco Endoscopy AG, Tübingen, Germany) has a simple method of application and is designed to create full-thickness closure by using teeth arranged in the shape of a bear trap. The OTSC is made of a super-elastic, shape-memory alloy (nitinol), which takes its former unbent shape after the clip is released, and thus exerts constant compression on the tissue between the jaws of the clip. The material is biocompatible and magnetic resonance imaging compatible and can remain in the body as a long-term implant, although it usually sloughs off with the healing of a lesion (sloughing time varies from weeks to months). The nitinol clip is mounted on a clear distal cap at the end of an endoscope and is deployed by turning a wheel on the shaft of the endoscope. Several ex-vivo, animal, and clinical studies have demonstrated the efficacy of the OTSC since 2007.[10-15] The strength of closure and the maximum diameter of closure, however, for a single OTSC are unknown. The aim of this study was to evaluate the maximum closure diameter and pressure threshold for a single OTSC.

Take-home Message

- A novel, over-the-scope clip (OTSC) system recently has been developed, which may be appropriate for closing various-sized, full-thickness defects in the GI tract.
- The OTSC system adequately and reliably closes full-thickness defects of up to 20 mm in the stomach and up to 30 mm in the colon.

MATERIAL AND METHODS

The study was exempt from institutional review board/IACUC approval because it involved no human or live animal subjects. Fresh ex-vivo esophagus-stomach-duodenum packages and distal colons were harvested from Yorkshire pigs weighing from 80 to 120 kg and used with the EASIE-R simulator platform (Endosim, LLC, Berlin, Mass). The ex-vivo specimens were a by-product of the meat processing industry. The volume of the stomachs ranged from 1000 to 1500 mL, comparable to a small adult human stomach. The length of the colon specimens was 40 cm, with diameters of 6 to 8 cm.

Creation of full-thickness defects

Standardized, full-thickness defects of 5 mm, 10 mm, 15 mm, 20 mm, and 25 mm were created in the body and greater curvature of the ex-vivo porcine stomachs, and full-thickness defects of 10 mm, 20 mm, 25 mm, 30 mm, and 35 mm were created 10 to 15 cm from the anal verge in the ex-vivo colons. The full-thickness, linear defects were made using a surgical scalpel and were measured with a ruler both inside and outside of the specimen (Fig. 1).

Defect closure by OTSC

The OTSC system was mounted onto the tip of a double-channel endoscope (GIF-2T 160; Olympus America, Inc, Center Valley, Pa). We used 12-mm OTSCs with short teeth (12-t) for closing defects in the stomach and 14-mm OTSCs with short teeth (14-t) for closing defects in the colon. The OTSC Twin Grasper (Ovesco Endoscopy, Tübingen, Germany), deployed through the working channel, was used to facilitate approximation of the tissue before closure. The Twin Grasper has two independently movable lateral claws (Fig. 2A-C). Thus, all layers of both incision edges can be grasped separately and approximated in preparation for full-thickness closure with the OTSC. The closure process was as follows: (1) The lesions were located from 6 to 12 o'clock in the endoscopic view (Fig. 3A), (2) the center of one of the lateral edges of the perforation was grasped by one arm of the OTSC Twin Grasper with assurance that all layers of the GI wall, including serosa, were contained in the bite (Fig. 3B), (3) the center of the other opposing edge of the perforation was grasped with the second arm of the OTSC Twin Grasper, sufficiently to bring the two sides of the perforation into complete contact (Fig. 3C), (4) the reapposed tissue was pulled into the OTSC cap at the tip of the endoscope. The grasper, including apposed tissue, was withdrawn into the cap before the clip was applied (Fig. 3D), (5) sufficient suction was maintained to aspirate the tissue surrounding the perforation into the cap (Fig. 3E), (6) the OTSC was then released by turning a wheel on the shaft of the endoscope, similar to the endoscopic band