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Balloon-Armed Mechanical Counter Traction and Double-Armed Bar Suturing Systems for Pure Endoscopic Full-Thickness Resection

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Endoscopic full-thickness resection (EFTR) is a gastric full-thickness partial resection. As tumor enucleation surgery, EFTR may be less invasive than laparoscopic partial resection. However, EFTR has many difficult technical challenges, such as visualizing a clear operative field under a collapsed stomach and endoscopic suturing device. Regarding suturing devices, the only commercially available device is the Over-the-Scope Clip (Ovesco Endoscopy GmbH, Tuebingen, Germany),[1] a clip-based suturing device that is easy to use. The recent development of the Overstitch System (Apollo Endosurgery, Austin, TX)[2] enabled full-thickness suturing with a suturing thread. To obtain the operative field, the lifting method or the mechanical counter traction device[3] have been reported; however, it was very difficult to obtain sufficiently the operative field at certain areas of the stomach, such as in the retroflexed view. We report a newly developed countertraction and full-thickness suturing device for the flexible endoscope.

Description of Technology

Flexible endoscopic treatments rely on insufflation with air to expand the digestive lumen. However, if the gastrointestinal tract is perforated, insufflated air flows into the peritoneum and the gastrointestinal tract can collapse rapidly. To obtain an operative field without insufflation, we developed the balloon arm-mechanical countertraction system (BA-MCTS; Figure 1*A*). Even for difficult lesions that needed to be retroflexed, the BA-MCTS can obtain a sufficient operative field, enabling full-thickness resection and suturing at any area of the stomach. The 1BA-MCTS is equipped with a single-sided, expanding balloon arm, and 2BA-MCTS with 2 single-sided, expanding balloon arms. The full-thickness suturing device and 2 balloons are located at the apices of an equilateral triangle and allow an en face approach to the perforation site. The 2 balloons can be expanded independently (Figure 1*B*, *C*). The double-armed bar suturing system (DBSS) has been developed, making it more economical, structurally simple, and safe (Figure 1*D*). The DBSS has a very tiny connector with an absorbable suture thread woven into it on both sides of the end of the first arm. A second arm is equipped with a needle that can be inserted into the gastric wall and connected to the connector of first arm. An interrupted suture of 4-mm bite and 4-mm pitch can be performed safely and easily. As smaller suturing device, the mini double armed bar suturing system (mini-DBSS) was developed for the final stages of suturing. As suturing and ligation proceed, the resected opening becomes smaller and retraction of the first arm from outside the gastric wall into the lumen becomes difficult. In these situations, the mini-DBSS is useful (Figure 1*D*). The ligation device was developed to be simpler and smaller. The 5-mm ligation device attaches to the penetrating needle (Figure 1*E*). To allow the suture thread to be cut even when drooping, a hook cutter was designed (Figure 1*F*).

Video Description

Video 1 shows an ex vivo experiment performed using a resected porcine stomach. A 30-mm perforation was made (Figure 2*A*), and the reliability of full-thickness suturing was examined without BA-MCTS and with the 1BA-MCTS or 2BA-MCTS. At the final stage of suturing, we demonstrate suturing of a narrow perforation site with the mini-DBSS. Suturing without countertraction, because the DBSS could not be placed in front of the perforation site, the second arm penetrated gastric wall in a semiblind manner.

For closure using 1BA-MCTS, a single-sided balloon (20-mm expanded diameter) expanding only in the opposite direction of endoscopic view was attached to the contralateral side of DBSS. The balloon was inflated near the perforation site to expand the collapsed gastric wall; however, the limited bidirectional expansion together with DBSS shaft could not obtain a sufficient operative field (Figure 2*B*).

Abbreviations used in this paper: **BA-MCTS, balloon arm-mechanical counter traction system; DBSS, double-armed bar suturing system; EFTR, endoscopic full-thickness resection.**

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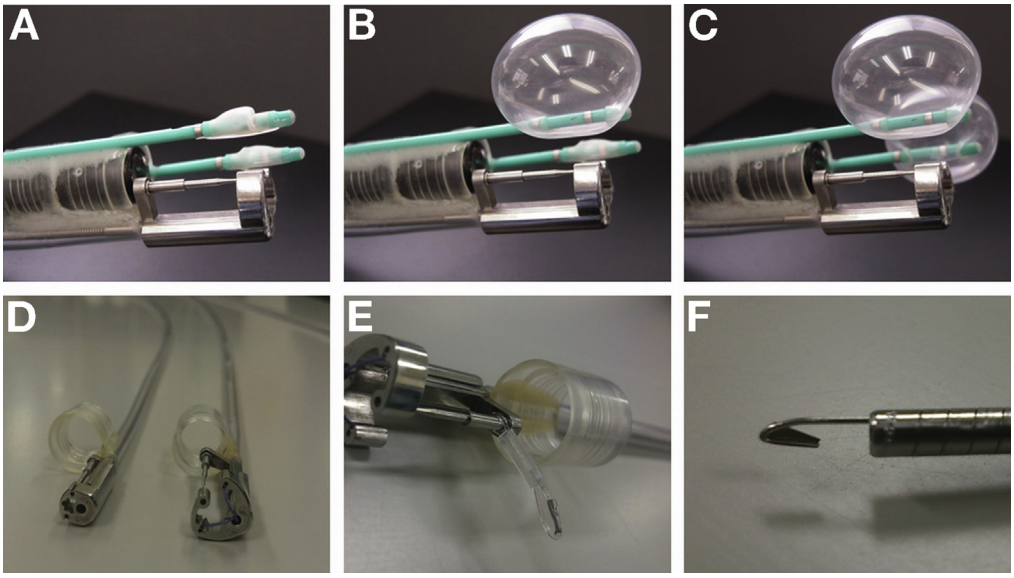

Figure 1. Balloon-arm-mechanical counter traction system (BA-MCTS) and suturing device. (*A*) The BA-MCTS is a single-sided expansion balloon device for obtaining an operative field without insufflation. It obtains a sufficient operative field, even in a retroflexed view, making full-thickness suturing possible without insufflation. (*B*) The left and right balloons can be expanded independently. (*C*) The full-thickness suturing device and the 2 balloons are positioned at the apices of an equilateral triangle, and can expand a perforation site en face. (*D*) Two types of double-armed bar suturing system (DBSS) make it more economical, structurally simple, and safe. The smaller mini-DBSS was developed for use in the final stages of suturing, and was designed to enable the easy retraction of the first arm when the resected opening narrows. (*E*) The ligation device was attached to the penetrating needle, and is approximately 5 mm in size. (*F*) By using the hook cutter, the suturing thread can be cut even when drooping. The hooked suturing thread can be cut easily by pulling between the sheath and the cutter on the inner surface of the hook.

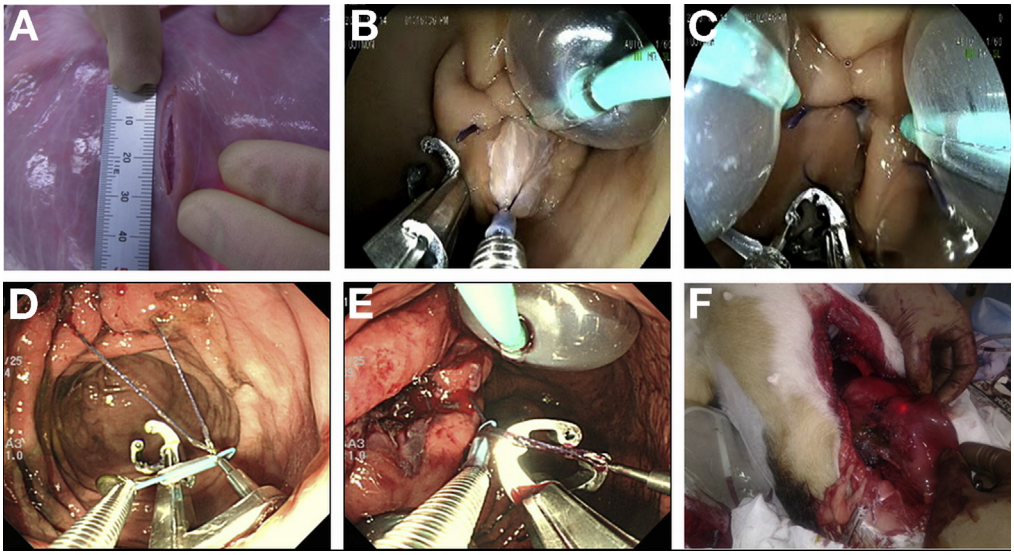

Figure 2. Ex vivo and in vivo experiments. (*A*) A 30-mm perforation made in an excised porcine stomach. (*B*) Suturing by single balloon-arm-mechanical counter traction system (1BA-MCTS), a single-sided balloon (20-mm expanded diameter) expanding only in the opposite direction was attached to the contralateral side of the double-armed bar suturing system (DBSS). The limited bidirectional expansion together with DBSS shaft could not obtain sufficient operation field. (*C*) The 2BA-MCTS, with DBSS and the 2 balloon arms located at the apices of an equilateral triangle, enabled a 3-point expansion of the operating field, obtaining sufficient operation field. (*D*) Endoscopic full-thickness resection (EFTR) of 30 mm of the lesser curvature of the lower body of the stomach successfully performed under the retroflexed view. (*E*) EFTR of the anterior wall of the middle body of the stomach performed with the 2BA-MCTS. (*F*) One dog survived for 1 year; the other 2 were humanely killed. A pressure leak test of 1900 Pa(G) was confirmed by leakage testing.

For closure using the 2BA-MCTS, DBSS and the 2 balloon arms were attached at the apices of an equilateral triangle, which enabled the expansion of the operation field at 3 points, allowing clear view of perforation site. Even in the collapsed stomach, expanding the operative field at 3 points allowed en face visualization of the perforation site without insufflation, and the appropriate expansion strength enabled accurate suturing bite and pitch (Figure 2*C*).

After 6 stitches were taken, the first arm was inserted into the remaining 6-mm perforation site and suturing continued; however, retraction of the first arm back into the stomach was very difficult. Therefore, further suturing was performed using the mini-DBSS. The mini-DBSS has a small arm on 1 end, and the back-and-forth movement of the second arm allows full-thickness suturing of narrow perforation of the gastric wall. It has the same basic structure as the DBSS. The 30-mm perforation was sutured using 7 stitches with 4-mm pitch and bite, performed using DBSS and mini-DBSS. In addition, to strengthen the closure, 2 mucous membrane purse-string sutures were performed using the mini-DBSS. Finally, we conducted an air leak test.

In Video Clip 2, we performed in vivo EFTR experiments on female Beagle dogs of 30-mm diameter hypothetical lesions in the lesser curvature of the lower body (Figure 2*D*), the anterior wall of the middle body (Figure 2*E*), and the posterior wall of the middle body of the stomach. In addition, the DBSS was used for full-thickness, simple, interrupted suturing with a 4-mm bite and a 4-mm pitch. Subsequently, 2 of the dogs were humanely killed and a pressure resistance capacity of 1900 Pa(G) was confirmed by leak test (Figure 2*F*).

Take Home Message

EFTR performed using only flexible endoscopy requires appropriate devices for obtaining the operative field and complete full-thickness suturing. In this study, we used animal models to show that EFTR can be performed safely in multiple locations within the stomach, and we believe that this technique can be applied clinically.

Supplementary Material

Note: To access the supplementary material accompanying this article, visit the online version of *Gastroenterology* at www.gastrojournal.org, and at http://dx.doi.org/10.1053/j.gastro.2014.06.030.

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Reprint requests
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Conflicts of interest
The authors disclose no conflicts.

Supplementary Methods

Stepwise Chronology of DBSS Technique

Step-1: One end of the first arm was inserted 4 mm into another edge of the serosal side of the resected opening. Step-2: The second arm (the puncture needle) moved forward and penetrated the full thickness of the gastric mucosa. Step-3: When the thread and connector joined the first arm and puncture needle, they were pulled out from the gastric mucosa. Step-4: The second arm were rotated and moved to align with the tip of the other arm. Step-5: Similarly, the arm was placed at the other resected margin, and the puncture needle of the second arm was passed through the gastric wall. Step-6: The full thickness of both resected margins was tied with an absorbent thread in the shape of an isosceles triangle. Step-7: the detainment snare was gradually contracted, and ligation was completed.

Advantages of DBSS Technique

I. The handling of the DBSS is very simple. Only the back-and-forth parallel movement of the second arm allows full-thickness suturing.

II. The DBSS and Mini-DBSS are attached to the conventional single channel endoscope very easily only to put the tip attachment equipped the DBSS. Two channeled endoscope is not necessary.

III. The first arm works as safety stopper of the second puncture needle arm to prevent adjacent organs.