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DYNAMIC MANUSCRIPT

Feasibility of pure EFTR using an innovative new endoscopic suturing device: the Double-arm-bar Suturing System (with video)

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Abstract

Background Endoscopic full-thickness resection (EFTR) requires a reliable full-thickness suturing device and an endoscopic counter-traction device to prevent the collapse of the digestive tract.

Objective The present study aimed to assess the reliability of newly developed flexible endoscopy suturing devices and the feasibility of pure EFTR.

Methods A total of 30 EFTRs were performed and allocated to three groups ($N = 10$ for each group). The full-thickness sutures were placed using over-the-scope clips (OTSCs), hand-sewn sutures, or the Double-arm-bar Suturing System (DBSS). Air leak tests were conducted in the three groups. The times required for the placement of one OTSC suture and single-stitch simple interrupted sutures (hand-sewn and DBSS sutures, respectively) were also compared.

Results All 30 full-thickness sutures were completely and successfully placed. Regarding the air leak tests, the Mann–Whitney U test showed significant differences between OTSC and hand-sewn sutures ($p = 0.003$). There was also a significant difference between OTSC and DBSS sutures ($p = 0.023$). There was no significant difference between hand-sewn and DBSS sutures ($p = 0.542$). A significant difference was found in the suture time for single-stitch simple interrupted sutures among the OTSC, hand-sewn, and DBSS sutures. The Mann–Whitney U test revealed a significant difference between OTSC and hand-sewn sutures ($p = 0.0001$). There was no significant difference between OTSC and DBSS sutures ($p = 0.533$), while a significant difference was found between hand-sewn and DBSS sutures ($p = 0.0001$).

Conclusions Pure EFTR is feasible if the mechanical counter traction system is used to expand a small operative field and DBSS is used to make full-thickness sutures. The high safety of full-thickness resection and full-thickness suturing allows for clinical applications of this method.

Keywords Pure endoscopic full-thickness resection · Over-the-scope clip · Double-arm-bar Suturing System · Air leak test

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In 2004, Kalloo et al. from Johns Hopkins University introduced transgastric peritoneoscopy [1], in which a flexible endoscope is used to make an incision in the gastric wall. Since then, natural orifice transluminal endoscopic surgery (NOTES) has increasingly attracted attention as a minimally invasive procedure [2–8]. The globally advanced Japanese endoscopic submucosal dissection (ESD) technique is fully available for procedures involving the abdominal cavity. Clinical applications of hybrid NOTES have also been reported [9]. However, two major problems must be resolved to realize successful pure NOTES: full-thickness suturing and securing the operation field. Full-thickness suture devices need to be structurally simple, inexpensive, highly reliable in terms of suture strength, and easy to operate. Many endoscopists and surgeons are working on the development of flexible endoscopic full-thickness suturing devices; however, to date, only a few full-thickness suture devices have been developed, including T-bars (Wilson-Cook Medical, Winston-Salem, NC, USA) [10, 11], the Eagle Claw (Olympus, Tokyo, Japan) [12], the Overstitch System (Apollo Endosurgery, Austin, TX, USA) [13, 14], and over-the-scope clips (OTSCs) [15, 16]. The only full-thickness suture devices that are commercially available in the USA are the Overstitch System and OTSCs.

In the present study, to perform pure endoscopic full-thickness resection (EFTR), it was necessary to use a highly reliable, full-thickness suturing device under a clear surgical field with counter-traction to prevent the collapse of the digestive tract during the full-thickness resection. Because counter-traction and a full-thickness suture device are together considered essential for EFTR, a series of procedures were performed, ranging from full-thickness resection of whole swine stomachs to full-thickness suturing of the resected perforation for verification of suture strength of our newly innovated devices using a leak test, as well as for verification of the feasibility of pure EFTR.

Materials and methods

A 40-mm diameter EFTR procedure was performed on 30 excised whole swine stomachs (Shounai Meat Co., Yamagata, Japan) from pigs of similar body weight using a mechanical counter traction system (MCTS) prototype without insufflation [17]. Figure 1 shows a flow diagram of this ex vivo study. The resection site was the anterior wall in the middle gastric body of the stomach. EFTR without insufflation was performed as follows. A prototype overtube (diameter 25 mm; length 800 mm; XEMEX Co., Tokyo, Japan) mounted onto the distal end was inserted into the stomach from the lower esophagus of excised swine stomachs (Fig. 2A). Under non-insufflation conditions, the resection site of the collapsed stomach wall was expanded with ten expansion arms; a dual knife was used in the forced mode (50 W, effect 4) to make a circular marking at the site representing a 40-mm diameter virtual tumor. The dual knife was used to achieve a full-thickness, full-circumference resection of the stomach wall in high-cut mode (150 W, effect 3) (Fig. 2B). Dr. Hirohito Mori (HM) invented the Double-arm-bar Suturing System (DBSS) device and obtained a patent for it (Patent No. 2011-13025). Subsequently, HM and the Medical Engineering section of Zeon Medical Co., Tokyo, Japan collaborated on the development of a prototype DBSS. The DBSS was manufactured by Zeon Medical Co., Tokyo, Japan. Dr. Hirohito Mori has no conflicts of interest and no financial arrangement with any company, institution, or third party.

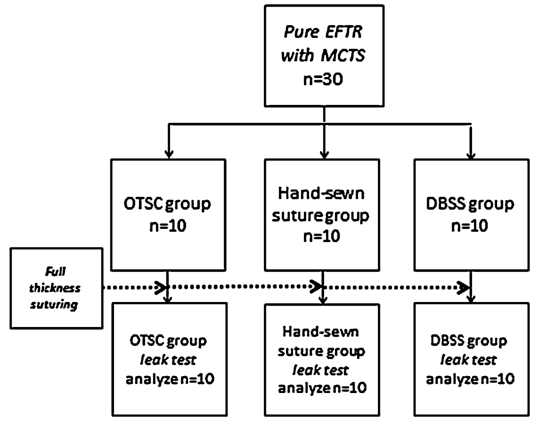

Fig. 1 Flow diagram of methods. Whole excised swine stomachs, including the esophagus and duodenum, were used to perform 30 cases of 40-mm pure EFTR using an MCTS prototype. Suturing with full-thickness sutures was performed in three groups, namely the OTSC, hand-sewn suture, and DBSS groups (ten cases in each group). *DBSS* Double-arm-bar Suturing System, *EFTR* endoscopic full-thickness resection, *MCTS* mechanical counter traction system, *OTSC* over-the-scope clip

Full-thickness suture (videos 1, 3, and 4 in Supplementary material)

Full-thickness sutures were utilized in three groups, namely the OTSC, hand-sewn suture, and DBSS groups ($N = 10$ cases in each group). Closures of the 40-mm puncture openings were performed with 10-stitch sutures at 3- to 4-mm intervals. Because of the OTSC clip width, an OTSC closure must be performed with no more than three stitches to close the 40-mm perforation site; thus, the suture was set to three stitches. Here, it is noteworthy to mention that to close 40-mm EFTR lesion sites using OTSCs, three-stitch sutures were sufficient, whereas ten-stitch sutures were necessary for both hand-sewn and DBSS procedures. Therefore, we compared three-stitch sutures using OTSCs and ten-stitch sutures using both hand-sewn and DBSS procedures for lesions of the same size. Figure 3 shows the schema of the DBSS procedure. Video 1 in Supplementary material shows a moving image of the DBSS. The method for DBSS is as follows. One end of the first arm is inserted 3–4 mm into another edge of the serosal side of the resection opening. The second arm (the puncture needle) moves forward and penetrates the full thickness of the gastric mucosa (Fig. 4A). When the absorbent thread and connector join the first arm and puncture needle, they are pulled out from the gastric mucosa. With this simple step, the absorbent string (2-0 or 3-0) can be passed through the full thickness of the tissue on another side of the perforation opening. The second arm is rotated and moved to align with

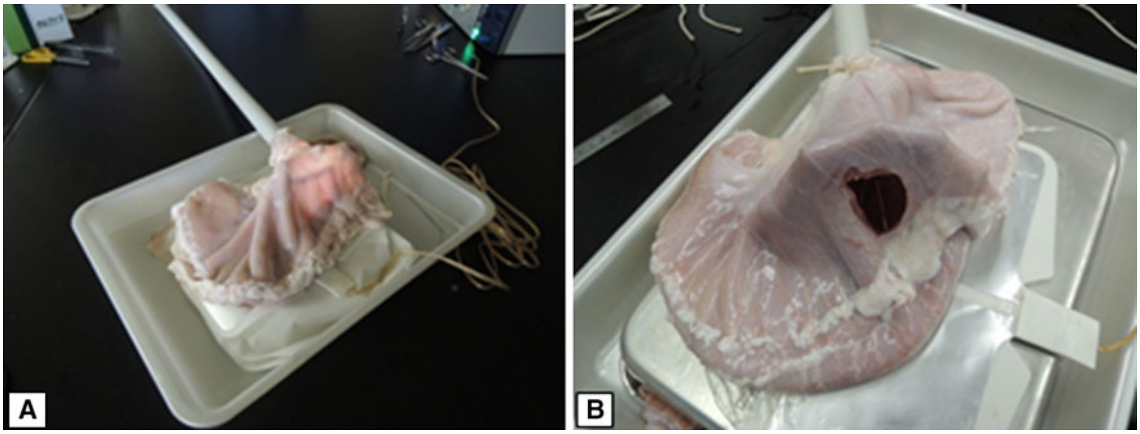

Fig. 2 MCTS prototype appearance and the EFTR ex vivo experimental system. **A** Ten arms are housed in the overtube, which, when pressed inside the stomach, expands to ~10 cm. The arm tip is spherical to protect the gastric mucosa. **B** Even after the full-thickness resection had been completed, the ten arms of the MCTS expanded the stomach wall and prevented stomach collapse, ensuring a surgical field of ~10 cm in diameter. *EFTR* endoscopic full-thickness resection, *MCTS* Mechanical counter traction system

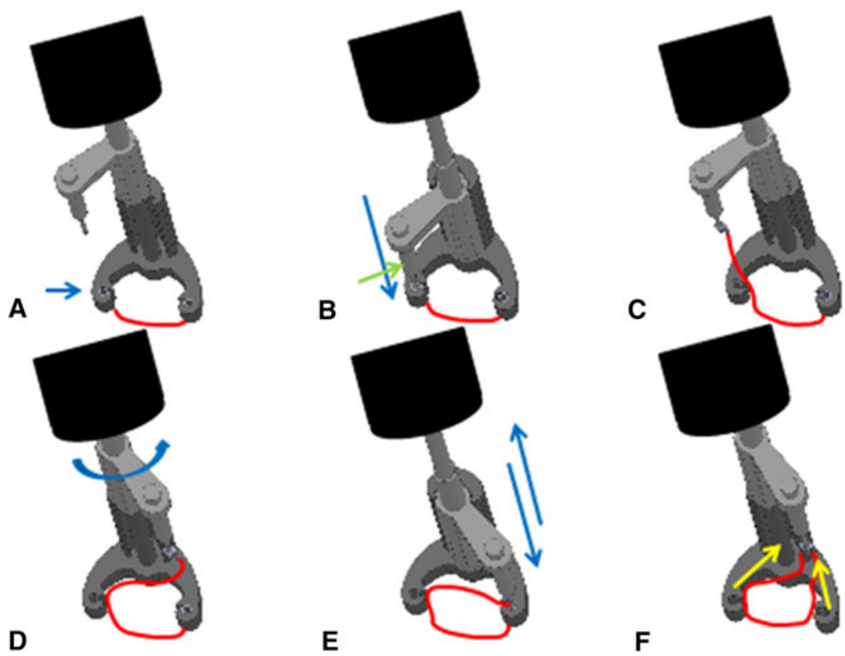

Fig. 3 The DBSS procedure. **A** The DBSS comprises two arms. The first arm holds the absorbable suture attached to the small connector, which is hooked by the needle on the second arm. The second arm has a puncture needle with a small hook. **B** The second arm (the puncture needle) (*green arrow*) moves forward (*blue arrow*). **C** After the small connector with the absorbent thread is connected with the puncture needle (second arm), they are pulled out from the gastric mucosa. In one simple step, the absorbent string (2-0 or 3-0) can be passed through the full thickness of the tissue to another side of the perforation opening. **D** The second arm is rotated and moved to align with the tip of the other arm (*blue curved arrow*). **E** Similarly, the arm is placed at the other resected margin of the resection opening, and the puncture needle of the second arm is passed through the full thickness of the gastric mucosa (*blue arrow*). **F** The full thickness of both resected margins of the resection opening are tied with an absorbent thread, which is shaped as an isosceles triangle, centered on the puncture needle (*yellow arrow*). The detainment snare is then gradually contracted, and ligation is performed by pressing slightly inward. The thread is cut with scissor forceps, and the full-thickness simple interrupted suture is complete. *DBSS* Double-arm-bar Suturing System

the tip of the other arm (Fig. 4B). Similarly, the arm is placed at the other resected margin of the resection opening, and the puncture needle of the second arm is passed through the full thickness of the gastric mucosa (Fig. 4C). The full thickness of both resected margins of the resection opening is tied with an absorbent thread in the shape of an isosceles triangle centered on the puncture needle (Fig. 4D). The second arm is gently pulled out from the resection opening,

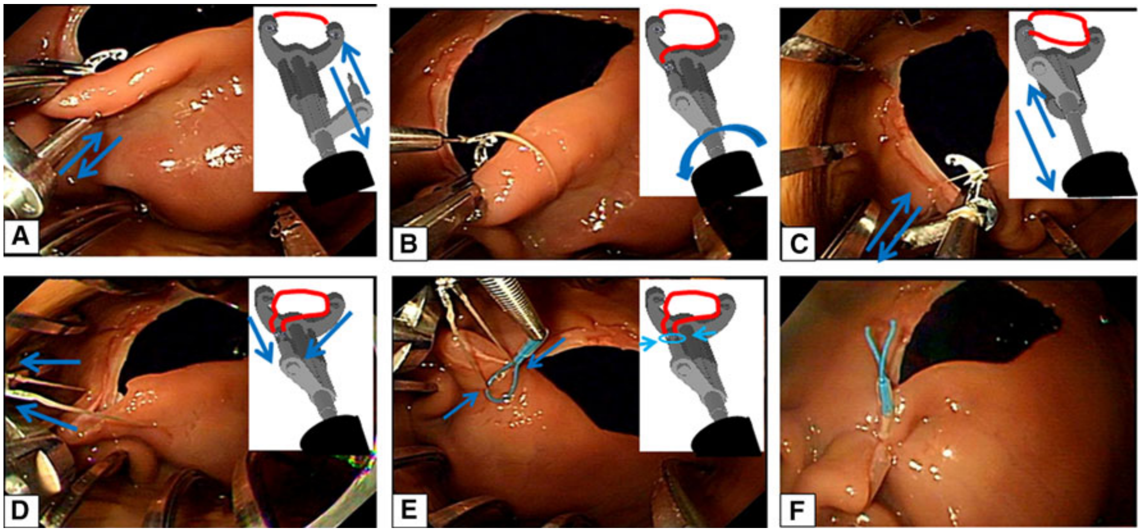

Fig. 4 DBSS suture procedure. **A** One end of the first arm is inserted 3–4 mm into another edge of the serosal side of the resection opening. The second arm (the puncture needle) moves forward (*blue arrow*) and penetrates the full thickness of the gastric mucosa. When the absorbent thread and connector join the first arm and the puncture needle, they are pulled out from the gastric mucosa. In this one simple step, the absorbent string (2-0 or 3-0) can be passed through the full thickness of the tissue on another side of the perforation opening. **B** The second arm is rotated and moved to align with the tip of the other arm (*blue curved arrow*). **C** Similarly, the arm is placed at the other resected margin of the resection opening, and the puncture needle of the second arm is passed through the full thickness of the gastric mucosa (*blue arrow*). **D** The full thickness of both resected margins of the resection opening are tied with an absorbent thread in the shape of an isosceles triangle centered on the puncture needle (*blue arrow*). **E** The second arm is gently pulled out from the resection opening, and tension is applied to the absorbent thread, with which both resected margins are tied from the puncture needle in the shape of an isosceles triangle. Next, the detainment snare is gradually contracted (*blue arrow*), and ligation is performed with slight inward pressure. **F** The thread is cut with scissor forceps, and the full-thickness simple interrupted suture is complete. *DBSS* Double-arm-bar Suturing System

and tension is applied to the absorbent thread, with which both resected margins are tied from the puncture needle in the shape of an isosceles triangle. In contrast, the detainment snare is gradually contracted, and ligation is performed with a slight inward pressing (Fig. 4E). The thread is cut with scissor forceps, and the full-thickness, simple interrupted suture is complete (Fig. 4F). Video 3 in Supplementary material shows ten interrupted hand sewn sutures at 3-mm intervals. Video 4 in Supplementary material shows three-stitch OTSC closures. The procedure of the OTSC closure is as follows. Opening of one branch and grasping one edge of the resected opening. Opening the other branch and maneuvering the grasper to the other edge of the resected opening and grasping this edge. Retracting the branches of the OTSC Twin Grasper into the cap. Releasing the clip with hand wheel. The OTSC suturing procedure is then completed.

Air leak test (videos 2, 3, and 4 in Supplementary material)

An intragastric pressure measurement instrument (digital manometer PG-100N-101R, SKY-I Co, Tokyo, Japan) was inserted into the middle part of the stomach, from the duodenal side of the excised swine stomach, and affixed to the duodenal side with a string (Fig. 5A, C). The overtube, with a mechanical counter-traction device mounted at the tip, was pulled out, and an overtube (diameter 20 mm; length 300 mm; TOP Co., Tokyo, Japan) with a backflow prevention valve was inserted into the lower esophagus and affixed with a string (Fig. 5A, C). An endoscope was passed through the overtube with the backflow prevention valve and inserted into the stomach, and insufflation was provided using the endoscope to raise the pressure inside the stomach. Detergent was applied to the serosal side of the full-thickness suture area, and the leak test was performed in the DBSS group (Fig. 5A, B) (video 2 in Supplementary material), with the time point at which air first began to leak out as the leak point (Fig. 5B). The leak test in the hand-sewn group is demonstrated in Fig. 5C, D, with the time point at which air first began to leak out as the leak point (Fig. 5D). Video 3 in Supplementary material shows the leak test in the hand-sewn group, and video 4 in Supplementary material shows that of OTSC group. Measurements were taken with the atmospheric pressure Pa (G) set to zero.

Operative devices

Endoscopes: OLYMPUS GIF TYPE Q260J (OLYMPUS, Tokyo, Japan). Incisional knife: Dual knife (KD-650L) and IT

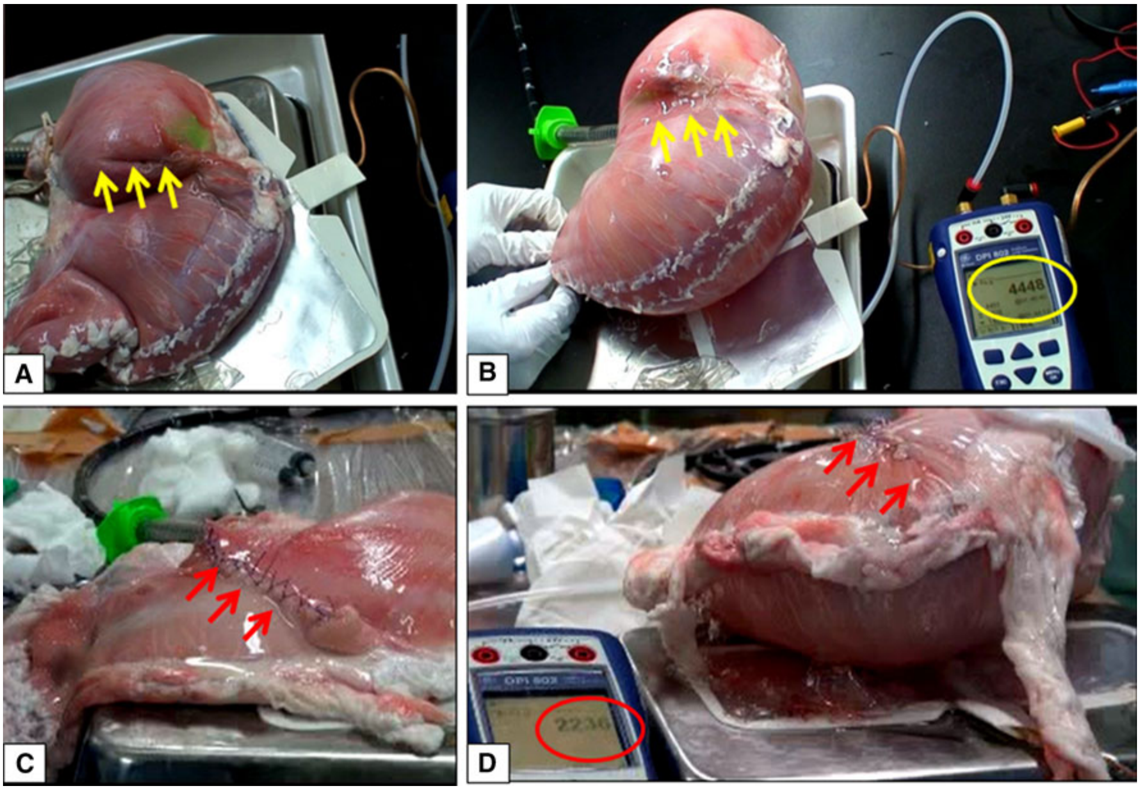

Fig. 5 Leak test with whole swine stomachs. **A** Insufflation of the stomach for the leak test in the DBSS group. The suture site (*yellow arrow*) is the anterior wall in the middle of the gastric body. **B** At the instant when the air leak began, the liquid detergent began bubbling (*yellow arrow*). The intragastric pressure was 4,448 Pa (G) (*yellow circle*). To verify the start of the air leak, the suture site was coated with a liquid detergent. **C** Insufflation of the stomach for the leak test in the hand-sewn group. The suture site (*red arrow*) (ten stitches at 3-mm intervals) is the anterior wall in the middle of the gastric body. **D** At the instant at which the air leak began, the liquid detergent began bubbling (*red arrow*). The intragastric pressure was 2,236 Pa (G) (*red circle*). *DBSS* Double-arm-bar Suturing System

knife 2 (KD-611L, OLYMPUS). Hemostatic forceps: Coagrasper (FD-410LR, OLYMPUS). Incisional generator device: ERBE VIO300D (Elektromedizin, Tübingen, Germany). CO_2 insufflation device: OLYMPUS UCR (OLYMPUS). OTSCs: 12 mm in diameter, gc version (Ovesco Endoscopy GmbH, Tüebingen, Germany).

Main outcome

Pressure resistance in the leak test with OTSCs, hand-sewn sutures, and the DBSS.

Secondary outcomes

Suturing time for a single stitch, simple interrupted suture among the OTSC closures, and hand-sewn and DBSS sutures.

Statistical analysis

The results of the air leak test for single-stitch sutures were compared among the OTSC, hand-sewn, and DBSS suture groups to determine significant differences, as well as the procedure time for the one-stitch sutures, using the Mann–Whitney *U* test, with the level of significance set at $p < 0.05$. Statistical analyses were performed using Graph Pad Prism version 5 for Windows (Graph Pad Software, San Diego, CA, USA).

Results

All 30 full-thickness sutures were completely and successfully placed. The Mann–Whitney *U* test, performed on the results of the air leak test, showed significant differences between OTSCs [median 1,660 Pa (G), 95 % confidence interval (CI) 1,610–1,750] and hand-sewn sutures [median 3,350 Pa (G), 95 % CI 2,470–4,250; $p = 0.003$]. There was also a significant difference between OTSCs and the DBSS [median 3,665 Pa (G), 95 % CI 1,600–4,400; $p = 0.023$]. There was no significant difference between hand-sewn sutures and DBSS ($p = 0.542$) (Fig. 6).

A significant difference was found in the suture time for single-stitch simple interrupted sutures among the ten OTSC, ten hand-sewn, and ten DBSS cases. The Mann–Whitney *U* test revealed a significant difference between

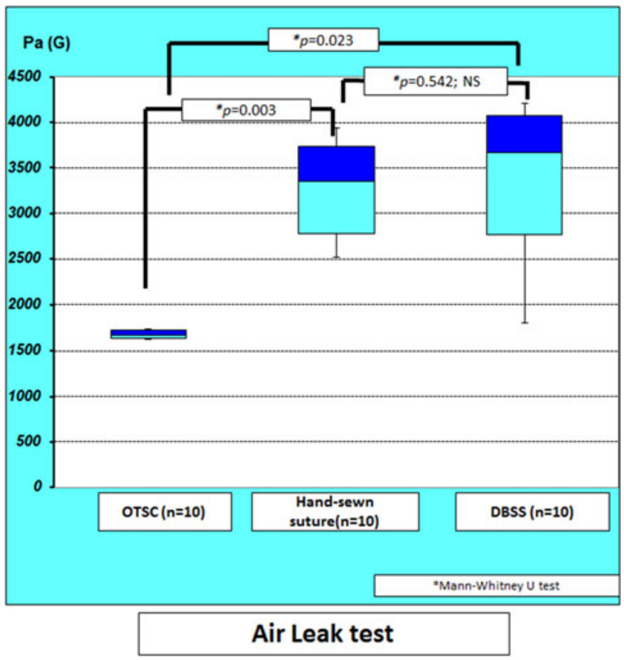

Fig. 6 Results of leak tests. Pressure resistance values derived from leak testing were significantly different between the OTSC, hand-sewn, and DBSS groups. A significant difference was found between OTSC and hand-sewn sutures ($p = 0.003$), as well as between OTSC and DBSS sutures ($p = 0.023$). No significant difference existed between hand-sewn and DBSS sutures ($p = 0.542$). *DBSS* Double-arm-bar Suturing System, *OTSC* over-the-scope clip

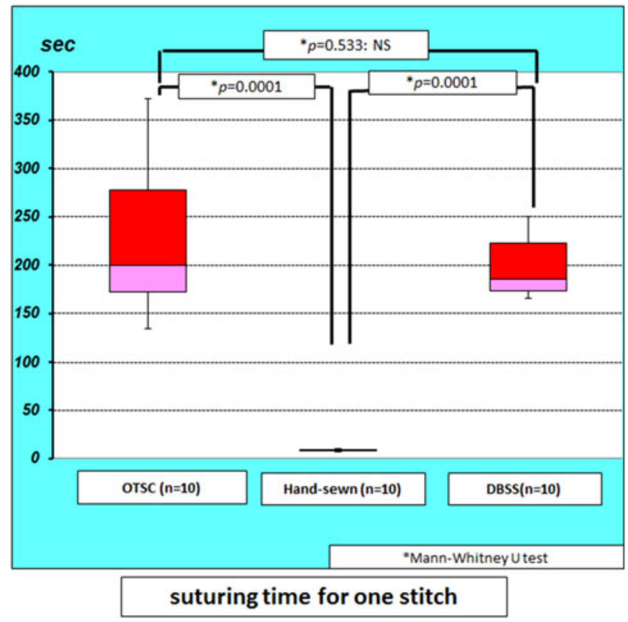

Fig. 7 Results of single-stitch suturing time. A significant difference was found between OTSC and hand-sewn sutures ($p = 0.0001$), as well as between hand-sewn and DBSS sutures ($p = 0.0001$). There was no significant difference between OTSC and DBSS sutures ($p = 0.533$). *DBSS* Double-arm-bar Suturing System, *OTSC* over-the-scope clip

OTSC (median 200 s; 95 % CI 100–400) and hand-sewn sutures (median 8.5 s; 95 % CI 6.0–11.0) ($p = 0.0001$). There was no significant difference between OTSC and DBSS sutures (median 185 s; 95 % CI 156–255) ($p = 0.533$). A significant difference was found between hand-sewn and DBSS sutures ($p = 0.0001$) (Fig. 7).

Discussion

ESD has been established as a minimally invasive endoscopic treatment for tumors of the digestive tract wall and has yielded high en bloc resection rates for larger tumors of the esophagus, stomach, colon, and similar organs [18–22]. Although various full-thickness suture devices have already been developed for flexible endoscopy [23–27], few studies have reported on the development of a safe and reliable full-thickness suture device. Because suture failure after surgery can lead to serious conditions, such devices must have a suture strength equivalent to that of hand-sewn sutures. The air leak test has also demonstrated that full-thickness suturing by DBSS yields a suture strength equivalent to that of hand-sewn suturing. OTSC is a powerful suture device that can be used with flexible endoscopy. Several reports have noted the suture capacity of OTSC for closure of puncture openings or fistulas, as well as for suturing full-thickness suture sites [24, 25]. In a previous report, air leak tests of OTSCs yielded a pressure resistance of 166 mmHg with an incision length of 10 mm, whereas that of a surgical suture is 146 mmHg [26, 27]; however, the puncture opening was not associated with full-thickness damage to the stomach wall, and the closure was for an incision wound. For the suturing of resection wounds >40 mm, as was performed in the present study, OTSCs are believed to have an even lower pressure resistance in leak testing. Suturing a resection wound that is >40 mm requires three OTSCs, and a gap of several millimeters is created between each OTSC; however, the mechanical clip is seen as a limitation because it makes complete closure impossible. Another previous report showed that iatrogenic puncture openings of 7–20 mm were successfully closed [23]; however, reliability is an issue for larger puncture openings. We consider that the puncture openings of less than 20 mm were successfully closed by OTSC and the reliability of closure is sufficient. But larger resected openings such as tumor resection need to be closed by DBSS, which can suture the large resected site as well as a hand-sewn suture.

With respect to ease of use, an OTSC can be easily mounted and can be installed onto an ordinary, single-channel flexible endoscope. The suture method itself is also relatively simple. With DBSS, mounting onto an ordinary, single-channel endoscope is possible, and the operation is very simple.

With regard to safety and reliability, although an OTSC is very safe because suturing is performed after the OTSC is drawn into the endoscope, the suture site is not visible at the instant of release; therefore, if the release site ever deviates, the considerable suture strength will make re-suturing difficult, and reliability of the suture strength is not clear. The Overstitch System is very safe because the puncture needle is used to ensnare the puncture opening, as is the case with surgical stitching. However, when the puncture is made with the puncture needle, there is no auxiliary tool to assist with gripping the perforation surface, so reliably suturing at 3- to 4-mm intervals is not possible. With DBSS, the leading edge of the arm is soundly inserted into the serosal surface, and the puncture is made with the puncture needle to clamp the stomach wall; therefore, the distal arm acts as a stopper, and there is no risk of accidental puncture. Moreover, precise suturing at 3- to 4-mm intervals is possible because the puncture and suturing are performed while checking the position of the arm. The suture strength also makes it possible to adjust the force of ligation with the suture string because the detainment snare is used to pull in the puncture surface for tying. Although this was an ex vivo study, in the future, it will be necessary to confirm the safety of the procedure using an in vivo animal study.

In conclusion, pure EFTR is feasible if MCTS is used to expand a small operative field and DBSS is used to perform suturing with full-thickness sutures. The high safety of full-thickness resection and full-thickness suturing allows for clinical applications of this method.

Study limitations

In the present study, to evaluate the capability of the DBSS under the same conditions and location, we used only the straight type of tube rather than the two-way bending type, which has already been developed.

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Disclosures Drs. Hirohito Mori, Hideki Kobara, Shintaro Fujihara, Noriko Nishiyama, Kazi Rafiq, Makoto Oryu, Masao Fujiwara, Yasuyuki Suzuki, and Tsutomu Masaki have no conflicts of interest and no financial arrangement with any company, institution, or third party.

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