

Transgastric small bowel resection with the new multitasking platform EndoSAMURAI™ for natural orifice transluminal endoscopic surgery

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Abstract

Background Recently, natural orifice transluminal endoscopic surgery has been introduced using flexible endoscopic technology. Traditional endoscopes lack several capabilities that are needed to perform complex surgical procedures safely. The purpose of this study was to evaluate the new multitasking platform for transgastric small bowel resection including dissection of the mesentery and suturing an anastomosis.

Methods A new prototype of endoscopic multifunctional platform, EndoSAMURAI™ (ES), was tested. A standardized in vitro setting was established with segments of small bowel and an anastomosis was sutured with the device and compared with that by stapler (ST) and hand-sewn (HS). Leak pressure was measured. In addition, the system was tested in an experimental in vivo situation by performing a transgastric small bowel segmental resection under general anesthesia.

Results Median time to perform an anastomosis in the bench test was 41 min; median leak pressure for the anastomosis by ES was 14 mmHg, by ST 25 mmHg, and HS 15 mmHg. For the in vivo study, the median total procedure time was 110 min and leak pressure 53 mmHg. These results show that the end-to-end small bowel anastomosis can be sutured sufficiently.

Conclusions This study has shown that with a multifunctional platform such as the EndoSAMURAI™, the majority of complex surgical tasks can be performed if technically independently moving instruments can be used

via an ergonomic workstation interface that allows for laparoscopy-like maneuvers by the operator. Even with the shortcomings of the prototype, it was possible to perform an anastomosis of the small bowel of acceptable quality within a reasonable time.

Keywords NOTES · Endoluminal surgery · Endoscopic manipulator · Endo-SAMURAI™ · Natural orifice surgery · Endoscopic small bowel resection

Recently, the techniques of natural orifice transluminal endoscopic surgery (NOTES) using flexible endoscopic technology have been introduced [1–5]. A remarkable amount of experimental work such as cholecystectomy and gastrointestinal and colorectal resections has been performed with commercially available traditional flexible scopes designed and developed decades ago for diagnostic procedures [6]. Although the level of skill and performance that has been reached with these traditional endoscopes is surprising, it quickly became evident that these traditional endoscopes lack several capabilities that are needed to perform complex surgical procedures safely [7–9]. These procedures require independent coordination and movements of two instruments that can be manipulated by the surgeon for traction and countertraction of tissue for precise dissection, hemostasis, and tissue approximation. In addition, for a safe surgical procedure these maneuvers have to be observed under camera vision with the possibility of a close-up view for detailed precise dissection and there has to be the option of an overview to control all aspects of the surgical site.

As a consequence, industry and physicians are developing multifunctional tools and endoscopes associated with possibly stable platforms in order to facilitate transluminal endoscopic procedures [10–15]. The requirements for such

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new platforms have been discussed and listed in several reports from working groups of the involved societies such as NOSCAR, EURO-NOTES, and D-NOTES [4, 16]. Good overview, stability, independent manipulation of working arms and instruments, good triangulation, ability of sufficient hemostasis, and sufficient maneuverability are needed, with full laparoscopic surgical capabilities [17].

After extensive experimental training in transgastric, transvaginal, and transanal procedures using traditional endoscopes, the authors had the opportunity to evaluate the newly developed prototype of an endoscopic multitasking platform, the EndoSAMURAI™ (Olympus Corporation, Tokyo, Japan). The purpose of this study was to evaluate the new multitasking platform for transgastric small bowel resection. This procedure includes major surgical steps such as endoscopic gastrotomy, intra-abdominal exploration and identification of organs, traction and countertraction of tissue, dissection of mesentery and bowel, and even suturing an anastomosis.

Methods

A new prototype of endoscopic multifunctional platform, EndoSAMURAI™ (Olympus Corporation, Tokyo, Japan), was tested and investigated to assess the feasibility of performing surgical procedures with this new device and the quality of the surgical performance with this new device was compared with that of traditional techniques.

The apparatus consisted of an endoscopic shaft with a rather traditional endoscopic steering unit and an ergonomic interface that can be used like a laparoscopic workstation to perform the maneuvers (Fig. 1). Two working arms are connected at the tip of the flexible endoscope. The arms

have channels and openings for the end-effector instruments, which can be run through working channels to the arms and brought out for surgical manipulation (Fig. 2). The two articulating working arms can be moved out of the original diameter of the scope and therefore provide more triangulation with an elbow-like function, which can be deployed within the lumen of the gut or within the abdominal cavity.

The shaft of the endoscope is connected to a regular traditional steering unit of the endoscope at its proximal end, and there is also a mechanical connection to a separate workstation from which the effectors can be maneuvered. This new endoscopic system fulfills two tasks since it can be steered in an endoscopic manner using standard endoscopic control knobs for up–down and left–right movement. The endoscopic control mechanism is run by the endoscopic camera assistant.

The surgeon operates the workstation in a way that is similar to a laparoscopic surgeon who works bimanually and observes his maneuvers on a video screen. The laparoscopic workstation mechanically transmits the motion of the handles of the effector instruments to the tips of the end-effectors, which are advanced through the flexible working channels into the working arms at the end of the endoscope.

The system is similar to a traditional endoscope with respect to light source and insufflation of gas, either air or carbon dioxide. There are also standard functions for suction and the possibility of rinsing the endoscopic lens. The light source and processor unit is a standard EVIS EXERA II Universal Platform (Olympus Corporation, Tokyo, Japan). This system consists of a classical endoscopic component, which is launched via a natural orifice in the body, and a laparoscopic workstation unit, which can be



Fig. 1 The EndoSAMURAI™ system: a multitasking platform with a flexible endoscope attached to an ergonomic surgical manipulator workstation. The end-effectors can be manipulated via this workstation



Fig. 2 Tip of the flexible endoscopic multitasking platform with two arms in triangulation for the manipulation of the end-effectors

operated by someone with laparoscopic surgical skills. Therefore, the system is operated best by two individuals: on the one hand there is the active surgeon at the workstation, which is an ergonomically adapted interface mechanically connected to the endoscopic platform, and on the other hand there is a camera assistant, who is responsible for the general maneuvering of the tip of the endoscope as well as the in–out movements of the endoscope in order to advance or withdraw the endoscope within the gut or in the abdominal cavity.

The mechanical connection allows for a triangulation of the instruments as well as pulling and pushing of tissue at the operative target area. Exchangeable instruments via the working channels of the scope allow for a variety of applications of the working arms, including grasping, retracting, tissue cutting, coagulation, hemostasis, and suturing with a needle holder. The stability of the platform is insured by the rigidity of the steerable overtube.

Study protocol

The evaluation program consisted of two sections. In section I, an initial training phase was started as an individual bench test so that the team could get acquainted with the system. Box-training was started using animal organs such as porcine liver, stomach, and small intestine in order to learn how to manipulate the tissue and get training in the initial steps of tissue retraction, dissection, and cutting. This initial training phase consisted of *in vitro* cholecystectomies and more complex maneuvers such as small bowel anastomoses.

Thereafter, a standardized *in vitro* setting was established with segments of small bowel that were fixed on a bench plate in the laboratory (Fig. 3). The task of the team was to perform a small bowel anastomosis using 3.0 suture

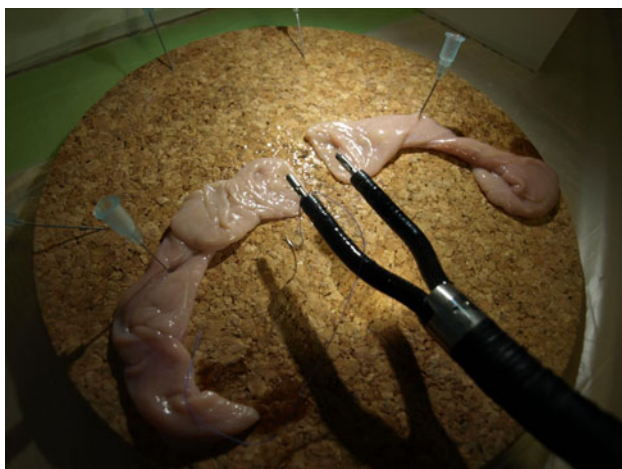


Fig. 3 Bench test of small bowel anastomosis with the EndoSAMURAI™

material and interrupted sutures. To assess the quality of the system's performance and that of the individual surgeon, the results of the anastomosis created using the EndoSAMURAI™ were compared with those of other suture techniques, thus creating three groups: group ES whose anastomoses were performed with interrupted sutures by the EndoSAMURAI™, group ST whose anastomoses were performed with a circular stapler (Power Medical CS 21, Power Medical Interventions Deutschland GmbH, Hamburg, Germany), and group HS whose anastomoses were performed by interrupted hand-sewn sutures.

The series was performed as a bench test in the laboratory. The sequence of the different procedures was not randomized; however, surgeon fatigue was avoided by providing sufficient breaks between the experimental sessions. Thus, the results were not affected by the sequence of procedures. Of course, there was a substantial difference in experience with stapling and hand-suturing on the one hand and suturing with the new apparatus on the other.

After finishing the anastomosis, a multichannel perfusion catheter was introduced into one lumen of the small bowel segment, while the other end of the lumen was closed. The manometry catheter had four independent channels and a central line for air insufflation. The bowel was closed around the manometry catheter. Then the small bowel segment was placed in a water bath and air was insufflated via the insufflation catheter at the rate of 0.4 l/min (6.6 ml/s) in order to determine the leak pressure at the anastomotic site. The pressure changes were recorded and the leak pressure was determined to be when air escaped at the anastomosis (Fig. 4). For statistical comparison of the pressure values, the Mann–Whitney test for unpaired samples was used.

In section II of this study, the system was tested in an experimental *in vivo* situation using the porcine model in an animal hospital. Three pigs were used to perform a

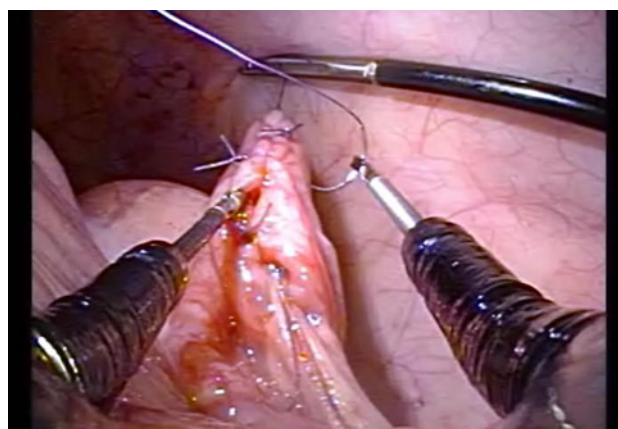


Fig. 4 Endoscopic view with the EndoSAMURAI™ in the abdominal cavity of the anastomotic site of a small bowel segment

transgastric small bowel segmental resection using this new multifunctional platform. The protocol was approved by the animal research authorities and permission to undertake the study was granted. Care was taken to follow good laboratory practices at all times. The animals were investigated under general anesthesia and at the end of the acute experiment they were killed. A veterinary doctor followed the procedures at all times, taking care that there was adequate management of the animals during the procedure. All operations were performed by the senior author.

In the first step, a capnoperitoneum was established with a Veress needle, and after the adequate safety tests a 5-mm trocar was inserted at the periumbilical region and a 5-mm camera was inserted to check the intra-abdominal status. Next, all endoscopic maneuvers were controlled by this camera during the procedures for safety reasons. A regular endoscope, mounted with an overtube, was brought into the esophagus and advanced into the stomach, and the overtube was brought into the stomach. Then the regular gastroscope was withdrawn and the tip of the EndoSAMURAI™ with narrowed arms was inserted through the overtube into the stomach. An adequate penetration site was identified and a gastrotomy was performed with a needle knife. The tip of the EndoSAMURAI™ and the overtube were advanced into the abdominal cavity.

First an exploration of the abdominal cavity with the new system was performed, advancing the flexible shaft of the EndoSAMURAI™ into four quadrants of the abdomen as far as possible in order to check the maneuverability of the system. Next, a small bowel loop was identified, usually found in the right lower quadrant of the abdomen. The loop was pulled using two graspers via the effector arms after they had been switched into triangulation mode. With a coagulation grasper, the dissection of the mesentery was started by coagulating the vessels, while the left arm grasper exposed the small bowel with its mesentery by lifting it up toward the ventral abdominal wall. After adequate coagulation the mesentery was severed with a needle knife or with scissors. Then a segment of bowel was resected by grasping the small bowel while cutting the bowel using a needle knife with the right arm. The open stump of the bowel was secured by an additional transabdominal minigrasper that penetrated the abdominal wall without using a trocar. The distal stump of the small bowel segment was transected and the specimen was placed at the urine bladder to be picked up later for removal transgastrically. The distant small bowel stump was secured via the grasper through the EndoSAMURAI™. A needle with a 3.0 suture was brought in via the assisting laparoscopic camera port while the camera was removed shortly thereafter. The needle was picked up by the needle holder of the right arm of the EndoSAMURAI™ and an interrupted sutured anastomosis was performed and completed in any case (Fig. 5).

After completion of several resections and anastomoses, a laparotomy was performed, the small bowel segment was harvested, and the specimen underwent manometric control investigations as described above. At the completion of the experiment the animals were killed.

Results

In study section I the median time to perform the interrupted suture anastomosis in the bench test was 41 min (range = 31–65 min). Figure 4 shows an example of the manometry and the leak pressure measurements. The results of the comparison of the leak pressures using the three different anastomosis techniques—EndoSAMURAI™, circular stapler, and hand-sutured—show comparable levels of values (Fig. 5). The leak pressure value for the EndoSAMURAI™ had a median of 14 mmHg (8–33), that for the stapler anastomosis was 25 mmHg (13–59), and that for the hand-sutured anastomosis was 15 mmHg (12–31). The data show that the quality of an end-to-end small bowel anastomosis sutured with the EndoSAMURAI™ was similar to those of other conventional techniques (Fig. 6). There was no significant pressure difference in the air leak rate; however, the stapler anastomosis tended to be superior. Given the fact that the investigators had extensive experience with hand sutures and stapling but only a short training time on the EndoSAMURAI™, these results were promising.

In section II of the study, the body weight of all subjects was 50 kg. There were seven small bowel resections performed in three animals, and the first two resections and anastomoses were used for training practice. The remaining five small bowel resections and end-to-end anastomoses were completed and assessed for further analysis. There were no intraoperative complications and none of the five procedures had to be interrupted because of any special problems.

The total time of the procedure, from the start of the resection until the completion of the anastomosis, was a median of 110 min (90–125) (Fig. 7). The median time to perform the anastomosis was 90 min (60–120), and in total, a median of 12 interrupted stitches (11–20) were placed. The leak pressure was 53 mmHg (19–68) (Fig. 8). These results show that the quality of an end-to-end small bowel anastomosis made with the EndoSAMURAI™ is sufficient in a rather thin small bowel wall of the porcine model.

The maneuverability of the EndoSAMURAI™ was sufficient to reach all quadrants; however, the advancement of the system was somewhat more time-consuming than a standard flexible endoscope since the system and the overtube both had to be adjusted when reaching in the corners of the abdomen. To the authors it seemed reasonable to consider

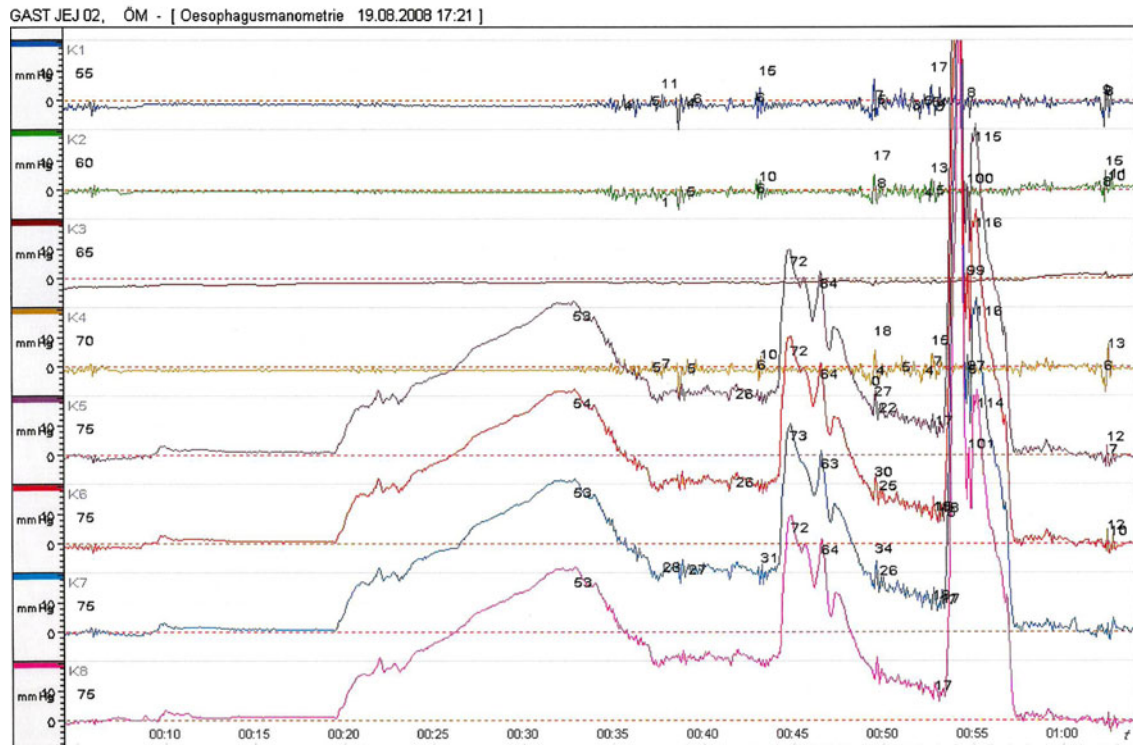


Fig. 5 Pressure graph of the leak test after small bowel anastomosis in a bench test. The rising pressure is demonstrated following a drop after the leak develops

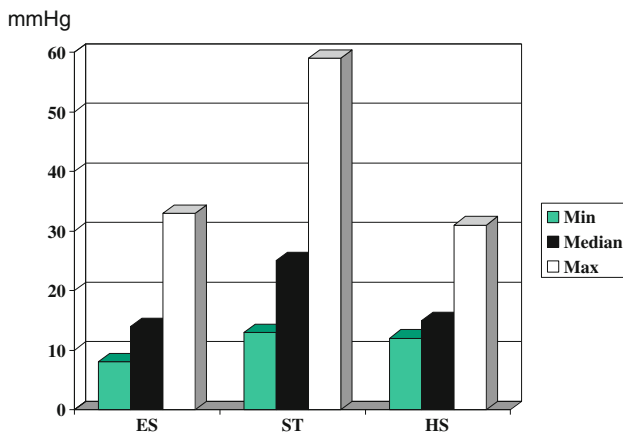


Fig. 6 Comparison of the leak pressure (mmHg) after a bench test of small bowel anastomoses created with the EndoSAMURAI™ (ES), the stapler (ST), and hand-suturing (HS)

using a regular endoscope for exploration via the overtube and then change to the EndoSAMURAI™ when real surgical tasks need to be performed.

The third working channel of the apparatus was also used intermittently for a grasping forceps; however, it gave a minor advantage since real countertraction was hardly possible due to a lack of triangulation of this channel. Instead, the use of the additional minigrasper without trocar

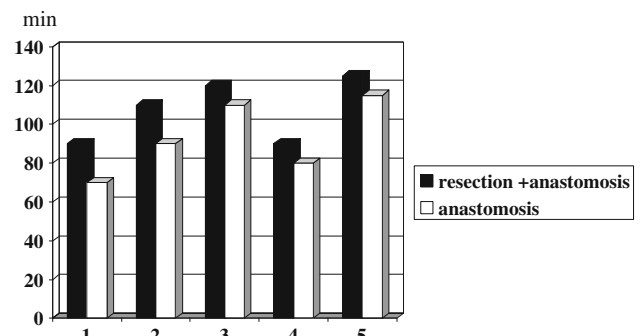


Fig. 7 Duration of resection and small bowel anastomosis using the multitasking flexible endoscopic platform

was very helpful for countertraction, stabilization of the bowel, and improvement of the exposure of the bowel loops during the suturing of the anastomosis, while the second arm of the EndoSAMURAI™ (left hand of the surgeon) was extremely helpful for the detailed work in presenting the anastomotic site during suturing.

These results demonstrate that the new endoscopic system serves well as a multifunctional endoscopic platform for the use of transluminal, in this case transgastric, small bowel resection and anastomosis. The manipulator can be placed transgastrically without complications into

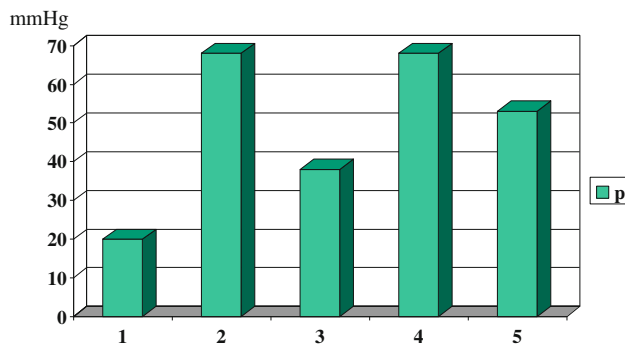


Fig. 8 Leak pressure after in vivo small bowel resection and anastomosis with the EndoSAMURAI™

the abdominal cavity and can be used to perform tasks as complex as resection and anastomosis.

Discussion

The idea of minimal access surgery and interventional endoscopic therapy has been further developed in the past decades into the most recent concept of natural orifice transluminal endoscopic surgery [4]. Currently, one can see the initial steps of these procedures going from the laboratory into patient care [7, 16]. However, it can also be seen that many of these procedures are still performed with a number of shortcomings because of the lack of adequate instrumentation. New multifunctional platforms and endoscopes are needed, as has been pointed out by several working groups in the past years [16]. When finishing initial training sessions and reflecting on the vast experimental experience, it became very clear that these new instruments would facilitate most of the endoscopic and transluminal intracavitary surgical procedures tremendously [8, 9, 16].

Therefore, it became necessary to focus on new endoscopic surgical systems [17]. However, these procedures were associated with a number of unknown critical issues such as technical feasibility, the danger of infection due to contamination of the natural orifice, and the limited maneuverability of the flexible endoscopes with a lack of platform stability, just to mention a few. To compensate for some of the lack of feasibility with traditional scopes, the current NOTES procedures are usually associated with the use of additional laparoscopic instruments in hybrid procedures. The limitations of traditional endoscopes for surgical tasks and their limited stability drove investigators and industry in the past few years to develop multifunctional platforms such as the EndoSAMURAI™.

From the surgical point of view, a system is needed that can be transported via the abdominal wall or a natural

orifice with a limited diameter of at best around 15 mm into the abdominal cavity where all surgical functions can be applied such as visualization, traction and countertraction, dissection, hemostasis, and suturing. The results of this study show that with this system the majority of these functions can be delivered and fulfilled in this experimental setting. The favorable factors were acceptable triangulation and traction and countertraction. However, traction and countertraction were limited to the area where the EndoSAMURAI™ was placed. Larger retraction maneuvers, e.g., retraction of a bowel loop to have good exposure for dissecting the mesentery, is rather impossible because the force and the mobility are lacking to strongly pull one organ, while the other arms of the platform focus on a precise dissection of the mesentery.

Also, hemostasis via the coagulation grasper or the application of a needle knife for transection of the small bowel was sufficient. The surgeon must take great care not to injure a larger vessel, since this might require application of a clip, which is not available in this version of the instrument.

The suturing function is also quite acceptable since the rotation of the end-effector arms is remarkable and allows for interrupted and running suturing without major problems. Of course, training will improve operating time with the EndoSAMURAI™, which is still high.

The workstation, which is an ergonomic user interface that enables the laparoscopic surgeon to perform surgical tasks in a familiar way, is essential in allowing the laparoscopically trained surgeon to operate this endoscope. At the same time, the well-trained endoscopist will have no problem operating the endoscopic handle in order to steer the EndoSAMURAI™. As a consequence, this platform will enable a sophisticated transluminal endoscopic procedure to be performed by a trained laparoscopic surgeon without extensive endoscopic experience since the maneuvers follow the laparoscopic paradigm. Of course, it is our opinion that for these NOTES procedures skills in advanced laparoscopic and interventional endoscopic techniques must be provided. Other groups have tested the system and have gone through a similar experience; they have shown that the possibility for the surgeon to focus on one device with bimanual coordination tasks with the EndoSAMURAI™ can be an advantage [17]. Other systems have been described. However, some of those need very close coordination and communication of at least two operators to perform the tasks. This could lead to coordination problems or very time-consuming procedures, which could be prevented if the majority of the maneuvers and manipulations are performed by one surgeon. The latter prerequisite is realized with the workstation of the EndoSAMURAI™, following the laparoscopic paradigm. With its connection to the flexible endoscope, it will

transform laparoscopy-like maneuvers at the workstation such as manipulations of the tip of the flexible endoscope.

Of course, this study has its limitations regarding the artificial circumstances of the bench test as well as the limitations of an acute experiment. However, the initial aim was fully reached by proving the possibilities of the transluminal approach and performing a complex surgical task in the abdomen with this new system. Before bringing the system to the patient, many more tasks need to be worked on such as the contamination and infection issue, availability of the system, and training issues to reduce operative time.

Conclusion

For further development of natural orifice transluminal endoscopic surgery as well as intraluminal endoscopic surgery, multifunctional platforms are necessary in the future. This study has shown that with a multifunctional platform such as the EndoSAMURAI™, the majority of complex surgical tasks involved in creating an anastomosis can be done if technically independently moving instruments can be used via an ergonomic workstation interface that allows for laparoscopy-like maneuvers for the operator. Even with the shortcomings of the prototype, it was possible to perform an adequate anastomosis of the small bowel of acceptable quality within a reasonable amount of time. The apparatus is currently being re-evaluated and developed further for transformation into a commercial product. These platforms should be developed further to improve all its features to enable endoscopic surgeons to practice and improve on their transluminal endoscopic skills.

Disclosures The senior author (KHF) is a consultant to Olympus Medical Corporation Tokyo. Wolfram Breithaupt has no conflict of interest or financial ties to disclose.

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