Developing Essential Rigid-Flexible Outer Sheath to Enable Novel Multi-piercing Surgery

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Abstract. We have developed a new generation device called rigid-flexible outer sheath with multi-piercing surgery (MPS) to solve the issues of tissue closure, triangulation, and platform stability in natural orifice transluminal endoscopic surgery (NOTES), and the problems of restricted visual field, organ damage, and removing a resected organ from body in needlescopic surgery (NS). The shape of the flexible outer sheath can be selectively locked by a novel pneumatic shapelocking mechanism. Major features include four directional flexion at the distal end, four working channels, and suction and water jet functions. The insertion part of the prototype is 330 mm long with a 25 mm maximum outer diameter. The outer sheath system has successfully preformed *in vivo* experiment using a swine on partial gastrectomy. The advanced outer sheath system has shown great promise for solving NOTES and NS issues.

Keywords: Outer sheath, Pneumatic shapelocking mechanism, NS, NOTES, MRI-compatible.

1 Introduction

Natural orifice transluminal endoscopic surgery (NOTES) is minimally invasive surgical procedure using a flexible endoscope to access to the abdominal cavity via transoral, transcolonic or transvaginal routes [1-3]. The major advantages of this method are the absence of associated abdominal wall complications, and providing cosmetic benefits. However, some problems remain unsolved in NOTES. Firstly, although many devices are under development to enable closure procedure [4-5], the closure of the internal entry point for NOTES presents a significant challenge. Secondly, usually the dual-channel endoscope is used in NOTES allowing procedures to be performed in a manner as laparoscopic surgery. The channels are close and parallel to the camera, leading to loss of triangulation and a more technically challenging procedure. Some devices have been developed to solve triangulation problem [6-7]. However, triangulation is still minimal by these devices. Finally, because the endoscope is flexible, attempting to manipulate tissues and organs may lead the endoscope to create an

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unstable operative platform. The TransPort (USGI Medical, San Capistrano, CA, USA) was designed for NOTES using ShapeLock technology [8]. However, because the TransPort uses wire tension to lock the shape of the shaft, they often suffer from problems of wire breakage and thus cannot be used safely. Additionally the mechanisms and structures of TransPort are complicated, costly, and difficult to achieve MRI compatibility. Needlescopic surgery (NS) is a laparoscopic surgical technique using instruments and ports smaller than 3 mm in diameter. NS can reduce the surgical incisions in the abdominal wall to a size which is difficult to detect macroscopically. However, NS has not been widely adopted for minimally invasive surgery as involving some limitations. Firstly, observations are restricted by the poor scope visualization and instantaneous loss of visual field due to blood and fat mist. Secondly, instruments used in NS are easy bending of the shaft caused by its small diameter and leading to risk of organ damage because the instruments themselves act as needle. Finally, it is difficult to remove a resected organ from the needlescopic ports which smaller than 3 mm in diameter.

We invented a novel procedural concept called multi-piercing surgery (MPS) [9]. MPS is defined as NOTES-assisted NS. Our new proposal in this paper is an ideal rigid-flexible outer sheath to solve the issues of access, and platform stability in NOTES. The outer sheath could provide a clear visual field, assist to resect the lesion, and remove a resected organ from the body. On the other hand, the tasks of NS in MPS are to perform the surgery itself, and open and close the incision safely in the gastrointestinal tract for NOTES. The outer sheath combined with NS could also solve the problems of triangulation in NOTES, and organ damage problems in NS. The outer sheath can exchange between flexible and rigid modes, and make instrumental path to the abdominal cavity. In MPS, an entrance wound is first created in the intestinal tract for the outer sheath by NS. Then, in flexible mode, the outer sheath is inserted through the entrance wound in the intestinal tract, and locates an internal organ. When the outer sheath approaches the target in the abdominal cavity, the surgeon locks the shape of the outer sheath and then inserts flexible instruments easily through the path created by the sheath. Then, NS can be performed easily with the outer sheath assisted. Once in place, variety of flexible instruments can be inserted again and again without damaging the tissues around the outer sheath.

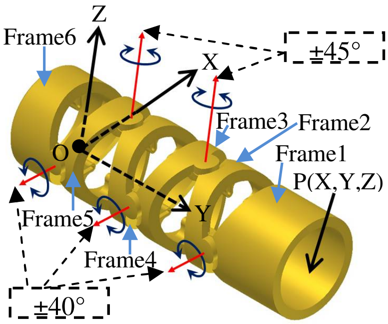
In this paper, a new prototype of the outer sheath with lockable operating part is presented. In addition, the paper reports the analysis of working space of the bending distal end and shape holding torque of the rigid-flexible shaft. Especially, the outer sheath system was first tested in *in vivo* partial gastrectomy experiments, and successfully preformed *in vivo* experiment using a swine.

2 Method

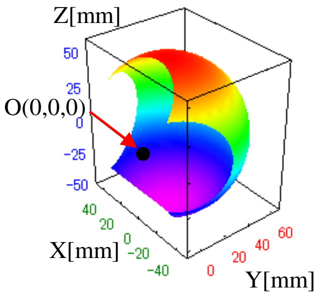
The outer sheath consists of a bending distal end for local treatment and route selection, and a rigid-flexible shaft for selective shapelocking of the shaft, and an operating part for simple operation by surgeon.

2.1 Bending Distal End Structure

The bending distal end consists of six aligned frames that mutually rotate 90° around their axes. The frames are driven by four wires that are 90° apart. For each frame, the rotating angle in the vertical and horizontal direction is ± 40° and ±45°, respectively, because of which the bending distal end can achieve a curvature of ±120° and ±90° in the vertical and horizontal directions, respectively (Fig. 1(A)). The workspace as an end effector of the outer sheath is given in Fig. 1(B). Furthermore, the bending distal end is manufactured in an integrated manner, and therefore, assembly of the frames is not necessary. The resin material (FullCure720, Objet Geometries Ltd., Israel) which used in the prototype was authorized as biocompatible material by FDA (the U.S. Food and Drug Administration). Because the breakdown limit of the bending distal end is about 58 N, it should be strong enough to be used in clinical practice.



(A)



(B)

Fig. 1. Structure of bending distal end. (A) Mechanism of bending distal end. (B) Workspace of the bending distal end P(X,Y,Z).

2.2 Rigid-Flexible Shaft Mechanism

The pneumatic shapelocking mechanism exchanging between a flexible and a rigid mode have been represented in [10]. The design consists of flexible toothed links, a bellows tube and sealed cover (Fig. 2(A)). The bellows tube and toothed link mechanism can be easily locked as well as relaxed by control of the vacuum, providing a smooth transition between flexible and rigid modes. An approximate model is built for design the toothed links (Fig. 2(A)). The relationship among the tooth top angle α, area S per tooth, atmospheric pressure P, coefficient of friction μ, number of teeth n per toothed link, distance d, and shape holding torque M are described by equation (1) and (2) with relations in Fig. 2(A). When n is 60, d is 9.5 mm, relationship among α, S, and M is shown in Fig. 2(B). Fig. 2(B) shows that, in rigid mode, the shape holding torque is decide by tooth top angle and area per tooth. The shape of the toothed links is designed base on this calculated value.

$$F = PS\sin(\frac{\alpha}{2})(\cos(\frac{\alpha}{2}) - \mu\sin(\frac{\alpha}{2})) \qquad (1), \qquad\qquad M = 3 \times F \times d \times n \qquad (2)$$

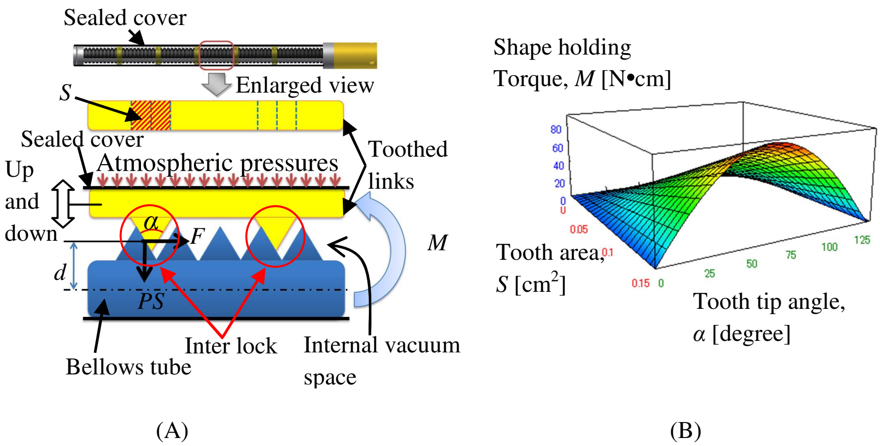


Fig. 2. Design of the toothed links. (A) Image of toothed link and bellows tube. (B) Relationship of shape holding torque, tooth area and tooth tip angle.

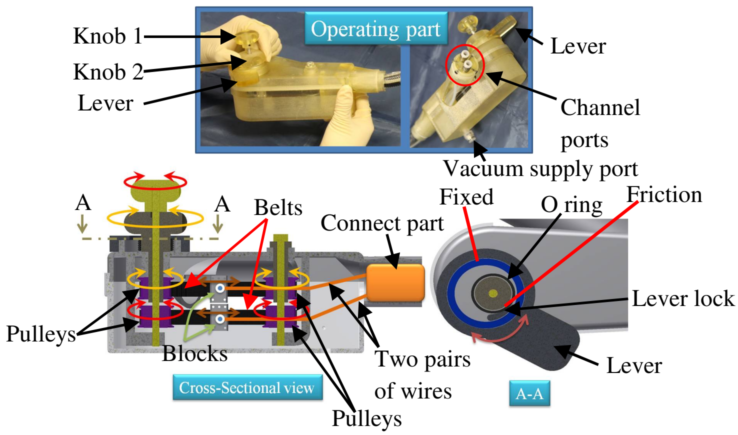


Fig. 3. Operating part of the outer sheath

2.3 Operating Part Structure

The operating part is shown in Fig. 3. To achieve smooth rotational movement and reduce backlash, belt and pulley structure is designed to control the bending angle of the distal end. Two pairs of wires (Fig. 3) for control of the bending angle are fixed on the Blocks (Fig. 3). Two sets of belt and pulley structure (two pulleys in common to one belt) allow for transmitting rotary movement of the pulleys to translatory movement of the Blocks (Fig. 3). Therefore surgeons can easily control the bending angle of distal end by rotating two knobs. Bending angles of ±120° in the vertical direction and ±90° in the horizontal direction can be achieved by Knob 1 (Fig. 3) and Knob 2 (Fig. 3), respectively. Furthermore, Surgeons can turn the lever to lock the rotation of the knob by the friction between rubber O ring (Fig. 3) and Lever lock (Fig. 3), and then the bending angle of distal end can be locked.

2.4 Prototype

The prototype of the outer sheath with endoscope and biopsy forceps can be seen in Fig. 4(A). The prototype has a maximum outer diameter of 25 mm, length of bending distal end 75 mm, and length of inserting part 330 mm. In addition, the model was equipped with one 7 mm, one 3 mm, and two 1.9 mm working channels (Fig. 4(B)). The flexible instruments like endoscope and forceps can be inserted from the 7 mm, 3 mm and 1.9 mm channels, and one of the 1.9 mm channels is used for suction and water jet (Fig. 4(C)). The rigid-flexible shaft consists of three long, flexible toothed links, a bellows tube, and a polyethylene cover. In addition, to get a better lock on the elementary part of rigid-flexible shaft, two short flexible toothed links are added on the base side of shaft (Fig. 4(D)). The outer sheath is connected to a vacuum pump (DTC-41, ULVAC KIKO Inc., Japan) and a vacuum controller to alternate between flexible and rigid modes by pushing a button. The sheath is also connected to a roller pump (RP-2100, Tokyo Rikakikai Co., Ltd., Japan) to jet water. Suction can be applied through vacuum supply ports in the operating room. The disposable inserting part can be separated from the operating part, and the outer sheath is separated from the vacuum controller and the vacuum source, to be cleaned and sterilized. All parts of the prototype are made of nonmagnetic material, and this ensures excellent MRI compatibility.

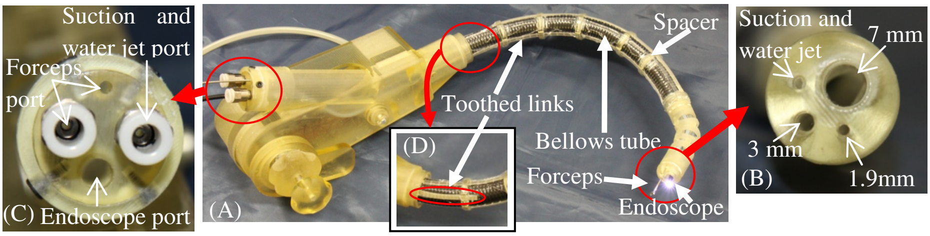


Fig. 4. Prototype of the outer sheath. (A) Image of prototype. (B) Enlarged view of bending distal end. (C) Enlarged view of channel ports. (D) Toothed links for locking base side of shaft.

3 Results

Using the outer sheath, MPS *in vivo* experiment using a swine (female, 43.5 kg) has been performed for partial gastrectomy (Fig. 5(A)). The needle devices were inserted through two 3 mm access ports in the upper abdominal region. We inserted the outer sheath through lower abdominal region as much as possible to near rectal route.

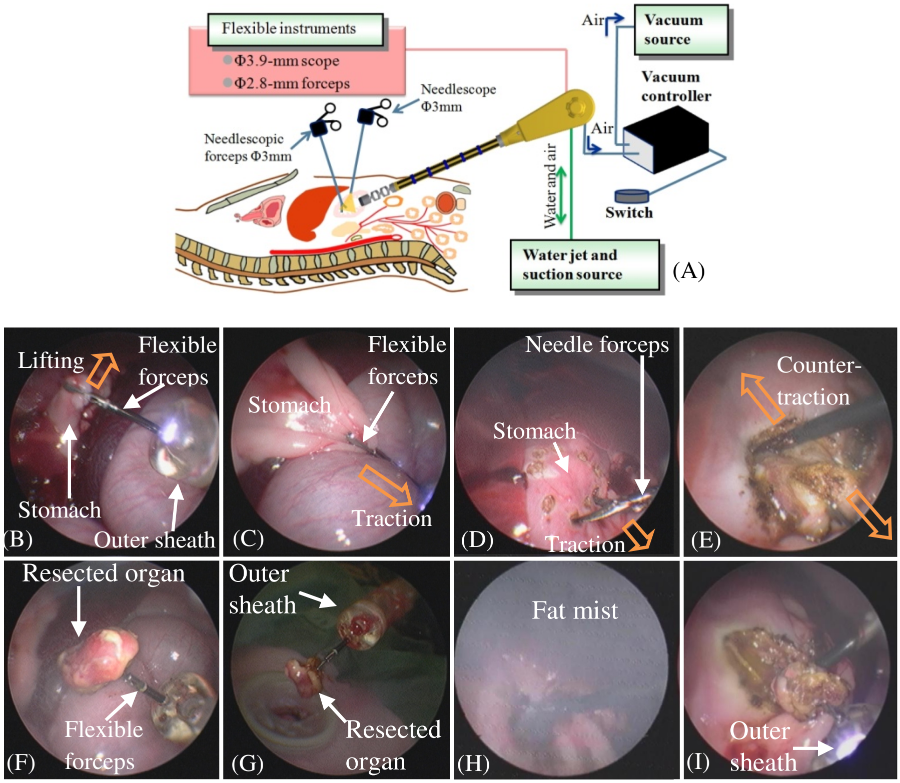


Fig. 5. 3 mm laparoscopic broad views of the abdominal cavity of a swine. (A) Outer view of *in vivo* experiment (B) Stomach clamping. (C) Stomach traction. (D) Gastric resection with traction. (E) Gastric resection with counter-traction. (F) Resected tissue clamping. (G) Removal of the resected stomach from body. (H) Image without suction from the outer sheath. (I) Image with suction from the outer sheath.

The incision part during insertion of the outer sheath was protected with a LAP DISK (Hakko Medical Inc., Japan). The instruments inserted into the outer sheath were a 3.9 mm industrial endoscope and a 2.8 mm flexible forceps. Fig. 5 (B) ~ (I) were views from a 3 mm needle scope (Karl Storz, Munich, Germany). Firstly, the outer sheath threaded its way through the large intestines and small intestines to locate stomach. We clamped the stomach surface (Fig. 5(B)), and exerted traction on stomach (Fig. 5(C)) to expose the hypothetical affected area for treatment using the 2.8 mm forceps inserted from the outer sheath. Secondly, we resected the hypothetical affected area by radiofrequency 3 mm needle forceps with traction on stomach using the 2.8 mm flexible forceps (Fig. 5(D)). Thirdly, we clamped the hypothetical affected area directly by 2.8 mm flexible forceps, and continued resection with counter-traction achieved by the outer sheath (Fig. 5(E)). The hypothetical affected area was successfully resected with the outer sheath assisted (Fig. 5(F)). Finally, we removed the resected organ from the outer sheath incision (Fig. 5(G)). Moreover, we tested the suction performance of the outer sheath. Fig. 5(H) was image of resection moment without suction from the outer sheath. The view was not clear by the fat mist. On the other hand, the image which suction was applied from the outer sheath was shown in Fig. 5(I). The clear view means that suction created by the outer sheath took effective action against fat mist.

4 Discussion and Conclusion

The workspace of the bending distal end was shown that the distal end cover a large range of bending motion, resulting in ease of application during endoscopic surgery. The measured shape holding torque was mostly in agreement with the identified equation in the straight condition. Because the number of engaged teeth diminished in curved condition, the shape holding torque was impaired as compared with the straight condition. The major distinguishing feature of the pneumatic shapelocking mechanism, besides its simple structure, is ability to achieve high shape locking power by inputting low power vacuum which is less than 1 kPa. The rupture of the sealed cover should be possible problem during inserting the outer sheath into body. However, the tissues near the outer sheath are protected from damage even in the event of air leakage (1 kPa), and the outer sheath can be removed easily from the body as it is flexible. Actually the air leakage problem has not occurred in *in vivo* experiment. Therefore, the design concept is an effective principle to produce high rigidity safely. The locking capability of bending distal end and rigid-flexible shaft allows the outer sheath to be positioned at the target field. Thus, the surgeon's hands are free. These features, combined with the flexible endoscope's four-directional flexion, enable more complex manipulation.

In *in vivo* experiment, the partial gastrectomy was successfully performed. The outer sheath has been easily located the target, and manipulated tissues stably, in comparison with conventional endoscope using in [9]. These results showed that the outer sheath has strong potential for solving access problems and stability issues in NOTES. Its robust size with 2.8 mm flexile forceps makes it easy to manipulate tissues or even to retract and lift the stomach, which are necessary maneuvers during partial gastrectomy. Because the large angle is achieved between the needlescopic devices and flexible instruments inserted from channels of the outer sheath, triangulation with separate optics and instrumentation is easy to realize. Therefore, the risk of impaired visual field, damaging tissue due to the unforeseen movements of forceps caused by clashing of devices can be minimized. In particular, two flexible instruments inserted from the outer sheath, combined with two needlescopic devices gave the surgeon the ability to manipulate tissue with traction and counter-traction almost in all planes. Furthermore, the suction from the outer sheath was very useful to draw in fat mist, which provided a clear visual field. The low resolution of the 3.9 mm industrial endoscope was not adequate for observing local fields. A high-resolution medical endoscope is scheduled for introduction. Because the flexible endoscope are inserted though the channel of the outer sheath, this makes the outer sheath itself less complex and therefore more cost effective. Furthermore, the performance of the prototype was tested in an MR environment by phantom experiment. The S/N decreasing ratio is 4.6% from introduction of the outer sheath into the phantom [10]. We will continue development of the outer sheath device focusing on a smaller diameter and better shapelocking capabilities including partially-lockable mechanism by changing the material and structure. Furthermore, the outer sheath with ultrasonic motor control system will be evaluated in an MR environment. MRI navigation and shape tracking technologies for the outer sheath will also be developed.

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