
Toshiaki Kobayashi1, Sean Lemoine1,2, Akihiko Sugawara1,2, Takaaki Tsuchida1, Takuji Gotoda1, Ichiro Oda1, Hirohisa Ueda3 and Tadao Kakizoe1

1National Cancer Center, 2Japan Association for the Advancement of Medical Equipment and 3Pentax Corporation, Tokyo, Japan

Received May 17, 2005; accepted August 25, 2005; published online November 8, 2005

Background: Surgery is a standard diagnostic and therapeutic procedure. However, its technical difficulty and invasiveness pose problems that are yet to be solved even by current surgical robots. Flexible endoscopes can access regions deep inside the body with less invasiveness than surgical approaches. Conceptually, this ability can be a solution to some of the surgical problems.

Methods: A flexible (surgical) endoscopic surgical system was developed consisting of an outer and two inner endoscopes introduced through two larger working channels of the outer endoscope. The concept of the system as a surgical instrument was assessed by animal experiments.

Results: Gastric mucosa of the swine could be successfully resected using the flexible endoscopic surgical system, thereby showing us the prospect and directions for further development of the system.

Conclusion: The concept of a flexible endoscopic surgical system is considered to offer some solutions for problems in surgery.

Key words: surgical robot – endoscopic surgery – surgery – robotics – endoscope

INTRODUCTION

We recently reported a new concept for endoscopic mucosal resection of gastric cancer with the use of a magnetic anchor. The anchor consisted of microforceps and a magnetic weight in order to grasp, stabilize and pull up the gastric mucosa (1). During the experiments, we thought that the procedure would be easier if one more endoscope was present to hold and stabilize the mucosa instead of the magnetic anchor.

Concerning flexible endoscopes, there are some ultrathin endoscopes that can be inserted into the working channels of standard endoscopes, such as gastrointestinal endoscopes. If the outer endoscope is able to contain larger and multiple working channels, several thin endoscopes could be inserted through the outer endoscope. This would allow for the resecting procedures. Such a system could also be applied to the fields where current surgical robots are targeting.

One of the problems with current surgical robots is inaccessibility to regions located deep inside the body, particularly regions reached through narrow and winding routes, such as the digestive tracts and blood vessels. However, some early gastric cancers can be resected endoscopically with much less invasiveness than surgery. These surgeries cannot be performed by current surgical robot systems because those regions were not originally considered places for the systems to operate.

An experimental flexible endoscopic surgical system was developed to cope with these problems of accessibility, consisting of a flexible outer endoscope with two working channels through which two inner flexible endoscopes could be inserted. These inner endoscopes were designed to have similar functions as flexible gastrointestinal endoscopes allowing for performance of standard endoscopic procedures even when introduced through the outer endoscope.

The uses of the flexible endoscopic system as a surgical instrument, as well as its functionality, were confirmed during gastric mucosal resection of the swine. This is in contrast to the current limitations for surgical robotics in terms of lesion access.

MATERIALS AND METHODS

FLEXIBLE SURGICAL ENDOSCOPE

As shown in Fig. 1, the flexible surgical endoscope consists of an outer flexible endoscope and two inner flexible endoscopes inserted into the working channel of the outer endoscope. The specifications of these endoscopes are listed in Table 1.
The outer endoscope also has a 2.8 mm working channel and a charge coupled device (CCD) enabling the endoscope to operate in a similar fashion as standard gastrointestinal endoscopes. The endoscopic images are observed on cathode ray tube (CRT) monitors in the same manner as video-endoscopes. Each of the inner endoscopes has a 2.0 mm working channel allowing accessories such as forceps and an electrocautery tip to be introduced and used. Unlike the outer endoscope, the inner endoscopes have optic fiber bundles for image visualization, instead of a CCD. These endoscopic images are also observed on CRT monitors. However, a video-adaptor, i.e. a small CCD video camera, must be connected onto each eye piece of the inner endoscopes in order to view the image on the monitors.

These combined endoscopes are manipulated manually by three physicians together with the help of several assistants. The system, as a whole, operates similar to surgical robotic systems.

PHYSICIANS

Two series of experiments were conducted. The first series was performed by a senior endoscopist and three resident physicians in order to assess the system with consideration to its endoscopic nature. The senior endoscopist was trained within the specialty of internal medicine, whereas one of the resident physicians was in training for internal medicine and the other two were for surgery.

The purpose of the subsequent series was to assess the concept of the flexible surgical endoscope from the viewpoint of surgeons. Consequently, the procedure was performed by two senior endoscopists, one having more than 15 year experience as a surgeon and the other having some surgical training, in addition to two residents who were in training for surgery.

These two series were performed on separate occasions, with none of the physicians performing in both series.

TEST SUBJECT

Three female swine, under intravenous anesthesia, were laid on an examination table in the left lateral position. Within the first experiment, a 35.6 kg and a 34.1 kg swine were used. In the following experiment, a 41.8 kg swine was used. During these experiments, the law for the humane treatment and management of animals was observed.

PROCEDURE

The procedure was similar to standard endoscopic mucosal resection with the exception of one more endoscope for stabilization of the gastric mucosa.

First, an incision was made in the mucosa surrounding the region of stomach intended for resection (2,3). The outer endoscope was inserted through the esophagus into the gastric cavity. Subsequently, using the telescopic connecting devices (Fig. 1), the inner endoscopes were inserted into the working channels of the outer endoscope and introduced into the gastric cavity.

The outer endoscope was placed near the region in which the first incision was made.Thereafter, the resecting procedure was performed using an electrosurgical knife through one of the working channels of the inner endoscopes, whereas the other contained forceps. Within the procedure, the operator decided which side of the working channels would use the electrosurgical knife.

These procedures were observed on three CRT monitors, each of which was connected to its endoscopic counter part.

The resecting procedures were performed on the anterior wall of the gastric angle, the anterior wall of the middle gastric body and the greater curvature of the middle gastric body in the

| Table 1. Specifications of the flexible endoscopic surgical system |
|-----------------------|---------------------|---------------------|
|                       | Outer endoscope     | Inner endoscope     |
| Total length (mm)     | 975                 | 1395                |
| Working length (mm)   | 665                 | 1050                |
| Insertion portion diameter (mm) | 20                | 4.9                |
| Tip bending (degree)  | 210/120, 120/120    | 210/120, 120/120    |
| (up/down, right/left) |                     |                     |
| Field of view (degree)| 140                 | 120                 |
| Depth of field (mm)   | 4–100               | 3–50                |
| Channel diameter (mm) | 7, 7, 2.8           | 2                   |

Figure 1. The flexible endoscopic surgical system. (A) The inner endoscope is inserted through a telescopic connecting device, which connects to the opening for the working channel of the outer endoscope near its control section. (B) At the tip of the outer endoscope two inner endoscopes protrude laterally, obtaining a certain distance between the two endoscopes.
first series for the assessment of endoscopic features. Within the following series, the resecting procedures were performed on two regions adjacent to the greater curvature of the lower gastric body.

RESULTS

Concerning insertion of the outer endoscope through the esophagus into the gastric cavity, some difficulties were encountered owing to the large diameter of the outer endoscope and the relatively small size of the swine in both experimental series. However, the outer endoscope was introduced into the gastric cavity.

As for insertion of the inner endoscopes through the working channels of the outer endoscope, there were no difficulties experienced, even when the outer endoscope was bent due to insertion through the esophagus. Access to regions of the gastric wall was limited to the greater curvature due to the rigidity of the outer endoscope.

Maneuverability of the flexible endoscopic surgery system was satisfactory regarding the experiments were the first experiences for the physicians involved, despite some problems to solve.

The images from the outer endoscope were similar to those of standard gastrointestinal video-endoscopes due to the CCD system used in the outer endoscope. However, the images from the inner endoscopes were inferior to those of the outer endoscope. This inferiority was attributed to the limited number of optical fibers within the inner endoscope and deterioration of the image caused by conversion from optical images to electrical images through the use of a video-adapter. Consequently, during most of the procedure, endoscopic images were mainly observed using the monitor for the outer endoscope.

Some differences in use of the inner endoscopes for the resecting procedures between the first series and the second series were noticed. In the first series, the physicians appeared to have difficulties in some of the procedures such as accessing the mucosa, stabilization of the mucosal flap and resection procedures. These procedures were considered standard techniques for actual surgery, which means surgical experiences are required even to maneuver the flexible endoscopic surgical system.

Within the second series conducted by endoscopists with surgical experience using the system (Fig. 2). Through cooperation between the operator and assistants using verbal commands, manipulation of the inner endoscopes and the outer endoscope could be achieved. The functions of the inner endoscopes could be modified by changing the instruments inserted into the working channels. The flexible nature of the inner endoscopes allowed additional functions such as stabilization of the gastric wall by the longitudinal flank of the endoscope, as shown in Fig. 2C.

Within all the experiments, resecting procedures were completed without any complications such as perforation of the gastric wall. Consequently, five mucosal pieces, with sizes of

2.8 \times 1.6 \text{ cm}^2, 2.8 \times 2.7 \text{ cm}^2 \text{ and } 2.6 \times 2.0 \text{ cm}^2 \text{ in the first series, and } 3.2 \times 2.7 \text{ cm}^2 \text{ and } 4.0 \times 3.4 \text{ cm}^2 \text{ in the second series were each resected in a single piece.}

DISCUSSION

Surgical procedures are good options for diagnosis and treatment providing several advantages over non-surgical
Flexible surgical endoscope

approaches, especially in cases of malignant diseases. Although surgery is well accepted as a standard procedure in medicine there are still some problems left unsettled.

The technical difficulty of surgery is a common problem particularly for trainees, but even for experienced surgeons who have some technical limitations. Surgical procedures are difficult for regions deep in the body because the visual field for surgeons is limited, the number of surgical instruments which can be introduced is limited and the movements of these instruments are limited. One of the exemplary regions of this problem is the pelvic cavity, which includes surgery of rectal and prostate cancers.

Invisibility is an inherent drawback to surgery, discouraging patients to undergo surgical treatment even when it is appropriate. It is true that surgery should be avoided when there are other less invasive alternatives.

Surgical robots such as the da Vinci system and the Zeus system are highly advanced medical instruments allowing for fine movements when appropriately manipulated by surgical experts. These systems are expected to solve some surgical problems such as invasiveness and the difficulty (4–8). Thus far, the systems have been able to solve some of the problems associated with surgery.

As for the invasiveness of surgery, endoscopic surgeries such as laparoscopy can be performed with robotic systems, utilizing smaller incisions than those of other standard open surgical approaches. The precise movements of surgeons are facilitated by robotic systems. However, laparoscopic procedures can be performed even without the robotic systems with the same amount of invasiveness.

Current robotic systems may also pose problems (4–8), such as the limited number of surgeons who can manipulate the system, which is usually one. Additional training for the specific manipulating methods of the systems is another problem, as well as introduction costs. Consequently, it is currently not clear what the benefits of these robotic systems are, especially when assessed from the patient side. Moreover, problems which even surgical experts suffer from have not been solved.

Flexible endoscopes have been developed to cope with the problems of accessing regions through narrow tracts such as the esophagus and the tracheobronchial tree. Even in these regions flexible endoscopes can perform surgical procedures similar to standard surgery. Therefore, endoscopes are naturally considered functional even in other cavities such as the abdomen and pelvic cavities.

It would be easier and more functional to perform an operation using several endoscopic instruments introduced through the end of one endoscope, rather than conducting resection using only one endoscopic instrument introduced into one endoscope, as done in standard endoscopic procedures. The simplest model for this concept is the flexible endoscopic surgical system we developed and examined within these trials.

We assumed that there would be several problems with the flexible endoscopic surgical system when used clinically as it is merely a conceptual model to confirm its feasibility of use. However, despite those problems, the system was able to perform surgical resection. In addition, the problems encountered within the first experiment were inherent in all technical procedures.

Of interest, these problems showed us that, when indicated for resecting procedures, the flexible endoscopic surgical system is easier to manipulate by surgeons and not by endoscopists despite its endoscopic appearances.

The images of the inner endoscopes were not satisfactory because a CCD was not used in these endoscopes. Consequently, resecting procedures were monitored by images from the outer endoscope which contained the CCD. In this situation, the operator had to control the inner endoscope via observations on the monitor of the outer endoscope. This is different from standard endoscopic procedures in which images are observed on the monitor of the endoscope which the operator is controlling.

In general, it is not easy for trainees to understand appropriate surgical procedures, i.e. where to cut and where to stabilize. Verbal communication during operation is important to facilitate appropriate assistance, which was not adequately utilized in the first series. These issues are to be learned through years of experience and cannot be achieved instantly.

As mentioned above, the difference between the two experiments may reveal that for these flexible endoscopes, surgical experience is an important factor, when the system is indicated for surgical procedures. The limitation of the inner endoscopes, not having CCD may have emphasized this issue. Consequently, the next system is to consist of two inner endoscopes with a CCD for each. This would allow the operators to control the inner endoscopes in such a manner as used for standard gastrointestinal endoscopic procedures.

Furthermore, we think that there should be two styles of design for future flexible endoscopic surgical systems; one with increased surgical maneuverability designed particularly for the techniques of surgeons, the other preserving flexible endoscopic maneuverability for endoscopists. Although it has not been decided yet which design is more appropriate for a future surgical system, endoscopists may be able to become accustomed to the flexible endoscopic surgical system with surgical maneuverability when the system is popularized.

In addition to the merits mentioned above, flexible endoscopic materials can theoretically be made compatible with X-ray systems such as fluoroscopes and computed tomography (CT) systems, exemplified by such procedures as X-ray guided bronchoscopy. In the future, the materials used for flexible endoscopic constructions are expected to acquire compatibility with the magnetic fields of magnetic resonance imaging (MRI) systems.

As mentioned before, limitations in visualization pose surgical problems even for experienced surgeons. This may only partially be solved by the subjective ability of surgeons to presume the identity of invisible objects using their tactile sense and their intuition. Actually, the compatibility with imaging systems was one of the important requirements for the design of the flexible endoscopic surgical system,
allowing visibility of anatomical information invisible to the surgeon’s eyes.

In order to make one more step towards the future for less invasive and more effective medical treatments, we believe that future surgical systems should acquire the accessibility to narrow regions located deep inside the body together with the compatibility of imaging systems such as CT and MRI. Thus, from the flexible nature and structural characteristics of a non-jointed, smooth outer sheath, we selected the flexible endoscope as the conceptual basis of development for our system. It is the combination of these and the aforementioned aspects that allows for minimization in invasiveness, through the use of pre-existing natural structures and tracts for lesion access to deep regions, and with the presence of multiple interchangeable inner-scopes, an increase in distal tip functionality at the surgical site. Although there are several factors still to discuss and develop, the concept of the flexible endoscopic surgical system is considered an appropriate development for a future surgical robotic system with this current system being a successful step towards that future.

Acknowledgments

This study was supported by a Grant-in-Aid for Research on Medical Devices for Analyzing, Supporting and Substituting the Function of Human Body from the Ministry of Health, Labour and Welfare.

References