Effects of Flexible Surgery Robot on Endoscopic Procedure: Preliminary Bench-Top User Test

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***Abstract*— Endoscopes are widely used for not only intraluminal diagnosis but also therapeutic procedures in the gastrointestinal area. However, conventional endoscopes present a few challenges such as nonintuitive manipulation, physical burden on the operator, and lack of dexterity. These challenges limit endoscope usage in complex surgical procedures. Moreover, endoscope operators undergo extensive and lengthy training to attain an adequate skill level. In this paper, we introduce a flexible surgery robot platform K-FLEX that facilitates teleoperation via an intuitive master interface and bimanual manipulation by means of two dexterous surgical robot arms. Its effects on endoscopic procedures, especially in terms of task performance, learning properties, and physical burden on the operator, are validated by conducting a user test. The experimental results demonstrate that the developed robotic assistant increases operation speed, especially for novices; simplifies the learning process; and reduces the workload on the operator compared to conventional endoscopes.**

I. Introduction

Endoscopes are widely used for not only intraluminal diagnoses in the gastrointestinal area but also therapeutic procedures, such as endoscopic submucosal dissection (ESD) and endoscopic mucosal resection in early cancer treatment [1][2]. Moreover, advances in endoscopic instruments and skills have facilitated more advanced surgical procedures, such as natural orifice transluminal endoscopic surgery (NOTES), which is performed by introducing an endoscope through a natural opening such as the mouth or the anus instead of an external incision [3]. Such endoscopic procedures can enhance clinical outcomes, for example, shorter recovery times and zero scarring [4][5].

However, conventional endoscopes present a few challenges, which limits their use in complex surgical procedures. Moreover, endoscope operators must be trained for extended periods to ensure they attain an adequate level of skill [6]. First, endoscope manipulation is not intuitive because the operator steers the bending section of an endoscope by rotating a knob [7]. Second, physical burden is imposed on the operator because the operator must hold the endoscope in their hand throughout the procedure. Third, the degree of freedom (DoF) of the surgical instrument is limited to two, namely, translation and roll, which does not allow for the dexterous motion required to accomplish complex surgical tasks. To overcome these limitations, several flexible surgery robot platforms for endoscopic therapeutic procedures have been developed in recent years. A few examples are as follows: ViaCath [8], FLEX [9], MASTER [10], STRAS(v2) [11], and i2Snake [12]. All of these platforms feature a flexible endoscope and two articulated surgical instruments with multiple DoFs that are teleoperated via a master interface. These flexible robots have been applied to endoscopic procedures, such as ESD or tumor resection, in in-vivo animal and human trials, and promising results demonstrating improvement in task-performance time or perforation rate compared to conventional endoscopes have been reported.

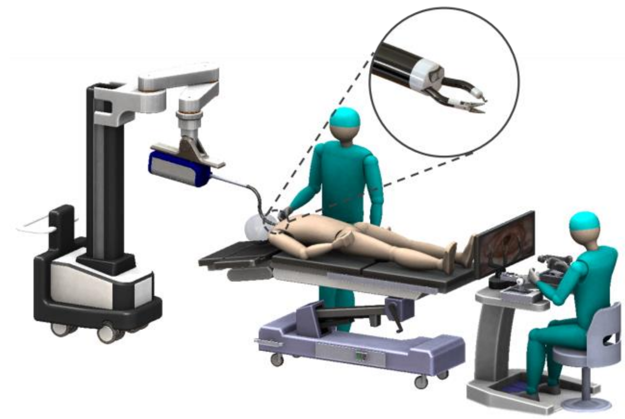

Figure 1. Conceptual design of flexible surgery robot platform (K-FLEX).

In the present paper, we describe a flexible surgery robot platform K-FLEX, shown in Figure 1, and validate its effectiveness in endoscopic procedures by means of a comparison with a conventional endoscope in a user test. We focus on how the proposed robotic assistant is different in terms of its learning properties and the physical burden it imposes on the operator, as well as in terms of task performed by both novice and expert operators. To the best of our knowledge, validation studies on abovementioned issues by using

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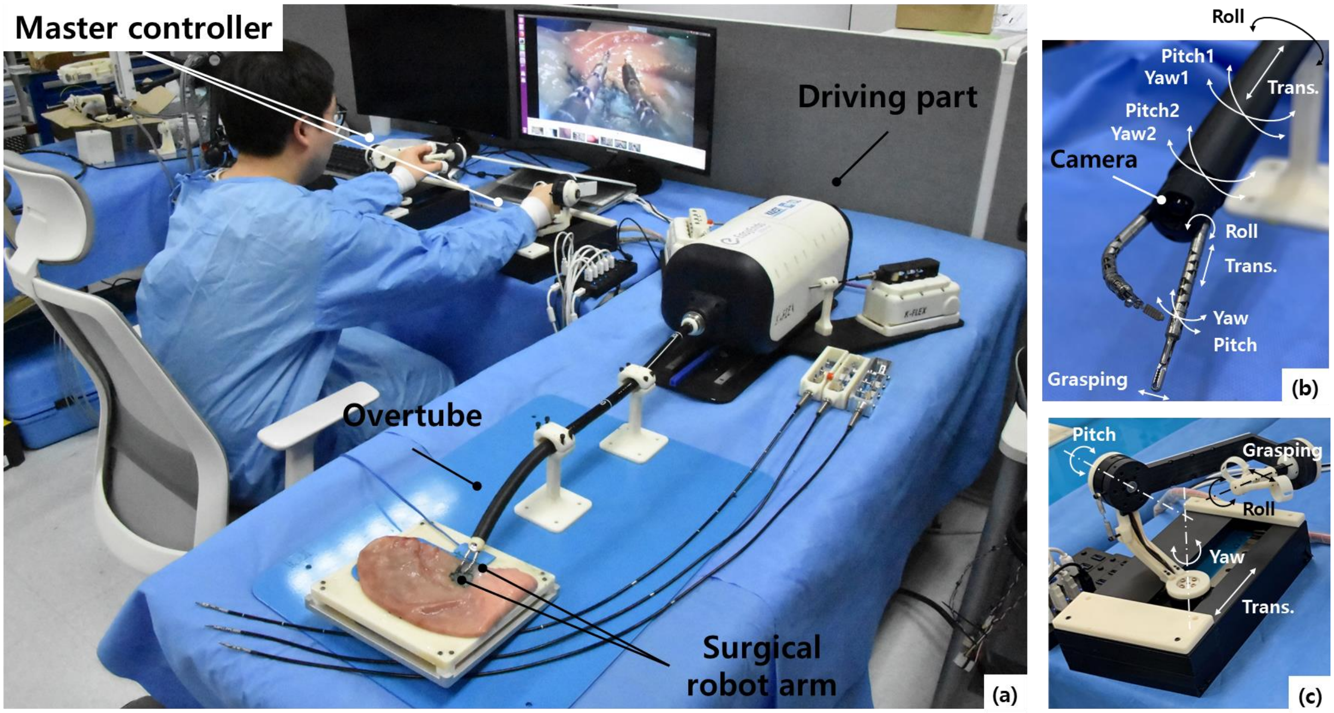


Figure 2. (a) Prototype of flexible surgery robot platform for endoscopic procedures. (b) Overtube and surgical robot arms with DoFs (c) Master controller with DoFs.

related robot platforms are scarce. Moreover, the identification of such characteristics will enhance our understanding of the advantages offered by robotic assistants in endoscopic procedures.

II. Flexible surgery robot platform (K-FLEX)

A. Robot concept

A prototype of K-FLEX, a teleoperated robot platform designed for endoscopic gastrointestinal surgery, is shown in Figure 2(a). It consists of a flexible and bendable overtube that houses an endoscopic camera, two dexterous surgical robot arms, a driving part, and master controller.

The bendable overtube is inserted into a patient's body through a single incision or a natural orifice such as the mouth or the anus. Then, the overtube, owing to the steering of its active bending section and flexible insertion tube, can proceed the target lesion through a curved pathway. After the overtube reaches the lesion, the surgical robot arms are introduced through the working channel inside the overtube to perform surgical procedures. The use of two surgical robot arms facilitates bimanual tissue manipulation, such as traction and cutting. The overtube and the surgical robot arms are controlled by one surgeon via the master controller.

B. Overtube

The overtube must be flexible so that it can access lesions through the curved and confined pathway, in addition to being able to maintain a stable shape under external loads during the procedure. The active bending section of the overtube is a hyper-redundant continuum manipulator composed of plural rolling-contact joints, the design variables of which are set to maximize the energy required to form a deformed shape. The design provides not only flexible bending capability but also resistance against shape distortion under external loads. The overtube houses a two-dimensional camera that is attached to its distal tip, two guide channels for surgical robot arms, and a service channel. It has six DoF in motion (translation-roll-yaw1-pitch1-yaw2-pitch2). Its outer diameter is 17 mm. Its length is 750 mm allowing to access lesion in stomach and descending colon. The active bending section can bend to the retroflex posture and the cobra-like posture.

C. Surgical robot arm

The surgical robot arms must be dexterous and capable of carrying large payloads while being compact themselves. The surgical robot arms have two configurations with same diameter but different DoF depending on their function. One is five-DoF (translation-roll-yaw-pitch-grasping) for enhanced dexterity as shown in Figure. 2(b), and the other is four-DoF (translation-roll-pitch-grasping) for enhanced payload capability. The active bending section in both surgical robot arms is a hyper-redundant continuum manipulator composed of plural rolling-contact joints. A specially designed constraining mechanism that mechanically limits shape distortion is employed as the active bending section of the four-DoF surgical robot arm [13]. This robot arm mechanism is a distinctive feature compared to other flexible surgery robot platforms and it provides enhanced payload with small size that the four-DOF surgical robot arm can stably lift 200 g weight with 3.7 mm diameter. This arm is designed to retract, which means a higher payload capability is more important than dexterity. The surgical robot

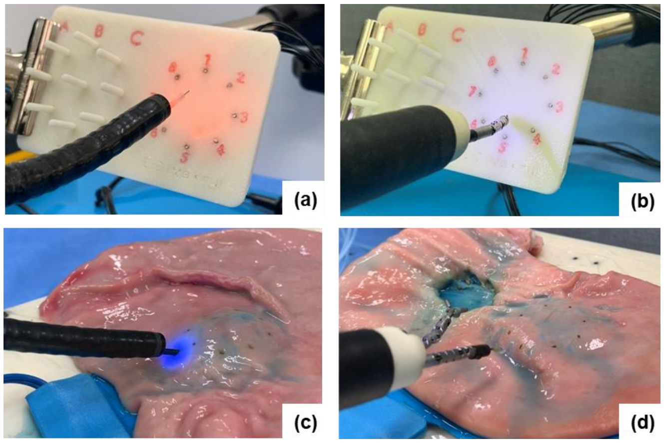


Figure 3. Experimental setup. Targeting task using (a) endoscope and (b) K-FLEX. Tissue-cutting task using (c) endoscope and (d) K-FLEX.

arms hold various instrument such as forceps, hook knife, and spatula bovie at its tip. It has a coupler at the proximal end, which helps with easy mounting or detachment of the surgical robot arm on the driving part. The surgical robot arm can bend by up to 90°. The bending motion of both the overtube and the surgical robot arm is achieved using the tendon-driven method [14], and SUS wire is used as an actuation wire.

D. *Master controller*

The master controller must be intuitive to operate. A kinematic design with the same DoF (five-DoF) and a similar joint arrangement (Translation-Yaw-Pitch-Roll-Grasping) as those of the instrument is proposed as shown in Figure. 2(c) [15]. This design offers improved intuitiveness to the user, resulting in faster task completion compared to commercial master controller. The orientation of the master controller is mapped to the orientation of the surgical instrument. The user can switch between the overtube or the surgical robot arm as the mapping target of the master controller by using the foot pedal.

III. User Test: Robotic versus Conventional Endoscopic Therapeutic Procedure

K-FLEX facilitates teleoperation via its intuitive master interface. We hypothesized that this platform could enhance task performance, learning curve properties, and reduce operator's burden compared to a conventional endoscope.

In addition, K-FLEX allows for bimanual manipulation by using surgical robot arms that can move dexterously. We hypothesized that this feature could improve task performance, especially in complex endoscopic procedures.

We designed a user test to validate the effects of the abovementioned robotic-assistance features of K-FLEX in endoscopic therapeutic procedures. The fundamental tasks associated with endoscopic therapeutic procedures can be categorized as follows: targeting, grasping, and cutting. Among these fundamental tasks, we selected targeting and cutting as bench-top tasks in this study. Targeting is the most basic task that can be achieved by means of endoscope (or overtube in K-FLEX) manipulation alone. We decided to validate the effect of teleoperation by using the intuitive master interface of K-FLEX to complete the simplest task as the first step. Cutting is one of the most complex endoscopic tasks. Dexterous bimanual manipulation may bring advantages for completing this task. We determined the detailed setup for each bench-top test to simulate ESD, a representative endoscopic therapeutic procedure.

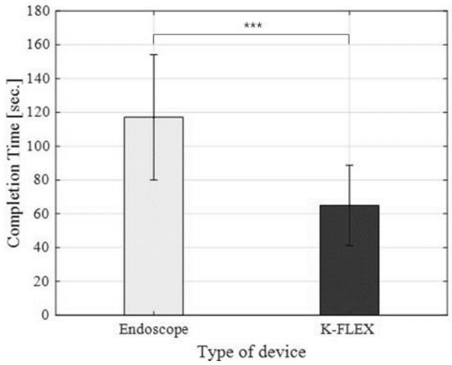
These tasks were performed using both K-FLEX and a conventional single-channel gastric endoscope (GIF-XQ240, Olympus, Japan).

A. *Targeting task*

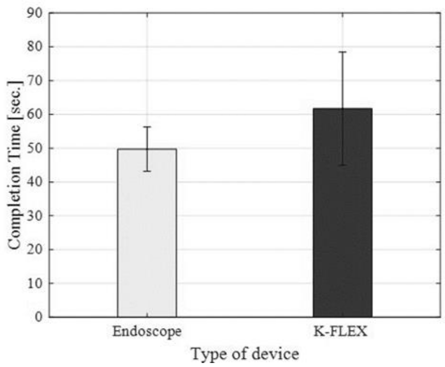
The experimental setup is shown in Figures 3(a) and (b). During ESD, circular markings are made around the lesion to define the dissection area (lesion marking). A touch board with eight target points arranged on the circumference of a circle measuring 30 mm in diameter was fabricated. The diameter of the circle was determined by referring to the typical size of a lesion subjected to ESD [16]. The endoscope and the overtube of K-FLEX have a hook knife attached to their tips. The operator was asked to manipulate the endoscope or the overtube to touch the target points in numerical order from 1 to 8. As the operator touched the target point precisely, a beep was generated, post which the operator could proceed to the next target point. We recorded the time required to touch all eight points and used this for evaluation value for task performance. The experiment was repeated 10 times for each subject and device. After completing the task for each device, we asked the subjects the NASA Task Load Index (NASA-TLX) [17] question to measure the workload associated with performing the task. The burden on the subjects was evaluated based on the overall workload score obtained from NASA-TLX.

B. *Tissue cutting task*

The experimental setup is shown in Figures 3(c) and (d). During ESD, the tissue around the lesion is cut along the markings (precut). Then, the tissue, including the lesion, is dissected using an electric knife (dissection). An ex-vivo porcine stomach tissue was used for this task. Marking and injection were completed beforehand. Eight points were marked on the tissue surface, and they were arranged on the circumference of a circle measuring 30 mm in diameter referring to the lesion size in ESD [16]. The volume of injection solution was set to 10 ml. The operator was asked to make a precut along the markings and then perform dissection. We allowed the operator to operate both the overtube and two surgical robot arms equipped with forceps and hook knife when using K-FLEX. When using the endoscope, we provided an assistant to the operator to help with manipulation of the hook knife. The completion times of the precut and the dissection tasks as well as the size of resected specimen were recorded. The cutting speed of the precut and the dissection was used for the evaluation value for task performance. The cutting speed was defined by dividing the specimen size by the completion time. Since all resected specimens presented an oval shape, the specimen size was calculated with an approximation to an ellipsoidal shape [18]. The experiment

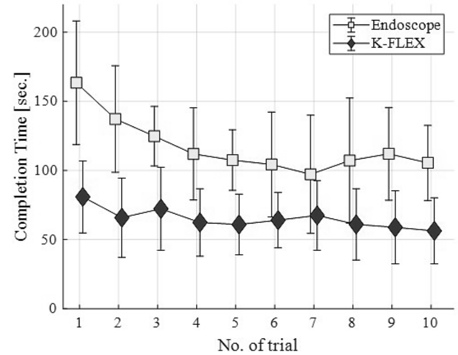


(a)



(b)

Figure 4. Experimental result of targeting task. (a) Completion time for novice. (b) Completion time for expert (***$p < 0.001$).



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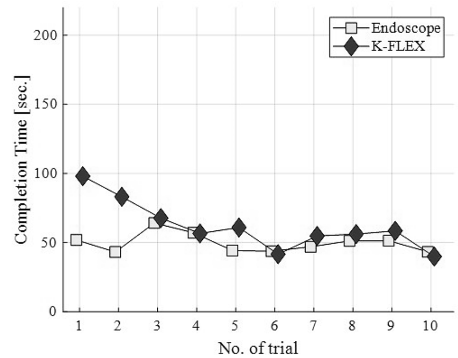

(b)

Figure 5. Change in completion time for targeting task in cases of (a) novice and (b) expert operators.

was performed with each device by an expert endoscopist. After completing the task for each device, we asked the subjects the NASA-TLX question to measure the workload associated with performing the task.

C. Subjects

We categorized the subjects into two groups; novice and expert. Novice was defined as a person with no experience of using the conventional endoscope or K-FLEX. Expert was defined as an endoscopist who has experienced more than 750 ESD procedures with conventional endoscope but no experience of using K-FLEX. For the targeting task, we included five novice and one expert operators as the participants. For the tissue cutting task, we included the expert who participated in the targeting task. Before the targeting task, all subjects were trained for a few minutes on manipulating the endoscope and K-FLEX. Because the tissue cutting task was performed after the targeting task, the expert had approximately 1 h of experience of using K-FLEX when he started the tissue cutting task.

IV. Result

A. Targeting task

The experimental results are shown in Figs. 4 and 5, and summarized in Table 1. The task completion times of the novice and the expert are shown in Figure 4. The mean ± standard deviation of the completion times of the novices were 117.1 ± 37.0 s and 65.0 ± 23.7 s with conventional endoscope and K-FLEX, respectively. The mean completion time with K-FLEX was approximately 55% shorter, and the completion times with the endoscope and K-FLEX differed significantly (Student's t-test, $p < 0.001$). In case of the expert, the mean ± standard deviation of the completion times were 49.7 ± 6.6 s and 61.7 ± 15.8 s with the conventional endoscope and K-FLEX, respectively. The mean completion time was approximately 24% longer with K-FLEX.

TABLE I. Overall workload score in targeting task

	Endoscope	K-FLEX
Novice	72.8	35.6
Expert	20.0	18.7

The changes in completion times over 10 repetitions by the novices and the expert are shown in Figure 5. In case of the novice, the completion time with K-FLEX was shorter than that with the endoscope in the first trial and it decreased gradually as the number of repetitions increased. In case of the expert, the completion time with the endoscope remained constant in all repetitions. The completion time with K-FLEX was longer in the first few repetitions, but it was comparable to that with the endoscope after the sixth trial. In case of the novices, the completion time with K-FLEX was 56.3 ± 21.4 s in the tenth trial; this value is comparable to the expert's mean completion time with the endoscope over 10 trials (65.0 ± 23.7 s).

The overall workload score measured based on NASA-TLX is given in Table 1. The value indicates the mean score of all subjects in each group. The novices reported a higher

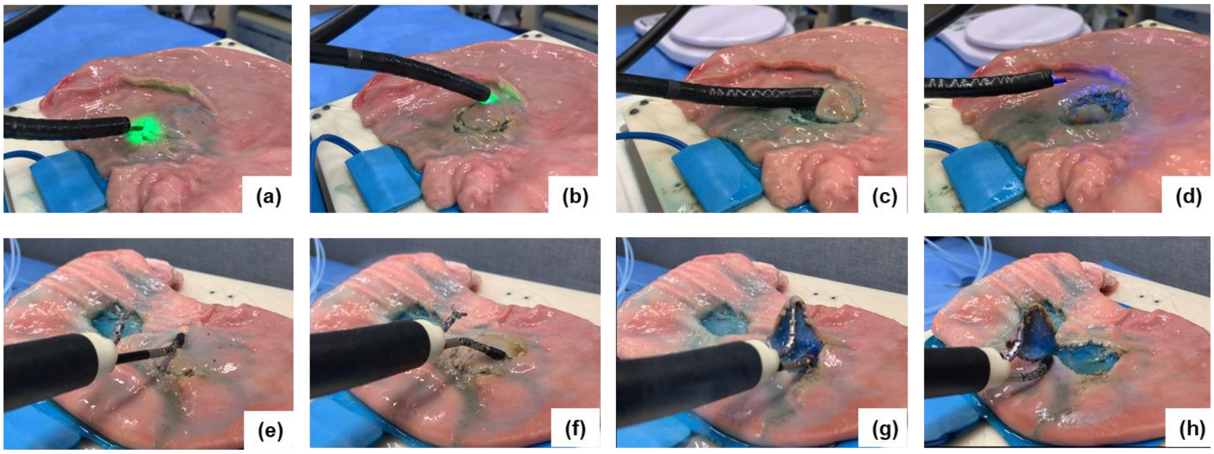

Figure 6. Tissue cutting process. (a) and (b) Precut using endoscope. (c) and (d) Dissection using endoscope. (e) and (f) Precut using K-FLEX. (g) and (h) Dissection using K-FLEX.

TABLE II. CUTTING SPEED IN TISSUE CUTTING TASK

	Device	Cutting speed [mm^2/s]
Precut	Endoscope (1st trial)	1.99
	K-FLEX (1st trial)	1.26
	K-FLEX (2nd trial)	2.37
Dissection	Endoscope (1st trial)	1.27
	K-FLEX (1st trial)	1.40
	K-FLEX (2nd trial)	1.69

TABLE III. OVERALL WORKLOAD SCORE IN TISSUE CUTTING TASK

	Endoscope	K-FLEX
Precut	24.6	21.7
Dissection	37.0	14.7

workload when they used the endoscope, and the difference between the two devices was significant (Mann–Whitney U test, $p = 0.034$). The values reported by the expert for the two devices did not differ significantly.

B. Tissue cutting task

The experimental results are shown in Figure 6 and summarized in Table 2 and Table 3. The subject were able to complete the task with the endoscope and K-FLEX, as shown in Figure 6. The subject used the left surgical robot arm with forceps for tissue lifting during the dissection task. The cutting speed for the precut with K-FLEX was slower than that of endoscope in the first trial, and it became faster in the second trial. The cutting speed for the dissection with K-FLEX was faster than that of endoscope from the first trial, as given in Table 2. The overall work load score for precut and dissection is given in Table 3. The subject reported a less than half of the workload when he used the K-FLEX for the dissection. The subject commented that dissection was easier with K-FLEX because the additional dexterous robot arm could be used to lift the tissue in order to expose the cutting plane and provide tissue tension for cutting.

V. DISCUSSION

In the targeting task, for novice users, the completion time and the overall workload were shorter and smaller with K-FLEX. Therefore, for novice endoscopists, the proposed teleoperation robotic assistant improved task performance speed and reduced the burden on the operator during the procedure. This might be because K-FLEX offers a more intuitive manipulation method compared to the conventional endoscope. For the expert, the completion time with K-FLEX was longer than that with the endoscope in the first few repetitions, but it was comparable after the sixth repetition. Although only one expert participated in the experiments, the result demonstrated the possibility that the proposed robotic assistant can facilitate easy and fast learning. The completion time with K-FLEX in case of the expert decreased over 10 repetitions, but further tracking is required to identify whether the completion time with K-FLEX can be shorter compared to that with the conventional endoscope. The completion time with K-FLEX in case of the novices in the tenth trial was comparable to that with the endoscope in case of the expert. The gap between the expert and the novices cannot be compensated in terms of task performance speed alone. However, even novices can possibly perform such tasks in endoscopic procedures at speeds comparable to that of an expert after a short training period when they use the proposed flexible robot platform. The overall workload imposed by K-FLEX did not differ significantly from that imposed by the conventional endoscope in case of the expert because the expert was used to handling the conventional endoscope. However, the result could change if the task is more complex and the operation time is longer.

In the tissue cutting task, the expert completed both precut and dissection with faster cutting speed with K-FLEX in his second trial. In the first trial with K-FLEX, the subject needed some time to get used to the operation such as switching between overtube and surgical instrument and bimanual operation for performing both tissue lifting and tissue cutting task simultaneously. In the second trial with K-FLEX, the subject showed a much improved operation. Although only one expert participated in the experiments and the number of trials was limited, these results suggest the possibility that the combination of intuitive operation and bimanual manipulation with dexterous instruments would be beneficial for performing complex endoscopic procedures, such as ESD. That the expert endoscopist could perform tissue cutting by using K-FLEX with speed comparable to or better than that with the endoscope after approximately 1 h of training is a promising result. Since applying cap to the conventional endoscope tip provides a better environment for the dissection, further comparison with the conventional endoscope with cap will be studied. In addition, the dexterity and manipulation force of the surgical robot arms proved to be adequate for tissue manipulation and cutting, which shows the feasibility of applying the surgical robot arm to ESD.

The present study has a few limitations. First, the numbers of subjects and trials were limited. A greater number of subjects, especially experts, is required for drawing more reliable conclusions. The analysis would have been strengthened had each participant continued to perform the task until they reached a clear plateau in the learning curve. This was our first step and a preliminary study for validating the effectiveness of the proposed robotic assistant. In subsequent studies, we will include a greater number of subjects and conduct a greater number of trials. Second, completion time alone is not representative of task performance. However, the significant differences between the completion times achieved with the devices used herein can serve as indicators of the effectiveness of K-FLEX from one major perspective. A few additional evaluation values such as quantified ESD quality and complications will be considered in our future study, since these factors are clinically important outcomes. Third, the present user test was performed with the bench top environment. In in-vivo situation, a few factors such as bleeding or organ movement would increase the difficulty in performing surgical task. In-vivo animal study will be conducted to comprehensively identify the effect of robotic assistance considering abovementioned factors.

VI. Conclusion

Herein, we presented the results of preliminary bench top user tests conducted to validate the effectiveness of the proposed flexible robot platform K-FLEX, featuring teleoperation via an intuitive master interface and bimanual manipulation by means of two dexterous surgical robot arms. The experimental results demonstrated that K-FLEX can offer advantages in endoscopic therapeutic procedures in terms of task performance speed, especially to novices; learning speed; and operator workload compared to the conventional endoscope.

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