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Abstract (Purpose) In minimally invasive surgery, instruments are inserted from the exterior of the patient’s body into the surgical field inside the body through the minimum incision, resulting in limited visibility, accessibility, and dexterity. To address this problem, surgical instruments with articulated joints and multiple degrees of freedom have been developed. The articulations in currently available surgical instruments use mainly wire or link mechanisms. These mechanisms are generally robust and reliable, but the miniaturization of the mechanical parts required often results in problems with size, weight, durability, mechanical play, sterilization, and assembly costs.

(Methods) We thus introduced a compliant mechanism to a laparoscopic surgical instrument with multiple degrees of freedom at the tip. To show the feasibility of the concept, we developed a prototype with 2 degree-of-freedom articulated surgical instruments that can perform the grasping and bending movements. The developed prototype is roughly the same size of the conventional laparoscopic instrument, within the diameter of 4 mm. The elastic parts were fabricated by Ni-Ti alloy and SK-85M, rigid parts were fabricated by stainless steel, covered by 3D printed ABS resin. The prototype was designed using iterative finite element method analysis, and has a minimal number of mechanical parts.

(Results) The prototype showed hysteresis in grasping movement presumably due to the friction, however, the prototype showed promising mechanical characteristics and was fully functional in 2 degree-of-freedom. In addition, the prototype was capable to exert over 15 N grasping that is sufficient for the general laparoscopic procedure. The evaluation tests thus positively showed the concept of the proposed mechanism.

(Conclusion) The prototype showed promising characteristics in the given mechanical evaluation experiments. Use of a compliant mechanism such as in our prototype may contribute to the advancement of surgical instruments in terms of simplicity, size, weight, dexterity, and affordability.

Keywords Minimally invasive surgery · Articulated surgical instrument · Compliant mechanism · Robotic surgery

1 Purpose

In minimally invasive surgery (MIS), instruments are inserted from the exterior of the patient’s body into the surgical field inside the body through the minimum incision, resulting in limited visibility, accessibility, and dexterity. MIS minimizes the invasiveness of surgical procedures, but results in limited visibility, accessibility, and dexterity because of the limited view through the endoscope and the restricted movements of the surgical instruments. To address this problem, surgical instruments with articulated joints and multiple degrees of freedom (DOF) have been developed and are commercially available.

The da Vinci system (Intuitive Surgical, USA) [1] is a well-known surgical robotic system that includes articulated robotic forceps and other instruments.

This system provides good dexterity for the surgeon, but is expensive and requires a cumbersome preparation process including drastic changes to the operating room (OR) before deployment. Hand-held robotic surgical instruments with articulated tips have also been developed, which are more compact and easier to deploy in the OR than the da Vinci system [2]-[5]. However, these devices are also complex, and are more expensive than conventional surgical instruments. JAiMY (EndoControl, France) [2] is a commercially available laparoscopic hand-held robotic instrument, which has a 5-mm diameter tip and three DOF. KIMERAX (Terumo Europe, Belgium) [3] [4] is another instrument with multiple DOF at the tip, which can be manipulated with a hand-held controller. However, production of KIMERAX has been discontinued, and it is not available at the time of writing. Another example is DEX robot from Dextérité Surgical [5] that is equipped with the multiple DOF at the tip.

In addition to robotic surgical instruments, use of non-motorized articulated surgical instruments has been widely studied in several areas of surgery. Non-motorized articulated surgical instruments usually have levers or dials with a mechanical connection to the tip of the instrument, which are used to manipulate the tip. As these instruments are hand-held and are not motorized, they are easy to deploy in the OR. Articulated instruments were introduced early in single-incision laparoscopic surgery [6] [7] [8], because surgery through a single incision restricts the ability to move the instruments, and movement with multiple DOF is important. A bendable needle holder for general laparoscopic surgery that has a series of bevel gears is commercially available from Tuebingen Scientific [9]. Mizuho produces forceps with a 3-mm diameter bendable tip [12] for use in endoscopic sinus surgery [10] and pituitary surgery [11], and the Serpent forceps with a bendable tip produced by Entrigue Surgical [13] are also used in sinus surgery.

Laparo-Angle Articulating Instrument from CambridgeEndo [14] is equipped with a bending articulation at the tip, and rotation and grasping motions are also feasible. The device has been designed for single-incision laparoscopic surgery.

The articulated surgical instruments described above all have wire or link mechanisms. The general mechanical setup of laparoscopic surgical instruments has previously been described [15]. The mechanisms are generally robust and reliable, but the miniaturized mechanical parts required result in problems with the size, weight, durability, mechanical play, sterilization, and cost. To address these problems, we developed a compliant mechanism for use in articulated surgical instruments. Use of a compliant mechanism enables development of simple, compact, light-weight, dexterous, and affordable instruments. Compliant mechanisms [16]-[18] use one or more deformable elastic structures to transmit force, rather than using a conventional hinge joint. Compliant mechanisms have no backlash, do not need lubrication, are free from mechanical noise and abrasion powder, and are simple, compact, and light-weight because of their monolithic structure. Lange et al. [19] used a topology optimization process to develop an instrument with a compliant mechanism for use in MIS.

Sato et al. [20] developed 1.4-mm diameter micro-forceps with an elastic hinge. We have previously described a robotic manipulator that used a compliant mechanism [21].

The aim of this study is to investigate the feasibility of the use of compliant mechanism for multiple DOF surgical instrument. We thus developed with 2 DOF (grasping and bending) with compliant mechanism that has a relatively simpler configuration than other higher DOF instruments, to assess the feasibility of compliant mechanism in surgical instruments.

2 Method

2.1 Mechanism design and prototype implementation

To assess the feasibility of using a compliant mechanism in surgical instruments, we developed the prototype shown in Fig. 1. The tip of the prototype has two DOF: grasping and bending. The user performs grasping movements by opening/closing the thumb and bending movements by sliding the middle finger. The handle was designed to allow the user to perform stable combined bending and grasping movements in an intuitive manner.

The tip of the prototype consists of two spring blades that use a compliant mechanism to move. The prototype is 4 mm in diameter and 410 mm in length, and the other dimensions such as the size of the handle are the same as in conventional laparoscopic instruments. The dimensions of the blade were optimized by iterative finite element method (FEM) analysis using DAFUL Ver.3.4 (Virtual Motion, Inc.) [22]. The working range is $\pm 45^\circ$ for bending and $\pm 60^\circ$ for grasping, even when the movements are combined. Optimization was achieved based on a design trade-off between the dimensions (thickness and beam length) and the maximum stress within the working area (which should be less than material's range of elastic deformation). Topological optimization

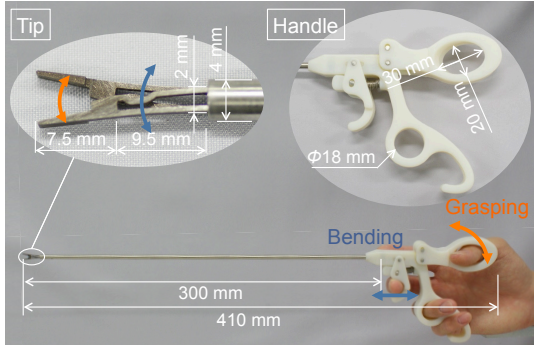


Fig. 1 Overview of the prototype. The tip has two DOF: bending (illustrated in blue) and grasping (illustrated in red). The force applied by the user's index finger and thumb is converted to the tip two DOF motion by the mechanism. Rotation around the long axis can be achieved by rotating the user's wrist.

regarding compliant mechanism by computation is recently investigated [23], however, it is known that the method is still under development and there still be the difficulties to deal with many three dimensional design parameters and computation time. Thus we tool an empirical method to optimize the shape of the elastic elements. The authors have conducted the design of compliant structure in an empirical manner for a relatively simpler structure [24]. The method is basically an iterative calculation in varying the shape in considering the design trade-off between the dimensions and the maximum stress within the working area, also the resistance force for bending, and ease of prototype implementation. In addition, the resistance force due to elastic deformation of the spring blades was taken into account to ensure that the user can easily perform the movements. As the spring blades are attached to a transmission bar and connected to the handle mechanism, the force exerted by the user is transmitted directly to the tip. The spring blades, mechanical bars, and handle were manufactured using Ni-Ti, SK-85M, and ABS resin, respectively.

Fig. 2 shows the results of FEM analysis for bending and grasping movements. One of the ends of the blade slides back and forth along the long axis while the other end is fixed, resulting in a bending movement. The two blades are placed symmetrically side-by-side. The tip bends when the blades bend in

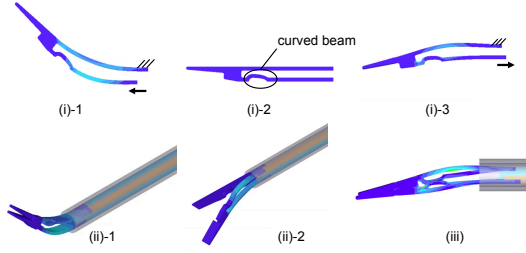


Fig. 2 FEM analysis of movement of the prototype. The color represents the distribution of stress. (i) FEM analysis of movement of a single blade. (ii) show combined bending and grasping movements, (iii) shows the effects of the curved beam during the grasping movement.

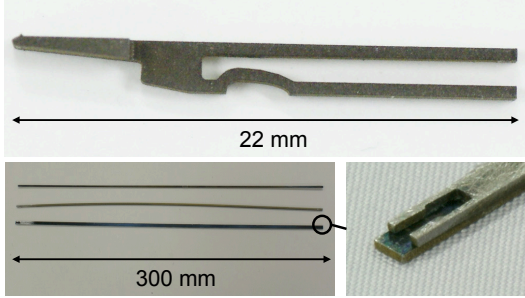


Fig. 3 Upper panel shows the fabricated spring blade. Two spring blades are fixed to the end of a rigid link bar to transmit the force from the handle mechanism, as shown in the lower panels.

the same direction, and grasps when only one blade bends while the other is fixed. A curved beam structure on the blade increases the grasping force by a local stress concentration effect, as shown in Fig. 2b(iii). The tip of the forceps consists of two spring blades, and is therefore simpler than in traditional surgical instruments. The two spring blades are fixed to the end of a rigid link bar to transmit the force from the handle mechanism, as shown in Fig. 3.

The handle mechanism was designed based on the conventional handles of laparoscopic surgical instruments. The surgeon thus can achieve the bending motion with the thumb, and the grasping motion with the index finger like as a trigger, in a way not much different from conventional surgical tools. To adequately transmit the driving force from the handle to the tip mechanism, each of the two spring blades is attached to the blue bar as shown in Fig. 4, to enable the bending movement. The other end of one spring blade is attached to the orange bar while another is fixed to the sheath enabling the bending movement of a single spring blade for the grasping movement. The mechanism thus performs the two DOF bending and grasping motion.

2.2 Experimental setup for mechanical evaluation

To show the feasibility of the use of compliant mechanism in surgical instruments with multiple DOF, we tested the mechanical characteristics of the developed prototype.

To test the grasping and bending motion, we developed the experimental setup shown in Fig. 5. The prototype was fixed to a rig, and grasping and bending movements were initiated by a linear motor that moved the handle. The movements of the tip were measured using a movement analysis camera, and the grasping forces were measured using a force sensor.

In the experimental setup, movements can be measured at the handle and the tip during grasping and bending. To measure the movement, the handle was moved using a linear motor (EC22, Maxon Co., Ltd.) with a ball screw and linear guide (LX26, Misumi Co., Ltd.). The movements at the tip were

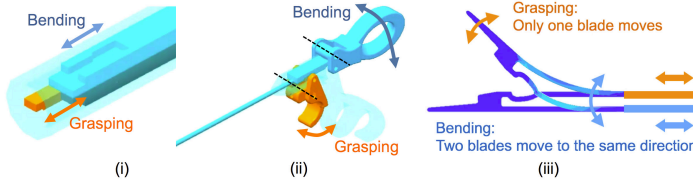


Fig. 4 (i) and (ii) show the bending and grasping movements are transmitted to the tip independently as two linear movements of orange and blue bars. Tip mechanism consists of two spring blades. One end of each spring blade is attached to the blue bar for the bending movement. The other end of one spring blade is attached to the orange bar while another is fixed to the sheath (shown as the gray part in (iii)) enabling the bending movement of a single spring blade for the grasping movement. The mechanism thus performs the two DOF bending and grasping movement.

then measured using a movement analysis microscope (VW-6000, Keyence Co., Ltd.). In addition, the resistance force can be measured using a load cell (LUR-A-SA1, Kyowa Electronic Instruments Co., Ltd.) attached to the handle. To measure the force of the grasping movement, the handle was moved by the motor as described above, and the grasping force was measured using a force sensor (FlexiForce A201-25, Nitta Co., Ltd., Japan). As the force sensor used in this test was originally a pressure sensor, we performed a pre-calibration test to determine the relationship between the output and the actual grasping force on the prototype.

3 Results

3.1 Grasping movement

We conducted 10 times of repetitive trials in each measurement, resulted in similar tendency. We thus show the representative result for each measurement in this section. Fig. 6 shows the grasping movement measurements. The vertical axis shows the grasping angle at the tip and the horizontal axis shows the linear movement of the handle by the linear motor. The blue line shows the pre-computed FEM analysis.

3.2 Bending movement

Fig. 7 shows the bending movement measurements. The vertical axis shows the bending angle at the tip and the horizontal axis shows the movement at the handle. The results differ from the pre-computed FEM analysis, in a similar manner to the grasping movement results. No hysteresis or mechanical play was observed. The maximum resistance force observed at the handle during movement was 13.5 N.

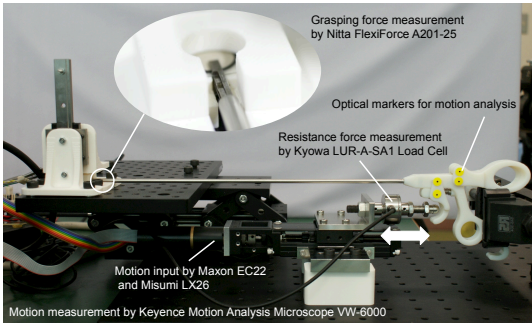


Fig. 5 With the prototype fixed to a rig, the handle was moved by a motor to achieve grasping and bending movements at the tip. The movement at the tip was measured by a movement analysis camera and the grasping force was measured by a force sensor.

3.3 Grasping force

Grasping test showed that the device is able to output more than 15 N of grasping force was achieved as shown in Fig. 8.

4 Conclusions

Based on the concept of improving the simplicity, size, weight, dexterity, and affordability of minimally invasive surgical instruments, we developed an MIS tool that uses a compliant mechanism. This paper described our prototype and its preliminary evaluation. The evaluation showed that use of our prototype is feasible. However, to further improve the design, the assessments regarding the discordance between FEM and measurement, and hysteresis are needed.

As shown in Section 3.1 and 3.2, the measured grasping angle did not reach the pre-computed angle because the FEM analysis did not consider friction within the instrument into account. Although no mechanical play was observed, the grasping angle did not recover to the initial angle, presumably because of friction. The grasping movement is converted to linear movement at the handle over a range of approximately 1.5 mm because of the limited space at the handle. In addition, only one spring blade bends during the grasping movement, resulting in friction between the rigid link bars. These two factors

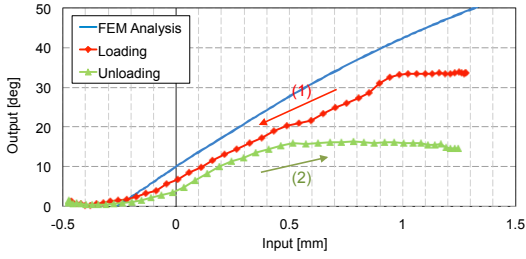


Fig. 6 Grasping movement measurements. The blue line shows the pre-computed FEM analysis. The results shows hysteresis between the handle and tip movements due to friction.

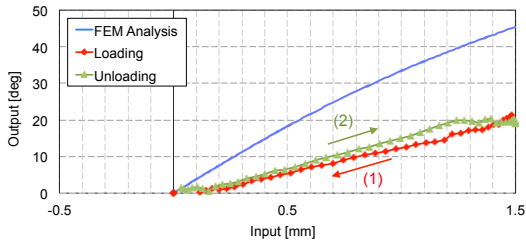


Fig. 7 Bending movement measurements. The blue line shows the pre-computed FEM analysis. The results do not show hysteresis or mechanical play between the handle and tip movements

that have not been taken into account in FEM analysis, may have resulted in enough friction to cause hysteresis. In our compliant mechanism, the elastic elements are not bending alone but together with all other elastic and (ideally) rigid elements. For example, we determined the power transmission link as a rigid material in FEM analysis for the ease of computation, however, the link is supposedly deformed slightly then the friction occurs against the sheath. Errors in manufacturing would be also involved to the friction. The rigorous simulation of whole mechanism model would be difficult due to the analytical accuracy and computational time. We thus used the FEM analysis for design optimization then developed the prototype to conducted the mechanical evaluation to assess the feasibility. As the mechanism showed that it is fully functional, the feasibility of the mechanism was positively shown.

Although the motion tests regarding bending and grasping were independently conducted, these motions could be performed simultaneously because the two motions are essentially performed by the same deformation (Single spring blade deforms in grasping, and both spring blades deform in bending in the same manner). These motions are performed in the preliminary task without particular effort by the user. In addition, although no mechanical play was observed, the grasping angle did not recover to the initial angle, presumably because of friction. The grasping movement is converted to linear movement at the handle over a range of approximately 1.5 mm because of the limited space at the handle. In addition, only one spring blade bends during the grasping movement, resulting in friction between the rigid link bars. These two factors that have not been taken into account in FEM analysis, may have resulted in enough friction to cause hysteresis.

As a preliminary test for the utility test of the prototype, we performed a suturing task using a laparoscopic training box, and an *in vivo* test was performed in a pig. Fig. 9 shows the setup of the suturing task performed using the training box, which was completed without any particular difficulties. The bending movement was used to insert the needle and the grasping movement was used to grasp the tip of the needle after it had pierced the membrane. Fig. 10 shows the experimental setup and the view through the endoscope at the *in vivo* test on a pig. The surgeon used the instrument with his right hand during the laparoscopic procedure. As shown in the right panel of Fig. 10, the bending

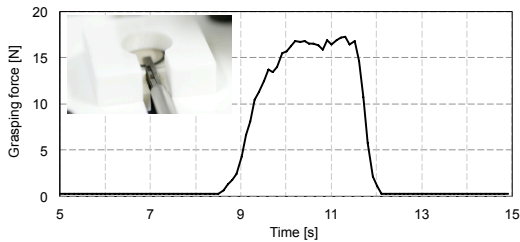


Fig. 8 Prototype achieved a grasping force of 15 N, which is sufficient for general laparoscopic surgical procedures.

movement was used to apply appropriate traction to the tissues during the procedure. No particular vibration caused by the mechanism characteristics observed during the test. Although the test showed that the prototype is fully functional, the performed test is preliminary, thus require a further evaluation tests (e.g. statistical analysis in comparison with standard instruments) to evaluate the usability.

Our prototype is simple, small, light-weight, low-cost, and simple structure supposedly increases the ease of sterilization compared with conventional articulated MIS instruments. On the other hand, there is a drawback in the compliant mechanism shown in the experiment. The maximum resistance force observed at the handle during movement was 12 N, which is higher than in conventional articulated surgical instruments. In addition, 34 N of motor output was needed to exert 15 N of grasping as shown in Fig. 8. The main reason of the resistance force is the compliance of the mechanism. In the proposed mechanism, the mechanism deforms the structure for the power transmission thus the efficiency of the mechanism is relatively lower than the conventional link mechanisms. This issue has been discussed in [16] as “Because compliant mechanisms have elastic members that deflect, energy is stored in the system in the form of strain energy. Thus the energy available at the output may be considerably less than was provided at the input. This energy is not lost, but is stored and released later.” In the proposed mechanism, the stored energy acts as the reaction force to deform the spring back to the initial shape (as shown in upper panel in Fig. 3). It should be noted that the issue regarding the resistance force is also coupled with the mechanical configurations of pivots at the tip and handle. Applying an improved mechanical leverage to the handle may decrease the resistance force. However, the modification should be made in considering the usability, since the displacement will be generally increased due to the mechanical leverage. As described above, a further usability test is required to assess this issue. Note that the resistance force can be also decreased by a further optimization of the structure if it is needed. (e.g. changing the spring blade to a softer material.)

Use of a compliant mechanism such as in our prototype may contribute to the advancement of surgical instruments (e.g. the bending DOF would be useful at the narrow surgical area to increase the dexterity). We are currently

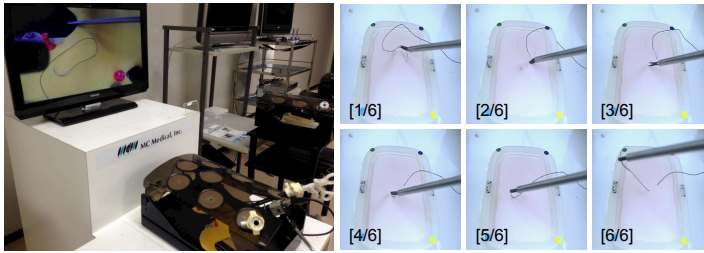


Fig. 9 Setup of the training box task (left panel) and a series of photographs taken during the suturing task (right panel).

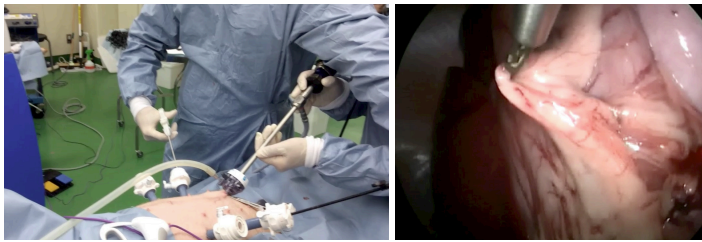


Fig. 10 Setup of the *in vivo* experiment (left panel) and view through the endoscope (right panel). The bending movement was used to apply appropriate traction to the tissues during the procedure.

working on further optimization of the spring blade design, and of the handle to improve usability and dexterity. The usability of the device will be tested further in complex surgical tasks such as suturing.

Conflict Of Interest

Jumpei Arata, Shinya Kogiso, Masamichi Sakaguchi, Ryu Nakadate, Susumu Oguri, Munenori Uemura, Cho Byunghyun, Tomohiko Akahoshi, Tetsuo Ikeda and Makoto Hashizume declare that they have no conflict of interest.

Human Participants and/or Animals

This article does not contain any studies with human participants performed by any of the authors. All procedures performed in studies involving animals were in accordance with the ethical standards of the institution or practice at which the studies were conducted.

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