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NEW TECHNOLOGY

A multi-degree-of-freedom needle driver with a short tip and small shaft for pediatric laparoscopic surgery: in vivo assessment of multi-directional suturing on the vertical plane of the liver in rabbits

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Abstract
Background Laparoscopic Kasai portoenterostomy has been performed in infants with biliary atresia at several institutions, but laparoscopic anastomosis requiring multi-directional suturing on a vertical plane of the liver remains a challenge. To assist multi-directional suturing, we developed a multi-degree-of-freedom (DOF) needle driver whose tip length was 15 mm and shaft diameter was 3.5 mm. The tip of the multi-DOF needle driver has three DOFs for grasp, flection and rotation. The aim of this study was to evaluate the performance of the multi-DOF needle driver in two kinds of in vivo experiments.
Methods Surgeons were asked to perform four-directional laparoscopic suturing on a vertical plane of the liver in six rabbits using the multi-DOF needle driver or a conventional needle driver. The needle grasping time, the needle handling time, the number of needle insertions, the number of liver lacerations, the suturing width and depth, and the area of necrotic tissues were analyzed and compared. Additionally, one surgeon was asked to perform laparoscopic hepato-jejunostomy in four rabbits to assess the feasibility of Kasai portoenterostomy using the multi-DOF needle driver.
Results The suturing depth using the multi-DOF needle driver was significantly larger than that using the conventional needle driver in both the right and downward suturing directions. No statistically significant differences were found in other metrics. Liver lacerations were observed only when suturing was performed using the conventional needle driver. The experimental laparoscopic hepato-jejunostomy using the multi-DOF needle driver was successful.
Conclusions Using the multi-DOF needle driver, uniform multi-directional suturing on a vertical plane of the liver could be performed. The short distal tip of the multi-DOF needle driver demonstrated its advantages in multi-directional suturing in a small body cavity. The multi-DOF needle driver may be able to be used to perform complex tasks in laparoscopic Kasai portoenterostomy.

Keywords Needle driver · Surgical instrument · Laparoscopic surgery · Minimally invasive surgery · Pediatric

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Kasai portoenterostomy in infants with biliary atresia is one of the most complex surgeries in the pediatric surgical field. Surgeons need high skills for precise laparoscopic needle placement in the fragile hepatic portal region of the liver in the small workspace of a 1-month-old infant. Recently, several groups have reported their experience in performing laparoscopic Kasai portoenterostomy [1–5]. However, lower survival after laparoscopic Kasai portoenterostomy with the native liver compared with the survival of those who underwent conventional surgery [1–3] and difficulty in performing laparoscopic anastomosis [2, 5] were reported.

Some institutes have used a robotic system, the da Vinci Surgical System (Intuitive Surgical, Inc., Sunnyvale, CA), in Kasai portoenterostomy [5, 6]. Robotic surgery can provide surgeons with additional degrees of freedom to allow more dexterous movements, for example, for laparoscopic multi-

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directional suturing in the hepatic portal region. Additionally, the learning curve of robotic surgery compared with that of conventional laparoscopic surgery was shorter [7, 8]. However, this robotic system has not been approved for use in infants of less than 10 kg in Japan. Furthermore, the instruments of the robot are too large for use in the pediatric intraabdominal cavity. High acquisition and maintenance costs are also problems with robotic pediatric surgery. Mahida et al. [9] reported that the cost of robotic surgery-associated hospitalizations for pediatric patients was higher than the cost of nonrobotic surgery-associated hospitalizations.

One of the possible options for enhancing dexterity in pediatric laparoscopic surgery is to employ a low-cost, handheld surgical instrument with multiple degrees of freedom (DOFs). Several multi-DOF surgical instruments of 5 mm or larger in diameter have been developed for adult patients, such as the Radius Surgical System (Tuebingen Scientific, Tuebingen, Germany) [10–14], KYMERAX (Terumo, Tokyo, Japan) [15], Autonomy Laparo-Angle Needle Holder (Cambridge Endoscopic Devices Inc., Framingham, MA) [16], and JAiMY (EndoControl, Grenoble, France) [17]. The tip of these instruments has three DOFs for grasp, flection, and rotation, enabling precise manipulation in laparoscopic multi-directional suturing. These instruments offer the advantages of a handheld design (low cost and with direct tactile feedback) as well as the advantages of a robotic system (greater degrees of freedom and shorter learning curve). Ohdaira et al. [18] developed a 3-mm-diameter handheld multi-DOF robotic manipulator for needlescopic surgery, and the tip length of the robot was 25 mm. However, a multi-DOF device for use in the small pediatric body cavity requires both a shaft diameter of 4 mm or smaller and a distal tip shorter than 15 mm.

Therefore, we developed a multi-DOF needle driver whose tip length was 15 mm and shaft diameter was 3.5 mm for pediatric laparoscopic surgery, in particular, for Kasai portoenterostomy [19–21]. We previously reported that in an ex vivo experiment, the multi-DOF needle driver demonstrated preferable needle placements in laparoscopic multi-directional suturing on a sponge vertically placed in a box trainer compared to a conventional needle driver [22]. To evaluate the performance of the multi-DOF needle driver in more realistic conditions, we designed two kinds of in vivo experiments in this study. Two surgeons were asked to perform laparoscopic four-directional suturing on a vertical plane of the liver in six rabbits using both the multi-DOF needle driver and a conventional needle driver. The influence of the suturing direction on the quality of needle placement was evaluated, and the multi-DOF needle driver was compared with the conventional needle driver as for the performance in two directions. In the other experiment, a surgeon was asked to perform laparoscopic hepato-jejunostomy in four rabbits using the multi-DOF needle driver.

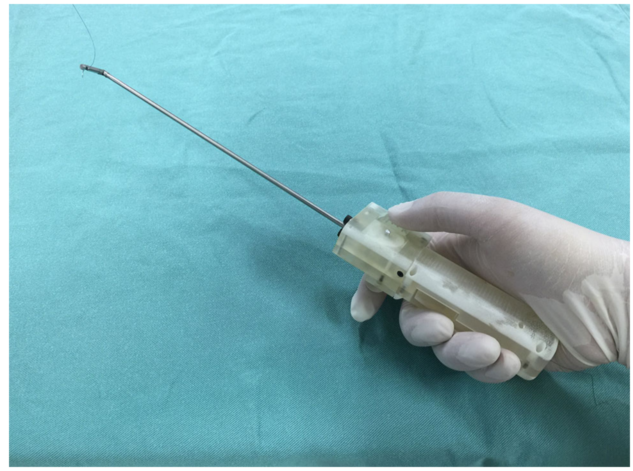

Fig. 1 Multi-DOF needle driver

Materials and methods

Multi-DOF needle driver

In order to facilitate multi-directional suturing, we developed a multi-DOF needle driver with DOFs for unlimited tip rotation, 90° tip flection and needle grasp, and its details were previously reported [19, 20]. The multi-DOF needle driver is shown in Fig. 1. The diameter of the multi-DOF needle driver, the length of the tip, and the total length of the shaft were designed to be 3.5, 15, and 200 mm, respectively. The tip joint can be deflected in five steps from 0° to 90°, allowing alignment of the tip rotational axis to be parallel to the suturing plane (Fig. 2A). The tip design employs a piston-type mechanism, and a needle grasped in the slit of the tip can be inserted in the suturing plane using the tip rotational DOF. The piston-type mechanism is cylindrical in shape and can generate a larger needle grasping force than a scissors-type needle grasping mechanism. For this study, the gears in the multi-DOF needle driver used in our previous studies were replaced with new ones to increase the mechanical strength and applicable torque. The applicable torques for flection and rotation of the multi-DOF needle driver used in the present study were 123.0 and 127.7 Nmm, respectively. The design of the handle was also modified to provide stable positioning of the tip during manipulation of the rotational DOF using the thumb (Figs. 1, 2B, C).

Design of experiments

The study protocol was approved by the Animal Care and Use Committee of the University of Tokyo (M-H14-204). Animal experiments were conducted according to the Law for the Humane Treatment and Management of Animals issued by the Ministry of Environment of Japan. Male New

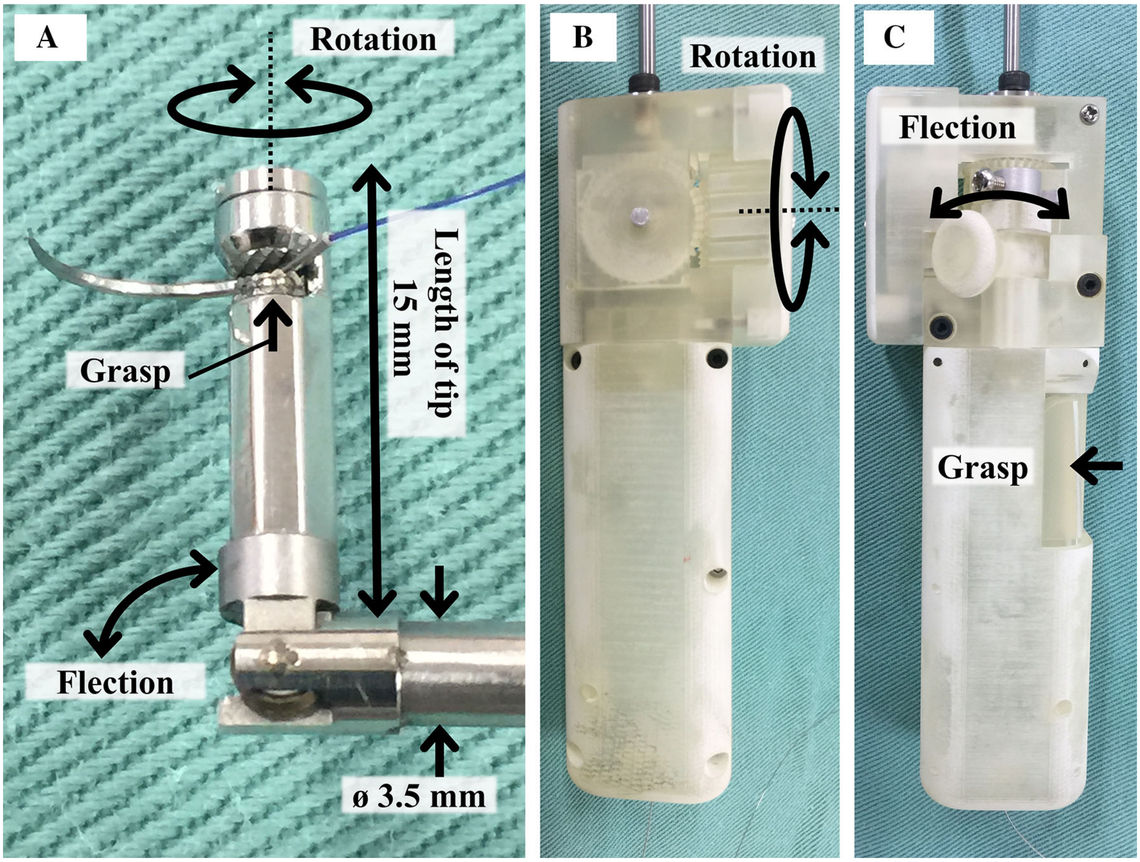

Fig. 2 Details of the multi-DOF needle driver. **A** The tip grasping a needle. The tip joint can be deflected in five steps from 0° to 90° and rotated. **B** User interface for rotation DOF. **C** User interface for flection DOF and grasp DOF

Zealand white rabbits (20 w, 3.5 kg) were obtained from Japan SLC (Shizuoka, Japan) for in vivo survival experiments. The animals were fasted 24 h before surgery, although water was provided ad libitum. Anesthesia was induced using intravenous propofol (1–2 ml/kg). After bronchoscope-aided tracheal intubation of the animal in the supine position, anesthesia was maintained with 2–4 % halothane. An isotonic intravenous fluid was administered at a rate of 4 ml/kg/h. During laparoscopy, pneumoperitoneum was established using carbon dioxide with 5 mmHg intra-abdominal pressure. The experiments employed a 5 mm, 30° endoscope inserted from a 5-mm port positioned in the center of the abdominal wall, and three instruments inserted from a 5-mm port in the left side of the abdominal wall and from two 3-mm ports in the right side (Fig. 3). The liver was retracted by an assistant surgeon using a forceps inserted from the cranial 3-mm port located in the right side to expose the visceral side of the liver. The visceral side was moved to be vertical to the body's coronal plane, and its position was maintained during suturing. During the suturing tasks, spontaneous breathing was blocked by intravenous vecuronium bromide (0.04 mg/kg) to stop the respiratory movement of the liver, and manual ventilation was provided. The

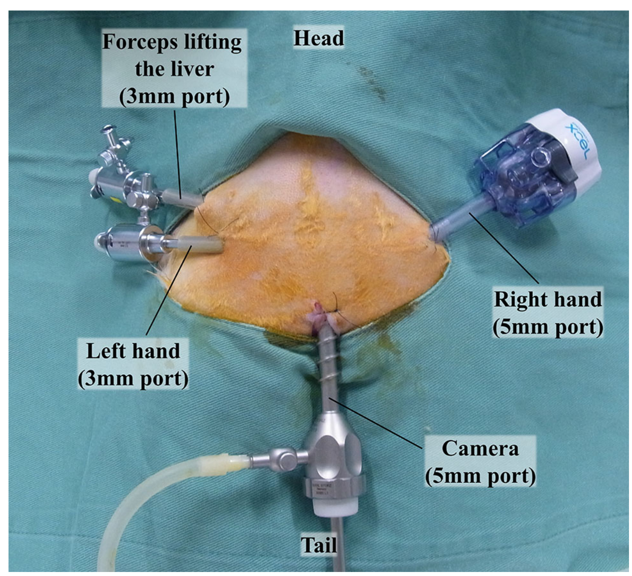

Fig. 3 Port placements on the ventral abdominal wall of a rabbit

multi-DOF needle driver was washed in an ultrasonic washing machine (UT-206H, Sharp, Osaka, Japan) after each animal experiment.

Experiment I: Multi-directional suturing on a vertical plane of the liver

Two board-certified pediatric surgeons participated in the experiment, and each participant performed laparoscopic surgical tasks on three rabbits. Both surgeons were right-handed and had abundant experience in using the multi-DOF needle driver. The task was four-directional suturing, namely suturing in the right, downward, left, and upward directions, using the multi-DOF needle driver, and two-directional suturing, namely suturing in the right and downward directions, using a conventional needle driver (3 mm in diameter, K26167 FNS, Karl Storz, GmbH & Co. KG, Tuttlingen, Germany). In our previous ex vivo study, we found that suturing in the right direction was the most difficult, and suturing in the downward direction was easiest, and thus suturing in the other directions was omitted in the task with the conventional needle driver [22]. The participants were asked to make three stitches in continuous suturing in each direction on the visceral side of the liver. After the third stitch, the needle was removed from the thread and the thread was left in place without knot tying to histologically evaluate the influence of the force applied during needle placement (Fig. 4). The surgical suture used in the experiment was 5-0 PDS II sutures (Ethicon Endo-Surgery, Cincinnati, OH, USA) with a 1/2 circle 13-mm needle, and a knot was preoperatively made in the tail of each thread to prevent the thread from falling off from the liver during the postoperative period. All experimental procedures were video-recorded.

After the experiment, the needle grasping time, the needle handling time, the number of needle insertions, and the number of liver lacerations were determined while watching each recorded video. In this study, the needle grasping time was defined as the time from the start of the needle grasping movement until the needle tip touched the liver surface. The needle handling time was defined as the time from the initial contact of the needle tip on the liver surface until the needle was totally extracted from the liver. Liver laceration was considered to have occurred only when the liver was completely torn and needle placement failed.

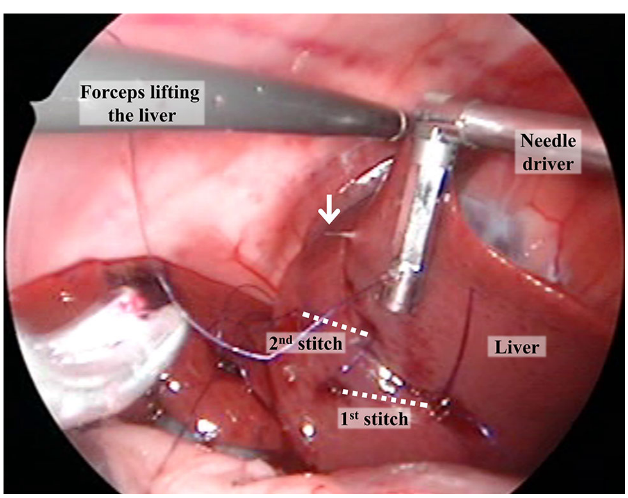

Fig. 4 Experiment I: Multi-directional suturing on a vertical plane of the liver. The picture shows the needle driver after making the third stitch of left directional suturing. *Arrow* the tip of the needle, *dotted line* the needle trajectory in the liver to make the first and second stitches

The rabbits were killed 3 days after the suturing experiment using intravenous propofol and potassium chloride, and the livers were fixed in neutral buffered formalin. The threads that fell off in the postoperative period were excluded from the following analysis. The suturing width, which was defined as the width from the needle insertion point to the exit point, was measured for each stitch. The liver specimen was cut in the center line of the insertion and exit points of each stich, and the suturing depth, defined as the distance from the liver surface to the thread in the cut surface, was measured. Thereafter, these specimens were embedded in paraffin, sliced in 5 μm thickness, and stained with hematoxylin and eosin. The area of necrotic tissues with cell deaths (both necrosis and apoptosis) and hemorrhages was microscopically determined and quantitatively measured using Medical Image Analyzer (Inotech, Hiroshima, Japan) in a blind manner.

All results in the following sections are presented as means ± standard deviations. The significance of the differences among the four suturing directions was analyzed using analysis of variance (ANOVA). All measurements in the right and downward directions were compared between the multi-DOF needle driver and the conventional needle driver using the two-tailed Student's *t* test. P values of less than 0.05 were considered to be statistically significant. Statistical analyses were performed using JMP Pro 11 (SAS Institute, Cary, NC, USA).

Experiment II: Hepato-jejunostomy

A board-certified pediatric surgeon (right-handed, with abundant experience in using the multi-DOF needle driver in laparoscopic surgeries, with no clinical experience of performing laparoscopic hepato-jejunostomy) performed laparoscopic anastomosis of the liver and the jejunum in four rabbits [23]. The surgeon retracted the liver using a pair of forceps and marked a circle with a diameter of 10 mm on the visceral side by electrocautery to specify the simulated hepatic portal region. The jejunum was retracted by an externally pulled suture, and then a 10-mm incision was created using an electric scalpel. The opening of the jejunum was anastomosed to the marked circle on the liver with 6 or 7 multi-directional stitches using a 5-0 PDS II suture (Fig. 5). The multi-DOF needle driver was used only

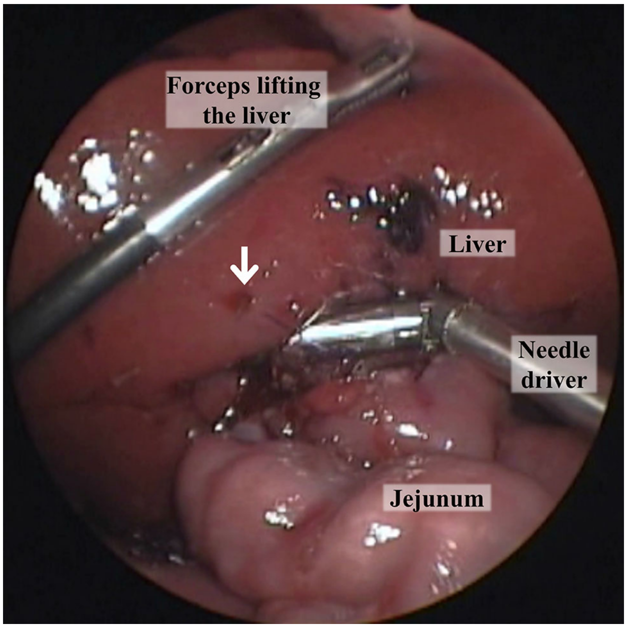

Fig. 5 Experiment II: Experimental laparoscopic hepato-jejunostomy. The picture shows upward directional suturing on the liver on the anterior side of the anastomosis. *Arrow* the tip of the needle

for needle placement, and the conventional needle driver was used for intracorporeal knot tying. The hepato-jejunostomy procedures were video-recorded.

The operation time, the insufflation time, and the anastomosis time in each task were measured. Intraoperative and postoperative complications were recorded. Two weeks after the operation, the rabbits were killed and the samples of anastomotic regions were fixed in neutral buffered formalin. Thereafter, these specimens were embedded in paraffin and sliced in 5 μm thickness. The specimens stained with hematoxylin and eosin were microscopically observed.

Results

Experiment I: Multi-directional suturing on a vertical plane of the liver

All planned procedures were successfully completed on the six rabbits and video-recorded. Two rabbits died after the laparoscopic surgery due to deep anesthesia and panperitonitis, and thus their specimens were excluded from the histological analysis. Seven of 108 pieces of thread fell off in the postoperative period in spite of the knot at the end of the thread and thus were excluded from the measurements of suture width and depth and the histological analysis.

The results of four-directional suturing by the multi-DOF needle driver are shown in Table 1. Liver laceration did not occur when the multi-DOF needle driver was used. There were no significant differences across the four suture directions in all metrics. The results in the right and downward directions were compared between the multi-DOF needle driver and the conventional needle driver (Table 2). There were no significant differences between the multi-DOF needle driver and the conventional needle driver in all metrics except for the suturing depth. The suturing depth of the multi-DOF needle driver was significantly larger than that of the conventional needle driver in both directions. Liver lacerations occurred using the conventional needle driver (one case in the right direction, and one case in the downward direction).

Experiment II: Hepato-jejunostomy

All four rabbits underwent successful anastomosis of the liver and the jejunum, and all of them were alive at the end of the operation. The surgeon manipulated the multi-DOF needle driver and performed multi-directional suturing. The size of the instrument was appropriate for use in a small abdominal cavity, and the needle insertion force was sufficient to suture the liver to the jejunum. The operation time (164 ± 41 min), insufflation time (139 ± 45 min), and anastomosis time (91 ± 23 min) decreased with each trial (Fig. 6).

Two rabbits died after the operation due to ileus and anastomotic leakage. The other two rabbits survived for 2 weeks and were killed for the histological study. Histological examination showed that the anastomosis was healed, and granulation tissues had developed in the anastomotic regions.

Discussion

The results of Experiment I showed that the multi-DOF needle driver was useful for laparoscopic multi-directional suturing on a vertical plane of the liver. The suturing time, suturing width, and suturing depth were not influenced by the suturing direction due to the enhanced dexterity in multi-directional manipulation. The piston-type needle grasping mechanism had a slit to hold the needle to enable needle placement with an appropriate needle insertion angle, and thus the needle placements were accurate and uniform in all directions. On the other hand, the way of grasping a needle and thread by the piston-type instrument is more complicated compared to that by a scissors-type instrument, particularly when the thread lay on an organ. Therefore, knot tying using the multi-DOF needle driver is feasible but time-consuming. One option is to use the multi-DOF needle driver only for needle placement as demonstrated in Experiment II. The participants in this study were proficient in using the multi-DOF needle driver as they were involved in developing the device. In our

Table 1 Comparison of parameters of suturing using the multi-DOF needle driver in four suturing directions

Metrics	Right	Downward	Left	Upward	*p* value
Needle grasping time (s)	46.4 ± 29.3[a]	47.6 ± 26.7	42.2 ± 18.3	43.9 ± 19.5	0.9053
Needle handling time (s)	22.9 ± 16.0	15.1 ± 4.6	20.3 ± 8.5	24.7 ± 28.1	0.3514
Number of needle insertions	1.1 ± 0.3	1.0 ± 0.0	1.0 ± 0.0	1.0 ± 0.0	0.1051
Number of liver lacerations	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	0.0 ± 0.0	
Suture width (mm)	8.2 ± 1.9	8.1 ± 2.2	8.7 ± 1.9	8.3 ± 1.7	0.8477
Suture depth (mm)	3.3 ± 1.2	2.8 ± 1.1	3.2 ± 1.2	3.6 ± 1.2	0.1966
Area of necrotic tissue (mm^2)	2.5 ± 3.6	0.6 ± 0.4	1.2 ± 1.8	3.3 ± 4.0	0.1132

Two surgeons performed multi-directional suturing in three rabbits each. The surgeon was asked to make three stitches in each direction

[a] Results are presented as the mean ± SD. Statistical analysis was performed by ANOVA

Table 2 Comparison of parameters of suturing between the multi-DOF needle driver and the conventional needle driver

Metrics	Right suturing direction			Downward suturing direction		
	Multi-DOF needle driver	Conventional needle driver	*p* value	Multi-DOF needle driver	Conventional needle driver	*p* value
Needle grasping time (s)	46.4 ± 29.3[a]	42.9 ± 18.9	0.6773	47.6 ± 26.7	47.5 ± 24.8	0.9949
Needle handling time (s)	22.9 ± 16.0	26.2 ± 13.8	0.5142	15.1 ± 4.6	17.6 ± 5.0	0.1360
Number of needle insertions	1.1 ± 0.3	1.4 ± 0.7	0.2608	1.0 ± 0.0	1.2 ± 0.4	0.0739
Number of liver lacerations	0 ± 0	0.06 ± 0.2	0.3244	0 ± 0	0.06 ± 0.2	0.3244
Suture width (mm)	8.2 ± 1.9	7.2 ± 2.9	0.2884	8.1 ± 2.2	6.6 ± 2.1	0.0549
Suture depth (mm)	3.3 ± 1.2	1.9 ± 1.2	0.0022*	2.8 ± 1.1	1.5 ± 0.8	0.0004*
Area of necrotic tissue (mm^2)	2.5 ± 3.6	0.9 ± 1.3	0.1666	0.6 ± 0.4	0.7 ± 0.6	0.8272

Two surgeons performed multi-directional suturing in three rabbits each. The surgeon was asked to make three stitches in each direction

* $p < 0.05$

[a] Results are presented as the mean ± SD. Statistical analysis was performed by the two-tailed Student's *t* test

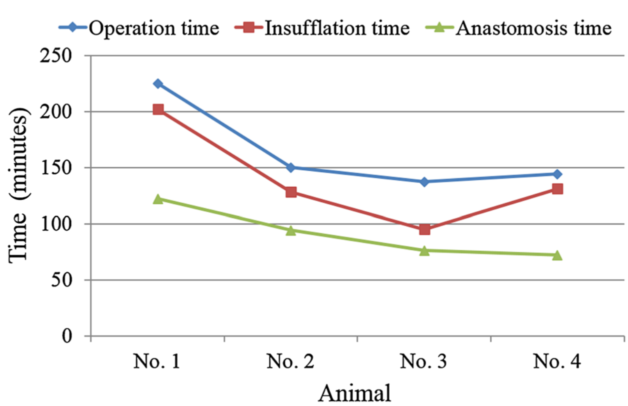

Fig. 6 Operation time and anastomosis time in hepato-jejunostomy. The operation time (164 ± 41 min), insufflation time (139 ± 45 min) and anastomosis time (91 ± 23 min) became shorter with each trial

future study, new users will be trained in using the instrument.

In our previous ex vivo study which involved multi-directional suturing on a sponge placed on a vertical plane on a box trainer, the multi-DOF needle driver demonstrated more accurate needle extraction, more perpendicular needle trajectory, and smaller applied force in the right suturing direction compared with a conventional needle driver, and no significant differences were observed in downward suturing [22]. In contrast, the multi-DOF needle driver demonstrated significantly deeper suturing depths compared with the conventional needle driver in both the right and downward suturing directions in Experiment I, although the suturing widths were almost the same (Table 2). The deeper suturing depth with similar suturing width suggested that the needle was inserted vertically to the liver surface, demonstrating that the enhanced dexterity led to preferable outcomes. It should be noted that comparison of the suturing depths between the multi-DOF needle driver and the conventional needle driver did not show a significant difference in the previous ex vivo study [22] probably because the sponge was much harder than the liver, and the multi-DOF needle driver did not have sufficient needle insertion force.

The multi-DOF needle driver did not cause any liver laceration because the needle insertion and extraction angles could be easily adjusted, avoiding unwanted directional force on the liver. Using the conventional needle driver, the surgeon had poor control of the needle insertion and extraction angles, and the resultant inappropriate needle placement led to unwanted force applied on the suturing site. Based on previous studies, we used the area of necrotic tissue as another indicator of tissue invasiveness. De et al. [24] reported that liver compression caused cell death associated with apoptosis with increases in stress magnitude. MacDonald et al. [25] reported that electrosurgical devices with low operating temperature demonstrated smaller lateral thermal damage than those with high operating temperature. In this study, the area of necrotic tissue was clearly identified and was not influenced by the suturing direction (Table 1).

The results of Experiment II showed that the experimental laparoscopic hepato-jejunostomy, which simulated Kasai portoenterostomy, using the multi-DOF needle driver was feasible. A short learning curve was demonstrated as for the metrics of operation time, insufflation time, and anastomosis time. Lorincz et al. [26] reported a survival porcine study of robot-assisted minimally invasive Kasai portoenterostomy using the Zeus Microwrist Robotic Surgical System, and it took an average of 96 min for the portoenterostomy procedure in the initial eight cases, which is equivalent with our result. We consider that the time required for the experimental laparoscopic hepato-jejunostomy was clinically acceptable. Some reports recommended the use of thin and short instruments in neonatal or infant surgery [27, 28]. The diameter and tip length of our multi-DOF needle driver were sufficiently small for manipulation in a small abdominal cavity, and dexterous, accurate, and safe manipulation was feasible with less obstructions of the laparoscopic view by the tip.

The experimental laparoscopic hepato-jejunostomy was performed without creation of a Roux-en-Y loop in this study to simplify the procedure, which caused anastomotic leakage and ileus. The protocol needs to be revised when increasing the number of experiments in the future. Granulation tissues were observed in the healed regions, but details of the pathogenesis are unknown [26, 29] and need to be further investigated.

In summary, using the multi-DOF needle driver in laparoscopic surgery, surgeons could perform uniform and accurate multi-directional suturing on a vertical plane of the liver. The short distal tip of the multi-DOF needle driver is of appropriate size for use in a small body cavity. The multi-DOF needle driver could be one of the solutions for complex laparoscopic surgeries, for example Kasai portoenterostomy, and will contribute to further development of pediatric minimally invasive surgery.

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Compliance with ethical standards

Disclosures Drs. Shinya Takazawa, Tetsuya Ishimaru, Kanako Harada, Kyoichi Deie, Jun Fujishiro, Naohiko Sugita, Mamoru Mitsuishi, Tadashi Iwanaka, and Mr. Masahiro Fujii have no conflict of interest or financial ties to disclose.

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