

Safety and feasibility of a novel non-thermal device for tissue dissection: A preliminary study of the DD1 differential dissector

Nao Yoshida¹, Shintaro Yamazaki^{1,*}, Masahiko Sugitani², Tadatoshi Takayama¹

¹Department of Digestive Surgery, Nihon University School of Medicine, Tokyo, Japan;

²Department of Pathology, Nihon University School of Medicine, Matsumoto, Tokyo, Japan;

Summary

Energy devices can cause significant thermal damage to surrounding tissues causing unanticipated organ trauma. To evaluate the safety and feasibility of a novel electric device (DD1) for soft tissue dissection. Three series of measurements were performed in a pig model. First, macro- and microscopic tissue damage was compared between the DD1 and an electric scalpel (ES). Second, the time course of tissue temperature was measured for the DD1 and three other energy devices (ES, Harmonic and LigaSure). Third, the time required for mobilization of a peripheral artery of the intestine was compared between the DD1 and manual, non-energized forceps. First, the tissue damage area caused by ES was significantly larger compared to that in the DD1 at all time points ($p < 0.0001$). The number of damaged cells due to thermal damage was significantly larger for ES than for DD1, even when the DD1 was applied to a single point at maximum power for 60 sec ($p < 0.0001$). Second, the maximum temperature of Harmonic was 160°C 3 sec after use and dropped to 68°C after 10 sec. At the same time points after use, we observed: ES (84°C, 45°C), LigaSure (61°C, 49°C), and DD1 (30.5°C, 29°C). Third, the median dissection time for the artery using DD1 was significantly shorter than that for dissecting forceps (DD1: 100 sec, range 70-205 sec vs. forceps: 130 sec, range 90-210 sec, $p = 0.0325$). DD1 was a safe non-thermal device which causes less tissue damage while also providing shorter dissection times than manual dissection.

Keywords: Tissue dissection, thermal damage, animal model

1. Introduction

Surgical dissection is a broad term that encompasses the general activities of separating and dividing tissues (1). It is usually divided into sharp and blunt dissection, distinguished as slicing tissues (sharp) and teasing tissues apart (blunt). Some surgeons would add a third type, energy or coagulating dissection, in which electric current or another source of heat is used to simultaneously coagulate and divide tissues (2-11).

Energy dissectors have undergone a tremendous transformation over the past 20 years, yielding instruments that are multi-functional (sharp, blunt, vessel sealing, e.g. bipolar and ultrasonic instruments) and that are now broadly used for almost all dissection

during a surgical procedure. Energy dissectors, however, have significant limitations due to the large amounts of heat they produce. These limitations lead to several intraoperative complications, such as accidental thermal trauma to blood vessels, nerves, ureters, and bowels (12-18). Furthermore, thermal instruments can unintentionally fuse adjacent layers, leading to misinterpretation of tissue layers and, subsequently, dissection into the wrong plane. Some studies indicate that by using powerful hemostatic device did not affect operative time (2-3). Therefore, surgeons need new instruments that improve blunt dissection, providing them with the ability to dissect quickly but without the safety compromises created by current energy dissectors.

The Model DD1 Differential Dissector is a newly developed non-thermal surgical instrument designed for blunt dissection (PhyScient, USA) which preserves vessels and nerves in connective tissues with minimal damage to the target organ. The DD1 is designed to selectively dissect loose connective tissue while having little effect on dense connective tissue. It thus selectively

*Address correspondence to:

Dr. Shintaro Yamazaki, Department of Digestive Surgery, Nihon University School of Medicine, 30-1 Ohayaguchi kamimachi, Itabashi-ku, Tokyo 173-8610, Japan.
E-mail: yamazaki-nmed@umin.ac.jp

dissects along tissue planes.

In this study, we assess the safety and feasibility of DD1, comparing other energy devices in an abdominal surgical model in pigs.

2. Materials and Methods

2.1. Overview of experiments

The DD1 has a plastic tip made of polyetheretherketone (PEEK) that rapidly vibrates to mechanically tease tissues apart. (Figure 1) Vibration is driven by a motor and batteries that are in the handle, making the device cordless. A control knob in the handle adjusts the vibration speed. The surgeon controls dissection by determining the point of application of the vibrating tip, the speed of vibration, the force with which the tip is pushed into the tissue plane, and the force of counter-traction.

Three different types of experiments were conducted on live, anaesthetized pigs: First, tissue trauma arising from transient contact with a variety of different tissues was evaluated for two devices: DD1 and electric scalpel (ES); Second, thermal measurements were made for four devices (DD1, ES, Harmonic (Ethicon, USA), and LigaSure (Covidien, Ireland)) *via* thermal videography. Third, the speed of dissection was compared between the DD1 and manual forceps for mobilizing the mesentery arteries of the small intestine. In our experience, 50% power setting (middle vibration speed) is suitable for most tissues. Additionally, the DD1 works best when the tissues are moist, so moistening the surface with saline permits more delicate dissection while also reducing the risk of desiccation.

2.2. Animals

Five pigs aged two to three months and weighing 35 to 45 kg were used. For anesthesia, a mixture of intramuscular ketamine (10 mg/kg), xylazine hydrochloride (2 mg/kg), and atropine sulfate (0.5 mg/head) were used. To keep anesthesia (PRO-45 Va, Acoma Inc. Tokyo, Japan), a mixture of 1 to 3% isoflurane and oxygen was given *via* a tracheal tube (NS-5000A, Acoma Inc., Japan). After the operation, the animals were put under deep anesthesia and blood was drained from the inferior vena cava. Each test site on the tissues was excised, fixed with 10% formalin, and embedded in paraffin. The paraffin block was sliced in 5 μ m slices at the marking site, then histopathological evaluation was performed after hematoxylin eosin (HE) staining. All procedures were performed by a single surgeon with 20 years of experience.

The handling of experimental animals was in accordance with *the National Academy of Sciences' Guide for the Care and Use of Laboratory Animals* as well as the Act on Welfare and Management of

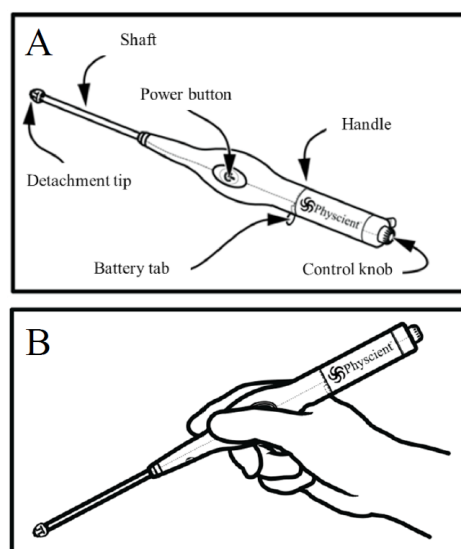


Figure 1. Schema of DD1. A plastic tip made of polyether/ether/ketone on the shaft of the DD1 vibrates to mechanically tease tissues apart (A). A control knob at the handle adjusts the vibration speed. The weight of DD1 is 150g, including the built-in batteries which allow cordless operation (B).

Animals (Act No. 105 of October 1, 1973). The study protocol of this study and the handling of animals were approved by the institutional review board (Animal Care and Usage Committee) of Narita Experimental Laboratory, NAS Laboratory Co., Ltd. (Approval number: 15L-S079, 16L-S002).

2.3. Tissue trauma arising from transient contact

DD1 is applied to tissues with force applied by the surgeon. To standardize treatments with the DD1 such that a force of approximately 100 ± 50 g was consistently applied, the surgeon practiced at the beginning of each surgery by pressing the DD1 against an electronic balance 20 times for 2 sets. Multiple sites on a variety of tissues were tested for trauma from dissection. (Table 1), including parenchymal organs (liver, kidneys, and pancreas), luminal organs (ureter, bladder, thick and middle arteries, and thick and middle veins), and nerves (femoral nerve). Treatments for these tissues were:

- Non-parenchymal tissues (ureter, abdominal aorta, inferior vena cava, common iliac artery and vein, renal artery and vein, and femoral nerves): only the DD1 was used – one speed (medium) for two durations of contact (5 and 30 seconds). Each tissue: 4 test sites per organ in each animal, 16 per tissue total. Bladder: 2 test sites per animal, 8 total.

- Liver: ES – 2 seconds contact at 30W; DD1– two speeds (medium and high) for four durations of contact each (5, 15, 30, 60 seconds). 36 test sites per animal, 144 total.

- Pancreas and kidney: ES – 2 seconds contact at 30W; DD1 – one speed (medium) for two durations

Table 1. Sites and number for test in DD1 and Electric scalpel

Items	DD1		Electric scalpel		Number of test sites per animal	Total
	Power	"Time (seconds)"	Power (W)	Time (seconds)		
Liver	maximum and middle	5, 15, 30 and 60	30	2	36**	144
Kidney	middle	5 and 30	30	2	6	24
Pancreas	middle	5 and 30	30	2	4	16
Thick and Medium artery	middle	5 and 30	.*	-	4	16
Thick and Medium vein	middle	5 and 30	.*	-	4	16
Nerve	middle	5 and 30	.*	-	4	16
Ureter	middle	5 and 30	.*	-	4	16
Bladder	middle	5 and 30	.*	-	2	8

* Not tested because damage is obvious and ES is never used clinically for these tissue. ** For 4 lobes per animal.

of contact (5 and 30 seconds). Kidney: 6 test sites per kidney, 24 total. Pancreas: 4 test sites per animal, 16 total.

Note that in parenchymal organs (liver, kidney, and pancreas), tissue damage caused by the DD1 was compared to ES because ES is widely used for dissection of these tissues. However, trauma from ES was not measured for the non-parenchymal organs (vessels, ureter and nerves) because such damage is obvious, and ES is never used clinically for the dissection of tissue planes around these tissues.

Each site was tested as follows: A randomized schedule for instrument use was prepared for each animal. Prior to treatment, the site was marked with indigo-carmin to permit later localization and excision. Then the respective instrument was applied to that site for a predetermined time and speed, according to the randomized schedule.

In the liver, kidney, and pancreas, the extent of tissue damage area (length \times depth measured on the histological slide) was evaluated macroscopically on a computer monitor after scanning the test site with a NanoZoomer (Hamamatsu Photonics Inc., Hamamatsu, Japan). Microscopic examination was used to measure cell degeneration, destruction of liver serosa, and intra-parenchymal bleeding. Microscopic analysis of trauma to the liver was determined by two metrics: the number of degenerate nuclei and the number of nuclei with an aspect ratio (ratio of height: width) > 1.25 . All cells were counted within a field of view for 400 \times magnification.

2.4. The time course of device temperature

The time course of temperature changes in the mesentery of the small intestine was measured for 4 devices: Harmonic, ES, LigaSure, and DD1. Prior to use, warm water was used to maintain all devices at 29°C. Each device was applied to the tissue for 3 seconds and then removed. The temperature of devices at the point of application was measured before activation of the devices (0 sec), immediately after energy was turned off and the instrument removed from

the tissue (3 sec), and again at 10, 20 and 30 seconds. Temperatures were measured by infrared thermography: Testo 875-2i (Testo Inc., Lenzkirch, Germany). The temperature was analyzed using software (Testo IRSoft, Testo Inc., NJ, USA), and the maximum temperature of the tissue for each device and the change of temperature after use was measured. Each device was measured ten times under the same conditions and compared with DD1.

2.5. Time for removal of the peripheral artery in the small intestine

The straight arteries in the mesentery of the small intestine were used to provide an array of similar vessels for comparison of dissection speed between the DD1 and another technique for cold dissection – non-energized forceps. The time required to mobilize a length of 3 cm of a single straight artery was compared between the forceps and the DD1. The success of dissection was evaluated as follows: if bleeding occurred during dissection, failure to achieve hemostasis by simply applying pressure for five seconds or failure to detect blood flow due to occlusion were deemed as failures. Dissection was performed at 15 sites for each technique in each animal (150 arteries mobilized total, 75 for each technique). The time and success of dissection were evaluated by a surgeon who was not involved in the study by video examination. As a second test, the mobilization of renal vessels also was performed and assessed from video examination by another surgeon.

2.6. Statistical analysis

All continuous variables are described as medians and ranges. For the comparison between the two groups, we used a Student's t-test for the parametric variables and Wilcoxon rank sum test for the non-parametric variables. *P* values of less than 0.05 indicated a significant difference. All statistical analyses were performed using JMP 10.0.2 (SAS Institute Inc., Cary, NC, USA).

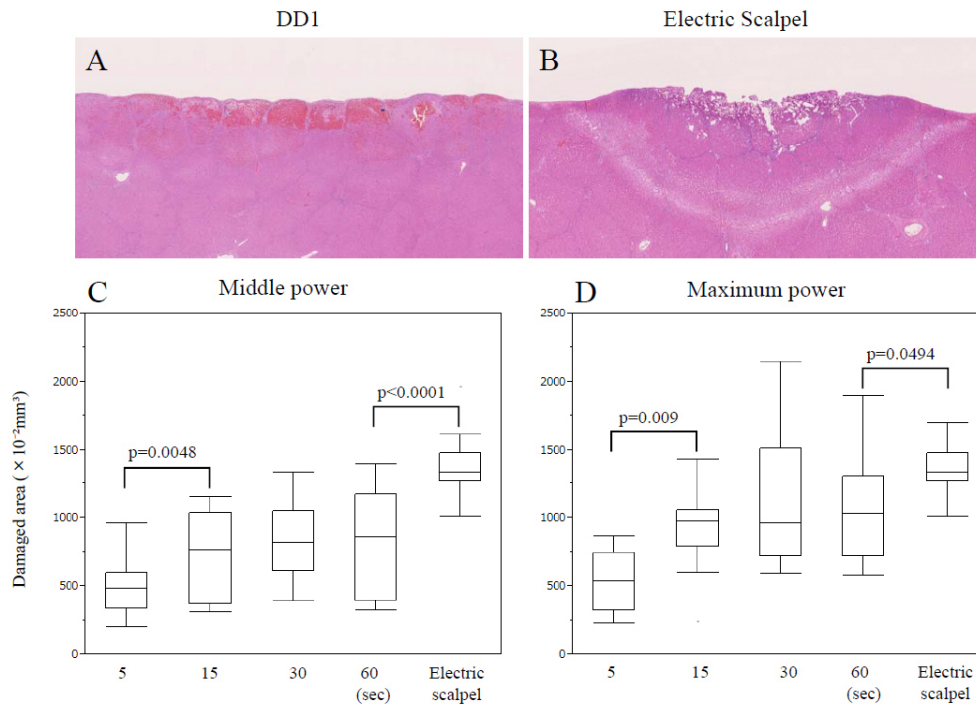


Figure 2. Macroscopic tissue damage and damaged area. DD1 resulted in a subserosal dish-shaped damage and minor subserosal bleeding without rupture of the serosa on the contact surface (A). Electric scalpel resulted in a wide semicircular damaged area with serosal rupture (B). The damaged area reached a plateau in 15 seconds. The damage area of DD1 in any time points were significantly smaller than that of electric scalpel at middle (C) and maximum power (D).

Table 2. Damaged area of the parenchymal and non-parenchymal organs

Organs	Damaged area ($\times 10^{-2}$ mm ³)			p value*
	Middle5	Middle30	Electric scalpel	
Liver	480 (0-1530)	821 (188-2100)	1330 (812-1960)	0.002
Kidney	0 (0-420)	172 (70-700)	1112 (825-2000)	0.0001
Pancreas	0 (0-21)	20 (0-108)	1046 (85-1675)	0.0037
Thick and Medium artery	Not damaged		N.T.	N.T.
Thick and Medium vein	Not damaged		N.T.	N.T.
Nerve	Not damaged		N.T.	N.T.
Ureter	Not damaged		N.T.	N.T.
Bladder	Not damaged		N.T.	N.T.

Data express, median with range, * middle 30 vs Electric scalpel, N.T.: Not tested.

3. Results

3.1. Macroscopic damage

In the liver, the DD1 for all durations of contact and both speeds resulted in mild subserosal dish-shaped damage but without serosal rupture on the contact surface (Figure 2A). The region of subserosal damage was characterized by minor bleeding within the parenchyma but with no evidence of liver tissue degeneration (Figure 2A). On the other hand, ES resulted in a larger semicircular damaged area at the contact surface with serosal rupture and wide liver tissue degeneration (Figure 2B). For the DD1, the range of damage of liver parenchyma reached a plateau in 15 seconds for both powers (Figure 2C, D). The damage area of DD1 at middle power was significantly

smaller than that of ES (30W, 2 seconds) for all time points (Figure 2C). Also at Maximum power (5, 15, 30, 60 sec), the damage area of liver parenchyma using DD1 was significantly smaller than that of ES (30 W, 2 sec) ($p = 0.0494$) (Figure 2D).

Similar results were observed for the other parenchymal organs (kidney/pancreas) (Table 2). The damage area of DD1 (middle power, 5, 30 seconds) was significantly smaller than that of ES (30 W, 2 seconds), (kidney: $p = 0.0001$, pancreas: $p = 0.0037$ for DD1, middle power, 30 seconds which was the harshest condition). At first, the microscopic study of the liver showed that DD1 was obviously less harmful rather than other energy device. Therefore, the similar results as the liver was expected, the experimental for other parenchymal organs were omitted. No macroscopic

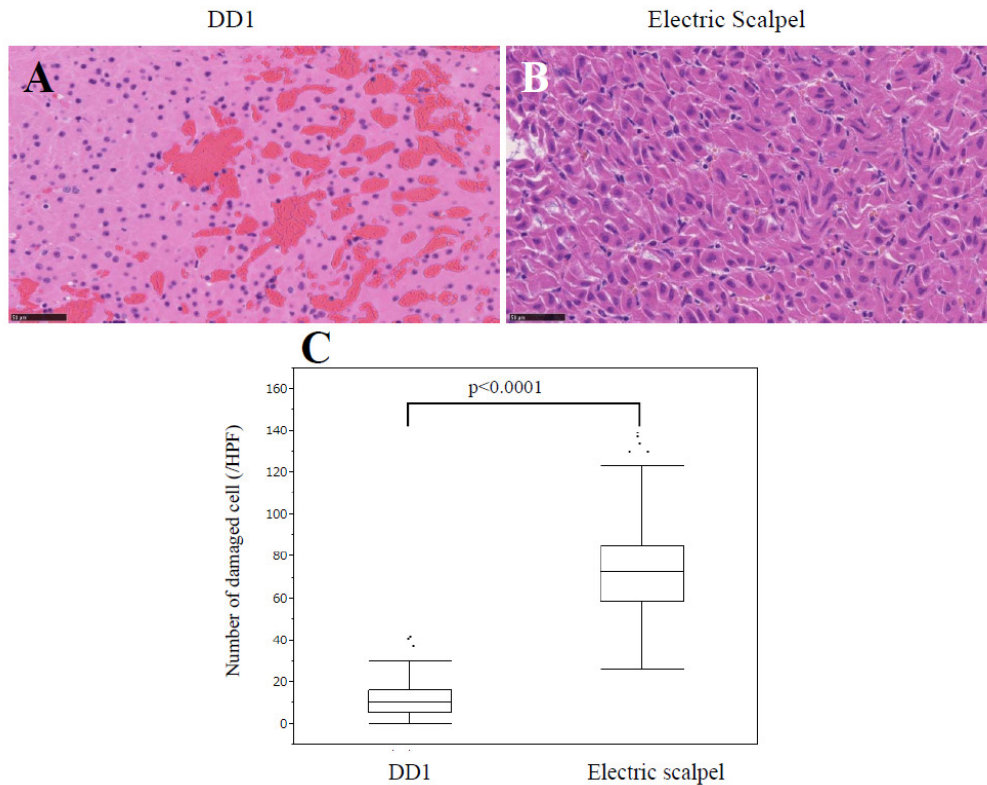


Figure 3. Microscopic findings and number of damaged cell. The damage caused by DD1 (maximum power, 60 sec) was slight intra-parenchymal bleeding without cell degeneration (A). In contrast, the electric scalpel caused massive cell degeneration (B). The damaged cell number recorded within the field of a 400× microscopic objective was significantly lower in DD1 than the electric scalpel (C).

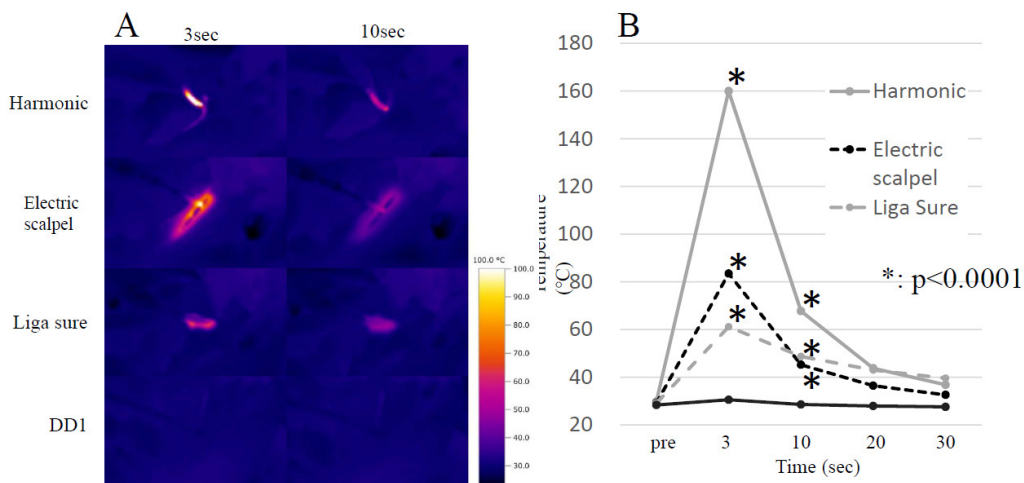


Figure 4. Time course of temperature in each energy device. The temperature rapidly increased after 3 seconds use of each energy devices. The temperature gradually decreased after 10 seconds. The temperature of DD1 was unchanged at any time points. (A) The temperature of the DD1 was always significantly lower than the temperature for the other devices for any time after use.

damage was seen from the DD1 in the non-parenchymal organs (vessels, ureters, and nerves).

3.2. Microscopic damage

The difference in the quality of tissue damage in liver caused by each device was significant. Most of the cells present in the range of damage of ES possessed H/W ≥ 1.25 (Figure 3B). As for DD1, there was no change other

than slight bleeding in the parenchyma, with the H/W of the nucleus preserved in most of the cells (Figure 3A). The number of damaged nuclei in DD1 was significantly less than ES ($p < 0.0001$) (Figure 3C).

3.3. Time course of temperature in each energy device

Significant increases in tissue temperatures were observed for Harmonic, ES, and LigaSure after three

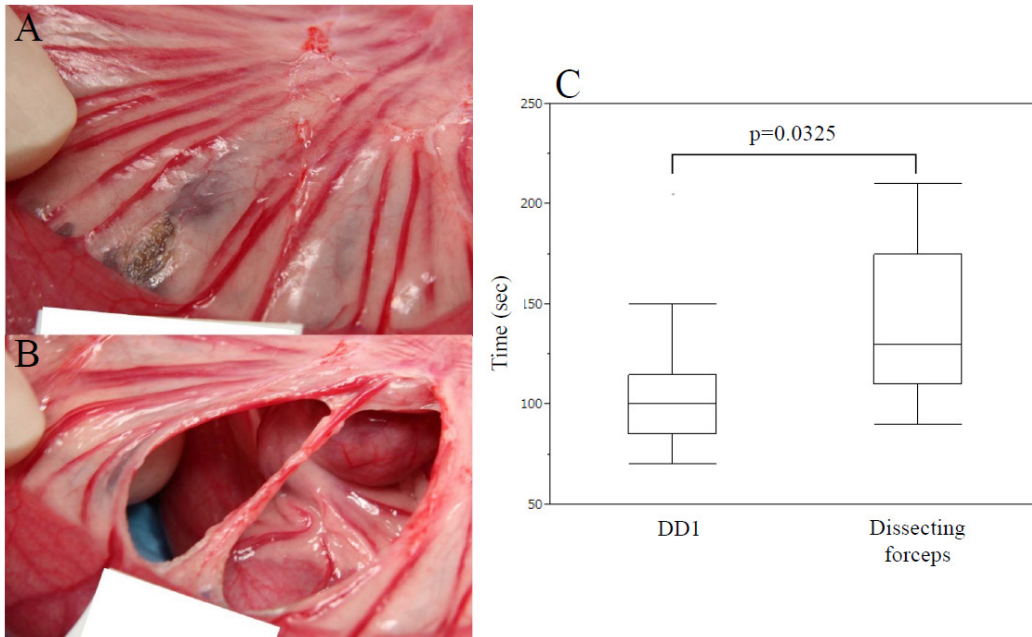


Figure 5. Removal of the peripheral artery in small intestine. The removal time of 3 cm or more in the longitudinal axis of the single straight artery in the mesentery of the small intestine was compared between dissecting forceps and DD1. (before (A) and after (B) dissection) The median time for dissection was significantly shorter in DD1 than that in the forceps (C).

seconds of energy application. The maximum measured temperature in the dissection field rapidly increased to 160°C for Harmonic, 84°C for ES, and 61°C for LigaSure at 3 seconds when activation ceased. After 10 seconds, the temperature gradually decreased to 68°C for Harmonic, 45°C for ES and 49°C for Liga Sure. On the other hand, the temperature of DD1 was unchanged at any time point (from 31°C to 29°C) (Figure 4A). The temperature of DD1 was significantly lower than that in any other energy device during activation ($p < 0.0001$) and after activation ($p < 0.0001$) (Figure 4B)

3.4. Time for removal of the peripheral artery and renal veins

In the dissection of the peripheral straight artery in the mesentery of the small intestine, there was no occurrence of dissection failures using either the DD1 (Figure 5A, B) or the non-energized forceps. The median removal time of DD1 was significantly shorter than that of the forceps (100 seconds vs. 130 seconds, $p = 0.0325$) (Figure 5C). In addition, for dissection and mobilization of the renal veins (a more complicated structure), DD1 was able to safely expose the target vessels as determined by visual inspection in surgery and confirmed by independent review of videotape (Figure 6A, B).

4. Discussion

DD1 is a novel category of electric device designed for tissue dissection with minimum damage. The intellectual property of DD1 is hold by Physcient in

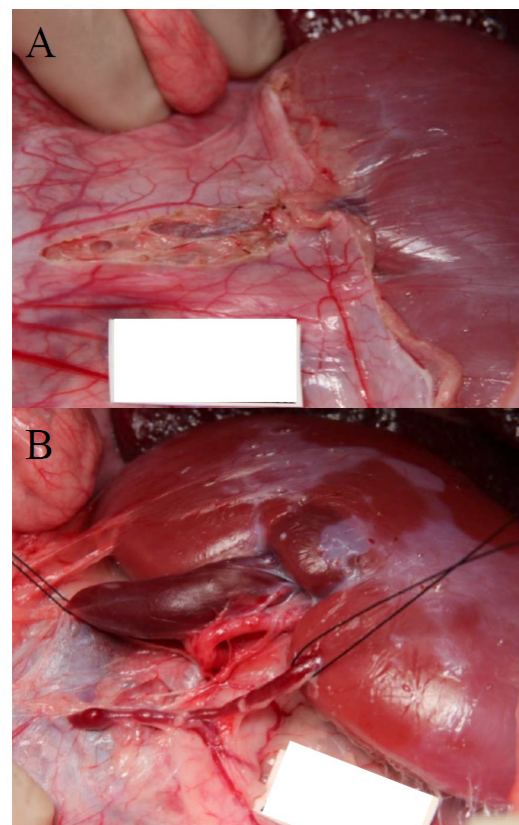


Figure 6 Removal of the renal vein. The incision was made in the serosa lining the renal hilus prior to the dissection (A). Dissection and mobilization of the renal structures (artery, vein and ureter) was performed without visible trauma to any of the structures (B).

U.S. DD1 is a commercial stage not only in U.S. but also in Japan. Several conventional surgical procedures

were performed safely with the DD1 without significant bleeding and without thermal trauma. During normal use, only a few seconds of contact time in a single point is required for dissection, so the durations of exposure tested here (as long as 60 seconds) demonstrate that DD1 has a sufficient safety margin for a variety of surgical procedures.

DD1 offers several advantages over other energy devices. Vessel sealing systems (*e.g.* Harmonic and LigaSure) perform coagulation hemostasis by generating heat at the tip of the device. However, unexpected secondary organ damage can occur by thermal injury (12-18). Therefore, it is necessary to maintain a safety margin such that heat does not directly spread into surrounding tissues during coagulation. This problem is sufficiently large that vessel sealers should not be used near vessels and nerves which need to be preserved (19-20). Conversely, DD1 quickly dissected tissues with only slight bleeding, generating a small damage area, and creating no rise in tissue temperature. No thermal trauma was observed. Even with the use of maximum power for 60 seconds, the damage area of the parenchymal organs was significantly smaller than ES. Additionally, DD1 did not induce unexpected reflexes by stimulation of nerves, unlike ES. Therefore, DD1 can be used safely without irreversible damage to tissues, even near important organs.

It is important to recognize the tissue planes separating blood vessels and nerves from connective tissues during dissection. DD1 is an electric device which dissects by using high-speed vibration. DD1 dissects the loose connective tissue alone. The tight connective tissue, blood vessel wall, nerve fiber and serosa do not have serious damage. When it uses suitable touch to the tissues, it can dissect with small amount of blood loss. Furthermore, the DD1 is faster than conventional blunt dissection with forceps, as demonstrated from measurements of dissection times for the peripheral thin artery in the small intestine. Thus, DD1 is a convenient device capable of consistent and safe dissection.

DD1 also has an advantage in cost because it is battery powered and does not require an energy generator. Furthermore, the battery is built into the main body, so there is no cord, and handling during surgery is better. Further improvements are planned for DD1 to enable use in laparoscopic operations.

We validated the safety and efficacy of the DD1 by demonstrating a reduction in tissue damage and absence of heat generation during dissection in surgical procedures simulating clinical use. The DD1 was effective for a variety of dissections in several different tissues. DD1 allows a safe and quick dissection in procedures including the preservation of nerve function, the complex dissection of vessels, and tunneling into tissues. We believe that DD1 can contribute to the safety and convenience of surgery and surgeons will find broad application in a variety of surgical

procedures. Now, we proceed to the clinical test phase and the safety of the DD1 will validate in near future.

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