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Intestinal Injury by Heat Conduction from Surgical Sealing Devices

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ABSTRACT

Background: There have been no investigations of intestinal injury induced by surgical sealing devices, especially focusing heat conduction from the back of active blades during laparoscopic surgery.

Objective: This study of damage to the small intestine by heat conduction from the back of active blades both physically and histopathologically was performed to establish safe usage of surgical sealing devices.

Materials and method: We compared seven types of bipolar sealing device and two types of ultrasonic coagulating shear in an animal model simulating laparoscopic surgery. Time-dependent changes in heat conduction from the back of active blades were measured using a direct contact thermometer during intracorporeal activation. Histopathological damage to the small intestine by the back of active blades in laparoscopic surgical application was evaluated. The backs of active blades were activated while attached to the serosa of the small intestine. The depths of histopathological changes were measured to evaluate the thermal effects of surgical sealing devices.

Results: Most devices generated temperatures >70°C even on the back of active blades. There were no significant differences in duration for cooling to ≤50°C among these devices. All devices induced histopathological heat damage in the submucosal layer or deeper.

Conclusions: Regardless of type, the backs of active blades of surgical sealing devices conduct high temperatures and can induce heat damage in the small intestine. Surgical sealing devices should not be activated while attached to surrounding tissue or organs in laparoscopic surgery.

Key Words: Sealing device, Intra-operative heat injury, Bowel injury, Animal model, Laparoscopic surgery.

INTRODUCTION

Hemostatic procedures, such as suture ligation and clipping, are sometimes difficult, time-consuming, and associated with risks of slipping in laparoscopic surgery, especially for inexperienced surgeons. Surgical sealing devices (SSDs) were developed to promote safety and save time in cutting and hemostasis during laparoscopic surgery, and have therefore become essential tools in such procedures. On the other hand, iatrogenic heat injury to organs induced by activated SSDs may cause fatal complications. In the report of the US Food and Drug Administration, 5 cases of heat injury at surrounding tissues in contact with SSDs have been reported in the past decade.[1] Although laparoscopic surgeons take great care to maintain sufficient distance between the tip of the SSD and organs to avoid iatrogenic heat injury, the tissue or vessels to be cut sometimes lie close to the surrounding organs. Inexperienced surgeons tend to activate SSDs with the tip of the blade in contact with the surrounding organs in such situations. However, even the back of activated SSD blades may achieve high temperatures by heat conduction and may induce iatrogenic heat injury to surrounding organs. Therefore, it is important for laparoscopic surgeons to have a precise understanding of adequate and safe use of SSDs with regard to heat conduction and histological changes to organs in contact with the back of active blades (ABs) of SSDs.

SSDs have a wide variety of tip shapes, including ultrasonic coagulating shears (UCSs). Some SSDs have double

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ABs inside the tips, while others have a double-edged AB. Therefore, many types of SSD should be evaluated to establish general evidence for safe use. Moreover, heat conduction from the tip of the SSD to the surrounding organs may be enhanced by laparoscopic surgical application. However, only a few types of SSD have been assessed for heat injury to organs under open surgical application.[2–8] Heat injury of surrounding organs has not been investigated with regard to heat conduction from the back of ABs under laparoscopic surgical application. Here, we assessed the iatrogenic intestinal injury induced by heat conduction in contact with the back of ABs for nine SSDs under laparoscopic surgical application in an animal model. This study was performed to gain an understanding of the heat conduction effect of SSDs to promote safety in laparoscopic surgery.

MATERIALS AND METHODS

Animals

A female 8-week-old pig weighing approximately 40 kg was used in this study.

Devices

We used seven bipolar SSDs—ENSEAL TRIO®, ENSEAL Round®, ENSEAL Articulating® (Ethicon Endosurgery, Cincinnati, Ohio, USA), LigaSure V®, LigaSure Blunt®, LigaSure Maryland® (Medtronic PLC, Dublin, Ireland), and BiClamp® (Erbe, Tübingen, Germany)—and two UCSs—HARMONIC ACE®+ (Ethicon Endosurgery) and THUNDERBEAT® (Olympus, Tokyo, Japan)—in this study (**Table 1**).

The side opposite to the part responsible for heat generation was defined as the back of the AB in the tip of the SSD (**Figure 1A**). ABs were inside, and the backs of ABs were covered by a seal plate to protect organs from heat injury for the bipolar SSDs. One of the blades was a double-edged AB, and the outside of the other, a movable blade, was defined as the back of the AB for the UCSs (**Figure 1A**).

Preparation and Experimental Setup

The pig was anesthetized using the following sedation, relaxation, and narcosis regimen: ketamine at a dose of 10 mg/kg intramuscularly, xylazine at a dose of 2 mg/kg intramuscularly, and atropine sulfate at a dose of 0.5 mg/head. Endotracheal anesthesia was performed with 1% to 5% isoflurane. The experimental animal was treated in accordance with the National Institutes of Animal Health Care Guidelines and the guidelines approved by the Animal Ethics Committee of the experimental facility.

Table 1.
Devices Used in this Study and their Features

Product Name	Manufacturer	Energy System	Function	Release Year
ENSEAL TRIO®	ETHICON (Blue Ash, Ohio, USA)	Bipolar	Sealing and cut coagulation	2010
ENSEAL Round®	ETHICON	Bipolar	Sealing and cut coagulation	2010
ENSEAL G2 Articulating®	ETHICON	Bipolar	Sealing and cut coagulation	2015
LigaSure V®	Medtronic, PLC (Dublin, Ireland)	Bipolar	Sealing and cut coagulation	2004
LigaSure Blunt®	Medtronic plc	Bipolar	Sealing and cut coagulation	2014
LigaSure Maryland®	Medtronic, PLC	Bipolar	Sealing and cut coagulation	2015
BiClamp®	ERBE (Tübingen, Germany)	Bipolar	Coagulation	2009
HARMONIC ACE®+	ETHICON	Ultrasonic	Sealing and cut	2015
THUNDERBEAT®	OLYMPUS (Tokyo, Japan)	Ultrasonic Bipolar	Sealing and cut coagulation	2013

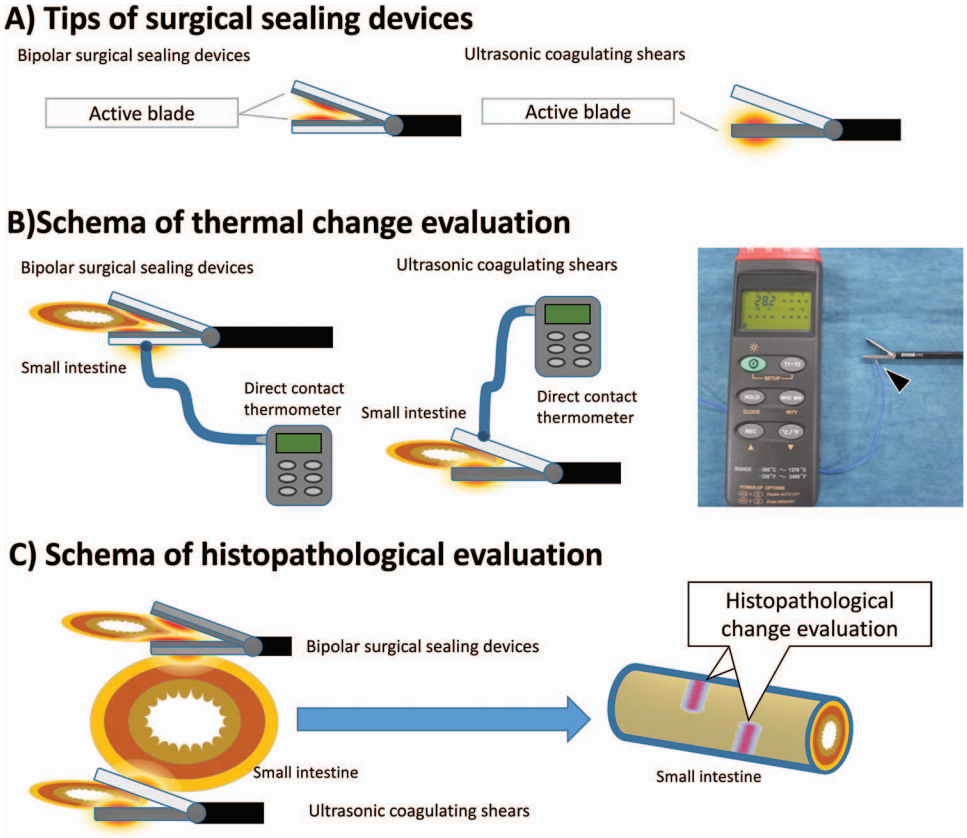

Figure 1. Schemas of this study. **(A)** The tips of bipolar surgical sealing devices (SSDs) and ultrasonic coagulating shears (UCSs). The active blades (ABs) are inside in the bipolar SSDs, and UCSs have a double-edged AB. **(B)** The back of the AB for each SSD was measured using a direct contact thermometer during intracorporeal activation. The thermometer was connected to the back of the AB of each sealing device (arrowhead). **(C)** The back of the AB was attached to the small intestine of pigs during activation to seal and cut other parts of the small intestine. The heat-injured part was cut and cross-sections were evaluated histologically.

Basic Surgical Procedures

A single surgeon and single assistant (TO) performed the surgical procedures. Briefly, a midline abdominal incision was made around the umbilicus 6 cm in length to insert Lap Disk® (Ethicon Endosurgery). Two trocars (10 mm and 12 mm) were then placed for introduction of the laparoscope and SSDs. Pneumoperitoneum was achieved by insufflating carbon dioxide to a pressure in 10 mm Hg during surgery. All of the devices were used to seal and cut the small intestine intracorporeally. Thermal change evaluation and histopathological evaluation were performed as described below.

Thermal Change Evaluation at the Back of ABs

First, the time course of thermal changes at the back of the AB among the SSDs was measured using a direct contact thermometer with a wire-type sensor (Thermo-Hygrometer; AS ONE Corp., Osaka, Japan) during intracorporeal activation. The left hand with a sensor to measure the temperature of the tip was inserted from the Lap Disk®. The sensor was placed on the back of the AB. The maximal temperature and duration for cooling down to ≤50°C were also measured and compared among the SSDs (**Figure 1B**).

Histopathological Evaluation

Second, the SSDs were used to cut the small intestine with attachment of the back of the AB to the rest of the small intestine intracorporeally. The duration to attach the SSDs to the small intestine was defined as the length of activation once cutting the small intestine. Heat injury to the small intestine was assessed histologically to determine the precise effects of the SSDs (**Figure 1C**). The wound part of the Lap Disk® was extended, and the small intes-

tine was resected for histopathological evaluation just after measurement of thermal changes. The resected small intestine was stained with hematoxylin and eosin for histopathological evaluation. A single pathologist (TU) evaluated the depth of heat injury changes induced by the SSDs in this study. Five specimens were evaluated for each device. For each specimen, the depth of heat injury change was evaluated and the number of specimens with heat injury change was counted.

Statistical Analysis

Statistical analyses were performed using JMP® (SAS Institute Inc., Tokyo, Japan). All data are expressed as means ± SEM. The results were analyzed using the Kruskal-Wallis test followed by the Steel-Dwass test for comparison of average maximal temperature and duration for cooling down to ≤50°C. In all analyses, $P < .05$ was taken to indicate statistical significance.

RESULTS

Thermal Change Evaluation

The temperature at the back of the AB increased by >60°C for all of the devices within 20 s, with maximal temperatures exceeding 80°C for LigaSure V® and BiClamp® (**Figure 2C**). The cooling times to ≤50°C are also shown in **Figure 2D**. The shortest time for cooling down was seen for ENSEAL TRIO®, while THUNDERBEAT® showed the longest time for cooling down among the devices examined. It took around 30 seconds for most of the devices to cool down to ≤50°C. There were no significant differences in maximal temperature or duration for cooling down to ≤50°C among the devices.

Histopathological Evaluation

Representative findings of histological changes induced by SSDs are shown in **Figure 3**. Degeneration was detected in the serosa and muscle layer, as well as the submucosal layers. Detachment of the mucosa was also detected in a representative specimen (ENSEAL G2 Articulating®).

The results of histological analyses are summarized in Table 2, where "+" and "−" indicate positive and negative findings with regard to heat injury changes, such as detachment and degeneration. The number of "+" signs indicates the number of specimens in which heat injury changes were observed.

In the histological specimens evaluating the degree of depth of heat injury change, the heat injury caused by LigaSure® series was relatively mild, while the other devices showed heat injury changes up to the vicinity of the mucous membranes. All of the devices induced heat injury deeper than the longitudinal muscle layer despite attaching to the back of the AB.

DISCUSSION

In laparoscopic surgery, SSDs allow safe tissue cutting with coagulation and can reduce surgical time and blood loss. These devices are widely used in surgical procedures. Toishi et al[9] compared intra-operative parameters with regard to SD use and ligation for thoracoscopic lobectomy in primary lung cancer, and reported that the SD group showed reduced intra-operative blood loss and surgical time. Janssen et al[10] systematically reviewed randomized controlled trials in abdominal surgery and compared the usefulness of SSDs, and concluded that SSDs are useful for decreasing bleeding volume and shortening the operation time. However, it is difficult to fully guarantee clinical safety of SSDs like new drugs with approval after randomized controlled trials.[11] Although SSDs were shown to be useful, more detailed investigations regarding safety, including clinical and animal studies, are required to establish adequate usage of new surgical devices.

Bowel injuries are complications that should receive particular attention by urologists when considering use of SSDs in laparoscopic surgery. Bishoff et al[12] reported eight bowel injuries in 915 patients (0.8%). In addition, in a single facility, the rate of intestinal injury associated with laparoscopic nephrectomy was reported as 0.6% in 505 patients.[13] In a meta-analysis of laparoscopic renal surgery, the frequency of intestinal injury was reported to be 0.6%.[14] In addition, Bishoff et al[12] concluded that 50% of intestinal injuries were due to thermal damage induced by surgical instruments. Nonthermal injuries can be repaired by direct closure with suturing, and minor thermal injuries can be managed conservatively with observation or surface suturing. However, in the case of major thermal injury, partial intestinal resection with an adequate safety margin or temporary colostomy may be required, and they are therefore very serious complications.[15] Several studies have evaluated the tip temperature of SSDs using thermography.[4–7] UCS were reported to reach temperatures >200°C and SSDs reached around 80°C. However, the temperature of the entire SD tip was evaluated in these studies. In another experimental study, thermal changes

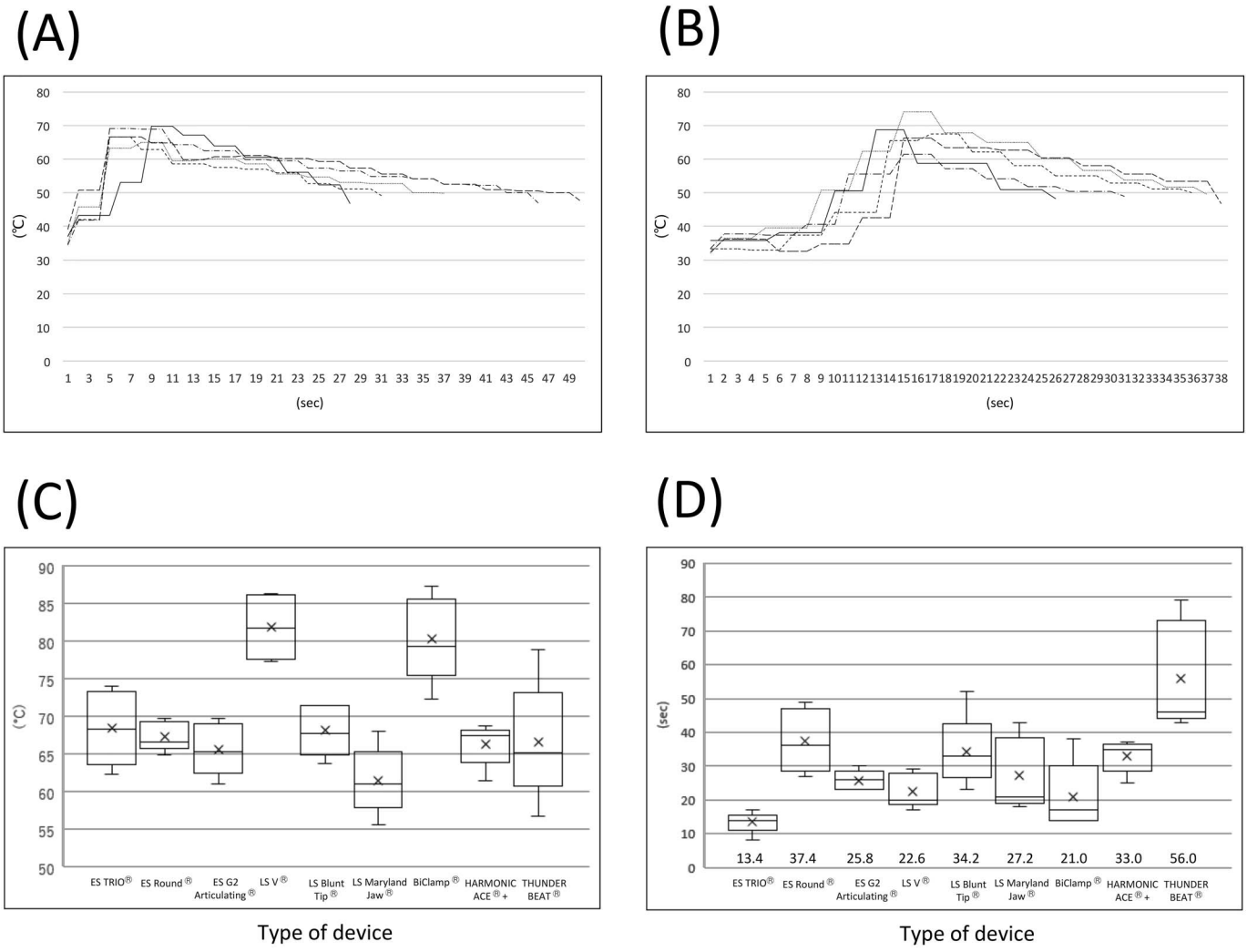

Figure 2. Results of the thermal experiment. (**A**) Representative results of time-dependent thermal changes on the back of the AB of bipolar surgical sealing device (SSD) (ENSEAL Round®). (**B**) Representative results of time-dependent thermal changes on the back of the AB of ultrasonic coagulating shears (HARMONIC ACE®+). (**C**) Summarized results of maximal temperature on the tips of the SSDs. (**D**) Summarized results of duration for cooling down on the tips of SSDs to ≤50°C. There were no significant differences among the devices examined. The averages of duration for cooling down were listed under each result.

in the back of ABs of three types of UCS—i.e., SonoSurg® (Olympus), AutoSonix® (Tyco, Pembroke, Bermuda), and Harmonic Scalpel® (Ethicon)—were evaluated extracorporeally with a direct contact thermometer. Histological changes around the back of ABs of SonoSurg® were evaluated in a laparoscopic animal model. At maximum power, the temperature on the back of the AB was >90°C with 20-second vibration and induced histological changes up to the mucosal layer.[2] Therefore, there has been insufficiently detailed evaluation of thermal changes and histopathological damage induced by SSDs.

In the thermal change experiment in this study, we compared the time-dependent changes in temperature by direct measurement among nine SSDs, including UCSs. We also focused on safe usage of the back of the AB in laparoscopic surgery. All of the SSDs generated high temperatures exceeding 60°C in the present study, with LigaSure V® and BiClamp® showing maximal temperatures >80°C. These results indicated that tissue or organs can be easily injured by attachment of the back of the AB among these two devices in laparoscopic surgery. However, the other devices also reached temperatures above 60°C, which are considered to cause protein denaturation

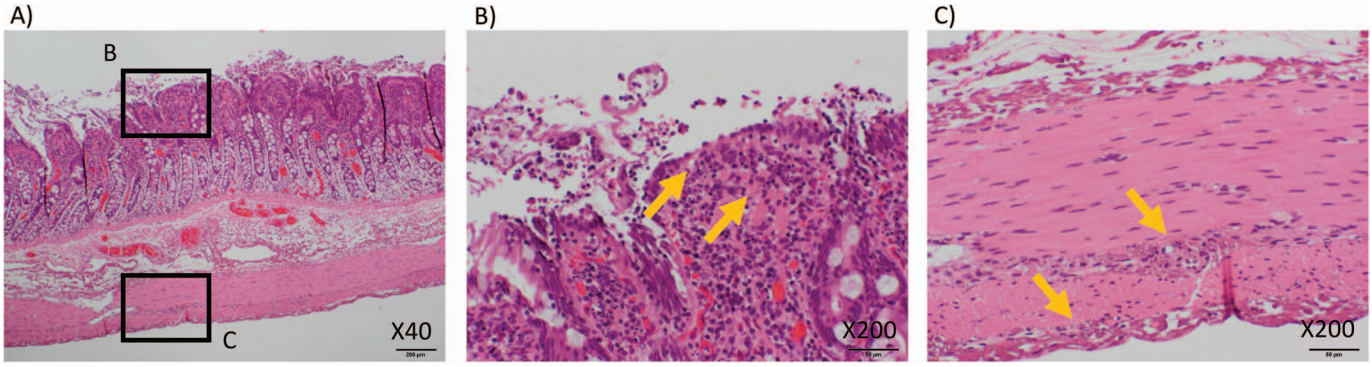

Figure 3. (**A**) Representative histological findings of the small intestine resected by ENSEAL G2 Articulating®. The black boxes are higher magnifications in panels (**B**) and (**C**). (**B**) The mucosal layer of the small intestine was detached and the submucosal layer was degenerated (arrow). (**C**) Degeneration of the serosa and muscle layer was revealed (arrow).

Table 2.
Histological Changes in the Pig Intestine Touched to the Back of the AB During Activation Were Compared for Each Device

Type of sealing devices	Depth of Heat Injury (+: a Sample with Thermal Denaturation)						
	Serous Membrane	Longitudinal Muscle	Circular Muscle	Deep Submucosal Layer	Shallow Submucosal Layer	Muscularis Mucosae	Mucosal Layer
ENSEAL TRIO®	++++	++++	++++	++++	+++	+++	+++
ENSEAL Round®	+++	+++	+++	+++	+++	+++	+++
ENSEAL G2 Articulating®	+++++	++++	−	++++	+	+	+
LigaSure V®	+++++	++	−	++	−	−	−
LigaSure Blunt Tip®	++	++	−	++	++	++	−
LigaSure Maryland Jaw®	+++++	++++	+	++++	++	−	+
BiClamp®	++++	++++	−	++++	++++	++++	−
HARMONIC ACE®+	+++++	+++++	++	++++	+	+	+
THUNDERBEAT®	+++++	+++++	+	+++	++	++	++

of the surrounding tissues. In addition, the temperature of each device rose above 60°C and gradually decreased from the maximal temperature. A period of almost 30 seconds was needed for the back of the AB to cool down to a safe temperature. These results correspond to the previous report by Sutton et al.[3] In this study, it took more than 30 seconds to cool down ≤50°C after activation in all of the SSDs. Laparoscopic surgeons should keep these results in mind, and should avoid bringing the tip of the SSD in contact with organs just after activation.

In histopathological evaluation, all of the small intestine in contact with the back of the AB showed thermal damage. The depth of histopathological change in the small intestine seemed to be shallower with the LigaSure® series in comparison with the other SSDs. The histopathological changes associated with the other SSDs reached layers deeper than the submucosal layers. Chikamoto et al[8] performed similar observations in the pig inferior vena cava with ENSEAL TRIO® and reported thermal damage to the contacted tissue. They conducted histopathological evaluation with two experimental setups, where the activated tip of ENSEAL® was touched directly to the vena cava surface or kept 1 mm away from the surface. Although the vena cava wall integrity was preserved by keeping the tip 1 mm away from the surface, direct contact of the SSDs disrupted the muscular layers of the vena cava wall and

caused shrinkage of cell nuclei. These results also indicated that it is necessary to avoid bringing the activated SSDs in contact with the surrounding tissue or organs for safe usage.

This study had some limitations. First, it was impossible to equalize the part of the small intestine for each trial to be cut exactly. The differences in blood supply and thickness of the intestinal wall would have influenced the results. Second, the surgical procedure, such as pressure on the small intestine, was unequal. Although the surgeon attempted to attach the SSDs to the small intestine in the same manner, technical bias should be taken into account when interpreting the results. However, this study was conducted in laparoscopic surgical application in a large animal, and the results can be extrapolated to clinical situations.

CONCLUSION

Even on the back of the AB, all of the SSDs generated heat exceeding 60°C, and induced non-negligible histopathological changes in layers deeper than the longitudinal muscle layer. The tips of SSDs should not be brought into contact with the surrounding tissues or organs during and at least 30 seconds after activation in laparoscopic surgery.

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