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DYNAMIC MANUSCRIPT

Repeated partial tissue bite with inadequate cooling time for an energy device may cause thermal injury

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Abstract

Background Over the past three decades, the use of ultrasonically activated device (USAD) and advanced bipolar device (ABD) has grown in minimally invasive surgeries. However, the thermal profile differences during repeated dissection with different grasping ranges of energy devices, which provide valuable information for preventing thermal injury by energy devices, remain unclear.

Methods We developed an ex vivo benchtop model to examine the temperature profile of the blade and jaws of two USADs (HARMONIC® ACE + and Sonicision™) and a ABD (Ligasure™ Maryland) with different grasping ranges (partial tissue and full tissue bite) in repeated dissection with minimum cooling time. The maximum temperature, time required for completion to dissection of 10 cm of porcine muscle, thermal spread, and cooling time to reach 60 °C were continuously measured using video thermography. In addition, to evaluate one more grasping range "no tissue", we performed a stress test that activated the USAD without tissue intervention to assess the effects of excessive load on the blade and jaw.

Results Repeated dissection of energy devices with minimal cooling time results in high blade and jaw temperatures proportional to the incision distance. In particular, the USADs with partial tissue bite showed a significantly higher temperatures at the blade and jaw, longer cooling times, and higher lateral thermal spread than those with a full tissue bite and the ABD. The stress test with a USAD showed an extremely high blade temperature exceeding 400 °C, with the tissue pad melting only 13.2 s after activation.

Conclusion Although USAD with partial tissue bite help ensure precise dissection, repeated long activation with inadequate cooling time may increase the risk of thermal injury during surgery. These results suggest that surgeons should use energy devices properly while understanding the risks of adjacent organ damage that could result from abuse of the device.

Keywords Energy device · Thermal damage · Laparoscopic surgery · Laparoscopic cutting scissors · Vessel-sealing system · Stress test

Recent advancements in energy devices have enabled surgeons to perform dissection more accurately with less blood loss and in less time than previously, thereby allowing for safer laparoscopic and thoracoscopic surgery [1, 2]. Ultrasonically activated device (USAD) and advanced bipolar device (ABD), also known as vessel sealer system (VSS), are distinct technologies that offer particular advantages over traditional diathermy [3, 4]. However, these different energy modalities produce localized temperature increases that can result in thermal injury to the surrounding tissue. Indeed, several reports of thermal injuries of the bile duct, intestine, inferior vena cava, and nerves during laparoscopic surgery have raised questions about the cooling properties of these devices as well as their temperature safety profile [5–10]. Many temperature studies of surgical energy devices have been reported and reviewed in the past [11–14]. However, most previous ex vivo investigations on thermal injury due to energy devices have been based on a single activation, while in clinical practice, surgeons perform consecutive

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dissection procedures during surgery. In addition, surgeons use different grasping ranges depending on the surgical situation, but few reports have focused on the differences in the thermal profile among different grasping ranges. We believe that the simulation conditions in experimental studies can provide valuable information by replicating actual clinical scenarios. Furthermore, an adequate cooling time between dissections is very important for the safe use of energy devices [5]. However, the effect of an inadequate cooling time on the temperature accumulation at the tip of an energy device over time has not been evaluated.

In the present study, we developed an ex vivo system to observe temperature changes of the blade and jaws during continuous dissection without allowing for adequate cooling time and verified the real-time temperature changes of the devices and the thermal spread to muscle with different grasping ranges of energy devices using thermography. To use such devices properly and safely, surgeons must be aware of what hazards are posed by the abuse of these devices. Therefore, we performed a stress test that activated a USAD without tissue intervention to evaluate the effects of excessive load on the blade and jaw.

Materials and methods

An original ex vivo benchtop model was built, and porcine muscle sliced into 3 mm-thick sections was used for this study (Fig. 1). While performing repeated dissection with minimum cooling time through 10 cm of muscle, moving the cart manually, the temperature changes of the energy devices and adjacent tissues were continuously recorded. Each experiment was conducted seven times.

Energy devices

The three energy devices used in this study were two USADs and a ABD. The USADs were the Harmonic® ACE + shears (ACE; Ethicon, Inc., Cincinnati, OH, USA), 36 cm in length and powered by the GEN11 generator, and the Sonicision™ Shears (SCN; Medtronic plc, Dublin, Ireland), 36 cm in length. The ABD was the LigaSure™ Maryland laparoscopic sealer/divider (LSM; Medtronic plc), 37 cm in length. The ACE was used in the energy activation mode at a power level of 5. The SCN was used at the maximum power mode. For the LSM, the power was automatically controlled by the Valleylab™ FT10 energy platform.

Device handling techniques

Two different device handling techniques for grasping ranges—the full tissue bite technique (FTB; Fig. 2A) and the partial tissue bite technique (PTB; Fig. 2B)—were evaluated in this study. The FTB allows for dissection of tissue using the entire ultrasonic shear blade, while the PTB fires the shears with blades closed when a small amount of tissue (3 mm) is present in the distal part of the blade.

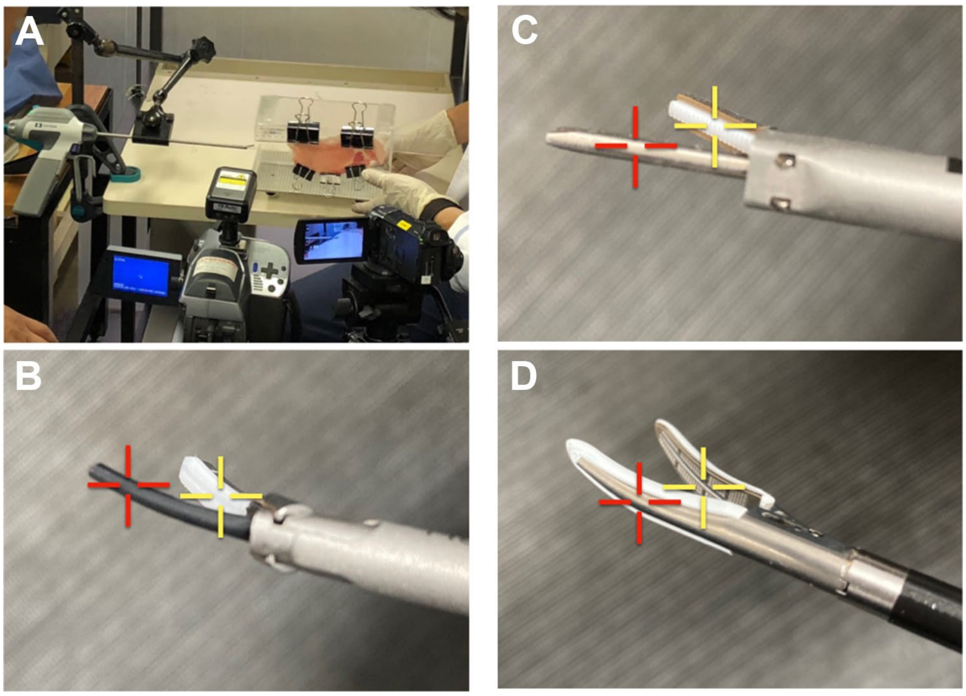

Fig. 1 Original benchtop model and the devices. **A** The rigid articulating holder arm with a table clamp, customized cart, and infrared camera (Avio TVS-500EX). **B** The blade of the HARMONIC ACE +. The active blade (red target mark) and passive jaw (yellow target mark) were measured. **C** The blade of the Sonicision. **D** The outside (red target mark) and inside of the jaw (yellow target mark) of LigaSure Maryland were corresponded and measured

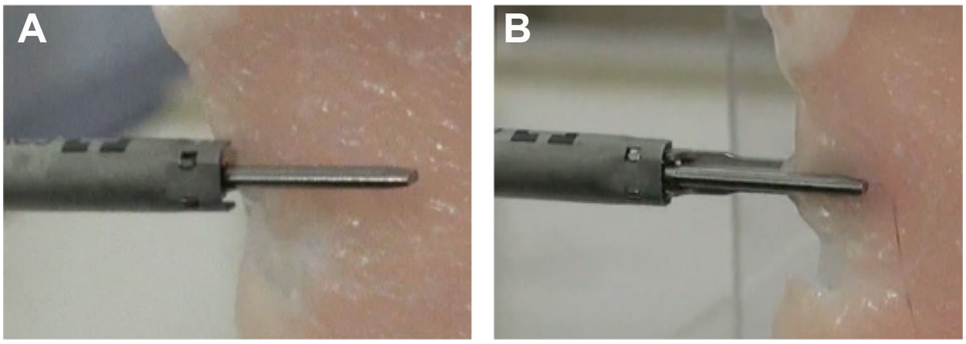

Fig. 2 Two different device handling techniques regarding grasping ranges: **A** The full tissue bite technique. **B** The partial tissue bite technique

Temperature and other parameter measurements

For device and tissue temperature measurements, a thermal imaging camera (TVS-500EX; Nippon Avionics, Tokyo, Japan) with a spectral range of 8 to 14 µm and a measurable temperature range from − 40 to + 500 °C was mounted 30 cm from the device and focused on the tip of the device. Complete infrared thermal recordings were obtained at 0.1 s intervals during and after repeated dissection. The blade of the USAD is defined as the active piece moving longitudinally during activation, while the jaw is considered the clamping piece with the Teflon strip that holds the tissue in place (Fig. 2). In the LSM, the outside and inside of the jaw were corresponded and measured. At the end of the cutting segment, the cutting time was recorded. Subsequently, the time required for the temperature to decrease to 60 °C after cutting 10 cm of muscle was also recorded.

Using the stored movie data, the time-discrete thermal changes of the blade and jaw were calculated using the infrared camera's included software program (ThermoMovieEditor; Nippon Avionics). The highest temperature of the spot in each frame and the heat diffusion range around the blade at the end of the cutting segment were measured and analyzed. According to previous reports, the range of the lateral thermal spread was defined as ≥ 45 °C of tissue temperature as the critical temperature for potential tissue damage to occur [15, 16].

Stress test of the USADs

To evaluate one other grasping range (no tissue), we performed a stress test. The SCN was activated at maximum power mode without any tissue intervention. The thermal and morphologic changes in the blade and jaw of SCN were recorded and assessed with normal and thermographic video data. Following the completion of activation of the SCN, the jaw was opened, and the condition of the tissue pad was continuously observed. To evaluate the rapid temperature increase in the blade, heat treat colors for steel according to the temperature using thermal radiation was employed in addition to thermography (Fig. 3) [17].

This study was an ex vivo animal study. The experiments followed the guidelines set forth in the Helsinki Declaration of 1975, as revised in 2000, concerning Animal Rights. This article does not contain human or animal subjects performed by any authors. There was no need for an approval of the institutional review board (IRB).

Statistical analyses

Student's *t*-test was performed using the Microsoft Excel for Mac software program (Microsoft, Redmond, WA, USA) to analyze the difference between the two groups.

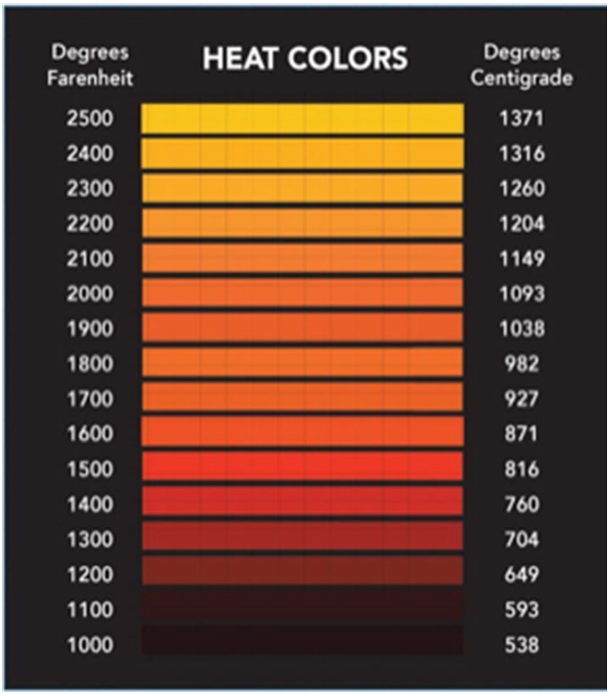

Fig. 3 The chart of heat-treated colors for steel according to the temperature using thermal radiation [17]

All *p* values caluculated were two-sided, and significance levels were set at 5%.

Results

Representative examples of the results obtained with each device and handling technique are shown in Fig. 4, and the average of all results is summarized in Table 1 and Fig. 5. Figures 4A and 4B show a thermographic picture of the ACE tip during a continuous 10 cm dissection with FTB and PTB. The highest temperature spot of the blade (red target mark) was graphed with elapsing time (Fig. 4C). At the first activation, the peak blade temperatures were 167 °C for the PTB and 125 °C for the FTB, with sharp temperature drops after the instrument was deactivated. The peak blade temperature gradually increased with the continuation of porcine muscle dissection, with maximum blade temperatures of 372 °C for the PTB and 197 °C for the FTB. The blade temperature increased with incision distance and elapsed time for both incision techniques, but the temperature rise was particularly steep with the PTB. The time to complete 10 cm continuous dissection was

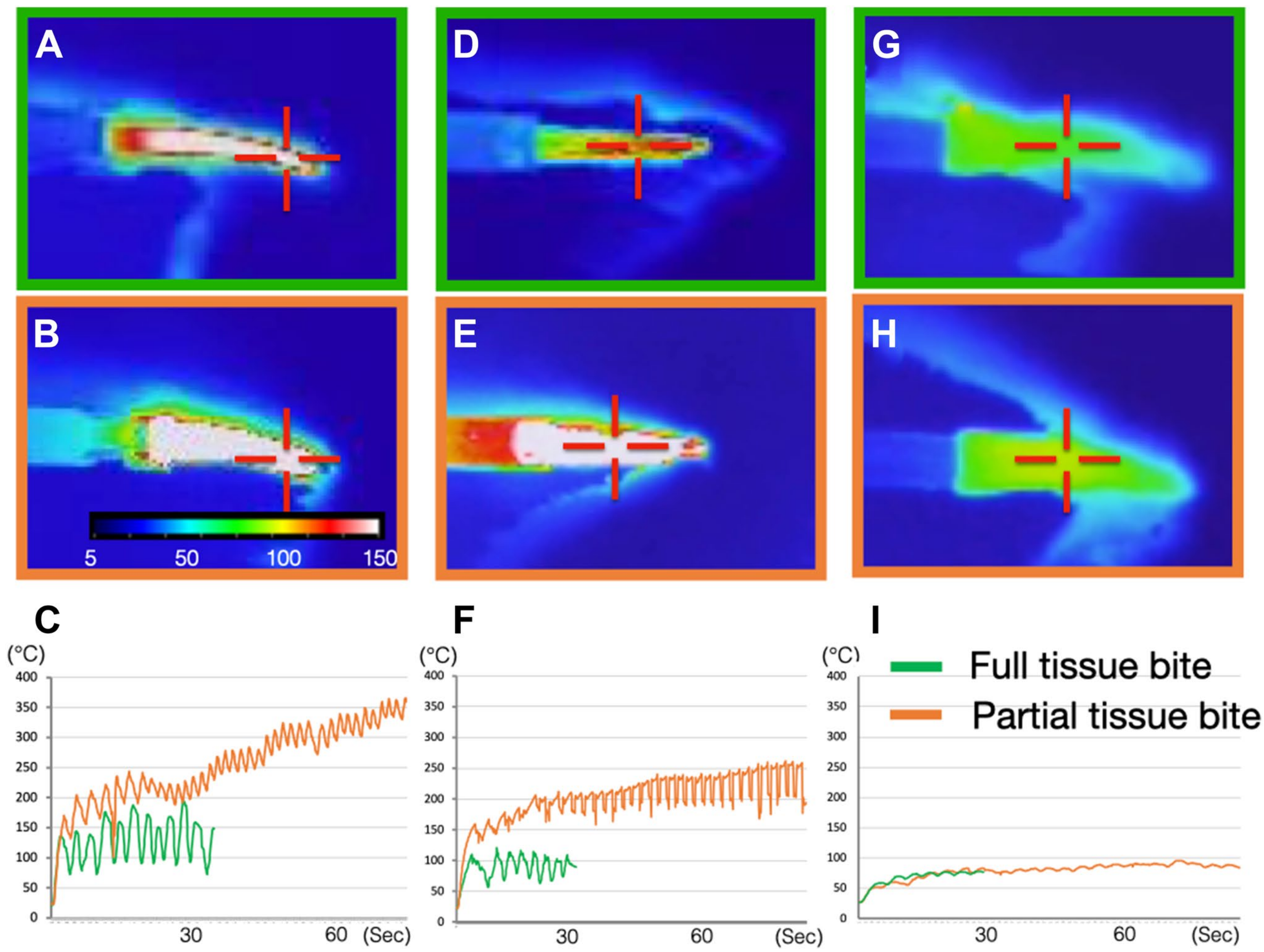

Fig. 4 Representative examples of the results obtained with each device and handling technique. **A** Typical thermographic image using the HARMONIC ACE+with the full tissue bite technique. **B** Typical thermographic image using the HARMONIC ACE+with the partial tissue bite technique. **C** Graphed temperature data of the HARMONIC ACE+with the full tissue bite and partial tissue bite techniques over time. The blade temperature increased with incision distance and elapsed time for both incision techniques, but the temperature rise was particularly steep with the partial tissue bite technique. **D** Typical thermographic image using the Sonicision with the full tissue bite technique. **E** Typical thermographic image using the Sonicision with the partial tissue bite technique. **F** Graphed temperature data of the Sonicision with the full tissue bite and partial tissue bite technique over time **G** Typical thermographic image using the LigaSure Maryland with the full tissue bite technique. **H** Typical thermographic image using the LigaSure Maryland with the partial tissue bite technique. **I** Graphed temperature data of the LigaSure Maryland with the full tissue bite and partial tissue bite techniques over time

Table 1 The averages of the maximum temperatures and other results achieved per instrument

	HAMONIC ACE+	Sonicision	LigaSure Maryland
Peak blade temperature (°C)			
Full tissue bite	202 ± 20.3	135 ± 18	81 ± 4.3
Partial tissue bite	330 ± 32.7	230 ± 39.7	95.6 ± 5.5
Peak jaw temperature (°C)			
Full tissue bite	211 ± 6.6	168 ± 12.8	96 ± 2.4
Partial tissue bite	341 ± 28.3	343 ± 40.9	115 ± 16.8
10 cm dissection time (seconds)			
Full tissue bite	34.7 ± 2.1	32.4 ± 6.9	27.7 ± 2.3
Partial tissue bite	76.9 ± 4.1	88 ± 16.8	88.8 ± 9.2
Cooling time (seconds)			
Full tissue bite	28.7 ± 3.5	29.4 ± 7.9	13.4 ± 2.8
Partial tissue bite	80.3 ± 7.2	95.7 ± 12.7	27.4 ± 1.9
Lateral thermal spread (mm)			
Full tissue bite	1.82 ± 0.3	1.29 ± 0.32	0.56 ± 0.13
Partial tissue bite	2.39 ± 0.3	2.33 ± 0.54	0.75 ± 0.1

All values are expressed as the mean ± SD

34 s for the FTB and 78 s for the PTB, with times being shorter for the FPT than for the SPT.

Figure 4D and E show a typical thermographic picture of the SCN tip during a continuous 10 cm incision. The highest blade temperature was 260 °C for the PTB and 117 °C for the FTB. Similar to the results observed in the ACE, the blade temperature increased with dissection distance and elapsed time for both incision techniques, but the temperature rise was particularly steep with the PTB. Figure 4G and H show a typical thermographic picture of the LSM tip during a continuous 10-cm incision using the FTB and PTB, respectively. In this case, as shown in Fig. 4I, the peak blade temperature reached a plateau early and at a relatively low temperature (about 80 °C). The highest blade temperature was about 80 °C for both the PTB and FTB.

Figure 5A shows the mean peak blade temperatures of the three devices with two handling techniques. The ACE showed the highest mean blade temperatures (330 °C for the PTB and 202 °C for the FTB, $p < 0.01$, $n = 7$) among the 3 devices for both PTB and FTB. In contrast, the LSM showed the lowest mean blade temperatures (96 °C for the PTB and 81 °C for the FTB) with statistically significant differences ($p < 0.01$, $n = 7$). Focusing on the handling technique, all devices showed higher temperatures for the PTB than for the FTB ($p < 0.01$, $n = 7$). The influence of the handling technique was more evident in the USADs than in the LSM.

Regarding the jaw temperature with the PTB, both the ACE and SCN showed an extremely high peak temperature (343 °C for the ACE and 341 °C for the SCN). Conversely, the LSM showed a lower jaw temperature (115 °C) than the USADs ($p < 0.01$, $n = 7$). Regarding the jaw temperature with the FTB, the ACE showed a higher peak jaw temperature (211 °C for ACE) than the SCN (168 °C) and LSM (91 °C) ($p < 0.01$, $n = 7$, Fig. 5B). The LSM showed a lower jaw temperature than the USADs ($p < 0.01$, $n = 7$). Regarding the handling technique, for all 3 devices, the PTB showed a significantly higher jaw temperature than the FTB ($p < 0.01$, $n = 7$). In terms of the 10 cm cutting speed, the ACE was the fastest with the PTB, and there was a statistically significant difference between the ACE and LSM ($p < 0.01$, $n = 7$, Fig. 5C). Regarding the handling techniques among all three devices, the PTB had a significantly longer cutting time than the FTB ($p < 0.01$, $n = 7$).

The cooling time (needed to achieve 60 °C) is shown in Fig. 5D and Table 1. The SCN had the longest cooling time (95.7 s) with the PTB ($p < 0.01$, $n = 7$). The cooling times for all three devices were longer with the PTB than with the FTB, with the SCN (95.7 s, 29.4 s) and ACE (80.3 s, 28.7 s) requiring twice as long a cooling time as the LSM in the FTB (27.4 s, $p < 0.01$, $n = 7$) and almost thrice as long a cooling time as the LSM in the PTB (13.4 s, $p < 0.01$, $n = 7$).

The thermal spread at the end of 10 cm dissection varied considerably among the energy device types and handling techniques (Fig. 5E and Table 1). The ACE had the highest lateral thermal spread of 2.39 mm in the PTB and 1.82 mm in the FTB (Fig. 5E), while the LSM showed significantly less lateral thermal spread than the ACE or SCN in the PTB and FTB (0.75 and 0.56 mm, respectively), with significance ($p < 0.01$, $n = 7$). For all three devices, the PTB showed a significantly wider lateral thermal spread than the FTB ($p < 0.01$, $n = 7$). Furthermore, the influence of the handling technique was more evident and significant in the USADs than in the LSM ($p < 0.01$, $n = 7$).

The results of the stress test of the USAD are shown in Movie 1 and Fig. 6A–F. Unexpectedly, the temperature of

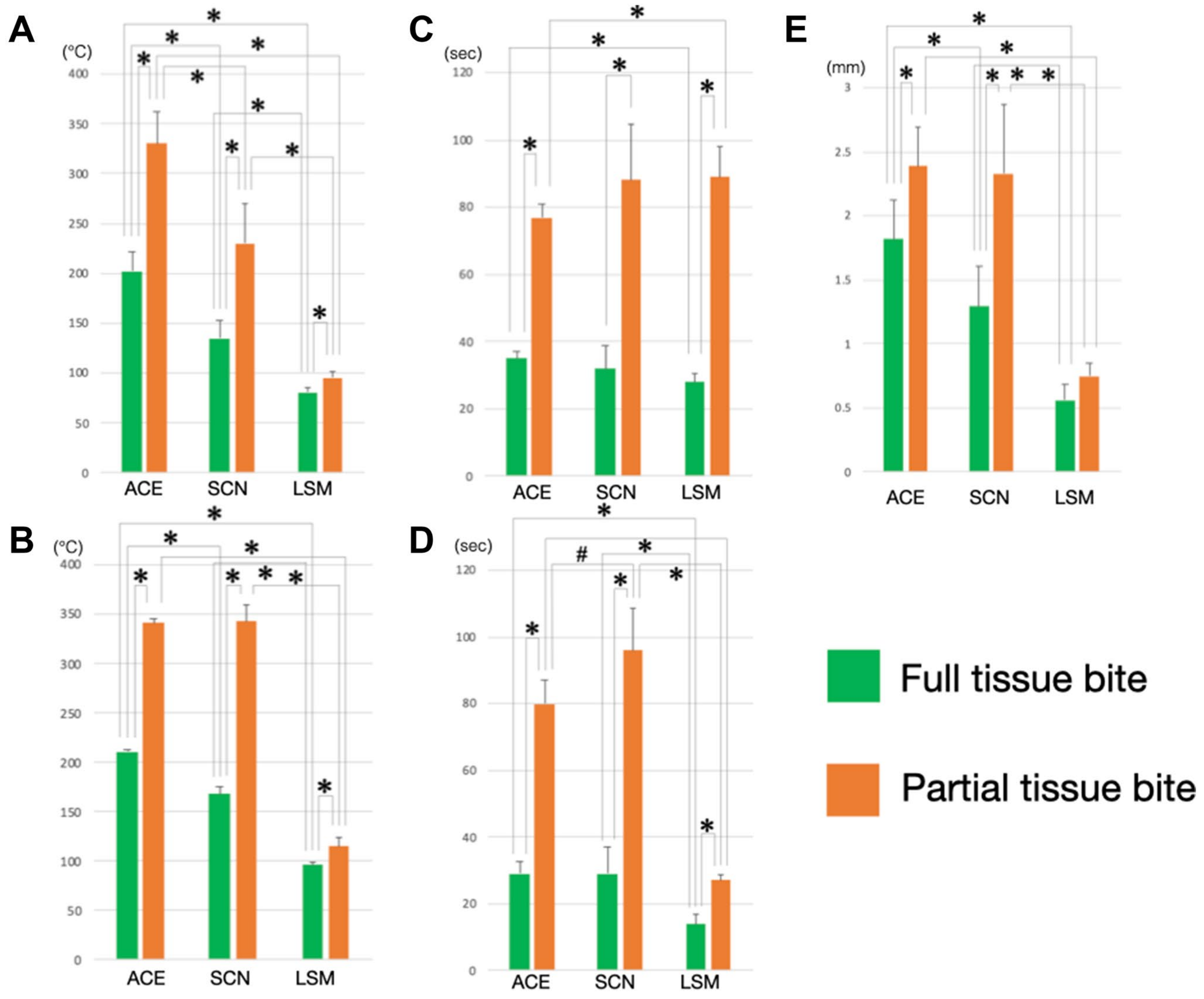

Fig. 5 Averages of all results obtained from each device with different handling techniques. **A** Peak blade temperature. **B** Peak tissue pad temperature. **C** Cutting speed. **D** Cooling time. **E** Lateral thermal spread. $n = 7$, $*p < 0.01$, $\#p < 0.05$. The ACE: HARMONIC ACE+, SCN: Sonicision, LSM: LigaSure Maryland

the blade using thermography rose sharply in proportion to the time after activation, reaching 420.3 °C in just 13.2 s and then breaking down with smoke, a flash, and a warning sound (Fig. 6A–D, Movie 1). Although the upper measurement range of the thermography device we used was 500 °C, the sudden increase in temperature close to the upper range may have resulted in inaccurate thermographic measurements. Referring to the chart of the heat-treated colors for steel by temperature using thermal radiation, surprisingly, we estimated the temperature to be about 900 °C when the blade flashed (Figs. 3, 6D). On closer observation of the thermography video, at 5 s after activation, something hot splattered out of the jaw (Movie 1, Fig. 6B). Considering the image of the normal video, they were recognized as the liquid drips and splatter from the jaw (Fig. 6C). Since the jaw is made of Teflon and has a melting point of 326.8 °C, we suspect that the stress test caused the jaw to become extremely hot, melt, and evaporate. Furthermore, careful observation of the opened jaw after deactivation revealed that the jaw had dramatically changed from translucent and gelatinous to white and solid due to the sharp decrease in temperature within a few seconds (Fig. 6E, F). Thus, the heat generated by excessive load caused abnormal temperatures, which resulted in thermal denaturation, gelation, vaporization, and the byproducts of the tissue pads.

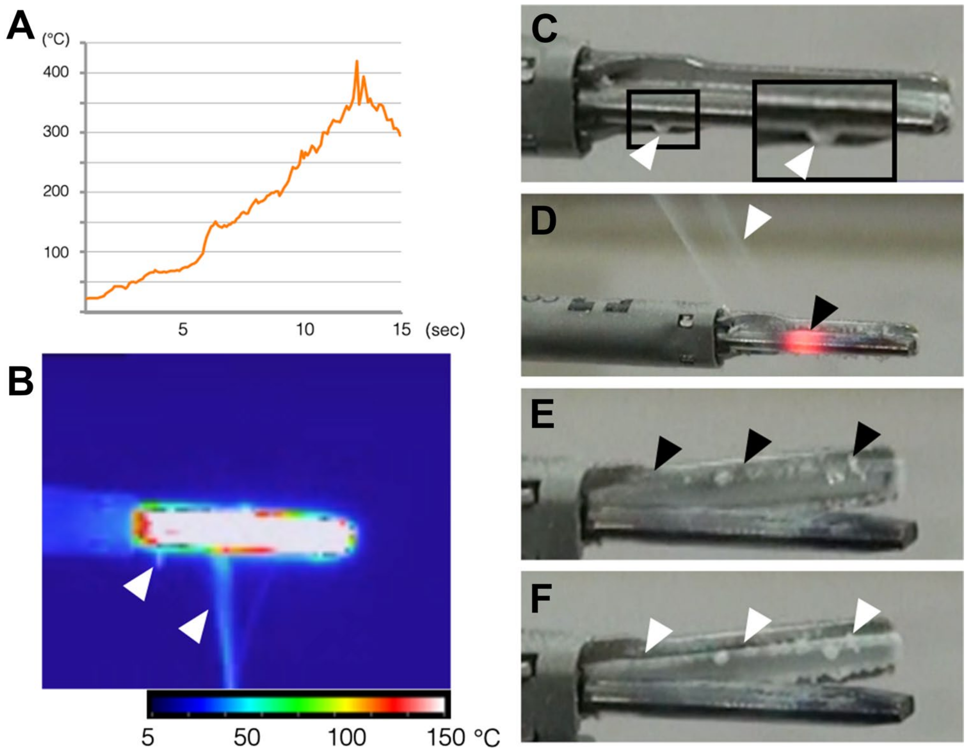

Fig. 6 The stress test of the USAD. The Sonicision was activated at maximum power mode without any tissue intervention (no tissue). **A** Graphed temperature data of the Sonicision over time. The temperature of the blade using thermography reached 420.3 °C in 13.2 s. **B** Thermographic image using the Sonicision. White arrow: the liquid drips and splatter from the jaw. **C**–**F** Morphologic changes in the blade and jaw of the Sonicision. **C** White arrow: the liquid drips from the jaw. **D** White arrow: smoke from the jaw. Black arrow: flash of the blade center. **E** Black arrow: translucent and gelatinous jaw. **F** White arrow: white and solid jaw

Discussion

While there have been a considerable number of reports in the experimental literature on tip temperature and thermal damage with the ACE, SCN, and LSM, the conclusions of these studies have been somewhat confusing. In the present study, the ultrasonic coagulation devices showed higher temperatures at the blade and jaw, especially with the PTB, longer cooling times, and greater lateral thermal spread than the LSM. This result was consistent with the findings reported by other researchers [5, 8, 11, 14]. In addition, the European Surgical Research reported that coagulation necrosis is greater if the utilization is continuous rather than disconnected or reconnected [5]. Our results also revealed that the LSM had lower temperatures at the blade and jaw, shorter cooling times, and less lateral thermal spread than the USADs. Similarly, previous reports also showed that the LSM had lower blade temperatures and a shorter cooling time with less thermal injury and a lower inflammatory response than USADs [8, 18, 19]. In this context, the LSM is considered to be safer than USADs with respect to thermal damage to the surrounding tissue. However, the LSM can also cause thermal damage if activated with the tip in contact with the surrounding tissue, although the damage is not as severe as with the USAD.

In contrast to the above findings, other studies have also shown that ultrasonic energy can be safely applied without a substantial increase in local temperature [4, 20]. In a comparative study using a porcine model, Landman et al. also showed that Harmonic scalpels produced less acute collateral tissue damage than an LSM [12]. Hayami et al. reported that the thermal spread induced by a vessel-sealing device was greater than that seen with USADs, which conflicts with the device temperature data [13]. They also reported that the grasping ranges do not influence the thermal spread with vessel-sealing devices or in USADs. However, of note: in all studies that produced results that contradict our own, the authors investigated the blade temperature and thermal spread only with a single activation, which may not be consistent with actual clinical practice. Because the blade temperature of single-activated USADs is much lower than that of repeated resection, the blade temperature, cooling time, and thermal diffusion using energy devices are different from our own results [21]. Confusion may also arise due to variations in experimental design, which include not only the application time and grasping range but also thermal measurements, the kind of tissue used, tissue tension, power settings, and the methods for assessing thermal damage.

The relationship between frictional heat and the degree of tissue grasping during USAD activation is shown in Fig. 7. In the FTB, since a large amount of tissue is grasped between the active blade and the tissue pad, the coefficient of friction is relatively low, and the rise in temperature at the tip is relatively slow (Fig. 7A). However, in cases of activation without interposed tissue, the tip temperature rises very rapidly and becomes extremely high because the coefficient of friction between the blade and the tissue pad is very high (Fig. 7C). In the PTB, the coefficient of friction

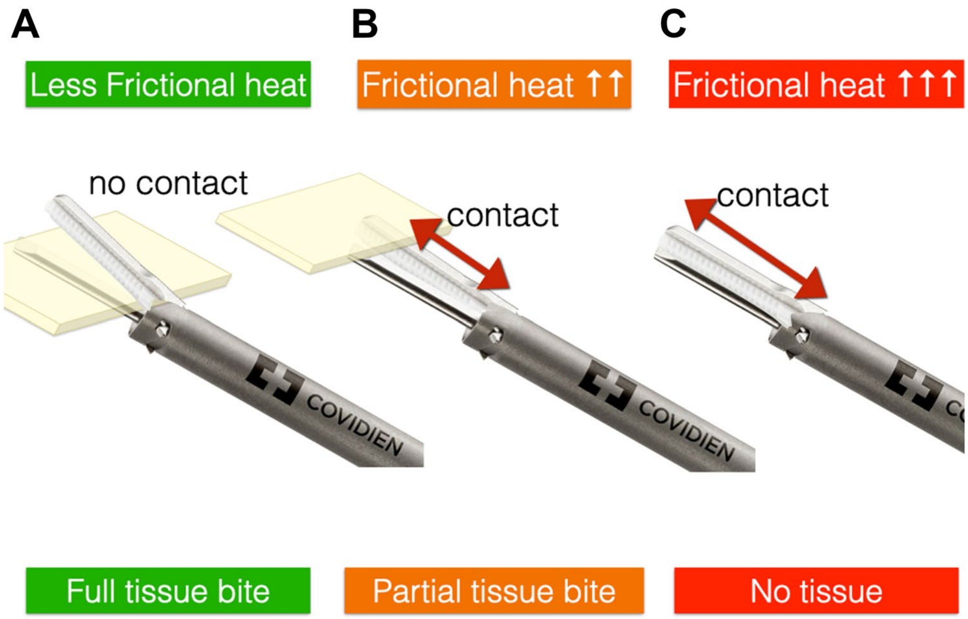

Fig. 7 The degree of frictional heat depends on the difference in contact area between the blade and jaw. **A** Full tissue bite technique. **B** Partial tissue bite technique. **C** No tissue

is slightly lower than during activation without interposed tissue because there is a small amount of tissue interposed between the blade and the tissue pad (Fig. 7B). However, since the coefficient of friction is much higher with the PTB than with the FTB, the tip temperature becomes very high. In general, as we showed, the continuous and long PTB can markedly increase temperatures, but this is an extreme situation not typically seen in surgery, where the PTB is used for meticulous dissection of nodes and vessels and therefore applied only very briefly. Instead, we wish for surgeons to pay close attention if they are performing repeated device activation with the PTB for more than 10 cm or over 1 min without sufficient intervals during actual surgery. Surgeons should thus take care not to touch vital organs with USADs immediately after their activation, particularly when used with a continuous and long PTB approach.

USADs convert electrical energy into ultrasonic vibrations via a piezoelectric or magnetic transducer to achieve coagulation and cutting of tissues simultaneously, but one of the undesirable products when the energy is applied to the tissue is a surgical plume of smoke [5, 22–24]. Polytetrafluoroethylene (PTFE), also known by the trade name Teflon, is a fluoropolymer resin composed of only fluorine and carbon atoms. It is used in the tissue pad of ultrasonic coagulation and incision devices of various manufacturer because of its chemical stability, heat resistance, and durability. Although PTFE itself is chemically inert and nontoxic, it begins to degrade when it reaches about 260 °C [25]. Regarding the jaw temperature in the PTB in the present study, both the ACE and SCN reached extremely high peak temperatures (343 °C and 341 °C, respectively), exceeding the melting point of Teflon (329.3 °C). Furthermore, in our stress test of the SCN, the blade temperature reached 420.3 °C just 13.2 s after the start of activation, and the blade failed. The excessive heat generated by the stress test caused abnormal temperatures, which resulted in thermal denaturation, gelation, and the vaporization of the tissue pads. In addition, we designed a stress test using the ACE as well as the SCN. However, when the ACE was activated without interposed tissue in a preliminary experiment, after a relatively short period of time, a tapered tip of about 2 mm in length became overheated, flashed, broke, and popped off. Based on the results of this preliminary experiment, we decided not to conduct the any further ACE stress test due to safety concerns for our researchers. These findings underscore the importance of managing heat control of the tip of a USAD to avoid thermal decomposition of the tissue pad and prevent thermal damage to the blade.

The inappropriate use of these devices may harm vital structures, and adverse events have been reported in the literature [2, 10, 26]. An instructional video from the manufacturer for the Harmonic scalpel reminds surgeons not to fire the scissors with the blade closed if no tissue is present or if only a small amount of tissue is present. This technique, known as "abuse mode," generates high blade temperatures, resulting in longer cooling times. Under these circumstances, the risk of damaging adjacent tissues may be increased (Harmonic. DVD-ROM, DSL# 06–0820; 2006; Ethicon Endo-Surgery, Inc.) [27]. Furthermore, the FUSE program describes residual heat as follows: “The most important risk associated with the use of ultrasonic surgical cutting and coagulating devices is that the shaft or blade can retain a "kill" temperature (> 60 °C) for about 45 s. Consequently, if the ureter or small bowel comes in contact with the active blade of the USAD, a full-thickness injury can occur.” [28–30]. Therefore, there are a number of factors to keep in mind when working with ultrasonic shears. In summary, safety measures to prevent injury due to extreme temperatures of the active blade of a USAD include (1) not activating the device unless there is tissue (or activating without tissue if you intentionally want to increase the instrument temperature), (2) not using the PTB continuously for long periods to avoid increasing the temperature, (3) Always seeing completely around the instrument, and (4) actively managing the instrument temperature through the any of five recommended ways (touch with a wet lap sponge or specimen; submerge in blood, water or saline; place on a wet towel; use slow mode; or leave sufficient cooling time between uses).

The present study had several limitations to be considered: (1) Energy devices were evaluated in an open environment at room air temperature using the benchtop model to document temperature changes in a serial disseciton. In laparoscopic procedures, insufflation of cold CO_2 may reduce the intracorporeal temperature. On the other hand, in such a closed environment, the device might heat the abdominal cavity and prolong the cooling time of the device. (2) The heat sink effect, which attenuates the temperature surge of the blade, may allow the tissue to absorb or transfer heat from the device after application. As this is ex vivo study using porcine muscle tissue, in vivo situation, blood flow may promote heat diffusion through heat sink effect [11]. (3) Finally, in this study, there is no histological analysis of thermal damage caused by energy devices. Therefore, care must be taken in interpreting the ex vivo data from these energy devices for human laparoscopic surgery."

Conclusion

In conclusion, each of the laparoscopic energy devices examined in this study showed a distinct temperature profile. Although using a USAD with partial tissue bite technique enables precise dissection, repeated, long performance of the PTB with inadequate cooling time may increase the risk of thermal injury during surgery. Therefore, surgeons should be careful not to touch any critical structures with the USAD during or after its activation. The LSM is considered to be safer than a USAD with respect to the blade temperature and thermal damage to the surrounding tissue. These results show the dangers of specific energy devices with abuse. As a result, it is important to use them properly and safely to prevent any unexpected thermal damage in accordance with the characteristics of each device.

Supplementary Information The online version of this article (https://doi.org/10.1007/s00464-021-08322-3) contains supplementary material, which is available to authorized users.

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Compliance with ethical standards

Disclosures Drs. Kazunori Shibao, Fumi Joden, Yasuhiro Adachi, Shiro Kohi, Yuzan Kudou, Yuta Kikuchi, Nobutaka Matayoshi, Nagahiro Sato, Ryota Murayama, and Keiji Hirata have no conflicts of interest or financial ties to disclose.

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