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Safety Profile of the New Harmonic Focus: Different Emissivity and Temperature Behavior Between the Active and the Inactive Blade

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Abstract: Ultrasonic devices disperse less energy in the tissues. The new Harmonic Focus+ (HF+) seems to be more efficient but thermal damages have been reported. This study examined the temperature and the emissivity profile of the active and passive blades of the HF+, on a pig tissue model at different power settings. The FLIR System B series thermal imaging camera has been used on various biological pig tissues to evaluate the emissivity of the ultrasonic device. The active blade heats up faster than the passive one and the increase in power increases the speed of the temperature raising only on the active blade. Increasing the power setting reduces the dissection time and the temperature of both blades. Active blade temperatures of <60°C are obtained with cutting times close to 5 seconds; with these cutting times, the inactive blade does not exceed 30°C. The HF+ emissivity profiles demonstrate that the behavior of the inactive blade is significantly different from the active one. To prevent thermal damages, keep the active blade toward the operator, do not exceed 5 seconds of activation, use the maximum power, and avoid the use of the instrument as a dissector immediately after its activation.

Key Words: ultrasonic devices, emissivity, temperature profile, Harmonic Focus+

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Developments in energy devices have played a major role in the rapid expansion of laparoscopic surgery. Among these, ultrasonic devices seem to disperse less energy in the surrounding tissue, than traditional diathermy.[1–4] In ultrasonic devices, piezoelectric ceramic disks convert externally provided electrical energy into mechanical motion through an ultrasonic, vibrating blade which acts on patient tissue. Thus, no electricity passes to or through the patient.

In 2017, a new ultrasonic device was introduced, the new Harmonic Focus+ (HF+) covered by 9 new patents,[5] which thanks to the Adaptive Tissue Technology determines better management of thermal energy by reducing the power when the active blade approaches the other one. The HF+ is even more efficient while working at lower temperatures but, if the characteristics of these devices are not well understood, serious complications may occur especially when activated for longer periods.[6–9]

A better understanding of the real thermal spread of the new HF+ is needed to prevent thermal injury and improve patient safety, in particular when we operate near nerve structures.[3,10–12]

In this study, we examined the temperature profile of the active and passive blade of the new HF+, during cutting and coagulation on porcine model tissue.

MATERIALS AND METHODS

The new HARMONIC FOCUS+ (Ethicon) model was used for experimental procedures in the laboratory, to examine the temperature profile of passive and active blades. It is equipped with curved shears and tapered tip that vibrates longitudinally at a max frequency of 55.5 kHz reached in 5 different growing step; it is specifically designed to perform fine and delicate surgical procedures for different biological materials and thickness.

Ultrasonic dissections were performed in pig's skin (3.5 mm of thickness) and liver (12 mm of thickness) for 5 different power settings. We have chosen these 2 biological tissues for the different characteristics of mechanical resistance and water content. To simulate the moist environment inside the body, the pig's skin and liver were wet in saline solution before every measurement and stretched with an experimental setup designed at the Department of Physics and Astronomy "Ettore Majorana" of the University of Catania[13] with controlled traction. In all the experiments, the activation time of the HF+ was recorded to establish a correlation between the duration of the cut and the temperature reached by the active and passive blades.

For temperature measurements, to record the heat blade mapping during ultrasonic dissections, a thermal imaging camera FLIR System B series with a spectral range of 7.5 to 13 μm and a measurable temperature range from −20 to +120°C was used.

The measurements were performed with controlled temperature (22°C) and humidity (30%) at a fixed relative distance between camera and samples of 0.4 m.

The emissivity of active and passive blades was measured before thermal imaging measurements when the blade reaches the standard temperature values of 60°C and 30°C respectively. Emissivity (ε), the relative power of a surface to emit heat by radiation, was calculated. This last is a dimensionless quantity depending on the temperature of the sample and the wavelength of used energy; its values range from $0 < \varepsilon < 1$.

The standard temperatures used as reference were measured with a thermocouple sensor and the corresponding

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TABLE 1. Known Temperature Measured With Thermocouple Sensor and Emissivity Related to Both Active and Passive Jaws Obtained Using Thermal Imaging Method

	Active Jaw	Passive Jaw
Known temperature measured with thermocouple sensor (°C)	60 ± 1	30 ± 1
Emissivity (ε) measured with thermal imaging method	0.49 ± 0.02	0.85 ± 0.03

emissivity value was simultaneously set in the thermal imaging camera.

RESULTS

Table 1 shows the emissivity experimental values obtained with thermal imaging method starting from a known temperature measured with a thermocouple sensor both active and passive blades.

Figures 1A and B show the cutting time and the temperature reached by the passive jaw at different power setting for both skin and liver. The increase in the power setting reduces the section time both in the liver and in the skin. However, the increase in section energy does not correspond with a proportional increase in temperature of the passive blade: instead, this determines the reduction of the activation times required for cutting with a lower passage of energy to the inactive blade and a reduction of its temperature. In the liver, the longer cutting times, compared with the skin, are probably because of a higher water content that requires more energy for drying the tissues. For this reason, the temperature values reached by the inactive blade are higher: however, by increasing the power levels, the cutting times become similar between the liver and the skin and the difference in temperature of the passive blade decreases progressively.

In both cases, liver and skin, to get cutting temperature ≤30°C of the passive blade, it is necessary to use a power setting ≥3 (intensity in arbitra unit reported on the ultrasonic device) to achieve cutting times of <6 seconds (Table 2).

Figure 2 shows the values of the temperature measured by active blade versus power intensity (A) and versus time cutting (B).

The active blade heats up faster than the passive one, so increasing the activation time its temperature proportionally increases. The increase in temperature of the active blade is directly proportional to the activation time regardless of the type of tissue: activation time is decisive for heat development (Fig. 2B). Paradoxically, higher values of the power intensity correspond to lower temperatures of the active blade (Fig. 2A).

Increasing the power setting causes a more rapid increase in temperature of the active blade as shown by the temperature increasing rate of the active blade (Table 2), but the greater cutting efficiency reduces the operative times with a reduction in temperatures as a final effect.

Moreover, the reduction of the activation times leads to a lower heat transfer to the inactive blade, which is not influenced by the power setting as shown by the passive blade's temperature increasing rate (Table 2).

To obtain active blade temperatures of <60°C, the section times must be close to 5 seconds. With these section times, the inactive blade does not exceed 30°C and it reaches 60°C in extreme conditions: this result can be obtained with the power setting between 3 and 4.

DISCUSSION

The vast majority of surgical procedures involve the use of devices that apply energy to tissue. Although various energy sources may be used, the fundamental principle involves tissue necrosis and hemostasis by heating: even the mechanical energy turns into thermal energy and is irradiated to the surrounding tissues. The process of denaturation of tissue begins around 60°C with the aggregation of macromolecules; beyond 100°C, the tissue vaporization begins, whereas tissue carbonization occurs beyond 200°C.[2]

These devices are potentially dangerous: the electrical current or the heat generation, in the complex environments in which they are used, can cause complications. Surgical burns and fires are commonly encountered and are listed in the Emergency Care Research Institute's (ECRI) Top 10 health technology hazards for 2018.[14] In laparoscopic surgery, the incidence of injury related to energy devices is estimated at 1 to 2 per 1000 patients.[15]

Furthermore, in a recent study, it was found that most of the surgeons have knowledge gaps in the safe use of energy devices and this further increases the risk of complications.[16]

To address this issue, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) has recently initiated the Fundamental Use of Surgical Energy (FUSE) program to develop an educational curriculum to prevent untoward events and promote their optimal use;

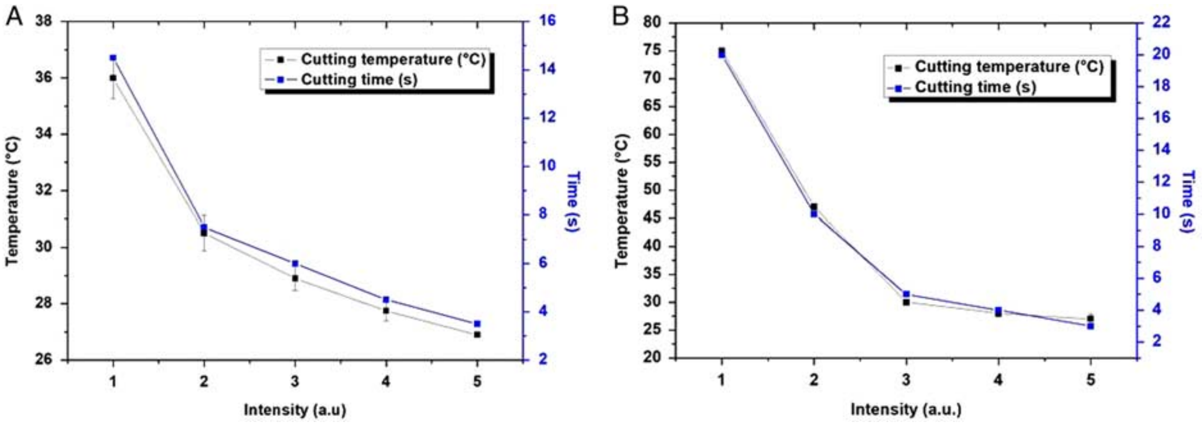

FIGURE 1. Behavior of the cutting temperature versus time for skin (A) and for liver (B).

TABLE 2. Cut Time, Cut Temperature, Temperature Rate Versus Power Setting, Both Active and Passive Blades, Experimentally Obtained for Skin and Liver

	Skin					Liver				
		Active Blade		Passive Blade			Active Blade		Passive Blade	
Power Settings (a.u.)	Cut Time (s)	Cut Temp (°C)	Temp Rate (°C/s)	Cut Temp (°C)	Temp Rate (°C/s)	Cut Time (s)	Cut Temp (°C)	Temp Rate (°C/s)	Cut Temp (°C)	Temp Rate (°C/s)
1	13.0 ± 0.1	95.7 ± 2.9	5.6 ± 0.2	36.0 ± 1.2	0.9 ± 0.1	20.1 ± 0.1	> 120	—	75.0 ± 2.6	2.6 ± 0.1
2	7.5 ± 0.1	70.7 ± 2.2	6.4 ± 0.2	30.5 ± 0.7	1.0 ± 0.1	10.2 ± 0.1	82.3 ± 2.5	5.8 ± 0.2	4.7 ± 1.0	2.4 ± 01
3	5.9 ± 0.1	61.0 ± 1.9	6.5 ± 0.2	28.9 ± 0.4	1.0 ± 0.1	5.2 ± 0.1	59.7 ± 1.8	7.1 ± 0.2	30.0 ± 0.5	1.4 ± 0.1
4	4.7 ± 0.1	56.3 ± 1.8	7.1 ± 0.2	27.8 ± 0.4	1.1 ± 0.1	4.3 ± 0.1	54.8 ± 1.7	7.4 ± 0.2	28.0 ± 0.4	1.3 ± 0.1
5	3.9 ± 0.1	54.5 ± 1.6	8.1 ± 0.2	26.9 ± 0.3	1.1 ± 0.1	3.2 ± 0.1	53.4 ± 1.6	9.5 ± 03	27.0 ± 0.4	1.3 ± 01

more accurate data on the temperature and hazards of these instruments are needed.[17]

Among energy devices, the ultrasonic dissector has been increasingly used worldwide as an alternative to electrical energy sources. It has optimized the operative procedures by improving dissection techniques, working at lower temperatures without the passage of electric currents throughout the body, showing to be safer in laparoscopic surgery.[1,18] When compared with electrosurgery or CO$_2$ laser, the HF causes 1 mm^2 of epidermal destruction and 0.5 mm^2 of dermal collagen denaturation as opposed to 2.5 and 4 mm^2 epidermal destruction or 1.5 and 2.5 mm^2 collagen denaturation for the electrosurgery and laser, respectively.[19]

However, inappropriate use of this device may harm vital structures and adverse events have been reported in the literature.[8,9,20] Several thermal studies have shown that heat generated as a result of stress and friction in the tissue is elevated: Owaki et al[11] demonstrate that the temperature of the HF exceeded 150°C after 30 seconds when it was not used for cutting. When used to cut rat muscle or fat tissue, the temperature exceeded 100°C after 20 seconds. Emam and Cuschieri[21] measured a temperature of 140°C at 1 cm from the tip of the instrument. Kim et al[7] measured a maximum cut temperature of 237.2°C and a coagulating temperature of 223.5°C. Devassy et al[22] confirm in their review the wide variability of the temperature measured at the tip of the instrument but consider it safe.[22] These temperatures could be extremely dangerous for the integrity of nerve structures, particularly sensitive to thermal changes: Lin et al[23] have shown that temperatures > 60°C for > 20 seconds could cause irreversible damage to the nerves.

Nevertheless, the published scientific data are controversial: Chávez et al[10] reported, in a porcine model, the possibility to use the HF+ at a distance of <1 mm from nerve structure without significant electromyographic alterations; Chen et al[3] state that using the instrument 2 mm from the sciatic nerve do not show significant electromyographic or immunochemical alterations. Sutton et al[4] declare that the blade temperature at maximum power for 15 seconds does not exceed 60°C, the threshold of protein denaturation; Pogorelic et al[18] confirmed that the lateral necrosis is <0.3 mm if the instrument is activated for 10 seconds at maximum power.

These conflicting results find explanation in the architecture of the HF+ consisting of an active blade that releases energy and a passive blade that heats up by thermal conduction when the blades come in contact: the temperature varies depending on the side on which the measurement is made and the contact times between the blades; by prolonging the dissection time, we have observed that the temperature of both blades increases progressively even though this increase will be much more evident for the active blade.

The new HF+ optimizes the process further by reducing the operating temperature: we demonstrated, by increasing the power setting of the instrument, that a greater amount of heat

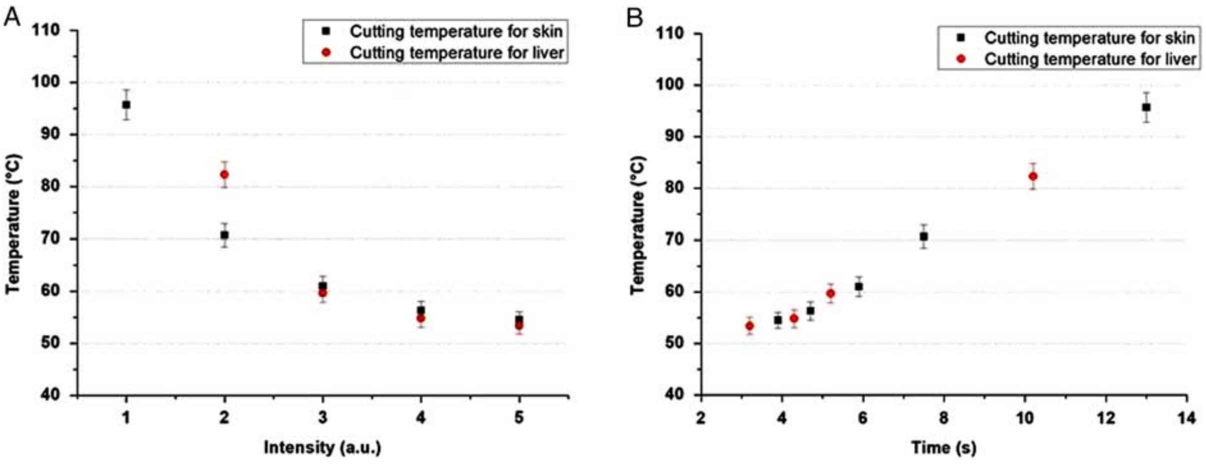

FIGURE 2. Cutting temperature by active blade versus power intensity (A) and versus cutting time (B) for skin (square) and liver (circle).

is generated in the active blade and transferred by contact to the inactive one. Although the power setting increase accelerates the production and the transfer of energy, the reduction of the cutting time determines, as a final effect, the lowering of the cutting temperature in both active and inactive blades. Furthermore, increasing the power setting does not accelerate the rate of increase in temperature of the inactive blade which reduces its temperature considerably. This is important because the instrument is certified to seal vessels up to 5 mm at any intensity of use, although for higher caliber vessels, it is safer to operate at low intensity and with longer times.

The activation time of the instrument is, therefore, the cornerstone in the heat generation mechanism, more than the power setting: to achieve temperatures > 100°C for the active blade, activation times of at least 10 seconds are necessary on both skin and liver tissue. Activation times of > 10 seconds are unlikely to occur in clinical practice: only for power settings of 1, the lowest value, > 10 seconds were needed on both the skin and the liver. The high temperatures reported by Owaki et al,[11] Emam and Cuschieri[21] and Kim et al[7] were measured on the active blade, with the old instrument at maximum power and with times of use much longer than those of normal clinical practice.

To determine the cutting times, we chose 2 biological tissues with opposite characteristics: a high mechanical resistance, such as the skin, or a parenchymatous structure, such as the liver, with thicknesses similar to those observed in clinical practice. We believe that the simulated conditions in the experimental study must take into account the real clinical scenario. In fact, the tissue thickness hardly exceeds 12 mm and the mechanical strength is not higher than the pig skin. For this reason, in our opinion, the temperature measurements obtained with prolonged activation times, which are not reflected in clinical practice, are not significant.

Using the HF+ with the power set to 3, we obtained temperature values around 60°C on the active blade, which therefore should be used cautiously close to the nerve structures, but already at the set power 4, the temperature falls below 60°C both on the liver and on the skin making the instrument safe. The inactive blade temperature has always been <60°C in any condition of use except on the liver, with power setting 1 never selected in clinical practice.

However, the possibility of repeated use of the instrument, in a short period of time, must be taken into account as this would determine, without adequate cooling times, a summing effect of the energy produced with a greater increase in the temperature of both the active and the inactive blades.[4,7] For this reason, when repeatedly applied, the instrument must be adequately cooled in physiological solution both to cool the instrument and to remove tissue debris improving the instrument performance.

CONCLUSIONS

The emissivity profiles of the new HF+ demonstrate its greater safety in use: the behavior of the inactive blade is profoundly different from the active one, reaching 60°C only in extreme conditions of use. Furthermore, the use of the instrument at higher power settings paradoxically reduces the heating of the active blade, lowering the risks of thermal damage.

For a safer use of the instrument and to prevent thermal damage, keep the active blade toward the operator away from the delicate structures, do not exceed 10 seconds of activation, use the maximum setting power, providing you are not coagulating large vessels, and do not use the instrument as a dissector immediately after its activation, must become rules in normal use.

Moreover, when applied repeatedly, the instrument must be adequately cooled in physiological solution. Near nerve structures, to coagulated small blood vessels, the instrument must be used cautiously with the higher setting power for a shorter time than 5 seconds to reduce its heating and improve its efficiency.

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