Measurement of temperature elevation in tissue for the optimum and safe use of scalpel-type ultrasonic surgery devices

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Abstract. Using temperature sensors of specific design, the temperature elevation during application of a Harmonic Scalpel was determined in liver tissue. The influence of different treatment techniques and application parameters on the heat produced was determined. The measurements can be used to assess the risk of harmful bioeffects and to optimise performance and treatment techniques with respect to minimum thermal load.

1. Introduction

Ultrasonically driven scalpel-type devices like the Harmonic Scalpel are widely used in open and endoscopic surgery [1-4]. They allow localised cutting and coagulation, and minimal injury as well as bleeding control is achieved. In endoscopic surgery the Harmonic Scalpel is an alternative method to mono-polar and bi-polar electrocautery with, however, the advantage of avoiding electrical current flow through the body.

The cutting process is accompanied by temperatures of about 100°C on the blade surface, and the tissue changes its chemical structure primarily as a result of protein denaturation. Although several mechanisms contribute to the performance of the Harmonic Scalpel, the tremendous temperature increase at the interface between blade and tissue is substantial, at least for the coagulation and coaptation process. The induced heat is, however, removed from the treatment site into the surrounding tissue, resulting in a temperature increase in the tissue not involved. In a first study the temperature in tissue was determined using special temperature sensors to assess the risk of unintentional harmful bioeffects [5, 6]. During the formulation of a safety margin it became clear that the temperature elevation is strongly influenced by many parameters and that it is difficult to give practical instructions for a safe use of the Harmonic Scalpel during the treatment. In the present study, the temperature increase was measured and compared for various application cases of the Harmonic Scalpel in liver tissue including different blades and cutting techniques. As the duration of the temperature elevation also plays an important role, the thermal dose was calculated and used as an important parameter to assess the thermal risk.

2. Material and methods

Tissue preparation
Liver tissue removed from a pig was investigated using the Harmonic Scalpel. *In vitro* measurements were made in fresh tissue from a butcher’s shop, which before application had been kept in a cooling box for several hours at about 4°C. To allow for the effect of blood perfusion, the temperature increase was in addition investigated in animal experiments using 2 hybrid pigs. The guiding principles set out in the Care and Use of Animals of Germany were followed. The animals were prepared for operation with 20 mg of ketamine/kg of body weight, 2 mg of xylazine/kg of body weight and 1 mg of atropine/kg body weight. Then they were intubated and anaesthetized using isoflurane of 1.5-2.0 vol%, N₂O and oxygen with a ratio of 1.0 l/min to 0.8 l/min. The bowl was opened and the liver was prepared. Finally, the animals were euthanized with 10 ml Embutramid 2% and Mebezonium 0.5% (T 61).

*Temperature sensors and data acquisition*

The temperature increase was measured by means of thermoelectric sensors designed for an application in tissue [6]. Since the sensors were to be reused many times, a robust construction which nevertheless allowed reliable temperature determination was required. A thermocouple (Siemens Matsushita K19, R₀ = 12 kΩ) with negative temperature coefficient and 0.4 mm in diameter was mounted to the end of a glass capillary with an outer diameter of 1.2 mm and fixed with standard epoxy adhesive. To make a measurement, the tissue was pierced and the sensor was inserted down to the measurement position. The distances from the blade were set as well as possible but due to tissue movement, the actual value could be exactly determined only afterwards by a ruler. No thermal coupling gel was necessary throughout the experiments. The electrical resistance was measured by digital meters (Keithley 2000 and 2700) and the data were acquired by a computer. The minimum sampling time was 80 ms and two sensors could be read simultaneously.

From the temperature measurements several parameters were obtained. The maximum temperature elevation ΔT<sub>max</sub> at the time point Δt<sub>max</sub> was defined as the maximum temperature at any time minus the temperature at the beginning of the treatment. To account for the time duration of heating, the thermal dose [7] was calculated. An equivalent duration at a fixed particular temperature (here 43 °C) was defined which would yield the same bioeffect as the heat at other temperatures and with different duration. Since the core temperature of pigs is near that of humans, no correction for core temperature was included [8]. If hyperthermia lasts the time t at the temperature T, the equivalent time t<sub>43</sub> is

\[
  t_{43} = t \cdot R^{(43-T)} \quad \text{with} \quad R = \begin{cases} 
  0.5 & T > 43^\circ \\
  0.25 & T \leq 43^\circ
\end{cases}
\]

To obtain t<sub>43</sub> from the measurement data, the thermal dose was calculated for every time interval t between two sample points of the temperature-time data. Summation of all interval values t<sub>43</sub> yields the final thermal dose.

The temperature sensors were carefully calibrated prior to the use in tissue. Nevertheless, several systematic (Type B) and random (Type A) contributions determine the uncertainty of the temperature measurement. The overall standard uncertainty of the calibration can be estimated to be \( u = 2.0\% \). Although the thermal conductivity of glass is about twice that of tissue, the heat removed from the thermocouple through the glass capillary could be neglected because of the thin walls of the glass tube. The heating of the thermocouple by ultrasound absorption and friction [9] in the sensor itself is less pronounced at low frequencies and was neglected. Taking into account an uncertainty of 5% due to the limited time response of the sensors, an overall measurement uncertainty of 11% (k=2) was estimated providing a confidence level of 95%. It must strongly be emphasised, however, that a strong variation of the results was induced by the experimental conditions such as the determination of the distances, movement of tissue, and loss of contact between blade and tissue.

*Ultrasonic scalpel and blades*
The ultrasonic surgery device used in the experiments was UltraCision® (UltraCision®, Ethicon Endo-Surgery, Norderstedt, Germany) operating at the frequency $f_{osc} = 55.5$ kHz. Two different blades were used, CS14C scissors with curved blade and LCS 6 shears with straight blade.

3. Results
The measured temperatures depend strongly on the distance from the blade. Figure 1 shows in vivo measurements in liver where the cut was made by the LCS straight blade. The left part of figure 1 shows an example of the temperature-time dependence during a cut of 20 s duration starting 5 s after the beginning of the measurement. The higher the distance the lower the temperature and the later the temperature starts increasing. In addition, the temperature near the tip of the blade was lower than aside at comparable distances. The right part of figure 1 summarises different measurements and gives the dose values in dependence on distance. Since the distance could only be determined with a high uncertainty, the rise time $\tau$ of the temperature after beginning was chosen as distance parameter. It could be shown that a linear relation exists between $\tau$ and distance. In addition figure 1b shows, as expected, that heating in liver tissue is much reduced in vivo in comparison with in vitro values.

![Figure 1a. Measured temperature in 2 mm depth](image1a.png)  
![Figure 1b. Dose in dependence on rise time as distance parameter](image1b.png)

For the Harmonic Scalpel several different blades and application techniques exist. To increase the coagulation effect, commonly blunt or large area blades are used. To investigate the thermal effect of changing the blade, the straight blade of the LCS shears was used in three different configurations. To make a cut in liver tissue, the sharp, the blunt and the flat side were used by rotating the knife in the grip. Table 1 summarises the results.

|                  | Side | Blunt | Sharp |
|------------------|------|-------|-------|
| $\Delta T_{\text{max}} / ^\circ C$ | 21.7 | 20.4  | 10.6  |
| Dose $t_{43} / \text{min}$     | 3090 | 1200  | 2.1   |
| Activation time / s            | 35   | 23    | 30    |

When the blade was used with the flat side highest temperature and dose time values were measured. The values decreased slightly when the blunt side was applied. The lowest values, however, were provided by the sharp side. The duration of activation did not seriously influence the results.
because blade activation times were comparable for all three cases and cutting with the sharp side did not proceed faster.

During a real treatment, the thickness of tissue to be sectioned may vary in a wide range. Most of the heat during an application is removed from the treatment site by perfusion and heat conduction, and the thickness of the tissue may influence the temperature elevation. Figure 2 shows the time-dependent temperature elevation for cuts of 5 mm and 17 mm thick tissue layers. Although the activation duration of the scalpel was longer for the 17 mm thick tissue, the measured temperatures are lower than in the case of 5 mm layer thickness. Figure 2 also shows limitations of the measurement technique. During the in vivo experiments, moving of tissue by the cutting procedure or breathing could not be avoided. To compensate the resulting sensor movement the sensors were held by hand, but sometimes the contact between sensor and tissue was lost which led to artefacts in the temperature measurement.

![Figure 2. Measured temperature elevation in 2 mm depth in vivo versus time for two different tissue layer thicknesses, straight blade, sharp blade side, distance 2 mm, sensor configuration as in figure 1, \( \Delta t_{act} \): activation time.](image)

For a quantitative comparison the most important parameters are summarised in table 2. It is obvious that during the cut of a thick tissue layer much less heat is produced than in the case of a thin layer.

**Table 2. Comparison of maximum temperature and dose for different tissue layer thicknesses**

|                      | 5 mm tissue layer thickness | 17 mm tissue layer thickness |
|----------------------|-----------------------------|-----------------------------|
| \( \Delta T_{max} \) / °C | 10.6                        | 4.5                         |
| Dose \( t_{43} \) / min  | 2.1                         | 9.2 \( 10^{-3} \)          |
| Activation time / s    | 30                          | 46                          |

**Table 3. Comparison of maximum temperature elevation \( \Delta T_{max} \) / °C versus depth for in vivo (sharp side) and in vitro (blunt side) measurements**

| Depth / mm | in vitro | in vivo |
|------------|----------|---------|
| 5          | 17.5     | 5.5     |
| 10         | 11.4     | 1.0     |
| 15         | 4.8      | 1.0     |
| 20         | 1.3      |         |
To investigate how the heat distributes in the tissue, the temperature was measured in dependence on depth in the tissue. A sensor was positioned near the tip of the blade and was inserted down to a depth of 5, 10, 15, and 20 mm. The temperature decreases with increasing depth and the time at which the temperature is maximum is more and more delayed (figure 3). Table 3 compares in vivo and in vitro values, and although the in vitro values were obtained with the blunt side it is very obvious that perfusion removes heat very efficient in the in vivo case.

| Depth (mm) | ∆t_{act} (s) |
|-----------|--------------|
| 5         | 27           |
| 10        | 38           |
| 15        | 47           |
| 20        | 44           |

**Figure 3.** Measured temperature elevation in vitro versus time in dependence on depth, straight blade, blunt blade side, ∆t_{act}: activation time.

**4. Discussion and conclusions**

Using temperature sensors of special design, the temperature elevation during the application of a Harmonic Scalpel was determined in liver tissue. Measurements of this kind are indispensable to both, to assess the risk of harmful thermal bioeffects and to optimise performance and operation techniques with respect to a desired minimal thermal load.

The temperature elevation depends strongly on the distance to the blade. Different treatment situations can only be compared when equal distances are set. As expected, smaller temperature elevations were measured in vivo since perfusion removes the heat effectively, in particular at larger distances from the blade.

The temperature elevation aside the blade was higher than the values measured at the tip. The zone with strong necrosis, clearly seen by eye because of the brown colour of the tissue, showed a parabolic shape and was broader near the shaft than at the tip of the blade. So, the temperature field represented by an isothermal line had a parabolic shape with the blade along the symmetry axis and the tip near the focal point. The higher heating potential along the blade causes this effect. A tissue piece aside is heated by the blade as a thermal line source whereas a tissue piece near the tip is only affected by a (weaker) point source. The common technique to cut only with the tip in sensitive ranges seems to be favourable with respect to thermal grounds.

The performance of a cutting procedure depends on properties of the blade involved. When a blunt blade was used, higher temperature values were measured than in the case of a sharp blade. Since the duration of activation was rather similar in the experiments, the form and properties of the interaction zone between blade and tissue play an important role. If large blades are involved, the contact area between blade and tissue is widespread and much heat is produced by friction processes and transferred into the surrounding tissue. In this case coagulation may be particularly efficient, but this advantage is accompanied by higher thermal load.
The thickness of the tissue to be cut strongly influences the temperature increase. Although the activation duration can be longer (this, however, is not generally the case), much lower temperature elevation values were measured. Most of the heat is removed from the treatment site by heat conduction and perfusion. The thicker the tissue the more heat can be removed. In accompanying experiments at colon (which is naturally a thin layer), much higher temperature elevations were found than in the (bulky) liver tissue. For practical purposes it can be concluded that cutting thick tissue layers can be favourable with respect to thermal grounds. Most important is, however, that the heat removing tissue is sufficient. Sectioning a thick tissue layer with several successive cuts of thinner layers may also generate less heat since the thick tissue layer acts as a large heat sink.

The temperature elevation decreases with increasing depth, and the deeper the sensing point is, the more efficient is perfusion. The differences between liver and lung tissue are tremendous at larger distances since lung tissue has low heat conductance. These findings support the assumptions of tissue behaviour in Ref. [6].

All measurements of this study are single results. The number of measurements was not high enough to allow a statistical analysis with significant results. So many conclusions drawn should be interpreted as trends, however with high credibility. In addition, a histological investigation was not included and the temperature measurements could not be supported by cytological investigations. Nevertheless, the study gives useful advice for practical application questions and helps to improve the safe and optimised use of the Harmonic Scalpel.

5. Acknowledgement
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6. References
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