**Abstract.** Background: Bipolar radiofrequency ablation (RFA) can avoid complications such as thermal tissue damage, a possible consequence of monopolar RFA. However, basic studies about the dosage/effect relationship of bipolar systems are missing. This is systematic research on ex vivo beef livers to find which capacity parameters produce high energy in the tissue and achieve large lesion volumes. Materials and Methods: The active lengths 20, 30 and 40 mm of a bipolar, internally cooled applicator were studied. The tissue was fresh ex vivo beef liver. Five measurements each for each active applicator with a power between 10 and 50 W were conducted. Results: The best power for the 20 mm applicator was 15 W, since the highest achieved volume was 5,599±1,760 mm³ and the highest amount of energy introduced to the tissue was 15±3 kJ. The best power for the 30 mm applicator was 20 W (volume 14,538±1,220 mm³, energy 24±1 kJ). For the 40 mm applicator, the best power was 20 W (volume 20,562±896 mm³, energy 24±0 kJ). Conclusion: The results of this study help clinicians determine which active length is required for the applicator and which presetting should be selected to achieve a defined coagulation volume size.

During the past few years, local in situ ablation procedures have become quite popular for the treatment of malignant liver tumors. Radiofrequency ablation (RFA), in particular, is a system that is frequently used for these patients (1-7). Usually, monopolar application systems are used. In this technique, the active electrode is inserted into the tumor. The electric circuit is closed by attaching a large-surface, cutaneous neutral electrode. Aside from causing tissue necrosis around the active electrode, the current also flows from its location through the patient to the neutral electrode. This can cause thermal tissue damage along the current’s path from the active zone to the neutral electrode (8, 9). Bipolar radiofrequency systems with both electrodes located on one applicator prevent these problems inherent to monopolar radiofrequency ablation.

Aside from the risk of thermal damage, the induction of sufficiently large coagulation volumes with a thermal safety corridor around the tumor is another basic problem of RFA. The problem occurs because heating the tissue also leads to its dehydration. Consequently, the tissue impedance increases, limiting the amount of current that can be introduced. The amount of power that accelerates or delays this process has not yet been studied. In the past, internally cooled applicators were used to reduce the problem of small lesion sizes (10, 11). This cooling process cooled the tissue close to the active electrode to delay tissue dehydration and the resulting increase in impedance. As a result, it became possible to achieve longer application times, to apply more current to the tissue and to achieve larger necroses (10-12).

Some clinical pilot studies were able to show that bipolar RFA with internal cooling can be conducted on patients in a safe and uncomplicated manner (13). What is still missing, however, is a thorough study of this system’s dosage/effect relationship so as to obtain an overview of the inducible lesion sizes with defined capacity parameters while preparing for RFA.

The goal of this experimental study was to research for the first time, in ex vivo beef livers, which powers are ideally suited for bipolar RFA with an internal cooling function to introduce the highest possible capacity into the tissue and thus achieve large lesion volumes.

**Materials and Methods**

**Radiofrequency ablation system/trial structure.** A bipolar RFA system (Celon AG und Medical Instruments, Teltow, Germany) that
uses a sinus-shaped high frequency current around 470 kHz, providing a maximum power of 250 W was used along with a bipolar, internally-cooled, rigid coagulation applicator (Celon Pro Surge, Celon AG) with a diameter of 1.8 mm and a shaft length of 15 cm. The bipolar applicator principle is based on the fact that both active electrodes are located on this applicator and separated by an isolator. The active lengths of the applicators varied. The tests were conducted with active lengths of 20, 30 and 40 mm. This coaxial electrode design allowed for a high frequency flow of current that started between the two ends closest to the isolator and then spread symmetrically around the electrodes. As a result, the tissue surrounding the electrodes was heated. The cooling fluid was pumped through a central tube to the tip of the applicator and flowed along the electrodes back to the proximal end of the applicator. A peristaltic pump with three pump rotators was used for all tests (Celon Aquaflo). The fluid delivery rate was preset at 30 mL/min per rotor for all tests. The cooling medium was demineralized water at a temperature of 20°C±5°C. All relevant parameters were recorded.

During the introduction of the high frequency current, the high frequency generator was controlled by an algorithm. The energy introduction was automatically interrupted for 2.5 seconds when tissue dehydration and the associated impedance increase set in, and reactivated once the tissue was sufficiently hydrated again. If an impedance of 500 Ω was reached during the application, the device automatically shut off.

Beef livers were used for this trial. The livers had a postmortem age of approx. 24 hours. The organs were procured from the meat wholesale market. Before starting the test, the livers were brought to a temperature of ca. 20°C±5°C by placing them in a water bath in a closed polyethylene bag. Immediately prior to each measurement, the liver was removed from the bag and placed on a plastic board. The positioning of the coagulation electrodes was chosen in such a manner that the uncoagulated liver tissue was evenly distributed around the electrodes. In addition, coagulation areas that had very few vessels were preferred.

**Application.** The application was automatically stopped by the device when the impedance increased to over 500 Ω. This was acoustically indicated through a beep. If the application duration exceeded 20 minutes, the device was turned off manually.

For each of the three examined applicator lengths (20, 30 and 40 mm), 5 measurements were taken with a current power of 10, 15, 20, 25, 30, 35, 40, 45, and 50 W. Each power was repeated 5 times in a rotation process. Preliminary tests with the active lengths 30 and 40 mm showed that a power of 10 W did not result in complete coagulation. Therefore, this power was not further researched for these applicator lengths.

The applicators were removed after each test and the lesion opened parallel to the applicator axis. To calculate the volume, a macroscopic measurement of the coagulation area was conducted. The color change from a grayish pink to dark red at the edge of the coagulation constituted the area to which coagulation was measured (Figure 7). To determine the volume, a ruler was used to measure the macroscopically visible diameter of the tissue change in an axial (Dax) and longitudinal direction (Dl). From this, the volumes of the thermally produced coagulation were calculated. The following formula was used to calculate the volume (V=ellipsoid: V=1/6 π (Pi) x Dax x Dl²). To draw a comparison, we also calculated the effectivity index (induced thermal lesion volume in cm³/10 kJ of applied energy) (14) of the mean values for the adjustments that generated the biggest volumes was calculated for each of the three applicator lengths.

**Statistical evaluation.** All measured parameters of the individual tests were loaded onto a database of the statistics program SPSS 11.5 for Windows 2000. For the descriptive evaluation, the mean group values and the standard deviations of the means were calculated. The tables show a summary of the results for each of the different applicator lengths. A chart illustrating the means and standard deviations of the parameters of the achieved coagulation volumes and the used current was generated.

**Results**

**Applicator length 20 mm.** Table I summarizes the determined parameters for the applicator with an active length of 20 mm in association with the power. The data show that it was only possible to introduce current to the tissue for a time period of 20 minutes, if the power was 10 W. The possible application time shortened as the power increased, because a tissue impedance of 500 Ω was reached. The longitudinal diameter of the coagulation necrosis for the 20 mm applicator was mainly influenced by the length of the active applicator and was not influenced by varying powers. The longest axial diameter of 24±2 mm was reached with a power of 15 W. The maximum possible volume of 5,599±1,760 mm³ was also achieved with a power of 15 W. As the power increased, both the axial diameter as well as the inducible volume gradually decreased (Figure 1). The optimal power for the active applicator length 20 mm was, accordingly, 15 W. This was also confirmed by the fact that the maximum introduced energy was 15±3 kJ (Figure 2).

**Applicator length 30 mm.** Table II summarizes the determined parameters for the applicator with an active length of 30 mm in association with the power. Since it was not possible to achieve complete coagulation with a power of 10 W, this power was not investigated further. It was possible to use the active applicator length of 30 mm up to a power of 30 W until...
the test was manually stopped after 20 minutes. Only when using a higher power did the possible application periods decrease. The tests conducted with the 30 mm applicator also showed that the longitudinal diameter of the coagulation necrosis is determined by the active length of the applicator and that they were almost the same, regardless of the power used. The axial diameter of the coagulation necrosis was significantly influenced by the power. The maximum of 28±1 mm was reached with a power of 20 W. Accordingly, also the maximum volume of 14,538±1,224 mm³ was reached with a capacity of 20 W. As the capacity increased, both the axial diameter as well as the coagulation volume continuously decreased (Figure 3). The optimal power for the active applicator length 30 mm was, accordingly, 20 W. This was also confirmed by the fact that the maximum introduced energy was 24±1 kJ (Figure 4).

Applicator length 40 mm. Table III summarizes the determined parameters for the applicator with an active length of 40 mm in association with the preset power. It was possible to continuously apply powers of 15 and 20 W until the test was manually stopped after 20 minutes. Even though it was not possible, with regard to the 40 mm applicator, to observe a gradual shortening of the applicator time as the power increased, these tests also confirmed that the application time decreased as the power increased. The longitudinal diameter of the coagulation necrosis for the 40 mm applicator was also influenced by the length of the active applicator, not by the power. The axial diameter clearly depended on the power and reached its maximum of 30±0 mm at a capacity of 20 W. The maximum achievable coagulation volume of 20,562±896 mm³ was also reached at 20 W (Figure 5). The maximum of the applied power was around 20 and 25 W (24±0 and 24±2kJ) (Figure 6). The optimal power seems to be around 20 W, since in addition to achieving the largest axial diameter and volume, it was also possible to apply current continuously until the test was terminated manually.

Discussion

Currently, surgical resection is considered the curative ‘gold standard’ therapy for patients with primary or secondary malignant liver tumors. This procedure, associated with a significant morbidity, is only an option for 20-30% of all patients concerned (15-19). In recent years, so-called in situ ablation procedures used to destroy the tumor locally have become quite popular for the treatment of primary and secondary liver tumors.

In particular, RFA is a procedure commonly used for patients (1-7). The currently most frequently used monopolar application systems, however, have several potential disadvantages. The electric circuit in monopolar applications is closed through an active electrode in the tumor and a cutaneous skin electrode. This can lead to thermal damage as the current travels from the active zone to the neutral electrode. Aside from local cutaneous burns, capacitive leakage current can lead to thermal damage in other organs (e.g. the intestines). An additional problem is insufficient lesion size. Larger tumors cannot be reached with a sufficient safety distance (6).

Bipolar ablation systems offer an alternative to the monopolar RFA systems. Both active electrodes of these bipolar applicators are located on one applicator and separated by an isolator. Therefore, the current only flows between the two active electrodes and only heats the directly surrounding tissue. Lee et al. have already conducted ex vivo tests with this system by using beef livers and were able to show that the bipolar technology can achieve significantly bigger lesion sizes than the monopolar technique (20, 21).

A big problem of RFA is, however, the lack of predictability of the inducible lesion size. This, however, is a significant parameter, since it is important to know before starting the treatment which power should be introduced to induce a sufficiently large lesion that also incorporates the entire tumor and a safety corridor. The volume of the created

### Table II. Parameters for active applicator with a length of 30 mm.

<table>
<thead>
<tr>
<th>Initial power (W)</th>
<th>Breaking time (s)</th>
<th>Introduced energy (kJ)</th>
<th>Axial diameter (mm)</th>
<th>Longitudinal diameter (mm)</th>
<th>Volume (mm³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>1200±0</td>
<td>18±0</td>
<td>25±2</td>
<td>32±1</td>
<td>10549±1960</td>
</tr>
<tr>
<td>20</td>
<td>1200±0</td>
<td>24±1</td>
<td>28±1</td>
<td>35±1</td>
<td>14538±1224</td>
</tr>
<tr>
<td>25</td>
<td>1200±0</td>
<td>20±4</td>
<td>23±4</td>
<td>36±1</td>
<td>10525±3982</td>
</tr>
<tr>
<td>30</td>
<td>1200±0</td>
<td>17±1</td>
<td>21±2</td>
<td>35±1</td>
<td>8390±2340</td>
</tr>
<tr>
<td>35</td>
<td>1129±126</td>
<td>16±2</td>
<td>19±1</td>
<td>34±1</td>
<td>6611±593</td>
</tr>
<tr>
<td>40</td>
<td>267±39</td>
<td>8±2</td>
<td>18±2</td>
<td>35±2</td>
<td>6294±1467</td>
</tr>
<tr>
<td>45</td>
<td>214±84</td>
<td>8±2</td>
<td>18±2</td>
<td>36±1</td>
<td>6524±2035</td>
</tr>
<tr>
<td>50</td>
<td>179±44</td>
<td>7±2</td>
<td>18±4</td>
<td>35±0</td>
<td>6445±2646</td>
</tr>
</tbody>
</table>

### Table III. Parameters for active applicator with a length of 40 mm.

<table>
<thead>
<tr>
<th>Initial power (W)</th>
<th>Breaking time (s)</th>
<th>Introduced energy (kJ)</th>
<th>Axial diameter (mm)</th>
<th>Longitudinal diameter (mm)</th>
<th>Volume (mm³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>1200±0</td>
<td>19±1</td>
<td>26±0</td>
<td>41±0</td>
<td>14512±0</td>
</tr>
<tr>
<td>20</td>
<td>1200±0</td>
<td>24±0</td>
<td>30±0</td>
<td>45±0</td>
<td>20562±1986</td>
</tr>
<tr>
<td>25</td>
<td>1164±80</td>
<td>24±2</td>
<td>28±1</td>
<td>45±0</td>
<td>19220±1988</td>
</tr>
<tr>
<td>30</td>
<td>1085±145</td>
<td>21±2</td>
<td>27±3</td>
<td>46±0</td>
<td>1782±2374</td>
</tr>
<tr>
<td>35</td>
<td>529±395</td>
<td>12±3</td>
<td>21±2</td>
<td>44±0</td>
<td>10450±1665</td>
</tr>
<tr>
<td>40</td>
<td>18±8184</td>
<td>16±7</td>
<td>22±5</td>
<td>47±2</td>
<td>12855±6382</td>
</tr>
<tr>
<td>45</td>
<td>663±493</td>
<td>15±6</td>
<td>21±2</td>
<td>45±2</td>
<td>10885±2200</td>
</tr>
<tr>
<td>50</td>
<td>368±90</td>
<td>15±3</td>
<td>24±3</td>
<td>45±0</td>
<td>1431±3874</td>
</tr>
</tbody>
</table>
Figure 1. Coagulation volume depending on initial power for active applicator 20 mm.

Figure 2. Introduced energy depending on initial power for active applicator 20 mm.

Figure 3. Coagulation volume depending on initial power for active applicator 30 mm.

Figure 4. Introduced energy depending on initial power for active applicator 30 mm.

Figure 5. Coagulation volume depending on initial power for active applicator 40 mm.

Figure 6. Introduced energy depending on initial power for active applicator 40 mm.
lesion is calculated by using the axial and longitudinal diameter and depends on the amount of current introduced to the tissue.

Therefore, it is important to have information about the parameters needed to apply the optimum amount of current to the tissue and to thereby reach the highest possible coagulation volumes.

This is the first study that systematically examines which power parameters are the best to produce the highest possible coagulation volumes.

The best power for the 20 mm applicator was 15 W, and for both the 30 mm and 40 mm applicator also 20 W. These powers achieved the largest axial diameters of the coagulation necroses and therefore also the largest coagulation volumes. Higher powers reduced the axial coagulation diameters of all researched applicators. The longitudinal diameter of the coagulation necrosis did not change with varying powers, since the length of the coagulation necrosis was predominantly determined by the length of the active applicator. The coagulation sizes were influenced by the power that was used. The higher the current applied to the tissue, the higher the coagulation volumes.

As expected, depending on the length of used applicator the effectivity index was 3.73 cm$^3$/10 kJ for the 20 mm applicator, 6.05 cm$^3$/10 kJ for the 30 mm applicator and 8.56 cm$^3$/10 kJ for the 40 mm applicator. This means that the 40 mm applicator was able to induce the largest lesion volume under same power input in comparison to the other applicators and therefore had the highest efficacy.

Another parameter impacting the coagulation volumes and the introduced current was the duration of the application. In this study, an application system was used that was subject to a control algorithm which automatically stopped the current going to the tissue for a short period of time when the impedance increased and resumed its operation after 2.5 seconds. When the impedance exceeded 500 Ω, the device turned itself off completely. Studies of the application times showed that the device turned itself off relatively quickly when a high amount of current was applied, despite the control algorithm. Very short application times were partly related to the active length of the applicator. The higher the power, the lower the possible ablation time and thus also the current power into the tissue during the ablation. This led to smaller coagulation volumes since the tissue dehydrated faster, leading to a carbonization of the tissue.

Due to the design of the study that had been planned as an ex vivo trial with beef livers and an initial tissue temperature of 20°C, the achieved coagulation sizes and volumes were small, as expected, and cannot be compared to other published coagulation sizes and volumes. The displayed results only serve as a comparison to the different applicator lengths studied in this trial and the researched current capacities.

The goal of this study was to evaluate the dosage/effect relationship of a bipolar application system to the radio frequency ablation of liver metastases. This ablation system makes it possible to avoid complications such as cutaneous burns or capacitive leakage current, inherent in monopolar ablation systems. It is therefore important to know which power settings can achieve the largest axial coagulation necrosis diameter and which power leads to a decrease of the coagulation volume. In addition, it is important to be able to predict which power can achieve the largest coagulation volume. In order to avoid tissue impedance from increasing power too quickly, it is also important to know which power only allows for a brief application time due to a rapid impedance increase. This ex vivo research on beef livers with an initial tissue temperature of 20°C showed that the optimal power, depending on the applicator length, is between 15 and 20 W. These powers achieved the largest axial diameters of the coagulation necroses, and therefore also the largest coagulation volumes. Higher powers led to smaller axial diameters and a shorter ablation times due to a quick impedance increase. In addition, these power parameters allowed for a maximum power into the tissue.

The results of this study help clinicians determine within the context of individualized treatment plans which active length is required for the applicator and which presetting should be selected to achieve a defined coagulation volume size.
References


