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An electrode array that minimizes blood loss for radiofrequency-assisted hepatic resection

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Received 2 November 2006; received in revised form 20 February 2007; accepted 4 May 2007

Abstract

Hepatic resection is currently the standard treatment for liver cancer. During hepatic resection part of the liver containing the tumor is surgically removed. This type of surgery is accompanied by high blood loss of ~0.6–1.35 L. Blood loss is associated with increased complication rates, prolonged hospital stay, and reduced patient survival, especially when transfusion is required. Other researchers have suggested using radiofrequency (rf) or microwave ablation to coagulate a tissue slice before resection to reduce blood loss, but conventional devices typically take several hours. We developed a device consisting of a linear array of blade-shaped, 1 cm wide radiofrequency (rf) electrodes 1.5 cm apart. Bipolar rf power is applied between pairs of adjacent electrodes, leading to high tissue temperatures between the electrodes that promote coagulation of large vessels (>3 mm) in the resection plane. Rapid switching of applied power between pairs of adjacent electrodes allows simultaneous heating and coagulation of the entire resection plane within 3–6 min. In seven *in vivo* trials in a porcine model, resection along a plane pre-coagulated with the device resulted in little (<20 mL) to no blood loss, while coagulating all vessels (up to 4.5 mm diameter in this study). Average treatment time (from placement of the device to transection) was 6.8 ± 0.5 min when four electrodes were used, and 11.3 ± 1.2 min when 5–7 electrodes were used. This device may reduce blood loss related morbidity during resection and reduce treatment time by coagulating all vessels in the resection plane.

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Keywords: Resection; Blood loss; Radiofrequency; Ablation; Liver; Coagulation; Electrode array

1. Introduction

Despite recent advancements in the efficacy of tumor ablation therapies, surgical resection remains the gold standard for treatment of both primary and metastatic liver cancer [1,2]. In a liver resection, either one of the two liver lobes is surgically removed (anatomical resection), or part of a single lobe is removed (partial resection), depending on tumor location(s). Hepatic resections are associated with a high

rate of intraoperative bleeding, with an average blood loss between 600 and 1350 mL [3,4]. As a result, 28–55% of patients undergoing a resection require blood transfusion [5,6]. Several studies have shown an adverse correlation between blood loss and complication rate, patient survival, and length of hospitalization [3,6,7]. Similarly, hepatic resections that require blood transfusion have higher complication rates and decreased long-term patient survival rates [5]. The further reduction of intraoperative blood loss (and therefore, a reduction in the number of transfusions) is thus advocated by many surgeons.

Several studies have suggested the use of radiofrequency (rf) or microwave ablation in conjunction with hepatic

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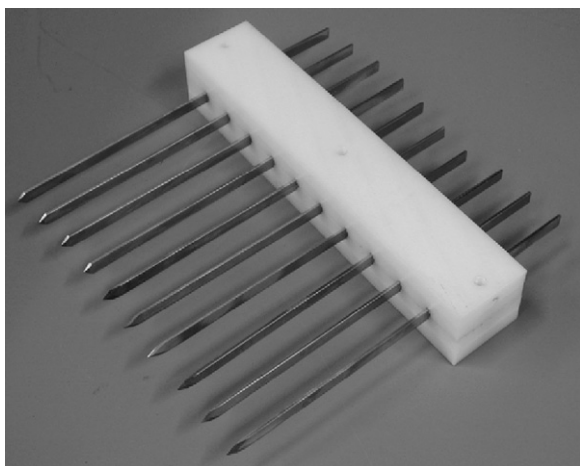


Fig. 1. The array of blade electrodes (shown with a full complement of 10 blades). The Teflon block ensures that the spacing between the blades is uniform, and maintains parallel alignment of all blades.

resection [8–11]. In this technique, a plane of tissue is coagulated by sequential applications of microwave or radiofrequency energy, using conventional ablation electrodes. Resections performed after thermal coagulation of the resection plane in this fashion exhibit a marked decrease in mean blood loss; one study employing a rf-assisted technique reported a mean blood loss of just 30 mL during partial resections [10]. Current limitations associated with these methods are the large number of sequential ablations required to precoagulate the resection plane, and the necessity to individually ligate all vessels larger than ~ 3 mm. Recently, two specialized devices have become commercially available for rf-assisted liver resection, the Tissuelink Floating Ball device (Tissuelink Medical, Dover, NH) and the Habib 4x device (Rita Medical Systems, Fremont, CA). However, the former device is not capable of coagulating all blood vessels in the resection plane (even with partial vascular occlusion) [12], while the Habib 4x requires a large number of sequential applications, resulting in long treatment times [13].

Our device applies rf energy in the bipolar mode to adjacent pairs of parallel blade-shaped electrodes in a linear array (Fig. 1). Rapid switching of the applied rf energy between single electrode pairs enables simultaneous thermal coagulation of the entire resection plane. We have previously presented preliminary *in vivo* results using an earlier prototype of this device demonstrating coagulation of a 1.5 cm thick plane of liver tissue in 3–6 min [14], which is significantly less time than other rf assisted resection methods. The device was also previously used successfully in a series of porcine *in vivo* partial nephrectomies [15]. In additional preliminary *in vivo* experiments in the porcine liver, however, we found that not all blood vessels were fully coagulated by the earlier prototype device in all trials. Therefore, we refined the device's power delivery algorithm, and present further *in vivo* results in this study demonstrating the ability of the device to fully coagulate all blood vessels present in the resection plane of the porcine liver, including quantitative data regard-

ing number and diameter of blood vessels from pretreatment intraoperative ultrasound scanning.

2. Materials and methods

2.1. Device description

Fig. 1 shows the electrode array used in this study. The physical dimensions of the blade electrodes and holder were derived from the dimensions of a typical human resection plane, which is 9 cm deep (max) by 15 cm long. The electrode array consists of 10 parallel stainless steel blades held in place by a Teflon holder. Each blade has a sharpened tip to reduce the force required for insertion into the tissue. The blades measure 1 mm by 10 mm and are each 15 cm long. The blade width (10 mm) was designed so that the plane of coagulation would be approximately 2 cm wide. This particular width was selected to allow enough coagulated tissue for effective transection without damaging excess tissue. The blade holder measures 2.5 cm by 3 cm by 16.5 cm. It consists of two blocks of machined Teflon that are held together by three set screws, which allow the user to adjust the clamping force as desired. The spacing between the blades is 1.5 cm, which was derived from computer models [14].

2.2. Experimental setup

We applied rf power to the blade electrodes in a bipolar mode. In this mode, a voltage from the rf generator is applied between two adjacent electrodes, resulting in current flow between them and subsequent heating of the tissue in the region between the electrodes due to ionic friction. This differs from the traditional monopolar mode of rf power application, in which current flows from an active electrode in the tissue to a large dispersive electrode located on the skin (thigh or back) some distance away from the ablation site. In addition, power application is rapidly switched between adjacent electrode pairs in a repeating sequential fashion with a fixed switching period of 150 ms (see example in Fig. 3).

Fig. 2 shows a block diagram of the system used in this experiment. We used a PDX 500 (Advanced Energy, Fort Collins, CO, USA) rf generator that can supply up to 500 W of

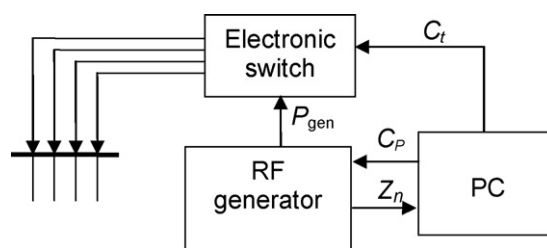


Fig. 2. Prototype system: an electronic switch relays power provided by a commercial rf generator to the currently active electrode pair. Generator output power is controlled by a software algorithm running on a PC, and is dependent on the number of currently active electrode pairs.

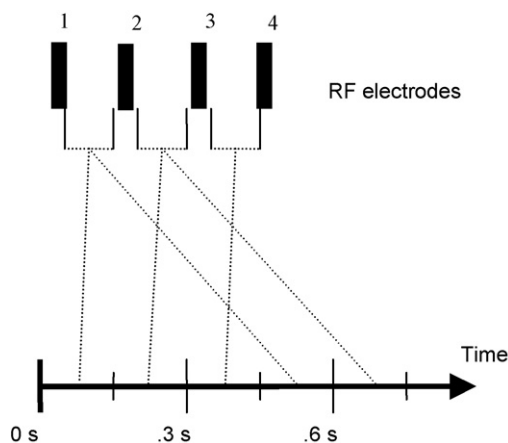


Fig. 3. Diagram of rapid switching scheme: in this example with four blades (i.e. three blade pairs), each pair of adjacent electrodes receives power for 150 ms every 450 ms. After the last pair is energized, power is reapplied to the first pair, and the cycle continues.

rf power at a frequency of 375 kHz. A Visual Basic program (Microsoft) running on a laptop PC controls the rf generator power P_{gen} by a control signal C_P , and the time period t_n for each electrode pair n by signal C_t via an electronic switch. During each switching cycle, the rf generator power P_{gen} applied to each pair was calculated based on the desired average power for that pair P_n and the number of currently active pairs, N :

$$P_{\text{gen}} = P_n \times N \quad (1)$$

Since each electrode pair is active only $1/N$ th of the time, N times as much power has to be applied to obtain the desired average power for each pair. Initially, 10 W average power (P_n) was applied to each pair, and then the power for each pair was increased stepwise by 2 W every 8 s. This initial value of P_n and the magnitude of the power increase were determined from preliminary *in vivo* experiments, with the goal of achieving temperatures near 100 °C in the target tissue in ~ 2 min.

The measured impedance for each electrode pair, Z_n , was calculated during each switching cycle and used to implement an impedance control algorithm similar to those used in commercial ablation systems (to prevent tissue charring and desiccation in the region near the electrodes). After 20 s, the program calculated an impedance threshold for each electrode pair, which is 130% of each pair's impedance value at that time (Fig. 6). Once Z_n for a particular pair reached its impedance threshold, that pair was left out of the switching cycle for 10 s (i.e. no power was applied to the pair). During this time, the applied rf power continued to switch between the other active pairs, unless Z_n for another pair also exceeded its impedance threshold (in which case it was also left out of the switching cycle for 10 s). After a pair that had reached its impedance threshold had been skipped for 10 s, it was reactivated in the power switching cycle with 30% lower power P_n (to deter further impedance rises for that pair).

2.3. *In vivo* experiments

Preapproval for animal experiments was obtained from the Institutional Animal Care and Use Committee, University of Wisconsin, Madison. A total of seven liver lobes were resected from two domestic swine (~ 55 – 60 kg) in this study. The animals were injected intramuscularly with the narcotic preanesthetic Telazol[®], anesthetized with inhaled halothane, and intubated via a tracheostomy. The abdominal wall was then incised to allow unencumbered access to the liver. At the conclusion of each experiment, the animals were euthanized by an intracardial injection of potassium chloride.

For each trial, between 4 and 7 blade electrodes were sequentially inserted along the desired resection plane, depending on lobe size. Intraoperative ultrasound (IOUS) was used before each trial to locate and measure all blood vessels in the resection plane that were greater than 2 mm in diameter. IOUS was also used during all electrode insertions to avoid puncturing blood vessels. A custom Teflon template was placed underneath the lobe to prevent puncture or thermal damage to other organs. Immediately prior to the insertion of the electrodes, hepatic inflow was occluded via the Pringle maneuver, in which the hepatic artery and portal vein were clamped. The total time of power application was dependent on the number of blades employed, since the electronic switch in our prototype device only had four channels allowing activation of four blades. Thus, for resection planes with four blades, power was applied for 3 min. For resection planes with five to seven blades, power was applied to the first four blades (three pairs) for 3 min, followed by the remaining blade pairs for 3 min, for a total power application time of 6 min.

After each trial was completed, the lobe was resected using a scalpel along the distal (in relation to blood flow) electrode edge. After transection, the device was carefully removed from the coagulated edge of the lobe. We then took photographs of each tissue slice using a digital camera and noted which blood vessels measured on IOUS before each trial were not coagulated. ImageJ software (NIH) was then used to determine the total coagulated area of each resection plane from the photographs.

3. Results

All seven lobes were successfully ablated and resected using our device. The coagulated slice was between 2 and 3 cm wide. A total of 19 vessels between 2.0 and 4.5 mm (median 2.8 mm) in diameter were found in the seven resection planes using IOUS (Table 1). After transection, none of the vessels exhibited bleeding that required ligation. The total blood loss after transection of each plane was estimated to be <20 mL by the attending surgeon (APO), and was 0 mL in the majority of cases ($n=4$) (Fig. 5).

Fig. 4 shows a representative lobe during one of the procedures, and Fig. 5 shows another lobe immediately after

Table 1
Vessels coagulated during the seven trials, sorted by diameter

Pig #	2	2	2	1	1	2	1	1	1	1	1	2	1	2	2	2	2	2	2
Lobe #	5	7	7	2	3	4	1	1	3	3	2	5	1	6	4	6	6	7	5
Vessel diameter (mm)	4.5	4.0	4.0	3.9	3.4	3.4	3.0	3.0	2.8	2.8	2.5	2.5	2.4	2.4	2.3	2.3	2.1	2.1	2.0

Each vessel was measured and recorded using IOUS prior to each trial. For vessel diameters, we report the smallest measured diameter to account for possible non-orthogonality of the vessel to the imaging plane. Lobes 1–3 were from pig #1 and lobes 4–7 were from pig #2

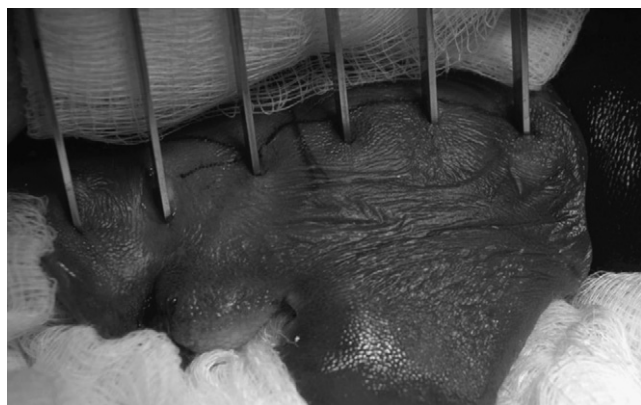


Fig. 4. A representative lobe during rf power application. Lines were drawn on the surface of the liver to indicate the desired resection plane and the location of large vessels.

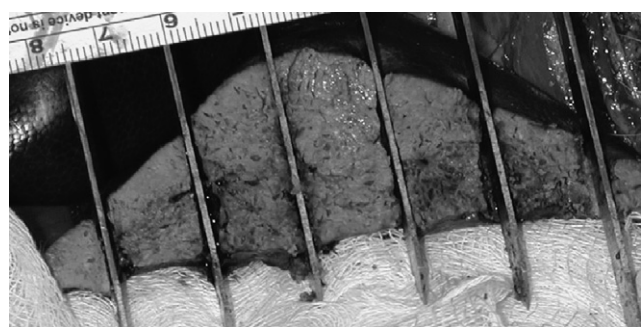


Fig. 5. In this particular trial with six blades, no bleeding occurred after the tissue was sliced. The area of the coagulated surface in this trial was 15.0 cm².

transection. In addition to the complete coagulation of all vessels, no bleeding or bile leaks from the liver parenchyma were observed in the regions between the blades in any of the trials. The average time required for each trial and the average area of the coagulated surface for each trial are summarized in Table 2. As previously noted, the time required for the five to seven blade trials was longer because they required two separate 3 min power applications (6 min total).

Fig. 6 shows the impedance between and power delivered to a representative pair of electrodes during the course of one

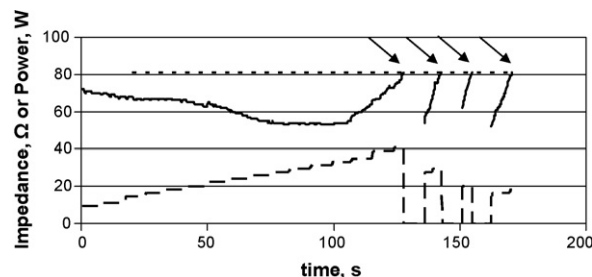


Fig. 6. The power (dashed line) applied to an electrode pair is increased every 8 s until the measured impedance (solid line) rises above (arrows) the impedance threshold (dotted line), which is calculated 20 s after the start of the trial (as 130% of the impedance value at that time).

of the trials. The average power delivered to each pair during all trials was 18.3 ± 4.1 W and the average maximum power delivered during each trial was 46.0 ± 5.4 W.

4. Discussion

The use of rf precoagulation to reduce blood loss during hepatic resections has become increasingly widespread with two specialized devices now commercially available. Although the reduction in mean blood loss reported by previous studies is encouraging, the techniques and devices employed require several individual applications of rf or microwave energy, with correspondingly long procedural times. In addition, standard rf devices are not able to fully coagulate vessels larger than 3 mm in diameter in the resection plane. To address these limitations, we developed a device capable of thermally coagulating a typical hepatic resection plane in 3–6 min, including full coagulation of all blood vessels [14].

The most straightforward method for precoagulating a plane of tissue with an electrode array would involve the insertion of the array along the desired plane and subsequent application of rf energy in the monopolar mode to all electrodes simultaneously. This method has several disadvantages. First, commercial clinical rf generators are incapable of supplying enough power to heat the tissue around a large

Table 2
Average procedural time and coagulated surface area for the seven trials

No. blades	No. trials	Procedural time (min)	Area (cm ²)	Coagulation rate (cm ² /min)
4	4	6.8 ± 0.5	6.0 ± 1.4	0.90 ± 0.10
5–7	3	11.3 ± 1.2	13.5 ± 1.3	1.19 ± 0.24

The device fully coagulated 0.90 and 1.19 cm²/min in the four blade and five to seven blade procedures, respectively.

number of electrodes simultaneously. More importantly, prior modeling results have shown that when multiple electrodes are placed in tissue in close proximity to each other and simultaneously energized, little current flows in the region between the electrodes, and thus little heating occurs there [14,16].

For these reasons, we used the bipolar mode of rf power application in our device. This mode has two advantages for this device. First, no ground pads are required since at any time, the rf power ground is connected to one of the electrodes in the tissue, not an electrode on the skin. Ground pad skin burns are already a common complication of clinical monopolar rf ablations (which use a maximum power of 200–250 W), and since rapid coagulation of a large tissue slice requires much higher power (up to ~400 W), skin burns below ground pads would be likely if the monopolar mode were used with this device. Secondly, previous computer modeling experiments have shown that bipolar ablation produces higher, more uniform temperatures between adjacent electrodes than monopolar ablation [14,17].

Initially, we created computer models where we applied bipolar power to all of the electrodes in the array simultaneously; i.e. the electrodes were all energized simultaneously with alternating polarity (+ polarity, – polarity, +, –, etc.). However, the resulting temperature profile was not uniform between each electrode pair. In addition, this method did not allow independent power regulation between each pair to account for variations in tissue thickness and the presence or absence of heat-sinking blood vessels.

As a result, we investigated the application of bipolar rf power to a single pair of electrodes at a time, rapidly switching the energy delivery to each pair of electrodes in the array in a repeating sequence (Fig. 3). This technique takes advantage of the relatively slow time constant of conductive heat transfer in tissue (typically in the range of seconds). If power application is switched sufficiently quickly between electrode pairs, little heat is transferred away from the target tissue during the time when each pair is not energized, and the whole tissue plane can be virtually heated simultaneously. This rapid switching technique has previously been used with monopolar rf energy to create large ablation zones in *ex vivo* tissue [18].

Computer models of this switched bipolar power application algorithm in combination with blade shaped electrodes showed excellent concentration of current density between the electrodes and correspondingly high, as well as uniform, temperatures (see Fig. 7) [14]. Additionally, since power is delivered to only a single electrode pair at a time, the applied power can be controlled individually for each pair, allowing more uniform heating of the entire tissue plane. In our prior study, power was switched between each pair every 600 ms [14]. This time period did not prove to be sufficient to fully coagulate all blood vessels in the resection plane, so in this study we modified the control software to switch the power between the electrode pairs every 150 ms. Since we were able to completely coagulate all blood vessels (up to 4.5 mm diameter) in this study, we believe that this switching

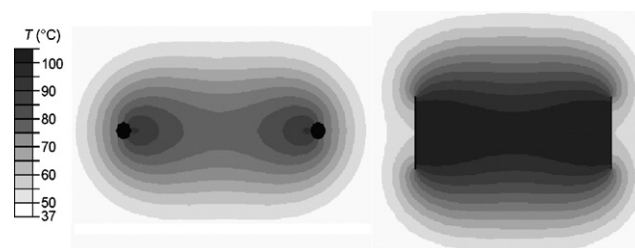


Fig. 7. Temperature distribution after 3 min ablation in bipolar mode between needle electrodes (left), and blade electrodes (right). Blade electrodes produce significantly higher, and more uniform temperatures. Reproduced with permission from [14].

period is sufficiently short for the device to be effective in this regard. However, as the number of active electrode pairs is increased (i.e. more than our current prototype's three pairs), the amount of time that a given pair will not have power applied to it will increase correspondingly, and the switching time period may need to be reduced to compensate.

To determine the ideal electrode design and spacing for this device, we relied on our previously reported computer modeling results demonstrating that bipolar rf ablation using rectangular, blade-shaped, electrodes produced significantly higher temperatures in the region between adjacent electrodes than standard needle electrodes [14]. Additionally, further modeling demonstrated that a 1.5 cm blade separation creates a more uniform ablation zone width than a 2 cm blade separation. The same models suggested that a 1.5 cm blade separation creates a similar ablation zone width as a 1 cm blade separation. Both of these modeling results were verified in preliminary *ex vivo* and *in vivo* experiments. We used the 1.5 cm separation in this study instead of 1 cm because it required fewer electrodes to span a given resection plane (e.g. for a 6 cm long resection plane, five electrodes would be required at 1.5 cm spacing, or seven electrodes with 1 cm spacing), resulting in less tissue trauma during electrode insertion.

We have in a previous study used an earlier prototype to perform partial kidney resection [15]. In the current study we applied the device to liver resection in a porcine model. We were able to provide a coagulation plane within 3 min for resection planes that required four electrodes or less, and within 6 min (2×3 min) if more than four electrodes were required. This is due to a limitation of the current prototype that allows switching between a maximum of four electrodes; a future design may circumvent this limitation. In addition, we were able to coagulate all blood vessels in all 7 trials in this study, which were up to 4.5 mm in diameter as measured by IOUS. This is close to the maximum blood vessel diameter expected in human liver resection (~5 mm). We used liver inflow occlusion during this study to ensure coagulation of all vessels, but currently have no data on performance of our device when occlusion is omitted.

While in initial studies tumor ablation electrodes were used to sequentially coagulate small tissue volumes along the hepatic resection plane [8–11], recently two commer-

cial devices have become available for this purpose. The Tissuelink device (Tissuelink Medical, Dover, NH) uses a small spherical electrode that is assisted by saline infusion; the electrode is manually moved along the resection plane to dissect tissue while coagulating [19]. This is a lengthy procedure and does not allow coagulation of vessels larger than 3 mm in diameter even when occlusion is used [12]. A second device, the Habib 4x (Rita Medical Systems, Fremont, CA) uses two pairs of needle electrodes with 1 cm spacing to precoagulate the resection plane with multiple sequential ablations—typically with blood inflow occlusion. While there is currently no extensive data available on performance of this device, the large number of required applications to create a coagulation plane results in significantly lengthier procedures than the device described in this study [13].

5. Conclusion

We developed a device that rapidly coagulated the hepatic resection plane in an animal model. Our prototype system was able to coagulate a 2–3 cm thick slice of tissue that spanned the length of the resection plane in 3–6 min, while successfully coagulating all blood vessels (up to 4.5 mm diameter) in the plane. This device shows promise in the effort to reduce blood loss and operating time during liver and kidney resections.

Acknowledgements

This work was conducted in a facility constructed with support from the National Institutes of Health, Grant Number C06 RR018823 from the Extramural Research Facilities Program of the National Center for Research Resources.

Conflict of interest statement

The authors founded 'Medical Engineering Innovations, LLC' to continue development of this device.

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