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Published online before print
10.1148/radiol.2342031122
Radiology 2005; 234:563–568

Abbreviation:
RF = radiofrequency

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Authors stated no financial relationship to disclose.

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Guarantor of integrity of entire study, D.H.; study concepts, D.H., F.T.L., J.G.W.; study design, D.H.; literature research, D.H., F.T.L.; experimental studies, D.H., D.J.S., L.A.S.; data acquisition, D.H., D.J.S., L.A.S.; data analysis/interpretation, D.H., J.P.F.; statistical analysis, J.P.F.; manuscript preparation, D.H., F.T.L., D.J.S.; manuscript definition of intellectual content and final version approval, D.H.; manuscript editing and revision/review, all authors

Large-Volume Radiofrequency Ablation of ex Vivo Bovine Liver with Multiple Cooled Cluster Electrodes[1]

Three methods of creating large thermal lesions with cool-tip cluster electrodes were compared. Three cluster electrodes were arranged 4 cm apart in a triangular array. Eight lesions were created ex vivo in fresh bovine liver (from a butcher) with each method: sequential ablation (three electrodes, 12 minutes each); simultaneous activation of electrodes (12 minutes); and rapid switching of power between electrodes (12 minutes), for which an electronic computer-controlled switch was developed. For sequential, rapid switching, and simultaneous methods, lesion volumes were 137.5 cm^3 ± 22.2, 116.4 cm^3 ± 15.2, and 22.3 cm^3 ± 6.4 ($P < .05$), respectively, and final temperatures at lesion center were 80°C ± 5, 97°C ± 8, and 41°C ± 3 ($P < .001$), respectively. Because of electrical interference between electrodes, simultaneous method led to little heating at the center between the electrodes and created small discontinuous lesions. Rapid switching created large round lesions by employing multiple electrodes concurrently, which substantially reduced treatment time and resulted in more effective heating between electrodes.

Radiofrequency (RF) ablation is widely used as a minimally invasive heat-based method to focally ablate cancer. It is currently used primarily for treatment of primary and metastatic liver cancer (1), but it is increasingly being employed to ablate benign and malignant tumors of the kidney, lung, bone, and adrenal gland (2–8). RF ablation can be applied percutaneously, laparoscopically, or through small incisions (9–11). However, current RF devices are limited to single-electrode ablations or multiple overlapping sequential ablations.

Multiple-electrode ablation can be performed with both cryoablation and microwave ablation (12,13). The need for multiple electrodes is particularly important when treating large or asymmetrically shaped tumors, tumors near blood vessels that may protect tumor tissue from heating by acting as "heat sinks" (14), and tumors near structures that are prone to damage by heating (gallbladder, diaphragm, colon, stomach).

The purpose of this study was to compare three methods of creating large thermal lesions by using three cool-tip cluster electrodes (15). It was our hypothesis that rapid switching between electrodes would provide unique advantages that may decrease treatment time and increase the effectiveness of RF ablation when applied in the clinical setting.

Materials and Methods

The three methods included *(a)* conventional sequential ablation, in which a large area of necrosis is created one burn at a time, currently the only method that is possible with commercially available RF devices, *(b)* simultaneous activation (16), in which power is applied simultaneously to all three electrodes, and *(c)* rapid switching between electrodes, a method based on switching power application between electrodes, so that each electrode acts as an electrically independent entity (17,18).

Figure 1. Three cool-tip cluster electrodes with template.

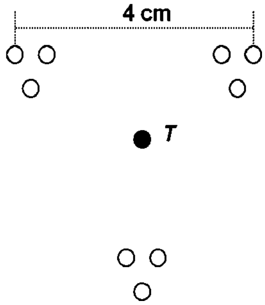

Figure 2. Diagram shows triangular array of cluster electrodes, with 4 cm distance between electrodes and a thermocouple *(T)* in the center.

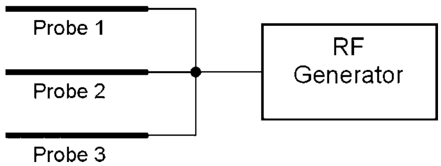

Figure 3. Diagram of setup for simultaneous method, in which power is applied simultaneously to all three electrodes. A custom-designed cable was used to split power between three cluster electrodes.

Computer Models

A computer simulation of all three multiple-electrode methods was performed, in which we calculated electric current density in the tissue. The electric current density determines where in the tissue the electric energy is converted to heat. We created two-dimensional models of three cool-tip cluster electrodes arranged 4 cm apart in a triangular array (Fig 2). We employed the finite element method (19), a computational method for solving differential equations, to calculate the electric current density for two methods of power application: *(a)* applying power simultaneously to all three cluster electrodes (simultaneous method) and *(b)* rapidly switching power between three cluster electrodes (rapid switching method). We used software (MATLAB; MathWorks, Natick, Mass) and a workstation (SUN Blade 1000; Sun Microsystems, Santa Clara, Calif) to create the geometry of the two-dimensional model and to solve the electrical problem. All computer simulations were performed by D.H., who is a biomedical engineer.

Ex Vivo Experiments

Experimental studies were designed by D.H., J.G.W., F.T.L., and D.M.M. Fresh bovine liver was acquired from a local butcher and was immersed in saline. The tissue was allowed to warm to room temperature (approximately 25°C) before the experiments were conducted. For each experiment, a separate piece of liver was used; the size of the piece was always at least 20 × 20 × 10 cm. Three cool-tip cluster electrodes (Cool-Tip; Radionics, Burlington, Mass) with an exposed electrode length of 2.5 cm were inserted into the liver 4 cm apart in a triangular configuration by using a Plexiglas template (Figs 1, 2). A thermal sensor (Physitemp, Clifton, NJ) was inserted into 18-gauge hypothermic needles and through the template into the tissue at the center of the triangle of cluster electrodes. Aluminum foil was placed in the saline bath and used as a dispersive electrode. All thermal lesions were created by using a 200-W generator, and all electrodes were cooled with chilled distilled water. A total of 24 thermal lesions were created in a randomized fashion by using three different methods: conventional sequential ablation ($n = 8$), simultaneous activation, in which power was divided between all three cluster electrodes ($n = 8$), and rapid switching ($n = 8$). For all experiments, the generator was set to maximum power. Ex vivo experiments were performed in collaboration by two biomedical engineers (D.H., D.J.S.) and a veterinary technician (L.A.S.).

Sequential Method

Sequential ablation is the only method that is currently available for clinical use. Three sessions were performed, 12 minutes in length each, in which one cluster electrode was energized individually in each session. We allowed for a 5-minute period between the individual power applications to mimic the clinical procedure; thus, the total time required to create each conglomerate sequential lesion was 46 minutes. The generator automatically controlled the power output with the standard impedance control algorithm. With this algorithm, power is turned off for 15 seconds whenever impedance increases 20 Ω above baseline levels (1). During this time, tissue cools, gas bubbles disperse, and impedance returns to baseline levels. Power is subsequently reapplied until impedance rises again (and so forth).

Simultaneous Method

For the simultaneous method, RF power was applied simultaneously to all three cluster electrodes for a period of 12 minutes (Fig 3). We removed insulation from the electrode connections, linked the three connections, and attached a cable between the electrodes and the RF generator. This way we split the RF energy between the three electrodes for this method. The generator automatically controlled the power output with the standard impedance control algorithm.

Rapid Switching Method

For the rapid switching method, RF energy was rapidly switched between the three cluster electrodes for a total of 12 minutes. The first cluster electrode was energized for 1 second, then the second cluster electrode was energized for 1 second, and so on (Fig 4); thus, each electrode was activated for 1 second every 3 seconds. It has been shown that this pulsing activation of two electrodes placed apart creates a thermal lesion the same size as that created by a single electrode with conventional single-electrode ablation (20). Thus we concluded no further pulsing time optimization was needed. If the impedance of one of the electrodes exceeded the threshold of 20% above baseline impedance, no power was applied to that particular electrode for 15 seconds (Fig 5). This algorithm is an extension of the standard impedance control algorithm currently used by Radionics for conventional RF ablation with a single electrode. We used a custom-designed electronic switch (21) that was controlled by a computer to switch the RF power between the electrodes. We implemented the impedance control algo-

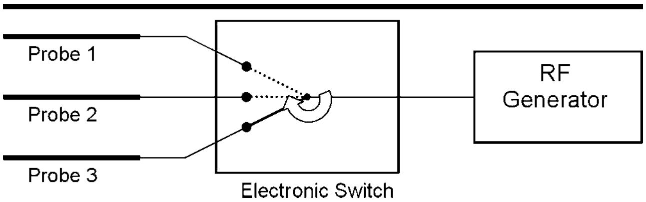

Figure 4. Diagram of setup for rapid switching method. A custom-designed electronic switch controlled by a computer was used in this method. The switch relays RF power to one of the three cluster electrodes at a time and switches in 1-second intervals between the electrodes.

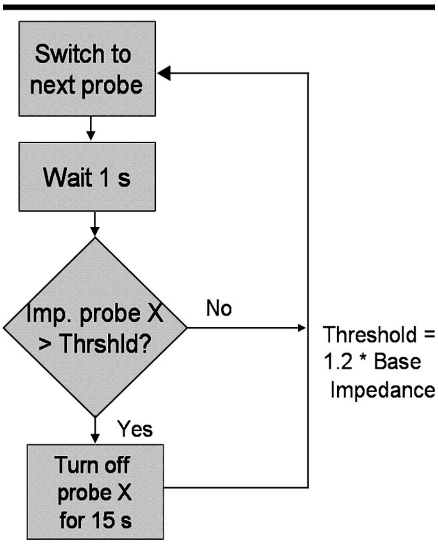

Figure 5. Flowchart of the impedance *(Imp.)*-control algorithm used in the rapid switching method.

rithm shown in Figure 5 in a program written in Visual Basic (version 6.0; Microsoft, Redmond, Wash). This program controlled the electronic switch according to the impedance control algorithm and acquired updated impedance for each electrode after switching to a new electrode. The computer was interfaced to the RF generator and to the electronic switch by means of a commercially available interface box (Module DI-700; DataQ Instruments, Akron, Ohio).

Evaluation

Temperatures were recorded at the center of all 24 thermal lesions at the end of each experiment, immediately after power was no longer being deposited into tissue. Tissue impedance was recorded 20 seconds after beginning power application for all 24 thermal lesions. After the ablation procedure was finished, the tissue was cut, perpendicular to the direction of electrode insertion, into 3–5-mm-thick slices. We then captured images of the slices with a digital camera and used software (ImageJ version 1.29; National Institutes of Health, available at *rsb.info.nih.gov/ij/*) to measure the area of the thermal lesions. The lesion boundaries of each slice were determined at visual inspection by one of the investigators (D.H., D.J.S., or L.A.S.) in blinded fashion. For the center slice of each thermal lesion, we measured cross-sectional minimum and maximum diameters and determined the isoperimetric quotient with the following formula: isoperimetric quotient = $4\pi A/P^2$, where A is the area and P is the perimeter (22). We then computed lesion volume by multiplying the lesion area of each slice by the slice thickness and integrating across all slices (D.H.) (23).

Statistical Analysis

We computed mean and standard deviation for lesion volume, center temperature, impedance, minimum and maximum diameters, short axis, and isoperimetric quotient. Diameters were measured orthogonally to the electrodes, and short axis was measured parallel to electrodes. For each variable, we compared means for simultaneous method versus rapid switching method, as well as for sequential method versus rapid switching method, by using two-sample *t* tests. All *t* tests were performed against a two-sided alternative, which does not specify the direction of the difference. We report *P* values from these tests and define statistical significance as indicated at *P* values less than .05. No formal power analysis for comparing group parameters was conducted in advance, as there was little a priori information on the key parameters in our pilot study. It was expected that the sample size of eight lesions per group would give adequate power for large group differences. We conducted a post hoc power analysis to confirm sufficient sample size. We used the software S-PLUS (version 3.4; MathSoft, Cambridge, Mass) for all statistical calculations. Statistical analysis was performed by J.P.F., who is a biostatistician.

Results

Computer Modeling

Figure 6 shows the electric current density profile for the simultaneous and rapid switching methods. The simultaneous method resulted in preferential heating directed radially outward from the array of cluster electrodes, while the rapid switching method heated uniformly around each cluster. For the rapid switching method, we showed the average current density over one switching cycle. However, recall that this model computes only current density and not temperature.

Ex Vivo Studies

Figure 7 shows cross sections of typical thermal lesions created with each of the three methods. The Table summarizes the lesion volumes, center temperatures, impedance, minimum and maximum diameters, short axis, and isoperimetric quotient (a value of 1 indicates a perfectly circular thermal lesion) for each method. Since the simultaneous thermal lesions are discontinuous, we did not report the minimum and maximum diameters or the isoperimetric quotient for these lesions.

The impedance for the simultaneous method was significantly lower compared with that of the other two methods ($P < .001$). Since all three electrodes were energized simultaneously, active surface area was increased compared with that when energizing a single electrode. The average lesion volume for the rapid switching method was 116.4 cm^3, which was more than five times larger than that for the simultaneous method ($P < .001$), for which average volume was 22.3 cm^3. The rapid switching method created thermal lesions that were 15% smaller in volume (116.4 cm^3 ± 15.2) than were those for the sequential method (137.5 cm^3 ± 22.2, $P = .047$), but there was no significant difference in minimum diameter ($P = .37$), maximum diameter ($P = .22$), and short axis ($P = .45$) between rapid switching and sequential methods. Significantly higher temperatures were found in the thermal center of the rapid switching lesions (97°C ± 8) when compared with lesions from the sequential method (80°C ± 5, $P < .001$) and the simultaneous method (41°C ± 3, $P < .001$). However, in contrast to the sequential method, we never observed an impedance rise in the rapid switching method, which suggests that rapid switching has not yet reached its potential for ablation, and a higher power generator would likely result in larger thermal lesions. The simultaneous method created much smaller discontinuous thermal lesions (22.3 cm^3 ± 6.4) than did the other two methods ($P < .001$). The short axis for the simultaneous method (34 mm ± 7) was significantly smaller ($P < .005$) than those for both the rapid switching method (46 mm ± 5) and the sequential method (48 mm ± 5). The rapid switching method created more circular lesions than did the sequential method ($P = .049$).

The post hoc power analysis confirmed that the sample size was sufficient to achieve 90% power to detect differences between impedance, volume, and temperature. For minimum and maximum diameter measurements, a sample size of 156 thermal lesions per group would be required to achieve 80% power with a two-sample *t* test and $\alpha = .05$, which is not feasible for the current study.

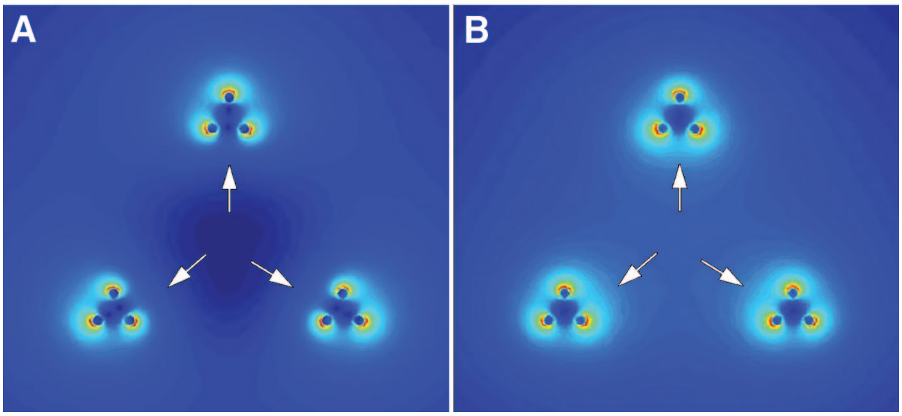

Figure 6. Computer model images of electric current density for, *A*, simultaneous method and, *B*, rapid switching method, averaged over one switching cycle. Electric current density determines where in the tissue RF energy is converted to heat. The simultaneous method results in little heating toward the center because of electrical interference between electrodes (arrows).

Discussion

Currently, RF units are limited to single-electrode use. Therefore, tumors that are beyond the treatment zone for a single electrode need to be treated by means of application of multiple ablations in a sequential fashion (24). Large tumors require increased treatment times, which in turn may lead to higher procedural and anesthetic risks. Local recurrence rates are also much higher when tumors larger than 3 cm are treated (10); this is likely due to the increased complexity of the procedure. Ultrasonography is the primary imaging modality for monitoring RF procedures but does not accurately show the area of thermal injury (9). With an increasing number of overlapping thermal lesions, the procedure becomes highly complex—the extent of the previous lesions can not be adequately imaged because of the creation of gas bubbles, tissue edema, distortion, and bleeding. Thus the spatial relationship between the current and previous electrode locations can be uncertain. As a result, the likelihood of an inadequate tumor margin rises and local recurrence rates increase when tumors larger than 3 cm are treated (10). Conversely, if multiple RF electrodes are placed prior to RF energy application, the spatial relationship between electrodes can be determined very precisely before tumor ablation has commenced.

Three different multiple-electrode RF methods have been investigated by different groups. The first method is bipolar RF ablation, in which current is applied to one electrode and flows toward a second electrode that acts as a ground (23,25–29). This method has the advantage of providing very high current densities (and therefore very high heating) between electrodes and does not require external grounding. However, this method is also limited by the requirement for precise electrode placement on each side of a targeted tumor, can only be performed with a maximum of two electrodes, and is dependent on electrode geometry (18,23). Applied power cannot be controlled independently for each electrode, which may result in nonuniform lesions (23). A second method applies the RF power to multiple electrodes simultaneously. This is currently the only commercially available method and forms the basis for the cool-tip cluster electrode used in our study. The simultaneous method is limited by electrical interference between the electrodes, which results in limited heating between the electrodes and unpredictable lesion shapes (18), since the amount of interference depends on electrode distance. Furthermore, similar to bipolar ablation, applied power cannot be controlled independently for each electrode (18).

Our group has investigated a different multiple-electrode RF ablation technique, one based on rapid switching between electrodes. Since power is applied to only a single electrode at a time, there is no electrical interference between electrodes. However, since the power is switched between electrodes more rapidly than tissue cooling can occur, from a thermal point of view the electrodes provide simultaneous tissue heating. Furthermore, the amount of applied energy can easily be adjusted for each electrode by regulating the duty cycle of each electrode. The rapid switching method has been previously applied in vivo for temperature-controlled ablation (17). In that experiment, it was demonstrated that by adjusting the duty cycle, each electrode could be kept at a desired target temperature. This results in the creation of multiple thermal lesions in virtually the same time that a single lesion can be created. The advantages of the rapid switching method compared with bipolar and simultaneous methods have been demonstrated in computer models of closely spaced four-prong electrodes (RITA Medical Systems, Sunnyvale, Calif) (18).

In our study, we have applied the rapid switching method to impedance-controlled ablation for the first time, to our knowledge, and compared it with the simultaneous method, as well as with the conventional method of creating lesions sequentially (sequential method). By using computer models, we have previously demonstrated reduced heating between multiple electrodes when power is applied simultaneously to all electrodes (18). This phenomenon is due to electrical interference between RF electrodes that are energized at the same voltage. Electric current flows between areas of different voltage (eg, the electrodes and the grounding pad). If three closely spaced electrodes are energized simultaneously, they are maintained at the same voltage because they are electrically con-

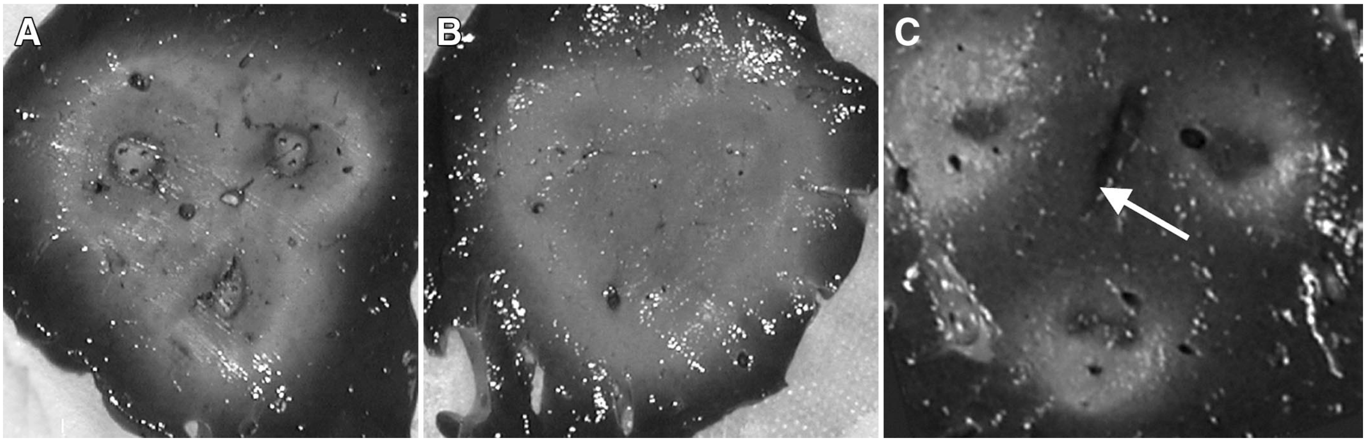

Figure 7. Cross sections of lesions created with, *A*, sequential, *B*, rapid switching, and, *C*, simultaneous methods. Simultaneous method creates small lesions because of electrical interference between electrodes, with little heating at the center (arrow).

Results of Three RF Ablation Methods

Parameter	Sequential (n = 8)	Rapid Switching (n = 8)	Simultaneous (n = 8)
Lesion volume (cm^3)	137.5 ± 22.2*	116.4 ± 15.2	22.3 ± 6.4†
Center temperature (°C)	80 ± 5†	97 ± 8	41 ± 3†
Impedance (Ω)	62 ± 6	60 ± 7	45 ± 6†
Minimum diameter (mm)	65 ± 6	62 ± 8	NA
Maximum diameter (mm)	73 ± 7	68 ± 9	NA
Short axis (mm)	48 ± 5	46 ± 5	34 ± 7‡
Isoperimetric quotient	0.88 ± 0.05*	0.92 ± 0.03	NA

Note.—Data are means ± standard deviations. NA = not applicable.
* $P < .05$ compared with rapid switching method.
† $P < .001$ compared with rapid switching method.
‡ $P < .005$ compared with rapid switching method.

nected by the splitter cable. As a result, little current flows between the electrodes. In the current study, we have created two-dimensional computer models of three cool-tip cluster electrodes for both the simultaneous method and the rapid switching method. In the simultaneous method, heating mainly occurs radially outward from each cluster electrode, but comparably little heating occurs toward the center of the array. This severely limits the ability to widen the distance between prongs while still creating lethal temperatures in the center of the lesion. With the rapid switching method, no electrical interference is present, and tissue is heated uniformly around each cluster electrode. The thermal lesions resulting from our ex vivo experiments confirmed our observations with the computer models. The rapid switching method creates one large, uniform lesion, whereas the simultaneous method results in three small, discontinuous thermal lesions. This is potentially important, since ablation time and applied power were the same for both of these thermal lesions.

By using our rapid switching multiple-electrode method, we were able to create conglomerate thermal lesions in 12 minutes that were very close to those created with the conventional (sequential) method—in approximately one-third of the time. In fact, the amount of time saved with our rapid switching method may be even greater, because the second and third electrodes can be placed very rapidly by using the first electrode placement as a guide. A second important benefit of our rapid switching method is the increased temperature created in the RF lesion. The average temperature at the thermal lesion center was 97°C for the rapid switching method compared with 80°C for the sequential method ($P <$ .001). Multiple electrodes could be arrayed around large vessels to help overcome vascular cooling and increase the effectiveness of perivascular ablation, which may decrease local recurrences.

The hypothesis that multiple-electrode ablation decreases local recurrences will have to be proved with an in vivo tumor model. Multiple-electrode ablation in vivo with three cluster electrodes will likely require a higher-power generator than is currently commercially available to overcome the effects of vascular mediated cooling. We expect that with the use of higher-power generators, the rapid switching method will result in larger thermal lesions than will the sequential method because of a thermally synergistic effect, as has been observed with multiple-electrode microwave ablation in a previous study (30). A disadvantage of the greater power requirement of multiple electrodes is the increased likelihood of grounding pad burns and the potential for increased injuries to biliary ducts and vessels. This issue has to be studied before a clinical application is feasible and may limit the maximum number of RF electrodes that can be used concurrently. Multiple-electrode RF ablation will also increase equipment costs because additional electrodes have to be purchased, but that cost may be offset by cost savings from reduced procedure time.

Our study had limitations. Our results will have to be confirmed in vivo, since results may differ when perfusion mediated cooling is considered. We evaluated only one configuration of electrode spacing. Different electrode distances will have to be investigated in vivo to determine ideal electrode configuration.

We have developed a prototype impedance-controlled multiple-electrode RF system that can create large-volume thermal lesions in less than one-third of the time of conventional sequential ablation. Once a commercial multiple-electrode device becomes available, we believe it

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will significantly reduce treatment time for large thermal lesions and multiple lesions and will potentially simplify RF procedures that would otherwise require placement, activation, and replacement of a single electrode multiple times. The rapid heating, the higher temperatures between electrodes, and the ability to simultaneously treat multiple tumors may ultimately result in more effective destruction of tumors.

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