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Sequential Activation of Multiple Grounding Pads Reduces Skin Heating

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Abstract- **Radiofrequency (RF) tumor ablation has become an accepted treatment modality for tumors not amenable to surgery. The need for larger ablation zones has required increase in RF generator power, with current generation devices delivering 200 – 250 W. Skin burns due to ground pad heating have become a common complication and are now a limiting factor for further increase in ablation zone and generator power. We performed ex vivo experiments with three ground pads (5 x 5 cm) placed on a tissue phantom. We applied 100W of power for 12 min between the pads, and an RF electrode while we measured leading edge temperature below each pad, and temperature profile on the pads using temperature-sensitive LCD-paper. We compared conventional operation (i.e. simultaneous connection of all three pads) to sequential activation of the pads where each pad is only active for ~0.5 s. The timing during sequential activation was adjusted to keep leading edge temperature equal between the pads. Temperature rise below the leading edge for proximal, middle and distal ground pad was 10.7±1.04, 1.0±0.15 and 0.3±0.07 ºC for conventional operation, and 4.8±0.16, 4.4±0.20 and 4.5±0.35 ºC for sequentially activated operation. The maximum leading edge temperature rise was more than twice as high for conventional compared to switched operation (p<0.001). Sequential activation of multiple ground pads resulted in reduced maximum leading edge temperature, and allows control of each pad such that leading edge temperature of all pads is the same. This may reduce the incidence of ground pad burns by allowing each pad to reach same temperatures independent of location, and may allow higher power RF generators due to reduced skin heating.**

***Keywords* - radiofrequency ablation; RF ablation; tumor ablation; cancer**

I. INTRODUCTION

Radio-frequency (RF) ablation is increasingly utilized as a minimally invasive treatment for primary and metastatic liver tumors, as well as tumors in kidney, lung, bone and adrenal gland in cases where surgery is not possible. In RF ablation, RF current is delivered to the tissue via electrodes inserted percutaneously (i.e. through a small incision in the skin), laparoscopically or during surgery. Tumor cell death results from the conversion of electromagnetic energy to heat by ionic agitation. Temperatures above ~50 ºC cause denaturation of intracellular proteins and destruction of membranes of tumor cells, eventually resulting in cell necrosis.

During RF ablation, ground pads (dispersive electrodes) serve as return path for the RF current. Current ground pad systems in clinical use are composed of one or more pads connected in parallel to the RF power source. Each pad consists of a flexible, thin-layered electrical conductor coated by an adhesive polymer that attaches to the patient's skin. This adhesive increases the contact surface area of the pad to the skin, and assures that contact is maintained over irregular surface contours. The ground pads for RF ablation are different from those in use with electrosurgery systems that are usually a simple metal plate. Electrosurgery systems are designed to create rapid superficial heating using short bursts of RF energy. RF ablation is characterized by much greater energy deposition than electrosurgery for a much longer amount of time (up to 45 minutes). This is due to the desire to create maximum tissue heating and large coagulation zones with RF ablation versus targeted, low volume surface coagulation in surgical electrocautery.

Since the introduction of RF ablation, the zone of coagulation has been a major limitation in treatment of large tumors. While initial systems created coagulation zones of ~1.5 cm diameter, current systems can create between 4 – 6 cm coagulation zones. This increase in treatment volume is a result of more sophisticated electrode design, as well as an increase in RF generator power. Initial systems used 25 W of power, while current systems use 200 – 250 W. Figure 1 demonstrates the increase of RF generator power with each new generation of devices for the three commercially available systems in the United States. This trend will likely continue as the interest in increasing size of the coagulation zone as well as speed of treatment continues, and is apparent in current research literature.

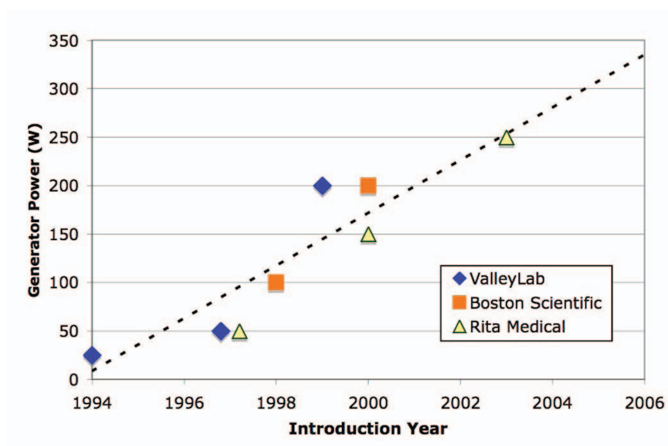

Figure 1. Generator power has been increasing since introduction of RF ablation.

With increasing generator power, incidence of skin burns due to ground pad heating has become fairly common. The current incidence of ground pad burns in the literature ranges from 0.1 – 3.2 % for severe skin burns (2nd or 3rd degree), with mild skin burns (1st degree) ranging between 5 – 33 % [1-3], though some recent studies suggest the incidence of skin burns after RF ablation may be under-reported [3, 4]. Figure 2 shows 2nd and 3rd degree skin burns as a result from insufficient grounding during RF ablation.

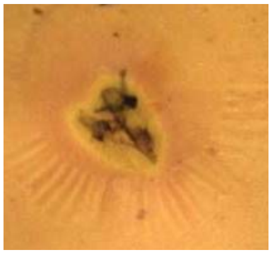

Figure 2. Third degree skin burn due to ground pad heating during RF ablation.

Efforts to reduce ground pad burns:

Because the early generation of RF devices were associated with low power output, to date there have only been rudimentary efforts to limit or avoid ground pad burns. Initially, the number of pads was increased, with current systems using 2-4 pads; this method has reached its limit since it is not feasible to place more than 4 pads equidistant from the RF electrode. RF current preferentially flows to the closest pad, and additional pads further away provide little benefit (Fig. 3).

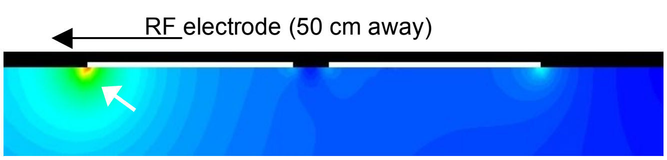

Figure 3. RF current density in a computer simulation. Current flows preferentially to the leading edge of the closest pad (*white arrow*).

Some studies suggest changing shape of the ground pads to reduce heating at the edges of the pad [5, 6]. Others suggest checking temperature at the leading edges of the pads [7], and using ice packs to reduce the risk of ground pad burns [4].

Due to increasing incidence of skin burns, two manufacturers recently introduced monitoring features in their latest RF devices. One system monitors current through each of the four pads and alerts the user of uneven current distribution among pads, promoting proper pad placement. Another system uses special pads with integrated temperature sensors and alerts the operator if skin temperature exceeds a safety threshold.

In this study we examine whether sequential activation of multiple ground pads can reduce ground pad related skin heating.

II. Methodology

Algorithm:

Ground pads were either activated simultaneously (i.e. connected electrically parallel to the RF generator ground), or sequentially (switched) using the activation pattern shown in Figure 4.

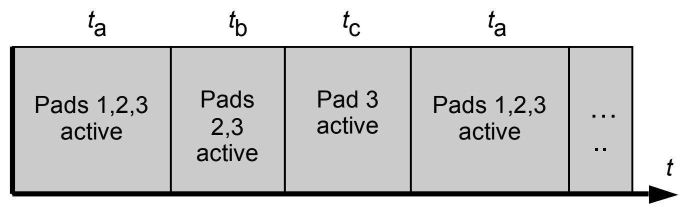

Figure 4. Activation pattern for three ground pads (Pad 1=proximal, Pad 2=middle, Pad 3=distal).

If all three pads are active, the closest pad dissipates the most power resulting in highest temperature below this pad (Fig. 3). We used the described activation pattern in an attempt to equilibrate heating between pads, and reduction of maximum tissue temperature.

In initial measurements we determined current through each pad when all pads are active, and when pads 2 and 3 are active. Assuming similar current profile below the pads due to large distance from the RF electrodes, we calculated the activation times such that average power deposited below each pad during one activation cycle is the same.

We developed software (Microsoft Visual Basic) that activates the ground pads according to the pattern described above (see Fig. 4), for an adjustable period of time. We then designed and built a relay switching circuit that interfaced with the program via a data acquisition device (Agilent 34970A). Figure 6 shows a block diagram of the electrical setup. The calculated activation times (from above) were adjusted using temperature data acquired during preliminary experiments to equilibrate temperatures between pads. The final activation times t_a, t_b, and t_c were 700, 800, and 550 ms, respectively.

Experimental Setup:

We filled a large plastic bath to a depth of 8 cm (approximately 16 L) with saline of electrical conductivity of muscle tissue at RF frequencies (σ=0.44 S/m, 0.25% NaCl). At one end of the bath, we fixed a stainless steel electrode for RF energy delivery. We then placed a block (35 cm long by 20 cm wide by 2 cm thick) made of Agar-water (5% Agar, 0.25% NaCl) on additional small Agar-water blocks in the bath such that the smooth top surface of the large block was approximately 2 mm above the surface of the saline. Three thin copper sheets (hereafter ‘pads’) with dimensions 10 cm wide by 5 cm long were placed on the surface of the block so that the leading edge of the first pad was ~30 cm from the stainless steel electrode. The two other pads were placed farther from the electrode such that there was a 4 cm distance between the pads (see Fig. 5). A small amount of saline was spread on the large agar block before placement to ensure uniform contact between each pad and the agar.

Each pad was connected to the switching circuit by a wire soldered to the top of the pad.

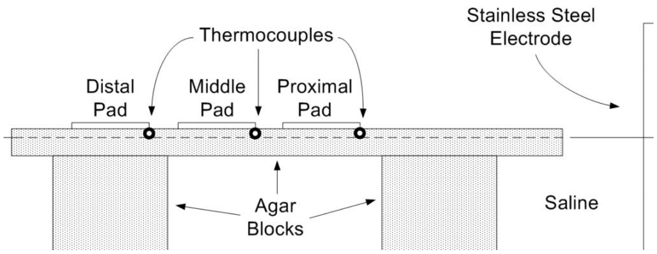

Figure 5. Side view of the experimental setup (not to scale). Thermocouples were placed at the center of the leading edge of each pad.

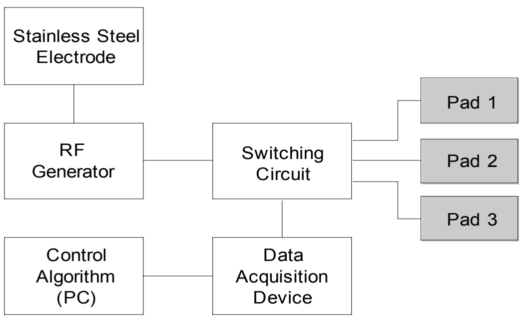

Figure 6. Block diagram of the setup. Software controlled the switching circuit to allow activation of different pad combinations. The activation times were selected to achieve uniform heating at the leading edge of each pad.

To measure temperature during the trials, we placed thermocouples at the center of the leading edge of each pad (see Fig. 5), as maximum temperatures are obtained at this location (see Fig. 3). A data acquisition device (National Instruments DAQPad-6020E) recorded the temperatures for later analysis. The thermocouples were pressed into the agar to a depth of approximately 1 mm so that they did not interfere with the contact between the pad and the agar. In addition we placed temperature sensitive paper that changes color in the range of 25 and 30 °C (Hallcrest Inc., R25C5W) on top of each pad, and took photographs during each trial at 1, 2, 3, 6, and 12 minutes. The location and orientation of the pads, thermocouples, and thermal paper were not altered between trials.

We performed a total of 12 trials in this study. We used a RF generator (Advanced Energy PDX-500) with a frequency of 350 kHz to apply a constant power of 100W between the stainless steel electrode and the ground pads for 12 min during each trial. In 6 of the trials, all of the pads were simultaneously connected to the RF power ground for the entire trial. In the other 6 trials, we used the program and circuit described above to sequentially activate (switch) different combinations of pads (see Fig. 4) over the course of each trial. The final temperature reached at each particular thermocouple for the simultaneous and switching cases was compared using the Student's t-test. Similarly, the final temperature reached at the three thermocouples for each particular case (switched or simultaneous) was analyzed using one-way analysis of variance.

III. Results

The average temperature at the leading edge of each ground pad versus time are shown below for the simultaneous (Fig. 7) and switched case (Fig. 8). The final temperature (12 min) between the 3 pads was significantly different for the simultaneous case ($p \ll 0.0001$), but not for the switching case ($p = 0.07$). Overall, the maximum temperature recorded in the simultaneous case was 10.7 +/- 1.0 °C (at the proximal pad), which was significantly higher ($p \ll 0.0001$) than that recorded in the switching case, 4.8 +/- 0.2 °C. At the middle and distal pads, the temperature was higher in the simultaneous case compared to the switched case ($p \ll 0.0001$).

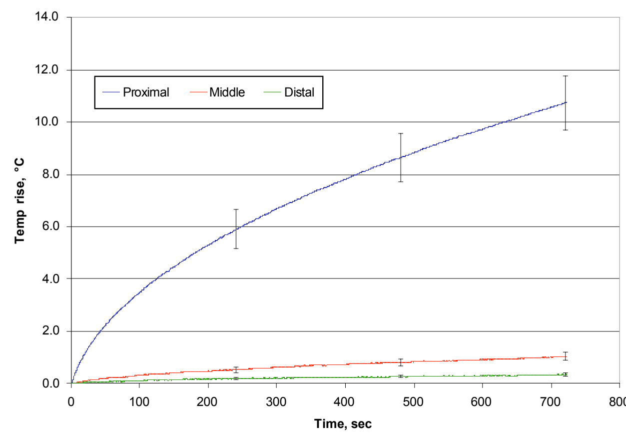

Figure 7. Leading edge temperature in the simultaneous activation trials. Increased current density at the leading edge of the proximal pad resulted in an average maximum temperature rise of 10.7 +/- 1.0 °C after 12 min, while the middle and distal pads showed little heating.

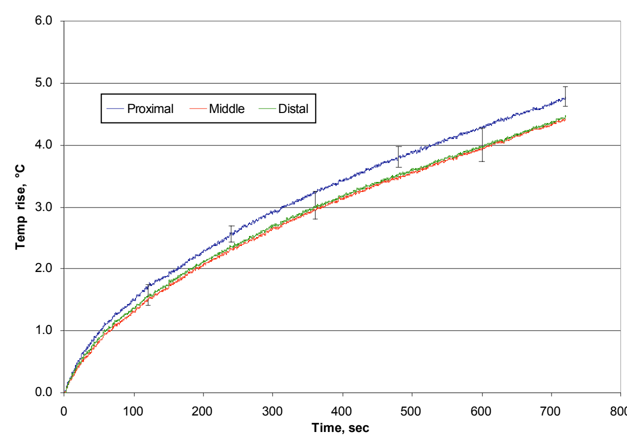

Figure 8. Leading edge temperature in the switched activation trials. The switching algorithm was successful in producing uniform heating at the leading edge of all three pads. The average maximum temperature rise was 4.8 +/- 0.2 °C, which was less than half of that seen in the simultaneous case.

Figures 9 and 10 below show the temperature profile after 12 minutes for a typical simultaneous and switching trial, respectively, using the temperature sensitive paper. In the simultaneous case, the dark blue coloring at the leading edge of the proximal pad denotes an area of high temperature (>30 °C), while the middle and distal pads show little temperature rise. In contrast, uniform average current density at each pad in the switched activation case leads to a relatively uniform temperature rise at the leading edge of each pad, as well as a lower overall maximum temperature.

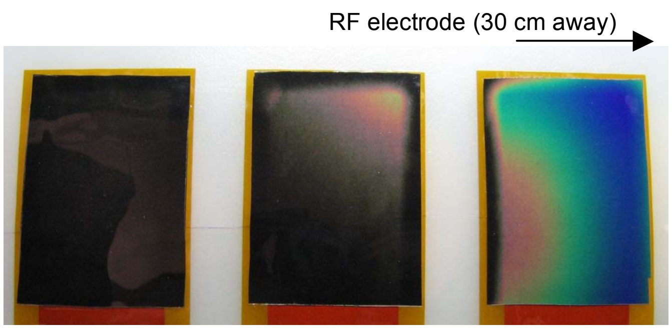

Figure 9. Representative image of groundpad heating when pads are activated simultaneously. The proximal pad (right) heats up most with little heating of the other pads. Temperature sensitive LCD paper shows pad surface temperature profile (red = 25ºC, blue = 30ºC).

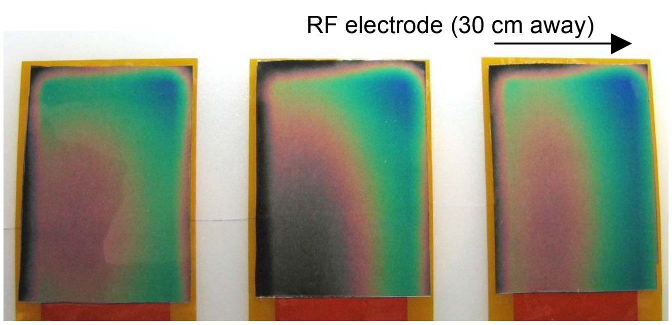

Figure 10. Representative image of groundpad heating when pads are activated sequentially. All pads reach similar temperatures, with reduced maximum temperature. Temperature sensitive LCD paper shows pad surface temperature profile (red = 25ºC, blue = 30ºC).

IV. Discussion

Skin burns due to ground pad heating are a common complication during RF tumor ablation, and are a limiting factor preventing further increase in RF power. Currently, up to 4 ground pads are placed equidistant from the RF electrode on the patient's thighs; placement of additional pads further away only provides minor benefits (see Fig. 3). To prevent skin burns, manufacturers have introduced monitoring of ground pad current and temperature in their recent devices. Other studies suggested use of ice packs to prevent ground pad heating [4].

We investigated sequential activation (switching) of multiple ground pads (Fig. 4) and compared this to the current methodology of simultaneous activation. By optimizing activation time of the pads we were able to reduce maximum temperature rise below the pads from 10.7 to 4.8 ºC (see Figs. 7, 8). In addition, we were able to achieve equal heating between different pads (Fig. 10), whereas simultaneous activation results in preferential heating of the closest pad (Fig. 9).

Since the activation times are selected to account for differences in the distance (and therefore impedance) from each pad to the ablation electrode, the equidistant placement of the pads is no longer a requirement. This means that ground pads can be placed virtually anywhere on the patient's body. This allows for a larger number of pads to be used than currently, and also reduces the possibility of operator placement error. Further studies are required to determine optimal ground pad size and spacing when using the switching method. In addition to RF tumor ablation, this method may be useful for other electrosurgical devices, especially in pediatric patients where skin surface area is limited.

V. Conclusion

Switched activation of multiple ground pads allows equilibration of heating and reduces maximum temperature below pads. This may allow for increase in RF generator power and reduction of skin burn incidence.

VI. References

[1] B. J. Bowles, J. Machi, W. M. Limm, R. Severino, A. J. Oishi, N. L. Furumoto, L. L. Wong, and R. H. Oishi, "Safety and efficacy of radiofrequency thermal ablation in advanced liver tumors," *Arch. Surg.*, vol. 136, pp. 864-869, 2001.

[2] T. Livraghi, L. Solbiati, M. F. Meloni, G. S. Gazelle, E. F. Halpern, and S. N. Goldberg, "Treatment of focal liver tumors with percutaneous radio-frequency ablation: complications encountered in a multicenter study," *Radiology*, vol. 226, pp. 441-451, 2003.

[3] K. Steinke, S. Gananadha, J. King, J. Zhao, and D. L. Morris, "Dispersive pad site burns with modern radiofrequency ablation equipment," *Surg Laparosc Endosc Percutan Tech*, vol. 13, pp. 366-371, 2003.

[4] J. Machi, "Prevention of dispersive pad skin burns during RFA by a simple method," *Surg Laparosc Endosc Percutan Tech*, vol. 13, pp. 372-373, 2003.

[5] V. T. Krasteva and S. P. Papazov, "Estimation of current density distribution under electrodes for external defibrillation," *Biomed Eng Online*, vol. 1, pp. 7, 2002.

[6] K. S. Tan and I. Hinberg, "Temperature distribution beneath pediatric electrosurgical dispersive electrodes: a model study," *Biomed Instrum Technol*, vol. 27, pp. 506-513, 1993.

[7] T. de Baere, O. Risse, V. Kuoch, C. Dromain, C. Sengel, T. Smayra, M. Gamal El Din, C. Letoublon, and D. Elias, "Adverse events during radiofrequency treatment of 582 hepatic tumors," *AJR. Am. J. Roentgenol.*, vol. 181, pp. 695-700, 2003.