

RADIOFREQUENCY ENERGY-INDUCED HEATING OF BOVINE CAPSULAR TISSUE USING A TEMPERATURE-CONTROLLED, BIPOLAR RF ELECTRODE

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INTRODUCTION

Increasing the temperature of collagen-based tissue causes it to become less redundant (1-5). The application of heat within the approximate range of 60° to 75°C has been reported to produce the desired effect of thermally modifying soft tissue for various clinical applications, including treatment of glenohumeral joint and anterior cruciate ligament instabilities (1-5). Recently, electrothermal arthroscopic surgery has gained in popularity as a means of producing the thermal effects necessary for reducing tissue redundancy (1-3). However, little data has been published with respect to the tissue heating effects associated with the various types of electro-surgical systems available for this application (3).

The determination of tissue temperature changes that occur for a given type of RF electrode and generator used at different settings is important for the safe and effective use of electrothermal arthroscopic surgery for modifying soft tissue structures. Excessive heating, particularly if undetected at sub-surface tissue levels, can damage tissue and/or injure sensitive neural and vascular structures. Therefore, the purpose of this *in vitro* study was to characterize the RF energy-induced heating produced by a newly-developed, temperature-controlled bipolar RF electrode (VAPR TC) and RF generator (VAPR II).

MATERIALS AND METHODS

Electrosurgical System and Bipolar RF Electrode. The electro-surgical device used in this investigation was the VAPR II System (DePuy Mitek, Inc., Raynham, MA). A temperature-controlled, bipolar RF electrode (DePuy Mitek, Inc., Raynham, MA) was utilized to apply RF energy. The electro-surgical system was used to deliver RF energy at the following settings:

- (1) 65°C, 20 W
- (2) 75°C, 40 W

Tissue samples. *In vitro* experiments were conducted using bovine capsular tissue. The tissue sample (approximate width, 15 to 20 mm; length, 50 to 75 mm; thickness, 6 to 7 mm) was placed on a plastic holder (width, 5 cm; length, 15 cm; thickness, 1 cm) designed to provide slight tension at the ends of the specimen using rubber bands. The amount of tension that was applied using this apparatus allowed shrinkage of the tissue to occur during application of RF energy-induced heating (6, 7).

The plastic holder with the tissue was submerged in a bath of 0.9% NaCl solution maintained at body temperature. The tissue sample was allowed to equilibrate in the saline bath for a minimum period of 1 hour prior to application of RF energy. This tissue sample preparation has been used for previous

experiments designed to assess temperature changes associated with the use of electrosurgical equipment (6, 7).

Measurement of Temperatures. Because of the well-known limitations of conventional thermometry methods operating in an RF environment (6, 7), a fluoroptic thermometry system (accuracy and resolution of measurements $\pm 0.1^\circ\text{C}$; Model 3100, Luxtron, Santa Clara, CA) was used to record the temperatures in this investigation. The non-metallic, electrically non-conducting thermometry probe responds rapidly (response time, 0.25 sec.) to determine temperature transients typically not detectable by other means in an RF environment (6, 7).

Measurement of Temperature at the RF Electrode-Tissue Interface. A single fluoroptic thermometry probe was calibrated and placed on the sample of bovine capsular tissue (i.e., which was immersed in the saline bath). The RF electrode was applied to the bovine tissue, in direct contact with the fluoroptic thermometry probe. This temperature measurement site is designated as the "RF electrode-tissue interface". Temperatures were recorded at this site to determine an extreme condition, since it is well known that RF energy-induced heating is the greatest at the "tip" of a bipolar RF electrode (6, 7).

Measurement of Tissue Temperatures at the Surface and Different Depths. Three fluoroptic thermometry probes were formed into a tight bundle and placed perpendicular into the tissue in a fixed position to measure temperatures at the tissue surface (0 mm) and at depths of 1 mm and 2 mm. The temperature-controlled, bipolar RF electrode was placed parallel, within 0.5 mm of this temperature probe array during delivery of RF energy. This method of recording tissue temperatures at the surface and different depths using a fluoroptic thermometry system during RF-induced heating has been previously described (6, 7).

Time Intervals for Temperature Measurements. Tissue temperatures were measured before, during the delivery of RF energy, and after the delivery of RF energy, as follows:

- (1) Baseline, 1 second intervals for 5 seconds
- (2) RF-On, 1 second intervals during the delivery of RF energy at 1 to 10 seconds for the RF electrode-tissue interface and at intervals of 1, 2, 3, 4, 5, and 10 seconds for the tissue surface and depths of 1 and 2 mm
- (3) RF-Off, 1 second intervals for 5 seconds after delivery of RF energy

Other Experimental Conditions. A new tissue sample was used for each data acquisition. Eight data acquisitions were obtained for each condition. To obtain consistent results relative to a simulated *in vivo* use of the RF delivery system, the same investigator manually controlled the contact pressure of the RF electrode to the tissue. This experimental procedure has been previously reported in the peer-reviewed literature (6, 7).

RESULTS

Using the temperature-controlled, bipolar RF electrode to deliver RF energy to the bovine capsular tissue, there were visual changes in the color of the tissue, with the initially shiny, white tissue turning a tan color or "blanching" during the heating process. Additionally, the tissue samples were observed to stiffen and shrink. After delivery of RF energy for 10 sec., all tissue samples had these

previously-described visual and physical signs localized to the sites where the RF electrode was applied.

Baseline temperatures were stable (i.e., P-value, not statistically significant) throughout the 5 sec. period that the eight separate recordings were obtained. Thus, these data were averaged and reported as mean values for each condition.

Tissue Temperatures at the RF Electrode-Tissue Interface. During the delivery of RF energy for the settings of 65°C, 20 Watts and 75°C, 40 W, the average temperatures at the RF electrode-tissue interface reached the “set temperatures” within 3 to 4 seconds (Figure 1). After reaching the set temperatures, the average tissue temperatures were maintained close to these levels during the delivery of RF energy.

Tissue Temperatures at the Surface and Depths of 1 and 2 mm. Temperatures measured at the tissue surface (0 mm) increased during the 1, 2, 3, 4, 5, and 10 sec. time intervals for the settings of 65°C, 20 Watts and 75°C, 40 Watts. In general, the temperatures measured at the surface did not exceed the “set temperatures” for the equipment settings that were evaluated (Figures 2 and 3). Temperatures measured at the 1 and 2 mm depths showed a gradient effect relative to the depth, exhibiting relatively small temperature increases (Figures 2 and 3).

Figure 1. Temperatures measured at the RF electrode-tissue interface for the temperature-controlled, bipolar RF electrode (VAPR TC) delivering RF energy at settings of 65°C, 20 Watts and 75°C, 40 Watts. Note that tissue temperatures increased rapidly and were maintained close to the set temperatures.

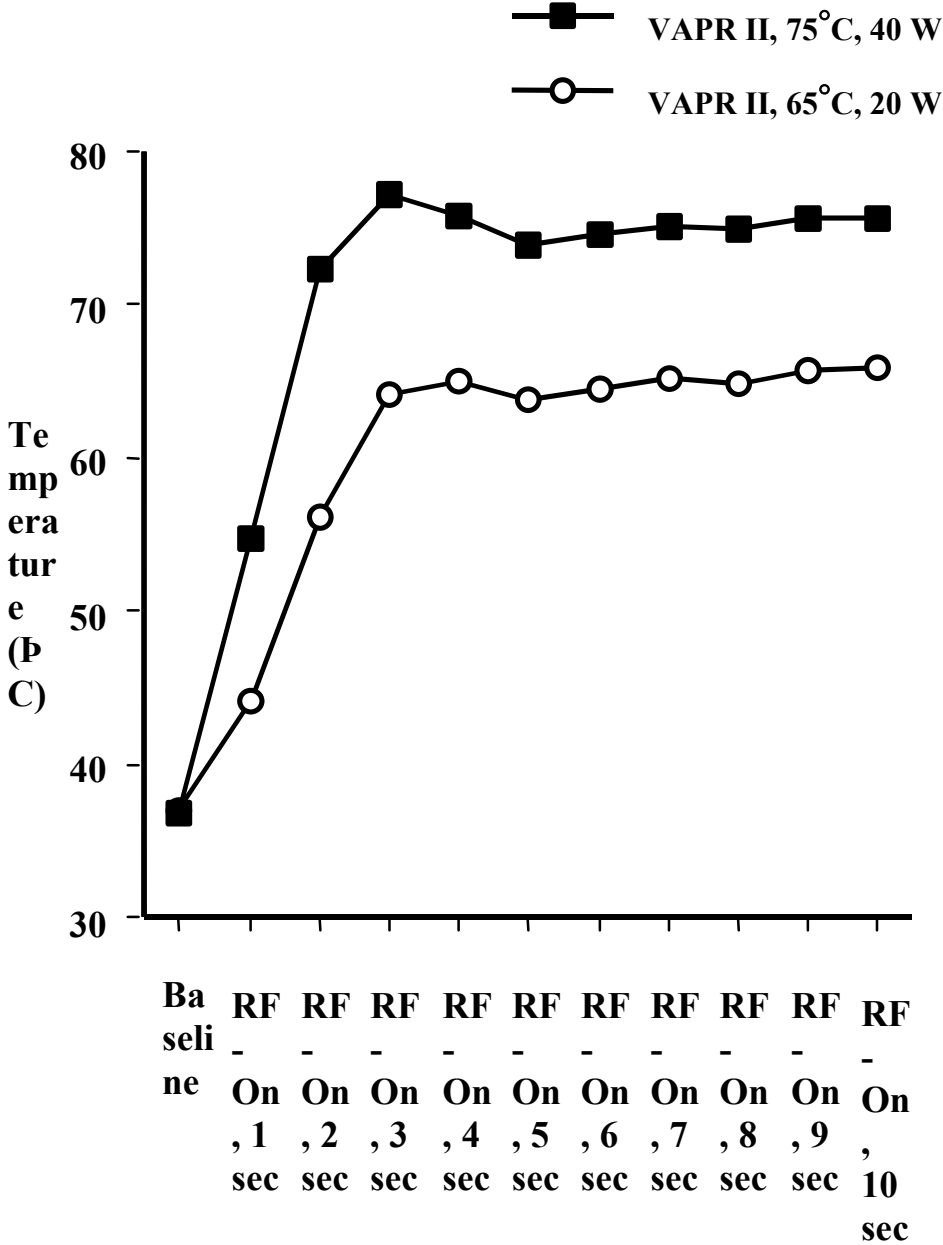


Figure 2. Temperature data for the temperature-controlled, bipolar RF electrode (VAPR TC) delivering RF energy at a setting of 65°C, 20 Watts. Temperatures measured on the surface and depths of 1 and 2 mm. Temperatures on the surface did not exceed the set temperature and there was a gradient effect for the temperatures measured at the depths of 1 and 2 mm.

**VAPR II, VAPR TC
65°C, 20 Watts**

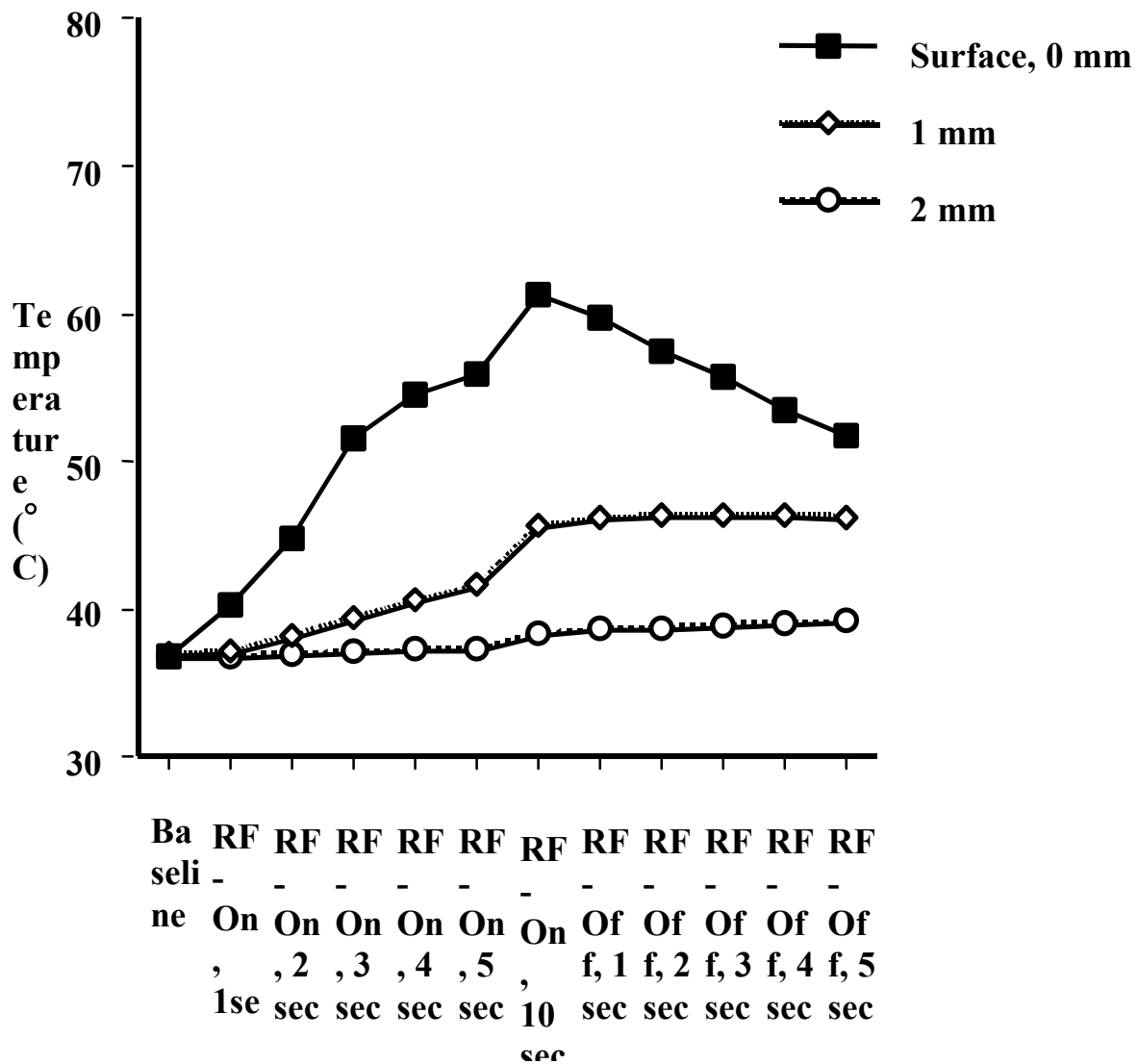
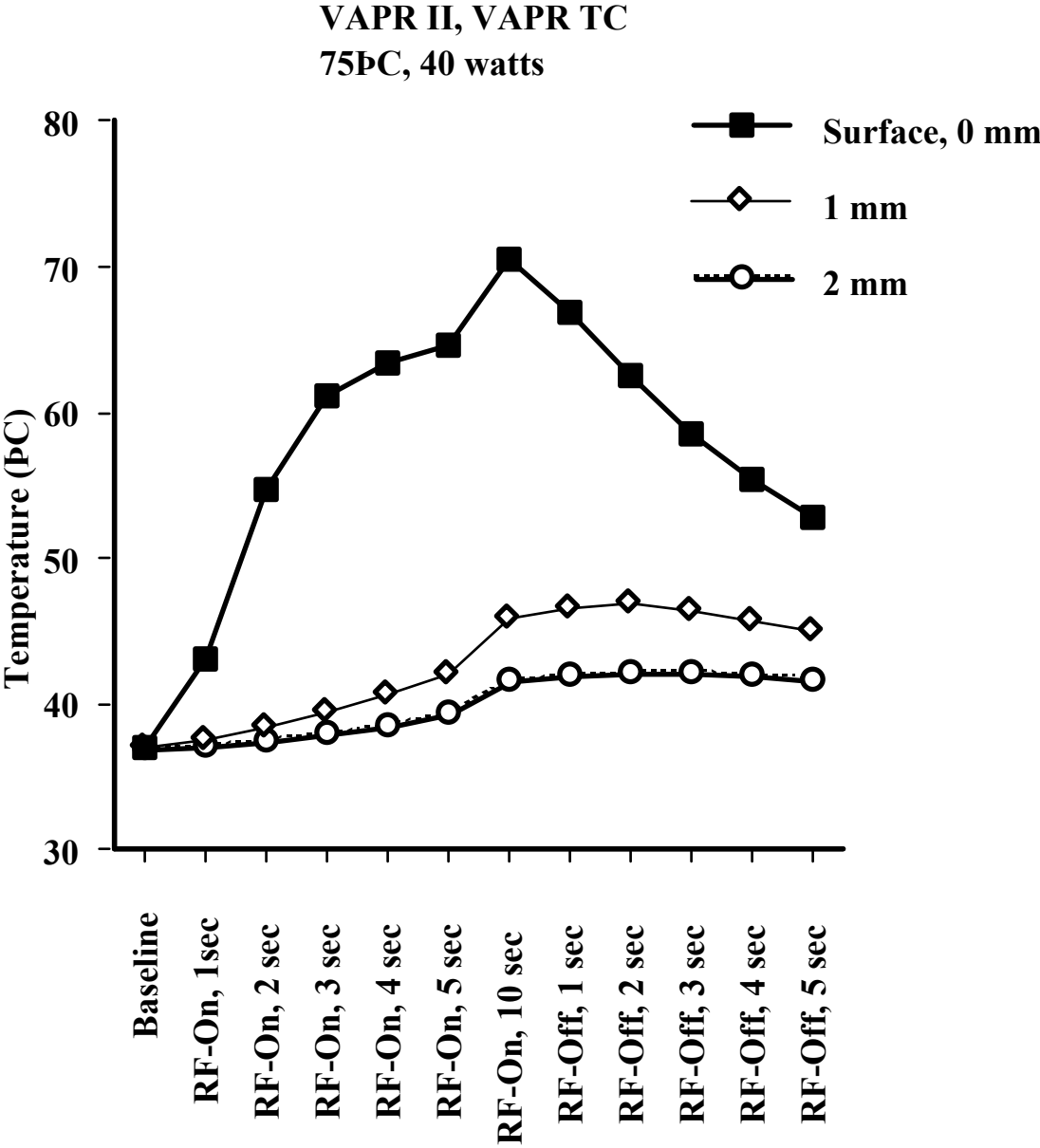


Figure 3. Temperature data for the temperature-controlled, bipolar RF electrode (VAPR TC) delivering RF energy at a setting of 65°C, 20 Watts. Temperatures measured on the surface and depths of 1 and 2 mm. Temperatures on the surface did not exceed the set temperature and there was a gradient effect for the temperatures measured at the depths of 1 and 2 mm.



DISCUSSION

This investigation characterized the RF energy-induced heating for a newly-developed, temperature-controlled, bipolar RF electrode used at two different settings. The findings indicated that the temperatures measured at the RF electrode-tissue interface were maintained close to the “set temperatures”. Therefore, the delivery of RF energy appears to be effectively modulated by the feedback control mechanism of this electrosurgical equipment.

In experiments using a fluoroptic thermometry array, temperatures measured at the surface of the tissue did not exceed the set temperatures. Temperatures measured at depths of 1 mm and 2 mm exhibited gradient effects that are well below the surface temperatures. These findings demonstrate that tissue heating at and below the tissue surface associated with the delivery of RF energy should not present a risk of injury to sensitive neural or vascular structures when the temperature-controlled, bipolar RF electrode is used at the settings evaluated in this investigation.

A recent study by Shellock (7) reported that the temperature-controlled, monopolar RF electrode and RF generator poorly modulated the delivery of RF energy, resulting in temperatures that greatly exceeded the equipment’s set temperature. By comparison, the temperature-controlled, bipolar RF electrode and generator produced tissue temperatures in bovine capsular tissue that were close to the set temperatures. Reasons for the good agreement between the set temperature and tissue temperature may be due to the unique designs of the RF electrode and control mechanism used in the RF generator. The distal electrode has a relatively small mass and, therefore, transfers the temperature quickly to the thermistor, permitting great accuracy for temperature measurements. The control mechanism of the RF generator system was specially-designed to be optimally “damped” to work with the bipolar RF electrode, thus preventing the development of inappropriate tissue temperatures.

SUMMARY AND CONCLUSIONS

In consideration of the findings provided by these experiments, the temperature-controlled, bipolar RF electrode, VAPR TC, appears to deliver RF energy in an acceptable manner insofar as the tissue temperature is maintained close to the “set temperature” of the RF system (VAPR II). Accordingly, this electrosurgical equipment should permit the safe and effective control of RF energy that is necessary for tissue shrinkage procedures.

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