Evaluation of Subcutaneous Fat Temperature and Optimization of Gap Distance Using Multiple Hands-Free Monopolar RF Handpieces

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INTRODUCTION

truSculpt iD is a monopolar RF device in which electric current flows between a single electrode and a grounding point. This unique device offers real-time temperature control to continuously monitor skin surface temperature while energy delivery is automatically adjusted to reach and hold a therapeutic temperature of >45°C in the fat while maintaining a skin temperature of 3-4°C cooler.

Analytical Modeling (COMSOL Multiphysics) of the interaction of Radio Frequency energy with the target anatomy (subcutaneous adipose tissue) depicts heating of the fat tissue beyond the physical footprint of a single electrode/HP as shown in Figure 1. This effect of heating the area outside the electrode footprint to therapeutic temperature can be accentuated in the area between handpieces placed adjacent to each other owing to the diffusion of energy from the handpieces. An experiment was designed to understand the thermal profile in vivo under the effect of perfusion and determine the optimal separation distance between electrodes while therapeutically heating maximum area between handpieces.

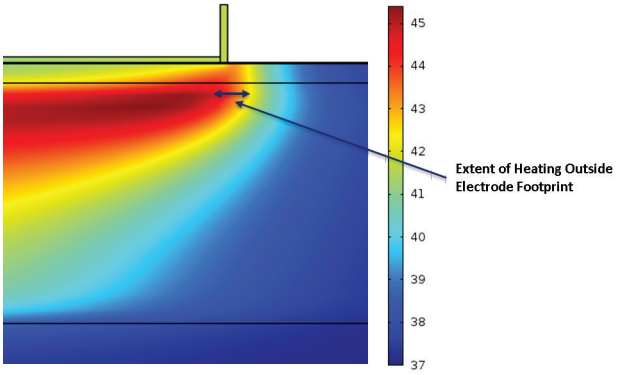


Figure 1. Energy-Tissue interaction post truSculpt iD shows heating of the fat extending up to 0.5 cm beyond the electrode edge.

An additional experimental goal was to establish the maximum separation distance between the truSculpt iD handpieces to ensure the therapeutic subcutaneous fat temperatures is reached under and between the handpieces and is consistently maintained.

STUDY DESIGN

The system used in this study was the truSculpt iD monopolar RF device. Two handpieces were applied to a single patient's abdomen a) 1.0 cm and b) 1.5 cm apart. Simultaneous, 15-minute treatments were conducted at a maximum of 43.5-44.0˚C on both handpieces using the device settings shown in Table 1. The subcutaneous fat temperature was measured at a depth of 15 mm in the gap between and under the handpieces.

Table 1. Study parameters and settings	
Handpiece Size	2 x 40 cm^2 Hands-Free
RF Power	Up to 300 W
Frequency	2.0 MHz
Skin Surface Temperature	43.0˚C to 44.0˚C

RESULTS

Handpiece separation with a gap of 1.0 cm resulted in less than 0.5˚C differential between the tissue under the center of the handpiece and that in the gap area. When the gap was widened to 1.5 cm, the temperature differential increased to greater than 1.5˚C. Figure 2 below shows the temperature of the subcutaneous fat layer over time with 1.0 cm and 1.5 cm gaps between handpieces.

In-Vivo Temperature Measurement with 1.0 and 1.5 cm Separation

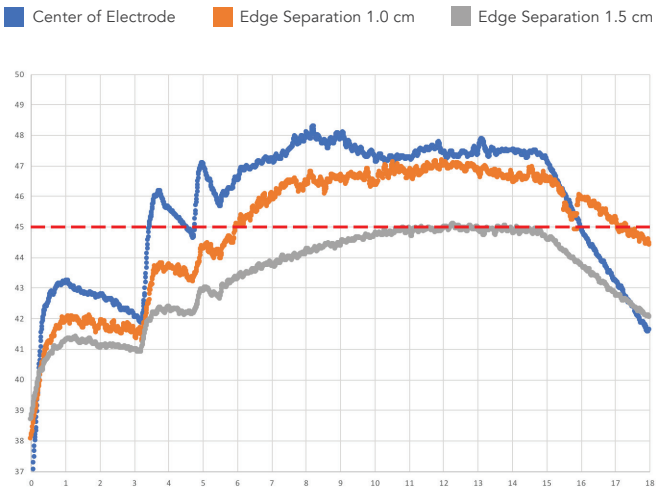




Figure 2. In vivo fat temperatures in the center of the handpiece and at the edge with separation distances of 1 cm and 1.5 cm between two handpieces.

FINDINGS

Two handpieces treated in parallel (as per this experiment) have shown to effectively heat the subcutaneous fat to therapeutic temperatures with up to a 1.0 cm separation. Including the plastic annulus around the electrodes which adds an additional 0.25 cm of separations, the resultant electrode distance to maintain therapeutic temperatures in the fat grows to 1.5 cm. Therefore, it is a fair and conservative assumption that a single 40 cm^2 handsfree handpiece has a heat distribution that ensures the fat between the two handpieces reaches therapeutic temperatures in the area up to 0.75 cm wider than the footprint of the handpiece. It can be safely assumed that therapeutic temperature is maintained within the entire distance of the gap. The skin surface temperature of the gap, will be approximately 7°C cooler than the temperature of the adipose tissue (as shown below) and will not have the same flushed appearance post-treatment.

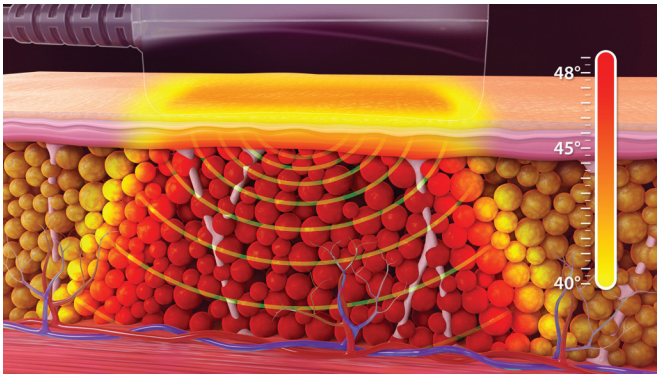


Figure 3. 3D representation of heat diffusion from truSculpt iD showing skin temperature of 3-4°C lower than fat temperature.

Given the findings of this experiment, when all six hands-free handpieces are in use during one 15-minute treatment, a minimum of 298 cm^2 surface area is receiving a therapeutic treatment. The diagram below shows how the total surface area is calculated when treating a patient with either three small or two medium size templates.

CONCLUSION

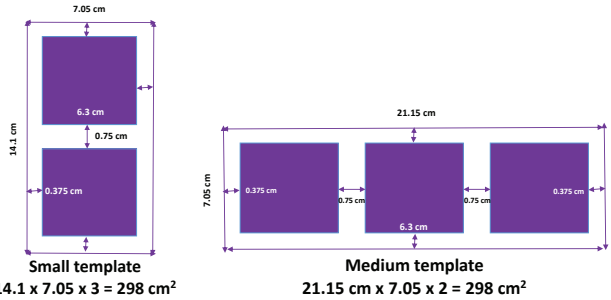


Figure 4. Examples of the small and medium treatment templates displaying less than 1 cm separation between handpieces.

Placing multiple truSculpt iD handpieces with no greater than a 0.75 cm gap provides consistent, therapeutic, subcutaneous fat treatment to induce apoptosis across and between handpieces.

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