Inflammatory and Adipocyte Cell Death Response Following A Single 15-Minute Monopolar Radiofrequency Treatment

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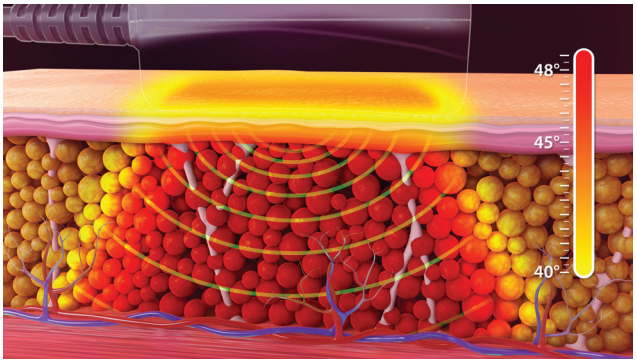
INTRODUCTION

truSculpt® iD is a monopolar radiofrequency (RF) device in which electric current flows between a single electrode and a grounding point. The temperature-controlled handpiece maintains the skin surface temperature between 43.0°C and 44.0°C while allowing the 2 MHz treatment frequency to create hyperthermic conditions within the subcutaneous fat layer (Figure 1). The temperature inversion effect is critical for adipocyte apoptosis without producing damage to the cutaneous layers. This study evaluated the performance of the truSculpt iD RF device for non-invasive lipolysis of abdominal fat. As part of the study, biopsy sections were evaluated from participants who had received a single RF treatment to examine and compare potential histological changes in cutaneous and subcutaneous tissues.



STUDY DESIGN

Eleven patients, age 24 to 58 years old, who were scheduled for an abdominoplasty were enrolled in the study prior to surgery. Patients were assigned to one of six treatment groups: surgery immediately post treatment, or 10, 20, 30, 60, or 90 days after truSculpt iD treatment. Each patient underwent a single treatment (Table 1) with the truSculpt iD device, and all patients reached peak surface treatment temperatures of 44.0°C in the abdominal region. An adjacent abdominal sub-area served as an untreated control. Incisional skin biopsies were harvested during the abdominoplasty from the treated and control areas for all eleven patients. Biopsies were processed and then reviewed by a board certified dermatopathologist.

Table 1. RF treatment parameters and settings

RF Treatment Parameters	Settings
Handpiece Size	40 cm^2
Skin Temperature	43.0-44.0˚C
Frequency	2 MHz
Treatment Duration	15 minutes

RESULTS

Control biopsies showed normal cutaneous and subcutaneous adipose tissue structures. In contrast, biopsies from the truSculpt iD treated areas showed adipocyte necrosis and/or inflammatory immune cell response in the subcutaneous fat and adipose tissues (Figures 2 and 3). There were no signs of adverse effects observed in the epidermis and dermis (Figure 2).

Tissue collected immediately to 20 days following treatment had gradation of inflammation characterized by adipocyte cell membrane degeneration, scattered inflammatory cell response, and foci of adipocyte lipolysis. Figure 1 shows adipocyte necrosis within the subcutaneous fat layer 10 days following treatment. Peak adipocyte cell death and fat lipolysis were observed by 30 days post-treatment. Approximately 33% of adipocytes were affected from just beneath the dermis to a depth of approximately 1.5 cm beneath the skin surface (Figures 3 and 4).

At 60 days following treatment, fat necrosis and active inflammation were still present although confined to small, focal areas and characterized by adipocyte cell membrane breakdown and neutrophils. At the 90-day time point, there was minimal inflammation, which suggests resolution of the hyperthermic injury to the adipocytes within the subcutaneous fat.

As expected, all subjects experienced transient, mild to moderate erythema, and edema post-treatment that lasted from a couple of hours to no longer than a day (1 patient). No adverse events were noted. Baseline patient characteristics are presented in Table 2.

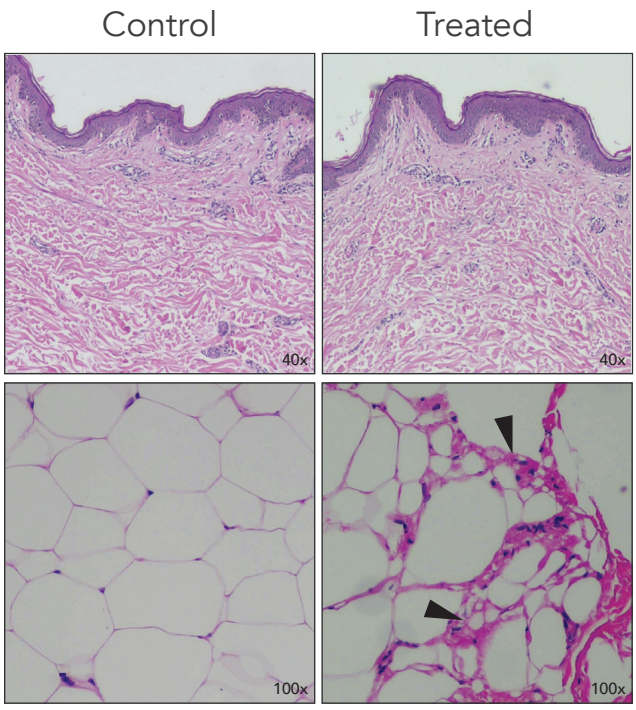


Figure 2. H&E stained sections of the cutaneous and subcutaneous layers from the abdominal region of a subject 10 days following a single truSculpt iD treatment. The dermal and epidermal layers from the subject abdomen compared to the untreated control (top row). No adverse effects were observed in the cutaneous layers. Subcutaneous fat 10 days following treatment show fat necrosis with no necrosis observed in the untreated control (bottom row). Black arrows: fat necrosis.

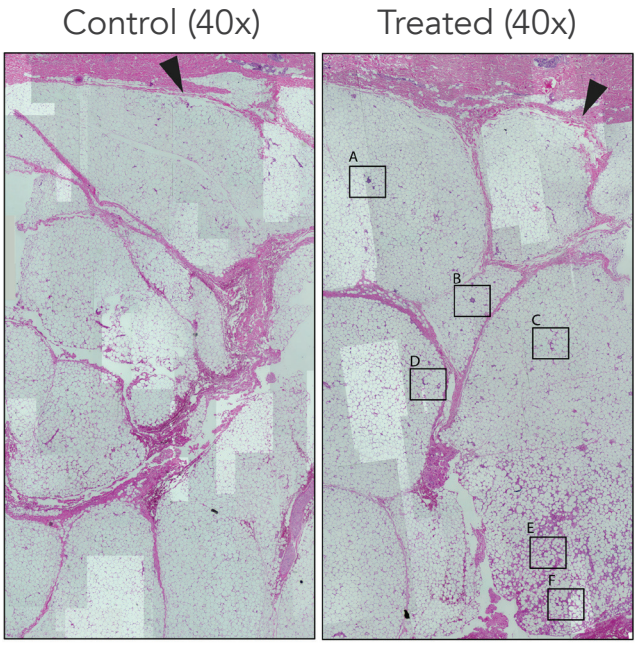


Figure 3: H&E stained sections of biopsies collected from the abdominal tissue after a single treatment with truSculpt iD in comparison to contralateral non-treated area control 30 days following a single truSculpt iD treatment. In the treated tissue (right column), fat necrosis extends from just beneath the dermis (black arrows) to 1.5 cm from the tissue surface. Within the subcutaneous fat, there are areas of hyalinization, inflammation, and fat necrosis characterized by lipid-laden histiocytes, scattered neutrophils, and lymphocytes. Higher magnification views of the treated subcutis labeled A-F are show in Figure 4 below. Fat necrosis or inflammation was not observed in the untreated control (left column)

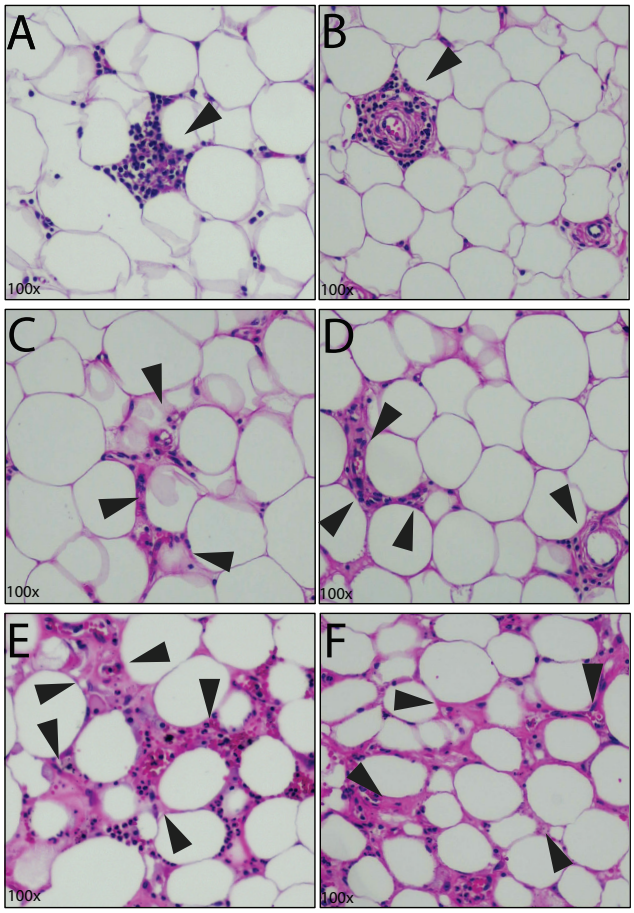


Figure 4: 100x magnification of sections displayed in Figure 2 (30 days post treatment): A and B show foci of lobular inflammation characterized by lymphocytes and neutrophils within fat lobules; C and D show areas of inflammation and degenerating adipocyte cell membranes; and E and F show degenerating adipocytes, lipid-laden histiocytes, and associated neutrophils and lymphocytes consistent with fat necrosis.

Table 2. Demographic and Baseline Characteristics of Patients

Subjects (n)	11
Median Age (range)	42 (24-58) years
Females, n (%)	11 (92%)
BMI, mean (range)	21-38.7
Skin Temperature (range)	43.0-44.0˚C

CONCLUSION

Apoptosis was observed spanning from immediately after the treatment with the truSculpt iD device to 60 days with peak expression at 30 days. Peak necrosis and inflammation following treatment was observed at 30 days with damage extending within subcutaneous fat to a depth of approximately 1.5 cm beneath the skin surface, without affecting the dermal or epidermal layers. By 90 days, there was no longer any fat necrosis and minimal inflammation. Treatment with the Cutera truSculpt iD device is a non-invasive, effective means of inducing abdominal lipolysis.