

A Novel Hands-Free Application of Monopolar Radiofrequency Treatment for Reduction of Waist Circumference

Ashish Bhatia M.D. F.A.A.D., Director Oak Dermatology Schaumburg Illinois
Joley Kauffman M.D., Director Skin Associates of South Florida

INTRODUCTION

Radiofrequency (RF) devices provide a non-invasive, safe and effective means of body contouring, in which unwanted excess fat pockets or bulges are reduced or removed. Surgery can provide definitive body contouring results, but is invasive, risky, and require significant recovery time.^{1,2}

The truSculpt® iD device is a monopolar RF system in which electric current flows between a single electrode and a grounding point. A temperature-controlled handpiece maintains the skin surface temperature between 43.0°C and 44.0°C and allows for deep volumetric heating of the tissue without damaging the epidermis. We report on a subset of three patients who completed a Cutera study to evaluate a novel hands-free configuration of the truSculpt iD RF device.

DEVICE SPECIFICATIONS

The device used in this study was the truSculpt iD, configured for hands-free operation. The application consisted of up to six (6) RF handpieces connected to the console via cables and adhesive return pads which return the electric current to the console during operation (Figure 1). Device settings and RF parameters are shown in Table 1.

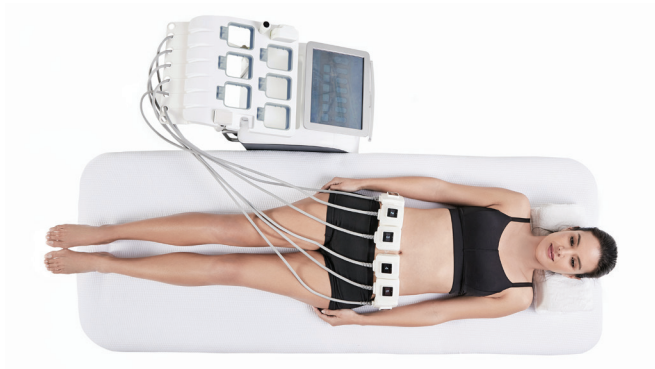


Figure 1. Application of the truSculpt iD device configured for hands-free use.

Table 1. Study parameters and settings	
Handpiece Size	40 cm ²
RF Power	Up to 300 W
Frequency	2.0 MHz
Skin Temperature	43.0°C to 44.0°C

STUDY DESIGN

This multi-center pilot study enrolled 27 patients, ages 18 to 65. Patients had body mass indices (BMI) between 19-28. Up to two treatments were administered to patients who were then evaluated at 12 weeks after the first or second treatment. Patient weight was collected at baseline visits and at the 12 week follow-up time points. A subset of eight patients had ultrasound images of the treated areas collected at baseline and at the twelve week follow up for assessment of fat thickness reduction. For one patient, an implantable thermal temperature probe was inserted into the subcutaneous fat during a single treatment cycle to record fat temperatures to evaluate adipolysis. Patient results were assessed using the Global Aesthetic Improvement Scale (GAIS) using baseline and 12-week digital photos (0=no change; +1=mild improvement; +2=moderate improvement; +3=significant improvement).

RESULTS

Three representative patients with baseline and twelve-week follow-up photos are shown in Figures 2-4. Fat thickness reductions up to 26% were observed for the subset of patients who had ultrasounds collected.

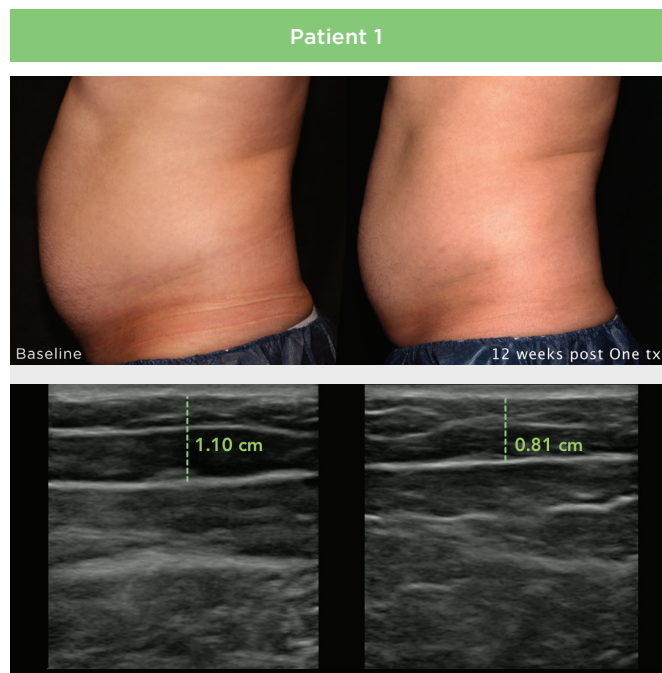


Figure 2. Photos courtesy of Ashish Bhatia, M.D. Patient 1 with before and after photos and ultrasounds which demonstrate a 2.9 mm or 26% fat thickness reduction.

Patient 2

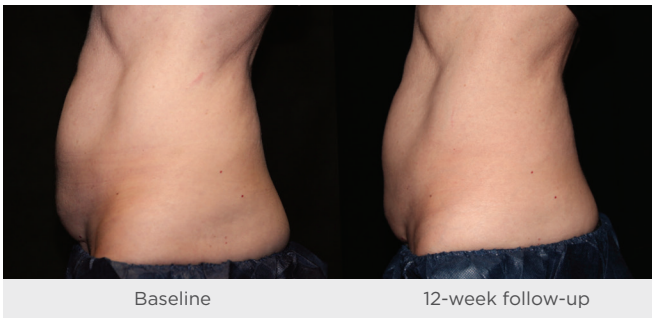


Figure 3. Photos courtesy of Ashish Bhatia, M.D. Patient 2 with before (left) and after (right) photos collected at 12 weeks after a single treatment.

Patient 3



Figure 4. Photos courtesy of Joely Kaufman, M.D. Patient 3 with before (left) and after (right) photos collected at 12 weeks after a single treatment.

Results of the GAIS assessment at twelve weeks following the first treatment indicated 87% of patients had mild to significant improvement results. Patient self-report survey revealed 75% and 25% of patients were either extremely satisfied or satisfied after a single treatment, respectively. Furthermore, 87% of patients were likely to recommend truSculpt iD to others.

The subcutaneous fat temperature from the abdomen in one patient during treatment is shown in Figure 5. The ramp up period (shaded grey) and the therapeutic time during which the fat temperature is within the range to achieve adipolysis (shaded green) is shown³. Temperatures on the skin surface were maintained at the 43.0°C - 44.0°C temperature during the single 15 minute treatment cycle.

15 min protocol for fat reduction treatment (single hands-free handpiece)

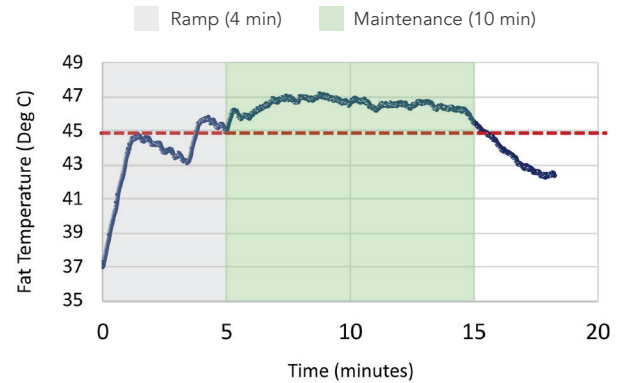


Figure 5. Patient subcutaneous fat temperature measurement throughout the treatment duration. Temperatures were maintained above 45°C which is within the adipolysis range.

CONCLUSION

Hands-free application of the truSculpt iD device for reduction in waist circumference is a promising configuration of RF fat thickness reduction. Patients experienced fat thickness reduction in line with the original truSculpt 3D fat thickness reduction results and this application effectively reaches the subcutaneous fat temperature necessary for stress-induced apoptosis.

¹ Sadick N. Tissue tightening technologies: fact or fiction. *Aesthet Surg J.* 2008 Mar-Apr;28(2):180-8. Review. PubMed PMID: 19083525.

² Alster TS, Lupton JR. Nonablative cutaneous remodeling using radiofrequency devices. *Clin Dermatol.* 2007 Sep-Oct;25(5):487-91. Review. PubMed PMID: 17870527.

³ Franco N. Hyperthermic Injury to Adipocyte Cells by Selective Heating of Subcutaneous Fat with a Novel Radiofrequency Device: Feasibility Studies. *Lasers Surg Med.* 2010 Jul;42(5):361-70. PubMed PMID: 20583242.