

EVALUATION OF SAFETY AND EFFICACY OF 15 MINUTE FAT REDUCTION TREATMENT WITH NOVEL 2MH_z MONOPOLAR RADIOFREQUENCY DEVICE

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INTRODUCTION

Surgery can provide definitive results with body contouring, but is invasive, risky, and requires significant recovery time.^{1,2} 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. The truSculpt iD® device is a monopolar RF system in which electric current flows between a single electrode and a grounding point. Up to six temperature-controlled handpieces maintain the skin surface temperature between 43°C and 44°C and allows for deep volumetric heating of the tissue without damaging the epidermis. We report on our findings to evaluate the safety and efficacy of individualized treatment with a novel hands-free configuration of the new truSculpt iD RF device for fat removal.

STUDY DESIGN

This single-center study included 15 patients ages 19-57 with BMIs ranging from 18 to 31. Study inclusion required patients to maintain weight within 5% of the baseline measurement. Patient weight, digital photos, waist circumference, and ultrasound images of the intended treated area were collected at baseline visits and at the 12 week follow up time points to evaluate treatment efficacy and safety. 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). Patients received a 15-minute treatment with 2MHz RF to the abdomen and flanks and were then evaluated at 12 weeks after treatment. The application consists of up to six RF handpieces that can be uniquely arranged to match the patients fat pocket distributions. Device settings and RF parameters are shown in Table 1.

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
Treatment time	15 minutes

RESULTS

Of the 15 patients in the study, 3 were excluded due to weight gain in excess of 5%. The 12 remaining patients measured with ultrasound had an average abdominal fat thickness reduction of 24%. Three representative patients with baseline and twelve-week follow-up digital photos are shown in Figures 1-3. Ultrasound measurements reveal fat thickness reduction for all patients ranged from 17-29%. Results of the GAIS assessment at twelve weeks following treatment included: 46% of patients with moderate improvement (+2) and 33% of patients with significant improvement (+3). The patient satisfaction survey revealed 100% of patients had improved body definition after treatment and were satisfied with their results. Furthermore, all study patients were likely to recommend truSculpt iD to others and all patients indicated they were comfortable throughout the procedure.

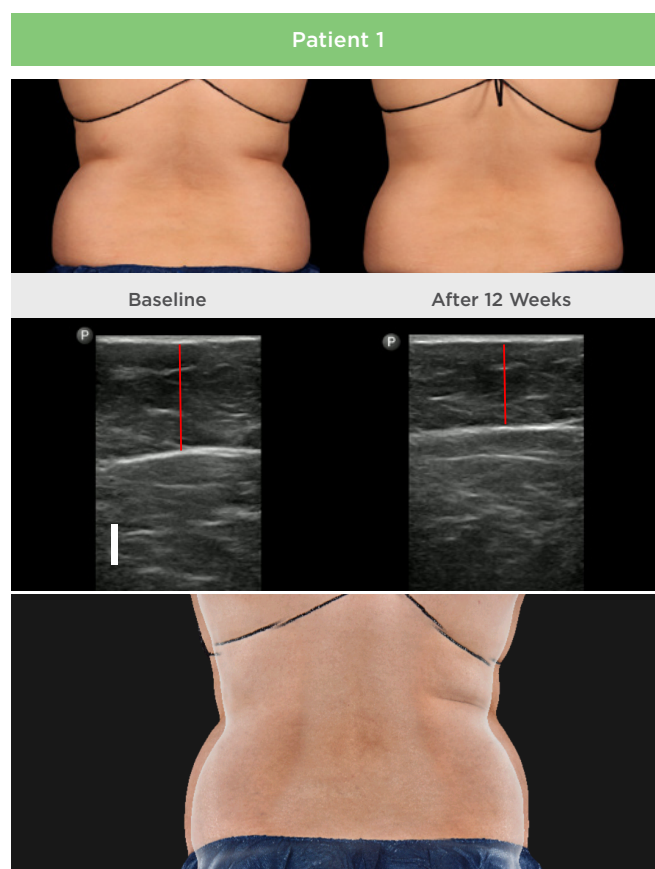


Figure 1. Photos courtesy of Stephen Ronan, M.D. (Top) Patient 1 with before (left) and after (right) photos collected 12 weeks after a single treatment. (Middle) Ultrasound measurements of the right flank indicate a 29% fat thickness reduction. (Bottom) Overlay silhouette photo of the patient before and after treatment. Scale bar 1 cm.

Patient 2

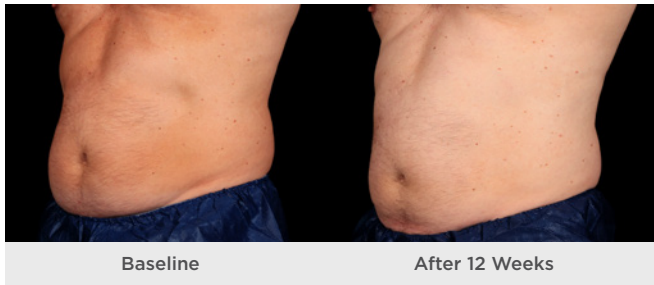


Figure 2. Photos courtesy of Stephen Ronan, M.D.
Patient 2 with before (left) and after (right) photos collected 12 weeks after a single treatment.

Patient 3

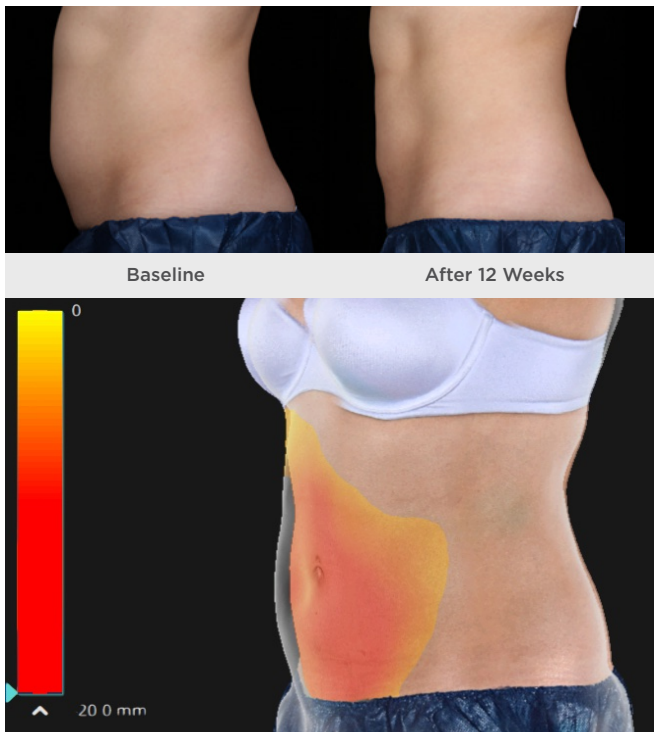


Figure 3. Photos courtesy of Stephen Ronan, M.D.
(Top) Patient 3 with before (left) and after (right) treatment photos.
(Bottom) 3D silhouette photos indicate volume loss in the treated abdominal area.

CONCLUSION

Hands-free application of the truSculpt iD RF device is a promising configuration for fat thickness reduction and waist circumference reduction. This application effectively reaches the subcutaneous temperature necessary for stress-induced apoptosis. Patients experienced fat thickness reduction in line with the truSculpt 3D fat thickness reduction results with a treatment time of 15 minutes.

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.