

Feasibility of the Cutera truSculpt® iD Device for Tissue Improvement of the Upper Arms

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INTRODUCTION

Body sculpting was the most popular procedure for the past year as unwanted excess fat pockets and bulges have been among the top concerns expressed by patients in the aesthetic field¹. Patients desire non-invasive methods that require less recovery time and fewer risks than surgery.

Radiofrequency (RF), laser, cryolipolysis, and a combination of these technologies have been developed to non-invasively reduce fat pockets and cellulite while minimizing recovery time and risks². Previous clinical studies have shown not only that these treatment devices can reduce fat in the abdominal and flank areas but have also been shown to be an effective treatment for the upper arm area³⁻⁶. RF devices have been studied at length and provide a safe treatment with effective results. We report on a feasibility study to evaluate the safety and efficacy of the truSculpt® iD RF device for tissue improvement of the upper arms.

DEVICE

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 RF handpieces connect to a console via an umbilical cable and an adhesive return pad which returns the electric current to the console during operation. The disposable adhesive return pads are applied to the subject's upper back and serves as the grounding point. The electrode is the temperature-controlled handpiece and allows for deep volumetric heating of the tissue without damaging the epidermis.

STUDY DESIGN

This single-center study with a total of 15 patients ages 26-60 with visible tissue irregularities in the upper arm region and who desired treatment with truSculpt® iD were consented and enrolled. Study inclusion required patients to maintain weight within 5% of the baseline measurement. Patient weight, digital photos, and ultrasound images of the treated arm area were collected at baseline visits. Participants received a single 15-minute treatment to each upper arm, using two handpieces in each area and were assessed at 8 and 12-weeks following the treatment to evaluate treatment efficacy and safety by comparing ultrasounds and blinded physician review of before and after digital photographs. Participants also completed a satisfaction questionnaire at the 12-week visit.

Table 1 . summarizes the device settings used in the study.

Table 1. Study parameters and settings	
Handpiece Size	40 cm ²
RF Power	Up to 300 W
Treatment Duration	15 minutes
Frequency	2.0 MHz
Skin Temperature	41.0°C to 43.0°C

RESULTS

As expected, treatment was well tolerated and all subjects experienced transient, mild to moderate erythema, and edema post-treatment that lasted no more than a couple of hours. No adverse events were noted. Representative photographic results are shown in Figure 1 and Figure 2 Below.

CONCLUSION

The truSculpt® iD RF device improved visual appearance, contouring and definition in patients with tissue irregularities of the upper arm without side effects. These results show feasibility of treatment with monopolar RF and a promising safety and efficacy profile.



Figure 1. Patient 1 following one treatment with the truSculpt iD RF device. Photos Courtesy of S. Ronan, M.D.

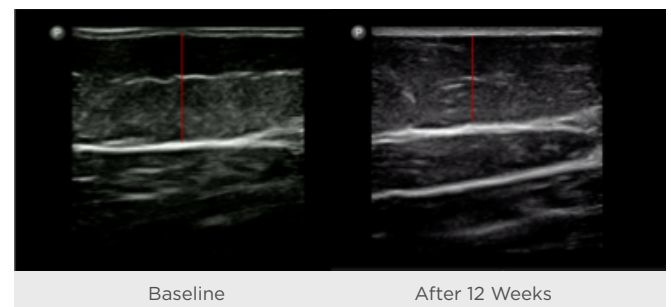


Figure 2. Patient 1 ultrasound images before treatment with truSculpt iD and 12 weeks after treatment.

¹ American Society for Dermatologic Surgery (ASDS) 2018 Consumer Survey on Cosmetic Dermatologic Procedures.

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 Carruthers J. Cryolipolysis for Reduction of Arm Fat: Safety and Efficacy of a Prototype CoolCup Applicator With Flat Contour. *Dermatol Surg*. 2017 Jul;43(7):940-949. PubMed PMID: 28595246.

⁴ Leclere F, Alcolea J, Moreno-Moraga J, Mordon S, Casoli V, Trelles M. Laser-assisted lipolysis for arm contouring in Teimourian grades I and II: a prospective study of 45 patients. *Lasers Med Sci*. 2015 Apr; 30(3): 1053-1059. PubMed PMID: 25596934.

⁵ Wanitphakdeedech R, Sathaworawong A, Manuskiatti W. The efficacy of cryolipolysis treatment on arms and inner thighs. *Laser Med Sci*. 2015 Nov; 30(8): 2165-2169. PubMed PMID: 26100004.

⁶ Brightman L, Weiss E, Chapas AM, Karen J, Hale E, Bernstein L, Geronemus RG. Improvement in arm and post-partum abdominal and flank subcutaneous fat deposits and skin laxity using a bipolar radiofrequency, infrared, vacuum and mechanical massage device. *Lasers Surg Med*. 2009 Dec;41(10):791-8. PubMed PMID: 20014259.