

Optimization of Treatment Times Using a Novel Monopolar Radiofrequency Device for Subcutaneous Adipolysis

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INTRODUCTION

Surgical interventions produce the most definitive results with body contouring; however, these invasive methods require significant recovery time and come with inherent risks. For patients interested in removing fat pockets and reducing skin laxity with a non-invasive treatment that has minimal recovery time and risks, radiofrequency (RF) devices have been studied at length and provide a safe treatment and effective results.^{1,2}

RF technology induces adipolysis by delivering a hyperthermic treatment to the subcutaneous tissue non-invasively. The efficacy of these treatments depends on two factors: temperature achieved in the subcutaneous tissue and the length of time the tissue is exposed to the RF energy. Prior clinical work has demonstrated improved efficacy of fat reduction by incorporating massage post hypothermic treatment.³ In this study, we evaluated the impact of varying treatment times on the efficacy of subcutaneous fat reduction using a monopolar RF device with and without massage.

STUDY DESIGN

Twenty patients, ages 24 to 65 years, were enrolled in the study. Patients had body mass indices (BMI) between 21 and 32. Four cohorts with five patients each received a single treatment to the abdominal region and flanks using the Cutera truSculpt iD (Table 1). Patients assigned to Cohorts 1, 2, and 3 all received 10-minute treatments of the right flank with a differing treatment time on the contralateral flank and abdomen. Cohort 1 received a 20-minute treatment on the left flank and abdomen and 10-minute treatment on the right flank. Cohorts 2 and 3 received 10-minute to the right flank and 30-minute treatment to the contralateral flank and abdomen, but only patients in cohort 3 had a post-treatment massage to both flanks and abdomen. Cohort 4 received 20-minute treatments to both sides with post-treatment massage on one side (right flank). Assessments included digital photographs and ultrasound measurements of all treated areas to evaluate fat thickness reduction at baseline, 8-, and 12-weeks post treatment.

Table 1. Study parameters and settings	
Handpiece Size	40 cm ²
RF Power	Up to 150 W
Pulse Duration	10, 20, and 30 min
Frequency	2.0 MHz
Skin Temperature	43.0°C to 44.0°C

RESULTS

Fat thickness reduction was achieved in all cohorts, with the best results observed with the 10-minute treatment time at the 3-month follow-up (24% reduction). Post-treatment massage had a statistically insignificant effect. Fat thickness reduction results are shown in Figure 1. Across all cohorts weight fluctuation was ± 4 pounds gained or lost. No unexpected adverse events were recorded during the study. Post-treatment tissue nodules were more prominent with 20- and 30-minute treatments. See Figure 3 below. Table 2 presents average fat thickness (FT) reduction results measured using ultrasound with representative patient photos shown in Figure 2.

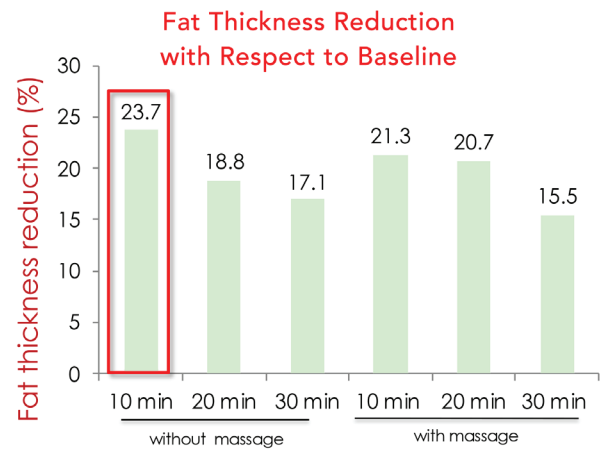


Figure 1. Average fat thickness reduction percentage measured with ultrasound 3 months following single treatment.

Table 2. Average Patient Fat Thickness Reduction 3 Months Following Treatment					
Patient ID	Treatment	Baseline FT (cm)	12-week FT (cm)	% FT reduction	Weight change (%)
1	10 min vs 20 min	1.88	1.31	30.3	-3.4
2	10 min vs 30 min	2.22	1.69	23.9	-3.1
3	10 min vs 30 min with massage	0.82	0.62	24.4	+2.6
4	20 min with and without massage	2.29	1.83	20.6	0

Patient 1

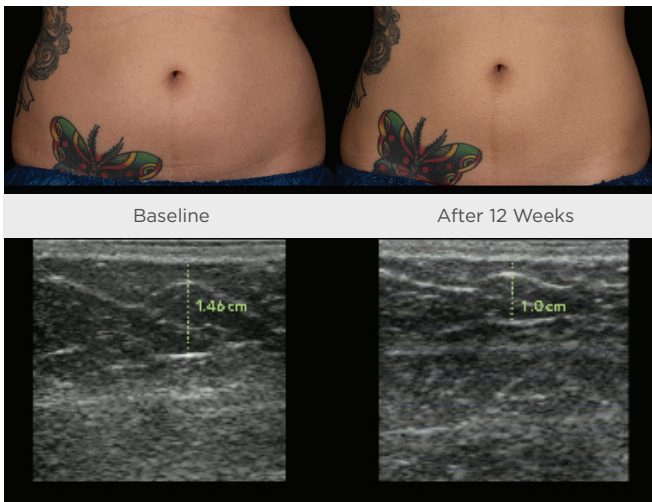


Figure 2. Photos courtesy of Stephen Ronan, M.D. Shows patient 1 who received a 10-minute treatment on the right flank, a 20-minute treatment on the left flank, and 20-minute treatment on the abdomen. Ultrasound shows 4.6mm or 32% fat reduction.

Patient 2

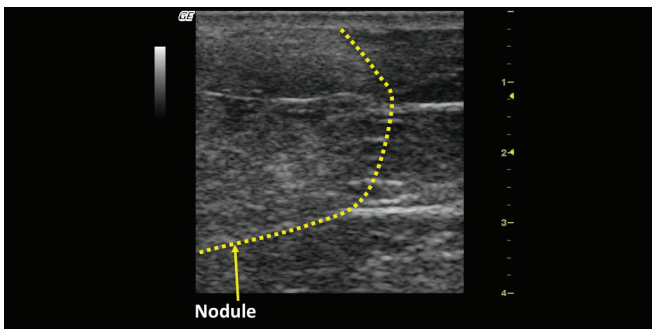


Figure 3. Shows ultrasound of nodule formation post 30-minute treatment.

CONCLUSION

Fat reduction did not increase with longer truSculpt iD treatments (> 10 minutes) at the 3-month follow-up while an increased number of nodules were present at these longer treatments. The 10-minute treatment patients were the most comfortable compared to the 20 and 30-minute treatment intervals. The highest rate of average fat thickness reduction, 24%, was seen with the 10-minute exposure without massage. Massage was not found to improve fat reduction over the RF treatment alone.

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 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.