

Improving Upper Arm Skin Laxity Using a Tripollar Radiofrequency Device

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ABSTRACT

Background: Non-ablative treatments for excess subcutaneous fat have been increasingly integrated into dermatologic practice.

Objective: The objective of this study was to determine the safety and efficacy of a tripolar radiofrequency device on tightening skin and reducing the circumference of the upper arms.

Methods & Materials: Twelve females received eight weekly non-ablative treatments using a tripolar radiofrequency device on the anterior and posterior upper arms. Evaluations included body weight, photographs, and circumference measurements at baseline and each subsequent week throughout the 8-week time period. The subjects and the investigator completed evaluations of clinical improvement using a 5-point assessment scale.

Results: A significant circumference reduction was achieved in each arm of all twelve patients. A mean reduction of 1.99 ± 0.94 cm ($P=0.001$) was observed between the initial and final measurements after the 8-week treatment period. At the 4-week follow up, the average circumferential reductions of the posterior and anterior upper arms were sustained. Patient evaluations indicated moderate to good improvement of size, tightness, and overall appearance. The procedure was well tolerated without pain.

Conclusion: Tripolar radiofrequency devices offer a safe and effective non-invasive technology with beneficial effects on the circumferential reduction and overall appearance of the posterior and anterior upper arms.

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INTRODUCTION

Radiofrequency technology is frequently used in dermatology for skin tightening and the reduction of fine lines, wrinkles, and cellulite. Radiofrequency energy is a form of electromagnetic energy that heats the skin and restores skin elasticity and firmness. This treatment is becoming significantly more popular, due to its efficiency, versatility, safety and efficacy in treating a broad range of body and facial regions.¹ Radiofrequency technology tightens skin through heat-induced shrinkage of collagen and augmentation of lipolytic activity.²

In contrast to lasers, which heat the skin through a pulse of light targeting chromophores, radiofrequency devices heat the skin by firing charged particles within the tissue as an electric current.³ Radiofrequency treatment induces a deeper tissue thermal effect than ablative lasers, thereby heating and denaturing a deeper layer of underlying collagen and stimulating fat metabolism.⁴ It is this depth of penetration that leads to a greater volume of tissue heating and significant circumference reductions in the thighs and abdomen, not previously seen with ablative laser treatments.⁵

In a monopolar system, energy is applied to tissue through one electrode and a grounding plate, which results in volumetric

deep heating of tissue.⁶ In a bipolar system, the superficial tissue is heated when the electric current flows between the two electrodes, both located on the site being treated.⁶ The electrical circuit needs to be closed to heat the tissue. Greater volume of tissue is treated with the monopolar system, thus this system requires a greater current and a higher level of energy as compared to the bipolar system.⁷

A tripolar device combines the deep tissue heating effects of the mono-polar radiofrequency system with the superficial heating effects of the bipolar radiofrequency system in one applicator, thereby minimizing power consumption while also maximizing the single treatment efficacy and duration of results.⁵ In the tripolar device, the radiofrequency current flows between three electrodes, one positive and two negative. This arrangement of electrodes causes each to act as a common pole, eliminating the need for cooling of the electrodes and skin, optimizing safety.⁸

Previous studies have demonstrated success in reducing the circumference of the abdomen and thighs using a tripolar device.^{2,5,9} The objective of the current study is to determine the safety and efficacy of a tripolar radiofrequency system in tightening skin and reducing the circumference of the posterior and anterior upper arms. We evaluated the treatment outcomes

through subjective patient and investigator assessments, objective circumference measurements, and clinical photography.

MATERIALS AND METHODS

Twelve healthy females (aged 33-66 years; mean, 58 years) participated in the study. Subjects were instructed to continue with their regular diet and exercise routines. They were also advised not have significant weight fluctuations throughout the duration of the study. Exclusion criteria included pregnancy or lactating, obesity, history of disease at the area treated, history of collagen or vascular disease, history of auto immune disease, history of any disease inhibiting pain sensation, implants or a peacemaker device, use of medication or device causing dermal hypersensitivity 30 days before treatment, and subjects anticipating the need for surgery or overnight hospitalization during the study.

The posterior and anterior upper arms of all subjects were treated once a week for a total of eight treatments. The device was used on both the left and right posterior and anterior upper arms. Each of these four locations was treated for six minutes for a total of 24 minutes per visit. The frequency range of the current used was 1 MHz at a power of 37.5 Watts. The medium sized applicator, with an area of 1.7 cm², was used for treatment of the upper arms.

All subjects signed an informed consent form. Following lubrication of the treatment area with glycerin oil, the applicator was applied continuously in a circular motion to heat the subcutaneous fat layer and the dermis. A non-contact, infrared thermometer (Thermofocus) was used to monitor external skin temperature. A skin temperature of 40-42°C was reached within two minutes and then maintained for the remaining exposure time of 4 minutes.

Treatment Evaluations

Evaluations included body weight, photographs, and circumference measurements at baseline and each subsequent week throughout the 8-week time period. Circumference measurements were obtained before and after each treatment session using the device. Standardized circumference measurements were taken 5 inches above the patient's antecubital fossa using a designated tape measurer.

Subjective Assessment

Both the subjects and a blinded investigator completed a 5-point assessment (1= worse, 2= no improvement, 3= moderate

improvement, 4= good improvement, and 5 = great improvement) in order to evaluate the reduction in size, tightness, and overall appearance of their upper arms.

Statistical Analyses

Statistics including mean, median, percentages of circumferential reduction, 95% confidence interval, and standard error were used to analyze the population mean in reference to our sample mean. Statistical analyses were performed using the JMP Version 10 Statistical Software System. A paired-samples t-test was used to determine statistical significance before and after the total 8-week treatment period.

RESULTS

Twelve female patients were enrolled in the study and all patients completed the 8-week treatment cycle. Three patients were lost to follow-up and did not receive 4-week follow-up measurements. Each patient received treatment on both the left and right anterior and posterior arms, resulting in a total of 24 circumferential measurements over the 8-week treatment protocol and 18 measurements at the 4-week follow-up.

The treatment was generally well tolerated and patients described the procedure as comfortable. There was a mild, transient circumferential increase and associated erythema noted immediately following the treatment of all patients. Both of these side effects subsided within 3 hours of treatment. No other adverse events were reported throughout the duration of the study.

Patient's weight measurements were taken at baseline and at each week of treatment. Over the course of the study there were no significant weight fluctuations (-0.083 ± 1.676 lbs, $P=0.567$) observed.

Objective Circumferential Measurements

Significant circumferential reductions for both the left and right arm of all twelve patients were observed, comparing the baseline and the 8-week final treatment. These results are summarized in Table 1. A statistically significant mean reduction of 1.99 ± 0.94 cm ($P=0.001$) was observed between the initial and final measurements after the 8-week treatment period (Figure 1). The maximum observed reduction was 4.10 cm (Figure 2). There is 95% confidence that the general population of included demographics would observe a mean circumference reduction of between 1.60 and 2.39 cm.

TABLE 1.

Baseline vs Final Treatment Statistics

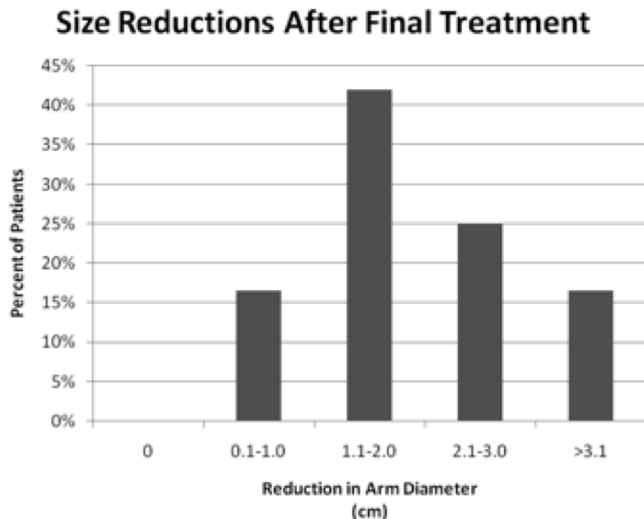
Arm	Mean \pm SD (cm) Preatreatment	Final Treatment	Mean Reduction	P-Value	Maximum Reduction (cm)
Left	28.03 \pm 3.28	26.11 \pm 2.76	1.93 \pm 0.74	0.001	3.30
Right	28.20 \pm 3.34	26.14 \pm 2.54	2.06 \pm 1.13	0.001	4.10

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FIGURE 1. Measured reductions in upper arm circumference after the final treatment.

There was no significant circumferential change between the final treatment measurements and the 4-week post-treatment follow-up for measurements from patients who completed a 4-week follow-up ($0.122\text{cm} \pm 0.24\text{cm}$; $P=0.579$, $n=18$).

Patient Assessment

Patients were instructed to use a 5-point assessment (1 = worse, 2 = no improvement, 3 = moderate improvement, 4 = good improvement, and 5 = great improvement) to subjectively evaluate improvements in size, tightness, and overall appearance from baseline. Average clinical improvement scores after the final treatment were 3.33, 3.33, and 3.58, respectively (Table 2). These scores correspond from moderate to good improvement of size, tightness, and overall appearance.

83% of patients reported seeing clinical improvement within the first 1 to 3 weeks of treatment. The remaining patients all reported seeing improvement at 4-6 weeks.

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Investigator Assessment

A blinded investigator rated the clinical improvements of size, tightness, and overall appearance of patients enrolled in the study at the initial visit and at each visit thereafter. The average investigator's clinical improvement scores for size, tightness, and overall appearance were 3.33, 3.33, and 3.41. This corresponds to a moderate to good improvement from baseline to week 8.

DISCUSSION

The primary objective of this study was to investigate the effect of a tripolar radiofrequency device on tightening skin and reducing the circumference of the posterior and anterior upper arms. The patients were evaluated on body weight change, clinical photography, circumference measurements, and clinical improvement assessments. The study was designed to detect any safety concerns attributed to the device and to monitor patient satisfaction levels.

The lack of significant data in the literature on the effects of a tripolar radiofrequency device on the upper arms prompted this study. Manuskiatti was the first to indicate the possibility of reduction of the arm, but did not indicate statistical significance. Levenberg later affirmed that potential when he observed 2 of 3 patients experiencing significant circumferential reductions of the arm (1.4cm and 2.8cm) with a tripolar system, but lacked a sufficient patient population.^{5,9} The present study demonstrates a significant reduction in upper arm circumference in a larger population of patients with all patients observing appreciable results.

In contrast to Manuskiatti, the present protocol uses an 85% increase in power (37 Watts vs 20 Watts) and an extended period of tissue temperature elevation (40-42 °C for 4 minutes vs 2 minutes). Brightman proposed that an increased duration of temperature elevation would allow for greater diffusion of heat to

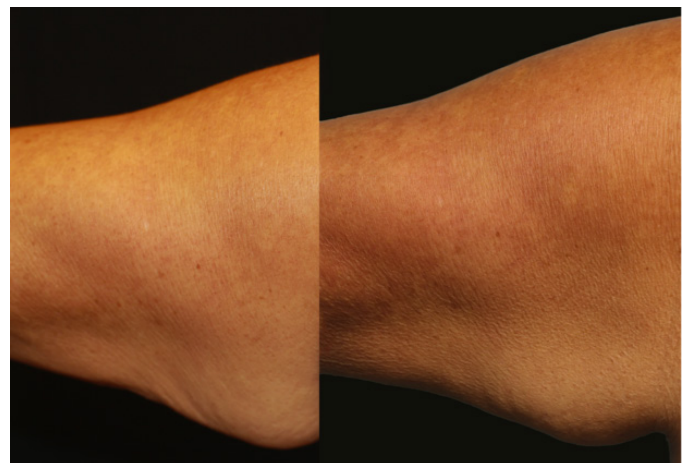
FIGURE 2. A 56-year-old, 178lb Caucasian female's left arm before treatment (left) and after 8 weeks of treatment (right). A circumferential reduction of 3.30cm was observed in this case.

TABLE 2.

Week 8 Patient Evaluations.					
Patient no.	Age	Weight	Reduction in Size	Tightness	Overall Appearance
1	66	117	3	3	3
2	55	178	3	3	4
3	58	147	4	4	4
4	55	164	3	2	3
5	66	135	4	4	4
6	60	105	4	3	4
7	62	137	4	5	5
8	62	122	4	4	4
9	56	136	3	3	3
10	58	104	2	2	2
11	65	99	3	3	3
12	33	114	3	4	4
Mean	58	129.83	3.33	3.33	3.58

A 5-point Assessment (1 = worse, 2 = no improvement, 3 = moderate improvement, 4 = good improvement, and 5 = great improvement) Was Used to Evaluate Improvements

surrounding tissue and effectively increase the extent of collagen denaturation and fat metabolism stimulation by radiofrequency treatment.¹⁰The greater observed efficacy in this study compared to previous data supports Brightman's proposal. Maintaining an elevated temperature for a longer period of time, 4 minutes, provided a significant and quantifiable circumferential reduction of the upper arm in all patients involved in this study.

The effect of tripolar radiofrequency treatment was noted to persist at least four weeks after the treatment was discontinued. Indeed the four-week follow-up measurements showed only a modest, statistically insignificant increase from the last treatment (0.122cm ± 0.24cm; $P=0.579$). This affirms current understanding that the circumference reduction effects of a tripolar radiofrequency system lasts at least 4 weeks after final treatment. Further investigation is warranted to explore the full expected duration of circumference reduction following the use of this technology through an expanded follow-up timeframe.

The study's investigator and patient improvement evaluations highlight the practical application of a tripolar radiofrequency system in improving tightness, overall appearance and size of the posterior and anterior upper arms. Indeed all of these metrics were reported to have a moderate to good improvement indicating both investigators and patients can be expected to observe changes based on a 5-point assessment scale. Though there were limitations on sample size and a lack of randomization, this is the first report to indicate consistent, significant circumferential reductions in both right and left arms for all patients involved in the study.

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In summary, our results demonstrate that a tripolar device can be used to effectively tighten skin and reduce the circumference of the posterior and anterior upper arms. These results are significant in that they extend the scope of successful treatment to the arms as other studies produced limited efficacy. Few other studies included treatment of the arm region, and those that did either yielded inconsistent results or studied a smaller population size. This study additionally confirms previous reports on the safety and efficacy of non-invasive radiofrequency technology for the treatment of excess fat and body contouring. With such understanding, a tripolar device is suitable for treatment on patients of any health condition that wish to reduce size and increase the tightness of the skin on a range of anatomical areas, without fear of permanent adverse effects.

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DISCLOSURES

None of the authors associated with this article have any commercial associations or financial interests to disclose.

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