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Unipolar radiofrequency treatment to improve the appearance of cellulite

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ORIGINAL ARTICLE

Unipolar radiofrequency treatment to improve the appearance of cellulite

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Abstract

Background: Previous studies suggest that radiofrequency (RF) energy may be effective as a treatment for cellulite. *Objective*: This bilateral paired blinded comparative study assesses the efficacy and safety of a unipolar RF device for improving the appearance of cellulite using a new quantitative cellulite grading system. *Methods*: In this randomized, blinded, split-design study, 10 individuals (aged 32–57 years) with a clinically observable excess of subcutaneous fat and cellulite (minimum grade 2 out of 4) on the thighs received up to six unilateral treatments (number of treatments at the investigator's discretion) at 2-week intervals with unipolar RF. The untreated side of the thigh served as an internal control. Treated thighs were randomly assigned by alternate allocation. Results were evaluated using study participant questionnaires and by two blinded evaluators (JSD, KAA) using photographs and the author's (MAA) cellulite grading scale at each treatment visit and at 1-month and 3-month follow-up visits after the final treatment. A novel quantitative four-point cellulite grading system is presented and applied, which separately grades dimple density, dimple distribution, dimple depth, diameter and contour. *Results*: All participants responded to treatment (mean of 4.22 and range of three to six treatments). The blinded evaluations of photographs using the cellulite grading scale demonstrated the following mean grading scores for the treated leg versus the control leg: dimple density of 2.73 vs 3.18 (11.25% mean improvement), dimple distribution 2.89 vs 3.32 (10.75% mean improvement), dimple depth 1.47 vs 1.54 (2.5% mean improvement), and mean score of 2.36 (SEM 0.45) vs 2.68 (SEM 0.57) ($8.00 \pm 2.84\%$ mean improvement). The treatment was painless and side effects included minimal to moderate erythema which resolved within 1 to 3 hours. No crusting, scarring or dyspigmentation was observed. *Conclusions*: This randomized, blinded, split-design, controlled study employing a quantitative four-point grading scale demonstrated that this unipolar RF device is safe for the treatment of cellulite. Clinically visible and quantified improvement which did not achieve statistical significance but showed a trend toward improvement was observed in all patients following a mean of four treatments at 2-week intervals.

Key words: *Body sculpting, cellulite, lasers, laxity, radiofrequency, skin tightening, unipolar, wrinkle reduction*

Introduction

The application of heat or thermal injury to skin resulting in shrinkage of redundant or lax connective tissues by collagen denaturation was first observed with ablative laser resurfacing (1). Since then, skin tightening and the treatment of cellulite specifically have been explored with non-ablative technologies. The most-studied category of devices in this arena is radiofrequency (RF) devices, which encompass that part of the electromagnetic spectrum with frequencies ranging from 3 kHz to 300 mHz. The delivery of RF is termed monopolar when the energy is applied as current between a single electrode tip and a grounding plate. When the energy is applied between two points on the tip of a probe, the electrode is considered bipolar. A newer application of RF involves the emission of electromagnetic radiation (EMR) rather than current. When RF is delivered as EMR, the delivery is called unipolar and no grounding pad is necessary.

A monopolar RF device (ThermaCool, Thermage) was the first to achieve approval by the US Food and Drug Administration (FDA) for facial wrinkle reduction in 2002, which was followed with approval for off-the-face treatments in 2006 (2,3). RF devices that combine bipolar RF with diode laser energy (4) or diode laser and intense pulsed light

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energies (5) have also been developed. The bipolar RF device (Velasmooth, Syneron) is the only device in this category to achieve FDA approval for the treatment of cellulite, which was granted in 2005 (6). The combination of diode (800 nm) laser and massage (TriActive, Cynosure) also obtained FDA approval for the treatment of cellulite in 2004 (7).

A new RF device with both unipolar and bipolar handpieces (Accent, Alma Lasers) has recently, in 2007, been cleared by the FDA for the treatment of wrinkles and rhytids. Penetrating up to 20 mm, the unipolar handpiece delivers RF energy to the subcutaneous adipose tissue, while the bipolar handpiece penetrates 2–4 mm to deliver RF energy to the dermis (8). A recent study suggests that this device is an effective and safe treatment for cellulite, with a volume reduction of 20% reported following two treatments (8). The study reported herein assesses the efficacy and safety of only the unipolar RF handpiece (Accent) for improving the appearance of cellulite.

Methods

Patient selection and randomization

This study was approved by the Essex Institutional Review Board. In this randomized, blinded-evaluated, split-design study, 10 individuals participated: age 32–57 years, mean age 48.6 years, standard deviation 7.5, skin type I–IV with a clinically observable excess of subcutaneous fat and cellulite (minimum grade 2 out of 4, employing comprehensive cellulite grading scale, see Table I).

Patients were randomized by alternate allocation to receive treatments to a unilateral thigh with the contralateral thigh serving as an internal control. Up to six unilateral treatments were performed at 2-week intervals with the unipolar RF handpiece. The number of treatments were at the investigator's discretion, but took into account the degree of improvement and patient satisfaction. Patients notified the instructor when they were satisfied with the level of improvement and wished to enter the follow-up period so that the contralateral thigh would be treated at the cessation of the follow-up interval. This ranged between three and six treatments (see 'Results').

RF protocol

Areas to be treated on the thigh were marked with grids 8×10 inches (20×25 cm) in size using a surgical marking pen (Figure 1). Mineral oil was applied to the skin. Treatment commenced on the anterior thigh, one grid at a time, followed by the posterior thigh. The unipolar RF handpiece was delivered at 150–200 W for a 30-second pass. During each pass, the handpiece is rapidly moved across the skin surface within the grid while making continual contact between the tip and the skin surface by applying gentle pressure. The handpiece should be moved in a circular motion, covering the entire surface area within the grid. Every few seconds, the skin surface temperature throughout the grid is measured until a uniform temperature is obtained. These passes were repeated at the same fluence until the skin temperature reached a target of 40–43°C, measured using an infrared surface thermometer. This temperature was selected as the desired endpoint on the basis of mathematical modeling estimating that a temperature of 60–65°C, which is required for collagen contracture, in the reticular dermis correlates with a surface temperature of 40–43°C. This was followed by three successive maintenance 30-second passes at decrements of 10 W. Once all the passes to a particular grid were administered, the aforementioned protocol was repeated for the adjacent treatment grid. Once all the grids on the anterior thigh were treated, the patient was asked to turn over for treatment of grids on the posterior thigh. A total of three to six treatments were administered at 2-week intervals.

Blinded evaluations and comprehensive grading scale

Results were evaluated by two blinded observers using both standardized before and after treatment photographs and the cellulite grading scale (Table I). The photographs were randomly ordered

Table I. Comprehensive cellulite grading scale.

Grade	Contour	Dimple density	Dimple distribution	Dimple depth	Diameter % change
0	smooth	0	0	0	$100 \times \{$[pre-post] / pre$\}$
1	1 indent	1–2/site	1 site	Shallow (1–2 mm)	
2	2 indents	3–5/site	2 sites	Moderate (3–4 mm)	
3	3 indents	6–8/site	3 sites	Advanced (5–6 mm)	
4	>3 indents	>9/site	4 or more sites	Deep (>7 mm)	

Contour: 0=smooth; 1=one indentation; 2=2 indentations; 3=3 indentations; 4=4 or more indentations; indent=overall indentation of contour to thigh. *Density*: 0=none; 1=1–2 per site; 2=3–5 per site; 3=6–8 per site; 4=9−10 or more per site. Sites (graded individually): buttock, anterior thigh upper, anterior thigh lower, posterior thigh upper, posterior thigh lower; upper refers to upper ½ and lower to lower ½ of thigh length. *Distribution*: 0=none; 1=1 site; 2=2 sites; 3=3 sites; 4=4 or more sites. *Depth*: 0=n/a; 1=shallow (1–2 mm); 2=moderate (3–4 mm); 3=advanced (5–6 mm); 4=deep ($\geqslant 7$ mm in depth). Dimple depth was estimated in the blinded evaluations of photographs. *Diameter*: mean difference in diameter (mm) on photographic superimposition.

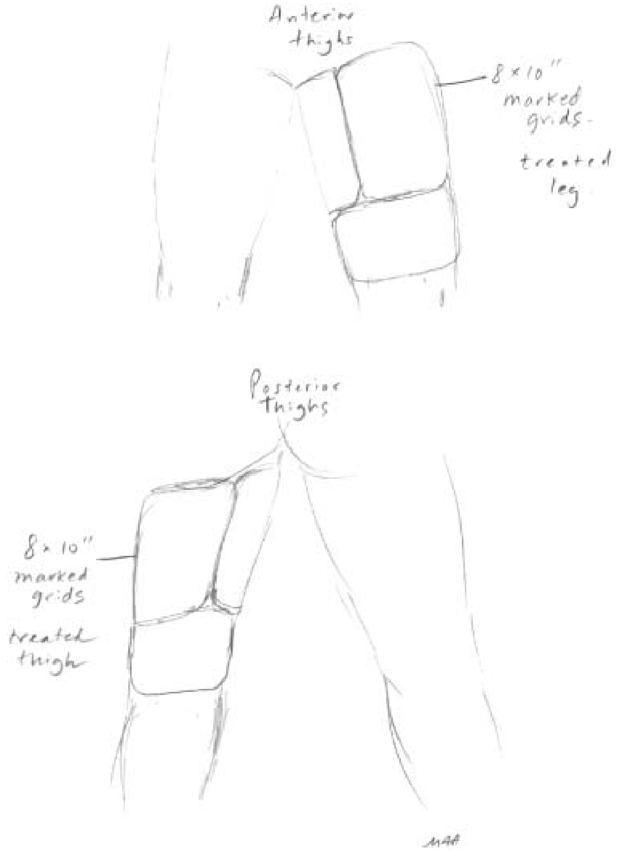


Figure 1. Schematic showing the placement of inked grids on the treated thigh. Inked grids of 8 × 10 inches (20 × 25 cm) in size are shown as they are drawn on the typical patient's thigh, usually with two grids vertically oriented on the upper thigh and one horizontal grid on the lower thigh (see 'Methods').

and not paired. Participants completed questionnaires at each treatment visit and at 1-month and 3-month follow-up visits after the final treatment. The global overall improvement was calculated as the mean of the means of improvement in each category, including dimple density, dimple distribution, and dimple depth.

Results

All patients responded to treatment following a mean of 4.22 (range 3–6) treatments at 2-week intervals.

Blinded evaluations of 3-month follow-up photographs are shown in Table II. Baseline grades were comparable between treated and control thighs with no statistically significant difference. Following treatment, improvements were observed in all categories of cellulite grading, using the quantitative classification system in Table I. The greatest improvement was observed in dimple density, with 11.25% improvement when comparing the treated versus the untreated thigh. Slightly less improvement was observed in dimple distribution, with 10.75% improvement compared to the untreated side. The least responsive parameter was the depth of the dimples, with only 1.75–2.5% improvement. The mean overall improvement of the anterior thigh was 8.25% (±3.74) and of the posterior thigh was 7.42% (±6.49), for a mean improvement of 7.83% (±3.05). The mean cellulite grade for the treated thigh was 2.36 (±0.45) compared to 2.68 (±0.57) for the untreated thigh, for a mean percentage improvement of 8.00% (±2.84) (Tables II–IV).

No significant adverse effects were observed. Mild-to-moderate erythema was observed which resolved within 1 hour in most patients and never lasted longer than 3 hours. No crusting, scarring or dyspigmentation was observed.

Clinical photographs at the 3-month follow-up interval for three of the 10 patients are shown in Figures 2–4. The treated leg is shown next to the contralateral untreated control, with evident differences in dimple density, distribution and depth between the two sides.

Discussion

The unipolar RF device used in this study for the treatment of cellulite appears to be safe with a visible and quantified efficacy that did not achieve statistical significance. Following a mean of four treatments at 2-week intervals, improvement was observed in all patients by blinded evaluation at 3 months of follow-up. The blinded evaluations were performed by two blinded evaluators (JSD, KAA). The photographs were randomly ordered and not paired during the analysis. Each thigh was graded independently but

Table II. Blinded evaluations by grades and improvements in each cellulite category.

	Anterior				Posterior			
Category	Treated Mean (SEM)	Control Mean (SEM)	Improvement (%)†	*p*-value (treated vs control)*	Treated Mean (SEM)	Control Mean (SEM)	Improvement (%)†	*p*-value (treated vs control)*
Dimple density	3.13 (0.44)	3.25 (0.41)	3.0	0.5983 NS	2.33 (0.55)	3.11 (0.47)	19.5	0.2286 NS
Dimple distribution	3.11 (0.48)	3.75 (0.25)	15.5	0.1395 NS	2.67 (0.50)	2.89 (0.45)	5.5	0.3466 NS
Dimple depth	1.50 (0.42)	1.75 (0.37)	6.25	0.5983 NS	1.44 (0.24)	1.33 (0.24)	−2.75	0.5943 NS
Mean score	2.58 (0.54)	2.92 (0.60)	8.25 (3.74)	0.6537 NS	2.15 (0.37)	2.17 (0.35)	7.42 (6.49)	0.6953 NS

*Paired *t*-test. †Improvement (%) = (mean control leg score – mean treated leg score / 4) × 100. SD = standard deviation; SE = standard error of the mean.

Table III. Improvements (%) in cellulite grading categories by blinded evaluations.

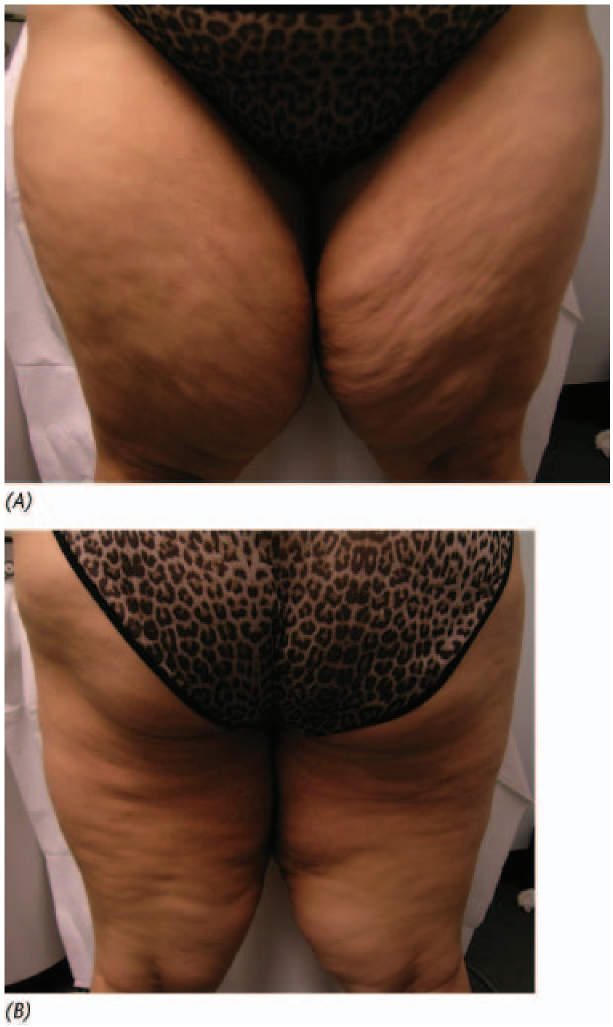
Category	Anterior	Posterior	Mean of anterior and posterior
Density	3.00	19.5	11.25
Distribution	15.50	5.5	10.50
Depth	6.25	−2.75	1.75
Mean (SEM)	8.25 (3.74)	7.42 (6.49)	7.83 (3.05)

SEM=standard error of the mean. Improvement (%)=(mean control leg score – mean treated leg score / 4) × 100.

Table IV. Grades* and improvements in cellulite grading categories by blinded evaluation.

Category	Treated leg	Control leg	Improvement (%)
Density	2.73	3.18	11.25
Distribution	2.89	3.32	10.75
Depth	1.47	1.54	2.50
Mean (SEM)	2.36 (0.45)	2.68 (0.57)	8.00 (2.84)

*Mean of anterior and posterior grades (Table II) SEM= standard error of the mean. Improvement (%)=(mean control leg score – mean treated leg score / 4) × 100.



(A)

(B)

Figure 2. A patient whose right thigh received four treatments with unipolar RF, with the left thigh serving as the untreated control. Anterior (A) and posterior (B) thighs are shown at 3 months of follow-up.

on the same photograph as the contralateral thigh using the quantitative grading scale (Table I). The study design and direct comparison of the two thighs precludes issues of lighting, weight or muscle mass changes, or subjective evaluation. The mean overall cellulite improvement was 8%, with improvement in dimple density of 11.3%, dimple distribution of 10.8%, and dimple depth of 2.5% observed in treated versus untreated thighs as quantitatively scored by two blinded evaluators (Tables II–IV). Although the improvements did not achieve statistical significance, the data indicate a trend toward improvement. The validity of the statistical analysis is limited due to the small number of patients. The encouraging results of this study warrant additional studies with more patients and higher statistical power.

The current device improved the appearance of cellulite following a relatively small number of treatments. The combination of bipolar RF, red light (700–1500 nm) and 200 millibar vacuum suction at 750 mmHg negative pressure (Velasmooth) is the only RF device FDA approved for the treatment of cellulite. The typical treatment regimen for this device is eight to 12 treatments at an interval of twice weekly. In several studies, this device improved cellulite and decreased thigh circumference following eight to 12 treatments in sample sizes ranging from 16 to 20 patients (6,7,9). In a randomized study comparing treated with untreated control thighs, a 0.8-cm reduction of thigh circumference was noted (6). In another similar study design of 16 patients, a reduction of 0.44–0.53 cm in the thigh circumference was reported (9). Use of the diode laser (800 nm) and massage (TriActive) has also been reported to visibly improve the appearance of cellulite following 12 treatments with no demonstrable difference in efficacy when compared to bipolar RF, red light and suction (7). In a randomized, comparative trial of 20 patients comparing the TriActive to the VelaSmooth, no statistically significant differences in reduction of thigh circumference or perceived changes in cellulite were detected between the two devices (7). The mechanism of improving the appearance of cellulite is unclear, but may be due to collagen contracture and neocollagenesis at the subcuticular junction and possibly due to lipolysis, although the hypothesized lymphatic drainage of dissolved fat remains theoretical. In the current study, a visible improvement was achieved following a mean of only four treatments spaced at 2-week intervals. Although comparative trials are needed, the current findings suggest that improvement may be achieved following a small number of treatments with this unipolar RF device. On the other hand, the current RF device does require a certain degree of technical expertise and the treatment

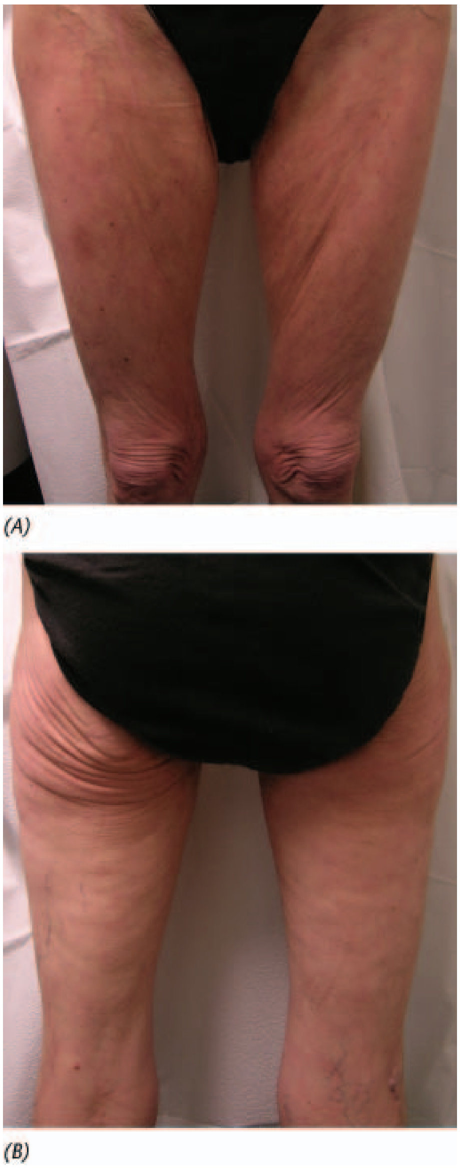


Figure 3. A patient whose right thigh was treated with three sessions of unipolar RF, with the left thigh as the untreated control. Anterior (A) and posterior (B) thighs are shown at 3 months of follow-up.

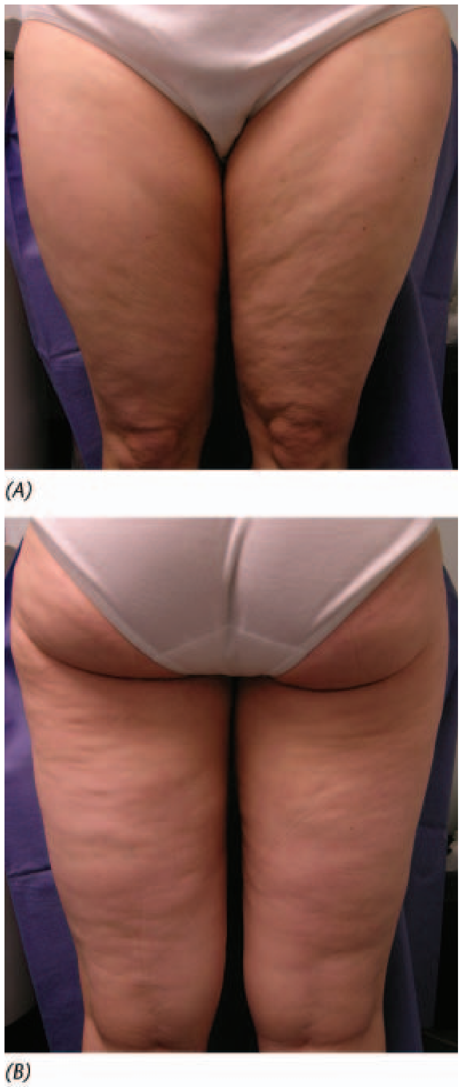


Figure 4. An example of a patient 3 months after four treatments with unipolar RF to the right thigh, with the left thigh serving as the untreated contralateral control. Anterior (A) and posterior (B).

sessions for bilateral thighs would require approximately 30 minutes, which is more time intensive than prior modalities.

The mechanism by which RF improves the appearance of cellulite may be due to collagen contracture and neocollagenesis at the subcuticular junction and possibly due to lipolysis, although the hypothesized lymphatic drainage of dissolved fat remains unproven. Cellulite is due to the herniation of subcuticular fat into the dermis. This is likely the result of a weak connective tissue structure in the deep dermis. Hormonal factors may be important in the development of this dermo-subcutaneous lattice, as cellulite is almost always observed in women and rarely in men. When a rapidly oscillating electromagnetic field such as RF is applied to tissues, charged particles in the tissue begin to move and this molecular motion resists the flow of current. This resistance to molecular movement generates heat by Ohm's law. A reverse thermal gradient is created through contact cooling, wherein temperatures increase with dermal depth). When dermal tissue reaches 65–75°C collagen denatures, wound healing begins, collagen contracts, and skin becomes tighter (10). Further neocollagenesis may explain the delayed improvements in laxity observed over many months. The increase in collagen formation at the dermal–subcutaneous junction has been demonstrated (11). The use of electromagnetic energy to lyse adipocytes has been postulated and may be a mechanism in the case of unipolar RF since a depth of penetration of 20 mm has been reported as an estimate (8). The application of ultrasound wavelengths may be operating in this manner (Alexiades-Armenakas, unpublished observations). It will be interesting to observe whether the most effective approach to cellulite treatment will be the augmentation of the collagen matrix at the dermo-subcuticular junction and to what degree lipolysis will play a role in the future of these therapeutic light and energy sources.

Conclusion

The unipolar RF device is safe for the treatment of cellulite. In this bilateral, paired, blinded comparative trial, the differences between the two sides were clinically visible and quantified by a grading scale and showed a trend toward improvement, though did not achieve statistical significance. In addition, the improvement was attained following a mean of four treatment sessions, making this technology a potentially important advance to the field.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

References

1. Ross EV, McKinlay JR, Anderson RR. Why does carbon dioxide resurfacing work? A review. Arch Dermatol. 1999;135:444–54.
2. Hsu TS, Kaminer MS. The use of nonablative radiofrequency technology to tighten the lower face and neck. Semin Cutan Med Surg. 2003;22:115–23.
3. Fitzpatrick R, Geronemus R, Goldberg D, Kaminer M, Kilmer S, Ruiz-Esparza J. Multicenter study of noninvasive radiofrequency for periorbital tissue tightening. Lasers Surg Med. 2003;33:232–42.
4. Sadick N, Alexiades-Armenakas M, Bitter P, Hruza G, Mulholland S. Enhanced full-face skin rejuvenation using synchronous intense pulsed optical and conducted bipolar radiofrequency energy (ELOS): Introducing selective radiophotothermolysis. J Drugs Dermatol. 2005;4:181–6.
5. Alexiades-Armenakas MR. Rhytides, laxity and photoaging treated with a combination of radiofrequency, diode laser, and pulsed light and assessed with a comprehensive grading scale. J Drugs Dermatol. 2006;5:609–16.
6. Alster TS, Tanzi EL. Cellulite treatment using a novel combination radiofrequency, infrared light, and mechanical tissue manipulation device. J Cosmet Laser Ther. 2005;7:81–5.
7. Nootheti PK, Mogpantay A, Yosowitz G, Calderon S, Goldman MP. A single center, randomized, comparative, prospective clinical study to determine the efficacy of the VelaSmooth system versus the Triactive system for the treatment of cellulite. Lasers Surg Med. 2006;38:908–12.
8. Del Pino E, Rosado RH, Azuela A, Graciela Guzmán M, Arqüelles D, Rodríguez C, et al. Effect of controlled volumetric tissue heating with radiofrequency on cellulite and the subcutaneous tissue of the buttocks and thighs. J Drugs Dermatol. 2006;5:714–22.
9. Sadick N, Magro C. A study evaluating the safety and efficacy of the VelaSmooth system in the treatment of cellulite. J Cosmet Laser Ther. 2007;9:15–20.
10. Fisher GH, Jacobson LG, Bernstein LJ, Kim KH, Geronemus RG. Nonablative radiofrequency treatment of facial laxity. Dermatol Surg. 2005;31(9 Pt 2):1237–41.
11. Goldberg DJ, Fazeli A, Berlin AL. Clinical, laboratory, and MRI analysis of cellulite treatment with a unipolar radiofrequency device. Dermatol Surg. 2008;34:204–9.