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CASE REPORT AND SHORT REPORT

A bipolar radiofrequency, infrared, vacuum and mechanical massage device for treatment of cellulite: A pilot study

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Abstract

Cellulite has a complex and multifactorial etiology. Synergistic action on treating cellulite has gained support in the treatment of cellulite. This study evaluated safety and efficacy of a bipolar radiofrequency, infrared, vacuum and mechanical massage device for cellulite treatment and reduction of body measures. This was a pilot study, which assessed 9 subjects who presented body mass index from 18 to 25 Kg/Kg and at least grade 6 in the Cellulite Severity Scale (CSS). All subjects underwent a 12-session treatment of posterior thighs and buttocks. There was a significant reduction of the hip circumference ($p = 0.001$), however, no changes in thigh circumferences were observed ($p = 0.4$). CSS has improved specifically on both buttocks [$p = 0.002$ (left side) and $p = 0.038$ (right side)], and no changes were observed on thighs. The studied device demonstrated efficacy in the reduction of cellulite severity and body circumference measures in the buttocks.

Key Words: *bipolar radiofrequency, cellulite, infrared, vacuum and mechanical massage*

Introduction

Cellulite is considered a non-inflammatory disorder of the subcutaneous tissue, giving the skin an orange peel, cottage cheese or mattress appearance (1,2). The pathogenesis of cellulite is not completely understood and multiple etiologies have been mentioned in the literature (1). These include alterations in the adipose tissue and in the microcirculation, sexually dimorphic skin architecture associated with hormonal and genetic influences (1,2). Flaccidity, laxity or sagging of the skin further aggravates relief alterations in most of the patients.

Cellulite is nearly ubiquitous in woman after puberty. It mainly affects thighs and buttocks, nevertheless other areas of the body such as abdomen, arms and back may also be affected (3–5). Although it is not a disease, cellulite remains a common cause of embarrassment and great concern for many women (6).

Diverse modalities of treatments have been proposed to treat this condition (7). They range from non-invasive treatments such as weight loss, massage and topical creams to invasive procedures such as laser-assisted lipolysis, liposuction and Subcision® (8). Recently, non-invasive devices employing radiofrequency and light technologies have gained support and popularity in the treatment of cellulite. As cellulite has a complex and multifactorial etiology, synergistic action on treating cellulite may be necessary to achieve promising clinical results (9).

Velashape™ is approved by the US Food and Drug Administration (FDA) for cellulite treatment and circumferential reduction (10). It delivers broad-spectrum infrared light (IR), bipolar radiofrequency (RF) and vacuum suction pulses to the skin surface with a handheld aplicator (11). The IR and RF act synergically, promoting heating in the target tissue, collagen remodelling and improvement of the adipose tissue metabolic rate (11,12). The negative pressure vacuum massage improves circulation and also allows the treatment of both the superficial and deeper dermal layers (11–13).

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The aim of this study was to evaluate safety and efficacy of this device for cellulite treatment and reduction of body measures, as well as to assess subjects' satisfaction.

Methods

This was a pilot study performed at the Brazilian Center for Studies in Dermatology, in Porto Alegre, Brazil, in accordance with good clinical practices. Eleven female subjects aged from 19 to 45 were enrolled and nine completed the study. All subjects provided written consent, however, one retreated for personal reasons and removed the consent.

The main inclusion criteria were: body mass index (BMI) from 18 to 25 kg/m^2, stable body weight in the previous four months, availability to maintain stable body weight ($\pm$ 1 kg) along the study, and at least grade 6 in the Cellulite Severity Scale (CSS) (14). Exclusion criteria included: pregnancy, recent exposure to the sun, intense physical activity, liposuction or Subcision® in the previous three months and the use of topical products to treat cellulite.

All subjects underwent a 12-session treatment with a bipolar radiofrequency, infrared, vacuum and mechanical massage device (Velashape®, Syneron™ Medical Ltd., Yokneam Illit, Israel), performed for 6 weeks and following the same patterns: each session lasted one hour in average and a specific lotion (VelaSpray Ease™) was used to promote a better performance of the device. Application technique included back and forward, circular and zigzag movements, and it was performed exclusively by qualified and trained massage therapists. Posterior thighs and buttocks were the treated areas for all subjects.

Subjects attended to 4 evaluation visits: screening/baseline (V1), after 6 sessions (V2), after 12 sessions (V3), and 4 weeks after having completed the treatment (V4). Investigators performed the following examinations in these visits: CSS grading, BMI and thigh and hips circumferences.

The CSS includes the assessment of important clinical and morphological aspects: number of evident depressions; depth of depressions; morphological appearance of skin surface alterations; grade of laxity, flaccidity or sagging skin; classification by Nürnberger and Müller. Each morphological aspect of cellulite is graded from 0 to 3, allowing a final sum of scores which ranges numerically from 1 to 15. This scale allows a quantitative and qualitative classification (14) of cellulite as mild: 1–5, moderate: 6–10, or severe: 11–15. Clinical evaluation and cellulite grading were performed by the same dermatologist in all visits (MDP).

Hip circumferences were obtained at: 5 cm below iliac crest; 5 cm below the first measure; 5 cm below the second measure. And thigh circumferences were measured at 10 cm above the patella, 10 cm above the first measure and 10 cm above the second measure. Photographs were taken in all visits according to standardized light patterns, position and camera settings. Besides these procedures, subjects answered self-assessment and satisfaction questionnaires at visits 2, 3 and 4. A urinary pregnancy test was performed at V1 and V4 for all subjects of childbearing potential.

Demographic data were expressed as mean $\pm$ standard deviation, percent and absolute number. CSS grading, body circumferences, and BMI data were analyzed using McNemar test and Friedman test (SPSS 16.0 Inc. Chicago, IL). Additionally, data acquired through the self-assessment and satisfaction questionnaires were descriptively analyzed.

Results

In this study, 11 female subjects were evaluated: one patient removed consent, and one patient dropped-out because of pain related to the treatment after first session. Therefore, data from nine subjects are described. The mean age of the patients was 28 $\pm$ 8 years old, and the mean age at cellulite onset was 16 $\pm$ 5 years old. Most of them were Fitzpatrick skin phototype III (66%, $n = 6$). The BMI of the subjects ranged between 18.5 and 24.9, mean 22.3 $\pm$ 1.6 kg/m^2. As expected, no changes on BMI were observed along the visits ($p = 0.72$), since stable body weight was an inclusion criteria. Table I describes the cellulite scores according to the CSS at baseline, in each area evaluated in this study. Significant changes were observed along the study. Cellulite grade has improved specifically on both buttocks $p = 0.002$ (left side) and $p = 0.038$ (right side), and no changes were observed on the thighs (Table II). Table III describes the variation of hip and thigh circumferences along the study: there was a significant reduction of the hip circumference. However, no changes in thigh circumferences were observed (Figures 1 and 2).

Table I. Grade of cellulite according with absolute result and the CSS.

Subject number	Right buttock	Left buttocks	Right thigh	Left thigh
1	8	8	12	12
2	10	10	10	10
3	13	13	8	9
4	8	8	–	8
5	6	8	7	9
6	7	8	7	9
7	14	14	7	7
8	11	11	11	13
9	7	7	7	7

From 1 to 5 points: mild; from 6 to 10 points: moderate; from 11 to 15 points: severe at CSS.

Table II. CSS grading during the study (before, during and post-treatment).

Area	V1	V2	V3	V4	*p*
Right gluteus	9.3 ± 2.8	7.9 ± 1.5	7.9 ± 2.6	7.3 ± 2.2	0.04
Left gluteus	9.6 ± 2.5	8.7 ± 2.1	8.7 ± 2.5	7.6 ± 2.6	0.002
Right thigh	8.6 ± 2.0	8.4 ± 1.7	8.6 ± 1.9	7.5 ± 2.2	0.35
Left thigh	9.3 ± 2.0	8.4 ± 2.0	8.5 ± 1.7	8.0 ± 2.3	0.20

Self-assessment and satisfaction questionnaires demonstrated that all subjects were bothered by cellulite's presence in, at least, one moment of their lives. All of them considered that there was an improvement in their cellulite appearance and most of them considered the improvement was fast: six of them observed improvement at the third week and one at the second week of treatment. Most of the subjects ($n = 7$) reported reduction in their body circumferences, mostly perceived in the buttocks ($n = 5$). When questioned about treatment satisfaction, most of the subjects reported they were satisfied, and all of them stated they would undergo this treatment again.

Discussion

This was a pilot study that evaluated the safety and efficacy of a bipolar radiofrequency, infrared, vacuum and mechanical massage device for the treatment of cellulite.

The methodology for this study was developed based on the manufacturer's definitions regarding the device settings, application techniques and frequency between applications. The CSS (14) was the tool chosen to assess cellulite severity. It is a photonumeric scale that objectively adds additional morphologic characteristics of cellulite to the previous classification (15). The CSS allows a consistent evaluation of the results obtained with treatment rather than just a subjective opinion on the reduction of cellulite.

Results showed significant improvement on the cellulite severity grading on the buttocks. Additionally, the measures of body circumference were also statistically significantly lower for the hips at the final visit. Reinforcing these results, participants' opinion suggested effectiveness of the tested device on the buttocks.

Cellulite severity on the thighs decreased along the study; however, it was not statistically significant. Similarly, thigh circumferences did not present statistically significant differences between baseline and final visit.

Since no changes in the BMI were observed along the study, it is possible to infer that patients followed recommendation of maintaining stable body weight (± 1 kg). This is important because larger variations of weight would be a bias, since it directly influences cellulite grading and body circumferences.

Another important result was obtained with self-assessment and satisfaction questionnaire, which indicated that all the subjects felt bothered by the presence of cellulite in at least one moment of their lives. These data are supported by some publications (6,16,17), which report cellulite as cause of embarrassment in social and affective relations.

A study reported the benefits of the studied device (12). Its efficacy and safety evaluated on upper arms, abdominal and flank circumferences showed significant reduction in circumference and improvement in appearance of arms and abdomen following treatment with this device (12). Other studies (13,18–20) have been conducted with a similar device (Velasmooth®, Syneron™ Medical Ltd., Yokneam Illit, Israel) which presents a technology also based on the simultaneous application of light energy to the tissue at a controlled infrared wavelength, conducted RF energy and mechanical manipulations of the skin and fat layer, but with a lower wattage system (12). These studies (13,18–20) showed that this device acts safely on the reduction of body measures and cellulite appearance.

The small sample size was a limitation of the present trial. This could explain the lack of statistically significant difference for CSS grading and circumferences for thighs along the treatment. Additionally, results regarding self-assessment and satisfaction

Table III. Circumference of the hip, right thigh and left thigh in four different visits (cm) for each subject.

Subject	Hip 1	Hip 2	Hip 3	Hip 4	Right thigh 1	Right thigh 2	Right thigh 3	Right thigh 4	Left thigh 1	Left thigh 2	Left thigh 3	Left thigh 4
1	96.0	93.6	93.7	93.8	54.3	52.6	53.2	52.5	53.6	52.6	54.0	52.8
2	102.5	101.8	100.0	100.3	54.8	54.7	54.7	55.2	54.2	54.6	57.3	54.3
3	98.5	97.5	96.27	96.0	50.5	50.5	50.4	50.0	51.2	50.5	50.7	50.5
4	89.5	89.0	88.5	87.8	48.8	48.8	48.2	48.7	47.8	48.8	47.2	47.3
5	96.0	95.3	94.7	93.9	52.3	52.2	51.8	51.3	52.5	52.2	51.7	51.3
6	83.7	83.5	83.2	83.7	48.8	47.7	46.4	47.2	47.6	47.7	46.4	47.0
7	94.5	94.5	94.2	94.0	53.8	52.8	52.3	52.5	55.2	52.8	51.5	51.7
8	97.8	96.8	95.5	96.0	51.6	49.8	50.3	51.2	52.0	49.8	51.2	51.2
9	98.6	98.7	98.0	99.0	51.5	51.7	51.5	52.1	50.5	51.6	50.7	52.2
Mean	95 ± 6	94 ± 5	94 ± 5	94 ± 5[a]	51 ± 2	51 ± 2	51 ± 3	51 ± 2[b]	51 ± 2	51 ± 2	51 ± 3	51 ± 2[b]

[a] $p = 0.001$, [b] $p = 0.4$ Friedman test.

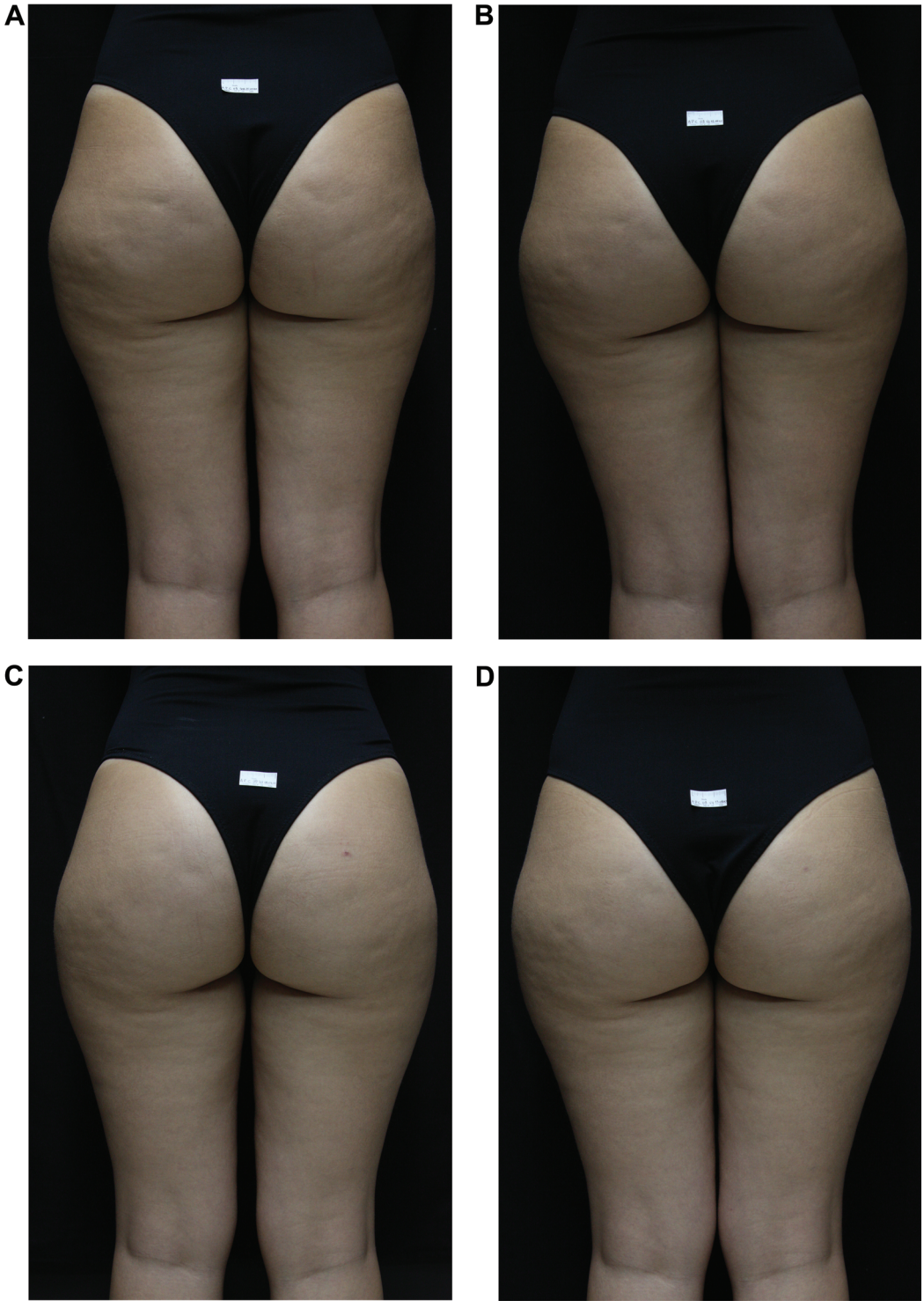

Figure 1. Subject 09 (A) at baseline; (B) after 6 sessions of treatment; (C) after 12 sessions of treatment; (D) one month after the last session of treatment.

questionnaires did not have any statistical treatment.

Considering that cellulite has an impact on the quality of life of both younger and more mature women, a significant number of treatments are being promoted, but few studies have been conducted to evaluate the results of different treatment modalities. This study showed the efficacy of a non-invasive treatment in cellulite appearance as well as indicated patient's satisfaction with results.

***Declaration of interest*:** This study was supported by the authors. The authors have no conflict of interest to disclose. The authors hereby affirm that neither

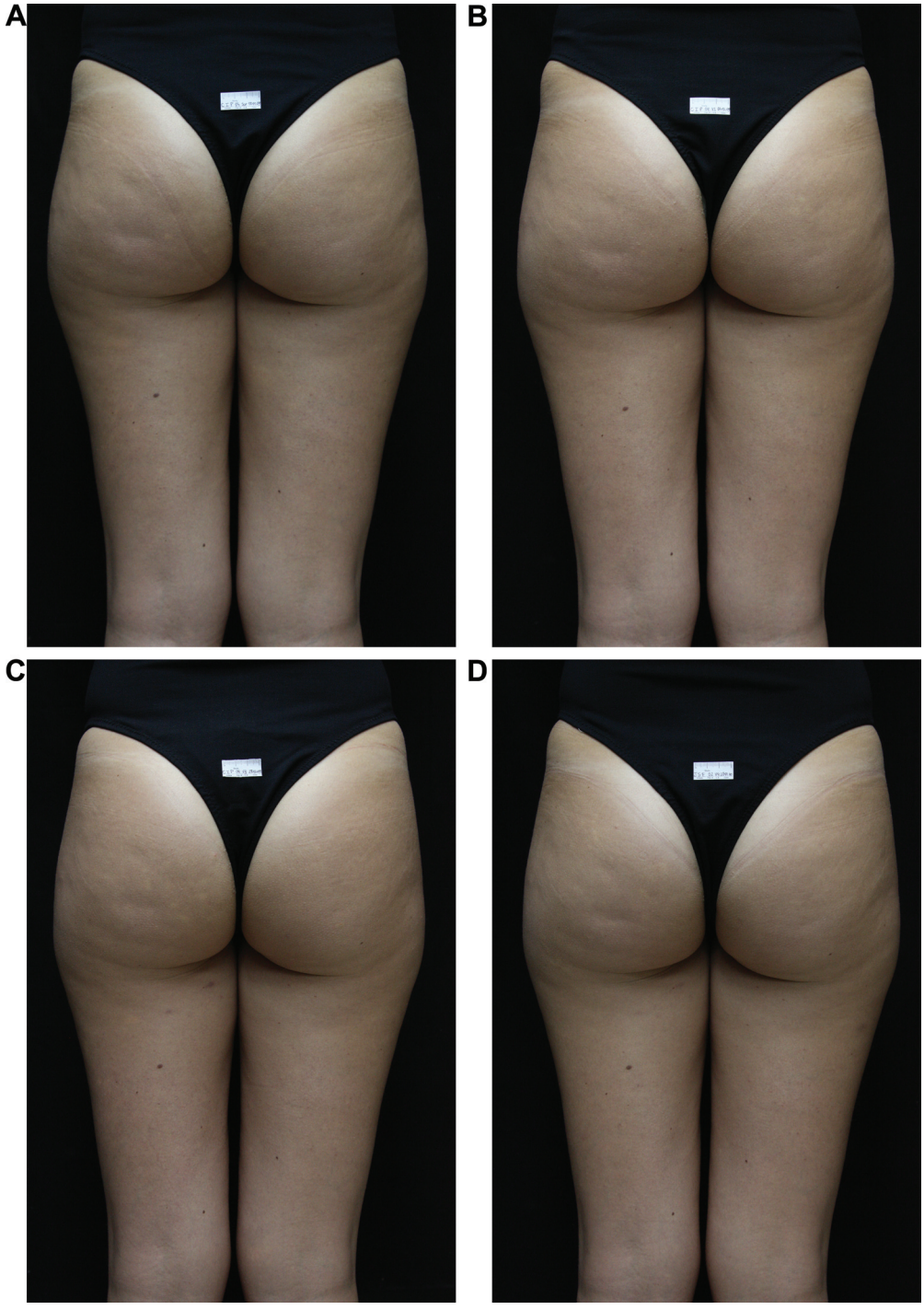

Figure 2. Subject 04 (A) at baseline; (B) after 6 sessions of treatment; (C) after 12 sessions of treatment; (D) 1 month after the last session of treatment.

the manuscript nor any part of it has been published or is being considered for publication elsewhere.

References

1. Khan MH, Victor F, Rao B, Sadick NS. Treatment of cellulite: Part I. Pathophysiology. J Am Acad Dermatol 2010; 62(3):361–70; quiz 371–2.
2. Hexsel DM, Abreu M, Rodrigues TC, Soirefmann M, do Prado DZ, Gamboa MM. Side-by-side comparison of areas with and without cellulite depression using magnetic resonance imaging. Dermatol Surg 2009;35(10):1471–77.
3. Wanner M, Avram M. An evidence-based assessment of treatments for cellulite. J Drugs Dermatol. 2008;7(4):341–345.
4. Ortonne JP, Zartarian M, Verschoore M, Queille-Roussel C, Duteil L. Cellulite and skin ageing: is there any interaction? Eur Acad Dermatol Venereol 2008;22(7):827–34.
5. Hexsel DM, Dal'forno T, Hexsel CL. A validated photonumeric cellulite severity scale. J Eur Acad Dermatol Venereol. 2009;23(5):523–528.
6. Hexsel D, Hexsel C, Weber M. Social Impact of Cellulite and its impact on quality of life. In: Goldman MP, Hexsel D, eds.

Cellulite: Pathophysiology and treatment. 2nd edition. New York: Taylor & Francis; 2010. pp. 1–4.
7. Rawlings AV. Cellulite and its treatment. Int J Cosmet Sci. 2006;28(3):175–190.
8. Hexsel D, Dal' Forno T, Soirefmann M, Hexsel C. Reduction of cellulite with Subcision®. In: Alam M, Pongprutthipan M, eds. Body Rejuvenation. New York: Taylor and Francis 2010; pp. 167–72.
9. Khan MH, Victor F, Rao B, Sadick NS. Treatment of cellulite: Part II. Advances and controversies. J Am Acad Dermatol 2010;62(3):373–84; quiz 385–6.
10. Trelles MA, Mordon SR. Adipocyte membrane lysis observed after cellulite treatment is performed with radiofrequency. Aesthetic Plast Surg. 2009;33(1):125–128.
11. Sadick NS. VelaSmooth and VelaShape. In: Goldman MP, Hexsel D, eds. Cellulite: Pathophysiology and Treatment. 2nd edition. New York: Taylor & Francis; 2010. pp. 108–114.
12. Brightman L, Weiss E, Chapas AM, Karen J, Hale E, Bernstein L, Geronemus RG. Improvement in arm and postpartum abdominal and flank subcutaneous fat deposits and skin laxity using a bipolar radiofrequency, infrared, vacuum and mechanical massage device. Lasers Surg Med 2009; 41(10):791–8.
13. Alster TS, Tanzi EL. Cellulite treatment using a novel combination radiofrequency, infrared light, and mechanical tissue manipulation device. J Cosmet Laser Ther. 2005;7(2):81–85.
14. Hexsel D, DalForno T, Hexsel CL. Severity Scale of Cellulite. J Eur Acad Dermatol Venereol. 2009;23:523–528.
15. Nürnberger F, Müller G. So-called cellulite: an invented disease. J Dermatol Surg Oncol. 1978;4:221–229.
16. Brum C. Psychological Impact of Cellulite on the Affected Patients. In: Goldman MP, Hexsel D, eds. Cellulite: Pathophysiology and treatment. 2nd edition. New York: Taylor & Francis; 2010. pp. 5–7.
17. Hexsel D, Brum C, Rodrigues TC, Mazzuco R. Psychologic aspects of women who underwent cellulite treatments: Pilot study. Poster presented at 67th Annual Meeting of American Academy of Dermatology, March 6–10th, 2009. San Francisco, California- PP1131.
18. Wanitphakdeedecha R, Manuskiatti W. Treatment of cellulite with a bipolar radiofrequency, infrared heat, and pulsatile suction device: a pilot study. J Cosmet Dermatol. 2006;5(4): 284–288.
19. Sadick NS, Mulholland RS. A prospective clinical study to evaluate the efficacy and safety of cellulite treatment using the combination of optical and RF energies for subcutaneous tissue heating. J Cosmet Laser Ther. 2004;6(4):187–190.
20. Romero C, Caballero N, Herrero M, Ruíz R, Sadick NS, Trelles MA. Effects of cellulite treatment with RF, IR light, mechanical massage and suction treating one buttock with the contralateral as a control. J Cosmet Laser Ther 2008; 10(4):193–201.