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

Lori Brightman, MD,* Elliot Weiss, MD, Anne M. Chapas, MD, Julie Karen, MD, Elizabeth Hale, MD, Leonard Bernstein, MD, and Roy G. Geronemus, MD
Laser & Skin Surgery Center of New York, New York, New York 10016

Background and Objectives: Skin laxity of the body is a growing cosmetic concern. Laxity can result from chronological or photoaging and changes in body dimensions during pregnancy or weight loss. The end result is loose, sagging skin, and localized fat deposits. Liposuction and abdominoplasty or brachioplasty are established approaches to these issues. Patient desire for alternatives to surgical correction has spawned the development of non-invasive body contouring devices. The combination of infrared light (IR), bipolar radiofrequency (RF), vacuum and mechanical massage (Velashape, Syneron Medical Ltd, Israel) has demonstrated efficacy in improving skin appearance and circumference of the thighs [Goldberg et al., Derm Surg 2008; 34:204–209; Fisher et al., Derm Surg 2005; 31:1237–1241; Arnoczky and Aksan, J Am Acad Orthop Surg 2000; 8:305–313; Alster and Tanzi, J Cosmetic Laser Therapy 2005; 7:81–85; Wanitphakdeedecha and Manuskiatti, J Cosmet Dermatol 2006; 5:284–288; Nootheti et al., Lasers Surg Med 2006; 38: 908–912], but only anecdotal evidence has supported its use on other anatomic locations. This study was designed to evaluate the efficacy and safety of Velashape on additional body sites and more rigorously examine the technology's impact on upper arm as well as abdominal and flank circumference.

Study Design and Methods: Subjects were 28–70 years old, skin types I–V. Nineteen subjects underwent 5 weekly treatments of the upper arms, and 10 subjects underwent 4 weekly treatments of the abdomen and flanks. Treatments were performed using Velashape. Circumference measurements, photographs, and subject weights were performed prior to treatment and at 1- and 3-month follow-ups. Subjects were asked to record their treatment satisfaction level.

Results: Change in arm circumference, at the 5th treatment was statistically significant with a mean loss of 0.625 cm. At 1- and 3-month follow-ups, mean loss was 0.71 and 0.597 cm respectively. Reduction of abdominal circumference at 3rd treatment was statistically significant with a 1.25 cm mean loss. At 1- and 3-month follow-ups, average loss was 1.43 and 1.82 cm respectively.

Conclusions: This study demonstrates with statistical significance, sustainable reduction in circumference and improvement in appearance of arms and abdomen following treatment with Velashape. Lasers Surg. Med. 41:791–798, 2009. © 2009 Wiley-Liss, Inc.

Key words: Velashape, circumferential reduction, body contouring, skin laxity, tightening

INTRODUCTION

Tissue laxity and localized subcutaneous fat deposits on the body are increasingly common complaints amongst our cosmetic patients. Chronological aging, photo-aging or substantial changes in body dimensions experienced during pregnancy or weight loss can all contribute to the formation of lax skin and localized fat. The most popular cosmetic procedures for addressing body contouring and tightening are surgical in nature with just under 500,000 cases of liposuction and abdominoplasty or brachioplasty reported as being performed in 2007 [1,2]. While surgical correction undoubtedly produces the most definitive results, it also requires significant recovery time for patients and carries inherent risks. These factors, along with today's cosmetic patients' active lifestyles and desire for results with minimal potential sequelae, have spawned the development of many new non-invasive body contouring devices to mitigate skin laxity and reduce body circumference.

Non-invasive tissue tightening and circumference reduction are postulated to result from the application of energy to the skin surface producing heat in the dermal and subcutaneous tissues with subsequent induction of collagen denaturation and neocollagenesis. These heat-stimulated effects were originally noted with ablative laser resurfacing [3,4]. Non-invasive technologies have evolved over time to induce the same tightening effects [5–10].

*Correspondence to: Lori Brightman, MD, Laser & Skin Surgery Center of New York, 317 East 34th street, New York, NY 10016. E-mail: lbrightman@laserskinsurgery.com
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It is well documented that when collagen is heated to 65–75°C, there is immediate collagen triple helix denaturation with subsequent recoil and contraction. This results in shorter, tighter collagen polymers as well as the long term remodeling effects of new collagen deposition and fibroplasia [3–5,9,11–14]. With non-invasive body tightening technology, these immediate and long-term thermal effects correspond clinically to a reduction in skin laxity and subsequent circumference reduction [4,5,7–11,13,15].

Non-invasive tightening devices currently include laser, broadband light (including infrared) and RF. Although laser- and light-based devices can target the deep dermal layers, the thermal effects of these devices are limited due to light scattering and energy absorption by the epidermal chromophore melanin [9]. Radiofrequency is electromagnetic energy ranging from 3 kHz to 1 MHz. Radiowaves are not scattered or absorbed by epidermal melanin, and can therefore treat all skin types and generate significant heat without jeopardizing epidermal integrity. The way in which RF energy can be delivered includes monopolar, unipolar, and bipolar. When RF current is delivered via one electrode tip to the skin surface with a grounding plate, it is a monopolar delivery system. When there is no grounding plate, it is unipolar delivery of current. Bipolar delivery occurs when there are two electrode tips and energy current is delivered between the two tips [4,5,9,13]. The electro-optical synergy (ELOS) technology device Velashape includes IR, bipolar RF, vacuum and mechanical massage. This technology was the first U.S Food and Drug Administration (FDA) class II medical device to receive clearance for cellulite reduction and the first to achieve approval for circumferential reduction in 2007 [16]. This combination of energies was developed in effort to address the confines of laser- and light-based technologies such as energy scatter and melanin energy absorption. This dual energy treatment allows for synergistic effects of energy with IR preheating the target tissue, mitigating impedance, allowing greater attraction of the RF current [5,7–9,13,17]. Prior clinical trials performed with a lower wattage system (Velasmooth) have demonstrated safety and efficacy in minimizing the appearance of cellulite and in generating circumferential reduction of thighs [5,16–22]. This study assesses the safety and efficacy of the 50 W electrooptical energy system on two different anatomical sites.

METHODS

The Essex Institutional Review Board approved this study. In this non-randomized clinical trial, all accrued subjects were healthy 28- to 70-year-old females with skin types I–V with clinically appreciable skin laxity and localized subcutaneous fat deposits of the upper arms or abdomen and flanks. Nineteen subjects underwent 5 weekly treatments of the upper arms, and 10 subjects (at least 9 months post-partum) underwent 4 weekly treatments of the abdomen and flanks with a combination of 50 W bipolar RF, 20 W IR (700–1,500 nm) and 200 mbar vacuum (750 mm Hg negative pressure).

Measurements of arm or abdominal circumference were performed at baseline, prior to each treatment, and at 1 and 3 months follow-up and in come cases 6 months follow-up. All measurements were taken with a Gullick II measuring tape. Baseline measurements were taken of the subjects' arms at the widest point of the upper arm. This measurement site was documented by recording the distance from the most distal point of the elbow. During the measuring process, the elbow and shoulder were both held at 90° angles to ensure the most consistent repeat measurements. The abdomen and flanks were measured at the umbilicus and approximately 3–4 cm below the umbilicus. The circumference measurement site was documented as distance from the floor, as marked on a measurement stand. Subjects were placed in the same standing position for each measurement through the use of a floor mat with a marked footprint.

Standardized digital photographs and subject weights were performed prior to each treatment and at 1 month and 3 months after the final treatment. Photographs were taken with subjects standing in the same standing position, as marked by a footprint placed on the floor. Digital photography software (Mirror Software, Canfield Imaging Systems, Fairfield, NJ) enabled the use of transparent overlay images to ensure precise reproducible photographs at baseline and subsequent visits.

All subjects reported their overall level of satisfaction (not satisfied, slightly satisfied, satisfied, very satisfied, extremely satisfied) at each follow-up visits.

Inclusion Criteria

Subjects were required to be at least 21 years of age and at least 9 months post-partum (for inclusion in the abdomen flank group). Eligible subjects had clinically appreciable skin laxity and subcutaneous fat deposits as determined by investigator. All subjects were either post-menopausal, surgically sterilized or using a medically acceptable form of birth control (i.e., oral contraceptive, intrauterine device, contraceptive implant, barrier method with spermicide or abstinence) for at least 3 months prior to entrance into the study.

Exclusion Criteria

The following conditions precluded subjects from being accrued to this study: a known photosensitive disorder, use of substances that cause photosensitivity, keloid scarring, use of isotretinoin within 6 months of treatment, use of non-steroidal anti-inflammatory drugs 2 weeks prior and 2 weeks post-treatment, pregnancy or breast feeding, active or history of cancer in the treated area, treatment with a laser or other device in the study areas within 6 months of treatment or during the study, contouring treatment in the areas intended for treatment within 9 months of treatment or during the study, having undergone any other surgery in the treated areas within 9 months of treatment or during the study, or suffering from hormonal imbalance which may affect weight or cellulite,

as per investigator's discretion. For post-liposuction areas, the procedure should not have been performed less than 2 years prior to this study.

Treatment Regimen

Prior to initiating treatment, a test spot was performed in the intended treatment areas. The treatment parameters were determined by degree of laxity, subcutaneous fat, skin type, and subject tolerance to treatment. Immediately prior to treatment, a thin layer of standard treatment lotion was applied to the treatment area and massaged into the skin. The treatment lotion provides for greater RF conductivity through the strateum corneum. Lotion was reapplied during the treatment when the applicator was not easily moving over the skin surface or the device handpiece indicated incomplete coupling.

Subjects underwent treatment with the combined IR, bipolar RF, vacuum and mechanical massage device at 50 W bipolar RF, 20 W IR (700–1,500 nm) and 200 mbar vacuum (750 mm Hg negative pressure). Those subjects whom underwent treatment of the upper arms were treated at equivalent zones on the upper arms (Fig. 1A), once weekly for 5 weeks. During treatment of the abdomen and flanks, two symmetrical zones approximately the size of half a sheet of paper, 5.5 in.×4.25 in. (from suprapubic to umbilicus and posterior flank) (Fig. 1B) were treated once weekly for 4 weeks.

All treatments were performed in a standardized manner.

Zone 1 was treated until reaching an external thermal temperature of 40–42°C for the first pass (this would on average take 7–9 minutes). Once this target temperature was achieved, zone 2 was treated to the same endpoint. Immediately after zone 2 was treated, a second pass was performed on zone 1. Time to clinical endpoint was shorter for the second pass due to residual heating from the first pass (approximately 2–4 minutes to reach clinical endpoint). Once the clinical endpoint of 40–42°C was obtained or patient tolerance exceeded, heat was maintained by continued treatment with a progressively reduced number of stacked pulses. The clinical endpoint temperature was then maintained for approximately 5 minutes.

Treatments started with a set parameter of eight stacked pulses. The number of stacked pulses were reduced as the external temperature increased or if the patient noted discomfort. During each pass, stacked pulses were delivered across the zone in a grid like fashion to deliver a uniform treatment. The majority of subjects were treated at parameters of level 3 RF, level 2 IR, and level 1–2 vacuum. Surface temperature was monitored via handheld external thermometer (Cleartemp Infrared Thermometer IRT0421 Kintrex, Vienna, VA).

RESULTS

Demographics

For the 29 subjects, age ranged from 28 to 70 years old (average 46.5) (Table 1). Delineation of subjects by Fitzpatrick Skin Type can be appreciated in Table 2.

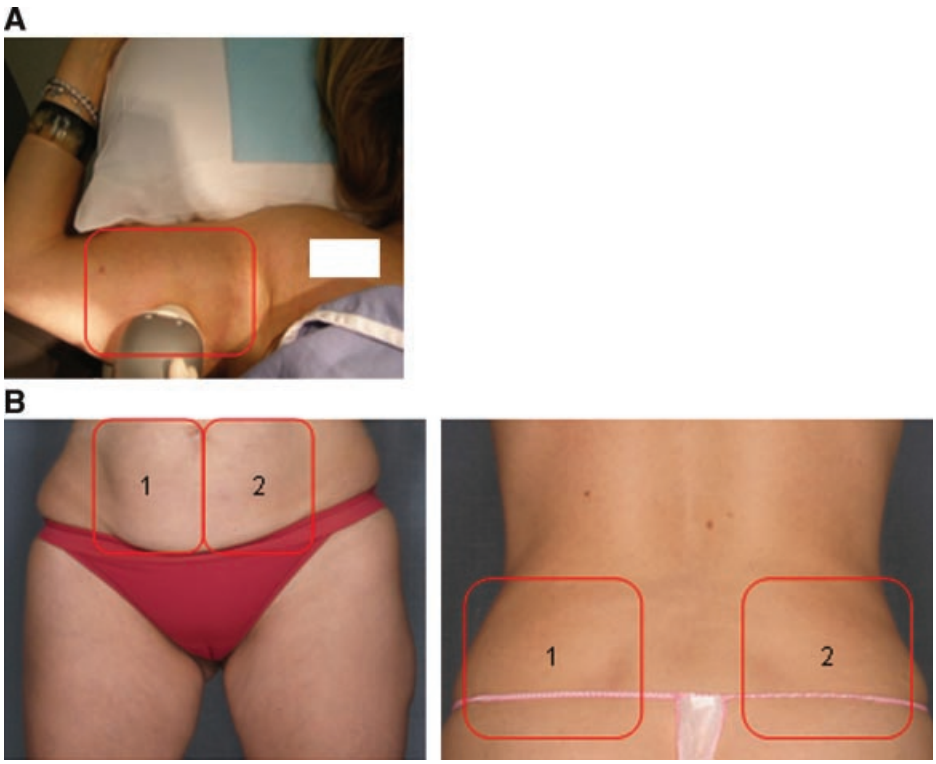

Fig. 1. **A**: Upper arm treatment zone. **B**: Symmetrical abdominal and flank treatment zones.

TABLE 1. Demographics by Age Group

Age group	Number of subjects
21–29	2
30–39	4
40–49	8
50–59	13
60–69	1
70–79	1

TABLE 2. Demographics by Fitzpatrick Skin Type

Skin type	Arms (%)	Abdomen/flank (%)
I	7	10
II	33	20
III	53	50
IV	7	19
V	0	1

For subjects who underwent arm treatments, the average baseline weight was 69 ± 13 kg, and at the last treatment the average weight was 69 ± 14 kg.

For subjects who underwent abdomen and flank treatments, the average baseline weight was 59 ± 8 kg and at the last treatment the average weight was 60 ± 9 kg.

Clinical Results

All treatments were well tolerated. No subject requested discontinuation of treatment due to discomfort. Treatment side effects included mild erythema in the treated area which dissipated in most patients within an hour of treatment. A few patients experienced small eccymoses which resolved within 5–7 days of treatment. One patient did experience a superficial crusting on the abdomen which resolved without sequelae within 2 weeks.

For subjects who underwent upper arm treatments, the reduction in the average arm circumference from baseline to the third treatment was significant at 0.387 cm lost (paired t-test $P = 0.0076$). The difference in the average circumference from baseline to the fourth treatment was also statistically significant at 0.603 cm lost (paired t-test $P = 0.0001$). After the fifth treatment, the mean loss in arm circumference for all 19 subjects was 0.625 cm. At 1-month post-final treatment, 19 subjects underwent follow-up circumference evaluation with a mean loss of 0.71 cm.

At 3 months post-final treatment, 18 subjects underwent follow-up circumference evaluation with a mean loss of 0.597 cm (paired t-test $P<0.019$). Measurements of arm circumference at the 6-month follow-up were obtained from 12 subjects, and the paired t-test P-value for the difference from baseline values was not significant (Table 3; Fig. 2).

For 10 subjects who underwent abdomen and flank treatments, the average reduction in the abdominal circumference from baseline to the third treatment was significant with a 1.25 cm loss (paired t-test $P = 0.0130$). There was limited further reduction in the abdominal circumference from the third to the fourth treatment. However, the difference in the abdominal circumference from baseline to the fourth treatment remained statistically significant with a 1.17 cm average loss (paired t-test $P = 0.0320$). At 1-month post-final treatment, average loss for the 10 subjects was 1.43 cm (paired t-test $P = 0.039$). At 3 months follow-up, six subjects were evaluated, and average circumference loss was 1.82 cm (Table 4; Figs. 3–5).

The 3-month follow-up measurements were to some extent better than those documented at 1 month. However, the difference in circumference measurements from baseline values were not statistically different (paired t-test $P = 0.1$), most probable because of the limited number of subjects returning for a 3-month evaluation.

Subjects' assessments regarding treatment improvement revealed the highest score at the 1-month follow-up. Subject satisfaction from the treatment was highest following the last treatment. Of note, in this study the physician objective assessment of improvement at the 1-month follow-up correlated highly with the subjects' own assessments of improvement (Pearson correlation, $r = 0.68$ $P = 0.005$; Figs. 6 and 7).

DISCUSSION

The IR, bipolar RF, vacuum and mechanical massage device used in this study safely produced quantifiable results that are statistically significant for both anatomic sites studied. This device was the first to achieve an FDA indication for circumferential reduction in 2007, based on clinical studies performed on thighs [5,16–22]. This study demonstrates the device to also be safe and efficacious on upper arms and abdomen and flanks.

In this clinical trial, the average loss in circumference of the upper arms and abdomen and flanks increased with

TABLE 3. Arm Circumference Measurements Data

Variable	Subjects	Mean	SD	Minimum	Maximum
Baseline	19	31.291	3.8288	25.750	39.500
Treatment 3	19	30.904	4.0118	24.950	38.500
Treatment 4	19	30.688	3.8855	24.850	37.750
Treatment 5	19	30.666	3.7952	25.250	38.150
1-month follow-up	19	30.584	4.1249	23.900	38.250
3-month follow-up	18	30.694	4.2301	24.050	37.100
6-month follow-up	12	30.671	4.6495	24.750	37.400

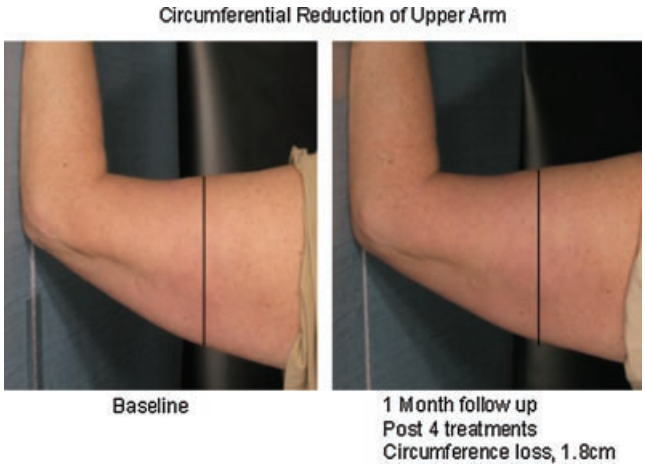

Fig. 2. Progression of circumferential loss of upper arm circumference after five treatments.

number of treatments and over time. The upper arm circumference reduction at treatment 4, treatment 5 and 1-month follow-up was 0.603, 0.625, and 0.710 cm, respectively. Abdominal circumference loss at treatment 4, 1 month, and 3 months follow-up was 1.25,1.41, and 1.82 cm, respectively. Treatment-induced circumference reduction is theorized to be secondary to an immediate tightening with heat-induced collagen fibril contracture as well as a heat-induced wound healing effect with progressive neocollagenesis along with reduction in volume of adipocytes.

The two important factors affecting tissue tightening are the peak temperature reached and the time over which the heat is maintained. The treatment technique of achieving a peak temperature and maintaining clinical endpoint temperature over a period of time produces progressive skin tightening and subsequent measurable decreases in circumference. This theory is based on the Arrhenius equation, $k = Ae^{-(E_a/RT)}$ in which k is the rate constant, A the frequency of collisions and their orientation, E_a/RT the fraction of molecules present in a gas which have energy equal to or in excess of activation energy at a particular temperature. According to this equation, collagen denaturation will occur not simply at one temperature point in time but over a range of temperatures with respect to time. For example, maintaining an external skin temperature of 40–42°C (suggested to be equivalent to an internal temperature of 60–65°C) for at least 5 minutes can produce the same collagen denaturation effects as reaching a much higher temperature but for a shorter period of time. The longer treatment time also allows for greater diffusion of heat into the surrounding tissue and hence a greater volume of tissue treated. This bulk or volumetric deep dermal heating produces the collagen changes seen 3-dimensionally as circumferential reduction. This treatment technique allows for delivery of a safe and comfortable level of heat for the subject over a period of time to produce clinically appreciable results [4–7,11–14,23,24]. In a quest to document this principal, Zelickson et al. demonstrated through ultrastructural analysis, increased diameter of collagen fibrils of human abdominal skin 3 and 8 weeks post-radiofrequency treatment. They also observed via Northern blot analysis an increase in collagen type I messenger RNA [12]. Goldberg et al. [10] showed histologic findings consistent with upper dermal fibrosis after radiofrequency treatment to the upper thigh area.

TABLE 4. Abdomen and Flank Circumference Measurements Data

Variable	Subjects	Mean	SD	Minimum	Maximum
Baseline	10	84.750	3.7212	81.000	94.000
Treatment 3	10	83.500	3.6209	79.500	91.500
Treatment 4	10	83.580	3.8032	77.800	91.000
1-month follow-up	10	83.320	3.5795	78.000	90.200
3-month follow-up	6	83.333	4.8132	75.500	90.500

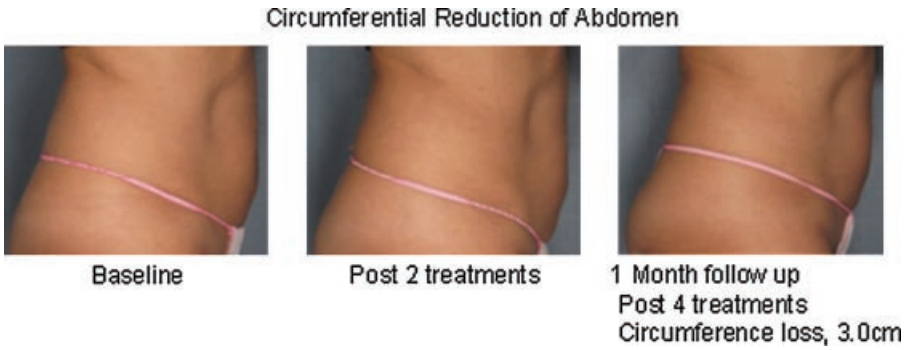

Fig. 3. Progression of circumferential loss of abdomen circumference after four treatments.

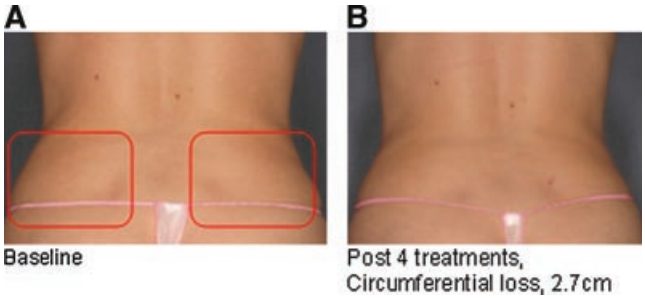

Fig. 4. Reduction of flanks. **A**: Baseline. **B**: Post four treatments circumferential loss, 2.7 cm.

In our study, nine upper arm patients submitted skin biopsies. One punch biopsy of a non-treated area and one punch biopsy of the treated area. The histologic results in all cases show increased cellular components of the extracellular matrix of the papillary dermis, likely fibroblasts, together with increased composition of collagen fibers. This is the likely source leading to increased density of the papillary dermis and in some cases the deeper reticular dermis with more "organized" with collagen bundles (Fig. 8).

The ELOS energy used in this device overcomes the constraints of using solely a light- or RF-based device. Unlike laser or light energy, radiofrequency is not scattered or absorbed by epidermal melanin and can therefore treat all skin types and generate significant heat without risk to the epidermis. The ability to treat all skin types was appreciated in our study. Subjects with skin types I–V were treated without complication or differences in efficacy. When treating darker skin types, the IR was occasionally decreased since these subjects can experience superficial heating much quicker than lighter skin types. In darker Fitzpatrick skin types, the clinical endpoint was still achieved and maintained during the second pass.

The optical IR energy is suggested to preheat the more superficial tissue, decreasing superficial tissue impedance (innate opposition to the flow of the alternating bipolar RF current) and allowing for greater attraction of RF energy. The heat that is then produced in the tissue is related to the resistance of the tissue to the RF energy. When RF is applied to the skin surface, the flow of RF current is inherently resisted by the tissue. This resistance generates heat based on Ohms law [4–6,9–11,24].

It is also theorized that the heat energy causes the adipocyte to decrease in size secondary to cell dehydration and increased metabolic use of stored energy. Perhaps that is due to greater natural impedance of fat tissue hence a greater degree of heat generated from radiofrequency application [9,25]. This may also help explain some variability in clinical results. The patients' reports of treatment satisfaction were greater in the abdomen and flank treated group as opposed to the arm-treated group, although both groups had statistically significant results (Figs. 6 and 7). The subcutaneous layer in the abdomen is usually much thicker than the subcutaneous layer in the upper arm, and treatment of a thicker/larger tissue target may explain the higher satisfaction levels and larger circumference losses in this group The large fraction of patients who were "not satisfied" despite having measurable circumference reduction highlights the importance of discussing realistic expectations with non-invasive body contouring treatments.

The negative pressure vacuum of the device allows for a controlled amount of epidermis and dermis to be folded in between the two electrodes of the bipolar current to treat both the superficial and deeper dermal layers with less total energy and less risk for epidermal damage when compared to delivering the same energy without vacuum folded skin.

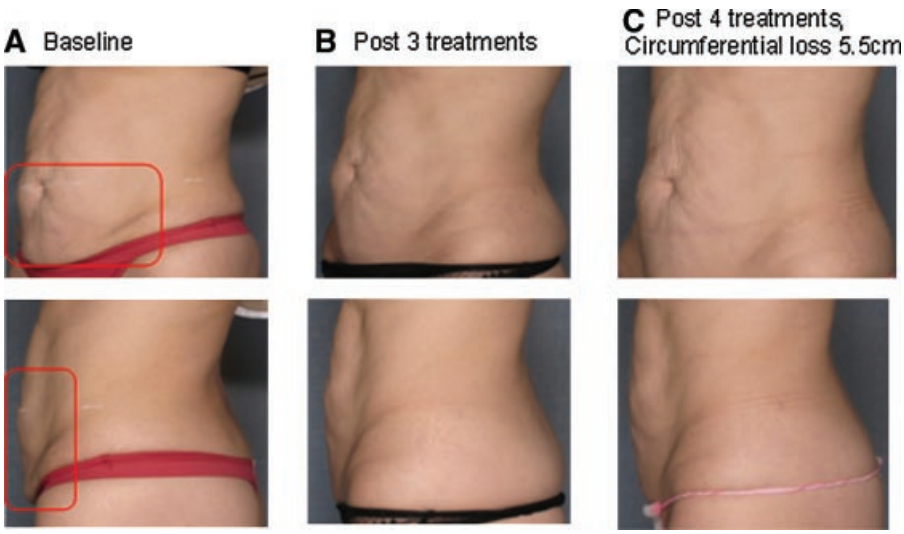

Fig. 5. Progressive circumferential tightening and reduction of abdomen. **A**: Baseline. **B**: Post three treatments. **C**: Post four treatments circumferential loss, 5.5 cm.

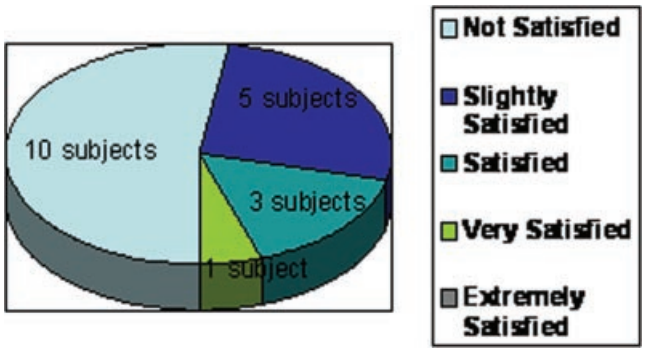

Fig. 6. Velashape upper arm satisfaction assessment. Patient satisfaction assessment at 1-month follow-up after treatment of the upper arms. 47.3% of patients slightly satisfied/satisfied/very satisfied.

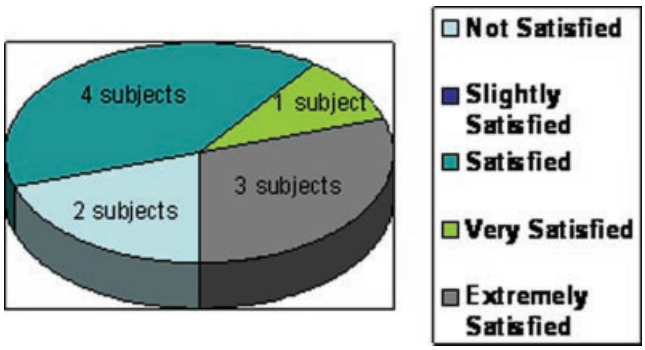

Fig. 7. Velashape abdomen satisfaction assessment. Patient satisfaction assessment at 1-month follow-up after treatment of the abdomen. Eighty percent of patients satisfied/very satisfied/extremely satisfied. Forty percent of patients very satisfied/extremely satisfied.

The vacuum application also purportedly enhances vascular diffusion in the area which may contribute to treatment efficacy by supplying fibroblasts with nutritional needs and enhancing lymphatic drainage [15,24].

As this technology also employs mechanical massage, one could also hypothesize that there is concomitant fibroblastic stimulation via mechanical stress contributing to neocollagenesis. Endermologie and other massage devices suggest tightening effects via mechanical manipulation of the tissue leading to fibroblast stimulation [15,18,24,26,27]. The mechanical massage is suggested to enhance lymphatic drainage of dissolved fat of lipolysed adipocytes. This however has not been proven.

Limitations of this clinical trial include small sample size, lack of extended follow-up evaluations and untreated control group, and the inherent imprecision of human measurement of circumference. Although every precaution was taken to ensure precise reproducible measurements for comparison, even the slightest alteration in tension of measuring tape can alter to some degree the reported data. In measuring the abdomen, it was appreciated that measurements needed to be taken at the same point in the respiratory cycle. It was also noted that some women would report bloating during pre-menses, and this could potentially alter circumference measurements. One can also assume that large meals or volumes of fluid taken directly prior to circumference measurement can affect the measurement result [28].

CONCLUSION

In conclusion, the IR, bipolar RF, vacuum and mechanical massage device investigated in this trial has been shown to be safe and efficacious for the treatment of

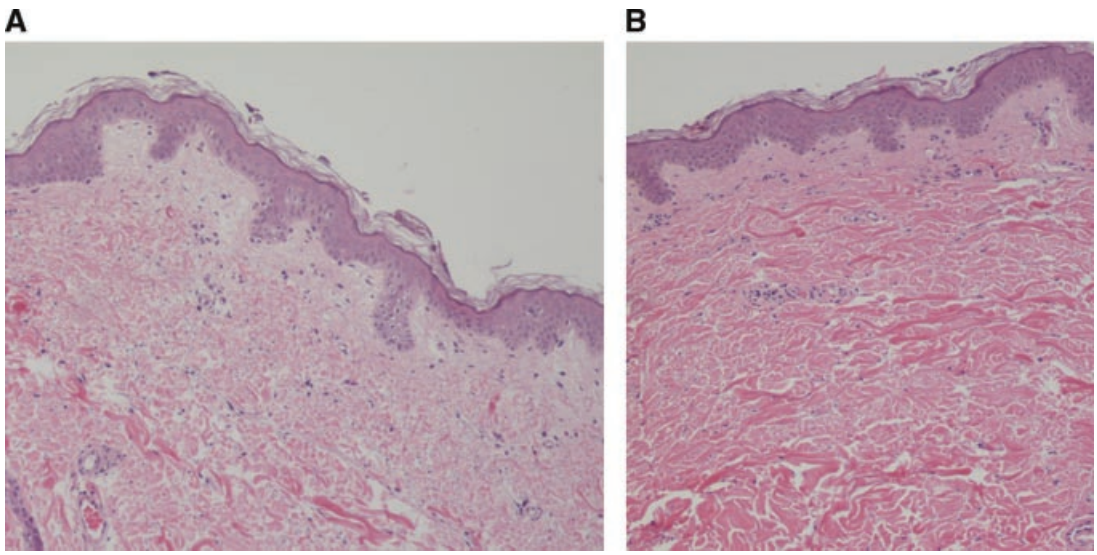

Fig. 8. Hematoxylin and eosin staining. **A**: Non-treated site on upper arm. **B**: Histologic results at 1-month follow-up after five treatments in same subject. Results demonstrate increased cellular components of the extracellular matrix in the papillary dermis. There is also increased composition of collagen fibers leading to increased density of the papillary dermis and the deeper reticular dermis with more organized with collagen bundles.

circumferential reduction and improved skin appearance of the upper arms and abdomen.

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