ORIGINAL ARTICLE

Circumference reduction and cellulite treatment with a TriPollar radiofrequency device: a pilot study

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Abstract

Background A wide variety of treatments for circumference reduction and cellulite are available, but most procedures offer suboptimal clinical effect and/or delayed therapeutic outcome.

Objective To determine the safety and efficacy of the TriPollar radiofrequency device for cellulite treatment and circumference reduction.

Methods Thirty-nine females with cellulite received eight weekly TriPollar treatments. Treatment areas included the abdomen, thighs, buttocks and arms. Subjects were evaluated using standardized photographs and measurements of body weight, circumference, subcutaneous thickness, and skin elasticity of the treatment sites at baseline, immediately after and 4 weeks after the final treatment. Physicians' evaluation of clinical improvement scores using a quartile grading scale was recorded.

Results Thirty-seven patients (95%) completed the treatment protocol. There was significant circumference reduction of 3.5 and 1.7 cm at the abdomen ($P = 0.002$) and thigh ($P = 0.002$) regions, respectively. At 4 weeks after the last treatment, the average circumferential reductions of the abdomen and thighs were sustained. No significant circumferential reductions of the buttocks and arms at the last treatment visit compared to baseline were demonstrated ($P = 0.138$ and 0.152, respectively). Quartile grading scores correlating to approximately 50% improvement in cellulite appearance were noted.

Conclusions Tripollar radiofrequency provided beneficial effects on the reduction of abdomen and thigh circumference and cellulite appearance.

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Keywords

cellulite, circumference reduction, localized fat, radiofrequency device

Conflict of Interest

The authors have no financial interest in this article.

In overweight persons, there is a redistribution of fat in specific patterns. One aesthetic problem for most obese individuals, who achieve modest or even significant degrees of weight loss due to a diet control program combined with physical exercise, is the inability to eliminate the accumulated fat at some specific anatomical sites, such as the abdomen, buttocks and thighs. These localized areas of fat accumulation cannot be solved by regular dietary control alone but require an additional body sculpting specific areas of cellulite occurrence, which is a common and distressing condition experienced by over 80% of postpubertal women.[3]

Cellulite is characterized by an irregular, dimpled of the skin, which is mainly found on the thighs, buttocks and abdomen.[4] Cellulite is best considered to be multi-factorial in aetiology, including structural, genetic, and endocrine abnormalities. It is evident that weakened connective tissues, enlarged fat cells and diminished microcirculation, play key roles in the pathophysiology of cellulite.[3,5] A variety of topical preparations, massage-based therapies and surgical techniques, including liposuction and subcision have been advocated to improve the cellulite condition

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by promoting microcirculation in the affected areas. However, most procedures offer suboptimal and inconsistent clinical effects and/or a delayed therapeutic outcome.

Recently, various technologies such as a radiofrequency (RF) device alone and combined RF and light source technologies have been introduced for tissue tightening by volumetric heating of the deep dermis.[6,7] Applications including a controlled RF energy source have become one of the most exciting modalities for the treatment of cellulite, skin tightening and body sculpting.[8–12] Modern RF systems use an RF source in one of two configurations: mono-polar and bi-polar. Previous studies reported beneficial effects of mono-polar and bi-polar RF in the treatment of cellulite and skin tightening. Mono-polar RF provides deep dermal heating, but the procedure is painful, with a delayed outcome, whereas bi-polar RF has a limited depth of tissue heating and is also with pain associated.

TriPollar RF is a novel technology producing homogenous and deep volumetric heating of tissue, thus combining the effects of mono-polar and bi-polar RF modalities in one applicator. The RF current flows between three poles (electrodes) and simultaneously heats superficial and deep skin layers at the same time. The densely focused current between three poles results in a high power density in the treatment area (Fig. 1) and therefore, low power consumption, providing clinical effects with longer-term results over successive treatments sessions without discomfort.

The present study designed to evaluate the safety and efficacy of the TriPollar RF technology–based device in obtaining long-term results for circumference reduction, cellulite treatment and skin tightening.

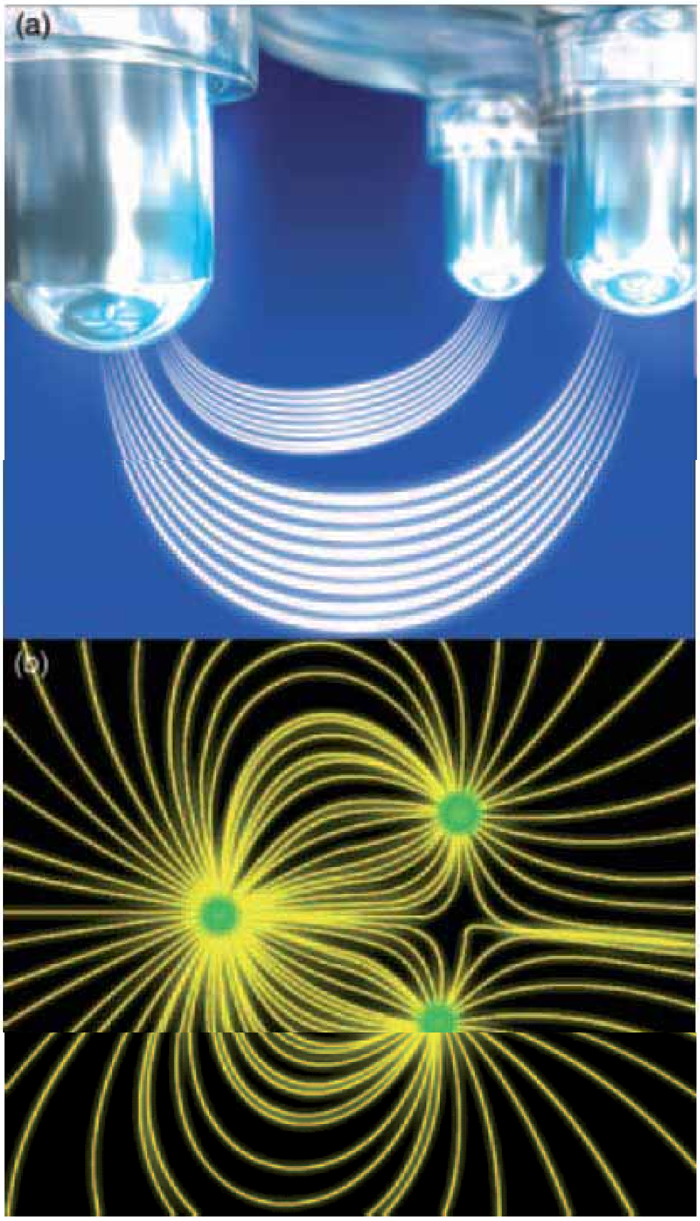

Figure 1 TriPollar RF system uses a three-electrode technology to deliver the focused RF current into the skin tissue (a); TriPollar electrode configuration; one electrode acts as a positive pole, while the other two act as negative poles. The current flowing through the common, positive pole is twice that of flows through each of the negative poles (b).

Materials and methods

The study protocol was approved by the Ethical Committee on Research Involving Human Subjects, Faculty of Medicine Siriraj Hospital, Mahidol University. Written informed consent was obtained from all study subjects.

Thirty-nine females (aged 23–60 years; mean, 41 years) with the presence of grade ≥2 cellulite (Nurnberger–Muller scale)[13] were recruited to the study between August 2007 and January 2008. Subjects were instructed to adhere to their regular diet, exercise program and life style with weight fluctuations not exceeding 2 kg from the preceding month. Exclusion criteria included scarring, inflammation or infection of the area to be treated, pregnancy or lactating, subjects with history of malignancy, implants or a pacemaker device, use of non-steroidal anti-inflammatory drugs or aspirin 2 weeks before and 2 weeks after the treatment, and prior treatment of the area with another method within 1 year of the baseline visit.

All subjects received treatments with a TriPollar RF device (Regen™, Pollogen Ltd, Tel Aviv, Israel) once a week for a total number of eight sessions. After applying a thin layer of glycerin oil on the treatment area, the applicator was employed with slight pressure in a continuous sweeping movement over the skin for simultaneously heating the subcutaneous fat layer and the dermis. A total of 20 and 28.5 W of RF energy was administered through a TriPollar RF electrode configuration at a frequency range of 1 MHz to the treatment area of arms, and those of the abdomen, thighs and buttocks, respectively. The energy levels were adjusted depending on the subjects' sensitivity and the skin response. During the treatment, heat sensation was regularly monitored verbally and physically. A sensation similar to a warm massage without pain was set as an ideal feeling during the treatment. The applicator was moved more rapidly or the energy level was reduced if there was an unpleasant feeling reported by the subject. The target sites were treated until the skin temperature was increased to 40–42 °C, which was often accompanied with the appearance of erythema. An increased temperature was maintained for approximately 2 min. The skin temperature was regularly measured using an infrared thermometer (Mini-Temp MT4; Raytek Corp, Santa Cruz, CA). The treatment session lasted approximately 30, 40, 45 and 60 min when treating the abdomen, arm, buttock and thigh areas, respectively.

Circumference measurements

Before each treatment session and 4 weeks after the final treatment, measurements of body weight and circumferences of the treatment sites were taken. Circumference measurements were done using one designated tape measure and were always taken at a constant distance from a specific anatomical landmark, e.g. umbilicus for the abdomen, a distance of 10 cm below the greater trochanter for the thigh, a distance of 10 cm below the anterior superior iliac spine for the buttock and a distance of 15 cm proximal to the olecranon for the arm regions.

Ultrasound measurement

At the abdomen and the thigh regions, a real-time scanning image ultrasound (iU22 ultrasound system, Philips Medical Systems, Bothell, WA) with a multi-frequency linear probe (5–17 MHz) was used to measure the distance between the epidermis and the superficial fascia (Camper's fascia) separating the superficial and deep subcutaneous layer[4,14] at a specific and consistent distance from an anatomical landmark of the thigh and abdominal regions. The measurements were evaluated at the baseline and the 8th week of treatment. Each measurement was evaluated on two planes by a blinded radiologist (N.L.): the first plane was parallel to the long axis of the abdomen or the thigh, and the second plane was perpendicular to the first one.

Skin elasticity measurement

A Cutometer® MPA 580 (Courage & Khazaka GmbH, Köln, Germany) was used to assess skin elasticity on the arms at the baseline and 4 weeks after the final treatment. This instrument measures the elastic properties of skin based on the principles of suction and elongation, utilizing an optical measuring unit described previously.[15,16] Parameters R2 and R7 are normally used as the main parameters to assess skin elasticity. These parameters showed the strongest correlation with age-related decreases in skin elasticity.[17] A higher value indicates an increase in skin elasticity.

Cellulite condition evaluation

Cellulite grading was determined utilizing the four-stage Nurnberger-Muller scale.[13] Standardized digital photographs using consistent patient positioning, camera angling, lighting was obtained at baseline, immediately after and 4 weeks after the final treatment. Clinical improvement scores of pre- and post-study digital photographs using a quartile grading scale ($0 \leq 25\%$, $1 = 25–50\%$, $2 = 51–75\%$, $3 \geq 75\%$ improvement) were graded independently by two blinded dermatologists (C.W. and S.V.) after the series of treatments. Adverse effects were observed and documented during each treatment session.

Statistical analyses

Descriptive statistics including mean, median, minimum, maximum, percentages of circumferential reduction and 95% confidence interval were used to describe demographic data and circumference measurements. The mean differences of circumference and body weight at pre and post treatment were analysed by a paired-samples *t*-test. All statistical data analyses were performed using statistical software (SPSS version 16.01; SPSS Inc, Chicago, IL).

Results

Of all 39 subjects enrolled, 37 subjects (95%) completed the treatment protocol. Two subjects were withdrawn from the study because they could not attend scheduled visits. A total number of 81 anatomical sites were treated including 21 of the thigh, 21 of the abdomen, 19 of the arm, and 20 of the buttock areas.

Immediately after the treatment, the treated skin became warm to the touch and erythema was observed. The erythema was reported to disappear within 2–3 h after completion of the treatment session by all subjects. Non-significant circumferential reduction, compared to before and immediately after the procedure, was noted. Treatment was well tolerated with minimal to no discomfort. The sensation most often described was a mild heating with occasional pinching.

The average body weights of the 37 subjects at the baseline, immediately after the final treatment and 4 weeks after the final treatment were 65.73 ± 9.65, 65.04 ± 9.74, and 65.08 ± 9.55 kg, respectively. An average body weight reduction of 0.69 ± 1.31 kg ($P = 0.003$) comparing the baseline and the last follow-up visit, was demonstrated.

Mean differences and percentages of change in circumference measurements are presented in Table 1. Significant reduction of circumferential measurements of the abdomen and thighs was seen, comparing between the baseline and 4 weeks following the final treatment visit, and were 3.50 ± 4.61 ($P = 0.002$) with a maximum reduction of 14.4 cm, and 1.71 ± 2.20 cm ($P = 0.002$) with a maximum reduction of 9.1 cm, respectively (Table 1; Figs 2 and 3). Reduction of circumference measurements of the arm (maximum reduction of 1 cm) and buttock (maximum reduction of 5.2 cm) areas comparing between baseline and 4 weeks following the final treatment visit was not statistically significant (Figs 4 and 5). There was a minor reduction in efficacy (less than 1%) between the final treatment and 4 weeks after the final treatment evaluation points but a significant improvement remained (Table 2).

Table 1 Baseline and 4 weeks after the 8th (final) treatment measurement

Region/circumference	Mean ± SD (cm)			P-value	Maximum reduction
	Pretreatment	4 week after the 8th Tx	Mean reduction		
Thigh circumference ($n = 21$)					
At 10 cm lower than GT level	54.62 ± 3.92	52.91 ± 4.19	1.71 ± 2.20	0.002*	9.10
Abdomen circumference ($n = 21$)					
Umbilicus level	93.25 ± 6.91	89.75 ± 6.93	3.50 ± 4.61	0.002*	14.40
Buttock circumference ($n = 20$)					
At 10 cm below ASIS level	103.87 ± 6.57	103.79 ± 6.37	0.08 ± 3.82	0.931	5.20
Arm circumference ($n = 19$)					
15 cm from olecranon	32.16 ± 3.05	32.33 ± 3.05	0.17 ± 0.98	0.461	1.00

n, number; GT, greater trochanter; ASIS, anterior superior iliac spine; Imm, immediated; Tx, treatment; *P-value < 0.05.

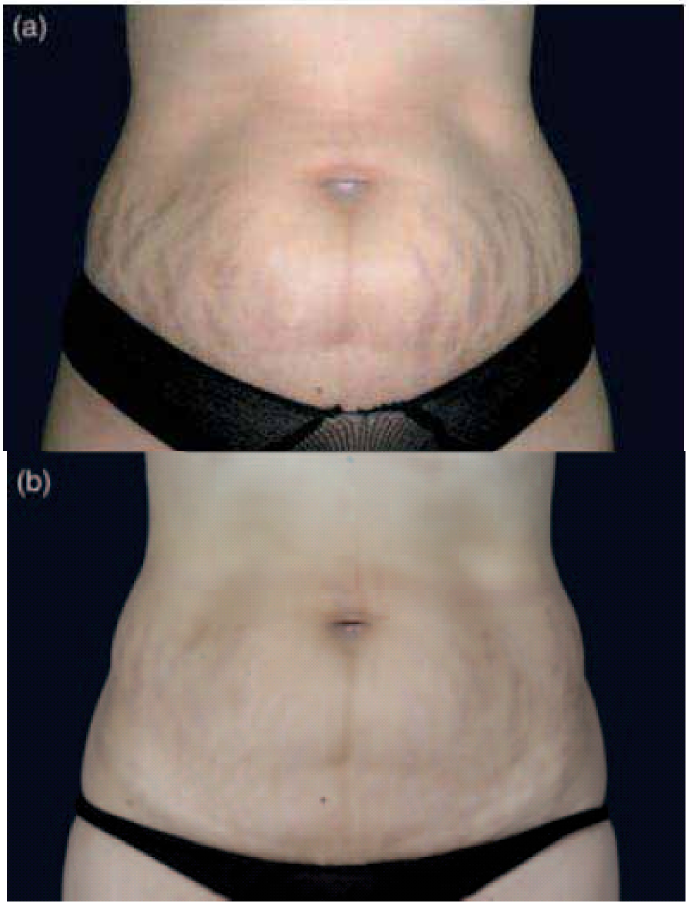

Figure 2 Abdomen region, before treatment (a), Clinical appearance at 4 weeks after eight treatments (b). Note the appearance of stretch marks, before and after the series of treatment.

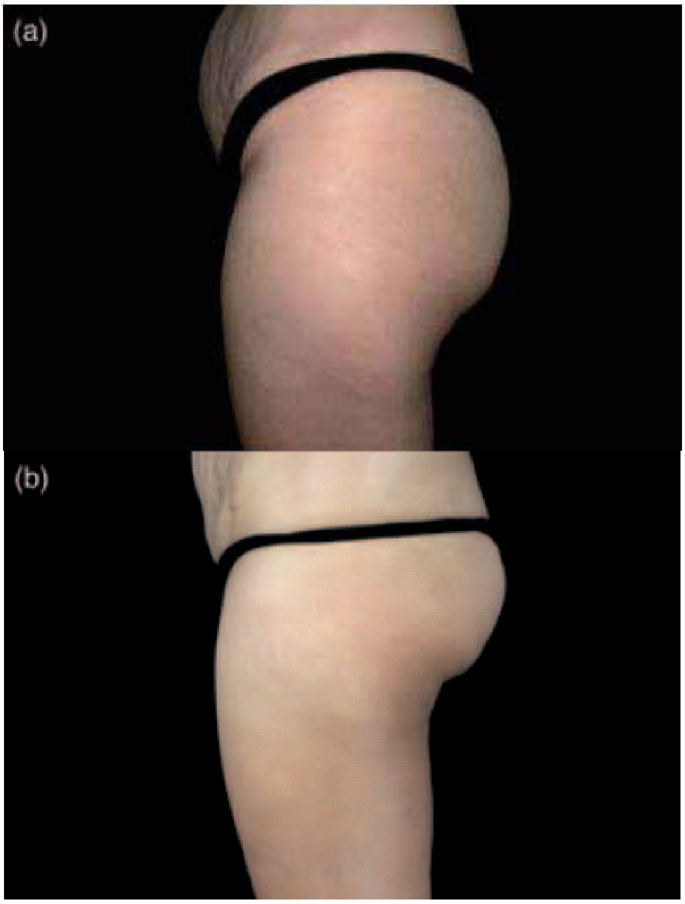

Figure 3 Thigh region, before treatment (a). Clinical appearance at 4 weeks after eight treatments (b).

Ultrasound measurements of the distance between the epidermis and the superficial fascia showed a distance reduction of 0.61 ± 2.1 mm ($P = 0.012$) representing an average reduction of 10.5% in the thickness of adipose tissue with a maximum reduction of 39% at the thigh region, and 0.34 ± 2.2 mm ($P = 0.418$) representing an average reduction of 4% in the thickness of adipose tissue with a maximum reduction of 31% at the abdomen region. This reduction was found to be statistically significant only at the thigh region when compared to the baseline (Table 3 and Fig. 6).

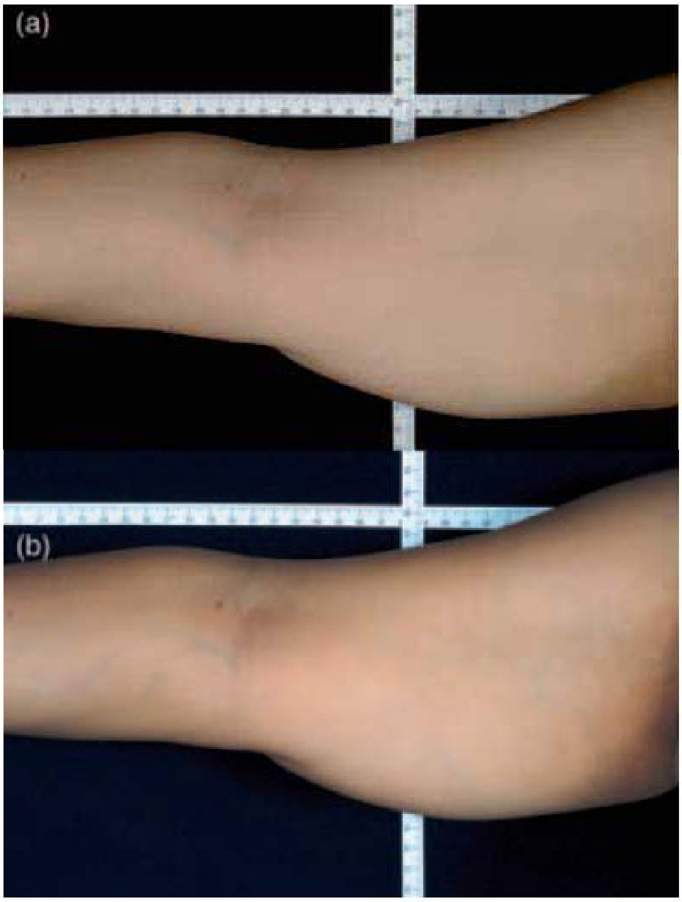

Figure 4 Arm region, before treatment (a). Clinical appearance at 4 weeks after eight treatments (b).

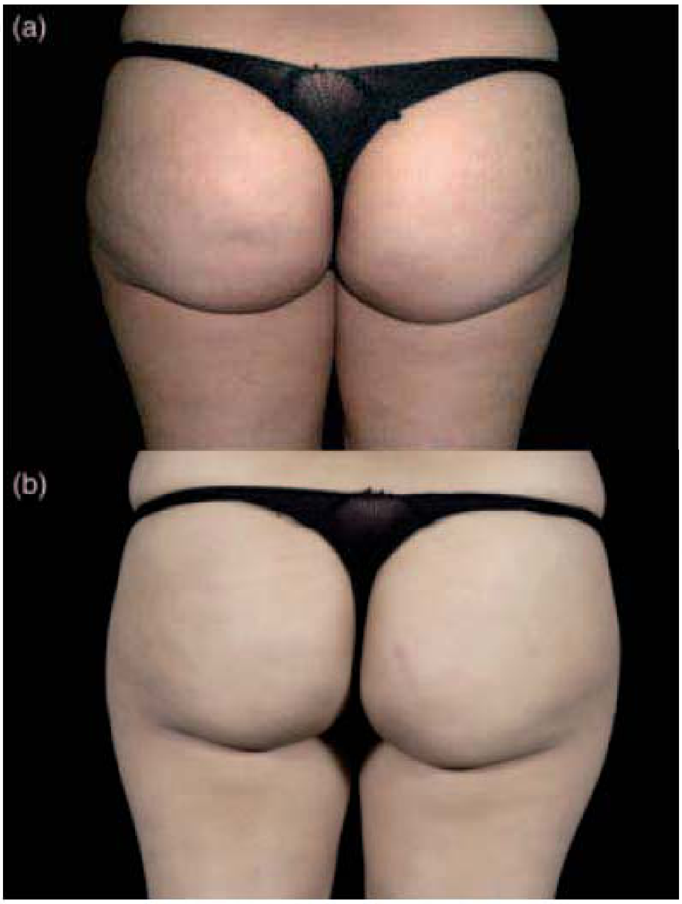

Figure 5 Buttock region, before treatment (a). Clinical appearance at 4 weeks after eight treatments (b).

Colour

Table 2 Comparison of measurement between immediately after the 8th (final) and 4 weeks after the 8th treatment

Region/circumference	Mean ± SD (cm)			*P*-value
	Imm post 8th Tx	4 weeks after the 8th Tx	Change (%)	
Thigh circumference (*n* = 21)				
At 10 cm lower than GT level	52.34 ± 4.12	52.91 ± 4.19	+0.57 ± 0.78	0.05
			(1.1 ± 1.47)	
Abdomen circumference (*n* = 21)				
Umbilicus level	89.04 ± 6.91	89.75 ± 6.93	+0.71 ± 3.52	0.364
			(0.8 ± 4.1)	
Buttock circumference (*n* = 20)				
At 10 cm below ASIS level	102.89 ± 7.03	103.79 ± 6.37	+0.91 ± 4.02	0.327
			(0.89 ± 4.12)	
Arm circumference (*n* = 19)				
At 15 cm from olecranon	31.63 ± 2.79	32.35 ± 3.12	+0.72 ± 1.15	0.05
			(2.28 ± 1.24)	

Table 3 Ultrasound measurement of the distance between the stratum corneum and superficial fascia

Region/measurement	Mean ± SD (mm)			*P*-value	Maximum reduction (%)
	Pretreatment	Imm post 8th Tx	Mean reduction		
Thigh	5.78 ± 1.52	5.18 ± 1.12	0.61	0.012*	39%
Abdomen	8.79 ± 2.19	8.45 ± 2.19	0.34	0.418	31%

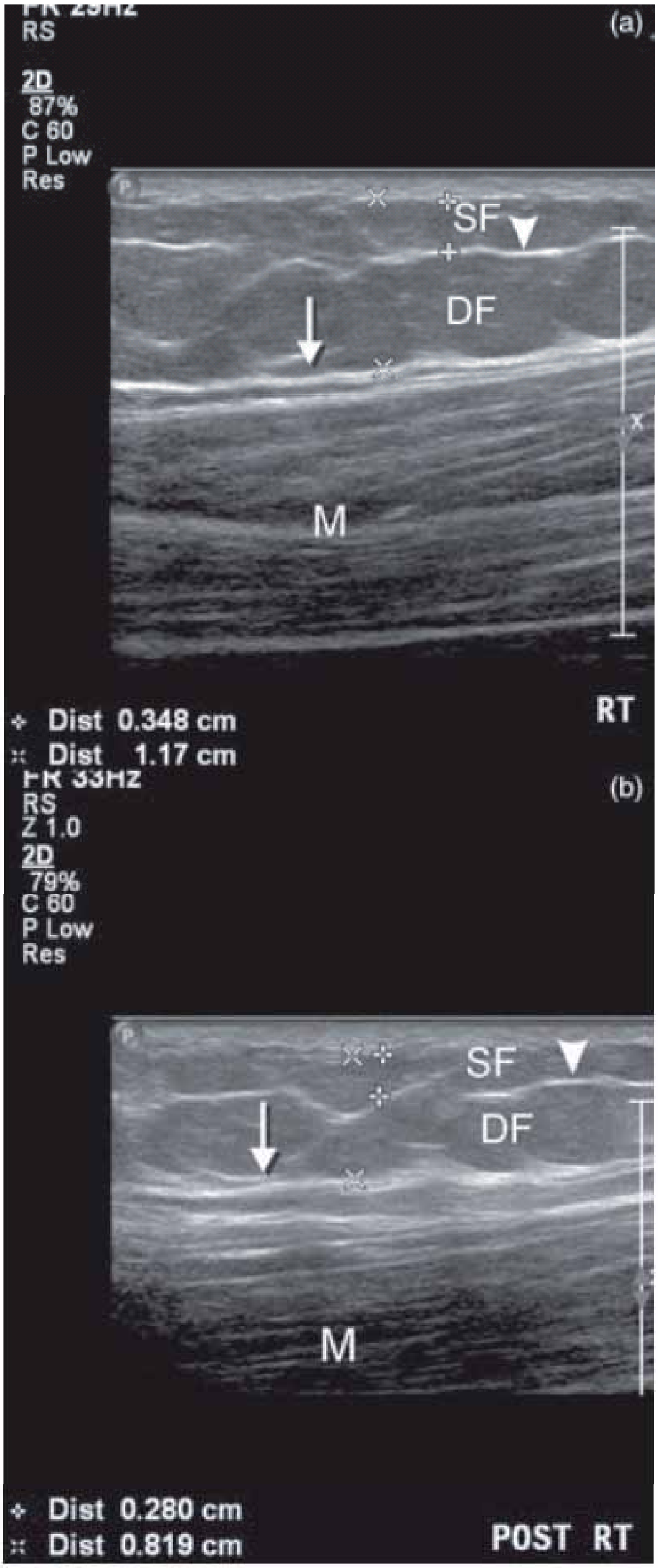

Figure 6 Ultrasound measurement of a thigh region. Before treatment, the thickness of superficial fat layer is 0.348 cm (a). After eight treatments, the thickness is 0.280 cm (b). SF, superficial fat layer; DF, deep fat layer; M, muscle; ▼, superficial fascia; ↓ deep fascia.

Table 4 Blinded physician ratings of the level of improvement in cellulite appearance

Score	% improvement	Number of treatment site (%)
0	< 25	0/81 (0%)
1	26–50	1/81 (1%)
2	51–75	51/81 (63%)
3	> 75	29/81 (36%)

Note: The total number of treatment sites = 81 (thigh = 21, abdomen = 21, arm = 19, buttock = 20).

Table 5 Adverse effects following TriPollar RF treatment

Adverse effect	Number of occurrence/ total treatment sessions (percent)
Erythematous papules	2/656 (0.3%)
Papular urticaria	1/656 (0.15%)
Primary degree burns	1/656 (0.15%)
Blisters	1/656 (0.15%)
Bruising	1/656 (0.15%)

Cutometer measurement of skin elasticity at the arm regions demonstrated non-significant higher values of R2 (0.01, $P = 0.093$) and R7 (0.01, $P = 0.059$) parameters comparing between baseline and the final follow-up visit.

Blinded investigators rated average overall clinical improvement scores of 2.35 (correlating to ~50% improvement in the appearance of cellulite; Table 4). Out of a total of 656 treatment sessions performed, low incidences of adverse effects including erythematous papules, papular urticaria, primary degree burns, blisters and bruising were observed (Table 5 and Fig. 7).

Discussion

The present study demonstrated that TriPollar RF technology provided beneficial effects on the reduction of abdomen and thigh circumferences and an overall improvement in the appearance of cellulite. This supports the findings of previous studies that volumetric tissue heating by RF energy alone[9] or combined RF light source technologies[8,10,13] are safe and effective treatment modalities for circumference reduction and cellulite treatment. We did not find any correlation between the degree of improvement and weight loss. However, we observed that the baseline severity of skin laxity and cellulite affected the degree of improvement. When there was less irregular skin surface, there was better response to the treatment.

The exact mechanism of the therapeutic effect of RF for cellulite treatment has not been clearly defined. Several modes of action have been hypothesized to occur following the selective electro-heating of dermis and subcutaneous tissue, including an increase

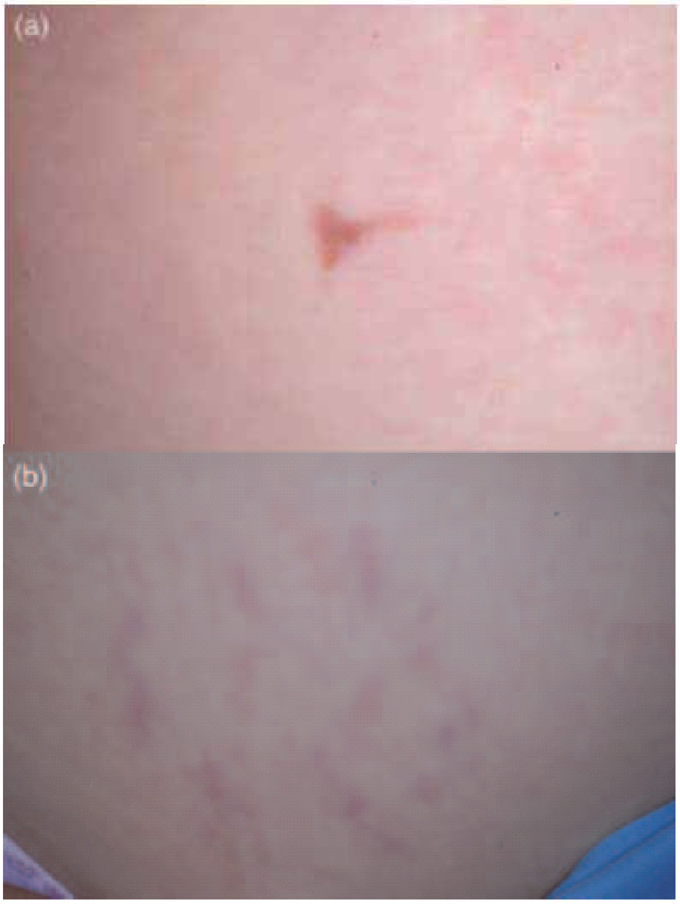

Figure 7 Adverse effects after TriPollar RF treatment: primary degree burn (a); bruising (b).

in the rate of fat metabolism, an increase in local circulation and lymphatic drainage of adipose tissue,[8,11,12] volumetric contraction of the connective tissue of the subcutaneous layer,[18] as well as a skin tightening effects caused by a formation of new collagen fibers.[9,18]

Similar to the findings of the present study, Del Pino and colleagues[18] evaluated the effects of a unipolar RF on subcutaneous tissue of the buttocks and thighs in 26 female subjects with visible cellulite grade 1 to 3 by measuring the distance between the dermis and the Camper's fascia with a real-time scanning image ultrasound. Their study showed that following two treatment sessions at 15 days apart, the thickness between the dermis and fascia was shortened, with an average reduction of 2.64 and 1.8 mm at the thigh and the buttock, respectively. In addition, during a longer follow-up period (45 days after the final treatment), a noticeable organization of fibrous lines as well as an increase of fibrous tissue and thickness of the fibers compared with that of the baseline was noted. This was confirmed by a finding of a previous study evaluating histological and MRI changes at 6 months following six sessions of cellulite treatment with a unipolar RF device demonstrating post-treatment dermal fibrosis without gross alterations in the subcutaneous layer.[9] Similarly, a recent study using a TriPollar RF device to treat *ex vivo* human skin models has also demonstrated statistically significant increases in collagen synthesis in the superficial and mid dermis when compared to the control, untreated skin.[19]

Clinical improvement in skin irregularity and circumferential reduction seen after RF treatment may occur as the following cascade. Initially, the selective volumetric heating causes dermal and subcutaneous tissue tightening, resulting in immediate circumference reduction. Collagen fibers shrink, initiate inflammatory processes and consequently induce fibroblast proliferation and collagen remodeling. The collagen remodeling process is perpetually induced through out the series of RF treatments. Logically, the assumption of Goldberg *et al.* that this dermal fibrous band thickening decreases the herniation of the fat into the dermis and thereby reduces the irregularities in the appearance of cellulite seems to be in line with the findings of our study. This also supports the findings of a previous investigation of cellulite morphology and biochemistry by Rosenbaum *et al.*[20] demonstrating that the connective tissue layer was more irregular and discontinuous in affected vs. unaffected individuals and that there were no significant differences noted in subcutaneous adipose tissue morphology, lipolytic responsiveness, or regional blood flow between the affected and unaffected sites within individuals. This evidence suggests that therapeutic attempts for cellulite reduction should be directed at the connective tissue.

The efficacy of the TriPollar RF device for circumferential reduction was comparable to that reported in a previous study using unipolar RF[9] and was better than those demonstrated by treating with a combined bipolar RF light source technology.[8,10] Four weeks after eight weekly treatments with the TriPollar RF device, the average circumferential reductions of 3.5 and 1.7 cm were demonstrated at the abdomen and the thigh regions with statistical significance in the present study. Goldberg *et al.*[9] evaluated 30 subjects with Nurnberger-Muller cellulite scale III–IV on the thighs and reported a mean decrease in leg circumference of 2.45 cm at 6 months after six biweekly treatments with a unipolar RF device coupled with a cooled tip. Alster and Tanzi[8] treated 20 females with eight bi-weekly treatments with a combined bi-polar RF, infrared light and pulsatile suction device (VelaSmooth system) and found a reduction of 0.8 cm in the circumferential thigh measurement with a clinical improvement of approximately 50% in all subjects. Another randomized comparative study to determine the efficacy of such a device vs. the TriActive system (low energy diode laser, contact cooling, suction and massages) for the treatment of cellulite also reported a similar treatment efficacy. Nootheti *et al.*[13] randomly treated 20 female subjects twice a week for a total treatment of 12 sessions with the VelaSmooth system on one side and the TriActive system on the other side and found that there was improvement in the reduction of cellulite for each device individually, but no significant difference.

RF systems for dermatologic applications use an RF source in two configurations including uni/mono-polar and bi-polar. When uni-polar RF energy is applied for volumetric heating of subcutaneous tissue, the RF current will find the path with less electrical resistance to flow in the body (i.e. blood and lymphatic vessels), so the benefit for heating the adipose tissue that has a higher electrical resistance is controversial. In contrast, with a bi-polar RF configuration, the electrical current propagation is limited to the area between the electrodes, and the depth of penetration under the skin is estimated to be approximately half the distance between the electrodes; thus, for a given system, the depth of penetration is constant and cannot be changed for various body areas or different skin conditions. Moreover, uni/mono-polar and bi-polar RF systems must use a cooling system in order to prevent epidermal overheating and the potential for burn injuries, thus reducing the efficacy of the treatment.

TriPollar RF is a novel technology developed to concomitantly deliver simultaneously homogenous and deep volumetric heating by using a three-electrode configuration. This special electrode configuration produces high density and focused RF energy of approximately 18 watts/cm^2 deep into all skin layers (unpublished data, Pollogen Ltd), compared with a bi-polar system[12] which produces 1.2 watts/cm^2 bi-polar RF energy density. The TriPollar high power density, combined with a deep penetration depth, is responsible for the promising results obtained in this study. The total maximum power of the TriPollar RF powered system is 30 watts compared to 200–300 W in uni-polar systems. This relatively low power consumption enables the TriPollar configuration to achieve safe and effective results without any active cooling as demonstrated in the current study.

In the present study, there was a minor reduction of less than 1% in therapeutic outcome after the treatment was discontinued for 4 weeks. Individual responses to RF heating and/or improper treatment skill including a too-slow movement of the electrode and an inadequate amount of glycerin oil used were likely responsible for the adverse effects, including erythematous papules, papular urticaria, primary degree burns, blisters and bruising, which were only observed after the first treatment sessions, but not as the treatment series progressed. All of the side-effects were mild, asymptomatic and self-limited within 1 week except the primary degree burns and blisters, which were treated with a week course of topical corticosteroids.

In conclusion, circumference and cellulite can be significantly and safely reduced with the use of the TriPollar RF technology. The effect of the TriPollar treatment appeared to be prolonged as long as 4 weeks after the treatment was discontinued.

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