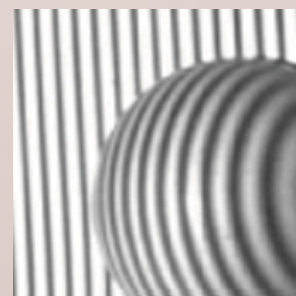
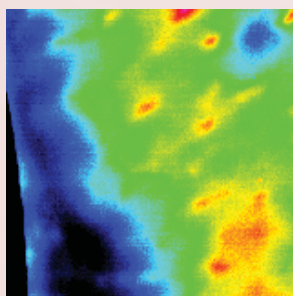
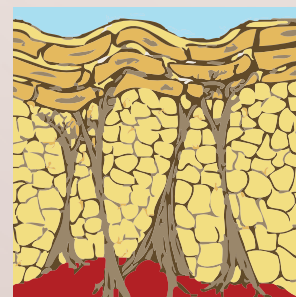
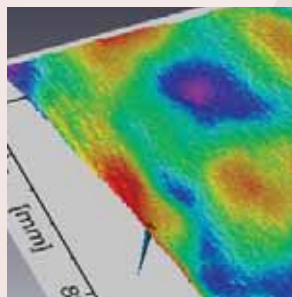


CELLULITE

Pathophysiology and Treatment

Second Edition



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Cellulite

PATHOPHYSIOLOGY AND TREATMENT

Second edition

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Cellulite

PATHOPHYSIOLOGY AND TREATMENT

Second edition

edited by

Mitchel P Goldman, MD

*Volunteer Clinical Professor of Medicine/Dermatology
University of California
San Diego, California
USA*

Doris Hexsel, MD

*Preceptor and Coordinator, Cosmetic Dermatology
Department of Dermatology
Pontificia Universidade Católica do Rio Grande do Sul
Porto Alegre, Rio Grande do Sul
Brazil*

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22 TriPollar™ Radiofrequency

Woraphong Manuskitti

Introduction

Radiofrequency (RF) energy is a wavelength situated in the range of electromagnetic rays. Propagation of RF through the cutaneous tissue rapidly oscillates electromagnetic fields causing a movement of charged ions within the tissue which subsequently creates an electrical current generating heat proportional to the dermis' and subcutaneous tissues' electrical resistance. The application of RF has been extensively used in surgery for hemostasis and tissue ablation (electro-surgery) [1–3], but more recently RF has been applied as a means of shrinking redundant or lax connective tissues through the mechanism of collagen denaturation [4–6]. Collagen molecules are produced by fibroblasts which synthesize three polypeptide chains that wrap around one another in a triple helix. The phenomenon of thermal shrinkage of collagen begins with denaturation of the triple helix of the collagen fibers. When collagen is heated, the heat-labile intramolecular cross-links are broken, and the protein undergoes a transition from a highly organized crystalline structure to a random, gel-like state (denaturation). Collagen shrinkage occurs through the cumulative effect of the “unwinding” of the triple helix, due to the destruction of the heat-labile intramolecular cross-links, and the residual tension of the heat-stable intermolecular cross-links. Heated fibroblasts are also implicated in new collagen formation and collagen remodeling which also contribute to the final cosmetic outcome. The precise heat-induced behavior of connective tissues and the extent of tissue shrinkage are dependent on several factors which include the maximum temperature reached, exposure time, tissue hydration and tissue age [7].

RF energy can be delivered to cutaneous tissue through either a single-electrode tip and a grounding plate (mono-polar—the first generation RF technology) [6,8] or a two-electrode applicator (bi-polar—the second generation RF technology) [9,10]. Less electrical current is required with a bi-polar RF than with a mono-polar one for achieving a similar tissue response, because the current penetrates through a much smaller volume of tissue. When a mono-polar RF energy is applied for volumetric heating of the skin, the RF current will find the path with the least electrical resistance to flow in the body (i.e. vascular and lymphatic systems), so the benefit of heating the adipose tissue, which has

a higher electrical resistance, is controversial. In contrast, with a bipolar RF, the electrical current propagation is limited to the area between the two electrodes, and the depth of penetration under the skin is estimated to be approximately half the distance between the electrodes. Therefore, the depth of penetration is constant and cannot be changed for various body areas or different skin conditions. Moreover, mono- and bipolar RF configurations must use a cooling device in order to prevent epidermal overheating and the potential for burn injuries, thus reducing the efficacy of the treatment (Table 22.1).

Developed in 2006, TriPollar™ RF is the third generation RF technology employing a multiple-electrode configuration (Figs. 22.1–22.2). TriPollar technology is based on the use of three or more electrodes to deliver focused RF current into the skin, thus generating heat through resistance in both the dermal and subcutaneous layers. The depth of heat penetration is approximately the average distance between the three electrodes. One acts as a positive pole while the other two act as negative poles. The current flowing through the common, positive pole is twice that which flows through each of the negative poles. To avoid overheating of this common pole and of the tissue in contact with this pole, a sequence of electrical modulation is applied so that each electrode, in turn, acts as the common pole. Due to its design, no active cooling of the electrodes or the skin is required.

Mechanisms of Action

The radiofrequency device is used to deliver selective and focused electro-heating to the dermis and subdermal layers of the skin, causing instant collagen contraction and subsequent remodeling [7,11]. An immediate tightening effect is visible on the skin following each treatment due to collagen fibers shrinking [8,12]. Thermal injury of the extracellular matrix initiates a cascade of wound healing phases including inflammation, proliferation, and collagen remodeling. The latter two phases of wound healing are thought to be the most important mechanisms responsible for the outcome of the treatment. These effects are more pronounced a few weeks to months following the treatment when the migration of fibroblasts into the inflammatory area initiates the production of new collagen fibers [13,14].

Table 22.1 Summary of current radiofrequency technology

Technology	Penetration depth	Required power	Pain level	Cooling device	Clinical outcome
Monopolar	Deep and uncontrolled 5–20 mm	High power (200–350 W)	Very painful	Always required	After 5–6 months
Bi-polar	Superficial and constant 1–5 mm	Medium power (10–200)	Painful	Sometimes necessary	After days-weeks
TriPollar	Dermal and subcutaneous layers 20 mm	Low power (5–30 W)	Warm massage-like sensation	No cooling needed	Some temporary immediate result. Long- term outcome noted after weeks



Figure 22.1. TriPollar radiofrequency applicator. The three-electrode configuration of TriPollar RF is aimed to deliver focused RF current into the skin tissue. (Courtesy Pollogen Ltd., Tel Aviv, Israel).

Moreover, simultaneously heating the superficial and deep layers of the skin may enhance local blood circulation and drainage of the free fatty acids to the lymphatic system. This is confirmed by findings of a previous study on the effect of TriPollar™ RF in *ex vivo* human skin harvested from a post-abdominoplasty skin sample and maintained in survival conditions [15]. Following a single treatment at 25 watts (W) to a skin model, a significant increase in glycerol release by the skin was observed, indicating an increase of tissue lipolytic activity (Fig. 22.3). In addition, following TriPollar™ RF treatment, neocollagenesis was demonstrated with a statistically significant repair of altered collagen in skin that was experimentally aged using UV radiation, with a tendency towards

increasing collagen synthesis (Fig. 22.4). The histological analysis of the subcutaneous layer after the TriPollar™ treatment demonstrated elongated and irregular-shaped adipocytes with shrunken and partially ruptured cell walls. No tissue necrosis or carbonization of the hypodermis was observed (Fig. 22.5). Similar to the aforementioned study, a recent histological examination of a skin biopsy taken after seven TriPollar™ RF treatments revealed an increase of 49% in dermal thickness, focal thickening of collagen fibers and focal shrinkage of fat cells [16].

Indications

The TriPollar™ RF system is currently used for

- Treatment of skin laxity (Fig. 22.6)
- Improvement of skin texture (Fig. 22.7)
- Treatment of cellulite (Fig. 22.8) and body contouring (Fig. 22.9)
- Localized fat reduction
- Improvement of striae appearance (Fig. 22.10)

Contraindications

There are several contraindications to using TriPollar™ RF device, including

- Having an implant in the treatment area, or an active implant (including pacemaker) anywhere in the body
- History of bleeding coagulopathies or use of anticoagulants

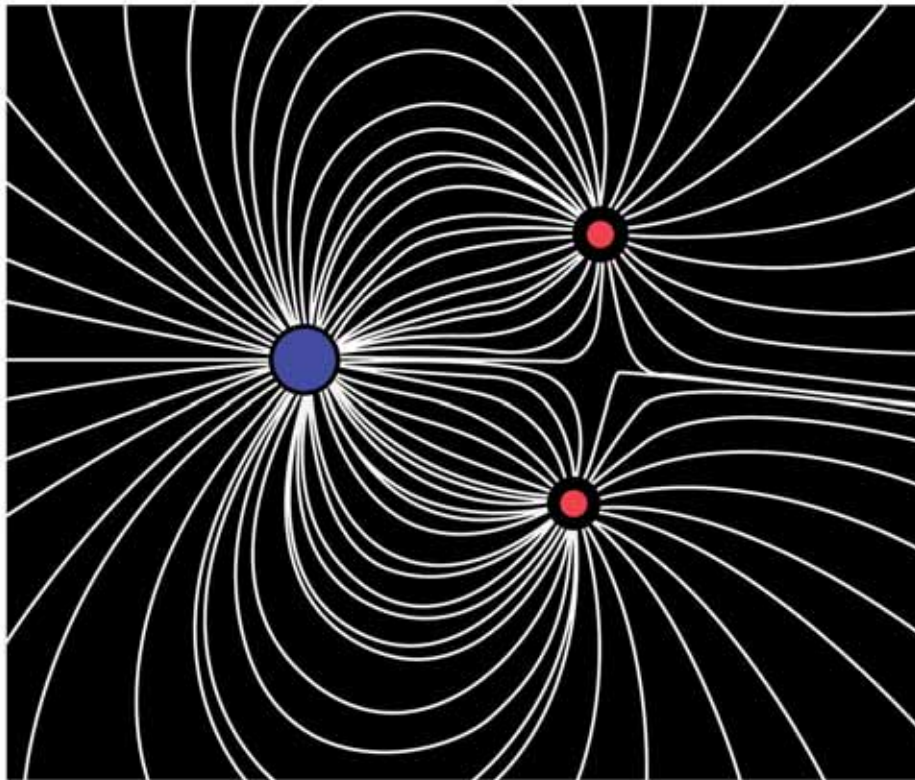


Figure 22.2 TriPollar electrode configuration. One electrode acts as a positive pole while the other two act as negative poles. The current flowing through the common, positive pole is twice that which flows through each of the negative poles. (Courtesy Pollogen Ltd., Tel Aviv, Israel).

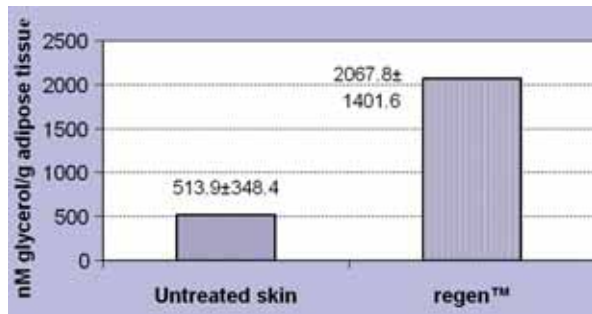


Figure 22.3 Evaluation of the lipolytic effect following a TriPollar™ RF treatment. A significant increase of glycerol release of the treated skin is demonstrated. (Modified from Boisnic S. Evaluation du dispositif de radiofréquence tripolaire Regen™ en utilisant un modèle expérimental de peau humaine. *Nouv Dermatol.* 2008;28:331–332.)

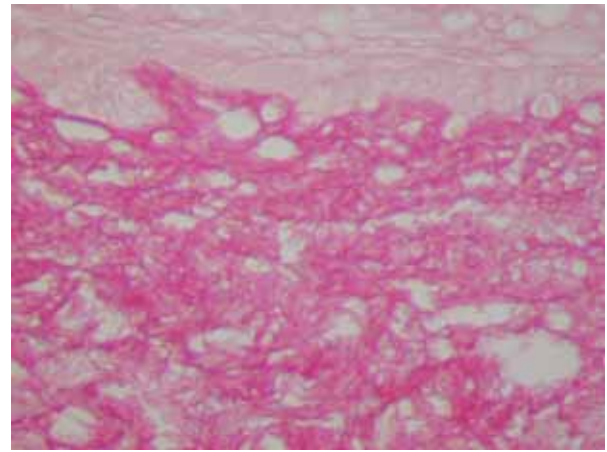
- Expectation of pregnancy, pregnant, having given birth less than three months prior, postpartum or nursing
- Having significant concurrent skin conditions, including infections, herpes simplex, open lacerations/abrasions or any inflammatory skin conditions affecting the areas to be treated
- Having or undergoing any form of treatment for active cancer, having a history of skin cancer or any other localized cancer in the areas to be treated, or having pre-cancerous lesions at the treatment areas
- Undergoing invasive or ablative procedures in the areas to be treated such as: liposuction, plastic surgery, any other surgery in the treatment area, laser resurfacing or deep chemical peeling during the course of the treatment, or before complete healing has occurred
- Taking medications, herbal preparations, food supplements or vitamins that might cause fragile skin or impaired skin healing such as prolonged steroid therapy, NSAIDs, warfarin, heparin, ginkgo, ginseng, garlic, etc.

System Overview

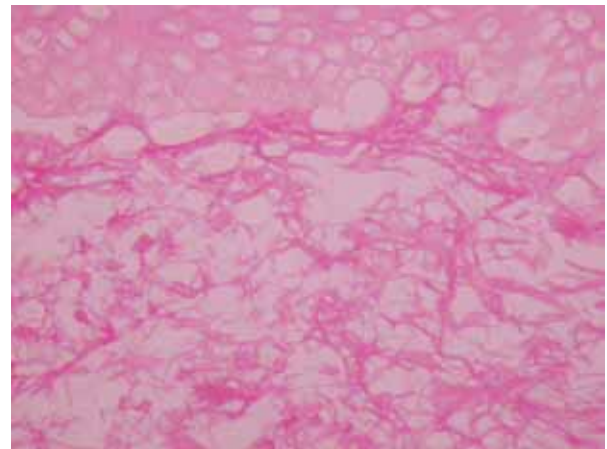
The Regen™ system (Pollogen Ltd., Tel Aviv, Israel) was the first system based on the TriPollar RF technology delivering energy at a frequency of 1 MHz and having a maximum power of 30 watts. Two applicators of different sizes are available for treatment of different anatomical sites including the face, neck, arms, abdomen, buttocks and thighs (Fig 22.11). Recently, the second generation of TriPollar RF—Apollo™ system with a maximum power of 50 watts has been launched (Fig. 22.12). Three sizes of applicators, large, medium and small, for the body, arms, neck, and face, respectively, are available.

Treatment Technique

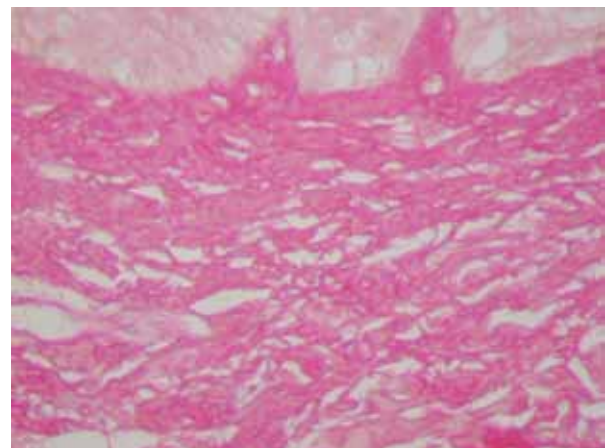
Prior to treatment, remove all jewelry, including necklaces, bracelets, watches, rings, etc. Clean the treatment area with soap and water and dry completely. Take pre-treatment photographs and circumference measurements at specific reference points, as a baseline assessment. Prepare the patient in a comfortable position for treatment. After that, set the appropriate treatment parameters for the specified treatment area. Then, lubricate the treatment area with a thin layer of glycerin oil. Glycerin oil acts as a lubricant. In addition, glycerin has high electrical resistance, thus ‘forcing’ the



(a)



(b)



(c)

Figure 22.4 Histological examination. (a) Untreated skin; (b) Ultraviolet (UV)-irradiated skin; (c) UV-irradiated skin follow by TriPollar™ RF treatment. Note the new collagen production induced by RF treatment. (Courtesy Sylvie Boisnic, M.D.)

electrical current to enter more deeply into the skin. Position the TriPollar™ applicator suitable for the treatment area on the skin and press the foot switch to begin treatment. During treatment, place the applicator on the area to be treated, with slight pressure and maneuver in linear or circular massaging movements, depending on the area. Both the patient and operator should

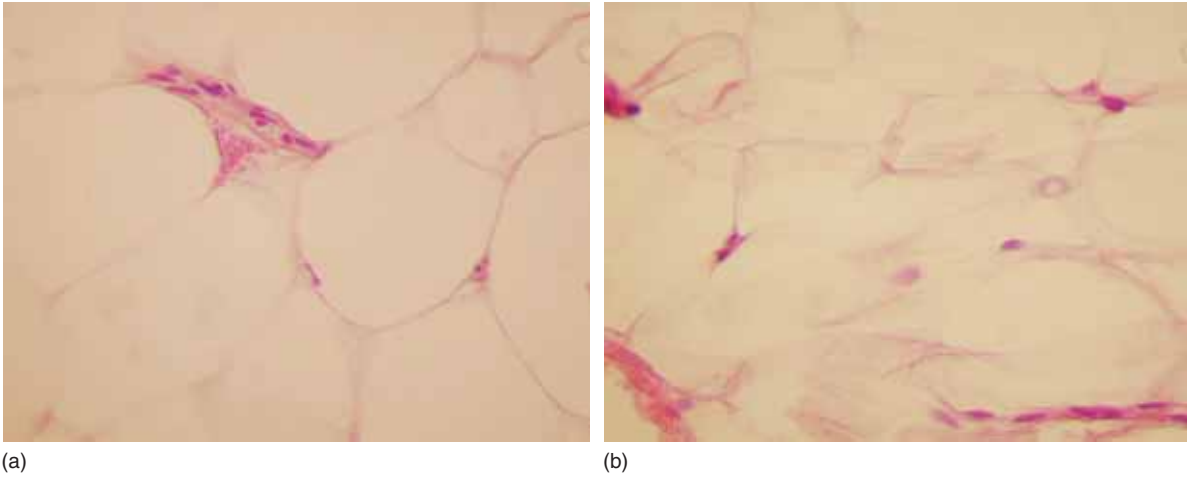


Figure 22.5 Histological finding of adipocytes in the subcutaneous layer after the TriPollar™ treatment demonstrates modifications in the shape (inhomogeneity: elongated, irregular) of the membrane (shrunk and some have partial ruptures of the cell wall). No tissue necrosis or carbonization of the hypodermis layer was observed. (Courtesy Sylvie Boisnic, M.D.)



Figure 22.6 Submental and neck skin, before treatment (a); immediately after TriPollar™ treatment (b); after six treatments (c). (Courtesy Alex Levenberg, M.D.)

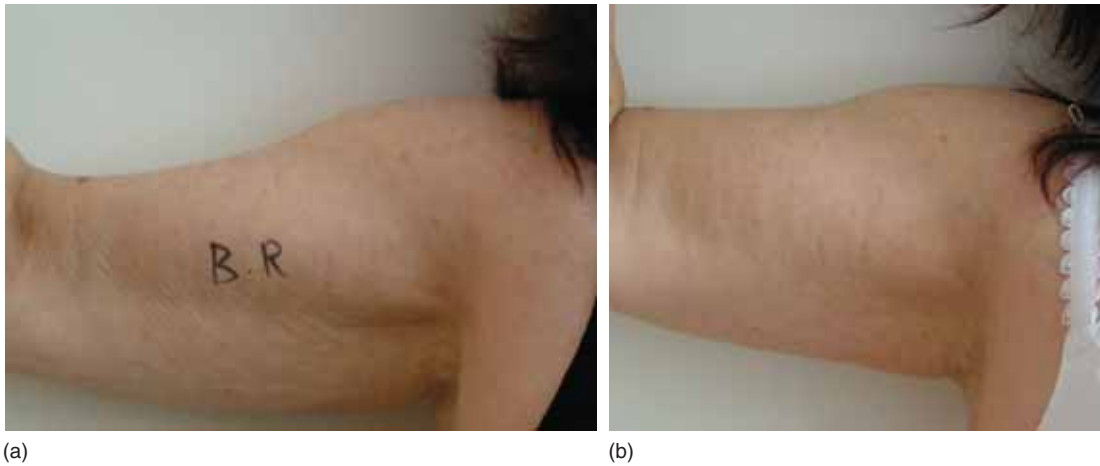


Figure 22.7 Arm skin, (a) before treatment; (b) after seven TriPollar™ treatments. Note the progressive skin tightening and improvement of skin texture. (Courtesy Alex Levenberg, M.D.)

monitor in real-time the treatment effects. The operator should constantly monitor skin tightness, warmth and erythema, while periodically measuring skin temperature using a non-contact IR thermometer. Shortly after commencing treatment there will be a noticeable tightening of the skin in most patients. Additionally, approximately three quarters of the way through the treatment, erythema should be visible (Fig. 22.13) and the skin should be warm to the touch. Measured skin temperature should be maintained between 40°C–42°C for safety reasons. The erythema usually disappears within 2–3 hours after completion of the treatment.

Treatment Regimen

Treatments shall be given once a week for a period of six to eight weeks [17,18]. A previous study demonstrated that the treatment effects appeared to be sustained as long as one and a half months after the treatment was discontinued [17]. However, monthly maintenance treatments are recommended to further enhance the clinical results achieved.

Initial Studies

Recent studies have demonstrated that TriPollar™ RF treatment is an effective and safe procedure for circumference reduction and cellulite treatment. Manuskiatti and colleagues [18] performed eight weekly treatments of TriPollar™ RF on 39 healthy females with cellulite measured as Nurnberger–Muller cellulite scale II or above. The study subjects were evaluated both quantitatively by measuring body weight, circumference and thickness of the superficial subcutaneous tissue, and qualitatively by photographic assessment and patient satisfaction questionnaire.

According to the study, significant reduction of circumferential measurements of the abdomen and thigh was observed, comparing between the baseline and one month following the final treatment visit, and were reduced 3.50 ± 4.61 cm with a maximum reduction of 14.4 cm, and 1.71 ± 2.20 cm with a maximum reduction of 9.1 cm, respectively. 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 one month following the final treatment visit was not

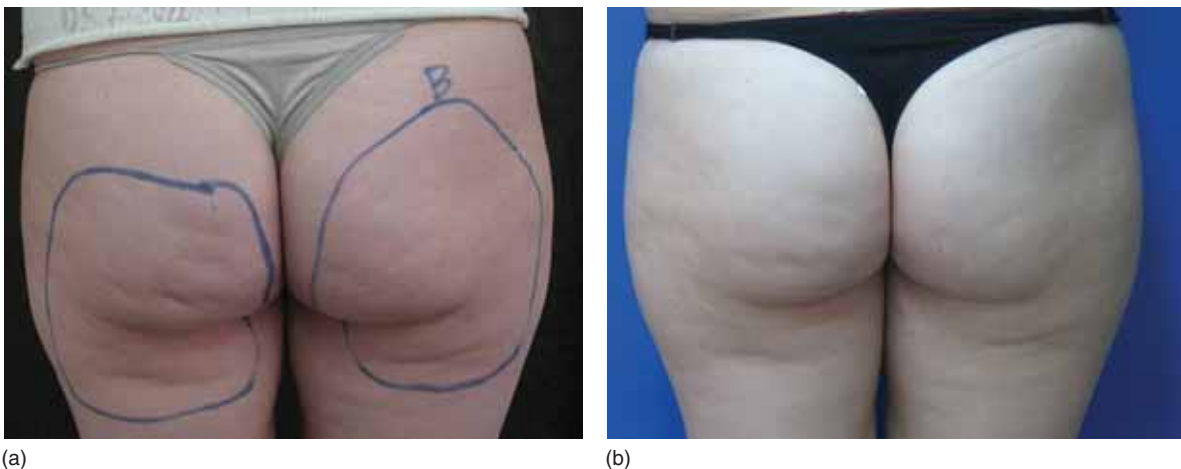


Figure 22.8 Cellulite on the buttock, (a) before treatment; (b) after five TriPollar™ treatments. (Courtesy Pollogen Ltd., Tel Aviv, Israel).



(a)



(b)



(c)

Figure 22.9 Body contouring. (a) before treatment; (b) four weeks after eight weekly TriPollar™ treatments with 9 cm reduction of the abdominal circumference; (c) eight weeks after treatment.

statistically significant. Evaluation of circumference measurement at one month after the series of treatments was stopped, confirmed that a significant circumference reduction was sustained (less than 1% reduction in efficacy was noticed). Quartile grading scores correlating to approximately 50% improvement in overall cellulite appearance were observed.

As is consistent with reports from prior studies on RF-induced skin tightening [5,6,19], initial studies using the TriPollar™ RF device [17,18] also noted considerable variability in the treatment outcomes, with some subjects achieving marked improvement and others showing minimal improvement or unchanged from



(a)



(b)



(c)

Figure 22.10 Striae rubra (a) before TriPollar™ treatment; (b) one month after six weekly treatments; (c) three months after six treatments. Note the progressive improvement at the longer follow-up period.

baseline. While the reasons underlying this variability remain unclear, further studies are warranted to fully elucidate this issue. However, we observe that the baseline severity of cellulite and skin laxity affects the degree of improvement. When there is less irregular skin surface and/or skin laxity, there will be better response to the treatment.

Ultrasound measurements of the distance between the epidermis and the superficial fascia revealed a distance reduction of 0.61 ± 2.1 mm, representing an average reduction of 10.5% in the thickness of superficial adipose tissue with a maximum reduction of 39% at the thigh region (Fig. 22.14), and a distance



Figure 22.11 Regen™ system having a maximum power of 30 W (a) and two sizes of applicators for the treatment of different anatomical sites including a small applicator for treatment of the face and neck (b), and a larger applicator for the treatment of the arms, abdomen, buttocks and thighs (c). (Courtesy Pollogen Ltd., Tel Aviv, Israel).

reduction at the abdomen region of 0.34 ± 2.2 mm, representing an average reduction of 4% in the thickness of adipose tissue, with a maximum reduction of 31%. However, this reduction of superficial subcutaneous thickness was found to be statistically significant only at the thigh region when compared to the baseline.

Given the proven efficacy in induction of collagen remodeling [15,20,21], TriPollar™ RF has recently been used to successfully improve stretch marks' appearance [17]. Seventeen females with striae distensae were enrolled for six weekly treatment sessions of 40–45 minutes each. Treatment evaluations, including standardized photographs and a UVA-light video camera were made at baseline, and at one and six weeks after the final treatment. In addition, the subjects were asked to rate their overall satisfaction at the last follow-up visit.

The result of the study indicated that TriPollar™ RF offered a beneficial effect on improvement of striae appearance. Evaluation performed at one week after a series of six weekly treatments noted 41.2% and 11.8% of the subjects having 25%–50% and 51%–75% improvement of their striae, respectively. Compared to the one-week follow-up visit, at six weeks after the last treatment, a higher percentage of the subjects were rated to have improvement of their striae including 26.5% showing 51%–75% improvement and 5.9% showing >75% improvement. None of the subjects was rated as having no improvement. According to the satisfaction survey, 12% (2/17), 23% (4/17), and 65% (11/17) of the study subjects reported their satisfaction with the overall improvement as slightly satisfied, satisfied, and very satisfied, respectively. In terms of treatment complications, there were no adverse effects, such as postoperative purpura, bullae, crusts, ulcerations, or dyschromia observed.



Figure 22.12 Apollo™ system with a maximum power of 50 W and available with three sizes of applicators, including large, medium and small applicators for the body, arms and neck, and face, respectively (Courtesy Pollogen Ltd., Tel Aviv, Israel).

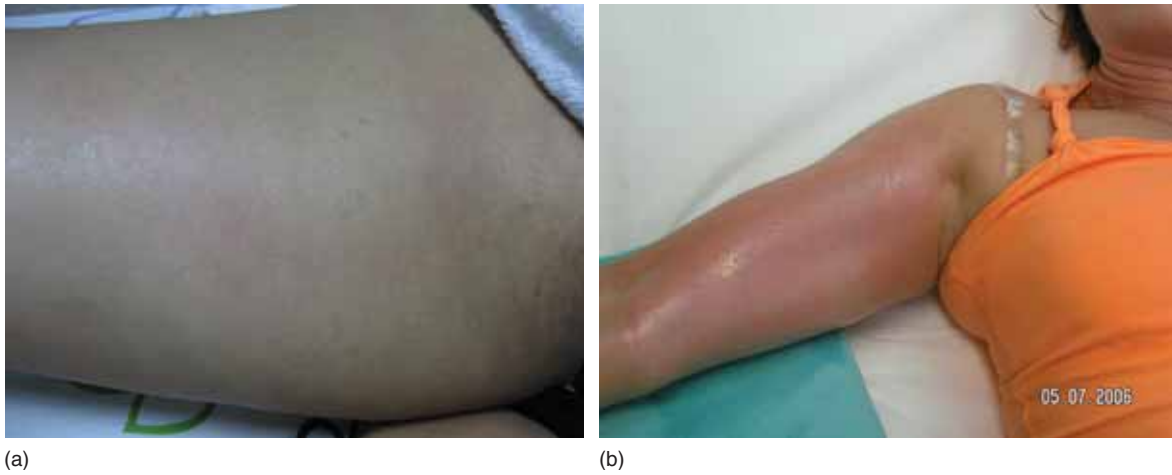


Figure 22.13 Endpoint of treatment is erythema and the skin is warm to the touch. (a) Erythema in a skin phototype V patient at a skin surface temperature of 40°C; (b) erythema in skin phototype II patient at the same surface temperature. Note the difference in the degree of redness. (Courtesy Alex Levenberg, M.D.)

Scanned images from a UVA camera did not reveal significant differences in the striae surface smoothness at one- and six-week follow-ups, compared with that of baseline. However, the sample size of this study may be too small to detect an objective improvement of skin surface smoothness, compared with that of baseline (Fig. 22.15). Moreover, at the six-week follow-up visit, there was an increase in the number of patients showing higher improvement scores as compared to that of the one-week follow-up visit. This suggests that the improvement is a long-term process and there may be advantages if the clinical follow-up can extend beyond six weeks, as more favorable changes may be noted with a prolonged follow-up period (Fig. 22.10).

Treatment Tolerability

Our early study [18] evaluating the use of the TriPollar™ RF device in 39 females who underwent 656 treatment sessions, has noted

that the treated skin became warm to the touch and erythema, immediately after the treatment. The erythema was reported to disappear within 2–3 hours after completion of the treatment session by all subjects. Treatment was well tolerated with minimal to no discomfort. The sensation most often described was a mild heating with occasional pinching. Another study using such a device to treat 17 patients for a total of 102 treatment sessions found that the procedure was well tolerated in all study subjects [17]. The subject's reported feeling during the treatment was described as comfortable in 29.4% (5/17) of the subjects, very comfortable in 64.7% (11/17), and extremely comfortable in 5.9% (1/17).

Side Effects

Experience in our recent study using the Regen™ system for circumference reduction and cellulite treatment noted that the

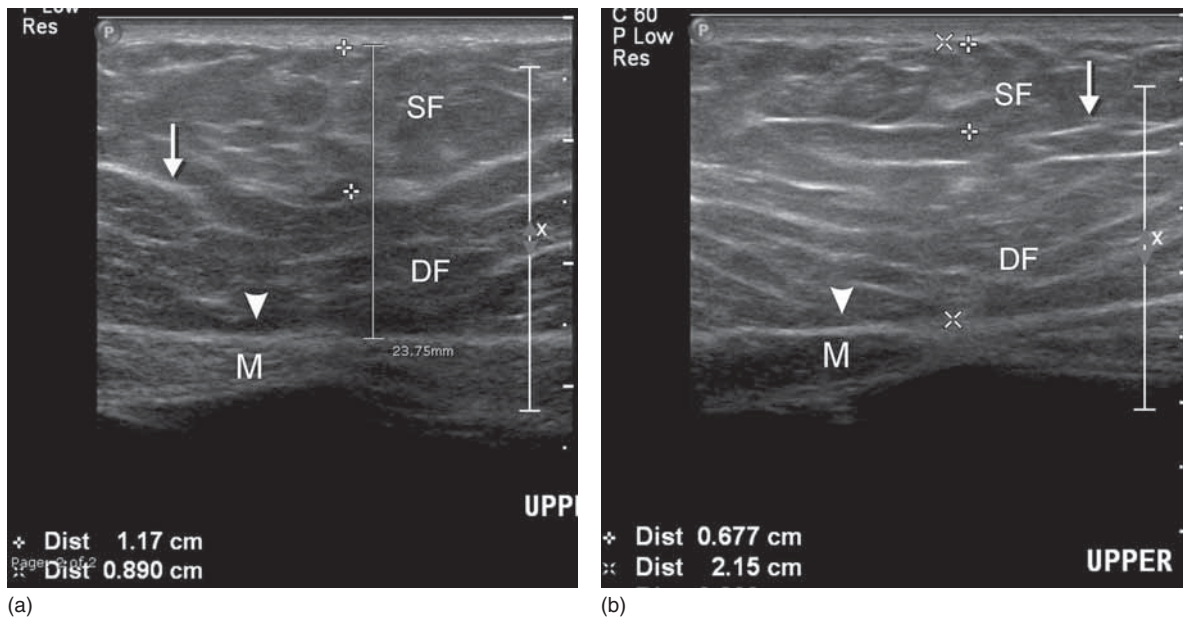


Figure 22.14 Ultrasound measurement of a thigh region. (a) Before treatment, the thickness of the superficial fat layer is 1.17 cm; (b) after eight TriPollar™ treatments, the thickness is 0.68 cm; SF, superficial fat layer; DF, deep fat layer; M, muscle; ↓, superficial fascia; □ deep fascia.

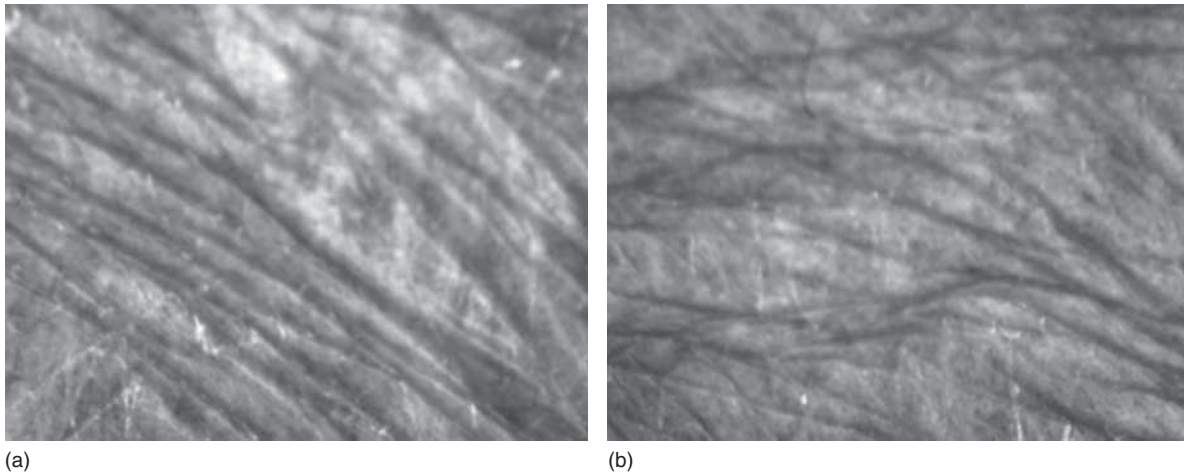


Figure 22.15 Images from a UVA-light video camera (Visioscan® VC 98, Courage-Khazaka, Köln, Germany) showing striae surface smoothness before treatment (a); (b) six weeks after six TriPollar™ treatments. Note the improvement of surface irregularity.

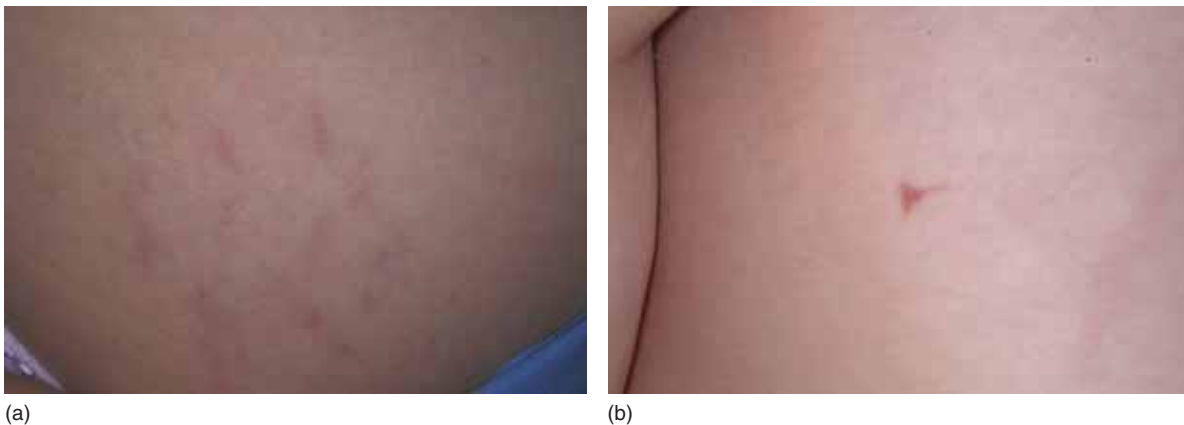


Figure 22.16 Side effects of TriPollar™ RF treatment. (a) bruise; (b) primary degree burn.

adverse effects in a series of 656 treatment sessions included erythematous papules, papular urticaria, primary degree burn, blister and bruising, observed in 0.3% (2/656), 0.15% (1/656), 0.15% (1.656), 0.15% (1/656), and 0.15% (1/656) of 656 treatment sessions, respectively (Figs. 22.16) [18]. We suspect that the reason for these adverse effects may be a result of individual reactions to RF heating and/or improper treatment skill of the treatment provider, including a too-slow movement of the electrode and an inadequate amount of glycerin oil used. All of the side effects were mild, asymptomatic and self-limited within one week except the primary degree burns and blisters, which cleared after a week course of topical corticosteroids.

Conclusions

The TriPollar™ RF device is a multi-polar RF system which can safely and effectively be used for skin tightening and circumference reduction, particularly on the body and facial areas, as well as for the treatment of cellulite, reduction of localized fat and improvement of striae appearance. Application of this treatment modality is simple, non-invasive and safe on all skin types. Qualitative as well as quantitative assessments have been documented

and the outcome from previous research studies has shown that the improvements are maintained as a long-term effect.

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