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Clinical experience with a TriPollar™ radiofrequency system for facial and body aesthetic treatments

Non-invasive aesthetic treatments aiming at circumference reduction and facial wrinkle improvement are becoming increasingly popular. TriPollar™ treatments for the purpose of body contouring and skin tightening procedures have recently gained interest. Our aim was to evaluate the safety and efficacy of the Apollo™ device for non invasive treatment of localized excess fat and facial tightening. 37 female patients were treated for wrinkles, laxity and circumference reduction on different facial and body areas. Facial results were objectively analyzed with the Primos 3D imaging system. Body results were evaluated using photographs and circumferential measurements. Five volunteer patients underwent blood tests to assess changes in liver function and lipid profile following treatment. Significant reductions in body circumferences were measured. The average circumference reduction in main body areas (abdomen, buttocks, thighs), was 3.6 ± 2.4 cm with a maximum reduction of up to 10.5 cm in the abdomen. An improvement of perioral and periorbital wrinkles was achieved and analyzed. No significant changes were found in any of the liver function and lipid profile indicators. Findings confirm safety and efficacy of the new treatment modality for localized fat reduction and for body and face contouring.

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Full body, non-invasive, energy-based, aesthetic treatments are becoming increasingly popular among female as well as male patients of all ages. Different technologies are presently available to rejuvenate skin, including therapeutic ultrasound, lasers and intense pulsed light (IPL), however radiofrequency has emerged as the most effective and versatile modality for the broadest range of body and facial treatments [1, 2].

Radiofrequency energy is a form of electromagnetic energy. When applied to tissues, rapidly oscillating electromagnetic fields cause movement of charged particles within the tissue and the resultant molecular motion generates heat.

RF heating of tissue has been a standard surgical tool for many decades for hemostasis and tissue ablation, but more recently has become popular as a means of shrinking redundant or lax connective tissues, through the mechanism of collagen denaturation. 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 a denaturization of the triple helix of the collagen molecule. 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 [3]. Heated fibroblasts are also implicated in new collagen formation and subsequent tissue remodeling which can also contribute to the final cosmetic result. 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.

Radiofrequency tissue heating has been previously demonstrated to affect thighs, arms, abdominal circumference, cellulite appearance, sagging skin, wrinkles and fine lines. In addition to immediate tissue tightening and new collagen formation, RF heating appears to stimulate fat metabolism thus enabling full body and facial aesthetic results even when applied as a single treatment modality.

Materials and methods

A total of 37 patients, all females, aged 23-82 years (average 47) were treated for wrinkles, skin laxity and cellulite on different facial and body areas with the Apollo radiofrequency system (Pollogen, Israel). The system is based on TriPollar technology which utilizes three or more electrodes, designed to deliver focused RF current deep into the skin to generate heat through resistance in both the

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dermal and subcutaneous layers. Penetration depth and the resultant clinical effect depends on the design and distance between the electrodes.
The system emits a RF current at a frequency of 1 MHz and a maximum power of 50 Watts. Three different applicators may be attached for treatment of different anatomical areas. A 9.4 cm^2 applicator for large body areas, a 1.7 cm^2 applicator for medium sized body areas and various facial areas and a 0.4 cm^2 applicator for small facial areas, such as the perioral and periorbital areas, as well as hands.
Anatomical areas treated included abdomen (16), thighs (9), face (9), buttocks (5), and arms (3). Treatments were performed once a week. Average number of treatments was 7 (range 2-15) as determined by each patient's condition and specific needs. Prior to treatment a medical history was taken to exclude any contraindication such as pregnancy, any implantable electronic device that could be disrupted by RF energy and any active dermatological or collagen-vascular disorder. Treatment areas were first cleaned and then lubricated with medical grade Glycerin. Patients were provided with a "bio-feedback control" which enabled them to stop the treatment should they experience some discomfort. Applicators were applied with continuous circular or elliptical movements, with slight pressure. A non-contact, infrared thermometer (Newtech Sources Co. Ltd.) was used to maintain an external skin temperature of 40-42 °C for a few minutes, according to the recommended exposure time.
All treatment sites were photographed using standard photography techniques at baseline, immediately after the first treatment for immediate results, and at the follow-up visit, one week following final treatment, for long term results. Circumference measurements were taken on the abdomen, buttocks, thighs and arm treatment sites before the first treatment session (base-line), before consecutive treatments and at the follow-up visit. Mean values were calculated from raw data and differences between base-line and follow-up measurements were analyzed using the paired Student's t-test at a significance level of $p < 0.05$.
Measurements were performed at standard conditions: same height from the floor or same distance from a defined anatomical point, constant distance between the subject's feet (about the width of the pelvis), arms crossed and positioned in front of the chest. In most cases, four marks at the same height at the front, back and sides of the anatomical area were made using a make-up pencil and then a measuring tape was placed across all marks. This procedure ensured a straight, horizontal and continuous line between the marks.
Results on perioral and periorbital facial areas were also evaluated with a three-dimensional (3-D) micro-topography imaging system (PRIMOS, GFM, Teltow, Germany). This imaging system projects light on a specific surface of the skin with a Digital Micro-mirror Device (DMD; Texas Instruments, Irving, Tx) and records the image with a CCD camera. Skin surface micro-topography is reconstructed using temporal phase shift algorithms to generate 3-D images. The imaging system has an overlap feature which enables precise matching of photos taken at different visits.
Objective PRIMOS evaluation was based on volume analysis and wrinkle depth analysis. Volume analysis represents the estimated volume (or occupied space) of skin cavities such as: fine lines, wrinkles or skin depressions, in a marked area below a reference plane. Volume analysis was conducted using 3-dimensional topographic photos of perioral and periorbirtal areas, taken before and after treatments. The photos taken before and after treatment were matched and the volume of a defined area was compared. The size of marked areas differed from one patient to the other, according to the visual improvement detected in the 3-D photos. Volume reduction is calculated as: (Vb-Va)/Vb (b- before, a- after). For wrinkle depth analysis, a single line is marked on the 3-D photo, across the same wrinkle before and after the treatment. The lines are analyzed and presented as a cross-sectional representation (graph) representing the depth of each line. Wrinkle depth analysis is measured according to the distance – height differences between two points of a cut-line which passes through two defined points: one at the curve before and the second at the curve after the treatment. Wrinkle depth analysis was conducted using 3-dimensional topographic photos of perioral and periorbital areas taken before and after the treatment. This analysis was done in those patients where the reduction of wrinkle depth and size was visualized in the 3-D representation by the reduction in intensity of dark colors, mainly the blue.
Finally, to evaluate any effects of Apollo treatments on liver function and lipid profile, five (5) volunteer patients, aged 33-56, underwent blood tests at baseline before the first treatment and on the morning after the second treatment. Liver function was assessed by ALKP, ALT, AST, GGT and total Bilirubin, while lipid profile was assessed by triglycerides, cholesterol, HDL and LDL.

Results

On patients who underwent body treatments, circumference measurements on the various body areas showed statistically significant reductions ($P < 0.0001$) following treatment. Average abdominal circumference reduction was 4.5 ± 2.7 cm ($P = 0.000003$) with a maximum reduction of 10.5 cm, average buttocks reduction was 3.1 ± 1.7 cm ($P = 0.0076$) with a maximum of 5 cm and average thigh reduction was 2.4 ± 2.0 cm ($P = 0.000019$) with a maximum of 6.4 cm *(figures 1A, B)*. Photographs demonstrated immediate and long term skin tightening and reduction in circumferences and in the appearance of cellulite following treatments *(figures 2A, B, C, D)*. Only three patients underwent arm treatment. Two of these patients experienced significant reductions of 1.4 and 2.8 cm. Patients' average weight before the treatments was 66 kg while at the end of the treatment sessions average weight was 65 kg.
In patients who underwent facial treatments, slight erythema and/or edema were detected at the end of the treatment and generally lasted for few hours and up to 1 day. This immediate effect contributed to an overall tightening and firming of the skin and the softening of facial fine lines and wrinkles, as was documented by photography and Primos results *(figures 3A, B, C, D, E)*.
Photography and Primos results following the full treatment sessions showed significant long term facial skin tightening with a reduction in the appearance of wrinkles. Changes in wrinkle depth and volume as recorded by the

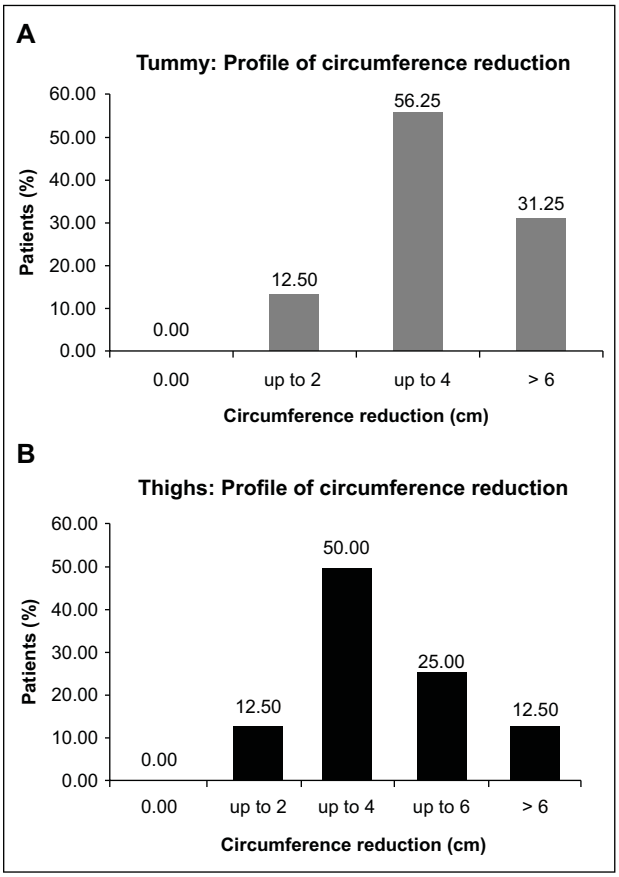

Figure 1. Profiles of circumference reduction in abdominal and thigh areas.

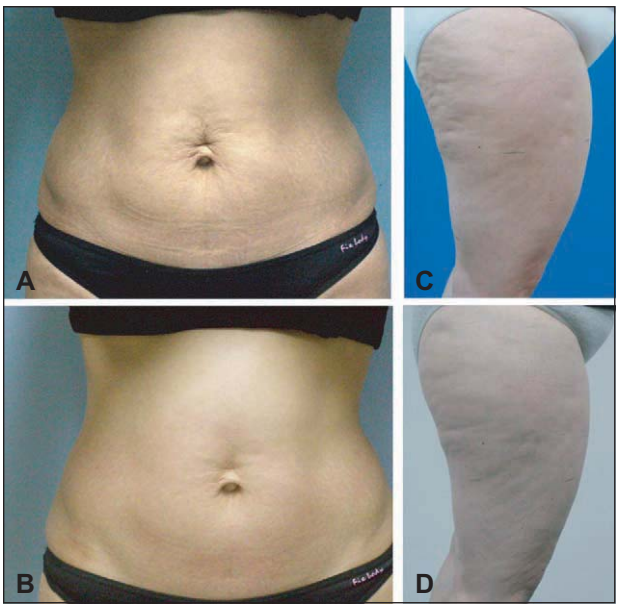

Figure 2. *Abdomen immediate results*. **A)** Before treatment. **B)** Immediately after one treatment. *Thigh cellulite and circumference reduction*. **C)** Before treatment, **D)** After 3 treatments, 1.3 cm reduction.

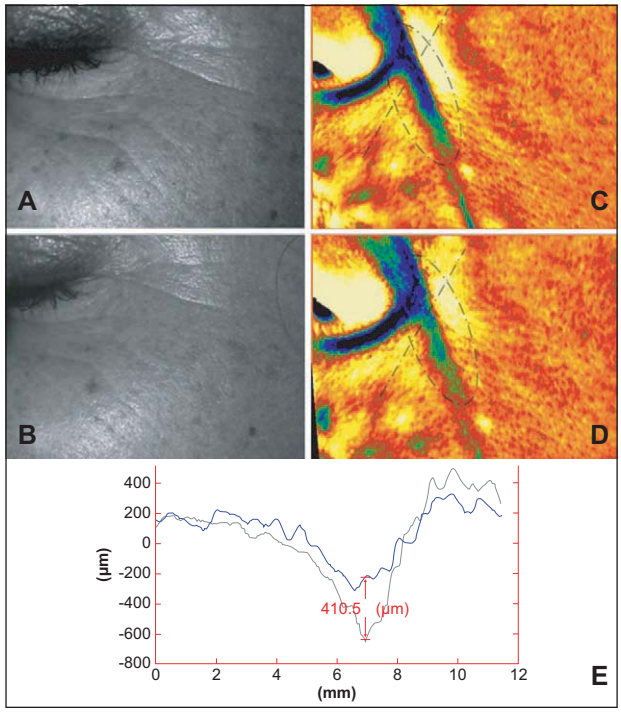

Figure 3. Primos 3D periorbital photos demonstrating an example of immediate facial results. **A)** Before treatment. **B)** Immediately after treatment. Example of immediate results in perioral area (naso-labial wrinkle) analyzed by Primos. Areas of wrinkle depth and volume analysis are marked. Calculated volume reduction was 42%. **C)** Before treatment. **D)** Immediately after treatment, note reduction in intensity of blue and green colors. **E)** Wrinkle depth analysis (Grey line represents depth before treatment, Blue line represents depth after treatment).

Primos system are presented in *figures 4A, B, C, D, E, F, G*. No significant adverse effects were recorded and most patients reported a pleasant feeling resembling a warm massage during treatment.

Subjects scored their sensation during facial treatments on a 5 score scale where 1 signified "very uncomfortable" and 5 signified "extremely comfortable". 85.7% of the patients rated their sensation as comfortable to extremely comfortable, with an average score of 4.1. In the five volunteer patients who underwent blood tests at baseline and after two treatments, no statistically significant changes were found in any of the liver function and lipid profile indicators. All changes measured represented normal fluctuations in blood test values. No undesired effects on liver function and lipid profile were found.

Discussion

Aesthetic dermatology procedures for non-ablative treatment of skin ageing or subcutaneous fat related aesthetic problems have become an integrated and essential part of everyday dermatology practice [4]. The clinical results obtained in this study for both facial and body aesthetic treatments correlate well with previous reports on the use of TriPollar radiofrequency technology for various body contouring applications. Manuskiatti [5]. studied the

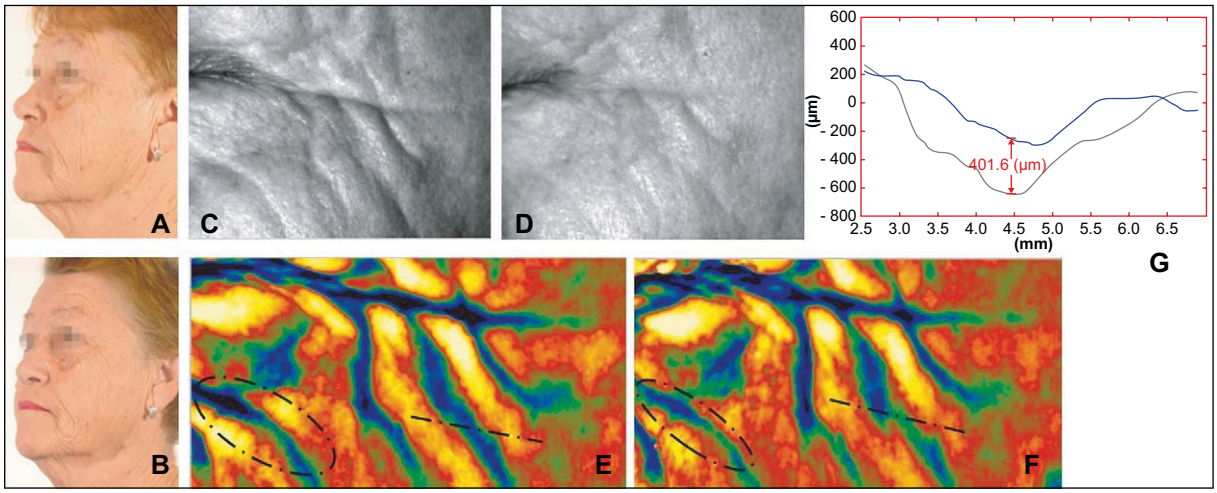

Figure 4. Example of long term results in a 68 year old patient. **A)** Before treatment. **B)** After 8 treatments. Primos 3D periorbital photos showing long term results. **C)** Before treatment. **D)** After 8 treatments. Primos 3D periorbital analysis of long term results (same patient). Areas of wrinkle depth and volume analysis are marked. Calculated volume reduction was 43%. **E)** Before treatment. **F)** After 8 treatments, note reduction in intensity of dark colors, mainly the blue. **G)** Wrinkle depth analysis (Grey line represents depth before treatment, Blue line represents depth after treatment).

effects of this technology on circumference reduction and cellulite treatment on thirty-nine females who underwent eight weekly TriPollar treatments on abdomen, thighs, buttocks and arms. Significant circumference reductions of 3.5 and 1.7 cm, at the abdomen and thigh regions respectively, were found, in line with the results of this study. A 50% improvement in cellulite appearance was noted, based on the physician's cellulite grading scores. Kaplan [6] evaluated the safety and efficacy of TriPollar technology on twelve (12) patients in reducing fat and collagen regeneration. One patient consented to a series of TriPollar treatments prior to her scheduled abdominoplasty and a controlled histopathology analysis was performed on skin samples taken during the abdominoplasty procedure. Histopathological examination revealed marked differences between treated and non-treated abdominal skin areas. An increase of 49% in dermal thickness, focal thickening of collagen fibers and focal shrinkage of fat cells was shown following treatments. Boisnic [7] studied the biological mechanism of the TriPollar RF device responsible for the clinical results. Human skin samples were collected from abdominoplasty surgery and facial lifts, in order to evaluate the lipolytic and anti-aging effects of the device, using an *ex vivo* human skin model. The anti-cellulite effect was evaluated by the dosage of released glycerol and histological analysis of the hypodermis. Skin tightening was evaluated by morphometric analysis of collagen fibers and the dosage of collagen synthesis. A significant increase of glycerol release by skin samples was found. The structure of fat cells was altered in shape and a modification of the fibrous tract was also detected in the fat layer. Additional findings indicated stimulation of the dermal fibroblasts with increased collagen synthesis. Finally, Manuskiatti [8] reported on the treatment of striae distensae with the TriPollar device. Seventeen females with striae received six weekly treatments. Participants were evaluated using standardized photographs and a UVA-light video camera. At 1 week after the final treatment, 38.2% and 11.8% of the subjects were assessed to have 25-50% and 51-75% improvement of their striae, respectively. At a 6-week follow-up, a higher percentage of the subjects were rated to have improvement of their striae.

This study is the first to report both subjective and objective facial skin tightening results with the TriPollar RF technology using specific system applicators indicated for facial treatments. The Primos system used in this study to obtain objective results has been previously deployed to provide rapid and quantitative assessment of skin surface topography and facial fine lines following treatments with non-ablative laser and other cosmetic procedures, correlating well with clinical and subjective responses [9, 10]. Of particular interest is the significant immediate wrinkle reduction result recorded with the PRIMOS system. This is due to edema which develops during the treatment and may last for several hours to a few days. This edema helps in maintaining an immediate effect until collagen shrinkage and remodeling establish the long term effect. The Primos results presented in this study reflect measurements conducted in a relatively small group of patients who received facial treatments, thus only examples of results showing a trend of wrinkle improvement were demonstrated. A study involving a larger group of patients is recommended to enable statistical analysis of the results to further confirm the presented Primos data. The Primos system has also been recently used to study a TriPollar facial home-device on twenty three (23) female subjects, aged 37-64 [11]. A statistically significant objective reduction of perioral and periorbital wrinkles was achieved in 90 and 95% of the patients respectively, with an average periorbital wrinkle reduction of 41%. This objective result correlated well with the subjective Fitzpatrick Wrinkle Classification Score periorbital result of 40%, although it was lower for the perioral region. All patients were satisfied to extremely satisfied with the treatments and all reported moderate to excellent visible results.

This study found no statistically significant effects on liver function and lipid profile following two TriPollar radiofrequency abdominal treatments. These results are in line with previous studies which have reported no effects on lipid metabolism following radiofrequency aesthetic treatments. Sadick [12] reported a study evaluating the safety and efficacy of the Velasmooth system in the treatment of cellulite and thigh circumference reduction. This system combines mechanical vacuum massage with radiofrequency and infrared dermal and subdermal heating. Sixteen subjects were treated twice weekly for 6 weeks. Blood was taken from five willing subjects for assessment of lipid and hormone levels and liver function. The samples were taken before the first treatment, after the final treatment and at the post-treatment follow-up visit, which occurred at 4 weeks. All blood tests results were normal throughout the study, while 71.8% of treated legs showed a decrease in thigh circumference. Goldberg [13] reported a clinical, laboratory and MRI analysis of cellulite treatment with a Unipolar radiofrequency device. Thirty subjects with upper thigh cellulite were treated every other week for a total of 6 treatments. Subjects were evaluated before and 6 months after treatment, with clinical photographs, clinical measurements, biopsies, MRIs, and blood lipid evaluations. Results demonstrated clinical improvement in twenty seven subjects. Histologic changes showed dermal fibrosis of the upper dermis. No undesired complications of the skin or lipid metabolism were noted.

Conclusion

This study presents objective facial improvement results following treatments with the TriPollar radiofrequency device and confirms previous reports on the safety and efficacy of this technology for the treatment of excess fat and body contouring. The study demonstrates that there are no undesired changes in lipid profile and liver function following the procedure. The treatment is painless and pleasant even when performed on sensitive areas with sagging and loose skin, such as the inner thighs, arms and neck. The TriPollar treatment is excellent for patients following pregnancy, liposuction or dramatic weight loss who have excessive loose skin. The treatment is also suitable for patients post face lift surgery, to improve the healing process. Following each treatment session, most patients benefitted from immediate as well as long term results. ■

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