

ORIGINAL ARTICLE

Home-use TriPollar RF device for facial skin tightening: Clinical study results

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Abstract

Background: Professional, non-invasive, anti-aging treatments based on radio-frequency (RF) technologies are popular for skin tightening and improvement of wrinkles. A new home-use RF device for facial treatments has recently been developed based on TriPollar™ technology. **Objective:** To evaluate the STOP™ home-use device for facial skin tightening using objective and subjective methods. **Methods:** Twenty-three female subjects used the STOP at home for a period of 6 weeks followed by a maintenance period of 6 weeks. Facial skin characteristics were objectively evaluated at baseline and at the end of the treatment and maintenance periods using a three-dimensional imaging system. Additionally, facial wrinkles were classified and subjects scored their satisfaction and sensations. **Results:** Following STOP treatment, a statistically significant 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 periorbital wrinkle classification result of 40%. All patients were satisfied to extremely satisfied with the treatments and all reported moderate to excellent visible results. **Conclusions:** The clinical study demonstrated the safety and efficacy of the STOP home-use device for facial skin tightening. Treatment can maintain a tighter and suppler skin with improvement of fine lines and wrinkles.

Key Words: home-use, radiofrequency, skin tightening, STOP™, TriPollar

Introduction

One of the most frequent signs of aging is the appearance of fine lines and wrinkles. Regardless of when wrinkles are first seen, they are an undesirable indicator of age, especially for people who are constantly seeking ways to look and feel their best.

Improved life expectancy has changed the perception of aging and, in turn, propelled scientific anti-aging research that has led to a multitude of anti-aging treatments. In recent years, skin anti-aging research has advanced at a rapid pace and non-invasive treatments such as lasers, intense pulsed light (IPL), infrared (IR) and radio frequency (RF) were developed scientifically to treat the signs of aging at professional clinics.

RF treatment has been gaining more and more acceptance over the past few years owing to its safety and efficacy. Unlike light-based treatments, RF is suitable for all skin types and colors.

RF 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. During the past few years this source of heat has been extensively used in aesthetic clinics worldwide as a means of shrinking redundant or lax connective tissues through the mechanism of collagen denaturation (1). Heated fibroblasts are also implicated in new collagen formation and subsequent tissue remodelling, which can also contribute to the final cosmetic result. Based on these mechanisms, large, high-power RF systems have been effectively used by dermatologists and aesthetic surgeons for indications such as skin tightening, wrinkle removal, body contouring and treatment of cellulite on various body areas, including the face, neck, arms, abdomen, buttocks and thighs (2). In these systems, RF energy is either applied to tissue between two points on the tip of a probe (bipolar) or between a single electrode tip and a grounding plate (monopolar) (3). The latest generation of RF-based systems, however, employs a unique TriPollar™ design (regen™ and apollo™; Pollogen Ltd), which is based on multiple electrodes with a proprietary sequence

of current modulation between these electrodes. This technique has been clinically demonstrated to be highly effective in focusing RF power deep into dermal layers while maintaining safe epidermal skin temperatures without active cooling (4).

STOP™ is the first home-use RF device for facial skin tightening, which has recently been developed based on TriPollar technology. The device focuses low RF power from four electrodes deep into the dermis to stimulate dermal activity, tighten collagen fibers and increase new collagen production. STOP has an automatic temperature monitoring mechanism. When the skin temperature reaches a pre-programmed threshold of up to 40°C, the power will turn off and on alternately to maintain the desired skin temperature and prevent epidermal overheating. The system is indicated for the treatment of skin laxity, to reduce fine lines and wrinkles, and improve skin texture. Based on prior clinical experience with TriPollar technology, it is expected to be safe and effective in reversing signs of skin aging on all skin types.

A clinical study was undertaken to evaluate both objectively and subjectively the STOP home-use device for facial skin tightening on various skin types. Objective evaluations were carried out using an in vivo three-dimensional microtopography imaging system (PRIMOS; GFM, Teltow, Germany). This imaging system projects light on to a specific surface of the skin with a Digital Micromirror Device (DMD; Texas Instruments, Irving, TX, USA) and records the image with a CCD camera. Skin surface microtopography is reconstructed using temporal phase shift algorithms to generate three-dimensional images. This objective technique has previously been demonstrated to provide rapid and quantitative assessment of skin surface topography and facial fine lines after treatments with non-ablative laser or other cosmetic procedures, correlating well with clinical and subjective responses (5,6).

Materials and methods

The study was conducted at a medical aesthetic clinic, in Paris, France from July to October 2008. Twenty-three healthy female subjects, aged 37–64 (mean 48.6) years, with skin types II (10 subjects), III (12 subjects) and V (one subject) participated in the study. Subjects were screened for any contraindications, which are similar to clinic-based RF or non-ablative laser skin rejuvenation contraindications, and signed an informed consent form. Prior to any treatment, standardized facial digital camera photographs were taken by a professional photographer as well as PRIMOS images, and the principal investigator scored the patient wrinkles, based on skin observation and touch, according to two scales: the Fitzpatrick wrinkle classification system (Table I) (7) and a skin aging atlas (8), which represent various

Table I. The Fitzpatrick wrinkle classification system (7).

Class	Wrinkling	Score	Degree of elastosis
I	Fine wrinkles	1–3	Mild(fine textural changes with subtly accentuated skin lines)
II	Fine to moderate depth wrinklesModerate number of lines	4–6	Moderate(distinct papular elastosis [individual papules with yellow translucency under direct lighting] and dyschromia)
III	Fine to deep wrinklesNumerous linesWith or without redundant skin folds	7–9	Severe(multipapular and confluent elastosis [thickened yellow and pallid] approaching or consistent with cutis rhomboidalis)

photographic scales of different facial areas based on skin sagginess, firmness and laxity.

Following baseline documentation, subjects were instructed on the proper use of the STOP device, underwent the first supervised complete facial treatment in the clinic and documentation immediately following this treatment was repeated. An additional 17 treatments, each takes typically 12–15 minutes, were self-performed by the subjects at home, three times a week for 6 weeks, with at least 1 day between treatments. Thereafter, subjects performed six additional maintenance treatments at 1-week intervals. Subjects returned to the clinic for follow-up visits at 6 weeks and 12 weeks following initiation of the study. Subjects were instructed to refrain from treatments at least 3 days before follow-up 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 three-dimensional (3D) topographic photographs of perioral and periorbital areas taken before and after treatments. The photographs 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 3D photographs. Volume reduction is calculated as:

$$(V_b - V_a) / V_b$$

where b = before and a = after.

For wrinkle depth analysis, a single line is marked on the 3D photograph 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 3D topographic photographs of perioral and periorbital areas taken before and after the treatment. This analysis was done in patients where the reduction of the wrinkle depth and size was visualized at the 3D representation by the reduction in intensity of dark colors, mainly blue.

Subjective patient evaluations were recorded after the first treatment and at each of the follow-up visits. These included evaluation of visible results (I = no result to V = excellent result), overall treatment sensation (I = very uncomfortable to V = very comfortable) and overall satisfaction (I = not satisfied to V = extremely satisfied). Additionally, at the 6- and 12-week visits subjects were asked to fill in evaluation forms which included questions on various clinical and operational issues.

Finally, any adverse effects, such as excessive erythema and/or edema, crusting, blistering, burn, dyspigmentation, pain and scars observed or reported by the patients were recorded.

Results

Objective PRIMOS analysis

Volume analysis results for the periorbital areas and perioral areas, immediately after the first treatment, at the end of treatments (6 weeks) and at the end of maintenance (12 weeks) are summarized in Table II. At the end of maintenance treatments (12 weeks), a statistically significant volume reduction of perioral and periorbital wrinkles was achieved in 90% and 95% of the patients, respectively. Average volume reduction was 19% and 41% at the perioral and periorbital areas, respectively, with a maximum reduction of 52% and 99%. Results on the periorbital

Table II. Volume analysis results.

		Periorbital	Perioral
Immediate	% Improved patients	86	80
	Average volume reduction (%)	39.7	27.9
	Maximum volume reduction (%)	95	56
	<i>p</i>	0.0197	0.0008
6 weeks	% Improved patients	73	68
	Average volume reduction (%)	17.3	7.6
	Maximum volume reduction (%)	74.6	36.4
	<i>p</i>	0.015	0.01
12 weeks	% Improved patients	95	90
	Average volume reduction (%)	41	19
	Maximum volume reduction (%)	99.4	52.3
	<i>p</i>	0.04	0.0029

areas were consistently better than those on the perioral areas.

The extent of wrinkle depth reduction varied between patients and according to the specific wrinkle measured but was clearly evident on most patients.

Figure 1 is an example of the height differences of one wrinkle before and immediately following the first treatment. All five lines from before treatment are deeper than after treatment.

A representative photographic sequence of a subject showing immediate periorbital results as documented and analyzed by the PRIMOS is represented in Figure 2.

Figure 3 demonstrates a sample case with long-term (12 weeks) perioral results.

Fitzpatrick wrinkle classification

The Fitzpatrick 3 class, 9 score, wrinkle scale was used to evaluate the degree of wrinkles/fine lines/rhytids and elastosis before the first treatment and at the 6- and 12-week follow-up visits. On the periorbital areas, the average Fitzpatrick class at baseline was 1.82 and the score was 4.27. At 6 weeks, the average class decreased to 1.55 while the average score was 2.77, a reduction of 35%. At 12 weeks, the average class decreased to 1.47 while the average score was 2.58, a reduction of 40% from baseline.

On the perioral areas, the average baseline class was 1.5 and the average score was 3.68. At 6 weeks, the average class reduced to 1.23 while the average score was 2.23, a reduction of 39.5%. At 12 weeks, the average class decreased to 1.21 while the average score was 2.05, a reduction of 44% from baseline.

In both areas and at both follow-up visits, the average score was reduced by substantially more than 1 point, the criteria set by the FDA for statistically significant wrinkle improvement when using the Fitzpatrick wrinkle classification system.

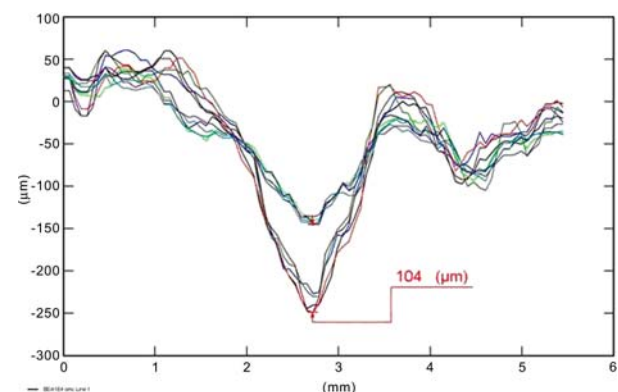


Figure 1. Wrinkle depth analysis showing the height differences of one wrinkle before and immediately following the first treatment. Lower lines - before treatment. Upper lines - after treatment.

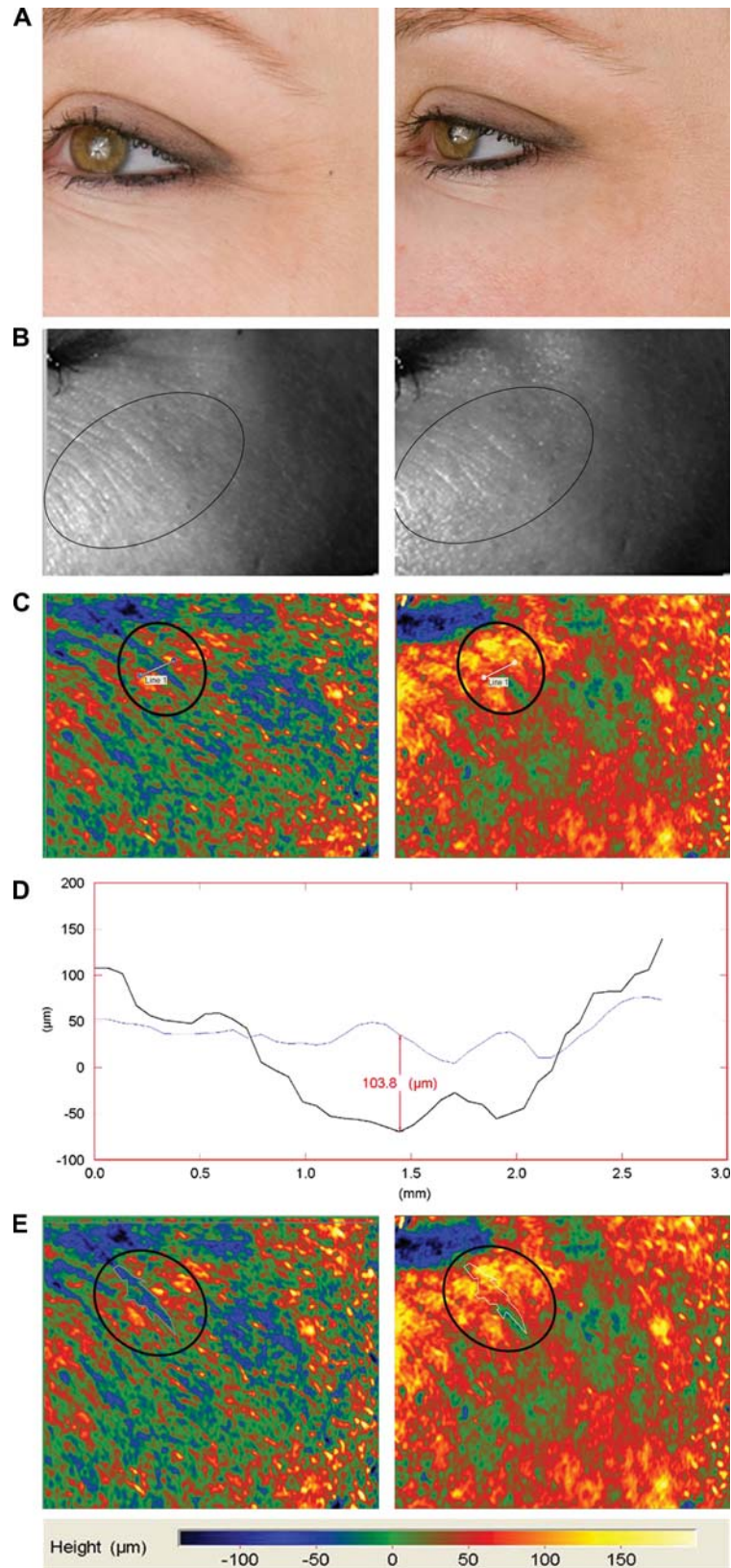


Figure 2. An example of immediate peri-orbital results. (A) Professional photographs: (left) before and (right) immediately after one treatment. (B) PRIMOS camera photographs: (left) before and (right) immediately after one treatment. (C) PRIMOS 3D photographs: (left) before and (right) immediately after one treatment; the area of wrinkle depth analysis is marked. (D) Cross-sectional representation of PRIMOS wrinkle depth analysis (grey line = before; blue line = after). (E) PRIMOS 3D photographs showing marked area for volume evaluation: (left) before and (right) immediately after one treatment.

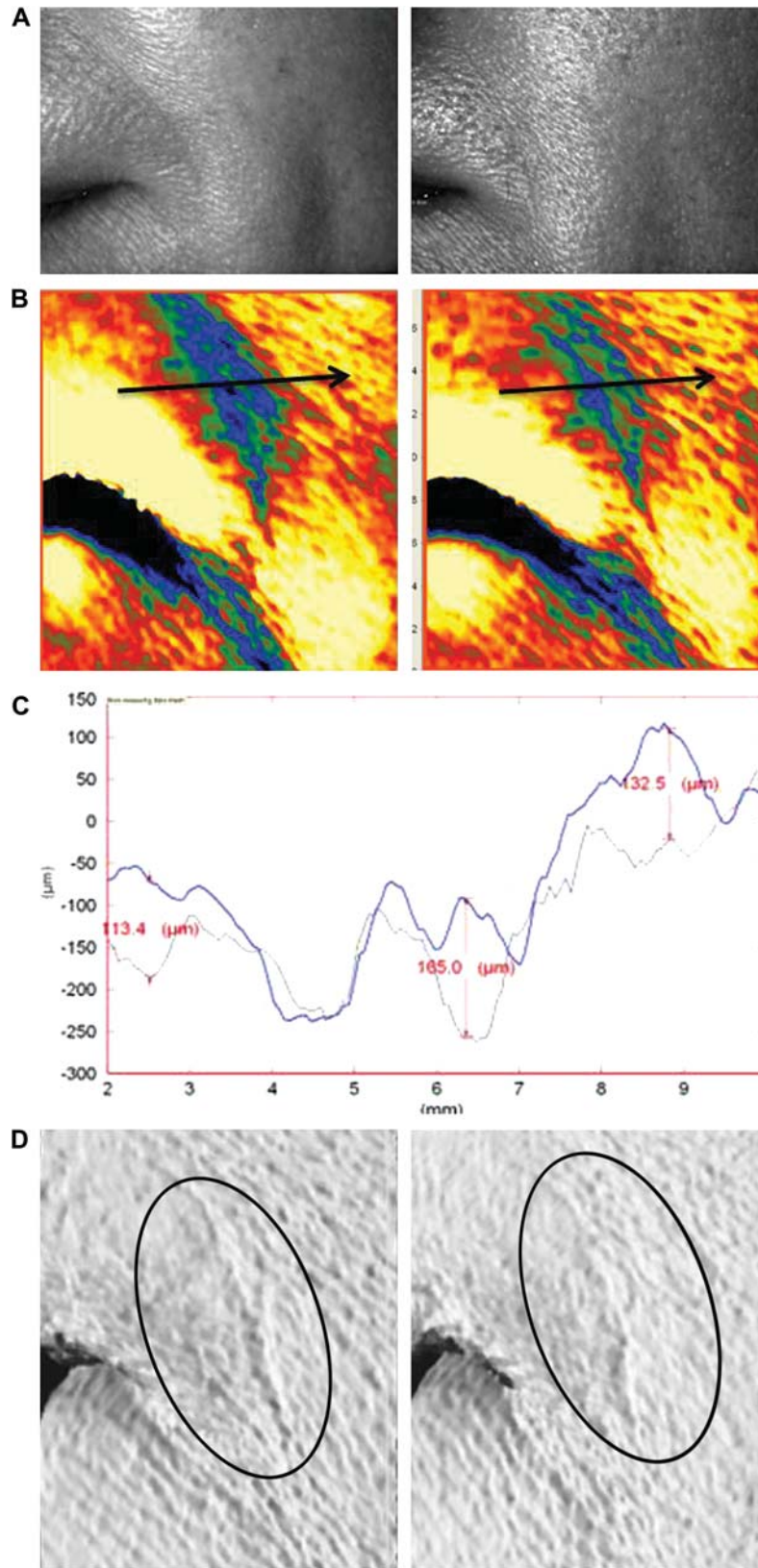


Figure 3. Example of long-term perioral results. (A) PRIMOS camera photographs: (left) before and (right) at 12-week visit. (B) PRIMOS 3D photographs: (left) before and (right) at 12-week visit; the area of wrinkle depth analysis is marked. (C) Cross-sectional representation of PRIMOS wrinkle depth analysis (grey line = before; blue line = after). (D) PRIMOS topographic photographs: (left) before and (right) at 12-week visit.

Skin aging atlas scale

The results according to this scoring method for different facial and neck wrinkled areas are summarized in Table III. For all areas and all patients, the average score at baseline was 2.79, at 6 weeks it was 1.86, and at 12 weeks it was 1.6. This represents a wrinkle score reduction of 33.5% and 42.7%, respectively, for the 6- and 12-week follow-ups, in line with the results obtained according to the Fitzpatrick system.

Patient satisfaction results

Following the first treatment, 72% of the subjects reported a moderate to excellent immediate result and 91% of the subjects felt comfortable to extremely comfortable with the treatment. No subject reported no immediate result or an uncomfortable feeling during the treatment. At the 6-week follow-up visit, 85.7% of the subjects reported moderate to excellent visible results with an average VAS score of 3.57; 90.5% of the subjects were overall satisfied to extremely satisfied with the treatment and the average satisfaction VAS score was 3.43; 95.2% of the subjects felt comfortable to extremely comfortable with the treatment and gave an average comfort VAS score of 3.29. Again, none of the subjects reported no result or any discomfort with the treatment. At the 12-week follow-up, 100% of the subjects reported moderate to excellent visible results and gave an average VAS score of 4.05; 100% of the subjects were satisfied to extremely satisfied with the treatment, giving an average satisfaction VAS score of 3.55.

Subject self-evaluation results

- 86.4% of participants noticed a skin-lifting effect
- 77.3% of participants noticed improvement in skin texture

- 63.64% of participants noticed improvement in skin smoothness
- 63.64% of participants noticed a reduction in wrinkles and rhythids.

The treatment protocol was found to be easy and comfortable to follow by 95% of the subjects and 65% of the subjects claimed they would definitely like to continue to use the device.

Adverse events reported, mostly excessive erythema, were all minor and transient, requiring no special treatment. In one case, where the subject reported pain felt on the chin during treatment, she was advised to reduce pressure on the skin while applying treatment and indeed the pain sensation was resolved.

Discussion

In recent years, RF has become an accepted modality, in dermatological and aesthetic clinics, for the non-ablative treatment of facial rhythids and skin laxity.

The first RF device aimed at skin tightening (ThermaCool™; Thermage Inc.) was initially studied using a standard guinea pig model (9). With this monopolar device, dermal heating as shallow as the papillary dermis or as deep as the subcutaneous fat was achieved. Histological results showed that heating the dermal layer of the skin is associated with collagen denaturation and subsequent thickening and shortening of collagen fibrils. This is followed by a period of increased fibroblast activity and neo-collagen formation over a period of several months. A multicenter, blinded, clinical trial was then performed with this device on 86 patients with periorbital wrinkles or skin laxity who underwent a single treatment (7). Treatment efficacy was evaluated with the Fitzpatrick wrinkle classification score (FWCS), by photographs, through a patient satisfaction questionnaire and by an objective technique to measure

Table III. Skin aging atlas scores.

Area	Score before (baseline)	Score at end of treatment (6 weeks)	Score at maintenance (12 weeks)	% Reduction at end of treatment (6 weeks)	% Reduction at maintenance (12 weeks)
Crow's feet, no.	3.05	2.05	1.79	32.8	41.24
Crow's feet, depth	3.5	2.41	2.16	31.1	38.35
Crow's feet, general	2.82	1.64	1.42	41.8	49.58
Under eyes	3.18	2.09	1.74	34.3	45.41
Between brows	2.82	1.86	1.37	34	51.44
Upper lips	2.82	1.64	1.32	41.8	53.31
Nasolabial	2.77	2	2	27.8	27.87
Jaw line	2.64	1.5	1.37	43.2	48.09
Saggingness of neck	2.27	1.95	1.68	14.1	25.89
Neck texture	1.77	1.36	1.11	23.2	37.32
Marionette	3.05	1.91	1.63	37.4	46.43
Total sum (AVG of all)	2.79	1.855	1.6	33.50%	42.70%

eyebrow lift. Subjects were followed-up at 2, 4 and 6 months and were also evaluated for potential adverse effects. Treatments were administered under topical anesthesia. Independent scoring of blinded photographs resulted in FWCS improvements of at least 1 point in 83.2% of treated periorbital areas at the 6-month follow-up. Fifty percent of subjects reported being satisfied or very satisfied with the results. Most patients experienced mild to moderate pain. Common immediate side effects included erythema (36%) and edema (13.9%). By 1 month only three (3.9%) had lingering signs of erythema. Overall, second-degree burn incidence was 0.36%. Three patients had small areas of residual scarring at 6 months.

Fritz et al. (10) were the first to report on a study comparing multiple RF treatments to a single RF treatment for mild-to-moderate laxity of the middle and lower face. Eleven patients received a single treatment and nine patients underwent two treatments spaced 1 month apart. Blinded assessment of standardized photography was used to rate improvement. At 4 months' follow-up, patients in the two-treatment group received higher scores than those in the single treatment group. The authors concluded that two RF treatments yielded significantly better improvement than a single treatment, although overall improvements were modest in both groups.

Friedman and Gilead (11) reported on the use of an RF device for the treatment of facial rhytids and lax skin, applying a unipolar handpiece for deep tissue heating and a bipolar handpiece for superficial tissue heating. Sixteen female patients received four to six successive multiple treatments spaced 2–3 weeks apart. No topical anesthesia was used on any of the treatment areas. Treatment was monitored using a laser thermometer to measure epidermal skin temperature immediately after each pass. A therapeutic temperature level of 39–43°C for at least 60 seconds was maintained. In all patients post-treatment erythema was detected, which resolved in 1–2 hours. No patients experienced burns, skin breakdown or scarring. At 1 month after the last treatment, the mean patient satisfaction was 3.06, representing satisfied/very satisfied. Younger patients had a higher satisfaction score. Photographic analysis showed moderate to significant improvement in 69% of the patients.

Another RF device for the treatment of wrinkles and elastosis has been described by Gold et al. (12). This vacuum-assisted, bipolar device (Aluma™; Lumenis Inc.) draws the skin between two parallel electrodes before applying the RF current. Forty-six subjects underwent eight facial treatments every 1–2 weeks. At 6 months' follow-up, patients were evaluated using the FWCS and a visual analog scale. Significant improvement in skin appearance and texture was observed during the treatment course and

continued to increase during the follow-up period. The mean FWCS was reduced from 4.5 to 2.5 by 6 months after treatment, representing a drop of an entire wrinkle class (from II to I) on this scale. No permanent complications occurred.

Finally, several recent publications have addressed the issue of safety with non-ablative RF skin tightening. Weiss et al. (13) published a retrospective analysis of efficacy and safety in over 600 RF facial tightening treatments performed between May 2002 and June 2006. A treatment algorithm evolved over this period from high-fluence, single treatment to multiple pass, multiple treatment, lower fluence, which is associated with better clinical outcomes and greater patient acceptance.

The experience gained and reported with these clinic-based RF devices has indicated a preference for a lower power, multiple-session treatment regimen, with no anesthesia, utilizing heat and pain sensations as a feedback mechanism to control treatment. This experience, backed by an extremely high level of safety, highlights the suitability of this technique for use at home, hence the development of the STOP device.

The STOP device is based on the clinically proven professional TriPollar RF technology adopted for home use. Using an ex vivo human skin model, Boissin demonstrated the skin renewal effects of the TriPollar technology (14) using morphometric analysis of collagen fibers and dosage of collagen synthesis. The study showed a statistically significant stimulation of the dermal fibroblasts and increased collagen synthesis following TriPollar RF treatment. The same ex vivo model was used to evaluate the STOP biological mechanism of action and results indicate a significant effect in terms of collagen regeneration (private communication, data publication in process).

Objective and subjective results obtained in this study with the STOP device used at home indicate efficacy and safety similar to those reported with the larger, clinic-based devices. The current STOP study demonstrates results obtained using the PRIMOS for objective analysis of wrinkles as well as subjective classification of wrinkles done by the investigator using two scales. Since the subjective classification of wrinkles was not done by blinded evaluators, the investigator used two different scoring systems and looked for correlation in trend with the results obtained from the PRIMOS objective analysis of wrinkles. 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 FWCS 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.

Of particular interest are the significant immediate wrinkle reduction results recorded with the PRIMOS system. These are 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.

Relatively slow dermal heating combined with the built-in, automatic temperature monitoring mechanism and the patient's heat and pain sensation, assure treatment safety, even without clinical supervision. Safety of the device for use at home was clearly demonstrated in this study.

Conclusions

This clinical study, which employed both objective and subjective skin analysis techniques, demonstrates the safety and efficacy of STOP, the first home-use RF device for facial skin tightening. Weekly application of the STOP device, on any skin type, can maintain a tighter, suppler skin with a significant reduction of fine lines and wrinkles which result from collagen depletion due to aging and photo damage. Early and consistent use of the STOP device at home may substantially defer these undesirable signs of skin aging.

Acknowledgements

A research grant for the study was provided by Ultra-gen Ltd, the study sponsor.

Declaration of interest: The authors report no conflicts of interest. The authors alone are responsible for the content and writing of the paper.

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