

Facial Tightening With an Advanced 4-MHz Monopolar Radiofrequency Device

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ABSTRACT

Background: Over the past 10 years, radiofrequency (RF) technology has been utilized for nonablative treatments for the treatment of rhytides and skin laxity. This manuscript reviews the scientific background of collagen synthesis in vivo and in response to RF energy as well as a clinical study of 17 patients receiving a series of facial treatments with a 4-MHz monopolar RF (Pellevé, Ellman International, Inc, Oceanside, NY). Clinical methods, results, and a review of the literature for RF aesthetic treatments of the face are presented.

Methods: Seventeen patients were treated in one site with 6 total treatments scheduled as follows: 1 session was performed every 15 days for 2 consecutive sessions, 1 session every month for 2 consecutive sessions, and 1 session every 2 months for 2 consecutive sessions. Both the treating physician and the patients via live viewing and comparison with baseline photographs performed assessment of results. Results are reported as averages across the 17 patients.

Results: Two weeks after the first treatment, patients noted an overall average of 25% to 30% improvement. Just before the last or sixth treatment, there was an average of 50% improvement noted by the physician, with patients ranking an average self-improvement of 48%. The treating physician rated average improvement of 46% compared with baseline, whereas the patients ranked average improvement of 30% compared with baseline at 1 year after treatment was initiated (6 months after the final treatment). Patients find this treatment to be very well tolerated, with minimal to no discomfort and no downtime or significant side effects.

Conclusions: The Pellevé 4-MHz monopolar RF device is effective, safe, and very well tolerated for treating laxity, texture, and wrinkles of the skin without complication or discomfort. Evidence in the literature supports the scientific mechanism of action of acute collagen modification and continued neocollagenesis observed with the system. In this cohort, patients maintain approximately 50% improvement on average at 6 months and a 30% to 50% improvement 1 year after beginning the treatments, 6 months after completion.

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INTRODUCTION

Skin is more than 15% of body weight¹ and is primarily composed of types I and III collagen. Type I collagen is 80% to 85% of the dermal collagen. Type III collagen is primarily observed in the papillary dermis and makes up 10% to 15% of the dermal collagen.

The amount of soluble collagen declines with age, while the insoluble collagen increases; this change is caused by the increase in stable multichain cross-linking and leads to a loss of skin elasticity.² The added stable cross-links also produce an increase in collagen tensile strength with age.³ The amount of new collagen production decreases with age as a result of fibroblast collapse.⁴ The collagen content of the dermis also decreases as a result of increased proteinases that degrade collagen.⁵ These changes lead to decreased collagen turnover, thickening of collagen fibers, more disorganized bundles, and thinning of the dermis. The epidermis also thins, and there is a loss of the rete ridges, which normally extend downward between the dermal papillae. The ratio of type I to type III collagen decreases because of the selective reduction of type I collagen.⁶

The exposure to ultraviolet (UV) radiation adds to these changes in the skin, resulting in accumulation of elastotic material in the papillary dermis and middermis; this process is termed *solar elastosis*. Exposure to UV radiation leads to activation of proteinases that degrade existing collagen.⁷ Collagen synthesis is also reduced; this may be related to fibroblast damage and protein oxidation.⁸

Nonablative radiofrequency (RF) treatment utilizes heat modification of collagen for the treatment of rhytides and lax skin. As collagen is heated, the intramolecular heat-labile bonds forming the chain cross-links are broken, while the heat-stable intermolecular cross-links are maintained.⁹ This unravels the triple helix and shortens the molecule. Electron microscopy has shown an increase in size of the collagen fibrils and a loss of distinct borders among the fibrils, with some fibrils merging together.^{10,11} The initial effect of heating to sufficient temperature stimulates neocollagenesis; however, if the temperature is too high, irreversible denaturation converts the orderly crystalline structure of collagen into the random form, gelatin. Even higher temperatures produce necrosis, scarring, and burning.

A reparative process follows the acute thermal shortening of the collagen molecule over the course of approximately 4 weeks. Three months posttreatment, epidermal hyperplasia and thickening with the development of rete ridges are seen; elastotic dermal material from UV damage is significantly reduced. The amount of newly synthesized collagen is significantly increased from the amount seen immediately following treatment.¹² Neo-collagenesis may occur for up to 6 months after treatment, with a 50% decrease of the thermally damaged collagen and replacement with newly formed dermal collagen.

The typical irreversible denaturation temperature of collagen in the dermis varies with species, collagen type, age, concentration, fiber orientation, temperature exposure time, electrolyte concentration, and hydration level of the tissue. Most in vitro and in vivo studies suggest that the temperature in the dermis should attain 45°C to 65°C (corresponding to lower skin surface temperatures) to achieve the desired clinical results of collagen molecule shortening, noting that the time that the temperature is maintained is directly proportional to the increased temperature.¹³

The heat produced in the tissue can be understood from the following equation:

$$E = (I/A)2 \times Z \times t,$$

where E is the energy deposited in the tissue, I is the current flow through an area A , Z is the tissue impedance (the alternating current tissue resistance), and t is the activation time that the current flows.

The equation has 3 important clinical ramifications: (1) The current density at the active electrode is high, while the current density at the return is low, limiting the heating effect to the tissue under the active electrode without thermally damaging underlying tissue. (2) Small active electrodes will produce higher energy under their area than will a large active electrode at a given energy and time (as a result of their higher current density) and, therefore, higher tissue temperatures. The differing energy density corresponds to differing depths of energy penetration with larger diameter penetrating deeper than smaller-diameter electrodes. (3) Energy is directly proportional to temperature and time. Thus, a high temperature and shorter time may result in the same energy as a lower temperature and a longer duration.

Several systems based on RF current are employed for thermal treatment to the dermis; this manuscript reviews an advanced 4-MHz monopolar device (Pellevé [PV], Ellman International, Inc, Oceanside, NY) used in a continuous motion technique. With this system, the epidermis is cooled in part by the gel and in part by convection to the surrounding air, which occurs because of the mobile technique employed by this device.

A proprietary safety handpiece (GlideSafe®; Ellman International, Inc) comes in multiple diameters to allow for deposition of the energy to both superficial and deeper dermis in a controlled manner. It also possesses a safety mechanism that turns off the energy if the device is not in full contact with the skin, preventing RF "arcing" with a feeling similar to a static shock, and in unusual cases, a surface burn.

Clinical Evidence

One of the authors (A.P.) undertook a study to evaluate both short-term and long-term effects of this system in a defined population in order to achieve tightening of the face and improvement of wrinkles.

METHODS

Seventeen patients were treated in one site (Rome, Italy) with 6 total treatments scheduled as follows: 1 session was performed every 15 days for 2 consecutive sessions, 1 session every month for 2 consecutive sessions, and 1 session every 2 months for 2 consecutive sessions. Both the treating physician (A.P.) and the patients via live viewing and comparison with baseline photographs performed assessment of results. Results are reported as averages across the 17 patients.

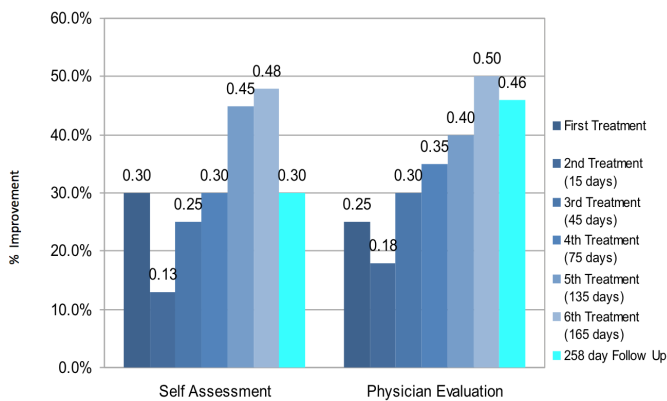
Protocol

Both the 5-mm and 10-mm handpiece were utilized for the procedure (the 5-mm handpiece is no longer available and was replaced with a 7.5-mm handpiece) with a 4-MHz system monopolar RF device (PV). Treatments were performed as follows: each cosmetic unit of the face was treated with a continuous motion technique using a tight, overlapping spiral pattern to achieve a surface temperature of 40°C to 42°C and maintaining that temperature for an additional 4 to 6 passes. Clinically, patients were treated until the erythema and clinical end point consistent with desired results were also sought and achieved.

RESULTS

Physician and patient self-ranked rates of improvement were assessed live at follow-up time points by comparison with a before-treatment photo. Two weeks after the first treatment, patients noted an overall average of 25% to 30% improvement (Figure 1). Two weeks after the second treatment (1 month after the first treatment), there was a reduction in results noted by both patients and doctors. After this data point, the results followed an upward trend; just before the last or sixth treatment, there was an average 50% improvement noted by the physician over all patients, with patients ranking an average self-improvement of 48% (Figures 2-4). The treating physician rated average improvement of 46% compared with baseline, whereas the patients ranked average improvement of 30% compared with baseline 1 year after initiation of treatment and 6 months after the final treatment (Figure 1).

FIGURE 1. Average improvement rated by physician and patient after each treatment, 165 days after last treatment, and 258 days after first treatment.



DISCUSSION

Clinical Literature of Skin Tightening and Radiofrequency

The first device cleared by the U.S. Food and Drug Administration using RF for an aesthetic application occurred in 2002 (Thermacool; Thermage Corporation, Haywood, CA). This device featured a monopolar capacitive coupling mechanism (MCRF) with internal cooling and was meant to deliver results in a single pass at high energy. Although greeted by much enthusiasm among core specialists at the time as the unveiling of the first nonsurgical face-lift, it would take 3 years to realize that a more moderate energy, multipass protocol would yield safer, more tolerable, and better results.¹⁴ The latter study¹⁴ examined 25 women who underwent a single treatment of 4 to 5 passes in those vectors judged to be the most beneficial for skin lifting and tightening. Bogle and colleagues¹⁵ took a large step forward when they performed a 66-patient study demonstrating that 84% to 92% of patients who had a low-fluence, multiple-pass technique with MCRF achieved a clinically demonstrable result at 6 months. A panel of 14 physicians later examined records of 5,700 patients and found that the rates of patient acceptance and positive results were greatly improved by the newer vs the older algorithm and that it was much safer and more tolerable.¹⁶

The same year of the publication of the panel's finding, the first paper on the first generation of the continuous-motion RF treatment (PV), as described in the current paper, was published.¹⁷ A group of 93 patients was evaluated prospectively; two treatments were performed 1 to 3 months apart, and the evaluating physicians were blinded. Results showed a 25% to 50% improvement both 1 month and 6 months after the first treatment. The majority of these patients noticed immediate tightening and were satisfied with the results. Although there was a period at 7 to 10 days postoperatively when this

FIGURE 2. Before and after treatment with an advanced 4-MHz monopolar radiofrequency device (Pellevé, Ellman International, Inc, Oceanside, NY). Photo courtesy of Andrea Palange MD.



effect diminished, the tightening reappeared at 1 month and improved thereafter. In a more recent study with PV,¹⁰ 32 patients had their periorcular areas treated (eyelids, forehead, and upper cheeks) with plastic eye shields inserted. Three blinded physician reviewers used the Fitzpatrick Wrinkle Scale (FWS) to evaluate the improvements at 1, 3, and 6 months after 1 session that took 35 minutes on average to complete. The patients also evaluated their improvement on a 9-point scale. Two patients had biopsies both pretreatment and posttreatment that were evaluated by both regular and electron microscopy (EM). At 6 months after 1 treatment, both the patients and the blinded physicians noted a 2 out of 9-point overall average improvement. Patients achieving a better result had an average initial FWS score of 3, whereas those experiencing less improvement had a poorer average initial FWS score of 7. Biopsies showed a dense band of collagen that was more organized than the pretreatment biopsy in the upper dermis as well as larger-diameter fibrils and less-defined borders in the after-EM evaluation.

Clinical Techniques

Nonablative skin-tightening protocols are aimed at achieving temperatures within the dermis from 45°C to 65°C for a long enough time to produce both immediate conformational changes of the collagen fiber and long-term collagen synthesis. Target skin surface temperatures of 40°C to 42°C as measured by infrared temperature probe throughout the procedure correlate to clinical end points observed. This temperature measurement technique is considered the optimal way to monitor the continuous motion (PV) treatment in order to ensure the desired treatment outcome is reached, although desired visual clinical end points should also be attained. It is important to know the visual clinical end points one is pursuing (Figures 5 and 6), as the best results over the ensuing months depend on both this and proper temperature monitoring.

FIGURE 3. Before and after treatment with an advanced 4-MHz monopolar radiofrequency device (Pellevé, Ellman International, Inc, Oceanside, NY). Photo courtesy of Andrea Palange MD.



FIGURE 4. Before and after treatment with an advanced 4-MHz monopolar radiofrequency device (Pellevé, Ellman International, Inc, Oceanside, NY). Photo courtesy of Andrea Palange MD.



The face and/or neck can be approached as a whole or in cosmetic subunits, depending on the patient's needs, desires, and budget. For upper-eyelid improvement, it is recommended to treat the forehead, upper lids (on or outside the bony orbit only, unless a plastic shield is inserted), and temples. If the entire periorcular area is desired, adding the lower eyelid outside the bony orbit and 1 to 2 cm inferior to the malar bone is recommended for best results. Treatment of the temples and cheeks down to 1 to 2 cm below the mandible will result in cheek tightening. For best results of the perioral area, treatment area would include 1 to 2 cm lateral to both nasolabial and melolabial folds. Optimal treatment of the neck includes 2 cm above the jawline.

Choosing the proper handpiece(s) for a given area is important in obtaining the desired results as well. There are 2 larger-sized handpieces (15 and 20 mm) and 2 smaller handpieces (7.5 and 10 mm). It is recommended that both a larger and a smaller handpiece are used for each treatment. The larger handpieces generate heat at a deeper plane in the skin than the smaller

FIGURE 5. Immediately after treatment with an advanced 4-MHz monopolar radiofrequency device (Pellevé, Ellman International, Inc, Oceanside, NY) to right cheek, forehead, and upper eyelid. Note elevation and reshaping of right cheek and brow. Photo courtesy of Amy Forman Taub MD.

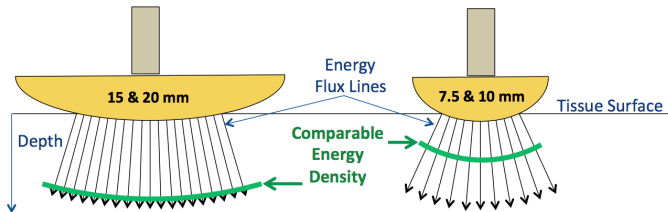


FIGURE 6. Before and immediately after treatment with an advanced 4-MHz monopolar radiofrequency device (Pellevé, Ellman International, Inc, Oceanside, NY) to right side of face. Photo courtesy of Andrea Palange MD.



handpieces (Figure 7). For optimal tissue tightening, one would treat both planes, except in very thin skin where the deeper plane is not present, such as the eyelids. Selecting the larger of the 2 handpieces allows the treating physician to reach target temperature quickly because of the fact that the heat that develops is spread over a larger area. The larger handpiece is the primary tool for achieving bulk tissue movement (lifting and tightening). Since the optimal temperature has already been obtained with the larger handpiece, reaching target temperature with the smaller handpiece in subsequent passes occurs quickly; the more superficial heating leads to improvement of surface wrinkles and texture as well as brightness of the skin.

FIGURE 7. Energy penetration profiles for device handpieces. Four device handpieces exist in order to match the depth and diameter with the specific area. The smaller handpieces are used for more superficial, smaller areas (such as the perioral area), whereas the larger handpieces are utilized in larger areas with more depth, such as the cheeks.



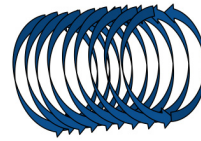
There has been a consensus by physicians who have performed many procedures that maintaining a tight spiral shape (using circles that are approximately 1.5 times that of the selected tip diameter) with the continuous motion technique is particularly effective and ensures complete coverage (Figure 8). Optimizing the tissue temperature at all times and not allowing the temperature to drop too much while the applicator is heating other areas is another way to optimize results. Treating an area the size of the palm, moving quickly but steadily, and using the larger of the 2 handpieces first most easily accomplishes this. Setting the initial temperature is also important for this. Beginning with too high a temperature can result in patient discomfort, whereas choosing too low a temperature can result in too many passes being required to reach the target temperature. Recommended treatment parameters include reaching 40°C to 42°C on the skin surface in a given area, as measured by an infrared temperature gun and then ensuring the complete area is treated using the overlapping spiral pattern with the handpiece; the process is then repeated with the smaller handpiece, alternating passes with the large and small handpieces, and alternating the direction of each pass (horizontally, then vertically) for a minimum of 5 passes (3 passes with the large size, 2 passes with the small size), although one author (A.F.T.) favors 8 to 10 passes for each.

There is an attenuation of results between the first treatment and the later, more long-lasting results achieved by subsequent treatments. The patient should be educated to understand that the immediate results are expected to diminish over the following week but will be recaptured over 1 to 6 months if the treatment course is completed. There are little data to determine the optimal number of treatments or their intervals. The 2 prior published studies were performed with a 1-treatment protocol and a 2-treatment protocol; in the current study, there is a 6-treatment protocol. Many experienced practices, including one author's (A.F.T.), perform 3 monthly treatments and reevaluate at 1 and 3 months.

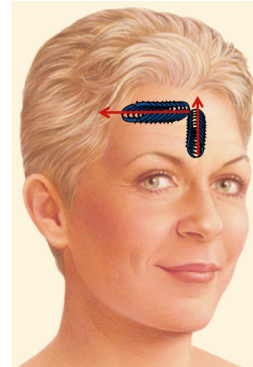
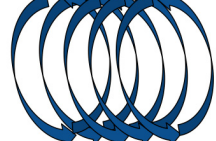
The experience of a procedure is important for patients considering cosmetic procedures. A factor influencing the widespread

FIGURE 8. Optimal treatment technique. Linear, overlapping cork-screw rows and columns in a given cosmetic area about 5 cm².

Tight circles optimal



Very loose = insufficient



"Maintaining a tight spiral shape (using circles that are approximately 1.5 times that of the selected tip diameter) with the continuous motion technique is particularly effective and ensures complete coverage."

adoption of cosmetic procedures is the patient experience; minimal-downtime, low-discomfort procedures have led the way. Certainly, the desire for enhancement is at an all-time high; patient decision making regarding the type of procedure includes degree of desire, affordability, and fear of the procedure. The latter may consist of fears of pain and/or unaesthetic results. There is a perception in the physician community that there is a trade-off between results and comfort/downtime; the more aggressive, the more effective. Most patients seek the least aggressive with the best results; sometimes more aggressive procedures are more economical in that they are associated with one cost and one period of downtime, but the majority of patients choose to avoid pain and downtime when possible.

The evolution of RF technology is an interesting one in that the search for a less painful procedure also resulted, paradoxically, in better results. The evolution went from one-pass, high-intensity treatments to a multipass approach with moderate intensity. Subsequent iterations of the first device (MCRF) have led to refinements, such as the addition of vibration to take advantage of the gatekeeper theory of pain and the redesign of the disposable tip to concentrate the heating to the center rather than the

periphery. This resulted in more tolerable procedures with better heating efficiency. Mobile treatments had been performed with monopolar RF,¹⁸ and creative practitioners realized it could be utilized for treatments that were effective and more palatable for patients.¹⁹ The idea that building heat to an effective temperature leads to a tolerance of the patient for higher temperatures is an attractive one for preserving patient satisfaction and enhancing their willingness to undergo the procedure.

It would be of great interest to determine how patients select treatments and how they weigh the various factors—cost, number of visits, tolerability of treatment, and results. These factors vary greatly depending on the individual. Of significant benefit to the treating physician is having the confidence to assure a patient that a procedure is safe, effective, and painless. It is important to maintain credibility with patients by giving them reasonable expectations, not only on the results, but also on the other factors. Whereas heat and pain perception are important features for selection of energy levels in MCRF, the PV noncooled RF device utilizes patient perception only for safety and comfort. Trying to maintain the temperature just below the threshold of discomfort results (MCRF) may result in some pulses that are subtherapeutic (“That one wasn’t warm”) or a bit too aggressive (“That one was too hot”), making the treatment session a bit more tense.

With the continuous motion technique (PV), the energy selection is correlated with skin temperature maintenance of 40°C to 42°C for 3 to 5 minutes, or at least 5 passes. Although it may be true that more treatments appear to be necessary with this device, pain-phobic patients accept this, as they often relate experiencing PV as pleasurable, similar to a warm massage. Ideally, however, reducing the number of procedures associated with reproducible results is always an excellent goal, as it is more economical for the patient.

The PV device also makes it easy to perform regional treatments. Popular areas are perioral and periocular. The disposable handpiece has limited use but is capable of being used for multiple treatments and patients. It is possible to perform these smaller-area procedures in an affordable manner for the patient. In the periocular area, one can perform treatments without insertion of a plastic ocular shield as long as the treatment does not extend into the bony orbital area. One cannot perform treatments directly on the eyelids, however, without the insertion of a plastic eye shield covering the globe.

Certainly, there are weaknesses in the current clinical cohort. There is no control group, and there are no blinded evaluators. Although it is heartening to see that the patient and treating physician evaluations are highly correlated, the fall-off at the last data point is concerning. One author (A.F.T.) finds her patients are frequently surprised by their before images; this

could be due to the lack of patients’ memory of their aesthetic defects once improved. With this discrepancy, we are left with not knowing whether the result at 1 year was closer to 30% or 50% average improvement in the full cohort. There are very few long-term tissue-tightening studies demonstrating results out to 1 year; this cohort represents a 6-month follow-up from the final treatment, but a 1-year follow-up from initial treatment.

One wonders whether 6 treatments are necessary to achieve the results that were obtained. The other 2 peer-reviewed, published studies as noted above for PV showed improvement after 6 months for a 1-treatment protocol (2 points out of 9 on the FWS) and a 2-treatment protocol (25%-50% improvement).^{11,17} Patients frequently ask how long a procedure will last; we often tell them 1 to 2 years for tissue tightening, although this is based on anecdotal information and not on scientific study. Further study on length of duration of RF-based treatment results as well as number of treatments necessary or if additional treatments give additional improvement would be valuable.

CONCLUSIONS

The Pellevé 4-MHz monopolar RF device is effective, safe, and very well tolerated for treating laxity, texture, and wrinkles of the skin without complication or discomfort. Evidence in the literature supports the scientific mechanism of action of acute collagen modification and continued neocollagenesis observed with the system. In this cohort, patients maintain approximately 50% improvement on average at 6 months and a 30% to 50% improvement 1 year after beginning the treatments, 6 months after completion.

DISCLOSURES

Dr. Taub received honoraria for one presentation more than 1 year ago but did not receive any compensation for this manuscript. Drs. Tucker and Palange have no relevant conflicts of interest to disclose.

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