

Nonablative 4-MHz Dual Radiofrequency Wand Rejuvenation Treatment for Periorbital Rhytides and Midface Laxity

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Purpose: To evaluate the wrinkle-reducing effects of 4-MHz radiofrequency (RF) energy applied to human periorbital, frontal, and midface facial skin using clinical wrinkle grading, patient self-satisfaction survey, and limited histologic studies.

Methods: Thirty-two patients, ranging from 29 to 71 years of age with skin types varying from class I to class III using the Fitzpatrick Wrinkle Classification system, underwent 8 weekly treatment sessions of nonablative RF therapy on the periorbital, frontal, and midface regions and were subjected to follow up for 6 months after treatment. Pretreatment and post-treatment evaluations were compared. Two female subjects gave informed consent for RF treatment for the right upper eyelid and no treatment for left upper eyelid. Specimens from both upper eyelids then underwent histologic examination using light and transmission electron microscopy.

Results: Pre- and post-RF treatment evaluation by 3 independent observers using the Fitzpatrick wrinkle classification system showed progressive improvements in wrinkle score at 1-, 3-, and 6-month intervals ($p < 0.01$). Self-evaluation of 32 patients using a 9-point rating scale after application of RF treatment also showed improving satisfaction ($p < 0.01$). The most commonly noted adverse reaction was transient erythema (62.5%) lasting from a few hours to a day. Transmission electron microscopy (25,000 \times) showed scattered diffuse changes in collagen fibril architecture with a shift from smaller-diameter collagen fibers in the untreated samples to larger-diameter fibers in the treated samples and a loss of distinct fibril borders.

Conclusions: Four-megahertz dual RF wand delivery rejuvenation treatment produces a reduction in periorbital and midface rhytides.

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Recent advances in the nonablative management of facial rhytides include the application of fractionated laser, mid-infrared lasers (e.g., 1320-nm Nd:YAG, 1450-nm diode, 1540-nm Er:glass), and radiofrequency (RF) treatments.^{1–7} RF causes skin tissue tightening through collagen denaturation, contraction, and fibroblast stimulation.^{1,8} This collagen remodeling is a long-term process that continues up to 4–6 months following treatment.⁹

RF is commonly used in oculofacial surgery.¹⁰ We have conducted a study to describe the clinical improvement of nonablative 4-MHz RF wand rejuvenation treatment using a popular commercially available RF device (Ellman Surgitron dual RF S5 device [Ellman International, Inc., Oceanside, NY]) on periorbital rhytides and midface laxity.

MATERIALS AND METHODS

Design. This study evaluated the clinical improvement of patients undergoing nonablative 4-MHz dual RF treatment for periorbital wrinkles and midface laxity using a commercially available RF device (Ellman Surgitron dual RF S5 device [Ellman International, Inc., Oceanside, NY]) and a wand delivery contact electrode method (Ellman Pellevé Wrinkle Reduction System [Ellman International, Inc., Oceanside, NY]) (Fig. 1). After informed consent, each patient received 8 RF treatments at weekly intervals with a standardized treatment procedure. Photographs were obtained before treatments and compared with photographs taken at 1-, 3-, and 6-month follow-up visits for all of the subjects' faces in the frontal, three-quarter right, three-quarter left, and periorbital views using the same camera, photographer, light setting, and surroundings. Patients were also followed up immediately after application (within 24 to 72 hours) and at 1, 3, and 6 months to note any side effects. Skin and tissue from treated right upper eyelid and untreated left upper eyelid were excised from 2 volunteer subjects and examined through light and electron microscopy.

Patients. The study included 28 female and 4 male subjects with ages ranging from 29 to 71 years old (mean 53 years) with Fitzpatrick skin wrinkle classifications from 1 to 3 presenting with upper and lower eyelid rhytids, skin laxity of the eyelids, and midface area rhytides were enrolled (Table 1). Exclusion criteria included prior surgeries involving the eyelid, cheek, or neck region; previous application of fillers or usage of botulinum toxin type A within 6 months; ablative or laser-based therapy to diminish skin rhytides within 1 year before enrollment; pregnancy; and the presence of a pacemaker.

The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki and was submitted to the Institutional Review Board of the University of Santo Tomas Hospital, Manila, Philippines.

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FIG. 1. Pellevé Skin Tightening System (Ellman Surgitron Dual RF S5, Pellevé Wrinkle Treatment Handpiece, Pellevé Treatment Gel, Ice Pack, Fluke Thermometer).

The commercial RF unit employs a patented energy coupling technology that allows a uniform delivery of RF to treated tissue.

Treatment Procedure. A chilled (ice-water temperature) thermal reduction gel (Pellevé treatment gel) was applied to the periorbital and midface regions after effective removal of make-up or other facial emulsions. No topical anesthesia or sedative was given. Plastic corneal protective shields were used to protect the underlying structures of the eyes during RF application to the upper and lower eyelids. A spherical 10-mm-diameter RF Nonablative Cone Handpiece (Pellevé wrinkle treatment handpiece) or “wand” was applied in a vigorous overlapping continuous scrolling or “scrubbing” circular motion covering the entire area of the periorbital, frontal, and midface areas (Fig. 2). Treatment time was approximately 35 minutes. The device was set at an initial power output intensity setting of 12 in the cut mode and was increased to the patient’s subjective level of temperature tolerance or until there was mild erythema at the treatment site. Immediately after treatment, facial icepacks were applied to cool the treated dermal and subdermal layers.

In 2 volunteers, the left upper eyelids were left untreated and the right upper eyelids were treated. Histopathologic analysis of biopsy specimens from the treated and control eyelids was performed.

Clinical improvement was independently assessed by 3 blinded observers using the Fitzpatrick wrinkle classification system (FWCS) on unlabeled preapplication and final postapplication photographs. The



FIG. 2. Ten-millimeter-diameter spherical radiofrequency Nonablative Cone Handpiece (Pellevé wrinkle treatment handpiece) or “wand” was applied in a vigorous overlapping continuous scrolling or “scrubbing” circular motion covering the entire area of the periorbital, frontal, and midface areas.

observers were asked to place attention on the condition of the periorbital skin and the nasolabial and midface region of each subject.

Subjects also graded improvement and satisfaction. A 2-tailed 9-point rating scale scheme was used ranging from -4 to $+4$ as follows: -4 = 100% to 76% (severe worsening), -3 = 75% to 51% (moderate worsening), -2 = 50% to 26% (mild worsening), -1 = 25% to 0% (minimal worsening), 0 = (no improvement), $+1$ = 1% to 25% (minimal improvement), $+2$ = 26% to 50% (mild improvement), $+3$ = 51% to 75% (moderate improvement), and $+4$ = 76% to 100% (excellent improvement). The overall satisfaction rate per subject was also noted. Wrinkles were classified at baseline (pretreatment) and then again during the post-treatment clinic visits at 1, 3, and 6 months.

RESULTS

Patients. All 32 subjects completed the wand RF treatment course with no losses to follow up after 1-, 3-, and 6-month evaluations.

Independent Physician Observer Outcomes. Pre- and post-RF treatment evaluation by 3 independent observers using the FWCS showed progressively increasing improvements in wrinkle score at the 1-, 3-, and 6-month study periods, as shown in Table 2.

Patient Self-Evaluation Outcomes. An average 9-point self-evaluation of 32 patients showed improving satisfaction at the first (1.56 ± 0.35), third (1.93 ± 0.34), and sixth (2.03 ± 0.45) months after the application of RF treatment. Results showed that 15 out of 32 (46.8%) patients of the study population noted minimal improvement, while 14 out of 32 (43.7%) noted mild improvement and 3 out of 32 (9.3%) noted moderate improvement after application of RF treatment at the 6-month follow-up visit. Overall, 99.8% of the patients showed minimal to moderate improvement at 6 months after treatment, supporting the theory that dermal collagen remodelling is a long-term process (Figs. 3 and 4). Patients with moderate improvement (age range: 50–67 years) at 6 months had a pretreatment wrinkle (FWCS) classification of 3; patients with minimal improvement (age range: 35–71 years) at 6 months had a pretreatment wrinkle (FWCS) classification of 7 or 8.

Side Effects and Complications. The most commonly noted adverse reaction was transient erythema (62.5%) lasting for a few hours to a day; tolerable pain (37.5%) during the procedure, described as a warm sensation; and mild edema (12.5%) lasting for 1 to 2 days. There were

TABLE 1. Fitzpatrick Wrinkle Classification and severity scores of 32 patients before radiofrequency treatment

Grading classification (subgroup)	Class	Wrinkling	No. of patients
1	I	Fine wrinkles	0
2			6
3			6
4	II	Fine to moderate-depth wrinkles, moderate number of lines; fine to deep wrinkles,	2
5			2
6			4
7	III	numerous lines with or without redundant skin folds	6
8			6
9			0

TABLE 2. Pre- and post-radiofrequency treatment average Fitzpatrick Wrinkle Classification system by 3 independent observers

Observer	Pretreatment Fitzpatrick Wrinkle Classification system score	1st month	3rd month	6th month
1	5.0625 (2.25)	4.8125 (2.17)	4.1875 (1.96)	3.65625 (2.07)
2	5.15625 (2.28)	4.875 (2.24)	4.25 (2.0)	3.6875 (1.99)
3	5.09375 (2.28)	4.84375 (2.13)	4.21875 (2.02)	3.71875 (2.07)

p values: between-observer = 0.25; between times = <0.01; observer vs. time = 0.95. All data are mean (SD).

no scarring, burns, bruising, dysesthesia, or asymmetries noted in any of the subjects.

Skin Biopsy Results. The skin in the pretreated section by light microscopy (10 \times) is typically normal. The epidermis is intact with multiple layers. The dermis is a mixture of loose and dense collagen with interspersed vessels with some elastic tissue (Fig. 5A). After treatment, it is apparent that there is focal edema in the epidermis and dermis. In the dermis there is an inflammatory infiltrate in the deeper dermis where it is possible to see granulation tissue. There is also a significant increase in the amount of dense collagen in the superficial and deep dermis (Fig. 5B). Transmission electron microscopy (25,000 \times) further showed scattered diffuse changes in collagen fibril architecture with a shift from smaller-diameter collagen fibers in the untreated samples (Fig. 6A) to larger-diameter fibers in the treated samples and loss of distinct borders compared with normal fibrils (Fig. 6B).

DISCUSSION

The use of RF energy in oculofacial plastic surgery has increased in popularity over the past few decades, notably including new solutions in skin tightening and rejuvenation and the treatment of facial rhytids.¹¹ The most frequently studied RF skin tightening system (Thermage, Inc., Hayward, CA) combines 6-MHz RF quantified energy delivery with a cryogen cooling system. In comparison, the 4-MHz RF wand wrinkle reduction system evaluated here employs external cooling using monoclysmic thermal gels; the actual energy delivery per unit of tissue is not quantifiable because the contact wand is in motion during treatment.

Prior RF studies have demonstrated that multiple treatments tend to give better results and lessen the risks of complications when compared with a single aggressive treatment.⁷ More recent clinical results have shown that multiple passes

with low energy settings are more tolerable and efficacious and may provide better safety outcomes than a single pass with high energy settings. In evaluating the effects of an RF-based nonablative dermal remodeling device as early as 2004, Zelickson et al.⁸ determined that a greater number of low-energy pulses produced acute morphologic changes similar to those produced by a single higher-energy pulse, in further support of multiple treatments.

Among the 32 patients who underwent the 4-MHz wand procedure, 15 (46.8%) noted minimal improvement, 14 (43.7%) noted mild improvement, and 3 (9.3%) noted moderate improvement during self-evaluation at 6 months after treatment. These results suggest a definite but modest improvement in appearance. Light and transmission electron microscopic analysis of the 2 untreated and treated skin biopsy samples revealed changes consistent with collagen response to RF energy delivery. Samples obtained 2 months after treatment showed ongoing dermal cellular infiltrations, which indicate a continuing remodeling of tissue.¹² Although the patients in this study were examined at 6 months after final treatment, a longer follow-up period is suggested since RF treatment induces tissue tightening through dermal collagen remodeling, a process that occurs over time.

Considering proper patient selection, the best candidates for skin tightening treatment appeared to be patients aged 35–60 with mild to moderate skin laxity.^{9,13} Sasaki et al.¹⁴ reported that patients with greater tissue laxity and a larger global motility score at baseline were nonresponders to nonablative monopolar RF treatment, while patients with minimal degrees of photoaging and shallower wrinkle fold were more likely to demonstrate a positive response. In this study, 3 of 32 patients with a pretreatment wrinkle (FWCS) classification of 2 or 3 showed moderate improvement upon self-evaluation (aged 50, 63, and 67 years) at 6 months after treatment. The 8 patients

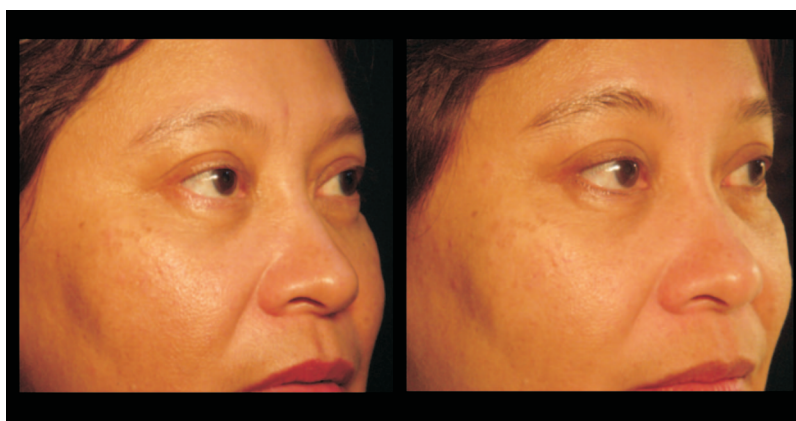


FIG. 3. Before and after radiofrequency treatment. Notice wrinkle reduction in the periorbital and glabellar forehead areas and decreased in depth of the nasolabial fold.

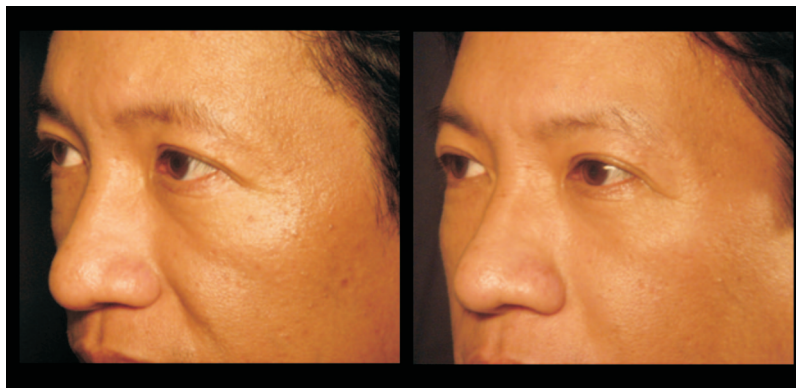


FIG. 4. Before and after radiofrequency treatment. Notice decrease in the glabellar fold, crow's feet, softening of the nasolabial fold and tightening of the cheek contour.

with mild improvement at 6 months (age range of 35–71 years) had a pretreatment wrinkle (FWCS) classification of 7 or 8. These results are consistent with those of Sasaki et al.,¹⁴ who found that patients with shallower wrinkle/fold depth are more likely to be associated with a positive response to the treatment. Tissue mobility proved to be the most consistent and principal factor for predicting positive response to monopolar RF treatment, whereas variables such as skin thickness and fat depth did not. Another influential variable was the stage of photoactinic aging of the skin, which included percentages of pigmented spots, pores, wrinkles, and evenness, and numerical counts of bacterial porphyrins and ultraviolet radiation-damaged spots.¹⁴

Nonablative monopolar RF treatment may be used in patients who have had prior cosmetic procedures,¹⁵ but those who have orbital fat prolapse, generalized excessive skin laxity, and/or excessive brow ptosis with unrealistic expectations of possible results are not considered good candidates.¹³ Absolute contraindications for this procedure are pacemakers and defibrillating device implants.^{13,15} Skin type does not play a role in predicting positive response to nonablative monopolar RF treatment because unlike laser and light treatment, RF current is neither scattered nor absorbed by melanin, so patients of all skin types can be treated.¹⁶

In selecting appropriate energy levels for treatment, power settings were adjusted based on individual patient comfort levels. The proper sensation should cause the patient to feel the skin heat to a tolerable warmth, not to a level of discomfort. Pain response is a key indicator in determining both power settings and the speed at which the contact wand should be

moved across the treatment area. The actual dose of energy delivered to a unit of tissue is uncontrolled to the extent that it is dependent upon the speed at which the electrode wand is moved across the skin surface, i.e., “dwell time.” Stated more clearly, the energy delivery per unit of time can be standardized based upon the 4-MHz unit output settings, but because the wand is in motion, one would have to know the skin surface area in contact with the moving electrode tip per unit of time to calculate the actual dose of energy per square centimeter of skin.

Power settings should also be adjusted according to the cone size of the ball electrode. It is important to note that the depth of energy delivery depends on the size and geometry of the electrode tip.^{13,15} In most facial regions, the central zone of the thermal gradient needs to be established to a depth of approximately 2.5 mm to achieve favorable clinical changes. However, delivery of heat to this depth on the eyelids might be harmful to the eyelid or the eye itself. Further studies may be helpful to establish safe parameters for 4-MHz eyelid treatment. If the preseptal eyelids are treated in the absence of such studies, then we strongly recommend using electrodes of smaller tip size, protective plastic corneal shields, and cautious energy settings to deliver maximum heating of approximately 1.2 mm depth or less beneath the skin's surface.⁷ In a unipolar system, electric energy is emitted through the metallic tip of the electrode and transmitted to the target tissue to a depth that can be estimated as half the electrode size. Therefore, a 0.5-cm or 1-cm tip can be used with a penetration depth of 2.5–5.0 mm.¹⁷

In this particular study, no preoperative anesthesia was given so as not to alter the impedance of the skin to be treated.

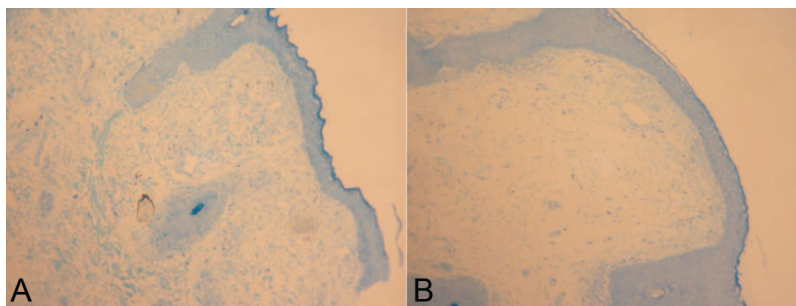


FIG. 5. **A**, Untreated. Pretreated section of the skin by light microscopy (10×) is typically normal. The epidermis is intact with multiple layers. The dermis is a mixture of loose and dense collagen with interspersed vessels with some elastic tissue. **B**, Treated. Epidermis and dermis after treatment shows focal edema. In the superficial and deep dermis, there is an increase in the amount of dense collagen. Inflammatory infiltrates are also present in the deeper dermis.

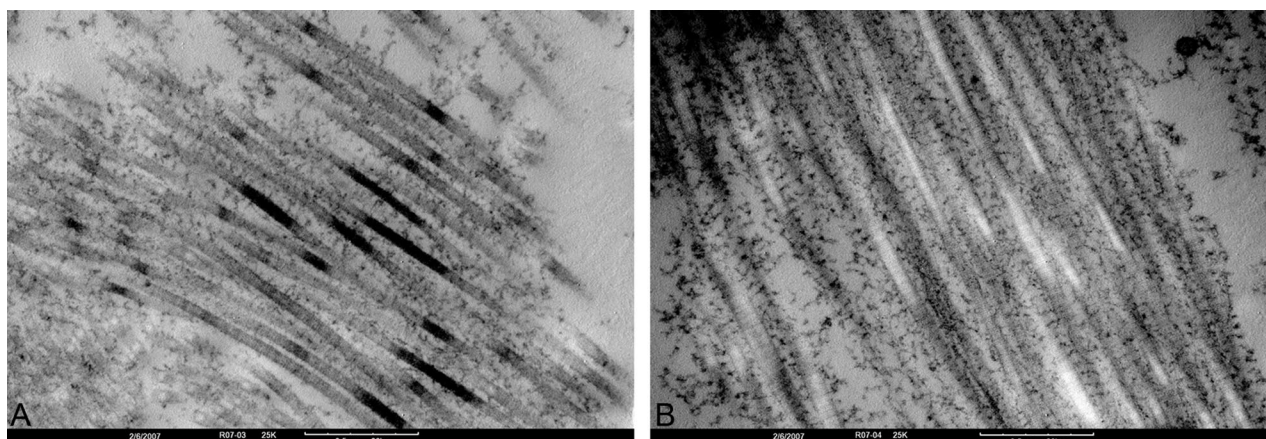


FIG. 6. A, Untreated. B, Treated. Transmission electron microscopy (25,000 \times) further showed scattered diffuse changes in collagen fibril architecture with a shift from smaller-diameter collagen fibers in the untreated samples (A) to larger-diameter fibers in the treated samples (B) and a loss of distinct borders compared with normal fibrils.

Kushikata et al.⁴ showed that in about three quarters of RF subjects, the unilateral application of anesthesia failed to produce any difference in pain threshold between the anesthetized and unanesthetized areas and did not affect the final efficacy of the treatment. Given the subjective nature of wand energy delivery, we felt it was pertinent to maintain minimal, tolerable pain during the procedure that served as the limit (along with transient erythema) of our energy adjustment and as a safety measure against burning or scarring.

One of the limitations of this study is the undetermined optimum number of treatments and their durations or intervals. In a 50-patient study by Alster and Tanzi,⁵ significant clinical improvement was observed after one treatment with an RF device in the majority of patients. Other studies, however, have advocated serial application of RF treatments at 1 month apart.^{3,6} Additional limitations include the lack of a control population, the small patient sample size, the lack of appropriate patient selection, and a standardized method but variable energy dose subject to operator hand movement and titrated according to skin erythema and pain response. Furthermore, we did not attempt to alter factors that would have provided the most favorable results, such as determining pretreatment pa-

tient characteristics. This accounts for the modest improvement noted 6 months after the treatment (46.8% minimal, 43.7% mild, 9.3% moderate).

In summary, we report that wand application of RF using the Pellevé 4-MHz RF apparatus produces a modest reduction in periorbital and midface rhytides without significant complications and recommend continued study of its usefulness in nonablative facial rhytid treatment. We also recommend objective clinical assessment scales for measuring skin thickness, subcutaneous fat depth, tissue mobility, wrinkle or fold depth, and degrees of photoaging via Visia Complexion Analysis System (Canfield Scientific, Inc., Fairfield, NV, U.S.A.) computerized complexion analysis, the clinical parameters for predicting efficacy or positive outcomes with the nonablative monopolar RF treatment device. Recently, we have been using the Reveal imager (Canfield Scientific, Inc., Fairfield, NJ) to document skin changes after monopolar RF treatment and allows the physician and the patient to examine wrinkles clearly through high-resolution imaging. The Reveal system also provides the ability to zoom and pan images in tandem for clear and easy comparison of magnified areas of interest before and after Pellevé treatment (Fig. 7). Optimal treatment param-



FIG. 7. Before and after Pellevé eyelid treatment. Initial tightening effect in the skin that smoothes skin texture and decreases wrinkles in the infrabrow area immediately after radiofrequency treatment.

eters and delivery methods are still undefined. Finally, we advocate extreme caution and further study of RF treatment in the eyelid area, due to the unknown potential hazards of energy penetration to the globe or cornea from periocular application of large electrodes over the thin eyelid structure.

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