Clinical Summary

Non-Ablative Treatment for Periorbital Rhytides and Midface Laxity

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Background: Non-ablative application of pulsed radiofrequency (RF) energy has been shown to improve the appearance of wrinkles, rhytides and skin laxity, but has been limited because of the discrete amount of energy applied. A novel approach utilizing the Ellman® Pellevé™ Wrinkle Reduction System (Ellman International, Oceanside, NY) to deliver continuous RF energy through the skin to the dermal tissue beneath without damaging the epidermis was evaluated. The gentle heating of the deep dermis induces collagen denaturization, contraction and subsequent synthesis. The collagen synthesis, in turn, creates a lifting effect that helps to eliminate mild to moderate facial wrinkles and rhytides. We present the findings to date of our ongoing clinical study of the efficacy of the Pellevé radiofrequency device.

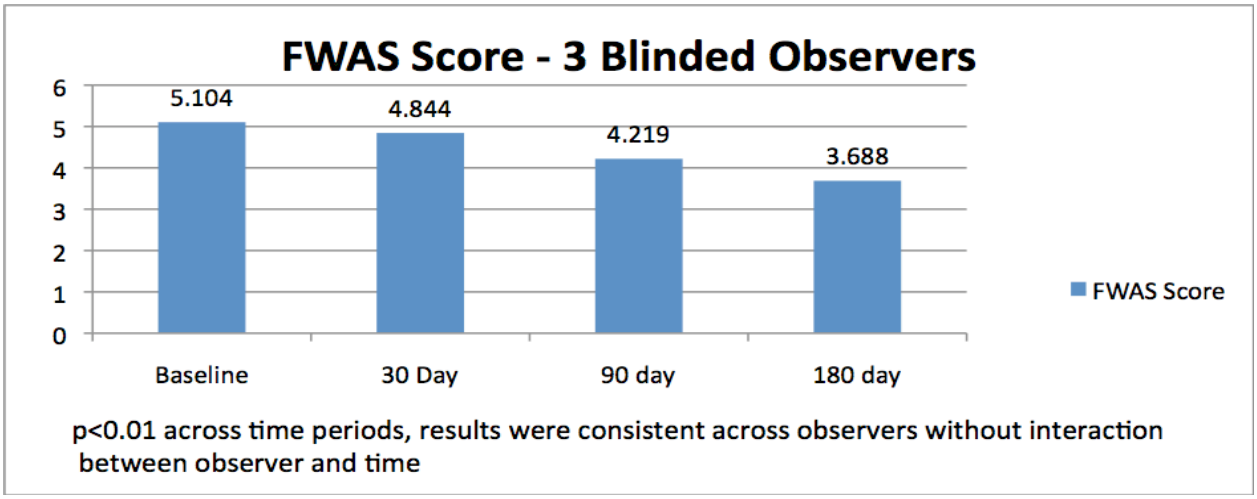
Method: Beginning in 2009, 62 subjects of skin types with sun-reactive skin types I-IV, and with wrinkle classifications I-III were enrolled for treatments with Pellevé. Subjects were followed for six months following their last treatment. The first 32 patients received weekly treatments for 8 weeks. Our treatment methodology has evolved such that the subsequent 30 patients have been treated an average of two times, with the second treatment 30 days following the initial treatment. Those few patients returning at 60 or 90 days following the second treatment that did not demonstrate improvement received an additional treatment. Efficacy was assessed using the Fitzpatrick Wrinkle Assessment Scale (FWAS) at baseline and at 30, 90 and 180 days post final treatment. FWAS scores were assessed independently by three blinded evaluators at baseline, 30, 90 and 180 days post-treatment. Patients also completed self-evaluations of improvement utilizing a 9-point scoring method (-4 = 75%-100% worse, -3 = 51%-75% worse, -2 = 26%-50% worse, -1 = up to a 25% worse, 0 = no change, 1 = up to 25% improvement, 2 = 26%-50% improvement, 3 = 51%-75% improvement and 4 = 76%-100% improvement). Standardized photographic analysis of all visits was performed. Since January 2010, photos have been taken utilizing the Canfield Reveal® System (Canfield Scientific, Fairfield, NJ) allowing for cross-sectional analysis of wrinkle depth.

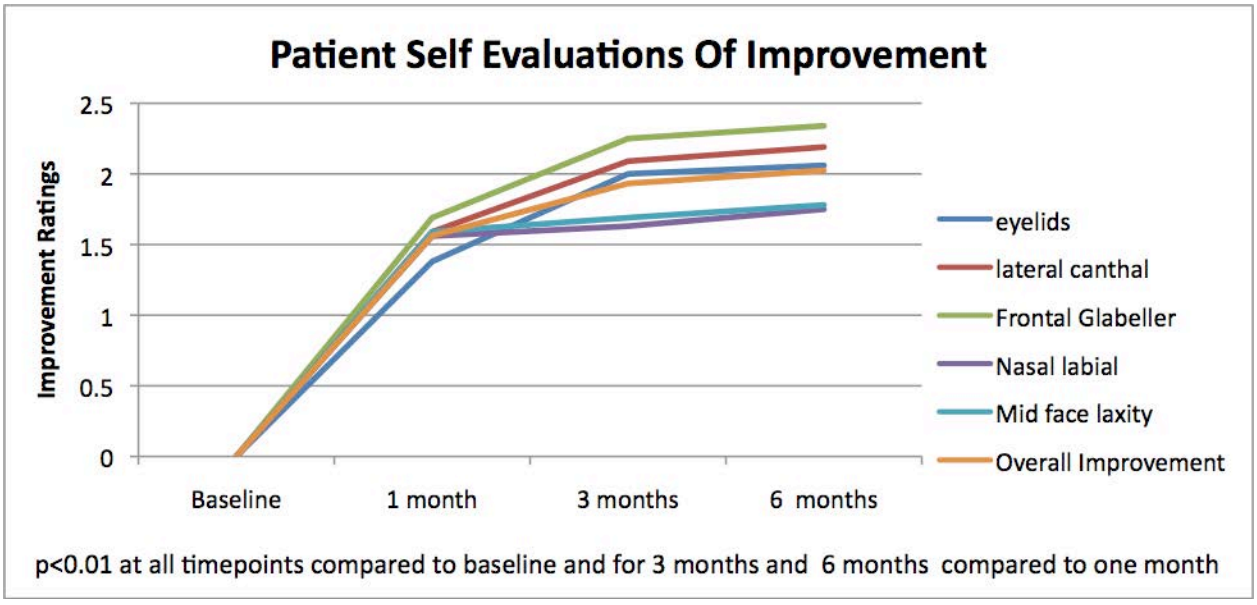
During treatments, 10 mm and 15 mm diameter Pellevé electrodes were utilized. Energy levels using the sine waveform were established based on patient pain tolerance level coupled with speed of moving the electrode with higher power settings required for the larger electrode. The electrodes were moved in a circular pattern to heat the subdermal tissue with an average treatment time of 35 minutes and 3-4 passes of raising skin temperature to 42°C over each region of the face. Pellevé treatment gel was kept cool in an ice water bath and utilized to assure proper coupling between the electrode and the patient.

Results: Treatment with the Pellevé radiofrequency device resulted in statistically significant improvement in both FWAS and in patient self-assessments of improvement with scores improving at each subsequent follow-up visit through 6 months following the final treatment.

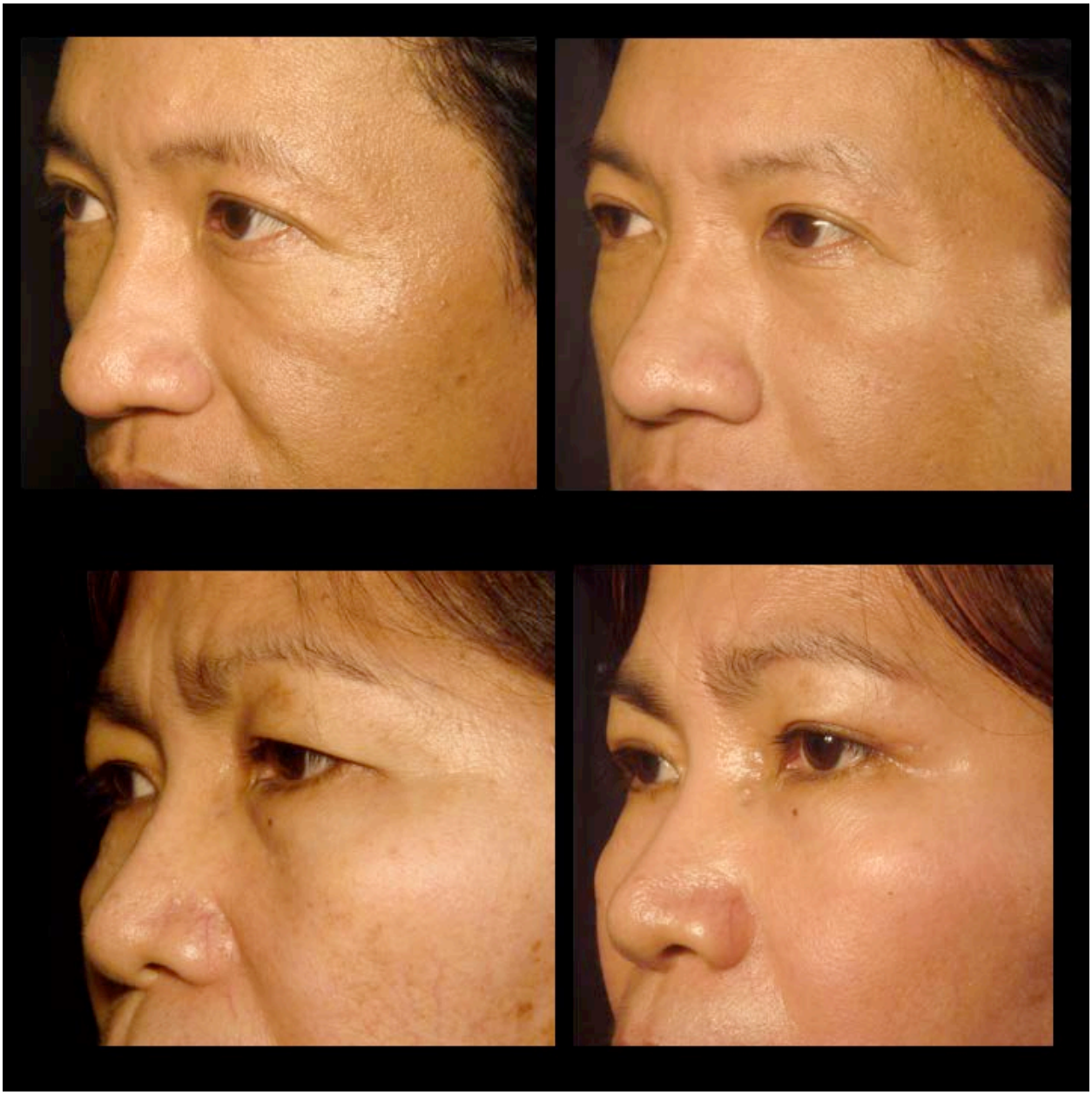
Patient self-improvement ratings demonstrated continuing improvement in all areas rated including eyelid, lateral canthal and frontal glabellar rhytides along with nasal labial folds and midface laxity. P values were <0.01 for all values compared to baseline and after the first month post-treatment. All patients rated their improvement compared to baseline as 1 or higher at each timepoint.

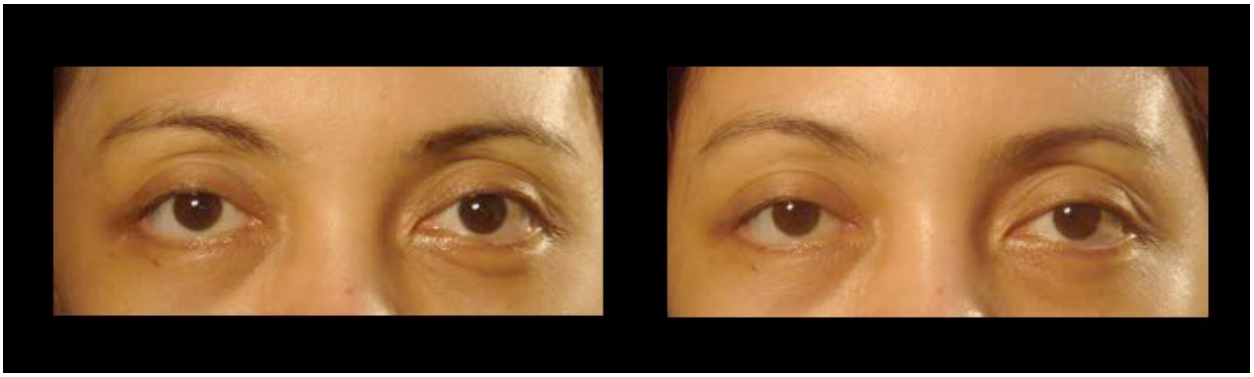
The only side effect and complications observed were transient erythema lasting for a few hours to a day (62.5%), tolerable discomfort during the procedure described as a warm sensation (37.5%) and mild edema lasting for 1-2 days (12.5%).



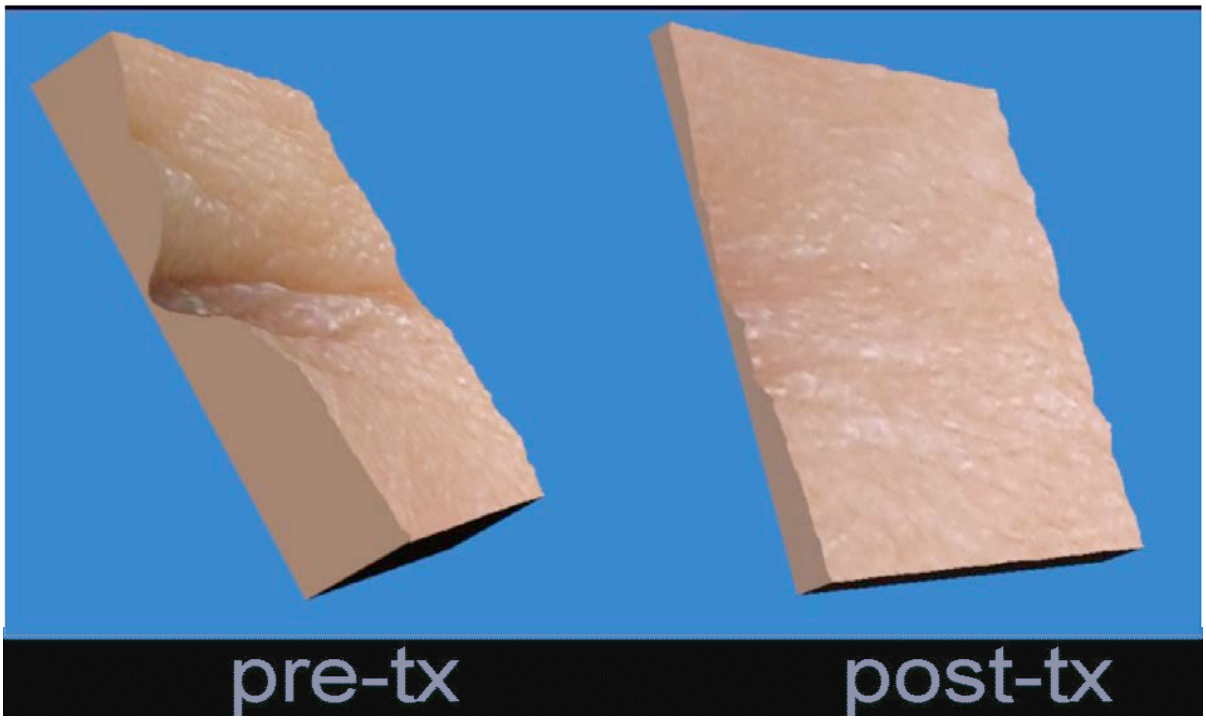


Patient photos demonstrate results at 6 months following final treatment.





We began utilizing Reveal recently for photographs and wrinkle depth assessment.



Conclusion: We have evolved our protocol from 8 weekly treatments to two treatments spaced one month apart with some patients requiring an additional treatment. All patients showed improvement both based on self-evaluations and blinded FWAS. Radiofrequency resulted in a measurable improvement in fine facial lines and wrinkles consistently for all of our patients.

References

Javate RM, Trakos N, Cruz RT. Radiofrequency Technology. In: Zilkha MC, ed. *Aesthetic Oculofacial Rejuvenation*. Missouri: Elsevier Saunders, 2010; pp. 74 – 81

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