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Prospective, Multicenter Study to Determine the Safety and Efficacy of a Unique Radiofrequency Device for Moderate to Severe Hand Wrinkles

Janelle M. Vega MD,[a] Vivian W. Bucay MD,[b] and Flor A. Mayoral MD[a]

[a]Mayoral Dermatology, Coral Gables, FL
[b]Vivian W. Bucay MD, San Antonio, TX

ABSTRACT

Radiofrequency has been shown in a number of studies to be effective in tightening the skin of the face and neck. This multicenter study was undertaken to determine the efficacy of a monopolar radiofrequency system (Pellevé S5 Wrinkle Treatment Generator; Ellman International Inc, Oceanside, NY) in tightening the skin of the hands and is the first such study assessing the improvement of skin laxity of the hands. A total of 31 female patients with a median age of 56 years were enrolled in 2 centers. Each had a single hand treated, with randomization of the hand to be treated. A total of 3 treatments were performed at 2-week intervals. Follow-up photos were taken at 45 and 90 days after the final treatment. At 90 days, 89% of patients had visible improvement of the appearance of the treated hand based on the visual Global Aesthetic Improvement Scale. Of these, 50% had visible improvement from baseline, and 39% had marked improvement from baseline. Patients reported only mild to moderate discomfort during the treatment. No adverse events or side effects were reported. Monopolar radiofrequency was found to be safe and effective for treating hand wrinkles.

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BACKGROUND

The cosmetic appearance of the hands is of concern to many patients, as it can accurately reflect their chronologic age.[1] Loss of elasticity, tortuous veins, thinning of the skin, and loss of subcutaneous tissue give an aged appearance to the hands.[2] Several modalities can be used for hand rejuvenation, including volume restoration, laser and chemical resurfacing, vein removal, and treatment of dyschromia.[3] To our knowledge, there are no studies or case reports assessing radiofrequency for the treatment of aging hands. By increasing dermal collagen production and tightening the skin, radiofrequency can be used to rejuvenate the aging hand by reducing the visibility of prominent veins and diminishing the appearance of wrinkles.[4-7]

MATERIALS AND METHODS

Study Design

A prospective, multicenter, single-arm, randomized study with an untreated hand as a control was undertaken with 31 female patients aged between 40 and 65 years (mean, 54 years; median, 56 years). Patients were treated at 2-week intervals for a total of 3 times. Photographs were taken at baseline and at each visit, as well as at 45 and 90 days after the final treatment. Patients were given the option of treating the contralateral hand once the study was finished. Photographs were evaluated based on a modified Global Aesthetic Improvement Scale (GAIS) that took into consideration improvement of the appearance of the veins.

Inclusion Criteria

Chosen subjects had moderate to severe hand wrinkles specified as grade 3 to 7 on the Fitzpatrick Wrinkle Scale. All subjects signed an informed consent approved by the Western Institutional Review Board. They had to have a willingness and ability to comply with protocol requirements, including returning for follow-up visits. Patients also had to have willingness and ability to apply sunscreen to the hands throughout the duration of the study and to provide written informed consent before performance of any study-related procedure. Subjects were also required to abstain from any exclusionary procedures for the duration of the study.

Exclusion Criteria

We excluded patients who were pregnant, nursing, or planning to become pregnant and/or who were not using a reliable method of birth control. Patients with actinic purpura were excluded, as were patients on anticoagulants or oral steroids. Subjects who had undergone cosmetic procedures to improve rhytides of the hands within the prior 12 months were also excluded. Those with active cuts, wounds, or infections as well as those on oral isotretinoin within the preceding year were excluded. Patients with a collagen vascular disease or any form of autoimmune disease, a history of diabetes mellitus (insulin dependent or independent), or any disorder affecting the perception of pain were not considered appropriate candidates. Those with a history of skin cancer over the treatment area were also excluded. Subjects who had implantable pacemakers, automatic implantable defibrillators, or any other implantable electronic device were excluded. Patients who had used, within 30 days, any medication that caused cutaneous hypersensitivity or affected skin characteristics were also excluded. Enrollment in any active study involving the use of investigational devices or drugs was also an exclusion criterion. Patients with history of poor cooperation or noncompliance

FIGURE 1. Baseline and 90 days after 3 treatments with radiofrequency. Patient scored +2 on Global Aesthetic Improvement Scale.

FIGURE 2. Baseline and 90 days after 3 treatments with radiofrequency. Patient scored +2 on Global Aesthetic Improvement Scale.

were excluded, as well as any patient on concurrent therapy that would, in the investigator's opinion, interfere with the evaluation of the safety or efficacy of the study device.

Methods

A radiofrequency generator (Pellevé S5 Wrinkle Treatment Generator; Ellman International Inc, Oceanside, NY) with a 20-mm handpiece (GlideSafe; Ellman International Inc) was used to treat all patients. Treatment gel was applied to the skin, and a neutral plate was placed under the patient's forearm. The treatment tip was activated on the Pellevé/Cut setting on the generator, and the level of energy used for the treatment was based on the verbal feedback about tip warmth from the patient. Patients were told that the treatment should feel hot, but without a burning sensation. The handpiece was moved in continuous overlapping corkscrew patterns to completely cover each of the 3 gel-coated treatment zones. When the skin surface temperature of the treated area reached 40 to 42°C, the treatment was continued for an additional 3 minutes. The sequence was repeated again for a total of 2 passes in each zone.

Treatment Evaluation

Signed consent, history, photographs, and randomization were performed during the initial visit. Patients were analyzed on the Fitzpatrick Wrinkle Scale. Photos were taken during the initial visit, before each of the 2 additional treatments, as well as 45 and 90 days after the final treatment, according to the standardized photography protocol. Photographs were taken with a Nikon D200 camera (Nikon Inc, Melville, NY) with a 60-mm lens and a Nikon Speedlight SB-800 flash. Hands were placed flat on a black background, and single and 2-hand photographs were taken each time. The flash was bounced off the wall, and the distance from the flash to the wall was standardized for each position to minimize variations in lighting. A subject satisfaction survey was administered at the 90-day follow-up visit. Subjects were not given guidance regarding appropriate expectations for the treatment, nor were they given before and after pictures to examine before completing the survey. A modified GAIS scale was used during follow-up visits to assess subjects by assigning grade –1 to +3 when compared with baseline. The modified scale took into consideration vein prominence, an important factor in the appearance of aging hands. Skin thickness and appearance of wrinkles were also considered in the GAIS assessments.

RESULTS

Of the 31 female patients enrolled in the study, 28 completed all 3 treatments and returned for both follow-up visits; 3 patients were lost to follow-up. Of those lost patients lost to follow-up, 1 completed all 3 treatments but did not return for follow-up photographs.

At only 90 days posttreatment, 89% of patients demonstrated improvement in the appearance of their hands, as evidenced by a reduction in wrinkles and/or an increase in skin tightness as rated by the physician. Of these, 50% had a 1-point GAIS improvement (visible improvement from baseline), and 39% had a 2-point GAIS improvement (marked improvement) from baseline (Figures 1 and 2). Of the 28 subjects evaluated, 21 (75%) expressed satisfaction with their outcome at 90 days posttreatment, keeping in mind that no expectations were set in advance of what typical outcomes would look like or what should be considered in the self-satisfaction appraisal. Of the 7 patients who were neutral or not satisfied, 5 had physician-rated GAIS score improvements of 1 or 2. Patients reported only mild to moderate discomfort while being treated; there were no reported adverse events during or after the study.

DISCUSSION

In this study, we found that a series of 3 treatments in short intervals with a monopolar radiofrequency device was effective in achieving a mild to moderate improvement in the appearance of the aging hand in 89% of the patients at 90 days after the final treatment. The advanced age of the cohort in this study (mean, 54 years; median, 56 years) is also notable, as wrinkle reduction and skin tightening can be more challenging in individuals with more aged skin. In the future, it would be useful to reassess patients after a longer interval of time, given that some radiofrequency studies have shown continued

improvement 4 to 6 months after treatment completion.[4,8] This was the case in our study, as supported by the fact that of the 12 patients who had not shown significant improvement at the 45-day follow-up evaluation, 10 (83.3%) demonstrated a significant positive change at the 90-day follow-up evaluation.

Our study used 2-week intervals between treatments. Radiofrequency treatments of the face and neck are frequently performed at 4-week intervals to maximize affected collagen during treatment. Nonetheless, additional clinical studies are needed to determine optimal treatment intervals. The standardized photography protocol used in the study ensured consistency between before and after photos. Bouncing the flash against the wall at a standardized distance ensures that photos accurately depict the skin quality without blanching or minimizing wrinkles, veins, or skin texture.

Improvement of facial appearance after radiofrequency treatment has been attributed to the production of new collagen after tissue injury from use of the device.[5] The dorsum of the hand is composed of multiple fatty lamina divided by fascial layers, wherein the tendons and vessels lie.[9] Many treatments for hand rejuvenation have been directed at volumizing this space with either autologous fat transfer or synthetic fillers to replace the loss of connective tissues. It is possible that radiofrequency-induced neocollagenesis within this small compartment masked the presence of the large reticular veins, accounting for an aesthetic improvement seen in some of our patients. Studies have shown that in addition to dyschromia and wrinkles, part of what patients perceive as an "aged hand" is one with prominent vessels.[1] For this reason, we included vessel visibility as part of our GAIS assessment.

Limitations of this study include the relatively small number of subjects and the fact that all participants were female. The latter may be due to the fact that aging hands are not of cosmetic concern for males. Given the nature of radiofrequency treatments, a double-blinded study was not possible. Each physician rated the photographs of the subjects treated at her site. A future study could use an independent blinded physician evaluator for assessment of the photographs using the GAIS.

The safety profile and encouraging results of this initial study suggest that the radiofrequency system may be a valuable addition to the treatment arsenal for hand rejuvenation.

CONCLUSIONS

The aging hand is characterized by 3-D changes that include thinning of the epidermis and a decrease in connective tissues, resulting in prominent veins and tendons. The aged appearance of the hands is compounded by dyschromia caused by chronic sun exposure.[2] Both the face and the hands are among the most exposed areas of the body. This lack of synchronicity between the appearance of the face and the hands is most noticeable in those patients who have undergone facial rejuvenation. Consequently, there has been a renewed interest in the "aging hand," and similar treatment modalities that have been employed for facial rejuvenation have been used with varying success to rejuvenate them.[3] The unique anatomic characteristics of the hand and the multiple contributing factors that result in aging of the hand suggest that a combination approach is optimal in achieving a more youthful appearance. Based on our study, treatment with a monopolar radiofrequency device is safe and effective for hand rejuvenation and should be considered as a procedure offered to patients seeking a more complete and harmonious improvement in their appearance.

DISCLOSURES

Ellman International Inc provided funding for this study. The authors have no other relevant conflicts of interest to disclose.

REFERENCES

1. Bains RD, Thorpe H, Southern S. Hand aging: patients' opinions. *Plast Reconstr Surg.* 2006;117(7):2212-2218.
2. Jakubietz RG, Kloss DF, Gruenert JG, Jakubietz MG. The ageing hand. A study to evaluate the chronological ageing process of the hand. *J Plast Reconstr Aesthet Surg.* 2008;61(6):681-686.
3. Fabi SG, Goldman MP. Hand rejuvenation: a review and our experience. *Dermatol Surg.* 2012;38(7 Pt 2):1112-1127.
4. Dierickx CC. The role of deep heating for noninvasive skin rejuvenation. *Lasers Surg Med.* 2006;38(9):799-807.
5. Bogle MA, Dover JS. Tissue tightening technologies. *Dermatol Clin.* 2009;27(4):491-499.
6. Narins DJ, Narins RS. Non-surgical radiofrequency facelift. *J Drugs Dermatol.* 2003;2(5):495-500.
7. Zelickson BD, Kist D, Bernstein E, et al. Histological and ultrastructural evaluation of the effects of a radiofrequency-based nonablative dermal remodeling device: a pilot study. *Arch Dermatol.* 2004;140(2):204-209.
8. Fitzpatrick R, Geronemus R, Goldberg D, Kaminer M, Kilmer S, Ruiz-Esparza J. Multicenter study of noninvasive radiofrequency for periorbital tissue tightening. *Lasers Surg Med.* 2003;33(4):232-242.
9. Bidic SM, Hatef DA, Rohrich RJ. Dorsal hand anatomy relevant to volumetric rejuvenation. *Plast Reconstr Surg.* 2010;126(1):163-168.

AUTHOR CORRESPONDENCE

Flor A. Mayoral MD
E-mail:.....flor@flormayoral.com