

FIGURE 1. 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.

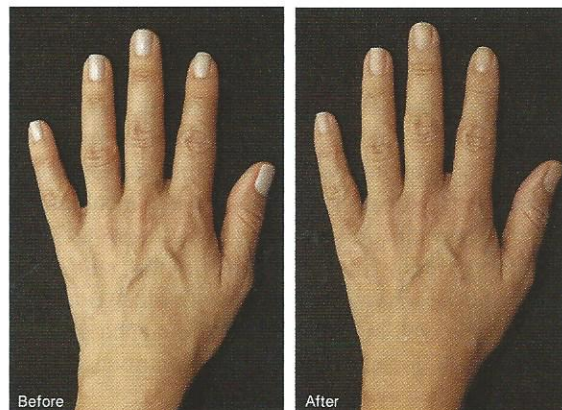
Methods

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 assign-

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



ing 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