

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

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## 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; Eilman 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 chronological age.<sup>1</sup> Loss of elasticity, tortuous veins, thinning of the skin, and loss of subcutaneous tissue give an aged appearance to the hands.<sup>2</sup> Several modalities can be used for hand rejuvenation, including volume restoration, laser and chemical resurfacing, vein removal, and treatment of dyschromia.<sup>3</sup> 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.<sup>4-7</sup>

## 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 Institu-

tional 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