

Response to “A Critique of Radiofrequency Treatments for Facial Rejuvenation”

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We thank Dr Swanson for his comments¹ on our study assessing the safety and efficacy of a combination treatment using fractional radiofrequency and a thermo-contraction system for facial skin rejuvenation.² He has noted the strengths of our study, and has also raised some questions and doubts, to which we respond below.

He stated that we have not used standardized photographs in Figure 3 of the article. This figure presents an image taken with the VisioFace Quick system (Courage & Khazaka electronic GmbH, Cologne, Germany), and the green specks show the measurement of the right nasolabial fold using CSI software, an approach that is well established and has been used successfully in a variety of studies.^{3,4} Therefore the measurement of the wrinkle area was not manual, but had been performed automatically by the software on original images, and is independent of the size of the photographs presented in the paper. We had at proof stage asked the journal to publish the photographs in the same size, and hope this will be corrected in the final print version of the paper.

Additionally, Dr Swanson refers to his use of the Canfield 7.4.1 mirror-imaging software and mentions that it “simply measures the distance between two landmarks for wrinkle measurement.” However, wrinkle analysis using CSI software is a 3-dimensional (3D) process and can evaluate the depth of a wrinkle, as well as the 2D surface area. The improvements in wrinkles reported in our study also included a significant decrease in wrinkle volume ($P = 0.031$), and this is related to reducing the wrinkle depth as well as the wrinkle surface area.

Dr Swanson claims that in spite of a significant improvement in the echo-density of the dermis 3 months after treatment, the measurement returned to below baseline at 6 months; in fact, however, there was no significant statistical difference in dermis echo-density when comparing month 6 with baseline ($P = 0.157$). Our study notes that the treatment was not sustainable and measurement has returned to baseline (not below baseline) after 6 months.

He also argues that the standard deviations (SDs) of the Glogau wrinkle scores (0.80 and 0.79) are relatively large and the difference in means is tiny. However, we can find small but significant differences in subjective categorical scales. For example, Gold et al⁵ reported a significant improvement in the Fitzpatrick wrinkling scale when the Fitzpatrick wrinkling scale decreased from 3.45 ± 1.4 at baseline to 3.12 ± 1.3 at month 3.

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Table 1. Results of Nonparametric Test (Kolmogorov-Smirnov) for Wrinkle Scores at Baseline and 3 and 6 Months After Last Treatment

	Wrinkle score		
	Baseline	Month 3	Month 6
Mean	2	1.86	1.75
Kolmogorov-Smirnov z	0.62	0.76	0.85
P value	0.83	0.60	0.45

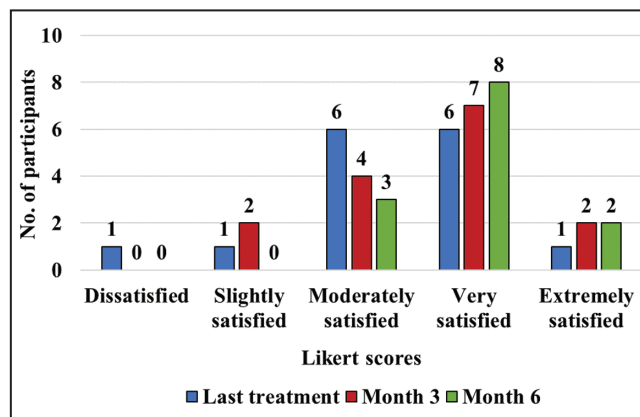
Large SDs are usually reported in results of categoric parameters, especially when using small sample sizes. Seo et al⁶ conducted a comparative study on 15 subjects treated with fractional radiofrequency alone, and fractional radiofrequency plus stem cell-conditioned medium. The mean degrees of improvement in their report using a 4-degree scale were 2.06 ± 0.70 and 2.20 ± 0.68 , respectively. The means and SDs reported by Seo et al are comparable to the values noted in our report.

Moreover, the wrinkle scores in our study had a normal distribution based on the Kolmogorov-Smirnov test, and therefore parametric tests were used to analyze these scores (Table 1).

A number of authors also accept that the “*t* test” is not the preferred method for comparing categoric scores; however, using *t* tests is not uncommon in aesthetic categoric assessments. Seo et al⁶ compared “patient’s overall satisfaction score” and “blinded investigator evaluation” (both categoric) in 2 interventions using paired *t* tests. Moreover, Gold et al⁵ compared Fitzpatrick wrinkling scale values before and after intervention through the use of paired *t* tests.

Dr Swanson inquired about the number of patients who were dissatisfied with the treatment. Detailed data about the number of participants and their satisfaction scores are shown in Figure 1. As it is clear there was only 1 dissatisfied participant in the final treatment session, we did not report this figure in the original paper due to space limitations.

We stated in the introduction to our paper that *it is claimed* that thermo-contraction can stimulate muscle contraction and can have a lifting effect. As Dr Swanson notes, we did not observe any findings that support this claim because the decrease in laxity score was not significant. However, using a larger sample size might lead to different results.

**Figure 1.** Number of participants and their satisfaction scores at the last treatment session, and 3 and 6 months later.

As we declared, Dr Kalantari, one of the authors, is a shareholder of the company that funded this study. He also is a physician with experience in aesthetic medicine and was involved in the study design, interpretation of data, and preparation of the manuscript, but had no role in the treatment and assessment of patients, or in the gathering and analysis of data. We therefore believe that his being a shareholder did not have any influence on the integrity of this study. Moreover, he did not receive any payment for the radiofrequency treatments, as the treatments and assessments were provided free of charge to the participants.

Dr Swanson claims that corporate-funded studies can be subject to financial conflicts. We are well aware of this limitation, and we therefore maximized our objectivity and limited any bias by performing neutral and blinded assessments of patients, by adhering to the principles of Good Clinical Practice, and by registering the study on an open clinical trial registry website.

As Dr Swanson mentions, nonsurgical thermal skin treatments might cause some burning discomfort, but the adverse effects are not comparable with surgery because they are mild in severity and duration.

In conclusion, we also believe that surgery remains the gold standard of treatment for advanced facial aging, but nobody can deny the increasing demand for minimally invasive procedures to improve the signs of aging, as shown by data provided by the American Society of Plastic Surgeons.⁷ Many patients are poor candidates for surgery or reluctant for various reasons to undergo surgery. Recent advances in energy-based devices have seen the introduction of several skin-rejuvenation systems—radiofrequency, lasers, high-intensity focused ultrasound, etc.—to improve skin aging. Several studies, both corporate funded and independent, have confirmed the efficacy of these treatments, many of which have now been approved by

regulatory agencies worldwide. Therefore, in contrast to Dr Swanson, we believe there is a place for the use of these devices in selected patients. Although none of these methods are comparable to surgery in terms of efficacy and longevity, these treatments could nevertheless be beneficial, especially in the early stages of aging, as they offer fewer side effects, less down time, and lower costs.

Disclosures


Dr Kalantari is the CEO of and a shareholder in Medaria Company (Tehran, Iran). The other authors declared no potential conflicts of interest with respect to the research, authorship, and publication of this article.

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