

Safety and Efficacy of a New Device Combining Radiofrequency and Low-Frequency Pulsed Electromagnetic Fields for the Treatment of Facial Rhytides

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ABSTRACT

Background: A distinct trend in aesthetic medicine is the patient's demand for efficient, noninvasive treatments with no downtime. Ongoing with this, these so-called lunchtime procedures are expected to be as safe and painless as possible. A new technique based on a combination of radiofrequency (RF) and pulsed electromagnetic fields (PEMF) was recently introduced and is supposed to be effective in the treatment of facial wrinkles and virtually pain free. The objective of this study was to investigate the safety and efficacy of this technology for the treatment of facial rhytides.

Methods: Thirty-one subjects with facial wrinkles and rhytides were entered into this study. Every subject received 10 treatments of the face with a device that combines 1 MHz radiofrequency with PEMF with a flux of 15 gauss. Patients rated the pain level immediately after the treatment by using a visual analog scale (VAS) for pain. Side effects were recorded at every visit. The study's efficacy end point was evaluated by 2 blinded physicians who rated the standardized pictures from baseline and 3-month follow-up using the Fitzpatrick Wrinkle and Elastosis Scale (FWES).

Results: No unexpected adverse side effects were detected or reported for the duration of the study. Both raters recognized improvements of at least 1 grade on the FWES in 30 of 31 subjects (97%). The score decreased from 5.2 before the first treatment to 3.6 at 3 months after the last treatment. Furthermore, all patients rated the treatment to be free of pain on the VAS pain scale.

Conclusion: The results of this study show that the combination of multipolar RF with PEMF is a safe, effective, and painless approach to treat facial rhytides and is suitable to answer the demands of patients for safe treatments without pain or downtime.

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INTRODUCTION

A distinct trend in aesthetic medicine is the patient's demand for efficient, noninvasive treatments with no downtime. Ongoing with this, these so-called lunchtime procedures are expected to be as safe and painless as possible. A new technique based on a combination of radiofrequency (RF) and magnetic pulses was recently introduced and is supposed to be effective in the treatment of facial wrinkles and virtually pain free.

The use of RF to tighten skin was first described by Ruiz-Esparza and Gomez in 2003.¹ The technique is based on volumetric heating of dermal tissue to initiate a denaturation of collagen accompanied by an immediate contraction of the fibers and a subsequent neocollagenesis.^{2,3} The heat generation is based on the tissue's natural resistance to the movement of ions within an electromagnetic field and other than lasers not diminished by tissue diffraction or absorption by epidermal melanin. As such, RF-based systems are appropriate for any skin type.⁴ However, the shrinkage of collagen is not dependent on a spe-

cific temperature, but is determined by a combination of time and temperature.⁵ This fact allows slow approaches with target temperatures around 60°C to 65°C as well as millisecond approaches with a target temperature of 85°C to be effective.⁶ As higher temperatures are accompanied by an increased risk of side effects and significant pain,⁷ slow approaches with lower target temperatures thereby seem to be safer and less uncomfortable for patients.

The safety and pain of RF treatments can also depend on the number of electrodes. Unipolar systems are associated with significant pain and a high rate of adverse effects such as second-degree burns due to the concentrated and deep-reaching heat production at their single electrode,⁸ whereas bipolar and multipolar systems distribute the heat energy equally and more superficially between their electrodes, resulting in minimal pain and a better safety profile.^{9,10} Alexiades-Armenakas et al¹¹ compared the unipolar and bipolar modes of an RF device with an uncommonly high frequency of 41 MHz in a randomized, blinded

FIGURE 1. Female patient (aged 53 years) before treatment (a) and after 10 treatments (b).

split-face study on 10 subjects. After 4 treatments at 1-week intervals, both approaches showed improvement of wrinkles and skin laxity, but no difference in efficacy, pain, or side effects between the unipolar and bipolar modes.¹¹ Other studies that directly compare unipolar devices with bipolar or multipolar devices with more common frequencies (0.5-6.0 MHz) haven't been published yet. However, in general, because of their deeper energy distribution, unipolar devices are supposed to be more efficient for skin rejuvenation, while bipolar and multipolar devices are supposed to be safer and less painful.

A new approach to reach a higher efficacy and keep the superior safety and pain profiles of multipolar RF is to combine it with pulsed electromagnetic fields (PEMF). The therapeutic effects of PEMF were first demonstrated by Bassett et al¹² and have been shown over time in clinical studies to be a safe and effective treatment for nonhealing bone fractures.^{13,14} Pulsed electromagnetic fields upregulate several cytokines such as bone morphogenetic proteins 2 and 4 and transforming growth factor- β that are important in promoting osteoblast differentiation during fracture repair.¹⁵ Tepper et al showed that PEMF also has a positive impact on angiogenesis, a process critical for successful healing of various tissues.¹⁶ In their in vitro study, PEMF increased the degree of endothelial cell tubulization and proliferation as well as the number of fibroblast growth factor β -2 (FGF-2) and other angiogenic growth factors. A stimulating effect of PEMF on collagen synthesis was first described by Murray and Farndale¹⁷ and later confirmed by Soda et al,¹⁸ who identified the participation of the p38 mitogen-activated protein kinase pathway in the process.

Because multipolar RF and PEMF have different mechanisms of action and target structures in the skin, their combination is complementary. The stimulation of neovascularity, fibroblast proliferation, and collagen neosynthesis by PEMF synergizes with the denaturation of existing collagen by RF accompanied

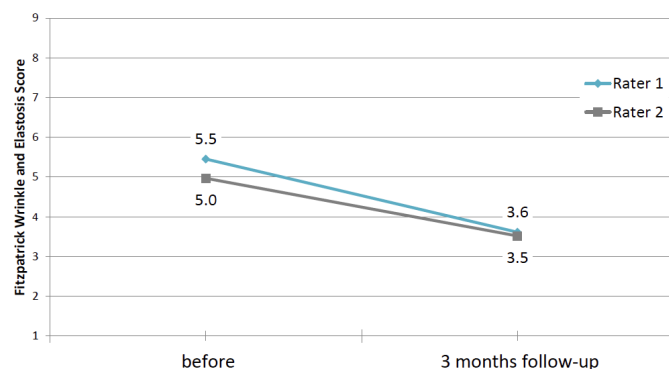
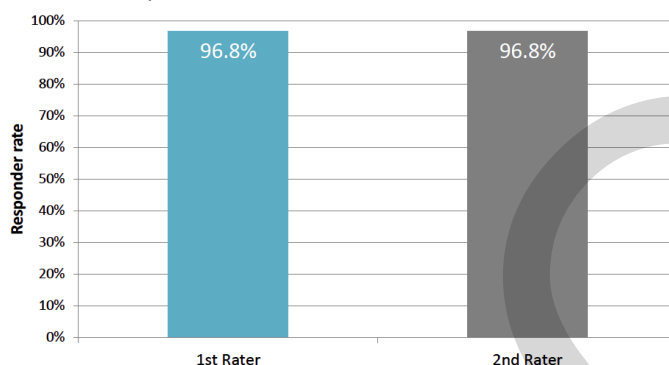
FIGURE 2. Female patient (aged 50 years) before treatment (a) and after 10 treatments (b).

by an immediate contraction of the fibers and a delayed synthesis of collagen and elastin fibers. Furthermore, the nonthermal mechanism of PEMF does not interfere with the thermal mechanism of the multipolar RF. However, as the effects of PEMF are well evaluated in vitro, their clinical effects on skin physiology and their compatibility with radiofrequency are still unclear. The objective of this study was therefore to investigate the safety and efficacy of a new device that combines PEMF and multipolar RF for the treatment of facial rhytides.

MATERIALS AND METHODS

The study protocol was approved by the Helsinki committee of Tel-Aviv Sourasky Medical Center (Israel), and all participants provided verbal and written consent before enrollment. Thirty-one subjects (30 females, 1 male) with facial wrinkles and rhytides were entered into the study. Inclusion criteria involved a score ≥ 4 on the Fitzpatrick Wrinkle and Elastosis Scale (FWES).¹⁹ Exclusion criteria were pregnancy or nursing, infection or inflammation in the treatment area, history of hypertrophic scars or keloids, and previous skin rejuvenation procedures in the face (eg, botulinum toxin, wrinkle or volume augmentation with an injectable filler, laser or RF treatments) in the past 6 months.

Before the first treatment, every patient was digitally photographed with a 10-megapixel camera (Evolv E-420; Olympus, Tokyo, Japan) in a standardized way. Treatments were performed with a device that combines 1 MHz RF with PEMF with a frequency of 15 Hz and a pulse duration of 0.5 ms (Venus Freeze™; Venus Concept, Karmiel, Israel). The magnetic field flux was 15 gauss (0.0015 tesla). Immediately after treatment, the treated area was visually assessed for skin responses, including edema, erythema, hypopigmentation or hyperpigmentation, and textural changes. In addition, patients were asked to rate the pain level perceived during the treatment by using a visual analog scale (VAS) for pain.

FIGURE 3. Change in Fitzpatrick Wrinkle and Elastosis Scale.**FIGURE 4.** Responder rate.

Every subject received 10 treatments of the face with individual treatment time and energy output adjusted to skin type. While the first 4 treatments were performed twice weekly, the following treatments were performed once a week. At follow-ups 1 month and 3 months after the last treatment, every patient was photographed in the same way as at the baseline visit. To evaluate the safety of the procedure, the occurrence of potential procedure-related side effects was monitored through the whole study. The study's efficacy end point was evaluated by 2 blinded physicians who rated the standardized pictures from baseline and 3-month follow-up using the FWES.¹⁹ In addition to the average score change, the responder rate was calculated by summarizing the number of subjects with an improvement of at least 1 grade on the FWES.

The software program SPSS Statistics 19 (IBM Corporation, Armonk, NY) was used for data preparation and statistical analysis. Mean, median, standard deviation, and standard error were calculated for every parameter. To identify statistically significant differences between baseline and follow-up, a significance level of .05 was determined and the nonparametric Wilcoxon signed rank test was used.

RESULTS

All 31 enrolled patients finished the study, including the 3-month follow-up, and were included in the analysis. The subjects ranged in age from 36 to 62 years (mean, 49.2±7.2) years.

Safety and Pain

No unexpected adverse side effects were detected or reported for the duration of the study. In some patients, posttreatment edema was detected, which resolved within 10 to 30 minutes without further treatment. No patients experienced more serious side effects like burns, skin breakdown, or scarring. Furthermore, all patients rated the treatment to be free of pain on the VAS pain scale.

Efficacy

The effect of the combination approach with RF and PEMF on facial rhytides was evaluated by 2 blinded physicians using the FWES. The comparison of the pictures (Figures 1-2) showed a statistically significant ($P<.001$) decrease in the average FWES score from 5.2 before the first treatment to 3.6 at 3 months after the last treatment (Figure 3). The median difference was 1.5 overall. Both independent raters recognized improvements of at least 1 grade on the FWES in 30 of 31 subjects (96.8%) (Figure 4).

DISCUSSION

The treatment of photoaged skin and signs of intrinsic aging was for a long time limited to ablative or minimal ablative approaches and, therefore, was associated with complications like prolonged erythema, infections, pigmentary alterations, or scarring.²⁰ The use of RF for facial and whole-body rejuvenation answers the demand of patients for noticeable improvement in combination with minimal risk and no downtime. The heat generated by the electric current causes a collagen contracture and remodeling deep in the dermis without appreciable epidermal disruption.² The main disadvantage of this technology was the level of pain generated by the first-generation RF devices.⁷ Subsequent generations of RF devices were developed to optimize the balance between clinical efficacy, safety, and pain. Therefore, the latest development is the use of multipolar RF in combination with PEMF for gentle tissue heating.¹⁰

The results of this study show that the combination of multipolar RF with PEMF is a safe, effective, and painless approach to treat facial rhytides. The rejuvenating effect, determined by an increase of at least 1 grade on the FWES, was ascertainable in 30 of 31 subjects (97%). The high responder rate together with the overall median decrease of 1.5 grades demonstrates that the efficacy of the combination approach evaluated in this study is noninferior or superior to approaches with unipolar or bipolar RF. Other studies using the FWES showed a responder rate of 83% to 100% with unipolar RF^{21,22} and 85% to 100% with bipolar RF.^{9,23,24} Particularly in studies investigating unipolar RF, the good efficacy was associated with mild to moderate pain levels and a high rate of side effects. Fitzpatrick et al²¹ described erythema (36%), edema (14%), second-degree burns (6%), and scars (3%) as side effects of the procedure. In studies on bipolar RF, largely no pain was described, although transient erythema and edema as well as burn/blistering, purpura, crusting, and tran-

sient hyperpigmentation occurred.^{9,23} In the current study, there was no pain experienced by any of the subjects during or post-treatment. The only observed side effect was edema in some patients, which resolved within 30 minutes after the treatment.

CONCLUSION

This uncontrolled pilot study demonstrates that the combination of multipolar RF with PEMF is an efficient and gentle approach for the treatment of facial rhytides. It is suitable to answer the demands of patients for safe treatments without pain or downtime. However, further studies in a randomized controlled design are necessary to confirm the results of this study and to evaluate the applicability of this technology for skin tightening of nonfacial areas or the treatment of other indications like cellulite or stretch marks.

DISCLOSURES

Neil S. Sadick is a consultant for Venus Concept and owns stock options in the company.

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