

Preliminary Report

The Simultaneous Application of Synchronized Radiofrequency and HIFES Technology Improves the Tone of Facial Muscles, as Assessed by Ultrasound Echo Intensity: A Pilot Study

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Abstract

Background: The condition of facial muscles is pivotal for a youthful appearance, because they define facial contours and significantly enhance overall facial aesthetics. Maintaining their tone and quality is, therefore, essential for preserving a refreshed and vibrant look.

Objectives: To explore whether high-intensity facial electromagnetic stimulation (HIFES) and synchronized radiofrequency (RF) therapy can effectively enhance the tone and quality of targeted facial muscles, offering a potential advancement in achieving an improved appearance.

Methods: Ten adult patients (2 males and 8 females) received 4 noninvasive HIFES + synchronized RF treatments. Photographs of the face, along with ultrasound scans of the *frontalis* muscle and *zygomaticus major* muscle to assess muscles' echo intensity (EI), were taken at baseline, after the last treatment, and during the 1- and 3-month follow-up visits. Patient satisfaction and comfort were assessed using a 7-point Likert scale, whereas pain levels were evaluated using a 10-point Visual Analog Pain Scale.

Results: The EI decreased in both *zygomaticus major* muscle and *frontalis* muscle at 3 months ($P < .005$). This indicates an improvement in muscle quality and resting tone. The Global Aesthetic Improvement Scale detected improvement of at least 1 point in 87.5% of patients at 3 months. Therapy was perceived as comfortable and accompanied by high patient satisfaction of 87.5%.

Conclusions: The simultaneous administration of HIFES + synchronized RF effectively stimulates the facial elevator muscles, possibly improving their quality.

Level of Evidence: 4 (Therapeutic)

Facial aging is a complex process that involves numerous changes to the skin and underlying tissues, including loss of volume and elasticity, changes in skin texture, and alterations in muscle tone.¹⁻³ Fat compartments become deflated, and skin and connective tissue frameworks lose elastin and collagen content, whereas facial muscles lose their tone and their performance is diminished because of aging.^{2,4} The synergy of these processes causes the dilapidation of the fascial framework, interconnecting muscles, and the skin.^{2,4-7}

This phenomenon affects not only specific muscle groups, the fascial framework, and the overlying skin separately but as a whole unit, and consequently, all of the mentioned processes can also lead to observable descent of the tissues over time.⁸ Concretely, the important role of the facial muscles bears the elevator muscles present in the forehead (*frontalis* muscle [FM]) and cheeks (*zygomaticus major*

[ZM], *zygomaticus minor*, *risorius*). They perform specific motions, such as lifts of part of the face, and create various facial expressions. The aging facial elevator muscles possess a lower resting muscle tone, as evidenced by a decreased electric signal,⁶ which requires increased muscle engagement and activation to secure overlying tissue in place and avoid sagging. The subsequent descent of the overlying skin and subcutaneous tissue is accompanied by the

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Aesthetic Surgery Journal Open Forum
2025, ojal028

Editorial Decision date: April 2, 2025; online
publish-ahead-of-print April 30, 2025.

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University Press on behalf of The Aesthetic
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development of wrinkles, sagging skin, changes in facial contour, loss of volume, and alterations in overall appearance.^{8,9} However, an increase in resting muscle tone enables the muscles to uphold the overlying tissue without drooping, eliminating the need for continuous contraction.¹⁰ Therefore, keeping elevator muscles in proper condition contributes to the youthful appearance of the face.^{2,8,9}

Although various cosmetic procedures like dermal (soft tissue) fillers and implants, muscle neuromodulator (neurotoxin) injections, and surgical muscle repositioning can reduce the severity of wrinkles and enhance facial contour, they do not actively address the overall condition of the facial muscles, which play an important role in natural skin mobility.^{11,12} Given the complex interplay of factors contributing to facial aging, a more comprehensive approach that also targets muscle tone and quality is necessary.

One such procedure comprising this combined approach to support the fascial framework through improved muscle tone and dermal structures is the simultaneous application of high-intensity facial electromagnetic stimulation (HIFES) and synchronized radiofrequency (RF) technology. HIFES technology employs electrical fields to generate supramaximal contractions in delicate facial muscles, specifically the FM on the forehead, as well as the *zygomaticus major*, *zygomaticus minor*, and *risorius* muscles on the cheeks, to stimulate muscle protein synthesis and densify muscle tissue,^{7,13} whereas RF heating primarily affects dermal and subdermal structures.^{14,15} The simultaneous application of both technologies causes adaptive changes in the overlying cutaneous tissue, connective tissue framework, and facial muscle unit.^{7,10,16-19}

Several technologies, including electromyography, MRI,^{20,21} and others, are now commonly used to evaluate muscle. These technologies offer different methods of assessing muscle and its properties, such as function, structure, composition, or performance.^{22,23} In this study, echo intensity (EI), measured through ultrasound (US) was employed as a marker to assess changes in muscle quality.²⁴⁻²⁶ Low EI values are thought to be indicative of superior muscle quality,²⁷ whereas high EI values are associated with muscle impairment²⁸ primarily indicating higher levels of fat and connective tissue.^{28,29} The validity of US measurements of muscle fiber mass and noncontractile tissues was proven in studies using MRI and computed tomography for comparison.^{29,30}

The authors of this study aim to determine whether HIFES and synchronized RF therapy can improve the quality of delicate facial muscles and detect them through changes in EI obtained from US images.

METHODS

The study design and treatment protocol were approved by the Advarra Institutional Review Board. This single-center, single-arm, open-label interventional study took place from June 2022 to May 2023 (trial registration: NCT05524740). The study included adult patients over 21 years of age who sought facial enhancement and had clearly sagging skin in the treated area, as determined by the investigator. General exclusion criteria included the presence of metal implants, pregnancy, unhealed wounds in the treated area, and any contraindications for the RF and electrical modalities. Additionally, concurrent cosmetic treatments were not allowed, and patients were instructed not to undergo any during the informed consent form signature. A history of previous cosmetic treatments was



Figure 1. The illustration of the actual electrodes placement on the patient's forehead and cheeks, courtesy of BTL Industries, Boston, MA.

possible for participation in this study; however, cosmetic treatment administered <3 months before the study enrollment was considered as a reason to exclude a patient from the study. By signing the informed consent form, patients were required to inform the principal investigator about any additional treatments received during the study course. Limits were not applied to ethnic backgrounds or skin types; all adults seeking treatment who fell within inclusion criteria and did not meet any exclusion criteria were eligible for enrollment. Before the start of the study, the informed consent form from all patients was collected, and a unique patient identification code was assigned to each patient to ensure their anonymity. Detailed instructions about the study were given to all patients.

Therapy consisted of four 20 min treatments spaced 1 week apart and 2 follow-up visits at 1 and 3 months after the last treatment. The HIFES and synchronized RF energies were administered simultaneously on all targeted areas (ie, both cheeks and forehead) through the EMFACE device (BTL Industries, Boston, MA) by self-adhesive, single-use applicators (Figure 1). The therapy parameters were adjusted according to patient feedback and tolerability on a scale of 0% to 100% separately for both HIFES and synchronized RF. Patients were treated in the supine position without the use of anesthesia. Before the treatment, the face was cleared of cosmetic products, jewelry, or prominent hair.

Echo Intensity Ultrasound Measurements

The US scans (Voluson E8, GE Healthcare, Chicago, IL) were performed to assess EI through grayscale histogram analysis²⁶ and detect changes in muscle quality. A predominantly brighter appearance suggests that there is a substantial amount of noncontractile tissue in the skeletal muscle, represented by intramuscular adipocytes and fibrous tissue. Conversely, the appearance of dark areas suggests the occurrence of contractile protein.³¹ Scans were conducted at the baseline, after the last visit, and during 2 follow-up visits. The imaging was performed with a linear probe on the same surface and parameters area each time (10 MHz frequency, gain parameter of 50, and 1.8 cm measurement depth). Before the procedure, a US technician applied US gel on the examined area on the surface of the forehead (FM) and cheeks (ZM). The US probe was always placed perpendicularly to the skin and in the same location to keep

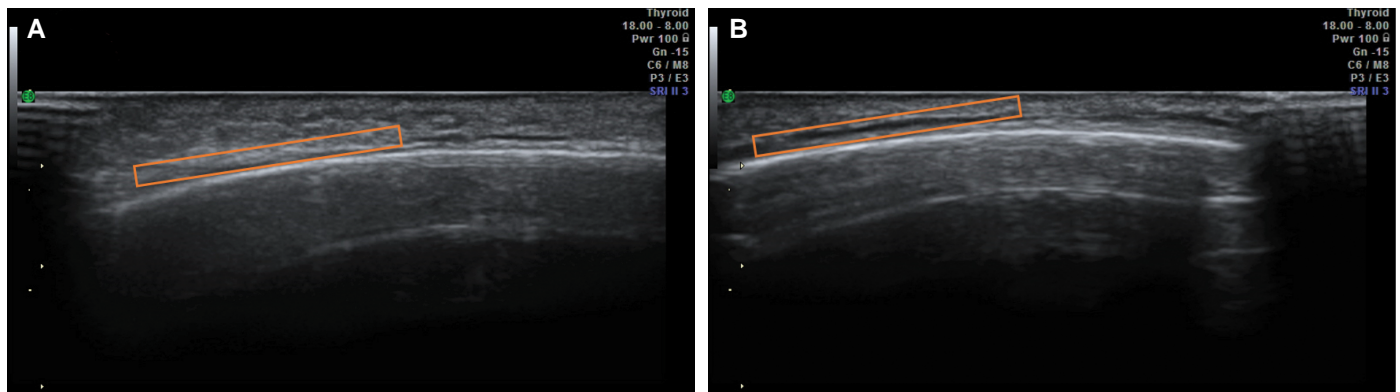


Figure 2. The figure displays an ultrasound scan of the *frontalis* muscle at baseline (A) and 3-month follow-up visit (B). An increase in contractile tissue in the region of interest, displayed as dark areas (framed area), is observed 3 months after the final treatment.

consistency in measured muscles. For the FM, the transducer was placed in the horizontal plane at 1 fingerbreadth cranial to the eyebrow, and for the *zygomaticus major*, over the inferior lateral edge of the orbital rim. Both sides of the face (left and right) were measured at each visit, emphasizing the examination of muscles in a relaxed state.³² After examination, a separate radiologist identified and marked underlying muscles in the US scan. Transverse US scans of the targeted areas were displayed and analyzed using a grayscale of 256 gray levels from 0 (black) to 255 (white).^{31,33} ImageJ software, version 64-bit Java 1.8.0_172,³⁴ was used to analyze and evaluate the grayscale histogram.

Objective Aesthetic Improvement Outcome Scoring (Global Aesthetic Improvement Scale)

The photographing was done at baseline, after the last treatment, and at follow-up visits. The digital photographs of the face were taken from different angles (front and both sides views) and were graded for the magnitude of change in facial appearance by 3 independent evaluators—specialists with a clinical aesthetic background, using the Global Aesthetic Improvement Scale (GAIS) score based on a 5-grade scale (−1 = worse, 0 = no change, 1 = improved, 2 = much improved, 3 = very much improved). The results were averaged.

Patients' Satisfaction and Comfort

The patient's satisfaction with the results was documented after the last treatment and at both follow-ups using the 7-point Likert scale (1 = strongly disagree, 7 = strongly agree). The Subject Satisfaction Questionnaire consisted of 7 questions related to facial appearance improvement, smoothness and tightness of the skin, overall satisfaction with treatment results, and recommendations to friends and family. Additionally, the patients were given a Therapy Comfort Questionnaire (combining a 7-point Likert scale and a 10-point Visual Analog Pain Scale) after the last treatment. The satisfaction rate was determined by calculating the proportion of patients who reported a score of "5" (somewhat agree) or higher, relative to the total number of patients who responded to the questions. The average percentage was then computed across all 7 questions.

Data Analysis

Descriptive statistics (mean and SD) were utilized to evaluate the obtained data, along with the Friedman test. The statistical tests were run at the level of significance $\alpha = .05$ (5%).

RESULTS

The study enrolled 10 patients (2 males and 8 females) aged 42 to 70 (mean age 53.4 ± 10.1) with Fitzpatrick skin types ranging from I to IV and weight from 99 to 200 pounds (mean weight 135.6 ± 34.0 pounds). All of the enrolled patients completed scheduled treatment sessions. Eight out of the 10 participants (1 male and 7 females) aged 43 to 70 (mean age 55.8 ± 10.0 , mean weight 130.3 ± 34.3 pounds) completed all follow-up visits. The treatment settings of HIFES were well tolerated. The synchronized RF energy was set to the maximum level on each treatment performed in this study.

Echo Intensity

Muscle quality was assessed through changes in EI only in patients, who completed both follow-up visit evaluations ($n = 8$). A significant improvement ($P < .005$) in muscle quality, indicated by a decline in EI values, was observed during all follow-up visits for both examined muscles (Figure 2A, B). The gradual decrease in EI ranged from −17.6% after the completion of therapy to −18.3% at 1 month and eventually reached −31.2% at 3 months on average for both muscles (Figure 3). The differences in EI values at 3 months compared with baseline were as follows: for FM, EI = −27.6 AU, and for ZM, EI = −16.2 AU.

Overall Improvement in Appearance and Satisfaction

The evaluation of digital photographs (Figures 4A-D, 5A, B), according to the GAIS showed a change of at least 1 point on the scale at 3 months posttreatment in 87.5% of patients (7 out of 8). The average patient satisfaction at 3 months was 87.5%, and 75.0% of patients felt their face was naturally more lifted, their overall facial appearance had improved, and most patients (87.5%) were satisfied with the treatment result. All patients who underwent the therapy felt that their

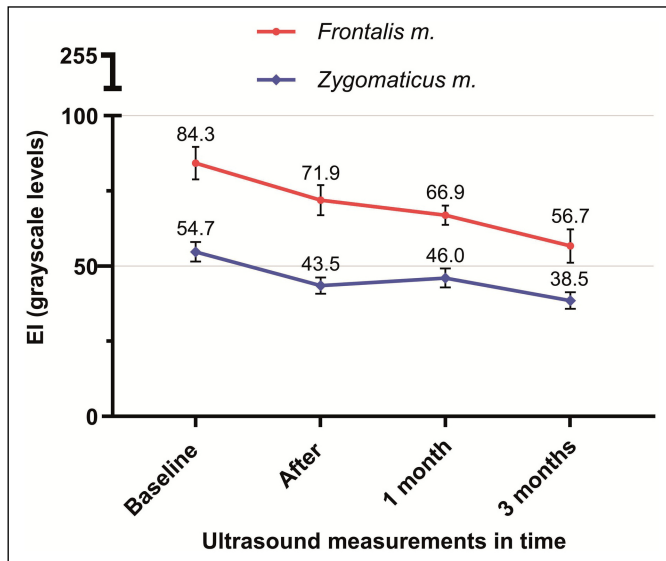


Figure 3. The changes in echo intensity (EI) detected during the course of therapy were assessed for different facial muscles (*frontalis* muscle and *zygomaticus* muscle), presented as average values. EI is represented by 0 to 255 grayscale levels.

face was more toned, tightened, and smoother after the treatments. The therapy comfort survey results indicated mild discomfort (average 2.9 ± 1.4 on Visual Analog Pain Scale). No adverse events occurred throughout the study course.

DISCUSSION

This study assessed changes in EI in specific facial muscles following HIFES and synchronized RF therapy. The advantage of this noninvasive and safe US-based evaluation method is that it provides information about the composition of the muscle, that is, the content of muscle tissue and noncontractile components from which the quality of the muscle can be inferred.²⁴ The condition of muscles is a critical factor in facial aesthetics, because they provide stability and maintain the positioning of facial soft tissues. By improving muscle quality and tone, the structural support of the face is increased, contributing to a rejuvenated appearance while minimizing the need for compensatory hyperkinetic movements that often lead to visible rhytids. This is externally manifested as a diminished prominence of hyperkinetic lines and lifting effect.^{2,35} The rejuvenation effect is observed with increased muscle tone and decreased muscle overactivity.

Throughout the study, the observed decrease in EI for both examined muscles, namely ZM and FM, indicated an improvement in facial muscle quality.^{24,36} This outcome pointed to structural changes in muscle tissue, supporting the previous finding connected to the remodeling of muscle tissue under the effect of HIFES and synchronized RF.⁷ Additionally, the evaluation of GAIS indicated a noticeable improvement, highlighting the comprehensive nature of the changes occurring from within the tissues to the outward condition and appearance of the face. A similar finding was presented by Gentile and Halaas when investigating primarily the effect of this technology on wrinkle appearance, where the positive changes were detected not only in the severity of wrinkles but also were projected to the overall appearance of the face as measured by GAIS score.¹⁸



Figure 4. (A, C) The baseline and (B, D) 3-month follow-up photographs of a 66-year-old female patient. Note the reduced wrinkles on the above-eyebrow area and tightened skin in the area of the nasolabial folds at the 3-month follow-up.

Kinney et al previously investigated the muscles treated by HIFES and synchronized RF and defined that temperature at 40°C positively affects treating delicate facial muscles in the sense of rejuvenation.⁷ RF heating affects the dermal and subdermal fascial framework composed of collagen and elastin. Induced heating triggers the remodeling of these components, resulting in enhanced elasticity and tightness of the fascial web because of neocollagenesis and elastogenesis.³⁷ Stimulation of delicate facial muscles by HIFES affects neuronal and muscle tissue and consequently depolarizes the membrane of the motor neurons that innervate the muscle. When motor neurons depolarize, a signal is created that travels to the neuromuscular junction, connecting the motor neuron to the muscle. This signal overcomes the junction and induces involuntary muscle contraction. HIFES stimuli are repeated without allowing facial muscles to relax, leading to continuous muscle contraction. Adjusting the electrical field intensity and frequency achieves a “supramaximal contraction” state.^{7,13} This triggers heat shock proteins (HSPs) and satellite cells (SCs) to participate in muscle remodeling by promoting muscle protein synthesis¹³ and myofiber development.¹⁴ SCs remain dormant until activated to generate new myonuclei or muscle fibers. HSP and SC activation alters muscle microprotein structure, leading to the densification of healthy muscle tissue or hypertrophic response in the atrophied muscle. The effects



Figure 5. (A) The baseline and (B) 3-month follow-up photographs of a 47-year-old female patient. Note the lifted lower face and reduced forehead wrinkles at the 3-month follow-up.

of their activation in muscle tissue are delayed,³⁸ justifying the gradual improvement up to a 3-month follow-up observed in this study and the findings of Kinney et al.⁷ The fascial layer is also remodeled in response to heat and mechanical stimuli.³⁷

The synergy of all mentioned processes provides the modulation of favorable changes in different face compartments and enhances blood circulation, increasing nutrient supply.^{39,40} Enhanced muscle quality directly contributes to improved muscle tone, because the myofibrils bear the majority of the resting tension in the muscles.⁴¹ Additionally, intramuscular fat, a contributor to increased echogenicity,³⁶ can impede neuromuscular activation.⁴² Although direct paralyzation of the FMs with neurotoxins also leads to aesthetically pleasing outcomes by reducing hyperkinetic lines, it causes brow ptosis, as muscles are weakened and overlying tissue descent.^{43,44} Therefore, it would be ideal to have muscles with higher muscle tone at a resting state to hold them in a higher position. Additionally, the heating effect of synchronized RF tightens the skin because of newly built structural elements, giving a tighter framework. The noninvasive nature of technologies allows no downtime after the procedure.¹⁹ Although the study had a small sample size, short-term follow-ups, and an uncontrolled design, it is notable that this is the pioneering pilot study investigating the effects of HIFES and synchronized RF on facial muscles using US in a human population. Moreover, the limitations of only 1 variable being examined from the US measurement and a selection bias must be considered when interpreting the results since enrollment criteria determined participants' inclusion. Also, the individual contribution of each technology to the observed visual enhancement should be further investigated, because the combined approach could impact the assessment of GAIS scores. Future studies should include a larger sample size with a long-term follow-up and investigate various muscle characteristics to build on these findings.

CONCLUSIONS

The simultaneous administration of HIFES and synchronized RF technology has a positive effect on ZM and FM, accompanied by an

improvement in overall face appearance. During the course of the study, both muscles exhibited a decrease in EI, indicating an improvement in muscle quality.

Based on this study, the therapy is deemed comfortable and effective and demonstrates promising potential as a new approach to facial treatments.

Disclosures

Dr Halaas is the clinical investigator for BTL Industries (Boston, MA). BTL Industries sponsored the study and provided the study device.

Funding

BTL Industries was the sponsor of this study and provided the study device. However, no funding for authorship and publication of this article was provided.

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