

# Impact of Synchronized Radiofrequency and High-intensity Facial Electrical Stimulation on Facial Muscles and the Superficial Fascial System in the Midface

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## Abstract

**Background:** Midfacial aging involves skeletal changes, muscle weakening, and fat redistribution, resulting in volume loss, skin sagging, and deepened nasolabial folds. High-intensity facial electrical stimulation (HIFES) combined with radiofrequency (RF) is a novel noninvasive method for addressing these changes by enhancing muscle mass and remodeling subcutaneous tissue.

**Objectives:** The goal of this study was to assess the efficacy of HIFES and synchronized RF in improving midfacial aesthetics, specifically muscle thickness, skin displacement, and facial volume.

**Methods:** This prospective, nonrandomized study included 37 participants who underwent 4 HIFES and RF treatments over 24 weeks. Assessments at baseline, 4, 16, and 24 weeks were performed with ultrasound imaging, electromyography (EMG), 3-dimensional surface imaging, and the Modified Fitzpatrick Wrinkle Scale. A related porcine study evaluated the treatment's histological effects.

**Results:** Zygomaticus major muscle thickness increased from 2.06 mm to 2.80 mm, with a 39.3% rise in EMG signal strength, indicating improved muscle function. Skin displacement analysis revealed horizontal (0.90 mm) and vertical (1.01 mm) shifts, particularly laterally. Midface volume increased by 1.43 cm<sup>3</sup> at 24 weeks. The porcine study confirmed increased muscle fiber size, myonucleus count, and mass density, aligning with human results.

**Conclusions:** HIFES and synchronized RF treatments significantly improved muscle thickness, skin displacement, and facial volume, effectively rejuvenating the midface. These clinical findings, supported by histological evidence, suggest a promising noninvasive approach for facial rejuvenation. Further randomized studies are needed to confirm these results and assess long-term effects.

## Level of Evidence: 4 (Therapeutic)

Midfacial aging is a complex, multimodal process that affects various facial structures. As individuals age, several significant changes occur in the midface region.<sup>1–6</sup> One of the primary alterations involves rotational changes in the maxilla, the central bone of the midface, which gradually shifts and rotates as we age. This movement can cause a noticeable alteration in facial appearance, contributing to a more aged look.<sup>7</sup> In addition to these skeletal changes, there is a descent of

the superficial nasolabial fat compartment and atrophy of the deep medial and deep lateral cheek fat compartments.<sup>5,6</sup> These deep fat pads provide essential support and volume to the midface. Over time, the loss of volume in these areas results in a more hollowed and sunken appearance. Additionally, the zygomaticus major muscle, which is responsible for lifting the corners of the mouth, loses tensile strength with age. The weakening of this muscle contributes to

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the drooping of the midface, further accentuating the aged appearance.<sup>2</sup>

These cumulative changes result in a midface volume deficiency and an accentuation of the nasolabial fold. Rejuvenation of the midface has become an area of significant interest in aesthetic medicine, with a wide array of treatment options available. These treatments range from non-invasive approaches to more invasive surgical procedures.<sup>8-13</sup> Noninvasive treatments, such as the application of radiofrequency (RF), have gained popularity due to their ability to tighten the skin and stimulate collagen production without the need for surgery. RF treatments are often performed as a preventative measure or to address early signs of aging. Recent investigations have explored the potential benefits of combining RF with high-intensity facial electrical stimulation (HIFES) for midface rejuvenation.<sup>14-16</sup> Animal model studies have shown that this combination can increase muscle mass in the treated areas, which may contribute to a more lifted and youthful appearance.<sup>17</sup> Moreover, preliminary clinical investigations have reported an improvement in the nasolabial fold following this combination treatment.<sup>14</sup> Despite these promising findings, controlled, objective data with reproducible and measurable outcomes remains elusive.

The objective of this study was to address this gap in the literature by assessing the efficacy of a combination treatment with HIFES and RF for treating midfacial aging. In this study, we aimed to employ objective means of measurement, such as standardized photographic analysis, 3-dimensional (3D) imaging, and quantitative assessment of skin elasticity and volume changes. By focusing on objective outcomes, with this research we sought to provide more reliable and reproducible data on the effectiveness of HIFES and RF in midface rejuvenation, ultimately contributing to the development of more effective and evidence-based treatment protocols for facial aging.

## METHODS

### Study Design

The study design has been described previously for treatment of the upper face. In brief, this was a nonrandomized, prospective, single-center study focused on synchronized RF and HIFES for treating midfacial aging. The clinical investigation plan, including its amendments, informed consent forms, and all relevant study-related documents, received approval from the local institutional review boards. The study was conducted in compliance with ISO14155:2011 standards, the principles of the Declaration of Helsinki, and applicable national laws. Participants underwent 4 synchronized RF and HIFES treatments, spaced 7 days apart ( $\pm$  3 days), with efficacy assessments conducted at 4, 16, and 24 weeks posttreatment. The study took place between June 2023 and February 2024.

### Study Cohort

Each patient underwent treatment following a screening process to determine eligibility. To qualify for enrollment, participants needed to be 18 years of age or older and exhibit at least mild static forehead lines, crow's feet, and nasolabial folds, as evaluated by the Modified Fitzpatrick Wrinkle Scale. Additionally, patients were required to have healthy facial skin and demonstrate a commitment to abstaining from any aesthetic or surgical procedures involving the face for the duration of the study. Individuals with compromised immune systems, skin-related autoimmune diseases, scarring in the treatment area, metal implants, pacemakers, internal defibrillators, or a current or previous history of skin cancer were excluded from participation.

## Treatment

Before treatment, the patient's midface was disinfected with a 95% alcohol solution to eliminate any grease that might interfere with the applicators. Once the skin was thoroughly degreased, the EMFACE applicators (BTL Industries, Marlborough, MA), which were disposable and intended for single-use only, were applied to the patient's midface. Following the correct placement of the 2 midface applicators and a neutral electrode on the abdomen, the EMFACE console, along with its proprietary software, was activated to begin the treatment. The procedure lasted for 20 minutes and involved synchronized RF and HIFES. The intensity of both the RF and HIFES treatments, adjustable between 0% and 100%, was gradually increased to 100% for all patients after a brief 20-second acclimation period to the sensation of the RF and HIFES. Upon completion of the treatment, the applicators were gently removed from the patient's face and abdomen, and the patient was subsequently discharged.

## Ultrasound Measurements

Ultrasound imaging was performed with a LG Logiq E10 (LG, Seoul, Democratic Republic of Korea). The probe was placed at standardized locations on the face: 2 cm lateral and 3 cm cranial to the modiolus in a 45° to 60° orientation caudally for visualization of the zygomaticus major muscle (ZMM), and 3 cm anterior to the tragus for visualization of the superficial musculoaponeurotic system (SMAS).

## Electromyography Measurements

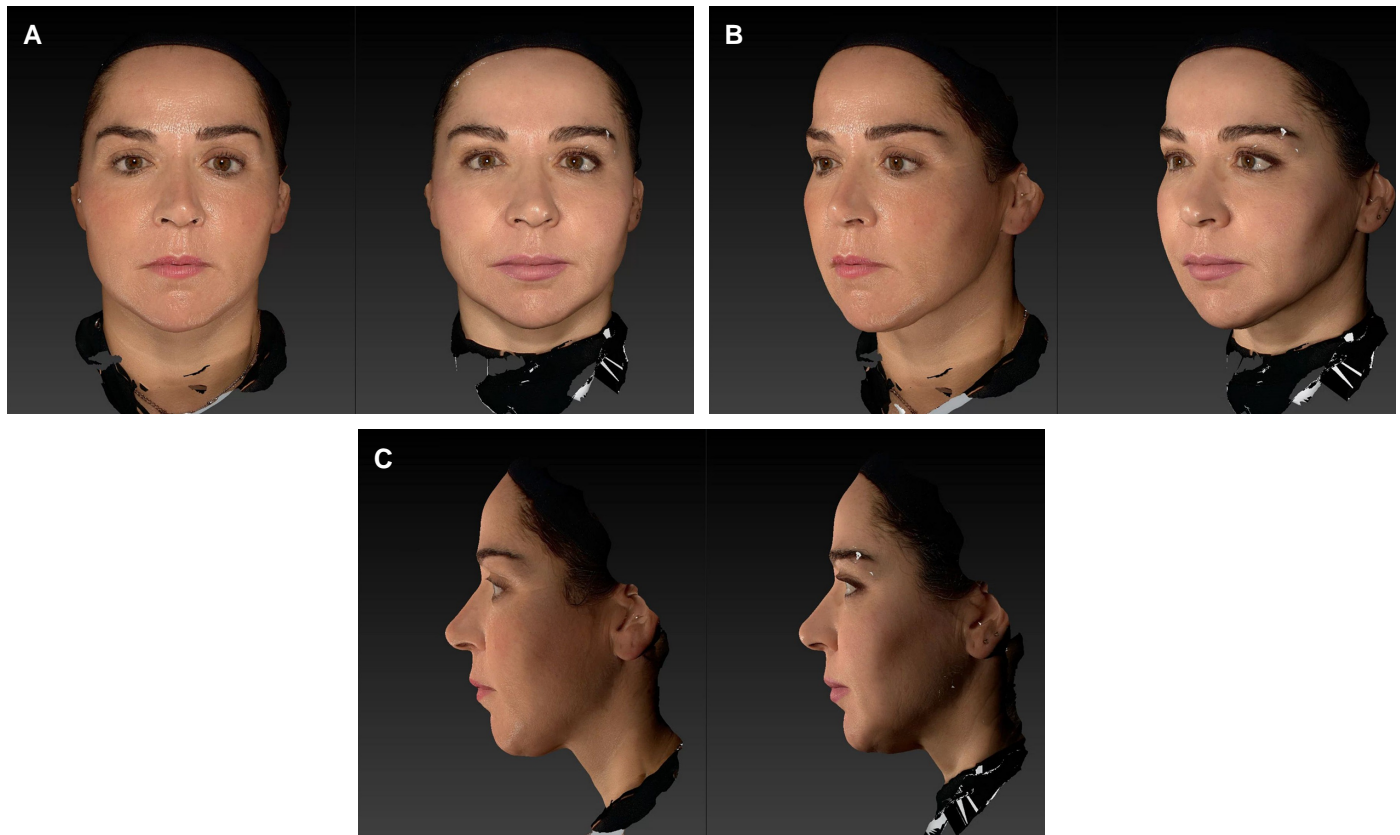
Surface electromyography (sEMG) was conducted on the ZMM with noninvasive, surface-adherent wireless sensors (Avanti Trigno Quattro; Delsys Inc., Natick, MA) positioned according to standardized protocols outlined in previous studies. In brief, the wireless sensors were affixed to the skin over the ZMM bilaterally after the skin was disinfected and degreased with a 95% alcohol solution. Participants were then instructed to perform a Duchenne smile (to activate the ZMM). The resulting EMG signals were captured and transmitted to the EMG workstation (Trigno Avanti Platform; Delsys Inc.) for subsequent analysis.

## Modified Fitzpatrick Wrinkle Scale

The Modified Fitzpatrick Wrinkle Scale was employed to evaluate the severity of the nasolabial folds. This scale, an adaptation of the original Fitzpatrick Wrinkle Scale, was designed to provide more precise assessments in both clinical and research environments. It classifies wrinkle severity on a scale from 0 to 4, for which 0 denotes no visible wrinkles, 1 represents very mild wrinkles that are barely noticeable, 2 corresponds to mild wrinkles that are visible but not prominent, 3 indicates moderate wrinkles that are clearly visible and prominent, and 4 signifies severe wrinkles that are deeply etched and highly prominent. Assessments were conducted at baseline and at 4, 16, and 24 weeks by a blinded evaluator, ensuring consistent and repeatable evaluations of wrinkle severity changes throughout the study.

## Dimensional Surface Imaging

A Vectra H2 (Canfield Scientific Inc., Fairfield, NJ) camera system was utilized to capture 3D surface imaging photographs of the patients during the screening process and at all subsequent follow-up visits. The Vectra Software Suite (Canfield Scientific Inc.) was employed for image analysis. Following an established protocol, changes in



**Figure 1.** (A) A 42-year-old female patient showing a visibly lifted midface with enhanced cheek volume and smoother contours, frontal view. Note the subtle reduction in the depth of the nasolabial fold, providing a more youthful appearance. (B) Patient showing a visibly lifted midface with enhanced cheek volume and smoother contours, oblique view. Note the subtle reduction in the depth of the nasolabial fold, providing a more youthful appearance. (C) Patient showing a visibly lifted midface with enhanced cheek volume and smoother contours, lateral view. Note the subtle reduction in the depth of the nasolabial fold, providing a more youthful appearance.

volume were assessed for the midface and lower face, which were delineated by an imaginary line running from the tragus to the modiolus. Additionally, vectorial skin movement was evaluated on both the medial and lateral sides of the face, separated by the line of ligaments.

## Statistical Analysis

The ultrasound and EMG measurements in this study did not follow a normal distribution, as determined by the Shapiro-Wilk test and further confirmed by visual inspection of normal Q-Q plots. Due to the abnormal distribution of data, nonparametric statistical methods were applied to evaluate changes in muscle thickness over time. Specifically, the Kruskal-Wallis test was utilized to assess the statistical differences in ultrasound and EMG measurements between baseline and subsequent follow-up at 4, 20, and 24 weeks posttreatment. All statistical analyses were conducted with SPSS version 24 (IBM, Armonk, NY), with significance set at  $P$  values less than .05.

## RESULTS

### Patients

A total of 37 patients (7 males and 30 females) participated in this study, with an average age of  $45.46 \pm 13.01$  years and an average BMI of  $21.84 \pm 1.91$  kg/m<sup>2</sup>. Among the participants, 3 were smokers. The distribution of Fitzpatrick skin types was as follows: 7 patients (19.0%) with Type II, 24 patients (64.8%) with Type III, and 6 patients (16.2%) with Type IV.

## Fitzpatrick Wrinkle Scale

At baseline, 26 nasolabial folds (35.1%) were rated as mild, 40 nasolabial folds (54.1%) as moderate, and 8 nasolabial folds (10.8%) as severe. After 4 weeks, 57 nasolabial folds (77.0%) improved by  $\geq 1$  point on the Fitzpatrick Wrinkle Scale (FWS) and 4 (5.4%) by  $\geq 2$  points. After 16 weeks, 64 nasolabial folds 86.5% had improved by  $\geq 1$  points and 6 nasolabial folds (8.1%) by  $\geq 2$  points. After 24 weeks, 52 nasolabial folds (70.3%) showed a  $\geq 1$  point improvement (Figures 1-3).

## Ultrasound Measurements

The thickness of the zygomaticus major muscle increased from  $2.06 \pm 0.63$  mm at baseline to  $2.51 \pm 0.69$  mm at week 4,  $2.51 \pm 0.56$  mm at week 16, and to  $2.80 \pm 0.61$  mm at week 24, with  $P < .001$  when comparing baseline with week 24. The thickness of the SMAS changed from  $2.22 \pm 0.74$  mm at baseline to  $1.96 \pm 0.55$  mm after 4 weeks, to  $2.31 \pm 0.64$  mm after 16 weeks, and to  $2.25 \pm 0.55$  mm after 24 weeks, with  $P = .003$  (Table 1).

## Electromyography Measurements

Mean signal of the ZMM, independent of side, was  $60.70 \pm 21.16$   $\mu$ V at baseline,  $68.53 \pm 36.41$   $\mu$ V at week 4,  $82.13 \pm 49.48$   $\mu$ V at week 16, and  $104.13 \pm 49.72$   $\mu$ V at week 24, with  $P < .004$ , reflecting an increase between baseline and week 24 of 39.3%. Post hoc analysis revealed a significant difference between baseline and Week 24, with  $P < .001$  (Table 2).



**Figure 2.** (A) A 71-year-old female patient demonstrating improvement in the definition of the nasolabial fold, with a smoother transition between the cheek and mouth area, frontal view. Additionally, there is visible tightening of the skin along the jawline and midface. (B) Patient demonstrating improvement in the definition of the nasolabial fold, with a smoother transition between the cheek and mouth area, oblique view. Additionally, there is visible tightening of the skin along the jawline and midface. (C) Patient demonstrating improvement in the definition of the nasolabial fold, with a smoother transition between the cheek and mouth area, lateral view. Additionally, there is visible tightening of the skin along the jawline and midface.

## Skin Displacement

In the lateral face, a laterally oriented horizontal skin displacement of  $0.83 \pm 0.7$  mm,  $0.88 \pm 0.8$  mm, and  $0.90 \pm 0.8$  mm was observed after 4, 16, and 24 weeks, respectively, and a cranially oriented vertical skin displacement of  $0.78 \pm 0.8$  mm,  $0.88 \pm 1.1$  mm, and  $1.01 \pm 1.1$  mm was observed after 4, 16, and 24 weeks, respectively. In the medial face, a laterally oriented horizontal skin displacement of  $0.64 \pm 0.5$  mm,  $0.63 \pm 0.5$  mm, and  $0.75 \pm 0.6$  mm was observed after 4, 16, and 24 weeks, respectively, and a cranially oriented vertical skin displacement of  $0.77 \pm 0.7$  mm,  $0.62 \pm 0.5$  mm, and  $0.78 \pm 0.6$  mm was observed after 4, 16, and 24 weeks, respectively (Table 3, Figure 4).

## Volume Shift

In the midface, a volume change of  $1.43 \pm 2.5$  cm<sup>3</sup> was observed after 24 weeks. In the lower face, a volume change of  $0.77 \pm 2.6$  cm<sup>3</sup> was observed after 24 weeks.

## Safety

No adverse effects and no significant discomfort were reported by participants during or following the treatment sessions. All patients tolerated the combined HIFES and RF procedures well, with no interruptions or modifications required due to discomfort. This absence of side effects supports the safety and tolerability of the treatment

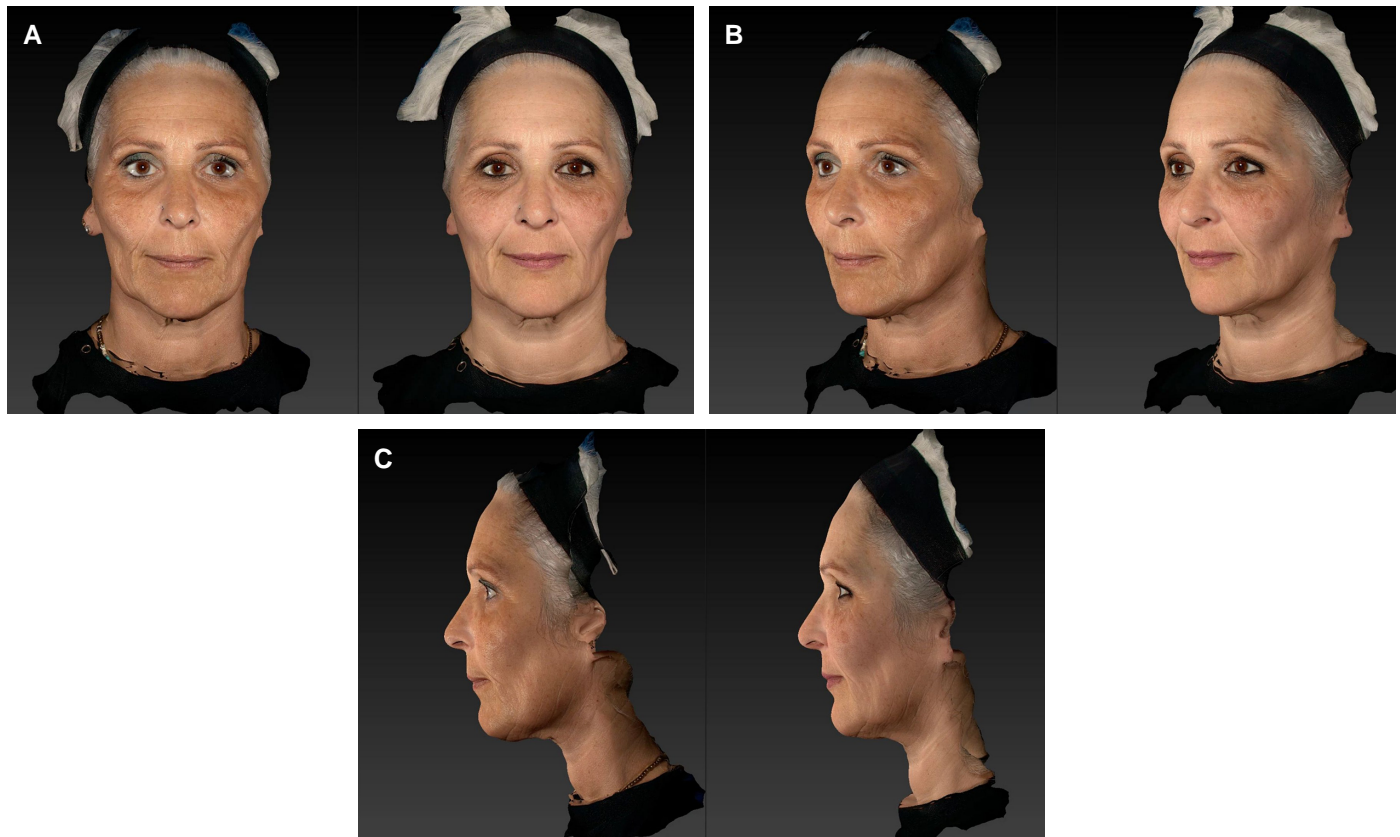
protocol, making it a viable option for aesthetic enhancement with minimal risk to patients.

## DISCUSSION

In this prospective, interventional clinical study, we aimed to investigate the efficacy of combined high-intensity facial electrical stimulation (HIFES) and synchronized radiofrequency (RF) treatments for midfacial rejuvenation. A total of 37 participants underwent 4 synchronized HIFES and RF treatments over 24 weeks, with assessments at baseline, 4 weeks, 16 weeks, and 24 weeks. The primary objective was to evaluate changes in ZMM thickness, skin displacement, and overall facial volume. Various measurement techniques were employed, including ultrasound, EMG, 3D surface imaging, and the modified FWS.

We demonstrated significant improvements following the combined HIFES and RF treatments. ZMM thickness increased significantly from 2.06 mm at baseline to 2.80 mm at 24 weeks, representing a robust response. Correspondingly, EMG data showed a 39.3% increase in muscle activity, indicating enhanced muscle function. Skin displacement measurements revealed notable lateral and cranial shifts, particularly in the lateral face, where the skin displaced 0.90 mm horizontally and 1.01 mm vertically at 24 weeks. Volumetric analysis showed an increase in midface volume of 1.43 cm<sup>3</sup> at 24 weeks, suggesting that the treatment effectively restored facial volume (Figures 1-3).

The findings of this clinical study, performed in human patients, align closely with those from a recently published porcine model



**Figure 3.** (A) A 58-year-old female patient highlighting a comprehensive tightening effect across the midface, with improved skin texture and firmness, frontal view. The nasolabial fold appears softened, and overall midface lift contributes to enhanced facial harmony. (B) Patient highlighting a comprehensive tightening effect across the midface, with improved skin texture and firmness, oblique view. The nasolabial fold appears softened, and overall midface lift contributes to enhanced facial harmony. (C) Patient highlighting a comprehensive tightening effect across the midface, with improved skin texture and firmness, lateral view. The nasolabial fold appears softened, and overall midface lift contributes to enhanced facial harmony.

study, which reported the effects of the same HIFES and RF technology on muscle tissue in an animal model. Both studies report significant increases in muscle mass and function, demonstrating that HIFES and RF can induce substantial functional enhancements in facial muscles. In the porcine study, a 19.2% increase in muscle mass density and a 21.2% increase in the number of myonuclei were observed after the treatment period, indicating that HIFES and RF effectively stimulated muscle growth and regeneration. These findings were consistent with the clinical data from this study, in which the ZMM showed a significant increase in thickness and EMG signal strength. The porcine model also documented an increase in the number and size of muscle fibers, which paralleled the observed increase in ZMM thickness and functional capacity in humans.

The skin displacement data in this study highlight the mechanical effects of the treatment. The lateral and cranial shifts in the skin, particularly in the lateral face, suggest that the increased muscle mass and strength contribute to a repositioning effect that improves facial contours. This is particularly important for addressing age-related sagging and volume loss, which are key concerns in facial rejuvenation. From an anatomical point of view, this can be explained by the parallel arrangement of the lateral midface, which allows a repositioning of the facial layers, which are stacked on top each other, comparable to the shells of onions.

The volumetric changes observed in this study, particularly the increase in midface volume at 24 weeks, suggest that the treatment not only enhances muscle and skin tone but also restores lost facial volume. This volumetric restoration is likely due to a combination

of muscle hypertrophy, RF-induced collagen remodeling, and increased extracellular matrix production. It could be hypothesized, furthermore, that the increased support by induction of collagen formation and the cranial repositioning of the superficial fat pads led to what was observed as vertical shift.

Clinically, the nasolabial fold severity decreased in a majority of the patients. Even though this assessment with a facial wrinkle scale is semiobjective, it is of high clinical importance, because it shows that signs of aging can be treated with a combination of HIFES and RF. The positive outcomes observed in this study, including increased ZMM thickness, enhanced muscle activity, skin displacement, and volumetric restoration, can be attributed to the combined effects of HIFES and synchronized RF treatment. HIFES likely induces hypertrophy of facial muscles through repetitive, high-intensity contractions, which stimulate muscle growth and strength. These contractions may lead to the accumulation of myonucleus and muscle fiber enlargement, as seen in parallel studies on porcine models, thereby contributing to the measurable increase in ZMM thickness and EMG signal. The RF component likely complements this effect by stimulating collagen remodeling in the dermal and subdermal layers, enhancing skin elasticity and supporting structural integrity. RF-induced collagen production may also promote extracellular matrix formation, which adds volume to the midface and reinforces the repositioning of facial layers. The observed lateral and cranial skin shifts may be explained by a synergistic effect, in which muscle hypertrophy provides a lifting support and collagen remodeling promotes the repositioning of superficial fat pads and skin layers,

**Table 1.** Changes in Thickness of the Zygomatic Major Muscle and SMAS, Measured by Ultrasound

| Time point | Zygomatic major thickness (mm) | SMAS thickness (mm) |
|------------|--------------------------------|---------------------|
| Baseline   | 2.06                           | 2.22                |
| Week 4     | 2.51                           | 1.96                |
| Week 16    | 2.51                           | 2.31                |
| Week 24    | 2.8                            | 2.25                |

SMAS, superficial musculoaponeurotic system.

**Table 2.** Electromyography Measurements of the Zygomatic Major Muscle (ZMM)

| Time point | Mean ZMM signal (uV) | Increase from baseline (%) | P value |
|------------|----------------------|----------------------------|---------|
| Baseline   | 60.7                 | —                          | —       |
| Week 4     | 68.53                | —                          | —       |
| Week 16    | 82.13                | —                          | —       |
| Week 24    | 104.13               | 39.3%                      | < .004  |

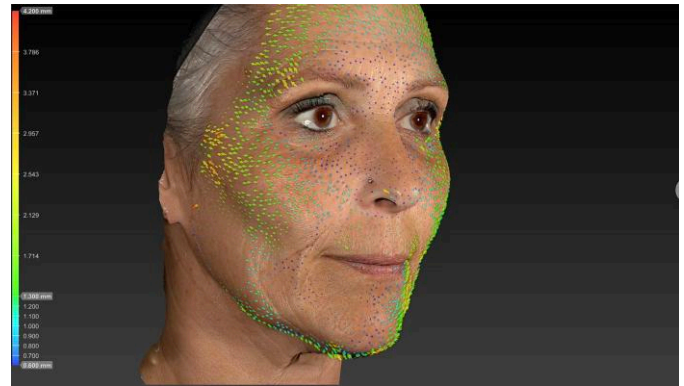
resulting in improved facial contours. Together, these mechanisms provide a multifaceted approach to midfacial rejuvenation, addressing both volume loss and skin laxity, which are central aspects of facial aging.

One of the key strengths of this study was the use of objective measurement techniques, such as ultrasound, EMG, and 3D imaging, which provided quantifiable data on the effects of the treatment. These objective measures are crucial for validating the efficacy of aesthetic treatments and ensuring that the observed outcomes are reproducible. Additionally, the study's design, which included multiple follow-up assessments over 24 weeks, allowed for the evaluation of both short-term and long-term effects of the treatment.

However, there are several limitations to consider. The study's nonrandomized design and relatively small sample size may limit the generalizability of the findings. Future research should include larger, randomized controlled trials to confirm these results. Additionally, although the porcine model provides valuable insights into the histological effects of the treatment, there are inherent differences between porcine and human facial anatomy that may affect the translational applicability of the findings. Furthermore, the study did not include a control group, which would have provided a more robust comparison of the treatment's effects.

## CONCLUSIONS

In conclusion, this study provides strong evidence that HIFES and RF treatments offer a promising noninvasive option for midfacial rejuvenation, with significant improvements in muscle thickness, skin displacement, and facial volume. Future studies should aim to address the limitations identified in this research and further explore the long-term effects and broader applications of HIFES and RF in facial aesthetics.

**Figure 4.** Three-dimensional surface imaging with vector analysis between baseline and 24 weeks. The patient is a 58-year-old female.**Table 3.** Horizontal and Vertical Skin Displacement at the Lateral and Medial Face

| Face area            | Week 4 (mm) | Week 16 (mm) | Week 24 (mm) |
|----------------------|-------------|--------------|--------------|
| Lateral (horizontal) | 0.83        | 0.88         | 0.9          |
| Lateral (vertical)   | 0.78        | 0.88         | 1.01         |
| Medial (horizontal)  | 0.64        | 0.63         | 0.75         |
| Medial (vertical)    | 0.77        | 0.62         | 0.78         |

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Therapeutic

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| <h3 style="text-align: center; color: #4a4a8a;">Objectives</h3> <p>To examine malignancies associated with non-breast IMDs. An expert medical librarian developed the search strategy for this review.</p>  | <h3 style="text-align: center; color: #4a4a8a;">Methods</h3> <p>Databases &amp; literature searched. PRISMA guideline was followed for the review. Risk of bias was evaluated.</p>  | <h3 style="text-align: center; color: #4a4a8a;">Conclusions</h3> <p>Oncologic risk of IMDs is low. Discussion of malignancy is important in consent process and should be considered.</p>  |
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**Non-Breast Implantable Medical Devices and Associated Malignancies: A Systematic Review**  
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