

# Noninvasive Facial Volume Harmonization Using HIFES and Synchronized RF Technology: A Retrospective Study

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**BACKGROUND** Age-related facial volume loss results from changes in skin, muscle, and fat distribution, leading to sagging and contour alterations. Traditional volume restoration techniques, such as dermal fillers, carry risks and require skilled application. Facial muscle electrical stimulation combined with synchronized radiofrequency (RF) offers a noninvasive alternative.

**OBJECTIVE** This study evaluates the volumetric effects of facial muscle electrical stimulation with synchronized RF for facial rejuvenation.

**MATERIALS AND METHODS** A retrospective analysis was conducted on 43 subjects (5 males, 38 females, aged 57 ± 12). Treatments consisted of four 20-minute sessions of facial muscle electrical stimulation + RF, with follow-ups at 1 and 3 months. Facial volume changes were assessed using 3D imaging systems. Patient satisfaction and comfort were recorded using questionnaires.

**RESULTS** At 3 months, zygomatic volume increased by +3.3 mL ( $p < .001$ ), while mandibular volume decreased by -2.3 mL ( $p < .001$ ). The net volume shift was 5.6 mL. Patient satisfaction was 94.6%, with minimal discomfort (visual analog scale: 1.6). No adverse events were reported.

**CONCLUSION** Facial muscle electrical stimulation with synchronized RF effectively restores facial volume noninvasively, offering a safe alternative to traditional fillers and surgery.

Age-related facial changes occur due to multifactorial biological processes ranging from molecular to macroscopic alterations.<sup>1</sup> These processes extend beyond the skin, affecting bone, fascia, muscles, and adipose tissue, progressively declining in physiologic function.<sup>2</sup> Facial aging is a multilayered 3-dimensional process with intricacies that play out within each layer independently and yet interdependently affect the surrounding layers.<sup>3</sup> Insomuch that the change in a single layer causes a cascade of events leading to alterations in other layers.<sup>4</sup> These cumulative small changes are amplified through the facial anatomical layers, leading to profound and exaggerated modifications in facial appearance.<sup>1</sup> A notable consequence of these changes is the loss of volume, resulting in the stigmata of an aged face.<sup>5</sup>

The contemporary framework describes the age-related loss of tone of the facial muscles, with a recent study implicating loss of strength and decreased resting tone of the zygomaticus major muscle.<sup>6</sup> The attenuation of the combined tensile forces of the superficial musculoaponeurotic system (SMAS) and zygomaticus major have been postulated to contribute to the lateral and medial cheek atrophy and sagging.<sup>7</sup> The SMAS delineates its superior border along the zygomatic arch and its inferior border along the platysma, illustrating the interweaving of facial fat distribution with the underlying musculature.<sup>8</sup> Regarding the aging process, alterations in muscle physiology directly influence the disposition of fat layers in the face and hence significantly affect the supportive framework for facial soft tissue.<sup>4</sup> Moreover, change in muscle tone negatively affects the harmonious distribution and positioning of facial fat, leading to discernible accumulations in lower facial regions.<sup>9</sup> The interconnected nature of facial fat and muscles emphasizes how changes in muscle tonus intricately modulate the appearance and distribution of facial adiposity throughout the aging process.

Evolutionary psychology confirms that the principal factor in perceiving health, beauty, and overall well-being of an individual is youthful appearance.<sup>10</sup> In the race against time, many strategies have been developed, ranging from preventive measures and topical solutions to invasive and noninvasive procedures.<sup>11</sup> Taking into consideration the complexity of facial aging, a 3-dimensional approach

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becomes the apparent choice in the fight against age-related volume loss.<sup>12</sup> Options for addressing facial volume loss typically involve injecting soft tissue augmentation agents such as biocompatible polymers. The most prevalent method employs cross-linked hyaluronic acid, which is administered directly into the dermis and subcutaneous fat using syringes or cannulas. The achieved results depend on the skill of the injector and may lead to “unnatural” and undesirable looks.<sup>13,14</sup> Moreover, they are not risk and complication-free. Tissue injury occurring from incidental intra-arterial injection has been reported to cause ischemia, possibly leading to necrosis and in some rare cases vision loss.<sup>15,16</sup> Patients experiencing extensive volume loss, including those affected by rapid weight loss medications, would require more filler injections, thereby increasing their exposure to potential adverse events and complications.<sup>17</sup>

Reflecting the demand for a comprehensive approach in facial rejuvenation, a device was developed to target the facial muscles and skin. The neuromuscular stimulation causes selective contraction of the frontalis muscle, the zygomaticus major and minor, and the risorius muscle by depolarizing associated motor neurons.<sup>18</sup> Muscle selectivity is achieved using specialized forehead and cheek applicators. Repeated supramaximal contractions, along with the benefits of RF component, cause structural muscle protein synthesis upregulation, leading to denser muscle mass.<sup>19</sup> Proven to be effective in wrinkle reduction, muscle strengthening, collagen, and elastin restoration,<sup>18</sup> the authors postulate a novel previously undescribed effect on facial volume. This retrospective study aims to characterize favorable volumetric changes in patients after completing treatments utilizing facial muscle stimulation in combination with synchronized radiofrequency (RF).

## Methods

### Study Population

This retrospective analysis included data from 43 ( $n = 43$ ) subjects (5 males and 38 females, skin types I–V, aged  $57 \pm 12$ ) who had previously participated in clinical trials evaluating noninvasive facial remodeling treatments at 6 ( $n = 6$ ) clinical sites (Figure 1). These subjects were initially recruited based on specific inclusion and exclusion criteria. Participants were adults over the age of 21 seeking facial remodeling treatments, with a willingness to refrain from other facial treatments during the study period. Exclusion criteria included any prior surgical procedures in the treatment area within 3 months of enrolment and the use of dermal fillers, botulinum toxins, or other therapies in the treatment area that could affect the results. A thorough review of participants’ medical history and eligibility was conducted at the time of original enrolment. Patients with metal implants, local infections, or unhealed wounds in the treatment area were also excluded.

### Ethical Consideration

Ethical approvals for the original studies were obtained from the Advarra Institutional Review Board, and all procedures

were conducted in accordance with the ethical standards outlined in the 1975 Declaration of Helsinki. The studies took place between November 2022 and August 2023, with all participants providing informed consent before any procedures were performed. Confidentiality was ensured by assigning each subject a unique identification number. For the purposes of this retrospective study, all collected data were anonymized, and no new patient interactions occurred.

### Treatment Protocol

Subjects in the original studies were treated using the EMFACE device (BTL Industries Inc., Boston, MA), which was applied to the forehead and cheeks with single-use adhesive applicators. Before each session, the treatment area was cleaned to remove any cosmetics, lotions, jewelry, or noticeable hairs. The treatment schedule involved 4 sessions, each lasting 20 minutes, with 5 to 10 days between sessions. During the treatments, the intensity of RF and facial muscle electrical stimulation was adjusted based on each patient’s feedback, ranging from 0% to 100%. Patients attended follow-up visits immediately after the final treatment, at 1 month, and at 3 months, with a small subset completing a 1-year follow-up. Throughout these visits, patients were monitored for any adverse events. For this retrospective analysis, data from all follow-up visits were reviewed.

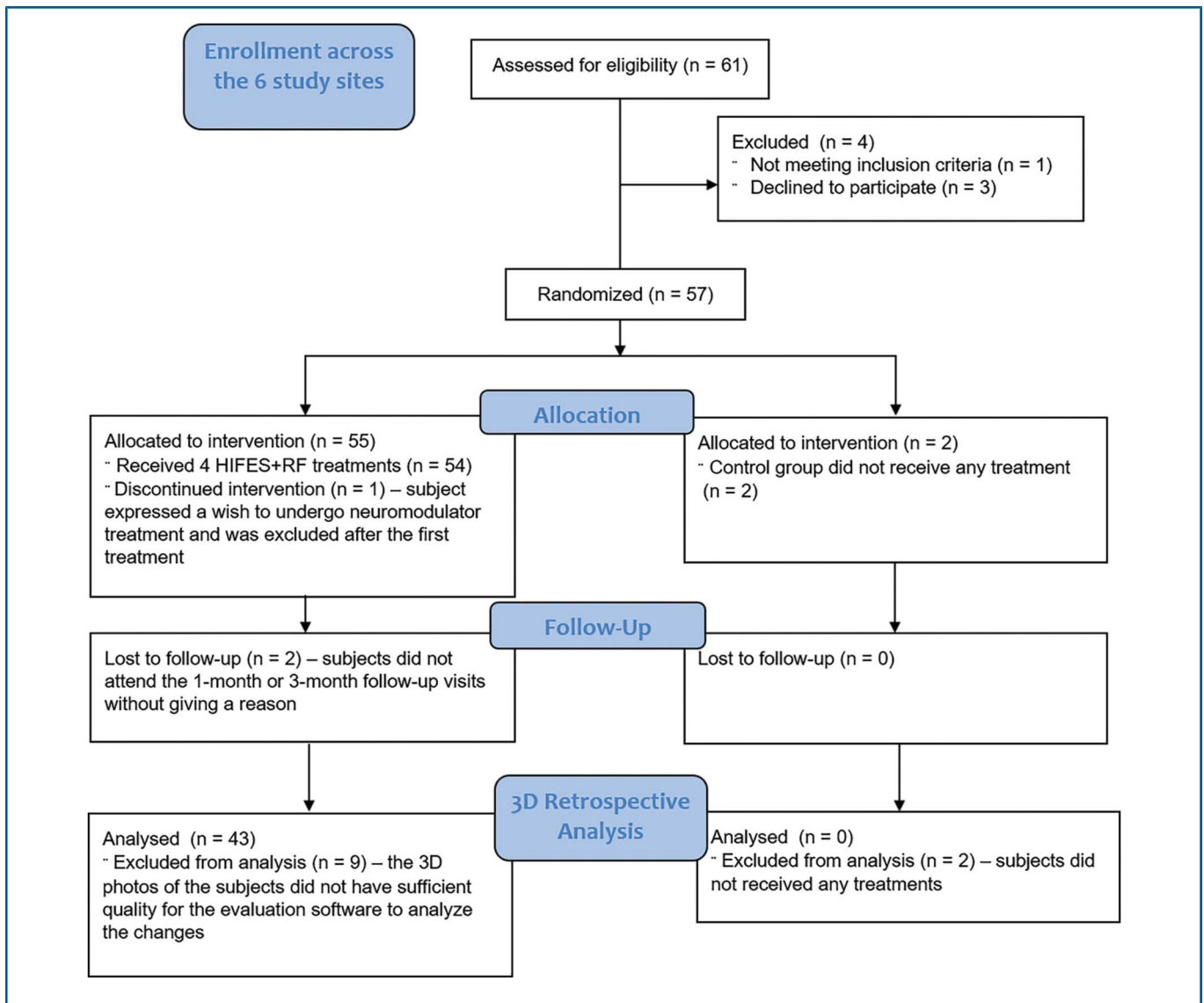
### Data Collection and Evaluation

Data from all 43 subjects was compiled and analyzed retrospectively. Volumetric data were categorized into 2 age-based groups. The first group ( $n = 19$ , aged 59–75, skin types I–V) represented the baby boomer generation, while the second group ( $n = 24$ , aged 27–58, skin types I–IV) comprised generation X and millennial participants. Volumetric facial changes were assessed using 2 standardized imaging systems available at clinical sites. Three-dimensional facial images were captured using the LifeViz Mini system (QuantifiCare S.A., Biot, France) at baseline and at the 1-, 3-month, and optional 1-year follow-up visits. These images were processed into 3D models using QuantifiCare’s software suite. In addition, VECTRA H2 camera images (Canfield Scientific Inc., Parsippany, NJ) were also captured and analyzed using Face Sculptor software. Both systems were used to assess volumetric changes in the mandibular and zygomatic areas.

In addition to the volumetric assessments, patient satisfaction was evaluated retrospectively through data collected using a 5-point Likert scale Subject Satisfaction Questionnaire administered at the final treatment and at the 1- and 3-month follow-up visits. Patient comfort was also assessed using the Therapy Comfort Questionnaire, which included the Visual Analog Scale (VAS) for pain (ranging from 0 to 10), and a 5-point Likert scale. No new data was collected for this retrospective analysis.

### Statistics

3D data were analyzed using descriptive statistics (average, mean, SD). Statistical significance between follow-up data was validated using the Student *t*-test and analysis of variance ( $\alpha = 0.05$ ).

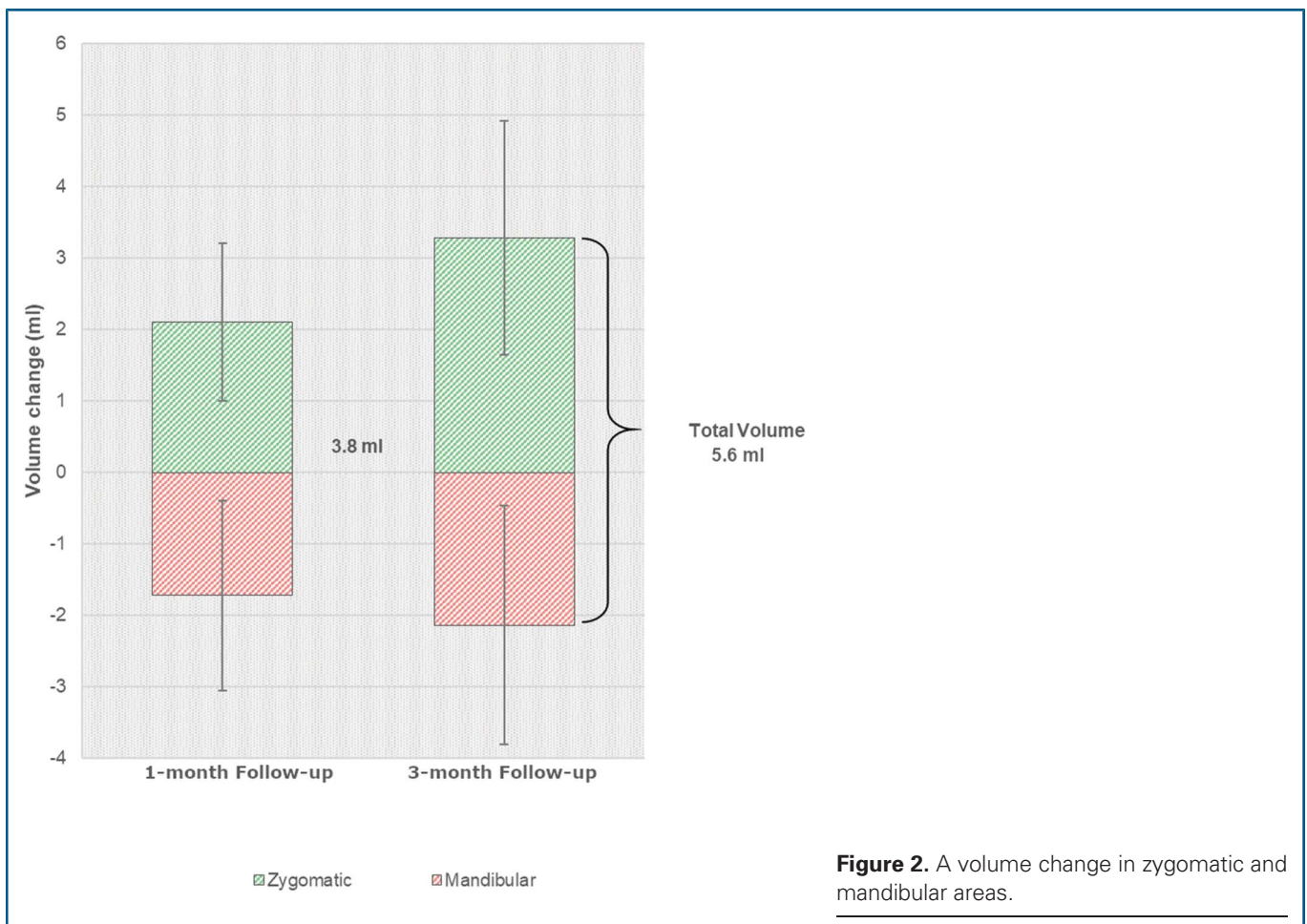


**Figure 1.** A consort flow diagram of enrolled subjects.

## Results

The study documents the volumetric changes of the mandibular and zygomatic areas at 1 and 3 months after treatment (Figures 2 and 3). For the cheekbone areas, the authors report an average increase in volume of the zygomatic areas across all sites of 2.3 mL at 1-month and 3.3 mL at 3-month follow-up ( $p < .001$ ), accounting for both sides of the face. For the lower face areas affected by laxity, the average decrease in volume of the mandibular area was  $-1.7$  mL at 1-month and  $-2.3$  mL at 3-month follow-up ( $p < .001$ ) accounting for both sides of the face. The combined volumetric changes observed in the zygomatic and mandibular areas result in a net total volume shift of 3.8 mL at the 1-month follow-up and 5.6 mL at the 3-month follow-up, respectively, accounting for both sides of the face. The generational group of Baby Boomers ( $n = 19$ ) had higher zygomatic gains, averaging at 3.7 mL in contrast to the Generation X +

Millennial group ( $n = 24$ ), which saw a 3.0-mL increase on average at the 3-month follow-up. There was no statistical significance on the volumetric difference in the mandibular area between the generational groups ( $p > .05$ ). Regarding the patients who completed the 1-year follow-up ( $n = 3$ ), maintenance of gained volume was observed, with the upper cheeks showing an improvement of  $+2.6$  mL and visible decrease in mandibular area of  $-2.7$  mL, meaning fluctuation between the 3-month peak and the baseline (Figure 4). Questionnaires reveal a high satisfaction rate ( $n = 43$ ) with average scoring of 94.55%, 93.21%, and 94.60% immediately after the last treatment, at 1- and 3-month follow-ups, respectively. Pain and comfort questionnaires reveal an average score of 91.6% ( $n = 43$ ) for comfort and an average score of 1.6 on the VAS scale ( $n = 43$ ) making the procedure highly comfortable. The therapy was administered with no adverse effects or complications.



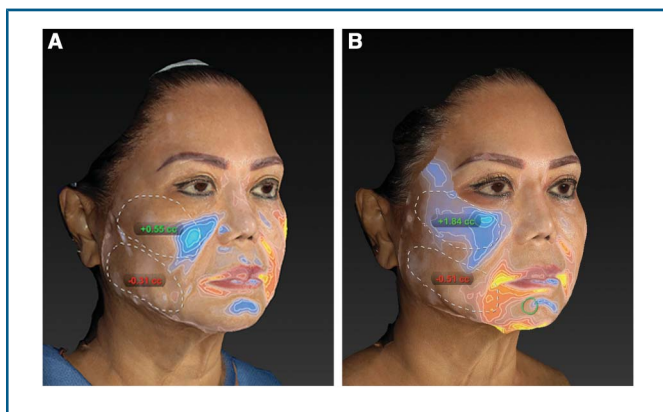
**Figure 2.** A volume change in zygomatic and mandibular areas.

## Discussion

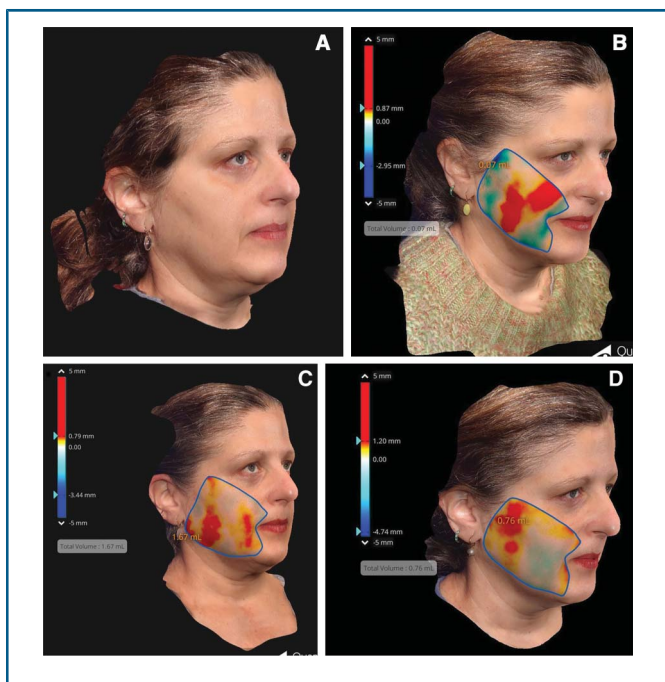
An extensive portfolio of facial rejuvenation strategies are available on the market today to address the problem of aging from various angles.<sup>20</sup> Current treatments include invasive procedures, such as surgical rhytidectomy, minimally invasive techniques, such as filler injections and

ablative laser resurfacing, and noninvasive procedures and skin care routines.<sup>21–24</sup> Surgical facelifts typically require significant financial investments, with a relatively long downtime, greater risk of local adverse events, permanent disfigurement, and even death. A facelift procedure alone does not comprehensively address volume loss; thus, supplementary procedures such as fat grafting or absorbable fillers may be performed in tandem.<sup>25</sup> Neuromodulators make up an entirely different injectable modality that can effectively address dynamic rhytids, but do not restore volume.<sup>26</sup> In the present study, the authors evaluated an innovative technology and its ability to restore age-related volume loss. The role of muscles in aging and facial rejuvenation has been long understudied. In light of recent research, the concept of muscle toning to restore youthful position with selective muscle inhibition with neuromodulators provides a new path forward for facial rejuvenation.<sup>27–30</sup> The current study details the volumetric changes observed in 43 patients using noninvasive, needle-free technology with very low discomfort scores and no downtime, as assessed through 3D modeling, corroborating these findings with high patient satisfaction rates.

The authors hypothesize that the beneficial changes observed are the result of enhancements in the tonicity of muscle tissue, which subsequently influences the



**Figure 3.** A 67-year-old woman showing a change in volume at 1-month (A) and 3-month (B) follow-up. The patient agreed that their skin feels tighter and lifted, as well as agreed to be satisfied with the results at the 3-month follow-up.



**Figure 4.** A 59-year-old woman, displaying volumetric change to the zygomatic and mandibular areas over the course of a year. Baseline (A), 1-month (B), 3-month (C), and 1-year (D) follow-ups. Note the gradual elevation of volume rising from the lower half and progressing upward toward the cheekbones, peaking at a 3-month follow-up, when a significant reduction in the jowls can be observed, as well as the increase of volume in the desired areas.

surrounding layers. As the cheek fat compartments are suspended and effectively “hammocked” by surrounding soft tissue, increasing the tone of the muscles that anchor them leads to reestablishing the dynamic of the facial layers to their predescent state.<sup>31</sup> The effect is two-fold: the upward pull leads to an increase in the trophic zygomatic areas (+mL), whereas the laxity-affected mandibular areas are diminished (–mL). The 3-dimensional evaluation shows all patients ( $n = 43$ ) have a notable volume restoration averaging +3.3 mL at 3 months after treatment in the cheek area and a decrease of volume averaging –2.3 mL at 3 months after treatment in the mandibular regions leading to the desired contoured remodeling, when accounting for both sides of the face.

In addition to the benefits of facial muscle electrical stimulation on the facial musculature, synchronized RF further enhances the effect via energy delivered to the skin. The dermis is heated to 42°C, breaking off the hydrogen bonds in the collagen and elastin fibers and causing coagulation.<sup>32</sup> Consequently, activation of the endogenous repair mechanisms leads to the restructuring of the extracellular matrix, providing the skin with firmness and elasticity through neocollagenesis and elastogenesis. The latest insights show that the facial musculature reaches temperatures of 40°C when treated with the same device.<sup>19</sup> Although located superiorly to the musculature, previous studies have shown that the adipose tissue reaches a temperature of 41.9°C during the treatment, well below

the lipolysis threshold.<sup>33</sup> The authors theorize that the SMAS layer, rich in thermoresponsive collagen and elastin fibers, might benefit from the RF component as well.<sup>34</sup> The effect is most pronounced in older patients ( $n = 19$ , 59–78 years old), with prominent jowls that have shown a total average volume shift of 5.6 mL. The authors propose that this is due to improved skin laxity along with the repositioning of adipose tissue in the superolateral direction. However, the efficacy of the device in treating younger patients is not to be disputed; the millennial and X generations show substantial results with an average of more than 5-mL total volumetric change when accounting for the face bilaterally.

When considering facial rejuvenation options, a health care professional must take into account multiple modalities to optimize patient results. The aforementioned treatment is easily integrated with neuromodulators or dermal fillers.<sup>32</sup> Depending on the patient and desired outcomes, as much as 8 to 10 mL of hyaluronic acid fillers has been reported to achieve a “liquid facelift”.<sup>35</sup> Although the volume injected as a filler modality is larger than the volume restored through the newly described energy device, the volume restored utilizing this device is achieved through natural repositioning of the facial soft tissues. This novel facial muscle electrical stimulation and synchronized RF technology establishes the structural foundation upon which other rejuvenation techniques including injectable fillers and neuromodulators are more efficiently and effectively utilized. In clinical practice, the authors consistently note reduction in the average volumes of filler necessary and amount of neuromodulator needed to achieve optimal cosmetic results. With fewer injections, there should be a reduction in the occurrence of adverse events. Overall, the retrospective study demonstrates the previously postulated favorable volumetric changes across a large population of subjects with a wide range of age (33–78) and skin type groups (I–V) observed across the 6 study sites.

The novel modality occupies a distinctive niche in the aesthetic market as the first technology to induce positive changes in the facial volume noninvasively. In future studies, weight changes should be recorded, an investigation of structural changes within the facial layers should be done, and a larger population with a mandatory 1-year follow-up should be arranged. Although all 3 patients who have completed the yearly follow-up have shown some degree of persistent results above baseline appearance, the small population does not allow for definitive conclusions.

## Conclusion

The treatment employing innovative facial muscle electrical stimulation technology combined with synchronized RF has led to notable volumetric improvements. According to 3D analysis outcomes, there was an observed average increase of 1.6 mL per side in the zygomatic areas, totaling an increase of 3.2 mL across both sides of the face, in contrast to an average decrease of 1.15 mL per side in the mandibular areas, amounting to a total decrease of 2.3 mL across both sides of the face, 3 months after

treatment. Consequently, facial muscle electrical stimulation and synchronized RF therapy has proven to be an effective noninvasive approach in addressing age-related volume loss.

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