EMFACE[®]

Simultaneous Emission of Synchronized Radiofrequency and HIFES[™] for Non-invasive Facial Rejuvenation

A unique combination of RF and HIFES

Facial aging is a complex process resulting not only from skin aging but also from changes in the volume and density of the underlying structures, including the fascial system, facial ligaments, and facial muscles.¹ EMFACE is the first device in the non-invasive facial aesthetic segment that utilizes the simultaneous application of Synchronized RF and HIFES technology to treat multiple facial layers simultaneously.

EMFACE effect on facial skin

The loss of the amount of elastin and collagen and quality impairment of the remaining fibers contribute to the worsening of skin quality and skin aging.² EMFACE uses unique Synchronized RF along with the real-time impedance-based system to quickly heat the skin tissue to 40-42°C³, the temperature needed to stimulate an increase in fibroblast activity, leading to an increased synthesis of new collagen and elastin fibers.⁴ In addition, the old collagen and elastin fibers decompose and denature and are rebuilt again.⁴

Clinical studies on EMFACE focusing on structural changes demonstrated a prominent skin remodeling effect. These studies found that collagen increase ranged between 26 - 27% and elastin increase ranged between 110-129% two to three months following the procedure.^{3,5} Additional study⁶ investigating changes in skin texture and facial appearance reported a 36.8% wrinkle reduction and 25.3% skin evenness improvement three months post procedure.

Although Synchronized RF heating ensures skin texture improvement, treating only textural concerns is not enough. As we age, facial tissue becomes saggy due to changes in the facial musculature and laxity in the connective tissue. Therefore, it is necessary to target the underlying structures to achieve a more youthful appearance.

EMFACE effect on facial muscles

To achieve a complete and more targeted approach to treating all facial layers, the EMFACE utilizes HIFES technology, specifically

designed to target the small delicate facial muscles. Facial muscles undergo atrophy and loss of muscular tone due to aging, similarly to the skeletal muscle, and also due to the long-term use of neurotoxins.^{7,8}

HIFES technology selectively induces supramaximal contractions in the facial elevator muscles. The intense contractions are strong stimuli that trigger a tissue response leading to promotion of muscle protein synthesis^{9,10} and to myofiber renewal¹¹. Such processes lead to structural remodeling of the targeted muscles, which has been seen in EMFACE study¹² showing 19.2% increase in muscle density and 21.2% increase in number of myonuclei, which provide the muscle with nutrition. These results were coupled with reduced fibrotic and fat infiltration within the muscle tissue at two months post-procedure.

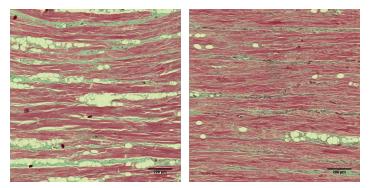


Figure 1: Histologic images of muscle tissues before (left panel) and 2 months after (right panel) the treatment with the EMFACE device.

The structural changes do manifest as increased resting muscular tone, which is necessary for maintaining the lifted facial appearance. The weaker the facial muscles are, the higher muscle effort is needed to avoid sagging and to hold the overlying tissues in place.¹³ When being too weak, they become unable to hold the tissue, resulting in e.g. eyebrow drop or cheek sagging. When the resting muscle tone is increased, the muscles have the strength large enough to hold the overlying tissue in place ¹³ EMFACE was found to increase the muscle tone by 30%¹⁴ which was then shown to lead to an overall lifting effect by 23.1%.⁶

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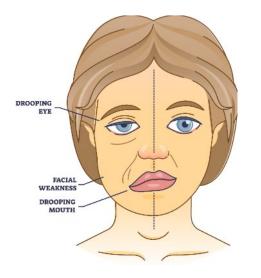


Figure 2: Visualization of the effect caused by weakened facial muscles on the left in comparison to healthy muscles on the right.

The synergy of RF and HIFES

The expression of HSP or SC is higher when the muscle is exposed to the simultaneous delivery of heating of around 40°C and supramaximal contractions compared to individual or consecutive energy applications.^{15,16} This simultaneous delivery induces a strong signal, which is followed by a stronger response in the skin, muscle and fascial tissue, leading to more pronounced structural remodeling.^{9,10,17-19}

Aside from the muscle and skin tissues, the EMFACE also affects the subdermal connective tissue. The facial fascial framework is largely composed of elastin, collagen, and connective tissue, and their degradation is part of the aging process. Synchronized RF heating with EMFACE may support the fascial framework via collagen and elastin remodeling, similar to what has been documented in previous skin tissue studies. In addition, the fascial support structures have also been found responsive to mechanical stimuli, which in case of EMFACE is delivered with HIFES stimulation.²⁰ The combination of both the heating and mechanical stress on the fascial support structures may lead to fascial remodeling, leading to increased fascial tightness and elasticity.²⁰

Clinical effects

Due to the unique design and energy delivery, EMFACE applicators do not induce the stimulation of the depressors since the stimulation of the depressors could potentially lead to a worsening of rhytides. The forehead application targets the frontalis muscle (brow elevator) and corresponding fascias while avoiding the depressors in the glabella. Restoring the tonus of the frontalis muscle and tightening the fascias in combination with the skin remodeling leads to reduced horizontal forehead lines, brow elevation, and skin texture improvement. The cheek application primarily targets the more superficial muscles of the cheeks (zygomaticus major/minor & risorius), which are all interconnected elevating units. In contrast, other deeper muscles, such as masseter m. are unaffected. Stimulation of these superficial muscles leads to an elevation of the entire cheek, increasing the midfacial volume and improving the nasolabial fold. Increasing the pull of these elevators further leads to a repositioning not only of the midface but of the lower facial soft tissues. The resulting clinical effect is a reduction in jowls and an increase in jawline contouring. The combined effect of HIFES with Synchronized RF manifests as an overall textural improvement of the skin.

Concluding comments

EMFACE uses Synchronized RF and HIFES energies simultaneously to target all facial layers; skin, fascia, connective tissue framework, and facial muscles to achieve full-face aesthetic remodeling. Affecting all these layers in a noninvasive manner leads to a textural improvement of the skin, wrinkle reduction, and an overall lifting effect visible in the cheeks and the forehead. Aside from multiple clinical studies using various evaluation methods, the results of the procedure are supported by a high patient satisfaction rate of 91.2%²¹.

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EMFACE* should only be used under the continued supervision of a physician or licensed practitioner. Patient should be continuously monitored and therapy discontinued immediately if the patient reports pain or excessive heat. Do not apply therapy over hair or scar tissue, or if patient has electronic or metal implants. Side effects may include temporary damage to natural skin (crust, blister, and burn). The Therapy Discomfort Button should a ways be accessible to the patient. Patient results and patient experience may vary. EMFACE* is indicated to provide heating for the purpose of elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation. EMFACE* applies muscle stimulation resulting in induced muscle workout. ©2022 BTL Industries, Inc. and affiliated companies. All rights reserved, BTL*, EM*, and EMFACE* are registered trademarks in the United States of America, the Europan Union, or other countries. The products, the methods of manufacture, or the use may be subject to one or foreign patents and papilications, see www.btlent.com/patents. Trademarks EMBODY, EMFACE, EMFEMME 360, EMSCLLPT, EMSCLLPT, EMSCLLPT, EMSCLEPT, EMSCLLPT, EMSC



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