EMSCULPT NEO
Simultaneous emission of novel Synchronized Radiofrequency and HIFEM (magnetic fields) in a single applicator for fat elimination and muscle building

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***Abstract*—EMSCULPT NEO is a device that delivers HIFEM and Synchronized RF energies simultaneously through a single applicator. The combined technology induces supramaximal muscle contractions and heating in the treated fat & muscle tissues. This simultaneous combination of two energies has synergistic effects that drastically enhance the results when compared to the individual treatments. RF heating during HIFEM muscle contractions increases activation of proteins stimulating muscle synthesis and enhances the hypertrophic effect. RF heating of fat tissue results in lipolytic and apoptotic processes leading to the permanent elimination of fat cells while being supported by increased metabolic activity due to the HIFEM contractions. Multiple clinical studies on this device documented results superior to any standalone or consecutive treatment regimens, which places the device far ahead of any devices currently used for body contouring.**

***Keywords* — HIFEM, Radiofrequency, Simultaneous, Application, Supramaximal, Contraction, Muscle, Fat, Reduction, Hypertrophy**

I. Introduction

Radiofrequency (RF) and HIFEM technologies are currently used extensively in aesthetic medicine for body shaping. The effect of RF technology is based on differential elevation of temperature in response to selective transformation of radiofrequency energy into heat in targeted tissues. Utilizing specific frequencies of the RF spectrum allows for selective heating, due to the difference in properties between the tissues in the targeted area of treatment. As such, RF is often used for fat reduction, skin tightening, or cellulite reduction. HIFEM technology, on the other hand, uses alternating magnetic fields to induce powerful skeletal muscle contractions via stimulation of the nerve pathways without significant, or even noticeable, elevation of temperature. HIFEM induced, supramaximal contractions are greater than voluntary contractions thanks to the specific stimulation patterns and frequencies. With repetition and over time, there is a tissue healing response that leads to increasing the muscle mass via amplified muscle fiber size.

EMSCULPT NEO is the first of its kind medical device combining novel Synchronized RF and HIFEM that are both emitted simultaneously using specially designed and patented dual-field applicators. The RF component enhances local blood circulation and delivers heat to underlying structures; skin, fat, and muscle, while HIFEM induces supramaximal muscle contractions at the same time. This unique combination has multiple synergistic effects and has been shown to make the simultaneous treatment more effective than any standalone or consecutive application. Studies have shown that the radiofrequency heating supports HIFEM's effects on muscles, while HIFEM enhances the radiofrequency's effects on fat.

II. The Effect in Adipose Tissue

The dual-energy application by EMSCULPT NEO has demonstrated uniform heating of adipose tissue above physiological levels, reaching 43-45°C (See **Figure 1**). The essential temperature of 42°C was achieved in fat in-vivo at approximately 4 minutes[1,2], while thermal imaging measurements showed safe values on the skin throughout the treatment thereby avoiding risks of epidermal damage. Temperature elevation in the fat has been shown to benefit fat reduction in two ways.

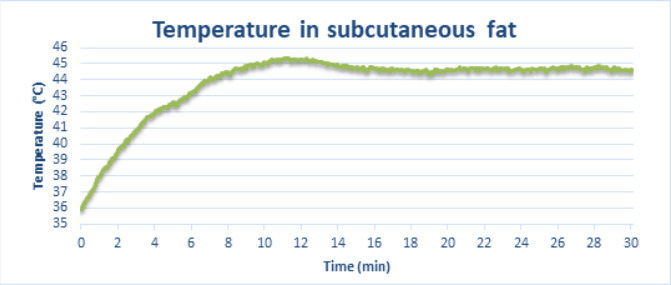

Fig. 1. Fat tissue temperature over time. The temperature is rapidly increased during the first few minutes and then oscillates just below 45°C for the rest of the treatment. Source: Weiss et al.

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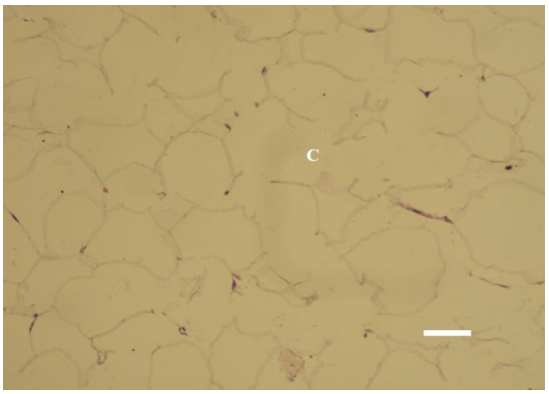

Fig. 2. Adipose tissue showing noticeable shape alternations at 2 weeks post-treatment, some cells are flattened of a smaller size. Numerous adipocytes show membrane ruptures. Source: Goldberg et al.

Initially, the elevated temperature results in increased blood flow and acceleration of metabolic activity. In response, the lipids stored in the fat cells, in the form of triglycerides, are broken down (hydrolyzed) into free fatty acids and glycerol; the two products are subsequently slowly and safely released into the bloodstream. As seen in **Figure 2**, the diameter of affected fat cells is smaller, and the overall response is exhibited as a nondestructive reduction of adipocyte volume aka lipolysis[3,4]. This phenomenon is further enhanced during the intense localized muscle work provided by HIFEM. The muscle load significantly increases the body's need for energy supply, resulting in an induced metabolic stress[5,6]. As such, applying RF and HIFEM at the same time brings the key synergy in the form of a significantly enhanced fat breakdown process.

The other direct effect of fat heating occurs when the elevated temperature is sustained for a sufficient period of time. Adipocytes exposed to temperatures of 43-45°C for several minutes lose their cellular integrity/viability, and a portion will be forced to enter into the apoptotic process, i.e., natural and permanent cell death and resorption[7–10]. The apoptotic cells subsequently lose their membrane integrity and are ultimately digested by macrophages (occasionally accompanied by other immune cells), responsible for clearing the degraded cells and the debris to maintain tissue homeostasis[11–13].

The efficacy of this novel dual-energy device for fat reduction has already been documented through clinical investigation. Histological examinations performed by Goldberg[1] and Weiss et al.[2] consistently revealed noticeable shape alternations of adipocytes after the treatments, including their flattening, shrinkage, and membrane ruptures. The release of intracellular content, due to the lipolysis led to a 33% decrease in the size of adipocytes. In addition, the ongoing apoptotic process was observed in the examined tissue through an increased presence of the adipocyte's pyknotic nuclei. These histological findings coincided with the scanning electron microscopy (SEM), which revealed smaller and deformed adipocytes, with ruptured membranes and noticeable extrusion of lipid droplets outside the cells. See **Figure 3.**

Multiple additional studies have further confirmed the histological observations. A study submitted to the FDA as part of the technology's clearance process evaluated 42 test subjects by ultrasound imaging and showed a reduction in abdominal fat by 29.8% at 3-months post-treatment[14]. Another study, by Jacob and Kent[15] used magnetic resonance imaging (MRI) to conclude a significant reduction of abdominal fat thickness by 30.8% at 3 months after the dual-energy treatments. Similarly, another study performed by Katz et al.[16] used an ultrasonographic examination and demonstrated an average decrease in fat thickness by 20.5% at 1 month. Results further improved to 28.3% at 3 months post-treatment. When compared to the previous HIFEM studies, the scale of documented improved results on fat reduction strongly suggests the beneficial effects of combined treatments.

Besides enhanced lipolysis, the simultaneous dual-energy application contributes to an even heat distribution. Localized accumulation of heat is often associated with thermal only treatments, and the so-called "*hot-spots*" can lead to various complications. In EMSCULPT NEO, the muscle contractions work as a natural massage and through an accelerated blood circulation[4,17] help distribute the heat homogeneously across the entire treated area.

III. The Effects on Muscle Tissue

The use of in-vivo temperature probes revealed that while fat is heated during the treatment, two simultaneous modalities also affect muscle tissue. Due to the relatively high thermal conductivity, the muscle tissue does not retain the same temperature profile that can be seen in the fat due to its lower

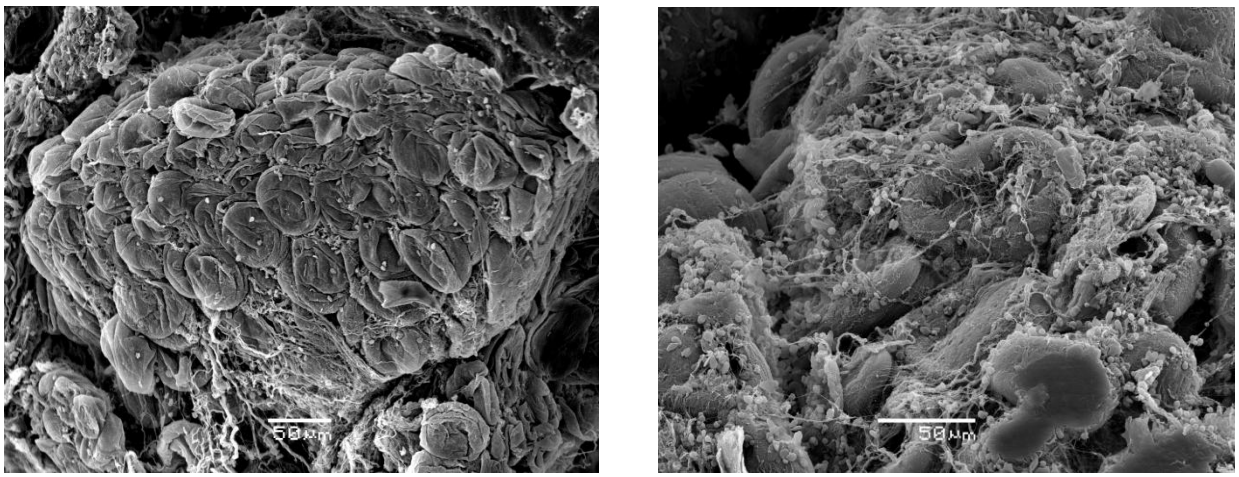

Fig. 3. SEM evidence of the fat cell shrinkage due to lipolysis which occurs 4 days after treatment (left) and fat cell destruction due to apoptosis seen 2 weeks after the last treatment (right). Source: Weiss et al.

thermal conductivity and higher thermal capacitance. The muscle is heated to temperatures ranging from 40-41°C, which is a combined result of the heat directly induced by RF, the heat produced by the muscle during supramaximal contractions, and the heat that physiologically spreads from the adjacent fat tissues. The muscle temperature over time can be seen in **Figure 4**.

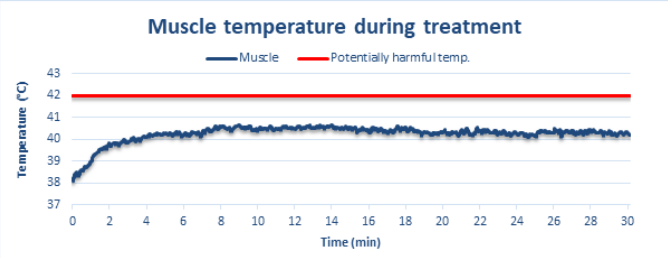

Fig. 4. During the first 2 minutes, the muscle temperature reached 40°C and was maintained between 40 and 41°C for the rest of the treatment. Safe temperature levels were sustained without any risks for the muscle tissue for the entire treatment. Adopted from Halaas et al.

Scientifically, it is well documented that muscle heating provides many physiological benefits. We intuitively warm up shortly before doing any strenuous weightlifting or other types of exercise to protect the muscles from injury for a reason.[19] Studies have shown that heating of the muscle tissue during contractions positively affects the muscle response in several ways:

Muscle heating causes vasodilatation, i.e., increased blood flow into the active tissue, which significantly increases the delivery of oxygen and nutrients to the strained muscle fibers.[20] The oxygen levels are directly affected by heating through dissociation of oxygen from hemoglobin at higher plasma oxygen concentrations, thus providing more oxygen to working muscles.[19,21] An increased oxygenation and nutrient supplementation promotes the anabolic processes and are necessary for faster muscle fiber regeneration and growth.[22]

Increased blood flow is also accompanied by a faster removal of toxic waste products (e.g., lactic and carbonic acid)[20]. Lactic and carbonic acids are by-products of the metabolic process that produce energy for the muscles during intensive muscle work.[23] High levels of these acids within the tissue are associated with muscle soreness and muscle

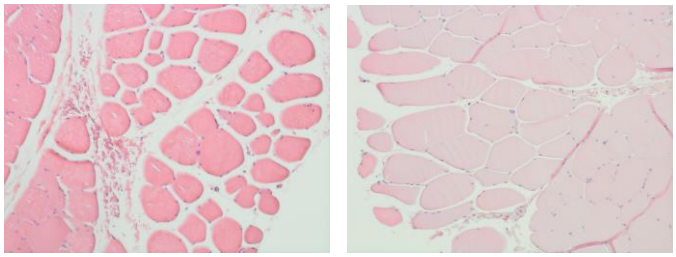

Fig. 5. Images of histological slices of muscle tissue collected at baseline (left) and 2 weeks after the last dual-energy treatment (right). The volume of individual muscle fibers is noticeably increased after the treatment. Adopted from Halaas et al.

fatigue.[24] A faster flush out of the waste leads to an attenuation of muscle soreness and muscle fatigue. This can be experienced the day after the treatment.[25] Furthermore, heated muscle contractions were described as “better”, “easier”, “stronger” and “less fatiguing” than muscle contractions in normal room conditions.[26] Heating thus increases the already high levels of patient’s treatment and post-treatment comfort.

Although all of the benefits mentioned above significantly contribute to the patients’ overall treatment experience, the main synergistic effect of the simultaneous delivery of RF and HIFEM lies in **the enhancement of muscle strengthening by hypertrophy**.

The HIFEM-induced supramaximal contractions produce a strong response, triggering muscle tissue hypertrophy[27]. During intense contractions, muscle fibers are stretched and relaxed, similar to resistance exercise, but with a higher intensity. Muscle workload of a sufficient intensity leads to micro-ruptures in muscle fibers.[28,29] This causes signaling molecules to be released to activate a regenerative process and muscle growth in order to strengthen the muscle and prepare it for another workload.[29] **Heat shock proteins (HSP)** are a family of such signaling molecules that play a crucial role in **muscle hypertrophy** through the **promotion of muscle protein synthesis**.[30,31]

Heat shock proteins may be activated by mechanical stress, such as intense muscle contractions, and heat stress. Several studies have documented increases in HSP levels and increased muscle protein synthesis in the muscle tissue after an application of heat at 40-41°C[30–34]. Goto et al.[33] compared the HSP expression following heat stress, mechanical stress,

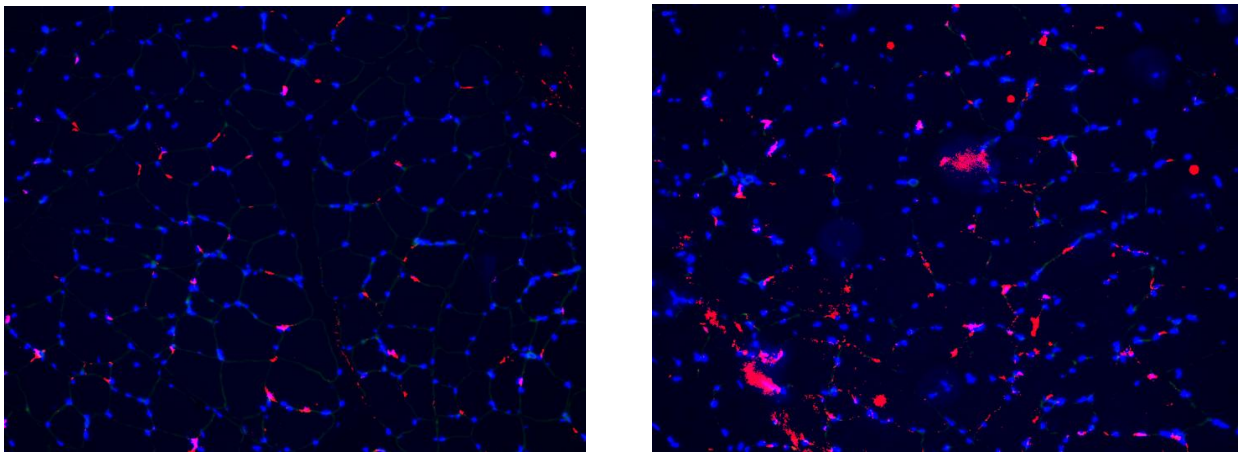

Fig. 6. Images of histological slices of muscle tissue collected at baseline (left) and 2 weeks after the last dual-energy treatment (right). The volume of individual muscle fibers is noticeably increased after the treatment. Adopted from Halaas et al

and simultaneous application of heat and mechanical stress. **The simultaneous application** showed a **significantly higher increase** in the expression of **HSPs** when compared to either heat or mechanical stress alone, which only confirms the synergistic effects of the two energies for muscle hypertrophy.

Another important element in muscle hypertrophy is the so-called satellite cells (SC). SC are muscle-derived stem cells, responsible for **myofiber development and renewal**.[35] In a resting state, the SC remain in a quiescent state, ready to be activated, enter differentiation to provide new myonuclei to existing muscle fibers, or to generate new muscle fibers.[36,37] They can be activated by an intense muscle exercise as a response to **regenerate and strengthen the existing muscle fibers**.[38] However, heat was also found to trigger activation of satellite cells[39]. Simultaneous application of heat and mechanical stress is presumed to result in magnification of the muscle strengthening and hypertrophy. Increased levels of the satellite cell pool after a set of dual-energy treatments have been documented in a study by Halaas et al.[18] The increased SC levels (See **Figure 6**.) were accompanied by histological observation of muscle hypertrophy and even newly formed myoblasts.

Satellite cells and heat shock proteins are not the only muscle bulk enhancing aspect. The increased tolerance of the contractions allows physicians to apply higher HIFEM intensities much earlier in the treatment process, and to use protocols with more intense muscle stimulation patterns.

The first clinical trials[15,16] on this novel dual-energy technology showed significantly more prominent muscle hypertrophy compared to previous studies investigating a standalone HIFEM procedure[40,41]. The average growth in muscle thickness was oscillating around 24-26%, while without the heating effects, the muscle thickening effects averaged at 16%. See **Figure 7** for illustrative MRI images.

One might presume that a consecutive application of RF and HIFEM delivered immediately following each other, would yield similar benefits as a simultaneous application. However, this was shown not to be the case. Muscle tissue, being rich in blood vessels, can dissipate the excessive heat accumulation as soon as it exceeds the blood temperature (appx. 37°C)[42]. Without continuous heat delivery, it is impossible to maintain the proper therapeutic temperature elevation in the targeted tissue, which is essential to achieve all the synergistic effects. This dual-field modality technology thus provides a unique solution that cannot be fully clinically substituted by any combination of two standalone applications.

IV. Concluding comments

Procedures primarily addressing fat and muscles non-invasively have been two separate worlds since their inception. This is due to the clinical as well as technical interferences of the two different concepts. EMSCULPT NEO represents the first-ever technology that, from an engineering standpoint, allows to simultaneously apply RF heating and HIFEM energies to the same targeted body area. This represents a breakthrough approach to non-surgical body

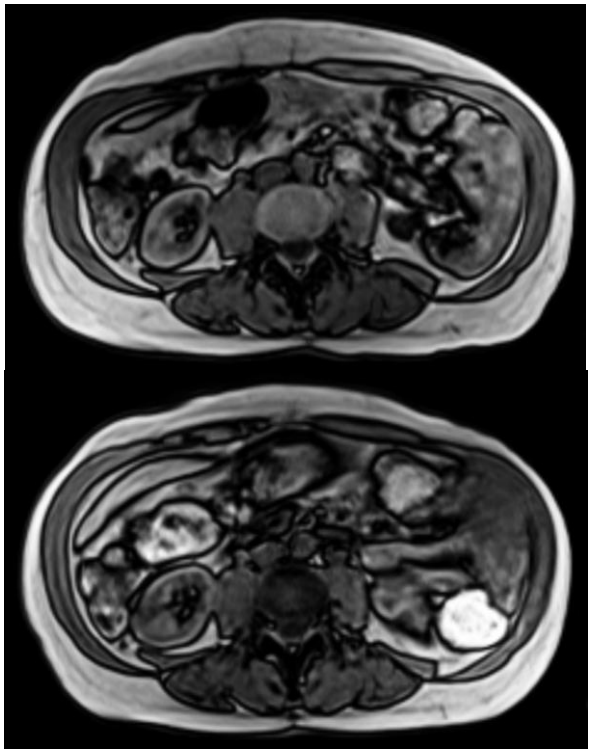

Fig. 7. MRI images of a male patient taken at baseline (left) and 3 month post-treatment (right). The images illustrate significant fat reduction and muscle thickening as a result of the dual field treatment. Adapted from Jacob et al.

shaping that allows us to clinically combine RF-induced fat elimination and HIFEM-induced muscle building in a wide range of patients, varying from trained athletes to sedentary or high-BMI individuals.

This new approach unlocks the various synergistic benefits that can only be seen when the energies are emitted at the same time. The fat-reducing effects of standalone radiofrequency are elevated by the aid of HIFEM and its side effects on fat metabolism. At the same time, the muscle-building effects of HIFEM are delivered on muscles that are pre-heated by the radiofrequency. These synergistic effects of the dual simultaneous delivery have been confirmed by multiple clinical studies documenting efficacy superior to any other standalone or consecutive treatment regimens. EMSCULPT NEO represents a new class of device far ahead of any devices currently in the marketplace for body contouring. Treatments are faster, safer and more effective than ever before.

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