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Lifting and Toning of Arms and Calves Using High-Intensity Focused Electromagnetic Field (HIFEM) Procedure Documented by Ultrasound Assessment

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ABSTRACT

Objective: The HIFEM procedure demonstrates positive outcomes on abdomen and buttock. This multi-center study aims to investigate its effect on adipose tissue and muscle mass located in upper arms and calves.

Materials and Methods: Twenty subjects (45.10±15.19 years, 24.44±3.22 kg/m^2) who underwent a HIFEM procedure (4 sessions; 20 minutes per muscle group) on arms and calves were evaluated. Overall, 7 patients were treated over biceps and triceps, 4 patients over calves, and 9 patients underwent treatment of both upper arms and calves. The changes in adipose and muscle tissue of musculus biceps brachii, triceps brachii, and gastrocnemius were evaluated by using ultrasound. The results from a 1-month, 3-month, and 6-month follow-up were compared to the baseline. Digital photographs, weight measurements, satisfaction, and comfort questionnaires were assessed at baseline and follow-ups.

Results: Ultrasound images revealed a significant ($P<0.05$) increase in the muscle mass of all studied muscles, with the most noticeable improvement in biceps brachii (+16.13% at 3 months). The fat deposits over arms and calves showed significant improvement ($P<0.05$), reaching -15.12% at 3 months. The results peaked at 3 months and were sustained up to 6 months with a slight but insignificant decline. Aesthetic enhancement of treated areas was documented while patients were highly satisfied.

Conclusions: The achieved outcomes showed that the HIFEM procedure is effective for muscle toning and fat reduction in arms and calves. The results suggest that the use of the HIFEM procedure is not limited only to abdominal and buttock shaping but is also effective for toning of arms and calves.

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INTRODUCTION

Aesthetic medicine aims at providing therapies designed to increase patients' satisfaction with their body image, hence helping with their quality of life. The general public perceives body imperfection as a concern since about 4.6 billion cosmetics procedures were performed in the US in 2019, according to the American Society for Aesthetic Plastic Surgery.[1] Of these, a total of 3.1 billion were non-surgical treatments. The demand for less invasive interventions is driven by the patients' desire for aesthetic improvement without any downtime and absence from work. On the other hand, the medical community must always seek to minimize the side effects and provide the patients with safer but effective treatment procedures.

The major concern of many lies in excess fat tissue and muscle laxity in particular areas and non-invasive modalities are mainly convenient for such issues. Excessive fat has been addressed by heating or cooling modalities[2–4] non-invasively for a long time, while muscle remained neglected. HIFEM technology, introduced in 2018, is the only non-invasive procedure that focuses on muscle contouring.

The technology utilizes a circular coil to create a high-intensity focused electromagnetic field that depolarizes neuromuscular tissue, which results in intense muscle contractions that cannot be achieved voluntarily.[5] The stimulation using HIFEM improves blood circulation, induces hyperplasia, and hypertrophy, leading to muscle sculpting effect.[6] Besides, the effect of HIFEM on fat tissue has been observed in several studies.[7–10]

The use of HIFEM technology in body contouring has been investigated in multiple studies that utilized several modalities such as ultrasound imaging,[8] MRI,[9] or CT[10] to assess the outcomes of HIFEM treatments. The results showed a significant muscle thickening effect ranging from 14.8% to 15.4% and reduction in fat layer ranging between 17.5% and 23.3%.[5] However, all previous studies focused on using HIFEM over the abdomen and buttocks.

A single case study[11] showed the feasibility of the treatments over arms and calves, but the effects have not yet been investigated in detail. Therefore, the goal of this study is to examine the safety and effectiveness of the technology for aesthetic improvement of upper arms and calves.

MATERIALS AND METHODS

The study population consisted of twenty-two enrolled subjects of whom twenty underwent subsequent evaluation (45.10±15.19 years, average BMI of 24.44±3.22 kg/m^2). Two subjects were withdrawn from the study. Before enrollment, the inclusion and exclusion criteria were checked for each subject and only patients who met the inclusion criteria were enrolled. The criteria included age ≥21 years, BMI ≤30kg/m^2, willingness to abstain from partaking in any treatments other than the study procedure, and willingness to maintain a regular pre/procedure diet and exercise regimen (patients were instructed to not vary their exercise routine during the post-treatment phase). Furthermore, patients with any metallic and electronic implants, and any medical condition contraindicating the use of electromagnetic fields, were excluded from the study. Women of childbearing potential were required to use birth control measures throughout the study duration.

The study design was approved by the Institutional Review Board (Advarra IRB) and conformed to the ethical guidelines defined in the 1975 Declaration of Helsinki. All the patients underwent four procedures, each lasting 20 minutes per muscle group, with a HIFEM based device (Emsculpt, BTL Industries) administered on arms and calves. Some participants opted to have two or three body parts treated (ie, biceps and triceps, for example). Overall, 7 patients were treated over biceps and triceps, 4 patients were treated over calves, and 9 patients received treatment over both upper arms and calves (N=20).

The effect of the HIFEM procedure on the underlying tissues was assessed using ultrasound imaging. The ultrasound images at baseline, 1 month, 3 months, and 6 months post-treatment were used for measuring the thickness of musculus biceps brachii, triceps brachii, and musculus gastrocnemius, as well as adipose tissue thickness at the treated sites. At each location (biceps b., triceps b., gastrocnemius m.), the measurements were always performed at the same predefined area where the muscle reaches its maximum thickness. For calves, both medial and lateral heads of gastrocnemius m. were measured. The average muscle and fat thickness were calculated out of the obtained values, and the post-treatment results were compared to the baseline.

The participants filled a Therapy Comfort Questionnaire after the fourth treatment, while their satisfaction with the therapy results was assessed by the Satisfaction Questionnaire. Digital photographs were taken to document the visual appearance of treated areas.

Paired T-test for means was used to determine whether the changes of fat and muscle thickness were statistically significant. *P*-values of less than 0.05 were considered significant when rejecting the null hypothesis.

RESULTS

A total of 20 subjects underwent the entire treatment procedure; two subjects dropped out during the treatment phase and were excluded (upper arms and calves group). All of the 20 subjects attended evaluation at 1-month and 3-month follow-ups. The 6-month follow-up visit was optional and was attended by 15 subjects. The evaluation of the Therapy Comfort Questionnaire, filled after the 4th procedure by all participants, revealed that the procedure was generally perceived as comfortable. Only a single subject reported mild discomfort during the treatment. No side effects or adverse events occurred, and no significant change was seen in patients' weight in any of the follow-ups.

Biceps brachii Muscle

In regard to the measurements performed at the biceps b. muscle, the average thickness of the muscle was increased by 15.4% (2.2±0.9mm) at 1 month and by 16.13% (2.3±0.8mm) at 3 months post-treatment. The thickness of the fat layer above the biceps b. muscle was decreased by 13.62% (-0.86±0.65mm) at 1 month and by 14.93% (-0.95±0.67mm) at 3 months post-treatment. At six months post-treatment, the eleven subjects who came back for the follow-up measurements of upper arms showed a 15.7% (2.2±0.7mm) muscle thickening and 14.63% (-0.87±0.63mm) fat reduction when compared to baseline. Detailed results can be seen in Table 1 and Table 2. Examples of patient results documented in photographs and ultrasound images can be seen in Figure 1, 3, and 6.

FIGURE 1. (A) 53 year old prior to study inception, front view. (B) Patient 3 months post-treatment.

FIGURE 2. Baseline (left) and 3-month (right) digital photographs demonstrating improvement of upper arm contour, with noticeable fat reduction, front view.

Triceps brachii Muscle

The evaluation at the backside of upper arms showed 13.66% (2.0±1.0mm) thickening of triceps b. muscle at 1 month, which was further improved at 3 months when the muscle was thickened by 15.18% (2.1±1.0mm). The fat thickness was reduced by 11.53% (-1.08±0.61mm) at 1 month and 14.27% (-1.38±0.74mm) at 3 months. The six-month measurements performed at 11 subjects showed 14.86% (1.90±0.94mm) muscle thickening and 13.41% (-1.24±0.76mm) reduction in the fat layer when compared to baseline. Detailed results can be seen in Table 1 and Table 2. Examples of patient results documented in photographs and ultrasound images can be seen in Figure 2, 3, 4 and 6.

FIGURE 3. Baseline (up) and 3-month (down) digital photographs demonstrating improvement of upper arm contour, achieved by enlargement of m. triceps and m. biceps, front view.

FIGURE 4. Baseline (up) and 6-month (down) digital photographs demonstrating improvement of upper arm contour, achieved primarily by enlargement of m. triceps and reduction of fat thickness, back view.

Gastrocnemius Muscle

The measurements at the gastrocnemius m. on the 13 subjects who underwent the treatments and consequent evaluation had shown 12.75% (1.9±0.84mm) thickening of the muscle at 1 month, which further improved at 3 months when the muscle was thickened by 15.46% (2.3±0.85mm) in comparison to baseline. The fat thickness over calves was reduced by 13.3% (-0.83±0.72mm) at 1 month and even by 15.12% (-0.90±0.50) at 3 months post-treatment. A total of 10 out of the 13 subjects attended the 6-month follow-up visit and showed an average 14.58% muscle thickening and 14.65% fat reduction at 6 months post-treatment. Detailed results can be seen in Table 1 and Table 2. Examples of patient results documented in photographs and ultrasound images can be seen in Figure 5 and Figure 6.

FIGURE 5. Baseline (left), 1-month (center), and 3-month (right) digital photographs demonstrating improvement of calves achieved by enlargement of m. gastrocnemius, side view.

FIGURE 6. Baseline (left) and 3-month (right) ultrasounds of m. biceps brachii (upper row), m. triceps brachii (middle row), and m. gastrocnemius (bottom row). The yellow line is representing the fat layer, and the red line represents muscle tissue.

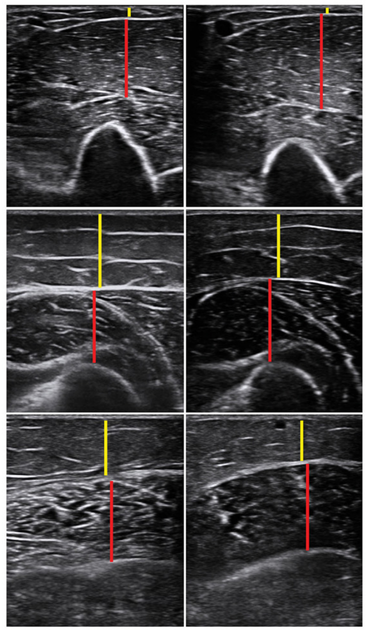

TABLE 1.

Average Muscle Thickness at Baseline, 1-month, 3-month, and 6-month Follow-ups				
Muscle/Thickness	**Baseline [mm]**	**1 Month [mm]**	**3 Months [mm]**	**6 Months [mm]**
Biceps b. m.	14.82±3.06 (N=16)	17.05±3.40 (+15.40%, N=16)	17.12±3.10 (+16.13%, N=16)	16.03±2.47 (+15.70%, N=11)
Triceps b. m.	15.99±6.45 (N=16)	17.95±6.52 (+13.66%, N=16)	18.11±6.48 (+15.8%, N=16)	14.75±4.17 (+14.86%, N=11)
Gastrocnemius m.	15.08±4.50 (N=13)	16.95±4.94 (+12.75%, N=13)	17.40±5.19 (+15.46%, N=13)	17.09±5.61 (+14.58%, n=10)

The average change against the baseline is shown in the parentheses along with the number of subjects (N). All the reported differences are statistically significant at *P*<0.05.

TABLE 2.

Average Values of Fat Layer Thickness in the Treatment Areas at Baseline, 1-month, 3-month, and 6-month Follow-ups				
Body Site	**Baseline [mm]**	**1 Month [mm]**	**3 Months [mm]**	**6 Months [mm]**
Biceps	6.09±3.43 (N=16)	5.23±2.91 (-13.62%, N=16)	5.14±2.97 (-14.93%, N=16)	4.95±2.97 (-14.63%, N=11)
Triceps	9.86±3.93 (N=16)	8.77±3.70 (-11.53%, N=16)	8.47±3.60 (-14.27%, N=16)	7.78±3.00 (-13.41%, N=11)
Calves	6.05±2.89 (N=13)	5.21±2.44 (-13.30%, N=13)	5.14±2.47 (-15.12%, N=13)	4.88±2.53 (-14.65%, N=10)

The average change against the baseline is shown in the parentheses along with the number of subjects (N). All the reported differences are statistically significant at $P<0.05$.

Satisfaction Questionnaire

The patients were highly satisfied with the treatment results as they reported that the treated muscles felt tighter, and the appearance in the treated area had been improved after the treatments. The satisfaction rate peaked at 3 months post-treatment as there were only 2 dissatisfied patients, and 90% of the subjects would recommend the treatment to a friend.

DISCUSSION

The HIFEM treatments resulted in a significant increase in the muscle thickness of all three analyzed muscles, with the improvement being most prominent at 3 months post-treatment with a slight but insignificant decline at 6 months. Although the muscle tissue improvements were consistent among the three locations, the largest increment in the thickness was seen for the biceps brachii muscle (+16.13%), which coincides with the general findings as the biceps muscle shows good responsiveness in muscle exercise programmes.[13,14] Similarly, for the fat tissue, the results peaked at the 3-month follow-up. The largest proportional fat reduction was seen at the calves (-15.12%). However, in absolute values, the most significant reduction was seen at the backside of upper arms since this anatomical location stores the most subcutaneous fat tissue of all three treated sites. The long-term results demonstrated that the outcomes are maintained up to 6 months with an insignificant decline.

The resistance training studies have intensively investigated the increase in muscle mass. Apparently, the muscle response seems to be load-dependent since high-load training appears to provide superior muscle growth, irrespective of muscle fiber type.[15] Nonetheless, during the exercise, multiple muscle groups are activated, which may affect various body areas. On the contrary, HIFEM can target specific muscle groups that allow focusing the treatment in particular areas of interest, ensuring principal activation in the treated site. Also, HIFEM stimulates muscles non-invasively and without any need for voluntary physical exertion. The effect of such procedures on the muscle tissue was previously described in detail by Duncan and Dinev,[6] who assessed the muscle tissue at the cellular level. They found that treated muscles respond to the HIFEM's supramaximal stimuli by increasing the size, primarily attributed to muscle fiber hypertrophy. However, the hyperplasia may be speculated since the authors noticed a certain increase in the numbers of muscle fibers.

The effect on fat tissue observed after the HIFEM therapy is metabolic in nature since there is no direct interaction selective to adipocytes when compared to other modalities that use temperature changes to affect fat cells. The intensive muscle contractions demand a considerable amount of energy supplied in the form of adenosine triphosphate (ATP), a high-energy nucleotide. However, the quantity of ATP ready for immediate use is remarkably limited in muscles. Thus, it must be synthesized from some abundant energy source, ie, free fatty acids (FFAs) stored in adipocytes. The effect of HIFEM-induced contractions on adipose tissue was already documented by Halaas and Bernardy,[16] who showed elevated levels of the FFAs in adipose tissue after the treatment. By depleting a portion of the adipocytes' content, adipose tissue thickness is expected to decrease, as documented by the ultrasound examination herein. The aesthetic improvement achieved by augmentation of the muscle tissue and reduced fat thickness was seen on the digital photographs (see Figures 1–5). Firming and toning the treated sites resulting in upper arms and lower legs improved contour was noticeable. Additionally, the high patient satisfaction documents that patients were able to recognize therapy outcomes themselves.

In addition to aesthetic benefit of the therapy, we suggest that HIFEM may also effectively combat sarcopenia (the involuntary loss of muscle mass). It has been documented that muscle mass decreases about 3–8% per year in the mid-age, while after reaching the age of 60 this rate of decline even accelerates. The degrading muscles are gradually losing its strength and function which negatively affect subjects' health.[17] By targeted stimulation, HIFEM procedure thus delivers a muscle anti-aging effect manifested by the significant muscle mass increase following four treatment sessions.

We recognize that our study has some limitations such as the relatively small sample size regarding the multiple treated areas and high dropout rate at the 6-month visit, albeit it was not mandatory. Nonetheless, the number of subjects was still sufficient to achieve statistical significance and provide relevant results.

CONCLUSION

In this study, the safety and efficacy of the electromagnetic stimulation using the HIFEM technology were documented for bicep, tricep, and calf muscles. No side effects were reported during or after the treatments. Results showed significant muscle thickening and fat layer reduction correspondingly in all treated areas, leading to more toned and firmed upper arms and lower legs. Outcomes have persisted up to 6 months, indicating that patients may benefit from the treatment in the long-term.

DISCLOSURES

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