Magnetic Resonance Imaging Evaluation of Changes in Gluteal Muscles After Treatments With the High-Intensity Focused Electromagnetic Procedure

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BACKGROUND High-intensity focused electromagnetic (HIFEM) field procedure induces changes in the gluteal muscles and improves the aesthetic appearance of the buttocks.

OBJECTIVE This study aims to objectively assess the hypertrophic response of the gluteal muscles after HIFEM treatments.

MATERIALS AND METHODS Seven subjects (40.00 ± 6.68 years) received 4, 30-minute HIFEM treatments of the buttocks. Magnetic resonance imaging of the pelvic region was obtained at baseline, 1-month, and 3-month follow-up to reconstruct 3D volumes of *musculus gluteus maximus*, *medius,* and *minimus*. Volumetric changes were calculated and statistically analyzed. Standardized photographs, weight measurements, patient satisfaction, treatment comfort, and adverse events were also documented.

RESULTS Volumetric analysis revealed a significant increase ($p = .001$) in the size of the examined muscles at 1-month (+10.81 ± 1.60%) and 3-month (+13.23 ± 0.91%) follow-up. A more profound hypertrophic effect was seen in the upper buttock region. This translated into a visible buttock lifting, also captured by patient photography. Gluteal adipose tissue was insignificantly affected. Patients were satisfied, and they found the treatments comfortable. No adverse events were observed.

CONCLUSION Simultaneous enhancement of gluteal muscles was documented. This represents the first objective evaluation of the HIFEM-induced structural changes in the gluteal muscles and physiologic documentation of the aesthetic improvement previously reported by other authors.

This was an investigator-initiated study. The author received financial support from BTL and serves on the medical board of BTL.

Aesthetic appearance of the buttocks is one of the essential attributes of beauty. Not surprisingly, the interest in buttock augmentation has increased over the past decade. According to 2018 statistics of the American Society of Plastic Surgeons (ASPS), more than 29,000 buttock augmentation surgeries are performed annually.[1] The most frequent buttock augmentation procedures include silicone implant placement; local flaps or tissue rearrangement; autologous fat grafting; and injections of various filler materials (although not FDA approved), such as hyaluronic acid gels, polymethyl methacrylate, or polyacrylamide.[2,3] These techniques, however, are accompanied by a relatively high complication rate.[2] The spectrum of observed complications is broad and includes both minor and major postoperative sequelae, such as prolonged pain, seroma, or occasional infection. Because of the inherent risks and postoperative complications after invasive buttock enhancement procedures, a safe, noninvasive and no downtime approach for buttock enhancement would be an attractive alternative to high-risk surgical procedures.

High-intensity focused electromagnetic (HIFEM) field procedure may represent an effective treatment alternative to riskier surgical procedures. High-intensity focused electromagnetic field procedure works

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through noninvasive stimulation of the gluteal muscles (gluteus maximus, medius, and minimus). It depolarizes peripheral motor neurons and elicits intense supramaximal contractions that impose the muscle to an extensive load. After several applications, muscles are expected to increase in size due to the muscle fiber hypertrophy and hyperplasia.[4–6] Recent studies found HIFEM as an effective and safe tool for buttock lifting with a lack of any significant adverse events.[7,8] However, the treatment outcomes were based on patient satisfaction and visual improvement. Therefore, an accurate, quantitative, and objective evaluation is needed to validate the treatment-induced changes apparent in previous studies.

A convenient tool for the objective evaluation of muscle changes is magnetic resonance imaging (MRI). Magnetic resonance imaging is the gold-standard method for the evaluation of skeletal muscles in terms of its shape or three-dimensional (3D) volume reconstruction.[9] Previously, MRI has been used for 3D volumetric examination of the gluteal muscles and was deemed to be a feasible objective measurement tool of muscle changes.[10,11]

This study aims to provide an objective evaluation of the expected hypertrophic response of gluteal muscles after HIFEM treatments by using MRI.

Materials and Methods

This was a prospective open-label single-arm study approved by the institutional review board (IRB). All procedures were performed with regard to ethical principles stated in the Declaration of Helsinki. Seven healthy and physically active women (mean age 40.00 ± 6.68 years; body mass index [BMI] 21.16 ± 2.08 kg·m^{-2}) participated in the study. Written informed consent was obtained from all participating subjects.

Study subjects aged ≥21 years were physically active and recommended to maintain at least minimum physical activity between the treatments to enhance muscle regeneration and thus facilitate its structural changes. Patients with large amount of fat deposits (BMI ≥30 kg·m^{-2}), previous surgery in the buttock/thigh area or any other concurrent treatments applied on the treated area during the study, pronounced skin laxity in the treated area, pregnancy, metal implants, and any of the contraindications listed in the operator's manual of the used HIFEM device were excluded.

In compliance with the IRB-approved protocol, each subject received 4 bilateral treatments with the HIFEM device (EMSCULPT; BTL Industries Inc., Boston, MA). Thirty-minute treatments were performed biweekly over 2 weeks. During the therapy, patients rested in a prone position. The applicators were placed on the buttocks and equally centered, to achieve simultaneous contractions of the gluteus maximus (gmax), medius (gmed), and minimus (gmin). A fixation belt was used to ensure the stable position of the applicators. Intensity of the HIFEM field was set to a maximum tolerable level (range of 0%–100%), and it was continuously adjusted according to the subject's feedback.

The primary outcome was to document hypertrophic changes of the gluteal muscles. Magnetic resonance imaging was performed at baseline, 1 month, and 3 months after treatment. Using a conventional system Philips Infinion 1.5T (Philips medical systems Inc., Andover, MA), the transverse, T1-weighted spin-echo images (from the iliac crest to the upper third of thighs) were acquired. Scanning protocols were set with regards to the optimal distinction of muscle tissue[12–14] as follows: time to repetition 600 ms, time to echo 13 ms, section thickness 3 mm, matrix size 512 × 512 and a field of view sufficient to cover the entire pelvic region. The obtained MRI scans in the Digital Imaging and Communications in Medicine format were slice-by-slice manually segmented to define 3D volumes of all 3 gluteal muscles (Figure 1). Evaluated slices at the baseline and follow-ups were chosen to be equivalent for further comparison of outcomes. The volume changes (in cm^3) between the follow-ups and baseline were calculated.

Standardized photographs of the subject's gluteal area (back and side view) were taken at the baseline, after the last treatment, at 1 month, and 3 months to evaluate changes in the physical appearance of buttocks.

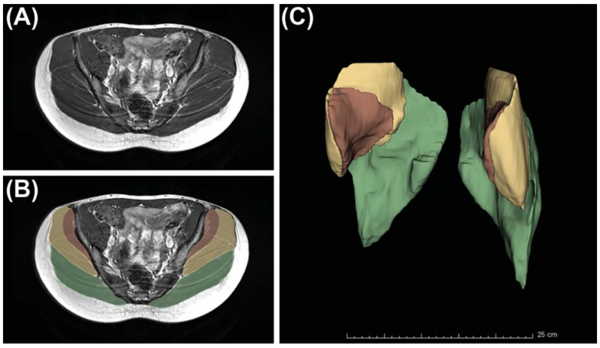

Figure 1. Example of the manual segmentation (B) of gluteal muscles in the transverse plane (A). Musculus gluteus maximus (green), medius (yellow), and minimus (red) are highlighted in colors. Three-dimensional reconstruction of muscle volumes can be seen on the right (C).

Weight and height measurements were also recorded. The occurrence of any adverse events was documented at each subject visit.

The patient's satisfaction and therapy comfort were assessed by using a 5-point Likert scale questionnaires. The satisfaction questionnaire consisted of 3 questions, and it was completed after the last treatment, at 1 month, and 3 months. Subjects reported their level of satisfaction with the appearance of the treated area, whether their buttocks felt tighter and more lifted as well as their overall satisfaction with treatment results. The therapy comfort questionnaire was assessed immediately after the last treatment.

Results of the volumetric muscle analysis were statistically analyzed using the two-tailed Wilcoxon signed-rank test for matched samples. p-values less than 0.05 (α = 5%) were considered as statistically significant.

Results

All subjects completed scheduled treatment sessions and study visits. The baseline weight of treated group was 57.99 ± 7.35 kg, and it insignificantly changed at 1 month (−0.25 kg; p = .20) and 3 months (+0.41 kg; p = .69). No adverse events were reported during or after the procedure or during the follow-up period.

Results of the 3D volumetric analysis at the 1-month follow-up revealed a highly significant (p = .001) increase in the size of the examined muscles when compared with baseline (Figure 2). The average muscle volume enhancement was 10.81 ± 1.60% (197.98 ± 40.93 cm^3; 6.69 oz). Also, it was seen a highly significant (p = .001) increase in each of the 3 gluteal muscles individually. In specific, gmax increased by 11.15 ± 1.91% (134.19 ± 31.58 cm^3; 4.54 oz), gmed by 10.21 ± 2.53% (47.35 ± 14.21 cm^3; 1.60 oz), and gmin by 9.92 ± 2.27% (16.44 ± 4.94 cm^3; 0.56 oz). The detailed data are shown in Table 1.

Three months after treatment, the gluteal muscles showed a further significant increase of 21.96% (+43.47 cm^3; 1.47 oz; p = .001) on average when compared with 1 month. The most noticeable improvement was observed in gmed and gmin, and the muscle growth was evident in each evaluated subject. The gmax increased on average by an additional 25.52 cm^3, gmed by 13.41 cm^3, and gmin by 4.54 cm^3 (Table 1). Compared with the baseline, the overall increment of muscle mass was equal to 13.23 ± 0.91% (241.45 ± 28.78 cm^3; 8.16 oz). Individually, the gmax improved by 13.33 ± 1.50% (159.71 ± 25.43 cm^3; 5.40 oz), gmed by 13.20 ± 1.62% (60.76 ± 9.93 cm^3; 2.05 oz), and gmin by 12.67 ± 1.45% (20.98 ± 4.03 cm^3; 0.71 oz).

An example of the comparison of 3D volumes is shown in Figure 3. Reconstructed baseline and follow-up volumes were positioned at the same coordinates to visualize its intersections. All displayed muscles are visibly thicker at the follow-up (red = muscle enlargement) in comparison with baseline (blue). The gmax showed the most noticeable enlargement (+13.02%), although gmed (+14.34%) or gmin

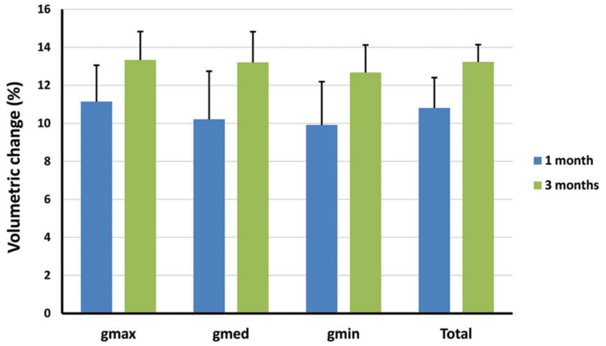

Figure 2. Volume enhancement at the 1-month and 3-month follow-ups (mean ± SD). gmax, gluteus maximus; gmed, gluteus medius; gmin, gluteus minimus.

TABLE 1. Results of the Volumetric Evaluation (Mean ± SD)

Muscle	Baseline	1 mo	3 mo
Muscle Volume (cm^3), *n* = 7			
gmax	1,197.26 ± 130.98	1,331.45 ± 155.49	1,356.97 ± 150.14
gmed	459.67 ± 46.38	507.02 ± 56.40	520.44 ± 53.68
gmin	165.56 ± 24.14	181.99 ± 28.22	186.53 ± 28.42
Total	1822.49 ± 133.48	2020.47 ± 168.00	2063.94 ± 158.61

gmax, gluteus maximus; gmed, gluteus medius; gmin, gluteus minimus.

(+14.45%) demonstrated relatively greater improvement against the baseline.

Standardized digital photographs showed improvement in aesthetic appearance (lifted and firmer buttock), which coincided with the muscle enlargement observed in MRI scans. Horizontal fragmentation (slice-by-slice evaluation) of the muscle changes revealed a more profound hypertrophic effect in the upper buttock region. As shown in Figure 4, the enlargement of gluteal muscles peaked approximately between the slices 23 to 36, which correspond to the anatomical area at the level of/above the femoral head. This translated into a visible buttock lifting, also captured by patient photography (Figure 5).

Magnetic resonance imaging scans did not reveal any visible changes in other underlying tissue structures, including gluteal fat layer. For instance, as can be seen in Figure 6, the fat deposits remained unaffected while the gluteal muscles are visibly thickened. To be more specific, the linear measurements of adipose tissue taken at 5 specified locations depicted in the figure showed a clinically insignificant reduction of 1.45%.

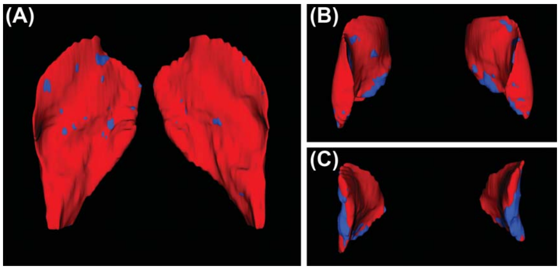

Figure 3. Comparison of reconstructed 3D volumes (gmax (A), gmed (B), and gmin (C)). Baseline volumes are highlighted in blue and 1-month follow-up volumes in red (an increase in volume). The average improvement is equal to 13.37%, front view.

Immediately after the last treatment, the patients reported a high level of satisfaction with achieved results, which further improved with time. At 3-month follow-up, all subjects agreed or strongly agreed that the aesthetic appearance of their buttocks improved, achieving a high score range of 4.6 to 4.9 on the 5-point Likert scale. The treatments were well tolerated (average score of 3.9) as 5 of the 7 patients found the treatments comfortable.

Discussion

Nonsurgical options for body rejuvenation are of increased value and interest when considering public awareness and risks associated with surgical options. By using the MRI examination, this study documented a significant change in the volume of gluteal muscles induced by a noninvasive HIFEM procedure. The volume enhancement showed to be uniform across the investigated muscles (Figure 2), and results were found to be continuously improving. The consistency of results among subjects may be attributed to the body constitution of participants because they were of similar BMI.

Muscle growth after the series of HIFEM treatments was previously documented by Kent and Jacob[5] and Kinney and Lozanova,[4] who reported increased thickness of rectus abdominis, reduction of abdominal separation, and a decrease of adipose tissue thickness. The muscle mass increase observed in this article corresponds with aforementioned

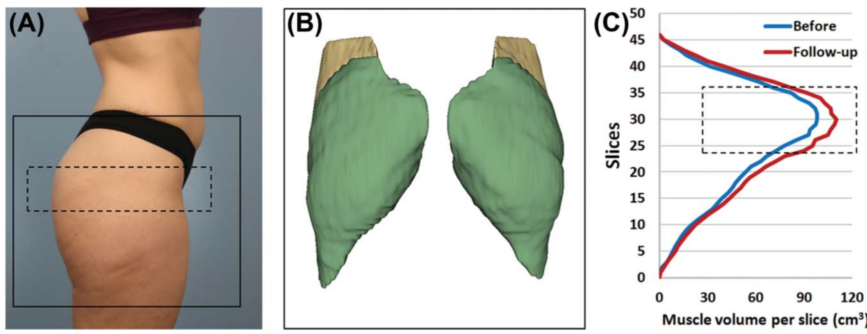

Figure 4. Horizontal fragmentation of overall muscle volume enhancement slice-by-slice at the 3-month follow-up (average improvement of 14.15%). The 3D volumes (B) are assigned to the standardized patient photography (A, side view). The more profound hypertrophic effect was observed in the upper buttock region (C, highlighted with a dotted line).

findings; however, the clinically significant reduction of fat thickness was not detected in this study (Figure 6). This may be attributed to the differences between the metabolism of adipose tissue in the buttock and abdominal region. It was documented that adipose tissue in the buttocks is metabolically less active and shows a significantly lower lipolytic rate.[15,16] Nevertheless, future studies should verify if any changes occur in the gluteal adipose tissue at the cellular level in response to HIFEM treatment, as was performed for abdomen.[17]

Until now, the application of HIFEM on the buttocks was studied only by subjective methods (quantification of visual appearance and patient satisfaction). According to the previously published multicenter study,[8] as much as 80% of patients reported that they felt more lifted and toned in the buttock region, and 71% of them were satisfied with the results immediately after the last treatment. Because of the simultaneous evaluation of MRI scans and standardized photographs presented in this article, one can infer that a noninvasive buttock-lifting effect is primarily associated with increment of muscle mass that peaked in the upper buttock region. Although Jacob and colleagues[8] noticed that patients with a lower BMI achieved a higher degree of visual improvement, sample size in this study was not large enough to reliably determine the correlation between BMI and the level of muscle volume enhancement.

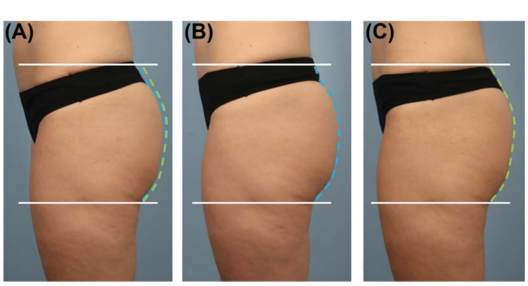

Figure 5. The baseline (A), 1-month (B), and 3-month follow-up (C) photographs. The dotted lines indicate a change in the buttock contour (improvement in muscle mass of 9.80% at 1 month and 12.67% at 3 months).

Gluteal enhancement is used to address aging changes of the muscle tissue or to improve gluteal contour and projection. Peak physical muscular capacity occurs in the second and third decade, and it then decreases with time,[18] a physiologic and predictable age-related muscular change referred to as sarcopenia.[19] Sarcopenia leads to a dramatic decrease in muscular mass and strength.[20] Also, the maintenance of lean mass has important consequences on slowing the increase in fat deposits and changes in body composition with age.[19,21] Fortunately, the age-related effects on skeletal muscle are mostly reversible[18] as seen after the strength training.[21] Nonetheless, noninvasive hypertrophic technologies could represent an alternative and possibly more efficient method of reversing muscle mass changes. In comparison to the voluntary exercise, HIFEM-induced supramaximal contractions forces muscles to contract selectively and under the greater load than possible voluntarily. This is beneficial for muscle hypertrophy response because it increases with tension of the contraction.[22]

Results of this study suggest that HIFEM-induced muscle fiber hypertrophy may represent advancement

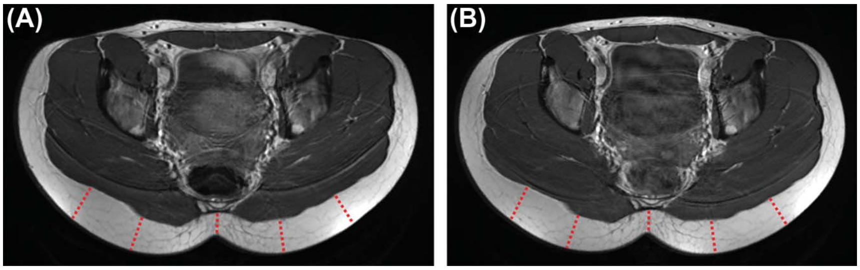

Figure 6. Baseline (A) and 3-month follow-up (B) MRIs of an HIFEM-treated patient. No structural changes in fat deposits were observed. The thickness of the subcutaneous layer was not significantly affected by the treatments (see the equally sized dotted red lines). The enlargement of gluteal muscles at the 3-month follow-up is visible. HIFEM, high-intensity focused electromagnetic; MRI, magnetic resonance imaging.

in the treatment of gluteal ptosis and volume loss. An average muscle volume increased by 197.98 cm^3 after 1 month and by 241.45 cm^3 at 3 months (Table 1). This amount is roughly equivalent to 8.2 ounces and is comparable but slightly lower than average volumes of injected fat during micro fat grafting procedures.[23] The greatest advantage of HIFEM therapy is that it achieves noninvasive buttock augmentation by using physiologic stimulation of the targeted muscle with no downtime. More importantly, HIFEM caused no adverse events during or after the treatment. It eliminates the risk of long-term postoperative adverse sequelae, such as muscle atrophy,[24] silicone implant migration,[25] or pulmonary fat embolism.[26]

One possible limitation of this study is relying on manual assessment of MRI slices. Slice-by-slice segmentation is limited because it is a time-consuming process. It is preferably used in specific case scenarios or as a reference for some easy method of evaluation.[10,27] To shorten processing time, it can be simplified by reducing the number of segmented slices or by use of automatic methods. However, reducing the number of slices may lead to a higher level of error in volume estimation and reconstructed muscle may also lose its inherent shape and contour. On the other hand, automated methods encounter issues with separation of gluteal muscles, especially the gmed and gmin, where the border is far from clear.[11] Despite the possible disadvantages, manual segmentation still produces the best possible results.

The major limitation of this study is the sample size. In addition, the subject group consisted predominantly of low BMI and physically active women without excessive fat deposits in the treated area. It is unclear whether these findings would be similar in subjects with a higher BMI (<30 $kg{\cdot}m^2$) who may have a significant amount of gluteal fat. Furthermore, a detailed physiologic explanation for the stability of the gluteal fat layer may be subject to further research efforts.

Conclusion

HIFEM application to the buttocks is safe, comfortable, and effective as a means of increasing volumetric muscle mass of the gluteal muscles. Patient satisfaction was high, and no adverse events were observed. Magnetic resonance imaging analysis revealed simultaneous enhancement of all 3 gluteal muscles at 1 month and 3 months after the HIFEM procedure. The gluteal fat layer was not affected by the treatment. The overall muscle mass increase peaked in the upper gluteal area; this corresponds with digital photographic documentation of a visible lifting effect on the ptotic buttocks region. This study had documented the first objective evaluation of structural changes of gluteal muscle tissue induced by an HIFEM procedure, which may explain the aesthetic improvement previously reported by other authors.

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