

ORIGINAL ARTICLE

Combination treatment for buttock and abdominal remodeling and skin improvement using HIFEM procedure and simultaneous delivery of radiofrequency and targeted pressure energy

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Abstract

Background: High-intensity electromagnetic field procedure (HIFEM) is an effective tool for body shaping and muscle toning. Radiofrequency (RF) combined with targeted pressure energy (TPE) provides the solution for skin laxity and cellulite.

Aims: To document the effect of consecutive use of HIFEM, RF, and TPE for treatment of abdomen and buttocks.

Methods: Fifteen subjects (44.3 ± 14.2 years, 22.3 ± 2.3 kg/m²) finished treatments and consequent follow-ups. They were treated over the abdomen (Group 1, N = 7) or buttocks (Group 2, N = 8), receiving four treatment procedures consisting of HIFEM treatment administered first, immediately followed by the simultaneous RF & TPE treatment. Each session took approximately 50 min (30 min of HIFEM; up to 20 min of RF & TPE) depending on the treated area. Study outcomes were assessed by the circumference measurement, satisfaction and comfort questionnaires, and digital photographs.

Results: Combined treatments were safe and comfortable. At 1 month, the abdominal circumference significantly decreased by 4.4 cm, while buttocks showed a significant increase by 1.0 cm. The abdomen (-4.1 cm) and buttocks (+1.2 cm) circumference results were sustained for three months without a significant decline. Satisfaction was high in both groups (93.3%) since most subjects noted that the appearance of the treated area has been improved, referring to both body sculpting and skin appearance.

Conclusions: The consecutive application of HIFEM, RF, and TPE treatments noticeably improved the appearance of the abdomen and buttocks. Subjects showed enhancement of abdominal body contour, buttock lifting, and improved skin quality manifested by reduced skin laxity and cellulite.

KEYWORDS

abdominal remodeling, buttock lifting, HIFEM, radiofrequency, targeted pressure energy

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1 | INTRODUCTION

The field of non-invasive procedures has become a well-established segment of aesthetic medicine, and its popularity is growing rapidly across the world. Physical appearance has become an essential aspect of personal identity. In today's modern society, up to 60.7% of men and 71.6% of women of the US population are dissatisfied with their body size.¹ The current population is losing the balance between the number of consumed calories and energy expenditure as the population suffers from a lack of physical activity. This is considered as the main reason for increased body fat accumulation. Body dissatisfaction is further enhanced by the media-driven images of ideal human bodies, which put a lot of pressure on the population, potentially resulting in chronic depression.² Hence, people try to equilibrate their input-output energy balance and improve their appearance through various available aesthetic procedures.

High-intensity focused electromagnetic (HIFEM) technology has proven to be an effective solution for body contouring. Since 2018, clinical studies on HIFEM²⁻⁵ have demonstrated the efficacy of this technology via increased muscle mass and reduced fat layer. The technology is based on Faraday's law of electromagnetic induction and is characterized by rapidly alternating magnetic fields generated by a wire coil to depolarize motor neurons, thus inducing intense involuntary muscle contractions. Treatments with HIFEM-induced supramaximal contractions result in both muscle hypertrophy and fat reduction in regions with excess adipose tissue, where HIFEM initializes a biochemical cascade leading to lipolytic fat reduction.

Both subcutaneous fat and muscle tissue are important factors affecting a patient's body contour as it comprises up to 66% of human body composition.^{6,7} Nevertheless, to achieve overall body remodeling, it is desirable not to neglect the most upper and thus most visible layer—human skin. The most frequent skin issues include skin laxity and cellulite. Recently, Kinney et al.⁸ evidenced that combining radiofrequency (RF) heating and targeted pressure energy (TPE) simultaneously may be an effective way to combat skin concerns. RF energy alone is used to treat both cellulite and skin laxity. However, the simultaneous RF delivery with TPE has been shown to enhance the clinical effect of RF heating on dermal^{9,10} and subdermal tissue.⁸ Combining RF & TPE procedure with HIFEM can thus result in complementary improvement in all three desired tissues: skin, fat, and muscles.

This study aims to determine whether a consecutive use of HIFEM and RF & TPE technologies can effectively deliver the overall aesthetic improvement in subjects who not only seek body contouring but at the same time also want an enhancement in skin quality.

2 | MATERIALS AND METHODS

2.1 | Study population

Seventeen subjects were recruited in an open-label, single-arm study. Enrolled patients were aged 24 to 64 years (mean age 44.3 ± 14.2 years) with a mean BMI of 22.3 ± 2.3 kg/m² (range

18.3–25.5 kg/m²) before the treatments. Two subjects were withdrawn due to reasons unrelated to the clinical study. The exclusion criteria included pregnancy, breastfeeding, any medical condition contraindicating the application of an electromagnetic field, heart disorders, unhealed wound in the treatment area, and any concomitant medication known to cause bloating or affecting weight. Out of the seventeen subjects, fifteen of them underwent four treatment sessions performed once per week. The study protocol conformed to the ethical guidelines of the 1975 Declaration of Helsinki, informed consent forms were obtained from each subject at the time of recruitment, and subjects were not financially compensated for either participation or completion of the study.

2.2 | Study design

Before the therapies, subjects were divided into 2 study groups (Group 1 and Group 2) depending on the treated body area. The treated areas included the abdomen ($N = 7$, Group 1) and buttocks ($N = 8$, Group 2). All participants received active therapy. The control or reference group was not included in the study. All subjects, regardless of the allocation, underwent four consecutive treatments by EMSCULPT device (BTL Industries Inc.) using a HIFEM technology followed by EMTONE device (BTL Industries Inc.) using RF and TPE technology simultaneously. The therapy sessions were performed twice a week for two weeks. HIFEM procedure was administered first, immediately followed by RF & TPE treatment. A single session consisting of consequent use of EMSCULPT and EMTONE devices took approximately 50 min, with the HIFEM treatment lasting 30 min, and RF & TPE treatment up to 20 min, depending on the treated area.

The HIFEM device consists of a control unit and a cable connecting the unit to a coil applicator, which is applied over the treatment area. The circular coil located in the applicator induces a magnetic field with intensities reaching up to 1.8 T with a penetration depth of approximately 7 cm. Conversely, the EMTONE device consists of two control units with combined output in one single applicator. The first unit generates a radiofrequency field (447 kHz), which provides heating to the dermal and subdermal layers. The second unit generates targeted pressure energy with a frequency of 10 Hz and pressure strength of 1.5–4 bar penetrating the treated tissue.

2.3 | HIFEM procedure

HIFEM treatment was applied in a supine or prone position with the applicator positioned over the subject's umbilicus or glutes depending on the allocated group. The applicators were secured by a fixation belt to avoid any movement during the treatment process. The operator adjusted the applicator position at the beginning of the treatment to ensure homogeneously distributed contractions of abdominal or gluteal muscles. The initial stimulation intensity was set according to the patient's tolerance threshold and was further increased during the treatment based on the patient's feedback. No anesthesia was required.

TABLE 1 Average changes in parameters of treated subjects

Measurement	Baseline	1 month	1-month difference	3 months	3-month difference
Waist circumference [cm] (Group1, N = 7)	80.4 ± 5.3	76.0 ± 5.4	4.4 ± 3.5 <i>p</i> < 0.05	76.3 ± 6.1	4.1 ± 4.6 <i>p</i> < 0.05
Hip circumference [cm] (Group2, N = 8)	96.0 ± 5.7	97.0 ± 4.1	1.0 ± 2.5 <i>p</i> < 0.05	97.2 ± 5.9	1.2 ± 3.8 <i>p</i> < 0.05
BMI [kg/m ²] (Group1, N = 7)	22.1 ± 2.3	21.9 ± 2.5	0.2 ± 0.8 <i>p</i> > 0.05	21.8 ± 2.2	0.3 ± 1.0 <i>p</i> > 0.05
BMI [kg/m ²] (Group2, N = 8)	22.4 ± 2.4	22.0 ± 2.4	0.4 ± 0.6 <i>p</i> > 0.05	22.1 ± 2.2	0.3 ± 1.0 <i>p</i> > 0.05

2.4 | RF & TPE procedure

Simultaneous RF & TPE treatment was also applied either in the supine or in the prone position with a handheld applicator, delivering both energies across the whole treated regions (umbilicus and gluteus). Before the therapy, conductive cream was applied on the skin to maintain good contact with the treated area and to facilitate applicator's movement. Skin temperatures of 40–45°C were reached and maintained during the therapy with the help of the infrared thermometer, which is built-in to the device's applicator. The intensity of the RF field was set to 50–80% of the maximum device output, and the TPE was set to the maximum output (4 bars), inducing sensations similar to an intensive massage.

2.5 | Evaluation methodology

Personal data such as age, height, weight, and BMI of patients were recorded at baseline visit and subsequent follow-up visits (1-month and 3-month). Waist circumference measurements of the hip and abdomen, and digital photographs were taken to document any changes in the appearance of the treated area. Furthermore, the satisfaction questionnaire (filled after the last treatment and at both follow-ups) and comfort questionnaire (filled after each treatment) using a 5-point Likert scale were assessed. Subjects reported their level of satisfaction with the appearance of the treated area, whether their abdomen or buttocks felt tighter and more lifted, and their feedback regarding overall satisfaction with treatment results. Throughout the study, patients were monitored for any side effects and/or adverse events. A sign test verified the significance of the obtained data, and the significance level was set to 5%.

3 | RESULTS

Except for two withdrawn subjects, participants from both study groups completed scheduled treatment sessions and follow-up visits. The results presented herein, therefore, comprise data from 15 patients. No adverse events or side effects were reported throughout the whole study. Subjects maintained their weight, and the average weight change did not exceed 1 kg during the whole study

process. Correspondingly, the BMI changes were insignificant (see Table 1).

Abdominal waist circumference gradually decreased in Group 1 over the course of the study, while Group 2 showed increased hip circumference. The baseline circumference was 80.4 ± 5.3 cm for the abdomen (N = 7) and 96.0 ± 5.7 cm for buttocks (N = 8). At a 1-month follow-up visit, the waist circumference significantly (*p* = 0.035) reduced on average by 4.4 ± 3.5 cm compared with the baseline. Also, hip circumference increased significantly (*p* = 0.035) on average by 1.0 ± 2.5 cm compared with the baseline. These results were also maintained at three-month follow-up visit without a significant decline. The abdominal circumference reduction at 3 months was 4.1 ± 4.6 cm, and for the buttocks, the average increase in circumference was equal to 1.2 ± 3.8 cm. For detailed results, see Table 1.

The treatments were well tolerated. The satisfaction questionnaire results after the last therapy showed that the majority of subjects (93.3%) found therapy sessions comfortable. Also, one month after the last therapy, 93.3% of subjects noted that the treated area had improved, referring to both body sculpting and skin appearance enhancement. At a 3-month follow-up visit, 86.6% of subjects still noticed improvement, and 2 (13.3%) were undecided. No subject reported that the appearance of the treated area worsened. In general, subjects were satisfied with treatment results, and they would likely undergo treatment again.

Examination of digital photographs corresponded to the satisfaction questionnaire results, showing that a combination of HIFEM and RF & TPE modalities resulted in overall aesthetic improvement of the treated body area. Visually, the skin quality enhancement manifested by diminished cellulite and/or skin laxity, which was observed in subjects from both groups. However, more dramatic changes were noticed in Group 1 since Group 2 lacked the subjects with a high degree of cellulite or laxity in buttocks (see illustrative results in Figures 1-4). The digital photographs also showed recognizable body shaping and buttock lifting effects attributed to the HIFEM procedure.

4 | DISCUSSION

The analysis of the study outcomes suggests that simultaneous application of HIFEM and monopolar RF & TPE technology effectively



FIGURE 1 Photographs of subject ID 8 taken at baseline (left) and at 1-month follow-up visit (right). The photographs illustrate improved shape of the abdomen and skin quality enhancement



FIGURE 2 Substantial changes in abdominal body contour shown by subject ID 15 at 1 month (middle) and 3 months (right)

improves the body contour and skin quality in the abdomen and buttocks.

High-intensity focused electromagnetic field induces supramaximal muscle contractions. Targeted tissue exposed to these intense contractions is forced to adapt to such conditions and responds with the remodeling of its inner structure—muscle hypertrophy.^{11,12} An increase in muscle density and volume leads to a better definition and muscle tone. Also, the muscle workload demands a considerable amount of energy to produce contraction, so the body's catabolic processes occur in the form of lipolysis since fat tissue usually acts as an energy source for demanding muscle activity. In addition to muscle definition, HIFEM, therefore, metabolically influences adjacent fat tissue, which explains the improved body contour seen in this study.^{13,14}

Generally, cellulite results in dimpled-looking skin that commonly occurs in the thigh, buttocks, abdomen, and arms. It forms when fat tissue pushes up against connective tissue, making protrusions into

the dermis. Cellulite is quite a prevalent condition since it occurs in most post-pubescent females (85%–95%).¹⁵ Collagen is the main component of connective tissue influenced by cellulite to form unnatural rigid structures of fibrotic collagen fibrils. When RF is applied together with TPE to the site that suffers from cellulite, dissociation of fibrils and formation of new collagen occurs. The contribution of mechanical energy (TPE) involves the proliferative activity of fibroblasts and the formation of suitable conditions for the neo-synthesis of collagen.^{16–18}

Similar to the findings mentioned above, the previously published data suggest that simultaneous application of RF with TPE induces changes in the connective and subcutaneous tissues. According to Fritz et al.,^{2,19} simultaneous RF & TPE therapy sessions resulted in a significant reduction in cellulite and skin laxity at 3-month follow-up compared with baseline. On a rating scale of 0–4 points depending on the severity laxity assessment, patients involved in the first study¹⁹ mentioned above achieved an average improvement of

FIGURE 3 Photographs of subject ID 2 taken at baseline (left) and at 3-month follow-up visit (right). The photographs illustrate gradual progress in the lifting of the buttocks and diminished skin laxity

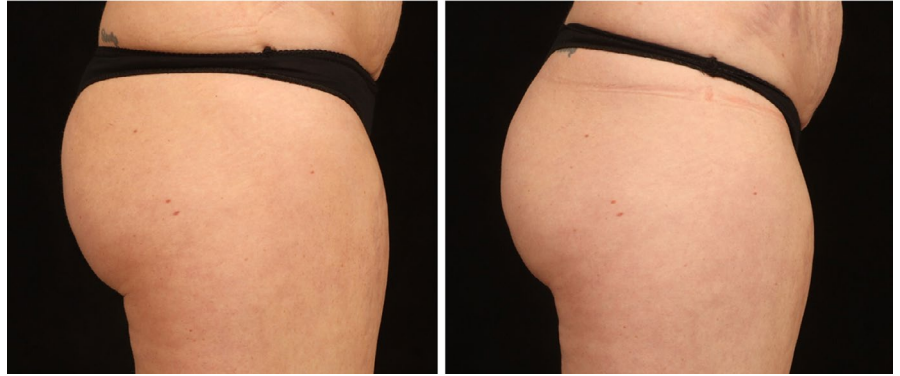


FIGURE 4 Photographs of subject ID 10 taken at baseline (left) and at 1-month follow-up visit (right). The photographs illustrate improved shape of the abdomen and skin quality enhancement



2.17 ± 0.95 . Further study² implies that viscoelasticity of abdominal skin was improved in 91% cases while subjects also showed positive changes in waist circumference. Although no quantitative measures of skin quality were utilized in this study, the digital photographs strongly suggest that corresponding changes manifested in our subjects.

HIFEM clinical studies^{2,3,20} showed that muscle growth occurs in the vast majority of treated patients. Corresponding findings were also noticed in this study. Although all the treated patients from Group 1 showed an overall improvement in abdominal body contour accompanied by a significant waist circumference reduction (see Table 1), the effect on the muscle tissue was also well visible on gluteal ptosis as the buttocks got lifted (see Figure 2).

This clinical study also has certain shortcomings. A limited number of subjects were recruited in this study. This fact was mainly caused by the allocation of patients into 2 sub-groups. Also, the study lacks a cohort of control subjects which would help to reduce the risk of bias. Therefore, future studies in larger sample sizes with greater statistical power are necessary to validate the outcomes of this study. Additionally, further follow-up visits (6-month for instance) might be realized by subsequent studies to determine the durability of achieved results since previous HIFEM studies showed that outcomes might persist up to 1 year.²¹ The possible direction of future research could yield more focus on pairing these technologies together, which may establish development for new devices utilizing benefits of consecutive or perhaps simultaneous use of HIFEM and RF & TPE.

5 | CONCLUSION

Based on the documented findings, the consecutive use of HIFEM and RF & TPE provides considerable improvement of body image and skin appearance in the abdomen and buttocks. This effect is mainly achieved due to the remodeling of dermal connective tissue, skeletal muscle hypertrophy, and fat lipolysis, leading to improved body contour, diminished skin laxity, and cellulite reduction.

ACKNOWLEDGMENTS

None.

ETHICAL APPROVAL

The authors confirm that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to and the appropriate ethical review committee approval has been received. Review and approval of the study was performed by the Human Ethics Committee by CITI certified evaluators.

CONFLICT OF INTEREST

I am a Clinical Investigator for BTL Industries Inc.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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How to cite this article: Duncan DI. Combination treatment for buttock and abdominal remodeling and skin improvement using HIFEM procedure and simultaneous delivery of radiofrequency and targeted pressure energy. *J Cosmet Dermatol*. 2021;20:3893-3898. <https://doi.org/10.1111/jocd.14554>