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HIGH INTENSITY FOCUSED
ELECTRO-MAGNETIC
TECHNOLOGY (HIFEM) FOR
NON-INVASIVE BUTTOCK
LIFTING AND TONING OF
GLUTEAL MUSCLES: A
MULTI-CENTER EFFICACY
SAFETY STUDY

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High Intensity Focused Electro-Magnetic Technology (HIFEM) for Non-Invasive Buttock Lifting and Toning of Gluteal Muscles: A Multi-Center Efficacy and Safety Study

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ABSTRACT

Objective: Surgical intervention has been the only method to improve the aesthetic appearance of buttocks apart from physical exercising. This study evaluates the efficacy of high intensity focused electro-magnetic (HIFEM) treatments as a non-invasive solution for improvement of buttocks through toning and lifting of gluteal muscles.

Materials and Methods: A total of 75 patients (aged 22-59) were treated using a device with HIFEM technology which stimulates gluteal muscles (EMSCULPT, BTL Industries, Boston, MA). The protocol included four 30-minute treatments. Patients' weight was monitored throughout the study. Standard photographs were taken at the baseline, after the 4th treatment, and at the 1-month follow-up. Two 7-point Likert scale questionnaires were used to evaluate patients' buttock and treatment satisfaction. Total score of buttock satisfaction was calculated as a sum of all individual questions to reflect the overall perception of patients' buttocks. The level of comfort during procedures was assessed on a visual analog scale (VAS).

Results: The overall buttock satisfaction score (range, 4-28) of all subjects improved from 13.1±5.7 at baseline to 18.4±5.2 after the treatment and 18.9±5.1 at follow-up. For subjects with initial buttock dissatisfaction the scores improved from 8.7±1.6 to 16.3±3.1 after the treatment and to 17.3±3.1 at follow-up. The average score of all treatment satisfaction questions (range, 1-7) was 5.2±1.2 immediately after the treatments and 5.1±1.3 at follow-up. In total, patients initially dissatisfied with the appearance of their buttocks reported a significant 85% improvement after the fourth treatment. Immediately after the fourth treatment, all the subjects reported that their buttocks felt more lifted and toned. Results were maintained at one-month follow-up. Weight of the patients didn't change significantly. Digital photographs showed aesthetic improvements of the buttocks for most of the patients. No adverse events were reported.

Conclusion: The results show that the investigated device safely and effectively improves the aesthetic appearance of buttocks non-invasively. The treatments not only resulted in a significant visual improvement but also increased patient confidence and satisfaction. The procedure is suitable for patients seeking improvement in tone, shape, lift, and tightness of the buttocks.

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INTRODUCTION

The popularity of surgical butt lifting, and augmenting procedures is rapidly growing. Since 2015, the number of performed procedures increased on average by 25% each year,¹ while the increase over the past two decades totals 342%,² with the total expenditures for these type of procedures reaching 120 million USD in 2016.² The most popular methods are represented by buttock augmentation using silicone implants, autologous fat grafting, and a traditional butt lift done by cutting out an ellipse of excess skin and suturing

the remaining skin back together. In general, these procedures are associated with one to four weeks of downtime.²

Surgical procedures are associated with risk of complications. The rate of complications related to buttock augmentation using silicone implants were reported to be as high as 21.6%³ and 38.1%,⁴ while for autologous fat grafting complications were reported to occur in 9.9% of all cases.³ The most common complications are wound dehiscence, seroma, and infection.³ Further-

FIGURE 1. A photograph of a patient during an ongoing treatment.

more, all surgical procedures focus on artificially increasing the subcutaneous volume of buttocks, yet they do not target the underlying gluteal muscles, which play a crucial role in the buttock shape definition and overall aesthetic appearance of buttocks.

Magnetic stimulation has been widely and successfully used before, eg, in the treatment of incontinence by strengthening the pelvic muscles,⁷ in cough restoration,⁸ or in augmentation of resistance training.⁹ This study investigates the efficacy and safety of a high-intensity focused electro-magnetic (HIFEM) technology (EMSCULPT, BTL Industries, Boston, MA) when used for non-invasive improvement of the appearance of buttocks. The device delivers magnetic impulses into the tissue where it stimulates the gluteal muscles (gluteus maximus, medius, and minimus) and induces supramaximal contractions of all these muscle groups simultaneously. The muscle tissue is forced to adapt to the supramaximal load, which then leads to muscle hypertrophy and hyperplasia.^{5,6} As a result, the gluteal muscles responsible for the aesthetic appearance of buttocks increase in size and become firmer. This application has been shown to lead to an improvement of buttock shape.

MATERIALS AND METHODS

In total, 76 subjects (74 females and 2 males) participated in the study. The age of recruited subjects ranged between 22 and 59 years (average, 36.6±8.3) with average BMI 21.5±2.2 kg/m². The participants received bilateral treatments of buttocks with a novel device based on the HIFEM technology (EMSCULPT, BTL Industries, Boston MA). The therapy protocol consisted of 4 treatment sessions which were spaced by 2-3 days, each session including 30 minutes of application. During the treatment, subjects were placed in a prone position and the applicator of the device was placed over the buttocks to simultaneously affect all the gluteal muscles as seen in Figure 1. A fixation belt was used to avoid any movements of the applicator during the treatment. The output intensity was kept just below each patient's tolerance threshold in order to maintain the supramaximal contractions throughout the entire treatment.

Patients were evaluated at the baseline, after the last treatment, and at 1-month follow-up. Digital photographs of the treated area were taken, and patients' weight were measured as a control indicator. Two different non-standardized questionnaires based on 7-point Likert scales were used to assess the effects of the treatment. The buttock satisfaction questionnaire focused on measuring if the treatments can change the way patients perceive and/or think about the appearance of their buttock area. The total possible score ranged from 4 points (lowest possible satisfaction) to 28 points (highest possible satisfaction). See Table 1. The responses were compared between the baseline, post-treatments, and the follow-up. After the last treatment and at the follow-up, the second questionnaire was used to evaluate patients' satisfaction with the results of the treatments. See Table 2. Average scores were calculated, and a paired t-test was used for statistical analysis.

A visual analogue scale (0-10) was used to assess the level of comfort during the treatments. Any side effects or adverse events were monitored.

RESULTS

In total, 75 subjects (73 females and 2 males) completed the full treatment protocol; four subjects withdrew before the follow-up for reasons unrelated to the study. The results presented herein thus include data from 71 subjects.

FIGURE 2. Patient photographs at the baseline (left) and 1-month post 4 treatments (right). Female, 31 years old.**FIGURE 3.** Patient photographs at the baseline (left) and 1-month post 4 treatments (right). The demarcation line shows the improvement and lifting of the gluteal fold.

The average buttock satisfaction scores significantly improved ($P<0.01$) after the last treatment and at the one-month follow-up, both when measured as a total and individually for each question. The total average score increased by 40.5% from 13.1 ± 5.7 at the baseline to 18.4 ± 5.2 post-treatments, and further improved to 18.9 ± 5.1 at the follow-up. The most significant improvement was seen in patients who were initially dissatisfied with the appearance of their buttocks prior to the treatments, with the average score increasing by 83% from 8.7 ± 1.6 to 16.3 ± 3.1 after the treatment, and on to 17.3 ± 3.1 at the follow-up. See Table 1.

Statistical analysis of the results revealed that 69% of patients who initially reported buttock laxity improved to a higher degree of buttock tightness post-treatments and at the follow-up. In total, 85% of the patients initially dissatisfied with the appearance of their buttocks reported a significant improvement immediately after the fourth treatment, which was maintained over the course of one-month follow-up. Furthermore 80% of the patients initially dissatisfied with the shape of their buttocks reported a significant improvement immediately after the fourth treatment and during the follow-up. 79% of patients with low confidence while wearing the bikini at baseline felt significantly more confident after the fourth treatment and continued to feel confident during one-month follow-up.

In the patient satisfaction questionnaire, 76% of patients reported that the appearance of their buttock area has been improved after the treatments and during the one-month follow-up, while

80% of all the patients reported that their buttocks felt more lifted and toned right after the fourth treatment as well as at the follow-up. In total, 71% of all patients were satisfied with the treatment results immediately after the fourth treatment as well as during the one-month follow-up. The average scores can be seen in Table 2.

Patients found the treatments comfortable with an average VAS score of 2.01 (corresponding to none or very mild discomfort).

The analysis of weight did not show significant changes. No adverse events were observed during the treatments nor as a consequence of the treatments. Digital photographs showed improvements in aesthetic appearance of the buttocks. See Figures 2 and 3 for examples of patient images.

DISCUSSION

As of today, there are no standardized measurement tools that could be used for evaluation of a non-invasive improvement of buttocks. This can primarily be attributed to the fact that most currently used methods are surgical by nature. The study presented focused mainly on the evaluation of the subjective perception of the treated patients. This subjective satisfaction assessment was then further supported by visual improvement captured in digital images.

The results show a statistically significant positive trend in all of the measured criteria. This suggests that the treatments can have a positive effect on the way patients perceive the ap-

TABLE 1.

Buttock Satisfaction Questionnaire Results					
Question (Score range, 1-7)	Baseline	After	Change	1M FU	Change
Please rate your subjective perception of your buttock laxity/tightness ¹					
Total (n=75)	3.4±1.6	4.6±1.5	+1.2 ($P<0.01$)	4.8±1.3	+1.4 ($P<0.01$)
Baseline score <4 (n=42)	2.2±0.7	4.0±1.6	+1.8 ($P<0.01$)	4.5±1.4	+2.3 ($P<0.01$)
I am satisfied with the overall aesthetic appearance of my buttocks ²					
Total (n=75)	3.2±1.5	4.8±1.3	+1.6 ($P<0.01$)	5.0±1.5	+1.8 ($P<0.01$)
Baseline score <4 (n=46)	2.2±0.7	4.4±1.5	+2.2 ($P<0.01$)	4.6±1.6	+2.4 ($P<0.01$)
I am satisfied with the shape of my buttocks ²					
Total (n=75)	3.4±1.6	4.7±1.6	+1.3 ($P<0.01$)	4.9±1.4	+1.5 ($P<0.01$)
Baseline score <4 (n=45)	2.3±0.7	4.1±1.6	+1.8 ($P<0.01$)	4.5±1.5	+2.2 ($P<0.01$)
I feel confident about my buttock area when wearing the bikini ²					
Total (n=74)	3.1±1.6	4.4±1.5	+1.3 ($P<0.01$)	4.3±1.6	+1.2 ($P<0.01$)
Baseline score <4 (n=48)	2.0±0.7	3.8±1.4	+1.8 ($P<0.01$)	3.7±1.6	+1.7 ($P<0.01$)
Total score	13.1±5.7	18.4±5.2	+5.3 ($P<0.01$)	18.9±5.1	+5.8 ($P<0.01$)
Total score (Baseline score < 4)	8.7±1.6	16.3±3.1	+7.6 ($P<0.01$)	17.3±3.1	+7.2 ($P<0.01$)

¹ 1 – Very loose, 2 – Moderately loose, 3 – Slightly loose, 4 – Neither loose/tight, 5 – Slightly tight, 6 – Moderately tight, 7 – Very tight.

² 1 – Strongly disagree, 2 – Disagree, 3 – Slightly disagree, 4 – Neither agree/disagree, 5 – Slightly agree, 6 – Agree, 7 – Strongly agree.

TABLE 2.

Treatment Satisfaction Questionnaire Results		
Question (range, 1-7) ¹	After	1-month FU
The appearance of my buttock area has been improved after the treatments	5.0±1.4	5.2±1.4
My buttocks feel more lifted and toned after the treatments	5.3±1.3	5.2±1.4
I am satisfied with the treatment results	5.2±1.3	5.1±1.4
I would recommend the treatment to a friend	5.1±1.5	4.9±1.5
AVERAGE SCORE	5.2±1.2	5.1±1.3

¹ 1 – Strongly disagree, 2 – Disagree, 3 – Slightly disagree, 4 – Neither agree/disagree, 5 – Slightly agree, 6 – Agree, 7 – Strongly agree.

pearance of their buttocks, their level of confidence and overall satisfaction.

For the analysis of subjects' buttock satisfaction, the data was adjusted for patients who initially had a negative perception of their buttocks (score <4) as this would likely be the primary target group of the treatments. This group showed greater improvements than the total study population, which suggests that this sub-group of initially dissatisfied patients are the ideal profile that can most benefit from the treatments.

Visual inspection of digital photographs showed visible aesthetic improvement in most patients. The best results were seen in patients with lower BMI and in patients who reported a more active lifestyle. However, patient expectation management is crucial as the changes to the buttocks should not be compared to any surgical intervention. Rather than large volume augmentation, the patients in this study showed a lifting effect coupled with an improvement in their gluteal folds, as well as an increase in the overall buttock tightness. We thus suggest that the investigated device should not be considered a replacement for a surgical butt lift procedure yet brings a new alternative to patients seeking more toned and athletically appearing buttocks.

CONCLUSION

The EMSculpt device proved to be effective and safe for non-invasive improvement of the aesthetic appearance of the buttocks. Future research should focus on bringing more evidence based investigational methods for the evaluation of non-invasive buttock treatments.

DISCLOSURE

Carolyn Jacob MD and Brian Kinney MD are medical advisors for BTL. Mariano Busso MD and Suneel Chilukuri MD are speakers for BTL. The other authors have no financial interest to declare in relation to any of the products or device mentioned in this article.

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