ORIGINAL ARTICLE



Abdominal body shaping using StarFormer high-intensity magnetic stimulation—A case series

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Funding information

No funding.

Abstract

Background: Magnetic stimulation of muscles has become a popular method for muscle toning and strengthening.

Aims: The aim of this case series was to investigate safety and effectiveness of a novel magnetic stimulation device.

Methods: The patients received 10 sessions of high-intensity magnetic stimulation of their abdominal muscles. Change in muscle tone was determined by anonymous evaluation of photographs and using patient satisfaction questionnaires before treatment and 10 weeks following the last treatment session. Weight and waist circumference were also measured before treatment and at the 10-week follow-up.

Results: Blinded evaluation of photographs has shown improvement of the appearance of abdominal muscles. Patient satisfaction was high. The patients also experienced a reduction in their waist circumference, while their weight did not significantly change.

Conclusions: The treatment using the StarFormer[®] high-intensity magnetic stimulation is an effective and noninvasive method for abdominal body shaping, which is safe and comfortable to the patients and results in high patient satisfaction and an objective improvement in abdominal body shape appearance.

KEYWORDS

aesthetic effects, body image, patient satisfaction

1 | INTRODUCTION

Lean and muscular body represents the ultimate symbol of health and beauty in modern society. Although exercise and healthy eating habits are the traditional and safest way to maintain a fit and firm body, today's sedentary and fast-paced lifestyle leads many people to search for faster and easier solutions to help them achieve their desired lean shape, while avoiding invasive procedures, such as liposuction.

Recently, there has been a surge in the application of energy-based devices to achieve noninvasive body shaping—the demand for noninvasive body sculpting procedures has risen more than 5x since 2012. Noninvasive body shaping procedures include nonsurgical procedures aimed at changing the body's appearance through modifying its size or shape. Body shaping procedures can achieve their goal by (a) tightening of the skin, (b) decreasing the subcutaneous fat layer, (c) increasing the subcutaneous muscle mass, as well as combinations of the 3 mechanisms

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mentioned above. Several noninvasive energy-based devices for body contouring have become available on the market in recent years—these include devices that work by thermal skin tightening and transdermal subcutaneous fat destruction—lasers, radiofrequency devices, and high-intensity focused ultrasound devices, cryotherapy devices that work by fat destruction through apoptosis induction in fat cells by freezing, and muscle stimulation devices that are aimed at increasing muscle mass, as well as indirect decrease in subcutaneous fat.²

The magnetic stimulation body shaping devices have been gaining popularity in the last decade. They share the equivalent mechanism of action with transcutaneous electrical muscle stimulation—high-frequency activation of motor neurons and consequential muscle contractions, which result with an increase in muscle size and strength. The important advantage of magnetic over electrical muscle stimulation is that it is less painful, penetrates deeper into the tissue, and does not require direct contact with the patients' skin—it can be also used over clothes. 4

The aim of this prospective case series was to investigate safety and effectiveness using a novel device (StarFormer) using high-intensity Tesla magnetic stimulation (HITS™) technology for abdominal muscle toning, shaping, and strengthening.

2 | METHODS

Eight participants (4 men and 4 women) took part in the clinical study, with a mean age of $33.25 (\pm 0.31)$ years.

The study has been performed in accordance with the Declaration of Helsinki; it was approved by an ethical committee; and all patients signed a specific informed consent.

The patients received 10 sessions of high-intensity Tesla magnetic stimulation (HITS™), using the StarFormer® device (Fotona, Slovenia). The intensity of the treatments can be varied from 2 to 100% of total intensity. During the course of the treatment, the intensity is increased up to the individual tolerability level of each participant. The treatment was 30 minutes long, with several steps including different frequency modulations in order to achieve stimulation of different muscle fibers. The sessions were done 3×/week for total of 3.5 weeks.

All participants were weighed at baseline and at the 10-week follow-up to check for potential changes in body weight that could affect the final visual result. Waist circumference was measured at baseline and at follow-up 10 weeks after the last treatment session. Waist circumference was measured at the level of anterior superior iliac spine (ASIC) as well as 3 cm above ASIC and 3 cm below ASIC.

Patient satisfaction was recorded using an original questionnaire, which asked the patients to rate their improvement of abdominal body

shape appearance and strength following the treatment on a 1–5 scale (1 = none; 2 = low; 3 = moderate, 4 = high, and 5 = very high).

All patients were photographed in a professional studio using professional lighting, under standardized conditions. The randomized photographs were evaluated using Global Aesthetic Improvement Scale (GAIS), as shown in Table 1, by 5 blinded evaluators. The blinded evaluators received randomized sets of before and after photographs. All evaluators had to firstly state which photograph was taken at baseline and which at the follow-up session, and then to determine the level of the improvement of the after photograph using the GAIS.

Anonymized data were entered into a spreadsheet and analyzed using standard spreadsheet software (Microsoft Excel, USA) and statistical software for descriptive and comparative statistics (Prism, GraphPad, USA).

3 | RESULTS

Average weight change from baseline at the 10-week follow-up was -0.31 kg, which was not statistically significant (p = 0.53). There was a significant decrease in waist circumference as compared to baseline, at all three measured locations (Table 2).

Digital photographs (Figure 1) were randomized—the evaluators first had to guess which image is before and which after (the order was random) and then had to assign a GAIS score to the image they have evaluated as the "after" image. Blinded evaluators had an average agreement rate of 80%. The average improvement grade of the whole case series was 1.375 ± 0.52 (Figure 2) on the GAIS (Table 1), indicating an overall improvement, as evaluated from digital photographs. Improvement was seen in all patients, while none of the patients were assessed as not changed or worsened.

The responses from the patient questionnaire indicated high patient satisfaction. The patients perceived strong muscle contractions and have seen improvement in muscle strength and abdominal body shape (4.125 and 4.375 average on a 1–5 scale, respectively) (Figure 3). All patients indicated readiness to repeat the sessions and would also recommend the treatment to others.

There were no reported adverse events during or after the therapy.

4 | DISCUSSION

We show here that treatment using the StarFormer® high-intensity magnetic stimulation is an effective and noninvasive method for abdominal body shaping, which is safe and comfortable to the patients and results in high patient satisfaction and an objective improvement in abdominal body shape appearance.

TABLE 1 The Global Aesthetic Improvement Scale, as used in blind evaluation of photographs

Score	Rating	Description	
3	Very much improved	An excellent corrective result	
2	Much improved	Marked improvement of the appearance	
1	Improved	Improvement in the appearance, better compared with the original condition	
0	No change	The appearance substantially remains the same compared with the original condition	
-1	Worse	The appearance has worsened compared with the baseline condition	

TABLE 2 Weight and waist circumference change

		Waist circumference change (cm)		
Patient #	Weight change (kg)	ASIC-3cm	ASIC	ASIC+3cm
1	0.3	-0.6	-1.3	-1.7
2	0.4	-3.2	-4.8	-5.5
3	1.7	-1.5	3-2.6	-2.2
4	-1.8	-3.3	-2.9	-2.5
5	-1.8	-3.3	-2	-3.5
6	0.8	-1.5	-1.6	-1.4
7	-1.9	-5.9	-4.1	-5.5
8	-0.2	-3.2	-1.5	-3.2
Average	-0.32	-2.8125	-2.6	-3.1875
Paired t-test	p = 0.53	p < 0.001***	p < 0.001***	p < 0.001***

Note: The Student's *t*-test was used to compare follow-up to baseline values; *p*-value lower than 0.05 was considered statistically significant. The paired Student's *t*-test was used to evaluate statistical significance.

This is the first published study on abdominal muscle toning using this particular device; however, prior studies using equivalent technologies have shown similar effects. 5-10

The visual improvement in abdominal muscle toning and body shape, as determined by blinded evaluators, was evident in all patients. The quantity of improvement, as evaluated by blinded evaluators was 1.375 on the GAIS (Table 1).

Photographic analysis in previous studies using similar methods showed detectable esthetic improvement after magnetic muscle stimulation in approximately 80% or more of treated patients. 6,7,11 Photo evaluation using the identical 5-point GAIS as in the current study showed a very similar improvement score of 1.5 ± 0.7 at the 3-month follow-up.

The visual improvement was also positively rated by the patients themselves. Patients were very satisfied with their visual improvement in abdominal body shape (4.1 on a 1–5 scale) and would unanimously repeat the treatment and also recommend it to others (Figure 3). Two previous studies also reported on how the esthetic improvement was evaluated by the patients, according to a 7-point scale, and have shown long-term reported improvement in 66–72% of patients.^{8,11}

Besides the visual improvement, there was also a significant decrease in waist circumference (up to 3 cm on average), which was seen in all patients, and was not connected to weight loss. Similar waist circumference reduction after abdominal magnetic stimulation was reported in previous research. 6.11-13

We can deduct from previously published papers that the change in visual appearance is due to both increase in muscle thickness and decrease in the subcutaneous abdominal fat, which could be the reason behind the overall waist circumference reduction. Several previously published papers have used different imaging methods (ultrasound, CT, and MRI)^{6,9,10,13,14} to show the decrease in the subcutaneous fat layer thickness following muscle stimulation. This effect is probably due to the indirect effect on subcutaneous fat tissue layer due to increased metabolic fat catabolism caused by intensive muscle contractions.

Limitations of this study include a small number of patients and a relatively short follow-up period. More studies including objective measures are needed for further evaluation of this technology.

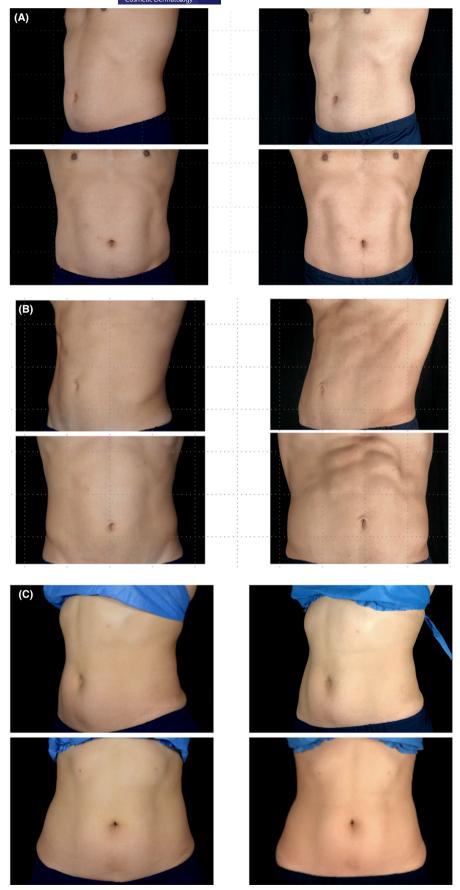


FIGURE 1 (A) Before (left) and after (right) digital photographs of representative Patient No 3. The patient was highly satisfied with the results, and the five blinded evaluators have also evaluated the after image as much improved (median interevaluator GAIS of 2). (B) Before (left) and after (right) digital photographs of representative Patient No 2. The patient was highly satisfied with the results, and the five blinded evaluators have also evaluated the after image as much improved (median interevaluator GAIS score of 2). (C) Before (left) and after (right) digital photographs of representative Patient No 7. The patient was highly satisfied with the results, and the five blinded evaluators have also evaluated the after image as improved (median interevaluator GAIS score of 1)

Blind evaluation of aesthetic improvement using GAIS scale

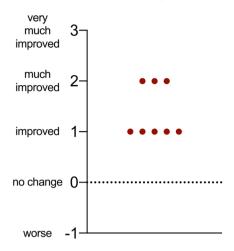


FIGURE 2 Median interevaluator scores from five blinded expert evaluators

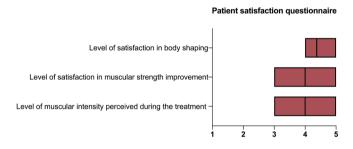


FIGURE 3 Patient satisfaction questionnaire. The upper graph shows box plots with mean, minimum, and maximum; the bottom graph shows individual patient's answers

5 | CONCLUSION

HITS™ magnetic stimulation seems to be an effective and safe method for muscle toning and body shaping, resulting with visible improvement and very high patient satisfaction rates.

CONFLICT OF INTEREST

The author declares no conflict of interest.

ETHICAL STATEMENT

All procedures performed in studies involving human participants were in accordance with the ethical standards of the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

PATIENT CONSENT

All patients signed the informed consent form after understanding the nature of the trial.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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How to cite this article: Valdivia R. Abdominal body shaping using StarFormer high-intensity magnetic stimulation—A case series. *J Cosmet Dermatol.* 2022;21:2021–2025. doi:10.1111/jocd.14808