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Research Article

Improving Core Muscle Strength, Physical Function, and Quality of Life in Postpartum women by consecutive noninvasive Abdominal and Pelvic Floor treatments with High-intensity focused electromagnetic and Radiofrequency devices

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ABSTRACT

Objective: Women's bodies undergo deleterious changes due to pregnancy. Regaining core muscle strength after childbirth is essential in managing pelvic floor disorders and abdominal separation. This study aimed to investigate the efficacy of abdominal HIFEM and synchronized RF with consecutive pelvic (standalone HIFEM) treatments for core muscle strengthening and improving quality of life postpartum.

Methods: Thirty-six female subjects (27-44 years, BMI 19.4 – 34.5 kg/m) were enrolled in case series study. The treatment schedule consisted of seven visits, four HIFEM+RF abdominal procedures spaced 5-10 days apart, and six standalone HIFEM pelvic floor procedures spaced 2-4 days apart. Both procedures were used consecutively at the first, third, and fifth treatment visits. The HIFEM+RF was applied prior to HIFEM-only treatments. The follow-up visits were scheduled one and three month's post-treatments. The primary evaluation included measuring the core strength (pressure biofeedback) and waist circumference. Patient satisfaction and comfort were documented.

Results: 32 patients completed the 3-month follow-up evaluation. Core muscle strength showed a +23.95% (+23.16±20.22 mmHg, $p<0.05$) increase at 1-month and +27.94 % (+25.67±26.96 mmHg, $p<0.05$) increase at 3-months follow-ups. Waist circumference reduced by -3.12±2.99 cm and -4.61±3.48 cm (p-value<0.001) at 1-month and 3-months follow-up. Patients found the treatments comfortable and painless (VAS=2.6). According to satisfaction questionnaires 97.0% of patients reported stronger core muscles (4.3±0.6), 94.0% of subjects felt a stronger pelvic floor (4.2±0.6), and 87.9% of subjects had improved physical performance during exercise 4.1±0.6). All patients stated they could perform daily routine without issue and spend quality time with their children (4.5±0.5). No adverse events or side effects were observed.

Conclusion: Three-month outcomes showed that the treatment regimen of consecutive HIFEM+RF and HIFEM-only procedures effectively improves core and pelvic floor strength, and function, through stimulation of abdominal and pelvic floor muscles. This resulted in improved patients' quality of life along with high satisfaction.

Keywords: Abdominal separation, Core strength, HIFEM, Radiofrequency, Non-invasive, Pelvic floor muscles, Postpartum, Abdominal circumference.

INTRODUCTION

Pregnancy and motherhood are cherished hallmarks of life, marking important personal milestones of maturity and family planning. Pregnancy, however, has psychological and physical effects on the female body. Several changes occur as the body naturally prepares to sustain a pregnancy [1, 2]. Furthermore, many anatomical and physiological alterations are deleterious to the musculoskeletal system, causing reduced/impaired functionality [3, 4].

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During pregnancy, the body's hormonal composition is altered as the ovaries and placenta produce relaxin and estrogen, which cause joint laxity in the pelvic floor [5-7]. The musculature of the abdomen is impaired as the *abdominis rectus* muscle separates at the midline (a persisting condition defined as diastasis recti that is present in more than 60% of pregnancies) [8]. The transversus abdominis muscle and core muscles are involved in spinal support, which is important to maintain intra-abdominal pressure (IAP; necessary for breathing, coughing, and continence), abdominal viscera and enable lumbopelvic support during locomotion [9, 10]. The abdominal and pelvic floor muscles work together, and their combined contraction can increase postpartum diastasis [11]. Current treatment methods include surgery, core stabilization exercises, biofeedback therapy [12-13], magnetic stimulation [15, 16], and electro stimulation modalities [17, 18].

Noninvasive administration of high-intensity focused electromagnetic (HIFEM) is a novel method developed to rehabilitate abdominal muscles and pelvic floor muscles (PFM). HIFEM noninvasively induces brain-independent concentric contractions referred to as supramaximal, lifting all PFM. Supramaximal contractions are of higher tension than maximum voluntary contractions and, therefore, cannot be achieved by voluntary muscle action. Radiofrequency promotes tissue neovascularization, safely induces apoptotic lipolysis of subcutaneous fat tissue and, in combination with HIFEM, significantly increases abdominis recti muscle thickness in the abdomen [19].

This study aimed to investigate the efficacy of abdominal HIFEM and synchronized RF with consecutive pelvic (standalone HIFEM) treatments for core muscle strengthening and improving quality of life in postpartum women.

METHODS

Study design

This was a prospective, single-arm, open-label, interventional case series study conducted at three sites. Thirty-six (n=36) female subjects (27-44 years old, BMI 19.4 – 34.5 kg/m^2) who had given birth within 6 to 60 months prior to enrolment in the study, aged over 22 years, were eligible for the study. Enrollment ran between 14 March 2022 and 13 June 2022. After providing written informed consent, subjects were screened, and those who fulfilled the selection criteria were enrolled. Participants were required to abstain from other treatments/procedures on the abdomen and pelvic floor during the study. In addition, subjects with drug pumps, electronic implants such as defibrillators, metallic intrauterine devices, patients after a recent surgery that might have affected muscle contraction, and expectant or nursing mothers were excluded. The study protocol and the subject consent form were approved by the Advarra institutional review board. This study is registered on clinicaltrials.gov (NCT05713864).

Study devices and treatment plan

Two devices were used in this study. The first device emits a standalone HIFEM modality through a chair applicator (EMSELLA, BTL Industries, Boston, MA). The patient sits upright on the chair while fully clothed during the 28-minute-long therapy.

The second device utilizes synchronized RF and HIFEM energies (Emsculpt Neo, BTL Industries, Boston, MA) delivered simultaneously. With the patient in a supine position on a medical table, the applicators were placed on the patient's abdomen and secured with a belt to maintain it for the 30-minute-long procedure.

The treatment schedule consisted of seven (7) visits, four (4) HIFEM+RF abdominal procedures spaced 5-10 days apart, and six (6) standalone HIFEM pelvic floor procedures spaced 2-4 days apart. Both procedures were used consecutively at the first, third, and fifth treatment visit. The HIFEM+RF was applied prior to HIFEM-only treatment (Table 1 shows a detailed treatment scheme). For both devices, the intensities of the HIFEM or RF were adjusted according to the patient feedback and tolerance throughout the treatment procedure (device settings from 0% to 100%). Two follow-up visits were scheduled at one month and three months post-final treatment.

Assessments

Primarily, the study objective was to determine abdominal and pelvic floor muscle performance by pressure biofeedback measurement (in millimeters of mercury, mmHg). The pressure biofeedback device (Stabilizer, Chattanooga Group Inc., Hixson, TN) has an air cell that compresses in response to muscle movements, changing the pressure and accurately measuring the corresponding body movement. The real-time feedback monitors the position of the lower back or cervical spine during muscle testing to determine if the patient can selectively isolate their abdominal and lumbopelvic core stabilization muscles. The measuring range is 0-200 mmHg analog pressure with an accuracy of +/- 3 mmHg pressure. Pressure biofeedback (PBF) was measured before treatment (baseline), after the final treatment session, and at the follow-up visits. Moreover, the impact of the treatment procedure on the subject's quality of life was assessed through the 5-point Likert scale Subject Satisfaction and Experience Questionnaire (SSEQ) after the last treatment and at the follow-up visits.

Secondarily, the toning effect of the abdomen was evaluated via waist circumferential measurement before treatment and at the follow-up visits. After the final treatment, patient satisfaction with the results and treatment comfort was evaluated using the Therapy Comfort Questionnaire (TCQ). Finally, blinded, independent reviewers evaluated the aesthetic improvement of the abdomen according to the Global Aesthetic Improvement Scale (GAIS) based on digital photographs obtained before treatment and at follow-up visits.

Statistical evaluation

Statistical analysis of the data sets employed descriptive summarization. The paired differences between the values of individual subjects were tested by using One Factor ANOVA

Table 1: The scheme of study treatments.

Study Device	Treatment Visit						
	1st	2nd	3rd	4th	5th	6th	7th
HIFEM only	X	X	X	X	X	X	
HIFEM+RF synchronized	X		X		X		X

Repeated Measures followed by Turkey HSD post-hoc test. The significance level α was set at 5% for all statistical tests.

RESULTS

From the 33 subjects, N=32 patients completed all treatment and follow-up visits (three subjects withdrew consent). The following Fitzpatrick skin photo types were represented: Type I (n=1), Type II (n=16), Type III (n=11), Type IV (n=4), and Type V (n=1). The patient's BMI did not change significantly ($p>0.05$) between baseline (25.17±3.45 kg/m^2) and 3 months follow-up (25.30±3.72 kg/m^2).

Pressure Biofeedback (PBF)

The average (i.e. mean) PBF at baseline was 106.33±18.49mmHg 95% CI [100.02, 112.64]. After the final treatment session (i.e. Visit 7) the average PBF had increased to 121.97±26.14 mmHg (+15.7%, $p<0.001$, CI 95% [113.06, 130.88]). At the 1-month and 3-month follow-up visits, the average PBF had increased to 129.50±19.43 mmHg (+23.95%, $p<0.001$, CI 95% [121.81, 137.19]) and 132.00±.20.22 mmHg (+27.94%, $p<0.001$, CI 95% [124.06, 139.96]), respectively (Figure 1).

Subject satisfaction and Experience questionnaire

According to a 5-point Likert-scale satisfaction questionnaire evaluated 3 months post-treatment, 97.0% of patients reported stronger core muscles (mean score 4.3±0.6), 94.0% of subjects felt a stronger pelvic floor (mean score 4.2±0.6), and 87.9% of subjects had improved physical performance during exercise (average score 4.1±0.6). Furthermore, 91.0% of patients reported being more comfortable in their clothes (average score 4.0±0.8). All patients (100%) stated they could perform daily routine/activities without issue and spend quality time with their children (average score 4.4±0.6).

The detailed results of the entire SSEQ with all nineteen criteria are shown in Table 2.

Waist circumference, Aesthetic improvement and Comfort

Before treatments, the average waist circumference was 89.48±9.06 cm CI 95% [86.34, 92.62]. Average waist circumference reduced by -3.12±2.99, CI 95% [2.08, 4.16] cm and -4.6±3.48 cm, CI 95%

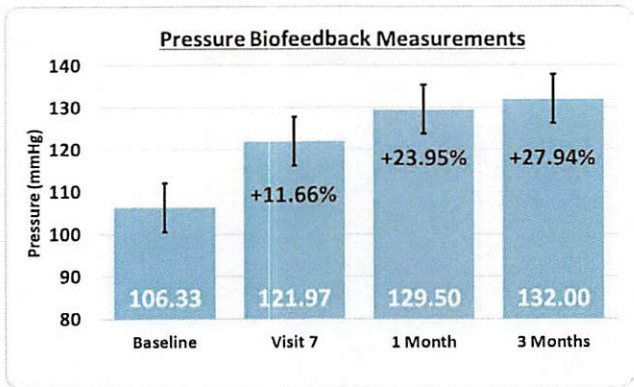

Figure 1: Detailed results of the pressure biofeedback (PDF) measurements with standard error bars depicted. The average (i.e. mean) PBF had significantly increased by +26.58 mmHg CI 95% [124.06, 139.95] (+25.21%) at 3 months post-treatment.

Table 2: Results of the Subject Satisfaction and Experience Questionnaire.

Criteria	Subjects in Agreement (N=33)
I feel I have a better posture after the treatments.	93.90%
My urinary incontinence has improved after the treatments.	84.89%
I feel that my core is stronger after the treatments.	97.00%
My workout performance improved after the treatments.	87.90%
My sexual performance has improved after the treatments.	78.80%
I am able to perform my daily activities without any issues after the treatments.	100.00%
My appearance has improved after the treatments.	84.90%
I feel more confident after the treatments.	91.00%
My pelvic floor feels stronger after the treatments.	94.00%
My pelvic floor feels tighter after the treatment.	91.00%
I can spend quality time with my child/children after the treatments.	100.00%
My back discomfort has improved after the treatments.	72.70%
I feel more comfortable in my clothes after the treatments.	91.00%
I feel more youthful after the treatments.	87.90%
I feel more intimate with my partner after the treatments.	81.80%
I am satisfied with the treatment outcomes.	94.00%
I would recommend this treatment to family and friends.	97.00%
My abdominal separation has improved after the treatments.	75.80%
I can get up easily from a lying-down after the treatments.	97.00%

[3.40, 5.82] (p-values < 0.001) at 1-month and 3-months follow-up, respectively. According to the Global aesthetic improvement scale, blinded reviewers' average scores indicated that 94% of subjects had improved by the 3-month follow-up visit (average score was 2 - *much improved*). Patients found the treatment procedures comfortable and painless. Response to the 5-point Likert scale question "I found the treatment procedure comfortable" was 4.03±0.87 on average indicating that subjects *agreed*. According to the Visual Analogue Scale (VAS), the average pain score was 2.6, inferring *little to no pain* associated with the treatments. No adverse effects occurred. Examples of patients' results can be seen in photographs - Figure 2 through Figure 4.

Figure 2 She had PBF increase of +10 mmHg (+11.76%), +25.00 mmHg (+29.41%), and +43.00 mmHg (+50.59%), respectively, after the last therapy session, at 1 month and 3 months follow-up. The patient strongly agreed that urinary incontinence, core strength, pelvic floor strength, and workout performance had improved. The patient had a circumferential reduction of -1.91 cm at 3 months follow-up.

Figure 3 She agreed posture, abdominal separation, core strength, sexual performance, and sexual intimacy with her partner had improved. She strongly agreed that pelvic floor strength improved and that she could perform daily activities without issue and spends quality time with her children after the treatments. The patient had a circumferential reduction of -0.76 cm at the 3 months follow-up. Photographs show at before (left, B) and 3 months follow up (right, A) results.

Figure 4 In her report, the patient strongly agreed that she could easily rise from a lying position, and had improved pelvic strength and tightness, core strength, and workout performance. Waist circumference reduction was -3.81 cm at 3 months post-treatment.

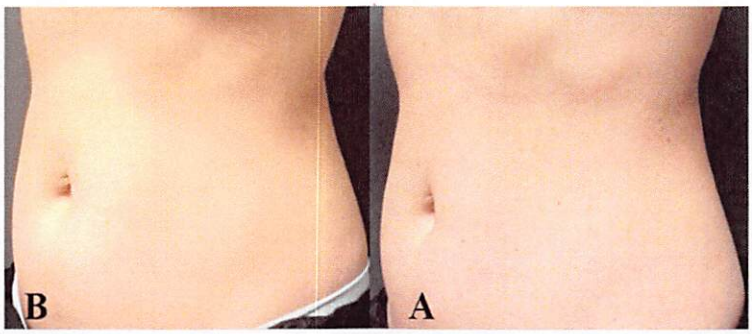

Figure 2: Patient 1 (40 years old, Skin Type III) at baseline (left, B) and 3 months follow up (right, A). She had PBF increase of +10 mmHg (+11.76%), +25.00 mmHg (+29.41%), and +43.00 mmHg (+50.59%), respectively, after the last therapy session, at 1 month and 3 months follow-up.

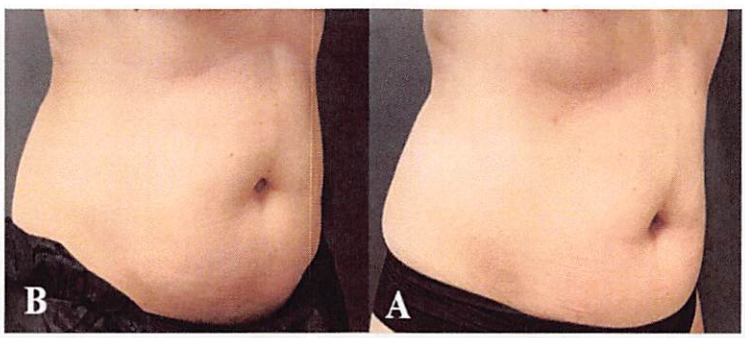

Figure 3: Patient 2 (33 years old, Skin Type III) showed a PBF increase of +15.33 mmHg (+15.54%), +12 mmHg (+12.16%) and +22.26 mmHg (+22.97%), after the last treatment visit, at 1 month and 3 months follow-up respectively.

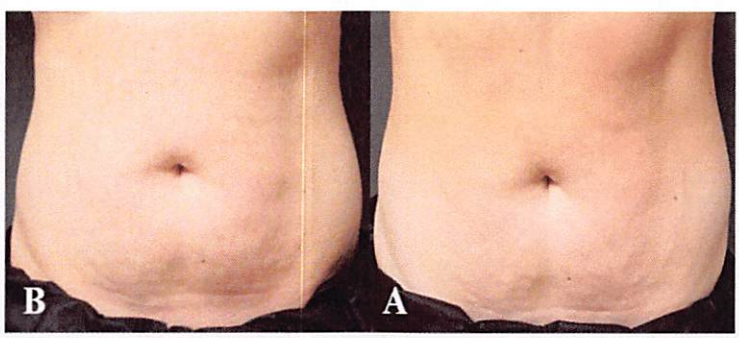

Figure 4: Patient 3 (31 years old, Skin Type III) at baseline (left, B) and 3 months after the final treatment (right, A). This patient's PBF had increased by +12 mmHg (+12.00%), +18.00 mmHg (+18.00%) and +30.00mmHg (+30.00%) after the last treatment visit, at 1 month and 3 months follow-up respectively.

DISCUSSION

Pelvic floor impairment and abdominal separation, characterized by poor core strength, is a health problem common in prim gravid and multiparous women. In addition, patients' quality of life is negatively affected as they cannot perform daily tasks or maintain a routine due to less physical activity and exercise, uncontrolled incontinence, and difficulty with sexual intimacy. The results of this study revealed a statistically significant ($p<0.001$) increase in core strength measured by pressure biofeedback, as well as an improvement in quality of life evaluated based on subject satisfaction and experience questionnaires, after consecutive treatment of abdominal (HIFEM+RF) and pelvic floor muscles (standalone-HIFEM).

Pelvic floor dysfunction (PFD) manifests characterized by urogynecological and colorectal symptoms (pelvic organ prolapse, incontinence, dyspareunia, paradoxical constipation) [20-22] and generalized problems such as spasms and lower back pain. Abdominal separation continues beyond childbirth and is present even in postmenopausal women. [23]PFD and abdominal separation are both related to the quality and functioning of the core muscle tissue, which provide support to the various internal organs while maintaining one's mobility. The PBF device provides biofeedback during muscle re-education. Previous research demonstrated that the synergetic co-activation mechanism of the *transversus abdominis*, internal oblique muscles, and PFM is insignificant in postpartum women, indicating altered motoric functions of muscles during gestation. [24-26] This herein investigation established a +27.9% pressure biofeedback increase three months post-treatment (Figure 1). Thus, it may be inferred from this study's outcomes, that the treatment plays an important role in supporting Valsalva maneuver (VM) execution, intra-abdominal pressure (IAP) and intrathoracic pressure (ATP) maintenance, as indicated by the observed PBF increase. Previous investigations that evaluated the effects of HIFEM treatments on women's abdominal muscle and fat tissue postpartum showed reduced abdominal separation, [27] increased *rectus abdominis* muscle thickness with standalone HIFEM or simultaneous HIFEM plus RF and reduced waist circumference [28, 29].

Noninvasive core strengthening may hasten the recovery process of parous women after various complications resulting from motoric, locomotive and mechanical changes. MV, IAP and ITP promote trunk stability, athletic performance and prevent injuries [30, 31]. This may offer parous women a faster post-gravid return to normal life and increased physical activity. Also, the treatments of female pelvic floor disorders represent an immense economic burden [32-34], thus novel techniques that are safe, and require no downtime are continuously being developed to restore health, functionality and increase productivity.

Reduced ambulation due to pain and discomfort drastically affects the time mothers can spend with their family and participate in sports or exercise, leading to poor social life and mental distress. Conversely, physical activity after childbirth promotes postpartum well-being and mental health [35-38]. To assess the treatment effect on the subject's quality of life, the SSEQ questionnaire was introduced, consisting of criteria represented in reliable surveys. In this study, subjects reported improved personal challenges of poor self-esteem and self-perception regarding appearance, sexual performance, and desirability during motherhood are counteracted by increased physical activity.

The therapy uniquely combines two devices that target different aspects of the muscle core, in an office-style procedure (patients may be fully clothed or in undergarments) and may be recommended for patients with reduced range of motion. Although this study faced some limitations due to a small sample size, a large subject set may improve the validity of outcomes, and a placebo or control arm may also be included in future research [39-41].

CONCLUSION

Outcomes indicated that the noninvasive treatment regimen of consecutive HIFEM+RF and HIFEM-only procedures effectively improves core and pelvic floor strength, and function, through stimulating abdominal and pelvic floor muscles in postpartum women. The enhanced function of the treated muscles resulted in improved patients' quality of life and high satisfaction.

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