ELECTROMYOGRAPHIC EVALUATION OF THE PELVIC MUSCLES ACTIVITY AFTER HIGH-INTENSITY FOCUSED ELECTROMAGNETIC PROCEDURE AND ELECTRICAL STIMULATION IN WOMEN WITH PELVIC FLOOR DYSFUNCTION

***SILANTYEVA ELENA**, MD, PhD, **ZARKOVIC DRAGANA**, MSc*
***SOLDATSKAIA RAMINA**, MD, **ASTAFEVA EVGENIIA**, MD, **ORAZOV MEKAN**, MD, PhD*

SUMMARY

Electromyography (EMG) effectively measures pelvic floor muscle (PFM) activity, revealing differences in muscle function in women with pelvic floor dysfunction (PFD). This study compares the efficacy of high-intensity focused electromagnetic (HIFEM) therapy and traditional electrical stimulation in treating PFD. Surface EMG and subjective assessments (Pelvic Floor Impact Questionnaire, PFIQ) were used to evaluate PFM strength, endurance, and relaxation changes. Results showed that HIFEM significantly improved muscle activation, relaxation, and endurance compared to electrical stimulation. The PFIQ scores also indicated a more significant improvement with HIFEM, suggesting it is more effective than electrical stimulation for restoring PFM strength and alleviating PFD symptoms. These findings highlight HIFEM's superior efficacy in PFM rehabilitation, offering a promising alternative for postpartum women and those with urinary incontinence or sexual dysfunction.

Keywords: Electrical stimulation, electromyographye HIFEM procedure, pelvic floor dysfunction; pelvic floor muscles

INTRODUCTION

Electromyography (EMG) is a method frequently used to examine the electrical activity of muscle tissue. Although this technology is relatively new, it is assumed to be reliable and objective while causing minimal or no discomfort to patients. Essentially, EMG uses the surface or intramuscular electrodes to record the intensity of signals propagating in the muscle fibers during the contraction because muscle tissue conducts electrical potentials similar to the nerves. The results of the measurements are expressed as a function of voltage over time. Except for single-fiber EMG, one

measured value represents a sum of all signals originating from the muscle tissue of a specific body area.[2-4]

Besides ultrasound,[5,6] magnetic resonance,[7] manometers,[8] dynamometers,[9] or simple palpation combined with observation,[10] surface EMG (sEMG) is one of the possible objective methods for monitoring resting level, strength, and endurance of the pelvic floor muscles (PFMs). The pelvic floor consists of 3 main compartments – anterior (bladder and urethra), middle (vagina and uterus), and posterior (rectum). Furthermore, there are morphologically complex multilayers of anatomical structures such as the pelvic diaphragm (composed of the levator ani and coccygeus muscles), urogenital diaphragm (consisting of connective tissue, perineum, bulbospongiosus, and ischiocavernosus muscles), and urethral/anal sphincters. These tissues are arranged in the pelvic area and have multiple attachments to the surrounding structures.[1] Under normal circumstances, the PFM prevents multiple disorders such as incontinence (urinary/fecal), sexual dysfunction, or pelvic organ prolapse accompanied by pain and discomfort. However, the atrophy and relaxation of PFMs may promote the manifestation of these health issues, collectively referred to as pelvic floor dysfunction (PFD),[10-12] occurring naturally with ageing or as a consequence of childbirth. Recording of sEMG in women who showed specific symptoms of PFD was reported previously by multiple authors. It has been found that EMG is a suitable method for the investigation of PFM functioning among healthy subjects and women with signs of urinary incontinence or PFM weakness.[13-21] Despite the various protocols and electrode configurations used, there is a clear relationship between the characteristics of the EMG signal and PFD. In comparison with the healthy and asymptomatic subjects, postmenopausal and even premenopausal women affected by some form of PFM impairment show distinctively lower EMG values. The intensity of maximum voluntary contraction (MVC) is reduced because the PFMs are weakened, and the endurance of contraction and muscle activity during rest are also affected.[13,14,18-20] Aside from sEMG, various subjective questionnaires (Pelvic Floor Disability Index, Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, Pelvic Floor Impact Questionnaire, International Consultation on Incontinence Questionnaire Vaginal Symptoms or Pelvic Floor Bother Questionnaire) were also used to document strengthening and reeducation of the PFM which helped patients to improve their symptoms.[22,23] Besides regular exercise,[24] the function of the weakened PFM can be enhanced by noninvasive PFM stimulation. With well-established electrical stimulation,[25,26] high-intensity focused electromagnetic (HIFEM) technology has been more frequently used in recent years.[27-29] Both technologies deliver electric currents into the pelvic floor to depolarize membranes of motoneurons to elicit action potential and achieve brain-independent muscle contractions when the action potential of sufficient strength reaches the neuromuscular junction.[30] However, despite the direct flow of electric charge through the electrode-tissue surface, the HIFEM induces electrical currents selectively in the PFM by the mechanism of electromagnetic induction.[31] As the magnetic field passes any medium without energy attenuation, the induced contractions may be achieved at greater depths and intensities[32] to provide better outcomes. Based on the previous rationale, this study aims to investigate and compare treatment outcomes of the HIFEM procedure and electrical stimulation in women suffering from PFD. The expected changes in PFM activity would be examined by subjective (Questionnaire) and objective (sEMG) methods. The measured values will be compared with asymptomatic subjects.

MATERIALS AND METHODS

Patient's Recruitment Criteria

The inclusion criteria were specified as follows: women of age 18-45 years, who had a vaginal delivery, and who already stopped lactation. There were three patient groups. The symptomatic patients who reported PFD symptoms related to weakened PFM as lower urinary tract or bowel symptoms (incontinence) and/or sexual dysfunction (dyspareunia, vaginal laxity, decreased sensitivity during intimacy, inability to achieve orgasm – anorgasmia) were randomly (2:1) divided into the G1 group treated by HIFEM and G2 group which received electrical stimulation. The third group, G3, consisted of healthy postpartum patients to obtain sEMG values of the normal population. Exclusion criteria were the presence of any metal implants or devices, which include metal components, pregnancy, malignant tumor, history of surgical procedure in the pelvic region, presence of pelvic organ prolapse of stage II-IV as per the Pelvic Organ Prolapse Quantification classification, and all general contraindications for physiotherapy. Patients were asked to perform pregnancy tests before the first treatment and then retest regularly.

Considerations

This study was approved by the local ethics committee of Hospital Lapino (MD medical group). It complied with ethical principles stated in the Declaration of Helsinki, Convention on Human Rights and Biomedicine, and International Ethical Guidelines for Health-related Research Involving Humans, and it completely excludes impairment of patients' interests and damage to health. All subjects were informed about the study's potential risks and possible benefits, and all participants provided written informed consent.

Treatment Protocol

Both intervention groups received ten treatments in total addressing the stimulation of PFM. The G1 group was treated using a BTL EMSELLA (BTL Industries Inc, Boston, MA) device, which uses HIFEM technology for noninvasive PFM stimulation and reeducation based on the principle of electromagnetic induction. The device consists of a generator connected to the chair where the stimulation coil is located. The coil emits a focused magnetic field of intensities up to 2.5 Tesla, responsible for the induction of muscle contraction up to depths of 10 cm. Each therapy with the BTL EMSELLA device lasted 28 minutes and was administered under a skilled physician's supervision at the Lapino Hospital. Patients were seated in a chair, and the intensity of the stimulus was modulated on the scale of 0-100% (0-2.5 Tesla) by their feedback up to the maximum tolerable threshold when patients felt a strong muscle contraction but without pain or discomfort. All patients have achieved 100% intensity during the first or second procedure. Treatments with HIFEM were addressed 2-3 times per week for four weeks. The sessions were planned to suffice this interval per the patient/device availability. Two consecutive treatments were spaced at least 48 hours apart to prevent muscle fatigue. The G2 group performed home-based and self-administered procedures with a BioBravo (MTR Vertriebs, GMBH, Germany) electrical stimulation device:

1. The patients were comprehensively trained to safely and effectively use a BioBravo stimulator.

2. They were instructed to finish treatments at home by repeating therapy every other day. The stimulation protocol was identical for both groups because the settings of the BioBravo device were adjusted to reflect those used by the BTL EMSELLA device.
3. Group G3 did not receive any treatment.

sEMG Measurements

The study's primary outcome was to perform sEMG measurements to determine the activation of the PFM in symptomatic and asymptomatic patients and to document the hypothesized changes caused by muscle strengthening. At first, by using a Myomed 632 myofeedback device (Enraf-Nonius B.V., Netherlands), the patients were instructed on how to correctly perform contractions of the PFM without (voluntary) involving the muscles of the anterior abdominal wall and gluteal or hip region. When performing contractions, patients were lying in the supine position. During the examination, they were requested to repeat three specified PFM activations, which consisted of the following: five short (quick flick) contractions at maximum intensity with an interval of 10 seconds, followed by sustained contractions and relaxation (both 10 seconds long, five repetitions) and finally the sustained contraction held as long as possible to determine PFM endurance.[33] The sEMG recordings were performed by the Myomed 632 device at the baseline (all groups) and after the patient's last treatment (only G1 and G2). To isolate the signal originating in the PFM, two types of superficial electrodes were used: the first was applied on the anterior abdominal area (served as reference), and the second (vaginal) electrode was mounted on the intravaginal probe. The neutral gel was always applied on the sensor introduced into the vagina. An experienced physiotherapist confirmed the correct placement of the intravaginal probe and PFM contractions. Concurrent registration of muscular electric potential by using the vaginal and skin electrodes allowed differentiating PFM contractions. During the sEMG examination, myofeedback (in the form of a graph) was displayed on the device's monitor and the external monitor unit connected to the device to enlarge the graphic output. The sEMG measurements were performed automatically by the Myomed device, following the pattern of PFM activations described above. These parameters were acquired for each patient during each visit: MVC, mean MVC, mean activity at rest/resting level (all in mV), and endurance of contraction (in seconds).

Standardized Questionnaire

The secondary outcome was to assess subjective changes in the perception of PFD by the PFIQ-7. This standardized Questionnaire was used to determine the impact of PFD on the patient's quality of life, as it was shown to be psychometrically valid and reliable in previous research.[34] Patients from groups G1 and G2 were given the PFIQ-7 at baseline and after the last treatment. Based on their answers, the PFIQ mean scores (on a scale from 0 = no distress to 300 = maximal distress) were calculated and compared against baseline and between both groups.

Safety

The safety of treatments, sEMG measurements, and possible adverse events (AEs) were monitored. Patients were also asked to report any signs of discomfort or pain during the therapies or caused by the positioning of the intravaginal electrode.

Statistical Analysis

All variables were checked for normality using the Kolmogorov-Smirnov test. Descriptive statistics were estimated by the sample mean with a 95% confidence interval. The differences between groups were tested using an analysis of variance test followed by Least Significant Difference post hoc tests. Levene's variance homogeneity test was run before variance analysis to verify the equal variances in groups. A student's t-test tested paired variables. All statistical tests were 2-tailed. A whole statistical analysis was conducted with Statistica v.6 (StatSoft Inc, Tulsa, OK), and the significance level was set as default to 0.05 (5%). Initially, the minimum sample size was verified by using Statistica software. At least 19 subjects must have been included in the three tested groups to achieve a power of 80% with a = 5%.

RESULTS

Patient Group Characteristics

In total, 95 patients were recruited between 2018 and early 2019 following the specified criteria and the current state of patients in the clinic: G1 (n=50), G2 (n=25), and G3 (n=20). See Table 1 for detailed characteristics of patient groups. All recruited patients from the G1 and G2 groups finished a prescribed number of treatment sessions. Eight patients with zero PFIQ-7 score at the baseline (G1=5, G2=3) were excluded from the questionnaire evaluation. No AEs were observed regarding the delivered treatments or sEMG measurements. Subjects seldom reported only mild discomfort when recording sEMG using an intravaginal electrode.

Table 1. ***Characteristics of patient groups at the time of recruitment (mean followed by 95% confidence interval)***

Group	Age (years)	BMI (kg/m2)	Vaginal deliveries	PFD symptoms (% of patients)
G1 (n = 50)	31.12 (1.52)	23.27 (0.76)	1.76 (0.22)	Urinary incontinence (74%); decreased sexual desire (36%); decreased sensitivity during intimacy (70%); dyspareunia (26%); hypo/anorgasmia (52%)
G2 (n = 25)	31.96 (3.20)	24.32 (3.70)	1.56 (0.27)	Urinary incontinence (72%); decreased sexual desire (44%); decreased sensitivity during intimacy (44%); dyspareunia (24%); hypo/anorgasmia (40%)
G3 (n = 20)	27.20 (2.02)	22.40 (1.27)	1.25 (0.21)	-

BMI = body mass index; PFD = pelvic floor dysfunction.

Quantification of the EMG Signal

The results of sEMG measurements are summarized in Table 2. In general, there are significant differences between the symptomatic groups in comparison with healthy patients. On the other hand, the changes in the measured values after the HIFEM or electrical stimulation were highly

statistically significant (P < .001) in comparison with the baseline, showing that stimulation of the PFM modifies the muscle (electrical) activity.

At baseline, the measured peak intensity of the MVC signal was significantly higher in healthy patients by approximately 22 mV on average than in the G1 or G2 group. At the same time, there was no change between the intervention groups. At the end of the study, the G1 group showed significantly higher EMG values than the G2 group (P < .001), reaching an average change of 10.58 mV (57.29%) and 1.44 mV (7.34%), respectively. Although the HIFEM treatment considerably increased the PFM activity, the G1 group still showed lower values than the control. Similar findings were observed in the case of average MVC. As expected, the average MVC magnitudes are lower in each group. A more profound increment was also observed in the G1 group (6.65 mV, 58.69%) compared with a modest increase in the G2 group (0.91 mV, 6.81%). There were also significant differences between the G1 and G2 groups after treatments (P < .05). Despite the observed improvement, asymptomatic subjects still showed greater EMG values.

Interestingly, the examination of muscle activity at rest revealed divergent tendencies. Initially, only the G1 group showed significantly different (higher) values from the control (P < .05), while after the last therapy, the G1 average resting level decreased at the level of G3 (2.08 mV and 1.90 mV, respectively). Conversely, the average resting level of the G2 group had risen from 2.42 mV to 3.94 mV. In conclusion, the G2 subjects manifested significantly higher EMG values than the control and G1 groups at the end of the study (P < .001). Regarding endurance, significant differences were observed between the symptomatic and the control groups at the baseline and after the treatments (see Table 2). The measurement of the G3 group showed that healthy patients could hold the contraction of the PFM on average for 62.25 seconds.

Furthermore, we observed a significant increase in the endurance of PFM contraction by 48.24% in the G1 group because the patients could hold a contraction by 13.44 s longer after their treatments, reaching 41.30 s in total. The G2 group improved by 36.26%, and PFM contraction was prolonged on average by 6.60 s.

Table 2. ***Results of the sEMG measurements at the baseline and after the last therapy for both treated groups (G1 and G2) and control subjects (G3) are presented as mean followed by a 95% confidence interval in brackets***

Measurement	Group	Baseline	After
Peak MVC (mV)	G1 (n=50)	19.49 (2.31)	30.06*** (3.75)
	G2 (n=25)	19.56 (2.93)	21.00 (2.82)
Average MVC (mV)	G1 (n=50)	11.33 (1.54)	17.99†,* (2.50)
	G2 (n=25)	13.39 (2.46)	14.30 (2.42)
Resting level (mV)	G1 (n=50)	3.83†,* (0.82)	2.08 (0.38)
	G2 (n=25)	2.42 (0.45)	3.94†,*** (0.60)
	G3 (n=20)	1.90 (0.63)	-
Endurance (s)	G1 (n=50)	27.86†,** (4.17)	41.30†,*** (5.21)

Measurement	Group	Baseline	After
	G2 (n=25)	24.80 (3.12)	32.69 (1.88)
	G3 (n=20)	41.96 (2.51)	62.25 (3.68)

*P < .05, **P < .01, ***P < .001.

Pelvic Floor Impact Questionnaire Short Form 7

The patient's subjective evaluation is summarized in Table 3 and Figure 1. The minimal variation in the baseline score of both symptomatic groups was insignificant. Nonetheless, after the last treatment, there was a significant difference in the PFIQ score between the G1 and G2 groups (P < .01). Although both treatment modalities resulted in highly substantial subjective improvement, the patients treated with HIFEM experienced more remarkable outcomes. In addition, 16 patients (35.56%) from the G1 group reached a score of zero after the HIFEM treatments (meaning 100% improvement against the baseline). Contrary to this, only three patients (12.00%) from the G2 group who underwent electrical stimulation reported zero scores at their last visit. The shift in PFIQ scores is visualized in Figure 1. As can be seen, the relative frequency of scores was remarkably changed in the G1 group, while almost 90% of patients fell into the low score categories (0-10 or 10-20) after the treatments. In addition, scores of more than 50 were eliminated from patient's responses. The G2 group showed minimal changes in patients' PFIQ scores distribution, corresponding to a moderate average improvement of 5.15 points (see Table 3).

Table 3. ***Results of the Pelvic Floor Impact Questionnaire Short Form 7 (PFIQ-7) for both treated groups (G1 and G2) at baseline and after the last therapy session presented as mean followed by a 95% confidence interval in brackets***

Group	Baseline	After
G1 (n=45)	37.16 (4.68)	15.95 (2.55)
G2 (n=22)	32.28 (5.92)	21.96 (3.37)

DISCUSSION

Our examination of PFM electrogenesis in patients who showed signs of PFD revealed a significant reduction of the generated EMG signal compared with the asymptomatic patients at baseline (MVC, mean MVC, and endurance). The results of intervention groups G1 and G2 denote that noninvasive PFM strengthening can positively influence PFM activity. As seen in Table 2, the sEMG measurements obtained after therapies with the BTL EMSELLA device or electrical stimulation showed increased values of maximum possible voluntary contraction and endurance. It suggested that at the end of the study, patients could have more robust and more complex PFM contractions, resulting in a reduction of PFD symptoms (whether incontinence or sexually based), also demonstrated by a significant decrease in the PFIQ-7 score.

In contrast to sEMG measurements, which demonstrated considerable PFM weakening in the G1 and G2 groups at baseline, the PFIQ resulted in relatively low scores in both groups. We attribute this to perhaps a less specific grading system of the PFIQ when evaluating patients who showed various PFD-related symptoms of different severity. In future studies, it might be beneficial to focus on evaluating a particular patient's symptoms by using condition-specific questions assessed by a visual analog scale or a 5 to 7-point Likert scale, for instance, to enhance grading possibilities.

A magnetic and electrical stimulation comparison showed a significant improvement in EMG values, observed in the G1 group, which was treated by HIFEM technology. Compared with electrical stimulation, the BTL EMSELLA device was shown to be substantially more effective in restoring muscle strength as the MVC, mean MVC and endurance parameters uniformly increased from 48 to 59% after HIFEM treatments. On the contrary, electrical stimulation induced only mild changes in MVC (7.34%) or mean MVC (6.81%) while reaching mild to moderate improvement (36.26%) in endurance. The sEMG measurements coincide with the results of the PFIQ. The patient's subjective evaluation showed more pronounced improvement in the G1 group (57.16%) than in the G2 group (32.18%), corresponding to the improvement rate in EMG values. The HIFEM procedure also substantially reduced high PFIQ scores after the last therapy session (see Figure 1).

PFM Electrical Activity and sEMG Measurements

Given the specific patient group and scarce evidence in the literature, control group G3 was established to obtain normative EMG values that were valid for the studied sample. In general, the results presented here coincide with the previously published findings. It has been documented by numerous authors[13-15,17,18,20] that women who are suffering from PFD show lower MVC and endurance values because of the impairment of the PFM. Properly stimulating the PFM allows patients to produce more significant voluntary contractions for longer durations. In addition, the PFD influences muscle activity at rest as the PFMs are less electrically active.

However, the PFM resting level evaluation revealed significant differences between both modalities in our study. Although the G1 group, after treatments, reached similar EMG values as the healthy population, patients from group G2 showed altered muscle activation with relatively high electromyogenesis at rest (3.94 mV on average, see Table 2). This indicates that G2 patients cannot correctly relax their PFM after treatments because they cannot isolate and control the appropriate muscle activation patterns, which was then reflected by the lower MVC amplitudes. The correct activation pattern during PFM contraction is associated with increased activation of the PFM and lower transverse abdominal wall with markedly less activation of the upper abdominal and chest wall. The inappropriate activation refers to increased abdominal and chest wall activation while PFM activation decreases,[16] resulting in lessened strength (MVC amplitude) of contraction.

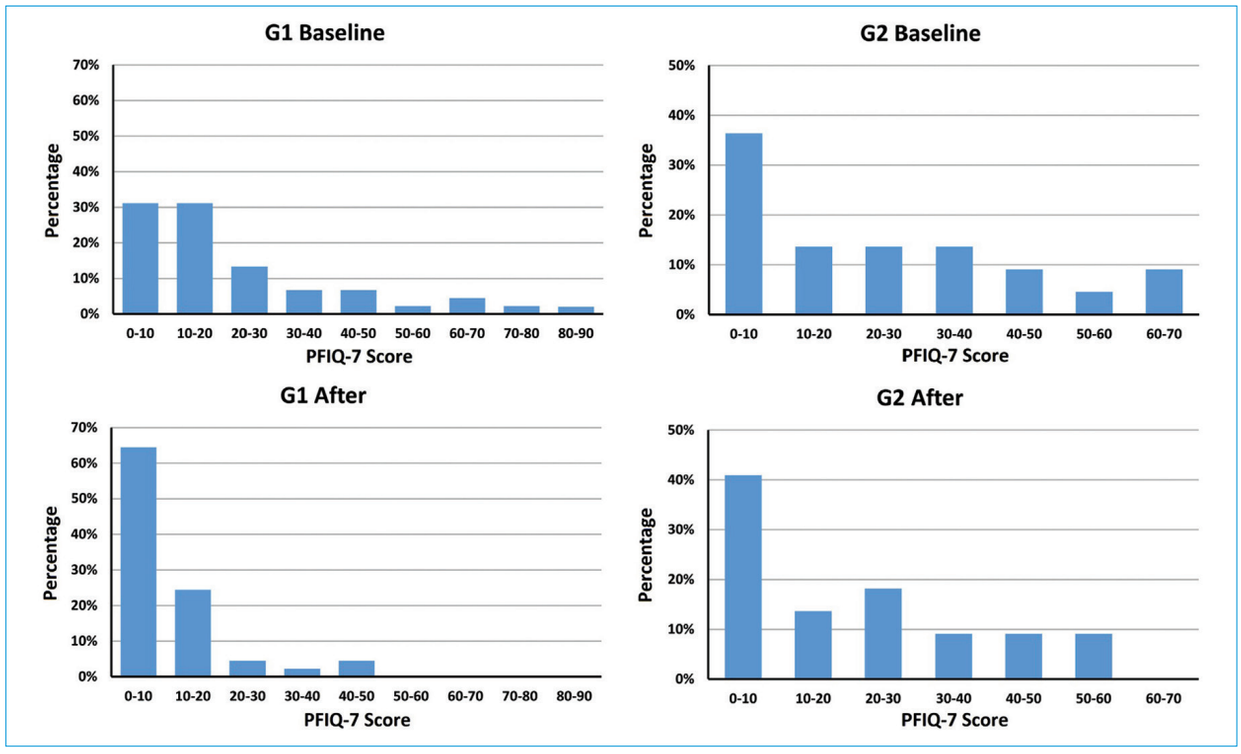
Showing high test-retest reliability,[13,14] the sEMG measurement is a valuable tool for detecting PFM activity. To record PFM electrical activity, we used an intravaginal electrode with a large surface to obtain EMG signals of sufficient amplitude with high sensitivity.[2,3] Fortunately, the PFM encompasses only a partial amount of subcutaneous tissue, possibly further attenuating the amplitude of EMG.[35] To prevent any systematic error during measurements, the skilled physiotherapist supervised the insertion and the position of the measuring electrode. Data normalization was

unnecessary as we assessed the same muscle group during one measurement session without removing the active electrode.[3] The selectivity of measured values was accomplished by the reference electrode placed on the abdomen. The signal obtained by the abdominal electrode was subtracted from the recording site to eliminate standard components and received EMG values, thus representing the summation activity of the whole PFM. To achieve an even greater degree of selectivity, the specific design of the vaginal electrode is required. For instance, Voorham-van et al.[14] have been able to successfully measure and compare the activity of selected pelvic muscles (pubococcygeus, puborectalis, bulbospongiosus, and ischiocavernosus) by using an experimental intravaginal probe with a matrix of 24 electrodes.

Study Limitations

Still, an sEMG measurement faces various challenges. The nature of the recorded electrical signal (amplitude, frequency, or noise) is influenced by several factors, such as the composition of measured muscle and the structure and position or placement of electrodes.[35] The core and skin temperature[36] or different humidity of measured environments may also influence the signal parameters. Because of the moisture and temperature within the vaginal lumen, it is challenging to ensure identical conditions at each visit during the intravaginal measurements. The moisture between the electrode and tissue may lead to decreased EMG amplitude. Furthermore, the electrode positioning is crucial for the reliability of sEMG measurement. Therefore, the operator must consistently insert the intravaginal probe into the measured muscles, as the electrode orientation affects the signal's power.[37] In addition, the intravaginal probes should be designed in such a way

Figure 1. ***The comparison of PFIQ-7 scores per group and appointment. The relative frequencies of scores reported by the patients of group 1 (G1) and group 2 (G2) are plotted in the graphs. There is a substantial shift toward the lower PFIQ-7 scores in the G1 group after the treatments.***



as to minimize any impact on the PFM by its insertion to avoid cross-talk and motion artifacts.[14] Indisputably, the appropriate planning of treatments is essential to achieve desired results. Unlike electrical stimulation, HIFEM is a relatively new technology that is still being investigated to some extent. In our study, the HIFEM treatments were administered at least 48 hours apart (2-3 per week) to maximize treatment outcomes and avoid muscle fatigue caused by overtreatment of the PFM, as the therapy with maximum settings produces intense muscle contractions. Presumably, the results would differ because of changes in the treatment frequency; however, this should be verified by future studies.

CONCLUSION

Electromyographic measurement of PFM activity proved to be a valid method for examination of patients with PFD (suffering from urinary incontinence and/or accompanied by sexual dysfunction) treated with HIFEM and electrical stimulation. Surface EMG of the PFMs showed more profound muscle activation after HIFEM treatments, along with improved relaxation and enhanced endurance. The PFIQ also indicates a greater effect of the HIFEM procedure based on the significant change in patient scores. Documented outcomes imply that the HIFEM procedure is substantially more effective in restoring PFM strength and treating PFD when compared with the electrical stimulation applied correspondingly in postpartum women.

Corresponding Author: Silantyeva Elena, MD, Hospital Lapino MD Medical Group, 111, Lapino village, Odintsovo District 143081, Moscow Region, Russia. Tel: +7-916-060-20-00; Fax: +7-495-433-73-79; E-mail: essdoktor@yandex.ru

Conflict of interest

None.

Funding

None.

Statement of Authorship

Category 1

(a) Conception and Design: Silantyeva Elena(b) Acquisition of Data: Silantyeva Elena; Zarkovic Dragana; Soldatskaia Ramina; Astafeva Evgeniia(c) Analysis and Interpretation of Data: Silantyeva Elena; Astafeva Evgeniia; Mekan Orazov; Soldatskaia Ramina

Category 2

(a) Drafting the Article: Soldatskaia Ramina; Astafeva Evgeniia(b) Revising It for Intellectual Content: Silantyeva Elena; Zarkovic Dragana; Mekan et al.

Category 3

(a) Final Approval of the Completed Article: Silantyeva Elena

Elena S., Dragana Z., Ramina S., et al. Electromyographic Evaluation of the Pelvic Muscles Activity After High-Intensity Focused Electromagnetic Procedure and Electrical Stimulation in Women With Pelvic Floor Dysfunction. Sex Med 2020;XX:XXXeXXX.

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