Kadın Cinsel Sağlığı

Efficacy of intravaginal biofeedback-assisted therapy in women with vaginismus

Vajinismuslu kadınlarda intravajinal biyofeedback destekli terapinin etkinliği

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ABSTRACT

OBJECTIVE: To investigate the effect of relaxation of vaginal muscles with EMG measurements after transmucosal electrical nerve stimulation (TENS) application. We planned to implement a method that would allow our treatment success data to be easily collected and analyzed with instant digital EMG data.

MATERIAL and METHODS: This study was conducted at our private clinic of between January 2022 and October 2024. The intravaginal device of the NeuroTrac MyoPlus2 Pro device (Verity Medical Ltd, Ireland) was placed into the vagina in an average of 30–45 seconds. Then, electromyography (EMG) measurements of voluntary contraction and relaxation were taken in the work and rest assessment mode, 5 seconds of contraction and 5 seconds of relaxation for 55 seconds. Then, intravaginal TENS was applied with the intravaginal apparatus in the current relaxation mode recorded in the device at 30 mA power for 20 minutes Then, EMG measurements of contraction and relaxation were taken during 5 seconds of voluntary contraction and 5 seconds of relaxation, for a total of 55 seconds.

RESULTS: 135 patients who underwent intravaginal device of the NeuroTrac MyoPlus2 Pro for vaginismus were included in this study. At work, average and lowest EMG values were significantly lower after therapy (22.8 vs 17.8 mV, p=0.013; 9.8 vs 8.1 mV, p<0.001, respectively). Highest EMG value and maximum voluntary contraction (MVC) value were similar before and after therapy. At rest, average, lowest, highest and MVC values were statistically significantly higher after therapy (3.8 vs 1.9 mV; 1.2 vs 0.6 mV; 13.8 vs 10.3 mV and 16% vs 13%, p<0.001, respectively).

CONCLUSION: The NeuroTrac MyoPlus2 Pro intravaginal device can be applied as an effective treatment modality in the management of vaginismus.

Keywords: electromyography, intravaginal device, transmucosal electrical nerve stimulation, vaginismus

ÖZ

AMAÇ: Transmukozal elektriksel sinir stimülasyonu (TENS) uygulamasından sonra EMG ölçümleriyle vajinal kasların gevşemesinin etkisinin araştırılması amaçlanmıştır. Anlık dijital EMG verileriyle tedavi başarı verilerimizin kolayca toplanıp analiz edilmesine olanak sağlayacak bir yöntemin uygulanması planlanmıştır.

GEREÇ ve YÖNTEMLER: Bu çalışma Ocak 2022 ile Ekim 2024 tarihleri arasında özel kliniğimizde gerçekleştirildi. NeuroTrac MyoPlus2 Pro cihazının (Verity Medical Ltd, İrlanda) intravajinal cihazı ortalama 30–45 saniyede vajinaya yerleştirildi. Ardından, çalışma ve dinlenme değerlendirme modunda, beş saniye kasılma ve beş saniye gevşeme süresince 55 saniye boyunca elektromiyografi (EMG) ile gönüllü kasılma ve gevşeme ölçümleri alındı. Ardından, cihazda kaydedilen akım gevşeme modunda intravajinal aparat ile 20 dakika boyunca 30 mA güçte intravajinal TENS uygulandı. Ardından, beş saniye gönüllü kasılma ve 5 saniye gevşeme süresince toplam 55 saniye boyunca kasılma ve gevşeme EMG ölçümleri alındı.

BULGULAR: Bu çalışmaya vajinismus için Neuro Trac MyoPlus2 Pro intravajinal cihazı uygulanan 135 hasta dâhil edildi. İş yerinde, ortalama ve en düşük EMG değerleri tedaviden sonra önemli ölçüde daha düşüktü (sırasıyla 22,8'e karşı 17,8 mV, p=0,013; 9,8'e karşı 8,1 mV, p <0,001). En yüksek EMG değeri ve maksimum istemli kasılma (MVC) değeri tedaviden önce ve sonra benzerdi. Dinlenme halinde, ortalama, en düşük, en yüksek ve MVC değerleri tedaviden sonra istatistiksel olarak önemli ölçüde daha yüksekti (sırasıyla 3,8'e karşı 1,9 mV; 1,2'ye karşı 0,6 mV; 13,8'e karşı 10,3 mV ve %16'ya karşı %13, p <0,001).

SONUÇ: NeuroTrac MyoPlus2 Pro intravajinal cihazı vajinismus yönetiminde etkin bir tedavi yöntemi olarak uygulanabilir.

Anahtar Kelimeler: elektromiyografi, intravajinal cihaz, transmukozal elektriksel sinir stimülasyonu, vajinismus

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Vaginismus is defined as the recurrent/ persistent involuntary contraction of vaginal musculature, which prevents penetrative sex and can be classified as primary (lifelong) and secondary (acquired) vaginismus. Globally, the rates of vaginismus prevalence exhibit wide variation, with Eastern cultures presenting a distinctly higher prevalence than the

Western countries. Moreover, the estimation of vaginismus prevalence is considered difficult and can be performed only from clinical surveys since patients tend to hide vaginismus, fearing the stigma that accompanies the sexual difficulties. [1] Regarding the classification of vaginismus in the contemporary classification systems, the fifth version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) categorized vaginismus together with dyspareunia under the term "genito pelvic pain / penetration disorder" (GPPPD), which is reflected in the recent literature. [2]

Sexual pain disorders were first reported in ancient documents, while the current research data show that these disorders comprise clinical syndromes with a complex etiology and need for multidimensional management. Vaginismus, as a clinical entity covered by the umbrella term GPPPD, is considered to be provoked by behavioral, cognitive, interpersonal, and biological factors.[3] Regarding the behavioral, and cognitive characteristics of GPPPD patients, affective temperaments, which include depressive, cyclothymic behavior patterns combined with high levels of anxiety and irritability, are detected more frequently among women with lifelong vaginismus (LLV). Interestingly, similar behavior patterns are recognized among the male partners of LLV patients, which contributes to the maintenance and deterioration of LLV.[4] In accordance with the previous report, Tetik et al. performed a comparative study between vaginismus patients and healthy controls and found that vaginismus was associated with increased anxiety levels and had no association with childhood trauma.^[5] In 2020, Dikmen et al. studied the association of cognition patterns (schemas) with vaginismus and found that maladaptive schemas, which contributed to the expression of negativity, approval/recognition-seeking behavior, hypercriticalness and sense of vulnerability to injury, were detected more frequently among women diagnosed with vaginismus. [6] According to a report by Ozdemir et al., another characteristic trait of GPPPD patients is alexithymia, a term that refers to emotion regulation and the insufficient ability for emotion recognition and description by the patient.^[7] Regarding the interpersonal factors and the social environment elements affecting them, a study by Yagci et al. demonstrated that LLV patients reported more frequently emotional neglect/ abuse, state/ trait anxiety, social phobia, and low self-esteem. [8] Interestingly, the age difference between parents and LLV patients, and maternal education level were positively correlated with vaginismus, which suggests that the above factors may establish increased emotional distance and hypercriticism in the family environment and subsequently painful sex in GPPPD patients.[9]

Significantly less scientific data exist on the association of vaginismus with organic factors, or measurable neurophysiologic parameters. In 2021, Eserdag et al. investigated the hypothesis of associating vaginismus with an increased pain perception among the respective women.[10] Their prospective study showed that vaginismus patients have a lower pain threshold compared to healthy controls, and this threshold is further decreased in higher vaginismus grades. According to a report by Yükselay et al., vaginismus seems to be associated with an impaired sensory information process, which allows sexuality-related fear conditioning (fear of penetration in vaginismus) to be aroused by visual sexual stimuli.[11] Among women with vaginismus, the researchers found deficits in sensory gating, which comprises a physiological process of filtering irrelevant stimuli out of the central nervous system (CNS). Regarding the association of parameters of the vaginal musculature of women diagnosed with vaginismus with peripheral neurophysiologic aberrations, Padoa et al. presented evidence of an etiological connection between the overactive pelvic floor (OPF) and sexual dysfunction in men and women. Genito pelvic pain / penetration disorder comprises one of the OPF-related sexual disorders and its manifestation seems to induce a further cycle of muscle overactivity and pain, which can explain the chronicity of the condition.[12]

Considering the investigation of the peripheral anatomical axis of vaginismus as a more direct approach to unveil further aspects of its pathophysiologic basis, we performed a study on the electrophysiological parameters of the vaginal musculature of women diagnosed with vaginismus. Moreover, provided that neuromodulation represents a promising treatment in patients with overactive pelvic floor and sexual dysfunction, we applied intravaginal neuromodulation to the women of the study cohort in a standardized manner to evaluate the effect on the electrophysiological activity of the vaginal muscles.[13] The rationale of the above intervention was to detect significant alterations after the neuromodulation session, which may have therapeutic implications for vaginismus patients. Reissing et al. (n=87) found that only 28% of the vaginismus group actually displayed a vaginal muscle spasm.[14] Another method of assessing vaginal muscle spasm criterion is electrical recording of muscle tissue by surface electromyography (sEMG) or needle electromyography. In our study, we observed EMG using an intravaginal probe. Results with needle EMG of vaginismus show a higher EMG application in the levator ani, puborectalis and bullocavernosus muscles at rest and induction of vaginismus reflex compared to controls with live paired subjects. [15] A surface EMG study confirmed that there was no significant difference in the

ability to contract and relax the pelvic floor muscles between women with and without vaginismus.^[16]

MATERIALS and METHODS

For this study, ethical approval was obtained from local ethics committee (Ethics committee approval number: 2024-BIAEK/04-25). This study was conducted at our private clinic of between January 2022 and October 2024. Patients who were diagnosed with vaginismus according to the 2013 American Psychiatric Association, DSM-5 Task Force Diagnostic and Statistical Manual of Mental Disorders: DSM-5™ criteria based on their examination and anamnesis were included in our study. Those who had previously received finger exercise, dilator exercise and botulinum toxin vaginismus treatment were not included in our study. Patients with pathological diagnosis of lichen sclerosus were not included in the study. Who refused this treatment were excluded from the treatment and no other treatment modality was applied. The ages of the patients ranged between 22 years and 49 years. Written informed consent was obtained from all participants. This study was conducted according to the standards of Good Clinical Practice (ICH-E6) and the principles of the Declaration of Helsinki.

The patient was placed on the lithotomy table. All metal and gold objects on the patient were removed so that the digital measurements would not be affected. After applying a 30% (25% lidocaine + 5% Procaine) numbing cream with a cotton ear swab into the vagina, it was waited for 30 minutes. The anesthesia we used was used only at the level of the hymen ring in a very small amount to reduce the feeling of tension in the patient with the first contact of the device. The hymen ring settings were never exceeded, thus preventing the development of hypoalgesia in the intravaginal pelvic muscles. 5 minutes after the numbing cream was applied, the patient was shown how to perform 5 minutes Kegel exercises with the help of an expert physiotherapist and how to control contraction and relaxation. After this approximately 5-minute training, the stage of placing the intravaginal device into the vagina was reached. Then, when the patient relaxed, the intravaginal device of the NeuroTrac MyoPlus2 Pro device (Verity Medical Ltd , Ireland) was placed into the vagina in an average of 30-45 seconds. After connecting the intravaginal device to the NeuroTrac MyoPlus2 Pro device with its cables, a Bluetooth connection was established with the laptop (Fig. 1A-F). The measurements during all procedures were monitored on the laptop screen (Fig. 2). During this procedure, water-based lubricant was applied to the intravaginal device, ensuring that the device was easily

placed into the vagina. All metal objects on the patients were removed before the test. In addition, the measurement was taken with an empty bladder to prevent the device from being affected during the measurement. The device was pushed into the vagina to the point where the patient showed the most resistance, in a position closest to the pubococcygeus muscle, and fixed after passing 1 cm and placed intravaginally. To prevent the device from coming out, the external part of the device was fixed to the labium majus with plaster bands. Then, electromyography (EMG) measurements of voluntary contraction and relaxation were taken in the work and rest assessment mode, 5 seconds of contraction and 5 seconds of relaxation for 55 seconds. In the Work and Rest mode, average EMG Value, lowest EMG value, highest EMG value and maximum voluntary contraction (MVC) measurements were made and recorded. Then, intravaginal Transmucosal electrical nerve stimulation (TENS) was applied with the intravaginal apparatus in the current relaxation mode recorded in the device at 30 mA power for 20 minutes. During this period, the patient was kept in the lithotomy position without performing any contraction or relaxation. After this procedure, the patient rested for 5 minutes and then voluntary contraction and relaxation exercises were performed in the EMG biofeedback games mode recorded in the device. Then, EMG measurements of contraction and relaxation were taken during 5 seconds of voluntary contraction and 5 seconds of relaxation, for a total of 55 seconds. Then, the device was removed from the vagina and the procedure was terminated.

Statistical Analysis

Coding and statistical analyses of the data were performed on computer using IBM Statistical Package for Social Sciences (SPSS) program version 22 software (IBM Corporation, Chicago, IL). Whether or not the variables were normally distributed was analyzed by Shapiro-Wilk tests. Variables were expressed as median (IQR). Wilcoxon test were used for the comparisons between dependent groups. p value of <0.05 was considered as statistically significant.

RESULTS

A hundred and thirty five patients who underwent intravaginal device of the NeuroTrac MyoPlus2 Pro for vaginismus were included in this study. At work, average and lowest EMG values were significantly lower after therapy (22.8 vs 17.8 mV, p=0.013; 9.8 vs 8.1 mV, p<0.001, respectively). Highest EMG value and MVC value were similar before and after therapy.

Table 1. Electromyography parameter changes before and after therapy

Parameter	Before (μV,) (n: 153)	After (μV,) (n: 153)	p
During work mode			
Average EMG value	22.8	17.8	0.013
Lowest EMG value	9.8	8.1	<0.001
Highest EMG value	42	37	0.312
Maximum voluntary contraction (MVC)	46%	42%	0.581
During rest mode			
Average EMG value	1.9	3.8	<0.001
Lowest EMG value	0.6	1.2	<0.001
Highest EMG value	10.3	13.8	<0.001
Maximum voluntary contraction (MVC)	13%	16%	<0.001

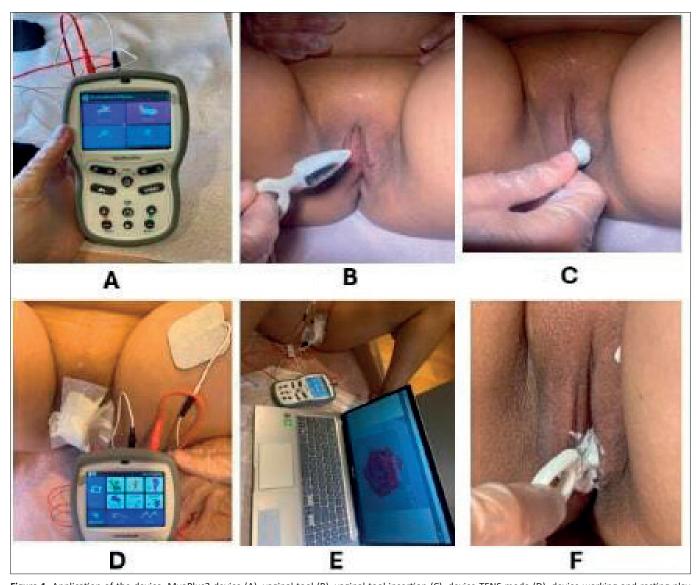
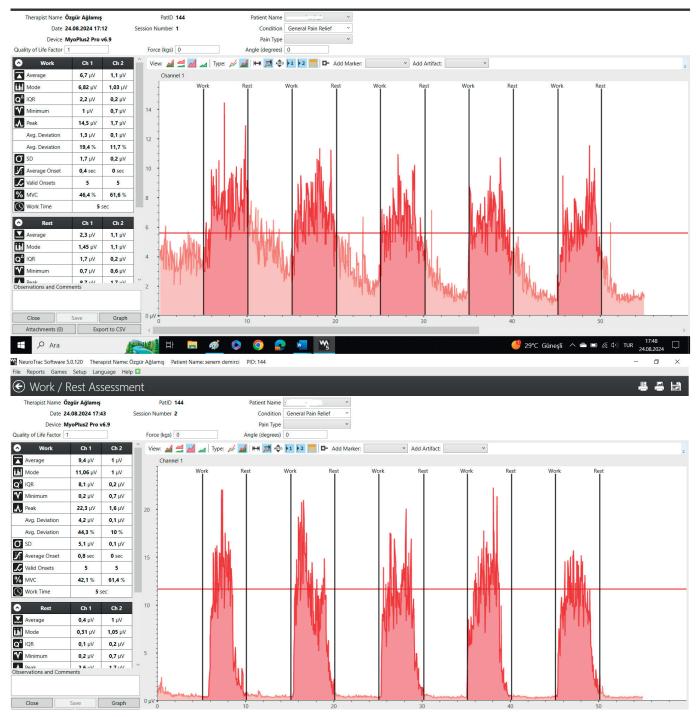


Figure 1. Application of the device. MyoPlus2 device (A), vaginal tool (B), vaginal tool insertion (C), device TENS mode (D), device working and resting play training mode (E), device removing (F)



 $\textbf{Figure 2.} \ \ \textbf{Monitoring of the measurements during all procedures on the laptop screen}$

At rest, average, lowest, highest and MVC values were statistically significantly higher after therapy (3.8 vs 1.9 mV; 1.2 vs 0.6 mV; 13.8 vs 10.3 mV and 16% vs 13%, p<0.001, respectively).

After the treatment, all patients' vaginismus problems were cured, the earliest being one day and the longest being 17 days. The average time to treatment for 153 patients was recorded as 6.7 days. We have accepted the day when the entire penis is inserted into the vagina without any pain or contraction so that patients can have full treatment. Every

patient who came to the clinic after successful sexual intercourse was re-evaluated with using DSM-V diagnostic criteria. In addition, secondary vaginismus was not observed in any of our patients in the controls follow-ups performed up to 1 year after treatment

DISCUSSION

In the current study, we applied a standardized protocol of neuromodulation by utilizing intravaginal TENS on women diagnosed with vaginismus, and we performed

measurements of the electrical activity of vaginal musculature and the muscular tone at contraction / rest before and after the neuromodulation session. The paired comparison of the measurement results showed that neuromodulation had a significant effect on the electrical activity of the contracted vaginal musculature by lowering the average and lowest EMG values, while the highest EMG value demonstrated a declining trend after TENS session without reaching statistical significance. On the contrary, no difference was recorded in the muscle tone at the contracted state after neuromodulation. At the relaxed state of vaginal musculature, the sum of measured EMG values was significantly lower after the TENS procedure, and more importantly, the muscle tone at relaxation was significantly decreased after neuromodulation. Among the above results, we consider the reduction of muscle tone at rest as the most promising outcome since vaginismus is mostly characterized by increased muscle tension during vaginal penetration without any intentional involvement of the patient.

The application of neuromodulation in the form of TENS represents an established method for alleviating neuropathic pain, while the mechanism of action of the method remains unclear, with modification of nerve electrical transmission, the release of endogenous opioids and blood vessel dilation being the most possible scenarios for the effect of TENS on pain mechanism.[17] Regarding the role of TENS in situations characterized by abnormally high muscle tension or spasticity, numerous reports support the application of TENS for alleviating abnormal muscle contraction, such as in children with cerebral palsy, in patients after stroke, in spinal cord injury, or even in more mild cases, such as in professional voice users with muscle tension dysphonia. [18-21] The putative TENS mechanism of action on muscle spasticity includes the stimulation of afferent nerves and the subsequent presynaptic inhibition of efferent fibers.[19]

We apply the same treatment protocol for all patients, regardless of the severity of the disease. By adhering to the same treatment protocol regardless of the severity, we have the chance to see that the method is effective for all severities.

In the patient cohort of our study, TENS provoked a decrease in muscle tension in the relaxed state of vaginal musculature, which may apply to the alleviation of vaginismus. In general, the contemporary management of vaginismus includes the application of cognitive-behavioral therapies, the introduction of vaginal dilators, and self-exercises (finger exercises), which can render penetrative sexual intercourse feasible, while additional sexual therapy is needed for increasing the overall sexual function of the couple. [22]

The early initiation of treatment seems to play a decisive role since the long-standing vaginismus without therapy needs a longer treatment duration and is accompanied by lower success rates.^[23]

From our literature search, we found no report on the therapeutic effect of TENS on vaginismus patients. On the contrary, according to a report by Mulroy et al., TENS demonstrates a promising potential in the management of genital arousal disorder/ genitopelvic dysesthesia.[24] Similarly, Vogel et al. propose the application of neuromodulation as a future direction of therapy for inadequately managed sexual pain in women.[25] The effect of neuromodulation on pain-related sexual dysfunction is also reported in a systematic review by Jin et al., where the researchers demonstrated that the above modality can improve the sexual life of women with dyspareunia. [26] In our opinion, neuromodulation may also be tested in patient cohorts regarding the real therapeutic results in vaginismus cases, while additional electrophysiological studies combined with our EMG measurements may allow a further understanding of vaginismus pathophysiology. The harmony between the couple and the joint application of the steps during intercourse are the factors that bring the earliest success after intercourse. However, conditions such as male-related erectile dysfunction emerge as conditions that prolong the success period in treatment. In addition, receiving psychiatric treatment for conditions such as anxiety disorder is also a factor that affects the process.^[27]

The study has some limitations. This study was organized in a single centre. Also, the absence of a normal control group is a handicap.

CONCLUSION

We performed electrophysiological and muscle tension measurements at the relaxed/ contracted status of vaginal musculature of a patient cohort diagnosed with vaginismus, and we repeated the above measurements after the application of intravaginal TENS, which was performed according to a standardized protocol. Almost all EMG values in both relaxed/ contracted statuses were significantly lower after applying TENS. Most importantly, muscle tension in the relaxed musculature status was significantly lower after the TENS session. The above finding may apply to the management of vaginismus, provided that the characteristic symptom of vaginismus is the involuntary, abnormal contraction of vaginal musculature, which renders penetrative sexual intercourse unfeasible. We believe that vaginismus treatment is a more applicable and data-collectible study with digital EMG measurements taken

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immediately and after treatment, rather than treatment methods such as finger exercises and botulinum toxin, which are not easily tolerated by the patient and do not provide instant digital results.

Ethics Committee Approval

The study was approved by Biruni University Scientific Research Ethics Committee. (date and number of approval: 21.10.2024/2024-BIAEK/04–25).

Peer-review

Externally peer-reviewed.

Conflict of Interest

No conflict of interest was declared by the authors.

Financial Disclosure

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