

Evaluation of a Mobile Electrode for Electrical Stimulation of the Perineal Muscle

Perez, Fabiana da Silveira Bianchi¹, Cruz, Cleyciany Barbosa², Soares, Fabiano Araujo^{3,4},
Carvalho, João Luiz Azevedo⁴, da Rocha, Adson Ferreira^{3,4}

¹School of Medicine, University of Brasília, Brasília, DF, Brazil

²Faculdade Padrão, Goiânia, GO, Brazil

³Faculdade UnB-Gama, University of Brasília, Gama, DF, Brazil

⁴Department of Electrical Engineering, University of Brasília, Brasília, DF, Brazil

Abstract—This work evaluates the effectiveness of a new type of electrode for functional electrical stimulation of the perineal muscle in women. The new electrode is shaped like a pen, with an active stimulation electrode located on its tip. The goals of the study are to (i) demonstrate that stimulation using the new device results in increased muscle strength; and (ii) compare the performance of the new device with that of a traditional (fixed) electrode. Eight women were evaluated, following a blind study protocol. The preliminary results suggest that stimulation with the new electrode achieves better results than stimulation with traditional electrodes, as higher increases in strength were observed in the group that used the mobile electrode.

I. INTRODUCTION

The perineum is a diamond-shaped muscle group located between the pubic symphysis, the ischial tuberosities, and the coccyx. It is separated from the pelvic cavity by a set of structures forming a pelvic diaphragm, which is composed by the pubococcygeus, iliococcygeus, and coccygeus muscles [6] [7]. These muscles occlude the pelvis, and provide support for the pelvic viscera when there is an increase in the intra-abdominal pressure due to physiological events such as coughing, bowel movements, laughing, carrying weight, pregnancy, birth delivery and sexual intercourse. This happens through the effective contraction and relaxation of the muscles of the pelvic floor. Perineal dysfunctions and psychosocial problems may occur if this coordinated action does not occur properly.

One solution to these dysfunctions is to strengthen the perineal muscles. This can be achieved through physical therapy techniques known as Arnold Kegel exercises [11] [3]. However, some patients are unable to perform such exercises. In such cases, electrical stimulation may be used. Electrical stimulation of the perineal muscles has shown satisfactory therapeutic results in many etiology studies [4]. Electrical stimulation has been widely used in the past years [4] [13] [12] [10] and has presented good results, especially using intracavitary electrodes. The performance of this technique depends on the choice of electrode, type of wave,

amplitude, cycle, pulse, and frequency [1] [9].

The treatment of perineal pathologies typically uses intracavitary electrodes. However, studies show adverse effects due to intravaginal electrical stimulation with this type of electrode: pain, unpleasant sensations, fecal incontinence, vaginal irritation and infection [14] [16]. Moreover, it is recommended that intracavitary electrodes be used only once [14][16], which increases the cost of treatment, making it barely accessible to public services or to the population from lower economic classes. It is an uncomfortable procedure, and impracticable in children and women without previous sexual activity. Due to these drawbacks, this work investigates a different, non-intracavitary type of electrode: the mobile electrode, which uses a different mode of application.

This study compares a treatment that uses a fixed electrode to stimulate the muscles of the perineum with a treatment that uses a mobile pen-shaped electrode. The choice of electrodes is based on the study of Modotti et al. [10]. The mobile electrode has the size of a pen-tip, and can more adequately stimulate the motor point and the fibers of the small muscles in comparison with the fixed electrode, which stimulates only one or two muscles, and whose size makes its adaptation to the perineal region more difficult.

We evaluate the effectiveness of the fixed electrode and the pen-electrode in the recruitment of muscle fibers of the perineum and the time required to achieve a given level of strength. Preliminary results are presented. Improved muscle stimulation may help in curing and preventing diseases, by strengthening the muscle.

II. METHODS

The study was conducted at Cerei Clinical Center (Goiânia, GO, Brazil). The protocol was approved by the ethics and research committee of the Faculty of Medicine of the University of Brasília. Female volunteers of 37.5 ± 7.65 (mean \pm s.d.) years of age were chosen according to the evaluation of a questionnaire for inclusion or exclusion. The patients selected should be linked to the institution, between 25 and 50 years old, with no surgical correction of perineal pelvic floor disorders, sedentary, non-users of medical drugs other than contraception, sexually active, non-obese and have agreed to participate voluntarily in the research. The

volunteers were blindly/randomly allocated into two groups, according to their arrival. After signing the consent, subjects were subjected to gynecological and strength evaluation using a Neurodyn Evolution perineal biofeedback device (Ibramed Ltda., Amparo, SP, Brazil) with a vaginal pressure probe (Ibramed Ltda., Amparo, SP, Brazil). The probe was coated with a condom, and lubricated externally with carbogel. The device measures the maximum and minimum vaginal pressure achieved by voluntary contraction of the perineum. After evaluation, the patient was subjected to the protocol of group A or B according to her assigned group.

The experimental protocol consists of two procedures, each applied to one of the two groups of subjects. In group A, the patients were subjected to electrical stimulation of the pelvic floor muscles by pen-electrode stimulation of five points around the vaginal opening in an arc that starts on one side of the groin and ends on the other side, passing through the center of the pubic arch. This stimulates five motor points in different muscles, by moving the mobile pen-electrode during the thirty minutes of therapy. The five points of the perineal region are: the pubic region, central tendon, bilateral inguinal region, near the *labium majus*, and in the direction of the vaginal opening. The stimulator generates seventy impulses at each session toward a total of 14 pulses per point muscle during each session. The pen-electrode was fixed during six minutes at each point in each session.

Group B participants were subjected to electrical stimulation using fixed electrodes. A group of four electrodes, arranged in a cross shape, were placed around the vaginal opening, thus stimulating only two muscles. The two electrodes from cable 1 were arranged on the central tendon and the pubis, thus stimulating this region. The two electrodes from cable 2 bilaterally stimulate the groin, closing the vaginal opening. Seventy impulses were used to simultaneously stimulate these four points during thirty minutes of therapy.

A Neurodyn Ruby stimulator (Ibramed Ltda., Amparo, SP, Brazil) was configured as follows for both groups: low frequency synchronous FES with the following envelope: frequency = 20 kHz; period = 50 μ s; rise = 7 s; on = 10 s; decay = 10 s; off = 5 s; time = 30 minutes. The current intensity was adjusted according to each patient's sensibility, provided that the electrical stimulation reaches the motor threshold of the muscle without triggering a painful stimulus. A vaginal probe was introduced in the vagina of the patient during electrotherapy, using a Neurodyn Evolution perineal biofeedback device (Ibramed Ltda., Amparo, SP, Brazil) to check the pressure before and after vaginal electrotherapy in order to observe whether there is increase in strength or muscle fatigue caused by the electrical stimulation. The FES frequency was chosen due to its extensive use in the literature [7] [12] [13] [16]. The protocol was repeated in 12 sessions, performed twice a week, at a total time of 30 minutes per session.

A comparative analysis of muscle fatigue of the subjects of group A compared to group B was performed. For each subject, the intra-session increase in muscle strength was calculated as the difference between end pressure (after electrical stimulation) and initial pressure (before electrical stimulation). The inter-session increase in muscle strength

was evaluated by linear regression of the measured pressures from each subject.

III. RESULTS AND DISCUSSION

This work presents current results from an ongoing study. Therefore, only data from the first 7 experimental sessions (out of 12) are presented. Statistical analysis was not performed yet due to the small number of subjects and sessions. However, the study is still in progress and complete results will be published at the end of the experiments.

Local muscle fatigue is a decrease in muscle response to a repeated stimulus, i.e. a normal physiological response of muscle is characterized by a decrease in amplitude of motor unit potential [8]. In Table I, a negative pressure difference indicates strength loss (muscle fatigue) during the session, caused by electrical stimulation. Group A presented higher fatigue (in average) than group B. The mobile electrode was expected to cause higher fatigue than the fixed electrode, because it stimulates five perineal muscle motor points, instead of only two.

Table II presents the measured pressure at the beginning of each session for each subject, and the angular coefficient of the linear regression on the 7 measurements (sessions) from each subject. Positive angular coefficients indicate a tendency of increasing pressure with each additional session, i.e., an increase in muscle strength due to periodic electrotherapy. Three out of four subjects in group A presented positive angular coefficients, while only one out of four subjects in group B presented positive slopes. These results suggests a trend of increased strength between successive sessions for subjects stimulated with the mobile electrode (group A), and a trend of strength loss in subjects stimulated with the fixed electrode (group B). The mobile electrode was expected to provide higher strength gain, because force production is directly related to the number of stimulated motor points [8].

IV. CONCLUSION

Preliminary results suggest that the pen-electrode is more effective than the fixed electrode in providing gain of perineum muscle strength. The comparison was performed using similar protocols with respect to duration and current administration, differing only for the fact that, with the pen-electrode, each point received 14 stimulated impulses during the thirty-minute pulse therapy, while seventy impulses were used for each of the four points during the sessions with the fixed electrode.

The preliminary results suggest that the pen-electrode may be a better option for electrotherapy than the fixed electrode. The group that received stimulation with fixed electrodes showed a reduction in strength, suggesting a slower perineal muscle response due to muscle fatigue, which occurs during prolonged simultaneous stimulation of the four fixed points. The mobile pen-electrode stimulates five points non-simultaneously. The increased strength resulting from a minor muscle fatigue can possibly shorten the therapy duration and reduce the financial costs to the patient.

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TABLE I
INTRA-SESSION MUSCULAR FATIGUE (FINAL PRESSURE MINUS INITIAL PRESSURE) (in mmHg)

GROUP	Session	S1	S2	S3	S4	S5	S6	S7	mean ± std. deviation
A	Subject 1	33	-44	0	0	-87	-11	-3	-16.0 ± 38.6
	Subject 2	0	-13	-13	7	-1	18	14	1.7 ± 12.2
	Subject 3	5	0	-5	-8	-6	10	-8	-1.7 ± 7.0
	Subject 4	8	0	3	11	17	18	1	8.3 ± 7.4
	Group mean	11.5	-14.3	-3.8	2.5	-19.3	8.8	1.0	
B	Subject 1	0	9	40	11	-8	4	5	8.7 ± 15.1
	Subject 2	-16	0	0	49	0	24	13	14.6 ± 17.9
	Subject 3	-3	-10	-34	-1	-2	-19	103	4.9 ± 44.9
	Subject 4	-17	3	-1	-14	-10	0	6	-4.7 ± 8.9
	Group mean	-1.0	0.5	1.3	11.3	-5.0	2.3	31.8	

TABLE II
INITIAL PRESSURE IN EACH SESSION (in mmHg) AND CORRESPONDING LINEAR REGRESSION
ANGULAR COEFFICIENTS

GROUP	Session	S1	S2	S3	S4	S5	S6	S7	linear regression angular coefficient
A	Subject 1	135	113	47	57	132	69	93	-4.6071
	Subject 2	64	39	92	77	73	72	84	3.8214
	Subject 3	41	49	41	42	45	42	64	3.8214
	Subject 4	51	50	62	39	48	51	56	0.1071
B	Subject 1	38	46	40	40	30	35	31	-1.8929
	Subject 2	1	40	52	2	14	72	87	10.1429
	Subject 3	79	76	131	106	101	105	2	-7.2500
	Subject 4	56	62	63	49	46	62	55	-0.7143