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Perineal Rehabilitation in Pelvic Floor Dysfunction: The Benefits of Vaginal Cone Training

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Abstract: Pelvic floor dysfunctions (PFD) are prevalent conditions that affect millions of women worldwide, encompassing a range of issues severely affecting women's quality of life. Pelvic floor muscle strength and function are fundamental to the management and prevention of PFD, and pelvic rehabilitation is a non-invasive approach that effectively improves symptoms, restores function, and prevents complications. This study aimed to evaluate the impact of pelvic floor muscle training program using weighted vaginal cones, on pelvic floor muscle function and quality of life in women with pelvic floor dysfunction (PFD). Fifty-four women aged 26-62 years, with different type of urinary incontinence, cystocele, and prolapse participated in this pre-post intervention comparative analysis. Pelvic floor muscle function was assessed using the PC test, which measures strength, endurance and fatigability, while the impact on patients' quality of life was assessed with the Pelvic Floor Impact Questionnaire - Short Form 7 (PFIQ-7). A three-month vaginal cone training regimen was implemented, with as-sessments conducted before the intervention (T0), one month later (T1), and three months later (T2). Data analysis showed a change with significant differences between the PC test score values at the level of each parameter and at each assessment ($p<0.05$, ES=0.254-511). The scores for bladder and urinary problems Urinary Impact Questionnaire (UIQ-7) significantly de-creased from 38.901 ± 1.268 at T0 to 29.366 ± 2.493 at T2 ($W = 1082.000$, $p < 0.001$, ES=0.570). In contrast, the scores for vaginal or pelvic problems (POPIQ-7) showed a slight, insignificant decrease from 12.699 ± 1.128 at T0 to 10.499 ± 2.362 at T2 ($W = 278.000$, $p = 0.800$, ES=0.053). fVaginal cone training significantly improves pelvic floor mus-cle function and reduces urynary symptoms in women with PFD.

Keywords: pelvic floor dysfunction, perineal rehabilitation, vaginal cone training, PC test

1. Introduction

Millions of women worldwide suffer from pelvic floor dysfunction (PFD), a global health issue that includes a wide range of interrelated clinical conditions that can neg-

atively affect women's lives. These conditions include fecal incontinence, urine incontinence, overactive bladder, pelvic organ prolapse, vaginal laxity, vaginal wind, and chronic perineal pain [1-4].

Perineal rehabilitation is considered as an indispensable therapeutic approach for various PFD, such as genital prolapse, urinary incontinence and chronic perineal pain. In addition, it is also highly recommended as a preventive approach during the postpartum period, in early stages of perineal dysfunction, in patients that must undergo pelvic surgery and immediately after perineal surgery. It can also be used in the event of neuropathy and in the management of urinary retention [5].

A key component of the treatment of the PFD is pelvic physical therapy. A few physiotherapeutic procedures that explicitly address the pelvic floor are pelvic floor muscle training, biofeedback, electrotherapy, vaginal cones, hypopressive abdominal techniques, and urotherapy [6]. Pelvic floor exercise has been shown to be effective, regardless of age, and more dependent on training intensity than type [7]. Previous research has established the efficacy of pelvic floor muscle training (PFMT) in improving symptoms of PFD, particularly urinary incontinence. Studies have demonstrated that consistent PFMT can significantly strengthen pelvic floor muscles, reduce the severity of incontinence, and enhance overall pelvic function [8-10].

Studies show that pelvic floor exercises, electrical stimulation, and vaginal cones (VCs) are equally effective treatments for incontinence [11, 12]. Vaginal con training is a non-surgical treatment method for strengthening the pelvic floor muscles (PFMs). This approach is particularly useful in managing symptoms associated with PDF. The treatment involves the use of weighted devices inserted into the vagina, which patients then hold in place using their pelvic floor muscles. This exercise aims to enhance muscle strength, endurance, and coordination. VCs are cheaper non-surgical treatments, in autonomous use, for women with stress urinary incontinence and are able to manage also some sexual dysfunctions caused by pelvic muscle relaxing [13]. Vaginal cones, have been shown to be particularly effective in providing resistance training for pelvic floor muscles and improved symptoms in urinary incontinence [14-16]. However, the impact of vaginal cone training on other aspects of PFD, such as pelvic organ prolapse (POP), has been less conclusive. While some studies suggest that vaginal cones can help manage mild cases of POP by enhancing muscle support, the results are often variable, and the improvements in symptoms are not always statistically significant [17-19]. Additionally, the role of vaginal cone training in improving the quality of life for women with PFD has been explored, with mixed findings. Some studies report significant improvements in quality of life metrics following cone training, particularly in relation to urinary symptoms, while others show minimal or no improvement in symptoms related to pelvic organ prolapse [20-22].

This study aims to build on the existing body of research, specifically examining the effects of a three-month vaginal cone training regimen on pelvic floor muscle function and quality of life in women with PFD, using a newly type of vaginal cone developed to strengthen the pelvic floor muscles in a practical, efficient and autonomous way. By assessing the training method's effects on general symptomatology, strength, endurance, and resistance of the pelvic floor muscles, the study seeks to ascertain the benefits of this approach.

2. Materials and Methods

2.1. Design and patient selection

This pre- post-intervention comparative analysis was conducted in the ambulatory service of the Obstetrics and Gynecology Department of the Emergency County Clinical Hospital in Arad, Romania, between January 2020 and December 2023. All patients who presented for a gynecological consultation with symptoms suggestive or a confirmed diagnosis of pelvic floor dysfunction (PFD were invited to participate in the study.

The criteria for inclusion in the study were: women over 18 years of age with diagnosed pelvic floor dysfunction (PFD) who were able to commit to the 3-month training protocol. Exclusion criteria included women with significant pelvic organ prolapse requiring surgical intervention, pregnancy, active or recurrent urinary tract infections, incapacity to contract the pelvic floor muscles (PC test-strength score = 0), atrophic vaginitis, vulvo-vaginitis, prior surgery for PFD, surgery during the study, involvement in a pelvic floor muscle training program within the previous 12 months, interstitial cystitis, persistently severe constipation, neurological disorders affecting pelvic floor control, or any contraindications to using vaginal cones, inadequate comprehension of the training program, failure to complete exercises, and lack of consent.

Of the 348 patients with various PDF consulted during the study period, 128 expressed an interest in participating. Of these, 81 were deemed eligible and agreed to participate after receiving additional information. At the end of the analysis, complete data was available for 54 patients who completed all assessments (Figure 1).

The study required the recruitment of 39 women as a sample size, with the selection criteria being a population prevalence of PFD of 32% [23], a 95% confidence level, and 80% power of test [24,25].

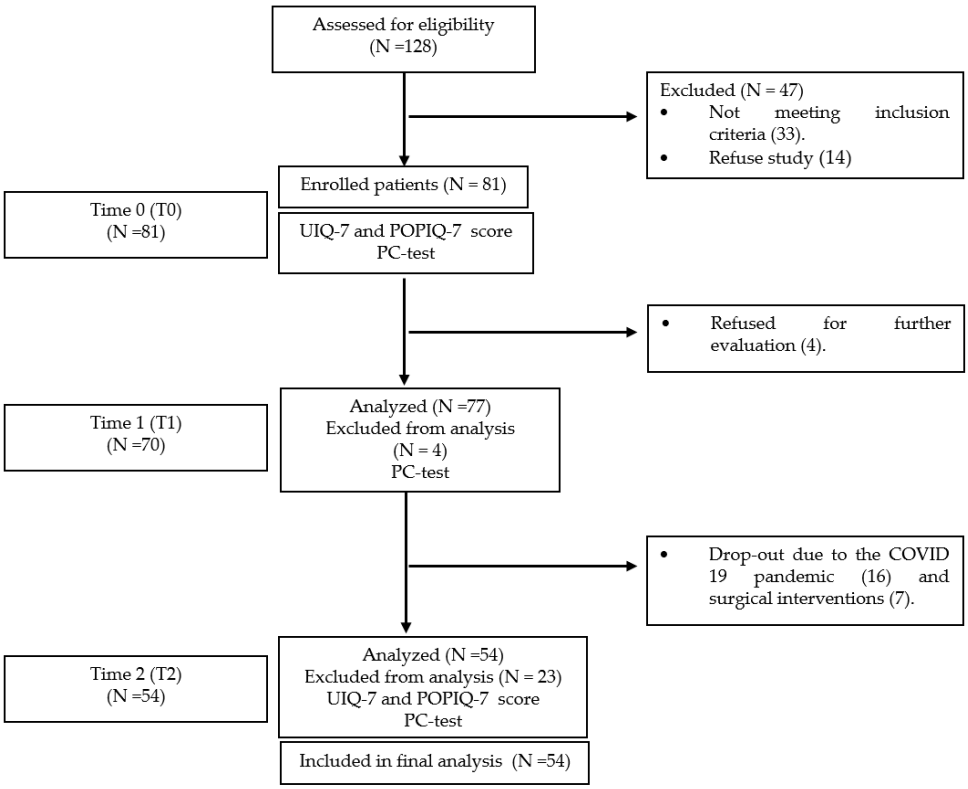


Figure 1. Flow-chart of the study.

2.2. Assessment methods

A personal and gynecological history was taken for each patient, including an objective and subjective general examination: weight, height, number of children and type of delivery, and current problems related to incontinence or other dysfunctions. Patient quality of life impact was assessed with the Pelvic Floor Impact Questionnaire - Short Form 7 (PFIQ-7) created by Barber and colleagues [4] to save time, while remaining effective, in clinical and research encounters. It is a health-related quality of life questionnaire that women with pelvic floor disorders must complete. It includes scales from the Urinary Impact Questionnaire (UIQ-7), the Pelvic Organ Prolapse Impact Questionnaire (POPIQ-7), and the Colorectal-Anal Impact Questionnaire-7 (CRAIQ-7), which are shortened versions of their longer versions It is useful for determining changes in symptom severity over time and before and after treatments.

The PFIQ-7 consists of 7 questions that need to be answered 3 times each (corresponds to the scales mentioned above) looking at symptoms related to the bladder or urine, vagina or pelvis and bowel or rectum and their effect on function, social health and mental health in the last 3 months. Responses for each question range from "not at all" (0) to "quite a bit" (3). To obtain the scale scores, the mean of each of the 3 scales is calculated individually, ranging from 0 to 3, this number is then multiplied by 100 and then divided by 3. The scale scores are then added together to obtain the total PFIQ-7 score, which ranges from 0 to 300. A lower score means there is a smaller effect on quality of life. In this study, we evaluated only two domains of the questionnaire: UIQ-7 and POPIQ-7 The Colorectal-Anal Distress Inventory (CRADI-7) was not included, as it is not relevant to our research; the women who participated do not suffer from colorectal or anal distress issues.

The UIQ-7 and POPIQ-7 are designed to assess how urinary incontinence and pelvic organ prolapse, respectively, affect the patient's daily life, emotional well-being, and overall quality of life. Each of them consists of the same seven questions related to the physical, social, and emotional effects of these conditions. The questions explore issues such as discomfort, embarrassment and impact on physical activity and relationships. Each item is usually scored on a Likert scale, where the patient rates the severity or frequency of the problem (from "not at all" (0) to "quite a bit" (3)). The total score (range 0-100) provides a quick assessment of the impact of urinary incontinence or pelvic organ prolapse on quality of life. A lower score means there is a smaller effect on quality of life. Both are used by health care providers to monitor the severity of symptoms, guide treatment decisions, and evaluate the effectiveness of interventions over time.

Each patient also had a vaginal examination and underwent a simple test to assess the function of the pelvic floor muscles (PC-test), which was performed by clinicians. The PC (pubococcygeus) test is a clinical assessment used to evaluate the strength, endurance, and fatigability of the pubococcygeus muscles. This test is typically performed during a gynecological examination to assess the condition of these muscles. In order to conduct the test, two fingers were inserted into the vagina. The subject was then asked to contract, and scores were assigned for strength of contraction (0–3), endurance (0–3, depending on the length of contraction from 0 to 9 seconds), and fatigue (0–3, depending on the number of repetitions from <2 to >9). The total score was 0–9, with 0 representing the least value and 9 representing the maximum value. During the gynecological examination, the patients were classified according to PC test.

2.3. Study protocol

A three-month vaginal cone training regimen was implemented, with assessments conducted before the intervention -T0, one month later -T1, and three months later -T2. The cone training protocol involved the use of the PELVIK® KIT, consisting of 3 medical silicone vaginal cones with a diameter of 29 mm, differently colored according to weight (white 30 g, light pink 47 g, deep pink 65 g), developed to strengthen the pelvic floor muscles in a practical, efficient and autonomous way. The cones were designed with the widest part towards the vaginal depth and the thin part, attached to a removal cord, remaining outside the vagina. The sensation of the cone sliding outwards was intended to mimic the feeling of urinary leakage, thereby passively stimulating the pelvic floor muscles and actively enhancing the patient's proprioception, leading to a perineal contraction.

Before the intervention, the patients were taught how to use the cones and to contract their pelvic floor muscles correctly. Additionally, each kit was accompanied by a leaflet, with detailed instructions and details on how to use and maintain the device. In order to understand their own pelvic floor, the patients were instructed to insert a finger, properly washed and lubricated, into the vagina for at least 2 cm, to feel the tightening of the vaginal walls when inducing the contraction of the pelvic muscles

(similar to the reflex to stop urination during urination). At first, experiencing vaginal contraction can be difficult. Through the specific vibration, this type of cones help participants to recognize the contractions and the use of the pelvic muscles, even from the first phases of the exercise.

The program involved starting the procedure with the lightest cone (white) in a position preferred by each patient. After inserting the vaginal cone, the pelvic muscles contract for around 2 seconds holding the vaginal cone. During the first days of training, it is suggested to contract the pelvic muscles in the supine position and later change to the standing position, to avoid the cone slipping due to a weakened of the pelvic floor muscles. The training was carried out progressively, depending on each individual, starting with contractions of a few seconds repeated 10 times, with breaks of 5/10 seconds after each contraction. The break interval can be increased, depending on personal need; but the contraction period must be the same during each set of 10 repetitions. It is important to focus on the pelvic muscles and avoid contracting the abdominal or gluteal muscles to maintain the cone. In case of loss of control over the pelvic muscles, the patients were advised to contact the specialist supervising her.

With the training of the pelvic muscles, the contraction time increases, and the duration of the pause necessary to end the training set decreases. To verify the need to use the next cone, with a higher weight, the following exercises were repeated: walking for at least one minute; going up and down the stairs; jumping on the spot for at least thirty seconds; cough ten to fifteen times; Groveling; Washing hands under cold water for one minute. Exceeding these exercises without sliding the cone leads to moving on to the next heavier weight cone, following the same training procedure.

The periods required to switch the level of the vaginal cones depend on each woman. Training was performed at least three times per week for 15 minutes and for twelve weeks. Control measures included weekly check-ins with patients to ensure adherence to protocol and correct and safe use of cones. Pelvic floor muscle function was assessed using the PC test at one month (T1) and three months (T2) to monitor progress and adjust the training regimen as needed. Impact on quality of life was assessed using the UIQ-7 and POPIQ-7 questionnaires, with assessments performed at T0 and T2.

2.4. Device description

The device consists of a set of 3 vaginal cones (diameter 29 mm) that have been developed in 3 different weights sufficient to carry out the entire training; respecting the medical guidelines of different weights. These cones, (Figure 6) compared to the vaginal cones previously designed, contain some changes:

- The cones are made of a single body in medical silicone without connections, steps, incisions, gluing, so they do not become a means of bacterial transmission. Each weight has been assigned a different color to maintain the characteristic listed above.
- Inside they are formed by a hollow sphere in plastic material with a small steel sphere inside to create mobility to the sphere, and a fixed secondary sphere that allows the increase in weight of each ovule. The cones have a prismatic and non-spherical cavity where a steel sphere moves freely. This movement creates a slight vibration caused by the rolling of the steel ball inside the plastic ball with irregular walls, which allows the muscles to be stimulated, during body movements, in a more direct way and giving the woman a more precise and sensitive indication of her pelvic muscles. Furthermore, it consequently allows a passive training caused by the slight vibration that stimulates the reflex perineal contraction.

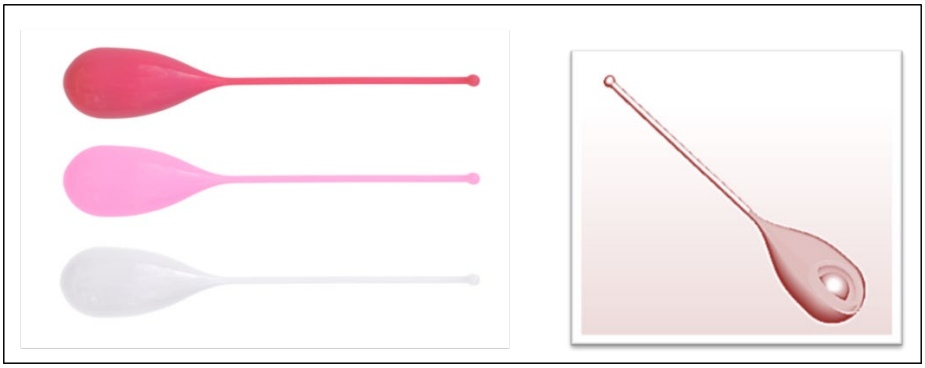


Figure 6. Set of vaginal cones

2.4. Ethical approval

The research was carried out in compliance with the World Medical Association Declaration of Helsinki and approved by the Ethics Council of the Emergency County Clinical Hospital of Arad, Romania (147/December 11, 2019). Each patient signed an informed consent form, and participation was completely voluntary.

2.5. Statistical Analysis

Data was collected using Microsoft Excel and were analyzed descriptively and analytically using JASP v18.3. Shapiro-Wilk test was used for the data distribution, which revealed that the data are not normally distributed. necessitating the employment of a non-parametric test. Mean and standard deviation (SD) were calculated for continuous variables. Percentage and frequencies were presented to describe the qualitative information. The relationship between parameters was investigated using the Kendall's (tau) correlation coefficients, a non-parametric measure that evaluates the strength and direction of association between variables. Additionally, to assess changes in evaluated parameters over time (at time points T0, T1, and T2- for PC-test and T0, T2 for UIQ-7 and for POPIQ-7), we applied a one-way repeated measures analysis of variance (RM-ANOVA) using non-parametric Friedman test, respective the non-parametric paired samples test Wilcoxon's Signed Rank. These tests allowed us to determine whether the parameters had statistically significant differences across the time points. When the F-ratio from the ANOVA indicated a significant difference (with a p-value < 0.05), we conducted a post hoc analysis using Conover's test to pinpoint where these differences occurred. The study set a significance threshold of α=0.05 to determine statistical significance. Additionally, effect sizes (ES) were calculated to assess the magnitude of parameter changes. The effect sizes were interpreted as follows: small (0.1–0.2), moderate (0.3–0.4), and large (> 0.5) [27]

3. Results

3.1. Baseline characteristics of the study group

54 patients with a mean age of 39.68 years ± 3.34 (range 26-62) were included in this pre- and post- intervention comparative analysis. Thirty-three women (61.11%) were multiparous, with at least two vaginal deliveries each; fifteen (27.78%) reported only one vaginal delivery; and the rest had cesarean sections (10/18.52%) or were nulliparous (6/11.11%). The average number of vaginal deliveries per patient was 1.64±0.894. All patients were white, and the mean values of body mass index (BMI) was 26.62 Kg/m^2 ±2.76 (range 22.30-33.00 Kg/m^2 PC test total score ranged from 1 to 9 with an average value of 4.24±2.4. The UIQ-7 score ranged from 4.719 to 80.958, with

an average of 38.901±12.268, while the POPIQ-7 score ranged from 0.00 to 52.36, with an average of 12.699±6.128 (Table 1).

In the anamnestic files we evaluated the symptomatology and static for pelvic floor, and impact on sexual activity. The more prevalent PFDs were the urinary dysfunctions, reported by 90.74% (50.00% urgence urinary incontinence, 18.52% stress urinary incontinence, 14.81% mixed incontinence, and 7.41% urinary retention). 16,6% of the women investigated had cystocele grade I (3.70%) and grade II (11.11%), and 7.41% had prolapse stage I (5.55%) and stage II (1.86%). Of these, 62.9% associated PFDs with an unsatisfactory sex life. Most of them (88.89%) reported a decrease in perception of their partner during sex due to muscle tissue laxity, while the others reported discomfort at the start of sex.

Table 1. Baseline characteristics of the group.

Demographic and clinic parameters	
Residence area (N/%)	
Urban	48/88.89
Rural	6/11.11
Years (mean ± SD)	39.68 ±3.34
Parity (N/%)	
Nulliparous	6/11.11
Uniparous	15/27.78
Multiparous	33/61.11
Birth delivery (N/%)	
Vaginal	38/70.37
Cesarean sections	10/18.52
BMI - Kg/m^2 (mean ± SD)	26.62 ±2.76
PC test score (mean ± SD)	4.24±2.46
PFIQ-7 score	
Bladder or urine problems (UIQ-7 score)	38.901±12.268
Vagina or pelvis problems (POPIQ-7 score)	12.699±6.128
Pelvic floor dysfunctions (N/%)	
Urinary dysfunctions	49/90.74
Sexual dysfunction	38/70.87
Prolapse (stage I/II)	4/7.40
Cystocele (grade I/II)	8/16.6%

N – number of patients, SD - standard deviation, PC-test – pubococcygeus test, PFIQ-7 - Pelvic Floor Impact Questionnaire - Short Form 7, UIQ-7-Urinary Impact Questionnaire, POPIQ-7 - Pelvic Organ Prolapse Impact Questionnaire.

3.2. Overview of the evolution of data during the therapy

At the T1 and T2 evaluations, there was a positive evolution of the PC test score at the level of all the parameters that test the functionality of the pelvic muscles involved in the pelvic floor static. When analyzing the score as a categorical value (Table 2), the following changes were observed:

- For strength, initially 61.11% of patients were in the category with score 1 and 16.67% in the category with score 3. At T1 and T2 assessments, the proportion of patients with score 1 decreased by 25.93% and 44, respectively, 44%, reaching

35.18. % at T1 and 16.67 at T2, while the proportion of patients with score 3 increased by 3.7% and 7.4, respectively, reaching 20.37 at T1 and 24.07 at T2.

- In the case of Endurance, at T0, almost 70% (68.52%) of patients scored 0 and 1, and at T1 and T2 this proportion decreased considerably, reaching 44.43 at T1 and 31.47 at T2. The rate of patients with score 3 increased from 7.41% at T0 to 14.18% at T1 and to 24.07% at T2. The rate of patients with score 0 decreased from 22.22% to 9.25%.
- For fatigue, at T0 61.11% of patients recorded values 1 and 2, and at T1 and T2 their rate dropped to 46.3% and 22.22%, respectively. At the T2 assessment, no patient scored 0, and the proportion of patients with a score of 3 increased from 22.22% to 50%.
- Total score analysis indicated that initially most patients had a score of 3 (38.9%), followed by those with a score of 6 (12.96%) and a score of 1 (11.11%). followed by those with a score of 1 (11.11%). score of 2 and 8 (9.26%) each. Only 7.46% registered the maximum score. At the final evaluation, most patients obtained scores of 7 and 9 (27.78 and 22.22, respectively), followed by those with scores of 6 and 5 (16.67% and 9.25%). Only 1.85% of patients had a score of 1.

Table 2. Distribution of patients based on PC test scores at the three evaluation points.

Score	T0		T1		T2	
	N	%	N	%	N	%
Strength						
0	0	0.0	0	0.0	0	0.0
1	33	61.11	19	35.18	9	16.67
2	12	22.22	24	44.44	32	59.26
3	9	16.67	11	20.37	13	24.07
Endurance						
0	12	22.22	5	9.25	5	9.25
1	25	46.30	19	35.18	12	22.22
2	13	24.07	22	40.74	24	44.44
3	4	7.41	8	14.18	13	24.07
Fatigability						
0	6	11.11	2	3.71	0	0.0
1	27	50.00	19	42.59	12	22.22
2	9	16.67	23	35.18	15	27.78
3	12	22.22	10	18.52	27	50.00
PC test total score						
0	0	0.0	0	0.0	0	0.0
1	6	11.11	1	1.85	1	1.85
2	5	9.26	4	7.41	4	7.41
3	21	38.90	14	25.92	4	7.41
4	2	3.70	3	5.56	3	5.56
5	2	3.70	3	5.56	5	9.25
6	7	12.96	19	35.18	9	16.67
7	2	3.70	1	1.85	15	27.78

8	5	9.26	8	14.81	1	1.85
9	4	7.41	1	1.85	12	22.22

T0 - pre-intervention assessment, T1- assessment after a month; T2-assessment after three months, N – number of patients, PC-test – pubococcygeus test

The evolution of the score by category, at the two evaluation points after beginning therapy, is illustrated in figure 2.

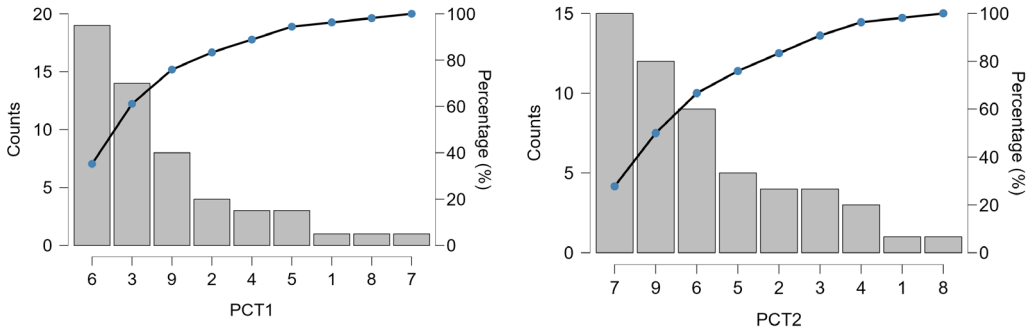


Figure 2. Pareto plot distribution of the PC total score category .a. T1, b. T2. PC-PC test total score.

The comparative analysis of the data obtained in the PC test, depending on the time of assessment, using one-way repeated measures analysis of variance (RM-ANOVA) showed a significant increase ($p<0.001$) in the average score after therapy, for all tested muscle parameters (strength. endurance, fatigability), indicating a significant increase at the level of pelvic floor muscle function. The mean strength score increased from 1.537 ± 0.794 at T0 to 1.833 ± 0.771 at T1 and further to 2.074 ± 0.640 at T2. This represents a significant improvement in muscle strength over the three assessment points (Kendall W = 0.299, $p < 0.001$). The endurance score also showed a significant increase, starting at 1.148 ± 0.833 at T0, rising to 1.611 ± 0.856 at T1, and reaching 1.833 ± 0.906 at T2, indicating a significant enhancement in the muscle's ability to sustain contractions over time (Kendall W = 0.452, $p < 0.001$). Improvements in fatigability were observed, with scores increasing from 1.481 ± 0.947 at T0 to 1.759 ± 0.779 at T1, and to 2.278 ± 0.811 at T2. This suggests that the muscles became less prone to fatigue as the intervention progressed (Kendall W = 0.490, $p < 0.001$). The overall PC test score, which combines the results of strength, endurance, and fatigability, significantly increased from 4.185 ± 2.548 at T0 to 5.148 ± 2.285 at T1, and further to 6.167 ± 2.247 at T2, reflecting a comprehensive improvement in pelvic floor muscle function (Kendall W = 0.668, $p < 0.001$). The analysis revealed the following effect sizes for the measured parameters: muscle strength (ES = 0.254), endurance (ES = 0.412), fatigability (ES = 0.473), and the total PC test score (ES = 0.511). These values suggest that the intervention had a small to moderate impact on muscle strength, a moderate to large impact on endurance and fatigability, and a large overall effect on pelvic floor muscle function (Table 3).

Table 3. Comparative analysis according to evaluation time

PC test score	T0	T1	T2	Kendal W	P*	ES
Strength	1.537±0.794	1.833±0.771	2.074±0.640	0.299	<0.001	0.254
Endurance	1.148±0.833	1.611±0856	1.833±0.906	0.452	<0.001	0.412
Fatigability	1.481±0.947	1.759±0.779	2.278±0.811	0.490	<0.001	0.473
PC total score	4.185±2.548	5.148±2.285	6.167±2.247	0.668	<0.001	0.511

*Fiedman Test, T0 - pre-intervention assessment, T1- assessment after a month; T2-assessment after three months, ES- effect size, N – number of patients, PC-test – pubococcygeus test

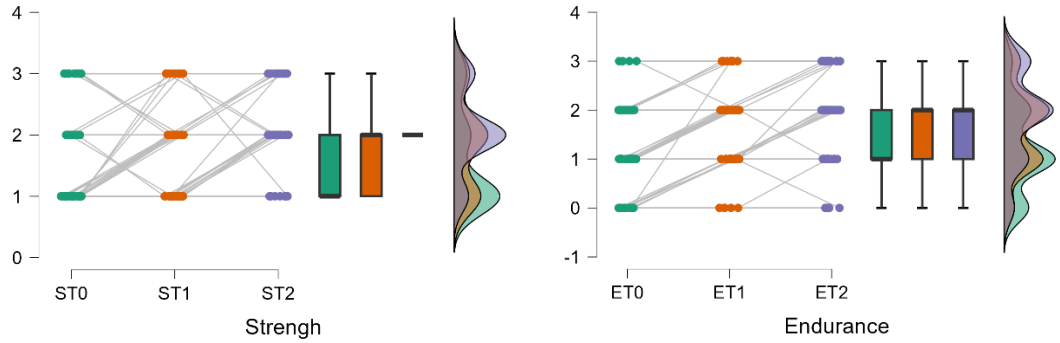
To further examine these improvements, a Conover's post hoc test was performed, comparing the scores between each pair of time points (T0 vs. T1, T1 vs. T2, and T0 vs. T2). The results confirmed significant differences in the PC test scores across all parameters at each time point, as can be seen in table 4.

Table 4. Conover's Post Hoc Comparisons for PC test

Parameters		T-Stat	p
Strength			
Strength T0	Strength T1	2.916	0.004
	Strength T2	5.619	< .001
Strength T1	Strength T2	2.703	0.008
Endurance			
Endurance T0	Endurance T1	4.470	< .001
	Endurance T2	6.705	< .001
Endurance T1	Endurance T2	2.235	0.028
Fatigability			
Fatigability T0	Fatigability T1	2.021	0.046
	Fatigability T2	6.885	< .001
Fatigability T1	Fatigability T2	4.864	< .001
PC test-total score			
PC total score T0	PC total score T1	3.927	< .001
	PC total score T2	8.344	< .001
PC total score T1	PC total score T2	4.417	< .001

Note. Grouped by subject, T0 - pre-intervention assessment, T1- assessment after a month; T2-assessment after three months, N – number of patients, PC-test – pubococcygeus test

The evolution of these parameters from the initial assessment (T0) to the end of the therapy (T2) is represented in Figure 3a-d, that illustrate the clear upward trend in pelvic floor muscle function across all parameters.



a b

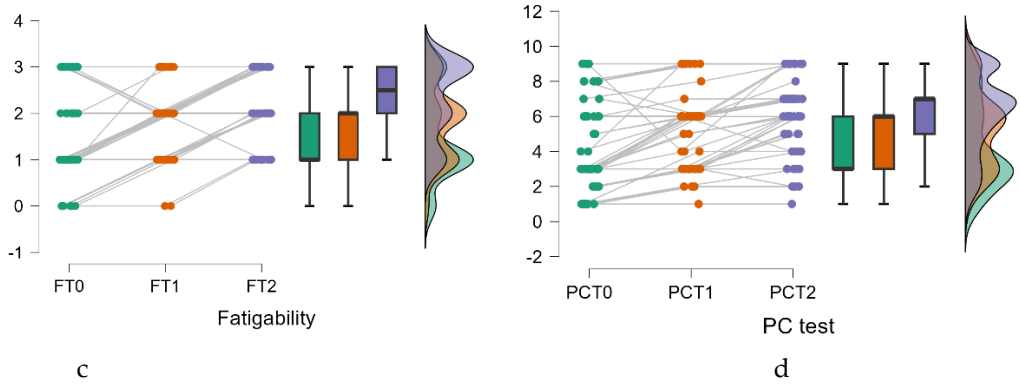


Figure 3. Results of the Friedman test for: a. Strength, b. Endurance, c. Fatigability, d. PC test total score. S-strength, E-endurance, F-fatigability, T0 - pre-intervention assessment, T1-assessment after a month; T2-assessment after three months, PC-test – pubococcygeus test.

Using the Wilcoxon signed-rank test, a significant decrease in UIQ-7 scores was observed from the start of the intervention (T0) to the end of the study period (T2). At baseline (T0), the mean UIQ-7 score was 38.901 ± 1.268, indicating a moderate to severe impact of urinary problems on the participants' quality of life. By the end of the intervention (T2), this score had significantly decreased to 29.366 ± 2.493 ($W = 1082.000$, $p < 0.001$) (Figure 4a). This significant reduction in UIQ-7 scores showed that the vaginal cone training effectively improved bladder and urinary function, leading to a substantial decrease in the symptoms associated with urinary incontinence. In contrast, the analysis of the POPIQ-7 scores revealed an insignificant decrease. At T0, the mean POPIQ-7 score was 12.699 ± 1.128, indicating a lower impact of vaginal or pelvic problems on the participants' quality of life compared to urinary issues. After the three-month intervention (T2), the mean POPIQ-7 score slightly decreased to 10.499 ± 2.362. However, this decrease was not statistically significant ($W = 278.000$, $p = 0.800$) (Figure 4b). The effect size analysis reinforces the statistical findings, indicating a large effect size for UIQ-7 (ES = 0.570), and a minimal effect size for POPIQ-7 (ES = 0.053).

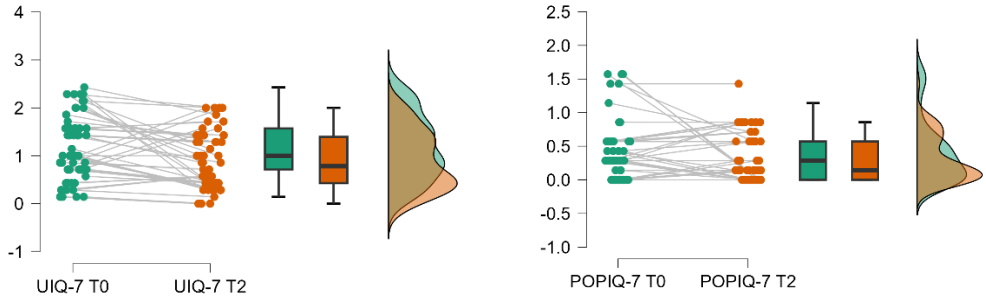


Figure 4. Results of the Wilcoxon signed-rank test for PFIQ-7 score evolution, a-blader and urine problems, b-vagina and pelvis problems. UIQ-7-Urinary Impact Questionnaire, POPIQ-7 - Pelvic Organ Prolapse Impact Questionnaire, T0 - pre-intervention assessment, T2-assessment after three months.

These insignificant changes in the POPIQ-7 score indicate that vaginal cone training had a smaller impact on alleviating pelvic organ prolapse symptoms than on urinary symptoms. This could be attributed to the nature of pelvic organ prolapse, which may necessitate more targeted or diverse interventions than simply strengthening the pelvic floor muscles to effectively manage symptoms and improve quality of life.

3.3. Correlation of the PC test score with demographic and clinic variable

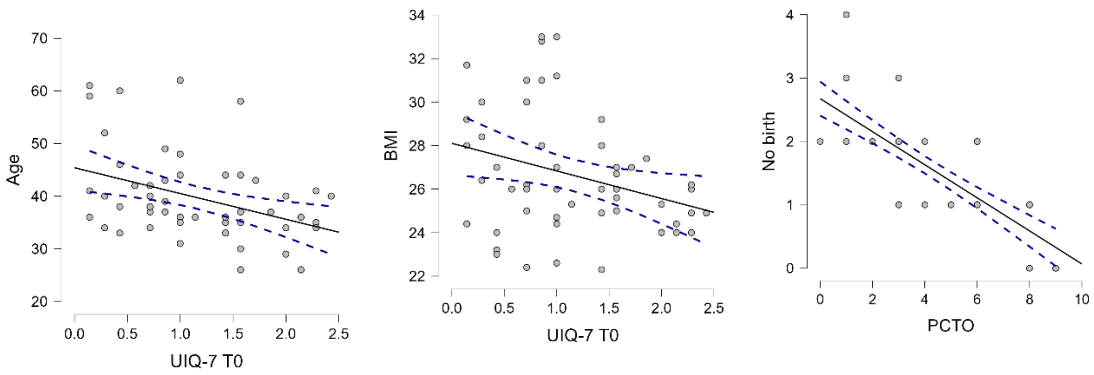
Kendall's (tau) correlation coefficients were used to investigate the relationship between analyzed parameters. The results showed a significant negative association for PC test with number of birth (T= -0.710, P<0.001). According to this result, pelvic floor muscle function, as determined by the PC test, tends to decline as the number of births increases. Similarly, a significant negative association was found between UIQ-7 scores and both age and BMI (P < 0.001). This implies that older age and higher BMI are linked to greater impairment in bladder and urinary function, as reflected by higher UIQ-7 scores. As women age or gain weight, the pelvic floor muscles may weaken or be subjected to greater stress, resulting in worsened symptoms of urinary incontinence (Table 4).

Table 4. Correlation between studied variable

Variable		PCTO	Age	BMI	No birth	UIQ-7 T0	POPIQ-7 T0
PCTO	Kendall's Tau B	—					
	p-value	—					
Age	Kendall's Tau B	-0.108	—				
	p-value	0.295	—				
BMI	Kendall's Tau B	-0.076	0.316 **	—			
	p-value	0.462	0.001	—			
No birth	Kendall's Tau B	-0.707 ***	0.000	-0.022	—		
	p-value	< .001	1.000	0.841	—		
UIQ-7 T0	Kendall's Tau B	-0.023	-0.281**	-0.209*	0.172	—	
	p-value	0.822	0.004	0.033	0.119	—	
POPIQ-7 T0	Kendall's Tau B	0.047	-0.133	-0.091	0.139	0.352 ***	—
	p-value	0.666	0.196	0.378	0.231	< .001	—

* p < .05, ** p < .01, *** p < .001

These significative association are presented in Figure 5 a-c. The downward trends in these figures emphasize the inverse relationships, highlighting the impact of increased parity, age, and BMI on pelvic floor muscle function and urinary symptoms.



a b c

Figure 5. Significant association a - UIQ-7 score with ag, b - UIQ-7 score with BMI, c -PC test with number of birth).

Starting with the significant association of the PC test score with the number of births, we detailed the analysis, testing the relationship between this variable and the muscle parameters included in the PC test. The findings showed that there was a negatively and significantly correlated relationship between the number of births and strength (T = -0.742, p< 0.001), endurance (T = -0.623, p<0.001), fatigability (T =-0.700, p< 0.001) (Figure 6).

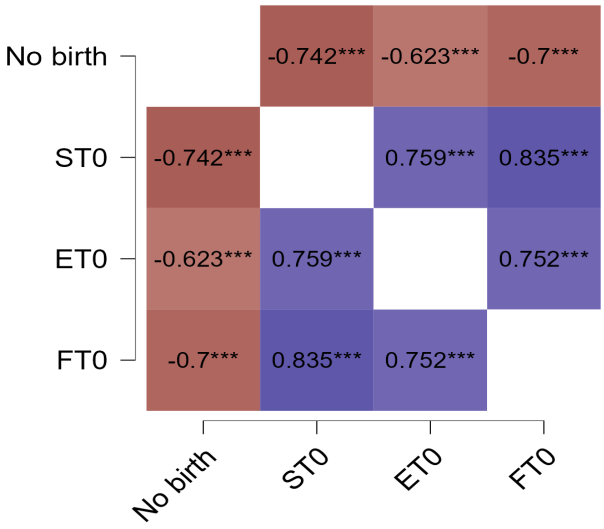


Figure 6. Kendall's tau B heatmap for association between number of birth and muscles parameters. S-strength, E-endurance, F-fatigability, T0 - pre-intervention assessment

The negative correlation suggests that the pelvic floor muscles may become weaker with repeated childbirth, which would reduce their strength and endurance—two essential qualities for the pelvic floor to function effectively. These results are consistent with previous research that indicates that aging, childbirth, and higher body mass index are among the variables that worsen pelvic floor dysfunction symptoms, especially incontinence.

3. Discussion

Pelvic Floor Dysfunction (PFD) encompasses a range of conditions that result from weakened or dysfunctional pelvic floor muscles, and significantly impact the quality of life for many women. Pelvic rehabilitation is a key component in the management of PFD, offering a non-invasive and effective approach to improve symptoms, restore pelvic floor function, and prevent complications [28].

Weighted vaginal cones were created to promote adherence to pelvic floor muscle exercise and assist patients in recognizing and controlling their pelvic floor muscles [29]. In this study, we evaluated the effectiveness of using a specific type of vaginal cone in perineal rehabilitation. This device represents an advancement in pelvic floor therapy, combining the traditional benefits of vaginal cone training with innovative features designed to improve outcomes. These cones include a spherical steel inside that, when the patient is in motion, produces weak vibrations and helps muscle proprioception, also gravity tends to pull out the weighted cone, the vibration and weight work in synergy to create a reflex of closure of the perineal muscles that stimulates the perivaginal muscles to contract to keep the cone in place. By gradually varying the weight of the cones this increases the contractile force and consequently the continence, improving the basic pelvic tone and the trophy of the pelvic muscles.

Its design promotes comfort, ease of use and hygiene, which can reduce the psychological barriers often associated with traditional training with vaginal cones.

The results showed that patients included in this study experienced improvements in pelvic floor muscle strength and function, as well as a reduction in symptomatology. Women of all ages experience pelvic floor dysfunction. In our study, the mean age of the patients was 39.68 years, which is within the range where PFD often become more pronounced, especially in women with a history of vaginal deliveries. The data show that a substantial proportion of the women (61.11%) were multiparous, with at least two vaginal deliveries each, and an additional 27.78% had experienced one vaginal delivery. The higher prevalence of PFD in these women is consistent with existing literature that identifies vaginal delivery as a major risk factor for the development of pelvic floor disorders, due to the stress it places on pelvic tissues and muscles [30,31]. The presence of PFD, including in women who gave birth by caesarean section and in nulliparous women, suggests that, while vaginal delivery is a significant risk factor, other factors, such as age, BMI, lifestyle, hormonal status and hysterectomy, also play a role in the development of PFD [32,33]. The mean BMI of the group was 26.62 kg/m^2, which is classified as overweight. Higher BMI is a known risk factor for PFD, as excess weight increases intra-abdominal pressure, further stressing the pelvic floor [16]. Bladder and urinary problems (UIQ-7) have a more significant impact on the participants than vaginal or pelvic organ prolapse problems (POPIQ-7). The wide range of UIQ-7 scores (4.719 to 80.958) suggests that the severity of urinary symptoms varies greatly among individuals, necessitating personalized treatment approaches. In contrast, prolapse symptoms, while still impactful, appear to be less severe on average but still require attention, especially for those experiencing more significant symptoms.

A significant 62.9% of the women associated their pelvic floor disorders with an unsatisfactory sex life, with 88.89% reporting a decreased perception of their partner during sex, primarily due to muscle tissue laxity. This highlights the broader quality of life issues faced by women with PFD, extending beyond physical symptoms to psychological and relational aspects. The association between pelvic floor dysfunction and sexual dissatisfaction is well-documented [32-35], and these findings reinforce the need for comprehensive treatment strategies that address both physical and emotional aspects of PFD.

Pelvic floor muscle strength and function are fundamental to the management and prevention of PFD [36]. Weak or dysfunctional pelvic floor muscles contribute to a range of symptoms, from incontinence to pelvic organ prolapse [37], and can significantly impact a woman's quality of life. The progression of PC test scores over the course of this study (T0, T1, T2) reflects significant improvements in the functionality of pelvic floor muscles among the participants. The data reveals a substantial increase in the strength of pelvic floor muscles over time. Initially, a majority of patients (61.11%) had a low strength score of 1, indicating weak pelvic floor muscles. By the time of the T1 and T2 evaluations, this proportion had decreased significantly—by 25.93% at T1 and by 44% at T2. Concurrently, the percentage of patients achieving a higher strength score of 3 increased steadily, from 16.67% at baseline to 20.37% at T1 and 24.07% at T2. This positive shift suggests that the vaginal cone training was effective in strengthening the pelvic floor muscles. Endurance, or the ability of the pelvic floor muscles to sustain contractions over time, also showed marked improvement. Initially, nearly 70% of patients had very low endurance, with scores of 0 or 1. This proportion decreased significantly at subsequent evaluations, dropping to 44.43% at T1 and 31.47% at T2. Meanwhile, the proportion of patients with the highest endurance score (score 3) more than tripled by T2, rising from 7.41% at T0 to 24.07% at T2. Fatigability also improved notably. Initially, 61.11% of patients scored between 1 and 2, indicating a high susceptibility to muscle fatigue. However, by T2, this proportion had decreased to 22.22%, with no patients scoring 0, which would indicate severe fatigue. Moreover, the proportion of patients achieving the highest fatigue resistance score (score 3) doubled from 22.22% at T0 to 50% at T2.

The overall PC test score analysis further corroborates the positive impact of the intervention. Initially, most patients had low to moderate scores, with most clustered around a score of 3. By the final evaluation (T2), the distribution had shifted significantly, with most patients achieving higher scores of 7 and 9, and only a small fraction (1.85%) remaining at the lowest score of 1. The significant gains in strength, endurance, and fatigue resistance, as well as the overall improvement in total PC test scores, suggest that this approach could be beneficial for patients suffering from pelvic floor dysfunction. These findings support the continued use and further development of structured pelvic floor rehabilitation programs, particularly those that incorporate progressive resistance training. Such improvements are likely to translate into better clinical outcomes, including reduced symptoms associated to PFD [38].

Findings of the comparative analysis of the impact of the intervention on quality of life, reveal a significant decrease in bladder and urinary problems (UIQ-7) and a non-significant decrease in vagina or pelvis problems (POPIQ-7). These results are consistent with previous research that supports the use of vaginal cones for urinary incontinence [39,40], but suggest that more comprehensive interventions may be required for pelvic organ prolapse [41]. The significant improvement in UIQ-7 scores suggests important clinical benefit in managing urinary incontinence, while the non-significant change in POPIQ-7 scores points to the need for more comprehensive treatment strategies for pelvic organ prolapse. These results underscores the effectiveness of the vaginal cone training in reducing urinary problems but also highlights the limitations of this approach in addressing other aspects of pelvic floor dysfunction, such as vaginal and pelvic problems. To improve outcomes for women with pelvic organ prolapse, it may be beneficial to combine cone training with other interventions, such as pelvic floor physiotherapy, pessary use, or surgical options, depending on the severity of the prolapse. Additionally, complementary therapies like biofeedback or electrical stimulation could enhance the effectiveness of pelvic floor exercises by providing real-time feedback or additional muscle activation. Future research should explore the integration of these therapies to create a more holistic approach to pelvic floor dysfunction (PFD), addressing both urinary incontinence and pelvic organ prolapse more effectively.

The results revealed a significant negative correlation between the PC test score and the number of births ($T = -0.710$, $p < 0.001$), indicating that increased parity is associated with reduced pelvic floor muscle function. Further analysis demonstrated that the number of births was negatively correlated with specific muscle parameters, including strength ($T = -0.754$, $p < 0.001$), endurance ($T = -0.681$, $p < 0.001$), and fatigability ($T = -0.776$, $p < 0.001$). Additionally, significant negative associations were found between UIQ-7 scores and both age and BMI, suggesting that older age and higher BMI are linked to greater impairment in bladder and urinary function. These findings are in line with a large body of research. Overweight, obesity, female sex, vaginal delivery, multiparity, menopause, advanced age, and prior genitourinary and abdominal surgeries are among the risk factors that have been most frequently linked to UI [42]. Age is a known risk factor for various forms of urinary incontinence, including stress urinary incontinence and urge urinary incontinence. As women age, several physiological changes occur that can contribute to urinary dysfunction, including: pelvic floor muscle weakness, hormonal changes, neuromuscular degeneration [43,44]. Research consistently shows that women with higher BMI are at greater risk for developing urinary incontinence [45]. Weight loss has been demonstrated in studies to improve urinary symptoms [46], highlighting the modifiable nature of this risk factor [48,49]. Our results reinforce the importance of considering both age and BMI in the assessment and management of urinary dysfunction in women. Clinicians should be aware that older women and those with higher BMI are at increased risk for urinary incontinence and may benefit from targeted interventions such as pelvic floor muscle training, lifestyle modifications, or weight management programs. Furthermore, these results suggest that early

intervention in women with higher BMI or those approaching menopause might prevent or mitigate the progression of urinary dysfunction. Tailored interventions could potentially improve quality of life and reduce the healthcare burden associated with urinary incontinence.

It is important to take into account some limitations of this study when evaluating the findings. The small number of subjects, the pre- post intervention design of the study without control group, and the uneven distribution of subjects with different pelvic dysfunctions are the main limitations of this study. Another limitation is represented by the digital palpation method we employed to evaluate pelvic floor muscle's function. The PC test, despite being a useful tool, widely used in physical therapy and clinical evaluation, has limitations due to its relatively simple scoring system. The narrow ranges for each parameter may not fully capture the complex interplay of muscle function factors that contribute to PFD symptoms. However, future research should aim to explore the long-term benefits of using this type of vaginal cones in perineal rehabilitation, particularly in comparison to other devices and traditional cone training. Studies could also investigate the device's effectiveness in diverse populations, including older women and those with complex pelvic floor disorders. Additionally, exploring the integration of the cone with other therapeutic modalities, such as pelvic floor physical therapy or electrical stimulation, could provide insights into developing comprehensive rehabilitation programs.

5. Conclusions

Vaginal cone training significantly improved pelvic floor muscle function and quality of life in women with pelvic floor dysfunction (PFD), showing a pronounced impact on urinary symptoms but minimal effect on pelvic organ prolapse symptoms. This suggests that a more comprehensive approach may be required to effectively treat PFD, particularly for problems related to prolapse. As a non-invasive intervention, vaginal cone training holds promise as a valuable retraining technique in perineal rehabilitation programs, particularly for women with urinary symptoms, offering potential for improved quality of life with minimal, cost-effective intervention.

However, to better understand the long-term benefits and comparative effectiveness of pelvic floor training with this type of vaginal cone, future research including control groups, comparisons with other established pelvic floor exercises, larger patient cohorts and extended follow-up periods are required.

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Council of the Emergency County Clinical Hospital of Arad (147 /December 11, 2019).

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data presented in this study are available on request from the corresponding author. The data are not publicly available due to privacy reasons.

Conflicts of Interest: Author F.V. is the inventor of patent N. 202016000076605, DISPOSITIVO PER LA GINNASTICA PELVICA, 31/01/2019, 00187 Roma, Italy. We confirm that F.V. was not involved in the investigation of the patients, and that there has been no financial support for this paper that could have influenced its outcome.

We attest that the experiments comply with the current laws of Romania.

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