PhD THESIS

SUMMARY

Pelvic floor dysfunction: prevention and conservative treatment

PhD Student: **Dr. Federico Villani**

Scientific supervisor**: Prof. univ. Dr. Cristian Furău**

UNIVERSITATEA DE VEST
"VASILE GOLDIȘ"
din ARAD

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INTRODUCTION

The pelvic floor remains a relatively new area of study, with many aspects still not fully understood. My growing interest led me to explore various rehabilitation techniques, from Kegel exercises to more modern technological interventions. However, I wanted to create a practical and affordable solution that women could use independently to manage their pelvic floor health. After evaluating several options, I focused on vaginal cones due to their simplicity, accessibility, and biological effectiveness. Although they had been studied extensively, I noticed gaps in how their potential had been fully realized.

The main scientific goals of this research were to investigate some point:

- Develop and certify a rehabilitation approach to provide women with a safe technique for managing the symptoms of urinary incontinence;
- Accredit preventive techniques for perineal damage which is among the major causes of urinary incontinence;
- Research and accredit predictive methodologies for perineal damage to protect and create awareness in the patient and the doctor of the greater risk of damage
- Create practical solutions for the management of postpartum dysfunctions

CURRENT STATE OF KNOLEGE

CHAPTER 1. PELVIC FLOOR

Recent research has shed light on previously unclear aspects of pelvic floor activity, providing new insights into its function and potential dysfunctions [1]. The musculature of the pelvic floor has been extensively studied using advanced techniques such as electromyography, sonography, magnetic resonance imaging, histochemistry, histology, and molecular research. Recent studies have expanded beyond urinary and gynecological aspects to include the biomechanics and dynamics of the pelvic floor, allowing for a more holistic understanding of this vital structure. These insights reveal that the pelvic floor plays a critical role in various whole-body functions, such as maintaining posture, walking, and overall physical behavior, all of which are intricately linked to urinary, genital, and intestinal functions.

Today, the pelvic floor is recognized as a complex musculofascial unit, where muscular bundles work in both synergistic and antagonistic ways to perform multiple roles. This perspective shifts the understanding of the pelvic floor from merely a structure responsible for closing the pelvic cavity to one involved in a wide range of activities essential for bodily function and stability. The interplay between these muscle groups reflects its dynamic involvement in maintaining not only pelvic health but also overall physical well-being [1].

CHAPTER 2. RELAXING PELVIC FLOOR PATHOLOGY

The pathophysiology of a relaxing pelvic floor traces its origins to human evolution, particularly the transition from quadrupedal locomotion to an upright posture. This shift resulted in a significant increase in pressure exerted on the pelvis and pelvic floor muscles. In an upright position, the pelvic floor must bear the weight of the abdominal organs and resist gravitational forces, leading to increased vulnerability in this region. Over time, these changes in pressure have contributed to a variety of pelvic floor dysfunctions, negatively affecting a person's quality of life—emotionally, socially, and professionally [2] .

Common conditions linked to relaxing pelvic floor dysfunction are:

- Urinary incontinence: involuntary leakage of urine due to weakened support of the bladder and urethra.
- Fecal incontinence: the inability to control bowel movements, often due to weakened muscles surrounding the anal sphincter.
- Anorectal prolapse: the descent or protrusion of rectal tissue into or outside the anus, caused by loss of support in the pelvic floor.
- Pelvic organ prolapse: the descent of pelvic organs (such as the bladder, uterus, or rectum) into or through the vaginal canal, due to the weakening of the muscles and ligaments that hold them in place.

These dysfunctions often manifest as a result of chronic strain, childbirth, hormonal changes, aging, or surgery. They can lead to severe discomfort, embarrassment, and diminished self-esteem, which greatly impacts personal relationships and social interactions. Moreover, the effects extend into the workplace, as individuals may struggle with daily activities, leading to reduced productivity and participation in professional life [3].

CHAPTER 3. NON-RELAXING PELVIC FLOOR DISFUNCTION

Non-relaxing pelvic floor dysfunction is an umbrella term encompassing a variety of conditions, symptoms, and dysfunctions. Dr. Faubion utilized this term when developing guidelines for the Mayo Clinic, aiming to consolidate the range of symptoms linked to these disorders, as there is still no standardized classification for them. This dysfunction is primarily characterized by different types of pain or functional issues in the pelvic or nearby regions, affecting multiple organs and physiological processes [4].

Non-relaxing pelvic floor dysfunction is primarily triggered by improperly learned neurofunctional mechanisms related to urination or defecation. When these processes are not correctly developed, they can lead to issues such as involuntary retention of urine or feces, which worsen over time due to factors like lifestyle, posture, and poor habits. These incorrect mechanisms contribute to the constant activation of pelvic muscles, creating a state of chronic contraction [5].

Several other conditions can also lead to this persistent contraction. For example, vaginal dysbiosis, recurrent vulvovaginitis, and vulvodynia may cause long-term discomfort or pain, which in turn can result in chronic pelvic muscle hypertonicity. Additionally, research suggests that the vaginal microbiota might play a role in the development of vulvovaginal conditions such as vulvodynia [6].

These dysfunctions can also lead to central and peripheral hypersensitivity, altering the body's pain response by lowering nociceptive thresholds. As a result, individuals may experience heightened sensitivity, known as allodynia, where pain is felt in response to stimuli that would not normally be painful [7-8]. Pain can spread between organs and muscles, further complicating diagnosis and treatment. Studies increasingly show that neighboring pelvic organs engage in neural cross-communication, making the mechanisms behind these dysfunctions difficult to fully understand [9].

Musculoskeletal and postural abnormalities can also be contributing factors, as they can trigger kinetic chains that hypercontract the pelvic muscles. Another significant cause is trauma, particularly sexual abuse, which can lead to pelvic floor dysfunction. Research highlights how emotional factors can influence gastrointestinal issues, chronic nonspecific pain, and chronic pelvic pain, further emphasizing the diverse and complex causes of non-relaxing pelvic floor dysfunction [10].

Given this wide range of triggers, the evaluation of non-relaxing pelvic floor dysfunction is inherently complex, as it involves a thorough understanding of the multiple physiological, neurological, and emotional factors at play.

PERSONAL CONTRIBUTION

1. WORKING HYPOTHESIS/PURPOSE/GENERAL OBJECTIVES

Pelvic floor dysfunction (PFD) is a common condition affecting women across their lifespan, often resulting from pregnancy, childbirth, and aging [11].

Recent data on PFD highlight the significant impact they have on quality of life, particularly in women. Pelvic floor dysfunction includes issues like urinary incontinence, fecal incontinence, pelvic organ prolapses, and pelvic pain, which can severely impair physical, emotional, and social well-being [12,13].

Preventive measures and conservative treatment strategies, such as perineal rehabilitation, antenatal training, and assessing anovaginal distance, can mitigate the occurrence and severity of PFD. Early intervention and targeted conservative treatments will improve functional outcomes, reduce the risk of perineal trauma, and enhance overall quality of life for women.

The purpose of this thesis is to investigate the role of conservative treatments in preventing and managing pelvic floor dysfunction in women, with a particular focus on the benefits of perineal rehabilitation, antenatal perineal training, and the use of anovaginal distance as a predictor of perineal trauma during childbirth. By conducting a series of clinical studies, the research aims to demonstrate the effectiveness of these approaches in preventing pelvic floor injuries and improving pelvic floor function in women throughout different stages of life.

The general and specific objectives that were the basis of the study hypotheses were the following:

1. To contribute to the development of preventive strategies and conservative treatment approaches for pelvic floor dysfunction that can be implemented across different stages of a woman’s life, promoting long-term pelvic health and quality of life.
2. To investigate whether the antenatal measurement of anovaginal distance can serve as a reliable indicator of perineal damage risk during pregnancy and childbirth, and its potential utility in identifying women at higher risk for pelvic floor dysfunction (Study 1).
3. To evaluate the role of antenatal perineal training in preventing perineal injuries during childbirth and to follow up on the effectiveness of this intervention in the postpartum period, particularly after the puerperium (Study 2).
4. To assess the effectiveness of perineal rehabilitation—specifically vaginal cone training—in improving pelvic floor function and reducing the symptoms of pelvic floor dysfunction (Study 3 and 4).

2. ANTENATAL ANOVAGINAL DISTANCE, A POTENTIAL INDICATOR OF PERINEAL DAMAGE DURING PREGNANCY/EXPERIMENT 1

Hypothesis/goal/objectives

The perineum, a soft tissue area extending from the anus to the posterior border of the vulvar vestibule, plays a critical role in childbirth. During pregnancy, increased blood flow occurs in this region, and the overstretching that can happen during vaginal delivery may result in trauma. [14]. Several studies have suggested that women with a shorter perineal length are more likely to undergo episiotomy and had a significantly higher risk of third- and fourth-degree perineal tears during vaginal delivery [15,16].

Despite these associations, there is limited data on how AVD measurements in the prenatal period correlate with perineal outcomes post-delivery. Therefore, this retrospective observational cohort study had the main objective of investigating the relationship between AVD and the incidence of perineal injuries, including episiotomy and different degrees of perineal laceration, in a population of pregnant women who presented for pelvic floor evaluation during the gestational period of 28 to 32 weeks. Understanding these associations may allow better identification of women at higher risk of severe perineal injury, potentially guiding more personalized obstetric care strategies to minimize these outcomes.

Materials and Methods

This observational retrospective cohort study was conducted at Breastfeeding and Pelvic Floor Clinic of the University Hospital of Padua, a tertiary university hospital in Padoua, Italy. This clinic specializes in the assessment and management of pelvic floor health and supports breastfeeding among new mothers.

The data of 472 patients who consecutively addressed the clinic for pelvic floor evaluation and gave birth in the same clinic, were checked for inclusion in the study. After applying the inclusion/exclusion criteria, 416 women were included in the final analysis. Based on the results obtained from AVD measurements in our study (from 0.5 cm to 4.0 cm) and data from the literature [16] we defined reduced AVD for values <2cm and normal AVD for values ≥2cm. According to AVD, the study participants were divided into 2 groups: AVD – N group, which included 252 patients with AVD ≥ 2 cm, and the AVD-R group, which included 164 with AVD < 2 cm. The results of the pelvic floor assessment and those related to childbirth were then examined in relation to AVD (reduced vs normal).

Results

416 women, mean age 34.24±3.93 (range 19-46), were included in this retrospective observational cohort study. 252 (60.58%) of them had normal AVD (≥2 cm) and 164 (39.42%) had reduced AVD (<2 cm).

Results of comparative analysis of the two groups, AVD-N (N=252) and AVD-R (N=164), across maternal and neonatal are presented in table I.

Table I. Associations of demographic and clinic characteristics with reduced AVD

Characteristic	AVD-N (N=252)	AVD-R (N=164)	P*
Maternal age (years)	34.01 (SD=4.009)	34.585(SD=3.795)	0.096
Maternal BMI (kg/m²)	21.756(SD=2.915)	21.951(SD=2.753)	*0.410*
Underweight/normal weight	221 (87.70%)	143 (87.19%)	0.638
Overweight	31 (12.30%)	21 (12.81%)	
Parity			
0	199 (78.97%)	131 (79.88%)	0.823
1	53(21.03%)	33 (20.12%)	
GW at AVD measured	30.556(SD=1.577)	30.659(SD=1.584)	0.407
28	47 (18.65 %)	29 (17.68 %)	0.693
28	27 (10.71 %)	16 (9.75 %)	
30	30 (11.91 %)	20 (12.20 %)	
31	35 (13.90 %)	16 (9.75 %)	
32	113 (44.84 %)	83 (50.61 %)	
AVD	*2.881 (SD=0.340)*	*1.375 (SD=0.330)*	*< 0.001*
Perineal tonicity			
Hypo	20 (7.94%)	9(5.488%)	< 0.001
Normal	134 (53.17%)	51 (31.10%)	
Hyper	98 (38.89%)	104 (63.42%)	

Characteristic	AVD-N (N=252)	AVD-R (N=164)	P*
Mode of delivery			
Spontan delivery	146 (57.29 %)	71 (43.29 %)	< 0.001
Spontan delivery +episiotomy	7 (2.78 %)	22 (13.42 %)	
Operative delivery	1 (0.40 %)	2 (1.22 %)	
Operative delivery+episiotomy	16 (6.34%)	33 (20.12 %)	
Induced delivery	82 (32.54 %)	36 (21.95 %)	
GW at delivery)	39.42 (SD=1.100)	39.29 (SD=1.12)	0.222
<40 weeks' gestation (37-39)	122 (48.41 %)	80 (48.78 %)	0.251
≥40 weeks' gestation (40-41)	130 (51.59%)	84 (51.22 %)	
Newborn weight (g)	3304.159 (SD=365.760)	3290.634 (SD=402.988)	0.868
Newborn head circumference (cm)	34.269 (SD=1.220)	34.367 (SD=1.298)	0.373
Episiotomy			
yes	23.00 (8.66%)	59 (35.97%)	< 0.001
no	229 (91.34%)	105 (64.03%)	
Tear degree at delivery			
Laceration grade 0	124 (49.20 %)	50 (30.49 %)	< 0.001
Laceration grade 1	85 (33.73 %)	38 (23.17 %)	
Laceration grade 2	43 (17.06 %)	60 (36.59 %)	
Laceration grade 3	0 (0 %)	13 (7.92 %)	
Laceration grade 4	0 (0 %)	3(1.63 %)	

The mean AVD was higher in the group without episiotomy (2.427 cm) compared to the group with episiotomy (1.718 cm). This indicates that the anovulvar distance is generally shorter when an episiotomy is performed. The results indicate that there are significant differences in AVD as the degree of perineal tear increases from 0 to 4 ($p<0.05$). Particularly, larger differences in AVD were registered as the tear degree increases, with tear degrees 3 and 4 associated with much lower AVD compared to lower degrees. The non-significant results between tear degrees 0 and 1 Mean Difference = 0.035, p-value = 1.000), as well as between 3 and 4 Mean Difference = 0.310, p-value = 1.000) suggest that AVD does not change as much between these adjacent degrees.

Two logistic regression analysis was performed with all related factors as independent variables and perineal injury (episiotomy and perineal tears) as dependent variable. Continuous variables included, age, BMI, newborn weight (g), newborn head circumference (cm). The categorical variables were assigned the following values: episiotomy: 0 = no episiotomy, 1 = episiotomy, tear degree 0=no (laceration grade 0 and 1), 1= yes (laceration grade 2,3 and 4), AVD: <2 = reduced, AVD ≥2 cm = normal.

After adjustment for confounding factors, the statistical significance OR was 3.588 (95% 0.972 1.120) for perineal tears predicting, and 6.346 (95% CI 3.560-11.311) for episiotomy The analysis highlights that reduced AVD is a significant risk factor for both perineal tears and episiotomy. It has a strong effect on increasing the likelihood of these injuries, independent of other factors such as age, BMI, and newborn characteristics.

Discussion

The results suggest that AVD could be a useful metric in prenatal assessments to predict the likelihood of perineal trauma during delivery. Women with a reduced AVD might benefit from targeted interventions, such as pelvic floor exercises or more careful monitoring during labor to minimize the risk of severe perineal tears or the need for an episiotomy. Evidence indicates that perineal massage can be initiated during the third trimester of pregnancy to enhance muscle elasticity and facilitate the stretching of the perineum during childbirth, which may help lower the risk of tearing or the need for an episiotomy [17]. Additionally, these findings could inform decisions about the mode of delivery, particularly for women identified as being at higher risk for perineal trauma.

Conclusions

By incorporating AVD measurements into routine obstetric assessments, clinicians may better identify women at risk for severe perineal trauma, leading to more personalized and effective care strategies. Future research should continue to explore the role of AVD and other anatomical measures in predicting and preventing perineal injuries, ultimately contributing to improved maternal outcomes in childbirth.

3. ANTENATAL PERINEAL TRAINING FOR INJURIES PREVENTION: FOLLOW UP AFTER PUERPERIUM /EXPERIMENT 2

Hypothesis/goal/objectives

The purpose of this study was to determine whether perineal training performed in the final weeks of pregnancy could lower the frequency and severity of perineal injuries sustained during childbirth, as well as to assess the long-term effects of these exercises by monitoring the participants following the puerperium period. The findings of this study may offer insightful information on the advantages of perineal training during pregnancy and its possible contribution to better maternal health outcomes.

Materials and Methods

This study is a three-year retrospective analysis evaluating the rate of perineal trauma and pelvic floor dysfunction based on the type of perineal preparation performed during pregnancy. One hundred and fifty women in their first pregnancy who accessed private clinics based in Padua (Italy) from September 2019 to November 2023, for prenatal evaluation, postpartum visit at 40 days and for pelvic floor evaluation within 6 months of delivery. The clinic is a facility specific to pelvic floor pathologies and pregnant women are referred by other specialists or present spontaneously for an evaluation of the pelvic floor during pregnancy. As a routine, the methods of perineal preparation for birth are presented and explained to women such as: perineal massage or perineal balloon, leaving the woman free to decide whether or not to use one of the techniques respecting a physiological pregnancy.

The methods for perineal preparation included perineal massage and stretching balloon training. Patients who used one of these techniques formed the study groups: balloon stretching group (BSG, N=50, 33.3%) and perineal massage group (PMG, N=39, 26.0%). Women who did not use any method of perineal preparation for childbirth made up the control group (CG, 61, 40.7%) (Figure 1).

Results

Among the selected patients, 150 fulfilled the requirements to be included in this retrospective analysis. Most patients (over 70%) were in the 30-34 and 35-39 age groups and resided in urban areas (90%). There were 74 cases (49.3%) of spontaneous births at term, 34 cases (22.7%) of induced births at term, and 25 (16.7%) cases of ventouse deliveries. Additionally, spontaneous births were observed at 36-39 weeks of gestation (12.3%).

Episiotomy was used in 39 cases (26%). In the case of patients with perineal tears, grade 2 lacerations were the most frequent (24%), followed by grade 1 lacerations (16%).

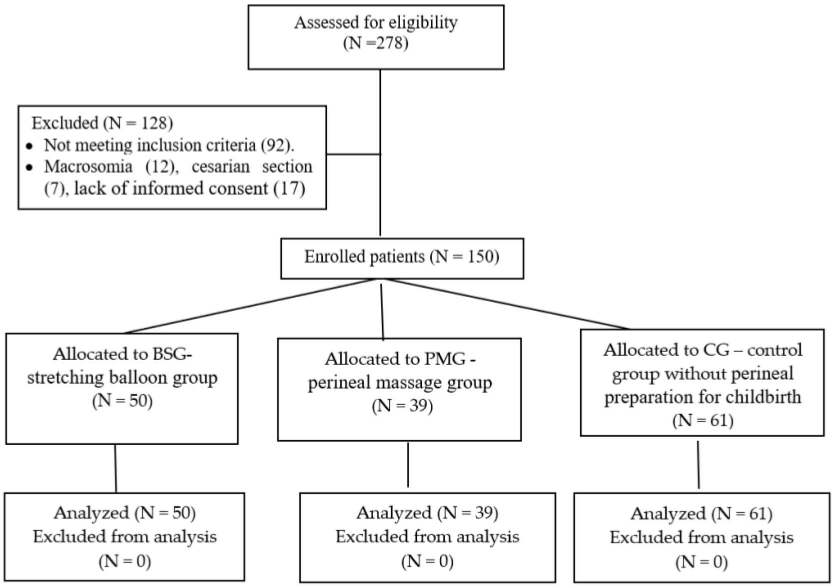


Figure 1. Flow chart of the study**.**

The postpartum period, or puerperium, was reported as regular in 130 cases (86.7%). However, there were 3 cases (2%) of peri sutural hematoma, 3 cases (2%) of postpartum hemorrhage, 10 cases (6.7%) of perineal pain and tension, 2 cases of congested hemorrhoid and suture pain, and 2 cases of suture diastasis. The most common pelvic floor dysfunctions were urinary incontinence of various types (42.7%), followed by dyspareunia (38%) and anal incontinence (22.7%).

At the level of the intervention groups (BSG vs PMG), the lack of perineal injury and episiotomy was significantly more frequent in the BSG group (72.5%n vs 51.3%, p=0.008, respectively 90.2% vs 74%, p=0.046), indicating a positive impact of the balloon stretching intervention compared to perineal massage on these parameters. BSG vs CG analysis indicated significant differences (p<0.05) in all tested parameters, with a higher frequency of positive results in BSG. In the PMG group, the free position of the fetus was significantly more frequent than in the control group (25.6% vs 0%, p<0.001), while the application of the Kristeller maneuver was significantly less (10.3% vs 28.2%, p = 0.032) (Table II).

Table II. Statistics for the frequency differences on the tested parameters between groups.

Variable	**BSG vs PMG**		**BSG vs CG**		**PMG vs CG**	
	X^2	P^1	X^2	P^1	X^2	P^1
Birth type	8.794	0.195	12.798	0.046*	10.786	0.095

Maternal position	1.365	0.054	38.248	<0.001*	173563	<0.001*
Kristeller maneuver	0.051	0.821	4.607	0.032*	4.632	0.032*
Perineal tears	111.834	0.008*	24.417	<0.001*	5.517	0.238
Episiotomy	3.991	0.046*	13.024	<0.001*	2.161	0.142

[1]Chi-square test, *significant values, BSG- balloon stretching group, PMG-perineal massage group, CG-control group

At the level of puerperium, the data analysis indicates a higher frequency of regular puerperium in BSG (96.1%) compared to PMG (87.2%) and CG (86.7%), but without significant differences ($p>0.05$) (Table 7). In BSG only peri sutural hematoma and postpartum hemorrhage appeared as complications with a frequency of 2% each, compared to PMG (2.6%) and CG (1.7%). At the BSG and CG level, other complications also appeared: perineal pain and tension (5.1% in PMG, respectively 13.3% CG), congested hemorrhoid and suture pain (2.6% in PMG, respectively 1.7% in CG), and diastasis sutures, present only in CG in 3.3% of cases.

At six months after birth, the frequency of pelvic floor dysfunctions was significantly different between groups ($p<0.05$), regardless of their type.

The comparison of the two treatment groups (BSG vs PMG) determined significant differences only in the case of dyspareunia, significantly more frequent in the PMG group (X^2=8.586, p=0.035). Urinary incontinence of different types was more frequent in CG, with significant differences compared to BSG (X^2=8.625, p=0.034) and insignificant differences compared to PMG (X^2=2.827, p=0.419). In the case of fecal incontinence, the data also indicate a higher frequency in the control group, with significant differences compared to BSG (X^2=8.746, p=0.003*) and insignificant compared to PMG (X^2=1.200, p=0.273). Dyspareunia was significantly more frequent in the control group, both compared to BSG (X^2=30.335, p<0.001*), and PMG (X^2=7.057, p=0.029*) (Table III).

Table III. Statistics for the frequency differences on the tested parameters.

Variable	**BSG vs PMG**		**BSG vs CG**		**PMG vs CG**	
	X^2	**P**	X^2	**P[1]**	X^2	**P**
Urinary incontinence	3.320	0.345	8.625	0.034*	2.827	0.419
Fecal incontinence	2.964	0.085	8.746	0.003*	1.200	0.273
Dyspareunia	8.586	0.035*	30.335	<0.001*	7.057	0.029*

[1]Chi-square test, *significant values, BSG- balloon stretching group, PMG-perineal massage group, CG-control group.

Discussion

The retrospective nature of the study provides insights into the practical application and effectiveness of perineal training in routine antenatal care and the detailed categorization and analysis of the groups provides insight into the distribution of perineal trauma and postpartum dysfunction, across the three groups. These findings underscore the importance of individualized care approaches that account for age-related factors, obstetric characteristics, and postpartum concerns to optimize the well-being of postpartum individuals and their newborns. This practical approach provides actionable insights for healthcare providers and policymakers. Choosing outcome measures that are universally relevant (e.g., rates of perineal tears, postpartum recovery) ensures that the findings are meaningful across different populations and settings However, the study has some limitations, the most important of which are determined by the retrospective design and the small number of patients included. As a retrospective study, there is an inherent risk of selection bias and confounding variables that could influence the outcomes.

Conclusions

Considering the data collected, stretching balloon and perineal massage can be chosen as a tool to prevent and reduce the rates of obstetric trauma during childbirth and to reduce the use of episiotomy as well as protecting from the development of dysfunctions of the pelvic floor.

We believe it is interesting that further large-scale studies using the correct lines of use of these techniques can be developed, to accredit the concept of prevention as a useful and functional practice for the quality of life of women after childbirth.

4. TREATMENT OF POSTPARTUM VAGINAL RELAXING WITH DYSPAREUNIA: PFMT VS VIBRATING VAGINAL CONE/EXPERIMENT 3

Hypothesis/goal/objectives

Vaginal devices, such as spheres or cones, are employed in perineal rehabilitation by using feedback from voluntary and involuntary muscle contractions [18,19]., often in conjunction with gravity, and can be used individually or with increasing weights for progressive strengthening. The aim of the study was to compare the efficiency of the perineal relaxing treatment using the single vaginal cone (VC) and the traditional exercises of PFMT in women who presented perineal muscle relaxation and sexual dysfunctions after delivery.

MATERIALS AND METHODS

This study is a one-year retrospective observational analysis evaluating the results of the randomized comparative study conducted at the Pelvic Floor Rehabilitation Clinic of Santa Chiara Hospital, Pisa (AOUP), enrolling postpartum women three months after childbirth, between November 2017 and November 2018.

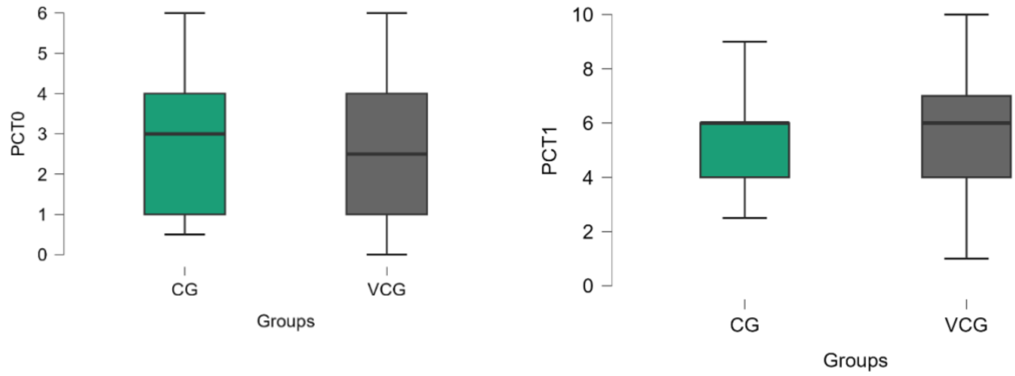
70 consecutive women who underwent perineal assessment during puerperium, and presenting perineal muscle relaxation and sexual dysfunction, were enrolled; the study group used VC (35 women) while the control practiced the traditional exercises of PFMT (35 women). All the participants had been assessed at baseline (T0- pre-intervention assessment, at 3 months after delivery) and reevaluating after 3 months of therapy (T1-3 months after delivery).

Results

There are no significant differences ($p>0.05$) in age, BMI, parity, episiotomy rates, or laceration grades between the two groups. Superficial (S) and severe (SP) dyspareunia was more common in the VCG at baseline ($p=0.017$). Pelvic floor muscle strength was comparable between groups, indicating similar initial conditions in terms of pelvic floor function. The FSFI score, an indicator of sexual function, is significantly higher in the VCG, implying better sexual function at baseline compared to the control group ($p=0.030$)

After therapy, both groups experienced significant improvements in dyspareunia, with the vast majority of women reporting no pain. In the vaginal cone group (VCG), 96.67% of participants reported no dyspareunia, compared to 80.95% in the control group (CG). Although both groups improved, the reduction in dyspareunia was more pronounced in the VCG, where only 1 woman (3.33%) still reported superficial pain, compared to 4 women (19.05%) in the CG. The chi-squared test at T1 showed that the differences between the two groups was no longer statistically significant ($p = 0.063$). This indicates that both interventions were effective in reducing dyspareunia, but the vaginal cones may offer a slight edge in enhancing pain relief.

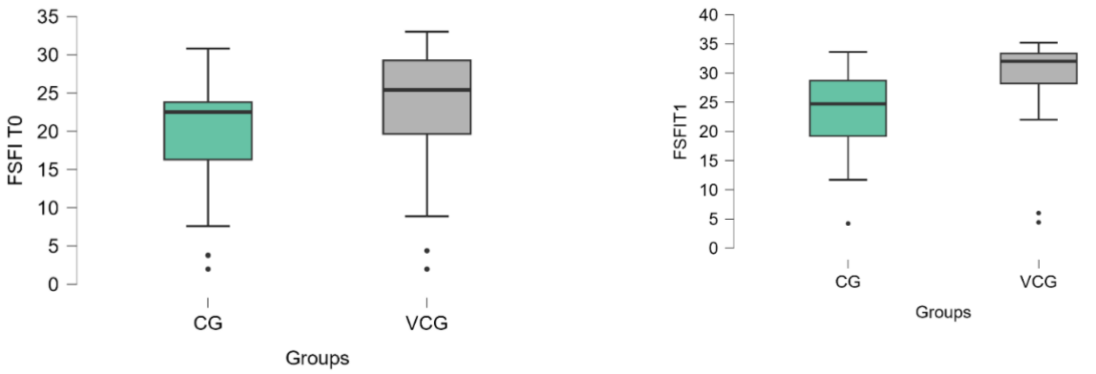
The results from the Mann-Whitney U Test (used here for comparing the two groups at baseline and after therapy) revealed no significant differences between the two groups at baseline (T0) or after therapy (T1) for any of the evaluated parameters ($p > 0.05$) (figure 2). This suggests that while both interventions were effective in improving pelvic floor muscle function, neither group showed a statistically superior outcome over the other at either time point. Therefore, the vaginal cone intervention did not outperform traditional pelvic floor muscle training, but both treatments led to meaningful improvements.



a b

Figure 2. PC test score distribution by groups: a-at T0, b-at T1

At the level of sexual function, the comparison between the control group (CG) and the vaginal cone group (VCG) showed that after therapy (T1), both groups improved significantly, but the VCG consistently achieved higher mean scores in each domain, notably in arousal (4.732 vs. 3.744, $p = 0.004$), desire (4.394 vs. 3.264, $p = 0.001$), and pain (5.355 vs. 4.640, $p = 0.004$). The total FSFI score improved significantly in both groups, but the VCG showed a greater increase (from 23.332 to 29.235, $p < 0.001$) compared to the CG (from 19.488 to 23.428, $p < 0.001$). The evolution of FSFI within the 2 groups is illustrated in figure 3.



a b

Figure 3. FSFI score distribution by groups: a-at T0, b-at T1

Discussions

This study provides valuable insights into the comparative effectiveness of traditional PFMT with simple exercises and vibrating vaginal cones (VC) in treating postpartum vaginal relaxation, dyspareunia, and sexual dysfunction. However, the study is one of the few to specifically address the impact of vaginal cones on sexual function, an area where research is still limited.

The findings suggest that vibrating vaginal cones may be more effective than simple pelvic floor exercises alone in addressing specific issues such as dyspareunia and sexual satisfaction. This could be due to the targeted stimulation and biofeedback provided by the cones, which enhance pelvic floor muscle activation and neuromuscular coordination. While both interventions are effective in strengthening pelvic floor muscles and improving sexual function, the cones seem to offer additional benefits, particularly for women suffering from pain during intercourse.

Conclusion

In conclusion, both PFMT, simple exercises and vibrating vaginal cones effectively improve pelvic floor function, reduce dyspareunia, and enhance sexual function in postpartum women. However, the vaginal cone group showed superior results in reducing pain and increasing sexual satisfaction. Further studies with larger sample sizes and longer follow-up periods are needed to confirm these findings and explore the long-term benefits of vibrating vaginal cones.

5. PERINEAL REHABILITATION IN PELVIC FLOOR DYSFUNCTION: THE BENEFITS OF VAGINAL CONE TRAINING/EXPERIMENT 4

Hypothesis/goal/objectives

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.

Materials and Methods

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 diagnostic of a pelvic floor dysfunction (PFD were invited to participate in the study.

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 4).

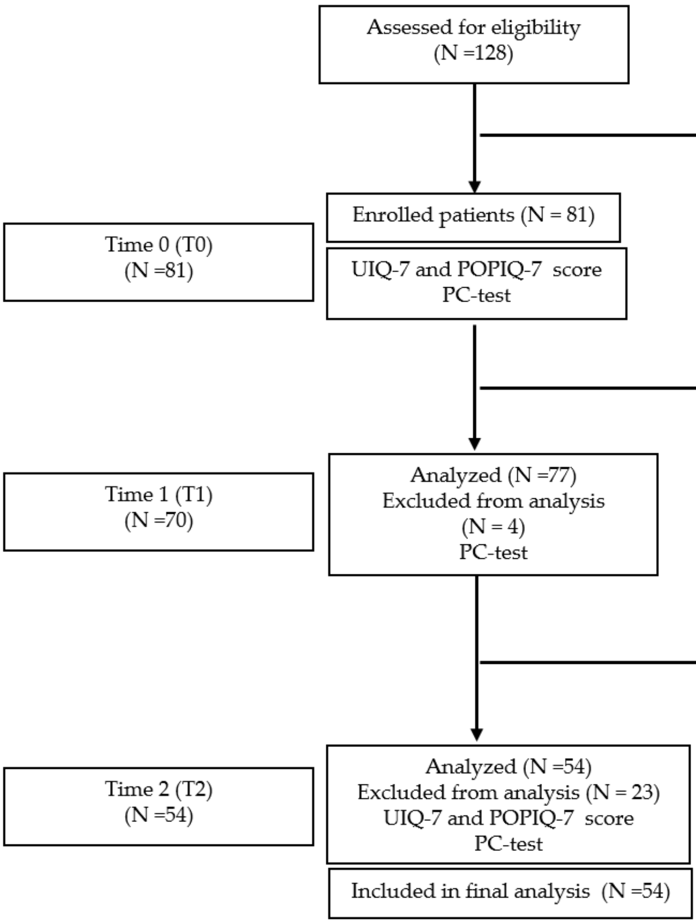


Figure 4. Flow-chart of the study.

Results

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.

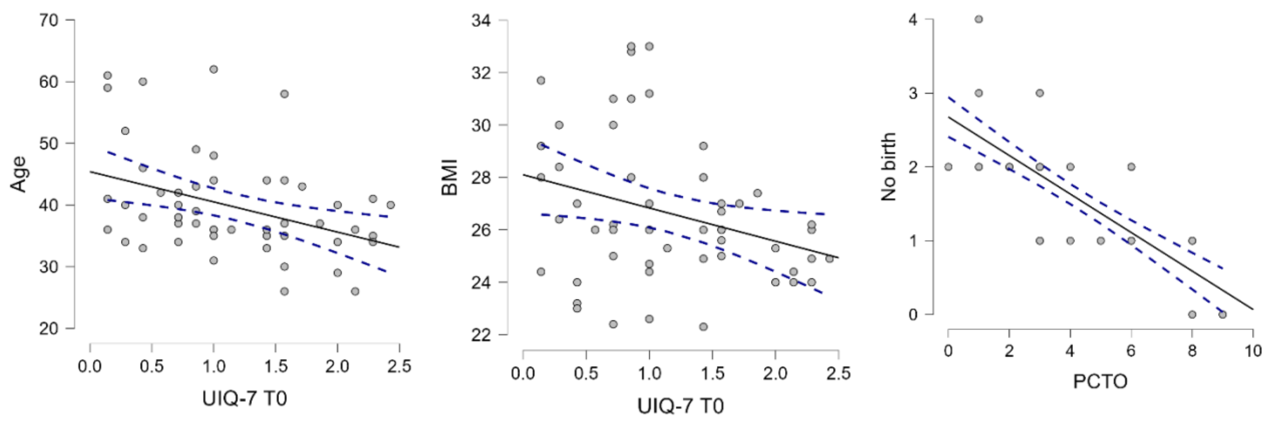
The more prevalent PFDs were the urinary dysfunctions, reported by 90.74% (50.00% urgence urinary incontinence, 18.52% stress urinary incontinence, 14.81% mixed incontinence, and 7.41% urinary retention). 16,6% of the women investigated had cystocele grade I (3.70%) and grade II (11.11%), and 7.41% had 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.

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

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

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, $p < 0.001$). 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, $p = 0.800$). 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).

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 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).

Discussions

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.

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. 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.

GENERAL DISCUSSIONS

This PhD thesis offers several original contributions to the prevention and conservative treatment of pelvic floor dysfunction (PFD), particularly in relation to pregnancy, childbirth, and rehabilitation. The insights and methodologies developed in this work significantly enhance both clinical practice and research in the field.

Overall, this thesis makes substantial contributions to the field by introducing new predictive tools, validating evidence-based therapies, and promoting personalized, patient-centered approaches. These findings have the potential to impact both healthcare policies and individual treatment plans, improving outcomes for women affected by PFD.

The studies presented in this thesis open new avenues for research in pelvic floor health. Future research should further investigate the long-term benefits of antenatal perineal training, particularly its impact on quality of life and pelvic floor function later in life. Additionally, exploring the role of technology, such as biofeedback devices and digital health applications, in delivering personalized perineal rehabilitation could enhance patient adherence and outcomes. The potential of artificial intelligence in predictive modeling for PFD risk and treatment outcomes also holds promise for future advancements in this field.

GENERAL CONCLUSIONS

This thesis has delved into a relatively underexplored yet critical area of women's health—namely, the prevention and conservative treatment of pelvic floor pathologies. Through a comprehensive approach, we have sought to cover all major aspects of pelvic floor dysfunction, from etiology to innovative therapeutic interventions.

The measurement of anovaginal distance (AVD) during pregnancy was investigated as a potential predictor of perineal trauma risk during childbirth. The study found that women with shorter AVDs were more likely to experience perineal tears, particularly third- and fourth-degree tears.

Antenatal perineal training has emerged as a critical strategy for preventing perineal trauma during childbirth. The data showed that women who underwent antenatal training experienced fewer perineal tears, reduced episiotomy rates, and faster postpartum recovery. Follow-up assessments indicated that these benefits extended beyond the immediate postpartum period, suggesting that early intervention can have long-term protective effects on pelvic floor function.

This thesis has also explored the development and application of innovative medical devices for managing pelvic floor dysfunctions, with a particular focus on two key areas: postpartum recovery and the early treatment of urinary incontinence.

Benefits of Vaginal Cone Training, explored the effectiveness of vaginal cone training as a conservative treatment for PFD, particularly focusing on its role in strengthening the pelvic floor muscles. The results demonstrated significant improvements in muscle tone, reduction in symptoms such as incontinence, and enhanced overall pelvic function among participants who adhered to the rehabilitation program.

This research underscores the need for broader adoption of conservative treatments for PFD in clinical practice. By incorporating routine screening for AVD and encouraging antenatal perineal training, healthcare providers can significantly reduce the incidence of perineal trauma and long-term pelvic floor dysfunction. Additionally, perineal rehabilitation, such as vaginal cone training, should be recommended as a therapy for women experiencing PFD symptoms, as it offers a non-invasive and effective treatment option.

BIBLIOGRAPHY (Selective)

1. Rossetti, S.R. Functional Anatomy of Pelvic Floor. *Arch. Ital. Urol. Androl.* **2016**, *88*, 28–37. https://doi.org/10.4081/aiua.2016.1.28.
2. Bortolami, A. *Riabilitazione del Pavimento Pelvico*; Edra S.p.A: Milan, Italy, 2014.
3. Urbankova, I.; Grohregin, K.; Hanacek, J.; Krcmar, M.; Feyereisl, J.; Deprest, J.; Krofta, L. The Effect of the First Vaginal Birth on Pelvic Floor Anatomy and Dysfunction. *Int. Urogynecol. J.* **2019**, *30*, 1689–1696. https://doi.org/10.1007/s00192-019-04044-2.
4. Faubion, S.S.; Shuster, L.T.; Bharucha, A.E. Recognition and Management of Nonrelaxing Pelvic Floor Dysfunction. *Mayo Clin. Proc.* **2012**, *87*, 187–193. https://doi.org/10.1016/j.mayocp.2011.09.004.
5. Murina, F.; Caimi, C.; Di Pierro, F.; Di Francesco, S.; Cetin, I. *Gynecology and Obstetrics*, Various Issues.
6. Woolf, C.J. Central Sensitization: Implications for the Diagnosis and Treatment of Pain. *Pain* **2011**, *152*, S2–S15. https://doi.org/10.1016/j.pain.2010.09.030.
7. Yoo, Y.M.; Kim, K.H. Current Understanding of Nociplastic Pain. *Korean J. Pain* **2024**, *37*, 107–118. https://doi.org/10.3344/kjp.23326.
8. Doggweiler-Wiygul, R. Urologic Myofascial Pain Syndromes. *Curr. Pain Headache Rep.* **2004**, *8*, 445–451.

9. Peng, H.Y.; Huang, P.C.; Liao, J.M.; et al. Estrous Cycle Variation of TRPV1-Mediated Cross-Organ Sensitization between Uterus and NMDA-Dependent Pelvic-Urethra Reflex Activity. *Am. J. Physiol. Endocrinol. Metab.* **2008**, *295*, E559–E568.
10. Akuthota, V.; Nadler, S.F. Core Strengthening. *Arch. Phys. Med. Rehabil.* **2004**, *85*, S86–S92.
11. Grimes, W.R.; Stratton, M. Pelvic Floor Dysfunction. In: StatPearls [Internet]; StatPearls Publishing: Treasure Island (FL), 2024. Available online: https://www.ncbi.nlm.nih.gov/books/NBK559246/ (accessed on 26 June 2023).
12. Peinado Molina, R.A.; Hernández Martínez, A.; Martínez Vázquez, S.; Martínez Galiano, J.M. Influence of Pelvic Floor Disorders on Quality of Life in Women. *Front. Public Health* **2023**, *11*, 1180907. https://doi.org/10.3389/fpubh.2023.1180907.
13. Rodríguez-Almagro, J.; Hernández Martínez, A.; Martínez-Vázquez, S.; Peinado Molina, R.A.; Bermejo-Cantarero, A.; Martínez-Galiano, J.M. A Qualitative Exploration of the Perceptions of Women Living with Pelvic Floor Disorders and Factors Related to Quality of Life. *J. Clin. Med.* **2024**, *13*, 1896. https://doi.org/10.3390/jcm13071896.
14. O'Kelly, S.M.; Moore, Z.E. Antenatal Maternal Education for Improving Postnatal Perineal Healing for Women Who Have Birthed in a Hospital Setting. *Cochrane Database Syst. Rev.* **2017**, *12*, CD012258. doi:10.1002/14651858.CD012258.
15. Moya-Jiménez, L.C.; Sánchez-Ferrer, M.L.; Adoamnei, E.; Mendiola, J. New approach to the evaluation of perineal measurements to predict the likelihood of the need for an episiotomy. *Int. Urogynecol. J.* **2019**, *30*, 815–821. https://doi.org/10.1007/s00192-018-3745-9.
16. Pihl, S.; Uustal, E.; Blomberg, M. Anovaginal distance and obstetric anal sphincter injury: A prospective observational study. *Int. Urogynecol. J.* **2019**, *30*, 939–944. https://doi.org/10.1007/s00192-018-3838-5.
17. Okeahialam, N.A.; Sultan, A.H.; Thakar, R. The prevention of perineal trauma during vaginal birth. *Am. J. Obstet. Gynecol.* **2024**, *230*, S991–S1004. https://doi.org/10.1016/j.ajog.2022.06.021.
18. Belo, J.; Francisco, E.; Leite, H.; Catarino, A. Pelvic floor muscle training with Plevnik's cones in women with urinary incontinence. *Acta Médica Portuguesa* **2005**, *18*(2), 117–122.
19. Wilson, P.D.; Borland, M. Vaginal cones for the treatment of genuine stress incontinence. *Aust. N. Z. J. Obstet. Gynaecol.* **1990**, *30*(2), 157–160.