**PAIN** 

# Low Dose, High Frequency Movement Based Dilator Therapy for Dyspareunia: Retrospective Analysis of 26 Cases



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#### **ABSTRACT**

**Introduction:** While two-thirds of women will experience dyspareunia and vaginal dilators are often used to treat dyspareunia, outside of a single case report, no study has investigated the potential of low-dose, high frequency movement-based dilator therapy for dyspareunia in premenopausal female patients.

**Aim:** To determine the utility of low-dose, high frequency movement-based dilator use for dyspareunia in premenopausal female patients.

**Methods:** Retrospective study of women presenting to outpatient hospital-based pelvic floor physical therapy office in a tertiary care center. All adult premenopausal female patients who were referred to pelvic floor physical therapy for dyspareunia and completed movement-based dilator therapy (MBDT) and met study criteria (n = 26) were included for analysis.

Main Outcome Measure: Patient change in pain level status using Numeric Pain Rating Scale with intercourse was compared between initial evaluation and time of discharge from pelvic floor physical therapy.

**Results:** Among the 26 women who met criteria for this study, the average pain score decreased from 8.3 (SD 2.2) before treatment to 1.3 (SD 2.0) after treatment and was statistically significant (P<.001). Complete resolution of dyspareunia was reported in 58% of patients. Patients completed between 2 and 6 total pelvic floor physical therapy visits (average 3.7, SD1.5), over 0–44 weeks (mean 9.6 weeks, SD 8.3).

Conclusion: Low-dose, high frequency, movement-based dilator therapy significantly reduced or resolved the experience of pain with penetrative vaginal intercourse with dyspareunia. Future prospective studies with larger samples and the inclusion of sexual functional status should be considered to explore the full potential of this modality in treatment of premenopausal patients with dyspareunia. Miles K, Miles S. Low Dose, High Frequency Movement Based Dilator Treatment for Dyspareunia: Retrospective Analysis of 26 Cases. Sex Med 2021;9:100344.

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Key Words: Dilator; Pelvic Pain; Dyspareunia; Pelvic Floor; Physical Therapy; Sexual Dysfunction

## INTRODUCTION

Two-thirds of women will experience superficial or deep dyspareunia in their lifetime, with the prevalence in the United

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States estimated between 10% and 20%.<sup>1,2</sup> Fifty percent of women with endometriosis experience deep dyspareunia, and it is thought to be due to deep infiltrating endometriosis or local neurogenesis surrounding endometriosis lesions.<sup>3</sup> Deep dyspareunia is also highly correlated with painful bladder and myofascial pain syndromes as well as depression and central nervous system sensitization.<sup>4</sup>

Vaginal dilator therapy is a common treatment modality used to restore vaginal length, caliber, and myofascial extensibility for women with history of pelvic radiation, vaginal agenesis, as well as dyspareunia. <sup>5–7</sup> Despite the widespread use of vaginal dilator therapy, adequate rationale of technique and duration of dilator usage for female dyspareunia is currently limited. <sup>5</sup> Common exercise

1

Sex Med 2021;9:100344

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2 Miles and Miles

prescriptions given to patients are highly variable, requiring anywhere from 5 to 120 minutes of self-led dilator therapy 3–7 times per week with little mention of technique. <sup>8–10</sup> The primary focus of these regimens is on dilator caliber progressions. <sup>8,11,12</sup> While a previous case report noted resolution of dyspareunia after 3 clinic-based visits over the course of 9 weeks with movement-based dilator therapy using progressively larger dilators (28–38 mm in diameter), there is a paucity of data examining low dose, high frequency movement based dilator therapy. <sup>13</sup> The objective of this study was to examine the utility of low dose, high frequency MBDT for the treatment of female dyspareunia. We hypothesize that low dose, high frequency MBDT is an effective first-line modality for premenopausal female patients as part of a home-exercise program to address dyspareunia.

## MATERIALS AND METHODS

This retrospective study was approved by the Walter Reed National Military Medical Center Institutional Review board (IRB Study #WRNMMC-EDO-2020-0482) on April 29, 2020. Informed consent was waived in this study approval. The study population comprised of all premenopausal adult (>18 years of age) female patients with the diagnoses "dyspareunia," "superficial dyspareunia," "deep dyspareunia," "unspecified dyspareunia," "dyspareunia not due to a substance or known physiological condition," who underwent pelvic floor therapy for dyspareunia, from March 2016 to March 2019 evaluated at Walter Reed National Military Medical Center (WRNMMC). WRNMMC is a military hospital in the United States that provides primary and specialty medical care exclusively active duty military service members and their respective dependents. Therefore, patients were able to seek pelvic floor physical therapy through a referral from a primary or specialty care provider within the military network and did not have to pay out of pocket for any medical services rendered or devices provided. Exclusion criteria included females less than 18 years of age, a history of gynecological surgeries, pregnant, or post-menopausal women, and patients with no baseline Numeric Pain Rating Scale (NPRS) recorded. Patients were provided with 100% high density polyethylene dilators (Syracuse Medical Devices, Syracuse, NY) free of charge by the pelvic floor physical therapy clinic. Initial dilator caliber was determined by resting length of introitus during the perineal and pelvic therapy examination. Progressive dilators were provided if and when patient endorsed pain symptoms associated with partner girth, after a minimum of 4 weeks of self-reported compliance with consistent MBDT. Movement-based dilator therapy was taught during the pelvic floor therapy sessions after a complete external perineal and intravaginal pelvic floor muscle examination was completed as previously described. 14 MBDT is an intravaginal dilator technique in which the patient performs a pelvic floor muscle contraction and then applies compressive force during the muscular relaxation phase. This Proprioceptive Neuromuscular Facilitation (PNF) contract-relax method used a 1:2 ratio of contraction to relaxation and was applied systematically to the puborectalis, pubococcygeus, iliococcygeus, obturator internus muscles bilaterally. PNF is a widely used technique to promote muscle elasticity and positively affect skeletal muscle range of motion. <sup>15,16</sup> This 1:2 ratio of contraction to relaxation was used to enhance patient proprioception of dilator-assisted pelvic floor relaxation for twice as long as voluntary isolated pelvic floor muscle recruitment. Exercise dose of MBDT was recommended in a range between 2–5 minutes and 5–10 minutes. Patients were instructed to engage in MBDT every day or every other day as long as it could be performed in a pain-free manner. Upon return to clinic for follow up-sessions, patients self-reported their compliance with MBDT (Table 2).

The primary outcome measure was change in pain with intercourse measured in NPRS from time of initial evaluation to discharge from pelvic floor physical therapy. NPRS is an 11-point scale used for self-reported pain intensity status, ranging from 0 to 10.17 The 2 anchors are 0 and 10, representing "no pain" and "worst possible pain," respectively. NPRS has excellent interrater reliability and has been validated to measure pain and change in pain in people 18 years and older. 18 The minimally clinically important difference of the NPRS for musculoskeletal pain conditions is a 2 point difference. 18,19 Secondary outcomes included number of pelvic floor physical therapy encounters, weeks of dilator use, and caliber of dilator used for movement-based dilator therapy. Discharge from pelvic floor physical therapy was mutually agreed upon between patient and therapist and based on therapeutic functional goals. MBDT frequency, duration, and compliance was collected verbally and documented at time of pelvic floor physical therapy visit via patient self-endorsement. A sample size calculation was not performed. Instead, all eligible participants were included. Data was collected and analyzed with Wilcoxon Signed Rank test and a Pvalue < .05 was considered to indicate statistical significance. All statistics were performed using SPSS version 25 software.

# **RESULTS**

A total of 102 patients were assessed for eligibility, of which 55 patients met study criteria (Figure 1). Among the excluded patients,

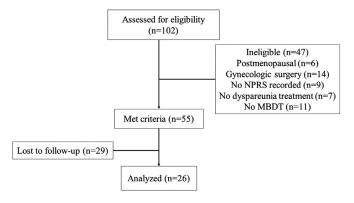


Figure 1. Study inclusion criteria.

Table 1. Patient characteristics

	MBDT treatment N = 26	
Age (y)	$34.2 \pm 8$	
Race/ethnicity		
White	11 (42)	
Black	3 (12)	
Asian/Pacific Islander	3 (12)	
Other	3 (12)	
Unknown	6 (23)	
Parous-Yes	13 (58)	
BMI (kg/m <sup>2</sup> )	$24.1 \pm 3.2$	
Baseline NPRS	$8.3 \pm 2.2$	
Discharge NPRS	$1.3 \pm 2.0$	
Total number visits	$3.7 \pm 1.5$	
Total weeks dilator use	$9.6 \pm 8.3$	

BMI = body mass index; NPRS = Numeric Pain Rating Scale. Data are mean  $\pm$  SD or n (%).

14 were excluded due to history of gynecologic surgeries including total or radical hysterectomies and female pelvic reconstructive surgeries, 7 were either abstinent or did not want to address dyspareunia as part of their pelvic floor physical therapy plan of care, and 11 did not receive MBDT and were not included in the analysis. Nine out of 102 were not included due to lack of NPRS. Six out of 102 were excluded due to documented menopausal or post-menopausal status. Of the patients meeting study criteria, 29 were lost to follow-up and did not receive treatment past their initial evaluation and were not included for analysis.

A total of 26 patients ranging in age from 21 to 47 years (average 34 years) endorsing dyspareunia were evaluated in this study (Table 1). These patients had a mean BMI of 25 kg/m². 42% of the patients "White," 23% were "Unknown," 12% were "Asian/Pacific Islander," 12% were "Black," and 12% were "Other" as self-reported in their patient demographics. In this patient series, 69.2% had a history of mental health conditions (major depressive disorder 34.6%, general anxiety disorder 23%, post-traumatic stress disorder 7.7%, borderline personality disorder 3.8%), 38.5% with a history of chronic pain (chronic low back pain 30.8%, fibromyalgia 7.7%), 11.5% with a history of sexual trauma (sexual assault 7.7 %, military sexual trauma 3.8%), 3.8% with diagnosed endometriosis, and 7.7% with vulvar lichens sclerosis.

Subjects completed a home exercise program consisting of low-dose, high frequency movement-based dilator therapy. Dilator diameter ranged between 13 and 35 mm with an average of 21.5 mm, which is equivalent to a small sized dilator (Figure 2). Home exercise programs consisted of patient self-directed MBDT with 35% of patients engaging in MBDT for 2–5 minutes a day, 7 days a week, 27% of for 2–5 minutes a day, 3–5 days per week, and 35% for 5–10 minutes a day, 3–4 days per week (Table 2).

Pain level status at baseline was a mean of 8.3 (SD 2.2) which decreased to an average pain level status of 1.3 (SD 2.0) with a mean change of -7.1 (SD 2.8, P< .001) at time of discharge

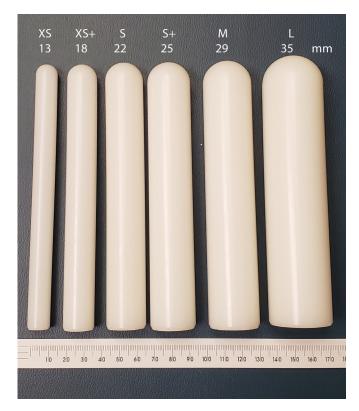


Figure 2. Dilator size chart.

from pelvic floor physical therapy (Figure 3). 58% of patients reported a pain level of 0 at discharge. The single patient who had no change in NPRS was seen for 2 visits and endorsed 0% compliance with MBDT due to orthopedic surgical management for a non-displaced femoroacetabular labral tear. Patients completed between 2 and 6 total pelvic floor physical therapy visits

**Table 2.** Movement based dilator therapy programming

	MBDT treatment (N = 26)		
Home exercise program			
2–5 min/7 days/week	9 (35)		
2–5 min/3–5 days/week	7 (27)		
5–10 min/3–4 days/week	9 (35)		
>10 min/day	1(4)		
Dilator caliber (mm)			
13	2 (7.7)		
13–25	1(3.8)		
13–29	2 (7.7)		
18	2 (7.7)		
22	12 (46)		
22–29	1(3.8)		
25	3 (12)		
25–29	1(3.8)		
29	1(3.8)		
29–35	1(3.8)		

Data are n (%). Dilators with size ranges depict progression to larger caliber.

4 Miles and Miles

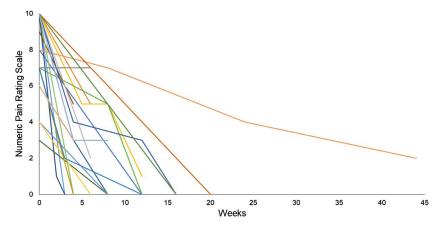


Figure 3. Time measured in weeks to reach Numeric Pain Rating Scale at time of discharge.

(average 3.7, SD 1.5), over 0–44 weeks (mean 9.6 weeks, SD 8.3) (Table 1). The patient who was seen over a span of 44 weeks had a total of 5 visits and reported using dilators for 10 minutes, 1–2 times per week (Table 3).

## DISCUSSION

In this cohort, 58% of the patients reported complete resolution of their dyspareunia and required, on average, only 3.7 visits with a pelvic floor physical therapist. This data supports MBDT as a time limited, adjunct for chronic pelvic pain with a dyspareunia component. Moreover, there is a paucity of data on the utility of vaginal dilation therapy for women with dyspareunia that is not related to the effects of advancing age, cancer, or oncologic treatments. Given the statistically significant reduction in pain with intercourse, it is reasonable to encourage future studies examining MBDT as first line treatment in premenopausal patients with dyspareunia.

It is important to recognize 44% of women who were referred and scheduled for an initial pelvic floor evaluation for a "dyspareunia" code did not present to their appointment. It is widely accepted that sexual pain and dysfunction is often multifactorial within a biopsychosocial context and can be highly distressing within patients' personal and interpersonal relationships. In spite of the relatively high prevalence of female dyspareunia, few women seek and pursue treatment. Pelvic rehabilitation studies investigating sexual dysfunction and pain often cite poor patient compliance and limitations due to patients being lost to follow-up. Our study included women with comorbid conditions that are known to contribute to dyspareunia, such as mental health disorders (69.2%), chronic pain history (38.5%), sexual trauma (11.5%), endometriosis (3.8%), and vulvar lichens sclerosis (7.7%).

Conceptually MBDT can be viewed as a method of behavior modification and a graded exposure technique. Using principles of neurophysiology, MBDT is a method using non-threatening or painless exposures for those patients who classically experience pain with vaginal penetration. The gentle self-generated movements used in MBDT assists with neuromuscular proprioception

of the pelvic floor as well as the normalization of non-noxious intravaginal input within the sensory-motor cortex. This framework supports directing treatment to "sensory and emotional" experience of pain, as defined by the International Association for the Study of Pain. <sup>22</sup>

This framework challenges the myofascial-centric perspective of dilator therapy as literal stretching or massaging of vaginal and muscular tissues. This historical theoretical dogma demanded clinic-based rehabilitation programs with therapist-delivered transvaginal myofascial techniques or large caliber, high volume and duration of vaginal dilation. <sup>21,23</sup> Such programs often required the patient to attend therapy for an average of 1–2 visits per week for 8–12 weeks. <sup>24,25</sup> Moreover, MBDT promotes patient autonomy, empowerment, and self-efficacy and correlates with subjective reduction in pain consistently within the first 4–6 weeks of use in the privacy of one's home.

One of the strengths of this study is patients were not limited by barriers commonly faced when seeking specialized care including socioeconomic status, insurance coverage, or geographic accessibility to pelvic floor physical therapy services. In addition, due to the nature of military medicine, pelvic floor physical therapists do not have conflicting interests between provision of services (ie, patient selection, frequency, duration, prolongation of plan of care) and economic incentives.

Limitations include the descriptive retrospective study design. We recognize that there may be women were missed in the data collection due to variable coding in diagnoses. Due to current insurance reimbursement restrictions in the United States, providers often avoid using dyspareunia codes and opt for codes such as "pelvic and perineal pain," "vaginismus," "vulvodynia," or "vestibulodynia." Between March 2016 and March 2019, there was a total of 187 referrals for "pelvic and perineal pain," 180 for dyspareunia diagnoses, and 30 for vestibulodynia, vulvodynia, or vaginismus at our institution. We acknowledge our small sample size and number of therapists limits generalizability. Only 35% (44 out of 102) of women who were referred to pelvic floor physical therapy for a diagnosis of dyspareunia were eligible for this study, with 29% were lost to follow up with no return

Table 3. Dilator progression through treatment

Study#	# Sessions	Baseline NPRS	Discharge NPRS	Total # weeks	Dilator size	Duration (weeks)
1	3	8	0	12	XS+	4
					М	8
2	2	10	5	б	XS+	б
3	4	10	0	8	XS+	8
4	б	10	1	12	S	8
					М	4
5	2	10	0	3	S	3
6	б	7	0	12	XS	8
					S	4
7	3	10	0	5	XS+	2
					S+	3
8	3	9	5	8	XS	8
9	2	10	0	4	S	4
10	3	9	3	4	XS+	4
11	2	10	0	8	S	8
12	5	10	0	8	S	8
13	4	б	0	8	S	8
14	5	8	2	44	М	44
15	б	10	2	6	S	6
					М	0*
16	2	4	0	6	S	6
17	3	10	0	4	S	4
18	3	10	0	4	S	4
19	5	10	0	12	S	12
20	6	10	0	20	М	4
					L	3
21	2	7	7	0	S+	0
22	3	7	0	12	S+	12
23	5	7	0	12	S	12
24	б	10	0	16	XS+	16
25	3	10	3	8	S	8
26	2	6	3	9	S+	8

XS: 13 mm; XS+: 18 mm, S: 22 mm; S+: 25 mm M: 29 mm dilator; L: 35 mm dilator.

visit after initial evaluation. The loss of follow up may represent bias toward patients motivated to continue therapy for their dyspareunia. This sample size was also limited by the lack of follow-up which is in part due to the peripatetic nature of military service members and their dependents.

Due to this study's retrospective study design, we were unable to control for possible variability in the instruction of MBDT technique. The data used in this study was collected from 3 different therapists that worked at the institution. However, all therapists provided the same brand of dilator and standardized handouts on MBDT to their patients to refer to as part of their pelvic health home exercise program. Future studies should examine the efficacy of concomitant gynecologic, behavioral medicine, and pelvic physical therapy with a respective multi-disciplinary plan of care. We postulate that this clinical framework could reduce over-utilization of health care services as well decrease the potential prescription of opioids as well as other medications and interventions for pain

management. Moving forward, clinicians should evaluate not only pain score with intercourse, but also sexual functional status with validated sexual function outcome measures for both clinical and research purposes. Future studies should consider a randomized control study design to further evaluate the effectiveness of MBDT for female dyspareunia.

In conclusion, low dose, high frequency movement-based dilator use is an effective modality for treatment of dyspareunia in premenopausal women. The limited number of sessions required to achieve resolution of dyspareunia should encourage practitioners to include pelvic floor physical therapy as an adjunct in treatment of female dyspareunia.

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 $<sup>^</sup>st$ Patient issued the medium dilator but did not return for scheduled follow up.

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#### STATEMENT OF AUTHORSHIP

Katherine Miles: Conceptualization, Methodology, Investigation, Writing — Original Draft, Writing — Review and Editing, Resources; Shana Miles: Conceptualization, Methodology, Investigation, Writing — Original Draft, Writing — Review and Editing.

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