

Online Observational Clinical Trial for Assessing the Effectiveness of an FDA-Cleared Expanding Dilator

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Introduction

Women are increasingly using the internet for self-diagnosis and treatment of medical problems.

Vaginismus a condition included in genito-pelvic pain/penetration disorder (GPPPD), is a disabling condition associated with an inability to tolerate voluntary vaginal penetration, such as with tampons, intercourse, or exams. Because of the stigma associated with this disorder, many women are reluctant

to seek professional help and may benefit from web access to services. Little is known about women seeking online care for vaginismus and their experience with the healthcare system.

Objective

To investigate the baseline characteristics and medical history of women self-diagnosed with vaginismus who are purchasing an expanding vaginal dilator online.¹

Method

Data was extracted from an online survey as part of an observational clinical trial to assess the effectiveness of an FDA-cleared expanding dilator.

Women purchasing the device through a commercial website completed a baseline questionnaire on gender, age, symptoms associated with penetration disorder, sexual function, pain scores, and previous experience with healthcare professionals.

Diagnosis of vaginismus was based on meeting the DSM-5 criteria for GPPPD.

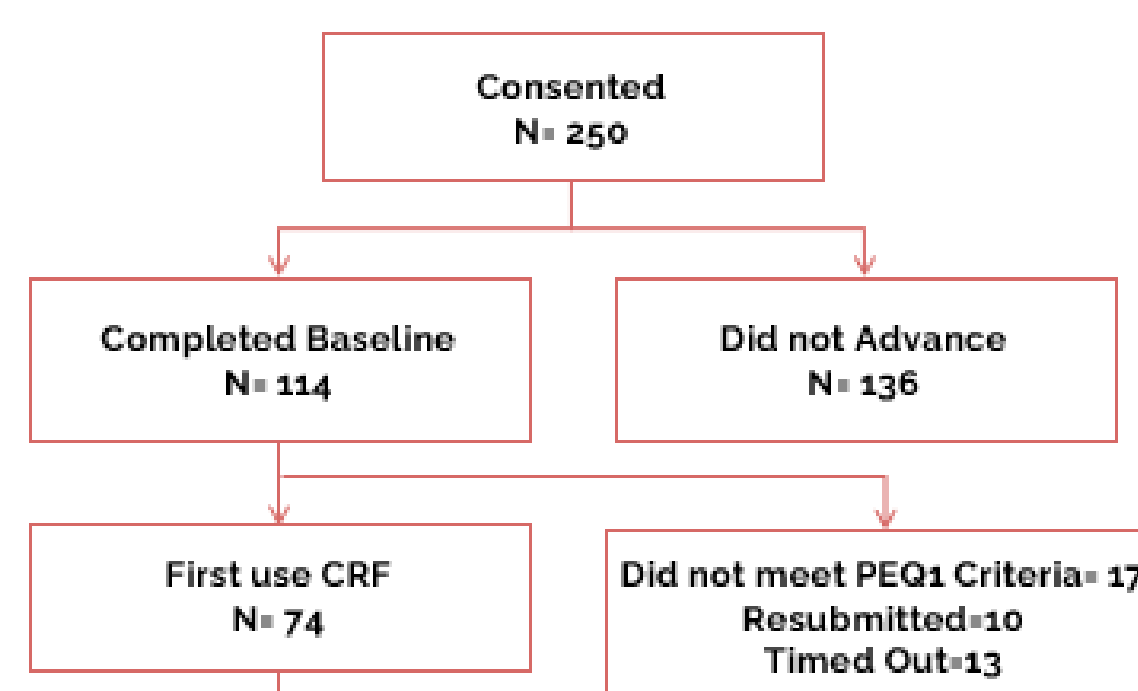
The severity of vaginismus was determined by use of the Lamont classification system, ranging from Grade 1 (able to relax for a pelvic exam) to Grade 4 (generalized retreat, buttocks lift up, thighs close). Participants indicated their average pain intensity during intercourse on a

scale from 0 (no pain at all) to 10 (extreme pain).²

Successful heterosexual intercourse over the previous four weeks was measured by experience with the partner's insertion, the first item of the Primary Endpoint Questionnaire (PEQ), scored on a Likert scale of 0 (not attempted) to 4 (attempted and always successful).³

Women with GPPPD were only included in the study if they scored ≤1 (attempted but unsuccessful) on PEQ Item 1.

Of the 1075 individuals who purchased Milli during the enrollment period May 1-Nov 20, 2024:



Results

Baseline Demographic Data from 74 participants:

- The mean age of participants is 50.8 years (range 18-77).
- The majority were nulliparous (62.2%).
- 43.2% previously used or were current static dilator users
- Before participation, 45.9% of subjects had seen at least 2 healthcare providers for evaluation and treatment.
- Over two-thirds (70.3%) of the participants had reported symptoms associated with vaginismus for over 3 years, with 23.0% for 3-5 years and 47.3% for over 5 years.
- On the Lamont scoring system, 43.8% were Grade 1, 19.2% were Grade 2, 21.9% were Grade 3, and 15.1% were Grade 4 (two subjects did not provide a grade).²
- A visceral reaction – extreme nervousness, palpitations, tremors, hyperventilation, sweating, and shaking – was reported by 28.4% of the participants.²



Milli® Expanding Vaginal Dilator
All-in-one device patient-controlled expansion 1mm at a time. The device provides 25 dilator sizes from 15mm to 40mm with optional vibration (low and high settings). The first and only FDA-cleared for over-the-counter sale.

Subject Demographics

Race [Ethnicity]	90.5% White 6.8% Asian 1.4% Black 1.4% Unknown [2.7% Hispanic]
Education	81.2% College Degree 13.5% Some College 5.4% High School Degree
Pregnancies	48.7% None 16.2% 1 24.3% 2 10.8% 3+
Vaginal Deliveries	86.5% None 5.4% 1 5.4% 2 2.7% 3
History of Static Dilator Use	56.8% None 28.4% Past 14.9% Current

Subject Scores by Age Groups

Age Groups	All Subjects n=74	Under 40 n=27	40-64 n=34	65+ n=13
PEQ ³ Composite Score Mean ± SD median Composite Score Range 0-21	8.3± 4.3 8 0-17	9.1± 4.1 10 1-16	7.8± 4.6 8 0-17	7.8± 3.8 7 3-14
FSFI ⁴ Score Mean ± SD median Score Range 0-36	13.3±7.3 14.5 1.2-24.8	16.5±7.1 18 1.2-24.8	11.5±7.1 13.2 1.2-24.0	11.5±6.6 12.6 2.4-22.2
Pain Score ⁵ with Intercourse Mean ± SD median Score Range 0-10	8.3±1.9 9 0-10	7.9±1.6 8 5-10	8.4±2.0 9 0-10	9.0±1.8 10 4-10

Conclusion

Women who self-diagnose vaginismus and purchase an expanding dilator using a web-based platform report significant limitations and discomfort associated with this disorder. Providing these women with an online option for accessing healthcare may help overcome barriers to diagnosis and treatment.

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