Remote Study Sub-Analysis of Adherence Data using Milli Expanding Vaginal Dilator

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Introduction:

Vaginal dilators are recommended tools for managing lifelong/acquired vaginismus and dyspareunia. However, static, rigid dilators often present significant patient barriers, including discomfort, difficulty with insertion, and the need to manage multiple sizes. These challenges often result in adherence ranging from 25-89% [Lee, 2018], yielding suboptimal outcomes. A single, expandable dilator that increases in one-millimeter increments may offer meaningful advantages, including simplified logistics and high patient adherence of greater than 85%. The Milli expandable dilator combines gradual mechanical expansion with optional vibration, representing a novel approach to address limitations.

Objectives:

This longitudinal web-based observational study's purpose is to assess the efficacy of an expandable dilator, in self-directed use, to resolve vaginismus and pain with heterosexual intercourse. Sub-analysis compares clinical outcomes on behavioral function primary endpoint questionnaire (PEQ), Female Sexual Function Index (FSFI), and Numeric Rating Score (NRS) for pain and anxiety based on dilation therapy adherence using the Milli expanding vaginal dilator.

Methods:

Participants who signed an Informed Consent submitted answers to baseline questionnaires on demographics, symptoms associated with dyspareunia (inability to have vaginal penetration, sexual function, penetration pain), previous treatments, and dilator experience. Participants qualified for inclusion after meeting DSM-5 criteria for GPPPD/vaginismus and inability to achieve intercourse, PEQ Item 1 score of 0 ("not attempted") or 1 ("attempted but unsuccessful"). Seventy-four participants completed the required initial use form, and 63 completed follow-up assessments at 6 months. Participants self-guided their use of the Milli expanding vaginal dilator with vibration from written instructions.

Participants reported their usage patterns, providing the number of days per week, minutes used per dilation session, frequency of vibration use, and device satisfaction. They rated their progress in dilation therapy at 6 months using validated questionnaires. Successful heterosexual intercourse was measured using PEQ Item 1 (successful penile insertion, scale of 0 = not attempted to 4=attempted, always successful). The FSFI provided a total score. Participants also separately rated pain and anxiety with intercourse from 0 (no pain/anxiety) to 10 (extreme pain/anxiety). Subjects reported goal progress for return to intercourse, less painful sex, and maximum dilator size reached.

Results:

Over 85% of the 63 participants who completed the 6-month assessments reported using Milli within or exceeding the suggested treatment parameters of 5–20-minute sessions 3-5 days per week (or a total of 15 to 100 minutes per week). This contrasts with the 48.5% of individuals with prior dilator experience who reported purchasing the Milli primarily because it was too difficult to advance to larger-sized static dilators. A total of 53 participants (84%) reported using the vibration feature some of the time, with 42 (67%) using the vibration feature at least half of the time they used their Milli. Higher usage of Milli or usage of the vibration feature over 50% of the time was correlated with better outcomes on nearly all measures and higher patient satisfaction.

Conclusions:

Participants reported high adherence to dilation therapy using the Milli Expanding Vaginal Dilator, with high rates of device satisfaction. At 6 months, improvement in participants' scores on all measurements appears correlated with increased Milli use and vibration. These data suggest that the incremental expansion of Milli is associated with a high degree of adherence to dilation therapy, which is linked to improved outcomes.

Results by Average Total Weekly Use of Milli

Endpoint	Average Total Weekly Use (mins/week)	
	Endpoint Met (n)	**Endpoint not met (n)**
PEQ Item 1 Score of 2 or 3	71.9 (n=31)	54.3 (n=32)
Total PEQ Improved	75.2 (n=40)	41.6 (n=23)
Total FSFI Improved	64.4 (n=49)	57.9 (n=14)
Pain NRS Improved	70.8 (n=51)	29.7 (n=12)
Anxiety NRS Improved	65.6 (n=47)	55.1 (n=16)
Would Recommend to a Friend*	65.4 (n=55)	45.6 (n=8)
Satisfied with Device Function*	69.8 (n=54)	21.4 (n=9)
*Marked "Agree" or "Strongly Agree" with the statement		

Results by Total Weekly Use

% Meeting Endpoint	Total Weekly Use (minutes/week)		
Endpoint	**Below Recommended Range (<15) N=9**	**In Recommended Range (15-100) N=43**	**Above Recommended Range (>100) N=11**
PEQ Item 1 of 2 or 3	44.4%	46.5%	63.6%
Total PEQ Improved	33.3%	65.1%	81.8%
Total FSFI Improved	66.7%	79.1%	81.8%
Pain NRS Improved	66.7%	79.1%	100%
Anxiety NRS Improved	66.7%	74.4%	81.8%
Would Recommend to a Friend*	77.8%	88.4%	90.9%
Satisfied with Device Function*	55.6%	88.4%	100.0%
Satisfied with Ease of Use*	100%	95.4%	100%
*Marked "Agree" or "Strongly Agree" with the statement			

Results by Vibration Usage

% Meeting Endpoint	Vibration Use**	
Endpoint	**<50% N=17**	**≥50% N=42**
PEQ Item 1 of 2 or 3	35.3%	52.4%
Total PEQ Improved	52.9%	69.1%
Total FSFI Improved	58.8%	83.3%
Pain NRS Improved	70.6%	85.7%
Anxiety NRS Improved	64.7%	76.2%
Would Recommend to a Friend	88.2%	88.1%
Satisfied with Device Function	76.5%	90.5%
*Marked "Agree" or "Strongly Agree" with the statement ** N=59, four participants preferred not to answer this question		