Title: A sub-analysis comparing subjects experienced with static dilators vs naive to dilation from the POMPOM study evaluating the efficacy of the Milli Expanding Dilator as a treatment for achieving intercourse.

Introduction:
Vaginal dilators are recommended tools for managing lifelong/acquired vaginismus and dyspareunia. However, static, rigid dilators often present significant patient barriers, including discomfort, insertion difficulty, and managing multiple sizes. These challenges frequently lead to poor adherence and suboptimal outcomes. A single, expandable dilator that increases in one-millimeter increments may offer meaningful advantages, including simplified logistics and improved patient adherence. The Milli expandable dilator combines gradual mechanical expansion with optional vibration, representing a novel approach to address limitations. POMPOM participants included 39.8% with previous dilator experience, of which 56.8% had discontinued by 6 months, suggesting a hard-to-treat subgroup. These participants primarily purchased the Milli because it was too difficult to advance to larger-sized static dilators.

Objective:
This longitudinal web-based observational study's purpose is to assess efficacy of an expandable dilator, in self-directed use, to resolve vaginismus and pain with heterosexual intercourse. Sub-analysis compares experienced vs naive dilator users.

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, behavioral function primary endpoint questionnaire (PEQ) Item 1 score of 0 ("not attempted") or 1 ("attempted but unsuccessful"). Seventy-four participants completed the required initial use form, 68 and 63 completed follow-up assessments at 3 and 6 months, respectively. Participants self-guided their use of Milli expanding vaginal dilator with vibration from written instructions.

Participants rated dilation therapy progress at 3 and 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 Female Sexual Function Index (FSFI) provided a total score and subdomain scores—desire, arousal, lubrication, orgasm, satisfaction, pain. 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:
Experienced dilator users reported lower baseline FSFI scores and similar pain and anxiety with intercourse ratings compared to naive users. Improvements in FSFI and pain/anxiety with intercourse were statistically significant in both cohorts at 3 months. The Milli maximum dilation average for experienced (32.6mm) and naive (32.3mm) participants falls between sizes 6 and 7 in two commonly used 8-device static kits. The average degree of improvement in PEQ-1 was statistically significant (versus zero) for the naive group at 3 and 6 months and the experienced group at 6 months.

Conclusions:
Results suggest experienced and naive dilator users may benefit from an expandable dilator, and the experienced users may find more benefit than they had with static dilators. A dilator that expands in one-millimeter increments may provide more perceived control at a larger size, perhaps reducing anxiety and being less intimidating than larger static dilators. Finally, the expandable dilator provides additional benefits, with the ability to insert at a smaller diameter and expand slowly once inserted, providing vibration.

The hard-to-treat population of participants who previously failed with static dilators takes slightly longer to see improvements, but can achieve successful intercourse within 6 months.

Tables

Table 1. 3-month Interim Comparative Analysis (n=68)		
% improvement from baseline	Experienced (n=33)	Naive (n=35)
Pain with Intercourse	22.5% (p=0.0028)	27.8% (p=0.0001)
Overall FSFI	35.1% (p=0.0080)	24.4% (p=0.0116)
Making Progress Toward or Met Return to intercourse (goal)	84.8%	85.7%
Reported Maximum Diameters Reached (Average)	32.6mm	32.3mm
Anxiety	15.8% (p=0.0291)	24.2% (p=0.0022)
FSFI Sub-Domains		
1-Desire	-2.9% (p=0.6999)	-3.1% (p=0.5912)
2-Arousal	33.9% (p=0.0394)	12.8% (p=0.2669)
3-Lubrication	28.1% (p=0.0303)	21% (p=0.0941)
4-Orgasm	34.9% (p=0.0838)	15.9% (p=0.1610)
5-Satisfaction	62.4% (p=0.0010)	42.5% (p=0.0023)
6-Pain	161.8% (p=0.0006)	155.6% (p<0.0001)

Table 2. Primary Endpoint: PEQ Item 1 (Ability to achieve intercourse with a partner)			
Experienced		Naive	
3 months (n=33)	6 months (n=30)	3 months (n=35)	6 months (n=33)
12.0% (p=0.6091)	54.2% (p=0.0349)	50.0% (p=0.0370)	84.6% (p=0.0030)
52.9% of participants who attempted intercourse were successful	65.0% of participants who attempted intercourse were successful	68.2% of participants who attempted intercourse were successful	81.8% of participants who attempted intercourse were successful