An interim menopause sub-analysis of the POMPOM study evaluating the efficacy of the Milli Expanding Dilator as a treatment for achieving intercourse

Sheryl Kingsberg, Ph.D.
University Hospitals Cleveland Medical Center

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Objective

The primary objective is to evaluate the effectiveness of the Milli Vaginal Dilator in achieving full vaginal penetration with intercourse as reported on the Behavioral Functioning Primary Endpoint Questionnaire (PEQ) Question #1 (of ≥2).[1]

Methods

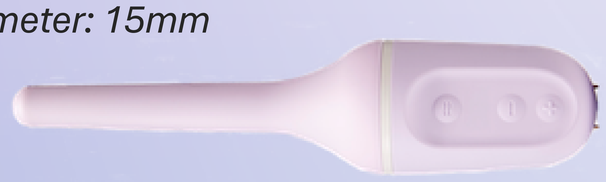
The Milli vaginal dilator is a novel, FDA-cleared, expandable all-in-one tool that allows the user to increase the diameter in small increments before or once the device is inserted. The dilator also incorporates a vibration feature and provides an interface for tracking dilation progress.

Women who made an online purchase[2] of the Milli vaginal dilator were invited to join an innovative, prospective, single-arm, longitudinal, web-based study. Inclusion criteria required subjects to meet the DSM-5 criteria for genito-pelvic pain/penetration disorder (GPPPD), specifically vaginismus, and a score of ≤1 (attempted but unsuccessful) on the Primary Endpoint Questionnaire (PEQ).[1]

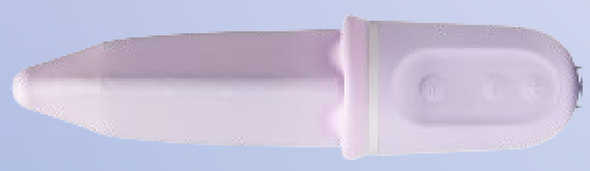
Demographic data included age, symptoms associated with dyspareunia, previous treatments, and experience with dilators. Enrolled qualified subjects (n=74) followed the Milli expanding vaginal dilator "instructions for use", dilating at home on a self-directed schedule (i.e., there was no healthcare professional guidance or intervention). After 3 months, subjects were prompted to report progress using validated measures: FSFI,[3] PEQ,[1] and Visual Analog Scale (VAS)[4] Pain with Intercourse.

Milli Expanding Vaginal Dilator

Starting diameter: 15mm



Fully expanded diameter: 40mm



Results

For this 3-month sub-analysis, 68 participants (74 ITT-6 lost to follow-up) completed interim surveys. Participants were divided into two groups by age, 50+ (n=43) and <50 (n=25), for comparison.

- The 50+ cohort began with slightly lower PEQ, FSFI, and VAS Pain scores at baseline vs <50.
- All subjects improved on total FSFI and PEQ scores, VAS pain with intercourse, and reported making progress toward the primary goal of successful intercourse.
- Both groups reached similar maximum dilation diameters.

Notable differences were observed in the 50+ cohort in the degree of improvement across 4 out of 6 FSFI subdomains.

- The 50+ (vs. <50) improved more on Arousal (25.9% vs. 16.9%), Lubrication (29.7% vs. 19.8%), Satisfaction (64.7% vs. 36.6%), and Pain (161.8% vs. 154.2%).
- No appreciable differences in improvement were reported in sub-domains of Desire and Orgasm between groups.

POMPOM 3-mo Interim Menopause Analysis (n=68)		
% with improvement from Baseline	**Age <50 (n=25)**	**Age 50+ (n=43)**
Primary Endpoint Questionnaire (PEQ)	48.0%	53.5%
Pain with Intercourse	72.0%	65.1%
Making progress toward/returning to intercourse (goal)	84.0%	86.0%
Reported Maximum Diameters Reached (Average)	32.9mm	32.2mm
Overall Female Sexual Function Index (FSFI)	72.0%	65.1%
% improvement from Baseline		
FSFI Sub-Domain 1-Desire	-3.5%	-2.7%
FSFI Sub-Domain 2-Arousal	16.9%	25.9%
FSFI Sub-Domain 3-Lubrication	19.8%	29.7%
FSFI Sub-Domain 4-Orgasm	25.3%	23.3%
FSFI Sub-Domain 5-Satisfaction	36.6%	64.7%
FSFI Sub-Domain 6-Pain	154.2%	161.8%

Conclusions

After 3 months of self-directed Milli expanding vaginal dilator home use, participants demonstrated progress toward the primary goal of intercourse, suggesting efficacy in the treatment of vaginismus using a self-guided intervention.

- Future studies can examine how expert clinician guidance might enhance improvements in the same time frame. Both groups reported reaching maximum dilation diameters that fall between static dilator sizes 6 and 7 (out of 8).

Furthermore, the 50+ cohort showed greater improvements in 4 of 6 FSFI subdomains compared to the <50 cohort.

- Further investigation is warranted to better understand the potential reasons for this difference, such as higher treatment adherence or differing underlying causes of vaginismus (e.g., genitourinary syndrome of #menopause) between age groups.

DISCLOSURES

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