POMPOM 3-mo Nulliparous sub-analysis
American Society for Reproductive Medicine (ASRM)

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TITLE: An interim sub-analysis of nulliparous subjects in the POMPOM study evaluating the efficacy of the Milli Expanding Dilator as a treatment for achieving intercourse.

ABSTRACT

OBJECTIVE:
The primary objective is to evaluate the effectiveness of the Milli Expanding Vaginal Dilator in achieving full vaginal penetration with intercourse as reported on the Penetration Efficiency Questionnaire (PEQ Score of ≥2 on PEQ Question #1).

MATERIALS AND METHODS:
Women who made an online purchase of the FDA-cleared Milli expanding vaginal dilator with vibration were invited to join a web-based, prospective, single-arm longitudinal 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).

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. After 3 months, subjects were prompted to report progress using validated measures: PEQ, Female Sexual Function Index (FSFI), and Visual Analog Scale (VAS) Pain with Intercourse.

Basic descriptive statistics were calculated at baseline and after 3 months of Milli use for several criteria, and where appropriate, a paired t-test was used to evaluate if improvements from baseline were statistically significant.

RESULTS:
For this 3-month sub-analysis, 24 participants were 18-44, and 20 (83.3%) were nulliparous; this is a higher incidence than the 52.1% in 15-44 from the CDC 2024 National Health Statistics.

a) 50% of nulliparous participants aged 18-44 reported some improvement in total PEQ.
b) There was a statistically significant improvement in Total FSFI score (p=0.0152) in nulliparous participants aged 18-44 with an average improvement of 21.9%.
c) There was a statistically significant improvement in VAS Pain with intercourse (p=0.0132) in nulliparous participants aged 18-44 with an average improvement of 21.7%.
d) 70.0% of nulliparous participants aged 18-44 reported some improvement in vaginal pain during intercourse and FSFI score.
e) 90% of nulliparous participants aged 18-44 were making progress toward or met return to intercourse goals after 3 months of Milli use.

CONCLUSIONS:
This sub-analysis suggests that the Milli expanding vaginal dilator with vibration may be a valuable tool in the treatment of vaginismus, particularly for nulliparous individuals of reproductive age who are seeking to overcome barriers to vaginal penetration. Clinically meaningful improvements in pain with intercourse, sexual function, and progress toward return-to-intercourse goals were observed after 3 months of use. Notably, the high proportion of participants making progress toward resuming intercourse highlights the potential of this device to support fertility goals in those with vaginismus-related infertility.

IMPACT STATEMENT:
These findings support the integration of patient-controlled, home-based dilator therapy as part of a broader strategy to address genito-pelvic pain/penetration disorder in individuals seeking to conceive.