POMPOM 3-mo Interim Report Measuring Effectiveness on Vaginismus and Dyspareunia Using a Novel Expanding Dilator

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PURPOSE/AIM

This novel web-based observational study assesses the efficacy of an expandable dilator, in self-directed use, to resolve pain with heterosexual intercourse and treat vaginismus.

METHODOLOGY

Milli expanding vaginal dilator purchasers[1] joined a web-based study to investigate the efficacy of self-directed dilation therapy to achieve successful heterosexual intercourse.

Participants signed an Informed Consent e-form, submitted answers to a baseline questionnaire on demographics that included symptoms associated with dyspareunia (inability to have wanted vaginal penetration, sexual function, penetration pain), previous treatments, and experience with dilators.

Subjects qualified for inclusion after confirming vaginismus meeting DSM-5 criteria for GPPPD and inability to achieve intercourse PEQ[2] score of 0 (“not attempted”) or 1 (“attempted but unsuccessful”) on Item 1.

For study inclusion, 74 qualified participants completed an initial use form, and 68 completed follow-up assessments 3 months after first use.

Participants self-guided their use of the Milli expanding vaginal dilator using written instructions.

No clinicians were involved.

Methodology continued:

At 3 months, subjects were asked to rate the progress of dilation therapy using validated questionnaires.

Successful heterosexual intercourse was measured using PEQ[2] Item 1 (successful penile insertion, scale of 0 = not attempted to 4=attempted, always successful).

The Female Sexual Function Index (FSFI) [3] provided a total score and subdomain scores—desire, arousal, lubrication, orgasm, satisfaction, and pain.

Subjects rated anxiety with intercourse from 0 (no anxiety) to 10 (extreme anxiety). [4]
Subjects reported progress for return to intercourse and less painful sex goals.

INTERIM RESULTS

At 3 months, compared to the baseline

- percentage of patients reporting statistically significant improvement
  - Total PEQ 51.5% (p=0.0121)
  - FSFI 67.6% (p=0.0002)
  - Pain with intercourse 67.6% (p<0.0001)
  - Anxiety with intercourse 57.4% (p=0.0002)
- 38.2% reported an improvement ≥1in PEQ-Q1 with an average improvement of 32.1%
- 35.3% reported the ability to achieve intercourse (PEQ at least 2)
- 85.3% reported making progress toward or met their return to intercourse goal
- 75.0% reported making progress toward or met their less painful intercourse goal

DISCLOSURES

Funded by Materna Medical, Inc., enrollment period May 1-Nov 20, 2024.
WCG IRB Tracking Number—20241369. ClinicalTrials.gov—NCT06397885

CONCLUSIONS

At the 3-month checkpoint, participants achieved statistically significant improvements in total PEQ, FSFI, Pain, and Anxiety with intercourse, as well as progress toward their goals.

These results support the effectiveness of an expanding dilator in treating vaginismus and dyspareunia.

Milli Expanding Vaginal Dilator

Starting diameter: 15mm

Fully expanded diameter: 40mm

REFERENCES

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