SEXUAL SATISFACTION WITH PHEXXI®, A HORMONE-FREE VAGINAL CONTRACEPTIVE: 
RESULTS FROM THE AMPOWER CLINICAL TRIAL
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INTRODUCTION
• Current guidelines recommend women who have been diagnosed with or are receiving treatment for cancer to avoid hormonal contraceptive methods due to the possibility of hormone-related risks and sensitivities, and to seek reversible and/or hormone-free methods.
• The vaginal pH modulator (VPM; Phexxi®) was developed as a novel, woman-controlled, vaginal gel for the prevention of pregnancy and sexually transmitted infections.
  - Compared with other vaginally administered products such as spermicides and vaginal rings that may contain surfactants, VPM is a surfactant-free, water-based, non-hormonal, non-systemic vaginal gel.
  - VPM has acid-buffering properties and is able to maintain the acidic vaginal environment (pH 3.5-4.5) even in the presence of alkaline semen.
• VPM has broad-spectrum and viscosity-retaining properties designed to contribute to the effectiveness of the gel (Figure 1)

Figure 1. VPM Has Unique Acid-buffering Properties and Can Maintain the Acidic Vaginal Environment

METHODS
AIM
• Given the lubricating properties of VPM, the objective of the current analysis is to report on sexual satisfaction and function in women participating in the AMPOWER trial.

METHODS
• AMPOWER (NCT03243305) was a phase 3, single-arm, open-label, IRB-approved trial in women aged 18-35 years and conducted at 112 US sites.
  - The primary efficacy endpoint was 7-cycle cumulative pregnancy rate and the secondary objectives included safety of VPM over 7 cycles of use.
  - Sexual satisfaction and function with VPM were explored.
  - Women were instructed to administer VPM intravaginally immediately before or up to 1 hour before each episode of vaginal intercourse.

Figure 2. AMPOWER Study Design

RESULTS
• Of the 1,384 women enrolled in AMPOWER, 1,330 used at least 1 application of the study drug and were included in the sexual satisfaction/function questionnaire analyses.
  - At baseline, most women (70.7%, 934/1,322) reported that sexual satisfaction with their most recent contraceptive method impacted their sexual function.
  - The sexual satisfaction questionnaire evaluated:
    - The impact that the women’s prior contraceptive and VPM had on their sex life.
    - Vaginal dryness during sexual activity.
    - Lack of sexual interest or desire.
    - Vaginal tightness.
    - Pain during penetration or intercourse.
    - Anxiety about your sexual performance.
    - Urinary incontinence.
    - Vaginal bleeding or irritation from penetration or intercourse.
    - Increased sensitivity of your skin to intimate touching.
    - Sharp pain inside or outside your vagina.
    - Other problem with sexuality.
• The sexual satisfaction questionnaire was administered at baseline (Visit 2) and at Visits 3-5.
• The sexual function questionnaire assessed if VPM impacted:
  - Vaginal dryness during sexual activity
  - Lack of sexual interest or desire
  - Vaginal tightness
  - Pain during penetration or intercourse
  - Anxiety about your sexual performance
  - Urinary incontinence
  - Vaginal bleeding or irritation from penetration or intercourse
  - Increased sensitivity of your skin to intimate touching

Figure 4. Improvements in Sexual Function Measures with VPM at Visit 3

• Most women reported “seldom” or “not at all” at baseline and showed little changes at any visit for the following issues: vaginal bleeding or irritation from penetration or intercourse, increased sensitivity of skin to intimate touching, sharp pain inside or outside vagina, and other problems with sexuality.

CONCLUSIONS
• In AMPOWER, approximately half (44.5%) of women surveyed reported “a lot” or “a little” improvement in their sexual satisfaction with VPM compared with 16.9% reporting these levels of improvement at baseline with their previous contraceptive method.
• After 1 cycle of use, most women reported improvements in many sexual function measures, which were maintained throughout the study.
• VPM has the potential of fulfilling an unmet need in women’s sexual and reproductive health as a non-hormonal, woman-controlled, contraceptive option that offers a high level of sexual satisfaction.

REFERENCES

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DISCLOSURE
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CD: Employee, Health Decisions, which received funding from Evofem Biosciences, Inc. to help conduct this study.
BH: Employee, Evofem Biosciences, Inc.
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