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FEMALE SEXUAL FUNCTION

Sexual Satisfaction Results With the Vaginal pH Modulator From the Phase 3 AMPOWER Study

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ABSTRACT

Background: The novel vaginal pH modulator (VPM; Phexxi) is a non-hormonal, woman-controlled, on-demand, water-based, surfactant-free contraceptive vaginal gel; VPM has also been cleared by the Food and Drug Administration for use as a personal lubricant.

Aim: The aim of this study is to report on sexual satisfaction results from the phase 3 AMPOWER study.

Methods: AMPOWER was a single-arm, open-label, multicenter study to assess the safety and efficacy of VPM in preventing pregnancy. Women were enrolled who were healthy, age 18-35 years, and sexually active with regular cyclic menses.

Outcomes: Women's satisfaction (including sexual satisfaction) was an exploratory endpoint measured at Baseline and Visits 3-5; sexual satisfaction-related patient reported outcomes (PROs) were assessed via 3 different questions: (i) a question related to the impact on a woman's sex life; (ii) a question from the Sexual Function Questionnaire (SFQ) related to the frequency of ten sexual problems; and (iii) and a question from the Female Sexual Function Index (FSFI) related to lubrication.

Results: For sexual satisfaction-related PRO measures with baseline assessments, the majority of women reported the same or improved scores at Visit 5 (ranging from 85.8% to 98.4%). The percentage of women who reported that their sex life was improved and/or maintained was higher in Visit 3, 4, and 5 (95.4%, 95.1%, and 93.6%, respectively) compared to Baseline (87.6%). The mean impact on sex life score significantly improved at Visit 5 compared to Baseline ($P < .001$). In the SFQ, the mean score significantly improved ($P < .005$) at Visit 5 vs Baseline in 7 of the 10 variables measured (vaginal dryness, lack of sexual interest and/or desire, vaginal tightness, pain, anxiety, unable to orgasm, and vaginal bleeding or irritation). In women who reported sexual activity in the last 4 weeks, the mean FSFI score also significantly improved from Baseline to Visit 5 ($P = .037$).

Clinical Implications: In this post-hoc analysis of the phase 3 AMPOWER study, the PRO results demonstrate a high level of sexual satisfaction with VPM.

Strengths and Limitations: The primary strength of this analysis was the large study size of 1,330 women. Limitations included the non-randomized study design, the post-hoc nature of the analysis, and the fact that sexual satisfaction was an exploratory endpoint.

Conclusion: As a non-hormonal, woman-controlled, on-demand, lubricating contraceptive gel, VPM offers women a unique set of benefits with positive impacts on their sexual health. **Thomas MA, Morlock R, Dart C, Howard B. Sexual Satisfaction Results With the Vaginal pH Modulator From the Phase 3 AMPOWER Study. J Sex Med 2022;XX:XXX–XXX.**

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Key Words: Vaginal pH Modulator; Sexual Satisfaction; Non-Hormonal Contraception; Vaginal Gel

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INTRODUCTION

The novel vaginal pH modulator (VPM; Phexxi, Evofem, Inc., San Diego, USA) is a non-hormonal, woman-controlled, on-demand, water-based, surfactant-free contraceptive vaginal gel.[1,2] Approved by the United States (US) Food and Drug Administration (FDA) in 2020 for prevention of pregnancy,

VPM (formerly ACIDFORM) maintains the acidic vaginal environment in the presence of alkaline semen resulting in immobilization of sperm.[2-4] VPM has also been cleared by the FDA for use as a personal lubricant[1] and is being studied for prevention of the sexually transmitted infections (STIs) chlamydia and gonorrhea in 2 trials − 1 has recently been completed[5] and 1 is ongoing (NCT04553068).

The single-arm, phase 3 AMPOWER study assessed the efficacy and safety of VPM in healthy, sexually active women, excluding women with a current urinary tract infection at screening or those with a history of ≥3 urinary tract infections in the last year.[6] VPM demonstrated a 7 cycle cumulative pregnancy percentage of 13.7% with typical use and 9.99% with perfect use.[6,7] Women's overall satisfaction with VPM increased compared to the women's contraceptive method used prior to enrollment (47% with prior method vs 85% and 82% with VPM at Visits 3 and 5, respectively).[6] Based on combined safety data from AMPOWER and a second clinical trial, the most common adverse reactions (≥10.0%) with VPM were vulvovaginal burning sensation (18.0%) and vulvovaginal pruritis (14.5%).[2] In male partners of study participants, 9.8% reported local discomfort. There were few cases (0.36%) of cystitis, pyelonephritis, and other upper urinary tract infections; of these, 1 case of pyelonephritis was considered serious and required hospitalization. In a post-hoc analysis of the AMPOWER trial, self-reported rates of genitourinary symptoms of burning and itching generally decreased over time and were higher when the product was used multiple times vs once per day.[8] Overall, 1% of women discontinued due to genitourinary symptoms.

Research suggests that personal lubricants might increase pleasure during intercourse in some women. In a double-blind, prospective, daily diary study of 2,453 sexually active women, use of both water-based and silicone-based lubricants during penile-vaginal sex was associated with higher rates of sexual pleasure and sexual satisfaction compared to when no lubricants were used.[9] These data suggest that VPM, as a water-based lubricant, could have a positive impact on sexual satisfaction. There has been no standardized or uniform instrument to measure sexual satisfaction and function in contraceptive trials.[10-12] One of the more common measures, the Sexual Function Questionnaire (SFQ, from the Fred Hutchinson Cancer Research Center) was originally developed to measure sexual function changes in cancer survivors and matched controls.[13-15] The SFQ assesses 9 domains of sexual function including interest, desire, arousal, orgasm, satisfaction, activity, relationship, masturbation, and problems. Another relatively common measure, the Female Sexual Function Index (FSFI, developed at multiple academic sites in the US), was originally designed to measure sexual function in women with female sexual arousal disorder.[16] The FSFI assesses 6 domains of sexual function including desire, arousal, lubrication, orgasm, satisfaction, and pain.

In this post-hoc analysis, we report on the impact of VPM on sexual satisfaction based on results of the AMPOWER study using, in part, elements of the SFQ and FSFI instruments.

METHODS

AMPOWER was a single-arm, open-label, Phase 3 study conducted at 112 sites in the United States. Detailed methods have been reported previously.[6] In brief, women were eligible for enrollment if they were healthy, age 18-35 years, had regular cyclic menses (21-35 days in length), and were willing to engage in at least 3 acts of penile-vaginal intercourse per cycle. All participating women provided informed consent at screening. Once enrolled, women were instructed to administer 1 dose of VPM intravaginally immediately before or up to 1 hour before each act of vaginal intercourse. Women attended 5 study visits: Visit 1 (Screening), Visit 2 (Enrollment/Baseline), Visit 3 (during the second study cycle), Visit 4 (during either the fifth or sixth study cycle), and Visit 5 (14 to 30 days after seventh study cycle). The primary endpoint of AMPOWER was the contraceptive efficacy of VPM over 7 cycles of use.

Women's satisfaction (including sexual satisfaction) with VPM was an exploratory endpoint. Sexual satisfaction-related patient reported outcomes (PROs) were assessed via 3 different questions: (i) a question devised specifically for this study related to the impact of the contraceptive product on a woman's sex life; (ii) Question 10 (Q10) of the formerly established SFQ,[15] which relates to the frequency of ten sexual problems; and (iii) Q10 of the formerly established FSFI,[16] which relates to lubrication. For the SFQ Q10, the ten variables that were assessed were as follows: vaginal dryness during sexual activity, lack of sexual interest or desire, vaginal tightness, pain during penetration or intercourse, anxiety about your sexual performance, unable to orgasm, vaginal bleeding or irritation from penetration or intercourse, increased sensitivity of your skin to intimate touching, sharp pain inside or outside your vagina, and other problem(s) with sexuality. These measures of sexual satisfaction were selected based on recommendations from experts in the field as a validated sexual satisfaction tool is not available for this population of healthy women seeking contraception. Only 1 question each from the SFQ and FSFI, which were originally designed for cancer patients and women with sexual disorders, respectively, were considered directly applicable to this population.

For each PRO at each visit, the percent of women endorsing a given response was assessed. Each response was assigned a point code and the mean scores at Baseline and Visit 5 were determined (for the full sexual satisfaction-related PRO questions, response options, and coding see Appendix A-C). For all PROs with baseline assessments, the change in the mean score from Baseline to Visit 5 was assessed, with each woman serving as her own control. The proportion of women who reported the same or improved satisfaction levels at Visit 5 vs Baseline was also determined.

Although not related specifically to sexual satisfaction, several other PROs were assessed that provide additional support for the acceptability of VPM (for full questions and possible responses, see Appendix D). Women's satisfaction (combining 'somewhat satisfied,' 'satisfied,' and 'very satisfied') with their current birth

control was assessed. Also assessed was the likelihood (combining 'somewhat likely,' 'likely,' and 'very likely') of women recommending the study product to other women who were considering a vaginal contraceptive gel or another birth control option. The final PRO assessment was the likelihood (combining 'somewhat likely,' 'likely,' and 'very likely') of women continuing to use the study product if it was available. The PRO assessments of likelihood of recommending the study product to other women and of continuing to use the study product were assessed only after study product use, not at Baseline.

Statistics

Descriptive summary tables of PRO measures were carried out as specified in the clinical statistical analysis plan. For each PRO at each visit, the frequency of each response and the percent endorsing each response were assessed in the Safety population, defined as enrolled women who used the study drug at least once. To assess the impact on sexual functioning, the post-hoc analysis was limited to participants who had sexual activity in the past 4 weeks. No imputations for missing values were used.

After the study was complete, a post-hoc analysis was performed to more fully characterize the PROs. PRO measures that were not pre-specified and that were assessed post-hoc included the following: the cumulative percent of women endorsing each response for each PRO at each visit; the change in women's assessments from Baseline to Visit 5 for each PRO measure; the proportion of women maintaining or improving scores on each PRO at each visit; for FSFI Q10, the percent of women endorsing each response at each visit for those who reported sexual activity in the last 4 weeks; and for participant satisfaction endpoints (ie, satisfaction with birth control method, likelihood to recommend to others, and likelihood to continue to use product), the proportion of women reporting the best 3 responses (eg, 'somewhat satisfied,' 'satisfied,' and 'very satisfied') at each visit.

Version 9.4 of the SAS statistical software package was used for all summaries, listings, statistical analyses, and graphical presentations. For the change from Baseline to Visit 5 in the mean score, a paired *t*-test analysis was performed.

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 and/or function questionnaire analyses. The mean number of study drug uses per cycle was 4.24.

Impact on Sex Life

The combined percentage of women who reported that their sex life was a lot and/or little better or no different from before was higher in Visits 3-5 compared to Baseline, whereas the combined percentage of women who reported that their sex life had worsened by a lot and/or little decreased in Visits 3-5 vs Baseline (Figure 1). When looking at individual category responses, the percentages of women who reported that their sex life was a little better or a lot better increased at Visit 5 compared to Baseline (Figure 2A-B). When the change from Baseline to Visit 5 was calculated, more women reported a maintained or improved sex life, represented by scores of 0 to +4, compared to women who reported a worsened sex life, represented by scores of -1 to -4 (Figure 2C). In total, 88.7% of women reported that VPM maintained and/or improved their sex life at Visit 5 compared to Baseline (Table 1). The mean impact on sex life score increased (improved) from 2.10 at Baseline to 2.61 at Visit 5 ($P < .001$).

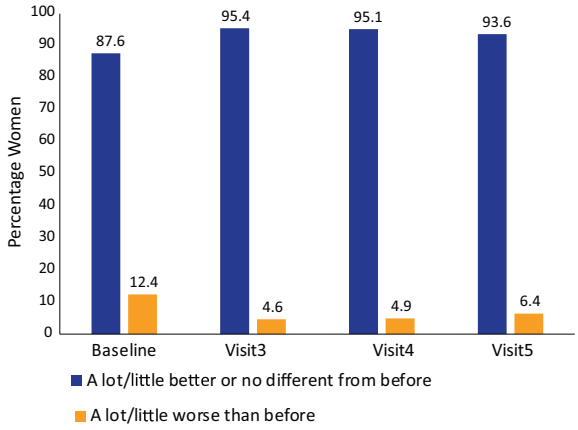


Figure 1. Improved and/or maintained vs worsened impact on sex life with the previous contraceptive method in the 4 weeks prior to study enrollment (Baseline) and with VPM at Visits 3-5.

SFQ Q10

Generally, the percentages of women who experienced some level (ie, always, usually, sometimes, or seldom) of the 10 sexual problems measured in the SFQ Q10 decreased at Visits 3-5 compared to Baseline (Figure 3). The mean score significantly decreased (improved; $P < .005$) between Baseline and Visit 5 in the following measures: vaginal dryness, lack of sexual interest and/or desire, vaginal tightness, pain, anxiety, unable to orgasm, and vaginal bleeding or irritation. The mean score did not significantly change ($P > .05$) between Baseline and Visit 5 in the following measures: increased skin sensitivity, sharp pain outside of vagina, and "other problem with sexuality." High percentages of women reported the same or improved levels at Visit 5 compared to Baseline for all 10 sexual problems (87.4–98.4%).

FSFI Q10

In women who reported sexual activity in the last 4 weeks, a higher percentage had no difficulty in maintaining lubrication in Visits 3-5 (82.6%, 79.4%, and 80.5% at Visit 3, 4, and 5, respectively) compared to Baseline (74.3%; Figure 4A-B). When the change from Baseline to Visit 5 was assessed, more women reported maintained or improved lubrication, represented by

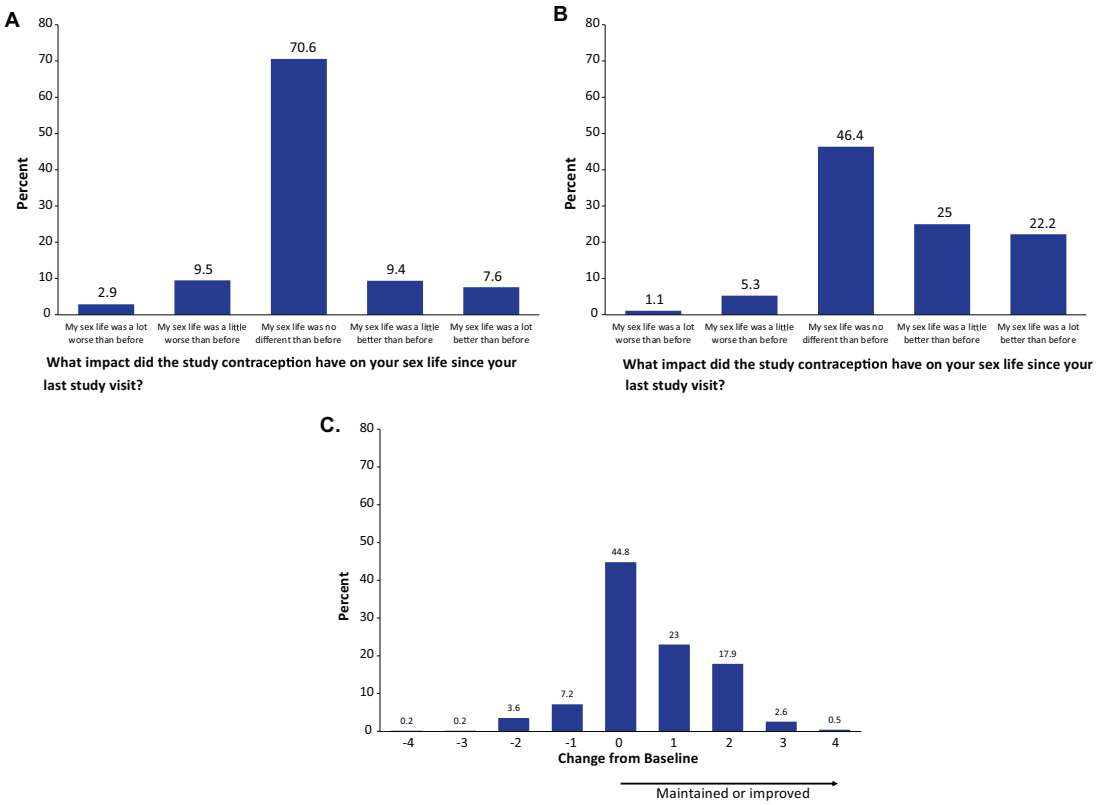


Figure 2. Impact on sex life; individual category responses for previous contraceptive method in 4 weeks prior to Enrollment and/or Baseline (A) and with VPM at Visit 5 (B), and change from Baseline to Visit 5 (C)[a,b] [a]Women served as their own controls. [b]A score of 0 represents the same (ie, maintained) impact, a score of ≥1 represents an improved impact, and a score ≤-1 represents a worsened impact.

scores 0 to +4, compared to women who reported worsened lubrication, represented by scores of -1 to -4 (Figure 4C). In total, 88.4% of women at Visit 5 reported the same or improved scores compared to Baseline. The mean FSFI score significantly increased (improved) from Baseline to Visit 5 ($P = .037$).

Other PRO Endpoints

More women reported being satisfied with VPM at Visits 3-5 (97.4%, 97.8%, and 93.6% reported being somewhat satisfied, satisfied, or very satisfied at Visit 3, 4, and 5, respectively) compared to their previous birth control method at Baseline (74.1%). In contrast, the percent of women who reported being somewhat dissatisfied or dissatisfied was 25.9% at Baseline and decreased to 2.6% at Visit 3, 2.2% at Visit 4, and 6.4% at Visit 5. The mean product satisfaction score significantly increased (improved) to 3.21 at Visit 5 from 2.32 at Baseline ($P < .001$) with 85.8% of women reporting the same or improved levels of satisfaction.

While in the clinical trial, 97.5%, 98.2% and 93.7% of women reported they were somewhat likely, likely or very likely to recommend the study birth control method to someone considering a vaginal contraceptive gel at Visit 3, 4 and 5, respectively. For those considering a different type of birth control method, 97.6%, 96.8% and 93.2% of women would recommend the study birth control method at Visit 3, 4 and 5, respectively. Similarly, a high percentage of women (95.0%, 94.3% and 86.7% at Visit 3, 4 and 5, respectively) reported they were somewhat likely, likely or very likely to continue to use the study product if it was available.

DISCUSSION

Overall, in this post-hoc analysis of the phase 3 AMPOWER study, the PRO results demonstrate a high level of satisfaction with VPM. For sexual satisfaction-related PRO measures with baseline assessments, the majority of individual participants reported the same or improved scores at Visit 5 (ranging from 85.8% to 98.4%) including in the Impact on Sex Life question, all ten variables of the SFQ Q10, and the FSFI Q10 on lubrication. Furthermore, VPM showed significant improvement ($P < .05$) at Visit 5 compared to Baseline in mean scores for the Impact on Sex Life question, 7 variables of the SFQ Q10 (vaginal dryness, lack of sexual interest and/or desire, vaginal tightness, pain, anxiety, unable to orgasm, and vaginal bleeding or irritation), and the FSFI Q10 on lubrication in women with sexual activity in the last 4 weeks. No significant difference ($P > .05$) was found at Visit 5 compared to Baseline in 3 variables of the SFQ Q10 (increased skin sensitivity, sharp pain outside of

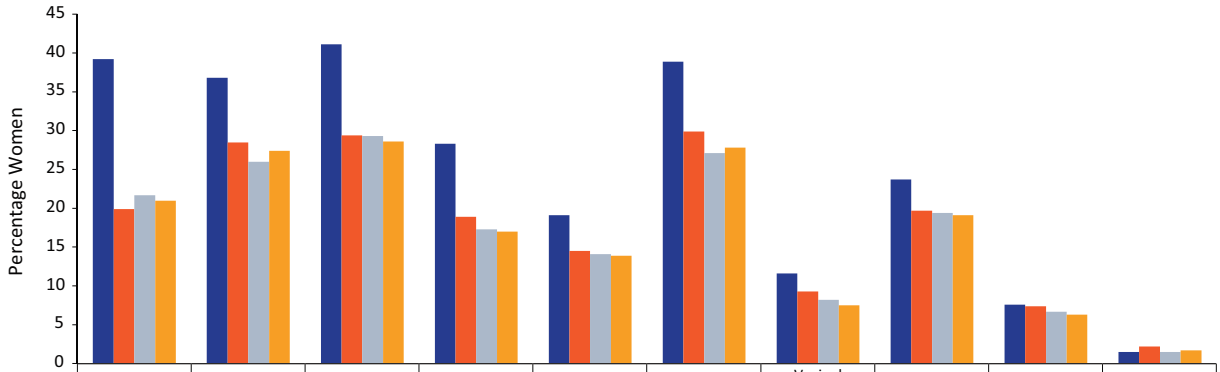
Table 1. Mean scores at Baseline and Visit 5 and the percentage of women who reported the same or improved scores for various PRO measures*

PRO	Mean score at Baseline	Mean score at Visit 5	*P* value (mean score at Baseline vs Visit 5)	Percentage who reported same or improved scores at Visit 5 vs Baseline
Impact on sex life question	2.10	2.61	$P < .001$	88.7%
SFQ Q10‡				
Vaginal dryness	0.532	0.263	$P < .001$	92.9%
Lack of sexual interest/ desire	0.521	0.384	$P < .001$	88.0%
Vaginal tightness	0.769	0.509	$P < .001$	87.4%
Pain during penetration/ intercourse	0.351	0.210	$P < .001$	92.4%
Anxiety about sexual performance	0.268	0.198	$P = .002$	91.8%
Unable to orgasm	0.660	0.466	$P < .001$	88.6%
Vaginal bleeding or irritation from penetration/ intercourse	0.138	0.093	$P = .002$	95.3%
Increased sensitivity of skin to intimate touching	0.392	0.338	$P = .107$	87.8%
Sharp pain inside or outside vagina	0.098	0.087	$P = .480$	95.3%
Other problem with sexuality	0.023	0.038	$P = .269$	98.4%
FSFI Q10 in women with sexual activity in last 4 weeks†,§	4.68	4.73	$P = .037$	88.4%
Satisfaction with contraceptive†	2.32	3.21	$P < .001$	85.8%

*Women were used as their own control at Visit 5 vs Baseline; only women who completed the questionnaires at Baseline and Visit 5 were included (n = 940).
†Increased score indicates improvement.
‡Decreased score indicates improvement.
§Only women who completed the FSFI Q10 questionnaire, and who reported sexual activity in the past 4 weeks, at both Baseline and Visit 5 were included (n = 911).

vagina, and other problem with sexuality). For the non-sexual satisfaction specific PROs, a high percentage of women at Visit 5 reported being satisfied with VPM overall and high percentages reported they would recommend it to others and would continue to use the product after the study if available.

The positive impact of VPM on female sexual satisfaction, combined with the non-hormonal, woman-controlled, and on-demand nature, give VPM a unique set of characteristics that might appeal to certain women. Although contraceptive efficacy and safety are generally the most important attributes for women in selecting contraception, research indicates that some women also value non-contraceptive characteristics such as impact on libido.[17] While combined oral contraceptives are highly safe and effective and have many non-contraceptive benefits, including reduced risk of ovarian and endometrial cancers as well as positive impacts on acne and heavy menstrual bleeding,[18] some studies suggest that they can lead to decreased libido and sexual satisfaction in a small number of women.[10-12,19,20] In a double-blind, randomized, placebo-controlled, single-institution trial of 340 women, sexual function domains of desire, arousal, and pleasure — as measured by the Profile of Female Sexual Function — were significantly reduced in women receiving a combined oral contraceptive compared to placebo.[11] Another prospective, randomized, single-institution study found a significantly lower total FSFI score as well as lower desire and arousal scores in women receiving a combined oral contraceptive vs the control group.[12] Two reviews of the literature found evidence for a negative impact of combined oral contraceptives on libido in a small percentage of women, with 1 review showing decreased libido only at lower doses of ethinylestradiol.[10,20]



	Vaginal dryness during sexual activity	Lack of sexual interest/desire	Vaginal tightness	Pain during penetration/ intercourse	Anxiety about sexual performance	Unable to orgasm	Vaginal bleeding or irritation from penetration/ intercourse	Increased sensitivity of skin to intimate touching	Sharp pain inside or outside vagina	Other problem with sexuality
Baseline	39.2	36.8	41.1	28.3	19.1	38.9	11.6	23.7	7.6	1.5
Visit 3	19.9	28.5	29.4	18.9	14.5	29.9	9.3	19.7	7.4	2.2
Visit 4	21.7	26	29.3	17.3	14.1	27.1	8.2	19.4	6.7	1.5
Visit 5	21	27.4	28.6	17	13.9	27.8	7.5	19.1	6.3	1.7

Figure 3. Percentage of women experiencing some level (ie, always, usually, sometimes, or seldom) of each of the sexual function measures in the SFQ Q10 at Baseline and at Visits 3, 4 and 5.

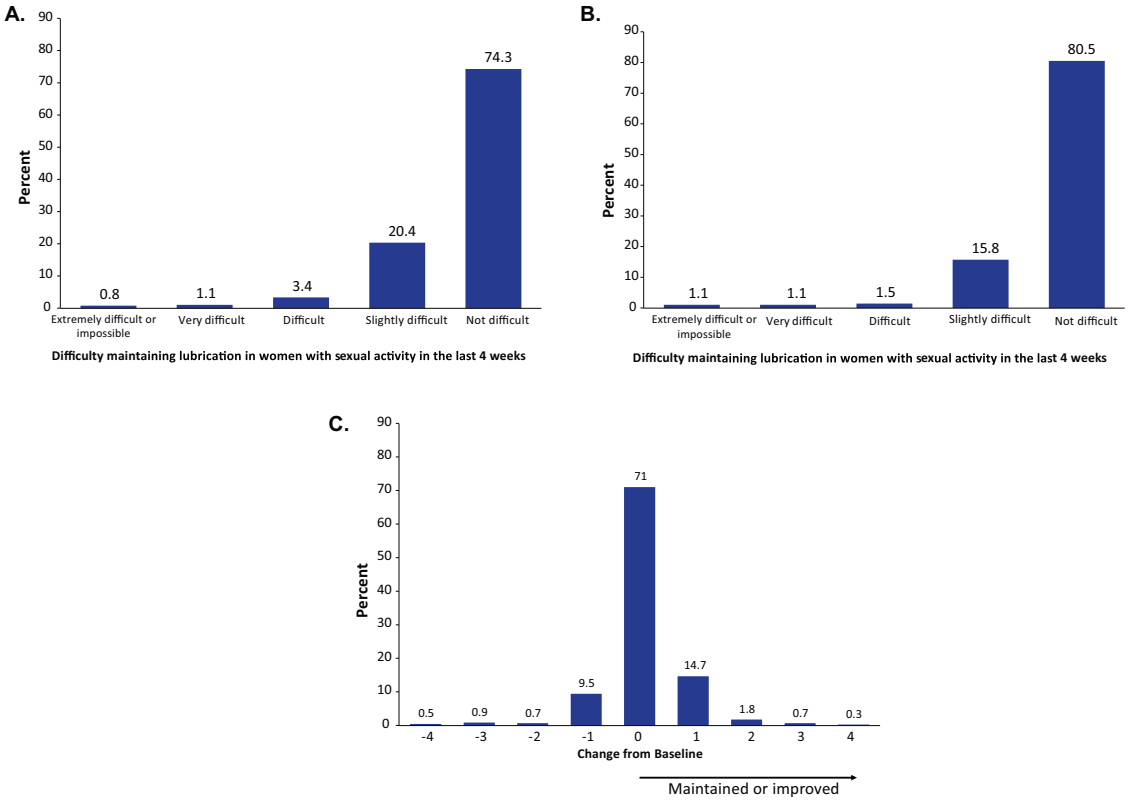


Figure 4. Amount of difficulty in maintaining lubrication during sexual activity as measured by FSFI Q10 in women reporting sexual activity in previous 4 weeks; individual category responses at Baseline (A) and with VPM at Visit 5 (B), and change from Baseline to Visit 5 (C) [a,b,c] [a]Women served as their own controls. [b]Seven participants at Baseline and 21 at Visit 5 report no sexual activity in the past 4 weeks. [c]A score of 0 represents the same (ie, maintained) lubrication, a score of ≥1 represents improved lubrication, and a score of ≤-1 represents worsened lubrication.

The primary limitation of this analysis is the non-randomized study design. The impact of VPM on sexual satisfaction was compared to the women's experience at Baseline. In total, 70% of women in the AMPOWER study reported using contraception at Baseline, with the most common types being the male condom (56.9%), withdrawal method (14.2%), and rhythm method (5.1%).[6] This study does not represent a direct, head-to-head comparison of the impact on sexual satisfaction of VPM vs these prior types of contraception; furthermore, no direct comparisons can be made between VPM and other contraceptive methods such as combined oral contraceptives. The active ingredients of VPM (lactic acid, citric acid, and potassium bitartrate) are designed to immobilize sperm through pH modulation,[1,2] there are no data to indicate that these ingredients would alter the vaginal environment in a way that could impact sexual satisfaction, although the genitourinary side effects experienced by some VPM users might negatively affect satisfaction.[6] In the authors' opinion, it is more likely that the lubricating properties of VPM, from the gelling agents (alginic acid and xanthan gum) and humectant (glycerin), possibly combined with the peace-of-mind associated with its contraceptive properties, are primarily responsible for the maintained and/or improved sexual satisfaction. Thus, it is possible that other contraceptive gels, to the extent that they provide lubrication, would have a similar impact on women's sexual satisfaction. Although not yet approved for this indication, the potential for VPM to reduce the risk of STIs, in contrast to the commonly used contraceptive gel nonoxynol-9, which does not protect against STIs,[21] might eventually add to a VPM user's peace-of-mind, sense of female empowerment, and satisfaction. In addition to the non-randomized design, another limitation of the current analysis is the fact that the AMPOWER study was not powered to examine women's satisfaction (including sexual satisfaction), which was an exploratory endpoint. The analysis is strengthened by the large number of women, 1,330 in the Safety population, that were included in the analysis as part of the AMPOWER study.

As a non-hormonal, lubricating, women-controlled gel, VPM has the potential of fulfilling an unmet need in women's sexual and reproductive health with data showing that it offers a high level of sexual and overall satisfaction.

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STATEMENT OF AUTHORSHIP

Contributor Role Conceptualization – M.A.T., R.M., C.D., B.H. – all equal Data curation – R.M. (lead), C.D. (supporting), B.H. (supporting) Formal analysis – R.M. (lead), C.D. (supporting) Funding acquisition – B.H. (lead) Investigation – M.A.T., R.M., C.D., B.H. – all equal Methodology – R.M. (supporting), C.D. (supporting), B.H. (lead) Project administration – B.H. Resources – M.A.T., R.M., C.D., B.H. – all equal Software – R.M., C.D. – all equal Supervision – M.A.T., R.M., C.D., B.H. – all equal Validation – R.M. (lead), C.D. (supporting), B.H. (supporting) Visualization – M.A.T., R.M., C.D., B.H. – all equal Writing-original draft – M.A.T., R.M., C.D., B.H. – all equal Writing-review & editing – M.A.T., R.M., C.D., B.H. – all equal.

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SUPPLEMENTARY MATERIALS

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jsxm.2022.03.221.