

HHS Public Access

Author manuscript *AIDS Behav.* Author manuscript; available in PMC 2021 October 14.

Published in final edited form as:

AIDS Behav. 2021 June ; 25(6): 1890–1900. doi:10.1007/s10461-020-03119-2.

Men's Sexual Experiences with the Dapivirine Vaginal Ring in Malawi, South Africa, Uganda and Zimbabwe

Elizabeth T. Montgomery¹, Ariana W. K. Katz¹, Zoe Duby¹, Leila E. Mansoor², Neetha S. Morar³, Kalendri Naidoo², Mercy Tsidya⁴, Miria Chitukuta⁵, Victor Guma⁶, Siyanda Tenza⁷, Jonah Leslie¹, Morgan Garcia⁸, Sarita Naidoo^{3,9}

¹ Women's Global Health Imperative, RTI International, Berkeley, CA, USA

² Centre for the AIDS Programme of Research in South Africa (CAPRISA), Durban, South Africa

³ HIV Prevention Research Unit, South African Medical Research Council, Durban, South Africa

⁴ UNC-Lilongwe, Lilongwe, Malawi

⁵ University of Zimbabwe College of Health Sciences Clinical Trials Research Centre (UZCHS-CTRC), Harare, Zimbabwe

⁶ Makerere University-Johns Hopkins University Research Collaboration, Kampala, Uganda

⁷ Wits Reproductive Health and HIV Institute, Johannesburg, South Africa

⁸ FHI360, Durham, NC, USA

⁹ The Aurum Institute, Johannesburg, South Africa

Abstract

The dapivirine vaginal ring has been well-tolerated and shown to prevent HIV in clinical trials. The ring is female initiated, yet endorsement for use is sought from male partners in many relationships. In clinical studies, participants have expressed worries about men detecting rings during vaginal sex, which introduces concerns about product use disclosure, sexual pleasure, penile harm, inter-partner dynamics, and ring removals. This study reports African men's firsthand sexual experiences with the ring. Qualitative data were captured through 11 focus group discussions and one in-depth interview with 54 male partners of ring-users at six research sites in Malawi, South Africa, Uganda and Zimbabwe. Following a semi-structured guide, and using demonstration rings, vulva and penis models, men were asked to discuss the ring's impact on sex and views on male engagement and ring use. Interviews were facilitated by local male social scientists, audio-recorded, translated into English, and analyzed thematically. 22 (41%) of the male partners reported feeling the ring during sex, often attributed to perceived incorrect insertion. Many men described the ring as "scratching" the tip of their penises, and sensations of "prodding" something that "blocked" the vagina and prohibited "full entry". In most cases,

Elizabeth T. Montgomery, emontgomery@rti.org.

Compliance with Ethical Standards

Conflict of interest There are no potential conflicts of interest (financial or non-financial) by any of the authors in regards to this manuscript. The research involved human subjects and no animal subjects. All researchers who collected data from humans were trained in the principles of Human Subjects. A written informed consent process, approved by local ethical review committees in all research settings, was undertaken with participants prior to any research procedures.

feelings dissipated with time or when sexual fluids increased. Less common descriptions included perceiving the vaginal texture, wetness and size as different, which increased pleasure for some, and decreased for others. Over half (59%) never noticed the ring; some attempting and failing to feel it during intercourse. A majority of men reported that the ring did not lead to changes in sexual positions, feelings, frequency or experience of sex, although some were initially afraid that the ring was a "magic snake" or "potion". Male partners expressed strong opinions that ring use was a shared prevention responsibility that men should be engaged in, especially for maintaining trust and open communication in relationships. The ring was noticed by many male partners, particularly during women's initial stages of ring use, although this led to few sexual problems or changes. Nevertheless, results suggest that risk of ring discovery should be discussed with women to mitigate any potential negative reactions or social harm. Strategies to increase male partner engagement will enhance support of this prevention method for women.

Keywords

Vaginal ring; Male partners; HIV prevention; Qualitative; Sexual experiences; Africa

Introduction

The dapivirine vaginal ring has been shown to reduce the risk of HIV acquisition in clinical trials by 37% to 61% in intention to treat and per protocol analyses [1, 2]. Subgroup analyses controlling for residual dapivirine levels have highlighted that the protective benefit of the ring increases when consistently worn, but many participants did not use the ring consistently [1–3]. In open label extension studies (OLE), the ring has similarly reduced risk of HIV acquisition, and reported higher adherence than the randomized trials [4, 5].

Challenges with women's adherence have frequently been attributed to actual or perceived resistance to ring use from male partners [6–8]. In clinical trials and smaller qualitative ancillary studies, male partners, community stakeholders, and female study participants have expressed worries about men detecting rings during vaginal sex, which adds enhanced context to concerns about product use disclosure, sexual pleasure, penile harm, partner conflict, and ring removals [6–9]. A woman's ability to use the ring without fear of partner detection could reduce ring removals, provide women with greater confidence around sustained ring adherence, and increase effectiveness of the ring at a population level.

Despite several reports from female trial participants about how their male partners feel about the ring, firsthand research with men about how women's use of a vaginal ring impacts men or male partners of ring users has thus far been limited [6, 8]. This analysis presents primary data about men's perceptions and experiences with the ring from male partners of women who used the dapivirine ring in the Microbicide Trials Network (MTN)-025/HOPE open label extension study. This is the first study to report on male partners' experiences having vaginal sex with women wearing the ring for HIV prevention. We explore the physical, psychological and emotional dimensions of the impact of the ring on men's sexual experiences. The European Medical Authority (EMA) recently issued a

positive opinion of the dapivirine vaginal ring, and male partner's opinions offer critical insight into future scale up activities.

Methods

Study Design and Settings

Twelve focus group discussions (FGDs), two per site, were planned at six clinical research sites in Malawi (Lilongwe), South Africa (two in Durban, Johannesburg), Uganda (Kampala) and Zimbabwe (Harare) as part of the MTN032 Adherence in HOPE and ASPIRE (AHA) study, which was a follow-on ancillary study to the HOPE study [3]. FGDs were selected as the primary mode of data collection so as to be able to gather a broad range of experiences having sex with a ring-user. We knew we wanted to focus on the intimate topic of sexual experiences which generally would be more suitable for an IDI, but we had concerns that we might unintentionally recruit partners who were unwilling to open up in an IDI, or that we would recruit a homogenous sample. We were also interested in gathering normative attitudes about men in the community and male engagement, which are better suited for FGD. Nevertheless, due to challenges recruiting enough men to form a second FGD at one site, the second FGD was replaced with an in-depth interview (IDI), resulting in an overall total of 11 FGDs and one IDI with 54 male partner participants. Eligible participants were male partners of women who had participated in HOPE [4]. Research sites were provided with two sequentially-ordered listings of randomly selected female participant identifications (PTIDs). The listings corresponded to women who exited from HOPE in either the first or second half of their cohort, to reduce an order effect from participation in the HOPE study. At their study exit, HOPE participants were asked if they provided permission for study staff to contact their male partners to participate in AHA, and it was clarified that AHA participation would reveal that she was in the study and had been offered the opportunity to use the ring. Those assenting provided male partner contact information. These male partners were subsequently contacted in the order designated by the randomized list and invited to attend a FGD with other men. The availability of male partners for recruitment varied substantially by site. At some sites, a small percentage (e.g., 12% or 30%) of female participants gave permission to contact their male partners, limiting the pool, while at other sites close to 100% granted permission. Due to conflicting schedules, contact challenges and lack of interest, scheduling was generally difficult for a group discussion at all sites.

Procedures

During recruitment, study staff explained what the study was about and assessed interest and availability to be part of the FGD or IDI. On the day of the FGD or IDI, male partners individually underwent an informed consent process with a study staff member and were asked socio-demographic and behavioral questions on a structured questionnaire. Following this, FGDs and the IDI were facilitated by a trained male social scientist using a semi-structured guide. A male note-taker was present at all FGDs. The FGD covered topics about men in the community and HIV risk perception, attitudes towards the HOPE study, knowledge about and opinions about HOPE and of the vaginal ring and its efficacy,

HIV prevention preferences, and male engagement in future projects. The IDI guide covered similar topics, but by definition, elicited more information about individual experiences.

Additionally, male partners were asked to discuss and to demonstrate how the ring impacted their sexual experiences, if at all. To facilitate a detailed discussion, study staff provided participants with a prototype of the vaginal ring, two penis models, and a fabric model of a vagina called a "vulva puppet" (Fig. 1). Key probes under this question related to whether male partners could tell if his partner was using the ring during sex, how he knew this, what it felt like, and how it was different to sex without the ring. Additional questions probed whether the ring led to changes in sexual positions. Men discussed whether and at what point they were informed about the ring by their female partners in the HOPE study.

Analysis

Interviews were audio-recorded, translated into English, transcribed and uploaded into Dedoose qualitative software (version 8.2.14) for analysis. Two social science analysts, one based in the United States (US) and one in South Africa, thematically coded the transcripts using an iterative process that verified inter-coder reliability on 10% of excerpts. The code of "SEX" was applied to all passages meeting the following criteria: Apply to comments about sex—frequency, practices, preferences, and general comments. Include discussion about how the vaginal ring affected the participants' sex lives, including how it felt to have sex with their partner using the ring and if they could feel the ring during sex. Also include if they changed sex positions or sex acts, and whether they discussed these changes or lack of changes with their partners. The lead author reviewed all coded excerpts coded as SEX and summarized data thematically, with illustrative quotations. Some repetitive or irrelevant text in quotations have been removed and are marked with "...".Within quotations, clarifying text is added with parentheses, and changes to translations that maintain grammatical flow are in square brackets. Interpretation of results were vetted with interviewers, site Investigators and/or co-authors representing each clinical research site. For analysis the lead author manually tabulated the number of participants who reported feeling the ring during sex, as presented in Table 2. Demographic data were summarized in Stata 15.0 (Statacorp, College Station, TX).

Ethical Considerations

During the FGDs, participants chose pseudonyms or were assigned respondent numbers to preserve confidentiality, and these are presented in the text below. Group participants were advised not to share information outside of the group, and were also reminded that they could abstain from answering any questions. Study procedures and interview guides were reviewed and approved at ethical review boards at all participating institutions.

Results

The characteristics of the study sample are presented in Table 1. Fifty-four men were enrolled, with an average age of 37.5 years (range 21–61). More than half the men (61.1%) had not completed secondary school, 44% were formally employed and 35.2% were self-employed. 61.1% were formally or traditionally married, and a further 9.3% were unmarried

reported that their female partner provided him with financial or material support. Most men (83.3%) reported being HIV-negative, and the majority (96.3%) indicated that they would support their partner using a ring in the future.

Men described the impact of the ring on their sexual experience across several dimensions, including physical sensations of the ring and how this impacted sexual experiences and pleasure. Additionally, men described some emotional and psychological reactions and fears related to ring use during sex, and attitudinal narratives about how sex with the ring was preferable to sex with male condoms.

Physical Feelings of the Ring on the Penis

Of primary interest was whether men could physically feel the ring during vaginal sex, and if they did, how it felt. Thirty-two (59%, Table 2) of the male partners *never felt* the presence of the ring, and some commented that despite concerted efforts of shifting positions and penile movement, they could not feel it. Of note, none of the men at one of the Durban sites reported feeling the ring, whereas at the other Durban site, the majority or all reported having felt the ring, and all attendees at the Johannesburg FGD felt the ring. Noticing the ring was reported by a fraction of the FGD attendees during the FGDs in Zimbabwe, Malawi and Uganda (Table 2).

Less than half (n = 22, 41%) of male partners reported feeling the ring during sex. Several of these men described the ring as "scratching" the tip of their penises, and sensations of "prodding" something that "blocked" the vagina and prohibited full entry. In many cases, men at all research sites attributed their feelings of the ring to their partners' incorrect insertions. Additionally, they posited that if the ring was inserted correctly, it could not be felt. Comments about feeling the ring on the glans, prodding and incorrect insertions were consistent findings across all research sites. The following excerpt from a FGD in Lilongwe demonstrates perceptions of how the placement of the ring impacted whether the ring could be felt in situ:

She would fold it into an eight and then she would insert it. When it is pushed further into the vagina, it would release from the eight shape and then settle on the cervix. No matter how hard I work [during sex], I still would not reach where it is... When she inserts it properly, I would even forget that she uses a ring. (R3, FGD 2, Lilongwe, Malawi).

A participant in Kampala described three sentiments about the ring heard in FGDs from other sites as well. Similar to the Lilongwe participants above, he noted how the placement of the ring impacted his ability to feel the ring. He also attributed feeling the ring to the type of sex that couples were engaging in, and that the feeling of the ring dissipated as they were more sexually aroused and as women spent more time in the study.

The problem I discovered is that it is possible that sometimes it can be inserted wrongly because there were times when I would hit on the ring. I hit on it before going deeper into the vagina. I would hit on it and I think that it would at times not reach into the area where it's supposed to rest. Secondly, I felt that it could

shift depending on the mood [of] the woman. When you and the woman [are] enjoying the sex, you feel the ring coming closer. I think it is like what Abdu said that it depends on the sex style you use. You feel that it has moved closer as if it is bouncing and that is the first thing I felt. This thing was felt when she had just started using the ring but we did not feel it later on. (Peter, FGD 2, Kampala, Uganda).

Men from another FGD in Kampala also mentioned that feeling the ring went away with time in the study and when sexual fluids increased during intercourse, primarily from women's vaginal lubrication.

The problem of the ring is here at the tip of the penis. When you are entering the vagina like this, the head of the penis hits the ring and you feel it. When you pull out the penis and fluids start flowing, then you stop feeling it (Cosmas, FGD 1, Kampala, Uganda).

The value of inserting the ring correctly so that it could not be felt was further explained by one participant, who shared his perception that if worn well, men would be encouraged to favor it:

I feel that using the ring well so that men should not feel it during sex, it is one way that can make men to like the ring even more (R1, Lilongwe, FGD 731).

Changes to Sexual Experiences from the Ring

Related to whether the ring was physically felt during vaginal sex was the question of whether the presence of the ring – whether felt or not - changed the feeling of sex for male partners. The majority of men reported that the ring did not change the positions, feelings, frequency or experience of sex. For many, use of the ring "did not change the sex style." As Rashid from Kampala explains:

Even if you hit on the ring, it does not affect you so much and it does not cause any pain. You hit on it and feel like you have hit on a small thing (Rashid, FGD 2, Kampala, Uganda).

Less common responses from male partners about the ring included their perceptions that vaginal texture, wetness and size were different, which increased pleasure and libido for some, and decreased for others. There were additionally some changes in preferences for different sex positions, the frequency and types of sex. Pido from Zimbabwe explained that he would "*perform carefully*" at first so as not to hurt his partner, but after he learned from experience that sex with the ring did not change any sensations, he resumed his usual pattern. Others described how they discussed changes in the sexual experience with their female partners and were reassured or offered explanations related to a particular sex position by their female partners.

Ah, nothing was happening. We did discuss but she assured me by saying, "I don't feel any pain. I don't have any discomfort." I then asked, "How come I sometimes prod the ring?" She said, "Maybe I would have raised my legs too high" (Gaza, FGD 2, Harare, Zimbabwe).

In Kampala, many men spoke about how sex positions were associated with feeling the ring. They said that with "*normal*", missionary-position sex they did not feel the ring, whereas when they used techniques like those in movies, and got "*deeper*" it could be felt:

There are those styles we see in movies for example where a woman has to raise up her legs and with such a sex style, you cannot avoid getting deeper into the woman's vagina and feel the ring. But if we have sex when we are just lying down, I do not feel the ring (FGD 632, Abdu, Kampala).

Also in Kampala, the ring was reported by male partners to have differing effects – one man reported that the ring caused soreness in some positions, which limited his sexual position options – a sentiment echoed in Harare. However, in one FGD in Durban, none of the men felt the ring or noticed any changes to sex, although one participant reported that his partner no longer wanted to have vaginal sex from behind, which he attributed to the ring causing a change in sexual preference:

It is the doggy style, which is the style she no longer likes... She does not like it anymore. She does not want it.... Yes, we discussed it but she was not clear whether it was the ring but I speculate it is the ring (P1, FGD 1, MRC Durban, South Africa).

Impact of the Ring on Sexual Pleasure

The presence of the ring was described to have improved both male and female sexual pleasure in some cases. One participant in Johannesburg believed that his partner's ring use increased their sexual frequency due to the way the ring was positioned in the vagina, which was sexually stimulating and arousing to his partner. He also noted that this was problematic rather than positive—because as a man he has so many demands on his time, and it was difficult and inconvenient when his partner wanted too much sex. (IDI respondent 2304, Johannesburg). Additionally, a participant in Uganda expressed concerns that an (upward) change in his wife's interest in sex might promote promiscuity:

Why I have said that the ring can promote promiscuity... I found out that when we had sex. We had sex and I was able to finish but she still wanted to continue with having sex. That is why you see that I asked whether that thing [ring] may not promote promiscuity because you reach the climax of sex but she still wants to continue (Jimmy, FGD 2, Kampala, Uganda).

Another male partner also associated increased sexual desire or pleasure with an increased sexual appetite, attributing this to knowing the ring offered protection:

Ah, nothing changed. However, what was interesting is that there was increase in sexual desire...That mental sense of protection makes you want more of it (Mdara Razor, FGD 1, Harare, Zimbabwe).

A participant in Durban gave an elaborate description of how much the ring improved his pleasure during sex - so much so that he would search for the ring in his partner's vagina using his penis - he would move his penis around - up and deeper inside her vagina, so that he could feel the ring.

Every time when I were about to have sex, I would insert the penis and move it upward because I wanted to feel it first... I searched for it... I moved the penis upwards and sometimes when I am searching for the ring when doing sex, I would feel big pleasure on the side only to find out it is the ring... I would focus on that area [laughing]... (Jomo, FGD 1, CAPRISA Durban, South Africa).

Emotional and Psychological Experiences with Ring Use

In addition to physical feelings of the ring on the penis and impacts on sexual behavior, men described how use of the ring had other impacts on the sexual experience, some of which can be classified as emotional or psychological reactions. For example, some men noted that the ring changed the feeling of the vagina, and these changes were linked to men's fears about the meaning of the altered vaginal environment. A participant in South Africa described how his lack of awareness that the ring was inserted scared him, and he feared that his partner had a snake in her vagina:

I would do it and do it [penetrate during sex], I didn't feel it all the time because at first, she was hiding it from me... You see she didn't tell me, but I could feel that there was something that was tickling me. [Using penis model and vulva puppet to demonstrate that he felt the ring with the tip of his penis]... I would be frightened and feel that this thing keeps on tickling me... Thinking maybe there was Mamlambo [the magic snake] because other women have a snake in their vaginas... When you are having sex, it would feel very nice because of the snake, I was shocked thinking no something is wrong here (Ayanda, FGD 2, CAPRISA Durban, South Africa).

Similarly, a participant in Harare reported that he felt something during sex and suspected that his female partner was using potions that changed the feeling of her vagina. Once he knew that she was using the ring, he changed his sexual technique and the ring was no longer felt.

At the beginning, I wanted to know; in my mind I suspected that perhaps my wife was using some potion... For tightening her vagina. She had not explained that she was using the ring. However, when she explained this, and after I had gone through the papers which she gave me to read, I reasoned that I probably needed to push the ring further. [Laughter]... and thereafter I never felt the ring again (Stembie, FGD 1, Harare, Zimbabwe).

Other male partners felt the ring and described it as "scary" to feel something unusual, and that the penis itself got scared and lost its erection, sometimes for extended time periods. A South African participant from Durban described this phenomenon:

Sometimes if you just see it [ring] and you have to do sex with her it takes some time for the penis to erect because you have noticed that something is wrong which is unfamiliar... when I first saw it, it took two days for my penis to erect again (Jomo) FGD 1, CAPRISA Durban, South Africa).

Other men discussed the importance of disclosure, of knowing that their female partners were using the ring – so that he does not get suspicious and alarmed by the feeling of foreign

She was supposed to inform me about such things. Will she be happy if I show up having inserted an earring on my penis? ... Will she be happy if I didn't tell her about it? (Khavava, FGD 1, CAPRISA Durban, South Africa).

Additional feelings of fear, or emotional concern or suspicion, arose when male partners talked about the investigational nature of rings and dapivirine, and uncertainty about what risks it might present. A participant in South Africa described fears of how it might impact their erections:

Actually, not that I didn't like anything; ... I didn't know how is going to make this feel, how is it going to change this, or affect penetration and all those things, do you understand. That was my fear... I thought maybe this ring is going to hurt me, do you understand what I am saying; that was my main fear... I think it's just like in any prevention case it (chemical composition of drug) makes men have problems with their erection. That is my concern (IDI, Johannesburg, South Africa).

Members of an FGD in Uganda worried about developing side effects from the drug in the ring. These fears were allayed when male partners came to the clinic and discussed their concerns with study staff. Below, a participant in Durban discussed fears of how dapivirine might affect him, not from ring exposure, but from oral sex:

I also asked myself if the dapivirine would not affect me when I am kissing the vagina... I had that in my mind because there is a dapivirine... If it would not infect me with bacterias or things like that you see (Menzi, FGD 2, CAPRISA Durban, South Africa).

Attitudes about Ring Use vs. Condom Use

Male partners at all sites noted that they greatly preferred using the ring during sex, as compared to male condoms, for several reasons: they did not feel the need to worry about condom use if a ring was being used, they found condom use to be tedious and inconvenient, sometimes painful or itchy, and bothersome to deal with. In short, use of the ring (versus condoms) was a sexual preference. Rings were favored because they allowed for flesh-on-flesh sex that felt better and allowed for "quickies" and spontaneous sex. Additionally, male partners recognized the benefit that the ring protected women when men did not wear condoms. Men who didn't want to wear condoms reported a sense of HIV protection from the ring, a relief from risk. Finally, a male partner from Kampala highlighted the benefit that sex workers using the ring will be able to earn more money from condomless sex if they have the ring. Illustrative quotes in Table 3 highlight male partner opinions about ring use versus condom use.

Discussion

The primary data from male partners about their experiences and interactions with dapivirine vaginal rings during sex offered several important findings that are relevant to wider scale implementation of the ring. First, less than half of this sample of male partners who

participated in these interviews reported physically feeling the ring during penile-vaginal intercourse. We are not able to stratify these reports by when and whether ring use disclosure occurred during HOPE, nor do we have a means of verifying men's self-reported experience of feeling the ring. Nonetheless, these findings suggest that rings cannot necessarily be worn discreetly by women who need or choose to hide their use. Providers and ring informational materials (electronic and print) should discuss potential ring detection with prospective users, and offer counseling guidance about ring disclosure skills for those who want negotiation assistance. Second, ring use was not reported to disrupt sex by many of the male partners. For those who did report disrupted sex, it did not pose a consistent problem – generally it was described to dissipate with time and women's comfort with the ring - both in terms of time in the study and time within a sexual episode. Third, ring use disclosure is an important consideration, not only because the ring itself or changes to the physical feeling of the vagina might be noticed, but also to avoid potential extreme assumptions about potions and promiscuity. As such, results suggest that the risks of ring discovery by a male partner should be discussed with women who are considering ring use in order to mitigate any potential negative reactions. Finally, the ring was greatly favored over male condoms. Men liked the ring, and preferred that women use it for a variety of reasons that included her own health, sexual pleasure and his convenience. Male partners can be an important resource in promoting rings as a favorable HIV prevention method option for women and couples.

The male partners in these interviews who described feeling the ring on their penises frequently attributed the sensation to incorrect insertions, and men described that once their female partners were more familiar with ring use in general, over time, or once they had removed and reinserted the ring, this situation resolved. The men also described that if they initiated sex quickly, or their sexual movements were too rapid without there being adequate vaginal fluid, they could feel the ring; whereas they could not when women were naturally stimulated and ready for sex. These findings point to two issues: ring placement and lubrication. It is unknown whether women actually had inserted the ring "incorrectly". The ring is a drug delivery system that is meant to be inserted and pushed in place against the cervix to minimize expulsion and optimize physical comfort, but can function as a drug delivery system if it is located anywhere inside the vagina. Consequently, there is no incorrect position or placement where the ring is less effective for HIV prevention. Nevertheless, suggestions to insert the ring against the cervix to minimize the chance of the ring disrupting sex, and to minimize perceptions of incorrect ring insertion could be incorporated into provider-initiated counseling for women or couples, and incorporated into informational materials. The use of over-the-counter sexual lubricants with the ring, although not likely to be available in African public health settings, could facilitate insertion and obscure the feeling of the ring.

The fact that men reported that feeling the ring dissipated with time is an interesting finding, which could have several explanations. One is that the couple became more familiar with the ring being part of their sexual experience, and men no longer noticed it during sex. Another is that women became more experienced with inserting or pushing the ring higher up inside their vaginas. Women may have been nervous about how the ring would change the feeling of sex for their partners or themselves. After a few intercourse experiences with the ring in situ, women were perhaps able to relax and enjoy sex more, and/or they were more readily

able to be aroused and naturally lubricated. As one participant noted, his partner enjoyed sex more with the ring because she felt protected. The finding that the ring did not impact negatively on sex for most male participants has important implications. Programmatic and regulatory gatekeepers, community members, potential ring users and others may carry this concern, and these data offer some firsthand accounts that sex disruption was an insignificant concern.

Women who were non-adherent to ring use in previous trials have described removing the ring during sex for the purpose of hiding its use from their male partners, and from avoiding its potential impact on his or her sexual pleasure. [6, 8, 9] Removing the ring prior to sex – the very point at which exposure to HIV may be the highest – is concerning. However, the terminal half-life of dapivirine is estimated to be 72–73 h in plasma and 15–17 h in vaginal fluid [10], and it is unclear whether ring removal for a short period of time has any impact on protection. More research on the pharmacokinetics of dapivirine is needed, as are evidence-based strategies for accurately and effectively communicating messages about safe intermittent ring use.

Although seemingly hyperbolic in description (e.g. imagined snakes or potions), it is understandable that men described initial fears about finding something foreign or unfamiliar inside their partner's vagina - a part of her body he had presumably encountered many times without such unexpected discoveries. The intravaginal placement of objects is not standard, and there are few medicines in sub-Saharan Africa that are distributed through a vaginal drug delivery platform (e.g. vaginal gel, tablet, ring or film). These research sites are within communities that are steeped in traditional medicine culture, with beliefs about witchcraft and/or Satanism as it relates to vaginal practices and sex [11, 12]. Importantly however, several of the male partner quotations about discovering the ring and attitudes towards the ring suggest underlying themes of gender power dynamics and sexual control that may be more salient than tradition or witchcraft. The ring was described as strong and powerful, scary, something that could defy a penile erection, and men cautioned that if women did not disclose using this device, it could cause distrust and arguments in a relationship. The ability for women to use rings autonomously, and to potentially use them without being discovered, enhances women's sexuality and power, and may be perceived to diminish that of male partners.

Nevertheless, male partners in this study expressed an overarching endorsement of the ring, for a wide range of reasons, which is encouraging for future ring use, and suggestive of a few topic areas where marketing or messaging of rings could be effective. Men appreciated that if a woman has a ring she is protected from HIV (a benefit to her and a proxy benefit to him), and that if they want to have sex at any time, she is ready and he does not need to fumble around looking for a condom. Similarly, he does not need to debate about condom use with his partner. In a generation of men who have spent their reproductive lives within an HIV epidemic environment, this offers a welcome change to HIV prevention. Other men highlighted the value of the ring to not change, and to potentially improve, the sexual experience. That said, the dapivirine rings do not confer full protection from HIV, and do not protect against pregnancy or other STIs. Many male partner comments about the ring presumed it would be used during sex without a condom, therefore it is important that

condom use is discussed with ring use. Rings should not be promoted as a replacement to condoms, but rather as a method to be used with condoms, or in situations where condoms will not be used.

Finally, male partners considered their engagement in ring use important and integral to women's successful ring use. This is consistent with other microbicide studies, where men frequently express the desire to be included in research and use of novel HIV prevention products [13–17]. Numerous studies have aimed to include men by inviting them to the clinic and hosting events such as meetings and workshops; however male attendance has historically been poor [14, 18, 19]. Indeed, we had low numbers of male attendees at several FGDs and were unable to recruit a second group at one site. Consequently, there is clearly a gap between attitude and action, suggesting that a change in the scope of strategies to effectively engage male partners is needed.

There are some potential limitations to the findings in this paper that readers should consider. First, male partners that came to these FGDs may not have been representative of other male partners in the study, nor of other men in their communities in important ways. Many HOPE participants, particularly those at the South African sites, did not give permission to contact their male partners for research activities therefore the male partners enrolled here were all in relationships with women who felt they might be suitable for participation. Women who had not disclosed study participation or ring use, and those who were in casual or unstable relationships, or who were not in relationships, might not have granted permission. Women with violent or emotionally abusive partners, or partners who resisted the ring, might not have granted permission for study staff to contact their partners. Cultural differences and country-specific gender roles could have impacted the discrepancy between participants granting contact permissions in non-South African vs. South African settings, although few country differences were evident in the results. Furthermore, the male partners who agreed to participate in the study may have been more likely to favor the ring or research. Due to FGD scheduling, they also may have differed in employment status from other male partners. Finally, there may have been social desirability bias in male partner's responses pertaining to feeling the ring during sex. For example, male partners may have wanted to report experiences of feeling the ring if others did so, and there may have been a perception that feeling the ring was associated with having a bigger penis. Similarly, although many male partners in this study were forthcoming and lively discussants, in a FGD context it may have been difficult for some male partners to report their sexual experiences for a variety of reasons including shyness, dominating speakers, privacy, desires to fit in with the group, wanting to appear well-informed, or other reasons.

In conclusion, this study found that male partners of women using the dapivirine vaginal ring sometimes noticed the ring during sex, particularly during ring initiation stages, but this led to few sexual problems or changes. Nevertheless, the risk of ring discovery should be discussed with women to mitigate any potential negative reactions or social harm. Ideally delivery settings will have capacity to offer couples counseling. Nondisclosure of ring use to male partners led to relationship distrust, suspicions of witchcraft and penile dysfunction. Male partners felt they have an important role in HIV prevention decision-making, and that their engagement could help support and promote the benefits of ring use to other men.

Acknowledgments

Funding The study was designed and implemented by the Microbicide Trials Network (MTN) funded by the National Institute of Allergy and Infectious Diseases through individual grants (UM1AI068633, UM1AI068615 and UM1AI106707), with co-funding from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the National Institute of Mental Health, all components of the U.S. National Institutes of Health (NIH). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIH.

References

- Nel A, van Niekerk N, Kapiga S, Bekker LG, Gama C, Gill K, et al. Safety and efficacy of a dapivirine vaginal ring for HIV prevention in women. N Engl J Med. 2016;375(22):2133–43. [PubMed: 27959766]
- Baeten JM, Palanee-Phillips T, Brown ER, Schwartz K, Soto-Torres LE, Govender V, et al. Use of a vaginal ring containing dapivirine for HIV-1 prevention in women. N Engl J Med. 2016;375(22):2121–31. [PubMed: 26900902]
- 3. Brown ER, Hendrix CW, van der Straten A, Kiweewa FM, Mgodi NM, Palanee-Philips T, Marzinke MA, Bekker LG, Soto-Torres L, Hillier SL, Baeten JM; MTN-020/ASPIRE Study Team. Greater dapivirinerelease from the dapivirine vaginal ring is correlated with lower risk of HIV-1 acquisition: a secondary analysis from a randomized, placebo-controlled trial.J Int AIDS Soc. 2020;23(11):e25634. 10.1002/jia2.25634 [PubMed: 33206462]
- 4. Baeten TP-PJ, Mgodi N, Ramjee G, Gati B, Mhlang F, Hunidzarira P, Mansoor L, Siva S, Govender V, Makanani B, Naidoo L, Singh N, Nair G, Chinula L, Mayo A, Szydlo D, Soto-Torres L, Nell A, Rosenberg Z, Hillier S, Brown E 2019 MTN-025/HOPE study team. High adherence and sustained impact on HIV-1 incidence: final results of an open-label extension trial of the dapivirine vaginal ring. IAS 2019; Mexico City, Mexico
- 5. Nel A 2019 Safety, adherence and HIV-1 seroconversion in DREAM-an open-label dapivirine vaginal ring trial [Abstract]. 9th SAAIDS Conference, Durban, South Africa
- Montgomery ET, Stadler J, Naidoo S, Katz A, Laborde N, Garcia M, et al. Reasons for nonadherence to the dapivirine vaginal ring: results of the MTN-032/AHA study. Aids. 2018. 10.1097/ QAD.00000000001868.
- Montgomery ET, van der Straten A, Cheng H, Wegner L, Masenga G, von Mollendorf C, et al. Vaginal ring adherence in sub-Saharan Africa: expulsion, removal, and perfect use. AIDS Behav. 2012;7:1787–98.
- Montgomery ET, van der Straten A, Chitukuta M, Reddy K, Woeber K, Atujuna M, et al. Acceptability and use of a dapivirine vaginal ring in a phase III trial. AIDS. 2017;31(8):1159–67. [PubMed: 28441175]
- Laborde ND, Pleasants E, Reddy K, Atujuna M, Nakyanzi T, Chitukuta M, et al. Impact of the dapivirine vaginal ring on sexual experiences and intimate partnerships of women in an HIV prevention clinical trial: managing ring detection and hot sex. AIDS Behav. 2017;22(2):437–46.
- 10. Drug database: Dapivirine health professional version 2020. Available from: https:// clinicalinfo.hiv.gov/drugs/dapivirine/health-professional.
- Chitukuta M, Duby Z, Katz A, Nakyanzi T, Reddy K, Palanee-Phillips T, et al. Negative rumours about a vaginal ring for HIV-1 prevention in sub-Saharan Africa. Cult Health Sex. 2019;21(11):1– 16. [PubMed: 29658825]
- Duby Z, Mensch B, Hartmann M, Montgomery E, Mahaka I, Bekker L-G, et al. Achieving the optimal vaginal state: using vaginal products and study gels in Uganda, Zimbabwe, and South Africa. Int J Sex Health. 2017;29(3):247–57. [PubMed: 30519370]
- Montgomery ET, van der Straten A, Chidanyika A, Chipato T, Jaffar S, Padian N. The importance of male partner involvement for women's acceptability and adherence to female-initiated HIV prevention methods in Zimbabwe. AIDS Behav. 2011;15(5):959–69. [PubMed: 20844946]
- 14. Montgomery ET, van der Straten A, Stadler J, Hartmann M, Magazi B, Mathebula F, et al. Male partner influence on women's HIV prevention trial participation and use of pre-exposure

prophylaxis: the importance of "Understanding." AIDS Behav. 2015;19(5):784–93. [PubMed: 25416076]

- Mngadi KT, Maarschalk S, Grobler AC, Mansoor LE, Frohlich JA, Madlala B, et al. Disclosure of microbicide gel use to sexual partners: influence on adherence in the CAPRISA 004 trial. AIDS Behav. 2014;18(5):849–54. [PubMed: 24633715]
- 16. Venables E, Stadler J. 'The study has taught me to be supportive of her': empowering women and involving men in microbicide research. Cult Health Sex. 2012;14(2):181–94. [PubMed: 22085043]
- Montgomery CM, Lees S, Stadler J, Morar NS, Ssali A, Mwanza B, et al. The role of partnership dynamics in determining the acceptability of condoms and microbicides. AIDS Care. 2008;20(6):733–40. [PubMed: 18576176]
- Montgomery ET, van der Straten A, Chidanyika A, Chipato T, Jaffar S, Padian N 2010 The importance of male partner involvement for women's acceptability and adherence to femaleinitiated HIV prevention methods in Zimbabwe. AIDS Behav. 15:959–69. Available from: http:// www.springerlink.com/content/y88454311504j172/.
- Roberts ST, Nair G, Baeten JM, Palanee Philips T, Schwartz K, Reddy K, et al. Impact of male partner involvement on women's adherence to the dapivirine vaginal ring during a phase III HIV prevention trial. AIDS Behav. 2019;24(5):1432–42.



Fig. 1.

Image of models provided during interviews to facilitate descriptions of how the ring felt during sex: "vulva puppet"¹ and penis model

Author Manuscript

Author Manuscript

Table 1

.

Author Manuscript

Montgomery et al.

Characteristics of the study population

	All sites $n = 54$
Site name and location	
WRHI – Johannesburg, South Africa	4 (7.4%)
CAPRISA – Durban, South Africa	7 (13.0%)
MRC – Durban, South Africa	11 (20.4%)
MU-JHU – Kampala, Uganda	8 (14.8%)
Zengeza – Harare, Zimbabwe	13 (24.1%)
UNC – Lilongwe, Malawi	11 (20.4%)
Age-mean (median, min-max)	37.5 (36,21–61)
How many children fathered-mean (median, min-max)	3.3 (3,0–14)
Highest level of education	
Primary school, not complete	10~(18.5%)
Primary school complete	23 (42.6%)
Secondary school complete	16 (29.6%)
College/university complete	5 (9.3%)
Earn income	
Formal employment	24 (44.4%)
Self employed	19 (35.2%)
Owns a mobile phone	50 (92.6%)
Relationship status	
Currently married	33 (61.1%)
Not married, cohabiting	5 (9.3%)
Not married	16 (29.6%)
Has a primary sex partner	54 (100.0%)
Same partner from HOPE	53 (98.1%)
Living with partner	37 (68.5%)
Partner provides you with financial/material support	35 (67.3%)
Is circumcised	28 (51.9%)
HIV status	

Author Manuscript

Author Manuscript

	All sites n = 54
HIV negative	45 (83.3%)
HIV positive	3 (5.6%)
Unknown	6 (11.1%)
Lifetime number of sex partners - mean (median, min - max)	9.5 (5,2–60)
Number of vaginal sex acts, past 7 days - mean (median, min - max)	3.0 (2,0–14)
Worried about getting HIV in the next 12 months	
Not worried at all	29 (56.9%)
A little/somewhat worried	17 (33.3%)
Very/extremely worried	5 (9.8%)
Would support your partner using a vaginal ring in future	52 (96.3%)

Montgomery et al.

Table 2

Description of male FGD and IDI sample

FGD number	Location	n	Reported feeling the ring -n
1	MRC Durban, South Africa	5	0
2	MRC Durban, South Africa	6	0
1	Johannesburg, South Africa	3	3
NA -IDI	Johannesburg, South Africa	1	0
1	CAPRISA Durban, South Africa	3	2
2	CAPRISA Durban, South Africa	4	4
1	Harare, Zimbabwe	8	1
2	Harare, Zimbabwe	5	3
1	Kampala, Uganda	4	2
2	Kampala, Uganda	4	3
1	Lilongwe, Malawi	5	2
2	Lilongwe, Malawi	6	2
TOTAL		54	22 (41%)

Author Manuscript

Illustrative quotes about preferences for the vaginal ring vs. male condoms during sex

It was a normal sex, the difference was that you are no longer using a condom because there is something that protects her.... Now you are hitting it meat to meat..... When there is a ring, there is this hope.... That she is protected when there is a ring this study helped us men because we are tired of using condoms. (Thulani, FGD 2, CAPRISA Durban, South Africa) Because it keeps her ready at any time ... let us say I get homy while we are in the kitchen, for me to go to the bedroom to get a condom from the shelf is too far do you understand. Let us say we are chilling in a park out there, or in that nice resort, the mood for sex arises, she is already prepared. Sex tends to just come randomly in a place you feel like we can do it two seconds or two minutes and you become okay... The advantage with the ring is that it gives you convenience. (King, FGD 2, Johannesburg, South Africa)

If you are drunk... And it happens that you are lazy to take the condom, but since she already has this thing [the ring] inside her its good, she is safe. ... We as men we sometimes are reluctant to use condoms but if the woman is always having the ring inside her... Then it is problem solved. (Khavava, FGD 1, CAPRISA Durban, South Africa)

When I look at it, the ring is perfect because it is "live" [natural sex without a barrier]. Condoms is like eating a sweet in its packaging as we always say. So, the ring allows for a live show [natural sex without a barrier]. (Mumu, FGD 1, Harare, Zimbabwe)

I am adding on what that gentleman has said. There are some who come and buy sex from sex workers. They tell them that they are to give them one hundred thousand shillings (100,000/ =) for unprotected sex. And if it is sex with a condom, they say they are to give them twenty thousand shillings (20,000/ =). Because the sex worker wants more money, she will tell him to give her the one hundred thousand shillings (100,000/ =) to it is set with a condom, they say they are to give them twenty thousand shillings (20,000/ =). Because the sex worker wants more money, she will tell him to give her the one hundred thousand shillings (100,000/ =) but if she has the ring, she will not get any problem. So, I conclude and say that the ring is good (Abdu, FGD 2, Kampala, Uganda)