Acceptability and Use of the Diaphragm and Replens® Lubricant Gel for HIV Prevention in Southern Africa

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Abstract The acceptability and use of the diaphragm and lubricant gel were assessed as part of a large randomized controlled trial to determine the effectiveness of the methods in women’s HIV acquisition. 2,452 intervention-arm women were enrolled at five Southern African clinics and followed quarterly for 12–24 months. Acceptability and use data were collected by face-to-face interviews at Month 3 and Exit. Participants were “very comfortable” with the physical mechanics of diaphragm use throughout the trial, and approval of the gel consistency, quantity and the applicator was high. At Exit, consistent disclosure of use (AOR 1.97, 95% CI: 1.10–3.55); an overall high diaphragm rating (AOR 1.84, 95% CI: 1.45–2.34) and perception of partner approval (AOR 1.75, 95% CI: 1.35–2.26) were the most significant acceptability factors independently associated with consistent use. Despite being female-initiated, disclosure of use to male partners and his perceived approval of the products were factors significantly associated with their consistent use.

Keywords Diaphragm · Lubricant gel · HIV prevention · Zimbabwe · South Africa · Acceptability · Product adherence

Background Globally the HIV epidemic continues to progress, with Southern Africa at the epicentre of the pandemic [1]. Within this region, women are more likely to be infected than men. Much of the escalated risk women face is attributed to their increased biological, socio-economic and cultural vulnerability to HIV infection [2–4]. In an attempt to address this gender imbalance, there are several ongoing investigations of female-initiated HIV prevention technologies, such as vaginal microbicides, cervical barriers, and combinations thereof. Female-initiated methods would offer women greater control over use, including undisclosed use, which may be important in relationships where women are unable to negotiate male condoms.

The Methods for Improving Reproductive Health in Africa (MIRA) study was a phase III randomized trial...
examining the effectiveness of the diaphragm, a non-contraceptive lubricant gel (Replens®) and condoms, compared to condoms alone in preventing HIV acquisition in Southern African women. As recently published, there was no additional protective benefit against HIV infection or cervical STIs, when the diaphragm and gel were provided in addition to condoms and a comprehensive HIV prevention package [5, 6]. A secondary objective of the trial was to assess the acceptability of the diaphragm and gel throughout the study period. As others have discussed, “acceptability” is a multi-dimensional concept which incorporates different meanings in different settings, and at different stages of a product lifecycle [7]. In MIRA, we focused on the clinical testing stage, and the broad domain of “acceptability” included an evaluation of user perspectives about the physical characteristics of product use (including comfort, ease of use, effect on sexual pleasure), as well as discrete use, female-initiation and partner support for use. This is the first large randomized study to examine the acceptability and use of the diaphragm and gel as a potential HIV/STI prevention method during 12–24 months of study participation.

Previous research on the diaphragm as a contraceptive has shown the device to be acceptable in several developing-country settings where historically it had not been widely available [8–10]. In a recent US contraceptive trial of the diaphragm, used with a contraceptive microbicide candidate or placebo, two-thirds of women reported strongly or somewhat liking the method [11]. In research settings where the diaphragm has been investigated as a potential HIV/STI prevention method, high user-acceptability has also been reported among diverse target groups, including reproductive health clinic attendees, sex-workers and “healthy” community-recruited women [12, 13]. Several studies in the developing world have also looked at acceptability of potential microbicidal gels, exploring issues regarding insertion, consistency, quantity, sexual pleasure and wetness among women and their male partners. Although the majority have reported the gels are acceptable, most of the studies have been small, short in duration, or have examined hypothetical acceptability [8, 9, 14–24].

Acceptability is presumed to be an important component of use, however, their relationship is inconsistent in the literature. A study in Zimbabwe preceding this trial reported an association between women’s diaphragm acceptability and consistent use, while another recent trial, also in Zimbabwe, reported that partner acceptability was independently associated with consistent diaphragm use, although women’s own diaphragm acceptability was not [21, 25]. Finally, a study of young women in the US that measured use under more “real life” conditions, acceptability of barrier methods was reported to be an unreliable predictor of future use [26].

This paper presents overall long-term acceptability of the diaphragm and gel, as well as acceptability of several specific attributes of their use as a potential HIV prevention method. We also examined whether these factors differed by time point, and which specific attributes of product acceptability were independently associated with consistent product use. The MIRA trial produced findings that would not warrant scale-up of the diaphragm and lubricant gel for HIV/STI prevention, but our results may have been different if use of the products had been higher [5]. Cervical barriers and microbicide gels are still under investigation for this indication, and acceptability and use results from MIRA are thus important to consider in this context.

Methods

Study Design and Participants

The MIRA trial enrolled 5,045 women HIV-negative, non-pregnant women at three sites in South Africa (2 clinics adjacent to Durban, 1 in Soweto) and Zimbabwe (2 clinics adjacent to Harare) between September 2003 and December 2006. Six participants were discontinued on the same date of randomization for not meeting inclusion criteria, or were later identified as under 18 and were excluded from the analysis dataset, resulting in an analytic sample of 5,039. Women were randomized in a 1:1 ratio to one of two study groups and received an Ortho All-Flex diaphragm, Replens® lubricant gel and male condoms (intervention group) or male condoms alone (control group). Participants were counseled to insert the diaphragm with one-applicator-full (2.5 g) in the dome at any time before sex; to insert an additional applicator-full of gel in the vagina at least 1 h prior to sex, to retain the products for at least 6 h post coitus, and to use all of their assigned study products for every act of sex. All women received a comprehensive package of voluntary counseling and testing for HIV, treatment for curable STIs, and intensive risk reduction counseling with health education. Participants were scheduled to attend a two-week post-enrollment visit and quarterly follow-up assessments that continued for 12–24 months, depending on the calendar date of their enrollment. Trial participants were recruited from family planning, well-baby and general health clinics, as well as through community outreach, local media and word-of-mouth (further detailed in: Padian et al. [5]). The MIRA study is registered with ClinicalTrials.gov (number NCT00121459).

This analysis focuses on the 2,521 women randomized to the intervention group. Acceptability of the intervention group products was assessed using an interviewer-
administered questionnaire delivered at the first quarterly follow-up visit (Month 3) and at the participant’s last visit (Exit). To understand if general or specific aspects of product acceptability changed with duration of use, we compared acceptability responses from Month 3 and Exit. The majority (2,485, 98.6%) of women had acceptability data from at least one time point. Eighteen participants were excluded from the analytic sample because they reported non-use of the diaphragm since the start of the study, and fifteen were excluded because they were late for their Month 3 Visit, and did not have an Exit visit. Of the 2,452 women remaining, 2,208 (88%), women had a Month 3 acceptability interview, 2,317 (92%) had an Exit acceptability interview, and 2,073 (85%) had data for both Month 3 and Exit. Because of the study’s staggered follow-up period, exit visits ranged in quarterly intervals from Month 12 to Month 24 (median Month 21). Thus for the exit visit data, 12% of responses were at Month 12, 16% each at Months 15 and 18, 14% at Month 21, and 42% at Month 24 (Fig. 1).

Measures

Product Acceptability

We measured participant’s general rating of the diaphragm and gel with the questions, “How would you rate the diaphragm overall?” and, “How would you rate the gel overall?” (strongly like vs. like/dislike/strongly dislike). We also focused on several specific aspects of acceptability that were relevant to use of the diaphragm and gel, and pertinent to use of female-initiated methods in general. These included women’s comfort inserting, removing, and wearing a device intravaginally (very comfortable vs. somewhat/not at all comfortable); comfort with the quantity and consistency of the gel (just right vs. not just right) and the insertion of an intravaginal applicator of gel (very comfortable vs. somewhat/not at all comfortable); effects on sexual pleasure and frequency (increased vs. no effect/decreased); use of the products continuously; use for dual protection (pregnancy/disease/both) and comparisons of the ease and preference for diaphragm vs. male condoms (prefer diaphragm vs. prefer condom/the same). We also assessed partner knowledge (he knew every time vs. <every time); and acceptance of product use (he strongly likes vs. all other responses) as well as decision-making regarding use (decided jointly/he decided/she decided).

Consistent Product Use

The outcome variable of consistent use of the combination product (diaphragm and gel) was derived from responses to two questions in the Acceptability questionnaire where exposure variables were also assessed. First we asked whether the diaphragm was ever used since the start of the study (yes/no). Those who answered affirmatively were then asked, “If there have been times during the study when you did not use the diaphragm and gel during vaginal sex, what was the most important reason?” From among nine responses, those who chose: “Not applicable, you used them for every sex act” were categorized as “consistent users” and all other responses as “inconsistent users.” Use of this “opt-in” technique which assumes participants had not been fully compliant with product use, has been shown to decrease social desirability bias in responses to sensitive behaviors [27]. Finally, the use data were collected in the same manner as the acceptability exposure variables, making associations easier to assess.

Potential Confounders

For the multivariate models evaluating the association between product acceptability and use, we considered a set...
of baseline socio-demographic (e.g. age, education, marital status), clinical (i.e. baseline STI) and risk perception (e.g. impression of partner’s fidelity) variables that could be associated with both acceptability and adherence and thus act as potential confounders. Those baseline characteristics that were associated in bivariate analysis at the $P \leq 0.20$ level, as well as age and site (irrespective of association level) were then included in multiple logistic regression models with the outcome of interest. Those potential confounders that remained significant at the $P \leq 0.20$ level were included in the final multivariate models.

Statistical Analysis

Measures of product acceptability were summarized for the two study time points (Month 3 and Exit) using descriptive frequencies. We ruled out multicollinearity in acceptability factors at each time by evaluating variance inflation factors and Spearman’s rank correlations. To examine the association between the specific aspects of acceptability and use, we constructed two multivariate logistic regression models, one for each time point of interest. Acceptability factors significant in bivariate analyses at the $P < 0.10$ level, and all potential confounders previously identified as significant in multivariate analysis (described above) were retained in the final models. Because of concerns that highly correlated variables were obstructing relationships with the outcome, we used a backwards selection procedure to determine the variables independently predictive of use. All data were analyzed using SAS, version 9.1.

Results

Table 1 displays the baseline characteristics of the MIRA intervention group sample. Over three-quarters (78.1%) of the participants were under 35; 59.4% were married and 67.9% report living together with their primary male partner. The majority reported two or more live births (58.1%). Less than half (44.8%) were high-school educated. Less than a quarter (23.2%) were formally employed; although many more (56.9%) report earning income in the past year. Fewer than half (42.9%) had running tap water inside of their homes. Approximately two-thirds of participants were using hormonal or longer-term contraceptives. Only one woman had previously used a diaphragm. Thirty percent of women reported that they knew or suspected their partner had another sexual partner in the past 3 months, and a further forty percent “didn’t know”. The subset of participants included in this analysis (92%) did not differ significantly on any variables examined for the entire intervention group (data not shown).

General Acceptability of Diaphragm and Gel

Overall, we found high reported acceptability of the diaphragm and gel at both the Month 3 and Exit visits (Table 2). Seventy-one percent of intervention group participants reported “strongly liking” the diaphragm at both time points, and the proportion of participants “strongly liking” the gel increased from 51.9% at Month 3 to 61.6% by Exit. At the end of the trial women were asked whether they would recommend the diaphragm and gel to a friend if they were shown to be effective in preventing HIV/STIs, and almost all (96.6%) responded affirmatively.

Physical Characteristics of Products and Their Use

At Month 3, the majority of participants reported feeling very comfortable inserting (88.9%), removing (90.1%), having the diaphragm in situ (88.2%), and retaining the diaphragm intravaginally for 6 h post-coitus (82.5%). Attitudes towards these components of use remained relatively constant or increased slightly between Month 3 and Exit (Table 2). Many felt that the quantity and consistency of the gel (83.6 and 89.2%, respectively) were “just right” at Month 3, and reported being very comfortable inserting the gel applicator (78.7%). Favorable attitudes towards these gel factors increased by Exit. A smaller proportion of women reported strongly liking the guideline to insert the gel within an hour of sex (41.8% at Month 3, 50.4% at Exit).

When asked to compare diaphragms to condoms, more women started out reporting that they preferred diaphragms to condoms (57.2%), and found them easier to use (55.1%). However, by exit, more women found them equivalent, or favored condoms.

Effect on Sex

An increased effect of the diaphragm and gel on sexual pleasure and frequency was minimal. Approximately one-third (33.1%) of participants at Month 3 reported that the diaphragm and gel increased their sexual pleasure, and 21.4% said it increased their sexual frequency. Both of these proportions declined by Exit to 23.5 and 16.6%, respectively.

Female-Initiation and Use Patterns

An important attribute of the diaphragm and gel is that it is female-initiated. Just under two-thirds of our study participants reported that they were the primary decision maker in the use of the products at both time points (59.7 and 63.2%, respectively: Table 2). While almost half of the women agreed at Month 3 that it was “very important” that
they could use the diaphragm and gel without their partners knowing, this proportion declined to 40.7% at Exit, and throughout the study period, the majority (range 70.5–71.8%) of participants disclosed use of the diaphragm to their partner(s) every time they had sex. The majority of women reported the perception that their partner felt use of the diaphragm was a good idea (71.0% at Month 3, 68.9% at Exit).

Participants were offered free hormonal contraceptives through the trial. Nonetheless, over half (53% at both time points) reported using the diaphragm for both disease and pregnancy prevention (although not necessarily their sole contraceptive method).

Association Between Product Acceptability and Use

At the Month 3 visit, 66.4% of women reported using the diaphragm and gel every time they had sex since the start of the study. This proportion decreased to 51.6% at Exit.

Several factors related to product acceptability were independently associated with consistent use of the device at both time points. At Month 3, women who “strongly

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Table 1 Baseline characteristics of MIRA intervention group participants, for the acceptability analysis sample (n = 2,452)

| Socio-demographic                        | n   | %    |
|------------------------------------------|-----|------|
| Age                                      |     |      |
| 24 years old or younger                  | 969 | 39.5 |
| 25–34 years old                         | 945 | 38.6 |
| 35 years old or older                   | 537 | 21.9 |
| Education                                |     |      |
| Less than high school education          | 1,352 | 55.2 |
| Marital status                           |     |      |
| Married                                  | 1,457 | 59.4 |
| Earned income in past year               |     |      |
| Yes                                      | 1,392 | 56.9 |
| Employed                                 |     |      |
| Employed                                 | 569 | 23.2 |
| Source of water                          |     |      |
| Tap water inside premises                | 1,050 | 42.9 |
| Tap water outside premises               | 956 | 39.1 |
| Well water                               | 365 | 14.9 |
| River/stream/rain water and other        | 77 | 3.2 |
| Site (main language used in trial)       |     |      |
| Harare, Zimbabwe (Shona)                 | 1,230 | 50.2 |
| Durban, South Africa (Zulu)              | 732 | 29.9 |
| Johannesburg, South Africa (Zulu, Sotho) | 490 | 19.9 |
| Parity                                   |     |      |
| 0 births                                 | 217 | 8.9 |
| 1 birth                                  | 811 | 33.1 |
| 2+ births                                | 1,424 | 58.1 |
| Current contraceptive use at screening   |     |      |
| Long term/user independent               | 736 | 30.0 |
| Pill                                     | 900 | 36.7 |
| Barrier                                  | 507 | 20.7 |
| Other/none                               | 309 | 12.6 |
| Ever used diaphragm                      | 2,451 | 99.9 |
| Sexual & risk behavior                   |     |      |
| Lifetime # of sexual partners, mean (range) | 2.2 (1–20) |
| Age at first sex, mean (range)           | 18 (10–29) |
| Number of sexual partners in the past 3 months |     |      |
| 0                                        | 152 | 6.2 |
| 1                                        | 2,094 | 85.6 |
| 2 or more                                | 201 | 8.2 |
| Know or suspect partner had other sexual partners in past 3 months |     |      |
| Yes                                      | 734 | 30.0 |
| No                                       | 723 | 29.6 |
| Don’t know                               | 990 | 40.5 |
| Baseline STI                             |     |      |
| Yes                                      | 377 | 15.4 |
| Baseline HSV-2                           |     |      |
| Yes                                      | 1,402 | 57.2 |
| Coital frequency                         |     |      |
| 3 times per week or less                 | 1,586 | 64.7 |
| High behavior risk                       |     |      |
| Yes                                      | 687 | 28.1 |
| High partner risk                        |     |      |
| Yes                                      | 1,679 | 68.6 |
liked” the diaphragm (AOR 1.69, 95% CI: 1.34–2.12), or reported that their partners reactions were favorable (AOR 1.59, 95% CI: 1.19–2.13), and those who made a joint decision with their partner to use the products (AOR: 1.53, 95% CI: 1.02–2.28) were more likely to consistently use the diaphragm and gel (Table 3). Women who felt the consistency of the gel was “just right” (AOR 1.54, 95% CI: 1.12–2.12), or that the diaphragm and gel increased sexual pleasure (1.36, 95% CI: 1.08–1.69), and those that preferred diaphragms to condoms (AOR 1.36, 95% CI: 1.11–1.67), were also more likely to consistently use (Table 3).

By Exit, several different characteristics of the diaphragm and gel emerged as independently associated with consistent use. The strongest association with consistent use occurred among those reporting that their partner knew about diaphragm use at every sex act (AOR: 1.97, 95% CI: 1.10–3.55). A somewhat complementary finding related to female-initiation and disclosure was that women who felt that it was “very important” to be able to use the products without the partner’s knowledge were less likely to consistently use them (AOR: 0.73, 95% CI: 0.60–0.89). Women’s own strong liking of the diaphragm, and the perception that her partner’s reactions were favorable remained independently associated with use (AOR 1.84, 95% CI: 1.45–2.34 and AOR 1.75, 95% CI: 1.35–2.26, respectively). Joint decision-making regarding diaphragm use also remained independently associated with use (AOR 1.52, 95% CI: 1.02–2.25). Those who were “very comfortable” waiting 6 h before removing the diaphragm were more likely to consistently use the diaphragm and gel.

### Table 2 Diaphragm and gel acceptability: overall and specific attributes at Month 3 and Exit

| Overall acceptability | Month 3 (n = 2,208) | Exit (n = 2,317) |
|-----------------------|--------------------|-----------------|
|                        | n   | %   | n   | %   |
| **Diaphragm**         |     |     |     |     |
| Strongly likes        | 1,583 | 71.7 | 1,646 | 71.1 |
| Likes                 | 577  | 26.1 | 574  | 24.8 |
| Dislikes/strongly dislikes | 48  | 2.2  | 95   | 4.1  |
| **Gel**               |     |     |     |     |
| Strongly likes        | 1,138 | 51.9 | 1,417 | 61.6 |
| Likes                 | 903  | 41.2 | 731  | 31.8 |
| Dislikes/strongly dislikes | 153 | 7.0  | 151  | 6.6  |
| **Would recommend to a friend if proven effective** | NA | NA | 2,263 | 96.6 |
| **Physical characteristics of products and use** |     |     |     |     |
| Very comfortable inserting diaphragm | 1,962 | 88.9 | 2,150 | 92.8 |
| Very comfortable removing diaphragm | 1,988 | 90.1 | 2,170 | 93.7 |
| Very comfortable waiting 6 h after sex before removing diaphragm | 1,821 | 82.5 | 1,906 | 82.3 |
| Very comfortable having diaphragm in situ | 1,946 | 88.2 | 2,103 | 90.8 |
| Very comfortable inserting gel applicator | 1,732 | 78.7 | 1,901 | 82.6 |
| Amount of gel is just right | 1,839 | 83.6 | 2,074 | 89.9 |
| Consistency of gel is just right | 1,961 | 89.2 | 2,183 | 94.7 |
| Strongly like inserting gel before sex | 918  | 41.8 | 1,162 | 50.4 |
| Prefers diaphragm to condoms | 1,262 | 57.2 | 943  | 40.7 |
| Thinks diaphragms easier to use than condoms | 1,215 | 55.1 | 880  | 38.0 |
| **Effect on sex**     |     |     |     |     |
| Diaphragm and gel increases sexual pleasure | 730  | 33.1 | 544  | 23.5 |
| Diaphragm and gel increases sexual frequency | 472  | 21.4 | 384  | 16.6 |
| **Female-initiation and use patterns** |     |     |     |     |
| Very important you can use diaphragm without partner knowing | 1,099 | 49.8 | 944  | 40.7 |
| Partner knew diaphragm in use every time | 1,584 | 71.8 | 1,633 | 70.5 |
| Partner thinks diaphragm is a good idea | 1,555 | 71.0 | 1,579 | 68.9 |
| She decides when to use diaphragm | 1,309 | 59.7 | 1,457 | 63.2 |
| Uses diaphragm for disease and pregnancy prevention | 1,177 | 53.4 | 1,240 | 53.6 |

*a Responses and proportions do not always correspond to full sample because of missing information"
(AOR 1.45, 95% CI: 1.12–1.88). Finally, while women who reported “strongly liking” condoms were more likely to consistently use the diaphragm and gel (AOR 1.31, 95% CI: 1.04–1.66), those who found diaphragms easier to use than condoms were also more likely to be consistent product users (AOR 1.23, 95% CI: 1.01–1.50).

**Discussion**

This study highlights several important findings that are relevant to the acceptability and introduction of novel female-initiated methods of HIV prevention. Diaphragms and gels for either contraceptive or disease prevention purposes were hardly known, available, or distributed prior to this study in these Southern African communities. Despite this fact, the majority of the study population found them easy and comfortable to insert, wear and remove over the entire study period, suggesting that women are receptive and capable of easily adopting new intravaginal technologies. The overall proportion of women strongly liking the diaphragm remained high (71%) over the 2 year study period, and improved over time for the gel. That said, fewer than 60% reported consistent use of the diaphragm throughout the course of the study, and while more than half the women preferred and found diaphragms easier to use than condoms in the early period, by Exit, more women found diaphragms and condoms equally preferable and equally easy to use. Since the acceptability of many specific attributes of the diaphragm and gel increased at Exit, the latter finding may be a result of successful condom counseling and condom use, rather than a decreased enthusiasm for the diaphragm and gel.

In this study, women’s report of strongly liking the diaphragm overall was associated with its consistent use in both the early and late time periods. This finding supports the association between acceptability and use, and corroborates findings reported from two smaller and shorter duration cervical barrier studies in Zimbabwe [21, 25]. Insofar as acceptability is linked to product use and ultimately effectiveness, and keeping into consideration that an important component of acceptability may be duration of use, there is a continued need for formative and ongoing evaluation of product acceptability in the pre-clinical, clinical testing and in roll-out/marketing stages of the development of other new female-initiated HIV prevention methods. Further it is important to consider that consistent use may not be associated with acceptability of each individual attribute of a given product, for example one may not like the feel or required negotiation of male condoms, but may use them because of their protective effect.

Several measures of male partner attitudes, support and communication between couples were also identified in

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**Table 3** Multivariate logistic regression model for the association between acceptability and consistent use of the diaphragm and gel at month 3 and exit*

|                        | Month 3 (n = 2,145)** | Exit (n = 2,247)** |
|------------------------|-----------------------|--------------------|
|                        | AOR       | 95% CI   | AOR       | 95% CI   |
| Physical characteristics of products and use |          |          |          |          |
| Very comfortable waiting 6 h after sex before removing diaphragm | NA       |          | 1.45     | 1.12–1.88 |
| Prefers diaphragm to condoms | 1.36     | 1.11–1.67 | NA       |          |
| Thinks diaphragms are easier to use than condoms | NA       |          | 1.23     | 1.01–1.50 |
| Strongly likes diaphragm overall | 1.69     | 1.34–2.12 | 1.84     | 1.45–2.34 |
| Diaphragm and gel increases sexual pleasure | 1.36     | 1.08–1.69 | NA       |          |
| Consistency of gel is just right | 1.54     | 1.12–2.12 | NA       |          |
| Strongly likes male condoms | NA       |          | 1.31     | 1.04–1.66 |
| Female-initiation and use patterns |          |          |          |          |
| Thinks it very important diaphragm can be used without partner’s knowledge | NA       |          | 0.73     | 0.60–0.89 |
| Partner knew diaphragm in use every time | NS       |          | 1.97     | 1.10–3.55 |
| Partner’s general reactions to using diaphragm good (vs. neutral or bad) | 1.59     | 1.19–2.13 | 1.75     | 1.35–2.26 |
| Both partners have final word on diaphragm use (vs. HE does alone) | 1.53     | 1.02–2.28 | NS       |          |
| Both partners have final word on diaphragm use (vs. SHE does alone) | NS       |          | 1.52     | 1.02–2.25 |

* Only acceptability factors significant at the p < 0.05 level presented. NA = variable not included in final model; NS = variable included in final model but not significant

** Also controlling for: site, age, source of water in the home, education, knowledge of other partners

*** Also controlling for: site, age, source of water in the home, education, contraceptive use, parity, number of sexual partners in the last 3 months
this study to be associated with consistent use. This underscores several opinion articles and evidence from other studies that even with female-initiated HIV prevention methods, the role of the male partner is critical for women’s uptake and continuous use [28]. Here, women’s perceptions that their male partner supported use of the study products was associated with consistent use at both time periods, as has been reported in other studies [21, 25]. Three indicators of couples communication measured in this study suggest important relationships with use: joint decision-making and full disclosure of product use were associated with consistent use, while valuing the importance of clandestine use was associated with inconsistent use. Thus, efforts to gain male partner support for study product use may improve adherence in similar trials of female-initiated methods. This might be accomplished through early involvement of male partners in trial enrollment procedures and product counseling. More research into the identification of innovative strategies for including male partners while still ensuring women’s autonomy is needed, and female trial participants may help inform this research.

One strategy for enlisting greater male partner support and potentially improving adherence to female-initiated methods might be to emphasize ways in which study products might enhance sexual pleasure. At Month 3, women who felt the diaphragm and gel made sex more pleasurable were more likely to be consistent users, although by the Exit Visit, this was no longer independently associated with use. The benefit of eroticizing disease prevention methods, or highlighting their potentially pleasurable attributes has been discussed by others, but perhaps still needs more emphasis in individual or couples-based counseling [7, 29, 30].

While the relationship and contextual dynamics regarding the use of intravaginal devices and gels are essential components of women’s acceptability, as many have argued [28, 31, 32], it is also important to continue to measure basic attitudes towards the physical properties of investigational products, even well past their developmental stage in phase III clinical trials. As described above, women in this study were very comfortable using the diaphragm and gel, and in particular, those who were “very comfortable” wearing the diaphragm for 6 h post-coitus were more likely to consistently use the products. This finding has implications for use of other female-initiated methods in coitally-dependent and continuous use regimens. A study in Madagascar has reported that continuous use of the diaphragm was acceptable in a sex worker population [16], and a safety and acceptability study comparing continuous use vs. pre-coital use of a diaphragm-like device (Duet®) for 14-days in a general population will further address these issues [33]. In the MIRA trial, participants were advised to use the diaphragm, gel and condoms for every act of sex. Nonetheless, substitution of products (i.e. use of the diaphragm and gel instead of condoms or vice versa) was a concern, which we explored in separate quantitative and qualitative analyses. In the former, 83.1% of women reported use of the diaphragm instead of condoms at least some of the time [34]. In this study, at Exit, both women who reported an overall “strong liking” of the diaphragm and gel and those reporting the same for male condoms were more likely to be consistent diaphragm and gel users, suggesting that a strong liking of male condoms does not necessarily preclude consistent diaphragm and gel use.

There are several potential limitations to this study. First, the measures of acceptability and adherence relied on self-report of participants’ attitudes and behaviors that may have been subject to social desirability and recall bias. This limitation is true of most studies of this nature, and underscores the need for better measures (including biomarkers) and techniques for eliciting honest reporting. Participants who were lost-to-follow-up did not receive an Exit acceptability assessment and may have missed a Month 3 assessment; and these participants may have been less likely to like the study products. We chose an outcome measure for consistent product use from the acceptability form that may have been less reliable than the Computer-based self-administered (ACASI) variables, however, we confirmed that the overall rate of consistent use reported by FTAFI was congruent and virtually identical with our ACASI data which collected consistent use in the past 3 months [5, 35].

In summary, we found high acceptability of a combination method as a potential HIV/STIs preventative in the MIRA trial. The overall rating of the diaphragm remained consistently high and that of gel increased with time. However, attitudes towards several specific attributes of the products changed with time, and in both directions. It is important for trials of female-initiated methods, particularly those with longer follow-up periods, to conduct multiple assessments of product acceptability, as some attitudes may change with sustained use. It is also important to measure several different aspects of investigational products (physical attributes, effect on sex, partner’s support, etc.) to understand the relative importance of each within the context of a given population, and over time, and this will be particularly important as products transition from clinical studies to the general public. Despite high levels of reported acceptability, the proportion of women that reported consistent use was only moderate (~50% at Exit). As a recent modeling paper highlighted, these suboptimal levels of adherence, as we observed in the MIRA trial, would dramatically decrease the measured efficacy of an intervention, thus eliminating the power of the study to

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detect an effect, if true biological efficacy existed [36]. This underscores the importance of understanding factors that promote or discourage consistent use. Here, several acceptability factors were independently associated with consistent use, most notably, partner approval/liking of the study products and open disclosure and joint decision-making around use. Thus, our results suggest that even though the diaphragm and gel are female-initiated, the role of the male partner is critical for product acceptance and use among women in stable partnerships participating in a clinical trial. Future studies of this nature might consider strategies to more actively engage male partners as a way to optimize product adherence. Nonetheless, women’s control over use of these products remains important: if female-initiated methods are proven effective and become widely available, women- and particularly select sub-populations such as unmarried women, those with casual or multiple partners or sex workers- might need or want to use them more autonomously than was observed in this study.

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