

The Acceptability of the Female and Male Condom: A Randomized Crossover Trial

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CONTEXT: Although studies have assessed the acceptability of male and female condoms, comparative trial data are lacking.

METHODS: A sample of 108 women in stable relationships recruited from an urban, reproductive health clinic were randomly assigned to use 10 male or female condoms, followed by use of 10 of the other type. A nurse provided instruction in correct method use. Demographic information was collected in a baseline questionnaire; acceptability data were collected in follow-up and exit questionnaires and coital logs. Nonparametric and chi-square statistics were used to analyze measures of the methods' relative acceptability. Bowker's test of symmetry was adapted to test the null hypothesis of no difference in acceptability between condom types.

RESULTS: Participants used 678 female and 700 male condoms. Although neither method scored high on user satisfaction measures, the 63 women completing the study protocol preferred the male condom to the female condom for ease of application or insertion, ease of removal, general fit, feel of the condom during intercourse and ease of penetration. Participants reported that their partner also favored the male condom, although women generally appeared to like this method more than their partner did. In a direct comparison between the methods at the end of the study, women generally judged male condoms superior on specified preference criteria.

CONCLUSIONS: Across a range of criteria, the female condom was less acceptable than the male condom to most women and their partners. Although both types had low acceptability, they are needed and valid methods of pregnancy and disease prevention. That neither rated high on user satisfaction measures underscores the need for more barrier methods that women and men can use.

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Correct and consistent use of male latex condoms reduces the risk of pregnancy, HIV infection and some other sexually transmitted diseases (STDs).¹ Nevertheless, many men refuse to use them, perhaps because they do not find them acceptable or convenient. The female condom has been marketed as an alternative barrier method, and it appears to provide adequate protection against pregnancy² and STDs.³ Although the acceptability of the female condom has been confirmed in many settings,⁴ few studies have evaluated acceptability beyond the first few uses,⁵ and none have compared the method's acceptability with that of the male latex condom among couples who have used both products.

We report results from a randomized crossover trial comparing the acceptability of the male and female condom among a group of female clinic patients and their male partners.

METHODS

Participants and Design

The study was conducted between January 2000 and July 2001 at an urban, outpatient reproductive health clinic in Birmingham, Alabama. Potential participants were recruited through flyers posted in the clinic and elsewhere in the surrounding vicinity. Women were eligible if they were aged

19 or older, were in a monogamous partnership of at least six months' duration, had engaged in four or more acts of sexual intercourse in the past 30 days, had had no STDs in the past six months and reported having no latex allergy.

After providing written, informed consent, each participant was given a study number. An investigator then consulted a predetermined randomization list and informed the participant of her assignment to begin the study using either the female or the male condom. (Given the obvious differences between the two condom types, blinding of participants and investigators was infeasible.) The random assignments had been computer-generated through a two-stage design that ensured a balanced allocation of participants in 2–6-person blocks.

Each participant completed a questionnaire to provide information on her and her partner's baseline demographic characteristics and sexual and reproductive history. Each participant was also given 10 condoms of whichever type she was assigned to use first and was asked to use them within eight weeks. A trained nurse instructed her in the correct use of the method. For the female condom, counseling was more intensive than that for the male condom, and the woman practiced insertion and removal with a plastic model of the female pelvis. Each participant also was

given brief questionnaires (coital logs) and instructed to complete one after each condom use, describing any problems that she or her partner encountered during intercourse. Participants were instructed to place their used condoms in ziplock bags within a sealed manila envelope, and to return these to one of two designated drop boxes at or near the clinic.

After using the 10 assigned condoms, each participant returned for a follow-up visit, at which she answered a questionnaire. Items with Likert-type scales asked the participant about the condom's ease of insertion or application and its ease of removal (scales for both items ranged from one, denoting very easy, to four, for very difficult), the general fit of the condom and the feel of the condom during sex (score options for both were one, designating very easy; two, good; three, average; four, below average; five, poor), and whether the condom made penetration easier or harder for her partner (one, representing easier; two, no change; three, harder). Dichotomous questions asked whether the participant and her partner had ever experienced pain during sex because of the condom, and whether she and her partner had ever experienced burning, itching or irritation when using the condom. In addition, the woman was asked whether she or her partner always, sometimes or never applied additional lubrication when using the condoms. Finally, the participant was asked how much she and her partner each liked using the condoms (response options were like a lot, like a little, doesn't matter, dislike a little, dislike a lot) and how sex with the condom felt compared with sex without a condom (a lot better, little better, no different, little worse, a lot worse).

On completion of the questionnaire, the participant received instruction and counseling in use of the other condom type, along with 10 such condoms. In addition, the participant's coital logs were reviewed briefly for completeness and logical consistency.

At a second follow-up visit, after testing of the second set of condoms was complete, women submitted their finished coital logs and filled out the same type of questionnaire used at the previous follow-up. Women also were asked to complete a final questionnaire that included a series of comparative questions about product characteristics and user satisfaction: For nine items, participants rated both condom types on a scale of one, meaning the male condom was much better than the female, to seven, meaning the female condom was much better than the male; a score of four denoted that both were equally good. This rating system had been tested and validated in a study assessing the safety and acceptability of a baggy latex male condom.⁶

Before data collection began, all study procedures, forms and questionnaires had been pilot-tested in a group of non-participants. Questionnaire items had most often been developed to reflect simple constructs and had been included for face validity. The institutional review boards of the University of Alabama at Birmingham and the U.S. Centers for Disease Control and Prevention approved the study.

Data Analysis

Univariate statistics and frequency distributions were used to describe the study group at baseline and to compare subgroups. In analyses involving items with Likert-type acceptability scales, we used nonparametric and chi-square statistics to compare responses about the female condom with those on the male condom. T-tests were used to assess differences in baseline characteristics (age, mean number of intercourse episodes in the past month and mean number of pregnancies) between all participants and those who completed the study protocol. In addition, we used Cochran-Mantel-Haenszel statistics to compare differences in participants' characteristics by race or ethnicity, marital status and relationship duration. Kappa statistics were used to evaluate the agreement between a woman's responses to the preference questions and the responses she gave for her partner. For scales measuring the relative acceptability of the two devices, Bowker's test of symmetry⁷ was adapted to test the null hypothesis that if the two condoms were equally acceptable, then scores equidistant from the neutral category were selected with the same frequency.

We used TeleForm and SAS software for data management, and SAS 8.2 for all data analyses.

RESULTS

Informed consent was obtained from 109 of 126 women who expressed interest in the study and who met the eligibility criteria. Of these, 108 women attended the initial study visit; 55 were randomly assigned to begin with the female condom and 53 with the male. Women randomly assigned to male condoms first were similar to those assigned to female condoms first with respect to all baseline variables (including those shown in Table 1, page 116).

The participants used a total of 1,378 condoms (700 male and 678 female). Among women who started with the female type, 33 completed use of the first set of condoms, and 30 completed use of all 20 condoms. Of those who started with the male condom, 36 completed use of the first set, and 33 completed use of all 20. In sum, 63 women (58%) completed the study protocol.

Among women randomly assigned to use female condoms first, the mean time to first follow-up was 62 days, and time to second follow-up was 49 days. Women who started with male condoms had average times of 49 and 47 days, respectively.

Characteristics of Participants

Participants' mean age was 33, one year younger than their partners'. They were mostly white (78%) and married or cohabiting (77%); more than half had been with their partner for more than four years (Table 1). On average, they reported 10 coital acts in the past month (not shown).

The birth control methods most commonly reported at baseline were barrier methods (33%), hormonal methods (26%) and sterilization (14%). Thirteen percent of women (including 10% who had had a hysterectomy) were using other methods, and 11% were using none. Most partici-

TABLE 1. Percentage distribution of all participants and of those who completed the study protocol in a trial comparing male and female condom acceptability, by selected characteristics at enrollment, Birmingham, Alabama, 2000–2001

Variable	All women (N=108)	Completers (N=63)
Race/ethnicity		
White	77.8	76.2
Black	21.3	22.2
Asian/Pacific Islander	0.9	1.6
Marital status		
Married/cohabiting	76.9	81.0
Single	21.3	17.5
Divorced	1.9	1.6
Relationship duration (yrs.)		
<1	8.3	3.2
1–4	34.3	34.9
5–9	30.6	30.2
10–14	13.9	15.9
≥15	13.0	15.9
Current method†		
Barrier		
Male condom	22.9	26.9
Spermicide	6.8	4.5
Diaphragm	3.4	3.0
Hormonal		
Pill	22.9	29.9
Injectable	3.4	1.5
Sterilization‡	14.4	11.9
Rhythm/withdrawal	2.5	1.5
Other§	12.7	11.9
None	11.0	9.0
Total	100.0	100.0

†Primary method at enrollment; women could report more than one. ‡Tubal ligation or vasectomy. §Mostly hysterectomy. Note: Percentages may not total 100.0% because of rounding.

pants (89%) had ever used a male condom with their current partner, and 30% had ever had one break; only 9% had ever used a female condom with their current partner, and only one woman had ever experienced female condom breakage (not shown). The characteristics of the 63 women who completed both study arms resembled closely those of all participants (Table 1); no statistically significant differences were found.

Of the 45 participants who did not complete the study protocol, 23 women (10 who started with the female condom and 13 with the male condom) returned no condoms. Another 12 did not complete the first set of male condoms, three completed the first set of male condoms but not the female condom set, four did not complete the first set of female condoms and three completed the first set of female condoms but not the male set. None of the social or demographic characteristics shown in Table 1 differed significantly between those who completed the study protocol and those who did not. Moreover, women not completing the study protocol were distributed about evenly between the two randomly assigned groups.

Reasons for noncompletion were collected from 41 women who could be traced. Ten of these women—five from each of the randomly assigned groups—cited dislike of condoms as their primary reason.

Measures of Acceptability at Follow-Up

Women judged application of the male condom to be easier than insertion of the female condom (mean score, 1.4 vs. 2.8—Table 2). In contrast, they viewed the female condom as being easier to remove than the male condom (1.4 vs. 1.7). General fit was, on average, considered better with the male condom than with the female condom (2.3 vs. 3.0).

Women rated the feel of the condom during intercourse to be better with the male condom than with the female condom; however, neither method scored very well (mean score, 2.7 vs. 3.7). Forty-eight percent of women stated that the male condom felt “good” or “very good” during sex, but 13% gave it a rating of “below average” or “poor.” By comparison, only 11% of women considered the feel of the female condom during intercourse “good” or “very good,” whereas 60% judged it to be “below average” or “poor” (not shown).

When asked whether the method made penetration easier or harder for their partner, women tended to give more favorable assessments to the male condom than the female, but again, neither condom scored well (mean score, 2.1 vs. 2.5). Indeed, only about one in 10 women reported that each condom type made penetration easier; one-third said the male condom, and almost two-thirds (65%) said the female condom, made it more difficult for their partner. The rest either thought it made no difference or were unsure. Additional lubrication was needed “sometimes” or “always” by 98% of women during female condom use but by only 60% during male condom use (p<.001).

Nearly half the women (48%) said they had ever felt pain or discomfort during intercourse with female condom use, compared with about one-fifth (19%) with male condom use (p<.001). In addition, 30% of women had ever felt burning, itching or irritation when using a female condom, and 17% had had such sensations when using a male condom; the difference was not significant. The proportions for women’s partners were lower than those for the participants but not inconsequential. Twenty-seven percent of women reported that their partner had ever had pain or discomfort during sex with female condom use, and 10% reported this for male condom use (p<.05). Partner experience of burning, itching or irritation was reported by 10% of women for female condom use and by 7% for male condom use (the difference was not significant).

TABLE 2. Mean scores (and standard deviations) for measures of condom acceptability among women completing the study protocol, by condom type

Measure (and scale range)	Male condom	Female condom
Ease of application/insertion (1–4)***	1.4 (0.6)	2.8 (0.8)
Ease of removal (1–4)*	1.7 (0.9)	1.4 (0.6)
General fit (1–5)***	2.3 (1.1)	3.0 (1.0)
Feel of condom during sex (1–5)***	2.7 (1.0)	3.7 (1.0)
Ease of penetration for partner (1–5)**†	2.1 (0.6)	2.5 (0.7)

*p<.05. **p<.01. ***p<.001. †Data missing on two women for male condom and one for female condom. Note: Lower scores represent more positive perceptions of the method (see Methods section, page 115).

TABLE 3. Percentage distribution of women completing the study protocol, by comparative rating of male and female condoms, according to method characteristic

Characteristic	Male much better	Male better	Male slightly better	Both equally good	Female slightly better	Female better	Female much better	Total
Easy to learn to use***	66.7	9.5	3.2	19.1	0.0	0.0	1.6	100.0
Easy to put on/insert***	71.4	15.9	6.4	4.8	0.0	0.0	1.6	100.0
Feels natural during sex***	38.1	19.1	7.9	19.1	3.2	4.8	7.9	100.0
Easy to keep on/in during sex***	46.0	15.9	9.5	23.8	0.0	1.6	3.2	100.0
Easy to remove*	23.8	6.4	6.4	49.2	3.2	6.4	4.8	100.0
Not messy***	41.3	14.3	9.5	28.6	4.8	0.0	1.6	100.0
Does not interrupt sex***	34.9	19.1	12.7	27.0	0.0	3.2	3.2	100.0
Makes sex enjoyable***	28.6	20.6	11.1	34.9	0.0	1.6	3.2	100.0
Feels good because it protects you**	19.1	12.7	6.4	54.0	1.6	3.2	3.2	100.0

*p<.05. **p<.01. ***p<.001. Note: P-values were derived from an adapted Bowker's test of the null hypothesis that ratings are symmetrically distributed around the neutral category ("both equally good").

Women's and Partners' Comparative Preferences

Most women (87%) and their partners (91%) disliked using the female condom; only 10% of women and 6% of men liked using it. By contrast, women lacked strong opinions on the male condom, but 64% said their partner disliked using it.

The vast majority of women reported that for themselves (91%) and for their partner (95%), sex felt "worse" or "a lot worse" with a female condom than with no condom. In addition, most women reported that they (62%) and their partner (78%) thought sex with a male condom felt at least somewhat worse than sex without a condom, including 19% and 35%, respectively, who found it "a lot worse."

The correlation between women's responses about their own preferences and those they provided about their partner's was poor to moderate (kappa, 0.3–0.5). Women systematically reported that their experience with using the male condom was more favorable than their partner's, but no clear pattern emerged for female condom use.

Direct Comparisons of the Methods

In general, women completing the study protocol judged male condoms to be better than female condoms (Table 3). The scores were highly skewed, indicating a clear preference between the methods, and all differences were statistically significant. For example, when asked which method was easier to learn to use and to apply, a majority (67% and 71%, respectively) said the male condom was much better than the female; and when asked which was easier to keep on during sex, nearly half (46%) said the male condom was much better. In addition, when asked which method was less messy and less interruptive during sex, the largest proportions (41% and 35%) rated the male condom much better than the female. At best, only a small proportion rated the female condom at all better: Sixteen percent thought the female condom felt more natural during sex, 14% considered it easier to remove and 8% believed it felt good because it protected them.

DISCUSSION

In this study, participants preferred the male condom to the female condom and were dissatisfied with multiple aspects of their experience using the female condom. The male

condom was rated better for ease of application and general fit. Moreover, participants' reports of their or their partner's experiencing discomfort or pain during sex were more common for female condom use than for male condom use. About nine out of 10 women reported that they or their partner disliked using the female condom and said that sex felt worse with it than without it. Women's report of their own objections to the male condom was less common than report of their partner's; however, levels of disapproval for this method were still high. When women's ratings at the end of the study on nine acceptability criteria were evaluated, the distribution was highly skewed in favor of male condom use.

In contrast to the women in several previous studies who appeared to find sex more enjoyable with the female condom than with the male condom,⁸ participants in this study reported that both methods diminished sexual sensitivity and pleasure, particularly the female condom. Previous research shows that although the female condom is difficult to use, counseling may help women to overcome initial problems and sustain consistent use of the method.⁹ In this study, however, women preferred the male condom because they considered it easier to use, despite receiving training and counseling in the proper use of the female condom. We do not believe that greater prior familiarity with the male condom than with the female condom explains this preference, because results for the women completing the study protocol were essentially unchanged when we performed additional analyses excluding the women whose primary contraceptive method at study entry was the male condom (not shown).

Many studies of short-term or hypothetical acceptability of the female condom have indicated high levels of acceptance,¹⁰ particularly among sex workers¹¹ and STD clinic patients.¹² Our study offers information on women attending reproductive health clinics, an important population to reach for condom promotion. Other research has indicated that even family planning clinic patients can be at high risk for STDs.¹³ Comparison of our results with those of other studies is challenging because of differences in questionnaires, study design, sampling population and selection criteria. The evidence from this randomized trial, which

compared the acceptability of female and male condoms to the same users, suggests that although the female condom is used and valued by some women and their partners, it is neither a popular option nor, in general, a substitute for the male condom. This assessment is consistent with findings of the few studies that have evaluated long-term use: All have shown that over time, use tends to be concentrated among a small minority of committed couples; however, these and other couples may also alternate between female condom use and male condom use, thereby likely increasing the overall proportion of protected coital acts.¹⁴

Our findings suggest that the female condom may not enjoy much acceptance for long-term use.

Our findings suggest that the female condom may not enjoy much acceptance for long-term use. Similarly, single women and married men with extramarital partners seemed to benefit most from the female condom's introduction in urban Zimbabwe.¹⁵ Women at high risk of STDs appear more likely to accept condoms and to continue using them than other women are, as has been shown in the United States,¹⁶ Zambia¹⁷ and Thailand.¹⁸ Targeting high-risk groups is a particularly cost-effective disease prevention strategy but may stigmatize condom use among persons in steady partnerships.

Several potential limitations need to be considered in interpreting the results of this study. First, 42% of enrolled participants did not complete the study protocol. Thus, attrition potentially threatens the validity of our observations. On the other hand, adherence to the protocol was remarkably high, given the demanding requirements made of participants. The two randomly allocated groups were well balanced and free of systematic differences. Similar acceptability measure used in the study questionnaires nearly always yielded consistent responses. Participants received standardized counseling (including careful instruction in female and male condom use), given in a neutral manner by a nurse to reduce the likelihood of response bias.

Second, participants were self-selected (as is common in clinical trials). They were mostly in long-term relationships, had low STD risk and had had more experience with the male condom than with the female condom (although previous experience with male condom use did not appear to influence our study findings). Thus, the experience and preferences of the study participants might approximate more closely those of the general population than those of high-risk women, who may be most in need of female condom use.

On the other hand, because we sought to compare women's experiences with using each condom type and to determine what factors might lead to preference of one over the other, the participants had to be willing to use both methods in equal measure. Thus, the study group may have systematically excluded low-risk women who had a clear bias against the female condom, and may give a somewhat optimistic view of the preferences of the general population. These concerns about the generalizability of our findings are mitigated by comparing our results with those of nonrandomized studies conducted among high-risk groups in Africa¹⁹ and the United States,²⁰ and among persons at

lower risk.²¹ Similarly, a randomized, community-level intervention trial conducted at Kenyan agricultural sites found that at 12 months—an even longer follow-up period than our study's—levels of consistent use among male condom users were about three times as high as those among female condom users.²² In these studies, women preferred the male condom over the female condom, and increasingly favored its use over time, despite their being potentially more in need of, and better disposed toward, the female condom; the results held even if the women had started out enthusiastic about the female condom and had received counseling and training in its correct use. A final limitation of our trial, shared by most investigations, is that the experience of using the female condom offered as part of a study may be different from that of users not participating in it, not least because women in the study received training in its use.

These limitations are offset by the considerable strengths of the study. First, the number of participants and number of condoms used were relatively large; in addition, the average duration of follow-up in our study was longer than those in most studies of condom acceptability. Second, our study collected information on men's reactions to each method (as reported by the participants); thus, partners' reactions and attitudes could be compared directly. Only a modest correlation was observed between women's preferences and those they reported for their partner; for items about the male condom, women's ratings were systematically higher than those for their partner.* Thus, participants tended to report real differences between their experiences and those of their partner.

Finally, the trial's randomized crossover design provides a robust framework for inference by comparing the acceptability of both methods to the same participants. Ultimately, scientific generalization relies more on the internal validity of a comparison than on the relation between the study group and any target population. Participants who completed the study protocol used the same number of both condom types. The randomly assigned groups were well balanced, and the proportions of women dropping out while using each condom type were similar. The crossover design allowed each woman to serve as her own control. The results consistently revealed a strong contrast in preferences between the two methods; most women clearly preferred the male condom after having used each method for some time. Large and statistically significant differences were identified across a range of acceptability criteria.

CONCLUSION

We found the acceptability of the female condom to be significantly lower than that of the male condom, although neither condom type scored high on user satisfaction measures. Participants also were more likely to report that their

*The pattern of discordance between a woman's response and her partner's was compatible with a random distribution for items pertaining to female condom preference, whereas it indicated that women systematically rated the male condom better than their partners did.

partner's level of condom acceptance, particularly for male condom use, was lower than their own. The fact that both the male and the female condom are deficient in the eyes of many potential users highlights the need for further research and development to improve contraceptive and prophylactic choices for women and men. Nevertheless, these results indicate that both the male and the female condom can win favor among committed users in relationships in which the risk of STDs is low. The female condom extends options for pregnancy and disease prevention, and offers a viable woman-initiated and potentially empowering complement to male condoms. Future modifications to the female condom may enhance its acceptability without compromising its effectiveness as a pregnancy or disease prevention method.

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