Female-Condom Use in a Gender-Specific Family Planning Clinic Trial

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Objectives. We evaluated female-condom use among women participating in an HIV/STD intervention designed to reduce unprotected sex and expand prevention strategies.

Methods. Women (n=360) were recruited from a family-planning clinic and were randomized into an 8- or 4-session intervention group or a control group. We conducted follow-up interviews at 1, 6, and 12 months.

Results. At 1 month, the odds ratios of first-time female-condom use were 9.49 (95% confidence interval [CI]=4.01, 22.20) in the 8-session group and 4.39 (95% CI=1.84, 10.49) in the 4-session group relative to controls. Repeated use (n=21) was predicted by perceived ability to use, by self and partner satisfaction, by dislike of male condoms, and by previous diaphragm use.

Conclusions. Gender sensitive cognitive-behavioral interventions can influence women to try the female condom. To increase long-term use, interventions may need to include self-insertion practice and involvement of male partners. (*Am J Public Health.* 2003; 93:1897–1903)

The female condom is an important addition to the arsenal of strategies for preventing sexually transmitted diseases (STDs) and unintended pregnancy. Its efficacy against pregnancy is estimated to be in the range of other barrier methods.[1,2] Laboratory studies demonstrate that it is a highly effective barrier against STD pathogens,[3] and 1 clinical trial has demonstrated its efficacy against trichomoniasis.[4] Three field studies provide evidence that its effectiveness in preventing STDs is probably comparable to that of the male condom.[5–7] In addition to expanding the range of contraceptive and disease prevention choices, the female condom may be a catalyst for women to engage in negotiations about safer sexual intercourse with their partners.[8,9] The female condom, therefore, may prove to be the first effective disease prevention method that can be initiated by women. It provides an option for those who are unable to convince their partners to use a male condom and for couples who dislike male condoms.

Findings from acceptability studies with diverse populations worldwide suggest that a substantial proportion of women find the female condom acceptable.[10,11] With few exceptions,[5–7,12–16] however, assessment of female-condom use has been short term, typically over a 1- to 3-month period. To design effective preventive interventions for women, long-term studies are needed to understand how best to introduce the female condom to both promote and sustain its use. Only long-term studies can determine whether offering the female condom in addition to the male condom decreases the number of unprotected sexual acts in the study population.

We present data on female-condom use during a 12-month follow-up period among women who participated in Project FIO (The Future Is Ours), a randomized trial of a gender-specific HIV/STD preventive intervention that was successful in reducing unprotected sex.[17] The principal outcome in Project FIO was a reduction in unprotected vaginal and anal intercourse, which was assessed postintervention by interviews at 1, 6, and 12 months. With a sample size of 360, the trial was projected to provide 80% power to detect a 0.45 standard deviation difference in the principal outcome. The main finding was that relative to control subjects, women assigned to the 8-session group were more likely to report maintaining consistent safer sexual intercourse practices or decreasing the number of sexual intercourse occasions not protected by a male or female condom at both the 1-month follow-up (odds ratio [OR]=1.93; 95% confidence interval [CI]=1.07, 3.48) and 12-month follow-up (OR=1.65; 95% CI=0.94, 2.90).

In this article, we examine the effects of the intervention on attitudes about and use of the female condom. Although the intervention focused on the male as well as the female condom, the data from this study allow us to address gaps in female-condom research. Specifically, we can examine the effects of the intervention over an extended period and those effects can inform us about women's use of the female condom in real-world contexts where, as in this intervention, a variety of protective strategies are available.

We address 4 questions: (1) Did the intervention promote positive attitudes toward the female condom, negotiation about its use, and actual use (a) in the short term (1 month) and (b) in the long term (6 months, 1 year)? (2) Did the addition of the female condom contribute to the previously reported reduction in unprotected sexual intercourse? (3) What were the initial reactions of women who used the female condom? (4) What were the predictors of (a) using the female condom for the first time and (b) repeated use (reporting use at more than 1 follow-up)?

METHODS

The trial, conducted between 1991 and 1997, is described fully elsewhere.[17] It comprised 8-session and 4-session group interventions that were compared with an assessment-only control group. The intervention sought to empower women by increasing their awareness of their sexual needs and rights, by considering their own and their partners' risk behaviors, and by becoming knowledgeable about and skilled in using a range of protective strategies, including the female condom.

Participants

Details of participant selection have been published elsewhere[17,18] and are briefly summarized here. Women (n=360) were recruited from the waiting room of a Planned Parenthood clinic in Brooklyn, NY. To be eligi-

ble for participation, women had to be clients of the clinic, be 18 to 30 years of age, possess a fluent comprehension of spoken English, report heterosexual activity within the previous year, have not received a blood transfusion from 1980 to 1985, report no illicit injected drug use in the past year, have unknown or negative HIV serostatus, and not be currently pregnant or trying to become pregnant.

At baseline, participants completed informed-consent forms, were assessed through individual semistructured interviews,[19] and then were randomized. Randomization was done in blocks of 18: 12 women were assigned to an intervention condition (predetermined for each block), and 6 were assigned to the control group. The order of the intervention conditions was determined by permuted block randomization and was unknown to any of the field staff. Within a given block, individuals were assigned to intervention or control by permuted block randomization with a 2-to-1 ratio. Interviewers were blind to participants' study condition.

The majority of participants were Black or African American (72%), and the mean age was 22 years. Most women (90%) had never married, 18% were currently living with a partner, and 42% had children. The median per capita income was $6057 ($1500–$84 000), with 26% of participants reporting an income below the poverty line. Forty-one percent of the women were currently employed, and 48% were in school.

A lifetime history of STDs was reported by 58% of the women, and 17% had been diagnosed with an STD in the past 3 months. Although 76% had had only 1 male sexual partner in the past 3 months, 41% of the participants reported knowing or suspecting that their partner had other partners since becoming involved with the participant, and 18% of the participants reported that their partners had had STD symptoms in the past 3 months. Consistent condom use was low (25%), although 75% reported some condom use in the past 3 months.

Measures

Study participants were asked about their number of sexual partners, their risk behaviors and those of their partners, their pregnancy history, and their use of various contraceptive methods. We elicited the number of vaginal- and anal-intercourse episodes separately for primary and for other partners, and we elicited the number of male- and female-condom–protected episodes. At the baseline interview, and at the second and third follow-up interviews, the recall period for current sexual behavior (sexual-behavior recall period) was the past 3 months. At the first follow-up interview, the sexual-behavior recall period was the past month in order to exclude the time during which the intervention was under way. For each sexual-behavior recall period, we calculated the number and the percentage of female-condom–protected vaginal-intercourse episodes.

We assessed beliefs about the efficacy of female and male condoms to prevent STDs and pregnancy with a 4-point scale (poor to excellent). Participants also were asked whether their overall impression of each method was positive, neutral, or negative. We assessed perceived ability to use the female condom by asking, "How sure are you that you would be able to use a female condom if you wanted to?" rated on a 6-point response scale (very unsure to very sure).

We used an open-response format when we asked the women whether they had discussed safer sexual intercourse with their primary partner since the last interview. Conversations with partners about female-condom use were credited in these analyses only if the woman had not reported talking about the female condom at baseline.

Participants were asked whether they had used the female condom for the first time since the last interview. For this variable, the recall period included the entire time since the previous interview in order to capture a behavior that could only occur once and that may have occurred while the intervention was under way.

Additional items were asked only of participants who had used the female condom for the first time. The women rated how difficult or easy it was to use and their satisfaction and that of their partner on a 4-point scale. Open-ended questions asked of first-time users included "What led to using the female condom for the first time?" and "What made it difficult (or easy) to use?"

The women who reported use of a female condom during a sexual-behavior recall period were asked whether they used the method primarily for prevention of pregnancy or HIV/STD and whether they planned to use the method again in the next 3 months (yes, no, not sure). Repeated female-condom use was defined as using a condom at least once during 2 or more sexual-behavior recall periods after the baseline interview.

Intervention

Details of intervention development and content are reported elsewhere.[20] Briefly, we modified the AIDS Risk Reduction Model (ARRM)[21] to make it gender specific, and we used this modification to guide the development of the intervention. Both the 8- and the 4-session interventions covered the same content areas and shared structure and sequence, with somewhat less role-playing and interactive activities in the 4-session intervention.

The female condom was first presented during the session titled "What's the Best Way to Protect Myself?" Participants had the opportunity to handle the female condom and to practice inserting it into a pelvic model. Advantages and potential difficulties of the female condom were discussed. The women were given 2 female condoms and were encouraged to try using them at home. During the following session, women discussed their experiences with the participants condom and how to overcome the difficulties of insertion and use. During subsequent sessions, the women enacted ways to introduce male and female condoms to new and established partners.

In addition to receiving female condoms when the condom was first introduced, intervention-group women could request female condoms at other sessions, and both intervention- and control-group women could request male and female condoms at each follow-up interview.

Statistical Analyses

We conducted analyses with intent-to-treat principles (i.e., according to the condition to which participants were randomized, regardless of the number of intervention sessions they attended). To assess intervention effects over time, we used linear regression for ordinal outcomes and logistic regression for dichotomous outcomes. We used a Poisson regression model to analyze the count data (number of female-condom–protected epi-

sodes) and a binomial logistic regression model to analyze the percentage data (percentage of female-condom–protected episodes). An overdispersion parameter was included in the latter 2 models to account for heterogeneity among the subjects. Generalized estimating equations (GEE) were used with these analyses to account for within-subject correlation.[22] Because the intervention was conducted in groups, the resultant intraclass correlation coefficient (ICC) was calculated; however, because it was negligible, we report results without this adjustment. We used ordinary univariate and multiple logistic regression to evaluate the predictors of first-time and repeated female-condom use.

RESULTS

Seventy-five percent (n=84) of women in the 8-session group (n=112) attended 1 or more intervention sessions where the female condom was presented, as did 66% (n=85) of the women in the 4-session group (n=128). Across all 3 conditions, 92% of women (n=331) returned for the 1-month follow-up interview, 90% (n=325) returned for the 6-month follow-up interview, and 97% (n=348) returned for the 12-month follow-up interview. One participant was excluded from all analyses because of unreliable female-condom data.

At baseline, only 14 of 359 study women (4%) had ever used a female condom, and 9 of those had used one at least once in the past 3 months (3% of 329 who engaged in vaginal intercourse). During the entire postintervention follow-up period, 109 women used the female condom for the first time (76, 17, and 16 at the first, second, and third follow-ups, respectively). During the 3 sexual-behavior recall periods, 72 women used the female condom—66 were first-time users, and 6 were previous users. The other 43 first-time users presumably used the female condom after the previous assessment but prior to the next sexual-behavior recall period. Duration of use was short: 71% of the 72 female-condom users reported use at only 1 follow-up interview, 23% reported use at 2 follow-up interviews, and 6% reported use at all 3 follow-up interviews. Only 21 women reported female-condom use at more than 1 follow-up interview. Female-condom use occurred predominantly with primary partners. Ninety-seven percent of women (70/72) reported having used the female condom with their primary partner, although eighty percent of the participants reported having only 1 partner at each follow-up interview.

Short-Term Effect of Intervention

At the 1-month follow-up, women in both intervention groups rated the female condom as more effective against STDs and pregnancy than did women in the control group. The GEE-estimated mean difference in the baseline to follow-up change in effectiveness ratings between the intervention and the control groups was 0.29 (95% CI=0.06, 0.53; $P<.02$) in the 8-session group and 0.33 (95% CI=0.09, 0.58; $P<.01$) in the 4-session group (not shown). For perceived efficacy to prevent pregnancy, this difference was 0.26 (95% CI=0.04, 0.48; $P<.02$) in the 8-session group and 0.25 (95% CI=0.01, 0.48; $P<.04$) in the 4-session group.

Women in the 8-session but not the 4-session group viewed the female condom more favorably at the 1-month follow-up than did women in the control group (8-session group: mean difference=0.28 [95% CI=0.04, 0.52], $P=.02$; 4-session group: mean difference=0.21 [95% CI=−0.02, 0.44], $P=.08$). There was no significant difference between groups in perceived ability to use the female condom. The odds of negotiating for the first time with a partner about female-condom use at the 1-month follow-up were 10 times greater for women in the 8-session group relative to those in the control group and almost 4 times greater for those in the 4-session group (Table 1).

The intervention had a significant short-term effect on use of the female condom for the first time since the baseline interview (Table 1). There were 76 first-time users at the 1-month follow-up, 69 of whom were in one of the intervention groups. Relative to the control group, the odds of first-time use were 9 times greater for women in the 8-session group and 4 times greater for those in the 4-session group.

First-time users in the intervention groups were more satisfied with the female condom than were those in the control group (69% in the 8-session group and 70% in the 4-session group were very or somewhat satisfied vs 33% in the control group; $\chi^2=13.78$; $df=6$; $P=.03$). There were no differences among the groups in reported ease of use or in partner satisfaction with the female condom (not shown).

During the sexual-behavior recall period at the 1-month follow-up, 24% of women in

TABLE 1—Effect of Intervention on Female-Condom Negotiation and First-Time Use Among 359 Family Planning Clients: Brooklyn, NY

	1 Month		6 Months		12 Months	
	N[a] (%)	OR (95% CI)[b]	N[a] (%)	OR (95% CI)[b]	N[a] (%)	OR (95% CI)[b]
Negotiation with partner about female condom[c]						
8-session group	80 (54)	10.28 (4.44, 23.81)	78 (22)	2.44 (1.01, 5.87)	87 (17)	3.56 (1.23, 10.18)
4-session group	89 (29)	3.86 (1.65, 9.03)	102 (20)	2.08 (0.89, 4.90)	99 (17)	3.67 (1.26, 10.7)
Control group	83 (10)	1.0	85 (11)	1.0	95 (5)	1.0
First-time female-condom use[d]						
8-session group	101 (42)	9.49 (4.01, 22.20)	98 (4)	0.54 (0.15, 1.92)	107 (5)	1.30 (0.90, 4.95)
4-session group	110 (25)	4.39 (1.84, 10.49)	113 (5)	0.73 (0.24, 2.23)	113 (6)	1.77 (0.51, 6.17)
Control group	103 (7)	1.0	97 (7)	1.0	110 (4)	1.0

[a]N represents the denominators (i.e., the number of observations that were used in the generalized estimating equation [GEE] analyses for each outcome at each follow-up). Percentages refer to women reporting the behavior.
[b]Odds ratios (OR) and 95% confidence intervals (CI) were calculated from a logistic regression model with GEE with an unstructured working correlation matrix. The model specifies the OR comparisons among the intervention groups and the control group at each follow-up.
[c]At any time since the last interview among women who had not reported this behavior at baseline. Women who did not report having a sexual partner at the respective follow-up were excluded.
[d]At any time since the last interview.

TABLE 2—Effect of Intervention on Female-Condom Use During Sexual-Behavior Recall Periods Among 359 Family Planning Clients: Brooklyn, NY

		1 Month		6 Months		12 Months	
	Baseline, N[a] (%)	N[a] (%)	Ratio of ORs (95% CI)	N[a] (%)	Ratio of ORs (95% CI)	N[a] (%)	Ratio of ORs (95% CI)[a]
Any female-condom use, %[b]							
8-session group	98 (2)	76 (24)	4.81 (0.29, 79.04)	85 (14)	1.13 (0.08, 15.80)	96 (12)	1.45 (0.10, 21.12)
4-session group	119 (5)	94 (12)	0.78 (0.06, 10.38)	106 (17)	0.49 (0.74, 5.10)	106 (13)	0.62 (0.06, 6.49)
Control group	112 (1)	88 (3)	1.0	94 (6)	1.0	96 (4)	1.0
Female-condom–protected episodes (mean among all women), %[c]							
8-session group	98 (<1)	76 (6)	17.99 (1.2, 273.14)	85 (2)	0.33 (0.02, 6.36)	96 (2)	2.10 (0.09, 46.53)
4-session group	119 (<1)	94 (4)	1.01 (0.07, 14.88)	106 (4)	0.06 (0.00, 1.13)	106 (2)	0.07 (0.0, 1.06)
Control group	112 (<1)	88 (<1)	1.0	94 (3)	1.0	96 (1)	1.0

[a]N represents the denominators (i.e., the number of observations that were used in the generalized estimating equations [GEE] analyses at each follow-up). Women who did not report vaginal intercourse at the respective follow-up were excluded from these analyses. Percentages refer to women using the female condom or female-condom–protected episodes.
[b]For this variable, odds ratios (OR) and 95% confidence intervals (CI) were calculated from a logistic regression model that used GEE with an unstructured working correlation matrix. This model specifies an OR that compares the odds of female-condom use at follow-up (FU) with the odds of use at baseline (B). Therefore, parameters of ORs are ratios of these ORs (e.g., [FU1 8-session ÷ BI 8-session] ÷ [FU1 control ÷ BI control]).
[c]For this variable, ORs and 95% CIs were calculated from a binomial regression model with GEE. The parameters of ORs refer to the cross-product ratio of the expected percentage use—comparing a follow-up time point with the baseline—and the table reports the ratios of these cross-product ratios.

the 8-session group, 12% of those in the 4-session group, and 3% of those in the control group reported use of the female condom (Table 2). Among users, the mean percentage of female-condom–protected vaginal-intercourse episodes was 27%, 34%, and 14% in the 8-session, 4-session, and control groups, respectively (not shown). The overall percentage of female-condom–protected vaginal-intercourse episodes was small (6%, 4%, <1% among women in the 8-session, 4-session, and control groups, respectively), although there was a significant difference between the 8-session group and the control group. There was no difference in the number of female condoms used (not shown).

Long-Term Effect of Intervention

At the 6-month and 12-month follow-ups, there were only a few significant differences among the groups. At the 12-month follow-up, women in the 4-session but not the 8-session group assessed the female condom as more effective against STDs than did women in the control group women (mean difference=0.13; 95% CI=0.01, 0.50; *P*=.04). Women in both intervention groups were more likely than were women in the control group to have talked about using the female condom with their primary partner (Table 1). However, there was no long-term effect on use (Tables 1 and 2).

Contribution to Unprotected Episodes

In analyses previously reported,[17] the 8-session intervention was found to reduce unprotected vaginal and anal intercourse. To assess whether female-condom use made a significant contribution to a reduction in unprotected intercourse, we compared intervention effects on 2 outcome variables—number of vaginal intercourse episodes protected by male and female condoms versus number protected by male condoms only. There was no significant difference between these 2 models, which indicates that female-condom use did not contribute significantly to reducing the number of unprotected vaginal-intercourse episodes among intervention-group women.

Reactions of First-Time Users

Among the 109 women who reported using the female condom for the first time at any follow-up, the most frequently cited reasons for initial use were a desire to try something new (47%) and having attended intervention workshops (43%). Fifty-nine percent of women were very or somewhat satisfied, as were 50% of their partners. Use was assessed as very or somewhat easy by 50% of women (n=53 of 106 who responded), whose most frequently cited reasons included ease of insertion (n=10), having learned how to use it in the workshop (n=13), partner willingness (n=11), novelty (n=6), and liking a method under their control (n=5).

However, among first-time users who found the female condom very or somewhat difficult to use (50%), 91% (n=48) cited insertion problems. Partner reluctance was cited by 5 women, and 14 women cited discomfort or difficulties with intercourse. Surprisingly, in view of other reports,[11] only 3 women cited aesthetic concerns.

Predictors of First-Time and Repeated Use

We compared the 109 first-time users with the 221 women who never reported first-time use. The strongest predictor of first-time use was being in an intervention group (Table 3). First-time users were somewhat more likely to have talked about safer sexual intercourse with their partners prior to the intervention and were more likely to have used male condoms, but their attitudes and their partners' attitudes about the male condom did not differ significantly from those of women/partners who did not try the female condom. First-time users also were less likely to be White.

In exploratory univariate analyses of the 93 women who reported use of the female condom for the first time at the first or second follow-up, we compared the 21 women who reported repeated use with the 72 who tried the female condom only 1 time. Women's atti-

TABLE 3—Predictors of First-Time Female-Condom Use: Brooklyn, NY

	N	Used for the First Time,[a] %	Crude OR (95% CI)[b]	Adjusted OR (95% CI)[c]
Intervention group				
8-session	107	48	4.55 (2.42, 8.57)	5.40 (2.78, 10.48)
4-session	115	35	2.67 (1.41, 5.03)	3.02 (1.56, 5.84)
Control	108	17	1.0	1.0
Any male-condom use at baseline				
Yes	230	37	1.89 (1.05, 3.42)	
No	75	24	1.0	
Consistent male-condom use at baseline				
Yes	81	42	1.59 (0.94, 2.69)	
No	224	31	1.0	
Impression of the male condom at baseline				
Negative or neutral	103	37	0.85 (0.52, 1.40)	
Positive	204	66	1.0	
Negotiation about safer sexual intercourse at baseline				
Yes	209	38	1.86 (1.09, 3.16)	1.83 (1.04, 3.21)
No	100	25	1.0	1.0
Race/ethnicity				
White and other	239	11	0.22 (0.08, 0.65)	0.22 (0.07, 0.67)
Hispanic/Latina	55	35	0.94 (0.51, 1.74)	1.17 (0.59, 2.30)
Black/African American	36	36	1.0	1.0

Note. OR = odds ratio; CI = confidence interval. Additional baseline variables that were examined and were found not to be significant included age, participant and partner risk characteristics, number and type of partners, relationship length and quality, partner attitude toward male condoms, use of other barrier methods, having refused sexual intercourse because of sexually transmitted diseases concerns, endorsement of gender norms, assertiveness, personal control, and baseline values of attitudes toward the female condom (perceived effectiveness, perceived ability to use, and overall impression).
[a]First-time use at the 1-month, 6-month, and 12-month follow-up interviews among women who had never used the female condom at baseline (109 first-time users compared with 221 women who did not report use of the female condom for the first time at any follow-up; 14 women had already used the female condom at baseline, and 15 were missing this variable at 1 or more follow-ups or had no follow-ups).
[b]OR and 95% CI were calculated with ordinary logistic regression.
[c]All variables shown in this column were controlled.

tudes and their partners' attitudes about the female condom after first-time use—including perceived ability to use, self and partner's satisfaction, and overall impression of the method—were positively associated with repeated use. Having used a diaphragm and holding an unfavorable view of male condoms at baseline were predictors of repeated use, but being in an intervention group was not (Table 4).

DISCUSSION

Our findings demonstrate a short-term effect of the intervention on female-condom attitudes and use. Women in the intervention groups assessed the female condom as more effective against pregnancy and STDs than did women in the control group. They also were more likely to negotiate female-condom use with their primary partner, to use a female condom for the first time, and to have a greater relative increase in the percentage of intercourse episodes in which the female condom was used. Satisfaction was higher among first-time users in the intervention groups.

These short-term findings are consistent in magnitude with the short-term results of other female-condom interventions.[23–25] Our intervention, as well as the others, included information and motivation enhancement, free samples, and instruction about use. We also included practice in inserting the female condom with a pelvic model and training in how to introduce it to male partners. Thus, it appears that introducing the female condom in a cognitive-behavioral intervention—where women have the opportunity to become familiar with the device and to practice inserting it and introducing it to their partners—can improve women's assessment of the method and increase their willingness to try it.

Trying a new method does not necessarily lead to its adoption, however. In our study, being assigned to an intervention group was the most important predictor of using a female condom for the first time, but this did not translate into sustained use. Whereas intention to continue using the female condom was high at each follow-up (68% at the 1-month follow-up, 50% at the 6-month follow-up, and 59% at the 12-month follow-up), duration of actual use was short. Among the study's 359 women, only 21 reported use of the female condom at more than 1 follow-up. Even though women in the intervention groups were more likely than women in the control group to talk with their partners about the female condom 1 year later, there was no effect of the intervention on any measure of use beyond the first follow-up.

Why were women willing to try the method but not willing to continue using it? The intervention was the most important predictor of trying the female condom, but repeated use was related to women's comfort in using the female condom after trying it. Previous experience with the diaphragm, self and partner satisfaction with first-time use, and perceived ability to use the method after the first try predicted continued use. In open-ended responses, more than 90% of women who found their first experience difficult cited problems with insertion.

Our findings suggest that practice on a female reproductive model may be insufficient for ensuring women's comfort with using the device. Female-condom interventions may need to include opportunities for women to engage in guided self-insertion practice and to obtain help in dealing with problems after they try the device for the first time.[26,27]

Because the female condom has been promoted as a method that can be used in the absence of a partner's support, it was striking to find several indications of male partners' influence on women's response to the female condom. Partner satisfaction with the method was associated with repeated use, and in open-ended responses, women who found

TABLE 4—Predictors of Repeated Female-Condom Use Among 93 First-Time Users: Brooklyn, NY

	N	Repeated Female-Condom Use,[a] %	Crude OR (95% CI)
Intervention group			
8-session	46	15	0.66 (0.15, 2.96)
4-session	33	33	1.83 (0.42, 7.95)
Control	14	21	1.0
Any male-condom use at baseline			
Yes	74	19	0.47 (0.14, 1.58)
No	15	33	1.0
Consistent male-condom use at baseline			
Yes	29	31	2.25 (0.80, 6.36)
No	60	17	1.0
Ever used diaphragm			
Yes	11	55	5.36 (1.44, 19.91)
No	82	18	1.0
Impression of the male condom at baseline			
Negative or neutral	31	32	2.92 (1.01, 8.43)
Positive	57	14	1.0
Talked about female condom at 1-month follow-up			
Yes	60	32	5.33 (1.14, 24.95)
No	25	8	1.0

	N	Repeated Female-Condom Use,[b] Mean (SD)	Crude OR (95% CI)
Perceived ability to use	93	5.4 (1.2)	1.89 (1.20, 3.00)
Impression of the female condom	93	2.7 (0.5)	3.54 (1.49, 8.40)
Satisfaction with use	91	3.5 (0.8)	2.32 (1.26, 4.27)
Partner satisfaction with use	90	3.6 (0.6)	4.32 (2.06, 9.06)

Note. OR = odds ratio; CI = confidence interval. Additional baseline variables that were examined and were found not to be significant included age, participant and partner risk characteristics, number and type of partners, relationship length and quality, partner attitude toward male condoms, negotiation about safer sexual intercourse at baseline, having refused sexual intercourse because of sexually transmitted diseases concerns, endorsement of gender norms, assertiveness, personal control, and baseline values of attitudes toward the female condom (perceived effectiveness, perceived ability to use, and overall impression).

[a]Reported use of the female condom at more than 1 follow-up among 93 women with first-time use at the 1-month follow-up or 6-month follow-up (21 with repeated use vs 72 with first-time use only).

[b]Values for these variables were taken from the 1-month or 6-month follow-up interview in which each woman reported use of the female condom for the first time.

the female condom easy to use frequently cited lack of partner objection. Almost all (97%) of the female-condom use reported during sexual-behavior recall periods was with primary partners. Other studies also have reported that men's reactions to the female condom are important in predicting women's use.[16,28,29] Although some level of male acceptance seems to contribute to successful female-condom use, women who have greater personal comfort with the method may place less importance on their partner's satisfaction. Regardless, it seems critical to find ways to promote the female condom among men.

There are few long-term studies of female-condom use with which to compare our results. Among STD clinic clients in Alabama, Artz et al[13] evaluated a female-condom intervention that included the opportunity to practice insertion under the guidance of a nurse. Although there was no comparison group, the overall proportion of protected episodes was estimated to be approximately 50% at 6 months, compared with 40% at baseline, after adjustment for women who had dropped out. In a couple-counseling intervention in Zambia, Musaba at al[12] reported that approximately one quarter of coital episodes were female-condom protected at the 12-month follow-up, although substantial loss to follow-up was not taken into account.

Our failure to find a long-term effect may be attributable to the fact that our intervention presented the female condom as an option among a range of alternative strategies rather than promoting it exclusively. Our response rate was higher than those of other studies, which also may account for the difference in our findings (e.g., we included female-condom nonusers who may have dropped out of other studies). Another difference is that participants in other studies were recruited from STD clinics and, therefore, may represent higher-risk populations. It also is possible that increasing women's adoption of female-condom use requires additional intervention components, such as problem solving after first-time use, repeated self-insertion practice, and more active involvement of male partners. It is notable that in interventions with long-term positive results, these components—additional insertion practice and involvement of male partners—were present.[12,13]

Another important, unresolved question about the effect of the female condom is whether adding it to the menu of preventive options will decrease total episodes of unprotected sexual intercourse. One concern has been that female-condom users may be those who were already using the male condom with their partners. Our study previously demonstrated that the intervention had both the short- and a long-term effect of reducing unprotected sexual intercourse, but the female condom did not contribute significantly to this outcome in the short or long term.

It is notable that in our study population, 75% of women reported some male-condom use at baseline, and consistency of male-condom use was not associated with trying or continuing to use the female condom. Because the intervention strongly and successfully encouraged women to try the female condom at least once, it is not surprising that those who used it for the first time during this study did not differ from those who did not with regard

to attitudes toward the male condom. However, repeat female-condom users had more negative views of male condoms. This suggests that women who are motivated to use disease protection but who do not like the male condom may be more inclined to adopt an alternative barrier method. Therefore, a significant effect on the prevention of STDs and unplanned pregnancy is possible if women who use the female condom tend to be those who are at high risk of discontinuing use of the male condom.

From the studies of female-condom interventions conducted to date, we conclude that cognitive-behavioral interventions grounded in a gender-sensitive framework can increase women's ability to negotiate with their partners about female-condom use and promote first-time female-condom use. At present, however, the female condom seems to be difficult for women to adopt without more extensive training in its use. Our data suggest that interventions designed to offer women greater opportunities to become comfortable with insertion and to garner the support of male partners may be more effective in increasing long-term use. Public policy changes are warranted as well, including increased promotion and price support, especially now that some studies have shown that it is safe to reuse the female condom after washing.[30] Without concurrent individual and structural interventions, the potential of the female condom to contribute to disease reduction will not be achieved. ■

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Contributors

S. Hoffman conceptualized and conducted the analyses and wrote the article. A.A. Ehrhardt, T.M. Exner, and Z. Stein designed the study and edited the article. T.M. Exner and C-S Leu assisted with the analyses.

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Human Participant Protection

This protocol was approved by the institutional review board of the New York State Psychiatric Institute.

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