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Female Condom Use Among Women at High Risk of Sexually Transmitted Disease

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Context: Whereas the female condom has been evaluated in many hypothetical acceptability or short-term use studies, there is little information about its suitability for the prevention of sexually transmitted diseases (STDs) or HIV over extended periods of time.

Methodology: As part of a six-month prospective follow-up study of 1,159 STD clinic patients, clients were interviewed during their initial visit, exposed to a behavioral intervention promoting condoms, given a physical examination and provided with instructions on completing a sexual diary. Potential predictors of trying the female condom were evaluated using logistic regression, and three condom-use groups (exclusive users of female condoms, exclusive users of male condoms and users of both types of condoms) were compared using multinomial regression.

Results: Among 895 women who reported having engaged in vaginal intercourse during the study period, one-half had sex with only one partner, while one-quarter each had two partners or three or more partners. A total of 731 women reported using the female condom at least once during the follow-up period—85% during the first month of follow-up. Multiple logistic regression analyses indicated that employed women and those with a regular sexual partner at baseline were significantly more likely to try the female condom. By the end of the follow-up period, 8% of participants had used the female condom exclusively, 15% had used the male condom exclusively, 73% had used both types of condom and 3% had used no condoms. Twenty percent of women who tried the female condom used it only once and 13% used it twice, while 20% used 5-9 female condoms and 32% used 10 or more. Consistent condom users (N=309) were predominantly users of both types of condom (75%), and were less often exclusive users of the male condom (18%) or the female condom (7%). According to a multivariate analysis, women who used the female condom exclusively or who mixed condom types were more likely to be black, were more likely to be employed and were more likely to have a regular partner than were users of the male condom.

Conclusions: Women at risk of STDs find the female condom acceptable and will try it, and some use it consistently. Mixing use of female condoms and male condoms may facilitate consistent condom use. The female condom may improve an individual's options for risk reduction and help reduce the spread of STDs.

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In 1993, the U.S. Food and Drug Administration approved marketing of the female

condom, a device that provides women who are unable to use latex male condoms with a potentially important alternative means of protecting themselves from sexually transmitted diseases (STDs). The limited information that is available suggests that the female condom may be effective in preventing STDs.[1] Studies indicate that most women and their male partners are willing to try the female condom, that it provides women with greater perceived control over safer sex practices and that it may help women achieve consistent barrier protection, at least in the short term.[2] To date, however, only two studies in developing countries have evaluated the acceptability of the female condom for STD prevention over an extended time period.[3] This article reports on the initial acceptability of the female condom and on patterns of female condom use during a six-month prospective follow-up study of women attending two urban STD clinics in Alabama.

METHODS

Study Design and Procedures

The investigation described in this article consisted of two components: a study of the efficacy of the female condom in preventing STDs, and a study of behavioral determinants of its use. The study design and procedures have been described in detail elsewhere.[4] Briefly, this was a prospective observational follow-up study of women attending two public STD clinics in Birmingham and Huntsville, Alabama.

A trained interviewer recruited potential participants in the waiting room of each of the STD clinics and carried out a brief interview to assess their eligibility for the study. To be eligible, women had to meet five criteria: They had to be 18-35 years of age, to be not currently pregnant or planning to become pregnant in the next six months, to have not undergone a hysterectomy, to be not taking antibiotics on a regular basis and to have no plans to leave the metropolitan area for any prolonged period during follow-up.

Eligible women who agreed to participate were scheduled to return for an initial visit 10 days after recruitment. At the initial visit, they provided informed consent and were interviewed by female research assistants. A nurse clinician delivered a one-on-one, intensive behavioral intervention promoting barrier contraception in general and female condom use in particular; each participant was then given the opportunity to practice inserting the female condom. The intervention consisted of a promotional videotape, a skills-oriented counseling session and assorted take-home items.[5] A licensed nurse clinician or nurse practitioner trained in the recognition of common STDs also examined each woman, following Centers for Disease Control and Prevention (CDC) guidelines.

Upon completion of the physical exam, women were provided with a free six-week supply of either male condoms (if they refused to try the female condom) or female condoms, with male condoms provided as a backup. They also were trained to complete a sexual diary, and were compensated $25. In this study, condom use was promoted specifically for STD prevention. Participants who also requested counseling about contraception were referred to the health department family planning clinics.

The first follow-up visit was scheduled four weeks after the initial visit. Subsequent follow-up visits were scheduled every four weeks thereafter until a woman either

completed six visits or withdrew from the study. At each visit, participants were asked a series of questions to assess whether they still met eligibility criteria, to assess their beliefs, attitudes and experiences concerning female and male condom use, and to evaluate sexual activity during the previous 30 days.

Participants also returned their sexual diaries at each follow-up visit, so data could be abstracted and coded; interviewers reviewed the diaries with participants to verify the completeness and accuracy of the information reported. Participants returned unused condoms and the wrappers of used condoms, which gave researchers an opportunity to confirm the accuracy of the number of male and female condoms that participants reported having used. At each follow-up visit, the women had a physical examination identical to the one at the initial visit. They were compensated up to $25 for each follow-up visit ($20 for making the visit and $5 for returning unused condoms and the wrappers of used condoms) and received an additional $50 when they completed the study.

Data Sources

This analysis employs data taken from the recruitment interview, the initial visit interview and the sexual diary. The recruitment interview contained social and demographic items and assessed the contraceptive and STD prevention strategies employed by participants before they entered the study. The interview at the initial visit consisted of an in-depth sexual history and a survey of beliefs, attitudes and experiences concerning condom use. The sexual diary was designed to let participants take personal notes and to encode for each sex act a few key variables: type of sexual activity; type of protection used, if any; partner's initials; and problems experienced.

Before data collection began, we conducted a pilot test with a sample of 60 women, and assessed the test-retest (one-week) reliability of all measures. All procedures and forms were reviewed and approved initially by the University of Alabama at Birmingham institutional review board, by the Alabama Department of Public Health institutional review board and by the Centers for Disease Control and Prevention institutional review board; they also were assessed annually by the University of Alabama at Birmingham institutional review board.

Data Analysis

The objectives of the analyses were to describe the characteristics of study participants who returned for follow-up; to describe patterns of sexual activity and condom use during the six-month follow-up period; to compare the characteristics of women who tried the female condom with those of women who did not; and to compare the baseline characteristics of women who displayed different patterns of condom use during the study.

Patterns of condom use were evaluated both dynamically, during each month of follow-up, and at the end of the follow-up period. In the first set of analyses, we considered individual months of follow-up as independent observations, and evaluated condom use separately within each month. In a second set of analyses, we cumulated monthly reports over the entire follow-up experience of a woman.

Frequency distributions, univariate descriptive statistics and standard contingency

table techniques were used in simple analyses. We used logistic regression to simultaneously evaluate multiple potential predictors of trying the female condom.[6] Multinomial regression was used to simultaneously evaluate potential predictors of three main condom use patterns observed during the study: exclusive use of the male condom, exclusive use of the female condom and mixed use.[7]

The multiple regression analyses took into account the effects of the following demographic, background and risk behavior variables: age, race, marital status, having a live-in partner, years of education, employment status, monthly income, age at first intercourse, lifetime number of sexual partners, having a regular partner at baseline, any use of a male condom at baseline, any use of a contraceptive method at baseline, having experienced the anger of a sexual partner during the 30 days prior to the baseline interview, having had sex while drunk or high within the 30 days prior to the baseline interview, having ever been pregnant, having had an STD in the past and having been diagnosed with an STD at baseline.

Recruitment and Follow-Up

Recruitment began July 14, 1995, and follow-up ended February 28, 1998. A total of 3,531 potentially eligible women engaged in recruitment interviews, 2,702 agreed to participate and 1,159 attended the initial visit. Among eligible women who were interviewed at recruitment, young women, those with less education, black women, those receiving income from welfare programs, those with a high lifetime number of partners, unmarried women and those with a history of STDs were more likely to agree to participate in the study. There were essentially no differences between those who actually participated in the study (N=1,159) and those who did not (N=1,543), except that participants had a higher lifetime number of sexual partners and were slightly more likely to have an STD history than nonparticipants. Overall, the variables associated with participation in the study were weak predictors, and are unlikely to have caused selection bias.

Follow-up information and diary data for one or more months were available for 919 (79%) of the 1,159 women who made the initial visit. A total of 525 women made all six follow-up visits—45% of those who attended an initial visit. The mean number of follow-up visits attended was 3.5. Women with an income above the median of the group and those with a high coital frequency during the 30 days preceding the initial visit and during follow-up were more likely to withdraw from the follow-up. Being older, being black, being interested in or committed to using the female condom regularly during the study period, having a history of STDs, using hormonal or barrier contraceptives and using condoms consistently during follow-up were all associated with a higher probability of completing the study, although all of these associations were relatively weak.

A completed sexual diary was returned in 3,838 (94%) of the 4,086 follow-up visits that were made. The interviewer was able to reconstruct sexual activity and condom use during the previous follow-up interval in 246 of the remaining 248 visits. Thus, essentially no follow-up information was lost because of missing diary data. Furthermore, the interviewer verified the diary data by comparing the number of condom uses reported in the diary with the number of wrappers and unused condoms returned by the participant at the follow-up visit. Wrappers or unused condoms were

returned for 90% of the diaries. Perfect concordance of diary and wrapper count was observed in 71% of the diaries with matching wrappers; in an additional 11% of instances, the diary count and the wrapper count differed by just one male condom or one female condom.

RESULTS

Baseline Characteristics

The 919 women who attended at least one follow-up visit and returned at least one sexual diary did not differ significantly in their baseline characteristics from the 240 other women who attended the initial visit (not shown). As Table 1 indicates, participants were generally young (62% were younger than 25), black (86%), single (75%), not educated beyond high school (63%) and low-income (68%). Slightly more than half (56%) were employed at the time of recruitment.

Table 1. Number and percentage distribution of female condom study participants, by selected characteristics at baseline

Characteristic	N	%
Age (in years)		
18-19	189	21
20-24	374	41
25-35	356	38
Race		
Black	789	86
Other	130	14
Marital status		
Single	689	75
Ever-married	230	25
Has a live-in partner		
Yes	201	22
No	718	78
Has a regular partner		
Yes	748	81
No	171	19
Education (in years)		
<12	235	26
12	341	37
>12	343	37
Employed		
Yes	516	56
No	403	44
Monthly income		
$0-300	356	39
$301-600	267	29
>$600	296	32
Age at first sex (years)		
<16	394	43
16	224	24

>16	301	33
Lifetime no. of partners		
1-2	130	14
3-4	276	30
5-9	385	42
>=10	128	14
Current condom use		
Yes	453	49
No	466	51
Current contraceptive use (other than condoms)		
Yes	319	35
No	600	65
Relationship violence (in past 30 days)		
No direct physical violence	787	86
Direct physical violence	132	14
Had sex while drunk or high (in past 30 days)		
Usually	39	4
Sometimes	100	11
Never	780	85
Ever pregnant		
Yes	667	73
No	252	27
Past STD		
Yes	618	67
No	301	33
STD at baseline		
Yes	330	36
No	589	64
Total	919	100

Most participants (81%) had a regular sexual partner, and 22% had a live-in partner; two-thirds (67%) reported having engaged in sexual intercourse by age 16, and 56% had had a total of five or more sexual partners (Table 1). Half (49%) reported using condoms (almost exclusively male condoms) for birth control, but only 27% reported using condoms consistently during the previous 30 days (not shown). About one-third (35%) reported using other contraceptive methods (oral contraceptives, the IUD, spermicides, the diaphragm, the implants, the injectable or the sponge).

During the 30-day period preceding their initial visit, 31% of participants had been exposed to a sexual partner's verbal abuse or to violence directed against objects (not shown), and 14% had had physical violence directed at them, while 15% reported having engaged in intercourse while high or drunk. A past pregnancy was reported by 73%. A history of STDs was reported by 67%, and 36% had been diagnosed with chlamydia infection, gonorrhea or syphilis in the 60 days before they entered the study.

Sexual Activity

Twenty-four (3%) of the 919 women who returned for follow-up and turned in at least one diary reported never having had vaginal sex during the study; seven of these

women dropped out of the study after one follow-up visit. Overall, the proportion of women reporting abstinence increased from 9% during the first month to 18% during the sixth month. This trend was still evident when the analysis was restricted to the subgroup of women who had completed all follow-up visits, indicating that the increase in abstinence over time was not explained by the early withdrawal of women with high coital frequency.

Of the 895 women who reported having engaged in vaginal intercourse during the study, 49% had had sex with only one partner, while 24% had had two partners and 27% had had three or more. The median number of sexual partners was two, and the maximum was 20. During the study, most women (97%) had sex with a regular partner (their husband, or a boyfriend for more than one month), while 32% had sex with a casual partner (neither the main partner for more than one month nor a new partner) and 26% had sex with a new partner (someone whom they had initially encountered during that month).

A total of 35,065 sex acts were reported during follow-up. Vaginal intercourse accounted for 84% and oral sex for 15% of the reported acts. About 88% of all reported sex acts were with a regular partner, 8% were with a casual partner and 4% were with a new partner.

Who Tried the Female Condom?

Among a total of 731 women who reported using the female condom at least once during follow-up, 85% used their first during the first month of follow-up. Simple analyses of the association of participants' baseline characteristics with use of the female condom during the study indicate that compared with women who did not try the female condom, those who tried it were more likely to be young ($p<.05$), to be employed ($p<.01$), to have a regular partner ($p<.001$), to have a live-in partner ($p<.05$), to be a male condom user ($p<.05$) and to have ever been pregnant ($p<.01$) prior to enrollment. In multiple logistic regression analyses, however, only being employed (odds ratio, 1.9; 95% confidence interval, 1.3-2.9) and having had a regular partner at baseline (odds ratio, 2.5; 95% confidence interval, 1.6-3.8) were statistically significant predictors of trying the female condom once the effects of all characteristics were taken into account (Table 2).

Table 2. Percentage distribution of sexually active study participants, by selected baseline characteristics, according to whether they tried the female condom, and adjusted odds ratios (and 95% confidence intervals) from logistic regression showing odds of having tried the female condom

Characteristic	Tried female condom (N=731)	Did not try female condom (N=164)	Odds ratio
Age (in years)			
18-20	29	19	0.6 (0.3-1.0)
21-25	37	42	1.0 (0.6-1.6)
26-35 (ref)	35	39	1.0
Race			
Black	86	87	0.9 (0.5-1.5)
Other (ref)	14	13	1.0
Marital status			

Single	79	74	0.9 (0.6-1.6)
Ever-married (ref)	21	26	1.0
Has a live-in partner			
Yes	24	15	1.4 (0.8-2.4)
No (ref)	76	85	1.0
Has a regular partner			
Yes	85	71	2.5*** (1.6-3.8)
No (ref)	15	29	1.0
Education (in years)			
<12	25	27	1.0 (0.6-1.6)
12	38	35	1.1 (0.7-1.7)
>12 (ref)	37	38	1.0
Employed			
Yes	59	45	1.9*** (1.3-2.9)
No (ref)	41	55	1.0
Monthly income			
$0-300	37	46	1.3 (0.8-2.0)
$301-600	30	23	1.5 (0.9-2.4)
>$600 (ref)	32	31	1.0
Age at first sex (in years)			
<16	43	42	1.1 (0.7-1.7)
16	24	24	1.1 (0.7-1.8)
>16 (ref)	32	34	1.0
Lifetime no. of partners			
1-2	17	13	0.8 (0.4-1.5)
3-4	32	30	0.9 (0.5-1.6)
5-9	38	43	1.0 (0.6-1.8)
>=10 (ref)	13	14	1.0
Current condom use			
Yes	50	46	1.3 (0.9-1.9)
No (ref)	50	54	1.0
Current contraceptive use (other than condoms)			
Yes	36	31	1.3 (0.9-2.0)
No (ref)	64	69	1.0
Relationship violence (in past 30 days)			
No direct physical violence	85	87	1.2 (0.7-2.0)
Direct physical violence (ref)	15	13	1.0
Had sex while drunk or high (in past 30 days)			
Usually	5	2	1.8 (0.6-5.5)
Sometimes	11	11	1.0 (0.6-1.8)
Never (ref)	84	87	1.0
Ever pregnant			
Yes	75	65	1.5 (0.9-2.2)
No (ref)	25	35	1.0
Past STD			
Yes	68	65	1.1 (0.7-1.6)
No (ref)	32	35	1.0

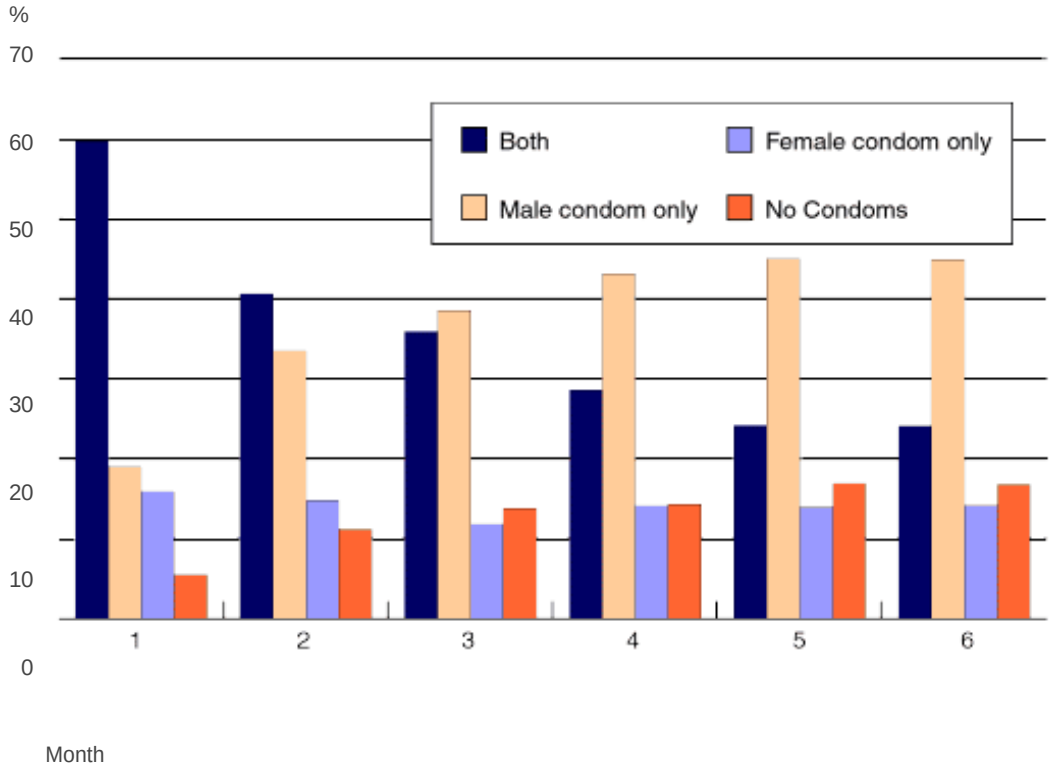
STD at baseline			
Yes	61	57	0.9 (0.6-1.2)
No (ref)	39	43	1.0
***Statistically significant at p<.001. *Note:* ref=reference group.			

Condom Use During Follow-Up

Of the 731 women who tried the female condom, 145 (20%) used only one, 92 (13%) used two, 113 (15%) used three or four, 149 (20%) used between five and nine, and 232 (32%) used 10 or more. Of those who used the product 2-4 times, most (82%) stopped within 14 acts of intercourse from having initiated use. This suggests that experimentation with the new product generally took place within a few narrowly spaced trials. Among women who used five or more female condoms, however, discontinuation of use was more widely distributed over time.

The proportion of women who reported using the female condom exclusively during the previous month remained relatively constant throughout the follow-up period, decreasing only slightly from 16% during the first month to 14% during the last month (Figure 1, page 142). The proportion of women who reported mixing types of condoms during the previous month declined over time, from 60% during the first month to 24% during the sixth. The decline in method mixing was partially offset by an increase in exclusive use of male condoms, from 19% in the first month to 45% in the sixth month. The proportion of women reporting no use of condoms in the previous month increased from 6% during the first month to 17% during the sixth month.

Figure 1. Percentage distribution of sexually active women, by pattern of condom use, according to month of follow-up



Overall, 309 women (35%) maintained consistent condom use (i.e., they used either the female condom or the male condom every time they had vaginal intercourse) during the entire follow-up period. In this subgroup, the most common pattern of protection was mixed use of both condoms (75%), followed by exclusive male condom use (18%) and exclusive female condom use (7%).

It is possible that mixed condom use is a transient behavior of women who tend to withdraw early from follow-up, and that women who maintain consistent condom use over time tend to shift from mixing condom types to using exclusively either the female condom or the male condom. To study this possibility, we first examine the distribution of condom-use patterns during the first month, comparing women who withdrew early with those who completed the follow-up period. Among 210 women who were consistent condom users during the first month and who withdrew before the end of the study, 63% mixed condom types during the first month. This proportion was virtually identical to that among the 197 women who were consistent users during the first month and who completed the study (62%).

Next, we evaluated condom-use patterns month by month among the 132 women who maintained consistent use over the entire six-month period. The proportion of women in this group who used both types of condoms declined from 61% during the first month to 35% during the sixth month, while the proportion who used the male condom exclusively increased from 24% to 48%. Thus, we can conclude that mixing condom types was not a characteristic behavior of early dropouts and persisted throughout the follow-up period, although its practice declined over time.

Characteristics and Patterns of Use

As of the end of the follow-up period, 75 women (8%) had used the female condom as their exclusive barrier method, 138 (15%) had used the male condom exclusively, 656 (73%) had used both the male condom and the female condom and 26 (3%) had used no condoms. In regression analyses comparing the baseline characteristics of the three groups of condom users, we found statistically significant differences among these groups for race (p=.01), employment status (p=.005) and having a regular partner at baseline (p<.001) (Table 3).

Table 3. Percentage distribution of sexually active women who had used the male or the female condom, by baseline characteristics, according to pattern of condom use, and p value for significance of characteristic in multinomial regression analysis (n=869)

Characteristic condom only	Used female condom only	Used male both	Used	p
	(N=75)	(N=138)	(N=656)	
Age				**.19**
18-20	13	28	19	
21-25	39	40	42	
26-35	48	32	38	
Race				**.01**
Black	75	90	87	
Other	25	10	13	
Married				**.61**
Single	69	84	75	
Ever-married	31	16	25	
Has a live-in partner				**.09**
Yes	29	10	23	
No	71	90	77	
Has a regular partner				**<.001**
Yes	87	68	85	

No	13	32	15	
Education (in years)				**.18**
<12	32	24	24	
12	39	39	38	
>12	29	37	38	
Employed				**.005**
Yes	60	46	59	
No	40	54	41	
Monthly income				**.49**
$0-300	31	46	38	
$301-600	36	23	30	
>$600	33	32	32	
Age at first sex (in years)				**.27**
<16	37	41	44	
16	24	25	24	
>16	39	34	32	
Lifetime no. of partners				**.35**
1-2	15	15	13	
3-4	35	32	30	
5-9	39	41	43	
>=10	11	12	14	
Current condom use				**.17**
Yes	61	53	51	
No	39	47	49	
Current contraceptive use (other than condoms)				**.30**
Yes	69	31	36	
No	31	69	64	
Relationship violence (in past 30 days)				**.42**
No direct physical violence	88	89	85	
Direct physical violence	12	11	15	
Had sex while drunk or high (in past 30 days)				**.68**
Usually	5	3	5	
Sometimes	9	10	11	
Never	86	87	84	
Ever pregnant				**.11**
Yes	80	62	74	
No	20	38	26	
Past STD				**.90**
Yes	68	67	68	
No	32	33	32	
STD at baseline				**.15**
Yes	24	36	40	
No	76	64	60	

Note: The 26 women who never used condoms during the study are excluded.

The racial heterogeneity among these three groups was due to the smaller proportion of black women among the exclusive users of female condoms (75%) than among exclusive users of male condoms and mixed users (90% and 87%, respectively).

Heterogeneity with respect to employment status was related to the smaller proportion who were employed among exclusive users of the male condom (46%) than in the other groups (about 60% in both). Heterogeneity with respect to having a regular partner at baseline arose from the smaller proportion with a regular partner among exclusive users of the male condom (68%) than in the other groups (87% and 85%).

DISCUSSION

Many women at high risk of STDs fail to achieve consistent protection against such infections. Until recently, because of the lack of alternatives to the male latex condom, men could exert disproportionately greater control over the decision to practice safer sex. This situation has prompted the call for safe and reliable female-controlled methods of STD and HIV prevention,[8] and has led to the female condom being welcomed as the best female-controlled prophylactic to come onto the market.[9] This article has presented results from a prospective study undertaken to evaluate the acceptability and efficacy of the female condom among women at high STD risk. The large size of the study group and its six-month follow-up period allowed us to evaluate early experience with the product as well as its use over an extended time period.

To promote female condom use, we developed an intensive, multifaceted behavioral intervention, the success of which we have documented elsewhere.[10] While selective retention of condom users tends to exaggerate the apparent effectiveness of the intervention, projections that take this problem into account suggest that condom use increased sharply after enrollment, then gradually declined during follow-up but remained elevated relative to levels at baseline.

This article presents a detailed description of patterns of female condom use during follow-up. As has been observed in short-term or in hypothetical acceptability studies,[11] most women were willing to try the female condom. Most of the women who agreed to participate tried the female condom, even though a commitment to try the new product neither was an eligibility criterion nor was emphasized in the recruitment procedures.

In a separate report, we have documented that several factors (perceiving that one is at STD risk, being unable to communicate effectively or having had a negative experience in communicating the need to use a condom, preferring to take control over the decision-making process, perceiving self-efficacy about using the male condom and lacking an aversion to barrier methods that require intravaginal insertion) predicted women's interest in trying the female condom.[12] Our data, however, do not support the notion that the female condom is more appealing to women whose partners are violent or whose partners strongly object to using the male condom. The analysis does show that among the potential correlates of trying the female condom, women who were employed or who had a regular partner at baseline were more likely to try it.

Even after an intensive behavioral intervention, maintaining female condom use over time appears difficult. Although a large number of women tried the device, use declined over time, and only a small group of women elected to use the female condom as their sole method of STD prevention. While experimentation with the female condom was very common early in follow-up, exclusive male condom use increased over time, suggesting that the male condom was preferred by most women and their

partners. Exclusive users of the female condom tended to less often be black than were exclusive users of the male condom or those who mixed use of both condoms. In contrast, exclusive users of the male condom less often were employed or had a regular partner at baseline than did those in the other groups.

Our most important finding, however, is that a large proportion of participants used both condom types throughout the follow-up period. In particular, the female condom appears to have played a role in allowing inconsistent users of the male condom to achieve high protection rates by mixing condom types over time. This finding is consistent with those of two other studies that evaluated female condom use over an extended time period. A small-scale follow-up study of high-risk couples in Zambia documented that those who used the female condom tended to have a higher proportion of protected acts than couples who only used the male condom.[13] Furthermore, in a randomized study of Thai sex establishments, a small increase in the proportion of protected acts was observed at sex establishments in which the female condom was made available to sex workers, compared with establishments where workers were exposed to an intervention promoting the male condom only.[14]

It is possible that making several options for protection available facilitates consistent use of a barrier method. Alternatively, the female condom may have been used as a replacement for the male condom. The issue of "condom replacement" is at the core of the controversy on whether promoting one method is preferable to promoting multiple methods. For example, promoting vaginal microbicides as a backup to condoms is perceived as potentially interfering with the message to use condoms consistently. In a study of commercial sex workers in Colombia, workers exposed to an intervention promoting both condoms and microbicides had lower rates of unprotected sex than workers given a control intervention that promoted condoms only, but they had lower rates of condom use as well.[15]

Similarly, replacement of male condom use with female condom use was evident in the randomized trial of Thai sex establishments;[16] however, since a very high proportion of protected sex acts was reported during follow-up in both arms of the trial (more than 97%), any female condom use necessarily produced a reduction in male condom use. In an evaluation of a hierarchical model developed by the New York State Department of Health AIDS Institute, female condom use among patients attending methadone treatment clinics in Harlem increased sizably without any reduction in male condom use.[17] Our preliminary analyses, in which we compared consistency of male condom use before and after the intervention, suggest that the number of male condoms used after the intervention was only slightly lower than the number expected to be used, given the level of consistency reported during the 30 days before someone entered the study. Thus, the net effect of our intervention appears to have been a large increase both in female condom use and in protected sex.[18]

Even though our study group consisted of women with a history of STDs, their history of risk behavior and their pattern of sexual activity during the study did not differ much from the behavior of the general population. The vast majority of sexual acts were with regular partners, and the participants' sexual behavior was otherwise quite similar to mainstream behavior. Presumably, the study participants' high STD risk results not so much from their own behavior as from their being part of a high-

prevalence community—and possibly from the behavior of their primary sexual partner.

This observation underscores the importance of addressing safer sex within long-term sexual partnerships: Women in such relationships need to be provided with motivation and skills that are adequate to ensure their protection from STD exposure through a nonmonogamous male partner. In our analysis, women who had a main partner were more likely to try the female condom and to use it either exclusively or with the male condom. Elsewhere, we have shown that the female condom was used more often by women who achieved consistent condom use with a regular partner.[19] Thus, the female condom may be particularly useful for the design of interventions to promote safer sex within emotionally intimate relationships.[20]

Our research has a few potential limitations that should be considered when interpreting the results presented here. First, the nonrandomized design limits the validity of our inferences. For example, we cannot show conclusively that women who maintained consistent condom use by mixing types of condoms would have used the male condom inconsistently had it been the only option available. Such a hypothesis could have been tested only in a randomized trial comparing the intervention employed here with one promoting exclusive male condom use.

In addition, because the participants received an intensive behavioral intervention, the use patterns observed here cannot be generalized to women who do not receive such interventions, such as those who purchase the female condom over the counter. As the intervention was effective in promoting female condom use,[21] it is prudent to assume that the female condom would have been less acceptable and would have been used less frequently in the absence of the intervention.

Further, the behavioral outcomes of this study were self-reported, and thus were subject to bias. Conceivably, participants felt some pressure to report fewer acts of intercourse and more condom use than they actually experienced. To minimize recall errors and self-presentation bias, we collected data on sexual activity and condom use prospectively, using diaries. Participants also received incentives to return the wrappers of used condoms, which we used to assess the accuracy of self-reports. Compliance with these procedures was high, and the diaries were in good agreement with wrapper counts. The data used in this article represent the best evidence available to the interviewer, and it seems unlikely that sexual behavior and condom use were grossly misreported.

Finally, the study group was drawn from among at-risk women attending two urban STD clinics in Alabama; this is clearly a select group. While the women who refused to participate differed somewhat from those who agreed, the vast majority of eligible women agreed to participate, and the impact of refusal on the validity of the study could not have been large.[22] In addition, the characteristics of the women who agreed to participate but did not attend the initial visit were virtually identical to those of women who participated in the study. Thus, the selection process is not likely to have been a major source of bias.

Withdrawal from follow-up may also have been a source of bias, as only about 50% of the women who participated in the initial visit actually completed the six-month

follow-up protocol. We carried out a comprehensive analysis of potential determinants of retention, evaluating both baseline characteristics of the participants and time-dependent covariates (including sexual activity and condom use during follow up). Although the data suggest that women who were at high STD risk at entry, who were committed to using the female condom and who achieved consistent condom use during follow-up were selectively retained, the association of these potential predictors with retention was usually weak.[2,3]

As a result of selective retention of consistent condom users, the effectiveness of the intervention was overestimated.[2,4] The patterns of use presented here also are conditional on retention, and are likely to overestimate condom use during follow-up. On the other hand, the descriptive statistics of female condom use (such as the distribution of women according to the number of female condoms they used) are unlikely to be biased, as few women who withdrew from follow-up used the female condom after leaving the study. Analyses of potential determinants of trying the female condom are unlikely to be affected by withdrawal from follow-up, as most women who tried the female condom did so early in the follow-up period.

The comparison of exclusive female condom users with other groups may be affected by withdrawal from follow-up, as the likelihood of becoming a user of both the female condom and the male condom is a function of retention. On the other hand, most variables associated with retention were weak predictors, and it is likely that any bias affecting the associations described in this article is small.

In summary, although the study group clearly was not representative of the population at large, it consisted of women whose risk profile was highly relevant for the study of STD epidemiology and represents an important target for public health interventions. Selective recruitment into the study, selective retention of consistent condom users and information bias are unlikely to be important sources of bias for the analyses presented here. Thus, we believe that the strengths of the present study offset its limitations, and that important generalizations can be made from the study results.

Women at high risk of STDs can be encouraged to use barrier contraception consistently. When the female condom is positively promoted, many women find it acceptable, and some successfully integrate it into a pattern of consistent barrier-method use. The frequency of female condom use declines over time, however, and only a small proportion of women elect to use the device exclusively. Although our results indicate that a majority of couples at risk of STDs prefer the male condom to the female condom, promotion of the latter may help increase the overall level of barrier method use, through the mixing of condom types. The availability of the female condom may play an important role both in improving a woman's options for risk reduction and in reducing STD transmission in the population at large.

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