Short-Term Acceptability of the Female Condom Among Staff and Patients at a New York City Hospital

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An acceptability study of the female condom undertaken at New York's Harlem Hospital between August 1993 and February 1994 enrolled 52 women aged 18–57, 41 of whom (79%) used the female condom at least once. Of these, one-half used the female condom at least three times and 40% used it once; on average, women used it 2.4 times. Two-thirds of users liked the female condom either very much or somewhat, 20% were neutral and 15% stated that they did not like it. One-half of the women reported that their partner liked the device, while 17% said he felt neutral about it and approximately one-quarter said he disliked it. Seventy-three percent of respondents and 44% of their partners preferred the female condom to the male condom.

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The female condom (marketed under the brand name Reality®) was approved by the Food and Drug Administration in 1993 for reducing the risk of unwanted pregnancy and the transmission of sexually transmitted diseases (STDs), including the human immunodeficiency virus (HIV). The device is a six-inch-long polyurethane sheath that is closed at one end. A free-moving pliable ring encased in the closed end of the female condom aids the user in inserting the device properly; an outer ring at the open end rests against the vulva during use. Effectiveness rates for the female condom determined from contraceptive trials have ranged from a use-effectiveness rate of 79% to a method-effectiveness rate of 95% over one year of use.[1]

Worldwide acceptability data indicate that women are often eager to try a device that is under their control: At least 50% of women in most studies have liked using the device, despite initial concerns about its appearance.[2] In the vast majority of studies, partners have acquiesced to its use, and sometimes have preferred the device to a male condom.

In order to maximize effective and consistent use, an in-depth understanding of user preferences and needs is required. Such information will help shape training programs for counselors, outreach efforts into various communities and counseling messages for women. Furthermore, user feedback will indicate appropriate directions for the development of alternative protective methods for women.

We conducted a trial of the acceptability of the female condom, employing a novel counseling approach, among women who were staff members or patients at an inner-city hospital. We report here the reactions of users and their partners during the first few months of female condom use.

Methods

The study was undertaken at New York City's Harlem Hospital between August 1993 and February 1994. To be eligible, women had to be 18 years of age or older, able to understand English-language instructions, and able to return to the clinic for at least one follow-up visit. Subjects were recruited via flyers posted in Harlem Hospital and by word of mouth. Nurses and other staff members at the hospital's Infectious Disease Clinic were themselves encouraged to enroll in the study, as well as to inform patients of the planned research.

The study protocol was explained to the volunteers, they were asked to sign an informed consent document, and they were given a short self-administered questionnaire requiring approximately 10 minutes to complete. Study personnel were available to answer any questions about the form.

Instructional sessions were conducted in groups of 5–10 women. (Space limitations were the sole constraint on the size of these groups.) The correct use of the device was demonstrated on a plastic model of the female pelvis, and potential problems that might occur during use (and their solutions) were reviewed. Women were encouraged to demonstrate use of the female condom to the instructor, using the plastic model, if they had any questions regarding its insertion or removal.

All information and enrollment sessions were open both to new recruits and to participants making a follow-up visit, an arrangement that allowed new enrollees to benefit both from the instructor's teaching and from the experience of women who had already used the device. Discussions held following instructional lessons ranged from a few minutes to a half hour, depending on the composition and size of the group.

Each participant initially was given six female condoms (judged to be a two-week supply) and was requested to return in two weeks to complete a follow-up questionnaire and pick up new supplies. Participants were also offered free male condoms. Those who had intercourse more than three times per week were encouraged to return when they had depleted their supply. Subjects were strongly urged to read the package instructions accompanying the device and to try the method more than once.

At the follow-up visit, participants were given a short self-administered questionnaire, as well as additional female condoms. Thus, women who chose to continue using the female condom beyond the first two-week period filled out multiple follow-up questionnaires.

Data analysis was undertaken using Version 6 of SAS. We obtained simple frequencies for demographic variables and for outcome variables describing female condom use patterns. Bivariate associations between predictor and outcome variables were investigated using chi-square tests for categorical variables and Student's t-tests for continuous variables.

Results

Subject Characteristics

A total of 52 women were enrolled in the study; they ranged in age from 18 to 57 years, with a mean of 35 (Table 1, page 156). The majority were black and had been born in New York City. Two-thirds

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Table 1. Selected characteristics of women enrolled in trial of female condom, New York City, August 1993–February 1994 (N=52)

Variable	Mean or %
Mean age (in years)	35
Race	
Black	87
Hispanic	12
Other	1
% born in New York City	76
Marital status	
Married	21
Divorced	8
Separated	8
Single	63
Education	
Some high school	25
High school	8
Some college	46
College graduate	21
Mean no. of pregnancies	3.5
Median no. of pregnancies	2.5
Mean no. of births	2.0
% with at least one STD in past year	29
% who asked partner to use condom in past six months	
Yes	23
No	50
Partner offered	23
No partner in past six months	4
Mean no. of acts of intercourse in past month	5.5
HIV status	
Negative	37
Positive	29
Don't know	34

of the women in the study sample were single, while 21% were married; however, 94% reported that they had one main sexual partner. Fifteen women (29%) reported that they were HIV-positive.

Three in four had at least a high school degree, and 21% had graduated from college. The majority (73%) reported being employed at least part-time (not shown). Study participants had had an average of 3.5 pregnancies and a median of 2.5; they averaged 2.0 live births, with a range of 0–8. Approximately 30% reported having had an STD within the past year.

Contraceptive Use

At the time of enrollment, 39% of subjects reported that their male partner always used condoms; only 12% had never used condoms. Twelve women (23%) said that their partner always used a condom without the woman specifically requesting it. Male partners' use of condoms did not appear to be significantly associated with HIV status (p=0.17 using Fisher's exact test). However, all HIV-infected subjects reported some condom use, whereas 16% of HIV-negative women reported never having used condoms.

Previous use of female barrier methods was also relatively common. Nearly three-quarters (73%) of the women had used either a physical or chemical vaginal barrier—35% foam, 31% the diaphragm, 17% soluble spermicidal film, 17% the sponge and 4% the cervical cap.

Twenty-three percent of the respondents (12 women) had ever engaged in anal sex. Among this subsample, six of the women reported that their partner had never used condoms during this practice, four said that he sometimes used condoms and only two women reported that their partner always used condoms during anal intercourse.

Use of the Female Condom

Forty-one women (79%) used the female condom during the follow-up period. Seven other women did not have a chance to try it, mostly because of not being sexually active during that time. The remaining four women were lost to follow-up. In terms of key demographic variables, users did not appear to differ from those lost to follow-up (data not shown).

Of the 41 women who used the device, seven returned more than one questionnaire. For these women, we analyze in this article only their responses from the first questionnaire. (Among the women who submitted additional questionnaires, an analysis of data from their last follow-up questionnaire revealed no important differences in responses compared with those gathered from the first follow-up questionnaire.) Overall, participants used the female condom up to eight times, with a mean of 2.4 times. One-half of the sample used the device at least three times, and 40% used it only once.

Study participants were asked to rate their overall reaction to the female condom on a five-point Likert-type scale (0=liked very much, 1=liked, 2=felt neutral, 3=disliked and 4=disliked very much). As is shown in Table 2, the women were generally positive in their opinions (mean score of 1.1). Similarly, when the women were asked to rate the method's ease of use (using a Likert-type scale ranging from 0=very easy to 4=very difficult), insertion was considered relatively easy (1.2) and removal very easy (0.3).

Two-thirds of the sample (27 women) reported liking the device either very much or somewhat. An additional 20% were neutral in their response to its use. Fifteen percent stated that they did not like the device. Women who used the device more than once gave it a more satisfactory overall rating than did those who used it once (p=0.001).

Table 2. Mean scores on measures of attitude toward female condom among women who used device at least once (N=41)

Measure	Score
Opinion in general	1.1
Ease of insertion	1.2
Ease of removal	0.3
Partner's opinion in general	0.7

Note: Scores are not directly comparable because they are graded along different scales.

We obtained information about the male partners' reactions to the female condom by querying the participants; a four-point scale was used to evaluate women's perceptions of their partner's reaction (0=liked, 1=neither liked nor disliked, 2=disliked and 3=would not use). Nearly one-half (49%) of the women reported that their partner said that he liked the female condom, while another 17% reported that their partner apparently felt neutral; approximately one-quarter of the women in our sample reported that their partner disliked the device. (Approximately 10% of the women did not respond to the question.) Thus, the mean score for the partner's opinion indicated a relatively positive reaction. Furthermore, only 7% of the women indicated that their partner said he would not use the device again; 54% said that he would try the device in the future. (An additional 29% of women reported that although their partner did not say as much, they felt he would cooperate with their attempt to use the device again.) Three women (7%) believed that their partner would not agree to future use, although he had not said so. One woman felt incapable of responding for her partner.

Table 3 shows that, according to the women, the best-liked features of the female condom were, in order of reported frequency, that it made them feel protected (50%), that they liked the sensation (soft, natural, nondrying) of the device (31%), and that they appreciated the fact that they could feel responsible for and in control of their own protection, with no need to negotiate with their partner (19%). Asked to cite the features of the female condom that they liked the least, the women most often mentioned difficulties in inserting or removing the device (32%) or problems with the inner ring (24%); 20% each experienced problems in keeping the female condom in place during intercourse or complained of too much or too little lubrication with the device.

These dislikes reflect some of the problems that study participants reported with using the female condom. Fifteen percent of respondents reported that their partner's penis sometimes became inserted between the sheath of the device and the vaginal wall (a situation described in previous research as "penile misrouting"[3]). Seventeen percent of users reported that the device was inadvertently removed when their partner withdrew his penis, and 22% said that the female condom's outer ring was pushed into the vagina by the partner's penis in at least one instance.

Nearly three-quarters (73%) of respondents and more than two-fifths of their partners (44%) preferred the female condom to the male condom (Table 4). In contrast, 23% of respondents and 22% of partners preferred the male condom to the female condom. Small proportions in each group had no preference, and one-fifth of the women could not report whether their partner had any opinion.

Discussion

Since the first premarket appearance of the female condom, some have questioned whether men who would not themselves use male condoms would allow their female partners to use a female condom. While most of the study population had partners who would use male condoms at least occasionally, some had completely uncooperative partners. Nonetheless, we received no reports that a male partner refused outright to acquiesce to female condom use, and such refusals are also relatively rare in the literature to date.[4]

The reasons why men refuse to use male condoms are complex. A pilot study conducted in the same setting at Harlem Hospital asked subjects "What things might get in the way of you and your partner using a [male] condom?" Responses sometimes referred to the partner's difficulty in maintaining an erection while wearing a condom.[5] With the female condom, this ceases to be an issue, as the device is nonconstricting for the man.[6] Thus, for women with partners who find these types of issues to be obstacles to their own condom use (versus, for example, deep-seated machismo or trust issues that would operate for any detectable form of protection), the female condom provides the first real protective option against STDs and AIDS. In addition, women have learned ways to incorporate the use of the female condom into a sexual sequence, without an awkward interruption, further increasing the chance that the device will be used consistently.[7]

This study was greeted with a very high level of enthusiasm in the clinic. Nurses and patients alike were eager to see and discuss the female condom. Qualitative material from discussion sessions suggested that the availability of the female condom gave women a new confidence and sense of control; this perception was borne out in responses to the questionnaire. Furthermore, a group discussion design was greatly appreciated by the subjects, with many indicating that they did not often get the opportunity to discuss sexual or relational matters with other women. Even differences among the study subjects by professional and economic status (i.e., the inclusion of both staff members and patients) did not seem to inhibit frank conversation.

A previous pilot study conducted at Harlem Hospital suggested that exposure to women's barrier methods of protection (spermicides, diaphragm and cervical cap) imbued women with a greater sense of comfort and confidence about their bodies, and aided in male condom negotiation, perhaps because of a newfound assertiveness or an increased sense of self-worth.[8] A small female condom study conducted among black women in New Orleans uncovered similar findings. The author found that when women no longer had to plead with men to use male condoms, they discovered "the power and right to refuse unsafe sex."[9] Although these findings require more elaboration and corroboration in other settings, the limited data suggest that the benefits to women of female condom use may extend far beyond what the device offers in terms of protection against STDs, HIV infection and pregnancy.

Women in our study used the female condom fewer times than we had expected they would, with 40% using it only once. This is particularly surprising, given that the devices were free. However, access to these free condoms was severely reduced by the limited number of hours study personnel were available to distribute them—only two hours per week, during working hours. In addition, we had decided to limit the number of female condoms given out each week to a two-week supply, in an attempt to encourage women to return. However, nonstaff study participants often had multiple commitments (child and family care, employment and medical appointments, among others) that were time-consuming and precluded regular appearances at the study site. Furthermore, our study was conducted during the winter, when weather often made hospital visits more difficult. Finally, other staff commitments sometimes conflicted with follow-up sessions.

The results of this small study regarding acceptability are in agreement with those of other studies on the female condom.[10] More than one-half of study subjects liked the female condom, with a somewhat smaller proportion of partners liking the device. Between 15% and 22% of subjects experienced problems with the female condom that theoretically could put them at greater risk of direct exposure to the penis or semen (such as displacement of the device and penile misrouting). These findings underscore the need for careful counseling on these points, and an emphasis on the need for a moderate degree of vigilance, especially among new users. Added lubrication has been recommended by the manufacturer as a strategy to help keep the female condom in place.

Nearly one-quarter of users in our study indicated that they felt the inner ring during intercourse, although only two women asked whether they could use the device without the inner ring. These women were counseled to insert the female condom with the inner ring inside the device, then add lubricant, and finally to remove the inner ring with an index finger, being careful not to pull the pouch away from the cervix. Both women in this study who modified use of the device in this way had no problems or discomfort subsequently.

Table 3. Percentage of women citing features of female condom that they liked most and liked least

Features	%
Most-liked (N=32)	
Felt protected, confident, safe	50
Agreeable feel of device*	31
Felt responsible or in control, liked change in roles, felt no need to negotiate	19
Least-liked (N=25)	
Removal or insertion	32
Inner ring	24
Need to guide partner, did not stay in place	20
Too much/too little lubrication	20
Noise	4

*Such as softer, does not dry out, more natural, "cleaner" and warmer (as compared with the male condom).

Table 4. Percentage distribution of women by their opinion of female condom relative to male condom and their partner's opinion (N=41)

Opinion	Women	Partners*
Liked better than male condom	73	44
Liked the same as male condom	5	12
Liked less than male condom	23	22
Unknown	na	22
Total	100	100

*One woman did not respond to this question. *Note:* Percentages are rounded and do not necessarily add to 100%. na=not applicable.

Because of the relatively small number of multiple follow-up questionnaires collected, we could not assess changes over time in women's attitudes toward this method. We encouraged participants to use the female condom more than once, given that women are generally not encouraged to use vaginal methods and may not feel comfortable about touching their genitals. Anecdotal evidence from group discussions suggested that women's attitudes changed substantially after their first one or two uses of the device.

Although there was an association between the number of times the device was used before a first follow-up visit and a woman's rating of the device, this could simply reflect a self-selection for continued use among women who were initially satisfied, rather than an effect of greater experience on user satisfaction. Studies of longer duration will be required to provide more definitive data on this question. Anecdotal data suggest that as has been found with other barrier methods, greater user experience with the female condom helps resolve any initial problems or concerns and thus increases satisfaction.

One-quarter of our population had practiced anal intercourse, the riskiest form of sex for transmission of HIV. This proportion is in line with other reports indicating a 10–50% prevalence of anal intercourse, depending on the sample.[11] The proportion of HIV infections among women that are attributable to anal intercourse is not known, but in some populations it may indeed compete with the risk attributable to vaginal intercourse. Nonetheless, methods for women to use as protection during anal intercourse are not being developed in tandem with methods for vaginal protection, although the need clearly exists.

While the female condom is not FDA-approved for use during anal intercourse, it may be modifiable for such use (for example, by removing the inner ring). This approach, as well as others, should be studied further. We are aware of only one (unpublished) study of the female condom for use in anal intercourse among gay men; it found that this method was acceptable to some men.[12]

The women enrolled in this study were not representative of the general population of U.S. women; for one thing, their reported rates of their partners' male condom use were relatively high. In our study, the frequency of male condom use did not differ statistically according to HIV serostatus. A previous study of STD clinic patients also found the prevalence of male condom use to be higher than national estimates, and suggested that "clients recognize their increased risk for STDs and try to adjust accordingly."[13]

Many women in this study who were not HIV-infected worked in the clinic and conducted daily counseling on male condom use, and might therefore be more persistent in negotiating male condom use than were women not living or working in a high-risk community. The same was true for nearly one-half of the HIV-infected women, who conducted street outreach AIDS education and referral.

This article does not address the long-term acceptability of the female condom, nor did it include women who perceived themselves to be at little or no risk of STDs or of HIV infection. Future work on these issues is crucial to the public health impact of this new method of protection.

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