

# Acceptability of the Female Condom Among Sex Workers in Thailand

## Results From a Prospective Study

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**Background:** The female condom may provide women with the first female-controlled barrier method that is effective against sexually transmitted diseases, including HIV infection.

**Goal:** This study evaluated the acceptability of the female condom among sex workers in Thailand.

**Study Design:** Data on use and acceptability of the female condom were collected using a structured questionnaire during an 8-week follow-up.

**Results:** Analyses included 148 women who were still in follow-up at week 8. Sex workers used, on average, 2.8 female condoms per week. The overall satisfaction rate with the female condom was 68%, although, among users, 31% had difficulties in device insertion, 37% had pain from the inner ring, and 22% reported itching sensations. The main reason for using the female condom in the future was its perceived safety, and the main reason for not using it would be the client's refusal.

**Conclusion:** Two-thirds of the sex workers were satisfied with the female condom. Difficulties at insertion, discomfort during use, and clients' attitude were potential obstacles to the use of the female condom in the future.

THE MALE CONDOM is the most effective barrier method currently available for the prevention of sexually transmitted diseases (STDs), including HIV infection.<sup>1</sup> This has been evidenced in studies of couples with discordant HIV serological status, with virtually no HIV transmission occurring when the condom is used correctly and consistent-

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ly.<sup>2,3</sup> The likelihood of using a male condom on every act of intercourse may seem questionable, because women wanting to protect themselves have to rely mainly on their partners' willingness to use a condom. The recently developed female condom may eventually provide women with the first female-controlled barrier method that is effective against STDs, including HIV infection.<sup>4,5</sup>

Since the beginning of the 1980s, male condom use has been actively promoted in Thailand as a means of protecting the population against STDs, including HIV infection. The promotion took place through an efficient program called the "100% condom program,"<sup>6,7</sup> and focused on sex establishments where most young Thai men would have their first sexual experience.<sup>8-10</sup> Although male condom use rose to high levels (>90% of sex acts in sex establishments) during this campaign,<sup>6,11</sup> still there were some clients who refused to use male condoms. This left sex workers with the unsatisfactory alternatives of taking unacceptable risk by having unprotected sex, by sometimes being abused by clients,<sup>12</sup> or by losing income by turning away these clients. Therefore, this study was designed to assess the additional protection offered to sex workers by giving them access to female condom use with clients who refused to use a male condom. Results on the effectiveness of this strategy, compared to male condom use alone, were reported elsewhere.<sup>13</sup> This paper reports the findings on the acceptability of the female condom among the sex workers and their clients.

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## Methods

### Study Design

Sex establishments from four different cities in Thailand (central Bangkok, central; Khon Kaen, northeast; Chiang Mai, north; Hat Yai, south) participating in a program of early diagnosis and treatment of STDs were considered for this study. Only sex establishments where sex workers reported having several Thai clients per day were included in the trial.

Participants were randomized into two groups by sex establishments and not by individuals, so that sharing of female condoms across study groups would be minimized. The two groups were: (1) the male condom group, in which sex workers would propose that their client use a male condom, and, if clients refused or could not use a male condom, they were instructed not to have sex; and (2) the male/female condom group, in which women, as a first choice, would propose that their client use a male condom, but would have the option of using a female condom if clients refused or could not use a male condom. Verbal explanation of the purpose of the study was given to all women. Eligible women were at least 18 years of age; not using a diaphragm, a cervical cap, or vaginal spermicides; had no evidence of STDs, pregnancy, or intravenous drug use; were willing to use the condoms as instructed, and willing to keep a pictorial coital log recording all sex acts with clients and noncommercial sex partners. After informed consent was obtained, women were interviewed regarding demographic variables, sex practices, and medical history. A physical examination, including a pelvic examination, was performed. Vaginal specimens were collected and tested for trichomonas and yeast, endocervical specimens for *Neisseria gonorrhoeae* culture and *Chlamydia trachomatis* test by enzyme-linked immunoassay (ELISA), and urine specimens for a pregnancy test. All women were counseled regarding transmission of HIV and other STDs and condom use; and each was given a free supply of condoms thereafter.

Effective enrollment started 1 week after the screening visit, when results of clinical and laboratory examinations confirmed that women were not pregnant and had no evidence of trichomoniasis, candidiasis, genital ulcer disease, gonorrhea, or chlamydial infection. During the week prior to enrollment, women from both groups were individually taught by a trained nurse how to complete the coital log. In addition, women in the male/female condom group followed a diagram to learn how to insert a female condom. Sex workers were also given a pictorial leaflet illustrating the proper fitting and discarding of female condoms and explaining the handling of common problems, such as improper insertion or penile misrouting. Each woman was required to fill out a hypothetical coital log diary. The duration of the training session was around 30–45 minutes.

During this training week, women who had problems using female condoms were asked to visit the clinic as needed. Sex workers who were diagnosed with STDs during the screening visit, were not enrolled until a cure was obtained.

Sex workers were asked to return for a follow-up every 14 days for 24 weeks. At each follow-up visit, women completed a questionnaire on medical history and sex practices. A pelvic examination was performed, and vaginal specimens were collected and tested for trichomonas and yeast, and endocervical specimens for chlamydia and gonorrhea. After vaginal examination, the coital log was reviewed with the interviewer, and women were given a new supply of condoms. If an STD was diagnosed, women were treated free of charge with antibiotics according to the national standards; they were re-enrolled into the study only if there was no clinical or laboratory evidence of STDs at the next follow-up visit. At weeks 8, 16, and 24, a detailed questionnaire on the acceptability of the female condom was administered to the women in the male/female condom group. The review included questions on experiences with the use of the female condom (ease of insertion, pain, discomfort, misuses, etc.), satisfaction with the device, clients' reactions, and future prospects about female condom use.

This protocol was reviewed and approved by the Secretariat Committee on Research Involving Human Subjects (SCRIHS) of the World Health Organization and by the Thai National Ethics Committee.

### Statistical Methods

The analyses described in this paper focus solely on the acceptability of the female condom, and the determinants of its use. Thus, women enrolled in the male condom only group have not been considered in this analysis. Loss to follow-up was considerable, and, thus, the analysis on women with follow-up data was done at week 8, and not at week 24, so that the number of sex workers available for comparison between groups would be large enough for meaningful statistical testing (the proportion of women who completed the 24 weeks of follow-up was only 27%).

The characteristics of the study participants were described using means and proportions, and compared between trial groups using Mann-Whitney *U* test and chi-square test where appropriate. For the comparison of proportions, tests of significance were adjusted for the clustering of events by sex establishments (the unit of randomization), after estimation of the design effect. Proportions within same individuals at different time periods were compared using the McNemar test. The coital logs recorded by the sex workers were used to compute the number of sex acts, the number of male and female condoms used during sex acts, and the number of condoms torn or slipping in or out during the study. The predictors of using a high number

of female condoms ( $\geq 14$  devices) during each 2-week period were identified using a generalized estimating equation (GEE) model for binary outcome, taking into account the correlation among repeated measurements from the same subjects. Variables kept in the model were those with a *P* value less than 0.05. All statistical analyses were carried out using Stata statistical software version 6.0 (Stata Corporation, College Station, Texas).

## Results

Of the 330 women who agreed to participate in the study and who were randomized to the male/female condom group, 276 (84%) were enrolled. The reason for nonenrollment was the presence of an STD at the screening visit, and failure to return to the clinic for a new examination after STD treatment was provided. The 276 women enrolled were working in 34 different sex establishments (mean and median number per sex establishment were 8.1 and 7, respectively). The majority of the sex workers were between 20 and 29 years of age (55%), Thai (86%), adopted sex work for two years or less (59%), used condoms consistently (69%), and considered themselves at risk of HIV infection (84%). The mean (median) reported number of clients per day, for the 3-month period preceding study entry, was 3.2 (3), and the mean (median) charge per client was 383 (120) Baht (1 \$US = 25 Baht in 1994) (Table 1).

At the end of the 1-week trial period prior to enrollment (week 0), coital log data were available for 272 (99%) of the 276 women subsequently enrolled. Of these 272 women, 101 (37%) had not used any female condom during week 0. Reasons for not using a female condom were: unwillingness (22%), all clients agreeing to use a male condom (16%), clients refusing after the sex workers talked about it (13%), clients refusing after seeing the device (19%), and other reasons (29%). Of the 171 (63%) sex workers who used at least one female condom, although the majority said that they were satisfied with the device (67%), many complained of difficulties at insertion (36%), pain (48%, including 38% having pain around the inner ring, 17% around the outer ring, and 8% elsewhere), excess of lubrication (41%), itching (10%), and excessive length (36%).

Of the 276 women enrolled, 159 (58%) attended the week 8 follow-up visit, and 148 (54%) had had complete coital log data at the last follow-up visit (week 7-8). As shown in Table 1, as opposed to women without follow-up data (*n* = 128), women with follow-up data (*n* = 148) were older, were more likely to be of Thai nationality, had more years of schooling, used condoms less consistently, were more aware of the risk of HIV infection, and were more likely to have heard of the female condom before. Also, they were more likely to have had difficulties in inserting the female condom (45% and 24%, respectively, *P* = 0.007) and to

have had pain while using the female condom during week 0 (55% and 39%, respectively, *P* = 0.04).

The analysis on frequency of sex acts and condom use over the total follow-up period (8 weeks) was carried out among sex workers with complete coital log data for each of the four follow-up visits (*n* = 101). Among these women, the mean (median) total number of sex acts was 168.3 (141), or an average of 21.0 per week; the mean (median) total number of male condoms used was 147.6 (121), or an average of 18.5 per week; the mean (median) total number of female condoms used was 22.6 (11), or an average of 2.8 per week; and the mean (median) total number of unprotected sex acts was 3.7 (0), or an average of 0.5 per week. Nine women (8.9%) did not use any female condom. The distribution of the mean number of condoms used for each 2-week follow-up period is shown on Figure 1. Slippage and tearing of condoms were relatively common events: 229/14907 (1.5%) and 312/14907 (2.1%) for male condoms, respectively; and 121/2285 (5.3%) and 14/2285 (0.6%) for female condoms, respectively. However, these events clustered among few individuals: 169/229 (73.8%) of all slippage events and 249/312 (79.8%) of all tearing events with the male condoms occurred among 9 and 18 users, respectively; and 93/121 (76.9%) of all slippage events and 14/14 (100%) of all tearing events with the female condom occurred among 10 and 9 users, respectively. In a GEE model, the following predictors of using a high ( $\geq 14$  devices) number of female condoms per 2-week period were identified: being 22 years or older, the total number of sex acts during the corresponding 2-week period, the number of female condoms used during the week 0 trial period, having reported satisfaction with the female condom at the end of the week 0 trial period, and having clients reluctant to use a male condom (see Table 2).

During the week 8 evaluation, only one-third of the sex workers (47/145 = 32%) reported that clients always agreed without discussion to use male condoms (three had no opinion). The main reasons for clients' unwillingness to use male condoms, as reported by the sex workers, were: decrease in sexual pleasure (56%), interruption of sex act (19%), drunkenness of clients (7%), incomplete protection against HIV/STD (3%), and other reasons (16%). With clients who were reluctant to use male condoms, the female condom could be used as a negotiating tool, as shown by the high proportion of women (82/136 = 60%) whose clients agreed to use a male condom after learning that the only alternative was the female condom. With clients who definitely refused to use any type of condom, 24/146 (16%) sex workers still agreed to have sex.

At the week 8 evaluation, 88/148 (59%) women had used at least one female condom in the past 2 weeks. When asked about their level of satisfaction with the female condom, 66 (79%) were satisfied, and 18 (21%) were not (four had no opinion). The majority of users acknowledged that female

TABLE 1. Sociodemographic Characteristics and Sex Work History at Enrollment, Comparing Women With and Without Follow-up Visit at Week 8

Characteristics	Total (%) N = 276	With (%) n = 148	Without (%) n = 128	P Value
Age category (y)				
<20	67 (24)	28 (19)	39 (30)	
20–24	98 (36)	51 (34)	47 (37)	
25–29	55 (20)	32 (22)	23 (18)	0.12
30–34	39 (14)	24 (16)	15 (12)	
35–39	12 (4)	8 (5)	4 (3)	
40–44	5 (2)	5 (3)	0 (0)	
Thai nationality				
Yes	236 (86)	139 (95)	97 (76)	<0.001
No	39 (14)	8 (5)	31 (24)	
Missing	1	1	0	
Education (y)				
0	55 (20)	21 (14)	34 (27)	
1–6	198 (72)	114 (77)	84 (66)	0.05
>6	23 (8)	13 (9)	10 (8)	
Years of sex work				
≤1	107 (39)	48 (32)	59 (46)	
2	54 (20)	32 (22)	22 (17)	0.05
3–4	60 (22)	33 (22)	27 (21)	
5–15	54 (20)	35 (24)	19 (15)	
Missing	1	0	1	
Clients per day, mean [median]	3.2 [3]	3.45 [3]	3.0 [3]	>0.05
Charge per client (Baht),* mean [median]	383 [120]	400 [150]	364 [100]	>0.05
Frequency of condom use with clients				
Never (0/5)	7 (3)	6 (4)	1 (1)	
Rarely (1–2/5)	4 (1)	2 (1)	2 (2)	
Sometimes (3/5)	25 (9)	20 (14)	5 (4)	0.06
Often (4/5)	49 (18)	27 (18)	22 (17)	
Always (5/5)	190 (69)	93 (63)	97 (76)	
Missing	1	0	1	
Has sex with clients who do not want to use male condoms?				
Yes	60 (22)	37 (25)	23 (18)	0.31
No	215 (78)	111 (75)	104 (82)	
Missing	1	0	1	
Considers herself at risk for HIV infection				
Yes	231 (84)	133 (90)	98 (78)	
No	43 (16)	15 (10)	28 (22)	0.01
Missing	2	0	2	
Has heard of the female condom				
Yes	142 (52)	86 (58)	56 (44)	
No	132 (48)	62 (42)	70 (56)	0.01
Missing	2	0	2	

\*1 \$US = 25 Bahts (in 1994).

condom use had become easier (69%), and more comfortable (67%), with practice. However, a substantial proportion of women still had difficulties in inserting the female condom (31%), suffered from pain from the inner (37%) or outer (9%) ring, found an excessive lubricant at insertion (55%) or during coitus (46%), suffered from itching sensations (22%), or found that the female condom was too long (41%). Of note, these proportions were similar to those found among the same women after their first week experiences with the female condoms (Table 3). During weeks 7–8 of the trial, sex workers experienced various incidents while using the female condoms, such as: female condoms being pushed inside during intercourse (6% of the sex workers); the device slipping outside during intercourse

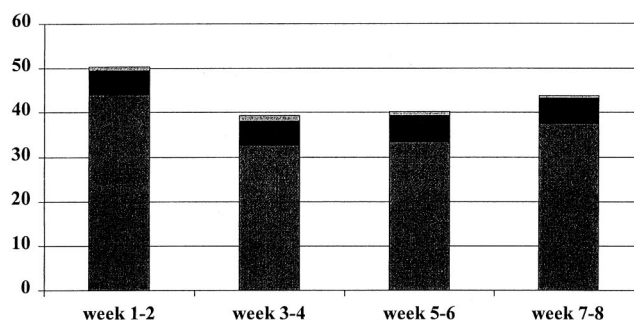


Fig. 1. Mean number of condoms used per 2-week period (medium grey: male condom; dark grey: female condom; light grey: no condom).

TABLE 2. Predictors of High ( $\geq 14$  Devices) Female Condoms Use Per 2-Week Period (n = 74)

	OR*	95% CI
Per additional sexual act in the 2-week period	1.02	1.01–1.03
Age < 22 years (25 <sup>th</sup> percentile)		
No	1	
Yes	0.17	0.05–0.61
Per additional female condom used during the trial period	1.29	1.15–1.44
Was satisfied with the female condom during the trial period		
No	1	
Yes	3.37	1.04–10.95
Had clients reluctant to use male condoms		
No	1	
Yes	1.65	1.16–2.34

\*Obtained from a generalized estimating equation (GEE) model for binary outcome, taking into account the correlation among repeated measurements from the same subjects. OR = odds ratio.

(7%); clients pulling the female condom out before sexual intercourse (6%); clients pulling the female condom out during sexual intercourse (12%); client's penis going be-

TABLE 3. User Experiences With the Female Condom at Week 0 and Weeks 7–8 (n = 86)

	Week 0 n (%)	Week 7–8 n (%)	P Value
Female condoms used (per week), mean (median)	3.6 (2)	3.8 (1)	>0.05
Had difficulties in inserting the female condom (n = 77)			
Yes	30 (39)	24 (31)	>0.05
No	47 (61)	53 (69)	
Suffered from pain with the inner ring			
Yes	34 (40)	32 (37)	>0.05
No	52 (60)	54 (63)	
Suffered from pain with the outer ring (n = 85)			
Yes	10 (12)	8 (9)	>0.05
No	75 (88)	77 (91)	
Found the female condom itchy			
Yes	11 (13)	19 (22)	0.08
No	75 (87)	67 (78)	
Found the female condom noisy (n = 85)			
Yes	21 (25)	23 (27)	>0.05
No	64 (75)	62 (73)	
Found the female condom too long (n = 83)			
Yes	27 (33)	34 (41)	>0.05
No	56 (67)	49 (59)	
Found that there was too much lubricant at insertion (n = 85)			
Yes	32 (38)	47 (55)	0.004
No	53 (62)	38 (45)	
Found that there was too much lubricant during sex (n = 85)			
Yes	28 (33)	39 (46)	0.03
No	57 (67)	46 (54)	

tween the female condom and the vaginal wall (11%). Although 66/85 (78%) of women said that they would occasionally use the female condom with their clients if it became available, 54/84 (64%) said that they would prefer using the male condom only. The main reasons given for using the female condom were its perceived safety (for 51% of sex workers), under a woman's control (27%), comfortable (11%), and that clients would prefer it to the male condom (10%). The main reason, (66%), for not using it was that the clients would refuse it. Overall, 70/84 (83%) of sex workers said that they would recommend the female condom to their friends.

The determinants of the sex workers' satisfaction with the female condom were also studied. For this analysis, the 66 women who said that they were satisfied were categorized as "satisfied," and the 18 who said that they were not were categorized as "not satisfied." Thirteen women, who said that they did not use any female condom in the past 2 weeks because they did not want to, and who had had complete data on the week 8 visit, were added to the category of women who were "not satisfied" with the female condoms (for a total of 18 + 13 = 31 women in that category). Thus, the overall satisfaction rate with the female condom was 68% (66/97).

The 66 women who were satisfied with the female condom did not differ from the 31 women who were not satisfied in terms of sociodemographic characteristics. Among the 84 women who had used at least one female condom during the past 2 weeks, the satisfied women had, compared to the nonsatisfied women, experienced fewer difficulties in inserting the female condom at week 0 (27% versus 56%,  $P = 0.05$ ), less pain at week 0 (42% versus 78%,  $P = 0.002$ ) and at weeks 7–8 (29% versus 56%,  $P = 0.05$ ), and less itching sensations at weeks 7–8 (15% versus 39%,  $P = 0.05$ ).

## Discussion

The female condom is a prelubricated, disposable, polyurethane vaginal sheath with two rings: one inside the closed upper end, which fixes around the cervix, and the other at the wider open bottom which forms the external edge of the sheath and remains outside the vagina after insertion. In vitro and few in vivo data suggest that it is as efficacious as the male condom in preventing pregnancy<sup>14–16</sup> and HIV/STDs.<sup>17,18</sup> However, its effectiveness (i.e., combination of efficacy and compliance) largely depends on its acceptability for both women and men. Several studies have evaluated female condom acceptability in various contexts in different settings.<sup>19–29</sup> However, such studies need to be repeated in each situation where female condoms potentially may be used, since acceptability may vary according to cultural factors, circumstances of use, and perceived preference and benefit of individual persons. This

study, focusing on the acceptability of the female condom among sex workers in Thailand, is unique for its prospective study design and meticulous use of a coital log to complement data obtained from a standard questionnaire.

The study has shown important findings regarding the acceptability of the female condom among sex workers in Thailand. However, a few study limitations should be borne in mind when the results are interpreted. First, the study was designed to examine the effectiveness of an intervention using the female condom as a back-up method with clients refusing to use male condoms: thus, sex workers were asked to use female condoms only with clients who refused male condoms. Therefore a low use of the female condom may correspond to sex workers who either did not want to use the female condom, or who had clients consistently using the male condom, or whose clients refused to use a female condom. Also, the female condom was evaluated with clients who had already rejected the male condom and were thus possibly predisposed to be negative regarding the use of other barrier methods. The second limitation of the study was the participants' considerable loss to follow-up. Sex workers are a mobile population, difficult to trace, and only 159/276 (58%) women were available for analysis after 8 weeks. Follow-up had continued for up to 24 weeks, but results were not presented because of low numbers. Women retained in the study were more likely to be older, of Thai nationality, better educated, with more years of sex work, and aware of the risk of HIV infection, compared to women lost to follow-up. Of note, women with more negative, rather than positive, experiences with the female condom during the 1-week trial period were more likely to stay in the study. This may have resulted in an underestimation of the true satisfaction rate with the female condom. The third limitation of the study was its reliance on a coital log to measure the number of male and female condoms used, with no parallel validation studies such as clients' interview or counting of used condoms. Besides the possible mistakes in filling the coital log, if done retrospectively for instance, biases may result from the fear of sex workers to report no condom use in the context of a Thai policy promoting 100% condom use in sex establishments.

The majority of the sex workers in this study were 20 to 29 years of age, of Thai nationality, and had been in sex work for two years or less. During the 8-week study period, sex workers had, on average, 21 sex acts per week, out of which 0 to 1 were unprotected, 18 were with male condoms, and 3 with female condoms. Although slippage and tearing of the female condom were relatively common events (5.3% and 0.6%, respectively), they tended to occur among few individuals. Indeed, 77% of all slippage events and 100% of all tearing events occurred among 11% and 10% of all female condom users, respectively. We have also previously reported that slippage events were more common during the first week of use (10% of all users), and tended to disappear

over time.<sup>13</sup> Women starting to use the female condom should therefore be made aware of the increased risk of slippage during first trials, and should be warned to ask further advise if slippage tends to recur.

The analysis of the predictors of high condom use should be taken cautiously, for the reasons mentioned at the beginning of this discussion. Nonetheless, the predictors identified in the GEE model were all quite logical, and thus deserve consideration. Sex workers more likely to use the female condom were older, were more sexually active, had better experiences with the female condom during the 1-week trial period (higher satisfaction rate and larger number of female condoms used), and more often had clients reluctant to use male condoms with whom they would be ready not to use any condom were the female condom not available. Overall, the use of the female condom was largely related to the personal experience of the sex workers with the device, and to the acceptability among clients. This latter point was further exemplified by the high proportion (32%) of clients' refusal among the reasons why sex workers did not use any female condom during week 0. In focus group discussions carried out at one site, the unattractive physical appearance of the female condom over the sex worker's vulva was the main reason for clients' dissatisfaction.<sup>28</sup> Clients' refusal of the female condom may however have a positive outcome if the female condom can be used as a negotiating tool to induce male condom use,<sup>30</sup> as was experienced by 60% of the sex workers during the 8-week follow-up period.

The overall satisfaction rate with the female condom was 68%. This rather promising result should be balanced with the substantial proportion of women who still complained at week 8 of difficulties in inserting the female condom (31%), pain while using the female condom (43%), excess of lubricants (56%), itching sensations (22%), and excessive length (41%). Although the majority of women found the female condom easier to use and more comfortable with practice, the proportion of women complaining of inconveniences related to the device did not change over follow-up (Table 3). Other studies have identified similar complaints, namely: difficulties at insertion,<sup>21,22,27,29</sup> pain/discomfort,<sup>19,22,23</sup> excessive lubricants,<sup>21</sup> and excessive length.<sup>21,22</sup> Instruction on use and practice with the help of peers have been shown in other studies to strengthen confidence in how to use the device.<sup>29,31</sup> Pain, reported as discomfort in other studies, would be a serious concern if it were associated with lesions, which may facilitate HIV transmission in the absence of condom use. In this study, investigators were asked to systematically examine the genital mucosa for the presence of erosions, ulcerations, and bruises, which might have been related to the use of male or female condoms. Investigators were instructed to tell women to stop using the female condom if they thought that genital lesions might be related to its use, and to inform the trial monitor immedi-

ately if such events occurred. In fact, there was no significant macroscopic genital lesion associated with long-term use of the female condom in this study, suggesting that the female condom was safe, as was observed in previous studies.<sup>32</sup> Nonetheless, vaginal colposcopy, which is often difficult to interpret in sex workers, would be required to rule out lesions not visible by speculum examination. The satisfaction rate with the female condom largely depended on the presence/absence of such complaints. Although 78% of the women who used the female condom throughout the trial period said that they would use the female condom with their clients if it became available, 64% said that they would prefer to use the male condom. The main reason for using the female condom in the future would be its perceived safety, whereas the main reason for not using it would be clients' refusal.

In conclusion, the female condom was found to be acceptable by the majority of the sex workers in this study, although many women experienced difficulties in inserting the device, or discomfort during use. Another factor, which may compromise the future use of the female condom in sex work, is its acceptability among the clients. Additional safe and effective female-controlled HIV/STD prevention methods, such as vaginal microbicides, are urgently required.<sup>33</sup>

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