

PN-ARU-361  
93664

**CONSUMER PREFERENCE STUDY OF A MODIFIED FEMALE  
CONDOM IN A SEXUALLY ACTIVE POPULATION AT RISK OF  
CONTRACTING AIDS**

**Final Report**

**Chuanchom Sakondhavat, M.D.**  
**Department of Obstetrics and Gynecology**  
**Faculty of Medicine**  
**Khon Kaen University, Khon Kaen, Thailand**

**Carol L. Joanis**  
**Associate Director Market Research**  
**Family Health International**  
**Research Triangle Park, NC, USA**

**March, 1993**

## **ACKNOWLEDGEMENTS**

The authors gratefully acknowledge the financial assistance and support given by Family Health International (FHI). In addition, thanks are to be extended to the Wisconsin Pharmacal Company for providing free supplies of the modified female condom. The cooperation and enthusiasm of the study participants, investigators and other parties involved are greatly appreciated and were indispensable to the success of this research. Finally, Tony Bennett was a valuable communication link between the investigators and FHI and contributed significantly to the management of the project.

This project was funded by FHI under a Cooperative Agreement with the United States Agency for International Development (USAID). FHI is an international, non-profit organization which conducts research and provides technical assistance in health, family planning, sexually transmitted diseases (STDs) and the Acquired Immune Deficiency Syndrome (AIDS). The company is based in Research Triangle Park, North Carolina, USA. The views expressed in this document are not necessarily those of USAID.

Additional investigators in Thailand that deserve special mention: Dr. Yuthapong Werawatakul, Mrs. Pattamavadee Pinitsoontorn, Ms. Chusri Kuchaisit, Mr. Soontorn Sakummai, Mrs. Pannee Kukieattikool, and Mrs. Kemtong Pongsatra. Ms. Carol Joanis was FHI's Project Director for this study and Mr. Jim McMahan was the Project Monitor. The authors also wish to thank Ms. Kazu Martínez, Mr. Scott Lamm, Ms. Kathy Hinson and Ms. Pat Stewart for their assistance in completing this manuscript.

## **ABSTRACT**

In early 1989, the female condom was evaluated by a group of twenty women in Thailand at high risk of contracting sexually transmitted diseases. This evaluation resulted in findings that the female condom, as it was then designed (sized), was too large and uncomfortable for the majority of women in the study population. Further, self application of the lubricant compounded the sizing problem, making the device messy and difficult to handle.

While most women preferred the male condom over the female condom, incorrect device sizing and inappropriate product presentation, could have negatively biased study results. A decision was made to repeat the study using a smaller, pre-lubricated female condom. In the second round of testing, twenty-one women at high risk of contracting sexually transmitted diseases evaluated a modified version of the female condom during 132 acts of coitus (18% of episodes).

Seventy-one percent (n=15) of the participants liked the condom while six of them (29%) reported that they disliked the product. Pre-lubricating the device did not improve ease of use or acceptability. Shortening of the length of the condom may have had an impact on improved positioning of the device, however. As a result, 95 percent of the users reported that both inner and outer rings stayed in place during intercourse. Most participants experienced some difficulty inserting the device, however twenty of the women felt that they had had sufficient instruction to use the female condom correctly.

While ninety percent would recommend it to others, less than half of the women would consider using the female condom in the future. The reasons for discontinuing use were that male partners objected to the device and that the inner ring was too hard and caused discomfort. The modified female condom did cause minor discomfort for most participants, as such, most preferred the male condom when there was a choice.

**TABLE OF CONTENTS**

**I. INTRODUCTION ..... 5**

**II. OBJECTIVES ..... 7**

**III. MATERIALS AND METHODS ..... 7**

**IV. RESULTS ..... 8**

**V. COMPARISON OF RESULTS BETWEEN TWO TRIALS ..... 12**

**VI. DISCUSSION ..... 14**

**VII. REFERENCES ..... 14**

**VIII. TABLES 1-14 ..... 16**

**APPENDIX A: FACT SHEET**

**APPENDIX B: VOLUNTARY AGREEMENT FORM**

**APPENDIX C: ADMISSION QUESTIONNAIRE**

**APPENDIX D: FOLLOW-UP QUESTIONNAIRE**

## **I - INTRODUCTION**

The female condom was developed by a Danish gynecologist expressly for the purpose of preventing the transmission of the Human Immunodeficiency Virus (HIV) which causes the Acquired Immune Deficiency Syndrome (AIDS) and other sexually transmitted diseases (STDs). The female condom represents another alternative in barrier methods and provides women with a method that is under their control and which offers protection against AIDS, STDs, and unintended pregnancy. The Wisconsin Pharmacal Company, Inc. a privately owned firm, acquired a patent and exclusive manufacturing and marketing rights for the United States in April, 1988. Wisconsin Pharmacal is currently seeking Food and Drug Administration (FDA) approval for this device.

A clinical trial for efficacy against pregnancy was conducted by FHI in conjunction with CONRAD (Contraceptive Research and Development). These trials began at sites in the U.S., Mexico and the Dominican Republic in May of 1990. Consumer preference studies of the device have been conducted in Denmark, the United Kingdom, Sweden and West Germany. Preliminary laboratory data of the female condom show that the human immunodeficiency virus (HIV) and the cytomegalovirus (CMV) do not penetrate the polyurethane barrier of the female condom in vitro. A human use study provided statistically significant data which showed leakage to be less with a female condom than with a male condom.

Among sexually active couples, the only available method for preventing STDs and AIDS is the male condom. This method has been a successful intervention among gay men, but for heterosexual couples, the picture is much less encouraging. Most heterosexual AIDS patients contracted the disease by practicing high risk behavior or through sexual intercourse with high risk partners. Condom use was assessed in a well-characterized prostitute population in Nairobi after a program of education about AIDS. In this study, 20 of 28 women who were non-condom users seroconverted compared with 23 of 50 women who reported some use of condoms.<sup>4</sup> These findings underscore the need for protection against HIV transmission during intercourse, yet few couples seem willing to adopt protective methods.

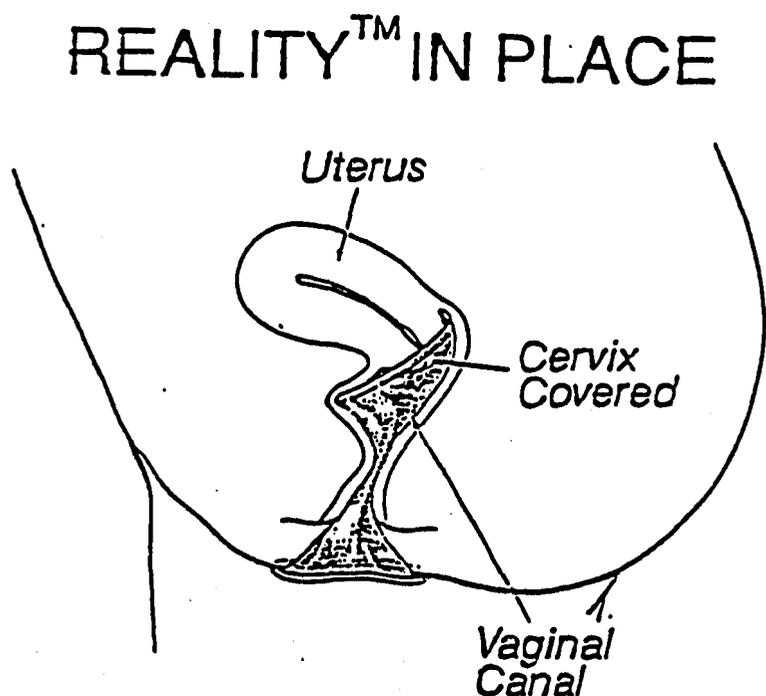
Lessons from family planning programs show that contraceptives are most effective when they are controlled by women. That experience could be applied to the prevention and control of STDs and HIV among heterosexuals. Yet of the studies presented at the 1988 and 1989 International Conferences on AIDS in Stockholm and Montreal, very few examined preventive methods that do not require active male participation.

In a commentary published by the American Journal of Public Health (April 1990), Zena Stein said that because men control their use, relying on the use of male condoms alone cannot stop the spread of HIV among heterosexual couples. She called for a greater emphasis on developing preventive methods which are used and controlled by females. Stein argued that the effectiveness of condoms depends on a woman persuading her partner to wear one. This requires women to exert a sexual dominance that is not traditional in Western and Asian societies, and with which many women feel uncomfortable.

A study of condom use in Africa, cited by Stein, shows that only 22 of 568 prostitutes used condoms every time they had vaginal intercourse. Although the 22 women were all seronegative, indicating the condom's efficacy, they comprised less than four percent of women interviewed for the study. The overall rate of seropositivity for the group was 11 percent. While several abstracts have explored chemical inactivation of HIV by spermicides, no research papers have yet appeared. One possibility for empowering women is a device called the female condom, which Stein refers to as "the pouch." Preliminary research indicates that, among 24 married or cohabiting couples who used the female condom, 63 percent of the men and 70 percent of the women report that sexual pleasure is the same or greater than with the male condom.<sup>5</sup>

The female condom was first evaluated in Thailand in 1988. The female condom, named Reality™ (formerly WPC-333), is a polyurethane device manufactured by Wisconsin Pharmacal. The Reality™ vaginal pouch consists of a soft, polyurethane pouch with an attached, flexible ring at the open end and a second, loose ring within the pouch which functions as an insertion mechanism and secures the device within the posterior fornix of the vagina. When the pouch is inserted properly, the flexible ring at the open end extends from the body and covers the vulval region (Figure A). In this way, the device may provide additional protection against such STDs as herpes and condyloma, which often are present on the external genitalia of both males and females. Other advantages of this device include: insertion prior to intercourse; compatibility with any type of lubricant (water or oil-based);

Figure A



under female control; because of its loose fit, there may be less reduction of sensitivity; the material is said to be stronger than latex, hence it is less likely to rupture; and it permits continued intimacy after ejaculation.

In July 1989, a final report was issued on an acceptability study of the Reality™ female condom among a small group of women at high risk for STDs and AIDS in Northeast Thailand.<sup>1</sup> The following key findings were reported:

- (1) The Thai women easily learned how to insert the female condom;
- (2) The female condom was uncomfortable to wear, inconvenient, and too large (long) for the study population;
- (3) The female condom was not popular with the sexual partners of these women; and,
- (4) Both the women and their partners preferred the male condom to the female condom.

The general assessment of the female condom by these women and their partners was negative. As these Thai women have no alternative to protect themselves from STDs and HIV if a man refuses to wear a condom, the investigators felt that it was important to repeat the study using a slightly smaller (15cm in length), pre-lubricated condom to see if changes in the product would improve acceptability and compliance.

The evaluation of alternate methods is all the more timely because of the unusually rapid increase of HIV among this population of low income, commercial sex workers (CSWs). Prior to the study, the national sentinel surveillance revealed that HIV infection rates exceed 25% among this group in three provinces.<sup>2</sup> In Khon Kaen, the site of both female condom studies in Thailand, the corresponding rate is 8 percent, up from 2 percent in June, 1988. In this setting, the use of barrier methods during commercial sex has the potential to become a significant intervention to slow the spread of HIV.<sup>3</sup>

## **II. OBJECTIVES**

This second trial of the female condom was an attempt to determine if modifications in the dimensions and pre-lubrication of the device could improve compliance and acceptability.

## **III. MATERIALS AND METHODS**

The modified female condom used in the second Thailand study was a 15cm, pre-lubricated Reality™ Vaginal Pouch. The study was conducted in Khon Kaen, a large provincial town in

the heart of northeast Thailand. The same brothel that participated in the first study was selected for the second evaluation; but it was not expected that the same group of women would be included in both studies due to the high turn-over rate of workers in commercial sex establishments (approximately 70% per year).

Twenty women were selected, screened and trained in the use of the modified female condom. Each trainee was given a preliminary supply of 10 female condoms and an instructional brochure. A follow-up visit was scheduled at two weeks but the women were able to obtain additional female condoms on demand.

The study site had to be changed when it was discovered that very few of the twenty trainees had used the condoms during the two week period. Furthermore, the trainees refused to return the unused condoms to the investigator. In order to salvage the study, the site was shifted to another brothel in the same town. The difference between the two brothels was the cost per episode of sex. The fee for sexual intercourse at the original site was approximately five times that for the second site (\$15.00 versus \$3.00). This price differentiation results in different client profiles, varying rates of coital frequency and a different emphasis on the need to please an individual client.

In the second brothel, there were 22 women and all were trained in the use of the female condom. In addition, gynecologists gave the women an overview of AIDS and how AIDS can be prevented. After the modified female condom was described to them, the participants were divided into four small groups to learn more about the female condom and to practice inserting the device on a full scale pelvic model. At the end of the small group sessions, each participant was given a Thai language pamphlet on how to insert and remove the female condom. Then they were given a supply of five modified female condoms and one bottle of water-based lubricant. The women were given the study Fact Sheet (Appendix A) explaining the benefits and risks of being in the study.

The Voluntary Agreement Form (informed consent) and admission (screening) questionnaires were filled out by all participants at the beginning of the project (see Appendices B and C). One-week and two-week follow-up visits were scheduled to resupply the participants and to administer the preference/device functioning questionnaire (Appendix D).

#### **IV. RESULTS**

Table 1 shows the baseline characteristics of the study population. Of the 22 women enrolled, 21 completed the study. The women ranged in age from 19 to 26 years, with a mean age of 20.1 years. Their educational attainment ranged from no education to the completion of primary school. Most of the women came from the north region of Thailand. As a group, three of these women had experienced pregnancy, but only one had had a live birth. Only two of the women indicated that they had participated in a previous study of the female condom.

Concerning the history of STD infection, the overall seroprevalence of HIV infection was zero, however more than half (57%) had had syphilis and 16 (76%) had had gonorrhea (Table 2). The women had been in commercial sex work between one and 24 months. The cost of sex service charged to customers varied from \$1.50 to \$5.00. On average, the frequency of vaginal intercourse was 29.6 episodes per woman per week during the course of study.

All participants reported current use of a method of birth control (16 used the pill, five used the injectable) (Table 3). Past barrier methods used included the condom alone (100% of participants), spermicide alone, spermicide with condom and the vaginal sponge. None of the women had used the diaphragm.

During the two-week study period, there were 744 reported episodes of vaginal intercourse. (Table 4) The participants used either the modified female condom or the male condom in 100 percent of sexual encounters, with the female condom being used in 132 or 18 percent of episodes.

Continuation of use of the modified female condom throughout the two week study period was 43 percent. Among those who stopped using the female condom, the most common reason cited was personal discomfort (10 cases), followed by messiness (7 cases) and inconvenience (5 cases). Partner reaction or discomfort was cited also by five women as a reason to cease use of the device. Table 5 gives a breakdown of the reasons cited for discontinuation.

User perceptions of the female condom are shown in Table 6. Most (n=15 or 71%) users in this trial expressed that they liked the modified female condom even though the majority (18 cases) said it was occasionally or often difficult to insert. In addition, pre-lubrication of the condoms, while less messy than self lubrication, made the device difficult to handle. This was compounded by the "springy" nature of the inner ring which further complicated the insertion process. Twenty users reported that both inner and outer rings stayed in place during intercourse. More than half (52%) said it was too baggy and eighteen (86%) women reported that it was too long. The majority (n=18) of users said that the modified female condom was not difficult to remove. All said the female condom was less convenient to use than the male condom.

No participants used the condom during menses (Table 7). All douched after using the condom and none reused the female condom. Most users in this trial expressed that they liked the modified female condom even though more than half said it was difficult to insert and it caused some pain. Most (62%) participants had only one practice insertion prior to actually using the device.

Eighty-one percent (n=17) of participants reported that some of their clients liked the modified female condom (i.e. some liked the female condom, some did not) while only 19 percent reported that all of their clients disliked the device (Table 8). Compared to using male condoms, five of the respondents said that the female condom affected negatively their

partner's overall sexual satisfaction. Twenty of the participants indicated that the inner ring of the condom could be felt by some or all of their partners. Reference was made as well about device noise (4 cases), aesthetics (2 cases), odor (1 case) and size (5 cases).

Most (90%) of the study population would recommend the female condom to other women (Table 9). Almost half (48%) of the women would like to use the modified female condom in the future. Reasons cited for recommending the female condom were: 1) the device was new; 2) other women should try it for themselves; 3) the device was durable; and 4) it was better than using no protection. Table 10 provides a listing of the best and least liked characteristics of the modified female condom as viewed by these study participants. As shown, ten of the women complained about discomfort caused by the hardness or size of the inner ring and five of the women felt that the inner ring should be made thinner and softer. Five participants mentioned that their partners experienced some discomfort with the inner ring as well. Twenty of the women indicated that their male partners would more than likely choose the male condom if given a choice between the two devices.

Some of the responses to the open-ended questions can help expand understanding in various aspects of acceptability of the modified female condom. Sixteen of the 71 items in the follow-up questionnaire (Appendix D) allowed for unprompted response to questions concerning the modified female condom. Fourteen of the 16 items elicited some response and most of these are summarized below:

- Item 9: Reasons for discontinuing use of the condoms before the end of two weeks included, "it was too large" (1 case) and "it hurt" (3 cases).
- Item 16: The lubricant was too sticky in the view of one user and too slippery in the view of two users.
- Item 19: Eleven of the 18 users who thought the condom was difficult to insert sometimes or always provided the following reasons for the difficulty:
- inner ring is springy when squeezed (8 cases)
  - inner ring is hard (2 cases)
  - too slippery (1 case).
- Item 37: Fifteen respondents reported why the female condom made them feel uncomfortable:
- the condom was noisy (10 cases)
  - the condom was a nuisance (4 cases)
  - the condom was too large, painful (3 cases)
  - the condom caused a feeling of internal compression (2 cases)
  - the condom shifted around (1 case)
  - the condom was malodorous (1 case)
  - the condom caused pain after intercourse (1 case)
  - the inner ring was too hard (1 case)

- the condom was difficult to insert: the outside was slippery while the inside was not slippery enough (1 case)
- the condom took too long to insert (1 case).

**Item 53:** The male clients' negative responses to use of the modified female condom included:

- the inner ring hurt (10 cases)
- sexual sensation was reduced (5 cases)
- the condom was noisy (4 cases)
- a nuisance (3 cases)
- the condom was too big or too long (3 cases)
- the condom did not appear attractive (2 cases)
- the condom was too big (2 cases)
- the condom was malodorous (1 case).

**Item 55:** Concerning clients' remarks on the difference between sex with and without the female condom, 11 women reported the following:

- the female condom made sex better, it was large enough not to notice the difference (2 cases)
- the female condom provided a nice fit (2 cases)
- it was more natural than using a male condom (1 case)
- there was no difference (1 case)
- the inner ring hurt (3 cases)
- the condom was too big (1 case)
- it wasted time to insert (1 case).

**Item 63:** In response to the question why they would recommend the female condom to others, the 19 eligible respondents said that:

- others should try it for themselves (8 cases)
- it was better than using no protection (4 cases)
- it was something new (3 cases)
- others might find it useful and desirable (3 cases)
- it was durable and would not rip (1 case).

**Item 68:** When the participants were asked to name two things they liked about the modified female condom, most could only cite one, these include:

- durable, would not rip (8 cases)
- good for STD prevention (2 cases)
- provided good lubrication (2 cases)
- outer ring was softer than the inner ring (1 case)
- did not have to depend on the man (1 case).

**Item 69:** When asked to cite two negative features of the modified female condom, more responses were given:

- the inner ring was too hard and caused pain (10 cases)
- the condom was too big, too wide (9 cases)
- it was difficult to insert (4 cases)
- the condom was too slippery (2 cases)
- caused pain after intercourse (1 case)
- the condom had an unpleasant odor (1 case).

**Item 71:** When asked to add comments relating to their own experience with the modified female condom the users responded as follows:

- the condom should be reduced in size (5 cases)
- inner ring should be thinner and softer (4 cases)
- it was okay if used only once a day, but might cause pain to use more often than that (1 case)
- it caused a compressed feeling inside (1 case)
- it caused uterine pain after intercourse (1 case).

Additional comments relating to the experience expressed by their clients included the following statements:

- the condom was too big (4 cases)
- feeling pain and scraping of genitals (3 cases)
- the man's genitals pushed against the inner ring (2 cases)
- liked the condom because of the loose sensation (more than with the male condom) (1 case).

## **V. COMPARISON OF RESULTS BETWEEN TWO TRIALS**

In a letter to the editor published by the American Journal of Public Health (April 1990), Sakondhavat described the first Khon Kaen study in which 20 prostitutes were fitted with the WPC-333 female condom.<sup>6</sup> Participants reported that the 17-cm device, while a bit too large, did not rip or tear during intercourse. Nineteen of the 20 subjects found the female condom inconvenient to insert and messy to lubricate, and four experienced some pain. One advantage of the female condom is that, like the diaphragm, it can be inserted prior to intercourse. Unlike the diaphragm, however, men are aware of the female condom because it protrudes from the vagina. In the first Khon Kaen study, half the study participants reported that their partners objected to its use. While many women stopped using the female condom due to their partner's objections, 18 of the 20 participants said that they would advise other women to try it. Based on the study results, it was decided that a second study should be conducted using a smaller (15cm), pre-lubricated device.

The purpose of the second study was to assess whether there would be improvements in the acceptability of the female condom after modification of the condom design and improvement

in the lubrication. To assess the full impact of these product changes, it is necessary to compare the results of Study I and Study II. There are three major obstacles to this comparison. First, one year elapsed between the two studies. During this time the prevalence of HIV increased dramatically and as a result, male condom use increased. Second, the participants in the two studies are different. Third, because the sex establishment in the second study charges much less per episode than the brothel used in the first study, the client profile is probably significantly different as well. These differences were unavoidable and should be kept in mind when interpreting the results.

The subjects in Study II were distinctly younger and less educated than those of Study I (Table 11). In the former, almost all were under age 25 and none had secondary or higher education. Study II participants had virtually no history of pregnancy and had higher levels of Gonorrhea and Syphilis infection than Study I subjects. More participants in the second study used the injectable but the pill was the most common method for both groups.

Variance between study groups existed also in the women's use of the study products (Table 12). In the first trial of the female condom in 1989, 247 episodes of sexual intercourse were reported during the two-week study period. The female condom was used in 78, or about one-third of episodes. In the second study, the number of sexual encounters was 744 and the female condom was used in 132 or 18 percent of episodes. Thus, use of the female condom in the 1990 trial was greater than in 1989, but the rate of protection with this method was lower. It is most noteworthy that the participants in Study II used either the female condom or the male condom in 100 percent of sexual episodes during the two week period.

Participation in the study increased in the second trial. Continuation of use of the female condom increased from 0 percent in the first study to 43 percent in the second. Personal discomfort was cited as the major reason for discontinuation among the 1990 study participants. This is in contrast to Study I where, for the most part, subjects discontinued use because of their partner's objections. In both groups no participant used the condom during menses. All douched after using the condom and none reused the devices.

More users in the 1990 study said they "liked" the female condom even though more thought it was difficult to insert and more experienced pain than the 1989 users (Table 13). It is not possible to assess whether pre-lubricating the condoms improved sensation or acceptability because both groups felt the condom was adequately lubricated. (It is possible that pre-lubrication actually rendered the condoms more difficult to insert because the outer surface was slippery.) Although the size of the inner ring was not modified, more users in Study II complained about this feature of the female condom. Likewise, fewer Study II users complained of the outer ring interfering with intercourse.

The shortening of the length of the condom may have had an impact on improved positioning of the device. Ninety-five percent of users of the modified device reported that both inner and outer rings stayed in place during intercourse compared to two-thirds of Study I

participants. The modified female condom was not difficult to remove and almost all respondents felt competent in using it. It did cause some pain in the majority of users and, possibly for this reason, all preferred the male condom when given a choice.

It has already been stated that the male clients of Study I and Study II users were different populations, thus were not strictly comparable. In addition, the reactions of male clients are based on the assessments of commercial sex workers. The data show that 81 percent of male clients expressed some level of satisfaction with the modified condom (Table 14). Only 19 percent reported that all clients disliked the device. This positive response occurred even though virtually all the clients of Study II participants could see the condom or could feel the inner ring during intercourse.

## **VI. DISCUSSION**

In general, 90 percent of study participants (both groups) would recommend the female condom to others. Most felt that other women would want to try it for themselves. The modified female condom received more favorable user reaction than the original Study I device. However, less than half of the users in the second study indicated that they would like to use the female condom in the future. When there is a choice, women (and presumably men) will choose the male condom. Thus, for this study population, it would seem that the female condom is only meaningful as an alternative to sex without any protection. The implication of this could be that the female condom is an acceptable option to avoid STDs.

This trial of a modified female condom has found that structural problems remain with regard to the inner ring size and the spread of the lubricant to the outside of the condom. At the same time, the modified female condom generally received more favorable reactions than the previous condom iteration. More women continued using the condom in the second trial and nearly twice the number of condoms were tested in the 1990 trial than in the 1989 trial.

Although continued modifications to the structure and improvement in lubrication of the female condom would probably reduce complaints, it is not likely that these modifications would significantly improve acceptability of the female condom among commercial sex workers. Instead, the improved acceptability of the female condom in the near future will probably be determined by the increasing spread and fear of HIV infection.

These two acceptability trials have demonstrated that even prostitutes with minimal education can be easily trained to insert and remove the female condom. Continued demand for the female condoms after the research supply was exhausted is also an indication that prostitutes would continue to use the female condom on a limited basis. The prostitutes in the second trial saw the advantage of the female condom as a back-up method for clients who refused to use male condoms. From the condom use data in the second trial, approximately 18% of brothel clients did not wish to wear the male condom but did not object to the

woman using her own protection. Without the availability of the female condom, unprotected intercourse and disease transmission could have occurred. If this pattern is typical, then the female condom, as currently developed, could already play a significant role in the prevention and control of HIV infection in Thailand.

Further research is urgently required to determine whether higher levels of compliance and protection can be achieved in other brothel populations.

## VII. REFERENCES

1. Sakondhavat C, Y Werawatakul, A Borkam, P Pinitsoontorn, C Kuchaisit, et al. 1991. "Consumer Preference Study of the FEMALE Condom in a Sexually Active Population at Risk of Contracting AIDS." Khon Kaen. (Unpublished monograph.)
2. Chutidamrong C. 1989. "AIDS Situation in Thailand." AIDS Newsletter Division of Epidemiology, Ministry of Public Health.
3. Sakondhavat C, A Borkam, S Chaichanawong, S Sakammai, and P Piniwatsoontorn 1989. "Study of AIDS Prevention Strategies in a High Risk Population." Thai Journal of Obstetrics and Gynecology 1:11-19.
4. Ngugi EN, FA Plummer, JN Simonsen, DW Cameron, M Bosire, et al. 1988. "Prevention of Transmission of Human Immunodeficiency Virus in Africa: Effectiveness of Condom Promotion and Health Education Among Prostitutes." The Lancet 2 (8616):887-70.
5. Bounds W, J Guillebaud, L Stewart, and S Steel. 1988. "A Female Condom (Femshield): A Study of Its User Acceptability." The British Journal of Family Planning 14:83-87.
6. Sakondhavat C and L Potter. 1990. Letter to the Editor, American Journal of Public Health April.

<b>TABLE 1: BASELINE CHARACTERISTICS OF PARTICIPANTS</b>		
<b>Variable</b>	<b>n</b>	<b>%</b>
<b>Age</b>		
≤ 19	(3)	14.3
20	(1)	4.8
22	(7)	33.3
23	(3)	14.3
24	(2)	9.5
25	(4)	19.0
26	(1)	4.8
Range: 19-26 years Mean: 20.1 years		
<b>Education</b>		
No education	(3)	14.3
Primary education	(18)	85.7
<b>Gravida</b>		
0	(18)	85.7
1	(3)	14.3
<b>Parity</b>		
0	(20)	95.2
1	(1)	4.8
<b>Participant in Previous Female Condom Study</b>		
No	(19)	90.5
Yes	(2)	9.5
<b>Total</b>	<b>(21)</b>	<b>100.0</b>

**TABLE 2: HISTORY OF SEXUALLY TRANSMITTED DISEASES (STDs) OF THE PARTICIPANTS\***

Reported STDs	n	%
HIV	(0)	0.0
Gonorrhea	(16)	76.2
Syphilis	(12)	57.1
Other STDs	(2)	9.5

\*Multiple responses allowed

**TABLE 3: PAST AND PRESENT CONTRACEPTIVE USE AND  
FREQUENCY OF INTERCOURSE OF PARTICIPANTS**

	n	%
<b>Barrier Methods Ever Used</b>		
Condom alone	(21)	100.0
Spermicide alone	(1)	4.8
Condom with spermicide	(1)	4.8
Sponge	(2)	9.5
Diaphragm	(0)	0.0
<b>Method Currently Using</b>		
Pill	(16)	76.2
Injectables	(5)	23.8
<b>Average Number of Acts of Intercourse Per Week</b>		
5	(1)	4.8
6	(1)	4.8
10	(1)	4.8
14	(1)	4.8
20	(1)	4.8
25	(1)	4.8
30	(7)	33.3
35	(4)	19.0
42	(1)	4.8
50	(3)	4.3
<b>X + S.D. = 29.62 + 13.08</b>		
<b>Number of Acts of Intercourse Since Receiving Female Condom</b>		
20	(2)	9.5
21	(1)	4.8
25	(3)	14.3
28	(1)	4.8
30	(5)	23.8
35	(3)	14.3
40	(2)	9.5
45	(1)	4.8
50	(1)	4.8
70	(1)	4.8
80	(1)	4.8
<b>X + S.D. = 35.43 + 15.40</b>		
<b>Total</b>	<b>(21)</b>	<b>100.0</b>

<b>TABLE 4: FREQUENCY OF USE OF CONDOMS AND PROTECTED ACTS OF INTERCOURSE</b>		
	<b>n</b>	<b>%</b>
<b>Number of Female Condoms Used</b>		
1	(1)	4.8
5	(13)	61.9
8	(2)	9.5
9	(1)	4.8
10	(3)	14.3
11	(1)	4.8
Total female condoms used = 132		
<b>Number of Male Condoms Used</b>		
15	(1)	4.8
16	(1)	4.8
17	(1)	4.8
19	(1)	4.8
20	(3)	14.3
21	(1)	4.8
25	(4)	19.0
30	(3)	14.3
32	(1)	4.8
35	(1)	4.8
37	(1)	4.8
40	(1)	4.8
60	(1)	4.8
70	(1)	4.8
Total male condoms used = 612		
<b>Number of Protected Coital Episodes</b>	<b>744</b>	<b>100.0</b>

**TABLE 5: USE OF THE FEMALE CONDOM AND REASON FOR DISCONTINUING USE**

	n	%
<b>Used the Female Condoms During Entire Testing Period</b>		
No	(12)	57.1
Yes	(9)	42.9
<b>Reasons for Discontinuing Use of the Female Condom*</b>		
Too difficult to insert	(4)	33.3
Caused physical discomfort	(10)	83.3
Caused physical discomfort to partner(s)	(5)	41.7
Inconvenient	(5)	41.7
Messy	(7)	58.3
Decreased sexual satisfaction	(0)	0.0
Partner(s) objected	(3)	25.0
Out of supplies	(0)	0.0
Other reason (eg., too large, pain)	(4)	33.3
<b>*Multiple responses allowed</b>		

<b>TABLE 6: PERCEPTION OF FEMALE CONDOM DURING USE*</b>		
	<b>n</b>	<b>%</b>
<b>How Well Liked the Female Condom</b>		
Liked a great deal	(2)	9.5
Liked a little	(13)	61.9
Disliked	(6)	28.6
<b>How Well Was Device Lubricated</b>		
About right	(2)	9.5
Too much	(19)	90.5
<b>Liked the Lubrication</b>		
No	(17)	81.0
Yes	(4)	19.0
<b>How Often Used Extra Lubricant</b>		
Never	(17)	81.0
Sometimes	(1)	4.8
Often	(3)	14.3
<b>Difficult to Insert Female Condom Properly</b>		
No	(3)	14.3
Sometimes	(6)	28.6
Often	(12)	57.1
<b>Felt Inner Ring During Intercourse</b>		
No	(4)	19.0
Sometimes	(4)	19.0
Often	(2)	9.5
Always	(11)	52.4
<b>Inner Ring Interfered with Intercourse</b>		
Sometimes	(5)	23.8
Always	(12)	57.1
No answered	(4)	19.0
<b>Did the Female Condom Stay in Place During Intercourse</b>		
Yes	(20)	95.2
No	(1)	4.8

<b>Held Female Condom in Place During Intercourse</b>		
No	(11)	52.4
Sometimes	(3)	14.3
Usually	(1)	4.8
Always	(6)	28.6
<b>TABLE 6: PERCEPTION OF FEMALE CONDOM DURING USE (cont.)</b>		
<b>Felt Outer Ring</b>		
No	(14)	66.7
Sometimes	(3)	14.3
Always	(4)	19.0
<b>Outer Ring Interfered with Intercourse</b>		
No	(3)	14.3
Sometimes	(2)	9.5
Always	(2)	9.5
Not answered	(14)	66.7
<b>Did Outer Ring Get Pushed up Into the Vagina During Intercourse</b>		
No	(20)	95.2
Yes	(1)	4.8
<b>Female Condom Easy to Remove</b>		
No	(3)	14.3
Yes	(18)	85.7
<b>Would You Say the Female Condom Was: (%)</b>		
Too baggy	(11)	52.4
Too tight	(7)	33.3
Too long	(18)	85.7
Too short	(0)	0.0
<b>Female Condom Become Easier to Use With Experience</b>		
No	(12)	57.1
Yes	(9)	42.9
<b>*Multiple responses allowed</b>		

<b>TABLE 7: PRACTICES WITH THE FEMALE CONDOM</b>		
	<b>n</b>	<b>%</b>
<b>Used the Female Condoms During Menstrual Period</b>		
No	(21)	100.0
Yes	(0)	0.0
<b>Douches After Using the Female Condom</b>		
No	(0)	0.0
Yes	(21)	100.0
<b>Reused the Female Condom</b>		
No	(21)	100.0
Yes	(0)	0.0
<b>Practices Inserting the Condoms Before Using</b>		
No	(2)	9.5
Once	(13)	61.9
Twice	(3)	14.3
More than twice	(3)	14.3

**TABLE 8: CLIENTS' OPINION OF FEMALE CONDOM**

	n	%
<b>Male Reaction to Female Condom</b>		
Inner ring caused discomfort	(10)	47.6
Reduction in sexual sensation	(5)	23.8
Condom was noisy	(4)	19.0
Condom was a nuisance	(3)	14.3
Condom was too big/large	(5)	23.8
Condom was not attractive	(2)	9.5
Condom was malodorous	(1)	4.8
Improvement in sexual sensation	(2)	9.5
Condom fit well	(2)	9.5
More natural (feel) than male condom	(1)	4.8
No different than male condom	(1)	4.8
<b>Compared to Using No Condom, Female Condom Affect Partners' Overall Sexual Satisfaction</b>		
No	(2)	9.5
Yes, affected some partners	(15)	71.5
Yes, affected all partners	(4)	19.0
<b>Compared to Using a Male Condom, Female Condom Affect Partners' Overall Sexual Satisfaction</b>		
No	(2)	9.5
Yes, increased satisfaction for all	(1)	4.8
Yes, affected some partners' satisfaction	(13)	61.9
Yes, decreased satisfaction for all	(5)	23.8
<b>Did Your Partner(s) Complain of Any Discomfort While Using the Female Condom</b>		
Some	(18)	85.7
All	(3)	14.3
<b>Did Your Partner(s) Complain of Any Burning While Using the Female Condom</b>		
No	(12)	57.1
Some	(9)	42.9
<b>Did Your Partner(s) Ever Feel the Inner Ring</b>		
No	(1)	4.8
Some	(14)	66.7
All	(6)	28.5

<b>TABLE 8: CLIENTS' OPINION OF FEMALE CONDOM (cont.)</b>		
<b>Did Your Partner(s) Know That You Were Using a Female Condom</b>		
No	(1)	4.8
Some did	(1)	4.8
All did	(19)	90.4
<b>Did You Tell Your Partner(s) That You Were Using a Female Condom</b>		
Told none	(1)	4.8
Told some	(1)	4.8
Told all	(19)	90.4
<b>How Did They Like the Female Condom</b>		
Some liked, some disliked	(17)	81.0
All disliked	(4)	19.0
<b>Would Your Partner(s) Say the Female Condom Was: (%)</b>		
Too baggy	(12)	57.1
Too tight	(15)	71.4
Too long	(10)	47.6
Too short	(20)	95.2
<b>In the Future, Which Would Your Partner(s) Be Most Likely to Choose</b>		
No condom	(1)	4.8
Male condom	(20)	95.2
<b>Did Your Partner(s) Mention Any Other Difference in Sexual Intercourse Cause by the Female Condom</b>		
No	(10)	47.6
Yes	(11)	52.4

**TABLE 9: PARTICIPANTS' FUTURE PREFERENCE AND ADVICE  
ABOUT THE FEMALE CONDOM**

	n	%
<b>Would You Advise Others to Use the Female Condom</b>		
No	(2)	9.5
Yes	(19)	90.5
<b>Do You Think Women Need to Have Someone Train Them to Insert the Condom or Can They Understand From the Leaflet Like the One You Were Given</b>		
Need training	(9)	42.9
Can learn from leaflet	(12)	57.1
<b>Do You Think You Know Enough to Train Others to Use it</b>		
No	(4)	19.0
Yes	(17)	81.0
<b>Do You Think Other Women Will Use it</b>		
No	(1)	4.8
Yes	(20)	95.2
<b>Would You Like to Use the Female Condom in the Future</b>		
No	(11)	52.4
Yes	(10)	47.6
<b>In the Future, Which Would You be Most Likely to Choose</b>		
No condom	(0)	0.0
Male condom	(21)	100.0
Female condom	(0)	0.0

**TABLE 10: CHARACTERISTICS LIKED BEST AND  
LEAST ABOUT THE FEMALE CONDOM**

Variable	n	%
<b>Characteristics Liked Best</b>		
Durable, would not rip	(8)	38.1
Good, coverage (for STD protection)	(2)	9.5
Good lubrication	(2)	9.5
Outer ring softer than inner ring	(1)	4.8
Did not have to depend on a man	(1)	4.8
<b>Characteristics Liked Least</b>		
Inner ring too hard, caused pain	(10)	47.6
Condoms was too big, too wide	(9)	42.9
Difficult to insert	(4)	19.0
Condom was too slippery	(2)	9.5
Caused pain after intercourse	(1)	4.8
Unpleasant odor	(1)	4.8
Condom caused a feeling of compression (internal)	(1)	4.8

**TABLE 11: COMPARATIVE ANALYSIS OF POPULATION CHARACTERISTICS OF STUDY I AND STUDY II**

Variable	Study I (n=20)	Study II (n=21)
<b>Age (years)</b>		
16-20	15.0	19.0
21-25	25.0	76.0
26-30	30.0	4.8
31-35	30.0	0.0
<b>Education</b>		
No education	5.0	14.3
Primary school	70.0	85.7
Secondary school	20.0	0.0
Junior college	5.0	0.0
Mean gravida	2.6	0.1
Mean parity	0.7	0.05
<b>History of STDs</b>		
Gonorrhea	65.0	76.2
Syphilis	30.0	57.1
Other	50.0	9.5
None	0.0	9.5
<b>Current Method of Contraception</b>		
Pill	90.0	76.2
Injectable	10.0	23.8

**TABLE 12: COMPARATIVE ANALYSIS OF THE USE  
OF THE FEMALE CONDOM**

Variable	Study I N=20		Study II (n=21)	
	n	%	n	%
<b>Use of a Condom by Number of Episodes of Intercourse</b>				
Female condom only	(70)	28.3	(132)	17.7
Male condom only	(82)	33.2	(612)	82.3
Both condoms	(8)	3.2	(0)	0.0
No condoms	(87)	35.2	(0)	0.0
<b>Total</b>	<b>(247)</b>	<b>100.0</b>	<b>(744)</b>	<b>100.0</b>
<b>Discontinued before 2 weeks</b>	<b>(20)</b>	<b>100.0</b>	<b>(12)</b>	<b>57.1</b>
<b>Reasons Discontinued Use of the Female Condom (%)</b>				
Discomfort to self	(6)	30.0	(17)	83.3
Discomfort for partner(s)	(10)	50.0	(5)	23.8
Inconvenient	(11)	55.0	(7)	33.3
Decreased enjoyment	(6)	30.0	(0)	0.0
Partner objected	(15)	75.0	(3)	14.0
Out of supplies	(13)	65.0	(0)	0.0
Used condoms during menses	(0)	0.0	(0)	0.0
Douches after using condoms	(20)	100.0	(21)	100.0
Reused condoms	(0)	0.0	(0)	0.0

**TABLE 13: COMPARATIVE ANALYSIS OF WOMEN'S PERCEPTIONS  
OF THE FEMALE CONDOM**

Variable	Study I N=20		Study II (n=21)	
	n	%	n	%
Liked the condom	(10)	50.0	(15)	71.4
Disliked the condom	(7)	35.0	(6)	28.6
Condom was well lubricated	(19)	95.0	(19)	90.5
Easy to insert	(10)	50.0	(3)	14.3
Inner ring interfered with sex	(6)	30.0	(17)	81.0
Condom stayed in place	(14)	70.0	(20)	95.2
Outer ring interfered with sex	(13)	65.0	(20)	95.2
Condom ripped	(1)	5.0	(0)	0.0
Easy to remove	(20)	100.0	(18)	85.7
Know enough to use properly	(19)	95.0	(20)	95.2
Caused pain	(7)	35.0	(17)	81.0
Male condom more convenient	(19)	95.0	(21)	100.0

**TABLE 14: COMPARATIVE ANALYSIS OF MALE'S REACTION TO THE FEMALE CONDOM**

Variable	Study I N=20		Study II (n=21)	
	n	%	n	%
Male could see the condom	(20)	100.0	(20)	95.3
Some liked the condom	(10)	50.0	(17)	81.0
All disliked the condom	(10)	50.0	(4)	19.0
Male could feel inner ring	(10)	50.0	(20)	95.2