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# ACCEPTABILITY OF THE FEMALE CONDOM AMONG A HIGH-RISK POPULATION IN CAMEROON

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## INTRODUCTION

The rapid spread of sexually transmitted diseases (STDs), including Acquired Immune Deficiency Syndrome (AIDS), has generated renewed interest in condoms in recent years. The female condom represents a new and potentially important addition to the existing choice of condoms. A female condom could potentially empower women by giving them a barrier method under their control, offering protection against the spread of AIDS and other STDs as well as unintended pregnancy.

Several manufacturers are presently refining their own versions of a female condom. Two manufacturers, Wisconsin Pharmacal Company, Inc. and M.D. Personal Products, Inc., are currently seeking Food and Drug Administration (FDA) approval for their devices. This study represents the fourth in a series of consumer preference and functionality studies that Family Health International (FHI) has supported with the Reality™ female condom manufactured by Wisconsin Pharmacal.

Preliminary laboratory data of the Reality™ female condom established that the human immunodeficiency virus (HIV) and cytomegalovirus (CMV) do not penetrate the polyurethane barrier of the female condom in vitro.<sup>1</sup> A human use study with 100 couples each using five female and five male condoms, provided statistically significant data which showed leakage to be less when using a female condom rather than a male condom.<sup>2</sup>

Early research on the female condom was very promising. A study of the Femshield™ female condom manufactured by Medicor International PLC reported that a majority of participants (63% men and 79% women) believed that sexual pleasure while using the female condom was increased or equal to sexual pleasure while using the male condom.<sup>3</sup>

Family Health International supported a consumer preference and functionality study of the Reality™ female condom, which is similar in design to the Femshield™, among high-risk women in Thailand.<sup>4</sup> All of the participants discontinued using the Reality™ female condom during the two-week study period. The most common reason for discontinuation was that the male partner objected to using the female condom. Another reason for discontinuation was that the Reality™ female condom was too large. FHI supported a second study of a modified (shortened) version of the Reality™ female condom in a similar population of Thai women.<sup>5</sup> The results of this second study were only marginally more positive, with 57% of this high-risk population (n=21) discontinuing before completion of the two-week study period. Eighty-three percent of the discontinuers reported they stopped using the device because they found it to be uncomfortable, despite the decrease in device length.

Data presented by a representative of Wisconsin Pharmacal Company, Inc. at the VI International Conference on AIDS showed

the Reality™ female condom to be acceptable to married or cohabiting women. Fifty-six percent of this study population reported the device to be "acceptable or more than acceptable".<sup>2</sup> Heretofore, many health care providers believed that the female condom was appropriate only in selected populations, notably those at high risk for STDs and AIDS.<sup>6</sup>

FHI decided that more research was needed with low-risk women and a study was undertaken with a group of married/cohabiting women in Nairobi, Kenya.<sup>7</sup> Similarly positive results were obtained from this study. Over three-fourths of the women liked the Reality™ female condom better or about the same as the male condom. Fifty-five percent of their male partners were reported to have liked the female condom as well.

The present study looks at the acceptability of the Reality™ female condom among a group of commercial sex workers (CSWs) in Yaoundé, Cameroon. Recent initiatives promoting male condom use have been successful in this population. Many of the CSWs are motivated to protect themselves given the risk of contracting STDs, including HIV.<sup>8</sup>

#### STUDY OBJECTIVE

The study objective was to examine the acceptability of the Reality™ female condom among a population of CSWs in Cameroon. Acceptability issues included general reaction of CSWs and clients to the female condom, ease of use, change in acceptability over time, perceived problems and device breakage. Neither the effectiveness nor safety of the device in preventing pregnancy or disease transmission was tested in this study.

#### STUDY DESIGN

A group of Peer Health Educators (PHEs) from the National AIDS Control Service in Yaoundé recruited a total of 40 CSWs to participate in the study. The study participants were active CSWs with multiple sex partners or clients and residents of Yaoundé. They were also currently using an effective, modern method of contraception, not pregnant or breastfeeding and in satisfactory reproductive health as determined by physical examination and specific laboratory tests. Women volunteering for the study were asked to sign an Informed Consent Form to indicate their voluntary consent to participate in the study. The PHEs assisted other study personnel in providing verbal and written instructions on the use of the Reality™ female condom prior to the initiation of the study.

The study design called for two, two-week test phases. At the end of the first two weeks of female condom use, an acceptability questionnaire was administered. Participants were then asked to participate in a second two-week evaluation. A similar

acceptability questionnaire was administered after the second phase. The purpose of dividing the study into two phases was to assess any differences in acceptability after initial reactions had worn off and after more prolonged use and practice with the device.

The PHEs furnished participants with pre-lubricated female condoms (approximately 20 per woman per study phase) and an extra bottle of water-based lubricant. The participants were instructed to use the additional lubricant as needed and to return to the clinic for more supplies if necessary. Also, the PHEs monitored the condom use and sexual activity of the study subjects on a daily basis using a participant maintained Daily Coital Log.

## RESULTS

Forty of the CSWs recruited for the study completed the first phase screening (demographic) interview, but two women did not return to fill out the Phase I questionnaire and were thus eliminated from later analyses. After the first phase, the remaining 38 participants indicated their willingness to continue into the second round of study. Two women were unable to complete the second phase due to illness or because they were traveling. Two additional women did not return to complete the Phase II questionnaire.

The study participants were, on average, 28 years old and had seven years of formal education (Table 1). Their frequency of sexual intercourse during the past year ranged from two to twenty times per week. Forty-five percent of the women reported an average frequency of six to ten times per week and 43% reported eleven to twenty times per week. All participants had previous experience with the male condom and 92% reported male condom use for at least half of their encounters. This relatively high rate of condom use is not surprising given the recent success of the PHEs in promoting male condom use in this population. Eighty-five percent of the CSWs reported having used over 100 male condoms in their lifetime.

The Coital Log recorded (on a daily basis) the number of male and female condoms used, the number of unprotected sexual acts (ie. times no condoms were used), the number of times both male and female condoms were used together, the number of partners, the number of sexual acts and whether any of the condoms broke. For both phases of the study, the women used a total of 1,367 female condoms and 606 male condoms (Table 2). Study participants averaged 19 partners and 25 sex acts during the first phase of the study and 19 partners and 24 sex acts during the second phase. A male condom and female condom were used together 272 times during the study with 33 women (87%) using the two condoms together at least once. Approximately, ten percent of all sex acts were not protected. Twenty-five women (66%) reported

unprotected sex (ie. sex with no condom of any type) at least once during the study. It is not known whether these encounters were with clients. More than half of the participants reported that during the study some of their clients had refused to use a male condom. Approximately three-fourths of the women reported that some clients had refused to allow use of the female condom.

A total of 129 (9%) of the female condoms used during the study broke (Table 3). Seventy-seven (13%) of all male condoms used during the study period broke. Thirty of the participants (79%) reported having at least one female condom break. The outer ring tearing away from the condom sheath was the most common breakage site followed by tears along the seam and holes in the condom. One participant reported that one female condom broke in half (ie. tearing across the film).

The reasons cited for the breaks indicated rough sexual practices which could also account for a high male condom breakage rate. Reasons most often cited were brutality (roughness) of the man and large penis size (diameter). Other reasons included: excitement, forceful penetration, internal ring got stuck and pulled on condom, forced insertion after removing inner ring, long penis, difficult insertion, holding on to outer ring during penetration, finger nails tore the material during insertion, dry condom, and outer ring broke off during removal. Some women could offer no explanation for the breakage. The impact of simultaneous device use on condom (male or female) breakage is not known.

The general reaction to the female condom was favorable for both phases of the study (Table 4). For the first phase, 36 out of 38 women (95%) stated that they liked the condom either "very much" or "fairly well". Two women (5%) did not like the female condom. Twenty-four participants (63%) preferred the female condom to the male condom and another eight participants (21%) liked the condom the same as the male condom. Six women (16%) stated that they liked the female condom less than the male condom. Results for the second phase were similar.

Client reaction (as reported by the CSW participants) toward the female condom was almost as positive (Table 4). For the first phase of the study, 30 out of 38 participants (79%) reported that, in general, their clients liked the female condom either "fairly well" or "very much" while eight (21%) stated that their clients did not like the female condoms. In comparing the female condom to the male condom, 15 of 38 participants (40%) reported that their clients preferred the female condom, 34% liked the condoms the same and 21% preferred the male condom. Results for the second phase of the study were slightly less positive. In the second phase, 17 out of 34 participants (50%) reported that their clients liked the female condom while 14 (41%) stated that their clients did not like the female condom. Also, 12 of 34 participants (35%) reported that their clients preferred the

female condom to the male condom, 21% liked the condoms the same and 32% preferred the male condom.

The declining favorable reaction by the CSWs' clients noted in the second phase of the study could possibly be due to the novelty of the device wearing off. It is not known what percentage of these clients were in both phases of the study, thus it is difficult to ascertain the impact of this occurrence on second phase results.

Study participants were asked the three things they liked best about the female condom. The most frequent responses included: protects against STDs and pregnancy, does not break, women have control, comfortable, excites men, passes undetected, well lubricated, less dirty, puts men at ease, big enough, doesn't lose sensation, and can be used more than once. Table 5 shows a complete listing of these characteristics as well as the number and percentage of responses for each characteristic.

Even though participants were instructed not to reuse the female condom, four participants mentioned using the condom more than once. Study investigators were able to interview one of these women and found that she would reuse the female condom with the same partner after removing the condom, washing it with water and then reinserting it after adding lubricant. She did not report any problems with breakage of these devices.

Characteristics liked least about the female condom included: condom breaks, difficult to insert, too big, lack of sensation, internal ring uncomfortable, abdominal or lower back pain, partner opposition, not natural, does not stay in place and not enough lubrication. A complete list of characteristics are given in Table 6. It is interesting to note that many of the characteristics liked best by some of the women were those characteristics liked least by others.

Ease of insertion of the female condom improved with practice. During the first phase of the study, 13 women (34%) reported that insertion was "somewhat difficult" and five women (13%) reported that insertion was "very difficult". Just over half of the women (54%) stated that the condom was easy to insert. For the second phase, three out of four women (74%) stated that insertion was easy while only nine women (26%) reported that insertion was "somewhat difficult". Almost all participants (94%) reported that insertion became easier with practice. Most women had no problems removing the female condom. Only two women during the first phase and four women during the second phase reported that the female condom was difficult to remove.

The most common problem experienced in using the female condom was the external ring being pushed inside the vagina during intercourse. This occurred with sixteen women (42%) during the first phase and fourteen women (41%) in the second phase. In order to avoid this problem, some women reported holding on to

the outer ring during penile thrusting. This practice may have contributed to some of the condom breakage. Another complaint was that the female condom stayed on the penis during withdrawal. Twenty-four percent of women during the first phase and 41% during the second phase reported this problem. Some women felt that this occurred more frequently if the inner ring was not anchored properly. Finally, 13 women (34%) during the first phase and nine women (27%) during the second phase reported that they experienced a client's penis entering between the condom and the vagina at least once during the study.

Most of the participants (74% for the first phase and 68% for the second phase) felt that the condoms had the right amount of lubrication. During the first phase, eight participants (21%) felt that the condoms were too dry and seven of these participants added more lubricant. Two women reported too much lubricant and one of these women removed some of the lubricant before using the condoms. For the second phase, nine women (27%) reported that the condoms were too dry and seven of these women added lubricant. Two women reported too much lubricant but did not remove any.

More than four fifths of the women (85% in Phase I and 79% in Phase II) reported that they liked the size of the female condom. For those who did not like its size, the most common complaint was that the condom was too big in diameter and that the opening was too large. A few complained that the condom was too long. Despite the large number of breaks, more than 90% of women reported that they liked the strength of the female condom. Most women (90% in Phase I and 88% in Phase II) liked the natural sensation of the condom as well.

In addition to the problems of insertion, lubrication, and size previously mentioned, 24% of the women in the first phase reported unpleasant noise and one participant reported an unpleasant odor. Several women reported some abdominal pain, one woman reported that the device was difficult to use with the male condom, and one participant stated that her partners became frustrated.

Comfort during use was a concern of many of the participants though it was evident that comfort levels improved with experience. More than nine out of ten women (91%) reported that the use of the device became more comfortable with practice. The common complaint that the inner ring was uncomfortable was reported by seven women (18%) during the first phase, and by only three women (9%) during the second phase. Some women felt that proper insertion would alleviate this problem. During the first phase, 18% also reported that the external ring caught hair, and 16% reported that the external ring was uncomfortable. There were no reports of the seam being uncomfortable.

The participants were asked whether their partners had complained of specific problems with the female condom. The most often

cited complaints by clients included: lack of or diminished sensation, condom was too big, unpleasant noise and external ring caught hair. A complete listing of client complaints and their frequency of mention by study phase are shown in Table 7. No client complaints were recorded for the female condom being too small, having an unpleasant odor, or the seam being uncomfortable. The greater number of complaints during the second phase corroborates the findings described above of less positive general reactions to the female condom during the second phase of study.

Prior to starting the study, all participants were given an instructional booklet and explanations on how to use the female condom. Most of the women (95% first phase, 96% second phase) felt that they had received enough information to use the condom correctly. Some women suggested that additional information should be provided on the possibility of female condoms preventing other diseases and precautions to take in order to avoid ruptures. Though not instructed to use the female condom in conjunction with the male condom, several women wanted information on the purpose of doing this.

Most women (87% first phase, 85% second phase) reported that they would use the female condom in the future, if available. Eleven percent of women during the first phase and 15% during the second phase stated that they would use the condom only if there were improvements. One participant did not want to use the female condom in the future. Suggestions for improving the condom included: making the inner ring less thick and rigid, removing the inner ring, making the condom smaller, making the external ring smaller (improve aesthetics), improving lubrication so that it doesn't dry out as easily, making the condom more resistant (stronger) to avoid breaks, making the condom shorter so that the external ring fits better, and providing different sizes.

## DISCUSSION

One of the most important observations from this study, despite some of the problems and a relatively high breakage rate, is that the general reaction to the female condom remained quite favorable for this selected group of commercial sex workers. More than 90% stated that they liked the condom either "fairly well" or "very much" and almost two thirds preferred the female condom to the male condom. Client reaction was also favorable though somewhat less so than for the CSWs.

Motivation for protecting themselves is quite high among this group of CSWs. Protection from STDs and pregnancies, and women having control were two of the most frequently cited advantages of the female condom. The female condom would provide these women another option for protection if male clients refused to use latex condoms.

The two-phase study design revealed changes in acceptability after prolonged use and practice with the device. Both ease of insertion and comfort in using the device improved with practice. A small decrease in satisfaction for the clients was noted from Phase I to Phase II. The reason for this is not known though it may be due to the novelty of the device wearing off.

The female condom breakage rate of 9% was higher than expected but compares favorably with the 13% breakage rate for male condoms used during the same study. Rough sexual practices and large (diameter) penis size may have contributed to most of the reported breaks.

The most commonly reported problems with the female condom were: condom size (too large), condom breakage, difficult insertion, decrease in or lack of sensation, and discomfort caused by the inner ring.

Some of the different and often conflicting problems noted by the participants indicate a need for providing more product options. Supplying a range of different sizes of the female condom, as suggested by one of the participants, might help to alleviate a number of the problems noted.

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**Table 1: Sociodemographic Characteristics of CSWs**  
(N=40)

	(N)	%
<b>Age</b>		
19-20 years	( 3)	8
21-25 years	(12)	30
26-30 years	(16)	40
≥ 31 years	( 9)	22
<i>Mean: 28</i>		
<b>Education</b>		
None	( 0)	0
1-3 years	( 2)	5
4-6 years	(20)	50
7-9 years	(11)	28
10+ years	( 7)	17
<i>Mean: 7</i>		
<b>Condom Experience in the Past Year</b>		
Never used a condom	( 0)	0
Used condom less than half the time	( 3)	8
Used condom half the time	(14)	35
Used condom more than half the time	(18)	45
Always used condom	( 5)	12

**Table 2: Numbers of Male and Female Condoms Used by CSWs During Study Period**

	Phase I (N=38)	Phase II (N=34)
<b>Male Condoms Used</b>	<b>320</b>	<b>286</b>
<i>Mean</i>	8.4	8.4
<i>Range</i>	1-30	0-30
<b>Female Condoms Used</b>	<b>708</b>	<b>659</b>
<i>Mean</i>	18.6	19.3
<i>Range</i>	4-32	8-27

**Table 3: Male and Female Condom Breakage**

	Phase I (N=38)	Phase II (N=34)
<b>Male Condom Breakage</b>	<b>40</b>	<b>37</b>
<i>Total condoms used</i>	320	286
<i>Mean breakage</i>	1.0	1.0
<i>Range</i>	0-6	0-5
<i>Breakage rate</i>	13%	13%
<b>Female Condom Breakage</b>	<b>67</b>	<b>62</b>
<i>Total condoms used</i>	708	659
<i>Mean breakage</i>	1.7	1.7
<i>Range</i>	0-6	0-10
<i>Breakage rate</i>	9%	9%

**Table 4: Reactions to the Female Condom by CSWs and Their Clients**

	Phase I (N=38)		Phase II (N=34)	
	(N)	%	(N)	%
<b>General Reaction</b>				
Liked it very much	(23)	61	(20)	59
Liked it fairly well	(13)	34	(12)	35
Neutral/no opinion	( 0)	0	( 0)	0
Somewhat disliked it	( 0)	0	( 1)	3
Strongly disliked it	( 2)	5	( 1)	3
<b>Compared to the Male Condom</b>				
Liked female condom less	( 6)	16	( 5)	15
Liked female condom the same	( 8)	21	( 7)	20
Liked female condom more	(24)	63	(22)	65
<b>Client Reaction</b>				
Liked it very much	( 4)	11	( 2)	6
Liked it fairly well	(26)	68	(15)	44
Neutral/no opinion	( 0)	0	( 3)	9
Somewhat disliked it	( 3)	8	( 9)	26
Strongly disliked it	( 5)	13	( 5)	15
<b>Client Comparison of Devices</b>				
Liked female condom less	( 8)	21	(11)	32
Liked female condom the same	(13)	34	( 7)	21
Liked female condom more	(15)	40	(12)	35
Don't know/no opinion	( 2)	5	( 4)	12

**Table 5: Characteristics Liked Best About the Female Condom**

	Phase I (N=38)		Phase II (N=34)	
	(N)	%	(N)	%
Protects against STDs	(15)	39	(24)	71
Comfortable, no problems	(11)	29	( 3)	9
Does not break, resistant	( 9)	24	( 9)	26
Protects against pregnancy	( 9)	24	( 8)	24
Women have control	( 9)	24	( 6)	18
Excites man, less time	( 6)	16	—	—
Well lubricated	( 5)	13	( 1)	3
Less dirty	( 5)	13	—	—
Puts man at ease	( 4)	11	( 1)	3
Big enough	( 4)	11	( 1)	3
STD and pregnancy protection	( 3)	8	( 1)	3
Passes undetected	( 3)	8	( 3)	9
Man appreciates, curious	( 3)	8	—	—
Can use more than once	( 2)	5	( 2)	6
Form fits well	( 2)	5	( 1)	3
Doesn't need to buy pills/douche	( 2)	5	( 1)	3
Material supple	( 2)	5	—	—
No contact with partner	( 1)	3	( 1)	3
Easy to use	( 1)	3	( 2)	6
Sensation/no loss of sensitivity	( 1)	3	( 3)	9
Does not rub like male condom	( 1)	3	—	—
Can use toilet without removing	( 1)	3	—	—
Gains more respect from clients	( 1)	3	—	—
Can be used with male condom	( 1)	3	—	—
More discrete	( 1)	3	—	—
Protects before sex	—	—	( 2)	6
Nothing	—	—	( 1)	3
Can insert condom before sex	—	—	( 1)	3
Can feel when condom breaks	—	—	( 1)	3
More secure	—	—	( 1)	3
OK, if partner not rough	—	—	( 1)	3

NOTE: Numbers reflect multiple responses.

**Table 6: Characteristics Liked Least About the Female Condom**

	Phase I (N=38)		Phase II (N=34)	
	(N)	%	(N)	%
Nothing, no problems	(10)	26	( 7)	21
Breaks, fragile	( 9)	24	( 7)	21
Difficult to insert	( 9)	24	( 6)	18
Lack of sensation	( 7)	18	( 2)	6
Too big	( 5)	13	( 5)	15
Partner opposition	( 5)	13	—	—
Internal ring uncomfortable	( 4)	11	( 2)	6
Abdominal/back pains afterwards	( 4)	11	( 2)	6
Not natural	( 3)	8	( 2)	6
Not enough lubrication	( 3)	8	—	—
Does not stay in place	( 2)	5	( 2)	6
Gets pushed into vagina	( 2)	5	( 1)	3
Man takes longer	( 2)	5	( 1)	3
Noise	( 1)	3	( 1)	3
Too much lubrication	( 1)	3	( 1)	3
Difficult to hold in place	( 1)	3	( 2)	6
Difficult with male condom	( 1)	3	—	—
Irritation	( 1)	3	—	—
External ring problems	( 1)	3	—	—
Painful period	( 1)	3	—	—
Man deceived/unnatural	( 1)	3	—	—
Pain when breaks	( 1)	3	—	—
Bothersome to man	( 1)	3	—	—
Odor	( 1)	3	—	—
Disliked/unrefined	—	—	( 2)	6
Need to improve opening	—	—	( 2)	6
Thickness	—	—	( 1)	3
Too small	—	—	( 1)	3
No choice of different sizes	—	—	( 1)	3
Pain at start	—	—	( 1)	3

NOTE: Numbers reflect multiple responses.

**Table 7: Client Perception of Female Condom  
(as reported by CSWs)**

	Phase I (N=38)		Phase II (N=34)	
	(N)	%	(N)	%
Device too big	( 6)	16	( 6)	18
Unpleasant noise	( 6)	16	( 4)	12
External ring catches hair	( 3)	8	( 5)	15
Too much lubricant	( 3)	8	( 2)	6
No sensation	( 2)	5	( 3)	9
External ring uncomfortable	( 2)	5	( 1)	3
Prefer male condom	( 1)	3	—	—
Inner ring uncomfortable	( 1)	3	( 3)	9
Sensation of material uncomfortable	( 1)	3	( 6)	18
Unpleasant odor	( 0)	0	( 0)	0
Seam uncomfortable	( 0)	0	( 0)	0
Device too small	( 0)	0	( 0)	0
Too little lubricant	( 0)	0	( 2)	6

NOTE: Numbers reflect multiple responses.