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ACCEPTABILITY OF THE FEMALE CONDOM IN DIFFERENT GROUPS OF WOMEN IN SOUTH AFRICA — A MULTICENTRED STUDY TO INFORM THE NATIONAL FEMALE CONDOM INTRODUCTORY STRATEGY

M E Beksinska, V H Rees, J A McIntyre, D Wilkinson

Objectives. To assess the acceptability of the female condom to different groups of women and their partners in South Africa.

Design. Descriptive, cross-sectional study.

Setting. Multicentre study conducted in five sites.

Subjects. The study recruited 678 women from five centres to an acceptability trial of the female condom. Acceptability and successful use varied between the centres.

Outcome measures. Factors affecting successful use and willingness and intention to use the method again.

Results. In total, 209 women used the condom at least once. Discontinuation rates were high, with partner reluctance to try the method as the main reason given for discontinuation at all sites. Women who had previous experience with the male condom or who received a more intensive training session generally found the device easier to use. The main issues concerning women were over-lubrication (27%) and concern that the device was too large (28%). The majority of women said that they would be interested in using the method again (86%) and would recommend it to friends (95%).

Conclusions. Overcoming partner opposition is an important issue to address when introducing the method. The study was used to address the national introductory strategy of the female condom, which began in 1998.

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South Africa is experiencing one of the fastest growing HIV epidemics in the world, with antenatal rates of infection rising from 26.9% in 1997 to 32.7% in 1998 in the worst-affected province, namely KwaZulu-Natal.[1] Annual incidence of symptomatic sexually transmitted diseases (STDs) is estimated at 9% in one area of this province.[2] Although male condoms have been promoted as a means of infection prevention, use of this method is still low.[3] Female-controlled barrier methods such as the diaphragm and the cervical cap are not available to women in the South African public health services, leaving the male condom as the only barrier method available. High rates of acceptability of male condoms have been reported in interviews with women,[4] although this has not generally been translated into increased use by their male partners. For many reasons women are often unable to negotiate male condom use with their partners.[5] There have been many calls for an effective female-controlled barrier method that would reduce HIV transmission and the transmission of other STDs.[6] The female condom fulfils such requirements and provides an important viable alternative to the male condom.

The female condom is a barrier contraceptive method consisting of a transparent polyurethane sheath that is inserted into the vagina before sexual intercourse. It is manufactured from a polyurethane material that is stronger than latex and initial studies have shown it to be stronger than the male condom.[7] Unlike the male condom, it is unaffected by oil-based products.[7] As a contraceptive method it has been shown that efficacy is similar to that of the diaphragm and cervical cap,[8] and also the male condom.[8] It has been suggested that the female condom could provide greater protection against STDs than the male condom for a number of reasons: the strength of the material, the outer ring partially covers the labia, and the device can be inserted before sexual foreplay takes place.[9]

Some acceptability studies[10,11] have reported a very positive response to the method, while other studies[12,13] have reported a mixed reaction. These results, together with other studies from the developed world, suggest that the female condom is acceptable to women who are highly motivated to use a barrier method of contraception or who require a preventive measure against HIV transmission.

The National AIDS Plan for South Africa,[14] developed by a task force of the National AIDS Convention (NACOSA) and accepted by the Department of Health, recognised the need to investigate female-controlled barrier methods and suggested that the female condom should be available in public sector services.

The purpose of the study was to assess the acceptability of the female condom to different groups of women and their partners in South Africa. The study also aimed to assess the information needs of women wanting to use the device and to investigate factors affecting successful or unsuccessful use.

METHOD

Volunteers were recruited from five sites (Table I), chosen to represent different groups of women. Inclusion criteria required women to be over 16 years of age, sexually active, using an effective contraceptive method and willing to return for a follow-up visit 2 weeks later. Eligible women were identified by clinic and research staff and were given an information sheet about the study. Those willing to take part in the study completed an interviewer-administered questionnaire collecting socio-demographic data and information on knowledge and attitudes about HIV infection, condom use and personal perception of the risk of HIV infection.

Table I. Study sites

Province	Area	Sample population
Gauteng	Johannesburg	STD clinic, urban (Hillbrow, Esselen St)
	Johannesburg	Family planning clinic, urban (Hillbrow, Jeppe St)
	Orange Farm	Community sample, peri-urban informal settlement
KwaZulu-Natal	Hlabisa	Hlabisa Hospital, family planning clinic, rural hospital
Cape Town	Khayelitsha	Family planning clinic

The female condom was demonstrated by trained research staff using diagrams and women had an opportunity to handle the device. All recruitment took place in the clinics except for Orange Farm where women were recruited directly from their households in the community. Households were randomly sampled from household stand maps of the area. Women were given the same demonstration and instructions as the women recruited from clinic sites. Those who agreed to participate were asked about symptoms of STDs. If such symptoms were present they were referred for treatment before enrolment into the study. Participants were then issued with seven female condoms and an illustrated instruction leaflet in the language of the woman's choice. They were asked to return after 2 weeks when an evaluation (follow-up) questionnaire was administered. Participants were given a contact name and number for any queries during the study. Further supplies of female condoms were available during this period, if required.

In addition, with the consent of the participating women, male partners of the women were asked to complete a short questionnaire. The follow-up questionnaire collected information on number of condoms used, ease of insertion and removal, technical issues on use, size and lubrication, effect on sexual pleasure, partner's reaction and woman's willingness to use the method again. The follow-up questionnaire was administered to women who had used at least one condom.

Those who agreed to take part but did not use the product completed a short questionnaire, which collected information on main reasons for not using the female condom.

Participants were offered reimbursement of their transport costs to attend the follow-up interviews. In the rural Hlabisa site the women were offered a financial incentive to return, which was higher than the transport costs. This was because the distances travelled by the rural group involved several hours in some cases, and as these women would not normally be returning to the clinic for 2 or 3 months, it was felt that they should be compensated for their time commitment.

The initial sample size of 100 women per site was increased for three of the sites, namely Esselen, Jeppe and Cape Town. Return for follow-up was found to be very poor at these sites and it was decided that the initial sample size would not be adequate to collect enough data on acceptability. Women who did not return for their 2-week follow-up visit were contacted by means of telephone calls or home visits.

There are no reported adverse effects of the female condom. As with other contraceptive measures, there is a failure rate in the prevention of pregnancy. For this reason, participants were required to be using an effective contraceptive method for the duration of the study. All participation was on a voluntary basis and women were free to withdraw from the trial at any time. Data were collected between 1996 and 1997.

Results were analysed using Epi-Info 6.04 (Centers for Disease Control, Atlanta). Female condoms for the study were supplied by the Special Programme of Research, Development and Research Training of the World Health Organisation.

RESULTS

Description of sample

All women (100%) who fulfilled the inclusion criteria and who were asked if they would be interested in the study agreed to take part. The samples in the five centres were different in many respects (Table II). Women from the two central Johannesburg sites had higher rates of past condom use compared with the other three sites, where less than one-third of women had ever used a condom before. A total of 678 women agreed to take part from the five centres. Response rates at 2-week follow-up for each centre are shown in Table III.

Follow-up rates varied considerably across the five sites. Women who did not return after 2 weeks were actively followed up if they consented to give their contact details. In the two central Johannesburg sites follow-up was extremely poor, with three-quarters of women from the Esselen Street site not returning to the clinic. In Orange Farm the women were recruited in their own homes and so did not need to return for follow-up. In this site the lost to follow-up group comprised women who were not available for interview at the 2-week home visit. In all cases, those who had not returned for follow-up and who had subsequently been contacted had not used any of the female condoms given to them. Participants who had not used any condoms were asked to complete a short discontinuation questionnaire, which collected information on the problems they had experienced in using the female condom (Table IV). They were also asked what problems their partner may have experienced. The main reason for not continuing

Table II. Characteristics of women who agreed to take part in the study

	Jeppe FPC (*N* = 122)	Esselen STDC (*N* = 216)	Hlabisa FPC (*N* = 100)	Cape Town FPC (*N* = 140)	Orange Farm (*N* = 100)
Mean age (range) (yrs)	29 (17 - 45)	25 (15 - 50)	23 (16 - 43)	27 (16 - 45)	30 (17 - 58)
Mean gravidity	1.6	1.2	1.8	2.1	2.3
Regular boyfriend (not cohabiting) (%)	47	49	80	34	27
Cohabiting (%)	23	36	10	17	16
Married (%)	24	8	10	49	53
Casual relationship (%)	6	7	0	0	4
Used male condom before (%)	67	80	25	28	29
STD in last year (%)	20	46	21	17	9
Knows person with HIV/AIDS (%)	14	26	55	5	4

FPC = family planning clinic; STDC = sexually transmitted diseases clinic.

Table III. Response rates

	Jeppe FPC	Esselen STDC	Hlabisa FPC	Cape Town FPC	Orange Farm
Agreed to take part (*N*)	122	216	100	140	100
Returned for 2-week follow-up; used condom at least once (%)	48 (39)	50 (23)	53 (53)	21 (15)	37 (37)
Returned for 2-week follow-up; did not use female condom (%)	0	0	47 (47)	0	49 (49)
Did not return; contacted and provided data (%)	11 (9)	7 (3)	0	75 (54)	N/A
Did not return; lost to follow-up (%)	63 (52)	159 (74)	0	44 (31)	14 (14)

FPC = family planning clinic; STDC = sexually transmitted diseases clinic.

Table IV. Main reasons given why women who agreed to take part could not use the female condom

Main reasons*	Hlabisa FPC (*N* = 47)	Cape Town FPC (*N* = 75)	Orange Farm (*N* = 49)	All sites
Partner unco-operative (%)	81	91	84	85
Difficult to insert (%)	2	2	0	1
Inner ring/ condom uncomfortable after insertion (%)	21	18	15	18
Over-lubrication (%)	10	0	12	7

* More than one reason was given by women.
FPC = family planning clinic.

with the study was lack of co-operation from the partner. Fitting and discomfort were also given as reasons for discontinuation; in these instances the women removed the condom and did not attempt to use it.

Follow-up

The follow-up questionnaire was administered to women who had used the condom at least once. The Esselen and Jeppe Street sites were not included, as follow-up rates were so low. Participants were asked a number of questions relating to use of the device, overall impressions and comfort (Table V).

Mean number of condoms used by women across all sites during the study period was 2.5. Most participants agreed that insertion became easier with practice, and nearly all women used the inner ring to insert the condom. The amount of lubrication used on the condom was considered to be about right, except for women in Hlabisa where two-thirds felt that the device was over-lubricated. Size was an issue in Hlabisa, where many women felt that the female condom was too large. Participants were asked if they experienced any problems, discomfort or irritation during use of the condom. The majority of women experienced few problems using the method. In Hlabisa, however, most women reported some difficulties in use of the device and one-third (34%) said that the inner ring was uncomfortable. Only one woman in the study reported that the condom had broken, and this occurred during sex. Some women reported that the outer ring was pushed inside the vagina during sex. Women were not always able to say when this happened and some thought that it was because they did not hold the female condom in place when the man was entering, and that it could have been pushed inside at that point. Removal of the female condom after use was a problem in Hlabisa where almost one-fifth of women found it difficult to remove. Most women from the other two centres found it easy or fairly easy to remove.

Women who had previously used a male condom were asked to compare the male and female condom and state which they preferred (Table VI). When compared with the male condom, the female condom was less popular with women in Hlabisa. In Cape Town all women liked the male and female condom approximately equally and none expressed a preference. The device was compared most favourably by women in Orange Farm.

Table VII shows male partner reaction to the female condom. Around half or more of the partners at Hlabisa and Orange Farm liked the female condom or thought it was all right. The female condom was least popular among the partners in Cape Town and Hlabisa. It is interesting to note that some women from Orange Farm said they thought their partner had not noticed that they were using the female condom. In some cases the male partner gave no comment or opinion on the method. The male questionnaire was only completed by a very small number of men and so has not been included in the results.

Table V. Technical issues in use of the female condom

	Hlabisa FPC (*N* = 53)	Cape Town FPC (*N* = 21)	Orange Farm (*N* = 37)	All sites
Ease of condom insertion				
Easy (%)	45	96	97	79
Fairly easy (%)	15	4	3	7
Difficult (%)	40	0	0	13
Lubrication				
Just right (%)	32	73	100	68
Too much (%)	64	27	0	30
Too dry (%)	4	0	0	1
Size				
Too big (%)	66	14	0	27
Too small (%)	0	0	0	0
Right size (%)	34	87	100	74
Outer ring				
Stayed in place (%)	87	86	100	91
Pushed into vagina (%)	13	14	0	9

FPC = family planning clinic.

Table VI. Preference for male or female condom*

Preference	Hlabisa FPC (*N* =26)	Cape Town FPC (*N* = 9)	Orange Farm (*N* = 24)	All sites
Liked the female condom less (%)	42	0	0	14
No difference (%)	31	100	50	60
Liked female condom more (%)	27	0	50	26

*Includes women who have used a male condom before only.
FPC = family planning clinic.

Women were asked if they would recommend the female condom to friends and also if they would continue to use the female condom now or at some point in the future. Most women (96%) from all centres said that they would recommend the female condom to friends and most were positive about future use. Women were less sure that their partners would want to use them on a regular basis. Women were asked if they would be prepared to pay for the female condom and how much. Those who were prepared to pay indicated that the cost should be similar to that of the male condom.

DISCUSSION

The initial response from women to the female condom and the study was very positive, and all women approached to take part were willing to try the method. This initial interest was not reflected in numbers who continued in the study and returned for follow-up. The process of contacting women who had not returned for follow-up after 2 weeks was often difficult; however, all who were contacted (85%) said that their partners were not willing to try the method. In all centres except for Hlabisa women who had not managed to use the method had not returned for their follow-up appointment. Most felt that because they had not used the method they did not need to return to the clinic. The 100% follow-up at the Hlabisa site and the higher proportion of those who used the method more than once was probably due to the financial incentive offered for women to return. In Orange Farm a community-based sample was used to investigate reasons for non-response. It seems that the reasons for discontinuation were similar in this sample to those of the clinic centres, with partner reaction and willingness to use the female condom being crucial to the decision to try out the female condom even once.

The issue of partner reluctance had not been anticipated on

Table VII. Partners' reaction to the female condom

Reaction	Hlabisa ($N = 53$)	Cape Town ($N = 21$)	Orange Farm ($N = 37$)	All sites
Liked it (%)	45	10	43	33
All right (%)	11	24	22	19
Disliked it (%)	40	62	5	36
No opinion given (%)	4	5	24	11
Did not know it was used (%)	0	0	5	2

such a scale, and so detailed information on why the partner was unwilling to try out the female condom was not collected. Some women said that on just showing it to their partners they had refused to use it, and there was no discussion on the matter. Other studies[11,13] also report that a major problem in use or the main reason for discontinuation was partner dislike of the device. This indicates that in many situations the method is not entirely woman-controlled. Some men volunteered to take part in the study, and it may be that in some instances the female condom may be more acceptable if introduced through the male partner. This is something that will be investigated in a further study.

Other acceptability studies[15] in developed countries have shown that the product is better accepted by couples who have previously used male condoms. The community sample follow-up group had reasonable success with use of the female condom, even though past experience with male condom use was low. This may be because although the interviewers gave the same demonstration to the women they had more time to explain how to use the product in the woman's own home. Low levels of male condom use were also reported in Hlabisa, and this group reported the most problems and difficulty in using the female condom. This centre may reflect the true picture of problems experienced in using the product by women who have little or no experience of the male condom. It may also be the case that partners' past and current use of the male condom is also an important factor in the willingness of the man to try out the female condom.

The main comments on the characteristics of the female condom found at different levels across all sites were size and lubrication. The issue of over-lubrication may be linked to the practice of dry sex, and some studies have found that condom use has been affected by dry sex practice.[16] Technical problems in use also varied between the sites. Although breakage was a rare event, the position of the female condom did cause problems for some of the women. The outer ring of the female condom should stay outside the vagina during sex. A number of women mentioned that the outer ring was pushed inside at some point during sex, but they were not sure when it happened. This issue is probably the major problem in terms of efficacy as a contraceptive method and also as a means of protection against STDs/HIV. In the instructions on use of the method, the woman should hold the outer ring and guide the penis into the vagina. Some women reported that they were not doing this, and this may have to be clarified and emphasised on the instruction leaflet. Issues of comfort mainly centred on the inner ring and the size of the device. Women in Hlabisa reported that the inner ring was uncomfortable; however, this was not a problem in the other centres. Women who said they felt the condom was too big often said that it felt uncomfortable — some said specifically that there was too much material inside them. This may be because the condom has not been positioned correctly in the vagina. Most women agreed that insertion got easier with practice. On average, each follow-up participant had used 2 - 4 condoms during the study period. It could be that there might have been fewer problems if the women had been given a longer time to get used to the method.

Partners of women showed a mixed response to the female condom, with about half liking the product or thinking it was all right, and about one-third to two-thirds disliking the product across the sites. A small number of women in the community sample had used the female condom without the partner's knowledge.

In general, womer were very positive about recommending the product to friends and using the condom in the future. They were also prepared to pay a small amount for the female condom. Overall, it seems that overcoming partners' opposition to use is the most important issue to address when introducing the female condom. Counselling should be provided on how women can introduce the female condom into a relationship. Another important issue will be ensuring that women are given good instructions in the use of the product, especially those who have never used the male condom. Many women gave up initially because they felt the device was uncomfortable; those who used the condom more

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than once said that insertion and comfort did improve, and so it would also be important to emphasise the need to practice fitting the device before use.

Strategy planning

The planning of the strategy used the results of the multicentred acceptability study to inform how best to introduce the female condom into the public services. Each province identified a limited number of public sector outlets for distribution of the female condom. Only two to three clinics were selected in each province because of the limited supply of female condoms. The criteria for the selection of sites was decided by each province, and was based on patient load, accessibility of the clinics, and also trying to include both rural and urban sites. Other distribution strategies include community-based distribution and youth services operated by the Planned Parenthood Association of South Africa (PPASA). A social marketing strategy has been devised by the Society for Family Health.

Health care professionals in all the participating sites have been trained in a 3-day workshop. The training aims to equip the providers with technical knowledge and skill to provide the female condom, and emergency contraception. Training also included a re-introduction of the male condom to strengthen existing knowledge and skills. The training emphasises dual protection strategies and provides counselling and risk assessment skills. Key issues from the acceptability study were discussed in the training. One of the main problems and reasons for discontinuation was partner reluctance to try out the female condom. This and other issues were addressed by ensuring that there was a major focus on examining provider attitudes and how to equip clients with negotiation skills.

Launch of the introductory strategy

From 1 June 1998, the female condom was available to women from the distribution outlets identified in the strategy. The female condom will be offered as part of the contraceptive method mix to all family planning clients attending the clinics. Women and men interested in trying out the method will be counselled on use of the method. The national and provincial co-ordinators are in the process of monitoring the introduction of the method. Data are being collected on the distribution of the female condom and the clients who accept the method. Users of the female condom, in particular those clients who become regular users of the method, will be identified and contacted for interviews to gain further information. This focused research will aim to identify the characteristics and type of client for whom the method may be most suitable.

The information gathered from the national monitoring and evaluation of the introduction of the female condom and the focused research will inform the national Department of Health on the feasibility and sustainability of the female condom as a method available to women in the public health services.

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