

## The female condom (Femidom) — a study of user acceptability

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**Objective.** To determine the acceptability of the female condom (Femidom).

**Design.** Questionnaire survey following the use of the Femidom during sexual intercourse.

**Setting.** Groote Schuur and Somerset Hospitals, Cape Town.

**Participants.** Nurses, secretaries, doctors and domestic staff of Groote Schuur and Somerset Hospitals who volunteered — 61 women were recruited, 8 did not use any female condoms, and 1 did not return. Many women refused, mainly because of the unaesthetic appearance of the Femidom and the fact that they had to continue using their regular contraceptive and they did not think their partners would co-operate.

**Outcome measures.** Sexual responsiveness compared with that without Femidom; acceptability of the method; women's and their partners' enjoyment of using the method; comparison with the male condom; awareness of HIV-AIDS and protective measures that can be used.

**Results.** Of the 52 participants, 23 used all 10 Femidoms issued to them. Thirteen women and 18 of their partners did not enjoy using the method and 9 had problems with it. Sex with the Femidom was the same or better in 51,9%. The Femidom was unacceptable in 32,7%, acceptable in 52% and very acceptable in 13,4%. Compared with the male condom, 50% of women and 44,2% of men considered the Femidom as good or better. Of the 61 women, 59 had heard of AIDS, and awareness of protective measures was good.

**Conclusion.** There was resistance to accepting the Femidom, mainly because of its unaesthetic appearance and because women were participating for altruistic reasons. Acceptance and ease of application improved with use. Comments regarding problems and subjects' and their partners' enjoyment varied from extremely positive to extremely negative; 65,4% considered sex using the Femidom acceptable or very acceptable. It is important to inform and obtain co-operation from the male partner. The female condom has been developed as an alternative for women to use if their partners refuse or dislike using male condoms. Perfect use of the Femidom

may reduce the annual risk of acquiring HIV by more than 90% in women who are sexually active with an infected male. The efficacy of the female condom has been described as equal to that of the diaphragm. The Femidom will increase the range of choices of contraceptives and prophylactic methods available for protective sex. It should become accepted as a method of contraception and an adjunct to other contraceptive methods as a prophylactic against sexually transmitted diseases and AIDS, particularly in relationships that are not mutually monogamous.

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Since the advent of HIV and AIDS, promotion and use of male condoms have increased. However, among many cultures (particularly in Africa) there is still reluctance to use condoms, owing to real and perceived drawbacks such as reduced sensation, interference with coitus, and the association of the condom with prostitutes and disease. Women who wish to protect themselves against sexually transmitted diseases (STDs) (and pregnancy) have to rely on use of condoms by their partners, but many patients at family planning clinics state that male condoms are not well accepted. The Femidom has been developed as a contraceptive barrier method for women. Many women who are not in stable relationships, and some married women who consider themselves at risk of STDs/HIV because of their partner's extramarital relationships, would welcome a contraceptive method which offers protection against STD that they could use if their partner(s) will not use condoms.

**Advantages of female condoms** are that the woman is in control, since it can be applied prior to coitus, interference with the act of intercourse is reduced, and sensitivity may be better than with the male condom.

The Femidom is a loose-fitting, soft polyurethane sheath 17 cm in length; the open end is attached to a flexible polyurethane ring 7 cm in diameter. A separate polyurethane ring 5,8 cm in diameter inside the condom serves as an introducer and a means of anchoring the device in the vagina. The Femidom acts as a vaginal liner and partially covers the vulva. It is prelubricated with a silicone-based lubricant and is intended for single use. Any form of additional lubrication may be used.

This study was undertaken to discover the acceptability of the female condom among sexually active women and their partners in the local population in Cape Town. It was offered to members of staff at Groote Schuur and Somerset Hospitals in order to facilitate follow-up and recall. The original intention was to recruit 100 subjects, but this proved difficult because: (i) many women found the device aesthetically unappealing; (ii) they did not think their partners would accept it; and (iii) they did not need it, because they were obliged to continue using their regular contraceptive (since this was a study of acceptability, not of effectiveness).

## Material and methods

Members of staff of Groote Schuur and Somerset Hospitals who attended their family planning clinic were invited to

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participate. The purpose of this study and the method of use of the Femidom were explained. After excluding gynaecological disease the investigator inserted the Femidom. The volunteer then inserted the device, to ensure that she was able to do it and found it acceptable. Ten Femidoms were then issued to be used during subsequent acts of sexual intercourse. The subjects were given written and verbal instructions on the correct use of the Femidom. At the return visit the questionnaire was completed by the investigator or the volunteer. The project was approved by the Ethics Committee, University of Cape Town. Subjects signed informed consent and were free to withdraw from the study at any time.

Only 61 women agreed to participate; 8 of them did not use any Femidoms, and 1 did not return.

**Inclusion criteria:** sexually active women between 18 and 45 years of age and free of gynaecological disease, who were using a non-barrier contraceptive method.

**Exclusion criteria:** pregnancy, pelvic inflammatory disease or a sexually transmitted disease. The subjects were told that they must continue to use their regular non-barrier method of contraception. On admission to the study information was obtained about age, occupation, marital/relationship status, parity, current method of contraception, previous condom use, number of sexual partners and frequency of sexual intercourse.

## Results

Sixty-one women entered the study; 8 did not use any Femidoms, and 1 did not return. Reasons for using no female condoms were as follows: relationship ended (2 cases), partner refused — unnecessary in monogamous relationship (1), partner refused — found the appearance of the Femidom offensive (2), partner threw them away (1), partner refused to co-operate (2). Fifty-two women therefore continued in the study. Their mean age ( $\pm$  SD) was 30,  $51 \pm 7,16$  years (range 21 - 45 years). There was no difference in age with regard to comments/use. The subjects had a median of  $11 \pm 3,24$  years of education (range 4 - 13 years). Twenty-five were married, 9 cohabitating, 16 single, and in 2 cases marital status was not recorded. When asked what day they would be most likely to conceive if they had a 28-day cycle, 31 (57,4%) of 54 who responded said day 14.

Numbers of Femidoms used were as follows: 23 subjects used 10, 4 used 8, 1 used 7, 2 used 6, 1 used 5, 7 used 4, 5 used 3, 6 used 2, and 3 used 1.

Commenting on why use of the Femidom was discontinued (Fig. 1), 13 women said they did not enjoy using the Femidom, 18 said their partner did not enjoy sex using the device, and 9 said they had problems with the device (some gave more than 1 answer, e.g. both she and he did not enjoy using the device, and some had more than one problem).

Reasons why women did not enjoy using the Femidom were that it was uncomfortable (6 cases), clumsy/difficult to insert (6), intrusive/reduced spontaneity (4), less sensation (2), irritating and painful (2), interfered with intercourse (2), embarrassing (1) and unsexy (1).

Reasons why the partner did not enjoy using Femidom were that he did not like it/found its appearance offensive (8 cases) or found it uncomfortable (the ring) (3). Men also felt

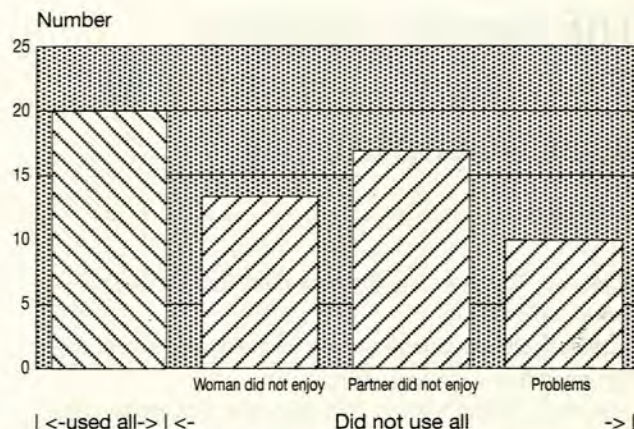


Fig. 1. User attitudes towards the female condom.

that it interfered with intercourse (2), was messy or had too much lubrication (2) or 'feels like a plastic bag' (2); other complaints were friction during intercourse (1), 'put him off sex' (1), reduced sensitivity (1), they don't need it, 'he wants flesh to flesh' (1), and reduced spontaneity (1).

Problems experienced were: difficulty with insertion (5 cases), too much lubrication (slippery) (4), it came out during intercourse (2), it was bulky and uncomfortable (2), it wrinkled and moved about (1), and the inner ring came towards the entrance (1).

Compared with sexual responsivity before entering the study, sex with the female condom was considered better than before in 9 cases (17,3%), the same as before in 18 cases (34,6%), and not as good as before in 24 cases (46,2%); 1 subject (1,9%) gave no answer. Of the women 51,9% therefore considered sex with the device the same or better.

On the question of acceptability (Fig. 2), 17 women (32,7%) found the device unacceptable (would not consider using it under any circumstances), 27 (52,0%) found it acceptable (would consider it under certain circumstances), and 7 (13,4%) found it very acceptable (would consider using it on a regular basis); 1 woman (1,9%) gave no answer. Of the women 65,4% therefore found it acceptable or very acceptable.

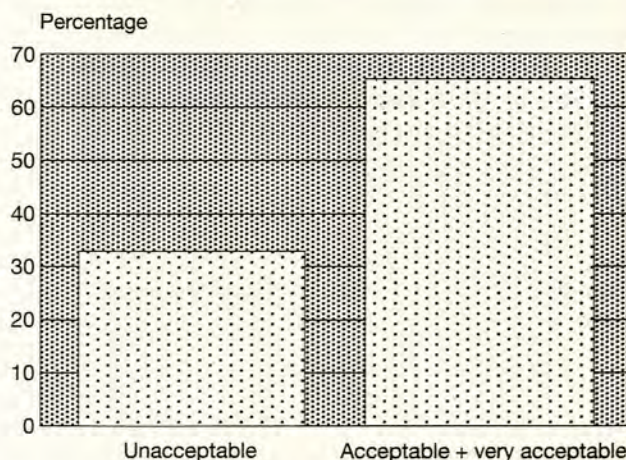


Fig. 2. Acceptability of the female condom.



Positive comments on acceptability were: comfortable/more comfortable (8 cases), increased intimacy/sensation (7), a positive idea for safe sex (5), it gets better with more use (5), (very) hygienic/less messy (4), felt in control/sense of self-protection (3), more sensation than with male condoms (3), no interference with sex (applied before) (2), easy to insert, more lubrication (1), it is acceptable for a one-night stand/in emergency if too shy to tell man to use condom (1), and acceptable, but male must agree (1).

Negative comments were: clumsy/difficult to insert (17 cases), interfered with foreplay (10), aware of partner's negative attitude (8), uncomfortable (9), unaesthetic, appearance offensive, huge (6), noisy (rustling plastic) (2), it moved in and out, slippery (2), the ring caused pain/discomfort (2), difficult to remove (1), 'like making love in a plastic bag' (1), 'it looks like a light bulb' (1), and limits positions (1).

Compared with the male condom, 20 women (38,5%) found the Femidom not as good, 15 (28,8%) found it better, and 11 (21,2%) found it as good; 5 women (9,6%) had never had sex with a man using a male condom, and 1 (1,9%) gave no answer. Of the women 50% therefore considered the Femidom as good as or better than the male condom.

Positive comparative comments were that the female condom becomes more acceptable with practice; is cleaner, not messy, much preferred; feels safer, as the male condom tended to slip off; is more comfortable, hardly noticeable, gives better sensitivity; and women can make a decision with regard to safe sex and can control prevention of pregnancy and STDs.

Negative comparative comments were that the female condom involves more struggle, is more difficult to insert, takes longer, and is more clumsy and inconvenient, and that women are expected to take all the responsibility.

Of the men, 25 (48%) considered the Femidom not as good as the male condom; 13 (25%) considered it better, and 10 (19,2%) considered it as good. Four men (7,8%) had never used the male condom before. Of the men 44,2% therefore considered the female condom as good as or better than the male condom.

Positive comparative comments were: less messy, more sensation, not as tight as the male condom, better lubrication, more comfortable, and no interference with sex; negative comments were: off-putting, takes time to insert, only suitable in a very close relationship, dislike the feel and appearance, the man feels more in control with the male condom.

Comments on features they liked or disliked about the Femidom or the male condom were that the Femidom should be lubricated inside as well, dislike male and female condoms, men don't like the idea of the Femidom because they are too old fashioned/set in their ways, doesn't feel like the real thing, 'wants flesh to flesh', put him off to wait for her, and male condom too small, female condom too big.

In reporting on the performance of the Femidom, all 52 women said that it did not tear before, during or after intercourse; 39 (75%) reported that it did not come out of the vagina during intercourse, but 13 (25,0%) said that it had done so. The Femidom tends to remain over the penis when it comes out of the vagina, so a barrier is still in place.

When asked if they had heard of AIDS, 59 of the 61 women originally recruited said that they had. Questions were asked to ascertain the level of awareness of HIV/AIDS

and protective measures that can be used; many women gave more than one answer.

'How do you believe people get AIDS?' elicited the answers: following sexual intercourse/casual /unprotected sex (57 replies), blood transfusion/contact (43), needle prick (14), sharing (dirty) needles (26), mother to child (10), sharing a toothbrush (10), homosexual relationships (3), and body fluids (1). Answers to the question 'How can people reduce their risk of getting AIDS?' were: safer/protected sex/use condoms (47), stick to one partner (41), sterile needles/don't share (8), abstain from sex (5), test blood for transfusion (3), accept that 'it can happen to me' (1). Awareness of the disease and protective measures was high. This is not surprising, since the staff have been exposed to information in the form of lectures, pamphlets and films.

## Discussion

Many women who attended the family planning clinics were asked to enter the Femidom study. On seeing the Femidom some laughed or looked amazed, some shuddered, and some made peculiar comments. Only 61 agreed to participate. Of those, 8 did not use any of the devices issued because their partner refused to or the relationship ended, and 1 did not return; 52 women therefore used 1 or more female condoms, but only 23 (37,7% of the original 61 subjects) used all 10. The women recruited were domestic workers, nurses, secretaries and doctors on the staff of Groote Schuur and Somerset Hospitals. Of the 61 women recruited 59 had heard of AIDS and all of these women were aware of one or more ways of contracting the disease, as well as one or more ways of reducing the risk. Only 59,6% of the women answered correctly regarding the expected day of ovulation in the menstrual cycle. This gives an indication of their awareness of the physiological processes of the reproductive cycle.

Regarding their sexual responsivity, 52 % of the women said it was the same or better using the Femidom, and 46 % that it was not as good as without it; 65% of the women said that the Femidom was acceptable or very acceptable and 33 % said it was unacceptable. Comments regarding their enjoyment or their partner's like or dislike of the method and the problems experienced were varied. However, only a few found it uncomfortable, and difficulty with insertion diminished with use. The unaesthetic appearance had a negative effect on many couples.

A major component of protective sex practice to reduce HIV infection is the consistent use of a barrier method. Until recently the only barrier method available was the male condom. A method that enables women to play a greater part in protecting their own health is urgently needed. One of the limitations of this study is that these women did not need to use the Femidom, and were participating purely for altruistic reasons. They agreed to use the method without consulting their partners, some of whom refused to co-operate. The main complaints were that the Femidom was aesthetically unappealing or even offensive, and clumsy and difficult to insert (although this improved with practice), and that its use had to be premeditated or it interfered with intercourse. Where couples, especially women, perceive the need for barrier protection against infection (and pregnancy), this method should become an appropriate method of



contraception and an adjunct to hormonal or intra-uterine contraceptive methods in relationships that are not mutually monogamous.

There are no large studies on efficacy, but Trussell<sup>1</sup> concluded that during perfect use the efficacy of the female condom is equal to that of the diaphragm, greater than or equal to that of the cervical cap, and greater than that of the sponge. Statistical comparisons of the contraceptive efficacy of female and male condoms are not possible because there have been no controlled prospective clinical trials of the male condom. Bounds *et al.*<sup>2</sup> reported a 15% use effectiveness failure rate (life table) at 12 months. The drop-out rate was 56% for a variety of method acceptability reasons, possibly influenced by the fact that about two-thirds of the acceptors took part out of curiosity as at that stage in the UK there had been no publicity or chance to see what a female condom looked like. Extrapolations from results on contraceptive efficacy suggest that perfect use of the female condom may reduce the annual risk of acquiring HIV by more than 90% among women who have intercourse twice weekly with an infected male.<sup>1</sup>

In the Groote Schuur study there were no cases of rupture of the device. Thirteen women reported that it came out of the vagina during coitus, and although in some cases it remained over the penis, this could increase women's risk of exposure to both HIV and pregnancy. Health promotional advice should emphasise careful use and the need to take prompt recourse to emergency contraception in the event of any failure of use.<sup>3</sup> Some couples commented that the Femidom interfered with foreplay and limited their coital positions, but it did not appear to have an important bearing on sexual sensitivity or responsiveness. Surprisingly, only 3 women commented on the fact that they were in control. This was probably because in this study most women were in a monogamous relationship and did not need to use the Femidom as a contraceptive.

The women who accepted recruitment were self-selected, and presumably more comfortable with their sexuality and handling their genitalia and more willing to try something new than the women who refused to participate. The most important negative features that were reported were related to interference with sexual activity involved at insertion, and the size and unaesthetic appearance of the device. It became evident that it is extremely important to educate the male partner and obtain his co-operation before promoting this method.

The female condom will increase the range of choices of contraceptive and prophylactic methods available for protective sex. This method is needed, because it enables women to play a greater part in protecting their own health. Where couples, and especially the woman, perceive the need for barrier protection against infection and pregnancy, the Femidom should become an acceptable method of contraception and/or an adjunct to other contraceptive methods as a prophylaxis against STD and AIDS.

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