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Short-term acceptability of the Reality® polyurethane female condom and a synthetic latex prototype: a randomized crossover trial among South African women

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Abstract

Purpose: This multisite, randomized, crossover trial comparing the acceptability of the Reality® female condom (FC1), with a new synthetic latex prototype (FC2) of similar design and appearance to FC1, was conducted in Durban, South Africa.
Methods: In total, 276 women were enrolled and 1910 FC1 condoms and 1881 FC2 condoms were used by 218 and 216 women, respectively.
Results: Overall experience of use was reported as good for over half the participants with both condom types (FC1=50.9%, FC2=55.1%). Similar acceptability issues were reported in like proportions for FC1 and FC2, with features such as the lubricant (FC1=36.7%, FC2=37.0%) and the material (FC1=36.2%, FC2=29.2%) most commonly viewed positively for both condom types. Negative aspects commonly reported for both female condoms were the lubricant (FC1=30.3%, FC2=31.5%) and the appearance (FC1=29.8%, FC2=34.0%). Preference for FC1 was 29.5% and was slightly higher for FC2 (36.6%). Some women felt that there was no real difference between the two devices (33.8%).
Conclusion: The acceptability of FC1 and FC2 was comparable, and women who find FC1 acceptable to use should also find FC2 acceptable.

Keywords: Acceptability; Female condom; Barrier methods; Reality®

1. Introduction

It is widely agreed that effective female-initiated barrier methods are urgently needed to provide protection against HIV and other sexually transmitted infections, and unwanted pregnancies [1–4]. Results from acceptability studies show that the short-term acceptability of the female condom is varied, but that it is acceptable to a number of men and women [5–10]. While two early acceptability studies undertaken in South Africa reported a mixed reaction to the Reality® female condom [3,11], a more recent evaluation of the female condom introductory strategy in South African public sector clinics suggests that it is acceptable to some South African women [12], and the number of clinics distributing the female condom continues to expand.

The introduction and distribution of the female condom is limited in resource-poor settings due to its high cost relative to the male condom [13]. Although few intervention studies have tracked patterns of female condom use over time, they do provide an indication that effective female condom interventions will lead to increased levels of protection [4]. This suggests that every effort should be made to make the female condom more affordable.

In an attempt to reduce costs, a prototype female condom made of a synthetic polymer (synthetic latex) has been developed by the Female Health Company [13]. It is similar in design to the Reality® female condom, but due to less expensive material and manufacturing, it could be considerably cheaper. The short-term acceptability of the synthetic latex prototype female condom (FC2) compared with the polyurethane female condom (FC1) is reported in this

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article. Findings from an evaluation of the performance of this new prototype female condom compared to the Reality® female condom are reported in a companion article in this issue [14].

2. Materials and methods

2.1. Materials

The FC1 is a transparent polyurethane sheath with a fixed outer ring that remains outside the vagina and an inner ring that is used for insertion. The FC2 is similar in appearance (size, shape, color) to the FC1, but the FC2 is made of synthetic polymer, is seamless, and the outer ring is rolled rather than preformed as in the polyurethane female condom ring, so that the FC1 ring is flat compared to a rounded FC2 ring.

2.2. Methods

The study was approved by the Human Research Ethics Committee of the University of the Witwatersrand. As described in the companion article [14], this multisite, randomized, crossover trial was conducted between January and September 2004 among urban and rural family planning clients, students, sexually transmitted infection (STI) clients and commercial sex workers in the Durban (eThekwini) district of the Province of KwaZulu-Natal, South Africa. The participants were the same as those described in the companion article [14].

The methods are described in detail in the accompanying article. To summarize, women were randomly assigned to one of two sequences — use of FC1 followed by FC2 or the opposite order; asked to use at least 10 of both condom types with their partners over 2–3 months; completed interviewer-administered questionnaires at baseline and at follow-up visits after 10 uses of each condom type; and kept coital logs over the course of the study. Although the two condom types are very similar in appearance, they are not identical, thus blinding of study staff and participants was done only to the extent possible. Furthermore, women were not informed of the actual condom use sequence assigned. The interviewer-administered questionnaire completed at follow-up visits after use of each condom type included questions on the number of female condoms used, type of partner, acceptability criteria, and adverse events. Performance criteria were assessed also and are described in the companion article [14].

2.3. Sample size, data collection and analysis

Pilot acceptability data collected prior to commencing the study indicated no difference between FC1 and FC2. The sample size was thus based on the number of participants required to determine differences between performance event rates of interest (e.g., clinical breakage rates) for the two condom types as described in the accompanying article [14]. Hence, we aimed to recruit at least 275 women by convenience sampling. Data were double-entered, and descriptive statistics were calculated using Epi-Info version 6.04d (Centers for Disease Control and Prevention, Atlanta, GA).

3. Results

As described in the companion article, a total of 276 women were enrolled in the study. In total, 1910 FC1 condoms and 1881 FC2 condoms were used by 218 and 216 women, respectively. The majority of women used at least eight condoms prior to each follow-up visit, and only 16 used less than five condoms. A flow chart describing the order in which FC1 and FC2 were used, the number of condoms used after the follow-up visits, and the response rates is shown in Fig. 1 of the accompanying article [14].

The mean age of study participants was 28.5 years with a younger student group (mean age, 23.2 years). Less than one third of the women were married or cohabiting, but 56% had a regular partner. In all groups, the majority had achieved secondary-level education. Thirty-two percent reported being employed full, part-time, or self-employed. Across all groups, 16 women said they had used FCs previously. Over one third (36.2%) of women reported that they were users of male condoms. A detailed description of baseline characteristics of participants by type of participant is described in the companion article [14].

3.1. Acceptability

Overall experience with use of both condoms was reported as good for over half of women (FC1=50.9%, FC2=55.1%) with under 2% in both groups saying they had an unsatisfactory experience (Table 1). About a third of women (FC1=29.8%, FC2=34.0%) said that the appearance of the device was what they liked least about using the

Table 1
Overall acceptability by condom type

	FC1		FC2	
Overall experience	*%*	*n=218*	*%*	*n=214*[a]
Good	50.9	111	55.1	118
Satisfactory	45.0	98	38.8	83
Neutral	2.3	5	5.1	11
Unsatisfactory	1.8	4	0.9	2
Most liked feature[b]	*%*	*n=218*	*%*	*n=216*
Lubricant	36.7	80	37.0	80
Material	36.2	79	29.2	63
Inner ring	25.2	55	24.1	52
Outer ring	14.2	31	15.3	33
Least liked feature[b]	*%*	*n=218*	*%*	*n=216*
Lubricant	30.3	66	31.5	68
Inner ring	21.6	47	17.1	37
Outer ring	11.5	25	8.3	18
Material	2.8	6	3.7	8

[a] Two missing responses.
[b] Multiple responses allowed for all questions.

Table 2
Specific acceptability issues by condom type

	FC1		FC2	
Ease of insertion	*%*	*n=218*	*%*	*n=214*[a]
Easy	58.7	128	57.5	123
Moderate	9.6	21	12.6	27
Difficult	4.6	10	2.8	6
Got easier with practice	27.1	59	27.1	58
Comfort	*%*	*n=218*	*%*	*n=214*[a]
Comfortable	88.5	193	89.7	192
Neutral	6.4	14	7.9	17
Uncomfortable	5.0	11	2.3	5
Problems with removal	*%*	*n=218*	*%*	*n=216*
Yes	8.3	18	8.3	18
Amount of lubricant	*%*	*n=216*[a]	*%*	*n=216*
Just right	60.6	131	62.5	135
Too much	35.6	77	36.6	79
Not enough	3.7	8	0.9	2
Feel	*%*	*n=218*	*%*	*n=216*
Like it	63.3	138	60.6	131
Okay	33.5	73	36.1	78
Dislike it	2.8	6	2.8	6
No opinion	0.5	1	0.5	1
Size	*%*	*n=218*	*%*	*n=216*
Right size	72.9	159	71.3	154
Too big	26.1	57	28.2	61
Too small	0.5	1	0.0	0
No opinion	0.5	1	0.5	1

[a] Two missing responses.

devices. Features most commonly liked were similar for the two condoms and included the lubricant (FC1=36.7%, FC2=37.0%) and the material (FC1=36.2%, FC2=29.2%) (Table 1). However, the lubricant was also the most commonly reported feature least liked for both devices (FC1=30.3%, FC2=31.5%) (Table 1). Few women mentioned experiencing noise during sex. Overall acceptability was similar across type of participant (data not shown), and women who had used FC1 before the study expressed similar acceptability issues.

The main perceived benefits of the female condoms were that it provided contraceptive protection (FC1=44.9%, FC2=46.3%) and more particularly STI/HIV protection (FC1=77.8%, FC2=74.5%). The dual protection role of the female condom in preventing pregnancy and STI/HIV infection was also recognized (FC1=14.4%, FC2=19.0%). Other benefits mentioned were that it could be used where the partner refused to use the male condom (FC1=15.3%, FC2=18.5%) and that it increases sexual pleasure (FC1=6.0%, FC2=9.7%). The majority of women said that both FC1 (82.1%) and FC2 (84.4%) were better than a male condom. Almost all said they would use it in the future. At the end of the study, many participants requested and were given more FC1 and were referred to a clinic for future supplies.

A similar proportion of women using FC1 and FC2 reported that insertion was easy (FC1=58.7%, FC2=57.5%) and that the female condoms were comfortable to use (FC1=88.5%, FC2=89.7%) (Table 2). Few women (FC1=8.3%, FC2=8.3%) reported problems with removal. Problems with insertion and removal decreased with experience, and those returning for their second follow-up visit reported improved comfort levels with 94.0% saying that the female condom was comfortable to use compared to 85.5% at the first follow-up visit.

The condom types were equally acceptable in terms of lubrication, feel, and size. Although just over a third of women felt that there was too much lubrication on the condoms (FC1=35.6%, FC2=36.6%), most reported that the amount of lubricant was "just right" (FC1=60.6%, FC2=62.5%) (Table 2). Almost all women said that they liked the feel or that it felt "okay." Most felt that the female condom was the right size (FC1=72.9%, FC2=71.3%), but it was considered too big by a quarter of women (FC1=26.1%, FC2=28.2%) (Table 2).

3.2. Perceived partner response to the female condoms

Women using the condoms were asked about their partner's response to the device, and the general reaction of the partner was perceived to be positive, with most women reporting that their partner liked the devices (FC1=80.7%, FC2=80.5%), few saying that their partners disliked them (FC1=13.3%, FC2=12.1%), and the

Table 3
Perceived partner response to female condoms

	FC1 (*n*)	FC2 (*n*)
Aspects liked		
Feels natural/does not reduce pleasure/sensation	29	29
Size/not too tight	29	15
Strong material/strength of condom	16	22
Dislike male condom	14	20
Female initiation/responsibility	14	19
Protection	13	17
Comfort for male	13	8
Insertion	6	5
Soft material/material texture	7	2
Lubricant	3	6
Equivalence to/alternate with male condom	4	5
Ability to support partner	4	2
Other	7	6
Aspects disliked		
Too much lubricant	10	9
Too big	4	10
Inner/outer ring uncomfortable	8	5
Unattractive	6	5
Holding during penetration	3	3
Reduces pleasure	3	2
Technical problems	4	1
Dislike of condoms in general	4	1
Time-consuming	3	1
Distraction/needing to be cautious	3	1
Noise	2	1
Other	4	4

remainder indicating that their partners were neutral (FC1=6.0%, FC2=7.4%).

The natural feeling, size of the condoms, and strength of the material were aspects reported to be most liked for FC1 and FC2 (Table 3). The female condom's role in sexual pleasure was reported to be important to many partners with women stating that their partners "felt like there was no condom" or that it was like "flesh to flesh," or that the condom "did not reduce pleasure." Around a third of women reported that their partners assisted in insertion (FC1=32.1%, FC2=30.5%).

Aspects perceived to be disliked by partners included that there was too much lubricant, the female condoms were too big, the inner or outer rings were uncomfortable during sex, and female condoms are unattractive. A few women reported that their partners found noise a problem during female condom use (FC1 $n=2$, FC2 $n=1$).

3.3. Overall preference

Preference for FC1 was 29.5% and was slightly higher for FC2 (36.6%). Some women felt that there was no real difference between the two devices (33.8%). Note that this question was added after women returning for follow-up started to express preference for one female condom type over the other; thus, responses were obtained from only 91% ($n=183$) of the total of 201 women who completed both follow-up visits.

4. Discussion

This is the first study to provide comparative data on the acceptability of FC1 and FC2. Visually, the two condoms appear almost identical in terms of size, shape and color, and many women participating in this study commented on their similarity. Overall experience of use was reported as good for over half the participants with both condom types. In general, similar acceptability issues were reported in similar proportions for FC1 and FC2, with features like the lubricant and the material most commonly viewed positively for both condom types. Negative aspects commonly reported for both female condoms were also regarding the lubricant and the appearance. Acceptability was similar across participant type. The majority of women reported that their partners, with whom they used the condoms, liked both devices.

There was also very little difference in the condom type women preferred, with a third finding no difference between the two, just under a third preferring FC1, and just over a third preferring FC2. These findings are consistent with the study undertaken by Latka et al. [15] in the United States, where about half the participants preferred the Reddy latex female condom prototype and half preferred the Reality® female condom. (The design and appearance of the Reddy female condom is not similar to the Reality® female condom.)

The acceptability issues reported for both condom types by the South African participants were similar to those documented in other published studies on acceptability. For instance, in our study, the appearance of the female condom was negatively regarded by about a third of the women, and the most common complaint documented in the World Health Organization review was related to the female condom's appearance [5]. In more recent studies [3,6,16], concerns about the female condom appearance have often been expressed. In line with our study, female condom lubrication has been reported to be disliked in some studies [3,5,9,16]. On the other hand, as with our study, the lubrication has also been favorably regarded [5,9]. Consistent with the study undertaken by Latka et al. [15] in the United States, noise during sex was not reported to be a problem with either condom type.

Insertion difficulties are often reported [4,5,7,16,17], but are also reported to decrease with instruction and practice [4,16–18]. In our study, women were given comprehensive counseling about female condom insertion and use by a provider with considerable training and experience in female condom provision. This may account for close to 60% of our participants reporting that insertion of both types of condoms was easy. Improvement in user experience with practice was present across almost every aspect of use in our study, and improvement in acceptability with practice is also documented in other studies [5,18].

4.1. Limitations

- Participants were selected by convenience sampling.
- Many women had used 20 condoms by the time they had returned for their second visit and they could be described as experienced in the use of the method. Although this may have been an advantage in this study to get a better perspective on use, it may have resulted in some loss of detail on user experience, as users typically returned around 5–6 weeks after receiving the condoms and may have forgotten some details of their experiences.

5. Conclusion

Women who find FC1 acceptable to use should also find FC2 acceptable. The acceptability issues reported for both FC1 and FC2 by South African women were similar to those documented in other published studies on acceptability.

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