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Original research article

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.