ELSEVIER

Contraception 73 (2006) 386–393

Contraception

Original research article

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

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Received 24 June 2005; accepted 28 July 2005

Abstract

Objective: This multisite, randomized, crossover trial comparing the performance of the Reality® female condom (FC1) with a new synthetic latex prototype (FC2) was conducted in Durban, South Africa.
Method: In total, 276 women were enrolled and 201 women completed the study. Altogether, 1910 FC1 condoms and 1881 FC2 condoms were used.
Results: Total breakage was 0.73% in FC1 and 0.85% in FC2 (95% confidence interval, −0.64 to 0.87). The number of clinical breakages (those that could result in a pregnancy or sexually transmitted infection) was similar for each condom type (FC1, $n=9$; FC2, $n=8$). Incorrect penetration (penis between condom and vaginal wall) was 1.26% and 0.64% for FC1 and FC2, respectively. Outer ring displacements (outer ring pushed into the vagina partially or fully) were comparable for both condoms (FC1, 3.14%; FC2, 2.98%). Slippage (condom came out of the vagina) was rare and reported in 0.37% or less of devices used. Total clinical failure was 5.24% in FC1 and 4.3% in FC2.
Conclusion: The FC1 and FC2 performed comparably within this trial.

Keywords: Female condom; Reality; Performance; Synthetic latex; Randomized trial; Barrier methods

1. Introduction

Effective female-controlled barrier methods are urgently needed [1,2]. Introduction of female-initiated barrier methods increases women's options for protection against sexually transmitted infection (STI)/HIV and unwanted pregnancy. The Reality® female condom was introduced in 1998 into a limited number of public health facilities in all provinces in South Africa [3]. This program has been expanded and Reality® is now available free of charge at over 200 sites nationally. Cost is one of the major barriers to expanded distribution of the female condom in South Africa and other countries, and it is important to find ways of decreasing the unit cost of the product.

A prototype female condom made of a synthetic polymer (synthetic latex), which meets the same specifications as the Reality® condom, but having lower material and manufacturing costs, has been developed by the Female Health Company (Chicago, IL). The aim of our study was to evaluate the functional performance and short-term acceptability of the Reality® female condom (FC1) compared to the synthetic latex female condom prototype (FC2) after a minimum of 1000 uses per device type. To accomplish our objective, we compared the rates of clinical, nonclinical and total breakage, outer ring displacement, incorrect penetration, slippage and adverse events between FC1 and FC2. Findings from the performance component of the study are reported here.

The expected outcome of the study from the reference condom (FC1) was a breakage rate of less than 5.0%. This rate is the same as the WHO standard applied to male condoms. If the breakage rate for FC2 exceeded this standard, the new condom would not be considered for further development and testing.

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doi:10.1016/j.contraception.2005.07.015

2. Materials and methods

This was a multisite, randomized, crossover trial conducted in the Durban (eThekwini) district, KwaZulu Natal province, South Africa, between January and September 2004. Two devices manufactured by the Female Health Company were used in this trial: the internationally marketed Reality female condom and a new synthetic latex prototype. The two condoms appear almost identical in size, shape and color. On closer inspection, it can be seen that the outer ring differs (the FC1 ring is flat as compared to the rounded ring of the FC2). Further, the FC2 is seamless. Prior to study initiation, the protocol and informed consent were approved by the Institutional Review Board of the University of the Witwatersrand.

The urban participant population was recruited from existing family planning, STI and student clients of Durban's Commercial City adult and youth clinics. The rural family planning participants were recruited from Umbumbulu Clinic. Commercial sex workers (CSWs) were recruited from an established sex worker lodge in central Durban. The polyurethane female condom (FC1) is available as a contraceptive method to clients at the Commercial City site only.

Clients interested in participating in the study contacted the study nurse; volunteers were screened, administered the informed consent and enrolled in the study. To be eligible for participation, the volunteer was at least 18 years of age; not pregnant or nursing (pregnancy test done where necessary); currently using a hormonal contraceptive method, IUD or sterilized (tubal ligation only); currently sexually active (defined as at least one sex act in the last month); and in good general and genital health as determined by medical history and a vulval/vaginal inspection. A pelvic examination was not conducted. A volunteer was excluded from participation if she had a syndromic diagnosis of STIs or she reported symptoms based on her previous medical history or experience; had allergies or known sensitivities to silicone and latex products or vaginal lubricants; or was within 6 weeks postpartum or postabortion.

The study nurse briefed the participants on their responsibilities and the procedures for participation in the study, and gave verbal instructions for inserting and removing female condoms. Education included information about the devices and the need to use it correctly.

Women enrolled in the study were randomly assigned to one of two female condom use sequences: use of FC1 followed by FC2, or the opposite order. They completed an interviewer-administered questionnaire at enrollment to obtain information on demographic characteristics, sexual and reproductive history and prior use of barrier methods. Each participant was asked to use both types of female condoms (10 of each) with her partner(s) within a 2- to 3-month study participation period.

Women were instructed to complete coital logs for the duration of the study. Information on number of acts of intercourse, condom slippages and breakages, and other problems encountered during use were recorded in the coital log. They were asked to return for a follow-up visit after 10 uses of each type of condom. At follow-up, an interviewer-administered questionnaire was completed, which included questions on the number of female condoms used, type of partner, functional performance during use (breakage, rips, tears, incorrect penetration, outer ring displacement and slippage) and adverse events. Acceptability criteria were assessed also, but will be reported in another paper.

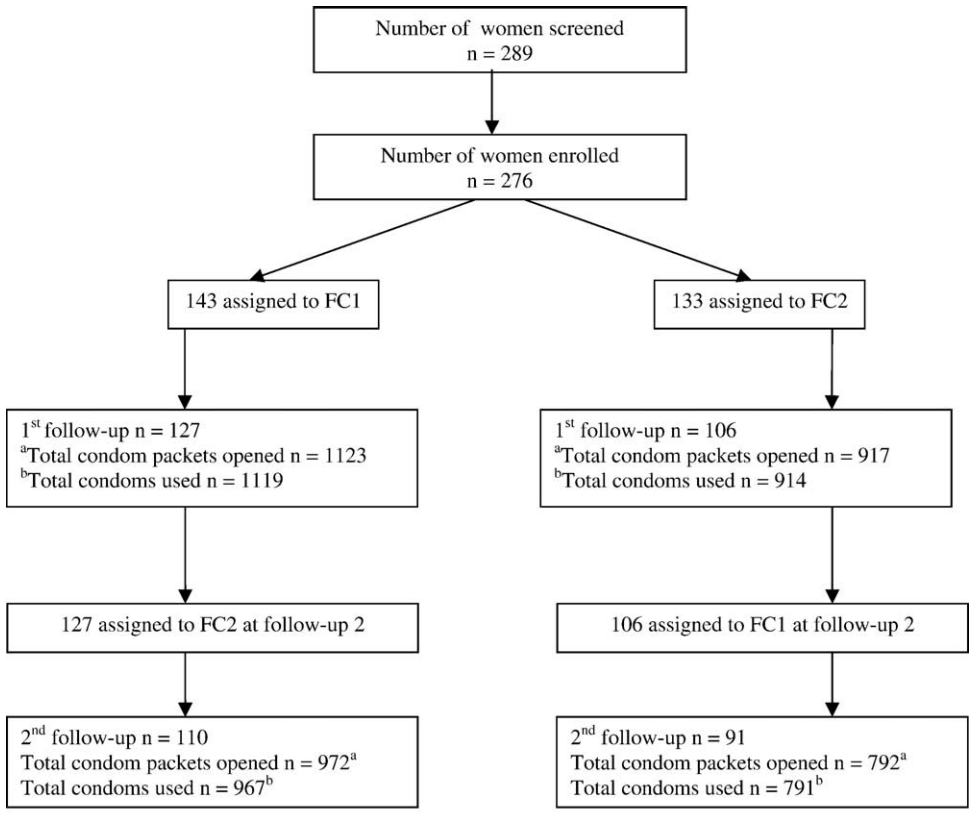
A vulval inspection to check genital health and a macroscopic examination of the vaginal epithelium was also conducted at each visit to check for irritation, burning or other adverse events.

2.1. Sample size and data collection

Because there are no established guidelines or standards for testing and evaluating female condoms, our sample size was determined by using the minimum sample size currently required by the International Standards Organization (ISO) Guidelines for evaluating male condom performance in human use [Working Group 17 of the Technical Committee 157 of ISO: "Working Group 17 Working Draft of Synthetic Condom Standard." (Cancun 2001, Dublin, Ireland 2002). Changed and modified in Kuala Lumpur, Malaysia 2002. Then presented to ISO Meeting in Denver, 2003]. These guidelines state that at least 1000 condoms per condom type should be used by at least 200 couples who have a minimum of 5 documented uses of both the "test" and "control" condoms. To achieve a total of at least 1000 uses per condom type and to allow for loss to follow-up, we aimed to recruit at least 275 women by convenience sampling. A target of 50 volunteers was set for each of the 5 participant groups: urban family planning clients, urban STI clients, students, rural family planning clients and CSWs. We recruited both novice and existing users of the Reality female condom (FC1), as it was anticipated that some women presenting for screening would have previously used this device.

Due to the low breakage rates reported for the FC1, the sample size required to detect such a small difference in performance between the two types of condoms would be too large for the resources allocated to the study [4]. To adjust for this, we presented 95% confidence intervals (CIs) about the differences between event rates of interest (e.g., clinical breakage rates for FC2 vs. FC1) in order to determine the size of difference in rates that can be ruled out with reasonable confidence, given our study size.

Although the two condom types were very similar in appearance, they were not identical; thus, blinding of study staff and participants was done only to the extent possible. Further, they were not informed of the actual condom use sequence assigned. Both types of condoms were contained in the same plain white plastic packages and labeled either "F" or "G". To minimize use order bias, we randomized the



[a]Total condom packets opened = Total number of packets opened (includes condoms not used for sex).

[b]Total condoms used = Total number of condoms used for vaginal intercourse.

Fig. 1. Flow chart of study participation and condoms used.

participants as to which device to use first. We used the random number list generator program (Epi-Info 6.04d) to create the list of numbers, with Number 1 assigned to condom "G" (FC1) and Number 2 assigned to condom "F" (FC2).

2.2. Data entry and analysis

Data were double entered and descriptive statistics were calculated using Epi-Info version 6.04d. Confidence intervals for the differences in event rates between FC2 and FC1 were calculated using PROC GENMOD of SAS (Cary, NC) to take into account the correlation among condoms used by the same couples [5].

Calculation of key functional parameters (breakages, incorrect penetration, outer ring displacement and slippage) was determined using a classification system for defining each event. We used the following definition of terms that was adapted from Steiner et al. [6].

2.3. Definitions

Clinical breakage is defined as the number of female condoms reported to have ripped/torn/broken during intercourse and is calculated by dividing the number of female condoms reported ripped/torn/broken during intercourse by the number of female condoms used during intercourse.

Nonclinical breakage is defined as the number of female condoms reported to have ripped/torn/broken prior to intercourse or after removal of the female condom from the vagina. It is calculated by dividing the number of female condoms reported to have ripped/torn/broken prior to intercourse or after removal by the number of packages opened.

Total breakage is defined as female condom breakage at any time before, during or after intercourse (both clinical and nonclinical) and is calculated by dividing the sum of the number of female condoms that ripped/tore/broke by the number of female condom packages opened.

Incorrect penetration is defined as vaginal penetration whereby the penis is inserted between the female condom and the vaginal wall and is calculated by dividing the number of reported incidences of incorrect penetration by the number of female condoms used during intercourse.

Outer ring displacement is defined as an outer ring that is pushed into the vagina (partially or fully) during intercourse and is calculated by dividing the number of incidences of reported outer ring displacement by the number of female condoms used during intercourse.

Complete slippage is defined as a female condom that slips completely out of the vagina during intercourse and is calculated by dividing the number of female condoms that

slipped out completely during intercourse by the number of female condoms used for intercourse.

Partial slippage is defined as a female condom that slipped partially out of the vagina without turning inside out and without acting as a male condom during intercourse or withdrawal; this was calculated by dividing the number of female condoms that partially slipped during intercourse or withdrawal by the number of female condoms used during intercourse.

Total clinical failure is defined as the number of female condoms that clinically broke, turned completely or partially inside out, slipped completely out during intercourse or was associated with reported incidences of outer ring displacement or incorrect penetration during intercourse (i.e., any event that could have resulted in semen and/or pathogenic organisms entering the vagina). Total clinical failure is calculated by dividing the number of female condoms that clinically broke, turned completely or partially inside out, slipped completely out during intercourse or was associated with outer ring displacement and incorrect penetration during intercourse divided by the number of female condoms used during intercourse.

3. Results

In total, 276 women were enrolled in the study. Eighty-four percent ($n=233$) completed the first follow-up visit, and 73% ($n=201$) completed both follow-up visits. Response rates by client group are shown in Fig. 1. Included in this figure are all women who used at least one condom.

The randomization process resulted in 51.8% ($n=143$) of the women using FC1 first and 48.1% ($n=133$) using FC2 first. In total, 1910 FC1 condoms and 1881 FC2 condoms were used by 218 and 216 women, respectively. Our data show that the majority of women used at least 8 condoms prior to each follow-up visit, and only 16 used less than 5 condoms. Seventy-five women were lost to follow-up: 43 did not return for the first follow-up visit and 32 did not return for the second. Attempts were made to contact by telephone all those not returning for the follow-up visits. For those contacted, the main reason for nonreturn was that they had not used all of the FCs given to them. In some cases, students were away on winter vacation and did not return.

Baseline characteristics of participants by client type are shown in Table 1. As expected, the student population was much younger than the other groups. Less than one third of the women were married or cohabiting, but 56% had a regular partner. In all groups, the majority had gone on to secondary level education. Thirty-four percent reported being employed full time, 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.

Table 2 shows baseline characteristics by degree of participation. Age was similar across all groups. The proportion of married women not completing the study (41%) was higher than the other relationship categories.

3.1. Condom breakage, outer ring displacement, incorrect penetration and slippage

Table 3 shows rates of breakage, outer ring displacement, incorrect penetration and slippage. The rates for all four events were low. The number of clinical breakages was similar in each group (FC1, $n=9$; FC2, $n=8$). In most cases ($n=16$), the women were unsure how the condom broke and only noticed the damage after removal. In all cases of

Table 1
Baseline characteristics of women at recruitment by client type

Characteristic	Students, $n=65$	Urban FP, $n=64$	Rural FP, $n=67$	STI, $n=21$	CSWs, $n=59$	Total, $n=276$
Mean age (years)	23.2	33.7	27.8	35.0	27.2	28.5
Relationship status, % (n)						
Married	3.1 (2)	25.0 (16)	10.4 (7)	33.3 (7)	3.4 (2)	12.3 (34)
Cohabiting	10.8 (7)	17.2 (11)	25.4 (17)	19.0 (4)	13.6 (8)	17.0 (47)
Regular partner	84.7 (55)	54.7 (35)	64.2 (43)	47.6 (10)	25.4 (15)	56.2 (158)
Casual partner	1.5 (1)	3.1 (2)	0.0 (0)	0.0 (0)	57.6 (34)	13.4 (37)
Mean education[a] (highest grade)	11.2	10.6	10.0	11.4	9.7	10.5
Occupation[b], % (n)						
Employee, full/part time	4.6 (3)	40.6 (26)	0.0 (0)	61.9 (13)	3.4 (2)	15.9 (44)
Self-employed	3.1 (2)	12.5 (8)	9.0 (6)	9.5 (2)	54.2 (32)	18.1 (50)
Unemployed	1.5 (1)	39.1 (25)	86.6 (58)	19.0 (4)	40.7 (24)	40.6 (112)
Student	100 (65)	7.8 (5)	4.5 (3)	9.5 (2)	1.7 (1)	27.9 (77)
Current contraceptive use[c], % (n)						
OCs	32.3 (21)	20.3 (13)	10.4 (7)	19.0 (4)	8.5 (5)	17.8 (49)
Injectables	66.7 (44)	65.6 (42)	85.1 (57)	47.6 (10)	88.1 (52)	74.3 (205)
IUD	0.0 (0)	0.0 (0)	3.0 (2)	4.8 (1)	1.7 (1)	1.5 (4)
Sterilization	1.5 (1)	14.1 (9)	3.0 (2)	28.6 (6)	1.7 (1)	6.9 (19)
Male condom	43.1 (28)	3.1 (2)	28.4 (19)	14.3 (3)	79.7 (47)	36.2 (100)
Female condom	3.1 (2)	10.9 (7)	0.0 (0)	9.5 (2)	8.5 (5)	5.8 (16)

[a] Educational grades 8–12 are equivalent to secondary education.
[b] Total sum in Column 2 occupation is greater then 100% as some students also reported part-time employment.
[c] Total sum for current contraceptive use exceeds 100% due to dual method use.

Table 2
Baseline characteristics of women by degree of participation

Characteristic	Nonreturners, $n=43$	First visit, $n=233$	Completers, $n=201$
Mean age (years)	27.9	28.6	28.6
Relationship status, % (n)			
Married	18.6 (8)	11.2 (26)	10.0 (20)
Cohabiting	4.7 (2)	19.3 (45)	20.4 (41)
Regular partner	62.8 (27)	56.2 (131)	55.2 (111)
Casual partner	14.0 (6)	13.7 (32)	14.4 (29)
Mean education (SD)	8.3	8.5	8.5
Occupation, % (n)			
Employed full/part time	16.3 (7)	15.9 (37)	12.9 (26)
Self-employed	7.0 (3)	20.2 (47)	20.9 (42)
Unemployed	32.6 (14)	42.1 (98)	44.3 (89)
Student scholar	44.2 (19)	21.9 (51)	21.9 (44)
Current barrier use[a], % (n)			
Male condom	34.9 (15)	36.1 (84)	35.3 (71)
Female condom	2.3 (1)	6.4 (15)	6.0 (12)

[a] Hormonal/modern method not shown as this was a study requirement.

uncertainty, a conservative approach was taken and the breakage was classified as clinical, that is, breakage occurred during sexual intercourse. Clinical breakage rates, that is, breakages that could result in a pregnancy or transmission of STIs, were 0.47% and 0.43% for FC1 and FC2, respectively. Nonclinical breakage was mainly damage caused by the user opening the package, or damage caused by the participants' fingernails during handling (FC1, 0.26%; FC2, 0.42%).

Twice as many women reported incorrect penetration while using FC1 (1.26%) compared to FC2 (0.64%); however, this difference was not statistically significant. Similar numbers of outer ring displacements were recorded (FC1, $n=60$; FC2, $n=56$), and there was no significant difference between the two devices. A small number of women (FC1, 6; FC2, 5) reported slippage events but were not always able to report with certainty whether the condom came out of the vagina and onto the male penis. In four cases, more than one event was recorded for the same condom. In two of these cases, the penis was inserted at the side of the condom (incorrect penetration) and then, subsequently, the condom was pushed inside the vagina (outer ring displacement). In the other two cases, there was outer ring displacement followed by breakage on trying to pull the condom back into the correct position.

With regard to total clinical failure (i.e., the sum total of any event that could result in a pregnancy or transmission of STIs), the condoms performed equally well. The failure rate for the FC1 condom was 5.24% and 4.3% for FC2.

The upper limit of the 95% CI of the difference between the proportions for the FC2 and FC1 condoms for all events analyzed (e.g., clinical breakage, total breakage, incorrect penetration, etc.) was about 1% or less. Thus, we can rule out differences as large as 1% (for FC2 vs. FC1) with a high level of confidence for all condom performance events examined. In addition, all CIs included 0%, so there is no evidence that either condom is superior to the other with respect to any of the performance events examined.

In comparing data from the first and second visits for incorrect penetration, outer ring displacement and slippage, there was a lower rate of events on the second visit as a proportion of total condoms used (data not shown). The number of breakages was similar in the second visit for FC1 and FC2. Qualitative information collected from the women indicated that practice and repeated use improved handling and reduced breakage and other performance events.

3.2. Discomfort and adverse events

Discomfort and adverse events are shown in Table 4. A similar number of women using FC1 and FC2 reported

Table 3
Performance areas of FC1 and FC2

Criteria	FC1						FC2						Difference in p per condom use (%)	95% CI	
	Condoms			Women			Condoms			Women					
	With event, n	Total[a]	p (%)	With event, n	Total	p (%)	With event, n	Total[a]	p (%)	With event, n	Total	p (%)		Lower (%)	Upper (%)
Breakage															
Total breakage	14	1915	0.73	9	218	4.13	16	1889	0.85	13	216	6.02	0.12	−0.64	0.87
Clinical breakage	9	1910	0.47	5	218	2.29	8	1881	0.43	7	216	3.24	−0.05	−0.62	0.53
Nonclinical breakage	5	1915	0.26	5	218	2.29	8	1889	0.42	8	216	3.70	0.16	−0.21	0.53
Incorrect penetration	24	1910	1.26	19	218	8.72	12	1881	0.64	11	216	5.09	−0.62	−1.33	0.09
Outer ring displacement															
Total outer ring displacement	60	1910	3.14	50	218	22.94	56	1881	2.98	40	216	18.52	−0.16	−1.24	0.91
Completely displaced	10	1910	0.52	8	218	3.67	17	1881	0.90	11	216	5.09	0.38	−0.25	1.01
Partially displaced	50	1910	2.62	42	218	19.27	39	1881	2.07	29	216	13.43	−0.54	−1.50	0.41
Slippage															
Complete slippage	4	1910	0.21	3	218	1.38	2	1881	0.11	2	216	0.93	−0.10	−0.39	0.19
Partial slippage	3	1910	0.16	3	218	1.38	3	1881	0.16	3	216	1.39	0.00	−0.25	0.26

p = proportion with event.

[a] The total number of uses for clinical breaks, incorrect penetration, outer ring displacement and slippage outcomes excludes uses for which nonclinical breaks were reported.

Table 4
Discomfort and adverse events in participants ever using FC1 and FC2

Type of event	FC1, $n=218$	FC2, $n=216$
	% (n)	% (n)
Discomfort during insertion	13.8 (30)	13.0 (28)
Discomfort after insertion before sex	3.2 (7)	1.9 (4)
Pain after insertion before sex	1.4 (3)	2.3 (5)
Pressure internally causing urge for micturition	0.9 (2)	0 (0)
Discomfort during sex	1.4 (3)	<1 (1)
Device uncomfortable to use	5.0 (11)	2.3 (5)
Burning/rash or itching	0 (0)	2.3 (5)
Bleeding[a]	0 (0)	<1 (1)
Confirmed STI[b]	<1 (1)	0 (0)

[a] The participant reported she was rough on insertion.
[b] White discharge confirmed as STI using syndromic management.

some discomfort during insertion. Fewer women mentioned discomfort once the device was in place. In most cases, women felt it was the inner ring causing the discomfort. A few women mentioned some internal pressure; however, only two women, both using FC1, mentioned that the pressure was enough to make them feel the need for micturition. Fewer women using FC2 (2.3%) reported that the device was uncomfortable to use compared to FC1 (5.0%). In five cases with use of FC2, women reported a rash or burning. Reports of discomfort were lower in the second follow-up visit (data not shown). Discomfort at insertion (FC1 and FC2 combined) went down to 5.0% ($n=10$), and reports that the devices were uncomfortable to use went down to 2% ($n=4$).

4. Discussion

This is the first study to provide a detailed reporting on the performance of the synthetic latex female condom (FC2). Although acceptability studies on the Reality® female condom are numerous, fewer studies have reported on actual performance in use [7–9]. Other studies have included some performance data; however, this was not the main objective of those studies [10–12]. Those that do report events of slippage and breakage often give the proportion of women experiencing the event and not the proportion of condoms used [10]. This makes comparisons between reports difficult. Breakage rates for male condoms are reported to range between 2.4% and 6% [13,14]. Breakage rates for Reality female condoms are lower than those reported for male condoms. For instance, in the first published study on female condom breakage, the rate was 1.6% of 441 condoms used [7]. In a recently published and the largest study on female condom use, a clinical breakage rate of 0.11% in 7895 condom uses was reported [9]. One study among sex workers in China reported that 1.3% of women experienced a breakage in the first or second use of the condom [10]. The breakage rate fell to zero in the last three uses; however, no clinical breakage rate was reported for total number of condoms used in this study. Another study from Thailand reported a breakage rate of 1.3%, but again, there was no clear definition of breakage and a lack of clarity on numbers of condoms used [11]. The total breakage rate in our study (FC1, 0.73%; FC2, 0.85%) is similar to a study among sex workers in Thailand, where FC breakage was found to be 0.6% [12]. Breakage rates have even been found to be low in studies of female condom reuse, where a breakage rate of 1.7% was found with condoms that had been used up to 10 times [15].

Our results show that total outer ring displacement was similar in both FC1 (3.14%) and FC2 (2.98%), and these rates are similar (2.8%) to the study by Valappil et al. [9], where outer ring displacement was described as slip-in. Leeper and Conrady [7] found the slip-in rate to be 2%, and the proportion of women (not condoms) experiencing slip-in in the Thai study was found to be 2.9% [11]. It is uncertain whether this is a valid comparison (i.e., women experiencing slip-in and the number of slip-in events reported), even though the percentages are similar.

In another FC study conducted by the researchers of the present study, clinical assessments of condom placement and fitting were directly observed by the study staff. One common problem noted with insertion was pushing the condom inside the vagina too far. This resulted in the outer ring being incorrectly positioned and not lying flat across the genital area. We believe that attempting sexual intercourse with the outer ring in this position could result in the penis catching the outer ring and pushing the condom inside the vagina. About a quarter (22.9%) of the women in our study experienced this event at least once with FC1, and slightly fewer (18.5%) experienced it with FC2; however, these figures improved with practice. This indicates that counseling and instructions in use should focus on this user problem specifically. We would recommend that instructions on proper placement should include that the outer ring be held by the woman during insertion, and that the couple should be aware of the outer ring during sex to ensure it does not get pushed inside the vagina.

Reporting of slippage of the condom out of the vagina varies, with the earliest reported FC evaluation, finding no slippage [7]. The highest rate reported is 2.8% [9]. One study does not report slippage rates for condoms but gives cumulative number of women experiencing slippage, which was found to be 11.8% after 16 weeks of use [11]. Our study found that slippage was a rare event; however, some women said they felt the condom move but were not able to confirm that it was a partial slippage.

Incorrect penetration (also called rerouting) occurs when the penis enters the vagina between the condom and the vaginal wall, and is a common problem reported in female condom studies [7,8,10,11]. In our study, incorrect penetration was found in 1.26% of FC1 devices used and 0.64% in FC2 devices used. This involved 8.7% of women using FC1 and 5.1% of FC2 users. This level is similar to other studies, one of which reported 7.1% of women experiencing

rerouting on first use of the device [10]. In the same study, the rate dropped to 1.3% by the last use of the device. A similar proportion of women (5.9%) experienced rerouting in the first week of use, and by 16 weeks, 8.8% of women had experienced rerouting [11]. In our study, incorrect penetration fell from 10.2% among users of FC1 at first visit to 6.6% at the second visit. Similarly, in FC2, the incorrect penetration rate dropped from 7.6% to 2.7%. We believe the elastic properties of the FC2 condom material may contribute to the reported lower rate of incorrect penetration by allowing the device to remain flat and lie more closely against the genitalia.

The total clinical failure rates of 5.24% for FC1 and 4.3% for FC2 are consistent with failure rates reported for male condoms [13,14]. A similar rate of 6% of all self-reported mechanical problems combined was found in a study that looked at effectiveness of FCs in preventing exposure to semen during vaginal intercourse [16]. Further, it is interesting to note that the nine clinical breaks reported for FC1 were experienced by five women. Multiple condom breaks by the same woman/couple is also consistent with male condom usage [13].

Adverse events such as itching/burning or rash were experienced by five women using FC2 in our study. These adverse events were not reported for FC1. In the Leeper and Conrady study [7], 6 of 98 couples experienced itching or irritation after use of FC1. The highest level of reported irritation was found in a comparative acceptability study of male and female condoms where 30% of women reported an experience of burning, itching or irritation during FC use [17]. It may be that our population of women are less likely to complain or that more probing questions need to be asked. In our study, the burning and itching reports were, however, raised during the physical examination, and women were asked if they had any problems. The low reports of adverse events may also be a timing issue where women forget to report their experiences if they occurred sometime earlier.

Fewer women using FC2 reported that the device was uncomfortable to use compared to FC1. Reports of discomfort were lower after the second follow-up visit. Discomfort at insertion went down to 5.0% ($n=10$), and reports that the devices were uncomfortable to use went down to 2.0% ($n=4$). This lower level of reported discomfort emphasizes the need for effective counseling and training, and the impact of experience on use-performance and acceptability.

The two condom types are alike in many aspects, and many women commented on their similarities. The improvement in user experience with practice was present across almost every aspect of use.

5. Conclusions

This study has shown that the synthetic latex condom performs as well as the polyurethane Reality® female condom in terms of breakage, slippage, outer ring displacement and incorrect penetration. Results of FC performance reported in this study are comparable to those reported by other researchers.

Acknowledgments

We would like to thank the staff from the participating clinics and management of the central Durban sex worker lodge for their time and assistance. We would like to express our appreciation to Drs. Rosalie Dominik, Marlina Nasution and Doug Taylor who kindly conducted the additional analyses to assess the performance of both condoms and provided advice and suggestions on our analysis and report. We would like to acknowledge the following organizations for funding the study: the Department for International Development (DfID), UK, the United States Agency for International Development (USAID), the Female Health Foundation, and the William and Flora Hewlett Foundation.

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