Performance and safety of the second-generation female condom (FC2) versus the Woman's, the VA worn-of-women, and the Cupid female condoms: a randomised controlled non-inferiority crossover trial

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Summary

Background New designs of female condom have been developed to reduce costs and improve acceptability. To secure regulatory approvals, clinical studies are needed to verify performance. We aimed to assess the functional performance and safety of three new condom types—the Woman's Condom, the VA worn-of-women (wow) Condom Feminine, and the Cupid female condom—against the existing second-generation female condom (FC2).

Methods We did a randomised controlled, non-inferiority, four-period crossover trial at three sites in Shanghai, China, and one site in Durban, South Africa, between May 1, 2011, and Jan 31, 2012. Participants aged 18–45 years who were sexually active, monogamous, not pregnant, and not sex workers, were eligible for inclusion if they were literate, had no known allergies to the study products; used a reliable, non-barrier method of contraception, and had no visible or reported sexually transmitted infections. We used a computer-generated randomisation sequence with a Williams square design of size four to assign patients (1:1:1:1) to the FC2 control device, or the Woman's, VA wow, or Cupid condoms, with 12 potential allocations. Randomisation was stratified by site. Participants were not masked to condom type, but allocation was concealed from study investigators. The primary non-inferiority endpoints were total clinical failure and total female condom failure, with a non-inferiority margin of 3%. Women were asked to use five of each condom type and were interviewed after use of each type. We also assessed safety data for each type. We did both per-protocol and intention-to-treat analyses. We calculated frequencies and percentages for each failure event and estimated differences in performance with a generalised estimating equation model. This study is registered, number DOH-27-0113-4271.

Findings 616 women were assessed for eligibility, of whom 600 were randomly assigned to condom-type order (30, 120, and 150 women in the three sites in China, and 300 women in the site in South Africa). 572 women completed follow-up, with at least one condom of each type. Total female condom failure was 3·43% for FC2, 3·85% for the Woman's Condom (difference 0·42%, 90% CI −1·42 to 2·26), 3·02% for VA wow (−0·42%, −1·86 to 1·32), and 4·52% for Cupid (1·09%, −0·60 to 2·78); total clinical failure was 2·88%, 3·05% (0·17%, −1·48 to 1·81), 2·49% (−0·25%, −1·75 to 1·26), and 3·87% (0·99%, −0·55 to 2·52), respectively. Only two (<1%) participants, in South Africa, reported serious adverse events, unrelated to use of the study products.

Interpretation Non-inferiority was shown for all condom failure events for the three new devices versus the FC2, within the predefined margin.

Funding Universal Access to Female Condoms (UAFC).

Introduction

Evidence is scarce about the effect of choice of contraceptive method on increased uptake of methods; however, a systematic review[1] in 2006 supported the theory that increased contraceptive choice for women is associated with increased uptake and better health outcomes (eg, lower pregnancy rates and fewer sexually transmitted infections [STIs]). Furthermore, women continue use of their chosen contraceptives to a greater degree than do those who are denied a choice.[2] The female condom is a barrier method that could increase choice for women worldwide. Although distribution of female condoms continues to increase worldwide, doubling from 25 million to 50 million units between 2007 and 2010, it is substantially lower than that for male condoms,

and accounts for only 0·19% of global condom procurement.[3] In 2011, the female condom was identified by the Reproductive Health Supplies Coalition as one of several underused reproductive health technologies that could expand choice in reproductive health and family planning programmes, add value to the method mix, and respond to the needs of various clients.[4]

Several new female condoms in the final stages of development, or that have recently become available, aim to reduce unit cost or improve acceptability.[5] The first-generation female condom (FC1), made by the Female Health Company, was approved by the US Food and Drug Administration (US FDA) in 1993 (now discontinued). Classified as class 3 medical devices by the US FDA, the regulatory process for female condoms is more complex

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than that for male condoms. This difference was compounded by the absence, until 2011, of an international standard to verify the quality of new devices. To secure regulatory approvals, including WHO–UNFPA prequalification, manufacturers need to do clinical studies to verify the performance of new designs of female condoms. In 2009, the US FDA approved the second-generation female condom (FC2) on the basis of results of a non-inferiority study[6] in which the investigators compared the functional performance of FC2 with that of FC1 with respect to condom failure events. Studies of the functional performance of condoms typically collect detailed data for small numbers of condom uses (five to ten uses) in a short period of time (4–6 weeks). Conversely, studies of condom effectiveness for prevention of pregnancy should be done over at least a 6 month period and are far more costly to do than are functional performance studies. Studies of contraceptive effectiveness were not needed for US FDA approval for FC2 and no studies of contraceptive effectiveness have been published for FC2. If new female condoms are non-inferior to FC2 in function, choices will increase and individual needs can be considered for women wanting to prevent pregnancy and STIs and HIV. We assessed the

functional performance and safety of three new female condom designs: the Woman's Condom, the VA worn-of-women (wow) Condom Feminine, and the Cupid female condom versus the FC2 device.

Methods

Study design and participants

We undertook this four-period, randomised, non-inferiority, crossover, clinical trial between May 1, 2011, and Jan 31, 2012, at three centres in Shanghai, China (the Shanghai Institute of Planned Parenthood Research Hospital and two affiliated family planning districts—XuJiahui and Xuhui), and one centre in Durban, South Africa (an urban reproductive health clinic). Participants aged 18–45 years who were sexually active, monogamous, and not practising sex workers, were eligible for inclusion if they had no known allergies to the study products (latex, synthetic latex, polyurethane); used a reliable, non-barrier method of contraception; and had no STIs (as established by pelvic examination and use of a syndromic diagnostic approach). Participants could be novice or experienced users of condoms, but had to be literate because take-home condom logs were used to obtain data. We excluded pregnant women (established by urine
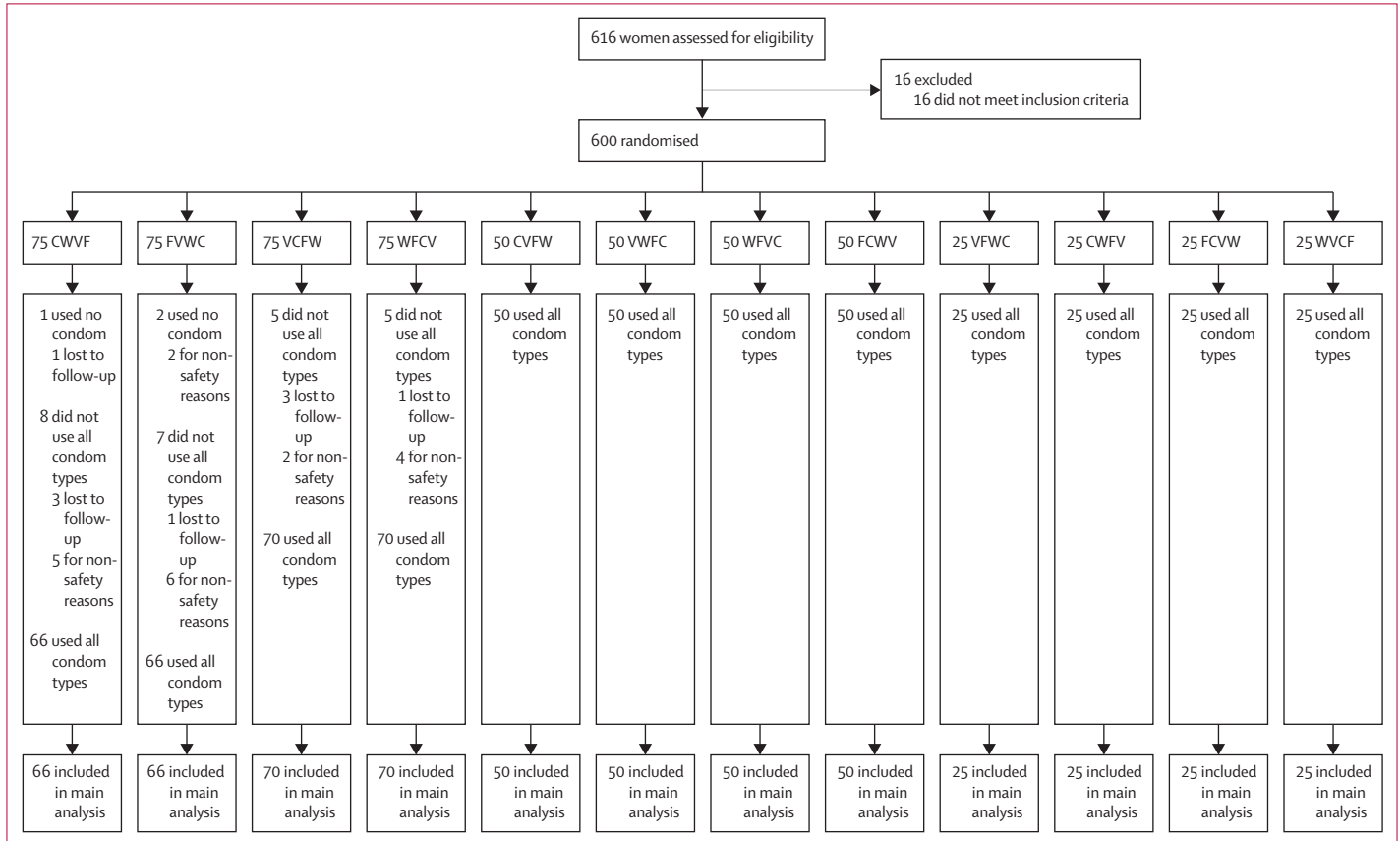

Figure 1: Trial profile
The numbers of women withdrawing after period one were two for the sequence CWVF, three for FVWC, none for VCFW, and three for WFCV; after period two were three, two, one, and two, respectively; and for period three were three, two, one, and two, respectively. C=Cupid. W=Woman's Condom. V=VA worn-of-women. F=second-generation female condom (FC2).

pregnancy test). Participants from the South African site were similar in profile and recruited from the same site as that in the study used to establish the comparative performance of the reference condom (FC2) to the predicate device, FC1.[6] Participants gave written informed consent before screening and enrolment.

The study was approved by the institutional review boards of the University of Witwatersrand Human Research Ethics Committee in South Africa and the Ethical Committee of Shanghai Institute of Planned Parenthood Research in China. The study was also approved by the National Population and Family Planning Commission (NPFPC) in China and by the provincial, district, and local departments of health in South Africa. Male partners were informed of the study through use of a fact sheet, which explained the purpose of the study and provided information about the study products and their role in the research. Our study methods are based on the recommendations of WHO–UNFPA.[7]

Randomisation and masking

We used a computer-generated randomisation sequence (SAS version 9.3[8]) to assign patients to one of 12 sequences of condom use (figure 1). Randomisation was stratified by site. We used a Williams design, which consisted of the random construction of a Williams square (first step) and the random allocation of women to the treatment sequences, independently at each site (second step).[9] These sequences were balanced for period and treatment, and each treatment had a different preceding treatment. To ensure such balance, the Williams design uses block sizes of four in a Latin square.

To devise a simple and effective method of concealment, we designed a scratch card per participant, containing the allocated treatment sequence, whereby each code for a given condom type was concealed beneath a separate foil square. For each card, research staff would remove (scratch) the foil corresponding to the visit number printed above the square, thereby revealing the next visit allocation in the sequence. This novel adaption of an existing technology had not been previously reported for concealment of the allocation sequence in a randomised crossover trial. The development and use of the cards for this trial has been reported elsewhere.[10] Participants were not masked to condom type because the designs are all quite distinct and required product-specific training.

Procedures

Our primary objective was to compare the functional performance of the four types of female condom within the selected study populations (figure 2). The FC2 was the control device, because the predicate device (FC1) ceased production in 2009. Each condom product was shipped by the manufacturer to Family Health International (now FHI 360) for quality assurance testing to ensure that products were of the quality specified by

The second-generation female condom (FC2)
In 2009, the FC2 replaced the polyurethane first-generation female condom (FC1; trade names include Reality and Femidom), which had been available since 1993. FC2 is similar in specification and appearance to FC1, but is made of synthetic nitrile rubber latex. FC2 has a flexible inner ring to insert the device and keep it in place during use. A ring at the open end lies flat across the genital area. FC2 was regarded as acceptable for bulk procurement by all UN agencies in 2007. In 2009, FC2 was approved by the US Food and Drug Administration.

The Woman's Condom
The Woman's Condom, designed and developed by the Program for Appropriate Technology in Health (PATH), is made of polyurethane. The condom sheath is tucked into an insertion capsule that dissolves after insertion. The four foam dots on the body of the condom ensure internal stability. The condom is not pre-lubricated and is supplied with a water-based lubricant. Licensed to the Dahua Medical Apparatus Company (Shanghai, China), the Woman's Condom received the CE Mark of the European Union in 2010, and the approval of the Shanghai Food and Drug Administration in 2011.
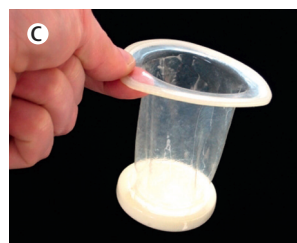
The VA wow Condom Feminine
The VA wow condom (Medtech Products, India) is made of natural rubber latex and encases a medical-grade sponge at the closed end. The sponge is used for insertion and the outer anchoring structure has a triangular-shaped frame. The condom is lubricated with silicone oil. The device carries the CE Mark of the EU, and has approvals from the India Drug Control Authority and the Ministry of Health in Brazil.
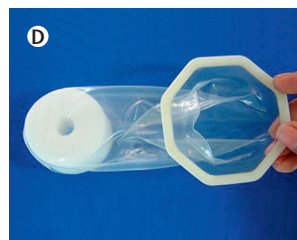
The Cupid female condom
The Cupid condom (Cupid, India), manufactured in India, is available in some European and African countries. Made of natural rubber latex, the condom has an octagonal outer frame and is inserted with a medical-grade sponge, which also holds the condom in place during use. The device is pre-lubricated with silicone oil and comes in natural latex and pink colours. The Cupid condom is the only scented condom of all those assessed. The condom holds the CE Mark of the EU, is prequalified by WHO–UN Population Fund and registered by the India Drug Control Authority.

Figure 2: **Description of study products**

Panel 1: Definitions of failure modes

- Total clinical failure: the number of female condoms that clinically break or slip, or that are associated with misdirection, invagination, or any additional failure modes identified in the risk assessment, which result in reduction of the protective function of the condom
- Total condom failure: a female condom for which a non-clinical breakage, clinical breakage, or slippage occurs, or that is associated with misdirection, invagination, or any additional failure modes identified in the risk assessment
- Clinical breakage: breakage of the condom during sexual intercourse or during withdrawal of the female condom from the vagina (potential adverse clinical consequences)
- Non-clinical breakage: breakage noticed before intercourse or occurring after withdrawal of the condom from the vagina (no potential adverse clinical consequences)
- Total breakage: the number of all condom breakages at any time before, during, or after sexual intercourse; includes both clinical and non-clinical breakages
- Slippage: when a female condom slips completely out of the vagina during sexual intercourse
- Misdirection: vaginal penetration whereby the penis is inserted between the condom and the vaginal wall
- Invagination: when the external retention feature of the female condom is partly or fully pushed into the vagina during sexual intercourse

the manufacturer and met International Organization for Standardization (ISO 25841-2011) requirements.[7]

The primary endpoints were self-reported total clinical failure and total female condom failure. Additionally, we assessed the component failure events of clinical breakage, non-clinical breakage, total breakage, slippage, misdirection, and invagination.[11] Panel 1 shows the definitions of each failure mode analysed. We also collected data for safety and acceptability. Failure events are recognised by WHO and other regulatory agencies.

Our secondary objectives were to assess the safety and acceptability of each condom type and to compare acceptability endpoints between the four types, with superiority hypotheses. We measured and assessed safety of each device according to number, severity, relatedness, and duration of adverse events. We collected standard acceptability measures and these data will be reported elsewhere.

In this study, each woman was asked to use five of each of the four condom types and to complete a condom log at home after each condom use. After women completed use of each condom type, they returned to the clinic to be interviewed about their experiences. Condom logs were used to obtain data for condom function and safety. We used interviewer-assisted questionnaires to gather acceptability and preference data.

Statistical analysis

We calculated the power to show non-inferiority obtained for different sample sizes, starting with a minimum of 200 couples completing the study as recommended by ISO 25841-2011 for functionality studies of acute failure events with female condoms based on self-reports.[12] We assumed a total failure rate of 4% for FC2 as reported from previous research,[6] and a correlation between uses of 0·15, as reported for male condoms.[13] With 3% as a clinically determined margin of non-inferiority and a significance level of 5% for the hypothesis of non-inferiority, 500 women (250 per country) completing the study would provide 98% power in each country. We expected a non-completion rate of 15% (ie, 85% would provide relevant follow-up data for at least one condom of each type); therefore, we increased the sample size to 600 women (300 per country). In the power calculation, we adjusted for various comparisons with the Bonferroni criterion.[14]

The hypothesis for the primary endpoints of total clinical failure and total female condom failure and their component failure events, was that each of the three new condoms was non-inferior to FC2 for the rate of events within a margin of 3·0%.

The main analysis for primary and secondary endpoints was according to the assigned condom use sequence in the subset of participants who provided relevant follow-up data for at least one condom of each type (per-protocol analysis). We did an additional analysis with women with complete or incomplete condom series (one to four condom types, one to five uses each; data not shown). This additional analysis was by intention to treat, but with exclusion of three participants for whom no data about condom function were available. All analyses were stratified by country.

To show non-inferiority, the upper limit of the two-sided 90% CI for the difference in the occurrence of events (new condom minus FC2) needed to be below 3·0%. If non-inferiority was shown, we tested superiority at a 5% level of significance using a two-sided 95% CI.

We analysed primary endpoints with a generalised estimating equation approach assuming a binomial

	China (n=300)	South Africa (n=272)	Total (N=572)
Age (years)			
Mean (SD)	36·3 (5·68)	27·9 (6·29)	32·3 (7·30)
Min–max	21–45	18–44	18–45
Ethnic group			
Asian (Chinese)	299 (>99%)	0	299 (52%)
Black	0	271 (>99%)	271 (47%)
Coloured	0	1 (<1%)	1 (<1%)
White	1 (<1%)	0	1 (<1%)
Completed years of school			
0–5	4 (1%)	2 (<1%)	6 (1%)
6–10	79 (26%)	24 (9%)	103 (18%)
11–15	160 (53%)	244 (90%)	404 (71%)
16–20	57 (19%)	2 (<1)	59 (10%)
Primary occupation			
Health or medical	39 (13%)	5 (2%)	44 (8%)
None or unemployed	34 (11%)	134 (49%)	168 (29%)
Office, public service, or government	104 (35%)	4 (1%)	108 (19%)
Sales	33 (11%)	12 (4%)	45 (8%)
Self employed or other	51 (17%)	21 (8%)	72 (13%)
Student		50 (18%)	50 (9%)
Teacher or lecturer	6 (2%)	3 (1%)	9 (2%)
Technical	13 (4%)	1 (<1)	14 (2%)
Unskilled labour	20 (7%)	42 (15%)	62 (11%)
Number of living children			
0	20 (7%)	50 (18%)	70 (12%)
1	266 (89%)	117 (43%)	383 (67%)
2	14 (5%)	70 (26%)	84 (15%)
≥3		35 (13%)	35 (6%)
Civil status			
Married or living together	298 (99%)	62 (23%)	360 (63%)
Not married and not living together	2 (<1%)	210 (77%)	212 (37%)
Duration of relationship with current spouse or partner			
<1 year	4 (1%)	17 (6%)	21 (4%)
1–5 years	61 (20%)	156 (57%)	217 (38%)
6–10 years	57 (19%)	58 (21%)	115 (20%)
>10 years	178 (59%)	41 (15%)	219 (38%)

Data are number of individuals (%) unless otherwise indicated.

Table 1: Baseline sociodemographic characteristics of the main analysis population by country and overall

distribution, and with an identity link function, including type of condom in the model at the couple-use level and defining couples as clusters, to take into account the crossover nature of the design. We used an interchangeable error structure within couples and adjusted results by multiplicity with Scheffé's method.[13] This trial is registered, number DOH-27-0113-4271.

Role of the funding source
The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. MEB, GP, JP, RG, and CJ had full access to the primary data. All other authors (JAS, JW, YZha, and YZho) had access to the data collected in their own country. All authors had final responsibility for the publication.

Results
Figure 1 shows the trial profile. 600 women were enrolled in the study (300 per country). 572 (95%) women completed the study with each woman using at least one condom of each of the four types. These women comprise the main analysis population. Only three women, in South Africa, did not use any condom.

Chinese participants were older than participants from South Africa (table 1). Women in both countries were well educated, with 72% in China and 90% in South Africa having more than 10 years of schooling (table 1). Most Chinese participants were married or living with their partners, whereas most South African participants were not married or residing with their partners (table 1). 188 (63%) of 300 Chinese participants and 272 (100%) of South African participants had used male condoms previously, whereas 39 (14%) of South African women had previous experience with female condoms compared with no participants in China.

11 350 female condoms were used in this study by women in the main analysis population (2838 Cupid, 2850 FC2, 2827 VA wow. and 2835 Women's Condoms). Table 2 shows the mean failure rate and failure difference of Cupid, VA wow, and Woman's Condom compared with FC2 for both countries combined. Non-inferiority was shown, within the non-inferiority margin, for all failure modes for the three new devices versus FC2 (data not shown) and for the two countries combined (table 2 and figure 3). The additional analysis done with women with complete or incomplete condom series provided similar results (data not shown).

We noted no evidence of superiority for any of the new condoms compared with FC2 in any of the failure modes (table 2).

Overall, the occurrence of adverse events and medical problems for the enrolled population was low (data not shown). Only two (<1%) participants in South Africa reported serious adverse events, unrelated to use of the study products. 27 (5%) adverse events were reported in the 597 women using at least one condom at least once. Adverse events occurred in fewer than 1% (range

0·14–0·38%) of participants for each condom type. Adverse event reports were vaginal burning (five with VA wow in China); vaginal itching (one with Cupid, one with FC2, and one with Women's Condom in South Africa);

	Mean failure rate (%)	Failure difference (%)			p value
		Difference with FC2	90% CI	95% CI	
Clinical breakage*					
Cupid	0·10	NE	NE	NE	..
VA wow	0·08	NE	NE	NE	..
WC	0·00	NE	NE	NE	..
FC2	0·25	NE	NE	NE	..
Non-clinical breakage					
Cupid	0·66	0·04	–0·61 to 0·69	–0·69 to 0·77	0·9991
VA wow	0·53	–0·09	–0·52 to 0·33	–0·57 to 0·38	0·9586
WC	0·74	0·12	–0·41 to 0·65	–0·47 to 0·71	0·9557
FC2	0·62	(Ref)	..	..	..
Total breakage					
Cupid	0·77	–0·05	–0·76 to 0·66	–0·84 to 0·74	0·9984
VA wow	0·67	–0·14	–0·67 to 0·38	–0·73 to 0·44	0·9226
WC	0·84	0·02	–0·57 to 0·60	–0·63 to 0·67	0·9999
FC2	0·82	(Ref)	..	..	..
Invagination					
Cupid	1·21	0·03	–0·85 to 0·91	–0·95 to 1·01	0·9999
VA wow	0·99	–0·20	–1·17 to 0·77	–1·28 to 0·89	0·9684
WC	0·47	–0·72	–1·46 to 0·03	–1·55 to 0·12	0·1247
FC2	1·18	(Ref)	..	..	..
Misdirection					
Cupid	1·22	0·62	–0·12 to 1·37	–0·21 to 1·46	0·2264
VA wow	1·19	0·58	–0·21 to 1·37	–0·30 to 1·47	0·3309
WC	1·13	0·53	–0·31 to 1·37	–0·41 to 1·47	0·4759
FC2	0·60	(Ref)	..	..	..
Slippage					
Cupid	1·48	0·50	–0·41 to 1·42	–0·52 to 1·53	0·5979
VA wow	0·43	–0·55	–1·17 to 0·07	–1·25 to 0·14	0·1760
WC	1·28	0·30	–0·64 to 1·24	–0·75 to 1·35	0·8880
FC2	0·98	(Ref)	..	..	..
Total clinical failure					
Cupid	3·87	0·99	–0·55 to 2·52	–0·73 to 2·70	0·4614
VA wow	2·49	–0·25	–1·75 to 1·26	–1·92 to 1·43	0·9823
WC	3·05	0·17	–1·48 to 1·81	–1·67 to 2·01	0·9957
FC2	2·88	(Ref)	..	..	..
Total female condom failure					
Cupid	4·52	1·09	–0·60 to 2·78	–0·80 to 2·98	0·4552
VA wow	3·02	–0·42	–1·86 to 1·32	–2·05 to 1·51	0·9809
WC	3·85	0·42	–1·42 to 2·26	–1·64 to 2·47	0·9553
FC2	3·43	(Ref)	..	..	..

NE=not estimable. Cupid=Cupid female condom. VA wow=VA worn-of-women Condom Feminine. WC=Woman's Condom. FC2=second-generation female condom. 2-sided 90% CIs for non-inferiority hypothesis at α=5% and 2-sided 95% CIs for superiority hypothesis, with p values, adjustment for multiplicity by Scheffé's method. *Estimated as mean proportions of 75 women each because generalised estimasting equation model did not converge.

Table 2: Mean failure rate and failure difference of Cupid, VA wow, and Woman's Condom in relation to FC2, complete condom series population, for both countries
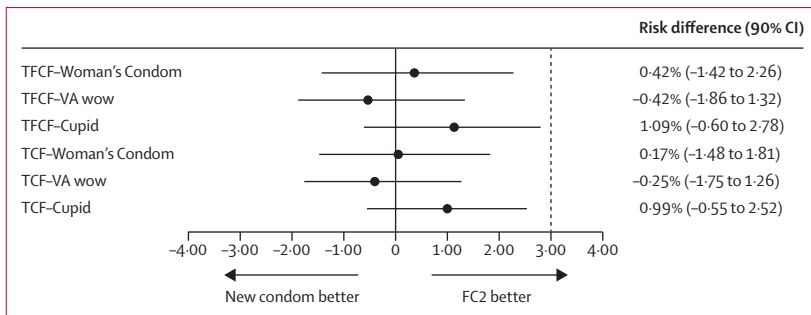
Figure 3: Estimates of the risk difference between failure of new female condoms and failure of FC2, for the primary outcomes of TFCF and TCF, showing the results for non-inferiority

TFCF=total female condom failure. VA wow=VA worn-of-women. TCF=total clinical failure. FC2=second-generation female condom.

vaginal pain or swelling (two with Cupid, two with FC2, one with VA wow in South Africa); penile itching, burning, rash, or swelling (one with FC2, two with VA wow, and one with Women's Condom in South Africa); general rash (one with Women's Condom in China); and unknown, unclear, or unrelated rash (three with Cupid, two with FC2, three with VA wow, and one with Women's Condom in South Africa). All events resolved without sequelae.

Discussion

Although individual failure rates vary by country and condom type, the three new devices assessed in this study were non-inferior to the reference condom (FC2) within the non-inferiority margin for all the functional parameters. The rates of total clinical failure, total female condom failure, and component failure reported were expected and are consistent with findings from previous, similarly undertaken studies.[6,15–17] Furthermore, the failure results reported in this study were from two culturally diverse study populations. That the results are similar between South Africa and China attests further to the validity of the findings. These data show that clinically, the new female condoms assessed function in a similar way to the FC2. Data from this study have been used to finalise the dossier submitted to WHO–UNFPA for the Cupid condom and resulted in its prequalification for public sector procurement in June, 2012.[18] The manufacturer of the Woman's Condom (Dahua, China) will use these data to finalise their dossier and submissions to WHO–UNFPA and US FDA. The VA wow condom is under review by WHO–UNFPA; however, manufacture of the product is suspended, possibly related to change of ownership of the factory.

On the basis of findings from this trial, these new female condoms could be important players in contraception and STI prevention. The availability of new types of female condoms will provide donors and users with more options and could reduce the unit price of devices.[4] Although prediction of how far the price of female condoms will reduce in the future is not possible, the Reproductive Health Supplies Coalition has published information comparing different unit costs to

Panel 2: Research in context

Systematic review

We searched PubMed between Jan, 2000, and Oct, 2012, for articles published up to November, 2012, with the search terms "female condom functional performance". No randomised trials, using any of the three new types of female condom—the Woman's Condom, the VA worn-of-women (wow) Condom Feminine, and Cupid—were identified, aside from one randomised, non-inferiority trial[6] used to establish the functional performance of the second-generation female condom, FC2, compared with the predicate device (FC1).

Interpretation

This study is the first randomised trial of the functionality of female condoms in China. The new female condoms were non-inferior to the reference condom (FC2) within a margin of 3% failure for all the functional parameters. This is the first trial that has provided important function data for these devices and has been used to compile evidence for WHO–UNFPA prequalification. Because of this trial, the Cupid condom has already been approved by WHO–UNFPA and is available for public sector procurement. Manufacturers of the other devices are using these data in their ongoing applications to regulatory authorities. Access to various types of female condoms could improve choice for women in need of a contraceptive method or of dual protection against pregnancy and infection.

the donor funded public sector, indicating that the Cupid female condom, which was prequalified in 2012, will be sold at a lower price per unit than FC2.[4] However, studies of contraceptive effectiveness and those showing effectiveness or reductions in STI incidence with these new female condoms are still needed.

Contraception is one strategy that can have an effect on and improve maternal health by reducing unplanned pregnancy. In 2009, estimates showed that if all women who wanted to avoid pregnancy used modern contraceptives, the number of unintended pregnancies in developing countries would fall from 75 million to 22 million annually.[19] Reasons for unmet need for contraception go beyond simple access to methods, and are attributable to a combination of factors including personal and cultural issues, religious restrictions, concern about side-effects, health concerns, and scarcity of knowledge. For this reason, the need to have a range of available contraceptive methods is crucial (panel 2).

A limitation of our study was that masking of the participants and research staff to the products was not possible because the products all differ in appearance. We used allocation concealment to ensure that this limitation was minimised. This study was based on only self-reported measures of condom use. Reporting of condom use by participants can be inaccurate compared with more reliable methods such as exposure to prostate-specific antigen, which provides a more objective

measure of condom failure.[20] However, techniques that use prostate-specific antigen are more expensive and study procedures more complex.

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