



Original article

Acceptability of the Woman's Condom in a phase III multicenter open-label study ☆☆☆



Beatrice A. Chen^{a,b,*}, Diana L. Blithe^c, Gitonga R. Muraguri^d, Audrey A. Lance^{a,n}, Bruce R. Carr^e, Jeffrey T. Jensen^f, Thomas D. Kimble^g, Amitasrigowri S. Murthy^{h,1}, Courtney A. Schreiberⁱ, Michael A. Thomas^j, Terri L. Walsh^k, Carolyn Westhoff^l, Anne E. Burke^m

^a Department of Obstetrics, Gynecology and Reproductive Sciences, University of Pittsburgh School of Medicine, 300 Halket Street, Pittsburgh, PA, USA

^b Magee-Womens Research Institute, 204 Craft Avenue, Pittsburgh, PA, USA

^c Contraceptive Development Program, Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, 6710B Rockledge Dr, Bethesda, MD 20817, USA

^d Health Decisions Inc., 2510 Meridian Parkway, Durham, NC 27713, USA

^e Department of Obstetrics and Gynecology, University of Texas Southwestern Medical Center, 5323 Harry Hines Boulevard, Dallas, TX 75390, USA

^f Department of Obstetrics & Gynecology, Oregon Health & Science University, 3181 SW Sam Jackson Park Road, Portland, OR 97239, USA

^g Department of Obstetrics and Gynecology, Eastern Virginia Medical School, 601 Colley Ave, Norfolk, VA 23323, USA

^h Department of Obstetrics and Gynecology, NYU School of Medicine, Bellevue Hospital Center, 462 First Ave, New York, NY 10016, USA

ⁱ Department of Obstetrics and Gynecology, University of Pennsylvania, 3400 Spruce Street, Philadelphia, PA 19104, USA

^j Department of Obstetrics & Gynecology, University of Cincinnati Medical Center, 234 Goodman St, Cincinnati, OH 45219, USA

^k Essential Access Health, 3600 Wilshire Blvd, Suite 600, Los Angeles, CA 90010, USA

^l Department of Obstetrics & Gynecology, Columbia University, 622 West 168th St, PH 16, New York, NY 10032, USA

^m Department of Gynecology & Obstetrics, Johns Hopkins University, 4940 Eastern Ave, Baltimore, MD 21224, USA

ⁿ Northland Family Planning, 35000 Ford Road, Westland MI 48185, USA

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ABSTRACT

Objective: This study aimed to evaluate the acceptability of the Woman's Condom (WC) over 6 months (183 days) and ≥ 6 menstrual cycles in a US-based multicenter open-label phase III contraceptive efficacy trial.

Study design: We assessed acceptability via written questionnaire at visit 2 (after the third cycle) and visit 3 (after the sixth cycle or >183 days, or upon early discontinuation). Key domains included ease of use, comfort/lubrication, sexual satisfaction, male partner satisfaction and confidence in pregnancy and sexually transmitted infection (STI) prevention. We analyzed quantitative data using descriptive statistics. We conducted a content analysis to identify major themes from four open-ended questions.

Results: Most women [327/405 (81%)] had limited or no previous experience with female (internal) condoms. Of 405 evaluable women, 346 women completed questionnaires at visit 2 and 303 women at visit 3; 282 women attended both visits. Of women attending both visits, 165/282 (59%) reported at visit 2 that WC insertion was easy/very easy; this increased to 195/282 (69%) at visit 3 ($p=.03$). Many women [166/281 (59%)] preferred the WC [105/281 (37%)] or were neutral [61/281 (22%)], while 115/281 (41%) preferred male condoms. Women

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* Corresponding author at: Department of Obstetrics, Gynecology and Reproductive Sciences, University of Pittsburgh School of Medicine, 300 Halket Street, Pittsburgh, PA, USA.

E-mail address: chenba@upmc.edu (B.A. Chen).

¹ Current affiliation: Planned Parenthood Hudson Peconic, 4 Skyline Dr, Hawthorne, NY 10532, USA.

attending visit 3 felt confident that the WC could prevent pregnancy [246/303 (81%)] and STIs [217/303 (72%)]. Many women expressed empowerment with having control over their contraception; some disliked the design, esthetics and insertion process. Most women (254/299 (85%)) would recommend the WC to a friend.

Conclusion: The WC's acceptability and ease of use is promising for wider dissemination as a female-controlled method that can protect against both pregnancy and STIs.

Implications: The WC's overall acceptability and ease of use is promising for a new female-controlled barrier contraceptive option that can protect against both pregnancy and sexually transmitted infections.

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1. Introduction

The US Food and Drug Administration (FDA) approved the FC1 (Reality) female condom in 1993. The FC2, manufactured from a synthetic polymer (nitrile) allowing for lower cost manufacturing, had similar design, effectiveness and acceptability [1,2], with improvement in noise associated with FC1 [3]. It replaced the FC1 in the United States after its 2009 FDA approval [4]. US female condom consumer experience has been limited to the FC1 and FC2 products (Female Health Company).

Female condoms, now referred to as internal condoms, are not widely used. In the 2006–2010 National Survey of Family Growth, only 1.7% of US women aged 15–44 years reported ever using internal condoms, while 93.4% ever used male condoms [5]. Internal condom distribution doubled globally between 2007 and 2010 [4], but in 2015, it accounted for only 1.6% of worldwide condom distribution [6]. Internal condoms provide multipurpose protection against human immunodeficiency virus (HIV; 94%–97% reduction), sexually transmitted infections (STI) and pregnancy [4,7], and offer an important protection option for women. A systematic review found that internal condoms are at least as effective as male condoms in preventing STIs [8]. Reasons for low uptake include low demand, negative media attention and inaccurate information [7,9,10]. Internal condoms cost more than male condoms, in part because regulatory barriers and low production have limited economies of scale [7]. Marginalization of promotion by international policymakers may also play a role in low uptake [7,11].

Consumer concerns about difficulty with insertion or the inner ring being painful or poorly fitting reduce acceptability of internal condoms [12]. A noninferiority study comparing FC1 to FC2 reported comparable clinical performance and less discomfort with the FC2 [1]. Similarly, a cross-sectional qualitative study describes high FC2 acceptability. However, factors limiting acceptability included slippage, perceived large size and difficulty of insertion [3]. Multiple internal condom designs are undergoing evaluation to improve ease of use and acceptability [4, 13,14]. PATH, an international nonprofit health organization with funding from the US Agency for International Development through CONRAD, developed The Woman's Condom (WC). An iterative user-centered design process aimed to improve the WC's functionality, acceptability and ease of insertion compared to prior designs [15]. The WC has shown noninferior efficacy and safety compared to other designs [13,15,16], and studies demonstrate short-term acceptability [17, 18]. In this planned analysis, we evaluated WC acceptability in a contraceptive efficacy trial among US women.

2. Materials and methods

This phase III, multicenter, open-label study (NCT01223313) was designed to assess contraceptive efficacy and safety of the WC over 6 months (183 days) and at least 6 menstrual cycles. WC acceptability was a secondary outcome. Eligible women were 18–40 years old, reported cyclic menses (21–35 days), were at risk for pregnancy, were willing to engage in at least four acts of heterosexual vaginal intercourse per month, and were willing to use the WC as their primary method of contraception. All site institutional review boards approved the study.

The WC (Shanghai Dahua Medical Apparatus Corp., Ltd., Fig. 1) is a 0.03-mm thick pliable polyurethane pouch that conforms to the vagina.

It is 22.9±0.3 cm (9±0.1 in.) long, with a flexible soft outer ring designed to hug the external genitalia. The WC has a dissolving polyvinyl alcohol capsule to facilitate insertion. Four foam shapes on its external surface cling to vaginal walls to ensure stability. The WC is not prelubricated; thus, participants were instructed to apply study-provided lubricant to the inside of the condom and the penis after the WC was inserted, and to wait 30–60 s for the capsule to dissolve. Women used a new WC with each act of intercourse. At least 30 WCs were dispensed at each visit; more were provided between visits if needed.

We evaluated women at baseline (visit 1), visit 2 (after the third menstrual cycle, visit window 45–137 days), and visit 3 [after the sixth menstrual cycle or 183 days, whichever was later (visit window 138 days and higher)]. If a participant attended visit 2 outside of the visit window but also attended visit 3, out-of-window visit 2 data were analyzed with visit 2. If a participant discontinued before day 137, the discontinuation visit was assigned to the visit 2 analysis window. If a woman discontinued early, but after day 137, she completed visit 3, including the acceptability questionnaire, as a discontinuation visit.

Written questionnaires assessed acceptability at visits 2 and 3 (see supplemental material). Thirteen questions used a 5-point Likert-type



Fig. 1. Woman's Condom, preinsertion (pouch packaged inside a dissolvable capsule). Photo credit: PATH.

scale, with the center (value of 3) being “neutral,” the left anchor (1) indicating negative experience (e.g., “very difficult,” “painful”), and the right anchor (5) indicating positive experience (e.g., “very easy,” “very comfortable”). The five response options were grouped into three categories: negative (responses 1 or 2), neutral (3) and positive (4 or 5). Key domains included ease of use, comfort/lubrication, preferences, sexual satisfaction, male partner satisfaction and confidence in the WC to prevent pregnancy and STIs. Four questions were open-ended, and one question addressed willingness to pay for the WC at multiple proposed price points.

Sample size was based on the FDA requirement to demonstrate contraceptive efficacy in 200 women over 6 months of use. With expected dropout of 50%–60% [19], we planned to enroll 500 participants. We analyzed a modified intent-to-treat population (MITT) that included all enrolled participants whose diaries indicated at least one coital episode using the WC, and for whom there was at least one report of pregnancy status. We also analyzed data from the subset of women who self-reported at least one WC failure using the daily coital diary. WC failures were defined as clinical breakage, misdirection (penis inserted between the WC and the vaginal wall), slippage (WC completely slipped out of the vagina during intercourse) and invagination (external component of WC pushed into the vagina during intercourse) [20]. Clinical failure rates were defined as the percentage of all study condoms used during intercourse with each type of failure (e.g. breakage, misdirection, slippage or invagination) and was calculated per participant.

We used descriptive statistics for participant characteristics. We compared categorical responses using Cochran–Mantel–Haenszel statistics. Changes in WC acceptability over time are based on women who completed the questionnaire at both follow-up visits. We conducted a sensitivity analysis where women who only attended visit 2 had their last response carried forward to visit 3. We also analyzed acceptability stratified by body mass index (BMI) <30 kg/m² (nonobese) and ≥30 kg/m² (obese).

For content analysis of four open-ended questions, two authors (BAC, AAL) reviewed responses and used an iterative process to identify themes and develop a codebook. Codes were then applied to the data using Dedoose Version 7.5.16 (Los Angeles, CA, USA). We assessed the frequencies of each code for an indication of the most common themes.

A code could be applied multiple times per participant if her response mentioned a theme more than once.

3. Results

3.1. Quantitative findings

Fig. 2 describes study flow. Of 676 women screened, 511 enrolled and 276 (54.0%) completed 6 months use. The MITT population included 405 evaluable women. Table 1 shows participant characteristics. A low proportion of participants reported use of combined hormonal contraceptives or long-acting reversible contraceptives (LARC) in the preceding 6 months. Women used the WC for a median of 38.0 days (range, 1–127 days). Fifteen of 405 women (3.7%) reported a pregnancy during the study. Three hundred forty-six women completed visit 2 acceptability questionnaires, 303 women completed visit 3 questionnaires, and 282 women completed both. Some women completed only visit 2 or visit 3 questionnaires due to missing study visits or discontinuing early.

Seventy-eight of 405 (19.3%) had prior internal condom experience, although only 9 (2.2%) had used the method more than 10 times. Table 2 describes changes in WC acceptability for women who attended visit 2 and visit 3. Of these, 165/282 (58.5%) reported at visit 2 that WC insertion was easy/very easy; this increased significantly to 195/282 (69.1%) at visit 3 (p=.03). Findings were similar for women who had never used internal condoms [visit 2: 126/225 (56.0%) vs. visit 3: 155/225 (68.9%), p=.02]. In the sensitivity analysis (n=346, including 282 who attended both visits and 64 who only attended visit 2, but whose responses were carried forward to visit 3), this difference was not statistically significant (p=.07). When these 282 women were asked at visit 3 whether they preferred the WC or a male condom, or were neutral about their preference, 166/281 (59.1%) either preferred the WC [105/281 (37.4%)] or were neutral [61/281 (21.7%)], while 115/281 (40.9%) preferred male condoms (Table 2). For women attending both visits 2 and 3, there was no change in whether participants felt the WC was comfortable. At visit 3, almost all women found it “comfortable” [153/282 (54.3%)] or were neutral [109/282 (38.7%)],

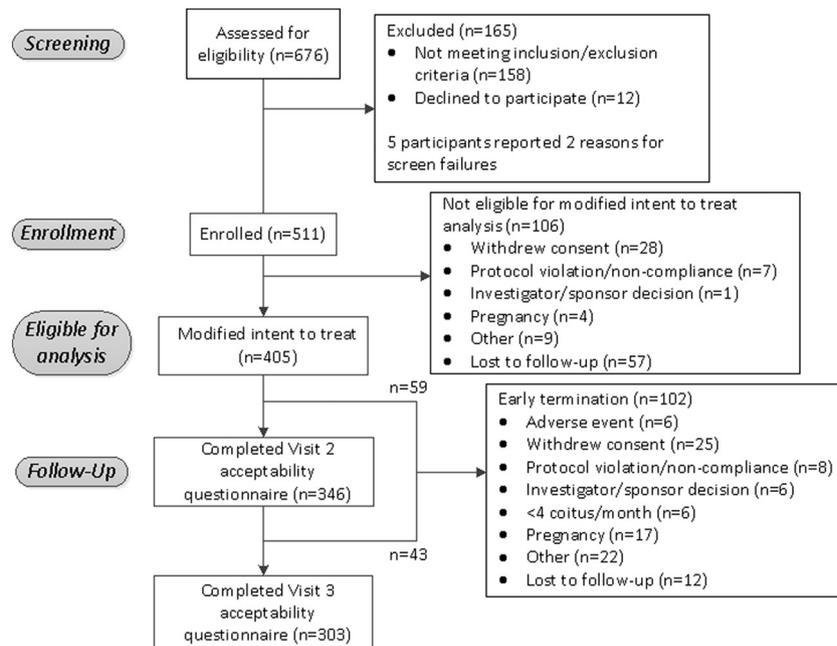


Fig. 2. Flowchart of participants*. *One enrollment protocol deviation occurred for a 41-year-old participant whose date of birth was incorrectly reported at screening. Missing questionnaires were due to participants not attending study visits or discontinuing early. Participants who discontinued early may have completed a questionnaire at time of discontinuation.

Table 1
Demographics and participant characteristics

Characteristic	Total (n=405)
Age (years), (n) range	29.0 (18–41)
Race, n (%) ^a	
White	162 (40.0)
Black or African American	204 (50.4)
Asian or Pacific Islander	22 (5.4)
American Indian or Native Alaskan	14 (3.5)
Other	24 (5.9)
Hispanic or Latina, n (%)	88 (21.7)
BMI at baseline, mean (SD)	29.2 (7.6)
Marital status, n (%)	
Never married	258 (63.7)
Married	101 (24.9)
Divorced	33 (8.1)
Separated or widowed	13 (3.2)
Highest level of education, n (%)	
Has not completed high school	25 (6.2)
High school or equivalent	78 (19.3)
Some college	169 (41.7)
College degree or higher	133 (32.8)
Prior experience with female condoms, n (%)	78 (19.3)
Contraceptive methods used in past 6 months, n (%) ^a	
Male condom	335 (82.7)
Female condom	9 (2.2)
Diaphragm	6 (1.5)
Spermicides	25 (6.2)
Natural family planning/rhythm method	46 (11.4)
Withdrawal	163 (40.2)
Abstinence	22 (5.4)
Emergency contraception	13 (3.2)
Oral contraceptive pill	36 (8.9)
Vaginal ring	14 (3.5)
Contraceptive patch	7 (1.7)
Intrauterine device	5 (1.2)
Implant	1 (0.2)
Injectables	1 (0.2)

^a Participants could select more than one response.

while only 7.1% (20/282) found it “painful.” Other acceptability findings for participants attending both visits are noted in Table 2.

Many participants [197/405 (48.6%)] reported at least one WC failure during the study. Women who experienced a WC failure and attended both follow-up visits nonetheless reported the WC was easy to insert [81/155 (52.3%) at visit 2, 105/155 (67.7%) at visit 3; $p=.02$]. More of these women preferred the male condom at visit 3 [75/155 (48.4%) over the WC (54/155 (34.8%); $p=.014$]; the remainder [26/155 (16.8%)] were neutral.

Of all women attending visit 3, 246/303 (81.2%) felt confident that the WC could prevent pregnancy and 217/303 (71.6%) felt confident that it could prevent transmission of STIs. Even women who experienced at least one WC failure remained confident in its ability to prevent pregnancy [115/139 (82.7%)] and STIs [109/139 (78.4%)]. Women were divided as to whether their partner was satisfied [113/303 (37.3%)] or dissatisfied [104/303 (34.3%)] with the WC. At the end of the study, most women [254/299 (84.9%)] would recommend the WC to a friend. When asked the most they would be willing to pay for a WC, with a range of \$3 to \$8, 235/302 (77.8%) were willing to pay \$4 or less. Additional acceptability findings for women who attended visit 2 and/or visit 3 are described in Supplemental Table 1; p values reflect the differences in the proportions of responses for all participants who attended visit 2 or visit 3.

We found no difference in ease of insertion, comfort during sex or movement during sex by BMI category. At visit 3 only, nonobese women felt more confident than obese women in the WC's ability to prevent pregnancy [145/171 (84.8%) vs. 85/111 (76.6%), $p=.003$] or STIs [126/170 (74.1%) vs. 76/111 (68.5%), $p=.01$]. However, obese women reported fewer WC failures compared to nonobese women [median, 0.0 (interquartile range, 0.0–5.0) vs. 2.0 (interquartile range, 0.0–10.0); $p=.03$].

3.2. Qualitative findings

Table 3 lists the frequency of code applications at visits 2 and 3. The most frequent themes focused on the WC design, including concerns about fit, material, capsules and lubrication. Many women stated that the WC “would be better if [it] came pre-lubricated.” Women also stated the WC was inconvenient and that it took longer than expected for the capsule to dissolve. One woman noted “Maybe the capsule should dissolve quicker. The 15 min [sic] wait time stresses the act.” Others noted the WC was “not good for a ‘quickie’” or interfered with intimacy.

Some women stated the WC should be smaller, or that the outside ring should be smaller or stiffer. Others found the WC awkward or unattractive. A few commented on the noise, with one participant reporting that it “felt like having sex w/a sandwich bag.” Participants also described condom failures, with slippage being the most frequent complaint (visit 2: $n=56$; visit 3: $n=47$). One participant noted “it either slipped out or it went inside me.”

The WC design also received many positive comments; women found it “very comfortable” and more natural than the male condom. One woman stated, “I liked that it felt like not having a condom on and I could ‘feel’ my partner more.” Some women liked the non-hormonal aspect; one woman would recommend it because she “didn’t have to take a pill or get a shot.” Many noted it was easy to use and insert, and that it “become[s] easier to use over time.”

Women commonly reported that the WC helped them feel protected from STIs and pregnancy. Some felt more protected than with male condoms, because the WC “covers the vagina to protect more than a male condom would.” Another woman stated, “I felt (once in) completely covered/safe.”

Female empowerment and control over contraception was a frequent theme; one woman liked the WC because she “was in control of making sure there was birth control.” Another woman stated, “It is nice to know I can protect myself—its [sic] female empowerment.” Several women noted that they liked not having to “rely on a man to have condoms.”

4. Discussion

Most women in this study found the WC easy to insert and remove, and felt confident in its ability to prevent pregnancy and STIs. Ease of use and women's preference for the WC increased over time. This is reassuring, since the failure rate of internal condoms decreases as women become more experienced [21]. Increased familiarity may also correlate with increasing acceptability.

Based on responses to the question about preference for WC versus male condom, over half of women preferred the WC or were neutral when compared to the male condom, and only a third felt their partner was dissatisfied with the WC. Content analysis suggested that for some women, WC acceptability related to a sense of control over their contraceptive options. Others specifically noted the multipurpose protection aspect of the WC. Given overall WC acceptability together with women's confidence in its ability to protect against both pregnancy and STIs, WC could fill an important need for individuals seeking multipurpose protection. This may be especially true for individuals for whom effectiveness of the FC is not the top priority in seeking a contraceptive method, or who seek a female-controlled method of STI prevention as a dual method.

Some women were dissatisfied with specific aspects of the WC related to design or inconvenience, in particular the need for the capsule to dissolve and lack of prelubrication. These specific concerns can inform design improvements. Notwithstanding these caveats, most women still would recommend the WC to others. Since this device was developed via an iterative user-driven process to address previous concerns about internal condoms, the overall acceptability of this product is reassuring and is consistent with the positive findings from a randomized crossover study of the WC and the FC1 [15].

Table 2
Changes in acceptability of the Woman's Condom for participants attending both visits (% , n/N)

Response	Visit 2 (n=282)	Visit 3 (n=282)	p Value
Ease of WC insertion			
Easy	165/282 (58.5%)	195/282 (69.1%)	.03
Neutral	92/282 (32.6%)	70/282 (24.8%)	
Difficult	25/282 (8.9%)	17/282 (6.0%)	
Ease of WC removal			
Easy	244/282 (86.5%)	232/282 (82.3%)	.15
Neutral	32/282 (11.3%)	36/282 (12.8%)	
Difficult	6/282 (2.1%)	14/282 (5.0%)	
Did the WC get easier to use over time?			
Easier	236/281 (84.0%)	242/281 (86.1%)	.62
Neutral	41/281 (14.6%)	37/281 (13.2%)	
Harder	4/281 (1.4%)	2/281 (0.7%)	
Comfort of WC during sex			
Comfortable	143/282 (50.7%)	153/282 (54.3%)	.59
Neutral	121/282 (42.9%)	109/282 (38.7%)	
Painful	18/282 (6.4%)	20/282 (7.1%)	
Movement of the WC during sex			
Not bothersome	123/281 (43.8%)	115/281 (40.9%)	.74
Neutral	92/281 (32.7%)	100/281 (35.6%)	
Bothersome	66/281 (23.5%)	66/281 (23.5%)	
Comparison of sexual satisfaction between male condom and WC			
Prefer WC	81/278 (29.1%)	84/278 (30.2%)	.93
Neutral	89/278 (32.0%)	85/278 (30.6%)	
Prefer male condom	108/278 (38.8%)	109/278 (39.2%)	
Do you prefer the WC or male condom?			
Prefer WC	89/281 (31.7%)	105/281 (37.4%)	.12
Neutral	81/281 (28.8%)	61/281 (21.7%)	
Prefer male condom	111/281 (39.5%)	115/281 (40.9%)	
How satisfied was your partner with this product?			
Satisfied	103/282 (36.5%)	105/282 (37.2%)	.96
Neutral	83/282 (29.4%)	80/282 (28.4%)	
Not satisfied	96/282 (34.0%)	97/282 (34.4%)	

N may not equal 282 due to missing responses. Questions used a 5-point Likert-type scale, with the center (value of 3) being "neutral," the left anchor (1) indicating negative experience (e.g., "very difficult," "painful") and the right anchor (5) indicating positive experience (e.g., "very easy," "very comfortable"). For analysis, the five response options were grouped into three categories: negative (responses 1 or 2), neutral (3), and positive (4 or 5).

Translating WC acceptability into use may be challenging. Obstacles include limited availability, cost and lack of familiarity. Without advocacy, knowledge may not translate to use: a South African study found

Table 3
Thematic analysis code application frequency at visits 2 and 3 for women who attended each visit^a

Frequency of code application	Visit 2 (n=346)	Visit 3 (n=303)
Positive themes		
Ease of use	171	164
Feeling protected from pregnancy and/or STIs	145	123
Feeling that WC gives women control over birth control	136	107
Positive attributes of WC design	112	75
Personal sexual satisfaction when using the WC	75	47
Positive comparisons to male condom	51	26
Specific situations in which the WC may be useful	22	8
Partner sexual satisfaction when using the WC	13	9
Cleanliness of the WC	12	15
Negative themes		
Negative attributes of WC design	340	267
Condom failures	75	56
Difficulty of use	71	52
Inconvenience of the WC	69	61
Personal sexual dissatisfaction when using the WC	61	35
Concerns about esthetic aspects of the WC	58	45
Partner sexual dissatisfaction when using the WC	27	10
Negative comparisons to male condom	18	17
Feeling unprotected from pregnancy and/or STIs	18	6
Side effects	17	8
Awkward or embarrassing nature of the WC	13	6

^a Codes could be applied more than once per participant if the theme was addressed more than once within the four open-ended questions.

that while over 75% of women knew about internal condoms, only 7% had ever used them [22]. Small as this is, this is higher than the usage reported among women in the United States. Multipronged approaches may be needed to increase use outside of study settings [12]. These could include market development, product promotion and tailored educational interventions for selected groups such as women residing in areas of high STI or HIV prevalence. Health departments, communities and providers can assume meaningful roles in diffusing knowledge and training [22–27]. The regulatory climate may also be improving. The FDA changed the classification of internal condoms from class III (the most highly regulated or "risky" devices), to class II, the less onerous classification that applies to male condoms, in September 2018 [28]. These changes could increase internal condom availability.

Study strengths included using a multi-item questionnaire that explored several domains of acceptability over 6 months, in contrast to short-term analyses [17,18]. Limitations included the anticipated high discontinuation rate, although completion was higher than initially predicted (54% of all enrolled; 68% of the MITT population). Women who had difficulty using the WC or were unhappy with it may have discontinued earlier, their absence thus biasing the analyses presented here. The "neutral" option in the Likert scales may have allowed women to avoid taking a stance on a question [29]. Limiting the question about cost to \$3 and above did not allow participants to say what lower price they were willing to pay.

Recent programmatic focus, particularly in the United States, has seemed to prioritize LARC. However, not every woman wants a LARC or a hormonal contraceptive; the potential for STI and HIV protection makes internal condoms one of few methods that can offer dual protection. In addition, the WC holds promise for vaginal delivery of HIV and STI prevention medications [30]. Female-controlled methods that can protect against STI, HIV and pregnancy would be a boon. The WC may

also have additional uses, with the now preferred term “internal condom” communicating potential for STI protection not restricted to heterosexual vaginal intercourse. Our results demonstrate that the WC is an acceptable method for most women, which is promising for wider dissemination.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.contraception.2019.02.006>.

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