

# Acceptability and Performance of the Menstrual Cup in South Africa: A Randomized Crossover Trial Comparing the Menstrual Cup to Tampons or Sanitary Pads

Mags E. Beksinska, PhD,<sup>1,2</sup> Jenni Smit, PhD,<sup>1,3</sup> Ross Greener, MSocSc,<sup>1</sup> Catherine S. Todd, MD,<sup>4</sup>  
Mei-ling Ting Lee, PhD,<sup>5</sup> Virginia Maphumulo, RM,<sup>1</sup> and Vivian Hoffmann, PhD<sup>6</sup>

## Abstract

**Background:** In low-income settings, many women and girls face activity restrictions during menses, owing to lack of affordable menstrual products. The menstrual cup (MC) is a nonabsorbent reusable cup that collects menstrual blood. We assessed the acceptability and performance of the MPower<sup>®</sup> MC compared to pads or tampons among women in a low-resource setting.

**Methods:** We conducted a randomized two-period crossover trial at one site in Durban, South Africa, between January and November 2013. Participants aged 18–45 years with regular menstrual cycles were eligible for inclusion if they had no intention of becoming pregnant, were using an effective contraceptive method, had water from the municipal system as their primary water source, and had no sexually transmitted infections. We used a computer-generated randomization sequence to assign participants to one of two sequences of menstrual product use, with allocation concealed only from the study investigators. Participants used each method over three menstrual cycles (total 6 months) and were interviewed at baseline and monthly follow-up visits. The product acceptability outcome compared product satisfaction question scores using an ordinal logistic regression model with individual random effects. This study is registered on the South African Clinical Trials database: number DOH-27-01134273.

**Results:** Of 124 women assessed, 110 were eligible and randomly assigned to selected menstrual products. One hundred and five women completed all follow-up visits. By comparison to pads/tampons (usual product used), the MC was rated significantly better for comfort, quality, menstrual blood collection, appearance, and preference. Both of these comparative outcome measures, along with likelihood of continued use, recommending the product, and future purchase, increased for the MC over time.

**Conclusion:** MC acceptance in a population of novice users, many with limited experience with tampons, indicates that there is a pool of potential users in low-resource settings.

## Introduction

**I**N LOW-INCOME SETTINGS, including South Africa, disposable sanitary towels and tampons may be prohibitively expensive. Consequently, many women and adolescent girls resort to using cloth, newspaper, or toilet paper, potentially

curtailing their regular activities. In 2010, the World Health Organization (WHO) reported that the lack of menstrual-hygiene facilities contributes to sporadic school attendance and dropout among young women.<sup>1</sup> In January 2011, the South African government pledged free sanitary towels to women and girls who cannot afford them.<sup>2</sup> The environmental impact

<sup>1</sup>Department of Obstetrics and Gynaecology, Maternal, Adolescent and Child Health Research, University of the Witwatersrand, Durban, South Africa.

<sup>2</sup>Department of Epidemiology and Public Health, London School of Hygiene and Tropical Medicine, London, United Kingdom.

<sup>3</sup>School of Pharmacy and Pharmacology, University of KwaZulu-Natal, Durban, South Africa.

<sup>4</sup>Clinical Sciences and Asia-Pacific Regional Office, FHI 360, Bangkok, Thailand.

<sup>5</sup>School of Public Health, University of Maryland, College Park, Maryland.

<sup>6</sup>International Food Policy Research Institute, Washington, DC.

of menstrual waste on sewage systems is considerable.<sup>3</sup> In Durban, South Africa, where this study was conducted, the eThekweni Water and Sanitation utility has reported problems of menstrual products routinely blocking pipes and joints. Blockages are costly and take time to resolve.<sup>3</sup>

The menstrual cup (MC) is an alternative to disposable hygiene products gaining popularity in developed countries.<sup>4</sup> It is a nonabsorbent reusable barrier cup that collects menstrual blood and is typically made of flexible medical-grade silicone. An increasing number of brands are being manufactured in several countries, with estimated durations of use ranging from 5 to 10 years. Studies on MCs conducted since the 1950s indicate that women find the device acceptable.<sup>5–11</sup> One of these more recent studies in Canada found that, after three cycles of use, 91% of women said that they would continue MC use and recommend it to friends.<sup>11</sup> Among British students, 55% continued MC use following study completion.<sup>12</sup> No MC acceptability studies have been conducted in Africa to date. However, in one qualitative study about feasibility of use of the contraceptive cervical barrier Duet™ (ReProtect LLC, Towson, MD, USA) in Zimbabwe, all 43 women interviewed expressed an interest in the device's potential for menstrual protection, stating that existing menstrual-management practices were unhygienic and products unaffordable.<sup>13</sup>

Although MCs are made in South Africa, distribution is limited to a small number of pharmacies or purchase over the Internet. In South Africa, the Mpower® MC (Mpower menstrual cups, Cape Town, South Africa), a medical-grade silicone MC, retails for R265.00 (£18.00, US\$26.50); a box of 32 tampons is approximately R40.00 (£3.00, US\$4.00). Unbranded MCs are available for online purchase for as little as US\$6.82 for a single unit. As the life span of one MC is typically 5 years, use of MC rather than tampons would represent a considerable cost savings over time, even at the full South African retail price.

To inform efforts to expand and improve women's access to menstrual-management options, we evaluated the acceptability and performance of the MPower® MC compared to tampon or pad use in eThekweni District, KwaZulu-Natal, South Africa.

## Materials and Methods

### Study design and participant population

We undertook this two-period, randomized crossover trial between January and November 2013 at an urban reproductive-health clinic center in Durban, South Africa. Participants aged 18 to 45 years with regular menstrual periods and a

menstrual cycle within 5 weeks of enrollment were eligible for inclusion. Participants also were willing to try an insertive menstrual product, had no intention of becoming pregnant or moving outside the area in the next 6 months, were using an effective contraceptive method, and had water from the municipal system as their primary water source. Women were evaluated for sexually transmitted infections (STIs); we excluded women with any potential cause of pelvic discomfort to best assess conditions related to product use. For STI evaluation, point-of-care testing for bacterial vaginosis and *Trichomonas vaginalis* (OSOM BV Blue and Trichomonas tests, Sekisui Diagnostics, San Diego, CA) was performed and clinical evaluation with syndromic assessment performed for other genital-tract infections. We excluded pregnant women (established by urine pregnancy test). Participants could be novice or experienced users of any menstrual product. The study protocol was approved by the University of Witwatersrand's Human Research Ethics Committee.

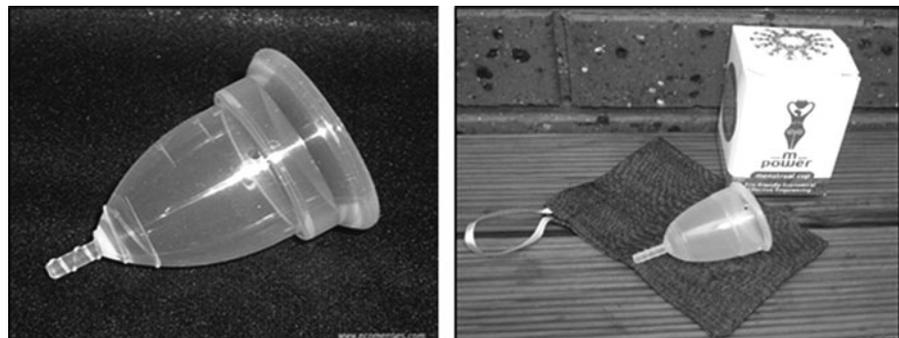
### Randomization and masking

We used a computer-generated randomization sequence using Stata 11.0 statistical software (StataCorp., College Station, TX, USA) to assign participants to one of two sequences (sequence 1, tampons or pads, depending on personal preference/usual product; sequence 2, the MC) of menstrual-product use in equal proportions (1:1), using permuted block randomization (in blocks of variable sizes 4 or 6). Allocations were concealed in sequentially numbered sealed envelopes. Participants and data-collection research nurses were not masked to menstrual product type.

### Procedures

Our primary objective was to compare acceptability and performance of the MC to pads or tampons within the selected study population. We also measured and assessed the safety of each product according to the number, severity, relatedness, and duration of adverse events. In our study, the South African-made silicone MPower® MC was used (Fig. 1).

Each participant was asked to use the assigned product for three complete menstrual cycles and was given instructions and training on correct use of each product. For the tampon/pad assignment, participants chose which product to use. Participants were instructed on keeping a menstrual diary for recording bleeding and product use and were asked to return monthly for follow-up visits, at which a questionnaire was administered. Verbal screening for vaginitis symptoms was performed. Following three consecutive cycles of use of one



**FIG. 1.** The MPower cup (Mpower menstrual cups, Cape Town, South Africa).

product, participants were asked to use the other product, with continuation of follow-up for six cycles in total.

### Measures

Sociodemographic and economic indicators, including usual water and waste-management sources, and menstrual and reproductive-health history were collected at baseline. Both baseline and follow-up questionnaires assessed product acceptability. All acceptability responses were measured using a five-point Likert scale. Product use and related problems were queried at each visit.

### Statistical analysis

We calculated power values to show differences in overall preference of the MC compared to the usual product. Based on existing preference data for MC versus tampons, we anticipated that between 55% and 91% of users would prefer the MC over their usual product.<sup>11,12</sup> The sample size of 100 was determined using Stata's *sampsi* command to detect a preference of at least 65% for one product over the other, with a *p*-value of 5% and power of 0.8. We expected a noncompletion rate of between 5% and 10% (i.e., 90% would provide relevant follow-up data for each product type); therefore, we increased the sample size to 110.

Analysis was performed with Stata versions 11.0 and 13.0. Descriptive statistics were generated, with comparison by study arm, using the Pearson chi-square test for categorical variables and *t*-test for continuous variables. Menstrual history and problems at baseline were described with counts and proportions. Baseline perceptions surrounding menstrual-product use, satisfaction, and disposal practices were calculated by proportions, means, and counts.

For all comparisons, data from the last recorded visit in a product-use sequence were used to reflect maximal use experience. The primary acceptability analysis was based on comparison of scores for the questions "How likely is it that you will continue using the product?" and "How likely are you to recommend this product to a friend or family member?" These scores were compared between products, using an ordinal logistic regression model with individual random effects to account for correlation among repeated observations, implemented using Stata's *meglm* command.<sup>14</sup> A binary variable indicating the product-assignment order was included in the model to account for potential order effects.

Reported product use and associated difficulties/learning were compared between products, using McNemar's chi-squared test for repeated dichotomous outcomes<sup>15</sup> and paired *t*-test for continuous outcomes (e.g., number of times product changed during cycle). Women using the MC were also asked to rate product comfort, quality, menstrual blood collection capacity), and overall satisfaction compared to the "usual product used," using a Likert scale. For these outcomes, we present the proportion reporting higher satisfaction with the MC compared to their usual product. Adverse events during the trial were summarized with simple counts. (This trial is registered on the South African Clinical Trials database [DOH-27-0113-4273].)

### Results

Of 124 women screened, 110 were enrolled in the study, 106 attended the first three follow-up visits, and 105 attended

the final three (Fig. 2). The main reasons for ineligibility were not using a contraceptive method and aged greater than 45 years.

Baseline socioeconomic and relevant health characteristics for participants are displayed in Table 1. Most participants had completed secondary school and been pregnant at least once, and half were not working or studying. There were no significant differences between study arms for any characteristic (Table 1). Hormonal injectable contraceptives were the most commonly used method (72.7%).

The sanitary pad was the menstrual product most women had used previously and most often; only 11% used tampons most often (Table 2). One woman had previously used an MC. A minority (12.7%) reported that inability to access a hygiene product had a negative effect on their ability to perform daily activities, and almost one-fifth (17.4%) of the women reported financial difficulty as a barrier to product access in the past 6 months.

Most women had access to a flush toilet, either at home (83%) or in a communal ablution block (5%). Used products were usually disposed of in garbage bins at home, work or school, and other places outside the home (82.6%, 92.7%, and 87.3%, respectively). Reported product disposal in the toilet was rare (ranging between 5.5% and 7.3% between sites).

In the interval visits, at least 97% of the women reported using the assigned product at any follow-up visit for either arm. At least 93% in the MC arm and 99% in the pad/tampon arm used the assigned product for the entire menstrual cycle, with no significant difference in rates of use by the final visit in the product-use sequence. The number of times required to empty the MC on heavy-bleeding days and for the entire menstrual cycle was lower than for changing pads or tampons (3.3 vs. 3.7 and 10.6 vs. 12.5, respectively;  $p < 0.01$  for both). MC users were more likely to report problems with use, but this difference was not statistically significant by the third month of use ( $p = 0.16$ ). Twenty-three women reported a total of 28 problems with any product, of which 24 (89%) were associated with MC use; discomfort with use ( $n = 20$ ), leakage ( $n = 3$ ), and general difficulty with use ( $n = 1$ ). Problems reported with pad/tampon use ( $n = 4$ ) included one report each of discomfort with use, leakage through the product, abdominal pain, and a rash. A total of 13 adverse events were reported, with 11 in association with MC use and 2 with pad/tampon use. Events occurring with MC use were vaginal pain with insertion ( $n = 10$ ) and vaginal irritation ( $n = 1$ ), whereas 1 pad/tampon user reported vaginal irritation and 1 reported dysuria. Ease of MC insertion improved markedly between months 1 and 3, with "very easy" ratings increasing from 38% to 96%. Similarly, ease of removal reported as "very easy" increased from 67% to 96%. Nearly all women reported washing their hands prior to cup insertion (98%–99%) and removal (99%) at all cycles of use, with 60%–76% reporting soap use. Most women reported emptying the MC into the toilet at home (91%–94% over all cycles of use), whereas women reporting not emptying the MC outside the home decreased over cycles of use from 59% to 38%. At home, most (93%) women reported cleaning their MCs with tap water. Women who did empty and clean their MC outside the home also reported cleaning the MC in the toilet facility (32%–44%). Two women reported that they carried tap water into the toilet to clean the MC. Most women

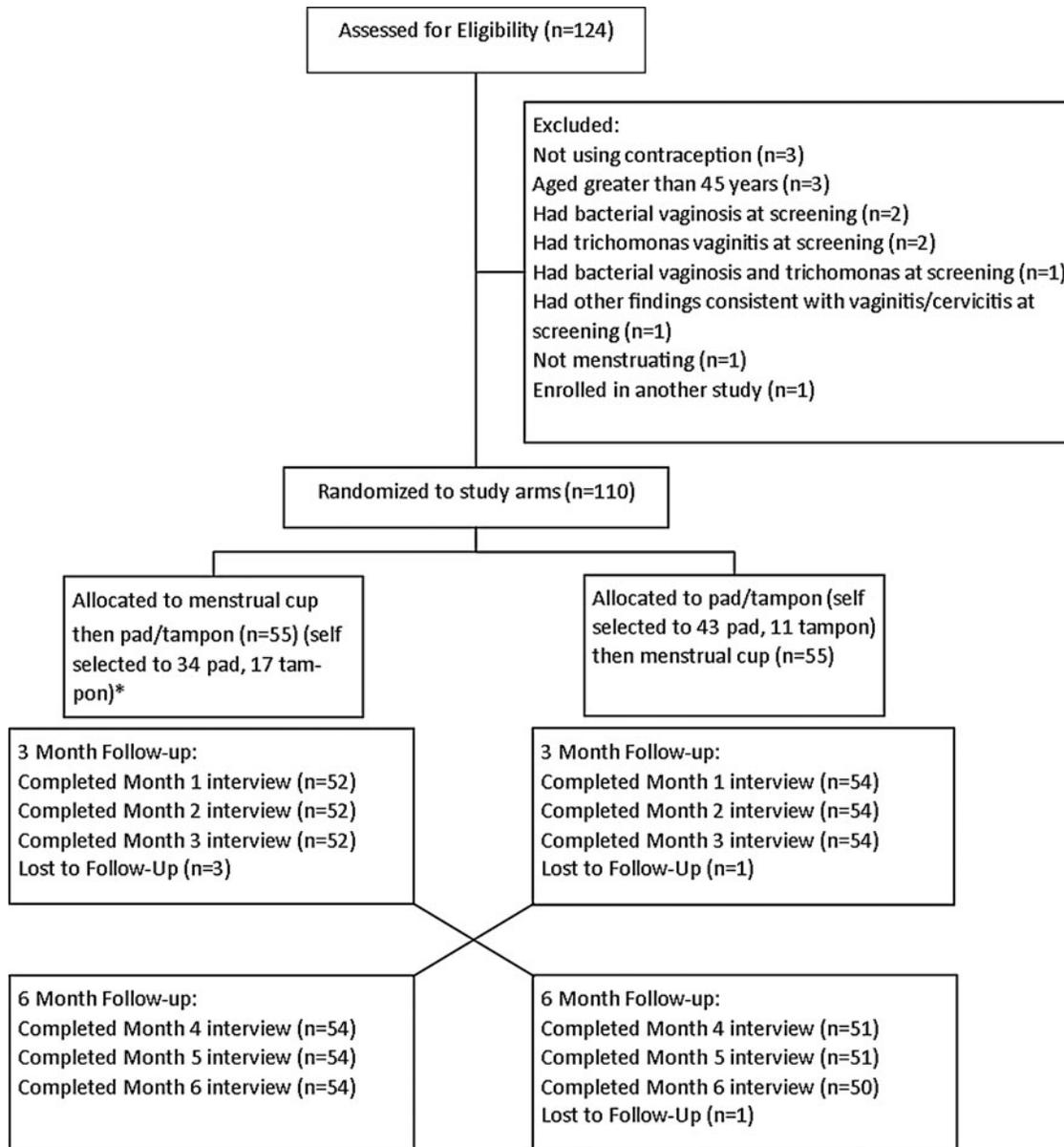


FIG. 2. The study flowchart. \*4 women dropped out after using MC as first allocation.

reported using the MC as their sole hygiene product overnight during menses, with this proportion increasing from 88% to 100% within the three-cycle use period.

By comparison to the product used most often, the MC was rated better by comfort, quality, menstrual-blood collection, appearance, and preference, with ratings increasing throughout the use period (Table 3). Satisfaction with both the MC and the comparison product was high in the primary-satisfaction outcome measures. Similar to the comparative measures reported in Table 3, reported likelihood of continued use, likelihood of recommending the product, and likelihood of future purchase increased for the MC over time. By the end of the 3rd month of using the MC, 90% of participants said that they were likely or highly likely to continue using it, compared to 85% after the first period. The proportion reporting that they were likely or highly likely to recommend the MC increased by 2 percentage points over the trial period,

reaching 94% by month 3, and those who said that they were likely or highly likely to purchase the MC reached 94%, reflecting an increase of 9 percentage points from month 1. Satisfaction with the comparison product was also high, with 86%, 87%, and 89% stating that they were likely or highly likely to continue use, recommend, and purchase the product at the end of the study period, respectively. However, the trend over time for these measures was flatter and in the opposite direction of the positive trend seen for reported satisfaction with the MC. Overall, users were 1.5 percentage points less likely to say that they were likely or highly likely to use, recommend, or purchase the comparison products during the third vs. the first follow-up visit.

We compared these outcome measures as reported in the final visit for each product arm, using an ordinal logistic regression model with random individual-level effects. Higher scores indicate greater likelihood of continued use of,

TABLE 1. BASELINE SOCIODEMOGRAPHIC AND HEALTH CHARACTERISTICS AND COMPARISON BETWEEN STUDY ARMS (N=110)

Variable	Overall	Arm 1 (n=55)	Arm 2 (n=55)	p-value
Mean age, years (SD)	29.0 (6.0)	28.5 (6.0)	29.4 (6.1)	0.44
Mean number living in home (SD)	5.2 (2.3)	5.0 (2.0)	5.4 (2.3)	0.35
Mean number living children (SD)	1.71 (1.0)	1.6 (1.0)	1.8 (1.1)	0.45
Ever pregnant, %	101 (91.8)	50 (90.9)	51 (92.7)	0.98
First language, %				0.60
IsiZulu	107 (97.3)	54 (98.2)	53 (96.4)	
Other	3 (2.1)	1 (1.8)	2 (3.6)	
Currently employed %				0.63
Full or part time	35 (31.8)	16 (29.1)	19 (34.5)	
Student	20 (18.2)	9 (16.4)	11 (20.0)	
Unemployed	55 (50.0)	30 (54.5)	25 (45.5)	
Highest grade level completed, %				0.33
Primary or less	3 (2.1)	2 (0.6)	1 (1.8)	
Some secondary	32 (29.1)	13 (23.6)	19 (34.5)	
Completed secondary	72 (65.5)	39 (70.9)	33 (60.0)	
Beyond secondary	7 (6.4)	4 (7.3)	3 (5.5)	
Civil status, %				0.90
Single	9 (8.2)	4 (7.3)	3 (5.5)	
Regular partner, live apart	82 (74.5)	42 (76.4)	40 (72.7)	
Cohabiting/Married	19 (17.3)	9 (16.4)	10 (18.2)	
Have a radio in home, %	104 (94.5)	52 (94.5)	52 (94.5)	0.99
Have a television in home, %	109 (99.1)	54 (98.2)	55 (100)	0.32
Have mobile phone, %	110 (100)	55 (100)	55 (100)	—
Home toilet facility, %				0.75
Pit latrine	14 (12.7)	6 (10.9)	8 (14.5)	
Indoor flush toilet	91 (82.7)	47 (84.5)	44 (80.0)	
Community ablution block	5 (4.5)	2 (3.6)	3 (5.5)	
Water source for hand washing:				
Piped water in home	97 (88.2)			
Piped water in community	13 (11.8)			
Hand washing after change of product	107 (97.3)			
Hand-washing practice:				
Water only	29 (26.4)			
Soap and water	81 (73.6)			
Ever experience problems with toilet facility (clogging) at home or work/school?				
Yes	10 (9.4)			
No	96 (90.6)			
Current contraceptive method, %				
Oral	19 (17.3)	10 (18.2)	9 (16.4)	0.80
Injectables	80 (72.7)	41 (74.5)	39 (70.9)	0.70
Sterilization	4 (3.6)			
IUD	4 (3.6)			
Condoms	3 (2.7)			

IUD, intrauterine device; SD, standard deviation.

recommending, and purchasing the product. Pad/tampon exposure is the control condition, and a variable indicating that the product was the second one received is included to capture order effects. The results indicate that participants were somewhat more likely to continue using, recommend to friends and family, and purchase the MC as opposed to the comparison product, though differences are not statistically significant (Table 4). There is a statistically significant order effect for all outcomes, with women less likely to say that they would continue using, recommend, or purchase, the second product received compared to the first. This could be owing to more realistic assessments of future behavior as the end of the study approached.

## Discussion

The results of our study indicate that women attending a reproductive-health clinic in central Durban were able to successfully use the MC over three consecutive menstrual cycles and reported highly positive experiences of their use, willingness to use in the future, and to recommend use to others. These results are similar to data shown from other studies in developed countries, where women have reported positive experiences and satisfaction with MC use.<sup>9–12</sup> Women also reported high satisfaction with their choice of pads or tampons. The significant order effect, with women less likely to say that they would continue using, recommending,

TABLE 2. MENSTRUAL HISTORY AND HYGIENE PRODUCT USE AND SATISFACTION AT BASELINE (N=110)

Variable	Mean (SD)	Range	
Age of menarche (years)	14.7 (2.5)	11–20	
Frequency of menses (days) in past 3 months	27.6 (3.6)	20–40	
Duration of menses (days)	4.3 (1.2)	2–8	
Number of heavy-bleeding days	1.6 (0.9)	0–4	
Number of times hygiene product changed on heavy-bleeding day	3.4 (1.0)	1–6	
Number of times hygiene product changed on day with average menstrual flow	2.6 (1.1)	1–12	
Number of usual hygiene-product units used in single menses	11.3 (3.9)	2–30	
Current menstrual problems:	<i>n</i> (%)		
Pain/cramps	47 (42.7)		
Heavy bleeding/clots	49 (44.6)		
Irregular bleeding	9 (8.2)		
Intermenstrual bleeding	8 (7.3)		
Purchaser of menstrual-hygiene products:	<i>n</i> (%)		
Self	86 (81.1)		
Head of house	16 (15.1)		
Boyfriend	4 (3.8)		
Menstrual-hygiene product use history:	Ever <i>n</i> (%)	Usual <i>n</i> (%)	Most often <i>n</i> (%)
Sanitary pads	110 (100)	102 (92.7)	98 (89.1)
Tampons	48 (43.6)	22 (20.0)	12 (10.9)
Cloth/rags	29 (26.4)	7 (6.4)	
Panty liners	65 (59.1)	33 (30.0)	
Toilet paper	38 (34.6)	19 (17.3)	
Newspaper	5 (4.6)	0	
Cotton	2 (1.8)	0	
Menstrual cup	1 (0.9)	0	
Product satisfaction scores: <sup>a</sup>	Very good/good <i>n</i> (%)	Average <i>n</i> (%)	Poor/very poor <i>n</i> (%)
Product comfort	106 (96)	3 (3)	1 (1)
Product cleanliness	107 (97)	3 (3)	0 (0)
Product absorbency	101 (92)	7 (6)	2 (2)
Product price	76 (69)	28 (25)	6 (5)
Product convenience	100 (91)	7 (6)	3 (3)
Product quality	104 (95)	4 (4)	2 (2)
Would recommend to friends	106 (96)	4 (4)	(0)

<sup>a</sup>Likert scale scoring: 1, Very good; 2, Good; 3, Average; 4, Poor, 5, Very poor. Ratings refer to product used most often: pads (89.1%) and tampons (10.9%).

TABLE 3. SUMMARY RATINGS FOR MENSTRUAL CUPS AT THE END OF PRODUCT-USE CYCLE AS COMPARED TO USUAL MENSTRUAL-HYGIENE PRODUCT (N=106)

Product characteristic	Visit 1 <i>n</i> (%)	Visit 2 <i>n</i> (%)	Visit 3 <i>n</i> (%)
Menstrual cup comfort			
Better	79 (75)	91 (86)	96 (91)
Same	14 (13)	10 (9)	7 (7)
Worse	10 (9)	5 (5)	3 (3)
Menstrual cup quality			
Better	83 (78)	98 (92)	98 (92)
Same	18 (17)	5 (5)	7 (7)
Worse	2 (2)	3 (3)	1 (1)
Menstrual cup capacity/absorption			
Better	89 (84)	94 (89)	99 (93)
Same	9 (8)	6 (6)	6 (6)
Worse	5 (5)	6 (6)	1 (1)
Menstrual cup appearance			
Better	70 (66)	77 (73)	87 (82)
Same	15 (14)	8 (8)	6 (6)
Worse	18 (17)	21 (20)	13 (12)
Like menstrual cup vs. usual product			
Better	84 (79)	90 (85)	97 (92)
Same	13 (12)	8 (8)	5 (5)
Worse	5 (5)	5 (5)	3 (3)

or purchasing the second product received compared to the first is difficult to interpret. We speculate that this difference may be attributable to greater awareness of the cost of the study products and the impending need to purchase these supplies as the second cycle finished; further investigation is required to explore this trend.

TABLE 4. ORDERED LOGISTIC REGRESSION COMPARING USER SATISFACTION WITH MENSTRUAL CUP VS. PAD OR TAMPON COMPARATOR

Outcome	Likely to continue using product	Likely to recommend product	Likely to buy product
Product assessed = Mcup	1.285	1.321	1.269
Standard error	(0.421)	(0.457)	(0.384)
Second product assessed	0.463*	0.392**	0.379**
Standard error	(0.159)	(0.142)	(0.121)
Observations	210	210	210
Individuals	106	106	106

Odds ratios are reported, representing the odds that satisfaction is assessed at the next-highest level, relative to the comparison category. A score of 1: Very unlikely; a score of 5: Very likely. Standard errors are shown in parentheses.

\**p* < 0.05.  
\*\**p* < 0.001.

The data show clearly that experience with MC use across the three use cycles resulted in improvements in use, with ease of insertion increasing from 38% of women at visit 1 to 96% at visit 3. At visit 1, over half (58%) the women reported that initial difficulties with insertion lessened with use. Similarly, ease of removal also improved over time, whereas problems related to discomfort with the MC at time of insertion declined. This practice effect has been noted with the female condom, whereby women need to practice insertion to reduce discomfort and build confidence in correct placement.<sup>16</sup>

The wider environmental benefits of MC use would lead to cost savings in reduction of waste and damage to fragile water systems. In our study population, less than 10% of the women at baseline mentioned disposing of sanitary products in toilets; however, in densely populated cities, such as Durban, disposal of sanitary products is reported as problematic for municipal waste-processing systems.<sup>3</sup>

There were some limitations in our study. Women were not randomly sampled, and the counseling they received from research staff, who gave participants a comprehensive demonstration session, including fitting, cleaning, and care of the MC, may have induced a bias toward a positive user experience. If MCs become more widely available in pharmacies, there would be limited support for users. However, if healthcare providers were trained about MC use even if they were not available in public-sector health facilities, women could purchase the MC and follow up on any user issues within these facilities.

## Conclusions

MC acceptance in a population of novice users, many with limited tampon experience, indicates that there is a pool of potential users in low-resource settings. Although the initial financial outlay may be prohibitive for this population, cost savings could be realized after 1 year of use. Women of all ages would be beneficiaries of MC use, especially young women in school, where there is potential for reduced attendance for those living in households that cannot afford quality sanitary products. Although we had no women under 18 years old in the study, almost one-fifth (18.2%) were students, another group that may be subject to financial constraints but willing to try a novel menstrual-management device.

The goal of free menstrual-hygiene products for women, stated by the South African government, has not yet been achieved. The MC has the potential to make the government pledge a reality and play a key role in women's health, with added benefits of an environmental nature.

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VH, CST, JS, and MEB conceived the study and designed it with RG. MEB, VH, JS, MLTL, CST, and RG had full access to the primary data. All authors had final responsibility for the publication. MEB had final responsibility from all the coauthors to submit for publication.

JS, RG, MEB, and VM managed the undertaking of the trial. VH, CST, MLTL, MEB, and RG conducted statistical analyses; VH, CST, MEB, JS, and RG interpreted the data. MB, JS, RG, CST, and VH drafted the article, with input

editing from VM and MLTL. All authors read and approved the final version.

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## Author Disclosure Statement

No competing financial interests exist.

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Address correspondence to:

*Mags E. Beksinska, PhD  
Department of Obstetrics and Gynaecology  
Maternal, Adolescent and Child Health Research  
University of the Witwatersrand  
34 Essex Terrace, Westville  
Durban 3629  
South Africa*

*E-mail: mbeksinska@matchresearch.co.za*