



**British Journal of Medicine & Medical Research**  
4(19): 3581-3590, 2014



SCIENCEDOMAIN *international*  
[www.sciencedomain.org](http://www.sciencedomain.org)

---

## **An Innovative, Reusable Menstrual Cup that Enhances the Quality of Women's Lives during Menstruation**

**Alfred Shihata<sup>1\*</sup> and Steven Brody<sup>2</sup>**

<sup>1</sup>*Scripps Institution of Medicine and Science, San Diego, CA, USA.*

<sup>2</sup>*UCSD School of Medicine, La Jolla, CA, USA.*

### **Authors' contributions**

*This work was carried out in collaboration between all authors. All authors read and approved the final manuscript.*

**Original Research Article**

**Received 20<sup>th</sup> February 2014**

**Accepted 7<sup>th</sup> April 2014**

**Published 15<sup>th</sup> April 2014**

---

### **ABSTRACT**

**Objective:** A) To evaluate the acceptability of a unique, Cost-effective, reusable, and environmentally safe device for menstrual blood collection among culturally diverse women. B) To enhance the quality of life for women during menstruation.

**Methods:** The first author developed a unique, reusable menstrual collection device as an alternative to sanitary pads and tampons. After successful research and development, the United States Food and Drug Administration (USFDA), as well as the European Union and Health Canada, granted their approval for the device.

The first author and five co-investigators recruited 146 women of diverse cultural and national backgrounds to evaluate the FemmyCycle. Women were instructed to use the FemmyCycle for three cycles, report any side effects and compare their experiences using the FemmyCycle with other sanitary products.

**Results:** Among all participants who used this new device for three cycles, 84% preferred the FemmyCycle over prior methods used for menstrual hygiene. These women rated the device superior to previously-used methods and safer for the environment than pads and tampons.

**Conclusions:** The majority of women preferred the FemmyCycle over their previous feminine sanitary protection methods. The device can protect the environment and enhance the quality of women's lives during menstruation, particularly working and

---

\*Corresponding author: Email: [alfred@femmycyclel.com](mailto:alfred@femmycyclel.com);

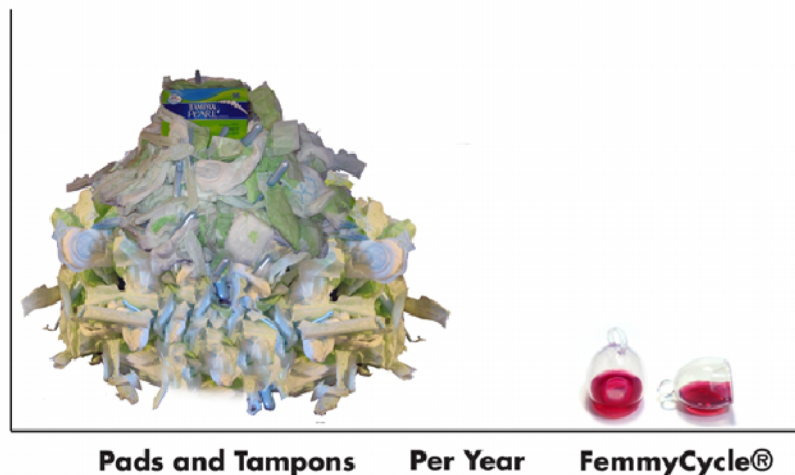
athletic women. This is due to the longer duration of protection, prevention of leakage, activity compatibility, as well as elimination of the risk of Toxic Shock Syndrome. This device may fill a major void in menstrual hygiene products and women's reproductive health worldwide.

**Keywords:** *Menstrual cup; FemmyCycle; alternative to pads and tampons; women's health; period.*

## 1. INTRODUCTION

Each year, western women dispose of about 20 billion contaminated pads and tampons, polluting the environment. An average woman will use as many as 17,000 pads and tampons in her lifetime. Until recently, menstrual hygiene has been neglected in developing countries [1]. Fig. 1 shows the environmental impact of pads and tampons vs. the FemmyCycle menstrual cup per year. Many are made out of a cotton and rayon blend that is bleached to achieve a clean, white sterile look. While the United States Environmental Protection Agency (USEPA) banned a more harmful bleaching process in 1998, current elemental 'chlorine-free' bleaching processes using chlorine dioxide still produce a small amount of dioxins. Dioxins can be toxic even in small quantities [2].

### Environmental impact of pads and tampons vs. the FemmyCycle® per year



**Fig. 1. Environmental impact of the FemmyCycle**

Women have tolerated the inconvenience of managing their menstruation since the beginning of human history. In western nations, feminine sanitary products are a fact of life. In developing countries, women still resort to reused rags which may be contaminated. Millions of girls and women in developing countries miss up to 50 days of school or work per year due to the lack of private facilities and access to affordable menstrual sanitary products, as well as the lack of a clean water supply [3].

In response to the lack of Cost-effective, environmentally safe options and in order to enhance quality of life for women during menstruation, the first author developed a unique, reusable menstrual collection device. This device was approved by the United States Food and Drug Administration (USFDA) [4], as well as the European Union and Health Canada.

## 2. METHOD

### 2.1 Description of the Device

The new menstrual cup is a One-size [5], wineglass-shaped device made of compressible, medical-grade silicone to facilitate its insertion into the vagina. The device has a unique, funnel-shaped lid that directs the blood into the receptacle and prevents it from spilling during removal. It has a no-spill design Fig. 2. incorporating an openable and closable lid Fig. 3. The device is made of a non-adhesive material that can be easily cleaned with mild soap and water. It is 5cm long and 4.5cm wide. It has a capacity to collect and hold one ounce of menstrual flow and can be reused for several years. The device has a removal ring that facilitates its removal by a single finger. The device also has resilience and a memory that restores it to its original shape once inserted into the vagina.

The FemmyCycle is placed in the lower part of the vagina Fig. 4. The USFDA evaluated the device's safety, as well as the biocompatibility of its silicone material to the environment of the vagina and its tissues before granting clearance.



Fig. 2. No-spill Design



**Fig. 3. FemmyCycle with open and closed lid**

The first author and five co-investigators recruited 146 women of diverse cultural and national backgrounds to evaluate the FemmyCycle from February, 2013 to June, 2013 Table 1. The study was conducted in private clinics in San Diego, California, USA, (where US participants that included Mexican, Brazilian and Columbian nationals were tested), as well as Stockholm and Falun, Sweden. Women who volunteered to test the FemmyCycle were instructed to use the FemmyCycle for three cycles and report any side effects. After the third cycle, the women filled out forms where they evaluated various attributes of feminine hygiene products by importance Table 2. Investigators also asked participants to fill out a questionnaire rating their satisfaction with the new cup compared to alternative feminine hygiene options, including pads, tampons, and other menstrual cups Table 3.

## **2.2 Ethical Considerations**

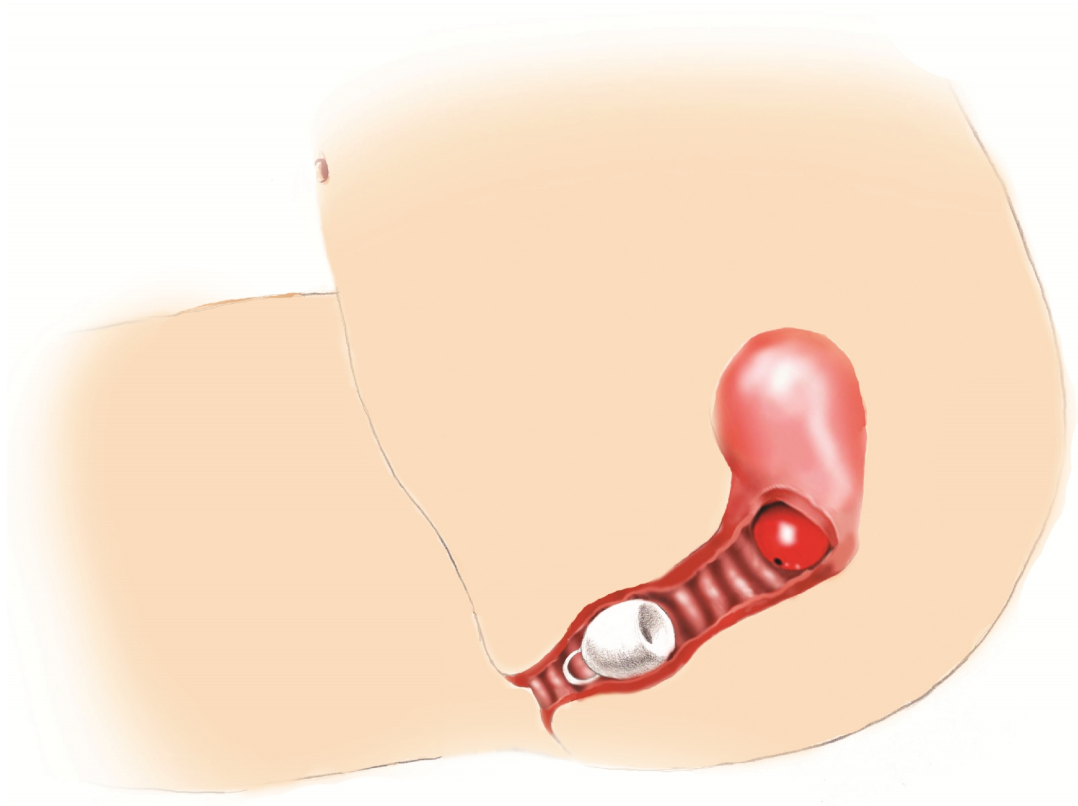
The privacy and confidentiality of all women who volunteered in the study was kept to the maximum according to US and Swedish law. The FemmyCycle, approved for use in the USA, Europe and Canada, is made out of non-allergenic medical grade silicone. There is no reported event of toxic shock syndrome associated with silicone menstrual cups, including

the FemmyCycle. All women in the study were free to stop participating at their own discretion.

### **2.3 Inclusion / Exclusion**

The study included women aged 18-40 with regular menstrual cycles. These women had to be able and willing to follow study protocols for three menstrual cycles and report any side effects. Participants also had to be able to understand and fill out an evaluation form.

Women with an aversion to touching their genitalia or women affected by fibroids or endometriosis were excluded.



**Fig. 4. FemmyCycle in the Lower Part of the Vagina**

**Table 1. Study participant demographics**

<b>Country of origin</b>	<b>USA</b>		<b>Sweden</b>		<b>Mexico</b>		<b>Brazil</b>		<b>Columbia</b>	
No. of participants who completed 3 cycles	No.	%	No.	%	No.	%	No.	%	No.	%
	50	40%	25	20%	24	19.2%	15	12%	11	8.8%
Percentage of participants working outside the home at time of study		75%		82%		58%		61%		49%
Obstetrical history	26 Never pregnant		13 Never pregnant		4 Never pregnant		7 Never pregnant		5 Never pregnant	
	8 Pregnant, no vaginal delivery		4 Pregnant, no vaginal delivery		6 Pregnant, no vaginal delivery		3 Pregnant, no vaginal delivery		2 Pregnant, no vaginal delivery	
	16 Vaginal delivery		8 Vaginal delivery		14 Vaginal delivery		5 Vaginal delivery		4 Vaginal delivery	
No. of participants who could not insert the device	1		0		4		0		1	
Number of women who had leakage	4		2		4		3		1	
Satisfied	46		23		18		10		8	
Not satisfied	4		2		6		5		3	

**Table 2. Evaluation of currently used menstrual hygiene products by women from Brazil, Columbia, Mexico, Sweden, and the USA**

Country:	First Name:	Age:	Start Date:	Finish Date:
<b>What did you use during your menstrual periods prior to using the FemmyCycle? (Circle all that apply.)</b>				
Pads	Tampons	Panty Liners	Menstrual Cup	Other    Combination of Products

<b>Please use the scale to the right to rate how much you personally value the variables below:</b>	1 - Very Important; 2 - Somewhat Important; 3- Neutral; 4 - Minimal Importance; 5 - Not Important At All
Leakage Prevention	1
Environmental Impact	1-2
Odor Prevention	1-2
Convenience	1-2
Comfort	1-2
Activity Compatibility	1
Duration of Use	1-2
Link to Toxic Shock Syndrome	4

**Table 3. Evaluation of the FemmyCycle compared to other menstrual hygiene products**

<b>Women's evaluation of each product in comparison with the Femmy Cycle for at least 3 cycles.</b>	<b>1 - Excellent; 2 - Good; 3 - Average; 4 - Fair; 5 - Bad</b>					
	<b>Pads</b>	<b>Tampons</b>	<b>Panty Liners</b>	<b>Other Cups</b>	<b>Combination of Products</b>	<b>FemmyCycle No. 105 = 100%</b>
Leakage Prevention	4-5	2-3	4-5	2-3	2-3	1-2 (84%)
Environmental Impact	5	5	5	1	4-5	1 (98%)
Odor Prevention	4	4	4	1	2-3	1 (92%)
Convenience	5	2	3	2	3-4	1-2 (80%)
Comfort	5	2	3	2	3-4	1-2 (84%)
Activity Compatibility	5	2	4	2	3-4	1 (96%)
Duration of Use	4	4	4	2	3-4	1-2 (80%)
Link to Toxic Shock Syndrome	1	4	1	1	2	1 (98%)

### 3. RESULT

At time of enrollment, 55% of the participants were using both pads and tampons; 25% were using pads; 15% were using tampons exclusively; and 5% were using menstrual cups and pads. In the course of the study, 5 women were lost to follow-up and 16 women declined to use the device. The reasons given for not using the device were: I am a virgin; I never used

tampons; the device is too big for me; and I do not want to keep blood inside me for 12 hours.

Of the 125 women who consented to use the device, 6 women could not insert the device on the second attempt and withdrew from the study. Another 14 women experienced leakage due to variable degrees of prolapse or low cervix and were discontinued after the second cycle. The FemmyCycle leaked only when used by woman who had uterine prolapse, a low cervix, or who pushed the device too far into the vagina. To be effective, the FemmyCycle must rest below the cervix Fig. 4.

The study subjects reported that the FemmyCycle needed to be emptied and replaced much less frequently (every 8-12 hours) compared with pads and tampons that required changing every 2-4 hours. Of the 105 participants who tested the FemmyCycle for three months, 81% decided to continue using it for sanitary protection.

After compiling the results obtained from the Evaluation Questionnaire, we found that 105 of the participants (84%) were satisfied and rated the FemmyCycle device superior to their prior method of menstrual protection. The vast majority (98%) rated the FemmyCycle much safer for the environment than pads and tampons.

We found a similarity of acceptability of this new menstrual cup among different cultures. However, there was higher acceptability among Swedish women and lower acceptability among Mexican women; 4 out of the 6 women who could not insert the device were Mexican, while none were Swedish.

#### **4. DISCUSSION**

Menstruation is still considered a taboo subject and is referred to as the Curse by some societies [6]. Our goal is to provide discreet, safe, comfortable, and hygienic sanitary protection that will improve the quality of life for women during their menstruation.

The FemmyCycle menstrual cup is an alternative to pads and tampons that is environmentally friendly because it is made of medical grade silicone and reusable. The preclinical trials and submission to the FDA did not detect any adverse effects. No safety issues have been reported during the post-marketing period or by any of the participants of this study.

Unlike the tampon [7], none of FemmyCycle users or study participants required physician-assisted removal of the device. This is due to the FemmyCycle's large, flexible removal ring. A few women disliked using their fingers to open the FemmyCycle lid when emptying the device, especially when their fingers contacted menstrual fluid. Investigators suggested those women lift the lid with an object such as a cotton swab to avoid skin contact with menstrual blood. In this study, a one-page illustrated instruction sheet allowed 99% of the participants to insert and remove the cup without assistance.

There is growing evidence that a simple, reusable, well-designed, and inexpensive menstrual cup could play an important role both in developed [8-12], as well as developing [13-15] countries. The aim of our study was to determine whether the FemmyCycle menstrual cup would be accepted by women of different ages, ethnicities and cultural backgrounds. We asked the 105 healthy female volunteers to record and compare the



frequency of changing their current sanitary protection, record leakage and make any other comments over the course of three menstrual cycles using the FemmyCycle.

## **5. CONCLUSION**

The FemmyCycle can enhance the quality of women's lives during menstruation, particularly working and athletic women. This is attributable to longer duration of protection and activity compatibility. It may also prevent girls and women in developing countries from missing school or work during their menstruation. The FemmyCycle may protect the environment from the yearly disposal of billions of pads and tampons. This device may fill a major void in menstrual hygiene products and women's reproductive health worldwide.

## **CONSENT**

Not applicable.

## **ACKNOWLEDGEMENT**

We are indebted to the women who consented and volunteered to participate in this research study. Our special thanks to: Dr. Melinda Nevins, of the USA; Dr. Maria Luisa B da Cunha of Brazil; Dr. Catalina Escobar of Columbia; and Midwives Birgit Linderoth and Constanca Johansson of Sweden. We also thank Ms. Marisa Engh who edited this manuscript. No funding was requested or received from any institution. The authors are solely responsible for the content of this article.

## **COMPETING INTERESTS**

Authors have declared that no competing interests exist.

## **REFERENCES**

1. Ten VTA. Menstrual hygiene: A neglected condition for the achievement of several millennium development goals. Europe External Policy Advisors. Oct; 2007.
2. Available: <http://www.epa.gov/pbt/pubs/dioxins.htm>.
3. Sommer M. Where the education system and women's bodies collide: The social and health impact of girls' experiences of menstruation and schooling in Tanzania. *J Adolesc.* 2010;33:521–529. [PubMed]
4. [510\(k\) Premarket Notification K121857](#)
5. North BB, Oldham MJ. Preclinical, clinical and over-the-counter post-marketing experience with a new vaginal cup menstrual collection. *Journal of Women's Health.* 2011;20(2).
6. Houppert K. *The curse—Confronting the last unmentionable taboo: Menstruation.* New York. Farrar Straus and Giroux; 1999.
7. Bright R, Dwyer D. Retained menstrual tampons: Hazards and epidemiology. International Society of Technology Assessment in Health Care Meeting; Canmore, Alberta, Canada; 2003.
8. Liswood R. Internal menstrual protection. Use of a safe and sanitary menstrual cup. *Obstet Gynecol.* 1959;13:539–543. [PubMed]
9. Wysocki S. New options in menstrual protection. A guide for nurse practitioners. *Adv Nurse Pract.* 1997;5:51–54. [PubMed]

10. Stewart K, Powell M, Greer R. An alternative to conventional sanitary protection: Would women use a menstrual cup? *J Obstet Gynecol.* 2009;29:49–52. [PubMed]
11. Pena E. Menstrual protection. Advantages of the menstrual cup. *Obstet Gynecol.* 1962;19:684–714. [PubMed]
12. Karnaky K. Internal menstrual protection with the rubber menstrual cup. *Obstet Gynecol.* 1962;19:688–691. [PubMed]
13. Oster EFT, Thornton RE. Menstruation and education in Nepal. National Bureau of Economic Research Working Paper Series. 2009:Vol.w14853
14. van der Straten A, Sahin-Hodoglugil N, Mtetwa S, et al. Feasibility and acceptability of cervical barriers among vulnerable youth: A pilot study in Zimbabwe. 4<sup>th</sup> IAS Conference on HIV Pathogenesis, Treatment, and Prevention; Sydney, Australia; 2007.
15. Averbach S, Sahin-Hodoglugil N, Musara P, Chipato T, van der Straten A. Duet<sup>®</sup> for menstrual protection: A feasibility study in Zimbabwe. *Contraception.* 2009;79:463–468. [PubMed]

---

© 2014 Shihata and Brody; This is an Open Access article distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/3.0>), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

*Peer-review history:*

*The peer review history for this paper can be accessed here:*  
<http://www.sciencedomain.org/review-history.php?iid=496&id=12&aid=4315>