

A Unique Menstrual Cup Design Enhances Convenience, Comfort & Safety.

Shihata Alfred*, Brody Steven A and Linderroth Birgit, Walker, Lori

¹Shihata Alfred, Scripps Institution of Medicine and Science San Diego, CA, USA

²Brody, Steven, MD, Ph.D. Medical Director, Life Span Institute San Diego, CA, USA

³Linderroth, Birgit, Midwife, Falun Sweden

⁴Walker, Lori, Nurse-Midwife RN, CNM

*Corresponding author: Shihata Alfred, MD Scripps Institution of Medicine and Science San Diego, California, USA.

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Abstract

Introduction: Menstrual hygiene products are a primary health need for all menstruating women. Menstrual cups are established female hygiene products that are gradually replacing pads and tampons. Menstrual cups are safer and more convenient than pads and tampons. Since the European regulatory bodies have declared that menstrual cups are no longer considered medical devices, and the U.S. FDA has waived the requirement of 510 K, the market has flooded with menstrual cups. They did not classify menstrual cups as medical devices because they do not treat or prevent any disease and are used by average healthy women.

Objectives: A) End the stigma associated with menstrual periods. B) Augment and reinforce menstrual hygiene education for school-age girls. C) Eliminate period poverty. D) Develop reusable, cost-effective, and safe menstrual hygiene products benefiting women and the environment. E) Minimize leakage and side effects from menstrual hygiene products.

Methods: A study of currently available menstrual cups demonstrated that most have almost the same design and similar drawbacks. They are cone-shaped, with the narrowest part pointed towards the vaginal opening. Most of these cups have a rigid stem intended for removal; however, the manufacturer of these menstrual cups recommends cutting the stem, making removal difficult and messy.

Most of these cups have a firm rim that may cause pressure over the urethra, which makes urination difficult. These cups are often colored with different dyes. The current menstrual cups usually have two sizes, small and large. The manufacturer recommends using the small cup for women younger than 30 and the large one for women older than 30. Sizing recommendations based on age don't have any anatomical or physiological basis. A 30-year-old woman who has never been pregnant will be fitted comfortably with a small menstrual cup, and a 17-year-old woman who delivered vaginally will be fitted with a regular size menstrual cup.

There have been no advances in menstrual hygiene products for more than 50 Years. We utilized a detailed study of the drawbacks of currently available menstrual cups to avoid them in the new design of the FemmyCycle. We also interviewed two midwives, one in Sweden and the second in the U.S., to learn from their experience and identify the requirements of an ideal menstrual cup.

Result: Education on menstrual hygiene needs to be improved and should be implemented. The need for a safe, easy-to-use, and cost-effective menstrual cup, particularly for working women and schoolgirls, is critical. This led us to develop a new device with a no-spill design, FemmyCycle, introduced in 2013.

Conclusion: Menstrual hygiene products are an essential health need that can no longer be ignored. The development of the FemmyCycle is a step toward improvement in this neglected area of women's health. This unmet need should be followed by more research and development.

Keywords: Menstrual Cups, Femmy Cycle, Pads, Tampons, Feminine Hygiene Products, Menstrual Bleeding

Introduction

Historically, women in the past and developing countries are using rags that may be contaminated. The introduction of menstrual cups in 1932 was not well accepted by women then.

Globally, 1.9 billion women are of menstruating age, spending an average of 65 days a year dealing with menstrual blood flow. Few good quality studies exist that compare menstrual cups to sanitary products, according to researchers at the Liverpool School of Tropical Medicine in the U.K. [1].

Despite significant advances in gynecology, there is an unmet need for menstrual hygiene education and products, particularly among low-income women who may experience “period poverty” [2,3].

Menstrual hygiene products have been neglected, particularly in developing countries, due to a lack of resources [4-5]. The average standard period was called many negative names, including the Curse [6].

Women in the western world consider feminine sanitary products a necessity of life. On average, a western woman disposes of 360-400 contaminated pads, tampons, and plastic applicators yearly. Figure 6 shows the yearly environmental impact of pads and tampons disposed of by one woman versus the annual use of one FemmyCycle menstrual cup.

Millions of women in developing countries miss up to 65 days of school or work per year due to the lack of private facilities, access to affordable menstrual sanitary products, and a clean water supply. Women missing that many days can cause a significant barrier to full participation in society. A menstrual cup can be a good solution for menstrual hygiene management in economically challenged settings [7].

Background and Purpose of this Research

The need to end the period stigma is critically important to resolve this significant problem that affects half of the adult population. Menstrual hygiene education and an ergonomically designed, reusable, safer, and cost-effective menstrual cup are urgently needed. More nurses and doctors are advocating using menstrual cups instead of pads and tampons [8,9]. The following

video is intended to end the period stigma: End Period Stigma.

Materials & Methods

We studied the most available menstrual cups, focusing on their benefits and shortcomings. This study was intended to help us avoid the drawbacks of the presently available cups. Armed with this information, we developed and patented a unique no-spill design menstrual cup that prevents menstrual leakage. The FemmyCycle was granted FDA clearance by 510 K in 2012 [10,11]. We ensured that this menstrual cup adapts to the changes in women's anatomy during pregnancy and delivery.

We interviewed a highly experienced midwife in the U.S., Ms. Lori Walker, about menstrual cups in general and Femmy Cycle in particular. She stated that menstrual hygiene products aren't a general topic for her patients. However, she was very interested in testing the FemmyCycle with her employees. If the employees favored the FemmyCycle over pads and tampons, she would be willing to recommend it to her patients. She watched an instructional video and was intrigued by the no-spill design and the removal ring that replaced the rigid stem of the standard menstrual cups. The following video will show the difference between the FemmyCycle and the standard menstrual cup: [The difference between the Femmycycle and the standard menstrual cup](#).

We interviewed a Swedish Midwife, Birgit Linderöth, who stated that young girls receive sex education from age 9-10 years, which includes menses and menstrual hygiene. Midwives in Sweden spend time educating women during their prenatal visits. Ms. Birgit Linderöth carries the FemmyCycle in her clinic and promotes it online at: <https://www.gronabarnmorskan.se/produkt/femmycycle-menskopp-normal>. She also lectures frequently on menstrual cups. She participated in the acceptability study of the FemmyCycle upon its European approval.

Even though the FemmyCycle was invented and developed in the United States, European are much faster in adopting new technology. In Switzerland, the FemmyCycle is available over the counter and promoted online at: www.ladyplanet.ch/de/infos-zu-menstruationstassen. Technical analysis of the features of menstrual cups was the basis of the research and development of the FemmyCycle menstrual cup [12].

FemmyCycle Sizes

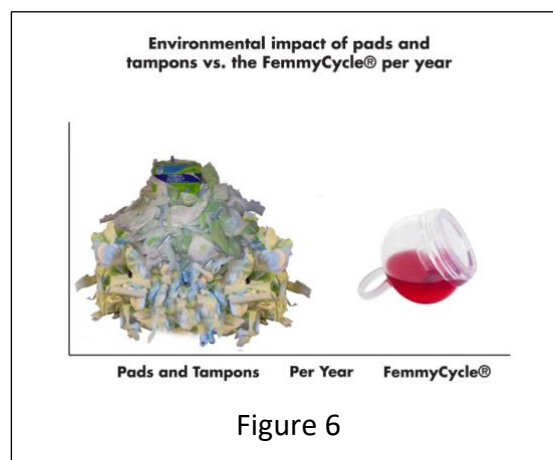
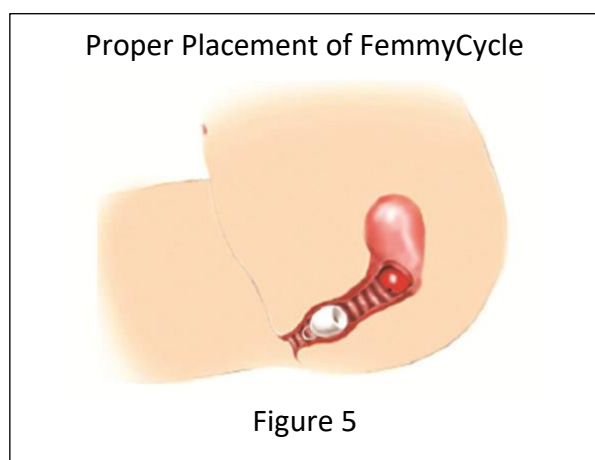
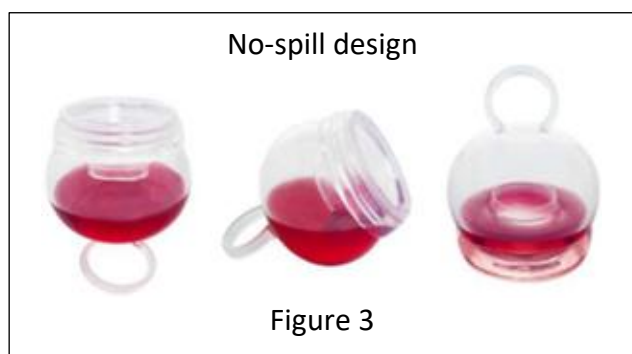


Figure 1

How to Empty FemmyCycle



Figure 2



The following table and the photos of the FemmyCycle and traditional menstrual cups demonstrate the difference between the conventional menstrual cups and the FemmyCycle

Table 1: Comparison of The Traditional Menstrual Cups and the FemmyCycle

	FemmyCycle	Traditional menstrual Cups
Sizing	Three sizes are available and correlated to the anatomical changes that occur during pregnancy and delivery, such as the descent of the of the cervix and decreased tone of the vagina	Two sizes usually based on age, small for women younger than 30; and large for women older than 30. This disregards the changes that occur during pregnancy and delivery
Leakage	Patented unique no-spill design that allow fluid inside the cup and prevent it from spilling outside	Spill can occur, sometimes frequently; particularly in active women and during removal
Removal	Easy removal: insert one finger into the vagina and hook the finger into the removable ring and pull it out	Difficult to find the stem and more difficult if the stem is removed, always messy
Comfort	Cannot be felt at all, women won't even know it is there. It is so soft and flexible that it conforms to the vagina.	The stems can be rigid and poke the labia. The rim is frequently rigid which could press against the urethra causing more discomfort, and difficulty during urination.
Material	Pure Medical Grade Silicone	Various materials, and frequently dyed with colors that serve no purpose and may be irritating
Shape	A rounder flask shaped	Cone-shaped with the narrowest part pointing downwards which make it susceptible to expulsion
Involuntary Expulsion	The unique design prevents the cup from being expelled	The cup could be expelled with coughing or sneezing

Description of the FemmyCycl

The FemmyCycle is wineglass-shaped and is made of compressible, medical-grade silicone. The device has a unique funnel lid that directs the blood into the receptacle and prevents it from spilling out during removal. The no-spill design (Figures 2 & 3) incorporates a lid for containing fluid when closed and pouring fluid out quickly and without a mess when opened.

The FemmyCycle menstrual cup comes in three sizes to adapt to most women's anatomy and physiology, that change by pregnancy and delivery.

The Teen Size (Figure 1) is 10% smaller in length and diameter than the regular size to accommodate young menstruating girls and users with a more petite body build.

The Regular Size (Figure 1) would be most suitable for adult women with an average or longer-than-average distance between the vaginal opening and the cervix. The Regular Size FemmyCycle is 5 cm long and has a diameter of 4.5 cm. The FemmyCycle can collect and hold one ounce of menstrual flow and can be reused for up to two years. The device has a flexible ring that makes removal easy with a single finger. The device also has resilience and memory that restores the cup to its original shape no matter how many times it has been compressed. The Low-Cervix (Figure 1) Model would be suitable for women who delivered vaginally and whose cervixes have descended into the vaginal canal. Users of the Low-Cervix cup have a distance between the vaginal opening and the cervix that is shorter than average but not less than 2 inches.

Cleaning the Device

Medical-grade silicone can be easily cleaned with mild soap and water.

Usage

To collect the menstrual fluid properly, the FemmyCycle should be placed below the cervix into the lower part of the vagina (Figure 5). The device's Safety and the Silicone's Biocompatibility with the vaginal tissues were evaluated before the FDA approved the FemmyCycle [11].

Enhanced illustrated written instructions are provided with the device, and several videos are available online.

Since the FemmyCycle device is sold over the counter, detailed, well-illustrated, written step-by-step instruction is provided with each device. The instructions explain the dynamics of the cervix and the vagina. The written and video instructions explain to women that the axis of the cervix is rarely in a straight line with the vagina, and most frequently, the cervix is tilted in any direction. The cervix may be tilted forward, the uterus tilted backward (also known as a retroverted uterus), the cervix may be tilted backward, and the uterus forward (known as an anteverted uterus), or the cervix may be tilted sideways. The cervix moves upwards during ovulation and downwards during menstruation. For a good collection of menstrual fluid, the menstrual cup must be placed below the cervix (Figure 5). Women are informed that they should never use a menstrual cup if they have any stage of

cervical and uterine prolapse or if the distance between the vaginal opening and the cervix is less than 2 inches during menstruation. It can collect and hold one ounce of menstrual flow and can be reused for up to two years. The device has a removal ring that facilitates removal by a single finger.

Results

We collected and analyzed 833 independent reviews on Amazon from women with prior experience using conventional menstrual cups [12]. Of these women, 716 out of the 833 (86%) preferred the FemmyCycle. The main reasons for the positive feedback are the lack of leakage and the ease of removal with the soft ring. Seven hundred and sixty-six women (766) out of the 833 women (92%) reported they were comfortable wearing the FemmyCycle compared to the discomfort of the stem poking them and the rigid rim pressing on the urethra of the typical menstrual cups. European Nurse-Midwives prefer the FemmyCycle over the standard menstrual cups because they can be used continuously for 12 hours without leaking and remains comfortable.

Discussion

Our main objective is to end period stigma and publicize that menstruation is normal and nothing to be ashamed of. Menstrual cups are generally much safer than tampons [13]. The standard menstrual cup comes in two or three sizes based on age: a small size before 30 and a large size for women over 30. This is an arbitrary way to determine the sizing and has no basis in anatomy. The FemmyCycle menstrual cup is designed based on the anatomy and physiology of the vagina and the level of the cervix rather than age. The FemmyCycle comes in 3 sizes: Regular, Low Cervix, and Petite, to accommodate the changes that can occur during pregnancy. FemmyCycle has a wine glass-shaped design, where the widest diameter is towards the opening of the vagina to eliminate involuntary expulsion. The cone shape of the standard cup is also pointed towards the vaginal opening but at the narrowest part and can cause displacement if the woman coughs or sneezes.

Removal of the FemmyCycle is effortless: the user inserts a finger into the vagina, hooks her finger into the removal ring, and pulls it out. This is in stark contrast when the user of the standard menstrual cup tries to find the rigid stem if it is not removed. The removal of standard menstrual cups can be very awkward and messy, particularly if the stem is removed. Our second objective is to raise awareness about women's basic unmet needs and end the stigma and misconception of menstruation [10, 12]. Despite the leakage and other side effects of traditional menstrual cups, women prefer menstrual cups over pads and tampons. The lack of innovation in menstrual hygiene products and disregard for woman's essential needs inspired the invention of the FemmyCycle. We studied and analyzed 833 independent reviews from Amazon to learn what women need. That study showed that women need a leak-free, easy-to-use menstrual cup that protects them for at least 8-12 hours. Nurses, teachers, athletes, and military personnel greatly need such a device.

Conclusion

The stigma of menstruation is still present in the twenty-first century. Menstrual hygiene education needs to be improved and

implemented for young schoolgirls, particularly in the U.S. and developing countries.

Menstrual hygiene products are urgently needed, particularly for low-income women and women in developing countries, to eliminate period poverty. The introduction of the FemmyCycle is a step in the right direction. A robust educational program for young girls is needed. The continued development of modern menstrual hygiene products should follow.

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