

MyFlowCup: A Novel Anatomically Adaptive Menstrual Cup Designed to Address Unmet Needs in Menstrual Hygiene

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ABSTRACT

Introduction: More than two billion women menstruate each month, yet many continue to lack access to adequate menstrual hygiene products. In many low-resource settings, women still rely on improvised materials such as leaves or rags. Menstrual cups have become increasingly accepted as a reusable alternative to disposable menstrual products. Despite increasing adoption, the basic cone-shaped menstrual cup design has remained largely unchanged since its introduction nearly a century ago. This presents an opportunity to improve user comfort, ease of use, anatomical fit, and prevention of leakage.

Objective: To develop and preliminarily evaluate a reusable, safe, easy-to-use, cost-effective, and environmentally sustainable menstrual cup designed to overcome the limitations of conventional pads, tampons, and traditional cone-shaped menstrual cups.

Methods: Existing menstrual hygiene products, including sanitary pads, tampons, and conventional cone-shaped menstrual cups, were evaluated to identify design limitations and common user concerns. We designed and manufactured multiple prototypes to improve ergonomics, simplify insertion and removal, reduce leakage, and provide reliable protection for up to 12 hours.

The final design incorporates features that allow the cup to rotate and adapt to normal anatomical variations, including uterine retroversion. We developed multiple sizes to accommodate women with varying cervical heights, including those with a low cervix. Volunteer participants evaluated the final prototype to assess ease of use, comfort, and leakage.

Results: Volunteer participants reported that folding, insertion, and removal of the device were easier after a brief learning period. No participant reported nighttime leakage. The only evidence of minimal leakage occurred during insertion or removal. Overall, participants described the device as comfortable and satisfactory in routine use.

Conclusion: The MyFlowCup is a novel menstrual cup designed to address several limitations of conventional menstrual products. Preliminary user evaluation suggests that it may improve comfort, ease of use, and protection against leakage while providing a reusable and cost-effective option for menstrual management.

KEYWORDS

Menstrual cup, Menstrual hygiene management, Reusable menstrual products, Sustainable menstrual health, Women's health.

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Introduction

Menstrual health is recognized as a fundamental component of sexual and reproductive health and is closely linked to human rights, gender equality, education, and economic participation. More than two billion women menstruate worldwide, yet an estimated 500 million women and girls lack access to adequate menstrual products, sanitation facilities, or menstrual hygiene education. According to the WHO, millions of women and girls continue to experience period poverty, limiting their health, education, dignity, and social participation [1,2].

Despite menstruation affecting half of the global population, innovation in menstrual care has progressed relatively slowly compared with many other areas of healthcare. Research and product development have historically been underfunded and overlooked, owing in part to longstanding cultural stigma surrounding menstruation and the marginalization of women's health [3]. As a result, many menstrual products remain expensive, while disposable menstrual products generate substantial environmental waste because billions of contaminated pads and tampons are discarded each year [4-6].

In addition to their environmental impact, disposable menstrual products may also represent a source of chemical exposure to women. Disposable menstrual products may expose users to chemicals that come into contact with the highly permeable vulvar and vaginal tissues. A recent systematic review identified endocrine-disrupting chemicals, including phthalates, volatile organic compounds, parabens, environmental phenols, fragrance chemicals, dioxins, and dioxin-like compounds, in commercially available pads and tampons. The authors concluded that these products contained measurable levels of chemicals that may represent an important route of exposure through the highly permeable vaginal and vulvar tissues, with potential implications for reproductive health [5].

Tampons have also been associated with the rare occurrence of Toxic Shock Syndrome, a potentially life-threatening condition caused by toxin-producing strains of *Staphylococcus aureus* or *Streptococcus pyogenes* [7]. Although uncommon, this risk has contributed to continued interest in safe, reusable alternatives for menstrual management [10].

Reusable menstrual cups represent one of the most promising advances in menstrual health [6]. Constructed from medical-grade silicone, they can safely provide up to 8 to 12 hours of protection and be reused for several years with appropriate care, substantially reducing both menstrual-related costs and the environmental waste generated by disposable contaminated menstrual products. Systematic reviews have demonstrated that menstrual cups are safe, effective, and associated with high levels of user satisfaction following an initial learning period [6,8,9].

However, despite these advantages, widespread adoption remains limited. Many of these challenges are related to variation in pelvic anatomy, cervical position, uterine orientation, and the rigidity and geometry of existing cup designs, highlighting the need for design innovations that better accommodate individual anatomical differences [6,12]. These usability barriers contribute to discontinuation and have limited the broader public health impact of menstrual cup technology [6,8,9].

The MyFlowCup was developed to address these limitations through a user-centered design intended to improve ease of insertion, positioning, removal, comfort, and leak prevention while preserving the established safety and sustainability benefits of reusable menstrual cups. This report describes the design rationale, key design features, and preliminary evaluation of the MyFlowCup, and discusses its potential to reduce barriers to menstrual cup adoption and improve access to sustainable menstrual care.

Materials

The MyFlowCup is manufactured from 100% medical-grade silicone, a biocompatible material widely used in reusable menstrual cups because of its flexibility, durability, chemical stability, and established safety profile.

Design Rationale

Conventional bell-shaped (cone-shaped) menstrual cups have remained largely unchanged since their introduction in the early 1930s, despite advances in materials and manufacturing. Several design characteristics may limit usability, particularly among first-time users. The firm rim, which forms the widest portion of the cup, may be difficult to fold and uncomfortable to insert. After insertion, users are commonly instructed to rotate the cup or insert a finger around the rim to confirm that it has fully opened and formed an adequate seal. In some users, the firm rim may exert pressure on the urethra, contributing to urinary discomfort or difficulty voiding. The narrow removal stem may also be difficult to locate and grasp, which may cause discomfort when contacting the vulva. Some manufacturers recommend trimming the stem to improve comfort; however, this may make removal more difficult.

These limitations highlighted opportunities to improve the ergonomic design of reusable menstrual cups while maintaining their established safety, effectiveness, and sustainability.

The principal design innovations of the MyFlowCup include an anatomically contoured body, a flexible rim, accommodation of variations in cervical height and uterine orientation, and a retrieval loop that replaces the conventional stem to facilitate removal. Collectively, these features were developed to improve ease of use while maintaining the established safety and sustainability advantages of reusable menstrual cups.



Prototypes

The pilot study of the MyFlowCup was developed to address the limitations of conventional menstrual cups through a user-centered design focused on improving ease of folding, insertion, positioning, removal, comfort, and leak prevention.

Multiple prototypes were designed, manufactured, and repeatedly refined to optimize ergonomics, anatomical fit, flexibility, and overall usability while preserving the established advantages of reusable menstrual cups.

The final design incorporates several novel features intended to facilitate insertion, improve positioning within the vagina, accommodate variation in cervical height and uterine orientation, and minimize leakage during routine use. The device was designed to provide reliable menstrual protection for up to 12 hours before removal, cleaning, and reinsertion. A flexible retrieval loop replaced the conventional removal stem to facilitate one-finger removal and improve user comfort. After repeated refinement, the final prototype was designated the MyFlowCup.



One Finger Removal

Clinical Evaluation of the MyFlowCup Menstrual Cup: A Pilot Feasibility Study

Introduction

Conventional cone-shaped menstrual cups have remained largely unchanged since their introduction in the early 1930s and may present challenges related to folding, insertion, positioning, removal, comfort, and leakage. The MyFlowCup was developed to

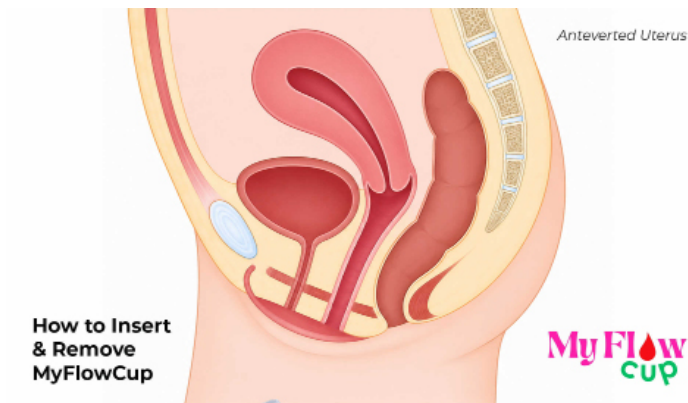
address these limitations through a user-centered design approach intended to improve usability while preserving the established safety and sustainability benefits of reusable menstrual cups.

The purpose of this clinical evaluation was to assess the safety, comfort, ease of insertion and removal, leakage performance, and overall functionality of the final MyFlowCup prototype during routine menstrual use.

Objectives

The primary objective of this study is to evaluate the final MyFlowCup prototype for the following:

- A) To evaluate the safety and comfort of the MyFlowCup compared with conventional cone-shaped menstrual cups.
- B) To evaluate the ease of folding, insertion, and removal.
- C) To evaluate leakage during routine menstrual use.
- D) To evaluate the overall functionality, performance, and user satisfaction of the final MyFlowCup prototype



Methods

Women who met the inclusion criteria were informed about the study and provided written informed consent before participation. Each participant used the final MyFlowCup prototype during one complete menstrual cycle (5 to 7 days).

Participants were instructed to clean the MyFlowCup with water and unscented liquid soap between uses. Participants were asked to compare their experience using the MyFlowCup with their usual menstrual products, including sanitary pads, tampons, or conventional cone-shaped menstrual cups.

The MyFlowCup was evaluated for safety, effectiveness, comfort, ease of use, and leakage performance. This pilot feasibility study enrolled 12 volunteer participants, of whom 10 completed the evaluation of the MyFlowCup during one complete menstrual cycle.

Principal Investigators

- Dr. Alfred Shihata
- Alyssa Domingo, BSN, RN

Subject Selection

Inclusion Criteria

- Women aged 18 to 45 years.
- Women who experience regular menstrual cycles.

Exclusion Criteria

- Women with very light menstrual flow.
- Women using hormonal contraceptives or hormonal intrauterine devices (IUDs).

Outcome Measures

Participants completed a standardized case record form documenting:

- Ease of folding, insertion, positioning, and removal.
- Comfort during use.
- Leakage during use, if any.
- Duration of wear before emptying the cup.
- Overall satisfaction with the MyFlowCup.

Study Procedures

Enrollment Visit

- Participants received an explanation of the study objectives, procedures, and potential risks.
- Written informed consent was obtained before participation.
- Participants received instructions regarding proper insertion, removal, cleaning, and care of the MyFlowCup.

Follow-up Visit

- Participants returned their completed case record forms.
- Investigators interviewed participant experiences and documented any adverse events or concerns.
- Participants compared their experience using the MyFlowCup with their usual menstrual management method.

Risk Analysis

No significant risks beyond those associated with routine menstrual cup use were anticipated. Participants were instructed to report any discomfort, adverse events, or unexpected symptoms during the study period. A monitoring system was established to track any adverse events occurring during the evaluation period. Participants could withdraw from the study at any time without penalty.

Confidentiality

Participant confidentiality was maintained throughout the study. Each participant was assigned a study identification number, and all study records were stored securely. Only the principal investigators had access to identifiable participant information.

Primary Endpoints

The study evaluated:

- Safety, defined as the absence of serious adverse events related to use of the MyFlowCup.
- Effectiveness, defined as comfortable wear for up to 8–12 hours with minimal or no leakage.
- Comfort during routine daily activities.
- Ease of folding, insertion, positioning, and removal.
- Overall participant satisfaction

Study Findings

Ten participants completed the evaluation of the final MyFlowCup prototype. Participants ranged in age from 22 to 42 years and evaluated the device during one complete menstrual cycle.

Ease of insertion, ease of removal, and leakage were evaluated

using participant-reported numerical rating scales. For insertion and removal, scores ranged from 1 (very easy) to 10 (very difficult). Leakage during use was assessed using a scale ranging from 0 (no leakage) to 10 (severe leakage), excluding any spillage during insertion and removal.

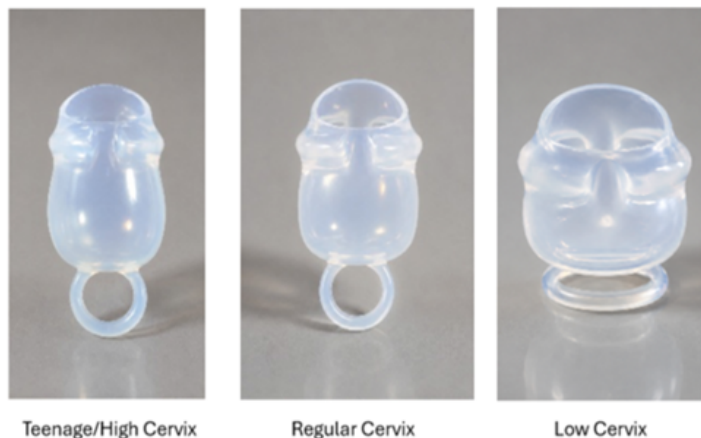


Table 1: Participant-Reported Usability Outcomes Following MyFlowCup Evaluation.

Outcome Measure	Rating Scale	Results
Ease of insertion	1 = easy; 10 = difficult	All participants rated insertion difficulty as 1/10
Ease of removal	1 = easy; 10 = difficult	All participants rated insertion difficulty as 1/10
Leakage during use	0 = no leakage; 10 = severe leakage	All participants rated leakage as 0/10

As shown in Table 1, all participants reported minimal difficulty with insertion and removal, with both measures receiving a score of 1/10. All participants reported no leakage during routine use, with leakage scores rated as 0/10.

Following a brief familiarization period, all participants successfully used the MyFlowCup without requiring additional assistance. No participants reported leakage during overnight use. No serious adverse events, significant discomfort, or safety concerns were reported during the evaluation period.

Participants reported high overall satisfaction with the device. The flexible retrieval loop was consistently identified as a beneficial feature, with participants reporting improved ease of removal and one-finger retrieval compared with traditional stem-based menstrual cup designs. Participants also reported favorable experiences related to comfort, positioning, overall usability, absence of typical menstrual odor, and ease of cleaning and maintenance of the MyFlowCup.

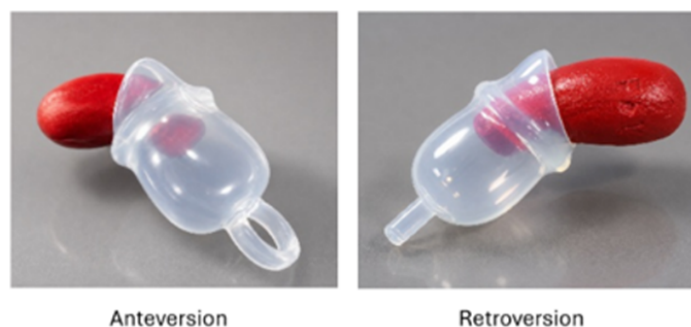
These preliminary findings demonstrate favorable user acceptability and the feasibility of the MyFlowCup prototype. The quantitative

and qualitative feedback collected during this evaluation will guide further refinement and support future clinical studies evaluating safety, effectiveness, anatomical compatibility, and long-term performance. Comparison between the Cone-Shaped Menstrual Cup and the MyFlowCup.

Discussion

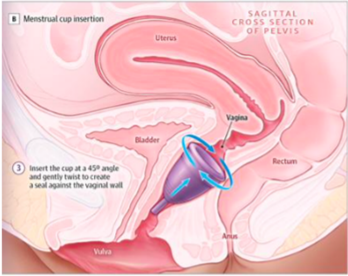
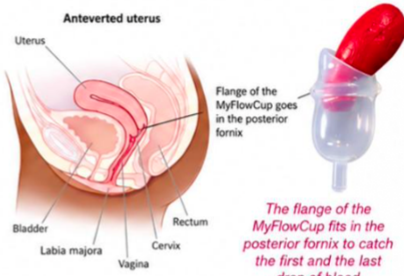
The primary objective of this project was to develop a reusable menstrual cup that improves ease of folding, insertion, positioning, removal, comfort, and leak prevention while maintaining the established safety and environmental advantages of reusable menstrual products. The preliminary evaluation demonstrated that these objectives were largely achieved. Participants reported that the MyFlowCup became easy to use after a brief learning period, with high overall satisfaction and minimal leakage.

Unlike conventional cone-shaped menstrual cups, the MyFlowCup was developed using an anatomically oriented, user-centered design approach. Current menstrual cups are generally symmetrical and designed to function similarly despite significant anatomical variation among users. However, uterine orientation and cervical position vary considerably among women. Approximately 75% to 80% of women have an anteverted uterus, whereas 20% to 25% have a retroverted uterus [12]. These anatomical differences may influence menstrual cup positioning, comfort, fluid collection, and the potential for leakage.



The MyFlowCup was specifically designed to accommodate these anatomical variations. The flexible flange-like rim and contoured geometry allow the device to conform more naturally to the orientation of the cervix and uterine tilt, with the goal of improving menstrual fluid capture throughout the menstrual cycle. The rim is designed to maintain contact with the vaginal anatomy to collect menstrual flow from the beginning to the end of menstruation, including the first and final drops of menstrual fluid, while reducing the likelihood of leakage caused by improper positioning.

An additional innovation is the replacement of the conventional removal stem with a flexible retrieval loop. Participants reported that this feature facilitated one-finger removal and improved comfort compared with traditional stem-based menstrual cup designs.

Feature	Traditional Cone-Shaped Cup For nearly a century, menstrual cups have followed the same bell-shaped design   The rim of a traditional menstrual cup presses on the urethra, causing difficulty with urination.	MyFlowCup – Designed for Anatomy  Anteversion Retroversion <i>MyFlowCup Displayed on a Model of the Uterus</i>  The flange of the MyFlowCup fits in the posterior fornix to catch the first and the last drop of blood
Design Philosophy	One generic shape for all women. Currently available cups do not consider the anatomical changes of the cervix and vagina. The cone-shaped menstrual cup design is identical to the one invented a century ago.	Designed by a physician and based on real anatomical variation, the MyFlowCup represents a new evolution in menstrual care hygiene. Engineered for fit, comfort, and performance. Accounts for Retroversion and Anteversion of the uterus, low and high cervix, and differences between nulliparous and multiparous women. Women's anatomy isn't one-size-fits-all.
Anatomical Fit	Does not follow the natural orientation of the cervix and vaginal canal.	Engineered to align with natural cervical positioning (anteverted, retroverted, low or high cervix).
Folding and Insertion	It is difficult to fold and difficult to insert  C-Fold S-Fold	The rimless design makes it smooth, easy to fold, and insert. 
Leak Prevention	It is harder to fold and to insert the widest part first. The blood dripping from the uterus will first hit the vaginal walls before the menstrual cup can catch it. This causes leakage during use. Menstrual Cup Leaking: 10 Reasons & 12 Tips to Fix It	The flange of the MyFlowCup fits in the posterior fornix to catch the first and last drop of blood. A wider base helps maintain position. Both contribute to minimizing leakage.
Comfort	The firm rim may cause discomfort due to pressure on sensitive areas.	Rimless, streamlined profile for improved comfort and easier insertion.
Removal Experience	Rigid stem that may be hard to locate. Often trimmed off, making it more difficult to remove. Usually needs two to three fingers for removal instead of just one. 	Expandable ergonomic loop. Easy to locate and remove with one finger. 
Materials	Often colored with added dyes.	Transparent material. Promotes visible cleanliness. No unnecessary dyes.
Sizing Options	Typically 2 basic sizes. Based on age or the amount of bleeding.	4 anatomically guided sizes. Designed for teenagers who have never been pregnant and adult women who have given birth vaginally.
Innovation	Traditional cone-shaped or bell-shaped designs are the same as the ones invented nearly 100 years.	Patent-pending physician innovation. A new evolution in menstrual cup design.



The photographs presented in this study intentionally preserve the natural appearance and color of menstrual blood without digital alteration. This approach reflects normal menstrual physiology and provides transparent documentation of the device's intended function in real-world use.

Although this preliminary evaluation included a limited number of participants, the findings support the feasibility of the MyFlowCup design and provide justification for larger clinical studies. Future investigations should evaluate safety, effectiveness, user satisfaction, anatomical compatibility, and long-term performance across a more diverse population.

Limitations

This preliminary evaluation has several limitations. The sample size was small, and participants were evaluated during only one menstrual cycle. Participants served as their own comparison group by evaluating their prior experiences with their usual menstrual products in comparison with their experience using the MyFlowCup. However, this evaluation was not designed as a randomized controlled study, and outcomes were based primarily on participant-reported assessments.

Larger, longer-term comparative clinical studies are warranted to further evaluate the safety, effectiveness, anatomical compatibility, durability, and user satisfaction of the MyFlowCup across a broader and more diverse population.

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