

Biopolymer-Based Cervical Cups: Current Formulation Approaches and Future Directions

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Abstract— Biodegradable cervical cups represent a significant advancement in menstrual hygiene technology, combining the reusability of conventional silicone cups with the eco-friendly disposal of biopolymeric materials. Traditional menstrual cups, though durable, contribute to long-term biomedical waste due to their non-biodegradable nature. In response, researchers have developed alternatives using sustainable polymers such as polylactic acid (PLA), polyhydroxyalkanoates (PHA), and natural fibers like bamboo, banana, chitosan, and alginate. These materials are biocompatible, hypoallergenic, and capable of decomposing into harmless by-products, thereby reducing environmental burden. The formulation of biodegradable cervical cups requires balancing critical properties including biocompatibility, flexibility, durability, controlled biodegradation, mechanical strength, shelf stability, and regulatory compliance. While promising, challenges remain in achieving mechanical performance comparable to silicone, maintaining shelf stability in humid climates, and overcoming high manufacturing costs. Regulatory hurdles and cultural acceptance also slow mainstream adoption. Future innovations focus on refining composite blends, advancing green chemistry, and scaling microbial fermentation to reduce costs and improve accessibility. Awareness campaigns and certification processes are equally vital to ensure user confidence and global acceptance. Overall, biodegradable cervical cups exemplify the intersection of women's health empowerment and environmental sustainability, offering a pathway toward responsible healthcare technologies and reduced menstrual waste.

Index Terms— Biodegradable Cervical Cups, Menstrual Cup, Safety, Effectiveness, Hygiene.

I. INTRODUCTION

The cervical cup, commonly known as a menstrual cup, is a reusable device designed to collect menstrual fluid. Traditional menstrual cups are made from medical-grade silicone or rubber, which are durable but not biodegradable [01]. With growing concerns about environmental sustainability and biomedical waste, researchers and innovators have begun exploring biodegradable alternatives [02]. These eco-friendly cervical cups aim to reduce long-term waste accumulation while maintaining safety and effectiveness for users [03].

A biodegradable cervical cup is manufactured using natural polymers or plant-based materials that can safely break down in the environment after disposal [04]. Unlike conventional cups that may persist for decades, biodegradable versions decompose into harmless by-products such as water, carbon dioxide, and organic matter [05]. This innovation aligns with global efforts to minimize plastic pollution and promote sustainable menstrual hygiene practices [06]. The primary advantage of biodegradable cervical cups lies in their dual benefit: they are reusable during their functional lifespan, and once discarded, they do not contribute to long-term environmental waste [07]. They also support women's health by offering a non-toxic, hypoallergenic option. Additionally, their eco-friendly nature makes them particularly suitable for regions where waste management systems are limited, ensuring that menstrual hygiene products do not burden the environment [08].

The introduction of biodegradable cervical cups represents a significant step toward sustainable healthcare solutions. Ongoing research focuses on improving material strength, flexibility, and safety to

match or surpass conventional silicone cups [09]. As awareness grows, biodegradable menstrual products could become mainstream, contributing to both women's health empowerment and environmental conservation. This innovation reflects the broader movement toward green healthcare technologies and responsible consumer choices [10].

II. SUSTAINABLE MATERIALS FOR BIODEGRADABLE CERVICAL CUPS

Biodegradable cervical cups are designed using innovative eco-friendly polymers that balance safety, flexibility, and environmental responsibility. Polylactic Acid (PLA), derived from renewable sources like corn starch or sugarcane, is one of the most promising materials [16]. It is biocompatible, meaning it does not irritate or harm cervical tissue, and it naturally breaks down into lactic acid, which is

harmless to the environment. Similarly, Polyhydroxyalkanoates (PHA), produced through microbial fermentation of sugars and lipids, offer strong mechanical properties and biodegradability, making them suitable for biomedical applications where durability and safety are essential [17].

In addition to synthetic biopolymers, researchers are exploring natural plant fibers such as bamboo and banana fiber, which provide comfort and biodegradability. These fibers, along with modified natural polymers like chitosan (from shellfish) and alginate (from seaweed), can be engineered to enhance elasticity, antimicrobial properties, and durability. Together, these materials ensure that biodegradable cervical cups remain functional during their lifespan but safely decompose after disposal, offering a sustainable alternative to conventional silicone cups while supporting women's health and environmental conservation [18].

Table no 01-Variou material used for the manufacturing of Biodegradable cervical cups [15-20]

Material	Source	Biodegradability	Strength & Flexibility	Medical Safety
PLA	Corn starch, sugarcane	High	Moderate flexibility	Biocompatible
PHA	Microbial fermentation	High (soil & water)	Strong, elastic	Biocompatible
Bamboo fiber	Plant cellulose	High	Moderate	Hypoallergenic
Banana fiber	Plant cellulose	High	Moderate	Hypoallergenic
Chitosan	Shellfish waste	High	Good flexibility	Antimicrobial
Alginate	Seaweed	High	Moderate	Biocompatible

III. SCIENTIFIC DETERMINANTS OF BIODEGRADABLE CERVICAL CUP PERFORMANCE

For biodegradable cervical cups, the choice of material is guided by several essential properties. Biocompatibility is the foremost requirement, ensuring that the cup does not cause irritation, allergies, or toxicity when in contact with cervical tissue [19]. Alongside this, flexibility and elasticity are critical so the cup can be easily inserted and removed while maintaining its shape to collect menstrual fluid effectively. These properties guarantee both safety and comfort for the user, which are non-negotiable in medical-grade products [20].

Equally important are durability during use and controlled biodegradation. The material must withstand repeated sterilization cycles such as boiling or autoclaving without losing integrity, since menstrual cups are reused for several years [21]. At the

same time, once the product reaches the end of its lifespan, it should degrade safely into harmless by-products without leaving persistent waste. This balance between long-term usability and eco-friendly disposal is what makes biodegradable cervical cups a promising innovation in sustainable menstrual hygiene [22].

IV. PROSPECTIVE INNOVATIONS IN BIODEGRADABLE CERVICAL CUP TECHNOLOGY

The future development of biodegradable cervical cups is centered on advancing material science and scaling sustainable menstrual hygiene solutions. Researchers are working to refine biopolymers like PLA and PHA to achieve the perfect balance between durability during use and rapid biodegradation after disposal. Composite blends of natural fibers and modified polymers are being tested to enhance

elasticity, antimicrobial properties, and comfort, ensuring that these cups meet medical safety standards while remaining eco-friendly [23].

Another key area of development is manufacturing technology and affordability. Current biodegradable materials can be expensive to process, limiting accessibility. Future innovations aim to reduce production costs through green chemistry techniques, microbial fermentation, and large-scale biopolymer synthesis [24]. This will make biodegradable cervical cups more affordable and widely available, especially in regions where menstrual hygiene products are scarce or waste management systems are weak [25].

Finally, the outlook includes regulatory approval, awareness campaigns, and global adoption for biodegradable cervical cups to become mainstream, they must pass rigorous safety and quality certifications while also gaining acceptance among users through education and advocacy [26]. As sustainability becomes a global priority, these cups could represent a new standard in menstrual hygiene empowering women with safe, reusable products while significantly reducing environmental impact [27].

Table no 02- Future Development of Biodegradable Cervical Cups [20-24]

Development Area	Focus	Expected Outcome
Material Innovation	Refining PLA, PHA, and composite blends with natural fibers	Enhanced elasticity, antimicrobial safety, and eco-friendly biodegradability
Manufacturing & Affordability	Green chemistry, microbial fermentation, scalable biopolymer synthesis	Lower production costs, increased accessibility in underserved regions
Regulatory & Social Adoption	Safety certifications, awareness campaigns, global menstrual health advocacy	Mainstream acceptance, improved sustainability, empowerment through reusable hygiene

V. CORE SCIENTIFIC CONSIDERATIONS IN CERVICAL CUP FORMULATION

1. Biocompatibility-

Biocompatibility is the most critical factor in cervical cup formulation. The material must be safe for intimate contact, non-toxic, hypoallergenic, and free from harmful leachable. Since the cup comes into direct contact with sensitive cervical tissue, any irritation or chemical reaction could lead to discomfort or infection [25]. Therefore, polymers like PLA, PHA, or natural fibers are chosen for their proven safety in biomedical applications. Beyond safety, biocompatibility also ensures long-term acceptance by users. A cup that does not cause itching, rashes, or allergic responses builds trust and encourages adoption [26]. Regulatory bodies require extensive testing of biocompatibility before approval, making this property the foundation of product development [27].

2. Flexibility & Elasticity-

Flexibility and elasticity are essential for user comfort and functionality. The cup must be soft enough to fold and insert easily, yet elastic enough to spring back and maintain its shape once inside [28]. This balance

ensures proper sealing against the vaginal walls, preventing leakage. Materials like modified biopolymers or blends with natural plasticizers are often used to achieve this property. Elasticity also plays a role in removal [29]. A cup that is too rigid may cause discomfort, while one that is too soft may collapse and spill. Therefore, careful formulation ensures the right mechanical balance, making the cup both practical and comfortable [30].

3. Durability During Use-

Durability ensures that biodegradable cervical cups can withstand repeated sterilization cycles such as boiling or autoclaving. Since menstrual cups are reused for several years, the material must resist degradation from heat, moisture, and mechanical stress [31]. PLA and PHA composites are often tested for their ability to retain strength after multiple sterilizations. Durability also extends to daily use. The cup must not tear, deform, or lose elasticity during insertion, removal, or prolonged wear. A durable formulation guarantees reliability, reducing the risk of product failure and ensuring user confidence [32].

4. Controlled Biodegradation-

Controlled biodegradation is a unique challenge for biodegradable cups. The material must remain stable

during its usable lifespan but degrade safely after disposal. This requires precise control of polymer crystallinity, moisture sensitivity, and microbial breakdown rates. Stabilizers or coatings may be added to delay degradation until the product is discarded. This property ensures environmental sustainability without compromising usability [33]. A cup that degrades too early would fail during use, while one that resists breakdown would defeat the purpose of being biodegradable. Controlled biodegradation balances functionality with eco-friendliness [34].

5. Mechanical Strength-

Mechanical strength is vital to prevent tearing or deformation. The cup must withstand pressure from vaginal muscles and securely hold menstrual fluid without collapsing. Tensile strength testing is performed to ensure the material can resist stress during folding, insertion, and removal. Strong yet flexible materials like PHA blends or reinforced natural fibers are often used to achieve this property [35]. Mechanical strength ensures that the cup remains reliable, preventing leakage and maintaining its structural integrity throughout its lifespan.

6. Shelf Stability-

Shelf stability ensures that biodegradable cervical cups remain intact during storage and distribution. The material must resist premature degradation caused by humidity, temperature fluctuations, or microbial exposure [36]. Packaging plays a crucial role in maintaining shelf stability by providing a protective barrier. A stable shelf life guarantees that the product reaches users in optimal condition. Without this property, cups might degrade before use, leading to waste and reduced consumer trust [37]. Proper formulation and packaging extend usability while preserving biodegradability [38].

7. Regulatory Compliance-

Regulatory compliance ensures that biodegradable cervical cups meet international medical device standards such as ISO, FDA, and CDSCO [39]. These certifications require rigorous testing of biocompatibility, durability, and safety. Compliance builds credibility and allows products to enter global markets. Beyond safety, regulatory approval also drives user confidence. Consumers are more likely to adopt biodegradable cups when they are backed by

recognized certifications [40]. Thus, compliance is not just a legal requirement but also a pathway to mainstream acceptance and success [41].

VI. MULTIDIMENSIONAL CHALLENGES IN BIODEGRADABLE MENSTRUAL DEVICE ENGINEERING

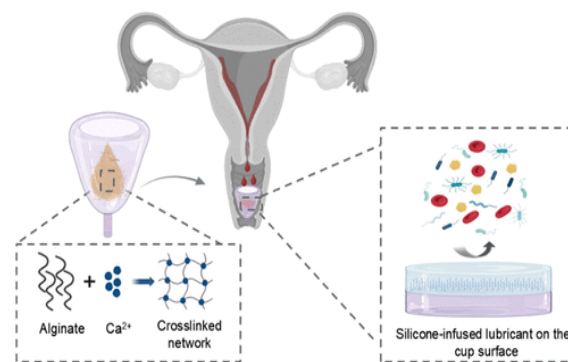


Fig- Challenges in Developing Biodegradable Cervical Cups

1. Material Limitations

Biopolymers such as PLA and PHA are promising for biodegradable cervical cups, but they often lack the mechanical strength and elasticity of medical-grade silicone, making it difficult to achieve the right balance between softness for comfort, elasticity for sealing, and durability for repeated sterilization [42]. Natural fibers or modified biopolymers, while eco-friendly, may degrade too quickly or lose flexibility, which limits their suitability for long-term use. To address these limitations, researchers are actively exploring composite blends such as combining PLA with natural fibers to enhance strength, elasticity, and overall performance while maintaining biodegradability. This ongoing research aims to create materials that are both user-friendly and environmentally sustainable, ensuring that biodegradable cervical cups can function effectively during their lifespan and still break down safely after disposal [43].

2. Controlled Biodegradation vs. Shelf Stability

A major challenge in developing biodegradable cervical cups is achieving controlled biodegradation while maintaining shelf stability [44]. The material must remain stable and functional throughout its usable lifespan yet degrade safely after disposal to fulfil its eco-friendly purpose. If breakdown occurs too

early, the cup loses safety and functionality; if degradation is too slow, the environmental benefit is compromised [45]. This balance is particularly difficult in regions with hot and humid climates, such as India, where premature degradation during storage and distribution is more likely. To address this, researchers are working on controlled degradation mechanisms by adjusting polymer crystallinity, moisture sensitivity, and microbial breakdown rates, while also exploring packaging solutions and stabilizers to extend shelf life without compromising biodegradability [46].

3. Manufacturing, Cost, and Regulatory Barriers-

Biodegradable cervical cups face several interconnected challenges that slow their development and adoption. First, biodegradable polymers are generally more expensive to produce and process than silicone, which makes affordability a major issue, especially in low-resource settings where menstrual hygiene products are already limited [47]. Scaling up

production requires advanced methods such as green chemistry techniques, microbial fermentation, and large-scale biopolymer synthesis, but these processes remain costly and technically demanding [48].

Second, regulatory approval is a significant hurdle, as products must undergo rigorous testing for biocompatibility, durability, and safety to meet international standards like ISO, FDA, and CDSCO. This process is time-consuming and expensive, delaying commercialization [49]. Finally, even if technical and regulatory barriers are overcome, awareness and acceptance among users must be built through education and advocacy [50]. Cultural taboos, lack of familiarity with menstrual cups, and hesitation toward new biodegradable materials can slow adoption. Together, these challenges highlight the need for innovation not only in material science but also in cost reduction, certification pathways, and community-level education to make biodegradable cervical cups a mainstream solution [51].

Table no 03- Challenge, its details & Implication strategies for the overcome Challenge

Challenge	Details	Implication
Material Limitations	Weak elasticity & strength in biopolymers	Difficult to match silicone performance
Biodegradation vs Shelf Stability	Risk of premature breakdown or delayed degradation	Balancing usability with eco-friendliness
Manufacturing & Cost	High production costs, limited scalability	Reduced affordability & accessibility
Regulatory Barriers	Strict ISO/FDA/CDSCO compliance required	Delays commercialization
User Awareness & Acceptance	Cultural taboos, lack of familiarity	Slower adoption in mainstream markets

VII. CRITICAL RISK DIMENSIONS IN BIODEGRADABLE CERVICAL CUP INNOVATION

Material Performance Risk

Biopolymers such as PLA and PHA, while eco-friendly, often fall short of the mechanical strength and elasticity offered by medical-grade silicone, making them prone to tearing, collapsing, or leakage during use; similarly, natural fibers or modified biopolymers tend to degrade too quickly or lose flexibility, limiting their long-term applicability [52]. To address these limitations, ongoing research is exploring composite blends like PLA reinforced with natural fibers that aim to enhance durability and elasticity while preserving sustainability, offering a promising pathway toward

more reliable and environmentally conscious biomedical materials [53].

Premature Biodegradation vs Shelf Stability

Balancing stability during use with safe degradation after disposal is a major challenge for biopolymeric medical materials, since premature breakdown compromises safety and functionality, while overly slow degradation undermines environmental benefits [54]. This balance becomes even more complex in hot and humid climates like India, where shelf stability is difficult to maintain, often requiring the addition of stabilizers and protective packaging to prevent early deterioration while still ensuring eventual eco-friendly breakdown [55].

Manufacturing & Cost Risk

Biodegradable polymers face a significant economic barrier compared to silicone, as their production is more expensive, making affordability a challenge in low-resource settings [56]. Large-scale manufacturing demands advanced processes such as microbial fermentation and green chemistry, which, while essential for sustainability, remain costly and technologically intensive, thereby limiting widespread adoption despite their environmental advantages [57].

Regulatory & Safety Risk

Biodegradable medical products must undergo extensive testing for biocompatibility, durability, and safety to comply with stringent regulatory standards such as ISO, FDA, and CDSCO, but this process is both time-consuming and costly, often delaying commercialization. The rigorous evaluations are essential to ensure patient safety and product reliability, yet they add significant financial and temporal burdens that slow down the transition from research to market availability [58].

User Awareness & Acceptance Risk

Cultural taboos surrounding menstruation and the lack of familiarity with menstrual cups often slow their acceptance, and this hesitation is compounded when new biodegradable materials are introduced, as users may be reluctant to trust their safety and reliability [59]. Without proper education, awareness campaigns, and advocacy, skepticism can persist, making it essential to combine product innovation with community outreach to build confidence and encourage adoption [60].

VIII. BIOPOLYMERIC INNOVATIONS FUNCTIONAL GAINS IN CERVICAL CUP DESIGN-

Biocompatibility and Safety

Biodegradable cervical cups are made from biopolymers such as PLA and PHA, which are specifically designed to be biocompatible and safe for vaginal use. Unlike conventional plastics or silicone, these materials are free from synthetic additives, dyes, and endocrine-disrupting chemicals, thereby reducing the risks of irritation, allergic reactions, or hormonal imbalance. Their natural composition ensures that they interact safely with the body's tissues, making them

suitable for women with sensitive skin [61]. This biocompatibility is crucial because menstrual products remain in contact with delicate mucosal tissues for extended periods. By minimizing chemical exposure, biodegradable cups provide a safer alternative that supports long-term reproductive health. Their natural polymer base reassures users that they are not introducing harmful substances into their bodies, which enhances trust and acceptance [62].

Reduced Risk of Toxic Shock and Infections

Traditional tampons can increase the risk of toxic shock syndrome (TSS) due to retained fibers and bacterial growth. Cervical cups, including biodegradable versions, collect menstrual fluid rather than absorbing it, which reduces bacterial colonization and lowers infection risks [63]. Their smooth, non-porous surface also makes cleaning easier, ensuring better hygiene and safer long-term use. This design advantage means that biodegradable cups not only protect against TSS but also reduce the likelihood of recurrent vaginal infections [64]. By offering a safer menstrual management option, they empower women to maintain better intimate health while benefiting from the eco-friendly nature of biodegradable materials [65].

Comfort and Flexibility

Biodegradable cervical cups are engineered to be soft and flexible, adapting to the body's natural contours. This reduces discomfort during insertion and wear, allowing women to move freely without irritation [66]. Their elasticity ensures a secure fit, preventing leakage while maintaining comfort for up to 8–12 hours of continuous use. The flexibility of these cups is particularly important for active lifestyles, as they provide reliable protection during sports, travel, or long working hours. By combining comfort with functionality, biodegradable cups enhance user confidence and encourage wider adoption of sustainable menstrual products [67].

Hormone and Chemical Safety

Many disposable menstrual products contain bleaching agents, fragrances, and plastics that can leach harmful chemicals into the body. Biodegradable cervical cups avoid these risks by using natural, non-toxic polymers, ensuring safer menstrual management without chemical exposure [68]. This reduces the risk

of endocrine disruption and supports healthier reproductive outcomes. Over time, cumulative exposure to toxins from conventional products can affect hormonal balance and overall health. By eliminating these risks, biodegradable cups provide a safer alternative that prioritizes women's well-being. This makes them not only an eco-conscious choice but also a health-conscious one [69].

Holistic Health and Sustainability

By reducing waste and avoiding harmful chemicals, biodegradable cups benefit both the environment and women's health. Women using these products experience fewer irritations and infections, while society benefits from reduced menstrual waste in landfills and incinerators [68]. This dual impact makes biodegradable cervical cups a progressive choice for menstrual hygiene. Holistic health here means addressing both personal and environmental well-being. Biodegradable cups empower women to make choices that protect their bodies while contributing to sustainability goals [69]. This synergy between health and ecology positions them as a forward-looking solution in menstrual care [70].

IX. CONCLUSION

Biodegradable cervical cups stand at the forefront of sustainable menstrual health solutions, addressing both environmental and biomedical concerns. Their development highlights the importance of material innovation, where biopolymers and natural fibers are engineered to balance durability, safety, and eco-friendly disposal. By reducing chemical exposure and minimizing waste, these cups not only safeguard women's health but also contribute to broader ecological conservation goals. Despite their potential, widespread adoption requires overcoming significant barriers in cost, manufacturing scalability, regulatory approval, and cultural acceptance. With continued research, awareness initiatives, and supportive policies, biodegradable cervical cups can evolve into mainstream menstrual products. Their success will symbolize a shift toward green healthcare technologies, empowering women with safe, reusable, and environmentally responsible choices that align with global sustainability priorities.

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