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BVBalance: A Bioresorbable Intravaginal Medical Device for Biofilm Disruption and Prevention of Recurrent Bacterial Vaginosis

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Introduction & Background

Bacterial vaginosis (BV) affects approximately 30% of women of reproductive age worldwide and is characterized by high rates of recurrence, with up to 80% of patients experiencing relapse within one year of treatment. Current therapies, including oral and topical antibiotics, provide only temporary relief and fail to address the underlying causes of recurrence. BV is associated with symptoms such as abnormal discharge and irritation and is linked to increased risk of pelvic inflammatory disease, adverse pregnancy outcomes, and heightened susceptibility to sexually transmitted infections, highlighting a significant unmet need for effective long-term preventative solutions in women's health.

Recurrent BV is driven in part by the formation of *Gardnerella vaginalis* biofilms, which protect pathogenic bacteria from antibiotic treatment and contribute to persistent infection. In addition, disruption of the vaginal microbiome leads to a loss of protective Lactobacillus species, increasing susceptibility to reinfection. These biological factors, combined with the limitations of current treatments, result in repeated infections, patient discomfort, and increased healthcare burden.

There is a critical need for therapeutic strategies that target both biofilm persistence and microbiome imbalance to effectively break the cycle of recurrence and improve long-term patient outcomes.

Mission Statement

Our mission is to develop a novel intravaginal therapy that prevents recurrent bacterial vaginosis by targeting *Gardnerella vaginalis* biofilms and restoring protective Lactobacillus populations. By addressing both bacterial persistence and microbiome imbalance, this approach aims to prolong recurrence intervals and improve long-term patient outcomes.

Final Product Specification

Bioresorption	Fully degrades within **25–30 days** without need for removal
Drug Release Profile	Antimicrobial release for **~10 days**; probiotic release initiated after **~Day 10**
Mechanical Properties	Soft, flexible, and compressible to allow insertion and in situ expansion
Geometry	Auxetic structure enabling **radial expansion** while maintaining structural integrity
Biocompatibility	Materials must be **non-toxic and compatible** with vaginal tissue environment
Delivery Method	Insertable via **tampon-like applicator** with minimal discomfort
Flow Accommodation	Maintains **hollow/porous structure** to allow natural fluid passage
Therapy Compatibility	Functions as an **adjunct to standard antibiotic treatment**
Therapeutic Performance	Achieves **biofilm disruption** and supports **Lactobacillus restoration**

Limitations of Current Treatments

Features \ Key Players	Antibiotics	Boric Acid	Over-the-Counter Probiotics	BVBalance
Targets Biofilm	X	◐	X	✓
Microbiome Restoration	X	X	✓	✓
Symptom Relief	✓	✓	X	✓
Prevents Recurrence	X	X	X	✓

Device Concept & Design

Objective: Disrupt bacterial biofilm and restore vaginal microbiota to prevent BV recurrence for 6–8 months
Auxetic, bioresorbable intravaginal scaffold delivering combination antimicrobial and probiotic therapy as an adjunct to standard metronidazole treatment, deployed using a **barrel-plunger-style applicator** with integrated hydrating lubricant
An **antimicrobial** embedded within a chitosan matrix diffuses into the mucus layer to penetrate and disrupt *Gardnerella vaginalis* biofilm, enhancing antibiotic effectiveness
Encapsulated ***Lactobacillus*** is released to re-establish a healthy vaginal microbiome and maintain physiological pH
A **hyaluronic acid surface layer** provides lubrication, reduces irritation, and improves comfort and retention during insertion

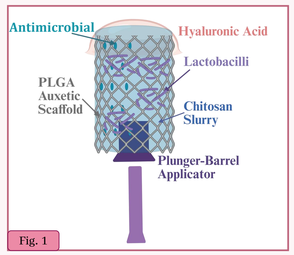

Fig. 1

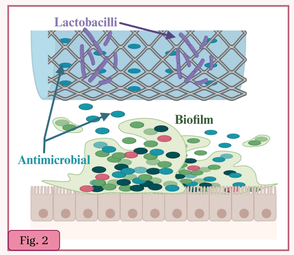

Fig. 2

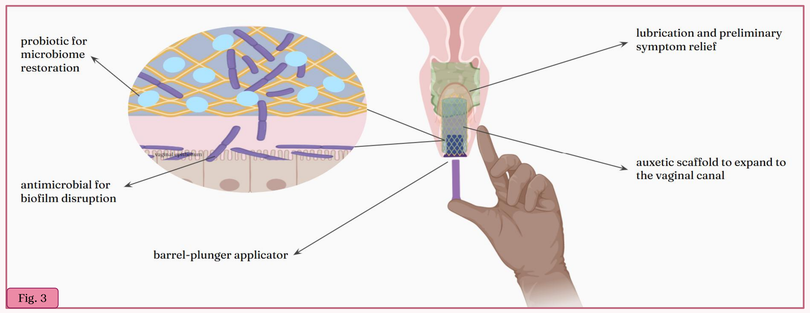

Fig. 3

Verification Results

Biofilm Disruption: Antimicrobial efficacy was evaluated against *G. vaginalis* using patient-derived samples at two concentrations. The majority of samples exhibited growth comparable to untreated controls, with limited instances of reduced growth and no observable concentration-dependent trend.
These findings suggest limited antimicrobial activity under the tested conditions and reflect the variability and complexity of patient-derived biofilms. Due to high colony density, analysis was qualitative, reducing sensitivity to subtle differences.
Future work will incorporate quantitative assays (e.g., CFU enumeration, biofilm-specific models) and optimized culture conditions to more accurately evaluate antimicrobial and biofilm disruption performance.

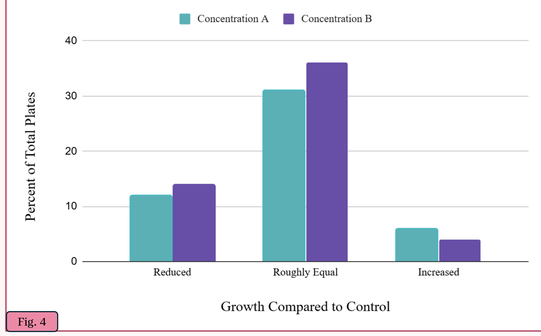

Fig. 4

Figure 4. Qualitative assessment of *G. vaginalis* growth from patient-derived samples following antimicrobial treatment. Most samples showed growth comparable to control, with no clear concentration-dependent effect.

PLGA Behavior: PLGA samples were tested at pH 4 (healthy), pH 5 (BV-relevant), and pH 7 (control), with percent mass change tracked over 9 days. All samples showed initial swelling (>100% mass) due to fluid uptake.
Under acidic conditions, rapid degradation followed, with complete mass loss by **day 7 (pH 4)** and **day 9 (pH 5)**. In contrast, pH 7 samples exhibited sustained swelling (~300%) with minimal degradation.
These results demonstrate **pH-dependent degradation**, supporting the requirement for **bioresorption within 30 days** and aligning with the target ~15-day functional lifetime.

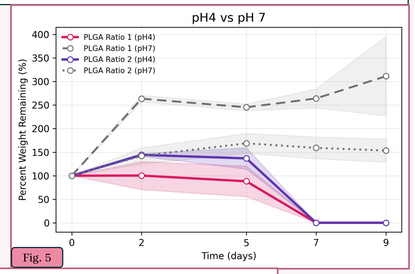

Fig. 5

Figure 5. PLGA mass change over time showing rapid degradation at pH 4 (~day 7) versus swelling without degradation at pH 7.

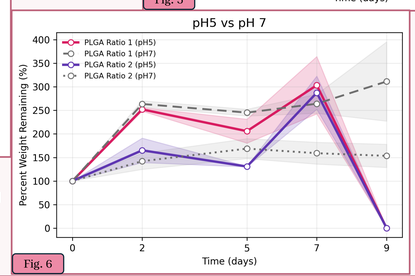

Fig. 6

Figure 6. PLGA mass change over time showing delayed degradation at pH 5 (~day 9) versus sustained swelling at pH 7.

Technical Model

Finite element analysis (FEA) was performed to evaluate the mechanical response of the auxetic PLGA scaffold under physiologically relevant intravaginal loading conditions. The model simulates an applied pressure representative of the vaginal canal to assess stress distribution, deformation behavior, and overall structural integrity of the scaffold. Results highlight localized stress concentrations at lattice junctions, while the overall structure demonstrates uniform load distribution. These findings suggest that the scaffold is capable of maintaining its shape and mechanical stability during use prior to degradation.

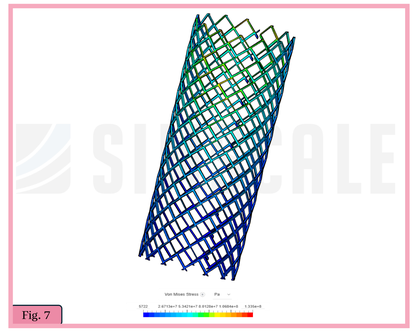
Fig. 7

Figure 7: Von Mises stress distribution in the PLGA-based lattice scaffold under simulated intravaginal pressure. Stress concentrations occur at lattice junctions, while overall distribution indicates the scaffold maintains structural integrity prior to degradation.

Design Status & Future Steps

Current Work: Early-stage prototype development and in vitro evaluation completed to assess device feasibility and performance. Preliminary testing evaluated material degradation behavior, mechanical properties, and biofilm disruption capabilities in collaboration with internal and external partners. Fabrication and testing of PLGA-based scaffold structures informed design optimization and material selection.

Future Work: Quantitative validation of antimicrobial efficacy, microbiome restoration, and controlled release profiles using physiologically relevant models. Continued development will include expanded preclinical testing and design refinement.

Regulatory & Translation: Anticipated regulation as a combination product with a biologic primary mode of action under CBER. Regulatory pathway to be determined through FDA engagement (e.g., De Novo or PMA). The team plans to continue development beyond capstone, including provisional patent filings.

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Balance starts with good design — scan for extended results, modeling, references, and more.