A Bioresorbable Intravaginal Scaffold Delivering Lauramide Arginine Ethyl Ester as an Adjunct to Antibiotic Therapy for Recurrent BV Prevention

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BVBalance™

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Mission Statement

Our mission is to develop a novel therapy for preventative measures that targets the biofilm of Gardnerella Vaginalis (*G. Vaginalis)* for a direct attack on the bacteria body and restore the Lactobacilli within the vaginal canal to prolong the recurrence period most women experience with Bacterial Vaginosis.

Introduction & Background

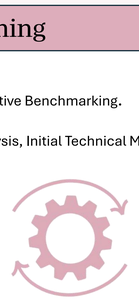
Bacterial Vaginosis (BV) is a persistent and frustrating condition that affects billions of women of reproductive age worldwide, (~30%), yet remains under-recognized and undertreated. Standard therapies, such as oral and topical antibiotics only provide temporary relief, with recurrence rates as high as (80%). The lack of effective preventative solutions represents a significant unmet need in women's health.

BV is a continuing issue and the gaps demonstrated are (1) recurrence rates: with up to 50-60% of women experiencing relapse within 12 months, most being within the first 3 months. (2) it is not only uncomfortable and disruptive but can be associated with emotional distress, strain intimate relationships, and contribute to long-term health risks, including pelvic inflammatory disease, infertility/adverse pregnancy outcomes, increased susceptibility to sexually transmitted infections and diminish Quality of Life. Despite prevalence and severity of recurrent BV, current treatments options fail to deliver consistent relief.

Current solutions for BV primarily rely on antibiotics which can temporarily alleviate symptoms but do not prevent recurrence and have related adverse side effects. The gap that is needing to be addressed is the biofilm associated with the bacterial *G. vaginalis* which becomes resistant to antibiotics if used constantly over time. Additionally, the biofilm causes a shift in the vaginal pH which begins to kill off the Lactobacilli bacteria. The target is to disrupt the biofilm of *G. vaginalis* bacteria to get a direct attack on the bacteria and restore the Lactobacilli within the vaginal canal.

Project Planning

Phase I: Design and Development Plan - Complete
Problem Identification, Voice-of-Customer Input, Competitive Benchmarking.
Phase II: Design Input - Complete
Concept Iteration, Business Model, House of Quality Analysis, Initial Technical Model
Phase III: Design Output - Complete
Bill of Materials, Refined Technical Model
Phase IV: Design Review - In Progress
Product Development Report, Stakeholder Input
Phase V: Design Verification
Phase VI: Design Validation
Phase VII: Design Transfer
Phase VIII: Design Changes
Phase IX: Design Launch
Phase X: Design Monitoring and Continuous Improvements



Design Inputs

Critical-to-Quality Customer Needs	Associated Metric
Prevents Recurrent BV for 6-8 Months	≥80% Biofilm Disruption, 2x10^8 Lactobacilli CFU / Day
Relief of BV Symptoms	Symptom-Relief Ointment Diffused in 24 hrs, Adjunct to Metronidazole
Little-to-No Side Effects	≥80% Cell Viability in Cytotoxicity Testing
Simple Maintenance	100% PLGA Degradation within 14 Days
Predictable Results	99% Results within ± 5% Anticipated Value in Testing
Comfortable Feel	Auxetic Struts and Ointment for Ease of Insertion, Elastic Material

Device Concept & Design

Objective: Disrupt biofilm and restore vaginal flora to prevent BV recurrence for 6-8 months
Auxetic intravaginal scaffold for delivery of **biofilm-disruptive and probiotic** combinational therapy as an adjunct to standard metronidazole treatment for recurrent bacterial vaginosis, deployed using a barrel-plunger-style intravaginal applicator with hydrating lubricant.
Biofilm Disruption: Lauramide Arginine Ethyl Ester (LAE) embedded within the chitosan matrix diffuses into the mucus layer to penetrate and **disrupt Gardnerella biofilm.**
Microbiome Restoration: Encapsulated Lactobacillus in matrix re-establishes a healthy vaginal pH and flora
Comfort + Retention: Hyaluronic acid (HA) surface layer **soothes irritation** and provides **comfortable insertion**

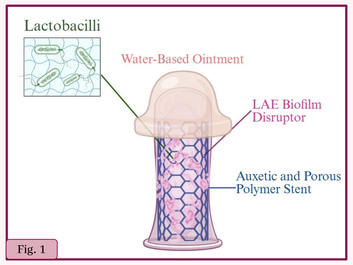


Fig. 1

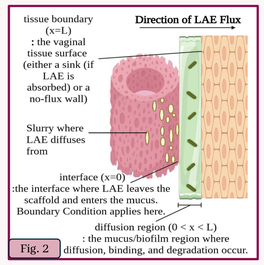


Fig. 2

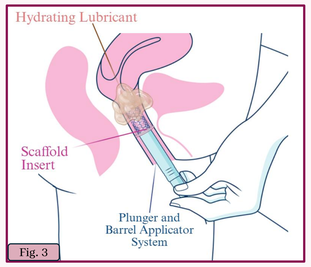


Fig. 3

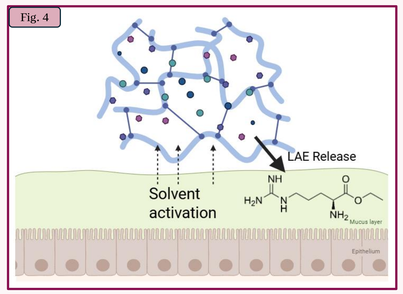


Fig. 4

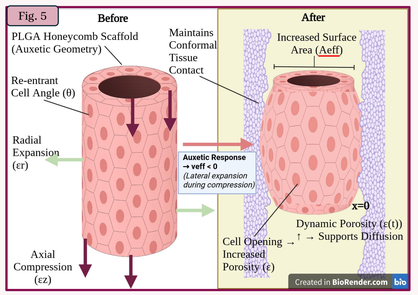


Fig. 5

Technical Models

Biofilm Disruption

Results indicate that therapeutic LAE concentrations are achieved in the vaginal canal and are maintained long enough to disrupt biofilms under physiologic conditions. Low and high discharge scenarios exceed the minimum biofilm-killing concentration within minutes, and exposure-based modeling predicts 90% kill by ~2 hours and 99% kill by ~4 hours. This demonstrates strong clinical feasibility for a fast-acting, localized, and low-toxicity biofilm-disrupting therapy.

PLGA Degradation

PLGA degradation models predicts the amount of time for bulk degradation based on various LA:GA ratios. In this mode, temperature is assumed to be 37 degrees Celsius and pH is between 3.0-8.0. These values are consistent with the vaginal canal environment. The k_eff values were determined from literature estimations and will be confirmed in testing.

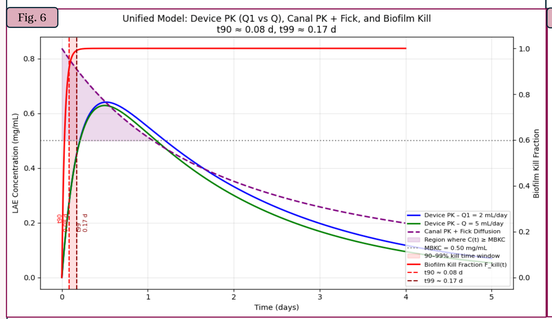


Fig. 6

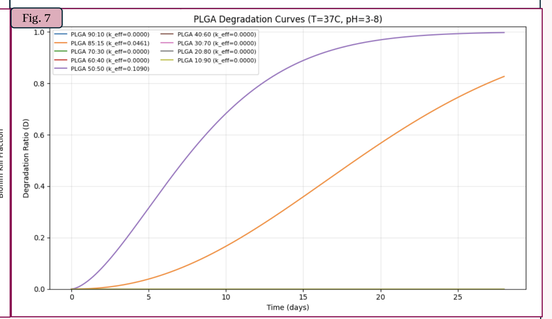


Fig. 7

Figure 6. *Unified PK–diffusion–kill model for BVBalance.* The blue and green curves show LAE concentrations delivered from the device under low (2 mL/day) and high (5 mL/day) discharge conditions. The purple dashed curve represents the canal concentration profile when accounting for Fickian diffusion loss. The shaded purple region indicates time above the MBKC threshold (0.50 mg/mL). The red curve shows the predicted biofilm kill fraction, with vertical dashed lines marking t_{90} (~0.08 days) and t_{99} (~0.17 days), and the red shaded band indicating the active kill window. Together, the curves demonstrate rapid attainment of therapeutic LAE levels and effective biofilm disruption within clinically relevant timescales
Figure 7. *PLGA Degradation Curves for BVBalance.* The purple line shows the PLGA degradation for an LA:GA ratio of 50:50. Roughly 90% degradation is reached in 15 days, and 100% degradation is reached in 25 days. The orange line shows PLGA degradation for an LA:GA ratio of 85:15. This curve degrades much slower, conveying that a higher LA content results in a slower degradation.

Manufacturing Design

Manufacturing Considerations
- PLGA 50:50 solvent-cast + porogen-leached to form porous auxetic scaffold
- Aseptic loading of LAE hydrogel into pores
- Gamma sterilization validated for PLGA
- Medical-grade pouch + applicator for single-use delivery

Major Cost Drivers
- PLGA + porogen
- LAE/hydrogel materials
- Solvent processing + molding
- Gamma sterilization
- Packaging + cleanroom labor

Component	Cost
Materials	$12–15
Processing + Labor	$6–8
Sterilization	$2–3
Packaging	$4–6
Total	$24–32

Final Product Specification

Material	PLGA ~50:50, bioresorbable
Geometry	Auxetic, porous scaffold
Pore Size	200–500 µm
Resorption Time	~14 days
Bioactive Agent	LAE (biofilm disruptor)
Release Mechanism	Rehydration-triggered pore diffusion
Applicator	Single-use, tampon-style
Compatibility	Adjunct to metronidazole treatment
Function	Disrupt biofilm + support microbiome restoration

Design Status & Future Steps

Current Status
- Developing technical models to define optimal component concentrations, mechanical design, and probiotic viability with consideration of all external factors and interactions
- Iterating design based on mentor feedback
- Finalizing access to Mayo Clinic lab space for experimental work

Next Steps
- Finalize all technical models
- Develop and perform protocols for in-vitro testing to inform prototype development
- Seek funding and investor support
- Pursue device patents

Looking Forward
- Transition device toward commercialization
- Conduct pre-clinical and clinical trials
- Meet FDA regulatory requirements for approval

Potential Challenges
- Securing sufficient funding for testing and prototyping
- Achieving proper sequential release timing of LAE and probiotics
- Translating technical models → in-vitro performance → clinical efficacy
- Addressing complexity and variability of the vaginal microenvironment

Acknowledgements

We would like to sincerely thank the members of our support network that have provided us with invaluable insight and feedback as we work through the development of our product. In particular, our team would like to thank Dr. Kling, Dr. Graf, and Dr. Handley-Kelly from Mayo Clinic for their clinical guidance. We also acknowledge ASU faculty, Dr. Vernon, Dr. Greger, and Instructor Carlos Mendez-Arias who have been endlessly helpful and supportive throughout our design process.

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