Bioresponsive Vaginal Drug Delivery Devices to Improve Global Women’s Health

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Objectives

- Global women’s health
- Preventive strategies
- Innovative drug delivery systems
- Performance *in vitro*
- Future opportunities
Global Women’s Health Facts:

- Tobacco use among younger women in developing countries ↑
- HIV-AIDS pandemic is increasingly “female”
- Physical and sexual violence against women ↑
- >90% of adolescent mothers live in developing countries
- Essentially all maternal deaths occur in developing countries

Source: WHO – Department of Gender, Women and Health
Global Women’s Health

Family Planning/Family Size

HIV/AIDS

Maternal Mortality
Global Women’s Health

Regional Demand for Family Planning in Africa

Source: African Population and Health Research Center
Impact of Economics on Family Planning Use in Africa

D. Clifton et al. *Family Planning Worldwide*, 2008
Global Women’s Health

Maternal Mortality

Source: World Bank, World Development Indicators
Global Women’s Health
Global Women’s Health

YOU ARE EITHER AFFECTED OR INFECTED WITH HIV/AIDS
Preventive Strategies

Saving Lives in the Future:

- Comprehensive primary health care
- Gender equality
- Nutrition
- Prevention of child abuse
- Social & emotional development
- Reduction in risky behavior
Preventive Strategies
Preventive Strategies
Preventive Strategies

Limitations:
- use of applicator
- temperature-dependent viscosity
- microbial safety
- distribution

Objective

- Development of an innovative preventive/therapeutic device that meets unique needs of women in underserved African regions:
  - self-administration without applicator
  - low-cost
  - socially acceptable
  - rapid effectiveness
  - safe
  - mucoadhesive
  - biodegradable
Innovative Drug Delivery Systems

Acidic Buffer Capacity


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Bioresponsive Viscosity

Innovative Drug Delivery Systems

Bioresponsive Viscosity

Innovative Drug Delivery Systems

Sol – Gel – Xerogel

- solid dosage form
- light-weight
- biocompatible & biodegradable materials
- chemical stability
- engineered device properties
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Carbopol® 974P

Hydroxypropyl methylcellulose

Viscosity [cP]

R = H or CH$_3$ or CH$_2$CH(OH)CH$_3$
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Tampon-like Xerogel Device

| Porosity [%] | 54.1 | 1.9 | 83.0 | 2.9 |
| Compression Force [N] | 13.2 | 1.8 | 11.8 | 1.1 |
| Hydration Rate [mg/s cm²] | 3.5 | 0.1 | 13.8 | 0.7 |
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Tampon-like Xerogel Device

Gynol II

3% mannitol
Innovative Drug Delivery Systems

Tampon-like Xerogel Device

5% trehalose

3% mannitol

Engineered Properties:

- porosity (20-90%)
- hydration rate (1-15 mg/s cm²)
- Compression force (5-60 N)
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Effect of Pore-forming Agent:

![Graph showing the effect of pore-forming agents on viscosity. The x-axis represents different concentrations, and the y-axis represents viscosity in cP (centipoise). The graph compares 2% CP/4% HPMC and 3% Mannitol.](image-url)
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Partial Rehydration of Tampon-like Xerogel Device

![Graph showing spreadability work comparison between gel and xerogel](image)
Partial Rehydration of Tampon-like Xerogel Device

![Graph showing spreadability work vs. seminal fluid simulant volume](image)
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Partial Rehydration of Tampon-like Xerogel Device

![Graph showing bioadhesion work over time for different materials.](graph.png)
Future Directions

Clinical Development of Tampon-like Xerogels:

- *in vitro* testing methods (efficacy/safety)
- women's acceptability/perception
- *in vivo* safety/efficacy
- scale-up/production
- pharmacokinetics of medicated xerogels
- regulatory path
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