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Assessing the potential of the Woman's Condom for vaginal drug delivery

Lindsay F. Kramzer[a,d], Jessica Cohen[b], Jesse Schubert[b], Charlene S. Dezzutti[c,d], Bernard J. Moncla[c,d], David Friend[e], Lisa C. Rohan[a,c,d,*]

[a]Department of Pharmaceutical Sciences, School of Pharmacy, University of Pittsburgh, 3501 Terrace Street, Pittsburgh, PA, 15261, USA
[b]PATH, 2201 Westlake Avenue Suite 200, Seattle, WA, 98121, USA
[c]Department of Obstetrics, Gynecology, and Reproductive Sciences, School of Medicine, University of Pittsburgh, M240 Scaife Hall, 3550 Terrace Street, Pittsburgh, PA, 15261, USA
[d]Magee-Womens Research Institute, 204 Craft Avenue, Pittsburgh, PA, 15213, USA
[e]CONRAD, 1911 North Fort Myer Drive Suite 900, Arlington, VA, 22209, USA

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Abstract

Background: The Woman's Condom is a new female condom that uses a dissolvable polyvinyl alcohol capsule to simplify vaginal insertion. This preclinical study assessed the feasibility to incorporate an antiviral drug, UC781, into the Woman's Condom capsule, offering a unique drug delivery platform.

Study design: UC781 capsules were fabricated using methods from the development of the Woman's Condom capsules as well as those used in vaginal film development. Capsules were characterized to evaluate physical/chemical attributes, *Lactobacillus* compatibility, in vitro safety and bioactivity, and condom compatibility.

Results: Two UC781 capsule platforms were assessed. Capsule masses (mg; mean±SD) for platforms 1 and 2 were 116.50±18.22 and 93.80±8.49, respectively. Thicknesses were 0.0034±0.0004 in and 0.0033±0.0004 in. Disintegration times were 11±3 s and 5±1 s. Puncture strengths were 21.72±3.30 N and 4.02±0.83 N. Water content measured 6.98±1.17% and 7.04±1.92%. UC781 content was 0.59±0.05 mg and 0.77±0.11 mg. Both platforms retained in vitro bioactivity and were nontoxic to TZM-bl cells and *Lactobacillus*. Short-term storage of UC781 capsules with the Woman's Condom pouch did not decrease condom mechanical integrity.

Conclusions: UC781 was loaded into a polymeric capsule similar to that of the Woman's Condom product. This study highlights the potential use of the Woman's Condom as a platform for vaginal delivery of drugs relevant to sexual/reproductive health, including those for short- or long-acting HIV prevention.

Implications: We determined the proof-of-concept feasibility of incorporation of an HIV-preventative microbicide into the Woman's Condom capsule. This study highlights various in vitro physical and chemical evaluations as well as bioactivity and safety assessments necessary for vaginal product development related to female sexual and reproductive health.

Keywords: Woman's Condom; Contraception; UC781; HIV prevention; Topical preexposure prophylaxis; Microbicide

1. Introduction

PATH, with CONRAD and international research partners, used an iterative user-driven development process to design a female condom that is easy to use, is comfortable and provides good sensation for both partners. The resulting product, the Woman's Condom (Fig. 1), is safe and has good performance in clinical studies across multiple countries [1–6]. The Woman's Condom has been preferred over other female condoms for its ease of use, appearance and fit [2,5]. In a multisite trial comparing new female condoms to the FC2 female condom, the Woman's Condom showed performance similar to the FC2 female condom, with the same low rates of safety concerns [6].

The Woman's Condom, manufactured by Dahua Medical Apparatus Company (Dahua, Shanghai, China), is approved by regulatory bodies in Europe, China, South Africa, Malawi and Zambia and is currently available in limited markets in

* Corresponding author at: Magee-Womens Research Institute, 204 Craft Avenue, B509, Pittsburgh, PA 15213, USA. Tel.: +1 412 641 6108.
E-mail address: rohanlc@upmc.edu (L.C. Rohan).

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Fig. 1. Woman's Condom. The PVA-based capsule contains the condom pouch and is used for condom insertion. Once the condom is vaginally inserted, the capsule quickly dissolves, and the condom is ready for use. PATH/Patrick McKern.

China and South Africa. Expansion of access to this new multipurpose prevention technology (MPT) for protection from sexually transmitted infections (STIs), including HIV, and unintended pregnancy is under way.

The Woman's Condom has several unique features. The thin, polyurethane pouch provides good sensation and comfort for both partners. The dissolving polyvinyl alcohol (PVA) capsule contains the condom pouch to facilitate handling and insertion. Once the capsule is inserted, it dissolves within 30–60 s, and the pouch unfolds inside the vagina. Although female condoms are designed to protect from both unintended pregnancy and STIs, exploring the feasibility of using this dissolving capsule as a vaginal drug delivery platform is of interest.

Several formulations and delivery platforms are under investigation for vaginal administration of drugs to prevent HIV and other STIs. These include gels, vaginal rings, cervical barriers such as diaphragms, tablets and polymeric

Table 1
Vaginal drug delivery methods

Type	Dosing regimens	Advantages	Disadvantages
Gel	Coitally independent: daily Coitally dependent: prior to coitus; before and after coitus	Female controlled Familiar vaginal dosage form Provides lubrication Can be utilized for MPT Easy to manufacture	Applicator is required (not discrete, product waste) Leakage/messiness Drug stability Frequency of application Adherence
Ring	Coitally independent: every 1–3 months	Female controlled No applicator required Long-term drug exposure Adherence Can be utilized for MPT	Unfamiliar vaginal dosage form Bulky/uncomfortable Unnecessary exposure to drug after cessation of product use Placement Manufacturing
Film	Coitally independent: daily; every few days to once a week Coitally dependent: prior to coitus; before and after coitus	Female controlled No applicator required Discrete Portable Easy to use Option for aqueous instable drug No leakage Can be utilized for MPT Easy to manufacture Cost	Disintegration of product and dissolution of drug depend on local hydration Cervicovaginal distribution may be of concern Unfamiliar vaginal dosage form Placement
Tablet	Coitally independent: daily; every few days to once a week Coitally dependent: prior to coitus; before and after coitus	Female controlled Discrete Option for aqueous instable drug No leakage Easy to manufacture Cost	Applicator may be required Disintegration of product and dissolution of drug depend on local hydration Cervicovaginal distribution may be of concern
Female condom	Coitally dependent: during coitus	Female controlled No applicator required Can be combined with film, gel or drug delivery Can be utilized for MPT	Integrity of barrier could become compromised Placement Cost
Cervical barrier, diaphragm	Coitally dependent: during coitus	Female controlled No applicator required Can be combined with gel or drug delivery Can be utilized for MPT	Integrity of barrier could become compromised Placement Cost