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Editors
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New FDA-approved woman-controlled, latex-free barrier contraceptive device “FemCap”

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Abstract. Objectives: To provide a woman-controlled vaginal barrier contraceptive device that not only prevents pregnancy, but also protects against sexually transmitted infections (STIs).

Methods: The FemCap is designed to cover and protect the cervix completely—the portal of entry for sperm, bacteria and viruses—and the site of chemokine coreceptors for the HIV virus (CCR-5 and CXCR-4). The FemCap is an FDA-approved cervical barrier device that is designed with a unique delivery system that stores and delivers any microbicid on the vaginal side. This ensures immediate contact of the microbicid with invading microorganisms and the HIV virus.

Results: Many microbicidcides, even soap and water, lemon juice, and Nonoxynol-9, can destroy the fragile HIV virus in the lab; none have proven yet to be effective in the vagina. In fact, Nonoxynol-9 increases HIV transmission if applied over the cervix. This is due to the disruption of the microbicidcides to the fragile columnar cervical and uterine epithelium.

Conclusion: To minimize the transmission of STIs/HIV it is critical to use a mechanical cervical barrier with a microbicidcide reservoir on the vaginal side such as the FemCap. This ensures immediate contact of the microbicidcide with the HIV virus upon deposition into the vagina. © 2004 Elsevier B.V. All rights reserved.

Keywords: FemCap; Chemokine coreceptors; CCR-5/CXCR-4; Microbicidcide

1. Introduction

The current pandemic of sexually transmitted infections (STIs), and acquired immune deficiency syndrome (AIDS), are responsible for an intense renewed interest in all barrier contraceptive devices. Presently, barriers are the only method that can protect against STIs [1,2]. There is an urgent and compelling need for a wider range of female-controlled barrier contraceptive devices that offers protection against STIs [1]. Unlike the currently available cervical barriers, the FemCap is designed with a unique delivery system—a reservoir—facing the vaginal opening (Fig. 1).

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This reservoir is designed to store and deliver any microbicide on the vaginal side [3]. This ensures immediate contact of the microbicide to the HIV virus upon deposition.

2. Methods

2.1. Design

The FemCap (Fig. 2) is designed to completely mechanically block the cervix—the main portal of entry—for sperm, bacteria, and viruses [4]. The cervix is also the site for the HIV coreceptors CCR-5/CXCR-4 (Fig. 3); the FemCap also protects the endocervical and endometrial columnar epithelium from the disruption caused by the microbicide [5].

The vagina expels the inserted microbicide to keep its potential cavity always empty. To retain the microbicide into the vagina the FemCap was designed with a unique delivery system—a reservoir—(Fig. 1) facing the vaginal opening. This reservoir is intended to store and deliver any microbicide into the vagina, to ensure immediate contact of the microbicide to the HIV virus upon deposition.
2.2. Materials

The FemCap is made from an inert material. It is inexpensive, soft yet durable, and nonallergenic. The FemCap can be squeezed repeatedly and still retain its original shape. It is easy to clean with soap and water. Neither contact with petroleum products or bodily fluids, nor exposure to extreme temperatures will cause any deterioration.

2.3. Size selection

The correct size FemCap was determined by obstetrical history during the clinical trials [6]—without any measurement. Three sizes were found to eliminate the laborious and time-consuming measurements taken by clinicians, and simplify the instruction and fitting process without sacrificing safety or effectiveness.

2.4. FemCap instruction

Every woman is provided with an instructional videotape to reinforce learning, and saves on clinician time. Women are instructed to insert the FemCap before any sexual arousal to ensure compliance, proper fit, and avoid interruption of spontaneity.

3. Results

The first-generation [6–8] FemCap was clinically tested in controlled randomized clinical trials [6] throughout the United States.

3.1. Safety

None of the participants had any significant side effects. This was documented through physical and colposcopic [6] examination. During the clinical trials, the risk of developing a urinary tract infection while using the FemCap was found to be significantly less than the risk to those women using the diaphragm.

3.2. Effectiveness

The first-generation FemCap [6] was successful in preventing pregnancy in 86.5% of the participants in the typical unadjusted use during the 6-month clinical trial. One pregnancy occurred among the 85 women who completed 8 weeks of the study to test the second-generation FemCap [9–11]. Due to the small number of participants and the relatively shorter duration, the confidence interval would be wide. Based on this study, the typical failure rate (Pearl index) of the second-generation FemCap was estimated to be 7.6 per hundred women per year. It is estimated that the FemCap may achieve up to 96–98% effectiveness if used properly, i.e., if the woman (a) uses the FemCap correctly every time she has sex; (b) applies spermicide with each act of intercourse; and (c) uses emergency contraception as a back-up measure in case she has forgotten to use the FemCap or used it incorrectly [9].
3.3. Acceptability

The FemCap is very highly accepted by women and their partners. In the clinical trials, the majority of women who had prior experience with the diaphragm preferred the FemCap [6].

4. Discussion

Currently, physical and chemical barriers offer the only defense against the spread of STIs. While female barriers are safe and effective, and provide a viable alternative to the condom, they are rarely used due to the constraints on the clinician’s time. The FemCap videotape and the lack of need for fitting and measurements greatly save on the clinician’s time. Unlike the currently available cervical barriers, the FemCap is designed with a unique delivery system—a reservoir for the microbicidal, facing the vaginal opening. The FemCap by itself has no microbicidal properties. The FemCap is designed to be used as a delivery system for any microbicidal.

5. Conclusion

The cervix is the main portal of entry for the HIV virus. The vagina is a conduit that expels the bulk of inserted microbicides to the outside, rendering it useless and to the inside of the cervix disrupting its fragile epithelium. This renders women more vulnerable to the HIV invasion. To minimize the transmission of HIV, it is critical to use a microbicidal with a device such as the FemCap. This protects the cervix from the deleterious effects of the microbicides and stores and delivers the microbicidal on the vaginal side. This ensures immediate contact of the microbicidal with the HIV virus as soon as it is deposited in the vagina.

References