

Research Article
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Non-Hormonal Contraceptive Device with Multiple Uses: Increases The Effectiveness of Fertility Awareness Methods and Controls Stress Incontinence

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ABSTRACT

This article addresses three unmet women's reproductive health needs, and how the FemCap can fulfill these needs. The FemCap is an FDA-approved, non-hormonal contraceptive device that can accommodate some deficient areas of women's health: 1. A scarcity of hormone-free contraceptive methods. 2. Enhancement of fertility awareness method that is infrequently used but is the safest method. 3. Help Millions of women who suffer silently from stress urinary incontinence. The FemCap blocks sperm from entering the cervix. It is time-tested to be safe and effective for contraception. Using the FemCap directly at the cervix, it can collect the fertile cervical mucus without mixing it with any other vaginal fluid. Current pessaries used to treat stress urinary incontinence (SUI) have significant drawbacks, including displacement, erosion, ulceration, of the vagina and urethral blockage. The rim of the FemCap performs the same function as the ring pessary by supporting the bladder neck. The outward flared brim restores the urethra and vaginal anatomy. At the same time, the bowl of the FemCap keep the cervix from prolapsing further. The FemCap is a long-established barrier method of contraception, and pilot studies results show it can improve fertility awareness methods and manage Stress Urinary Incontinence. It would be ideal and cost-effective to have a single reusable device with several functions for contraceptives, increasing the acceptability and effectiveness of fertility awareness methods, and stress urinary incontinence control. The FemCap would be an ideal alternative to the condom.

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Introduction

It is well established that the male condom is the only device that can prevent both pregnancy and sexually transmitted diseases (STDs). However, the condom is not well accepted by either partner, and thus may not be used as well as expected by people at higher risk for STDs. The Following is a comparison between the Male condom and the FemCap:

	The Male Condom	The FemCap
Gender Control	Male - controlled	100% percent woman-controlled and can be applied without the knowledge of the man.
Spontaneity of intercourse	The condom interrupts the spontaneity of intercourse to both partners, which may lead to inconsistent use.	The FemCap does not interrupt spontaneity as it should be applied before sexual arousal.
Sexual sensations	It reduces the pleasurable sensations of intercourse to both males and females.	It does not reduce sensation to either partner.
Acceptability	It is not well accepted by either partner, particularly the male.	It is universally accepted by both males and females.
User's failure and timing of application	Men rush to apply the condom to avoid the loss of erection. They may apply it incorrectly or may not even apply it at all, during the heat of the passion (poor timing).	Once the woman learns how to apply the Fem Cap it will become an easy routine with minimal chance for user's failure. The woman can apply the FemCap at any time of her choosing when she is not rushed.

Breakage and leakage	The condom can leak and break even if it is used consistently and properly.	Is made of durable material that is impossible to leak or break during usual use.
Allergic reaction	Most male condoms are made of Latex, which can cause serious allergic reaction.	Is made of an inert non-allergenic silicone material.
Storage and shelf life	Latex material deteriorates very quickly if it is not stored properly particularly in hot tropical countries.	Is made of durable material that can withstand extreme temperatures without any deterioration.
Cost	Costs \$.90 - \$1.00 for a single use, which translates to \$108-\$120 per year assuming it is used 3 times a week for 40 weeks per year of use.	It comes with an instructional online DVD and Costs \$89, and it is reusable for more than one year.
Hazard to the environment	May pose environmental hazard if not properly disposed.	Does not pose any environmental hazard.

In the medieval times European women used half a lemon to cover their cervix to prevent pregnancy. This modality is the closest to modern cervical cap, while the rind of the lemon act as a mechanical barrier and the lemon juice act as spermicide. Prentif cervical cap was invented in 1838. (Figure 1)



Figure 1: Prentif-cavity-rim Cervical Cap



Figure 2: Average size Diaphragm

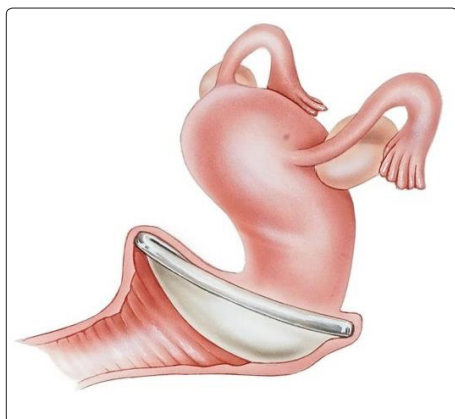


Figure 3: The Diaphragm displayed into the pelvis



Figure 4: FemCap



Figure 5: FemCap Views Diagram



Figure 6: FemCap lateral view

Comparison Between the FemCap & the Diaphragm

	The FemCap(Figures 4-11)	The Diaphragm (Figure 2-3)
Material	Non-allergenic, medical-grade silicone Made of one piece that heats and cools uniformly, allowing for autoclave sterilization. Durable, cannot be punctured by fingernails. Withstands temperature extremes as well as petroleum products. Several easy cleaning methods. Does not absorb or cause odors.	Made of Latex or silicone and a steel wire in the rim, that heats and cools differently. Natural latex rubber can cause allergic reaction. Can be punctured easily by a fingernail. Deteriorates quickly if exposed to petroleum products, high temperatures or light. Needs special care for cleaning. Can cause odor.
Design	Anatomical design with dome covers the cervix completely and brim flare outwards and conforms with the vaginal wall. The rim of the FemCap does not cause any undue pressure on the vagina, cervix, or urethra. Designed to protect the cervix with a unique groove (delivery system) facing the vaginal opening that stores the spermicide while trapping sperm, bacteria, and viruses. (Figure 5)	Large cup-shaped with metal wire in the rim. It extends from the posterior fornix to the symphysis pubis. It does not adapt to physiological changes during intercourse. The metal rim causes pressure on the vaginal walls and the urethra. Spermicide placed in the bowl of the cup disrupts cervical cells, and, if applied without removing the diaphragm across the convex side, it leaks outside the vagina.
Safety	A removal strap is placed across the dome, eliminating potential for fingernail abrasion during removal. (Figure 11)	Removal can potentially cause vaginal abrasions or puncture the rubber.
Size Selection	No measurement is required. Size is determined by obstetrical history. Small for women who have never been pregnant. Medium for women who have had miscarriage, abortion or delivered by c- section. Large for women have had vaginal delivery.	Sizing is required and measurements can be time consuming due to the multiple sizes. Size needs to be examined and possibly changed due to weight gain or loss of 10 lbs. or more.
Education Materials	Several Instructional videos available online at: https://femcap.com/new/femcap-insertion-removal	Video available, but rarely provided with the diaphragm.
UTI	Low risk and no increased incidence of urinary tract infection UTI.	Higher risk and increased incidence of UTI.
Duration of Use	Provides continuous protection for 48 hours.	Recommended for 24-hour use only.

FemCap™ Discription and Its Evolution

The obsolete First -generation FemCap was designed to confirm to the anatomy of the cervix and to adapt to the physiology of the vagina [1-6].

The improved second-generation FemCap design [Figures 4,5,6,7,8,9,10,11] the DOME covers the cervix completely (Figure 5, 9). The RIM (Figure 5, 15) fits snugly into the vaginal fornices, and encircles the opening of the FemCap that fits over the cervix. A LIP (Figure 5) was created inside the rim to gently grip the cervix. The BRIM (Figure 5, 15) was designed to flare outward so it would push against the physiological inward contraction of the vagina. This pressure/ counter-pressure causes the BRIM (Figure 5, 15) to adhere and conform to the vaginal walls creating a tight seal. In keeping with vaginal anatomy, the BRIM was designed to be longer posteriorly (Figure 5,9). The FemCap is designed with a GROOVE (Figure 5). This groove is intended to trap sperm and store any spermicide or microbicides that may be developed in the future to protect against sexually transmitted infections.

Size Selection

Because all women are unique in their anatomy it only made sense that one size could not fit all. The FemCap comes with 3 sizes, the smallest 22mm is designed for women who have never been pregnant, the medium 26mm for women who have been pregnant but did not deliver vaginally such as C-section or miscarriage and the large 30mm is for women who have delivered vaginally.

The utilization of the 3 sizes eliminated the need of time consuming measurement and custom fitting. Instead size selection is determined by the womans obstetrical history. The most striking observation

of this study is that the diameter of the cervix has very little relation to height and weight of the woman. The ONLY factors having a major impact on the cervical diameter and the elasticity of the vagina are pregnancy and delivery.

An initial concern with the first- generation FemCap was; would it be too difficult for women to correctly place the FemCap over a tilted cervix? To remedy this we designed an applicator to place the FemCap correctly. Actual data showed that women in fact didn't have trouble placing the FemCap over the cervix even if tilted however, they did have difficulty in removing it. Since the insertion wasn't an issue, the applicator became obsolete.

To ease the difficulty when removing the FemCap we designed a strap over the dome of the FemCap (Figure 11) to alleviate the difficult removal in the new version known as the second generation. The second generation FemCap is currently the only cervical cap available in the entire world with FDA & CE approval (Figure 4-11).

The first generation FemCap also had a lowered rate of effectiveness for women who had given birth vaginally. This reduced efficacy was due to a decline in vaginal tone, which increased dislodgment. To compensate for the decreased vaginal tone in multiparous women we increased the dimension of the brim to maximize the surface contact between the vaginal walls and the FemCap. This helped to improve the stability, prevent dislodgment and thus enhance effectiveness.

The FemCap is designed with a unique groove facing the vaginal opening (Figure 5). This groove is intended to trap sperm while

keeping the spermicide from touching the cervix to minimize any possible irritation. The bulk of spermicide/ microbicide is intended to meet the sperm, bacteria, and/or viruses as soon as they are deposited in the vagina to prevent sexually transmitted infections. This is unlike the diaphragm and Prentif cervical cap, in which the spermicide is applied directly against the cervix.



Figure 7: FemCap Covering Cervix

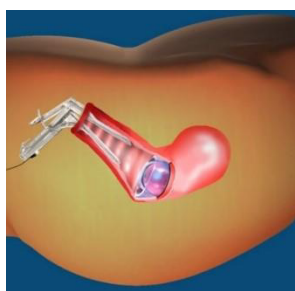


Figure 8: FemCap Speculum View

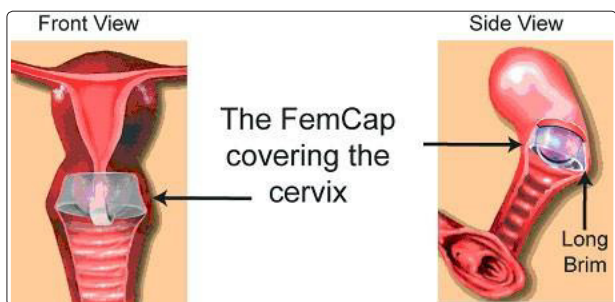


Figure 9: FemCap Over Cervix

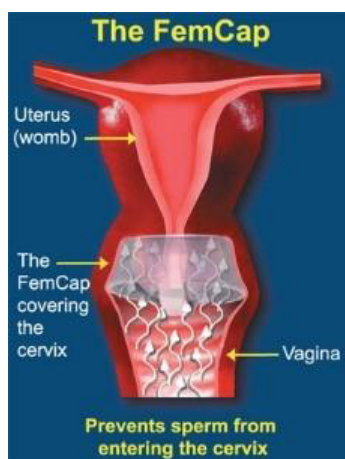


Figure 10: How the FemCap Works



Figure 11: Using Removal Strap

FemCap in Contraception Safety, Effectiveness, and Acceptability

During the extensive clinical trials in 10 universities across the United States and two decades of use in the market, the FemCap did not have any reported significant side effects. The second generation FemCap was found to be 92.4% effective in preventing pregnancy [4,5,6]. In terms of the effectiveness of the second generation FemCap, one pregnancy occurred among 85 women who completed 8 weeks of study. Because of the small number of participants and the relatively short duration, the confidence interval is wide. Based on this study, the typical failure rate (Pearl index) of the second generation FemCap is approximately 7.6 per 100 women per year. The effectiveness rate of the FemCap could be much higher for women who are highly motivated and who use the FemCap consistently before each act of intercourse and before sexual arousal [7]. The FemCap is highly acceptable. In these clinical trials 75% of women preferred the FemCap over the diaphragm [3].

The Fertility Awareness Method is the safest and the most cost-effective of all contraceptives, yet it is the least prescribed by doctors and the least used by women. We attribute this to the fact that women miss the most important sign of ovulation during their fertile window (Figure 12), which is the fertile cervical mucus (Figure 13). The FemCap allows women to collect a high-quality sample of their fertile cervical mucus directly from the source. The FemCap also prevents the fertile cervical mucous from mixing with other vaginal secretions [8-15]. We previously conducted a pilot study using the FemCap which allowed women to see the distinction of the mucus. It resembles clear raw egg-white and stretches about 2.- 3 inches before it breaks. This is the most important sign in identifying ovulation and the fertile window with astonishing precision. This methodology shortened the fertile window to 3 days for conception and 8 days for contraception. This simple non-invasive and low-cost method can maximize the chance of conception or contraception in healthy women having regular periods. It should be noted that the efficacy of this method depends intensively on user motivation, compliance, and accurate, and consistent recording.

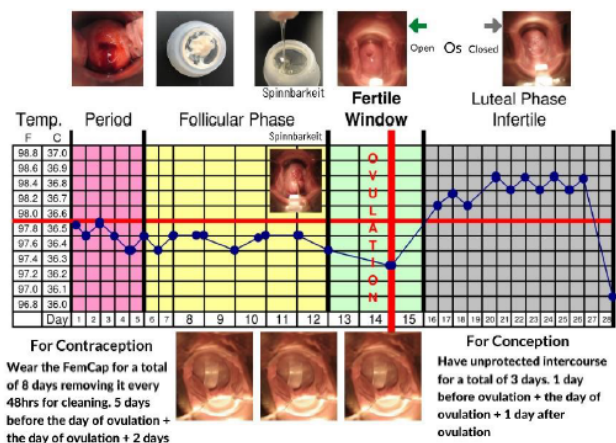


Figure 12: Basal Body Temperature Chart

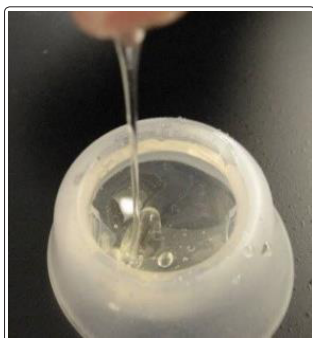


Figure 13: Cervical Mucus Collected by FemCap

The use of the FemCap to collect the cervical mucus can pinpoint the day ovulation and thereby enhance Fertility Awareness methods.

Stress urinary incontinence management

A woman who was using the FemCap for contraception reported to me that she was also suffering from Stress Urinary Incontinence (SUI). She reported to me that the days she used the FemCap she did not have any episode of stress incontinence. This led me to investigate the use of the FemCap as a SUI pessary (Figure 15). Stress Urinary Incontinence (SUI) is very prevalent among women of all ages, particularly menopausal women. SUI is under-reported by women as well as under-diagnosed and under-treated by doctors. The first line of SUI treatment is pelvic floor muscle (Kegel) exercises and vaginal pessaries. The ring pessary is most widely used however, more pessaries of different shapes and sizes (Figure 14, 16) have been introduced into the market with the hope of achieving better results.



Figure 14: Pessaries for SUI

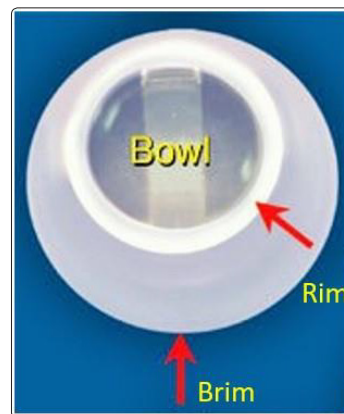


Figure 15: FemCap Brim & Rim



Figure 16: Ring Pessary

Currently available pessaries have significant limitations such as displacement, erosion or even ulceration and urethral obstruction [16,17,18,19]. The FemCap shows marked similarity to the ring pessary. The Rim of the FemCap is similar in shape and function to the ring pessary that supports the bladder neck. The outward flaring brim restores the anatomy of the urethra and the vagina. The bowl of the FemCap supports the cervix and prevents it from prolapsing, which provides further support. The FemCap's rim is like the ring pessary in shape and function to support the bladder neck. The brim flares outward to support and restore the urethra's anatomy and the vagina. Lastly, the bowl of the FemCap supports the cervix to prevent it from descending. We conducted a pilot clinical trial to check the feasibility of the FemCap in controlling stress urinary incontinence. 16 women out of 19 were completely dry [20]. It would be ideal and cost-effective for women to acquire one multipurpose device that can be used for contraception, to control stress incontinence, and enhance fertility awareness methods.

Summary

The intravaginal contraceptive devices available are extremely limited, and women need safe and effective alternatives that correlate with their lifestyle. Non-hormonal options are especially important for women who have contraindications or aversion to hormones or IUDs. **The FemCap is a multipurpose device that functions in three major areas of unmet women's health.** The unique sailor hat design conforms to the cervical anatomy and prevents pregnancy by blocking the sperms' access to the cervix. Ensuring the device is easy to use was a main factor in development. FemCap requires minimal one-on-one training from a health care professional, and the user has full control. Because it sits directly at the cervix, it is a great tool to collect cervical mucus used to pinpoint ovulation with the fertility awareness method. Recently, it was discovered that the FemCap will also help manage Stress Urinary Incontinence.

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