

New Advances in the Fertility Awareness Method and the Treatment of Stress Urinary Incontinence (SUI)

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ABSTRACT

Background: This article addresses women's unmet reproductive health needs:

1. Limited options for hormone-free birth control methods.
2. The rarely utilized fertility awareness method is the safest.
3. Women endure stress incontinence silently.

Objectives: Provide women with one device that can be used for contraception, fertility awareness, and stress urinary incontinence.

Materials and Methods: The FemCap is an FDA approved contraceptive device that can fulfill the three basic reproductive health needs for women:

1. The FemCap is a safe, effective, time tested, barrier contraceptive device.
2. Collect the fertile cervical mucus with the FemCap directly at the cervix, without mixing any other vaginal fluid.
3. Pessaries currently utilized to control SUI have significant limitations such as displacement, erosion, or even ulceration and urethral obstruction. The FemCap shows marked similarity to the ring pessary. The rim of the FemCap function is the same as the ring pessary in that it supports the bladder neck. The outward flaring brim of the FemCap restores the anatomy of the urethra and the vagina, and the bowl provides support to prevent the cervix from descending further.

Results: The FemCap is a well-established barrier contraceptive device. In pilot studies, FemCap has proven to enhance the effectiveness of fertility awareness methods and control SUI in pilot clinical trials.

Conclusion: It would be ideal and cost-effective to have one reusable device with multi-functions for contraception, fertility awareness, and to control stress incontinence.

Keywords

FemCap, Contraception, Urinary stress incontinence, Fertility Awareness Method.

Background

The FemCap (Figures 1-6) is the only cervical cap available in

the world. The FemCap (Figures 1-6) began as an indication for HIV prevention when combined with microbicide. The best way to prevent a woman from contracting HIV and support her reproductive health is by protecting her cervix [1-5]. The FemCap is designed to conform to the anatomy and adapt to the physiology of the cervix and vagina [6-10]. The FDA approved the FemCap

as a safe, effective, non-hormonal option for contraception. Hormonal birth control has many undesirable side effects for both women's health and the environment. Study after study, we find the chemicals in these contraceptives can cause heart attack, stroke, cancer, mood swings, depression, and other unwanted issues. Today, a woman can do a quick internet search to find a long list of side effects caused by hormonal contraceptives. Women are obviously in need of more non-hormonal birth control options.

The Fertility Awareness Method

The Fertility Awareness Method is the safest and the most cost-effective of all contraceptive options, yet, it is the least prescribed by doctors and the least used by women [11-13]. We attribute this to the fact that women miss the most vital sign of ovulation during their fertile window, which is the fertile cervical mucous (Figure 7 & 8). The FemCap allows women to collect a large quantity and

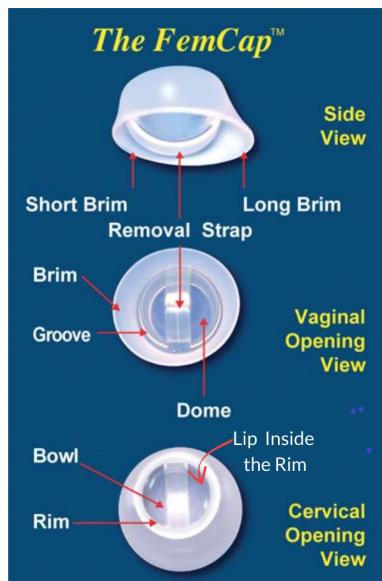


Figure 1: FemCap 3 Views



Figure 2: Lateral View

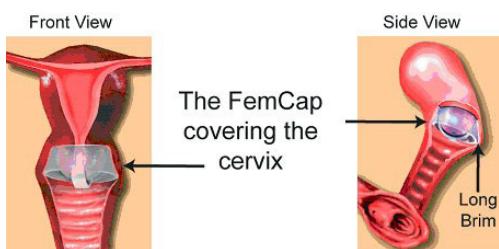


Figure 3: FemCap Covering Cervix

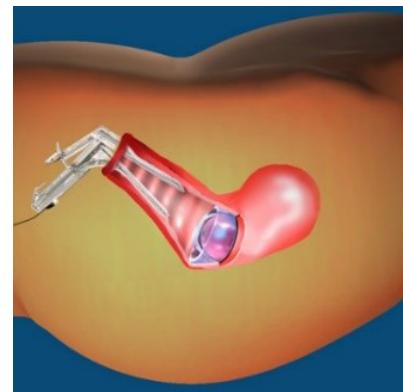


Figure 4: Speculum View

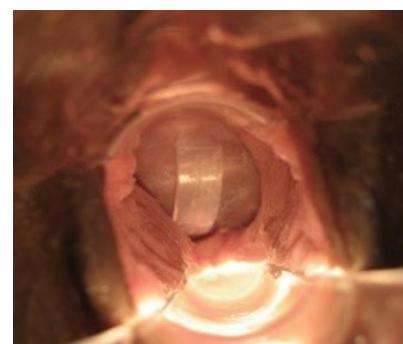


Figure 5: Live View Over Cervix

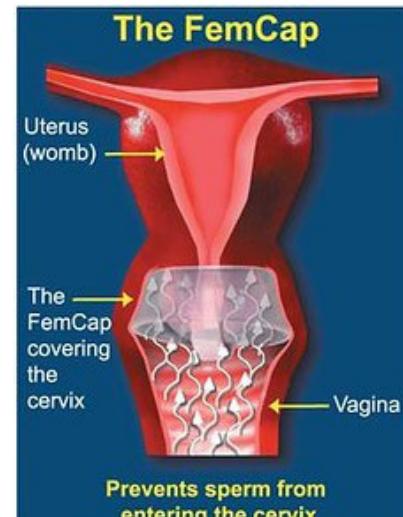


Figure 6: How FemCap Works

a high quality of their fertile cervical mucous directly from the cervix. The FemCap also prevents the fertile cervical mucous from mixing with other vaginal secretions.

Stress Urinary Incontinence (SUI)

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. A woman using the FemCap as a contraceptive revealed that she had suffered from stress urinary incontinence, but when using the FemCap (Figure 1,2,11), her SUI subsided. Thankfully, she shared her experience,

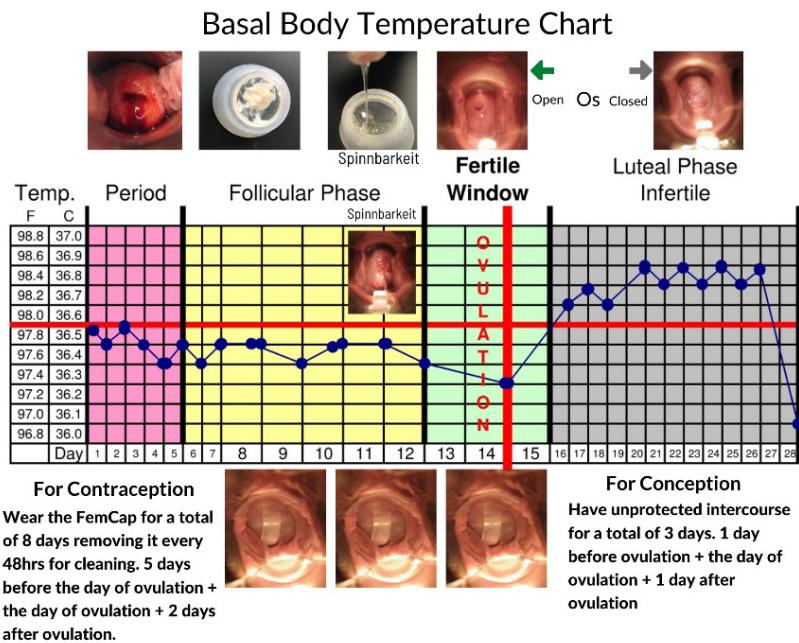


Figure 7: The Entire Menstrual Cycle with Contraception and Conception

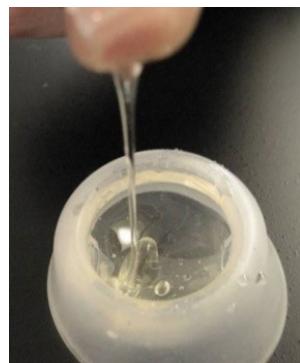


Figure 8: Fertile Cervical Mucus Sample Collected with FemCap



Figure 9: Pessaries Used for SUI



Figure 10: Ring Pessary



Figure 11: FemCap

FemCap Stress Urinary
Incontinence Study by
Dr. Alfred Shihata

Questions? Call Us: (858) 922-7673

Name: Emma from Sweden

Date Before using
Femcap :



How many times per day you have stress incontinence,
during the last week BEFORE using the FemCap you when
you:

	Mon	Tues	Wed	Thurs	Fri	Sat
Cough	2	2	1	3	3	2
Sneeze	3	1	2	2	3	3
Laugh	1	2	1	1	1	1
Stand up	1	3	2	2	2	2
Get out of a car	1	2	3	3	2	3
Lift something heavy	1	2	2	2	1	2
Exercise	3	1	3	2	2	2
Do you wear a pad?	Yes	Yes	Yes	Yes	Yes	Yes

You should insert the FemCap first thing in the morning*. Don't remove it until bedtime and then wash and store it in container until you use it the next morning.

*If you are using FemCap for birth control use spermicide

*If you are using FemCap for incontinence only use with a water soluble lubricant.

Figure 12: Before FemCap

Date After using
FemCap :

How many times per day you have stress incontinence, during the second weeks while using the FemCap:

	Mon	Tues	Wed	Thurs	Fri	Sat	Sun
Cough	0	0	0	0	0	0	0
Sneeze							
Laugh							
Stand up							
Get out of a car							
Lift something heavy							
Exercise							
Do you still wear a pad?	Yes	Yes	Yes	No	No	No	No

1. Did have any side effects from the FemCap? No
2. Will you consider using the FemCap in the Future to control your (SUI)? Yes
3. Comments I didn't have leakage when jumping on the trampoline while using the FemCap. Coughing and sneezing no longer was an issue when I had a cold while using FemCap

Figure 13: After Using FemCap

which led me to investigate a new usage for the FemCap as an SUI pessary (Figure 9-11) [6,7,8,9,10]. The first line of SUI treatment is pelvic floor muscle (Kegel) exercises and vaginal pessaries. The most popular is the ring pessary; however, a variety of shapes and sizes (Figure 9) are now available in hopes of achieving better results.

Methods

Ten universities throughout the United States have researched the FemCap. The FDA approval required the FemCap to pass three phases successfully. To ease the difficulty when removing the FemCap, we designed a new version known as the second-generation. The second-generation FemCap is currently the only cervical cap in the entire world with FDA & CE approval. A strap was added over the dome of the FemCap to alleviate the difficult removal. The first-generation FemCap was not as effective for women who had given birth vaginally. This reduced efficacy is due to a decline in vaginal tone, which increased dislodgment. To compensate for the decreased vaginal tone in multiparous women, we increased the brim's dimension to maximize the surface contact between the vaginal walls and the FemCap. The increased surface area helped improve stability, prevent dislodgment, and enhance effectiveness.

We previously conducted a pilot study using the FemCap to collect cervical mucus. The study showed that women could predict their ovulation day with precise accuracy [14]. In the study, we recruited 40 healthy women with regular periods. Participants used the FemCap (Figures 1, 2) to collect their cervical secretion directly from the cervix. The samples were taken from the end of menstruation until the fertile mucus was collected. Women recorded their basal body temperature on the basal temperature chart (Figure 7).

First, I looked at the similarities between the FemCap and vaginal ring pessary with support. The bowl of the FemCap dome (Figure 11) covers the cervix entirely and prevents it from prolapsing. The rim fits snugly into the vaginal fornices that support the bladder neck. The brim flares outward, pushing against the vaginal walls and the urethra anteriorly, thus putting pressure against the bulging of the urinary bladder into the anterior vaginal wall (cystocele). In other words, the brim restores the anatomy of the urethra and the anterior vaginal wall. This feature of the FemCap that restores the anatomy makes it ideal for the treatment and prevention of Stress Urinary Incontinence. The FemCap has similar features to the ring pessary with support, commonly used to control mild to moderate stress incontinence. The Rim of the FemCap supports the bladder neck, the brim supports the mid-urethra and the vagina, and the Bowl of the FemCap (Figure 14) supports the cervix and prevents it from descending into the vagina. The two investigators, Alfred Shihata, M.D, and Birgit Linderoth, Midwife of Falun of Sweden, had to investigate the feasibility of using the FemCap to manage SUI. The FemCap is soft and pliable with no metal inside.

We tried to recruit 30 women who would be eligible for a limited pilot study for three weeks. Eleven women declined to complete

the requirements. Nineteen women agreed to enroll and signed the consent form after explaining the risks and benefits as well as all the medical and surgical alternatives. Week one, we used as a control and asked the participants to record all the events that caused any SUI (Figure 12). In weeks 2 and 3, we instructed the women to insert the device in the morning and remove it, wash it, and store it in its container at night. They would continue this for two weeks (Figure 13). We also instructed them to report any side effects on the case record at the final check-in.

Results

FDA approved the second-generation FemCap and determined the device to be safe and effective for its intended use as a non-hormonal birth control method [6-10].

Women using the FemCap identified their preovulatory cervical secretions in 96% of cases. They also verified their ovulation by a positive urinary LH surge (Luteinizing Hormone). The Basal Body Temperature charts were biphasic and consistent with the LH surge results [14].

Sixteen out of 19 women or approximately 84% were completely dry after using the FemContinence. Two women or approximately 11% were partially dry more than half of the time. One woman or approximately 5% did not notice any change (Figure 14). We asked every woman to cough as hard as she could while wearing the FemContinence; nobody reported any leakage. Eight of them stopped wearing the sanitary pad because they were confident the FemContinence was working. The participants said they would use the FemContinence if available in the future and recommend it to friends and relatives. None of the participants reported any side effects from wearing the FemContinence.

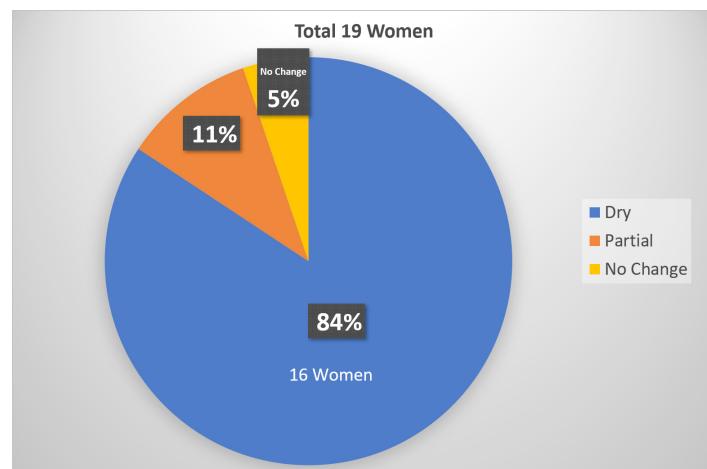


Figure 14: Data from SUI Study

Conclusion

The FemCap has many attributes and advantages over the current non-hormonal birth control options. Compared to the condom, it does not interfere with sexual pleasure for either partner. Compared to the IUD, the FemCap is non-invasive and under the control

of the woman, not a doctor. Unlike hormonal birth control, the FemCap does not have any significant side effects. In conclusion, the FemCap is safe, effective, and acceptable for contraception as declared by the FDA [6-10].

The FemCap, in combination with fertility awareness, women could pinpoint their ovulation day with astonishing precision [14]. This method shortened the fertile window to 3 days for conception and eight days for contraception (Figure 7). The FemCap let these women collect large quantities of their cervical secretions which, they described as clear raw egg-white that stretched about 2.5 - 3 inches before it broke. This simple non-invasive and low-cost method can maximize the chance of conception or contraception in healthy women having regular periods.

FemContinence is a simple, reusable, self-administered device, which is useful in preventing stress urinary incontinence. The design of the FemCap allows for anatomical restoration between the bladder, the bladder neck, and the urethra. In 90% of cases, it diminished or eliminated the symptoms of stress incontinence, interfering with the participants' quality of life. In 80% of the women, there was complete relief of urinary stress incontinence. The device kept these women completely dry when measured using eight dimensions of physical stress-induced incontinence. Based on our findings, more clinical trials are warranted to prove the utility of this device. The availability of a simple, low-cost, and non-invasive method should encourage clinicians to address more readily the usually "unspoken condition" of stress urinary incontinence.

Acknowledgment

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