RESEARCH ARTICLE

Multipurpose, Reusable, Female Contraceptive Device That Enhances the Effectiveness of Fertility Awareness Methods and Controls Stress Incontinence

Authors

*Corresponding author
*Shihata Alfred, M.D Scripps Institution of Medicine and Science San Diego, CA, USA alfred@femcap.com
Brody, Steven A. MD, PhD, Director of Life Span Medical Institute San Diego, CA, USA sbrody@gmail.com
Linderoth, Birgit, Midwife in Falun Sweden birgit@femcap.se
Julia Barrett- Mitchell, FemCap Inc., Clinical coordinator, 14058 Mira Montana Drive Del Mar CA 92014 julia@femcap.com

Abstract

Introduction: There is a significant deficiency in women's reproductive health needs:
1) Lack of options of non-hormonal contraceptive methods.
2) Fertility awareness method is the safest and yet it is rarely utilized.
3) Women suffer from Stress Incontinence silently.

Objectives: To provide women with one device that can be used for **1**) *Contraception* by stopping sperm from entering the cervix, **2**) *To enhance the effectiveness of Fertility Awareness Methods by accurately detecting ovulation day* and ***3****) Control Stress Urinary Incontinence* by supporting the bladder neck.

Materials and Methods: We selected the FDA approved FemCap contraceptive device to determine its utility to fulfill the three basic reproductive health needs for women.
1) The FemCap is a safe and effective, time tested, barrier contraceptive device.
2) The FemCap can collect a large amount of fertile cervical mucous, that is not mixed with vaginal secretions.
3) The use of currently available pessaries have significant limitations such as displacement, erosion or even ulceration and urethral obstruction.
The FemCap shows marked similarity to the ring pessary with support. The Rim of the FemCap is similar in shape and function to the ring of the 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 descending, which is like the supported pessary.
Results: 1) The FemCap is a well-established barrier contraceptive device. **2)** It is also has proven in pilot studies to enhance the effectiveness of fertility awareness methods and **3)** control stress incontinence.
Conclusion: It would be ideal and cost effective for women to acquire one multipurpose reusable device that can be used for contraception to enhance fertility awareness and to control stress incontinence.

Keywords: FemCap, contraception, urinary stress incontinence, Fertility Awareness Method

Background:

1) The FemCap (Figure 1,2,3,4,5,6) was originally designed in response to the HIV epidemic. The best way to protect a woman and support her reproductive health from HIV, is by protecting her cervix. In this case, that meant targeting the place where protection mattered the most; at the cervix![1,2,3,4,5] The FemCap was designed to conform to the anatomy and adapt to the physiology of the cervix and the vagina.[6,7,8,9,10] The FDA approved the FemCap as a safe, effective, non-hormonal option for contraception. Hormonal birth control has some dangerous effects on women's health and on the environment. Study after study we find the chemicals in these contraceptives can cause heart attack, stroke, cancer, mood swings, depression etc. A woman today can do a quick internet search to find a long list of side effects associated with hormonal contraceptives. Not only do these hazardous chemicals effect women they also wreak havoc on the environment. Women are obviously in need of more non-hormonal birth control options to protect themselves and the environment.

2) 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.[11,12,13] We attribute this to the fact that women miss the most important sign of ovulation during their fertile window, which is the fertile cervical mucous (Figure 7). The FemCap allows women to collect a large quantity and 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.

3) 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. A woman who was using the FemCap for contraception reported that she was suffering from Stress Urinary Incontinence. She stated that the days she used the FemCap (Figure 1,2,14) she did not suffer from SUI. This led me to investigate the use of the FemCap as a SUI pessary (Figure 10,13). [6,7,8,9,10]

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 10) have been introduced into the market with the hope of achieving better results. The most recent are Introl (Figure11) and Uresta (Figure 12). [15,16]

Figure 1: cervical, lateral and vaginal view

Figure 2: lateral view of FemCap

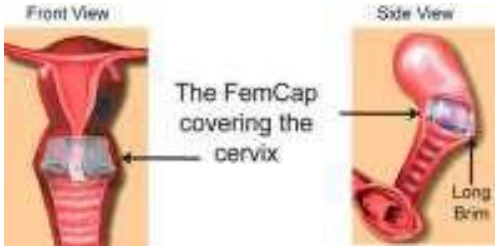


Figure 3: FemCap Covering the Cervix

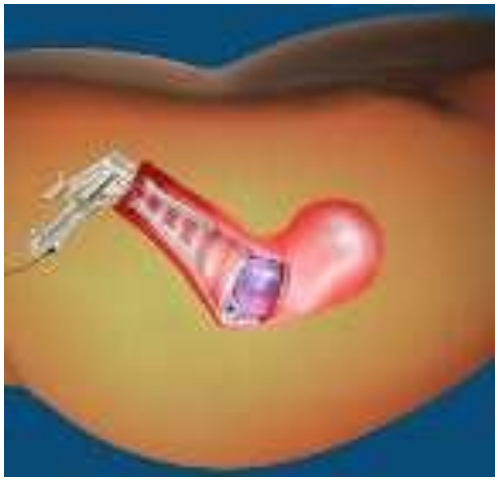


Figure 4: FemCap Seen Through the Speculum.

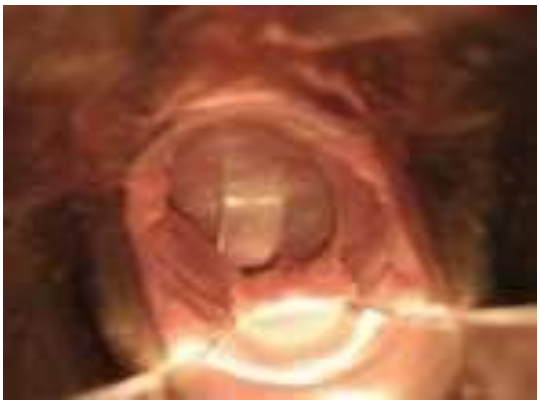


Figure 5: Live View of FemCap Covering the Cervix

Figure 6: How FemCap Works

Methods:

1) The FemCap was investigated in 10 universities throughout the United States. There were three phases required by the FDA that FemCap passed successfully. To enhance the effectiveness and the acceptability of the FemCap, a removal strap was added, and the dimension of brim was increased to enhance stability and effectiveness. This increased the surface contact between the brim of the FemCap and the vaginal walls did increase stability and effectiveness of the FemCap. This led the FDA to grant approval of the FemCap is referred to as the second generation.

2) We previously conducted a pilot study using the FemCap to collect cervical mucous that has shown that women can predict their ovulation day with precise accuracy.[14] This can greatly enhance the usability of the Fertility Awareness Method. In the study we recruited 40 healthy women with regular periods. Participants used the FemCap (Figure 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) which showed a biphasic temperature which is higher after ovulation.

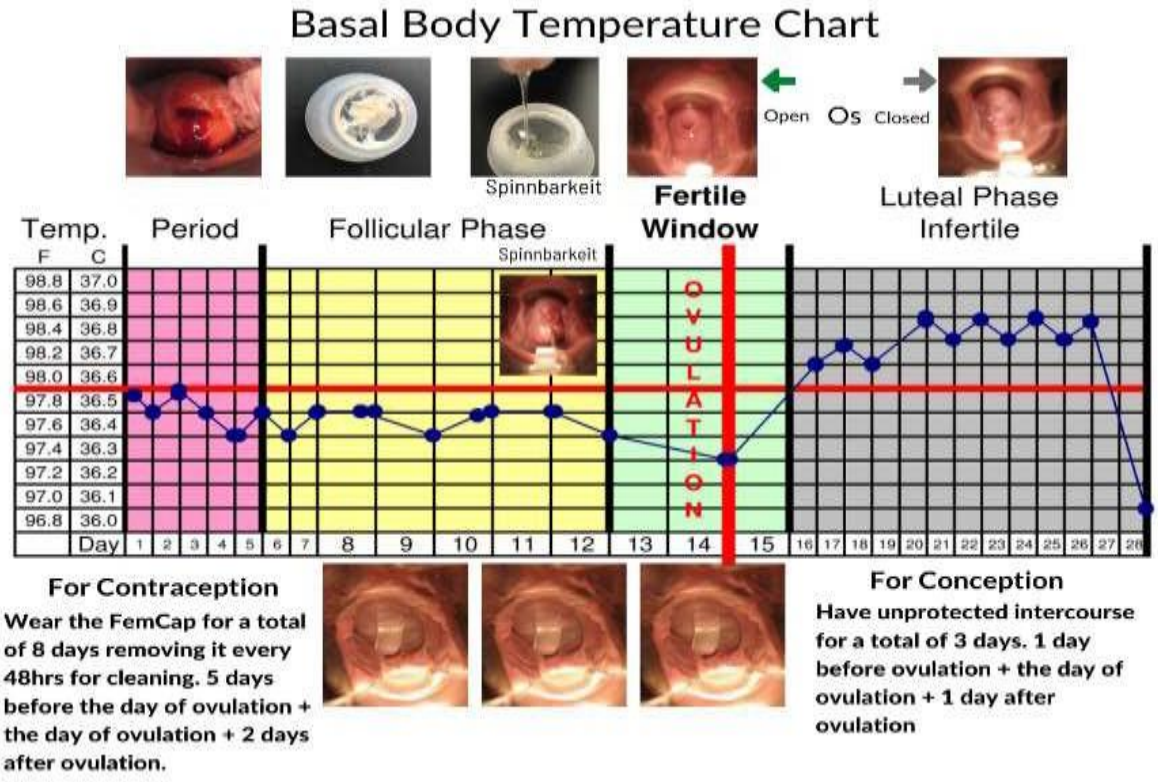
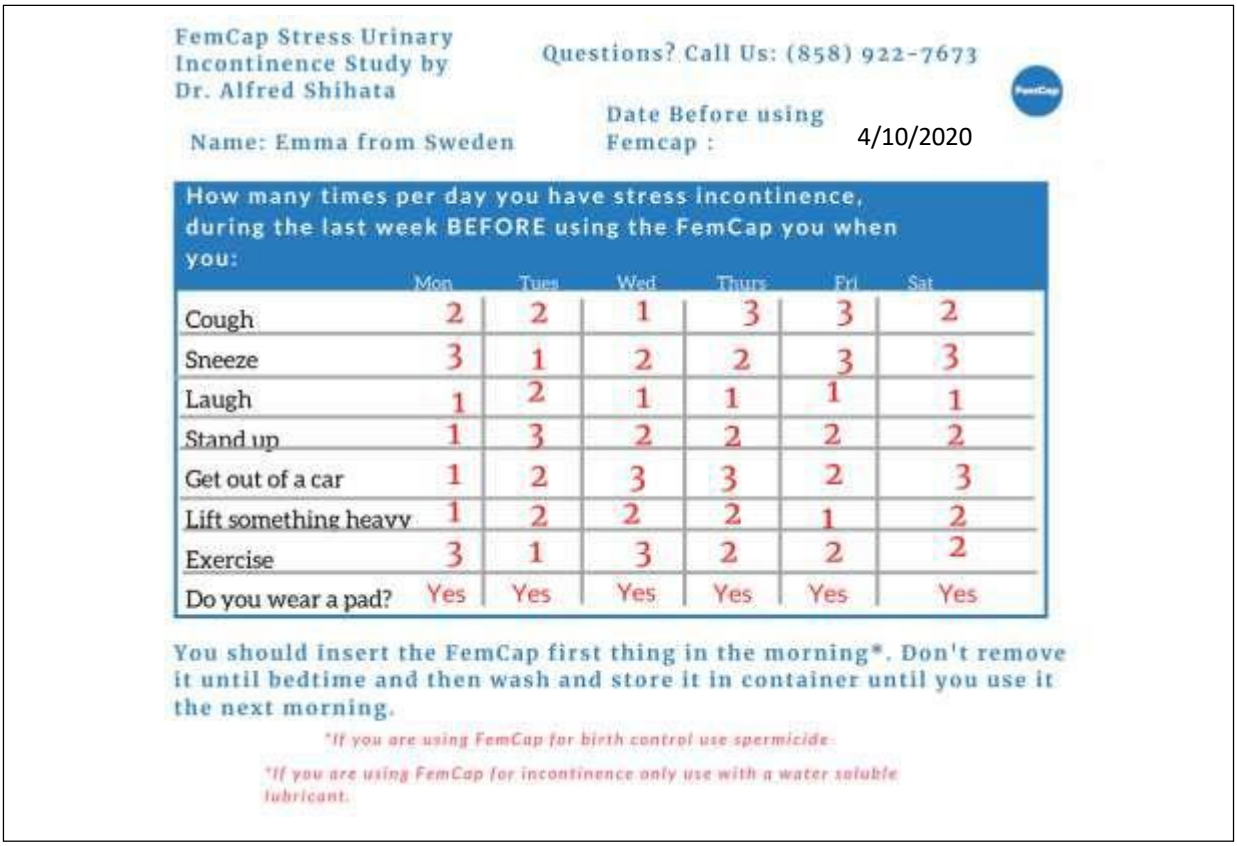


Figure 7: The Entire Menstrual Cycle with Contraception and Conception

3) First, I looked at the similarities between the FemCap and vaginal ring pessary with support. The bowl of the *dome* of the FemCap (Figure 14) covers the cervix completely and prevents it from prolapsing. The *rim* fits snugly into the vaginal fornices that supports the bladder neck. The *brim* is designed to flare 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, which is 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, MD 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 two weeks. 11 women declined to go through the study. 19 women agreed to enroll and signed the consent form after we explained the risks and benefits as well as all the medical and surgical alternatives. We instructed the participants to insert the device in the

morning and remove it, wash it and store in its container at night before going to bed. They would continue this for two weeks. We also instructed them to report any side effects on the case record form at the final check in.

Example Case Record form before using the FemContinence



FemCap Stress Urinary Incontinence Study by Dr. Alfred Shihata

Questions? Call Us: (858) 922-7673

Name: Emma from Sweden

Date Before using Femcap : 4/10/2020

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 8

Example case Record form while using the FemContinence

Date After using FemCap : 5/8/2020

How many times per day you have stress incontinence, during the second week 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

None

1. Did have any side effects from the FemCap? Yes

2. Will you consider using the FemCap in the Future to control your (SUI)?

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 9

State of the Art Pessaries

Figure 10

Figure 11

Figure 12

Figure 13

Figure 14

Results

1) FDA has approved of the second generation FemCap, and determined the device to be safe and effective for its intended use as non-hormonal birth control method .[6,7,8,9,10]

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

3) 16 women out of 19 women or approximately 84% of the participants were **completely dry**. Two women or approximately 11% were partially dry more than half of the time.
One woman or about 5% did not notice any change

Total 19 Women Finished the Clinical Trial

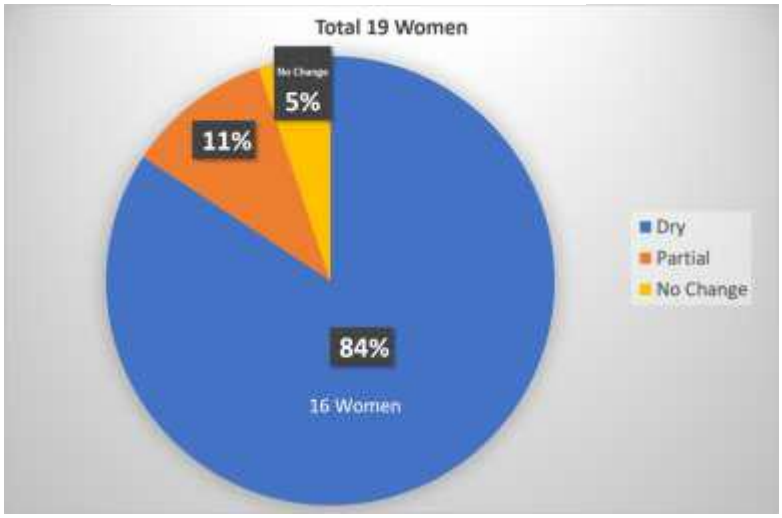


Figure 15

All participants showed up and were willing to procced with the clinical trials however, only 19 finished the clinical trial. 16 out the 19 that finished the clinical trial and were successful were completely dry all day. We asked every woman to cough as hard as she could while wearing the FemCap, none them reported any leakage. Eight of them stopped wearing the sanitary pad and said they will use the FemContinence if it is available in the future and will recommend it to friends and relatives. NONE of the participants had any side effects from wearing the FemCap.

Conclusion:

1) The FemCap has many attributes and advantages over the current non-hormonal birth control options. Compared to the condom it does not interfere with spontaneity or sexual pleasure for either partner. When comparing to the IUD the FemCap is non-invasive and under the control of the woman not a doctor. When looking at hormonal methods of birth control the FemCap does not inhibit desire or pleasure for the women and does not

have any significant side effects. In conclusion, the FemCap is safe, effective, and acceptable for contraception as declared by the FDA. [6,7,8,9,10]

2) Using 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 8 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.

3) FemContinence, (FemCap) is a simple reusable self-administered device which can be used for urinary stress incontinence. The design of the device allows for restoration of the anatomical relationships between the bladder, the bladder neck and the urethra. In 90% of cases it diminished or eliminated the symptoms of stress incontinence, which interfered with the quality of life of the participants. In 80% of the women there was complete relief of urinary stress incontinence. The device kept these women completely dry even when challenged by asking them to cough as much as they can to induce 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 noninvasive self-administered device should encourage clinicians to more readily address the usually "unspoken condition" of stress urinary incontinence.

Acknowledgement

This research article was submitted at the request of Dr. Smith Editor, Journal of Medical Research Archives. We are indebted to the women who consented to participate in this research study, and to Dr. Steven Brody who co-authored and edited this manuscript**.,** Ms. Linderoth Birgit. Midwife in Sweden and her patients who volunteered for the study. No funding was requested or received from any institution. The authors are responsible for the contents of this article.

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