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Advances in Hormone-Free Contraceptive Devices

Alfred A. Shihata, Steven A. Brody and Birgit Linderoth

Abstract

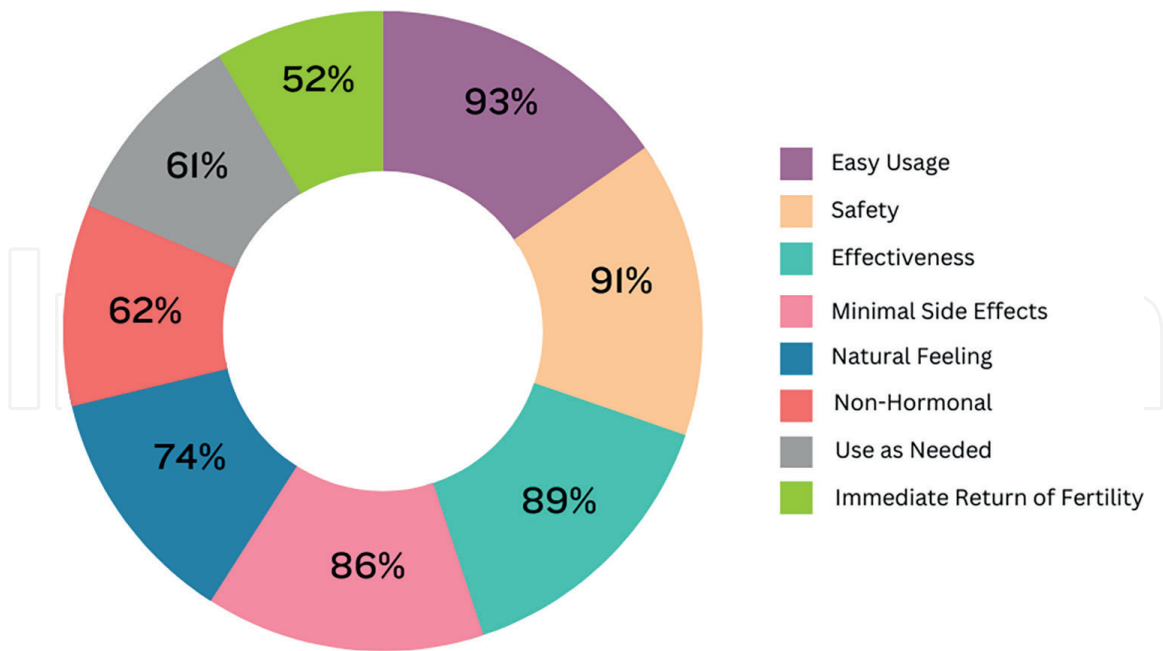
Up to (99%) of women worldwide may use birth control for at least 30 years. However, most modern female contraceptives containing hormones can have undesirable side effects. Among the limited hormone-free options, the fertility awareness method is the safest and most effective when used correctly. This study explores a time-tested, safe, and effective barrier contraceptive called FemCap. FemCap not only aids in pinpointing the day of ovulation but also integrates electronic period-tracking technology to enhance the efficacy of the fertility awareness method. Stress Urinary Incontinence is a prevalent issue affecting women of all ages, often suffering in silence. Our research aims to address the unmet needs in women's reproductive health. We have discovered that FemCap can function as a pessary to manage Stress Urinary Incontinence by providing support to the bladder neck and straightening the urethra, thereby restoring the competence of the urethral sphincters. FemCap has emerged as a powerhouse for fertility awareness and stress urinary incontinence. However, due to the limitations of this study, the authors welcome any investigators who can validate our findings as well as provide suggestions to enhance the overall value of this research for the benefit of all women.

Keywords: hormone-free barrier contraception, fertility awareness methods, FemCap, stress urinary incontinence, vaginal drug delivery, pairing FemCap with electronic period tracking application

1. Introduction

The authors organized a series of small focus groups to discover what women consider the ideal birth control (**Figure 1**). Over the past decade, a noteworthy breakthrough has been the creation of a hormone-free contraceptive device known as Caya diaphragm, which is designed to fit most women due to its unique one-size feature (**Figure 2**). Microbicides are experimental products that could prevent Human Immune Virus (HIV) transmission from male to female and vice versa (**Figure 3**).

Male and Female condoms are the only devices approved for preventing Sexually transmitted diseases (STDs). Though FemCap is not approved for the prevention of STIs, it has all the biological and plausible potential for the prevention of STIs, see the comparative (**Table 1**).



A Woman's Ideal Birth Control

Figure 1.
A women's ideal birth control.



Figure 2.
Caya Diaphragm vs. Wide Seal Diaphragm.

2. FemCap design and its evolution

The cervix was determined to be the main portal of entry for HIV and Sexual Transmitted Infections (STI) organisms for transmission from men to women. This is due to the Os opening of the cervix as well as the presence of chemokine co-receptors for HIV on the cervix, called Chemo Chine Receptor 5 (CCR5) and Chemo X Receptor 4 (CXR4). HIV first fuses with these co-receptors and then invades the immune cell CD4 (**Figure 4**) [1].

In response to the HIV/Acquired Immune Deficiency Syndrome (AIDS) pandemic and according to the scientific recommendation for the prevention of transmission of HIV from male to female [2], the first author developed the



Figure 3.
FemCap Used to Deliver Microbicide.

Comparison of the Male and Female Condoms with the FemCap			
	Male Condom	Female Condom	The FemCap
Gender Control	Male – controlled	Female- 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.	Can be applied 8 hours in advance of intercourse.	The FemCap does not interrupt spontaneity as it should be applied before sexual arousal.
Sexual sensations	It reduces the pleasurable sensation of intercourse to both partners.	Impaired sensation to both Male and Female	It does not reduce sensation to either partner.
Acceptability	It is not accepted by either partner, particularly the male	It is NOT Accepted by both partners. Particularly the female. It may not be used at all	It is well accepted by both partners
User failure	Men must apply the condom on erect penis. They must rush to avoid the loss of erection. This may lead to incorrect application or skipping the application completely.	User failure is common. Males penetrate between the condom and vagina, Condom expelled before, or during intercourse, which lead to failure.	The FemCap must be applied before any sexual arousal when the woman is not rushed. Once the woman learns how to apply the Fem Cap it will become an easy routine with minimal chance for user's failure.

FemCap, specifically designed to mechanically covers and seal the cervix and store and deliver the microbicide. He also developed a microbicide/spermicide to kill the sperm and invading HIV and STIs organisms upon deposition into the vagina. Both were patented [3, 4]. However, the microbicide was abandoned due to the presence of Nonoxyl-9.

Comparison of the Male and Female Condoms with the FemCap			
	Male Condom	Female Condom	The FemCap
Leaking and Breakage	The condom may leak or break even when it is used properly	It may leak	The FemCap does not to leak or break during usual use.
Allergy	Most male condoms are made of Latex, which can cause serious allergic reaction.	It is made of hypoallergenic materials.	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.	Storage at room temperature Has longer shelf life	Is made of durable material that can withstand extreme temperatures without any deterioration.
Cost	Costs \$.90 - \$1.00 for a single use.	Cost \$ 2-4 Dollars for a single use.	It comes with an instructional video online and Costs \$89, and it is reusable for 1-2 years, depending on the user.
Typical effectiveness	Effectiveness depends on the user. 83%	Effectiveness depends on the user. 79%	Effectiveness depends on the user. 92.4%
STIs prevention	If used properly from the beginning to the end of intercourse.	If used properly from the beginning to the end of intercourse.	Has the plausible potential for, Prevention however, it was not yet tested.
Hazard to environment	May pose environmental hazard if not properly disposed.	May pose environmental hazard if not properly disposed	Does not pose any environmental hazard.

Table 1.
Comparison of the Male and Female Condom with the FemCap.

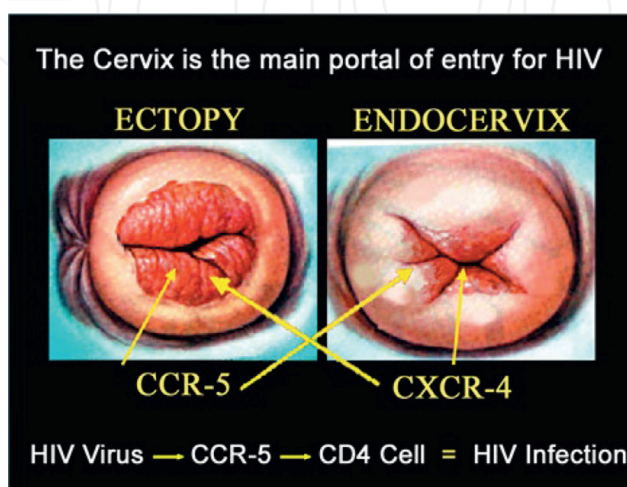


Figure 4.
HIV + CCR5+ CXR4 + CD4 cell = AIDS infection.

The first-generation FemCap (**Figure 5**) was not approved by the Federal Food and Drug Administration (FDA) due to the difficulty of removal and poor efficacy in multiparous women (**Figures 5–10**).

The second generation FemCap that is FDA APPROVED has a removal strap that improved its safety by eliminating the fingernail abrasion to the cervix. The increased dimensions of the brim increased the surface contact between the vagina and the FemCap, improving its stability. This is due to the fact that FemCap is held by the vaginal contraction preventing dislodgment and thus increasing its effectiveness and acceptability.

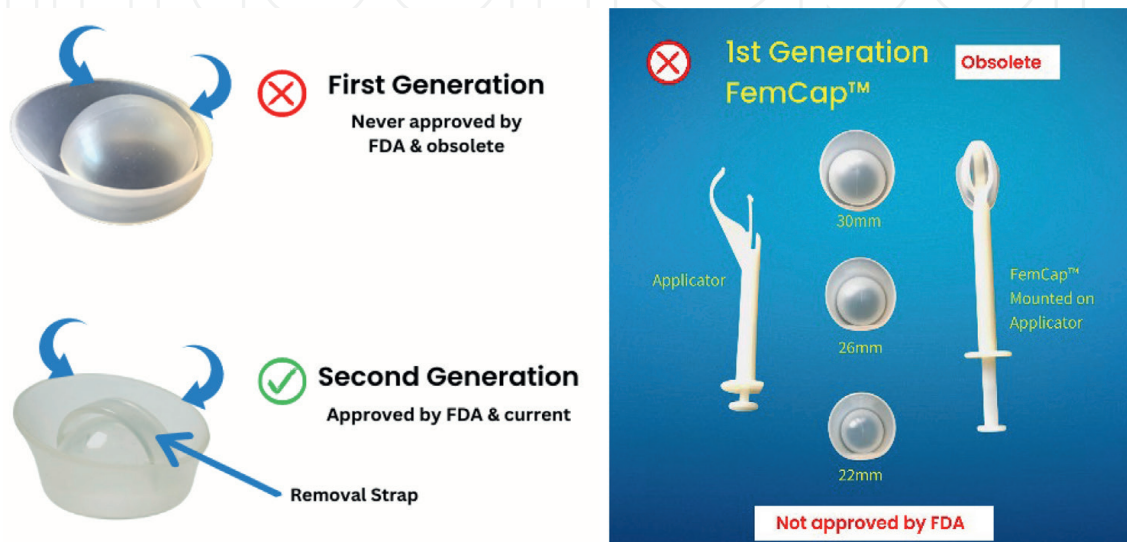


Figure 5.
First generation FemCap and the improved second generation.

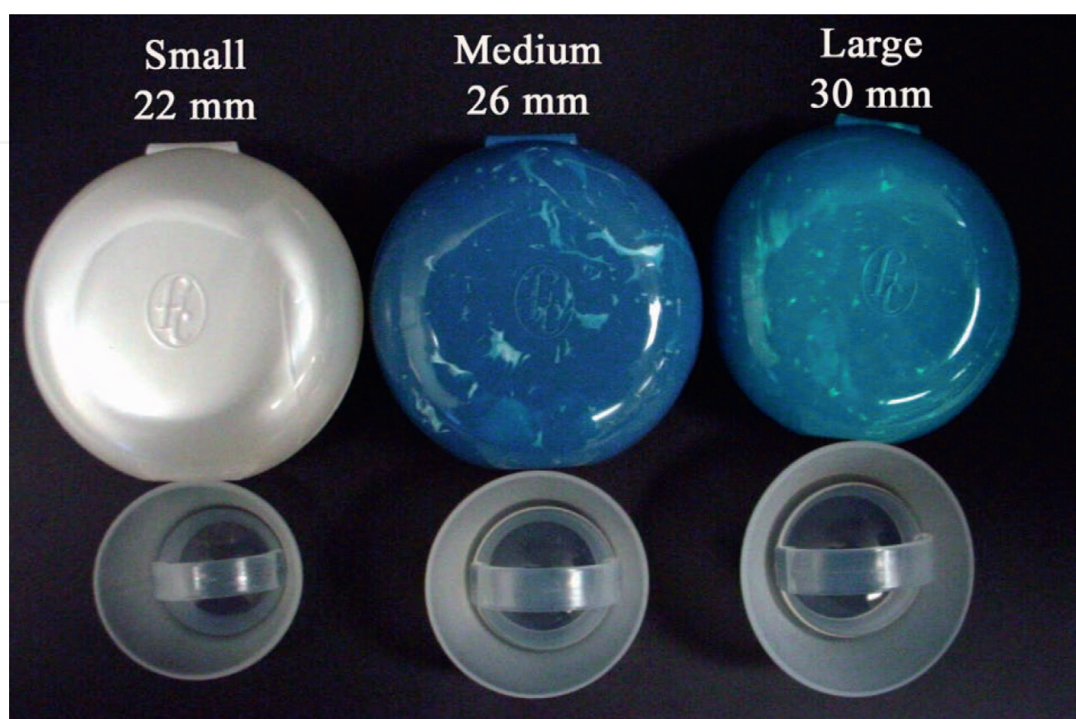


Figure 6.
FemCap three sizes.

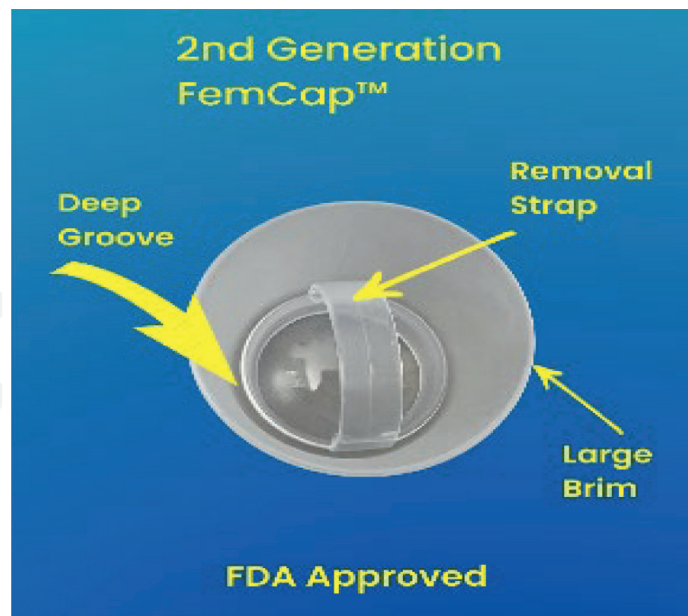


Figure 7.
Second generation showing improvements.

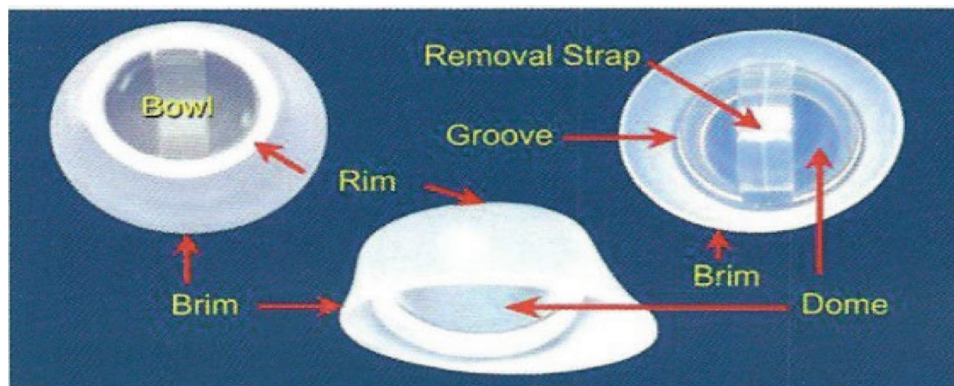


Figure 8.
FemCap diagram all views.

Unfortunately, some institutions still cite the obsolete effective rate of the first generation that was not used or approved by the FDA.

The following Video 1 (https://www.youtube.com/watch?v=4FgvJbl_X_M) will visually demonstrate the difference between the obsolete first-generation and the FDA-APPROVED second-generation. The references [5–8] will cite the difference in the effective rate of the first versus the second-generation FemCap.

Careful consideration was taken when designing FemCap's second-generation model. Its DOME provided full coverage for protecting the cervix and preventing it from prolapsing, while its RIM fits snugly into the vaginal Fornices and encompassed its entrance (**Figures 7–10**). A LIP was implemented to grasp onto her cervix to secure its hold (**Figure 10**). Regarding its BRIM formation, it had an outward flare to press against the inward vaginal contraction (**Figures 7, 10 and 11**), thus creating a tight seal, preventing sperm from penetrating along the vaginal walls. Anatomically wise as well, it possessed a more extended posterior section than other parts. Together these features bring about a comfortable and secure fitting of the FemCap.

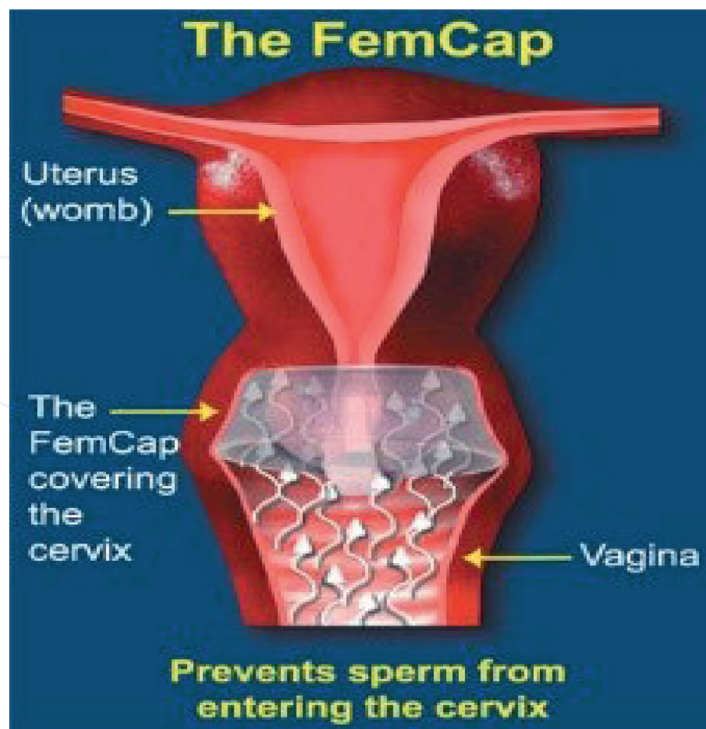


Figure 9.
FemCap covering cervix.



Figure 10.
FemCap views.

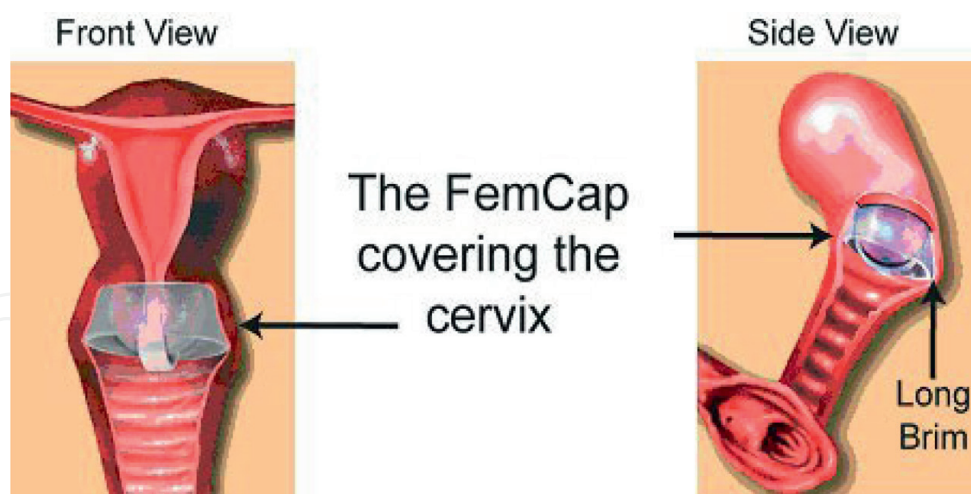


Figure 11.
The FemCap covering the cervix.

3. Size selection

Vaginal anatomy varies in different women and even in the same woman in response to pregnancy and delivery, so a one-size-fits all approach simply will not work. To solve this issue the FemCap comes with three sizes to choose from, the 22 mm for those who have never been pregnant, 26 mm for those who have experienced pregnancy without vaginal delivery (e.g. C-section or miscarriage) and 30 mm for women who have delivered vaginally (**Figure 6**).

Utilizing the 3 sizes eliminated the need for time-consuming and inaccurate measurement and custom fitting. The woman's obstetrical history determines the FemCap size selection.

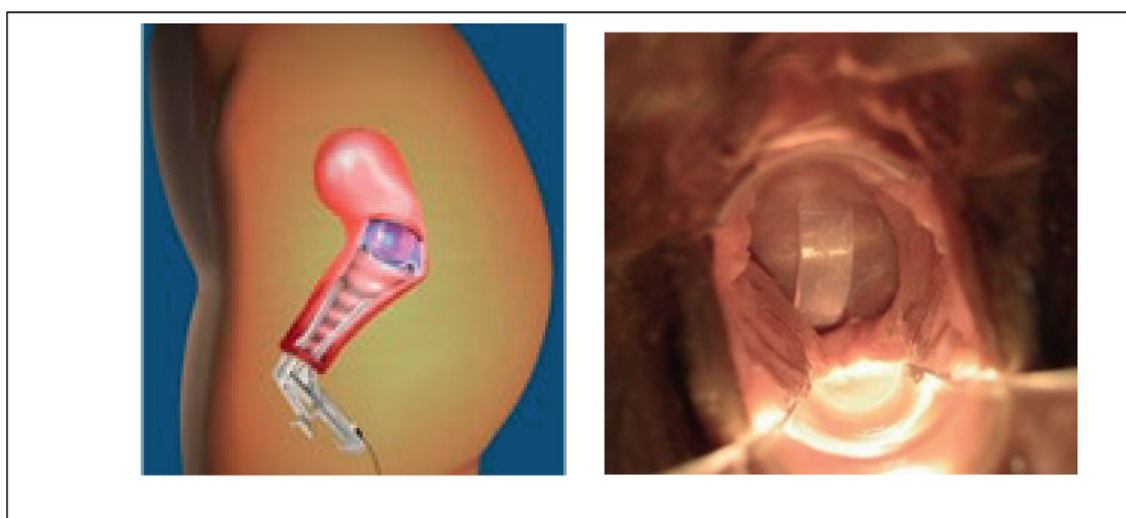
This study yielded an interesting outcome; the height and weight of women have no or very little relation to cervical diameter or vaginal elasticity. It was found out that pregnancy and delivery are the only factors that influence these two characteristics.

The FemCap is designed with a unique deep groove facing the vaginal opening. (**Figures 6, 7, and 9**) This groove was intended to trap and expose the sperm and bacteria or viruses to the spermicide upon deposition into the vagina for a prolonged period to ensure the complete killing of sperm and microorganisms (**Figure 7**).

The following Video 2 (<https://www.youtube.com/IZkxCbZ0WtU>) will visually explain the features of the second Generation FemCap versus the obsolete cervical cap.

FemCap provided a much-needed alternative to traditional hormone-based birth control and was quickly approved for contraception in both United States and Europe. Unfortunately, approval of FemCap for HIV/AIDS prevention was denied due to ethical and logistical considerations (**Figure 12**).

The FemCap is a well-established, time-tested, safe, and effective non-hormonal contraceptive device [5–12]. The FemCap have been used by women world-wide for two decades with good success and without any reported side effects. It has never been withdrawn from any country for any reason. The FemCap's unique storage groove for spermicide/microbicides can potentially be utilized to treat sexually transmitted infections topically (**Figures 8–11**).



FemCap viewed by Speculum.

Figure 12.
FemCap viewed by speculum.

4. The fertility awareness method

The Fertility Awareness Method (FWM) is the safest and most cost-effective contraceptive method, yet it is the least prescribed by clinicians and used by women. This method does not need equipment, drugs, or professional supervision after the initial training. There is also a common misconception that this method is difficult to learn and has a high failure rate. The subjective observation of collecting the fertile cervical mucous from the underwear or inserting a finger in the vagina may yield a very small amount of cervical secretions mixed with vaginal fluid. All the above factors might lead to missing the fertile window [13, 14].

We spared no effort in enhancing the effectiveness and simplifying the learning of this wonderful method [13–24]. We attributed the high failure rate to the fact that women miss the most vital sign of ovulation and thus miss their fertile window.

We used a two-prong approach to enhance this method's effectiveness and simplify its learning [13–24]. We utilized FemCap to collect the fertile cervical mucous directly from the cervix. Starting 2 days after the end of menstruation until the clear translucent stretchy preovulatory mucous (Spinnbarkeit) (**Figure 13**) appears just before ovulation. The FemCap allowed women to collect a large quantity and excellent quality of their fertile cervical mucous directly from the cervix. The FemCap also prevents the fertile cervical mucous from mixing with other vaginal secretions.

The following Video 3 (<https://www.youtube.com/watch?v=oYoYb0gM-w4>) will visually teach and simplify the learning of this method.

The second prong was using the Smart Telephone technology (**Figure 14**) to monitor the menstrual cycle and inform women of the fertile and infertile days. This innovative technology allowed women to pinpoint the precise day of ovulation, and thus they can decide whether to become pregnant or prevent it.

We recruited 40 healthy women with regular periods to participate in this pilot research. We randomized twenty women to use the traditional Fertility Awareness Method (FAM) with basal body temperature and the usual subjective

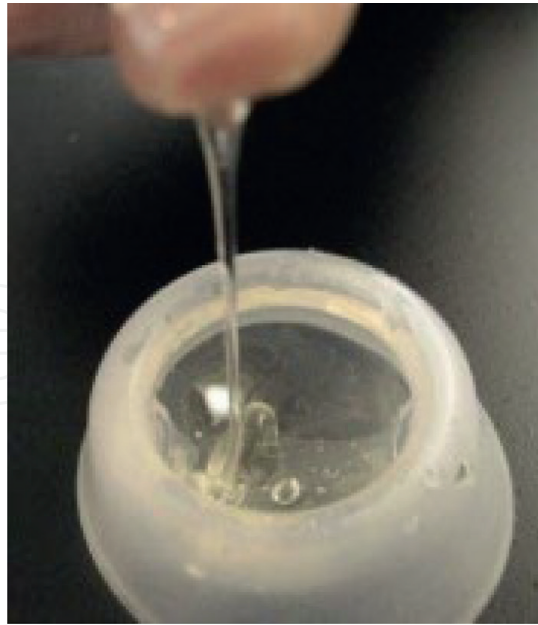


Figure 13.
Spinnbarkeit.

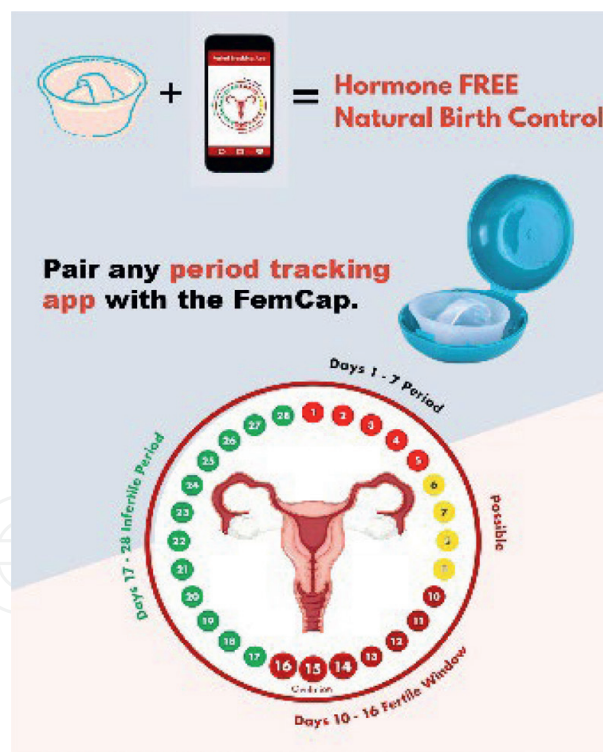


Figure 14.
FemCap paired with period tracking technology.

collection of fertile cervical mucus. The other 20 women used the FemCap to collect their fertile cervical mucus (Spinnbarkeit) directly from the cervix from day nine until they detected fertile mucus [22]. We also instructed women to record their findings and any side effects on the basal temperature chart (**Figure 15**) [14, 23].

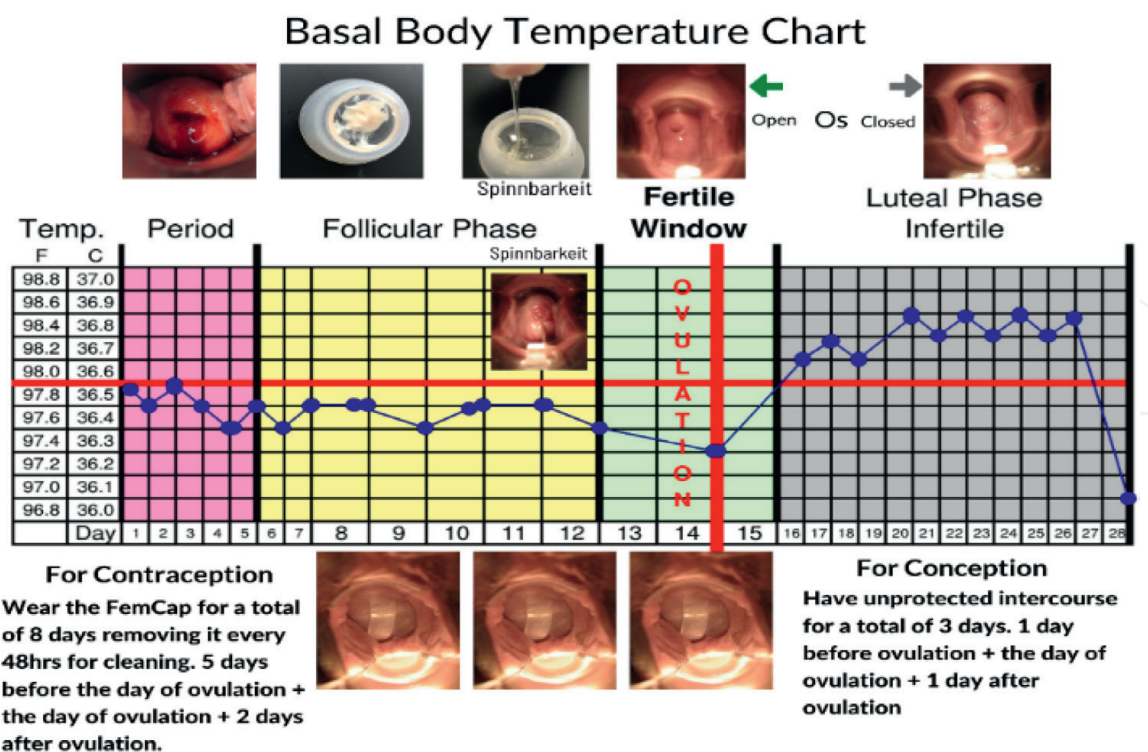


Figure 15.
 Basal body temperature chart.

5. Result

The results of this study utilizing the FemCap to collect the cervical mucus showed that 95% of the participants could accurately identify preovulatory fertile cervical mucus. These same users also verified ovulation with a positive urinary L.H. (Luteinizing Hormone) surge, accompanied by biphasic Basal Body Temperature charts (Figure 15) that supported the L.H. surge results.

However, the control group that used subjective detection of their fertile cervical mucus were successful in only 55%. Collecting cervical mucus directly from the cervix without mixing with any vaginal fluid content yielded higher quantities and better-quality samples (Spinnbarkeit). This enabled women to shorten fertile window to three days for conception, and eight days for contraception (Figure 15).

6. Conclusion

Collecting mucus directly from the cervix yielded a large quantity and excellent quality of fertile mucus. This allowed women to pinpoint the day of ovulation with astonishing precision.

The Smartphone Technology teamed up with FemCap, ultimately providing women with an unprecedentedly accurate prediction of their ovulation day. This new method established a three-day window for conception and eight days for contraception (Figure 15).

Women reported that FemCap allowed them to collect large amounts of top-notch cervical secretions that resembled clean egg whites; moreover, these could be stretched up to 2 inches before breaking. This simple, affordable strategy can

maximize success rates when trying to conceive or avoid pregnancy among healthy women with regular menstrual cycles.

Synergy created between the FemCap and a Smartphone application (**Figure 14**) provides the safest and most cost-effective birth control without side effects. Investigators and nurses should be encouraged to validate this pilot study.

7. Stress urinary incontinence

Stress Urinary Incontinence (SUI) is prevalent among women of all ages, particularly menopausal women. Women are embarrassed to complain about stress incontinence and silently endure the inconvenience and shame. The (SUI) is under-reported by women, which leads to under-diagnosis and under-treatment [24].

A woman using the FemCap for contraception reported to the first author that she noticed that on the days she wore the FemCap, for contraception, she did *not* suffer from incontinence. Consequently, she decided to wear the FemCap even when she did not need it for contraception [25–27].

This woman's observation led us to investigate a new usage for the FemCap as an SUI pessary (**Figures 16–18**). The current state of the treatment for SUI is pelvic floor muscle (Kegel) exercises and vaginal pessaries. The most popular is the ring pessary; however, various shapes and sizes (**Figures 19–21**) are now available to hopefully achieve better results before recommending surgery. The most recent are Uresta (**Figure 20**) and Introl, and Revive (**Figure 21**).

We began our analysis by comparing the FemCap with the vaginal ring pessary with support (**Figure 16**). The bowl of the FemCap (**Figures 16 and 17**) is designed to secure itself entirely around and below the cervix thereby preventing it prolapse. Additionally, its rim fits closely into the fornices, providing support to the bladder neck (**Figure 21**). The out flaring of the brim distributes pressure evenly against the vaginal wall, the cystocele and over the mid- urethra to restore the anatomy of the cystocele and to straighten the urethra. The FemCap offers a unique advantage when treating or preventing Stress Urinary Incontinence.



Figure 16.
Ring pessary with support.



Figure 17.
FemContinence pessary.



Figure 18.
Vaginal pessaries.

Unlike the ring pessary with support, that usually have a metal knob (**Figure 16**) The FemCap is composed entirely of soft, pliable material. The knob and the rim of the ring pessary with support has an internal metal to exert pressure against the Cystocele and the urethra (**Figures 16** and **20**).

The investigators, Alfred Shihata and Birgit Linderth, Midwife of Falun of Sweden, did investigate the feasibility of using the FemCap to manage SUI (**Figure 21**) [28].

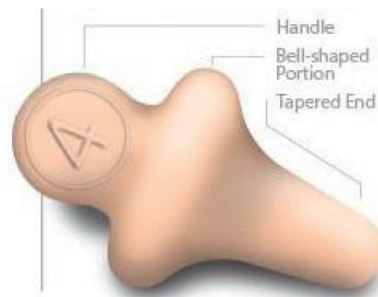


Figure 19.
Courtesy of Uresta.

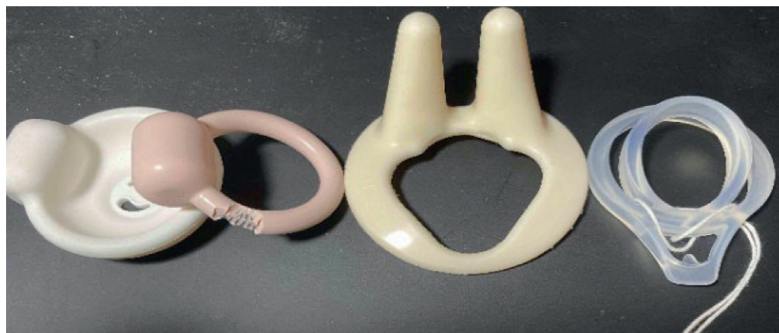
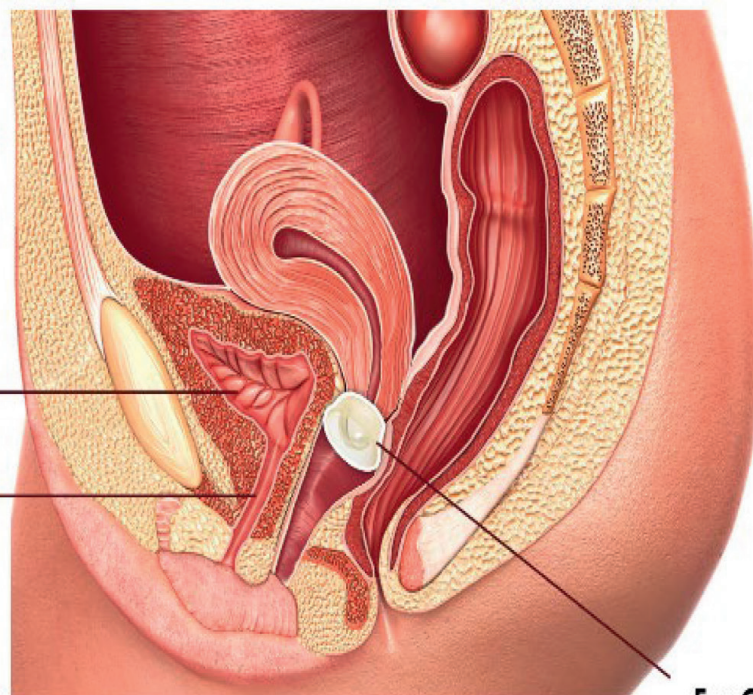


Figure 20.
Ring pessary with support & knob, intral, revolve.

**Restored
Normal
Anatomy**

Bladder

Urethra



FemCap

Figure 21.
FemCap Restores Anatomy.

The Current management of mild to moderate SUI is Kegel exercise and ring pessary. We conducted a limited pilot study for 2 weeks to validate the experience of the woman who used the FemCap to control her Stress incontinence. We were pleasantly surprised to validate her experience [29]. We were encouraged and decided to expand the study into Sweden and increase the number of participants [28]. It is worth mentioning that we enrolled 118 women in a very short time.

This study protocol included women with mild to moderate SUI, but those with severe incontinence or 3rd-degree prolapse were excluded.

We asked women to record each episode of incontinence and what precipitated it for one week before using the FemCap, (Table 2), as the women's her own control.

We instructed women to follow the same protocol above while using the FemCap (Table 3). That Shows the same woman's experience while using FemContinence (FemCap).

7.1 Results

99 women completed the study; 85 were completely dry while using the FemCap. Nine (9) women were partially dry, and 5 women were not satisfied with the results. Ninety-four women, including the partially dry said, they would like to use the FemContinence if available. No side effects were reported by the participants, and pelvic examinations did not show any erosion or ulceration of the vagina. (Tables 2 and 3) are an example of a woman who became completely dry [28].

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[*]. Do not 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.						

Table 2.
 Incontinence tracker the week before trying FemContinence.

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?							
2. Will you consider using the FemCap in the Future to control your (SUI)?							
3. Comments I did not 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							

Table 3.
Vaginal drug delivery.

7.2 Conclusion

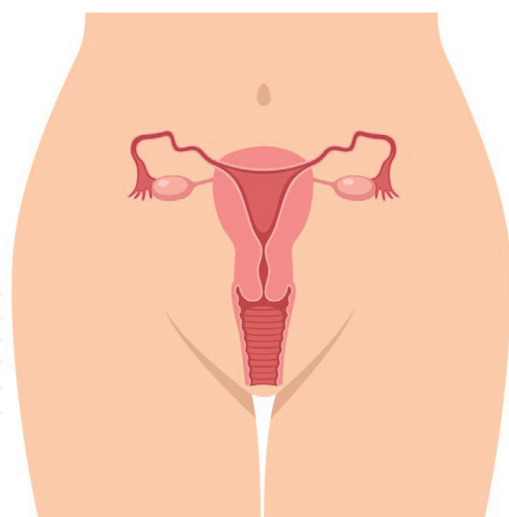
The innovative *FemContinence* (FemCap) device provides a safe, reusable, and self-administered treatment to help manage stress urinary incontinence. The FemCap was able to restore the anatomical structure of the bladder, the bladder neck, and the urethra. Research has revealed that in 85% of cases, this device reduced or eliminated symptoms that negatively impact the overall quality of life. This presents an ideal, low-cost, non-invasive solution for clinicians treating a condition often unspoken about. Further clinical trials should be conducted to verify these results.

Due to the small number of the participants and limitation of this study we welcome any investigator who would like to validate this study. As a token of our appreciation, we will provide all the FemCap (FemContince) free of charge for treating or preventing mild to moderate Stress Urinary Incontinence (SUI). We would not have achieved this result unless the FemCap did restore and maintain the anatomy and by supporting the bladder neck and straighten the urethra and thereby made the urethral sphincters competent.

8. Vaginal drug delivery by the FemCap

Millions of women have used and still using vaginal applicators to introduce creams and gels into the vagina. The regular rhythmic contraction of the vagina is designed to rid itself of menstrual blood and cervical discharges, as well as any treatment-oriented vaginal creams that could be rendered them less effective through these natural forces (**Figures 22 and 23**).

Video 4 (<https://www.youtube.com/watch?v=6JNFIOoXeLI>) describe the alternative to the currently available vaginal Applicator.



Vaginal Expulsion of cream

Figure 22.
Vaginal expulsion of cream.



Figure 23.
Shower-head applicator.

The first author developed a showerhead applicator for better distribution and retention of therapeutic vaginal medications. Unfortunately, the vagina did expel the cream rendering them less effective.

The primary focus of this study was to analyze the possibility of offering women an alternative to traditional vaginal applicators and investigate how long FemCap, a new cervical barrier, could keep therapeutic preparations in contact with the cervix and vagina. We wanted to see whether FemCap could effectively treat Bacterial Vaginosis, Candida infections, and some sexually transmitted diseases topically. To prove this concept, we recruited 40 women to insert a stained gel with Gentian violet into the vaginas.

To assess the efficacy of the FemCap device, we randomized women into two groups. Group A of 20 women used a vaginal applicator as the control, and group B employed the FemCap to insert the identical gel into their vaginas. Pads were provided for monitoring any expulsion of the gel while using the traditional applicators and the FemCap. We photographed the cervix and the vagina at 12 and 24 hours.

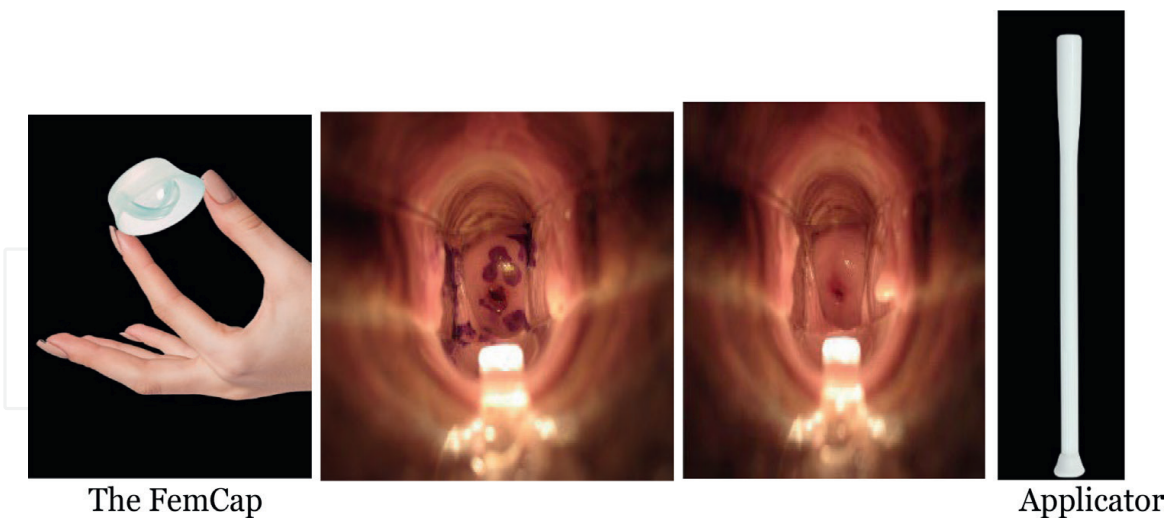


Figure 24.
The FemCap retained stain over 24 hours vs. The applicator.

(See **Figure 24**).

8.1 Results

During the study, no adverse effects were noted among participants in either group that used the stained gel. Interestingly, several women reported leakage while using a vaginal applicator. While none of the women who used the FemCap had any leakage. Upon examination of cervical photographs taken 12 hours and 24 hours after insertion. Women who used the vaginal applicators had no visible stain after 12 hours. The Stain was visible over the cervix, 24 hours after insertion, with the FemCap.

8.2 Conclusion

This pilot study results showed that, applications of vaginal preparations by the FemCap into the vagina will have better retention and distribution than if it were applied with vaginal applicator.

Further research should investigate whether FemCap can effectively treat ailments such as bacterial vaginosis, candida, and some STIs like gonorrhoea and chlamydia topically.

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