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Smartphone Technology Paired with a Vaginal Conforming Cap to Enhance the Fertility Awareness Method for Modern Women

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ABSTRACT

Background: Fertility Awareness Method (FAM) cost-effective and the safest contraceptive method yet it is rarely used.

Objectives: A) Familiarize women, and clinicians with the enhancement to the fertility awareness method.

- B) Persuade investigators to validate this pilot study by providing additional research.
- C) Allow women to pinpoint the precise day of ovulation.

Materials and Methods: We recruited 40 healthy women with regular periods to participate in this pilot research for 3 months. 20 used the traditional FAM with basal body temperature and fertile cervical mucus. The other 20 women used the conforming vaginal cap to collect their fertile cervical mucus (Spinnbarkeit). Starting at day 9 they collected samples directly from the cervix until they detected fertile mucus. We also instructed them to record their findings and any side effects.

Results: Women using the vaginal conforming cap identified preovulatory fertile cervical secretions in 95% of cases. They also verified ovulation with a positive urinary L.H. (Luteinizing Hormone) surge. Basal Body Temperature charts were biphasic and consistent with the L.H. surge results. The control group who used the subjective detection were only 55% successful.

Conclusions: Collecting mucus directly from the cervix yielded a large quantity and excellent quality of (Spinnbarkeit). This allowed women to pinpoint the day of ovulation with astonishing precision. This shortened the fertile window to 4 days for conception and 9 days for contraception. The Synergy created between the vaginal conforming cap and a Smartphone application will provide the safest, most cost-effective birth control without side effects.

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Introduction

A woman produces one egg per month [1]. This egg will stay viable for fertilization for only 24-36 hours. If the egg is not fertilized, it washes out with menstrual fluid. On the other hand, sperm can remain viable in the cervix for 5-7 days waiting to fertilize the egg [2]. The basal body temperature stays below its baseline before ovulation and then rises by 0.6-0.8°F after ovulation (biphasic basal body temperature). The level of cervix remains low before ovulation, then becomes higher in the vagina after ovulation, the cervical OS becomes wide open, during ovulation. The most important sign of ovulation is the fertile cervical mucus (Spinnbarkeit) [3]. (Figure 1) The Spinnbarkeit mucus is stretchy and translucent like an egg white to facilitate the upward movement of the sperm to fertilize the egg. These symptoms will aid women in deciding whether to conceive or contracept. Infertility and subfertility are major problem worldwide and it keep getting

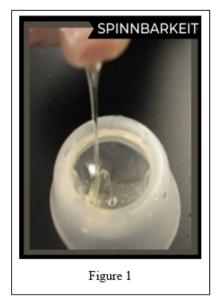
worse, particularly in major metropolitan cities which are cause low sperm count due to pollution and stress. Timing of intercourse during the fertile window would help a couple to conceive if their subfertility is due to low sperm count.

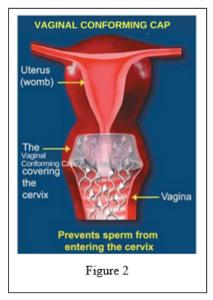
Materials and Methods

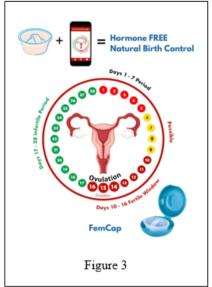
We recruited 40 healthy women with regular periods (every 28 days) to study the Fertility Awareness Method for 3 months. We instructed women to collect their fertile cervical mucus (Spinnbarkeit) directly from the cervix with a vaginal conforming cap (FemCap) [4-10]. (Figure 2) This is to ensure collecting an excellent quality of cervical mucus without any vaginal fluid. We also instructed women to collect their fertile cervical mucus daily starting from day 9 and onward until they identified the translucent stretchy mucus (Spinnbarkeit). We asked women to bring the FemCap with fertile cervical mucus to the clinic for verification. This can determine the exact time of ovulation, thus enhancing the fertility awareness method. The woman will pair the vaginal conforming cap (FemCap) with any smartphone period tracking application to understand where she is in her cycle. (Figure 3)

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To maximize the potential of this innovation, the basal body temperature can narrow the window and increase the accuracy even further.

If the woman wants to prevent pregnancy she should wear the vaginal conforming cap before intercourse, during the fertile window for 9 days, six days before ovulation, the day of, and two days after ovulation. (Figure 4) On the other hand, if the goal is to conceive, the woman should have unprotected intercourse during the fertile window. The fertile window starts with the appearance of the pre-ovulatory fertile cervical mucus (Spinnbarkeit) and ends 2 days after ovulation a total of 4 days. This can precisely predict the fertile window. Since ovulation occur following the (Spinnbarkeit), Women can pinpoint when they are ovulating and engage in unprotected intercourse.

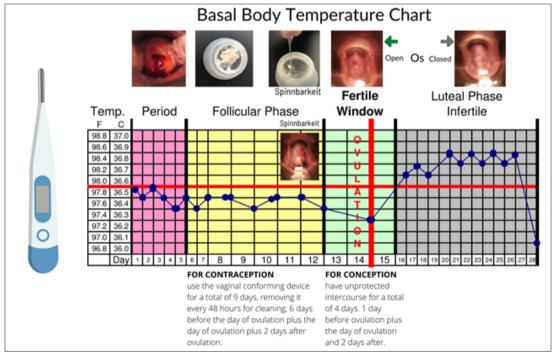


Figure 4

Pro: Natural, no side effects, non-hormonal and non-invasive.

Cons: Does not protect against sexually transmitted diseases. Work best for women who have regular period.

Results

Of the 20 women in the control group, 11 (55%) were successful in detecting their fertile mucus. The control women used the subjective traditional detection of cervical mucus by inserting their finger into the vagina to examine the collected mucus for clarity and stretchability. Nineteen (19) out of 20 women (95%) using the vaginal conforming cap (FemCap) did identify their preovulatory fertile cervical secretions. They also verified their ovulation by a positive urinary L.H. (Luteinizing Hormone) surge. Their Basal

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Body Temperature charts were biphasic and consistent with the L.H. surge results.

Data Collection

The data below shows the control group of 20 women. 9 of them or 45% missed the detection of the fertile mucus. (Table 1) This is due to mixing vaginal contents with the fertile cervical mucus, which masks the clarity and strechabilty. In the variable research group of 20 women using the FemCap,19 out of 20 (95%) were successful in detecting their fertile mucus.

Table 1

	Table 1	Detection of Fertile Cervical Mucus (Spinnbarkeit)						
	Using the Vaginal Conforming Cap				Using traditional subjective method (control)			
	Name Code	Month 1	Month 2	Month 3	Name Code	Month 1	Month 2	Month 3
1	SS	+	+	+	MA	+	+	+
2	NA	+	+	+	KC	+	+	+
3	KR	+	+	+	LS	•	•	•
4	LS	•	•	•	NR	+	+	+
5	NC	+	+	+	EL	+	+	+
6	KA	+	+	+	MS	•	•	•
7	LC	+	+	+	NR	•	•	•
8	NA	+	+	+	CK	+	+	+
9	MS	+	+	+	MI	•	•	•
10	VG	+	+	+	VR	•	•	•
11	EI	+	+	+	IG	+	+	+
12	SR	+	+	+	KR	•	•	•
13	AB	+	+	+	EI	+	+	+
14	KA	+	+	+	MA	•	•	•
15	NE	+	+	+	AS	•	•	•
16	MR	+	+	+	NA	+	+	+
17	AB	+	+	+	MR	+	+	+
18	MR	+	+	+	OG	+	+	+
19	LC	+	+	+	AR	+	+	+
20	NI	+	+	+	ME	•	•	•

Discussion

The FemCap is an FDA, and EC approved birth control method. Since its introduction to the market over 20 years ago, the FemCap has been used by thousands of women worldwide and is more relevant today. The FemCap has no systemic or local side effects and can be used as a stand-alone contraceptive. FemCap is designed to conform and adapt to the physiology of the anatomy making intercourse feel more natural. It comes in 3 sizes to allow fitting for all women. The smallest size 22mm fits nulligravida women, the medium size 26 mm fits women who have been pregnant but did not deliver vaginally. Some examples would be miscarriage, abortion or Cesarian section. The 30mm is designed for women who delivered vaginally. The recent technology of menstrual cycle tracking applications on a Smartphone is useful in determining what stage of the menstrual cycle they are in fertile or infertile. Pairing the smartphone technology with the vaginal conforming cap created a new way to enhance fertility awareness method. Conclusions: Women are in desperate need of non-hormonal and non-invasive and self -employable birth control method. The synergy created by collecting the fertile cervical mucus by the vaginal conforming contraceptive device, (FemCap) in conjunction with smartphone allowed women for the first time to precisely pinpoint the ovulation time and thus enhancing the fertility awareness metho [11-19].

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