Evaluation of the Lady Free Biotester® in Determining the Fertile Period

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Small hand-held microscopes have been developed for self-observation of salivary ferning patterns to detect the fertile time of a woman's menstrual cycle. The purpose of this study was to evaluate one such microscope, the Lady Free Biotester®, by comparing it with the self-observation of cervical-vaginal mucus and with the self-detection of luteinizing hormone (LH) in the urine. Twelve natural family planning teachers (average age 34.6 years) observed their cervical-vaginal mucus, tested their urine for LH, and observed salivary and cervical-vaginal mucus ferning patterns (with the Lady Free Biotester) for two menstrual cycles. Data indicated that there was a strong correlation between the LH in the urine and the peak in self-observed cervical-vaginal mucus ferning (r = 0.99, p ≤0.001) and salivary ferning (r = 0.98, p ≤0.001). However, it was difficult to assess the beginning and end of the fertile time based on the salivary ferning patterns. Further testing of salivary ferning patterns is recommended before widespread use of these devices for family planning.

In recent years, a variety of small hand-held microscope "fertility testers" have been developed and marketed for the purpose of self-observing ferning patterns in either saliva or cervical-vaginal mucus. Theoretically, the ferning (or crystallization) pattern of saliva coincides with the female fertile period. The ferning is caused by NaCl, which cyclically increases under the influence of estrogen.[1] A user of these "fertility tester" microscopes either licks or smears saliva on a small plastic slide and, after drying for 5–20 min, looks through the lens (in front of a light source) for a defined ferning pattern. If there is an observed ferning pattern, the woman is fertile; if there is none, she is not. These microscopes are small enough to be placed in a purse, range in price from US \$39 to \$75, are reusable, and have a magnification of about 50–75 times.

In 1993, two studies were reported in which participants had interpretable salivary ferning patterns using a pocket microscope during the same period as other markers of fertility, including basal body temperature, cervical mucus, and ultrasound-observed follicular collapse.[2,3] The reseachers in these two studies recommended that further research be conducted to improve the use of salivary ferning for family planning. One method of determining the accuracy of hand-held microscope fertility monitors is to compare them with standard markers of ovulation, eg, cervical-vaginal mucus changes and luteinizing hormone (LH) in the urine.[4,5] The purpose of this study was to evaluate the accuracy of one handheld microscope, the Lady Free Biotester® (KMC International, Pasadena, CA), by comparing it with self-observation of cervical-vaginal mucus and urinary LH.

Materials and Methods

The participants were 12 volunteer, married, female, natural family planning (NFP) teachers. Their mean age was 36.7 years (range 30–44); they had an average of 3.3 children (range, 0–7), had been married a mean of 13 years (range 1–22 years), and had used NFP for an average of 12 years (range 6–20). All of the participants were nonsmokers and had no known fertility problems.

The LH surges in the urine was self-detected by use of the OvuQuick One-Step ovulation predictor (Quidel Corp., San Diego, CA). The test has a reported LH sensitivity of 30 mIU/mL. Laboratory studies have shown OvuQuick to have an accuracy >99% and in consumer studies an accuracy >96%.

The peak day of cervical mucus was determined by means of the Creighton model (CrM) vaginal discharge recording system (VDRS), developed through research conducted at St. Louis and Creighton University over a 5-year period.[6] The recording system requires that women check for cervical mucus by wiping the outside of their vaginas (the vulvar area) every time they void and once before going to bed. The women check mucus for color, stretch, and consistency. The VDRS is used to rate and chart the mucus most likely to indicate fertility. The VDRS has a reported 99% method-effectiveness and a 95% use-effectiveness for determining fertile and nonfertile days of the menstrual cycle.[6–8] According to the CrM the peak day of fertility is the last day of self-observed cervical-vaginal mucus in a woman's menstrual cycle that is clear, stretches more than an inch, or has a lubricative sensation. The fertile period with the CrM is defined as starting from the first day of self-observed cervical-vaginal mucus and continuing through the third full day after the peak day.

Salivary and cervical-vaginal mucus ferning was determined by viewing dried saliva and cervical-vaginal mucus on a small plastic lens with the Lady Free Biotester (see Figure 1). The ferning was rated from 1–3, with 1 = no visible ferning (random and unconnected dots), 2 = partial ferning (a combination of dots and ferns), and 3 = full or peak ferning (complete fernlike patterns). The manufacturer of the Lady Free Biotester considers the #1 rating to be nonfertile, the #2 rating as a transition stage and potentially fertile, and the #3 rating as fertile. Some manufacturers (eg, that of the PFT-123) consider the complete fern-like pattern to be the time of ovulation. For this research study, the peak in salivary and cervical-vaginal ferning was considered the last day of the highest rated ferning pattern.

Twelve experienced, female, NFP teachers were solicited in person and by telephone from the membership of the American Academy of Natural Family Planning. All participants signed written consent forms that explained the study, level of participation, risk involved, and option for withdrawing at any time. The study was approved for human subjects through the Marquette University Office of Research and Sponsored Programs. Each participant was given verbal and written instructions along with

two LH ovulation prediction kits, two Lady Free Biotesters, and two fertility charts. The LH test kits provided enough material for 9 days of testing. The participants were provided with both oral and written instructions for the proper use of the Lady Free Biotester (ie, how to test their saliva and cervical mucus for a ferning pattern) and how to use the LH test kits. One Biotester was to be used for the saliva and the other for the cervical-vaginal mucus. Participants were asked to check their urine once a day for the LH surge and record the results on their fertility charts. They were also asked to test for salivary ferning with the Lady Free Biotester twice a day, once in the morning and once in the evening, to conduct daily observations of their cervical-vaginal mucus based on the Creighton Model ovulation method, to test the cervical-vaginal mucus for ferning with the Lady Free Biotester and to test for an LH surge in the urine. Participants collected their salivary samples by placing a small amount of nonfoamy saliva on the glass slide of the Biotester with their finger (or by licking it with their tongue) and letting it dry for 5–7 min. They were instructed not to smoke, eat, or drink alcohlic beverages for 2 h before salivary testing. Cervical mucus samples were collected by wiping the vulvar area with tissue each time the participant voided and before going to bed. When cervical-vaginal mucus was present on the tissue, participants removed a small amount and smeared it on the glass slide of the Biotester. Like the salivary samples, the cervical-vaginal mucus samples were allowed to dry for 5–7 min before viewing with the eyepiece of the microscope. Participants recorded the results of the salivary and cervical ferning, LH detection, and cervical-vaginal observations on a specially designed fertility chart for two complete menstrual cycles. At the end of two recorded cycles, they were asked to return the Biotesters and the fertility charts.

The Statistical Package for the Social Sciences (SPSS) for Windows (SPSS Corp., Chicago, IL) was used to enter and analyze data. Pearson's moment product correlations were used to determine relationships between the day of the LH surge and the variables of the days of salivary and cervical mucus ferning, as well as the peak day of cervical mucus.

Results

Twenty-four cycles yielded interpretable data. Three cycles did not have an observed LH surge. In 20 of the 21 (95.2%) cycles with an LH surge, the peak day in cervical mucus fell within ±3 days of the LH surge; in 14 of the 21 cycles (66.6%) the peak in cervical-vaginal ferning fell within ±3 days of the LH surge; and in 16 of the 21 cycles (76.2%) the peak in both the AM and PM salivary ferning fell within ±3 days of the LH surge. Table 1 shows the distribution of the peak day of salivary and cervical-vaginal mucus ferning in relation to the day of LH surge.

There was a highly significant correlation between the LH surge in the urine and the peak day of salivary and cervical-vaginal mucus ferning, and between the LH surge and peak day of cervical-vaginal mucus (Table 2). There was also a significant correlation between the peak in cervical-vaginal ferning and

the AM salivary peak ferning (r = 0.98, p ≤0.001) and between the peak in cervical-vaginal ferning and the PM salivary peak ferning (r = 0.97, p ≤0.001). Table 1 also illustrates the wide range between the minimal and maximal day on which the various biological markers of peak fertility occurred. This wide range was due to long cycles experienced by one of the participants.

Discussion

The results of this study did show an interpretable peak in fertility as determined by observed ferning in saliva and cervical mucus, but only in context of other markers of fertility: that is, the LH surge in the urine and the peak in cervical-vaginal mucus. These findings were similar to the results of Barbato et al, in which a strong relationship was found among salivary ferning patterns, basal body temperature shifts, and appearance of cervical mucus in 28 woman-cycles.[2] The Barbato et al study, however, also reported a discernible ferning pattern that lasted a mean of 6.2 days, began 1–2 days before the cervical mucus appearance, and averaged 7.2 days before the first day of the temperature shift. The authors of the current study were not able to determine an observable fertility pattern based on ferning days. There was no discernible beginning or end to fertility as determined by salivary or cervical-vaginal ferning. In many of the cycles, ferning days were found throughout the cycle, and in other cycles, ferning was found only on 1 or 2 days. There was also no discernible beginning or end to the fertility cycle as determined by the self-observation of cervical-vaginal mucus: that is, there was either continuous mucus or continuous bleeding, or a combination of the two.

Another problem is that the peak in ferning for the saliva and mucus was determined as the last day of either a #2 (partial ferning) or #3 (full ferning). In only 11 of the 20 (55%) cycles was there an observed full cervical-vaginal ferning pattern; in only 12 of 20 (60%) was there an observed full PM salivary ferning pattern; and in only nine of 21 (43%) was there a recorded full AM salivary ferning pattern.

Of interest is that one of the participants placed AM salivary samples on a regular glass microscope slide every day for an entire cycle. Both researchers in the present study observed the slides using a standard laboratory microscope under ×100 power and were able to observe salivary ferning throughout the entire cycle. Furthermore, one investigator was able to obtain excellent (level 3) ferning patterns with his own saliva. Previous researchers have also noted finding male ferning patterns and nondiscernible ferning patterns in female cycles.[3] These investigators attributed the nondiscernible patterns to menstrual disorders. This could explain the nondescript fertility pattern in the current study, in that a number of the participants had unusual cycles with respect to continuous mucus, continuous bleeding, or long cycles (probably due to stress). There is an indication, based on the continuous bleeding,

long cycles, and continuous mucus, that there were hormonal variations in the cycles.

Other variations in the results may be due to the quality of the saliva on the slides or to the variation in the quality of the microscopes. Although subjects were given verbal and written instructions on how to place the saliva on the slides, there could have been individual variations in the collection process.

The microscopes themselves, although small and compact, leave some desire for quality and resolution. The best quality seems to be the microscopes with their own built-in light sources. The small plastic slide surface could miss the ferning of the salivary sample. Both ferning and nonferning can be observed in the same sample of dried saliva when viewed through a normal microscope with a wide field of vision. Actually, the hand-held microscope that the author found had the best resolution and field of vision was none of the microscopes sold as fertility monitors but rather the Radio Shack (Fort Worth, TX) hand-held ×100 power microscope with built-in light source. The Radio Shack microscope at the time of purchase also was the least expensive, at US $9.98.

The conclusion of this small evaluation study of ferning patterns in saliva and cervical-vaginal mucus is that the peak ferning patterns in both fluids (when viewed in context of other markers of fertility) coincide closely with other standard markers of fertility in detecting the approximate time of ovulation. There was, however, no discernible fertility pattern with the salivary or cervical-vaginal ferning, in that there was no identifiable beginning or end to the fertile period. Many of the cycles did not have an observable full ferning pattern with either the saliva or the cervical-vaginal mucus. There is also some question regarding the theoretical basis of salivary ferning, in that ferning is also discovered in male saliva and can be found throughout the female cycle.

Until more definitive tests with salivary ferning patterns are conducted, the investigators of the present study would recommend that the hand-held microscopes not be used as a means for avoiding pregnancy. These instruments could be used as a means for helping to determine the optimal time of fertility, but only in conjunction with other tested markers of fertility.

Acknowledgment

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Appendix

Table 1: Distribution of peak day of salivary and cervical mucus ferning in relation to day of luteinizing hormone (LH) surge.

LH-4	LH-3	LH-2	LH-1	LH	LH+1	LH+2	LH+3	LH+4
○●	○	♦●	♦●	♦○●	♦○●	♦○●	○	♦○●
♦		♦	●	♦○●	♦○●	♦○●	○	○●
			●	♦○	♦○●	○●	○	
			●	♦○		●		
			●	♦○		●		
				♦○		●		

○ = Peak day of AM salivary ferning.

● = Peak day of PM salivary ferning.

♦ = Peak day of cervical mucus ferning.

Table 2: Correlation of the day of the luteinizing hormone (LH) surge with the peak day of salivary and cervical mucus ferning and cervical-vaginal mucus (N = 24)

Variable	Mean	SD	Minimum	Maximum	r
Peak day of AM salivary ferning	19.68	11.03	10	63	0.98*
Peak day of PM salivary ferning	19.36	10.70	11	62	0.98*
Peak day of mucus ferning	19.50	12.05	10	63	0.99*
Peak day of cervical mucus	19.42	10.22	13	63	0.99*
Day of LH surge	18.81	11.08	12	63	

*$p \leq 0.001$.

Figure 1: Lady Free Biotester[®].