# ACCURACY OF THE OVULON FERTILITY MONITOR TO PREDICT AND DETECT OVULATION

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ABSTRACT

The purpose of this pilot study was to correlate the three biologic markers of the Ovulon fertility monitor (a long-term predictive peak about 6 days before ovulation, a short-term predictive peak about 1 day before ovulation, and a nadir at the time of ovulation) with the peak in cervical mucus and the luteinizing hormone (LH) surge in the urine. Ten volunteer subjects (mean age 30.2 years) monitored their cervical-vaginal mucus, the surge of LH in the urine with a home assay test, and their vaginal electrical readings (with Ovulon monitors) on a daily basis for one to four menstrual cycles. In 19 of the 21 cycles that indicated a LH surge, there was a strong positive correlation between the LH surge and the peak of cervical-vaginal mucus ($r = 0.96$, $P \leq .01$), and between the LH surge and both the Ovulon nadir and Ovulon short-term predictive peak ($r = 0.84$, $P \leq .01$), and a modest positive correlation between the long-term Ovulon predictive peak and the LH surge ($r = 0.62$, $P \leq .01$). The time of optimal fertility as determined by the peak in cervical mucus, the LH surge, and the Ovulon was similar. The Ovulon has potential as a reusable device to help women determine their fertile period. 

The ability to predict and detect ovulation is critical for women who wish to achieve or avoid pregnancy. The most common methods of predicting ovulation in use today are monitored basal body temperature (BBT), self-observation of cervical-vaginal mucus, and self-testing of luteinizing hormone (LH) in the urine. All three of these methods have advantages and disadvantages. In recent years, a number of technological devices have been developed to help women determine their optimal time of fertility. This technology is important for women who are trying to achieve or avoid pregnancy. The devices include electronic and computerized BBT, hormonal test kits, cervical-vaginal fluid volume meters, and crystallization monitors (1).

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A recently developed device to aid in the prediction and detection of ovulation is the Ovulon fertility monitor (Conception Technology Inc.; Fort Collins, CO). The Ovulon prototype consists of a hand-held digital monitor and a vaginal sensor that is inserted like a tampon, for about 30 seconds, on a daily basis (Figure 1). The vaginal sensor harmlessly detects bioelectrical measurements. The measurements are harmless because of two design features: 1) the biocompatible (carbonaceous) material of the active elements cannot release any harmful or potentially harmful substances into the vagina and 2) the electrical mode of measurement is such that no electrical energy is passed into the body and no electrochemical reactions (electrolysis) can occur.

The device is based on the changes in electrical admittance as a result of the sensitivity of the cervical tissues to steroid hormones such as preovulatory estrogen that stimulate the production of and changes in cervical epithelium and mucus. The electrical changes are theoretically produced by the oxidative-reduction reactions that take place in the mucus glycoproteins of the cervical mucus. The electron transfer reactions in the biologic material interact with the electronic structure of the active elements, and the interaction is detected by the measured admittance.

The Ovulon monitor can be used to both predict and confirm ovulation. The Ovulon monitor produces three biologic markers: a long-term predictive peak in electrical admittance about 5–7 days before ovulation, a second short-term peak about 1 day before ovulation, and a nadir of electrical admittance on the day of ovulation.

A device superficially similar to the Ovulon, the CUE fertility monitor, was developed by the Zetek Corporation (Aurora, CO) (2–4). Unlike the Ovulon, the CUE monitor uses both a salivary and vaginal sensor and is based on ionic conductivity as a result of aldosterone-stimulated concentrations of salt and water in the cervical mucus and saliva.

The Ovulon monitor has never been widely tested. Dr. Benedetto of the University of Torino Institute of Obstetrics and Gynecology tested an early model of the





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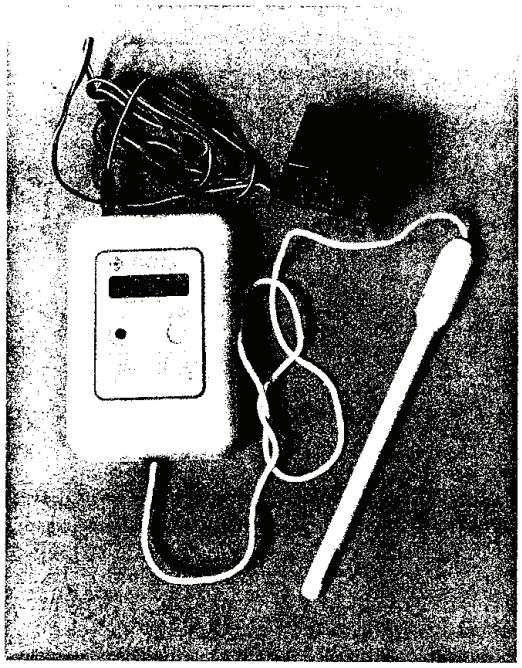

FIGURE 1.
Prototype Ovulon fertility monitor.

Ovulon with four young healthy women and reported in an unpublished study that they were all able to demonstrate a long-term predictive peak before the ovulation marker of the instrument and a short-term predictive peak about the day before ovulation, except for one case where a probable luteal phase defect was associated with the absence of the predictive peaks. Further study of the Ovulon monitor needs to take place to determine its applicability for family planning.

One method of determining the Ovulon's accuracy in detecting the fertile period is to compare it with other standard markers of ovulation. Two commonly accepted and researched methods of detecting ovulation are the self-observation of cervical-vaginal mucus and the self-detection of LH in the urine. The detection of LH in plasma or urine is considered by experts to be a standard method to predict ovulation (5,6). Manufacturers of ovulation tests kits claim a greater than 90% accuracy in detecting the urine LH surge, which occurs about 12–24 hours before ovulation (7,8). Optimal or "peak" cervical-vaginal mucus (defined as mucus that stretches 2.5 cm or more, is clear on appearance, and/or has the sensation of lubrication) as obtained from the vaginal opening also correlates closely with the day of ovulation and the day of the LH surge (9,10). The specific aim of this pilot study was to determine the accuracy of the Ovulon fertility monitor by comparing and correlating the peak in cervical mucus and the LH surge in the urine with the three biologic markers of the Ovulon monitor.

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## METHODOLOGY

Ten volunteer female subjects (mean age 30.2 years) with regular menstrual cycles (ie, cycles of 21–38 days in length) who were trained in the use of the Creighton model ovulation method of natural family planning (NFP) (mean months of use 32.0) monitored their cervical-vaginal mucus, the surge of LH in the urine with the OvuQuick assay test, and their vaginal electrical/chemical readings (with the Ovulon monitor) on a daily basis for one to four menstrual cycles using 10 prototype Ovulon monitors.

The LH surges in the urine were self-detected by use of the OvuQuick self-test kit. The OvuQuick is based on monoclonal enzyme immunoassay of LH in the urine. The test has a reported LH sensitivity of 30 mIU/mL. OvuQuick has shown a 98% agreement with other tests in detecting the LH surge (5).

The peak day of cervical mucus was determined by means of the Creighton model vaginal discharge recording system (VDRS), developed through research conducted at St. Louis and Creighton Universities over a 5-year period (11). The recording system requires that women check for cervical-vaginal mucus by wiping the outside of their vaginas (the vulvar area) every time they go to the bathroom to void and once before going to bed. The women check mucus for color, stretch, and consistency. The VDRS has a reported 99% method effectiveness and a 95% use-effectiveness for determining fertile and nonfertile days of the cycle (11,12).

An algorithm was developed to standardize the determination of the biologic markers of fertility asdetermined by the three methods, ie, the Ovulon monitor, the LH, and the cervical-vaginal mucus. The decision criteria for the Ovulon data are as follows:

- LH—the last day of the LH surge as detected in the urine with the home test kit and recorded on the fertility chart.

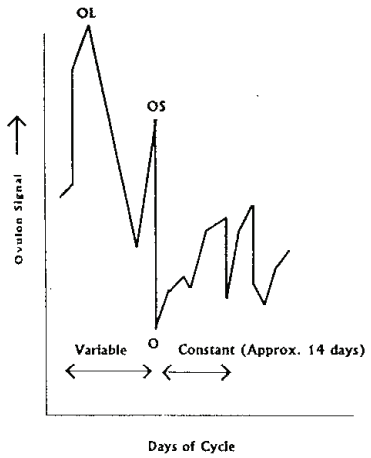


FIGURE 2.
Ovulon baseline pattern with three biologic markers.

- P—the last day of mucus that was either clear on appearance, stretches an inch or more, and/or had the sensation of lubrication as observed by the subject and recorded on the fertility chart.
- OS—the day of the highest Ovulon reading. "OS" stands for the short-term Ovulon predictor (Figure 2).
- OL—the day of the highest Ovulon reading preceding the OS. "OL" stands for the long-term Ovulon predictor.
- O—the day of the lowest Ovulon reading after the OS.

Using the above algorithm, interrater reliability was determined between the decision of the principal researcher and a graduate student research assistant on the day of the observed biologic markers. The interrater ratio of the observed day of LH, P, O, and OS was 100% and the OL day was 90%.

## RESULTS

Nineteen of the 21 menstrual cycles indicated an LH surge (Table 1). In the 19 cycles with an established LH surge, there was a strong positive correlation between the LH surge in the urine and the peak day of cervical mucus ($r = 0.96$, $P \leq .01$), between the LH surge and the Ovulon nadir "O" ($r = 0.84$, $P \leq .01$), and between the LH surge and the Ovulon short-term predictive peak "OS" ($r = 0.84$, $P \leq .01$). There was a modest positive correlation between the long-term Ovulon predictive peak "OL" and the LH surge ($r = 0.62$, $P \leq .01$). There also was a strong positive correlation between the peak day of cervical mucus and the Ovulon nadir ($r = 0.86$, $P \leq .01$). In the 19 cycles in which an LH surge was detected, the Ovulon short-term predictive peak was within ± 3 days of the LH surge.

TABLE 1
**Comparison of the Three Ovulon Biological Markers (O, OS, and OL) with the Day of the Luteinizing Hormone Surge and the Peak in Cervical Mucus**

| *Subject/Cycle* | *Age (y)* | *N/M* | *LH* | *Peak* | *O* | *OS* | *OL* |
|---|---|---|---|---|---|---|---|
| 1.1 | 35 | M | 17 | 17 | 16 | 14 | 11 |
| 1.2 | | | 16 | 16 | 17 | 13 | 07 |
| 2.1 | 33 | M | 14 | 14 | 17 | 15 | 12 |
| 2.2 | | | 14 | 14 | 14 | 12 | 06 |
| 3.1 | 42 | M | 13 | 13 | 14 | 13 | 12 |
| 3.2 | | | 17 | 18 | 17 | 15 | 11 |
| 4.1 | 33 | N | 13 | 13 | 15 | 13 | 07 |
| 4.2 | | | 11 | 12 | 14 | 11 | 07 |
| 5.1 | 30 | M | 19 | 20 | 20 | 18 | 12 |
| 6.1 | 38 | M | 15 | 16 | 19 | 15 | 08 |
| 6.2 | | | 15 | 16 | 18 | 15 | 08 |
| 7.1 | 29 | N | 16 | 17 | 18 | 16 | 10 |
| 7.2 | | | 14 | 13 | 15 | 14 | 08 |
| 8.1 | 19 | N | 21 | 23 | 21 | 18 | 12 |
| 8.2 | | | — | 21 | 24 | 21 | 14 |
| 9.1 | 41 | N | 14 | 15 | 18 | 16 | 08 |
| 9.2 | | | 13 | 14 | 13 | 12 | 09 |
| 9.3 | | | 15 | 16 | 18 | 15 | 10 |
| 9.4 | | | 14 | 13 | 15 | 13 | 07 |
| 10.1 | 22 | N | — | 09 | 12 | 10 | 07 |
| 10.2 | | | 10 | 12 | 10 | 08 | 06 |

N, nulliparous; M, multiparous.

## DISCUSSION

Although the Ovulon monitor is based on a different technology than the CUE fertility monitor, the results of this study are similar to the strong correlation between the LH surge and the predicted day of ovulation ($r$ = 0.79) found by Moreno et al. (4). The Ovulon's predicted day of ovulation "O" correlated positively with the LH surge ($r$ = 0.84) and the peak in cervical mucus ($r$ = 0.82). The conclusion, therefore, is that the Ovulon monitor has similar accuracy in predicting ovulation as the ovulation method of NFP, the urine LH detection kits, and the CUE fertility monitor. The short-term Ovulon ovulation predictor also had a strong correlation with the LH surge ($r$ = 0.84) and the peak in cervical mucus ($r$ = 0.86). The Ovulon short-term predictor ranged from 1 to 4 days with an average of 2.3 days before the Ovulon nadir. This short-term predictive peak would be especially beneficial for those women and couples trying to achieve pregnancy because fertility drops dramatically shortly after ovulation (13). The short-term predictive peak would not give enough warning time for those wishing to avoid pregnancy.

The long-term Ovulon marker, however, has potential for women and couples trying to avoid pregnancy. Except for one of the cycles, the OL to O period ranged from 4 to 11 days with an average of 7.2 days. This length is somewhat longer than the average length of the total fertile period (6 days) as defined by the ovulation method. The long-term Ovulon predictive peak only had a modest correlation with the LH surge ($r$ = 0.61) and with the peak in cervical mucus ($r$ = 0.71). The conclusion is that at this time the OL is a very rough predictive marker of the beginning of the fertile period.

A limitation of the study is that the Ovulon was only tested on a small number of healthy women who had relatively regular menstrual cycles. Also, the Ovulon monitors were prototype instruments. For the Ovulon to be useful as a family planning method further testing will need to take place with women with varying cyclic patterns (eg, postpartum, breastfeeding, infertile, long cycles) and with refined instruments. Another limitation of the study is that the LH surge in the urine and the peak day of cervical mucus are indirect tests of ovulation. Use of serial transvaginal ultrasonography would add more precision and validity to the study. The expense of serial ultrasonography was beyond the scope and budget of this study. A final limitation of this study is that Ovulon data from 5 cycles (ie, in cycle number 3.2, 8.1, 8.2, 9.1, and 10.2) were interpreted in light of the peak in cervical mucus rather than by strict adherence to the established algorithm. These were cycles with Ovulon profiles that deviated from the expected or baseline pattern for reasons that are not understood. The expectation is that a larger study with a variety of reproductive categories with a range of clinical and biochemical measurements will provide that understanding.

Nurse-midwives and nurses have long incorporated teaching women about their body's physiology as part of educating women in self-care measures. Use of convenient, safe, and accurate devices to monitor physiologic process, such as a woman's fertility cycle, should be advocated. A benefit of the Ovulon monitor is that it is a reusable instrument, unlike the urine LH test kits that need to be purchased for each cycle. The Ovulon fertility monitor has potential to be a very useful device to assist nurse-midwives in fertility and infertility assessment, therapy, and family planning.

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## Note about further insight into the published data

The long-term predictive peak OL correlates, in baseline menstrual cycles, with the length of the cycle because cycle length is dependent on the length of the follicular phase, i.e., on the phase before ovulation. This is in turn dependent on the rate of the dominant follicle maturation, which controls the width of the long-term predictive peak (i.e., how far the OL is in front of the ovulation marker O). Therefore, the OL is not expected to correlate with the OS and/or with the O marker.

Various deviations from baseline occur in the naturally variable non-baseline cycles, which is why the complete menstrual cycles must be monitored to capture and account for the natural variability.

The above study with non-baseline women was designed and performed independently of us in order to assure objectivity, and the then evolving proprietary theory of Folliculogenesis In Vivo™ was not disclosed.

An examination of the Marquette study data reveals the following two categories of menstrual cycle data as yielded by the non-baseline type of subjects enrolled in the study.

**I. Normal cycles**

Table 1 shows that in 11 of the 20 recorded cycles (55%) the ovulation marker O falls within one day of either the LH surge or the peak mucus (Pk) or both. This is a good agreement, considering the inherently limited accuracy of the two reference methods.

Table 1. NORMAL CYCLES
DEFINED AS THOSE WHERE O IS WITHIN 1 DAY OF LH OR Pk

| Subject #.cycle # | age, parity | OL | OS | O | LH | Pk |
|---|---|---|---|---|---|---|
| 1.1 | 35, M | 11 | 14 | 16 | 17 | 17 |
| 1.2 | 35, M | 7 | 13 | 17 | 16 | 16 |
| 2.2 | 33, M | 6 | 12 | 14 | 14 | 14 |
| 3.2 | 42, M | 11 | 15 | 17 | 17 | 18 |
| 5.1 | 30, M | 12 | 15 | 20 | 19 | 20 |
| 7.1 | 29, N | 10 | 16 | 18 | 16 | 17 |
| 7.2 | 29, N | 8 | 14 | 15 | 14 | 13 |
| 8.1 | 19, N | 12 | 18 | 21 | 21 | 23 |
| 9.2 | 41, N | 9 | 12 | 13 | 13 | 14 |
| 9.4 | 41, N | 7 | 13 | 15 | 14 | 13 |
| 10.2 | 22, N | 6 | 8 | 10 | 10 | 12 |

Parity: The number of children borne by the woman
Parity is either N (nulliparous) where the woman has never given birth;
or M (multiparous) where the woman has previously given birth.

In this group of normal menstrual cycles, the temporal relationship between the OS (short-term predictive peak) and the reference indicator LH is OS < LH, i.e., the short-term predictive peak occurs before the urinary LH indication. Since the short-term predictor OS is thought to be due to an ovarian signal indicating the readiness to ovulate, this temporal relationship between the OS and the LH is as would be expected because the urinary LH occurs practically concurrently with ovulation (LH peaks several hours before ovulation).

**II. Challenged cycles**

Table 2 shows that in 9 of the 20 cycles in the Marquette study (45%), the ovulation marker O is not within 1 day of either of the reference indicators, and that it always follows later, delayed by 1 to 3 days. In these so-called challenged cycles, the sensor detects ovulation 1 to 3 days later than indicated by the reference indicators LH and Pk. Recall that these are indicative of hormonal input signals, the LH and estrogen hormones, respectively.

Table 2. CHALLENGED CYCLES
DEFINED AS THOSE WHERE O IS NOT WITHIN 1 DAY OF LH OR Pk, AND IS ALWAYS HIGHER = DELAY OF OVULATION

| Subject #.cycle # | age, parity | OL | OS | O | LH | Pk |
|---|---|---|---|---|---|---|
| 2.1 | 33, M | 12 | 15 | 17 | 14 | 14 |
| 4.1 | 33, N | 7 | 13 | 15 | 13 | 13 |
| 4.2 | 33, N | 7 | 11 | 14 | 11 | 12 |
| 6.1 | 38, M | 8 | 15 | 19 | 15 | 16 |
| 6.2 | 38, M | 8 | 15 | 18 | 15 | 16 |
| 8.2 | 19, N | 14 | 21 | 24 | none | 21 |
| 9.1 | 41, N | 8 | 16 | 18 | 14 | 15 |
| 9.3 | 41, N | 10 | 15 | 18 | 15 | 16 |
| 10.1 | 22, N | 7 | 10 | 12 | none | 9 |

In this group of challenged menstrual cycles, the temporal relationship between the OS (short-term predictive peak) and the reference indicator LH is different from that in the normal cycles, namely OS > LH or OS = LH, i.e., the short-term predictive peak occurs either after the LH or coincides with it. In these cycles, not only does the ovulation marker O occur 1 to 3 days later than both the LH and peak mucus, the short-term predictive peak also can occur later than in the normal cycles (later with respect to the LH indication). This is consistent with the concept of asynchrony as the mechanism of the challenged cycles.

Ref.: *Abnormal ovarian cycles as diagnosed by ultrasound and serum estradiol levels*, M. Lake Polan, M. Totora, B.V. Caldwell, A.H. DeCherney, F.P. Haseltine, and N. Kase, Fertility and Sterility (37) 342, 1982 . Précis: 35% of menstrual cycles found abnormal due to asynchrony of ovarian and brain pacemakers, and a smaller size of the dominant follicle.