Critique of the Zetek Cue/OvaCue fertility monitor

By Vaclav Kirsner, Ph.D.
Email: vaclavkirsner@yahoo.com
Telephone: (970) 484-1272

The Cue (OvaCue) fertility monitor from Zetek, Inc. is an electronic device with two probes. One probe is used in the mouth to measure the electrical resistance of the saliva, which provides an advanced warning of forthcoming ovulation. The other probe is for use in the vagina where it measures the electrical resistance of the vaginal fluids, in order to attempt detecting ovulation. In the current OvaCue iteration of the Zetek technology, the vaginal probe is only optional.

Both Cue probes respond to the concentration of electrolytes, and particularly sodium, in the respective body fluids, saliva and vaginal fluid. Zetek's physiological rationale for the salivary resistance variations invokes the action of estrogen on the renin-angiotensin system (the blood pressure regulator), and the adrenal cortex increasing the secretion of aldosterone, which in turn alters sodium excretion and retention in body fluids. This is an indirect means of monitoring the reproductive cycle via the effects of the circulating pre-ovulatory estrogen on the liver and the kidneys. The consequence is inevitable - lack of accuracy. Zetek claims that the salivary signal occurs approximately six days before ovulation (regardless of the length of the menstrual cycle). Below we shall see the consequence of this arbitrary constant on the performance of the Cue monitor in Zetek's own data.

The changes in the resistance of cervical mucus before and about the time of ovulation (due to higher sodium and water content) reflect changes in estrogen concentration in blood circulation. The estrogen concentration increases in preparation for ovulation as outlined elsewhere in relation to the Unipath instrument (Persona, Clearblue) for urine analysis. The problem is that the cervical mucus changes are not sharply defined, and extend over several days. This was highlighted in the discussion of the so-called peak mucus as a measure of the most fertile mucus in the subjective monitoring of mucus discharge according to the rules of natural family planning. The fertile mucus can be observed from 3 days before to 3 days after the estimated day of ovulation. It can be argued that Zetek's data reflect this spread.

Another problem about the Zetek vaginal probe is that it samples, in fact, a mixture of vaginal fluids and cervical mucus, which further reduces the precision of the determination. This is a fundamental problem, not merely a small detail, because the two body fluids are very different from each other and serve two different physiological roles.

Zetek's solution is a complex method of comparing the salivary and vaginal fluid resistance readings, in an effort to deduce the time of ovulation. Ovulation is assessed to occur on the day on which one of two conditions is satisfied. One condition is that a rise after a nadir in the vaginal resistance readings is observed - when such a day is within 6 days of the salivary resistance peak. The alternative is that ovulation is postulated to have occurred exactly 6 days after the salivary peak - if no rise in the vaginal readings is obtained within that period. No rationale is offered for this arbitrary assignment.

Note that this arbitrary postulate of 6 days long estrogen-driven signal anticipating ovulation amounts to an implied postulate of a constant (subject- and cycle-independent) rate of ovarian function. It also implies the assumption that, empirically, the follicular phase should be constant and that it will be constant unless otherwise indicated by the vaginal resistance readings. These assumptions are wrong because they are not substantiated by known facts of reproductive physiology and endocrinology.

Both the oral and vaginal determinations by the Cue instrument are only approximate, which is evidenced by the wide statistical distributions of the indications of ovulation as predicted (orally) and detected (vaginally) by the instrument. Zetek's 1989 patent shows that, 6 days after the oral probe's peak of salivary resistance, the LH peak correlate of ovulation was observed in only some 33% of menstrual cycles, with some 22% on day 5 and 25% on day 7. There is a bell-shaped statistical distribution around the sixth day after the predictive peak, and the distribution is 7 days wide.

This is a considerably wide spread, even if the inherent one-day uncertainty is allowed for the LH correlate of ovulation, which was used instead of the direct detection of ovulation by ultrasound scans of the ovaries. In over 150 menstrual cycles, there is a similar distribution around the Cue's vaginal marker of ovulation. The Cue ovulation marker coincides with the LH peak in only some 40% of menstrual cycles; about 33% of ovulations occurred one day later, about 15% two days later, and about 10% occurred one day before the Cue ovulation marker.

With such large margins of error, it is not surprising that the FDA has approved the Zetek instrument only for use by those seeking to get pregnant. The instrument is not approved for birth control use. This is in the context of the Vatican having expressed approval of electronic fertility monitors. However, even more important for the consideration of consumer appeal is the fact that the Cue procedure is rather involved. It can be argued that, even if it were FDA-approved for birth control use (if it were effective), the Cue would not be a very attractive proposition for those women who are not as motivated as those trying to get pregnant.

The use of the Cue is quite complicated, and includes a fairly involved interrogation of the user by the instrument's data-processing electronics. The oral probe is applied daily from the beginning of the menstrual cycle, and later on the vaginal probe is applied as well, or instead, in order to “confirm” the ovulation event. A cumbersome user interface results from this dual sensor system, and this criticism is quite apart from a criticism of the fundamentals of their method of measuring the conductivity of the respective body fluids as a means of fertility monitoring. Arguably, the safety factor has been misjudged by the FDA.

In closing this critical overview, let us bring out the most important aspect of fertility status determination. It is that the technique must be responsive to the effects of a number of timing mechanisms involved in the menstrual cycle. It is known that various neuroendocrinological influences impinge on the functioning of the complex components of the menstrual regulatory mechanism by disrupting the proper interaction between the brain and the reproductive tract. Disturbances in the menstrual cycle occur in response to exercise and physical demands, stress and emotional demands, and diet and nutritional demands (quoting Ferin). Proper functioning of the menstrual cycle requires a proper interaction between the mechanisms of the so-called clocks (e.g., a circamensual clock and a circhoral clock) and hormone generators (e.g., GnRH and LH pulse generators). Zetek's science of the Cue does not recognize these fundamentals. The device is as inaccurate an ovulation detector as any of the other products not approved for birth control, and for the same reason: It does not detect ovulation. It cannot detect ovulation because it merely monitors effects of estrogen. That hormone anticipates ovulation, prepares the body for it, but it does not mean that ovulation will occur - and when.

Written in 2000. Contact data amended in 2006. OvaCue and no-ovulation-detected comments added in 2011.