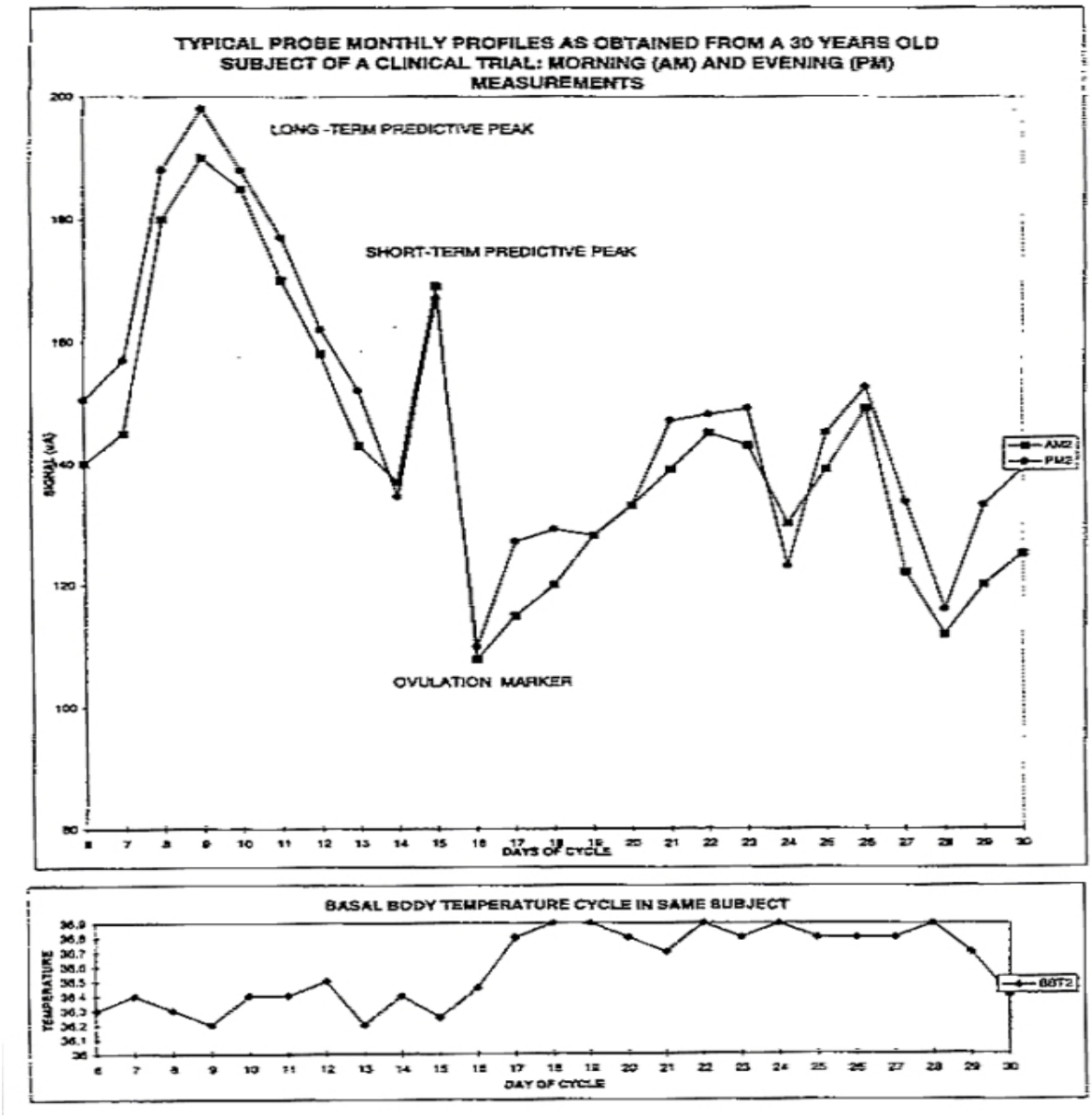
bioZhena's Menstrual Cyclic Profile Features

The Ovulona sensor detects the overall effect of all the biological stimuli (hormonal and neurological) that the cervical tissue receives from the ovaries and from the brain. This is called the end-organ effect of folliculogenesis (the mechanism of menstrual cycles).

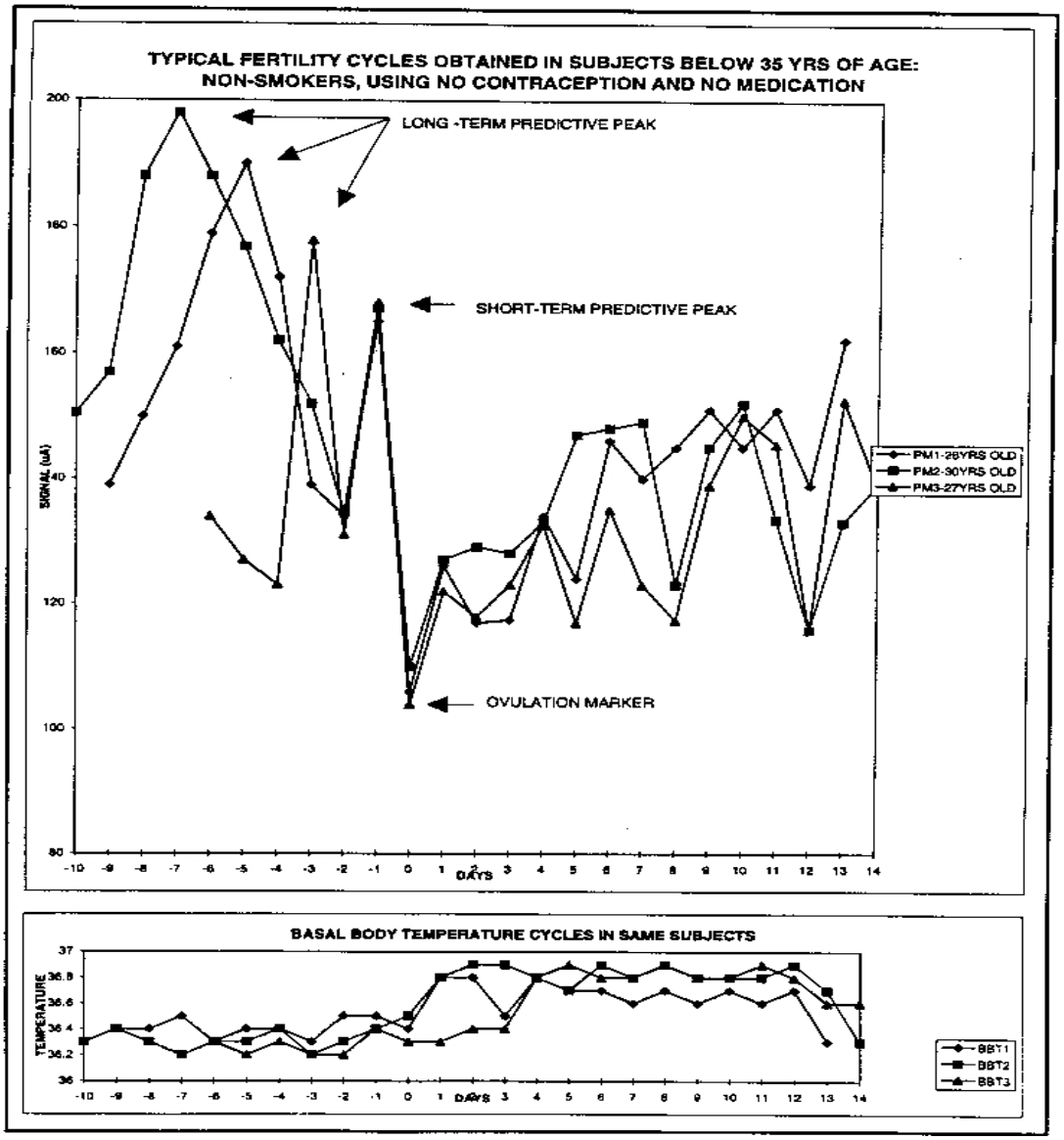
The multitude of repeatable features of Ovulona's cyclic profile throughout the menstrual cycle makes it possible to determine the boundaries of the current fertile window by any woman in any month. A key distinction of this cervical tissue-monitoring technique is that the dynamic range (the vertical span of readings) is the same in all cycles in all women. This is one of the reasons that the technique can be practical for use in natural birth control by fertility awareness.



In the graph above there are the morning and evening cyclic profiles from one of several baseline subjects of a study using this technology. In addition to the long-term and the short-term predictive peaks and the ovulation marker minimum, we see also the follicular waves in the luteal phase of the recorded cycle. BBT temperature profile of the woman is recorded for comparison.

The morning and evening curves were later superimposed on the day of the ovulation marker. The superimposition of the morning and evening profiles suggests that the data reflect the folliculogenesis process in progress over the course of the hours between the morning and evening measurements. We see subtle quantitative differences:

- Higher dominant-follicle-driven data (the long-term predictive peak) in the evening;
- Properly developed first follicular wave (post-ovulatory part of the profile) in the PM data;
- All three waves are higher in the PM than in the AM record, which is consistent with folliculogenesis progressing during the day.



This is a graph showing the evening measurement records from 3 different baseline subjects. It shows how the cycle length depends on the rate of maturation of the dominant follicle (the long-term predictive peak). The basal body temperatures (BBTs) generated by the same subjects were included for comparison. The definition of "baseline subject" is given in the title describing the baseline subjects' characteristics.

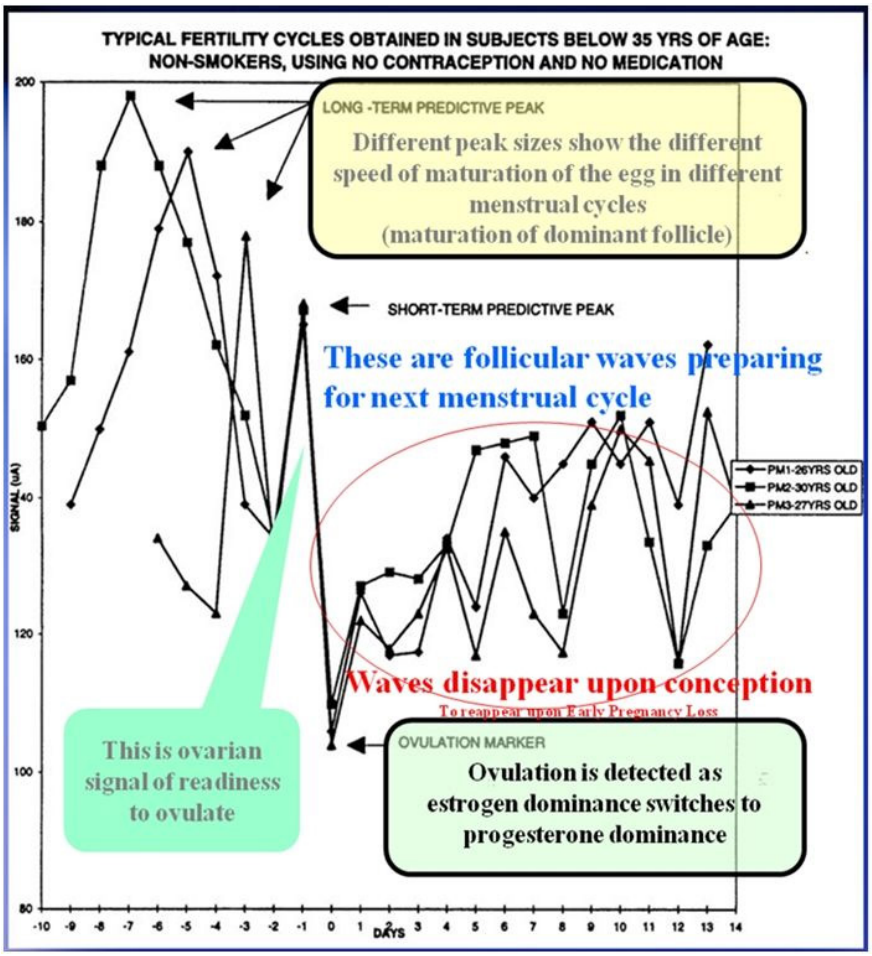
The cyclic pattern, captured by the Ovulona to be optionally displayed by the Ovulograph, exhibits a number of well-defined peaks and troughs.

The first repeatable feature is the first post-menstruation minimum occurring typically on day 6, 7 or 8. This is driven by the *selection* of the dominant follicle. The signal then rises to a maximum (the long-term predictive peak), which indicates the *maturation* of the dominant follicle.

This is followed by the narrow short-term predictive peak, which falls off directly into a trough (the lowest reading in the cycle) marking *ovulation*.

Based on the sensor's in vivo responses to estrogen and progesterone, this ovulation marker is understood to be the effect of the switch in hormone levels upon ovulation (estrogen to progesterone dominance). Note that the corresponding BBT curves rise to the post-ovulatory high level after the ovulation marker. This indicates, to the extent to which the BBT data can be relied on, that ovulation did in fact occur. We have found the ovulation marker to correlate with the LH and FSH urinary hormone peaks that are known to precede ovulation by about 12 hours, therefore marking the day of ovulation.

Therefore, to reiterate:



The post-ovulation (luteal phase) peaks and valleys have only recently been recognized as associated with the *follicular waves*. This means that this part of the cyclic profile can now be used as a diagnostic tool to help identify the rate of the depletion of the ova or eggs – how fast a woman is approaching menopause. It can also provide a very early detection of pregnancy (waves will not appear after conception) and an early indication of pregnancy loss (waves will reappear) – unique capabilities that no other ovulation-predicting device can replicate. Both are important for women trying to get pregnant.

The Ovulona sensor stores the data, which can be downloaded into the Ovulograph system for use by healthcare professionals. This will enable the correlation of symptometric and other auxiliary data with folliculogenesis, enabling both better diagnosis and treatment capabilities. With this added functionality, the technology can reach way beyond fertility monitoring, providing a feedback for treatment and for behavioral changes, such as in hormone therapy or, say, in smoking cessation or in treatment of PMS and PMDD.

By virtue of being an end-organ effect monitor, it can help in the management of the highly prevalent menstrual cramps, PMS/PMDD, peri-menopause, and - as a tool for management of PCOS (Poly Cystic Ovary Syndrome) - it can be explored to help prevent major killer diseases of women: diabetes, cardiovascular disease, ovarian cancer, and strokes. This is consistent with the NIH recognition that "like blood pressure and heart rate a woman's menstrual cycle is a sign of her overall health." That is why it is now considered women's 5th vital sign.

P.S.

The fertile window is an empirical factor, which should be consistent with the fertilizable lifetimes of the gametes (the egg and the sperm). The fertilizable lifetimes are uncertain but currently accepted figures are up to 12 (or maybe 24) hours for the egg, and at most 3 days for the sperm. (These times must overlap, of course; they are not additive.) With the information-rich cyclic profile produced by the cervical tissue sensor, it will be possible to bring certainty into this, via a carefully designed clinical trial.

For further insight, refer to https://biozhena.wordpress.com/folliculogenesis-in-vivotm/

An animated 3-slide summary of how we track the process
https://biozhena.files.wordpress.com/2018/03/wealth-of-info-elucidation-silent-3-slides-animated-ed.pps
(includes how the long-term predictive peak tracks the maturation of the dominant follicle that subsequently ovulates - the graph labels are also explained in the above referenced article).

And, for the sake of completeness: The fertile window is 3 days wide, not 6, which 6-day belief originated in a flawed 1995 study https://biozhena.wordpress.com/the-fertile-window-is-3-days-wide-not-6-which-6-day-belief-originated-in-a-flawed-1995-study/