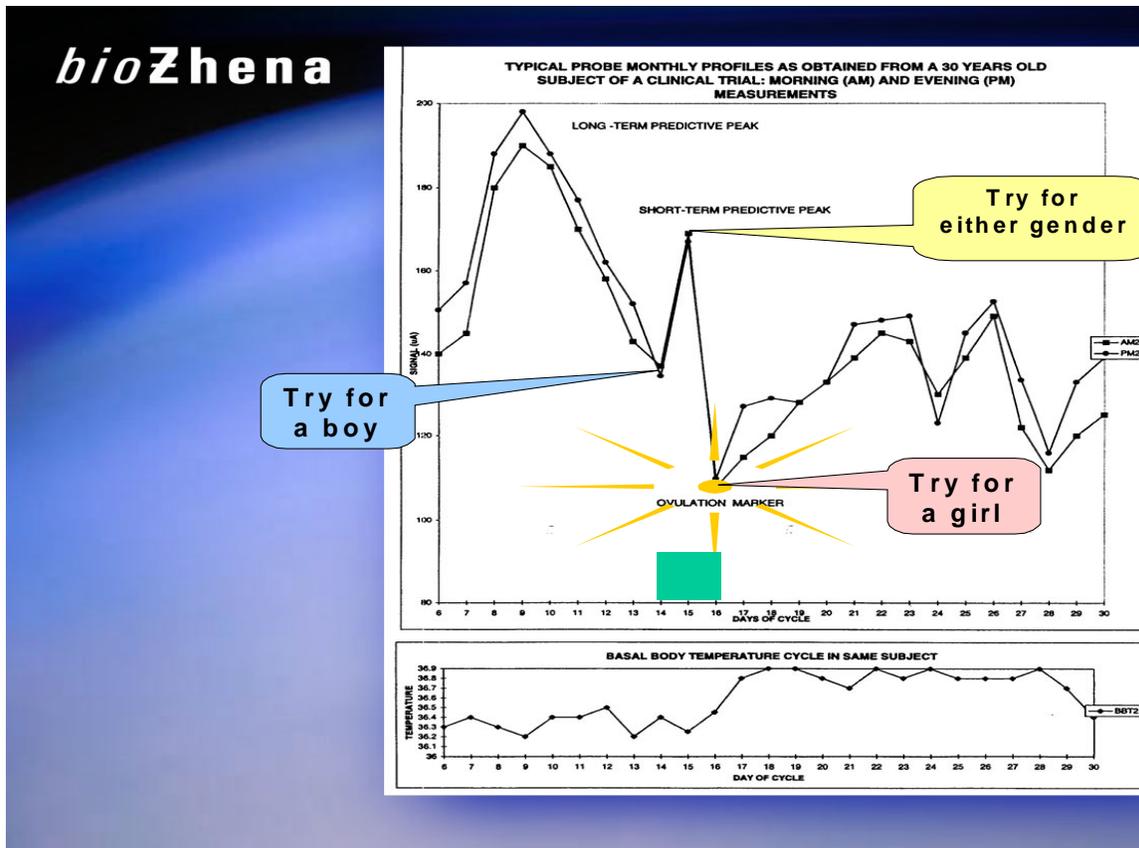


Fetal sex preselection – illustrated

The following illustration is adapted from one of our slides. The data were generated in a clinical study, and show the morning and evening cyclic profiles from one of the baseline subjects studied by the gynecologist Dr. Benedetto of the University of Turin, Italy.



The multitude of predictable features of the cyclic pattern – the always present peaks and the valleys between them – these features make it possible to determine the boundaries of the fertile window for every individual cycle. That is what is needed, rather than having to rely on some assumption of unchanged timing of certain events from cycle to cycle in the manner of the methods of prior art. This is why our technology can be used for birth control whereas the prior art methods and technologies cannot. This is also why we have a tool for trying to conceive a baby of desired gender.

Let us summarize where this comes from. Namely, we paraphrase from our detailed white paper, which is available for study upon request:

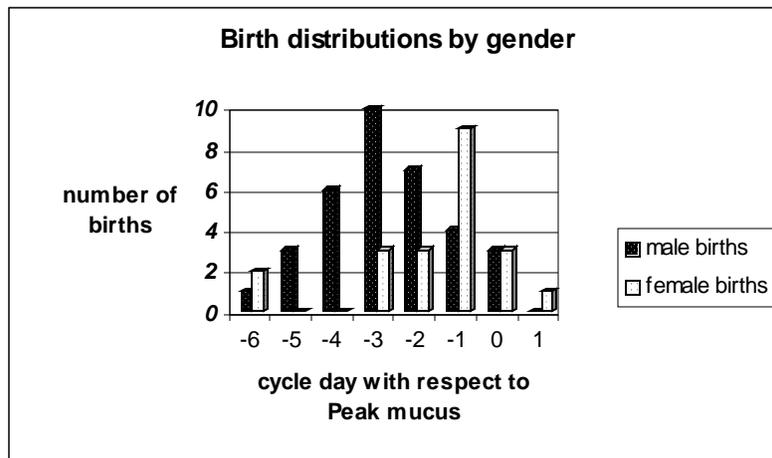
...a 1992 publication by John T. France et al., reporting data from 55 pregnancies (and births). Their study design generated data whereby only one coitus [intercourse] per fertile period occurred, and three different markers were used to estimate the time of ovulation.

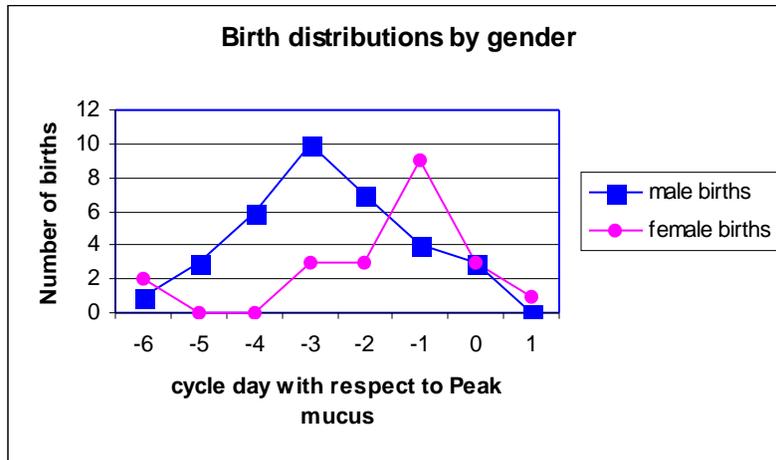
Understand this: Because ovulation cannot be detected by any prior art method for home use, and because all those methods are inaccurate in predicting ovulation, it was a good idea for France et al. to use more than one method of anticipating ovulation. It was also an extremely important and insightful feature of their study design that they demanded of couples to only try to conceive once during the estimated fertile period. Any pregnancy could therefore be tied unequivocally to the given day of cycle (albeit with the cycle days numbered in three different ways because of the three inaccurate methods employed to estimate ovulation).

The stringency of the study design by France et al. went as far as to exclude 29% of pregnancies from the fetal sex evaluation in terms of timing of conception with respect to ovulation, because of more than one act of intercourse during the fertile period. Significantly, the birth sex ratio was 0.50 for this excluded group but far from 0.50 for the good study population.

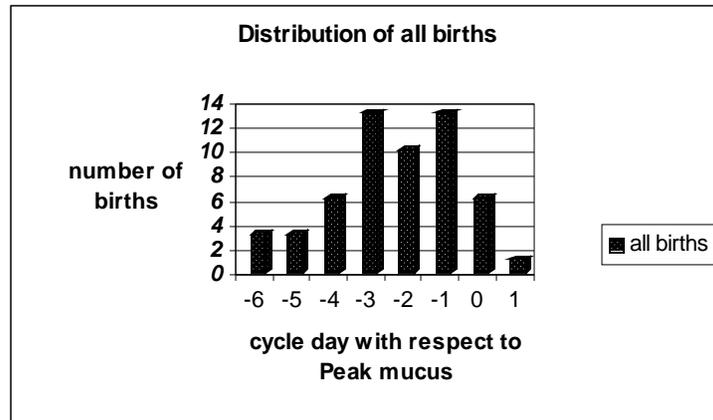
The results of the France et al. study were as follows: Of the 34 male infants born, 65% were conceived 2 to 5 days before ovulation, and 71% of the born girls were conceived from intercourse timed between 1 day before to 1 day after the estimated time of ovulation. Understand this: The significant outcome is the existence of the two distinct peaks in the counts of the birth of baby boys and baby girls, respectively. The numbers are not absolute because of the errors due to the inaccuracy of the ovulation estimates.

Here are two ways of graphing their data:



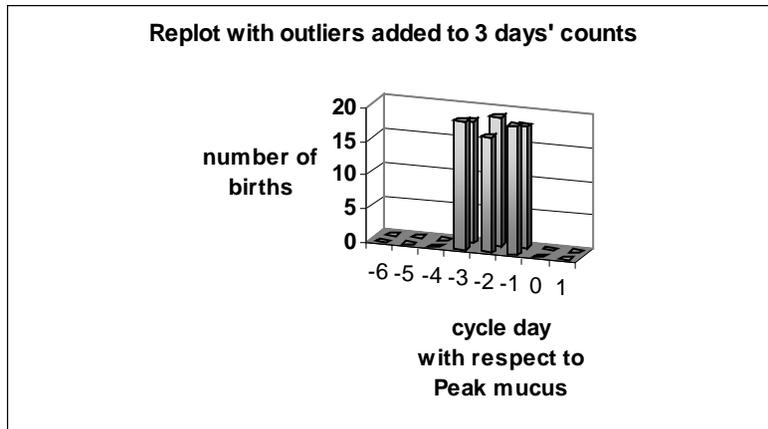


However, there was a great uncertainty about the actual ovulation day because in only 9% of the cases did the three ovulation markers agree with each other. In 68% of the cycles, agreement was within +/- 1 day. The peak cervical mucus marker was one while the other two markers were the onset of the LH surge, and the basal body temperature (BBT) rise. We show here only the data on the Peak mucus scale. This is the plot of all the births added together:



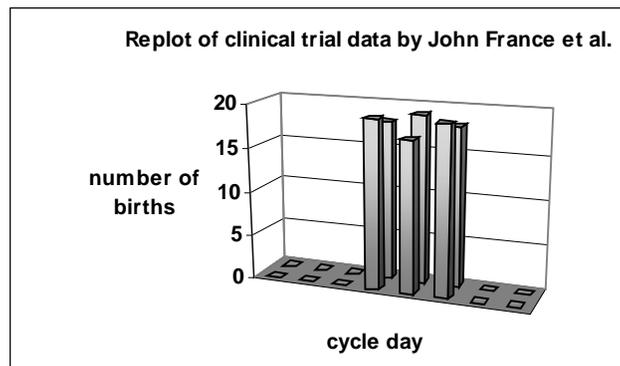
It is clear that there are three days of high birth counts, and considerably lower counts on both sides. The three high-count days are consistent with the best data on the viable lifetime of the sperm and egg (ovum). Also, another large study by a N.I.H. team (Wilcox et al.) has yielded the same outcome of three days of high birth counts.

And here now is a replot of the all-births data where we have considered that the very low birth counts on both sides of the 3 day group of high birth counts were data outliers due to the inaccurate methods of ovulation prediction used in the study. When we add the outlier data points to the main group of high counts, we get the following:



This manipulation of data was done by having taken the birth count outliers and adding them to the group of high counts (in two different ways, hence the two resulting levels on day -2). The purpose of this manipulation of the other investigators' data is to show the 3-day fertile window when it is not obscured or distorted by the inaccurate methods of estimating ovulation (inaccurate because the investigators could not detect ovulation, nor could they anticipate ovulation reliably, and certainly not with two predictive signals).

Removing the reference to the Peak mucus day as the time scale (i.e., leaving the ovulation day undefined, as it in fact was in those studies) yields the graph with three days of high birth counts on a time scale with unknown day zero (day of ovulation).



Our device, the Ovulona™, will take care of that, and will detect and indicate day 1, day 2 and day3 (ovulation day) in every individual cycle.

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