

# Ovulation Assessment and Fertile Period Prediction by Portable Computerised Vaginal Temperature Analysis – The OvuSense Advanced Fertility Monitoring System

Dr. S. Papaioannou, MD, FRCOG.<sup>1</sup>, Dr. M. Aslam, BSc, PhD<sup>2</sup>, Mr. R. C. Milnes, BA<sup>2</sup>, T.G. Knowles, BSc MSc PhD<sup>3</sup>. <sup>1</sup>Obstetrics and Gynaecology, Heart of England NHS Foundation Trust, Birmingham, U. K., B9 5SS; <sup>2</sup>Fertility Focus Ltd., Warwick Innovation Centre, Warwick, U.K., CV34 6UW and <sup>3</sup>School of Veterinary Science, University of Bristol, U. K., BS40 5DU.

## Introduction

For the majority of the numerous couples taking an interest in their fertility, ovulation assessment and prediction of their optimal fertile period are important considerations.

For many decades, these have been based on the assumption that some historic principles are applicable to all women and to all their cycles. Unsurprisingly, current fertility prediction methods have been proven to be inaccurate.

Computerized analysis of standardized core body temperature measurements represents an opportunity for reliable prospective fertility prediction for the individual woman and her partner.

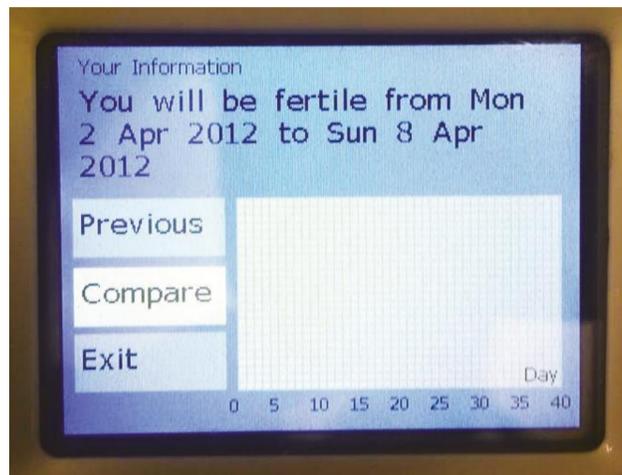


Fig.1: Prospective fertility prediction

## Results

Ovusense was a more accurate predictor of ovulation than the oral temperature method (mean distances to the true day of ovulation 1.57 and 3.10 days respectively,  $P = 0.025$ ,  $df = 20$ ,  $t = 2.415$ ,  $95\%CI = 0.20$  to  $2.84$ ).

There was no significant difference between Ovusense and the LH method (mean distances to the true day of ovulation 1.54 and 0.81 days respectively,  $P = 0.159$ ,  $df = 21$ ,  $t = 1.462$ ,  $95\%CI = -0.31$  to  $1.76$ ). Ovusense predictions overshot the true ovulation day on 13 occasions and undershot on 3 occasions. A binomial test showed this to be a significant bias ( $P = 0.011$ ).

There was no significant bias in the estimates made by the oral method (12 overshoots and 7 undershoots,  $P = 0.180$ ). No adverse events were reported by Ovusense users.

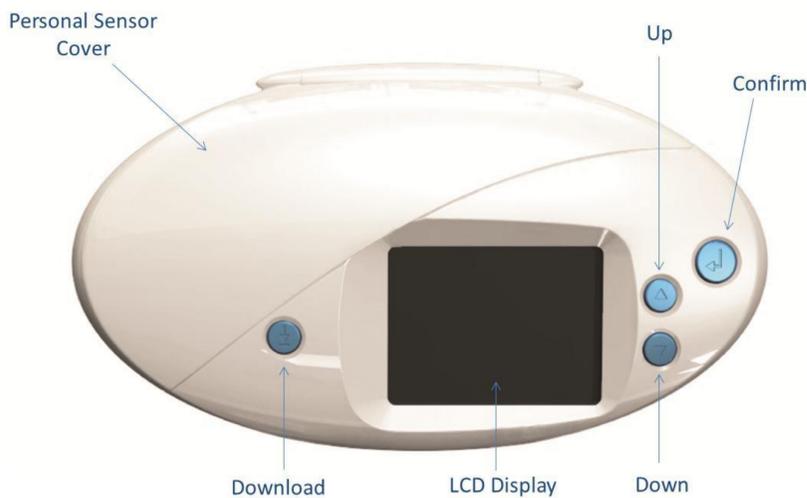


Fig. 2: OvuSense Device I



Fig. 3: OvuSense Device II

## Materials and Methods

A novel system (Ovusense) of a vaginal sensor, which records core body temperature at 5 min intervals during night time sleep and a portable reader, to which this information is downloaded, has been developed. An algorithm has been established, which, through analysis of this information, records ovulation during the index cycle and predicts the individual user's fertile period in the following cycle. In this initial trial, 20 women used the system for a total of 23 cycles. The women also recorded daily oral temperature and urinary LH testing results. Ultrasound was used to ascertain ovulation and establish the accuracy of the system's predictions in comparison to the oral temperature and LH methods.

Comparison between these methods was made by measuring the distance of the day of ovulation given by each method from the true day of ovulation as recorded by ultrasound and then comparing the distances by means of a paired t-test.

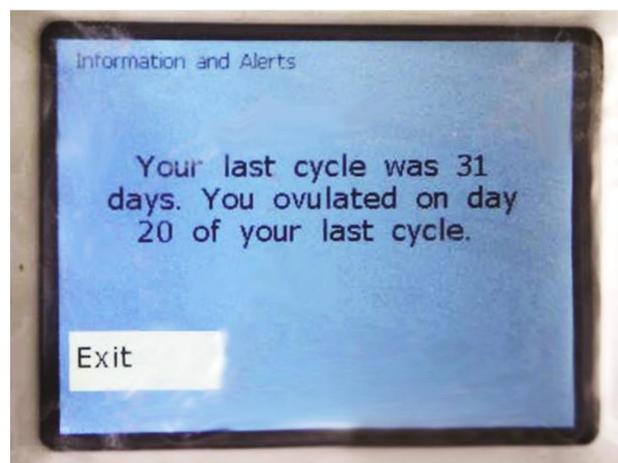


Fig.4. OvuSense confirms normal ovulation

## Conclusions

The Ovusense system represents a novel approach to addressing the common knowledge need for assessing ovulation and predicting the period of maximum fertility, for fertility aware couples and women. This it achieves by collecting and storing the individual's core body temperature data which are then used to explore the fertility of that individual woman. Ovusense appears to be better or as good a fertility prediction method as commonly used such methods.

The Ovusense algorithm thus far has been developed from theory. Trial data can be tested for bias in the direction of the error in estimating the day of ovulation. The results indicate that it should be possible to improve its predictive power by its adjustment on this basis. Furthermore, the algorithm is expected to produce more accurate results the more information is input. We are conducting a bigger trial of the Ovusense system and will be reporting further data in the near future..

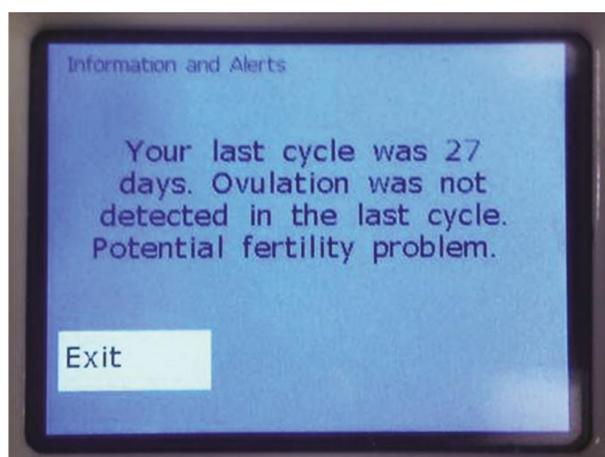


Fig 5. OvuSense will detect ovulation problems early

## References

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fertility focus