
Peer reviewed version

Link to published version (if available):
10.3109/01443615.2013.817984

Link to publication record in Explore Bristol Research
PDF-document

University of Bristol - Explore Bristol Research
General rights

This document is made available in accordance with publisher policies. Please cite only the published version using the reference above. Full terms of use are available:
http://www.bristol.ac.uk/pure/about/ebr-terms
User’s acceptability of OvuSense: A novel vaginal temperature sensor for prediction of the fertile period

S. Papaioannou1, M. Aslam2, B. H. Al Wattar1, R. C. Milnes2 & T. G. Knowles3

1Department of Obstetrics and Gynaecology, Heartlands Hospital, Birmingham, 2Fertility Focus Ltd, Warwick, and 3School of Veterinary Science, University of Bristol, Bristol, UK

Measuring changes in core body temperature provides a valid method to detect ovulation and increase fertility. ‘OvuSense’ is a novel vaginal sensor that can predict the fertility window by recording and analysing the changes in intravaginal temperature records. This study aimed to determine patients’ acceptability and satisfaction after using OvuSense. We approached 13 women to complete a patient satisfaction survey after using OvuSense in a prospective, longitudinal, comparative study, to test its validity and accuracy in detecting ovulation over a minimum period of three cycles. All 13 women agreed to participate in this survey. The majority of the participants found the usage of the reader to be very easy; 76.9% of the women said it was extremely comfortable to use the device during the night and 76.9% found the idea of using the intravaginal reader to be very convenient. Overall, 69.2% of women were extremely satisfied using the device. The idea of detecting intravaginal core body temperature changes appears to be highly acceptable by women.

Keywords: Fertility and assisted reproduction, fertility control, general gynaecology

Introduction

Ovulation and fertile period prediction, despite a number of different developments in this area, remain questions important for a significant number of women and their partners, to which clear answers are still difficult to find. Oral temperature recording represents one, still common, approach to address this issue. Although the principle behind it is well understood, its practical application has been shown to be unreliable, even misleading (National Institute of Clinical Excellence, NICE 2004). It is subject to error variation due to external factors and variation in technique. In contrast, core body temperature is not influenced by such factors and should be a much better reflection of internal hormonal changes within the menstrual cycle.

A novel vaginal sensor, which records core body temperature at 5 min intervals during the night, thus removing any bias due to technique variation and differing behaviours, has been developed. Temperature information is downloaded to a special reader. This reader uses a specifically developed software algorithm to analyse the data and calculate the fertile period during the forthcoming cycle on entry, by the user, of the date of the first day of her menstrual period. This system has already achieved CE marking in the UK and is commercially available as OvuSense (Fertility Focus Ltd).

One of the potential drawbacks of the vaginal approach to temperature recording is the inconvenience that a vaginal device, which needs to be used overnight, might cause. In this paper, we record the self-reported experience of users of this device, who participated in the clinical trial for its licensing.

Methods and materials

The prospective, longitudinal, comparative study of OvuSense (OS) vs ultrasound detection of ovulation, was approved by the Leeds Research Ethics Committee (West), UK. It was also approved by the Medicines and Healthcare Products Regulatory Agency (MHRA), UK. Volunteers were recruited through advertisements in the local press. The inclusion criteria were as follows: (1) age between 20 and 37 years; (2) cycle length of between 26 and 36 days; (3) body mass index within the range 19–29; (4) no use of oral contraception or hormonal treatments or lactation for the previous two cycles; (5) no regular medication which could alter basal body temperature (BBT), cycle or ovulation; (6) able to pass an inspection for vaginal health to include a Chlamydia cervical swab; (7) sign the informed consent form; (8) must be available for ultrasound scan for up to three consecutive days at around the time of ovulation and (9) has had fewer than three miscarriages. Women with known ovulation abnormalities or abnormal cycles, as well as women with abnormal patterns of sleep or shift workers were excluded. An honorarium was paid to each subject at completion of successful participation in the study.

Following the initial screening as above, each study participant was issued with an individually identified OS fertility monitor, comprising of a reader and a disposable personal sensor (Figure 1). The sensor dimensions are: overall length tip to tail: 118 mm; maximum outside diameter: 23 mm; minimum thickness of outer coating on sensor body: 1 mm; thickness of internal shell: 1 mm and tail-length, 96 mm; diameter: 3 mm. Each sensor was used for up to three cycles. The sensor was self-inserted into the vagina when the woman went to bed each night and was removed when she got up in the morning. The sensor was then cleaned with water and soap and dried and was then placed in its cradle on the reader, so that the data collected could be downloaded. Women started using the sensor on the day after menstruation ended and continued using...
it each night until the start of the next period. The principal investigator (SP) or a research nurse, were available 24 h/day to respond to any questions.

After completion of a cycle, each subject attended the investigation centre where progress was reviewed and the data for the cycle were downloaded by the principal investigator, from the reader to a laptop computer. After completion of at least three cycles, the first 13 participants were asked if they could fill in an online survey, something to which they all agreed.

**Results**

Of the 13 women who participated in the survey, seven wanted to become pregnant, while the rest did not. Summarised users’ responses to the survey questions can be seen as barcharts in Figures 2–5.

There were no differences between the women who wanted to become pregnant who would be expected to be more motivated and the women who did not want to become pregnant. Such a breakdown of results is not given here, given the small overall number.

The majority of the participants found the usage of the reader to be very easy: 76.9% of the women said it was extremely comfortable to use the device during the night; 23.1% said it was comfortable and none said it was uncomfortable (Figure 2).

Furthermore, 76.9% found the idea of using the intravaginal reader to be very convenient and never forgot to insert it (Figure 3); 76.9% found the insertion and removal of the reader to be very easy (Figure 4) and 91.6% found cleaning the reader to be extremely easy or easy (Figure 5).

The device software was very user friendly and received good feedback from the participants; none of the participants needed more than 5 s to work out what to do next (Figure 6) and 53.8% never had a problem downloading the data from the sensor to the reader (Figure 7).

Overall, 69.2% of women were extremely satisfied using the device; 23.1% were moderately satisfied and only 7.75% were moderately dissatisfied (Figure 8).

**Discussion**

The results of this OvuSense user’s survey, document high levels of satisfaction with the device, as well as high levels of acceptance of the concept and use of a vaginal sensor. Overall, during the study, as well as during the recruitment and screening periods before it commenced, no reluctance or concern about the use of the vaginal sensor was voiced by any participant.

These results are in agreement with those of many similar previous studies of vaginal devices. Recently, there has been a significant expansion in the possible new uses of the vaginal route in the improvement of all aspects of female healthcare; acceptance of such techniques by women has been documented to be high. These include, self-diagnostic tests for the detection of the human papilloma virus (Huynh et al. 2010; Anhang et al. 2005); the detection of increased vaginal pH (Donders et al. 2012); the contraceptive vaginal ring (Novak et al. 2003); new contraceptive diaphragms for microbicide delivery (Frezieres et al. 2012; Coffey et al. 2008); stress incontinence treatment devices (Thyssen et al. 2001), as well menstrual cups and feminine hygiene industry products (Howard et al. 2011). Furthermore, the vaginal route has been employed for the study of intra-abdominal pressure (Coleman et al. 2012) and changes in the vaginal blood supply (Palti and Bercovici 1967).

The development of a vaginal device such as the OvuSense Sensor to record core body temperature is a logical continuation of the efforts to take advantage of vaginal access for the improvement of female healthcare, in this case, within the context of reproductive medicine. Vaginal temperature sensors have been used before for the study of the function of different tampons (Hill et al. 2010). A possible relationship between the timing of ovulation and the shift in basal body temperature was first
suggested in 1904 by the Dutch gynaecologist, Theodoor Hendrik van de Velde (Anon 1978). The principle behind this method is sound; the rise in progesterone in the second half of the cycle does result in a rise in basal body temperature due to the qualities of progesterone (Zuspan and Rao 1974). Oral temperature recording however, by far the most common approach in utilising this principle, has been found to be reliably unreliable (Bauman 1981).

The OS system introduces a number of contemporary improvements to the delivery vehicle of the old idea of basal body temperature charting: (i) the number of temperature recordings used is far increased; from once in the morning to every 5 min during night sleep; (ii) these temperature recordings are now obtained far closer to the body core than any other method and (iii) analysis of this data is not left to the individual woman and her partner, but is accomplished by computerised analysis through a specifically developed algorithm that removes user variability and bias from the process and which has been shown to offer a marked improvement in accuracy of ovulation detection (Papaioannou et al. 2012).

Some concerns about the use of such devices have been created among some women, as well as among some health professionals, by the well known complication of toxic shock syndrome reported in association with tampon use. However, the risk of this complication has been documented to correlate with the absorbency of the tampon responsible and infections that occur during menstruation (Reingold 1991). The OvuSense Sensor is
non-absorbent and is used only during the days of the cycle that the woman is not menstruating, thus there is no concern regarding toxic shock. There were no side-effects or complications reported by any of the participants throughout the study.

The reasons of the high acceptance rates recorded with the OvuSense Sensor, as well as with other vaginal devices, could be various. Women value the self-control that a discreet portable user dependant device offers, as opposed to visiting health professionals. The motivation of women to become pregnant would be another reason, although in our population, women who joined the study without wanting to become pregnant showed similar acceptance rates. Contemporary women, exposed to an increasing number of vaginal products, perhaps are more accustomed to the idea of using such products.

Despite a possible perception of inconvenience with vaginal devices, our data showed that in-line with other vaginal devices, user acceptance of this sensor is high.

Declaration of interest: The authors alone are responsible for the content and writing of the paper. S. Papaioannou and T.G. Knowles are paid consultants of Fertility Focus Ltd. M. Aslam is an employee of Fertility Focus Ltd. R.C. Milnes is the CEO of Fertility Focus Ltd. B.H.A.L Wattar has no conflict of interest.

References
Anon. 1978. Classic page in obstetrics and gynecology. Ueber den Zusammenhang zwischen Ovarialfunction, Wellenbewegung und Menstrualblutung, und ueber die Entstehung des sogenannten...


Papaioannou S, Aslam M, Al Wattar BH, Milnes RC, Knowles TG. 2012. Ovulation assessment by vaginal temperature analysis (the OvuSense advanced fertility monitoring system) in comparison to oral temperature recording. American Society for Reproductive Medicine, 68th Annual Conference, San Diego, USA.
