

ATYPICAL VAGINAL TEMPERATURE PATTERNS MAY IDENTIFY SUBTLE, NOT YET RECOGNISED, CAUSES OF INFERTILITY

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Objective

To determine if averaged nocturnal vaginal Core Body Temperature measurements recorded during non-menstruation by use of the Ovusense system (OS), could describe atypical patterns potentially associated with reduced fertility.

Study Design

Retrospective, longitudinal, comparative, observational study.

Materials and Methods

10,463 ovulatory cycles from 6,647 OS users aged 20 to 52 (if age provided), with cycle length 11 to 190 days (90% 22 to 47 days).

Participants used OS vaginally at night to monitor Core Body Temperature (CBT), having voluntarily been asked to provide date of birth and identify how long they had been trying to conceive before OS use. OS produces a representative "raw" CBT for each night of recordings taken every 5 minutes, which are then assessed with a proprietary moving averaged calculation to produce a "smooth" CBT analysis curve.

The main outcome measures were: proportions of normal and atypical OS CBT patterns as classified by observation of the smooth curve and applied mathematical criteria, frequency of their occurrence, and associations between patterns.

Support

The study was financially supported by Fertility Focus Ltd.

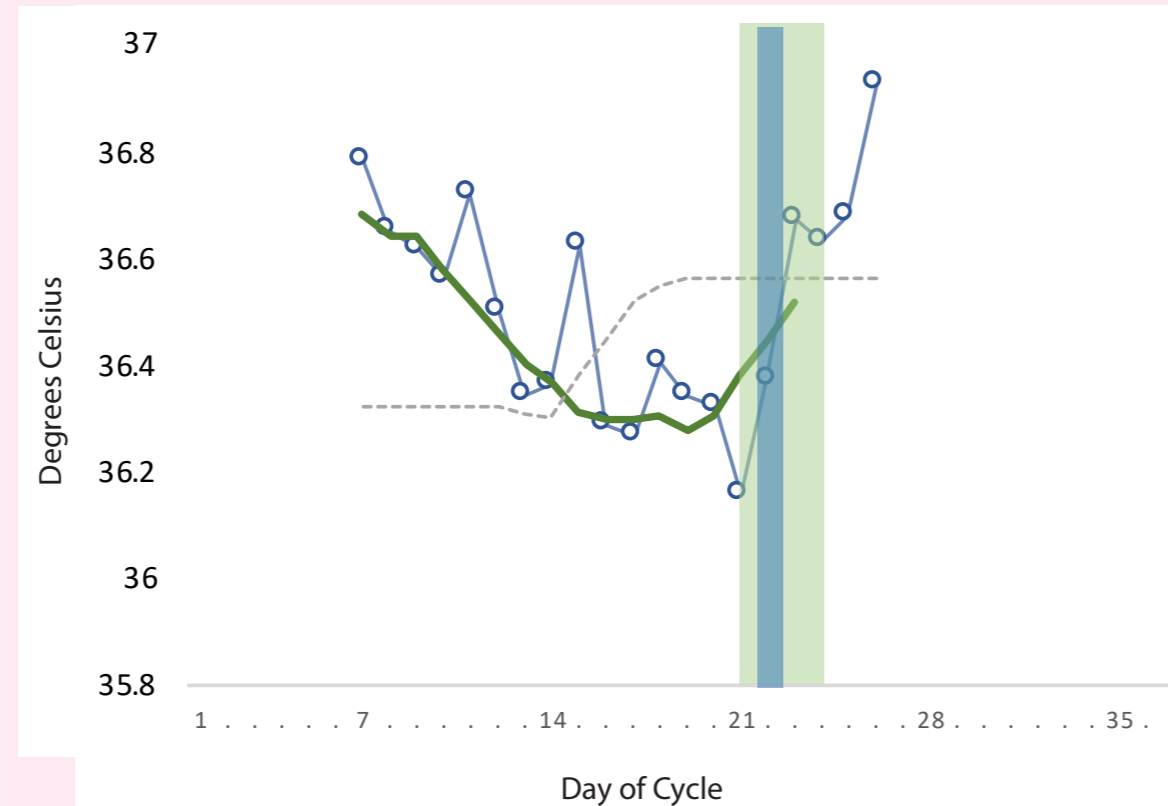
Results

3,721 cycles exhibited one or more novel 'atypical' core body temperature patterns (a), (b), or (c).

(a) "Crash To Baseline" = first nightly averaged CBT falls by >0.2 degrees Celsius (°C) to lowest averaged CBT point in cycle (baseline): 1,481 cycles (14.2%) from 1,352 OS users (20.3%)

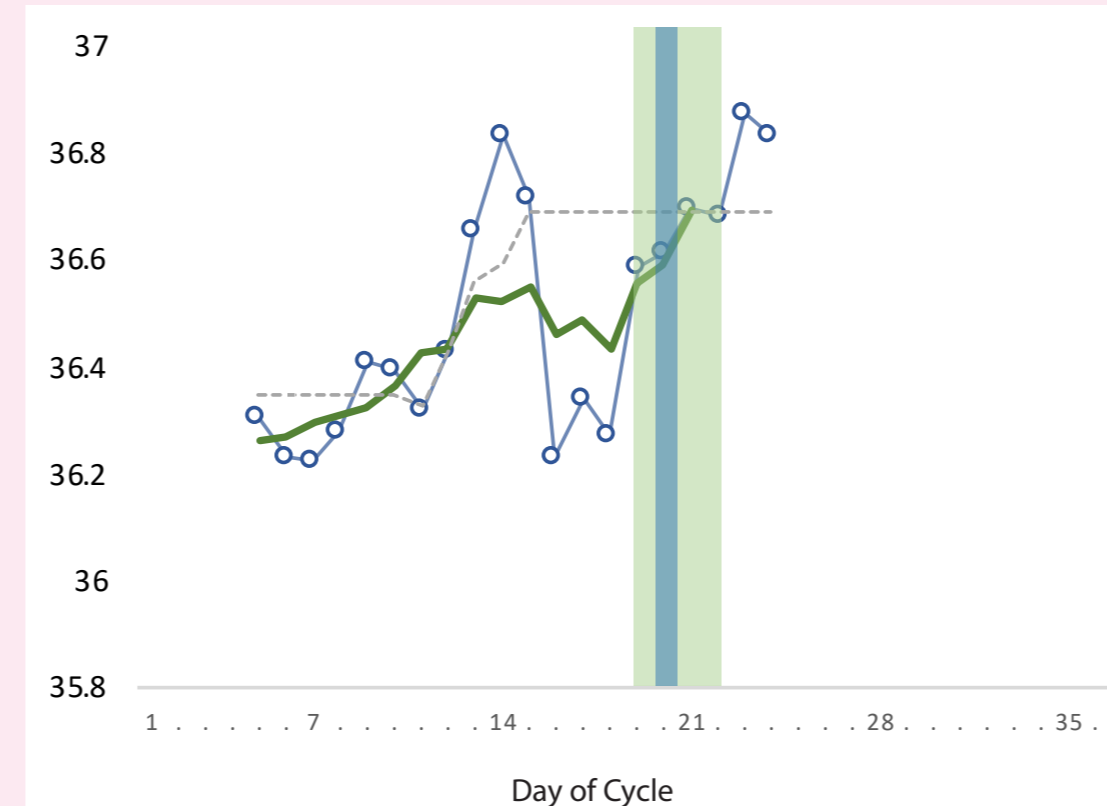
(b) "False Start" = rise of >0.1 °C did not result in ovulation but instead a return to baseline CBT followed by ovulation two or more days later in the cycle: 981 cycles (9.4%); 939 users (14.1%)

(c) "Crash After Ovulation" = final "raw" CBT >0.2 °C lower than the post ovulatory peak averaged CBT: 1,259 cycles (12.0%); 1,062 users (16.0%)



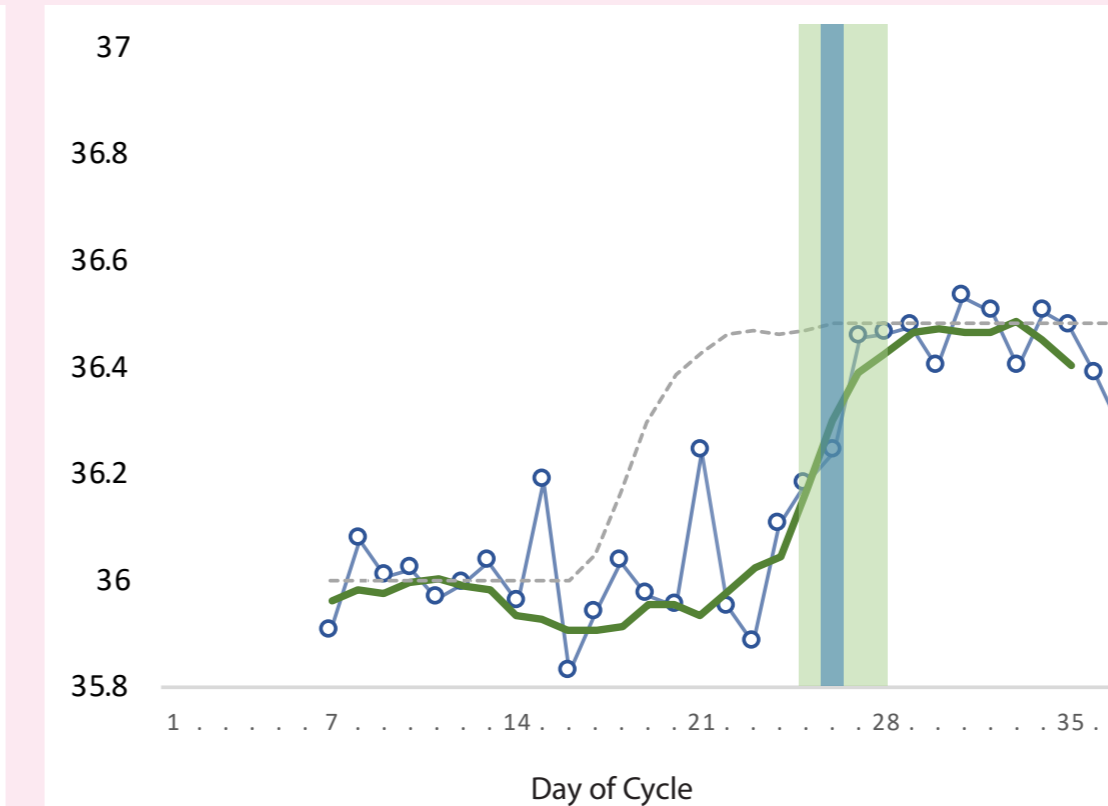
"Crash To Baseline" example

- OS user age: 37
- Trying to conceive: 1-2 years prior to use of OS
- Cycle length for this cycle: 26 days
- OS recordings taken: from day 7 to day 26
- OS confirmed ovulation: day 22
- Similar CBT pattern for user: 3 out of 7 recorded cycles



"False Start" example

- OS user age: 30
- Trying to conceive: 0-6 months prior to use of OS
- Cycle length for this cycle: 24 days
- OS recordings taken: from day 5 to day 24
- OS confirmed ovulation: day 20
- Similar CBT pattern for user: 3 out of 7 recorded cycles



"Crash After Ovulation" example

- OS user age: 29
- Trying to conceive: No information provided
- Cycle length for this cycle: 38 days
- OS recordings taken: from day 7 to day 38
- OS confirmed ovulation: day 26
- Similar CBT pattern for user: 6 out of 10 recorded cycles

Additionally, Short Luteal Phase (SLP) (d) was noted with menstruation 9 or fewer days post-ovulation - 871 cycles (8.3%); 793 users (12.0%). SLP co-existed with pattern (a), (b), or (c) in 237 cycles (2.3%); 231 users (3.5%). SLP co-existed with (a) 133 cycles; 128 users, with (b) 155 cycles; 153 users, with (c) 7 cycles; 7 users. SLP co-existed with pattern (a) + (b) 33 cycles; 32 users, and as in low frequency with (a) + (c) 1 cycle; 1 user, and (b) + (c): 2 cycles; 2 users.

Explanation of Charts

OS plots standard charts on a daily basis. The blue line shows the best representative "raw" CBT value produced by the OS algorithm for each set of overnight measurements taken every 5 minutes. The green "smooth" weighted average CBT curve is used by the OS algorithm to predict ovulation up to 24 hours in advance using this current cycle's data, and then confirm ovulation. A grey "textbook" smoothed curve has been added to these charts for the purpose of this paper to show the typical pattern which might have been expected for this cycle, taking into account an expected "textbook" middle of the cycle ovulation.

○ Representative "raw" CBT overnight values — "smooth" weighted averaged CBT analysis - - - "textbook" smoothed curve for this cycle Green shading is "ovulation window" from ovulation day -1 to ovulation day +2 Blue shaded line is Ovusense detected day of ovulation

Conclusions

It is likely OS continuous vaginal temp patterns closely reflect luteal progesterone changes, hence describe subtle progesterone secretion or metabolism anomalies, which not yet have been recognised.

(a) suggests high progesterone early in the cycle, (b) suggests an initial LH surge and accompanying small progesterone rise may not always be followed by ovulation within 48 hours. (a) and (b) would be expected to occur in women with PCOS, and further studies are planned to examine this within the OS population.

(c) suggests that progesterone may fall sharply in some women before onset of menses, and it is possible that fertility may be impaired in these cycles.

The co-existence of SLP with patterns (a), (b), and/ or (c) indicates vaginal, core-body temp monitoring may represent a promising method of identifying previously undetectable causes of infertility in women with "normal" ovulation. It should also be noted that ovulation generally occurs much later in each of these patterns than the "textbook" middle of the cycle.

References

1. Papaioannou S, Delkos D, Pardey J (2014) Vaginal core body temperature assessment identifies pre-ovulatory body temperature rise and detects ovulation in advance of ultrasound folliculometry. ESHRE 30th Annual Conference.
2. Papaioannou S, Aslam M (2012) Ovulation assessment by vaginal temperature analysis (Ovusense Fertility Monitoring System) in comparison to oral temperature recording. ASRM 68th Annual conference.