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

Hurst B. MD.[a], Pirrie A. BSc[b], Milnes R.C. BA[b], Knowles T.G. BSc MSc PhD[c]
a Department of Assisted Reproduction, Carolinas Medical Center, Charlotte, NC, United States;
b Fertility Focus Limited, Warwick, Warwickshire, United Kingdom; c Faculty of Medical and
Veterinary Sciences, University of Bristol, Bristol, Somerset, United Kingdom.

fertility focus

Study Introduction

Objective

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

Study Design

Retrospective, longitudinal, comparative, observational study.

The OvuSense System

Core Body Temperature (CBT) Readings

Every 5 minutes, nightly

Using Vaginal Sensor and Android/ iOS App

Enables

- 24 hour advance prediction of ovulation

- Confirmation of date of ovulation

- Continuous proxy monitoring of progesterone level throughout cycle

Materials and Methods

10,463 ovulatory cycles, from

6,647 OvuSense users,

aged 20 to 52 (if age provided),

with cycle length 11 to 190 days (90% 22 to 47 days).

Participants used OvuSense 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.
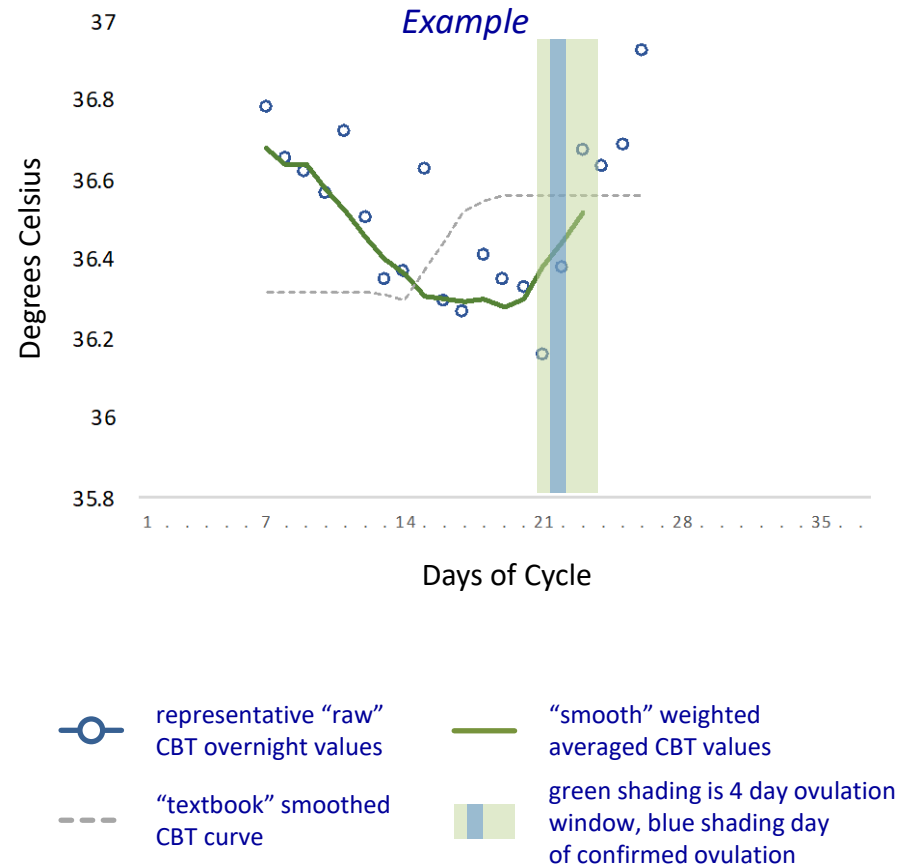
Outcome Measures

The main outcome measures were:

- proportions of normal and atypical OvuSense CBT patterns

- as classified by observation of the smooth curve

- and applied mathematical criteria,

- frequency of their occurrence,
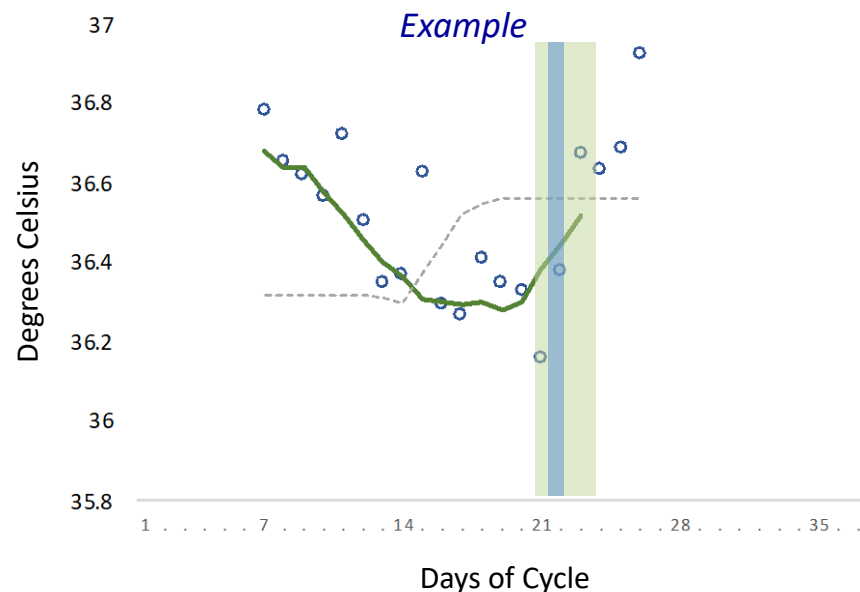
- and associations between patterns

- 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.

Example

Days of Cycle

○—○ representative "raw" CBT overnight values

— "smooth" weighted averaged CBT values

--- "textbook" smoothed CBT curve

green shading is 4 day ovulation window, blue shading day of confirmed ovulation

Novel Atypical Temperature Pattern a "Crash To Baseline"

- First nightly averaged Core Body Temperature falls by >0.2 degrees Celsius to lowest averaged CBT point in cycle (baseline)

- 1,481 cycles (14.2%)

- from 1,352 OvuSense users (20.3%)

- Suggests high progesterone early in the cycle

- Expected to occur in women with PCOS, further study will examine this within OvuSense population

Example

Degrees Celsius

Days of Cycle

Age	37
Trying to conceive	1-2 years prior to OS use
Cycle length	26 days
OS recordings taken	from day 7 to day 26
OS confirmed ovulation	day 22
Similar CBT user pattern	3/ 7 recorded cycles

○ representative "raw" CBT overnight values

— "smooth" weighted averaged CBT values

- - - "textbook" smoothed CBT curve

green shading is 4 day ovulation window, blue shading day of confirmed ovulation

Novel Atypical Temperature Pattern b
"False Start"

- Rise of >0.1 degrees Celsius 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%)

- from 939 OvuSense users (14.1%)

- Suggests an initial LH surge and accompanying small progesterone rise may not always be followed by ovulation within 48 hours

- Expected to occur in women with PCOS, further study will examine this within OvuSense population

Example

Degrees Celsius / Days of Cycle

representative "raw" CBT overnight values	"smooth" weighted averaged CBT values
"textbook" smoothed CBT curve	green shading is 4 day ovulation window, blue shading day of confirmed ovulation
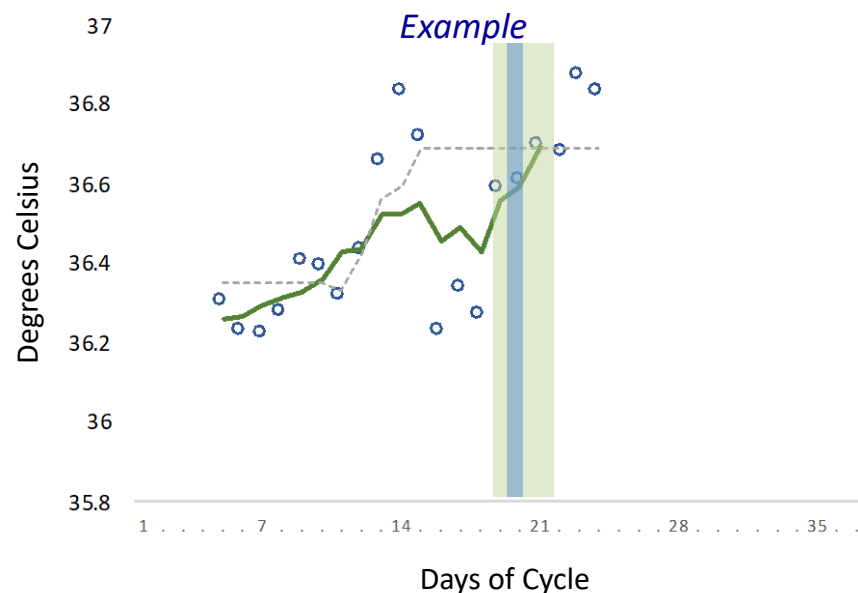
Age	30
Trying to conceive	0-6 months prior to OS use
Cycle length	24 days
OS recordings taken	from day 5 to day 24
OS confirmed ovulation	day 20
Similar CBT user pattern	3/ 7 recorded cycles

Novel Atypical Temperature Pattern c
"Crash After Ovulation"

- Final "raw" CBT >0.2 degrees Celsius lower than the post ovulatory peak averaged CBT

- 1,259 cycles (12.0%)

- from 1,062 OvuSense users (16.0%)

- 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.
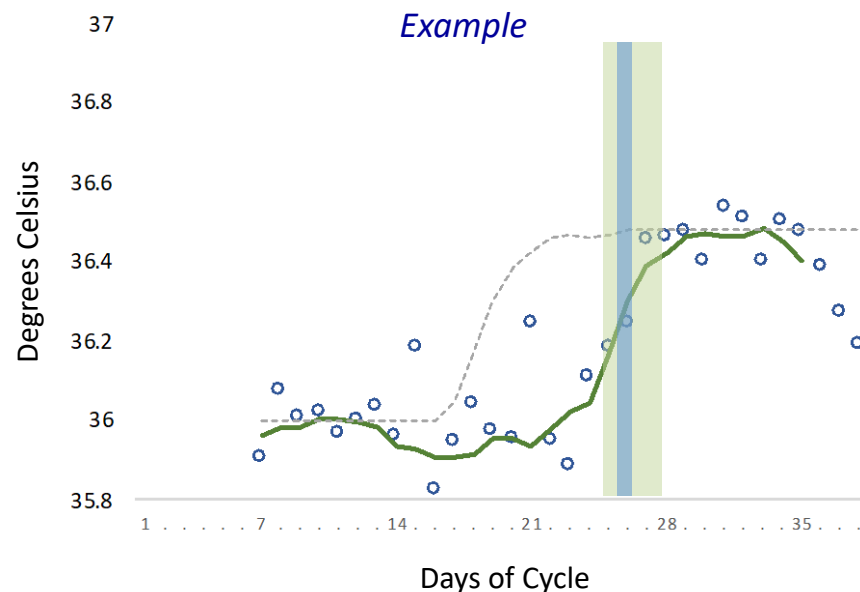
Example

Degrees Celsius — Days of Cycle

Age	29
Trying to conceive	No information provided
Cycle length	38 days
OS recordings taken	from day 7 to day 38
OS confirmed ovulation	day 26
Similar CBT user pattern	6/ 10 recorded cycles

representative "raw" CBT overnight values

"smooth" weighted averaged CBT values

"textbook" smoothed CBT curve

green shading is 4 day ovulation window, blue shading day of confirmed ovulation

Co-Existence with Short Luteal Phase (SLP) d

- 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.

Example SLP co-existent with a Luteal Phase 6 days
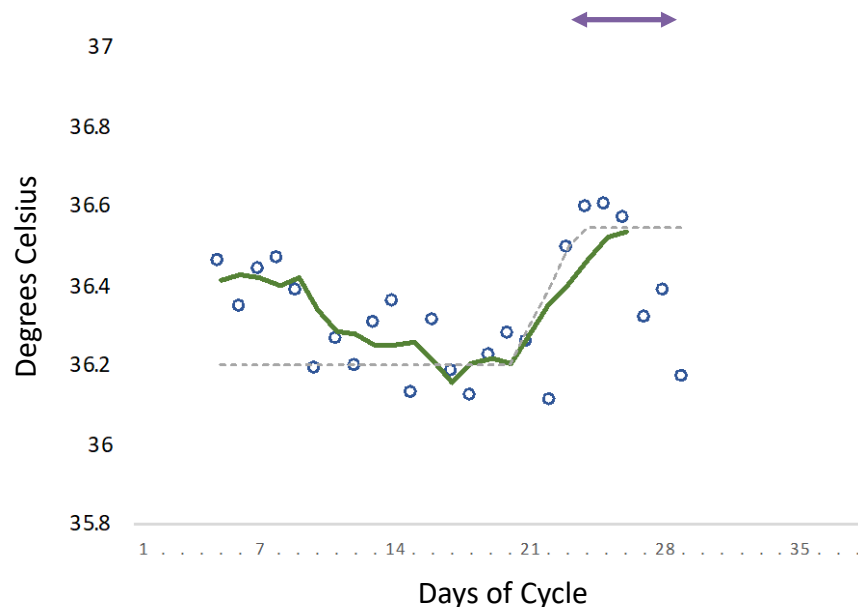
Days of Cycle

Age	35
Trying to conceive	3-5 years prior to OS use
Cycle length	29 days
OS recordings taken	from day 6 to day 29
OS confirmed ovulation	day 23

representative "raw" CBT overnight values

"smooth" weighted averaged CBT values

"textbook" smoothed CBT curve

green shading is 4 day ovulation window, blue shading day of confirmed ovulation

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.