ATYPICAL TEMPERATURE PATTERNS AS AN AID TO IDENTIFY INFERTILITY ISSUES AND MISCARRIAGE RISK
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Study Question
To determine if ovulatory abnormalities and risk of miscarriage were associated with atypical Patterns of vaginal core body temperature (CBT) measurements from the OvuSense system.

Study Design, Size, Duration
Retrospective, longitudinal, comparative, observational study. Participants used OvuSense nightly at home from March 2016 and December 2019. A detailed medical questionnaire was then used to study participants and the answers from 375 respondents accounting for 1,491 of the recorded cycles was used for further assessment.

What Is Known Already?
Three novel, atypical CBT Patterns published previously, confirmed in updated population of 18,679 ovulatory cycles: (A) "Crash To Baseline" = first nightly averaged CBT falls by >0.2 degrees Celsius (°C) to lowest cycle CBT point in cycle (baseline), (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, (C) "Crash After Ovulation" = final CBT falls by >0.2°C lower than the post ovulatory peak CBT. It is likely Ovum patterns closely reflect progesterone changes, hence cycle-related hormonal abnormalities may be associated with atypical patterns.

Participants / Materials, Setting, Methods
TSP used to confirm prevalence of cycle Patterns (A)-(C); and questionnaire assessed per respondent for each following existing ‘Diagnosis’: 1. Any infertility related diagnosis, 2. PCOS, 3. PCOS and regular cycles; 4. Previous miscarriage = gravida >0, number of miscarriages >0. Diagnostic Odds Ratio (OR) calculated as (w/x)/y/z) for each Pattern + Diagnosis combination together with their 95% confidence interval: w: Positive Diagnosis (+D), Pattern >1 cycle for respondent (+P); x : -D+P; y: +D-P; z: -D-P.

Results

18,679 cycles from 8,653 OS users in Total Study Population (TSP). Detailed medical questionnaire then responded to by 375 users accounting for 1,491 cycles.

Example Cycle Details

<table>
<thead>
<tr>
<th>Pattern</th>
<th>Description</th>
<th>Example</th>
<th>Cycles</th>
<th>Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>(A) &quot;Crash To Baseline&quot;</td>
<td>first nightly averaged CBT falls by &gt;0.2 °C to lowest CBT point in cycle (baseline)</td>
<td>a. 37 b. 1-2 years prior to OS c. 26 days d. from day 7 to day 26 e. day 22 f. 3-7 recorded cycles</td>
<td>263 cycles (17.6%)</td>
<td>164 respondents (43.7%)</td>
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<tr>
<td>(B) &quot;False Start&quot;</td>
<td>rise of &gt;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</td>
<td>a. 38 b. 0-6 months prior to OS c. 24 days d. from day 5 to day 24 e. day 22 f. 3/7 recorded cycles</td>
<td>202 cycles (13.5%)</td>
<td>133 respondents (36.5%)</td>
</tr>
<tr>
<td>(C) &quot;Crash After Ovulation&quot;</td>
<td>final “raw” CBT &gt;0.2 °C lower than the post ovulatory peak averaged CBT</td>
<td>a. 29 b. Not provided c. 38 days d. from day 7 to day 38 e. day 26 f. 6 / 10 recorded cycles</td>
<td>216 cycles (14.4%)</td>
<td>128 respondents (34.1%)</td>
</tr>
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The Role of Chance
These results indicate strong associations between reported Historic Diagnosis and the atypical CBT Patterns identified using the OS system. The high OR for each Pattern associated with miscarriage merits further investigation, as the cohort has a low pregnancy rate.

Limitations, Reasons for Caution
The authors note the co-existence of Pattern + Diagnosis is not strictly “predictive”, as each Diagnosis is by definition historic. The population is by definition biased to one or more Historic Diagnosis as over 57% of respondents report having been trying to conceive for a year or more prior to use.

Wider Implications of the Findings
Results suggest that atypical CBT Patterns may aid diagnosis, and in particular elevated risk of miscarriage. It should be noted of an existing of an existing Historic Diagnosis does not necessarily render the results with positive Patterns "false", and the existence of a Pattern could anyway indicate investigation for ovulatory abnormalities.

References

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.

Study Funding/Competing Interests
Study was financially supported by Fertiity Focus Ltd.