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Evaluating the Accuracy of O'Tracker: A Stick-To-Skin Wireless BBT Sensor to Identify Fertility Window

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ABSTRACT

Objective: The study identifies the event of ovulation using an IoT-based device called "O'Tracker" in contrast with the transvaginal ultrasound in trying to conceive women.

Methods: This prospective study includes a total of 30 cycles from 27 women who were trying to conceive. They were asked to use the O'Tracker device from the 10th day of their menstrual cycle to the 18th day, i.e., 8 days for 7 hours per night.

Result: In the conclusive evaluation, a total of 30 cycles underwent scrutiny, wherein the O'Tracker predictions of the ovulation window were aligned with physicians' predicted ovulation window from the USG reports in 27 cycles, indicating a commendable accuracy rate of 90%. Upon proximity to the ovulation window predicted by O'Tracker with those derived from the USG report (considered as the ground truth for validation) the concordance was observed in 25 out of 27 accurately predicted ovulatory cycles. Furthermore, when compared to the physician-predicted ovulation window from USG reports, O'Tracker exhibited concordance in 23 out of 27 cycles.

Conclusion: The study evaluation reveals that O'Tracker attains a 90% accuracy in predicting ovulation as compared to physician assessment, demonstrating a match rate exceeding 90% with fertile windows ascertained through ultrasound monitoring. This level of precision stands on with established traditional diagnostics methodologies. O'Tracker manifests a user-friendly and accessible digital ovulation monitoring platform.

Keywords: Ovulation monitor, Fertility window, Basal body temperature, Conception, FemTech, Digital fertility tracker.

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INTRODUCTION

The menstrual cycle is an interplay of various hormones, viz., Gonadotropin-releasing hormone (GnRH), Follicle stimulating hormone (FSH) and luteinizing hormone (LH)). It is divided into two phases: follicular phase and luteal phase. The follicular phase starts from the first day of menses until ovulation, and the luteal phase starts after ovulation until and before the next menses. The average length of the menstrual cycle is considered to be 28 days.[1]

Prediction of the fertility window and identification of the precise time of ovulation is of utmost importance for women trying to conceive. There are various methods for ovulation detection, of which transvaginal ultrasonography is a gold standard technique to detect ovulation. The high-frequency probes with deep penetration result in higher resolution and more detailed pictures, making monitoring structural changes in the ovaries and follicular growth more reliable.[2,3] USG is highly reliable in monitoring ovulation, especially the transvaginal one, but it is difficult in low-middle-income countries (LMIC). A recent review article, which documented training opportunities for USG in LMICs, concluded that the majority of health personnel using ultrasound in LMICs did not meet the minimum WHO training standards.[4] Transvaginal sonography, which is currently the most common method of ovulation tracking, is an invasive, expensive and inconvenient technique mainly used as part of fertility-related treatments. The other commonly used home-based method for ovulation prediction is, luteinizing hormone (LH) measurement, which can be done by a radioimmunoassay technique that measures serum LH level, or a home-based urine LH test kit. Surveillance detection methods for urine LH have a higher incidence of false-negative results than radioimmunoassays

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applied to serum, but frequent measurements from serum are invasive and expensive.[5]

In terms of comparing O'Tracker to LH measurement, the current study was primarily concerned with determining the accuracy of O'Tracker in predicting ovulation based on sonographic outcomes, are indicated in the results. The LH measurement was not included in the study design; hence, no data regarding LH measurements and their comparison with O'Tracker predictions are supplied. However, it is important to note that our research efforts are continuous, and we are now accomplishing a separate study with healthy participants. We actively include LH measures in this ongoing study as part of our investigation to thoroughly evaluate and contrast O'Tracker's performance with LH readings. In a study of Chronological aspects of ultrasonic, hormonal, and other indirect indices of ovulation 326 menstrual cycles, ultrasonography evidenced ovulation in 283 cycles with a tight temporal correlation to luteinizing hormone (LH) peaks.[11] However, 10% exhibited premature LH-expected dates, and 23% displayed late dates. In contrast, a rise in basal body temperature (BBT) occurred in 98% of cycles, underscoring its superior reliability. BBT's consistent association with ovulation highlights its paramount importance, emphasizing its significance alongside other markers for a comprehensive understanding of menstrual cycle dynamics.

Monitoring the changes in the basal body temperature (BBT) is a time-honored method for anticipating ovulation. Due to the thermogenic effect of progesterone, BBT rise of 0.5-1.0ºF can be observed, indicating the occurrence of ovulation, and sustains until the start of menses. The biphasic shift in temperature can be used as a confirmatory marker of ovulation. The reliability of BBT results for ovulation detection gives an average 90.5% true positive rate, and approximately 4% false negative rate.[6] It is possible that repeated measurements of BBT throughout the night may give more accurate results for ovulation prediction than single-time recordings of BBT after waking up. [7]

O'Tracker™ is a Smart Healthcare IoT solution that brings personalized ovulation tracking with support from Gynaecologists. It is supplied with a smart sensor to track BBT accurately, it tracks the smallest changes in the body temperature. The O'Tracker™ app wirelessly records the temperature along with sleep data and uploads it to the cloud server. It measures the BBT continuously during the fertile window, and the smart AI algorithm and our proprietary software compare temperature curves to give precise measurements and ovulation identification.

Better understanding the specificities of own menstrual cycles and identification of fertile days would help women exercise their bodily autonomy and rights. Identifying a fertility window is key for women trying to conceive. At the same time, getting more specific qualitative information about factors like cervical fluid consistency, sleep disturbance and emotional stress would help doctors in treating menstrual irregularities and fertility-related problems. In this situation, O'tracker, a Healthcare IoT solution for personalized ovulation tracking with support from Gynaecologists, could be helpful for d.octors as well as for women. O'Tracker has been designed to help women understand their menstrual cycles, communicate more effectively about menstruation with health providers, and assess how their bodies respond to treatments.

O'Tracker provides an easy and non-invasive platform for monitoring ovulation, which may help medical professionals by providing a viable window. Its efficacy in a therapeutic context is supported by its prediction accuracy, which agrees with sonographic interpretations. Additionally, physicians may schedule sonography appointments using the data that O'Tracker provides due to its remote patient monitoring. This ability helps physicians manage their cycles more effectively, allowing them to track and improve patient care from a distance. Medical professionals may find managing their patients' reproductive cycles simpler using O'Tracker's real-time data and continuous tracking capabilities.

METHODOLOGY

Female patients visiting the IVF department at Deenanath Mangeshkar Hospital and Research Centre were recruited for the study. IEC approved the study at Deenanath Mangeshkar Hospital & Research Centre. The PI screened and referred the patients who fulfilled the inclusion criteria to the researcher. The inclusion criteria were as follows: Women in the age group of 20 to 45 years, women who are trying to conceive, women willing to undergo transvaginal ultrasound, and willing to use the O'Tracker device and comply with the study protocol. Subsequently, the researcher explained the study and device use to the potential participants. Participants were enrolled on signing the consent form and reading the PIS thoroughly and in accordance with the approval of the ethics committee. A CRF sheet was also filled out, which included a basic questionnaire about the demographic details of the patient and the details about their menstrual cycle, anthropometric measurements, and the current medications given. Total 63 participants were screened as eligible for the study, out of which 40 participants consented to participate. Out of these 40 participants enrolled, 27 participants eventually completed 30 cycles, which were included in the final analysis.

Individuals whose menstrual cycle lengths fell within the normal range as defined by the World Health Organisation (WHO) were included in the study. According to the WHO, a menstrual cycle should last 28 days on average, with variances between 21 and 35 days considered appropriate.[12] During the screening phase, each participant was asked directly about the duration of their menstrual cycles to verify that these requirements were being followed. Only individuals whose reported cycle lengths fell within the normal range 21 to 35 days were enrolled for the study. The rigorous selection procedure was designed to preserve participant consistency in menstrual cycle data, hence enhancing the validity and dependability of the study's conclusions.

Participants were asked to use O'Tracker every night in their fertility window, starting from their second sonography visit till two days after the sonography was completed. The participants were explained the app installation process at the time of enrollment. Each participant was first registered with a unique ID in the O'Tracker doctor's app (to maintain anonymity), access to which was only with the research team. Participants were asked to log a daily diary in the app prior to connection, which included questions regarding the number of hours of sleep, stress level and exercise level on a scale of 1-5 (1 being the lowest and 5 being the highest), the cervical mucus consistency, and symptoms if any.

After giving these inputs the participants were asked to connect the device and stick it on the flat area of the chest with the help of the adhesive stickers provided. The device was programmed to disconnect automatically after seven hours of use, and a single BBT reading was uploaded to the server every morning, which was reflected in both the patient's and doctor's apps. A graph was created after continuous use for 8-10 days and the smart AI algorithm compared the temperature curves to give precise measurements and accurate ovulation identification.

Participants visited the IVF department according to their scheduled visits for transvaginal USG; the PI performed sonography scans for all the participants. Investigators performing the sonography were blind to the outcomes given by O'Tracker till the end of the study, and the O'Tracker team was blind to the sonography outcomes.

For the final analysis, the ovulation prediction by O'Tracker was matched with the outcome from the USG reports. Due to the absence of exact ovulation dates in sonography, the ground truth for ovulation was established as the period between the last USG showing follicular development and the subsequent USG showing collapsed follicule, indicating the termination of the sonographic sequence. This interval was deemed the probable ovulation window. Sonographic Ground Truth Determination.

For the secondary outcome measure analysis, the physician provided ovulation windows based on clinical assessment, which served as a reference for comparing the O'tracker predictions. In the end, the two outcomes were matched. If the window predicted by O'Tracker matched exactly to the window by USG or by a difference of ± 1 day, the outcome was considered to be concurrent, i.e. a single common date in both the windows was considered as matching of the window.

The physician's predictions and those from O'tracker were normalized to a three – day window for a consistent comparative framework.

RESULTS

A total 63 patients were screened, fitting in the criteria for inclusion and eligible for the study. However, 40 participants had consented to participate in the study, of which 27 could complete the required sample size of 30 cycles; one used the device for three consecutive cycles, and one used the device for two consecutive cycles.

Table 1 shows the participants' demographic details included in the final analysis. Among the recruited participants, the majority were in the age group of 26-30 years. One-third

Table 1: Socio-demographic details of the participants

Total Participants (n = 27)	
Age (years)	*No. of participants*
21–25	4
26–30	14
31–35	9
Education	*No. of participants*
Below HSC	5
Graduate	14
Post-graduation and above	8
Occupation	*No. of participants*
Homemaker	10
Working professional	17

Table 2: Menstrual details of the participants

Menstrual Cycle	
Regular	18
Irregular	9
No. of days of menstrual bleeding (days)	
<3	7
3–5	19
>5	1

(9 participants) were in the age group 31 to 35 years, whereas 4 participants were in the age group of 21-25 years. Regarding educational attainment, of the participants is mentioned in Table 2. The majority of the participants (14 out of 27 participants) had completed graduation, eight had attained post-graduate degrees and 5 had studied up to Higher Secondary. Seventeen out of the 27 were working professionals, whereas10 participants were homemakers.

Figure 1 shows that a larger part of the study group (18 out of 27 participants) had regular menstrual cycles. Mostly, the cycle length varied between 28 to 35 days. One-fourth of the participants had short menstrual cycles less than 28 days, whereas five participants had menstrual cycle more than 35 days in length. More than two-thirds of the participants reported having bleeding for 3 to 5 days. One-fourth of the participants reported bleeding for less than 3 days and one participant reported bleeding for more than five days.

As per the Figure 2 BMI calculations, 3 participants were underweighted, 5 participants had a BMI within the healthy range, whereas most participants were overweight.

From Table 3, 30 cycles analyzed, the detection of the event of ovulation by O'Tracker matched the outcome from USG reports in 27 cycles (calculated using SPSS (v. 23)). O'Tracker ovulation prediction identified only three cycles as False Positives, indicating an accuracy of 90%.

The O'Tracker algorithm did not detect even a single cycle as a false negative, indicating a sensitivity of 100%. However,

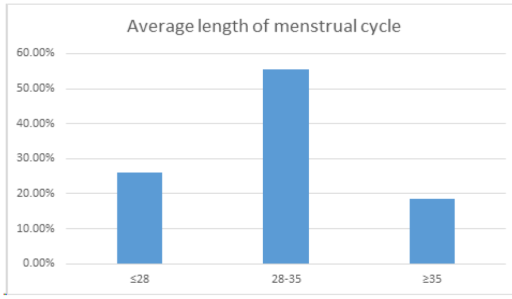

Figure 1: Average menstrual cycle length of the participants

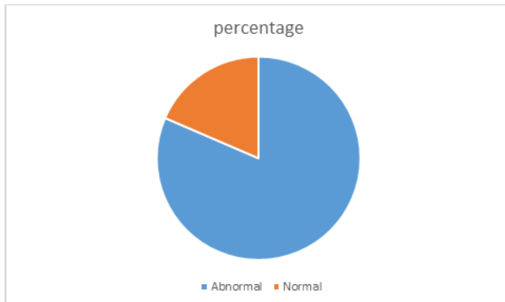

Figure 2: Representation of participants with normal & abnormal BMI ranges

the device failed to detect the true negative cases. Hence, the specificity calculated was 0%.

The calculated positive predictive value for the device is 90%, and the negative predictive value is 0%.

The formulae used for calculating the sensitivity, specificity, PPV and NPV were as follows:

Sensitivity = [True Positives/ (True Positives + False Negatives)] x 100

Specificity= [True Negatives/ (False Positives + True Negatives)] x 100

Positive predictive value (PPV) = [True Positives/ True Positives + False Positive)] x 100

Negative predictive value (NPV) = [True Negatives / (False Negatives + True Negatives)] x 100

As shown in Table 4 when the ovulation windows predicted by O'Tracker were matched with the windows from USG reports, matching in 25 (windows matched exactly in 19 cycles, and a marginal deviation of 1 to 3 days was observed in six cycles) out of the 27 true ovulatory cycles was observed, which indicates an accuracy of 93% and in the remaining two cycles, a deviation of four days was observed in one cycle and five days' deviation was observed in the other cycle.

And when the windows given by O'Tracker were compared with the windows predicted by the physician from the USG reports, the windows were matched in 23 out of the 27 true ovulatory cycles (windows matched exactly in 18 cycles, and a marginal deviation of 1 to 3 days was observed in five cycles). For the other four cycles, a deviation of four days was observed in one cycle, and a deviation of five days was observed in the other three cycles. O'Tracker could not detect any of the True Negative cycles.

Table 3: Ovulation prediction outcomes by O'Tracker and USG

		Outcome by O'Tracker Yes	*Total*
Outcome by USG	yes	27	27
	No	3	3
Total		30	30

Table 4: Ovulation window analysis

Metric	*Versus Physicians (cycles)*	*Versus Ultrasounds (cycles)*
Matched windows*	23	25
4 day gap	1	1
5 day gap	3	1

DISCUSSION

This study was conducted at the IVF department of Deenanath Mangeshkar Hospital and Research Centre to assess the accuracy of ovulation detection by O'Tracker, which is a home-based ovulation tracking device, compared with the outcomes from USG report. O'Tracker is India's first fertility tracking device, which measures the BBT continuously during the fertile window. The smart AI algorithm compares temperature curves to give precise measurements and ovulation identification.

The medical devices market in India is one of the world's top 20 medical device markets. However, India does not manufacture many devices indigenously and still imports approximately 70% of its medical devices.[8] Most ovulation trackers based only on BBT and using smart AI algorithms in the Indian market are imported and available at high prices. Moreover, these devices are required to be used for the complete menstrual cycle, as they study the temperature trends in both the follicular and luteal phases. 6 Whereas O'Tracker needs to be used for only 8 to 10 days, which are the most fertile days of the menstrual cycle predicted by the app algorithm based on the menstrual cycle history (Last menstrual period date and menstrual cycle length).

Several methods that rely on algorithms derived from the aforementioned biological criteria were developed recently. An exploratory cross-sectional audit study conducted of 90 fertility tracking applications reported that most apps only tracked menstrual cycle dates (n = 49 [54.4%]); and it is known that calendar apps are giving women inaccurate information about their fertile window. The remainder tracked at least one fertility-based awareness method (BBT, cervical mucus, LH) (n = 41 [45.6%]), and 28.6% of these apps that track other fertility indicator measures do not incorporate such measures into their prediction algorithms. Again, this gives women inaccurate information about their fertile window.[9] Ovulation day varies considerably for any given menstrual cycle length, thus it is not possible for calendar/app methods that use cycle-length information alone to accurately predict the day of ovulation.[10]

The limitations to the study were the limited sample size, as participant recruitment took longer time than the anticipated duration. The study enrollment was started in January 2023 and monitoring of 30 menstrual cycles was completed in October 2023. A total 63 patients were screened eligible for the study, but only 40 participants consented to participate. Eventually, only 27 participants completed the study. Given the limitations, O'Tracker shows potential as an accessible and convenient digital ovulation monitoring platform. Further studies incorporating a larger sample size and longitudinal tracking could substantiate the efficacy of the O'tracker. Integration with clinical protocols for fertility assessment and the examination of user experience metrics would further enhance its applicability.

Our strategy required participants to maintain a constant sleeping environment for the 10-day O'Tracker usage period to address potential implications on Basal Body Temperature (BBT). This safety precaution was taken to ensure the validity of our study results by removing potential outside influences such as AC(Air conditioner) temperature, jet lag, substance use, and use of electric blankets. Our work used a proactive method to account for any variations in Basal Body Temperature (BBT) caused by elements like cold or illness. The participants used the O'Tracker programme to keep a daily journal in which they were advised to record their overnight experiences, including any symptoms they may have had. When participants complained of feeling sick or showed symptoms of sickness, we told them not to use the device on those particular days. This safety step was taken to make sure that outside variables, such as diseases that cause fever, wouldn't impact BBT measurements and improve the accuracy of our study's findings.

CONCLUSION

The analysis shows that O'Tracker has 90% accuracy in ovulation prediction against physician assessment and more than 90% match rate to fertile windows determined by ultrasound monitoring. O'Tracker could not predict true negative cycles. Hence, the specificity for the device is 0%. However, the number of anovulatory cycles (true negatives), was only 1% of the complete sample size (i.e. 3 out of the 30 cycles monitored). Perhaps, conducting a study with a larger sample size with greater number of anovulatory cycles could be beneficial for evaluating the specificity of the device.

Larger sample size as well as multi centric study would be useful to detect true negatives. Accurately detecting real negatives requires a multicentric investigation with a higher sample size. We are actively addressing this in our ongoing research by increasing the sample size to 120 cycles at one study site and carrying out a separate study with 100 cycles with healthy individuals. With a focus on identifying real negatives, our method seeks to improve the reliability of our results and offer a thorough evaluation of the O'Tracker's performance in a variety of populations and environments.

The O'tracker has shown potential as a feasible tool for tracking of the ovulation window. Its predictive accuracy, in alignment with sonographic interpretations, underscores its utility in clinical and personal settings. The three instances of false positive predictions by O'Tracker warrants further investigation into causes of inaccurate ovulation signals. But overall, study results support O'Tracker as a robust and reliable ovulation window prediction tool.

Given the non-invasive nature and ease of use, the O'tracker represents a promising tool for individuals seeking to optimize their chances of conception. The technology may serve as a valuable adjunct to conventional sonographic monitoring by continuously estimating the fertile window.

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ADDITIONAL INFORMATION

India's first digital, stick-to-skin, wireless BBT sensor for fertility window identification is marketed as "OvuPro."

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