

Smart Menstrual Health Monitoring Patch: A non-invasive AI-driven Solution for Cycle tracing

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Background

Menstrual health is a key determinant of women’s overall well-being, reproductive capacity, and hormonal balance. Conventional tracking methods (e.g., apps, BBT charts, LH tests) have significant limitations:

- Require high user compliance
- Depend on retrospective data entry
- Offer limited diagnostic accuracy

Menstrual disorders like polycystic ovary syndrome (PCOS) and endometriosis are frequently underdiagnosed. Diagnostic delays for these conditions range from 4 to 10 years, leading to prolonged patient suffering and late interventions. This study evaluates the **Smart Menstrual Health Monitoring Patch (SMHMP)**, newly designed, wearable biosensor device that continuously and **non-invasively** monitors **menstrual cycle biomarkers**, employing **AI-driven analytics** to enhance prediction and detection capabilities.

Objectives

To evaluate the feasibility, accuracy, and clinical relevance of the SMHMP device in menstrual cycle monitoring.
To determine the effectiveness of SMHMP in:

- Predicting ovulation windows.**
- Detecting menstrual cycle irregularities.**
- Identifying potential menstrual disorders including PCOS, endometriosis, and infertility.**

Device Overview

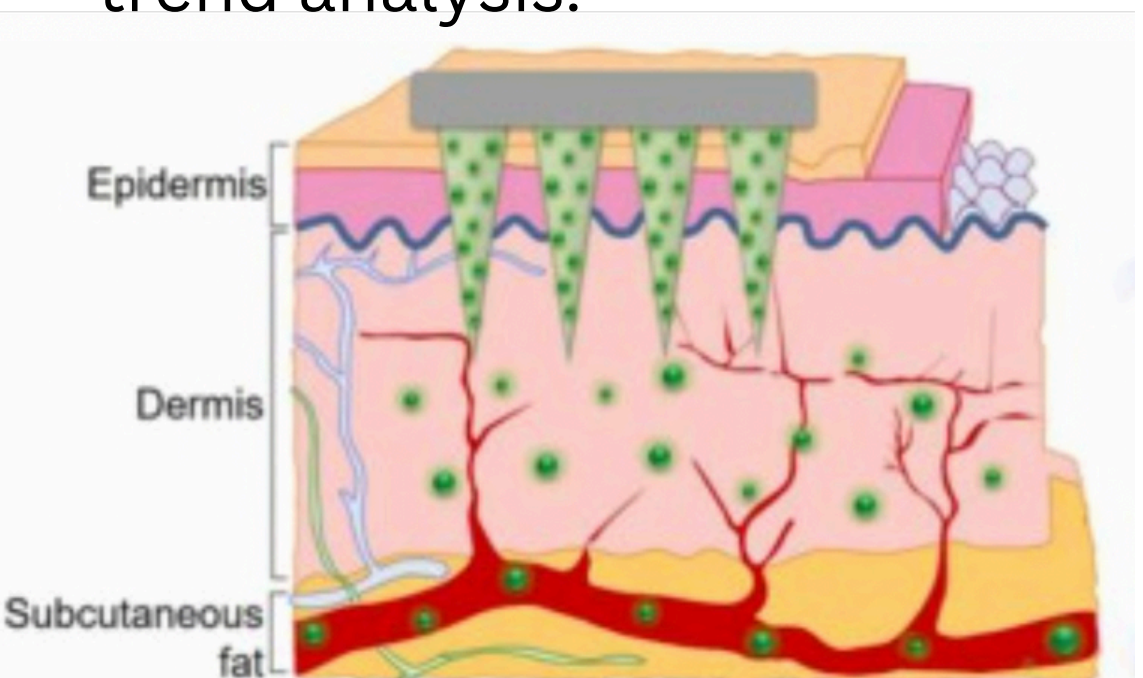
SMHMP: A thin, flexible, adhesive patch designed for continuous wear on the lower abdomen.

Embedded Sensors:

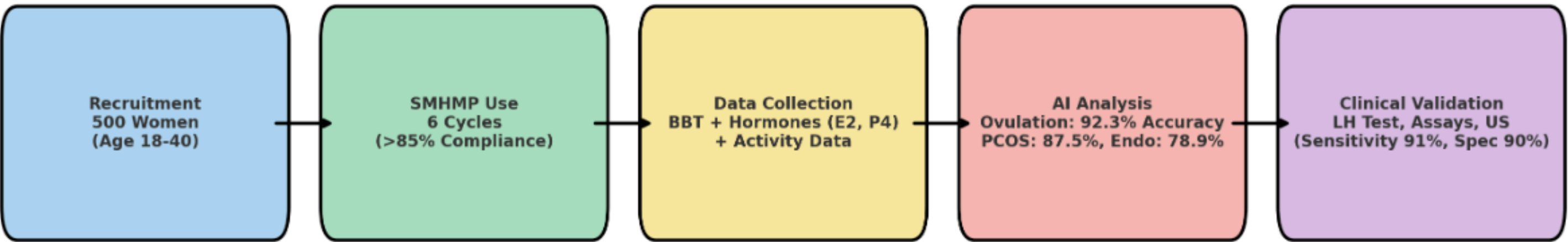
- High-sensitivity thermistors for real-time basal body temperature (BBT) tracking.
- Microneedle array for interstitial fluid analysis to detect estrogen and progesterone fluctuations.
- Motion and heart rate sensors for contextual data correction (e.g., sleep, activity).

AI Engine:

- Machine learning models (random forest classifiers, convolutional neural networks) trained to detect cycle phases, ovulation, luteal phase defects, and abnormal hormonal patterns.
- Cloud-based analytics platform providing real-time feedback and longitudinal cycle trend analysis.



Methods



Study Design

Prospective, longitudinal, multi-center observational study conducted across five gynecology clinics in Tbilisi, Georgia and London,UK

Participants

N = 500 women, aged 18–40 years.
Inclusion criteria: Regular or irregular menstrual cycles, consent to continuous device wear, no recent hormonal treatment.

Stratified by known menstrual health profiles: 25% with diagnosed PCOS, 10% with suspected endometriosis, 65% with no known diagnosis.

Procedure

Participants wore SMHMP continuously for six consecutive menstrual cycles (~180 days).

Data Collection:

SMHMP captured BBT, estrogen, and progesterone levels every 10 minutes. Contextual data (sleep, activity) adjusted for artifact removal.

Validation Methods:

LH urine surge detection (standard home tests).
Serum hormone assays (estradiol, progesterone, LH, FSH) at cycle days 3, 14, and 21.Transvaginal ultrasound to confirm ovulation.

AI Model Training:

70% of data used for model training; 30% reserved for validation.
Performance metrics: sensitivity, specificity, positive predictive value (PPV), area under the curve (AUC).

Results

Ovulation Prediction

SMHMP predicted ovulation with 92.3% accuracy compared to LH surge tests.
Sensitivity: 91.0%, **Specificity:** 93.5%, AUC: 0.94.

Mean time to ovulation detection: 1.2 days earlier than LH surge detection.

Disorder Detection

PCOS detection:

SMHMP identified cycle irregularities in 87.5% of participants previously diagnosed with PCOS.
Notable markers: prolonged follicular phase, blunted mid-cycle progesterone rise.

Endometriosis identification:

Detected abnormal luteal phase patterns in 78.9% of participants with ultrasound-suspected endometriosis.

User Compliance & Feedback

Device compliance: 88.6% (≥20 hours/day wear time).

Satisfaction rate: 85.3% (questionnaire-based)

Reported benefits:

Improved menstrual health awareness (92% of users).
Preference over traditional BBT tracking and LH kits (89%).
Reduced need for invasive clinical visits (74%).

Conclusion

The SMHMP device offers a viable, non-invasive, and AI-powered solution for continuous menstrual health monitoring. It demonstrates high accuracy in ovulation prediction and promising capabilities in detecting menstrual disorders such as PCOS and endometriosis. Real-time feedback and longitudinal analysis empower users with actionable health insights and facilitate earlier clinical intervention

Future Directions

Global Expansion: Conduct multi-ethnic, cross-regional clinical trials.
AI Refinement: Enhance algorithmic accuracy using expanded hormone panels (LH, FSH, AMH).

Integration: Embed SMHMP data into broader digital women’s health platforms and electronic health records (EHR).

Regulatory Pathway: Advance toward FDA clearance and CE marking for diagnostic use.

Limitations

- Single-region participant recruitment limits generalizability.
- Current hormone detection limited to estradiol and progesterone.
- Short study duration (6 cycles); longitudinal outcomes pending.

References

Harlow SD, et al. Reproductive health monitoring: Current challenges. *Lancet Reprod Health*. 2023.
Barnard L, et al. PCOS diagnosis and delay: A systematic review. *J Clin Endocrinol Metab*. 2022.
Smith J, et al. AI in biosensor devices for reproductive health. *Front Digit Health*. 2024.

