Utility of Cervical mucus electrical impedance as an indicator of cervical mucus observations

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INTRODUCTION

Hormone urine strips and basal body temperature (BBT) are often used by patients to track infertility. However, their reliability in detecting all days within the fertile window is low.

Alternatively, cervical mucus observation is well established as an indicator for determining fertile window and time of ovulation[1-4]. Clinical studies have shown advantages of using cervical mucus observation over other modalities, including BBT. However, self-monitoring of mucus can be time-consuming and inaccurate due to insufficient patient training.

Measuring electrical impedance (EI) trends in the cervical mucus may provide a novel approach to tracking the fertility window and predicting ovulation. Previous study has reported high sensitivity, specificity, and accuracy for detecting the ovulation window compared to BBT with the use of a medical device inserted vaginally to measure electrical impedance (Kegg™, Lady Technologies Inc. San Francisco, CA)[5].

OBJECTIVE

To determine: 1) the association between EI measured from cervical mucus and cervical mucus observation with regard to fertility status; and 2) the ability of detecting mucus appearance change across different fertility phases with an at-home cervical mucus based EI monitor device.

METHODS

With IRB approval and consent waiver, a retrospective review was performed on the real-word data collected from the Kegg device (**Figure 1**).

All cycles meeting the following criteria were included in this study:

- the user had ≥ 2 cycles recorded
- ≥ 14 days of EI and cervical mucus observations collected within cycle
- 28-34 days in length (regular cycle)

Each mucus observation was quantified by assigning a numeric value accordingly as following: 0 – no mucus/dry; 1 – sticky; 2 – creamy; 3 – watery; 4 – slippery.

Ovulation date for each cycle was identified based on the lowest EI value. EI and mucus observation were compared across ovulation and the early, middle, and late phases of the follicular and luteal periods (ANOVA).

The rate of change in EI and mucus observation were assessed across a set of time windows (ovulation ± 1, 3, and 7 days, as well as each day for ± 10 days further out). Correlation between the rates of change in EI and mucus observation was assessed within subphases and time windows using Spearman ranked correlation.

Average mucus observation were compared across the periods before, during, and after the device-identified fertile window (ANOVA and post-hoc Tukey test).

All analyses were performed in GraphPad Prism V.10. Statistical significance was defined as $p < 0.05$.

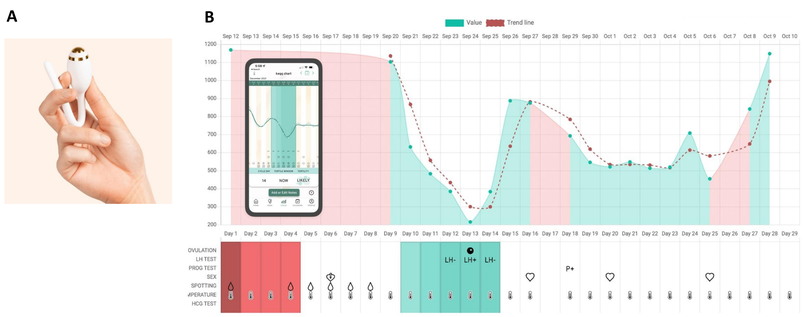


Figure 1. (A) The Kegg™ pod. (B) Bluetooth interface with companion phone app showing a representative the measurement of a healthy cycle and historical trend of the same user.

RESULTS

Analyzed cohort included 77 women (age: 36.3 ± 5.4 yrs) and 253 cycles (length: 29.5 ± 3.5 days).

EI at ovulation was significantly lower than other sub phases, while mucus did not show significance.

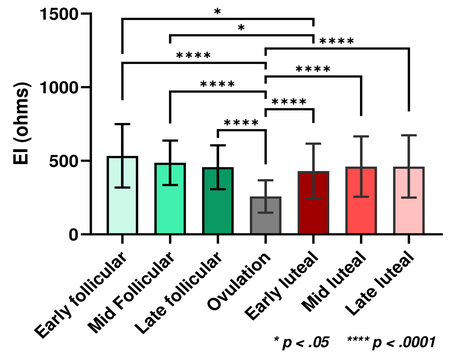


Figure 2. EI across subphases of the cycle.

Significant higher mucus value was observed during the Kegg predicted fertile window, compared to the phase before and after the window.

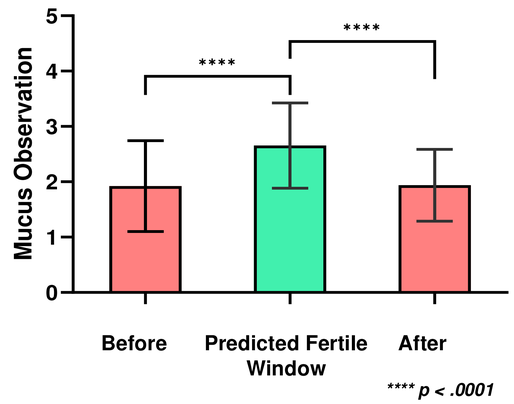


Figure 3. Mucus observation before, during, and after Kegg predicted fertile window.

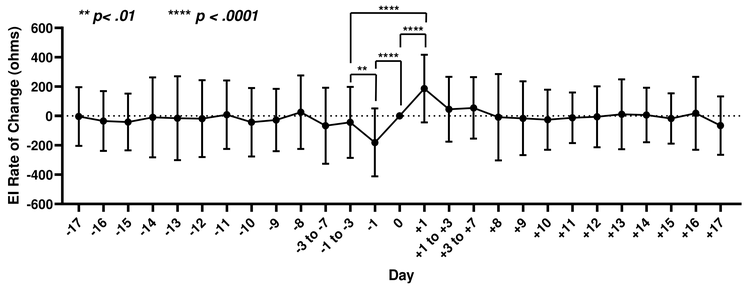
The rates of change in EI and mucus were found to be significantly correlated

Table 1. Spearman's correlation between the EI rate of change and mucus rate of change.

Stratification Method	
Time Windows	
r	-.1365
P	.0005
Sub-phases	
r	0.5674
P	< .0001

Significant differences in EI rate of change were observed

- Across the day prior (Day -1), of (Day 0), and after ovulation (Day +1)
- Between the day prior to ovulation (Day -1) and later time windows



Multiple significances found across cycle, with those found between days -3 to +1 marked on the plot.

Figure 4. EI rate of change across cycle (plotted range: ± 17 days around ovulation). All values were calibrated regarding Day 0 (Ovulation).

Significance in mucus rate of change were found between the 3-day window pre- and post-ovulation.

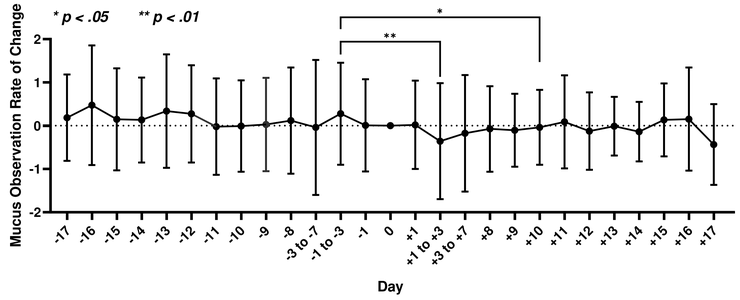


Figure 5. Mucus rate of change across cycle (plotted range: ± 17 days around ovulation). All values were calibrated regarding Day 0 (Ovulation).

DISCUSSION

Although being a mainstream modality for identifying fertility status, cervical mucus observation can be challenging to implement in real-world setting.

This study demonstrated that cervical mucus-based EI can be an objective measure of cervical mucus changes, potentially enabling women and clinicians to efficiently track cycles and monitor treatment.

- The data support the EI monitor device in detecting a strong differentiation between various cycle stages that align with the change in the physical appearance of cervical mucus during the fertile window.
- The study further strengthened the published evidence[4] on the utility of EI to serve as an objective supplement to cervical mucus observation for aiding conception and fertility treatment.

Limitations of this study are inherent from analysis of any real-world dataset, including: 1) training of the users for a reliable mucus observation may be variant; 2) data was not consistently collected daily throughout the cycle. These limitations may be addressed with a future prospective clinical study.

CONCLUSION

Self-assessment of cervical mucus impedance using a novel mucus EI based fertility monitoring device potentially allows for longitudinal tracking of critical physiological indicators of fertility and ovulation with reliable and personalized data, enabling women and clinicians to efficiently track cycles and monitor treatment.

References: (1) Salleh et al. 2022 Biotechnic & Histochemistry; (2) Gould et al. 1981 Contraception; (3) Ansari et al. 1986 Adv Contracept; (4) Kopito et al. 1973 Fertility and Sterility; (5) Tabbaa et al. 2024 Contracept Reprod Med..