Research and published case studies using Mira

mira

Collaborative Research and Clinical Trials

Duquesne University

Study Focus: Menstrual cycle data comparison in individuals with/without PCOS.

Goal: Identify common hormone patterns and enhance PCOS diagnostics.

Johns Hopkins University

Study Focus: Statistical analysis to refine Mira's algorithms.

Goal: Improve data accuracy and algorithm performance.

University of British Columbia

Study Focus: Validation of Mira's results with ultrasound and blood tests.

Goal: Ensure accuracy of Mira's readings.

University of Melbourne

Study Focus: Sex hormones' associations with metabolism, immune, and cardiovascular systems.

Goal: Explore impacts in post-viral syndrome individuals.

Icahn School of Medicine at Mount Sinai Hospital

Study Focus: Cortisol, sex hormones, and long COVID symptoms.

Goal: Investigate hormonal influences on long COVID.
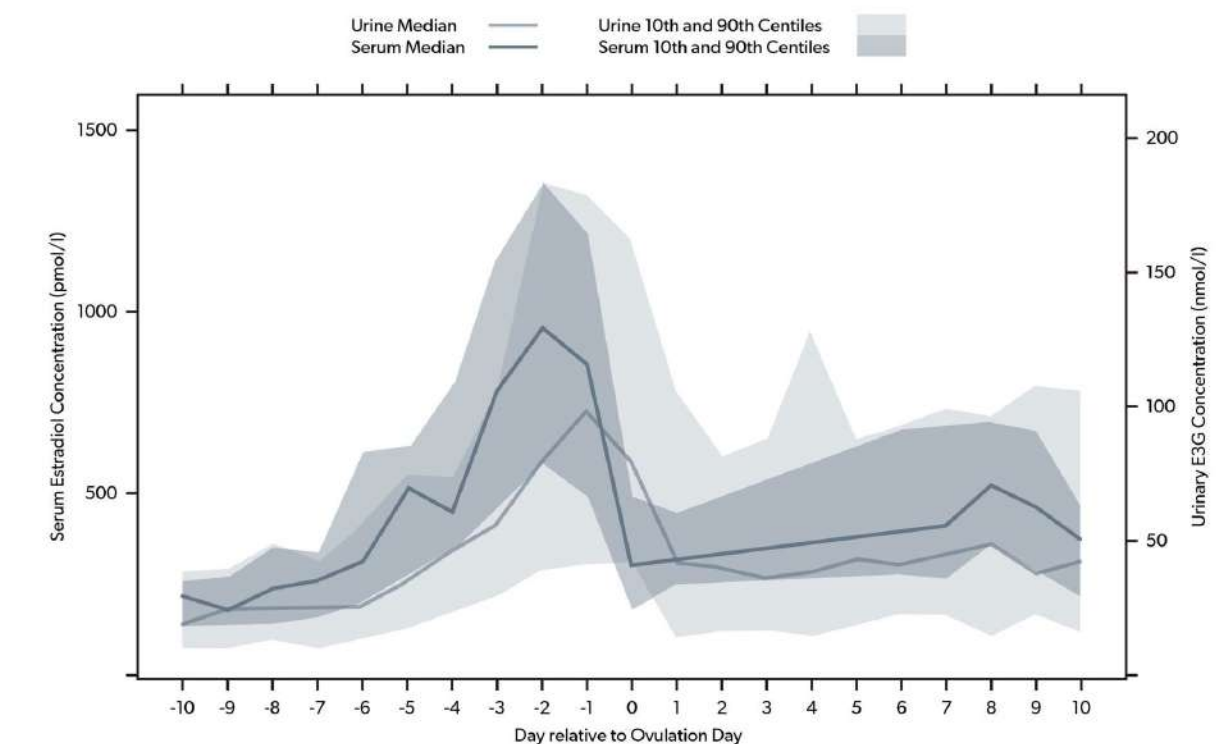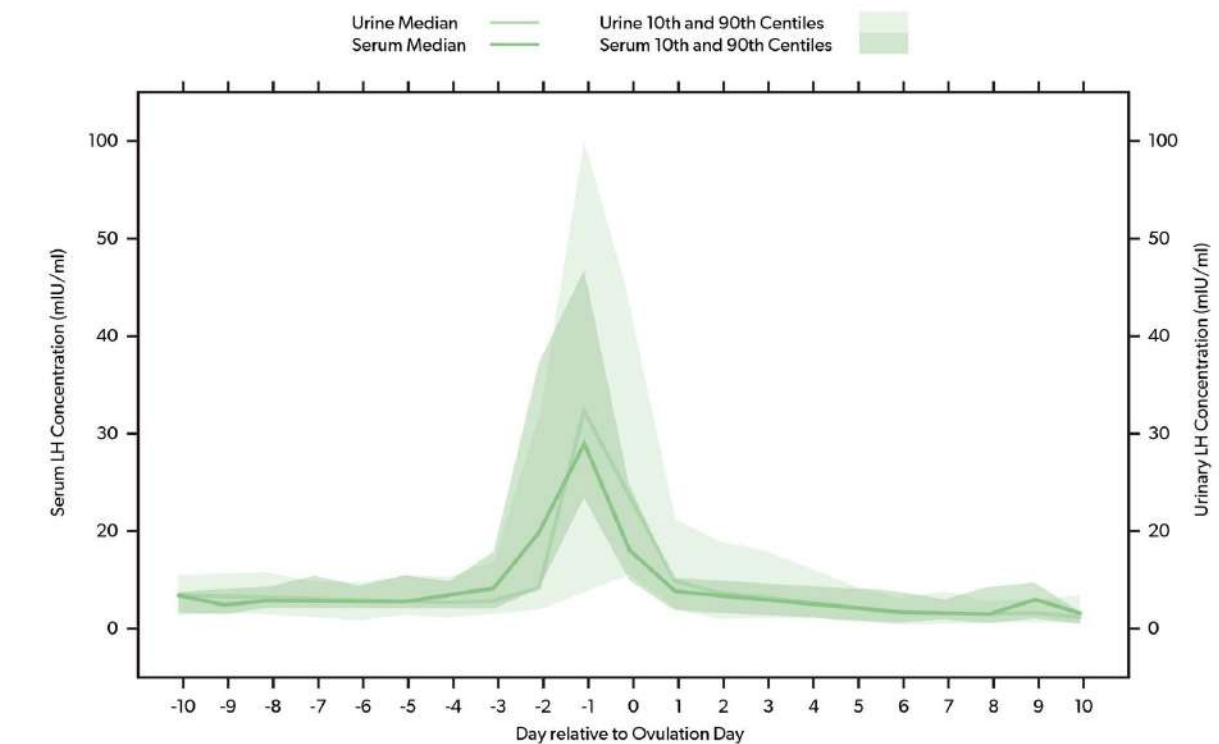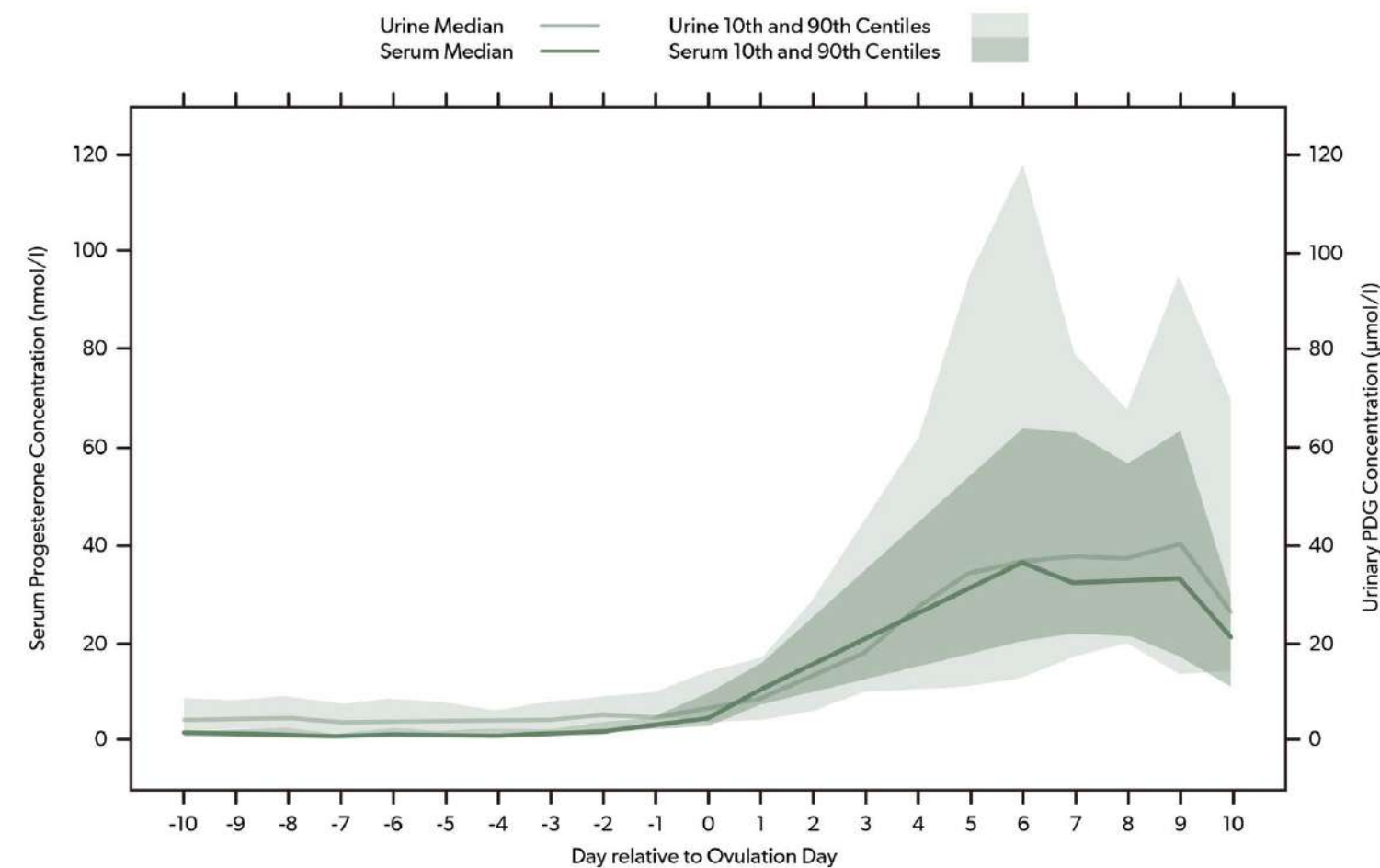
Athletica

Study Focus: Effects of training load on menstrual cycle and ovulation.

Goal: Understand exercise impacts on menstrual and reproductive health.

Research studies validating Mira against gold standards such as serum and ultrasound.

Comparison of urinary and serum reproductive hormones referenced to true ovulation (n=40)

Urinary and serum reproductive hormones showed excellent agreement and may be used interchangeably. The beginning of the surge in serum and urinary LH was an excellent predictor of ovulation. The rise in progesterone and P3G above baseline was a consistent marker of luteinisation confirming ovulation. Both LH and progesterone surges delivered clear, sharp signals in all volunteers, allowing reliable detection and confirmation of ovulation.

Roos J, Johnson S, Weddell S, Godehardt E, Schiffner J, Freundl G, et al. Monitoring the menstrual cycle: Comparison of urinary and serum reproductive hormones referenced to true ovulation. Eur J Contracept Reprod Health Care. 2015;20(6):438-50. Epub 2015/05/29. doi: 10.3109/13625187.2015.1048331. PubMed PMID: 26018113.
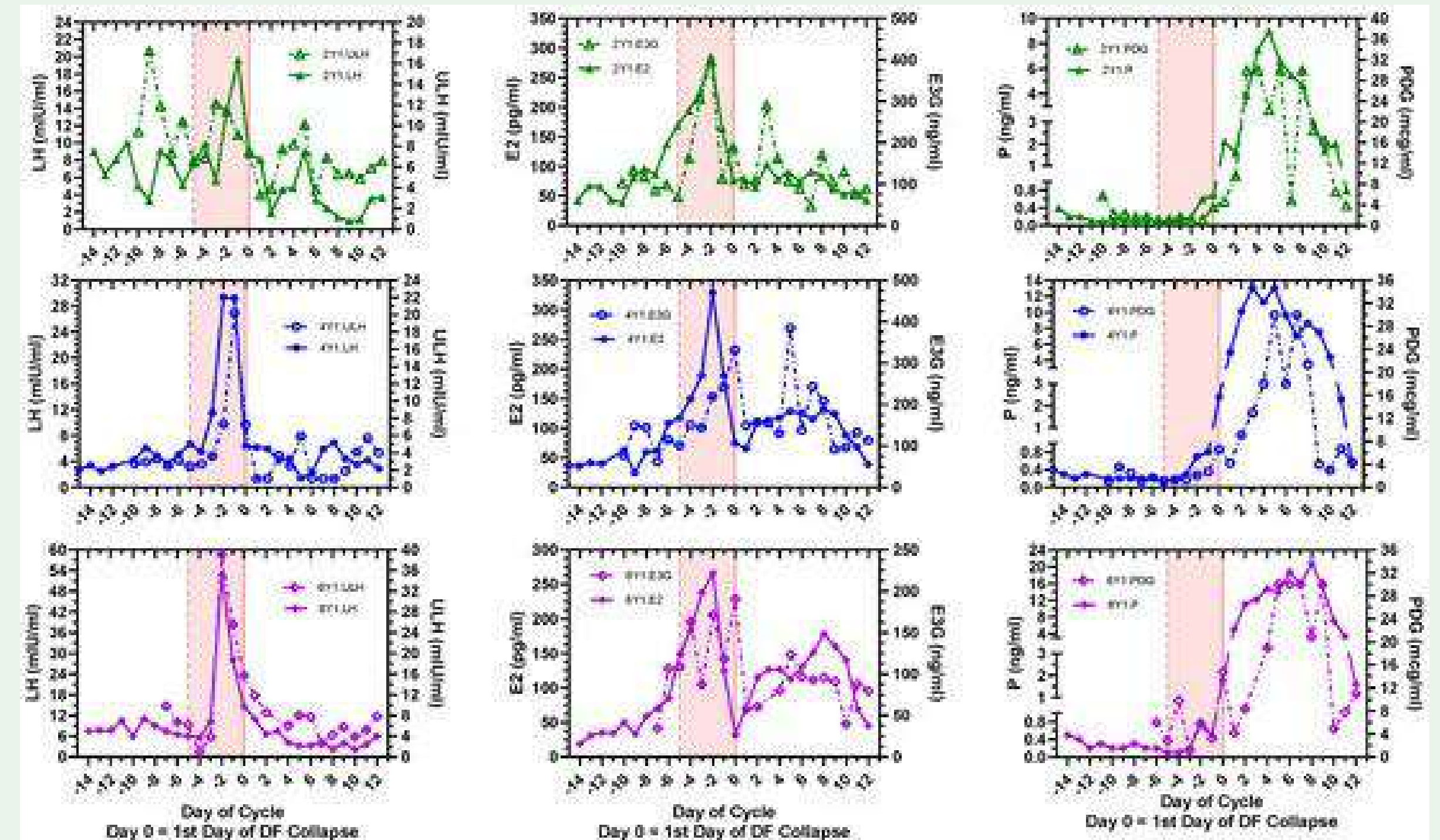
Comparison of Day-Specific Serum LH, Estradiol, and Progesterone with Mira Monitor Urinary LH, Estrone-3-glucuronide, and Pregnanediol-3-glucuronide Levels in Ovulatory Cycles

Conclusions:

The Area Under the Curve algorithm with (E2, P) or (E3G, PDG), showed that both serum and MiraTM hormone measurements could pinpoint the 24 h interval of ovulation and transition to the luteal phase.
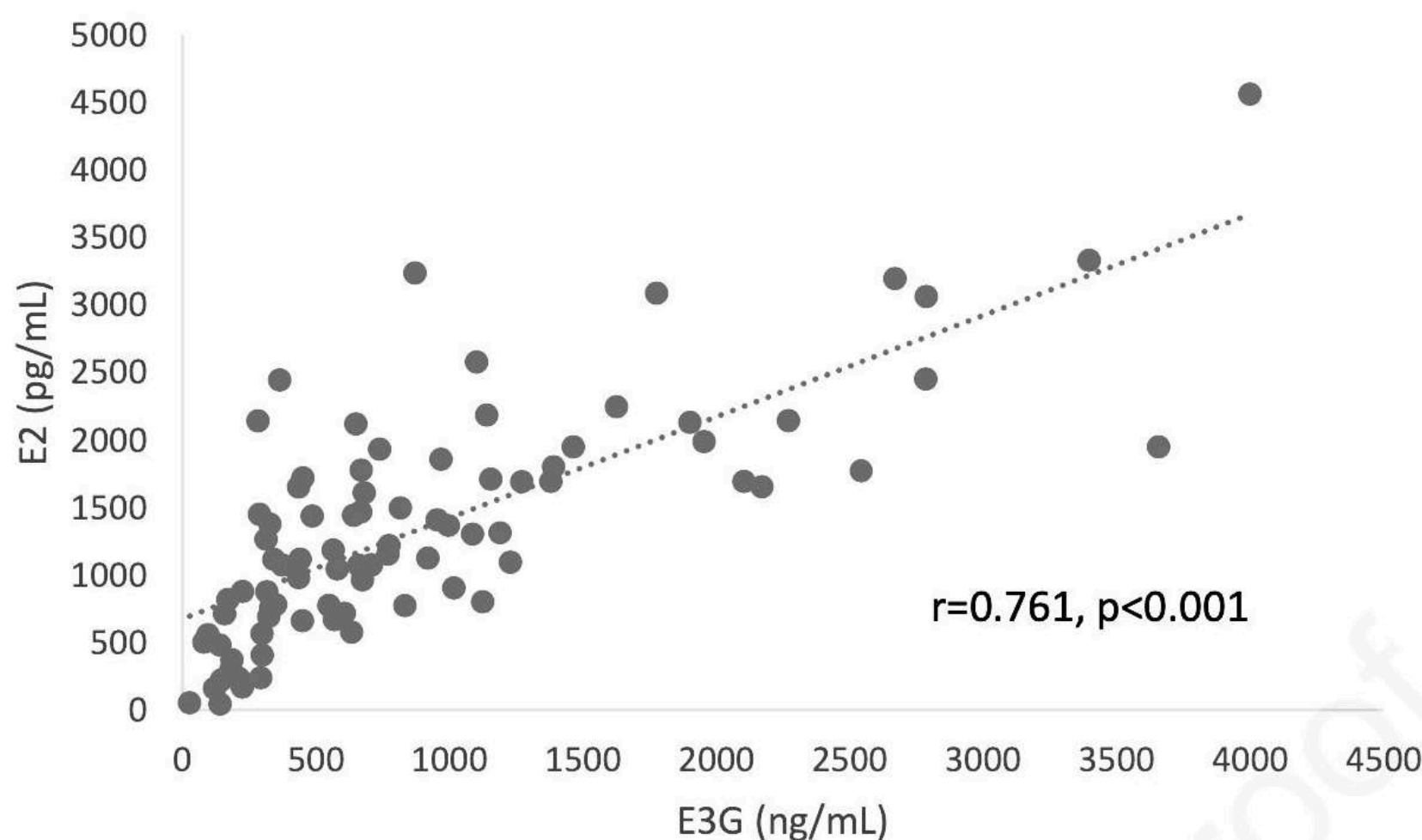
The AUC (E3G, PDG) algorithm should be applicable to existing urinary hormone monitors. Serum E2 and P have promise as improved biomarkers for timing the major events during the menstrual cycle.

Comparison of Day-Specific Serum LH, Estradiol, and Progesterone with MiraTM Monitor Urinary LH, Estrone-3-glucuronide, and Pregnanediol-3-glucuronide Levels in Ovulatory Cycles by Stephen J. Usala, David D. Vineyard, Maria Kastis, A. Alexandre Trindade and Harvinder Singh Gill.

At-home urine estrone-3-glucuronide quantification predicts oocyte retrieval outcomes comparably to serum estradiol

Summary:

Urine E3G monitoring is comparable to serum E2 for predicting retrieval outcomes and offers a viable at-home alternative to traditional serum monitoring, potentially enhancing patient experience.

Key Findings:

Urine E3G levels, measured by the Mira Fertility Plus® analyzer, and serum E2 concentrations on the day of trigger both show significant correlation with oocyte retrieval outcomes. E3G demonstrated a slightly higher correlation with the number of M2 oocytes (r = 0.485) compared to E2 (r = 0.391). The Pearson correlation coefficient between matched E3G and E2 levels was 0.761 (p<.001). The determination coefficients for daily trends during stimulation were 0.7066 for E3G and 0.6102 for E2.

Nakhuda GS, Li N, Yang Z, Kang S, At-home urine estrone-3-glucuronide quantification predicts oocyte retrieval outcomes comparably to serum estradiol., F&S Reports (2023), doi: https://doi.org/10.1016/j.xfre.2023.01.006.

Urine estrone–3-glucuronide (E3G) assay: is there any place during ovarian stimulation for IVF cycles?

Association between FSH levels in urine and serum in premenopausal women

Urine FSH strongly correlated with FSH in serum in premenopausal (R^2 = 0.98) women.
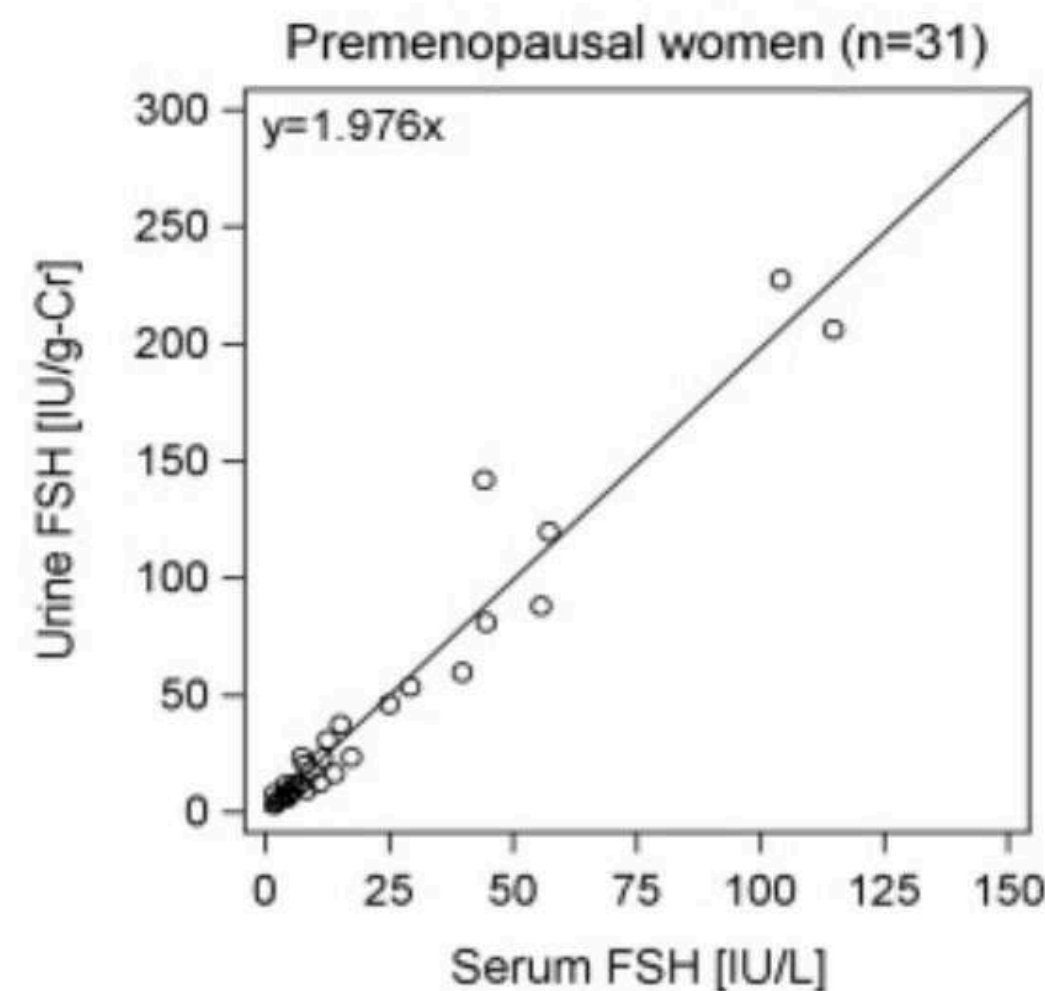
Quantitative analysis of total β–subunit of hCG concentration in urine

An excellent correlation of total hCGβ IMR signals between urine and serum was noted (R^2=0.994).

Yoko Onizuka, Kazue Nagai, Yuki Ideno, Association between FSH, E1, and E2 levels in urine and serum in premenopausal and postmenopausal women, Clinical Biochemistry, Volume 73 (2019), pp. 105-108; Chen-Yu Chen, Yuh-Ming Hwu, Chie-Pein Chen, Quantitative analysis of total β-subunit of human chorionic gonadotropin concentration in urine by immunomagnetic reduction to assist in the diagnosis of ectopic pregnancy, Int J Nanomedicine (2015)10:2475-83. doi: 10.2147/IJN.S81201. eCollection 2015.

At-home urine estrone-3-glucuronide quantification predicts oocyte retrieval outcomes comparably to serum estradiol.

Key Findings:

Both urine E3G (measured by fluorescent immunoassay Mira Fertility Plus® analyzer) and serum E2 concentrations on day of trigger significantly correlated with retrieval outcomes to a similar extent, with E3G demonstrating slightly higher correlation to the number of M2 oocytes compared to E2 (r = 0.485 vs 0.391, respectively). The Pearson correlation coefficient for matched E3G and E2 levels was 0.761 (p<.001). The correlations of determination for daily trend of E3G and E2 during stimulation were 0.7066 and 0.6102, respectively. Measured on the day of trigger, urine E3G monitoring during gonadotropin stimulation is comparable to serum E2 for predicting oocyte retrieval outcomes. Matched daily samples confirm good correlation of urine E3G and serum E2. The option of at-home estrogen monitoring with devices such as Mira offers an alternative to traditional serum monitoring that may improve the patient experience.
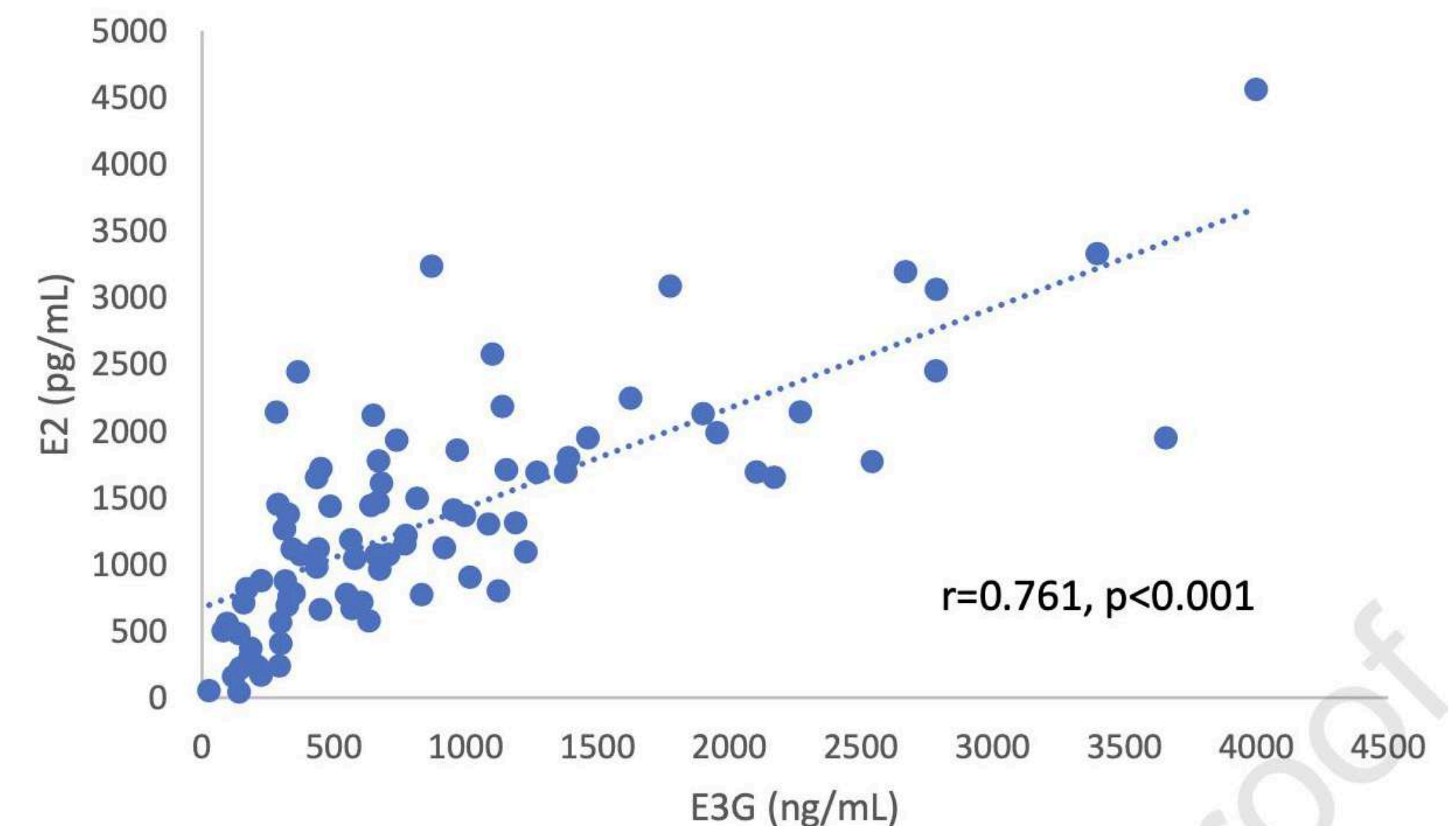
r=0.761, p<0.001

Nakhuda GS, Li N, Yang Z, Kang S, At-home urine estrone-3-glucuronide quantification predicts oocyte retrieval outcomes comparably to serum estradiol., F&S Reports (2023), doi: https://doi.org/10.1016/j.xfre.2023.01.006.

Urine estrone–3-glucuronide (E3G) assay: is there any place during ovarian stimulation for IVF cycles?

Key Findings:

Serum E2 values were assessed routinely, while E3G values were measured and validated using a fluorescent immunoassay Mira Fertility Plus® analyzer. The urine E3G of the assay was validated for intra and inter-assay variability with a coefficient of variation of < 20%. It was also validated for analytical and functional sensitivity and sample stability. Linear regression of serum E2 and E3G values of 56 early morning urine samples who had evaluated between days 4 and 13 of the menstruation cycle provided an r = 0,81. Urine E3G values also correlated to follicle growth. Patient survey results showed that urine sampling was the preferred method of a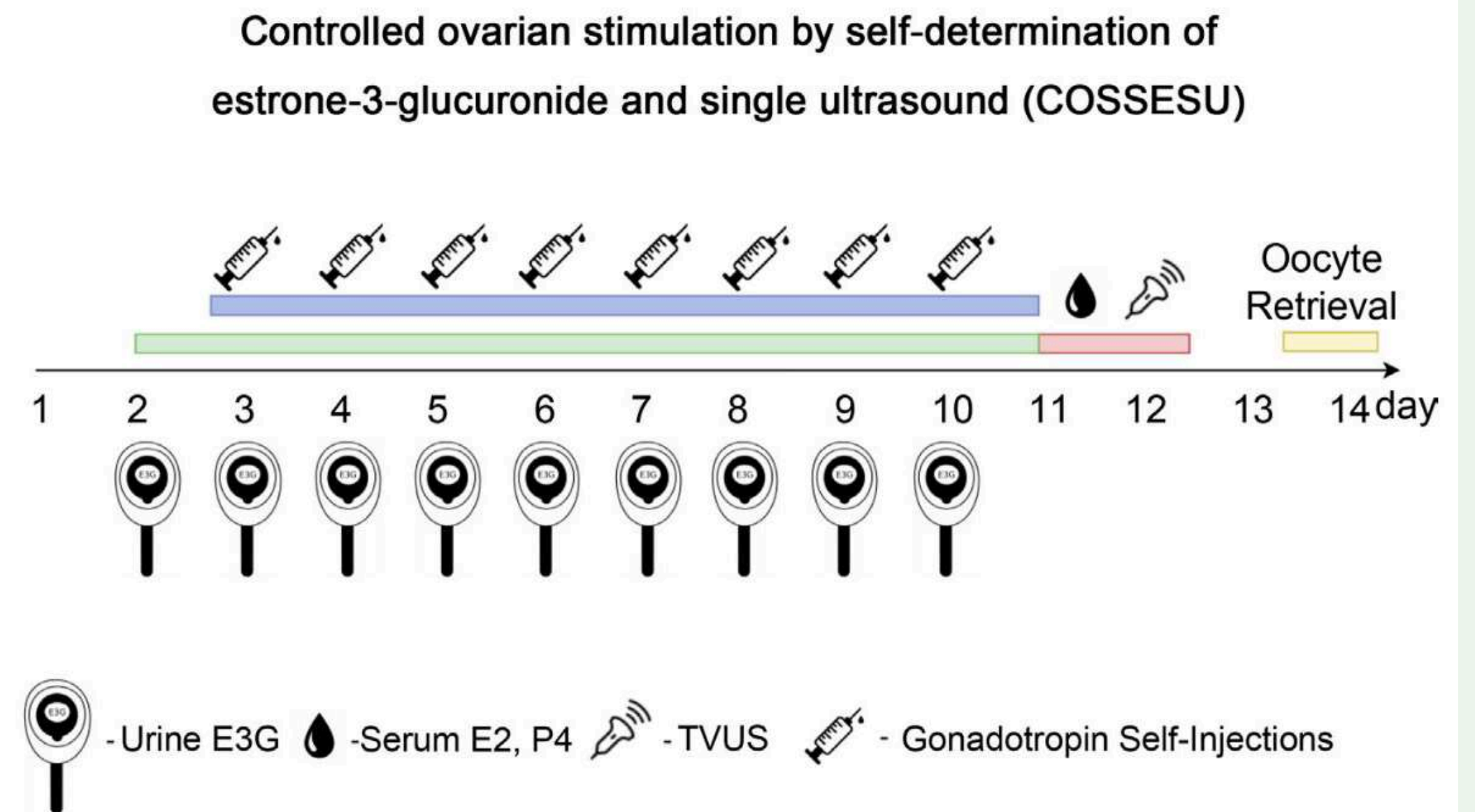nalysis. Urine E3G testing correlates well to serum E2 assessment in COH. Urine E3G assay provides an alternative to serum-based assessment.

Controlled ovarian stimulation by self-determination of estrone-3-glucuronide and single ultrasound (COSSESU)

I Vladimirov, V Martin, T Desislava, P–670 Urine estrone–3-glucuronide (E3G) assay: is there any place during ovarian stimulation for IVF cycles?, Human Reproduction, Volume 36, Issue Supplement_1, July 2021, deab130.669, https://doi.org/10.1093/humrep/deab130.669;

Vladimirov, I. , Vladimirov, M. and Tacheva, D. (2021) A New Protocol for Controlled Ovarian Stimulation Monitoring by Self-Determination of Estrone-3-Glucuronide and Single Ultrasound (COSSESU). Open Journal of Obstetrics and Gynecology, 11, 1217-1228. doi: 10.4236/ojog.2021.119115.

Viability of home monitoring of estrone–3–glucuronide (E3G) urine levels in controlled ovarian stimulation: A pilot study

Key Findings:

The average female age was 32,1 years (±4.4), BMI 22,9 kg/m2 (±4,3), AMH 3,9 ng/ml (±2,7), stimulation days 10,1 (±1,2), collected oocytes 12,6 (±8,5), MII oocytes 10,8 (±7,9), fertilization rate 83,4% (±22,7), blastocyst formation 66,9% (±28,6), good quality blastocysts 31,1% (±16,6).

The log-linear mixed effect model (LLMM) estimation produced reasonable estimates of 49% average day-to-day growth rates (slope fixed effect), with one standard deviation (SD) range of 25% to 77% across patients (SD of the slope random effect).

Moreover, there was a comparatively high correlation of 0.76 between the individual growth rates of E3G estimated over days 3-6 (the slope random effects of the LLMM model) and the E3G levels at day 10. In this way, the estimated slope random effects appear to have a prognostic value and may potentially have therapeutic implications, for example, adjustment of the stimulation dose. Moreover, the Spearman correlation between Estradiol and E3G was 0.83

After analyzing interviews and questionnaires, patients evaluated the applied method as easy and convenient, with 97% of them preferring OS monitoring to be performed in this manner compared to the standard method, which includes regular ultrasound examinations and determination of serum hormone levels.

REMOTE MONITORING OF QUANTITATIVE URINE HORMONE PATTERNS DURING OVARIAN STIMULATION WITH CLOMIPHENE AND LETROZOLE WITH AN AT–HOME DEVICE.*

Objective: A descriptive analysis to determine if at-home quantitative urine hormone monitoring is feasible and informative during ovarian stimulation with clomiphene and letrozole.

Results: Twenty-six patients (mean age 34.3, S.D. 3.8 years) completed 69 cycles with a cumulative data set of 1387 quantitative urine hormone results. Patients either had a diagnosis of PCOS (n=13, 45 cycles) or unexplained (UE) infertility (n=13, 24 cycles). Clomiphene 100mg was used in 22 cycles (PCOS- 3, UE- 19) and letrozole 5mg in 47 cycles (PCOS- 42, UE- 5). The day of the peak LH detection was significantly earlier for patients with UE than PCOS (13.4 vs. 15.3, p=0.008), as was the day of peak E3G detection (12.8 vs 15.2, p=0.003). Peak [LH] was higher in UE than PCOS (52.9 vs 27.7 mIU/mL, p<0.001) as was peak [E3G] (318.6 vs 195.7 ng/mL, p<0.001).

Patterns of urine hormone concentration changes approximate those of analogous serum patterns in age and diagnosis matched patients.

Conclusions: Remote monitoring of urine hormone concentrations during ovarian stimulation is feasible and appears to accurately reflect expected serum patterns. The patient experience is improved by reducing the burden of care caused by repetitive clinic visits and phlebotomy.

OLIVE _fertility centre_

"Mira is a game-changing tool - it seems to be the best of all worlds to improve fertility experience."

Dr. Gary Nakhuda

MD, FACOG OB/GYN, Reproductive endocrinology

Correlation of urinary and serum hormone levels in natural cycle frozen embryo transfer cycles. [Ongoing]

Objective: The objective of the proposed study is to evaluate whether the use of home urinary testing of quantitative estradiol metabolites and LH can be used to accurately predict ovulation and serve as a trigger for the gold standard of serum LH monitoring in a natural cycle protocol for frozen embryo transfer (FET).

We hypothesize that this at home device will provide a reliable alternative to daily bloodwork, thereby reducing the number of daily visits for serum monitoring. We predict increased satisfaction and quality of life with the implementation of their use within these cycles.

OLIVE *fertility centre*

OTTAWA FERTILITY CENTRE
HELPING FAMILIES GROW SINCE 1994

Establishing a Gold Standard for Quantitative Menstrual Cycle Monitoring

Preliminary results (2/3 of the study): Mira has detected 100% of the ovulations confirmed via ultrasound.

Ongoing study (will be published in May '25):

Background and Objectives: The Quantum Menstrual Health Monitoring Study will measure four key reproductive hormones in the urine (follicle-stimulating hormone, FSH; estrone-3-glucuronide, E13G; luteinizing hormone, LH; and pregnanediol glucuronide, PDG) to characterize patterns that predict and confirm ovulation, referenced to serum hormones and the gold standard of the ultrasound day of ovulation in participants with regular cycles.

Hypothesis: The Mira monitor quantitative urine hormone pattern will accurately correlate with serum hormonal levels and will predict (with LH) and confirm (with PDG) the ultrasound day of ovulation in those with regular cycles as well as those with irregular cycles.

Rationale: Once the ultrasound validation is complete, tools like the Mira monitor with a customized app may become a new standard for at-home and remote clinical monitoring of the menstrual cycle without having to use labor-intensive follicular-tracking ultrasound or follow serum hormone changes.

"We are seeing promising results, and it has fantastic potential" - Dr. Thomas Bouchard, MD

Bouchard, T., Yong, P., & Doyle-Baker, P. (2023). Establishing a Gold Standard for Quantitative Menstrual Cycle Monitoring. Medicina, 59(9), 1513. https://doi.org/10.3390/medicina59091513

Mira vs.
Laboratory Readers

Quantifiable Concentration Ranges

Dynamic range of Mira Tests

Hormone changes during Menstrual cycle	LH	E2 or E3G	Progesterone or PdG
Serum	0-200 mIU/ml	0-2000 pg/ml	0-20 ng/ml
Urine	0-200 mIU/ml	0-4000 ng/ml	0-15 µg/ml
Mira test	0-400 mIU/ml, customizable to 0-1000 mIU/ml	0-640 ng/ml, customizable to 0-4000 ng/ml	0-30 µg/ml

Mira's technology is based on the immunofluorescence method with accuracy equivalent to laboratory readers

The Mira LH and hCG measurements strongly correlated with Abbott ARCHITECT i2000SR. A good linear correlation (R^2>0.9) was displayed by The Mira Analyzer and Abbott ARCHITECT i2000SR for both LH (R^2=0.944; slope=1.042) and hCG (R^2=0.926; slope=0.922)*.

LH

hCG

$y = 1.0421x - 2.9127$
$R^2 = 0.9438$

$y = 0.9221x - 179.06$
$R^2 = 0.9257$

* Under editor's review
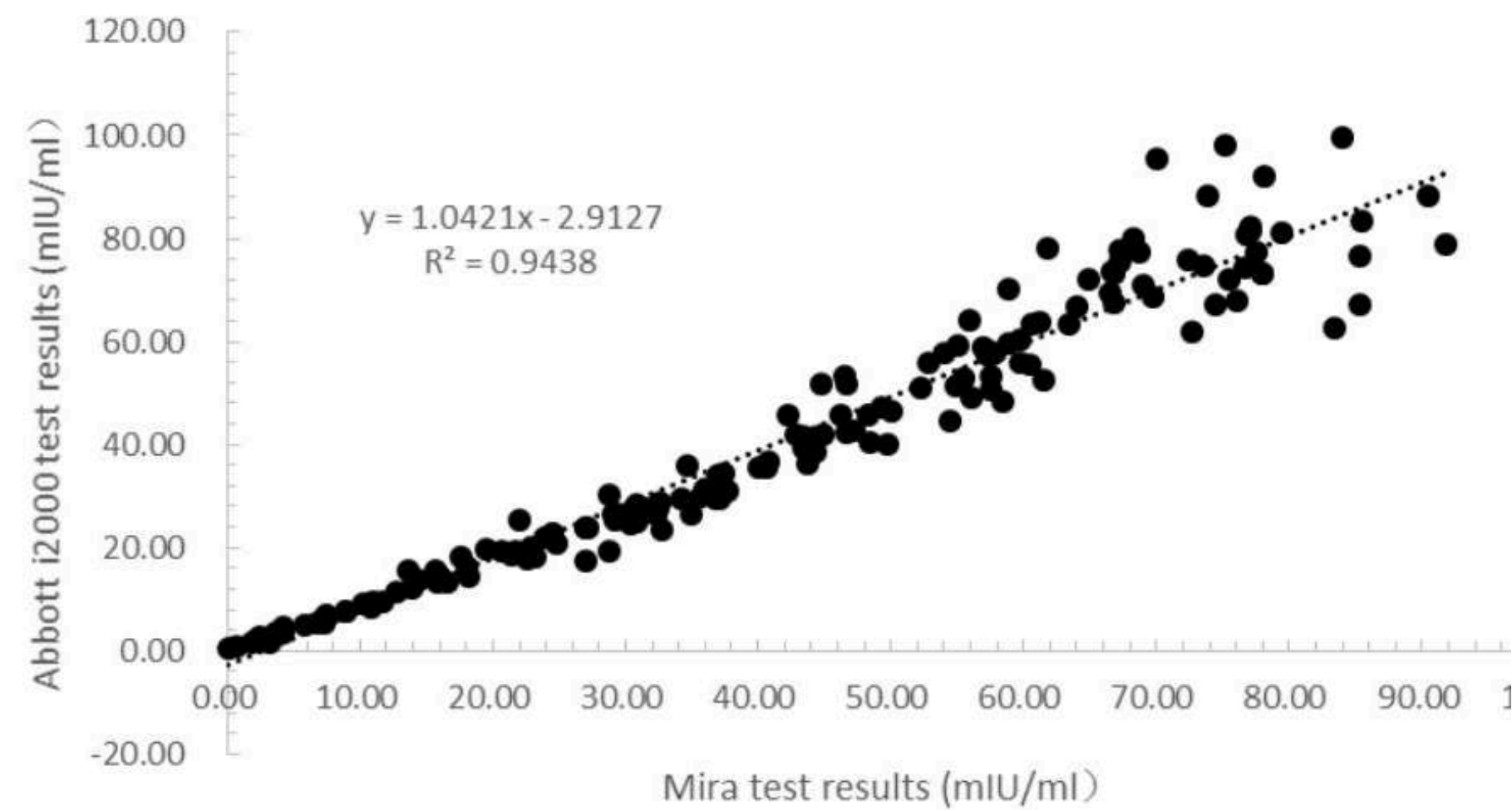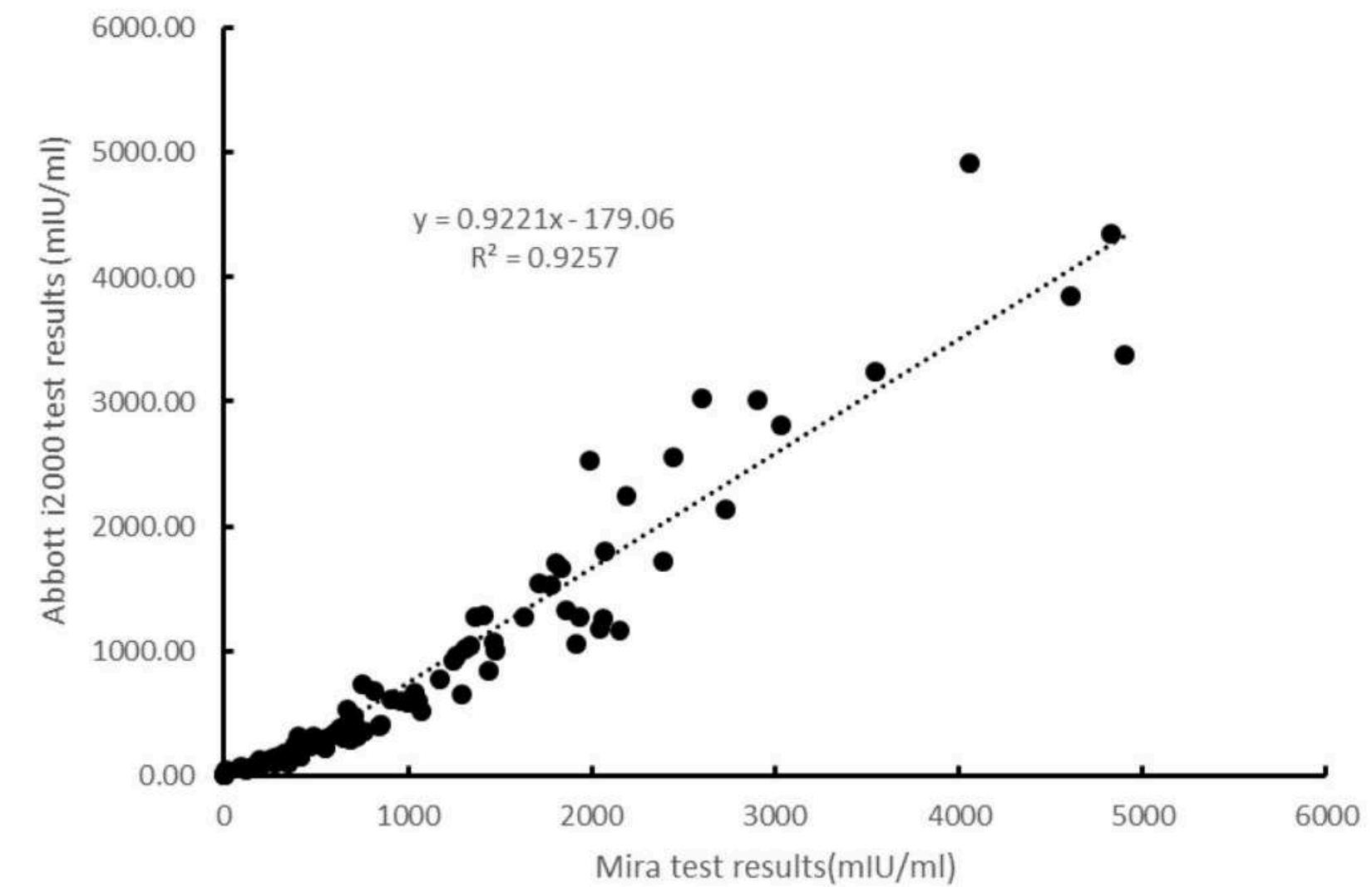
Additional Research involving Mira

Innovative Approaches to Digital Health in Ovulation Detection: A Review of Current Methods and Emerging Technologies

Conclusions:

By integrating tools such as mobile apps, wearables, and hormone-tracking devices, these technologies offer valuable insights into family planning, early health issue diagnosis, treatment adjustments, and the tracking of menstrual cycles during assisted reproductive techniques. The accumulation of big data from these devices can deepen the understanding of menstrual health and its broader connection to women's overall health, an area that remains under-researched. Furthermore, the increasing use of digital health tools by women presents an opportunity to fill the research gap in women's health. The article highlights the promising role of these technologies in advancing women's health research and improving the management of fertility and related health concerns.

Oscillations of estradiol and gonadotropins are a missing link to solving the mystery of mono-ovulation in humans

Key Findings:

The research explores the patterns of the urinary metabolite of estradiol (E3G) across the menstrual cycle. It finds that, unlike the luteal phase where E3G levels remain relatively stable, E3G concentrations in the follicular phase fluctuate significantly. This fluctuation is not a linear increase but varies within a broad range. The study suggests that this pattern reflects the complex interplay between gonadotropins, which stimulate follicular development, and the ovarian production of estradiol. The findings highlight the dynamic hormonal relationships that govern the follicular phase, in contrast to the more consistent hormonal behavior observed during the luteal phase.

Dozortsev DI, Pellicer A, Diamond MP. Oscillations of estradiol and gonadotropins are a missing link to solving the mystery of mono-ovulation in humans. Fertil Steril. 2021 Sep;116(3):630-632. doi: 10.1016/j.fertnstert.2021.05.107. Epub 2021 Jul 22. PMID: 34303510.

Intelligent algorithms combined with a device that detects luteinizing hormone and E3G levels can significantly improve the prediction accuracy of ovulation day

Key Findings:

The accuracy of predicting the LH surge day was compared among three solutions: the traditional calendar method, using LH hormone only, and using both LH and E3G hormones together. Calculated in a retrospective analysis, from 1 to 7 days before the actual LH surge day.

Optimized with more than 7M data points and 600K+ menstrual cycles, the Mira algorithm is 6X more accurate than traditional calendar method and 5X more accurate than traditional ovulation prediction solutions offered over the counter.

The accuracy of predicting the LH surge day.
Comparision of traditional calendar method and Mira's product

Number of users: 20,827
Number of menstrual cycles: 89,388

Legend:
- Traditional calendar method
- Prediction with only LH
- Prediction with Mira Fertility Plus (LH + E3G)

Y-axis: Days before LH Surge day
X-axis: Improvement

Days before LH Surge day	Traditional calendar method	Prediction with only LH	Prediction with Mira Fertility Plus (LH + E3G)
-7	1.0x (9.16%)	1.0x (9.17%)	2.1x (19.01%)
-6	1.0x (9.16%)	1.0x (9.37%)	2.0x (18.68%)
-5	1.0x (9.16%)	1.0x (8.83%)	2.2x (19.84%)
-4	1.0x (9.16%)	1.1x (10.12%)	2.6x (23.41%)
-3	1.0x (9.16%)	1.1x (9.82%)	3.0x (27.16%)
-2	1.0x (9.16%)	1.1x (10.39%)	5.4x (49.44%)
-1	1.0x (9.16%)	1.5x (13.80%)	6.0x (55.22%)

Yang Z, Kang S, Li N, INTELLIGENT ALGORITHM COMBINED WITH DE-VICE THAT DETECTS LUTEINIZING HORMONELEVELS CAN IMPROVE THE PREDICTION ACCU-RACY OF OVULATION DAY, FERTILITY & STERILITY, VOLUME 114, ISSUE 3, SUPPLEMENT, E407, SEPTEMBER 2020

Using Quantitative Hormonal Fertility Monitors to Evaluate the Luteal Phase: Proof of Concept Case Study

Key Findings:

By utilizing at-home hormone monitoring, such as Mira, women can track their individual cycle variations, moving beyond the traditional assumption of a standard 28-day cycle with ovulation on day 14. This personalized approach allows for more accurate identification of cycle abnormalities and enables healthcare providers to tailor treatments to each woman's unique needs. The study highlights the three distinct processes of the luteal phase—luteinization, progestation, and luteolysis—and demonstrates how quantitative hormone tracking can help diagnose luteal phase deficiencies, anovulation, and optimize fertility treatments. Further validation of fertility monitors like Mira is necessary through larger clinical trials to confirm their reliability in supporting these clinical insights.
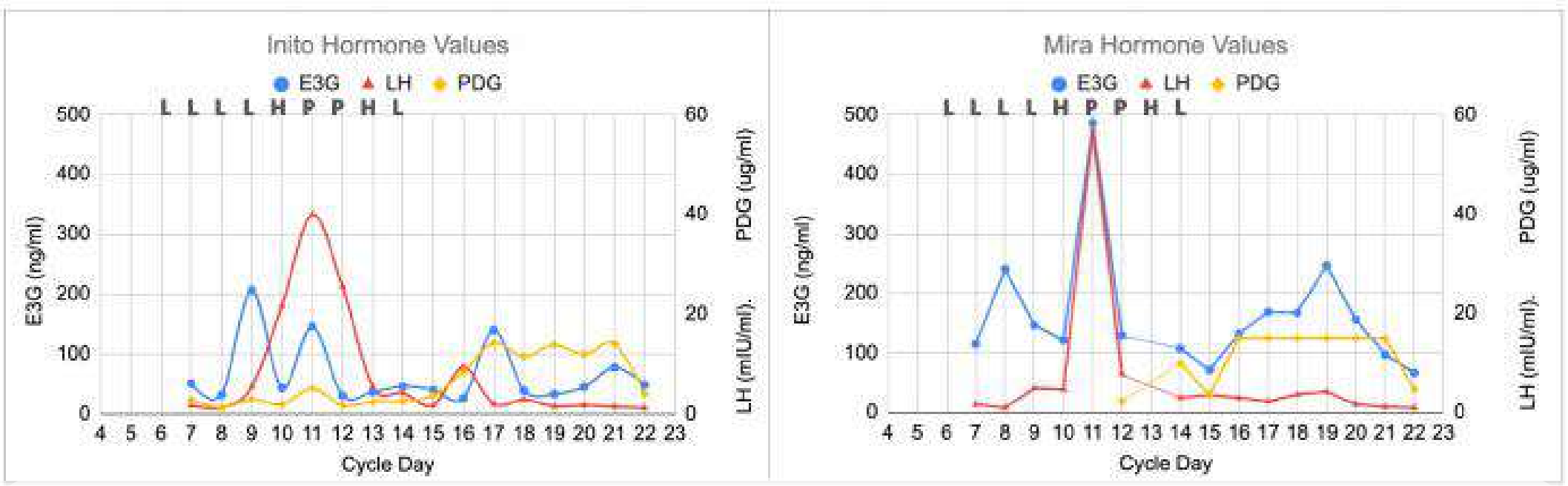
Figure 1: Normal cycle showing all three monitors with agreement on the peak day, with the highest LH value on that day (cycle day 11). The ClearBlue results (L = Low, H = High, and P = Peak) are shown above each graph on the respective days. The estimated day of ovulation was day 12 (day after LH peak). The luteal phase was 13 days (cycle length of 25 days). PDG initially rose on day 16 on the Inito monitor and on day 14 on the Mira monitor.

Bouchard TP. Using Quantitative Hormonal Fertility Monitors to Evaluate the Luteal Phase: Proof of Concept Case Study. Medicina (Kaunas). 2023 Jan 10;59(1):140. doi: 10.3390/medicina59010140. PMID: 36676764; PMCID: PMC9866173.

Blood glucose variance measured by continuous glucose monitors across the menstrual cycle

Conclusions:

"In this study, we identified significant associations between blood glucose and the individuals' menstrual cycles. We observed a biphasic pattern across the menstrual cycle where daily median glucose levels peaked during the luteal phase and declined during the late-follicular phase. The increase in glucose levels from the late-follicular phase to the luteal phase was also robust to a number of confounders, including step count, estrogen, food cravings, fatigue, and sleep issues.

Our results serve as a basis for conversations on the interpretation of glucose levels with respect to menstrual health. Individuals who anticipate adjusting their behaviors (e.g., diet and sleep) based on their glucose variation may need to consider how menstruation influences their interpretation of this data. For example, those who have higher glucose levels while experiencing stronger food cravings might contemplate different symptom management strategies depending on how far along they are in their menstrual cycle."
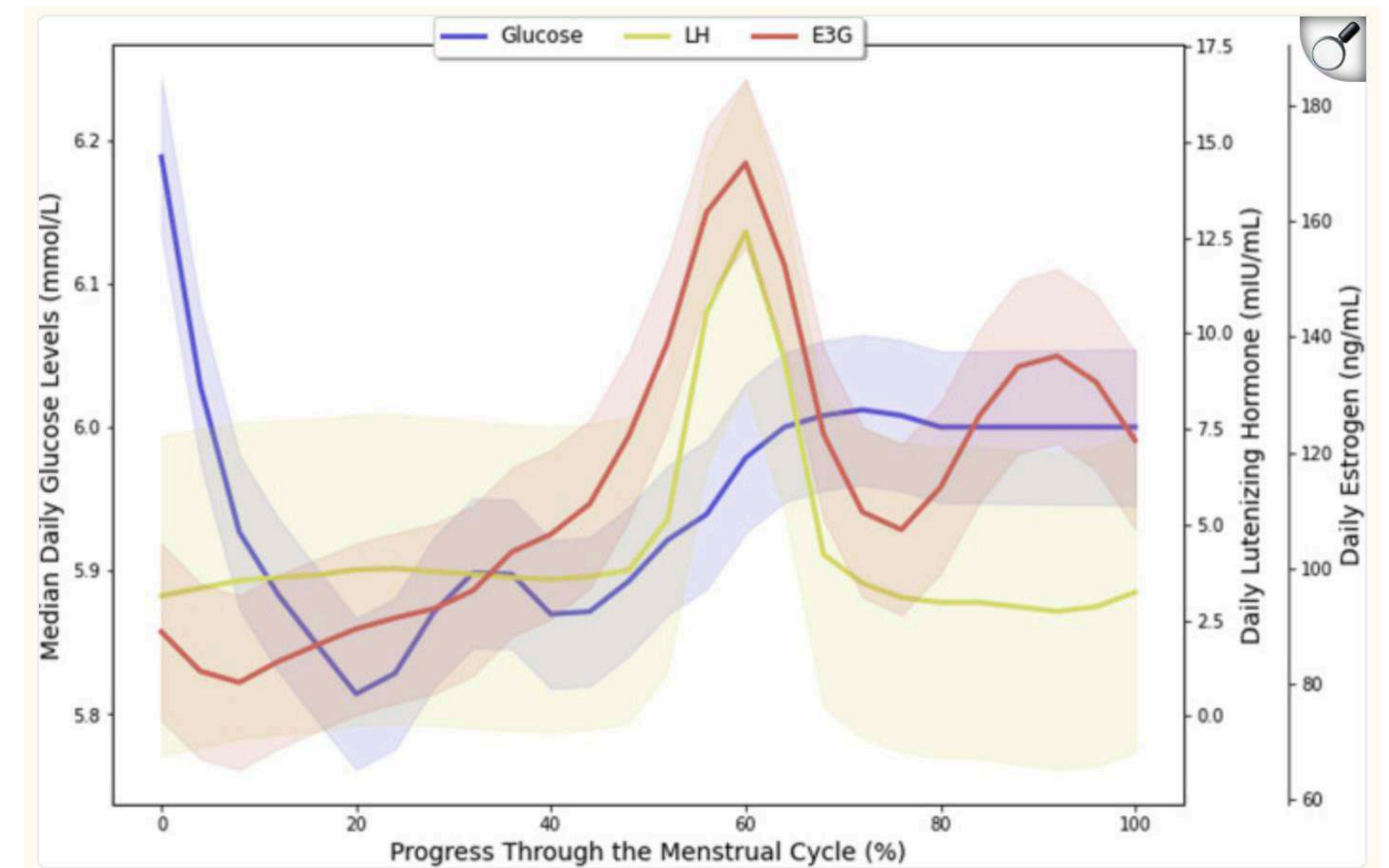
Blood glucose variance measured by continuous glucose monitors across the menstrual cycle by Georgianna Lin, Rumsha Siddiqui, Zixiong Lin, Joanna M Blodgett, Shwetak N Patel, Khai N Truong, Alex Mariakakis.

Case Reports from Women Using a Quantitative Hormone Monitor to Track the Perimenopause Transition

Conclusions:

Tracking fertility during Perimenopause with a quantitative hormonal device is a novel idea. A quantitative hormone monitor allows for the exact measurements of hormones in a woman's cycles and can give more accurate results of cycle patterns, especially as she ages. This study of women in perimenopause has revealed certain cycle characteristics unique to this period, which include cycles with delayed LH surges, quick rises in E3G toward the LH surge, low E3G and LH levels in a cycle, double LH surges in one cycle with corresponding FSH elevation during the highest LH surge, continuous high levels of E3G and LH throughout the cycle, and low PdG levels after an LH surge.

Figure 10. Variable cycle with MIRA: 49 yo with late LH peak, no PdG rise, and a 29-day cycle.

Case Reports from Women Using a Quantitative Hormone Monitor to Track the Perimenopause Transition
by Maria Meyers, Richard Jerome Fehring and Mary Schneider.

Mira used for fertility awareness based methods

Quantitative Versus Qualitative Estrogen and Luteinizing Hormone Testing for Personal Fertility Monitoring (Natural Family Planning — Marquette Method)

Key Findings:

The study established that due to the quantitative measurement of LH the peaks that indicates the most fertile period of the menstrual cycle by Mira monitor throughout 3 menstrual cycles, only 2% of LH peaks have been missed in comparison to 5% of peaks missed when using qualitative measurement with ClearBlue Fertility Monitor.

Mira E3G and LH values relative to EDO

	-10	-9	-8	-7	-6	-5	-4	-3	-2	-1	0	1	2	3
LH average	1.7	1.9	1.6	1.6	1.5	2.5	1.6	2.3	5.4	24.0	7.1	3.3	2.6	2.2
E3G average	142.0	154.1	167.7	159.6	164.4	203.5	231.5	250.1	293.6	298.8	268.7	245.3	220.0	197.2
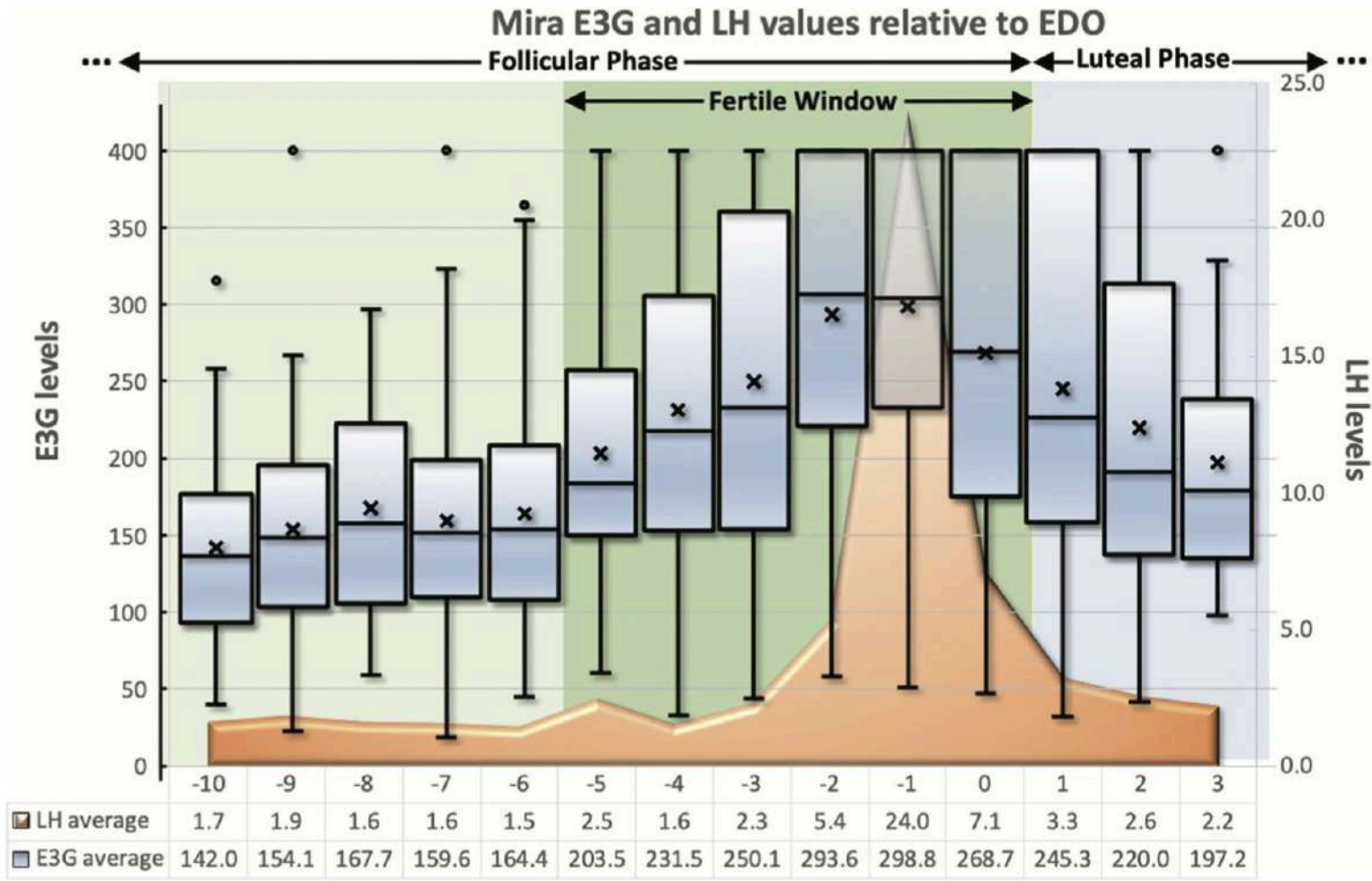
Figure 5. Quantitative Mira levels of E3G (in ng/ml, blue box-and-whisker plots) and LH (in ng/ml, orange mean daily values). The Mira EDO (day 0) was defined as the day after the peak LH day, which is why the LH surge is noted on day -1. LH and E3G mean values are shown in the table below, with peak E3G at 298.8ng/ml and peak LH at 24.0 mIU/ml. E3G values were represented with 25-75 percentile boxplots with min/max whiskers (excluding outliers), The (x) represents the average (mean) for the day, and the horizontal line represents the median for values in the range. The Follicular Phase is defined from the first day of the menstrual period up to and including the day of ovulation. The Fertile Window is defined as the 6-day interval from 5 days before (-5) up to and including the estimated day of ovulation (EDO = 0). The Luteal phase is defined as the day after EDO until the past day of the menstrual cycle.

Thomas P. Bouchard, Richard J. Fehring & Qiyan Mu (2021) Quantitative versus qualitative estrogen and luteinizing hormone testing for personal fertility monitoring, Expert Review of Molecular Diagnostics, 21:12,1349-1360, DOI: 10.1080/14737159.2021.2000393

Quantitative versus qualitative estrogen and luteinizing hormone testing for personal fertility monitoring

Key Findings:

In this preliminary trial, the Mira monitor was shown to be effective at delineating the fertile window and ovulation. We demonstrated the feasibility of applying the Marquette Method algorithm with the use of the Mira monitor. Satisfaction differences between the two monitors did not reach statistical significance. We anticipate that quantitative fertility monitoring will give couples and health-care providers new and unprecedented insights into the menstrual cycle and fertility.

Using Quantitative Hormone Monitoring to Identify the Postpartum Return of Fertility

Conclusions:

In Cycle 0, higher thresholds of LH are required to trigger ovulation, so a higher thresh- old of LH (i.e., LH < 15), along with a more conservative E3G threshold (i.e., E3G < 100) to reflect the average E3G levels within the fertile window of Cycles 0–6 postpartum (Table 3), could be used in Cycle 0 for avoiding pregnancy (Table 6). This protocol will be the basis of a larger effectiveness study using the Mira Analyzer for avoiding pregnancy postpartum.

Table 3. Estrone-3-glucuronide (E3G) values in ng/mL for days leading up to estimated day of ovulation (EDO = 0).

|	−6	−5	−4	−3	−2	−1	0	1
Cycle 0 (n = 10)	89 ± 58	105 ± 41	117 ± 63	159 ± 101	216 ± 132	255 ± 103	177 ± 176	129 ± 51
Cycle 1 (n = 10)	133 ± 162	142 ± 125	126 ± 73	148 ± 71	161 ± 76	155 ± 71	239 ± 180	236 ± 190
Cycle 2 (n = 8)	95 ± 55	111 ± 80	129 ± 62	119 ± 50	165 ± 60	216 ± 113	251 ± 191	300 ± 242
Cycle 3 (n = 8)	127 ± 76	110 ± 71	157 ± 97	190 ± 64	284 ± 142	207 ± 81	296 ± 189	197 ± 136
Cycle 4 (n = 5)	100 ± 58	88 ± 64	137 ± 33	133 ± 79	181 ± 106	212 ± 108	252 ± 229	167 ± 65
Cycle 5 (n = 4)	190 ± 170	166 ± 172	138 ± 89	135 ± 117	186 ± 88	232 ± 118	367 ± 108	128 ± 84
Cycle 6 (n = 2)	162 ± 73	116 ± 78	227 ± 249	106 ± 71	199 ± 88	294 ± 143	331 ± 83	175 ± 94

Table 6. Revised Cycle 0 protocol with updated thresholds based on the current pilot data. This is based on users testing daily.

	Available Day for Intercourse?
If E3G is <100 today and yesterday AND If LH is <15 today and the last 4 days	Yes
If E3G is ≥100 today or yesterday	No
If LH is ≥15 today or the last 4 days	No

Using Quantitative Hormone Monitoring to Identify the Postpartum Return of Fertility by Thomas P. Bouchard, Katherine Schweinsberg, Amanda Smith and Mary Schneider.

Using Quantitative Hormone Monitoring to Identify the Postpartum Return of Fertility

Key Findings:

Higher LH thresholds in Cycle 0 suggest a decreased responsiveness of the ovaries to LH stimulation from the pituitary. This study replicates postpartum hormone patterns from a previous study. Larger studies are planned to evaluate the effectiveness for avoiding pregnancy using the Mira Analyzer in the postpartum return of fertility.
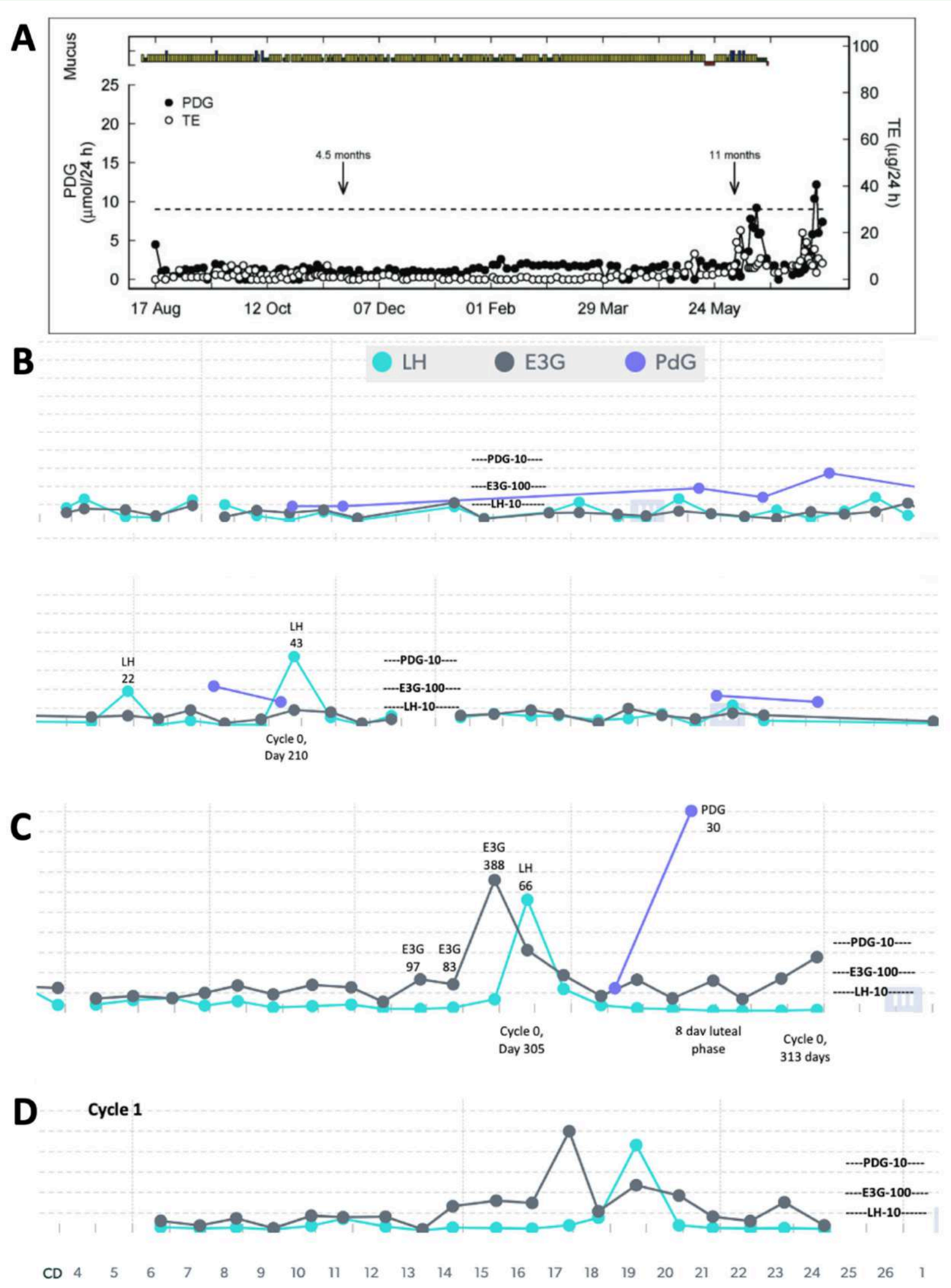
Bouchard, T. P., Schweinsberg, K., Smith, A., & Schneider, M. (2023). Using Quantitative Hormone Monitoring to Identify the Postpartum Return of Fertility. Medicina, 59(11), 2008. https://doi.org/10.3390/medicina59112008

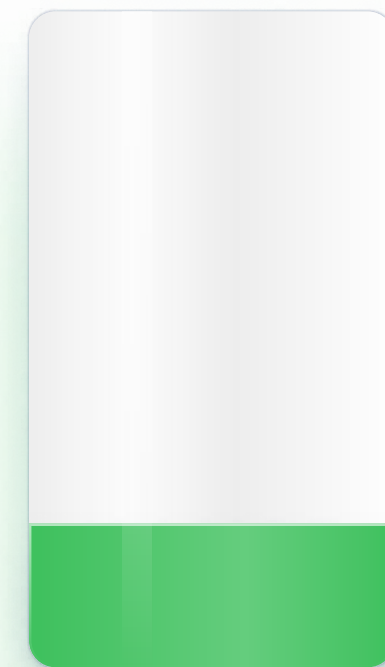# How Mira Supports Fertility and Boosts Conception Success

People experience a variety of challenges during their fertility journey

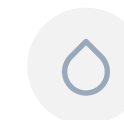OPKs are confusing, create anxiety and don't present the full picture
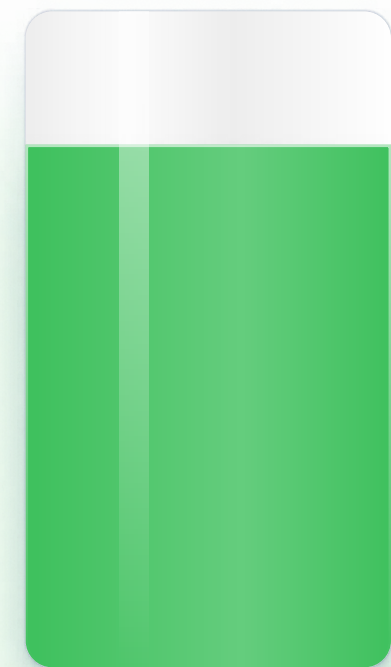
80% of TTC women experience hormone imbalances*

Spending excessive time in clinics, testing and commuting

22% of people take time off work for appointments**

Lack of proper diagnostics with continuous monitoring

Blood work only provides a snapshot analysis

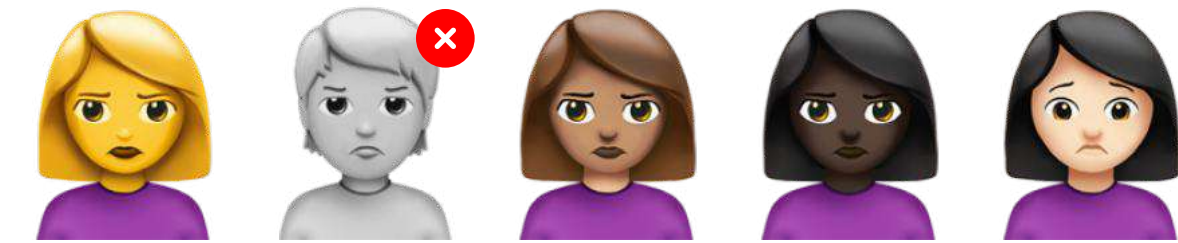The extreme price tag of diagnostics and fertility treatments

One IUI cycle costs $2,000 and IVF – $19,200

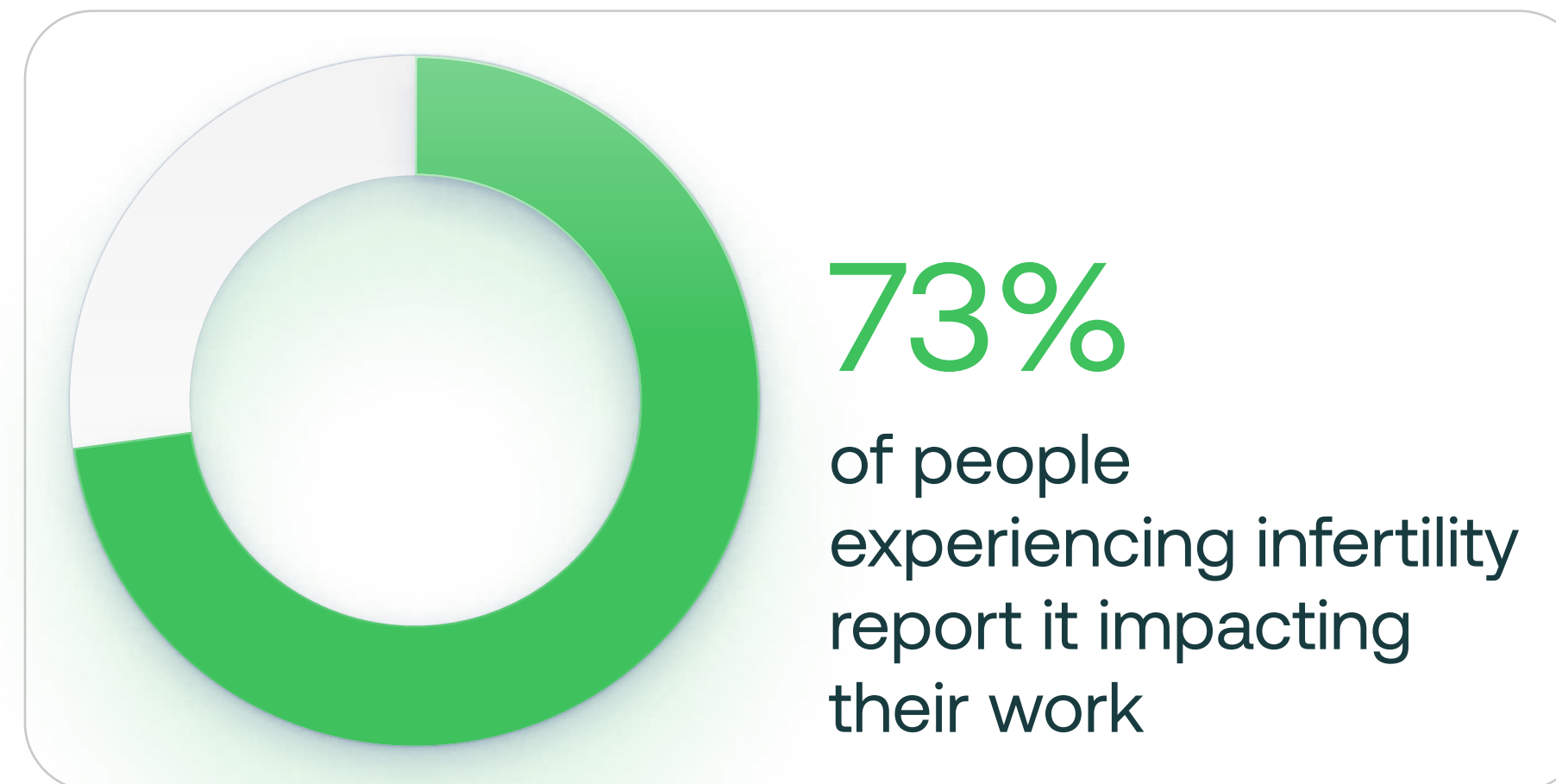*11 unexpected signs of hormonal imbalance ↗

**Progyny report: "How to Support Your Employees: A Guide to the Mental Health Impact of Infertility for HR & People Leaders"

Infertility rates across the world are on the rise 1 in 5 struggle to conceive after a year of trying*

Infertility affects employee productivity**

55%
feel infertility is more stressful than unemployment

73%
of people experiencing infertility report it impacting their work
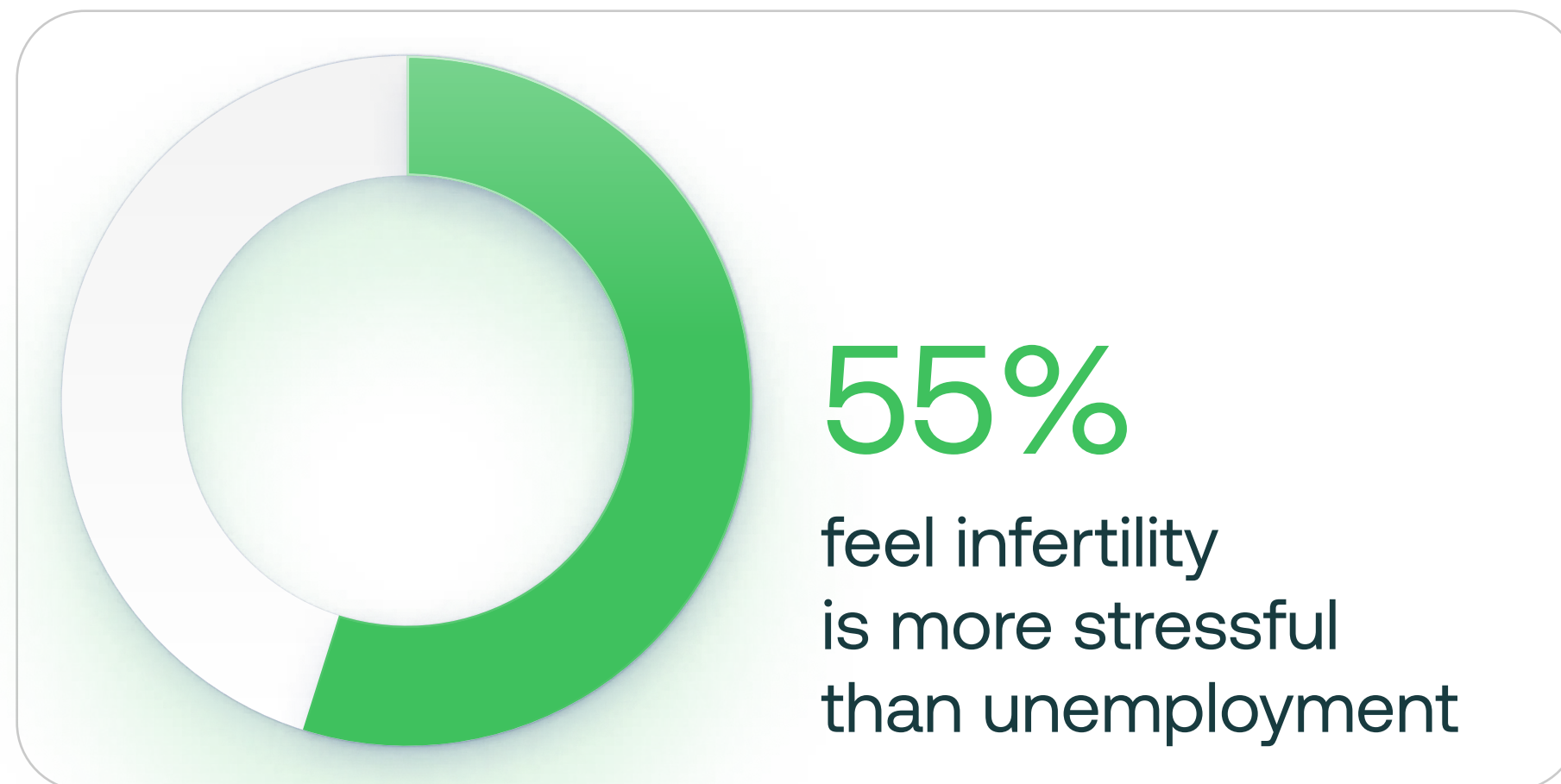
*Infertility Prevalence Estimates ↗

**Progyny report: "How to Support Your Employees: A Guide to the Mental Health Impact of Infertility for HR & People Leaders"

Participant background

All participants were qualified as candidates for IVF by the provider (TTC for more than 1 year)

- ✓ Median age: 34

Diagnosed conditions: PCOS, LPD, POI, diminished ovarian reserve, endometriosis, anovulation, hypothalamic amenorrhea, high prolactinoma

Study design

1. Participants had their initial appointment with a provider (OB/GYN and REI) to:
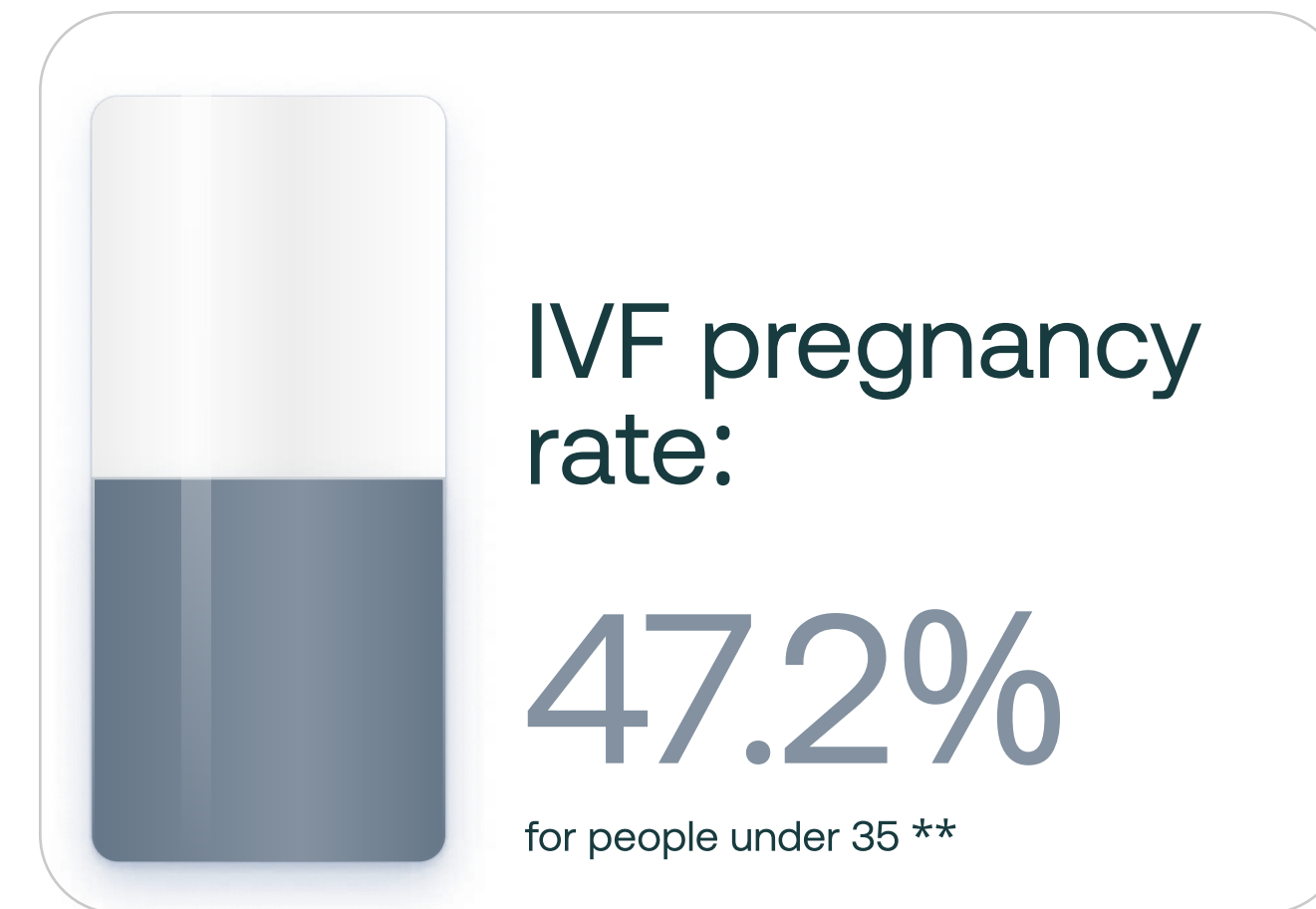
   - ✓ analyze history
   - ✓ order additional labs if appropriate
   - ✓ prescribe medications

2. All participants used Mira to monitor their cycle throughout the treatment

44% of participants got pregnant after 2 months of working with the provider

To compare:

Pregnancy rate of people with PCOS:

26.7%

IUI pregnancy rate:

20.0%

7-10% for natural cycles *

IVF pregnancy rate:

47.2%

for people under 35 **
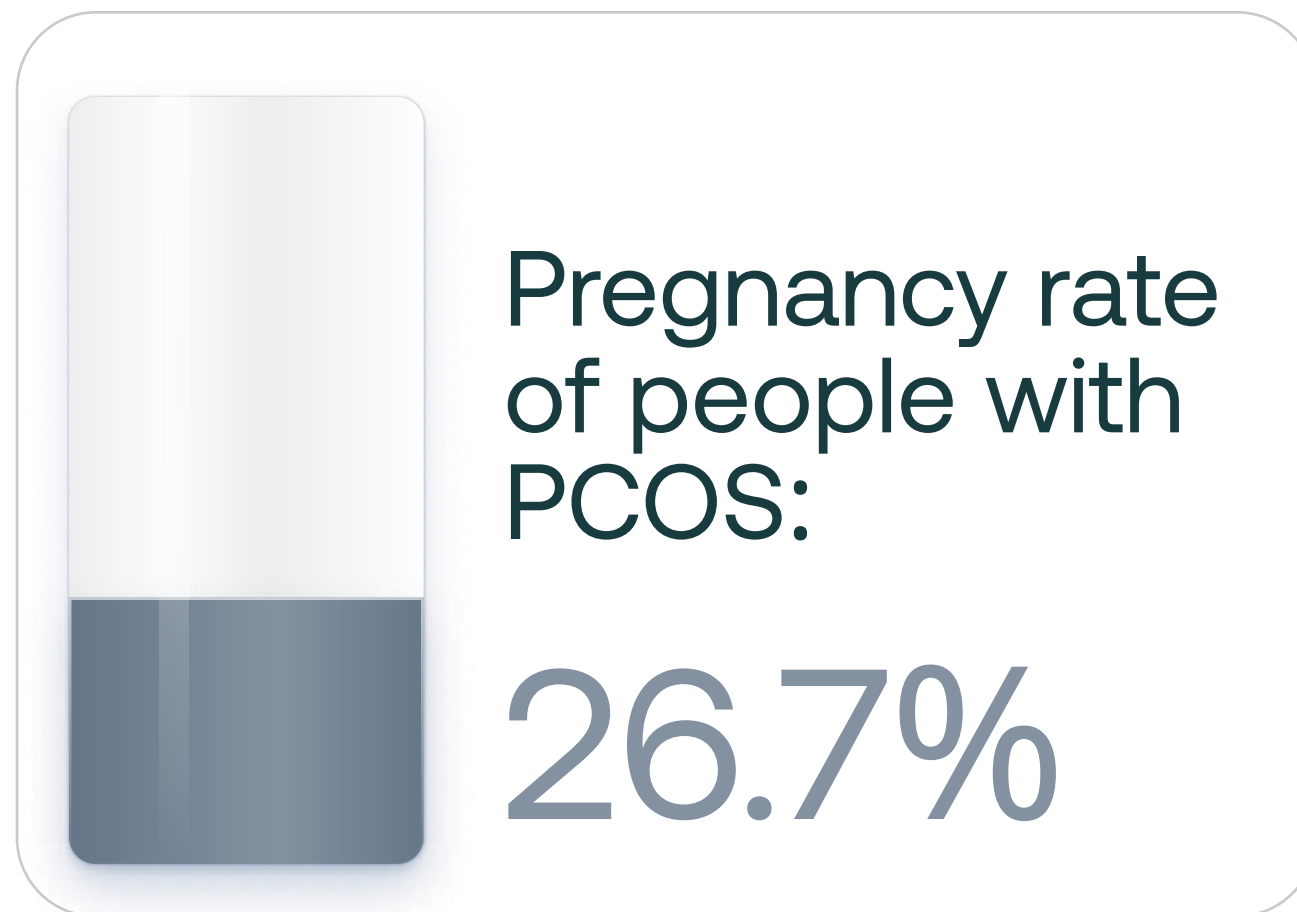
* IUI success rates
** IVF success rates by age ↗

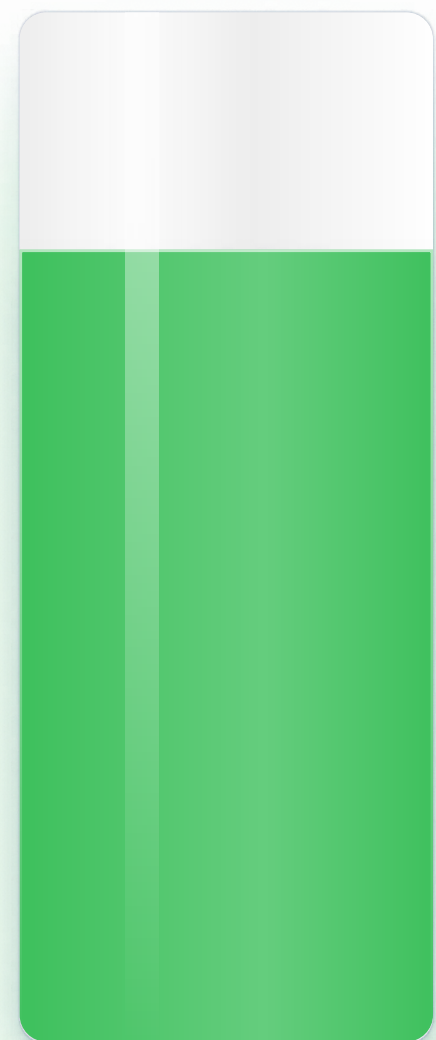# 100% of participants were engaged and compliant during the treatment

82%

of patients claimed that they were engaged, as providers were looking at their data

62%

of patients booked follow-up appointments

72% of people were diagnosed with the help of Mira

79%

of Mira users report that Mira helped them become more informed about their body

Mira helped providers:

- ✓ Observe clear signs of anovulation and hormonal imbalances
- ✓ Order and time other diagnostic tests accordingly
- ✓ Personalize treatment plan and reduce blood work

Patient 1
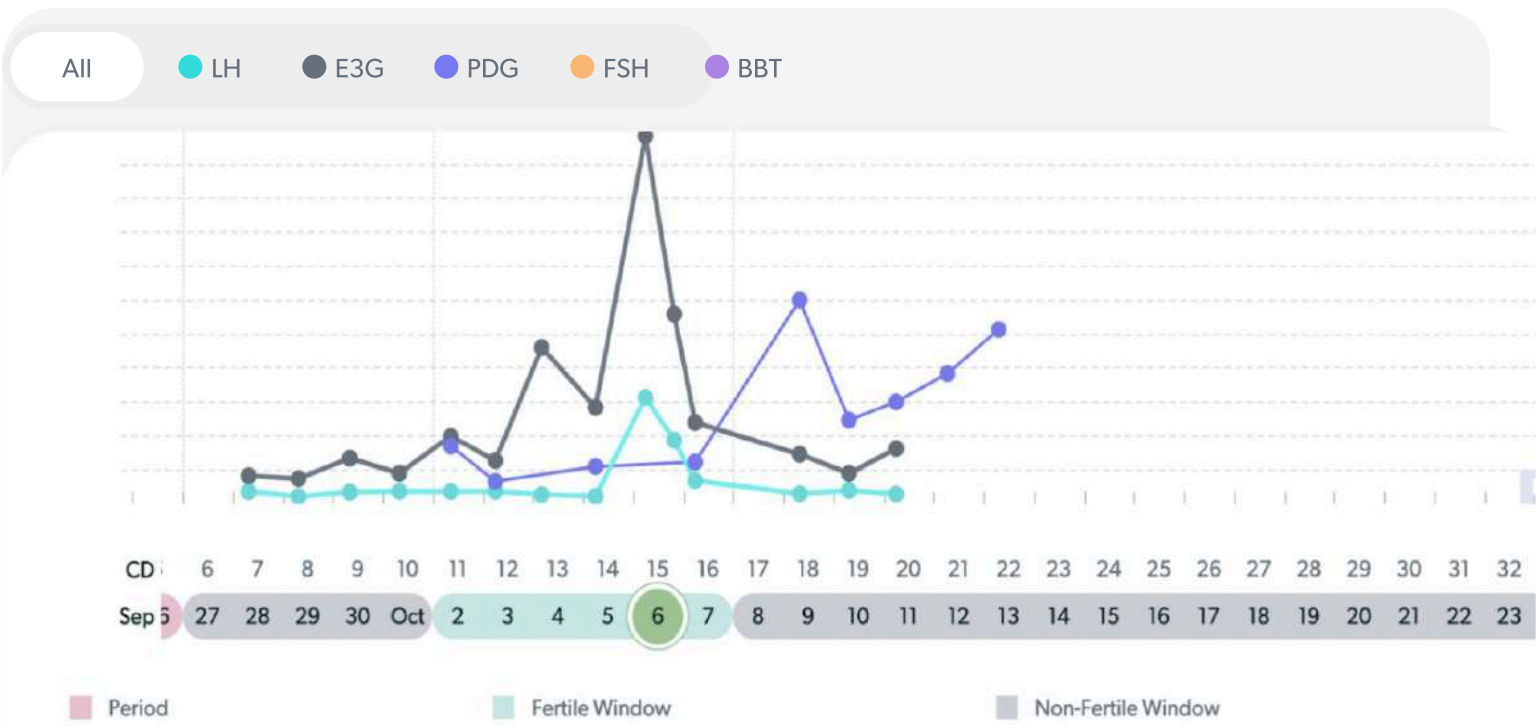
Hypothalamic Amenorrhea and Anovulation

Before treatment (May '23)

Ovulation Induction and HCG Trigger: Pregnant (September '23)

Patient 2

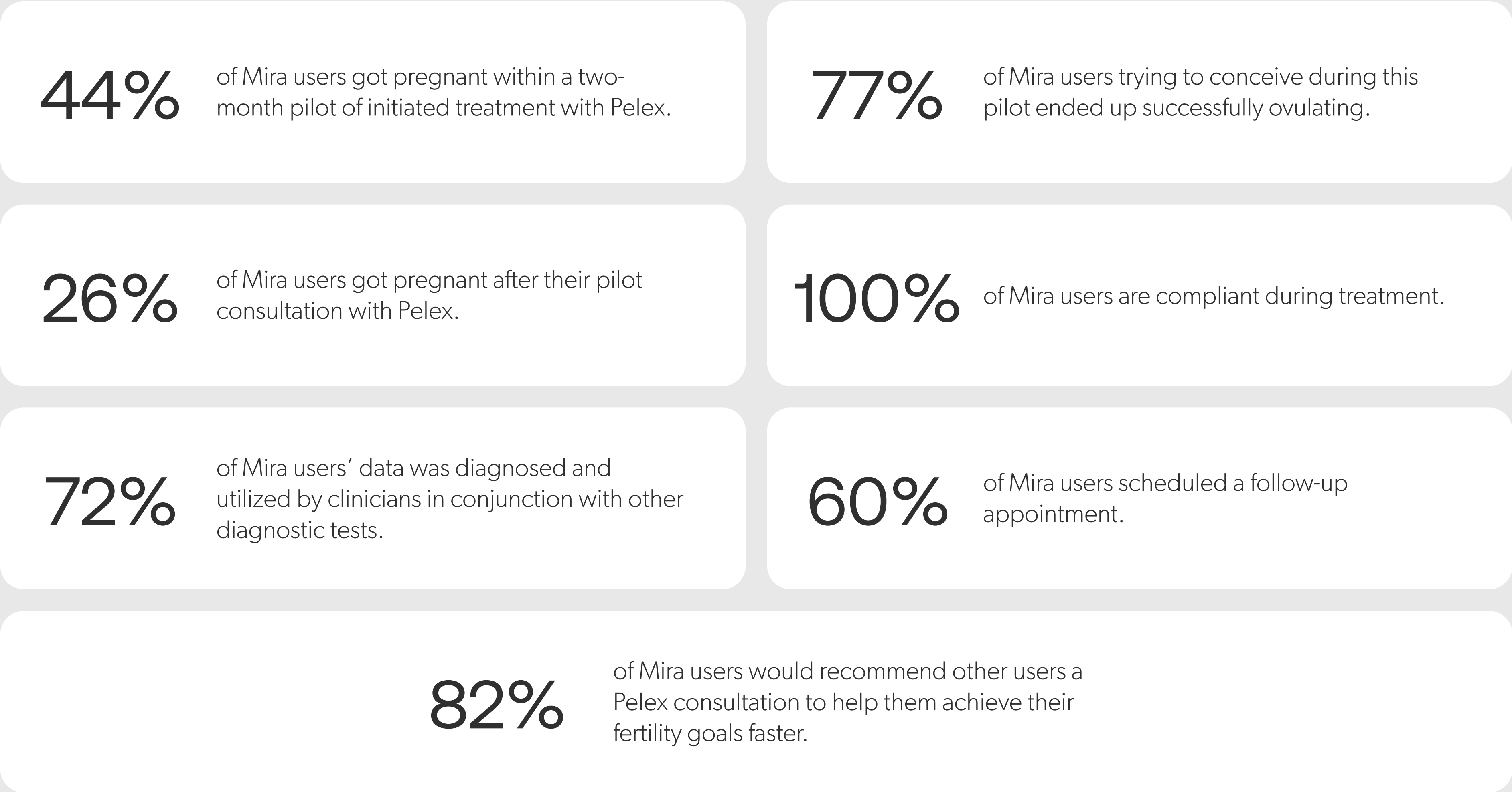## Diminished Ovarian Reserve (AMH 0.6), Obesity, Anovulation, Luteal phase defect, Hypothyroidism
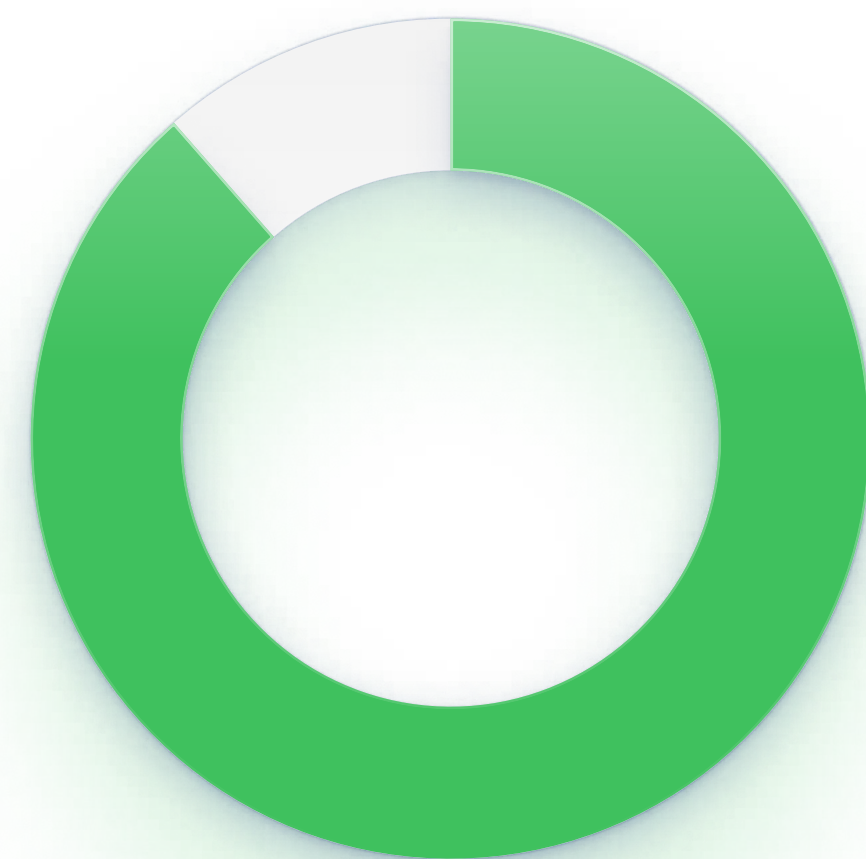

Before treatment (June '23)

Metabolic Nutrition, Trulicity, Clomid ovulation induction, HCG trigger, Progesterone: Pregnant (November '23)

Summary of the pilot results

44% of Mira users got pregnant within a two-month pilot of initiated treatment with Pelex.

77% of Mira users trying to conceive during this pilot ended up successfully ovulating.

26% of Mira users got pregnant after their pilot consultation with Pelex.

100% of Mira users are compliant during treatment.

72% of Mira users' data was diagnosed and utilized by clinicians in conjunction with other diagnostic tests.

60% of Mira users scheduled a follow-up appointment.

82% of Mira users would recommend other users a Pelex consultation to help them achieve their fertility goals faster.

Interesting Facts and Success Rates

89%
of Mira users conceive in 6 cycles

130,000+
users across the globe

70.6%
Regular cycles

70.1%
After miscarriage

55.4%
PCOS

*Self-reported data combined with quarterly survey results