ASRM 2025
Global Collaboration to Advance Reproductive Health
San Antonio, Texas
October 25-29, 2025

Kinetix Sperm FcR Binding Assay Accurately Predicts the Success of Day 5 Blastocysts

H. YAZDEKHASTI[1], R. HOLMES[1,2], J. WALSH[3], Z. CHEN[3], B. COHEN[3], N. CIRAY[4], E. SCHNELLINGER[5], L. LIPSHULTZ[6] AND J. SWAIN[2]

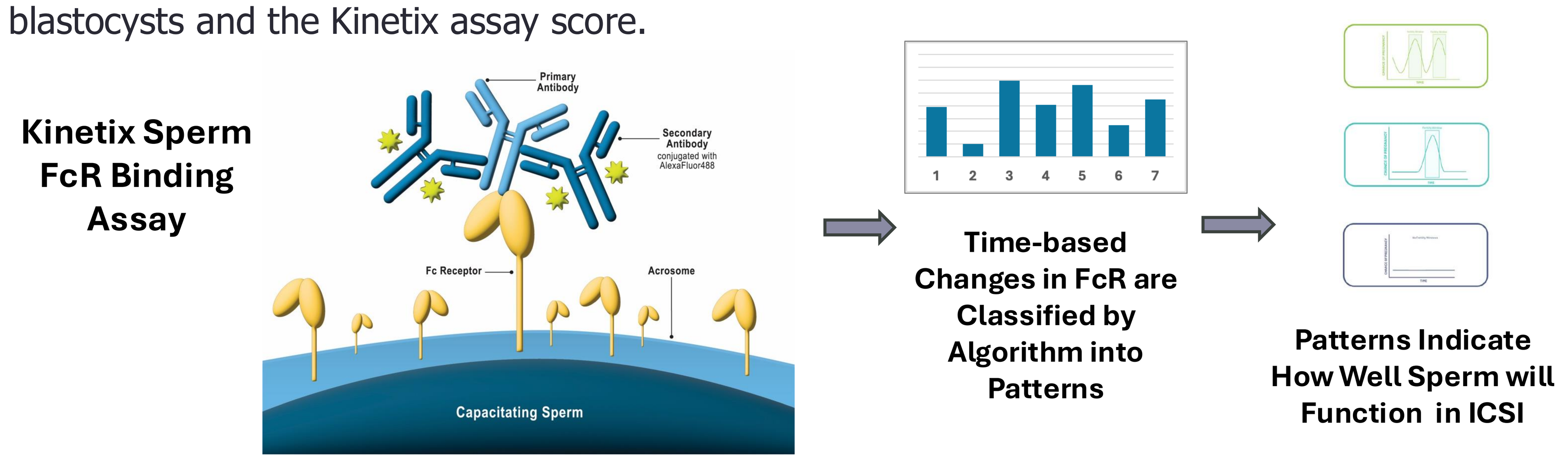
[1]CCRM Boston, Chestnut Hill, MA, USA; [2]CCRM Fertility Network, Lone Tree, CO, USA; [3]Arex Life Sciences, Watertown, MA, USA; [4]OvoScore LLC, Rockville, MD USA; [5]United Network for Organ Sharing, Richmond, VA, USA; [6]Baylor College of Medicine, Department of Urology, Houston, TX USA

PURPOSE & OBJECTIVES

To identify distinct expression patterns of the Fc Receptor (FcR) uncovered on the sperm head as it capacitates over time (Kinetix FcR binding assay) (1,2). These temporal patterns have been shown to define short-lived groups of capacitating sperm which arise, mature and senesce, as has been reported by the laboratory of Michael Eisenbach (3) and others. These patterns were evaluated to determine if a new assay could be leveraged to identify better quality sperm samples and possibly improve ART outcomes, as Sedor and colleagues had previously reported an association of infertility with ejaculates containing less of this ligand (4).

MATERIAL & METHODS

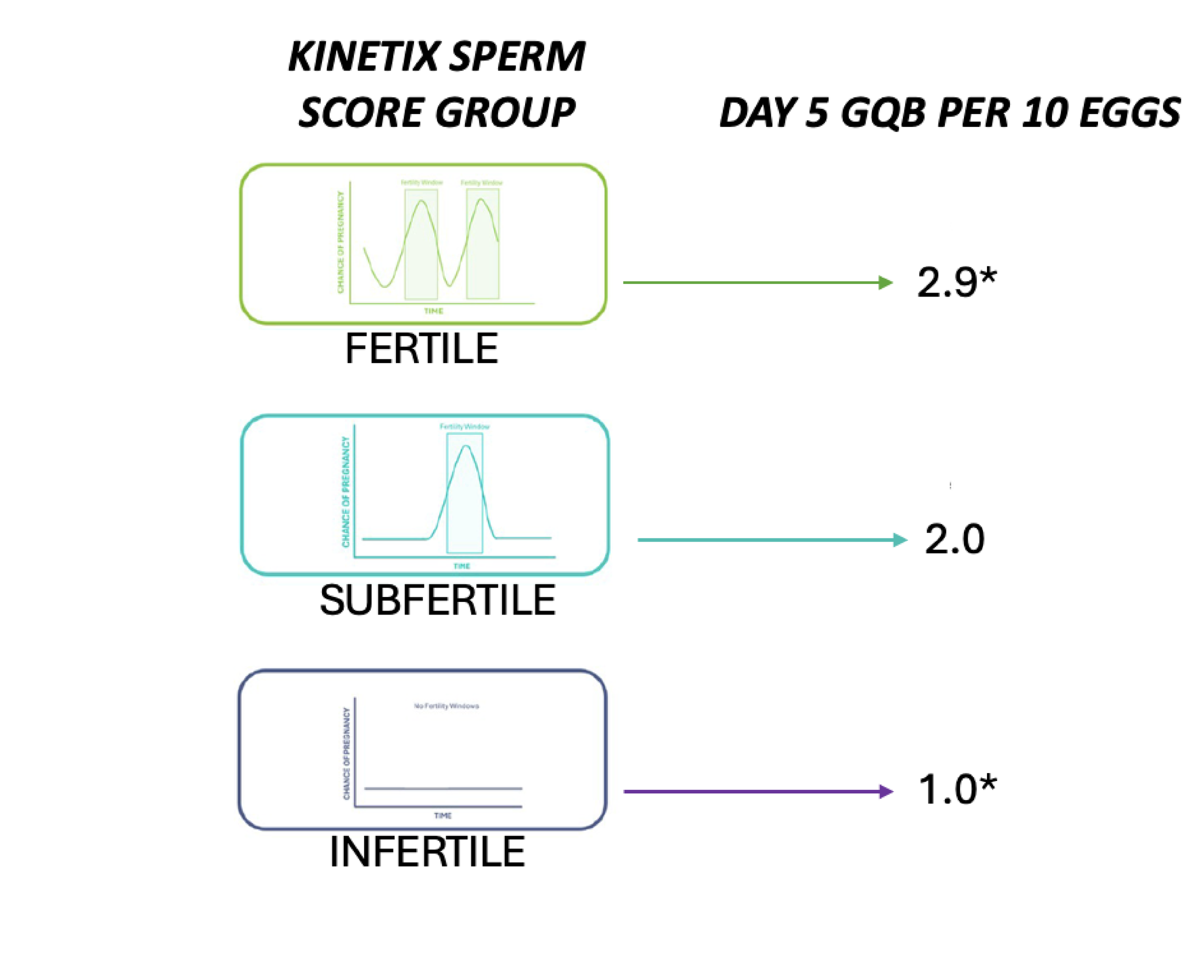
In a prospective observational study, this unique assay that detects levels of sperm Fc receptor (FcR) over time was performed on semen samples during ICSI procedures (n=138). 5uL aliquots of semen were analyzed at 30-min intervals to measure the changing proportion of sperm expressing the FcR over time. Semen samples were then categorized as "Infertile", "Subfertile" or "Fertile" depending on the pattern of functional sperm populations. The fertilization rate, yield of Day 5 total and Good Quality Blastocysts as determined by the standard Gardner assay were quantitated to see if associations existed between these optimal blastocysts and the Kinetix assay score.



RESULTS

Ejaculates were classified into three groups (Fertile, Subfertile and Infertile) based on FcR sperm expression. The number of total as well as good quality blastocysts (GQB) on Days 5-7 per normally fertilized oocyte (2PN) were assessed. There was no statistical difference among Kinetix score groups regarding male and female demographics. While fertilization rates and total blastocyst yield per fertilized oocyte were similar across Kinetix assay groups, more importantly, yield of good quality blastocysts was very different. We found 2.9 times more Day 5 GQB/2PN using sperm identified as Fertile compared to the Infertile group (one-way ANOVA p=0.008, Tukey HSD post-hoc test p=0.01) comparing Fertile and Infertile groups. This was due in part to the high failure rate of sperm demonstrating poor function to produce Day 5 GQB. No Day 5 GQB were produced in 65% of cycles using sperm from the Infertile group, while failure to produce Day 5 GQB only occurred in 35% of cycles in the Subfertile group and dropped to 23% of cycles in the Fertile group. The difference in the frequency of failure among the three groups was statistically different when comparing the Fertile and Subfertile groups to the Infertile group (P=0.007, Chi-square Test among these three groups, p=0.003 for Fertile vs Infertile and p=0.03 for Subfertile vs Infertile). Results suggest the sperm FcR binding assay (Kinetix assay) presented here has the potential to identify unexplained infertility and to improve ICSI outcomes by selection of the highest quality ejaculate based on this novel Kinetix assessment of sperm.

Improved ICSI Outcome with Functioning Sperm



*p=0.008 one way ANOVA, Tukey HSD post-hoc test p=0.01

- Improved yield of Day 5 GQB up to 2.9-fold
- Identify ejaculates at 65% risk of no Day 5 GQB

CONCLUSIONS

In the context of ICSI procedures, the present study demonstrated that temporal analysis of FcR expression patterns in sperm, assessed using the sperm FcR binding assay, enabled identification of ejaculates associated with statistically significantly higher Day 5 Good Quality Blastocyst yields per fertilized oocyte. Notably, the sperm functional characteristics revealed by the Kinetix sperm FcR assay were irrespective of semen quality. It is likely that a higher Kinetix score reflects the presence and ultimate injection of higher quality sperm, which improves the yield of Day 5 Good Quality Blastocysts.

REFERENCES

1) Librach et al., Human Sperm "Cycle" Between States of Fertility and Infertility, the Knowledge of Which Can Predict IUI Success. American Society of Andrology May 7-10, 2022; La Jolla, CA.

2) Yazdkhasti, et al., A Sperm Function Assay Identifies Previously-undiagnosable Male Factor in Assisted Reproductive Technology (ART), Fertility and Sterility, Volume 120, Issue 4, e288 - e289.

3) Cohen-Dayag A, Tur-Kaspa I, Dor J, Mashiach S and Eisenbach M. Sperm capacitation in humans is transient and correlates with chemotactic responsiveness to follicular factors. Proc. Natl. Acad. Sci. USA (1995) 92:11039-11043.

4. Sedor J, Callahan J, Perussia B, Lattime E, and Hirsch I. Soluble Fc(gamma)RIII and immunoglobulin G levels in seminal plasma of men with immunological infertility. J. Andro. (1993) 14:187-193.

RESULTS

# Ejaculates	TOMO (10^6 cells), average (total motile sperm)	Kinetix Score
52	103.9	Fertile
69	98.2	Subfertile
17	71.9	Infertile

Kinetix Score	Cycles (n)	# Oocytes Retrieved, Average	# Oocytes Injected, Average	Mean # Day-5 GQB/10 eggs fert normally
Fertile	52	12.4	10.7	2.9
Subfertile	69	13.7	10.5	2.0
Infertile	17	11.0	9.65	1.0

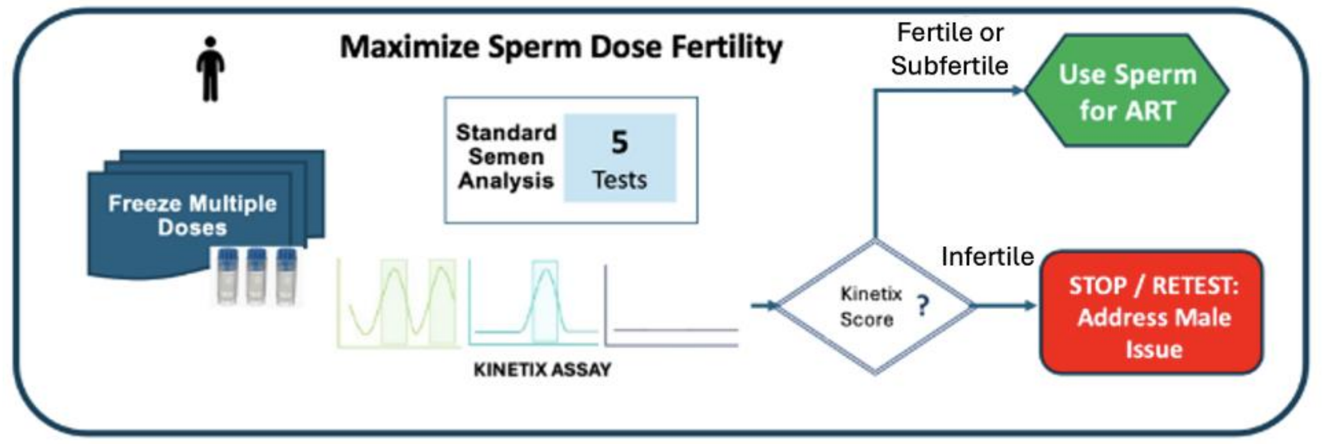
*p=0.01

*One-way ANOVA (p=0.008) followed by Tukey HSD post-hoc test comparing Fertile and Infertile groups p=0.01

Kinetix Score	Number of Cycles with no D5 GQB/Total	% Cycles with no D5 GQB
Fertile	12/52	23%
Subfertile	24/69	35%
Infertile	11/17	65%

*p=0.003
**p=0.03

Chi-square test among three groups (p=0.007), *Fertile vs Infertile p=0.003 and **Subfertile vs Infertile p= 0.03



ACKNOWLEDGEMENTS

We thank Angelo Allard of Seattle Sperm Bank for research specimens.

CONTACT INFORMATION