

A Novel Sperm Function Assay as an Adjunct Tool for Initial Male Fertility Assessment

Blair Stocks¹, Barb Cohen², John Walsh², Zimu Chen², Angelo Allard³, Niki Parikh¹, Taylor Kohn¹, Mahdi Bazzi¹, and Larry Lipshultz¹

(1) Baylor College of Medicine, Department of Urology, Houston, TX, USA; (2) Arex Life Sciences, Watertown, MA, USA, (3) Seattle Sperm Bank, Seattle, WA, USA

INTRODUCTION AND OBJECTIVES

The Kinetix Semen analysis assay is a novel semen analysis that correlates to male fertility. This functional assay measures temporal expression of a sperm Fc receptor as sperm capacitate and become fertile, which in healthy ejaculates occurs over time in sequential groups. Published work has demonstrated that semen samples which rapidly and consistently show good FcR expression produce improved IUI and ICSI outcomes. We characterized samples from men presenting to a tertiary infertility clinic hypothesizing these would demonstrate poor expression.

METHODS

From June 2023 to Jan 2024, we identified 28 patients presenting for their initial male infertility consultation. Excess semen samples were cryopreserved and shipped to Arex for Kinetix analysis. Ejaculate samples were stained with a fluorescently tagged antibody to detect surface FcR expression on post thaw spermatozoa and analyzed using flow cytometry in a multipoint process at 30-min intervals. Relative FcR surface expression over time was calculated and the quality of samples were graded (5-good to 0-poor). We also determined whether clinical variables such as WHO standard semen analysis and serum hormone levels correlated with Kinetix assay grading. The assay was validated with sperm bank samples (higher fertility) that skew toward “good” or “fertile” grading.

RESULTS

In the 28 presenting patients, Kinetix assay reported 7% of infertile patients were graded good (n=2), 61% medium (n=17), and 32% poor (n=9), consequently skewing toward poor quality. In sperm bank donors, 37% were graded good (n=10), 63% medium (n=17), and 0% poor (n=0). Infertile patients were then grouped into categories of infertility: unexplained (n=13), failed IVF (n=6), history of testosterone use (n=8), and fertile control (n=1). We detected no difference in Kinetix grading between the presenting groups (Kruskal-Wallis test) and no significant associations between Kinetix grading and serum hormones (testosterone, LH, FSH, estradiol), testicular size, or standard semen analyses parameters (Kruskal-Wallis test). The Kinetix assay reported an independent assessment of patient phenotypes based on fertility potential.

The **Kinetix Semen Analysis Assay** measures sperm function in ejaculated specimens by detecting expression patterns of an Fc Receptor over time.

- Men presenting with fertility concerns have poorer Kinetix Scores
- Kinetix Scores did not correlate with clinical parameters such as WHO standard semen parameters as expected
- Kinetix Scores *did correlate* with fertility in IUI and ICSI
- With a fertility metric, it becomes possible to establish which clinical interventions improve Kinetix Score

Sperm Fertility Fluctuates as Groups Capacitate

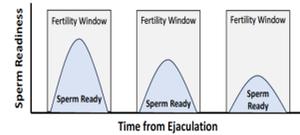
Austin (1951)
Chang (1951)

Sperm acquire fertility post-ejaculation



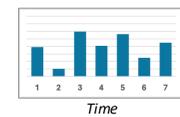
Eisenbach Lab
Cohen-Dayag (1995)

Sperm capacitate after ejaculation in sequential groups that create the presence of fertile sperm



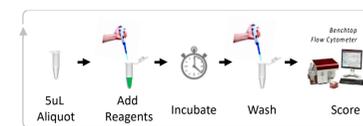
Arex Life Sciences

Kinetix identifies times fertile sperm are present

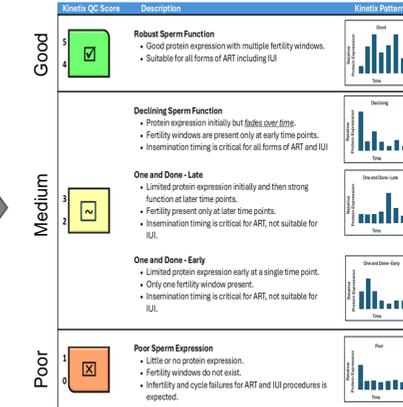
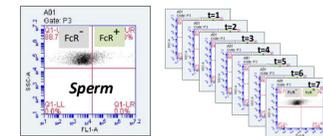


Protein Expression Pattern Reflects Capacitation and Fertility Potential

Kinetix Assay Phenotypes Ejaculate Fertility

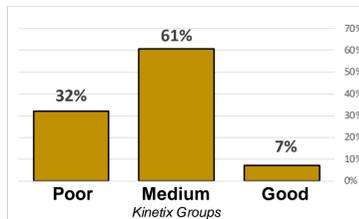


FcR Expression in Lab Aliquot Measured Over Time to Generate Protein Expression Profile & Identify Phenotype

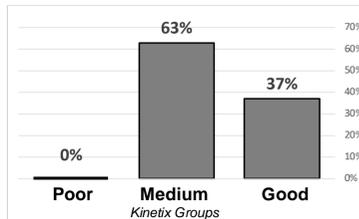


Comparison to Control

Urology Study Sample Distribution



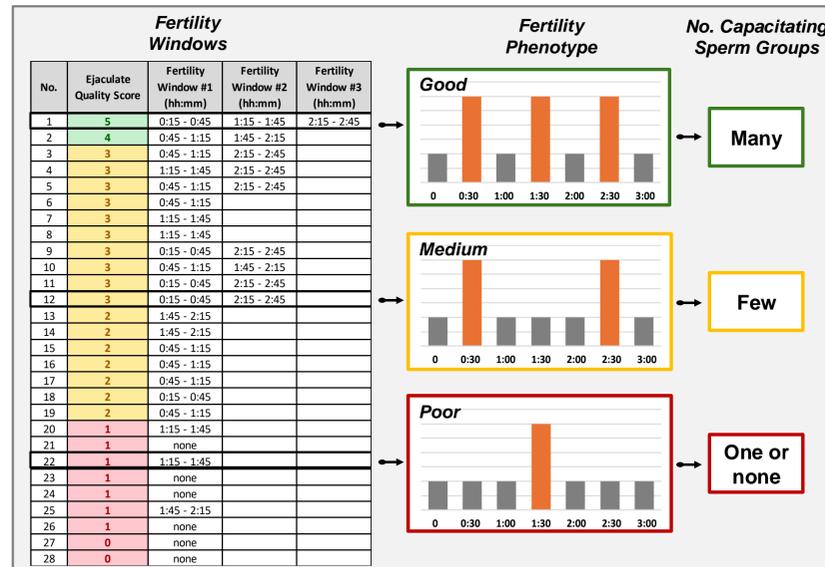
Sperm Bank Sample Distribution



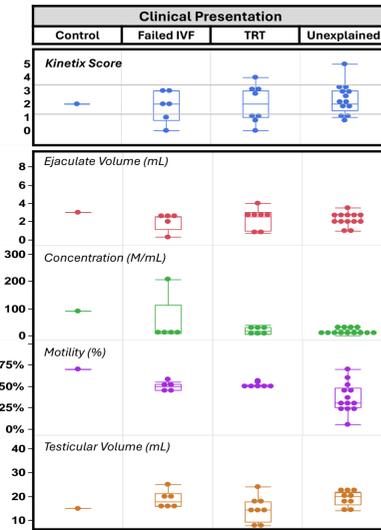
Distribution of Urological Samples

	Kinetix Score and Fertility Phenotype					
	0	1	2	3	4	5
	Poor		Medium		Good	
Unexplained Infertility		•••	••••	•••••		•
Failed IVF	•	•	••	••		
Testosterone Use	•	•••		•••		•
Fertile Control				•		

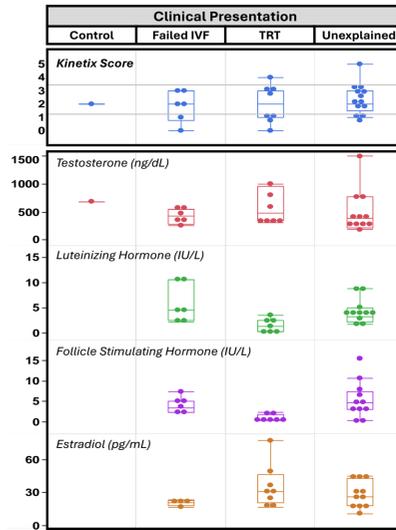
Assay Enables Fertility Phenotyping



WHO Semen Parameters



Hormone Levels



CONCLUSIONS

Standard semen analysis tests provide limited information in the understanding of male infertility. Based on physical and genomic approaches, these tests are only a snapshot of the underlying biological function. The Kinetix assay is a new approach that measures the biological function over time. The results provide the ability to independently phenotype samples based on function that does not correlate to a specific groups or treatment but an overall assessment of sperm function.

REFERENCES

1. Cohen-Dayag (1995) PNAS 92: 11039-11043
2. Austin (1951) Aust J Sci Res B 4: 581-596
3. Chang (1951) Nature 168: 697-698
4. Librach, et al., American Society of Andrology May 7-10, 2022; La Jolla, CA.
5. Yazdekhasi, et al., Pacific Coast Reproductive Society, March 22-26, 2023; Indian Wells, CA.

CONTACT

To whom correspondence may be addressed.
Email: cohen@arexlifesciences.com Phone: +1-617-312 6345

Please photograph QR code to obtain copy of this poster.

