EVALUATION OF INTRA- AND INTER-OBSERVER RELIABILITY OF THE OXIDATION-REDUCTION POTENTIAL TEST FOR OXIDATIVE STRESS IN MALE FACTOR INFERTILITY

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ABSTRACT

Objective: Oxidative stress (OS) plays a role in male infertility. Because OS is a state in which oxidant activity exceeds antioxidants protection, a measure of both would be the best indicator of OS in male infertility. ORP is a measure of the relationship between oxidants and antioxidants. Measuring ORP is a novel approach to testing infertility as such the repeatability of an ORP test is crucial for its clinical application. The objective of this study was to evaluate the intra-observer and inter-observer reliability of the ORP test.

INTRODUCTION

Male infertility is a relatively common medical condition affecting up to 12% of men globally. Oxidative stress (OS) results from a number of endogenous and exogenous stresses believed to play a central role in the pathogenesis of male infertility. A delicate balance in the redox system is required for essential physiologic functions of the spermatozoon such as chromatin compaction in maturing spermatozoa, capacitation, hyperacrosion, acrosome reaction and sperm-oocyte fusion. Currently available assays for OS may only measure a discrete quantity of oxidants (ROS by chemiluminescence assay), antioxidants (TAC assay) or post-hoc damage (MDA assay). OS describes a state of the redox system in which the activity of the oxidants exceeds the capabilities of the antioxidants to quench them.

We have recently introduced the oxidation-reduction potential (ORP), a measure of the relationship between oxidants and antioxidants that provides a comprehensive measure of the redox system and thus of OS. The ORP test is novel in the area of infertility. It is a novel technology based on a galvanostatic measure of electrons — the MiOXSYS System — that measures the amount of oxidant or reductive stress (redox balance) in semen samples by measuring the ORP.

RESULTS

The reliability of the ORP test was determined by assessing the differences between ORP (mV/10^6 sperm/mL) measurements using intra- and inter-observer settings (Table 1).

Intra-observer reliability

1. The intra-observer reliability was based on 27 ORP measurements made by three experienced observers (Observers 1 – 3) for each sample in order to calculate the extent to which there was agreement between observers (Figure 3A). This was determined by the difference between observer means, and correlations among observers. ANOVA was used to verify this. The intra-observer reliability was determined by the average %CV of all three observers.

2. Ten semen samples were measured four times (replicates A – D) by three experienced observers from ten semen samples measured in four replicates.

3. The intra- and inter-observer reliability of the ORP test was measured 4 times by 3 observers. The extent to which there was agreement between observers was determined by the difference between observer means, correlation, and %CV.

4. The %CV across observers was 3.61%. Similar ORP values across observers, high correlations between them, and a low %CV supports a strong level of intra-observer reliability.

5. Overall %CV was 8.39%, suggesting a strong level of intra-observer reliability. The %CV across observers was 3.61%. Similar ORP values across observers, high correlations between them, and a low %CV supports a strong level of intra-observer reliability.

CONCLUSIONS

1. The results of the intra- and inter-observer reliability experiments confirm the reproducibility of the MiOXSYS System for use in a clinical setting.

2. It is important to validate the new test/instrument irrespective of its ease of use and simplicity. This is especially important when a system is used in a clinical setting to report patient results.