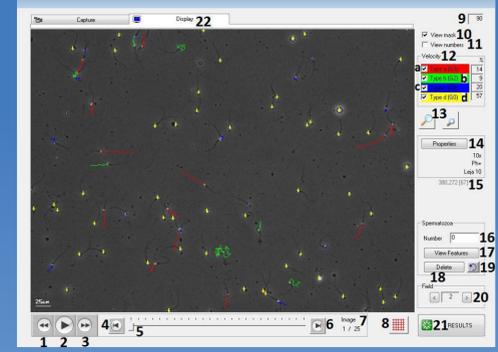


INCREASING PRECISION AND REDUCING VARIATION IN SPERM ASSESSMENTS USING THE SPERM CLASS ANALYZER®.

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Background

CCB endeavors to optimize precision of sperm count and motility calculations by reducing potential procedural sources of variation. The adaptation of real-time video imaging software has made Computer Assisted Semen Analysis (CASA) more versatile and practical for the end users. In fact, this technology allows for remote capturing of video images (i.e., satellite labs) to be processed at one central location, thus eliminating inter-technician/facility variation.

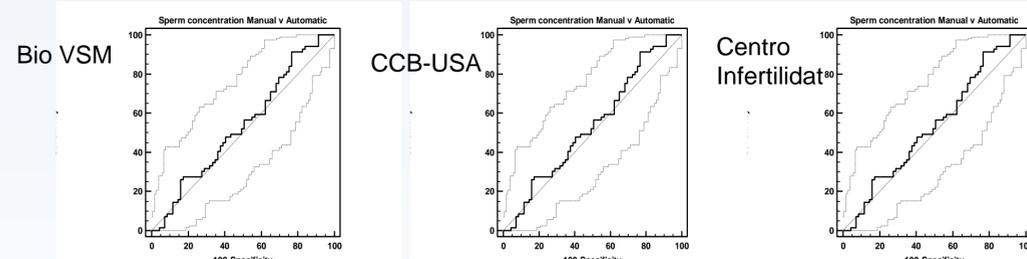
Objectives

This prospective validation study aimed to compare sperm concentration and motility determinations by manual (Makler chamber) or automated (Sperm Class Analyzer {SCA}, Microptics, Barcelona, Spain) methods. Two different technicians (one per method) were used to eliminate technical bias.

Methods

- IRB-approved, FDA-supported validation trial of the SCA unit
- 50 specimens acquired from potential sperm donors consenting to research participation
- Complete semen analysis was performed on each sample by means of: 1) standard manual evaluation using a Makler chamber, or 2) SCA analysis, using Leja SC 20 disposable slides and standard phase contrast microscopy. Using the SCA Motility program, at least 5 separate fields were captured using a 10X objective under green-filtered low light. Centralized regions from the opening to the base of the chamber were documented. The highest and lowest sperm concentration outliers were eliminated.

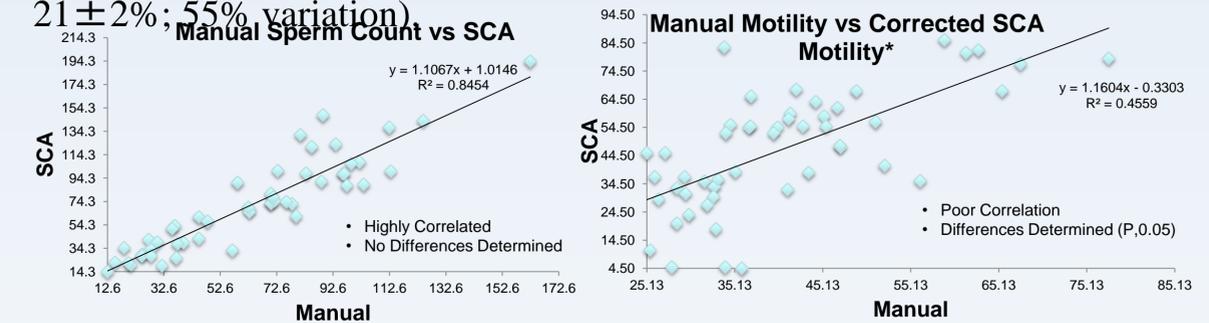
* Complex statistical analyses were performed independent of the Test sites in the FDA trial. A strong correlation was found between the SCA –Leja analysis and the Control manual Hemocytometer (below):



From ROC curve analysis there was no difference in Manual versus SCA assessments. The data almost fully on 45 degree line with area under ROC curve only 0.538, 0.511 and 0.536, respectively for the 3 centers. All data points were within 95% confidence intervals. (dotted lines on both sides of curve)

Results

The SCA-CASA system assessed an average of 848 sperm/analysis, while Makler chambers evaluated 83 sperm/analysis. The mean concentration of specimens analyzed with the Makler was 10.9% lower, but not different ($P>0.1$) than those analyzed with the SCA (64 ± 3.6 vs 71.8 ± 2.3 , $\times 10^6/\text{ml}$). The manual method produced greater dispersion in motility estimates; total motility estimates were lower ($48 \pm 5.4\%$ vs $61 \pm 3.8\%$; 22% variation) and progressive motility estimates higher ($32 \pm 4\%$ vs $21 \pm 2\%$; 55% variation).



Conclusions

The reproducibility of sperm count and motility calculations will always be subject to a degree of variation inherent to this biological product. Eliminating procedural variation and optimizing technician precision are important QC laboratory goals. A centralized SCA unit has the potential to provide superior evaluation and video documentation of specimens. It appears that the SCA is more sensitive to slight motions and more critical of progressive motility, as defined by WHO 5 criteria. In turn, manual estimates of motility tend to produce an intermediate value. Additional verification studies are being conducted on post-thaw samples.

* This study was conducted as part of an FDA trial comparing the SCA to manual Hemocytometer determinations. CCB was the beta – test site in the USA, along with a laboratory in France (Bio VSM) and in Micoptics native country of Spain (Centro Infertilidat 1).

