CLINICAL EVALUATION OF A FULLY AUTOMATED SEMEN ANALYSIS SYSTEM (LensHooke™ X1 PRO) BASED ON THE NEW AIOM (ARTIFICIAL INTELLIGENCE OPTICAL MICROSCOPIC) TECHNOLOGY

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Introduction

• The major shortcomings of standardizing manual semen analysis (MSA) are due to subjectivity of this test and its dependence on skills of the operator.
• The development of computer-assisted semen analyzers has allowed partial automation of routine semen analysis but with limited success due to its complicated operation, and lack of accuracy at a low and high sperm count range.
• The objective of this study was to evaluate the performance and efficiency of the LensHooke™ X1 PRO (X1 PRO) semen analysis device using the clinical application of precision, accuracy and time.

Experimental Design

• This pilot study was approved by the Institutional Review Board and was conducted at the Andrology Center, Cleveland Clinic in August 2018.
• Operation time for semen analysis including concentration, total motility, and morphology between MSA and X1 PRO (Fig. 1) by a single operator was evaluated on 20 samples.
• The intra-observer correlation between MSA and X1 PRO for sperm concentration and motility was calculated on 16 samples.
• The inter-device correlation among 5 different X1 PRO devices was evaluated by analyzing sperm concentration and motility on 16 samples.

Results

• The X1 PRO took 90% lesser operation time than MSA method (52.5 ± 4.8 vs. 5.2 ± 0.5 minutes, P < 0.0001) (Fig. 2)
• The regression correlation coefficient of the X1 PRO with MSA was > 0.95 for sperm concentration and motile sperm concentration (MSC) (Fig. 3 and Table 1).
• Intra-observer’s precision (CV%) of the X1 PRO for concentration, motility, and progressive (PR) motility was less than 10% (Table 2).
• Inter-device precision (CV%) of the X1 PRO for concentration, motility, and PR motility was lower than 10% (Table 2).

Conclusion

• The new artificial intelligence optical microscopic technology-based device has a higher level of precision and agreement compared to the MSA method.
• The LensHooke™ X1 PRO is a simple and quick device which offers reliable and reproducible results of semen analysis.