

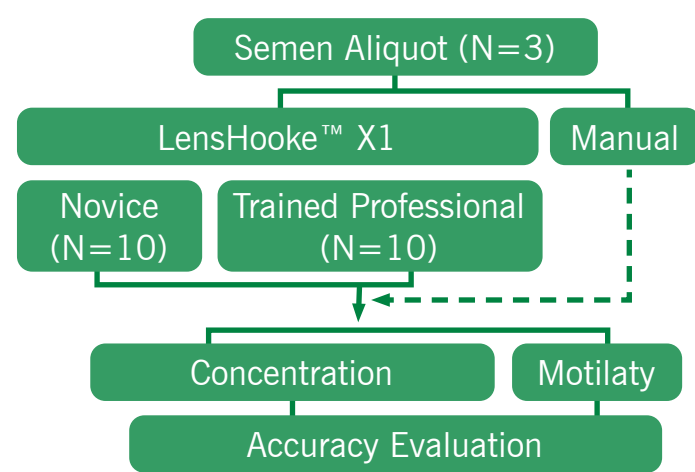
Introduction

Home-based semen quality analyzer (HBSQA) provides private, convenient and rapid evaluation of semen samples. However, there is no information in literature on post-surgical (varicocele repair or removal of ejaculatory duct obstruction) semen quality monitoring (SQM) using HBSQA. Most HBSQA measures only one or a few parameters at a time and thus cannot replace standard laboratory analysis of a semen specimen. LensHooke™ X1 semen quality analyzer, a new generation HBSQA can analyze multiple semen parameters. This study is aimed to evaluate LensHooke™ X1, a fully automated HBSQA for its accuracy, reproducibility, precision and usability as a SQM device.

Experimental Design

Experiment 1:

Semen Analysis Using LensHooke™ X1



Experiment 2:

Semen Quality Monitoring Simulation

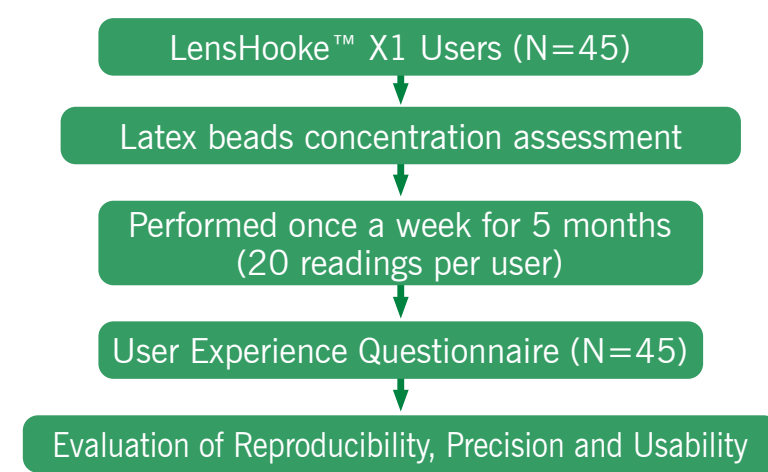
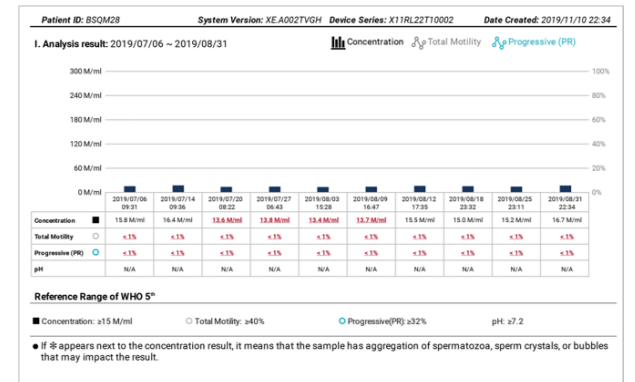


Diagram showing the LensHooke™ X1 semen quality analyzer, the specimen liquefaction test cup C-KUP™ with the semen test cassette CS1 and the example of time-course report form one of this study.



Results

- Accuracy:** Both novice and trained professionals showed high degree of accuracy in sperm concentration and total motility (>90%). There were no significant differences between the two groups (Fig 1, Table 1).
- Reproducibility:** High degree of reproducibility (98.6%) for the measurement of latex beads concentration (Fig 2, Table 2).

- Precision:** Average CV% for the measurement of latex bead concentration was 9.7%. (Fig 2, Table 2).
- Usability:** Received excellent positive feedback (96%) on the overall impression of LensHooke™ X1 and satisfaction rate of 98% on the user-experience with an average score of 3.32 out of 4 points.

Table 1. Evaluation of LensHooke™ X1 semen quality analyzer: Semen analysis results between novice and trained professional

Semen Analysis				
		Reference	Novice (N=10, Mean ± SD)	Trained Professional (N=10, Mean ± SD)
Concentration (10 ⁶ sperm/mL)	Semen Aliquot 1	0	0	0
	Semen Aliquot 2	15.4	14.3 ± 6.10	14.8 ± 4.22
	Semen Aliquot 3	50.8	48.1 ± 9.00	51.1 ± 9.95
Accuracy			90%	93%
paired sample t-test			p = 0.84	
Total Motility (%)	Semen Aliquot 1	0	0	0
	Semen Aliquot 2	60	59.1 ± 5.02	60.6 ± 5.06
	Semen Aliquot 3	72	72.2 ± 6.75	72.7 ± 4.88
Accuracy			90%	90%
paired sample t-test			p = 0.94	

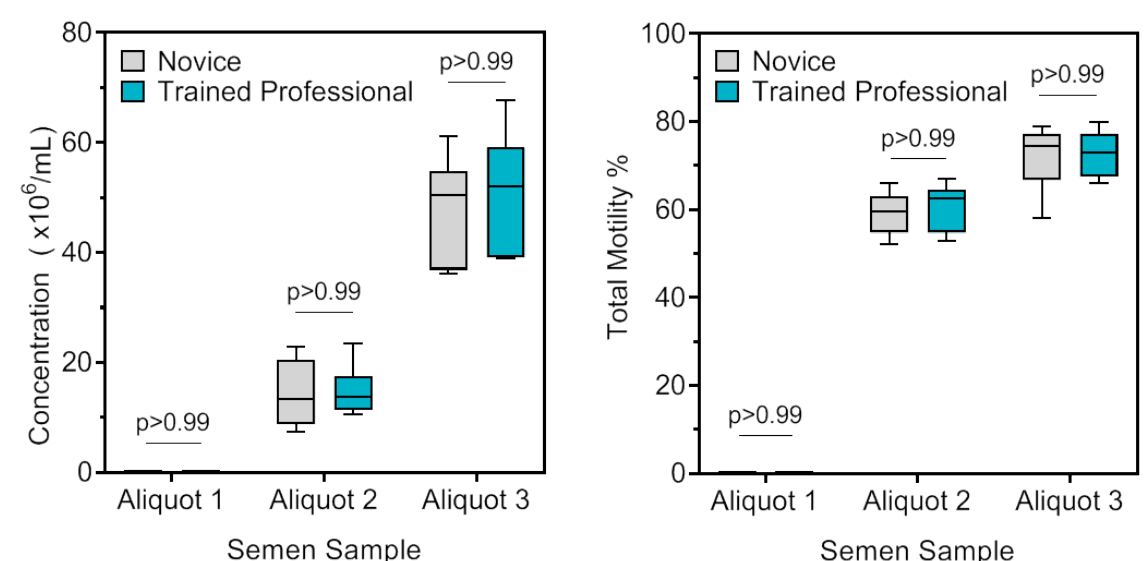


Figure 1. Comparison of semen analysis results between novice (N=10) and trained professional participants (N=10) using LensHooke™ X1.

Table 2. At-home semen quality monitoring simulation: Evaluation of latex bead concentration (N=45)

SQM Simulation				
Reference Conc. (10 ⁶ /mL)	95% CI (Ref. ± 1.96 x SE)	User Conc. in 10 ⁶ /mL (Mean ± SD)	Reproducibility	User CV % (Mean)
15.2	7.6 – 22.8	15.2 ± 1.48	98.6%	9.7%

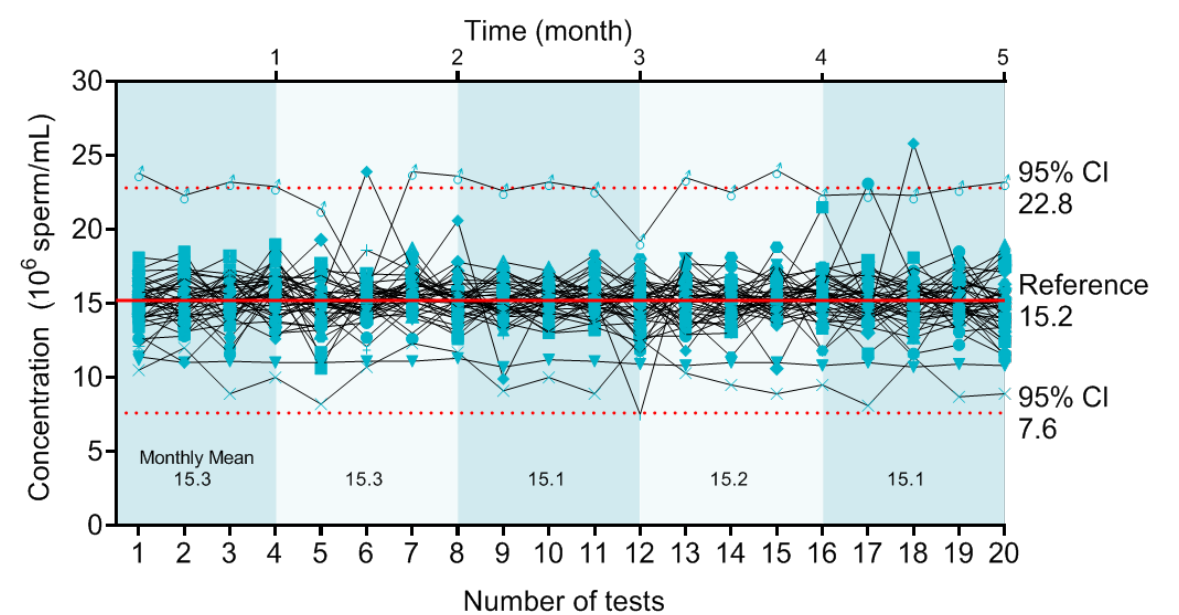


Figure 2. The time course of concentration from 45 users performing at-home SQM simulation test. Blue dots indicates concentration of each test (900 tests in total).

Conclusion

LensHooke™ X1 accurately measures the sperm concentration and total motility. Users can operate LensHooke™ X1 and obtain reliable results without hands-on experience or additional training. Furthermore, this user-friendly device has high reproducibility to determine the concentration of latex beads. As a result, LensHooke™ X1 may be used for long term monitoring of semen quality post reproductive surgery such as varicolectomy and removal of genital tract obstruction.

