הכינוס השנתי ה-66 של
האגודה הישראלית לחקר הפוריות (איל"ה)
7 במאי 2024, מלון דיוויד אינטרקונטיננטל, תל אביב
האגודה הישראלית לחקר הפוריות (איל"ה)
THE ISRAEL FERTILITY ASSOCIATION (IFA)
الجمعية الإسرائيلية لأبحاث الخصوبة

Preliminary Clinical Outcome Using the Q300™ Device in a Reproductive Laboratory Environment

Y. Michailov[1,2], E. Amsalem[2], N. Umanski[2], V. Tamadaev[2], M. Levi, S[3]. Friedler[1,2], B. Saar-Ryss[1,2]

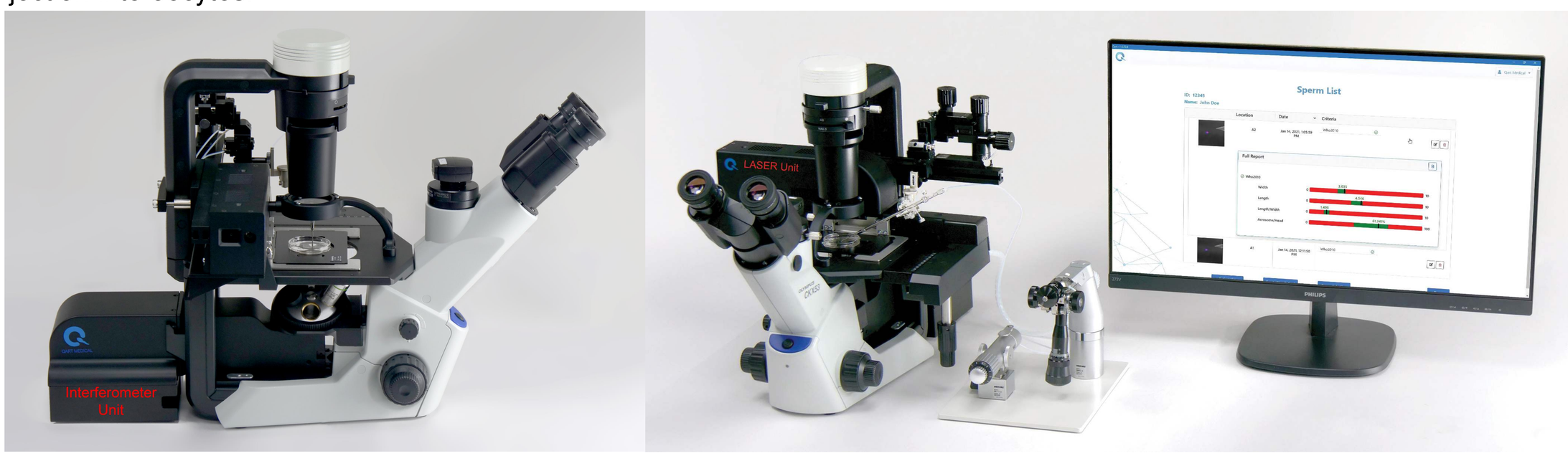
[1]Ben Gurion University of the Negev, Faculty of Health Sciences, Beer Sheva, Israel.
[2]Barzilai Medical Center, IVF unit-Obstetrics and Gynecology Department, Ashkelon, Israel.
[3]Meir Medical Center, IVF unit- Obstetrics and Gynecology Department, Kfar Saba, Israel.

INTRODUCTION

The Q300™ is an optical imaging system that uses quantitative-phase microscopy and holographic imaging for advanced human semen morphological analysis. It captures live and motile sperm cells for ICSI procedures and compares the assessment to WHO criteria in real time. This study aims to assess the usability and preliminary clinical outcome of the Q300™ device under “real-life conditions” in a fertility laboratory setting.

RESULTS

14 couples were recruited from Barzilay Medical Center in Ashkelon, Israel. The average fertilization rate was 79.1% (Vienna consensus competency is ≥65%), the day 3 embryo development rate was 55% (Vienna consensus competency is ≥45%), and the good blastocyst development rate was 42.5% (Vienna consensus competency is ≥30%). The implantation rate (day 3+day5) was 36.8% (Vienna consensus competency is ≥ 25% for day 3 embryo transfers and ≥ 35% for blastocyst transfers). The intended users performed the procedures with no reported malfunctions. 270 sperm imaging procedures were performed using the Q300 device to select 109 morphologically suitable cells for injection in ICSI. The utilization of the product resulted in approximately a 40% yield of correct selections by the embryologist. Consequently, out of every 10 cells deemed compliant by the embryologist, only 4 were confirmed by the device, with roughly 3 falling within a margin of 10% around the WHO measurement range. Moreover, only about 1 of these selections fell within the boundaries defined by the WHO standards. This observation offers insights into the characteristics of cells routinely chosen for injection into oocytes.



The Q300TM device set up and the Image of the Q300TM results screen.

CONCLUSION

This study intends to provide an understanding of the practical usability and early clinical impact of the Q300™ device in the IVF laboratory. The initial data suggests favorable outcomes, and further research is necessary to identify the patient subgroups that can benefit from this system the most. Also, it is important to validate and statistically power the outcome measures and compare them with clinical control groups in the future. In the next generation of the product, incorporating an objective selection based on sperm motility can further improve its functionality.

REFERENCES

Barnea I, Karako L, Mirsky SK, Levi M, Balberg M, Shaked NT. Stain-free interferometric phase microscopy correlation with DNA fragmentation stain in human spermatozoa. *J Biophotonics* [Internet] 2018;11:e201800137.

Michailov Y, Nemerovsky L, Ghetler Y, Finkelstein M, Schonberger O, Wiser A, Raziel A, Saar-Ryss B, Ben-Ami I, *et al.,*Stain-Free Sperm Analysis and Selection for Intracytoplasmic Sperm Injection Complying with WHO Strict Normal Criteria. *Biomedicines*. 2023;11(10):2614.

Nygate YN, Levi M, Mirsky SK, Turko NA, Rubin M, Barnea I, Dardikman-Yoffe G, Haifler M, Shalev A, Shaked NT. Holographic virtual staining of individual biological cells. *Proc Natl Acad Sci* [Internet] 2020;117:9223–9231.

ESHRE Special Interest Group of Embryology and Alpha Scientists in Reproductive Medicine.The Vienna consensus: report of an expert meeting on the development of ART laboratory performance indicators. Reprod Biomed Online 2017; 35(5):494-510

ACKNOWLEGEMENTS

With gratitude to the IVF Unit at Barzilai Medical Center. The Q300™ system is developed and manufactured by QART Medical Ltd.