A novel device for real time automated strabismus detection and pupil analysis

Simon Barnard1,2, Yuval Yashiv2, Ron Mao2, Mike Stroud2, Carolin Truckenbrod3, Alex Levit3, Ellis Johnson2,3, Richard London4

1 PhD, FAAO, Department of Optometry & Visual Science, Hadassah College, Jerusalem, Israel; 2 IRISS Medical Technologies Ltd, London, UK; 3 Optometrist, London

Introduction
Strabismus is a risk factor for amblyopia and in pre-school children has a prevalence of 3.9%.1 Alignment tests increase the sensitivity of preschool vision screening to detect strabismus. The Hirschberg test of ocular alignment evaluates centricity of corneal light reflections.2 IRISS Medical Technologies are developing, a novel real-time strabismus screening/measuring device, based on automated processing and analysis of high-resolution digital photographs of the first Purkinje image (Figures 1 & 2).

Results
Study 1 Prevalence of manifest strabismus in the study sample was 6.34%. Sensitivity of IRISS to detect strabismus was 95%, specificity 91%.

Study 2 Prevalence of strabismus in the study sample was 7.64%. Sensitivity of the IRISS to detect strabismus was 91% (1 FN) and specificity 96% (1 FP).

Study 3 Difference between IRISS and observers was 0.34 mm; inter-observer difference was 0.37 mm.

Discussion
Strabismus is a prevalent risk factor for amblyopia and it is widely recognised that early detection of strabismus improves treatment outcomes. The IRISS technology is being developed as a portable, inexpensive, automated screening and measurement device for use by eye care specialists and paediatricians.

It also provides an objective measurement of the amplitude of strabismus and other data including pupil sizes, corneal diameter and eye lid Margin Reflex Distance (MRD) with a tolerance of +/-0.25mm.

Methods
The Research and Ethics Committee of the UK Institute of Optometry approved relevant parts of the study.

Study 1. 331 individuals in primary schools (n=56) and an optometry practice (n=275). Age: 179 ≤ 10 years, 152 ≥ 11 years) underwent unaided visual acuity (LogMAR or crowded single letters/pictures), cover/uncover test and Randot stereopsis by a study-accredited optometrist and the results compared to IRISS analysis results.

Study 2. Experienced optometrists in an a primary care practice examined 187 patients (age < 40 years; average age 10 years) and the results compared to IRISS.

Study 3 Validation measurements to determine limits of agreement were made by two independent masked observers who took measurements from photographs of two patients wearing a scale attached to their foreheads (Figures 4a & 4b).

Conclusions
Early results obtained with the IRISS technology suggest that it compares favourably with other eye alignment tests used by optometrists for the detection of strabismus and measures pupil size accurately. IRISS is more accurate than manual human measurements. Further independent validation trials are planned.

References

Acknowledgements
The research was funded by IRISS Medical Technologies Ltd, who also acted as study sponsor. Financial Disclosure: SB, YY, RM, MS, EJ and RL have a financial interest in the technology.