



Detecting strabismus

Optometrists in the UK understand very well the importance of diagnosing amblyopic risk factors in infants and young children, the most prevalent of which are strabismus and hypermetropic anisometropia.

Amblyopia is defined by Grounds¹ as a deficiency predominantly of form vision affecting either one or both eyes, occurring generally before the age of seven years, which cannot be corrected purely by accurate refraction. Further, it should not be associated with any recognisable pathological cause, but should be attributable to an amblyogenic (amblyopia-causing) risk factor.

The most critical period for the loss of binocularity and for the development of functional amblyopia is the first 18 months of life.² After this, the plasticity of the visual system seems to decrease rapidly at first, and thereafter gradually with some sensitivity remaining until around seven years.

Evans³ cites Hugonier and Clayette-Hugonier⁴ asserting that strabismic amblyopia is by far the most frequent cause of functional amblyopia.

Strabismus is by definition a misalignment of the two eyes. Strabismus is a common eye condition, and has a prevalence of approximately 2 per cent to 4 per cent

Dr Simon Barnard and **Ellis Johnson** offer an introduction to the epidemiology of strabismus and amblyopia and a new device that may help in their screening and management

in infants and young children across the world.^{5,6,7} Strabismus was shown to be a risk factor for amblyopia and in pre-school children has a prevalence of 3.9 per cent.⁸ The latter study also showed that tests for eye alignment increase the sensitivity of preschool vision screening to detect strabismus.

Amblyopia is thought to occur in 2 per cent to 4 per cent of the general population. In the population under the age of 20 years, amblyopia is 10 times more common a cause of visual loss than all the others taken together, whether caused by trauma or disease.¹

It is widely accepted that amblyogenic risk factors should be diagnosed as early as possible and there is evidence that screening programmes that screen babies and pre-school children reduce the risk of amblyopia.

The Dutch child vision screening programme of babies and pre-school children may reduce the risk of persistent amblyopia (VA >0.3 logMAR) at age seven by more than half. Children who were less frequently screened had a higher chance of poor vision (>0.3 logMAR) at age seven.⁹ From 1968, children between the ages of one and two years in Haifa, had been systematically screened

for amblyopia and amblyogenic risk factors. In 1995, the prevalence and severity of amblyopia in two populations of eight-year-old children in elementary school were assessed. In the first group of 808 children from Haifa who had been screened in infancy, the prevalence of amblyopia in the group was found to be 1.0 per cent. This compared to a prevalence of 2.6 per cent in a control population of 782 eight-year-old children from another town who had not been screened in infancy. It was concluded that a screening programme for amblyopia and amblyogenic risk factors in infants, followed by appropriate treatment, is effective in significantly ($P = 0.0098$) reducing the prevalence and severity of amblyopia in children.¹⁰

The challenge

The American Association of Paediatrics, the American Association of Paediatric Ophthalmology & Strabismus (AAPOS) as well as the UK National Screening Committee and similar bodies around the world recommend that children undergo vision screening at least by the age of 4-5 years. The problem lies in the fact that while it is very desirable to detect these conditions even in



Figure 1 IRISS Eye Check device



Figure 2 IRISS Eye Check in use



Figure 3 Test results are analysed in real-time and displayed on the device



Figure 4 A pdf data sheet is uploaded automatically to tablet or computer

babies and infants, this pre-verbal (often uncooperative) population is very difficult to screen and diagnose accurately and reliably. This is the reason why many cases of amblyopia and strabismus are detected at the age of six or more, when it is almost too late for effective treatment.

How then might screening babies and pre-school children for strabismus be carried out cost effectively and with acceptable sensitivity and specificity?

A recent overview of assessing babies and pre-school children for strabismus discussed the various methods of checking eye alignment including the cover test and the Hirschberg test.¹¹ All of these methods are highly subjective and require significant skill. Hence there is a need for reliable and practical automatic screening and diagnostic

technology for strabismus that can be used by optometrists and ophthalmologists alike. Such a tool would aid diagnosis during eye examinations and could be used as a screening tool for non-eye care practitioners such as health visitors or paediatricians to enable optometric referral of patients who fail the test.

Innovation

IRISS Medical Technologies is a medical device company specialising in ophthalmics. Based in London, England, IRISS Medical was founded in 2011 by Dr Simon Barnard and a team of specialists including Yuval Yashiv and Ron Maor, combining expertise in optometry, digital image analysis and mathematics. Based on a strong heritage in digital imaging technologies, the original IRISS technology was the world's first

commercially available technology for automatically removing red eye seen in digital flash photographs.

The company will soon be launching a unique diagnostic-assistance tool. The technology performs automatic detection and measurement of strabismus and other eye conditions relating to pupils, irises and other features of the cornea. This technology will be used within a simple-to-use, handheld diagnostic-assistance device. The patented technology incorporates the Barnard-Maor off-centre fixation system. The initial development has been carried out on populations of non-strabismus and strabismus patients by Dr Barnard in his primary care optometry practice and on 500 strabismic patients by a clinical research team at Moorfields Eye Hospital.

What does IRISS detect and measure?

Initial studies of IRISS show that it measures a number of eye features to a potential resolution of 0.04mm with an accuracy of approximately 5 per cent of the structure being measured.¹² Further studies are taking place to validate these results.

Amblyogenic risk factors

In early 2013, the IRISS technology made its debut at the American Association of Paediatric Ophthalmology & Strabismus (AAPOS) annual meeting in Boston, where data was presented suggesting a first estimate of test accuracy. Testing 331 primary schoolchildren, 6 per cent of whom had strabismus, sensitivity to detect strabismus was 95 per cent, and specificity 91 per cent. In a smaller study including 30 children, a later version of the IRISS technology had 100 per cent sensitivity and 93 per cent specificity. This work was presented at the British Isles Paediatric Ophthalmology and Strabismus Association (BIPOSA) meeting in Leeds in October 2013.

While a key function of the technology is to detect and measure strabismus, early data suggests that significant anisometropic hypermetropia is flagged by IRISS as a screening failure in a significant proportion of at-risk children.

The results captured by the test are analysed in real-time, displayed both on the device (Figure 3) and automatically uploaded as a PDF data sheet to the optometrist's tablet or computer (Figure 4). The PDF provides a pass/fail notification



Instruments

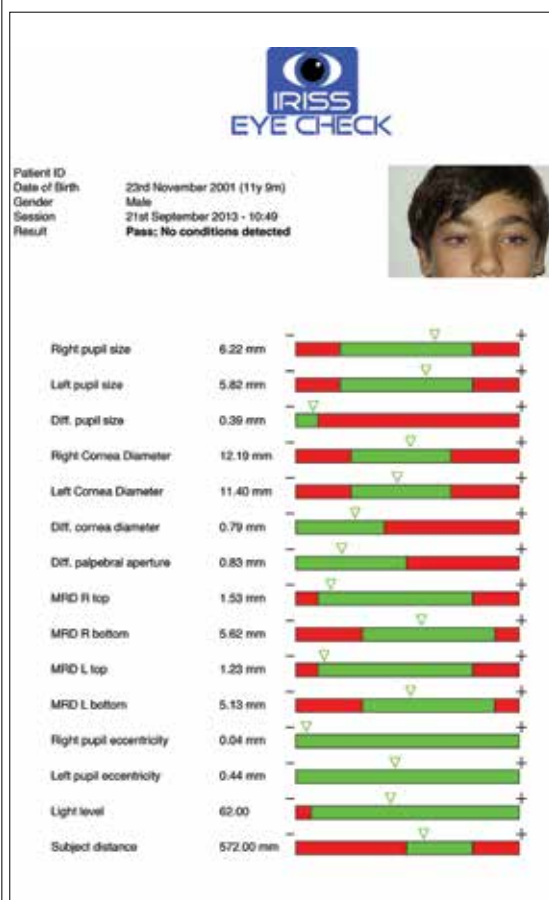


Figure 5 IRISS Eye Check data sheet showing normal data

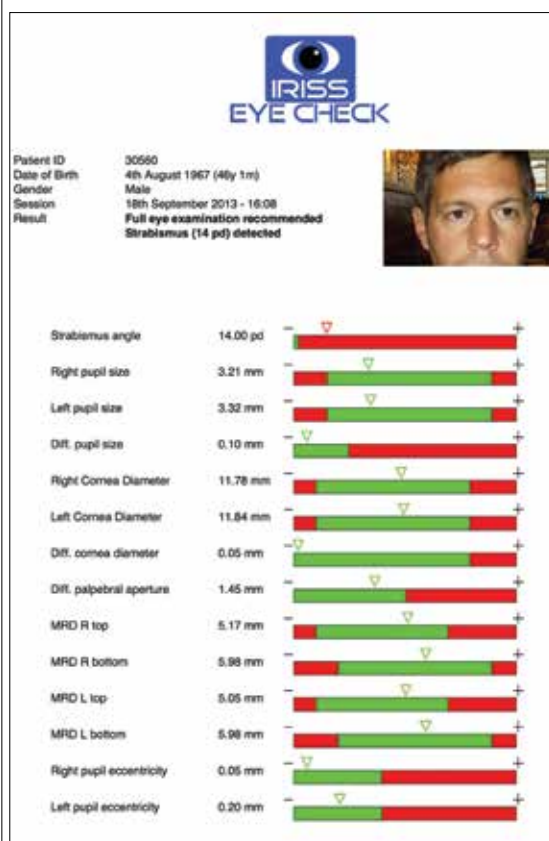


Figure 6 IRISS Eye Check data of strabismic patient displayed immediately following data capture

for strabismus, hypermetropic anisometropia, anisocoria, and buphthalmos with the direction and size in prism dioptres of any strabismus detected. Also shown are seven different measurements including pupil size, corneal diameter, palpebral aperture, MRD and pupil eccentricity, as well as light level of the patient's face (Figures 5 and 6).

Pupil sizes

Initial trials show that the accuracy of the system enables pupil sizes to be measured to approximately 0.25mm, enabling clinically significant anisocoria to be detected and documented. Further trials are currently being carried out.

Corneal diameter and pupil eccentricity

Corneal diameter and pupil eccentricity are measured automatically. While it is envisaged these data will be useful in the field of contact lens design and fitting, ophthalmologists specialising in buphthalmos have already identified the importance of measuring the size of buphthalmic corneas without the need for general anaesthesia.

MRD

The term 'margin to reflex distance' (MRD) is used to describe the eyelid positions relative to the corneal light reflex. These eyelid position measurements are important in the context of ptosis or lid retraction. These measurements are also of interest to eyelid surgeons and endocrinologists.

Normative data

The technology enables cloud-based aggregation of clinical data and its use for the establishment of normative data and statistics on a range of measures including pupil size and eccentricity, corneal diameter and lid positions.

Conclusions

The IRISS technology is potentially a breakthrough diagnostic-assistance tool for eye care specialists, in particular in the area of strabismus as well as in the measurement of other eye parameters. It may also prove to be a very useful screening and referral tool for non-specialists such as GPs, paediatricians and health visitors. ●

● The IRISS technology is not currently sold in any country. Further information is available at www.irissmedical.com

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