Automated strabismus detection and pupil analysis

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Conflicts of interest

Dr Barnard is a Director & Chief Medical Officer of IRISS Medical Technologies Ltd, London

Ellis Johnson is Clinical Trials Co-ordinator of IRISS

IRISS Medical is a partner of Volk Inc., USA
Revisiting some measurements

Despite enormous advances in technology over the last few years we still gather some clinical data in primary care practice using techniques that have been around for a century, for example to measure

- eye position
- pupil size
- eye lid position
- horizontal visible iris diameter

Eye position

- Are the eyes straight?
Assessment of eye position for the presence of strabismus is routinely carried out using three tests, the most important of which is the cover test (early description Clarke, 1893).

Other commonly employed techniques are the Hirschberg test and the prism fusion test.

Strabismus is a risk factor for amblyopia and in pre-school children has a prevalence of 3.9% (The Vision in Preschoolers Study Group, 2007).

Amblyopia is thought to occur in 2 to 4 % of the general population (Grounds, 1996).

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 (Grounds, 1996).
• 80% of amblyopia is caused by
  - either strabismus (45%) or combined strabismus and anisometropia (35%)
  - with solely anisometropia accounting for (17%), and form deprivation in 3%
    (Shaw et al, 1988)

Cover test

• Requires skill – optometrist, orthoptist or ophthalmologist

• Measurement of amplitude of strabismus made either by estimating the size of the movement or by neutralising the movement using prisms (the prism cover test)

• Difficult to detect small amplitude strabismus – microtropia (AAPOS <8 ^)
**Prism fusion test**

- Requires patient co-operation and well honed skill and experience
- Not always possible on uncooperative infants

**Hirschberg test**

- First described by *Hirschberg* in 1885
- A penlight is directed towards the patient who, it is hoped, is gazing towards it
- The practitioner observes the position of the *corneal reflex* (Purkinje image) relative to the centre of the pupil
• **Corneal reflex** not usually positioned in the centre of the pupil but decentred due to *Angle Kappa*

• To determine the presence of strabismus, the practitioner must detect a relative difference in *corneal reflex* between right and left eyes

• A critical limitation of the Hirschberg test is that a 1 mm asymmetry is possible to discern and an 0.5 mm may just be possible to detect
• Problem with this limitation is that a 1mm asymmetry is produced by strabismus of amplitude of approximately 21 °
Pupil size

We are looking for anisocoria e.g.,
  • Horner
  • Adie

There are pupillometers but most optometrists and ophthalmologists measure with a millimetre ruler

How accurate is this?

Photographs of two iris/pupil colors to illustrate the difficulty in assessing the pupil/iris border, especially in darker colored irides
Horizontal Visible Iris Diameter (HVID)


Important for:
- Contact lens fitting
- Detection/investigation/monitoring of buphthalmos
  - Probably measured most accurately with OCT and some aberrometers (?)
  - Not every practitioner has such sophisticated equipment
Margin-Reflex-Distance (MRD)

The distance of the centre of the corneal reflex to superior lid margin (MRD1) and inferior lid margin (MRD2)

- Important measures for documenting ptosis
  - Endocrinology: thyroid eye disease
  - Neuro-ophthalmology: Horner

- For ptosis repair under Novitas (largest medicare carrier in USA, MRD1 must be less than 2mm to be medically covered)
MRD case example

- Bilateral pseudophake
- Difficulty with vision
- Improves if opens his eyes very wide
- Bilateral ptosis
- Discussed surgery
Pupil Eccentricity

- Not currently measured (?)
- Important for specialist contact lenses such as concentric and translating multifocals
Mother age 49

Daughter aged 22

Son aged 21
From *mm* ruler to fully automated technology

- IRISS Medical Technologies has developed a hand held device which captures and fully automates, in real time, the analysis and display of diagnostic eye data (eye position, pupil size and eccentricity, MRD and HVID)
- Algorithms developed from patient data obtained from Moorfields Eye Hospital & Dr Barnard’s practice

- Data acquisition with 2 or 3 flash photographs
- Real time analysis
- Data displayed on device and instantly uploaded as pdf to medical record, tablet or PC
The device is available as the *Volk Eye Check*
Strabismus studies: compare to clinicians

Methods

• The Research and Ethics Committee of the UK Institute of Optometry approved relevant parts of the studies
• In all three studies the results of experienced optometrists or an orthoptist were compared to *Volk Eye Check* results (independent operator)
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 the device.

Study 2
• Experienced optometrists in a primary care practice examined
• 187 patients (age< 40 years; average age 10 years) and the results compared to the device.
**Study 3** Between August 2013 and February 2014, optometrists in a primary care practice examined

- 368 patients (mean age 10 years 11 months; range 0-37 years); 188 patients (51%) were male; 19 (5%) were strabismic and the results compared to the latest version of *Volk Eye Check* (software v.49, February 2014)

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**Results**

**Study 1** Prevalence of manifest strabismus in the study group was 6.34%  

*Volk Eye Check*

Sensitivity to detect strabismus was 95%

Specificity 91% (*Barnard et al, 2013*)
Results

**Study 2** Prevalence of strabismus in the study group was 6.0%.

**Volk Eye Check**
- Sensitivity to detect strabismus was 91%
- Specificity 96% (*Barnard et al, 2013*)

Results

**Study 3** Prevalence of strabismus in the study sample was 5.0%.

**Volk Eye Check**
- Sensitivity to detect strabismus was 84%
- Specificity: 99%
Other data: Limits of Agreement Study Methods

- 3 optometrists measured IPD, HVID and MRD
- LE & RE; n = 8 healthy volunteers
- Masked observers
- IPD measured using Essilor pupillometer
- *Volk Eye Check* session for each subject by independent observer
- Another independent observer measured these values, as well as pupil eccentricities, in two of the volunteers, from magnified photographs
Limits of Agreement study: Results

- Comparison between *Volk Eye Check* and Essilor pupillometer for IPD showed LOA on average of 2.1mm.
- LOA for the group of human observers were as follows: Variability of
  - HVID up to 1.5mm; average 0.9mm
  - Pupil diameter up to 2.0mm; average 0.9mm
  - MRD up to 2mm; average 1.1mm

- Measurement results using *Volk Eye Check*
  - For all but one case fell close to the average of the observers
  - In all cases, measurement using *Volk Eye Check* came very close to that obtained by measuring on a magnified photograph.
• Compared with the “gold standard” pupillometer measure of IPD, there is evidence that Volk Eye Check data is clinically useful for all but extreme cases.

  ≥Pupil Diameter difference (anisocoria)

  ➢ Volk Eye Check agreed with the average of three observers, to within 0.31mm on average.
  ➢ When comparing to measurements on a magnified photograph, Volk Eye Check agreed with these to within 0.03mm thus highlighting the possible inaccuracy of human observers on such small differences.
Studies conclusions
1. Detection of strabismus

3 studies show a range of sensitivity and specificity values
- Sensitivity between 84% and 95%
- Specificity between 91% and 99%

• Strabismus is a prevalent risk factor for amblyopia (80% of all amblyopes) and it is widely recognised that early detection of strabismus improves treatment outcomes

• As well as the quantitative values obtained for strabismus amplitude, these values suggest this technology may have promise as a screening method as well as an adjunct test for practitioners
Studies conclusions
2. Other clinical data

- Where there is no universally accepted “gold standard” for the measurement of ocular characteristics, as HVID, pupils and MRD, *Volk Eye Check* demonstrated itself to be at least as good as a group of experienced practitioners.

- In most cases *Volk Eye Check* was shown to be better than a stand alone experienced practitioner.

*Volk Eye Check* provides accurate measurements of pupil eccentricity, which are practically unobtainable in any other way in clinical practice.
Conclusions & Summary

- *Volk Eye Check* is a diagnostic assistance tool that is clinically useful in obtaining fast simultaneous results of many ocular characteristic measurements, without the prerequisite of an experienced professional.

References & Bibliography

References & bibliography available on request

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