

Institution: The University of Edinburgh
Unit of Assessment: 4
Title of case study: K: Invention and commercialisation of Saccadic Vector Optokinetic Perimetry: development of visual-field testing technology and its translation to clinical practice and the marketplace
<p>1. Summary of the impact (indicative maximum 100 words)</p> <p>Impact: New business, intellectual property, employment and clinical diagnostic capability resulting from the invention, development, validation and manufacture of a peripheral vision-measuring device.</p> <p>Significance: A new technology, Saccadic Vector Optokinetic Perimetry (SVOP) has been developed and commercialised. SVOP enables the testing of visual fields in patients who previously could not be tested. A spin-out company, i2eye Diagnostics Ltd., raised £900K to commercialise the technology, employs five people and has made sales internationally.</p> <p>Beneficiaries: Commerce; ophthalmologists, opticians and optometrists; previously untestable patients.</p> <p>Attribution: UoE team comprising Professor Bob Minns, Professor Brian Fleck, Dr Ian Murray and Dr Harry Brash are inventors on the granted patent for SVOP. The UoE BioQuarter commercialisation team formed the spin-out company and recruited the management team.</p> <p>Reach: Worldwide: SVOP instruments are now in use in the US, EU and Australia. The technology is suitable for the 30% of patients worldwide whose visual field could previously not be measured.</p>
<p>2. Underpinning research (indicative maximum 500 words)</p> <p>A UoE clinical research team comprising Professor Robert Minns (Professor of Paediatric Neurology, UoE, 1979–2008), Professor Brian Fleck (Consultant Paediatric Ophthalmologist and Honorary Professor, UoE, 2006–present), Dr Ian Murray (Research Associate, UoE, 2004–2005 and 2006–present) and Dr Harry Brash (Medical Physicist, UoE, 1965–2007 and 2008–2010) addressed the large unmet medical need for a technique to measure the visual field of intractable patients. Their new technique led to an award-winning spin-out company that, within 10 months, was shipping products to customers on three continents.</p> <p>Visual field assessment is a vital ophthalmologic test in the management of a wide range of disorders including cerebral visual impairment, stroke, brain tumours, increased intracranial pressure and glaucoma. It is estimated that 30% of patients cannot be tested using traditional methods such as Automated Static Perimetry (ASP) and Goldmann Kinetic Perimetry because of their requirement for conscious involvement, cooperation and considered feedback for several minutes during the test. Untestable patients include frail elderly patients, stroke or trauma victims and patients with mental or physical disability. In addition, visual field assessment in children is especially problematic and there is a pressing need for a reliable and sensitive method to monitor visual field changes in children prescribed vigabatrin for epilepsy. Among the many documented problems that prevent accurate ASP testing in children and vulnerable adult populations are: (1) having difficulty in learning the skills required to perform the task; (2) maintaining a stable fixation on a central target; and (3) sustaining attention and concentration.</p> <p>Between 2007 and 2011, the UoE team developed a system for testing visual fields that did not rely on active patient involvement. This system makes use of advances in eye-tracking technology and comprises a personal computer, VDU display, and an eye-tracker to monitor gaze position when stimuli are presented in the visual field. The natural saccadic eye movement to fixate on the stimuli, if seen, can be detected and measured to produce a visual field plot. The technology,</p>

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termed Saccadic Vector Optokinetic Perimetry (SVOP), has been validated in the clinic as a means of quantifying visual fields in children and adults with normal visual fields and visual field defects [3.1–3.3].

The novel technology was patented in the EU, US, Japan, China, India, Australia and Canada; the patents were fully granted in 2012. The intellectual property was used by the Edinburgh BioQuarter commercialisation team (Dr Giles Dudley, Business Creation Executive, UoE, 2011–present; Dr Mike Finnen, Head of Operations, UoE, 2010–present) as the foundation for a University spin-out company, i2eye Diagnostics Ltd. (SC387359; established in 2012). The technology is now being used routinely in the clinic, is commercially available and sales have been made to the worldwide clinical marketplace.

3. References to the research (indicative maximum of six references)

3.1 Murray I, Fleck B, Brash H, MacRae M, Tan L, Minns R. Feasibility of saccadic vector optokinetic perimetry: a method of automated static perimetry for children using eye tracking. *Ophthalmology*. 2009;116:2017–26. DOI: 10.1016/j.ophtha.2009.03.015.

3.2 Murray I, Fleck B, Brash H, MacRae M, Minns R. An automated visual field assessment technique for children utilising eye tracking. Association for Research and Vision in Ophthalmology (ARVO) Annual Meeting, 2008, Fort Lauderdale, FL. [Available on request.]

3.3 Murray I, MacRae M, Fleck B, Brash H, Tan L, Minns R. Automated visual field assessment in young children using eye tracking - preliminary data from 9 children. (Poster). American Association for Paediatric Ophthalmology and Strabismus (AAPOS) Annual Meeting, 2009. San Francisco, CA. [Available on request.]

PATENT FILINGS

“Testing Vision”. US8337019; WO2008139137; JP2010526623; EP2148609; CN101742957; CA2687409; AU2008249842.

4. Details of the impact (indicative maximum 750 words)

Pathways to impact

The spin-out company, i2eye Diagnostics Ltd. [5.1], has put in place a Quality Management System to ISO13485, obtained clearance to market in the US and EU and engaged fully with the market to confirm strong market traction with a lead list of over 80 confirmed prospects. Orders have been received from leading paediatric eye centers in the US, Australia and Europe and the company started shipping product to customers in November 2012, only 10 months after starting commercial operations [5.2, 5.3].

The initial value of the market targeted by i2eye is estimated at US\$280M in the United States, with markets of similar potential available in Europe and Asia out of of a total addressable worldwide market of £15B.

Impact on clinical practice

The development of the SVOP system meant that, for the first time, the visual fields of the 30% of people who were previously untestable could be tested reliably and routinely. SVOP is now being used in the US, EU and Australia and is rapidly being accepted by the international ophthalmological community. One customer, the Director of the Neuro-ophthalmology Service at Boston Children’s Hospital, said “*We are incredibly excited about this technology as the first of its kind....We anticipate that this tool will be an invaluable asset...*” [5.3]. The technique was featured in *Ophthalmology Times Europe* (March 2012) [5.4].

Impact on commerce

In April 2012, following the successful closing of a seed investment with Kelvin Capital (£200,000), Edinburgh BioQuarter announced the launch of i2eye Diagnostics Ltd., a company to deliver the

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world's first visual field analyser for children and vulnerable adults. In January 2013, the company hit all technical and commercial milestones necessary to close a follow-on round led by Kelvin Capital (£700,000). It presently employs five staff.

In only 10 months, the company sold 8 units and up to 16 more are in the pipeline.

In February 2013, i2eye Diagnostics Ltd. won the Scottish Enterprise Life Science Award for the best new life science company in Scotland [5.5]. It is one of 12 companies that won a Scottish Enterprise-supported place on the prestigious Entrepreneurship Development Programme at the Massachusetts Institute of Technology, Boston. It has been featured in the media (The Scotsman; [5.6], in Edinburgh taxis [5.7], and has a social media presence on Twitter.

5. Sources to corroborate the impact (indicative maximum of 10 references)

- 5.1 i2eye Diagnostics Ltd. website. www.i2eyediagnosics.com.
- 5.2 Letter from Orthoptist, Moorfields Eye Hospital, London. *[Available on request. Confirms purchase of an SVOP system from i2eye Diagnostics Ltd. and its use in clinical research.]*
- 5.3 Letter from Director, Neuro-ophthalmology Service, Boston Children's Hospital, USA. *[Available on request. Confirms purchase of an SVOP system from i2eye Diagnostics Ltd. and conveys great enthusiasm about its potential.]*
- 5.4 Q&A: i2Eye visual field analyser. Ophthalmology Times Europe website, 19th March 2012. <http://www.oteurope.com/ophthalmologytimeseurope/Latest+News/bQampAb-i2Eye-visual-field-analyser/ArticleStandard/Article/detail/764753>. *[Describes SVOP technology to clinicians.]*
- 5.5 Scotland's life sciences sector champions revealed. Scottish Enterprise website, Feb 2013. <http://www.scottish-enterprise.com/news/2013/02/scotland-life-science-sector-leaders-revealed.aspx>. *[Confirms that i2eye Diagnostics Ltd. won the best life science company in Scotland.]*
- 5.6 Vision firm eyes US sales. The Scotsman, 20th January 2013. <http://www.scotsman.com/business/management/vision-firm-eyes-us-sales-1-2747832#.UP0To5HDMcg.twitter>. *[Media coverage of business.]*
- 5.7 i2eye BioQuarter case study in Edinburgh taxis! Twitter post, 4th Feb 2013. https://twitter.com/peter_estibeiro/status/298455154506752000/photo/1. *[Media coverage of business.]*