

Institution: University of Plymouth		
Unit of Assessment: UoA3		
Title of case study: Assessment of the visual outcomes and stability of intraocular lenses leading to increased commercial revenue and patient benefits		
Period when the underpinning research was undertaken: 2011 to present		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s): Professor Phillip Buckhurst	Role(s) (e.g. job title): Professor of Optometry, Academic Lead for Optometry	Period(s) employed by submitting HEI: 2011 to present
Period when the claimed impact occurred: 2014 to present		
Is this case study continued from a case study submitted in 2014? N		
<p>1. Summary of the impact (indicative maximum 100 words)</p> <p>Intraocular lenses (IOLs) are medical devices that are implanted into the eye during cataract surgery. Buckhurst's research in North America was pivotal for the Food and Drug Administration (FDA) approval of both the Trualign and EnVista toric IOLs. Subsequently, the manufacturer of these IOLs, Bausch and Lomb (B&L), has sold 53,387 and 79,582 (respectively) generating gross sales of [text removed for publication] Buckhurst's European study on B&L Incise IOLs was instrumental in maintaining their CE-mark under the European Medical Device Regulation. The continued adherence to safety regulations and marketing of the lenses has enabled the manufacturer to sell 190,000 of the Incise IOLs since 2015. The sale of these 320,000 lenses worldwide has resulted in life changing visual benefits to patients. Domestically, his work into the visual outcomes of toric IOLs with the University Hospital Plymouth NHS trust has directly led to the implantation of toric lenses in more than 80 patients.</p>		
<p>2. Underpinning research (indicative maximum 500 words)</p> <p>Cataract surgery is one of the most common surgical procedures worldwide and involves the removal and replacement of the eye's natural crystalline lens with an artificial intraocular lens (IOL). These IOLs are classified as a Medical Device and require the approval of the American Food and Drug administration (FDA) for their use in North America and CE marking for the use within Europe. Many different types of IOLs have been designed to correct various aspects of vision. This case study is underpinned by research into the stability and visual outcomes of a range of IOLs, namely toric, multifocal and micro-incision. The results of the research have been used for both the commercial promotion of the lenses and for the approval of the lenses for use by the regulatory bodies in North America and Europe.</p> <p>Research into toric IOLs</p> <p>Toric IOLs correct a particular aspect of vision called astigmatism. Approximately 20% of the population have significant levels of astigmatism and hence would benefit from toric IOL implantation. For toric IOLs to correct astigmatism, it is vital that they are orientated correctly and that they do not rotate. Buckhurst's research, as part of a multicentre clinical trial within North America, demonstrated the stability of the lenses, revealing that less than 5% of these IOLs rotated more than 5° [3.1]. This was a key outcome measure that formed the basis for the FDA approval of the EnVista and Trualign toric IOLs and meant that these IOLs received approval to be implanted throughout North America.</p>		

Within the United Kingdom, toric IOLs are not commonly available within the NHS. Since November 2016, Buckhurst has worked with the local Plymouth University Hospital trust to establish a care pathway to undertake toric IOL implantation and to research the visual outcomes of patients implanted with these lenses. The research demonstrated an impressive correction of vision in the sixty-six eyes examined, with two thirds of patients able to meet European driving standards without the need for spectacles as a consequence of the toric implantation [3.2].

Research into multifocal IOLs

A standard IOL does not allow for someone to change their focus between distance and near tasks, whilst multifocal IOLs have been specifically designed to provide vision at both distances without the use of spectacles. Buckhurst's research into the visual outcomes of multifocal IOLs examined vision at a multitude of distances. For both the Biflex M IOL [3.3] and Lentis MPlus [3.4], the research was able to demonstrate improved vision for near and intermediate tasks relative to a standard IOL. These results were used to market the lenses.

Research into Micro-incisional IOLs

Micro-incisional IOLs are lenses that can be implanted through a sub 2mm corneal incision. To allow these lenses to fold through such a small incision, they need to have different design properties relative to a standard IOL. The Incise IOL is a micro-incisional IOL and, as well as being thinner than a standard IOL, it has been manufactured with a particular profile that is designed to reduce the incidence of a particular post-operative complication (posterior capsular opacification (PCO)). Buckhurst's research demonstrated that the lens holds a stable position within the eye, with the lenses having a mean absolute decentration of 0.35 (\pm 0.36) mm relative to the centre of the cornea; at two years postoperatively, the lenses had a minimal score for PCO (0.01 ± 0.03 within the central region) [3.5]. These results were used to promote the lenses for launch and to support the claims and benefits in the clinical evaluation report for the lens.

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

- 3.1 Pepose JS, Hayashida J, Hovanesian J, Davies J, Labor PK, Whitman J, Carter H, Colvard M, **Buckhurst PJ** & Khodai O (2015). Safety and effectiveness of a new toric presbyopia-correcting posterior chamber silicone intraocular lens. *Journal of Cataract and Refractive Surgery* 41, (2) 295-305.
- 3.2 Swampillai AJ, Kaabneh AK, Habib NE, Hamer C & **Buckhurst PJ** (2019). 'Efficacy of toric intraocular lens implantation with high corneal astigmatism within the United Kingdom's National Health Service' *Eye*. 34, (6) 1153-1153.
- 3.3 Law E, Aggarwal R, Buckhurst H, Kasaby H, Marsden J, Shum G & **Buckhurst P** (2020). Visual Function and Subjective Perception of Vision following bilateral implantation of monofocal and multifocal intraocular lenses: A Randomised Controlled Trial. *Journal of Cataract and Refractive Surgery*. 46, (7) 1020-1020.
- 3.4 **Buckhurst PJ**, Wolffsohn JS, Naroo SA, Davies LN, Bhogal GK, Kipioti A & Shah S (2012). Multifocal Intraocular Lens Differentiation Using Defocus Curves. *Investigative Ophthalmology and Visual Science*. 53, (7) 3920-392.
- 3.5 Dick HB, Schultz T, Lesieur G, Morselli S, Toso A, Alio JL, **Buckhurst PJ** & Johansson B (2019). Evaluation of clinical outcomes following implantation of a sub-2-mm hydrophilic acrylic MICS intraocular lens. *International Ophthalmology*. 39, (5) 1043-1054.

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

The volume of cataract surgery has increased dramatically around the world over the past 20 years and there are approximately eight million cataract operations performed each year worldwide. Many different types of artificial intraocular lens (IOLs) have been designed to

correct various aspects of vision. These lenses need to be stable as a malposition will cause a reduction of vision which, if significant, requires a secondary procedure to either get the lens into the correct position or to explant the lens and put in a new one. Buckhurst's research solved this problem through the development and clinical implementation of novel measures that demonstrated stability and visual function post cataract surgery, which has led to commercial and patient benefits.

Food and Drug administration (FDA) approval leading to commercial benefits

There have been rapid technological advances in IOLs; however, traditional measures of visual function do not demonstrate the efficacy of these lenses.

Buckhurst developed innovative methods for establishing the rotational stability and centration stability of novel IOLs and implemented these into multicentre clinical trials. Buckhurst's method requires specialised training and, as such, prior to the start of each study Buckhurst trained (in person) at nine hospitals across North America and Canada [5.1]. Buckhurst's research was used to demonstrate the safety and efficacy of the toric IOLs and led to the approval of the Trualign toric and enVista toric by the Food and Drug administration (FDA) in June 2018 [5.2]. The immediate beneficiary of this was the manufacturer, Bausch and Lomb (B&L). Their Director of Medical Affairs, Dr George Lau, said *"[Buckhurst's] work demonstrated the rotational stability of our toric IOL platforms which was pivotal to the FDA approval of the Trualign toric and enVista toric IOL."* [5.3] Following FDA approval, the Trualign toric has been implanted in 53,387 eyes resulting in an income of [text removed for publication] . In addition, the enVista toric has been implanted in 79,582 eyes leading to an income of [text removed for publication] [5.3].

Demonstrating the safety of IOLs enabling regulation compliance

To sell medical devices in the European Union (EU), companies must obtain or apply CE Marking for their product. However, from May 2020, a new set of regulations, the European Medical Device Regulation (MDR), that governed the production and distribution of medical devices in Europe were implemented. Compliance with the regulation is mandatory for medical device companies that want to sell their products in the European marketplace. Buckhurst's research was instrumental in demonstrating the safety of the Incise IOL and it was the basis of evidence to support the claims and benefits for B&L's Clinical Evaluation Report, needed to maintain CE-marking [5.4]. Their Director Surgical Global Medical Devices / Clinical Evaluation Group, Dr Anne Willart said, *"Buckhurst's research was instrumental in demonstrating the safety of B&L's lens and it was the basis of the evidence to support the "claims and benefits" for our Clinical Evaluation Report, which we required to maintain our CE-marking under the new European Medical Device Regulation."* [5.5]

Buckhurst's European study on the Incise IOL, Biflex M IOL, and Lentis MPlus X was used to promote these lenses in Europe. His data was included in B&L's marketing brochures [5.6, 5.7 & 5.8] and used for their launch. B&L's Dr Anne Willart said *"Your independent work has supported both podium presentations during main congresses at the time of the launch, publications and Akreos brochures. The continued adherence to safety regulations and marketing of the lens has enabled us to sell 190,000 of the Incise IOLs since 2015."* [5.5]

National and international patient benefits

Domestically, Buckhurst's collaboration with University Hospital Plymouth NHS trust led to them establishing a care pathway to undertake the toric IOL implantation in patients who were due to undergo routine cataract surgery. This collaborative approach to patient care was realised in November 2016 and Buckhurst's research was pivotal for supporting the development of the pathway and for the ongoing assessment of performance through the analysis of visual outcomes. This has led to a direct benefit to the patients whose vision is substantially better than if they had been implanted with a standard lens. Indeed, two thirds of these patients have vision better than or equal to the driving standard without the use of spectacles. Professor Nabil Habib, Consultant Ophthalmologist, University Hospitals Plymouth NHS trust said, *"more than 80 patients having been implanted with a toric IOL at our hospital. The outcomes for these patients has been exceptional."* [5.9] Before treatment, patients often

struggle to see, both with and without glasses, and the implant of the toric IOL dramatically improves their quality of life. A patient who was implanted with toric IOLs to correct for both cataract and astigmatism in 2020 said. *"I now have 20 20 vision in both eyes, simply lifechanging. I have clarity, colour and definition. Just fantastic. My quality of life has improved so much... I am a massive rugby fan and watching both live and on TV is now absolutely brilliant. I can see so much more."* John, patient [5.10].

Internationally, the implantation of 130,000 B&L toric IOLs within North America and a further 190,000 in Europe has led to wide reaching, life-changing benefits to patients.

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

- 5.1 Training logs for study from Promedica International
- 5.2 FDA's approval of enVista® One-Piece Hydrophobic Acrylic Toric Intraocular Lens <https://www.fda.gov/medical-devices/recently-approved-devices/envistar-one-piece-hydrophobic-acrylic-toric-intraocular-lens-p910056s027>
- 5.3 Testimonial from Dr George Lau, Director of Medical Affairs, B+L Surgical
- 5.4 Clinical Evaluation Report -- Claims and benefits
- 5.5 Testimonial from Dr Anne Willart Director Surgical Global Medical Devices / Clinical Evaluation Group
- 5.6 Lentis Brochure <http://www.oculentis.com/Downloads/LentisMplusX-Info-EN.pdf> accessed 09/12/2020
- 5.7 Medicontur http://www.medicontur.com/files/For_professionals/Liberty/CE%20Change/6.%20Liberty_Brochure_EN_202004_WEB.pdf accessed 09/12/2020
- 5.8 Incise brochure
- 5.9 Testimonial from Professor Nabil Habib, Consultant Ophthalmologist, University Hospitals Plymouth NHS trust
- 5.10 Patient testimonial, John Elesmore.