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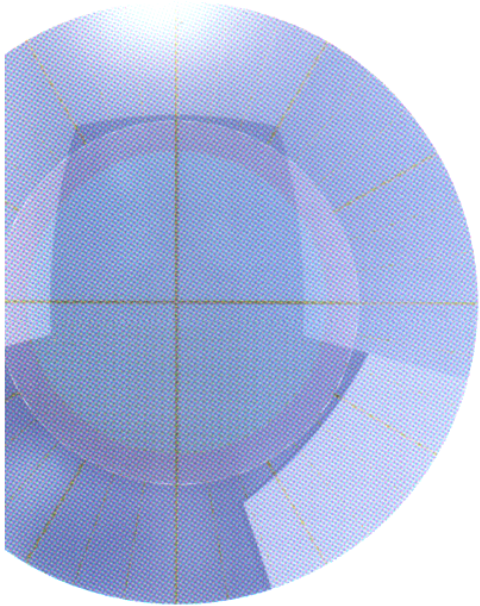
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Aussie innovation creates new retinal drugs



There has been a surge in popularity of anti-VEGF drugs as patients attempt to thwart blinding retinal disease. But the preference for cataract and refractive surgery provided by ophthalmic surgeons remains very strong.

Added to the challenge of using injections to retain often declining visual acuity is the mechanical problem of repeated intravitreal injection, which carries risks such as endophthalmitis, pseudo-endophthalmitis, discomfort and other infections. Medical literature has also recognised the problem of resistance, or tachyphylaxis, facing patients receiving anti-VEGF injections.

In the face of uncertainty and confusion there is some comfort to be found in a back-to-basics approach.

As the inventor and patent holder of Triamcinolone acetonide, including the intravitreal injection procedure used in ophthalmology, I have never underestimated the power of more basic drugs, such as steroids, in improving eye conditions based on inflammation, exudation and neovascularisation. This is especially important for ophthalmic injections, where a plethora of new anti-VEGF drugs has actually led to a resurgence of use for intravitreal Triamcinolone acetonide, often as a 'co-therapy' for wet AMD (and for a mono-therapy for inflammatory indications such as uveitis, or for diabetic eye conditions).

This was similarly true for patients undergoing photodynamic therapy with Visudyne and other PDT photosensitisers who saw marked improvements with steroids being added to the mix. These tried and tested steroids are typically from the Glucocorticoid class, or GR class, one of the two product classes of steroids such as Triamcinolone acetonide, dexamethasone and others.

The use of steroids as an alternative treatment led to the incorporation of EyeCo, now with research partnerships in place with ANU and Monash University, for the purpose of formulating new ocular injections from other Mineralocorticoid class (MR) steroids. These are adapted to the unique needs of the blood ocular barrier and delicate structures of the eye. These new formulations (now granted patents) actually target the 'exudation' or fluid absorption. This fluid buildup often accompanies diabetic retinal conditions, ocular cancers, and inflammatory conditions.

Our research has indicated that MR steroids can work co-therapeutically with other steroids in 'mixtures,' as well as with anti-VEGF drugs. We are completing pre-clinical and other testing to be followed by human clinical trials.

What this means for Australian ophthalmologists is that they will soon have further treatment options, whether co-therapeutically or as monotherapies, based on known compounds with long histories of

safety and efficacy of humans, which have been re-formulated precisely for retinal, oncological and inflammatory eye conditions. MR class drugs work differently within the eye as they trigger both GR and MR receptors, especially those involving edema.

University of Western Australia has published favorable pre-clinical work on this technology, as has Tulane University in the USA, and Monash and ANU are helping with the final steps of product development and commercialisation.

As a backdrop to this new product development, routine steroid injection is again on the increase, with presentations of favorable results at meetings in Australia, Japan and the USA. Use of Triamcinolone acetate is increasing for cataract surgery

(intracameral injection) and for vitreous surgery (surgical visualisation of the clear vitreous) and for back of eye procedures (ILM).

The product in its 'preservative free' form is by far the most popular, and approved by various regulatory bodies, including the US FDA. As a monotherapy for uveitis, cystoid macular edema, BRVO and other indications continue to call for intravitreal steroids, as they boost function and strengthen the blood retinal barrier. Contraindications (IOP) can be easily managed by anti-glaucoma drugs.

Philip Pentold PhD

For further information, visit www.eyeco.com.au.

Philip Pentold holds an adjunct appointment at ANU's Centre of Excellence in Visual Science and is editor of Macular Degeneration (Springer).



Juggling Invention, Innovation and Ophthalmic Surgery

By Laurence Sullivan
FRANZCO & William Ardrey
PhD

INTRODUCTION

Finding time to innovate, among competing commitments of surgical lists, demands of patients, and attempts to inject some family time and work-life balance is a challenge for any medical specialist attempting to create new medical products. Successful inventions require a long journey of investigation, innovation, patent protection, further R&D, prototype manufacture, testing, and sale. Unfortunately, new technology does not sell itself. Since it is more profitable to own a 'market' rather than simply one device or one patent, the sales and marketing and in many cases licensing or partnering efforts can be very substantial.

RESEARCH AND COMMERCIALISATION

None of the innovation and patenting pathway is taught in medical school. Any of the eye care community using iPads or Apple products, or Healon™ visco-elastics, would realise that most innovation and invention of new products go through lengthy product creation initially, but subsequently processes of product improvement in order to gain and sustain traction in the marketplace.

The ASO encourages Australian ophthalmic innovation but tangible support is rare. It is a fortunate surgeon who can quit his or her day job to focus full-time on new products and research. For the benefit of ASO members we here discuss a case study of the PrecisionIOLGuide™ process of opportunity screening followed by commercial business planning

and some initial financing for an ophthalmic device invention developed in Melbourne. It was first conceptualised in 2010 but recently gained significant momentum and by 2014 has had some encouraging wins.

AWARDS AND RECOGNITION

Surgeons have difficulty innovating new technologies in their own rooms, or surgical suites, and often set up their own private companies purely for the purposes of earning additional 'passive' income through successful development of inventions and technology improvements. Australia has seen global inventions such as the technologies behind Vision Blue™, Triesence™ and various solid-state laser and scanning technologies, as well as leadership in new bionic and other retinal technologies.

The initial company in this case was established in 2010 to commercialise the innovation and the trade name for the product (PrecisionIOL Guide) was selected. By 2014 the company had gained significant momentum. The most important proof of this was a win involving the award of an Innovation Voucher Program grant for \$25,000 from the Victorian Government. This prestigious and competitive grant has funded cooperation with Swinburne University (including biomaterials research), and with the precision laser engineering firm Opto Tech P/L. The federal government also confirmed an Advanced Finding under its improved Research and Development Tax Incentive. This additional funding will be used for further patent and IP protection

through patent lawyers, improved prototype development and design and product improvements. An invention and a company to commercialise the invention are entities separate from the surgeon, and it is helpful to see the validation that these sorts of awards convey.

PROTOTYPE PRODUCTION

The PrecisionIOLGuide™ is now in prototype form as a novel, disposable device designed to guide manual capsulorhexis and placement of specialty Premium intraocular lenses, particularly toric IOLs. There are a number of additional and improved products also under development. The core benefits of all of these enhancements include greater accuracy and safety, faster surgical work-flow, more precision, and a strong business case compared with expensive video-based systems. An elegant mechanical approach avoids the latency problems inherent in video-based scanning systems and the fact that the guide sits on the cornea minimises parallax error.

In addition to the original development, patent protection and other innovation activities, a strong opportunity needs a strong market. Market research - also not taught in medical school - was also required. ASO members would appreciate that research demonstrated a substantial global market of some \$3 billion for cataract and lens surgery. But what was really needed was an effort to segment markets, target specific segments, then position the product. The product name 'PrecisionIOLGuide' and IP protection via copyright and trademark filings as well as



patent filings helped achieve this. The prime target market is for more complex lenses (torics) and growing elective markets (RLE). A new market challenge has been alignment with the surgical work-flow of Femtosecond laser cataract surgery practices and that opportunity is now being assessed further.

Our business plan involved the initial production of prototypes. The illustration is a 3D mockup of the contact lens-based guide for toric IOL placement, designed to sit on the cornea during capsulorhexis and IOL alignment. The product has a number of cost, work-flow efficiency and surgical precision advantages over competing technologies in the market, including for more precise placement of lower-powered, toric and specialty lenses.

VENTURE OR 'VULTURE' CAPITAL

Financing the venture has faced its own challenges, as venture capital in Australia is not easy to find. Large partners and their licensing and business development teams are hesitant to look at very early stage medical devices until the prototypes and initial testing are complete, sufficient for their own business cases and analyses. Ophthalmologists may know some people with some spare cash, but these days any investor is carefully comparing the rate of return offered by investing in a medical device, alongside some potentially easier money to be made in real estate, the stock market, or through other non-medical businesses. Raising equity capital in Australia anyway has many compliance requirements,

and also requires dilution of both voting power, and of shares in the company, as well as the need to share any dividends or returns earned with other investors.

Doctors who do careful research may find that the early stages of medical innovation may be better supported by government than originally thought. The steps of pro-actively seeking government funding has been successful thus far for the PrecisionIOL Guide™ as it has been non-dilutive. The 'vulture capitalists' have not been able to gobble up control of the company in these early stages and part of the Victorian government funding scheme helps fund partnerships with Victorian university and technology firms. These were exactly the extra resources the company needed, and the Ausindustry R&D Tax Incentive also subsidises any owner-invested funds injected by the inventor, which are related to R&D.

The company will also compete for a Commercialisation Australia competitive grant and other innovation competitions for further validation and funding. This will put us in a strong position for subsequent funding discussions which may be with partners, commercial licensing co-development stakeholders or distributors seeking an exciting product. One of the additional innovations developed has been 'tools' to assist with the efficient manufacture, including incorporation of laser precision manufacturing technology, so that partners can take on not only the products themselves, but also the processes and procedures for optimal and efficient production.

AN EYE ON THE FUTURE

Various politicians tell the eye-care community that jobs for the future will involve higher value-adding and technology-focused employment as some traditional manufacturing moves off shore. Medical and ophthalmic technologies are precisely these sorts of jobs and we applaud the ASO for reminding Canberra of the competitive and differential advantages Australia has in these sorts of specialty areas.

Busy ophthalmologists can, and should, give thought to ways of doing things better and more efficiently and seeing if they can conceptualise, develop, patent-protect and commercialise new products and methods. This will continue to support Australia's role as an important stakeholder in ophthalmic innovation. The PrecisionIOL Guide™ is currently completing an R&D cycle, with prototype products shortly available for review, commercial discussions, and with results to be presented at major eye meetings and in various journals.

*Dr Laurie Sullivan FRANZCO is an ASO member and is the inventor of and investor in the technology, and a cataract corneal and refractive surgeon, educator and eye researcher, practicing in Melbourne at Bayside Eye Specialists and Laser Sight. <http://www.precisioniolguide.com>

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