MONASHVISIONGROUP

2014 | ANNUAL REPORT

AUSTRALIAN RESEARCH COUNCIL
SPECIAL RESEARCH INITIATIVE IN BIONIC VISION SCIENCE AND TECHNOLOGY

MONASHVISIONGROUP

Monash Vision Group (MVG) is a unique cross-sector consortium with collaborative partners Monash University, Grey Innovation, MiniFAB and Alfred Health. MVG has two key goals;

- to develop a commercially and clinically viable cortical vision prosthesis or 'direct-to-brain' bionic eye;
- to build upon existing knowledge to create outstanding research capabilities in bionic vision science and technology in Australia.

www.monash.edu/bioniceye

TheAlfred

Alfred Health is a leader in healthcare delivery and improvement, striving to achieve the best possible health outcomes for patients and the community by integrating clinical practice with research and education. Alfred Health is recognised as a pacesetter in the national healthcare arena and is consistently linked to progressive developments in healthcare and services, medical research and healthcare teaching. Alfred Health is providing expertise in MVG's clinical program, including the recruitment, testing and after-care of patients.

www.alfred.org.au

GREY INNOVATION
TECHNOLOGYCOMMERCIALISATION

Grey Innovation is a cutting edge engineering company with experience in complex software, hardware and mechanical architectures across a number of industries and markets. Grey Innovation provides a unique product development and commercialisation service from initial strategy through design, testing, technology innovation, manufacture and market penetration. Grey Innovation is providing expertise for the development of MVG's external electronics and processing components of the vision system.

www.greyinnovation.com

miniFAB™
The Micro - Nano - Bio Company

MiniFAB is an ISO 13485 certified, privately-held contract engineering firm providing custom development and manufacture of polymer micro-engineered products, disposable diagnostics and medical devices. Established in 2002, MiniFAB's product development process covers the entire spectrum, from converting early stage product concepts into prototypes, through to full-scale, high throughput OEM & ODM manufacturing. MiniFAB is providing expertise in the design and manufacture of MVG's implantable devices and tooling.

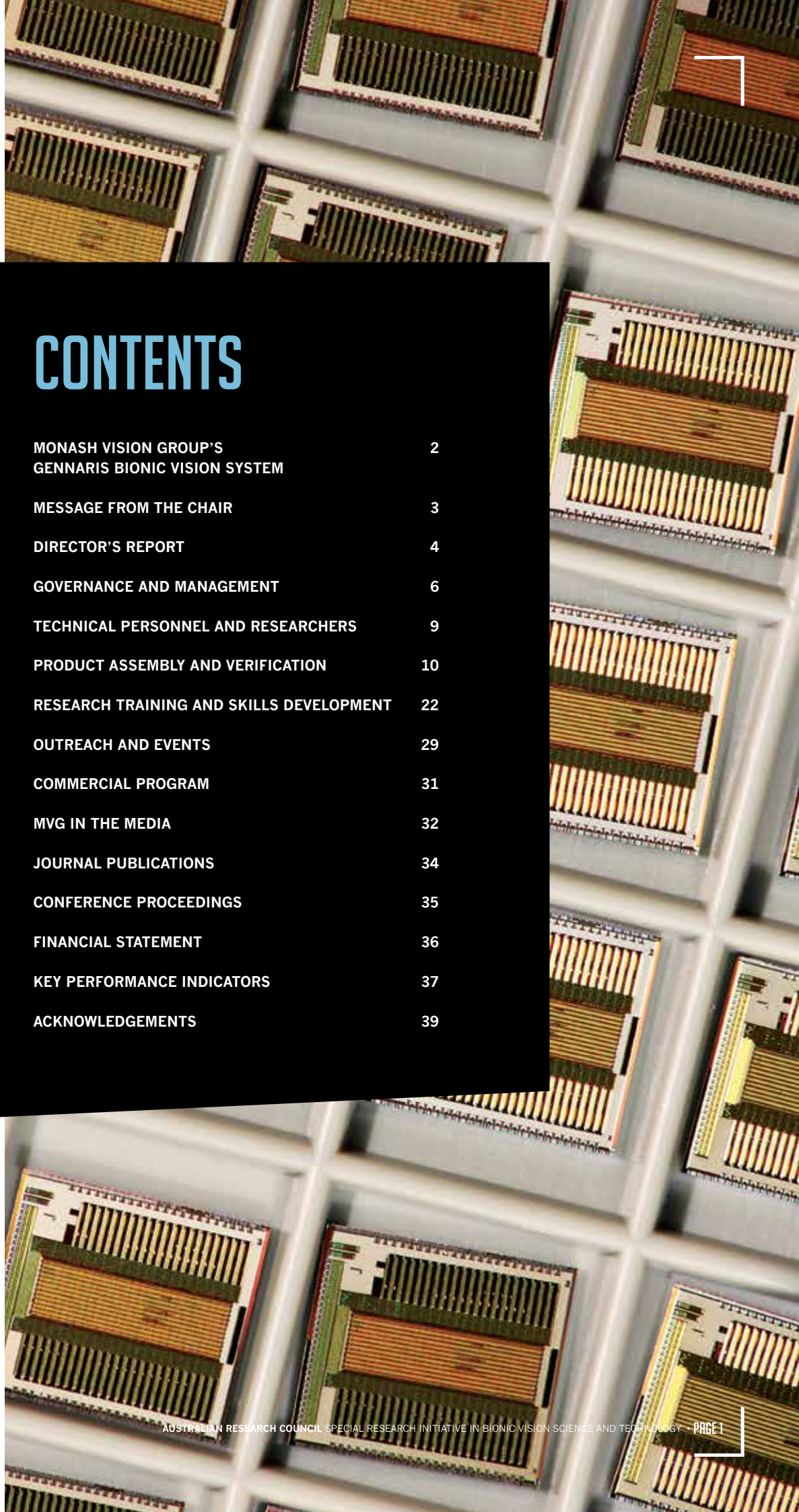
www.minifab.com.au

MONASH University

Monash University is one of Australia's leading universities with an enviable record for research and development leading to commercialisation. MVG has Chief Investigators from departments within the Faculty of Engineering and the Faculty of Medicine, Nursing and Health Sciences, with key inputs into all aspects of the Monash Vision project.

www.monash.edu

Front cover: Stylised representation of brain imagery captured during MRI Visual Cortex Study.



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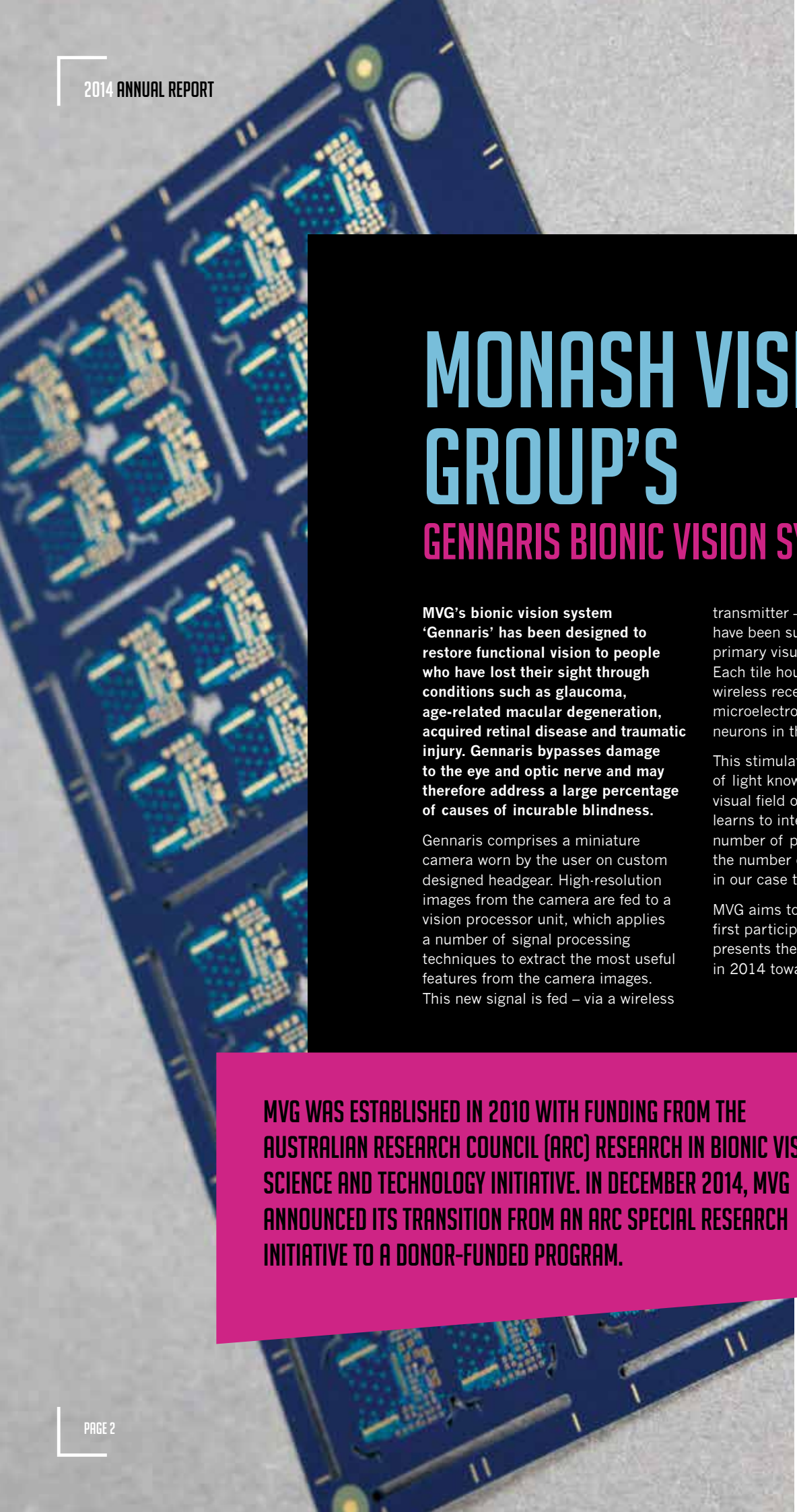


MONASH VISION GROUP'S

GENNARIS BIONIC VISION SYSTEM

MVG's bionic vision system 'Gennaris' has been designed to restore functional vision to people who have lost their sight through conditions such as glaucoma, age-related macular degeneration, acquired retinal disease and traumatic injury. Gennaris bypasses damage to the eye and optic nerve and may therefore address a large percentage of causes of incurable blindness.

Gennaris comprises a miniature camera worn by the user on custom designed headgear. High-resolution images from the camera are fed to a vision processor unit, which applies a number of signal processing techniques to extract the most useful features from the camera images. This new signal is fed – via a wireless transmitter – to up to 11 tiles that have been surgically implanted in the primary visual cortex of the brain. Each tile houses its own circuitry, wireless receiver and 43 hair-thin microelectrodes that stimulate the neurons in the primary visual cortex.

This stimulation evokes brief flashes of light known as 'phosphenes' in the visual field of the user, which the brain learns to interpret as images. The number of phosphenes depends upon the number of implanted electrodes, in our case this will be up to 473.

MVG aims to implant Gennaris in first participants in 2016; this report presents the progress made by MVG in 2014 towards this key goal.

MVG WAS ESTABLISHED IN 2010 WITH FUNDING FROM THE AUSTRALIAN RESEARCH COUNCIL (ARC) RESEARCH IN BIONIC VISION SCIENCE AND TECHNOLOGY INITIATIVE. IN DECEMBER 2014, MVG ANNOUNCED ITS TRANSITION FROM AN ARC SPECIAL RESEARCH INITIATIVE TO A DONOR-FUNDED PROGRAM.

MESSAGE FROM THE CHAIR

PROFESSOR DAVID DE KRETSER AC

I WOULD LIKE TO OPEN THIS YEAR'S REPORT BY SAYING HOW DELIGHTED I AM THAT WITH THE CONCLUSION OF THE AUSTRALIAN RESEARCH COUNCIL'S SPECIAL RESEARCH INITIATIVE (ARC-SRI), MONASH VISION GROUP IS ABLE TO CONTINUE ON ITS JOURNEY TOWARDS FIRST IN HUMAN TRIALS AND THE PRODUCTION OF A CLINICALLY VIABLE BIONIC VISION SYSTEM.

This is the result of two cornerstone donations; $1M from Drs Marc and Eva Besen and $1M from The Finkel Foundation. Further to this, Monash University continues to demonstrate its support of this ground-breaking project by committing a further $1M beyond what has already been contributed during the ARC-SRI. A common hurdle in the development of cutting edge medical technologies is the funding gap that exists in late stage research/early stage development, when a project is often considered too advanced for government funding and premature for commercial investment; this is the stage at which MVG finds itself. My sincere thanks go to all of our benefactors for their insight and willingness to support the development of this landmark technology that has the potential to impact on the lives of millions of people in years to come.

Their generosity is in no small part due to the excellent progress and continued dedication of the MVG team. Expertly led by Professor Arthur Lowery, MVG has made impressive strides towards an ambitious and challenging goal. I have every confidence that this transition to a donor-funded program will enable MVG to complete the First in Human demonstration with the Gennaris bionic vision system.

MVG has been fortunate to have the support of a dedicated and passionate Advisory Board and I thank them for their continued involvement over the past year. On a personal note, I would also like to congratulate Professor Lyn Beazley on being awarded Western Australia Australian of the Year 2014 – a well-deserved and impressive achievement.

Finally, I would like to acknowledge the Australian Research Council, without whom this project would never have been established. The decision to fund a cross-sector research consortium with clear clinical and commercial goals has provided an opportunity for MVG to demonstrate the importance of industry-academic linkages in developing life-changing medical technologies. On behalf of all at MVG, I thank the ARC for its support and I look forward to the next phase of this inspirational project.

PROFESSOR DAVID DE KRETSER AC

Advisory Board Chair,
Monash Vision Group

DIRECTOR'S REPORT

PROFESSOR ARTHUR LOWERY

DURING 2014, WE MANUFACTURED AND BENCH TESTED THE ENTIRE GENNARIS BIONIC VISION SYSTEM, INCLUDING THE WIRELESSLY POWERED HERMETICALLY SEALED IMPLANT TILES.

I am delighted to report that the system has passed its bench tests, meaning we can measure the stimulation currents out of the wireless tiles that result from the camera picking up images, the processor processing them, the transmitter transmitting power and data and the implant tiles decoding these signals then generating appropriate stimulation pulses for each electrode. This testing has been an important milestone for our design and manufacturing teams, representing the culmination of four years of work. The manufacturing of the tiles themselves is highly complex with over sixty steps and our industry partners are commended for their stewardship of this process. I sincerely thank the whole team for their outstanding effort in developing and testing the entire system and its many component parts.

We are aiming to have full testing completed mid-2015, which will be followed by our First in Human implantation in 2016.

The project is undergoing a change in funding base, though I am thankful to report that the project plan is unchanged. The initial project funding was for four years, from 2010 to 2013 inclusive, under the Australian Research Council's 'Research in Bionic Vision Science and Technology Initiative'. In 2013, after a successful mid-term review, the ARC gracefully extended the funding for a further year, until the end of 2014. However, this left a gap in funding until the First in Human trial, which will be partially supported by an NHMRC Development Grant. Fortunately, our benefactors – Drs Marc and Eva Besen and The Finkel Foundation – in total donated $2M to continue the project and with an additional $1M contribution from Monash University, MVG has $3M to cover the gap and ensure that we have the resources to support the First in Human trial. I am eternally grateful for this generosity, as are the team.

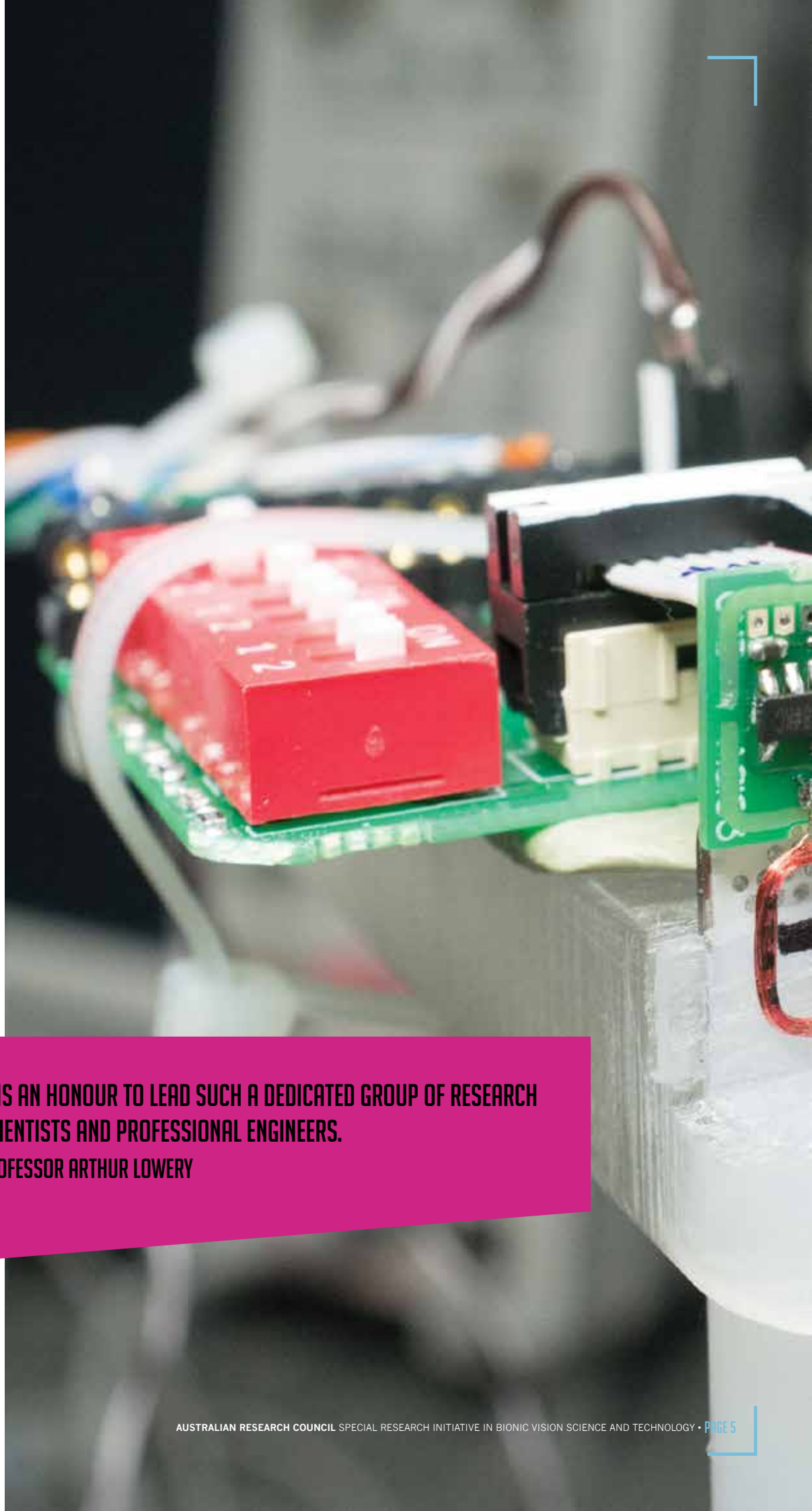
In 2015 our plans are to manufacture a second batch of implant tiles. We are developing automated test methods to evaluate every electrode's output under a wide range of test conditions. After this evaluation, we shall conduct preclinical testing on this batch of devices to gain full confidence of their safety and efficacy.

The remainder of this report details our progress and successes of 2014, highlighting the contributions of our researchers. Technical updates have been provided by our scientists and engineers, all of whom are commended for their outstanding effort this year.

Once again, I should like to thank Jeanette Pritchard, the whole development and testing team, our Steering Committee and Chair Ms Vicki Tutungi, Advisory Board and Chair Professor David de Kretser AC and our finanicial supporters, for getting us to the stage of having a full working system, together with a verified manufacturing process and detailed test methodologies. It is an honour to lead such a dedicated group of research scientists and professional engineers.

PROFESSOR ARTHUR LOWERY

Director and Project Leader, Monash Vision Group



> IT IS AN HONOUR TO LEAD SUCH A DEDICATED GROUP OF RESEARCH SCIENTISTS AND PROFESSIONAL ENGINEERS.
>
> PROFESSOR ARTHUR LOWERY

GOVERNANCE AND MANAGEMENT

ADVISORY BOARD

THE ADVISORY BOARD MET AT THE MONASH CONFERENCE CENTRE, MELBOURNE CBD ON 27TH FEBRUARY, 22ND AUGUST AND 2ND DECEMBER.

PROFESSOR DAVID DE KRETSER AC

Chair, MVG Advisory Board
Sir John Monash Distinguished Professor, Monash University

PROFESSOR JIM PATRICK

Chief Scientist,
Cochlear Ltd

PROFESSOR ARTHUR LOWERY

Director, Monash Vision Group
ARC Laureate Fellow

PROFESSOR LYN BEAZLEY

Chief Scientist, Western Australia (2006-2013) and ARC Nominee

MR GERARD MENSES

CEO,
Make a Wish Foundation

DR DAVID LYSTER

Manager, Research Partnerships,
Monash University

STEERING COMMITTEE

MS VICKI TUTUNGI
Independent Chair,
MVG Steering Committee
Managing Director, ProLearn

MS HALINA OSWALD
Director, Monash Research Office
Monash University

DR EROL HARVEY
CEO,
MiniFAB (AUST) Pty Ltd

PROFESSOR ARTHUR LOWERY
Director, Monash Vision Group
ARC Laureate Fellow

DR DAVID LYSTER
Manager, Research Partnerships
Monash University

MR JEFFERSON HARCOURT
Director,
Grey Innovation Pty Ltd

PROFESSOR JEFFREY V ROSENFELD AM OBE
Director of Neurosurgery,
Alfred Hospital and Head, Division of Clinical Sciences and Dept Surgery,
Central Clinical School,
Monash University

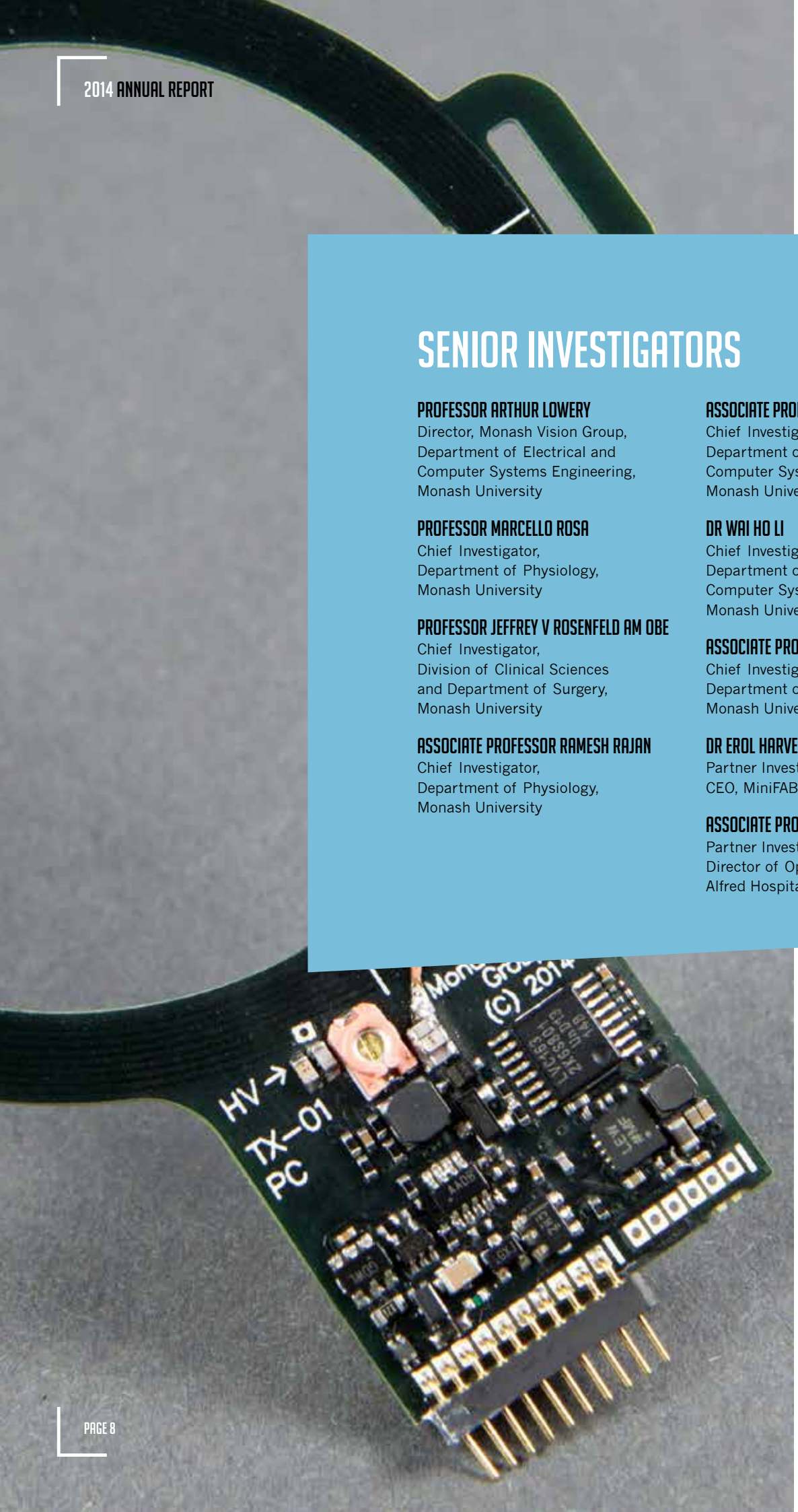
PROFESSOR MARCELLO ROSA
Deputy Head of Physiology,
Monash University

EXECUTIVE TEAM

PROFESSOR ARTHUR LOWERY
Director

DR JEANETTE PRITCHARD
General Manager

MS SUZANNE HAYSTER
Administrative Assistant



SENIOR INVESTIGATORS

PROFESSOR ARTHUR LOWERY
Director, Monash Vision Group,
Department of Electrical and
Computer Systems Engineering,
Monash University

PROFESSOR MARCELLO ROSA
Chief Investigator,
Department of Physiology,
Monash University

PROFESSOR JEFFREY V ROSENFELD AM OBE
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Division of Clinical Sciences
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Department of Materials Engineering,
Monash University

DR EROL HARVEY
Partner Investigator and
CEO, MiniFAB

ASSOCIATE PROFESSOR ANTHONY HALL
Partner Investigator and
Director of Ophthalmology,
Alfred Hospital

TECHNICAL PERSONNEL AND RESEARCHERS

MONASH UNIVERSITY

ELECTRICAL AND COMPUTER SYSTEMS ENGINEERING

DR ANAND MOHAN
Research Engineer

DR COLLETTE MANN
Clinical and Psychophysics Coordinator

DR DAMIEN BROWNE
Test Systems Coordinator and Research Engineer

MR ANDREW STEPHENS
Contract Engineer

MR HORACE JOSH
PhD Candidate

MR TITUS TANG
PhD Candidate

MS EMMA BRUNTON
PhD Candidate

MS PEI CHERN KUNG
PhD Candidate

MR HENRY CHIU
Undergraduate Summer Student

MR JACOB TUTUNGI
Work Experience Student

MR AKSHAY KUMAR
Undergraduate Summer Student

MS AMI PASRICHA
Undergraduate Summer Student

MR DANIEL JONG
Undergraduate Summer Student

PHYSIOLOGY

DR NIC PRICE
Lecturer

DR LEO LUI
Research Fellow

DR SAMAN HAGHGOOIE
Biomedical Engineer

DR EDWIN YAN
Preclinical Coordinator and Research Scientist

DR KOSTAS CHATZIDIMITRAKIS
Research Fellow

MR JONATHAN CHAN
Research Assistant

MS KAHLI CASSELLS
Technician

MS SIMONE CARRON
PhD Candidate

MR TRISTAN CHAPLIN
PhD Candidate

MS AMANDA DAVIES
PhD Candidate

MONASH ART, DESIGN AND ARCHITECTURE

PROFESSOR ARTHUR DE BONO
Head, Department of Design, Associate Dean, Research

PROFESSOR MARK ARMSTRONG
Practice Professor Industrial Design; Eva and Marc Besen International Research Chair in Design

MR KIERAN JOHN
Industrial Designer

MONASH BIOMEDICAL IMAGING

PROFESSOR GARY EGAN
Director

MR RICHARD MCINTYRE
Senior Radiographer

DR MICHAEL EAGER
Computational Imaging Scientist

DR AMANDA NG
Computational Imaging Scientist

MONASH ALFRED PSYCHIATRY RESEARCH CENTRE

PROFESSOR JAYASHRI KULKARNI
Director

PROFESSOR PAUL FITZGERALD
Deputy Director

DR JEROME MALLER
Research Fellow

DR RICHARD THOMSON
Research Fellow

ALFRED HOSPITAL

DR PHILIP LEWIS
Scientific Officer

DR HELEN ACKLAND
Advisor

GREY INNOVATION

MR MIKE SMITH
Chief Technical Officer

MR GARTH CALLENDAR
Project Manager (August - December)

MR GEORGE GREENALL
Project Manager (January - April)

MR GRAHAM LYFORD
Principal Engineer

MR ALISTAIR WEBB
Principal Engineer

MR WARWICK FIFIELD
Quality Systems Manager

MR RAFAL WADOWSKI
Engineer

MINIFAB

MR PETER BETTONVIL
Project Manager

DR MICAH ATKIN
Manager and Technical Lead

MR MATTHEW SOLOMON
Senior Engineer

MR BRODY PAYNE
Project Engineer

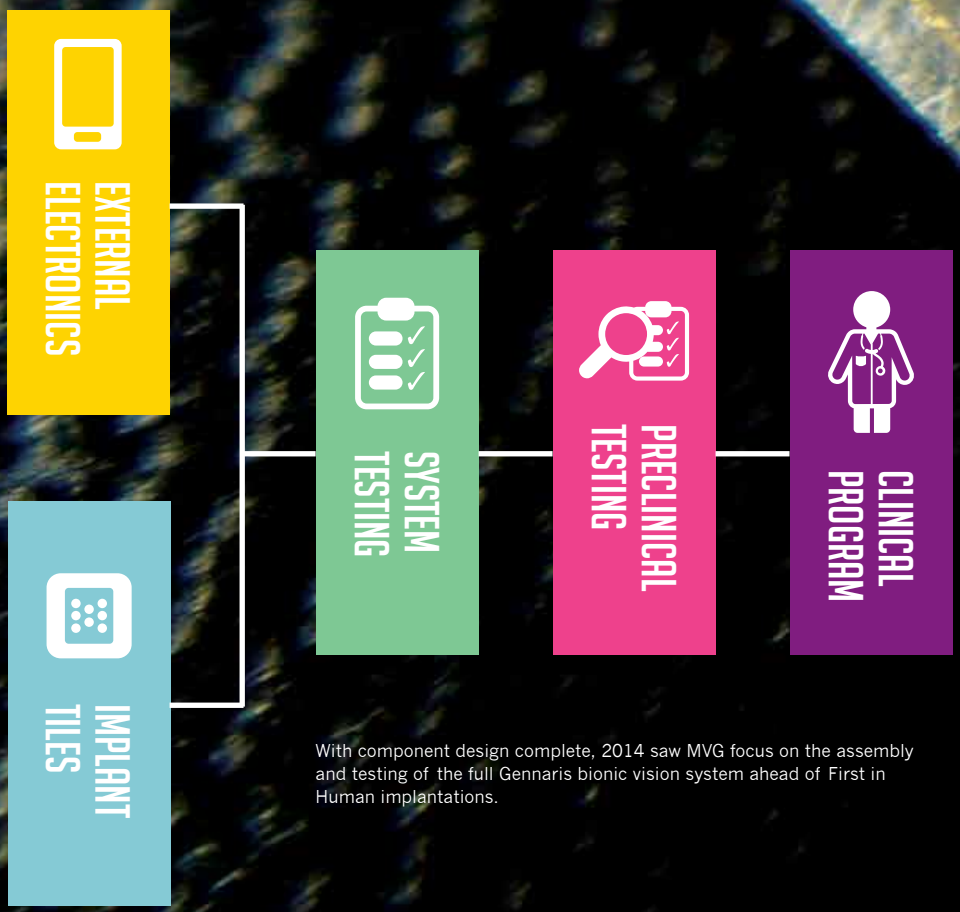
MR BRENDAN RUYS
Project Engineer

MR MICHAEL PACKIASAMY
Technician

MR ALEXANDER STANKOVIC
Production Worker

PRODUCT ASSEMBLY AND VERIFICATION

DURING 2014, TECHNICAL ACTIVITIES WERE FOCUSED ON THE ASSEMBLY, MANUFACTURE AND TESTING OF THE COMPLETE GENNARIS BIONIC VISION SYSTEM. THE FOLLOWING SECTION DESCRIBES THE PROGRESS MADE AND ALSO OUTLINES CLINICAL PREPARATIONS FOR THE FIRST IN HUMAN TRIAL.



With component design complete, 2014 saw MVG focus on the assembly and testing of the full Gennaris bionic vision system ahead of First in Human implantations.

USEFUL MVG DEFINITIONS

ALGORITHM	Step-by step instructions telling a computer how to do something, such as turning an image into phosphenes
ASIC	Application Specific Integrated Circuit, also referred to as microchip
ASIC1	MVG's first prototype ASIC, fully wired electrode stimulator
ASIC1B	Second prototype, incorporating wireless capability (low voltage)
ASIC2	Third prototype, incorporating wireless capability (high voltage)
ASIC3	Fourth prototype, incorporating additional safety features (high voltage)
ASIC4	Fifth ASIC, to be used in First in Human implantation
CAD	Computer-Aided Design
DISTRIBUTION BOARD	Interface providing connectivity between the ASIC, electrodes and active electronic components
DURA MATER	Outermost membrane covering the brain and spinal cord
HATPACK	Portable headwear designed and built by MVG engineers to simulate the bionic vision experience
HERMETIC	Impermeable to fluid ingress / leak resistant
FIH	First in Human
IMPLANT TILE	MVG implantable device, including ASIC, distribution board, wireless receiver and 43 electrodes
MAC1	Fully wired MVG implant tile (43 electrodes, 43 wires)
MAC2	Partially wired MVG implant tile incorporating ASIC1 (43 electrodes, 14 wires)
MADA	Monash Art, Design and Architecture
MRI	Magnetic Resonance Imaging
PHOSPHENE	Perceived spots of light generated through electrical stimulation of the visual cortex
PSYCHOPHYSICS	Quantitative assessment of the relationship between physical stimuli and the sensations / perceptions they affect
PTIR	Platinum-Iridium
SEM	Scanning electron microscope
V1	Primary visual cortex – the area where the first stage of processing of visual information occurs in the brain and where MVG's implant tiles will be placed
VISION PROCESSOR	Portable computer incorporating signal processing algorithms - the user's interface to the device

EXTERNAL ELECTRONICS

IMPLANT TILES

SYSTEM TESTING

PRECLINICAL TESTING

CLINICAL PROGRAM

EXTERNAL ELECTRONICS AND PRODUCT DESIGN

THE INDUSTRIAL DESIGN TEAM AT **MADA** MADE FURTHER ADVANCES TOWARDS FINALISING THE 'COMMERCIAL UNIT' **HEADGEAR** DESIGN, WITH UPGRADES AND REVISIONS BEING THE SUBJECT OF A US INTELLECTUAL PROPERTY FILING IN JUNE.

Front and rear perspectives of Gennaris commercial headgear concept.
The design has been upgraded to improve usability, including the incorporation of removable lenses *(Images courtesy of MADA).*

Class E transmitter, including coil and associated electronic circuitry.

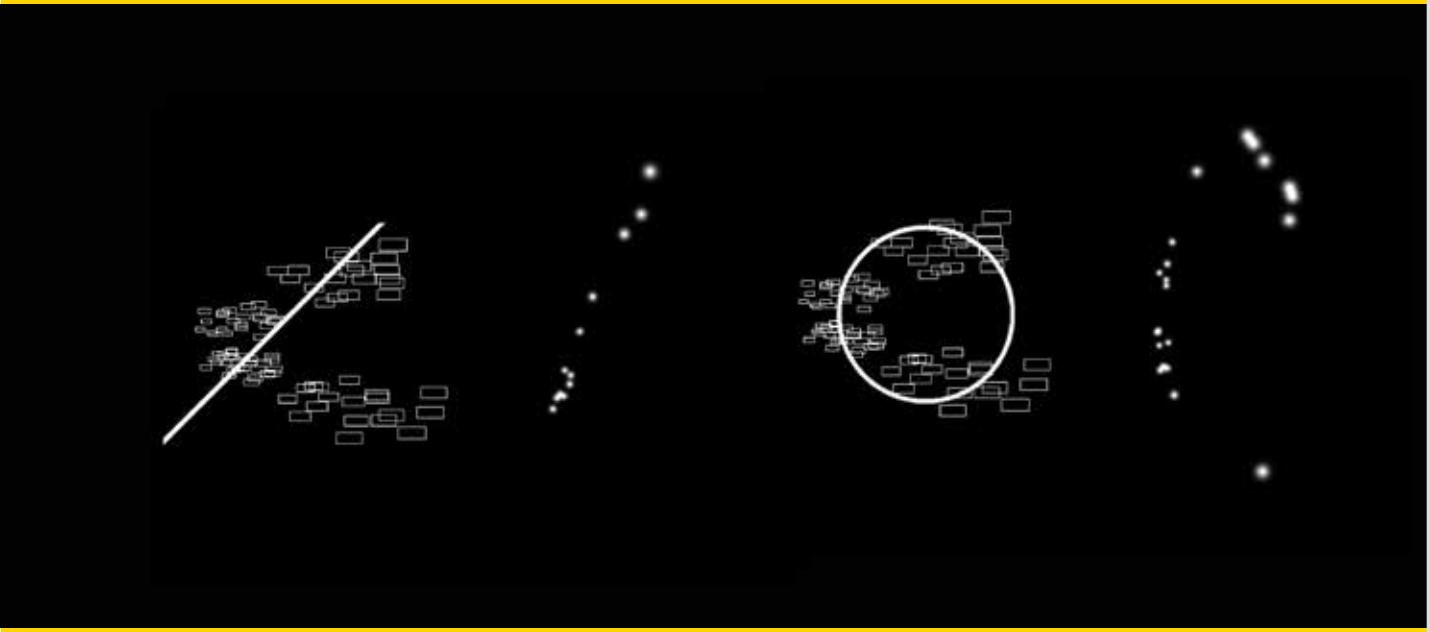
The purpose of the commercial unit is to satisfy broad end-user needs as well as providing a stable mounting platform for the external electronics. The design intent is to help humanise complex technology by creating a normalised aesthetic, where recipients feel confident and proud to wear the device; while formulating sophisticated mechanical housing systems capable of withstanding the rigours of the user environment.

The unit will be ergonomically evaluated for biomechanical and cognitive performance. The commercial unit prototype was fabricated using the latest additive manufacturing technology – in cooperation with **Amaero Engineering Pty Ltd.** – to produce structural components in 3D printed titanium and aluminium alloy. The design integrates a suite of mechanical adjustments that provide vertical and lateral adjustment to the position sensitive coil.

The **wireless transmitter circuit design** was refined and optimised to bring it to FIH standard. The development has allowed an increase in power output to achieve greater coil-tile separation and improved interface with the vision processor control system. The updated wireless transmitter will undergo verification testing in 2015. The **wireless transmitter coil geometry** was also optimised; testing and characterisation of several alternate coil designs involved measuring power output, inductance, bandwidth and resonant frequency to maximise the efficiency of the wireless system.

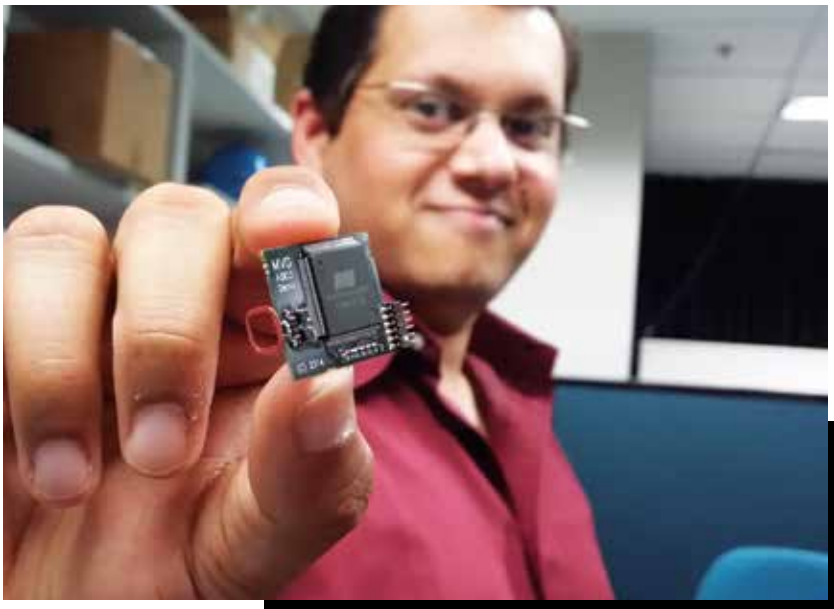
In 2013, fast and flexible **software algorithms** capable of dealing with realistic irregular phosphene patterns were developed for the wearable vision processor. These signal processing algorithms were tested against a variety of expected phosphene patterns. The results show that the algorithms and implemented software is able to operate in real-time under real-world conditions, resulting in the filing of an Australian provisional patent. In addition, these innovations have been leveraged to optimise the simulated prosthetic vision system ('HatPack') used to evaluate signal processing approaches so that visual psychophysics experiments can be performed using a highly portable embedded computer instead of a laptop. This opens up a range of phosphene mapping opportunities for the FIH trial.

The **vision processing software** has been extended to support the novel phosphene mapping concept, allowing the system to be easily tailored for each user's unique perspective. In addition, industry standard real-time image processing protocols have been added to improve the processing performance and ease of algorithm development.



Signal processing algorithm generating irregular phosphene patterns based on two different test inputs. This is used to validate correct algorithm operation. Similar test inputs will be used with FIH participants to refine the phosphene map ahead of psychophysics trials.

IMPLANT TILE ASSEMBLY



Dr Anand Mohan with the ASIC3 demo board assembly, including wireless receiver.

THE IMPLANT TILE COMPRISES A PLATINUM-IRIDIUM RING WELDED TO A CERAMIC PACKAGE, 43 STIMULATING ELECTRODES THROUGH THE PACKAGE BASE AND A CAP THAT IS WELDED OVER THE ELECTRONICS. THE ELECTRONICS WITHIN THE IMPLANT PACKAGE, INCLUDING THE ASIC, SITS UPON A DISTRIBUTION BOARD SUB-ASSEMBLY, TO WHICH THE RECEIVE COIL IS ALSO ATTACHED. THE EXTERNAL ELECTRONICS POWERS AND CONTROLS THE STIMULATION VIA A TRANSMITTER, WHICH IS POSITIONED ON THE BACK OF THE USER'S HEAD. THE AUTONOMOUS IMPLANT TILES HAVE BEEN DESIGNED TO OPTIMISE THE NUMBER OF ELECTRODES THAT CAN BE IMPLANTED IN EACH TRIAL PARTICIPANT, THEREBY IMPROVING THE LIKELIHOOD OF PROVIDING MORE PHOSPHENES AND ULTIMATELY IMPROVING THE QUALITY OF THEIR VISION.

Implant tile handling tool. This tool was custom-designed to avoid damage to the implant tiles and electrodes during assembly and testing.

ASIC3 devices were delivered to MVG in April 2014. Testing showed an excellent yield of ~99% and highlighted the need for some minor design changes, to improve the performance in power usage, range of operation and inter-device variability. This resulted in the design and submission of **ASIC4,** which will be delivered in March 2015 and will be used in the FIH system. Following fabrication and testing, the **distribution board** design was optimised to align with the requirements of ASIC4. New distribution boards will be delivered in early 2015 to align with production timelines for ASIC4 and incorporation into implant tile assemblies.

Throughout 2014, **implant tile assembly** processes were reviewed and optimised to improve the process yields and to ensure that the devices for the FIH program are of the highest quality. The implant tile is made of biocompatible, sintered ceramic with 43 brazed electrode feed-throughs and a surrounding sealing ring to ensure hermeticity. Two key challenges of the implant tile assembly were addressed during 2014. The **brazing connection** between the metallic and ceramic parts was optimised and shown in testing to withstand resistance to corrosion under mock *in vivo* conditions.

Additionally, the **sealing ring** was optimised following initial trials, with a material change from titanium to platinum-iridium (PtIr). This has a number of advantages; it reduces the number of materials that the patient is exposed to and greatly simplifies the implant tile assembly process. The hermetic seal with newly assembled implant tiles incorporating PtIr rings will be tested in 2015. To facilitate the fabrication process and further improve yields, a custom-designed tool was developed that will avoid damage to the electrodes during **implant tile handling.**

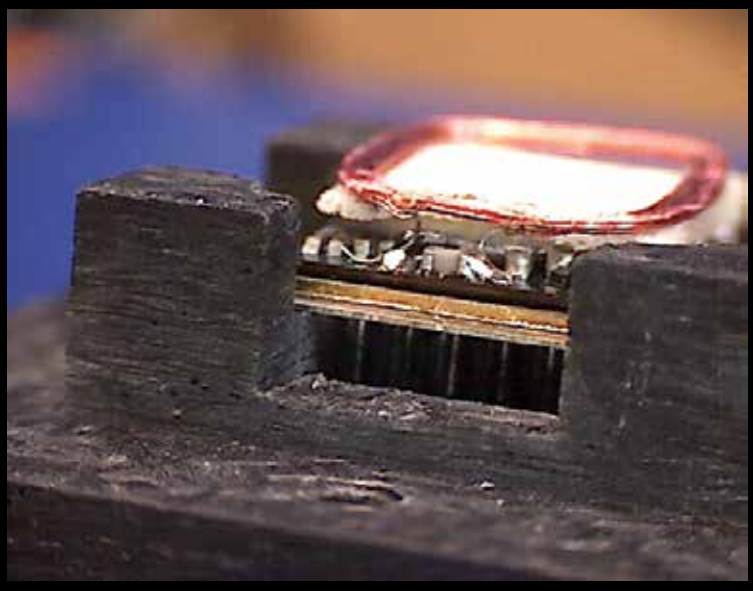
The design of the **wireless receiver** was also modified to accommodate the implementation of ASIC4. The presence of the hermetic seal ring was considered to be a significant design risk to the functionality of the wireless devices; however, the first complete operation of the full receiver circuitry in the presence of the hermetic seal ring was demonstrated and with a small number of design improvements, the operation of the wireless receiver circuitry was improved further. The complete device has been shown to operate while submerged in saline, demonstrating that the design is robust with respect to environmental changes and is unlikely to suffer any loss of efficiency while implanted.

SYSTEM TESTING

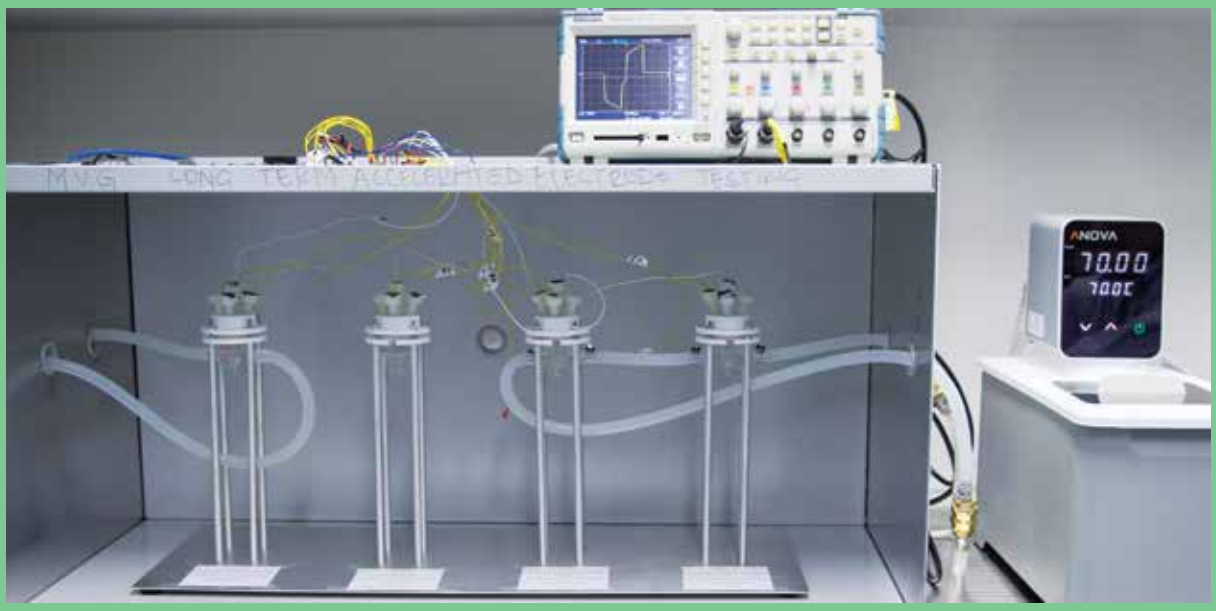
WITH THE NEAR FINAL IMPLANT DESIGN READY AND FABRICATED, THE RELIABILITY OF THE DESIGN AND THE DETECTION OF EARLY LIFE FAILURES NEED TO BE ASSESSED.

The **ASIC3 distribution board** was subjected to a series of tests designed to detect problems with yield, functionality, variability and reliability. In particular, a test was initiated to detect early life failures. Commonly known as burn-in testing, this process accelerates the ageing of the devices. Devices were run for the equivalent of one month of normal use and once this was complete, the devices were subjected to all tests again. If devices are susceptible to early life failures they are excluded from further use. However, results showed that the design is reliable with zero failures post burn-in.

As 2014 was the first year in which completed devices were assembled, the effects of the packaging were tested using the design assembly techniques MVG has created. The result of this testing has allowed MVG to more accurately measure the **wireless link efficiency** and **reliability of the data transmission.** This led to updates to the design of the wireless transmitter to improve the reliability of the data link to the implanted electronics.



Wireless receiver coil mounted on distribution board.



Long-term test setup, to verify electrode stability and integrity.

A bench study to verify the **long term stability and functionality** of MVG electrodes was established, to confirm that there is no electrical or physical change to the electrodes over the expected lifetime of the device. Continuous bi-phasic and direct current stimulation was applied to the electrodes for 24 hours per day.

Three tests were conducted in parallel:

- **ACCELERATED AGEING -** to verify electrode stability under conditions that simulate use over many years. This is achieved by continually stimulating the electrodes over 250 days at an elevated temperature; in this case 70 °C. At completion, the test will demonstrate an equivalent functional lifetime of 20 years, assuming at least 8 hours of stimulation per day.
- **INTEGRITY OF ELECTRODE COATING –** involves taking measurements to detect leakage of stimulation current through the electrode coating materials. The test is run at 37 °C to mimic an *in vivo* environment.
- **STABILITY -** to determine the impact of a known continuous direct current applied to the electrodes over the lifetime of the experiment.

After 25 days continuous testing, no discernable changes in electrode behaviour were observed with any of the tests described. In the case of the accelerated ageing, this yields an effective electrode lifetime of 2.25 years at 8 hours of stimulation per day.

PRECLINICAL TESTING

MVG'S ELECTRODES COMPRISE PTIR TAPERED WIRE OF DIAMETER 125 µM WITH A 27,489 µM² ANNULAR REGION, CORRESPONDING TO AN ANNULUS HEIGHT OF 70 µM. THE ELECTRODE DESIGN HAS BEEN OPTIMISED TO ENABLE EFFECTIVE STIMULATION OF NEURONS OVER CHRONIC PERIODS, AT CURRENT DENSITIES WITHIN A RANGE CONSIDERED TO BE SAFE FOR PTIR ELECTRODES. ELECTRODES AND SURROUNDING BRAIN TISSUE MAY CHANGE FOLLOWING ELECTRODE IMPLANTATION AND IN RESPONSE TO ELECTRICAL STIMULATION. IT IS IMPORTANT TO ENSURE THE IMPLANT TILE AND ELECTRODES ARE SAFE AND CONTINUE TO FUNCTION AS REQUIRED OVER CHRONIC PERIODS OF IMPLANTATION.

The following studies are a snapshot of those undertaken to verify electrode safety, stability and efficacy:

STABILITY – electrodes were implanted in a small animal model and stimulated for four-six hours per day for at least five days per week. Weekly voltage transient measurements showed no permanent changes in the electrode-tissue interface associated with stimulation. Similarly, SEM images show no signs of stimulation-related damage on the surface of the electrodes.

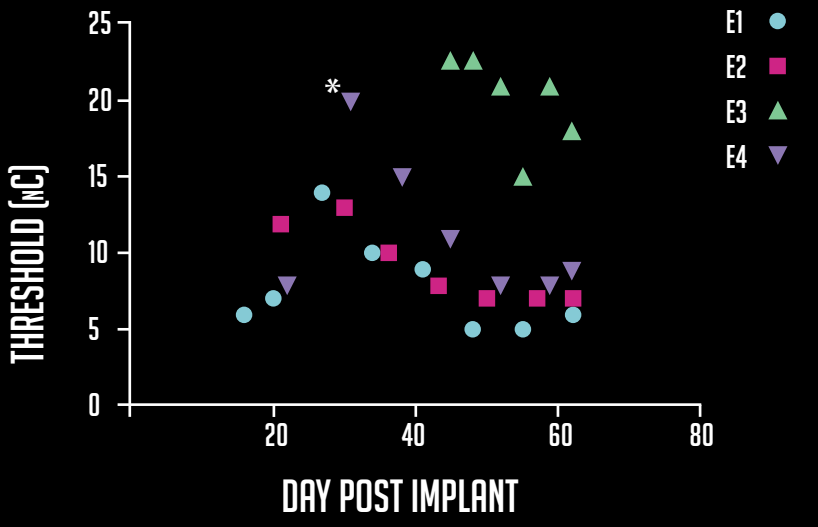
SAFETY - the stability and safety of the device were tested in a large animal model over an accumulative 900 hours electrical stimulation. Over this period the device continued to operate as designed and weekly recorded electrical parameters indicated the electrodes were stable and safe in delivering electrical stimulation. Additional studies will be performed with both wired and wireless devices.

SAFETY - The wireless link used to transmit data and power to the implant tiles will produce heat during operation. The standard for active implantable medical devices EN 45502-1 states that the maximum allowable temperature rise for such devices is 2 °C. Using a large animal model, four temperature testing tiles were implanted under the Dura mater on the brain's surface and the change in temperature within the tile recorded while a maximum of 50 mW power was being dissipated. This power level is nearly double that expected with normal operation of the MVG device. Weekly temperature measurements, taken over a six week period demonstrated that the maximum temperature rise was 1.07 °C.

EFFICACY – building on previous studies, which focused on evoking a motor response in response to stimulation using a small animal model, stimulation of the somatosensory cortex was undertaken to evoke a perceptual response. A 4-electrode array was implanted for nine weeks and the threshold current amplitude required to evoke a perceptual response measured weekly. A response was evoked on all electrodes over the nine week period. The maximum charge required to evoke a response was 22.5 nC and for three out of the four electrodes, the threshold charge stabilised from weeks seven to nine at less than 10 nC. This is within the safe charge injection limit estimated in previous studies [1].

EFFICACY – the ability of the Gennaris to elicit phosphenes from stimulation of the visual cortex can be assessed using a large animal model, where training can be undertaken on visual tasks to detect when phosphenes are produced.

[1] T. L. Rose and L. S. Robblee. "Electrical stimulation with Pt electrodes. VIII. Electrochemically safe charge injection limits with 0.2 ms pulses (neuronal application)". IEEE Trans.Biomed.Eng. vol. 37, pp. 1118-1120, 1990.



Threshold charge required to evoke a perceptual response versus days post implanted for all electrodes on a four electrode array. Stimulus frequency was 50 Hz. *Indicates the highest charge that was trialled on this day, where no response was seen *(Data produced by Rajan Laboratory).*

A MAC1 array was successfully implanted and, similarly to a previous study, the animal experienced no health issues for over six months post-surgery as a result of the implantation. Validation and optimisation of testing protocols was then undertaken, ahead of testing with wireless implant arrays in 2015. Training of animals for these studies was also initiated, using more elaborate behavioural tasks. These tasks include the presentation of a greater variety of visual stimuli to any random screen location, and also reaching towards a very brief flash presented on a touch screen. This generalisation of both stimuli and animal responses will be important for detecting the variable effects of the implant stimulation.

Immunohistochemical analysis will be undertaken after completion of each of the experiments described to confirm whether damage or changes to brain tissue have occurred. Additionally, all studies will be repeated to gather sufficient information to support the ethics submission for FIH implantation.

Temperature testing tile used in preclinical experiments to verify that the temperature rise due to wireless transmission of power and data is within safe limits.

CLINICAL PROGRAM

The Clinical Program comprises three key areas:

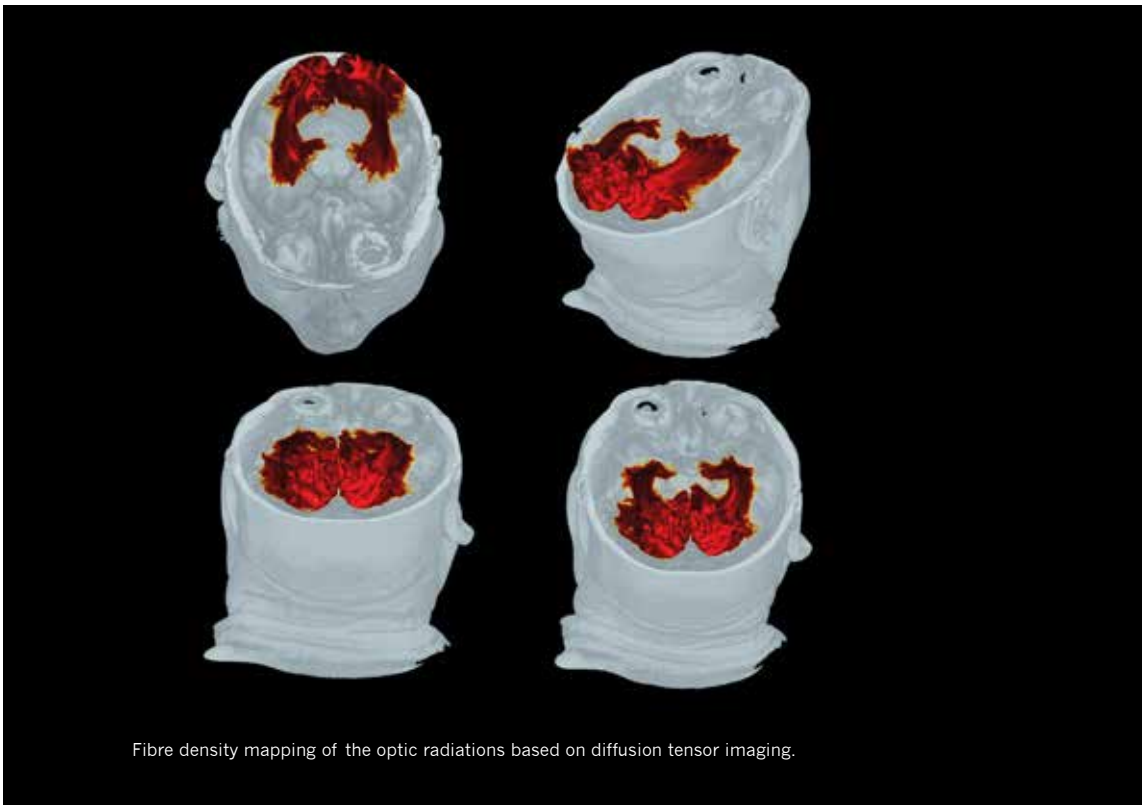
I. PYSCHOPHYSICS TESTING - to develop methods for expediting the training and rehabilitation of FIH trial participants undergoing surgical implantation of the Gennaris device.

II. MRI VISUAL CORTEX STUDY - to statistically determine whether there are regional cortical morphometric differences in the visual cortex between sighted and non-sighted individuals.

III. FIH IMPLANT STUDY - to assess the efficacy of the Gennaris for the microstimulation of the primary visual cortex in profoundly vision-impaired individuals.

The Psychophysics Program has two overarching goals; to provide a better understanding of what a trial participant undergoing implantation may experience and how their rehabilitation can be facilitated; and to ensure consistency in testing and reporting of outcomes with all FIH participants. This includes the development of standardised methodologies for phosphene mapping.

Discussions continued with the Bionics Institute (BI) to determine the software requirements required for phosphene mapping with FIH trial participants. MVG is also one of a number of global research teams involved in an International Joint Task Force focused on the standardisation of methodologies and reporting standards, in psychophysical testing of people implanted with a vision prosthesis. To this end, Professor Arthur Lowery presented at The Eye and The Chip Conference in Detroit in September, which was co-organised by Dr Lauren Ayton, Centre for Eye Research Australia (CERA) and Executive Committee Member of the Joint Task Force.



Fibre density mapping of the optic radiations based on diffusion tensor imaging.

In additional planning for psychophysics testing with trial participants, a 'clinical trial' headgear design was developed by MADA. This unit will be used for testing with FIH participants, in a controlled environment with the support of a trained clinician. The design is less focused on aesthetics compared with the commercial headgear unit, with greater emphasis on integrating purpose built mechanical systems enabling incremental adjustments, as well as precision coil control according to implant positioning. The resultant prototype will be tested against ergonomic and usability parameters to evaluate biomechanical performance, comfort and electronic component stability.

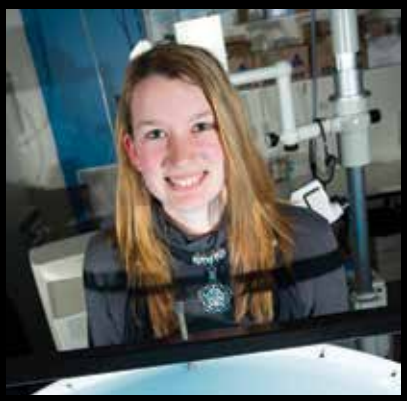
The MRI Visual Cortex Study was successfully completed in 2014 with 20 participants (10 cases and 10 age and gender-matched controls). 3-Tesla MRI was used to identify the size and location of V1 through visualisation of the stria of Gennari. The study, conducted at the Monash Biomedical Imaging (MBI) facility at Monash University, indicated that non-sighted individuals have altered white matter microstructure, specifically along the optic radiations, compared with sighted individuals and that the duration of blindness plays a significant role. A key outcome of this study was the development of novel MRI techniques and data analysis to accurately identify the stria of Gennari and the optic radiations as well as other relevant neural structures. This will enable identification of V1 in the FIH trial participants ahead of device implantation, hence lowering the risk of the surgical procedure. These findings have led to the submission of two manuscripts for publication.

Discussions were initiated with experts at the Alfred Hospital to confirm that MVG will be compliant with hospital procedures in preparation for the **FIH Implant Study,** such as sterilisation of implant tools and inpatient practices. MVG aims to submit documentation to the Human Research Ethics Committee for FIH implantation of Gennaris in late 2015.

Whole brain white matter tractography based on diffusion tensor imaging.

CLINICAL PROGRAM

RESEARCH TRAINING AND SKILLS DEVELOPMENT



AMANDA DAVIES

PhD THESIS: NEURAL CORRELATES OF DETECTING MOTION IN VISUAL AREA MT

SUPERVISOR: PROFESSOR MARCELLO ROSA

Results from the first phase of Amanda's project showed that changing the type of movement that a stimulus undergoes changes the responses of neurons in cortical area MT (the main cortical centre for perception of motion and one of the areas that could be stimulated by the Gennaris device in the future). Specifically, Amanda found that a stimulus that resembles the natural movement of objects in the visual field, stimulating consecutive areas of space in a predictable way, increases the degree of speed-tuning of neurons – therefore producing more useful signals for behaviour. This result was increased with the use of a slightly modulated stimulus so that the increase of speed-tuned neurons is that from approximately 5% to 50% of neurons responding to speed. An additional stage was added into Amanda's project, examining the same stimulus within the area V1 (the location that the Gennaris device is currently targeting) in order to determine whether there is any change to stimulus properties. This data is currently being analysed, but thus far no speed-tuning has been detected, as expected.

In the final stage of her project, Amanda is using the Blackrock multi-electrode recording array to determine how populations of neurons jointly represent motion. This involves a combination of smooth-moving stimuli and stimuli where the object is perceived to jump from point to point, or take unlikely paths. This will provide a better understanding of how the brain creates the concept of motion, which will allow for better integration of information into the brain. Five datasets have been collected, comparing four simplistic stimuli graded from predictable, semi-predictable and non-predictable. Initial analysis will examine neuron communication during only the predictable stimuli, in order to isolate the mechanisms responsible for the changes found in the first part of this study. Consequent analysis will then compare stimuli in order to further isolate predictive mechanisms that operate in neurons when they compute visual motion. Amanda plans to submit her thesis for examination in September.

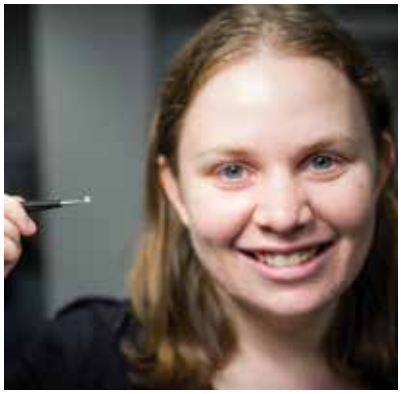
SIMONE CARRON

PhD THESIS: WHICH TYPE OF NEURONS ARE SUSCEPTIBLE TO DAMAGE FROM IMPACT FORCES AND CAN THEY BE RESCUED?

SUPERVISOR: A/PROFESSOR RAMESH RAJAN

Simone investigates if particular subtypes of neurons are more susceptible to impact forces, such as those caused by the insertion of an electrode array into the brain. In 2014, Simone's work involved examining the long term effects of impact forces and differential susceptibility of neuronal populations in cortical and subcortical brain areas by using molecular markers to immunohistochemically characterise in particular the various subtypes of inhibitory neurons and changes in their neuronal numbers.

In 2015, Simone will extend her studies to investigate the acute or short term effects of impact forces on various neuronal populations and also investigate the effects on brain neurons following a different model of impact force, such as the delivery of a fluid pressure pulse to the brain.



EMMA BRUNTON

PhD THESIS: OPTIMISING CORTICAL MICROELECTRODES FOR PROSTHETIC DEVICES

SUPERVISORS: PROFESSOR ARTHUR LOWERY AND A/PROFESSOR RAMESH RAJAN

Electrodes that are chosen for a cortical vision prosthesis need to be capable of evoking phosphene perception without causing considerable damage to the surrounding tissue and the electrodes themselves. Emma has been investigating how different electrode geometries and materials may affect the efficacy and safety of electrical stimulation in the brain. She has used analytical and finite element modelling to determine how the electrode's geometry and surface area affect the electric field generated in the tissue. This study showed that the novel annulus electrode geometry used in Monash Vision Group's bionic vision system distributes current more evenly over the electrode's surface, improving the safety of the stimulation.

Emma has also completed acute *in vivo* electrical stimulation studies in the motor cortex. The results of these studies showed that coating the electrodes with porous titanium nitride greatly increased the charge injection capacity of the electrodes, without adversely influencing the efficacy of stimulation. In 2014 she completed her final study investigating how long periods of electrical stimulation impacted the stability of the electrode-tissue interface. She compared electrodes with and without a coating of porous titanium nitride. No indications of irreversible changes to the electrode-tissue interface due to electrical stimulation were found for either electrode type, over the test period. Emma's goal is to publish these findings and complete her thesis by April 2015.

HORACE JOSH

PhD THESIS: LOW RESOLUTION VISION FOR THE MONASH BIONIC EYE

SUPERVISOR: A/PROFESSOR LINDSAY KLEEMAN

Horace's research seeks ways to effectively convey information via the highly limited visual interface provided by a bionic eye implant, in the hope that quality of life for bionic eye recipients will be improved. As part of his work, Horace has developed the HatPack - an immersive real-time simulator on which several 2D image processing functions have been implemented. Improving on limitations of platforms in existing research, Horace's system emphasises portability and low latency real-time operation through a low power FPGA-based implementation. A number of psychophysics trials have been carried out in order to evaluate effectiveness of system functions and the ability of users to complete simple tasks that resemble everyday activities.

During 2014, Horace extended functionality of his research to the 3D domain via non-visual sensing using a Microsoft Kinect v2 sensor and implementation of more complex functionality through real-time fitting of planes. The plane fitting algorithm developed, has been applied to tasks such as object recognition and way-finding, which may further improve the quality of life for bionic vision users. Nearing completion, Horace intends to publish the results of his recent work and complete his thesis by mid 2015.

PEI CHERN KUNG

PhD THESIS: HEAT DISSIPATION OF BRAIN IMPLANTED TILES BY CEREBRAL BLOOD FLOW

SUPERVISORS: PROFESSOR ARTHUR LOWERY AND A/PROFESSOR RAMESH RAJAN

Implanting devices such as the MVG implant tile that require power, runs the risk of overheating of the device, especially in an enclosed environment such as the brain. It is crucial to know the amount of heat being dissipated by the implant tiles to ensure that there will be no damage to the surrounding tissue. Pei Chern's research investigates how cerebral blood flow helps in dissipating the heat generated from the implant tiles. She has developed a bench-top test rig as an *in vitro* model that represents a one dimensional flow rate. Her next step will be to expand her current system to simulate an *in vivo* environment as closely as possible. She also plans to use *in vivo* studies to verify her *in vitro* model – this will allow MVG to verify that the implant tiles to be used in First in Human studies are safe, conform to current standards and ultimately will not harm the recipient.

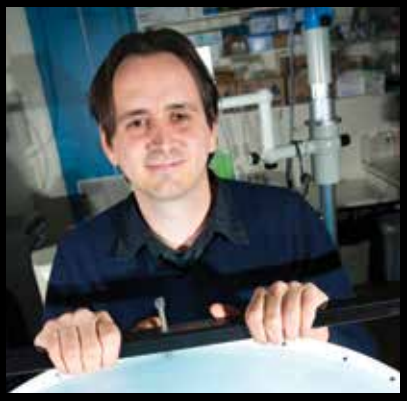
TITUS TANG

PhD THESIS: INTERACTIVE ASSISTIVE TECHNOLOGIES FOR THE VISION IMPAIRED

SUPERVISOR: DR WAI HO LI

Titus' research involves developing assistive technologies that could work in complement with bionic vision. His PhD focuses on two technologies. Firstly, he has been looking at the feasibility of using depth sensors as part of vision prostheses. Depth sensors provide distance information that is intended to augment the 2D vision expected in bionic vision. Titus has developed computer vision algorithms that process and extract information from depth data to help the person with vision-impairment. An example is the development of a staircase detector in 2012.

Secondly, Titus has been investigating the feasibility of using spatial (3D or binaural) audio cues to complement the visual information expected in bionic vision. Spatial audio cues are used to convey to the user depth and 3D information obtained from depth sensors. Using a visual aid prototype that he developed, Titus has conducted numerous user trials over the past two years to validate this novel approach of using depth sensors and computer vision algorithms in combination with spatial audio. His work won the Best Paper Award at the International Symposium on Wearable Computers (ISWC) in Seattle in September. Titus aims to submit his thesis for final examination in February 2015.



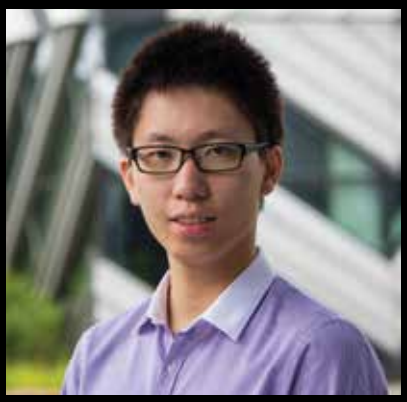
TRISTAN CHAPLIN

PhD THESIS: NEURAL CORRELATES OF AUDIO AND VISUAL MOTION PERCEPTION

SUPERVISORS: PROFESSOR MARCELLO ROSA AND DR LEO LUI

Tristan's project is aimed at examining how the visual cortex processes motion under imperfect, noisy conditions. This is fundamental for understanding the brain's ability to process the signals delivered by any vision prosthesis. He has recorded from motion sensitive neurons in the visual cortex, while presenting stimuli which varied in terms of how difficult it was to discern the direction of motion. He is finding that some neurons are remarkably good at detecting motion under noisy conditions, similar to the psychophysical thresholds in normal-sighted humans. Other studies have shown that stimulation of just a few of these neurons may induce the perception of motion. These results may help in the development of Gennaris to give users improved perception of motion.

In 2015, Tristan aims to examine the influences of auditory motion in the visual cortex. He hypothesises that presenting a moving auditory stimulus in addition to the visual stimulus will influence the motion sensitive neurons in the visual cortex, perhaps increasing their sensitivity to visual motion. This may have useful implications when training Gennaris users - combining stimulation with an auditory stimulus may improve their ability to detect motion.



HENRY M. H. CHIU

FOURTH YEAR BACHELOR OF BIOMEDICAL SCIENCE/BACHELOR OF ENGINEERING – ELECTRICAL AND COMPUTER SYSTEMS SUMMER INTERN 2014-2015

Henry was a summer research student working under the supervision of Dr Wai Ho Li during the end-of-year break from 2014 to 2015. He investigated the use of modern low cost virtual reality systems as a means to conduct simulated prosthetic vision experiments. Such a system will enable prosthetic vision researchers to conduct a range of psychophysics experiments in a highly quantitative and precise manner since the visual stimuli shown to the user, as well as the user's interaction with the virtual environment, can be measured via software.

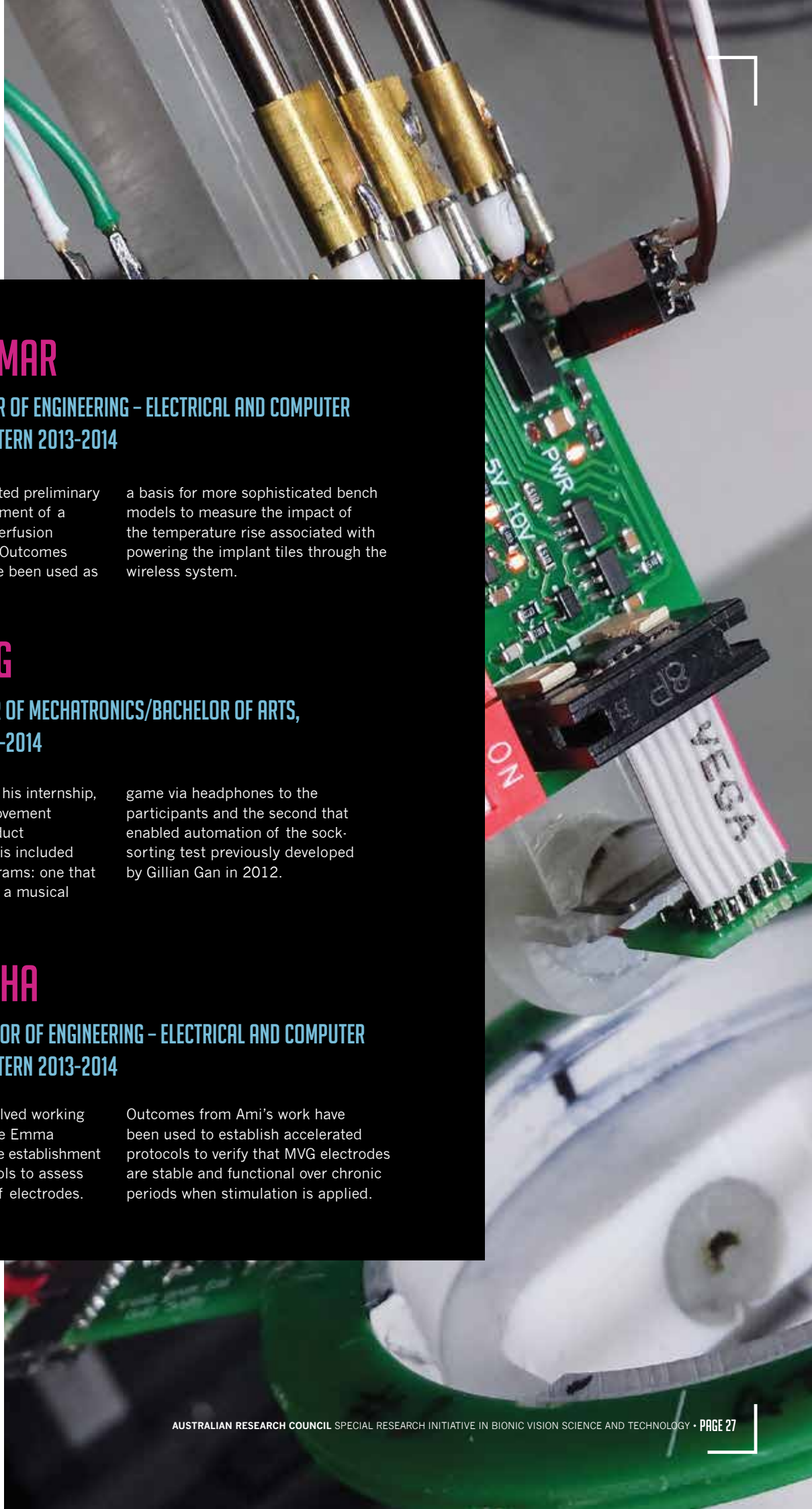
Henry helped with the design and implementation of software that bridged between virtual reality graphics rendering engines, head mounted display hardware ('VR Goggles') and existing Monash Vision Group code bases for signal processing and simulated prosthetic vision visualisation. The software may also enable the virtual reality simulation of various diseases such as age-related macular degeneration.

JACOB TUTUNGI

YEAR 10 WORK EXPERIENCE STUDENT, SCOTCH COLLEGE

Over his week long work experience placement, Jacob assisted the MVG engineering team with the processing and analysis of output waveforms from the ASIC3 stimulator.

Jacob also learnt skills in software development and software/hardware interfaces using the Arduino micro-controller development kit, providing him with an insight into electrical and computer systems engineering.



AKSHAY KUMAR

THIRD YEAR BACHELOR OF ENGINEERING – ELECTRICAL AND COMPUTER SYSTEMS, SUMMER INTERN 2013-2014

In 2014, Akshay conducted preliminary studies into the development of a bench test to emulate perfusion conditions in the brain. Outcomes from Akshay's work have been used as a basis for more sophisticated bench models to measure the impact of the temperature rise associated with powering the implant tiles through the wireless system.

DANIEL JONG

FIFTH YEAR BACHELOR OF MECHATRONICS/BACHELOR OF ARTS, SUMMER INTERN 2013-2014

During the latter part of his internship, Daniel focused on improvement of software to help conduct psychophysics trials. This included completion of two programs: one that allowed transmission of a musical game via headphones to the participants and the second that enabled automation of the sock-sorting test previously developed by Gillian Gan in 2012.

AMI PASRICHA

SECOND YEAR BACHELOR OF ENGINEERING – ELECTRICAL AND COMPUTER SYSTEMS, SUMMER INTERN 2013-2014

Ami's work in 2014 involved working with MVG PhD candidate Emma Brunton to assist with the establishment of bench testing protocols to assess the functional lifetime of electrodes. Outcomes from Ami's work have been used to establish accelerated protocols to verify that MVG electrodes are stable and functional over chronic periods when stimulation is applied.

STUDENT LECTURES AND SEMINARS

PROF ARTHUR LOWERY	**MENG1010:** Process Systems Analysis (Monash)
	'Overview of MVG's Cortical Vision Prosthesis System' (Aston Brain Centre, Birmingham UK, 3rd October)
MS EMMA BRUNTON	**ECE4081:** Medical Instrumentation guest lecture (Monash)
MR JEFFERSON HARCOURT	Telecomms, Electrical & Biomedical guest lecture (Swinburne)
A/PROF LINDSAY KLEEMAN	**ECE4075:** Real Time Embedded Systems (Monash)
DR NIC PRICE	**BMS1052:** Biomedical Sciences - Medical Bionics (Monash)
A/PROF RAMESH RAJAN	**PHY2011:** Neuroscience of Sensation, Brain and Movement (Monash)
	MED1022: Neuroscience (Monash)

MVG AIMS TO CREATE OUTSTANDING RESEARCH CAPABILITIES IN BIONIC VISION, SCIENCE AND TECHNOLOGY IN AUSTRALIA. WE ARE ACHIEVING THIS GOAL BY TRAINING THE NEXT GENERATION OF TECHNICAL SPECIALISTS THROUGH STUDENT ENGAGEMENT AND RESEARCH PROGRAMS.

OUTREACH AND EVENTS

MVG WAS INVOLVED IN MANY ACTIVITIES TO RAISE PUBLIC AND INDUSTRY AWARENESS OF THE BIONIC VISION INITIATIVE.

Highlights included a two week visit to MVG in March by **Professor Partha Mitra** from **Cold Springs Harbour Laboratories** (New York) and the opportunity for **Professor Arthur Lowery** and **Professor Lyn Beazley** to meet with Deputy Leader of the Australian Liberal Party, **Hon. Julie Bishop MP** in Perth in May. MVG's involvement in the **Melbourne Now Exhibition** at the National Gallery of Victoria was also very successful, with the event attracting over 753,000 visitors over 121 days. As part of the **KIOSC Careers in Science and Technology information night** during Science Week, **STC** and **MiniFAB** welcomed 250 school students to its facility, which included a custom MVG display. MVG was also highlighted during the **MADA Trans-Form** exhibit in July, including the custom headgear prototype unit and an electronic demonstration of the end-to-end Gennaris system.

MEMBERS OF MVG VISITED A LARGE NUMBER OF NATIONAL AND INTERNATIONAL RESEARCH, INDUSTRY AND GOVERNMENT FACILITIES AND ENGAGED IN INDUSTRY AND COMMUNITY EVENTS:

FACILITY VISITS

ALLEN BRAIN INSTITUTE, US (Mr Tristan Chaplin)

ANHUI MEDICAL UNIVERSITY, CHINA (Dr Edwin Yan)

ASTON BRAIN CENTRE, UK (Professor Arthur Lowery)

DEFENSE ADVANCED RESEARCH PROJECTS AGENCY, US (Professor Jeffrey V Rosenfeld)

LIFESCIENCES ALLEY, US (Dr Jeanette Pritchard)

OSPREY MEDICAL, US (Dr Jeanette Pritchard)

OUTWARE, AUSTRALIA (Dr Wai Ho Li)

UNIVERSITY OF BOLOGNA, ITALY (Dr Konstantinos Chadzimitrakis)

UNIVERSITY OF MINNESOTA – MEDICAL DEVICES CENTRE, US (Dr Jeanette Pritchard)

UNIVERSITY OF MINNESOTA – UNIVERSITY ENTERPRISE LABS, US (Dr Jeanette Pritchard)

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES, US (Professor Jeffrey V Rosenfeld)

UNIVERSITY OF PISA, ITALY (Dr Konstantinos Chadzimitrakis)

WYSS INSTITUTE FOR BIOLOGICALLY INSPIRED ENGINEERING, US (Dr Erol Harvey)

XI'AN JIAOTONG UNIVERSITY, CHINA (Dr Edwin Yan)

YORK UNIVERSITY, UK (Professor Arthur Lowery)

INDUSTRY EVENTS

ADVAMED 2014, US (Dr Jeanette Pritchard)

BIOSA: THE ROAD TO DIVERSIFICATION - OPPORTUNITIES IN MEDICAL DEVICE MANUFACTURING, AUSTRALIA (Mr Jefferson Harcourt)

SLAS 2014 (SOCIETY FOR LABORATORY AUTOMATION AND SCREENING), US (Dr Erol Harvey)

COMMUNITY AND PUBLIC ENGAGEMENT

Invited Talk at MELBOURNE GPU USERS MEET-UP sponsored by Nvidia (Dr Wai Ho Li)

Invited Talk at MELBOURNE MATH AND SCIENCE MEET-UP (Dr Wai Ho Li)

Presentation at MELBOURNE NOW EXHIBITION, NGV (Professor Mark Armstrong)

Attendance at the OPHTHALMOLOGY INNOVATION SUMMIT 2014, US (Dr Jeanette Pritchard)

Presentation to PHILANTHROPY AUSTRALIA'S HEALTH AND DISABILITY GROUP (Dr Erol Harvey)

Presentation at TECHFEST 2014 (Dr Collette Mann)

Presentation at MONT ALBERT ROTARY CLUB (Dr Jeanette Pritchard)

Presentation at the SOCIETY FOR NEUROSCIENCE (Professor Marcello Rosa)

MVG AND BVA

Members of Monash Vision Group and **Bionic Vision Australia** formally met on eight occasions and had a number of informal discussions at conferences and seminars. The groups held a joint retreat in Melbourne on 20th June, which was chaired by Professor Lyn Beazley and attended by over 100 senior staff, researchers and students. MVG and BVA students and early career researchers had further opportunity to network during two, half-day professional development workshops, organised by BVA and run by **Professor Jonathan Rosen** from Boston University on 18-19th August.

Facilitated by **Dr Erol Harvey,** the groups also established the **Bionic Health Roundtable** initiative. Senior members of MVG and BVA met three times in the latter half of the year to devise a strategy for interactions across the Australian bionics community, beyond the ARC Special Research Initiative.

COMMERCIAL PROGRAM

INTELLECTUAL PROPERTY

Application #	Title	Filing Date	Type
2012304260	System and method for processing sensor data for the visually impaired	30-Aug-11	National Phase (AU)
621477	System and method for processing sensor data for the visually impaired	30-Aug-11	National Phase (NZ)
14/241182	System and method for processing sensor data for the visually impaired	30-Aug-11	National Phase (US)
12827966.8	System and method for processing sensor data for the visually impaired	30-Aug-11	National Phase (EU)
2014901055	Image processing method and system for irregular output patterns	25-Mar-14	Provisional patent (AU)
PCT/ AU2014/000153	Pools of Liquid Electrode Tester	8-Mar-13	PCT patent
2013900897	Micro-stimulator Device	15-Mar-13	Provisional patent (AU)
29/456362	Wearable Visual Sensor and Transceiver Apparatus	30-May-13	Design registration (US)
29/492435	Wearable Visual Sensor and Transceiver Apparatus MARK II	30-May-14	Design registration (US)

FUNDRAISING

With support from the Monash External Relations, Development and Alumni team, MVG was successful in securing a further $3 million for continuation of the project - $1M from The Finkel Foundation, $1M from Drs Marc and Eva Besen and a further $1M from Monash University. MVG will continue to seek additional funds to support the program beyond 2015.

MVG IN THE MEDIA

TV APPEARANCES

Dr Erol Harvey appeared on the **ABC News** on 6 March discussing 'Hi-tech's problem with getting the ear of investors'.

PRESS RELEASES

'Bionic eye research among NHMRC funded projects' (18 February)
http://monash.edu/news/releases/show/bionic-eye-research-among-nhmrc-funded-projects

'$3M funding takes Monash bionic vision closer' (2 December)
http://monash.edu/news/releases/show/3m-funding-takes-monash-bionic-vision-closer

RADIO INTERVIEWS

DR COLLETTE MANN — **VISION AUSTRALIA RADIO**
'3RPH' (broadcast 10 March).

DR NIC PRICE — **ABC LOCAL**
'Sundays with James O'Loghlin' (broadcast 7 December).

PRINTED MEDIA

MARCH — **VIRGIN AUSTRALIA VOYEUR**
Australian Designers (March 2014, Issue 152, page 115).

WINTER EDITION 2014 — **GLAUCOMA NEWS**
The Gennaris Bionic Eye (No. 53, page 5).

YOUTUBE

http://youtu.be/hQTmUvkfbd8
Mr Titus Tang, An assistive eyewear prototype that interactively converts 3D object locations into spatial audio (June 2014).

http://youtu.be/OMErZgrtUew
Dr Wai Ho Li, Wearable camera module and computer vision system for IVP (July 2014).

http://youtu.be/3BBzQGGBjhY
Dr Wai Ho Li, Computer vision for IVP running on synthetic images (July 2014).

http://youtu.be/HbmKFA57O2s
Dr Wai Ho Li, TR4Tegra – System overview (October 2014).

https://www.youtube.com/watch?v=Kq-9IINcKqo
Dr Alan Finkel AO discusses convergence science (November 2014).

ONLINE MEDIA

FEBRUARY

NINEMSN
http://www.health.ninemsn.com.au/healthnews/8801932/ipad-apps-could-improve-eyesight-beyond-20-20-vision
iPad apps could improve eyesight beyond 20/20 vision.

UBERGIZMO
http://www.ubergizmo.com/2014/12/wireless-eye-replacement-idea-gets-the-nod/
Wireless eye replacement idea gets the nod.

MARCH

ABC NEWS
http://www.abc.net.au/news/2014/03/06/hi-techs-problem-with-getting-the-ear-ofinvestors/5304532
Hi-tech's problem with getting the ear of investors.

OCTOBER

THE SCIENTIST
http://www.the-scientist.com/?articles.view/articleNo/41052/title/The-Bionic-Eye/
Into the brain. (Collette Mann, Arthur Lowery, and Jeffrey V. Rosenfeld)

MONASH UNIVERSITY NEWS AND EVENTS
http://monash.edu.au/news/show/monash-duo-win-international-accolade-for-wearable-computer
Monash duo win international accolade for wearable computer.

AUSTRALIAN MANUFACTURING
http://www.australianmanufacturing.com.au/13810/monash-receives-grant-to-test-bionic-eye-device-to-help-the-clinically-blind
Monash receives grant to test bionic eye device to help the clinically blind.

DECEMBER

THE AGE TECHNOLOGY
http://www.theage.com.au/technology/sci-tech/monashs-bionic-eye-closer-to-human-trials-20141202-11yeyf.html
Monash's bionic eye closer to human trials.

As a result of The Age Technology reporting MVG's donor funding in December, over 140 international news sources reported the story.

MONASH UNIVERSITY NEWS AND EVENTS
http://monash.edu/news/show/3m-funding-takes-monash-bionic-vision-closer-1
$3M funding takes Monash bionic vision closer.

NEWS MEDICAL
http://www.news-medical.net/news/20141203/Monash-Vision-Group-moves-a-step-closer-to-Bionic-Eye-clinical-trials.aspx
Monash Vision Group moves a step closer to bionic eye clinical trials.

GLOBAL SOURCES EET INDIA
http://www.eetindia.co.in/ART_8800707463_1800010_NT_132a7150.HTM
Landmark donations bring bionic eye closer to reality.

THE REGISTER
http://www.theregister.co.uk/2014/12/03/donors_back_monash_machine_eye_with_millions/
Donors back boffins' wireless eye replacement.

INTERNATIONAL BUSINESS TIMES
http://au.ibtimes.com/3m-funding-supports-monash-bionic-eye-quest-1394999
$3M funding supports Monash bionic eye quest.

OTHER ONLINE ARTICLES

VISION LOSS Resources for vision impairment
http://visionloss.org.au/bionic-vision/
Bionic vision how far away are we?

JOURNAL PUBLICATIONS AND SUBMISSIONS

Brain (February 2014), (Epub 16 April 2014), page 1-8 doi:10.1093/brain/awu072 'Occipital bending in depression' (Maller, Rosenfeld *et al.*).

Cerebral Cortex Advance Access (March 2014), doi:10.1093/cercor/bhu055 'The roots of Alzheimer's disease: are high-expanding cortical areas preferentially targeted?' (Anders *et al.*).

Frontiers in Neural Circuits (August 2014), 8;8:96 doi:10.3389/fncir.2014.00096 'A simpler primate brain: the visual system of the marmoset monkey' (Rosa).

Health Policy and Technology (August 2014), doi:10.1016/j.hlpt.2014.08.001 'Criteria employed by potential recipients considering adopting emerging visual technologies: the case of visual prostheses' (Anderson, Warren, & Lee).

Cerebral Cortex Advance Access (September 2014), doi: 10.1093/cercor/bhu214 PMID: 25246511 'Organizing principles of human cortical development – thickness and area from 4 to 30 years: Insights from comparative primate neuroanatomy' (Amlien *et al.*).

Neuroscience Research (September 2014), pii: S0168-0102(14)00215-6 doi: 10.1016/j.neures.2014.09.004 'Representation of central and peripheral vision in the primate cerebral cortex: insights from studies of the marmoset brain' (Yu, Chaplin, Rosa).

Journal of Neurological Engineering (submitted September 2014), 'Sputtered titanium nitride improves acute *in-vivo* charge injection capacity of platinum iridium electrodes' (Brunton *et al.*).

Neuroscience Research (October 2014), pii: S0168-0102(14)00223-5 doi: 10.1016/j.neures.2014.09.012 'Structure and function of the middle temporal visual area (MT) in the marmoset: Comparisons with the macaque monkey' (Lui, Rosa).

Brain Research (November 2014), doi: 10.1016/j.brainres 'Restoration of vision in blind individuals using bionic devices: A review with a focus on cortical visual prostheses' (Lewis, Ackland, Lowery, Rosenfeld).

CONFERENCE PROCEEDINGS

34th Annual Meeting of the Australasian Neuroscience Society (ANS) (Adelaide, 31 January 2014). Poster presentation 'Cortical neuropathology following implantation of wireless multiple electrode array for bionic eye prosthesis' (Yan *et al.*).

34th Annual Meeting of the Australasian Neuroscience Society (ANS) (Adelaide, 31 January 2014). Poster presentation 'Registering cortical mapping data to the marmoset atlas' (Chaplin *et al.*).

11th Annual World Congress of the Society for Brain Mapping and Therapeutics (Sydney, 17-19 March 2014). Invited Speaker 'The development of bionic vision at Monash University' (Rosenfeld).

The 11th International Conference on Low Vision. Plenary Session 2 (Melbourne, 31 March 2014). Invited Speaker 'The development of bionic vision at Monash University' (Rosenfeld).

Fort Detrick, US Army Medical Research Institute (Maryland USA, 11 April 2014). Invited Speaker 'The development of bionic vision at Monash University' (Rosenfeld).

23rd Annual Conference of the Australasian Society for Biomaterials and Tissue Engineering (Mantra Resort, Lorne, Victoria, Australia, 22 – 24 April 2014). Invited Speaker 'The development of bionic vision at Monash University' (Rosenfeld).

Royal Australasian College of Surgeons (RACS) Annual Scientific Congress and ANZCA Annual Scientific Meeting (ANZ Journal of Surgery 84 Supplement 1 NS01, Singapore 5-9 May 2014). Oral presentation 'Developing a bionic vision device for vision restoration in the blind' (Rosenfeld).

Vision Sciences Society (VSS) Annual Meeting 2014 (Florida, US, 16-21 May 2014). Poster presentation 'Temporal stability of reference frames in a 3D reaching task in monkey area V6A' (Fattori *et al.*).

Techfest 2014 (Adelaide, 30 May 2014). Invited Speaker 'Technology & eye research advancements – Part II' (Mann).

9th Meeting of the Federation of European Neuroscience Societies (Milan, Italy, 4-9 July 2014). Poster presentation 'Evolution of reference frames in posterior parietal area V6A of macaques during arm movements in 3D space' (Hadjidimitrakis *et al.*).

European Conference on Computer Vision (Zurich, Switzerland, 6-12 September 2014). Poster presentation 'A fast and flexible computer vision system for implanted visual prostheses' (Li).

International Symposium on Wearable Computers (Seattle, US, 13-17 September 2014). Oral presentation 'An assistive eyewear prototype that interactively converts 3D object locations into spatial audio' (Tang).

International Symposium on Wearable Computers (Seattle, US, 13-17 September 2014). Poster presentation 'An assistive eyewear prototype that interactively converts 3D object locations into spatial audio' (Tang, Li).

Festschrift – Gavin Fabinyi Royal Australasian College of Surgeons, Scientific Meeting (Melbourne, 15 September 2014). Named Lecture 'Bionic vision using a cortical approach' (Rosenfeld).

Special Symposium (Bionics Institute, 15 October 2014). Invited Speaker 'Development and testing of electrodes for the Monash Vision Group bionic eye' (Brunton).

The Eye and the Chip (Detroit, 3 October 2014). Invited Speaker 'Overview of MVG's Cortical Visual Prosthesis System' (Lowery).

Advances in Epilepsy: Neuroimaging, Radiosurgery and Brain Mapping (Milan, Italy, 20 November 2014). Invited Speaker 'Visual restoration: an update from the field' (Rosenfeld).

G20 World Brain Mapping & Therapeutic Scientific Summit (Brisbane, Queensland, Australia, 13 November 2014). Invited Speaker 'A new generation of prosthetics: bionic vision' (Rosenfeld).

The 6th Mt Lofty workshop on Frontier Technologies for Nervous System Function & Repair (Mt Lofty House, Adelaide Hills, 28-30 November 2014). Invited Speaker 'Vision Restoration using cortical vision prostheses' (Lowery).

FINANCIAL STATEMENT

Revenue, Expenditure and Contributions: 1 January – 31 December, 2014

FUNDS RECEIVED*	
ARC	$2,188,677
Monash University#	$150,000
Total Revenue	**$2,338,677**
ARC carry forwards from 2013	$500,573
Monash University carry forwards from 2013	$0
Other funds^	$184,500
Total funds available in 2014	**$3,023,750**

EXPENDITURE

ARC funds	$2,458,352
Monash University Funds	$196,313
Other	$172,390
Total Expenditure	**$2,827,055**
Total carry forwards to 2015	$196,695

IN-KIND CONTRIBUTIONS	
Monash University	$1,974,563
Alfred Hospital	$4,320
Grey Innovation	$117,324
MiniFAB	$208,740
Total In-Kind Contributions	**$2,304,947**

NOTES:

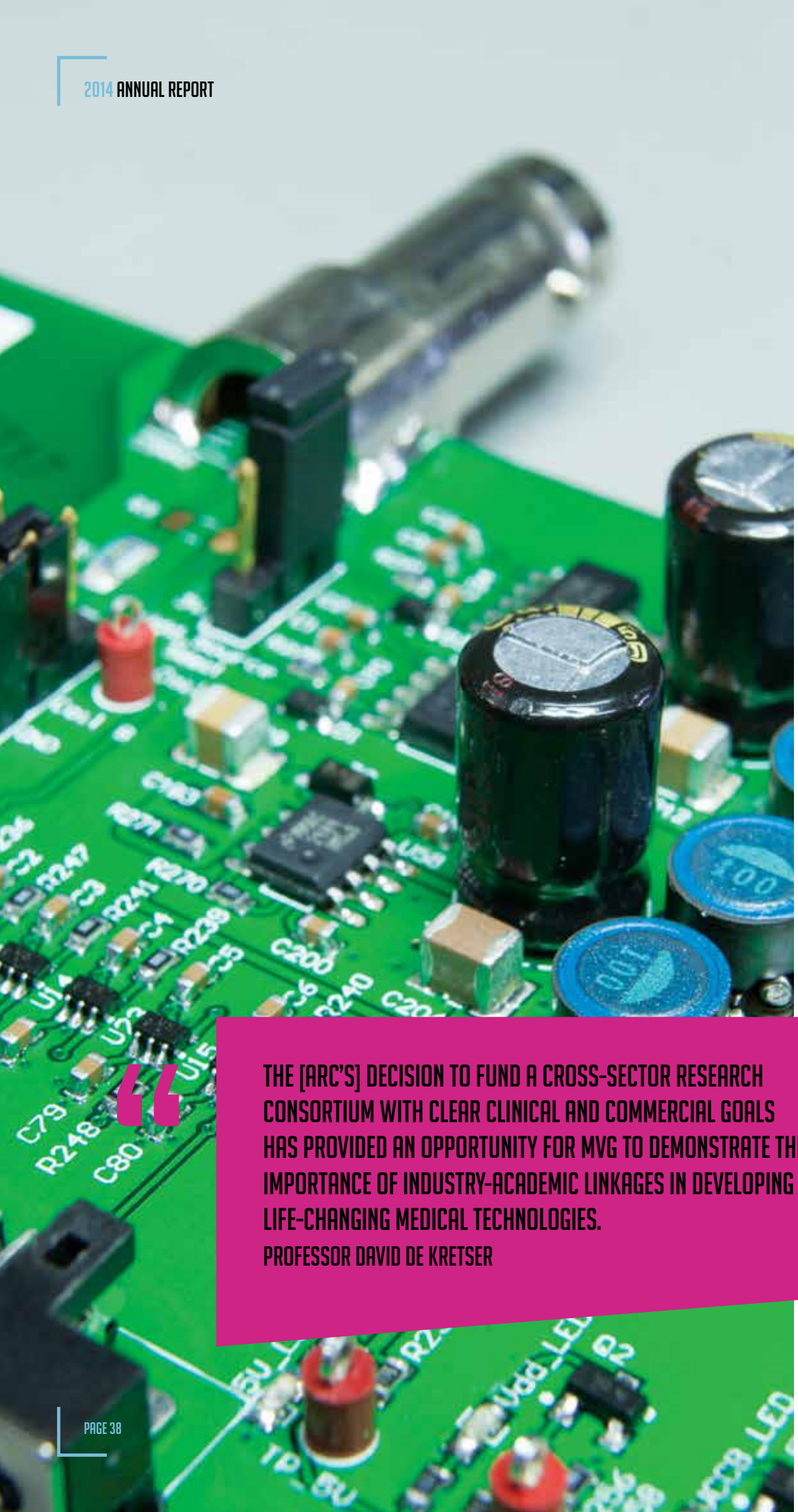
*Donations totalling $701k were received during 2014 from The Finkel Foundation, Drs Marc and Eva Besen and public donors. This funding will be carried forward in full into 2015 to cover MVG operations after the ARC Initiative closes.

^Funds recovered from The Alfred for clinical work not undertaken in 2010-2013.

Monash University provided $750k in advance in 2014 to sustain operations following the ARC Initiative closure. These funds will be carried forward in full into 2015.

KEY PERFORMANCE INDICATORS

KEY RESULT AREA	PERFORMANCE MEASURE	2014 TARGET	RESULT
DEVICE DEVELOPMENT	Final ASIC (microchip) delivered	1	1
	Functional demonstration of MVG implant in preclinical models	1	0
	Ethics approval for First in Human implantation obtained	1	0
	Device ready for First in Human implantation	1	0
GOVERNANCE	Breadth/experience of Advisory Board	Reviewed	1
	Frequency/effectiveness of meetings	2	3
	Quality of strategic plan (judged by Advisory Board)	Reviewed	1
	Adequacy of KPI's (judged by Advisory Board and ARC)	Reviewed	1
RECRUITMENT OF NEW STAFF AS A RESULT OF PROJECT	Research and development staff	0	0
	Technical support staff	0	0
	Administrative staff	0	0
SKILLS DEVELOPMENT	Undergraduate projects	4	4
	Postgraduate students recruited	0	1
	Postdoctoral researchers recruited	0	0
	Industry secondment (to and from industry)	2	2
	Visit to international facilities	2	14
RESEARCH OUTPUTS	Publications in journals that are ranked in the top 25% of their field	8	8
	International conferences (peer reviewed)	6	12
	Invited review papers and invited conference presentations	4	12
	Patent applications	2	5
	International visitors staying more than two weeks	1	1
OUTREACH AND COMMUNICATION	Webpage developed	N/A	N/A
	Press releases	4	2
	Press articles	8	>8
	Media appearances	4	7
	Expressions of interest in future human trials from sight-impaired people	20	>200
	Internal task/issue tracking/communication	Report annually	1
	External stakeholder communication	Report annually	1
	Meetings with related research teams	2	6
	Annual report	1	1
	Lectures to students	8	8
COLLABORATION	Meetings with Bionic Vision Australia group	2	8
COMMERCIAL	Annual in-kind and cash contributions met	1	1
	Commercialisation plan	1	0
	Funding strategy	1	1
	Funds raised	1	1
	Autonomous business entity	1	1



> THE [ARC'S] DECISION TO FUND A CROSS-SECTOR RESEARCH CONSORTIUM WITH CLEAR CLINICAL AND COMMERCIAL GOALS HAS PROVIDED AN OPPORTUNITY FOR MVG TO DEMONSTRATE THE IMPORTANCE OF INDUSTRY-ACADEMIC LINKAGES IN DEVELOPING LIFE-CHANGING MEDICAL TECHNOLOGIES.
>
> PROFESSOR DAVID DE KRETSER

ACKNOWLEDGEMENTS

MVG GRATEFULLY ACKNOWLEDGES THE SUPPORT OF THE FOLLOWING ORGANISATIONS AND INDIVIDUALS:

- Alfred Health and The Alfred Hospital
- Amaero Engineering Pty Ltd
- Australian Research Council
- Bionics Institute of Australia
- Bionic Vision Australia
- Blind Citizens Australia
- Centre for Eye Research Australia
- Cochlear Ltd
- Drs Marc and Eva Besen
- The Finkel Foundation
- Glaucoma Australia
- Grey Innovation
- Guide Dogs Victoria
- MiniFAB
- Monash University
    - o Monash Biomedical Imaging
    - o Central Administration and Monash Research Office
    - o External Relations, Development and Alumni
    - o Faculty of Engineering and Department of Electrical and Computer Systems Engineering
    - o Faculty of Health, Medicine and Nursing Sciences
    - o Industry Engagement and Commercialisation
    - o Monash Art, Design and Architecture
- Mr Gerard Menses
- Ms Vicki Tutungi
- Professor David de Kretser AC
- Professor Iain Clarke
- Professor James Patrick
- Professor Lyn Beazley
- Professor Peter Seligman
- Professor Ron McCallum
- Retina Australia
- Vision Australia

MVG also wishes to thank all volunteers who have participated in our research programs.

NOTES

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www.monash.edu/bioniceye

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Special Research Initiative in
Bionic Vision Science and Technology