Monash Vision Group 2012 Annual Report

Australian Research Council
Research In Bionic Vision Science And Technology Initiative

Monash Vision Group

Monash Vision Group is an ARC-funded Special Initiative with collaborative partners Monash University, Grey Innovation, MiniFAB and Alfred Health. This unique cross-sector consortium has two key goals; to develop a cortical vision prosthesis for testing in patients in 2014 and to build upon existing knowledge to create outstanding research capabilities in bionic vision science and technology in Australia.

www.monash.edu/bioniceye

The Alfred
Alfred Health is one of the four founding partners of the Alfred Medical Research and Education Precinct (AMREP), established five years ago on The Alfred campus. Alfred Health is providing expertise in the clinical program, including the recruitment, testing and after-care of patients.

miniFab (trademark)
The Micro–Nano–Bio Company

MiniFAB is a privately owned Melbourne-based company with a core business in the design, integration and manufacture of polymer micro-engineered systems for the Biotech, Health, Agriculture, Food and Environmental Sectors. MiniFAB is providing expertise in the design and fabrication of implantable devices and tooling.

Grey Innovation
Technology Commercialisation

Grey Innovation is a cutting edge engineering technology commercialisation company with experience in complex software, hardware and mechanical architectures across a number of industries and markets. Grey Innovation is providing expertise for the development of external electronics and processing components of the vision system.

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 Faculties of Engineering, Science and Medicine, Nursing and Health Sciences, with key inputs into all aspects of the Monash Vision project.
Introduction: The Monash Vision Group

The Monash Vision Group (MVG) bionic vision system is in development by a partnership between Monash University, Grey Innovation, MiniFAB and The Alfred Hospital, all located in South-East Melbourne, Australia. The group is truly multidisciplinary, using an electrical engineering approach to address a biomedical problem.

MVG draws on the skills of electronics, materials and mechanical engineers, robotic vision specialists, physiologists, neuroscientists, mathematicians, surgeons and ophthalmologists, psychologists, industrial designers and importantly people who are clinically blind.

The MVG system comprises a miniature camera worn externally by the user. High-resolution images from the camera are fed to a custom-designed pocket processor, 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 microchip or ASIC (Application Specific Integrated Circuit), 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 vision. The number of phosphenes depends upon the number of implanted electrodes, in our case this will be up to 473.

As the MVG device is ‘direct to brain’, it bypasses damage to the eye and optic nerve and may therefore provide benefit to up to 85% of people with currently untreatable
clinical blindness. MVG is on track to demonstrate its device in patients in early 2014. This 2012 Annual Report presents progress by MVG over the past twelve months towards this key goal.

Start of picture caption: As the MVG device is ‘direct to brain’, it bypasses damage to the eye and optic nerve and may therefore provide benefit to up to 85% of people with currently untreatable clinical blindness.
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**Message From The Chair**

**Professor David De Kretser AC**

In my first report as Chair of the Monash Vision Group Advisory Board, I am delighted to convey that the team is making excellent progress in its endeavours towards achieving its primary goal of demonstrating the ‘direct to brain’ bionic eye in patients in 2014. When I joined the Board in 2012, the team had produced a design for the full system and was in the process of manufacturing components for testing. 2012 saw the successful manufacture of the first end-to-end device, which is now undergoing optimisation and extensive testing prior to implantation in our first patients.

This progress has not come without challenges and issues to resolve. MVG has set itself a highly ambitious goal with a timeframe that does not allow for slippage or error. It is therefore a great credit to the whole team that we are on track and have developed an integrated and strong collaborative culture across our academic, industry and clinical partners. This collaboration is driving progress towards a successful outcome. Our sound financial management has provided us with a framework for optimising our outputs within budget and with additional support from Monash University we have retained expertise that may otherwise have been lost before the project’s conclusion. I would like to acknowledge and thank Monash University for these contributions and continued support of the initiative.

One of my key roles over the past year as Chair of the Advisory Board has been to assist the team in strategic planning for beyond 2013, including securing future funding. I am particularly pleased to report that in close collaboration with Professor David Penington of Bionic Vision Australia, we have high hopes of both of these important projects continuing beyond this first phase. Without a second round of funding, we run the risk of losing the value of the great scientific advances that have been made. Equally we are likely to lose the expertise and capabilities that have been central to the team’s success so far. This would be a tragedy for MVG, Monash University, the vision impaired community and more widely the medical bionics industry.

MVG is very fortunate to have a supportive Advisory Board that brings scientific, strategic and commercial acumen to the project. This has been instrumental in building a strong national and international profile and in providing important feedback to our management team, both on technical approaches and in our interactions with
government, industry and of particular importance the community that is blind. I would like to thank the MVG Advisory Board members for their time and valued input over the past twelve months.

Vision Science and Technology, MVG is well positioned to meet the challenges ahead. We will continue to strive towards our objectives and I am confident that through continued focus, dedication and the strong leadership from Professor Arthur Lowery, MVG will successfully achieve all of its goals in the coming year.

PROFESSOR DAVID DE KRETSER AC
Advisory Board Chair,
Monash Vision Group

Start of photo caption: “… it is to the credit of the whole team that we are on track and have developed an integrated and strong collaborative culture across our partners that is driving progress towards a successful outcome. ”
End of photo caption

Director’s Report

Professor Arthur Lowery

Start of photo caption: “This team now has the experience to take on new challenges and lead the world in biomedical systems engineering”
End of photo caption

Awarded $8M of Government funding
The Monash Group have contributed over $5M of in-kind contributions
Monash University contributed $3M in cash towards the project

I am delighted to deliver the third Annual Report of the Monash Vision Group. We are progressing well towards our goal of developing a prototype vision prosthesis, which could be developed into a product to benefit tens of thousands of people who are vision impaired. We are on track for a First in Human demonstration in 2014, provided we can guarantee funding to at least support the first recipient with training and technology upgrades.

This report covers the third year of development in a 4-year project that is funded by the Australian Research Council’s ‘Research in Bionic Vision Science and Technology Initiative’. In 2010, Monash Vision Group was awarded $8M of government funding to develop a cortical prosthesis, and Monash University has contributed $3M in cash towards the project. Monash Vision Group comprises Monash University, Grey Innovation, MiniFAB and The Alfred Hospital, who together have contributed over $5M of in-kind contributions to date.

Our system is designed to benefit the majority of people with untreatable clinical blindness, as it stimulates the brain directly with several hundred electrodes. Thus it is
the only solution for those who have lost their sight through trauma to the eye or optic nerve.

The flow of an image through the system starts with a miniature camera. As readily-available cameras (for mobile phones) provide megapixel images, we have developed sophisticated computational methods to extract the most important features of this image for ‘display’ on our electrode array. For example, in one mode, we can extract horizontal surfaces, such as tables and stairs, and display these to the user. In another mode, we can extract faces, and simplify them to emoticons—which are especially useful when talking to an audience, in meetings or social situations. This computation is performed by a pocket-sized processor worn externally to the body. The Pocket Processor communicates to a set of implant tiles, which sit beneath the skull on the surface of the brain. Each tile receives power and data from a transmitter coil placed at the back of the head—above the visual region of the brain. The tiles contain sophisticated electronics, to receive wireless power and data, and decode it to turn electrodes on and off. We have developed and tested a 500,000 transistor integrated circuit to perform this task. The electronics in the tiles is hermetically sealed into a ceramic case, with small electrodes on its base to stimulate the brain.

In 2010 we designed the system as a series of blocks. Key decisions were made after detailed investigations, such as using multiple implant tiles with no wiring between them. This considerably simplifies surgery and improves reliability, but requires a more efficient and complex wireless link. We then identified the materials and processes that would be required for manufacturing, and started testing them for biocompatibility and stimulation efficiency.

In 2011 we began developing the electronic system, including sending the first version of the integrated circuit for manufacture in August. This did not have a wireless link, but gave us valuable information on designing the data decoders and electrode drive circuitry.

2012 has been a year of developing the manufacturing processes for these tiles, then testing their functionality. We have also developed the pocket processor, its operating system and image processing software. We have demonstrated that the processor can power-up and communicate with several tiles using the wireless link, now incorporated into the second version of our integrated circuit. We have also developed tools and procedures for the actual implantation. Thus we now have a functional end-to-end system, from camera to electrodes, and a method of implanting it. This is a great achievement.

In 2013 we will be conducting extensive testing and simulation of this complete system, so we are sure of its safety and efficacy.

This will require the final design and manufacturing of the system to be ‘locked-down’ and our design engineers will become test engineers, critical of their own designs. We will continue to develop signal processing algorithms and test these using our simulation system. This system has goggles with small displays for each eye. Using MRI scans we have been able to map which part of a brain represents an image for a particular subject. Thus, we can predict which parts of an image they will see if a certain part of their brain’s surface were to be stimulated. We can then present this cropped
image to their eyes, and see how well they are able to function in the psychophysics tests that we have developed this year. We can then improve the image processing algorithms to suit different situations.

Developing a bionic vision system is a huge challenge. To meet this challenge we have built a team comprising many disciplines, across engineering, neurophysiology, psychology and clinical practitioners. 2012 has shown that the team is able to deliver complete systems, designed to meet the challenges of integrating biological and engineering systems. This team now has the experience to take on new challenges and lead the world in biomedical systems engineering, not just for bionic vision, but for any system requiring stimulation of the brain, such as to bypass damaged senses.

I look forward to 2014 when we will be ready for our First in Human demonstration and thank our supporters for their belief in our capabilities.

PROFESSOR ARTHUR LOWERY
Monash Vision Group director and project leader

Start of picture caption
Spectacles:
Camera
Electronics
Coil – wireless link to Cortical Implant

Cortical Implant:
Electrodes
Visual Cortex

Pocket Processor – electrical cord linking to spectacles
Signal Processing
Rechargeable Battery
Audible Feedback

Laptop – electrical cord linking to spectacles:
Clinician Interface
End of picture caption

Governance & Management

Advisory Board

The Advisory Board met at the Monash Conference Centre, Melbourne CBD on 17th April and 10th December 2012.

Start of photo captions
PROFESSOR DAVID DE KRETSER AC
Chair, MVG Advisory Board
Sir John Monash Distinguished Professor, Monash University

PROFESSOR LYN BEAZLEY
Chief Scientist
Western Australia and ARC Nominee

PROFESSOR JIM PATRICK
Chief Scientist
Cochlear Ltd

MR GERARD MENSES
Former CEO
Vision Australia

PROFESSOR ARTHUR LOWERY
Director
Monash Vision Group

DR DAVID LYSTER
Manager
Research Partnerships
Monash University
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Steering Committee
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MS VICKI TUTUNGI
Independent Chair
Managing Director
ProLearn
Level 3, 450 St Kilda Road,
MELBOURNE, VIC

PROFESSOR ARTHUR LOWERY
Director
Monash Vision Group and Head of Department
E C S E (January-April 2012)
Monash University, CLAYTON, VIC

PROFESSOR JEFFREY V. ROSENFELD AM
Director of Neurosurgery Alfred Hospital and Head, Division of Clinical Sciences and Department of Surgery, Central Clinical School
Monash University
The Alfred Centre, PRAHRAN, VIC

MS HALINA OSWALD
Director
The Steering Committee met on the following dates during 2012:
15th February
21st March
18th April
16th May
20th June
18th July
15th August
19th September
17th October
21st November

MANAGEMENT & ADMINISTRATION:
PROFESSOR ARTHUR LOWERY
Director

DR JEANETTE PRITCHARD
General Manager

MS SUZANNE HAYSTER
Administrative Assistant
Senior Investigators

Professor Arthur Lowery
Director and Project Leader, MVG

Professor Marcello Rosa
Chief Investigator, Department of Physiology, Monash University

Professor Jeffrey V. Rosenfeld AM
Chief Investigator, Division of Clinical Sciences and Department of Surgery, Monash University

Associate Professor Ramesh Rajan
Chief Investigator, Department of Physiology, Monash University

Associate Professor Lindsay Kleeman
Chief Investigator, Electrical and Computer Systems Engineering, Monash University

Dr Wai Ho Li
Chief Investigator, Electrical and Computer Systems Engineering, Monash University

Associate Professor John Forsythe
Chief Investigator, Department of Materials Engineering, Monash University

Professor Kate Smith-Miles
Chief Investigator, School of Mathematical Sciences, Monash University

Professor Ben Adler
Chief Investigator, Department of Microbiology, Monash University

Professor Julian Rood
Chief Investigator, Department of Microbiology, Monash University

Professor Erol Harvey
Partner Investigator and CEO, MiniFab

Associate Professor Anthony Hall
Partner Investigator and Director of Ophthalmology, Alfred Hospital

“Monash Vision is a great example of academic and industry collaboration. We were working as a team from the outset, with the researchers focusing on answering fundamental questions in their field of expertise, and industry delivering the platform that embodies the research. It’s efficient, constructive, and beneficial to both groups. We at Grey Innovation hope very much that this is the model for innovation going forward in Australia.”

Mr Jefferson Harcourt

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MVG implantable ASIC1 prototype assembled on a distribution board for preclinical
Production Development, Supporting Research And Testing

The primary objective of MVG is to develop an artificial system that restores central vision to patients who have no vision and/or damaged eyes or optic nerves. The MVG strategy has been to maintain focus on the development of the complete bionic eye system and is on track to proceed with the First in Human (F I H) pilot study in early 2014. The goal of the F I H product is to provide a functional system that incorporates design features that allow the product to progress to a commercially viable solution to assist people who are blind or vision impaired. In addition, the MVG system has been designed to retain the flexibility to be used in further research and discoveries, not only in bionic vision but also in other neurobiological research.

This section of the report describes the progress and status of the component design, manufacture and testing and the integration of these components into a working system that will be used in the First in Human study.

Core members of each team are listed below; MVG also acknowledges the extended teams at MiniFAB and Grey Innovation whose input is greatly valued. In addition to the core team members listed, MVG also acknowledges Professor Iain Clarke and his team at Monash University for their important input into the preclinical studies.

Schematic showing the flow of MVG components and testing, from camera through to clinical testing.
Background: ASIC1B Verification Hardware

Start of transcriber's note
Camera - arrow pointing right to pocket processor, arrow pointing right to signal processing, arrow point right to wireless link, arrow pointing down to implant tiles, arrow pointing down to surgical tools, arrow point right to preclinical testing, arrow pointing right to clinical program.

Inplantable electronics – arrow pointing right to implant tiles
Electrodes – arrow pointing left to implant tiles
End of transcriber's note

Engineering Team – Monash University
Prof Arthur Lowery
A/Prof Lindsay Kleeman
A/Prof John Forsythe
Dr Wai Ho Li
Dr Dennis Lui
Dr Damien Browne
Dr Anand Mohan
Dr Kun Zhou
Mr Andrew Stephens
Mr Horace Josh
Mr Titus Tang
Ms Emma Brunton
Prof Arthur de Bono
Prof Mark Armstrong
Mr Kieran John
Ms Jessica Cassar

Engineering Team – Grey Innovation
Mr Jefferson Harcourt
Mr Peter Bettonvil
Mr Mike Smith
Mr Graham Lyford
Ms Nicola Andrews
Mr Matthew Pennycuick
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Engineering Team - MiniFAB
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Engineering Team – Alfred Hospital
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Preclinical Team – Alfred Hospital
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Clinical Team – Monash University
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Dr Jerome Maller
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Ms Collette Mann
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Clinical Team – Grey Innovation
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Clinical Team - MiniFAB
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Clinical Team – Alfred Hospital
Prof Jeffrey Rosenfeld
Prof Anthony Hall
Prof Paul Fitzgerald
Prof Jayashri Kulkarni
Prof Harvey Newnham
Dr Helen Ackland
Dr Sanjeeva Ramasundara

External Electronics & Product Design

The Pocket Processor is a handheld device that can be worn, for example on a belt clip or in a shirt or trouser pocket and which supports the main video processing, user interface (indicators and controls) and clinician interface (data port). It is battery powered to meet medical safety isolation requirements and distributes power to all other elements in the system, with the exception of the external hardware running the clinician interface. The Pocket Processor has been designed to provide user controls with haptic and audio feedback, with the user able to select the algorithm and adjust menu functions which affect the way the camera image is interpreted.

In 2012 the prototype Pocket Processor was developed and demonstrated. The hardware and embedded software was designed and implemented with three different vision processing algorithms: Integral Sample, Edge Detection and Intensity Thresholding. These take the visual information from the camera in real-time and then process the image to identify the appropriate electrodes to stimulate to replicate key visual information to the user.

The Pocket Processor hardware was further developed, integrated into test stimulator platforms and used to test the early prototypes of the Implant Tiles, prior to preclinical studies.

MVG initiated Industrial Design work during 2012, which focused on the development of concepts for the wearable components of the bionic vision system. The engineering and industrial design teams sought guidance from technical staff at Vision Australia to assist in the development of four primary product concepts, which have been designed to be minimally intrusive to the wearer whilst retaining the required functionality.

During 2013, these concepts will be trialled with potential users to obtain feedback for further optimisation of the device design and functionality. This provides the engineering team with the focus needed to ensure that the product modules can be integrated into a workable, ergonomic system that is fit for purpose.
Signal Processing

During 2012, the Signal Processing team built upon software and hardware developments in 2011, for use in psychophysics testing and the First in Human pilot study. They also pursued research questions for next generation devices.

In preparation for the First in Human pilot study, the team has spent significant effort on the development of signal processing software for the Pocket Processor, in particular custom Digital Signal Processing (DSP) code to further optimise performance of the device in terms of power and speed.

Software tools were developed for supporting the Psychophysics and Signal Processing programs. Challenges included achieving real time performance on computationally and power limited hardware, such as that being used for the Pocket Processor. New software tools were built to facilitate the generation of phosphene patterns based on visuotopic maps from neuroscience findings, in conjunction with expected surgical placements of individual implant tiles.

This work will continue throughout 2013 and will be used to feed into the protocols used in psychophysics testing to mimic as closely as possible our understanding of the vision that will be perceived by a user of the MVG bionic vision system.

The MVG Hatpack developed in 2011 is a portable simulation device that utilizes a digital camera to capture high resolution video, which is processed by a hardware-based image processing implementation on an FPGA.

The image stream is transformed into a low resolution pattern of phosphenes, based on a neurophysiological mapping model and made viewable via a head-mounted display. Building on this hardware, a second Hatpack design was developed in 2012, incorporating a 3D sensor and improved ergonomics, which was used to investigate RGB-D (3D and colour) sensing. The falling cost and miniaturisation of 3D sensors makes this an easy to integrate option with real promise for next generation devices.
Additionally, mapping of indoor environments and localisation of people within the environment was explored and a staircase detector developed and tested.

The Hatpack underwent further modification to enable its use in the development of psychophysics test protocols (see Clinical Program – Psychophysics). New user interface modes (manual and automatic) for image thresholding were developed and refined along with corresponding algorithms and assembly/interfacing of external components.

As well as the requirements for the First in Human pilot study, non-invasive approaches for vision supplementation have been investigated. The team met a number of times with technical staff at Vision Australia to understand the kinds of tools that might be useful for the communities that are blind and vision impaired.

This work has been supported by seed funding awarded to Dr Wai Ho Li in 2011 by the Faculty of Engineering at Monash University. This will progress further during 2013, with discussions and psychophysics tests with a Vision Australia technology focus group.

In other work, a lightweight algorithm to perform plane detection and segmentation was proposed for implementation on the FPGA. This hardware based approach was refined and implementation began on a high-end FPGA that was deemed suitable after careful research of currently available technology.

The Signal Processing team have embraced many opportunities to demonstrate their work, presenting at three international conferences during 2012 and the provisional patent filed in 2011 describing novel signal processing techniques also progressed to PCT during 2012. Dr Wai Ho Li enjoyed media attention when he was featured describing the Hatpack and signal processing techniques on Al Jazeera English television, filmed at MVG in May.

**Wireless Link**

During 2012, the wireless link went from a concept of the modulation scheme, to a complete functioning system. Fundamental to the design of the link, was the power and data requirements of the ASIC. Significant time was spent working with the ASIC team to understand what voltage and currents were needed to power the ASIC and the electrodes, also to understand the signal integrity requirements of the recovered data. This formed the basis of the link development.

Preliminary simulations were performed to determine what factors were critical and the most appropriate circuit topology. It showed the coupling coefficient (how much power is transmitted) between the transmit coil and receive coil was very important. The link needed to be designed such that it would work with a large variation in distances and
orientations between the coils. It was evident that the variation in coupling coefficient needed to be minimised.

Several receive coils and a variety of transmit coils with different shapes and sizes were constructed and tested. The geometry of the transmit coil was determined, to achieve the optimum range of coupling coefficients for the transmit/receive coil positioning. Preliminary link measurements were performed, to determine the voltage gain and frequency response of the link.

Circuitry for the transmitter was developed and used to further optimise the transmit coil, to provide the most efficient and reliable power and data transfer, for the chosen carrier frequency and modulation scheme. The receiver circuit was investigated, which had to be robust, reliable and small enough to fit inside the implant tile. Many circuits and ideas were investigated, simulated and tested. A complete tile (using large manageable parts) was fabricated, which comprised the prototype receive circuit, ASIC1B and LEDs to represent electrodes. A complete end to end wireless system from camera to LEDs (electrode equivalent), was successfully demonstrated.

Start of photo caption
Thermal testing of prototype receive coils
End of photo caption

ASIC2 will have different power and data requirements to ASIC1B, therefore during 2013 the new requirements will need to be determined and the receive circuit and receive coil revised accordingly. They will be optimised for power efficiency reliable data transfer, patient safety and longevity.

The prototype receive circuit and receive coils will be built and extensively tested. Tests will include; the region of operation for a single coil and multiple coils, thermal, overload and failure mode testing. A complete miniaturised version of the circuit, including ASIC2 will then be fabricated and tested extensively ahead of incorporation into the final First in Human implant package.

Start of photo caption
Prototype transmit and receive coils
End of photo caption

**Implantable Electronics**

This year saw the implementation of MVG’s second generation Application Specific Integrated Circuit (ASIC1B). This prototype provides the functionality of the ASIC1, but is capable of decoding wireless data. A single ASIC1B can drive up to 45 electrode channels - MGV will be using 43 of these channels for simulating electrodes in each implant tile. The power required to operate ASIC1B is derived by a small number of components externals to the ASIC but are within the implanted package. Up to 11 devices can be driven from the same wireless coil, which equates to a maximum of 473 stimulating electrodes.
All of these electrodes can be programmed individually with a stimulation waveform, which are expected to be patient and electrode specific. Each electrode can be stimulated individually, or in conjunction with other electrodes. To reduce the power requirements of the system, new techniques were employed in the implementation of the ASIC1B digital circuit, which yielded significant power savings. A smaller and lower voltage technology was employed, which has resulted in the digital core of ASIC1B using approximately one quarter of the power required by ASIC1.

The analogue electrode driving circuit was also redesigned for the new technology and architectural changes to the analogue stimulation circuitry have delivered significant power reductions relative to ASIC1.

ASIC1B was delivered after fabrication in late 2012. The devices have been tested and show a higher yield (97.5%) compared with ASIC1 (90%). Wireless testing of the devices has also verified their functionality. Testing has provided additional insights into the circuit’s behaviour. This new information has resulted in significant changes and improvements to the ASIC2 design, with other experiments also having provided information about device safety, the results of which have influenced the ASIC2 design.

The implementation of ASIC2 began in 2012; this will be the First in Human prototype ASIC. The architecture of ASIC2 provides the functionality of ASIC1B with the addition of safety devices and circuitry more suited to in vivo stimulation. It is expected that the device will have improved performance over the ASIC1B, including savings in power usage and safer operation. Part of the design of ASIC2 is being completed by a microchip design house, as a risk mitigation process that will reduce the time to completion of the device and provide third party independent feedback to the design team at Monash University. The ASIC2 will be ready for fabrication by early March 2013, with delivery expected in June 2013.

These ASICs are developed with testing in mind, for which the Monash Vision Group has designed and implemented equipment and protocols. The tests will ensure a high quality of device, suitable for use in the First in Human demonstration in early 2014.

“I love working on engineering problems that directly impact people’s lives. This project has allowed me to do just that while tackling novel research challenges alongside an interdisciplinary team of experts; nothing is better!”
Dr Wai Ho Li

Start of photo caption
ASIC1B mounted in a CPGA package for bench testing

**Implant Tile And Packaging**

Active implantable medical devices such as the Implant Tiles are required to reside safely in the human body for extended periods of time, in many cases for years. As such, these types of implantable devices have many additional requirements compared to non-implantable products to maintain safety and efficacy, whilst implanted into a person. In particular the biocompatibility, the ability of the implant to perform its function
inside the body with the appropriate host response, is critically dependent on the materials used, the geometric structure of the device, and its hermetic seal.

During 2012 the team investigated the fundamental application requirements, the required materials and fabrication processes to build the Implant Tiles. Many Tiles and implant components were designed and fabricated to assess various critical aspects of the system design, including electrode geometry, stimulation criteria, isolative and stimulating coatings stability, host response to materials, surgical technique, biological response to surgery and chronic implantation and trials for testing and packaging the internal electronics.

Important outcomes from this work were the establishment of:
- The implant design
- The impact of implant design on system architecture
- Materials to be used in the implant, suppliers and fabrication houses
- Production process flows
- Test criteria

MVG has chosen to use a ceramic package to hermetically encapsulate the ASIC, with 43 stimulating electrodes fed through the package base and a cap welded over the electronics. The electronics, including the ASIC, will sit upon a circuit board subassembly within the implant. This subassembly will connect the ASIC to the electrodes and the frontend of the wireless system. It has been designed to be assembled and electronically tested before being placed within the ceramic package.

In 2013 this work will be extended to finalise the implant design, implement testing procedures, build further test implants and manufacture the final implants for use in preclinical testing and the First in Human pilot study.

**Implantable Electrodes**

**Electrical and Mechanical Design**

Significant work was performed during 2012 on improving and optimising electrode performance by the use of insulating and stimulating coatings. The process of coating the implantable electrodes with a 2-3 micron layer of insulating material was refined, which improved reproducibility in terms of coating thickness, adhesion of the coating to the platinum electrode and the formation of the stimulating region of the electrode. All of
this work was performed in–house by MVG.

The team identified materials which could improve the stimulation parameters of the electrodes, potentially resulting in the ability to generate phosphenes at lower thresholds, thereby improving the safety and efficacy of the device. Suppliers coated the MVG electrodes with these new materials, which will be tested in preclinical studies in 2013. Should the results be successful, these are likely to be used in the First in Human implant.

There was a continuous schedule of fabrication and delivery of single electrodes and implant arrays (constituting 4 and 45 electrodes, with both wired and unwired versions) to the preclinical team for biocompatibility, safety and stimulation assessment, as well as testing of functional coatings. For the delivery of the chronic implantable devices the MVG team used an E t O method of sterilisation and established links with several local sterilisation service providers. The assessment of this sterilisation method will progress into 2013. The delivery of implantable devices will continue into 2013 for further chronic studies and functional preclinical testing in preparation for the first in human study in 2014.

Start of diagram caption
Impedance (left) and cyclic voltammetry (right) measurements demonstrate the increase in charge storage capacity (a lowered impedance) of Pt/Ir electrodes coated with graphene/polyelectrolyte multilayers compared with uncoated Pt/Ir
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End of transcriber’s note

**Functional Coatings Research Plan**

In 2012, different types of coating were developed to enhance the performance of the implantable electrodes. Although these coatings will not be used in the First in Human implants, they constitute an important part of next generation products to extend the operational lifetime of the implants and minimise damage to surrounding tissue upon implantation of the device into the visual cortex.

To enhance the electrical property of Pt/Ir electrodes in terms of decreasing impedance and improve the charge injection density, a graphene/polyelectrolyte multilayer coating was built up on the Pt/Ir electrode surface. The resulting coating provided an increase of charge storage capacity compared to unmodified Pt/Ir electrodes, which enable the use of much lower current/voltage to achieve the same level of stimulation to surrounding neurons.

Another approach to improve the electrical stimulation efficiency is to lower inflammatory responses (less reactive astrocytes) after surgery/electrode insertion, since fibrosis/astrocytes around electrodes following array insertion will pose a physical/electrical barrier to the electrical signals, especially for chronic applications. In
this case, xyloglucan, a polysaccharide with a potential anti-inflammatory effect has been immobilized onto the polyethylenimine pretreated Pt/Ir electrodes. By coating electrodes with this sub-micro layer of xyloglucan, fewer astrocytes were found around electrodes based on our preliminary study, compared to unmodified Pt/Ir electrodes at 21 day time point.

During 2013, coatings with biomolecules present at the electrodes surface will be investigated. Two candidates will be studied; One to increase cell survival after electrode insertion into the brain and the other to lower inflammatory responses following device implantation.

**Component & System Testing**

In parallel with device development, a number of test systems were designed and fabricated by the engineering team ready for use in verification procedures during 2013. These systems are critical to verify the performance of each of the system modules both prior to and during the functional preclinical test phase.

**ASIC Verification hardware** - Every generation of the MVG ASIC has been designed to have progressively more functionality. This approach allows each function to be thoroughly tested prior to final implementation. Test boards were designed, whereby the ASIC is packaged in a ceramic pin grid array (CPGA) and the test board allows the performance of the microchip to be verified. The boards were designed such that the Pocket Processor can provide stimulation signals directly to electrodes in the first generation implant tiles via a series of wires. Two additional CPGA boards were also designed and built for the ASIC1B testing, including wireless transmission.

**Implant Electrode Tester** - Prior to implantation each electrode array must be tested to verify the safe operation of all the stimulation circuits. The implant electrode tester jig provides facility to confirm the electrode signals without directly contacting the electrodes.

**Preclinical Stimulation System** – A series of stimulation systems have been designed and produced to facilitate the testing of each iteration of the Implant tile – from fully wired to fully wireless – prior to preclinical testing.

Wireless Coil Transmitter – The transmission between the external coil and implanted ASIC is a unique amplitude and pulse width modulation. Transmission hardware has been developed, which encodes commands from the Pocket Processor. The prototype transmitter utilises a linear driver to provide the flexibility necessary for initial testing; this will be developed further and optimised during 2013 for integration into the patient-worn headgear.

“An integrated well-designed system has its own intrinsic beauty.”

Professor Erol Harvey

Start of photo caption
MVG’s end-to-end system - from camera to implantable electrodes (left) Wireless
Surgical Aid Development

The MVG Surgical Aid program includes the development of tools for surgically implanting the tiles into the human brain with minimal damage and also packaging for the Implant Tiles to protect the electrodes and improve handling during device fabrication, testing and surgery.

The custom-designed surgical tool produced in 2011 underwent extensive testing during 2012, followed by a number of upgrades to both the tool and control unit to improve:

- The insertion parameters
- The tolerance of handling the Implant Tiles to minimise damage to the patient and electrodes during surgery.
- The transfer of the arrays in and out of the packaging
- The manual pickup of the arrays which can facilitate easier removal of the arrays if required.

Further to this, an adaptor for a commercially available implant tool was designed and fabricated to enable the preclinical team to compare performance of this with the MVG tool. The adaptor facilitated transfer of the Implant Tiles within a surgical setting during preclinical testing without the need for manual handling, with the design also reducing the risk of damage to the electrode tips.

The implant tile packaging was upgraded and now provides not only housing to protect the electrode arrays during transportation, handling and use in surgery but also provides a means of housing the arrays during non-destructive bench testing, which allowed verification of array functionality prior to implantation.

Preclinical Program

Biocompatibility, Safety and Functionality of Implants and Tools

During 2012, the preclinical team has successfully tested stimulation efficacy and durability of functional implants and their compatibility with brain tissues using newly developed novel electrodes, implantation techniques and stimulation protocols. These results have laid a solid foundation for pursuing and optimising the new electrode design for achieving better outcomes in implant safety and efficiency. Experimental
findings will be prepared for publication during 2013. In close collaboration with the engineering team, detailed verification protocols were developed for implantation of MVG tiles using custom-designed and commercially available implant tools.

This work involved extensive collaboration between the preclinical and clinical teams and MVG’s industry partners. This multi-disciplinary approach proved to be critical to the success of the work being undertaken. Every design decision has a multitude of difficulties due to the number of requirements of both the engineering and biological systems. The full extent of experimental outcomes was used to contribute to many aspects of product development for the MVG prosthesis, including, but not limited to, design and development of electrode geometry, surface coatings and optimising stimulation parameters for improving stimulation efficacy and ensuring safety of stimulation to brain tissues. Our robust repeatable methods of array implantation have been developed for the next phase of clinical trial.

A large body of our extensive preclinical work on determining safety, functionality and longevity of the implants would also ensure the fulfilment of regulatory requirement for the proposed device to be used in the human trials.

**Functionality and Effectiveness of Advanced Systems**

This research program has two aims, which represent key steps in the development of the MVG cortical implant. It provides important functional data about the effectiveness, durability and biocompatibility of the electrode arrays in realistic conditions, similar to those likely to occur following implantation in a human volunteer. It also explores a number of specific questions relating to the organisation of the visual system, with the aim of obtaining a better model of the circuitry underlying conscious vision. This basic understanding of the visual cortex is necessary to optimise the outcomes expected from the implantation of the MVG device. In both cases, the information is obtained based on electrophysiological experiments, which provide the necessary level of precision in quantification of the effects of ‘natural’ visual stimulation, as well as electrical stimulation of the cortex.

**2012 Landmarks**

**Development of Techniques for Multiple Receptive Field Mapping**

In order to predict the locations of the phosphenes elicited by each electrode, we must be able to map the location of the receptive fields of neurons near each electrode. We have developed a new technique to do this automatically. Shown here are receptive field maps obtained simultaneously from 49 electrodes in the same array. All receptive fields are located to the right of the fixation point (white cross), as expected for recordings from V1 in the left hemisphere. These experiments demonstrate the precise topographic nature of the visual information that is likely to be elicited by
microstimulation of V1.

Discovery of a New Visual Area

As part of the tests involved in mapping the representation of the visual field in the primary visual area, the team came across some unexpected data, in the form of very large receptive fields in the far periphery of the visual field (i.e., the outer boundaries of what a person can see). A more careful exploration of this region demonstrated the existence of a novel visual field representation in the primate brain, named area prostriata. This area is unique in that most of its neurons are monitoring what is happening ‘out of the corner of the eye’.

This new finding was reported in a paper published in the journal ‘Current Biology’ and resulted in the appearance of Professor Marcello Rosa on a number of radio programs to explain this discovery.

Clinical Program

Psychophysics

The purpose of the psychophysics program is to design and validate test methodologies for training and rehabilitation of the first patient(s) undergoing surgery.

Existing literature on visual prostheses simulation is sparse and as research grows in this new area of bionics, there is a great need for simulation or visualisation of the possible results of such an implant. Visual prostheses simulators such as the MVG
Hatpack serve as excellent platforms for researchers to investigate the effectiveness of implemented algorithms and understand the importance of certain parameters prior to tests with patients. The MVG psychophysical tests involve normally sighted individuals attempting to complete tasks with the limited vision provided by a simulator.

The aim of this study is to determine the most practical and user-friendly format on a set of common tasks including object identification, hand-eye coordination and navigation of the everyday environment. Results from these tests and discussions from formal focus groups will be used by MVG engineers to determine algorithmic protocols for the device. The results will also provide information on how to train users of the device, as well as highlighting areas for improvement.

The MVG Hatpack was used to test and evaluate different image processing algorithms and functions through psychophysical experimentation; given that there will be a binary level limitation on stimulation for initial implant recipients, the simulated phosphenes will need to be converted from full greyscale values to either black (no intensity) or white (full intensity) so that the patient can differentiate contrast. In order to achieve this conversion, a threshold needs to be chosen which effectively defines whether a pixel should be black or white depending on its luminance. The challenging part of this process is in the definition and selection of a good threshold. The Hatpack provides three different modes of threshold selection: Static, Manual and Automatic. Using these modes, preliminary tests were conducted with Monash staff and students, to establish which luminance threshold selection method would be most pragmatic and useful for implementation in the MVG device. This first phase of testing demonstrated the minimal information required by a normal-sighted person to recognise shapes of varying monochromatic dimensions, using the three different luminance threshold modes in a stationary task.

In the next phase of testing, the same participants will be recruited to conduct a hand-eye coordination test using the same three luminance threshold selection methods. Navigation tests will also be conducted incorporating phosphene drop-out rates and varied detection modes. Once the most suitable algorithms have been determined, then implemented, from these series of tests with Monash staff & students, MVG will recruit age-matched participants from the public domain and conduct the same three series of tests with this larger sample.

**Patient Care**

A high priority for MVG is patient care post-implantation; patients will initially need extensive training and guidance on use of the device, the nature of which will depend on how much of their sight is restored. With this in mind, MVG has held discussions with affiliate groups such as Vision Australia and Guide Dogs Victoria in connection with their respective areas of expertise and how the patients may benefit from involvement from these groups. Interactions have included discussions on the types of algorithms that may be useful, the development of Mobility and Orientation programs and also more broadly public information sessions to members of Vision Australia, Retina Australia and Blind Citizens Australia with question and answer time. It is probable that potential patients will be members of these affiliate groups.
Focus Group

MVG wished to collect the perspectives and expectations of the vision impaired and blind community regarding the bionic eye and its trials, so as to inform the design and refinement of protocols and procedures, and the development of the technology itself.

Four focus groups were held with small groups of adults who are legally and/or fully blind. Prior to the focus groups, the participants heard an information session presented at Vision Australia by Professor Jeffrey Rosenfeld on the bionic eye and plans for patient tests. The focus group discussions surrounded topics including expectations, motivations, concerns and other factors in the participants’ decision-making surrounding the bionic eye and participation in its early trials and how the information session changed or influenced their decision-making. The participants’ discussions were analysed for recurring and prominent themes, with the discussion being characterized by five major themes.

1) Motivations - The participants described multiple factors which would make them more likely to accept the bionic eye and take part in its early tests.
2) Barriers - In contrast, a number of factors that participants’ believed would discourage their trial participation and acceptance of the bionic eye were identified.
3) Supports and processes - Participants discussed many practical considerations regarding their participation in the bionic eye’s early tests and in their decision process regarding such participation.
4) Frames of reference - Particular factors influenced how they viewed the bionic eye and the opportunity to participate in its tests.
5) Uncertainty - Many participants expressed a desire for finding out more about the technology and the program to help with participant rehabilitation.

In general, the insight into the decision-making of vision impaired persons provided by this study will inform the procedures and protocols that MVG develop to recruit participants in the first in human pilot study and ensure all interested test candidates clearly understand what participation entails. More specifically, understanding the desired therapeutic benefits which may motivate people with vision impairment to accept the bionic eye is invaluable to MVG. The findings from these focus groups will be compiled into a manuscript and submitted for publication in 2013.

MRI Visual Cortex Mapping

This study involves the 3-Tesla Magnetic Resonance Imaging (MRI) investigation of the anatomical extent of the primary visual cortex (V1), the visualisation of the relevant identifying landmark, the band of Gennari and subsequent detailed anatomical mapping of the cortex. Detailed structural and diffusion analyses of the images are conducted following each participant’s scan. The study involves the comparison of age-matched severely vision impaired participants with normally sighted control participants and the MRI scans are conducted at the Monash Biomedical Imaging facility at Monash University. The findings of this study will allow the development of predictive algorithms.
aimed at the identification of the anatomical areas of V1 in vision-impaired patients via MRI and the subsequent planning of the electrode grid design and placement of the implanted electrodes in the ensuing surgical implantation component of the Bionic Eye Project.

Participant recruitment is complete for the Visual Cortex MRI Study and a number of participants have undergone the required MRI imaging. After each imaging session, the images have been examined and relevant adjustments made to the imaging procedure to optimise visualisation of the band of Gennari in subsequent sessions. The study is expected to be completed by the end of 2013.

First In Human Implant Study

The First in Human Implant Study is a clinical pilot study to be undertaken at The Alfred Hospital. The aim of the project is to assess the level of clinical feasibility of the subdural surgical implantation of an electrode array for the purposes of microstimulation of the primary visual cortex in severely vision-impaired patients. The pilot study will include 1-2 patients only, who have such severe vision impairment that there is no perception of light. A comprehensive submission was made to The Alfred Hospital Human Research and Ethics Committee and is currently under review. In addition, a submission was made to The Alfred Hospital Clinical Innovations Committee and received favourable review. Following approval, participant screening will begin in order to recruit optimal participants for the FIH pilot project, with implantation surgery scheduled to be conducted in Department of Neurosurgery at The Alfred Hospital early in 2013. Planning for the extensive medical and psychological screening processes involved in recruitment has been confirmed and the screening procedures and relevant staff participation have been confirmed.

Research Training & Skill Development

Postgraduate and Undergraduate Student Projects and Internships

Amanda Davies
First Year PhD (physiology)
PhD Thesis: Neural correlates of detecting motion in the visual area MT
Supervisor: Professor Marcello Rosa

The aim of Amanda’s project is to increase our understanding of how neurons communicate within the brain when processing motion, so that we can better understand what information is required for input into devices for creating vision. In her
first year, Amanda has co-authored a paper in Current Biology, and has a further paper in the draft stage.

Simone Carron  
First Year PhD (Physiology)  
PhD Thesis: What neurons in cortex are susceptible to damage from impact forces and can they be rescued?  
Supervisor: Associate Professor Ramesh Rajan

Insertion of an electrode array into the brain involves an impact force from insertion and a travelling surface stress wave that may itself cause damage to brain neurons, especially in the cortex. Simone is examining if particular cortical neurons are more susceptible than others to impact forces and if this susceptibility can be reduced by systemic treatment with agents such as progesterone that reduce brain inflammation and neuronal damage.

Emma Brunton  
Second Year PhD (Electrical Engineering/Physiology)  
PhD Thesis: Optimising cortical microelectrodes for prosthetic devices  
Supervisors: Professor Arthur Lowery and A/Professor Ramesh Rajan

Broadly, Emma investigates how electrode geometries affect the efficiency of electrical stimulation in the brain.

She has completed two studies using computer modelling to determine the ideal shape of the activating surface to be used on an electrode and how this will affect the power consumption, an important factor that will determine the utility of any cortical prosthetic device. During 2013 Emma is extending her studies to examination of novel electrode materials and their physiological effects for activation of neurons in cortex.

Andrew Coohson  
Second Year PhD (part-time, Mathematics)  
PhD Thesis: Optimisation of electrode array currents for neural prosthetic applications  
Supervisor: Professor Kate Smith-Miles

Andrew aims to use mathematical modeling techniques to optimise current flow around bionic eye cortical electrodes. During 2012, he has produced a simplified model which optimises accuracy of voltages produced at target regions of the brain, assuming that the current would not interact with neural function. Most recently, Andrew has extended the model, in which the effect of the optimised current on neural membrane potential and spiking probability of neurons are also optimised.

Horace Josh  
Third Year PhD (Electrical Engineering)
PhD Thesis: Low resolution vision for the Monash bionic eye  
Supervisor: Associate Professor Lindsay Kleeman

Horace is investigating the effects of different image processing functions, algorithms and techniques in order to find the best possible way of presenting visual information to the implant recipient. After development of the Hatpack, which includes a range of different image processing functions/algorithms, a number of preliminary psychophysical tests were carried out during 2012 in preparation for a more rigorous set of tests that will be performed during 2013, involving participants from the general public.

Titus Tang
Third Year PhD (Electrical Engineering)
PhD Thesis: Interactive assistive technologies for the vision-impaired  
Supervisor: Dr Wai Ho Li

Titus' research looks at combining the rich information provided by colour and depth sensing technologies and the usefulness of stereo audio into assistive devices that help vision-impaired people in navigation and object manipulation. Some tasks, such as sorting objects by their colour, are deemed difficult or even impossible to be performed by the vision-impaired. Titus' research is based on the idea that such tasks can be made easier or possible with the aid of intelligent software that extracts semantic information from visual data and converts it into an alternative form that is both intuitive and meaningful to the vision-impaired user. Research throughout 2012 has seen the development of a prototype device that uses stereo sound and speech to convey spatial and visual information to the end user. His work is targeted to work in complement with prosthetic vision and will involve collaboration and consultation with Vision Australia and the vision-impaired community in general.

Ajay Singh, Loretta Romano & Lambrini Kahogiannis
Masters in Business (Science and Technology)
Supervisors: Professor Michael Vitale, Dr Jeanette Pritchard

Ajay, Lambrini and Loretta's task for their Master's project with MVG was to examine the commercial opportunities available for the MVG bionic eye and to provide recommendations for the best commercial pathway for the technology. The project built upon the work undertaken in early 2012 by the 2011 Master's graduates (see Business Plan, pg37) and culminated in the team producing a 70-page document, which included a description of the MVG system, the addressable market, commercialisation strategies reimbursement pathways and a suggested business plan.

Ross Anderson
Honours (Psychology)
Honours Thesis: Cortical visual prostheses and vision impaired persons: Exploring expectations, motivations, concerns and decision-making  
Supervisors: Dr Stuart Lee, Dr Narelle Warren, Associate Professor
Ramesh Rajan, Dr Helen Ackland Ross' Honours project involved running a series of focus groups with individuals who are blind and vision impaired to understand their perspectives and expectations regarding the bionic eye and plans for first patient tests. MVG will use the outcomes of these focus groups for the design and refinement of test protocols and procedures and the development of the technology itself. Ross' project was run in close collaboration with Vision Australia, Guide Dogs Victoria and Blind Citizens Australia.

Yun Tan
Honours (Electrical Engineering)
Thesis: Wireless Power Transfer for Biomedical Implants using Class E RF Power Amplifier with Amplitude Modulation
Supervisor: Dr Jean-Michel Redouté

The aim of Yun's project was to design an AM modulated Class E RF Power Amplifier with 10MHz operating frequency. Simulations illustrated that the circuit achieved 90% power transfer efficiency as well as a maximum data rate of 25 kbps.

Yang Cui
Honours (Electrical Engineering)
Thesis: Wireless Inductive Link for Implants
Supervisor: Dr Mehmet Yuce

The aim of Yang's project was to design a wireless transmitter and receiver for data transmission through two coils, for which he successfully produced a prototype system.

Judy Tran
Third Year Marketing Internship (Bachelor of Commerce/Bachelor of Science)
Thesis: Informing the public of new science: The effective communication of science in society to assist in the commercialisation of innovations and technology
Supervisor: Dr Jeanette Pritchard

During Judy's 12-week marketing internship with MVG, she focused on bionic eye educational activities for schools and devised a work plan that culminated in her conducting a series of presentations at local establishments - St Mark's Catholic Primary School in Dingley on World Sight Day and Sir John Monash Science School in Clayton, which was attended by local member for Clayton Mr Hong Lim. Judy's presentations introduced MVG and the bionic eye concept and more broadly discussed the importance of eye health. Judy also identified a number of opportunities for MVG to expand its marketing and outreach with new materials such as the ‘Bionic Eye Word Search’ and MVG-badge magnifier bookmarks.

Gillian Gan
Second Year Mechatronics Summer Intern
Supervisor - Mr Horace Josh
Gillian had two overarching objectives for her summer intern project. The main objective was to develop an automated process for the conduction of psychophysics tests, allowing these tests to be run by one person rather than two or three as previously required. This involved developing a custom Graphical User Interface (GUI)-based computer program that allowed for simple control of timing, result recording and spreadsheet generation. The second objective, to be performed in 2013, involves the redesign of the Hatpack construction to facilitate easy access to power and control switches and use in mobile testing.

Tegan Connelly
Graduate in Graphic Design

Tegan undertook a short term project with MVG to develop graphic concepts for use in MVG promotional activities. Tegan produced a series of images to illustrate each element of the MVG device in an easily understandable manner in addition to producing abstract images for use in presentations and marketing materials.

Lectures To Students

Prof Arthur Lowery
ENG4081: Medical Instrumentation ‘Monash Vision Group Bionic Eye Project.’
ENG1110: Biomedical Instrumentation ‘Developing a Bionic Eye’ (1st year Engineering).

Prof Marcello Rosa
PHY3111: Sensation and Movement (3rd year Science) – two lectures including bionic eye.

Prof Kate Smith-Miles
MTH1000: Special Topics in Mathematics (1st year Science).

A/Prof Ramesh Rajan
PHY2011: Neuroscience of Sensation, Brian and Movement (2nd year Science).
MED1022: Neuroscience (2nd year MBBS).

A/Prof Lindsay Kleeman
ECE4063: Large Scale Digital Design (4th year Engineering elective).
ECE2072: Digital Systems (2nd year Engineering core unit).
ECE3073: Computer Systems (3rd year Engineering core unit).

Dr Wai Ho Li
ECE4078: Intelligent Robotics (4th year Engineering elective).

Dr Nic Price
BMS1052: Human Neurobiology (1st year) ‘Bionics and Neural Prosthetics’.
BMS1052: Human Neurobiology (1st year) ‘Visual system’.
PHY3111: Sensation and Movement (3rd year) ‘Electrical Micro-stimulation and
Prosthetics'.

Dr Damien Browne  

Prof Jeffrey Rosenfeld  
2012 Monash Leadership Program Lecture (Scotch College, 9th August) to 50 Year 10 students.

Dr Jeanette Pritchard  
MVG Overview at Faculty of Engineering Research Information Evening (19th September).

Commercial Program

Intellectual Property

APP. No.: P34726USP1  
Title: System and method for processing sensor data for the visually impaired  
Inventors: Lui, Browne, Kleeman, Drummond, Li  
Stage: PCT  
Filing Date: 30 Aug 12

APP. No.: 2011904816  
Title: Apparatus and method for surgical insertion of an implantable device  
Inventors: Atkin, Marsden, Payne, Rajan, Solomon  
Stage: PCT  
Filing Date: 30 Aug 12

A further five US provisional patents are in draft at the time of writing that cover novel aspects of the MVG device design, test systems and fabrication methods developed during 2011-2012.

Business Plan

MVG worked with Professor Michael Vitale, Manager of the Masters in Business (Science and Technology) at Monash University to engage graduates and new students to undertake commercial analyses for MVG.
A three week intensive project with four 2011 graduates from the Masters course – \textbf{Kate Nurse, Carissa Ogden, Rob Shepherd} and \textbf{Claire Penney} - resulted in a 56-page business document, including a competitor analysis intellectual property and freedom to operate analysis and recommendations, an initial market analysis and also investigations into reimbursement strategies.

This was expanded upon by the Masters in Business (Science and Technology) students - \textbf{Lambrini Kakogiannis, Ajay Singh} and \textbf{Loretta Romano} with the resulting package also including options for future funding beyond 2013 and comprising the basis of an Information Memorandum and Business Plan.

\section*{Regulatory Affairs}

MVG - through industry partners MiniFAB and Grey Innovation - has continued to implement quality control and quality assurance practices into the device development program in line with requirements for the manufacture of an implantable medical device and consistent with SO 13485 regulatory standards, including patient risk and harm analysis, technical risk analyses for the device design and architecture and device and component verification and validation processes.

This has resulted in the engineering and preclinical teams producing detailed documentation, which will be the basis of the production and testing of the final device to be used in the FIH pilot study and will be submitted to the Human Research Ethics Committee.

In preparation for the first patient demonstrations in early 2014, the Clinical Team presented the project status to the Human Research Ethics Committee and Clinical Innovations Committee at the Alfred Hospital in Q4 2012 and received positive feedback and recommendations. The Clinical Team continues to interact with both Committees with input from all team members on the technical development and testing strategy with an aim to submit ethics documentation for the FIH pilot study during 2013.

"If anyone had told me 5 years ago that in 2013 I would be part of a team that is this close to a cortical prosthesis, I would have called them crazy. It never ceases to amaze me how far we have come in such a short time."

Professor Marcello Rosa

\section*{Outreach & Events}

MVG continued to engage with the community that is blind, through formal presentations at conferences such as the \textbf{Blind Citizens Australia State Convention} in Geelong (Professor Arthur Lowery) and the \textbf{Retina Australia AGM} (Dr Jeanette Pritchard).
Professor Jeffrey Rosenfeld presented an Information Session for members of the community that is blind at Vision Australia in July which provided details of upcoming focus groups being run with MVG Psychology Honours student Mr Ross Anderson. MVG was also delighted to present at the October Vision Australia Board Meeting, at which Professor Arthur Lowery and Dr Jeanette Pritchard provided an update on technical developments and in particular the outcomes of the focus group studies. Dr Jeanette Pritchard was also invited to present at the Vision Australia Optometrist Professional Development Convention, held in Kooyong in June. MVG has welcomed the opportunity to discuss technical developments with staff members from Vision Australia, which has provided invaluable information relating to external device design, signal processing requirements and general discussions to identify other areas in which the groups could collaborate.

MVG was thrilled to further develop its relationship with Guide Dogs Victoria, with a number of discussions focusing on requirements for patient training following the first MVG implantation in 2014. Meetings were attended by Associate Prof Ramesh Rajan, Dr Helen Ackland, Prof Michael Vitale, Dr Jeanette Pritchard and Ms Collette Mann.

Lectures, Seminars & Public Engagement

Professors Arthur Lowery and Erol Harvey presented at the SEMIP Innovation Showcase in March to an audience consisting representatives from industry, government and academia. Arthur and Erol's presentations highlighted importance of industry-academic collaboration and the positive impact this model has brought to the MVG initiative.

MVG was represented at the Bio21 Health and Medical Research Expo at Queens Hall, Parliament House in Melbourne in May which celebrated the contribution of the vital health and medical research sector to Victoria and the world.

Professor Marcello Rosa presented at the Monash Biomedical Imaging Institute Opening in May, at which he presented data from the MVG MRI Visual Cortex Study collected using MBII facilities.

Professor Kate Smith-Miles presented a Lecture at the Port Philip Probus Club in May titled ‘Mathematical modelling of the human face ... no more lying about your age!’ which mentioned Kate’s work with MVG.

The Market of the Mind National Science Week event held in City Square, Melbourne in August provided MVG with the opportunity to demonstrate the Hatpack and Transformative Reality concept to the general public and also provide general information about the project and MVG approach.

Professor Jeffrey Rosenfeld presented a lecture at the Annual Dinner of Order of St John Ambulance Australia on 19th October titled ‘Building a bionic vision device for sight restoration in the blind’. Professor Arthur Lowery was invited to speak about MVG at the Monash University Faculty of Medicine MedTech Forum in November, with the presentation focusing on the importance of cross-disciplinary collaboration.
Monash Vision Group & Bionic Vision Australia

Members of MVG formally met with Bionic Vision Australia eleven times to discuss opportunities to work together on marketing, stakeholder engagement, student training, future funding and technical collaborations. This resulted in the groups running a joint Industry Careers Workshop at the Small Technologies Cluster (STC) in Scoresby in April, at which researchers and students were provided with information about career options and advice from industry representatives. Hosted by Professor Erol Harvey, the afternoon also consisted of a tour of STC’s facilities and an opportunity to network. MVG and BVA shared speaker slots and a booth at the Blind Citizen's Australia State Convention and Vision Australia Texpo respectively; both of these events provided important opportunities for the groups to discuss their respective approaches with members of the blind and vision impaired communities.

MVG's Professor Marcello Rosa and BVA's Professor Michael Ibbotson jointly presented an evening seminar covering cortical and retinal vision prostheses in May at the Australian College of Optometry in Carlton, Melbourne.

Considering the future, Professor's David de Kretser and David Penington developed a strategy for securing funding for both projects beyond 2013, which they presented to members of Federal and State Governments and the scientific community.

Visits And Visitors

MVG was delighted to welcome Professor Partha Mitra from Cold Springs Harbour Laboratories in New York in February for a two week visit. With a background in theoretical physics, Partha is now focused on building his understanding of how the brain works using mathematical modeling methodologies. During his visit, Partha built upon his existing collaboration with Professor Marcello Rosa and spent extensive time with MVG's physiologists and engineers, discussing their research and looking at the tools the team are using to design the implant. Partha's visit was reciprocated when Dr. Hsin-Hao Yu from Marcello's team visited Cold Springs Harbour Laboratories later in the year.
Mr Kian Torab from Blackrock Microsystems (US) visited MVG in March and gave a public seminar describing the latest technical developments at the company, which markets equipment and devices for intra-cortical stimulation in research applications.

Building on established links with Professor Phil Troyk, MVG hosted a visit by Professor Frank Lane from NT, Chicago in July who works in close collaboration with Phil looking at the psychological impact on patients who have received a cortical vision prosthesis. Frank provided invaluable insights into his ongoing work with recipients of the Dobelle implant, in addition to discussing appropriate protocols for focus group activities with Psycholgy Honours student Mr Ross Anderson.

In October, Professor Marcello Rosa welcomed esteemed guest Mr Dominic Man-Kit Lam to Monash Physiology to celebrate the 50th Anniversary of the Monash Medical School. Dominic, Chairman of the World Eye Organisation, has a background in ophthalmology but has more recently turned his focus towards painting and unveiled and donated one of his pieces to the Medical School during his visit.

The MVG Electrical Engineering Lab welcomed a variety of guests throughout 2012, who were shown demonstrations of the Hatpack simulator, Transformative Reality concepts and given presentations on the MVG project. Guests included Lord Sir Alec Broers - who also visited MVG in 2011 - in addition to student groups from Universiti Teknologi Malaysia (UTM), National Science Youth Forum and Suzanne Cory High School (Werribee).

Outward bound trips included a visit by Professor Jeffrey Rosenfeld to Louisiana State University Health Sciences Centre in Shreveport, US in October. During his visit, Jeffrey presented at the Neurosurgery Inaugural Woodard Symposium with the seminar title ‘Multi-electrode cortical prosthesis for vision restoration in the blind’. Jeffrey also continued MVG’s close interactions with Professor Phil Troyk with a visit to NT in Chicago in October.

Professor Marcello Rosa met with Professor Claudio Galletti from the EYESHOTS EU Consortium, at University of Bologna in July. Marcello and Claudio conducted joint experiments aimed at defining the areas of the cerebral cortex involved in the control of eye movements. This visit resulted in the recruitment of Dr Konstantinos Hadjidimiatrakis to MVG, who will start his employment at Monash University in 2013.

During their time at ICRA 2012 in May Drs Wai Ho Li and Dennis Lui visited the Robotics Laboratory at Stanford University and upon their return to Melbourne followed up their conference interactions with Dr Denny Oetemo with a visit to the Laboratory of Robotics in Biomedical Applications at the University of Melbourne in June.

“The creativity of the Monash Vision team is greater than the sum of the individual contributions. A spark of creative energy is ignited when the different bionic vision disciplines start talking together.”

Professor Jeffrey Rosenfeld
MVG In The Media

TV Appearances

Professor Arthur Lowery and Dr Wai Ho Li appeared on Al Jazeera English online tv on 27th May, which features on YouTube - http://www.youtube.com/watch?v=uMEObkiOGa8

Professor Jeffrey Rosenfeld appeared on the Channel 7 evening news on 28th May with the story focusing on Jeffrey's volunteer work with the St John Ambulance organization.

Radio Appearances

It was the year of the Radio for MVG in 2012, with a number of MVG staff partaking in live and recorded interviews on local and national stations including:

Professor Jeffrey Rosenfeld - BC 774 (live, 12th June) which not only covered Jeffrey's work with MVG but also highlighted his achievements in the world of classical music.

Professor Marcello Rosa - ABC 774 (live, 24th July) to discuss his discovery on new methods for mapping the brain and the link with peripheral vision, published in Current Biology.

Dr Jeanette Pritchard - 3RRR's Detour programme (live, 28th March) to discuss MVGs project and the group's involvement in the South East Melbourne Innovation Precinct's Innovation Showcase.

Lindy Burns ABC show (recorded, 4th April), ABC pm show and 3AW (recorded 5th April) discussing progress in microchip development and testing at MVG.

ABC 774 (recorded, 30th August) responding to BVA announcement of first patient implant.

Vision Australia Radio (recorded, 24th August) discussing advances in bionic eye development at MVG.

Mr Ross Anderson - Blind Citizens Australia New Horizons radio show (recorded, 9th July) to inform community of the MVG educational session at Vision Australia on 14 July.

Online Media and Newspaper Articles

January - AUSTRALASIAN SCIENCE (in print and online)
February - THE NEW INDIAN EXPRESS (online)
http://newindianexpress.com/editorials/article318676.ece
COURIER MAIL, Queensland (in print)
‘Visionary project places world of blind in clear view’ [18-19 February 2012]
IT NEWS ONLINE

March - THE STAR, Greater Dandenong (in print)
‘Spotlight on Enterprise’ [8 March 2012]

April - THE AUSTRALIAN IT SECTION (in print and online)
TIME OUT Melbourne (online)
MIVISION (in print and online)
THE DAILY MAIL, UK (in print and online)
http://www.dailymail.co.uk/sciencetech/article-2136864/Scientists-conduct-human-trials-bionic-eye.html
THE SUNDAY TIMES, UK (in print and online)
http://www.thesundaytimes.co.uk/sto/news/uk_news/Science/articlel027290.ece
INVEST VICTORIA online blog:
NINE NEWS TECH (online)

May - CANBERRA TIMES (online)
ARTIFICIAL EYES Blog on Erickson Eyes Northwest, US (online)
YORKE PENINSULA COUNTRY TIMES, South Australia (in print) ‘Aussie bionic eye a step closer’ [22 May 2012]
INVEST VICTORIA (online) blog
NATIONAL MEDICAL JOURNAL OF AUSTRALIA (online)
June - GOOD online article ‘5 Amazing Tech Breakthroughs First Seen in Movies’ (online) http://www.good.is/posts/5-amazing-tech-breakthroughs-first-seen-in-movies/
DIVINE Victorian Government online community website by and for people with a disability (online) http://www.divine.vic.gov.au/main-site/tech-talk/assistive-technologies/bionic-eye; story Id, 7283
TRADE ARABIA online http://www.tradearabia.com/articles/tag/113053

MEDICAL NEWS TODAY (online) http://www.medicalnewstoday.com/articles/248272.php
MCDONALD ADAMS OPTOMETRISTS LTD NEWSLETTER, New Zealand (online) http://www.mcdonaldadams.co.nz/files/newsletters_ll_4276244039.pdf

MEDICAL DESIGN BRIEFS (in print and online) http://www.medicaldesignbriefs.com/component/content/article/14348

DAILY HERALD (online) http://www.dailyherald.com/article/20120908/business/709089983/

December - THE AUSTRALIAN JEWISH NEWS (in print) ‘A bionic eye in sight’ [7 December 2012]

MVG Internal Communication

MVG continued to circulate its Quarterly Newsletter, which is used as a mechanism for
providing members of the Group, in addition to the ARC and other key stakeholders updates on all aspects of the project. A Senior Staff Briefing was held in September and was used to discuss overall progress, the focus of research programs and other strategies such as external communication and stakeholder engagement. MVG continues to use Confluence as an internal communications tool for highlighting recent events and as a central repository for documentation including presentations and publications and international news stories of relevance.

Communication across the technical team is frequent; there are weekly meetings held by the Technical Architecture team to discuss engineering issues and progress, which will also involve members of the preclinical team as testing of the full system commences in 2013. Fortnightly meetings are held by the researchers working on all aspects of the electrode design and testing and Project Review meetings are held monthly prior to each Steering Committee, to review progress against the Project Plan and highlight any risks that may arise.

MVG continues to provide all external information in formats accessible to sighted, blind and vision impaired individuals, with documentation being provided in large print as well as in screen-reader compatible format on CD.

2012 Highlights

January - Professor Jeffrey Rosenfeld AM awarded Honorary Clinical Research Fellowship at Bionics Institute.

February - Mr Horace Josh awarded Best Student Paper Prize at BioDevices 2012 International Conference in Portugal.
MVG welcomes visitor Professor Partha Mitra to Monash University from Cold Springs Harbour Laboratories (US).
Professor Erol Harvey awarded ‘Enabling Entrepreneur of the Year’ for his contributions towards the uptake of technologies within Australian manufacturing businesses.

April - MVG formally appoints Professor David de Kretser as Chair of the Advisory Board.
MVG in the news following press release describing successful testing of second generation microchip.
MiniFAB hosts ‘Career Development Workshop’ for MVG and BVA students and early stage researchers.

July - Professor Arthur Lowery and Dr Jeanette Pritchard attend Centre Director/COO Meeting in Canberra.
MVG welcomes Professor Frank Lane from NT (US) to Monash University.
Professor Marcello Rosa receives international acclaim following publication in Current Biology.
Ms Emma Brunton awarded first prize for her poster and oral presentations in 2012 Postgraduate Research Forum: ‘Optimising electrode geometry for a cortical visual prosthesis’. 
August - MVG demonstrates the Hatpack to the general public at National Science Week’s ‘Market of the Mind’ in Melbourne City Square. Members of MVG and BVA share a booth and interact with the community that is blind at Vision Australia Texpo in Kooyong, Melbourne. Professor Jeffrey Rosenfeld AM awarded the Monash Medal at the Melbourne Rotary.

October - Ms Judy Tran of MVG celebrates World Sight Day with St Mark’s Catholic Primary School (Dingley Melbourne). MVG presents at the BCA State Convention in Geelong and Retina Australia AGM in Melbourne.

November - MVG files PCT applications for surgical aids and transformative reality concepts. MVG presents at Monash University MedTech Forum.

December - MVG Board Members meet with Bionic Vision Australia Board and Executive to discuss strategies for future funding and collaborative opportunities.

MVG also welcomed a number of new staff and students during 2012: Mr Ajay Singh, Ms Amanda Davies, Mr Andrew Stephens, Prof Arthur de Bono, Ms Carissa Ogden, Ms Claire Penny, Ms Collette Mann, Dr Edwin Yan, Ms Gillian Gan, Ms Jessica Cassar, Ms Judy Tran, Ms Katie Nurse, Mr Kieran John, Dr Kun Zhou, Ms Lambrini Kakogiannis, Ms Loretta Romano, Prof Mark Armstrong, Mr Peter Bettonvil, Ms Simone Carron, Ms Tegan Connelly, Mr Richard Thomson, Mr Rob Shepherd, Mr Ross Anderson.

Issues Arising And Mitigation Strategies

- Identification of Replacement Advisory Board Chair. Following the resignation of Dr Mike Hirshorn in August 2011, MVG was delighted to appoint Professor David de Kretser AC into the position, which was formally endorsed by the ARC in April 2012.
- Difficulty in recruiting PhD candidates with less than 2 years remaining on project. Due to limitations with timeframes, MVG was unable to recruit the required number of new PhD students during 2012 and therefore requested permission from the ARC to modify the associated Performance Indicator descriptor to ‘Postgraduate students recruited’. The ARC formally approved this modification in May.
- Retention of research staff. In order to retain research staff within the university until the end of 2013 and ensure that all technical and clinical goals were met, MVG required additional cash funding to cover staff salaries and specific technical aspects of the program. Following discussions with Monash University Central Administration, MVG received an additional $595,000 from Monash University in addition to the annual $600,000 cash contribution received, which will allow the Group to retain its research team until the end of the initiative.
- Difficulty in engagement of silicon foundries through university for manufacture of implantable microchip It is traditionally very difficult for educational establishments
to interact efficiently with foundries for the manufacture of ASIC products; this is further impeded when the product is to be integrated into an implantable medical device. Monash University was encountering such difficulties when attempting to identify and engage a suitable foundry, which was placing a high risk on the ability of the team to deliver the microchip design in the required timeframes. Through existing industry links, Grey Innovation facilitated the establishment of a relationship between MVG and a microchip design house and through this interaction, MVG has successfully identified and engaged a foundry for the manufacture of ASIC2.

“This project has opened my eyes and broadened my horizons. I was pleasantly surprised to find engineers were human too.”
Associate Professor Ramesh Rajan

Publications

Conference Proceedings

**Australian Neuroscience Symposium 2012** (Gold Coast, 21-23 January 2012). Poster presentation 'The rat motor cortex whisker area can evoke whole movement patterns with successive behaviourally-relevant stimulation results' (Haghgoieie, Wang, Cassells, Rajan).

**Australian Neuroscience Symposium 2012** (Gold Coast, 21-23 January 2012). Poster presentation ‘Latencies of responses to visual stimuli in cortical areas DM and MT are related to size-summation properties’ (Lui, Rosa).


**IJCNN 2012** (Brisbane, 10-15 June 2012). Poster presentation ‘Optimisation of Electrode Array Currents for Neural Prostheses’ (Cookson).

**34th Annual International IEEE EMBS Conference** (San Diego, 28 August - 1 September 2012). Oral presentation ‘Transformative Reality: Improving bionic vision with robotic sensing’ (Lui, Browne, Kleeman, Drummond, Li).

**Congress of the Neurological Surgeons** (Illinois, 6 October 2012). Poster presentation ‘Multi-electrode cortical prosthesis for vision restoration in the blind’ (Rosenfeld).


Journal Publications And Submissions

Current Biology (July 2012). 22, 1351-1357. ‘A specialized area in limbic cortex for fast analysis of peripheral vision’ (Yu, Chaplin, Davies, Verma, Rosa).


Journal of Comparative Neurology (April 2012). 521(5): 1001-19. ‘Representation of the visual field in the primary visual area of the marmoset monkey: magnification factors, point-image size and proportionality to retinal ganglion eel density’ (Chain, Yu, Rosa).

Frontiers in Neuroengineering (September 2012) v5, Article 23. ‘A comparison of microelectrodes for a visual cortical prosthesis using finite element analysis’ (Brunton, Lowery, Rajan).

Frontiers in Neuroscience (September 2012). v6, Article 158. ‘Accurate reading with sequential presentation of single letters’ (Price, Edwards).


Start of photo caption
MVG’s Collette Mann and Judy Tran celebrate World Sight Day 2012 with students from St Mark’s Catholic Primary School, Dingley. The 75% signs held by the students – provided by Vision 2020 – is an estimation of the percentage of blindness and vision
loss in Australia that is preventable or treatable.
End of photo caption

Financial Statement

2012 Revenue, Expenditure and Contributions: 1 January – 31 December, 2012

Funds received

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<thead>
<tr>
<th>Source</th>
<th>Amount</th>
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</thead>
<tbody>
<tr>
<td>ARC funds</td>
<td>$2,153,438</td>
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<tr>
<td>Monash University funds (as per Agreement)</td>
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<td>Monash University funds (additional)</td>
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<td><strong>Total Revenue</strong></td>
<td><strong>$3,348,800</strong></td>
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<td>ARC carry forwards from 2011</td>
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<td>Monash University carry forwards from 2011</td>
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<td><strong>Total funds available in 2012</strong></td>
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Expenditure

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<td>ARC funds</td>
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<td>Monash funds</td>
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<td><strong>Total Expenditure</strong></td>
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<td><strong>Balance Remaining</strong></td>
<td><strong>$407,037</strong></td>
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<td>ARC funds to be carried forward to 2013</td>
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In-Kind Contributions

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<td>Monash University</td>
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<td>Alfred Hospital</td>
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<td>Grey Innovation</td>
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<td>MiniFAB</td>
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Key Performance Indicators

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<tr>
<th>Key Result Area</th>
<th>Performance Measure</th>
<th>2012 Target</th>
<th>Result</th>
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<tr>
<td>Governance</td>
<td>Breadth/experience of Advisory Board</td>
<td>Reviewed</td>
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<tr>
<td></td>
<td>Frequency/Effectiveness of Meetings</td>
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<td>2</td>
</tr>
<tr>
<td></td>
<td>Quality of strategic plan (judged by Advisory Board)</td>
<td>Reviewed</td>
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<tr>
<td></td>
<td>Adequacy of KP’s (judged by Advisory Board and ARC)</td>
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<tr>
<td>Recruitment of New Staff as a result of project</td>
<td>Research and Development Staff</td>
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<td>Technical Support Staff</td>
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<td>Administrative Staff</td>
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<tr>
<td>Skills Development</td>
<td>Undergraduate Honours Projects</td>
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<td>Postgraduate students recruited</td>
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<tr>
<td>Postdoctoral researchers recruited</td>
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<tr>
<td>Industry secondment (to and from industry)</td>
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<td>2</td>
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<tr>
<td>Visit to international facilities</td>
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<td>5</td>
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<tr>
<td>Research Outputs</td>
<td>Publications in journals that are ranked in the top 25% of their field</td>
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<td>International conferences (peer reviewed)</td>
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<td>Invited review papers and invited conference presentations</td>
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<tr>
<td>Patent applications</td>
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<td>2 filed, 5 in draft</td>
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<td>International visitors staying more than two weeks</td>
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<td>Outreach and Communication</td>
<td>Press releases</td>
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<td>9 (exclude online)</td>
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<td>Media appearances</td>
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<td>8</td>
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<td>Expressions of interest in future human trials from sight-impaired people</td>
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<td>Greater than 80</td>
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<tr>
<td>External stakeholder communication</td>
<td>Report annually</td>
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<tr>
<td>Meetings with related research teams</td>
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<td>Annual report</td>
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<td>Lectures to students</td>
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<td>Collaboration</td>
<td>Meetings with Bionic Vision Australia group</td>
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<td>Funding strategy</td>
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<td>Funds raised</td>
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**Acknowledgements**

MVG gratefully acknowledges the support of the following organisations and Individuals

- Alfred Health and the Alfred Hospital
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VIC 3800 Australia

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Australian Government
Australian Research Council
Research in Bionic Vision Science and Technology Initiative

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