Monash Vision Group
2011 Annual Report
Australian Research Council
Research in Bionic Vision Science and Technology Initiative

<transcriber's note> In the printed edition of this report, there are images appearing at various places in the text. While there are some descriptions, these images do not appear in this version and any enquiries regarding images can be directed to 03 9905 9526. </transcriber's note>

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

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.

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.

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.

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 and Medicine, Nursing and Health Sciences, with key inputs into all aspects of the Monash Vision project.

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At a Glance - The Monash Vision Group

The Monash Vision Group (MVG) is a consortium of engineers, scientists and medical researchers from Monash University and Alfred Hospital in Melbourne, along with Victorian companies - Grey Innovation and MiniFAB. The MVG was established in April 2010 to develop a "direct to brain" bionic eye and is supported by an $8 million grant from the Australian Research Council. Its first human implant is scheduled for 2014.

How will this "Direct to Brain" bionic eye work?

The MVG's "direct to brain" bionic eye system will combine state-of-the-art digital and biomedical technology with consumer-friendly eye glasses. A digital camera embedded in the glasses will capture images from the user's environment. The camera will be linked to a cutting edge digital processor, which will modify the image captured by the camera. Using a wireless transmitter, the processor will send the modified image as a signal to an implanted chip at the back of the brain under the skull. The implant will then directly stimulate the visual cortex of the brain with electrical signals, which the brain will learn to interpret as sight. The implant will have many tiles, each with 45 electrodes designed to give over 650 pixels in all. The device also may be tuned to cope with different situations such as indoor tasks and outdoor navigation.

How will the device be inserted?

Using standard neurosurgery techniques, a small area of the skull will be temporarily cut away in surgery. A sterile, biologically inert chip will be implanted directly into the visual cortex of the brain. The small area of the skull will then be replaced and will heal to provide a natural barrier to protect against infection.

Who will it help?

This device is being developed for people of all ages with vision impairment caused by such conditions as glaucoma, macular degeneration and diabetic retinopathy. These three conditions cause up to 85% of cases of untreatable clinical blindness. The device can also help patients who have suffered physical trauma to the eye or do not have a functional optic nerve, which is often a limitation of other bionic eye technologies.

There are reportedly more than 160 million people experiencing some form of blindness worldwide. The figure for Australia is over 50,000. Importantly, when fully developed, the MVG "direct to brain" system may enable patients to continue using their regions of good sight with brain stimulation improving sight in deteriorated regions.

Note from the Chair

Calling the Monash Vision Group a special initiative seems to be quite an understatement. This group of dedicated researchers, surgeons, physiologists, engineers, manufacturers, and entrepreneurs have set themselves the audacious goal of implanting the first MVG bionic eye in a human subject by April 2014.

The growing list of MVG's accomplishments that are reported within this document are evidence that this incredible journey is well underway. Design and prototyping of key elements of the system have been finalised, and preclinical testing has been undertaken on sub-assemblies.

Key achievements over the past year include hitting technical milestones such as the development and delivery of the ASIC 1 design, production and preclinical testing of prototype surgical aids and development of signal processing algorithms, all of which have contributed towards the filing of two patent applications. It is also worth noting the Group's interactions with Bionic Vision Australia, which have resulted in discussions at both the Board and technical level around how to make the most efficient and effective use of resources on a combined basis.

This year the detailed plan includes integration of the full system and complete end to end bench and preclinical testing of the device itself. This phase is critical–communication across the Group will be the key in producing a functioning prototype device suitable for clinical use. This year is also the year for the Group to consider business strategies and make commercial decisions–this again will be the driver for the future development of the MVG prosthetic device beyond the current program of work and is where the benefits of our Industry Partners involvement will become further evident.

There are a number of significant challenges that the team will face this year, and whilst it is far from obvious how some of these will be overcome, the single mindedness of the team to achieve its ultimate goal will drive them to success.

Ms Vicki Tutungi
Independent Steering Committee Chair, Monash Vision Group

Director's Report

I am proud to deliver the second annual report of Monash Vision Group. As you will read, we are progressing well with our development of a prototype visual prosthesis that will improve the lives of tens of thousands of people who are vision impaired, and build an Australian based capability for bionic brain implants.

In 2009, the Australian Research Council announced it would fund two projects under the "Research in Bionic Vision Science and Technology Initiative". Monash Vision Group received a grant of $8,000,000 for a 4-year project, "Direct Stimulation of the Visual Cortex: a Flexible Strategy for Restoring High-Acuity Pattern Vision".

Our system uses a conventional (mobile phone) camera to view the world. This image is processed to extract the most important information from the scene, which is sent through a wireless link to an implant. The implant sits beneath the skull and stimulates the brain using small and short pulses of current. Through direct stimulation of the brain, the system is designed to work for people whose eyeballs and optic nerve have been irreparably damaged. It will also work for people whose retinas have degraded or been damaged.

Our implant is actually a set of 10-12 tiles, which cover the V1 region of the visual cortex. Each tile has 45 electrodes, which penetrate into the surface of the brain, to stimulate the axons that communicate information between the neurons. Thus the electrodes can trick the neurons into thinking that they have been stimulated by visual input to the eye.

In Year 1 of the project, during 2010, we firmed up on the system design of the prototype, after investigating many alternate designs and implementations. Because many of the components, including the electrodes, implantable electronics (ASIC), hermetic packaging and external electronics are not available off the shelf, considerable effort has been expended on custom designs. In the case of the electrodes and the implant package, this has meant developing our own micro-manufacturing and microfabrication techniques.

At the end of Year 2 (2011) we have a full end-to-end system design, including the pocket processor, ASIC and electrodes. Many of the parts have been prototyped, including the electrodes, implant casing, implant insertion tool, external electronics and wireless link, with the first ASIC design being provided to suppliers for manufacture in August 2011. We have made extensive use of computer simulation to verify our designs, and make design choices early on and have conducted preclinical trials on the subsystems to verify their operation.

In Year 3 we will produce a full bench-type prototype and a set of test jigs, so that we can test components, sub-assemblies and the whole system end-to-end.

A key challenge of this project is to develop a biocompatible implant. Unlike other medical devices for cochlear and heart stimulation, our device needs hundreds of electrodes to present a suitably-detailed image to the brain. In order to simplify the insertion procedure and improve reliability, we have avoided using a festoon of wires, as they are likely to put unpredictable mechanical forces on the electrodes during and after insertion process. This means that the electronics has to fit directly on top of the electrodes, limiting its area. This presents many design challenges for the electronics and mechanical design teams.

I am delighted that Dr Mehmet Yuce has joined us from Newcastle University, NSW, as a Senior Lecturer in the Department of Electrical and Computer Systems Engineering. Mehmet brings ten years of experience in electronics for biomedical implants, including high-speed wireless data and power links. Mehmet has also designed Application-Specific Integrated Circuits for implanted electronics, and is working with Dr Jean-Michel Redouté who has developed the first MVG prototype ASIC for the project with his team, Drs Damian Brown, David Fitrio and Anand Mohan.

Great advances have been made by our robotics vision specialists, Drs Wai Ho Li and Dennis Lui, who are applying powerful 3-D gaming sensors to the pre-processing of images. This technology allows the "important parts" of a scheme to be separated out from the camera's image. An example is removing far-away clutter from a visual scene, so the important foreground objects are presented to the brain. Thanks to the power of new microprocessors developed for the mobile computing market, our bionic eye can implement the latest advances in vision processing in a device that fits in the pocket.

The efficient management of the project is of critical importance given the short timescale and the unique combination of academic and industry partners in a research project with a development outcome. We have increased the interaction of the academic and industry teams by reorganising the project so the primary goal is to create a product, rather than to develop research ideas towards becoming useful for a prototype. There are still many academic questions to be answered, and innovations to be made; however, our efforts are concentrated on achieving the primary goal.

The management of the group is performed chiefly by the Steering Committee, which has representatives from all MVG partners who meet monthly. The Steering Committee sets the high-level goals of the project, including the requirements specifications and functional specifications, measures progress against their project plan, and allocates resources to fulfil the plan.

During 2011 Steering Committee has been chaired and driven by the late Dr Mike Hirshorn, AO, who contributed strongly to the efficient management of the project until he sadly passed away, using his vast experience at Cochlear and ResMed. I am delighted that Ms Vicki Tutungi, previously CEO of OptiScan Ltd, a high-resolution endoscope company, has taken over Mike's role on a pro-bono basis.

During 2010, the Technical Review Committee was formed to monitor technical progress and examine technical documents and designs in detail. This meets monthly, reports to the Steering Committee and includes members of the technical teams that are developing and testing the prototype. The technical specification and review process is critical to the design of the prototype, as each part of the project must function in conjunction with all other parts. Also critical is how the prototype can be manufactured, which often puts constraints on the materials that can be used. Most critical is how the prototype will interact with the human body. This requires the experience of our materials, physiology and neurosurgery teams.

The Advisory Board has members from government, end-users and the senior members from project itself. Its job is to ensure that the project is meeting the expectations of the government and community by monitoring the projects progress and suggesting strategic initiatives such as industry and community engagement. The Advisory Board met three times in 2011, chaired by Dr Mike Hirshorn twice, then by Professor Lyn Beazley.

A key objective of the board is to encourage close interactions with Bionic Vision Australia, in the interests of ensuring that research tasks are not duplicated and that information is shared equally. To further this objective, the Advisory Boards of both Groups held a joint meeting in December, at which areas of mutual interest were identified, and a joint strategy for further Bionic Vision research developed.

Professor Arthur Lowery
Director, Monash Vision Group

In Memory of Dr Mike Hirshorn

We begin the 2011 MVG Annual Report on a sad note with the passing of Mike Hirshorn. On behalf of all MVG partners and contributors, we would like to pass on our sincere condolences to Mike's family and friends.

Mike served as the Independent Chair of the MVG Advisory Board and Steering Committee from September 2010 to August 2011. His contribution to the medical device industry was significant - in 2004 he was awarded an Order of Australia Medal for his work in commercializing medical technology. It was while working for Telectronics that Mike's attention was caught by a grant application for an implantable hearing device. That morning's work changed the lives of the 250,000 people that currently use a Cochlear hearing device.

Mike was a Founding Director of ResMed, a global leader for the development, manufacture and distribution of medical equipment for treating, diagnosing and managing sleep-disordered breathing, a condition that reports suggest affect 20 per cent of the population. He was also involved in companies such as Biotron Ltd, Dynamic Hearing Pty Ltd, TGR BioSciences Pty Ltd, CathRx Ltd and LBT Innovations Ltd and in 1999 Mike established Four Hats Capital with friend and colleague, Simon Uzcilas.

In the 2010 MVG Annual Report, Mike talked about the possibilities of the bionic eye project. "MVG, through cortical stimulation, has the potential to help a wide range of people. Coupled with other work in retinal stimulation, significant progress should be made towards this goal. Working in a field such as this is a privilege and builds on Australian technical and commercialisation strengths," he said. Mike's passion for advancing medical technologies was palpable and his absence from the MVG team and Australian medical device industry will be felt.

Governance and Management

Advisory Board

Dr Michael Hirshorn, Independent Chair (August 2010-August 2011)
Director, Four Hats Capital

Professor Lyn Beazley (Acting Chair, September-December 2011)
Chief Scientist, Western Australia

Professor Jim Patrick
Chief Scientist, Cochlear Ltd.

Mr Gerard Menses
CEO, Vision Australia

Professor Arthur Lowery
Director, Monash Vision Group

Dr David Lyster
Manager, Research Partnerships, Monash University

The Advisory Board met on the following dates during 2011:
9th March–Monash University, Clayton
8th August–Monash University, Clayton
1st December–Monash Conference Centre, Melbourne CBD

Steering Committee

Dr Michael Hirshorn, Independent Chair
(August 2010–August 2011)
Director, Four Hats Capital

Ms Vicki Tutungi, Independent Chair
(September 2011 to present)
Managing Director, ProLearn
Level 3, 450 St Kilda Road,
MELBOURNE, VIC

Professor Arthur Lowery
Director, Monash Vision Group and
Head of Department, ECSE
Monash University CLAYTON, VIC

Professor Jeffrey Rosenfeld
Director of Neurosurgery, Alfred Hospital and
Head of Department of Surgery,
Central Clinical School,
Monash University
The Alfred Centre, PRAHRAN, VIC

Ms Halina Oswald
Director, Monash Research Office
Monash University, CLAYTON, VIC

Dr David Lyster
Manager, Research Partnerships
Monash University, CLAYTON, VIC

Professor Marcello Rosa
Deputy Head of Department, Physiology
Monash University, CLAYTON, VIC

Professor Erol Harvey
CEO, MiniFAB
1 Dalmore Drive, Caribbean Park, SCORESBY, VIC

Mr Jefferson Harcourt
Managing Director, Grey Innovation
255 Mary Street, RICHMOND, VIC

The Steering Committee met on the following dates during 2011:
23rd February
16th March
20th April
25th May
15th June
20th July
17th August
14th September
26th October
30th November

Commercial Committee

The Commercial Committee is a sub-group of the Steering Committee, which focuses on commercially relevant issues. The Commercial Committee met twice during 2011, with members:
Ms Vicki Tutungi
Professor Arthur Lowery
Dr David Lyster
Professor Erol Harvey
Mr Jefferson Harcourt
Professor Jeffrey Rosenfeld

Executive Team:

Professor Arthur Lowery, Director
Dr Jeanette Pritchard, General Manager
Ms Suzanne Hayster, Administrative Assistant

Senior Investigators

Professor Arthur Lowery
Director, MVG and Head of Electrical and Computer Systems Engineering, Monash University

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

Professor Jeffrey V. Rosenfeld
Chief Investigator, Department of Surgery, Monash University

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

Associate Professor Lindsay Kleeman
Chief Investigator, Department of Physiology, Monash University

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

Dr Jean-Michel Redouté
Electrical and Computer Systems Engineering, Monash University

Dr Mehmet Yuce
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

Dr Nemai Chandra Karmakar
Chief Investigator, Department of Electrical and Computer Systems Engineering, Monash University

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

Professor Erol Harvey
Principle Investigator and CEO, MiniFAB

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

Product Development, Supporting Research and Testing

System Overview

Monash Vision Group is developing a complete end to end system for bionic vision, which will use an off-the-shelf digital video camera as its input. High quality images can be obtained from a web-cam like device, which is small enough to fit onto a pair of spectacles. These images are sent to a Pocket Processor, which is a powerful yet energy efficient portable computer. The main function of the Pocket Processor is to process the signals from the camera, extract the most important features and map these onto a low-resolution image that will be sent to the brain. This operation is called signal processing, as signals from the camera are processed to become signals for the implant.

The Pocket Processor is connected to a wireless transmitter coil, held on the outside of the head in close proximity to the implant location. This transmits power and the processed data to the Implant Tiles, which are placed beneath the skull on the surface of the visual region of the brain. It is expected that 10 -12 implant tiles will be used per patient.

The Implant Tiles themselves are programmed to recognise which data is for them. They decode this data and drive appropriate currents to each of their 45 electrodes. The electronics with each tile is miniaturised onto an Application Specific Integrated Circuit (ASIC), which contains analog and digital circuits on a single piece of silicon, with the electrodes serving as the information interface to the brain.

Project progress, from design and prototyping of the Pocket Processor to the geometry and materials for electrodes will be described on the following pages.

How does an electrode induce a visual sensation?

The key to bionic vision using a cortical implant is to inject a small electrical current into the brain, close to the axons that carry signals between the neurons in the visual cortex. This current causes a small voltage drop around the electrode, which in turn, causes currents to flow within the axon. These axonal currents cause a build-up of charge at the nodes of Ranvier in the axon, causing the sodium channels in the axon's membrane to open, producing a spike in voltage. This spike in voltage is exactly as would occur if the axon had received a signal from the cell body of the neuron. Thus, via a chain of events, the electrode current causes the brain to think it has seen something.

The technical challenge is to develop electrodes that can inject sufficient current into the brain, without causing any damage. Damage could result from the mechanical insertion process and from the electrochemical reactions that could occur if there is too much voltage between the electrode and the brain. The performance of the electrodes could also degrade over the longer term because of the brain's response to foreign materials–the generation of protective cells that coat the implant. To address these issues, MVG is designing electrodes with very specific geometries to minimise mechanical damage, whilst ensuring a low-impedance contact between the electrode and the brain. In the short-term well-tested, conventional materials will be used; however, MVG is also testing and developing next generation electrode materials and coatings to improve the electrode-brain interface, which could result in a more sophisticated system in the longer term.

Camera and Pocket Processor

Program Leader–Mr Mike Smith, Grey Innovation
Development Team–Mr Peter Bettonvil, Mr Dennis Greco, Mr Matt Pennycuik, Mr Paul Chiha, Mr Graham Lyford, Mr Nathan Lee

The Pocket Processor is a powerful computational unit that performs signal processing computations on the images from the camera and provides a coded output to the wireless link. Although it can be worn anywhere around the body, the term "Pocket Processor" has been adopted by the team to define its maximum size.

The Pocket Processor will include a high-capacity, lightweight battery that powers the camera, the processor itself and the implant electronics via the wireless link. The battery will be charged using the same socket that is used by the wireless link, so that there is no possibility of the user connecting the system to the mains while it is in use. The processor can also be reprogrammed via the same socket. The controls of the processor will be simple push buttons, each with braille labels.

The electronics design has been largely completed in 2011, with schematics and circuit board designs ready for release to production in 2012. The design uses the very smallest of components and is being manufactured by a high-precision assembly company in Australia.

The processor has its own operating system and drivers for the camera, wireless link and programming interfaces. The operating system and core drivers have been tested on the processor by the software team at Grey Innovation, who have successfully streamed image data from a miniature camera on to the Pocket Processor development platform - a key milestone.

During 2012, the Pocket Processor first prototype design will be finalised and units– with both transcutaneous and tethered communications - provided to the Monash Physiology team for preclinical testing.

Caption: CAD representation of the Pocket Processor, which will be used to optimise the nature of the signal provided by the camera and delivered to the implant.

Signal Processing Research Program

Program Leaders–A/Prof Lindsay Kleeman and Dr Wai Ho Li
Research Team–Dr Wen Lik Dennis Lui, Mr Titus Tang, Mr Horace Josh, Mr Benedict Yong

The aim of the signal processing research program is to identify and develop novel techniques to ensure that the most pertinent and useful information is taken from the external video capture system and presented to the implanted electrodes.

This first stage of this project has been dubbed the "HatPack"–this relates to headwear that has been developed that contains electronics, a camera and visual displays in front of the eyes so that a fully-sighted researcher can experience the image that the implant is designed to provide to a person who is vision impaired. Later, these tools will also be used in the psychophysics test program, to develop appropriate and applicable patient testing protocols pre- and post-device implantation. Two "HatPack" systems were developed by the team in 2010, to enable testing of signal processing techniques.

During 2011, image processing and basic gaze tracking algorithms were implemented and Landholt-C psychophysics eye testing software developed. The team initiated simulated prosthetic vision psychophysics testing and three algorithms to process RGB-D (Red, Green, Blue and Depth signals) were also implemented. These extract information depending on the mode they are set to; Ground Plane Detection is useful for navigation–the carpet or floor is highlighted which shows a clear path for the user to follow. Structural Edges mode shows the outlines of objects such as tables and door frames. People Detection mode identifies the presence of people in the user's environment. By flicking between these modes, the user could navigate to a room or office, pass through its door, find the furniture and then identify the locations of other people in the room. Furthermore, an algorithm derived from robotics, the ICP algorithm, has been implemented into the HatPack to help users localise themselves within their environment. The HatPack systems have been used to evaluate these modes in a simple indoor test environment, both by MVG staff and visitors, with all users quickly learning to interpret the information they are presented with.

Another arm of this research is to assess the impact of the positioning of the electrodes on the V1 region of the visual cortex. Just as the brain allocates more surface area to the fingers than the fore-arms, the visual cortex allocates more surface area to the central vision than the peripheral vision. For bionic implants with a regular array of electrodes, the perceived vision is more detailed at its centre; however, it also distorts the image. To assess the impact of this distortion, the HatPack has been programmed to represent this effect to a fully-sighted user. This model was further improved through collaboration with Drs Hsin-Hao Yu and Tristan Chaplin from Monash Physiology.

In October, Dr Wai Ho Li presented research results at ISMAR 2011, the IEEE Augmented Reality International Conference, including a live demonstration to attendees. A further outcome from this research program was the filing of a US provisional patent application. Discussions between the Signal Processing team and staff at Vision Australia have also been initiated to explore the value of the algorithms for non-invasive methods of vision enhancement.

During 2012, the Signal Processing team will generate more research outputs in the form of conference papers and journals. Psychophysics trials will be conducted to test the usefulness of various kinds of signal processing, which will help inform the preclinical and clinical programs. Algorithms and HatPack devices will continue to be improved and developed, with an aim to assist users who are vision impaired and blind.

Caption: Mr Benedict Yong models the [portable head-mounted display, or "HatPack"

Caption: Advanced Signal Processing–the use of algorithms to optimise the bionic eye experience.
(a) Camera image
(b) Traditional bionic
(c) Structural edges
(d) Face detection
(e) Body segmentation
(f) Face and body

Signal processing improves utility

Present technology means that all bionic eyes have a limitation in how many "dots" or pixels can be presented to the retina or the brain: no device will be high-definition in the near term. MVG aims to provide several hundred pixels, which means a grid of 25 × 25 pixels at most. Although this does not seem many, it should be sufficient to present valuable information to the user. For example, a single dot representing a person could provide information about the person's location, movement and speed–just like a dot on a radar screen provides essential information about an aircraft. But how do you extract a person from a crowded visual scene, such as a street? This is where signal processing comes to the rescue: signal processing is a sub-discipline of electrical engineering which uses fast computation of sophisticated algorithms to extract useful information from signals, be they radio signals, images, audio or radar. Fortunately, because the power of computing chips is growing every year, highly sophisticated signal processing can be implemented in hand-held devices, provided engineers design compact and clever algorithms. Also, sensors such as cameras and rangefinders are becoming smaller and more accurate; so much more information can be fed to the signal processing algorithm, to separate people from backgrounds, for example. The benefit of signal processing is that it can be tuned on-the-fly for different applications, thus, instead of representing a person as a moving dot, one can zoom in and represent their emotions with visual clues such as emoticons, or zoom out and trace a path to avoid them. MVG plans to continue developing "apps" for the bionic eye, driven by feedback from the vision impaired community into what can really improve their quality of life and independence.

Wireless Link

Program Leader–Dr Mehmet Yuce, Monash University
Research Team–Mr Peter Crowhurst, Mr David Petzer

The MVG wireless link comprises a transmitter, placed on the outside of the back of the head, and a receiver within each implant tile. The wireless link must transmit electrical power to each tile, so that it can generate sufficient currents in the electrodes and also have power for its electronics and data. Furthermore, the wireless link sends a clock signal to all of the tiles, so that they know when each data bit has been sent and can also run their electronic processes with accurate timing.

During 2011, MVG investigated the optimum type of signal for the wireless power, data and clock transmission, otherwise known as the modulation format. The MVG modulation format is a modified form of pulse-width modulation, which enables extraction of a reliable clock from the signal, which is necessary to extract reliable data.

Electromagnetic simulation software has been used to compare different designs of inductive coils that are used in the transmitter and receivers, with simulations initially being verified with hand-wound prototypes. During 2012, verification will also be performed using machine made coils to reduce variation from coil to coil.

The circuit design of the wireless transmitter has been developed using electronic circuit simulation software and a prototype transmitter circuit has been built and tested. The wireless receiver is similar to the 1960's version, with an important exception - it will be followed by a sophisticated digital logic circuit incorporating approximately 500,000 transistors. A prototype of the front-end of the receiver has been built, and the signals from this captured by a high-speed digital oscilloscope. These signals have been used to stimulate a model of the back-end of the receiver, which converts the analog signals into digital data pulses; this will enable the digital design to be verified with real signals during 2012.

Caption: Photograph of early stage prototype transmitting and receiving coils for the wireless link. The coils are positioned next to a to-scale silicon replication of a human brain produced by MiniFAB, which will be used for trialling both surgical aids and array implantation techniques. Further development on the wireless coil design is underway as the planar system demonstrated here will not be suitable for use in the final devise.

Early wireless bionic vision

The first bionic vision experiments by Brindley in the 1960's [1] used a very similar concept to that of the MVG implant tile, in that electrodes were fed current from wireless receivers. However, in those days only very simple electronics could be fitted into the human head, as a single electronic component was as large as a powerful processor is today. This meant that each electrode had its own radio receiver, similar to the battery-less "crystal set" receivers popular with hobbyists in the 1930's, but using a glass-encapsulated semiconductor diode for rectification. Brindley simply moved the transmitter over the surface of the head to stimulate part of the visual field. Due to the size of each receiver, these were fitted under the majority of the scalp, with wires connected to the electrodes on the visual cortex. This required careful surgery in order to place the wires neatly across the skull.

Astounding advances in electronics and miniaturisation over the last 40-50 years has allowed the electronics to be built on the same scale as the spacing of the electrodes, so that the electronics for 45 electrodes sits directly above them, in a "tile". The electronics is far more sophisticated than a single diode, because it must decode the wireless signals, then ensure the correct electrodes are activated to form a picture.

[1] G. S. Brindley and W. S. Lewin, "The sensations produced by electrical stimulation of the visual cortex," J. Physiol. (Lond.),vol. 196, p. 479, 1968.

Implantable Electronics (ASIC)

Program Leader–Dr Jean-Michel Redouté, Monash University
Research Team–Dr Damien Browne, Dr Anand Mohan, Dr David Fitrio

The first MVG Application Specific Integrated Circuit (ASIC) prototype–ASIC 1 - was designed during 2011, which incorporates a mixed-signal circuit containing 500,000 transistors and 45 analog electrode drivers, interconnected by 45 digital to analog converters. Following verification, the chip design was provided to the foundry for tape-out and manufacturing as part of a multi-chip project–a process whereby chips from many designers are placed onto a single wafer to reduce prototyping costs by a factor of between 10 and 100.

ASIC 1 can decode signals sent to it on a single wire and then drive each electrode with a positive or negative current for a prescribed duration. It can be programmed with different pulse widths and currents, and will then use these settings each time it is asked to turn an electrode on by the Pocket Processor.

Delivery of ASIC 1 is expected in February 2012, following which bench testing and characterisation will be performed. This process requires a test platform to be both designed and manufactured–development of the platform was initiated in 2011 and will be finalised prior to chip delivery in 2012. During early 2012, a test board and ASIC test modules will be manufactured by Grey Innovation, which will be available upon delivery of the chips from the foundry. The test board will be driven from an FPGA evaluation board programmed at Monash University, to produce test signals for ASIC 1.

Following bench testing and verification, ASIC 1 will undergo further processing to be incorporated into the implant tile, which in turn will allow the chip to communicate with the electrodes. Building and both bench and preclinical testing of the packaged system will be undertaken during 2012.

Learnings from ASIC 1 will also be used towards the development of a further two ASIC designs during 2012:

• ASIC 1b will include the functionality of ASIC 1 plus additional circuits for wireless communication between the external visual processor and the stimulating electrodes. This device will be designed for a more advanced fabrication process to enable inclusion of wireless communication; however, it will be the same device size as ASIC 1.

• ASIC 2 will be implemented in the latter half of 2012. This will have the functionality of ASIC 1b with improved electrode stimulation circuitry, which will make it suitable for use in the MVG clinical program.

Creating microchips for brain implants

The key challenge in the development of the MVG ASIC has been the incorporation of a vast amount of functionality and capability in a chip that is of an area equivalent to a child's fingernail. Chips used in the IT industry, with a similar level of functionality, are generally a factor of 100 larger in area. This has required the ASIC team to use highly sophisticated software and verification techniques to implement the design features that are required for a Class III implantable device. One example is the requirement for safety circuitry, which will provide failsafes against dangerous levels of stimulation in the brain and package failure. Additionally, the ability to drive

45 electrodes per tile–and hence per ASIC–requires double the number of digital-analog converters and amplifiers than are used in the latest Cochlear implants.

Implant Tile - Mechanical Design

Program Leader–Dr Micah Aitkin, MiniFAB
Development Team–Mr Brody Payne

The key to a successful medical implant is the packaging, which must protect the electronics by preventing contact with body fluids (also known as "hermetic sealing") and also prevent bacteria from colonising the implant, which could ultimately result in failure in device functionality.

During 2011, three design variations for the implant tile were produced by MiniFAB and assessed for their viability, through extensive discussions with multinational suppliers of implantable medical devices. Materials options were also discussed and finalised, with consideration given both to the robustness of the materials and evidence of previous use in approved implantable devices. This provides MVG with a high level of confidence that they are both suitable and safe for use in the human body.

MVG has chosen to use a ceramic package to hermetically encapsulate the ASIC, with- 45 stimulating electrodes fed through into the package base and a cap welded over the electronics. The electronics, including the ASIC, will sit upon a ceramic circuit board subassembly within the implant. This subassembly will carry the circuit tracks that connect the ASIC to the electrodes and the front-end of the wireless system. It has been designed to be assembled and electronically tested before being placed within the ceramic package.

Each tile package will cover an 8-mm square area of the brain and provide 45 electrode sites spaced 1-mm apart. The materials in contact with the body are generally considered to be biocompatible and have previously been approved for use in medical implants. These materials include the ceramic, platinum-iridium, titanium and polymer coatings.

MiniFAB is leading the development of the ceramic package and subassembly, in addition to developing manufacturing and assembly processes for the complete implant. During 2012 and following delivery of the ASIC 1, 1b and 2, the implant tile will be assembled with the corresponding circuitry and electrodes and provided to the Monash Physiology team for preclinical testing. This systems integration will result in hermetically sealed, fully packaged implant tiles that will ultimately, with ASIC 2, be used in first patient tests.

Caption: CAD representation of 435 electrode array tile.

Caption: Manufactured ceramic package from the bottom and top.

Implantable Electrodes - Electrical and Mechanical Design

Program Leader–Dr Micah Aitkin, MiniFAB
Development Team–Mr Brody Payne, Dr Matthew Solomon

The electrode design and materials, including non-functional coatings, are critical for effective stimulation of the visual cortex and subsequent generation of pixel-like spots, which are also known as phosphenes, in the user's visual field. Prior to finalising these parameters, consideration has also been given to the electrode geometry from the point of view of strength, to ensure that it remains robust following implantation into the brain tissue. Different geometries result in different voltage fields around the electrode, so it can be designed to actuate specific orientations of axons at various depths within the brain. To help the design process, mathematical and computer models of the axons and the electrodes have been generated by MVG PhD students and Research Assistants during 2011, which allow rapid comparisons by plotting the activation function around a given geometry. This work crosses traditional discipline boundaries as it combines mechanical engineering, electrical engineering, electrochemistry and materials engineering. With the aid of these models, the electrode geometry can be optimised and experimental observations can be explained.

Following such studies, platinum-iridium has been chosen for the electrodes and is likely to be used for the first-in-human prototype. This material system has previously been approved for cortical implants, which is a key advantage with the aim of first patient tests in 2014. Also resulting from this work has been the ability to reduce the current, required to stimulate the axons, by a factor of four. This reduction in stimulation current has a positive impact on the whole system, including the size and power consumption of the implanted electronics, the design of the wireless link, through to the battery life of the full device.

Using the information provided through the research team at Monash Engineering, MiniFAB has designed and–using state of the art fabrication techniques - prototyped single electrodes and electrode arrays for testing by the Monash Physiology preclinical team. Mechanical robustness, stimulation capability and operational lifetime of the electrodes and arrays have been assessed during 2011, with longer term studies continuing into 2012.

Caption: Electrode test array produced by MiniFAB for use by the Monash Physiology preclinical team.

Functional Coatings Research Program

Program Leader–A/Prof John Forsythe
Research Team–Dr Kun Zhou, Mr Peter Nicholls

The aim of the functional coatings research program is to improve the performance of the electrode arrays, following implantation in the brain. In 2011, a method of coating electrodes was developed, which is compatible for coating different base materials and geometries. These thin coatings maintain the low impedance of the electrode design and importantly act as a platform for attaching biological molecules. These biological molecules can reduce the brain's response to foreign objects–a process known as astrogliosis. Through collaboration with the Monash Physiology team, coatings were shown to be robust, as they withstood shear forces upon injection into brain tissue and also that they did not elicit a major inflammatory response.

The team also developed methods to make the coating itself electrically conducting, which reduced the impedance of the electrode. Importantly, this results in the use of smaller currents and lower voltages, improving safety and reliability of the electrodes in the human brain.

The coatings will also be used as a platform to attach anti-inflammatory molecules. Three biomolecules with interesting properties have been identified and strategies to covalently attach the coatings will be developed during 2012, with a focus on ensuring the coatings will remain robust and not detach from the electrode surface over extended periods of time. This will result in regulation of inflammatory processes around the electrode, but not away from the electrode surface in the bulk brain tissue, which could result in harm to the patient over long periods of time.

Caption: Scanning Electron Micrograph of acutely inserted electrode showing the integrity of the coating has been preserved.

Improving electrode performance

There are a number of physiological responses that occur upon implantation of a material that the body considers "foreign"–and a fine line between ensuring that while these responses should not limit or affect the functionality of the implant, they should still be allowed to occur so as to not have a detrimental effect on the patient's health. Parallels can be drawn with organ donations, which if not compatible, can be rejected by the recipient's body. MVG is looking into different methods of reducing some of these responses by developing coatings for the electrodes that will control the physiology of the surrounding tissue, reduce tissue damage upon insertion of the electrode arrays and keep the implant functional for a longer period of time. There are many materials that have the properties for this function; however, as with all implantable materials they need to be extensively tested in preclinical safety studies to demonstrate that there is no risk of harm to the patient over the lifetime of the implant. Many groups believe that the majority of damage occurs immediately following implantation and therefore biocompatible electrode coatings that are designed to reduce this acute damage are of particular interest.

Surgical Aids

Program Leader–Dr Micah Aitkin, MiniFAB
Development Team–Mr Brody Payne, Dr Matthew Solomon, Mr Luke Marsden

The surgical aids are the surgical array packaging and the surgical tool. The surgical packaging fulfils a number of important functions, including protection for the arrays during general handling and transportation, providing a holding mechanism for the sterilisation processes and to assist the neurosurgeon with array handling during the implantation procedure.

The surgical tool will be used by the neurosurgeon during the implantation procedure to precisely and reliably insert the electrode arrays. This tool is not only critical for providing a simple and easy-to-use implantation procedure for the neurosurgeon, but also to minimise damage to the electrodes and brain tissue during the implantation procedure and to ensure the electrodes are implanted reliably in the same region of the visual cortex.

During 2011, prototypes of both the packaging and tool were developed by MiniFAB and tested extensively by the Monash Physiology preclinical team. These trials resulted in design modifications, with a close-to-final version of each due for delivery during early 2012. These surgical aids will be assessed further by the preclinical teams and also be reviewed and considered by the clinical team for their suitability for use in a surgical environment.

Caption: Surgical tool and packaging prototypes, which underwent preclinical assessment during 2011.

Preclinical Program - Biocompatibility, Mechanical Assessment and Functionality of Prototype Systems

Program Leader–A/Professor Ramesh Rajan
Research Team–Dr Chun Wang, Dr Saman Haghgooie, Ms Kahli Cassells

A key component to developing a human implant is verifying its functionality and compatibility with a biological system. Where possible, MVG has used extensive computer simulations to optimise the design of electrodes and implantable components, but it is critical to build confidence that the device will be both effective and safe. This requires testing individual components for functionality and longevity.

In 2011 the preclinical group focused on testing the design of the electrodes for the implant in addition to assessing the usability of the custom-designed and built surgical tools developed by MiniFAB. This included testing and developing new designs for the electrodes' geometry and non-functional coatings to define stimulating regions, developing methods to compare different insertion speeds of the electrodes into brain tissue and developing repeatable methods for assessing the functionality of the electrodes. Well-defined processes for pre-insertion quality assurance have been developed to ensure that the number of preclinical trials is reduced to a minimum, whilst maximising the learnings.

This work was performed in close collaboration with the industry partners, so that learnings were fed back into the design of both the electrodes and surgical tooling within one design cycle. The designs evolved with inputs and suggestions from all partners. This interaction has been critical to the project, as every design decision has a multitude of ramifications.

The nature of the work, focusing on the development of tools (including electrodes and appropriate test systems), precluded the publication of much of the data obtained in 2011. Nevertheless a strong body of work was obtained on motor cortex stimulation by various electrode geometries. This is being compared with computer models, and has also been accepted for publication in 2012.

Caption: Development of in vitro test systems–still frame showing the insertion of an electrode array held in an MVG prototype insertion device into agar with the same consistency as the human brain.

Caption: Histological examination: horizontal brain tissue section, in which a 4-electrode array was implanted using slow insertion system.

Preclinical Program - Functionality and Effectiveness of Advanced Systems

Program Leader–Professor Marcello Rosa
Research Team–Dr Nic Price, Dr Leo Lui, Dr Sofia Bakola, Dr Saman Haghgooie, Ms Claire Annunziata

This research program has two aims, which represent key steps in the development of the MVG cortical implant. On one hand, 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. In parallel, it explores a number of specific questions related to the organization 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 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.

In 2011, a series of visual discrimination and eye tracking tasks were designed and implemented, which will allow the long-term testing of the effectiveness of the electrode arrays. This has required substantial infrastructure investment by Monash University, in the form of a new, world-class preclinical facility, dedicated to studies correlating perception and behaviour. This represents a unique national resource, which will be of benefit not only for this immediate project, but for the longevity of medical bionics development in Australia. Validation trials of the behavioural assays using currently available technologies have been initiated, which will be used as a baseline for comparison with the new, advanced intelligent electrode arrays currently under development by MVG.

In parallel, significant discoveries have been made about the organization of the visual cortex, which have immediate outcomes in the form of pointing to strategies for optimisation of the placement of the electrode arrays. One such outcome was the development of programs for visualisation of the pattern of visual representation in the normal primary visual cortex (V1), and the consequent creation of the most accurate mathematical model of the way visual information is distributed to cells in different parts of this area. In addition, preliminary data have been obtained about the manner in which visual information is projected to other areas of the cortex, and what are the likely functions of the analyses performed in these other areas. These data will be fundamental for the future development of more advanced cortical prostheses, capable of eliciting more natural sensations of motion and colour, and prostheses that can be used by people who lose vision due to stroke affecting the occipital lobe.

In 2012 the studies of long-term effectiveness and compatibility of the electrode devices will be continued, focusing on issues such as potential failure rates as a function of time, and testing the outcomes of different modes of electrode insertion. On the basic science program, the mode of representation of rapidly moving stimuli in the brain will be investigated, including the neural signals used to compute the speed of different objects, and the types of electrical activity that enable the perception of a continuous, smooth motion.

Caption: Mathematical model of the normal primary visual cortex (V1).

Clinical Program - Psychophysics and Multi-Sensory Integration

Program Leader–Dr Stuart Lee
Research Team - Associate Professor Ramesh Rajan, Associate Professor Anthony Hall, Mr Ross Anderson

This arm of the MVG Clinical Program is for the development of programs to test for multi-sensory integration, specifically, auditory and visual integration. The rationale for this emphasis was the determination that cross-sensory input could help facilitate the learning by patients of how to use the "phosphenes" evoked by cortical electrical stimulation. This could significantly improve the ability of patients to use the information provided by cortical electrical stimulation and could speed up the time for a patient to confidently navigate a closed-set environment.

Two programs were successfully developed, which will be validated and tested in fully-sighted people during 2012 to determine normative normal-vision parameters. 2012 will also see the development of a suite of tools for haptic-vision integration, based on these same principles. An important aspect to the program in 2012 will be to carry out an evaluation of patient and carer expectations of outcomes from a visual prosthesis–this will be conducted by Mr Ross Anderson, an Psychology Honours student.

Clinical Program - MRI Visual Cortex Mapping

Program Leader–Professor Jeffrey Rosenfeld
Research Team - Ms Helen Ackland, Professor Gary Egan, Dr Jerome Maller, Dr Sanjeeva Ramasundara, Professor Marcello Rosa, Associate Professor Ramesh Rajan, Associate Professor Anthony Hall

This study involves the investigation of the anatomical extent of the primary visual cortex which must be identified via visualisation of the band of Gennari, and detailed anatomical mapping of the cortex using high resolution MRI. Such evidence will allow for planning of the placement of the implant tiles in the ensuing surgical implantation component of the MVG Project, via the development of predictive algorithms aimed at the identification of the anatomical areas of V1 in vision impaired patients.

Patient recruitment was initiated during 2011 and will be completed in early 2012. Patients and age-matched controls have been recruited from the Ophthalmology Outpatient Clinic at The Alfred Hospital, and from Vision Australia Low Vision Clinics. An ethics submission was prepared and approved by the Alfred Hospital Ethics Committee in 2011.

MRI scans will be conducted at the Monash Biomedical Imaging facility at Monash University in March, 2012, and the appropriate software update for the analysis and comparisons of the MRI scans at The Alfred Hospital has been purchased and installed in preparation for the imaging structural and diffusion analysis to be conducted during 2012. Data analysis and reporting will follow, with the project reaching completion by the end of 2012.

Caption: Fractional anistropic map and white matter tractography of the human brain based on diffusion weighted magnetic resonance images. Similar tools will be utilised in the MRI Visual Cortex Study, to understand the anatomical areas of V1 in greater detail.

Clinical Program - First In Human Implant Study

Program Leader–Professor Jeffrey Rosenfeld
Research Team–Ms Helen Ackland, Associate Professor Ramesh Rajan, Associate Professor Harvey Newnham, Professor Jayashri Kulkarni, Professor Paul Fitzgerald, Associate Professor Anthony Hall

The First In Human (FIH) Demonstration project is a clinical pilot study to be undertaken at The Alfred Hospital, to ascertain the level of clinical feasibility of the subdural surgical implantation of an electrode array for the purposes of subsequent biophysical testing and training to develop artificial vision in severely vision impaired patients. The first patient will be the start of a small pilot study, with the device being composed of biocompatible and non-toxic components that have been manufactured according to the necessary regulatory and quality processes to ensure patient safety. The participant(s) will have severe bilateral vision impairment existing for a period of 12 months or longer, with visual acuity of Snellen's Test Type 6/60 or less and a history of normal vision in adulthood. Potential participants will either be identified by clinicians at Vision Australia, who will have received study information via the office of Chief Executive Officer of Vision Australia, or will have directly contacted the Monash

Vision Group at Monash University via the dedicated website. An extensive participant screening process will ensue, prior to the selection of the optimal patient(s).

Two background publications are planned for submission in 2012, and are currently in draft form. These include review papers pertaining to the restoration of vision using bionic devices, and the Monash Vision clinical program.

The Project Protocol has been finalised for this project, and submission will be made to The Alfred Hospital Human Research and Ethics Committee in February, 2012. Following approval, screening will begin in order to recruit optimal patient(s) for the FIH pilot project, with implantation surgery scheduled for early 2014. Planning for the extensive medical and psychological screening processes involved in recruitment has been confirmed, and the screening procedures are in place. In addition, a focus group study involving vision impaired participants is currently in the planning phase. This study involves understanding and analysing participant expectations and will be conducted by Mr Ross Anderson, a psychology honours student, who will be supervised by A/Professor Ramesh Rajan, Dr Stuart Lee and Ms Helen Ackland.

Caption: Professor Jeffrey Rosenfeld, demonstrating the location of the MVG implant in the primary visual cortex.

Research Training and Skills Development

Focus on ... PhD Students

Profile–Emma Brunton

PhD Thesis: Optimising cortical microelectrodes for prosthetic devices
Supervisors: Professor Arthur Lowery and A/Professor Ramesh Rajan

Emma is investigating how electrode geometries affect the electric fields produced by stimulation in the brain. She is using computer modelling and physiological studies to determine how these different electric fields affect damage and activation of neurons in the primary visual cortex.

Profile–Andrew Cookson

PhD Thesis: Optimisation of electrode array currents for neural prosthetic applications
Supervisor–Professor Kate Smith-Miles

Andrew is investigating mathematical methods to optimise stimulation for bionic vision. He is initially working on stimulation of the barrel cortex, involving computational modelling of axonal stimulation using penetrating electrode arrays.

Profile–Horace Josh

PhD Thesis: Low resolution vision for the Monash bionic eye
Supervisor: A/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. Development of a portable simulator system ("HatPack") has been completed, which will be used as psychophysical test platform for the trialling and investigation of newly developed functions/algorithms.

Profile–Titus Tang

PhD Thesis: Interactive assistive technologies for the vision impaired
Supervisor: Dr Wai Ho Li

Titus's research aims at developing a framework for interactive assistive technologies - devices with intelligent software that provide improved service to a user through both implicit understanding of context and explicit feedback from the user. Developing a user friendly and efficient two way communication channel between device and user is critical. The research will involve conducting detailed surveys with the vision impaired community, designing a two-way feedback-centric system that best meet user needs and conducting user trials.

MVG has also provided opportunities for young graduates to get involved in both industry and academic projects. Luke Marsden, a Mechanical Engineering student at Monash University, spent 2011 working part-time at MVG industry partner MiniFAB and was integral in designing and fabricating the first prototype of the surgical tool for array implantation. Benedict Yong, Aupi As-Saber and David Petzer–previously enrolled as undergraduates in the Faculty of Engineering, worked as Research Assistants in the MVG Electronics lab on signal processing, modelling of electrode stimulation in brain tissue and wireless transmission respectively. Kahli Cassells has provided expertise as a research technician in the physiology group, with a focus on processing histological tissue samples to inform the design and insertion procedure of arrays into the brain. Peter Nicholls performed his Honours project with A/Professor John Forsythe to study functional coatings for reduction of gliosis in brain tissue following insertion of arrays and Andrea Vagnarelli performed his graduate project with Professor Marcello Rosa, towards mapping of visual representations in the cortex. MVG was also delighted to provide a Year 10 work experience placement for Guillaume Garnier, who assisted the Signal Processing team with psychophysics experiments.

Lectures to students:

• Marcello Rosa–provided lecture to MVG Engineering students on brain anatomy.
• Marcello Rosa - PHY3111 Sensation and Movement Course (Year 3): "Restoring the function of adult visual system".
• Wai Ho Li - ECSE Lecture Course ECE3091 Engineering Design (Year 3) elective with 70 students.
• Wai Ho Li–ECSE Lecture Course ECE2072: "Digital Systems".
• Wai Ho Li–ECSE Lecture Course ECE4075: "Real time and Embedded Systems".
• Jefferson Harcourt - Guest Lecture for ECE3091 Engineering Design (Year 3): "Requirements, design and architecture".
• Damien Browne–Guest Lecture for ECE3091 Engineering Design (Year 3): "ASIC and FPGA design".
• Dennis Lui–Guest Lecture for ECE3091 Engineering Design (Year 3): "Refactoring image processing and robotic sensing software".
• Arthur Lowery - Medtech Student Forum (Monash): "Importance of early industry engagement".
• Arthur Lowery–ECSE Lecture Course ENG1110 (Year 1) "Biomedical Engineering"
• Arthur Lowery–ECSE Lecture Course ECE4087 (Year 4) "Medical Technology Innovation"
• Arthur Lowery–Lecture at Institute of Neuroscience, Newcastle upon Tyne, UK (September) "Bionic Eyes from Australia–Monash Vision Group's Cortical Visual Implant"

Commercial Program

Intellectual Property

2011 saw the filing of the following patent applications:

Application Number	Title	Application Date	Inventors
P34726USP1 (US Provisional)	System and method for processing sensor data for the	30-Aug-11	Lui, Browne, Kleeman, Drummond, Li

	visually impaired		
2011904816 (Australian Provisional)	Apparatus and method for surgical insertion of an implantable device	18-Nov-11	Atkin, Marsden, Payne, Rajan, Solomon, Rosenfeld

In addition, the following provisional patent application was re-filed in 2011:

Application Number	Title	Application Date	Inventors
2011901539 (refile of 2010901662)	Intelligent electrode tiles for bionic eye	27-Apr-11	Lowery; Rosa; Rosenfeld; Li

To ensure that all patent applications, design registrations and know-how that is developed will add value to the MVG portfolio, the company IP Pragmatics was engaged to perform a patent landscaping exercise across a number of areas relating to bionic vision.

Shown below is an example of an analysis map generated by IP Pragmatics, highlighting key areas of IP generation being pursued globally by groups and companies working in the field. This report has enabled MVG to define strategic areas for the generation of novel technologies and processes for the direct to brain bionic eye and associated spin-off products. The information produced within the report also forms the basis of the ongoing IP and Freedom to Operate analysis being conducted by MVG.

Business Plan

During 2011, MVG established a Commercial Committee to govern aspects of the project relating to the business plan, IP management and next phase funding. The Commercial Committee met twice over the course of the year and agreed that following delivery of the IP Pragmatics report, additional assessment of freedom to operate, competitive analysis, market analysis and reimbursement were required. This resulted in discussions with Professor Mike Vitale, manager of the Masters in Business (Science and Technology) course at Monash University to engage graduates and new students to undertake commercial analyses for MVG. Projects were scoped and will be undertaken during the early part of 2012. The Committee agreed to discuss the need for establishment of an autonomous business entity following compilation of this information.

Regulatory Affairs

In July 2011, MVG engaged regulatory experts Brandwood Biomedical to perform a workshop highlighting regulatory requirements for the development of a Class III medical device such as the direct to brain bionic eye. The workshop consisted of a briefing from MVG management, a Brandwood Biomedical presentation to MVG staff covering Australian and US regulatory frameworks and requirements and concluded with a detailed question and answer session relating to specific processes and documentation to be implemented for each MVG device development program.

MVG - through extensive input from industry partners MiniFAB and Grey Innovation– has also implemented a number of quality control and quality assurance practices into the device development program in line with requirements for the manufacture of a device of this type (consistent with ISO 13485 regulatory standards), including patient risk and harm analysis, technical risk analysis for the device design and architecture and device and component verification and validation processes.

Events and Communication

Conferences

Medical Bionics 2011–held in Philip Island in November 2011, MVG had a large contingent present at the conference. In addition to a Keynote presentation by Professor Jeffrey Rosenfeld, MVG presented four posters and was attended by eleven staff and students. MVG was also delighted to provide sponsorship towards Professor Richard Normann from the University of Utah, who was a Plenary Speaker and who discussed many aspects of his work in developing cortical vision prostheses with members of MVG over the duration of the conference. Professors Arthur Lowery and Jeffrey Rosenfeld also entertained delegates during the conference dinner, playing a homemade fretless bass guitar and soprano saxophone respectively.

ISMAR 2011–IEEE International Symposium on Mixed and Augmented Reality. This is the top conference in its field with an acceptance rate <20%. Dr Wai Ho Li presented his work on improving the saliency of bionic vision and also demonstrated the Hatpack prototype system live at the conference to an audience of 100 delegates.

ACRA 2011–Australasian Conference on Robotics and Automation. Held at Monash University in December 2011, ACRA was organised and Chaired by MVG Chief Investigators Dr Wai Ho Li and A/Professor Lindsay Kleeman. The conference attracted top international researchers from Europe and the US, with five additional attendees from MVG who presented posters and performed live demonstrations of the Hatpack prototype system.

Caption: Professor Lowery with Professor David Pennington, Chair of the Bionic Vision Australia Board.

Caption: Professors Lowery and Rosenfeld entertain delegates at the conference dinner.

Caption: Drs Wai Ho Li and Dennis Lui demonstrate the HatPack at ACRA 2011.

Outreach and Stakeholder Engagement

At the Blind Citizens Australia National Convention in October Dr Jeanette Pritchard took the opportunity to speak directly with the blind community about the project, with a recording of her presentation being available on the BCA website for downloading. Professor Jeffrey Rosenfeld was also invited to present to over 80 members of Glaucoma Australia in August. Such events are particularly valuable for the MVG team as they provide the opportunity to directly address any queries or concerns from the blind and vision impaired communities.

Following a presentation to the Vision Australia Board earlier in 2011 by Professor Arthur Lowery, MVG and BVA were invited to have a joint presence at the Vision Australia Texpo in Melbourne and Sydney, which was an excellent opportunity to present information on both projects. AusMedTech and STC's Eye to Eye seminar in September brought MVG and BVA together again, with MVG's Dr Nic Price and BVA's Professor Rob Shepherd presenting to representatives from the medical device sector.

Caption: Prof John Forsythe explains the MVG system to ARC CEO Prof Margaret Sheil and Senator the Hon Kim Carr at the ARC Expo.

At the Monash Business Breakfast in November an audience comprising government, industry, healthcare providers and advocacy groups gathered to hear an overview and status report on the MVG project from Professors Arthur Lowery and Jeffrey Rosenfeld and Dr Jeanette Pritchard in addition to hearing about the end-user perspective from Mr Gerard Menses and Mr Kevin Murfitt, Vision Australia CEO and Chair of the Board respectively. Many attendees commented that the presentations provided them with a clear understanding of the project and the advantages of a cortical prosthetic device.

At the ARC Expo Associate Professor John Forsythe demonstrated the MVG array to Senator the Hon Kim Carr. This event was also attended by Mr Jefferson Harcourt from Grey Innovation. Dr Jeanette Pritchard also attended the ARC Directors Forum during September, on behalf of Professor Arthur Lowery who was visiting the Institute of Neuroscience, Newcastle upon Tyne (UK). This one day event provided the opportunity for Directors and Managers to convene with representatives from the ARC and discuss achievements, challenges and other key issues associated with Special Initiatives and Centres of Excellence.

Professor Erol Harvey was invited to present at the National Elite Sports Council 2011 Forum, held at the Australian Institute of Sport in Canberra in November, where he provided an update on MVG activities. MVG has also been active in providing information to future students, with Dr Wai Ho Li demonstrating real-time Hatpack simulations to hundreds of onlookers at the Monash Open Day.

Importantly, MVG has welcomed the opportunity to meet with members of Bionic Vision Australia on a number of occasions throughout 2011. Discussions have covered opportunities for the groups to collaborate technically, in addition to working together to actively promote the Initiative and jointly provide information to the blind and vision impaired communities. A highpoint of these interactions was a joint meeting with the members of MVG and BVA Boards in December, who discussed strategies for working together over the remainder of the projects and beyond.

Caption: Members of the MVG and BVA Boards at the meeting in December: Professor Peter Blamey, Dr Hamish Meffin, Professor Anthony Burkitt, Professor Nigel Lovell, Professor David Pennington, Dr Jeanette Pritchard, Professor Lyn Beazley, Professor Jim Patrick, Ms Julie Anne Quinn, Professor Colin Sutton, Ms Tamara Brawn, Professor Gregg Suaning, Professor Arthur Lowery

Visits and Visitors

Building on the biomedical alliance between Monash University and the University of Newcastle-Upon-Tyne, in November MVG received a visit from Dr Andrew Jackson, a Wellcome Trust Research Career Development Fellow at the Institute of Neuroscience in Newcastle. Andrew's visit followed visits by Professor Colin Ingram, Director of the Institute of Neuroscience May 2011 and a subsequent visit to Newcastle upon Tyne by Professor Arthur Lowery during September 2011. Andrew's research areas include neural mechanisms of motor control, cortical plasticity and spinal cord physiology. During his visit to Melbourne Andrew spent time with the MVG physiology, clinical and engineering teams, discussing device test methodology and exploring opportunities for future collaborations.

Earlier in 2011, MVG hosted Professor Gunter Ehret from the Institute for Neurobiology at the University of Ulm (Germany). In April Gunter spent a week with the Physiology and Engineering departments, discussing his work in auditory communication, modelling of functional neuronal networks, neuroanatomy and neuroplasticity.

In late November, MVG was delighted to host a visit by A/Professor Phil Troyk, from the Department of Biomedical Engineering, Illinois Institute of Technology (US). Phil leads a multi-centre project on the development of an intra-cortical visual prosthesis. This was a splendid opportunity for members of MVG to speak with Phil about his work and to explore potential opportunities for collaboration, with the groups already identifying further opportunities for future visits to their respective facilities.

In December, MVG was equally pleased to co-sponsor, with IEEE, a visit by Professor Andrew Schwartz from the Pittsburgh Motor Lab (US). Andrew spent a few days visiting the Monash Physiology team and also performed a public lecture as part of the IEEE Distinguished Lecture Series at Engineers Australia in Melbourne, titled "Progress toward high-performance brain-machine interfaces".

Professor Marcello Rosa visited the Cold Spring Harbor Laboratory in Long Island (US) during July, where he met with Professor Partha Mitra, an expert in neuroscience and theoretical biology. Marcello's visit is likely to be followed up by a return visit to MVG by Professor Mitra during 2012.

Professor Arthur Lowery and Dr Micah Atkin of MiniFAB visited the new Cochlear Ltd facility in New South Wales during March to discuss a number of critical aspects of the MVG system architecture.

Media and Marketing

MVG has retained a corporate communications consultant with expertise in science and innovation to assist with media and PR activities. Mark Kestigian, through his company KM-Associates, has introduced MVG to reporters from two high impact journals who are both keen to draft MVG articles early in 2012. Two media releases and a project overview: "MVG–At a Glance" were also drafted and provided to interested journalists.

Taking advice from both KM-Associates and members of the Advisory Board, MVG has approached media and marketing in a targeted manner to ensure appropriate management of expectations of the general public and other stakeholders. 2011 articles that reference the Monash Vision Group, either as a primary or secondary focus, are listed below:

• The Australian Online, 29 January 2011: "Aussies blinkered in vision race: local researchers face global competition in bionic market". http://www.theaustralian.com.au/news/health-science/aussies-blinkered-in-vision-race-local-researchers-face-global-competition-in-bionic-market/story-e6frg8y6-1225995765005

• The Australian Online, 5 February 2011: "An eye on the future: bionic vision". http://www.theaustralian.com.au/news/health-science/an-eye-on-the-future-bionic-vision/story-e6frg8y6-1225999806112

• The Age Online, 1 April 2011: "The bionic eye: we have the technology, the microchip has arrived". http://www.theage.com.au/technology/technology-news/the-bionic-eye-we-have-the-technology-the-microchip-has-arrived-20110331-1cngn.html

• Electronic News, 21 October 2011: "Solid tracking for Bionic Vision Australia, but eyes commercialisation hurdles". http://www.electronicsnews.com.au/news/solid-tracking-for-bionic-vision-australia-but-ey

• Brighton Secondary College Newsletter–Edition 14, 25August 2011. Reference to Cochlear and Australian Bionic Eye.

• Lightspeed - Australian Synchrotron e-Newsletter, December 2011: "Bionic eye team looks at synchrotron". http://www.synchrotron.org.au/index.php/news/publications/lightspeed-newsletter/lightspeed-articles/679-bionic-eye-team-looks-at-synchrotron

• The Conversation, 12 December 2011. Article by MVG PI Professor Anthony Hall: "We have the technology–progress in the race to the bionic eye". http://theconversation.edu.au/we-have-the-technology-progress-in-the-race-to-the-bionic-eye-3019

MVG Internal Communication

MVG was delighted to launch its Quarterly Newsletter during 2011, 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 Chief Investigator Forum was held in September 2011 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 tool for highlighting recent events, both within and external to MVG that might be of interest to different members of the group and also as a central repository for any documentation, including presentations and publications, for all members to access easily.

The importance of providing information to the blind and vision impaired community was also a priority for MVG in 2011, with all documentation being provided in large scale print as well as in screen-reader accessible format on cd.

Infrastructure

Further to the establishment of the MVG Headquarters in the Faculty of Engineering, Monash University, MVG has continued to access and utilise the following Infrastructure:
• Monash Preclinical Facilities–brand new facilities built and fitted out by Monash University during 2011 are being utilised extensively by MVG, to perform preclinical studies. The facility complies with all regulatory and ethics requirements necessary for one of its type.

• Australian Synchrotron–accessed by the MiniFAB team to undertake critical exploratory work that resulted in significant cost and time savings in materials choices for the implantable arrays. Discussions with the Australian Synchrotron progressed during the latter half of 2011, with a core group of MVG Investigators and Management meeting with the Australian Synchrotron Executive to discuss opportunities for future projects.

• Monash BioMedical Imaging Centre–due to be utilised extensively during 2012-2013 for the Clinical Program, particularly the MRI Visual Cortex study.

• Discussions have been initiated with the Bionics Institute, through Professor Peter Blamey of BVA, with the potential to access psychophysics testing facilities already established within the Institute.

• The Implantable Electronics team at Monash University has been allocated space for a dedicated Electronics Laboratory within the Department of Electrical and Computer Systems Engineering. This space will be used for the extensive bench testing of the implantable electronics and wireless transmission components of the MVG system and is due to be fully established in early 2012.

Caption: Members of the Monash Vision Group and the Australian Synchrotron during a facility tour.

2011 Highlights

February–Dr Damien Browne, Dr Dennis Lui and Dr Zorana Mayooran join the MVG Engineering Team.

May–MVG produces animation for promotional use.

June–Professor Jeffrey Rosenfeld is awarded Member (AM) of the Order of Australia in the Queens Honours birthday list, for service to medicine through clinical leadership and academic roles.

August–Dr Mehmet Yuce joins Monash University and MVG from University of Newcastle, NSW.

August–MVG files US provisional patent application for novel signal processing concepts.

September - Vicki Tutungi joins MVG as Chair of the Steering Committee.

September–First ASIC prototype design is provided to foundry for tapeout.

October–University of Bologna undergraduate student in Pharmacy Andrea Vagnarelli joins the MVG physiology team to undertake his graduate project in mapping of visual representations in the cortex.

October–Dr Sofia Bakola joins the MVG physiology team and is awarded ARC Fellowship.

November–MVG files Australian provisional patent application to cover novel designs in surgical aids.

November–Eleven representatives from MVG attend the 2011 Medical Bionics conference, held in Phillip Island.

December–Monash University Department of Electrical Computer Systems Engineering hosts ACRA 2011, the largest Australasian robotics conference, with MVG Chief Investigator Dr Wai Ho Li acting as Program Chair.

December–MVG Chief Investigator Dr Wai Ho Li receives $27,000 seed funding from Monash Faculty of Engineering for a project on non-invasive applications of signal processing for low vision users.

December–MVG Newsletter launched.

December–MVG Board Members meet with Bionic Vision Australia Board and Executive to discuss strategies for future collaboration.

Issues Arising and Mitigation Strategies

• Identification of Replacement Steering Committee and Advisory Board Chairs. Following the resignation of Dr Mike Hirshorn from both positions in August 2011, MVG initiated discussions with potential replacements for both of these roles. Ms Vicki Tutungi joined MVG as Chair of the Steering Committee in September 2011; discussions are ongoing with candidates for the role of Advisory Board Chair. As ARC Nominee on the Advisory Board, Professor Lyn Beazley agreed to act as stand-in Chair for the MVG Advisory Board Meeting held in December 2011.

• Chief Investigator changes–During 2011, A/Professor Leslie Yeo, Dr Elaine Saunders and Professor James Friend were removed as Chief Investigators from the Monash Vision Group with the approval of the ARC. Following some restructuring and re-allocation of research staff, this did not impact on project progress or on the overall strategy of the Group.

• Delayed delivery of implantable electronic components due to supplier delays. To ensure this did not result in overall project delays, the flow of the implantable electronics plan was modified to perform further development on the next design iteration at an earlier stage whilst waiting for delivery of components for testing. The Technical Architecture Team is also exploring back-up foundries to reduce the risk of this arising in future iterations.

• Research staffing. The Advisory Board has suggested that MVG research be primarily undertaken by post-doctorate staff rather than postgraduate students. This is primarily due to the high level of experience required to develop a Class III biomedical device and the short timeframe of the project compared with PhD candidature. The Board and MVG management also expressed concerns over the difficulty in attracting PhD students during the latter half of the project, as candidature would continue after the end date of the project. This advice is reflected in the current status of the research KPIs.

Financial Statement

2011 Revenue, Expenditure and Contributions: 1 January - 31 December, 2011

Funds Received

ARC funds	$2,073,654
Monash University funds	$600,000
Total Revenue	$2,673,654
ARC carry forwards from 2010	$1,436,771
Monash University carry forwards from 2010	$345,743
Total funds available in 2011	$4,456,168

Expenditure

ARC funds	$2,347,308
Monash funds	$945,743
Total Expenditure	$3,293,051
Balance Remaining	$1,163,117
ARC funds to be carried forward to 2012*	$1,163,117

In-Kind Contributions

Monash University	$2,417,236
Alfred Hospital	$0
Grey Innovation	$196,101
$328,181	$328,181
Total In-Kind Contributions	$2,941,518

* Unspent funds include commitments to external suppliers to the value of approximately $450,000, which will be reconciled in early 2012.

Key Performance Indicators

Key Result Area	Performance Measure	2011 Target	Status
Governance	Breadth/experience of Advisory Board	Reviewed	1
	Frequency/Effectiveness of Meetings	2	3
	Quality of strategic plan (judged by Advisory Board)	Reviewed	1
	Adequacy of KPIs (judged by Advisory Board and ARC)	Revised and Approved	1
Recruitment of New Staff as a result of project	Research and Development Staff	3	4
	Technical Support Staff	0	0
	Administrative Staff	0	1
Skills Development	Undergraduate Honours Projects	8	5
	PhDs recruited	6	2
	Postdoctoral researchers recruited	2	5
	Industry secondment (to and from industry)	2	2
	Visit to international facilities	1	2
Research Outputs	Publications in journals that are ranked in the top 25% of their field	4	2
	International conferences (peer reviewed)	2	2
	Invited review papers and invited conference presentations	1	1
	Patent applications	2	2
	International visitors staying more than two weeks	2	2
Outreach and Communication	Webpage developed		
	Press releases	2	1
	Press articles	4	3
	Media appearances	2	2
	Expressions of interest in future human trials from sight-impaired people	3	11
	Internal task/issue tracking/communication	Report annually	1
	External stakeholder communication	Report annually	1
	Meetings with related research teams	2	6
	Annual report	1	1

	Lectures to students	4	12
Collaboration	Meetings with Bionic Vision Australia group	2	5
Commercial	Annual in-kind and cash contributions met	1	1
	Commercialisation plan	1	1
	Funding strategy		
	Funds raised		
	Autonomous business entity	1	0

Publications

Conference Proceedings

"Transformative reality: Augmented reality for visual prostheses"–Oral and Poster Presentation, Lui, W.L.D. and Browne, D. and Kleeman, L. and Drummond, T. and Li, W.H., Mixed and Augmented Reality (ISMAR), 2011 10th IEEE International Symposium on, pp253-254, Basel, Switzerland, 2011

"The Development of Bionic Vision at Monash University"–Oral Presentation, Professor Jeffrey Rosenfeld, Medical Bionics 2011, Silverwater Resort, Philip Island, Victoria, Australia

"Brain Implanted Integrated Electrode Driver for Visual Intracortical Stimulation in a 0.35um High Voltage CMOS Process"–Poster Presentation, Damien Browne, David Fitrio, Lindsay Kleeman and Jean-Michel Redoute, Medical Bionics 2011, Silverwater Resort, Philip Island, Victoria, Australia "Mobile Cortical Visual Prosthesis Simulator"–Poster Presentation, Horace Josh, Benedict Yong, Lindsay Kleeman, Medical Bionics 2011, Silverwater Resort, Philip Island, Victoria, Australia

"Development of Medical Tool for Electrode Array Insertion into Visual Cortex"–Poster Presentation, Luke Marsden, Matthew Soloman, Arthur Lowery, Medical Bionics 2011, Silverwater Resort, Philip Island, Victoria, Australia

"Transformative Reality: Intelligent Algorithms to Improve Low Resolution Bionic Vision"–Poster Presentation, Wen Lik Dennis Lui, Damien Browne, Lindsay Kleeman, Wai Ho Li, Medical Bionics 2011, Silverwater Resort, Philip Island, Victoria, Australia

"A lightweight approach to 6-DOF plane-based egomotion estimation using inverse depth"–Poster Presentation, Tang, T.J.J. and Lui, W.L.D. and Li, W.H., Australasian Conference on Robotics and Automation, Melbourne, Australia, December, 2011

Journal Publications and Submissions:

Kun Zhou, George A. Thouas, Claude C. Bernard, David R. Nisbet, David Finkelstein, Dan Li, and John S. Forsythe "Enhancing neural interfaces using bioactive and conductive graphene-polyelectrolyte multilayer coatings" Adv. Func. Mater. (submitted Dec 2011)

Lui LL, Dobiecki AE, Bourne JA, Rosa MGP (in press) Breaking camouflage: responses of neurons in the middle temporal area to stimuli defined by coherent motion. European Journal of Neuroscience Passarelli L, Rosa MGP, Gamberini M, Bakola S, Burman KJ, Fattori P, Galletti C. (2011) Cortical connections of area V6Av in the macaque: a visual-input node to the eye/hand coordination system. Journal of Neuroscience 31: 1790-1801.

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- Faculty of Engineering
- Faculty of Health, Medicine and Nursing Sciences
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• Professor James Patrick
• Professor Lyn Beazley
• Dr Michael Hirshorn
• Professor Peter Seligmann

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