Annual Report

Transforming lives

2016 – 2017

Bionics Institute

The Bionics Institute embraces innovation and collaboration to create life-changing medical devices.

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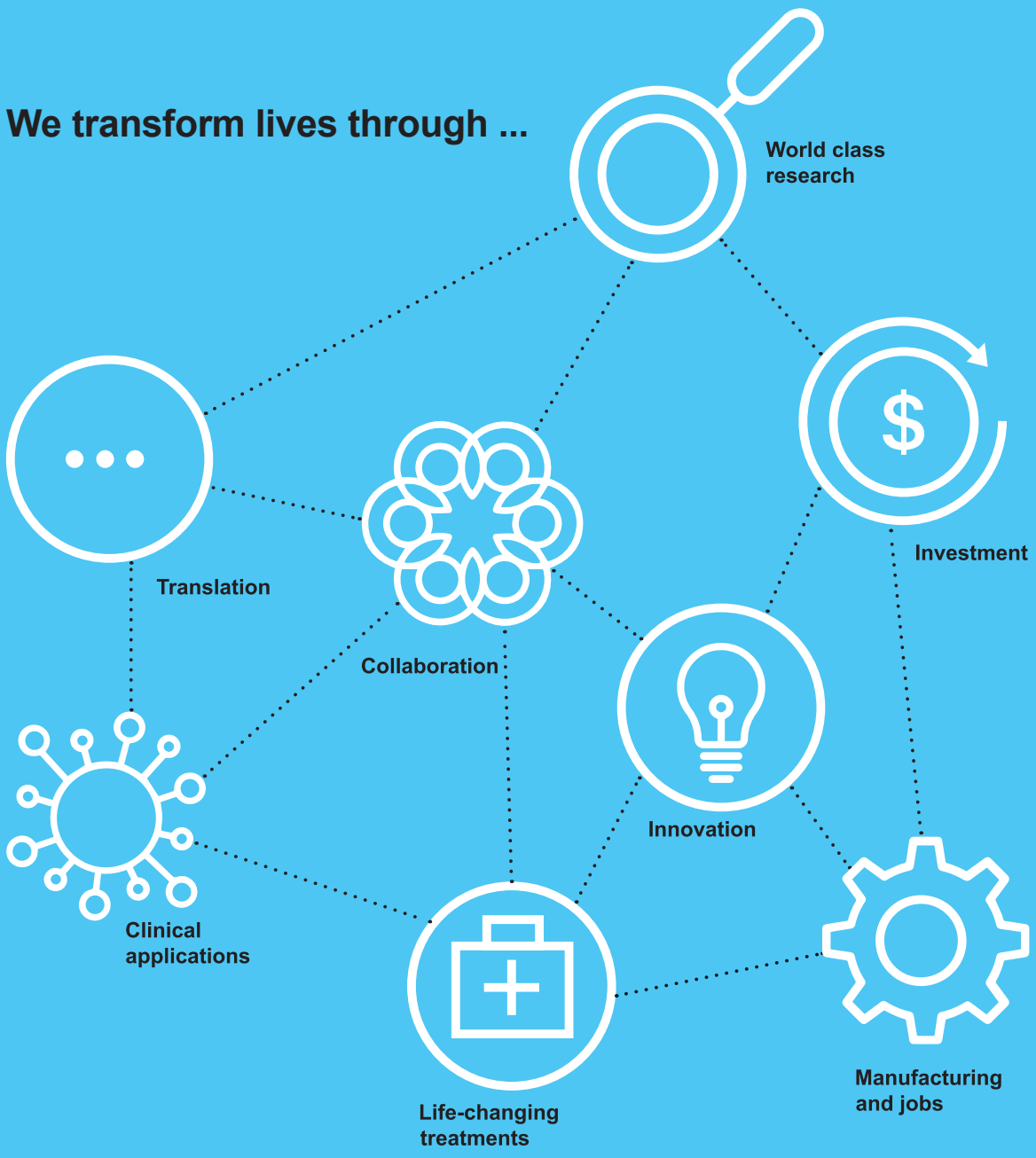
We transform lives through ...



We help people with ...

Deafness | Blindness | Epilepsy | Parkinson's disease | Inflammatory bowel disease | Stroke

Chairman's message

It is a privilege to be Chairman of the Bionics Institute at such an exciting time. This year has seen us take some significant steps to secure the future of the Institute. With the appointment of a new CEO and an increased focus on translating our research, we are moving into a phase of growth and new possibilities.

Robert Klupacs was appointed CEO after an international search for a leader to replace our former director, Professor Rob Shepherd. We are delighted that Professor Shepherd has continued on with the Institute in a research capacity, enabling him to focus on his passion and to guide our younger researchers.

We are very excited to have Robert Klupacs leading the Bionics Institute. Robert brings great energy and experience, gained through more than 30 years of involvement in medical research and technology development. Robert will drive our increased focus on aggressively pursuing opportunities to translate our research into devices and products to help patients around the world.

Research excellence continues to underpin everything we do. We have achieved many successes this year and you can read about each of our research themes in this report. I would like to highlight one achievement in particular. We are immensely proud that the Bionics Institute was awarded top-ranked Development Grant at the 2016 National Health and Medical Research Council (NHMRC) Research Excellence Awards. This prestigious and highly competitive accolade recognised the work of Associate Professor Chris Williams, Dr David Nayagam and colleagues at the Centre for Eye Research Australia (CERA) developing a novel eye implant to delay progressive blindness.

I acknowledge the support of my fellow board and subcommittee members and thank them for their significant contributions to the Institute. This year saw a couple of changes; we welcomed Ms Kathleen Jordan back to the Board in March, and we said farewell to The Hon Steve Bracks, who stepped down in October. I thank Steve for his involvement with the Institute.

I look forward to the year ahead as a time of great opportunity for the Bionics Institute.

John Stanhope AM
Chairman

CEO's message

The Bionics Institute is at one of the most exciting points in its thirty year history. We are expanding our bionic technologies to treat more conditions, enabling us to transform the lives of more people in Australia and around the world.

I am delighted to be presenting my first CEO's report, having joined the Bionics Institute in May 2017. In the time I have been leading the organisation, even I have been surprised by the depth and breadth of our work. We are well known for our hearing research and we continue to be known for this, but the range of projects and ideas we are pursuing is much broader. It's a direct reflection of our ability to "think outside the box" to develop new clinical solutions and provide new hope for patients with some of the most debilitating and refractory conditions.

One of the most exciting areas of research for us at the moment involves using bionic technology to treat diseases of the brain and central nervous system. These include epilepsy, Parkinson's disease, inflammatory bowel disease (IBD) and stroke. The advances we are making are the result of innovative collaborations between passionate clinicians and highly skilled scientists and engineers. One such example is our world-first, implantable epilepsy device that has been informally dubbed the "fitbit for the brain". Working with renowned neurologist Professor Mark Cook, we have made significant progress on this project over the past year and anticipate commencing first-in-human clinical trials in 2018. This is one of many successful collaborations, and we hope to facilitate more in future, because delivering real-world outcomes for patients is our absolute top priority.

Deafness and blindness continue to be key focuses for the Bionics Institute. Our bionic hearing and vision programs have grown over the past year, with some exciting milestones reached. After much work, we are moving closer to the clinical trial of the second-generation Australian bionic eye. Our hearing research is multi-faceted and spans everything from drug delivery to the inner ear to restore and protect hearing cells, to new imaging techniques that will help audiologists "tune" cochlear implants for babies too young to speak. You can read about all these projects, and more, in this report.

Our work would not be possible without the donors, trusts and foundations that have supported us over the past year. We are immensely grateful for the generosity of these individuals and organisations who share our vision to improve the lives of people with chronic and debilitating conditions. There are many individuals and families who are unsung heroes, having supported us quietly and without fuss for many years. I take this opportunity to thank all our donors and supporters equally for the contributions they make.

We gratefully acknowledge the funding we receive from the Victorian Government from its Operational Infrastructure Support Program, and the Federal Government through its competitive National Health and Medical Research Council granting schemes. This funding continues to be vital for enabling our research programs.

On behalf of the Institute, I sincerely thank our board members for the guidance and support they have provided over the past year. I particularly acknowledge the direction and commitment of our Chairman, John Stanhope AM, whose vision has helped us on a path to growth and increased translation of our research discoveries.

We have many exciting stories to tell and I hope you enjoy reading this report. Thank you for supporting our work "transforming lives".

Robert Klupacs
Chief Executive Officer

Deafness and hearing impairment

3.6 million Australians are affected by hearing impairment

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Hearing impairment is estimated to cost the economy AU$16 billion this year

For over thirty years the Bionics Institute has conducted research to help prevent or improve outcomes for people with deafness and hearing impairment.

Deafness and hearing impairment affects one in seven Australians and millions of people around the world. With our ageing population this number is expected to increase. Hearing loss can severely impact a person's life, causing problems with communication, education, employment and social inclusion. Ongoing research is vital to help improve outcomes for people with hearing loss and reduce the impact on the economy.

Bionic hearing

While hearing aids can help those with mild to moderate hearing loss, for those with more severe deafness the most appropriate intervention is a cochlear implant. Developed in the seventies by Bionics Institute founder, Professor Graeme Clark, cochlear implants are today used by 450,000 people around the world. Our bionic hearing program aims to improve clinical outcomes for people who have cochlear implants and other hearing devices so that they gain the maximum benefit from these interventions.

How does the cochlear implant work?

The cochlear implant is designed to produce hearing sensations by electrically stimulating the inner ear's auditory nerves to relay sound information to the brain. It consists of an implanted electrode array within the cochlea and a stimulator that is surgically placed under the skin behind the ear. An external sound processor sits behind the ear (similar to a hearing aid).

It captures sounds and converts them into a digital code. This information is sent wirelessly to the stimulator which converts the coded sound into electrical impulses and sends them along the electrode array. This stimulates the auditory neurons, which send impulses to the brain where they are interpreted as sound.

Sam's story

Eighteen-year-old Sam McLarty is making history as the first person with a cochlear implant to play AFL football. Born profoundly deaf, Sam was Collingwood Football Club's top draft pick for 2017. Sam's mother Cynthia also happens to be an ambassador for the Bionics Institute.

Sam's parents received the deafness diagnosis when he was nine-months-old after noticing he wasn't responding to loud noises. Cynthia and Sam's father, Deane, spent a huge amount of time and energy researching cochlear implants and wondered if they were making the right decision. They decided to proceed, and Sam became one of the youngest children in Victoria to receive a cochlear implant at 14-months-old.

Having the implant from a young age enabled Sam to develop normal speech and language and attend a mainstream school. "Sam caught up with other kids and was speaking normally by the age of four with the help of his cochlear implant," said Cynthia.

Since then Sam has thrived and excelled in many fields. He was school captain at Yarra Valley Grammar School in 2016, and in addition to playing basketball and junior footy at Beverley Hills Football Club, he has also represented Victoria in swimming.

Sam will be an inspiration to many but he didn't set out to be a role model – he's lived a pretty normal life with the help of his cochlear implant. His parents are very glad they made the decision to get the implant at a young age. "We tell other parents that we don't regret it – it was the best thing for Sam. We are so grateful to the Bionics Institute for enabling Sam to talk and live a full, normal life," said Cynthia.

Sam McLarty

Improving cochlear implants

Cochlear implants deliver life-changing benefits for many people. Despite many advances with modern hearing devices, there is still some variation in their effectiveness. Some people do not receive the full benefits from their device and the reasons for this are not well understood.

Our aim is to understand why some people do not understand speech well with their cochlear implant or hearing aid, while others do. We want to be able to identify those who will have difficulty adjusting to their hearing device and to develop ways to help those people get optimum benefit from their new hearing aid or cochlear implant.

Associate Professor James Fallon

Do you hear what I hear?

Accurate speech perception is crucial to learning language and participating fully in the world around us. Hearing aids and cochlear implants enable people with hearing impairment to access sounds, in particular speech sounds. Unfortunately, some cochlear implant users still need to lip-read to understand speech, while some people with hearing aids consign them to a drawer because the aid does not help them as much as they expected.

It is always easier to understand what someone is saying when we can see their face. Combining what we see and what we hear is essential when there is a lot of noise or when we cannot hear very well. However, when someone is hard of hearing, they rely even more heavily than usual on seeing the person. This emphasis on vision can gradually change the way the language parts of the brain work. Sometimes, the parts dedicated to understanding sound are changed so that they become dedicated to understanding vision or touch instead. This brain reorganisation may create difficulties when hearing is restored and explain why some people cannot understand speech well with their new cochlear implant or hearing aid.

Hearing music and understanding speech in noisy environments

Music brings so much pleasure and richness to life. Unfortunately, cochlear implant recipients are currently not able to enjoy music like people with normal hearing. It's a little like hearing somebody playing the piano with a boxing glove on. While cochlear implant recipients typically receive significant benefit in speech understanding in quiet environments, the clarity drops severely in noise and they can't appreciate the rich aural texture of music or tonal languages.

Cochlear implants convey sound to the user by electrically stimulating auditory neurons. Unfortunately, they have a limited number of effective stimulation sites, due to the highly conductive nature of the fluid-filled cochlea, and stimulate only a single site at a time. Current-focusing, which restricts the field of neuronal excitation by simultaneously stimulating multiple electrodes, increases the spectral precision of cochlear implants and allows multiple locations to be simultaneously stimulated. However, current-focusing has not yet been proven safe for use.

Led by Associate Professor James Fallon, we conducted a study that established the safety of current-focused stimulation. Our next step is to develop current-focused stimulation regimes for clinical devices. It is anticipated that replacing existing cochlear implant stimulation regimes with current-focused stimulation will enhance recipients' speech perception in noisy environments and their comprehension of music and tonal languages.

Professor Colette McKay

Helping deaf babies and children hear more clearly

An estimated 32 million children worldwide have a disabling hearing loss. This produces severe delays in communication, social and emotional skills. Early intervention to identify and address a hearing loss improves language performance and may promote better developmental outcomes in deaf children.

Currently, the clinical methods used to test auditory function in children range from classical behavioural testing to more objective and complex methods. However, they have some limitations. For example, they are not suitable for every child and do not provide enough information about how the sounds are being processed by each individual. We are investigating a novel method to test hearing in children as a complementary tool in the auditory assessment battery.

A new way of seeing the hearing brain

We are exploring the use of a brain imaging technique called functional near-infrared spectroscopy (fNIRS) in hearing assessments of infants and young children. fNIRS is an optical imaging technique that uses infrared light to detect changes in brain blood flow as a measure of neuronal activity. The technique is non-invasive, suitable to use at any age, and compatible with all hearing devices.

We have begun by investigating the fNIRS response and how it changes with different sound intensities in normal hearing children. This is being done with children aged four to five years and results have been promising. The outcomes we have obtained are the first step for further research on auditory assessment of deaf children using fNIRS technology.

Welcome to our BABILab

Professor Colette McKay and her team have created a facility named the BABILab at our offices in East Melbourne. The BABILab is a welcoming space where young children and babies can come to participate in fNIRS research. This work aims to improve auditory assessments in children too young to provide feedback on what they are hearing. We hope this research will one day allow doctors to tune hearing devices specifically to every child, maximising the benefits they receive.

In the BABILab, participants wear a customised cap embedded with light sources and detectors that can monitor the amount of oxygen in the blood.

As the children are exposed to different speech stimuli, McKay's team can visualise which areas of the brain become activated by tracking the regions that contain more oxygen. In previous studies on adults, the researchers discovered 'brain signatures' that corresponded to recognition of language.

Professor McKay and her team are working in partnership with the Taralye oral language centre for deaf children to trial and develop the technology for children. Having successfully tested the fNIRS technique in healthy children, the next step is to trial it with hearing impaired children as young as 18 months.

Dr Rachael Richardson and Dr Andrew Wise

Restoring and protecting inner ear cells

Damage to the sensory cells in the inner ear can lead to deafness. Once these cells are lost they cannot be replaced. It is vital to develop strategies to protect and potentially repair hearing before significant cell loss occurs.

Our researchers are investigating ways to protect and repair damaged cells in the inner ear. They are using the latest techniques in gene therapy, stem cell therapy and nanoengineering. The aim is to restore or replace cells that have died in order to maximise the residual hearing a person may have, and ensure the effectiveness of cochlear implants.

A new drug delivery system to protect inner ear cells

Hearing loss can occur when the sensory cells inside the cochlea – which convert sound waves into neural signals and convey these signals to the brain – do not function properly as a result of a congenital abnormality or acquired trauma (for instance, due to exposure to loud noises). While drugs that can protect and regenerate inner ear sensory cells have been identified, there is not yet any safe and effective method for delivering these drugs to the inner ear.

Recent nanoengineering advances have made it possible to create particle-based delivery systems that can store large payloads of a drug and slowly release these over time. These particles offer an appealing but previously untested method for delivering drugs to the inner ear to combat hearing loss.

Led by Dr Andrew Wise, our researchers used cutting-edge techniques to incorporate therapeutic drugs into a nanoengineered delivery system. We have shown that this system can release drugs at therapeutic levels over extended time periods. We applied this drug delivery system to the inner ear shortly after the inner ear was exposed to drugs that cause hearing loss. We found that this system protected sensory nerve cells from dying. Encouraged by these results, we are now investigating how this novel drug delivery system can be used to treat other forms of deafness. Ultimately, our goal is to develop the first clinical treatment for hearing loss.

Pharmacokinetics: how do drugs disperse in the inner ear?

Pharmacokinetics is the science of how drugs move throughout the body. In order to develop and optimise drug delivery strategies for the inner ear, we need to be able to measure the amount of a target drug in this area of the body. We have a project underway to determine how drugs disperse through the inner ear when administered by novel drug delivery systems.

We are treating the inner ear with drugs that experimentally have been shown to protect cochlear sensory cells from trauma. These drugs are delivered by small pumps or by nanoengineered drug delivery systems. Measuring the amount of drug delivered by different delivery strategies will enable us to improve the efficacy of these systems. Understanding how drugs disperse through the inner ear and demonstrating that the chosen drug and delivery method is safe for use is an important step towards clinical translation of inner ear drug therapy to treat hearing loss.

Investigating “hidden” hearing loss

Understanding speech is crucial to participating in the world around us. However, some patients with hearing loss exhibit normal sound sensitivity in clinical hearing tests, yet have difficulty understanding speech, especially in noisy environments. This condition is termed “hidden” hearing loss because it cannot be detected with conventional testing. Patients with hidden hearing loss do not benefit from sound amplification alone and, in the absence of a viable alternative therapy, their disorder often remains untreated.

The underlying cause of hidden hearing loss is unclear, but it appears to be related to exposure to moderate levels of noise. Anatomically, hidden hearing loss is associated with a loss of connections between cochlear inner hair cells – the cells responsible for converting sound into neural signals – and auditory nerve fibres. The pathology of hidden hearing loss must be better understood to progress towards a clinically viable therapy for this disorder.

Led by Associate Professor James Fallon, we recently developed an experimental model of hidden hearing loss, which provides us with a valuable investigative tool to better understand how this disorder impairs hearing. We hope to leverage our experience of delivering drugs to the cochlea to rapidly develop a clinically viable treatment for this disorder.

Optically stimulating auditory neurons: a better alternative?

Cochlear implants use electricity to stimulate auditory neurons. However, electrical current spreads, and this is the main reason that cochlear implants do not convey complex sounds like music effectively.

Optical stimulation represents a possible alternative to electrical stimulation. Dr Rachael Richardson is leading a study investigating optical stimulation, which involves genetically modifying inner ear cells to make them highly responsive to light. Early results indicate that optical stimulation activates auditory parts of the brain more precisely than electrical stimulation, potentially enabling a more realistic listening experience for cochlear implant users.

More specific stimulation of auditory neurons through the use of optical stimulation would result in major clinical improvements for cochlear implant users. Importantly, a breakthrough of this nature could also have significant implications for other bionic devices including the bionic eye, where precise stimulation is the key to obtaining useful visual information, along with deep brain stimulation treatments for neurological disorders including Parkinson’s disease.

Learning more about auditory neuropathy

Auditory neuropathy is a hearing disorder in which sound reaches the cochlea normally, but the resulting neural signals are not correctly transferred from the cochlea to auditory processing centres in the brain. It is characterised by normal hair cell function but absent auditory nerve and brainstem responses.

Patients suffering from auditory neuropathy may perceive sound of diminished quality, which results in a difficulty understanding speech in noisy environments. Auditory neuropathy is a poorly understood condition for which there is not yet any reliable treatment.

We have a project underway to develop an experimental model of auditory neuropathy. In doing so, we hope to learn more about the causes and mechanisms of this disorder and progress toward an effective clinical treatment.

Vision loss and blindness

More than 380,000 Australians have blindness or low vision

Vision loss can severely impact a person's life, and even milder levels can make it difficult to read signs, recognise faces and perform many of the tasks of daily living.

We conduct research and develop devices that aim to treat – and hopefully prevent – blindness and progressive vision loss. Our ambitious vision research program currently involves two projects: development of the Australian bionic eye with a team of collaborators, and development of a novel retinal implant to delay vision loss. Our main aim is to improve the quality of life for people with retinitis pigmentosa. Hopefully, down the track, our work will also benefit people with other eye diseases including glaucoma and macular degeneration.

To prepare for the clinical trial of the next generation bionic eye, we have carried out extensive testing of all components to ensure they are safe and effective.

What is retinitis pigmentosa?

Imagine not being able to see your children, your partner or your friends and family. Imagine finding out that you would lose your vision when you had previously been able to see. This is what people face when diagnosed with retinitis pigmentosa. Retinitis pigmentosa refers to a group of inherited eye disorders that damage light-sensitive cells at the back of the eye (retina). It is the major cause of inherited blindness and can present at any age from childhood to a person's fifties. However, it typically begins in early adulthood. The disease, which currently affects around one in 3,000 people, has no cure or treatments to slow the progression of the disease. Most commonly, patients lose their sight slowly, eventually developing tunnel vision and usually becoming completely blind in the late stages of the disease. Patients with retinitis pigmentosa have difficulty with mobility, navigation and night-vision.

Dianne's story

Dr Dianne Ashworth was just 24 years old and the mother of a young baby when she was told she would lose her sight. She still recalls the shock and devastation of being diagnosed with retinitis pigmentosa. At the time Dianne only had 10% vision and it was degenerating steadily. "It kept decreasing, until I could only see light and dark and a mass of swirls," she said.

More than 20 years later she was selected as one of the first recipients of Australia's first prototype bionic eye. In 2012 Dianne was fitted with the device during surgery at the Royal Victorian Eye and Ear Hospital in Melbourne.

After the device was switched on Dianne recalled seeing flash of light. For the first time in decades, Dianne was able to navigate around obstacles using the prototype device and she was able to see shapes and outlines, including a person standing in front of her. "The phosphenes gave me an outline of him and I knew there was someone in front of me. It was just an amazing feeling," she said.

Dianne's feedback on the prototype bionic eye has helped researchers develop the next generation of devices, which will have a wider view and more electrodes to generate a higher-resolution image.

Dianne Ashworth

Bionic vision team members Sam Titchener, Dr Matt Petoe and Dr Mohit Shivdasani

Progressing Australia's Bionic Eye

The Australian bionic eye has been in development for several years and the Bionics Institute is an important contributor to this exciting – and challenging – project.

A prototype bionic eye was successfully trialled between 2012 and 2014. The prototype device was implanted in three Victorian patients with retinitis pigmentosa. It safely and effectively evoked visual images for the patients, allowing them to perceive shapes, movement, and navigate around objects.

The Bionics Institute was responsible for the design, manufacture and safety testing of the prototype bionic eye, as well as testing patients' perceptions in our purpose-built laboratory. We are now working towards the clinical trial of the second-generation bionic eye, which is anticipated to take place in early 2018.

What is the bionic eye?

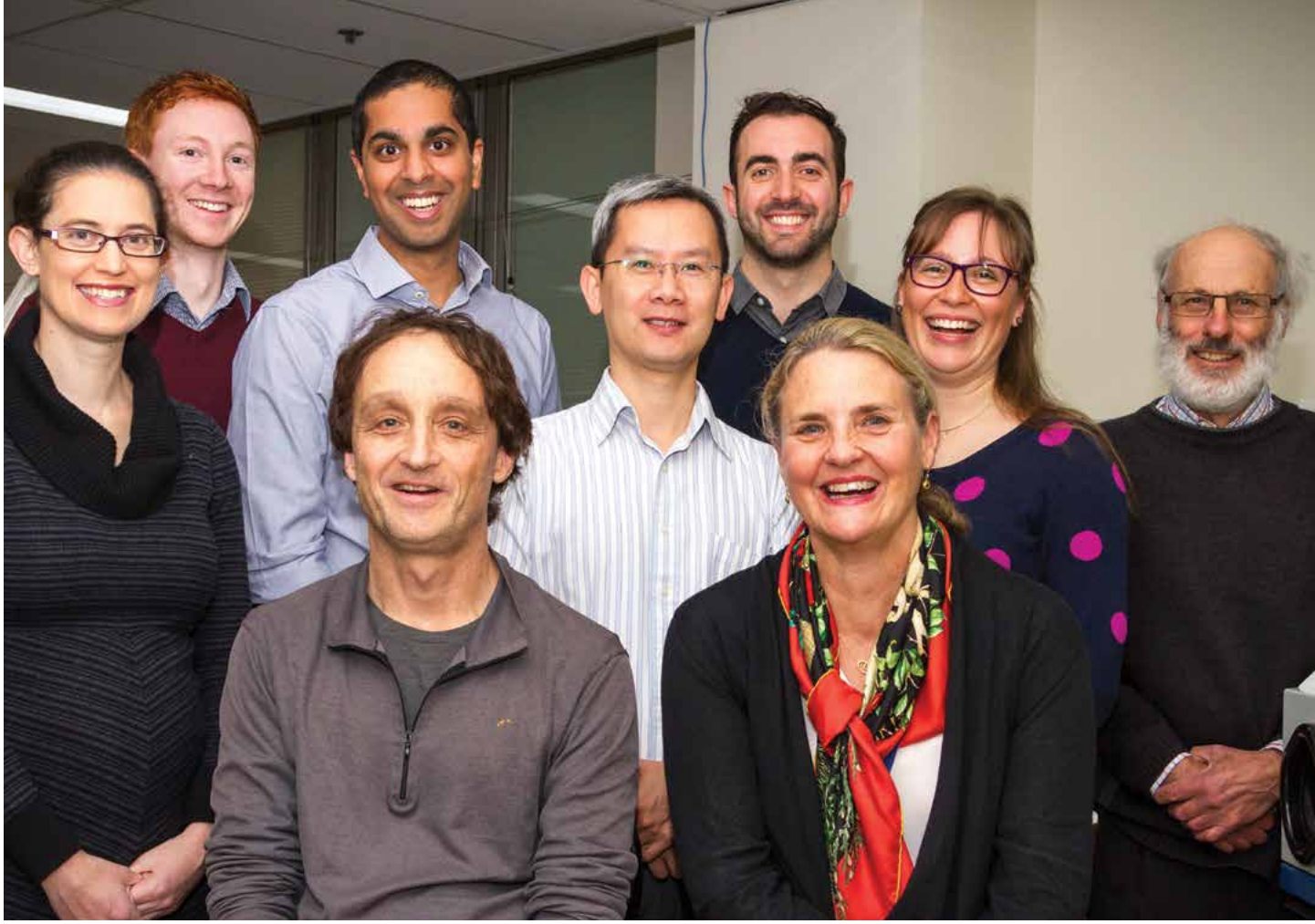
The bionic eye helps the brain form a visual image when cells in the eye have been damaged by disease. The bionic eye consists of a small video camera that is fitted to spectacles. The camera captures visual scenes in front of the viewer. It then sends these images to a visual processor, which converts the images into a coded pattern and sends them to a stimulator. The stimulator activates an electrode array implanted close to the retina using electrical impulses.

Each electrode stimulates a nearby area of retina and the cells that project to the visual areas of the brain, evoking a localised flash of light termed a phosphene. Multiple phosphenes are created by stimulating different electrodes in rapid succession and the brain pieces these together to form a visual image.

What does bionic vision look like?

The vision provided by a bionic eye is not like natural sight. Rather, it is a series of flashing spots and shapes the person uses to interpret their environment. Training is required to do this, and right now, the best outcomes rely heavily on patient engagement and rehabilitation.

The vision provided by the first generation bionic eye is very basic and can be used for tasks such as identifying the location of an object, detecting a person or finding a doorway. Dr Mohit Shivdasani hopes that future bionic eye devices will provide higher resolution vision. He is exploring different patterns of electrical stimulation to improve detailed vision without the need to add more electrodes to the implant (which comes with several inherent challenges).



The team developing an implant to delay blindness – (L-R standing) Dr Carla Abbott (CERA), Ross Thomas, Dr David Nayagam, Associate Professor Chi Luu (CERA), Owen Burns, Stephanie Epp, Professor Peter Seligman; (front) Associate Professor Chris Williams and Dr Penny Allen (CERA, Royal Victorian Eye and Ear Hospital)

Psychophysics: research to refine the bionic eye

The goal of our bionic eye psychophysics program is to improve fitting and training methods for bionic eye recipients, so that they can intuitively use the artificial vision they are receiving through their device. For example, over the past year our researchers have been investigating how to recreate the natural experience of using eye movement.

The external camera in a bionic eye system is mounted on glasses in a fixed position. This means that patients cannot use their normal eye movements to redirect their field of view and must instead move their entire head. Any eye movements would usually cause misalignments between the perceived location of an object and its real-world location. This is unintuitive, and can impede hand-eye coordination.

Led by Dr Matt Petoe, our researchers have been working on eye-tracking technology to incorporate into the next generation device. This will enable patients to use natural eye movements to direct their field of view. This is being done with a technique called "gaze compensation", whereby the input image captured by the head-mounted camera is shifted in response to measured eye movements.

By studying healthy volunteers wearing bionic eye simulation equipment, our researchers have been exploring the potential benefit of gaze compensation on hand-eye coordination.

An eye implant to delay blindness

We have a team of researchers investigating whether we can delay vision loss for people diagnosed with retinitis pigmentosa using bionic technology.

Our researchers are in the early stages of developing a world-first, tiny eye implant that could potentially delay blindness for people diagnosed with degenerative eye disease.

The world-first device has been dubbed the "Minimally Invasive Retinal-degeneration Arrestor" (MIRA). MIRA aims to prolong and extend the years of useful vision by slowing the decline in patients with degenerative retinal disease using low-level electrical stimulation.

We were very excited when the MIRA project was awarded Best Development Grant 2016 at the highly competitive National Health and Medical Research Council (NHMRC) Research Excellence Awards. NHMRC development grants are designed to drive research toward real-world applications for clinicians and patients. The award was shared by our researchers, Associate Professor Chris Williams and Dr David Nayagam, in collaboration with colleagues at the Centre for Eye Research Australia (CERA).

MIRA is still in the early development phase, but in addition to delaying the course of retinitis pigmentosa, researchers hope the technology may also have the potential to help people with other eye conditions including glaucoma and macular degeneration.

"It is early days but this device provides some hope for people diagnosed with degenerative eye diseases who are destined to lose their sight. We hope this device will allow them to continue seeing the world around them for a much longer period of time," said Dr Nayagam.

Associate Professor Chris Williams

Neurological disorders

Neurobionics researcher Dr Joel Villalobos

The principle behind our bionic medical devices is simple: electricity is used to stimulate nerve cells in the body. More and more, we are finding that this basic principle can be used to develop new treatments for chronic diseases and conditions.

We have coined the term "Neurobionics" to describe our work developing medical devices that interface with the brain or peripheral nervous system. These devices stimulate nerves electrically to provide a therapeutic benefit.

Our neurobionics team is truly multidisciplinary, bringing together scientists, engineers and clinicians to create innovative implants and therapies. This unique approach allows us to develop and tailor therapies to meet specific clinical needs and to deliver tangible benefits to patients with some very debilitating disorders.

Epilepsy – transforming diagnosis and care

We are developing a novel implant that will transform the way epilepsy is diagnosed and managed. Having proven the efficacy of our device, which some have likened to a "fitbit for the brain", we are making steady progress with this ground-breaking project.

The most common chronic brain disorder

According to the World Health Organisation, epilepsy is the most common chronic brain disorder globally. It is estimated nearly 10 per cent of the population will have a seizure at some time during their life, but only about one third of these will have seizure recurrence and approximately one per cent will eventually be diagnosed with epilepsy. In addition, not everyone who has recurrent seizures will necessarily be diagnosed with epilepsy.

Blackouts are a common complaint affecting up to 50 per cent of people at some point in their life. However, they may be due to seizures, heart irregularities or other causes. Definite diagnosis is often difficult because these events are typically infrequent, perhaps weeks or months apart.

At present, clinicians and patients have limited options to diagnose the cause of blackouts. Conventional EEG recordings, in which electrodes are placed on the patient's scalp, require periods of hospitalisation for monitoring, which are expensive and often do not capture any events.

A world-first seizure monitoring implant for epilepsy

We have created a minimally-invasive implant that will be placed under the scalp to enable long-term monitoring of brain activity. This implant has been designed in close consultation with clinicians in order to provide the information required for accurate diagnosis. The implant has been specifically designed to sit under the scalp requiring minimal surgery and risk to the patient. The "real time" data it captures can be accessed by the patient's doctor for analysis, and will help with diagnosis as well as tailoring medications to suit an individual's requirements in order to improve symptom management.

We have carried out the critical pre-clinical studies and confirmed that the sub-scalp system is safe and effective. We have designed and tested the associated recording hardware and software and the associated surgical toolkit. Having finalised the implant design, we are currently in discussions with potential manufacturers in order to build the device and conduct first-in-human clinical trials early in 2018. Our researchers are also hopeful there will be other applications for the device, including monitoring electrical changes in people with sleep disorders, as well as monitoring unconscious head trauma patients. The first step is epilepsy and we aim to make this device available to neurology clinics around the world as soon as possible. In conjunction with the manufacturing and regulatory discussions, we are actively seeking investment opportunities to make this happen.

(L-R) Ross Thomas, Associate Professor Graeme Rathbone, Owen Burns and David Hill

Michael's story

Around ten years ago, in his early fifties, Michael O'Reilly noticed his right arm wasn't swinging normally when he walked. He had the inkling that it could be Parkinson's disease. After visiting two doctors, the third confirmed the diagnosis.

At first Michael was philosophical. "Worry about the things you can change, accept the things you can't," he thought. But there was uncertainty about the future, how fast the disease would progress and how it would affect his loved ones. Michael had always talked about crossing the Simpson Desert with a friend, so after the diagnosis he decided to do it while he had the chance.

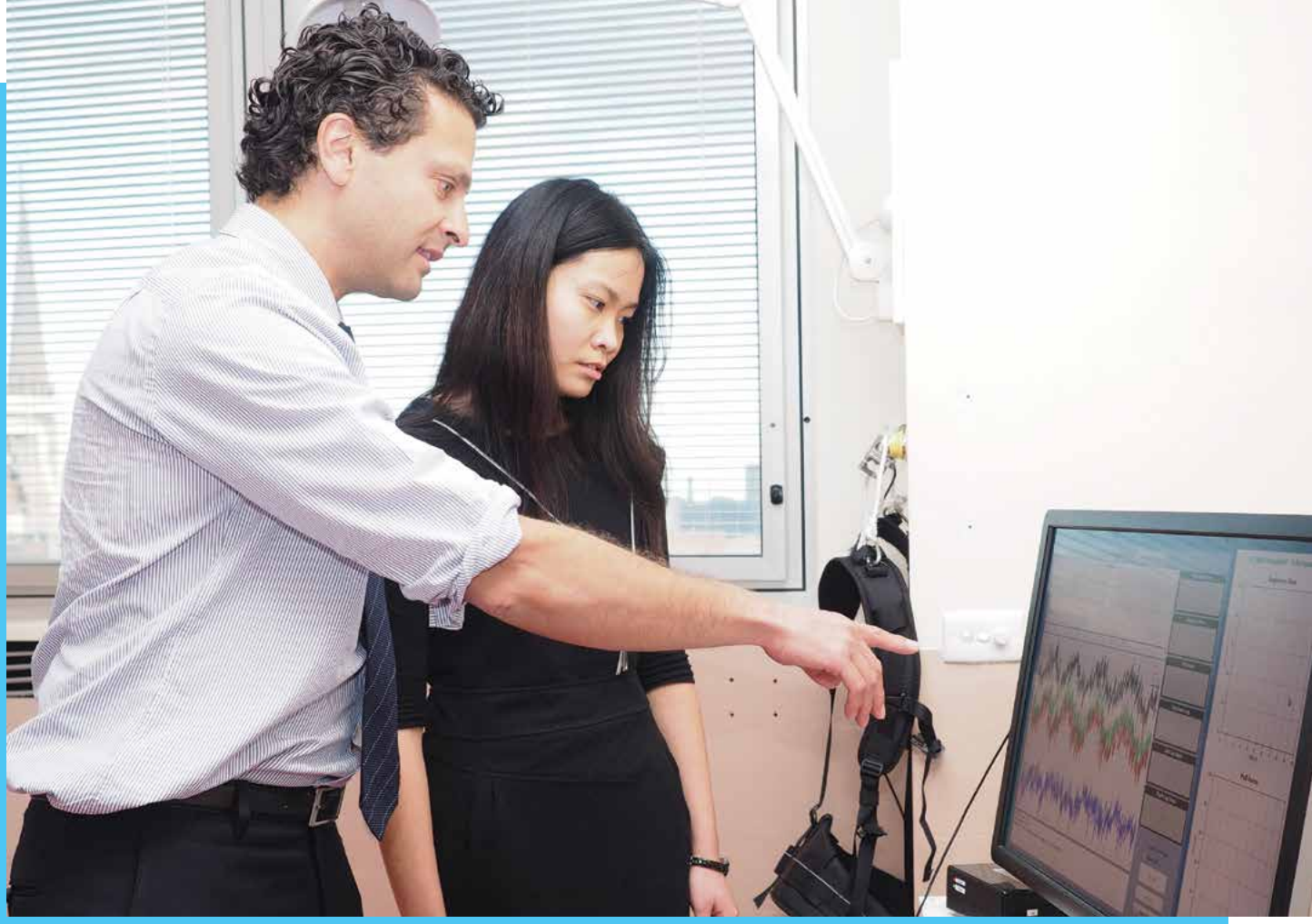
After 10 years of traditional medications Michael saw Melbourne neurologist Dr Wes Thevathasan, who suggested he was an ideal candidate for deep brain stimulation (DBS). However, Michael initially declined as he felt his symptoms were under control and he was concerned by the risk of brain surgery. Daily life was becoming more difficult though. He had to reduce his work in the Department of Defence from full-time to three days per week due to tiredness. Using a computer mouse was difficult. He had very noticeable dyskinesia, to the point where his wife likened him to one of the inflatable, flailing men seen outside car yards.

After much contemplation and speaking with others who had DBS, Michael eventually made the decision to proceed. The operation went well, and Dr Thevathasan was able to implant the probes very close (within 1mm) of target areas in Michael's brain. Once the probes were turned on and adjusted Michael began to feel better. He has noticed a "huge improvement" since having DBS. Apart from a small problem with walking and writing legibly, many of his symptoms have reduced.

"Parkinson's disease need not be a sentence to shakes, stiffness and dyskinesia," said Michael, who is now aged 62 and keeping busy in retirement. "Try to be positive, and if you have the opportunity to have DBS, from my experience I can recommend it."

Accurate placement of the probes in a patient's brain is crucial to the success of DBS surgery. Dr Thevathasan is working together with the Bionics Institute on ways to improve the accuracy of the surgical procedure even further, so that the benefits of DBS can be maximised for all patients.

Michael O'Reilly

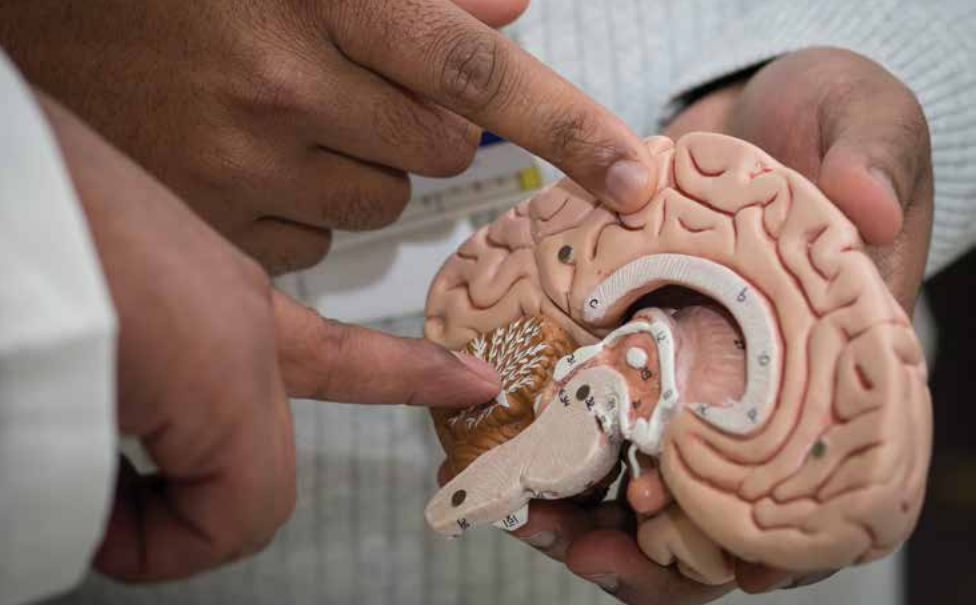


Dr Wes Thevathasan and Joy Tan are part of our team developing more sophisticated deep brain stimulation methods for Parkinson's disease

Around 75,000 Australians are affected by Parkinson's disease – Thirty per cent of patients do not get adequate symptom relief from medication

Parkinson's disease is a degenerative brain disorder caused by the progressive loss of certain nerve cells located in a brain area that is crucial for normal movement. This leads to a progressive and debilitating loss of motor function, with typical symptoms of tremor in the arms and legs, muscle stiffness, stooped posture and a slow, shuffling gait.

Unfortunately, up to 30 per cent of patients do not obtain adequate symptom relief with conventional medications. Deep brain stimulation (DBS) is an effective treatment option for some but existing systems have limitations that can result in poor or variable symptom relief or other complications.



Developing smarter deep brain stimulation systems

Deep brain stimulation involves having a medical device similar to a heart pacemaker surgically implanted by a neurosurgeon. Once in place, the device delivers electrical stimulation to specific areas in the brain that affect movement. The DBS system consists of electrode arrays implanted in both sides of the brain and extension leads that connect to a stimulator implanted under the skin. The stimulator delivers electrical pulses to the brain which block or alter abnormal neural activity. This alleviates the motor symptoms in disorders such as Parkinson's disease and essential tremor.

We have several projects underway to develop more sophisticated DBS technology and systems that will deliver greater benefits for patients. Our goal is to optimise therapy and provide the most effective symptom relief, while minimising undesirable side-effects.

Improving surgical accuracy

Accurately positioning electrodes within the very small target brain structures is a major challenge for neurosurgeons doing DBS surgery. The difficulty of selecting the best stimulation settings for each individual patient, especially when patient needs are continually changing, can limit clinical outcomes.

Led by Professor Hugh McDermott, our team of researchers is working to improve the clinical outcomes of DBS therapy using feedback signals derived from brain electrical activity. We aim to:

- **Improve electrode positioning by guiding implantation to the target structure.**
- **Develop methods for rapidly, and automatically, identifying the most beneficial stimulation settings for each individual patient.**
- **Develop stimulation techniques that automatically adjust to the patient's continually fluctuating needs, in order to provide the best therapy at all times.**

Clinical studies are currently being performed with movement disorder patients (primarily Parkinson's disease) undergoing DBS implantation surgery. The results obtained so far show great promise for guiding electrode implantation to the target structures, automatically identifying the most beneficial stimulation parameters, and for adaptively adjusting stimulation according to patient needs.

Developing better DBS technology

There are still an unacceptable number of complications associated with the current DBS brain electrodes and chest-implanted electronics. These can relate to inaccurate insertion or coarse spacing between electrodes. Complications related to the hardware are also not uncommon; these can include lead breakage, infection or lead migration.

We aim to improve DBS technology by developing an electrode array with optimal geometry for improved selectivity and easier surgery, and developing electronics that can be placed on the head. We are currently designing and testing the electrodes, implantable lead, connector and electronics interface we have developed. This will include a comparison of the existing DBS hardware and our new technology through side-by-side implantation of the current and new electrode systems. After completing testing, we anticipate that the technology will be ready for a first-in-human trial within the next four years.

Improving balance control for patients

Balance control is an issue for many people with movement disorders. Conventional DBS does not improve the loss of balance that many people struggle with. This ultimately leads to falls and hospitalisation. At the Bionics Institute, we have been studying the world's largest cohort of patients implanted with stimulators in a novel brain target known as the pedunculopontine nucleus, which is thought to improve balance deficits in Parkinson's disease.

Our world-first study showed that DBS devices implanted in this area of the brain improve balance control and benefit those suffering from balance deficits who are unresponsive to medication and conventional DBS. This was also the first study to validate the use of computer modelling of balance in Parkinson's disease. The use of these novel modelling tools can revolutionise the scientific field of balance and posture.

Measuring rigidity in Parkinson's disease

People with Parkinson's disease can experience symptoms of tremor, rigidity and bradykinesia (slowness). At present, the severity of these symptoms is assessed using a clinical rating scale (similar to a questionnaire). Clinicians manipulate the patient's limbs and subjectively gauge the force required to complete movements along the full range of joints. Such assessments are used to diagnose Parkinson's Disease as well as adjust therapy. Although wearable devices for measuring tremor and bradykinesia exist, none have been developed for rigidity.

We have developed a new device that patients wear on the palm to measure rigidity. In testing this device, we found that the rigidity data collected matched the observations reported by the clinical assessments. The enhanced accuracy and the long-term tracking provided by our instrument can help clinicians better treat their patients. The device may also help in diagnosis and classification as well as applications in other areas such as arthritis. Further work is underway to fund new studies and to move towards commercialising this technology.

Multiple sclerosis: can Botox relieve tremor?

Multiple Sclerosis (MS) is an auto-immune disease and the most common disease of the central nervous system among young Australians. The cause of MS is unknown and, as yet, there is no cure. Tremor is a common symptom that often emerges as the disease progresses, significantly adding to disability. The underlying cause of the tremor is poorly understood and treatment is challenging. There is little evidence to support medical therapies and surgical therapies expose patients to potentially serious side-effects.

In conjunction with scientists at the Bionics Institute, neurologists at the Royal Melbourne Hospital are injecting tremor-causing muscles with Botulinum Toxin (Botox) as part of a phase-II clinical trial. A precise tremor measurement instrument, developed at the Bionics Institute, will be used to monitor patient outcomes throughout the trial. People afflicted with MS worldwide could benefit from this treatment. Closer to home, the evidence we build can help place Botox on the Medicare PBS and make it accessible for everyone.

Dr Sophie Payne works on our IBD project and Dr Thushara Perera works on Parkinson's disease and movement disorders

New hope for bowel disease sufferers

Life can be very difficult for the one in 250 people affected by inflammatory bowel disease (IBD). We are investigating new ways of treating and monitoring these conditions, including the development on automated, implantable device to safely and effectively treat the symptoms of IBD.

What is inflammatory bowel disease?

The two major types, Crohn's disease and ulcerative colitis, are chronic, debilitating conditions that first emerge in young adulthood and can relapse throughout patients' lives. To make matters worse, stigma and embarrassment around bowel problems mean that many people suffer in silence. Australia has one of the highest prevalence rates of IBD, with around 70,000 people affected. The number is expected to rise to 100,000 by 2020 and rates of IBD are also increasing around the world. The disease is being diagnosed in patients younger than ever before.

The exact causes of these conditions are unknown. Progressive damage of the intestines leads to profound fatigue, pain, and diarrhoea, and often results in the need for multiple surgical resections. Many patients experience significant impairment in their quality of life and ability to engage in activities of daily living. Immunosuppressive drugs are the main form of therapy but they have serious side effects and there is an unmet need for better disease monitoring and treatments. Also, these drugs are often inadequate in relieving symptoms.

How can bionics help?

The vagus nerve runs from the brainstem to the gut and plays a key role regulating gut function. However, the critical role of the vagus nerve in the immune function of the intestine has only recently begun to be described. Research has shown that stimulating the vagus nerve may provide a novel therapy for IBD.

The device we are developing will constantly monitor the degree of inflammation in the gut of people with IBD. When a certain level of inflammation is detected, a signal will be sent to a stimulator implanted under the skin. The stimulator will then send electrical impulses to an electrode array that contacts the vagus nerve. The timing and pattern of stimulation will automatically adjust depending on levels of inflammation, resulting in reduced pain and symptoms. Compared to traditional therapies, a bionic device like this will have minimal side effects and will reduce the need for people with IBD to visit their clinician so frequently.

What stage is the research at?

We've shown the efficacy of vagus nerve stimulation using a custom made prototype device and a novel stimulation site in a model of IBD. Once our pre-clinical safety and efficacy studies with our collaborators are completed, we will conduct first-in-human trials with IBD patients at the Austin Hospital, with the ultimate aim of making this device available to IBD sufferers around the world.

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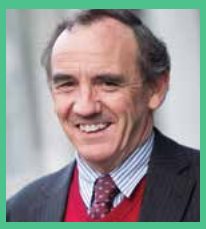

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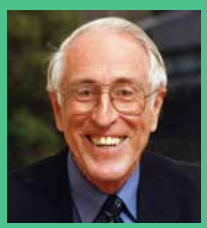

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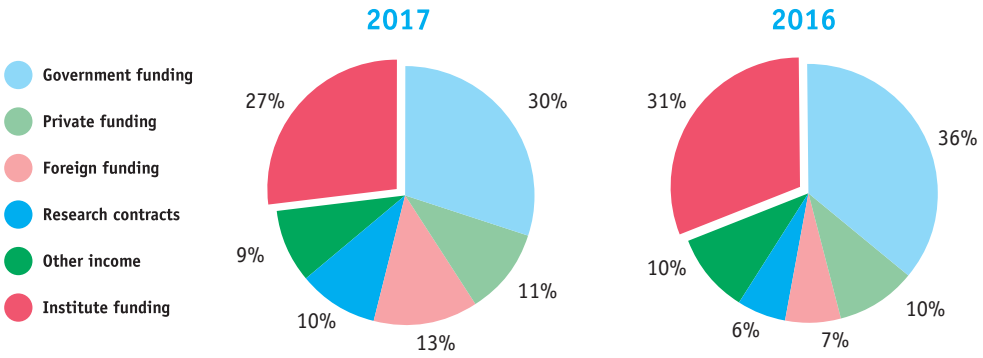
MBBS, MS, PhD, FRCS, FRACS, FAA, FRS

Abridged financial statement for the year ended 30 June 2017

CONSOLIDATED INCOME STATEMENT	2017	2016
	$	$
REVENUES FOR ORDINARY ACTIVITIES		
Federal Government grants	2,078,891	2,171,550
Victorian Government grants	456,243	483,936
Foreign grants	1,059,123	502,039
Trusts & foundations	756,425	580,550
Public fundraising	174,757	168,477
Research contracts	833,541	465,565
Investment & interest income	606,638	631,052
Other income	767,522	732,030
TOTAL REVENUE FOR ORDINARY ACTIVITIES	6,733,140	5,735,199
less expenditure on ordinary activities	(8,334,318)	(7,431,531)
DEFICIT ON ORDINARY ACTIVITIES	(1,601,178)	(1,696,332)
Gain on sale of property	–	1,712,307
Loss on sale of available-for-sale financial assets	(648)	(467,236)
NET DEFICIT	(1,601,826)	(451,261)

FUNDING OF OUR RESEARCH



CONSOLIDATED STATEMENT OF FINANCIAL POSITION	2017	2016
	$	$
Current Assets	3,900,883	5,125,444
Non-Current Assets	13,052,921	12,883,523
TOTAL ASSETS	16,953,804	18,008,967
Current Liabilities	3,028,205	2,918,312
Non-Current Liabilities	285,036	95,937
TOTAL LIABILITIES	3,313,241	3,014,249
NET ASSETS	13,640,563	14,994,718
TOTAL INSTITUTE FUNDS	13,640,563	14,994,718

The financial information and statements presented in this report are based on the audited financial report.
This differs to previous years where the unaudited management accounts were presented.
Full audited financial statements are available from the Institute's registered office by request.

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We'd love to hear from you!

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